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Implementing "from here to there": A case study of conceptual and practical challenges in implementation science

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ABSTRACT

There is a significant challenge in global health and development research that pivots on the difficulties of delivering (cost-)effective treatments or interventions that are scalable *and*transferable across settings. That is, how does one deliver "true effects", proven treatments, into new settings? This is often addressed in pragmatic trials or implementation research in which one makes adjustments to the delivery of the treatment to ensure that it works *here* and *there.* In this critical analytical review, we argue that the approach mis-characterises the cause-effect relationship and fails to recognise the local, highly contextual nature of what it means to say an intervention "works". We use an ongoing randomised controlled trial (RCT)—an informal settlement redevelopment intervention in Indonesia and Fiji to reduce human exposure to pathogenic faecal contamination—as a vehicle for exploring the ideas and implications of identifying interventions that work in global health and development. We describe the highly contextualised features of the research and the challenges these would pose in attempts to generalise the results. In other words, we detail that which is frequently elided from most RCTs. As our critical lens, we us the work of American philosopher, Nancy Cartwright, who argued that research produces *dappled* regions of causal insights—lacunae against a backdrop of causal ignorance. Rather than learn about a relationship between a treatment and an outcome, we learn that in the right sort of context, a treatment reliably produces a particular outcome. Moving a treatment from *here* to *there* becomes, therefore, something of an engineering exercise to ensure the right factors (or "shields") are in place so the cause-effect is manifest. As a consequence, one cannot assume that comparative effectiveness or cost-effectiveness would be maintained.

1. Background

"Universal law is for lackeys. Context is for Kings." Gabriel Lorca, *Star Trek: Discovery*, S01E03 (Goldsman, 2017).

There is a significant challenge in global health and development (GHD) research that pivots on the difficulties of delivering effective (and cost-effective) treatments or interventions that are scalable *and* transferable across settings. The prevailing approach characterises this challenge as one of implementation. Based on the research, the intervention that works is identified; once identified, the objective is to scale up the delivery and get the intervention to work everywhere (Peters et al., 2013b). The processes of moving a successful intervention from "here" to a plurality of "theres" relies on implementation research to understand the contextual factors in different settings that might prevent the known, effective treatment from working everywhere.

We argue, however, that the problem of moving working interventions into new settings lies, in part, in a mis-characterisation of the cause-effect relationship. When we say, "the intervention works", we are beguiled by the notion of single causes. We do not look beyond the

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intervention in question to larger features of the "here" in which the intervention works, which themselves contribute to success. In failing to appreciate the complete relationship between the intervention and an array of contextual factors, we oversimplify the nature of "working". The failure to consider the complexity of this relationship results in limited understanding and unrealistic expectations of the implementation of interventions in population-based programmes in GHD.

In the following sections, we present a theoretical review of critical ideas about the nature of cause-effect relationships, their identification and generalisation. In particular, we use Cartwright's argument about local causation to think about GHD interventions' effectiveness (Cartwright, 2007a). We then illustrate the bindings of context and cause in a case study of an on-going randomised controlled trial to reduce enteric parthenogenesis in children (Brown et al., 2018; French et al., 2021; Leder et al., 2021). We conclude with a discussion of the implications of local causation for designing interventions in GHD, the value of fully describing the context of the interventions, and what this might mean for implementation research and the wider generalisation of results.

1.1. Rethinking causation in trials

The randomised controlled trial (RCT) is the gold standard method for determining cause-effect relationships in the biomedical and clinical sciences and increasingly in the field of GHD (Burns et al., 2011; Banerjee and Duflo, 2012; Deaton and Cartwright, 2018; Athey and Imbens, 2017; Duflo and Banerjee, 2017). The RCT was the linchpin technology, for instance, underlying the 2019 Nobel prize for economics on the "experimental approach to alleviating global poverty" (Burtless, 2019; The Sveriges Riksbank Prize in Economic Sciences, 2019). Other experimental, quasi-experimental and observational methods have also evolved so that, given certain assumptions, they allow for inferences about the relationship between a cause and an effect (Attanasio and Cavatorta, 2017; Cousens et al., 2011; Freedman, 2006).

There is no question that a well-conducted RCT has good internal validity—that is, it gives rise to valid inferences about the cause of observed differences between groups within an experiment (Shadish et al., 2015). Unfortunately, good internal validity does not warrant good external validity. There have been spectacular failures in trying to generalise experimental results from an original trial into new settings (Allotey et al., 2008), many examples of which are described in the literature (Banerjee et al., 2017; Deaton and Cartwright, 2018; Deaton, 2009; Pritchett and Sandefur, 2014). One such example comes from the World Bank's integrated nutritional program (INP), implemented in Tamil Nadu, India and Bangladesh (Cartwright and Hardie, 2012, p.3). The INP in Tamil Nadu showed remarkable success in improving height and weight outcomes in children under the age of five. The Bangladesh INP, modelled on the Tamil Nadu program, showed no such success (Hossain et al., 2005; White, 2005). While mothers in the intervention areas in Bangladesh demonstrated improved knowledge and reported changed behaviour, nutritional outcomes in children did not improve. Indeed, food supplements were not reaching children, but rather were shared with other children or treated as replacement feeding, thus zeroing the effect of the program on child outcomes (White, 2005).

