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A review of medical law and regulation over the last decade (or so): significant legal events that are affecting health care practice and practitioners

by

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Introduction

This article celebrates the 10th anniversary of Orthopaedic & Trauma Times by reviewing some of the changes that have occurred within medical law and regulation, which affect the practice of health care practitioners, over roughly the same time period.

One thing to bear in mind about the events discussed below is that whilst they all affect medical law and regulation, they did not all arise as a result of someone perceiving a need to change the law.

Health care and medical law

Whilst health care can be said to advance at a rate that is almost visible to the naked eye law, in contrast, seems to be something that is a static entity. However, this is neither fair nor accurate. Law can, and does, change. It changes in response to the society it represents, so that it can continue to represent the values and expectations of that society. However, as law represents society and its values, it generally needs society to make the first move and then the law follows.

For the medical law and regulation arena, the law follows what happens in the health care areas. The changes in the practice of health care practitioners; whether that be due to changes in their roles, the techniques and processes they use or the framework in which they work. From the perspective of medical law, the last 10 years have seen changes that are affecting the practice of health care to this day.

Picking events that can be seen as significant over a given time period is not an easy task. Does one pick events that everyone will know about; those that are more obscure and need illuminating; those that had an effect at the time but have been overtaken by subsequent events; or those that may not have been noticed at the time but can, in hindsight, be seen to be significant?

The areas that are discussed in this article have been selected because they represent the breath of medical law and regulation, and because they are areas that affect most health care practitioners. Also, the changes that they represent are ones that have, and are likely to continue to have, a lasting effect.

The medical law changes that follow are presented in chronological order, rather than an indication of their importance to health care practice. This is because it is impossible to state the importance of all the changes, as each area of health care practice will be affected by some of the events in different ways. Although, as we will see, some changes in medical law and regulation can have a far-reaching lasting effect on all areas of health care practice.

The Shipman Inquiry and its aftermath

Harold Shipman, the prolific serial killer and general practitioner, probably needs no introduction to health care practitioners. It is estimated, by the Inquiry (The Shipman Inquiry), that between 1975 and 1998, when he was finally caught, he killed 250 of his patients. In January 2000 he was convicted of murder and sentenced to life imprisonment. On 13th January 2004 he hanged himself in his prison cell. To date, he remains the only doctor to have been convicted of killing his patients.

Including Shipman and the subsequent Inquiry into his activities may be thought of a little bit of a cheat as the Shipman Inquiry commenced in March 2000 and produced its sixth and final report in January 2005. A whole 2 years before the Orthopaedic & Trauma Times came into existence. However, whilst this is true, it took time for the recommendations to be enacted and there has been action on the recommendations throughout the life of the Orthopaedic & Trauma Times. Indeed some of the recommendations have only finally been acted upon in the past couple of years or so, having had a long consultation period. It can be said, with some confidence, that the aftermath of the Shipman Inquiry still has ramifications for health care practice and health care practitioners to this day.

There were many recommendations made by the Shipman Inquiry including: changes in the regulation of controlled drugs; the training of coroners; introduction of whistleblowing processes; changes to the death certification process; accountability of the regulatory bodies; and changes to the professional regulatory bodies and thus to the regulation of health care practitioners (Secretary of State for the Home Department and the Secretary of State for Health (2004)).

One of the regulatory changes that have been enacted in recent years that can be linked back to the Shipman Inquiry is that of revalidation. 'Revalidation has been seen as the way forward for professional regulation specifically the way of determining if a healthcare practitioner is fit to practise within their professional sphere' (Cornock 2016 p. 9). In essence, revalidation is a way of ensuring that health care practitioners remain competent to fulfil their roles by requiring them to demonstrate that they are fit to practise on a periodic basis.

The General Medical Council introduced revalidation for doctors on 3rd December 2012. However, 'it should be noted that the GMC was already considering revalidation as far back as 1998, prior to any attempt to impose it upon them by an external organisation...however, although initially set to commence in 2005, development and introduction of revalidation by the GMC was delayed following comments and issues raised by Dame Janet Smith in the Shipman Inquiry fifth report' (Cornock 2008 p. 300). Nonetheless, the form in which revalidation was ultimately introduced was different to that initially proposed, and was amended in the light of the recommendations from the Shipman Inquiry.

For nurses and midwives, revalidation was introduced on 8th October 2015. The first nurse and midwives to undergo revalidation did so in April 2016.

