

# Moving Beyond Effectiveness: On Evidence Based Health Information (EBHI) as a Complex Intervention

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## Abstract

Over twenty years evidence based practice has become established as a dominant frame of evaluation within health services management and public health. Its influence extends to all aspects of information and communication. Evidence Based Health Information (EBHI) seeks to get the best available evidence used by patients, clinicians, managers and policy makers and to use evidence based methods to communicate them. Increasingly the public health community is shifting its collective attention to so-called complex interventions, from 'what works' to 'what works for whom under what circumstances'. The author briefly reviews the background to these developments before giving examples of the practical value of this wide lens approach. The author uses a recent case study to illustrate how health service managers and public health decision makers can benefit practically from recommendations produced as a result of using a complex interventions based approach.

**Key words:** evidence based public health, logic models, realist synthesis, systematic reviews, literature searching

**Słowa kluczowe:** zdrowie publiczne oparte na dowodach naukowych, modele logiczne, synteza realistyczna, przegląd systematyczny



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## Introduction

More than twenty years ago the phrase 'evidence based public health' entered the world's vocabulary. While many might argue exactly when this occurred and who was the first to use this new phrase, we can reconstruct two starting points. Retracing our steps teaches us much about our contemporary world of decision-making and how this impacts on our day-to-day practice. One of our two starting points derives from research, the other from the medical community.

Type the phrase 'evidence based public health' into the PubMed MEDLINE database and the earliest bibliographic reference originates from 1996, *Hand searching the Journal of Epidemiology and Community Health as part of the Cochrane Collaboration* [1]. The article describes the efforts of two public health practitioners to identify the evidence base for effective treatments and

policies so that policy makers could make effective decisions. The two authors painstakingly combed through every single printed issue of one of the key public health journals from 1947 to 1994 looking for reports of randomised controlled trials. This salvage operation sought trials that had previously been missed on the MEDLINE database. Having eluded the 'dragnet' of National Library of Medicine indexing these studies were carefully fished out one by one by two investigators armed with a 'fishing rod'. Thirty one previously unidentified trials were found by the pair of authors; eight that predated MEDLINE (i.e. pre-1966) and 23 not retrieved from a literature search even though they were included on the MEDLINE database.

What can we learn from this nostalgic journey? Three lessons come to mind. First, this activity was conducted 'as part of the Cochrane Collaboration' [1]. Over the last twenty years this international network of volunteers has

transformed evidence production, championing the methods and achievements of systematic reviews. Second, the trials were identified to populate the Cochrane Library, the world's largest database of controlled trials. The 82 trials found by the two authors in 22 hours of searching 48 volumes of the journal from cover to cover add to what are now 887,455 trials on the Cochrane Library to benefit the international health community. Finally, the fact that only 51 of 74 trials (69%) were retrieved from MEDLINE even though they were known to be on the database emphasises the key role played by skills in finding the evidence. In short these lessons focus on the evidence producer end of the production line.

Type the phrase 'evidence based public health' into Google Scholar, the academic full-text search engine, and a handful of the results date back even further – to 1994. 1994 was a key date for evidence based medicine in the United Kingdom. In that year Professor David Sackett came to Oxford to set up the Centre for Evidence Based Medicine. Appropriately the first result is a brief tutorial in the British Medical Journal (BMJ) by David Sackett, entitled *Understanding Clinical Trials* [2]. He describes how the randomised controlled trial has 'revolutionised how we decide whether a treatment or intervention does more good than harm'. He then describes trials as a cornerstone, not only for evidence based medicine but also 'for evidence based public health, evidence based hospital administration, evidence based purchasing, and evidence based consumerism' [2].

What can we learn from our second nostalgic trip? Three further lessons come to mind. First, as with the article from "Journal of Epidemiology and Community Health", Sackett links trials with decision-making. Rather than being a remote and detached academic exercise evidence based practice is about making decisions, making changes that matter. Whether these changes affect an individual patient, a population, a health service or a jurisdiction – evidence based practice is about making a difference. If we don't want to practice evidence based public health then we don't want to make a difference – to people's health, their quality of life or even in saving their lives.

Second, Sackett's paper highlights that it is important to be able to read a research study critically. Sackett points out that presenting research results as relative, not absolute, measures makes treatments seem more effective than they actually are. Of course relative results are what pharmaceutical companies use to make their treatments seem better [3]. Sackett advocates use of 'the number needed to treat' a more meaningful metric for any decision-maker. As a member of the Evidence Based Medicine Working Group, based in McMaster University Canada, Sackett contributed to a series of Users' Guides to the Medical Literature designed to help a busy health practitioner or manager to make rapid sense of a published research study and how it informs their practice. These User Guides were originally published in JAMA – the Journal of the American Medical Association – and fundamentally remain the basis for most contemporary published checklists on how to read a paper [4].

Finally, although David Sackett did himself contribute to the systematic review movement, as a founding member of the Cochrane Collaboration and its first Chair, he focused on the consumer (i.e. patient, clinician, manager, and policy maker) end of the evidence production line. His Centre for Evidence Based Medicine in Oxford was set up to spearhead attempts to get research evidence into practice.

