

The value of process evaluation for public health interventions: field-case studies for non-communicable disease prevention and management in five countries

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Abstract

Complex interventions are needed to effectively tackle non-communicable diseases. However, complex interventions can contain a mix of effective and ineffective actions. Process evaluation (PE) in public health research is of great value as it could clarify the mechanisms and contextual factors associated with variation in the outcomes, better identify effective components, and inform adaptation of the intervention. The aim of this paper is to demonstrate the value of PE through five case studies that span the research cycle. The interventions include using digital health, salt reduction strategies, use of fixed dose combinations, and task shifting. Insights of the methods used, and the implications of the PE findings to the project, were discussed. PE of complex interventions can refute or confirm the hypothesized mechanisms of action, thereby enabling intervention refinement, and identifying

Resumen

Las intervenciones complejas son necesarias para abordar eficazmente las enfermedades no transmisibles. Sin embargo, las intervenciones complejas pueden contener una mezcla de acciones eficaces e ineficaces. La evaluación de procesos (EP) en la investigación en salud pública es de gran valor, ya que puede aclarar los mecanismos y factores del contexto asociados con la variación de los resultados, identificar mejor los componentes eficaces e informar sobre la adaptación de las intervenciones. El objetivo de este artículo es demostrar el valor de la EP a través de cinco estudios de caso que abarcan el ciclo de investigación. Las intervenciones incluyen el uso de la salud digital, las estrategias de reducción de sal, el uso de combinaciones de dosis fijas y la “delegación de funciones”. Se discuten las implicancias de los métodos utilizados y del uso de los resultados de la EP para el proyecto. La EP

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implementation strategies that can address local contextual needs, so as to improve service delivery and public health outcomes.

Keywords: implementation science; process assessment; noncommunicable diseases

de intervenciones complejas puede refutar o confirmar los mecanismos de acción hipotetizados, permitiendo así el perfeccionamiento de la intervención y la identificación de estrategias de implementación que puedan abordar las necesidades contextuales locales, a fin de mejorar la prestación de servicios y los resultados en salud pública.

Palabras clave: ciencia de la implementación; evaluación de procesos; enfermedades no transmisibles

Achieving Sustainable Development Goal target 3.4 of reducing premature mortality from non-communicable diseases (NCD), by one third in 2030, will require widescale implementation of effective interventions.¹ Interventions for NCD prevention and treatment may involve multiple components requiring implementation at different levels of the health system, and in other sectors beyond health.^{2,3} The so-called ‘best buys and other recommended interventions’ identified by the World Health Organisation (WHO) include a total of 88 interventions, grouped by four key NCD risk factors, and six main objectives.^{4,5} Diverse cost-effective NCD interventions and enabling strategies may be included in different programs, which makes understanding the effectiveness and scalability of NCD interventions challenging. While most randomised controlled trials are designed to evaluate whether an intervention is effective in relation to a primary outcome (*e.g.* blood pressure control) at a particular endpoint (*e.g.* at six months of intervention), the complexity of intervening for NCDs requires a broader evidence base. Process evaluations (PE) provide, we argue below, complementary, and essential information for evaluation of public health NCD interventions.

PE is a methodology in implementation science that seeks to understand “What happened on the ground? and/or What needs to be improved?”.⁶ PE provides an analysis of context, intervention implementation and end-users’ perspectives.^{5,7}

In this paper, a group of researchers (the authors of this paper), who have conducted PEs of NCD interventions in diverse country settings, present our experience of reflect on the value of PEs for public health interventions aiming to address NCDs. The objective of this paper is to provide an overview of the evolution of PE; a brief summary of relevant implementation theories and frameworks and five case studies of PEs of NCD interventions from diverse contexts –these were conducted in Peru, Mexico, India, China and Australia. In doing so, we hope to provide further insights about this

methodology and the unique implications of PE findings to the practice and policy.

