BMJ Global Health

Health policy and systems research: towards a better understanding and review of ethical issues

Valerie Ann Luyckx,[1] Nikola Biller-Andorno,[1] Abha Saxena,[2] Nhan T Tran[3]

To cite: Luyckx VA, Biller-Andorno N, Saxena A, *et al*. Health policy and systems research: towards a better understanding and review of ethical issues. *BMJ Glob Health* 2017;**2**:e000314. doi:10.1136/bmjgh-2017-000314

Received 8 February 2017
Revised 1 April 2017
Accepted 4 April 2017

[1]Institute of Biomedical Ethics and History of Medicine, Universität Zürich, Zürich, Switzerland
[2]Global Health Ethics Unit, World Health Organization, Geneva, Switzerland
[3]Alliance for Health Policy and Systems Research, World Health Organization, Geneva, Switzerland

Correspondence to
Dr Valerie Ann Luyckx;
valerie.luyckx@uzh.ch

ABSTRACT

Given the focus on health systems in the post-millennium development goal era and moving towards the sustainable development goals, there is a compelling need for a common framework for health policy and systems research ethics to guide researchers and facilitate review by research ethics committees. A consultation of global health policy and systems research and ethics experts was convened to identify ethical considerations relevant to health policy and systems research based on existing knowledge and to identify knowledge gaps through a scoping review and further expert deliberation. Health policy and systems research is highly complex and, in the absence of guidance documents, there is significant variability in ethics review. Although fundamental ethical principles pertain to both traditional clinical research and health policy and systems research, the application of these principles requires a comprehensive understanding of the nature of health policy and systems research with its distinct challenges. Such awareness must be raised among researchers and research ethics committees. Current research ethics committees lack familiarity with health policy and systems research and because health policy and systems research is conducted in real-world contexts, committees often have difficulties in determining whether a project is indeed research and/or requires ethical review. Given the strong current focus on health policy and systems research to rapidly improve health and health systems functioning globally, greater engagement and dialogue around the ethical concerns is required to optimise research review and research conduct in this rapidly evolving field.

INTRODUCTION

The WHO identified the need to develop a framework outlining ethical considerations relating to health policy and systems research. The need for capacity building in local research ethics committees to improve quality and efficiency of review of global health research is also highlighted in the literature.[1] Appropriate ethical conduct and review of health policy and systems research requires a broad understanding of the practicalities of health policy and systems research, how it differs from clinical and other health research, which ethical principles apply and how they may be upheld despite different applications.

Health policy and systems research aims to promote generation, dissemination and use of knowledge relating to all aspects of the health system.[2–5] Its major goals include understanding existing health system functioning, how system components interact, how health policy is generated and implemented and how to improve efficiency and performance of health systems. Health policy and systems research differs from clinical research where often a single disease is studied; usually under controlled conditions, interventions are implemented at an individual subject level and outcomes are measured in the same subject. Health policy and systems research is often conducted in 'real-world' contexts, embedded within existing policies and practices which may have inherent risks. The line between research and practice may therefore be blurred. Many circumstances in contexts where health policy and systems research is conducted are beyond the researchers' control, raising questions regarding the accountability of researchers regarding the research activities. The benefits of health policy and systems research are realised through impact on communities, institutions and systems functioning rather than changes in an individual's health. The main users of health policy and systems research are policy makers and managers who focus on system-wide health issues, in contrast to clinicians in clinical research.[5 6]

The role of the research ethics committee is to review research protocols and provide feedback and guidance to researchers to optimise the ethical conduct of research. Given the embedding of health policy and systems research in real-world contexts, there is a need to separate what should be governed by the ethics of health systems practice and policy making and what should be governed by the ethics of research. Research ethics committee

Key questions

What is already known about this subject?

- There are no comprehensive guidelines/guidance on the ethics of health policy and systems research.
- Research ethics committees are more familiar with ethical implications of traditional clinical research compared with health policy and systems research which hampers ethics review of health policy and systems research and may result in delayed and disparate reviews across study sites.
- Current literature on ethics of health policy and systems research focuses primarily on the ethical domains of upholding autonomy, risk–benefit balance, justice and determination of the need for ethical review; however, more comprehensive understanding by researchers and research ethics committees of the different applications of ethical principles between clinical research and health policy and systems research is important to enhance ethical review and conduct of health policy and systems research.

What are the new findings?

- Guidance is required to ensure comprehensive ethical review of health policy and systems research because of the evolving nature of projects within an uncontrollable and unpredictable environment.
- Varying levels of ethical review (waiver, expedited, full) may be required for health policy and systems research but must also be considered for monitoring and evaluation and quality improvement initiatives.
- Many ethical considerations must be specifically addressed in planning, conduct and review of health systems and policy research including: responsiveness of research to local needs; the nature of equipoise; implications of study design; operationalisation of informed consent; potential exacerbation of inequality; anticipating risks and benefits in all groups; levels of accountability of all stakeholders for post-study obligations, sustainability and ancillary care; maintenance of confidentiality and the importance of data sharing.