What about the remaining items retrieved by this Google Scholar search? One letter, again from the BMJ in 1994, illustrates how dramatically evidence based public health shook the existing paradigm and polarised debate. This letter, entitled 'Evidence Based Public Health' counterposes 'objective measures of health gain, efficiency, and effectiveness' against professional judgement [5]. In support of his defence the author cites Britain's Lord Kelvin's observation: 'until you have measured it, you don't know what you are talking about'. I am reminded of the comment by Professor Sir John Muir Gray, the person who lured David Sackett to Oxford, that evidence based practice must never lose its ability to stimulate and to irritate!

These complementary streams hold personal meaning – in 1995, I attended the first UK Evidence Based Medicine Workshop at the Centre for Evidence Based Medicine in Oxford. Lacking a medical specialty, such as paediatrics or emergency medicine, I was thrown among a heterogeneous group of those working in public health and health management. In 1996, I attended my first Cochrane Colloquium in Adelaide, Australia the start of a more than twenty-year association that continues to this day. Subsequently I have been involved in both producing evidence, as a systematic reviewer, and in teaching doctors, nurses, managers, librarians and public health students how to be informed consumers in using and interpreting research evidence.

In summary what have we rediscovered? That evidence based public health is about better decisions about treatments and interventions, based on high quality trials and systematic reviews [6]. It is supported by key skills of searching for, and critically appraising, the literature. It seeks to engage at both the producer and consumer ends of the evidence production chain. And if evidence based practice doesn't stimulate you it should at least irritate you [7]. How do we take these reminders forward into our own day to day decision-making?

### ***Evidence Based Health Information***

While evidence based public health can be considered the 'envelope' the message itself takes the form of Evidence Based Health Information (EBHI). If we want to make a reliable and appropriate decision we need to be informed on the best course of action in our particular circumstances. Evidence Based Health Information (EBHI) seeks to get the best available evidence used by patients, clinicians, managers and policy makers and to use evidence based methods to communicate this evidence [8].

As a busy decision maker, whether clinician, manager or policy maker, you require information that is reliable

and that is easy to comprehend and action. Reliable public health information rests on four pillars of information quality – we use the abbreviation CART (Completeness, Accuracy, Relevance, Timeliness) to remember them [9].

First comes Completeness – to make a reliable decision, we need to be sure that we have the full picture. If any part of the picture is missing, then at best the information is inadequate, but at least we can identify what is missing. At worst, however, the information is not only incomplete it is also biased. Not only are we now less likely to make a right decision we are also more likely to make a wrong one. Importantly the presence of bias means not only can we not trust the information as reliable but we don't know how much of an effect the bias is exerting – we do not know exactly how wrong the information is going to be. Suppose, for example, a decision maker is planning to introduce a healthy eating policy and an enthusiastic nutrition expert provides several papers that show how the policy has worked. If they do not also submit papers that show when the policy does *not* work this selective evidence would create a worryingly high expectation of success. We would not know how many times the policy would fail. Suppressing information on the failures would also deny us important contextual detail on when and under what circumstances the policy does not work. The same is equally true for studies of patients, operations, or managerial decisions. If we do not have all the information we require then the next best alternative is to have a very clear picture of what information is missing.

Next comes Accuracy – to make a reliable decision we need to be confident that the information that we have is a reasonable representation of the truth. A precise result that is later revealed as wrong might lead us confidently to make the wrong decision. We would rather have an approximate answer bounded by estimates of the best possible result and the worst possible result. We could then be reasonably confident that the actual true result lies somewhere between the two. If the best possible result and the worst possible result are both beneficial we can be confident that we are making the right decision. Furthermore, the closer the two results are to one another the more confident we become. Suppose, for example, that multiple studies consistently show a particular immunization programme to have a success rate of between 70% and 80% we can be reasonably confident that the result for a similar programme in our locality, all other factors being equal, lies within this same range. Furthermore, we can calculate the cost-benefit ratio for both the best case and the worst case and decide whether we can afford to implement the programme.

Third, comes Relevance – to make a reliable decision we need to be confident that the information that we have is appropriate to the context in which we plan to use it. Of course, this is a very subjective decision. Typically, we can either argue that two contexts are similar or, equally, that the same two contexts are different. Suppose, for example, we compare Poland and the Czech Republic – an outsider might reason that these countries lie in close geographical proximity so their context is similar. Alternatively, you might bring to bear detailed

knowledge of differences in the population, the culture or the health systems of Poland and the Czech Republic and conclude that these contexts are very different. In our international project on the transferability of research findings [10] we observed that in a relatively 'uncontrolled' environment, such as lay health workers working in the communities of low and middle income countries [11], differences in context are likely to be very important. In contrast, in controlled environments such as an intensive care unit [12] differences in context across health systems are likely to be less important, unless they relate to the availability of resources, such as skills, facilities, and equipment.

