Real World Evaluation Strategies
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Introduction

Public health interventions are by nature complex and are implemented in contexts and with social actors who have a mutual influence on each other. It thus becomes nearly impossible, and more or less irrelevant, to control the interventions or to find direct causal relationships. It follows that most public health interventions are natural experiments for which appropriate methodological fit should be the gold standard. Therefore, researchers should adopt a pragmatic, non-dogmatic position; be responsive; and adapt to the natural environment of the real world (as there is no such thing as a laboratory setting for public health interventions). Because of their complexity, we need to go beyond just knowing the interventions’ effects; we also want to know how those effects are produced, for whom, and under what circumstances. Methods should be selected that allow us to understand the inherent complexity of public health interventions. The social sciences have contributed significant methodological suggestions to the field of evaluation of complex interventions. In this context, the war of paradigms is unproductive. However, taking into account real-life situations does not mean abandoning the use of theories, conceptual frameworks, or the intervention theories identified in the preevaluation phase (evaluability assessment). Moreover, the issues related to an evaluation often extend beyond just methods. Budget constraints need to be considered, as well as the usefulness of the responses to the questions and concerns in terms of effecting change in practices and interventions (see the Oxford Bibliographies article “Knowledge Translation and Exchange”). Beyond studying effects, it also becomes essential to examine interventions’ implementation (fidelity and adaptation) and operationalization, as well as their relevance, appropriateness, sustainability, and acceptability. Thus the evaluation questions and concerns should guide the methods, and not the reverse. To the extent possible, we will present all these consubstantial aspects of a pragmatic and real-world evaluation approach from a conceptual perspective and then illustrate their application. (The authors wish to thank Donna Riley for translation and editing support.)

Journals

Generally speaking, interdisciplinary journals in the public health field publish evaluations, including those that meet the criteria described in this article. For this reason, those journals are not listed here. Notable exceptions are Global Health Promotion, which focuses specifically on the themes of population health and health promotion, and the Milbank Quarterly, which does not hesitate to offer evaluations using innovative methods, such as realistic evaluation. The American Journal of Evaluation and Evaluation are devoted to advancing practices and knowledge about evaluation and represent streams of thought from both sides of the Atlantic. The Journal of Mixed Methods Research and Qualitative Health Research also publish real-world evaluations, but from a methodological perspective, which is their focus. Finally, given that the aim of real-world evaluation is also to respond to questions arising from the field, Implementation Science is useful for understanding issues concerning the use of knowledge coming out of evaluation and research in the health field.

American Journal of Evaluation. 1981–.
Formerly *Evaluation Practice* (1981–), this journal is known for having hosted a debate between Carol H. Weiss and Michael Quinn Patton on the use of evaluation. The interdisciplinary journal aims to advance both theoretical and practical knowledge about evaluation.

*Evaluation*. 1995–.
This is a European journal devoted to evaluation in several fields, including health.

*Global Health Promotion*. 1994–.
Although it does not specialize in evaluation, this journal regularly publishes evaluations of programs in health promotion and population health and also provides more theoretical articles in this field. Articles may be in English, Spanish or French, and all supplements are open access.

*Implementation Science*. 2006–.
This open-access journal focuses on the use of research and evaluation in the health field. The journal contains not only empirical articles, but also articles that are conceptual or theoretical.

*Journal of Mixed Methods Research*. 2007–.
The primary aim of this journal is to advance knowledge and practice with respect to mixed-methods research in the social sciences, humanities, and health. For this reason, particular attention is given to empirical studies, particularly evaluations.

*Milbank Quarterly*. 1923–.
Formerly *New York Health Demonstrations* (1923–1930), the *Milbank Memorial Fund Quarterly Bulletin* (1931–1933), the *Milbank Memorial Fund Quarterly* (1934–1972), and the *Milbank Memorial Fund Quarterly, Health and Society* (1973–1985). This is a high-caliber journal that concentrates on different types of evaluations, as well as on theoretical and conceptual reflections on evaluation, in the fields of health and health policy.

*Qualitative Health Research.*
This is one of the few journals that have allowed qualitative research specialists to demonstrate the relevance of this approach in the field of health sciences, especially through program evaluations.

