HEALTH INTERVENTION RESEARCH

Understanding Research Design & Methods

SOURAYA SIDANI

HEALTH INTERVENTION RESEARCH

SAGE was founded in 1965 by Sara Miller McCune to support the dissemination of usable knowledge by publishing innovative and high-quality research and teaching content. Today, we publish more than 750 journals, including those of more than 300 learned societies, more than 800 new books per year, and a growing range of library products including archives, data, case studies, reports, conference highlights, and video. SAGE remains majority-owned by our founder, and on her passing will become owned by a charitable trust that secures our continued independence.

Los Angeles | London | Washington DC | New Delhi | Singapore

HEALTH INTERVENTION RESEARCH

Understanding Research Design & Methods

SOURAYA SIDANI

SAGE

Los Angeles | London | New Delhi
Singapore | Washington DC

Los Angeles | London | New Delhi
Singapore | Washington DC

SAGE Publications Ltd
1 Oliver's Yard
55 City Road
London EC1Y 1SP

SAGE Publications Inc.
2455 Teller Road
Thousand Oaks, California 91320

SAGE Publications India Pvt Ltd
B 1/I 1 Mohan Cooperative Industrial Area
Mathura Road
New Delhi 110 044

SAGE Publications Asia-Pacific Pte Ltd
3 Church Street
#10-04 Samsung Hub
Singapore 049483

First published 2015

Editors: Michael Carmichael and Jai Seaman
Editorial assistants: Keri Dickens and Lily Mehrbod
Production editor: Katie Forsythe
Copyeditor: Jane Fricker
Proofreader: Sarah Cooke
Indexer: Silvia Benvenuto
Marketing manager: Camille Richmond
Cover design: Wendy Scott
Typeset by: C&M Digitals (P) Ltd, Chennai, India
Printed and bound by CPI Group (UK) Ltd, Croydon, CR0 4YY

Library of Congress Control Number: 2014936874

British Library Cataloguing in Publication data

A catalogue record for this book is available from the British Library

ISBN 978-1-4462-5616-9
ISBN 978-1-4462-5617-6 (pbk)

CONTENTS

ABOUT THE AUTHOR

Souraya Sidani is Professor and Canada Research Chair at the School of Nursing, Ryerson University. Her areas of expertise are in quantitative research methods, intervention design and evaluation, treatment preferences, and measurement. Her research areas of interest focus on evaluating interventions and advanced practice roles, on examining patient preferences for treatments, and on refining research methods and measures for determining the clinical effectiveness of interventions.

PREFACE

In an era characterized by an emphasis on evidence-informed practice, research plays a central role in helping us understand human conditions, behaviors, and emerging problems; and identifying interventions that effectively address the problems and promote well-being. Empirical evidence on the effects of treatments guides decision making regarding the selection, implementation, and evaluation of interventions to improve various domains of life at the local, national, and international levels. However, to be useful, research studies must be well planned and executed. Careful planning involves the selection of research designs and methods that 1) are appropriate to capture the problem under investigation, 2) are consistent with the study's purpose and aims, 3) ensure validity of the inferences and minimize potential biases, and 4) are feasible within the context in which they are applied. Careful execution consists of developing a detailed study protocol, adhering to it when carrying out research activities (i.e., recruitment, data collection, implementation of the intervention, and data analysis), and closely monitoring the study in order to ensure quality of performance, and to identify and remedy any challenges or deviations.

A range of research designs and methods is available to study the effects of interventions. Some have been commonly considered as the most useful in generating credible evidence, and others have been advanced as plausible alternatives in response to recent critique of commonly used designs and methods. The critique was prompted by the realization that most, if not all, designs and methods are based on assumptions and recommendations which have been taken for granted and not been systematically and critically evaluated. These are derived from logic that may no longer be tenable in light of accumulating experience and emerging empirical evidence. Specifically, the adoption of the experimental or randomized controlled trial as the 'gold standard' for determining the effects of interventions was based on theoretical reasons and intuitive attractiveness rather than a compelling evidence base of data. Empirical evidence derived from meta-analyses shows that results of randomized trials and well-designed non-randomized studies evaluating the same interventions are comparable in determining the success of the intervention. These findings raise questions about the necessity and utility of randomization in reducing selection bias and enhancing validity of causal inferences. Randomization increases the likelihood that study groups are similar at baseline, but it does not guarantee it. Further, it introduces biases related to who takes part

in studies and the influence of their perception of the intervention on treatment adherence and outcomes. Practical, pragmatic trials and partially randomized clinical or preference trials have been proposed to enhance representativeness of the sample, account for participants' treatment preferences, and reduce attrition. Similarly, evidence is emerging that questions the utility of other methods such as the use of placebo.

