

Publication

The ethical oversight of learning health care activities in Switzerland: a qualitative study

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OBJECTIVE: This study aims to identify the key issues regarding the ethical oversight of health care improvement activities in Switzerland. **DESIGN:** Individual semi-structured qualitative interviews, analysed using conventional content analysis. **SETTING:** Interviews were conducted in Switzerland between July 2017 and February 2018. **PARTICIPANTS:** A purposive sample of 38 key stakeholders from four different groups: health care improvement researchers and practitioners (n = 19), representatives of clinical trial units (n = 3), clinical ethicists (n = 5), quality heads of university hospitals (n = 5), and cantonal ethics committee members (n = 6). **RESULTS:** There appears to be widespread uncertainty regarding when certain learning health care activities require ethical review by a research ethics committee in Switzerland. This situation is exacerbated by legislative ambiguity and limited guidance. It was reported that the lack of other oversight mechanisms for activities outside of the Human Research Act is also leading many investigators to submit projects to research ethics committees to avoid barriers to publication. **CONCLUSIONS:** The continuous, integrated, and dynamic nature of learning health care poses significant challenges to the current regulatory framework. It will be important that more clarification and guidance is provided regarding which activities require ethical review, and that it is considered how the ethical oversight of activities falling outside human research legislation can be strengthened. However, the traditional model of ethical oversight is poorly suited to learning health care and may need to be replaced with new systemic oversight approaches.' The Author(s) 2019. Published by Oxford University Press in association with the International Society for Quality in Health Care. All rights reserved. For permissions, please e-mail: journals.permissions@oup.com.

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