Reinterpreting responsiveness for health systems research in low and middle-income countries

Abstract: The ethical concept of responsiveness has largely been interpreted in the context of international clinical research. In light of the increasing conduct of externally-funded health systems research (HSR) in low and middle-income countries (LMICs), this paper examines how responsiveness might be understood for such research and how it can be applied. It argues that four features (amongst others) set HSR in LMICs apart from international clinical research—a focus on systems, being context-driven, being policy-driven, and being linked to development objectives. These features support reinterpreting responsiveness for HSR in LMICs as responsiveness to systems needs, where health system performance assessments can be relied upon to identify systems needs, and/or responsiveness to systems priorities, which entails aligning research with HSR priorities set through a country-owned process involving national and sub-national policymakers from host countries. Both concepts may be difficult to achieve in practice. It is argued that more work is, therefore, needed to identify strategies for how the responsiveness requirement can be ethically fulfilled in HSR in LMICs under non-ideal conditions such as where host countries have not set HSR priorities or conducted health system performance assessments. Embeddedness is proposed as one approach that could be the focus of further development.
INTRODUCTION

Responsiveness has been identified as a key ethical requirement for externally-funded health research in low and middle-income countries (LMICs) in research ethics guidelines. The responsiveness requirement was first articulated in the Council for International Organizations of Medical Sciences’ (CIOMS) International Ethical Guidelines for Biomedical Research with Human Subjects. It has since been incorporated into the Declaration of Helsinki and endorsed by national bioethics commissions. The development of the requirement reflected increasing recognition that LMIC communities who participated in externally-funded health research were not benefiting from its outputs. Upholding responsiveness is essential for ensuring that limited resources for international research are directed to health problems that are actually of concern or burdensome in its host communities or countries. This, in turn, is necessary for host communities and countries to have the opportunity to benefit from externally-funded research, though responsiveness alone cannot ensure

that health benefits accrue to them.⁵ For example, even if a study’s research question is relevant to its host communities, its finding may show that the intervention-under-study is not effective or, where an intervention is proven effective, it may not be made available to host communities post-study. In both scenarios, meeting the responsiveness requirement would not be sufficient to ensure that health benefits accrue to host communities.

So far, consideration of how responsiveness should be interpreted and applied in practice has been limited to international biomedical research. Responsiveness is typically defined as alignment of research with the health needs and/or health priorities of its host community or country. As such, two main conceptions of responsiveness have emerged—namely, responsiveness to health needs and responsiveness to health priorities.⁶ The former requires the research question to address a health condition or disease that is present in the selected host community or country. This health condition may also be a priority, but it does not have to be. The latter demands that the research question address a health priority.⁷,⁸ Debate continues as to whether responsiveness entails focusing on health conditions that

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⁷ Ibid.

⁸ Here, it is assumed that the relationship between health priorities and health needs is one where health priorities fall within the broader domain of health needs. They constitute a sub-category of health needs that are especially urgent to address.
are also priorities or whether it is sufficient to focus on health conditions that are simply represented in a host community or country.⁹

When applying responsiveness to health needs, Shah, Wolitz, and Emanuel note that there are two approaches to determining what conditions are health needs.¹⁰ Health needs might be defined as any health conditions that exist within a particular community or country, irrespective of their level of burden, or as only those health conditions that constitute a sufficiently high burden of disease (for example, as measured by their disability-adjusted-life-years (DALY) burden). The former would allow a very broad spectrum of diseases to be the focus of externally-funded biomedical research in LMICs. The latter would permit research on fewer diseases and require setting some sort of threshold of disease burden to identify what counts as a health need.¹¹ When applying responsiveness to health priorities, Shah, Wolitz, and Emanuel call for relying on established priorities for biomedical research in host countries.¹²

Yet renewed attention to health system strengthening in LMICs has resulted in greater support for health systems research (HSR), which often does not focus on specific diseases.¹³ Growing consensus on the need for health system strengthening