Evolution of process evaluation

The concept of PE appeared in the 1960s and was first developed by Suchman, though it was not labelled as “process evaluation”.⁸ He mentioned “In the course of evaluating the success or failure of a program, a great deal can be learned about how and why a program works or does not work...an analysis of process can have both administrative and scientific significance, particularly where the evaluation indicates that a program is not working as expected”.^{8,9} Later, in the 1970s, the term ‘process evaluation’ and a definition was put forward by Green, Kreuter, Deeds, and Partridge: “In process evaluation, the object of interest is professional practice, and the standard of acceptability is appropriate practice”.^{9,10} In the mid-1980s, a key publication by Basch and colleagues¹¹ set the foundations for modern PE, highlighting its crucial role in ensuring avoidance of the type III error, specifically “evaluating a program that has not been adequately implemented”. In 2000 Baranowski and Stables defined PE as entailing information on components of recruitment, maintenance, context, resources, implementation, reach, barriers, exposure, initial use, continued use and contamination.^{9,12}

The UK Medical Research Council (MRC) guidance on complex interventions in 2000,¹³ updated in 2008,¹⁴ summarises previous definitions and scope of PEs. In 2015, Moore and colleagues published practical guidance for PE and an evaluation framework which included context, mechanisms of impact and implementation outcomes.⁷ Moore and colleagues highlighted that PE is to “be used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes”.¹⁴ While the importance of PEs is now accepted by funding bodies and researchers,¹⁵ the application of available guidance about how to conduct PEs is patchy.¹⁶

Which implementation science frameworks and theories can be applied in process evaluation?

Within the field of implementation science, theoretical frameworks, theories and models can help facilitate the description, explanation and systematic evaluation of program implementation.¹⁷ Nilsen and colleagues described theoretical approaches and organized them in: (i) process models to guide the process to translate research in practice; (ii) evaluation frameworks to evaluate implementation; and (iii) classic and implementation theories as well as determinant frameworks to describe or explain influences on implementation outcomes.^{17,18} Indeed, there are a range of theoretical approaches published and developed specifically for use in PE based on different contexts, settings and sectors.¹⁹ Table I²⁰⁻³⁸ summarises the advantages and disadvantages of some common approaches, with some illustrative examples.

How do we conduct PE? Illustrative field-case studies

Case studies and an overall synthesis developed from the authors' involvement in five PEs of NCD interventions in Latin America and the Asia Pacific region are provided below, with further details in table II.³⁹⁻⁴⁵ A short description of each PE, the methods used, and the implications of the findings are provided, followed by a synthesis of our learnings. These case studies span the research cycle -from pilot randomised controlled trial/cluster randomised controlled trial (RCT/cRCT) to post trial PE.

Case 1. Assessing the feasibility, acceptability, patient satisfaction, and recruitment strategies in two pilot studies of Conemo, a digital intervention addressing depression in people with comorbid hypertension and/or diabetes in Peru.

Process evaluation aims. To assess: (i) the feasibility of implementing Conemo within the public health system; (ii) the acceptability and satisfaction of patients with Conemo; and (iii) the recruitment strategies.

Methods of the PE. The pilot studies were implemented in 2015 and 2016, including 33 patients with hypertension and/or diabetes and clinically relevant depressive symptoms (Patient Health Questionnaire-9 [PHQ-9] score ≥ 10) attending public healthcare facilities. The first pilot included a hired nurse to support the patients, whereas the second worked with six nurses

from the public system. A mixed-methods approach was used, combining data captured automatically by the Conemo technology system to monitor patients and nurses' performances (e.g. completion of sessions), a baseline and follow-up surveys with patients (n=31), and semi-structured interviews with patients (n=29) and nurses (n=6). Detailed methods and results have been published elsewhere.^{46,47}

Implications of the methods. The use of a mixed-method approach, combining three data collection methods and gathering information at multiple time points, provided a rich and comprehensive data that was useful for identifying which intervention features should be maintained, and where improvements were required. A key challenge was that, after identifying potential improvements through the PE, there was too little time and resources allocated to optimally modify the intervention prior to the full trial.

Implications for the project. The results suggested that Conemo was potentially effective and well accepted by the patients, and that it was feasible to conduct an RCT with the recruitment strategies used. Based on patients' suggestions and experiences, the Conemo application was significantly improved, enriching its content, adding new features and activities to make it more tailored and interactive, including the addition of more videos and testimonies from patients. The training for the application was improved with enhanced instructions and a training video, and the installation of the app was simplified to make it easier and faster. The nurse dashboard, used to monitor their patients, was redesigned to make the nurses' work and the patients follow-up easier. Importantly, after the pilot studies, and considering the work overload of the health system professionals, three project nurses were hired to support 216 patients receiving Conemo in the RCT. The trial in Peru found a positive intervention effect⁴⁸ supporting the value of this mixed methods PE during the pilot phase.

Case 2. Assessing the feasibility and acceptability of AppSalt platform delivered in schools in China to reduce excessive salt intake to inform scale-up in EduSaltS.