Recommendations for policy

- Capacity building within research ethics committees is required to enhance understanding and performance of ethical review of health policy and systems research and to harmonise reviews across sites.
- Researchers must be aware of all ethical implications of health policy and systems research to ensure appropriate planning and conduct of health policy and systems research and to communicate clearly with research ethics committees.

members are traditionally not familiar with these differences and therefore development of guidance is needed to facilitate appropriate review.

An expert consultation, led by the WHO and the Institute of Biomedical Ethics at the University of Zurich, was convened in July 2015 (http://www.who.int/alliance-hpsr/news/2015/erczur/en/). Twenty-eight global experts from 14 countries (see Acknowledgements), including health policy and systems research researchers, policy makers, health administrators and representatives of research ethics committees from the Eastern Mediterranean, Latin America, Africa, Western Pacific and India, and the WHO participated in the consultation to identify common challenges in ethics review of health policy and systems research, to discuss core ethical issues identified from the literature with specific relevance to health policy and systems research and to expand on current knowledge gaps relevant to ethical review and practice of health policy and systems research. This informed discussion lays the foundation for the development of a framework to enhance capacity building in ethical practice and review of health policy and systems research.

Prior to the consultation, a scoping review of current practices in ethical review of health policy and systems research in the literature was commissioned.[7] No current systematic guidelines for ethical review of health policy and systems research were identified. Two existing guidance documents relating to the ethical conduct of cluster-randomised trials and one on patient safety in research were found.[8–10] Most existing documents focus on the ethical issues of consent and autonomy, balancing risks and benefits and determining the need for ethical review. Ethical issues insufficiently addressed in the literature include: protection of research participants from exploitation; ancillary care needs identified during the research; the obligation of local research capacity strengthening; responsiveness of the research to health system needs; fair subject selection; risk of exacerbating inequality through the research and determination of minimal risk.

Given the inherent differences between clinical and health policy and systems research, the predominant familiarity/training of research ethics committees with clinical research, the acknowledged variability in ethics review across institutions and countries and the gaps identified in the literature, *there is a clear need for a harmonised ethical review framework for health policy and systems research.*[11–13]

ETHICAL THEMES AND CONSIDERATIONS RELEVANT TO HEALTH POLICY AND SYSTEMS RESEARCH

Application of ethical principles in health policy and systems research and clinical research

Ethical principles of biomedical research are relevant to both clinical and health policy and systems research but have different implications as summarised in table 1.[6 14–20] Awareness of these differences is crucial for ethics review and conduct of health policy and systems research. Ethical concerns relating to public health research, which shares similarities with health policy and systems research, are also included in table 1.[21 22] The methods and conduct of health policy and systems research include steps required during the planning, implementation and post-study phases.[2 23 24] Each step is important for study rigour, but it also has important ethical implications which researchers and research ethics committees must consider. There may be instances where these research requirements may conflict with professional codes of conduct which in turn may have implications for the ethics of conducting health policy and systems research and must be taken into account, both by researchers and by ethics committees.

Table 1 Relevance of ethical considerations in health policy and systems research versus clinical research

Ethical principle	Ethical consideration	Health policy and systems research	Clinical research	Public health research
General considerations	Purpose	Address healthcare disparities Improve health system functioning Policy development	Answer questions related to specific disease process/intervention	Identification of population health determinants, disease levels, establishing effectiveness, safety and costs of public health interventions
	Methods	Variable, often multidisciplinary	Ideally randomised controlled trial, variable	Variable, may be multidisciplinary
	Need for ethical review?	Blurred line between research and practice	Usually required for research	Blurred line between public health interventions and research
		Research versus quality improvement, Monitoring and Evaluation (which may not require review)		Nature of public health interventions, observational studies, programme evaluation (which may not require review)
		Data review (no human subjects)		
	Type of intervention	Is study addressing a local health priority?	May be very specific/detached from public health priorities	Should address a locally relevant public health question
		Is the study responsive to local health needs?		
	Study context	Embedded within health system, interdependent relationships, social context	Typically controlled circumstances for study, strict inclusion/exclusion criteria	Public health system, community, pragmatic real-life conditions
		Local health system, not controllable		
	Ancillary care	Need to consider who is responsible, link with standards of care	May/not be relevant	May be relevant
	Data	May be very large databases on whole communities/institutions	Usually strict rules governing privacy, etc.	May be very large databases on whole communities
		Who owns the data?	Researchers often “own” data	Usually public health system
		How to ensure privacy? Community members may not be aware that their data exist/are being shared	Subject de-identification, individual consent accept risks	Community members may not be aware that their data are being collected
	Responsibility for post-study care	Scalability/sustainability–state responsibility	Often limited post-study obligations to study participants only — study funders, researchers	Public health programmes should be ongoing if effective
	Accountability	Researchers, state, funders?	Researchers, sponsors	Public health policy makers and practitioners
	Obligation for health system strengthening	Yes	Not usually primary goal	Not usually primary goal
	Conflict of interest	Ministry of Health/health agency may commission a study to evaluate its own actions	Research versus marketing	Public health agency evaluating its own interventions