**Moving from Randomized Clinical Trials**
This section presents some fundamental references to gain a comprehensive view of the elements specific to a real-life evaluation approach. Petticrew 2013; Petticrew, et al. 2005; and Rootman, et al. 2001 discuss the nature of evidence and intervention complexity. Bamberger, et al. 2006 and Patton 2008 explain how to deal with multiple evaluation constraints, such as time, budget, policies, and access to data. Patton 2008 stresses the importance of taking into account results use in
choosing evaluation approaches. Gilson 2012 calls for consideration of the context and social actors in evaluating interventions, especially in low- and middle-income countries. Chelimsky 2013 and Patton 2008 highlight the importance of methodological fit and appropriateness.


Based on their numerous experiences with evaluation practice around the world, the authors advise looking at constraints related to time, resources, data access, and, finally, policy. They propose seven steps for carrying out such evaluations. Numerous examples are provided. An essential text for anyone starting out on this path.


The author recommends more systematic dialogue between evaluation theoreticians and evaluators. There will always be tension between scientific requirements and the constraints of real-world evaluation. Such dialogue would be beneficial for guiding the selection of research design, discerning evaluation issues more clearly, and overcoming the challenges of results use.


This is a synthesis of concepts on and approaches to research on systems and policies in the context of real-world evaluation strategies, where the questions guide the methods, and not the reverse. The focus is on strategies for increasing research rigor and validity. An annotated list of reference articles is included to illustrate the concepts.


The culmination of long experience of practice and reflexive analysis, this foundational book gives a general introduction to the evaluation process. Patton stresses the imperative of ensuring that evaluation results are useful and used. He suggests numerous tools and strategies for achieving this, which he illustrates with an abundance of examples.


Petticrew nuances the debates on evidence hierarchies by placing emphasis on their utility for public health policy. He believes that randomized control trials have utility but that, in viewing them as the gold standard, we lose sight of both the methodological challenges of complex interventions and decision makers’ needs and expectations regarding scientific evidence.


In this reference article, the authors make a case for conceiving the evaluation of public health interventions as natural
experiments. The authors propose that researchers do not take sufficient advantage of opportunities to conduct such evaluations, whereas there is a demand for them among decision makers.


This book is the fruit of a major collective reflection on evaluation approaches best suited to health promotion. The authors present a general framework for analysis, concentrating on an approach that deals with the values, contexts, and complexity of programs and offering numerous examples on a variety of topics.

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**The Multiple Epistemological Foundations**

Whether anchored in practice or part of a scientific research process, evaluation cannot easily be envisioned outside the framework of certain epistemological principles from which it derives legitimacy. In this section, we present three streams of thought in which context is considered to be a key element in understanding interventions: constructivism, pragmatism, and complexity. Constructivism is the cornerstone of the seminal work by Guba and Lincoln 1989 on evaluation. Schwartz and Lellouch 2009 discusses pragmatism in the specific frame of therapeutic trials, whereas Robson 2011 bases the entire research process within a pragmatic stance. Complexity, notably conceptualized by the French philosopher Edgar Morin (Morin 2005), is at the heart of Pawson's work on the realistic approach to evaluation (Pawson 2013) and is envisioned in Tremblay and Richard 2014 as the future paradigm for health promotion.


Fourth generation evaluation is founded on two principles: taking into account stakeholder concerns and conducting evaluations from a constructivist perspective. Guba and Lincoln stress the ontological foundations and methodological issues of this type of evaluation, which is firmly anchored in practice and incorporates context.


In this essay, Morin invites readers into his complex thinking. Using concrete examples drawn from basic and social sciences, history, and literature, he provides keys to looking beyond linear causality as a way of understanding the world. For an English introduction to Morin’s thinking, see the author’s 2008 *On complexity* (Creskill, NJ: Hampton Press).


In his most recent work, Pawson revisits the epistemological foundations of the realistic approach to evaluating interventions. He presents the theoreticians who inspired him, the seven characteristics of complex interventions, and the foundations of the realistic approach. Numerous examples advance understanding of how realistic evaluation should be conducted. Additional references on realistic evaluation are included.