Process evaluation aim. A nested PE was designed and conducted to analyze the implementation of the intervention in real-world settings and collect evidence to optimize the intervention design in EduSaltS program to promote the scaling-up of a school-based education program to reduce salt in China.

Table 1
THEORETICAL APPROACHES, THEIR ADVANTAGES AND DISADVANTAGES AND ILLUSTRATIVE EXAMPLES

Theoretical approach	Key components	Advantages and disadvantages	Example
MRC Framework ² -Evaluation Framework	A framework for designing and conducting process evaluation of complex interventions. According to this framework, process evaluations should answer questions related to three components: implementation (what is delivered and how?); Mechanisms of impact (how does the delivered intervention produce change?) and Context (how does context affect implementation and outcomes?). Along with the context and the mechanism of impact, it emphasises the need to spell out the key causal assumptions or the programme theory.	Advantage: Widely used since the publication of its guidance, it could be adapted to different types of studies, and it is simple to apply. Disadvantage: It is not specific about how to evaluate implementation outcomes, the mechanisms of impact and context.	A study that implement a national salt reduction intervention in Fiji conducted a PE to measure fidelity, reach, context and costs. The authors mentioned that the "The process evaluation approach was informed by the Medical Research Council (MRC) framework and guided for process evaluations of complex interventions supplemented by a review of process evaluations of similar nutrition related interventions." ²⁰
Realist Evaluation ²¹ -Evaluation Framework	Realist evaluation provides focuses on testing the programme theory and answering 'What works for whom in what circumstances and in what respects, and how?'. Key components in realist evaluation are the context (C), the mechanism(M) and the outcome (O).	Advantage: Evaluate specific aspects of implementation to determine its success. Disadvantage: It could introduce self-report bias as well as the need of making inferences about unobservable mechanisms of intervention effect.	The PE of the RCT Consumer Navigation of Electronic Cardiovascular Tools (Connect) conducted in Sydney, Australia. ²² The interview guide was designed using the Realist Evaluation framework to explore the hypothesised impact of various intervention features from the intervention experiences. In the analysis, they looked for narratives of different configurations of C-M-O considering the different experiences of the interviewees.
Normalization Process Theory ²³ -Implementation Theory	A theory which focuses on how complex interventions become 'normalised' or embedded in routine practice. It helps to understand facilitators and barriers in adoption and routinisation of an intervention. Includes four main components: coherence (sense making), cognitive participation (engagement), collective action (work done for intervention to happen), and reflexive monitoring (taking measure of costs and benefits of the intervention).	Advantage: Provide a valuable set of conceptual tools for understanding aspects of implementation as a dynamic process. It is a theory used and applied in diverse studies. Disadvantage: Poor emphasis in the context; too much focus in those that delivered the intervention and not in those who received it. There is some overlapped between constructs and the technical vocabulary of the theory is difficult. ²⁴	The Stepping Up project is a pilot study that develop a model for insulin initiation in routine practice in Australia. The Normalization process theory was used to develop the model of care as well as the process evaluation. ²⁵
Theoretical Domains Framework (TDF) ²⁶ -Determinant Framework	TDF is an overarching framework of behaviour change. It is useful in identifying key determinants of behaviour change and designing appropriate behaviour change interventions. TDF has grouped constructs from 33 behaviour change theories into 12 domains. A few of these domains are Knowledge, Skills, Motivation & goals, etc.	Advantage: Provide a robust theoretical basis for implementation studies with good coverage of barriers and facilitators. It could be used with a qualitative and qualitative approach. Disadvantage: The analysis is complex due to the number of domains and certain overlapped between them. The analysis team needs to be well trained. ²⁶	A study conducted in China examined barriers and enablers to the delivery of psychological care to patients with Type 2 diabetes from the perspective of Community Health Centre doctors. Two focus groups were conducted with physicians and the discussion guide applied the Theoretical Domains Framework (TDF) to explore current practice and identifies key barriers and enablers perceived to influence practice. ²⁷
Consolidated Framework for Implementation Research (CFIR) ²⁸ -Determinant Framework	A comprehensive framework that can be used for design and evaluation of interventions. It provides both individual and organisational level constructs that can help explain factors which influence implementation. The five CFIR domains under which constructs are grouped are- Intervention, Outer Setting, Inner Setting, Individual and Process.	Advantage: It has been widely used across a range of studies. There is guidance about how to select, operationalize, measure, and report findings of CFIR. ²⁹ Disadvantage: Some challenges distinguishing between related constructs. It has been reported lack of consideration of the CFIR for scale-up, spread and sustainability. ³⁰	This study was conducted in Mexico and evaluated the implementation of clinical practice guidelines (CPG) in the public health system. A semi-structured interview guide was designed to obtain information on barriers and facilitators to implement the diabetes mellitus CPG based on the CFIR and was applied to the components of the CPG program. ³¹
PRECEDE-PROCEED ^{32,33} -Evaluation Framework	PRECEDE-PROCEED is a model that is useful for planning and evaluation of health promotion related interventions. PRECEDE stands for Predisposing, Reinforcing, and Enabling Constructs in Educational/ environmental Diagnosis and Evaluation; and PROCEED stands for Policy, Regulatory and Organizational Constructs in Educational and Environmental Development. The model focuses on both individual as well as environmental-level factors, for design and evaluation of health promotion interventions.	Advantage: As other frameworks, it specifies aspects that could be evaluated to determine implementation success. Help to improve the understanding of the relationship between variables. Also, it is a good framework for health intervention programs in screening contexts. ³⁴ Disadvantage: The disadvantage of the PRECEDE-PROCEED is that it gives precise instructions to follow that may not be viable in certain contexts.	This study was conducted in Thailand to evaluate the feasibility and potential efficacy of a program for improving glycaemic control and self-management among people with diabetes. The program included an open-source telecommunications programming language for weekly interactive voice response messages lasting 5-10 minutes each during 12 weeks. The PRECEDE-PROCEED model guided the intervention development and the selection of measures. ³⁵
RE-AIM ³⁶ -Evaluation Framework	A framework which provides five key dimensions or constructs that can be used to evaluate health interventions. These constructs include Reach, Effectiveness, Adoption, Implementation and Maintenance.	Advantage: Use mostly in physical activity, obesity and disease management. The constructs follow a logical sequence. RE-AIM has evolved since 1999. ³⁷ Disadvantages: When researchers applied the framework, the definitions of reach and adoption are confused. Poor emphasis in contextual factors.	A process evaluation of the Attend Trial (family led rehabilitation trial after stroke trial in India) was conducted. Family carer were trained by physiotherapist to deliver a rehabilitation. The project used the RE-AIM framework with the objective of address questions of generalizability and translation into practice. ³⁸