Generalisation of experimental results is more complicated than simply establishing whether a treatment that works *here* (the original study setting) will also work *there* (a new setting in which the successful intervention is to be located). Generalisation in GHD research is as much about the *truth* of a cause-effect relationship as it is about the relevance of the intervention in a new context. Complicating the simple "does it work?" question, policymakers are often also concerned with the comparative effectiveness of a treatment (i.e., is treatment $\mathbf{T_A}$ *better* than some alternative treatment $\mathbf{T_B}$, and how much better?), its total cost (i.e., can we afford to implement treatment $\mathbf{T_A}$, given available resources?), and its comparative cost effectiveness (i.e., is the incremental benefit of $\mathbf{T_A}$ given the unit cost of $\mathbf{T_A}$ greater than the incremental benefit of $\mathbf{T_B}$ given the unit cost of $\mathbf{T_B}$?).

Unfortunately, one can readily identify reversals in the hierarchy of effectiveness of treatments as they are translated from setting to setting. In one setting $\mathbf{T_A} > \mathbf{T_B}$ while in another setting, the reverse may be true: $\mathbf{T_B} > \mathbf{T_A}$. Even when the hierarchy of effectiveness remains constant across settings (i.e., $\mathbf{T_A}$ is always more effective than $\mathbf{T_B}$), cost-effectiveness can vary with changes in the cost of implementation, and under some circumstances, the hierarchy may even reverse. For example, if the cost of $\mathbf{T_A}$ is far greater *there* than it is *here*, whereas the cost of $\mathbf{T_B}$ remains constant, then in terms of cost-effectiveness, $\mathbf{T_A} > \mathbf{T_B}$ *here* and $\mathbf{T_B} > \mathbf{T_A}$ *there*.

1.2. The boundaries of effect: nomological machines

The American philosopher, Nancy Cartwright, writes about how evidence from RCTs can be generalised (Cartwright, 2007b, 2011; Cartwright and Hardie, 2012; Deaton and Cartwright, 2018). One of her key messages is that an RCT may tell us whether treatment $\mathbf{T_A}$ *caused outcome* **O** (i.e., whether treatment $\mathbf{T_A}$ "worked") but the insight does not generalise beyond the confines of the trial (i.e., *here*). In particular, our belief that $\mathbf{T_A}$ worked should be limited to the conditions that operated during the trial. In other words, the cause-effect relationship is contextually bound. Thus, a well-conducted RCT allows for strong claims to be made about cause-effect relationships within the constraints that operated during the experiment. However, the more certain one might be about the cause-effect relationship within one setting (i.e., the more tightly controlled the experiment), the less certain one can be about generalising the results to new settings.

These ideas about the challenges of generalisation are not new and are the subject of many introductory courses on experimental design in the health and social sciences. However, Cartwright goes further and argues that lawful, universal causal relationships are rare or non-existent and that the hunt for such causes is something of a fool's errand (Cartwright, 2007a). We should not expect to be able to generalise the findings of an experiment without considerable additional data. Our science, she suggests, is one of *dappled* regions of causal insights (Cartwright, 1999). She explains this notion with reference to "nomological machines" or "nomological engines" which are:

> "a fixed (enough) arrangement of components, or factors … that in the right sort of … environment will, with repeated operation, give rise to the kind of regular behavior that we represent in our scientific laws (Cartwright, 1999, p. 50)."

Scientific laws are, thus, statements about relationships within nomological machines. The idea that a particular cause-effect relationship does not exist everywhere but only within an appropriately arranged and bounded system may seem counter to experience. The claim is at odds, for instance, with an apparent abundance of readily observable, every day, lawful, cause-effect relationships. The causal laws of physics seem to offer a multitude of counterexamples to Cartwright's dappled world. Computers in a mobile phone work in the same way in Swaziland as they do in Switzerland. In the words of Ian Hacking, however, one must remember that "most of the phenomena of modern physics are manufactured" (Hacking, 1983, pp. 227–8). They are not "in the world" waiting to be observed, they occur in well-engineered environments (Christiansen and Rump, 2006).

