Crossing borders: the PACK experience of spreading a complex health system intervention across low-income and middle-income countries

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ABSTRACT

Developing a health system intervention that helps to improve primary care in a low-income and middle-income country (LMIC) is a considerable challenge; finding ways to spread that intervention to other LMICs is another. The Practical Approach to Care Kit (PACK) programme is a complex health system intervention that has been developed and adopted as policy in South Africa to improve and standardise primary care delivery. We have successfully spread PACK to several other LMICs, including Botswana, Brazil, Nigeria and Ethiopia. This paper describes our experiences of localising and implementing PACK in these countries, and our evolving mentorship model of localisation that entails our unit providing mentorship support to an in-country team to ensure that the programme is tailored to local resource constraints, burden of disease and on-the-ground realities. The iterative nature of the model's development meant that with each country experience, we could refine both the mentorship package and the programme itself with lessons from one country applied to the next—a 'learning health system' with global reach. While not yet formally evaluated, we appear to have created a feasible model for taking our health system intervention across more borders.

SPREADING A COMPLEX HEALTH SYSTEM INTERVENTION

Finding health system interventions that sustainably improve the quality and outcomes of care in low-income and middle-income countries (LMICs) is not easy, but there are some examples: 'promising practices' showcased by the Primary Health Care Performance Initiative¹ and notably, WHO strategies Integrated Management of Childhood Illness,² Mental Health Gap Action Programme (mhGAP)³ and Practical Approach to Lung Health (PAL).⁴ The WHO interventions focus on delivering applicable and evidence-based clinical guidance to primary care providers in LMICs. Developing and successfully

Summary box

- ▶ Frameworks exist to guide localisation, and scale up of knowledge translation interventions focussed on specific conditions or a narrow range of clinical practices.
- ▶ But there is little describing how to spread comprehensive health service delivery programmes across borders to different low-income and middle-income country (LMIC) health systems.
- ▶ We have developed an acceptable and seemingly viable model for spreading our comprehensive clinical decision support programme, Practical Approach to Care Kit (PACK), in LMICs and have implemented it in several countries, including Botswana, Brazil, Nigeria and Ethiopia.
- ▶ A mentorship model to support in-country programme localisation and implementation achieved local ownership and successful piloting and is sustainable within the restricted resources of our unit.
- ▶ Vital for this success were regarding localisation of clinical decision support as the first step in programme implementation and drawing in key stakeholders throughout.

implementing such interventions is one, not inconsiderable, achievement, but the ability to spread a successful health system intervention to other settings is another challenge.^{5–7}

The knowledge translation and implementation science community has developed processes and frameworks that promote standardised, transparent strategies for adapting clinical guidance,^{8–11} even coining the term 'adoption'—the combination of the adoption, adaption and de novo development required to tailor evidence-based clinical guidance to another setting. However, these frameworks are generally used to implement single disease guidelines but not for adapting comprehensive and integrated clinical guides

that address all presenting illnesses and the multimorbidity increasingly encountered in LMIC primary care.¹³

Research and strategies¹⁴ addressing the spread of health systems interventions use various terms: ‘diffusion’ describes passive spread of an innovation, ‘dissemination’ the active and planned efforts to encourage target groups to adopt an innovation and ‘scale-up’ the widespread use among target populations.¹⁵ The latter can refer to the expansion of an intervention within one country or across borders at global scale.

This paper describes our experiences of disseminating a complex health system intervention to eight LMIC settings. We do not describe the direct implementation of the intervention, but rather the approach we use to spread the intervention to other countries. As far as we are aware, there is no published literature for this “upstream” implementation. We share the challenges and lessons that have informed the development of a feasible and reproducible approach for taking our health system innovation across borders.

