



Universität
Basel

Research Project

The ethics of doing research in developing countries

Third-party funded project

Project title The ethics of doing research in developing countries

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Organisation / Research unit

Ethik / Bio- und Medizinethik (Elger)

Department

Project Website <http://ibmb.unibas.ch/research/research-ethics/resource-limited-countries/>

Project start 01.09.2013

Probable end 31.08.2016

Status Completed

DEVELOPING AN ETHICAL FRAMEWORK FOR RESEARCH USING SURVEILLANCE DATA IN RESOURCE LIMITED COUNTRIES:

Data routinely collected as part of surveillance activities in public health (PH) is increasingly being used for research purposes. This occurs because activities such as the routine documentation of interventions and monitoring of epidemiological data, that characterize surveillance, offer representative or comprehensive data that can be used for later research. However, there is an increasing realization that because surveillance does not ordinarily warrant ethical requirements, the data gathered within it, which may subsequently be used for research, may not undergo ethical reflection either. There is also a conceptual challenge of differentiating between “research” and “non-research” in surveillance, so as to develop appropriate criteria for ethical distinctions. Questions on whether, which aspects and at what point research using surveillance data (RUSD) should fit in existing ethical frameworks, have also been inadequate. Currently, there is consensus that ethical reflection is important for all evidence-generating initiatives, whether or not they constitute formal research. However, questions on who is responsible for ethical judgments, and what processes are adequate for RUSD remain unanswered. Moreover, existing ethical frameworks that have been produced are either suited to PH initiatives or research but not to both, as is thought to be necessary in the case of RUSD. There is consequently, a dependence on extrapolations from research ethics frameworks and PH ethics guidelines for RUSD. The resultant imprecision of stakeholders’ interpretation, adaptation and implementation of ethical standards have potentially serious implications for research ethics goals and public accountability. The danger is that contemporary PH evidence generation and RUSD models in resource limited countries, such as Health and Demographic Surveillance Sites, may not be to meeting the right ethical standards, even when critical ethical issues are raised.

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Is Social Value a Determinant of the Overall Standard of Care Provided in Infant Vaccine Research?

An Empirical Study of Infant Malaria Vaccine Trials in Ghana and Tanzania.

Summary of Research Plan

Introduction: Vaccine research may have inherent value by contributing to the understanding of scientific advancement, but fundamentally it must establish instrumental value to benefit society, this constitutes the social value of research (Emanuel, Wendler et al. 2004). In practice however, individuals of resource limited settings can fail to gain from research in which they have participated because the process of translating research into local health improvements is uncertain (Graham, Logan et al. 2006). For this reason general access to proven health interventions at the outcome of a trial cannot be relied upon and therefore other mechanisms must be developed to enhance the social value of research. This empirical study asks, is then the ethical requirement of social value a determinant when setting the overall standard of care in research (SOC)? At present, this standard of care is poorly defined in guidance, if at all, and the approaches range from providing the 'best care in the world' to accepting the local healthcare system, which may be non-existent. This project examines whether the SOC of infant vaccine trials is set at a level that contributes to developing local knowledge and generalized health improvements, so providing social value. This project is an ethical evaluation of the overall standard of health care in research, with consideration for the socioeconomic and healthcare settings in which vaccine trials operate. The study asks, whether, if at all, the concept of social value operates as a determinant of this standard in the study institutions.

Background: The main concerns surrounding the standard of care are the creation of a "double standards" for developed and developing countries (Shapiro and Benatar 2005). In addition there are specific issues when discussing infant malaria vaccine trials, in respect of trial endpoints and the differing methods of combating malarial transmission and disease. Furthermore, current guidelines and legislation make no direct reference to *standard of care*. As ethical concerns (Indian Supreme Court 2013) continue to surround infant vaccine research, there is a need to better understand the SOC provided in prevention trials, how SOC is defined and whether social value is a determinant of it. As vaccine trials continue to occur and focus primarily on children under 5 years of age (A. Petryna 2009), this population becomes the focus of this empirical study.

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Published results

3706239, Anane-Sarpong, Evelyn; Wangmo, Tenzin; Sankoh, Osman; Tanner, Marcel; Elger, Bernice Simone, Application of Ethical Principles to Research using Public Health Data in The Global South: Perspectives from Africa, 1471-8847, Developing World Bioethics, Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

4133852, Anane-Sarpong, Evelyn; Wangmo, Tenzin; Ward, Claire; Sankoh, Osman; Tanner, Marcel; Elger, Bernice Simone, "You Cannot Collect Data Using Your Own Resources And Put It On Open Access": Perspectives From Africa About Public Health Data-Sharing, 1471-8731 ; 1471-8847, Developing world bioethics, Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

4118137, Ward, Claire Leonie; Shaw, David; Anane-Sarpong, Evelyn; Sankoh, Osman; Tanner, Marcel; Elger, Bernice Simone, Defining Health Research for Development: The perspective of stakeholders from an international health research partnership in Ghana and Tanzania, 1471-8731 ; 1471-8847, Developing world bioethics, Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

4118141, Ward, Claire Leonie; Shaw, David; Anane-Sarpong, Evelyn; Sankoh, Osman; Tanner, Marcel; Elger, Bernice, The Ethics of Health Care Delivery in a Pediatric Malaria Vaccine Trial: The Perspectives of Stakeholders From Ghana and Tanzania., 1556-2654, Journal of empirical research on

human research ethics : JERHRE, Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

4511108, Anane-Sarpong, Evelyn; Wangmo, Tenzin; Tanner, Marcel, Ethical principles for promoting health research data sharing with sub-Saharan Africa, 1471-8731 ; 1471-8847, Developing world bioethics, Publication: JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

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