This book represents a compendium of research designs and methods, encompassing commonly used ones and recent advances that can be used in the evaluation of interventions. The book content describes the theoretical, empirical, and practical knowledge required in choosing among designs and methods for intervention evaluation. Theoretical knowledge covers the logic underlying different designs and methods; it provides the rationale or the 'why' for methodological decisions. Empirical knowledge looks at the results of studies that investigate the effectiveness, utility, or efficiency of different methods; it informs the 'what', 'when', and 'where' of methodological decisions. Practical knowledge involves descriptions of the procedure for implementing different research methods; it points to the 'how' for carrying out selected methods. The aim is to inform researchers of the nature and effectiveness of various designs and methods. This information is essential to 1) make researchers aware of different designs and methods, each having its strengths and limitations at the theoretical and empirical levels, 2) assist researchers in making appropriate decisions related to the selection of most suitable methods that best fit the context of particular studies, 3) help researchers recognize that methodological decisions should be based on evidence rather than mere traditional recommendations which may not be well supported logically and empirically, and ultimately 4) move the research enterprise out of the 'inertia' of using commonly recommended designs and methods that produce empirical evidence of limited utility to decision making and policy development, and into the world of generating, testing, and using alternative relevant designs and methods.

ACKNOWLEDGEMENTS

The author gratefully acknowledges the encouragement, support, and informal feedback from colleagues and students, and the instrumental support of staff at the Health Intervention Research Center (Sarah I. and Laura C.).

1

AN OVERVIEW OF HEALTH INTERVENTION RESEARCH

Intervention forms a central element of healthcare in primary, acute, rehabilitation, and long-term care settings. Healthcare professionals assess clients' condition to identify the problems requiring remediation, select and implement interventions to effectively address the problems, monitor clients' responses to interventions, and evaluate their achievement of beneficial outcomes. Healthcare professionals include physicians, nurses, allied health therapists such as respiratory, physical, occupational and speech language therapists, psychologists, social workers, and health educators. They implement interventions, independently or collaboratively, that target problems manifested in different domains of health and experienced by individuals, families, groups (defined in terms of socio-cultural or clinical characteristics), or the entire community. The selection and implementation of interventions are informed by the best available evidence of their success in producing beneficial outcomes (Guyatt et al., 2002).

Research is widely recognized as a source of evidence because of its systematic process aimed at making valid inferences about the causal effect of the intervention on outcomes. Research is guided by a comprehensive understanding of the intervention, and of the notions of causality and validity. In this chapter, the logic of intervention research is described relative to the notion of causality. It rests on a lucid knowledge of the intervention and its contribution to the hypothesized outcomes, as delineated next. Validity is discussed in Chapter 2.

HEALTH INTERVENTION RESEARCH

Health intervention research involves the systematic evaluation of the merit, worth, or value of interventions. The value of interventions is indicated by the extent to which the

interventions are appropriate, safe, and effective in managing clients' problems and in improving their health. The goal of health intervention research is to demonstrate the causal relationship between interventions and anticipated outcomes. The causal relationship implies that the interventions, and no other contextual factors, are responsible for inducing the beneficial changes in outcomes. Evaluation of the interventions' effects on outcomes requires an understanding of the problem that the intervention targets, the intervention, the outcomes, the mediators or mechanisms through which the intervention exerts its effects on the outcomes, and the moderators or factors that influence the intervention effects.