⁹ London, op. cit. note 1; Shah et al., op. cit. note 6.
¹⁰ Shah et al., op. cit. note 6.
¹¹ Ibid.
¹² Ibid.
led to recognition that evidence was not available on what barriers existed to hinder the delivery of health services in LMICs or on what strategies were required to overcome them. Reports from the World Health Organization (WHO) and global ministerial summits, therefore, drew attention to the fact that the Millennium Development Goals (MDGs) would not be reached without more funding for HSR in LMICs. In response, HSR has increasingly been invested in by international organisations, aid agencies, and philanthropic foundations and performed in LMICs over the past decade. More recently, beyond the MDGs, such research has been linked to establishing universal health coverage and creating people-centred health systems. 

This paper considers how the concept of responsiveness might be understood and applied in the context of externally-funded HSR in LMICs. HSR has been defined as the production of new knowledge to improve the performance of health systems. 

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is a relatively young and evolving field, with conceptual work currently being done to better define its goals and methods. Consensus is emerging that the field is delimited by the topics and scope of its research questions. Remme has noted that research to improve health systems involves not only research on health systems challenges (i.e. HSR) but also operational research and implementation research. Others have used these terms interchangeably but, while all three domains of research utilise the same types of quantitative and qualitative methods, they differ in the types of research questions they address. Operational research and implementation research are action-oriented. The former solves operational issues that arise in health programmes and organisations (e.g. clinics and hospitals) and the latter aims to develop strategies to improve access to specific health products (including vaccines and drugs) or services.

HSR is broader and seeks to enhance the performance of health systems as a whole by focusing on their building blocks (i.e. financing mechanisms, human resources, governance, and service delivery mechanisms). HSR questions can encompass


20 Ibid.

21 Ibid.
the following topics: describing health system components and the relationships and interactions between them, exploring how and why health systems do not meet their goals, and identifying what to do to improve health system functioning to meet those goals.\textsuperscript{22} Here, the term health system is used to refer to both public health and health care systems.\textsuperscript{23,24} HSR is a much more expansive field than health services research, which some suggest comprises a sub-domain of HSR.\textsuperscript{25} HSR focuses on all health systems components, which include but are not limited to service delivery, and their interactions. Thus far, the geographical focus of HSR has primarily been LMICs, though it can and has been performed in high-income countries.\textsuperscript{26} This paper was written with the conduct of HSR primarily in mind, but its ideas may also apply to operational and implementation research.

\textsuperscript{22} Gilson, op. cit. note 18.

\textsuperscript{23} In some countries, a single system provides public health and health care services to the population, while other countries have two separate systems to fulfil these functions. Where a country has two systems, they collectively comprise the health system.

\textsuperscript{24} Some public health research can be considered HSR. Hoffman (2012, p. 13, see note 23) states that '[t]he overlap [of HSR] with population health research, however, is less clear, but likely includes research on the public health system and the delivery of non-personal public health programs and interventions. Excluded from health systems research would be population health research’s focus on measuring or describing health, examining the determinants of health status and outcomes, and assessing the effects of specific health promotion interventions.'


\textsuperscript{26} Sheikh et al., op. cit. note 17; Gilson, op. cit. note 18.
Despite the growth of investment in HSR in LMICs, there has not been concurrent conceptual work done to clarify the field’s ethical dimensions.\textsuperscript{27} At most, there has been some discussion of the application of certain research ethics concepts to externally-funded HSR in LMICs such as consent and post-study benefits.\textsuperscript{28} This paper will first briefly argue that HSR in LMICs has distinctive features that distinguish it from clinical research in LMICs—namely, a focus on systems, being context-driven, being policy-driven, and being closely linked to the development sector.\textsuperscript{29} It will then discuss how responsiveness should be interpreted by the field in light of these characteristics. Given that HSR often does not focus on specific diseases, the paper suggests that it may be more appropriate to consider responsiveness in HSR as being to systems needs and/or priorities rather than health needs and priorities. This encompasses public health and health care system needs and priorities. After defining the concepts of responsiveness to systems needs and responsiveness to systems priorities, how they might be applied and the challenges inherent in doing so are considered.

