Addressing Ethical Issues for Health and Demographic Surveillance Systems in Sub-Saharan Africa

Thesis

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Addressing ethical issues for health and demographic surveillance systems in sub-Saharan Africa

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A dissertation submitted for the degree of Doctor of Philosophy

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*Two photographs (Figure 2 and 4) have been removed from this thesis version.*
Abstract

In this thesis, I discuss ethical issues for health and demographic surveillance systems (HDSS). HDSS involve the longitudinal monitoring of vital events, such as births and deaths, in a relatively small, geographically defined population, without a specified end date. Methodologically and in their aims, HDSS occupy a grey area between research, health care and public health. Despite involving millions of people in sub-Saharan Africa and other settings that face significant health and socioeconomic challenges, HDSS have received little attention in the empirical ethics literature and guidelines.

To address the empirical and normative gaps in HDSS ethics, I conducted a qualitative study based on a case study design. This included three interlinked phases; 1) formative research in six HDSS across sub-Saharan Africa to map out key ethical issues 2) a case study of two HDSS in Kenya to explore ethical issues in depth, 3) an assessment of the wider relevance of the case study findings. I explored the views and experiences of HDSS research and community stakeholders through interviews, observations, document reviews and focus group discussions. I drew on this empirical data, and the wider bioethics and social science literature to develop normative conclusions on HDSS ethics.

Overall, the benefits and burdens of HDSS appear disproportionately distributed among stakeholders. Verbal autopsy respondents and interviewers bear most of the severe burdens in HDSS, with significant emotional and moral distress respectively. HDSS residents are also exposed to a wide range of risks (such as to privacy) regularly over a long timescale. Although HDSS have contributed to scientific publications which could inform policy and practice, this potential social value, as well as more immediate local benefits, are not well-articulated or demonstrated in practice. I make recommendations to minimise burdens and enhance the social value of HDSS in sub-Saharan Africa.
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List of Acronyms and Abbreviations

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<tr>
<td>APHRC.</td>
<td>African Population and Health Research Centre</td>
</tr>
<tr>
<td>CAB.</td>
<td>Community Advisory Board</td>
</tr>
<tr>
<td>CDC.</td>
<td>Centres for Disease Control</td>
</tr>
<tr>
<td>CHW</td>
<td>Community Health Worker</td>
</tr>
<tr>
<td>CIOMS.</td>
<td>Council for International Organizations of Medical Sciences</td>
</tr>
<tr>
<td>CRVS.</td>
<td>Civil Registration and Vital Statistics Systems</td>
</tr>
<tr>
<td>GPS.</td>
<td>Global Positioning System</td>
</tr>
<tr>
<td>HDSS.</td>
<td>Health and Demographic Surveillance System</td>
</tr>
<tr>
<td>HSRE.</td>
<td>Health Systems and Research Ethics Department</td>
</tr>
<tr>
<td>INDEPTH.</td>
<td>International Network of field sites with continuous Demographic Evaluation of Populations and Their Health</td>
</tr>
<tr>
<td>KCR.</td>
<td>KEMRI Community Representative</td>
</tr>
<tr>
<td>KEMRI.</td>
<td>Kenya Medical Research Institute</td>
</tr>
<tr>
<td>KHDSS.</td>
<td>Kilifi HDSS</td>
</tr>
<tr>
<td>KWTRP.</td>
<td>KEMRI Wellcome Trust Research Programme</td>
</tr>
<tr>
<td>LMICs.</td>
<td>Low and Middle Income Countries</td>
</tr>
<tr>
<td>MEIRU.</td>
<td>Malawi Epidemiology and Intervention Research Unit</td>
</tr>
<tr>
<td>MIA.</td>
<td>Minimally Invasive Autopsy</td>
</tr>
<tr>
<td>NHRC.</td>
<td>Navrongo Health Research Centre</td>
</tr>
<tr>
<td>NUHDSS.</td>
<td>Nairobi Urban HDSS</td>
</tr>
<tr>
<td>REC.</td>
<td>Research ethics committee</td>
</tr>
<tr>
<td>SAPRIN.</td>
<td>The South African Population Research Infrastructure Network</td>
</tr>
<tr>
<td>SERU.</td>
<td>Scientific and ethics review unit</td>
</tr>
<tr>
<td>VA.</td>
<td>Verbal autopsy</td>
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<tr>
<td>VAST.</td>
<td>Vitamin A Supplementation Trial</td>
</tr>
<tr>
<td>WHO.</td>
<td>World Health Organisation</td>
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*Throughout this thesis I will use the terms HDSS research stakeholders (referring to HDSS research staff, managers, field workers and funders) and community stakeholders (referring to HDSS community members and community representatives).*
Health and demographic data are valuable resources. They contribute to the promotion of public health, protection of human rights, evaluation of public health interventions and to evidence-based policy-making (AbouZahr, de Savigny, et al., 2015; Lietz et al., 2015; Maduekwe, Banjo, & Sangodapo, 2017; Ngom, Binka, Phillips, Pence, & Macleod, 2001; Pisani et al., 2016; Setel et al., 2007; United Nations, 2013). These data, which include morbidity, mortality and socioeconomic data, are primarily collected from individuals during health care, government programmes and health research. Individual-level data are aggregated to provide valuable information on population health and wellbeing (Byass, 2016a; United Nations, 2014).

Many countries in sub-Saharan Africa are unable to generate reliable population-level health-related data because of challenges in health care facilities and government registration and statistics agencies in effectively collecting, analysing and disseminating the data (Aragona & Zindato, 2016; Mikkelsen et al., 2015). In these countries, health and demographic surveillance systems (HDSS) are an alternative way to collect, analyse and disseminate a wide range of health-related data, albeit for small, geographically defined populations. The HDSS also act as platforms for more specific research activities (INDEPTH, 2002; Sankoh & Byass, 2012; Ye, Wamukoya, Ezeh, Emina, & Sankoh, 2012). Researchers have described the overall characteristics and importance of HDSS (INDEPTH, 2002; Sankoh & Byass, 2012), but HDSS have received little attention in the empirical ethics literature and guidelines (Carrel & Rennie, 2008). Using an empirical approach in this thesis, I identify the key ethical issues in HDSS in sub-Saharan Africa and make recommendations on how research stakeholders should respond to the issues identified.

In this chapter, I give an overview of the practical and ethical challenges around health and demographic surveillance systems. HDSS are located in countries without well-functioning civil registration and vital statistics (CRVS) to generate comprehensive population-level data (Hill, Lopez, Shibuya, & Jha, 2007; Sankoh & Byass, 2012; United Nations, 2014; Ye et al., 2012). I will therefore describe CRVS in Section 1.1, to highlight the context in which HDSS operate, before introducing HDSS in Section 1.2. In Section 1.2 I include an overview of HDSS functioning (including
verbal autopsy), an international organisation bringing together a large number of HDSS sites (the INDEPTH Network) and ethical issues. I finish this chapter with the thesis objectives and an outline of the rest of the thesis chapters.

1.1.1 Civil Registration and Vital Statistics Systems

Civil registration refers to the recording of vital events in a country or region in accordance with the law (United Nations, 2014). The most common vital events include births, deaths, marriages, divorces and adoptions. Civil registration generates vital statistics on the occurrence and characteristics of vital events in a population and provides individuals with legal documents such as birth, marriage and death certificates (United Nations, 2014). Civil registration and vital statistics systems (CRVS) are considered to be the most comprehensive sources of population-level data because they are routine, compulsory and universal (AbouZahr, de Savigny, et al., 2015; United Nations, 2014). However, the majority of low- and middle-income countries (LMICs) lack well-functioning civil registration and vital statistics systems, which makes it challenging to plan, implement and evaluate public interventions, and to protect the rights of individuals (Mikkelsen et al., 2015).

In a series of research articles in the Lancet Journal, global health researchers highlighted the lack of reliable population-level data especially from Africa and Asia (mainly due to incomplete CRVS), and recommended measures to address this challenge (Lopez et al., 2007). First, the researchers suggested that this lack of data impedes efforts to identify and address the challenges faced by people living in LMICs (Setel et al., 2007). Second, they recommended that the global health community should develop tools to assess and monitor CRVS improvements (Mahapatra et al., 2007). Thirdly, they acknowledged that alternative sources of population-level data in LMICs could be used to complement CRVS in these countries (Hill et al., 2007). Finally, the researchers called for a global effort to strengthen CRVS systems through international coordination, technical innovations and financial support (AbouZahr et al., 2007).

The publication of the Lancet ‘Who Counts?’ Series was followed by increased attention to CRVS by international agencies, individual countries and researchers. This attention was attributed to the recognition, by governments and global health actors,
that effective CRVS demonstrated good governance and provided the best tools for tracking progress in health and socioeconomic development (AbouZahr, De Savigny, et al., 2015). Also, one could argue that the influence of the Lancet Journal and series authors (who had affiliations with international health organisations such as WHO, global health research institutes and governments across the world) contributed more widely to an increased attention to CRVS. For example, universities and research centres established departments to focus on CRVS and collaborated with international health organisations to develop CRVS resource kits (WHO & The University of Queensland, 2013). The United Nations has also taken a leading role in efforts to strengthen CRVS by establishing commissions, organising regional workshops and developing guidelines for CRVS implementation (United Nations, 2013, 2014, 2017). The development of CRVS implementation resources and provision of funding has led to the establishment of various country-level and regional initiatives to strengthen them (Suthar et al., 2019).

Despite the attention to CRVS, many countries within Africa and Asia are still unable to effectively register and certify vital events; for instance, a recent analysis of birth registration and certification coverage in 94 countries across the world showed that more than two thirds (73.1%) of children under the age of five in Eastern and Southern Africa did not have a birth certificate (Bhatia et al., 2017). In addition, a comprehensive global assessment of the overall quality of CRVS systems in terms of their accuracy, completeness and availability of data, showed that CRVS in sub-Saharan Africa and other LMICs were of low quality and had shown little improvement over the years (Mikkelsen et al., 2015). This chronic underperformance has been attributed to reductionist approaches to strengthening CRVS that focus on technical solutions such as digitization rather than on the social, economic and political contexts in which CRVS operate (Cobos Muñoz et al., 2018). Assessment of countries that have succeeded in strengthening CRVS indicate the importance of using multiple policy approaches that acknowledge the CRVS socio-political context (Suthar et al., 2019).

Alternative sources of population-level data in countries without well-functioning CRVS include population censuses, demographic health surveys, sample registration and demographic health surveillance systems. These alternative sources have well
acknowledged strengths and weaknesses (Hill et al., 2007). Population and housing censuses are usually conducted every 10 years in an entire country or region. Census data are valuable for validating other population-level data, given their extensive coverage, but they might be unreliable because of the long intervals between data collection (Aragona & Zindato, 2016; Hill et al., 2007). In addition, the increased use of technology, which generates population-level data from business and administrative interactions, is gradually making the traditional door-to-door census redundant in some countries (Aragona & Zindato, 2016).

A demographic and health survey involves the collection of data every 5 years in a representative sample of households in a country or region in order to evaluate the impact of public health interventions. DHS data are widely accessible and have contributed to understanding important public health issues such as child mortality. However, they involve small samples and do not include adequate indicators to make reliable estimates outside the specific area of interest (Hill et al., 2007). Sample registration systems involve ongoing registration of births and deaths in a randomly selected sample of the population (Jha et al., 2005). Sample registration systems record most vital events in the target population but they can be expensive to administer (Hill et al., 2007). This thesis focuses on health and demographic surveillance systems (HDSS). Overall, alternative sources of population-level data are considered to be inferior to well-functioning CRVS mainly because they do not provide individuals with legal documents or generate continuous and comprehensive vital statistics (AbouZahr, de Savigny, et al., 2015).

1.1.2 Health and Demographic Surveillance Systems: An overview

1.1.2.1 INDEPTH Network HDSS Sites

A Health and Demographic Surveillance System (HDSS) is a methodological approach for the longitudinal monitoring of vital events in a geographically-defined population (INDEPTH, 2002; Sankoh & Byass, 2012; Ye et al., 2012). An HDSS site typically starts with a baseline census of the target population followed by regular re-enumeration of this population, whereby field workers visit households to record data on births, deaths, migrations and to collect a wide range of additional socioeconomic and health data, such as cause of death through verbal autopsy (INDEPTH, 2002; Sankoh
HDSS sites have important differences with CRVS and other sources of population-level health and demographic data. Unlike CRVS and population censuses, which involve enumeration and certification of vital events in large populations in accordance with the law (United Nations, 2014), HDSS sites cover relatively small populations and collect data from consenting households without issuing legal documents (Sankoh & Byass, 2012; Savigny et al., 2018). Also, while demographic health surveys and sample registration systems involve the one-time sampling or longitudinal collection of data from randomly selected populations (Jha et al., 2005), HDSS populations are purposively selected and the same households are followed up without a specified end-date (INDEPTH, 2002; Sankoh & Byass, 2012). Therefore, HDSS use research-based methods to provide some of the most comprehensive population-level data in contexts with incomplete CRVS.

There are several national and international networks of HDSS sites. The largest of these (and the focus of my study) is the International Network for the Demographic Evaluation of Populations and their Health (INDEPTH Network), which is an umbrella organisation for 53 HDSS sites located in 20 countries across Africa, Asia and Oceania. The majority (40/53) of INDEPTH Network HDSS sites are in sub-Saharan Africa, where they follow up over 3.5 million people in 14 countries (INDEPTH, 2002; INDEPTH Network, 2016a). The INDEPTH Network HDSS sites collect a wide range of health and demographic data from all residents in a geographically-defined area (INDEPTH, 2002; Sankoh & Byass, 2012; Ye et al., 2012). This is unlike other international networks of health and demographic surveillance systems, which focus on women and children (Child Health and Mortality Prevention Surveillance, 2019) or on specific diseases (Kotloff et al., 2012; Levine et al., 2012). The INDEPTH Network also includes some other smaller networks. The South African Population Research Infrastructure Network (SAPRIN) for example brings together HDSS sites located in South Africa, and the SAPRIN sites are also members of the INDEPTH Network (South African Population Research Infrastructure Network, 2019). HDSS sites can therefore belong to multiple networks based on research interests and geographic location.

Research stakeholders in LMICs established the INDEPTH Network in 1998 to improve the functioning and impact of HDSS sites (Sankoh & Byass, 2012). Since its establishment, the INDEPTH Network has built a community of HDSS research
stakeholders by holding international conferences that focus on HDSS methodology, enabling sharing of best practices between sites and by training HDSS researchers (INDEPTH Network, 2016b). It has collaborated with other global health stakeholders, such as the World Health Organisation, to develop and refine research tools including verbal autopsy questionnaires, which enable collection of cause of death data in areas without medical certification of death and international comparison of mortality patterns (Baiden et al., 2007; Ye et al., 2012). Appendix 1 shows a sample verbal autopsy questionnaire, all the VA questionnaires developed by WHO and other research stakeholders can be found on the WHO website (WHO, 2020). In addition, the Network has facilitated the wider sharing of HDSS data by building trust among research stakeholders and by providing online data repositories and HDSS data visualisation websites (Herbst et al., 2015; Sankoh et al., 2013). Finally, the INDEPTH Network has coordinated multi-site research projects that have provided valuable information about populations living in LIMCs, including age-structure (Sankoh, Sharrow, et al., 2014), and the impact of migration on health (Gerritsen et al., 2013), among other public health issues (Bangha et al., 2010; Chisumpa et al., 2019; Sankoh, 2017). Therefore, the INDEPTH Network brings together a large community of HDSS sites, mostly based in sub-Saharan Africa, which collaborate with each other and collect comprehensive health and demographic data using standardised methods. Partly for these reasons, this study focused on INDEPTH Network HDSS sites in sub-Saharan Africa.

1.1.2.2 Verbal autopsy in HDSS

The verbal autopsy (VA) is a key component of INDEPTH Network HDSS sites (Baiden et al., 2007; Sankoh & Byass, 2012, 2014). It involves conducting a structured interview with a close relative or final caregiver of a deceased person to collect data about the signs, symptoms and circumstances that preceded a death, and analysing the data to determine a probable cause of death (Caleo et al., 2018; Chandramohan et al., 2005; de Savigny et al., 2017; E. Nichols et al., 2013). The verbal autopsy process, which generally involves identifying a death, and collecting and analysing data, has received some research attention, in terms of its accuracy and implementation (Hazard et al., 2018; Leitao et al., 2014; E. Nichols et al., 2013). Various research stakeholders have shared their experiences and approaches to
verbal autopsy. For instance, in some HDSS sites, community volunteers identify and report deaths to research centres, who then organise specially trained field workers to conduct verbal autopsy interviews (Crampin et al., 2012). Some researchers have shown that community members with limited academic qualification and research experience can collect cause of death data using the standard verbal autopsy questionnaires (Engmann et al., 2009; Nabukalu et al., 2019). Furthermore, studies conducted in HDSS and other contexts suggest that collecting verbal autopsy data using handheld electronic devices, when compared with paper-based systems, reduces time and costs of interview, and data entry errors (Flaxman et al., 2018; McLean et al., 2017; Yu et al., 2009). Overall, the empirical evidence suggests electronic-based methods of data collection are preferable to paper-based methods and that individuals with varying levels of education and training can effectively collect verbal autopsy data.

There are two main ways of analysing verbal autopsy (VA) data to ascertain probable cause of death; by physicians (physician certified verbal autopsy) or through computer algorithms (computer coded verbal autopsy) (Fottrell & Byass, 2010). Consequently, research has focused on assessing the performance of these different analysis methods. For instance, Hererra et al. (2017) highlighted that verbal autopsy methods perform poorly in identifying deaths from malaria, mainly because of low sensitivity and the lack of a gold standard to assess the accuracy of VA results (Herrera et al., 2017). In addition, Leitao et al. (2014) reviewed 19 studies, which assessed the performance of physician certified VA and community coded VA methods, and concluded that no one method outperformed the rest in assigning causes of death (Leitao et al., 2014). Research stakeholders acknowledge the difficulties of comparing verbal autopsy methods because the accuracy of VA is significantly influenced by the type of disease and data collection processes (Byass et al., 2015; Leitao et al., 2014; Snow et al., 1992). However, computer coded verbal autopsy is seen as a cost-effective alternative to medically-certified cause of death, especially in large-scale verbal autopsy studies (Byass et al., 2019; Hazard et al., 2018). Furthermore, most research stakeholders acknowledge that the verbal autopsy is a pragmatic approach for generating population-level mortality data (D’Ambruoso et al., 2017; Fottrell & Byass, 2010; Sankoh & Byass, 2014). The
INDEPTH Network HDSS sites seem to conduct verbal autopsies in this context; to generate mortality data for research in settings with incomplete CRVS, rather than provide cause of death results and legal documents for individuals.

1.1.3 Ethical issues in HDSS: An overview

The Belmont Report, which was published by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research in 1979, outlined three basic ethical principles to guide research involving humans. These principles include respect for persons, which entails the treatment of individuals as autonomous agents and protection of those with diminished autonomy; beneficence, which refers to the ethical requirement to maximise the benefits of research, minimise harms and to do no harm; and the principle of justice, which largely refers to fairness in distribution of benefits and burdens (Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014). Over the years, research stakeholders have significantly applied and discussed these ethical principles. For instance, ethics scholars have provided frameworks to guide researchers in applying and weighing the principles, especially in contexts where these principles conflict with each other (Beauchamp & Childress, 2013). These principles have also influenced international ethics guidelines for health-related research (CIOMS and WHO, 2016; CIOMS & WHO, 2008; Emanuel et al., 2004). In addition, researchers have shared their views and experiences of applying various strategies to adhere to ethical principles, such as informed consent to demonstrate respect for persons, and balancing benefits and burdens of research towards ensuring beneficence and justice (Baiden et al., 2016; Boga et al., 2011; Rid & Wendler, 2010).

It has been argued that this principle-based approach to ethics (ethical principlism) can lead to a focus on respect for persons at the expense of other ethical principles (Azétsop & Rennie, 2010; Baum et al., 2007; Kingori, 2013), and on individuals rather than the influence of the social context, such as community norms, health and social inequalities (Azétsop & Rennie, 2010; Parker & Bull, 2009; Participants in the Community Engagement and Consent Workshop, Kilifi, Kenya, 2013; Quinn, 2004;
Weijer et al., 1999). Recognising these challenges, ethics scholars have developed ethics guidelines and frameworks that seek to address ethical issues in diverse socioeconomic and political contexts, and that consider a wide range of relevant ethics principles, norms and values (Emanuel et al., 2004; Kass, 2001; Klingler et al., 2017; McLennan et al., 2018; Rubel, 2012; Tsoka-Gwegweni & Wassenaar, 2014; Willison et al., 2014).

In this thesis, I describe ethical issues drawing on ethical principles, previous research at my research institution and the characteristics of health and demographic surveillance systems. I refer to ethical issues as situations where an ethical principle is not fulfilled or where two principles conflict (Beauchamp & Childress, 2013; Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014; Klingler et al., 2017); I also include issues that researchers at the KEMRI Wellcome Trust (my host research institution) have traditionally investigated using an ethics lens, including community engagement, consent processes, and study benefits and data sharing (Boga et al., 2011; Jao et al., 2015a; Kamuya et al., 2013, 2014; V Marsh et al., 2008; Vicki Marsh et al., 2013; Molyneux et al., 2012; Molyneux, Peshu, et al., 2005; Njue et al., 2014). Finally, HDSS are social programmes that involve entire communities and collaborations across geographic and socioeconomic contexts, as described earlier in this chapter. Therefore, to define ethical issues in this thesis, I considered ethics guidance that shift the focus from individuals to populations, for instance, social justice (Kass, 2001). Overall, I adopted a broad definition of ethical issues to incorporate multiple perspectives and conceptualisations of ethics.

1.1.3.1 HDSS ethics

Ethical issues for health and demographic surveillance systems (HDSS) have received little attention in the empirical ethics literature and guidelines. Carrel and Rennie (2008), in a conceptual article, highlighted that the operation of HDSS raises ethical issues related to conflicts between the ethical principles of respect for persons, beneficence and justice. For instance, providing health care to HDSS participants only, while beneficial to the participants, can create health inequalities and decrease the potential of HDSS data to reflect disease patterns in surrounding areas. In addition, Carrel and Rennie (2008) argued that HDSS are indistinctly positioned between
research, health care and public health practice, which makes it challenging to determine the relevance of traditional ethics guidelines in HDSS (Carrel & Rennie, 2008). Furthermore, there is little documentation of ethical issues from the INDEPTH Network HDSS sites, which makes it challenging to determine the types of ethical issues that emerge in conducting HDSS (Hyder et al., 2012). Nevertheless, a few publications that I will discuss in Chapter 2 have focussed on ethical issues around data sharing (Anane-Sarpong et al., 2016; Chandramohan et al., 2008), community engagement (Mondain, 2013; Mondain et al., 2016; Twine et al., 2017), and verbal autopsy (Aborigo et al., 2013) in HDSS.

1.1.3.2 Verbal autopsy ethics

A recent review of ethics reporting in 288 peer reviewed verbal autopsy studies found inadequate reporting on ethically relevant issues such as consenting, data confidentiality and timing of verbal autopsy interviews (Joshi et al., 2018). Some empirical studies conducted in and outside HDSS contexts, and a few conceptual studies, have highlighted the potential burdens of verbal autopsy, including community stigmatisation and emotional burdens for verbal autopsy respondents and interviewers (Aborigo et al., 2013; Allotey et al., 2015; Brolan et al., 2014; Chandramohan et al., 2005; Gouda et al., 2017; Morrison et al., 2018). In addition, HDSS stakeholders have advocated for the greater integration of verbal autopsy in routine civil registration systems to enhance the value of verbal autopsy and the quality of population-level mortality data (de Savigny et al., 2017; Sankoh & Byass, 2014). This thesis contributes empirical evidence on ethical issues for verbal autopsy in the context of HDSS.

I gradually focussed on ethical issues for verbal autopsy in HDSS through a prolonged (Nov 2015 – Jan 2018) and highly iterative process, which was informed by literature review, insights from field work, consultations with other researchers and ongoing data analysis. I began my thesis with conducting formative research (November 2015-December 2016) in purposively selected HDSS sites across sub-Saharan Africa to map out the range of ethical issues in HDSS. During this formative phase, I observed surveillance activities, including verbal autopsy interviews, and held informal discussions with HDSS research staff. I observed that the verbal autopsy interviewers had to ask sensitive questions about the health and behaviour of the deceased, which
made some respondents look uncomfortable. During informal discussions, HDSS research staff highlighted the challenges of conducting verbal autopsy, such as the discomfort of community members with discussing death and lack of human resources for analysing verbal autopsy data. Based on overall findings from the formative phase, I revised my interview guides for the in-depth case work in Kenya, to add specific questions on potential ethical sensitivities in collecting verbal autopsy, pregnancy and household income data in HDSS. In 2017, I administered the revised interview guide to research staff in the Kilifi and Nairobi HDSS sites in Kenya. After the first 11 interviews, and based on my discussions with my supervisors, and other researchers during various scientific seminars, workshops and conferences, I decided that the verbal autopsy was an important focus for exploring the key ethical issues in HDSS. In 2018 and 2019, I revised my interview guides and other data collection tools to focus on ethical issues for verbal autopsy in HDSS. Therefore, after the first 11 interviews in Kenya, data collection – including all focus group discussions, secondary data analysis, field observations and individual in-depth interviews (IDI12-IDI29) focussed on exploring ethically-relevant views, experiences and practices around verbal autopsy in HDSS.

1.2 Rationale for the Study

Most low and middle income countries (LMICs) lack well-functioning civil registration and vital statistics systems (CRVS) to collect population-level health and demographic data, which are essential for public health, evidence-based policy making, research and protection of human rights (Mikkelsen et al., 2015; United Nations, 2014). Alternative sources of population-level data in these countries include health and demographic surveillance systems, which collect data on births, deaths, causes of death, migration and other health-related data (Hill et al., 2007; INDEPTH, 2002). Although there are different types of HDSS sites, the INDEPTH Network HDSS sites are arguably the most comprehensive and well-established sites because they collect a wide range of health and socio-economic data from entire geographically-defined populations especially in sub-Saharan Africa (INDEPTH, 2002; Sankoh & Byass, 2012; Ye et al., 2012). The verbal autopsy is an integral component of INDEPTH Network HDSS sites; conducting verbal autopsies is a requirement for full membership to the Network and the INDEPTH Network HDSS sites have played a key role in the
development and validation of verbal autopsy methods (Baiden et al., 2007; INDEPTH Network, 2016b; E. Nichols et al., 2013; Sankoh & Byass, 2012).

HDSS have received little attention in the empirical ethics literature and guidelines (Carrel & Rennie, 2008; Hyder et al., 2012). Most research publications on HDSS have focussed on data sharing and the practical elements of research processes such as collecting and analysing verbal autopsy data but with little ethics analysis (Herbst et al., 2015; Leitao et al., 2014; Savigny et al., 2018). The empirical studies on ethically relevant issues in verbal autopsy that have been conducted (as mentioned above) have been conducted outside INDEPTH Network HDSS sites (Brolan et al., 2014; Hutain et al., 2019; Morrison et al., 2018; Nabukalu et al., 2019). Furthermore, these empirical ethics studies have primarily used research ethics frameworks. Challenges include that sub-Saharan Africa is generally under-represented in the generation of international ethics guidelines for health-related research (Iyer, 2018; Klingler et al., 2017; Okeke et al., 2017; van Panhuis et al., 2014), and that general health related guidelines do not respond adequately to the indistinct positioning of HDSS between research, health care and public health.

Given the empirical and normative uncertainty in HDSS ethics, this thesis seeks to identify the key ethical issues in HDSS and to make recommendations on how research stakeholders (funders, reviewers, researchers and managers) should respond to these issues. In particular, this thesis contributes empirical evidence of the potential burdens and benefits of verbal autopsy in the context of HDSS sites in sub-Saharan Africa. It acknowledges the influence of the social context on ethical issues in verbal autopsy through collection of empirical data in diverse contexts across sub-Saharan Africa and the use of multiple ethics frameworks for analysis.

1.3 Context of the Study

I conducted this PhD project while based at the KEMRI Wellcome Trust Research Programme (KWTRP), which is an Accredited Research Centre of the Open University, UK. The KWTRP was established in 1989 and has been conducting research on the biomedical, clinical, epidemiological and social aspects of health. At the KWTRP, my PhD project was hosted within the Health Systems and Research Ethics Department (HSRE). The HSRE department has a strong track record of conducting social science
studies. Researchers within the department conduct health systems, health economics and empirical ethics studies. These include studies on consenting, community engagement, data sharing, and benefits and burdens of health-related research. My two PhD supervisors – Professor Sassy Molyneux and Professor Vicki Marsh – have worked at KWTRP for many years and have extensive experience in conducting empirical ethics research and health systems research, especially around health-related research in LMICs. Prior to this PhD project, my research interest in ethics and health systems research had developed through my training in public health and by conducting research on end of life care using civil registration and public health data.

In 2001, the KWTRP established a health and demographic surveillance system in Kilifi Kenya. The Kilifi HDSS is a member of the INDEPTH Network and has been collecting data from households in Kilifi using the methodological design and procedures that I have described in this chapter. The idea for an empirical ethics study on HDSS originated from this context; the empirical and normative uncertainty around HDSS ethics, the experience of my supervisors and my interest in health systems and research ethics, and the existence of the KHDSS at KWTRP and a support system within the HSRE department. Ultimately, the research project involved in-depth and exploratory empirical research in seven HDSS sites across Kenya, Ghana, Malawi, South Africa and Uganda, as I will describe in detail later in this thesis.

1.4 Thesis Objectives

1.4.1 Main Objective

To identify the key ethical issues for HDSS sites in sub-Saharan Africa and to make recommendations on how research stakeholders should respond to potential ethical issues in HDSS.

1.4.2 Specific Objective One

To describe the characteristics of HDSS sites in sub-Saharan Africa in terms of their history, context and current functioning, and to map out the key ethical issues.
i) History: What was the rationale and process for establishing HDSS in sub-Saharan Africa, who was involved and how have the HDSS changed over time?

ii) Context: What are the geographic and socioeconomic features of the areas in which HDSS in sub-Saharan Africa are located?

iii) Functioning: How do HDSS sites in sub-Saharan Africa function in terms of ethics oversight, consenting, community engagement, benefits and data sharing?

iv) What are the experiences and perceptions of research stakeholders on ethical issues for HDSS sites in sub-Saharan Africa?

1.4.3 Specific Objective Two

To explore, in depth, ethical issues for verbal autopsy in a rural and an urban HDSS site in Kenya, from the perspectives of research and community stakeholders.

1.4.4 Specific Objective Three

To explore the relevance of key verbal autopsy findings from the two Kenyan sites to a wider range of HDSS sites in sub-Saharan Africa.

1.4.5 Specific Objective Four

To draw on the empirical research findings and wider ethics literature to describe the nature of key ethical issues in HDSS sites in sub-Saharan Africa, and to make recommendations on how research stakeholders should respond to these ethical issues.

1.5 Overview of Methodology and Study Design

Empirical bioethics brings together empirical evidence with ethics analysis to make normative conclusions on bioethical issues (Dunn et al., 2012; Kon, 2009). Ethics journals are increasingly publishing studies that use empirical bioethics methodologies (Wangmo et al., 2018). These methodologies are highly heterogeneous because of variations in strategies for combining empirical and philosophical aspects of research, epistemological commitments.
and variations in types of normative conclusions (Davies et al., 2015). Despite efforts to develop standards of practice in empirical bioethics, there is no universal consensus on the appropriate research methodology (Ives et al., 2018; Mertz et al., 2014).

Various authors have provided guidance that might be useful in conceptualising, implementing and reporting empirical bioethics. Some have suggested that empirical bioethics research falls into two broad categories; dialogical and consultative approaches. In dialogical approaches, researchers integrate ethical analysis and the drawing of normative conclusions with collecting empirical data, while in consultative approaches the researchers draw normative conclusions after collecting empirical data (Davies et al., 2015). Given that these are broad categories, with significant variations especially within consultative approaches (Davies et al., 2015), some research projects may include elements from both dialogical and consultative approaches (Morrison et al., 2018). Other scholars have focused on categorising empirical bioethics based on research objectives. For instance, Kon (2009) ranks empirical bioethics research into four levels; research that (a) seeks to describe ethically relevant features, (b) assess how ethical processes compare to ethical norms, (c) explore effective strategies for improving ethical practice, or (d) change ethical norms (Kon, 2009). Similarly, Huxtable and Ives (2019) outline a framework for empirical bioethics research suggesting that researchers can identify the ethically relevant features around an issue (Mapping), explore ethical issues in depth through empirical research (Framing) and issue recommendations (Shaping) (Huxtable & Ives, 2019). Unlike Kon (2009), Huxtable and Ives (2019) emphasise that it is important to have a bridging methodology to link the different phases and aspects of an empirical bioethics research project. Most authors agree on a few features for strengthening empirical bioethics research methodologies. First, since all researchers adopt particular epistemological beliefs (whether or not these are stated) on how knowledge is gained (John Creswell, 2012), empirical bioethics researchers should explain the underlying philosophical underpinnings of their knowledge claims. Second, they should describe the process used to integrate the empirical and normative aspects of a research project. Finally, empirical bioethics researchers should state the types of normative conclusions they seek to make (Davies et al., 2015; Hedgecoe, 2004; Ives et al., 2018).

This was an empirical bioethics project because it combined a case study methodology and ethics analysis to identify the key ethical issues in HDSS in sub-Saharan Africa and to make recommendations on how research stakeholders should
respond to these ethical issues. The research project aligned with the Mapping-Framing-Shaping Framework (Huxtable & Ives, 2019) in that I conducted preliminary literature review and formative research (Mapping), an in-depth case study (Framing) then linked the empirical data to ethics literature to issue recommendations (Shaping). The underlying philosophical underpinning of the case study methodology was pragmatic constructivism, which assumes that reality is constructed through understandings developed socially and from experience (Harrison et al., 2017; Merriam, 1998). I explored the views and experiences of researchers and community members on ethically relevant issues in HDSS sites across sub-Saharan Africa, through individual interviews, focus group discussions, document reviews and non-participant observations. As illustrated in the research objectives, I sought to make context-specific recommendations on ethical issues in HDSS rather than universal normative conclusions. Besides paying attention to the available guidance for conducting empirical bioethics research (Ives et al., 2018; Mertz et al., 2014), I adhered to widely accepted guidelines for qualitative research, including by demonstrating reflexivity and transparency (Conklin, 2007; Sinkovics & Alfoldi, 2012; Stronach et al., 2007). In summary, this empirical bioethics research involved using a case study methodology with a pragmatic constructivist approach to develop particularistic recommendations on ethical issues in HDSS.

1.6 Thesis Chapter Outlines

In Chapter 2, I will present a literature review of ethical issues and ethically-relevant processes in HDSS. This will include a description of HDSS in terms of their histories, geographic and socio-economic contexts and current functioning. In this chapter, I will also provide an overview of ethical issues for HDSS sites around consenting, community engagement, benefits, burdens and ethics oversight. This chapter will highlight the research gap that this thesis seeks to address.

In Chapter 3, I will give a detailed description and justification of the methodology. This thesis was based on a qualitatively-driven case study of two HDSS sites in sub-Saharan Africa. I will describe the philosophical underpinnings of case study research, the study procedures and sites. In addition, I will describe my positionality in the case study including the social context in which I conducted the study.
Chapter 4 is the first of three findings chapters. It draws on empirical data collected in this study, and a review of relevant documents and websites, to describe HDSS sites in sub-Saharan Africa and to map out the range of ethical issues for HDSS. These data add to the limited literature on HDSS ethics and identify potential ethical sensitivities such as the verbal autopsy.

Chapter 5 focusses on verbal autopsy in the Kilifi and Nairobi Urban HDSS sites in Kenya. It describes verbal autopsy interviewers in these sites in terms of their training and background, as well as the timing and procedures of verbal autopsy. In Chapter 5 I also present the views and experiences of HDSS research and community stakeholders on consenting, community engagement, data sharing and ethics oversight for verbal autopsy. Benefits and burdens of verbal autopsy are shown to be important ethical issues.

Chapter 6 describes the benefits and burdens of verbal autopsy from the perspective of research and community stakeholders in the Kilifi and Nairobi HDSS sites. Also included are potential influences on benefits and burdens and study participants’ recommendations on how research stakeholders should minimise burdens and maximise benefits of verbal autopsy.

In Chapter 7, I draw on the empirical data from this study and the wider bioethics and social science literature to define the key ethical issues for HDSS sites in sub-Saharan Africa and to make recommendations on how research stakeholders should respond to these ethical issues. Specifically, I argue that the verbal autopsy involves significant emotional burdens and minimal benefits for HDSS respondents and field staff. I highlight the strengths and limitations of this study and point out the implications for policy and practice, and further research needs.
2 CHAPTER 2: What is known about the Ethics of HDSS?

Scoping the Literature

In this chapter, I will highlight the research gap in HDSS ethics that this study seeks to address. This includes the empirical and normative uncertainty around HDSS ethics in sub-Saharan Africa. I will discuss the literature on the characteristics of HDSS sites in sub-Saharan Africa in terms of how and why they were established, their current geographic locations, socioeconomic contexts and functioning. Building on my description in Chapter 1 of the methodological approach of an HDSS and of features of INDEPTH Network sites, I will highlight the indistinct positioning of HDSS not only between research, health care and public health practice (Carrel & Rennie, 2008) but also between different health-related research.

Next, I will discuss the literature around HDSS ethics; specifically on ethics oversight, consenting, community engagement and data sharing processes, and benefits and burdens. For each of these topics, and given the indistinct positioning of HDSS, I will begin by considering the current ethics guidelines and empirical research for traditional and non-traditional health-related research. Throughout, I use ‘traditional health research’ to refer to clinical and biomedical research, which have dominated discussions and practices in bioethics (Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014; Emanuel et al., 2004; Setouhy et al., 2004), and ‘non-traditional health-related research’ to refer to research that shifts focus from individual patients and participants or collection of biological samples to the collection of a wide range of health-related information from individuals, institutions and populations through diverse research methods. These include learning health care systems, public health research, and epidemiological and health systems research (CIOMS and WHO, 2016; CIOMS & WHO, 2008; Klingler et al., 2017; Luyckx et al., 2017; McLennan et al., 2018; Willison et al., 2014). Throughout this review of ethics literature on HDSS, I will include specific consideration of verbal autopsy, which is a key component of INDEPTH Network HDSS sites and emerged as a key interest in this thesis (Baiden et al., 2007; INDEPTH, 2002; Sankoh & Byass, 2012, 2014; Ye et al., 2012). I will conclude each section with a summary of the key research gaps for the specific topic. In the last
section of this chapter, I will present the overall research gap around HDSS ethics to highlight the need for in-depth investigation of ethical issues in HDSS sites within sub-Saharan Africa.

2.1.1 Characteristics of HDSS Sites in sub-Saharan Africa

In 2012, a special issue of the International Journal of Epidemiology profiled the INDEPTH Network and several HDSS sites. Between 2012 and 2018, this journal then published over 30 HDSS site profiles using a systematic format that provided information on why the sites were established, site location, size, field procedures and key findings (Ferrie, 2012; Sankoh & Byass, 2012). Researchers working in HDSS have also described HDSS sites in peer-reviewed articles published in a wide range of journals. In this section, I will draw on the literature to describe the history, context and functioning of HDSS sites in sub-Saharan Africa. In Chapter 4, I will provide further details about the characteristics of these HDSS sites based on my field observations, document reviews and interviews with HDSS research stakeholders.

2.1.1.1 Establishing HDSS: rationale, process and actors

The HDSS sites in sub-Saharan Africa typically emerged from pre-existing health-related projects conducted by health research centres. These projects were diverse in terms of their objectives, duration and study populations. For example, the Malawi Epidemiology and Intervention Research Unit (MEIRU) – host research centre for the Karonga HDSS in Malawi – had conducted two large population surveys in 1979-1984 and 1986-1989 with a research focus on Leprosy and Tuberculosis before establishing the Karonga HDSS in 2002 (Crampin et al., 2012). In addition, the Ghana Vitamin A Supplementation Trial (VAST) that only involved women and children under 5yrs preceded the establishment of the Navrongo and Kintampo HDSS sites in Ghana (Oduro et al., 2012; Owusu-Agyei et al., 2012; Ross et al., 1993). Also, research stakeholders established the Kaya HDSS in Burkina Faso to evaluate community health interventions (Kouanda et al., 2013) and the Agincourt HDSS in South Africa to strengthen the district health system (Kahn et al., 2012) while the Dodowa health research centre in Ghana established the Dodowa HDSS to enumerate and register HDSS residents into a health insurance scheme (Gyapong et al., 2013). The projects that preceded HDSS sites followed up specific population groups to address specific
diseases or public health issues. Research centres (with the coordination of the INDEPTH Network) gradually transformed these projects into HDSS sites collecting a wide range of data from entire populations (INDEPTH, 2002). Overall, research centres across sub-Saharan Africa established HDSS sites primarily to support health-related research by generating comprehensive population-level data.

Apart from research centres in sub-Saharan Africa and the INDEPTH Network, other local, national, and international stakeholders contributed to the establishment of the HDSS sites. Through community consultation and information sharing meetings, local community members shared views and information, which enabled researchers to identify HDSS area boundaries, locate households and to obtain consent from most households within the HDSS areas (Gyapong et al., 2013; Kouanda et al., 2013; Thysen et al., 2019; Wanyua et al., 2013). Other key stakeholders at the regional and national level included government agencies, especially research departments affiliated with Ministries of Health and universities. For example, a clinical research unit operating under the Ministries of Health and Research in Burkina Faso established the Nanoro HDSS site (Derra et al., 2012) while the Haramaya University in Ethiopia established the Kersa HDSS site (Assefa et al., 2016). International stakeholders that significantly contributed to the establishment of HDSS sites in sub-Saharan Africa included universities and research funders based in the United Kingdom (Asiki et al., 2013; Crampin et al., 2012; Delaunay et al., 2013; Hennig et al., 2015; Jasseh et al., 2015; Kahn et al., 2012; Oduro et al., 2012; Scott et al., 2012), France (Pison et al., 2014, 2018; Rossier et al., 2012), Norway (Alabi et al., 2014; Alberts et al., 2015), Netherlands (Kishamawe et al., 2015), Switzerland (Geubbels et al., 2015; Koné et al., 2015), Spain (Sacoor et al., 2013), the United States of America (USA) (Mrema et al., 2015; Odhiambo et al., 2012; Sifuna et al., 2018) and Japan (Wanyua et al., 2013). This support highlights that most HDSS sites in sub-Saharan Africa were established through international collaborations for health.

2.1.1.2 HDSS geographic and socioeconomic context

HDSS sites are located in the Eastern, Western and Southern regions of sub-Saharan Africa, with each site following up an average of 87,796 individuals. A common criticism of HDSS sites is that they are not representative of the wider populations
and geographic areas in which they are located because they involve a relatively small, geographically defined populations within a country (Hill et al., 2007; Kim Streatfield et al., 2014; Ye et al., 2012). Some suggest that we should compare HDSS data with routinely collected population-level data such as national censuses and civil registration to assess the representativeness of HDSS sites (Savigny et al., 2018; Ye et al., 2012). However, these alternative sources of data are usually of poor quality and provide little information about populations outside HDSS areas in LMICs (Mikkelsen et al., 2015; Sankoh & Byass, 2012).

In contrast, some studies have suggested that the INDEPTH Network HDSS sites (despite covering small areas and populations within countries) are likely to represent the wider environmental and socioeconomic conditions in Africa and Asia. For example, Tatem et al. (2006) analysed satellite images of Africa including 21 HDSS sites in sub-Saharan Africa and suggested that the sites covered all the major environmental zones in the continent but with few sites in hot and arid areas (Tatem et al., 2006). Additionally, Jia et al. (2015) showed that the INDEPTH Network sites comprehensively cover the broad environmental and socioeconomic features in Africa and Asia. They supported their claim by comparing a wide range of environmental and socioeconomic indicators in the HDSS sites and other areas in Africa and Asia. These indicators included vegetation cover, rainfall, economic output, temperature and population density (Jia et al., 2015). Describing and comparing large populations over time is associated with various uncertainties; for example transient communities might be invisible in HDSS data because HDSS only enumerate and follow up permanent residents (Emina et al., 2011). To address these uncertainties, Utazi et al. (2016) used a statistical modelling approach to show that HDSS sites represented wider environmental and socioeconomic features (Utazi et al., 2016). Furthermore, HDSS sites can have similar demographic and health indicators even when they are located in different countries (Edson Utazi et al., 2018). These studies suggest that some findings from the INDEPTH Network HDSS sites may be extrapolated to other areas of Africa and Asia with some confidence.
2.1.1.3 HDSS functioning: data and procedures

The data collected in each HDSS site are influenced by adherence to core scientific principles of HDSS methodology, requirements of the INDEPTH Network, and by the disease burden in the HDSS area (INDEPTH, 2002; Sankoh & Byass, 2012; Ye et al., 2012). At a minimum, a HDSS site needs to collect data on births, deaths and migrations in order to determine population size and health outcomes. Since HDSS collect these data longitudinally and at the household level, each individual is issued with a unique identification number to facilitate the tracking of vital events, and the formation and dissolution of households (INDEPTH, 2002). Beyond the minimum data, HDSS sites collect a wide range of additional health and socioeconomic data depending on the research interests of each site. These data enable researchers to identify the risks for specific diseases and health-related outcomes (INDEPTH, 2002; Ngom et al., 2001; Sankoh & Byass, 2012). Furthermore, the INDEPTH Network has promoted the collection of cause of death data through the development of verbal autopsy tools and by requiring HDSS sites to conduct verbal autopsy as one condition for network membership (INDEPTH Network, 2016b). Overall, most INDEPTH Network sites regularly collect data on births, deaths, migrations, cause of death, pregnancies, residence and household status, physical characteristics of residential units and additional site-specific data (Baiden et al., 2007; Ekström et al., 2016; INDEPTH, 2002; INDEPTH Network, 2016b; Sankoh & Byass, 2014; Ye et al., 2012).

Scientific considerations and contextual factors influence the current HDSS procedures. To identify vital events and determine health risks and outcomes, HDSS need to collect data longitudinally about individuals living within the HDSS areas through household visits (INDEPTH, 2002). Therefore, each HDSS resident is issued with a unique identification number, which also enables the linkage of household surveillance with other sources of data about an individual or household (INDEPTH, 2002; Sankoh & Byass, 2015). The frequency of HDSS household visits, also referred to as update rounds or cycles, depends on the data collected in an HDSS and pragmatic considerations. For example, sites with highly mobile populations might need frequent household visits to identify the numbers and patterns of migration (Emina et al., 2011; Sankoh & Byass, 2012). Also, the availability of funding determines the frequency and consistency of HDSS household visits (Gyapong et al.,
Hence the frequency of household visits vary across sites; from annual (Alberts et al., 2015; Pison et al., 2014) to quarterly visits (Jasseh et al., 2015; Odhiambo et al., 2012; Scott et al., 2012).

HDSS field workers usually collect data through household visits. In some HDSS sites, health workers and community key informants also collect HDSS data during health care in HDSS-linked facilities (Asiki et al., 2013; Derra et al., 2012; Scott et al., 2012) or informal interactions in the community (Alabi et al., 2014; Crampin et al., 2012; Odhiambo et al., 2012; Oduro et al., 2012). These HDSS stakeholders collect data using paper-based or electronic methods. HDSS sites collect data longitudinally using procedures that are influenced by scientific and pragmatic considerations such as linkages with health care facilities and availability of a community key informant system.

2.1.1.4 Indistinct Positioning of HDSS

Methodologically, HDSS can be seen as indistinctly positioned between research, health care and public health practice (Carrel & Rennie, 2008). Research has traditionally been distinguished from health care mainly based on intent; the explicit intention to produce or contribute to generalisable knowledge using pre-defined and systematic methods is taken as a key feature of research (Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014; Rubel, 2012). Health care refers to activities that seek to enhance the wellbeing of individual patients using evidence-based or routine methods that are reasonably expected to be successful (Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014). Perhaps health and demographic surveillance systems are research because they contribute to generalisable knowledge. However, HDSS data and platforms also support public health practice and health care (Asiki et al., 2013; Derra et al., 2012; Sankoh & Byass, 2012; Scott et al., 2012). The practical and conceptual challenges of distinguishing research from health care especially in situations where these activities occur in the same context, are well-acknowledged (Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014).
2.1.1.4.1 Non-traditional health research

Research stakeholders widely accept that some health-related research, such as learning health care systems, public health surveillance and research, epidemiological and health systems research, differ from traditional health research (CIOMS and WHO, 2016; CIOMS & WHO, 2008; Klingler et al., 2017; Luyckx et al., 2017; McLennan et al., 2018; Willison et al., 2014). I will briefly describe these non-traditional health research in relation to HDSS.

2.1.1.4.2 HDSS as learning health care systems

As a response to the challenges of distinguishing health research from health care, the idea of a learning health care system has become widespread in recent times. In a learning health care system, research evidence is generated and applied as part of health care delivery (Olsen et al., 2007). Some HDSS can be described as learning health care systems or health systems research based on their linkages with health care facilities and other stakeholders (Luyckx et al., 2017; McLennan et al., 2018) but little is known about these linkages and most HDSS do not describe themselves as part of a health care system.

2.1.1.4.3 HDSS as public health practice or research

All HDSS sites, in contrast, could arguably be described as public health activities. Public health has been defined as “the science and art of promoting and protecting health and wellbeing, preventing ill-health and prolonging life through the organised efforts of society” (Nutbeam et al., 1998). It focuses on the health of populations rather than on individual patients (Childress et al., 2002; Griffiths et al., 2005). Critical public health activities include surveillance, epidemiological investigations, evaluation and monitoring (Hodge, 2005). Public health surveillance is the “systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary” (Porta et al., 2014; World Health Organization, 2017). However, a systematic literature review of ethical issues in public health surveillance, which sought to be comprehensive and broad enough to inform WHO ethics guidelines on public health surveillance, did not include any evidence from HDSS sites (Klingler et al., 2017). Given that HDSS involve millions of people across LMICs in surveillance
activities, their omission in the review suggests that research stakeholders do not view HDSS as public health surveillance or that there is limited ethics research in HDSS.

Public health practitioners and scholars have sought to differentiate public health research from non-research activities based on concepts that were originally outlined in the Belmont Report, whether an activity is systematic and contributes to generalisable knowledge (CDC, 2010; Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014; Remme et al., 2010). Using these criteria, public health research refers to the systematic collection of data to generate knowledge that could be applicable and useful for public health beyond a study area or population (Hodge, 2005; Rubel, 2012). Public health activities that focus on controlling public health problems or on improving practice within a specific area or population are not regarded as research (CDC, 2010). However, these criteria are often inadequate for distinguishing research and non-research in public health given the considerable overlap between these activities (Otto et al., 2014; Rubel, 2012). Some scholars have suggested that contextual factors should inform the distinction (such as who runs the activity) rather than based on intent (Hodge, 2005; Lee, 2019; Remme et al., 2010); based on this reasoning, public health surveillance, emergency response and programme evaluations that are conducted in public health practice should not be regarded as research even if they employ systematic procedures and produce generalisable knowledge (Lee, 2019). All HDSS collect population-level health-related data for research purposes and can be viewed as public health research. In addition, some HDSS are run by government and could therefore be viewed as either public health practice (CDC, 2010; Hodge, 2005; Lee, 2019). The heterogeneity of HDSS in terms of who runs them and how they function makes it challenging to describe them as public health practice or research.

2.1.1.4.4 HDSS as epidemiological research

HDSS may be classified as epidemiological research. Epidemiology is the study of the distribution and determinants of health and diseases in a population to improve public health (Salerno et al., 2019). An epidemiological study design can involve the repeated observation of an entire population living in a particular geographic area in
order to measure health risks, exposures, and outcomes (Pearce, 2012). Such a design is similar to the core HDSS methodology (INDEPTH, 2002). Furthermore, the majority of HDSS site profiles have been published in the International Journal of Epidemiology (Sankoh & Byass, 2012). Also, key components of INDEPTH Network HDSS sites such as the verbal autopsy are considered as standalone research projects when conducted outside the HDSS context (Jha et al., 2005; Joshi et al., 2018). These factors strengthen the arguments for seeing HDSS as research in general and as epidemiological research in particular. However, unlike typical epidemiological research, HDSS do not have a specified end-date and only collect disease incidence and prevalence data if they are linked to health facilities or disease-specific studies.

Summarising across this section, HDSS have important similarities and differences with other non-traditional health research. In theory, all HDSS are epidemiological studies (Pearce, 2012) but the longitudinal and universal nature of HDSS sites distinguishes them from typical epidemiological designs. Some HDSS may be classified as learning health care systems or public health research or practice depending on who runs them and their linkages with health care systems. In summary, the methodological features of HDSS, their histories, geographic and socioeconomic contexts and current functioning suggest that they are non-traditional health research.

2.2 Ethical Issues for Health and Demographic Surveillance Systems

HDSS have received little attention in the ethics literature. Although various ethics principles, frameworks and guidelines have been developed for research, health care and public health (Baum et al., 2007; CIOMS and WHO, 2016; Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014; Emanuel et al., 2004; Kass, 2001), it is not clear how these apply to HDSS, particularly given their indistinct positioning described in the previous section (Carrel & Rennie, 2008). Furthermore, few HDSS research stakeholders have documented their views and experiences of ethical issues (Carrel & Rennie, 2008; Hyder et al., 2012; Mondain, 2013; Mondain et al., 2016; Twine et al., 2017). A systematic literature review of ethics reporting in 288 peer reviewed verbal autopsy studies, conducted in Africa and Asia between 1974 and 2016, highlighted an
inadequate reporting of specific ethical issues. For example, 60% of these studies did not report whether consent was obtained from verbal autopsy respondents (Joshi et al., 2018). This illustrates the inadequate empirical ethics research on routine HDSS and the verbal autopsy.

Recognising the limited ethics literature specifically for HDSS and building on earlier descriptions of the characteristics of HDSS, in the following sections I will draw on the ethics literature and guidelines for traditional and non-traditional health research, as defined in the introduction, to highlight potential ethical issues for HDSS in six core areas; namely, processes of ethics oversight, informed consent, community engagement, data sharing, benefits and burdens.

2.2.1 Ethics review for HDSS

Independent and competent research ethics committees (REC) that use transparent processes and involve all relevant stakeholders can provide credible ethics oversight for health research (Emanuel et al., 2004). However, research ethics committees in LMICs face many challenges, including lack of resources, appropriate ethics guidelines and qualified personnel to review and monitor studies (Kass et al., 2007; Kruger et al., 2014; Nyika et al., 2009), and poor coordination between different RECs reviewing the same studies (Ng et al., 2015). Lack of clarity over what forms of ethics oversight are needed for non-traditional forms of health-related activities that blur boundaries between research, public health and health care adds considerable complexity to these challenges.

The lack of specific ethics guidelines for reviewing non-traditional health research is likely to result in unnecessary barriers for minimal risk studies and the approval (or exemption from a review) of unethical projects (Luyckx et al., 2017; McLennan et al., 2018; Piasecki et al., 2017). Also, since non-traditional health research involve multiple stakeholders across different settings, the prospect of lengthy ethics review including by multiple committees, could make researchers design their studies less rigorously to avoid burdensome oversight process, hence risking the safety of participants (McLennan et al., 2018). Overall, important ethical issues in non-traditional health research, such as the withdrawal of personal information from public databases (Piasecki et al., 2017), accountability, responsiveness to local needs
and ancillary care (Luyckx et al., 2017), and population-level ethical issues (Tsoka-Gwegweni & Wassenaar, 2014) seem to be inadequately addressed through the traditional research ethics review processes, which focus on individual-level issues for research participants (Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014; Tsoka-Gwegweni & Wassenaar, 2014).

After highlighting the conceptual, practical and ethical challenges of reviewing traditional and non-traditional health research, ethics scholars and other research stakeholders have proposed solutions to these challenges (Baum et al., 2007; McLennan et al., 2018; Rubel, 2012; Willison et al., 2014). Most of these proposals seek to strengthen research ethics committees by having more flexible review procedures (Ondrusek et al., 2015), highlighting neglected ethical issues and by building capacity for review including through ethics training (McLennan et al., 2018; Ng et al., 2015; Nyika et al., 2009). Notably, these discussions on ethics oversight for health-related research including non-traditional research, have proceeded with little consideration of views and experiences from HDSS in sub-Saharan Africa. Highlighting the ethical issues encountered in HDSS in sub-Saharan Africa, including ethics review process, would be an important contribution towards strengthening ethics oversight processes for health-related research.

2.2.2 Consenting processes in non-traditional health-related research including HDSS

Obtaining individual informed consent in HDSS is an ethically challenging process (Carrel & Rennie, 2008). To start with, HDSS require the participation of most residents to be effective and are sometimes associated with the provision of health care. These factors can make it difficult for individuals or households to refuse participation or withdraw from the HDSS – lest they create tensions with those who decide to participate. In addition, given the longitudinality of HDSS and their involvement of entire communities, it can be difficult for researchers to decide when and from whom to seek consent (Carrel & Rennie, 2008). Moreover, there is a lack of clarity on the necessity for obtaining informed consent in HDSS, given their indistinct positioning. Civil registration systems, which also collect vital events data, do not usually seek individual informed consent (Sankoh & Byass, 2012; United Nations, 2014). A general argument against the need for individual informed consent
processes in HDSS might come from the wider public health ethics literature, which shifts the focus from individual-level issues such as individual informed consent to population-level issues such as public benefits, accountability and community acceptability (Baum et al., 2007; Kass, 2001). For instance, some have argued that collecting public health data without informed consent is ethically justifiable if the data is used to improve public health, when burdens to individuals are minimised, when allowing individuals to consent would compromise data quality or harm others, and when the data is collected by legitimate institution such as a state agency (Klingler et al., 2017; Lee et al., 2012; Rubel, 2012). As I highlighted in Chapter 1 and in this chapter, HDSS have important differences with public health practices such as civil registration and public health surveillance, hence arguments for public health without informed consent might not apply to HDSS.

The International ethical guidelines for health-related research involving humans, recommend that researchers (including those working under a government agency) should obtain individual informed consent from research participants, or seek a waiver of informed consent from a research ethics committee (CIOMS and WHO, 2016). To get such a waiver, researchers should demonstrate that obtaining the informed consent would be impractical and that the proposed research has social value and minimal risks (CIOMS and WHO, 2016). Therefore, regardless of whether one views HDSS as research or practice, it seems that ethical justification of collecting HDSS without individual informed consent would need to show the necessity of such procedures, their public benefits or social value and the measures in place to protect individuals. HDSS research stakeholders have not argued or demonstrated that obtaining individual informed consent would be impractical or harmful, other than stating that HDSS obtain consent at the household (Sankoh & Byass, 2012). Later in this chapter and in Chapters 5 and 6, I will highlight the difficulties of determining that HDSS have social value and minimal risks.

Besides the unsettled arguments by ethics scholars on appropriate consenting processes for different types of health-related research and practice, consenting processes in HDSS are generally not described in publications (Hyder et al., 2012; Joshi et al., 2018). It is well-acknowledged that HDSS obtain consent at the household level (Carrel & Rennie, 2008), but only a few HDSS research publications describe the
frequency (Rossier et al., 2012) or type of consent (Asiki et al., 2013; Mrema et al., 2015; Rossier et al., 2012), or the age of those eligible to consent (Asiki et al., 2013). This is despite the guidance from the International Committee of Medical Journal Editors requiring researchers to include information on consent processes in published articles (Editorial, 2017). Literature reviews of ethics reporting in verbal autopsy studies conducted within and outside HDSS contexts have also highlighted gaps in the reporting of consent process (Chandramohan et al., 2005; Joshi et al., 2018). For instance, out of 288 verbal autopsy studies published in peer-reviewed journals up to 2016, 48% reported obtaining consent from participants; among these, 30% obtained verbal consent, 27% written consent, 4% either written or verbal, while 40% of the studies did not indicate the type of consent sought (Joshi et al., 2018).

Considering the number of HDSS sites globally (Sankoh & Byass, 2012) and the significant focus in bioethics on consent (Azétsop & Rennie, 2010), few empirical studies have focused on the ethics of HDSS consent processes, including voluntariness and community understanding of HDSS. Through a qualitative study that involved interviews with community stakeholders in the Agincourt HDSS in South Africa, Twine et al. (2017) observed that some HDSS residents did not understand the potential and actual uses of HDSS data or the relevance of collecting particular HDSS data such as socio-economic status (Twine et al., 2017). Additionally, Mondain et al. (2013), through a qualitative study that involved community members and field staff in four HDSS sites across Senegal and Burkina Faso, reported that HDSS residents felt inadequately informed about the procedures and value of HDSS activities, especially the collection of data on migration and household socioeconomic status, and that some residents seemed to consent to HDSS mainly because of their relationships with field staff, expectations of future health care support and because refusing would be culturally inappropriate. Furthermore, Mondain (2013) suggested that some field workers did not understand the objectives and value of HDSS well enough to explain it to residents (Mondain, 2013).

