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Ancillary Care in Community-Based Public Health Intervention Research

Maria W. Merritt, PhD, Holly A. Taylor, PhD, MPH, and Luke C. Mullany, PhD, MHS

Community-based public health intervention research in developing countries typically takes place not in clinics but in people's homes and other living spaces. Research subjects and their communities may lack adequate nutrition, clean water, sanitation, and basic preventive and therapeutic services.

Researchers often encounter unmet health needs in their interactions with individual subjects and need ethical guidelines to help them decide how to respond.

To what extent do researchers have an ethical obligation to provide ancillary care—health care beyond what is necessary to ensure scientific validity and subjects' safety? We discuss a case example from Nepal and propose a simple 2-step sequence of questions to aid decision making. (*Am J Public Health.* 2010;100:211–216. doi:10.2105/AJPH.2009.168393)

PEOPLE LIVING IN LOW-RE-source settings around the world suffer disproportionately from preventable or treatable conditions, including respiratory infections, diarrheal diseases, malnutrition, neonatal infections, and complications of pregnancy and childbirth. To alleviate the global burden of disease, it is crucial to develop and evaluate new approaches to the delivery of health interventions in low-resource settings. To this end, community-based public health intervention (CBPHI) research is designed to assess the effectiveness of health interventions delivered in the absence of advanced clinical facilities. For example, a group of simple preventive and curative newborn care interventions, delivered to women in their homes by community health workers, reduced neonatal mortality by 34%, as compared with services normally available in rural Bangladesh.[1]

In CBPHI research, by contrast with similar efforts based in facilities such as clinics, semiskilled local community health workers and data collectors typically carry out research activities in people's homes and other functional living spaces. (CBPHI research may be, but is not necessarily, community-based participatory research, in which community members collaborate actively in all phases of research, from the choice of objectives to the communication of results.[2]) Host communities may lack adequate nutrition, clean water, sanitation, and basic preventive and therapeutic health services. CBPHI research workers therefore often encounter unmet health needs in their interactions with subjects. For instance, pregnant women invited to enroll in studies of interventions directed at neonatal health outcomes may lack access to basic antenatal care such as micronutrient supplementation.

To what extent, and for what reasons, do CBPHI researchers have an ethical duty to respond to such unmet needs on the part of subjects in their studies?[3] This is a question of obligations to provide ancillary care. Ancillary care is health care that research subjects need but that is not necessary to secure scientific validity in meeting research objectives or to prevent or redress research-related harms.[4,5] Ethical analysis of obligations to provide ancillary care has focused mainly on clinic-based trials.[4–8] Here we extend this ethical analysis to CBPHI research. After briefly reviewing key elements of the

current ancillary care discussion, we outline 3 attributes that frequently occur together in CBPHI research and illustrate these attributes with a case example from Nepal. We propose a simple 2-step sequence of questions to aid decision making about the provision of ancillary care, and we illustrate the practical implementation of this sequence through analysis of the case example.

ANCILLARY CARE AND THE DUTY OF RESCUE

A positive obligation requires taking active steps to help another person, by contrast with the negative obligation simply to avoid harming someone.[9] The authors of a recent consensus paper listed several arguments in support of the conclusion that researchers and their sponsors have "some positive moral obligation" to provide or facilitate some ancillary care for needy research subjects in low-resource settings.[8(p0712)] We focus here on 1 argument that is considered fundamental but has been underanalyzed to date: duty of rescue.

Richardson and Belsky, in an article introducing the concept of ancillary care as a distinct concern, invoked the duty of rescue as an elementary moral principle: "[E]veryone has a duty to help a person who is in need and whom no one else can help, at least when one can provide the help without serious sacrifice or risk."[4(p26)] The duty of rescue is a general obligation: it holds for anyone who is present and able to respond, regardless of whether the observer has any special relationship to the person in need. Accordingly, whenever it is said of a particular case that the duty of rescue requires researchers to offer ancillary care, this means that they ought to do so simply because they are in the right place at the right time with access to the needed resources. Richardson and Belsky noted that duties of rescue "establish a basic orientation" for ethical deliberation about what researchers owe to subjects in practice.[4(p26)] Yet the exact application of the duty of rescue to ancillary care remains unexplored.[6] Our aim is to consider how the duty of rescue as a general obligation can guide decision making about providing ancillary care in the context of CBPHI research.

COMMUNITY-BASED PUBLIC HEALTH INTERVENTION RESEARCH

Three attributes frequently occur together in CBPHI research: orientation of research goals around disease prevention rather than treatment, large sample sizes, and community-embedded research operations.