Continued

Table 1 Continued

Ethical principle	Ethical consideration	Health policy and systems research	Clinical research	Public health research
Autonomy	Units of study	Communities, institutions, Individuals	Individuals	Communities, institutions, individuals
	Consent	Group permission, gatekeeper Waived (provision of information) Individual	Individuals	Waived (provision of information), permission, gatekeeper Individual (less common)
	Community engagement	Necessary to engage with and inform participants	Often not necessary, subjects informed during individual consent process	Generally necessary to engage with and inform communities
	Opt-out possibilities	Sometimes not possible to opt out without imposing large burden	Integral to informed consent process	May not be possible to opt out without imposing large burden
	Gatekeepers	Appropriate choice of person/institution	Often not required/relevant	If required, appropriate choice of representative
Non-maleficence	Risks/harm	May not be the same recipient as beneficiary Broader risks may not be obvious upfront How to balance benefits gained by one group and risks taken by another? Long term risks may not be initially apparent/recognised	Usually risk taken by beneficiary (phase III, IV clinical trials)	Risks may apply to individuals while benefits may accrue to communities May infringe on individual autonomy for common good
	Minimal risk definition	Definition of ‘minimal risk’	Risk to the individual participant should be acceptable relative to potential benefit	Definition of 'minimal risk'
	Stigmatisation	Of groups selected for study Institutional reputational risks, may be difficult to 'blind' data	Less risk because of individual consent	Of communities receiving an intervention
Beneficence	Benefits	Benefits may be gained by groups not directly targeted by study How to balance benefits gained by one group and risks taken by another?	Usually gained by individual who takes the risk Common good	Usually common good, extend to broader local population Balance cost-effectiveness versus priority of need
	Minimal benefit	Study should only be undertaken if reasonable expectation of meaningful outcomes	Clinical equipoise should guard against 'useless' study	Study should only be undertaken if reasonable expectation of meaningful outcomes

Continued

Table 1 Continued

Ethical principle	Ethical consideration	Health policy and systems research	Clinical research	Public health research
Justice	Inclusion in study	Representation of vulnerable groups	Eligibility and exclusion criteria clear	Entire community
		Fair subject selection		Vulnerable groups
	Equity	Concern not to aggravate inequalities or even work towards more equitable care	Usually 'inequity' accepted to some degree for randomisation or inclusion/exclusion criteria	Justice and fairness are key
	Community/stakeholder engagement	Frequently required, may depend on nature of intervention to be tested	Often not necessary, subjects informed during individual consent process	Frequently required, may depend on nature of intervention to be tested
	Standard of care	Relevant especially for control arm	Often clear	Relevant especially if control group
	Equipoise	May be procedural or contextual equipoise, usually not clinical	Clinical equipoise required	May be contextual and clinical
	Dissemination of findings	To policy makers to impact policy, other researchers, decision makers, communities who participated	Obligation to report both positive and negative results of clinical trials, at the very least in a publicly available clinical trials registry. Outcome of all clinical research to be reported back to research participants where relevant	To public health policy makers to impact policy, other researchers, community, health workers

Concepts developed from references.[6 14–21 27–29]

Familiarity of research ethics committees with health policy and systems research

As highlighted in table 2, unanswered questions remain relating to ethics review of health policy and systems research. Research ethics committees are generally more familiar with clinical compared with health policy and systems research which leads to inconsistencies in reviews. In addition, the embedded nature of health policy and systems research within the real-world context creates uncertainty as to whether research requires ethical review, how to deal with the inherent unpredictability in health policy and systems research and what level of accountability should be expected of the research ethics committee.

Requirement for ethical review

It may be important in health policy and systems research to establish boundaries between research and practice, even though these boundaries may seem artificial to some. Indeed, given the continuum between health policy and systems research, public health practice, quality improvement and monitoring and evaluation activities, researchers and reviewers often struggle to identify whether a project is 'research' and therefore whether it requires ethical review. Mere labelling of a project as quality improvement or monitoring and evaluation may lead to insufficient attention being paid to the 'non-research' projects from an ethical perspective. For example, some existing bodies define any knowledge-generating activity as requiring of ethics review.[9] Alternatively, the need for patient/subject protection or avoidance of harm may be the primary determinant of whether ethical review is required, regardless of whether a project is research, quality improvement or monitoring and evaluation. Universal requirement for full ethics review of all projects however may lead to unnecessary delays. Formal consensus on when health policy and systems research may require full ethics review and expedited review or be exempt from ethics review would facilitate uniformity of ethical review. Clear communication between researchers and research ethics committees is crucial to facilitate these decisions.