This is a teaching manual on social sciences research in which all the stages of a research process are explained, as well as the different paradigmatic perspectives. The authors, firmly grounded in a pragmatic perspective, compare fixed and flexible designs, mixed methods, and action research processes.


Originally published in 1967. A foundational article containing the essential arguments for using the pragmatic paradigm, even in evaluations with controlled trials. That the article was reprinted suggests that the authors’ call for researchers to take more pragmatic intellectual positions has not yet been sufficiently heeded.


The authors describe the relationship between the complexity paradigm and health promotion principles, not only at the epistemological level, but also at the theoretical and methodological levels. They recommend grounding health promotion in this paradigm to give it a disciplinary basis.

**Design and Nature of Data**

Beyond paradigmatic issues, taking into account complexity and the real world when evaluating complex interventions will influence the study design and methods employed to respond to research questions. This section offers the essential writings on the main designs, approaches, and methods associated with this pragmatic and realistic position. Yin 2013, Yin 2014, and Simons 2009 are important readings for understanding the case study approach to evaluation. Creswell and Plano Clark 2011 and Tashakkori and Teddlie 2010 elaborate on the mixed-methods paradigm, design, and instruments and provide interesting examples. Patton 2002, Patton 2011, and Maxwell 2004 show how qualitative methods may be the most appropriate to study complexity.


In this manual the authors present the foundations of mixed-method research, propose a classification of possible research designs based on the research subject, and describe the research process for each design, supported by examples. Each chapter concludes with practical activities and supplementary bibliographic references.


In a rare article on this subject, Maxwell shows how qualitative data can help explain causal relationships in evaluating an intervention. He addresses issues of philosophical credibility and rigorous methodological practice related to this possibility and recommends distinguishing between explanations stressing variables and those stressing processes and mechanisms.

This book is the ideal companion for conducting intervention evaluations using qualitative data. The entire qualitative approach is covered in detail; all the useful tools are included, many examples are given, and questions about sampling, validity, and generalization from data are comprehensively discussed.


Renowned for his utilization-focused evaluation approach (see Patton 2008, cited under Moving from Randomized Clinical Trials), Patton here puts forward another evaluation strategy, in which the evaluator guides stakeholders through a process of evaluative reflection, with the aim of improving the intervention as it is being implemented. This is essential, because interventions must necessarily adapt to a dynamic context and complex realities.


This manual outlines a different but complementary method of carrying out case studies, mainly concentrating on single case studies and using qualitative methods anchored in a naturalist paradigm. The book suggests several steps and concludes with a chapter on case study myths and how to counteract them.


This book is a gold mine for understanding the issues concerning mixed methods in the social sciences, especially as they apply to evaluation. Numerous contributors offer conceptual and theoretical reflections, and many chapters provide practical examples of ways of combining qualitative and quantitative data. Issues of validity are also addressed in several chapters.


The author reviews the methodological challenges of case studies in program evaluation, specifically with regard to internal and external validity. He submits several solutions (rival explanations, triangulation, and so on) and encourages the reader to pursue further examination of the case study method for evaluation.


Case study is undoubtedly the most appropriate methodological strategy for studying complex interventions in real-life contexts. Yin explores the entire range of approaches to single and multiple case studies, with one or more levels of analysis, contrasted or exemplary. He proposes a stepwise process and furnishes numerous examples for each step.

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**Evaluability Assessment**

A first step in any evaluation is to verify that we are actually able to carry it out. This is the preevaluative phase, or evaluability assessment. This essential step uncovers the intervention theory and presumed causal relationships, as well as issues related to use of results and the stakeholders involved.
THEORY


An important activity in evaluability assessment is the description of the theory of the intervention. This can be done by the evaluator alone, but can also be done with the stakeholders. This article provides a simple, clear, and illustrated presentation of how to engage stakeholders in describing the logic of their intervention.


The authors propose a six-step process for performing an evaluability assessment of a complex intervention and suggest a list of the elements that should, at the end of that process, make up the evaluation plan.


The author summarizes the use of the preevaluative phase over a twenty-year span by analyzing twenty-three studies. Useful for understanding how evaluability assessments have been conducted. The author concludes with recommendations for improving them.


