Medico-legal Concerns Relating to Healthcare-Associated Infections

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Healthcare-associated infections (HAIs) are a major global public health concern. Numerous reports demonstrate that HAIs result in increased morbidity and mortality rates and also healthcare costs. In the US, it has been estimated that five of the most common HAIs resulted in an additional USD 9.8 billion in healthcare costs in 2012. The US Centers for Disease Control and Prevention estimates that 1.7 million admitted patients acquire HAIs and an estimated 98,000 die due to HAIs, annually. In a point prevalence study of 5,415 patients conducted between years 2015 and 2016 in Singapore hospitals, one in nine adult inpatients had at least one HAI.[1] Many HAIs are considered preventable and must be considered a patient safety issue for the healthcare institutions and healthcare workers (HCWs).

Despite these alarming figures, Robert Steinbuch reported that written legal judgements concerning HAIs were few.[2] In this article, we will highlight the relevant medico-legal concerns which relate to HAIs, so as to improve the practice of doctors in the increasingly litigious environment of medical negligence cases.

Medical negligence

As a starting point, HAI is defined as an infection that developed more than 48 hours after admission to a healthcare facility and which was not present or incubating at the time of admission. Simply put, HAIs are infections that patients acquire while receiving healthcare. It is usual to subcategorise HAIs according to the target organ and/or tissue system affected, such as the urinary tract, lungs, bloodstream, wound infections, etc. HAI is the preferred term rather than nosocomial infections.

The term "medical negligence" generally refers to claims of negligence under tort law, which involves a healthcare institution and/or worker as the respondent. It is therefore helpful to break down medical negligence into its component legal doctrines before we discuss how it relates to HAIs. The three components are:

1. Duty of care;
2. Causation; and
3. Harm.

Duty of care

A duty of care in medical law generally refers to the intrinsic responsibility of a HCW when taking care of a patient. While there are many important sub-questions to be answered when asking whether a duty of care exists, the most relevant question for discussion is what legal standard the HCW or institution is held to when administering their services. This obviously varies greatly depending on one's specialisation or position held within the institution and, with the recent amendments to the Civil Law Act 1909 (CLA),[3] the kind of service being provided by the HCW.

For diagnosis and treatment, the duty is set out in the simple Bolam-Bolitho (BB) test which has two stages. First, the court will ask whether the doctor acted in accordance with responsible medical opinion; and secondly, if the answer is yes, the medical opinion must be capable of withstanding logical analysis.[4,5]

For the provision of medical advice, the test was formerly the Modified Montgomery test,[6] which is now codified under Singapore law in section 37 of the CLA. Per the wording of the statute, it seems to echo similar sentiments as the BB test, mentioning both "reasonable professional practice" and such practice being "logical" in sections 37(1) and 37(5), respectively. The key difference, however, is the supplementary requirement that for a professional opinion to be relied upon, it must contain all information "material" to the patient and must also justify any non-provision of information to the patient.[3] Moreover, the "logical" portion of the test explicitly states that the opinion must, *inter alia*, have been made after considering the "comparative risks and benefits" of the medical issue at hand as per section 37(5)(a) of the CLA. This slightly raises the bar of the BB test to be more "patient-centric", as confirmed by the court in their landmark judgement.[7]

Causation

The second important aspect of medical negligence is proving causation, which is as its common-sense meaning suggests – it must be shown that it was the breach of the duty of care (ie, failing to reach the professional standard of reasonable care) which caused harm to the patient. Causation is more relevant when considering claims made against negligent treatment or diagnosis but is likely quite straightforward for cases involving negligent advice. This is easy to illustrate with an example: in an English case, a patient visited a hospital due to arsenic poisoning, but was negligently refused treatment due to a shortage of staff and he eventually died from the poisoning. The challenge was in proving whether the delay in treatment caused his death, as it was not clear whether he would have survived even with timely treatment.[8] Conversely, if a HCW failed to administer the appropriate advice to a patient, the court has generally believed a patient's claim that if not for the failure to provide proper advice, they would not have undertaken the action (or omitted to take an action) which caused them harm.[9]

Harm

The final important aspect of a medical negligence claim is harm; specifically, harm that is caused by the specific breach of duty by the HCW. This is quite a straightforward aspect, and rarely do we see medical negligence cases involving non-physical harm. Harm can include complications, deterioration of one's condition, and of course, HAIs.