Finally comes Timeliness – to make a reliable decision, we must be confident that the information that we have is the most up-to-date that is available. The closer the point in time between when we make a decision and when the research was conducted the more confident we are that the situation has not changed. In the past delays in research studies getting published, delays in readers of journals or textbooks finding out about the research and delays in putting research into practice resulted in a long and slow dissemination pipeline [13]. Nowadays open access routes, plus the greater speed of the production process, lead to research being published more speedily. Even more critically the advent of the World Wide Web means that it is far easier to identify that research has been published and to gain access to research articles than under the previous paper-based system.

## Why reviews?

The brief description of the CART requirements above identifies systematic reviews as a possible response to what decision makers need, and may even want. With regard to Completeness a systematic review takes precautions to ensure that the review team assembles the most complete set of studies possible to answer a particular well-defined question. As a consequence information specialists supporting a systematic review team search across a wide range of relevant databases. They also take precautions to ensure that their search strategies do not omit search terms that would miss a substantive quantity of the available literature. According to a *Dictionary of Epidemiology*, a systematic review is 'the application of strategies that limit bias in the assembly, critical appraisal, and synthesis of all relevant studies on a specific topic' [14]. A decision maker reading a well-conducted systematic review can therefore have a reasonable degree of confidence that they are viewing a complete picture of evidence relating to the very specific review question. This is achieved through strategies that limit the effect of bias.

In connection with Accuracy a systematic review pays careful attention to the quality of the studies that are included. Put simply a review either sets a quality hurdle so that only studies that meet or exceed this standard are included or else a review admits studies of variable quality but alerts the reader to the quality of each individual study. In some cases the review team informs the reader what the review would look like both with and without

the included studies, what is called technically a sensitivity analysis [15]. A decision maker reading a well-conducted review can therefore have a reasonable degree of confidence that the review is as close a representation of the true effect as is possible given the identified limitations of the existing research.

With reference to Relevance a systematic review seeks to ensure that it includes sufficient information for the reader to gain a picture of the context in which the original studies have been conducted. A review team extracts as much data as they consider necessary to capture the relevant context [16]. In the past quantitative systematic reviews have been criticised for essentially stripping away important contextual detail from the contributing studies. Increasing awareness of the complexity of public health interventions, together with the contribution that qualitative evidence can make to decision-making, has led to an increasing number of methods that seek to preserve this important detail. A decision maker reading a well-conducted review should be able to identify the extent to which the body of evidence, that is all the studies collectively, or individual studies included in the review, match the context for their own particular decision.

Finally, concerning Timeliness systematic reviews are conceived as 'live' documents that seek to incorporate new studies that can contribute to the review question as soon as possible after they are published. The Cochrane Collaboration originally aspired to updating its systematic reviews on a two-yearly basis although this has proved difficult to achieve in practice [17]. As a consequence, methodologists have focused attention on methods for updating reviews and for methods of identifying which reviews need updating most urgently [18]. It is helpful to identify the 'tipping point', i.e. how many studies with how many patients are needed to overturn the existing take-home message of an existing review? If new studies appear in the literature have they included sufficient participants to make a difference? It is interesting to note that many journals, when accepting systematic reviews for publication, now require that an update search is conducted within 12 months of proposed publication. Clearly timeliness is an important characteristic. A decision maker reading a well-conducted review can therefore assess how much the findings of that review still apply to their context or whether the existing studies have been superseded. I am reminded of colleagues who spent several years conducting a randomised controlled trial only to find that, by the time of publication, the control was no longer the most valid comparator for the new treatment [19].

### ***The role of reviews – and other evidence based products in public health***

The previous section rehearses arguments for the information quality of systematic reviews. Clearly systematic reviews carry many hallmarks for high quality evidence based health information. A further important consideration relates to how this evidence based informa-

tion is communicated. Notwithstanding the attraction of systematic reviews as a 'package' within which complete, accurate, relevant and timely information is bundled together, they can tend to be lengthy, dense, measured scientific studies that do not fit well to the brief windows of managerial decision-making or policy-making [20].

Fortunately, the evidence based health information movement has achieved much in attempting to steer these unwieldy juggernauts. First attention has focused on producing plain language summaries, aimed initially at members of the public but equally useful for the busy decision-maker, who seeks to gain an initial understanding of a complex technology [21]. In conjunction with plain language summaries the systematic reviews community has sought to make systematic reviews structured and navigable; just as a qualified driver can more or less get into any car and start to drive the experienced systematic reviewer encounters a common structured and easily navigable format when reading most reviews. Cochrane reviews follow a standard template whereas, more generally, systematic reviews and now even protocol documents, are required to follow standard reporting formats such as PRISMA [22], ENTREQ [23], and PRISMA-P [24]. Use of these standard formats also makes it easier to assess systematic reviews for quality and applicability as the checklists are designed around a generic review structure.

Of course an initial challenge relates to how to navigate around the evidence landscape in the first place; how does a busy decision-maker find the item of evidence upon which he can subsequently base his/her decisions? Information specialists at McMaster University have devised the 'Six S pyramid' [25], an information seeking hierarchy where you drill down through successive layers (or types) of evidence until you find an item that addresses your question. The six layers are shown in **Table I**.