Problem

Problems are alterations in clients' health condition that put them at risk for illness or that interfere with their engagement in healthy behaviors and activities of daily living. The alterations include: bio-physiological malfunctions such as high blood sugar and hypertension; physical limitations such as difficulty walking; cognitive impairment such as delirium; emotional symptoms such as anxiety; engagement in risky behaviors such as smoking; and social issues such as isolation. An understanding of the problem clarifies its nature, manifestations, determinants, and level of severity. Nature of the problem refers to the domain of health in which it is experienced. Manifestations are the indicators (i.e., signs and symptoms) that point to the occurrence of the problem. Determinants are causative factors that contribute to the experience of the problem. Level of severity reflects the intensity with which the problem is experienced. This understanding of the problem is necessary for determining the appropriateness of the intervention and for guiding the design of the intervention evaluation study.

Interventions are considered appropriate when they are reasonable and logical in that they specifically address the problem requiring remediation (hereafter referred to as health problem). The nature of the intervention fits with the nature of the health problem. Awareness of the nature, determinants, and manifestations assists in identifying the aspects of the health problem that are amenable to change and hence, targeted by the intervention. Also, it is instrumental in delineating intervention strategies that are consistent with the modifiable aspects of the health problem and, hence, relevant in addressing or resolving it (Lippke and Ziegelman, 2008; Slater, 2006). Knowledge of the level of severity with which the health problem is experienced helps in specifying the dose at which the intervention is given to induce the desired changes in the problem experience (Sidani and Braden, 2011). Congruence between the health problem and the intervention enhances the specificity of the intervention. The intervention targets what exactly and significantly contributes to the health problem; it does not address its 'wrong' aspect and therefore, miss the target (Green, 2000; Nock, 2007). The specificity of an intervention increases its effectiveness.

A thorough understanding of the health problem informs the identification of the client population and the sample selection criteria for the intervention evaluation study.

The population is generally defined relative to the experience of the problem targeted by the intervention. The sample selection criteria are specified to ensure that persons report the particular aspects of the problem specifically addressed by the intervention. These persons are expected to benefit most from the intervention.

Intervention

Health interventions are treatments, therapies, procedures, or actions that are implemented by healthcare professionals to, with, or on behalf of clients, in response to the health problem with which clients present, to improve their condition and achieve beneficial outcomes. Interventions consist of a set of interrelated activities that healthcare professionals perform; the activities reflect the cognitive, verbal, and physical functions within the scope of the professionals' practice. Health interventions include bio-physical treatments such as medications or administration of intravenous fluids; physical procedures such as surgical removal of a cyst and therapeutic massage; psychological, cognitive, behavioral, motivational, and educational interventions to promote engagement in healthy lifestyle; and social actions such as facilitating social gathering of older adults residing in long-term care institutions.

Understanding of an intervention taps into its goals, specific and non-specific elements, mode of delivery, and dose. An intervention's *goal* refers to its overall direction, that is, what the intervention is set to achieve relative to the targeted health problem, such as prevention, management, or resolution of the problem, and to the clients' general condition such as improved functioning. The *specific elements* are the active ingredients that characterize an intervention and distinguish it from others. The active ingredients are theoretically expected to induce changes in the health problem and clients' general health condition. The *non-specific elements* are strategies or activities that facilitate the implementation of the active ingredients but are not anticipated to contribute to changes in the health problem and the clients' condition (Hart, 2009; Stein et al., 2007). For instance, stimulus control therapy is a behavioral intervention for the management of chronic insomnia. Its primary goal is to assist persons to re-associate the bed and the bedroom with sleep. Its active ingredients consist of instructions regarding activities to avoid (such as reading or thinking) and activities to do (such as getting out of bed if one can't fall asleep) around bedtime. Its non-specific elements include monitoring the application of the instructions for feedback and discussing barriers to the implementation of the instructions. *Mode of delivery* reflects the medium, format, and approach for offering the intervention. Medium is the means through which the intervention is given, which can be oral (e.g., facilitation of group discussion on barriers to healthy behavior performance), written (e.g., distribution of pamphlet), and hands-on (e.g., surgery, massage). Format is the specific technique used for providing the intervention. Different formats are available such as face-to-face meetings or videotaped presentations within the oral medium, and booklet and computer-based application within the written medium. Approach is the structure selected for providing the intervention, which can be standardized or tailored.

