3-2021

The injustice of unfit clinical practice guidelines in low-resource realities

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Recommended Citation

Maaløe, N., Ørtved, A. M. R., Sørensen, J. B., Dmello, B. S., van den Akker, T., Kujabi, M. L., ... & Housseine, N. (2021). The injustice of unfit clinical practice guidelines in low-resource realities. *The Lancet Global Health*.

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The injustice of unfit clinical practice guidelines in low-resource realities

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To end the international crisis of preventable deaths in low-income and middle-income countries, evidence-informed and cost-efficient health care is urgently needed, and contextualised clinical practice guidelines are pivotal. However, as exposed by indirect consequences of poorly adapted COVID-19 guidelines, fundamental gaps continue to be reported between international recommendations and realistic best practice. To address this long-standing injustice of leaving health providers without useful guidance, we draw on examples from maternal health and the COVID-19 pandemic. We propose a framework for how global guideline developers can more effectively stratify recommendations for low-resource settings and account for predictable contextual barriers of implementation (eg, human resources) as well as gains and losses (eg, cost-efficiency). Such development of more realistic clinical practice guidelines at the global level will pave the way for simpler and achievable adaptation at local levels. We also urge the development and adaptation of high-quality clinical practice guidelines at national and subnational levels in low-income and middle-income countries through co-creation with end-users, and we encourage global sharing of these experiences.

Introduction

"The women are in pain, some look frightened and many are calling for my attention. It is a typical night duty in the maternity ward. Eighteen women are admitted in the congested labour room, two in each bed. A young nurse and I are the only staff in the room. I see a head crowning in bed four and an oxytocin drip next to bed two running too fast. The nurse reports that one of the women with severe preeclampsia is fitting. It is a long time since any woman had assessments of foetal heart rates, and their unborn babies may have been crying out for help in silence. I am quickly casting a glance on the room's wallpaper of guidelines. They all are there, from the Ministry of Health to international aid organizations. Fading instructions and illustrations depict the what-if scenarios if only I had one woman with one illness at a time. I force my gaze back at reality and feel alone" (reconstruction of lived experiences of health professionals in Tanzanian maternity units, unpublished data).

Each year, more than 295 000 maternal deaths and 5 million stillbirths and neonatal deaths occur worldwide, of which the vast majority of these deaths take place in low-income and middle-income countries (LMICs).[1,2] Many of these deaths would be preventable with access to quality health care during pregnancy and childbirth, and the economic and psychosocial return on investment would be massive for families and societies.[3] However, although the number of facility births have increased, the quality of care has not adequately followed suit.

During the past two decades, the development of clinical practice guidelines (CPGs) has been a central strategy to cost-efficiently improve maternal health care in low-resource settings.[4–6] Moreover, the rapidly expanding number of CPGs have laid the foundations for a variety of other interventions. However, as we found in a literature search of childbirth CPGs in African hospitals (appendix p 4), fundamental gaps between international recommendations and realistic best practice continue

to be reported in low-resource settings, and evaluation of the implementation and effectiveness of CPGs is largely neglected. Similar discrepancies between CPGs and realistic best practice are reported in other fields of medicine,[7–9] and such discrepancies have also been exposed by the interim COVID-19 guidelines (appendix p 2).[10,11] Within and beyond maternal health, these discrepancies cause alarming risks of preventing actual use of CPGs, disenfranchising and demoralising health providers, draining resources, and, paradoxically, causing unintentional harm in clinical practice.[12–14] This issue raises the question of whose views count in CPG development, implementation, and aspiration?[15]

In this Viewpoint, we address this underexposed yet long-standing injustice of leaving health providers without useful guidance. We suggest ways forward, and we call for action, at global and local levels, to develop contextualised, realistic CPGs for health providers practising where guidance is most acutely needed.

Whose perspectives count in current CPGs?

