

PARALLEL SESSION 1

Thursday 10 November 2016 13:50 – 14:50

1.A. Round table: Challenges to Ethical Research Conduct: Perspectives, Issues and Implications for Practice and Policy

Organised by: EUPHA section Ethics in public health
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Chairperson(s): Jihad Makhoul - Lebanon, Els Maeckelberghe - The Netherlands

The workshop is a round table of a 90-minute session with 4 panel discussants and a moderator. Each will make a short presentation and will be discussed between the members and audience.

The global surge in funding for and the corresponding increase in the conduct of public health research have fueled a growing interest in the development of research ethics regulations and human subjects protections. However, ethical clearance is not well established in public health and non-therapeutic research across disciplines, and is further challenged with the variety of research methods, tools and protocols. Empirical research investigating research conduct, regulation and experiences of stakeholders in the research process is timely, and is needed to provide evidence for the understanding of the issues, challenges and gaps in responsible research conduct. The round table aims to present 4 cases from Europe and Lebanon highlighting research findings pertaining to: challenges of ethics review board practices for health and policy research, including multi-methods and digital devices; misconceptions about non-therapeutic research ethics; and human participants' views of their involvement in health research with a focus on recruitment and consenting processes.

The added value of a round table is the critical look at the practice of research ethics in varying health research settings and contexts using empirical research findings to highlight the challenges that may go unnoticed and which have policy/practice implications. Researchers have used desk reviews, content analysis of ethics committee archives, cross-country mapping of ethical clearance practices and in-depth interviews with research participants.

The presentations discuss challenges to research conduct for researchers and reviewers. Research ethics reviews vary in scale of responses and requirements across types of ethics committees, countries and research institutions. The lack of attention to and misconceptions about ethical issues in phone apps and non-therapeutic research increases the risk of research harm and unethical publication practices. Meanwhile, research participants are unduly influenced in recruitment and consenting processes by family members, trust in healthcare providers, and the need for healthcare.

In conclusion, the high level of variations across discipline specific review boards suggests that applied ethics are greatly influenced by reviewers' expertise and training rather than by overarching ethical guidelines and principles. The varying ethics clearance practices and the lack of uniform guidance hamper international and multi-site research using social science methods. Despite the presence of review boards and regulatory guidelines, the conduct of ethical research falls short

of fully protecting research participants' rights in resource poor settings.

Key messages:

- There is a need to develop contextually sensitive and clear ethical guidelines
- There is a pressing need to build research ethics competencies for researchers and reviewers to design, conduct, publish and review ethically sound research

Juggling With Varying Ethics Clearance Practices: Experiences From A 7-Country Policy Study

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Ethics clearance in clinical research is well established. In public health research, especially using social science methods, the clearance traditions are less developed or harmonized across countries.

Research into Policy to enhance Physical Activity project (www.repopa.eu) (2011-2016) uses social science methods of document analysis of policies, stakeholder interviews, group interventions for researchers and policymakers, and a Delphi study to develop indicators for evidence-informed policy-making. The REPOPA countries are Canada, Denmark, Finland, Italy, the Netherlands, Romania, and UK. Ethics clearance practices of the countries were mapped using a matrix developed. Further, in the course of the project, using process evaluation approach, ethics clearance steps, questions, problems and updates were collected.

The ethics clearance practices were strictest in Canada, where full clearance was needed for all data gathering and renewed annually. UK's one-entry system was somewhat lighter and similar to the Finnish system. All other countries lacked ethics clearance for social science research; from these an official exemption document was needed though it was hard to find the body granting it. Due to so varying practices and lack of explicit regulation from the project funder, European Commission, the project created its own ethics guidance, accepted by the Consortium. The ethics juggle delayed the start of the data gathering over 6 months. When submitting manuscripts from the project, it has been a challenge to report on ethics since there is no single, uniform ethics clearance for the whole project.

The varying ethics clearance practices and the lack of uniform guidance hamper international research projects using social science methods. Horizon2020 guidance for ethics self-assessment (March 2016) attempts to clarify the situation and provides links to relevant documents. However, harmonization of guidance would enhance research.

The Smartphones Study: An Analysis Of Disciplinary Differences In Research Ethics Committee Responses To Phone App-based Automated Data Collection

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Digital devices provide a means to collect vast quantities of data relevant to health and social research with minimal respondent burden, but the automated harvesting of data without active participation raises ethical issues.