It should be noted that the ethical concept of responsiveness that is the focus of this paper is different from the concept of responsiveness often used when referring to

\textsuperscript{27} Mills, op. cit. note 17.


\textsuperscript{29} This is not an exhaustive list. These four features are highlighted in the paper because they each bear on how responsiveness should be reinterpreted for HSR in LMICs.
health systems. According to the 2000 *World Health Report*, health system responsiveness ‘is not a measure of how the system responds to health needs, which shows up in health outcomes, but of how the system performs relative to non-health aspects, meeting or not meeting a population’s expectations of how it should be treated by providers of prevention, care or non-personal services.’ The responsiveness of health systems refers to how individuals are treated (e.g. with respect for autonomy, dignity, maintenance of confidentiality) and the environment in which they are treated (e.g. quality of health facilities, promptness of attention, access to social supports for hospitalized individuals, and choice of health provider). The concept of responsiveness discussed in this paper differs in terms of how it defines the features of responsiveness (i.e. alignment with systems needs and priorities rather than patient satisfaction with their interaction with the health system) and in terms of what entity or activity it identifies as having to achieve them (i.e. a research project rather than a health system).

**FEATURES OF HEALTH SYSTEMS RESEARCH**

HSR in LMICs differs from international clinical research in a number of ways. Four distinctive characteristics of such research are highlighted below because, as will

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subsequently be shown, they affect how the concept of responsiveness should be understood and put into practice.

Rather than testing disease-specific interventions such as new drugs or vaccines, where HSR seeks to improve health system functioning, it assesses the efficacy of a variety of systems-level interventions. This might consist of a novel delivery mechanism for public health and medical services of known efficacy, a new method of creating demand for existing efficacious services, an output-based payment mechanism to boost staff productivity, or a community based insurance mechanism to promote access to care and financial risk protection. In some instances, systems-level interventions may have a particular disease focus, but they frequently address aspects of the health system like human resources or financing that generate impacts across a broad range of diseases. HSR can also be descriptive or exploratory, focusing on the interactions between different components of health systems or determining the causes of poor system performance. Again, such studies often do not address single diseases.

Given that health systems vary considerably across different settings, HSR questions must invariably be context-driven. As affirmed by Bennett et al., HSR: unlike clinical or biomedical research—should be driven by understanding of local contexts. At all stages of the research endeavour, from prioritization of research questions, to conceptualization and conduct of the research, to interpretation of and communication of findings, [health systems research] will
benefit from being embedded within a particular context and close engagement with local actors.\textsuperscript{33}

Research questions must reflect the specific circumstances or problems facing the health system of the host community or country. Interventions must be designed to address the weaknesses of the particular health system in which they are to be implemented and evaluated.\textsuperscript{34} Moreover, HSR is policy-driven, with an emphasis on translating findings into policy and practice that is stronger than in other types of health research. This key feature of HSR relates to its frequently being of (direct or indirect) instrumental value, leading to changes that improve health system functioning over the short-term and/or long-term.\textsuperscript{35} Bennett et al. note that the belief that HSR should have an effect on policy and practice has led to a focus on research uptake and knowledge translation within the field.\textsuperscript{36}

Finally, because HSR focuses on improving the health-related social structures within societies, it is seen to be a key component of health aid and development efforts in LMICs. It is frequently connected to the achievement of global development

\textsuperscript{33} Bennett et al., op. cit. note 17, p. e1001081.

\textsuperscript{34} In clinical research, intervention design may be context-driven in the sense that a vaccine, for example, is developed for resource-poor settings where refrigeration cannot be guaranteed or for a particular region in terms of the strains of an illness it is protective against, but such interventions are not usually designed for specific host communities or countries.