Evolving ethical challenges over time

Health policy and systems research projects inherently evolve over time, and unforeseen changes impacting the study protocol may be needed. Integration of mechanisms for ongoing expedited ethical review throughout the research process is important to allow flexibility in response to these needs. To minimise unforeseen challenges, however, researchers should engage with all relevant stakeholders during project design, to engage appropriately with communities affected and to communicate this effectively to the research ethics committee. Accelerated review is important in health policy and systems research conducted during humanitarian crises.[25] Recent experiences have highlighted the urgent need to optimise existing research ethics review processes to facilitate important but ethical study of questions that may only be answerable during epidemics.[26]

Realm of accountabilities of the research ethics committee

The boundaries of responsibility of the research ethics committee regarding legal and safety implications of a project are not clearly defined and may pose significant ethical dilemmas for committee members in some countries, given their limited reach as an oversight body. For example, if an approved intervention not previously implemented in a given country is being studied, or if implementers are required to operate outside their traditional roles, it may be unclear where the responsibility lies should an adverse event occur. The responsibility for the legal and safety implications cannot lie purely with the research ethics committee, but it also lies with the study investigators, funders and other stakeholders. Accountability and duty of all parties should be clearly identified by the researchers upfront, and considered in the ethics review.

Implications of core ethical principles in health policy and systems research

The fundamental ethical principles apply equally to clinical and health policy and systems research, but because of differences in application of these principles in health policy and systems research, guidance is required. These differences are summarised in table 1.

Respect for autonomy

It may be more challenging to uphold in health policy and systems research compared with clinical research. In health policy and systems research, individuals usually participate within a collective, for example, a community or institution. As such, individual consent may not be feasible (eg, large subject numbers). Consideration must therefore be given to informing the group and a waiver of consent with opt-out possibilities, through effective and appropriate community engagement. Group consent however raises many issues and is generally not recommended. Another important example relating to research subject autonomy is the use of incentives in resource-limited contexts which is ethically questionable. Heightened awareness of the nuances and complexity of respecting autonomy in health policy and systems research is crucial for appropriate ethical review.

Risk–benefit and research burden

The considerations in health policy and systems research are more complex than those in clinical research. In clinical research, the individual study participant generally incurs risk but may also accrue benefit and, therefore, can personally weigh the risk versus benefit and give informed consent. Often in health policy and systems research, one group is subject to an intervention, but the benefits and risks of that intervention may accrue in separate groups. Additional groups potentially placed at risk may not be obvious. Direct and indirect risks must therefore be considered at all levels including individuals, groups, institutions

Table 2 Current challenges in research ethics committees review of health policy and systems research

Challenge	Relevant considerations	Examples
What to review	► Is the study research or not? ► Does the study require full review, expedited review, waiver of review? ► 'Piggy-backing' problem: as a project evolves an unanticipated research component may develop requiring further/additional review	Debate exists whether quality improvement or monitoring and evaluation exercises are indeed research. The research—practice continuum is often blurred in health policy and systems research.
Research components	► What is the intervention and why (ie, prioritisation)? ► Define who/what subject of research is (ie, justice, equity considerations) ► What level of consent is required/feasible? ► What methods are used? Are they appropriate for research question? ► Does the study increase risk/burden/compromise interests in any way that would not have occurred if learning activity were not present? ► Identify possible consequences or problems? ► Who assumes ancillary care responsibilities? ► Have all stakeholders been meaningfully engaged in planning phase?	In an intervention providing taxi vouchers to pregnant women as incentives to increase institutional deliveries, performance at local clinics will be monitored to determine impact of voucher intervention on outcomes. In this case, the intervention is directed at pregnant women but could benefit taxi drivers or destabilise the local taxi economy and impact on local clinic capacity, which may become rapidly overwhelmed unless adequate planning occurred. Should informed consent be obtained from pregnant women, taxi drivers or clinic staff? Should the care provided by the clinic staff be considered a research activity or is it practice? Women living in areas without taxi facilities may be marginalised. Individuals with other urgent conditions, although not pregnant, would not have access to the intervention. How sustainable is the intervention? Has the community/stakeholders been engaged with in study design?
Potential conflict of interest	► Role of those commissioning or funding the research?	The state may commission a study to evaluate its own interventions/programmes
How to deal with individual risk/autonomy	► Balance risk and benefits for individuals versus community or health system ► Is 'minimal benefit' a form of potential harm (ie, is the study worth doing?) ► 'Reputational risk' to researchers, states, stakeholders ► The risks of health policy and systems research are experienced at different levels; therefore, more comprehensive global risk assessment must be required. ► Redefine concept of an 'adverse event' outside of clinical research, as the perspective is far broader in health policy and systems research	In health policy and systems research, those exposed to the risks of an intervention may be different from those who benefit from the intervention. For example, an intervention testing a vaccine to prevent transmission of malaria from an infected individual to others would expose the vaccinated individual to the risk of vaccination but only protect other individuals from malaria. Study and reporting of institutional/district performance, although anonymous, may still permit identification of institutions/districts and may lead to stigmatisation. Such stigmatisation could be classified as an adverse event/unintended consequence of a health policy and systems research study.