This literature highlights the normative and empirical uncertainty in relation to consent processes for HDSS, including the verbal autopsy. These uncertainties seem to be influenced by the indistinct positioning of HDSS between research, health care and public health practice, which makes it difficult to determine how ethical
arguments for or against individual informed consent apply to HDSS. Also, the limited empirical research on consenting highlight the significant influence of social relations and health inequalities on consenting processes, which has been described by other health-related research in LMICs (Baiden et al., 2016; Boga et al., 2011; Molyneux, Wassenaar, et al., 2005; Mungwira & Nyangulu, 2015). However, it is not clear how ethical issues for HDSS differ with those for other health-related research, given the empirical and normative uncertainty. Addressing these uncertainties requires context-specific research to describe consenting processes (for example, type of consent), benefits, burdens and community engagement in HDSS. For instance, some have argued that arguments in support of foregoing informed consent should be based on evidence of the benefits and burdens involved in particular contexts. Additionally, ethics scholars have suggested that issues around consenting in HDSS and other health-related research could be addressed through community engagement (Bull et al., 2013; Mondain, 2013; Twine et al., 2017), which I discuss next.

2.2.3 Community engagement

2.2.3.1 Community engagement in routine HDSS census

In general terms, a community refers to a group of people with shared characteristics (Ragin et al., 2008). It often pre-dates a study (for instance, people of a certain age or gender) but study selection criteria and procedures could also create communities (Bandewar et al., 2010; Montgomery & Pool, 2017). An HDSS community is geographically defined and can be thought to pre-date the HDSS and to refer to everyone living within a specific HDSS area (INDEPTH, 2002). Community engagement generally refers to a wide range of activities linking researchers and study participants or communities, where these activities have different aims and involve different forms and levels of power sharing. One broad categorisation of engagement strategies between researchers and communities could be based on aims of information sharing, consultation or building partnerships, to meet a diverse set of possible research, health and ethical goals (Kamuya et al., 2013; V Marsh et al., 2008; Sharp & Foster, 2000; Tindana et al., 2007).

The majority of reports on community engagement in research are limited in their accounts of the policies, practices and perspectives on HDSS community engagement.
HDSS researchers have reported consulting community members in establishing the sites (Gyapong et al., 2013; Kouanda et al., 2013; Thysen et al., 2019; Wanyua et al., 2013), and shared their experiences of one-time reporting of HDSS results to community members (Mondain et al., 2016). In order to strengthen research processes and relationships with the community, most HDSS host research centres recruit field workers locally (Sankoh & Byass, 2012) and some maintain networks of community key informants (Crampin et al., 2012; Derra et al., 2012; Odubo et al., 2012) and representatives (Kamuya et al., 2013). Also, researchers working in the HDSS areas have shared their views and experiences of community engagement for specific studies or research institutions (Boga et al., 2011; Bull et al., 2013; V Marsh et al., 2008; Tindana et al., 2007). Some HDSS host research centres have institutional review boards that include community members (Nyika et al., 2009). Although, Community Advisory Boards (CABs) have become a popular way of trying to bring community views into research decision-making and oversight, there are challenges in identifying which individuals should be included in a CAB, ensuring that views of CAB members reflect those in the wider community, and that members are accountable to the communities they represent (Simwinga et al., 2018). It is important to note that these policies and practices, such as having CABs or recruiting field workers locally, do not seem to be specific to HDSS; they apply to all activities of HDSS host research centres.

However, some researchers have conducted empirical research on community engagement in HDSS. Researchers in the Niakhar HDSS in Senegal, designed and evaluated a community engagement activity to share information about the HDSS with community members (Mondain et al., 2016). The activity involved inviting HDSS residents to community meetings that involved theatre performances, question-and-answer sessions, and PowerPoint slide presentations. An evaluation of this community engagement activity showed that research staff faced challenges in selecting the information to share during the community meetings given the wide range of research activities that had been conducted in the HDSS over five decades. In addition, it showed that women and particular HDSS regions had been under-represented in the community engagement activity (Mondain et al., 2016). Researchers in Senegal and South Africa have also conducted empirical research to
explore community awareness of HDSS specifically, which might be important in designing HDSS community engagement in these settings (Mondain, 2013; Twine et al., 2017).

2.2.3.2 Community engagement for verbal autopsy

Research conducted in and outside the HDSS context in sub-Saharan Africa suggests that research centres should engage a wide range of stakeholders in conducting verbal autopsy to meet various research and ethical goals. For instance, Aborigo et al. (2013) advised that verbal autopsy practitioners should consult community members, research ethics committees and civil registration officers. They argued that such consultations could contribute to a deeper understanding of local community bereavement practices and inform the design of verbal autopsy procedures that respect HDSS communities, enable researchers to identify and minimise burdens for respondents, and improve the quality of verbal autopsy data (Aborigo et al., 2013). Additionally, a study in Nepal that explored the potential for feeding back VA results at the individual level (respondents and bereaved families) suggested that decisions to feedback results should be supported by initial and ongoing community engagement, in order to address potential practical and ethical challenges. It also recommended further research on the perceptions and ethical implications of sharing VA results at the community level (Morrison et al., 2018). Another study that assessed the feasibility of implementing mobile automated verbal autopsy in the Agincourt HDSS, and the views of HDSS researchers and community members on reporting VA results to respondents, also highlighted the need for wider community consultation in verbal autopsy (Bird et al., 2013). For instance, it showed that community members and field staff involved in the study supported feeding back of VA results to individual respondents, in contrast to researchers who felt that VA results were not accurate enough to be reported to individuals and that such reporting would change the nature of HDSS from surveillance to interventions and raise practical and ethical concerns around confidentiality and ancillary care responsibilities (Bird et al., 2013). In summary, this literature suggests that engaging researchers, community members and research ethics committees in verbal autopsy is important because it can show respect for study communities, minimise burdens for individuals and institutions, and enhance the scientific validity of data.
In addition to reporting views on community engagement, some researchers have shared their experiences of community engagement for verbal autopsy. For instance, one empirical study conducted in Sierra Leone suggested that engaging community health workers to report deaths in the community and reporting verbal autopsy results at community meetings can enhance community acceptability of verbal autopsy and provide locally relevant cause of death data. In addition, the study noted that sustaining such a programme would require enhanced support for community health workers and institutional capacity to conduct verbal autopsy for all deaths identified through community reporting, given that more than half of CHWs did not submit monthly reports of deaths in their allocated areas (Hutain et al., 2019). Another study conducted in Uganda, outside HDSS context, demonstrated that community health workers working for the study could administer the WHO VA questionnaires, and that they performed better than passive surveillance systems in identifying deaths, including deaths that occurred in health facilities (Nabukalu et al., 2019). Many community-based health related projects (including HDSS) across Africa and Asia seem to engage community members to collect health-related data such as births and deaths (E. K. Nichols et al., 2019), but few HDSS sites have documented how they engage community members in collecting data.

In summary, there is little documentation of community engagement processes in INDEPTH Network HDSS sites. Few studies have documented the types of community engagement activities specifically for HDSS, including types of engagement, experiences of researchers and community members, and the goals of engagement. Where researchers have documented community engagement activities in HDSS and similar contexts (such as community engagement for verbal autopsy outside HDSS), they have emphasised the importance of ongoing community engagement and context-specific research to explore community awareness, views and experiences on various engagement activities such as partnerships for data collection and reporting HDSS results (Aborigo et al., 2013; Bird et al., 2013; Hutain et al., 2019; Mondain, 2013; Mondain et al., 2016; Morrison et al., 2018; Nabukalu et al., 2019).
2.2.4 Benefits and burdens

2.2.4.1 Introduction

The need to maximise benefits and minimise burdens underlies various ethical processes in health-related research such as ethics review, data sharing and community engagement; for example, engaging local health professionals in all stages of health-related research has been shown to enhance the use of research findings to address local community health needs (Kok et al., 2016). At the broadest classification, the benefits and burdens of health-related research can be physical, social or psychological (Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014), and can be experienced at the individual or population level either through direct or indirect mechanisms (Anane-Sarpong et al., 2019; Daniels & Sabin, 1997; V Marsh et al., 2011; Setouhy et al., 2004). There are therefore a wide range of potential benefits and burdens in health-related research, indicating the need for context-specific considerations.

2.2.4.2 Benefits and burdens in health-related research

For clinical research in developing countries, Emanuel et al. (2004) developed an ethical framework which included practical guidance intended to assist researchers in maximising benefits and minimising burdens. For instance, they recommended that researchers should identify the benefits and beneficiaries of research, ensure a favourable risk-benefit ratio and minimise the burdens to the existing health system (Emanuel et al., 2004). Some have argued that this framework is general enough to be applied across a range of study types, including non-traditional research. For example, Wassenaar et al. discussed applying the Emanuel framework to the ethics review of health systems research, arguing that it could be used to consider the benefits and burdens of research on relationships and institutions, including the implications of failing to translate research evidence into practice (Wassenaar & Rattani, 2016). Public health usually prioritises population-level interests such as community wellbeing and the reduction of overall morbidity and mortality (Baum et al., 2007; Kass, 2001). In the public health context, practitioners could justify minimal burdens to individuals by demonstrating public benefits (Baum et al., 2007; Kass, 2001; Klingler et al., 2017; Rubel, 2012). In order to assess the fairness of a particular
health-related research and to inform strategies for maximising benefits and minimising burdens, it would be essential to determine the types of benefits and burdens involved, and their distribution among stakeholders.

### 2.2.4.3 Benefits and Burdens in HDSS

In a similar way to other potential ethical issues, benefits and burdens of HDSS have received little attention in the empirical ethics literature. HDSS research stakeholders have mentioned that study fatigue is a potential burden of HDSS, given the long-term and frequent household visits (Crampin et al., 2012; Emina et al., 2011; Gyapong et al., 2013; Wanyua et al., 2013). Also, it has been suggested that HDSS sites could indirectly benefit residents economically and socially; for instance, by attracting professionals and creating employment locally (Baiden, 2006).

HDSS research stakeholders, have pointed out that HDSS sites generate data and support research that could inform policy and practice, ultimately benefiting HDSS residents and global health (Bangha et al., 2010; Kim Streatfield et al., 2014; Sankoh et al., 2013; Sankoh, Welaga, et al., 2014; Sankoh & Byass, 2012). While there is some evidence that HDSS data have contributed to global health estimates and to advocacy on various public health issues (Byass, 2016a; D’Ambruoso et al., 2017; Kim Streatfield et al., 2014; Sankoh, 2010), there are also concerns about the social value and fairness of these estimates and data (Bezuidenhout et al., 2017; Bezuidenhout & Chakauya, 2018; Pisani & Kok, 2017). Moreover, most of these claims on HDSS burdens and benefits do not seem to be supported by empirical evidence. In addition, the few empirical studies that have explored the benefits and burdens of HDSS in sub-Saharan Africa, have either taken a research ethics approach or focussed on HDSS data use (Anane-Sarpong et al., 2016; Anane-Sarpong et al., 2019; Jao et al., 2015b; Mondain, 2013; Twine et al., 2017). Ballantyne (2019) has suggested that a public health ethics approach would be more appropriate than a research ethics approach in addressing the collective benefits and burdens of complex health data (Ballantyne, 2019). Furthermore, there is limited empirical research on burdens and benefits of HDSS aspects other than the use of data.
2.2.4.4 Benefits and Burdens of Verbal Autopsy

Although verbal autopsies are not exclusively conducted in the context of HDSS, the available research can contribute to an understanding of benefits and burdens of verbal autopsy in HDSS within sub-Saharan Africa. Overall, the benefits of verbal autopsy have been discussed as part of HDSS; that is, the provision of cause of death data that could be used for various health-related purposes (de Savigny et al., 2017; Sankoh & Byass, 2012, 2014). However, conceptual and empirical studies, including one conducted in an HDSS site in sub-Saharan Africa, have highlighted the potential of verbal autopsy to cause emotional distress for respondents and interviewers (Aborigo et al., 2013; Chandramohan et al., 2005; Gouda et al., 2017; Morrison et al., 2018). One of these studies suggested that verbal autopsy interviewers with training in health might be able to cope better with emotional distress of the bereaved and that despite using standardised questionnaires, were not emotionally neutral; in other words, the interviewers seemed to be affected and to react to the respondents’ emotional state (Allotey et al., 2015). Beyond burdens to individuals, the verbal autopsy could contribute to stigmatisation of bereaved families based on cause of death (Brolan et al., 2014). Furthermore, the verbal autopsy methods that require two or three physicians to review verbal autopsy interview data and generate a probable cause of death, might burden the health system by drawing away physicians from providing health care (Byass et al., 2019). Also, the accuracy of verbal autopsy results varies depending on type of disease and other study procedures (Flaxman et al., 2018; Fottrell & Byass, 2010; Herrera et al., 2017; Leitao et al., 2014). Therefore, reporting verbal autopsy results to individuals poses the risks of giving inaccurate causes of death, which can damage trust in institutions and create tensions between interviewers and respondents (Bird et al., 2013; Morrison et al., 2018). The verbal autopsy seems to be associated with a wider range of burdens to different stakeholders than the rest of HDSS activities, but overall, there is limited empirical evidence on benefits and burdens in HDSS context.

2.2.5 HDSS data sharing

Perhaps unsurprisingly, the INDEPTH Network has given significant attention to issues around data sharing; the Network was established primarily to address the lack of population-level health-related data across low and middle income countries (Sankoh
The INDEPTH Network has developed HDSS data sharing policies (Sankoh & Byass, 2012), an online data repository and an HDSS data visualisation website (Herbst et al., 2015; Sankoh et al., 2013). It has also contributed to the standardisation of data collection methods, including verbal autopsy tools and training of HDSS data managers (Baiden et al., 2007; Byass et al., 2019; Sankoh, Sharrow, et al., 2014). Furthermore, the INDEPTH Network has promoted the greater use of HDSS platforms and data by advocating for more HDSS funding (Ekström et al., 2016), use of HDSS to track progress towards health-related international development goals (Bangha et al., 2010; Sankoh, 2017), strengthen the civil registration systems (de Savigny et al., 2017; Sankoh & Byass, 2014; Savigny et al., 2018) and health systems (D’Ambruoso et al., 2017; Tollman & Zwi, 2000), and to inform public policy (Herbst et al., 2015; Ngom et al., 2001; Sankoh & Byass, 2015).

As I highlighted in Chapter 1, data from INDEPTH Network HDSS sites has supported a wide range of research on important public health issues in LMICs such as assessing the effectiveness of vaccines (Sankoh, Welaga, et al., 2014) patterns of HIV/AIDS mortality (Byass et al., 2015; Kim Streatfield et al., 2014) and the impacts of climate change (Hondula et al., 2012) and migration on health (Gerritsen et al., 2013). For these efforts, the INDEPTH Network is viewed as a model for best practices in data sharing within low and middle income countries (Pisani et al., 2016; van Panhuis et al., 2014).

There are widely acknowledged challenges of data sharing, which the INDEPTH Network seems to have addressed to varying degrees. Researchers in low and middle-income countries might lack the resources needed to effectively and equitably share data (Bezuidenhout et al., 2017; Chawinga & Zinn, 2019; Mikkelsen et al., 2015; van Panhuis et al., 2014). In additions, researchers might not share data because of concerns over potential loss of trust, flawed secondary analyses, exploitation and because of inadequate data sharing policies (Bezuidenhout & Chakauya, 2018; Bull et al., 2015; Chandramohan et al., 2008; Chawinga & Zinn, 2019; van Panhuis et al., 2014). Therefore, the data sharing infrastructure (online repositories) best practices and policies supported by INDEPTH Network are likely to minimise potential challenges of data sharing (Herbst et al., 2015; Sankoh & Byass, 2012). Some have argued that in such contexts (where challenges seem to have been addressed and
there is evidence of data use), the benefits of data sharing outweigh potential harms (Pisani et al., 2016).

The efforts by the INDEPTH Network to enhance HDSS data sharing and use might not address some important ethical issues. First, sharing data through online repositories - without sharing governance tools, analysis skills and software - could encourage unfair practices, where researchers in low resource settings mainly share data without accessing or analysing data from others (Bezuidenhout et al., 2017; Bezuidenhout & Chakauya, 2018; Pisani et al., 2016). Second, the INDEPTH Network and other HDSS stakeholders have advocated for the greater integration of HDSS data (especially the verbal autopsy) with other data sources (D’Ambruoso et al., 2017; Sankoh & Byass, 2014, 2015; Savigny et al., 2018), usually without acknowledging important ethical challenges of such integration (Gouda et al., 2017). Third, aggregated data from INDEPTH Network sites contribute to global health estimates (Sankoh, 2010) but these estimates might not inform local public health improvements (Pisani & Kok, 2017), hence leading to unequal distribution of benefits from data sharing.

It seems that the INDEPTH Network has focussed on addressing the technical and organisational barriers to data sharing to enhance the social value of HDSS data, but with less attention to other ethical issues. To illustrate this emphasis on social value, the INDEPTH Network leadership, when proposing greater integration and wider use of HDSS data for research and public health purposes, noted that:

“We are aware that the enhancements we propose need substantial developments in resources, expertise, and capacity, and will have substantial opportunity costs. Robust ethical safeguards also have to be considered. However, now is the moment to firmly state that the world cannot continue to work without essential and large-scale population health information.”

(Sankoh & Byass, 2015)

One could argue that initiatives of the INDEPTH Network such as standardising data collection tools, providing online data sharing platforms and encouraging sharing of best practices (Baiden et al., 2007; Herbst et al., 2015; Sankoh & Byass, 2012), addresses other ethical issues such as minimising burdens for respondents (for
example, by reducing time spent in interviews) and protecting the interests of HDSS researchers. However, the evidence suggests that the INDEPTH Network has primarily focussed on supporting HDSS sites to share data widely, and on advocating for greater use of HDSS data in global health.

Notably, HDSS data sharing policies, practices, and perspectives have mostly been documented at the level of the INDEPTH Network rather than at site-level. In addition, the limited empirical research has explored the perspectives of researchers on ethical issues in using public health data for research, with HDSS data as a case study (Anane-Sarpong et al., 2016). Overall, there is limited empirical research, especially from low and middle-income countries, on the policies, practices and perspectives involved in the sharing of different health-related data (Bezuidenhout & Chakauya, 2018; Bull et al., 2015; Chawinga & Zinn, 2019; Cheah et al., 2015; Denny et al., 2015; Jao et al., 2015b; van Panhuis et al., 2014; Waithira et al., 2019). Data sharing can enhance research by minimising the cost of future research and enabling the reproducibility and verification of research findings, it can also contribute to the improvement of health, good governance and achievement of ethical goals of research (Bull et al., 2015; Laine et al., 2016; Pisani & AbouZahr, 2010). However, there are various technical, organisational, economic, legal and ethical challenges to data sharing, which have been addressed to varying degrees (van Panhuis et al., 2014). In particular, there is limited documentation of ethical issues in sharing HDSS data. This highlights the need for empirical research to describe the policies and practices of data sharing in individual HDSS sites, and to explore the perspectives of researchers and community members around HDSS data sharing, towards informing evidence based policy and practice.

2.3 Summary

The literature indicates that INDEPTH Network HDSS sites in sub-Saharan Africa were established, and currently operate, through international research collaborations for health. Methodologically, HDSS sites appear to be indistinctly positioned between various forms of health activities such as health research and public health (Carrel & Rennie, 2008), but they can be regarded as non-traditional health-related research based on available evidence. However, there is little documentation of individual
HDSS characteristics, including history, socioeconomic context and current functioning. Describing these features for each site would help to clarify the methodological approach of HDSS, and to lay a firm foundation for understanding and addressing potential ethical issues.

Ethical issues for health-related research in sub-Saharan Africa, and for HDSS in particular, have been studied to varying degrees. Given the indistinct positioning of HDSS and that relatively little empirical research has focused in this area, it is challenging to determine how the available ethics guidance apply to HDSS in sub-Saharan Africa. For instance, most ethics review committees use ethics guidelines that were originally developed for clinical research and current recommendations to adapt these guidelines for non-traditional health-related research does not seem to have considered practices and perspectives from HDSS sites in sub-Saharan Africa. A description of HDSS characteristics and ethical issues would contribute to the identification of the appropriate ethics oversight processes for HDSS sites.

There is a paucity of empirical research on HDSS ethics including on consenting and community engagement process, data sharing, benefits and burdens. The literature highlights specific ethical issues in HDSS for empirical research. First, HDSS are complex programmes that involve entire geographically defined populations, empirical research would provide evidence on what residents and field workers understand about HDSS, and the extent to which individuals and households feel that they participate voluntarily. Second, there is a need for clarity on what HDSS community engagement entails, including whether and how it differs from programme-wide and project-specific community engagement activities that common in health-related research within sub-Saharan Africa. In particular, conducting some HDSS activities, such as the verbal autopsy, is likely to require an understanding of local community reactions to death and it is unclear how HDSS research stakeholders gain this understanding. Third, it seems HDSS sites make data available to the global health community and researchers through the INDEPTH Network or online repositories but there is a lack of evidence on site-specific HDSS data sharing policies and practices, including the local use of data and perspectives on data sharing. Fourth, most of the literature presents sites as minimal risk activities that seek to address the data gap left by the weak civil registration and vital statistics
systems in LMICs. However, unlike CRVS, which provides direct benefits to individuals and contributes to government policies, there is limited evidence of HDSS benefits beyond the potential uses of HDSS research data. Studies have suggested that verbal autopsy might involve important psychological and social burdens for individuals, communities, and institutions in HDSS. Finally, most of the research on HDSS and related activities has drawn from research ethics perspectives that emphasise individual-level issues such as individual autonomy. This is despite HDSS sites being multidimensional programmes that involve a wide range of stakeholders, data, objectives and procedures.
3 CHAPTER 3 Methodology

In Chapters 1 and 2, I highlighted the paucity of empirical ethics research and guidelines for health and demographic surveillance systems (HDSS). I showed that the few empirical studies on HDSS ethics do not take a holistic perspective; they mainly focus on specific components of HDSS giving little attention to contextual factors. In Chapter 1, I outlined the objectives of this study; to identify the key ethical issues in HDSS within sub-Saharan Africa and to make recommendations on how research stakeholders should address potential ethical issues in HDSS.

In this chapter, I will describe the overall methodological approach, including the study design and its philosophical underpinnings, methods of data collection and analysis, study areas and participants. The methodological approach is based on a case study design following a pragmatic constructivist paradigm and largely draws on qualitative methods. I will describe the overall features of the seven HDSS sites and 151 individuals that I involved in the empirical component of this study.

To enhance the transparency of the study methods and the trustworthiness of the findings, I will describe the research tools and process, theoretical frameworks and my positionality. In addition, I will describe the ethical review process and other ethical considerations in this study and conclude by highlighting the strengths and weaknesses of this methodological approach in relation to the study objectives.

3.1 Case Study: Ethical Issues for HDSS sites in sub-Saharan Africa

3.1.1 Overview of Case Study Research

There are diverse conceptualisations and applications of case study research. Prominent case study researchers and scholars include Robert Stake, Robert Yin and Sharan Merriam; their recommendations on case study research have gained widespread acceptance in different academic disciplines including sociology, education, law and business (Hyett et al., 2014; Yazan & De Vasconcelos, 2016). Informed by a post-positivist paradigm, Yin views case study research as an empirical inquiry that can use both quantitative and qualitative methods to get as close to the reality as possible (Yin, 2003). Merriam takes a pragmatic constructivist approach and advises that case study researchers should prioritise qualitative methods when the
aim is to generate an in-depth understanding of an issue rather than to test hypotheses (Merriam, 1998). Stake’s interpretivist approach to case study research emphasises the importance of the researcher’s role and social context in generating evidence (R. Stake, 1995). These different perspectives illustrate that researchers can approach case study research from diverse philosophical positions and academic disciplines (Harrison et al., 2017). However, the multiple interpretations and applications of case study research often lead to misunderstandings (Hyett et al., 2014).

Despite its different interpretations and applications, case study research has several defining features. Most scholars agree that case studies are suitable for investigating complex issues in their social contexts. Also, case studies usually involve multiple sources of evidence, a detailed description of the social context, researchers’ role, and philosophical underpinnings of study methods (Mats Alvesson et al., 2004; Barnes, 2017; Grant & Newcombe, 2004; Merriam, 1998; R. Stake, 1995; Yazan & De Vasconcelos, 2016; Yin, 2003). This shows that a case study is a comprehensive research strategy that entails careful consideration, description and justification of study methods. In the following sections, I will first clarify the philosophical underpinnings of my methodological approach and then describe the study procedures.

3.1.2 Philosophical underpinnings of my case study approach

I adopted a pragmatic framework for this case study (Morgan, 2007). This allowed me to use multiple data collection methods and theoretical frameworks as necessary. From the outset, I was aware that the research questions, procedures, participants and themes were likely to evolve, especially during the initial stages. As I will explain later, I adopted primarily qualitative methods, drawing on inputs and expertise from colleagues in my department who have significant experience of conducting empirical ethics research using qualitative social science methods. Overall, the philosophical foundation of this study aligns with Merriam’s pragmatic constructivism (Harrison et al., 2017; Merriam, 1998). However, I did not exclude other interpretations of case study research. For example, I incorporated other case study scholar’s recommendations for enhancing study rigor, generalisability and trustworthiness (Smith, 2018; R. Stake, 1995; Yin, 2003), as discussed further below.
3.1.3 The HDSS as a “Case”

A “case” in case study research can be a person, event, policy, programme or any other contemporary phenomena (Merriam, 1998; R. Stake, 1995; Yin, 2003). It is usually restricted to a specific location or topic. Merriam defines a case as “a specific, complex and functioning thing, which has a boundary and working parts” (Merriam, 1998). The INDEPTH Network HDSS sites fit Merriam’s and other scholars’ definition of a “case” (Merriam, 1998; R. Stake, 1995; Yazan & De Vasconcelos, 2016; Yin, 2003). First, the sites are contemporary programmes; there are 53 INDEPTH Network HDSS sites located across Africa, Asia and Oceania (INDEPTH Network, 2016b). Second, the sites have unique defining characteristics, including the long-term monitoring of vital events in geographically defined populations through household visits (Sankoh & Byass, 2012). Finally, HDSS sites are complex social programmes because they involve multiple actors, outcomes, objectives and procedures, which are sensitive to the social context and prone to iteration (Carrel & Rennie, 2008; Pawson et al., 2004; Sankoh & Byass, 2012; Ye et al., 2012). For these reasons, a “case” in this study refers to a health and demographic surveillance system.

3.1.4 Unit of analysis: ethical issues in HDSS

The unit of analysis refers to the focus of a study; the specific issue for which a researcher collects data (VanWynsberghe et al., 2016). Case study researchers can determine the unit of analysis before they start collecting data (Yin, 2003), or they can identify and refine the unit of analysis by collecting and analysing data (Merriam, 1998; R. Stake, 1995). Although I determined the unit of analysis (ethical issues for HDSS sites) at the start of the study, I refined it through an iterative research process that involved reviewing the literature, and collecting and analysing data. Eventually, this study strongly focussed on ethical issues for verbal autopsy in HDSS sites within sub-Saharan Africa, particularly the benefits and burdens of verbal autopsy in two Kenyan HDSS sites. In this chapter, I will describe the iterative research process that I followed. Here, I wanted to highlight the important distinction between a unit of analysis and a case (VanWynsberghe et al., 2016), and to note that I determined the unit of analysis at different stages of the study through deductive and inductive approaches.
3.1.5 Defining Case Study Research

Recognising the diverse conceptualisations of case study research, and the essential role of clarifying the unit of analysis, VanWyndenberghe and Khan (2007) argued that the use of multiple paradigms and the process of identifying the unit of analysis are the defining features of case study research (VanWyndenberghe & Khan, 2007). In addition, Yazan (2015) advised that researchers could combine different research paradigms and tools in conducting case study research (Yazan & De Vasconcelos, 2016). Case study research can involve multiple cases and methods of collecting data such as observations and interviews (John Creswell, 2012).

This case study research combined the three perspectives above (John Creswell, 2012; VanWyndenberghe & Khan, 2007; Yazan & De Vasconcelos, 2016), with a pragmatic constructivist approach (Harrison et al., 2017; Merriam, 1998). It was transparadigmatic (used constructivist and post-positivist perspectives) transdisciplinary (relied on concepts from social science and ethics), and involved multiple cases across sub-Saharan Africa and diverse sources of evidence. Cases are often defined by their intended purpose; they can be exploratory, descriptive, explanatory, intrinsic or instrumental (Barnes, 2017; J. W. Creswell et al., 2007; Lloyd-Jones, 2017; R. Stake, 1995). While Yin recommends structured case study procedures (Barnes, 2017; Yin, 2003), Stake advocates for a flexible study design where researchers can make major changes as the project progresses (Participants in the Community Engagement and Consent Workshop, Kilifi, Kenya, 2013; R. Stake, 1995). Merriam’s account of case study research includes a semi-structured design that allows both deductive and inductive study procedures (Merriam, 1998).

This study involved multiple cases (HDSS sites). I divided the study into three interlinked phases – formative research (Phase 1), an in-depth case study (Phase 2) and a final phase to assess the wider relevance of findings from the in-depth cases (Phase 3). In the following sections, I will discuss each of the three study phases including the objectives, study procedures and linkage with each other.
3.2 Phase One: Exploratory Case Study

3.2.1 Objective: Getting a Lay of the Land

To ensure a focussed investigation, case study researchers are advised to develop research questions, theoretical frameworks or study propositions in the early stages of research, including through literature reviews (Merriam, 1998; Yin, 2003). At the start of this study, I conducted a preliminary literature review on ethical issues for health and demographic surveillance systems.

It can be challenging to determine the exact point at which a study starts (R. Stake, 1995; R. E. Stake, 1981). As an illustration, my host research centre (KEMRI Wellcome Trust) has been operating the Kilifi HDSS since 2001 and is a member of the INDEPTH Network (Scott et al., 2012). In addition, my PhD supervisors had conducted some preliminary literature reviews and consulted KHDSS research staff and community members as part of their long-term empirical ethics research at KEMRI Wellcome Trust. Therefore, even at the very early stages of my study, the social context (previous experience of ethical issues in HDSS) significantly influenced the choice of research questions. Recognising that ethics can only be understood in context, the objectives of the formative research were to:

i. To describe the similarities and differences of HDSS sites in sub-Saharan Africa in terms of their history, context and functioning.

ii. To describe HDSS research stakeholders’ perceptions of the nature of ethical issues within HDSS sites in sub-Saharan Africa, and their underlying influences.

I viewed this initial phase of the study as an orientation to get ‘a lay of the land’ around HDSS ethics issues on the ground, and to inform research questions for Phase 2 and 3. This phase had important implications for study procedures and the ethics review process, as I will describe in the following sections and under ethical considerations.

3.2.2 Selecting Study Areas and Participants for Phase 1 Research

To represent the range of HDSS characteristics and views on ethical issues across sub-
Saharan Africa, I selected Phase 1 study areas and participants using purposive sampling (Howarth, 2012; Mays & Pope, 1995). The aim of purposive sampling is to select information-rich cases for in-depth study rather than to achieve statistical representativeness (Patton, 2002). I used snowball and maximum variation purposive sampling, by requesting initial participants to recommend other potential participants, and by purposefully including study areas and participants with diverse characteristics (Isaacs, 2014; Mack et al., 2005). I selected six HDSS sites located in Eastern, Western and Southern Africa and representing a wide range of features in terms of population size, year of establishment and geographic size, as shown below.

Table 1 Characteristics of Phase One HDSS sites

<table>
<thead>
<tr>
<th>HDSS Site</th>
<th>Country</th>
<th>Urbanicity</th>
<th>Size of Site (km²)</th>
<th>Population¹ (Approximate)</th>
<th>Inception Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Karonga</td>
<td>Malawi</td>
<td>Rural</td>
<td>135</td>
<td>39,000</td>
<td>2002</td>
</tr>
<tr>
<td>Kilifi</td>
<td>Kenya</td>
<td>Rural</td>
<td>891</td>
<td>280,000</td>
<td>2000</td>
</tr>
<tr>
<td>Kintampo</td>
<td>Ghana</td>
<td>Rural</td>
<td>7,162</td>
<td>140,000</td>
<td>2003</td>
</tr>
<tr>
<td>Kyamulibwa</td>
<td>Uganda</td>
<td>Rural</td>
<td>28</td>
<td>22,000</td>
<td>1989</td>
</tr>
<tr>
<td>Nairobi</td>
<td>Kenya</td>
<td>Urban</td>
<td>6.6</td>
<td>65,000</td>
<td>2002</td>
</tr>
<tr>
<td>Navrongo</td>
<td>Ghana</td>
<td>Rural</td>
<td>1,675</td>
<td>156,735</td>
<td>1992</td>
</tr>
</tbody>
</table>

In each site, the formative research involved individuals who were likely, through their direct experiences of working with the HDSS, to have noted issues of ethical importance from their perspectives. These included what I refer to as HDSS ‘research stakeholders’, who include:

1. Research staff - Individuals working with the HDSS host research centres as researchers or research ethics committee administrators and who may occasionally interact with the HDSS. For instance, reviewing HDSS protocols, requesting HDSS data or recruiting HDSS residents into nested studies.

2. HDSS Managers – Individuals working with the HDSS and whose responsibilities include overseeing HDSS functions. These include HDSS site coordinators, data managers and supervisors, and INDEPTH Network administrators.

3. HDSS Census Field workers – Individuals whose primary responsibilities

¹ Data Sources: HDSS site profiles, INDEPTH Network and host centre websites
include visiting households in the HDSS areas to conduct routine census enumerations, includes individuals collecting data from health facilities affiliated with the HDSS.

4. Verbal Autopsy Interviewers: Individuals with responsibilities for conducting verbal autopsy interviews. Some verbal autopsy interviewers also work as HDSS field supervisors.

Besides these strategies for ensuring diversity, pragmatic considerations also influenced the selection of study areas and participants in Phase 1. I considered social access, geographic proximity and availability of time and other resources for research. For instance, my supervisors and I had established relationships with several researchers in the HDSS listed in Table 1, which made it easier for me to work with these sites. In addition, I selected the Nairobi HDSS not only because it is one of the few urban sites but also because it is in Kenya, where I was based during this study. When visiting the Navrongo HDSS in Ghana, I also decided to briefly visit the Kintampo HDSS and the INDEPTH Network headquarters, which are also in Ghana. This sampling strategy enabled me to select diverse study areas and study participants, and to collect data through informal discussions, non-participant observation and document review.

3.2.3 Informal Discussions with HDSS Research Stakeholders

I held informal discussions with research stakeholders (as defined in the previous section) from six HDSS sites in sub-Saharan Africa and the INDEPTH Network (Table 2). Through these discussions, I sought information about the history, socioeconomic context and functioning of HDSS sites, including the participants’ experiences and views on ethical issues. However, the subject of discussion varied depending on the responsibilities of the participant in the HDSS. For instance, discussions with HDSS managers included more details on HDSS functioning than discussions with researchers, as expected. Through these discussions, I also learned about publications on ethically relevant issues in HDSS.

I talked to research stakeholders at whatever time and in whatever place they found convenient. This entailed having discussions during and outside working hours, in
individual and shared offices, in public spaces such as restaurants, during field work and while travelling together. Given the informal context of these discussions, the lack of refined research tools or ethical approvals, and my view of this Phase as an orientation, I did not audio-record. However, I took extensive field notes.

Table 2 Number of participants in Phase One informal discussions

<table>
<thead>
<tr>
<th>HDSS Site</th>
<th>HDSS Research Stakeholders</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Managers</td>
<td>Research Staff</td>
</tr>
<tr>
<td>Nairobi</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Kintampo</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Navrongo</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Karonga</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Kyamulibwa</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Kilifi</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>INDEPTH</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>15</strong></td>
<td><strong>13</strong></td>
</tr>
</tbody>
</table>

3.2.4 Reviewing Documents: Phase One

The orientation visits also enabled me to access grey literature with relevant information about HDSS characteristics and ethically relevant processes. Research stakeholders either handed me the relevant documents or directed me to online platforms. Table 3 shows the key documents I accessed through this process.

Table 3 Documents obtained through Phase One research activities

<table>
<thead>
<tr>
<th>Types of documents obtained from HDSS sites in Kenya, Ghana, Uganda and Malawi</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Information sheets and consent forms - Kintampo, Kilifi, Nairobi, Kyamulibwa</td>
</tr>
<tr>
<td>- HDSS questionnaires and protocols - Kyamulibwa, Kilifi, Nairobi</td>
</tr>
<tr>
<td>- HDSS annual reports - Kintampo</td>
</tr>
<tr>
<td>- Ethics review committee guidelines - Navrongo</td>
</tr>
<tr>
<td>- HDSS ethics clearance letter - Karonga and Nairobi</td>
</tr>
<tr>
<td>- Data Sharing Guidelines - Kilifi and Nairobi</td>
</tr>
<tr>
<td>- Benefit Sharing Guidelines - Kilifi</td>
</tr>
<tr>
<td>- Communication material – HDSS information booklets, radio programme guides...</td>
</tr>
</tbody>
</table>

3.2.5 Observing HDSS Surveillance Activities: Phase One

Case study researchers commonly use non-participant observation as a method of data collection. This method enables researchers to observe and understand activities in their real-life context (Liu, F., & Maitlis, 2010). During Phase 1 of the study, I observed various HDSS surveillance activities. These activities - shown in Table 4 - included routine HDSS census and verbal autopsy interviews. I prepared field notes.
on the interview setting, number and gender of field workers and respondents, language, type of data, time taken, meeting agendas, reactions of HDSS community members to field workers and other features of the interactions between HDSS research stakeholders and residents that I found noteworthy.

Some have argued that case study researchers should collect and analyse observation data first because it would inform the collection and analysis of non-observation data, and reveal issues that participants might be unwilling or unable to discuss (S. Morgan et al., 2017). Indeed, my first data collection activities for this study involved observing surveillance and community engagement activities at the Kilifi HDSS. However, my overall data collection strategy was highly iterative and dependent on pragmatic considerations such as social access. In sites other than Kilifi, I held informal discussions with HDSS managers and other research staff before observing HDSS surveillance activities in households or health facilities.

**Table 4 Observation of HDSS surveillance activities during Phase One orientation visits**

<table>
<thead>
<tr>
<th>HDSS Site</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Karonga</td>
<td>Routine Census in 4 Households accompanied by 1 Field Staff</td>
</tr>
<tr>
<td></td>
<td>Verbal autopsy Interviews in 2 households</td>
</tr>
<tr>
<td></td>
<td>Monthly Community Key Informants Reporting Meeting</td>
</tr>
<tr>
<td>Kilifi</td>
<td>Routine census in 36 households accompanied by three field staff</td>
</tr>
<tr>
<td></td>
<td>KHDSS Field Staff training on electronic data collection. KCRs refresher training.</td>
</tr>
<tr>
<td></td>
<td>Tour of KCH male and paediatric wards</td>
</tr>
<tr>
<td></td>
<td>EDD CAST meeting, KWTRP Open day</td>
</tr>
<tr>
<td>Kintampo</td>
<td>Routine Census in 2 Households accompanied by 3 Field Staff</td>
</tr>
<tr>
<td>Kyamulibwa</td>
<td>Routine Census in 1 Household accompanied by 1 Field Staff</td>
</tr>
<tr>
<td></td>
<td>The Biannual Community-based medical survey</td>
</tr>
<tr>
<td></td>
<td>Tour of the General Population Cohort Health Centre</td>
</tr>
<tr>
<td>Nairobi</td>
<td>Routine Census in 4 households in Viwandani and 1 Household in Korogocho field sites, accompanied by 1 Field Staff in each field site.</td>
</tr>
<tr>
<td>Navrongo</td>
<td>Routine Census in 3 Households accompanied by 2 field staff</td>
</tr>
</tbody>
</table>

3.2.6 Phase One Data Management and Analysis

The main research data from Phase 1 included handwritten field notes from non-participant observations and informal discussions. I typed the field notes into a
Microsoft Word document and stored them in a password protected computer. In addition, I stored the handwritten field notes and unpublished documents such as HDSS questionnaires in a locked cabinet. I analysed these data in relation to the first objective of the study (To describe the characteristics of HDSS in sub-Saharan Africa and to map out key ethical issues), and considering the predominant issues in bioethics. Hence, the analytical framework, included the following themes:

a) HDSS history: Year established, rationale for establishment, actors involved in establishing sites.

b) HDSS context: Geographic location and size, population size, socio-economic features of HDSS population.

c) HDSS functioning: Types of data collected, respondents, methods and frequency of data collection.

d) Policies, practices and perspectives on HDSS ethics review, consenting, community engagement, data sharing, benefits and burdens. For instance, views on benefits for HDSS communities and strategies for minimising burdens for individual respondents.

I compiled a report for each of the six HDSS sites through an analysis process that involved linking the empirical data to the framework outlined above, and drawing from my reflections from the orientation visits and consultations with my PhD supervisors. Overall, the formative research enabled me to describe HDSS sites in sub-Saharan Africa and to map out potential ethical issues for HDSS. In Chapter 4, I will present the detailed findings of the formative research. Here, I want to point out that the formative research highlighted significant diversity in terms of HDSS characteristics, uncertainty over ethics processes such as ethics review and consenting, and that some HDSS activities such as verbal autopsy interviews, raised similar ethical issues across diverse settings. In addition, the formative research enabled me to refine research questions and procedures for Phase 2 and 3 of the study.
3.3 Phase Two: In-depth Case Study

Following the formative research, which identified potential ethical issues in HDSS across sub-Saharan Africa, including particular sensitivities such as HDSS questions around socioeconomic status, pregnancies and verbal autopsy interviews, I designed Phase 2 of the study to explore these ethical issues in depth. Following preliminary analysis of initial interviews with HDSS researchers and managers in the Kilifi and Nairobi sites, I decided to focus on the verbal autopsy; it was confirmed as a particularly sensitive activity (as I will describe in Chapter 4) and therefore a suitable lens for exploring key ethical issues in HDSS (such as the balance of HDSS benefits and burdens, and the ethical implications of HDSS indistinct positioning). Therefore, the objective of the in-depth case study evolved to be:

To explore, in depth, ethical issues for verbal autopsy in a rural and an urban HDSS site in Kenya, from the perspectives of research and community stakeholders.

3.3.1 Selecting In-depth Case Study Sites

I conducted the in-depth case study in the Kilifi and Nairobi HDSS sites in Kenya. I selected the two sites based on scientific and pragmatic considerations, as outlined in Section (3.2). The rural-based Kilifi HDSS is the largest INDEPTH Network HDSS by population size and is run by a semi-autonomous government organisation (Scott et al., 2012), while the Nairobi HDSS was the pioneer urban-based HDSS and is run by a non-government research organisation (Beguy et al., 2015). Investigating these cases, which have unique and contrasting features, can contribute to an in-depth understanding of the unit of analysis and enhance the wider relevance of the study findings (Yin, 2003). Pragmatic considerations such as social access, my language skills and geographic proximity also influenced the selection of the Kilifi and Nairobi HDSS sites for in-depth case study.

3.3.1.1 An overview of the Kilifi HDSS

The Kilifi HDSS is located on the Indian Ocean coast of Kenya in Kilifi County and is run by the KEMRI Wellcome Trust Research Programme (KWTRP). The KWTRP is a semi-autonomous government organisation that was established in 1989 as a partnership
between the Kenya Medical Research Centre, the Wellcome Trust and University of Oxford (Scott et al., 2012). Currently, the KWTRP has three research hubs (Kilifi and Nairobi in Kenya and Mbale in Uganda), where researchers conduct a wide range of studies on the biomedical, clinical, epidemiological and social aspects of health (KEMRI Wellcome Trust, 2019). The KWTRP established the KHDSS to provide population-level data to support health research and evaluate community-based interventions in the HDSS population. The KHDSS conducted the baseline household census between September 2000 and October 2001 and linked the household census with hospital-based surveillance in 2002 (Scott et al., 2012).

According to the 2019 Kenya national census, Kilifi County has a population of 1,453,787 and a population density of 116 people per square kilometre (2019 Census). The KHDSS follows up about a quarter million people living within 15 administrative locations in Kilifi that cover an area of 891km² (Scott et al., 2012). Although Kilifi County is largely rural, it has a few urban and peri-urban areas, including Mtwapa, Kilifi and Malindi towns. A report on access to goods and services across Kenya, which the Kenyan National Bureau of statistics published in 2013, showed that Kilifi is one of the most deprived and unequal counties in Kenya. For instance, it showed that 58% of Kilifi residents lacked access to improved sanitation facilities and that the wealthiest residents spent 20 times more than the poorest residents. Also, the report suggested that people living in the urban areas of the county, when compared to those in rural areas, had better access to goods and services (KNBS, 2013).
3.3.1.2 An overview of the Nairobi Urban HDSS

The Nairobi Urban HDSS comprises two separate urban areas (Viwandani and Korogocho) located in Nairobi, the capital city of Kenya. It is run by the African Population and Health Research Centre (APHRC), which is a non-profit, non-government pan-African health research organisation that was established in 1995 to conduct policy-relevant research on population, health, education, urbanisation and related development issues across Africa (Beguy et al., 2015). APHRC established the Nairobi NUHDSS in 2002, as the first urban-based HDSS in Africa, to investigate the social, economic and health implications of urban residence and to provide a platform for evaluating interventions that focus on the urban poor in Africa. To establish the NUHDSS, APHRC conducted baseline censuses in four urban areas in Nairobi county; Kawangware, Korogocho, Njiru and Viwandani, then selected Korogocho and Viwandani for long-term follow up (Beguy et al., 2015; Emina et al., 2011).
According to the 2019 Kenya national census, Nairobi County has a population of 4,397,073 and a population density of 6,247 per square kilometre (2019 census). The NUHDSS follows up a population of 65,000 living within Viwandani and Korogocho administrative locations, which cover a combined area of 0.97km² (Beguy et al., 2015; Emina et al., 2011). On average, Nairobi residents seem to have better access to services and goods compared to residents in other areas of Kenya (KNBS, 2013). However, research by APHRC has highlighted that residents of poor urban areas such as Viwandani and Korogocho are likely to have worse health and demographic outcomes than residents of other areas in Kenya, including rural Kenya, and have lower school enrolment and higher unemployment rates (African Population and Health Research Center (APHRC), 2002; Beguy et al., 2015).

Figure 3 Nairobi HDSS map [http://www.indepth-network.org/Profiles/Nairobi%20UHDSS.pdf](http://www.indepth-network.org/Profiles/Nairobi%20UHDSS.pdf)

Figure 4 Redacted photograph of NUHDSS residents and interviewer, available @ (Beguy et al., 2015)

3.3.2 Selecting Study Participants in the in-depth case studies

I used a purposive sampling strategy (Howarth, 2012; Mays & Pope, 1995) to select participants with direct experience of the case study sites (KHDSS and NUHDSS),
either as research stakeholders at the host institutions (KWTRP and APHRC) or as HDSS residents. The participants included HDSS research stakeholders, and what I refer to as HDSS ‘community stakeholders’ – who are:

1. Community Members – Individuals living within the HDSS areas.

2. Community Representatives – Individuals with responsibilities for representing community members in community engagement or research oversight processes, including Community Advisory Committee Members in the NUHDSS and KEMRI Community Representatives in the KHDSS.

Individuals have multiple identities and responsibilities depending on context; for instance some researchers might be HDSS residents and community representatives are drawn from community members. However, defining the different participant groups as described above enabled me to use stratified purposive sampling (Margarete, 2000), where I selected individuals who share broad characteristics (for example, research stakeholders) but vary in terms of specific attributes (verbal autopsy interviewers). Throughout this study, the term “community stakeholder” refers to community members and community representatives, while “research stakeholders” refers to HDSS research staff, managers, census field workers and verbal autopsy interviewers.

Personal characteristics such as age, education, religion, and profession can influence an individuals’ perspectives (Kuper et al., 2008). Therefore, besides selecting participants based on their social responsibilities, I included individuals with diverse personal characteristics. For community stakeholders, I included male and female participants from different regions of the HDSS areas. However, when selecting research stakeholders, I mainly considered their roles within the HDSS sites rather than other personal characteristics. Overall, I included participants with diverse personal, academic and professional backgrounds, including diverse experiences with the case study sites.

3.3.3 Data Collection Methods: Phase Two

Some have argued that case study researchers should prioritise qualitative methods of data collection such as interviews and observations, especially when the objective
is to develop an in-depth understanding of a complex issue (Merriam, 1998; R. Stake, 1995). It is widely accepted that, regardless of the study methods chosen, researchers should describe their data collection processes to enhance study validity and trustworthiness (Harrison et al., 2017; Yin, 2003).

Between 2016 and 2019, I conducted individual in-depth interviews with research stakeholders, held focus group discussions with community stakeholders and observed HDSS data collection in the Kilifi and Nairobi Urban HDSS sites in Kenya. In addition, I obtained and analysed unpublished documents and verbal autopsy data from these two case study sites. I started by collecting data in the Kilifi HDSS, where I had social and physical access, before moving to the Nairobi HDSS, where I needed to build relationships and negotiate access. I interviewed research stakeholders before the focus group discussions with community stakeholders because holding the focus group discussions required detailed planning to refine research questions, recruit participants, make appointments and facilitate the discussions. In summary, I collected the data through an iterative process informed by scientific and pragmatic considerations.

### 3.3.3.1 Individual In-depth Interviews with Research Stakeholders

In-depth interviews are commonly used to collect data in qualitative research. All prominent case study scholars – including those with a post-positivist philosophical leaning – view in-depth interviews as suitable methods of collection in case study research (Yin, 2003). Researchers conduct individual in-depth interviews on the assumption that a focussed conversation can contribute to a rich understanding of individual perspectives and fundamental features of the subject being investigated. The researcher co-creates meaning with the participant by asking mostly open-ended questions on a particular subject (Merriam, 1998; Nigel et al., 2018).

Across the two sites, I conducted individual in-depth interviews with 24 HDSS research stakeholders, whom I selected for based on scientific and pragmatic considerations as described above. Because HDSS research stakeholders have varying experience and responsibilities in HDSS, the interviews included a co-learning session to build mutual understanding about the HDSS and ethics. Therefore, I started all interviews by asking general questions to the participant about their responsibilities.
in the HDSS and their experience of ethically challenging situations, before exploring their views on various ethical issues in HDSS such as consenting. On the twelfth interview, I began to focus the discussions on ethical issues for verbal autopsy, which had clearly emerged as key area of ethical sensitivities in HDSS from earlier interviews, and from Phase 1. Appendix 3 shows the research interview guides. I audio-recorded the interviews with consent from each participant. Table 5 below shows basic features of the participants and context of the interview.

Table 5 Features of individual in-depth interviews in Phase Two

<table>
<thead>
<tr>
<th>Interview Code</th>
<th>HDSS Site</th>
<th>Sex</th>
<th>Designation</th>
<th>Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDI01_HDSS_Ethics</td>
<td>Kilifi</td>
<td>M</td>
<td>Researcher</td>
<td>65</td>
</tr>
<tr>
<td>IDI02_HDSS_Ethics</td>
<td>Kilifi</td>
<td>M</td>
<td>Researcher</td>
<td>66</td>
</tr>
<tr>
<td>IDI03_HDSS_Ethics</td>
<td>Kilifi</td>
<td>M</td>
<td>HDSS Manager</td>
<td>90</td>
</tr>
<tr>
<td>IDI04_HDSS_Ethics</td>
<td>Kilifi</td>
<td>M</td>
<td>HDSS Manager</td>
<td>61</td>
</tr>
<tr>
<td>IDI05_HDSS_Ethics</td>
<td>Kilifi</td>
<td>M</td>
<td>HDSS Manager</td>
<td>101</td>
</tr>
<tr>
<td>IDI06_HDSS_Ethics</td>
<td>Kilifi</td>
<td>F</td>
<td>Government Official</td>
<td>72</td>
</tr>
<tr>
<td>IDI07_HDSS_Ethics</td>
<td>Kilifi</td>
<td>F</td>
<td>Researcher</td>
<td>78</td>
</tr>
<tr>
<td>IDI08_HDSS_Ethics</td>
<td>Nairobi</td>
<td>F</td>
<td>HDSS Manager</td>
<td>36</td>
</tr>
<tr>
<td>IDI09_HDSS_Ethics</td>
<td>Nairobi</td>
<td>M</td>
<td>HDSS Manager</td>
<td>43</td>
</tr>
<tr>
<td>IDI10_HDSS_Ethics</td>
<td>Nairobi</td>
<td>F</td>
<td>Researcher</td>
<td>45</td>
</tr>
<tr>
<td>IDI11_HDSS_Ethics</td>
<td>Nairobi</td>
<td>F</td>
<td>Researcher</td>
<td>71</td>
</tr>
<tr>
<td>IDI12_HDSS_Ethics_VA</td>
<td>Kilifi</td>
<td>M</td>
<td>Researcher</td>
<td>61</td>
</tr>
<tr>
<td>IDI13_HDSS_Ethics_VA</td>
<td>Kilifi</td>
<td>F</td>
<td>Researcher</td>
<td>57</td>
</tr>
<tr>
<td>IDI14_HDSS_Ethics_VA</td>
<td>Kilifi</td>
<td>F</td>
<td>HDSS Field Worker</td>
<td>70</td>
</tr>
<tr>
<td>IDI15_HDSS_Ethics_VA</td>
<td>Kilifi</td>
<td>M</td>
<td>HDSS Manager</td>
<td>54</td>
</tr>
<tr>
<td>IDI16_HDSS_Ethics_VA</td>
<td>Kilifi</td>
<td>F</td>
<td>Researcher</td>
<td>57</td>
</tr>
<tr>
<td>IDI17_HDSS_Ethics_VA</td>
<td>Kilifi</td>
<td>M</td>
<td>Researcher</td>
<td>49</td>
</tr>
<tr>
<td>IDI18_HDSS_Ethics_VA</td>
<td>Kilifi</td>
<td>M</td>
<td>VA Interviewer</td>
<td>65</td>
</tr>
<tr>
<td>IDI19_HDSS_Ethics_VA</td>
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<td>M</td>
<td>HDSS Manager</td>
<td>45</td>
</tr>
<tr>
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<td>F</td>
<td>VA Interviewer</td>
<td>59</td>
</tr>
<tr>
<td>IDI21_HDSS_Ethics_VA</td>
<td>Nairobi</td>
<td>M</td>
<td>VA Interviewer</td>
<td>45</td>
</tr>
<tr>
<td>IDI22_HDSS_Ethics_VA</td>
<td>Nairobi</td>
<td>M</td>
<td>VA Interviewer</td>
<td>64</td>
</tr>
<tr>
<td>IDI23_HDSS_Ethics_VA</td>
<td>Nairobi</td>
<td>F</td>
<td>VA Interviewer</td>
<td>54</td>
</tr>
<tr>
<td>IDI25_HDSS_Ethics_VA</td>
<td>Kilifi</td>
<td>M</td>
<td>VA Interviewer</td>
<td>61</td>
</tr>
</tbody>
</table>

3.3.3.2 Focus Group Discussions with Research and Community Stakeholders

Focus group discussions entail discussions among a small group of people around a focused topic or set of issues to explore the views and experiences of a particular population group. The researcher in focus group discussions takes the role of a moderator to encourage interactions between participants and to focus the discussion (Krueger et al., 2000; Qu & Dumay, 2011).
I held 12 focus group discussions involving 86 community stakeholders and HDSS field workers across the two case study sites. Each focus group involved 4-9 participants drawn from different regions within the HDSS sites, as shown Table 6. Each focus group discussion included a substantial co-learning session to build mutual understanding about the topic of discussion. For the co-learning session, I – with the assistance of a senior field worker in each site – explored participants' understanding and experience with KWTRP, APHRC, health research, routine HDSS census, verbal autopsy and ethical issues. The co-learning sessions across the two sites were interactive; participants shared information about their experiences and directed questions to fellow participants or to the moderators – to illustrate, one participant asked “why is the KHDSS only conducted in some areas of Kilifi”; I responded by asking others in the group what they thought, and then explained using information from the KHDSS research stakeholders how the areas covered were selected.

Table 6 Features of focus group discussions in Phase Two

<table>
<thead>
<tr>
<th>Focus Group Discussion</th>
<th>Participant Group</th>
<th>Location</th>
<th>M</th>
<th>F</th>
<th>Total</th>
<th>Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>FGD01_KHDDS_Ethics_KWTRP</td>
<td>HDSS Field Workers</td>
<td>Kilifi</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>60</td>
</tr>
<tr>
<td>FGD02_KHDDS_Ethics_KWTRP</td>
<td>VA Interviewers</td>
<td>Kilifi</td>
<td>4</td>
<td>0</td>
<td>4</td>
<td>87</td>
</tr>
<tr>
<td>FGD03_KHDDS_Ethics_Junju</td>
<td>KCRs</td>
<td>Kilifi</td>
<td>4</td>
<td>4</td>
<td>8</td>
<td>119</td>
</tr>
<tr>
<td>FGD04_KHDDS_Ethics_Township</td>
<td>KCRs</td>
<td>Kilifi</td>
<td>5</td>
<td>3</td>
<td>8</td>
<td>97</td>
</tr>
<tr>
<td>FGD05_KHDDS_Ethics_Tezo</td>
<td>KCRs</td>
<td>Kilifi</td>
<td>4</td>
<td>3</td>
<td>7</td>
<td>125</td>
</tr>
<tr>
<td>FGD06_KHDDS_Ethics_Junju</td>
<td>HDSS Residents</td>
<td>Kilifi</td>
<td>4</td>
<td>4</td>
<td>8</td>
<td>142</td>
</tr>
<tr>
<td>FGD07_KHDDS_Ethics_Tezo</td>
<td>HDSS Residents</td>
<td>Kilifi</td>
<td>4</td>
<td>3</td>
<td>7</td>
<td>126</td>
</tr>
<tr>
<td>FGD08_NUHDSS_Ethics_Viwandani</td>
<td>HDSS Residents</td>
<td>Nairobi</td>
<td>4</td>
<td>4</td>
<td>8</td>
<td>82</td>
</tr>
<tr>
<td>FGD09_NUHDSS_Ethics_Viwandani</td>
<td>CACs</td>
<td>Nairobi</td>
<td>5</td>
<td>3</td>
<td>8</td>
<td>90</td>
</tr>
<tr>
<td>FGD10_NUHDSS_Ethics_Viwandani</td>
<td>HDSS Field Workers</td>
<td>Nairobi</td>
<td>2</td>
<td>6</td>
<td>8</td>
<td>84</td>
</tr>
<tr>
<td>FGD11_NUHDSS_Ethics_Korogocho</td>
<td>CACs</td>
<td>Nairobi</td>
<td>4</td>
<td>3</td>
<td>7</td>
<td>77</td>
</tr>
<tr>
<td>FGD12_NUHDSS_Ethics_Korogocho</td>
<td>HDSS Residents</td>
<td>Nairobi</td>
<td>3</td>
<td>6</td>
<td>9</td>
<td>60</td>
</tr>
</tbody>
</table>

KCRs - KEMRI Community Representatives. CACs - Community Advisory Committee Members

After the co-learning session, I would focus the discussion on ethical issues for verbal autopsy (see Appendix 4 for FGD topic guides). I developed these guides through an iterative process involving literature review, consultations with my supervisors and review of preliminary findings from previous research phases. I first developed the guides in English then translated them to Kiswahili with the assistance of two senior field workers at KWTP who have extensive experience of translating research documents.
Non-Participant Observations of HDSS Surveillance in Case Studies

In addition to IDIs and FGDs, I collected data through non-participant observation. I observed two HDSS census interviewers (1 Male, 1 Female) as they collected data over four days in the Chasimba, Kauma and Mavueni areas of the KHDSS. I also observed two verbal autopsy interviewers (1 Male, 1 Female) as they conducted interviews in the KHDSS (5 interviews) and NUHDSS (2 interviews).

To start with, I observed two field workers for two days each as they conducted routine household censuses in the Kilifi HDSS. This prolonged observation was meant to address potential observer effect (Liu, F., & Maitlis, 2010). Based on my preliminary analysis, the issues that emerged from this observation in the KHDSS did not seem different from those in Phase 1 of the study. In addition, it would have been more difficult to organise prolonged field observations in the Nairobi Urban HDSS for security reasons and other pragmatic considerations (for instance, costs). For these reasons, and given that verbal autopsy had emerged as a particular sensitivity, I focussed on observations of verbal autopsy interviews in the case study sites.

Prior to the field observations in each case study, I held information sharing sessions with HDSS research stakeholders. These sessions included addressing the HDSS field workers and responding to their questions, meetings with groups of HDSS managers and supervisors, and with individual field workers. These information sharing sessions had practical and ethical goals; to create awareness about the study in order to gain social access, and to minimise burdens and enhance informed consenting. For instance, the meetings with HDSS managers and supervisors enabled me to identify the least disruptive timing for field observations. In addition, the sessions enabled me to reassure field workers about the objectives of the study and my level of seniority (PhD Student) to minimise their potential to feel anxious about my presence during field observations.

Document reviews and verbal autopsy data

I obtained unpublished documents through informal discussions and interviews with research stakeholders in the two case study sites. These documents included verbal autopsy information and consent forms and questionnaires. These documents provided additional information about consenting practices, and the potential and
perceived burdens and benefits of verbal autopsy. Furthermore, I requested verbal autopsy data from the two case study sites in order to describe the context in which potential ethical issues arise. These included verbal autopsy data collected in the KHDSS between 2011 and 2018, and in the NUHDSS between 2002 and 2015. The data included information on causes and place of death, timing of verbal autopsy interviews, and characteristics of deceased persons and verbal autopsy respondents. In addition to deepening my understanding of contextual issues, the process of submitting the data requests enabled me to develop a better understanding of data sharing policy and practice within the case study sites.