Mobile phones do not work because the theory of quantum physics is universally true. They work because we can generate the "nomological machines" that ensure a regular solid-state transistor effect (conforming with theory), shielded from the interference of the everyday world by what is, in effect, a highly manufactured, experimental, pocket-sized laboratory, created at scale, for little cost. The experimental results are robust (i.e., you can make a phone call) only insofar as the shielding surrounding the experiment does not fail. The ubiquity of the nomological machines of quantum effects does not speak to the universal nature of the cause-effect relationship but to our capacity to engineer

isolated, shielded environments (Christiansen and Rump, 2006).

Analogously, in a typical randomised controlled drug trial, the nomological machine is not just the treatment (such as the drug), nor is it reducible to the patient group (age, sex, immunity profile, nutritional status, etc.), nor the randomisation protocol. The nomological machine includes the shielding around the observed effect, i.e., the training of the people delivering the drug; the governance, policies, and infrastructure of the clinical setting; the wider health system; the levels of education of the patients; cultural views about drugs and disease; the incidence of disease; the socio-political, physical, and ecological environment that mediates the disease; and so forth.

The error in the classic RCT conceit lies in the idea that the causal relationship is a singular dependency between the treatment and the outcome, rather than a multifaceted entanglement of interacting factors that bind the treatment within a context that allows the cause-effect relationship to manifest.

1.3. Relationship to implementation research

The growth of interest in "pragmatic trials" (Zuidgeest et al., 2017) and "implementation research" (Bauer et al., 2015; Garrett, 2008; Sanders and Haines, 2006) indicates an awareness of the need to overcome the external validity challenge posed by RCTs. The pragmatic trial is intended to answer whether a proven intervention works in real life, across a broad range of settings (Patsopoulos, 2011; Schwartz and Lellouch, 1967). Implementation research explores the factors required for a proven intervention to work in new settings (Peters et al., 2013a). There is some divergence in opinion about the separation between these two ideas (Morrato, 2018; Pawson, 2019), yet even if they are separable, both pragmatic trials and implementation research are broadly committed to generalising treatments that work in a trial setting to a plurality of other settings; i.e., moving the singular cause from *here* to *there*. Moreover, in discussions of both methodologies, the causal relationships in question are assumed to be true, in a general sense, and failure to observe the effect in new contexts is assumed to be reflective of problems of application rather than a misunderstanding of causation (Cumming et al., 2019; Pritchett and Sandefur, 2014). The failure to transfer the effect from *here* to *there* is assumed to indicate a peculiarity in the *there,* not in the *here* where the "true effect" was identified.

An alternative view is that cause-effect relationships are local and can only be replicated across contexts by reproducing the shielding—the "fixed-enough arrangements" required for the cause-effect relationship to manifest *here*. Treating causal relationships as emergent properties of nomological machines encourages researchers to understand, in detail, the context of the original research (Christiansen and Rump, 2006). Simply put, for the cause-effect to manifest in a new setting, there must be substantive conformity between *here* and *there* in terms of relevant characteristics of the shielded environment.

The following section is an illustrative case study of the contextual factors operating in a GHD intervention. This context creates the shielding within which a cause-effect relationship is to be observed. We selected this case study because it is one with which we were familiar (Jackson, 1991). Furthermore, the study was designed to facilitate interdisciplinary thinking about what might be necessary to support generalisation for a specific GHD intervention. Significant attention was therefore given to the collection of contextual details of the study.

The study is ongoing and therefore data on intervention outcomes are not yet available. nonetheless, as a significant project in GHD, it represents a setting that is illustrative and germane to implementation science. We describe a range of geographical, environmental, social, cultural, political, and economic shields that sit over a central RCT and are relevant to generalisation of the intervention. These are the very *types* of shields that sit over all GHD trials; and while the specifics will change according to the intervention and context, they represent valuable exemplars.

2. Case study: RISE

Diarrhoeal disease remains one of the leading causes of mortality in children under the age of five. Deaths occur predominantly in the low- and middle-income countries (LMICs) of sub-Saharan Africa and Asia (Wang et al., 2016). Exposure to enteric pathogens is via the faecal-oral route; children (and adults) are exposed to contaminated food, water, hands, soil, and fomites (Baker et al., 2016). Enteric pathogens in children are also associated with significant morbidity contributing to long-term malnutrition and stunting (Kotloff, 2017).

Informal settlements (or "slums"– these terms are often used interchangeably) are home to around one-quarter of the world's population, mostly in rapidly growing urban areas of LMICs (UN-Habitat, 2015). They typically lack access to the improved water or sewerage infrastructure necessary to manage faecal and water waste safely (Davis, 2017; United Nations Task Team on Habitat III, 2015). They are often prone to flooding (Davis, 2017; Risi et al., 2013) and, given poor water and waste management, residents often have high levels of environmental exposure to enteric pathogens (Nassar and Elsayed, 2017).