\textsuperscript{36} Bennett et al., op. cit. note 17.
objectives such as the MDGs and universal health coverage.\textsuperscript{37} A number of high-level meetings in Africa culminated in the articulation of the \textit{African Health Strategy 2007-2015}, which also affirms the centrality of research to health system strengthening that aims to achieve better care for the poor.\textsuperscript{38} HSR in LMICs is largely funded by bilateral aid agencies from high-income countries\textsuperscript{39} as opposed to the pharmaceutical industry or national research bodies (often the funders of clinical research), which further reinforces its role in serving development goals.

\textbf{REINTERPRETING RESPONSIVENESS}

Since HSR often does not focus on specific diseases, we purport that responsiveness should be interpreted as responsiveness to \textit{systems needs and/or systems priorities}. A systems need can be said to exist where a health system is failing to meet its goals (for example, health and equity, financial protection, people-centredness), achieve intermediate objectives (efficiency, equity, quality), or carry out key functions adequately (financing, provision, stewardship, and resource generation). Using the case of Afghanistan, its balanced scorecard performance

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\textsuperscript{39} Bennett et al., op. cit. note 13.
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assessment tool indicates that the national health system faces challenges in the equity of its service delivery, especially to the poor and to women. System weaknesses in the equity domain are larger than weaknesses in other domains like quality and patient safety. Responsive HSR might then investigate the causes of these groups’ low utilisation of health services and/or develop interventions to address them. For example, the Afghanistan Ministry of Public Health commissioned a pilot study to compare various community financing mechanisms. Three interventions were piloted: 1) a standardized user fee scheme, with a fee waiver card scheme for very poor and female-headed households; 2) a community health fund (voluntary pre-payment scheme); and 3) free services, which were considered an intervention as the majority of facilities were charging fees at the time.

Responsiveness to systems priorities requires HSR to focus on particular health systems weaknesses that have been identified as being of urgent or high concern by national or sub-national policymakers in host countries. For instance, Rwanda’s national health sector policy identifies priority interventions for improving its health system, including developing incentive structures to ensure there is an equitable distribution of qualified health personnel across the country and improving financial

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accessibility to health services, particularly for the poorest and most vulnerable. HSR that is consistent with these aims would be considered responsive to systems priorities. This might include a study that piloted a form of community-based health insurance called mutuelles in three districts of Rwanda in 1999. Mutuelles is progressively financed to the extent that the poorest are exempt from annual premiums.

What the application of these two concepts of responsiveness might entail in light of the aforementioned distinctive features of HSR is considered below in further detail.

Systems needs

Applying the concept of responsiveness to systems needs means determining what counts as a systems need. Exercises to measure health system performance can identify areas where the system as a whole is falling short. Yet the goals of health systems are not uniform across countries and measurement of health system performance is not an exact science. The methods and metrics to assess the extent to which health systems achieve their goals is perhaps less well established than ways of measuring burden of disease.


43 Lu et al., op. cit. note 37.

An increasing number of countries conduct assessments of their health care system performance, including high-income countries (the United States, United Kingdom, Canada, Australia, and the Netherlands) and LMICs (South Africa, Mexico, Afghanistan, and Indonesia). These assessments generally focus on the health care system, with simultaneous evaluation of public health systems less common, though the Pan American Health Organization’s *Health in the Americas* report is one exception. The frameworks used to make the assessments vary by country, which means that countries differ in their domains of evaluation and operational indicators. For example, the United States’ health care system performance framework measures indicators across the following six domains: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. In contrast, Australia’s framework focuses on nine domains: efficiency, effectiveness, safety, appropriateness, responsiveness, accessibility, continuity, capability, and sustainability. Afghanistan’s balanced scorecard approach measures five domains: patient and

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45 Van Olmen et al. (2012) suggests that this is because work has mainly focused on understanding health systems rather than measuring their performance in the wake of the highly critical response to the 2000 World Health Report. While the conceptual contributions of the report on the nature of health systems were widely accepted, the report’s effort to quantify and rank the performance of countries’ health systems was largely panned. See J. Van Olmen, B. Marchal, W. Van Damme, et al. Health Systems Frameworks in their Political Context: Framing Divergent Agendas. *BMC Public Health* 2012; 12: 774.