3.3.4 Managing and Analysing Phase 2 Data

3.3.4.1 Data Management

The main types of data from Phase 2 were field notes from non-participant observations, audio-recordings and transcripts from interviews and focus group discussions, documents and quantitative verbal autopsy data. I managed the field notes as described in Section 4.3. I transferred the audio-records into a password protected computer within hours of data collection and deleted the audio files from the recorder. After gaining permission to access the quantitative verbal autopsy data, I downloaded and stored these data in my password protected computer. I shared the audio records with senior field workers within my research department to assist with transcription. In addition, the field workers translated the focus group transcripts from Kiswahili to English. I used the QSR International's NVivo 10 software and Microsoft Excel (2013) software to manage the qualitative data and the R statistical software (R Core Team, 2019) to manage and analyse the quantitative data.

3.3.4.2 Data analysis

I used the Framework Approach to analyse the qualitative data. The Framework Approach involves six analysis steps; transcription, familiarisation, identifying a thematic framework, indexing, charting, mapping and interpretation (Ritchie et al., 2003). This approach is commonly used to analyse interviews and focus group discussions, but it is suitable for analysing a wide range of textual data including documents (Jones, 2000) and observation field notes (Gale et al., 2013).

When analysing the qualitative data, I used both inductive (informed by study data)
and deductive (informed by literature, especially bioethics and public health ethics) approaches. After each individual interview and focus group discussion, I would listen to the audio-record and write a summary. In the summary, I noted the characteristic of the interview/FGD participants, context of data collection (place and time) and key learnings in relation to pre-selected themes; consent, community engagement, benefits, burdens and ethics oversight. Listening to the audio-records, preparing the summaries and discussing them with my supervisors enabled me to become familiar with the data. When I had collected most of the qualitative data, I developed a thematic framework. To do this, I and my two supervisors independently coded two interview transcripts based on pre-selected themes and themes emerging from the data. We discussed the three different sets of codes, shared ideas and structures, and I applied the agreed thematic framework (Appendix 5) across all interview and FGD transcripts.

Coding entailed reading each transcript and coding the data according to the identified thematic framework. Once all the data were coded, I developed framework matrices (see Appendix 6 for sample matrix) which enabled me to explore patterns emerging from the coded data by comparing themes across participant groups and HDSS sites. Finally, I combined these analyses with my literature and document reviews, descriptive statistics, notes and reflections from field observations to outline important features of the key ethical issues for the Kilifi and Nairobi Urban HDSS sites.

3.4 Phase 3: Checking Wider Relevance of Case Study Findings

The process of generalising findings from qualitative research is highly contested (Rule & John, 2015; VanWynsberghe & Khan, 2007; Yazan & De Vasconcelos, 2016; Yin, 2003). The dominant philosophical assumption in qualitative research is that there are multiple realities and that knowledge is socially constructed (John Creswell, 2012; Merriam, 1998; D. L. Morgan, 2007). This position can make it challenging to generalise findings from qualitative research, in a similar way to findings from quantitative research (Smith, 2018). However, qualitative research can have relevance beyond the context in which it is conducted. For instance, research stakeholders can adopt the findings and recommendations of qualitative research
conducted in a different context if they feel that these findings and recommendations are relevant to their own situations and experiences (Smith, 2018; R. Stake, 1995). In addition, qualitative research can develop and refine a particular social theory, which others can apply in their specific context (Smith, 2018; Yin, 2003). The formative research showed the diversity of HDSS sites in sub-Saharan Africa and highlighted that verbal autopsy is a particular sensitivity across these diverse sites. In Phase 2, I explored, in depth, ethical issues for verbal autopsy in two very different HDSS sites in Kenya. On this background, the objective of Phase 3 research was to explore the relevance of key verbal autopsy findings from the Kenyan sites to a wider range of HDSS sites in sub-Saharan Africa.

Specifically, this involved exploration of ethics oversight, benefits, burdens and other ethical issues for verbal autopsy, from the perspectives of HDSS research stakeholders outside Kenya.

3.4.1 Selecting Study Areas and Participants: Phase 3

As with Phases 1 and 2, I selected study sites and participants for Phase 3 based on scientific and pragmatic considerations. I purposively selected HDSS sites representing diverse geographic and socio-economic features. These included all the sites outside Kenya that I visited during the formative research and the Africa Health Research Institute HDSS in South Africa. Unlike in Phase 1 and 2 where I collected data using multiple methods and from multiple sources, in Phase 3, I conducted individual interviews with HDSS research stakeholders only. This was partly because of resource limitations and partly because the objective was not to replicate the in-depth case studies but to test the wider relevance of the case study findings and enhance the academic and social impact of overall research findings.

3.4.2 Phase 3 Data Collection, Management and Analysis

I conducted 5 individual interviews with HDSS research stakeholders from 4 HDSS sites, as shown in Table 7. I conducted the interviews through telephone and online calls. In addition to the interviews, I held an informal discussion with one research stakeholder who was working with several HDSS sites across South Africa. The discussion and interview questions were informed by findings from the in-depth case study and consideration of HDSS characteristics, which I had identified through
literature review and the exploratory case study. The interview guide that I used in Phase 3 is attached on Appendix 7. I managed and analysed Phase 3 interviews as described in Section 3.5; I audio-recorded the interviews, managed data through Nvivo 10 and analysed them using the Framework Approach; and I was able to apply the same coding framework across Phases 2 and 3.

Table 7 Features of individual interviews in Phase Three

<table>
<thead>
<tr>
<th>Interview Code</th>
<th>Country</th>
<th>Sex</th>
<th>Designation</th>
<th>Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDI24_HDSS_Ethics</td>
<td>South Africa</td>
<td>M</td>
<td>HDSS Manager</td>
<td>47</td>
</tr>
<tr>
<td>IDI26_HDSS_Ethics</td>
<td>Ghana</td>
<td>M</td>
<td>Research Staff</td>
<td>65</td>
</tr>
<tr>
<td>IDI27_HDSS_Ethics</td>
<td>Uganda</td>
<td>M</td>
<td>HDSS Manager</td>
<td>42</td>
</tr>
<tr>
<td>IDI28_HDSS_Ethics</td>
<td>Uganda</td>
<td>F</td>
<td>Researcher</td>
<td>36</td>
</tr>
<tr>
<td>IDI29_HDSS_Ethics</td>
<td>Malawi</td>
<td>F</td>
<td>HDSS Manager</td>
<td>49</td>
</tr>
</tbody>
</table>

3.5 Researcher’s Role

The subjective experiences of researchers and study participants, including their social interactions, influence the construction and production of knowledge (JW Creswell & Creswell, 2014; Denzin, 2011). For these reasons, qualitative research values reflexive practice. Reflexivity is the process through which researchers become aware that their personal characteristics, institutional affiliations, beliefs and positioning in society, affect how they frame research questions, collect, analyse and interpret research data (M Alvesson & Skołdberg, 2009; Lloyd-Jones, 2017; Stronach et al., 2007). For instance, qualitative researchers select participants purposively rather than randomly, which makes it important to describe and reflect on the reasons for these selections. Reflexivity can demonstrate trustworthiness and rigour in qualitative research (Gilbert, 2002).

Despite the widespread mention of reflexivity and its benefits in the qualitative research literature, there is little guidance on how researchers can practice or demonstrate reflexivity. The most commonly described methods of practicing reflexivity include critical self-evaluation and monitoring whereby researchers turn the attention onto themselves and their interactions in the study context (Bradbury-Jones, 2007; Denzin, 2011; Rule & John, 2015). Researchers can demonstrate their reflexivity in writing by sharing their reflections on their research processes and interactions (Mats Alvesson et al., 2004). So far, I have described the philosophical
underpinnings of this research, and described the study areas, procedures and participants. In the following paragraphs, I will describe my personal, academic and professional background and the social context in which I conducted this study.

I am a male Kenyan citizen with a BSc degree in Medical Laboratory Science and an MSc degree in Public Health. I was born in Nairobi, Kenya, where I have lived most of my life. During my undergraduate studies in Kenya, I learned about the biomedical causes and manifestation of diseases in humans, through taught modules such as human anatomy, biochemistry, histopathology and medical microbiology. In addition, I worked as a pathology intern in three hospitals in Nairobi, where I conducted medical laboratory investigations to contribute to medical diagnoses of disease and cause of death, including observing a few medical autopsies. In my postgraduate studies in the UK, I learned about the wider determinants of health, through taught modules such as health promotion, health economics, research methods, critical appraisal skills, epidemiology and public policy. In addition, I worked as a research intern at Public Health England, where I analysed national morbidity and mortality data to inform a public health approach to end-of-life care for liver disease patients in England. Before my PhD studies, I worked in other research and health projects collecting and analysing qualitative and quantitative data in hospital and community settings.

As I outlined in Chapter 1, I conducted this study within the Health Systems Research Ethics (HSRE) department at the KEMRI Wellcome Trust Research Programme (KWTRP) in Kilifi, supported by two supervisors who have extensive experience in conducting health systems and research ethics studies. One has an academic background in human geography (Sassy) and one in medicine (Vicki). Besides my PhD studentship, I had a bursary fellowship from the Global Health Bioethics Network (GHBN), which is an international collaboration between health research centres across Africa, Asia and Europe, which seeks to build ethics research capacity. The bursary fellowship and PhD studentship enabled me to attend bioethics conferences and workshops and to interact with researchers and policy-makers with a wide range of expertise, including in ethics of surveillance.

These personal and social features facilitated the study at different stages and at
varying degrees. First, the research topic - ethical issues for HDSS sites – built on and aligned with previous research at HSRE, my research interests and those of my supervisors, illustrating the high interest in the research project from the outset. Second, the long-term relationship of the KWTRP and APHRC with the HDSS communities, and support from the HSRE department and my supervisors, enabled me to recruit participants and facilitate the focus group discussions in the two communities. Finally, because of the funding and support from the bursary and studentship, including the international linkages with other research stakeholders across the world, I could collect empirical data from multiple sources in HDSS sites across Kenya, Ghana, Malawi, South Africa and Uganda.

My positionality also raised particular tensions and challenges, which I addressed using different strategies and to varying degrees. Given my academic background, I had limited formal training in ethics when I started the PhD study. Therefore, I enrolled in ethics courses, attended regular bioethics workshops and seminars and discussed ethical issues with my supervisors during our fortnightly meetings. Both my supervisors have worked together at KWTRP for many years, including in similar research projects, but the potential lack of diversity was counter-balanced by our membership of the GHBN, which provided diverse expertise and critical insights into my research project. While living in Kilifi and working at KWTRP, I interacted with colleagues in formal and informal contexts. These informal interactions provided opportunities for some insights and data on ethical issues for the KHDSS, but also challenges around confidentiality and in considering ‘what data counts’ for data analysis.

I presented this project at several scientific seminars at KWTRP not only to get the input of other KHDSS research stakeholders but also to create awareness about the study objectives and procedures, which might have addressed potential concerns about the purpose of the study. Finally, conducting this multi-site project from Kilifi Kenya presented various logistical and ethical challenges, especially around ethics review processes. I will discuss the ethics review process later in this chapter. Here, I want to highlight that my physical location in Kenya, and my identity as an outsider to all the other research centres except KWTRP, made it challenging to gain scientific and ethics approval. However, I obtained the approvals by coordinating the
application process with the research stakeholders I had met during the formative research.

### 3.6 Ethical Considerations

Given the subject of this research - ethical issues for HDSS sites in sub-Saharan Africa - I considered ethical issues at every stage of the research. My preliminary review of the literature to develop research questions involved reading a wide range of research and public health ethics articles and guidelines. These included empirical ethics research conducted at the KWTRP, and international ethics guidelines on health-related research (Baum et al., 2007; CIOMS & WHO, 2008; Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014; Emanuel et al., 2004; Kass, 2001). I took online courses to deepen my understanding of research ethics and to adhere to research governance regulations. For instance, I took a course on ethics of sharing individual-level health research data because data sharing was an important theme in my study, and a course on research ethics partly because this was necessary to gain ethics approval from research ethics committees. In addition, I attended numerous scientific meetings (where I presented this research), which involved detailed discussions of ethics health-related research. These included the fortnightly seminars at the HSRE department at KWTRP, the annual ethics summer schools by the Global Health Bioethics Network and the biannual Oxford Global Health and Bioethics international conference (OGHB). For instance, I presented preliminary findings from the Phase 1 of this study at the 2017 OGHB, where I received valuable feedback and interacted with conference participants including the WHO representatives who were launching the WHO ethics guidelines for public health surveillance. I have continued to be immersed in the ethics literature throughout the study. Overall, the literature reviews, ethics courses and workshops, regular discussions with my supervisors and other social science and ethics scholars, enabled me to consider and address ethical issues in this study.

#### 3.6.1 Ethics Review

Independent ethics review of research can enhance public accountability and protection of participants (Emanuel et al., 2004). This research was reviewed and
approved by nine ethics and scientific review committees across Kenya, Ghana, Malawi and Uganda.

1. KEMRI CGMRC-Wellcome Trust Research Centre Scientific Committee
2. KEMRI Scientific and Ethics Review Unit
3. Uganda Virus Research Unit REC
4. Uganda National Commission for Science and Technology
5. London School of Hygiene and Tropical Medicine ethics committee
6. Malawi National Health Sciences Research Committee
7. Kintampo Health Research Centre Scientific Review Committee
8. Kintampo Health Research Centre Institutional Ethics Committee
9. Navrongo Health Research Centre Institutional Review Board

In addition, I submitted requests for verbal autopsy data to Data Governance Sub-Committees at the KWTRP and APHRC. Overall, the application process involved preparing and submitting research proposals describing the objectives of the study, study participants, procedures and ethical considerations. Next, I responded to comments from the various research ethics committees. This involved clarifying key concepts in the study such as verbal autopsy and purposive sampling, revising the information and consent forms and study procedures. After the initial approval in each site, I committed to annual renewal of ethics approval. I only applied for renewal of ethics clearance in Kenya; for the sites outside Kenya, I completed the studies within one year following the initial ethics approval.

The ethics review process varied across the sites, especially between the case studies and the other sites. I did not seek prior ethics approval for the formative research because the purpose of the orientation visits was to familiarise with the HDSS sites and to learn about the history, context and functioning of the HDSS sites though informal discussions and observations. However, I gained valuable insights from these orientation visits. Therefore, I applied for post hoc ethics approval to use Phase 1 information at the same time I was applying for approval to conduct Phase 3 individual interviews. Given the different ethics review practices and guidelines at
each site, including the need to submit hard copies of various documents, this was a lengthy and challenging process, involving significant back and forth to ensure all necessary documentation was provided and questions answered. Nevertheless, the application process gave me an opportunity to learn about the ethics oversight processes at each of the HDSS sites, which was particularly useful for this research.

3.6.2 Informed Consent

During the formative research, I explained the purpose of the study to each participant before requesting permission to hold an informal discussion or to observe data collection. I did not seek written consent at this stage because I did not see these discussions as formal data collection but as an orientation visit. I obtained individual written consent from each participant during the in-depth case study of the Kilifi and Nairobi HDSS sites in Kenya. This included written consent from each interviewee and focus group participant, and from each field worker that I observed during household data collection. For the individual skype/telephone interviews in Phase 3, I sent an information consent form to potential study participants through e-mail prior to the interviews. Some of the interviewees signed and emailed the information and consent forms to me; I audio recorded each interviewee’s verbal consent.

The consenting process in this research was also influenced by trust. Before the individual interviews, I had interacted with most of the HDSS research stakeholders during the formative research and while working at the KWTRP. Also, most HDSS community members were aware that KWTRP and APHRC are health research institutions. The long-term interactions of community members with these institutions might have influenced their decisions to participate. There were no explicit refusals in this study. Two HDSS research stakeholders did not respond to my emails requesting an interview. All the individuals who read the information and consent form agreed to take part in the study. As I highlighted in Chapter 2, the consenting process is highly influenced by social relations. I included all the information I felt would be needed to make an informed decision about participation, checked whether participants had read the consent forms, provided additional information and checked whether participants had any questions or concerns about the study. However, I acknowledge that my positionality, including the reputations of
the research institutions involved, might have influenced individuals’ decisions to consent to this study.

### 3.6.3 Privacy and Confidentiality

While describing the study procedures, I showed that I collected, stored, and managed the data in a manner that aimed to protect the privacy and confidentiality of study participants. This involved collecting data in environments convenient for the study participants because of the privacy they provided and because they were familiar and accessible to the participants. In addition, I stored the field notes and recorders safely and de-identified the data as described in section 3.3.

Conducting a research project in a small community poses risks to privacy and confidentiality. For example, it is possible to reveal the identities of study participants even without mentioning personally identifiable details such as names and job titles. I recruited participants from small participant groups, for instance, HDSS managers at NUHDSS. Therefore, I remained aware that others could deduce the identities and views of study participants based on their knowledge of my study areas, procedures and participants. This reflexivity enabled me to be careful when presenting study findings and having informal conversations with colleagues. Besides explaining the data protection measures in place, I informed participants that some risks to their privacy remained. For instance, some individuals who take part in a focus group discussions can later reveal the views of other participants to people who were not present during the discussion.

### 3.6.4 Benefits and Risks

The benefits and burdens of research can be direct or indirect at the individual or population-level. I informed the potential participants that this study did not provide direct benefits. I purposively selected study areas and participants that could benefit from the findings and recommendations of this study. The study outcomes are likely to advance knowledge on ethical issues, including the burdens and benefits of verbal autopsy in HDSS, and to influence ethics practices, which could benefit HDSS community members, researchers, field workers and research institutions involved in this study. To minimise potential physical burdens for participants, I collected data in venues that were physically comfortable for participants. This entailed hiring rooms
and seats for focus group discussions with community participants; I held interviews and discussions with research stakeholders in their usual places of work, such as offices. Also, FGDs typically took longer than interviews and participants had to be away from their homes and usual areas of work; therefore, I provided refreshments for all FGD participants. To avoid risks of stigmatisation and loss of privacy, I protected the data at all stages of the study including during data collection and dissemination of findings. To minimise potential economic costs, I compensated all focus group participants for time spent in the discussions and reimbursed their travel expenses. I did not specifically select the bereaved. I was concerned that bereaved relatives were already likely to be struggling with their situation and perhaps had already taken part in a verbal autopsy interview. Also, reaching data saturation would have required including many bereaved individuals, which could have increased burdens across the population. For these reasons, bereavement or experience of a verbal autopsy interview were not essential inclusion criteria in this study. However, I noted in community discussions where participants had direct or indirect experiences with verbal autopsy interviews.

3.7 Summary

In Chapters 1 and 2, I highlighted the few research publications and limited guidelines on HDSS ethics. Specifically, I highlighted the lack of holistic research on the influences and responses to ethical issues for HDSS in sub-Saharan Africa. In this chapter, I hope to have shown that a qualitative research approach, using a case study design, was appropriate for meeting the objectives of this thesis.

As described in this chapter, the qualitative approach enabled me to explore the views and experiences of HDSS research and community stakeholders on various ethical issues ranging from consenting to benefits and burdens. With a case study design, based on a pragmatic constructivist framework, I collected empirical data in diverse contexts across sub-Saharan Africa and using multiple methods of data collection. This included collecting empirical data in Kenya, Ghana, Malawi, South Africa and Uganda, through interviews, focus group discussions, document reviews and observation. In addition, I analysed the data drawing from multiple analytical frameworks. I have also described the philosophical underpinnings, methodological
approach and my positionality in this study. This research approach is likely to
demonstrate transparency and generate reliable evidence about ethical issues in
HDSS and the context in which they arise.

In the next three chapters, I will present the findings from the empirical
component of this research, as described in this chapter. These empirical findings will
lay the foundation for my discussion, in Chapter 7, of the key ethical issues in HDSS in
sub-Saharan Africa and recommendations for HDSS ethics policy and practice.
4 CHAPTER 4 Health and Demographic Surveillance Systems in sub-Saharan Africa: Characteristics, Policy, Practice and Perspectives on Ethical Issues

The first objective in this study was to describe the characteristics of HDSS sites in sub-Saharan Africa in terms of their history, context and current functioning, and to map out the key ethical issues. In this chapter, I present empirical findings in relation to the first objective. As I have described in depth in Chapter 3, I collected empirical data from HDSS sites at three different levels. On the first level, I collected data on key characteristics of HDSS through a formative research that involved seven HDSS sites across sub-Saharan Africa. Next, I conducted an in-depth case study of the Kilifi and Nairobi HDSS sites in Kenya. Finally, I interviewed research staff in HDSS across sub-Saharan Africa to explore the wider relevance of findings from the Kenyan case studies. The findings presented in this chapter, and the next two chapters, reflect the differences in the types and levels of data collected.

I will start by presenting the overview characteristics and reported ethical issues for all HDSS sites in sub-Saharan Africa with specific illustrations from the Navrongo, Kintampo, Kyamulibwa, Karonga, AHRI, Kilifi and Nairobi HDSS Sites. Next, I will give a more detailed description of the Kilifi and Nairobi HDSS sites. Throughout this chapter, I will present the characteristics of HDSS sites in terms of history, geographic and socio-economic context, and functioning. Also, I will describe ethically relevant processes in these sites such as ethics oversight, consenting, community engagement and data sharing including research stakeholders’ perceptions on the key ethical issues for HDSS sites. By describing ethics processes and features of HDSS sites, this chapter also provides important background information for chapters 5 and 6, which focus on ethical issues for verbal autopsy.

4.1 Characteristics of HDSS Sites in sub-Saharan Africa: History, Context and Functioning

4.1.1 HDSS Sites in sub-Saharan Africa: Historical context

The HDSS sites typically emerged from pre-existing research projects run by the HDSS host research centres. These projects were diverse in terms of their objectives,
duration and study populations. For example, the African Population and Health Research Centre established the Nairobi HDSS to investigate the long-term impact of urban residence, the Karonga and Kyamulibwa sites to support studies on infectious diseases, while the Kintampo HDSS was established to conduct research on diseases of national and international public health importance. Table 8 shows the specific reasons given for establishing 36 out of the 40 HDSS sites in sub-Saharan Africa. The most commonly mentioned reason for establishing these HDSS sites was to provide reliable population-level data to support specified health-related research and public health programmes. Regardless of the original rationale for their establishment, HDSS sites in sub-Saharan Africa have evolved into complex programmes involving multiple actors and collecting data from all HDSS residents mainly to support a wide range of health-related research.

I learned that some community members in the Navrongo and Karonga HDSS refer to the host research centres as “Ghana VAST” and “Lepra/KPS” respectively, referring to the vitamin A supplementation trial (BINKA et al., 1999; Oduro et al., 2012; Ross et al., 1993) and studies on leprosy (Crampin et al., 2012), which preceded the HDSS. This illustrates the long-term influence of the initial studies on the identity and functioning of the HDSS, including community perceptions. In addition, I learned that the sites, despite being in remote rural areas in sub-Saharan Africa, bring together researchers from all over the world to work on a wide range of health-related research. My informal discussions with HDSS research stakeholders at the INDEPTH Network further highlighted that HDSS are international collaborations for health research, given that HDSS researchers and managers interact regularly through scientific meetings and multi-site research collaborations. In summary, findings from the formative research largely confirmed the account provided in Chapters 1 and 2 about the rationale for establishing HDSS sites and the INDEPTH Network, including the actors involved.
<table>
<thead>
<tr>
<th>HDSS and Host Countries</th>
<th>Rationale for establishment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Kenya</strong></td>
<td></td>
</tr>
<tr>
<td>Kilifi</td>
<td>To create a longitudinal community-based study linked to hospital morbidity surveillance in order to define the incidence and prevalence of local diseases of childhood, evaluate the impact of community-based interventions against infectious diseases and to provide an epidemiological sampling frame for studies at the KWTRP (Scott et al., 2012).</td>
</tr>
<tr>
<td>Nairobi</td>
<td>To provide a platform to investigate the long-term social, economic and health consequences of urban residence, and to serve as a primary research tool for intervention and impact evaluation studies focusing on the needs of the urban poor in sub-Saharan Africa (Beguy et al., 2015; Emina et al., 2011).</td>
</tr>
<tr>
<td>Kisumu</td>
<td>To support a large insecticide-treated bed net trial. HDSS sustained post-trial to provide multi-disciplinary research data (Odhiambo et al., 2012).</td>
</tr>
<tr>
<td>Kombewa</td>
<td>To support regulated clinical trials, nested studies and local disease surveillance, by integrating household and health-facility-based data (Sifuna et al., 2014).</td>
</tr>
<tr>
<td>Mbita</td>
<td>To establish baseline data on health, demographic, socio-economic and environmental characteristics of communities in Mbita District. To evaluate impact of health and socioeconomic interventions, support research on communicable and non-communicable diseases, and provide platform for education and training (Wanyua et al., 2013).</td>
</tr>
<tr>
<td><strong>Ghana</strong></td>
<td></td>
</tr>
<tr>
<td>Dodowa</td>
<td>To enable registration of households into a pilot community health insurance scheme (2003). Could not be sustained after initial census due to lack of funding. With research funding in 2005, re-established to provide platform for large scale trials and surveillance (Gyapong et al., 2013).</td>
</tr>
<tr>
<td>Kintampo</td>
<td>To research diseases of public health importance nationally and internationally and contribute to reducing these diseases by developing interventions and sharing data with ministry of health and other health organisations.</td>
</tr>
<tr>
<td>Navrongo</td>
<td>To support evaluation of a permethrin impregnated bed net trial. Preceded by surveillance activities that focussed on children &lt;5 years as part of the Ghana Vitamin A Supplementation Trial (Odouro et al., 2012).</td>
</tr>
<tr>
<td><strong>Uganda</strong></td>
<td></td>
</tr>
<tr>
<td>Iganga/ Mayuge</td>
<td>As a research setting to provide data for informing local and global policy. To serve as platform for developing operational research capacity for graduate students and academic staff at Makerere University, and to generate continuous population data for evidence-based policy-making at district and national level.</td>
</tr>
<tr>
<td>Kyamulibwa</td>
<td>To examine trends in prevalence and incidence of HIV infection and their determinants (Asiki et al., 2013).</td>
</tr>
<tr>
<td>Rakai</td>
<td>To support a community-based randomised control trial on STD control and HIV prevention (Wawer et al., 1998).</td>
</tr>
<tr>
<td><strong>Malawi</strong></td>
<td></td>
</tr>
<tr>
<td>Karonga</td>
<td>To provide a platform for epidemiological studies of HIV and HIV-associated infectious disease and to monitor the impact of interventions (Crampin et al., 2012).</td>
</tr>
<tr>
<td>Location</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Kaya</td>
<td>To generate regular data for assessing population health, evaluating health interventions and supporting research (Kouanda et al., 2013).</td>
</tr>
<tr>
<td>Nanoro</td>
<td>To provide a highly standardized means of monitoring the population living within the catchment area of a district hospital in Nanoro and to support a large pharmacovigilance study on artemisinin-based combination treatments (ACT) and a phase 3 vaccine trial (Derra et al., 2012).</td>
</tr>
<tr>
<td>Nouna</td>
<td>To provide reliable demographic and health indicators for a rural population in Burkina Faso, and to generate an infrastructure and a sampling frame for epidemiological and clinical studies nested into this dynamic cohort (Sié et al., 2010).</td>
</tr>
<tr>
<td>Ouagadougou</td>
<td>To address the problems of the urban poor, by collecting data on the lives of people in one informal and one formal neighbourhood in Ouagadougou (Rossier et al., 2012).</td>
</tr>
<tr>
<td>Sapone</td>
<td>Not available</td>
</tr>
<tr>
<td>Côte d’Ivoire</td>
<td></td>
</tr>
<tr>
<td>Taabo</td>
<td>To serve as a platform for evaluating health interventions with the aim of reducing morbidity and mortality especially from malaria and NTDs in Taabo, Côte d’Ivoire and sub-Saharan Africa. To conduct interdisciplinary research and build capacity in health research (Koné et al., 2015).</td>
</tr>
<tr>
<td>Ethiopia</td>
<td></td>
</tr>
<tr>
<td>Arba Minch,</td>
<td>Not available</td>
</tr>
<tr>
<td>Butajira</td>
<td></td>
</tr>
<tr>
<td>Dabat</td>
<td>To generate longitudinal data on health and population at district level and provide a study base and sampling frame for community-based research.</td>
</tr>
<tr>
<td>Gilgel Gibe</td>
<td>Not available</td>
</tr>
<tr>
<td>Kersa</td>
<td>To create a framework for research at the community level, given the lack of reliable information about health problems of public health importance (Assefa et al., 2016).</td>
</tr>
<tr>
<td>Kilite Awlaelo</td>
<td>To generate longitudinal health and demographic data for a rural low-income population (Weldearegawi et al., 2014).</td>
</tr>
<tr>
<td>Gambia</td>
<td></td>
</tr>
<tr>
<td>Farafenni</td>
<td>To generate health and demographic data for the evaluation of a primary health care programme by The Gambian government (Jasseh et al., 2015).</td>
</tr>
<tr>
<td>West Kiang</td>
<td>To support research and provision of healthcare services (Hennig et al., 2015).</td>
</tr>
<tr>
<td>Guinea Bissau</td>
<td></td>
</tr>
<tr>
<td>Bandim</td>
<td>To assess the prevalence of neonatal tetanus and to collect data on child mortality to monitor the impact of a Danish International Development Agency (DANIDA)-sponsored project to strengthen primary healthcare (Thysen et al., 2019).</td>
</tr>
<tr>
<td>Mozambique</td>
<td>Not Available</td>
</tr>
<tr>
<td>Chokwe</td>
<td></td>
</tr>
<tr>
<td>Manhica</td>
<td>To provide data on fertility, migration and mortality and support epidemiological studies of infectious diseases for children &lt; 5yrs and pregnant women (Sacoor et al., 2013).</td>
</tr>
<tr>
<td>Nigeria</td>
<td>To support research for informing policy health service delivery (Alabi et al., 2014).</td>
</tr>
<tr>
<td>Nahuche</td>
<td>To generate timely and reliable data to inform policy makers on differences in population characteristics and access to health services.</td>
</tr>
<tr>
<td>Cross River</td>
<td></td>
</tr>
<tr>
<td>Senegal</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>Site</td>
</tr>
<tr>
<td>---------</td>
<td>------</td>
</tr>
<tr>
<td>Bandafassi</td>
<td>To study the health and demographic situation of a rural West African population and assess changes over time, including causes of these changes. Preceded by a genetic study that involved collection of blood samples and demographic information to investigate survival rates in various genotype sub-groups in the population (Pison et al., 2014).</td>
</tr>
<tr>
<td>Mlomp</td>
<td>To provide health and demographic data for a rural population that differed from that in Niakhar and Bandafassi in terms of historic, economic and ethnic characteristics, and therefore enhance the coverage of the diverse demographic and epidemiological characteristics in Senegal (Pison et al., 2018).</td>
</tr>
<tr>
<td>Niakhar</td>
<td>To demonstrate the capacity to record reliable demographic and epidemiological data in rural areas of Africa. Because previous population-based data collection and civil registration had excluded African populations in rural areas (Delaunay et al., 2013).</td>
</tr>
<tr>
<td>South Africa</td>
<td>Agincourt</td>
</tr>
<tr>
<td></td>
<td>AHRI</td>
</tr>
<tr>
<td></td>
<td>Dikgale</td>
</tr>
<tr>
<td>Tanzania</td>
<td>Ifakara</td>
</tr>
<tr>
<td></td>
<td>Rufiji</td>
</tr>
<tr>
<td></td>
<td>Magu</td>
</tr>
</tbody>
</table>

4.1.2 Current Functioning: Data, study methods and staff

Through the formative research and interviews with HDSS researchers and managers, I learned that the types of data, frequency and methods of HDSS data collection varies between sites and over time. Table 9 shows the basic features of six HDSS sites at the time of my formative research.
The INDEPTH Network requires member sites to conduct verbal autopsies besides collecting other core data. My discussions with the INDEPTH Network administrators highlighted that many HDSS sites often lack reliable funding and expertise for conducting verbal autopsies and collecting other HDSS data. To illustrate this, the Kyamulibwa HDSS was not conducting verbal autopsies at the time of my orientation visit, during my Phase 3 interviews I learned that the site was planning to resume conducting verbal autopsies.

Although some researchers have documented the frequency and methods of collecting data in HDSS, I learned that in practice the frequency and methods of collecting data changes depending on the availability of funds. For example, Navrongo HDSS research staff had been conducting semi-annual re-enumerations since 2009, previously they had conducted 3-Monthly (1993-2006) and 4-Monthly (2007-2008) household re-enumerations. In addition, most HDSS in sub-Saharan Africa have been collecting data using paper-based questionnaires, but they are increasingly adopting electronic methods. When I visited the Karonga HDSS site, I found research stakeholders scanning the archived HDSS paper-records and storing them in computers as part of a process of migration to an electronic data management system. In addition, I observed the piloting and implementation of an electronic data collection system at the Kilifi HDSS.

In most HDSS, field workers visit households to collect data using electronic or paper-based methods, from eligible respondents. However, I learned that some HDSS sites

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2 Population size estimated from INDEPTH Network, site profiles and websites, and discussions with HDSS managers.
have a system of community key informants, who also record and report vital events to field staff during monthly meetings; I observed one such meeting in the Karonga HDSS. Also, I learned that research staff at the AHRI HDSS collect data over the telephone in addition to household visits. The eligibility criteria for an HDSS respondent vary across the sites. Most sites require respondents to be of a particular age, for example, more than 13yrs (Navrongo), 15yrs (Kilifi) or 18yrs (AHRI).

Like other studies and publications on HDSS functioning, this study provides information on the data collected in HDSS, including frequency and methods of data collection. Notably, findings from the formative research suggest that data collection and field procedures in HDSS are likely to be highly context specific and influenced by INDEPTH Network rules, research regulations in particular countries, community norms, history and socioeconomic context of each site.

4.1.3 Geographic and Socioeconomic Context of HDSS Sites in sub-Saharan Africa

HDSS sites differ in terms of key characteristics such as population size and the duration they have been in operation, as shown in Table 10. Through the formative research, I learned that the sites have similarities in terms of their geographic and socio-economic context. Most (38/40) HDSS sites in sub-Saharan Africa are in rural areas, but even in the rural sites I visited, I observed that there were several urban regions, highlighting the differences within sites. Although the HDS populations are multi-ethnic or have a dominant ethnic group, I learned that each site has common languages. While visiting households, especially those in rural HDSS sites, I found many residents working on their farms or running small-scale businesses, reflecting the claim in most HDSS publications that agriculture and informal employment are the main economic activities for HDSS residents. During the site visits, I realised that some HDSS sites and regions within the sites are not easily accessible. For instance, to get to the Karonga and the Navrongo HDSS sites, I had to travel by car for over six hours from the nearest airport or city. Also, some areas within the HDSS sites that I visited are not accessible by car and we had to use motorbikes to reach HDSS participants’ households. Field workers in Kilifi and Navrongo informed me that some HDSS areas are not accessible at all during the rainy season because of bad roads, which makes it difficult for them to collect data.
Table 10 Characteristics of INDEPTH Network HDSS sites in sub-Saharan Africa

<table>
<thead>
<tr>
<th>Country</th>
<th>HDSS Site</th>
<th>Inception Year</th>
<th>Population</th>
<th>Size of Site (km²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenya</td>
<td>Kilifi</td>
<td>2000</td>
<td>280,000</td>
<td>891</td>
</tr>
<tr>
<td></td>
<td>Nairobi</td>
<td>2002</td>
<td>65,000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kisumu</td>
<td>2001</td>
<td>230,000</td>
<td>700</td>
</tr>
<tr>
<td></td>
<td>Kombewa</td>
<td>2007</td>
<td>141,956</td>
<td>369</td>
</tr>
<tr>
<td></td>
<td>Mbita</td>
<td>2006</td>
<td>54,014</td>
<td>163</td>
</tr>
<tr>
<td>Ghana</td>
<td>Dodowa</td>
<td>2005</td>
<td>132,690</td>
<td>1,528</td>
</tr>
<tr>
<td></td>
<td>Kintampo</td>
<td>2003</td>
<td>140,000</td>
<td>7,162</td>
</tr>
<tr>
<td></td>
<td>Navrongo</td>
<td>1992</td>
<td>156,735</td>
<td>1,675</td>
</tr>
<tr>
<td>Uganda</td>
<td>Iganga/Mayuge</td>
<td>2004</td>
<td>79,794</td>
<td>218</td>
</tr>
<tr>
<td></td>
<td>Kyamulibwa</td>
<td>1989</td>
<td>22,000</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>Rakai</td>
<td>1989</td>
<td>50,000</td>
<td>320</td>
</tr>
<tr>
<td>Malawi</td>
<td>Karonga</td>
<td>2002</td>
<td>39,000</td>
<td>135</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>Kaya</td>
<td>2007</td>
<td>64,480</td>
<td>1,090</td>
</tr>
<tr>
<td></td>
<td>Nanoro</td>
<td>2009</td>
<td>54,780</td>
<td>594</td>
</tr>
<tr>
<td></td>
<td>Nouna</td>
<td>1992</td>
<td>93,000</td>
<td>1,841</td>
</tr>
<tr>
<td></td>
<td>Oagadougou</td>
<td>2008</td>
<td>82,387</td>
<td>182</td>
</tr>
<tr>
<td></td>
<td>Sapone</td>
<td>2005</td>
<td>86,069</td>
<td>803</td>
</tr>
<tr>
<td>Cote d’Ivoire</td>
<td>Taabo</td>
<td>2009</td>
<td>42,480</td>
<td>629</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Arba Minch</td>
<td>2009</td>
<td>68,802</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Butajira</td>
<td>1986</td>
<td>78,000</td>
<td>797</td>
</tr>
<tr>
<td></td>
<td>Dabat</td>
<td>1996</td>
<td>69,468</td>
<td>379</td>
</tr>
<tr>
<td></td>
<td>Gilgel Gibe</td>
<td>2005</td>
<td>62,235</td>
<td>419</td>
</tr>
<tr>
<td></td>
<td>Kersa</td>
<td>2007</td>
<td>129,200</td>
<td>174</td>
</tr>
<tr>
<td></td>
<td>Kilite Awlaelo</td>
<td>2009</td>
<td>65,848</td>
<td>768</td>
</tr>
<tr>
<td>Gambia</td>
<td>Farafenni</td>
<td>1981</td>
<td>50,455</td>
<td>882</td>
</tr>
<tr>
<td></td>
<td>West Kiang⁴</td>
<td>2004</td>
<td>14,364</td>
<td>990</td>
</tr>
<tr>
<td>Guinea Bissau</td>
<td>Bandim</td>
<td>1978</td>
<td>105,000</td>
<td>803</td>
</tr>
<tr>
<td>Mozambique</td>
<td>Chokwe</td>
<td>2010</td>
<td>99,834</td>
<td>600</td>
</tr>
<tr>
<td></td>
<td>Manhica</td>
<td>1996</td>
<td>92,000</td>
<td>2</td>
</tr>
<tr>
<td>Nigeria</td>
<td>Nahuche</td>
<td>2009</td>
<td>137,823</td>
<td>902</td>
</tr>
<tr>
<td></td>
<td>Cross River</td>
<td>2012</td>
<td>32,301</td>
<td>2057</td>
</tr>
<tr>
<td>Senegal</td>
<td>Bandafassi</td>
<td>1970</td>
<td>13,378</td>
<td>990</td>
</tr>
<tr>
<td></td>
<td>Mlomp</td>
<td>1985</td>
<td>8,200</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>Niakhare</td>
<td>1962</td>
<td>43,000</td>
<td>203</td>
</tr>
<tr>
<td>South Africa</td>
<td>Agincourt</td>
<td>1992</td>
<td>115,000</td>
<td>420</td>
</tr>
<tr>
<td></td>
<td>AHRI</td>
<td>2000</td>
<td>168,000</td>
<td>97</td>
</tr>
<tr>
<td></td>
<td>Digkale</td>
<td>2010</td>
<td>36,000</td>
<td>21</td>
</tr>
<tr>
<td>Tanzania</td>
<td>Ifakara*</td>
<td>1997</td>
<td>168,000</td>
<td>2080</td>
</tr>
<tr>
<td></td>
<td>Rufiji*</td>
<td>1998</td>
<td>105,503</td>
<td>2313</td>
</tr>
<tr>
<td></td>
<td>Magu*</td>
<td>1994</td>
<td>35,000</td>
<td>167</td>
</tr>
</tbody>
</table>

³ See footnote 2, total population under HDSS surveillance in sub-Saharan Africa is 3,511,796
⁴ Associate member – Site run by a research centre that does not meet criteria for full membership to INDEPTH Network (INDEPTH Network, 2016a)
* See footnote 4
4.2 Policy, Practice and Perspectives on Ethics in HDSS sites within sub-Saharan Africa

4.2.1 Ethics Oversight for HDSS sites in sub-Saharan Africa

There is little documentation of HDSS ethics oversight processes, including ethics review. This is despite HDSS operating in research contexts where scientific and ethics review is common. Through the formative research and Phase 3 interviews, I learned that HDSS in sub-Saharan Africa have different ethics review processes. In some the sites, the ethics oversight processes have changed over time, generally moving from approval by government and study communities to formal review by scientific and ethics committees. The following comments from HDSS research stakeholders illustrate the variation in HDSS ethics review and oversight processes:

“I think in early 2010 and then 2011, they [HDSS] modified some of their tools and submitted [to REC]... the submission included their consent forms, the data collection tools...for other protocols even if they [REC] give approval it is only valid for a year and then there are protocol renewal, continued review, with the DSS, that is not what happens, after we renewed in 2011, that was that.” IDI26_Research_Staff_Ghana

“From the outset, we have always applied for ethics approval, when we were establishing the DSS we applied for approval from the National and Health Sciences Commission. Every time we have a new tract of funding when we introduce new procedures, we apply for approval. We also send annual updates to the ethics committee for renewal” IDI29_HDSS_Manager_Malawi

Studies supported by the HDSS platform usually apply for ethics approval to various scientific and research ethics committees, which differ in terms of review procedures, membership and ability to grant final approval. For instance, some committees comprise members drawn from local government authorities, community members and researchers, among other social groups. In contrast, other committees primarily include research staff. The review processes by these institutional committees range from checking if an ethics application has included all required documents, to a more detailed review of the application, including inviting study investigators to present the study to the committee and respond to questions. Table 11 shows some of the
scientific and research ethics committees that review HDSS nested studies and/or the routine HDSS.

**Table 11 Scientific and ethics committees in selected HDSS sites**

<table>
<thead>
<tr>
<th>HDSS</th>
<th>Review Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nairobi</td>
<td>• KEMRI Scientific and Ethics Review Unit</td>
</tr>
<tr>
<td>Kilifi</td>
<td>• KEMRI CGMRC-Wellcome Trust Research Centre Scientific Committee and SERU</td>
</tr>
<tr>
<td>Kyamulibwa</td>
<td>• Uganda Virus Research Unit REC</td>
</tr>
<tr>
<td></td>
<td>• Uganda National Commission for Science and Technology</td>
</tr>
<tr>
<td></td>
<td>• London School of Hygiene and Tropical Medicine ethics committee</td>
</tr>
<tr>
<td>Karonga</td>
<td>• Malawi National Health Sciences Research Committee</td>
</tr>
<tr>
<td>Kintampo</td>
<td>• Kintampo Health Research Centre Scientific Review Committee</td>
</tr>
<tr>
<td></td>
<td>• Kintampo Health Research Centre Institutional Ethics Committee</td>
</tr>
<tr>
<td>Navrongo</td>
<td>• Navrongo Health Research Centre Institutional Review Board</td>
</tr>
<tr>
<td></td>
<td>• Navrongo Health Research Centre Scientific Review Committee</td>
</tr>
</tbody>
</table>

4.2.2 Consenting Processes: HDSS sites in sub-Saharan Africa

My discussions with research staff and observations in selected sites across sub-Saharan Africa, confirmed that HDSS research staff obtain consent at the household rather than at the individual level. This empirical study provided further evidence on consenting processes in HDSS including information sharing, seeking consent and perceptions of voluntariness.

4.2.2.1 Information giving and understanding

Across the HDSS sites in Phase 1, I observed that field workers commonly informed HDSS residents about the procedures and potential benefits of HDSS sites. Most field workers informed residents that the HDSS was a project of the host research centre that involves the collection of health-related data for research and to improve public health. While the field workers often mentioned that they would collect data on births and residence status, they rarely mentioned collection of data on deaths or pregnancies. Perhaps this omission shows the perceived sensitivity of these data. In
addition, field workers rarely mentioned the potential burdens of HDSS, other than the time spent in the interview. One of the three HDSS consent forms that I reviewed state that individuals might experience discomfort from some questions, especially questions about death, but the other two state that there are no risks to taking part in HDSS. Even though some of the HDSS questionnaires were in English, the field workers held discussions with residents and collected the data using common local languages, which the residents appeared to understand.

4.2.2.2 Seeking consent

HDSS research staff obtain consent at the household level, which raises concerns about the ability of individual household members to participate voluntarily. All the sites involved in Phase 1 research obtain verbal consent from household heads, with the exception of the Kyamulibwa HDSS, which obtains written consent. HDSS research staff and managers across the sites mentioned that there were very few refusals. Among the 59 households I visited during field observations in Phase 1 and 2, I observed a refusal in one household only. The household head, who had recently immigrated from another area within the HDSS, stated that she no longer wanted her household to participate in the HDSS. Some authors have argued that it can be challenging for some community members to refuse participation in health-related research, including HDSS, as they may fear damaging relationships with other community members or missing out on benefits (Carrel & Rennie, 2008; Gikonyo et al., 2008; Kingori, 2013). While demonstrating that some households are able to refuse or withdraw from HDSS, despite the challenges noted above, this observation of a refusal highlighted another important ethical issue; that most individuals are not asked to consent to HDSS. However, HDSS research staff obtain individual consent for verbal autopsy interviews.

4.2.3 Community Engagement in HDSS Sites in sub-Saharan Africa

4.2.3.1 Information sharing as a form of engagement

Community engagement activities can include information sharing, consultation or building partnerships (Sharp & Foster, 2000). Also, community engagement activities are closely linked to consenting processes (Participants in the Community Engagement and Consent Workshop, Kilifi, Kenya, 2013).
Information sharing emerged as the most common form of community engagement in the HDSS sites. HDSS field workers share information with residents during the consenting process and while collecting data. As I noted in the previous section, some field workers might not share information about potential burdens of HDSS. From my observations, the few residents who asked questions to the field workers; these were mostly questions about medical conditions and the value of the HDSS. Besides sharing information at the point of data collection, I learned that HDSS research staff occasionally use mass media platforms and community meetings to share information about the HDSS, host research centres and research. For example, the Navrongo Health Research Centre (NHRC) had a radio programme named “Time with Ghana VAST” which aired weekly on a local community radio station. Navrongo HDSS research staff who appeared on the radio programme talked about various activities of the NHRC including the ethics review process, HDSS and research projects. The researchers explained concepts such as ‘research’ and ‘health care’ to listeners. The following excerpt, highlighting some differences between research and health care, is from a document that the NHRC issued to research staff who took part in the Time with Ghana VAST radio programme, to guide them through the radio programme interactions.

“...formal consent is required of a research participant while the same might not be necessarily the case when a patient visits a health institution for routine health care except in special cases...the benefits that are derived from health research might not be immediate, whereas patient who goes for routine health care benefits immediately/directly from the service provider...”

In addition to sharing information with residents, I learned that HDSS research staff consult community members through networks of community representatives, as I will describe later in this chapter. The community meetings and other engagement opportunities provide opportunities for research staff to consult community members on the activities of the HDSS. In addition, some HDSS engage community members in collecting data, as highlighted in Chapter 2. My field observations, discussions with research staff highlighted that most of the engagement activities described above, are designed to support all activities of the host research centres,
Table 12 Key community engagement activities around selected HDSS sites

<table>
<thead>
<tr>
<th>HDSS</th>
<th>Information Sharing</th>
<th>Community Consultation and Partnership in Data Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kilifi</td>
<td>Open days, radio, information, leaflets</td>
<td>KEMRI Community Representatives</td>
</tr>
<tr>
<td></td>
<td>consenting</td>
<td></td>
</tr>
<tr>
<td>Nairobi</td>
<td>Consenting</td>
<td>Community Advisory Committees</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Karonga</td>
<td>Community meetings, consenting</td>
<td>Community Key Informants</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kintampo</td>
<td>Community Meetings, consenting</td>
<td>Community Key Informants</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kyamulibwa</td>
<td>Community Meetings, consenting</td>
<td>Community Key Informants</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Navrongo</td>
<td>Community Meetings, consenting, radio</td>
<td>Community Key Informants</td>
</tr>
</tbody>
</table>

4.2.4 Data Sharing: HDSS Sites in sub-Saharan Africa

As I highlighted in Chapter 2, HDSS sites and the INDEPTH Network were established to address the lack of population-level health related data in LMICs (Sankoh & Byass, 2012). Also, I highlighted the diverse challenges to data sharing, and that there is little documentation of data sharing policies, practices and perspectives (Bull et al., 2015; van Panhuis et al., 2014), including from individual HDSS sites. At the time of this study, 27 and 15 out of the 40 HDSS sites in sub-Saharan Africa were sharing aggregated and disaggregated data respectively, through the INDEPTH Network (Ekström et al., 2016; Herbst et al., 2015). The formative research showed that HDSS face significant technical and organisational challenges in sharing data. Until recently, most HDSS have been collecting data using pen and paper, which produce a large number of documents and data that are challenging to manage and share. I observed that some the sites need warehouses to store the voluminous documents generated over a long period of HDSS data collection. Also, retrieving HDSS records for analysis can be challenging. In one of the sites, I found research staff scanning HDSS
documents and storing them in computers to enable easy retrieval in future. Overall, HDSS need a lot of research staff to record, process, store and share data. This resource intensive process seems to be one of the key barriers to sharing HDSS data.

In addition to the technical challenges, the HDSS face organisational challenges to data sharing. For instance, discussions with HDSS research staff and managers highlighted that the responsibilities of HDSS to share data beyond research is unclear, given that the HDSS operate in research contexts and are primarily funded by non-government organisations. Some HDSS managers felt that they had little control over data sharing policies. Despite visiting the HDSS sites and meeting senior HDSS managers and researchers, I could only access data sharing policies from 2 and of the 6 sites. It seems that decisions on data sharing policies in some of the sites are made by other research stakeholders.

4.2.5 Benefits: HDSS Sites in sub-Saharan Africa

Most of my informal discussions with research staff and review of unpublished documents emphasised the perception in the literature that the HDSS provide population-level data that could be used for research and public health planning (Sankoh & Byass, 2012; Ye et al., 2012). For example, one of the consent forms that I reviewed states that “The information collected in the HDSS will help the government plan public health services...” Whenever I asked research staff to give examples of HDSS benefits, most mentioned the benefits of studies nested in the HDSS, or the employment opportunities that the sites provide to the local community. Few participants discussed benefits for individuals or benefits that could emerge during the collection of HDSS data.

HDSS procedures might have some direct benefits for individuals and households. I observed that most residents appeared happy or excited by the HDSS field workers’ visits. Also, I observed that some HDSS sites number all residential units within the HDSS area. I learned, through informal discussions, that some HDSS residents use these HDSS numbers as house addresses. In addition, HDSS provide residents with various goods and services, which can be described as ancillary care because HDSS do not have to provide them to achieve their main research objectives (Brownsword et al., 2008; Carrel & Rennie, 2008; CIOMS and WHO, 2016). For example, one of the
sites had a temporary arrangement with the civil registration office, which enabled the HDSS to issue birth certificates to residents. In this arrangement, HDSS field workers would record details about births, during routine household surveillance, and share these details with the registrar of births. The civil registration office would then generate birth certificates and give them to HDSS field workers to take to the respective HDSS residents. In addition, some HDSS may provide residents with financial support, soap, free health care or transport, as these comments illustrate:

“When a participant reports to the clinic with some ailments, and you find you cannot have them in here, because of either you don’t have the expertise or you don’t have the equipment or the drugs, then we refer them and transport them to the referral hospital, and if it necessitates for us to meet some of the costs for their treatment, then we do the same.”
IDI28_HDSS_Manager_Uganda

“We have a funeral plan for the community key informants. When a key informant dies, we support some of the costs for their funeral.”
IDI29_HDSS_Manager_Malawi

Few authors acknowledge the benefits of HDSS beyond the benefits that might emerge from the use of HDSS data. The empirical evidence in this study highlight that HDSS could have direct individual benefits, including those associated with ancillary care. In Chapter 7, I will discuss HDSS research stakeholders’ ancillary care responsibilities, including recommendations to enhance individual and public benefits.

4.2.6 Burdens: HDSS sites in sub-Saharan Africa

Researchers acknowledged that conducting HDSS involves time and economic costs for residents (Crampin et al., 2012; Sankoh & Byass, 2012). The empirical evidence in this study largely confirms this claim. I observed that collection of routine HDSS census interviews can take a long time, depending on household size and data being collected. In particular, the interviews seemed to take a long time when the field workers had to review vaccination cards, collect migration data (especially destinations and reasons for migration), make biophysical measurements or assess
the literacy of school-going children. In addition, collecting data using paper-based questionnaires took longer compared to electronic data collection.

Some HDSS questions and procedures raise concerns about confidentiality and can present emotional burdens for HDSS residents and field staff. Findings from the formative research suggested that questions around pregnancy, socioeconomic status and death and particularly sensitive. I observed that some field workers asked the household head (or key respondent) to state whether anyone in the household was pregnant, which can risk the privacy and confidentiality of individuals, especially when field workers conduct these interviews in a communal setting. I also observed some male field workers requesting to speak to female residents in private to ask about pregnancy status and other reproductive health questions, which might also raise concerns among other household members. Field workers shared that some residents seem annoyed or confused by questions around marital status, income and ownership of socioeconomic assets such as land and electronics. In one site, I observed a young boy who was so terrified by the weighing scales that he had to be restrained from running away, and he cried throughout the weighing. Across all the HDSS sites, HDSS research staff and managers felt that questions about death, including verbal autopsy interviews, were the most sensitive because of the complex community reactions to death, potential emotional distress to respondents and risks to data confidentiality. During the formative research, I observed two verbal autopsy interviews where the respondents appeared emotionally distressed; one respondent felt that someone had bewitched her daughter while the other was in grief for losing her young child.

4.3 Characteristics and Ethical Issues for the Kilifi and Nairobi HDSS Sites

4.3.1 Characteristics of the Kilifi HDSS: Rationale for Establishment, Socio-Economic Context and Current Functioning

In Chapter 3, I described the Kilifi HDSS in terms of its history, location and organisation. In this section, I will provide further information on why the KHDSS was established, its socio-economic context and current functioning.
4.3.1.1 Rationale for Establishment

As noted above, research centres primarily established HDSS sites to support their own research activities and interventions rather than to support the local CRVS. The Kilifi HDSS was set up to support research projects and community-based interventions by the KEMRI WTRP in Kilifi (Scott et al, 2012). This support includes providing a denominator population and a sampling frame, which would otherwise be provided by a well-functioning CRVS system. Discussions with research staff and HDSS managers further highlighted that the research centre established the site for research, and to complement other sources of population-level data:

“The DSS is a stepping stone to national vital registration...in the absence of national vital registration, you need to invest consolidated resources in sub-populations to find out what any other government would find out through national vital registration...it’s also an important tool to do research because one of the principal measures of disease burden is incidence of disease... the principal advantage of DSS is that it gives a denominator population for research...when we set up this DSS, we said there would be research about it, it would be a framework for random sampling...” IDI17-KHDSS Researcher

KWTRP research stakeholders also established the KHDSS to coordinate the community-based studies that they were implementing in the Kilifi area:

“...it became very apparent that a lot of people wanted to access the community in different ways through different types of studies. We all got together to work out the best ways things should work out. We realised that rather than everybody doing little studies all by themselves we were better off joining forces and doing one big study that we could draw benefit from which was sort of the birth of the DSS which we established in 2001...so the birth of the DSS was pragmatic.” IDI15-KHDSS Manager

4.3.1.2 Socio-economic Context

The majority of people living in the Kilifi HDSS belong to the Mijikenda ethnic group, are Christian and practice subsistence farming. Nevertheless, the KHDSS community is diverse and has been changing over time especially around the Kilifi town area where
institutions such as KWTRP and the Pwani University are located. The KWTRP has engaged the KHDSS community for many years including through conducting community based studies, implementing community programmes and establishing a community engagement strategy to build mutual understanding between the KWTRP and the KHDSS community (Kamuya et al., 2013; V Marsh et al., 2008). Furthermore, the KWTRP headquarters are located within the KHDSS area. This long-term engagement has built a strong relationship between the research centre and HDSS residents. The majority of KHDSS residents seem to be familiar with KWTRP based on their direct or indirect interactions with the centre. These relationship potentially builds expectations, trust and misconceptions (Molyneux, Peshu, et al., 2005; Njue et al., 2014). For instance, while I was observing KHDSS household enumeration, one middle-aged man, after learning that we were KWTRP staff, told us that he was very grateful to KWTRP because his son who had been severely ill from Pneumonia, received treatment at KEMRI and that he was now back to his motorcycle transport business.

4.3.1.3 Current Functioning

The KHDSS conducts household enumerations every 3-4 months. These enumerations start in the Northern region of the KHDSS area and finish in the Southern region. The routine household enumerations are conducted by 41 KHDSS field workers, also referred to as census field workers. Additional KHDSS field workers conduct verbal autopsy interviews and collect data from Kilifi county hospital patients for clinical surveillance. At the end of each enumeration round, field workers usually get a one-week break from field activities to attend refresher training sessions. I observed one of these sessions where field workers were trained on how to use the newly piloted electronic data collection system (EDCS). During these trainings, the field workers who had piloted the EDCS shared their experiences with fellow colleagues and trainers. The EDCS was later introduced for use by all KHDSS field workers. The KHDSS field workers operate from the KWTRP headquarters in Kilifi town; every morning, the census field workers gather at the research centre and travel to the households using KWTRP vehicles; a small number of field workers, especially verbal autopsy interviewers, normally visit households using motorbikes.
4.3.2 Policies, Practices and Perspectives on Ethical Issues in the Kilifi HDSS

4.3.2.1 Perceptions of the need for Kilifi HDSS Ethics Oversight

The KWTRP established the KHDSS after a period of consultation among, and between, research and community stakeholders. These stakeholders included funders, researchers at KWTRP, community members and government agencies.

“...there was a lot of communication with the stakeholders...the community, chiefs, the sub-chiefs, the civil registration departments, the Kenya national bureau of statistics, they were all positive about this kind of work. There was a lot of internal consultations and discussions to okay the thing (KHDSS) to start.” IDI3-KHDSS Manager

While establishing the KHDSS research stakeholders consulted the national research ethics committee (REC) but did not submit a research protocol for review was not subjected to a research ethics review because they did not view the KHDSS as a research project:

“...we wrote a letter to the ethics committee and said we’re doing this activity but we really don’t think this is research and we don’t think it is any of your business to review it... I don’t know whether they wrote back saying ‘yes we agree’ or whether they didn’t write back, I can’t remember, it’s a long time ago, must have been about 16 years ago, but that’s how we set it up.” IDI17-KHDSS Researcher

Therefore, between 2000 and 2015, the KHDSS operated with the approval of the HDSS residents and local government officials such as chiefs but without formal approval from a research ethics committee. Over time, and perhaps influenced by a global movement towards formal review of health-related research, views around ethics review changed leading to the development of a KHDSS proposal that was submitted to the national ethics committee, KEMRI Scientific and Ethics Review Unit (SERU), for approval. Some of the KHDSS managers did not seem convinced that the KHDSS should be subjected to a research ethics review process; they welcomed the idea of an alternative or customised review process such as a standardization body while at the same time recognising the need to conform and adhere to the current...
ethics governance regulations as this participant explained:

“...in the end we did put together a research proposal to go through SERU. For fifteen years we operated on a premise that the platform itself was surveillance. It is very light touch, we don’t actually do very much apart from count births, deaths, migration events to see whether people are there or not and whether they moved in or out and whether there have been any deaths or births. The actual DSS itself is non-invasive, non-interventionist, doesn’t have blood taking or anything that the studies that go into it do. But it became clear as time went on that attitudes changed and the regulation and governance moved on and that there were issues of ethics so that’s why we put together the proposal.” IDI15- KHDSS Manager

KHDSS researchers, especially those who were not closely involved in managing the KHDSS, felt that the KHDSS should be reviewed by an independent ethics committee. From the perspective of these researchers, an independent ethics review could identify potential benefits and burdens and enable the KHDSS to demonstrate accountability, as these two researchers explained;

“...many of the people who argue that DSS is not research, that it’s a grey area and therefore it shouldn’t be reviewed...probably there are certain things that they just want to put under the carpet for reasons best known by them...if indeed we have benefits for the community and minimal risk, it’s for the reviewers to determine that...”IDI1-KHDSS Researcher

“...this time they might be asking about mosquito nets, the next time they are asking about pregnancy, the data that is being collected is more and more, and some of these data might be sensitive so it might require additional thought on how it’s packaged, whether you can ask it within the DSS enumeration or whether it needs to be packaged as a different study” IDI2- KHDSS Researcher

Another justification for supporting independent ethics review and approval of the KHDSS was that ethics approval allows research stakeholders to publish KHDSS data in scientific journals. This justification was particularly given by KHDSS managers who
felt that the uncertainty over ethics approval for the KHDSS restricted them from publishing the KHDSS data:

“The Kilifi DSS is not based on any protocol... this has hindered us from publishing this data or writing papers... we really can’t do that... I think it will be important for us to maybe think of a way of getting a protocol that will undergo review and enable us also to able to publish of this data.” IDI4-KHDSS Manager

“...right now if I want to write something on in-migration, the first thing you see on those forms is ‘which protocol is it anchored on? If I want talk about deaths under five I will have to talk to [researcher X] because his protocol has something on under five neonatal deaths. I think that this is the big challenge for us who are trying to publish on the DSS.” IDI5-KHDSS Manager

4.3.2.2 Consenting Processes: Kilifi HDSS

As I described in Chapter 2, some have questioned whether it is necessary to seek consent for collection of HDSS data given that other programmes such as CRVS that collect the same data as HDSS, do not seek consent. However, the majority of study participants felt that the KHDSS field workers should seek informed consent from residents before collecting data. This view seemed to be informed by the understanding that the KHDSS operates within a research context. While participants widely agreed that KHDSS residents’ consent was necessary, there was a diversity of opinion on how KHDSS field workers should obtain consent, as this participant explained:

“So, nobody that I am aware of in relation to the Kilifi DSS thinks that there should be no consent, everyone says there should be informed consent. The debate has been whether it should be written or verbal...” IDI7-KHDSS-Researcher

The most common argument in support of verbal consent, was that the KHDSS census is a low risk and less intrusive activity compared to other research projects, as these comments from a KHDSS manager and field worker illustrate:
“I think it is right that we don’t do written consent for the surveillance for a number of reasons; one is because the risk is small, the [time] costs are also relatively smaller unless it is a very large household and you’ve got some very elderly man who’s not quite with it.” IDI17-KHDSS Manager

“... I was told the census does not have very sensitive or confidential information... you are seeking information like age whereas almost everyone will know your age. If it is your sex, of course everyone knows you are male. If it is whether or not you are resident, everyone will know that you are resident. So, the census information is not very sensitive, that is the explanation I was given.” IDI14-KHDSS Census Interviewer

One KHDSS Manager supported written consent arguing that it provides evidence that the residents consented to the collection and use of data.