Table II
FURTHER DETAILS ABOUT FIELD-STUDY CASES

Study project	Country and setting	Background	Study design and type of intervention	Trial outcome	Results of the PE	Challenges of the PE
Conemo	Peru, two PHCs and one hospital	The Latin America Treatment & Innovation Network in Mental Health (LATIN-MH) was a six-year research project to reduce the treatment gap for people with comorbid mental and chronic physical diseases. LATIN-MH included RCTs in Peru (NCT03026426) and Brazil (NCT02846662) to assess the effectiveness of Conemo.	Pilot studies in preparation to the RCT were conducted. Conemo, a six-week digital intervention aimed at reducing depressive symptoms among people with comorbid hypertension and/or diabetes.	Conemo intervention was accepted by the participants and it was feasible to conduct an RCT.	Almost 8% of patients approached during recruitment were included. At follow-up, 81.3% (13/16) and 70.6% (12/17) of the patients from the first and second pilot, respectively, had PHQ scores below 10, referring to no or mild symptoms of depression. Most patients perceived improvements in their mental health because of Conemo, whereas many also reported better physical health. Patients' satisfaction with and adherence to the intervention were very high according to all data sources. The application was considered easy to use, and the nurses' support was positively valued. The interviews also revealed that some patients had difficulties with the application but resolved them with practice. Patients suggested improvements in the training, more regular contact with nurses and more videos. Most nurses reported difficulties in completing their tasks, explaining that the intervention competed with their routines within the public system.	Time and resource constraints to translate all the potential improvements identified in the pilot studies into the intervention to be tested in the trial. The intervention components were significantly improved based on the pilots' findings.
AppSalt	China, primary schools	Reducing salt intake is one of the best-buys to control the growing burden of NCDs. A mHealth-based salt reduction platform, named AppSalt, was developed and tested in a RCT at three cities in China. ³⁹	cRCT, Multi-component salt reduction program delivered through a smartphone application.	Not reported yet.	The total number of families recruited for the intervention was 1 124. During the program, 34 students dropped out which resulted in a retention rate of 97%. The intervention was implemented to a high level of fidelity against the protocol. The adherence to intervention activities was high at most intervention schools. About 80% of participants completed all nine sessions of online salt reduction courses, with a significant difference across the three study sites (Shijiazhuang 95%, Luzhou: 73%, Yueyang: 64%). The smartphone app in this program was perceived as a feasible and engaging health education tool by 75% of the interviewed parents. However, some students and parents suggested that the education materials (videos, posters, leaflets, etc.) could be improved and be more attractive. Through the interviews with participants and key stakeholders, some barriers were identified to implement this program at primary schools, including the left-behind children who usually live with their grandparents and have limited access of smartphones; perceived adverse effects of smartphones on children (e.g. eyesight damage), and the overlooked health education at Chinese primary schools.	Time and resource constraining.
Meta Salud Diabetes (MSD)	Mexico, PHCs operated by the Ministry of Health	The primary aim of this research project was a cluster-randomized controlled trial to assess the effectiveness of Meta Salud Diabetes (MSD), a community health worker intervention aimed at reducing behavioural and clinical risk for cardiovascular disease among adults with type 2 diabetes mellitus (T2DM). ⁴⁰	cRCT, a community health worker intervention aimed at reducing behavioural and clinical risk for cardiovascular disease among adults with T2DM.	The intervention reduced CVD risk and improved emotional wellbeing.	The RCT showed a reduction of CVD risk among intervention groups as measured by the Framingham Risk Score and improvement of emotional wellbeing as measured by the Diabetes Distress Scale. ⁴¹ PE identified four contextual factors relevant to adoption and sustainability: institutional support, staff capacity, clinical resources, and program monitoring. ⁴² GAM facilitators were generally able to understand and implement MSD successfully with adequate training. They recognized the benefit of the intervention but indicated the constraints to maintaining depended on institutional factors related to their workload and the fact that MSD implementation competed with other health center demands, as well as lack of training and recognition of the work being done in the GAM and current (limited) requirements for GAM accreditation.	Time- and resource-consuming. Lack of mechanisms for translating PE recommendations into policy.

