1. A general introduction

Thierry Vansweevelt and Nicola Glover-Thomas

Why a book series on health law? This book series aims to bring together the existing and emerging body of research in several important areas of health law, and to provide a comparative, critical and analytical lens through which to view fundamental concepts. Health law, both as a distinct discipline and in practice, has gained significant traction over the last 40 years and this is set to continue. Health is something which has global reach – as individuals, we are all invested in the notion of good health and the systems in place to help us achieve and maintain good health. All countries are confronted with the same medico-legal problems; yet political and cultural differences often result in very different solutions. These diverse responses are not always easy to access: linguistic challenges, the inaccessibility of foreign legal sources, historical, social and political knowledge gaps and different jurisprudential contexts present significant challenges when trying to understand how the law operates in practice in particular countries. As global interconnections continue to increase, this is a fitting time to publish a comparative view of the field and to provide international analysis of the different approaches around the world to diverse medico-legal issues.

The editors hope that this book series will serve as a respected reference that presents a comprehensive picture of the field. The books in this series will also provide detailed critical depth when considering current controversies and play an important role in moving the field forward. The topics covered by this book series will be enlivened by the cross-jurisdictional dialogue of contributing authors, most of whom are recognized experts in their respective parts of the world.

This book series is directly linked with the World Association of Medical Law (WAML). Since its inception, the WAML has become the largest international association for medical law. Its members include lawyers and healthcare workers across a broad range of specialisms. The WAML was established in 1967, when it met for the first time in Ghent, Belgium. It now boasts a membership of over 650 associates across more than 30 countries. It hosts an international meeting annually, which is attended by more than 300 participants

from all around the world. The WAML provides a broad international platform that encourages scholarship and collaborative research among its members.

Changes in the healthcare landscape have been rapid in many parts of the world. Advances in medical technology and innovation have also provided scope for many people – at least in theory – to access medical interventions that were previously unavailable. At the same time, significant changes have occurred. This first book in the series focuses on informational disclosure and informed consent – a key foundational concept in health law that in many countries acts as the initial gateway to medical intervention. At the heart of contemporary medical ethics is the notion of self-determination and choice. Ensuring that a choice is a true reflection of the patient's wishes requires evidence that the choice has been made properly. The decision should be rigorously scrutinized to ensure its validity – a validity that is achieved when the decision is made freely, based on full information, by an individual who is mentally capable of making a decision. Sometimes these requirements are not always met; and while decisions are made all the time, not all of them will be regarded as valid. How the concept of information disclosure and informed consent is understood and executed in different countries varies widely, yet it maintains some common characteristics that are shared and recognized around the world.

In this book, these critical rights are examined from a variety of country perspectives. Attention is paid, among other things, to the provider and recipient of the information; the content of the information; the information of vulnerable patients; the exceptions to the information; and the protection of patients' physical and mental integrity. The legal foundations of the concept of informed consent may be found in international human rights, national laws on health law and patients' rights, and national case law.

The importance of informed consent is growing, both nationally and internationally. More patients are aware of their rights and are seeking to reinforce them. More patients are willing to complain when they do not receive the information necessary to make informed medical choices. Increasing focus is being placed on the way in which information is disclosed, the language used and the patient's level of understanding.

The countries covered in this book have been chosen to provide insight across continents and represent a mix of the following:

- jurisdictions from both:
  - the common law tradition (Australia, Canada (except Quebec), United Kingdom, United States); and
  - the civil law tradition (Belgium, China, France, Germany, Russia, the Nordic countries, South Africa);

- jurisdictions in which the principle of informed consent has been adopted either:
  - in the Constitution (Germany);
  - in a health code (France, South Africa) or Federal Law on Health Protection (Russia); or
  - in a specific Patient's Rights Act (Belgium, Nordic countries, South Africa) or other act (China); and
- jurisdictions with no legislation on informed consent (Australia, Canada, United Kingdom).

This sample of country coverage, while not offering a comprehensive picture of the way in which informed consent is understood and applied, seeks to offer a broad evaluation of the role and versatility of the concept of informed consent from a global perspective. In this volume, the contributions focus on the following aspects:

- The function of informed consent: Does it promote self-determination as an individual right? Is it a family right? Or is it ultimately still the physician who decides?
- The scope of the obligation to inform: On which aspects must the health-care worker inform the patient?
- Enforcement of the duty to inform: How is this duty enforced and how should it be enforced? What are the problems associated with enforcement?
- Objectives of informed consent: What are the objectives of the doctrine of informed consent? And to what extent is the doctrine effective in realizing these objectives?

The legal recognition of informed consent is in itself a confirmation of the importance of this principle. It empowers the rights of the patient, and in particular the right to self-determination. The courts have an important role to play in enforcing and developing the informed consent principle.

While the goal of the informed consent principle – to protect patients – is laudable, it is not beyond criticism. It has been argued that the informed consent doctrine has overshot the mark. As a neurosurgeon once wrote:

> Informed consent sounds so easy in principle – the surgeon explains the balance of risks and benefits, and the calm and rational patient decides what he or she wants – just like going to the supermarket and choosing from the vast array of toothbrushes on offer. The reality is very different. Patients are terrified and ignorant.

His judgement about informed consent forms is also devastating:

> He (the surgeon) handed the consent form – a document that has become so complicated of late that it even has a table of contents on its front cover – to the patient

> with a pen and the man quickly scribbled his signature without looking at it. . . He did not read it – I have yet to find anybody who does.

The doctrine has been criticized for leading to the 'juridicisation' of the doctor–patient relationship, encouraging patients to adopt a litigious attitude which undermines the trust between doctor and patient. Increasingly, doctors face the risk of their administrative workloads overtaking their clinical duties. Yet the knowledge inequality between clinicians and patients and their families is one that cannot be ignored. While the duty to inform does not fundamentally change this gap because of the inherent knowledge imbalance, the principle of informed consent provides a framework to equalize this power relationship.

In the end, the objective of informed consent is to achieve a fairer balance between informing the patient about proposed treatment so that an informed decision or a shared decision with the doctor can be made, and creating an open and honest working relationship between patient and doctor in which the pros and cons of any treatment are discussed.