Continued

Table 2 Continued

Challenge	Relevant considerations	Examples
Use of incentives	► Unclear if incentives are moral in any form in a poor country (size and nature of incentive) ► If questionable sustainability of incentives for the long term, they may not be ethical to study	Incentives used in studies conducted in communities/regions where poverty is high may induce participation that would otherwise have been against the will of a participant for example, payment for blood sampling. Is a taxi voucher scheme to increase institutional deliveries sustainable over the long term?
Justice	► Ethical value of repeating an intervention known to be valid elsewhere (clinical versus contextual equipoise) ► Is randomisation justified? ► What is an acceptable standard of care for control groups? ► Research may be a tool to introduce an intervention into a country but this may exacerbate regional inequalities at least initially	A stepped-wedge trial evaluating delivery of a new vaccine, known to be highly effective in prevention of diarrhoeal illness, in a community with historical reluctance to vaccination may be justifiable to evaluate acceptability of the vaccine in the community, but given the known effectiveness of the vaccine, leaving 'control' communities unvaccinated especially in the early stages of the study could be interpreted as permitting harm. Introduction of piped water and soap to schools in poor overcrowded urban communities may improve hand hygiene practices and reduce diarrhoeal illness in children but would further exacerbate inequities between urban and rural children
Legal concerns	► Implementation of interventions outside the law may be tolerated (eg, testing an unapproved medication or task shifting), but where does the accountability lie for adverse events?	Study of the effectiveness of using community health workers to diagnose and empirically treat pneumonia in young children in rural areas goes beyond the usual scope of practice of the community health workers. If a child is misdiagnosed or incorrectly treated by a community health worker, where does the responsibility lie?
Post-study	► Must there be assurance of sustainability post-study? ► Does the study enhance local infrastructure/research capacity?	The use of incentives to induce changes in health behaviour may not be sustainable long term. Studies conducted by research groups based outside of the country may bring their own experts/tools and not strengthen local capacity
Role of research ethics committee	► Distinguish ethical risks inherent to the public health practice being studied versus those intrinsic to the research study itself ► What is the research ethics committee's role (if any) in ensuring appropriate post-study activities?	Randomisation to intervention versus control itself may constitute a risk if an intervention is known to be effective Research may more clearly identify risk groups as compared with public health practice and thereby increase the risk of stigmatisation of the risk groups

Continued

Table 2 Continued

Challenge	Relevant considerations	Examples
Strategies to improve quality of ethical review	▲ Research ethics committees must be familiar enough with specific relevance of ethical issues to health policy and systems research to reduce variability across sites ▲ Research ethics committees should include representatives of variety of stakeholder groups to enhance appropriateness of the review process and anticipation of challenges ▲ Research ethics committees must be independent bodies and not tools of external stakeholders. ▲ Engagement between research ethics committees and researchers and establishment of a guidance tool with ethical practice expectations to reduce perceived 'rubber stamping' role of research ethics committees	Research committees reviewing the same health policy and systems research protocol at various sites may issue different reports which may cause important delays in study initiation and create difficulties for researchers conducting studies in multiple sites. Accelerated research ethics review during the recent Ebola outbreak facilitated conduct of time-sensitive research but identified many challenges that must be addressed to optimise this process.[26 30]

and the health system. Importantly, risks may also be experienced by health professionals or community workers especially if functioning outside their usual roles in a study. The ethical challenge of weighing the relative risks to the individual versus the collective is important in health policy and systems research. Researchers must implement risk mitigation strategies, such as the inclusion of multi-stakeholder engagement in study design, adequate support for healthcare workers and so on. Who 'owns' the responsibility for the identified risks is also relevant. Researchers must clearly communicate their consideration of all risks to facilitate appropriate ethical review and to optimise ethical study conduct.

Justice and equity

Although *justice and equity* issues are equally important in both clinical and health policy and systems research, the inclusion and exclusion boundaries in clinical research are generally scientifically determined and may not be fully equitable. Health policy and systems research researchers working within the real-world context must consider justice in terms of distribution of risks and benefits, inclusion of vulnerable populations, avoidance of exacerbating disparities through the research and potential sustainability of the intervention over the long term. Fundamental to achieving justice in health policy and systems research is that the research question must address a local health priority in context. In addition, some health policy and systems research aims specifically at informing strategies to reduce healthcare disparities, for example, testing established interventions in a new context with a strong focus on advancing equity. Researchers must clearly communicate their consideration of justice and equity, recognising that these may be nuanced issues, and research ethics committees should interpret these in context.

Community engagement

It is an ethical imperative in much health policy and systems research and overlaps with all the other ethical considerations. Community engagement is important to fully inform the community about an intervention; identify and include vulnerable populations; identify potential burdens, barriers, relevant practices and beliefs (in gatekeeper selection) and identify all potential stakeholder groups including those indirectly impacted. Community engagement may be required even if health policy and systems research does not involve direct interaction with individuals, especially if there is likelihood of any potential impact on patient privacy. Researchers should communicate their community engagement strategies to the research ethics committee, which must be aware of the depth and breadth required.

