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Commentary

Beyond direct impact: Evidence synthesis towards a better understanding of effectiveness of environmental health interventions

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ABSTRACT

Systematic reviews are a cornerstone of evidence-based public health, and there is much discussion on how this method may need to be modified to do justice to complex interventions, such as environmental health interventions. This paper asserts that intervention effectiveness is influenced by variability in five distinct layers – direct (intrinsic) impact, user compliance, delivery, programming and policy measures – which are embedded in the broader geographical, socio-economic, political and cultural context. The multi-component, multi-sectoral nature of most environmental health interventions results in a complex relationship between these layers of influence, involving systemic interactions. As illustrated with examples, understanding environmental health interventions critically relies on considering all of these layers. These distinct layers of influence can serve as a framework towards the comprehensive analysis of environmental health interventions in systematic reviews, drawing on quantitative and qualitative methods and a variety of disciplines.

Introduction

Environmental health interventions affect large population groups, bind financial and personnel resources, may run against individual freedom of choice and can produce adverse health effects. Drawing on the World Health Organization's definition of the environment (WHO, 2006), we define environmental health interventions as "any modifications to the natural or physical environment, or of behaviours related directly to them, which are undertaken with the intention to protect or improve health". They range from programmatic activities that initiate direct, proximal changes in a specific technology or behaviour to those that bring about indirect, more distal changes in policy (Rychetnik et al., 2004), and often combine several components. Consequently, evaluating such complex interventions is far from straightforward and there is much discussion as to how evidence should be gathered, synthesized and used in decision making (Craig et al., 2008; Kelly et al., 2010; Lavis et al., 2004; Rychetnik et al., 2002; 3ie, 2011; Thomson et al., 2004).

Evidence-based medicine (EBM) "is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett et al., 1996). It relies on a well-established set of methods for evaluating interventions, collating evidence systematically, grading evidence and making recommendations. In contrast, evidence-based public health (EBPH) represents a relatively new concept of particular relevance to environmental health. One of several proposed definitions describes EBPH as "the development, implementation and evaluation of effective programmes and policies in public health through application of principles of scientific reasoning, including systematic uses of data and information systems and appropriate use of behavioural science theory and program planning models" (Brownson et al., 2009).

The effectiveness of interventions in determining health outcomes lies at the heart of both EBM and EBPH. Systematic reviews represent the dominant method of evidence synthesis for assessing such effectiveness (Lavis et al., 2004). The transfer of this method from clinical medicine, with its concern for the individual patient, to the societal perspective of public health and environmental health has not been straightforward. In particular, limiting systematic reviews to randomized controlled trials (RCTs) may dismiss as noise much of what others would consider to be the signal. Consequently, there is much interest in extending the boundaries of systematic reviews and to "develop new methods and better frameworks within which different types of research evidence can be integrated to inform decision-making" (Petticrew, 2009).

This paper aims to add to the theory and methods underlying systematic reviews of complex interventions. It proposes that intervention effectiveness is influenced by variability in five distinct layers, and that judging the effectiveness of environmental health

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interventions in a meaningful way critically relies on considering all of these.

Layers of influence on intervention effectiveness

We assert that five distinct layers of influence determine an intervention's impact on health at population level (Fig. 1), drawing on "simple" clinical and "complex" environmental health examples with particular relevance to developing countries. On closer examination this simple versus complex dichotomy becomes somewhat artificial, as simplicity and complexity are only partly inherent features of interventions (Craig et al., 2008). Indeed, more often simplicity and complexity are a consequence of the perspective adopted (e.g. medical versus public health or health systems perspective) and the research question formulated (Petticrew, 2011). Keeping this in mind, the examples below are chosen to illustrate extremes on a spectrum ranging from a simple perspective on a simple intervention to a complex perspective on a complex intervention.

The first layer represents the *direct (intrinsic) impact* of an intervention. For example, the administration of a single dose of treatment, where dose is controlled and compliance is verified, largely isolates this direct impact. An environmental health example is controlled, centralized treatment of drinking water to inactivate pathogens. In both cases external influences that modify the outcome are minimized, the intervention is tightly defined and individuals essentially become passive recipients. Any variation between subjects is determined by differences in genetics and physiology.

The second layer relates to *user compliance*. For example, the usually lifelong intake of thyroxin among patients suffering from hypothyroidism requires daily consumption of a tablet well before the first meal of the day. Similarly, the exact practice and duration of handwashing with soap impacts its hygienic effectiveness, and this habitual practice must be sustained over time. Recipient behaviour thus exerts a major influence on effectiveness.