In a standardized approach, the same intervention is carried out in the same way, at the same dose, across all clients. In contrast, a tailored approach consists of customizing the intervention, its mode of delivery, and its dose, to be responsive to clients' characteristics, needs, and preferences. *Dose* is defined as the level at which the intervention is to be given in order to successfully achieve the preset goals. It is operationalized in terms of amount (i.e., number of sessions, length of each), frequency (i.e., number of times the sessions are given within a specified period of time), and duration (i.e., total time period for giving all sessions).

Knowledge of the intervention's goals, active ingredients, non-specific elements, mode of delivery, and dose gives direction for the operationalization of the intervention. This, in turn, facilitates its implementation with fidelity and monitoring its delivery. Implementation of the intervention with fidelity in an intervention evaluation study is critical for initiating the mechanisms responsible for producing the outcomes (Borrelli et al., 2005).

Operationalization of the intervention consists of translating the knowledge of the intervention's goals, active ingredients, and non-specific elements into components and activities that are performed within the selected mode of delivery and dose, by the healthcare professionals responsible for delivering the intervention (hereafter referred to as interventionists) and by clients receiving the intervention. A *component* is a set of interconnected activities that address one modifiable aspect of the health problem or that target a particular domain of clients' general condition. The number of components determines the level of intervention complexity. Simple interventions comprise a single component, for example, acupressure for the management of nausea and vomiting, or education for enhancing clients' knowledge of factors that trigger dyspnea. Complex interventions involve multiple components. The components may address different aspects of the health problem or domains of clients' general conditions. For example, a diabetes self-management program would include a component aimed at increasing clients' engagement in physical activity and a component aimed at promoting a low carbohydrate diet. The components may also represent different strategies to manage the same problem; the strategies may target individuals (e.g., cognitive and behavioral strategies to improve adoption of health behaviors), or several constituents in a community (e.g., behavioral strategies for individuals, organization of support groups, and involvement of the community in maintaining safe neighborhoods, to increase participation in physical activity). A list of specific activities is generated to operationalize each component and integrated into a meaningful sequence of activities to be carried out, in the specified mode, within and across all intervention contacts or sessions. A detailed description of these specific activities is compiled in the intervention protocol, which is detailed in a manual.

The nature of the intervention's specific activities point to the professional qualifications and personal characteristics required of the interventionists. The interventionists should have the professional qualifications (e.g., formal training, licensing) that enable them to carry out the intervention activities, as determined by respective regulatory bodies. Some personal characteristics (e.g., gender, ethnicity) may be important to facilitate delivery of some interventions such as those addressing sensitive topics to some client populations. For example, women are more comfortable discussing sexuality issues with female interventionists.

The intervention protocol is foundational for training interventionists in the competencies required for an appropriate implementation of the intervention (Borrelli et al., 2005). The competencies relate to the conceptual underpinning of the intervention and the practical skills for carrying out its activities. Through intensive training, interventionists should gain an understanding of the health problem targeted by the intervention; the intervention's goals, active ingredients, non-specific elements, mode of delivery, and dose; and the mechanisms responsible for producing its effects on the outcomes. The interventionists also should be familiar with the intervention protocol, the rationale for each specific activity, the standards for carrying out the activities, potential challenges in carrying out the activities and ways to manage them (Sidani and Braden, 2011).

The intervention protocol serves as the reference for implementing the intervention and for developing instruments to monitor fidelity of intervention implementation. Interventionists are requested to follow the protocol when delivering the intervention. The activities to be performed are incorporated in an instrument for assessing the fidelity of implementation (Stein et al., 2007). Fidelity refers to the consistency between the actual delivery and the original design of the intervention; that is, the specific activities constituting the intervention are carried out as specified in the protocol. Deviations in the implementation of the intervention from its original design and across clients result in inconsistency in the intervention activities to which clients are exposed. This inconsistency contributes to variation in the level of outcome improvement reported by clients following implementation of the intervention, which reduces the power to detect significant intervention effects (Carroll et al., 2007; Leventhal and Friedman, 2004).