“...if you have a verbal consent there is a likelihood that someone can come back and say ‘no I did not give it’...you have published this data but we didn’t agree what you should use my data for and to what extent you can share my data. So if you have written consent where someone can sign or places a thumb print...“IDI5-KHDSS Manager

All research stakeholders, regardless of whether they supported written or verbal consent, felt that the consenting should be accompanied by ongoing community consultation. From their perspective, this community consultation would enable creation of awareness about the KHDSS, identification of the appropriate consenting process and community attitudes to consenting. The following comment from a KHDSS researcher illustrates the view by several researchers that consenting should be a process rather than an event:

“The consent itself should begin with the homestead head if possible then go to each of the household within the homestead, make sure that everybody is happy and continue to explain to individuals within that household why you are doing what you are doing and back all of that up with a really good communication community engagement strategy.” IDI7-KHDSS Researcher

Indeed, two participants reported that KWTRP had consulted KHDSS community
representatives to find out community members’ views about KHDSS consenting processes, in particular, verbal and written consent. The community members felt that written consent is verifiable while others wondered why the KHDSS wanted to introduce written consent when the community had not complained about verbal consenting. There were concerns among KHDSS researchers that written consent would introduce unnecessary refusals and potentially reduce the scientific validity of the KHDSS. The comments below by a KHDSS manager and researcher highlight the process and outcome of these consultations with community representatives in the KHDSS:

“Since 2000 when the DSS was started, we have been using verbal consenting...there was a time when we wanted to have written consenting but then a survey that was carried out by the community liaison group showed that community members were feeling like ‘why should I sign when all along I’ve just been giving the permission[without signing]’, some of them felt like if they sign they would be tying themselves into something they are not sure...so we decided to stick to the verbal consenting as it were.” IDI4-KHDSS Manager

Therefore, KWTRP research stakeholders made the decision to continue with verbal consenting for the KHDSS taking into account the diverse opinions of community representatives. Some community members preferred verbal consent because they viewed it as being less coercive compared to verbal consent. Other study participants preferred written consent because they felt it gave residents a formal opportunity to refuse or consent to the KHDSS. However, the majority of KHDSS managers and researchers, based on their experience of working with KHDSS residents, felt that most people were able to make a voluntary decision on KHDSS participation:

“...there’s evidence that you can exert your will, you have autonomy, you have voluntariness and the evidence is there that people that don’t want to join say no, I have a long list of people who’ve said no, we don’t bother them anymore.” IDI17-KHDSS Researcher

Another commonly described reason for preferring written consent was that it would demonstrate respect to KHDSS residents; by providing them with an information sheet disclosing the key features of the KHDSS, and asking them to sign the consent
form to show that consent had been given voluntarily. However, some KHDSS researchers felt that the signing of consent forms was primarily aimed at protecting the interests of researchers rather than those of KHDSS residents, and that residents could still give informed voluntary consent even without signing forms.

4.3.2.3 Community Engagement: Kilifi HDSS

The KHDSs is supported by programme-wide and project-specific community engagement activities. Most of the programme wide activities, including the KCR network, open days at the KWTRP, school engagement and a radio programme are implemented within the KHDSS area. Although the KWTRP does not expect KCR members to pro-actively disseminate information about the KWTRP, my discussions with KCRs showed that they informally share information about the research centre with other community members:

“I think that the members of the community have a better understanding of KEMRI. KEMRI choses members of the community (KCRs)... so if someone says it is not that way let me teach you, let me teach what I understand. It isn’t like in the past where there were issues of devil worshiping...that mentality seems to have changed.” FGD3-Kilifi-Junju KCR

The KCR network was established and is managed by KWTRP; however, I learned that KCR members also belong to other important community based networks such as the Nyumba Kumi (translates to “10 houses” – an initiative of the government to promote good neighbourliness) and Community Health Volunteers (CHVs). The Nyumba Kumi Initiative was introduced nationally by the government; Nyumba Kumi elders are expected to have knowledge of residents in a small area within the community, including migrations of individuals and households. Community Health volunteers work closely with the Ministry of Health and other community-based organisations interested in public health. The CHVs are not government employees in the same way that KCRs are not employed by KWTRP, but they occasionally get opportunities for paid work:

“Honestly, the CHVs are not necessarily paid...Kilifi County government said it would compensate them... like recently we were distributing the drugs, you are paid for that. When there comes a piece of work that involves moving around...
The KCR network is an important platform for the KWTRP and KHDSS residents to build mutual understanding. For instance, in a KCR workshop that I attended at the KWTRP in Kilifi, researchers described their research and explained concepts such as the distinction between research and treatment, while KCR members discussed community members’ attitudes and experiences with research. One KCR reported that a KWTRP field worker once entered into a health facility compound holding a GPS device and started walking around without introducing himself, which raised tensions; most people were not sure what he was doing. Such information and associated discussions can inform training and evaluation of field workers, and build KCR understanding of research and KWTRP activities.

The other programme-wide activities - open days, radio programme and school engagement - provide further opportunities for information sharing and building mutual understanding about the KWTRP and its activities. For instance, at one of the open days at KWTRP, I observed researchers informing community members about the KHDSS including its geographic coverage and type of data collected. In addition, KHDSS managers and KWTRP facilitators have appeared on a radio programme in a radio station that broadcasts within the Kenyan coast (including the KHDSS area). During the radio programme, the KHDSS research stakeholders shared information about the key features of the KHDSS.

The KHDSS-specific community engagement activities include the distribution of information leaflets and information sharing by field workers. The information leaflets provide information about the location, history, aims, functioning and benefits of the KHDSS. For instance, the 2015 leaflet includes a map of the KHDSS area and states that the KHDSS data was used to control a cholera outbreak in Kilifi. KHDSS field workers also share information with residents during data collection. I observed field workers explaining the key features of the KHDSS to residents during household re-enumerations. Overall, field workers informed household members that the KHDSS was being conducted by KWTRP through 3-4 monthly household visits to collect different types of data including births, migrations and residency status. Like in other sites during the formative research, I noted that field workers often omitted
mentioning some potentially sensitive but routinely collected data such as deaths and pregnancy.

My field observations and discussions with community members indicated that the majority of residents are familiar with the KHDSS probably due to their regular interactions with field workers and the long-term presence of the KWTRP in Kilifi. Also, I learned that the establishment of the KHDSS was accompanied by a large scale communication initiative, which might have contributed to community familiarity with the KHDSS. This involved holding 10 open days meetings for community members at the KWTRP, distributing information leaflets to households and training field workers to inform residents about the KHDSS during data collection. The open days meetings involved a total of 330 community leaders and representatives drawn from the KHDSS area. These included a wide range of community stakeholders such as district commissioners, district health officers, village elders and community health workers. In addition, the KWTRP distributed information leaflets to each household in the KHDSS area. Field workers were also trained and supported to share information about the KHDSS whenever they visited households for data collection. The most common information shared with attendants of the open days meetings, through leaflets and by field workers, included information about the KWTRP, the KHDSS and explanation of what research entailed (unpublished documents).

4.3.2.4 Data Sharing: Kilifi HDSS

As I noted earlier in this chapter, I only accessed data sharing guidelines/policies for two (Kilifi and Nairobi) out of the six HDSS sites involved in the formative research. The KWTRP data sharing guidelines categorise the types of data collected by the research centre, and outline the ethical principles and processes for data sharing. According to the guidelines, the three main groups of KWTRP data, include routine clinical data, study-specific and Kilifi Integrated Data Management System (KIDMS) data. The KIDMS data include data collected through the KHDSS. In addition, the guidelines state that the data should be shared to promote scientific utility of research, and in a manner that ensures transparency, accountability and protection of the interests of research participants, investigators and other stakeholders. Furthermore, the guidelines group data requests into two broad categories; internal and external requests. A data governance committee (DGC) at the KWTRP oversees
data sharing. The DGC draws its membership from KWTRP researchers and the Ministry of Health. When I asked one group of community members whether they would like representation in the DGC after describing its membership, one of the participants, supported by others in the group, felt that the presence of the Ministry of Health in the DGC was adequate representation for the community. My discussions with KHDSS research stakeholders and review of documents highlighted that the KWTRP data, including KHDSS data, are shared online and usually with researchers. KWTRP researchers can request data using the research centre’s intranet while external researchers have to write to the Data Governance Committee to request data. As the following comment by a KHDSS researcher indicated, it can be challenging for individuals external to the KWTRP to access the data:

“I have been involved in testing the online platform that will now be governed by DGC for requesting data. But even with that online platform, it is basically the same form that you filled in before but just online, they ask you ‘what are you going to do with the data, what data are you looking for, are you protected by a protocol?’ Which of course somebody requesting data from outside... from Nairobi... would not have... so if you are ministry of health and you want information about deaths in Kilifi, So you don’t need a protocol to get that information? Do you?” IDI16-KHDSS Researcher

However, the KHDSS, after three years of exclusive analysis, shares aggregated data with through the INDEPTH Network, which makes the data available online (Herbst et al., 2015).

4.3.2.5 Benefits and Burdens: Kilifi HDSS

All the reported benefits of the KHDSS were related to the use of KHDSS data for interventions and to support nested studies. Study participants mentioned the various benefits of studies and interventions that had been conducted within the KHDSS especially to address malaria and disease outbreaks. These include the mass distribution of mosquito nets attributed to the reduction of malaria mortality and morbidity. One of the KHDSS information leaflets also notes that KHDSS data was used to show reduction of mortality following introduction of a pneumonia vaccine, and that KHDSS data helped to identify and address the causes of a cholera outbreak.
in Kilifi. The majority of researchers, also reported that the KHDSS platform had enabled them to generate hypotheses and recruit participants for their studies.

In addition, the KHDSS recruits field workers from the local community, not only because of their expected understanding of the community but also as an engagement strategy. The KHDSS is also likely to create indirect employment by supporting local businesses. This economic impact, supported by ethics review that ensures that studies conducted by KWTRP within the KHDSS area demonstrate respect for local communities, is likely to generate community goodwill and acceptance of KHDSS and other KWTRP programmes. During field work in the KHDSS households, I also observed that most residents were friendly and seemed happy to be visited. Indeed, one KHDSS manager, pointed out that other than reduction of morbidity and mortality, and employment, the KHDSS may have other “hard to measure” benefits for residents. For instance, some residents may appreciate being visited because this shows that someone cares about their wellbeing.

The most commonly described burden of KHDSS were time costs. Through the different information sharing platforms such as open days, research stakeholders often mentioned the main burden of KHDSS participation for residents is the time spent for data collection. I observed that the KHDSS involves questions that might be sensitive or distressing for respondents. These include questions on pregnancy status and outcomes and death. Unlike the NUHDSS, where research stakeholders mentioned potential burdens for field workers, most of the burdens mentioned in the KHDSS were for individual respondents and KHDSS community including stigmatisation. Furthermore, one participant pointed out that the KHDSS is not a low risk activity as it might first appear to be; because it can lead to invasion of privacy:

“...Although the DSS itself does not contain any particular revelations...there are obviously contentious issues of knowing paternity, people living in houses which perhaps they shouldn’t be, perhaps they are not married... so there is information that people might not want to make widely available, and then within the programme who has access to that information? We have people within the programme who are able to see data, names and places on databases and potentially that could be misused if it got in the wrong hands or...”
Characteristics of the Nairobi Urban HDSS: Rationale for Establishment, Socio-Economic Context and Current Functioning

The APHRC established the NUHDSS after conducting a cross-sectional survey of several slums in Nairobi and selecting the Korogocho and Viwandani slums for long-term follow up to investigate socio-economic and health implications of slum residence. Like the KHDSS and other sites, the NUHDSS was established primarily to address the lack of reliable population-level data.

As I described in Chapter 3, the NUHDSS has a multi-cultural population. The two NUHDSS areas - Korogocho and Viwandani - are densely populated and residents seem to face a wide range of health and socio-economic challenges including poor access to clean water and sanitation facilities. During my visits to the NUHDSS areas, I observed that most residents were engaged in diverse economic activities, including running small businesses. In addition, despite the reported diversity in terms of ethnicity, most residents speak Kiswahili - the National language. Researchers and field staff reported that the Viwandani site has a young and mobile population compared to Korogocho, and that this is because a significant number of residents in Viwandani work as casual labourers in the nearby industrial area. While the KWTRP headquarters are located in the KHDSS area, the APHRC is located outside the NUHDSS area.

The number of enumeration rounds in the NUHDSS has been reducing over time. From 2002, there were four rounds per year, this reduced to three rounds and from 2016 the site has been conducting two enumeration rounds per year. NUHDSS field workers collect data using mobile electronic devices. Since the two NUHDSS field sites are relatively small and densely populated, field workers rarely use vehicles or motorcycles, instead, they walk from household to household to collect data.

Policy, Practices and Perspectives on Ethical Issues in the Nairobi Urban HDSS Site

Perceptions of the Need for NUHDSS Ethics Oversight

Unlike KHDSS, the APHRC sought ethics approval for the NUHDSS from the national
ethics committee - KEMRI SERU – right from its inception in 2002. This is because researchers at the APHRC viewed the NUHDSS as a research project to investigate the impact of urban residence on health. In 2006, the NUHDSS received another ethics approval, but this time, as part of a study on urbanisation, poverty and health dynamics in sub-Saharan Africa (UPHD). However, this study ended in 2011, leaving the NUHDSS without ethics approval. At the time of data collection, the NUHDSS did not have a current research ethics approval. The statement below summarises the history, including the uncertainties, of ethics review for the NUHDSS:

“We sought ethical approval for the DSS, then at some point there was a project funded by the Wellcome Trust that had specific research questions but which depended on the DSS entirely. So we sought approval for that project incorporating the DSS. We went up to I think…2011…that’s when the project ended. The DSS had been sort of absorbed by the project, when the project ended, it did not occur to us to extract the DSS and continue seeking approval…so we are trying to have discussions with KEMRI [SERU] to see what we can do, because we have collected data for the last four or five years, without ethical approval…So we’ve tried to go back and track the last approvals we had I think either in twenty eleven or twenty thirteen…” IDIO8-NUHDSS Manager

An ethics approval letter for the NUHDSS is attached on Appendix 2.

4.3.4.2 Consent Processes: Nairobi Urban HDSS

NUHDSS field workers obtained written consent from household heads during the baseline census in 2002. At the time of this study, they were obtaining written consent from new households only and verbal consent during the six-monthly household re-enumerations. The NUHDSS nested studies usually obtain individual written consent from study participants. However, particular studies might have consenting processes resembling those of an HDSS. I learned about a study on household air quality monitoring that sought consent from the household head rather than from each household members, indicating that researchers can adapt consenting processes based on the specific field procedures involved.

While the NUHDSS information sheets and questionnaires are available in both
English and Kiswahili, I observed that the field workers usually conduct the household interviews in Kiswahili as this is the language that most residents understand. The electronic data collection device has a section where field workers indicate whether respondents have given consent. From discussions with NUHDSS researchers and field workers, I learned that whenever an individual refuses to take part in HDSS, another field worker preferably with a similar personal background to the resident, visits the household. If the resident still refuses, a field supervisor or community development officer visits the household to explore the reasons for refusals. Overall, discussions with community and research stakeholders in the NUHDSS regarding consenting processes, reflected those in the KHDSS showing that field workers explain the HDSS activities to residents in an understandable format, for instance, by using local languages, and that residents can refuse participation.

4.3.4.3 Community Engagement: Nairobi Urban HDSS

Programme-wide community engagement activities at the APHRC - host centre for NUHDSS - involve Community Advisory Committees (CACs), free annual medical camps and policy engagement. At the time of this study, each of the NUHDSS field sites had a CAC with 10 members. CAC members represent the different social groups and community stakeholders in the NUHDSS areas such as youth and religious groups. This is in contrast to KCRs who are elected in different in different administrative areas in the KHDSS. Like KCRs, CAC members are not expected to proactively disseminate information about the APHRC and are not employees of the research centre. However, researchers often consult CAC members before beginning studies within the NUHDSS areas. During my discussions with CAC members in the two NUHDSS field sites, I learned CAC members work with other community-based networks such as CHVs and Nyumba Kumi Initiative and that they are familiar with the local population and cultures. The APHRC also runs free annual medical camps in the Viwandani and Korogocho field sites. As I mentioned earlier, APHRC research staff, managers and field workers view these medical camps as a public benefit and community engagement activity. During the free medical camps, field workers reported that residents learn about the activities of APHRC. Like the KWTRP, APHRC actively engages with policy makers to enhance the translation of research into policy and practice. For instance, the KWTRP works closely with the Ministry of Health and
other research stakeholders to maximise the utility of research locally and globally while the APHRC has a dedicated policy engagement office which works with government and non-government agencies to improve APHRC research impact.

These programme-wide engagement activities are likely to support the NUHDSS; for instance, by creating community awareness and acceptability of NUHDSS and enabling engagement with policy makers. However, field staff in particular, felt that APHRC had neglected NUHDSS-specific community engagement activities and prioritised other short-term studies conducted within the NUHDSS area by APHRC researchers. The field staff reported that other than the programme-wide engagement and information sharing by field workers during data collection, the NUHDSS did not have study-specific engagement activities.

4.3.4.4 Data Sharing: Nairobi Urban HDSS

I learned that unlike the KHDSS, which only shares aggregated data with the INDEPTH Network, the NUHDSS shares both aggregated and disaggregated data with INDEPTH. In addition, the APHRC has a microdata portal, which allows anyone with access to the internet to view APHRC data, make a request and download data as this participant explained:

“The microdata portal is web-based, so anybody can access it and download the questionnaires and the study reports. But if you want to explore the data, you need to write a short abstract explaining what you are going to do with the data, and that you are going to acknowledge APHRC and the study participants”.IDI10-NUHDSS Manager

The NUHDSS and other APHRC data are available online but discussions with NUHDSS research stakeholders indicated that in practice, the data are primarily accessed and used by researcher. One of the field staff reported that she had used NUHDSS data for her postgraduate studies but the majority of field workers in particular said that although they were aware that the data were available, they had never used it. Furthermore, field workers and researchers felt that community members do not access the data due to various barriers including lack of access to internet and analysis skills. One participant suggested that aggregated NUHDSS data such as on population size could be useful for some resident
“...you never know what someone might want the data for...I remember there was someone who wanted to develop a proposal to apply for government funds for youth. I don’t know whether they wanted to use findings from the DSS but I am just imagining that if they wanted even simple statistics such as on population size, how would they access it because I don’t think they even have internet or anything, they write the proposals by hand”. IDI11-APHRC Researcher

The KWTRP data sharing guidelines outline the ethical principles of data sharing. On the other hand, the APHRC data sharing policy state that data is a public good that should be shared widely; the focus is on the terms of sharing and technical aspects such as the microdata portal. The APHRC data sharing policy also seem to prioritise requests from postgraduate students especially those affiliated with the APHRC. Overall, data from the two case studies are available to the public through online platforms or requests to the host research centres, in practice, it appears that the data are mostly accessed and used by researchers.

4.3.4.5 Benefits: Nairobi Urban HDSS

Study participants described the social and public health benefits that had emerged through the use of NUHDSS and nested studies. One researcher explained that the NUHDSS data was used to describe the feature of primary school education in the Korogocho and Viwandani sites. The data showed that many children in the NUHDSS areas were not benefiting from the free primary education by government since they were attending unregistered and poor quality private primary schools. This information led to government registration and funding for some schools, as this participant explained:

“In 2003, Kibaki’s government introduced free primary education to help all children including from poor families, access primary education...we did a study in 2005 to find out how many public schools there are and how they are funded, how many school-age children there are and where they go to school...the project helped us monitor the impact of free primary education. We shared the findings with government and government considered funding some private schools. Some of these schools had been registered with the
In addition, research and community stakeholders mentioned a wide range of APHRC studies and projects conducted in the NUHDSS, which they felt had benefited the NUHDSS residents. These included studies on air quality, a study on maternal and child health, which raised community awareness about childhood malnutrition and trained mothers on breastfeeding, and the “Permanence Study”. Research stakeholders and community members both field sites widely mentioned the Permanence study, which used the NUHDSS data and platform, as an example of how the NUHDSS had benefited residents. The study provided evidence that poor access to good quality maternity health care was contributing to pregnancy-related deaths in the NUHDSS areas. This evidence contributed to the implementation of a context-specific intervention that involved upgrading health facilities and providing security for women to visit the facilities at night. Three health facilities in each of the field sites were renovated and equipped to handle maternal and child health care including deliveries. In addition, the projects worked together with youth groups and village elders to ensure that women who needed to deliver at night could access the health facilities.

4.3.4.6 Burdens: Nairobi Urban HDSS

Like the KHDSS, the most commonly described burdens of NUHDSS were fatigue, time and economic costs for residents. Research and community stakeholders mentioned that the NUHDSS has been going on for many years and that this can cause fatigue for the households and individuals involved:

“...some of them feel that we have collected this data so much that they’re now tired”. IDI22-Nairobi-Viwandani-VA Interviewer

In addition, the NUHDSS data collection, including routine enumerations can take a significant amount of time depending on the data collected and household size. As I mentioned earlier, migration and childhood vaccination data take longer to collect; I highlighted that the NUHDSS has a mobile population which could make data collection take longer. Furthermore, I observed that most of the respondents were engaged in some form of economic activity, especially running small businesses, when the NUHDSS field worker approached them for an interview. Therefore, the
NUHDSS involves some time and economic costs for residents.

The NUHDSS seems likely to pose risks to the privacy and mental health wellbeing of respondents. The NUHDSS area is densely populated and most houses are poorly constructed; therefore, whereas field workers in the KHDSS usually interviewed residents in spacious compounds with only close family members present, I observed that field workers in the NUHDSS conducted interviews inside houses or outside where neighbours and other people passing by could hear the conversation. In addition, study participants mentioned that some of the NUHDSS questions, especially on household income, pregnancy status and causes of death, are sensitive. Asking these questions, especially in such a context where confidentiality is not guaranteed is likely to risk the privacy of respondents and make them emotionally distressed.

In addition to burdens for NUHDSS residents, research stakeholders reported the potential burdens for NUHDSS field workers. These burdens include insecurity and emotional distress. One participant pointed out that field workers face risks of being physically assaulted or being robbed especially because they occasionally visit households at odd hours to find residents;

“There are challenges we face generally as field interviewers. Sometimes finding respondents can be difficult. So we may be forced to go very late in the evening or very early in the morning and being that we work in informal settlements we have security challenges.” IDI23-NUHDSS Manager

A community representative reported that APHRC field workers had been robbed while working in the NUHDSS area.

“There is somewhere that the field workers went into, I won’t mention the area. I don’t know whether the field workers had told the village elders that they had tablets or whether they knew there were criminals there. The tablets were stolen and the field workers were beaten”. FGD9-P3-Nairobi-Viwandani-CAC Member

Furthermore, field workers reported that they often encounter people engaging in illegal activities, or residents facing severe social, health and economic challenges;
and that these encounters can be emotionally distressing for field workers.

“We are working in an informal settlement where there are so many challenges that we encounter on a daily basis. You go into a location, you find somebody who has no food, somebody who is sick, somebody who has been bereaved, somebody who has been raped, and you do not have any solution...”
IDI21-Nairobi-Viwandani-VA Interviewer

4.4 Summary

In this chapter, I have described the characteristics of HDSS sites in sub-Saharan Africa and the range of ethical issues encountered in these sites, using data that I collected through document reviews and empirical research in HDSS sites across Kenya, Ghana, Malawi, South Africa and Uganda.

I have shown the similarities and differences between the sites in terms of their histories, socioeconomic and geographic context, and current functioning. A key similarity is that researchers and research funders (mostly from Europe and Africa) established the sites through international collaborations and for health-related research. In addition, most sites are in areas characterised by various health and socioeconomic challenges. Despite this similarity, the HDSS operate areas with diverse geographic and environmental features including forested, savannah and coastal regions. The sites collect a wide range of data, but unreliable funding seems to affect most HDSS procedures. In particular, the empirical evidence highlighted that HDSS face various technical and ethical challenges when collecting cause of death data through verbal autopsy.

In this chapter, I highlighted significant uncertainty among participants and diversity in policies and practices in terms of ethics processes for HDSS including ethics review, consenting, community engagement, burdens, benefits and data sharing. Some HDSS sites started without the usual research ethics review because of uncertainty about the importance or necessity of such a review, given the indistinct positioning of the HDSS methodology, while others applied for ethics review from the outset. Most participants view the routine HDSS census as a low risk activity, except for the verbal autopsy, but my field observations and discussions with participants highlighted that
even the routine census interview can involve substantial time, economic and emotional costs for some residents.

The empirical findings from the in-depth case study sites reflected the ethical uncertainties and diversity of HDSS sites in other sites. Discussions with research stakeholders in the in-depth case study sites highlighted the uncertainty over HDSS methodology, ethics review and consenting, among other issues. Overall, these uncertainties were even more pronounced regarding the verbal autopsy. Researchers and field staff described the verbal autopsy either as a component of the HDSS or a nested study. The empirical evidence from the formative research and early stages of the in-depth case study suggested that the verbal autopsy is the most ethically challenging HDSS activity. In Chapters 5 and 6, I will discuss the key features and ethical issues for verbal autopsy in the Kilifi and Nairobi HDSS.
5  CHAPTER 5  Conducting Verbal Autopsies in the Case Study Sites: An Overview of Methodological and Ethical Issues

In the last four chapters, I have highlighted that HDSS research stakeholders, including the INDEPTH Network and HDSS researchers, consider the verbal autopsy an essential component of an HDSS. I showed that most INDEPTH Network HDSS sites conduct verbal autopsy and that there is little documentation of ethical issues in verbal autopsy. In Chapter 4, I highlighted that the verbal autopsy emerged as key area of ethical sensitivities in HDSS across sub-Saharan Africa.

The second objective of this study was to explore, in depth, ethical issues for verbal autopsy in a rural and an urban HDSS site in Kenya, from the perspectives of research and community stakeholders. To meet this objective, I conducted an in-depth case study of the Kilifi and Nairobi HDSS (case study sites), as described in Chapter 3. In this chapter, I will first describe study findings on the historical background and current structure of the verbal autopsy in the case study sites, including the rationale for its establishment, current verbal autopsy methods and characteristics of verbal autopsy interviewers. Next, I will describe findings on the policies, practices and perspectives on ethically relevant processes for verbal autopsy, including ethics oversight, consenting, community engagement and data sharing in the case study sites.

5.1  The History and Background to the Verbal Autopsy

The KHDSS introduced verbal autopsy as an activity in 2008 - seven years after conducting the baseline census. As I showed in Chapter 4, the KWTRP (host research centre for KHDSS) had been conducting research and surveillance through forms of census activity in Kilifi since 1989, and before establishing the KHDSS in 2001. The NUHDSS began conducting verbal autopsy during their baseline census in 2002, although this initial formal exercise was also preceded by a cross-sectional study of slums in Nairobi in 1998.

The KHDSS and NUHDSS researchers chose the WHO verbal autopsy tool because they felt it was the most appropriate tool available for determining the causes of death in an HDSS where most deaths are not officially registered and where the aim is
to generate data for research rather than certification. These two comments from HDSS managers further illustrate why and how the case study sites introduced the verbal autopsy:

"...initially, the verbal autopsy was not a key thing here. Later, we realised that over 60% of people were dying at home without records of what killed them. When you are doing health research knowing what kills people is key. So we started looking around for a tool that could enable us to have an idea of what people were dying from...we found the WHO VA tool and began preparations to implement it in the KHDSS". IDI3-Kilifi-HDSS Manager

“...because when you are doing the DSS...you find yourself... following up on mortalities. So if you are following up on mortalities, you can only do this say through the verbal autopsy studies.” IDI9-Nairobi-HDSS Manager

Verbal autopsy tools and methods have undergone various changes over the last 12 years. Some critical changes to verbal autopsy, as I showed in Chapter 2, have included the shift from paper-based questionnaires to electronic data collection and the development of software such as inter-VA to analyse verbal autopsy data (Byass et al., 2019; Fottrell & Byass, 2010). In line with these changes, the case study sites have conducted verbal autopsy using different verbal autopsy tools and methods.

Overall, the case studies initially collected verbal autopsy data using paper-based questionnaires; medical doctors, employed by the case study sites, then analysed the data. Over time, the case study sites adopted electronic data collection and automated verbal autopsy data analysis. However, at the time of this study, neither of the case study sites used the most recent verbal autopsy tools - the 2016 WHO VA questionnaire and InterVA-5. These recent tools can provide a probable cause of death immediately after a verbal autopsy interview (Byass et al., 2019; Morrison et al., 2018). Informal discussions with case study site managers highlighted that adopting a new verbal autopsy tool can be challenging because it usually requires retraining staff and re-structuring data management systems. Also, the additional value of adopting a new verbal autopsy tool might not be compelling from the perspectives of HDSS managers.
5.2 Verbal autopsy interviewers

Most of the verbal autopsy interviewers involved in this study were experienced field workers, who had worked as census interviewers before joining the verbal autopsy team. Table 13 shows their years of experience as verbal autopsy interviewers with total number of years as HDSS field worker in brackets.

Table 13 Characteristics of verbal autopsy interviewers in the case study sites

<table>
<thead>
<tr>
<th>Kilifi HDSS</th>
<th>Sex</th>
<th>Years of experience as VA interviewer (as field workers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interviewer 1</td>
<td>Male</td>
<td>7 (10)</td>
</tr>
<tr>
<td>Interviewer 2</td>
<td>Male</td>
<td>7</td>
</tr>
<tr>
<td>Interviewer 3</td>
<td>Male</td>
<td>7</td>
</tr>
<tr>
<td>Interviewer 4</td>
<td>Male</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Interviewer 5</td>
<td>Male</td>
<td>9 (24)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nairobi HDSS</th>
<th>Sex</th>
<th>Years of experience as VA interviewer (as field workers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interviewer 1</td>
<td>Female</td>
<td>5 (13)</td>
</tr>
<tr>
<td>Interviewer 2</td>
<td>Female</td>
<td>8 (12)</td>
</tr>
<tr>
<td>Interviewer 3</td>
<td>Male</td>
<td>12 (15)</td>
</tr>
<tr>
<td>Interviewer 4</td>
<td>Male</td>
<td>2 (5)</td>
</tr>
</tbody>
</table>

5.2.1 Kilifi Verbal Autopsy Interviewers: Their Background, Training and Roles

The verbal autopsy interviewers in the Kilifi HDSS are experienced fieldworkers (See Table 13). Before joining the verbal autopsy team, the interviewers had worked as KHDSS census field workers or in other KWTRP projects, as this statement by a VA interviewer illustrates:

“I started working at KEMRI in 2007 in a study on genetics. After that, I joined the KHDSS census. I worked with the KHDSS census for around a year and then three of us from the census joined the verbal autopsy in 2011.” IDI18-Kilifi-HDSS-VA Interviewer

At the time of my data collection, the KHDSS did not have any female verbal autopsy interviewers. I learned that the KHDSS has only had male verbal autopsy interviewers from 2011. One HDSS manager explained that female field workers find it challenging

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5 Column shows the number of years that each participant had worked specifically as a verbal autopsy interviewer, with total number of years they had worked as field workers shown in brackets.
to ride motorbikes, the main transport means for verbal autopsy interviewers, hence the lack of female verbal autopsy interviewers.

In addition, all the KHDSS verbal autopsy interviewers come from the Kilifi community and speak the two main local languages - Kigiriana and Kiswahili. This is because the KWTRP mainly recruits verbal autopsy interviewers, and other field workers, from the local community. This decision to recruit field workers locally is based on the expectation that local staff will be more familiar with local languages and culture, which will facilitate their field work.

The interviewers receive generic and specific training to support them in their duties, which involve collecting routine HDSS and verbal autopsy data. The training focuses on developing field workers’ communication skills and ability to fill out KHDSS questionnaires. While all KHDSS field workers receive refresher trainings every three months, specific training for verbal autopsy interviewers, such as on counselling, has been infrequent. At the time of my data collection, one verbal autopsy interviewer had undergone a one-week training on verbal autopsy and held a diploma in psychology. The other interviewers had only received brief, 1-3 days, occasional training on collecting verbal autopsy data. Overall, the interviewers felt that the training they receive is inadequate to help them address the challenges they face while collecting verbal autopsy data.

“Our supervisor is one of the pioneers of this group (VA interviewers) and had undergone some training on counselling but the rest of us have not.” IDI18-KHDSS VA Interviewer

5.2.2 Nairobi Verbal Autopsy Interviewers: Their Background, Training and Roles

The NUHDSS verbal autopsy interviewers, like those in the KHDSS, are experienced field workers (See Table 13). The interviewers had been given increasing responsibilities over time; they joined NUHDSS as census field workers or data clerks and later became verbal autopsy interviewers in charge of collecting cause of death data and supervising other field workers as this statement illustrates:

“I’ve been with the DSS since its inception in August 2002. I started as a field interviewer. In 2005 I became team leader [VA Interviewer]...I was in charge of
Unlike the KHDSS, where all the VA interviewers are male, the NUHDSS has two female and two male verbal autopsy interviewers. The NUHDSS is smaller than the KHDSS in terms of population size and surface area; field workers do not need to use motorbikes or vehicles to visit households to collect data, which might explain the differences between the two sites in terms of the gender of verbal autopsy interviewers.

In the same way as the KWTRP, the APHRC employs field workers from the HDSS community. Researchers in particular viewed recruitment of local staff as a strategy for creating employment, building good relations and enabling effective data collection. The verbal autopsy interviewers mentioned that they have lived and worked in the NUHDSS area for many years and that they were familiar with the NUHDSS community. This familiarity with the local community could enable verbal autopsy interviewers, and other field workers, to collect data. It might also influence the perceptions of other HDSS research staff on the ability of verbal autopsy interviewers to cope with burdens, as this comment from a HDSS manager indicated:

“Our field staffs are born and raised in the community...they know the community, they know the conditions well, they help us there, they know how to relate or interact with the community members...when I go there (field site), it’s very traumatizing to me but to them (field staff) this is life, this is normal.”IDI10-NUHDSS Manager

Despite their experience in collecting data and familiarity with the local community, the majority of NUHDSS field workers felt inadequately prepared to meet their responsibilities and to deal with the challenges they encounter in their work. To start with, the verbal autopsy interviewers supervise small teams of routine census fieldworkers but receive little training on management skills. Secondly, the interviewers reported that collecting data can be emotionally distressing for them and the respondents but interviewers only receive brief and infrequent training on how to address psychological issues. Finally, the verbal autopsy interviewers have no training in health care that could enable them to advise respondents or diagnose
diseases or causes of death. These feelings, by interviewers, of inadequacy in the face of diverse responsibilities and challenges, is highlighted by this comment:

“...the VA personnel are leaders in the field...in most cases they are field interviewers who got promoted [to VA interviewers]... so sometimes they don’t have a higher education or professional training [than] the people they supervise”. IDI23-Nairobi-HDSS Manager

5.2.3 Perspectives on Verbal Autopsy Interviewers in the Case Studies

In this section, I will describe study participants’ views on aspects of verbal autopsy interviewers in both case studies. These views were mainly around the training and personal characteristics of verbal autopsy interviewers.

Researchers, HDSS managers and field staff in the two case study sites agreed that verbal autopsy interviewers should receive training that would enable them, for instance, to identify and comfort an emotionally distressed respondent,

“[I would propose] retraining of VA interviewers on counselling. So that you are equipped with the right skills to answer this person [respondent], walking him through bereavement and leaving that person better than you found them.”IDI22-Nairobi-Viwandani VA Interviewer

However, verbal autopsy interviewers in both case studies differed with researchers and HDSS managers on the appropriate types of training on counselling for interviewers. Overall, the seven researchers and HDSS managers who shared their views on training for interviewers felt that the training was adequate or appropriate in the context of verbal autopsy. For instance, one HDSS manager mentioned that interviewers had received 1-2 hours of training on how to interview the bereaved. In addition, some researchers felt that interviewers receive training on communication skills, which they could apply when interviewing the bereaved. In contrast, verbal autopsy interviewers in the two sites felt that this training was inadequate. For instance, one NUHDSS verbal autopsy interviewer reported that in the last ten years there had been two training sessions on how to interview the bereaved. While the interviewers in the two sites recommended that they should be trained on how to...
counsel the bereaved, researchers, especially in the KHDSS were hesitant to make this recommendation as illustrated by this comment:

“I think we have to be careful we don’t build people up to a level where they start to think that [counselling] is their job. The truth is, there is limited time for the homestead visit. It’s just unrealistic to expect someone to do a lot of good in terms of counselling. And I think that badly done counselling is probably more harmful than no counseling.” IDI13-KHDSS Researcher

Furthermore, two KHDSS researchers felt that communication skills training conducted by trainers at the KWTRP, and involving a customised curriculum informed by the bereavement literature and field experiences, would prepare verbal autopsy interviewers to handle some of the challenges of collecting cause of death data:

“...there is a kind of communication skills that is not supposed to be about counselling. It’s supposed to be about developing your own emotional intelligence...recognising when somebody is distressed and knowing how to respond to that in a normal way of interacting with people not trying to deal with that or help that person to deal with that problem.” IDI12-KHDSS Researcher

In contrast, verbal autopsy interviewers in the KHDSS seemed to prefer formal training in counselling, which they felt would enable them help emotionally distressed respondents.

“...not that in-house training, we have said that we want to be taken to a college...that’s what we are fighting for because that is the place we can build our skills for helping the person that we will be attending to at that time.” FGD2-P2-Verbal Autopsy Interviewer

While research staff and field workers mainly talked about training, community stakeholders mostly shared their views on the personal attributes of verbal autopsy interviewers. They felt that a verbal autopsy interviewer should be respectable, friendly and able to withstand the challenges of collecting data (such as handling hostile residents). From the perspective of community stakeholders, these attributes
would enable interviewers to collect data and deal with cultural sensitivities in the case study contexts,

“I don’t see any good in sending a small kid to conduct [such an] interview. You [should] choose mature people...They arrive there with their dignity, they greet you well and they are heard. There won’t be doubts and questions about them.” FGD5-Kilifi-Tezo KCR

“...you cannot send a person who does not have a good reputation in the community...He cannot be given that information...unless he has discipline and presents himself well.” FGD11-P6-Nairobi-Viwandani CAC Member

Finally, some felt that having an interviewer with similar characteristics to the respondent in terms of gender, religion or ethnicity can make it easier to collect data in particular circumstances. For instance, one community representative explained that it would be easier for a female verbal autopsy interviewer to interview a Muslim widow during the mourning period:

“It’s easier for a woman [interviewer] to be allowed to go inside. They [Muslim Widow] will talk to the interviewer even if she is a Christian. There are no mixed feelings about this as it will be a woman to woman conversation.” FGD5-Kilifi-Tezo KCR

5.3 Verbal autopsy methodological issues

5.3.1 Verbal autopsy procedures, respondents, timing and tools

In both case study sites, field workers identify deaths during the routine household census, as I described in Chapter 4. In addition, the Kilifi Integrated Data Management System enables the KHDSS to identify deaths that occur at the Kilifi County Hospital. Although the case study sites do not have a formal community informant system, one NUHDSS manager reported that field staff occasionally identify deaths informally, for instance, through out-of-work conversations with community members.

Regardless of how research stakeholders identify deaths, the timing and duration of the verbal autopsy interviews is similar in the case study sites. The interview is usually conducted at least 21 days after a death in the KHDSS and after a month in the
NUHDSS. However, in the NUHDSS, the interview may be conducted earlier if the verbal autopsy team determines that the respondents might travel for burial, a feature of the multi-ethnic NUHDSS population that was not evident in Kilifi. For instance, I observed one interview that was conducted 4 days after a death because the NUHDSS field staff, after consulting the bereaved family, had determined that the family was planning to travel outside the NUHDSS for burial. Regarding the duration of the interview, interviewers in both sites informed respondents that the interview would take approximately 30 minutes. In practice, I observed that the cause of death significantly influenced the duration of the interview with interviews for deaths from injuries taking less time than those for deaths from chronic diseases.

From my observation, the characteristics of verbal autopsy respondents in both case study sites were similar. Unlike the HDSS census where any knowledgeable member of the household above 13 years could be a respondent, all the verbal autopsy respondents were adults. In addition, all the respondents I observed were close relatives of the deceased such as parents, spouses and siblings. This is unsurprising because a close relative is likely to be aware of the symptoms and circumstances that preceded a death, an important criterion for selecting verbal autopsy respondents. However, interviewers in the NUHDSS described that they occasionally interview respondents who are not related to the deceased, such as neighbours, especially in cases where the bereaved family out-migrate or when the deceased was living alone.

At the time of this study, the case study sites differed in terms of consenting for the verbal autopsy and issuance of condolence fees. In contrast to the NUHDSS interviewers, who obtained verbal consent, the KHDSS verbal autopsy interviewers obtained written consent from respondents. Later in this chapter, I will discuss consenting processes for verbal autopsy in depth. In addition to consenting, another key difference between the two case studies is that a condolence fee of KSH 500 was issued to bereaved families in the NUHDSS while no such fee was issued in the KHDSS. I will discuss the issuance of condolence fee in Chapter 6.

Currently, the interviewers collect data using electronic devices. Also, both sites analyse the verbal autopsy data using the inter-VA software. However, the NUHDSS uses two methods of ascertaining cause of death from verbal autopsy data –
automated analysis (inter-VA) and physician review. One participant pointed out that this enables comparison of the two methods. The sites share verbal autopsy data through the institutional data sharing structures of their host research centres, which I described in Chapter 4.

5.3.2 Perspectives on Timing of VA Interview in the Case Studies

In the preceding section, I described how the verbal autopsy is conducted in the case study sites in terms of field procedures, type of respondents and tools, and timing of interview. In this section, I will describe study participant’s views on the timing of the verbal autopsy interview in the KHDSS and NUHDSS. The majority of these views are from community members and community representatives, but also researchers and field workers.

Study participants felt that the verbal autopsy interview should be conducted soon after death, including during the mourning period, or much later, such as after burial. They recommended diverse timings for the interview ranging from one day to three months after death. As I will show in this section, these recommendations were informed by concerns over data quality and need to minimise burdens and maximise benefits for verbal autopsy stakeholders, especially the bereaved family and verbal autopsy respondents. The table below shows timing of verbal autopsy interviews in the case study sites and is important in contextualising the views of participants on timing of verbal autopsy interview. For instance, these data shows that 10% of all verbal autopsy interviews in the NUHDSS were conducted within a week following a death, compared to 0% in the KHDSS, which reflects the different policies and practices in timing of interviews in these sites. Most verbal autopsy interviews in the two sites were conducted between three to six months after a death.
Table 14 Timing of verbal autopsy interviews in the case study sites

<table>
<thead>
<tr>
<th>Time between death and VA interview (days)</th>
<th>Kilifi HDSS</th>
<th>Nairobi HDSS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Interviews (n)</td>
<td>%</td>
</tr>
<tr>
<td>0-6</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>7-20</td>
<td>166</td>
<td>2%</td>
</tr>
<tr>
<td>21-30</td>
<td>243</td>
<td>3%</td>
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<tr>
<td>31-60</td>
<td>848</td>
<td>10%</td>
</tr>
<tr>
<td>61-90</td>
<td>914</td>
<td>11%</td>
</tr>
<tr>
<td>91-180</td>
<td>2637</td>
<td>32%</td>
</tr>
<tr>
<td>181-365</td>
<td>2044</td>
<td>25%</td>
</tr>
<tr>
<td>366-730</td>
<td>1118</td>
<td>14%</td>
</tr>
<tr>
<td>&gt;730</td>
<td>151</td>
<td>2%</td>
</tr>
</tbody>
</table>

5.3.2.1 Support for conducting VA soon after death

Community members and representatives recommended that the verbal autopsy interview should be conducted as soon as possible for three main reasons. First, they felt that conducting the verbal autopsy interview soon after death would allow collection of data since most respondents would be available, including those who usually out-migrate following a death, and because it would allow interviewers to collect high quality data since most respondents will not have forgotten important details about the death, as this comment by a community member in the NUHDSS illustrates:

“*I also say that they should come during the time that I am mourning because that is the time you can tell the person everything because you would not have forgotten...*”FGD8-P6-Nairobi-Viwandani Community Member

Second, the community stakeholders expected that if the verbal autopsy interviewers visited soon after death, the interviewers would make a financial contribution or offer other forms of assistance that would benefit the bereaved family. This expectation is based on the fact that in the case study sites, community members assist the bereaved through financial contributions towards funeral preparations, free services and by providing food for mourners.

“*...if you go after the burial and you contribute, your money won’t help at the time. You should have gone earlier. And the bereaved will ask why you didn’t...*”
come at the time when the person passed away. So, it’s advised you go earlier.” FGD5-Kilifi-Tezo KCR

Third, some community stakeholders felt that if the verbal autopsy was conducted after a burial or a long time after death, it could also make the respondents emotionally distressed. For this reason, they recommended that the interview should be conducted at the earliest opportunity as this comment by a community member in the NUHDSS illustrates:

“I am also suggesting it should be a short time, because if you delay, by the time you come you will be reminding me of what I went through.” FGD8-P3-Nairobi-Viwandani Community Member

Finally, the majority of community members and representatives felt that conducting the verbal autopsy earlier would enable researchers to identify the causes of death and inform quick responses, which could benefit the bereaved family or the public health in general. For instance, identifying a disease outbreak early could prevent further morbidity and mortality in a family, community or region.

“That [21 days] is a long period because maybe that person died due to diarrhoea, and maybe that area has an outbreak. Then they take such a [long] period of time...many will die. So in my opinion...right immediately after the burial the [verbal autopsy] should be done in order to save the rest.” FGD7-Kilifi-Tezo Community Member

Community stakeholders’ who recommended that the verbal autopsy should be conducted soon after death, appeared to have high expectations of the verbal autopsy. HDSS research stakeholders in the case study sites do not share cause of death findings for individuals and it might take long to determine cause of death using verbal autopsy, which can make verbal autopsy unreliable in responding to outbreaks. Furthermore, interviewers especially in the KHDSS do not issue condolence fees or give cash to the bereaved family. However, bereaved families in the NUHDSS can benefit if the verbal autopsy is conducted early because interviewers issue a condolence fee. Although the community stakeholders recognised some of the potential challenges of visiting a bereaved family soon after death, they felt that
such a visit could benefit the bereaved family and others. In practice, these benefits are difficult to achieve.

5.3.2.2 Support for a longer waiting period

Other community stakeholders, and research stakeholders in both case study sites, either supported the current timing of verbal autopsy interviews or recommended a longer waiting period. They felt that conducting the interview after the mourning period, and usually after burial, improves quality of verbal autopsy data, demonstrates respect to local mourning norms and reduces burdens for respondents and interviewers.

From the perspective of the study participants, conducting the verbal autopsy too soon after death could risk the quality of data. For instance, the respondents might not be in the right emotional state to answer questions accurately. Also, the respondents or bereaved family could refuse to participate if they are approached for an interview before they have conducted burial. Therefore, the participants felt that conducting the interview too soon after death could lead to collection of inaccurate or incomplete data:

“After the burial they give them like three weeks...Do not go before or even the day of the burial, you may be talking to the person but he’s still in tears...so you won’t get the information.”

FGD8-P8-Nairobi-Viwandani Community Member

In addition, the participants agreed that conducting the interview after the mourning period is likely to be less sensitive for respondents and interviewers. To start with, if the interview is conducted soon after death, the respondent might be emotionally distressed and the interview could exacerbate this distress. Second, other community members are likely to be at the household during the mourning period, which could make the respondent and interviewer concerned about privacy and confidentiality. Third, the bereaved might be offended that the interviewer is visiting too soon after a death; they might view this as a lack of respect. This perception by the bereaved could increase emotional distress or risk the safety of interviewers. In Chapter 6, I will discuss the burdens of verbal autopsy interviewers and respondents. Here, I highlight that some study participants felt that conducting a verbal autopsy interview too soon
after a death could influence these burdens. For these reasons, they felt that interviewers should visit the bereaved household to collect data after the mourning period and usually after burial.

In practice, KHDSS and NUHDSS field workers usually collect verbal autopsy data after a burial has taken place. This practice is informed by some of the issues that study participants raised, that is, the need to minimise burdens and protect data quality. Furthermore, I reported that NUHDSS field workers occasionally conduct verbal autopsy before burial, mainly to ensure completeness and accuracy of data and after careful consideration of contextual issues. Therefore, one can argue that the timing of the verbal autopsy interview in the case studies is reasonable. However, study participants suggested that the sites could be more flexible when timing the interviews. For instance, in the KHDSS, where verbal autopsy is conducted after at least three weeks following a death, the visit might come too soon in some instances, as this comment by a verbal autopsy interviewer indicated:

“...but surprisingly when you go there [after 21 days], you find that he has [not been buried]. In such a situation you start thinking what can be done or learned through the community so as to give them [bereaved] ample time? Also it should not be a long period of time such that they become forgetful.” FGD2-P2-KHDSS VA Interviewer

On the other hand, the bereaved family could out-migrate. To address this challenge, one participant suggested that the KHDSS interviewers could conduct particular verbal autopsies even before the 21 days are over, like in the NUHDSS:

“...you must have records of the different residents...In my opinion, the 21 days are okay to the residents who will be going nowhere. In a town like Chodari, I believe that you’ll find almost all the residents [after 21 days]. You might reduce the period for those who make some contributions then take the body for burial elsewhere and migrate. So there might be differences in the durations...” FGD6-Kilifi-Junju Community Members

Another important recommendation was that the verbal autopsy should include staged visits involving an initial visit to specifically offer condolences and a second
one to collect data. This recommendation was related to a commonly reported view by community stakeholders in both case studies that verbal autopsy research stakeholders should demonstrate solidarity with the HDSS residents by visiting the ill, taking part in funeral preparations or by attending burials. Community stakeholders felt that this would enable research stakeholders, especially field staff, to know the appropriate time to visit for an interview, and that it would show that they were not only interested in collecting data, which could make the bereaved more willing to participate in a verbal autopsy interview, as this community representative explained:

“...the first thing is to go and give condolences to that family before you even start to ask the questions about the death. Next time when you come to ask questions, at least they are familiar with you and they know that this person stood with us when we had a funeral. So it’s not going there to give your condolences at the same time you want to start asking questions.”FGD11-P4-Nairobi-Korogocho CAC Member

5.4 Ethics Oversight for Verbal Autopsy

5.4.1 Introduction

As I discussed in Chapters 2 and 4, there is empirical and normative uncertainty around ethics oversight for verbal autopsy in HDSS. This uncertainty is partly driven by a lack of clarity regarding the methodological definition of verbal autopsy; is verbal autopsy a research activity or not? The same question is posed for the overall HDSS but the verbal autopsy adds an extra layer of uncertainty. In fact, one participant suggested that the KHDSS should be considered a research project because it includes verbal autopsy:

“...we have this component of the verbal autopsy, which rightly sits in the DSS...so if you look at the component of the verbal autopsy then you may say it is research, but if you leave out the component of the verbal autopsy, the way I see it, the DSS here is kind of a platform.”IDI05-KHDSS Manager

Although the verbal autopsy is conducted within an HDSS, it involves specialised methods and field staff, as I have described in this chapter. In the case study sites, HDSS managers mentioned that the verbal autopsy has a separate protocol.
Researchers, HDSS managers and field staff in the case studies had diverse views on how to define verbal autopsy in an HDSS:

“I think the VA, for me, it’s more of a health project…” IDI23 - NUHDSS Supervisor

“For us I think it (VA) is research.” IDI20 - Nairobi-Korogocho VA Interviewer

“I think it (VA) is part and parcel of the surveillance activity, I think it is just one component of the DSS which adds an extra dimension and value beyond just counting the facts of deaths and births.” IDI15 - KHDSS Manager

5.4.2 Perspectives on ethics oversight for verbal autopsy in case studies

Regardless of whether they viewed it as a public health programme, research project or HDSS activity, the research staff, HDSS managers and field workers widely agreed that the verbal autopsy should undergo ethics review. This is in contrast to their views on the routine HDSS census, where despite the same methodological uncertainty, research stakeholders did not strongly support ethics review. Research stakeholders felt that the verbal autopsy should undergo ethics review for three key, inter-related reasons; the verbal autopsy is conducted in a research context, it is a particularly sensitive activity and ethics review would help research stakeholders to identify and address potential ethical issues for the verbal autopsy. I explore these views in the following paragraphs.

Both the KWTRP and APHRC - host institutions for the KHDSS and NUHDSS - are research centres. These centres implement a wide range of research-related activities, as I highlighted in Chapter 4. National and institutional guidelines regulate the activities of these research centres. The fact that verbal autopsy is conducted in a research context informed participants’ recommendation that it should undergo ethics review,

“Regarding data collection within the centre (APHRC) one of the requirements is that you cannot roll out any study unless that study has been approved by the ethical committee. So for any research to be rolled into the field there has to be an ethical approval.” IDI19 - NUHDSS Manager

“…in general terms about what we do here at KEMRI, there was an issue about
different researchers and projects doing their own things. Some guidelines were given...I think it is good for us to be aware of the guidelines on what to do and when. Of course we can go off-course but there will be reasons as to why one thing is different from another.” FGD1-P1-Kilifi-Community Member

Another reason that participants described, in support for ethics review, is that the verbal autopsy is a particularly sensitive activity. This reflects the argument that categorising an activity as research or non-research does not justify why it should be subjected or exempted from ethics oversight, and that ethical considerations should be based on what the activity entails (Ondrusek et al., 2015; Rubel, 2012). Research and community stakeholders in both case study sites felt that the verbal autopsy is a sensitive activity for all stakeholders, but especially respondents and interviewers, because it involves holding difficult discussions about death.

Finally, research stakeholders felt that the review process would help verbal autopsy practitioners to identify and address potential ethical issues. These views, that the verbal autopsy should undergo ethics review because it is a sensitive research activity and because the review would be helpful, are best illustrated by this comment:

“I think it [VA] should [undergo ethics review], particularly now because our whole HDSS is under a scientific protocol...we review at the centre level and at the national level the tools...so, it would seem odd if we didn’t include the verbal autopsy in that because as we say it’s way more sensitive and so you need way more scrutiny about these processes of how you consent, who is doing it and how their capacity will be built to do this sensitively...how researchers are encouraged to think carefully about the benefit burdens balance. That’s exactly what the ethics review is thinking about.” IDI12-KHDSS Researcher

The majority of research stakeholders suggested that the verbal autopsy should be reviewed by the same committees that review research projects for KWTRP and APHRC; the respective institutional ethics committees and the national research ethics committee. However, one participant felt that the verbal autopsy should be reviewed by an ethics committee within a public health institution:
"I tend to think it [VA] is more of health project, a place like AMREF or even Kenyatta National Hospital would understand why we are doing VA." IDI23-NUHDSS Supervisor

This statement highlights a common perception among research stakeholders that the verbal autopsy in the case studies is not a conventional research project. Recognising this perspective, I explored research stakeholders’ views on alternative review and approval approaches. One alternative approach would be a standardisation body that would review and approve verbal autopsy projects. All the participants who commented on this approach felt that it would not be feasible in the context of the case study sites because the current review policies and practices prioritise stringent forms of ethics oversight, as this HDSS manager explained;

“It sounds like a good idea but I don’t think it would fly in Kenya. I think we have moved to a different place in the last 20 years where there’s a lot more regulation and documentation of all sorts of things but in specifically as we talk about research ethics it’s getting more and more scrutinised...times have changed and there’s a lot more self-determination in Kenya to try and make sure things are properly done and people are not taken advantage of.” IDI15-KHDSS Manager

5.5 Consent for verbal autopsy interviews

5.5.1 Current Consenting Processes for Verbal Autopsy in the Case Studies

At the time of this study, verbal autopsy interviewers in the NUHDSS were obtaining verbal consent from respondents while those in the KHDSS were obtaining written consent. In both cases, the interviewers would introduce themselves, explain that they were visiting to find out about the cause of death for the particular household member, ask whether the respondent had any questions, then seek permission to collect data. Although both sites have written documents to guide interviewers on the type of information they should give to respondents, I observed that the interviewers did not read any document during the consenting process. This is probably because the interviewers were experienced and familiar with the contents of the information sheets. Whenever an individual agreed to be interviewed in the KHDSS, they would sign two information and consent forms, keep one form and give
the other to the interviewer. I did not observe any of the respondents in the KHDSS reading the consent forms. The consenting process at the NUHDSS did not involve the issuance or signing of information and consent forms. After gaining the respondent’s consent, the interviewer would indicate this on the electronic questionnaire then proceed to collect data.

5.5.2 Perspectives on Consenting for Verbal Autopsy Interviews in the Case Studies

Research and community stakeholders’ recommendations on whether verbal autopsy interviewers should seek consent from respondents, and on the appropriate types of consenting, were largely influenced by their perception of verbal autopsy sensitivity and methodological design. For instance, the majority of study participants felt that interviewers should seek consent because the verbal autopsy is a research or research-related activity. However, one community member felt that participation in a verbal autopsy interview should be compulsory due to the potential public health benefit of cause of death data.

While research and community stakeholders in both case studies agreed, almost unanimously, that it was necessary to seek consent for a verbal autopsy interview, their views on whether this consent should be written or verbal varied widely. Those who supported written consent felt that it ensures transparency, provides proof of consent and demonstrates legitimacy of the activity and respect for the respondents. On the other hand, those who supported verbal consent felt that it involves less burdens for interviewers, respondents and institutions conducting verbal autopsies. Some of these views appeared to be related to general concerns about written consent and trust issues between HDSS residents and research centres, rather than the verbal autopsy in particular. However, the perceived sensitivity of verbal autopsy emerged as a key influence on views around the appropriate consenting process for verbal autopsy in the case studies. In the sections below, I will first present the views of participants who supported written consent and, next, those who supported verbal consent.