The third layer, *delivery*, comprises variation in a diagnostic tool or public health technology, including the behaviour of the delivery agent. In Integrated Management of Childhood Illness incorrect diagnosis – either due to the sensitivity and specificity of a clinical algorithm or due to human error by the health worker – can lead to over- or under-delivery of treatment. An environmental health example is the variation in the manufacture and installation of improved stoves, which can modify their effectiveness in reducing household air pollution and associated respiratory diseases.

The fourth layer, *programming*, is characterized by different programmatic approaches (e.g. fully market-based versus subsidized promotion of latrines), and by different delivery agents (e.g. administration by government versus non-governmental organizations). Programming can directly impact effectiveness (e.g. recognized greater use of insecticide-treated bednets that were purchased versus those that were provided free of charge) and determine which socio-economic groups are reached (e.g. pro-poor targeting), and may thus exacerbate socio-economic inequalities where the most affected populations are less likely to receive educational, technological or financial interventions.

The fifth layer reflects means by which a government operates to secure a desired change through *policy measures*. These can include formulation of policy itself, associated budget lines, regulation, economic incentives and capacity-building. These may be targeted directly at the recipient population (e.g. health education campaigns) or at intermediary actors (e.g. plumbing regulations, incentives to utility service companies).

All five layers above are amenable to manipulation as part of intervention design, implementation and public policy-making, and are embedded in and potentially interact with the overall geographical, socio-economic, political and cultural context of a setting or country (Fig. 1).

Differential influences of layers in "simple" and "complex" health interventions

Many clinical interventions are single-component and implemented by the health sector in a healthcare setting. They are typically designed to influence one health outcome, with causal pathways being relatively short and direct (Victora et al., 2004). Clinical interventions target sick individuals who seek and receive care, an "activated" population in need of help, with the intervention aiming to bring about improvement or cure immediately or over a short period of time. Therefore, for many clinical interventions the outer layers tend to operate in a linear fashion (Fig. 2a).

In contrast, environmental health interventions usually have multiple health and social goals and often comprise several components, involving interactions within and across layers and between multiple sectors and actors (Fig. 2b). As causal pathways between intervention and outcome are long and complex, examining the more distal elements is as important as assessing direct impact (Rychetnik et al., 2004). Environmental health interventions tend to be implemented in household or community settings and through regulatory or policy means; they are directed at at-risk populations that may not be aware of any need for change. While risk reduction for some individuals can be immediate, population-level changes may be progressive (as described by diffusion theory; Rogers, 1995). Indeed given the preventive nature of many environmental health interventions, health benefits may be unapparent (arising from the difficulty of demonstrating a non-event) or detected indirectly by statistical tools after months, years or decades.

In principle, the effectiveness of any curative or preventive intervention is influenced by all layers as well as the interactions between them. In clinical settings, however, evidence of direct impact, as assessed through RCTs of efficacy under controlled conditions, has become widely accepted as a reliable indicator of effectiveness. Due to their high internal validity, well-conducted RCTs generate context-free evidence to explain universal truths about what works in ideal circumstances. For many clinical interventions, RCTs also tend to show good external validity, allowing for replication under routine conditions and extrapolation to other settings (Victora et al., 2004). This means that a change in policy, programming and delivery is principally mediated through its impact on the quantum of effort (e.g. more funding for surgery enables more operations) with effectiveness per person treated as constant. Consequently, shedding light on the upstream layers is usually not essential for assessing the effectiveness of a clinical intervention.

In contrast, Figs. 1 and 2b illustrate that assessing the effectiveness of an environmental health intervention cannot rely on direct impact alone – all five layers co-determine effectiveness per person in a complex causal network. An analysis limited to any single layer is likely to be misleading, as actual impact may be substantially greater or lesser. Furthermore, several phenomena of environmental health interventions, such as sustainability, are the result of interactions and feedback loops between people, intervention components and the context in which the intervention is implemented. System-level thinking and an analysis of system-level properties and processes are therefore essential (Galea et al., 2010).

Let us illustrate these differences by comparing two critical interventions to tackle the more than one million global deaths per year due to pneumonia among children under five years of age (Liu et al., 2012): antibiotic treatment versus improved stoves to reduce household air pollution from solid fuel use.