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Polypill	Australia, primary care including private general practices, and Indigenous Health Services	Kanyini- Guidelines Adherence with the polypill study, was a pragmatic RCT evaluating a polypill-based strategy for high-risk primary and secondary cardiovascular disease prevention. It was part of the SPACE collaboration of independent and publicly funded trials, using similar formulations conducted elsewhere in India, New Zealand, United Kingdom, Ireland and the Netherlands.	Pragmatic RCT, evaluating a polypill-based strategy for high-risk primary and secondary cardiovascular disease prevention.	Significant greater use of combination indicated treatment as compared to usual care without significant differences in systolic blood pressure or total cholesterol.	Cost saving, easiness and convenience of a daily-dosing pill seemed to be the underlying mechanism for patient acceptability. Given the high cardiovascular disease burden in Indigenous populations, the polypill strategy was perceived to be a beneficial addition to the Indigenous Health Services model of care. The inflexibility of the fixed-dose regimen, with inadequate dosages for patients with complex management needs, was perceived as a critical barrier. Suggestions for different polypill formulations with varied strengths and classes of medications may overcome this barrier. Many providers suggested the polypill strategy in its current formulations, might be more suited to high-risk primary prevention patients. ⁴³ Key trial implementation issues such as research governance by the Aboriginal community-controlled health services, ⁴⁴ the need to streamline trial processes in pragmatic trials, and balancing intensive service delivery requirements with demanding trial-related procedures were identified. ⁴⁵	It is very resource and time intensive. We had to apply for a separate grant for the process evaluation. We found barriers to trial implementation late in the study that could potentially have been addressed earlier if the PE was conducted prospectively. By not articulating the theory of change or logic mode earlier, we had to gather data sources post hoc which was time consuming.
SMARTHealth	India, 18 rural PHCs	SMARTHealth India was a cRCT conducted over a period of two years in 18 Primary Health Care Centers (PHC) clusters in West Godavari District in rural Andhra Pradesh, India. Prior to the trial, a mixed-methods pilot study found that the intervention was feasible to implement in the health system, and acceptable.	cRCT, a multi-faceted intervention involving capacity strengthening of PHC doctors and Accredited Social Health Activists (ASHAs) through use of a mobile device based clinical decision support system in people at high CVD risk.	The main trial results found overall improvements in BP control in both the intervention and control trial periods, and an overall null intervention effect.	There was substantial cluster-level variation in local context, implementation (particularly follow up by PHC doctors), and trial outcomes. There were 9/18 clusters showing positive intervention effects on the primary outcome, with 8 of these also showing positive intervention effects on one or more secondary outcomes. ASHA's screened over 85% of the target population for CVD risk in all clusters but follow up of those at high CVD risk by PHC facility doctors varied (range 48-89%). Community trust and acceptability rate of ASHA's new roles were generally high, and enabled in different contexts by their working with different higher-level providers (not just the PHC facility), and taking on non-remunerated tasks in response to community needs. Developing awareness of risk (so that people identified as at high CVD risk) would be motivated to attend the PHC for follow up care was enabled by ASHA's prior experience and knowledge, and connections with local services. ASHA's referred those at high risk to different local services, influenced by availability of BP control medications, and community perceptions of local services, and trust in them. A range of local health providers outside of the government PHC system became engaged in follow up care for CVD risk.	PE generates and draws on substantial data. These data need to be stored in a way they can be easily and accurately retrieved – that will help efficiency. There needs to be adequate resourcing for analysis of the data at different time points in the study- time take to analysis qualitative data in particular.