For health care practitioners, revalidation is here and it is staying. It may not affect all health care practitioner groups as present but it seems most likely that it will. It would be a ludicrous situation to have some health care practitioner groups involved in direct patient care undergoing revalidation and some not. Revalidation is affecting the practise of health care practitioner and will continue to do so, because they will have to periodically go through the revalidation process to show that they remain fit to practise.

Assisted suicide

However you term it, voluntary euthanasia, physician assisted death or assisted suicide, this is a contentious topic that tends to polarise people including health care practitioners into those that support it and those that oppose it.

Until August 1961 it was a crime to commit suicide. Those who attempted suicide but were unsuccessful could find themselves sent to prison. With the enactment of the Suicide Act 1961, suicide was decriminalised, meaning that suicide and attempting suicide would no longer be treated as a crime (section 1). However, assisting someone to commit suicide remained and continues to remain a crime (section 2), and can carry a prison sentence of up to 14 years (section 2(1C)).

Assisting suicide means more than just actually helping the person with the physical act of their suicide. According to the Suicide Act 1961, it also includes encouraging the individual with regard to their suicide (section 2A). The word encouraging nor the word assisting is not defined within the Act and so can mean anything that would aid the individual in the actual act of suicide. The person who is committing suicide does not actually have to succeed for a person to be charged with assisting their suicide: if there is an attempt at suicide the offence of assisting suicide can be committed (section 2A).

Over the years since the enactment of the Suicide Act 1961 there have been calls for assisting suicide to be decriminalised. Indeed many health care practitioners support assisted suicide, and others have voiced their willingness to assist individuals with their death, for instance see Templeton 2016.

In an effort to have the law changed, several individuals have brought challenges in the court to the legality of the provisions relating to assisting suicide and challenged whether they are compatible with human rights. One such individual was Debbie Purdy; Mrs Purdy suffered from progressive multiple sclerosis. Mrs Purdy's legal argument was that because the Director of Public Prosecutions (DPP) appears to have a discretion under section 2(4) of the Suicide Act 1961, which states 'no proceeding shall be instituted for an offence under this section [assisted suicide] except by or with the consent of the Director of Public Prosecutions', she is entitled to know when the DPP would bring such a case (*R (on the application of Purdy) v Director of Public Prosecutions*).

The case was ultimately heard in the House of Lords (coincidentally this was the last case to be heard by the House of Lords before it was superseded by the Supreme

Court) where it was held that Mrs Purdy's human rights were being infringed as she was not able to regulate her behaviour without knowing what factors the DPP would take into account when deciding to prosecute a case for assisted suicide. As a result in February 2010 the DPP issued the 'Policy for Prosecutors in respect of cases of Encouraging or Assisting Suicide'.

This document clearly outlines the factors that would favour a prosecution and those that would tend against prosecution, so that it is possible to determine what actions can be taken to assist someone with their suicide or death, without fear of prosecution. For health care practitioners, a key factor in favour of prosecution is number 14 which states the defendant was 'acting in his or her capacity as a medical doctor, nurse, other healthcare professional, a professional carer [whether for payment for not], or as a person in authority, such as a prison officer, and the victim was in or her care' (Crown Prosecution Service 2010 p. 7). Thus health care practitioners need to consider that their actions, when acting in a professional capacity, will be judged differently to ordinary members of the public.

The changes in this area of the law demonstrate the law has responded to change in societal values by publicly establishing the factors that would lead to a prosecution for assisted suicide. However, it is apparent that health care practitioners need to be especially vigilant about their role in the death of patients in their care.

Duty of candour

In 2009 the media exposed the poor care, substandard treatment and high death rates that were occurring as a result of serious failings at the Stafford Hospital, part of the Mid Staffordshire Foundation Trust. On 9th June 2010 it was announced that a public inquiry would be held to examine the problems and determine why nothing was done earlier to address the serious issues that had occurred (Francis Inquiry website).

The final report of the Mid Staffordshire NHS Foundation Trust Public Inquiry was published on 6th February 2013. It was held that a system failure had occurred. A total of 290 recommendations were made to prevent such situations occurring again.

One issue that was identified was that staff concerns were repeatedly ignored by managers and that regulators failed to identify the problems. A key aspect of the failings was poor nursing care, understaffing of nursing and a low ratio skill mix of qualified to unqualified nursing staff. Warning signs were reported to managers but these were not acted upon.