In one of the few books devoted to this subject, the author covers the entire process for the preevaluative phase. He posits that four conditions must be met before an evaluation is possible and details several steps to follow in carrying out this preliminary process.

CASE STUDIES

These four articles contain field examples of how evaluability assessments are conducted—D’Ostie-Racine, et al. 2012, with a nongovernmental organization in Africa; Afifi, et al. 2011 and Thurston, et al. 2003, using a participative approach; and Sanou, et al. 2011, for a national vaccine program.


In the same vein as Wholey 2004 (cited under Evaluability Assessment: Theory), this case study demonstrates how it is possible to involve an intervention’s stakeholders in developing the program’s theory, showing again that the process is possible in a sensitive context.

This is one of the rare case studies carried out in the field of humanitarian aid. The study reveals not only how useful the evaluability assessment process can be for understanding an intervention, but also how feasible it can be, even in contexts where it is not often practiced.


This useful article discusses an evaluability assessment done in Africa, spelling out the entire process and providing details about the tools used. The article concludes with a very interesting reflexive analysis of the process.


In this Canadian case study the authors detail their evaluability assessment and analyze the process. They underline how the assessment was useful to stakeholders in clarifying the components, objectives, and target public for their mental health intervention. The evaluability assessment became a process for improving the intervention.

### Implementation Evaluation

Evaluating the impacts of interventions is useful but not sufficient, as it is also essential to understand how the impacts were achieved and, when they were not, why not. This understanding is facilitated by analysis of the implementation process, the roles of the actors involved, and the context. Moreover, for an intervention to meet its objectives, it needs to be implemented according to plan. Evaluating the fidelity of implementation thus also becomes a very useful tool.

### THEORY

The seminal article, Dobson and Cook 1980 shows the importance of analyzing implementation, which is further emphasized by the meta-analysis in Durlak and DuPre 2008 of the factors that reduce the effectiveness of interventions. Linnan and Steckler 2002 reviews the history and concepts underlying implementation analysis, and, more recently, Peters, et al. 2013, a World Health Organization guide on this subject, attests to the importance being given to this type of evaluation at the international level.


This fundamental article adapts the concept of type I and II errors, used in epidemiology, to propose a type III error, which consists of evaluating a program when it is not implemented according to plan. The article examines especially the concept of dose response in the scope of an intervention's impacts.

This quantitative meta-analysis shows how the implementation of interventions can influence their impacts, demonstrating in particular that the potential effectiveness of interventions can be reduced by nearly 50 percent, as they are generally subjected to many limiting factors related to implementation. The study proposes a framework for analyzing the effectiveness of implementation.


In this synthesis the authors review the history of the process evaluation concept and of the various analytic frameworks proposed. The authors analyze the use of these frameworks in public health and recommend seven dimensions to be studied. They conclude by suggesting a series of steps for conducting a process evaluation.


Based on an analysis of the literature, this book is a complete guide for studying implementation. The authors propose a definition of implementation study, show its utility, and present a list of eight implementation outcomes. The authors also describe the process of conducting evaluations and survey possible methods, all covered in this article.

**CASE STUDIES**

Empirical studies on implementation are still in short supply, but these articles present four examples, showing the range of possible approaches. Butterfoss 2006 is a major synthesis of the literature on the subject, whereas Walker and Gilson 2004 provides a classic example of the importance of studying the roles of the actors in the implementation. Hasson, et al. 2012 adapts a classic framework for the analysis of implementation fidelity, and Pérez, et al. 2013 underlines the need to go further and give attention to the adoption of interventions.


This literature survey analyzes how process evaluations were conducted in order to study interventions that used community participation. In particular, the article describes various methods of data collection.


This empirical study builds on the analytic framework of Carroll, et al. (2007) and improves on it by studying the role of context and participant recruitment. In-depth qualitative analysis demonstrates how certain factors influence implementation fidelity.
The authors suggest associating this framework with specific analyses of relationships between factors modifying implementation.


