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Clinical Guidelines: Litigation, Patient Safety and the Law Conference

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By Beth Whitehead

The purpose of the conference was to explore how evidence-based clinical guidelines are used by defendants, lawyers and the courts in clinical negligence litigation and in attempts to improve patient safety. It also showcased preliminary findings from the Guidelines Project team's (Dr Conrad Nyamutata, Professor Jo Samanta and Dr Ash Samanta) research on the topic before publication in February 2019. The project was funded by the British Academy/Leverhulme.

The conference had a high calibre of attendees from a range of legal, medical and academic backgrounds. The day kicked off with a talk on informed consent and information disclosure by Rob Heywood, Professor of Medical Law at University of East Anglia. He referred to the case of Montgomery v Lancashire [2015] and the inconsistency in whether judges believe guidelines should have been adhered to or not.

Pritesh Rathod gave a lively account of a barrister's perspective on the use of clinical guidelines in clinical negligence litigation. There appears to be a trend of judges challenging medical expert opinions. The legal landscape is moving towards engaging patients in the decision-making process, valuing informed consent and considering individual cases rather than blind adherence to guidelines.

Legal director Laurence Vick gave a detailed explanation of the role of guidelines and protocols in clinical negligence litigation. He highlighted that in recent years there has been a proliferation of guidelines and protocols issued at local, national and international level by NICE, Royal Colleges, NHS Trusts and other organisations. While their aim is to facilitate best practice in a standardised way to ensure consistency of care, improving patient safety and minimising cost of negligence claims against the NHS, they may be vulnerable to challenge in court cases if not shown to be the product of an unquestionable decision-making process or if the process of dissemination and publication of a guideline is inadequate. Guidelines may be seen as one-size-fits-all, too prescriptive, restricting clinical discretion and being inflexible to the individual. In maternity settings, this approach causes a shift away from women-centred care by not including women in the decision making process fully through thorough conversations to support their autonomy.

I found the account by Dr Marwan Habiba, Consultant Obstetrician and Gynaecologist at the University Hospitals of Leicester NHS Trust, of guidelines and patient safety from a practitioner's point of view interesting. He highlighted the dilemma between prescriptive guidelines on how caesarean births are to be performed and the limitations of research and practice. Inconsistencies in gestational diabetes diagnosis criteria exist between different organisations and their guidelines. We need to be mindful of the different ways that guidelines are interpreted. If used prescriptively for clinical decision making, it means the individual's needs may not have been considered and it poses potential danger and ethical issues.

The project team gave a stimulating introduction to the hierarchy of guidelines (organisational versus regional versus global). There may be conflicts between these guidelines and there can be inconsistencies between healthcare providers on which guidelines are used in practice. They also talked about how the NICE guideline can be used in practice as "a reasonable body of opinion" in mitigating risks of litigation. They gave a preliminary overview of the findings on their research on the various guidelines and the emerging themes.

In the afternoon, attendees were broken up into small groups to discuss different themes. These included the constraints on whether clinical guidelines can be followed; how can optimal use of clinical guidelines be facilitated, to what extent is clinical autonomy constrained by their usage, should failure to follow guidelines affect a legal professional's decision-making on clinical negligence cases and should healthcare regulatory bodies be responsible for promoting the use of clinical guidelines? There were some excellent discussions about the ethical and practical aspects of having clinical guidelines, their usage in practice and how practitioners try to deal with the volume and conflicting advice from guidelines issued by different levels of organisations.

A member of the audience with NHS and legal experience gave an example of how a patient was harmed due to a delayed diagnosis. There was lack of an incident register and risk management or investigation to rectify issues with process to improve patient safety and prevent similar incidents in the future. Another person raised the issue of when a concern is being investigated, sometimes the practitioners are not informed nor consulted of the matters so valuable lessons were not learned. They thought that some kind of incidents recording and shared risk register in the system would help to improve patient safety. Learning from mistakes to improve quality of care and safety can only be a good thing. It will increase public confidence in the healthcare system.

Dr Ash Samanta gave an example of how when an incident happens in the airline industry there are thorough independent investigations to ensure improvement in safety and high standards. However, when a member of the audience raised the issue of how there is significant lack of independence in investigating NHS incidents, he retorted, “Who is going to pay for it?” The reply was “taxation” and it was pointed out that users have paid for healthcare services already. Independent investigation can be valuable in improving patient safety and increasing public confidence as well as improving the culture of care and accountability amongst healthcare workers.

Another attendee asked Dr Ash Samanta for the definition of safety in their research, e.g. whether it encompasses psychological as well as physical safety but he simply referred to the NHS’s definition which is “the avoidance of unintended or unexpected harm to people during the provision of health care”. I was surprised at how vague and non-committal the NHS definition is. There is still a long way to go in terms of acknowledging the importance of compassion and body integrity in providing safety in health care. A well-rounded definition of safety is important in forming a foundation for framing and evaluating discussions about its improvement and around usage of clinical guidelines.

Overall, the conference provided thought-provoking multidisciplinary discussions. This is much needed in communicating the difficulties and ethical and human rights issues medical and legal professionals face. It was a constructive forum in challenging practice models, clinical guidelines and care culture. More openness and independence are needed in the healthcare system. It will take working hand in hand with various health care providers and patients to improve safety and standards.