Equipoise

In clinical research, equipoise (genuine uncertainty) about the effectiveness of a certain intervention is required to justify randomisation and study. In health policy and systems

research, in contrast, such clinical equipoise may no longer exist (ie, a drug *is known* to be effective), but equipoise may still exist because it is unknown how the intervention will be taken up in a particular context or at scale. Research ethics committees must recognise that implementation/procedural/contextual equipoise does exist in health policy and systems research. Researchers should clearly communicate how equipoise is still preserved to facilitate ethical review.

Given the lack of clinical equipoise, justifiability of randomisation of subjects to a no-treatment control arm in health policy and systems research may be questionable. Reviewing such study designs may be problematic for ethics committees, especially if not familiar with health policy and systems research. For example, stepped-wedge approaches are proposed as ethically acceptable alternatives to randomisation. In reality, governments do roll out programmes stepwise; therefore, this approach may be acceptable. However, some untreated people remain at each stage. Realistically also, as health policy and systems research is conducted in real-world contexts and may be embedded within policy decisions, delineating the boundaries of research and practice and the extent to which researchers can be held accountable for or influence study design remains challenging.

Privacy and confidentiality

It is a universal ethical consideration in research. Health policy and systems research may involve multiple layers of data collection, analysis of many different kinds of data, feedback loops and macro-scale monitoring; therefore, both researchers and research ethics committees should be aware of possible higher risks of unanticipated stigmatisation, for example, if regions or centres remain identifiable. How health policy and systems research can uphold the principle of transparency without infringing on privacy and confidentiality is a key consideration.

Data use and sharing

As the data generated in health policy and systems research are highly relevant to multiple sectors of the health system or may be generalisable to similar heath systems, there is a duty to share both positive and negative findings. An extra layer of complexity may arise with data ownership when studies are driven by external funders. While research ethics committees require researchers to uphold transparency as a value, it remains unclear to what extent research ethics committees should require data sharing commitments in health policy and systems research.

Attribution of responsibility and accountability

The level of accountability that health policy and systems researchers should bear, and the extent to which they could (or should) influence conditions under which the research is being conducted will vary from study to study. It may be unclear where the researcher's responsibility ends; whether the researcher's responsibility differs depending on who commissioned or funded a study; whether the researcher's responsibility extends to ancillary care findings during a study and, If not, then who is responsible for ancillary care findings during a study and where responsibility lies if poor outcomes are identified or an intervention fails. There may be an ethical imperative for interim analysis and feedback of results to inform an iterative process of implementation adaptation if necessary. Consideration of responsibility and accountability are imperative in study design and ethics review of health policy and systems research.

Post-trial obligations

Post-trial obligations are relevant to both clinical and health policy and systems research. In health policy and systems research, with the goal of strengthening the heath system through research, there is an expectation that these obligations be fulfilled. The responsibility for the scale-up and roll-out of successful interventions should fall to the State, which is often involved from the planning stages, and interventions should be integrated into health policy. In countries with limited resources, however, the potential for adequate scale-up and long-term sustainability of an intervention may be uncertain. In such circumstances, it remains unclear whether the research ethics committee should require commitment for scale-up of an intervention and fulfilment of ethical obligations following health policy and systems research that extend beyond the study per se as an imperative for study approval and, if so, from whom. Burdening researchers with safe-guarding post-trial implementation may be unreasonable; however, researchers should clearly communicate the long-term implementation strategies (if applicable) to the committee.

CONCLUSION

Health policy and systems research is a rapidly evolving and broad research field and there is a growing need for researchers and research ethics committees to understand the ethical implications.[1] Because research ethics committees may be less familiar with specifics of health policy and systems research, to date, researchers have been frustrated by the variability and delays in ethical review of the same protocol between different sites. The need for greater engagement and dialogue between researchers and research ethics committees about the ethical obligations and challenges inherent in the planning and conduct of health policy and systems research is crucial as this is an evolving field. Although open questions still remain, starting from the identification of existing knowledge and knowledge gaps in a scoping review of the literature, and enhanced through expert opinion, this consultation has helped us to plan a move beyond the *status quo* of a relatively unstructured approach to ethical review of health policy and systems research and has laid the ground work for the development of an ethical guidance tool to be used by both research ethics committees and researchers (table 3). The purpose of the proposed guidance tool is to promote awareness of

Table 3 Key features to be considered in development of a guidance tool/ethical framework for health policy and systems research

