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Ancillary Care for Public Health Research in Developing Countries

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BELSKY AND RICHARDSON¹ DEFINED ANCILLARY CARE AS care needed by research participants but not necessary to ensure scientific validity, prevent study-related harms, or address study-related injuries and introduced a framework for evaluating ancillary care based on 2 questions.² Does a participant's need for care fall within the scope of the investigator's responsibility for the participant's health, as defined by aspects of health implicitly entrusted to the investigator through the participant's consent to comply with research procedures? If so, what is the strength of the participant's moral claim on the investigator to address that need? The strength of the claim is modulated by attributes of the participant-investigator relationship, such as depth of involvement, degree of participant's vulnerability, and degree of participant's dependence, together with limits on available resources.² Dickert et al³ questioned the narrow limits of Belsky and Richardson's definition of the investigator's scope of responsibility and exposed the tensions between vulnerability, dependency, cost, and scientific objectives in assessing the strength of a potential ancillary care claim. Participants at a workshop also high-lighted the need for additional ethical guidelines to address ancillary care.⁴ They proposed 4 "guidance points" to help researchers and sponsors act on their ancillary care obligations—identifying a positive duty, planning for ancillary care, building partnerships, and making practical provisions.⁴

Although the contributions reviewed above move the discussion of ancillary care forward, they are constrained by 3 issues. First, by focusing on the ethics of researchers' relationship to the individual participant, the discussion to date has yet to consider studies in which the primary unit of research interest is a group. Second, separate analyses of research-specific and context-specific factors might help stakeholders assess the strength of ancillary care claims more systematically. Third, an operational process is needed to help researchers and sponsors implement the proposed guidance points. The goal of this Commentary is to advance the discussion of ancillary care in developing countries addressing these 3 issues.

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Ancillary Care in Public Health Research Dealing With Groups as the Unit of Interest

Existing accounts of the ancillary care obligation tend to assume that all relevant health needs are defined with respect to individuals only.^{1,5} However, public health studies often deal with groups as the units of research interest—communities, populations, and even larger geographical areas such as districts. For example, a study on public health behaviors might use mass media messages targeted to communities to change habits such as smoking, research on risk factors for heart disease might use towns or cities to assess the influence of changes in population dietary patterns, and public health systems research might use districts to evaluate the influence of a new health insurance scheme on access to care (Table).

In public health studies dealing with groups as the unit of interest, the participant role in the participant-researcher relationship is occupied primarily by the group. The participant group may have collective unmet health needs, which are often best addressed by services offered at the group level. The ancillary care obligation should be extended to such group-level research contexts in developing countries, with special attention to the characteristic orientation of public health to prevent illness and injury, and promote the welfare of populations. Thus, preventive programs and services offered to groups are candidate ancillary care interventions that public health investigators should consider in the design and conduct of their studies (Table). This includes preventive interventions that will not work unless a group receives them. Clinical preventive services (such as screening for diseases), safety promotion (such as injury prevention devices), and infrastructure development (such as training) might also be considered candidate ancillary care interventions (Table).

Although debate is needed about the precise ethical justification of ancillary care obligations, many ethicists agree that researchers and sponsors conducting health research in developing countries have some obligation at least to consider participants' unmet health needs. Possible justifications include duties to attend to the welfare of participants, to alleviate at least some health burdens broadly attributable to global injustice, and to honor participants' entrustment of health-related information to researchers through consent for research.⁴ The consideration of ancillary care obligations extended explicitly to group-focused public health research studies is consistent with any of these ethical justifications.

Criteria for Assessing the Strength of Ancillary Care Claims

The proposed extension is consistent with varying degrees of breadth in criteria for limiting the scope (ie, the range or extent) of candidate needs that researchers have an obligation to consider seriously. It is also consistent with omitting any scope criterion and specifying researchers' ancillary care obligations simply by assessing the strength of candidate claims. Either way, assessment of strength is necessary. An organizing framework based on separate analyses of research-specific and context-specific factors should be implemented.

Research-specific factors pertain to the identity of the researchers and sponsors, the health status of participating populations and dimensions of their vulnerability, and the duration of the study. International investigators and sponsors with access to external resources might

have a stronger obligation to support the local health system. Attention to specific differences in socioeconomic status, sex, and urban-rural differences among the study population would help to identify internal vulnerabilities, the presence of which might strengthen ancillary care obligations. Longer-term research endeavors might also strengthen ancillary care obligations.

Context-specific factors pertain to the economic, social, and health status of the general national population of the country or region where the research is conducted, and differentials between the national and local populations. Indicators such as the Human Development Index⁶ might be used to assess the national economic and development context of the general population. Information on mortality, morbidity, and disability allows for a more specific assessment of the regional health context. Defining inequalities between the health of the participating group and the surrounding population (within town, district, or nation) is useful in establishing the contextual criteria for ancillary care. Greater disparities between the participant group and the national population, greater health needs of the general population, and lower indices of human development might all strengthen the ancillary care obligation.

Defining a Process for Consideration of Ancillary Care

An operational approach to identifying candidate ancillary care needs, assessing the strength of participant groups' claims on researchers and sponsors to meet those needs, and fulfilling the specified ancillary care obligations will require a systematic process by researchers and sponsors. A 10-step process is suggested for consideration of ancillary care as follows: (1) understand the goals and objectives of the research study (necessary to consider whether delivery of a given ancillary care option might interfere with the research mission); (2) understand the range of options that might be considered as ancillary care (Table); if a scope criterion is used to limit the range of options, it would be applied at this step; (3) assess the research-specific and contexts specific factors influencing strength of participant group's claims to options under consideration; (4) rank options in order of greater to lesser strength of claim; (5) identify costs, risks, and benefits of each option under consideration over specified period (using quantitative methods if possible); (6) engage in a locally driven deliberative process among concerned stakeholders, to include elicitation of participant group's preferences (eg, through direct talks, representatives); (7) define the package of ancillary care that will be offered with rationale resulting from deliberative process; (8) disseminate information about package of ancillary care and rationale widely to key stakeholders; (9) monitor implementation and use of ancillary care over life of research study; and (10) analyze generalizeable lessons from experience of systematic provision of ancillary care.

Conclusion

An operational analysis of ancillary care is complex and involves defining the potential content of ancillary care and reflection on the need for ancillary care in specific contexts. More discussion of ancillary care as an important emerging issue for global reflection in research ethics is needed. Public health researchers and sponsors should reflect on ancillary

care issues characteristic of group-focused public health research in low-resource settings. A promising pathway forward would be to evaluate the 10-step process across several countries representing different development contexts and develop guidelines for its use. In addition, innovative, empirical approaches to the quantitative assessment of ancillary care needs and evaluation of ancillary care delivery would strengthen current global capacity for analysis of ancillary care.

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Table

Ancillary Care in Public Health Research Dealing With Groups as the Unit of Interest

Type of Action	Ancillary Care Candidates		
	Chronic Disease as Topic of Public Health Study	Infectious Disease as Topic of Public Health Study	Injury Prevention as Topic of Public Health Study
Medical care (disease-specific)	Free medical treatment for all those patients with disease	Chemoprophylaxis for infectious disease prevention in a group	Stocking local clinic with splints for treatment of patients or blood transfusion service at clinic
Preventive clinical services	Screening for hypertension in a community	Training community health workers in towns	Community-wide fall prevention program
Infrastructure development	Building ramps in a community for disabled members	Building soak pits for households in a community	Playground safety improvements in schools
Personal safety promotion	Provision of home safety devices for aged or elderly persons	Distribution of oral rehydration solution in community	Provision of helmets in the community for all motorcycle riders