47 Arah et al., op. cit. note 46.
community satisfaction of services, provider satisfaction, capacity for service
provision, quality of services, and overall vision of pro-poor and pro-female health
services. The WHO and OECD also have their own health care system
performance frameworks. There is no consensus on which domains are essential
to measure and what indicators reflect the best way to measure performance on
them. As a result, some countries may not collect data on certain domains like equity
or people-centredness. This can have significant implications for what systems
needs are identified. It is, therefore, important to recognise the value judgements that
underlie system performance assessments and to consider their consequences for
the identification of systems needs.

Although some domains like efficiency and effectiveness are commonly part of
existing frameworks, there may still be variations in how countries measure them.
Despite the lack of standardisation, responsiveness to systems needs might be
interpreted as requiring externally-funded HSR to target a public health or health
care system weakness identified by its host country’s performance assessment,
irrespective of the framework used. Where HSR focuses on the sub-national level,
the health system weaknesses identified by a national assessment should be evident
in the districts or provinces where the study is undertaken. Since HSR should be
context-driven, studies must be responsive to needs at the level of the health system
that they address. For example, if a study focuses on addressing inequalities in the
utilisation of primary health care services because national performance
assessments show disparities in utilisation exist, host district populations should

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48 Edward et al., op. cit. note 40.
49 Arah et al., op. cit. note 46.
experience lower levels of service access relative to other districts’ populations or disparities in utilisation should be evident within host districts that mirror national trends.

This understanding of responsiveness may be sufficient in most cases. However, there is at least one possible acceptable exception. Research may still be responsive if it focuses on a domain that is not included in a country’s national health system performance assessment, provided that there is strong evidence of health system shortcomings on the particular domain. Consideration should, therefore, be given to important domains not measured by a host country’s health system performance assessment and to the implications of their exclusion in regards to what systems needs are identified. For example, if a country’s assessment does not measure system performance on equity, it would not be able to show whether the health system generates inequalities in service utilisation, financial protection, or quality of care. Such inequalities would, in effect, not be identified as systems needs. In cases where a national performance assessment does not measure certain significant domains like equity but other evidence suggests weaknesses exist in these domains, responsive HSR could focus on such domains.

An approach of identifying systems needs using health system performance assessments may also run into the threshold problem described by Shah, Wolitz, and Emanuel.\textsuperscript{50} One option is to say that any sub-optimal score on a domain demonstrates a systems need. Another option is to take the position that not all health system failings constitute a systems need. Only those shortfalls from levels of

\textsuperscript{50} Shah et al., op. cit. note 6.
high performance that are of a certain size matter. A system must be doing fairly
badly on a domain for there to be a systems need. The difficulty here is to determine
how suboptimal performance on a domain must be to constitute a systems need.
Adding to the complexity, these thresholds may have to vary by country because
different frameworks are being used. There is also potential that very poor scores on
certain indicators may be masked by overall domain performance scores, suggesting
there may be a need to set thresholds for indictors too.

Beyond the threshold issue, upholding a requirement for HSR in LMICs to target
systems needs may be obstructed by a lack of available data. Less information is
generated on health system performance relative to burden of disease in LMICs. 51
Where LMICs do not conduct assessments of their health systems, the concept of
responsiveness to systems needs cannot be applied as described above. Other
sources of system performance data may exist that can be relied upon, but it is
important to consider who carried them out (is it a credible source?) and the quality
of the assessment. One limitation of assessments not performed by national
governments is that they may not be comprehensive and, therefore, will not give a
clear picture of performance across domains (which domains are performing worse
relative to other domains). For example, the recent Social Health Insurance for
Equity in Less Developed countries (SHIELD) project provided excellent in-depth
assessment of the health systems of Ghana, Tanzania, and South Africa on a single
domain—equity. 52

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51 Boerma et al., op. cit. note 44.