Feature	Comments
What is health policy and systems research?	► Definitions outlined by Alliance for Health Policy and Systems Research[2 31] ► Range of study methods and types with examples ► Develop a matrix with links to database of cases as examples ► Health policy and systems research does not always involve an intervention, may be policy analysis, strategy study
Identify key areas of difference between health policy and systems research and clinical research	► Scoping review findings[7] ► Existing documents outlining methods/codes of conduct[2 24] ► Ottawa Statement[9] ► Secretary's Advisory Committee on Human Research Protections[8] ► WHO guidelines on patient safety research[10]
Identify target audience for document	► Research ethics committee members ► Researchers ► Public health practitioners ► Non-governmental organisations ► Policy makers ► Research funders ► Healthcare workers
Goal of document	► Structured tool highlighting ethical domains where consideration and elaboration are required as a guide design and conduct of health policy and systems research and ethical review of health policy and systems research ► Living document, with integration of ongoing feedback and evaluation of the review process by the research ethics committee and researchers
Does ethics review always need to be done?	► Does health policy and systems research increase risk/burden/compromise interests in way that would not have occurred if learning activity were not present? If yes, review likely required. ► How to enhance review? ► Identify ethical issues that need additional attention ► Avoid additional burden for the research ethics committee (emphasise that health policy and systems research review is not an additional review, it is a different approach to the review)
Identify study participants at multiple levels	► Individual: for example, definition of a participant in Ottawa statement[9] ► An intended recipient of an experimental or control intervention; ► A person who is the target of an experimental or control manipulation of their environment ► A person with whom an investigator interacts for purpose of collecting data about that individual ► A person about whom an investigator obtains identifiable information for purpose of collecting data about that individual) ► Communities ► Districts ► Institutions ► Policies

Continued

Table 3 Continued

Feature	Comments
Emphasis on respect for researchers and their perspective	► Ensure good understanding of researcher's purpose/meaning ► Importance of written communication between researcher and the research ethics committee
Highlight challenges particular to ethical review of health policy and systems research	► Responsiveness to local needs ► Blurring boundary between research and clinical practice ► Balance need for ethical guidance versus need for more/better empirical evidence to understand issues/challenges and improve health system functioning ► Question of equipoise should be clearly answered, how a given health policy and systems research project achieves equipoise ► Distinguish between ethics review, scientific review and funding review ► Evolving research field ► Units of analysis ► Autonomy and risk/benefit of research in groups, imbalance between risk and benefit accrued by different groups/individuals ► Ancillary care responsibilities ► What are the ethical duties of all stakeholders? ► Who owns responsibility for study and outcomes? ► What is the appropriate response after a project is complete? ► When other forms of oversight might be needed, even if activities are not research?

ethical conduct in health policy and systems research and to improve consistency of ethical review. Such a document will build on existing ethical guidance for clinical research, but it must expand on this to provide direction as to how existing ethics principles should be considered and applied to the review and conduct of health policy and systems research.

Acknowledgements Meeting participants included Aasim Ahmed (Aga Khan University, Pakistan), Abha Saxena (WHO), Adnan Hyder (Johns Hopkins University, USA), Ahmad Mandil (WHO Eastern Mediterranean Regional Office, Egypt), Aissatou Toure (Pasteur Institut, Senegal), Bridget Pratt (Johns Hopkins University, USA), Calvin Ho (National University of Singapore, Singapore), Carla Saenz (Pan American Health Organization, USA), Charles Weijer (University of Western Ontario, Canada), Daniel Strech (Medizinische Hochschule Hannover, Germany), Jerome Singh (University of Kwazulu-Natal, South Africa), Joseph Ali (Johns Hopkins University, USA), Mahnaz Vahedi (TDR/WHO), Manju Rani (WHO Western Pacific Regional Office, Phillipines), Maria Magdalena Guraiib (WHO), Melba Gomes (WHO), Milo Puhan (University of Zurich, Switzerland), Mina Mobasher (Kerman University of Medical Sciences, Iran), Monica Taljaard (Ottawa Hospital Research Institute, Canada), Nancy Cass (Johns Hopkins University, USA), Nhan Tran (WHO), Nikola Biller-Andorno (University of Zurich, Switzerland), Rajendra Shukla (SEAR, India), Valerie Luyckx (University of Zurich, Switzerland), Sassy Molyneux (Kenyan Medical Research Institute, Kenya), Soraya Elloker (City of Cape Town Department of Health, South Africa), Tum Nguyen (WHO European Regional Office, Denmark) and Verina Wild (University of Zurich, Switzerland)

Contributors NTT, AS, NB-A and VAL all participated in planning of the manuscript. VAL wrote the first draft of the manuscript. All authors participated in draft revisions and approval of the final version.

Funding The meeting was funded and organized by the Alliance for Health Policy and Systems Research and the Global Health Ethics Unit at the WHO and was hosted and supported by the Institute of Biomedical Ethics and History of Medicine, University of Zurich.

Competing interests None declared.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement There are no additional unpublished data relating to this manuscript. The Scoping Review conducted prior to this consultation has now been published and is included as a full reference in this manuscript.

