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Title: The spectrum of ethical issues in a Learning Health Care System: a systematic qualitative review.

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Abstract

Background: The "Learning Health Care System" (LHCS) concept proposes integrating clinical research and clinical practice in order to achieve continual improvement in health care. While learning health care potentially has a number of significant advantages, the normative and empirical literature has highlighted various ethical issues. There have not been, however, any systematic reviews of these issues.

Aim: To determine systematically the spectrum of ethical issues that is raised for stakeholders in a LHCS.

Methods: A systematic review in PubMed and Google Books (publications in English or German between 2007 and 2015) was conducted. Data was analysed and synthesised using qualitative content analysis. Ethical issues were defined as arising when a relevant normative principle is not adequately considered or two principles come into conflict.

Results: Our literature search retrieved 1258 publications of which 65 were included in the final analysis. A total of 67 distinct ethical issues could be categorised under different phases of the LHCS life-cycle. An overarching theme that was repeatedly raised was the conflict between the current regulatory system and learning health care.

Conclusion: The implementation of a LHCS can help realise the ethical imperative to continuously improve the quality of health care. However, the implementation of a LHCS can also raise a number of important ethical issues itself. This review highlights the importance for health care leaders and policy makers to balance the need to protect and respect individual participants involved in learning health care activities with the social value of improving health care.