The goals of CBPHI research are typically to evaluate a potential biomedical or behavioral intervention as an approach to the prevention of disease and to generate new knowledge about its appropriateness or value. What is under study is seldom a new compound or drug but typically a simple, low-tech intervention or service delivery approach intended to prevent disease effectively and inexpensively. Initially, many CBPHIs are evaluated in efficacy trials, in which the research team attempts to carefully control all or most aspects of delivery and implementation of the intervention. After establishing efficacy, the CBPHI may be further evaluated in effectiveness studies, to assess the overall population-level effect of the intervention under programmatic delivery.

Among the population of individuals eligible for participation in a CBPHI study, the proportion either symptomatic with respect to the condition of interest or likely to develop the outcome of interest is often small. This frequently necessitates the accumulation of large samples, on the order of tens of thousands of individuals, necessary to ensure sufficient statistical power.

The research goals and sample size typical of CBPHI research require most studies to be embedded in the daily life of host communities in at least 2 important ways. First, in addition to recruiting subjects from the community, researchers must hire and train up to several hundred local workers to carry out day-to-day research operations. Second, study implementation often occurs not in a clinical setting but in people's homes or other functional living spaces in the community.

CBPHI study staff are likely to encounter the health needs of prospective or enrolled subjects through several types of research activity that require contact with subjects: recruitment for study participation, delivery of the intervention (or control) under study, and collection of data on morbidity and mortality upon enrollment or during follow-up. In addition to morbidities closely related to the condition under study, workers might also encounter a wide variety of miscellaneous health-related conditions afflicting subjects in and around their homes (e.g., poor hygiene, malnutrition, infection, snakebite, etc.).

The homes of subjects and nonsubjects alike are typically clustered together in a village or densely populated urban setting. Research activities are publicly visible on a regular, even daily, basis. The arrival of a CBPHI project worker at a household might be a public event, likely to captivate the attention of neighbors and passersby who gather round to look on. Project workers are often readily recognizable (through style of dress or identification badges) as representatives of the research project and may be perceived as having privileged access to scarce resources.

THE NEPAL NEWBORN WASHING STUDY

The Nepal Newborn Washing Study (NNWS) was a community-based, cluster-randomized, placebo-controlled efficacy trial of 1-time chlorhexidine skin cleansing for newborns.[10] The study was conducted in Sarlahi District, where most people are impoverished. Access to basic antenatal care, care during labor and delivery, and postnatal care for mothers and newborns is limited at best.

The goal of NNWS was to estimate the impact of a simple preventive intervention to save newborn lives in a population in which the vast majority of mothers (>95%) give birth at home. NNWS enrolled 17 306 mother–infant pairs over 30 months. Newborns were cleansed as soon as possible after birth with wipes

presoaked in either a 0.25% chlorhexidine solution (intervention; n=8519) or a water-based placebo solution (control; n=8787 infants). All-cause mortality by 28 days was the primary outcome measure.

More than 475 local workers carried out day-to-day research operations in the midst of participating communities. Local female workers, known as ward distributors, kept track of pregnancies in the study area. Women were invited to enroll in the study around the time of their sixth month of pregnancy. Upon delivery, ward distributors performed the newborn cleansing procedure in the women's homes.

A different team of study workers trained in data collection visited participants' homes up to 11 times in the first 28 days after birth. Data collection on newborns' health during these visits included measuring weight at birth, taking the axillary temperature, examining the newborn for skin and umbilical cord infections, directly observing respiratory rate and chest in-drawing, and recording signs of sepsis, diarrhea, dysentery, tetanus, and other common morbidities, as reported by the caretaker.

AN AID TO DECISION MAKING

We propose a simple 2-step sequence of questions to help guide investigators and other study team leaders in considering the duty of rescue as they make decisions about providing ancillary care in the context of CBPHI research. Step 1: What are the candidate needs for the duty of rescue? Step 2: For which candidate needs might the study team leadership appropriately bear a duty of rescue?

It is of practical importance to distinguish between needs that study team leadership can anticipate during study planning and ad hoc needs that community-embedded study workers encounter while in the field. We propose the 2-step sequence as an aid to decision making for anticipated needs. The prospective ancillary care interventions selected by the NNWS study team serve to illustrate our proposed 2-step sequence. Ancillary care interventions planned and implemented through NNWS standard operating procedure fell into 2 broad categories: (1) preventive and curative interventions for pregnant women encountered during recruitment and referral and (2) basic advice for the care of newborns.