THE PRACTICAL APPROACH TO CARE KIT (PACK)

The PACK programme aims to support primary care health workers in LMICs reorganise the care they deliver so that it speaks to the needs of their growing patient load. Expanded from a South African version of PAL that tackled respiratory conditions and HIV, (Practical Approach to Lung Health and HIV/AIDS in South Africa, PALSA PLUS), PACK was developed by a small team of health systems researchers, content developers and training programme designers at the Knowledge Translation Unit (KTU) in Cape Town, South Africa. The principles of the programme are that it be comprehensive, evidence informed and policy aligned and speak to the needs of end-users.¹⁶ It comprises the delivery of comprehensive clinical decision support for adult care, the PACK Adult guide, using an evidence-informed implementation programme.¹⁷ Key to its implementation is that PACK is localised—locally tailored and addressing

health systems issues like health worker scope of practice, referral pathways and resource availability. Now adopted by government to support national primary care initiatives in South Africa,¹⁸ the programme has been developed, implemented and evaluated over almost 20 years and mixed methods evaluations, including pragmatic randomised trials, have shown multiple modest, consistent and reproducible improvements in quality of care, health outcomes and clinician work satisfaction.^{19–24}

PACK has been localised to other LMICs—Mexico, Malawi, Botswana, The Gambia, Brazil, Nigeria, Ethiopia—and receives ongoing interest from many more. To service this interest and the in-country engagement, the KTU entered into a non-profit strategic partnership with the BMJ Publishing Group, drawing on BMJ’s global footprint and operations and expertise in publishing, technology, communications and partnerships, with a shared vision to improve health and healthcare, focusing on areas of greatest need. The partnership also provided the mechanism to streamline localisation and maintenance of the PACK guide. Drawing on BMJ evidence synthesis product, Best Practice, the KTU created the ‘PACK Global Adult’ guide, where each of the over 2300 diagnostic, screening and management recommendations are informed by evidence and, to reflect an LMIC reality, are aligned to WHO guidance. This PACK Global guide serves as an up-to-date template for in-country localisation. Development of the PACK guide is described elsewhere.²⁵

DESCRIPTION AND COMPARISON OF IN-COUNTRY LOCALISATIONS

The process of adapting the PACK programme and predecessor PALSA PLUS to other LMICs has evolved over the past 8 years. Figure 1 depicts the timeline for these localisations.

Once success of the programme in South Africa became known through research publications and as an example of the PAL strategy,²⁶ pulmonologists from two countries

Figure 1 Timeline for in-country PALSA PLUS and Practical Approach to Care Kit (PACK) localisations.

localised PALSA PLUS to their own setting independent of the KTU—Minas Gerais state, Brazil²⁷ and Mexico. We called this approach an independent model of localisation as this work occurred without the involvement or subsequent evaluation by KTU.

Separately, the KTU embarked on localisation of first the PALSA PLUS programme in Malawi²⁸ and then PACK in Botswana.²⁹ During both localisations, the KTU Content team led localisation of guide content and interrogation of related health systems issues (like medication and test availability), and the Training team adapted the training material, delivered the first level of training and capacitated local partners to lead the programme with ongoing KTU training lead guidance. This we called a consultancy model of localisation as it relied on our unit leading and conducting the localisation process with support from local parties.

The Gambian Ministry of Health National TB Programme leads then approached the KTU to assist with localising and implementing PALSA PLUS. As we had no capacity to do so in the limited timeframe and budget, we deferred this consultancy to the programme manager from the NGO organisation we had worked with on the Malawi localisation and implementation.

Following these experiences, we were reluctant to replicate such a consultancy model, because it was too resource intensive and time-consuming to be reproducible at scale. We were also concerned that this model did not create sufficient local ownership of the programme, potentially compromising scalability and sustainability.

Thus, when approached by a Brazilian team, we tried a mentorship model of localisation where the KTU team mentored in-country stakeholders to localise the programme and tackle the health systems issues that localisation surfaced. This 'letting go' of the process on the part of the English-speaking KTU team was also necessitated by the fact that the content, implementation and subsequent evaluation were in Brazilian Portuguese. The Brazil localisation is described in another paper in this Collection.³⁰

We have since refined this mentorship model to support PACK localisations in Nigeria³¹ and Ethiopia,³² with some variation in response to local resources, timeframes and funding models.

The features of each in-country localisation are compared in table 1.