### **Looking for evidence and appraising it for quality**

When looking for evidence for a particular decision the decision-maker therefore follows a three step process. First, they clearly specify the information that they need. Next, they work their way through the pyramid drilling down until they find evidence that looks appropriate to their question. Finally, they assess that item of evidence to determine whether it is good enough (internally valid) and whether it is appropriate (externally valid) to the decision-making context.

### ***So how does this apply in practice?***

#### **A Realistic Scenario**

30% of Halfway's adults and over 20% of children (at age 10) are 'obese' – worse than national/regional averages. A task group is set up to review healthy eating among children and young people in Halfway. The Task Group wishes to start by targeting sugar-sweetened drinks, being particularly concerned at the high consumption of these drinks in the local kindergartens, primary schools and secondary schools. They ask you to lead on identifying appropriate evidence for producing a 'Sugary Drinks Policy'.

**Table I.** 6S Evidence Seeking Pyramid Schema

Layer	Definition	Example
Systems	Systems integrate information from further down the hierarchy with individual patient records/population data, offering an ideal resource for decision-making.	Proprietary decision support systems
Summaries	<b>Summaries</b> are regularly updated guidelines or textbooks that integrate evidence-based information about specific problems.	National Guideline Clearinghouse; DynaMed Plus, UptoDate
Synopses of syntheses	<b>Synopses of syntheses</b> , summarize information found in <b>systematic reviews</b> . They focus on the conclusions from products further down the hierarchy presenting only sufficient detail to support decision-making.	Cochrane Summaries; Cochrane Podcasts
Syntheses	Best known as systematic reviews, a synthesis represents a comprehensive summary of all relevant evidence for a clearly defined review question.	Cochrane Library
<b>Synopses of single studies</b>	<b>Synopses of single studies</b> summarize evidence from high-quality studies and are typically found in evidence-based abstract journals.	Evidence-Based Medicine ACP Journal Club
Single studies	<b>Studies</b> represent reports of unique research conducted to answer a specific question.	MEDLINE, CINAHL, PsychINFO

Source: Own elaboration based upon G. Guyatt, *Users' Guides to the Medical Literature: a Manual for Evidence-Based Clinical Practice, 2nd ed.*, American Medical Association. Evidence-Based Medicine Working Group, McGraw-Hill Medical, New York, London 2008 [4].

**Table II.** Populated 6S framework for sugar-sweetened drinks

Layer	Reference
Systems	None Available.
Summaries	A duty on sugar-sweetened beverages. A position statement.
Synopses of syntheses	Sugar-Sweetened Beverages and Obesity among Children and Adolescents: A Review of Systematic Literature Reviews [26].
Syntheses	Evidence that a tax on sugar-sweetened beverages reduces the obesity rate: a meta-analysis [27].
Synopses of single studies	Children who consumed sugar-sweetened beverages between meals $\geq 4-6$ times/week at 2.5-4.5 years of age were more likely to be overweight at 4.5 years of age [28].
Single studies	Grab a Cup, Fill It Up! An Intervention to Promote the Convenience of Drinking Water and Increase Student Water Consumption During School Lunch [29].

Source: Own elaboration.

A framework, such as that shown in Table II, can be populated relatively efficiently by using five principal resources:

- 1. PubMed Clinical Queries** – <http://www.ncbi.nlm.nih.gov/pubmed/clinical> – a filtered resource offering a subset of only clinical studies and systematic reviews from the PubMed database.
- 2. Cochrane Library** – <http://www.cochranelibrary.com/> – premier source of references and full text reviews covering systematic reviews and controlled trials.
- 3. PubMed Special (Health Service Research) Queries** – <https://www.nlm.nih.gov/nichsr/hedges/search.html> – a filtered resource offering a subset of only health service research studies and qualitative research studies from the PubMed database.
- 4. TRIP (Turning Research Into Practice)** – <https://www.tripdatabase.com/> – a meta-search engine of high quality evidence sources.
- 5. SumSearch 2** – <http://sumsearch.org/> – another meta-search engine that searches high quality medical sites.

## Shifting the focus to complex interventions

Increasingly practitioners, policymakers, and researchers within the public health community are shifting their collective attention to the evaluation of so-called complex interventions. What is a complex intervention? The United Kingdom Medical Research Council's (MRC) guidance 'A framework for development and evaluation of RCTs for complex interventions to improve health', published in 2000 [30] and revised and extended in 2008 [31] describes complex interventions as being 'built up from a number of components, which may act both independently and inter-dependently' [30]. These components include behaviours, behaviour parameters and methods of organising those behaviours, and they may have an effect at individual patient level, organisational or service level or population level (or all of these in some cases):

The canvas on which public health operates is broader than [clinical medicine]. It also works at the levels of individual human mind and collective social behaviour and its delivery is at community, population and societal levels. This introduces disciplines which do not have the same analytic foci as biomedicine and operate with differing epistemological precepts, different methods and produce different types of evidence [32].

Other features contributing further to this complexity include the numbers of components and their interactions, behaviours, organisational levels and outcomes, the variability of desired outcomes and the degree to which flexibility or tailoring of the intervention is permitted.

