

Applying a systems lens to understand patient safety effectiveness in low-and-middle-income countries

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Ensuring patient safety in low-and-middle-income countries (LMICs) requires tailored approaches that are appropriate to the unique challenges faced by health systems in LMICs. To date, the evidence on how to effectively improve patient safety in LMICs is limited and although we can infer lessons from high-income countries (HICs), there are meaningful differences between HICs and LMICs that require careful study. The study by Hall *et al*¹ in this issue of *BMJ Quality & Safety*, which used implementation science methods to study what helped or hindered the roll-out of a patient safety programme in Guatemala, is therefore a welcome addition to this evidence base.¹ Based on the findings from Hall *et al*,¹ and the growing focus in the field of implementation science to analyse mechanisms by which implementation strategies work (or do not work), we argue that patient safety endeavours globally should consider systems-level barriers and explicitly include tailored strategies to overcome them.² LMICs have unique contextual factors that require interventions to be adapted, rather than directly transported from HICs.

Mixed-methods implementation science studies like those employed in Hall *et al*'s paper¹ are particularly helpful for increasing our understanding of how to translate systems thinking into real-world practice. Hall *et al*¹ used the Consolidated Framework for Implementation Research (CFIR)³ to identify facilitators and barriers for implementation and inform the optimisation of patient safety implementation strategies in Guatemala. They evaluated implementation determinants acting across multiple levels, including the individual, inner organisational context, and external environment which led to several insights related to the overall

health system and context. The authors found that clinical staff were intrinsically motivated to provide high-quality and safe care for their patients, but often faced systems barriers of insufficient time, resources and staff to implement known evidence-based protocols. Some of these are similar as experienced in HICs, but others unique for the context of LMICs. In addition, due to the hierarchical structure of the system, staff mentioned the need for increased governance and system/organizational-level structures to support and encourage patient safety.

While the CFIR framework proved to be a helpful tool in the Hall *et al*¹ study for identifying individual determinants, many existing implementation science theories, models and frameworks fail to consider the characteristics of the overall health system within which a discrete implementation strategy is embedded. For example, the current Expert Recommendations for Implementing Change compilation of implementation strategies has generated a list of 73 discrete implementation strategies that can be adopted for patient safety.⁴ Yet, we question whether any discrete implementation strategy can—or should be—divorced from the overall system in which strategies operate. Our group recently proposed a modified version of the CFIR framework for use in LMICs, which includes a new domain focused on 'Characteristics of Systems' to address this gap. Systems design features such as the degree of centralisation, availability of supplies, public/private mix and remuneration mechanisms can strongly influence the degree to which policies and practice are taken up and need to be considered when studying implementation success. Although we strongly advocate for the inclusion of a systems domain in both high-income and low-income



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settings, LMICs face unique systems-level contextual determinants, which warrant specific exploration in implementation science studies and local strategy adaptation to maximise implementation effectiveness.

In contrast to many of the challenges facing high-income health systems, many health systems in LMICs are still focused on guaranteeing a minimum level of facilities, people and supplies, without which delivering high-quality care may be nearly impossible. Facility readiness surveys across 10 LMICs have shown that only 1% of health centres have all the diagnostics tests and medicines required to perform basic patient services.⁵ A similar assessment in Mozambique found that essential medicines for primary care were stocked out 20% of the time and upwards of 50% for mental health medications.⁶ With very limited trained human resources for primary healthcare, nurses in Mozambique are often forced to deliver sub-standard care as they race to evaluate 60 or more patients in a day and patients wait hours in the heat to be seen.⁷ Similarly, throughout the COVID-19 pandemic, providers in India,⁸ Nigeria,⁹ Brazil and around the world¹⁰ have had the impossible job of trying to deliver safe and effective care when their health systems have failed to guarantee basic supplies like oxygen, resulting in numerous preventable deaths. Providers cannot be expected to focus on preventing unnecessary infection when they do not have latex gloves or N95 masks to prevent themselves from contracting COVID-19, Ebola or other infectious diseases. Similarly, we cannot expect to achieve high-quality mental healthcare with only one psychiatrist per 2 million people and when the antipsychotic medication a patient was prescribed last month is now out of stock in an entire province.¹¹ When health systems struggle to guarantee the basics needed to provide essential primary healthcare, providers cannot be expected to provide optimal care. Patient safety efforts must address underlying systems weaknesses and not only add burden—or worse—blame providers who are trying the best they can to provide quality care under circumstances designed by the systems in which they operate.