5.5.2.1 Reasons for supporting written consent

Study participants commonly supported written consent for verbal autopsy because they felt it proves that the interviewer collected data with the consent of the
respondent. From the perspective of study participants, this proof of consent could ensure transparency and protect interviewers, respondents and data quality. For instance, verbal autopsy interviewers would be able to show that they obtained consent therefore protecting themselves against potential accusations of collecting data irregularly. In addition, it would enable field supervisors to verify whether the respondents were interviewed with their consent therefore preventing coercion or deception of respondents, and fabrication of data as this participant indicated:

“If I go to do a spot check to verify that someone did a verbal autopsy, without written consent it is a bit difficult... with the electronic data collection you cannot verify for sure... if we have a requirement for signing, it will be easier for me to follow up to know that this interview was consented.” IDI23-NUHDSS Manager

Other participants pointed out that the verbal autopsy is a sensitive activity with serious implications for all stakeholders. They therefore felt that written consent, which involves leaving respondents with signed information and consent forms, would show respondents that the verbal autopsy was a legitimate activity and allow them to make an informed decision on participation as this study participant explained:

“I think for the verbal autopsy, there are two differences, one is that the time cost is much greater and there’s this emotional cost because you're taking somebody through a traumatic process when they're just trying to heal from it so there is a cost. You may wish to explain the cost and the benefit and allow someone to decide more formally...” IDI17-KHDSS Researcher

One of the criticism against written consent that participants in this study raised, is that written consent may lead to unnecessary refusals. These are refusals that are influenced by individual’s concerns over signing rather than the research procedures. However, study participants who supported written consent, suggested that unnecessary refusals can be prevented through creation of general community awareness about activities of the research centres and by building trust.
5.5.2.2 Reasons for supporting verbal consent

Other research and community stakeholders in the case studies supported verbal consent saying that the verbal autopsy is a particularly sensitive activity. They argued that verbal consent would minimise burdens for respondents and interviewers. To start with, the bereaved might be already distressed and requiring them to sign documents, especially in a context where signing is likely to raise concerns, can increase these burdens for respondents;

“...VA is not like any other interview. You have to tone down...when you are toned, you make him comfortable. A verbal consent makes the respondent more comfortable than when you have to issue a written document and maybe the person you want to interview is not that well-read.” IDI22-Nairobi-Viwandani-VA Interviewer

Second, collection of signatures is sometimes associated with issuance of cash or other goods. For instance, a programme officer or field worker may collect signatures to show the number of people who have been reimbursed. This perception of the purpose of a signature, coupled by the fact that a condolence fees are not issued in the KHDSS, and the socio-economic marginalisation of residents in both case studies, can make respondents suspicious of the verbal autopsy interviewers and damaging of relations;

“...but the one you tell to them to sign for you, they’ll end up thinking that you’ve gone there to look for cash.” FGD6-Kilifi-Junju Community Member

Finally, verbal autopsy interviewers in the KHDSS pointed out that written consent was not essential because they were able to collect data as long as the respondent gave verbal consent; meaning that, in practice, respondents had the option to sign or not;

“...somebody is ready to give you the information but they are not ready to sign the consent. I’ve done some interviews with somebody saying yeah I’m ready but I’m not signing. I’ve done such interviews.” IDI18-KHDSS VA Interviewer
Recognising the challenges of requesting written consent, some participants recommended alternative approaches that could be used without requiring verbal autopsy respondents to sign forms. These include training and supporting field workers to prevent malpractices, leaving all the information and consent forms with the respondents so that they are not concerned about how their signatures will be used and at the same time providing them with relevant information about verbal autopsy and enabling supervisors to verify whether interviewers collected data (by revisiting households and asking residents in they had taken part in an interview), and creating greater general community awareness about the verbal autopsy and research centres. These recommendations were similar to those given for consenting in the routine HDSS. However, given the perceived sensitivity of verbal autopsy, study participants strongly supported either written or verbal consenting, unlike the routine HDSS where verbal consent was widely seen as acceptable. Overall, views on whether consent for verbal autopsy should be written or verbal were based on underlying concerns around burdens for different types of stakeholders. I have described the alternative approaches to addressing these concerns from the perspective of study participants. Furthermore, most of these concerns could be addressed by prioritising the consenting process, which might involve community engagement as this participant suggested:

“I think our focus should always be on the quality of the consent as a process and the signing of forms is something that we’ve kind of got a bit trapped into by clinical trials practice which are quite driven by concerns of litigation, that if anything goes wrong we need to show that somebody signed and agreed to it that is the source of that kind of thinking and I don’t think it necessarily applies to this sort of situation.” IDI12-KHDSS Researcher

5.6 Community Engagement for Verbal Autopsy

As I showed in Chapter 4, the host research centres for the case study sites, run centre-wide and study-specific community engagement activities, as defined and described in Chapters 2 and 4. Because the HDSS sites cover a large area involving the majority of the target population for the research centres, HDSS and centre-wide activities are seen to be synonymous. Furthermore, research staff describe the verbal
autopsy as a component of the HDSS. Based on different sources of evidence used in this study, the community engagement activities for verbal autopsy and the routine HDSS census in the case studies were described at the same time. This is despite the verbal autopsy having important differences and sensitivities compared to the other components of the HDSS sites.

In this section, I will present study participants’ views on why and how researchers should engage other stakeholders in conducting verbal autopsy. In addition, I will discuss some of the challenges of community engagement for verbal autopsy.

5.6.1 Perspectives on Community Engagement for Verbal Autopsy in Case Studies

Study participants in the case study sites thought that community engagement can improve data quality, demonstrate respect to the bereaved and increase the utility of verbal autopsy data. First, community engagement, from the perspective of study participants, can facilitate the timely identification of deaths and collection of accurate data on cause of death. Verbal autopsy interviewers in the case studies mainly rely on HDSS census field workers to identify and report deaths. Given that the census field workers visit households after every three months or six months in the KHDSS and NUHDSS, respectively, it might take a long time to identify deaths and some deaths might not be reported at all. However, both case studies have networks of community representatives - KCRs and CACs - who live within the HDSS communities, regularly interact with the research centres and who visit households within the HDSS area to collect data for other community-based health programmes (for instance, as part of their responsibilities as community health volunteers). Therefore, some community stakeholders felt that community representatives could report deaths and share information about causes of death with research stakeholders, which could improve the completeness and accuracy of verbal autopsy data:

“...here on the ground there are people called CACs [Community Advisory Committee Members], before you go to that family you are supposed to seek their advice. For example if a person was sick in the community for a long time the CAC member will have information about this person.” FGD9-P7-Nairobi-Viwandani CAC Member
Sharing of information about the verbal autopsy and causes of death even at the community level, from the perspectives of some study participants, can increase community acceptability of verbal autopsy. For instance, respondents are likely to participate in the verbal autopsy and to give accurate information if they understand the aims and uses of the data, further improving the quality of verbal autopsy data:

“...it is important for them [community members] to know some of the diseases killing most people in Kilifi area and what can be done to stop them or improve healthcare...then they won’t hold back on some information if they understand that this is what the stakeholders rely on to bring about programmes that will help.” FGD2-P3-KHDSS VA Interviewer

Second, one can argue (from a research ethics perspective) that sharing information about verbal autopsy demonstrates respect for the bereaved and HDSS community. Disclosure, comprehension and voluntariness are considered to be the key features of informed consent and respect to autonomy (Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014). Community engagement, especially information sharing, can contribute to demonstrating respect:

“It is important for them (bereaved) to understand (VA) because they are the people affected by the death.” IDI22-Nairobi-Viwandani - VA Interviewer

Third, community engagement can increase the social value (Emanuel et al., 2004) of verbal autopsy data. For instance, engaging policy-makers including the Ministry of Health and other government agencies could enhance the translation of verbal autopsy evidence into policies. The verbal autopsy is the only source of comprehensive longitudinal mortality data within the case studies. The research centres, as I described in Chapters 2 and 4, established the HDSS and verbal autopsy due to the lack of reliable population-level data in these settings. However, the centres have a research mandate and would need to engage local and national policy-makers to increase the impact of verbal autopsy on public health as this participant suggested:

“What we really need is genuine engagement within the ministry on the value
of these kinds of information and that comes from within, it doesn’t come from outside so there is a lot of external pressure to do all these stuff but in the end it’s got to come from inside…” IDI17-KHDSS Researcher

In addition, some community stakeholders and field staff in both case studies recommended that results of verbal autopsy should be reported to individual respondents and bereaved families including through issuance of death certificates. I will discuss data sharing in the next section and death certificates in the chapter 6. Here, I wanted to note that some study participants felt that researchers should feedback verbal autopsy results to respondents as part of community engagement.

While sharing their views on why and how researchers should engage other stakeholders in conducting verbal autopsy, study participants highlighted potential challenges of community engagement for verbal autopsy in the context of the case studies. The most commonly reported challenge was that death is a particularly sensitive issue and talking about it can be really difficult or culturally inappropriate. For instance, unlike the routine HDSS which involves everyone within the target area, the verbal autopsy involves relatively few families and specific individuals within these families. Therefore, community-wide sensitisation about verbal autopsy could have unintended negative impacts because residents might not be prepared to talk about death.

Another challenge with community-wide sensitisation for verbal autopsy is the lack of resources. This sensitisation is likely to be resource intensive because it would cover the entire HDSS population and have no specified end-date. Furthermore, research stakeholders might not see the need for verbal autopsy specific sensitisation because verbal autopsy is seen as part of the HDSS. In fact, community engagement for the HDSS in general might not be given as much attention as other studies:

“…sincerely speaking, since nested studies came on board, I think the centre has a lot of priorities. So we don’t really get attention. It’s been more than ten years since we did dissemination for our DSS.” IDI23-NUHDSS Supervisor

Other than community-wide sensitisation and dissemination of results, several community stakeholders and field staff in both case studies suggested that verbal
autopsy results should be reported to individual respondents and bereaved families. However, most researchers and HDSS managers cautioned that the verbal autopsy method is relatively imprecise in determining the causes of death at the individual-level and reporting such results might not be helpful. As I will discuss in Chapter 6, most researchers, and some community members, agreed that reporting causes of death at the population-level would be more useful.

A potential use of population-level cause of death data would be to improve local public health and to inform public policy-making. However, the case studies operate in research-contexts and discussions with HDSS managers and researchers highlighted that there was limited engagement with local public health practitioners and policymakers regarding the use of verbal autopsy and other HDSS data.

Finally, most community stakeholders recommended that community members should be involved in collecting mortality data, to ensure the timely identification of deaths in the community. In response to this recommendation, some community members and field staff were concerned that community members might not be adequately trained and supported to report deaths or collect cause of death data. They therefore recommended that such an approach - collection of VA data by community members - should be accompanied by comprehensive training including on research ethics and financial support. One participant pointed out that many community-based organisations were already collecting data, including on morbidity and mortality, within the HDSS area and suggested that the NUHDSS should engage with such organisations;

“...all these organisations could be meeting and giving each other the information that they have, they can then combine so that they can know what it is going on.FGD8-P6-Nairobi-Viwandani Community Members

5.7 Verbal Autopsy Data Sharing: Policy, Practice and Perspectives

5.7.1 Introduction

The data sharing policies and practices of the KWTRP and APHRC, which I outlined in Chapter 4, inform the sharing of verbal autopsy data in the case study sites. The
policies categorise verbal autopsy as one of the sensitive types of data whose sharing might require careful ethical considerations as this participant indicated:

“...so HIV will be sensitive and verbal autopsy data will be sensitive so when they come to data governance committee, people will be looking at who is using the data and for what...” IDI12-KHDSS Researcher

Some of the issues around sharing of HDSS and research data in general also emerged when discussing the sharing of verbal autopsy data. However, the unique features of verbal autopsy data raise specific practical and ethical issues which I will highlight in this section. I will present study participants’ views on access to verbal autopsy data. In addition, I will describe some of the challenges of sharing verbal autopsy data. Most views about data sharing came from research stakeholders.

5.7.2 Who should have access to verbal autopsy data and why?

Research and community stakeholders in the case studies agreed that verbal autopsy data should be shared with a wide range of stakeholders. They felt that researchers should share the data in a timely manner and format that would increase the utility of the data and protection of verbal autopsy participants including respondents, bereaved family and HDSS community. From the perspective of HDSS research staff, managers and field workers, sharing verbal autopsy data could support research and inform local and international public health policies. Discussions with research staff and managers highlighted that sharing of verbal autopsy data can be challenging mainly because of lack of data management capacity and the potential to harm individuals, communities and institutions.

The stakeholders that study participants thought should have access to verbal autopsy data include field staff, researchers, community members, public health practitioners, government and non-government agencies at the local, national and international level. They felt that verbal autopsy data could enable these stakeholders conduct research, protect their health, enhance their careers and make policies to improve public health. This perception among research stakeholders, that verbal autopsy data should be shared widely, is well illustrated by these comments:

“I think everyone ought to have access. That is me the primary data collector,
the community participants and the researchers.” FGD10-P2-NUHDSS Census Field Worker

“I think all stakeholders should have access...first, the community, they need to know what verbal autopsy means, what it’s been used for. Second, the people collecting it [VA data] and collating it and aggregating it. Then of course the public health government type policy makers to plan and implement whatever they need... fourth layer is somebody like WHO, who rely on secondary input from the local government to put in publication and say Kenya has X number of non-communicable diseases. Then, people like the global burden of disease study.” IDI16-KHDSS Researcher

Research and community stakeholders recommended that verbal autopsy should be shared in an anonymised format in order to protect participant and HDSS managers reported that these data are anonymised. As I will highlight in this section and in Chapter 6, some study participants pointed out that it might be difficult to fully anonymise cause of death data and that anonymised data could still be used to stigmatise communities. Here, I note that anonymising data was the most commonly described approach protecting participants as this description by a community representative illustrates;

“It is like as we are here (focus group discussion), we have been numbered. Now we are being protected, they (VA respondents) can be protected like we are here, no one’s name is being mentioned...the name is anonymised somewhere.” FGD4-Kilifi-Township KCRs

Another key recommendation, aimed at protecting VA stakeholders’ interests, was that researchers should share the data with trustworthy individuals and institutions. The data sharing policies and practices in the case study sites require all those who request data to state the intended use of the data and institutional affiliations. These details are used to assess the legitimacy of the data request. In addition, I have shown that the case study sites share data within trusted networks such as the INDEPTH Network.
To increase the utility of verbal autopsy data, several study participants suggested that verbal autopsy data should be shared in a disaggregated format to support research in particular, and in a timely manner to inform public health action, as these participants described;

“INDEPTH stats just gives births, death, migrations which is rather crude, people who want to do specific studies would probably want to see the information broken down by small areas or whatever else…” IDI15-KHDSS Manager

“… [It’s a challenge] if this information is not shared in real time...because I think the reasons we want to elicit the symptoms is so that doctors can take action. Like today I have reported five deaths with similar symptoms…” IDI22-Nairobi-Viwandani VA Interviewer

5.7.3 Challenges of sharing verbal autopsy data

Although study participants recommended the wider sharing of verbal autopsy data, evidence from this study indicates that the verbal autopsy data are mostly accessed and used by researchers in the case studies and other global research stakeholders such as the WHO and the Global Burden of Disease Study. This inequality in terms of data access and use seems to be mainly driven by lack of resources and the particular sensitivities of verbal autopsy data.

On the one hand, HDSS managers indicated that the case study sites do not have adequate staff and other resources to make verbal autopsy data available to all those who might need it. As I have reported in this thesis, collecting and managing verbal autopsy data is resource-intensive. It requires highly experienced field workers, use of specialised analysis software and in some instances, employment of medical officers. Therefore, it might be challenging for case study sites to share data with stakeholders in a timely manner and appropriate format.

On the other hand, even when researchers make verbal autopsy data available, field staff, community members and government agencies might be unable to access and use it due to a lack of data analysis capacity and knowledge. For instance, some researchers and HDSS managers especially in Kilifi felt that the county government
would be unable to analyse and use verbal autopsy data, if such data were shared regularly, due to a lack of data management and analysis skills. In addition, verbal autopsy interviewers in both sites reported that they do not access or use verbal autopsy data, as illustrated by these interviewers from Nairobi and Kilifi;

“I know that when we collect data it goes to the researchers, from there I’m not very much sure…” IDI21-Nairobi-Viwandani - VA Interviewer

“To tell you the truth, our gathering of information about death ends with the report.” FGD2-P2-KHDSS VA Interviewer

Other than the lack of resources, findings from this study suggest that HDSS researchers’ uncertainties about their responsibilities or obligations to share data, could restrict the wider sharing of verbal autopsy data. For instance, as the participant below indicated, researchers might feel that they don’t need to regularly share their research findings with government especially when such sharing is not supported by a research protocol or budget;

“...if it’s in a research context, you are going to be asking particular research questions. For you to start submitting surveillance type data on a yearly basis, that requires additional man power to say 2in Kilifi over the last 5 years, these are the numbers of deaths that have occurred, and this is the probable cause of death”. That is not your mandate as a researcher... well that is not your direct mandate as a researcher. But again I think maybe we need to start thinking widely and start having policy-related input…” IDI16-KHDSS Researcher

Finally, cause of death data generated through verbal autopsy are sensitive and researchers might be hesitant to share it lest it is misinterpreted. Whenever such data are misinterpreted (for instance, due to lack of analysis skills) and shared with the public, the researchers in the case studies might be compelled to respond to ‘set the record straight’ and prevent reputational damage. Such responses are likely to further burden the data analysts and researchers working on verbal autopsy in the case studies. Given these concerns, the case study research stakeholders can be
especially careful and selective when sharing verbal autopsy data, which could restrict the wider sharing and use of the data.

5.8 Summary

In this chapter, I have described the key characteristics of verbal autopsy in the Kilifi and Nairobi HDSS, including the perspectives of research staff, field workers and community members on verbal autopsy methods, ethics oversight, consenting, community engagement and data sharing. The case study sites introduced verbal autopsy as a pragmatic approach for determining causes of death in the HDSS populations primarily for research. In both sites, highly experienced and relatively senior field workers, recruited locally, conduct the verbal autopsy interviews. At the time of this study interviewers at the NUHDSS obtained verbal consent from respondents, while those in the KHDSS obtained written consent. Based on institutional policies and practices, the NUHDSS interviewers issued a condolence fee to verbal autopsy respondents; while interviewers in the KHDSS issued no such fee.

Study participants expressed significant uncertainties and diversity of views on various ethics processes in verbal autopsy. Although HDSS researchers and managers have previously applied (or were applying) for ethics review of verbal autopsy, most were uncertain whether the current research ethics review system is appropriate for verbal autopsy, given its indistinct positioning. However, most study participants agreed that an oversight body should review the verbal autopsy because it is a sensitive activity. Unlike for routine HDSS census, where most participants felt verbal consent would be appropriate, both verbal and written consent for verbal autopsy received strong support from all groups of study participants. Community members recommended that the case study sites should engage community members in collecting verbal autopsy data to improve data quality. Although, study participants supported wider sharing of verbal autopsy data to increase its social value, only researchers in the case studies and other global health research stakeholders seem to access and use verbal autopsy data.

Despite the diversity of views on ethics processes in verbal autopsy, study participants’ recommendations appeared to share a common aspiration; to minimise burdens and maximise benefits for verbal autopsy stakeholders. For instance, some
participants felt that written consent would protect interviewers from unfair accusations of malpractice while others felt that verbal consent would put respondents at ease and avoid unnecessary emotional distress. Also, most participants supported wider sharing of verbal autopsy data because they felt that this would lead to public health benefits. There is little empirical evidence on whether these proposals, if implemented, would lead to desired outcomes. However, the empirical evidence described in this chapter highlighted the concerns around the benefits and burdens of verbal autopsy in the case study sites. In Chapter 6, I will discuss the perceived benefits and burdens of verbal autopsy in HDSS.
In this chapter, I will mainly discuss the benefits and burdens of verbal autopsy in the Kilifi and Nairobi HDSS. The findings in this chapter include empirical evidence from my field observations, review of documents and the views of research staff, HDSS managers and community members and representatives in the case study sites. These findings are organised around the benefits and burdens of verbal autopsy to two different groups in turn: verbal autopsy respondents (drawing on all interview groups, including community members and representatives), followed by verbal autopsy interviewers (drawing particularly on interviews with research stakeholders and interviewers themselves). I then draw on all data to discuss findings around the potential benefits and burdens for HDSS residents and institutions associated with implementation of the verbal autopsy.

I will show that emotional distress emerged as the most common and serious burden of verbal autopsy for respondents and interviewers, and that all study participants commonly described cause of death information as a potential benefit of verbal autopsy both at individual and community levels. To conclude the chapter, I will describe the views of HDSS research staff and managers from other sites across sub-Saharan Africa, to explore the wider relevance of findings from the case study sites. The findings in this chapter will provide important background information for discussion in Chapter 7, around the balance of benefits and burdens in HDSS.

6.1 Burdens and Benefits for Verbal Autopsy Respondents

In this section, I discuss the burdens and benefits that respondents may experience from participating in the verbal autopsy interview. Notably, the description of burdens for this group was a long and complex discussion, while the section on benefits is, in this chapter, relatively short.
6.1.1 Burdens for Verbal Autopsy Respondents

Perhaps unsurprisingly, emotional distress was the most common and serious burden of verbal autopsy for respondents, as described by all study participant groups across the two case studies. Other burdens described were an ‘invasion of privacy’ and the burden of time spent in interviews. All of these types of burdens were dependent to some degree on features of the bereavement and the context in which it occurred. Given their complexity, for clarity, I describe these influences in a separate section - 6.2.1.2.

6.1.1.1 Emotional Distress

6.1.1.1.1 Forms of emotional distress

As would be expected, participants widely recognised that the death of a relative or friend, and discussions about that death, are likely to be emotionally distressing:

“Death is not a good thing to talk about, it’s saddening”. *FGD7-Kilifi-Tezo-Community Member*

The verbal autopsy interview, which I described in Chapters 2 and 4, involves asking respondents to recount the circumstances around the death of a close relative or friend. Some participants described bereavement as a wound whose healing the verbal autopsy interview could interfere with, for instance, by reminding respondents of a death.

“...when you go there to talk about a deceased person, maybe that person [respondent] is like ‘we have gone through this, we have talked about it’ and you are reminding him or her”. *IDI22-Viwandani-Nairobi-VA Interviewer*

The types of negative emotions seen to be associated with talking about a recent death in this way were grief (as the most common reaction) but also guilt, frustration, anger, anxiety, sadness, shame and helplessness. Some of these emotions are discussed below, followed by a section exploring the way that verbal autopsy respondents might recognise and respond to these emotions.

The ‘additional grief’ placed on families by the verbal autopsy was seen as the major
emotional burden, where grief was described as the pain or sadness of bereavement and its memory:

“...the primary issue is that it’s just a really painful thing to go and talk, as a stranger, to somebody who has experienced losing somebody who is close to them...” IDI12-KHDSS Researcher

Several participants also mentioned that the verbal autopsy could introduce or exacerbate feelings of guilt associated with particular types of death, as will be discussed more in the later section on influences on burdens.

“...not everybody wants to revisit the problems that led to a death, maybe there is some self-blame, children died suddenly and they feel they didn’t do enough [to prevent it]”. IDI15-KHDSS-Researcher.

Other emotions that some participants mentioned as possibly emerging in the context of a verbal autopsy interview were annoyance, frustration or anger. In this case, these emotions were described as related to a perception of unfairness in terms of who would gain and who would have most to lose as part of the verbal autopsy process. Overall, study participants across both case study sites felt that burdens to verbal autopsy respondents were disproportionate to benefits. Later in this chapter I will talk about perceptions around fairness for the verbal autopsy, but here I note that perceived unfairness was seen to make respondents feel frustrated or annoyed as these participants highlighted:

“You can go to compile a report and she [respondent] is crying...then she asks “Why are you asking me so many questions, what are you going to give me and my loved one is gone?” They are just disturbing me.” FGD7-Tezo –Kilifi HDSS Resident

“...when you have lost a relative like I did, then someone comes here and starts to ask questions... in the process reminding you and you start feeling bad. So you are hurting me and you are not helping me with anything, you can tell the person “go away! You are disturbing me”. FGD8-P5-Viwandani-NUHDSS Resident
“…that person cannot come back to life, what is the need of asking and reminding them [respondents]? ...that annoys them (respondents) very much”. FGD11-P1-Korogocho CAC Member

In addition, some verbal autopsy respondents might be anxious that others will find out about the cause of death and that this will have negative repercussions for the bereaved family and the respondent depending on the circumstance of death. For instance, in cases of crime-related deaths, the respondents might be anxious that the information will be passed to the police, and they themselves will be implicated, including that someone later convicted of the crime based on information shared during the verbal autopsy interview, will blame the respondent or even seek revenge:

“…when I report at the Administration Police they come and arrest the person. When this person gets arrested...he would ask who has given information. If they reveal, it will be a risk to me...when this person comes out is a threat to you.” FGD9-P5-Nairobi-Viwandani-CAC Member

In practice, HDSS sites share data for research and public health use; the NUHDSS data sharing agreement states that those requesting data should not use it “for law enforcement purposes”. Therefore, it’s unlikely that HDSS sites would share verbal autopsy data with the police like the CAC member quoted above suggested. However, concerns about others learning about cause of death point to a potential lack of trust in those collecting the data including the systems in place to protect data and confidentiality of respondents.

6.1.1.1.2 Signs of Emotional Distress

When discussing the types of emotions that people were likely to experience as a result of being involved in a verbal autopsy interview, study participants also talked about how they would know the types of emotions that respondents were experiencing. From the perspectives and experiences of the study participants, crying was the most common sign of emotional distress and was common during verbal autopsy interviews:

“…I was doing a verbal autopsy for a child who had been poisoned at a party. Halfway through the interview, not even halfway, maybe a third of the
interview, the husband came, I was speaking to his wife and we continued the interview. He would give responses, but at some point he just broke down and started crying. I was like, ‘maybe he’s never cried’, but I never continued with the interview. He told me “Please don’t continue with this interview.” IDI20-NUHDSS VA Interviewer

Crying can be an obvious sign that the respondent is emotionally distressed and an indication to pause or stop the interview. In addition, crying could signal to others around the interview that the respondent is emotionally distressed. Verbal autopsy interviewers in both sites felt that crying could create tensions as people wonder what is distressing the respondent.

“...when you mention the death to someone they break down, they cry. It can continue like that until the information is lost because every time we go she would break down. They can also raise issues as in ‘you were talking and now...she’s crying’ and some don’t cry softly.” FGD2-P3-Kilifi VA Interviewer

However, from my field observations, and the experiences of verbal autopsy interviewers, not all respondents cry during the interview. In some of the verbal autopsy interviews I observed, the respondents occasionally smiled and laughed while responding to questions. This is perhaps a coping strategy for some individuals but it might also suggest challenges in relying on crying as the main sign of emotional distress. Other than individual personality traits, cultural norms and expectations could prevent respondents from crying. Take, for example, this participant’s suggestion that according to religious teachings, crying for the dead is inappropriate:

“Christians and Muslims are explained through the Bible or the Quran that crying especially is not okay. There is this verse that Jesus says that ‘you should cry for yourself, don’t cry because of the person who has died, cry for yourself’...also...everyone will go through that phase. There are people who don’t understand those rules.” FGD5-Kilifi – Tezo - KCRs

Another challenge with seeing crying as a good indicator of emotional distress is that respondents might experience and display such forms of distress once the
verbal autopsy interviewer has left:

“...it may be that it [the VA] wasn’t particularly traumatic at the time but months later, the mother says ‘you know I was doing all right and then this man came around and asked me about Beth and I nearly fell apart when he left’.” IDI17-KHDSS Researcher

6.1.1.1.3 Responding to Emotional Distress

Field staff in the case studies, including census and verbal autopsy interviewers, shared their experiences and views on reacting to the emotional distress of respondents, and how this might impact families and data collection. While most of the verbal autopsy interviewers felt that their responses were likely to support families who had been recently bereaved, two researchers pointed out that any benefits to the family would depend on the circumstances of death and the training of the interviewers. Later in this chapter, I will discuss the interviewers’ training and perceived ability to assist respondents. The type of help typically described as offered by verbal autopsy interviewers was through the act of listening:

“... you find that if I have been living alone, and this person has come, and I’ve let it out...shared it with somebody else, it helps this person heal.” FGD10-P2-NUHDSS Census fieldworker

While verbal autopsy interviewers were trained to stop collecting data when participants showed signs of distress, some noted that responding to emotional distress could help the respondent and often help the interviewer to collect data once the immediate distress was relieved, through strengthening the interpersonal relationship:

“You start talking to somebody who doesn’t want to open up but as you continue the interview, somebody starts opening up gradually until he gives whatever you needed...they get that relief by talking to somebody like me they did not know...maybe somebody was holding information and may not have had someone ask them these questions. I think it does help.” IDI18-Kilifi-VA Interviewer
At the same time, the types of emotional support offered ranged from friendly words of comfort to more concerted efforts to support a bereaved respondent, including through adapting styles of communication and, in some cases, drawing on a shared faith and knowledge of the local culture:

“...I will walk him (respondent) through that journey and reassure him that it is not happening to you alone. That God knows everything that is happening, that if he’s our refuge...you will overcome this. By the time you get out of that house you will leave this person in a different position than you found him...those people need somebody to talk to, because the community is everyone for himself, God for us all. They may not have somebody to talk to.”

IDI22-Nairobi-VA Interviewer

6.1.1.2 Invasion of Privacy and Time Costs

The verbal autopsy seems to pose risks to the privacy of respondents for a number of reasons. First, the key respondent - as described in Chapters 4&5 - is often interviewed in the presence of other household members. For instance, I observed two parents being interviewed about the death of their son, a respondent being interviewed in the presence of her son about the death of her husband and another respondent being interviewed about the death of her mother in the presence of her teenage daughters. The interviewer usually lets the key respondent decide who else can be present during the interview. For example, one of the respondents asked her son to be present during the interview because she felt he could help with responding to the questions. I also observed one respondent asking children to leave so that she could be interviewed alone. Secondly, the Nairobi HDSS area is densely populated, which makes it difficult to ensure privacy during interviews. Therefore, the verbal autopsy interviews are occasionally conducted in communal settings that could risk data confidentiality and lead to loss of privacy.

Third, privacy may be undermined in a less direct way where cause of death data is requested of people outside the family of the deceased, and reported in ways that the family would not have wished. For example, in the Nairobi HDSS, interviewers may collect cause of death data from individuals not closely related to the deceased when they fail to find a close relative of the deceased after five household visits or if
they determine that the bereaved household members have out-migrated the HDSS area. Verbal autopsy data may then be collected from a neighbour of the deceased, without the knowledge of the immediate family.

Finally, and in both case studies, verbal autopsy interviewers mentioned that they occasionally talk about the cases they encounter in the field as a strategy for coping with the emotional challenges of collecting cause of death data.

“...if you go to the field and you get an extreme case which you feel this was not one of those simple interviews...you just try to narrate it to some friends so that you can get it off.” ID18-KHDSS VA Interviewer

However, it can be difficult to anonymise respondents in such discussions between field staff and this could lead to invasion of privacy and breach of confidentiality as this participant explained:

“...we are a close-knit group. We have worked together for quite some time so people develop friendships over time. So previously people used to share experiences from the field and we really didn’t know how to anonymize the respondents. So you find that most cases were not very confidential. For example if there was an extreme case in the field that maybe somebody had died of unusual circumstances it would be discussed in the office.” ID23-NUHDSS Manager

Additionally, the time taken in a verbal autopsy interview can interfere with the respondent’s income generating activities or household chores. The interview, as described in Chapter 5, lasts 30 minutes on average but the actual duration is significantly influenced by the context of death and interview, for instance, interviews where the respondent cries may take longer. While observing verbal autopsy interviews in the case studies, I noticed that each of the respondents had to abandon a household chore or economic activity to participate in the interview. These activities included cleaning the house, washing clothes, farming and operating a water vending kiosk.
6.1.1.3 Influences on Burdens for Verbal Autopsy Respondents

Discussions with study participants and field observations highlighted that the burdens of verbal autopsy to respondents were to some extent context-specific. The most commonly described contextual influences, as I go on to describe in this section, are the cause of death, characteristics of the deceased, the relationship between the respondent and the deceased and the timing of the verbal autopsy. These influences are best illustrated by the following comment by a study participant in Kilifi:

“...for example, if this was a mother whose teenage child had committed suicide, I think this is really sensitive and that individual could take a long time to feel able to talk about that. If you are talking to an adult about how their grandparent who passed away quietly while asleep that will be relatively insensitive.” IDI12-KHDSS Researcher

6.1.1.3.1 Cause of Death

For a bereaved family, the cause of death of their loved one had an important influence on the way that the family was able to cope with the loss, emotionally and practically. In turn, the acceptance or non-acceptance of this loss directly influenced families’ ability to cope with a verbal autopsy interview, in the aftermath of the loss. The nature of fatalities in a given area could therefore be predicted to influence the acceptability and emotional and practical burdens associated with a verbal autopsy interview, as I will go on to explain in this section. Table 15 and 16 show the causes of death in the Kilifi and Nairobi HDSS sites and is important in contextualising the views and experiences of study participants on how ‘cause of death’ influences burdens.
Table 15 Causes of deaths in the Kilifi HDSS - 2011-2018

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Number of Deaths</th>
<th>Percentage of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-communicable Diseases</td>
<td>3742</td>
<td>36%</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>2653</td>
<td>25%</td>
</tr>
<tr>
<td>Communicable Diseases</td>
<td>2248</td>
<td>21%</td>
</tr>
<tr>
<td>HIV/AIDS related death</td>
<td>849</td>
<td>8%</td>
</tr>
<tr>
<td>Assault</td>
<td>299</td>
<td>3%</td>
</tr>
<tr>
<td>Other Injuries</td>
<td>211</td>
<td>2%</td>
</tr>
<tr>
<td>Road traffic accident</td>
<td>199</td>
<td>2%</td>
</tr>
<tr>
<td>Severe malnutrition</td>
<td>175</td>
<td>2%</td>
</tr>
<tr>
<td>Intentional self-harm</td>
<td>100</td>
<td>1%</td>
</tr>
<tr>
<td>Unspecified</td>
<td>6</td>
<td>0%</td>
</tr>
<tr>
<td>Total</td>
<td>10523</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 16 Causes of deaths in the Nairobi HDSS - 2002-2015

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Number of Deaths</th>
<th>Percentage of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injuries</td>
<td>961</td>
<td>18%</td>
</tr>
<tr>
<td>AIDS/HIV</td>
<td>726</td>
<td>14%</td>
</tr>
<tr>
<td>Non-Communicable Diseases</td>
<td>681</td>
<td>13%</td>
</tr>
<tr>
<td>Other Communicable Diseases</td>
<td>577</td>
<td>11%</td>
</tr>
<tr>
<td>Indeterminate 1</td>
<td>496</td>
<td>9%</td>
</tr>
<tr>
<td>Physician Cod Not Yet Assigned</td>
<td>474</td>
<td>9%</td>
</tr>
<tr>
<td>Respiratory Tract Infections</td>
<td>440</td>
<td>8%</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>399</td>
<td>7%</td>
</tr>
<tr>
<td>Other Non-Communicable Disease</td>
<td>348</td>
<td>6%</td>
</tr>
<tr>
<td>Neonatal Causes</td>
<td>205</td>
<td>4%</td>
</tr>
<tr>
<td>Malnutrition</td>
<td>69</td>
<td>1%</td>
</tr>
<tr>
<td>Total</td>
<td>5376</td>
<td>100%</td>
</tr>
</tbody>
</table>

In particular, it was commonly felt that deaths associated with violence and with suspected witchcraft would be particularly sensitive for families to deal within and report on in a verbal autopsy. In the Nairobi HDSS, where there were a significant number of deaths of young men associated with gunshot wounds through criminal activity or police (extrajudicial) shootings, these incidents were reported as particularly sensitive contexts for a verbal autopsy. These types of death also seem

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6 Unspecified maternal cause of death (3), unspecified external CoD (12), Unspecified neonatal CoD (32)
7 Physicians or InterVA algorithm could not determine cause of death after reviewing VA interview data
likely to be more common in urban settings with high levels of crime. No such deaths were talked about, for example, in the largely rural setting of the Kilifi HDSS. However, other types of traumatic deaths such as homicides and suicides were discussed in both sites, while deaths from suspected witchcraft were primarily discussed in the Kilifi HDSS site.

6.1.3.1.1 Deaths from shooting in Nairobi HDSS

Community members and field staff in the Nairobi HDSS recognised that deaths from shootings could result from criminal activities or accidents. However, the majority of participants described these deaths more specifically as criminals being shot dead by police;

“There are young people here and adults and other idlers here who go to steal... when they are found by police they are usually shot because they are armed thieves” FGD8-P7-Nairobi-Viwandani – CAC Member

Where a death resulted from police shooting, regardless of whether the deceased was a criminal, study participants felt that the death and verbal autopsy interview would be emotionally distressing to respondents. For instance, this participant explained that even if an individual was accidentally shot dead, the death would attract police investigations and extra burdens for the bereaved:

“...the police might be chasing a thief... then they fire and it hits a passer-by. This becomes a very big problem, it becomes a police case, and there will be investigations and demonstrations. So many different issues will arise” FGD11-P1-Nairobi – Korogocho CAC Member

Field staff and community members felt that a verbal autopsy interview, where the deceased had been shot dead, could introduce or increase feelings of annoyance, anger, frustration, guilt, shame, sadness, helplessness or anxiety.

Where death was related to a shooting, feelings of anger, annoyance or frustration in the family were often linked to a sense of injustice related to the cause of death itself, and compounded by a failure to understand what extra value a verbal autopsy interview could have in this circumstance:
“...you find that someone has been shot accidentally... like during the election time when the police were trying to disperse protestors... a baby was shot dead accidentally near Jogoo road... if you go to do an interview [verbal autopsy] with the parent they may fail to understand your research because they are angry that their innocent child is dead.” FGD8-P8-Nairobi-Viwandani CAC Member.

Since deaths from shootings were strongly associated with crime, family members might feel they could have prevented the death by supporting the deceased to change their behaviour, a sense of guilt that verbal autopsy interviewers might exacerbate through their questions:

“Maybe this boy was killed by police...so when the researcher asks “why was he killed, did you sit down and talk to him?” You know that means I did not sit down and talk with that child and that is why he was killed...” FGD12-P8-Nairobi –Korogocho-Community Member

In the above quote, it should be noted that it would be unusual for an interviewer to ask a question like ‘did you sit down and talk to him?’ because verbal autopsy questions are largely structured and involve limited probing. However, the open-ended section of the interview involves asking the respondent to explain how the death occurred. While the aim of this section is to establish the facts of the death, such as when the deceased was shot and by whom, some family members might see such questions as judgemental, and as shown in this quotation.

Deaths from shootings, and verbal autopsy interviews for such deaths, can make respondents feel ashamed and anxious, especially when the shootings were crime-related. Firstly, study participants felt that deaths from crime-related shootings can damage the reputation of the bereaved family. For this reason, some respondents might not want to discuss such deaths as this participant explained:

“...when you ask about someone who died, you will be told that the person is not dead. It’s because the family doesn’t want to be associated with the evil of stealing...” FGD10-P4-Nairobi – Viwandani Census Fieldworker

Secondly, the respondent might be anxious if they feel that the interviewer is a crime
investigator disguised as a researcher. As the participant in the comment below reported, some individuals go to great extents to hide deaths that were caused by crime-related shootings.

“You can think that someone is sent to find out what my child has died of and I do not want to reveal my child’s badness. Some parents like to hide the crimes of their children. If the child is killed, they will say the child fell sick and died. Some transfer the body from the city mortuary to another mortuary near their home so that people don’t go to view the body. They don’t want people to know the child was a thief.” FGD8-P5-Nairobi-Viwandani-CAC Member

Stigmatisation was described as one of the key reasons that respondents might be emotionally distressed while talking about deaths from shooting. Study participants reported that the bereaved might be stigmatised by society or even by other household members following a death by shooting. For instance, the police and chiefs can disrupt funeral committee meetings where they suspect that the deceased was a criminal. This participant explained why chiefs might not support the bereaved if the death was crime-related.

“As chiefs there are some meetings we don’t permit because they are a disturbance. Let’s say a person was a thief and you have given them a permit for fundraising, the people who will come to that meeting are his fellow thieves. That’s where they will be robbing and stabbing people and planning crime. So we don’t really encourage hard core thieves to gather and raise funds for a funeral unless there is someone else controlling the family.” FGD11-P3-Nairobi-Korogocho CAC Member

This stigmatisation can also come from other household members. Some household members are likely to be blamed for a death and abandoned during burial arrangements especially if the cause of death was crime-related shooting as this comment indicates:

“…there is this man whose son used to harass people very much... the son was shot dead. The man said that the son should not be taken back home for burial and should be discarded at Langata cemetery. He refused to go for the funeral.”
The mother (of the deceased) struggled.” FGD11-P3-Nairobi-Korogocho CAC Member

6.1.1.3.1.2 Other traumatic deaths

Besides deaths from shootings, study participants from the NUHDSS and KHDSS felt that traumatic deaths such as those associated with illegal activities, accidents and suicides, are sensitive. For instance, one community representative in the Nairobi HDSS reported that respondents would be hesitant to talk about deaths perceived to be illegal, such as deaths related to an abortion. This could be due to reasons similar to those that prevent respondents from discussing particular deaths from shootings, that is, fear of being arrested or stigmatisation.

“There is that pregnancy that terminates because of abortion or miscarriage... there are those who view that death as a crime...it’s a mistake that should not be broadcast.” FGD11-P3-Nairobi-Korogocho-CAC Member

Homicides were also mentioned as an example of illegal deaths that are sensitive. In addition to grief, the bereaved are likely to be experiencing feelings of anger and vengeance following a homicide which could influence the types of emotions experienced by respondents during a verbal autopsy interview.

“Some people are murdered here... suppose a person was stabbed to death, when people from Western and Nyanza areas of Kenya take the person upcountry for burial, I hear the person is buried at night, while holding a knife so that the spirits can take revenge against the killers”. FGD11-P6-Nairobi-Korogocho CAC Member

In both case studies, deaths from accidents were also described as having a significant influence on burdens for respondents. Participants in the NUHDSS discussed a wider range of deaths from accidents including accidental shootings, factory and road accidents. One would expect NUHDSS participants to mention these deaths since they are context-specific; for instance, accidental shootings are related to the reported high rates of crime in both NUHDSS field sites while factory accidents are linked to the large number of factories in the Viwandani site. In contrast, participants from the Kilifi HDSS mostly talked about deaths from road accidents.
Three community stakeholders and one researcher in the KHDSS and one community stakeholder in the NUHDSS, talked about deaths from suicide without prompting. The participants pointed out that deaths from suicides and verbal autopsy interviews for such deaths can be particularly distressing as one Nairobi community representative described:

“If the person was murdered, committed suicide or drowned, so those are the deaths that elicit emotions.” FGD9-P3-Nairobi-Viwandani CAC Member

Another study participant in the Kilifi HDSS shared her experience of taking part in a verbal autopsy interview when her mother-in-law committed suicide. In the same way that the community member in Korogocho thought that verbal autopsy interviewers would want to know why the deceased engaged in crime or was shot dead, this community representative in Kilifi felt that the interviewer wanted to find out why her mother-in-law committed suicide:

“They came, introduced themselves and started calling out the names until they reached my mother-in-law. We told them she died and they wanted to know from what disease. We told them she hung herself and they wanted to know why she had done that. We did not have the answer because she had not told anyone. They wanted to know if she had been ailing from anything. We told them she had diabetes and pressure and the condition was getting worse and that’s why we thought she hang herself.” FGD5-Kilifi-Tezo KCR

Unlike a social autopsy, which seeks to “understand the social barriers and errors behind a death”, a verbal autopsy, as I have so far discussed, aims to indirectly determine the medical causes of death. Therefore, a respondent in an interview where the deceased committed suicide would be asked an open ended question - “Could you tell me about the illness/events that led to her his/death?” followed by a series of structured questions requiring ‘Yes’ or ‘No’ responses; “was the injury self-inflicted?” and “do you think s/he committed suicide?” However, respondents might think that the purpose of the verbal autopsy is to find out the specific reasons for suicide which could induce feelings of guilt. In this instance, the participant might feel that she could have prevented the suicide by supporting her mother-in-law with health care. In addition, some respondents might worry that they will be accused of
causing a suicide, leading them to give inaccurate information or to be emotionally
distressed during the verbal autopsy interview as this comment suggests:

“When someone hangs themselves, those being interviewed about the death
might not be open even if they know the reasons for the suicide. They might be
afraid it will be known that they were not in good terms with the deceased or
the deceased was not in good terms with another person. So the fear is a
challenge” FGD4-Kilifi Township KCRs

Discussions with study participants showed that sudden unexpected deaths, such as
those from homicides, accidents and suicides, were perceived to be more distressing
than deaths that occurred after a long illness.

“When someone dies abruptly, probably in a car accident… interviewing their
son, father, wife or husband becomes a challenge…they start crying because
the memories of deceased are still fresh because they died suddenly” FGD4-P-
Kilifi Township – KCR

“Here in Korogocho, there are different causes of deaths… deaths from murder
are very sad because the person’s life has been cut short. When a person has
been sick for five, six months or one year you will know this person has
suffered but if someone is stabbed one evening and they die, that is very
painful.” FGD11-P6-Nairobi-Korogocho

6.1.3.1.3 Suspected Witchcraft

Study participants in both case studies, and especially community members in the
Kilifi HDSS, felt that deaths where witchcraft was suspected to be the cause were
likely to be emotionally distressing for the bereaved. To start with, the participants
reported that many HDSS residents believe that witchcraft can cause death as
illustrated by these statements:

“In this community, when a person dies, there are many people who say that
the person has been bewitched.” FGD11-P3-Nairobi-Korogocho CAC Member.

“Every tribe has its own cultures and traditions. For us Mijikenda, when
someone dies we usually say that the person has been bewitched... so many
These beliefs can make a verbal autopsy interview emotionally distressing for the respondents in three main ways. First, since the bereaved are likely to be already distressed by the death, asking them about the cause of death can bring back negative emotions as this participant explained:

“Many times in our community, we take deaths to have a reason behind them... we say this one has been bewitched. When the cause of death is asked, it is likely to stir up emotions... and maybe people had begun forgetting how they had been bewitched ...” FGD1-Kilifi-Community Member.

Second, the respondents could be suspicious of the interviewer’s intentions potentially making the respondents hostile or angry. This is more likely to happen if the respondent suspects that the deceased was bewitched and if they do not trust the interviewer as indicated by these statements by study participants in Nairobi and Kilifi:

“If you come after three weeks to ask questions, you are the witch now! It is very easy to be called a witch. Maybe the person was thinking that the neighbour bewitched their child... and you go there asking what disease caused the death... you will be seen like you have been sent by the witch to find out if the bereaved know who and what killed their child” FGD11-P3-Nairobi-Korogocho CAC Member.

“I think it has to do with the sensitivities of death within a community. There are certain communities that view death in such deep, deep, deep ways, “I mean why do you want to find out about my uncle who died?” it also come to “did you bewitch him, that’s why you are asking me?”. “ IDI16-KHDSS Researcher

Third, beliefs in witchcraft can make individuals delay seeking treatment for themselves and their relatives and if this is seen to lead to death respondents might be afraid or anxious about participating in a verbal autopsy interview. In the following excerpt, a community representative in Kilifi explains how one of his relatives delayed
seeking treatment due to beliefs in witchcraft and that this delay led to death:

“...my nephew was admitted as an emergency in the ward... then, his father and mother-in-law from Malindi came and said that they had found a very good doctor in Malindi who uses clean water as medicine for bewitchment. They thought he had been bewitched but I had been with him in hospital and knew which disease he had. They took my nephew from the ward and took him to Malindi. If he had stayed in the ward, he could have survived. But they held him back up to the last minute, when they finally took him to the hospital, he did not last more than two days...” FGD4-Kilifi-Township KCR

Furthermore, one of the verbal autopsy interviewers in Kilifi explained that the reasons that the verbal autopsy is conducted for all HDSS residents, including those who die in hospital, is because some individuals delay seeking treatment:

“...Somebody may fall sick today and people are not in a hurry to take them to hospital. When he is taken to hospital and the clinician asks how long the person has been sick, out of fear somebody may say “one week or two to three days”. So, the hospital information will miss the other two weeks that somebody was at home with no medication.” IDI18-VA Interviewer

These delays in seeking treatment could be caused by various factors including lack of funds to travel to hospitals or to pay for formal healthcare. However, discussions with community and research stakeholders especially in Kilifi highlighted that belief in witchcraft leads to delayed treatment seeking. While commenting on the risks of obtaining written consent from verbal autopsy respondents, one of the participants highlighted that respondents for a verbal autopsy interview where death could be associated with delayed treatment seeking are likely to be emotionally distressed during the interview.

“...it seems that by asking for a signature, we might now both make the person feel more anxious or worried about what you will be doing and that might actually impact the data they are prepared to share. For example, if that person thinks that there are legal connotations, they might start worrying about exactly what they say in terms of their treatment seeking behaviour.
Finally, respondents who believe that a death was caused by witchcraft might not see the need for detailed questions, which can make them feel annoyed or angry if the interviewer continues asking about the cause of death after the respondent states that someone bewitched the deceased. However, I observed respondents explaining the signs and symptoms that preceded a death even in circumstances where they felt that the death had been caused by witchcraft.

6.1.1.3.2 Characteristics of Deceased

Besides the cause of death, study participants felt that the characteristics of the deceased influences the types and levels of burdens to verbal autopsy respondents. These characteristics include the age, religion and social status of the deceased.

6.1.1.3.2.1 Age of the deceased

Several community and research stakeholders in both case studies reported that from the perspective of the community, deaths of infants or the very old would be less sensitive compared to deaths in other age groups. For instance, this participant referred to how the community reacts to deaths in different age groups to argue that deaths at both extremes of age are seen as less sensitive.

“If a one week or two weeks baby dies, the family doesn’t take that with so much concern. Most of the time you will find that the child has been buried without people knowing. But if it’s a mature person who died abruptly... people take it with so much weight. But for that one who had reached 90 years, 100 years, people will be celebrating that life.” FGD11-P7-Nairobi-Korogocho CAC Member

Although participants did not share their views on why the deaths of the very young (infants) would be seen as less sensitive, some participants – as described later in this section – pointed out that the sensitivity of a death would depend on the relationship between the deceased and respondent. Given that the very young would have had limited interactions with other members of their community and household, their deaths could be seen as less sensitive by other community members.
In contrast to other age groups, deaths among the very old were seen as potentially natural and acceptable ends to suffering as indicated by these comments:

“For an old person who is so old until it looks like they are playing with their feces, if they die, you say this one should go and rest. P9: But for a child you will feel pain.” FGD12-P10-Nairobi-Korogocho Community Members

“...there’s losing a youth like me through accident and there’s losing that old grandmother who has lived her life so well. So when you compare the sensitivity of the two you would say that... family losing a young person or a promising life hurts more than losing that old lady who has lived so gracefully.” FGD10-P7-NUHDSS Census Field Worker

“So many people can be really devastated by the death of the young baby than this woman. Because it is said that the child has not started his life then he dies.” FGD7-Kilifi-Tezo Community Member

However, community members in the Kilifi HDSS reported that elderly individuals might leave specific wishes on how they should be mourned and buried after death and that the bereaved often feel compelled to respect wishes of the dead. Failure to respect these wishes can distress the bereaved.

6.1.1.3.2.2 Influence from organised faith

As I highlighted earlier in this chapter, the religion of the deceased and bereaved can influence mourning and burial practices. These practices could in turn influence the burdens experienced by respondents during the verbal autopsy interview. In particular, participants suggested that Muslims are more accepting of death regardless of the cause but that they might be less willing to talk about the dead, as this religious leader explained:

“People don't really bother about the cause of death. We (Muslims) believe that the person’s time (to die) has come...so they are taken and buried.” FGD9-P8-Nairobi-Viwandani CAC Member

6.1.1.3.2.3 Loss of socioeconomic potential

According to research and community stakeholders across the two case studies, the
deaths of household heads, breadwinners and community leaders are likely to be particularly distressing. The following comment from a community representative in Kilifi illustrates a common view among study participants that respondents would be emotionally distressed during a verbal autopsy interview about the death of an important household member such as the household head or breadwinner:

“...maybe he was an important person at home and he has died suddenly...when you interview the son, father, wife or husband (of the deceased), answering you becomes difficult, they start crying because they still have fresh memories of the deceased, so they are thinking ‘who will take over?’” FGD4-Kilifi Township KCR.

6.1.3.2.4 Closeness of relationship

One community representative in Nairobi pointed out that the types and levels of emotional distress experienced by the respondent would depend on the relationship between the respondent and the deceased, such as parents and their children:

“...like the saying goes ‘the pain of a child - the person that knows it is the parent’, if it is my child who has died and you want to ask me questions about my child, the pain is still inside of me. If it is my mother who has died and you want to ask me questions about my mother am still in pain. So it depends with who you’re talking to about whose death.” FGD11-P5-Nairobi-Korogocho-CAC Member

Relatives, friends, colleagues and supporters of the deceased are likely to mourn the death regardless of other community members’ reaction to the death. These mixed reactions to a death could make the respondent anxious about the intentions of the interviewer and frustrated at the lack of support from other community members.

“If the person was troublesome and known to be a criminal and by good luck or bad like he dies, some people who had been bothered by him, maybe he stole from them, will feel relieved. But for his family, it does not make a difference if that person was a thief.” FGD8-P7-Nairobi-Viwandani Community Member
6.1.1.3.3 Timing of Verbal Autopsy and Duration of Interview

In Chapter 5, I described the timing of the verbal autopsy interview in the case studies noting that the interview lasts approximately 30 minutes and is conducted at least 21 days or a month after a death in the Kilifi and Nairobi HDSS sites respectively. In addition, I described study participants’ views on when the verbal autopsy interview should be conducted and how long it should last. Overall, participants’ recommendations on timing of the verbal autopsy were informed by concerns around emotional distress for respondents, data quality and the need to maximise benefits for the bereaved and HDSS communities. In this section, I will briefly highlight the ways in which the timing of the verbal autopsy could influence burdens for verbal autopsy respondents.

Based on local views in this study, the verbal autopsy interview can interfere with the respondent’s grief if it is conducted too soon after death and before the respondents have had time to come to terms with the death. As the following comments by participants in Kilifi and Nairobi indicate, a verbal autopsy interview that is conducted before the respondent is ready to discuss the death can induce negative emotions leading to termination of the interview:

“The challenge is that these 21 days are not enough. To give you an example, I went to talk to this woman who had lost her child. Midway through the interview, she said “that’s enough” the memory was still fresh in her mind.”
FGD2-P2-Kilifi-VA Interviewer

“They should not come too soon because one will be in grief.”
FGD8-P7-Nairobi-Viwandani-CAC Member

While commenting on the influence of interview timing on data quality, this participant suggested that failing to respect social norms could cause emotional distress. For instance, if the interviewer visits a household too soon after a death, the respondents might be grieving or angered by the visit such that they are unable to provide cause of death data.

“If you go in earlier, you get more accurate data, if you delay you get more inaccurate data but equally if you go in early and you offend some social
norms you won’t get any data at all.” IDI17-KHDSS Researcher

In addition, if the interviewer visits too soon after death, the respondent might be anxious during the interview and suspicious of the interviewer’s intention. These anxiety and suspicions could be related to concerns around bewitchment and lack of trust especially when the deaths are crime-related as described in earlier in this chapter.

6.1.2 Benefits of the Verbal Autopsy to respondents: Learning about the cause of death

When discussing the emotional distress for verbal autopsy respondents earlier in this chapter, I showed that field staff reported that they often offer emotional support to the bereaved by drawing on their communication skills, knowledge of local culture and a shared faith. Emotional support, such as comforting a crying respondent, was sometimes described as a benefit of verbal autopsy to respondents. Unlike emotional support, which seems to be largely aimed at addressing the emotional distress that is introduced or exacerbated by the verbal autopsy interview, information about cause of death was described as a potential benefit to respondents that emerges from the verbal autopsy including through sharing data with other stakeholders who could use the data to ultimately benefit respondents and the bereaved family.

In principle, learning about the cause of death of a friend or relative could help the bereaved achieve closure or alleviate suffering for particular individuals as this research stakeholder explained:

“I know from experience of groups who have done minimally invasive tissue sampling... that families sometimes might be put at rest by understanding what the cause of death is. I think that might also apply to the verbal autopsy if the family don’t know what caused the death...”IDI12-KHDSS Researcher

In addition, community stakeholders felt that cause of death information being fed back to families, at least for some causes of death, could help in preventing morbidity and mortality at the household and community level as illustrated by the comment below from a community representative.
“...after KEMRI have known that in a certain family, the mother had a certain sickness and it has manifested again in the child, maybe if they could follow up on that family, for example, this child for example, they have the sickness, they are not dead, maybe they could test their children as well to know who could be affected.” FGD3-Kilifi-Junju KCRs

In order for the cause of death information to benefit respondents as suggested in the comments above, it would need to be shared with the bereaved, or - for a more indirect benefit - with other stakeholders such as the Ministry of Health who could use the verbal autopsy data to control a disease outbreak in the community. However, as I showed in Chapter 5, verbal autopsy results are not shared with individual respondents or bereaved families. In Chapter 4, I also described the various technical, organisational and ethical challenges that prevent HDSS sites from regularly sharing data with other stakeholders. Currently, the case study sites mainly share aggregated verbal autopsy data only upon request, through research networks such as INDEPTH and through publications in international research journals.

Even if the cause of death for individuals was reported back to individuals and communities, most stakeholders felt it was unlikely to benefit respondents. This perception was informed by the fact that the verbal autopsy is designed as a pragmatic tool for determining causes of death at the population level, and because some respondents are usually aware of the cause of death before the verbal autopsy interview:

“I think one of the problems with verbal autopsy scheme is it is relatively imprecise for those causes of death, so it’s not that much of a comfort to the family and I’m sure a lot of family members will say “so what’s the answer?”, well I could have figured that out myself.”IDI17-Kilifi-HDSS Researcher

6.2 Burdens and Benefits for Verbal Autopsy Interviewers

In this section, I describe the burdens and benefits of verbal autopsy interviewers from the perspective of HDSS research stakeholders and verbal autopsy interviewers’ experiences of collecting data in the case study sites. The burdens of verbal autopsy to interviewers, as described by study participants, seem to outweigh the perceived
benefits and this imbalance is reflected in the amount of detail presented in each of the two areas in this section.

6.2.1 Emotional Distress

Not surprisingly, the types and levels of emotional distress that verbal autopsy respondents experienced were reflected in the emotional experiences of verbal autopsy interviewers. As discussed above, verbal autopsy respondents can experience a complex mix of emotions including sadness, guilt, grief, anxiety, frustration, annoyance and anger. Similarly, research staff and especially verbal autopsy interviewers reported that interviewers can feel guilty, helpless or anxious in with the interview situation and the emotions displayed by the respondents.

The most prominent emotion reported was verbal autopsy interviewers feeling guilty for making respondents emotionally distressed. Interviewers reported experiencing guilt more strongly if the respondent cried. In the following excerpt, an interviewer explains her reactions and feelings when a respondent started crying during an interview:

“...in fact I didn’t stop immediately, we stayed for a while. We talked and I don’t know whether I’m the one who was emotional but I couldn’t just leave. I just stayed, and then the wife was like “no no no, don’t get worried my daughter” -she is an older woman-, “he’ll come back, don’t worry that he’s crying”. Now she was like even consoling me...I felt guilty. The guilt that look what I’ve done to such an old man, he was in his fifties. Then I was like really what have I done to this man? Why did I have to do this interview?” IDI20-Nairobi-Korogocho VA Interviewer

This illustrates that interviewers could experience and display emotional distress to an extent that respondents and other household members feel the need to comfort the interviewers. Although the interviewers shared their experiences of offering emotional support to respondents, they also reported feeling helpless in the face of families and respondents facing emotional and socio-economic challenges. Most interviewers might feel powerless because of a lack of appropriate expertise and medical knowledge, financial resources, control over when and how to conduct
interviews and a lack of authority to make referrals. First, interviewers felt that they
did not have adequate counselling skills to support the bereaved and emotionally
distressed respondents as illustrated below:

“If there were trainings on counselling that would help, instead of someone
breaking down and you are left telling them sorry, sorry, sorry and it ends
there” FGD2-P3-Kilifi-VA Interviewer.

Second, the interviewers reported that even when they encounter families facing
severe economic challenges, they are often unable to help them. Finally, the
interviewers are unable to refer respondents and the bereaved for professional
assistance such as health and social care. This is mainly because of the lack of a
referral system in the current HDSS organisational structure; for example,
interviewers cannot give a formal referral to a health facility. In addition, interviewers
may not know where to refer respondents, even informally, and respondents might
not afford available services even after being referred. All these factors contribute to
making verbal autopsy interviewers feel helpless and powerless.

Besides feeling guilty, helpless and powerless, interviewers also mentioned being
unable to forget some particularly traumatic cases that they encounter during data
collection. These traumatic cases are likely to affect the interviewers’ mental health
wellbeing.

“You get different cases every day. Somebody narrates a story and you feel
really sorry for them. In a day, you may get two or three cases which you
cannot forget”. IDI18-KHDSS VA Interviewer

“I undergo some trauma, because when I find somebody still really wondering
if this (death) has truly happened, you see, we are also emotionally affected.”
IDI22-NUHDSS-Viwandani VA Interviewer

Other research stakeholders not directly involved in collecting verbal autopsy data
also acknowledged that the verbal autopsy can be emotionally distressing for
interviewers:

“Well I think there are strains on all parts, I think the fieldworkers, it is not a
particularly cheerful job for field workers who have to do it day in day out.”IDI15-Kilifi-HDSS Manager

The personal characteristics of the interviewer can influence their reactions to the circumstances of an interview including the emotional state of the respondent as this participant described.