Inspired by Everett M. Rogers's five-stage conceptual model of the innovation–decision process, this article clearly illustrates how those stages can be used to study implementation beyond the concept of fidelity. The analysis was conducted in Cuba, looking at a participative implementation process for an intervention to control dengue fever. The article discusses how the intervention was adopted, modified, and adapted by local actors.

Walker, Liz, and Lucy Gilson. 2004. ‘We are bitter but we are satisfied’: Nurses as street-level bureaucrats in South Africa. *Social Science & Medicine* 59.6: 1251–1261.

In this case study conducted in South Africa, the authors analyze the implementation of a health policy in depth. They stress the importance of studying the role of frontline actors to understand a policy's process.

**Realistic Evaluation**

Realistic evaluation aims to understand how interventions work (or not), for whom, and under what circumstances, a now-famous evaluation question. Realistic evaluation is rooted in critical realism, on the premise that reality can be known but can only be apprehended through our senses. Causation is generative, and not successionist, as understood in the post-positivist paradigm. According to generative causation, an intervention does not produce outcomes per se, but rather certain mechanisms are activated in certain contexts. Realistic evaluation is particularly useful for understanding complex social interventions, such as public health policies and programs. Its core principles are also used to conduct realistic reviews.

**THEORY**

Realistic evaluation has been the subject of many conceptual publications, especially by Ray Pawson, who is its figurehead, and Nick Tilley (Pawson and Tilley 1997) as well as Henry, et al. 1998. Realistic evaluation is part of the stream of theory-based evaluation, of which Huey-Tsyh Chen (Chen 2004) and Carol H. Weiss (Weiss 1997) are emblematic figures. One of the core concepts of this type of evaluation, the mechanism, is defined in Astbury and Leeuw 2010. Realistic evaluation is making its way into the panoply of evaluative approaches in public health, as shown by the case studies.


The core subject of this article is the concept of mechanism, which is at the heart of realistic evaluation. The authors review the different definitions of this concept in the various evaluation traditions and explain its meaning within a realistic perspective.


Chen shows that theory-based evaluation can be used to carry out effective program evaluations, to the extent that evaluation
sponsors are guided in identifying strategies and approaches that best respond to their needs. He proposes a taxonomy and four steps to achieve this.


The authors position their reflections within a perspective they call emergent realist evaluation. Combining their experience as evaluators with the principles of realism, they propose a new theory of evaluation that is responsive to the concerns of sponsors.


This is the foundational text on realistic evaluation. The authors present the fundamental concepts of the realistic approach to program evaluation. In particular, they compare the contributions of this type of evaluation with those of experimental approaches and provide concrete examples of realistic evaluations outside the field of health.


The author reviews the tenets of theory-based evaluation, the stream within which realistic evaluation fits. She presents twelve challenges that appear to have limited the use of theory in evaluation and offers conceptual clarifications and methodologies for overcoming each of these.

CASE STUDIES

There are few realistic evaluations and reviews conducted in the field of public health, and most are found in health systems and health-care organization research, as shown by the following case studies. Byng, et al. 2008 details a realistic evaluation of interventions in mental health, whereas Marchal, et al. 2010 focuses on health-care organization and performance. McMahon and Ward 2012 uses realistic review in the field of HIV prevention. Because the realistic approach is an evaluative innovation, some authors have adopted a reflexive position to highlight the practical challenges of conducting realistic evaluation or review, as evinced in Robert and Ridde 2013.


The authors demonstrate the advantages of combining a randomized control trial with a qualitative realistic evaluation to examine the black box of a mental health intervention.


The authors used realistic evaluation to understand the mechanisms at work in the management approach practiced in a regional hospital in Ghana. The authors followed the principles of realistic evaluation rigorously, drawing methodological lessons from their experience.

The concepts of critical realism have been adapted to systematic reviews, or realistic reviews. This article is an excellent example of an application to a preventive health intervention. The numerous supplementary files reveal the complexity and depth of this review, especially with respect to understanding the mechanisms at work.


In a didactic style, the authors present, to a francophone audience of evaluators and students, the bases and concepts of the realistic approach. The authors illustrate these concepts with a case study (realistic review), highlighting the methodological challenges encountered.