We aim to present findings from research on ethics committees' opinions of a project that used a smartphone app to collect location, calls and text, leisure activities, illicit drug use and photographic data from schoolchildren. A research protocol for this school based study of substance use and social networks using a phone app for data collection was sent to 13 ethics committees and the research governance office in Queen's University Belfast. The committees were asked to give the protocol scrutiny as if it were being submitted as a research study for approval. The protocol, and the proposal to submit it to other committees, was approved by the Sociology ethics committee. Thematic content analysis was conducted based on the returned comments.

Out of 13 ethics committees invited, five provided responses; five were humanities or physical sciences where the project was of no relevance, and Medical, Nursing, and Geography committees did not respond. All responding committees gave a favourable opinion but requested further information or minor changes. Emergent themes included: providing participant information regarding automated data collection; anonymising geographical and call information; awareness of digitised & online identity; and data security. There were large variations in the scale and content of responses, with the education research ethics committee providing the most varied and largest number of issues.

Phone app based data collection, even with a high level of invasiveness and in relation to sensitive topics is generally viewed favourably. The variation in ethics committee responses suggests that applied ethics are greatly influenced by reviewers' expertise and training rather than by adherence to overarching ethical principles.

Common Misconceptions And Publication Ethics Issues In Non-therapeutic Research

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Non-therapeutic research is usually considered less ethically challenging since it is not related to new drug testing or use of placebo. However, principles of Declaration of Helsinki are not less valid and ethical expertise of researchers is not less important in non-therapeutic protocols. If therapeutic research is the main accelerator of clinical practice, non-therapeutic research is of utmost public health importance providing evidence of causation in epidemiology and contributing to the development of health policies.

The aim of this report is to present and discuss common misconceptions and publication ethics issues related to non-therapeutic research.

Methods included an analytic study based on literature review and content analysis of archival documents of IRB of Medical University of Pleven.

In academic institutions contrary to healthcare establishments non-therapeutic types of research prevail. Since they are not interventional researchers often take for granted that harmful consequences are not inflicted. The analysis of experience of IRB in Medical University of Pleven show little or missing sensitivity to the resulting risks of the reuse of archival biological samples, need of ethical review of application of sociological approaches of investigation, adaption of information for target and control groups (22% of recommendations). Dependent relationships are rarely recognized as ethically nonpermissible in the recruitment of participants (10% of recommendations). Incorrect authorship teams and several other violations of principles of good publication practice have been observed.

Researchers' level of ethical knowledge is generally low. Harmonizing ethical competencies is getting more and more important in the light of international collaboration in multi-centered research projects. Development of a proper form of ethical training for researchers is a long-term area of academic collaboration.

Completing The Picture: Research Participants' Experiences Of Biomedical Research

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The recent rise in research institutes and funding for scientific and medical research involving human subjects in the Arab world raises concerns about ethical research conduct. The empirical literature on participants' perspectives about recruitment, benefits and how they are treated is scarce. Findings from our recent study with academic researchers in Lebanon and Qatar about their research conduct indicate that research regulation and capacity for ethical conduct is weak, and that deviations in the use of consent forms and consent seeking processes are abundant. This has adverse impacts on human subjects protection but may go unnoticed if participants' views of their experiences are not explored.

The aim is to investigate the experiences of adult participants in medical or health research in Lebanon, whose social context is one of social exclusion and inequitable access to healthcare, pertaining to recruitment, consenting and benefits.

Qualitative in-depth interviews were conducted with 30 men and women participants in biomedical research from 5 university-hospital sites. Thematic analysis identified recurring patterns and themes.

Preliminary findings point to possible undue influence in participants' recruitment into research, incomplete informed consent and a blurring of boundaries between research and healthcare provision. Family members and healthcare provider influence, reputation of the research institution and the need for medical care were among the influential factors. Reasons why the basic universal elements of informed consent (voluntariness, comprehension and capacity) are not always met are discussed and linked to the research context.

In conclusion, participants' perspectives of their involvement in research are important to provide a lay view of the research process and to identify weakness in research conduct. Power relations, values and inequitable access to resources have an important role to play in people's decisions to partake in research.