Furthermore, knowledge of the intervention's active ingredients, non-specific elements, and dose is necessary for:

1. Selecting the comparison treatment that serves as a control condition for determining the effects of the intervention on outcomes. The comparison treatment should not contain components or activities that may reflect the intervention's active ingredients in order to maintain a clear distinction between the two treatments and maximize the difference in the outcomes.
2. Identifying the most appropriate time, within the trajectory of the health problem, to provide the intervention such as before, during, or following its experience.
3. Determining the most accurate methods for collecting data on the intervention dose to which clients are exposed and for conducting dose-response analyses, which is important in specifying the optimal dose associated with beneficial outcomes.

Outcomes

Outcomes represent the consequences of the intervention. They capture the changes in a clients' condition expected to take place following receipt of the intervention and reflect

the criteria for determining its benefits. Outcomes are derived from the goals of the intervention and classified into immediate and ultimate outcomes. Immediate outcomes entail the expected changes in the aspects of the health problem that are directly targeted by the intervention, and occur within a short time interval after the implementation of the intervention. Immediate outcomes are operationalized as modifications in the health problem's determinants, manifestations, or level of severity. Ultimate outcomes include resolution of the problem and improvement in other aspects of clients' general condition such as prevention of illness and promotion of healthy functioning. Achievement of ultimate outcomes follows changes in the immediate outcomes. Therefore, the immediate outcomes mediate the effects of the intervention on the ultimate outcomes. For example, stimulus control therapy is designed to assist persons with insomnia to re-associate the bed and the bedroom with sleep. Application of its instructions is expected to reduce the time it takes to fall asleep and the time awake after sleep onset, which yields an increase in sleep efficiency (immediate outcomes). Increased sleep efficiency is associated with the perception of low levels of insomnia severity (resolution of the problem), which decreases daytime fatigue and improves physical, psychological, and social functioning (ultimate outcomes).

Understanding the nature, classification, and interrelationships among outcomes has implications for outcome assessment and analysis in the intervention evaluation study. Awareness of the outcomes' nature directs their operationalization. Each outcome should be clearly defined at the conceptual level; its domains and dimensions that are expected to demonstrate changes post-intervention delivery (i.e., post-test) are identified, as they will guide the selection of the instrument to measure the outcome. A correspondence between the outcome domains and dimensions as defined conceptually and as captured in the content of the instrument is required to accurately assess the outcome and quantify the changes in the outcome. For example, the cognitive, more so than the physical, domain and the intensity, more so than frequency, dimension of daytime fatigue are expected to improve after delivery of the stimulus control therapy.

Classification of outcomes into immediate and ultimate informs the specification of the anticipated pattern of change in the outcomes. Usually, significant changes in immediate outcomes are hypothesized to take place within a short time (e.g., 1 week) post intervention and maintained over time (e.g., 9 months). No or small changes in ultimate outcomes are expected immediately following intervention delivery; however, the amount of change is anticipated to increase gradually over time. The anticipated pattern of change helps in specifying the points in time following implementation of the intervention to assess the outcomes; carefully planning the post-hoc comparisons to determine when the changes in outcomes actually occur; and interpreting statistically significant or non-significant findings related to the intervention effects on the immediate and ultimate outcomes at different time points post-intervention.

Knowledge of the interrelationships among the outcomes is necessary for elucidating the mechanism underlying the intervention effects and for planning outcome analysis accordingly.

The analysis focuses on examining the direct impact of the intervention on the immediate outcomes and the indirect effects of the intervention on the ultimate outcomes.

Mediators

The mechanism underlying the intervention effects reflects the pathway of changes that are responsible for producing the anticipated improvement in the outcomes. It refers to the series of events or alterations in status that occur during and after receipt of the intervention and that mediate the effects of the intervention on the ultimate outcomes (Nock, 2007; Vallance et al., 2008). The mechanism is operationalized in a causal path that links the delivery of the intervention with the mediators and subsequently the ultimate outcomes. There are three general categories of mediators: clients' reactions to the intervention, enactment and adherence to the intervention, and immediate outcomes.