When comparing multiple international, high-quality maternal health CPGs, important inconsistencies and disagreements are seen, even between concurrently published so-called high-quality CPGs.[16] These inconsistencies and disagreements highlight limitations in experimental studies and the strong influence of values, culture, and professional tradition, even in what are considered high-quality CPGs.[17] Translating evidence into recommendations inevitably requires judgements about the balance between benefits and risks, and involves combining selective and restricted study findings. However, the front-line health providers, who are the experts in low-resource clinical practice and the pivotal agents of sustainable development, are rarely invited to participate in such judgements and tailoring. Not only are these clinical experts scarcely represented in CPG development, pilot testing among end-users of

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See **Online** for appendix

CPGs and postimplementation evaluation are largely neglected.[5]

Multilateral health agencies appear to take for granted that their CPGs will be adequately adapted to local contexts regionally, nationally, or subnationally.[4] However, it is generally acknowledged that few LMICs are equipped with the necessary human, technical, and financial resources to carry out such adaptations, including time, access to evidence, knowledge and training on synthesising and applying evidence, and coordination of the different stakeholders.[9,12,18,19] Therefore, international recommendations are typically endorsed nationally after varying degrees of suboptimal adaptation by a panel of experts, or even (inappropriately) directly adopted. Front-line health providers are often not invited to influence these processes of GPG development or adaptation nationally, but they are asked to use CPGs that are dangerously incomplete, irrelevant, impractical, or outdated.[12,18,19] Some of the CPGs are predictably unachievable, which can catalyse stress and resistance to change among already strained health providers, instead of achieving goals and increasing commitment and job satisfaction.[14] For instance, spending 10 min half-hourly with each labouring woman counting fetal heart rate and contractions is mathematically impossible when simultaneously caring for three or more women.[19] Other recommendations might appear achievable but are resource consuming and harmful. For instance, risk ratios of vaginal breech births versus caesarean sections differ between high-resource and low-resource settings, given that the surgical safety that can be achieved in high-income countries (HICs) can rarely be met when resources are scarce.[20] Likewise, although the use of oxytocin augmentation is recommended in LMICs as it is in HICs, higher risks of adverse perinatal outcomes are predictable in settings without one-to-one care and poor surveillance, no electronic drip counts, and delayed access to emergency surgery and blood transfusion.[19] Yet other recommendations might unintentionally over-influence practice, leaving other essential care further under-resourced. As elaborated in the appendix (p 2), WHO's non-integrated, vertical COVID-19 guidelines is an example of this. For instance, as COVID-19 symptoms mimic obstetric emergencies, triaging women with concomitant obstetric complications might be delayed if vertical COVID-19 responses overinfluence care.[10]

Astonishingly, augmentation of the technical bar for evidence synthesis in CPG development, which has occurred over the past two decades, has not been matched by a strengthened focus on pilot testing and post-implementation evaluation. This finding stands in contrast to CPG research in HICs, and implementation science in general, in which co-creation, pilot testing, and postimplementation evaluation are acknowledged to be central means for success.[13,21,22] Notably, while medications have to pass through multiple phases of trials before approval, as well as post-approval monitoring, CPGs (eg, for drug dosages and indications) are often disseminated without any pilot testing or postimplementation testing of effects, and side-effects. In the original AGREE appraisal tool, the go-to tool to assess methodological rigour in CPG development, pilot testing was included as an integrated part of stakeholder involvement. In the second version, however, pilot testing was reduced to one of many additional suggestions for what might be included in the methodological assessment.[6] Strengthening evidence synthesis of CPGs could even, paradoxically, have counteracted the influence of end-users, by predominantly focusing on evidence generated through experimental study designs, which control for the essential contextual factors.[5,23]

Making end-users' perspectives count
At national and sub-national levels
From the scarce literature regarding co-created CPGs in low-resource settings (appendix p 4),[7,8,16] we present two examples from sub-Saharan Africa in this Viewpoint. Both examples provide elaborate descriptions of CPG development and evaluation, and they expose potentially essential factors for effectiveness in such processes.[9,19]