ASHAs: Accredited Social Activists, BP: Blood pressure, CVD: Cardiovascular Disease, RCT: randomised controlled trial, cRCT: Cluster randomised controlled trial, PE: Process Evaluation, PHCs: Primary Healthcare Centres, T2DM: Type 2 diabetes mellitus

Methods of the PE. Informed by the framework proposed by Linnan and Steckler,⁴⁹ the PE evaluated five dimensions: fidelity, dose delivered, dose received, reach, and contextual factors. A mixed-method approach was adopted, with quantitative data and qualitative data collected sequentially. Quantitative data were collected during the intervention process, which included routinely collected monitoring data, app usage metrics and activity logs. Qualitative data were collected in one-on-one semi-structured interviews with purposively selected students (n=33), adult family members (n=33), teachers (n=9), heads of schools (n=9), and key informants from local health and education departments (n=8). The overall participation rate and intervention activities were calculated and compared across study sites. The data were analysed thematically using Nvivo 12. Quantitative data and qualitative data were integrated during the process of data analysis and interpretation.

Implications of the methods. The PE framework by Linnan and Steckler was found to be practical and fit for purpose. The framework emphasises participants' interactions with intervention strategies, with less emphasis on the broader setting which could influence the implementation and scaling up. In the future, this PE framework will be combined with the MRC framework or RE-AIM framework to guide the PE of EduSaltS program.

Implications for the project. The PE demonstrated the feasibility and acceptability of using smartphone applications in the education system to engage families in China to reduce excessive salt intake. It also identified potential barriers to scale up that will be accommodated in future scale-up of EduSaltS program to other provinces in China, including accommodating more flexibility in the intervention design for various socioeconomic settings. For example, a combination of online and offline salt reduction intervention package will be designed in the EduSaltS program, allowing policy makers to choose suitable intervention activities according to their local context. In addition, based on suggestions from end-users, cartoon style characters will be used in the intervention materials to improve its attractiveness to the target populations.

Case 3. Using Normalization Process Theory in an implementation study evaluating the sustainability and potential scale-up of Meta Salud Diabetes alongside a cluster-randomized controlled trial in Mexico.

Process evaluation aim. To evaluate sustainability and potential scale-up of the intervention, including a continuous PE to understand the barriers and facilitators

to implementing Meta Salud Diabetes (MSD) under existing conditions within the Mexican health system.⁵⁰

Methods of the PE. MSD was implemented in 12 health centers operated by the Ministry of Health in the Mexican state of Sonora. Existing health center staff in charge of facilitating Grupos de Ayuda Mutua (GAM)—support groups for patients with chronic diseases—were trained in the MSD curriculum and enrolled at least 20 participants with Type 2 Diabetes Mellitus into the 13-week intervention. Risk factors for cardiovascular disease were assessed at baseline, three months (immediately after the intervention) and at 12 months. Outcomes in the participants from the intervention group were compared to those in control group, drawn from 10 health centers. Extensive qualitative data were collected and analyzed using Normalization Process Theory (NPT). Data sources included MSD session observation at the intervention sites to assess fidelity; stakeholder meetings (n=34) to engage health center leadership and staff and feedback meetings with facilitators after MSD implementation. Further data were collected from four successful intervention sites to develop case studies of these sites. Further, in-depth interviews were conducted with federal and state health officials (n=16) to explore barriers and facilitators to scale-up.