Candidate Needs

What makes a particular health need a candidate for the duty of rescue? Relevant factors include seriousness (severity or urgency or both) and susceptibility to remediation by means that are clearly identifiable at the level of individual action.[11] The term "rescue" in ordinary usage connotes emergency situations such as walking past a pond where one notices a person about to drown, in which case one has a duty either to save the person or to call for help immediately.

Although the duty of rescue as a moral obligation applies at the very least to emergencies, nonemergencies may also satisfy the conditions of seriousness and susceptibility to remediation by individual action, so that what is meant by "rescue" extends to other situations that may present themselves, most obviously through direct personal contact, in which one can easily prevent something very bad from happening.[12] As an example of how the duty of rescue applies to researchers working in developing-country settings, Richardson and Belsky cited the provision of deworming drugs to children at risk for malnutrition (assuming the local system cannot provide them).[4] Although risk of malnutrition caused by helminthic burden is not an emergency in the way that drowning is, it is a candidate need for the duty of rescue, because it is a serious condition that can be remediated by safe, effective, and inexpensive individual action.

The range of candidate needs for the duty of rescue tends to be expansive in CBPHI research. In the course of planning research operations, the study team leadership can predict with near certainty that research activities will routinely bring study workers into contact with persons who have pressing needs.

Neonatal survival studies such as NNWS are often designed to enroll pregnant women in advance, so that workers can prepare to administer the study intervention to each newborn as soon as possible after birth. The activity of recruiting pregnant women heightens the salience of women's unmet antenatal needs, such as undernutrition and lack of basic information about hygienic delivery.

Given such needs, investigators' knowledge of the relevant evidence base makes them prospectively aware of likely opportunities to offer proven preventive or therapeutic interventions, especially when government policies and programs are absent or still under development in the host country. Where investigators have a history of working with a particular host population, they may also know that certain characteristics of the population meet criteria set by the World Health Organization for the provision of interventions. For instance, NNWS investigators would have been aware that the high prevalence of hookworm (estimated at 75%) would render pregnant women in the study population eligible for the World Health Organization's recommended presumptive treatment with albendazole, a deworming agent.[13,14] Moreover, investigators might themselves have evaluated interventions in the same location in the past and found them to be efficacious under local conditions, as investigators in the NNWS team had indeed previously found for weekly vitamin A supplementation during pregnancy.[15] Finally, it could be foreseen that study workers delivering the intervention and collecting data would encounter common treatable morbidities among newborns.

Duty to Rescue

With respect to a given candidate need, what makes a particular individual or organized group of individuals, such as the investigators and field directors leading a CBPHI study team, an appropriate bearer of a duty of rescue? Relevant factors include

(1) possession of expertise sufficient to meet the need safely and effectively, (2) ability to apply that expertise without incurring inordinate costs, (3) absence of other individuals or organizations able to meet the need (e.g., the local health system), and (4) freedom from competing obligations that preclude taking the action otherwise called for.

Relevant competing obligations include the duty to consider other claims on limited resources, to protect local health system integrity, and—arguably most important—to avoid compromising the study's data and outcomes. A necessary condition for the ethical justification of health research with human subjects is the study team's ongoing fulfillment of the obligation to produce high-quality, scientifically valid results.[16] Without this obligation, the study team would have no justification to interact with the study population in the ways expected to bring workers into contact with unmet health needs.

The candidate needs for which the study team as an organization can actually bear a duty of rescue are often limited by the operational demands of CBPHI research. Subjects are routinely in contact not with physicians or other highly skilled personnel but with local study workers who have no formal training in health care. Their training typically focuses on making home visits, obtaining informed consent, delivering study interventions, and collecting data. The NNWS workers, for instance, were secondary school graduates at most and had some study-specific training in data collection and recognition of basic signs of morbidity.

Efforts to offer ancillary interventions to all subjects require systematically training and equipping such workers, typically by the hundreds. These efforts must not tax the workers' ability to carry out their primary research-related assignments, which they are obligated to fulfill as agents of the study team. Strictly speaking, it is primarily the study team leadership—the investigators and field directors—who can be said to possess the relevant expertise, which includes knowing how to add safe, effective, and relatively simple care delivery components to study workers' routine activities.

The candidate needs NNWS researchers had to consider included the health risks their pregnant participants faced, such as lack of secure access to a nutritious diet and the likelihood that they would give birth at home in incompletely hygienic environments. It was far beyond the technical capacity and the acceptable social role of NNWS to offer a full nutritious diet to more than 17 000 pregnant women. A wholesale attempt to reorganize families' home environments to promote better hygiene would have been not only infeasible but also insulting and intrusive.