“...maybe the person you are going to interview is used to crying and shouting and all that but you are not, maybe you mourn inside. Or vice versa, you may expect the person to be crying because the death is fresh. When you go there, it will affect you because you are not used to that.” FGD10-P1-NUHDSS Census Field Worker

6.2.2 Insecurity

Verbal autopsy interviewers risk their safety and security during data collection. The types and levels of risks faced by interviewers are closely linked to the key features of the verbal autopsy process and the socio-economic characteristics of the case study sites. As I have described so far, the verbal autopsy interview entails asking potentially sensitive questions, and may involve a particularly sensitive situation or type of death. The interviewers need to respect local cultural and mourning norms, and respondents often experience a complex mix of emotions including anger. This interview environment risks the security of the interviewer:

“If there is a burial or if there is a matanga (funeral), you don’t go there trying to ask questions about the death. It is sort of a simple deed of social sensitivity and respect...you don’t want to end up beaten up and left in a ditch...”IDI13-KHDSS Researcher

The respondents’ perceptions of the interviewer and the cause of death can also determine the levels of risk to the interviewer. For instance, in one of the focus groups in Nairobi, a community representative stated that the local chiefs do not support some funerals where the deceased had been shot. Another participant in the same group pointed out that it would be risky for a verbal autopsy interviewer to visit such a household:
“Also a funeral like that one, a researcher cannot go there to ask the cause of death, you may go there and they revenge on you.” FGD11-P3-Nairobi-Korogocho-CAC Member

Other than the nature of verbal autopsy interview questions and the cause of death, the socio-economic characteristics of the case study sites have an influence on risks for interviewers. For example, the NUHDSS field sites are characterised by relatively high rates of crime including armed robbery. All individuals who live and work in these areas, including field community members and field workers, are therefore at risk of being victims of crime. For verbal autopsy interviewers these risks are increased by having to make repeated household visits to interview a specific individual, and by carrying valuable equipment such as electronic devices:

“There are challenges we face generally as field interviewers. Sometimes finding respondents can be difficult. So we may be forced to go very late in the evening or very early in the morning and being that we work in informal settlements we have security challenges.” IDI23-NUHDSS Manager

6.2.3 Time and Financial Cost

As I have described so far, death in the case study sites is often accompanied by fundraising and most people who visit a bereaved household are expected to make a contribution towards funeral arrangements. The NUHDSS provides a condolence fee of KSH 500 for bereaved families but verbal autopsy interviewers in Nairobi reported that they also occasionally make a personal financial contribution either out of empathy, pressure to conform to bereavement practices or because of institutional delays in disbursing the condolence fees.

“It becomes very difficult for us sometimes, I may even go deeper in my pocket to give something beyond the five hundred. I may see that these people are really stranded so what more can I do as a person?” IDI21-Nairobi-Viwandani VA Interviewer

Although community members and field staff in the KHDSS also mentioned that visitors to a bereaved household are expected to make a contribution, none of the interviewers in Kilifi reported issuing condolence fees or other tokens to the bereaved
during verbal autopsy data collection.

Verbal autopsy interviewers may take a long time to identify the specific respondent they need to speak to and some interviews might last longer depending on cause of death and emotional state of the respondent. The time taken can interfere with the work schedule of the interviewer as suggested by these comments:

“...for the census, any adult at home can give information but for the verbal autopsy they mostly want the deceased’s caregiver. So, the field worker can be back two or three times to the same homestead looking for respondents”

FGD1-P2-Kilifi Community Member

“There are others who you start talking to them, they reach a point where they are crying and they (interviewers) are informed that let them just cry, after sometime you continue talking to them. But gain it can take some of your time and maybe you have targets of doing some of your work. FGD10-P3-NUHDSS

Census Field Worker

6.2.4 Information on Causes of Death as a Potential Benefit for VA Interviewers

Information about the causes of death was seen as a potential benefit to verbal autopsy interviewers because it could act as a form of health education about common medical conditions in the community, and therefore help them identify signs of serious illness and prevent deaths. Interviewers become aware of the diverse causes of death through repeated interactions with respondents. This awareness could increase interviewers’ perception of risk influencing them to make lifestyle changes or to seek treatment for themselves or their families. Therefore, while the interviewers could become emotionally distressed from collecting cause of death data, they could also gain some benefits as this interviewer explained:

“But to me as a person, other than that disadvantage, I have learnt so much, like neglecting small things can make someone lose their life. I did a VA of someone who had tonsillitis, they died of meningitis because of the tonsils, they burst, so the infection spread to the brain and they got meningitis. I have learned so much, even that I should not ignore a kid who has high temperature. I have learned so much…” IDI20-Nairobi-Korogocho - VA
Interviewer

While interviewers had described feeling unable to adequately assist respondents, for instance, because of limited counselling skills and funds, one participant suggested that the extent to which they can offer comfort to the bereaved can be a source of satisfaction for verbal autopsy interviewers:

“...speaking to people who have been doing it, there are some sort of benefits to all. I think the fieldworkers are not always dragged down by the misery of it. They can find some uplifting things to talk with people and find they have been in some way helpful to them.” IDI15-KHDSS Manager

6.3 Burdens and Benefits for of Verbal Autopsy for Public Health

As described in Chapters 1 & 2, verbal autopsy has the potential to provide long-term public health benefits but has limited direct benefits for individuals (Hill et al., 2007; Sankoh & Byass, 2012). The literature highlights potential burdens for verbal autopsy respondents and interviewers but rarely for other stakeholders (Aborigo et al., 2013; Bird et al., 2013; Morrison et al., 2018). The social burdens of research and public health can include community discrimination, isolation, exclusion from care or reputational damage (Baum et al., 2007; Kass, 2001; Klingler et al., 2017). In this section, I present study participants’ views on the potential benefits and burdens for HDSS residents and institutions associated with implementation of the verbal autopsy.

6.3.1 Information on Causes of Death as a Benefit for HDSS Residents and Institutions

From the perspective of study participants, especially community stakeholders in the case studies, verbal autopsy data on causes of death can be used to address a wide range of local public health problems which could benefit HDSS residents. These problems include disease outbreaks, genetic diseases, snake bites, road accidents, alcohol abuse and crime. Across both sites, community stakeholders commonly mentioned that cause of death information could be used to control infectious disease outbreaks in the HDSS areas such as tuberculosis, HIV/AIDS and other outbreaks with unspecified causes as illustrated by these comments:
“Yes, there are benefits. If it’s an infectious disease like TB, other people will be taken care of so that they don’t die early...” FGD7-Kilifi-Tezo-KCR

“The cause of death is likely to be an outbreak of certain illnesses, so that they know how they will deal with it.” FGD8-P2-Nairobi-Viwandani Community Member

Community stakeholders in Kilifi commonly mentioned that verbal autopsy data could be useful in identifying and addressing disease outbreaks or inherited diseases in their communities.

“...there are those chronic diseases, people call them inherited diseases...it will reach a point to ask ‘was there another person or other people, great-grandfathers who died because of this disease? That can help KEMRI know that these diseases are in this family. It will be easier for them [bereaved family] to go and get checked so that they can know they have that disease or not.” FGD5-Kilifi-Tezo-KCR

In contrast, community stakeholders in Nairobi commonly mentioned a wide range of potential public health benefits of verbal autopsy data including controlling alcohol abuse, reducing road accidents and crime and improving the life opportunities of young people in the NUHDSS field sites. In both sites, the public health benefits that community members mentioned were aspirational, that is, the participants made recommendations on how the research institutions could use cause of death information to benefit the local HDSS communities, as the following participant illustrates:

“I would also like this organization to find how they can help us get out of this disaster and they also help some of our children who are being killed by gunshots they help us so that the children can get out of this environment.” FGD12-P10-Nairobi Korogocho Community Member

Research stakeholders in Kilifi and Nairobi also reported that verbal autopsy data could benefit the local HDSS communities. However, unlike community stakeholders, research stakeholders also emphasized that verbal autopsy could benefit society and that these benefits were likely to be evident after a long time, as illustrated by this
comment:

“I guess in the long-term yes there might be benefit eventually when you come back up to say in this area most deaths are caused by snake bites. Then people would begin to be aware that ok the bite would lead to death, but I’m not sure if there is a direct benefit.” IDI16-KHDSS Researcher

In sharing their views on how information on causes of death could be useful, study participants also mentioned the types of stakeholders who were likely to use this information to benefit HDSS communities. These stakeholders include HDSS community members, public health practitioners and researchers. First, from the perspective of study participants, learning about the causes of death in their area can make community members change behaviour such as avoiding alcohol abuse and crime.

“…let’s say we investigate and know the cause of death is something that participants themselves can prevent…let’s say around December we have ‘crime-related’ deaths as people are looking for money for Christmas. Then we can really talk to our youngsters and make them have something that will give them money to make them stop stealing.” FGD10-P2-NUHDSS Census Field Worker

Second, public health practitioners and policy-makers could use cause of death information to develop context-specific public health programmes or to plan health services as this ministry of health official from the Kilifi county government described:

“Recently, the [National] Ministry of Health wanted to look at birth defects in some counties. We [Kilifi County] requested KHDSS data to look at morbidity and mortality trends by age group. We were able to see that we have an issue with birth defects and were selected as one of the participating counties. We were supported to refer children with birth defects to Kijabe hospital, so that was a positive for us in terms of resource and creating links.” IDI06-Kilifi-County Government Official

Finally, researchers could use verbal autopsy data together with other sources of data, and in collaboration with other community and research stakeholders, to
implement public health interventions as this Nairobi HDSS manager explained:

“...The DSS provides a platform to do more research and try to understand why ABCD is happening. So from the DSS it was clear that so many expectant women were dying, as well as children. So the researches got interested and wanted to look at the component of maternal and child death, they wrote the proposal ...upgrading a few clinics in the community to offer ante-natal services so women wouldn’t have to go to Pumwani or Kenyatta Hospital...three clinics were upgraded in Korogocho and three in Viwandani...” IDI19-NUHDSS Manager

6.3.2 Community Discrimination and Stigmatisation

The predominant reported potential burdens of verbal autopsy for HDSS residents were discrimination and stigmatisation. Study participants felt that HDSS communities could be stigmatised or even discriminated if others learned about the causes of death in these communities. As I will highlight in this section, stigmatisation and discrimination of HDSS communities could occur even without formal reporting of causes of death at the community level. Participants discussed HDSS communities by four main categories, by geographic location, ethnicity, age and gender.

For example, cause of death information could lead to discrimination of community members who live within a specific area of the HDSS as this participant indicated:

“If it is known there is a lot of HIV in Mtondia, people will avoid the area fearing infection, even doctors might refuse to come and work here”. FGD-Kilifi-Tezo-Community Member

In addition, based on their experiences of collecting cause of death information, verbal autopsy interviewers could develop negative attitudes and stereotypes about causes of deaths in particular areas of the HDSS:

“...according to our experiences, there are some areas when we visit where we know that most of the cases are of murder due to land issues and witchcraft.” FGD2-P2-Kilifi VA Interviewer

Some areas of the NUHDSS experience relatively high levels of residents being shot
dead, therefore, some people could develop stereotypes about the characteristics of residents of areas where crime-related deaths are reported or perceived to occur in large numbers:

“...If you ask where a hardcore thief comes from, you will hear it is Lunga Lunga Centre. If you ask where the most renowned thief comes from? You will be told it is Lunga Lunga Centre...” FGD9-P7-Nairobi Viwandani CAC Member

As I reported earlier in this chapter, some families who lose household members in the NUHDSS through gun-related deaths might be discriminated against by the police and other local government officials. Therefore, it’s likely that this discrimination could be extended to an entire community where it’s perceived that particular deaths are crime-related.

National reports on causes and number of deaths are often presented by region. Since specific regions are usually associated with particular ethnic groups, some individuals might perceive these reports to reflect the causes and numbers of deaths in a particular ethnic group which could lead to stigmatisation of and discrimination of individuals who belong to these ethnic groups.

“There was a time it was said that a lot of Luos were dying from AIDS. The Luos started complaining because even when a Luo boy wanted to marry a Mijikenda girl, they were not being allowed” FGD4-Kilifi-Township KCR

Age and gender might also be used to group and potentially stigmatise community members. For instance, a common perception in Nairobi was that many young men engage in crime. Participants often referred to the perceived high number of people that are shot dead by police to argue that many young men are criminals. In addition, one NUHDSS verbal autopsy interviewer felt that young women in the NUHDSS areas die from HIV/AIDS because of engaging in prostitution.

“...So thuggery is here and also prostitution amongst the young girls. They tend to do prostitution to get their daily bread. So HIV is very common here.” IDI21-Nairobi -Viwandani VA Interviewer
6.3.3 Damage to Reputation of Institutions

Discussions with research and community stakeholders in the case studies highlighted that failing to address the potential challenges of verbal autopsy, such as emotional distress for respondents and poor understanding of verbal autopsy by HDSS residents, could damage the reputation of research institutions associated with verbal autopsy. For instance, community members who do not understand the procedures and aims of verbal autopsy, might feel that the institutions conducting the activity are untrustworthy or malicious:

“I had two neighbours who died at the hospital, (VA) was conducted for only one of them. To date, the family asks themselves what KEMRI really wanted”
FGD6-Kilifi-Junju-Community Member

“They come up with many stories, that after being asked by this one (census field worker) another one (VA interviewer) comes to follow up on that without having been involved in that issue...they bring in culture, they say that these people are the cause of the death of this person.”
FGD9-P7-Nairobi-Viwandani-CAC Member

Even when respondents and other community members understand the procedures and aims of the verbal autopsy, they might still feel that the verbal autopsy and the research institution in general, is unfair to them. This perception of unfairness could make HDSS residents less willing to participate in other activities of the research institutions conducting verbal autopsy:

“When I was a HDSS census field worker, I would get some refusals from households that had previously participated in VA. They would tell me ‘your colleague came here and spent a lot of time asking me these questions. Even though they explained why they were asking the questions, it left me feeling that I have been engaged for long, I have been asked questions that reminded me what I had forgotten and this has not brought back the dead”
IDI20-Nairobi-Korogocho - VA Interviewer

Other institutions associated with the verbal autopsy could suffer reputational damage if the verbal autopsy offends HDSS residents:
“It [KEMRI] is often perceived as being part of the hospital if not the hospital itself. And if we are going to annoy people they may be unwilling to use health care services as a result of feeling separated by their experience. ”IDI13-KHDSS Researcher

Therefore, the verbal autopsy could make community stakeholders feel that research institutions - and other institutions associated with verbal autopsy - are untrustworthy, malicious or unfair. This reputational damage could negatively affect the operation of these institutions such as conducting research and providing health care.

6.4 Views on proposed benefits for verbal autopsy respondents: condolence fees and death certificates

In Chapter 5, I highlighted some of the support that bereaved families receive including condolence fees in Nairobi, and recommendations made around the issuance of death certificates as a benefit in both case study sites. In this final chapter section, I will describe the debate between participants on the value of these proposals.

6.4.1 Issuance of Condolence Fees to the Bereaved

A condolence fee is issued to bereaved families in the NUHDDS (KSH 500) but not in the KHDSS. NUHDSS research stakeholders explained that condolence fees were introduced to minimise burdens for interviewers and adhere to local mourning norms. NUHDSS residents are not informed about the source or amount of the condolence fees because, as a VA interviewer explained, ‘it would seem like peanuts’.

I discussed with KHDSS community stakeholders that a condolence fee of KSH 500 is issued in NUHDSS but not in the KHDSS, but did not discuss issuance of condolence fees with KHDSS research stakeholders because I became aware of this practice in NUHDDS during data collection.

6.4.1.1 Reasons for issuing condolence fees

Community stakeholders in the case studies and research stakeholders in the NUHDSS widely supported the issuance of condolence fees. First, participants felt that
giving condolence fees would show solidarity with the bereaved family, in line with local mourning norms, and provide some assistance with funeral arrangements. Second, some participants felt that the condolence fee would incentivise the bereaved to take part in the verbal autopsy interview and so facilitate collection of verbal autopsy data. Finally, study participants described the condolence fee as compensation for time taken in the interview given that the interview can take a while depending on cause of death and emotional state of respondent and that respondents usually have household chores and economic activities they would otherwise be getting on with.

However, two participants emphasized that the condolence fee should be seen as a gesture of solidarity with the bereaved rather than a form of compensation:

“...Compensation is for someone who has killed your kinsman and is financing. That is the one to pay compensation...that one must go through a long process...” FGD11-P1-Nairobi-Korogocho-CAC Member

6.4.1.2 Appropriate processes for issuance of condolence fees

Community participants in both case studies reported that they would welcome a condolence fee of any amount. It seems that this view was based on the mourning norm that each individual contributes according to their ability and that the show of solidarity is more important than the amount given, as these participants explained:

“...Compensation is for someone who has killed your kinsman and is financing. That is the one to pay compensation...that one must go through a long process...” FGD11-P1-Nairobi-Korogocho-CAC Member
bereaved family and the community might expect a research institution such as the APHRC to make a larger contribution than individual community members. For instance, while many participants mentioned that a contribution of any amount or a few hundred shillings would be appropriate, this participant suggested that APHRC could contribute a few thousand shillings:

“In the Muslim community when someone dies, you place a tent and you mourn for three days. You know who has money in the community and take fifty thousand for the funeral. You use the money you collect within the three days to pay back the money to where you had borrowed it from. It’s good for the organisation to participate in those contributions... they say “we as APHRC, a research organisation within the community this is our contribution of one thousand, two thousand three thousand...in that way you have created friendship...” FGD11-P1-Nairobi-Korogocho CAC Member

In Kilifi, community representatives in one of the focus groups felt that verbal autopsy interviewers should make an out-of-pocket contribution and that any amount would be acceptable.

“I have worked in an office..., when we sent people to the field, they had lunch and they never went without an allowance to help them when they work. Whatever little they get, they have something to contribute, it’s not from the organisation, whatever they are blessed with, they should go ahead and contribute.” FGD5-Kilifi-Tezo KCRs

In Nairobi, community representatives pointed out that non-monetary support to the bereaved was also acceptable:

“P3: And if there is no money you can carry food basket, after the funeral they have finished the burial when you go to the household you carry a basket which has sugar inside [[P6: Flour]] flour inside, when you reach there you are welcomed and all your questions will be answered.” FGD11-Nairobi-Korogocho CAC Members
Despite the widespread support for issuance of condolence fees, some community members and verbal autopsy interviewers in Kilifi cautioned that introducing condolence fees would raise community expectations of payment from KEMRI field workers regardless of the type of study or amount of time spent with the field workers. In addition, community and research stakeholders in Kilifi felt that issuance of condolence fees could raise tensions if some HDSS residents felt discriminated against, either by interviewers failing to conduct verbal autopsies in particular households or to issue condolence fees as expected.

To address the challenges that could arise from the issuance of condolence fees, participants across the case studies recommended that research stakeholders should engage community members to build mutual understanding of the verbal autopsy between community members and research stakeholders. The participants thought that community members should be informed about the amount to be issued and that this would be a condolence fee and not payment to participate in research:

“They should be educated and told a condolence fee will be issued. They should be told the amount so that information won’t leak in a bad way...they should be called together and educated.” FGD6-Kilifi-Junju Community Members

“...on undue influence you see...from our biblical point of view, when people are mourning, you mourn with them. So I have come here to mourn with you, it’s not that I am buying you, I am mourning with you.” IDI22-Nairobi-VA Interviewer

In addition, participants felt that interviewers should consult the bereaved family or use their communication skills and knowledge of local community to select the appropriate interview respondent and recipient of the condolence fee:

“If you don’t consult family to select who is respondent ...the moments of condoling with them will bring about hatred. Often, a place with money has drama.” FGD6-Kilifi-Junju Community Member.
6.4.2 Death Certificates as a Potential Benefit to Respondents

Study participants, especially community stakeholders and field staff, recommended that the KHDSS and NUHDSS should issue death certificates to bereaved families or support the families to access the certificates. This recommendation was based on a common belief among participants that the death certificate is a valuable document. First, the death certificate could enable the bereaved to access various forms of services and social support including bursaries for orphans:

“We have this organization of orphans I’m one of the committee members, when we fill a form like this and you do not have death certificate, even when the committee here in Ruaraka village agrees to provide the money...when it goes to Nyayo House it will not be approved...most of these children lack assistance because of that.” FGD12-P10-Korogocho Community Members

Second, community stakeholders felt that the death certificate could be used to settle disputes including court cases such as land inheritance disputes:

“...maybe the person who died is the head of a homestead, there is a farm and some inheritance. If they have four kids, let’s say two female, two male and he has left four acres of land, in order for you to inherit that farm, that death certificate will be needed at some point...they will need to know who owns the land. And if they passed away, what proof is there that they died. So it does have its importance.” FGD5-Tezo KCRs

Finally, one participant suggested that issuance of death certificate would support a closer working relationship between the HDSS sites and government and that this relationship would enable the government to identify deaths in the community more effectively.

While recognising that death certificates are important, study participants also reported that most HDSS residents do not have death certificates for the deceased. This could be due to lack of education or perceived value of death certificates among HDSS residents as these participants explained:

“I don’t think that the Viwandani community have so much value for death
certificates. I’m saying this because if a person has died and you don’t see people getting concerned…” FGD9-P3-CAC Members Korogocho

“They do not understand the importance of that thing [death certificate]. They focus on their loss and burying the deceased…” FGD7-Tezo-Residents

However, some community stakeholders and field staff pointed out that community members might value the death certificates but face barriers in accessing these documents. One of the perceived barriers to accessing the death certificate, is that the certificate application process is expensive and time consuming. The process involves visiting the death registration offices located in Nairobi city centre and Kilifi town, paying application fees, providing original and copies of documents such as the identity card of deceased, and filling application forms, as these participants described:

“I have gone through the process...you need to have all the documents from the mortuary on what that person died from and affidavits from the police if that person died in the community. I took them to the births and deaths registrars’ office. There is a lot queuing, there is a lot of stuffs needed depending with where the person died.” FGD10-P1-NUHDSS Census Field Worker

“When you want that death certificate, the burial permit is required ...people who have those papers go to the office for births where they are given forms to fill. When they are done filling the forms, the deceased’s identification card is put there and their admission sheet, all are put there with their photocopies and are taken and recorded and that will enable one to get the death certificate.” FGD5-Kilifi-Tezo KCR

Study participants recommended that HDSS research stakeholders could advise and educate residents on how to access death certificates. Although the HDSS sites do not have formal linkages with local civil registration systems and field staff are not expected to advise residents as part of their normal duties, one verbal autopsy interviewer reported advising respondents on where to get the death certificate.

“I normally tell them, they can link up to where we normally go for births,
that’s where they should go for them. Then they’re like Huduma Centers? I’m like no, you can’t get a death certificate at Huduma Center. It’s at the Births and Registration offices.”IDI20-NUHDSS VA Interviewer

Other than advising residents on the application process, some participants recommended that the research centres conducting verbal autopsy should have a more proactive role by producing the death certificates or working with government stakeholders to provide the certificates to HDSS residents.

“…the organisation can ensure that there is some assistance in getting those certificates or they could be brought to the chief who then distributes them. Because I think that many don’t have the certificates.”FGD7- Kilifi Tezo Community Member

6.5 Wider relevance of case study findings

One of the objectives of this study was to explore the relevance of key verbal autopsy findings from the case study sites in Kenya to other HDSS sites in sub-Saharan Africa. To meet this objective, I interviewed five research stakeholders representing different HDSS sites across Ghana, Malawi, South Africa and Uganda, as I have described in section 3.4.2. The formative research (see section 3.2), despite preceding the in-depth case study, generated useful information for exploring the wider relevance of the case study findings. Therefore, the findings in this section are based on data from Phases 1 and 3 of the research project.

In Chapter 4, I described the overall characteristics and ethical processes for HDSS sites in sub-Saharan Africa and highlighted the verbal autopsy as an area of potential ethical sensitivities. In Chapter 5, I focussed on the methodological aspects and ethical issues for verbal autopsy in two Kenyan case study sites – Kilifi and Nairobi. I highlighted that the key ethical issues in the Kenyan case study sites were around the benefits and burdens of verbal autopsy. So far in this chapter, I have presented the views and experiences of research and community stakeholders in the case study sites on the benefits and burdens of verbal autopsy. These views and experiences, when added to evidence from my field observations, document reviews and secondary data analysis, suggest that verbal autopsy respondents and interviewers
bear the most severe burdens of HDSS, including moral and emotional distress, and that the benefits of verbal autopsy depend on how the data is used and by whom.

The findings that I will present in this section extend the progressive focussing in this study; from mapping out ethical issues for a wide range of HDSS across sub-Saharan Africa to investigating the benefits and burdens of verbal autopsy in the Kilifi and Nairobi HDSS sites using multiple sources of evidence. The findings in this section come from a small sample of HDSS research staff but representing HDSS with a wider range of geographic and socioeconomic characteristics. Therefore, the findings deepen our understanding and indicate the wider relevance of the key verbal autopsy findings from the case study sites.

To contextualise the views on benefits and burdens of verbal autopsy of these HDSS research staff (representing HDSS sites in Ghana, Malawi, South Africa and Uganda), I will first give an overview of methodological and ethical processes for verbal autopsy in these sites. HDSS research staff involved in this study viewed the verbal autopsy as a component of HDSS. There seems to be few differences between verbal autopsy and other components of HDSS in terms of ethics review, consenting, data sharing and community engagement. I will later examine these ethical processes, noting any similarities and differences between sites and between verbal autopsy and other routine HDSS surveillance. Table 17 shows a summary of these processes, including the case study sites for comparison.

**Table 17 Similarities and differences of verbal autopsy in selected sites across sub-Saharan Africa**

<table>
<thead>
<tr>
<th>HDSS Site</th>
<th>Overall HDSS Ethics Review Process</th>
<th>Overall HDSS Consent</th>
<th>VA Consent</th>
<th>Condolence Fee Issued</th>
<th>Interview Timing (days/months after death)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kilifi</td>
<td>A Verbal</td>
<td>Verbal</td>
<td>No</td>
<td></td>
<td>Three Weeks</td>
</tr>
<tr>
<td>Nairobi</td>
<td>A Verbal</td>
<td>Verbal</td>
<td>Yes ($5)</td>
<td></td>
<td>Flexible</td>
</tr>
<tr>
<td>AHRI</td>
<td>B Written</td>
<td>Written</td>
<td>No</td>
<td></td>
<td>Three Months</td>
</tr>
<tr>
<td>Karonga</td>
<td>B Written</td>
<td>Written</td>
<td>No</td>
<td></td>
<td>Two Weeks</td>
</tr>
<tr>
<td>Kintampo</td>
<td>A Verbal</td>
<td>Verbal</td>
<td>No</td>
<td></td>
<td>Flexible</td>
</tr>
<tr>
<td>Kyamulibwa</td>
<td>B Written</td>
<td>Written</td>
<td>Yes ($1.5)</td>
<td></td>
<td>Three Months</td>
</tr>
</tbody>
</table>

8 A-Initial ethics approval but no annual review, B-Initial ethics approval and annual review

6.5.1 Methodological processes: Verbal autopsy interviewers and interview timing in selected HDSS across sub-Saharan Africa

As in the Kenyan case study sites, verbal autopsy interviewers in the selected sites outside Kenya are among the most experienced field workers. Although some of these interviewers have training in health care, particularly nursing, the sites seem to prioritise field work experience and other personal attributes when recruiting verbal autopsy interviewers, as these comments illustrate:

“[There are people with experience in collecting such data [VA]. A small boy or girl can’t make this inquiry since it would be inappropriate. So, you need an elder person to collect VA. The [HDSS] takes care of that consideration when assigning VA interviewers. They go for experience more than academic qualification.” IDI26_Research_Staff_Ghana

“We had verbal autopsy interviewers with varying qualifications over time, we cannot pinpoint a particular agreed approach. Important thing is to recognise the verbal autopsy interviewer needs to be someone who understands the process and probably has the appropriate background. Last time VA was done here, the designated interviewer was a nurse, she could speak Luganda and was from the local area.” IDI27_HDSS_Researcher_Uganda

As shown in Table 17, the timing of the verbal autopsy varies across the sites. The Kintampo HDSS, like the NUHDSS, seems to have a flexible timing for verbal autopsy interviews; decisions on when to visit a bereaved household for an interview are based on the specific circumstance of each death. In the other sites, verbal autopsy interviews can only be conducted after a specified period of time following a death; for example, after three weeks in Kilifi or three months in Kyamulibwa and AHRI sites. These differences in timing of VA interview across the sites seem to be influenced by HDSS socioeconomic context, functioning and geographic features. For example, participants in sites with a fixed timing for verbal autopsy, including Kilifi, pointed out that the timing was informed by an understanding of local mourning and burial norms. In Kintampo, most HDSS field workers operate from the community, which gives them opportunities to identify deaths quickly, and to determine the appropriate
time to visit for an interview given their close and frequent interactions with community members. Furthermore, the NUHDSS covers a relatively small geographic area and has a mobile population, hence the ability and need for flexible timing of interviews.

6.5.2 Ethics review and consenting practices for verbal autopsy in selected sites

In Chapter 4, I described the ethics review and consenting processes for HDSS sites across sub-Saharan Africa, including when and how the sites introduced these processes. In Chapter 5, I focussed on ethical processes for verbal autopsy in the case study sites. Overall, the HDSS sites applied for ethics approval at some point – either before establishing HDSS, some years after establishment or when introducing verbal autopsy into the HDSS. However, only half of the sites involved in the empirical phase of this study apply for annual ethical approval. Notably, the research staff in all the six sites reported that ethics review processes for verbal autopsy are the same as those of the routine HDSS census. Unlike the AHRI, Kyamulibwa and Karonga sites, the two case study and Kintampo sites do not seek annual renewal of ethics approval. These differences in ethics review processes seem to be influenced by country-specific research regulations rather than differences in HDSS methodology. As I described in section 5.4, research staff in the case study sites felt that the verbal autopsy should be subjected to ethics review because it is a research activity that should adhere to established research practices, it is intrusive or sensitive and because a formal review would help practitioners identify and address ethical issues. Similarly, research staff in the other sites outside Kenya supported ethics review for verbal autopsy:

“I have the view that since it was set up for research purposes, it should be treated like any other research activity or project. It should go through the normal review we have, with yearly renewal.”

IDI26_HDSS_Research_Staff_Ghana

Sites that apply for annual ethics review obtain written consent for the routine HDSS census and verbal autopsy, while the others obtain verbal consent. This is because viewing verbal autopsy as research or as part of HDSS and subjecting it to the traditional ethics review process leads to requirements for written consent as this comment indicates:
"Our HDSS has three components; the usual socio-demographic census, verbal autopsy and telephone data collection. We collect personal data including telephone numbers and blood samples and also involve minors. According to POPI, the protection of personal information Act, you cannot collect and keep certain details about people without their consent. For us to demonstrate legally that we have consent, we need to have written consent. So to [streamline] our work, we decided to have written consent for every aspect of the HDSS." IDI24_HDSS_Manager_South Africa

On the one hand, HDSS sites without annual ethics review (Kilifi, Nairobi and Kintampo) seem able to adapt their consenting practices to respond to changes in verbal autopsy methodology and ethical sensitivities. For example, during the course of this study, the consenting process for verbal autopsy in the Kilifi HDSS changed from written to verbal. In 2017, I observed verbal autopsy interviewers in the Kilifi HDSS obtaining written consent. I later learned about the change to verbal consenting, including some of the reasons for the change, during a follow-up interview with a senior VA interviewer:

"From the start [of verbal autopsy], we used to do written consenting...it continued like that until when we came to electronics...we had to stop because we found sometimes fieldwork is dynamic...as people keep on being educated on some issues they also come up with questions. So, why do you want me to sign and I just want to give you information about a dead person? Is it because you want to come and victimize me again? For instance, the person was murdered or hang himself, there is that fear that if I sign, then you might take the consent form to the police...So, we opted not to sign again...we are doing verbal consenting." IDI25_KHDSS_VA_Interviewer

On the other hand, sites that have annual ethics review (AHRI, Karonga, and Kyamulibwa) seem restricted in terms of their ability to choose and adapt consenting processes for verbal autopsy, as this comment illustrates:

"[verbal consenting] is not acceptable to the regulatory authorities. You have to make a very, very strong case for verbal consenting, it is very rare, I can get it [approval for verbal consenting] for some of the social science observations
6.5.3 Community engagement and data sharing for verbal autopsy in selected sites

Community engagement processes for verbal autopsy in the selected sites outside Kenya, as well as in the case study sites, appear inseparable from those of the overall HDSS. There was no evidence of VA-specific community engagement in all the sites involved in the empirical component of this study. In section 2.2.3, I highlighted the paucity of empirical evidence on community engagement processes for routine HDSS census and verbal autopsy in sub-Saharan Africa. Based on empirical data from the formative research, I showed in section 4.2.3 that information sharing was the most common form of community engagement in six HDSS sites across sub-Saharan Africa. However, with the exception of the case study sites (Kilifi and Nairobi), the other sites (Karonga, Kintampo, Kyamulibwa and Navrongo) had community key informant systems, which can be described as partnerships for collecting data. The case study sites maintain a network of community representatives, which are strategies for community consultation (Kamuya et al., 2013; Sharp & Foster, 2000). Through the in-depth case study, I highlighted that research stakeholders have given little attention to HDSS and VA-specific community engagement (see sections 4.3.2.3, 4.3.4.3 and 5.6.1). This is despite recommendations from study participants and the literature that there should be more HDSS and VA-specific community engagement to demonstrate respect, improve data quality, protect participants and enhance social value. The Phase 3 findings around community engagement aligned with those from the formative research and in-depth case study. These findings suggest there is very little VA-specific community engagement in HDSS sites across sub-Saharan Africa.

Like in the case studies, the other sites share verbal autopsy data using the research centre or HDSS-wide data sharing platforms. These include online data repositories maintained by the host research centres (NUHDSS and AHRI sites) or by the INDEPTH Network (all sites). Overall, the sites make the verbal autopsy data readily available online or share it upon request.

“Our data is put in a public repository, there are rules regulating the repository but basically freely available to whoever who wants to rationally use the data. Whether [it’s] individuals, institutions or agencies they will be
“Any time you want to use DSS data, you have to apply directly to both the institution and the ethics committee. The ethics committee reviews your protocol... I don’t know specifically where the government gets the verbal autopsy data but individuals analyse and publish the data. [It’s then] through the publications the government and others can become aware [of public health challenges] and intervene.” IDI26_HDSS_Research_Staff_Ghana

Discussions with research stakeholders in the selected sites across sub-Saharan Africa reflected the findings from the case study sites; that HDSS sites share and use data primarily for research regardless of their affiliations to government agencies.

6.5.4 Benefits and burdens of verbal autopsy in selected sites

The empirical evidence from the case study sites in Kenya indicate that the key ethical issues for HDSS are around benefits and burdens of verbal autopsy. These ethical issues include severe emotional burdens for individuals and disproportionate distribution of benefits and burdens. The evidence from the case study sites suggest that the socioeconomic context, methodological and ethical processes for routine HDSS and verbal autopsy significantly influence benefits and burdens in verbal autopsy. I have described the general HDSS characteristics, and methodological and ethical processes for verbal autopsy in purposively selected HDSS sites across Ghana, Malawi, South Africa and Uganda. In the following sections, I will present the views of research stakeholders from the selected sites regarding benefits and burdens of verbal autopsy, in order to assess the relevance of findings from the case study sites to other sites across sub-Saharan Africa.

6.5.4.1 Perspectives on burdens: Emotional distress for respondents and strategies for addressing burdens

All the five research staff from the four HDSS sites outside Kenya acknowledged the potential of a verbal autopsy interview to cause emotional distress for respondents. Even when prompted to, they rarely discussed other types of burdens or burdens for other stakeholders involved in verbal autopsy, such as emotional distress for interviewers or community stigmatisation. While most of the research staff stated
that the verbal autopsy is emotionally distressing for respondents, some only implied this by suggesting that other forms of collecting cause of death data would be less distressing, or by recommending strategies for reducing emotional distress. Overall, the research staff felt that emotional distress for respondents was the most common burden for verbal autopsy in HDSS, as illustrated by this comment:

“Some participants lose loved ones and you are trying to ask reasons for the death, some can break down with emotions. Burdens for the investigators I don’t know, I think it’s more for the participants.”

IDI26_HDSS_Research_Staff_Ghana

Each of the five research staff felt that the likelihood of emotional distress for verbal autopsy respondents is reduced when field workers with the appropriate training and personal attributes conduct the interview after observing a locally defined mourning period. Table 17 shows that the timing of verbal autopsy interviews varies across sites, because of differences in the socio-economic context and HDSS functioning. Across all sites, the expectation is that interviewers will draw on their training and character to address respondents’ social and emotional burdens:

“We used to have a small team, but all our verbal autopsies are now done by a single man, he is well known and liked in community, he is a medical assistant himself, he treats people in the health facilities as well, I think people respond very well to him” IDI29_HDSS_Manager_Malawi

Verbal autopsy interviewers in the Nairobi HDSS reported that issuing condolence fees reduces some emotional and social burdens, at least for the interviewers. Some research staff involved in Phase 3 interviews did not support issuance of condolence fees because they felt it would constitute an undue inducement. Others felt issuing condolence fees shows respect for local community culture and compassion for the bereaved. Overall, the research staff from the selected sites outside Kenya felt that emotional distress for respondents is the main potential burden of verbal autopsy and that this burden can be addressed through appropriate timing of interviews and careful selection of interviewers.
The research staff commonly mentioned that information about causes of death, presented as interview results for bereaved families or mortality data for research and public health interventions, was a potential benefit of verbal autopsy. However, they all acknowledged that the individual respondents and bereaved families do not receive verbal autopsy results. As most HDSS researchers in the case studies pointed out, verbal autopsy results might be useful for some respondents but we should recognize that the verbal autopsy method is relatively imprecise and that the cause of death might be obvious, for instance road traffic injuries. Similarly, most research staff in Phase 3 emphasized that the key benefits of verbal autopsy emerge from provision and use of population-level mortality data rather than results for individuals. They also highlighted the challenges of sharing and using HDSS data in general, reflecting the challenges described in sections 2.2.5, 4.2.4 and 5.7.3. Furthermore, none of the sites issue death certificates and HDSS research staff did not provide specific examples of how verbal autopsy data had contributed to improvement of local health services or to informing policy, other than mentioning the benefits that could emerge from the use of population-level HDSS data:

“The data we collect in the HDSS, we link it with service records from different ministries like the department of health, department of home affairs, which registers births and deaths, department of education... we give them empirical data [Through online data repositories] to say whether they are meeting their targets. For example, under department of home affairs every person must have a death certificate and ID, we don’t give data at the individual level, we show the department the number of people in a given community without these documents to inform their service delivery.”

IDI24_HDSS_Manager_South Africa

Although most of the discussions around benefits focused on the potential uses of data, one research staff felt that the verbal autopsy interview could have some direct individual benefits for some respondents:

“From talking to people who actually do the verbal autopsy, when we discuss as a group and from my interactions with them, we have found that people find it [VA interview] quite cathartic. When people have been distressed by the
death, they find it rewarding that somebody is interested and somebody cares about how and why that person died.” IDI29_HDSS_Manager_Malawi

From the perspective of HDSS research staff in selected sites across sub-Saharan Africa, emotional distress for respondents and population-level mortality data are the main burdens and benefits of verbal autopsy respectively. The research staff felt that the current field workers have the necessary training and background to address respondents’ emotional distress but did not discuss interviewers’ burdens. Furthermore, they described the potential uses of verbal autopsy data particularly for policymaking and service delivery but without specific examples. This supports the key findings from the in-depth case study around benefits and burdens of verbal autopsy in HDSS. In the case study, participant groups other than field staff rarely discussed burdens for verbal autopsy interviewers while other types of burdens and influences on burdens emerged from field observations, focus group discussions and secondary data analysis. Empirical evidence from Phase 3 suggests that key findings from Kilifi and Nairobi might be relevant to a wider range of HDSS sites across sub-Saharan Africa, but assessing the relevance of other findings from the Kenyan sites might entail conducting in-depth case studies in other sites.

6.6 Summary

Discussions with study participants in the case study sites, including field observations and document reviews, highlighted that emotional distress for verbal autopsy respondents is the most common and serious burden of verbal autopsy. This emotional distress refers to a complex mix of negative emotions including sadness, grief, anxiety and anger. Respondents’ emotional distress influences the types and levels of other burdens for other verbal autopsy stakeholders. For instance, verbal autopsy interviewers reported that they often feel guilty whenever respondents start to cry. In addition, bereaved families and respondents who are offended by the verbal autopsy interview might lose trust in institutions associated with the verbal autopsy including hospitals.

Information on cause of death was the most commonly described benefit of the verbal autopsy especially for the HDSS community and research institutions. The stakeholders who bear the most burden of verbal autopsy, that is respondents and interviewers, seem to gain the least benefit in terms of using the cause of death
information. This is because the verbal autopsy results are not reported to individual respondents and the interviewers do not use the verbal autopsy data. Furthermore, while there is a consensus in the scientific community that the verbal autopsy benefits the population rather than individuals, there is little evidence on how verbal autopsy data has been used to inform public health policy or to improve local health services. Discussions with researchers and managers in other HDSS sites largely supported the case study findings on the potential benefits and burdens of verbal autopsy. These discussions also reflected the findings in Chapter 4 and 5; that some ethics policies and practices in HDSS such as condolence fees are highly context-specific.

The multidimensional poverty in most of the case study areas, and the perceived wealth of the research institutions, means that there are many unmet expectations in the HDSS areas. Study participants recommended that KHDSS and NUHDSS research stakeholders should issue condolence fees and death certificates in order to minimise burdens and maximise benefits of verbal autopsy. The NUHDSS already issues condolence fees and this appears to have reduced burdens for interviewers to a small extent. Issuance of death certificates, which was widely recognised as a potentially important benefit of verbal autopsy, would require collaboration between the HDSS sites and local civil registration and vital statistics systems.
CHAPTER 7  Discussion

7.1 Introduction

Health and demographic surveillance systems (HDSS) generate important health-related data in sub-Saharan Africa and other low and middle-income countries where civil registration and vital statistics systems, and other sources of population-level data, are incomplete (Hill et al., 2007; Sankoh & Byass, 2012; Ye et al., 2012). As noted in Chapter 2, despite generating population-level health-related data on millions of people in LMICs, and operating in some of the most research intensive contexts, HDSS have received little attention in the empirical ethics literature and guidelines (Carrel & Rennie, 2008). Few studies provide a holistic and grounded perspective on HDSS ethics; most studies on HDSS ethics are conceptual or focused on particular components of HDSS. Overall, there is a lack of empirical evidence on the ethical issues involved in HDSS and a lack of specific guidelines on how to address potential ethical issues in HDSS.

This thesis sought to address the empirical and normative gaps in HDSS ethics by:

i) Describing the characteristics of HDSS sites in sub-Saharan Africa in terms of their history, context and functioning, and mapping out the key ethical issues in HDSS (Objective 1).

ii) Exploring, in depth, ethical issues for verbal autopsy in two different HDSS sites in Kenya (Objective 2).

iii) Assessing the wider relevance of key verbal autopsy findings from the Kenyan sites to a wider range of HDSS sites within sub-Saharan Africa (Objective 3).

iv) Drawing on the empirical research findings (Objectives 1-3) and the wider social science and ethics literature to describe the key ethical issues in HDSS, to propose recommendations for HDSS ethics policy and practice.
The research project involved an in-depth case study of two HDSS sites in Kenya and an assessment of the wider relevance of the case study findings through qualitative research in diverse HDSS sites across sub-Saharan Africa. Study participants included HDSS research and community stakeholders. The research processes, including data collection and analyses, aligned with the predominant themes in ethics research and guidelines for health-related research, such as ethics review, consenting, community engagement, data sharing, benefits and burdens. In the following section, I will present a summary of the empirical study findings. In the rest of the chapter, I will relate these findings to the literature in addressing the fourth objective of the study.

7.2 Summary of Findings

The findings that I will summarise in this section reflect the progressive focusing and varying scope of the three interconnected research phases, which I described in Chapter 3. Most of the findings (see Table 18) come from the in-depth case study sites in Kenya and are largely about the practices, perspectives and experiences of ethics at the frontline of HDSS.
### Study Findings - Presented in detail in Chapter 4 (Objective 1) and in Chapters 5 & 6 (Objectives 2&3)

**Objective 1:** To describe the characteristics of HDSS sites in sub-Saharan Africa in terms of their history, context and current functioning, and to map out the key ethical issues from the perspectives of HDSS research staff and field workers

**HDSS Characteristics: History, Context, Functioning**

- The majority of HDSS sites were established for research purposes through international collaborations, with the INDEPTH network bringing HDSS sites together to strengthen the HDSS methodology and to promote HDSS data sharing and use.

- HDSS sites are located in deprived areas; mainly in rural areas and a few urban and peri-urban slums.

- Despite sharing a common methodological approach, in practice, HDSS sites vary widely in terms of field procedures. Over time, many sites have reduced the frequency of household visits and have adopted electronic data collection methods.

- To ensure the timely identification of vital events, sites that conduct household enumerations annually (Karonga, Kyamulibwa, Kintampo, Navrongo) have community-based key informants or field workers. In contrast sites that have more frequent household enumerations (Kilifi, Nairobi, AHRI) collect data primarily through field workers who operate from the research centres.

**HDSS Ethics Oversight and Processes**

- Research stakeholders expressed significant uncertainty and diversity of views regarding the appropriate HDSS ethics processes.

- Ethics oversight processes vary widely across the HDSS sites ranging from one-time approvals from government ministries with no formal ethics review to initial approval and annual review by scientific and ethics committees.

- Other ethics processes such as consenting, community engagement, benefits and data sharing vary widely based on the particular characteristics of each site.

- Across all sites, consent for HDSS data collection is obtained at the household level but the type of consent (written or verbal) is determined by whether the HDSS undergoes annual ethics review.

- HDSS-specific community engagement activities are limited by practical and conceptual challenges such as unreliable funding to sustain long-term engagement, and lack of clarity on whether a HDSS is a distinct project requiring a separate community engagement strategy.

- With the exception of the Kilifi HDSS, the HDSS sites lack detailed institutional-level policies outlining the ethical justification and processes for data sharing.

- Across all sites, residents are not compensated for time taken to respond to HDSS questions.

- Study participants largely viewed the routine HDSS data collection as a low-risk activity that has potential community/public benefits.

- The verbal autopsy emerged as the most sensitive activity in HDSS because of its potential burdens to individuals, communities and institutions.

**Objective 2 &3 :** To explore, in depth, ethical issues for verbal autopsy in a rural and an urban HDSS site in Kenya, from the perspectives of research and community stakeholders, and to check the wider relevance of findings from the Kenyan sites through interviews with research staff working in other HDSS sites across sub-Saharan Africa.
VA Burdens and Benefits

- The most severe and commonly described burdens of VA across all sites were emotional distress for VA interviewees and interviewers.

- Study participants agreed that majority of potential benefits from VA lay at the community-level rather than individual-level. However, while researchers mostly referred to potential long-term societal benefits from use of VA data, community members referred to potential uses of VA data to address proximate public health issues such as local crime and disease outbreaks.

- To minimise potential burdens for stakeholders and enhance the quality and utility of VA data, HDSS mainly employ experienced field workers as VA interviewers, visit households after observing a mourning period (fixed or flexible), issue condolence fees to VA interviewees and share VA data with other stakeholders.

- Some study participants, particularly researchers and field staff, talked about the potential of VA interviews to provide some emotional relief for the bereaved. However, VA interviewers felt inadequately prepared to support VA interviewees during data collection citing lack of skills, financial resources or time to offer appropriate support.

- Benefits and burdens of VA seem to be disproportionately distributed; the stakeholders (community members and field staff) who bear the most burdens (emotional distress, invasion of privacy) seem to gain the least benefits (benefits from uses of HDSS data).

- In the two sites that issue condolence fees – Nairobi and Kyamulibwa – funds are not always available at the time of data collection mainly because condolence fees are not viewed as compensation for research participation (hence not prioritised) and because interviews might be conducted impromptu to avoid loss to follow up.

VA Consenting and Community Engagement Processes

- While the majority of study participants felt that verbal consenting was adequate for routine HDSS data collection, there were diverse opinions on the appropriate consenting for VA.

- Regardless of whether they preferred written or verbal consenting, participants recommended that the consenting process should be designed to reduce burdens for respondents (anxiety/inconvenience from signing forms) show respect for VA interviewees (disclosure in ICF) and to protect interviewees, researchers (from unfair accusations of collecting data without consent) and data quality (avoid unnecessary refusals).

- Community engagement for VA is particularly challenging; because of sensitivities around death, it’s difficult to talk about death before it happens, VA involves a small proportion of HDSS population, VA-specific CA might make it stand out from rest of HDSS activities, raising concerns.

- HDSS sites do not report VA findings to individuals or issue legal documents, mainly because of low accuracy of VA findings at the individual level and because HDSS is generally viewed as a research activity rather than official registration and certification of vital events.

VA Ethics Oversight

- HDSS sites do not seem to have separate ethics oversight, community engagement or data sharing processes for VA and routine census.

- Although VA is not subjected to annual ethics review in all HDSS sites, the majority of study participants, especially researchers and HDSS managers, felt that VA should undergo ethics review either because they perceived VA as a separate research project, a particularly
7.2.1 HDSS as international collaborative health research

HDSS sites in sub-Saharan Africa were established and currently operate through collaborations involving a wide range of local, national, regional and international actors. These actors include HDSS community members, Ministries of Health and universities in host countries, global health funders such as the Wellcome Trust, and research institutions based in North America, Japan, United Kingdom and other Western European countries. Most of these actors have worked together for many years in running the HDSS sites.

The actors established the HDSS sites primarily to support health-related projects, particularly health research. Overall, the current HDSS sites in sub-Saharan Africa can be seen as long-term international collaborations for health research. Ethical issues for these forms of collaborative research are well recognised in the literature. They include issues around fairness, responsiveness, balancing disparate ethics systems, sustainability and respect for study populations (Emanuel et al., 2004; Grady, 2006; Parker & Kingori, 2016; Tharyan, 2006).

7.2.2 HDSS populations face multiple deprivations

Current HDSS sites in sub-Saharan Africa are located in areas of multiple deprivations. These include rural areas and urban slums. My exploratory study, which included document reviews and field work in diverse HDSS sites across sub-Saharan Africa, highlighted that most HDSS populations have constrained socioeconomic opportunities, access to health care and other opportunities to lead healthy lives. There are also significant inequalities among HDSS residents.

The HDSS communities in my case study seem to differ from each other, with particularly strong differences between rural and urban HDSS areas. The more rural areas (such as most areas of the Kilifi site) appear to have more of a shared ethnic identity, language and cultural practices, whereas the urban areas (such as NUHDSS and the Kintampo HDSS town area) have greater diversity in those features. These similarities and differences have potentially important implications for community
engagement and consent processes and for intra-community integration, as returned to below.

7.2.3  HDSS as non-traditional health research

While HDSS support research, they do not function like traditional research projects. Despite sharing a common methodological approach, HDSS function in an iterative and context-specific manner. The frequency of data collection, research focus, data collection methods and other processes in HDSS are highly influenced by historical factors, and geographic and socioeconomic context. The long-term nature of HDSS and the fact that they involve intense follow-up of entire populations in deprived areas seem to distinguish them from other types of research. The empirical evidence in this study, coupled with a review of the literature, suggests that INDEPTH Network HDSS sites are a form of non-traditional health research.

Findings from this study support the claim that ethics guidance developed for traditional health research might be unsuitable for addressing ethical issues in non-traditional health research such as consenting and ethics oversight in HDSS within sub-Saharan Africa.

7.2.4  Consent and community engagement processes in HDSS

There is significant diversity in the consenting process across HDSS in sub-Saharan Africa. While all sites obtain consent at the household level, the type of consent is either written or verbal. Some sites have maintained the same type of consenting since baseline census while others have changed. In some sites consent for verbal autopsy is different from that of routine HDSS. Study participants varied in their recommendations regarding appropriate consent types and processes, but all agreed that consenting processes in HDSS should be accompanied by community engagement. However, many HDSS sites seem to face various practical and conceptual challenges regarding community engagement, including lack of funding to sustain long-term community engagement and uncertainties on the appropriate community engagement strategies.
7.2.5  Ethics oversight and data sharing in HDSS

Ethics oversight processes across HDSS sites in sub-Saharan Africa range from one-time approvals from government ministries, with no formal ethics review, to initial approval and annual review by scientific and ethics committees. The majority of study participants felt that the verbal autopsy, unlike routine HDSS, should be subjected to formal ethics review to identify and minimise potential burdens, a recommendation I go on to discuss in section 7.5.

HDSS sites primarily share data through the INDEPTH Network and using standardised procedures. However, some sites have detailed data sharing policies while others appear to have none. The majority of study participants felt that HDSS data should be shared widely to advance science, health and other legitimate public health goals. In practice, it seems that HDSS data are mainly accessed and used by researchers for research purposes.

7.2.6  Benefits and Burdens of HDSS

This study identified little to no benefits from the HDSS for individual HDSS residents and communities. Community members felt that HDSS data should be used to address local public health challenges such as crime while research staff emphasised that the value of HDSS lay in supporting health research, towards a longer term social value of potential relevance to the communities involved.

Study participants described various potential burdens of HDSS including fatigue, time and economic costs of participating in routine household censuses; discomfort, invasion of privacy and emotional distress from verbal autopsy interviews, questions around socioeconomic and pregnancy status, and reputational damage or community stigmatisation from sharing of HDSS data. In particular, study participants associated the verbal autopsy interview with the most severe burdens in HDSS.

7.2.7  The burdens of verbal autopsy in HDSS sites within sub-Saharan Africa

Emotional distress for verbal autopsy respondents emerged as the most common and severe burden in HDSS. Findings from the in-depth case studies suggest that the context of death, characteristics of the deceased, and timing of the interview significantly influence emotional distress for verbal autopsy respondents. The
emotional distress of verbal autopsy respondents seems to influence other burdens, including economic burdens, moral distress for interviewers and risks of reputational damage for institutions.

I learned that HDSS sites have implemented various strategies to address the burdens of verbal autopsy such as issuance of condolence fees, with these strategies raising further ethical issues. Overall, a core emerging ethical issue in my findings was concern about fairness in burdens and benefits experienced by families and interviewers through their roles in verbal autopsy. I take this issue forwards in more depth next.

7.3 Burdens and Benefits at the frontline of verbal autopsy in health and demographic surveillance systems in sub-Saharan Africa.

As I showed in Chapter 6, HDSS residents and field staff seem to bear most of the burdens and to gain the least from HDSS. This imbalance raises various ethical issues, which I discuss in this chapter. In this section, I will discuss burdens for verbal autopsy respondents and interviewers. Later in this chapter, I will more briefly discuss the overall social value of HDSS including ethical issues around the distribution of benefits and burdens among HDSS stakeholders.

It is widely recognised that researchers have a responsibility to minimise the burdens of research and to provide an ethical justification for the burdens involved in research (CIOMS and WHO, 2016; Emanuel et al., 2004). The terms “risks”, “harm” and “burdens” are used interchangeably depending on context. However, these terms have particular differences; “burden” is an umbrella term for a wide range of adverse outcomes of research for individuals and populations, while “harm” has traditionally referred to specific types of burdens, mostly at the individual-level (Rid & Wendler, 2010; Wikler, 2017). A risk refers to the likelihood that a harm or burden will occur (Westra et al., 2011). Recognising these distinctions and diverse uses of the terms, I will use the term “burdens”, unless referring to commonly described concepts in bioethics such as risk-benefit ratio (Emanuel et al., 2004) and minimal risk (Westra et al., 2011). To justify specific research on ethical grounds, a comprehensive assessment of the actual and potential burdens and benefits is essential. In the following sections, I draw on the empirical findings and the wider ethics literature to
highlight ethical issues around emotional distress for verbal autopsy respondents and moral distress for interviewers; the most common and severe burdens of HDSS that this study identified.

7.3.1 Emotional distress for verbal autopsy respondents

As shown in Chapter 6, emotional distress for verbal autopsy respondents was the most severe and commonly described burden of HDSS. Emotional distress refers to a wide range of negative emotions including guilt, sadness, frustration and grief. The most obvious sign of emotional distress was reported as crying, and verbal autopsy respondents shared their experiences of stopping interviews where a respondent started to cry. The study highlighted that cause of death, characteristics of the deceased, relationship between a respondent and the deceased and timing of the verbal autopsy interview significantly influence levels of emotional distress in verbal autopsy. For example, findings from the in-depth case study highlighted that verbal autopsy respondents are likely to experience high levels of emotional distress in interviews for deaths related to homicide, accidents and suicide. I also learned that HDSS sites across sub-Saharan Africa have adopted various strategies for minimising emotional distress for verbal autopsy respondents. The most common of these strategies are the recruitment of the most experienced field workers as verbal autopsy interviewers and conducting the interviews after observing a locally defined mourning period.

Despite the well-acknowledged responsibility for researchers to minimise the burdens of research for participants (CIOMS and WHO, 2016), HDSS across sub-Saharan Africa face challenges in identifying emotionally distressed respondents and it is unclear whether HDSS strategies to minimise emotional distress are effective. Furthermore, against the ethical principle of beneficence (Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014), verbal autopsy could introduce particular burdens for respondents in certain contexts.
7.3.2 Challenges of identifying and responding to emotional distress during verbal autopsy interviews

Verbal autopsy interviewers interact regularly with verbal autopsy respondents and other HDSS residents, which gives them opportunities to identify the burdens of verbal autopsy in an HDSS. Given the limited training of field staff across sub-Saharan Africa, including on communication skills and research ethics (Alexander & Richman, 2008; Kombe, 2015; Moyo et al., 2017), and based on the empirical findings in this study, verbal autopsy interviewers are likely to rely on their field experience and knowledge of local culture to identify emotional distress and to assess its severity. To illustrate the severity of the emotional distress, interviewers in the in-depth case studies emphasised that some male respondents wept uncontrollably during interviews, in a culture that encourages men to project power and strength rather than emotional vulnerabilities (Mathews et al., 2011; Siu et al., 2014). There are diverse bereavement practices across sub-Saharan Africa; study participants, especially in the multicultural Nairobi Urban HDSS reported that some ethnic groups encourage displays of grief such as wailing. These bereavement practices and cultural norms can help interviewers to identify emotional distress in respondents by noting unusual behaviour. They can also make it challenging for verbal autopsy interviewers to identify and respond to emotional distress. First, cultural norms (including religious beliefs), might prevent some respondents from crying, hence removing one of the most common indicators for verbal autopsy interviewers to respond to emotional distress. Second, the knowledge that bereaved relatives and neighbours might cry because of cultural expectations, rather than as a reaction to emotional distress, could limit the ability of verbal autopsy to identify emotionally distressed respondents. Finally, respondents might experience and display emotional distress after the interviewer has left. Therefore, verbal autopsy interviewers are unlikely to identify some emotionally distressed respondents because of personal, cultural, and institutional factors.

Ethics guidelines for health-related research involving humans recommend that researchers should systematically evaluate the burdens of research and have criteria for stopping burdensome procedures (CIOMS and WHO, 2016). As discussed above, identifying the burdens of HDSS at the point of data collection (such as emotional
distress), can be challenging. Even when interviewers successfully identify burdens during fieldwork, they might not report and address these burdens. In general, health-related research involving humans should be stopped or modified through an assessment of benefits and burdens, and consultation with study communities, research ethics committees and other research stakeholders (CIOMS and WHO, 2016). In contrast to randomised clinical trials, non-traditional health research lacks well-established guidelines for the systematic monitoring of benefits and burdens (Deichmann et al., 2016; McLennan et al., 2018). This lack of specific guidelines poses the risk of modifying or stopping non-traditional health research procedures based on inadequate evidence (McLennan et al., 2018). Some interviewers pause or end verbal autopsy interviews after realising that a respondent is emotionally distressed. However, these decisions by interviewers are highly context-specific and it seems that there are no formal mechanisms for experiences from individual interviews to contribute to ongoing assessment of burdens at the site-level.

So far, I have highlighted how social interactions, such as the display and identification of emotions, influence the identification of emotional burdens of verbal autopsy at the point of data collection. However, because I have only mentioned some of the most extreme cases of emotional distress (interviews that make respondents cry), and given the limited empirical evidence and guidelines on burdens of verbal autopsy, one might wonder whether the typical verbal autopsy interview is emotionally distressing for respondents.

7.3.3 The verbal autopsy interview is not a minimal risk procedure.

A minimal risk procedure is one in which the risks involved are not greater than the risks that individuals encounter in their daily lives, during routine medical examinations or charitable activities (Kopelman, 2004; Wendler et al., 2005). Research stakeholders can use the minimal risk concept to determine the necessity of extra protection for participants, waiver of requirement for informed consent, and whether the risks are permissible when compared to potential benefits (CIOMS and WHO, 2016). There are two areas of debate around the minimal risk concept; whose life should we consider when assessing the risks of daily life and what is the ethical justification for subjecting individuals to minimal risks in research (Binik & Weijer, 2014; Resnik, 2005). Binik (2017) provides a compelling argument that minimal risks
should refer to the risks that flourishing individuals encounter in their daily lives, mainly because these risks represent a reasonable trade-off between personal safety and the lives that individuals and society have reason to value. In particular, Binik (2017) argues that the risks of daily life for flourishing individuals are ethically justifiable because they are socially acceptable and because they would at most substitute rather than increase risks for research participants (Binik, 2017). Some study participants suggested that the verbal autopsy interview does not present additional or significant risks to respondents because conversations about death, including causes and circumstances of death, are common in bereaved households. However, the verbal autopsy, as I discussed in Chapters 2&3, is not an ordinary conversation about death. It involves asking a series of close-ended questions and seeking sensitive information that respondents would normally share with close relatives and friends only, or with health care workers when seeking treatment. Therefore, the risks that the verbal autopsy interview involves seem to be greater than those that respondents would encounter in an ordinary conversation about health and death.