THE PACK MENTORSHIP MODEL OF LOCALISATION

Figure 2 details a nine-step mentorship process that the KTU team (project manager and content and training team mentors) applied throughout the Brazil, Nigeria and Ethiopia localisation experiences. The steps comprise local engagement and introduction to the PACK programme, KTU mentorship of the in-country localisation of the guide, training programme and tackling of health systems issues, user testing, initial implementation and concurrent evaluation. Key to each step

is an emphasis on applying the PACK principles and continuously engaging local stakeholders.

Before embarking on the localisation work, we invested time to introduce the teams to one another and to the elements of the PACK programme and the plan for mentorship, localisation and implementation. Visits by the localising teams to South Africa occurred to allow them to experience the programme first-hand.

Localising the guide, training materials and tackling health systems issues was an iterative process, with PACK Global guide content prompting interrogation of health systems issues, and clinical scenarios and health systems realities and priorities altering guide content. This made stakeholder input vital and end-user testing a key step. In Nigeria, for example, a questionnaire and consultation log that required end-users to work off priority guide pages, like 'cough and difficulty breathing' and 'HIV' helped to identify gaps and errors.

We borrowed agile development concepts from the information technology industry³³ to make tackling comprehensive content more manageable. We divided guide content into sections for localisation, provided attentive project management and regarded the localised guide as 'Version 1' which allowed the teams to park lower priority content (like hair loss in Ethiopia) for future editions in order to maintain momentum of localisation and stakeholder engagement.

Thus far, the KTU has managed the artwork of the guide and most training materials. As some of the PACK guide's appeal is its design—full colour, carefully formatted algorithms and checklists, illustrations and photographs—design expertise and expensive graphic artwork programmes are needed to maintain its high quality. Localising teams have had neither the capacity nor resources to perform this function. It has also enabled the KTU content mentor to have 'sign-off' of all guide content.

At the outset, the in-country localising team received a PACK Manual for Localisation and Implementation with an accompanying Toolkit. The manual conveys PACK principles and gives step-by-step guidance for the localisation process. The toolkit contains the components of the programme—the PACK guide, lists of medication, equipment and tests and training materials—as well as the tools used for localisation and implementation: localisation schedule, evidence and decision support document for guide localisation (with references underpinning each guide recommendation), editable templates of guide and training programme and materials and printing specifications.

CHALLENGES OF THE MENTORSHIP MODEL OF PACK LOCALISATION

Each of the Brazil, Nigeria and Ethiopia PACK localisation mentorship experiences met challenges along the way.

Table 1 Comparing in-country localisations of PALS PLUS and Practical Approach of Care Kit (PACK) programmes