52 D. McIntyre & A. Mills. Research to Support Universal Coverage Reforms in Africa: The SHIELD
Project. Health Policy Plan 2012; 27: i1-i3
Systems priorities

Applying the concept of responsiveness to systems priorities could consist of relying on the health system or health research priorities set by host countries. Doing so is seemingly straightforward where countries have established such priorities. Yet, for HSR to focus on systems-level problems, be context-driven, be policy-driven, and effectively advance health development in LMICs, it must be responsive to HSR priorities set through a specific type of process.

National research priority setting processes frequently rely on disease-driven methods, which generally determine what burden of specific diseases may be averted by: developing new drugs and technologies, improving existing drugs and technologies, and extending the uptake of existing interventions. HSR falls into the third of these categories and may be identified as a priority where a significant burden of a certain disease is due to poor intervention uptake. Examples of this approach include the Combined Approach Matrix (CAM) and the Child Health and Nutrition Research Initiative (CHNRI) method. When the CHNRI method was

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53 Shah et al., op. cit. note 6.

applied in South Africa, experts selected three research priorities in the three aforementioned categories for each of the seven leading causes of child death.\textsuperscript{55,56}

Linking HSR questions to specific diseases contributes to the fragmentation of HSR and frequently results in HSR questions being systematically de-prioritized because doing so ignores their impact across multiple diseases.\textsuperscript{57} Where disease-driven approaches are employed, they may, therefore, identify more priorities for biomedical research than HSR. These approaches may also give priority to HSR focused on health care over HSR focused on public health because public health interventions are rarely new medical technologies. Disease-driven approaches can occasionally give rise to HSR priorities that are difficult to interpret.\textsuperscript{58}

It has been suggested that HSR priorities are better set separately from disease-focused (biomedical) research priorities, using interpretive (or other) approaches, to capture the full range of urgent research topics.\textsuperscript{59} Interpretive priority setting exercises generally involve a consultative process during which a range of

\textsuperscript{55} Tomlinson et al., op. cit. note 54.

\textsuperscript{56} The resulting proposed research priorities were then ranked according to five criteria: likelihood that question can be answered in an ethical manner, likelihood of efficacy and effectiveness, likelihood of deliverability and affordability, maximum potential for disease burden reduction, and likely impact of equity in population. For each research option, that ranking was then combined with its proposed cost to determine a final list of priority research options (Tomlinson et al., 2007).


\textsuperscript{58} Ibid.

\textsuperscript{59} Ibid.
stakeholders are convened to identify priority research topics and/or research questions.\textsuperscript{60} It is essential that policymakers (public health and health care officials and administrators) from the host country play a significant role in the priority setting process in order to ensure that HSR is policy-driven. If policymakers are not involved, the likelihood that HSR will address policy-relevant questions diminishes.\textsuperscript{61} It is also desirable that HSR questions should align with sub-national priorities or national priorities (rather than global priorities) to ensure that projects are context-driven.

If HSR is to effectively contribute to health system strengthening in LMICs, ideas from development practice shed further light on the nature of priorities with which responsive HSR should be consistent. The concept of \textit{country ownership} put forward as part of the \textit{Paris Agenda for Aid Effectiveness} and the \textit{Accra Agenda for Action} is relevant.\textsuperscript{62} This stems from the relationship of country ownership to the principle of alignment, which requires aid flows to align with country priorities and, therefore, overlaps to some extent with the concept of responsiveness to priorities. David Booth notes that, where the principle of alignment is achieved, it may, nonetheless, be meaningless if the priority setting process (or development of the national poverty

\textsuperscript{60} Ibid.


reduction strategy) was not country-owned. Country ownership exists when countries are governed by people for whom national development, including improved health and equity, is a central objective and these in-country actors and civil society (not donors) drive priority setting processes for health research. It denotes ‘a quintessentially political struggle, namely the wrestling of power from the hands of donors and the subsequent transfer of agency into the recipient governments’ hands’ and ‘represents a shift of power in the aid relationship.’