Clients' reactions to the intervention include their understanding of the treatment recommendations they are expected to carry out in their day-to-day life (Borrelli et al., 2005) and their satisfaction with the intervention (i.e., perceived usefulness of treatment in managing the presenting problem). Client reactions contribute to the enactment (i.e., initiation) of and adherence (i.e., consistent and appropriate application) to the treatment recommendations. Clients who develop a good grasp of what the treatment is about and view it as helpful in addressing the health problem are likely to engage in the intervention and perform the treatment recommendations in the correct way and at the prescribed dose in their daily life (Carroll et al., 2007). Adherence to treatment yields improvement in the immediate outcomes, which in turn is associated with changes in the ultimate outcomes. To illustrate, the following generic mechanism underlies the effects of an educational intervention on quality of life: 1) clients attending all sessions of the intervention gain an understanding of the information relayed and find it meaningful, that is, suitable to address the problem, applicable within the context of their lifestyle, and useful in producing the outcomes of interest to them; 2) clients showing these favorable reactions to the intervention retain the information taught and apply it; 3) clients who apply properly what they learned experience improvement in the immediate outcomes; and 4) improvement in the immediate outcomes motivates clients to continue application of the treatment recommendations and produces the ultimate outcomes.

Understanding the mechanism mediating the intervention effects on the ultimate outcomes guides the following aspects of the intervention evaluation study:

1. Generation of conceptual definitions of the mediators, which directs their operationalization and selection of instruments to measure them directly;
2. Delineation of the points in time during and following the implementation of the intervention at which the mediators are to be assessed; and
3. Specification of the path model for testing the hypothesized interrelationships among receipt and dose of the intervention, mediators, and ultimate outcomes.

Moderators

Moderators are factors that influence the implementation of the intervention, the mechanism underlying its effects, and/or the achievement of ultimate outcomes. The moderators include characteristics of the clients who receive the intervention, the interventionists who deliver the intervention, and the setting within which the intervention is implemented. Client characteristics influence the experience of the health problem; for instance clients with a particular characteristic may experience a severe level of the problem, which may not be successfully managed by the intervention. Client characteristics affect the understanding, enactment, or adherence to treatment recommendations; for example, clients with low levels of education or high levels of cognitive impairment may not fully grasp the treatment, precluding them from applying the recommendations appropriately; thus, they do not show the expected improvement in outcomes. Client characteristics influence responses to the intervention; clients with a particular characteristic or certain level of the characteristic respond more favorably than others to the intervention. The favorable responses are exhibited in higher improvement in immediate and ultimate outcomes. For example, clients who lead an active lifestyle prior to cancer therapy report larger reduction in fatigue after receiving a behavioral intervention to promote physical activity, than those who had a sedentary lifestyle.

Interventionists' characteristics relate to their personal qualities (e.g., communication skills) and professional qualifications (e.g., experience working with the target population). These characteristics may interfere with the implementation of the intervention. For example, interventionists with poor communication skills may not relay information about treatment recommendations clearly and in simple terms. Interventionists' characteristics may affect the development and maintenance of a working alliance with the clients. This alliance impacts clients' satisfaction with and adherence to treatment, and improvement in outcomes (Dinger et al., 2008; Fuertes et al., 2007).

Setting characteristics relate to physical (e.g., high ambient temperature during performance of relaxation, and non-availability of walking trails in the neighborhood) and social (e.g., gender composition of clients attending a group session to discuss intimate sexual behaviors for the prevention of HIV, and neighborhood safety) features of the environment in which the intervention is delivered or the treatment recommendations are applied. Some features facilitate and others hinder performance of a subset or all intervention activities by the interventionist, and of the treatment recommendations by the clients.

Understanding of the moderators has implications for the design of the intervention evaluation study. Client characteristics that interfere with the implementation of the intervention, the trigger of the intervention mechanism, and the achievement of outcomes are considered potential confounds, and are controlled experimentally or statistically. Experimental control is exerted by screening clients and excluding those who have the characteristics. Statistical control is done by including clients with these characteristics, collecting pertinent data, and

residualizing their influence when examining the intervention effects. Interventionist characteristics that affect the intervention delivery are specified and used for selecting interventionists, and are addressed during training. Clients' perception of the interventionists' working alliance is assessed and accounted for when evaluating the intervention effects. Setting characteristics guide site selection and assessment of the site features, particularly if more than one site is included in the study. Differences across sites are accounted for at the stage of data analysis.