This interest in evaluation of complex interventions derives from an imperative to further develop the evidence base on the effectiveness of healthcare and public health interventions. Furthermore it marks increasing awareness that evaluation must acknowledge the challenges faced as we move along the spectrum from 'simple' towards more complex interventions [33]. This focus on complexity is also driven by ongoing debate about the most appropriate methods for evaluating health systems. Increasingly the dialogue is being framed not just in terms of whether health system interventions 'work', but also about when, why, how and in what circumstances such interventions work well [30, 31].

There is some debate about whether the complexity is a feature of the intervention, the context or the lens through which the decision problem is being viewed. Commonly observers label an intervention 'complex' purely as a negative attribute, that is not being 'simple'. However, it is challenging to define any intervention as 'simple'. Take, for example, taking a pill or tablet. Superficially, this intervention looks simple [34]. A patient takes a tablet, the tablet affects the patient's metabolism to a greater or lesser degree and in a reasonably predictable percentage of cases the tablet achieves its desired effect. In this case the causal chain appears reassuringly short and simple. However, is the taking of the tablet truly the beginning of the causal chain? What factors determined whether the patient would present to the doctor in the first place? How does the doctor decide that the

tablet is required? Does the patient believe that the treatment will work? Does the doctor believe that the treatment will work? What further influences impact on the decision – the patient's friends and relatives, the doctor's experiences with other patients? Is the patient a priority when compared with the needs of other patients with differing degrees of severity? Will the patient keep taking the tablet outside the initial evaluation period? Will there be harmful effects?

For many of us the presence of any human interaction or motivation makes an intervention complex. While such a view makes undoubted sense it is poorly able to discriminate between interventions. While the intervention itself may not necessarily be delivered by a human (in contrast to human-mediated interventions such as counselling, physical therapy or speech and language therapy) it is almost certainly going to be prescribed by a human and, failing that, it relies on the attitudes and behaviours of a human, a patient, in order to achieve its effectiveness! In this sense, then, all interventions are complex. Consequently, it makes more sense to describe the evaluation lens as being either simple or complex. We can examine a decision problem through a simple evaluation lens, such as a Population-Intervention-Comparison-Outcome (PICO) question [35], requiring a limited number of evidence sources (e.g. on effectiveness and cost effectiveness). Alternatively, we can scrutinise that same decision problem through a complex evaluation lens, requiring mapping using a logic model [36, 37], and an almost infinite number of types of data; quantitative and qualitative, textual, numerical and graphical, local, national and international, from research or from anecdote etcetera [38].

Trying to apply the laser-like RCT approach [from clinical medicine] is akin to trying to light up a football field with a slowly moving laser pointer – very precise, rigorous, and artificially intense but not very illuminating [39].

Consequently, Petticrew evokes the terminology of design in describing the challenges of representing what are known as 'wicked' real world problems [40].

To explore the inherent complexity of simplicity let us further examine the example of sugar-sweetened beverages. On the face of it the decision as to whether to have drinks vending machines in school is a fairly simple one. To have a drinks machine or not have a drinks machine – that is the question. It can be framed in a standardised PICO format:

**Population** – school children

**Intervention** – a drinks vending machine

**Comparison** – a water cooler, or no vending machine

**Outcome(s)** – consumption of sweetened beverages, sugar intake, and ultimately childhood obesity.

However, when we start examining the problem more closely we identify greater complexity. For example, if sugar sweetened drinks are not available in the school would children bring them from elsewhere? Might this lead to them being late for school or leaving the school premises at break times? Could this have implications for road safety and the likelihood of pedestrian accidents

among this age group? Might it be preferable to offer a limited number of lower sugar drinks in the school than for them to purchase cheap high sugar content drinks elsewhere? Could it be that by making a decision to prohibit vending machines the school authorities are actually missing the chance to influence the children's nutritional behaviour in a more directive, positive manner?

As mentioned above, the evidence based healthcare narrative has thus moved in recent years from 'what works' to 'what works for whom under what circumstances' [41]. This recognises that, for example, under one set of circumstances or contextual factors removing the vending machines is the correct decision. However, under a different set of circumstances, as in a different population, the correct decision is to keep them. So, for example we may establish that older teens are less likely to be at risk outside the school premises during their lunch break but that 11–13 year olds are at a high risk of pedestrian accidents. We may make different recommendations for these two different populations.

Recent years have seen increased interest in engaging with theory when seeking to interpret evidence from systematic reviews. Reasons for this include recognition that use of theory may result in a more generalizable explanation for how a complex intervention is thought to work. In considering theory, we need to understand essential differences between grand-, mid-range and programme theories. A grand theory, for example a theory of social inequality, is formulated at a high level of abstraction. Grand theories are designed to facilitate generalisations across different domains [42]. In contrast, mid-range theories are theories with a specific area of application that lie between 'minor working hypotheses' and the 'all-inclusive speculations comprising a master conceptual scheme'. Typically designed by academic researchers, mid-range theories may help those developing and delivering a service by helping them to understand a decision problem. Programme theories are 'small' theories that are specific to a particular programme or intervention [42]. Programme theories are purposely designed to be practical and accessible. As a working model a programme theory seeks to specify (i) components of a programme (or intervention) intended to mitigate or solve a decision problem, an intervention's expected outcomes and the methods for assessing those outcomes, often taking the form of a logic model; (ii) the programme's 'theory of change', that is the rationale and assumptions about mechanisms that link a programme's processes and inputs to intended and unintended outcomes, as well as specifying the context necessary for effectiveness. Thus a fully specified programme theory contributes both pictorial and narrative features to help understand a complex intervention [42]