It was identified that in future there needs to be a health care system where openness, transparency and candour all feature. This was in fact a theme in the recommendations. Recommendation 181 was concerned with the creation of a statutory duty on healthcare providers and also on health care practitioners to observe a duty of candour.

It can be argued that health care practitioners already had an ethical duty of candour, to be honest with their patients and speak up when failings or poor practice is observed, as a result of their professional codes of conduct. The recommendation was that this should be legally enforceable through the creation of a criminal offence

The full recommendation is:

‘A statutory duty should be imposed to observe a duty of candour:

- On healthcare providers who believe or suspect that treatment or care provided by it to a patient has caused death or serious injury to a patient to inform that patient or other duly authorised person as soon as is practicable of that fact and thereafter to provide such information and explanation as the patient reasonably may request.*
- On registered medical practitioners, registered nurses and other registered professionals who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare provider by which they are employed has caused death or serious injury to the patient to report their belief or suspicion to their employer as soon as is reasonably practicable.*

The provision of information in compliance with this requirement should not of itself be evidence or an admission of any civil or criminal liability, but non-compliance with the statutory duty should entitle the patient to a remedy.’ (Francis Inquiry 2013 Executive Summary p. 104).

The organisational duty was implemented through regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The duty on health care practitioners was first outlined in the Joint statement from the Chief Executives of statutory regulators October 2014. In June 2015, the General Medical Council and the Nursing and Midwifery Council issued joint guidance on what they expect from their registrants with regard to the duty of candour. The duty, which is enforceable through the respective fitness to practise procedures of the regulators, is that all health care professionals must be open and honest with their patients and this includes, amongst other things, informing patients when something has gone wrong and offering an appropriate remedy; and also being open and honest with their employers and other organisations.

Although the duty, to be honest and open with patients and relatives, was already in existence, as a result of the Mid Staffordshire NHS Foundation Trust Public Inquiry it has been strengthened. The regulators of health care professionals have issued specific guidance with regard to this aspect of practice. Therefore this is an additional requirement that all health care practitioners need to be aware of as they undertake their clinical practice and in their interactions with patients, relatives and their managers and employers.

Dishonesty test

A further element of being honest, well in fact not being dishonest, brings us right up to date with a case that received its judgement on 25th October 2017. This is the *Ivey v Genting Casinos (UK) Ltd [2017]* case.

In cases brought before the professional regulatory bodies for dishonesty, for example General Medical Council and the Nursing and Midwifery Council, the regulators have had to prove two things since 1982 in order to prove dishonesty against the registrant. These are that: the conduct complained of was dishonest by the lay objective standards of ordinary reasonable and honest people; and that, the defendant must have realised that ordinary honest people would so regard his behaviour as dishonest (*R v Ghosh [1982]*). If either of these was missing then the registrant could not be found dishonest.

The Ivey case concerns a professional gambler who was suing a casino that was withholding his winning because they believed he had cheated in order to win. As a result of this case, the health care regulators do not have to prove that the registrant must have realised that others would regard his behaviour as dishonest. All they have to prove is that the ordinary and honest reasonable person would see it as dishonest. The reason for the change is, in the view of the Supreme Court, 'the more warped the defendant's standards of honesty are, the less likely it is that he will be convicted of dishonest behaviour' (Ivey v Genting Casinos at para 57), because if they do not perceive something as being wrong then they most likely will not consider that others do.

For health care practitioners this means that in future they will be judged solely by an objective test and not a subjective one as well. It remains too early to see how this will be implemented by the health care professionals' regulators but it is an important change in how dishonesty will be judged.

Conclusion

In this deliberation of the changes in medical law and regulation over the last ten years that affect the current health care practitioner, we have moved from consideration of a serial killer, via someone who wanted certainty about their death, through institutional substandard care to a professional gambler suing for his winnings. All this shows that it is not just the changes in actual medical law, the legislation and cases, which have a direct effect on the health care practitioner. The modern health care practitioner of today faces challenges from a variety of sources, all of which affect the way that they undertake their role and account for it. The changes discussed above have arisen from two public inquiries, one legal case that can be said to form part of medical law and a legal case concerned with suing for one's property.

A final thought: there were so many other changes in medical law and regulation, that have occurred over the past ten years, that could have been chosen, but these are a wide representation of what affects the health care practitioner now and for the future – until the law and regulation changes again.

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The Shipman Inquiry website can be accessed at:

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