Challenges regarding HAIs

From the above discussion on medical negligence cases, a few important issues regarding HAIs which would be of interest to readers can be identified:

- Causation and probability
- "Right" and "wrong" medical opinions
- Personal vs institutional liability

Causation and probability

The practice of medicine is based on science and data, but it is ultimately from their application that many treatments are derived. A difficulty that arises with causation in medical negligence cases is that the typical situation is not one of binary outcomes but probabilistic ones – "there is a 1% chance of this occurring"; "it occurs in a likelihood of 5 in 250 cases"; "the data from study X suggests…". It is not uncommon to have heard these phrases used in medical practice, and it accurately reflects the reality of practising medicine. As such, it is hard to accurately quantify how much of a risk the patient was exposed to due to the HCW's actions, and in turn, the proportion of liability that should be subsequently attached to the HCW.

It is for this reason that negligence claims involving HAIs from a healthcare institution or worker are often challenging. The potential sources and origins of the bacteria, virus or fungi that resulted in the HAI also constitute major hurdles in establishing causality. It is for this reason that plaintiffs and judges instead focus on legal arguments such as negligence in diagnosis and delayed treatment of HAI, or failure to disclose risk of infection to strengthen their claims for liability. The bottom line, however, is that risk will eventually materialise, and it might not necessarily be the fault of the HCW involved. How healthcare institutions and workers can subsequently "protect" themselves in the case of such materialisation of risk is covered later in the section "Safeguards and Standards". A comforting note is the fact that courts are quick to recognise the various acute clinical and emergency situations doctors find themselves in and adjust their expectations of the appropriate standard of care accordingly.[10]

"Right" and "wrong" medical opinions

When talking about the negligent behaviour of the healthcare institution or worker, it is not helpful to discuss actions that are *clearly negligent*, and which clearly fail to meet a common-sense standard that is obvious even to laypersons and judges. This is covered by the doctrine of *res ipsa loquitur* – that the wrong speaks for itself. In such cases, it is likely that an out-of-court settlement will be sought by the healthcare institution or worker.

The focus of this discussion is thus the borderline diagnosis, treatment or advice that generates controversy and disagreement – that can be argued either way and forms the driving force of medico-legal suits. A pertinent question to ask then: is there a right or wrong medical opinion? While there are some situations where one could answer with a resounding "Yes", it is likely that most HCWs would avoid stating categorically that their (or another's) opinion is indisputably right or wrong.

The difficulty then is how this will be dealt with by the courts. In the case of HAIs, it is always possible that even despite following all the "right" guidelines and practices, it would still lead to the "wrong" outcome, resulting in HAI. It is for this reason that the courts and the law choose to adopt a different kind of language, one of **reasonability** rather than right or wrong. Nonetheless, reasonability is an equally indeterminate and controversial concept – after all, doctors can only do so much with their limited time, information and knowledge of the human body. In a battle of two reasonable opinions however, there is in truth no battle – all that matters to the judges is whether there is a reasonable and logical opinion supporting the HCW or institution's practice in question. In fact, the court summarily rejected an argument that Singapore courts should follow the UK approach of accepting "right" and "wrong" opinions when looking at possibly negligent diagnosis.[11] It reaffirmed that the reasonable and logical BB test still prevails.[10]

Personal vs institutional liability

On the topic of personal and institutional liability, one may expect HAIs to be solely the subject matter of the former – after all, any failure to prevent infection is on the onus of the HCW rather than the institution, which merely instructs and manages such workers. Nonetheless, there are two ways in which institutional liability may link back to HAIs.

The first involves a concept called vicarious liability – that an employer can essentially be sued for an employee's wrongdoing, so long as such wrongdoing was committed in the course of their employment. This is typically used to prevent corporations from escaping liability for any harm they caused and is typically less relevant in medico-legal negligence suits.

The more relevant and illustrative example of what institutional liability for HAIs can look like is the case of *Noor Azlin Binte Abdul Rahman v Changi General*.[10] Here, the personal liability of each doctor, as well as the institutional liability of the healthcare institution was considered in turn. Notably, two of the three doctors did not breach their duty, while instead, the healthcare institution was liable for a breach of their duty. The specific duty in such a case was to "ensure proper follow-up on a [patient's]" medical treatment.[10] A logical extension of such a duty would be for the healthcare institution to ensure that there are not only written protocols and processes but also adequate enforcement of infection prevention and control practices, sterilisation of equipment, etc, and training provided to HCWs to minimise the risk of HAIs.