Implications of the methods and for the project. While the trial showed positive intervention effects, the PE revealed considerable barriers to wider-scale implementation. Qualitative data analysis using NPT as a framework was instrumental in allowing researchers and health system partners to identify pertinent policy recommendations for both the local and national level. These included recommendations for adapting MSD to different contexts and prioritizing continuous training in health promotion for primary-level health centre staff. NPT was useful and relatively straightforward to apply for researchers with a social science and public health background, but may be difficult to use by health center staff during future scale-up; other, more accessible and less time-consuming PE tools would be needed for this purpose.

Case 4. Using a Realist lens to understand health providers' and patients' perspectives of the fixed-dose combination polypill, and pragmatic trial implementation in primary health care in Australia.

Process evaluation aim. To explore health provider and patient attitudes toward the use of a cardiovascular polypill, and barriers and facilitators to trial implementation.⁴³

Methods of the PE. For the PE of Kanyini GAP; in-depth, semi-structured interviews (n=94) were conducted with patients and health providers from the Australian primary care system, including private general practices and Indigenous Health Services. The interviews explored acceptability of polypill strategy, factors impacting adherence to medication, and pragmatic trial implementation at these primary care facilities, most of which had had very limited prior engagement in research studies. The data were analysed thematically, drawing on a realist lens to identify context, mechanisms and outcomes of the intervention.

Implications of the methods. The PE was highly resource- and time-intensive. A maximum purposive sampling frame was used that resulted in a large sample for face-to-face individual interviews, across three states in Australia. This would not have been feasible if not for the success of a supplementary grant funding application. Two trained qualitative researchers conducted inductive and deductive analysis to map out the relationships across emerging codes. The realist lens was helpful in drawing together all the disparate codes meaningfully across the individual, organisational and policy level contexts, and to unpack for whom, how, why and in what contexts, the polypill worked.

Implications for the project. The PE was useful in guiding next steps for the intervention in the following ways. First, it informed the next National Health and Medical Research Council funded pragmatic RCT's use of multiple polypill versions to address high risk patients, and was supplemented by a pharmacist intervention targeting patient knowledge, attitudes and behaviour towards their CVD medications.⁵¹ Second, lessons learnt about trial implementation, such as staff difficulties in balancing service delivery with research in the polypill trial, especially at busy Indigenous health services, provided useful recommendations for future trials.^{44,45} Third, the PE findings of the polypill's acceptability, and limitations were reported in the application for inclusion of the polypill in WHO's essential medicines list, which informs countries' procurement of medicines.⁵²

Case 5. Using the RE-AIM framework and Realist lens to understand the mechanisms resulting in variation of outcomes in a cluster RCT of SMARTHealth, a digitally enabled primary health care strengthening intervention in India.

Process evaluation aim. By examining how implementation and outcomes differed across the clusters, this PE aimed to identify how local context influenced trial outcomes.

Methods of the PE. The researchers conducted a cluster-level analysis of the trial monitoring and outcome data. This included, for each trial cluster, percent of the target population screened for cardiovascular risk by Accredited Social Health Activists (ASHA), percent high risk followed up by ASHAs and doctors, and proportions of the target population taking indicated blood pressure medications, adopting guideline-indicated lifestyle changes, and with target levels of blood pressure control. Guided by the RE-AIM framework for evaluating public health interventions, trained interviewers conducted focus groups with ASHAs (n=14) and interviews with primary health care facility doctors and ASHAs (n=12), and post-hoc interviews with field team managers to test emerging themes. Drawing on principles of realist evaluation, the researchers developed explanations for how local contextual factors may have influenced trial outcomes.

Implications of the methods. There are many different aspects of context that may influence the effectiveness of interventions in local primary health care systems. The RE-AIM framework while helpful in many respects, does not strongly emphasise contextual factors. In future PEs, more systematic data collection about how the intervention interacts with local contextual factors would be useful. For example, in this PE, it would have been helpful to explore with more depth and rigour what local resources community members used following ASHA screening, and with what effects. Also, some important issues only emerged during implementation of the trial. PEs need to aim to adapt to emerging findings and issues, and include flexibility in applying methods. The post-hoc interviews with field team managers, elicited their insights into explanations for observed outcomes, and was an effective and useful way to expand the scope of data available for the study. This had not been part of the original design.

Implications for the project. The finding of wide variation in trial outcomes supports calls made by others for more emphasis and publication about consistency of effects that can help interpret trial results. By exploring how the intervention achieved its effects in different local contexts, strategies were identified to enhance effectiveness of similar interventions in various local contexts. These are relevant for scale-up of Digital Health Interventions into primary health care systems in India and beyond. The trial PE findings underscored the importance of earlier intervention modifications (addressing barriers in medication supply and support to Primary Healthcare Centre doctors to conduct village visits), but also identified where and how wider aspects of the local context

outside the government service sector (such as trust in services, quality of care received by other providers) were important local influences on trial outcomes.