2.1. Water interventions

Historically, the standard, municipal engineering approach to managing enteric pathogens in urban environments is "big pipes" trunk infrastructure (TI). Urban residential areas are integrated into large, centralised networks of faecal and wastewater sewerage infrastructure, in combination with an equivalent network of piped, improved water. TI approaches, however, are expensive to build and inflexible in design (Londong, 2019).

Informal settlements rarely benefit from extensive, networked infrastructure because informality, by definition, signals the kind of uncertainty and potential impermanence inconsistent with TI investment. Indeed, it is not uncommon to see "big pipes" bypass informal settlements entirely, on the way to more permanent, wealthier settlements. Retrofitting TI infrastructure to previously-existing housing is also more expensive and socially disruptive, hindering investment in existing informal settlements.

To evade the pitfalls of TI implementation, one standard approach to water management in informal settlements has been unconnected or loosely networked local water, sanitation, and hygiene (WASH) solutions. In 2015, approximately US$85 Billion was spent on WASH interventions, with about 10% coming from Overseas Development Assistance (ODA) budgets (UN-Water, 2017). A typical WASH intervention includes treatments such as (Darvesh et al., 2017; Yates et al., 2017):

i. Improving drinking water at source-or-point of use, such as household chlorination of drinking water ("WAter");
ii. Safe disposal of faeces, such as improving or building community latrine facilities to include water seals, venting and faecal sludge management ("Sanitation");
iii. Behavioural interventions to increase hand washing, including soap distribution ("Hygiene").

Concern exists, however, about whether such traditional WASH approaches are fit for purpose, particularly in high-density, urban, informal settlements. The banner term WASH belies highly varied implementation (Luby et al., 2006; Clasen and Boisson, 2016; Komarulzaman et al., 2017; Ercumen et al., 2018; Wolf et al., 2018), and alternative, more structural interventions have been sought (Ross et al., 2020; Satterthwaite et al., 2019). For example, calls have emerged for "transformative WASH", which incorporates better housing in a complex intervention (Cumming et al., 2019; Levy and Eisenberg, 2019; Pickering et al., 2019).

One alternative strategy to TI and WASH involves "water sensitive" (WS) interventions (Brown et al., 2016; Wong and Brown, 2009). WS

involves the provision of modular, minimally or un-networked, localised, improved water, faecal and wastewater infrastructure in combination with environmental re-engineering. The approach integrates ecologically and economically sustainable water infrastructure into local buildings and landscapes in—in this case—informal settlements (Wong and Brown, 2009). It is not a single deliverable, but (analogous to WASH) a suite or toolbox of techniques and technologies that can be variously configured to deliver improved water and sanitation by re-developing critical parts of the lived environment. The WS toolbox includes (RISE, 2020):

1. reshaping the topography of settlements to redirect or prevent pluvial, fluvial and surge flooding, and reduce faecal contamination and re-contamination of the physical landscape (i.e., improved drainage);
2. building self-sustaining, plant-based, surface and sub-surface wetlands (bio-filters) for treating waste water;
3. installing minimally networked toilets connected to the settlement-scale sanitation system (wetlands) to manage the direct human faecal load entering the environment. Faecal waste is managed through the surface and sub-surface wetlands;
4. utilising low-cost, readily available, local materials; and
5. co-design to ensure culturally appropriate development with community co-ownership (Brown et al., 2009).

WS has been employed as a sustainable approach to water and effluent management in wealthier settings, but never, previously, in informal settlements. Here, the aim of WS replicates that of the TI approach: to provide faecal and wastewater infrastructure and improved water to residents, alongside improved resilience to water-related hazards (e.g., flooding – including from climate change – infectious disease transmission, pollution).

Thus broadly defined, the WS intervention is a development with potentially significant impacts on the health of billions of people. It does not rely on levelling and rebuilding an informal settlement, but rather on retrofitting, redesigning, and re-engineering. If it works—that is, if it demonstrates a significant reduction in enteric pathogen exposure while being low cost, cost-effective (Walker, 2001), and ecologically sustainable—it could radically change the delivery of improved water and sanitation to informal, urban settlements. Of course, adoption pivots on the "if" of "if it works", raising questions, therefore, about how to evaluate the WS intervention.

2.2. The RISE intervention

The *Revitalising Informal Settlements and their Environments* (RISE) study is a community-based RCT in 24 informal settlements in Indonesia (N = 12) and Fiji (N = 12) that seeks to test a WS intervention (Brown et al., 2018; Ramirez-Lovering et al., 2018). The broad complexity of the intervention was well appreciated, and managing and understanding that complexity—and documenting key learnings—was acknowledged as critical during the early stages. In developing the trial, the investigators hoped the empirical results of the study would "… give a blueprint [of] how to do water and sanitation better, in a more sustainable way …"(Hunt, 2017), and "… provide an evidence-based proof of concept that will improve slum upgrading and revitalisation" (Brown et al., 2017).