Country ownership is an outcome that needs to be constructed and is not an established fact for many LMICs. ‘The assumption that country ownership in this sense already exists, and the only issue for international actors is how to avoid undermining it [by aligning their projects with national priorities], is completely unrealistic, at least in low-income Africa.’ Thus, it is not sufficient for HSR questions to simply align with national (or sub-national) research priorities. These priorities must have legitimacy, which is derived through their being set via a fair process that includes national and sub-national health policymakers and members of civil society. Their being set by the government alone is not sufficient to achieve country ownership in many cases, especially where leaders have come to power by force. To ensure HSR is context-driven, national priorities should also not simply be recycled from global development agendas or donors’ list of priorities.

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65 Ibid: 15.
Achieving responsiveness to systems priorities then constitutes a significant challenge in current practice. So far, there have been few national processes in LMICs (Brazil, Myanmar) that set separate HSR priorities on a regular basis, with enough detail to guide the selection of research questions.\textsuperscript{66} Priority setting for HSR is not viewed as being of high importance due to resource limitations.\textsuperscript{67} Relying on health systems priorities may then be a more feasible option in many countries. Delivering country ownership of such priority setting processes is also a substantial hurdle:

Many definitions of country ownership ascribe a degree of fairness to democratic processes that are simply not evident. Nascent democracies in many parts of the world do not have systems set up to hear and deal with the multiple voices that the principle of “country ownership” assumes they do. The systems also, importantly, don’t have protective policies in place to ensure there are safe spaces for vulnerable individuals or groups to speak their mind.\textsuperscript{68}

Country ownership of health system priority setting requires LMICs to have leaders and institutions\textsuperscript{69} that are committed to health development, are willing to engage meaningfully with civil society, and possess the capacity to set national priorities.

\textsuperscript{66} Ranson & Bennett op. cit. note 57.


\textsuperscript{68} K. Macintyre. 2014. The Good, the Bad and the Uncomfortable in Country Ownership. Aidspan. Available at: 

\textsuperscript{69} Here, the term institution refers not only to entities like ministries of health but also to the social norms and rules that promote health development.
This also draws attention to how vital it is for research capacity building to target the systems level in order to build capacity for core functions like priority setting, rather than solely focusing upon the individual and institution levels. Achieving country ownership further entails minimising donors’ influence over health-related priority setting processes in LMICs. This is also a significant challenge. The nature of existing funding and international agendas distort priority setting for the health sector in African countries. Evidence from the aid sector (development assistance for health in the context of HIV) indicates that donors have been able to supplant the meaning of country ownership in ways that depoliticise it. Rather than being about recalibrating the locus of power in priority setting for health aid, the concept of country ownership has primarily been used as a tool for donors to limit their accountability by shifting responsibility for program implementation to host countries.

DISCUSSION

The paper has considered how responsiveness might be understood and applied in the context of HSR in LMICs. Due to its systems focus, it is more appropriate to

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72 Esser op. cit. note 64.
consider responsiveness in HSR in terms of systems needs and/or priorities.

Responsiveness to systems needs could entail relying on health system performance assessments to identify research targets. However, effectively applying this concept of responsiveness would require overcoming operationalization issues (setting threshold levels of poor performance for numerous domains) and translation issues (lack of available data on health system performance, especially public health aspects).

Responsiveness to systems priorities entails selecting research questions that are consistent with established national or sub-national HSR priorities. Three distinctive features of HSR—being context-driven, policy-driven, and linked to development objectives—mean that these priorities should be determined through a particular type of process that will be challenging to immediately achieve in practice in most LMICs. As a result, the concept of responsiveness as systems priorities may require more time for application to be feasible compared to responsiveness as systems needs in HSR in LMICs.