AIMS OF INTERVENTION RESEARCH

The overall goal of intervention research is to generate evidence that supports the appropriateness, safety, and effectiveness of interventions in producing the beneficial outcomes. The evidence is used to develop guidelines that inform healthcare professionals' practice. To help in directing healthcare professionals' decision making about client care, empirical evidence synthesized across studies evaluating the same intervention has to provide answers to the following clinically relevant questions: What clients, presenting with which personal, health, and clinical characteristics, benefit most from which treatment, given at what dose, in what mode, and in what context?

Underlying these questions and relevant empirical evidence is the notion of causality. In other words, the evidence should demonstrate that the intervention causes the outcomes and that this causal relationship is robust, meaning that it is observed when the intervention is implemented by different healthcare professionals, to different clients, in different contexts, and in different modalities and doses.

CAUSALITY

A causal relationship is a structural relation that underlies the dependence among phenomena (*Stanford Encyclopedia of Philosophy*, 2008). In intervention research, the focus is on demonstrating the causal relationship between the intervention and the outcomes. This is accomplished by determining the causal dependence of the outcomes on the intervention. Causal dependence means that changes in the outcomes are contingent on the receipt of the intervention in that improvement in the outcomes occurs in the presence of the intervention and conversely, no changes in the outcomes take place in the absence of the intervention. This view of causal dependence is rather simplistic and deterministic, emphasizing the direct connection between an intervention and an outcome, and ignoring the context in which the intervention is implemented and the mechanisms through which the intervention produces its effects (Pawson and Tilley, 1997).

There is increasing acknowledgement of multi-causality in the health field. Multiple factors, experienced in different domains of health (e.g., physical, psychological) and at different

levels (e.g., individual, community), are recognized as determinants of the health problems of clients requiring remediation. For instance, engagement in a healthy behavior is conceptualized as a function of the interpersonal, intrapersonal or individual, institutional or organizational, community, and public policy factors (National Institutes of Health, National Cancer Institute, 2005). The complexity of these problems demands multi-component interventions to comprehensively address them. Multi-component interventions contribute to changes in several interrelated outcomes. Accordingly, the simplistic view of causal dependence is no longer tenable, yielding a reformulation of causality as a chain representing the set of conditions that promote the connection between the intervention and the outcomes, and the interdependence among the intervention and the outcomes (Cook, 1993; Tilley, 2000). This notion of multi-causality highlights the importance of examining the mechanisms that mediate the effects of an intervention on the outcomes; and the factors that could moderate the ability of the intervention to trigger the mechanism and to produce the intended effects on the outcomes.

The criteria for inferring simple and multi-causality are temporality, covariation, contiguity, congruity, and ruling out plausible alternative causes of the intervention effects (Larzelere et al., 2004; Shadish et al., 2002). Although the same criteria are used, the evidence required to support the criteria differs slightly when inferring simple or multi-causality.

Temporality

Temporality has to do with the temporal order of the cause and the effect, where the cause should occur prior to its effects. Thus, the intervention has to precede changes in the outcomes in order to logically attribute the improvement in outcomes to the intervention. If the changes in the outcomes are observed before the implementation of the intervention, then they cannot be linked to the intervention because the changes in outcomes occurred irrespective of the intervention. To determine temporality, the outcomes should be assessed before and after delivery of the intervention. Changes in the level of the outcomes that are observed post-intervention represent the evidence to support temporality in simple and multi-causality.

Covariation

Covariation is the criterion that operationalizes causal dependence. It implies that the changes in the outcomes occur when the intervention is delivered, and do not occur when the intervention is not given. Covariation is often demonstrated by creating two groups of persons who experience the health problem targeted by the intervention. The groups are comparable in all respect except receipt of the intervention; that is, the intervention is given to one group and withheld from the other group. Evidence required for inferring

covariation should show comparability of clients in both groups before implementation of the intervention, changes in the outcomes in the hypothesized direction among clients who receive the intervention, no changes in the outcomes among clients who do not receive the intervention, and significant differences in the outcomes between the two groups assessed post-intervention (Shadish et al., 2002).