**Evaluation for Practice**

Besides theoretical and conceptual works on evaluative research, some authors have written on and developed a particular expertise in the concrete implementation of evaluations. The processes these authors propose, which are very diverse, are perfectly suited to the realities and contexts of public health interventions and are often geared toward fostering the use of research results in knowledge transfer activities. Reason and Bradbury 2001, Craig 2009, and Israel, et al. 2013 are textbooks that provide both detailed explanations and empirical illustrations. Bryson, et al. 2011 and Ir, et al. 2010 also present some illuminating examples. Morell 2010 is one the few works to explore the issue of unintended effects, which are often encountered but rarely studied. See also Weiss 1998 and the *Oxford Bibliographies* articles “Action Research” and “Community-based Participatory Research.”


This article is intended to be practical, as it gives evaluators numerous tools for involving stakeholders throughout the evaluation process. The examples presented are very useful for understanding how to use the tools.


This is one of the best manuals for teaching action research, with the author guiding the reader through the different steps of the process. This is an excellent book for students, with numerous examples and exercises to facilitate learning.


This article is a very good empirical illustration of how it is possible to analyze a posteriori how progressive construction of evidence through pilot projects fostered the emergence of public policies that promote equity in health.

The product of a great many experiences, this book covers all aspects of action research practice. The many chapters are written by academics and practitioners who offer both theoretical reflections and a wide range of concrete applications and tools. Also included are several very useful technical appendices.


Although evaluators most often focus on whether public health interventions have achieved their intended objectives, very few have also examined unintended effects. This is one of the rare books to explore this topic. The work demonstrates the importance of anticipating the surprises that emerge during evaluations and contains numerous illustrative case studies.


This book is the perfect starting point for studying the concepts and practice of action research, a useful research approach for fostering the use of results. The book has conceptual and theoretical material, but most chapters provide examples of action research conducted in many countries and in different fields of study.


Weiss, who for a long time debated the use of evaluation with Michael Quinn Patton, poses three questions framing the issues: What do we mean by use? What is used from evaluation? Who are the users? She reminds us that collective actors, such as organizations and the public, are also potential users.

**Pragmatic Trial**

The initial call of Schwartz and Lellouch 2009 (cited under Multiple Epistemological Foundations) appears not to have been sufficiently heard, say Patsopoulos 2011 and Tosh, et al. 2011, and in the early 21st century, particularly in the field of clinical research and randomized clinical trials (RCTs), several works, such as Treweek and Zwarenstein 2009 and Glasgow 2013, have encouraged researchers to return to a more pragmatic position. At the same time, however, this call could also be heard by researchers evaluating public health interventions (Fairall, et al. 2012, Ridde and Haddad 2013), as the tenets of this approach stress that decision makers are looking for research that offers solutions.


In this scientific presentation the authors explain the relevance of a pragmatic approach, which they illustrate by comparing RCTs conducted in South Africa on HIV. The use of the pragmatic-explanatory continuum indicator summary (PRECIS) tool is
also illustrated.


The author reviews the essential characteristics of a pragmatic approach and discusses the PRECIS tool. He compares this approach with both an intervention model and a classic evaluation model (reach, effectiveness, adoption, implementation, maintenance [RE-AIM]). The author stresses the importance of participative processes and the use of research results.


This article revisits the fundamental elements of the pragmatic approach in clinical trials and its value in analyzing the effectiveness, but not the efficacy, of interventions. The author analyzes the development of pragmatic trials and reviews the criticisms of them. He also concentrates on the importance of involving decision makers in the research process.


The authors briefly review the basic principles of a pragmatic approach. The article is useful in that it presents two examples of evaluative research on population-based interventions. Most of the concepts we address are illustrated here.


This is a detailed presentation of the PRECIS tool for evaluating studies, using RCTs, on the basis of ten criteria, scored from one to five. Each criterion’s dimensions are explained, and examples of mental health interventions illustrate differences between a pragmatic RCT and a classic explanatory RCT.


This article covers all the steps researchers should follow in conducting pragmatic trials. The authors stress the importance of taking context into account and describing it in detail. Offering two illustrative examples, they suggest that issues of applicability of results should be studied and advise researchers to focus on how results can be used.