Instead, the risks identified could be more feasibly and acceptably reduced by means of simple interventions that were already intermittently available through the local health system but unlikely to reach most of the population unless provided directly by the study team. Thus, at recruitment all pregnant women were offered the following preventive interventions: vitamin A and iron–folic acid supplements; tetanus immunization, if indicated by their immunization history; education on antenatal nutrition, hygienic delivery, and neonatal care; and a clean-birthing kit, including a plastic sheet, soap for hand washing by a birth attendant, a clean blade to cut the umbilical cord, and cord ties.

In response to the need for deworming, as recommended by the World Health Organization for settings with a high prevalence of hookworm, NNWS offered presumptive treatment with albendazole to all pregnant women.[13,14] This intervention was both curative (reducing pregnant women's helminthic burden) and preventive (reducing the risk of low birth weight).

Did the universal provision of these ancillary interventions compromise the NNWS researchers' ability to meet their obligation to answer the original scientific question of interest? By improving pregnant women's health status and health knowledge, these ancillary interventions might have reduced neonatal mortality—the primary scientific outcome measure—in the population overall. Of course, that is precisely why such interventions are included in national or global policy recommendations for antenatal and newborn care. However, because both allocation groups in NNWS had equal access to these ancillary interventions, their provision did not confound the researchers' ability to answer the scientific question. It did, however, require a priori recognition that the scientific question about efficacy concerned the additional effect of chlorhexidine cleansing beyond whatever benefit might have resulted from this basic set of antenatal interventions.

For newborn care, by contrast, the study team's operational capacity to bear a duty of rescue for anticipated candidate needs was severely limited. For the preponderance of common morbidities encountered while delivering the study intervention and collecting data in the homes of newborns, individual study workers were not clinically qualified to provide the needed care safely and effectively. Nor did the study team as an organization command the resources to import or train skilled personnel in sufficient numbers. As is the case for most CBPHI studies, it was ex hypothesi not feasible for NNWS to muster local physicians, nurses, or other highly skilled personnel to provide advanced newborn care to the entire study population. The expected long-term absence of highly qualified providers and advanced clinical facilities in the local health system is precisely what necessitates the evaluation of low-tech interventions through CBPHI research.

Lacking the requisite clinical training, NNWS study workers were not authorized to provide specific care for newborns. Instead, they were enabled to provide basic advice on essential newborn care, messages that they reiterated throughout their home visits. They also provided a baby blanket to help prevent hypothermia. Upon noting certain signs and symptoms requiring skilled care, study workers referred newborns to the nearest subhealth post, health post, or health center. In general, however, compliance with

referral recommendations was expected to be low, in part because of families' unfavorable perceptions of the adequacy of care that could be expected from the local health facilities. The public peripheral health system in rural Nepal is marked by poor geographical coverage, inconsistent and limited availability of supplies, and a shortage of personnel in general or lack of skills to address newborn health needs. The sad reality, then, was that for many cases of treatable newborn morbidity observed by NNWS study workers, there was little help available from any quarter.

Finally, how does the duty of rescue apply to ad hoc needs (e.g., infection, birth defects requiring corrective surgery, injuries, lack of sanitation and clean water) that CBPHI study workers encounter among subjects and nonsubjects in the community? Here, because of probable lack of technical capacity and the obligations of study workers to meet their research responsibilities, we recommend a default policy of fostering relationships with representatives of local agencies and nongovernmental organizations, who may be better able to offer needed help and who equally share the duty of rescue once the situations of people in serious need are brought to their attention. For example, the NNWS study team leadership identified infants with cleft lip (whether subjects or nonsubjects) and arranged for Operation Smile to hold surgery camps in the study area. Exceptions to the default policy would be triggered by acutely life-threatening emergencies (e.g., snakebite, near drowning, or road traffic injury, when help can be rendered by actions such as providing transportation to local health facilities), for which the duty of rescue might override day-to-day study responsibilities.

CONCLUSION

Our aim was to consider how the duty of rescue can help to guide decision making about the provision of ancillary care in the context of CBPHI research. Our proposal was primarily intended to stimulate further examination of the duty of rescue as a type of moral obligation that has been underanalyzed in the ancillary care discussion. The proposed 2-step sequence of questions is not meant to deliver a definitive answer about what is ethically required in any particular case. Rather, at best, it could help researchers to identify specific candidate ancillary care needs for which it would make sense to recognize a duty of rescue. This leaves open the possibility that many specific needs may be thus identified, so that the study team is not able to respond to all of them, in which case it remains necessary to deliberate further, appealing to additional considerations to give some needs higher priority than others.