The RISE study has been dynamic, with investigators' thinking about the core of the intervention developing over time in response to the realities of implementation of an RCT in a community setting. As evolved, the study is a comprehensive, multidisciplinary program of research that attempts to capture and understand the broader factors that affect the implementation of the WS intervention and, therefore, the generalisation of the intervention from *here* to *there*.

Interested readers can find additional details about the RISE study in other articles, and the trial is registered on the Australian New Zealand Clinical Trials Registry (Trial ID: ACTRN12618000633280) (French et al., 2021; Leder et al., 2021) In this paper, rather than attempt to describe an evolving idea, we focus on early developments within RISE, when the two lead authors of this paper had the greatest involvement. Thus, this article is not a critique of RISE in its present evolution, because it has continued and does continue to evolve—indeed, the study is not completed. RISE does, however, present an ideal case study for critical learning and realist analysis of Cartwright's dappled world of local causation. A significant advantage of the RISE study, in marked contrast to most GHD studies, is the quality and quantity of information the investigators are collecting about the context of the intervention.

The general hypothesis of the trial remains constant even as the intervention iterates. Specifically, a WS intervention (**treatment**), relying on re-engineering informal settlements, will reduce human exposure to pathogenic faecal contamination and flooding hazards over no intervention (**control**). The intervention's primary outcome will be a significant reduction in enteric pathogenesis in children under five (**outcome$_p$**). Secondarily, the observed "sentinel pathogen" load in community open spaces, indoor spaces, and drinking water will also be significantly reduced (**outcome$_s$**).

> The project sites are variously characterised by combinations of tidal inundation with occasional storm surges, fluvial and pluvial flooding, and poor drainage. In addition, sites suffer from intermittent water supply of varied quality and inadequate or absent sanitation systems. This results in high rates of exposure to environmental faecal contamination (Ramirez-Lovering et al., 2018, p. 462).

Even within this description of the trial, we intentionally elide detail. For instance, we do not describe what a "significant reduction" means, how one might measure it, how sentinel pathogens are sampled and identified, which pathogens are sentinel pathogens, etc. Instead, we focus on the conceptual issue of the cause-effect relationship between the treatment and the outcome in the noisy, real-world, setting of GHD for informal settlements.

2.3. The shields

2.3.1. Site selection

Drawing on the notion of the nomological machine, construction of shielding began early in the development of RISE—before substantive funding had been secured or the details of the intervention settled. The universe of possible cities within which the study could take place defined the sampling frame for informal settlements. An Indonesian city on the island of Java was initially considered and rejected. While it had informal settlements that may well have benefited from engineering work to improve health and well-being, the effect size of the WS intervention would have been less than in other places. Situating the study in that location would reveal a difference without a distinction, giving rise to a Type II error (i.e., one might falsely conclude that the WS intervention had no effect). The decision to reject one city in favour of another recognised that context is critical to the manifestation of the cause-effect relationship. Because a WS intervention will have varying impacts in different contexts, it may not be suited to informal settlements in all cities.

Further decisions had to be made about which informal settlements within the selected cities should be selected for intervention and analysis. Budget was a constraint. The number of settlements (the unit of randomisation) had to be balanced against the number of dwellings within each settlement, both of which affected the cost. Based on simulations, six intervention and six control settlements in each city were identified as the right number for randomisation, with an average of 50 houses per settlement, ideally ranging between 30 and 100 dwellings (Leder et al., 2021). Limiting selection to this range is a form of shielding that may limit applicability of results in either very small or very large informal settlements, which could have substantially different cultural,

ecological, or socioeconomic features, or where intervention could imply substantially different costs.

The physical environment surrounding the informal settlement was a further consideration. As much as possible and given the small size of the settlements involved, the choice had to constrain potential contamination from surrounding communities or carried in from elsewhere by inadequate surface-water management. All settlements suffer from boundary contamination, which needs to be manageable within the resource constraints of the intervention. In this respect, the ideal study settlements were "physically separated from other settlements with clear physical boundaries" (Ali et al., 2019; Leder et al., 2021). While this criterion facilitates the evaluation of the intervention effect, it also represents a form of shielding not replicable in all potential intervention sites.

Land tenure arrangements were also a key concern. While it was a criterion for study site selection, informality is not a dichotomy. Informal settlements were sought where occupants had security of tenure, but where other key elements of informality (e.g., lack of formal employment, representation in governance, provision of infrastructure and services, etc.) pertained (Leder et al., 2021). Chosen settlements had to be informal but "permanent enough" to make investment in revitalisation viable (Van Gelder, 2010). The informal settlements of the truly marginalised, the most vulnerable, were excluded because the very source of their vulnerability made them, their housing, and their settlements too uncertain. Again a form of shielding was created within the RISE nomological machine that would affect effectiveness and cost-effectiveness.