One example is a Kenyan approach to co-creation of paediatric CPGs, which was carried out at national level and applied top-down.[9] The other example is the Zanzibar initiative for obstetric CPGs (the PartoMa project), which was based on a bottom-up approach, in which CPGs were co-created with health providers in one hospital and later scaled up.[19] There are many similarities between these programmes, which both followed overarching principles of "problem-driven iterative adaptation".[13] First, locally identified problems led the structured CPG development process, and CPGs were updated in response to emerging local issues and other feedback from end-users, as well as emerging external evidence. Second, to ensure legitimate, relevant and supportable recommendations, and to avoid CPG duplication and contradictions, the co-creators included clinicians with and without speciality training (ie, the end-users, while taking their limited time into account) as well as other stakeholders (eg, community members and policy makers). Third, the end product was a short booklet of integrated, basic routine and emergency management, presented as infographics for busy health providers without specialty training. Finally, the CPGs were widely disseminated at knowledge and skills courses, which included trainers who were directly involved in the CPG co-creation (once in Kenya and recurring in Zanzibar). The Kenyan CPGs have been integrated into undergraduate and postgraduate paediatric training, and CPGs from the PartoMa project are currently being modified and tested in Dar es Salaam, Tanzania. Both programmes have reported concurrent improvements in clinical practice. Also, they report enthusiasm among CPG co-creators and users, including greater appreciation of the value and limitations of evidence and an emerging

sense of ownership. An added benefit of CPG co-creations with end-users is that the need for better evidence to inform CPG development processes in low-resource settings is disclosed.[9,19,23]

The Kenyan approach was used to develop CPGs de novo, whereas the primary focus of the PartoMa project was on adapting internationally-derived CPGs.[9,19] Although de-novo synthesis might strengthen a sense that the local team's role "is not just to endorse global recommendations",[9] high-quality contextualisation and adaptation of international CPGs might have greater potential to make the best use of scarce resources.[7] However, CPG adaptation processes in low-resource settings remain unrealistically time-consuming and resource-draining because of the discrepancies between externally derived CPGs and realistic best practice, and due to missing information in the externally derived CPGs (eg, on what human resources are needed to follow recommendations, on cost-effectiveness, and on how the values and preferences of the targeted population were evaluated). High-quality CPGs that have already been developed in comparable low-resource settings would ease adaptation to new locations, and such development experiences and products should be routinely shared internationally.[7,12,18,19,24] Moreover, as self-reflected by WHO's Guidelines Review Committee, tools for CPG adaptation, implementation, and updating should be planned from the beginning of each CPG development and not merely "treated as afterthoughts".[5]

At the global level

It should be achievable to develop useful and effective CPGs at global level that are closer to realities in LMICs, thereby paving the way for simpler adaptation. Although there are some promising examples of more specific CPGs with lesser need for adaptation (eg, for neonatal resuscitation),[25] the effectiveness of directly adopted broader, integrated CPGs for complex clinical management is questionable (eg, intrapartum guidance to avoid the underlying neonatal asphyxia; appendix p 4). To take better account of linkages between interventions and contexts in CPG development, WHO launched an initiative in 2016 to broaden their evidence synthesis and better incorporate qualitative data and complex intervention research. This initiative resulted in the WHO-INTEGRATE framework, which encourages a structured process of reflections during CPG development (ie, integrating health benefits and harms, human rights and sociocultural acceptability, financial and economic considerations, health equity, equality, and non-discrimination, societal implications and feasibility, and health systems considerations).[23] This framework can hopefully assist in stratifying CPGs to different contexts already at global level, so that the CPGs are in accordance with, for example, health provider-to-patient ratios. Notably, this approach would follow WHO's long-standing aspiration to develop "conditional recommendations"[4]

when interventions are suitable for some locations only, of which the WHO's essential drugs list is a successful example.[24]