REFERENCES

1. Ng LC, Hanlon C, Yimer G, *et al*. Ethics in global health research: the need for balance. *Lancet Glob Health* 2015;3:e516–7.
2. Alliance for Health Systems and Policy Research. *What is Health Policy and Systems Research and why does it matter?* Geneva: World Health Organization, 2007. http://www.who.int/alliance-hpsr/resources/Alliance HPSR - Briefing Note 1.pdf?ua=12015
3. Ghaffar A, Tran N, Kieny MP, *et al*. Putting health policy and systems research on the map. *Bull World Health Organ* 2012;90:797–797A.
4. Ghaffar A, Tran NT, Reddy KS, *et al*. Changing mindsets in health policy and systems research. *Lancet* 2013;381:436–7.
5. Remme JH, Adam T, Becerra-Posada F, *et al*. Defining research to improve health systems. *PLoS Med* 2010;7:e1001000.
6. Hyder AA, Rattani A, Krubiner C, *et al*. Ethical review of health systems research in low- and middle-income countries: a conceptual exploration. *Am J Bioeth* 2014;14:28–37.
7. Pratt B, Paul A, Hyder AA, *et al*. Ethics of health policy and systems research: a scoping review of the literature. *Health Policy Plan* 2017;32:890–910.
8. SACHRP. *Attachment C: recommendations on regulatory issues in cluster studies*. Washington, D.C: U.S. Department of Health & Human Services, 2014. https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-november-2-2016-letter/index.html
9. Weijer C, Grimshaw JM, Eccles MP, *et al*. The ottawa statement on the ethical design and conduct of cluster randomized trials. *PLoS Med* 2012;9:e1001346.
10. World Health Organization. *Ethical issues in pateint Safety Research. Interpreting existing guidance*. Geneva, Switzerland: world Health Organization, 2013. http://apps.who.int/iris/bitstream/10665/85371/1/9789241505475_eng.pdf?ua=12015
11. Guta A, Nixon SA, Wilson MG. Resisting the seduction of "ethics creep": using Foucault to surface complexity and contradiction in research ethics review. *Soc Sci Med* 2013;98:301–10.
12. Hyder AA, Merritt M, Ali J, *et al*. Integrating ethics, health policy and health systems in low- and middle-income countries: case studies from Malaysia and Pakistan. *Bull World Health Organ* 2008;86:606–11.
13. Hyder AA, Pratt B, Ali J, *et al*. The ethics of health systems research in low- and middle-income countries: a call to action. *Glob Public Health* 2014;9:1008–22.
14. Bamford R. Ethical review of health systems research: vulnerability and the need for philosophy in research ethics. *Am J Bioeth* 2014;14:38–9.
15. Dereli T, Coşkun Y, Kolker E, *et al*. Big data and ethics review for health systems research in LMICs: understanding risk, uncertainty and ignorance — and catching the black swans? *Am J Bioeth* 2014;14:48–50.
16. Rennie S. Tinkering with the health of the poor. *Am J Bioeth* 2014;14:43–4.
17. Gupta S. Ethical review of health systems research in low- and middle-income countries: research-treatment distinction and intercultural issues. *Am J Bioeth* 2014;14:44–6.
18. Hurst SA. Simplicity as progress: implications for fairness in research with human participants. *Am J Bioeth* 2014;14:40–1.
19. Olson NW. Conceptualizing ancillary care obligations in health systems research. *Am J Bioeth* 2014;14:46–7.
20. Daniels N. Toward ethical review of health system transformations. *Am J Public Health* 2006;96:447–51.
21. Petrini C, Gainotti S. A personalist approach to public-health ethics. *Bull World Health Organ* 2008;86:624–9.
22. Otto JL, Holodniy M, DeFraites RF. Public health practice is not research. *Am J Public Health* 2014;104:596–602.
23. Gopichandran V, Luyckx VA, Biller-Andorno N, *et al*. Developing the ethics of implementation research in health. *Implement Sci* 2016;11:161.
24. Gilson L, ed. *Health Policy and Systems Research: a methodology reader*. Geneva: Alliance for Health Policy and Systems Research, World Health Organization, 2012.
25. Schopper D, Upshur R, Matthys F, *et al*. Research ethics review in humanitarian contexts: the experience of the independent ethics review board of Médecins Sans Frontières. *PLoS Med* 2009;6:e1000115.
26. Schopper D, Ravinetto R, Schwartz L, *et al*. Research Ethics Governance in Times of Ebola. *Public Health Ethics* 2017;10:49–61.
27. Baum NM, Gollust SE, Goold SD, *et al*. Looking ahead: addressing ethical challenges in public health practice. *J Law Med Ethics* 2007;35:657–67.
28. Gostin LO. Public health, ethics, and human rights: a tribute to the late Jonathan Mann. *J Law Med Ethics* 2001;29:121–30.
29. Lee LM. Public health ethics theory: review and path to convergence. *J Law Med Ethics* 2012;40:85–98.
30. Saxena A, Gomes M. Ethical challenges to responding to the Ebola epidemic: the World Health Organization experience. *Clin Trials* 2016;13:96–100.
31. Ghaffar A, Tran N, Røttingen JA, *et al*. Health policy and systems research: building momentum and community. *Bull World Health Organ* 2014;92:851.