An actual case study that we can learn from was an outbreak of Hepatitis C infection in the renal wards at Singapore General Hospital (SGH) in 2015. There were eight deaths in this cluster, of which seven were thought to be related to the infection. After the cluster of infection was reported to the Ministry of Health (MOH), an independent review committee was convened and their findings indicated multiple overlapping factors and gaps in the surveillance system that led to the outbreak.[12] Four MOH and 12 SGH senior staff in leadership positions were disciplined, which may point towards the possibility of healthcare institutions being held liable for future HAIs.

Safeguards and standards

To reduce the risk of HAIs in healthcare facilities, MOH has published national guidelines on infection prevention and control for acute healthcare institutions in 2017, which were recently updated in 2022.[13] Similar national guidelines for infection prevention and control specific for community hospitals, long-term care facilities and dialysis centres have also been published.[14,15,16]

To reduce the risk of HAIs in surgical procedures, the *National Surgical Antibiotic Prophylaxis Guideline (Singapore)* was published in September 2022 by the Academy of Medicine, Singapore (AMS); National Centre for Infectious Diseases; College of Surgeons, AMS; College of Anaesthesiologists, AMS and Chapter of Infectious Disease Physicians, College of Physicians Singapore.[17]

These guidelines provide the standard of care expected and will likely form the basis for any regulatory or medico-legal action if the healthcare institution and/or surgeon or physician deviates and/or falls short of these guidelines.

Much has already been discussed on the role of informed consent in medicine and, where relevant, it will be important to incorporate "infection" as a known complication for the surgical procedure. Unless it has been expressly stated, it should not be assumed that the consent process for the surgical procedure will also cover post-operative complications that occur in "high risk surgeries", including a need for prolonged mechanical ventilation, multiple catheters and parenteral nutrition, which all increase the risk for HAIs. It is less clear on where to draw the line on informed consent with respect to HAIs associated with "simple, common" ward procedures like placement of a nasogastric tube, intravenous line or indwelling urinary catheter.

Even if all the standards are adhered to, HAIs may still occur. It is the authors' opinion that good communication forms the core safeguard against complaints and legal action by the patient and/or relatives. This is elaborated below.

An argument from perspective

Doctor's perspective

To many doctors, even receipt of a complaint letter would cause one much frustration and anxiety, let alone that of a civil suit of negligence. They might feel that it is unfair that a patient can essentially engage in frivolous complaints or lawsuits on the basis of mere medical disagreement, especially in the rise of compensation culture and medico-legal litigation. Feelings may arise that the patient and/or relatives were particularly ungrateful, or merely finding someone to blame. Such feelings are exacerbated by time constraints, excess patient workload, guideline overload and excessive focus on documentation rather than direct patient care. Lack of autonomy and medico-legal liabilities all add to HCW "burnout".

Patient's perspective

On the other hand, the patient (or family member) likely sees his/her personal loss as a result of the medical service as front and centre to their claim. Moreover, tertiary medical care can be expensive to the layperson, and financial compensation of any unexpected loss may be justified in their eyes. Other considerations for patients and relatives pursuing negligence include lack of transparency and accountability for any harm which occurred, and expecting an accompanying explanation or apology for the conduct leading to such harm.

Legal perspective

In any case involving tort law, the key consideration of the court is compensation on the basis of risk apportionment. Therefore, the law is theoretically concerned about who should bear the burden of the materialised risk, and so who should compensate for the loss which emanated. For HAIs, there are also other arguments from policy – that the court wants to discourage and deter any bad practice in an individual or the system leading to such HAIs, or at the very least provide some form of monetary justice to patients who suffer from HAIs.

The key takeaway here is that all of us are humans – patient, HCW and the judge included. It may be hard to do so, but taking the perspective of others can help us to empathise and understand their plight. Though litigation is ultimately an adversarial affair, we should not let such attitudes exemplify the healthcare relationship.

Concluding remarks

Ultimately, healthcare is about the patient, though we cannot leave the doctor's stake out of the equation. HAIs are a bad outcome measure that requires HCWs to reflect and relook at the unfortunate outcome to improve patient safety. As HCWs, it is our responsibility to restore trust when HAIs occur, as it is this trust which forms the cornerstone of the doctor-patient relationship. ◆

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