An alternative approach to defining minimal risk shifts the focus from comparing risks in different contexts to assessing the likelihood and magnitude of risk of harm (Westra et al., 2011). This approach also emphasises the importance of empirical data, expert opinion and review of study procedures in determining the likelihood and magnitude of harm (small, moderate, severe harm) to research participants. For example, a procedure presents a minimal risk if the evidence shows that it is likely to cause a small harm (e.g anxiety) for \(<1/100\), or a severe harm (e.g long-term psychological harm or death) for \(<1/1000000\) individuals involved (Westra et al., 2011). Even with this alternative definition, the verbal autopsy would not qualify as a minimal risk procedure. Most study participants agreed that the verbal autopsy is an invasive procedure but some research staff pointed out that it is an infrequent procedure and suggested that only a few respondents would be emotionally distressed. However, empirical data in this study show that annually, the NUHDSS and the KHDSS conduct around 500 and 1000 verbal autopsy interviews, respectively. From the field observations, I learned that some verbal autopsy interviews include more than one respondent. Furthermore, findings from this and other empirical
studies (Aborigo et al., 2013; Allotey et al., 2015; Bird et al., 2013; Morrison et al., 2018), highlight that verbal autopsy respondents and interviewers are likely to experience negative emotions such as anxiety, guilt and anger depending on the context of death. For example, 117 out the 6218 verbal autopsy interviews conducted in the NUHDSS between 2002 and 2015 were for individuals who had been shot dead. It is likely that some of these interviews introduced or exacerbated the respondents’ negative emotions such as anxiety and anger. As I have noted, the verbal autopsy procedures, including the content and structure of questions and timing of interview, can make respondents emotionally distressed. Overall, the empirical evidence suggests that the verbal autopsy in the HDSS context is not a minimal risk procedure, mainly because it is highly likely to cause emotional distress for the individuals involved. Regardless, some argue that a study procedure that involves a minor increase or more than minimal risk to individuals can be ethically justifiable when conducted with the informed consent of individual participants and study communities, with the approval of an ethics review committee, and if the study has social value.

7.3.4 Influence of consenting practices on burdens for verbal autopsy respondents

The practice of seeking informed consent from research participants aims to achieve the ethical principle of respect for persons. There was a lack of consensus among participants involved in this study around the ideal consenting practices in verbal autopsy. The overall argument for written consent, as outlined in the literature and from the perspectives of participants in this study, is that verbal autopsy is an invasive (more than minimal risk) research procedure hence individuals need to give a formal and verifiable consent. Those who were against written consent for verbal autopsy pointed out that it could exacerbate emotional distress for respondents. For instance, findings from the in-depth case studies highlighted that requiring respondents to sign consent forms, especially where the deceased died from a perceived illegality such as suicide and shooting, was likely to cause anxiety, fear and mistrust.

As I described in Chapter 3 and in Section 7.2, most of the in-depth empirical data in this study comes from the Kilifi and Nairobi Urban HDSS sites. I learned, from work in these case study sites, that trust and expectations of reciprocity form the foundation of consenting processes in verbal autopsy. Given their long-term presence in the
HDSS areas, the verbal autopsy interviewers and host research centres seem to enjoy high levels of trust in the community. Also, study participants felt that residents would be more comfortable being interviewed by someone they could trust; for instance, someone of the same gender or religion as respondent. In fact, some HDSS managers usually consider the similarities (in terms of sociodemographic features) between interviewers and potential respondents when allocating work to verbal autopsy interviewers. The ethics literature acknowledges the significant influence of trust, expectation of reciprocity and other social relations on consenting for health-related research, especially in contexts of health and social inequalities (Baiden et al., 2016; de Melo-Martin & Ho, 2008; Geissler et al., 2008; Kingori, 2013; Molyneux, Peshu, et al., 2005). Despite the potential for written consent to increase burdens for verbal autopsy respondents and the significant influence of social relations on consenting processes, policies developed in some of the HDSS sites in this study require verbal autopsy respondents to give written consent for interviews. These policies are informed by international ethics guidelines for traditional health research, which prioritise individual written consent. On the basis of findings from this study, I argue that written consent for verbal autopsy interviews in HDSS sites within sub-Saharan Africa is unlikely to achieve its intended ethical goals. Instead, requiring respondents to read and sign consent forms is more likely to increase burdens and reduce the social value of verbal autopsy.

Alternative approaches for meeting the intended ethical and practical goals of written consent could include enhancing community engagement activities to ensure that individuals are informed about research (Bull et al., 2013) and building the ethics and communication skills of fieldworkers to collect data effectively while showing respect to participants (Kombe, 2015). Enhanced capacity in ethics and communication, coupled with appropriate institutional policies, could enable interviewers to determine the appropriate consenting process based on the specific circumstances at each interview. Like some participants in this study, some authors have suggested that instead of written consent, researchers could use alternative methods of documenting consent, including video and audio recording to reduce burdens for research participants (Bhutta, 2004). Also, audio records of verbal autopsy interviews can provide valuable qualitative data on perceptions and understanding of
respondents, and a proof of consent (Allotey et al., 2015). However, empirical findings from this study highlight the need for careful consideration of the social context of verbal autopsy interviews to avoid increasing burdens unnecessarily. In contexts where respondents are anxious about signing forms, audio-recording the interview might not be a reasonable alternative. As I will discuss later in this chapter, building the capacity of verbal autopsy interviewers and modifying some institutional policies and practices, is an alternative strategy that could demonstrate respect and minimise burdens for verbal autopsy respondents without requiring them to sign consent forms.

7.3.5 The social determinants of burdens for verbal autopsy respondents

In addition to consenting processes and relations between verbal autopsy respondents and interviewers, there are wider social determinants of emotional distress for verbal autopsy respondents. These include socioeconomic and health challenges for HDSS residents, and ethical tensions between local and international interests.

It has been argued that researchers, especially those working in areas with a high burden of disease, have ancillary care responsibilities (Mzombwe et al., 2019). Ancillary care broadly refers to the assistance that researchers give to individuals primarily to alleviate suffering, respond to urgent need and appreciate participants’ trust, rather than to meet research objectives (Brownsworth et al., 2008; CIOMS and WHO, 2016). Specifically for HDSS, Carrel and Rennie (2008) argued that research stakeholders have significant ancillary care responsibilities to HDSS residents, since they engage the residents for many years in contexts of unmet socioeconomic and health needs (Carrel & Rennie, 2008). As an illustration of these needs, verbal autopsy interviewers and other HDSS field workers in this study reported learning about cases of extrajudicial killings, suicides associated with chronic diseases such as diabetes, and individuals who were living in extreme poverty or who had been raped within the HDSS areas. In these contexts of unmet needs and long-term relationships, HDSS research stakeholders may be seen (or expected) to provide connections to health and social care. Indeed, I observed interviews where HDSS residents requested medical advice from field workers. Field workers can advise residents informally about health and social issues, and some host research centres provide free health
care services. However, because of a wide range of practical and ethical reasons that I will discuss in more detail in Section 3.2 and 4, HDSS research stakeholders are unable to fully address the health and socioeconomic challenges of HDSS residents. Here, I want to highlight that the actual or perceived inability of HDSS research stakeholders to meet their ancillary care responsibilities is likely to contribute to emotional distress for verbal autopsy respondents.

Ethics scholars have criticised autonomy-based bioethics for its emphasis on individual-level issues such as consenting, and its inadequate attention to the social issues that influence health and research (Azétsop & Rennie, 2010; Baum et al., 2007). The findings in this study add to the ethics literature on health-related research in sub-Saharan Africa, which shows the significant influence of the social context (bereavement practices, trust and social inequalities) on research practices (Aborigo et al., 2013; de Melo-Martin & Ho, 2008; Kamuya et al., 2014; Parker & Kingori, 2016). Applying a biomedical and individual-based ethics framework to a highly social activity such as verbal autopsy interview in HDSS, without careful consideration of the social context is likely to generate poor quality data and to introduce burdens for verbal autopsy respondents (Aborigo et al., 2013). For example, research across sub-Saharan Africa has shown a widespread belief in witchcraft as a cause of death, especially for deaths without an obvious external cause, and among children and women of reproductive-age (Fottrell et al., 2012). Participants in this study acknowledged the prevalence of beliefs in witchcraft in the HDSS sites, including some verbal autopsy respondents who felt that someone bewitched the deceased. Therefore, HDSS research stakeholders need to consider the potential social reactions to death in designing verbal autopsy procedures and tools, such as timing of the interview, to minimise burdens for respondents, including emotional distress.

Other than the WHO verbal autopsy used in INDEPTH HDSS sites, alternative methods of collecting cause of death data in settings with incomplete CRVS include social autopsy and minimally invasive autopsy, as described in Chapter 2. Minimally invasive autopsy (MIA), unlike verbal autopsy (which is based on interviews with the bereaved), involves sampling tissues from body organs and fluids to conduct biomedical tests and generate a cause of death (Byass, 2016b; Maixenchs et al.,
Social autopsy involves interviewing the bereaved in a similar way to verbal autopsy except that it focuses on collecting information on the social and cultural causes of death, especially the barriers to health care seeking (Kalter et al., 2011; Moyer et al., 2017).

Recognising the multiplicity of values and interventions in public health, Grill and Dawson (2017) developed an ethical framework to guide public health decision-making. In this framework, they suggest that practitioners should identify alternative interventions, assess empirical differences, judge the alternatives against all values and submit results of the evaluation to an oversight institution (Grill & Dawson, 2017). One could evaluate verbal autopsy, social autopsy, minimally invasive autopsy and full body autopsy against widely accepted ethical principles and values of scientific validity and social value (Emanuel et al., 2004), community acceptability and effectiveness (Baum et al., 2007; Kass et al., 2007) or beneficence (Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014). For instance, a full body medical autopsy is viewed as the gold standard for identifying the cause of death but it might not be acceptable or feasible in certain socioeconomic contexts (Byass, 2016b; Leitao et al., 2014). While the verbal autopsy is relatively imprecise, especially at the individual level and for infectious diseases (Fottrell & Byass, 2010; Herrera et al., 2017), it has contributed population-level mortality data in LMICs, which could be used to improve public health (de Savigny et al., 2017; Sankoh, 2010; Sankoh & Byass, 2014).

Minimally invasive autopsy has been shown to have a high accuracy in determining the cause of death at the individual level (Bassat, 2017), including for infectious diseases in low and middle income countries (Castillo et al., 2016), indicating its scientific validity and potential to provide direct benefits and social value. However, conducting MIA presents practical and cultural challenges, since it entails collecting bodily fluids and samples soon after death (Byass, 2016b; Maixenchs et al., 2019). Unlike MIA, social autopsies collect cause of death data through interviews (like VA), and might be the only option for generating cause of death, in contexts where a body is not available for medical examination (Moyer et al., 2017). In addition, social autopsies are likely to generate locally relevant data but they have not been widely validated like the verbal autopsy (Byass et al., 2019; Caleo et al., 2018; Kalter et al., 2019).
Selecting the best programme for determining cause of death (from an ethical and scientific perspective), including through using a framework such as that proposed by Grill and Dawson (2017), would require comprehensive empirical evidence (on burdens, benefits and scientific validity, for example) and ethical justifications. HDSS managers in this study mentioned that they use the verbal autopsy tool mainly because it enables comparison of data across sites, and partly because VA has been promoted by INDEPTH and other international stakeholders to produce global health estimates.

7.3.6 Ethical considerations when selecting verbal autopsy respondents

Ethics guidelines for health-related research recommend that researchers should select study participants in a manner that ensures scientific validity, enhances social value and minimises the burdens of research (Emanuel et al., 2004). To ensure scientific validity, verbal autopsy interviews involve individuals who are likely to have accurate information about the circumstances and symptoms that preceded a death, including close relatives or final caregivers of the deceased. In this study, I learned that HDSS sites conduct verbal autopsy interviews for all deaths in the HDSS areas; including deaths that occur in hospital with a medically certified cause. HDSS research staff explained that this was necessary because of delayed treatment seeking among some residents and weaknesses in civil registration systems, the medically certified causes of death can be inaccurate. I also found that most verbal autopsy respondents are female relatives of the deceased for scientific and pragmatic reasons (they are usually the primary caregivers and are more likely to be available for interviews). This is despite studies across Africa and Asia having suggested that home-based birth attendants and health care workers, rather than bereaved mothers, can provide credible information about stillbirths and early neonatal deaths (Engmann et al., 2012).

In summary, a wide range of social factors are likely to contribute to emotional distress for verbal autopsy respondents. HDSS sites are located in areas with multiple deprivations, including high morbidity and mortality rates, with those who have experienced a death in a particularly vulnerable situation. Given their roles in households and communities, women are more likely to be directly exposed to the additional emotional distress of a verbal autopsy interview than men. These burdens
are inequalities are less visible to senior HDSS staff than to verbal autopsy respondents and frontline staff.

7.3.7 Moral distress for verbal autopsy interviewers

Verbal autopsy interviewers seem to experience the same symptoms of emotional distress as verbal autopsy respondents (such as regret, helplessness, guilt and anxiety), but the sources, frequency and intensity of emotional distress can vary significantly between these two groups. The emotional distress of respondents seems to influence that of interviewers. For example, interviewers might feel frustrated or helpless if they cannot manage the emotional distress of verbal autopsy respondents. Also, compared to verbal autopsy respondents, interviewers are more likely to encounter emotionally distressing situations because of their regular interactions with respondents to conduct the potentially invasive verbal autopsy interview in an environment of multiple ethical sensitivities. To illustrate the frequency and sensitivity of these interactions, each interviewer in the KHDSS conducted an average of 263 verbal autopsy interviews in 2018 while an interviewer in NUHDSS reported conducting at least 5 interviews for deaths from shootings (See Chapter 6 for numbers and causes of death).

7.3.7.1 The Under-recognised emotional burdens of verbal autopsy interviewers

The emotional burdens of verbal autopsy interviewers have received little attention in the wider ethics and social science literature. Studies across sub-Saharan Africa have highlighted a wide range of structural and personal factors that contribute to financial, psychological and social burdens for field workers in health-related research (Kingori, 2013; Kombe, 2015; Molyneux et al., 2013; Van Zyl et al., 2019). However, most of these studies have focussed on field workers in short-term research projects. In addition, the few studies around verbal autopsy ethics have prioritised discussion of emotional distress for verbal autopsy respondents rather than interviewers (Aborigo et al., 2013; Allotey et al., 2015; Chandramohan et al., 2005; Morrison et al., 2018). As I have described so far in this thesis, HDSS have important differences with other forms of health-related research, and verbal autopsy interviewers are a unique cadre of HDSS field workers. In the following sections, I will draw on the moral
distress literature to contribute to an in-depth understanding of the emotional burdens of verbal autopsy interviewers in HDSS within sub-Saharan Africa.

7.3.7.2 Defining moral distress

The philosopher Andrew Jameton defined moral distress as “arising when one knows the right thing to do, but institutional constraints make it nearly impossible to pursue the right course of action” (Jameton, 1984). Following this original definition, researchers have proposed a wider range of potential causes and symptoms of moral distress, and applied the concept in research with social and health care workers, particularly nurses. Morley et al. (2019) have outlined the conditions that are necessary and sufficient for moral distress to arise, which include:

- Experience of a moral event: could be moral uncertainty, dilemma or constraint (1)

- Experience of psychological distress: referring to a wide range of negative emotions such as guilt, regret, anger, frustration and powerlessness (2)

- A direct causal relation between 1 & 2 (Morley et al., 2019)

When understood in the terms stated above, moral distress refers to psychological (or emotional) responses to ethically challenging situations (Fourie, 2015; Morley et al., 2019). I will use this conceptualisation because it captures the fundamental features of moral distress; it is concise and yet inclusive of the diverse ways in which researchers have defined and applied the moral distress concept.

7.3.7.3 What makes emotional distress ethically relevant?

In Chapter 6, I highlighted that verbal autopsy interviewers experience a wide range of negative emotions including guilt, regret, helplessness, sadness and anxiety (these emotions are commonly referred to as psychological or emotional distress in the literature). Ethics guidelines recommend that researchers should identify and minimise the physical, social, economic and psychological burdens of research. Based on this perspective, emotional distress is an ethically relevant issue because researchers have an obligation to do no harm (for instance, not to make participants emotionally distressed) and to ensure a favourable balance between potential
burdens and benefits (CIOMS and WHO, 2016; Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014; Emanuel et al., 2004). I took this perspective when discussing emotional distress for verbal autopsy respondents. Here, I will use the moral distress framework to explore the social and ethical dimensions of emotional distress for verbal autopsy interviewers.

One can experience emotional distress without experiencing an ethically challenging situation and vice versa. For example, more senior research staff in this study shared their experiences of ethical uncertainties or dilemmas with little evidence that they experienced emotional distress from these situations. This is probably because of their distant location from the frontline of HDSS data collection. Verbal autopsy interviewers can experience emotional distress that may or may not be a response to ethically challenging situations from their perspective. Some verbal autopsy interviewers described being unable to forget disturbing details that verbal autopsy respondents shared. These details are likely to distress interviewers and HDSS research stakeholders should support interviewers to cope with these burdens.

However, most of these emotionally distressing situations were not cases of moral distress, as described earlier in this section. Discussions with study participants showed that interviewers could experience moral distress in two main ways. Firstly, verbal autopsy interviewers can experience moral distress when personal or institutional factors constrain them from doing what they think is right. Most interviewers feel that they have a responsibility to assist bereaved families, including through financial contributions and counselling. This perceived responsibility emanates from the interviewers’ need to adhere to bereavement practices, alleviate suffering, or maintain relationships with HDSS residents. Unlike other contexts, where field workers might feel that study participants’ expectations are too high, interviewers and other participants in this study agreed that it would be reasonable for interviewers to support bereaved families and verbal autopsy respondents. Despite being convinced of the right thing to do, interviewers often cannot help the bereaved because of various constraints (Chapter 6) including perceived lack of counselling skills and a lack of money. This left interviewers feeling helpless and frustrated.
A constraint to acting on moral judgement is a sufficient but not a necessary condition for moral distress (Morley et al., 2019). Individuals can experience emotional distress even when they act as they desire (Fourie, 2015; Morley et al., 2019). Discussions with verbal autopsy interviewers in this study showed that they occasionally make out-of-pocket contributions to help bereaved families. This resonates with empirical studies across sub-Saharan Africa, which show that ethics and research practices at the point of data collection might differ with those prescribed at the policy-level (Kingori, 2013; Van Zyl et al., 2019). For instance, Kingori (2013) reported that, against institutional ethics policies that focused on avoiding undue inducement and respecting individual autonomy, field workers in a medical research project in Kenya often issued money to deprived participants, as a way of exerting their moral agency (Kingori, 2013). But exerting one’s moral agency involves personal and professional risks, and taking such risks is also a key feature of moral distress (Dudzinski, 2016). If verbal autopsy interviewers give money to the bereaved in a context where this is explicitly or vaguely prohibited, there is a risk that this might adversely affect their careers if found out. In addition, assisting the bereaved can be a significant financial burden to verbal autopsy interviewers, given that HDSS involve long-term engagement of entire populations in deprived areas. In summary, verbal autopsy interviewers are likely to experience moral distress, regardless of any constraints to doing what they think is right.

Secondly, verbal autopsy interviewers can experience moral distress in relation to ethical uncertainties and dilemmas. Several interviewers reported experiencing ethical conflicts between their professional responsibilities, personal values, and the need to protect participants. Interviewers’ roles entail collecting cause of death data for all deceased HDSS residents, but sometimes interviewers may feel that they are imposing unnecessary burdens on respondents, leading to feelings of guilt. In addition, research ethics guidelines and practices require data collectors to explain the procedures, burdens and benefits of a proposed activity to potential participants (Boga et al., 2011; Emanuel et al., 2004). Although acknowledged by one interviewer, it is likely that some interviewers feel that they are deceiving respondents when they tell them that the verbal autopsy interview has potential long-term public health benefit. This is because the HDSS sites have operated for many years without obvious
public health benefits, from the perspectives of some field staff and community members. Other than these conflicts between professional responsibilities and personal values, interviewers may be uncertain about the right strategies to minimise burdens for respondents. One interviewer captured this uncertainty by saying that even when the HDSS procedures involve observing a reasonable locally defined mourning period before verbal autopsy interviews, some respondents cry every time they have to talk about the deceased. Hence, verbal autopsy interviewers may feel introducing burdens to respondents is inevitable, whether or not they accept and adhere to institutional procedures for protecting participants. These ethical uncertainties and dilemmas seem to contribute to verbal autopsy interviewers’ feelings of guilt, regret, frustration and other negative emotions.

7.3.7.4 Impacts of moral distress

So far, I have shown that verbal autopsy interviewers in HDSS sites within sub-Saharan Africa are likely to experience high levels of moral distress. Among health care workers, moral distress is associated with high staff turnover, burnout and compassion fatigue, which can adversely affect patient care (Corley, 2002; Rushton et al., 2015). Although they are essentially health research field workers, verbal autopsy interviewers have important similarities with health care workers; they routinely interact with individuals experiencing emotional distress and often encounter ethically challenging situations, given the sensitivity of death. The evidence on the impact of moral distress on verbal autopsy interviewers in this study is inconclusive: I did not set out to investigate moral distress or its impact but this concept emerged during the study. However, I did not find evidence of high staff turnover, with most of the verbal autopsy interviewers in this study having worked with the HDSS for many years. Also, while observing the verbal autopsy interviews, I found the interviewers to be sensitive and caring towards verbal autopsy respondents and bereaved families. Perhaps the low staff turnover reflects the lack of alternative job opportunities for HDSS residents.

Even without formal support mechanisms for interviewers to address the various challenges of conducting verbal autopsy, the interviewers seem to draw on informal support systems to cope with their emotional burden. The impact of long-term moral
distress on verbal autopsy interviewers in HDSS, including coping mechanisms, is a potential area of further qualitative and quantitative research.

The literature predominantly characterises moral distress as a negative phenomenon that should be reduced or eliminated (Tigard, 2019). Consequently, health research stakeholders have shared programmatic experiences of addressing moral distress. Programmes to address moral distress have involved creating awareness about patient care through education (Brandon et al., 2014), promoting interactions between different cadres of health care workers (Karanikola et al., 2014) and offering moral distress consultation services (Hamric & Epstein, 2017). Experiences from these programmes have highlighted the need for addressing the wider determinants of moral distress, such as institutional policies (Hamric & Epstein, 2017). However, the links between institutional policies and moral distress are likely to be complex rather than linear, and therefore require a nuanced understanding (Musto & Rodney, 2016). Furthermore, some have argued that moral distress is not an entirely negative phenomenon that we should always try to reduce or eliminate; experience of moral distress can show moral maturity, provide opportunities for moral lessons and highlight systemic weaknesses that need addressing (Dudzinski, 2016; Tigard, 2019). In all cases, most authors agree that we should identify and address the negative effects of moral distress. This thesis provides a nuanced account of moral distress among verbal autopsy interviewers in health and demographic surveillance systems in sub-Saharan Africa. The verbal autopsy interviewers’ moral distress arguably demonstrates their concern for the wellbeing of respondents, their need and ability to reflect ethically, and the system-wide implications of empirical and normative uncertainty in HDSS ethics. However, if this moral distress does not lead to improvements in HDSS policies and practices, and the experiences of individuals at the frontline, it would remain an unnecessary burden for verbal autopsy interviewers.

7.4 Moving beyond the frontline: broader benefits and burdens in HDSS and assessing social value

So far, I have discussed emotional distress for verbal autopsy respondents and moral distress for verbal autopsy interviewers, which emerged as the most severe burdens of HDSS. The moral distress that verbal autopsy interviewers experience highlights
systemic challenges in HDSS ethics practice and policy, and the importance of considering the social value of the HDSS.

7.4.1 The organisational influences on emotional burdens in HDSS

Regarding HDSS ethics practice and policy, I described in Chapter 2 that there are significant empirical and normative uncertainties in HDSS ethics (Carrel & Rennie, 2008; Joshi et al., 2018). For instance, there is a lack of clarity on the appropriate processes for consenting, timing of interviews, and the nature of burdens and benefits involved in verbal autopsy. The indistinct positioning of HDSS between research, health care and public health practice, and of verbal autopsy between routine HDSS and nested studies, coupled with international collaborations, means that HDSS stakeholders might rely on different (sometimes conflicting) strategies for addressing ethical issues. Given the inadequate empirical evidence and ethics guidelines (Carrel & Rennie, 2008; Joshi et al., 2018), HDSS managers and field staff have to grapple with a wide range of ethical challenges with little documented experience or formal guidance to draw upon.

In this thesis, I have shown that verbal autopsy interviewers seem to experience emotional distress and to encounter ethically challenging situations more frequently and intensely than other stakeholders. Despite their first-hand experience of ethical challenges and their important role in ensuring ethical practice, HDSS fieldworkers, including verbal autopsy interviewers, seem to have limited influence on formal HDSS ethics policy and practice. Verbal autopsy interviewers and other field workers usually have lower academic qualifications and training (including in research ethics) compared to research staff (Kombe, 2015; Molyneux et al., 2013) and are therefore in less senior positions in research institution hierarchies, with little apparent ability to change institutional policies and practices. I did find instances where the views and experiences of verbal autopsy interviewers contributed to changes in ethics practices in the case studies, as reported by the interviewers and research staff. These instances include introduction of condolence fees and a shift from written to verbal consenting in verbal autopsy, and consultation with HDSS fieldworkers on in Kilifi HDSS on appropriate consent processes for routine HDSS. In addition, this study provided the first opportunity for some interviewers to share their views and experiences of ethical issues in verbal autopsy, which could contribute to evidence-
based policy and practice in HDSS ethics. Regardless of these reported and potential influences on institutional policy and practice by HDSS field workers, this study highlighted the prevalent feelings of powerlessness and other negative emotions among HDSS field staff, which may contribute to the moral distress described above. As I will discuss in Section 7.5, HDSS research stakeholders should support programmes that would enable HDSS field staff to regularly share their experiences of ethically challenging situations, as has been described in research and health care settings (Hamric & Epstein, 2017; Jepkosgei et al., 2019; Molyneux et al., 2016).

7.4.2 The wider burdens of HDSS

Beyond the emotional burdens of verbal autopsy respondents and interviewers, this study highlighted other potential burdens for HDSS respondents, communities and local health systems, as described in Chapters 4 and 6. These include invasion of privacy, fatigue, time and economic costs, community stigmatisation and reputational damage. For instance, I reported that interviewers collect information about pregnancy from all females of a reproductive age and usually in communal settings. Most of the interviewers I observed could ask this question discretely, but this and other questions pose a risk to residents' privacy. In addition, the time taken in an HDSS routine census or verbal autopsy interview can be significant depending on number of household members and the emotional state of the respondent, and it is a time burden that is repeated every three months (routine census), indefinitely.

A well acknowledged potential burden of health-related research in developing countries is that they might supplant the local health system (Emanuel et al., 2004). As I described in Chapters 2 and 4, some HDSS operate health facilities, which could arguably impede the development of official local health systems. Also, the HDSS could provide services that have traditionally been the responsibility governments. For instance, I learned through field observations that some HDSS residents use the HDSS numbering of residential units as informal house addresses. In addition, some participants mentioned that HDSS, especially the sensitive verbal autopsy interviews could damage the reputation of host research centres and associated health facilities, adversely affecting research and treatment seeking among residents. Overall, HDSS procedures could lead to new relationships between research and community
stakeholders (Twine et al., 2017) that might supplant official health and civil registration systems.

Most of these wider burdens were not commonly described by study participants, and HDSS stakeholders might not feel that they are significant. However, based on field observations, and recognizing the universality and longitudinality of HDSS, HDSS residents are likely to experience these other burdens more often compared to the burdens of verbal autopsy, which are relatively infrequent for residents. While the HDSS is presented as one programme, it is essentially composed of different research procedures with varying levels of benefits and burdens. Given that ethics scholars have recommended that research stakeholders should assess and aggregate the risks for each procedure in a study (CIOMS and WHO, 2016; Westra et al., 2011), it may be that the burdens of HDSS to communities, as well as frontline staff, in sub-Saharan Africa are generally underestimated.

7.4.3 Assessing the social value of HDSS

From a public health ethics perspective, conducting research that subjects individuals and communities to some burdens can constitute ethical practice, as long as the research has social value (Baum et al., 2007; CIOMS and WHO, 2016; Emanuel et al., 2004; Klingler et al., 2017; Rubel, 2012; Salerno et al., 2019). Most ethics scholars point out that the social value or public benefits should not be abstract; practitioners need to provide evidence of benefits or evidence that a particular intervention is likely to be effective (Baum et al., 2007; Kass, 2001; Klingler et al., 2017). However, it can be difficult to measure the social value of complex health programmes and research especially in contexts that lack appropriate systems to translate research evidence into practice and policy, and to evaluate interventions (Black & Donald, 2001; Emanuel et al., 2004; Hanney et al., 2003; Pawson et al., 2004).

Emanuel et al (Emanuel et al., 2004), outlined an ethical framework for assessing the social value of health-related research in developing countries. In this framework, research stakeholders should specify research beneficiaries, enhance the value of the research including through collaborative partnerships and minimise burdens, to ensure the social value of research (Emanuel et al., 2004). As I have highlighted throughout this thesis, HDSS have operated for many years in sub-Saharan Africa,
Asia and Oceania but there is limited empirical evidence on burdens, benefits and other ethical issues in HDSS sites (Carrel & Rennie, 2008; Hyder et al., 2012; Joshi et al., 2018; Sankoh & Byass, 2012). Scholars, including HDSS research stakeholders, have highlighted that HDSS sites operate primarily for research purposes and with limited linkages to local health care and civil registration systems (de Savigny et al., 2017; Sankoh & Byass, 2015; Savigny et al., 2018). In this study I identified some public benefits from HDSS including provision of free and emergency health care services to HDSS residents, employment opportunities, and increased national and global awareness of public health problems in the HDSS areas through publications in scientific journals. This social value is difficult to measure and evaluate, and has an indirect and long term link back to HDSS communities themselves, if any. The direct and indirect benefits of reliable population-level data such as CRVS is well acknowledged (Mikkelsen et al., 2015; Phillips et al., 2015), and one might expect HDSS data to have similar benefits. Notably, my study contributes substantial empirical evidence of burdens at the frontline of HDSS in sub-Saharan Africa, which should be considered together with the actual or potential benefits of HDSS.

7.4.4 Social determinants of ethical issues in HDSS across sub-Saharan Africa

Social relationships have a significant influence on ethical issues in HDSS, as I have highlighted throughout this thesis. For a more direct discussion of social relationships and their influences on ethical issues in HDSS, I will apply three theoretical concepts in social relationships; power, social capital and the capability approach. Social capital refers to the resources found in social relationships (Woolcock, 2001). These can include trust, norms of reciprocity and membership in social groups (Bourdieu, 1986; Ehsan et al., 2019; Putnam, 2000). Sociologists have focused on studying the distribution of social capital in society or on the impacts of social capital on health (Kawachi et al., 2008; Moore, 2006). The social capital concept provides a valuable framework for understanding social inequalities and drivers of collective action (Bourdieu, 1986; Moore, 2006; Putnam, 2000). At its broadest conceptualisation, power is the ability to influence others and to achieve one’s will (Clegg & Haugaard, 2009). There are different sources, levels and manifestations of power in social relationships. For example, individuals and organisations can derive power from technical expertise, personality, social networks or access to money (Pantazidou, 2012; Sriram et al., 2018). Applying this concept enables an in-depth understanding of
the social aspects of policymaking and programme implementation. The central issue addressed by the capability approach is human capability. A capability is a person’s potential to be or do (collectively referred to as functioning) something that they have reason to value (Alkire, 2005; Sen, 1990). For example, the capability to be healthy (Venkatapuram et al., 2015). The capability approach places human wellbeing at the centre of normative evaluations, such as social justice and measuring poverty (Robeyns, 2003). These three concepts are powerful lenses for examining the nature and influences of social relationships on HDSS ethics. Since I have already discussed most of these social aspects of ethical issues especially for verbal autopsy, I will apply the three theoretical concepts to the empirical evidence in this study to give an overview of social relationships and ethical issues in HDSS, including perspectives from different HDSS stakeholders, sites across sub-Saharan Africa and focusing on a wide range of ethical processes.

7.4.4.1 Ethics review of HDSS in sub-Saharan Africa

Ethics review for HDSS in sub-Saharan Africa has been shifting from informal to formal processes. Most sites started their activities following approval from government and HDSS communities and operated for many years without formal annual ethics review by an ethics review committee. Currently, most of these sites submit annual reports or requests for ethics approval to various ethics review committees. High social capital is associated with informality; it acts as a lubricant of social relations by reducing transaction costs. In social groups where there are high levels of trust and reciprocity, people are unlikely to need formalised structures of social interactions (Putnam, 2000). This shift from informal to formal ethics review in HDSS, which also affected other forms of health-related research across Africa (Kass et al., 2007; Nyika et al., 2009), indicates a reduction of social capital, especially trust.

The establishment of formal ethics review processes seems to have altered the power balance among HDSS stakeholders. Initially, some research centres were able to avoid submitting HDSS protocols to formal ethics review processes, as I described in Chapter 4. This exemption was not only influenced by uncertainties over ethics oversight for HDSS, but also the ability of HDSS research staff to leverage on their research expertise, goodwill from government and community acceptability. Over
time, government agencies and ethics review committees have exerted their powers requiring all research activities, including HDSS, to undergo ethics review and approval. Although some research staff felt that the current ethics oversight processes are inappropriate for HDSS, most HDSS research staff felt obliged to adhere to research regulations by government and ethics review committees. Furthermore, HDSS sites have been unable to leverage on their membership to the INDEPTH Network to influence international and national ethics guidelines in favour of HDSS. Currently, ethics review committees seem to hold most of the power in relation to ethics oversight since they are able to influence ethical practices in HDSS, such as prescribing written informed consent or annual renewal of ethics approval for HDSS, sometimes against the wishes of HDSS research staff.

7.4.4.2 Informed Consent and community engagement in HDSS: Cognitive social capital and power

As this and other studies have shown, trust and norms of reciprocity influence consenting practices in health-related research. In particular, relationships between participants and field staff, community perceptions of research institutions and expectations of direct individual benefits can have a significant influence on consenting practices. This study adds onto the extensive literature around the challenges of obtaining informed consent for health-related research in low-income settings (Azétosop & Rennie, 2010; Baiden et al., 2016; Boga et al., 2011; Gikonyo et al., 2008; Kingori, 2013; Molyneux, Peshu, et al., 2005; Mungwira & Nyangulu, 2015). Cognitive social capital refers to the perception of trust and reciprocity (Ehsan et al., 2019; Kawachi et al., 2008). The longitudinality and universality of HDSS seem to increase social capital. HDSS field workers interact with HDSS residents often, which could create a sense of familiarity and increase perceptions of trust and expectations of reciprocity. Furthermore, HDSS host research centres have been implementing various community engagement strategies that might increase perceptions of reciprocity and trust. These strategies, which I described in sections 2.2.3, 4.2.3, 4.3 and 5.6, include holding community meetings to build mutual understanding of HDSS, maintaining networks of community representatives and recruiting field workers and community key informants locally.
Carrel and Rennie (2008) pointed out that it is challenging for individual residents and households to withdraw from a HDSS because research staff obtain consent at the community and household level. Some individuals might only participate in HDSS to avoid damaging relations with other household and community members (Carrel & Rennie, 2008). Also, they might not be consulted in making decisions on whether to participate in HDSS. Although some HDSS research staff attribute low refusal rates to successful community engagement strategies and high levels of trust in the host research centres, these low refusal rates could also indicate the unequal power dynamics among HDSS stakeholders; power of household heads over other household members and power of research staff and institutions over HDSS residents.

7.4.4.3 Benefits and burdens in HDSS: Community and research stakeholders

HDSS stakeholders experience benefits and burdens depending on their positioning in the social hierarchy. As I have described throughout this thesis, the main benefits of HDSS are linked to the use of data, information sharing and employment opportunities while the main burdens result from interactions between field workers and residents during data collection.

7.4.4.3.1 HDSS field workers social positioning

HDSS Field workers are socially positioned between HDSS researchers and community members. They are recruited from local communities primarily to collect HDSS data. This social positioning influences the benefits and burdens that the field workers experience. Most HDSS communities face diverse health and socioeconomic challenges and field workers may have uncertain career pathways, limited academic qualifications and research skills. Therefore, field workers recruited locally might be unable to use HDSS data, such as publishing research articles, to advance their careers. But the field workers may enjoy a high social status in the community because of their regular interaction with community members, affiliation with research centres and by having formal employment. Bonding social capital refers to the resources available to individuals from relatives, close friends, neighbours or other individuals with similar socio-demographic characteristics (Ehsan et al., 2019). Field workers are able to some extent to leverage on bonding social capital to secure
and maintain employment with HDSS host research centres. Their knowledge of local languages and culture, including their relationships with other community members, makes them essential for conducting research. This social capital can work to the advantage for field workers in power relations with other HDSS research staff and community members.

The social positioning of HDSS field workers also contributes to their emotional and socioeconomic burdens. As I have discussed so far in this thesis, HDSS field workers encounter high expectations from community members but fieldworkers often have limited resources to respond to these expectations fully. For example, they might be expected or feel obliged to issue condolence fees to bereaved families because of their social status (employed), relationship with the bereaved (neighbour or relative) or need to adhere to cultural practices (shared faith or ethnicity). Their inability to meet these expectations might also be influenced by institutional policies that do not account for the complex social roles of field workers as both research staff and members of the local community. Furthermore, field workers might not have the professional skills and financial resources required to respond to the emotional and socioeconomic challenges of collecting data in HDSS. These nuanced social relationships between HDSS field workers and community members, and the reduced capabilities of these two groups of HDSS stakeholders, influence burdens for HDSS field workers.

7.4.4.3.2 HDSS residents and researchers: Their powers, social capital and capabilities

The ability to access and use social capital, and other forms of capital, is not equally distributed in society (Bourdieu, 1986). For example, not all community members are able to leverage on bonding social capital to secure employment in HDSS. In most HDSS, the majority of field workers are male and often recruited from the dominant local ethnic groups. Although the main benefits of HDSS include the use of data (for instance, publications and policymaking) and information (for instance, learning about cause of death), most HDSS residents do not access HDSS results or analyse HDSS data. This inability of most HDSS residents to directly benefit from HDSS is linked to long-term socio-economic deprivation. In addition, female residents are disproportionately represented among HDSS respondents and are likely to bear most of the burdens associated with HDSS data collection, as I discussed in section 7.3.6.
Compared to HDSS community members, researchers are more likely to benefit from HDSS data because they have more research training, higher academic qualifications and professional networks. In theory, anyone with data analysis skills and access to internet can use HDSS data, given that most HDSS data are available online (Herbst et al., 2015; Sankoh et al., 2013). From a capability approach perspective, the open data movement and data sharing initiatives by the INDEPTH Network have expanded the capabilities of individuals, institutions and countries across the world to benefit from HDSS data. In practice, researchers with stronger social networks and capacity to analyse data and publish in scientific journals, including those working in research centres outside sub-Saharan Africa, seem to benefit the most from HDSS data.

7.4.4.3.3 Conclusions

Social relationships among HDSS stakeholders have a significant influence on HDSS ethics, including issues around ethics oversight, consenting, community engagement, burdens, benefits and data sharing. These relationships are characterised by profound inequalities within and between communities, institutions, individuals, professions and countries. These inequalities, coupled with HDSS procedures and policies, mean that HDSS stakeholders possess and use different forms of power, social capital and capabilities. For most of this thesis, I have combined empirical evidence with ethics principles, frameworks and guidelines to recommend that HDSS research stakeholders should focus on reducing emotional burdens for individuals and on enhancing the social value of HDSS. Applying the concepts of power, social capital and capability approach would lead to similar recommendations but emphasise the importance of understanding power relations among HDSS stakeholders and how they shape ethics policy and practice, the value of enhancing trust-building strategies to increase social capital and the need to prioritise the wellbeing of HDSS residents and frontline research staff.

7.5 Study Recommendations and Conclusions

I set out to explore the key ethical issues for health and demographic surveillance systems in sub-Saharan Africa and to make recommendations on how research stakeholders should address potential ethical issues in HDSS. Through empirical research involving multiple sources of evidence in HDSS across sub-Saharan Africa, I
highlighted the significant emotional burdens for verbal autopsy respondents and interviewers and the limited evidence of social value in HDSS.

Overall, I suggest that the benefits and burdens of HDSS are disproportionately distributed among stakeholders. Verbal autopsy respondents and interviewers seem to bear most of the severe burdens in HDSS, especially emotional and moral distress. In addition, HDSS residents are exposed to a wide range of risks (such as risks to privacy) regularly over a long, often indefinite, period. The HDSS support various health-related research and have contributed to publications on the health and lives of HDSS residents, which could inform policy and practice at the local, national and international level. However, this potential social value of HDSS is not well-articulated or demonstrated in practice.

This makes it challenging to ethically justify HDSS in their current form, regardless of the ethics analysis framework adopted. Given the potential burdens to individuals and communities highlighted by this study, and considering the absence of specifically tailored ethics oversight systems, it is important for HDSS research stakeholders to establish strategies for minimising burdens for individuals, and to enhance or demonstrate the social value of HDSS. In this section, I make recommendations for policy and practice towards minimising burdens and enhancing the social value of HDSS in sub-Saharan Africa.

7.5.1 HDSS field worker recruitment, training, and support

This thesis supports previous recommendations for more investment in capacity building for field workers, including context-specific training, career development and institutional recognition of field workers’ complex roles (Kombe, 2015). Specifically for verbal autopsy, some have argued that interviewers should have minimum counselling skills that would enable them to comfort emotionally distressed respondents (Chandramohan et al., 2005). Most interviewers in this study also felt that they required bereavement counselling skills that they could use to minimise burdens for respondents. In addition, some felt that training on professional counselling would enhance their careers.
However, the overall analysis in this study indicates that training verbal autopsy interviewers as professional counsellors (formal training in an academic institution) alone, is unlikely to minimise burdens for respondents or address the challenges of the verbal autopsy interviewers. To start with, requiring interviewers to provide professional counselling at the point of data collection is likely to increase the time and economic costs for respondents, and to increase expectations of interviewers. Given that most of the interviewers reported being able to comfort the bereaved even without professional training in counselling, and the costs of counselling training to HDSS, requiring interviewers to offer counselling services might not be appropriate or feasible in many HDSS. Even if such training in counselling for interviewers were possible, it could raise further challenges. As I noted earlier, the empirical evidence in this study indicates there has been little staff turnover among interviewers in the case studies perhaps because of few alternative career options. Therefore, it is likely that verbal autopsy interviewers, once qualified as professional counsellors would leave the HDSS team. This would require HDSS to regularly train new staff, with adverse cost implications as well as negative implications for good quality, comforting, verbal autopsy interactions with respondents.

Training verbal autopsy interviewers and other field workers should be part of institutional policy and practice to improve the working conditions of the field workers. To meet the interests of respondents, interviewers and research institutions, research stakeholders should explore strategies to train fieldworkers in handling emotionally stressful situations, and to allow verbal autopsy interviewers and other HDSS fieldworkers to contribute regularly to discussions on ethics issues at the front line. The latter is particularly important in supporting respectful practice in locally appropriate ways because verbal autopsy interviewers and HDSS field workers are recruited partly because of their knowledge of local communities and experience with field procedures. New supportive strategies could include regular ethics reflections sessions with fieldworkers to share their experiences of ethically sensitive situations during data collection. Such ethics reflections sessions have been shown to be feasible, sustainable and useful, including in research contexts within sub-Saharan Africa (Jepkosgei et al., 2019; Molyneux et al., 2016). In addition, HDSS research stakeholders could explore moral distress consultation services (Hamric & Epstein,
2017), where interviewers (after encountering a particularly distressing case) can request a meeting with a trained counsellor to discuss and reflect on the experience. These approaches seem likely to mitigate the emotional and moral distress of HDSS field workers.

7.5.1.1 Recruitment of verbal autopsy interviewers

HDSS sites have traditionally recruited the most experienced local HDSS fieldworkers as verbal autopsy interviewers. This is because the verbal autopsy questionnaire is relatively complex to administer compared to the routine HDSS census. Nevertheless, through regular revisions of verbal autopsy methods over the years, the current verbal autopsy questionnaires are relatively short with many close-ended questions (Caleo et al., 2018; Flaxman et al., 2018; Leitao et al., 2014; E. Nichols et al., 2013). Consequently, individuals with limited academic qualifications and experience of collecting research data can collect cause of death data (Hutain et al., 2019; Nabukalu et al., 2019). There have also been increasing calls to scale up verbal autopsy methods for use in routine registration systems (D’Ambruoso et al., 2017; de Savigny et al., 2017; Sankoh & Byass, 2014). These developments seem to underestimate the potential burdens for verbal autopsy respondents and interviewers described in this study. For interviewers, collecting verbal autopsy data goes way beyond asking the highly-standardised verbal autopsy questions; it involves addressing various health, emotional and socioeconomic challenges. Inability to appropriately respond to these challenges may adversely affect social relations and the scientific validity of verbal autopsy data. Therefore, HDSS research stakeholders should recruit diverse interviewers (male and female), with experience of collecting research data, and prioritise the ongoing training and support of these interviewers to address the social and ethical sensitivities of verbal autopsy.

7.5.2 Consenting practices for routine HDSS census and verbal autopsy interview

Recognising that HDSS research and community stakeholders should identify context-specific consent processes, including through community engagement and research, it seems that verbal consenting for verbal autopsy and routine HDSS census interviews is associated with the least burdens. Empirical evidence in this study indicates that written consent in HDSS in sub-Saharan Africa is likely to increase
burdens for stakeholders without achieving its intended practical and ethical goals. Furthermore, there are alternative methods for demonstrating respect for study participants and to prevent research malpractices in data collection. Alternative methods include carefully planned community engagement strategies and supporting field workers to collect data in a respectful and ethical manner.

Adopting verbal consenting in some sites will require engagement and consultations with research ethics committees to determine the appropriate consenting practices for HDSS. It should be noted that verbal informed consent still requires careful consent processes; it is just that information and consent sheets are not signed by participants. Research ethics committees can waive requirements for individual informed consent altogether, if research stakeholders can demonstrate that the proposed research activity would not be possible if individual consent was required, that it has social value and that there is minimal risk (CIOMS and WHO, 2016). Most sites have been able to show that it would be nearly impossible to obtain individual informed consent from every single adult HDSS resident in every home. It is also challenging to show that HDSS has minimal risk or social value. Evidence from this study shows that written consent from every individual is likely to increase burdens and that HDSS research activities differ in their level of risks to respondents. Therefore, I recommend verbal consent by household heads and those adults present in households when HDSS visits take place. To strengthen the argument for verbal consent by present household heads, research stakeholders should focus on training of frontline staff in ethics, informed consent and good communication, and work to enhance and demonstrate the social value of HDSS.

7.5.3 Compensation for verbal autopsy respondents

HDSS research stakeholders should compensate verbal autopsy respondents, as research participants, instead of offering condolence fees. Verbal autopsy interviews involve burdens, including emotional distress, time and economic costs, with little to no benefits for individual respondents. Individuals who participate in similar research procedures are usually compensated for time and research risks. Some HDSS sites offer condolence fees to verbal autopsy respondents. However, these fees are given informally and as goodwill leading to inconsistencies that might damage reputations. Instead of condolence fees, verbal autopsy projects should have dedicated funds for
compensating respondents. Paying participants is a common practice in health research, which also raises ethical concerns ranging from risks of undue inducement to coercion (Grady, 2019). Some have argued that the socioeconomic context in most LMICs is already too coercive even without payments (Kingori, 2013) and that researchers should focus on assessing and compensating the costs of research participation (Njue et al., 2014). In addition, public health ethics scholars have argued that the costs of conducting a public health programme should be a key ethical consideration given the opportunity cost involved in public health (Baum et al., 2007). Given the large scale nature of verbal autopsy in the context of HDSS, one could argue that paying verbal autopsy would be costly or impractical. However, HDSS support research projects every year where participants are compensated, the verbal autopsy is conducted in a research rather than public health context and there seems to be significant uncompensated burdens of participating in a verbal autopsy interview. Therefore, the evidence suggests that research stakeholders (research centres, funders) should compensate verbal autopsy respondents. Compensation in HDSS should be accompanied by community engagement to build awareness about the amount and purpose of the compensation. In particular, compensation for verbal autopsy, rather than condolence fees, is likely to ensure fairness, and minimise burdens for verbal autopsy interviewers, respondents and research centres.

7.5.4 Enhancing the social value of HDSS

Research stakeholders justify HDSS based on the assumed social value. Such justifications include the potential for HDSS to provide data for research, policy-making and improvement of health (Bangha et al., 2010; Sankoh & Byass, 2015; Ye et al., 2012). However, in order to address the disproportionate distribution of benefits and burdens in HDSS, and to justify various HDSS ethics processes, research stakeholders need to enhance and demonstrate the social value of HDSS. In particular, HDSS research stakeholders should strengthen the careful assessment of community level benefits (Njue et al., 2014). In addition, they should engage with local, national and international stakeholders to enhance the translation of HDSS evidence into policy and practice.

In particular, HDSS research stakeholders should work closely with civil and vital registration offices to issue legal documents to HDSS residents (especially birth and
death certificates) and to strengthen data quality in routine systems. This would increase direct benefits for individuals and institutions, and entire HDSS communities. Furthermore, HDSS should use the research data for advocacy, either themselves, or through developing collaborations with individuals and organisations better placed to use the data to have a positive impact. HDSS collect detailed data about the lives and health of residents and such data can be used to highlight and address social injustices. Finally, HDSS research stakeholders should strengthen international networks to enhance the uptake of research, promotion of HDSS methodology and establishment of new HDSS sites in strategic locations. These strategies for ensuring the social value of HDSS should be viewed as ethical requirements for the existence of HDSS in sub-Saharan Africa.

7.5.5 Future Research

Throughout this thesis, I have highlighted areas that need further research and consultation. Further research in the following three areas would be particularly useful.

7.5.5.1 Piloting and evaluation of training and support programmes for HDSS field workers

HDSS field workers, especially verbal autopsy interviewers, face unique challenges. Therefore, in addition to regular training for field workers on the technical aspects of data collection, research stakeholders should design and evaluate customised training and support systems for HDSS field workers. This can include ethics and moral distress consultation services. As I described, such support programmes have been shown to be feasible in research and health care settings including in sub-Saharan Africa. A careful documentation and evaluation of training and support systems across diverse settings would be invaluable for all HDSS sites, and for frontline health and research staff more widely.

7.5.5.2 Assessing the emotional burdens of verbal autopsy respondents and interviewers

This study has highlighted the emotional and moral distress of verbal autopsy respondents and interviewers. However, further qualitative and quantitative research is needed to examine the extent and nature of these burdens in different contexts more deeply. For instance, researchers could explore the emotional distress of verbal
autopsy respondents depending on cause of death. In addition, they could assess the levels and impacts of moral distress using the various moral distress measures that have been developed over the years (Dudzinski, 2016; Morley et al., 2019). Such studies may suggest changes in how verbal autopsy is conducted in certain contexts to minimise moral distress. The longitudinal approach of the HDSS provides a suitable platform for assessing the development, features, management and outcomes of moral distress, and strategies to ease this, among field workers over time.

7.5.5.3 Exploring the social value of HDSS

Demonstrating social value is essential for ethically justifying HDSS, given the disproportionate distribution of benefits and burdens. This study identified potential benefits of HDSS that might be difficult to determine using the conventional measures of research benefits used in qualitative and quantitative evaluations of benefits in HDSS. Researchers can assess the impact of regular HDSS household visits and HDSS procedures on the capabilities and functioning of HDSS residents, including access to services and being part of a community (Deneulin & McGregor, 2010; Nussbaum, 2003; Robeyns, 2007). Most research and community stakeholders mentioned that the HDSS creates employment and other indirect economic benefits for the local HDSS communities. While this is plausible, there is limited empirical evidence on the economic impact of HDSS sites. Other scholars have also pointed out the long-term research projects should incorporate economic impact assessment (Hyder et al., 2012). Given that HDSS bring together diverse researchers, and collect a wide range of data from the target population, it might be possible to conduct economic impact assessments (including cost-effectiveness of HDSS procedures) that would contribute to the overall assessment of the social value of HDSS. Some public health ethics scholars have argued that the ultimate goal of public health interventions (including the key outcome measure) should be to reduce morbidity and mortality at the population level (Baum et al., 2007; Kass, 2001; Klingler et al., 2017). As I showed in Chapter 6, most community members support HDSS on the expectation that they will address public health challenges, including at the community level, while research staff felt that HDSS can improve public health and advance science. However, there is little empirical evidence of the impact of HDSS on morbidity and mortality. Statistical analyses have shown that well-functioning civil
registration and vital statistics systems improve health; that they are public health interventions (Phillips et al., 2015). Similar statistical analyses would provide the much needed evidence on the social value of HDSS.

7.6 Conclusion

In this thesis, I have shown that HDSS in sub-Saharan Africa present important ethical challenges that researchers have not previously described in detail. These challenges include severe emotional burdens for verbal autopsy respondents and interviewers, and the disproportionate distribution of benefits and burdens among HDSS stakeholders. I have argued that HDSS in sub-Saharan Africa that include the verbal autopsy are unlikely to be minimal risk activities from the perspective of HDSS residents and field staff. I have based my arguments on evidence from a comprehensive empirical ethics study that combined the views and experiences of HDSS stakeholders across sub-Saharan Africa with ethical analysis informed by the wider ethics and social science literature. In the following paragraphs, I summarise my views on HDSS ethics, including recommendations for strengthening HDSS ethics practice and policy.

To determine whether an activity is ethical, one needs to assess the activity against a specified ethical standard. Ethics scholars and governance institutions have developed ethical standards either for research or non-research health-related activities (CIOMS and WHO, 2016; Department of Health, Education & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014; Emanuel et al., 2004; Klingler et al., 2017; Luyckx et al., 2017; Otto et al., 2014; Wassenaar & Rattani, 2016). Although some have pointed out the practical and ethical challenges of distinguishing research from non-research (practice) health-related activities (Kass et al., 2013; Salerno et al., 2019), the research-practice distinction continues to shape contemporary ethical debates and processes in health-related activities (Doshi, 2020; Swaminathan et al., 2020; Weijer, 2020). Recognising the challenges and potential value of the research-practice distinction, the history, current functioning and objectives of HDSS across sub-Saharan Africa, I have argued that HDSS are non-traditional health-related research. Consequently, we should assess ethical issues in HDSS against a wide range of ethical standards, including
standards developed for non-research health-related activities, such as health care, public health surveillance, and health-related research.

Ethical standards for health-related activities aim to balance multiple interests and ethics principles in defining an ethical activity. Discussions about benefits and burdens, whether at the individual or population level, are prominent in most ethical standards. The evidence in this thesis suggests that HDSS that include the verbal autopsy are unlikely to be minimal risk activities, as it has previously been suggested in the literature. These HDSS are likely to involve severe emotional burdens for verbal autopsy respondents and interviewers, and repeated exposures to minor burdens for many HDSS residents, field staff, communities and affiliated institutions. It is currently thought that HDSS have a high social value that outweighs any potential burdens, but these potential burdens, or risks, had not been well described before this study. It is plausible that HDSS have public and long-term benefits at the local, national and global level. HDSS have provided population-level data, which have supported a wide range of health-related research and the generation of global health estimates; this contribution is well documented in the literature. Therefore, one could argue that some of the potential social value of research and global health estimates should be attributed to HDSS. This study found limited empirical evidence of HDSS benefits for local communities.

A holistic ethical assessment of an activity can inform judgements on whether the activity is ethical, recommendations for strengthening ethical processes or terminating the activity. My assessment of ethical issues in HDSS involved collecting empirical evidence, defining HDSS as non-traditional health-related research and applying diverse ethical standards. First, I conclude that the current conduct of routine HDSS surveillance does not generate significant ethical challenges and should therefore continue. Most participants in this study agreed that collecting HDSS data is necessary to provide population-level data, given the lack of well-functioning CRVS in HDSS areas. Furthermore, public health ethics scholars have argued that it is ethical for some individuals to bear minor burdens to promote the common good. Second, I recommend that HDSS research stakeholders should consider halting verbal autopsy interviews that are likely to cause particularly high levels of emotional distress for respondents and interviewers. It is unethical to subject individuals to health-related
research activities with significant risks and injustices regardless of the potential social value, and when the goals of the activity can be achieved through alternative methods (CIOMS and WHO, 2016). HDSS research stakeholders could stop conducting verbal autopsies for deaths from shooting, suicide, road traffic injuries and deaths that occur in health facilities affiliated with the HDSS. Routine HDSS census interviewers and community key informants collect information that is sufficient to determine the causes of such deaths; conducting a verbal autopsy interview when the cause of death is known would constitute exposing individuals to unnecessary burdens.

Besides identifying the key ethical issues in HDSS and outlining how research stakeholders should address these issues, I have made additional recommendations for strengthening ethical practices in HDSS in sub-Saharan Africa. Drawing from empirical evidence in this study and the wider ethics and social science literature, I have recommended that HDSS research stakeholders should prioritise the training and support of HDSS field workers, verbal consenting and consider compensating verbal autopsy respondents. In addition, I have recommended that HDSS research stakeholders should invest in understanding power relations among HDSS stakeholders and building trust, and that they should consider the promotion of human wellbeing as a central goal of operating a HDSS. Adopting these practices and values could ensure that HDSS in sub-Saharan Africa are efficient, respectful and fair.

Translating these recommendations into policy and practice, in the case studies and other HDSS sites, will require further multidisciplinary research and consultation. HDSS research stakeholders could conduct pilot studies to assess the feasibility of alternative methods of collecting data, psychological studies to quantify emotional burdens, social science studies to explore the nature and outcomes of power relations among HDSS stakeholders, economic impact assessment and statistical analyses to evaluate the social value of HDSS and empirical ethics studies, like the case study described in this thesis. In addition, HDSS research stakeholders would need to engage with ethics review committees, community members and policymakers to assess the acceptability of proposed changes in HDSS ethics processes, such as verbal consenting and partnerships with CRVS. If more HDSS research stakeholders across LMICs conducted multidisciplinary research on ethical
issues and shared context-specific experiences of addressing ethical challenges, then this could contribute to the development of international ethics guidelines for HDSS and similar non-traditional health-related research. In this thesis, I have identified the key ethical issues for HDSS in sub-Saharan Africa and made specific recommendations on how research stakeholders should address these issues to promote ethical policies and practices in HDSS.
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Appendix 1 2012 WHO Verbal Autopsy sample questionnaire

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<th>CODING CATEGORIES</th>
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<tbody>
<tr>
<td>2A120</td>
<td>Name of verbal autopsy interviewer:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Surname</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Name</td>
<td></td>
</tr>
</tbody>
</table>
2A140 RECORD THE DATE OF INTERVIEW

DAY

MONTH

YEAR

2A130 RECORD THE TIME AT START OF INTERVIEW

MORNING/EVENING

MORNING =1

EVENING=2

HOUR

MINUTES

2A100 Name of verbal autopsy respondent:

Surname

Name

2A110 What is your relationship to the deceased?

FATHER

MOTHER

SPOUSE

SIBLING

OTHER RELATIVE

(SPECIFY)

NO RELATION

2A115 Did you live with the deceased in the period leading to her/his death?

YES

NO

SECTION 2. INFORMATION ON THE DECEASED AND DATE/PLACE OF DEATH

1A100 What was the name of the deceased?