It is also important to note that ethically relevant countervailing considerations, such as cost, scientific validity, and local health system integrity, are appropriately weighed within the 2-step sequence (at step 2) in the form of competing obligations that would preclude the action otherwise called for. Ideally, then, the proposed sequence or a similar set of questions focusing on the duty of rescue would be used in a broader decision-making context that includes researchers' other obligations and practical concerns.

Further conceptual work is needed to develop more comprehensive ethical guidelines, and further empirical work is needed to document the relevant experiences of researchers, communities, and other stakeholders.[8] For example, future empirical work could seek to identify and compare the ancillary care decision making challenges confronted by investigators who conduct research in developing countries and by investigators who conduct research in impoverished communities in developed countries.

Further conceptual and empirical studies are also needed to identify and avoid potential adverse consequences of a more explicit, systematic recognition of ancillary care obligations, such as increased burdens on researchers based in developing countries or disincentives for sponsors to fund research on conditions that afflict the poorest populations.[8] ■

About the Authors

Maria W. Merritt and Holly A. Taylor are with the Berman Institute of Bioethics, Johns Hopkins University, Baltimore, MD. Holly A. Taylor is also with the Department of Health Policy and Management, Bloomberg School of Public Health, Johns Hopkins University, Baltimore. Maria W. Merritt and Luke C. Mullany are with the Department of International Health, Bloomberg School of Public Health, Johns Hopkins University, Baltimore.

Correspondence can be sent to Maria W. Merritt, Health Systems Program, Dept of International Health, Johns Hopkins Bloomberg School of Public Health, 615 N Wolfe St, Suite E8132, Baltimore MD 21205 (e-mail: mmerritt@jhsph.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints/Eprints" link.

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Contributors

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The Impact of Food Prices on Consumption: A Systematic Review of Research on the Price Elasticity of Demand for Food

Tatiana Andreyeva, PhD, Michael W. Long, MPH, and Kelly D. Brownell, PhD

In light of proposals to improve diets by shifting food prices, it is important to understand how price changes affect demand for various foods.

We reviewed 160 studies on the price elasticity of demand for major food categories to assess mean elasticities by food category and variations in estimates by study design. Price elasticities for foods and nonalcoholic beverages ranged from 0.27 to 0.81 (absolute values), with food away from home, soft drinks, juice, and meats being most responsive to price changes (0.7–0.8). As an example, a 10% increase in soft drink prices should reduce consumption by 8% to 10%.

Studies estimating price effects on substitutions from unhealthy to healthy food and price responsiveness among at-risk populations are particularly needed. (*Am J Public Health.* 2010;100:216–222. doi: 10.2105/AJPH.2008.151415)

THE INCREASING BURDEN OF diet-related chronic diseases has prompted policymakers and researchers to explore broad-based approaches to improving diets.[1,2] One way to address the issue is to change the relative prices of selected foods through carefully designed tax or subsidy policies. The potential of price changes to improve food choices is evident from growing research on how relative food prices affect dietary quality and obesity, particularly among young people, lower income populations, and those most at risk for obesity.[3] Experience from tobacco tax regulation further underscores the power of price changes to influence purchasing behavior and, ultimately, public health.[4]

Experimental research in both laboratory and intervention settings shows that lowering the price of healthier foods and raising the price of less healthy alternatives shift purchases toward healthier food options.[5–8] Although these studies demonstrate price effects in specific, isolated settings or on 1 or 2 individual product changes, to our knowledge, the expected effects of broader food price changes have not been systematically reviewed. Such information would be helpful in designing policies that change the relative food and beverage prices paid by all or many consumers.

Relatively small-scale, cost-neutral approaches to improving nutrition in vulnerable populations include the 2009 changes in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) food packages; whole grains, fruits and vegetables, and soy-based milk alternatives were added to these packages, indirectly subsidizing healthy foods for WIC participants.[9] Another larger scale approach is to change prices directly through taxing products such as sugar-sweetened beverages[1,10] or subsidizing healthier foods (e.g., a refund on the costs of fruits and vegetables to Supplemental Nutrition Assistance Program participants).[11] Some states already tax soft drinks and snacks at higher rates than other foods, but thus far taxes have been small and designed to generate revenue rather than influence consumption.[12]