However, actual use of the WHO-INTEGRATE approach might be challenged by the often scarce number of complex implementation studies with detailed descriptions of context.[21] Hence, interpreting and combining the findings of trials with restricted real-world applicability is still a central part of CPG development. Inspired by a model for large-scale CPG development in HICs, we propose that context stratification based on pre-decided criteria, as depicted by the WHO-INTEGRATE framework (eg, provider-to-patients ratios), is viewed only as the first of three steps at global level, after which iterative cycles of adaptation, implementation, and evaluation are implemented nationally and sub-nationally (appendix p 3).[22] The second step at global level should require field visits in different settings, to identify less predictable barriers to implementation and effectiveness, and to identify possible side-effects. WHO's Better Outcomes in Labour Difficulty (BOLD) project provides an encouraging example of such negotiation of best possible standards among end-users and target populations in selected Ugandan and Nigerian health facilities.[26] Field visits should also include assessment of risks for contradictive recommendations, counterproductive guidelines overload, or vertical guidance over-influencing care. Finally, merely distributing CPGs is not sufficient to reach high-quality clinical decision making. Even easily adaptable recommendations enter a local process of becoming politically and institutionally embedded, and the third step at global level concerns supporting this process. This third step might, for instance, include development of realistic performance measures for evaluation of CPG use and effects, CPG-related undergraduate and postgraduate training components, and user-friendly CPG algorithms and manuals. Notably, the brief infographics in the aforementioned Kenyan and PartoMa CPGs follow the evidence of decision science on the centrality of heuristics in decision making. Also within clinical practice in HICs, such fast and frugal clinical decision support tools are called for, which should not overwhelm health providers by their sheer volume of recommendations, but should stimulate dialogue with colleagues and patients (eg, by presenting pros and cons lists) and assist with multiple simultaneous actions in complex realities.[27] Notably, particularly in resource-scarce settings with suboptimal undergraduate and postgraduate training, CPGs could be a central means to stimulate creativity and flexibility of the mind, which is crucial to provide best possible care for the many with the limited resources available.

Digital health, including artificial intelligence, might become central in designing cost-efficient models for CPGs targeting LMICs by, for instance: (1) assisting in CPG development, such as systematic reviews, expert

consensus, Delphi approaches, and data mining; (2) developing CPGs with embedded algorithms, which cost-efficiently stratify recommendations to resource levels and other contextual features, and allow for the possibility of rapid modifications; (3) strengthening CPG use through digital decision support tools that reduce workloads; and (4) embedding feedback loops to facilitate rapid learning from end-users.[28] However, in current CPG-based digital decision-support tools for LMICs, pre-made so-called best-practice eHealth solutions often appear non-adjustably based on generic CPGs. For instance, an evaluation in Kenya of an electronic partograph to assist in timely surveillance during birth raised concerns of how this potentially effective intervention could be implemented at busy sites where only a small number of health providers are available. The electronic partograph releases audible reminders when clinical measurements are due, but the intervention developers and evaluators have not assessed contextual feasibility of WHO's recommendations for labour surveillance, which were adopted directly into the intervention.[29]

Ethical considerations

Pragmatic CPG development might be criticised for promoting suboptimal practices, inefficiently replicating previous interventions, failing to meet global standards, or prolonging the unacceptable status quo.[13] We do acknowledge ethical dilemmas in producing acceptable guidance for unacceptable realities with the human resources crisis at its centre. Yet, acceptable guidance is a moral duty to deal with realities that must not be accepted in the long run, but that do currently exist. Settings with scarce resources should thoroughly consider efficiency and equity of resource use, and global health care should not imply identical health care: "this is the balance between globalizing evidence and localizing decisions that will improve health care worldwide".[30] In line with the Paris Declaration on Aid Effectiveness and the Accra Agenda for Action, this redirection of accountability at global, national, and subnational levels enables health providers in resource-constrained facilities to improve control and influence how problems and solutions are outlined at the global level.[15] Overworked birth attendants require access to professional development and supervision, for which realistic CPGs are fundamental.[31] Such aspirations for respectful work conditions (Sustainable Development Goals 3c and 8·8) are pivotal for providing best possible safe and respectful care and strengthening the accountability of health systems (Sustainable Development Goals 3.1, 3.2, and 5.1).

A call for action at global and local levels

In the era of personalised medicine in HICs, context-stratified, realistic CPGs for LMICs are long overdue. Such CPGs should be formulated to facilitate implementation, and with embedded feedback loops to stimulate rapid experiential learning throughout development and implementation. Funding constraints can be argued as a central challenge that influences both priority setting and quality of CPG development.[5] Meanwhile, the current isomorphic mimicry of nations adopting poorly fitting CPGs causes capability traps, where scarce resources are effectively lost in developing and implementing ineffective CPGs.[13] The case is clear: the need for evidence-informed and cost-efficient health care without wastage is urgent in LMICs, within and beyond maternal health, and translating evidence into practice is most successful when contextual differences and needs are factored into the decision-making process.[16,23,30] We believe that development and adaptation of high-quality, contextualised, realistic CPGs will assist health providers in saving lives rather than causing immobility by a desire for perfection.

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