2.3.2. Population density

The RISE WS intervention addresses sewerage and waste water with septic tanks and surface and sub-surface wetlands co-located within the study communities (Ramirez-Lovering et al., 2018). Unlike in TI approaches, the waste is not removed and processed elsewhere. Hence, the wetlands require unused physical space either within or adjacent to the settlement area. Availability of space is thus a key concern for a WS intervention in informal settlements, as is population density, which determines the amount of sewerage and wastewater generated—thereby determining management requirements—and also influences whether sufficient free space will be available. As with the site selection elements above, free space and population density are thus further shielding elements, which must be accounted for in determining whether a treatment effect is likely to be transferable or cost-effective.

2.3.3. Site management

The examples of animal husbandry and land reclamation in the RISE study sites illustrate essential interplays between the socio-cultural and material re-engineering of the sites and the increased need for community governance to maintain the intervention's integrity. These too become a part of the RISE nomological machine.

2.3.3.1. Animal husbandry. Livestock (poultry, goats, sheep, pigs, and cattle) are significant sources of income and food in many informal settlements. They are also a potential direct and indirect source of disease in humans (Correa and Grace, 2014), which creates a tension between the costs and benefits of animal husbandry within informal settlements (Penakalapati et al., 2017). The type, quantity, and distribution of livestock can affect a WS intervention—altering costs and complexity as well as effectiveness and cost-effectiveness.

In some of the informal settlements in Fiji, residents kept domestic pigs that were free-ranging or loosely corralled around households. Although the RISE WS intervention is based on management of human faecal contamination, exposure to pig faeces also carries a risk of human pathogenesis which needs to be managed (Ström et al., 2018; Zambrano et al., 2014). Furthermore, foraging of free-ranging pigs risked damage to the surface and sub-surface wetlands or alteration of other WS structures, essentially re-re-engineering the topography of the intervention-settlements. Therefore, modifying animal husbandry practices was critical to preserving the structural changes introduced by the intervention.

Animal husbandry, however, involves not only material practices, but cultural considerations. Preferences for specific styles of husbandry are not fixed across contexts. For the purposes of the study, greater control over pigs' movement is rational, but there is a moral economy with an impact on the communities (Scott, 1977). Free-ranging pigs manage at least part of their own daily protein and caloric needs; closely corralled, they are entirely dependent on human labour and procurement for their food.

2.3.3.2. Land reclamation. In a number of the sites in Fiji, discarded car tyres are used by residents as part of a land reclamation and water inundation management strategy. Access to land is at a premium in informal settlements, and the capacity to claim additional land is an important resource, not peculiar to Fiji (Ahmed et al., 2018). However, to maintain the integrity of the intervention, *ad hoc* land reclamation had to cease, lest changes in topography alter the effect of the intervention itself—for instance, by changing water flows and increasing pooling.

The livestock and land management examples illustrate how broader socio-cultural systems can become enmeshed in the nomological machine underpinning successful interventions and can speak to intervention costs. In most informal settlements, the occupants are *de* facto urban planners, guided by their needs, limited resources, and vernacular knowledge of place-making (Sawira and Rahman, 2018). In contrast, formal settlements are guided by rules developed by professionals. The rules result in template outcomes often divorced from necessity, affordability, or cultural diversity. Regularising a formal sewerage network—even a RISE-style WS sewerage strategy—means that individual residents can no longer continue as informal "planners guided by need". They must adhere to broader community planning principles—even if those are part of an initial co-design process (which we discuss later)—and they must commit concrete resources. The capacity of a settlement to take these steps is thus part of the shielding required for the cause-effect relationship in question (i.e., the WS intervention's impact on enteric disease) to manifest.

2.3.4. Waste management

Many informal settlements in Fiji and Indonesia feature significant quantities of surface waste: general refuse, plastic and metal containers and bottles, plastic bags, etc. This waste can affect drainage and wetlands. Therefore, household waste management is a critical part of the intervention strategy.

Household waste is a material, socio-cultural, economic, and political matter because it relates to individual and household behaviours and attitudes and community expectations about refuse management. If local government takes responsibility for household waste management in informal settlements, then the nature of their informality begins to shift. Service provision necessitates greater formality–and more regulation. In the absence of government action, community management requires new structures and processes of internal governance; this, too, modifies the informality of settlements as community obligations grow. Communities with significant population turnover have more difficulty self-regulating than communities with a stable population.