Clearly this level of complexity is much less likely to be captured by the monolithic PICO question formulation. Increasingly therefore, as mentioned above, those reviewing the evidence use logic models to capture the complexity of the initial decision problem, to guide the extraction of data and to communicate and present the final results. Logic models are narrative or graphical de-

pictions of processes in real life that communicate the underlying assumptions upon which a specific activity is expected to lead to a specific result. Logic models thus illustrate a sequence of cause-and-effect relationships on a path towards a desired result [43].

**Box 1.** *How Do Things Work? (Programme Theories, adapted from Tille) [41]*

Mechanisms whereby reduction of sugar-sweetened beverages may impact on childhood obesity:

- a) If children view ads containing sugar-sweetened beverages they are **more likely to view consumption of such drinks as normalised behaviour and purchase those drinks.**
- b) If schools prevent children from purchasing sugar-sweetened drinks at school then students are more likely to compensate with **external purchase of inferior drinks with a higher sugar content.**
- c) If soft drink manufacturers sell sugar-sweetened drinks in larger bottle sizes then **children are more likely to consume higher quantities of sugar-sweetened drinks.**
- d) If children drinking sugar-sweetened beverages do not feel as full as from the corresponding amount of calories of solid food then they are **less likely to compensate by drinking less.**
- e) If children consume higher quantities of sugar-sweetened drinks then they find themselves at **higher risk of type 2 diabetes.**

...etcetera.

## Towards new evidence products

A new generation of review products seeks to pay attention to conceptual (i.e. theory) or contextual detail within the process of synthesis. Recently a group of methodologists within the Cochrane Collaboration has sought to explore diverse ways in which theory might be incorporated within a review [44]. Review methods such as best fit framework synthesis [45–47] seek to use an initial theory as a scaffold and then to populate this with data from included studies. Data can either be qualitative or quantitative. Furthermore, systematic review teams are starting to use new methods of review such as realist synthesis [38] underpinned by the same cause-and-effect logic that underpins logic models. Realist review is attractive in offering a flexible alternative to traditional systematic review approaches, recognising that health services are delivered in a complex, multi-faceted and dynamic environment [48]. Given the continual changes that take place within a particular context and population, and even within a single intervention, it becomes of limited value to be able to say that an intervention works on average or to a certain extent.

Realist review seeks to provide explanations for why interventions may or may not work, in what contexts, how and in what circumstances. For example, Greenhalgh and colleagues sought to explain the apparently limited success demonstrated by a Cochrane review of school feeding programmes [49]. Applying the realist review approach they demonstrated that while school feeding programmes might guarantee that the recipient has nutritional intake from at least one meal a day this efficacy was subverted because parents of a child participating in such a programme displaced that child's food at home to their siblings.

As the above suggests the realist approach involves identifying underlying causal mechanisms and exploring how they work under what conditions. The stages of a realist review do share some similarities with conventional systematic reviews. They include defining the scope of the review, using methods such as concept mining and framework formulation; searching for and scrutinising the evidence; extracting and synthesising the evidence; and developing the narrative, including hypotheses [48]. Generally however this tends to be an iterative and recursive process, moving between generating theory and then testing it using data from included programmes. Realist synthesis lends itself to the review of complex interventions because it accounts for context as well as outcomes in the process of systematically and transparently synthesising relevant literature. While realist synthesis demands flexible thinking and the ability to deal with complexity, it offers potential for more pragmatic conclusions than alternative systematic review approaches. Of particular relevance to this paper is that realist synthesis offers a mechanism for making use of other types of data in explaining exactly what is going on within a particular programme. This also requires detective work in the form of following up leads to all possible reports associated with a particular study [50].

### ***A case study – TURNUP***

Put simply a realist synthesis looks for patterns in the evidence (such as variation in outcomes) [51]. The synthesis then seeks to explain the relationships underlying these patterns through the use of theory [52]. So, for example, we might sort a group of studies on baseline attendance rates for particular health services from highest to lowest. We then might observe that studies that send out a general non-personalised invitation (such as for donation of blood) have lower baseline attendance rates than those that represent a personalised invitation. At the top of the list we might identify studies where a patient is scheduled to receive a particular intervention, as opposed to a general examination, or preparation for a future health event (such as a pre-operative assessment) or studies where parents are bringing their children to an appointment. We might theorise that the greater the extent to which an invitation to appointment secures a commitment from the patient the more likely that patient is to attend. Related to that parents may demonstrate more commitment to an appointment for their child than for their own appointment. We can then use quantitative and qualitative data to explore these hypotheses and articles accessing theory to suggest what commitment involves [53].