Brazil (Minas Gerais)		Mexico	The Gambia	Malawi	Botswana	Brazil (Florianópolis)	Nigeria	Ethiopia
Name of local programme	PAL GARD Brasil (Practical Approach to Lung Health/ Global Alliance against Respiratory Disease)	PAL AIRE Accion Integrada Por La Respiración/ Integrated Action for Respiration	PALS PLUS Gambia	Practical Approach to Lung Health and HIV/AIDS in Malawi (PALM PLUS)	Botswana Primary Care Guideline	PACK Brasil Adulto – Versão Florianópolis	PACK Adult Nigeria	Ethiopian Primary Healthcare Clinical Guidelines
Driver of innovation	Need to improve diagnosis and management of respiratory disease	Need to improve diagnosis and management of respiratory disease	Need to implement PAL to address TB epidemic	Need to provide clinical support for integration of TB and HIV care	Need to prioritise and integrate non-communicable disease care in primary care	Need for integrated clinical guidance as part of primary care system overhaul	Need for clinical decision support for primary care health workers	Need for a standardised package to guide integration of communicable and non-communicable disease clinical care
Localisation model	Independent model	Independent model	Regional technical support—consultancy model	Consultancy model	Consultancy model	Mentorship model	Mentorship model	Mentorship model
Localiser	Local respiratory physicians	Led by local respiratory physicians with input from respiratory health stakeholders	Ministry of Health National TB programme supported by WHO Gambia office	Localising NGO partner in collaboration with Ministry of Health	University Family Medicine department collaborating with Ministry of Health Non-Communicable Diseases directorate	Municipal primary care team	Localising partner with close ties to Ministry of Health	Federal Ministry of Health Primary Care directorate
Funding source	Minas Gerais Province Health Authority	Unknown	The Global Fund to Fight AIDS, TB and Malaria Round 9	International Development Research Centre; Canadian International Development Agency	United States' HRSA (Health Resources and Services Administration) funded Medical Education Partnership Initiative	Sowerby Foundation	Nigerian State Health Investment Project	United Kingdom's National Institute of Health Research
Research	Small study of family physician management of respiratory cases, not yet published	None	Pilot study in two health regions ³⁹	Cluster randomised trial ⁴⁰ A study of health worker satisfaction ⁴¹	Ministry of Health-led evaluation underway focussing on non-communicable disease care	Pragmatic randomised controlled trial ⁴² Process evaluation—study submitted for publication 2018	Pretraining and post-training evaluation	Implementation research planned to evaluate the integration of depression and non-communicable disease care
Impact on health system	Prompted an extensive respiratory health intervention for all levels of care	Unknown	Unknown	Unknown	Expansion of Botswana essential medicines list	Improved interprofessional collaboration and task sharing between nurses and doctors; Improved healthcare worker morale	Pilot showed some reduction in polypharmacy	Not yet implemented
Adoption by government	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
	State level	National level	Federal level		National level	Municipal level	Federal and state level	Federal level

Continued

Table 1 Continued

	Brazil (Minas Gerais)	Mexico	The Gambia	Malawi	Botswana	Brazil (Florianópolis)	Nigeria	Ethiopia
Current status	No longer active: project shelved by State Authority, reason unclear.	No longer widely active due to health system fragmentation: various authorities leading on different aspects of respiratory health, TB and primary care at both State and Federal level meant the absence of a unifying lead for the programme.	No longer active, reason unclear.	No longer active: political instability and funding constraints prevented further implementation and scale up.	Active	Active	Active—post pilot, embarking on scale-up	Active—starting country-wide implementation

Localising team availability was limited at times

Except in Brazil where the localising team lead was relieved of other responsibilities, members of the localising teams had to fit PACK between ongoing work commitments. The Ethiopia team addressed this by convening 2-week intensive localisation workshops for local clinical experts who then took time out from their usual responsibilities; the Nigeria team scheduled regular late-afternoon meetings after the work day was done.

Communication and language differences could be frustrating

Regular communication between the KTU mentors and localising teams in Nigeria and Ethiopia was often frustrated by poor internet and telephone connectivity. In Brazil, the language difference occasionally made communication difficult but was especially apparent in localising guide content where Brazilian Portuguese required more space than the English equivalent, necessitating careful editing.

Conveying the PACK principles was challenging

At times, localising teams lost sight of the PACK principles, attempting to add more content to the guide (overwhelming in both volume and layout) or speed up the delivery (which can undermine efforts to embed the programme into practice). Team visits helped to mitigate this, clarifying the principles when pages were workshopped together and localising teams experienced PACK in action during on-site training.

Funding was limited

PACK localisation is time intensive, requiring detailed attention from both teams. However, the costs of this work are often beyond government budgets, and local regulatory constraints make it difficult for governments to contract with and transfer funds to external organisations like the KTU and BMJ that do not have in-country operating entities. As a result, PACK localisations usually occur with minimal funding and extensive in-kind support from KTU, BMJ and localising partners. Thus, early implementation is slow and small, making it difficult to demonstrate the level of embeddedness in the health system and definitive positive outcomes to justify further roll-out. This is an experience not unique to PACK,⁶ but it has placed severe financial pressure on the soft-funded KTU.

Political instability was disruptive

Localisation and implementation were interrupted or slowed by country-wide political instability (Malawi, Brazil) and changes in health organisation structuring and leadership (Nigeria, Brazil, Ethiopia). This argues the case for acquiring both high level and on-the-ground buy-in for the programme that can then weather fluctuating political environments—demonstrated by PACK's survival in Florianópolis, Brazil.