The financing of patient safety programmes is also important to consider, as it reflects priorities, potential for scale, as well as possible interruptions or delays in implementation. The Hall *et al*¹ study identified the lack of financial support and organisational incentives as a barrier to implementation effectiveness. LMICs continue to rely on significant contributions from donor assistance and are at greater risk of a mismatch in the priorities of funding agents compared with HICs.¹² Donor-assisted funds also tend to be earmarked and time-bound, restricting health systems' ability to flexibly use the funds and hampering a smooth transition from pilot stage to scaled implementation. The modified CFIR that our group proposed includes these constructs, as well as the perceived ability for a programme to scale, particularly in LMICs

where fragmented implementation efforts and pilots are rampant.

It is also critical to consider the administrative design of health systems in LMICs as a construct in the modified CFIR, as rolling out a patient safety programme in a highly centralised system versus one that is highly decentralised or even federated will influence implementation effectiveness. The Hall *et al*¹ study found that providers were highly motivated on their own to focus on patient safety, but felt limited by their own decision-making autonomy, and lack of national or facility level policies and organisational support. If patient safety efforts focus on isolated implementation strategies that are divorced from an understanding of the system within which it will be integrated, the results will be poor.

Patient safety efforts also require that adverse events are reliably monitored, reported and properly incentivised. According to WHO, 'each year 134 million adverse events occur in hospitals in LMICs due to unsafe care, resulting in 2.6 million deaths,'¹³ yet those figures only capture reported events. Providers who participated in the Hall *et al*¹ study felt that patient safety would not progress in their Guatemalan setting without accurate patient outcome data, accountability, incentives aligned to outcomes and clear governing policies. The strength of the health information system in LMICs, the culture around reporting and the way leaders use those data are therefore critical determinants that we argued should be included in a modified CFIR. Taking a systems lens would also highlight that data reporting is linked with financing. The variables collected to monitor effectiveness of health programmes in LMICs are often dictated by donor priorities leading to proprietary, siloed systems and inefficiencies for health workers,^{14 15} an issue which many donors are now trying to combat.¹⁶

The field of implementation science can help us critically evaluate policies and norms that are considered essential for 'safe' care in HICs, but which lack real-world evidence in LMICs. We need to recognise that HICs and LMICs may differ in their definition of 'safe' and the way to minimise errors and adverse events may differ across settings. For example, in Western countries, only physicians were initially allowed to monitor HIV/AIDS treatment—it was considered 'unsafe' for anyone else to do so. Yet, studies in LMICs have demonstrated that care can be effectively and safely administered by non-physician clinicians, such as nurses,¹⁷ an approach that may or may not be accepted in HICs. We have seen the same pattern demonstrated with task-sharing in family planning,¹⁸ mental health,^{19 20} surgical equipment²¹ and other non-communicable diseases.²² Implementation science can continue to build our understanding of what patient safety means in LMICs.

How we achieve healthcare delivery with no adverse events in LMICs will differ across cultures and

health systems contexts. Implementers, researchers, managers and policy-makers should consider building patient safety programmes that use implementation strategies targeting the numerous barriers that exist at the provider level and also at the level of the health system as a whole. Future implementation research efforts to improve patient safety in LMICs should use frameworks, such as the expanded CFIR adapted for LMICs, to evaluate determinants of patient safety at all levels with a specific focus on the systems domain. Without this holistic focus, narrowly defined patient safety programmes will likely have limited effects to improve care for patients and their outcomes. Worse, these programmes could demoralise the limited number of trained health providers who are already overburdened as they work on the front lines to ensure ‘health for all’ across LMICs.

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