The advantages of realist synthesis are best illustrated by an example. In 2012 a team of reviewers from the two universities in Sheffield were commissioned to conduct a systematic review of Appointment Reminder Systems [54]. We aimed not only to review the plentiful effectiveness literature but also to gain a better understanding of how such systems achieve their effect. Using realist evaluation principles, we sought to gain an insight into whether particular technologies, such as SMS messages,

emails, phone calls, or postcards worked better for particular populations. The review of effectiveness revealed little if any difference in effect between appointment reminders received one week before an appointment from those received two weeks prior to the appointment.

Furthermore, while the literature problematized ‘the forgetful patient’, evidence suggests that forgetfulness is a minor consideration [54]. Patients miss appointments for all sorts of reasons – claiming to have forgotten their appointment (a simple mistake) is typically viewed less judgementally than missing the same appointment because something better had come up (a deliberate choice). Therefore, a patient may consider it more acceptable to claim to forget even where this was not their genuine reason for non-attendance. This explains, at least in part, the minimal difference between reminders sent one- or two weeks ahead of the appointment. Having dispelled an overall ‘myth of the forgetful patient’, although the myth undoubtedly pertains in some cases, we can then choose a reminder system that facilitates the filling of slots that have become vacant with replacement patients who are given sufficient notice (counter-intuitively two weeks rather than one week) to attend. Scheduling of the appointments is thus privileged over the assumptions of the universally forgetful patient. Other behavioural insights included the fact that posting an announcement of how many people kept their appointments was more efficient than posting a similar announcement with how many people had missed their appointments [55] – the latter risks legitimising the problem behaviour of non-attendance. The movement within this review from single lens complexity to the realisation that evidence operates within complex systems theory is an important advance in evidence production [56–58].

Although we tried to answer ‘which appointment reminder systems work for which populations under what circumstances’ we encountered difficulties in using the evidence base. Existing trials reported an average for appointment attendance over the entire population, not figures for individual population subgroups. However, we were able to challenge other persistent ‘myths’ about appointment attendance. For example, researchers often assume that people who live local to a hospital or clinic are more likely to attend than those who live more remotely. In actuality there was limited evidence to suggest that patients ‘batched up’ their visits to hospital to make them more efficient [59]. Having multiple appointments on the same day may increase the perceived importance of the appointed day making a patient travelling from distance more likely to attend.

In addition to realist synthesis methodologies, relating to cause and effect, we can improve our understanding of what is happening within a given context using narrative-based approaches to review of the evidence [60]. For example, Swinglehurst and colleagues, when studying repeat prescribing, identified three different narratives for what was taking place within a primary care setting [61]:

1. local artefacts such as repeat prescribing protocols (**the proxy routine**);



2. abstracted understandings held by staff of how a routine is enacted (**the so called ostensive routine**), arrived at by asking ‘what gets done, by whom, and how?’; and
3. the range of ways in which the routine is actually enacted (**the performative routine**), arrived at by direct observation.

The existence of multiple narratives has implications for any evaluation activity. If the received wisdom on an intervention varies so greatly then we need to combine documentation (to identify what should be done), narrative (to capture what is understood about how things are done and observation (to perceive what is actually done) [61].

## Other types of evidence

The literature on decision-making tells us that other forms of evidence are important when contemplating innovation:

Public health questions are only sometimes answered by RCTs and that evidence drawn from other methods and designs would have to be appraised. It was recognised too that the data and evidence that would be drawn upon in the public health work would be broad and go beyond medical science to include the social sciences [32].

Such a conclusion is unsurprising given a shortage of RCTs in many areas. Take housing for example – it is estimated that a good RCT only appears in connection with housing once every twenty years [62]. In this ‘gold standard vacuum’ good practice from other, preferably comparable, settings or contexts may help to inform our choice of interventions. However, we should recognise that such good practice is typically unevaluated good practice. The criteria by which a project is labelled good practice are often unclear. In performing reviews of the evidence for health service delivery for the National Institute for Health Research we have found it important to identify relevant initiatives from the United Kingdom, even where they are unevaluated. A useful useable report therefore includes both rigorous and relevant material. Each type of evidence has its place but it is important to recognise that these types of evidence are not interchangeable. We can compare their respective roles to the stages of brainstorming where the generation of items (what could be done – good practice) is separated from deliberation on their value (what should be done – research evidence). Both RCTs and good practice are ways of improving the coverage of the evidence base:

Building an evidence base is analogous to laying a floor-on the one hand you could cover the terrain with large carefully interlocking research studies rather like laminated flooring, on the other hand you could painstakingly piece together a myriad of service evaluations like a Roman mosaic [63].

In addition to challenges associated with the assessment of good practice significant obstacles relate to the actual identification of good practice. Good practice examples offer a compelling way to demonstrate actual instances where a planning system has been able to con-

tribute to a healthier local environment. They are thus able to help to identify where partnerships between public health and planning departments have succeeded in the past, with the implication that such success can be replicated in future programmes. However, the multi-disciplinary nature of public health and health services research has important implications for the sources being utilized. ‘Practice-based’ evidence (case studies from areas that have attempted similar work), are afforded a low subordinate place in the typical hierarchy of evidence and yet typically prove valuable for decision-makers. This explains in part why commentators prefer to refer to taxonomies of evidence, rather than the single monolithic evidence pyramid.