Problematically, relying on the above interpretations also means that the responsiveness requirement could potentially be met without external researchers taking direction from or even consulting with host country researchers when selecting a research question. Determining whether a project is responsive to a systems need, for example, would simply require access to data on health system performance for a host country and knowledge of appropriate threshold levels for poor performance on domains. Yet this seems inappropriate and inconsistent with the concept of country ownership. At the very least, applying responsiveness should
entail joint selection of and consensus on a systems need or a systems priority to target by external and local researchers, but this does not seem to be a necessary component of the concept of responsiveness. We propose that responsiveness (for all types of international research) might be expanded to constitute not only an outcome-oriented component (alignment with needs) but also a procedural component (joint selection process led by host country researchers) to promote greater ownership of research question selection by host country researchers. Although differences in research capacity may make such procedural components difficult to achieve in certain cases, it is, nonetheless, an important ethical objective to strive towards. Further work is then needed to clarify the procedural aspects of responsiveness and to identify practical strategies to fulfil them in order to ensure that they are not rendered meaningless on the ground in the face of power disparities between external and local researchers.

Since applying the concepts of responsiveness as systems needs and systems priorities will often not be straightforward, we believe that the next step in redefining responsiveness for HSR is for bioethicists and health systems researchers to consider how the concepts might be ethically applied under non-ideal implementation/translation conditions—where countries do not perform health system assessments (regularly), where their health system assessments fail to measure key domains, where countries have not established HSR priorities, or where country-ownership of HSR priorities will be difficult to achieve (fragile states). The challenges in the concepts’ application should not be viewed as a reason to abandon the responsiveness requirement. Responsiveness is an important ethical consideration that international research should endeavour to fulfil. Although meeting
the requirement cannot prevent exploitation on its own, doing so is a necessary condition for ensuring that the potential exists for host communities and countries to gain health benefits from externally-funded health research.

Perhaps one strategy that external researchers might rely upon to increase the likelihood of their HSR being responsive to systems priorities, where host countries have not set HSR priorities, is *embeddedness*. While the precise features of such a strategy must be fleshed out in more detail, the general concept of embeddedness entails external research institutions and researchers situating themselves in close proximity to health policymakers, researchers, and organisations representing vulnerable groups in a particular host country.\(^{73}\) This means developing connections with health policymakers at various levels (national, district, village) that are of good magnitude and high quality, spending considerable time in-country, and working with local researchers to build an understanding of the health system context.\(^{74}\) Where junior researchers adopt such an approach to their work, by the time they have risen to the position of principal or chief investigator and have responsibility for selecting research questions, they will be more likely to work with local researchers and policymakers to choose topics that reflect the priorities of their host country.


\(^{74}\) Ibid.
Finally, with regards to the debate over whether responsiveness should entail focusing on systems priorities or whether it is sufficient to focus on systems needs, we would suggest that it may make more sense to rely on responsiveness as systems priorities in contexts of limited resources. At present, funding for international research is generally low, especially for HSR in comparison to clinical research. Under such circumstances, there will always be a need to rank systems needs as more or less urgent. Thus, requiring HSR to focus on systems needs that are also priorities seems the logical option to choose.

CONCLUSION

Four features (amongst others) set HSR in LMICs apart from international clinical research—a focus on systems, being context-driven, being policy-driven, and being linked to development objectives. These features support reinterpreting responsiveness for HSR in LMICs as responsiveness to systems needs, where health system performance indicators are relied upon to identify systems needs, and/or responsiveness to systems priorities, which entails aligning research with HSR priorities set through a country-owned process involving national and sub-national policymakers from host countries. They further draw attention to the fact that the concept of responsiveness should be expanded to constitute not only an outcome-oriented component (alignment with needs and/or priorities) but also a procedural component to promote greater ownership of HSR by in-country actors. Given that both concepts of responsiveness will be difficult to achieve in practice, it is
also argued that more work is needed to describe how the responsiveness requirement can be applied in HSR in LMICs under non-ideal conditions. Embeddedness is proposed as one strategy that could be the focus of further development.

ACKNOWLEDGEMENTS

The authors would like to thank Paul Ndebele and David Bishai for their helpful comments on earlier drafts of this manuscript. BP would also like to thank the Hecht-Levi Fellowship Program at the Johns Hopkins Berman Institute of Bioethics for its support.