LESSONS LEARNT

From our experience of supporting the localisation of PACK in a variety of LMIC settings, we have learnt lessons

Figure 2 Step-by-step mentorship of PACK programme localisation and initial implementation. PACK, Primary Approach of Care Kit; KTU, Knowledge Translation Unit; M&E, Monitoring and evaluation.

about both the localisation process and the mentorship of that process.

Mentorship is a good model for localisation

A mentorship approach to localisation appears to be a good and viable model. All three countries completed localisation successfully, Brazil and Nigeria have completed pilot implementation with plans for expansion and Ethiopia is set to embark on nationwide roll-out. Mentorship ensured quality assurance and adherence to the PACK principles. However, the process must be flexible, with each localisation adjusting the model as required: Brazil repackaged the modularised PACK training programme as ongoing sessions that focused on participant need, to expedite completion, Ethiopia conducted intensive localisation workshops rather than sticking to the PACK 4-month schedule and Nigeria is adding paediatric content in the Adult guide during its 2018 update.

Achieving stakeholder buy-in is key

To ensure successful localisation and then adoption of PACK, stakeholder buy-in has been key from the outset. Able clinicians in touch with on-the-ground realities but with the political capital to draw on relevant stakeholders

need to lead programme localisation and implementation. Family physicians, often leaders in primary care, are ideally placed to do so and in each localisation played an important role. In Nigeria, end-user testing led to buy-in from both end-users and managers, and early engagement with both policy makers and pilot facilities ensured PACK Nigeria's successful implementation in all but one pilot facilities.³⁴

Although both PAL³⁵ and mhGAP³⁶ implementation frameworks advise gaining high level government buy-in as a first step, in our experience, this has been difficult to achieve from the outset, and only once a pilot has showcased the programme and its potential has it generated national level interest.

Regard localisation as the first step of implementation

Shifting the perspective that localisation is a separate, preimplementation activity to one that is integral to implementation has both facilitated localisation and achieved stakeholder support. The Nigeria localisation saw the interrogation of policies, update of medicines lists, equipment and test availability and adjustments to scope of practice and referral pathways occurring in parallel with stakeholder engagement sessions, end-user

testing and facility readiness preparations which meant the guide was completed in time and its uptake enthusiastic in pilot states.

Apply mentorship learnings from one localisation to the next

Localisation prompted the development of setting-specific content for example, Chikungunya in Brazil, sickle cell anaemia in Nigeria. As these conditions are regional issues, we chose not to include them in the global guide and toolkit update but might draw on them if needed. However, some local changes were generic enough to be absorbed into the global update and then implemented in other localisations like tobacco cessation from Brazil and an expansion of palliative care guidance from Ethiopia, depicted in figure 3.

In addition to content innovations, there were instances where enhancements to the localisation process were then absorbed into the mentorship of other countries. Brazil introduced a project management app that has since supported each localisation and also identified the need to clearly explain the training approach, prompting expansion of the toolkit to include videos explaining the features and principles of the guide and training.

Team visits are necessary and useful

Face-to-face visits, while costly, have been vital to building KTU-localising team relationships. The visits provided the opportunity to workshop challenging localisation issues together and facilitated localising team participation in PACK training—experiencing the programme in action helped to adjust implementation plans and facilitated high fidelity to PACK principles.

FUTURE DEVELOPMENTS

Where next?

We have decided to focus initial PACK expansion efforts on large LMICs in different regions of the world. This might allow us to recoup some of the investment in upfront localisation and piloting through wider in-country applicability and see whether emerging similarities hold true across diverse environments. Ultimately, we envisage PACK regional technical support hubs—for example, the Brazil team supporting Latin American localisations, Nigeria supporting West African. We shall prioritise LMICs over high-income countries, although recognise the potential of PACK in that setting³⁷ given the need for cost reduction and inequalities in healthcare.