Consider for example if we were conducting a desk-based review on the topic of the influence of the environment on obesity. Clearly we would have to start by narrowing down the topic; there are so many different ways in which the environment might have an impact. We might start by producing some form of conceptual framework, logic model or evidence-based map of obesity drivers. From this we might identify clear families of intervention types. For example, we might seek to control unhealthy consumption of certain types of food and drink, for example by introducing restrictions on hot-food takeaways. Alternatively, we might take positive steps to increase the availability of healthy food and drink, for example by offering incentives for the sustainment and growth of farmers’ markets. As yet another alternative we might seek to increase opportunities for local food production, for example by offering incentives for the redevelopment of allotments and agricultural land.

We can already identify how diffuse the evidence base might be if we were to produce a briefing on just these three policy options. We might seek to facilitate international comparisons so that we can determine whether countries with higher densities of fast-food outlets actually have higher levels of obesity. In contrast reviews of smaller scale studies may report conflicting findings on the fast-food/obesity association, given that fast-food takeaways frequently cluster around schools. From socio-economic studies we might find good evidence that poverty and area deprivation act as barriers to the purchase of fresh or unfamiliar foods. However, some social commentators may maintain that culture and habits exert a stronger influence on eating patterns than spatial planning.

Academic evidence linking the built environment to diet and health is likely to prove suggestive, but not conclusive. Questions about causality persist, particularly as it is not feasible to establish cause and effect through RCTs. We would also seek to examine existing public health policy which might be more influential among planning colleagues than an uncertain academic evidence base. They might reason that if planning decisions are aligned with existing policy demonstrates willingness to balance potentially competing interests (e.g. health and economic growth). Other important evidence might include guidance from evidence producing bodies such as the World Health Organisation or national bodies such

as the National Institute for Health and Care Excellence (NICE).

Last, but by no means least, we would seek to access good practice. This may lie in diffuse and relatively uncontrolled sources. We may seek to identify innovation from details from research in progress, from academic web pages or from research registers, or from the Web pages of funding bodies. Beacons of good practice are often included as case studies in government reports or those produced by independent organisations or consultancies. Innovation may also be captured through early-stage reports such as feasibility studies, pilot studies and unpublished process evaluations. Typically, in a UK context, we conduct searches of the general Web limited to health service (nhs.uk), academic (ac.uk), or government (gov.uk) web sites [64, 65] and this approach is likely to be transferable to other countries.

### What is wrong with the evidence we have?

Many feel that we have not yet realised the full potential offered by systematic reviews of the evidence. Essentially the systematic review process strips study reports of their all-important context in a quest to facilitate comparison between otherwise different looking published reports. However detail of context is needed if users of the reviews are to understand how the context of included studies has contributed to the success or failure of particular programmes and the extent to which lessons learnt from elsewhere can be applied to a target population and context [66, 67]. This requires that those producing systematic reviews expand their brief to cover these important contextual issues or adopt a wider or more versatile toolkit of review methods in order to deliver what decision-makers need for the future. Paradoxically this may require that review authors utilise those aspects of a report previously left on the ‘cutting room floor’. Such elements may include the Background and Setting of trial reports, the Discussion section as a potential source of theorising and accompanying process evaluations that supply important contextual detail.

### The way forward?

What is required to take evidence based decision-making into a new age? First, we need more joining up of health services research (the content of the evidence base) and health informatics (the delivery mechanism for the evidence base). This requires development of both information professionals and decision-makers so that information specialists achieve a better knowledge of the characteristics of well-constructed evidence:

Public health decision-making requires knowledge of not just whether something works under particular circumstances but also how, when, and why for broad application [39].

As implied above, such a multi-faceted view of what works under what circumstances requires that evidence producers and stakeholders work together on surfacing theory, context and mechanisms. Correspondingly man-

agers need to develop a greater awareness of the potential of information technologies to deliver that evidence. Over the last decade several information professionals and managers have sought to identify and document that knowledge [68–70]. This requires that all disciplines exploit the unique multidisciplinary nature of evidence based health information.

It may prove most feasible to target ‘quick wins’ where short causal chains can be identified, so as to demonstrate a direct and immediate effect on population health and well-being. The mention of health and well-being is significant here. The increasing greying of the population and the increasing burden on health service expenditure requires a transfer of attention from ‘sick care’ and health services to more upstream interventions targeting achievement of a healthy population. Greater involvement of multi-agencies, from outside the health sector, further requires understanding of the use, value and production of evidence within these different sectors. So, for example, in the United Kingdom evidence based social care contributed a focus on individual client needs and preferences, offering a useful counterpoint to the population emphasis of evidence based public health [71]. While challenges of building research and evaluation capacity exist for all sectors we can conclude that public health is much further evolved than its counterparts in social care [72] and other aspects of public management (e.g. housing, transport and employment).

Above all we require to effect a cultural transformation such that ‘evidence based’ becomes so pervasive, as the preferred way of making resource decisions, that we no longer need the label to imply that this is something different or special. It should be just the way it is!

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