Discussion

Looking across the case studies, we have illustrated how PE can be applied meaningfully across the research cycle, enabling us to better understand for whom, how and why the interventions were implemented in the field; which is of great value to public health interventions. Process evaluation findings could help to improve intervention design and its future implementation within local health system structures. The diversity of methodologies applied show that there is flexibility in how PE can be conducted, but that fundamentally it involves a better understanding of contextual factors, the mechanisms influencing feasibility, adoption and acceptability of the intervention, and ways to evaluate implementation fidelity to account for type III error.

The described field cases have two common characteristics: involvement of stakeholders, and the use of a theory driven evaluation based on intervention theory. During evaluation of health system interventions, interviews should be conducted not only with study participants and health providers but also with health authorities, community members and decision-makers. This stakeholder involvement is crucial, as the sustainability and scale-up of the interventions rely on buy-in from different stakeholders and provision of resources. Being clear about the underlying theory of how the intervention works, can be a useful way to co-design with stakeholders in developing an appropriate intervention; identify feasible implementation strategies, and unpack outcome variations within the local context to improve the intervention. Indeed a theory-driven evaluation aligns with current MRC guidance as it enables a systematic and comprehensive evaluation. However, even while the use of theories or frameworks for PE is relevant and encouraged, the wide array of frameworks available and their diversity, presents a challenge to researchers to select the most appropriate for their PE, and to operationalising them. Some advantages and disadvantages have been identified, and at times (table II) it may be helpful to use more than one framework and/or theory at different stages of the PE, or to help unpack different types of outcomes and their influences.

Through the use of PE, in collaboration with stakeholders, researchers can identify strategies to overcome implementation barriers in real time, and optimise trial implementation. For instance, identifying health system and staff characteristics that are needed to facilitate intervention implementation or what health system

building blocks are needed to improve the intervention impact (*e.g.*, Conemo: limited human resources available; SMARTHealth: low availability of medicines; EDUSalt: health education curriculum; MSD: continuous training).

Importantly, regardless of the trial outcomes, PE provides a much-needed understanding to refute or confirm the hypothesized mechanism of action of the complex intervention. Ideally this can be done at the pilot/feasibility phase during which the intervention design can be optimised. It can also be done post hoc, as seen in Polypill and SMARTHealth case studies.^{44,53}

However, in our experience, PE can be time- and resource-consuming, and often gets relegated in priority and resource and personnel allocation; when researchers, and funders prioritize quantitative findings that are more easily published in high impact journals. Additionally, the research team should carefully consider what staff (additional researchers or existing health staff) could help in the data collection and allocate sufficient resources for training. For example, in Mexico, without well-documented PE data, it is difficult to engage public policymakers and other key partners involved in intervention scale-up. Furthermore, PE must be continued during scale-up to help enable successful implementation in different settings. This points to the need for accessible yet effective PE tools. Secondly, to be efficient, with PEs embedded early in the research cycle, we should be clear of core questions and ensure that the data collection is meaningful and targeted. This includes prospectively collected process data with streamlined project management tools. Thereby, reinforcing the benefit of having a clear theory-driven evaluation framework and data sources identified a-priori, iterative analysis, and with sufficient flexibility in collecting new data if required.

Research projects will often need to make changes based on PE results in real-time or for future practice. This is not always easy to do in an RCT, given current funding incentives and requirements. As illustrated by the field cases provided in this paper, PE can be useful to inform adaptation of interventions prior to trials, for guiding transferability of interventions at local, national and global levels, improving the features of e-health components, and identifying barriers to wider-scale implementation.

Conclusions

PE goes beyond p-values and aids interpretation of overall trial results. It helps to identify both positive and negative (unintended) outcomes, for whom, and why interventions are effective. It also provides the basis for

identifying what needs to change or to be refined to enable more effective implementation.⁹ As shown in this paper, PE has evolved in the last decades, and further development is needed. The field cases presented here showed the value of embedding PE across the research cycle, as well as the diversity of methods and approaches to collect and analyze data. Insights related to implications of the methods used and for the project, as well as insights of the theories and frameworks can be used by other researchers to promote and improve PE methodology, and contribute significantly to implementation science with a long-term vision of improving population health and reducing premature mortality from NCD by a third in 2030.

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