In the RISE context, therefore, we must consider the capacity of the intervention communities to assume new obligations and costs and to evolve their socio-cultural processes related to waste management as part of the shielding that allows the intervention to be effective.

2.3.5. Economics and politics

Perhaps the apex of shielding is political. Is a government supportive of the revitalisation of informal settlements and, if so, at what level of

government does support exist: national, provincial, city or district? In many countries, the existence of an informal settlement is evidence of political failure, and therefore informal settlements are to be ignored or destroyed, not revitalised (Satterthwaite, 2010). Conversely, informal settlements in many contexts provide convenient, low-cost housing for the perennially underpaid workforce that keeps large cities functioning, without the need to address such thorny political issues as a living wage (D'souza, 1979). There is nonetheless a presumption that formality is desirable (Scott, 1977, 1999, 2017).

Government funding for slum interventions represents a layer of formalisation of the informal. In the RISE study, "the build"—i.e., the substantial re-engineering of the housing, communal infrastructure, and settlement topography—relies to a significant degree on grants from the Asian Development Bank (ADB) and the Australian Department of Foreign Affairs and Trade, and development assistance from the New Zealand Government. The project in Fiji also includes a contribution from Fiji's Government through the national budget. Funding of this type represents an imprimatur from one or more governments, signaling their political desire for the project to be supported and to succeed–and in some cases elevating the intervention to a position as part of a political relationship between nation-states. (Ravuwai, 2020). This is a critical form of shielding that affects the intervention's nature and delivery. Replicating the intervention may require shielding that is at least as strong in delivering those kinds of support.

2.3.6. Co-design

A final, critical element in the RISE intervention is co-design, a collaborative approach that engages the community in each informal settlement in the design of the intervention—e.g., the location of paths and wetlands, management options, etc. In global development and urban planning, co-design is increasingly regarded as critical for the sustainable success of interventions. Another project in Indonesia described the importance of co-design as follows.

> Where the formal system focuses on the physical elements first, Tamansari [an informal settlement] has been formulated through the exact opposite process. Here, the process is [more] important than the product. Here, a set of people get engaged in the process of place making rather than someone else dictating the spatial pattern who is not a part of the community … (Sawira and Rahman, 2018, p. 11).

Co-design intends, among other goals, to provide inclusion and agency for marginalised communities that are traditionally excluded from decision making processes. It is a valuable and empowering approach to the development and management of interventions involving community urban planning.

One of the benefits of co-design for the RISE intervention is that it commits residents to formalising the informal: to sharing responsibility for the development and, perhaps more importantly, maintenance of their revitalised community. It also establishes what appears to be a necessary shield for the cause-effect relationship to manifest. Considerable effort has been put into developing and understanding the co-design approach in RISE. This provides a thorough understanding of what was done and how; but it does introduce a challenge in the development of template co-design strategies as one generalises from one context to another. As highlighted above, it will be difficult to generalise learning about a cause-effect relationship from a tightly controlled experiment to new settings.

The intensity of the process also gives rise to likely future inconsistency in the success of so-called participatory processes because "it's hard to do well" and therefore hard to replicate (Deheer, 2019, p. 7). Deeply committed teams will achieve exceptional results, but expecting deep commitment during scaleup is unrealistic. As others adopt the "blueprint" of the intervention, therefore, maintaining the magnitude of the effect during the implementation of a scaled-up intervention becomes more challenging. When the scale-up is massive (e.g., to thousands of communities encompassing millions of residents), the cost and management of effective co-design in each settlement may be seen by developers as prohibitive, whereas, in the context of relatively small trials, it is seen by researchers and community developers as an exciting and worthwhile process. Nonetheless, RISE offers important opportunities to identify key-elements of co-design which may be scalable (i.e., critical aspects of shielding necessary for the intervention to "work").

3. Discussion

The RISE study, and the detail with which information about the development and implementation of study has been collected, illustrates likely contextual dependencies of cause-effect relationships—even in the absence of final results. The treatment effect of a WS intervention on human exposure to pathogenic faecal contamination does not exist "in the world" at large. It exists, rather, in a highly-specified context—a bright spot within the dappled world, characterised by rich information and thus allowing for causal interpretations (within a well described nomological machine).

. The nomological machine within which the cause-effect relationship may manifest incorporates shielding that is geographical, topological, political, cultural, social, and economic. It will rely on very low-level factors such as the (in)formality of a community and their preparedness to be managed and to change behaviour, as well as high-level factors associated with notions of property, tenure, and ownership, and the political will of the city, provincial and national governments. Initial choices about specific cities, informal settlements, and land-tenure requirements, for instance, create a "rigidity" to any potential findings, limiting the ease with which universal claims could be made about generalisability.

