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COMMENTARY

Improving the Ethical Review of Health Policy and Systems Research: Some Suggestions

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Consistent and well-designed frameworks for ethical oversight enable socially valuable research while forestalling harmful or poorly designed studies. I suggest some alterations that might strengthen the valuable checklist Rattani and Hyder propose in this issue of *Journal of Law, Medicine & Ethics*[1] for the ethical review of health policy and systems research (HPSR), or prompt future work in the area.

Institutional Versus Individual Interventions

Rattani and Hyder describe HPSR as "investigation, evaluation, and/or implementation of healthcare strategies or issues at the institutional or systems-level."[2] But their case study involves an *individual*-level intervention — a conditional cash transfer — for which individual informed consent was obtained, just as in traditional clinical research. In contrast, much HPSR involves changes to *institutional* rules or policies, such as changes to health system budgets, staffing, or supply chains, where individual consent is infeasible. More detail about how the checklist applies to institutional HPSR, and who should review it, would strengthen the project. It is not obvious that research ethics committees should review institutional-level HPSR,[3] and current law in the United States exempts some types of HPSR — such as research on the design of benefit programs — from research ethics committee review, though not from review altogether.[4]

The distinction between individual and institutional HPSR might also help clarify the proper role of gatekeepers. When individual consent is feasible, respect for autonomy supports a presumption in favor of leaving enrollment decisions in the hands of potential participants, not gatekeepers. By contrast, the infeasibility of individual consent for institutional HPSR makes representatives more relevant. Yet identifying legitimate representatives is challenging. If institutional HPSR is proposed for a political jurisdiction, politically legitimate representatives are appropriate gatekeepers. But in the absence of recognized structures of representation, authorizing informal representatives to approve or veto studies presents complexities.[5]

Incentives, Harm, and Undue Influence

Rattani and Hyder suggest that "the use of incentives creates a unique risk for harm, especially in LMICs, where the socioeconomic effects of poverty may inappropriately influence participation."[6] Incentives to participate in a risky study could in principle produce undue influence by leading participants to misjudge risks, though the reality of that danger is empirically uncertain.[7] But harm from undue influence requires that the *underlying intervention* be risky: incentives cannot make a low-risk intervention into a high-risk one. Meanwhile, though incentives may activate financial motivations, financial motivations do not make participation inappropriate.[8] I worry that the checklist's concerns about incentives may amplify existing misconceptions among research ethics committees that incentives undermine autonomy[9] and motivate disproportionate scrutiny of incentive-based research.

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It is doubtful that providing an intervention without consent — as institutional-level HPSR often involves — raises fewer concerns than incentivizing its use.

Further, the same "incentives that expand a participant's range of opportunities" may also "entice participants to undergo risks they would not otherwise"[10]: an incentive can expand opportunity while leading participants to assume risks. This is recognized outside research: "in the realm of work it is ethically permissible and not undue influence to offer money as an incentive to get people to perform activities that they would otherwise not."[11] Likewise, workers can accept time-limited incentives (like bonuses) without being harmed by their temporary receipt. This calls into doubt the suggestion that consensual provision of temporary incentives in research is harmful.

The "principlist" (autonomy, beneficence, nonmaleficence, justice) framework familiar in clinical ethics is used to ground the checklist. This framework fits uneasily with research ethics, especially the systems-level ethical issues HPSR presents. For instance, Rattani and Hyder find themselves driven to transmute principlist respect for autonomy to a nonspecific principle of respect. Similarly, it is not clear that beneficence and nonmaleficence should be understood as distinct principles, or separate from justice, in research. Rattani and Hyder understand justice to include improving the well-being of the worst off, which seems like a species of beneficence. Grounding the checklist in ethical frameworks more commonly used in research ethics, and/or frameworks used in public health or population-level bioethics, might enhance the ethical review of HPSR.

Avoiding Research Exceptionalism and Overbroad Mandates

Many HPSR interventions, including conditional cash transfers, could be implemented outside research — either by governments or by employers and philanthropists — without research ethics committee review, and often even without consent. This distinguishes many HPSR interventions from investigational treatments, for which consent is required even outside research. And it raises an important question about research exceptionalism: why should providing an intervention via HPSR prompt greater ethical review than simply implementing the intervention without research?

While the checklist's goal of improving consistency in HPSR review is laudable, imposing clinical-style REC review on HPSR, or imposing more stringent duties of justice on researchers than non-researchers, creates counterproductive incentives to implement policy changes without research.[12] Clarifying which aspects of the checklist entail mandates as opposed to encouragement could help address this concern. Consent when practicable and not waived (II(2a)), and a reasonable balance of risk and benefit (VII(6)), should be mandatory. By contrast, other aspects of the checklist, such as the details of community engagement and research translation, support encouragement but not mandates.

Excessively aspirational mandates risk either obstructing valuable research or prompting conceptual contortions from research ethics committees and researchers. For instance, while global health research *as an enterprise* should promote health equity and the interests of the worst off, *each* HPSR study in a LMIC need not necessarily to realize those goals. Many low- and middle-income countries are large and economically diverse, and mandating that all HPSR in low- and middle-income countries achieve global justice goals will incentivize overbroad definitions of equity and poverty. It would be better to recognize that just as some HPSR in Boston that neither serves nor harms global justice is acceptable, so is some similar research in Bangalore. Similarly, mandating equipoise in HPSR, as opposed to a reasonable risk/benefit balance, seems dubious given the contested status of equipoise even in medical research.[13]

Mandating "[e]quality in the distribution of power to make decisions, object, or modify various aspects of the study … between researchers and communities"[14]

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likewise presents concerns. The researcher-community relationship better fits a separation-of-powers model than equal, coextensive power. Typically, participants (whether groups or individuals) have decisive — not merely equal — power to decide whether to enroll or withdraw. But they do not have equal power to modify the design of ongoing studies, and permitting such modification without careful planning can erode the social value and scientific validity needed for research to be ethical. Research ethics should consider how to ensure fairness and prevent harm under conditions of unequal power, rather than imposing a requirement of equal power as a precondition to research.

Selecting the Best Ethical Framework

The "principlist" (autonomy, beneficence, nonmaleficence, justice) framework familiar in clinical ethics is used to ground the checklist.[15] This framework fits uneasily with research ethics, especially the systems-level ethical issues HPSR presents. For instance, Rattani and Hyder find themselves driven to transmute principlist respect for autonomy to a nonspecific principle of respect. Similarly, it is not clear that beneficence and nonmaleficence should be understood as distinct principles,[16] or separate from justice, in research. Rattani and Hyder understand justice to include improving the well-being of the worst off, which seems like a species of beneficence. Grounding the checklist in ethical frameworks more commonly used in research ethics,[17] and/or frameworks used in public health or population-level bioethics,[18] might enhance the ethical review of HPSR.

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