PACK continues to be spread with support from the KTU using an ever-evolving mentorship approach. The Peking University Family Medicine department has embarked on PACK localisation in China. Funding constraints and language barriers might limit mentorship, allowing us to examine successes and challenges of a relatively unsupported localisation and to enhance the PACK Localisation Manual and Toolkit.

PACK global movement

The PACK programme receives interest from leaders in both PACK-implementing and PACK-interested

PACK Global Adult 2017
The 'Life-limiting illness: routine palliative care' page guides the provision of palliative care and integrates with relevant symptom and chronic condition pages in the guide. The PACK Global Adult 2017 edition provided WHO-aligned guidance around the assessment and management of pain in the patient receiving palliative care, but that assessment was limited to the presence or absence of pain, and the management to first line.

'PACK Ethiopia' Ethiopian primary health care clinical guidelines 2017

The 'Life-limiting illness: routine palliative care' page guides the provision of palliative care and integrates with relevant symptom and chronic condition pages in the guide. The PACK Global Adult 2017 edition provided WHO-aligned guidance around the assessment and management of pain in the patient receiving palliative care, but that assessment was limited to the presence or absence of pain, and the management to first line.

PACK Global Adult 2018

The KTU Content Team, while updating PACK Global Adult 2017, reviewed the localised pages of each of the Ethiopia, Nigeria, Brazil PACK guides, and implemented improvements into the PACK Global Adult 2018 guide. The palliative care page has adopted the additions made in the Ethiopia revision, triangulating them with evidence sourced through Best Practice and WHO guidance, including WHO Essential Medicines List.

PACK Brasil Adulto 2018

The Brazil localising team adopted the expansion to the PACK palliative care content in their PACK Adulto 2018 update, consulting the PACK Global Evidence and Decision Support document for underlying evidence and aligning it to local policy, available medications and health worker scope of practice.

Figure 3 Applying learnings from one localisation to the next.

countries, global health leaders, academic institutions, technical advisory organisations and healthcare providers and funders. The KTU and BMJ are launching a “PACK Global Movement” of PACK implementers and advocates that share experiences from PACK implementations and collaborate on evaluation activities. The movement could also create the impetus to achieve ongoing funding to sustain global and in-country PACK activities.

Supporting in-country upscale and sustaining of PACK

In 2017, the KTU supported the update of the PACK guide and training materials in Brazil and is currently mentoring the update and upscale of the programme in Nigeria (see the timeline in [figure 1](#)). Future work will include finalising a manual, toolkit and mentorship package for the update, upscale and sustaining of the programme in-country.

Evaluation

This practice paper is a description of the PACK localisation experiences, not a formal evaluation of the PACK approach to spread. We plan to formally evaluate how best to localise PACK in an effective way that ultimately needs minimal external support. First, using key role-player interviews, we need to deepen our understanding of the localisation experiences thus far, whether through an independent, consultancy or mentorship model. Evaluations of future localisations could include qualitative comparative case studies and pragmatic trials to examine outcomes like quality of guide localisation, effectiveness of the implementation strategy, acceptability of the programme among policymakers and health workers, its scalability and sustainability, and ultimately impact on quality of care. We also need to develop and evaluate different approaches for maintenance and in-country scale up, as local programmes mature. Such evaluations would contribute to the literature on localising and disseminating health systems interventions to LMIC settings.

CONCLUSION

The PACK localisation experience, though still in its infancy, has thus far been successful in several LMICs. Crucial throughout has been balancing the PACK principles with a degree of local reinvention, addressing health system strengthening and involving local stakeholders. Ultimately, PACK has been championed by local clinicians with an understanding of and a strong vision for integrated primary care.

Using a mentorship model to support in-country localisation has been feasible within the limited resources of our team and allowed for the iterative improvement of both the model and the PACK programme from one localisation experience to the next—a learning health system³⁸ with global reach. The lessons that have emerged have helped to craft a viable model for taking

PACK to other countries that now requires formal evaluation to test for its effectiveness and reproducibility across borders. Such evaluations could also contribute to an understanding of how different models for spreading health systems innovations work.

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