For implementation research to produce findings that are transferable and scalable, there needs to be a detailed understanding not only of the intervention, but also of the context or shielding that enables the cause-effect relationship to manifest. The design of the RISE study and the detail with which information about its development and implementation has been collected provide an opportunity to assess potential transferability. Any treatment effect of a WS intervention on human exposure to pathogenic faecal contamination must be interpreted in light of the dappled world, in the sense that small contextual changes may drastically vary the impact of the intervention.

In the label, "global health and development", the essence of the endeavour is captured. The Multilateral Development Banks and the overseas development assistance community seek widely generalisable solutions to the major health and development challenges facing the world (Gonzalez Asis and Woolcock, 2015). Very local solutions that cannot be scaled and do not generalise will, ultimately, be condemned because they fail a reproducibility test (Baker, 2016; Nichols et al., 2019). The very idea of the reproduction of cause-effect relationships, however, has been predicated on a notion of a "true" cause that exists beyond our dappled understanding—outside the nomological machine within which it was first identified (Cartwright, 1999).

Some of the challenge of context is recognised in a traditional formalisation of implementation research, a critical component of which requires the assessment of "fidelity" (Eboreime et al., 2020). That is:

> "… the methodological strategies used to monitor and enhance the reliability and validity of … interventions. The overall goal of enhancing treatment fidelity is to increase scientific confidence that changes in the dependent variable are attributable to the independent variable. Careful consideration of treatment fidelity helps to explain study findings, revise interventions for future testing, and increase statistical power and effect size by reducing random and unintended variability. Enhancing treatment fidelity has the effect of not only increasing internal validity but also increasing external validity, as a high degree of treatment fidelity is needed both for

study replication and for generalization of treatments to applied settings" (Borrelli et al., 2005, p. 852).

From a dappled world perspective, "fidelity" is, in effect, the shielding that defines the nomological machine within which cause-effect relationships are reliably manifest. Co-opting the earlier words of Borelli et al., well-chosen and well-constructed shields "can increase statistical power and effect size by reducing random and unintended variability". In the RISE case study, the rejection of a city on the island of Java for the WS intervention, for instance, avoided the potential for too small an effect size, which would have reduced the power of the intervention. Explicitly controlling the waste management in sites to avoid clogging the wetlands with refuse reduces unintended variability in the treatment. The argument for fidelity is, thus, just as powerful illustration of the need to understand the shielding of the nomological machine, if the intervention is to be replicable (maintaining the effect) in new treatment areas.

Generalisability has a distinctly different meaning in a dappled world. The usual notion is:

> EXTERNAL VALIDITY (Syn: generalizability, transportability): The degree to which results of a study may apply, be generalized, or be transported to populations or groups that did not participate in the study (Porta, 2014, p. 288).

In contrast, generalisability may more productively be understood as the capacity to engineer, in a diversity of settings, the necessary nomological machine within which the treatment-effect will manifest.

Some or all of the various types of shielding observed in the RISE project (and perhaps others) may be needed if the WS intervention is to work in Accra, Caracas, Chattogram, Lilongwe, Mombasa, Mumbai, or Nairobi. In capturing the details of the study context we illustrate the kinds of factors that will need to be considered (for any successful GHD intervention) when trying to move the intervention from *here* to a plurality of *theres*.

If our view is correct, perhaps what is most surprising about GHD interventions is that we are not more explicit about re-engineering a plurality of disparate contexts so that they are more like the *here*, whence the original evidence derives. If the intention of GHD research is to generalise or scale up—not just make a difference in a single context—the typical focus of implementation research on the single cause (and not on understanding the nomological machine that gave rise to the cause-effect relationship) will increase the challenge of reproducing effective treatments.

The advantage of the proposed approach is pragmatic. In GHD we want interventions that work. More precisely, we want proven interventions that we can make work in a new context with little or no additional effort. It is, however, unusual for new, proven interventions to work out-of-the-box in new contexts (i.e., to be universally generalisable). Nonetheless, if we can create a suitable nomological machine with some low-effort local engineering (tinkering) to allow the cause-effect relationship to manifest, then the argument is moot. Such an approach relies on an appreciation of the shields that may be needed. The amount of tinkering required will depend on (i) the extent to which the necessary shields are already in place, (ii) the ease with which necessary, missing shields can be identified; and (iii) the required cost/effort of creating the necessary, missing shields.

If detailed information about the context of the original trial is a routinely collected, as in the case of RISE, it may be possible to evaluate some of the shielding requirements in a new context and, therefore, the cost/effort required to move the intervention from *here* to *there*. If, with each new adoption of the intervention, more contextual information were collected, a knowledge-base of nomological shields could potentially be developed to support further scale-up. It may even be that universal insight could be gained from a bird's-eye view of what are now essentially disparate local causal models.

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