Surname

Name
<table>
<thead>
<tr>
<th>NO.</th>
<th>QUESTIONS AND FILTERS</th>
<th>CODING CATEGORIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A110</td>
<td>Was the deceased female or male?</td>
<td>FEMALE MALE</td>
</tr>
<tr>
<td>1A200</td>
<td>Is date of birth known?</td>
<td>YES NO</td>
</tr>
<tr>
<td></td>
<td>+ When was the deceased born?</td>
<td>DAY MONTH YEAR</td>
</tr>
<tr>
<td>1A210</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is date of death known?</td>
<td>YES NO</td>
</tr>
<tr>
<td></td>
<td>+ When did s/he die?</td>
<td>DAY MONTH YEAR</td>
</tr>
<tr>
<td>1A230</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1A240</td>
<td>How old was the deceased when s/he died?</td>
<td>AGE IN YEARS</td>
</tr>
<tr>
<td>1A400</td>
<td>Was this a woman who died more than 42 days but less than 1 year after being pregnant or delivering a baby?</td>
<td>YES NO DON'T KNOW</td>
</tr>
<tr>
<td>1A500</td>
<td>What was her/his citizenship/nationality?</td>
<td>CITIZEN BY BIRTH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NATURALIZED CITIZ.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ALIEN</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>1A510</td>
<td><strong>What was her/his ethnicity?</strong></td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>--------------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ETHNICITY A</td>
<td></td>
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<td></td>
<td>ETHNICITY B</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ETHNICITY C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OTHER (specify)</td>
<td></td>
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</table>

<table>
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<tr>
<th>1A520</th>
<th><strong>What was her/his place of birth?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Larger admin area (e.g., province)</td>
</tr>
<tr>
<td></td>
<td>LARGER ADMIN AREA</td>
</tr>
<tr>
<td></td>
<td>SMALLER ADMIN AREA</td>
</tr>
<tr>
<td>2</td>
<td>Smaller admin area (e.g., county)</td>
</tr>
<tr>
<td></td>
<td>LOCALITY</td>
</tr>
<tr>
<td>3</td>
<td>Locality (e.g., city, village)</td>
</tr>
<tr>
<td>4</td>
<td>Urban/Rural</td>
</tr>
<tr>
<td>5</td>
<td>Other country</td>
</tr>
<tr>
<td></td>
<td>OTHER COUNTRY (specify)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1A530</th>
<th><strong>What was her/his place of usual residence?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Larger admin area (e.g., province)</td>
</tr>
<tr>
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<td>LARGER ADMIN AREA</td>
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<tr>
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<td>SMALLER ADMIN AREA</td>
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<tr>
<td>2</td>
<td>Smaller admin area (e.g., county)</td>
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<td>LOCALITY</td>
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<tr>
<td>3</td>
<td>Locality (e.g., city, village)</td>
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<tr>
<td>4</td>
<td>Urban/Rural</td>
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<td>5</td>
<td>Other country</td>
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<td>OTHER COUNTRY (specify)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1A540</th>
<th><strong>What was her/his place of normal residence 1 to 5 years before death?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Larger admin area (e.g., province)</td>
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<tr>
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<td>LARGER ADMIN AREA</td>
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<tr>
<td></td>
<td>SMALLER ADMIN AREA</td>
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<tr>
<td>2</td>
<td>Smaller admin area (e.g., county)</td>
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<tr>
<td></td>
<td>LOCALITY</td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td></td>
<td>3 Locality (e.g., city, village)</td>
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<td>---</td>
<td>---------------------------------</td>
</tr>
<tr>
<td></td>
<td>4 Urban/Rural</td>
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<td></td>
<td></td>
</tr>
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<td></td>
<td>5 Other country</td>
</tr>
</tbody>
</table>

1A550 Where did death occur?

<p>| | |</p>
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<tbody>
<tr>
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<tr>
<td>2</td>
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<td>LOCALITY</td>
</tr>
<tr>
<td>3</td>
<td>Locality (e.g., city, village)</td>
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<tr>
<td></td>
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</table>

1A560 What was the site of death?

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<tr>
<td></td>
<td>HOSPITAL</td>
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<td></td>
<td>OTHER HEALTH FACILITY</td>
</tr>
<tr>
<td></td>
<td>HOME</td>
</tr>
<tr>
<td></td>
<td>OTHER (specify)</td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
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</table>

1A600 What was her/his marital status?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>NEVER MARRIED</td>
</tr>
<tr>
<td></td>
<td>MARRIED/LIVING WITH A PARTNER</td>
</tr>
<tr>
<td></td>
<td>WIDOWED</td>
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<td></td>
<td>DIVORCED</td>
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<td></td>
<td>SEPARATED</td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
</tr>
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</tr>
<tr>
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<td>-----------------------</td>
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<tr>
<td>1A610</td>
<td>What was the date of marriage?</td>
</tr>
<tr>
<td></td>
<td>RECORD '98' IF DON'T KNOW DAY OR MONTH</td>
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<table>
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<th>QUESTIONS AND FILTERS</th>
<th>CODING CATEGORIES</th>
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</thead>
<tbody>
<tr>
<td>1A630</td>
<td>What was the name of the mother?</td>
<td>Surname, Name</td>
</tr>
<tr>
<td>1A620</td>
<td>What was the name of the father?</td>
<td>Surname, Name</td>
</tr>
<tr>
<td>1A640</td>
<td>What was her/his highest level of schooling?</td>
<td>NO FORMAL EDUCATION, PRIMARY, SECONDARY, HIGHER, DON'T KNOW</td>
</tr>
<tr>
<td>1A650</td>
<td>Was s/he able to read and write?</td>
<td>YES, NO, DON'T KNOW</td>
</tr>
<tr>
<td>1A660</td>
<td>What was her/his economical activity status in year prior to death?</td>
<td>USUALLY ECONOMICALLY ACTIVE, MAINLY EMPLOYED, MAINLY UNEMPLOYED, NOT ECONOMICALLY ACTIVE, HOME MAKER, STUDENT, PENSION, OTHER (specify), DON'T KNOW</td>
</tr>
<tr>
<td>1A670</td>
<td>What was her/his occupation, that is, what kind of work did s/he mainly do?</td>
<td></td>
</tr>
</tbody>
</table>
### SECTION 3. DEATH REGISTRATION AND CERTIFICATION

<table>
<thead>
<tr>
<th>Death registration number</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date of registration</th>
<th>DAY</th>
<th>MONTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>RECORD '98' IF DON'T KNOW DAY OR MONTH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RECORD '9998' IF DON'T KNOW YEAR</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Place where the death is registered:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Larger admin area (e.g., province)</td>
</tr>
<tr>
<td>2 Smaller admin area (e.g., county)</td>
</tr>
<tr>
<td>3 Locality (e.g., city, village)</td>
</tr>
<tr>
<td>4 Urban/Rural</td>
</tr>
<tr>
<td>5 Name of local registrar</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National identification number of deceased</th>
</tr>
</thead>
</table>

### 2012 WHO VERBAL AUTOPSY [FORM 3]

#### DEATH OF A PERSON AGED 15 YEARS AND ABOVE

<table>
<thead>
<tr>
<th>NO.</th>
<th>QUESTIONS AND FILTERS</th>
<th>CODING CATEGORIES</th>
</tr>
</thead>
</table>

#### SECTION 4. RESPONDENT'S ACCOUNT OF ILLNESS/EVENTS LEADING TO DEATH
Could you tell me about the illness/events that led to her his/death?

<table>
<thead>
<tr>
<th>CAUSE OF DEATH 1 ACCORDING TO RESPONDENT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUSE OF DEATH 2 ACCORDING TO RESPONDENT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

**SECTION 5. CONTEXT AND HISTORY OF PREVIOUSLY KNOWN MEDICAL CONDITIONS**

I would like to ask you some questions concerning the context and previously known medical conditions the deceased had; injuries and accidents that the deceased suffered; and signs and symptoms that the deceased had/showed when s/he was ill. Some of these questions may not appear to be directly related to his/her death. Please bear with me and answer all the questions. They will help us to get a clear picture of all possible symptoms that the deceased had.

<table>
<thead>
<tr>
<th>3A100</th>
<th>Was there any diagnosis of Tuberculosis?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3A110</th>
<th>Was there any diagnosis of HIV/AIDS?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3A120</th>
<th>Did s/he have a recent positive test for Malaria?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3A130</th>
<th>Did s/he have a recent negative test for Malaria?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3A140</th>
<th>Was there any diagnosis of Measles?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>NO.</td>
<td>QUESTIONS AND FILTERS</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------------------------------------</td>
</tr>
<tr>
<td>3A150</td>
<td>Was there any diagnosis of High Blood Pressure?</td>
</tr>
<tr>
<td>3A160</td>
<td>Was there any diagnosis of Heart Disease?</td>
</tr>
<tr>
<td>3A170</td>
<td>Was there any diagnosis of Diabetes?</td>
</tr>
<tr>
<td>3A180</td>
<td>Was there any diagnosis of Asthma?</td>
</tr>
<tr>
<td>3A190</td>
<td>Was there any diagnosis of Epilepsy?</td>
</tr>
<tr>
<td>3A200</td>
<td>Was there any diagnosis of Cancer?</td>
</tr>
<tr>
<td>3A210</td>
<td>Was there any diagnosis of Chronic Obstructive Pulmonary Disease (COPD)?</td>
</tr>
<tr>
<td>3A220</td>
<td>Was there any diagnosis of Dementia?</td>
</tr>
<tr>
<td></td>
<td>3A230</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>3A240</td>
</tr>
<tr>
<td></td>
<td>3A250</td>
</tr>
<tr>
<td></td>
<td>3A260</td>
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<td></td>
<td>3A270</td>
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<td></td>
<td>3A280</td>
</tr>
<tr>
<td></td>
<td>3A290</td>
</tr>
<tr>
<td></td>
<td>3A300</td>
</tr>
<tr>
<td></td>
<td>3A310</td>
</tr>
<tr>
<td>NO.</td>
<td>QUESTIONS AND FILTERS</td>
</tr>
<tr>
<td>------</td>
<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>3E100</td>
<td>Did s/he suffer from any injury or accident that led to her/his death?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3E110</td>
<td>+ Did s/he suffer from a road traffic accident?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3E120</td>
<td>++ Was s/he injured as a pedestrian/walking?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3E130</td>
<td>++ Was s/he injured as an occupant of a car vehicle?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3E140</td>
<td>++ Was s/he injured as an occupant of a bus/heavy transport vehicle?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3E150</td>
<td>++ Was s/he injured as a driver or passenger of a motorcycle?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3E160</td>
<td>++ Was s/he injured as a pedal cyclist?</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Options</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>+ + Do you know anything about the counterpart that was hit during the road traffic accident?</td>
<td>YES NO</td>
</tr>
<tr>
<td>+ + + Was it a pedestrian?</td>
<td>YES NO DON'T KNOW</td>
</tr>
<tr>
<td>+ + + Was it a stationary object?</td>
<td>YES NO DON'T KNOW</td>
</tr>
<tr>
<td>+ + + Was it a car vehicle?</td>
<td>YES NO DON'T KNOW</td>
</tr>
<tr>
<td>+ + + Was it a bus or heavy transport vehicle?</td>
<td>YES NO DON'T KNOW</td>
</tr>
<tr>
<td>+ + + Was it a motor cycle?</td>
<td>YES NO DON'T KNOW</td>
</tr>
<tr>
<td>+ + + Was it a pedal cycle?</td>
<td>YES NO DON'T KNOW</td>
</tr>
<tr>
<td>+ + + Was it something else?</td>
<td>YES (specify)</td>
</tr>
<tr>
<td>+ + + Was it something else?</td>
<td>NO</td>
</tr>
<tr>
<td>+ + + Was it something else?</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>Was s/he injured in a non-road transport accident?</td>
<td>YES NO DON'T KNOW</td>
</tr>
<tr>
<td>Was s/he injured in a fall?</td>
<td>YES NO</td>
</tr>
<tr>
<td>NO.</td>
<td>QUESTIONS AND FILTERS</td>
</tr>
<tr>
<td>------</td>
<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>3E320</td>
<td>++ Did s/he die of drowning?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3E330</td>
<td>++ Did s/he suffer from burns?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3E340</td>
<td>++ Did (s)he suffer from any plant/animal/insect bite or sting ++ that led to her/his death?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3E400</td>
<td>+++ Was it a dog?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3E410</td>
<td>+++ Was it a snake?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3E420</td>
<td>+++ Was it an insect?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3E500</td>
<td>+++ Was s/he injured by a force of nature?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>3E510</strong></td>
<td>+ + Was there any poisoning?</td>
</tr>
<tr>
<td><strong>3E520</strong></td>
<td>+ Was s/he subject to violence or assault?</td>
</tr>
<tr>
<td><strong>3E530</strong></td>
<td>+ Was the injury or accident intentionally inflicted by someone else?</td>
</tr>
<tr>
<td><strong>3E600</strong></td>
<td>+ + Was s/he injured by a fire arm?</td>
</tr>
<tr>
<td><strong>3E610</strong></td>
<td>+ + Was s/he injured from a stab, cut or pierce?</td>
</tr>
<tr>
<td><strong>3E620</strong></td>
<td>+ + Was s/he injured by machinery?</td>
</tr>
<tr>
<td><strong>3E630</strong></td>
<td>+ + Was s/he struck by an animal or object?</td>
</tr>
</tbody>
</table>
### Section 7. Symptoms and Signs Associated with Illness of Women

<table>
<thead>
<tr>
<th>NO.</th>
<th>Questions and Filters</th>
<th>Coding Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>3B720</td>
<td>Did she have an ulcer or swelling in the breast?</td>
<td>YES, NO, DON'T KNOW</td>
</tr>
<tr>
<td>3B800</td>
<td>Did she have excessive vaginal bleeding in between menstrual periods?</td>
<td>YES, NO, DON'T KNOW</td>
</tr>
<tr>
<td>3B810</td>
<td>Did her vaginal bleeding stopped naturally during menopause?</td>
<td>YES, NO, DON'T KNOW</td>
</tr>
<tr>
<td>3B820</td>
<td>Did she have vaginal bleeding after menopause?</td>
<td>YES, NO, DON'T KNOW</td>
</tr>
</tbody>
</table>

### Section 8. Symptoms and Signs Associated with Pregnancy
<table>
<thead>
<tr>
<th>3C100</th>
<th>Was she neither pregnant, nor delivered, within 6 weeks of her death?</th>
<th>YES</th>
<th>skip pregnancy section if YES</th>
<th>NO</th>
<th>DON'T KNOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3C110</td>
<td>Was she pregnant at the time of death?</td>
<td>YES</td>
<td></td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>OR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3C120</td>
<td>Did she die within 6 weeks of giving birth?</td>
<td>YES</td>
<td></td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>OR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3C130</td>
<td>Did she die within 6 weeks of a pregnancy that lasted less than 6 months?</td>
<td>YES</td>
<td></td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C200</td>
<td>+ Did she die within 24 hours after delivery?</td>
<td>YES</td>
<td></td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C210</td>
<td>+ Did she die during labour, but undelivered?</td>
<td>YES</td>
<td></td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C220</td>
<td>+ Was she breastfeeding at death?</td>
<td>YES</td>
<td></td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C230</td>
<td>+ How many births, including stillbirths, did she have + before this baby?</td>
<td>NUMBER OF BIRTHS/STILLBIRTHS</td>
<td>DON'T KNOW</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3C240</td>
<td>+ Did she have any previous C-section?</td>
<td>YES</td>
<td></td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C250</td>
<td>+ Did she die during or after a multiple pregnancy?</td>
<td>YES</td>
<td></td>
<td>NO</td>
<td></td>
</tr>
</tbody>
</table>
### 2012 WHO VERBAL AUTOPSY [FORM 3]
#### DEATH OF A PERSON AGED 15 YEARS AND ABOVE

<table>
<thead>
<tr>
<th>NO.</th>
<th>QUESTIONS AND FILTERS</th>
<th>CODING CATEGORIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>3C260</td>
<td>During pregnancy, did she suffer from high blood pressure?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
<td></td>
</tr>
<tr>
<td>3C270</td>
<td>Did she have foul smelling vaginal discharge during pregnancy or after delivery?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
<td></td>
</tr>
<tr>
<td>3C280</td>
<td>During the last 3 months of pregnancy, did she suffer from convulsions?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
<td></td>
</tr>
<tr>
<td>3C290</td>
<td>During the last 3 months of pregnancy, did she suffer from blurred vision?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
<td></td>
</tr>
<tr>
<td>3C300</td>
<td>Did she give birth to a live, healthy baby within 6 weeks of death?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
<td></td>
</tr>
<tr>
<td>3C310</td>
<td>Was there any vaginal bleeding during pregnancy or after delivery?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
<td></td>
</tr>
<tr>
<td>3C320</td>
<td>Was there vaginal bleeding during the first 6 months of pregnancy?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DON'T KNOW</td>
<td></td>
</tr>
<tr>
<td>3C330</td>
<td>Was there vaginal bleeding during the last 3 months of pregnancy but before labour started?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO</td>
<td></td>
</tr>
</tbody>
</table>

297
<table>
<thead>
<tr>
<th>Code</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Don't Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>3C340</td>
<td>+ + Was there excessive vaginal bleeding during labour?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C350</td>
<td>+ + Was there excessive vaginal bleeding after delivering the baby?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C360</td>
<td>+ Was the placenta not completely delivered?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C365</td>
<td>+ Did she deliver or try to deliver an abnormally positioned baby?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C370</td>
<td>+ Was she in labour for unusually long (more than 24 hours)?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C380</td>
<td>Did she attempt to terminate the pregnancy?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C390</td>
<td>+ Did she recently have a pregnancy that ended in + an abortion (spontaneous or induced)?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C400</td>
<td>+ Did she give birth in a health facility?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3C410</td>
<td>+ Did she give birth at home?</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NO.</td>
<td>QUESTIONS AND FILTERS</td>
<td>CODING CATEGORIES</td>
<td></td>
<td></td>
</tr>
<tr>
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<tr>
<td>3C420</td>
<td>+ Did she give birth elsewhere, e.g. on the way to a facility?</td>
<td>YES   NO   DON'T KNOW</td>
<td></td>
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</tr>
<tr>
<td>3C430</td>
<td>+ Did she receive professional assistance for the delivery?</td>
<td>YES   NO   DON'T KNOW</td>
<td></td>
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</tr>
<tr>
<td>3C440</td>
<td>+ Did she have an operation to remove her uterus shortly + before death?</td>
<td>YES   NO   DON'T KNOW</td>
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</tr>
</tbody>
</table>

2012 WHO VERBAL AUTOPSY [FORM 3]
DEATH OF A PERSON AGED 15 YEARS AND ABOVE

<table>
<thead>
<tr>
<th>NO.</th>
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<th>CODING CATEGORIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>3C450</td>
<td>+ Did she have a normal vaginal delivery?</td>
<td>YES   NO   DON'T KNOW</td>
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<tr>
<td>3C460</td>
<td>+ Did she have an assisted delivery, with forceps/vacuum?</td>
<td>YES   NO   DON'T KNOW</td>
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<tr>
<td>3C470</td>
<td>+ Was it a delivery with caesarean section?</td>
<td>YES   NO   DON'T KNOW</td>
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<tr>
<td>3C480</td>
<td>+ Was the baby born more than one month early?</td>
<td>YES   NO   DON'T KNOW</td>
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### SECTION 10. SYMPTOMS NOTED DURING THE FINAL ILLNESS

<table>
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<tr>
<th>Code</th>
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<th>DON'T KNOW</th>
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<tbody>
<tr>
<td>3B100</td>
<td>Did s/he have a fever?</td>
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<tr>
<td>3B110</td>
<td>+ For how long did s/he have a fever?</td>
<td></td>
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<tr>
<td>3B120</td>
<td>+ Did s/he have night sweats?</td>
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<tr>
<td>3B130</td>
<td>Did s/he have a cough?</td>
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<tr>
<td>3B140</td>
<td>+ For how long did s/he have a cough?</td>
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<td>3B150</td>
<td>+ Was the cough productive with sputum?</td>
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<tr>
<td>3B160</td>
<td>+ Did s/he cough out blood?</td>
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<tr>
<td>3B180</td>
<td>Did s/he have any breathing problem?</td>
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<td>3B190</td>
<td>Did s/he have fast breathing?</td>
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<td>3B210</td>
<td>Did s/he have breathlessness?</td>
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<td>3B220</td>
<td>For how long did s/he have breathlessness?</td>
<td>NUMBER OF DAYS</td>
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<tr>
<td>3B230</td>
<td>Was s/he unable to carry out daily routine activities due to breathlessness?</td>
<td>YES</td>
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<td>3B240</td>
<td>Was s/he breathless while lying flat?</td>
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<tr>
<td>3B280</td>
<td>Did s/he have diarrhoea?</td>
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<td></td>
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<td>+ For how long did s/he have diarrhoea?</td>
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<td>3B300</td>
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<td>3B310</td>
<td>Did s/he vomit?</td>
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<tr>
<td>3B320</td>
<td>+ Did s/he vomit &quot;coffee grounds&quot; or bright red/blood?</td>
<td>YES</td>
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<td>Did s/he have any abdominal problem?</td>
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<tr>
<td>3B340</td>
<td>+ Did s/he have severe abdominal pain?</td>
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<td>+ + For how long before death did s/he have severe abdominal + + pain?</td>
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<tr>
<td>3B360</td>
<td>+ Did s/he have more than usual protruding abdomen?</td>
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<tr>
<td>+ + For how long did s/he have a more than usual protruding + + abdomen?</td>
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<td>NUMBER OF DAYS</td>
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<tr>
<td>DON'T KNOW</td>
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<tr>
<td>+ Did s/he have any lump inside the abdomen?</td>
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<td>YES</td>
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<td>+ + For how long did s/he have the lump inside the abdomen?</td>
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<tr>
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<tr>
<td>Did s/he have a severe headache?</td>
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<td>YES</td>
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<td>DON'T KNOW</td>
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<tr>
<td>Did s/he have a stiff or painful neck?</td>
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<td>YES</td>
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<tr>
<td>DON'T KNOW</td>
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<tr>
<td>+ For how long did s/he have a stiff or painful neck?</td>
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<tr>
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<tr>
<td>Did s/he have mental confusion?</td>
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<td>YES</td>
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<td>+ For how long did s/he have mental confusion?</td>
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<td>Was s/he unconscious for more than 24 hours?</td>
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<tr>
<td>3B450</td>
<td>Did the unconsciousness start suddenly, quickly (at least within a single day)?</td>
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<td>3B460</td>
<td>Did s/he have convulsions?</td>
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<td>+ For how long did s/he have convulsions?</td>
<td>NUMBER OF MINUTES</td>
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<td>3B480</td>
<td>+ Did s/he became unconscious immediately after the convulsion?</td>
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<td>3B490</td>
<td>Did s/he have any urine problems?</td>
<td>YES</td>
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<td>+ Did s/he pass no urine at all?</td>
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<td>3B510</td>
<td>+ Did s/he go to urinate more often than usual?</td>
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<tr>
<td>3B520</td>
<td>+ During the final illness did s/he ever pass blood in the urine?</td>
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<tr>
<td>3B530</td>
<td>Did s/he have any skin problems?</td>
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<td>DON'T KNOW</td>
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<tr>
<td>3B540</td>
<td>+ Did s/he have any ulcers, abscess or sores anywhere except the feet?</td>
<td>YES</td>
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<td></td>
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<td>------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>+ Did (s)he have any ulcers, abscess or sores on the feet + that were not also on other parts of the body?</td>
<td>YES, NO, DON'T KNOW</td>
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<tr>
<td>+ During the illness that led to death, did s/he have any skin rash?</td>
<td>YES, NO, DON'T KNOW</td>
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<tr>
<td>+ + For how long did s/he have the skin rash?</td>
<td>NUMBER OF DAYS, NUMBER OF WEEKS, DON'T KNOW</td>
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<tr>
<td>+ + Did s/he have measles rash?</td>
<td>YES, NO, DON'T KNOW</td>
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<td></td>
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<tr>
<td>+ + Did s/he ever have shingles/herpes zoster?</td>
<td>YES, NO, DON'T KNOW</td>
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<tr>
<td>Did s/he have bleeding from the nose, mouth, or anus?</td>
<td>YES, NO, DON'T KNOW</td>
<td></td>
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<tr>
<td>Did s/he have weight loss?</td>
<td>YES, NO, DON'T KNOW</td>
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<tr>
<td>+ Was s/he severely thin or wasted?</td>
<td>YES, NO, DON'T KNOW</td>
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<tr>
<td>Did s/he have mouth sores or white patches in the mouth or on the tongue?</td>
<td>YES, NO</td>
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<td>NO.</td>
<td>QUESTIONS AND FILTERS</td>
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<tr>
<td>3B640</td>
<td>Did s/he have stiffness of the whole body or was unable to open the mouth?</td>
<td>DON'T KNOW</td>
<td></td>
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<tr>
<td>3B650</td>
<td>Did s/he have swelling (puffiness) of the face?</td>
<td>YES</td>
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<td></td>
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<td>NO</td>
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<td>DON'T KNOW</td>
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<tr>
<td>3B660</td>
<td>Did s/he have both feet swollen?</td>
<td>YES</td>
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<td></td>
<td></td>
<td>NO</td>
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<td>DON'T KNOW</td>
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<tr>
<td>3B670</td>
<td>Did s/he have any lumps?</td>
<td>YES</td>
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<td></td>
<td></td>
<td>NO</td>
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<td>DON'T KNOW</td>
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<tr>
<td>3B680</td>
<td>+ Did s/he have any lumps or lesions in the mouth?</td>
<td>YES</td>
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<td></td>
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<td>NO</td>
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<td></td>
<td>DON'T KNOW</td>
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<tr>
<td>3B690</td>
<td>+ Did s/he have any lumps on the neck?</td>
<td>YES</td>
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<td></td>
<td></td>
<td>NO</td>
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<td></td>
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<td>DON'T KNOW</td>
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<tr>
<td>3B700</td>
<td>+ Did s/he have any lumps on the armpit?</td>
<td>YES</td>
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<td></td>
<td></td>
<td>NO</td>
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<td></td>
<td></td>
<td>DON'T KNOW</td>
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<tr>
<td>3B710</td>
<td>+ Did s/he have any lumps on the groin?</td>
<td>YES</td>
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<td></td>
<td></td>
<td>NO</td>
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<tr>
<td>3B730</td>
<td>Did s/he have paralysis of one side of the body?</td>
<td>DON'T KNOW</td>
<td></td>
<td></td>
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<tr>
<td>3B740</td>
<td>Did s/he have difficulty or pain while swallowing liquids?</td>
<td>DON'T KNOW</td>
<td></td>
<td></td>
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<tr>
<td>3B750</td>
<td>Did s/he have yellow discoloration of the eyes?</td>
<td>DON'T KNOW</td>
<td></td>
<td></td>
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<tr>
<td>3B760</td>
<td>Did her/his hair colour change to reddish or yellowish?</td>
<td>DON'T KNOW</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3B770</td>
<td>Did s/he look pale (thinning/lack of blood) or have pale palms, eyes or nail beds?</td>
<td>DON'T KNOW</td>
<td></td>
<td></td>
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<tr>
<td>3B780</td>
<td>Did s/he have sunken eyes?</td>
<td>DON'T KNOW</td>
<td></td>
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<tr>
<td>3B790</td>
<td>Did (s)he drink a lot more water than usual?</td>
<td>DON'T KNOW</td>
<td></td>
<td></td>
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<tr>
<td>3G100</td>
<td>Was s/he adequately vaccinated?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
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<tr>
<td>3G110</td>
<td>Did s/he receive any treatment for the illness that led to death?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3G120</td>
<td>+ Did s/he receive oral rehydration salts?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3G130</td>
<td>+ Did s/he receive (or needed) intravenous fluids (drip) treatment?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3G140</td>
<td>+ Did s/he receive (or needed) a blood transfusion?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3G150</td>
<td>+ Did s/he receive (or needed) treatment/food through a tube passed through the nose?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3G160</td>
<td>+ Did s/he receive (or needed) injectable (IV or IM) antibiotics?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>3G170</td>
<td>+ Did s/he have (or needed) an operation for the illness?</td>
<td>YES</td>
<td>NO</td>
<td>DON'T KNOW</td>
</tr>
<tr>
<td>Question</td>
<td>YES</td>
<td>NO</td>
<td>DON’T KNOW</td>
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<tr>
<td>3G180 Did s/he have the operation within 1 month before death?</td>
<td></td>
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<tr>
<td>3G190 Was s/he discharged from the hospital very ill?</td>
<td></td>
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<tr>
<td>SECTION 11. RISK FACTORS</td>
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<tr>
<td>3F100 Did s/he drink alcohol?</td>
<td></td>
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<tr>
<td>3F110 Did s/he smoke tobacco. (cigarette, cigar, pipe, etc.)?</td>
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<tr>
<td>SECTION 12. BACKGROUND</td>
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<tr>
<td>4A100 In the final days before death, did s/he travel to a hospital or health facility?</td>
<td></td>
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<tr>
<td>4A110 Did s/he use motorised transport to get to the hospital or health facility?</td>
<td></td>
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<tr>
<td>4A120 Were there any problems during admission to the hospital or health facility?</td>
<td></td>
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<td>NO.</td>
<td>QUESTIONS AND FILTERS</td>
<td>CODING CATEGORIES</td>
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<tr>
<td>4A130</td>
<td>Were there any problems with the way (s)he was treated (medical treatment, procedures, inter-personal attitudes, respect, dignity) in the hospital or health facility?</td>
<td>YES, NO, DON'T KNOW</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4A140</td>
<td>Were there any problems getting medications, or diagnostic tests in the hospital or health facility?</td>
<td>YES, NO, DON'T KNOW</td>
<td></td>
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</tr>
<tr>
<td>4A150</td>
<td>Does it take more than 2 hours to get to the nearest hospital or health facility from the deceased's household?</td>
<td>YES, NO, DON'T KNOW</td>
<td></td>
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</tr>
<tr>
<td>4A160</td>
<td>In the final days before death, were there any doubts about whether medical care was needed?</td>
<td>YES, NO, DON'T KNOW</td>
<td></td>
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<tr>
<td>4A170</td>
<td>In the final days before death, was traditional medicine used?</td>
<td>YES, NO, DON'T KNOW</td>
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<tr>
<td>4A180</td>
<td>In the final days before death, did anyone use a telephone or cell phone to call for help?</td>
<td>YES, NO, DON'T KNOW</td>
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<tr>
<td>4A190</td>
<td>Over the course of illness, did the total costs of care and treatment prohibit other household payments?</td>
<td>YES, NO, DON'T KNOW</td>
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</table>
Appendix 2 Nairobi HDSS ethics approval letter

KENYA MEDICAL RESEARCH INSTITUTE

Dr. A. Koch
AEO:
Medical Research Centre 2nd Floor, Langata Road, Nairobi 00205
Tel: +254 20 7205275, 7226204, Fax: +254 20 7226207, Email: a Koch@kemri.or.ke

Nairobi, December 20, 2016

Dear Dr. A. Koch,

I am writing to inform you of the ethics approval for the Nairobi HDSS study. The Ethics Committee of the Kenya Medical Research Institute has approved the research proposal for the Nairobi HDSS study. The study has been approved by the National Ethics Review Committee of the Nairobi HDSS.

The study will be conducted by a team of researchers from the University of Nairobi and the Kenya Medical Research Institute. The study will be supervised by the study coordinator and the principal investigator.

The study will be conducted in collaboration with the Ministry of Health and the Nairobi HDSS. The study will be conducted in accordance with the ethical guidelines set by the Kenya Medical Research Institute and the Ministry of Health.

Thank you for your consideration.

Yours faithfully,

[Signature]

[Name]

[Position]

[Institution]
Appendix 3 Individual in-depth interview guide Phase Two

Sample main interview guide – Researchers (KWTRP-APHRC) – HDSS Ethics

Check if read consent form

Ask if any questions about the research

Okay to record?

Reassure - No right or wrong; trying to learn about views and experiences on an area which is quite grey in the literature/any guidelines

Roles within KHDSS

How long have you worked with KEMRI? What are your current roles and responsibilities? Have you had different roles/positions in the past? Relation to KHDSS?

There is a lack of clarity in existing literature on whether HDSS are research projects or public health programmes. Based on your knowledge of the KHDSS, how would you define it?

Views and Experiences of Ethical Issues

We all face challenges of different kinds in our work. Some challenges are quite practical (e.g. having the right kind of computer or vehicles) and some are more ethical where we’re not sure what the right thing to do is. While working with the KHDSS site have you faced any ethical issues or dilemmas? i.e any issues or situations that made you uncertain/wonder/reflect about what the right thing to do is? Can you give some examples? Which are the most important ones? When did this happen?

[If nothing forthcoming] - For example some people have told us about dilemmas or being unsure about issues related to the amount or type of information that people
in communities are given, or about what to do when they encounter people with health needs.

**Verbal Autopsy is a key component of many HDSS sites, it has emerged as an important area of focus in my study. I would like to ask you a few questions on specific ethical issues for VA.**

---

**Verbal Autopsy**

The Verbal Autopsy is an indirect technique for determining the cause of death.

It involves interviewing close relatives, friends or caregivers of a recently deceased person to find out the signs, symptoms or circumstances that preceded death. In KHDSS VA interviews are conducted at least 21 days after a death has occurred.

The interviewers may take pictures of any available health care documents such as clinic cards and laboratory test results.

This information is then analysed by medical doctors (Physician Certified VA) or by software applications (Inter-VA) to assign the probable cause of death.

VA data is important because it provides public health authorities with evidence to inform policies, planning and implementation of public health interventions.

The majority of HDSS sites (47/53) conduct Verbal Autopsies on deaths that occur within their HDSS area.

---

*I value the insights you’ll be able to give on the KHDSS and VA in particular.*
Benefits and Burdens of VA

I would like us to talk about the value of VA. What benefits/compensation do individuals and families gain from participating in VA interviews?

*Individuals/families – counselling, health awareness, closure, tokens, death certificates…*

*KHDSS Community – Support to health care system, public health interventions…*

*KHDSS researchers – data to support projects, career development…*

*Ministry of Health – Informing policy, interventions, programme evaluation*

*Global Community – Advancing science, knowledge of global burden of disease*

Are these benefits/compensation reasonable/adequate/fair? Why/why not?

Some people feel that it’s a difficult thing to visit people in their homes after a family member has died to talk about events that led to death. Could you explain what specific problems this visit and VA interview might generate for people within household and how this might happen?

*Individuals/families- time taken, loss of income, emotional distress*

*Particular concerns for VA during puerperium, for deaths that occur through assault/accidents/suicide.*

*Community – potential for stigmatization*

*HDSS fieldworkers – distress/trauma*
Would you say that benefits and burdens associated with VA are fairly distributed among different groups of HDSS residents? *By gender, age, location, socio-economic status... why/why not?*

*Concerns that women take on most of the burdens associated with VA since they are the majority of VA respondents.*

What do you think can be done to reduce burdens, maximize benefits of VA?

Overall, what do you feel about the balance between benefits and burdens for VA? Is it worth doing at all?

**Consent**

What do you think KHDSS community members understand about the Verbal Autopsy? *Who conducts VA, how and why?*

What type of information should they have and for what reason?

How should consent be obtained for Verbal Autopsy? *What makes you say that?*

Who should consent and be interviewed? *Home-based caregivers, healthcare workers, relatives, friends, traditional healers...*  

How? – Written, verbal, both, other options...

*The KHDSS obtains individual written consent for collection of Verbal Autopsy data and not for other routinely collected HDSS data such as pregnancy, migration or socio-economic data.*

What do you think of this approach? Is it appropriate? *What makes you say that?*
Why and how was this decision made?

What are the refusal rates for VA compared to other HDSS activities.

What do you think are the goals and justifications of having individual written consent for Verbal Autopsy?

Community Engagement

Does community engagement differ at the moment for collection of verbal autopsy data? Should it? If so how and why?

To conduct VA, it might be important to learn about local community bereavement practices. How does the KHDSS gain knowledge about these practices? How is this knowledge used in the design and implementation of VA?

Overall, do you think KHDSS community engagement activities have influenced community understanding or acceptability of the Verbal Autopsy? If yes/no, in what way?

VA may be seen as being intrusive and time consuming compared to other types of KHDSS data.

Is there anything more that you think could be done to increase community understanding of VA? What more and for what reason?

Overall do you think the collection and use of VA data has been adequately responsive to community health needs, needs of researchers and funders? What makes you say this?
Data Sharing

What do you think about the current data sharing system at KWTRP?

*In terms of fairness, efficiency, accessibility, protecting privacy and interests of KHDSS stakeholders?*

*How well are community members interests represented when sharing KHDSS data?*

What criteria do you think should be used in considering who can have access to KHDSS data?

*Type of institutions? Where based, the reason data is being sought, existing partnerships?*

Should VA data be treated differently in terms of storage, analysis and sharing? Why?

*Some HDSS stakeholders have argued that it is difficult to fully anonymise Verbal Autopsy data given that individuals might be identified if they died from a unique disease/circumstance, analyses increasingly interested in small geographic areas and that leading cause of death given for an entire community.*

Are you aware of any harms and benefits that have emerged from sharing of Verbal Autopsy data? *Can you give some examples?*

Oversight of the KHDSS
Should KHDSS proposals and tools undergo scientific or ethics review? If yes, why and how often *(annually, each re-enumeration round, new tools only...)* which committees?

*Should VA have a separate protocol, ethics review process? Why/why not?*

Who should monitor KHDSS activities, and be involved in decisions on ethics review and governance? How and why?

*HDSS tool standardization and audit vs review by ethics committee*

To wrap up – special sensitivities of and approaches to verbal autopsy?

Overall, noticing some differences with VA and the rest of the KHDSS data re consent and benefits etc. Anything else to comment on re the similarities and differences? What makes the VA so different? What’s the value of the VA data? On balance should it be done at all? If so, for what reason? Should the approach to VA be reconsidered?

You’ve mentioned a range of ethics dilemmas/issues, including specific ethical issues for VA, when these are faced by you or others, do you have anyone or any system to refer to assist? Can you tell me about that? Give me examples?

ANY LAST POINTS/QUESTIONS? - MANY THANKS!

Sample main interview guide – Researchers (KWTRP/APHRC) – VA Ethics

Check if read consent form
Ask if any questions about the research

Okay to record?

Reassure - No right or wrong; trying to learn about views and experiences on an area which is quite grey in the literature/any guidelines

Roles within KHDSS

How long have you worked with KEMRI? What are your current roles and responsibilities? Have you had different roles/positions in the past? Relation to KHDSS?

What does the KHDSS include? What information? What type of an activity do you think the KHDSS is? Lack of clarity in existing literature on whether HDSS is Research, public health, health care?

[I value the insights you’ll be able to give on the KHDSS based on “Q1-2”].

Views and Experiences of Ethical Issues

We all face challenges of different kinds in our work. Some challenges are quite practical (e.g. having the right kind of computer or vehicles) and some are more ethical where we’re not sure what the right thing to do is. While working with the KHDSS site have you faced any ethical issues or dilemmas? i.e any issues or situations that made you uncertain/wonder/reflect about what the right thing to do is? Can you give some examples? Which are the most important ones? When did this happen?

[If nothing forthcoming] - For example some people have told us about dilemmas or being unsure about issues related to the amount or type of information that people in communities are given, or about what to do when they encounter people with health needs.
[I’ll now ask you about some issues that are typically considered ethical issues, to see where that takes our conversation].

Consent

What do you think community members understand about the KHDSS? What type of information should they have about KHDSS and for what reason?

How is consent currently obtained for the KHDSS? (When? From whom? How?)

What do you think about this approach? Is it appropriate? What makes you say this?

The KHDSS obtains individual written consent for collection of verbal autopsy data and not for other routinely collected HDSS data such as pregnancy, migration or socio-economic data. Why and how was this decision made? Is the decision appropriate?

What would you say about how consent should be obtained for the KHDSS? What makes you say that?

Are there particular types of KHDSS data that you think would require a different consent process? If so which ones? Deaths, pregnancy, migration, morbidity data, socio-economic data, VA?

Some have argued that HDSS should be treated as Civil Registration and Vital Statistics Systems or National Censuses which do not emphasize requirements for consent. What do you think about that argument?

Community Engagement
What kinds of community engagement activities are currently in place specifically for the KHDSS?

*For example* - General community information giving? Consulting the community/getting their advice? Feedback of KHDSS findings? (eg mortality/morbidity/fertility rates, migration patterns)

Are community members involved in planning for the KHDSS? Or deciding what can happen with KHDSS data?

What do you think about this approach? Is it important to engage in these ways and if so why? Should more be done? What more and for what reason? Anything to give particular emphasis to?

Does engagement differ at the moment for collection of verbal autopsy data? Should it? If so how and why?

*For example* - supporting the bereaved? Learning about local bereavement practices to minimize harms and maintain good relationships...

Overall, do you think community engagement activities have influenced community understanding or acceptability of the KHDSS? If yes/no, in what way?

Overall you think the KHDSS has been adequately responsive to community health needs, needs of researchers and funders? *What makes you say this?*

**Data Sharing**

Who currently has access to KHDSS data, and how do they go about getting access?
What do you think about that system? Any way to improve it?

*Re fairness, efficiency, accessibility, protecting privacy and interests of KHDSS stakeholders?*

What criteria do you think should be used in considering who can have access to KHDSS data?

*Eg type of institutions? Where based, the reason data is being sought, existing partnerships?*

Should any of the data collected in HDSS sites be treated differently? Eg VA data? Why?

Are you aware of any harms and benefits that have emerged from KHDSS data sharing? *Can you give some examples?*

**Benefits and risks/disadvantages**

In what ways have community members benefited from the KHDSS? employment, health improvement, health and research awareness…

What challenges/disadvantages/risks have community members faced due to the presence of the KHDSS in this area?

What do you feel about the balance between the benefits and disadvantages overall? What about for the verbal autopsy in particular? Worth doing at all?
Oversight of the KHDSS

Who does the KHDSS data belong to? Who should have a say in what data is collected and used, and how? Can the current system be strengthened in that regard?

Eg should KHDSS proposals and tools undergo scientific or ethics review? If yes, why and how often (annually, each re-enumeration round, new tools only...) which committees?

Who should monitor KHDSS activities, and be involved in decisions on data use? How?

To wrap up – special sensitivities of and approaches to verbal autopsy?

Overall, noticing some differences with VA and the rest of the KHDSS data re consent and benefits etc. Anything else to comment on re the similarities and differences? What makes the VA so different? What’s the value of the VA data? On balance should it be done at all? If so, for what reason? Should the approach to VA be reconsidered?

You’ve mentioned a range of ethics dilemmas/issues... when these are faced by you or others in the team, do you have anyone or any system to refer to assist? Can you tell me about that? Give me examples?

ANY LAST POINTS/QUESTIONS? - MANY THANKS!
Appendix 4 Focus group discussion guide Phase Two

**Focus Group Discussion Guide: Addressing Ethical Issues for Health and Demographic Surveillance Systems in sub-Saharan Africa**

FGD code [__][__][__][__]  Date _____________________ Place ______________________

*Participants:*

<table>
<thead>
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<th></th>
<th>Age</th>
<th>Gender</th>
<th>Education</th>
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</table>
Throughout - explore what participants understand about KEMRI, KHDSS and Verbal Autopsy. Ask questions first before sharing information and then asking more.

A – Understanding of KEMRI and health research

• **Does anyone know what KEMRI is and what it does?**
  
  o Government institution (State Corporation) responsible for carrying out health research in Kenya.
  
  o Works in partnership with MoH, whose responsibilities include making health policies, responding to public health concerns such as outbreaks and delivering health care services in Kenya.

• **Does everyone understand what health research is?**
  
  o Health research involves systematically collecting and analysing information or samples in order to increase our knowledge about a particular health issue.

B - Explore participants’ understanding & experiences of KHDSS

• **Have any of you had any experience of the KEMRI census activity? Do you know much about what information they are collecting and why?**

• **What of that information is collected regularly, and less regularly? What information is more and less sensitive?**

• The census includes about 280,000 people in 16 locations - since 2001.

• KEMRI field workers visit homesteads every 3-4 months to collect information about individuals - e.g who has moved in or out - households e.g source of drinking water – and about buildings – e.g type of building material and location of building.

• The fieldworkers obtain verbal consent before asking questions. Any knowledgeable member of the household who is ≥13yrs can give consent and provide information on behalf of other household members.

• The collected information is stored safely in password protected computers.

• KEMRI works together with the Ministry of Health; this enables information collected from homesteads to be linked with that collected from the Kilifi
County Hospital. This information is analysed by KEMRI researchers. It may also be shared with other researchers outside KEMRI.

- The census has enabled KEMRI to determine the number of people living within the KHDSS area, their ages, migration patterns, diseases among other important details about people’s lives. *Show pictures 1-7.*

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Less Sensitive</th>
<th>More Sensitive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Every time</strong></td>
<td>Births, migration, deaths, residence status, building units, building location (GPS data)...</td>
<td>Pregnancy, Verbal Autopsy</td>
</tr>
<tr>
<td><strong>Sometime</strong></td>
<td>Ownership and use of bed nets, source of drinking water, sanitation facilities, vaccination status, education level...</td>
<td>Income, ownership of economic assets, National ID...</td>
</tr>
</tbody>
</table>

C - Explore participants’ understanding & experiences of Verbal Autopsy
The death of a family member or a friend is usually a difficult thing for many people to bear. If a person living within the KHDSS dies, KEMRI fieldworkers visit the homestead to ask further questions about the death. What do you know about when, where, how and why these questions are asked?

What are some of the important things for KEMRI to learn about local community practices around death, burials and mourning? How might KEMRI learn about these things?

As far as you are aware, are there any differences between the Verbal Autopsy interview and the routine census interview? In terms of how permission to go ahead is obtained, who conducts the discussions, duration of interview, setting...

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**Verbal Autopsy**

In settings with well-functioning health and vital events registration systems, the majority of deaths are officially recorded and the cause of death given. In addition, a death certificate is issued. The cause of death is determined based on information collected in health facilities and the report of a pathologist. Enumeration and certification of deaths is important because it enables public health practitioners and policy makers to understand the causes of death in a population and to inform interventions.

In many African countries, the majority of people receive care away formal health care facilities and die at home. Furthermore, when an individual dies, post-mortem investigations are rarely conducted. This makes it difficult to determine the number of deaths and their causes. The lack of this information creates challenges for efforts aimed at reducing morbidity and mortality.

The Verbal Autopsy is commonly used in areas without effective death enumeration and certification systems such as Kilifi.

- The Verbal Autopsy is an indirect technique for determining the cause of death.
• It involves interviewing close relatives, friends or caregivers of a recently deceased person to find out the signs, symptoms or circumstances that preceded death.

• Unlike the census field workers who visit households every 3-4 months, VA field workers visit a household only when a death has been reported.

• Usually, VA interviews are conducted by experienced field workers with basic counselling skills.

• In KHDSS VA interviews are conducted at least 21 days after a death has occurred.

• Information from VA interview is used to assign a probable cause of death.

• VA is not very accurate at determining the cause of death for an individual. However, when conducted for many people over a long period, VA gives researchers a good idea on causes of death in a community.

• Unlike in some research projects, VA respondents are not compensated for time they spend to participate in the interview. The VA interview can take about 30 minutes and is normally held in the participants’ home.

• In the absence of reliable data from health facilities and government agencies on the causes of death, VA is the best available source of information on deaths.

• Researchers at KEMRI and others all over the world can use VA information to support other research projects while the government and global community can use VA to make policies and implement various health and development programmes.

Benefits and Burdens

1. What do you think about the approach that I’ve just described that KEMRI takes? Is there anything else that should be considered?

   - For example are there deaths that are particularly sensitive and require special handling?
- Age, gender, religion and other personal details of the person who died

- Relationship of the VA respondent to the deceased.

- Treatment-seeking before death (from linked hospital data) and general circumstance of death?

- Duration of interview

- What kind of changes in practice would you suggest are needed in different cases?

2. What are some of the challenges that might emerge during and after the Verbal Autopsy interview?

- Emotional distress/anxiety/discomfort of the respondent and VA interviewer

- Loss of income due to time taken for the VA interview

- Breach of confidentiality

- Stigmatization of the community based on causes of death reported

- How should these challenges be addressed?

3. Recognising that these interviews will always be difficult is there anything that individuals and families might gain from participating in a Verbal Autopsy interview?

- A chance to share/discuss what happened?

4. Has anyone here ever given a suggestion about how the Verbal Autopsy should be conducted (including a complaint)? How did this happen, how was it handled, and what did they feel about the outcome? [Collect views on any episodes from the group].

Consent

Before a VA interview in KHDSS, individual participants are asked to sign a piece of paper to show that a field worker has clearly explained Verbal Autopsy to them and
that they have made a free decision to participate. The participant needs to be someone who was closely involved in caring for the deceased or someone with information about circumstances that led to a death. This is unlike the KHDSS census where verbal consent is obtained from any knowledgeable member of the household.

1. **What do you think about this consenting process for VA in KHDSS?**
   - There are some HDSS sites where field workers still make sure that people have been informed and that they have made their own decision, but field workers do not ask people to sign a piece of paper about this.
   - **What type of consenting do you think is most appropriate for VA interviews in KHDSS and why?**

**Community Engagement**


3. KEMRI carries out various community engagement activities to create mutual understanding with KHDSS residents. These activities have included community meetings, open days at KEMRI, information leaflets and radio programme. They provide opportunities for community members to give feedback and ask questions about KEMRI. Before a Verbal Autopsy interview, field workers inform respondents about KEMRI, KHDSS and VA.
   - **What is the information that should be provided to the general community about VA and why do you think this information is important?**

4. At the moment, a separate team of KEMRI staff who are specially trained, come out to do VA interviews. **What do you think about this approach? Might there be a better one?**
   - **e.g health workers vs fieldworkers**
   - At KHDSS it’s only KEMRI census field workers who collect information about deaths in the community and share it with the VA interviewers. However, in some HDSS sites, in addition to census field workers, selected community members are trained to record deaths that occur in their neighbourhoods and to share this information with the HDSS at least once a month. VA interviewers then visit the household to collect further information. Would you support such an arrangement for KHDSS? What are the advantages and disadvantages of current KHDSS system of reporting deaths and conducting VA? Pros and cons of alternatives?
5. Currently, the KHDSS does not report findings of VA to individuals and families that participate in the VA interview. This because the Verbal Autopsy is not very good at determining the cause of death for one individual. However, the causes of death at the community level are regularly shared during community meetings, open days at KEMRI and through publications in scientific journals.

- What do you think about this practice of reporting findings of VA in the KHDSS?

Should the findings of Verbal Autopsy be reported back to individual participants/families? Why and how should this be done?

Data Sharing

6. Data collected by KEMRI is stored safely in protected computers and cabinets. These data can be shared with others in and outside KEMRI to help them generate more knowledge, make policies or implement programmes. KEMRI has a committee that reviews data requests to ensure that shared data is used for the right reasons. Who should have access to the verbal autopsy data that KHDSS collects and why?

- KEMRI researchers, global research community, NGOs...
- Kilifi County and national government...
- Everyone with the intention of using data to improve public health...

7. How should the interests and rights of VA respondents and KHDSS community be protected when sharing VA data?

- Community representatives in data governance committees...
- Community consultation before sharing of VA data to others outside KEMRI...
- Data anonymization – note difficulties of fully anonymising population-level Verbal Autopsy data.

8. Would anyone here be interested in accessing VA findings/results? If yes, VA findings for whom (family members, friends, neighbourhood, entire KHDSS) when (on request, monthly, annually...) for what reasons?

9. Should VA data be treated differently compared to rest of KHDSS in terms of storage, analysis and sharing? Why/why not?
Oversight of the KHDSS

10. Who should permit and monitor the activities of the KHDSS including Verbal Autopsy? How and why?
   
   - Ministry of Health, county government, KEMRI internal/national RECs, INDEPTH Network...

11. Any further recommendations on how ethical challenges involved in Verbal Autopsy should be responded to?

12. Is the Verbal Autopsy worth doing at all? Why/why not?

Appendix 5 Sample coding framework

Appendix 6 Sample framework matrix
<table>
<thead>
<tr>
<th>Study Participants</th>
<th>Emotional Burden</th>
<th>Other Burden (economic costs, privacy and legal concerns)</th>
<th>Influences on Burden</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Community Members – Kilifi</strong></td>
<td>Death: Participants driven from the community widely agreed that death is sadly a sensitive and saddening thing that can be difficult to talk about. A few participants commented on the various ways in which the VA interview can introduce emotional burden. Interviewing someone who had recently lost a loved one could lead to: Poor quality data. Others who carelessly respond to questions not present. Also, respondent may have withheld information of being interviewed alone.</td>
<td>Respondents commented that having something to do with the death others will expect the wants to speak in private in order to “hide the evidence”. One participant commented on the opportunity costs to respondents if they stay at home waiting for the VA interview or therefore missing out on income generating activities.</td>
<td>Witchcraft: In the community, especially Wachonyi, especially Giriama, they have strong beliefs in witchcraft causing death. Respondents mentioned that the converse had been witnessed. There will also be notice of warnings and conflicts due to accusation of witchcraft. Premature Deaths: Deaths from suicide and accidents might be associated with unusual mourning practices a society not shared and is buried in separate grave. Could lead to further suspicions and discontinuation.</td>
</tr>
<tr>
<td><strong>KEMRI</strong></td>
<td>Three KCRs, supported by most participants in FGD 4 &amp; 5, mentioned that there is sadness after a death. BUT VA interview has to be conducted despite sadness. Drought Quality: That if respondents cry, they would not be able to give the right information.</td>
<td>Key response is not interview: please, this may lead to poor quality data or misattribution of privacy through the following means: 1. The illness/cause of death may have been a secret between deceased and respondent, so respondent might not talk about it if other family members present. 2. Respondent might be embarrassed to give some information that is otherwise present. 3. If village elder present, respondent might not speak freely.</td>
<td>Discontinuation of interview: Discontinuation of interview may lead to respondents withholding information about HIV/AIDS and leave the respondents feeling embarrassed and potentially accused of witchcraft if their husbands/husbands kept endless refusal to talk about HIV/AIDS and inheritances.</td>
</tr>
<tr>
<td><strong>VA Interviews – Kilifi</strong></td>
<td>Based on previous experiences of conducting VA interviews in Kilifi, participants reported that the interviews can be emotionally distressing with respondents displaying this by: holding back tears – crying out loudly. This can lead to: -Discontinuation of interview -Raising/mention/concerns in the area if respondent crying loudly. One interviewer mentioned that individuals can refuse VA interview because it will remind them of the good times they had with the deceased.</td>
<td>Confidentiality/Privacy: Sometimes, field workers have to conduct VA in crowded places eg. marketplaces. This risks confidentiality of information given and questions that respondent is infected with HIV since talking to KEMRI staff. Respondent might withhold information about HIV/AIDS. This will raise suspicion that respondent is also HIV/AIDS positive. Economic costs: VA can cause long impeachment respondents, interfering with their income generating activities or household duties.</td>
<td>Witchcraft: Symptoms and symptoms might indicate death for HIV/AIDS but respondents themselves that their death was from HIV/AIDS. Also, a baby can be buried and people move on. For mourning for an adult might continue beyond burial. Economic costs and privacy: Some adults especially elderly can leave “instructions” on how they want to be treated and lead to their deaths.</td>
</tr>
</tbody>
</table>

### Cause of Death

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Characteristic of Deceased (Age, religion, status in household and community)</th>
<th>Time (Time Taken and Timing of VA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Will be important in household: respondent might be crying and have difficulties answering VA questions.</td>
<td>Time: VA household visited after 21 days, likely that other mourners who might help respondents to answer questions will have left already. Note: respondents not having support emotional support, help with questions, impact on data quality.</td>
</tr>
<tr>
<td>Suicide</td>
<td>Will be important in household: respondent might be crying and have difficulties answering VA questions.</td>
<td>Time: VA household visited after 21 days, likely that other mourners who might help respondents to answer questions will have left already. Note: respondents not having support emotional support, help with questions, impact on data quality.</td>
</tr>
<tr>
<td>Accidents</td>
<td>Will be important in household: respondent might be crying and have difficulties answering VA questions.</td>
<td>Time: VA household visited after 21 days, likely that other mourners who might help respondents to answer questions will have left already. Note: respondents not having support emotional support, help with questions, impact on data quality.</td>
</tr>
<tr>
<td>Other</td>
<td>Will be important in household: respondent might be crying and have difficulties answering VA questions.</td>
<td>Time: VA household visited after 21 days, likely that other mourners who might help respondents to answer questions will have left already. Note: respondents not having support emotional support, help with questions, impact on data quality.</td>
</tr>
</tbody>
</table>

### Influences on Burden

- **Time (Time Taken and Timing of VA)**
  - Time: VA household visited after 21 days, likely that other mourners who might help respondents to answer questions will have left already. Note: respondents not having support emotional support, help with questions, impact on data quality.
Sample main interview guide (HDSS Research Stakeholders)

Research Objectives

i. To describe the historical context and processes involved in planning, reviewing and conducting HDSS activities.

ii. To describe key informants’ perceptions of ethical issues for X HDSS in X country and other country settings, including through reflection on findings from in-depth case studies conducted in Kenya.

iii. To draw on the above research, the literature, and in-depth case studies and other sites to make recommendations on the nature of key ethical issues in HDSSs.

- Check if read consent form
- Ask if any questions about the research
- Okay to record?
- Reassure - No right or wrong; trying to learn about views and experiences on an area which is quite grey in the literature.any guidelines

Roles within Research Centre/HDSS Site

1. How long have you worked with the “Research centre /HDSS site”? What are your current roles and responsibilities? Have you had different roles/positions in the past? Experience working with HDSS site?

2. Views and Experiences of Ethical Issues

We all face challenges of different kinds in our work. Some challenges are quite practical (e.g. not having the right kind of computer or vehicle) and some are more ethical where we’re not sure what the right thing to do is. While working with X HDSS have you faced any ethical issues or dilemmas? i.e. any issues or situations that made you uncertain/wonder/reflect about what the right thing to do is? Can you give some examples? Which are the most important ones? When did this happen?

[If nothing forthcoming] - For example some people have told us about dilemmas or being unsure about issues related to the amount or type of information that people in communities are given, or about what to do when they encounter people with health needs.
Verbal Autopsy is a key component of many HDSS sites, it has emerged as an important area of focus in my study. I would like to ask you a few questions on specific ethical issues for VA.

**Verbal Autopsy**

- The Verbal Autopsy is an indirect technique for determining the cause of death.
- It involves interviewing close relatives, friends or caregivers of a recently deceased person to find out the signs, symptoms or circumstances that preceded death.
- This information is then analysed by medical doctors (Physician Certified VA) or by software applications (e.g Inter-VA) to assign the probable cause of death.
- VA data is important because it provides public health authorities with evidence to inform policies, planning and implementation of public health interventions.
- The majority of INDEPTH Network HDSS sites (47/53) conduct Verbal Autopsies on deaths that occur within their HDSS area.

I value the insights you’ll be able to give on the KHDSS and VA in particular.

**Benefits of VA**

1. I would like us to talk about the value of VA. What do you think are the benefits of VA to stakeholders? *Can you give some examples?*

   - VA respondents/bereaved families – emotional support, learning about causes of death, condolence fees...
   - HDSS Residents – Support to health care system, public health interventions...
   - HDSS researchers/field workers – data to support projects, career development...
   - Ministry of Health/research centres – Informing policy, interventions, programme evaluation
- Global Community – Advancing science, knowledge of global burden of disease

**Burdens of VA**

2. Could you mention any specific problems that you think the VA in this HDSS might generate for the people and institutions involved?

- VA respondents/bereaved families- time taken, economic costs, emotional distress
- VA interviewers – Emotional distress...
- Public Health Burdens – community stigmatisation, reputational damage, unfair resource allocation

3. In your opinion, what influences the problems associated with the VA interview in this HDSS? Type of death, timing of interview, characteristics of deceased/respondent/interviewer...

**Condolence Fees**

4. In one Kenyan HDSS site, VA respondents/bereaved families are given a condolence fee of about $4 after the interview. What are your views on this practice? Do you think issuance of condolence fee would be necessary/feasible/acceptable in your HDSS site? Why...

**Training and Education Status of VA Interviewers**

5. What type of training and education should VA interviewers have and for what reasons? In some settings, community members with limited education and training have been recruited to identify deaths and conduct verbal autopsies... also suggestions by some HDSS stakeholders that VA interviewers should receive training in bereavement counselling?

**Timing of VA Interview**

6. In this HDSS, when would be the right time to visit a household for a VA interview, and for what reasons? After burial, X days/weeks/months after death...

**Weighing Benefits and Burdens**

7. Would you say that benefits and burdens associated with VA are fairly distributed among different groups of HDSS stakeholders? Prioritizing public
health benefits over individual burdens, sense of unfairness to respondents, field staff women... why/why not?

8. Overall, what do you feel about the balance between benefits and burdens for VA? Are burdens and benefits fairly distributed among VA stakeholders? Why/why not? Is VA worth doing at all?

Consent and Community Engagement

9. What do you think HDSS community members understand about the Verbal Autopsy? Who conducts VA, how and why?

   a. What type of information should they have and for what reason?

   b. Is there anything more that you think could be done to increase community understanding of VA? What more and for what reason?

10. What are the VA-Specific community engagement activities in this HDSS?

   a. Is there anything more you think could be done to increase research stakeholders understanding of death and bereavement practices in the local community or involvement of community members in VA? What more and for what reasons?

11. I have learnt that some HDSS sites obtain individual written consent from respondents for collection of Verbal Autopsy data while others obtain verbal consent.

   a. How is consent obtained for VA in your HDSS site?

   b. In your opinion, how should consent be obtained and for what reasons? Verbal/written, from whom, when...

Data Sharing and Use

12. Who has access to the VA data collected in your HDSS site? Who can access, when, how and for what purposes...
What are your thoughts about the current VA data sharing arrangements?

- In terms of fairness, efficiency, accessibility, protecting privacy and interests of participants?

- How well are community members interests represented when sharing VA data?

13. Can you give any examples on how VA data from your HDSS has been used? research projects, policies, PH interventions, advocacy...

Oversight and Ethics Review

14. Have the VA protocols and tools been reviewed by a scientific and ethics committee? Why not/ if yes, how often (annually, new tools only...) which committees?

- Should VA be subjected to an ethics review process? For what reasons?

15. In your opinion, who should monitor VA implementation and be involved in decisions on ethics review and governance? How and for what reasons?

- HDSS tool standardization and audit vs review by ethics committee

ANY LAST POINTS/QUESTIONS? - MANY THANKS!