The utility of having the two groups to demonstrate covariation is being questioned on two grounds. First, historically the effectiveness of several interventions, such as insulin for decreasing high blood glucose, blood transfusion for hemorrhagic shock, and closed reduction for fracture, was established in a series of case studies rather than comparison of outcomes for clients who did and did not get treatment (Cook et al., 2010; Glasziou et al., 2007). Second, withholding the intervention may be unethical, which is the case when equipoise (i.e., not knowing whether treatment is better than no treatment) cannot be maintained (e.g., antibiotics to control septicemia) when the target population is in critical, immediate need for treatment (e.g., severely dehydrated infants), and when depriving clients from the intervention is associated with unfavorable reactions that negatively contribute to the outcomes (i.e., clients who do not receive the intervention exhibit worsening of the outcomes). In these instances, covariation can be inferred from repeated observations of the same clients under two conditions: 1) when they are not offered the intervention (which precedes the second condition) and 2) when they receive the intervention. Outcomes are assessed before and after each condition. Evidence indicating no changes in the outcomes following the first condition (i.e., no treatment) and significant changes in the outcomes after the second condition (i.e., treatment), supports the criterion of covariation (Rossi et al., 2004) in simple and multi-causality.

Contiguity and Congruity

Contiguity has to do with the time lag between implementation of the intervention and the occurrence of changes in the outcomes. In simple causality, the changes in outcomes are expected within a short time interval following the intervention delivery. In multi-causality, changes in the immediate outcomes take place within a relatively short time interval after the implementation of the intervention, whereas changes in the ultimate outcomes occur within a long time interval and once the immediate outcomes are achieved.

Congruity reflects the magnitude of the changes in the outcomes, which should be congruent with the nature and dose of the intervention. In simple causality, interventions that are highly specific to the health problem, intense, and of high dose, are expected to yield large changes in the outcomes. In multi-causality, congruity is considered in association with contiguity, based on outcome data gathered repeatedly following implementation of the intervention. The evidence supporting these criteria includes: 1) large changes in the immediate outcomes are observed within a short time frame post-intervention; this level of change is maintained or a small increment is reported in the immediate outcomes over time; 2) small, if

any, changes in the ultimate outcomes are found within a short time frame post-intervention; however, the amount of change in these outcomes increases gradually or sharply over time; and 3) the magnitude of the relationship between the intervention and the immediate outcomes is larger than the magnitude of the direct relationship between the intervention and the ultimate outcomes; this expectation is consistent with the mediating role of the immediate outcomes (Green, 2000; MacKinnon and Fairchild, 2009).

Ruling out Other Plausible Causes of the Intervention Effects

This criterion is considered the most defensible warrant for simple and multi-causality (Cook et al., 2010). It implies that the changes in the outcomes found after the implementation of the intervention are solely and uniquely attributable to the intervention. In other words, the outcomes are consequences of the intervention itself, and not other factors inherent in the context in which the intervention is delivered and evaluated. The factors are substantive or methodological. The substantive factors are associated with the characteristics of the clients who are included in the intervention evaluation study and who receive the intervention; the interventionists who deliver the treatments under evaluation; and the context of the study or the implementation of the intervention. Methodological factors relate to issues in the conduct of the evaluation study such as measurement of outcomes and statistical tests used in data analysis. Substantive and methodological factors present sources of bias or threats to the validity of inferences regarding the effects of the intervention on the outcomes, as discussed in Chapter 2.

Threats to validity, or biases, reflect alternative explanations for the intervention effects. Ruling out plausible causes involves: 1) exerting experimental control by eliminating possible sources of bias, as is done in the experimental or randomized controlled trial (RCT) design and 2) identifying, *a priori* and based on the theory underlying the intervention (i.e., understanding of the health problem, intervention, outcomes, mediators, and moderators), factors that could potentially confound the intervention effects, collecting data on these factors and examining statistically the extent to which the factors influenced the implementation of the intervention and the achievement of its outcomes, as is recommended when investigating the intervention under less well controlled conditions of day-to-day practice (Nock, 2007; Schafer and Kang, 2008).

Summary

- Design of an intervention evaluation study starts with a good understanding of the intervention and the notion of causality
- Understanding of intervention guides the plan and conduct of the evaluation study as follows: