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Review Article

EVALUATION OF RANDOMIZED CLINICAL TRIALS FOR THE IMPROVEMENT OF PUBLIC HEALTH INTERVENTIONS

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ABSTRACT

Public health interventions are intended to promote, protect and prevent ill health in communities or populations. They are differentiated from clinical interventions, needed to be individually prevented or treated. The interventions are evaluated or implemented in a social, political and organizational setting. The contextual characteristics vary with the public health intervention which includes factors in the political and organizational environment and socioeconomic or demographic features of the populations. There is a growing emphasis on evidence-based medicine, to initiate the effectiveness and safety of patients and incorporation of high-quality evidence into public health practice and its cornerstone of evidence-based medicine is the randomized controlled trial (RCT). The World Health Organization defines a clinical trial as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health research outcomes. Fewer than 10% of Clinical studies reported in journals mostly surgical, are RCTs and only half of the surgeries are based on RCTs as a mode of treatment in internal medicine.

Keywords: *Public Health, Clinical Research, Randomized Clinical Trial*

INTRODUCTION

Randomized clinical trials and Complex interventions are widely used in the in public health practice, also in areas of social policy that have significant health consequences. Conventionally, as interventions with interactive components, throw challenges for the evaluators to the practical and methodological difficulties that any successful evaluation must overcome. Many of the problems relate to the difficulty of standardizing the design and delivery of the interventions because of their sensitivity to features of the local context as well as the organizational and logistical difficulty of applying experimental methods to service and the length and complexity of the causal chains linking intervention with outcome [1].

In 2000, the Medical Research Council published a "*Framework for the Development and Evaluation of RCTs for Complex Interventions to Improve Health"*, to help researchers for further knowledge and adoption of proportionate methods. The guidelines proved to be very resourceful and have been thoroughly followed. A Framework was given in 2000 with an interest in the evaluation of complex interventions with a certain number of limitations: (1) the adoption of a model based on the phases conventionally used in

the evaluation of new drugs, and the linearity implied by the structure of the model; (2) the lack of evidence for many of the recommendations; (3) the guidelines to approach developmental and implementation phase studies; (4) an assumption that conventional clinical trials provide a template for all the different approaches to evaluation; (5) a lack of knowledge on how to tackle highly complex or non-health sector interventions, e.g. programs made up of several complex interventions; and (6) the lack of attention to the social, political or geographical context in which interventions take place.

Public health interventions gets integrated within the community, there is always a need of growing imperativeness in the evidence based evaluation. RCTs have been described unaccommodating the complexity and flexibility that characterizes complex interventions. They are considered off limits often since they believed to be flexible for simple, standardized and unvarying interventions being inappropriate for public health interventions [2].

Such criticisms of the RCT are based on a consideration of "classic" RCTs in which the intervention is standardized and the individual is the unit of randomization. Cluster trials can accommodate communities, schools or other "clusters" as the unit of analysis, and RCTs have a long history of successful application in evaluating the effectiveness of social interventions. The strength of this study design with the use of a non-randomized study where RCTs would have been feasible represents a lost opportunity. Our concern is that evaluators around the world may move away from favoring RCTs in public health for what we see as the wrong reasons; that is, a mistaken belief that experimental designs are only useful for evaluating standard, simple interventions aimed at individuals.

It has been reaffirmed that a well conducted RCT is the best (albeit sometimes impractical) study design for determining a causal relation between an intervention and its putative outcomes. However, study design alone cannot suffice as the main criterion for the credibility of evidence about public health interventions.

Intervention is defined as a set of actions with a coherent objective to change or produce obvious outcomes. These include regulations, single and multiple strategies. *Public health interventions* are intended to promote or protect health or prevent ill health in communities or populations differentiated from clinical interventions, intended to provide individual ailment or preventiveness. Context refers to the Socio-economic setup where the intervention ought to be implemented or evaluated. The contextual characteristics that are relevant vary with the type of intervention which characterizes for a public health intervention might include factors in the political and organizational environment and socioeconomic or demographic features of the population.

Recently public health epidemiology was chiefly concerned with etiological hypotheses, than evaluative hypotheses. To strengthen the criteria for appraising evaluative research in public health we have narrated a broad-based literature beyond the fields of epidemiology and evidence-based medicine [3].

INTERVENTION STUDIES IN HEALTH PLANNING

The health planning can be assissted with information on the effectiveness of the intervention is available.

The effectiveness of the intervention to reduce risk factor A has been found to be 95%, factor B 75% and factor C 50%, which applied to the attributable risk to work out the actual expected reduction in deaths in the population if a particular risk factor intervention program succeeds. Information about effectiveness should come from community-based studies and not from randomized controlled trials conducted on highly selected (unrepresentative of the community) hospital clinic based studies. For example, studies evaluating tuberculosis efficacy are conducted on patients who have been selected on the basis of being compliant, unlikely to default, unlikely to suffer severe side-effects, willing to be hospitalized for a certain time period and able to be followed up with ease [4].

CHOICE OF INTERVENTIONS

Clinical trials usually focus on outcomes, whereas evaluation of public health promotion interventions is often exclusively concerned with the process of effecting change. An understanding of process can provide useful insights into why an intervention achieves or fails to achieve the expected outcomes, but a process evaluation will be non informative if conducted without reference to outcomes, and may sometimes be misleading if perceptions differ markedly from actual outcomes.

Randomized control trials are regarded as the 'gold standard' when evaluating the effectiveness of intervention. It is not ethically justified to conduct such trials when using interventions of known effectiveness. Evaluation of the impact of interventions using surveys becomes expensive. Community-based surveillance systems for sentinel events need to be incorporated into health service management with inbuilt checks for under-reporting, over-reporting and misclassification [5].

There are several different approaches to applying interventions to populations. A disease-specific approach can be followed which has a role in reducing the impact of diseases such as measles and tetanus but is unlikely to have any major impact on diseases which are of multifactorial causation. An alternative approach is forms of integrated primary health care approach such as UNICEF GOBI-FFF.

Public health interventions tend to be complex, programmatic and context dependent. Their effectiveness evidence must be sufficiently comprehensive to encompass that complexity. The evaluation of evidence must distinguish between the fidelity of the evaluation process in detecting the success or failure of an intervention. The evidence should help to determine the cause of failure of the intervention. Evidence-based interpretation depends on the descriptive information available on the intervention and its context, further to determine the authenticity of the evidence. To fulfill certain requirements, an expansion of the criteria that are used in clinical medicine for appraising research is suggested. We draw on evidence-evaluation schema that was developed for epidemiological and qualitative research,

health promotion program evaluations and health economic evaluations [6].

LEVELS OF EVIDENCE AND CAUSALITY

The assessment of evidence-based health casualty mostly depended upon the level of evidence, which defined by the study design used in evaluative research which are graded by the potential to eliminate bias. A hierarchy of study designs was suggested the levels of evidence based on study design were proposed by Fletcher and Sackett for the Canadian Taskforce on the Periodic Health Examination in 1979. The Systematic reviews of randomized controlled trials (RCTs) have become widely accepted as providing the best evidence (level 1) on the effects of preventive, therapeutic, rehabilitative, educational or administrative interventions in medicine. 1 2 2 3 Levels of evidence have also been applied to other areas of evidence-based decision making in health analysis and implementation cycle which includes inventory resources, develop health improvement strategy. RCT is a far superior evaluative mechanism for answering specific types of questions compared with the evaluation approaches that are currently popular in the health promotion field [7].

RELATIVE RISK, ATTRIBUTABLE RISK AND ABSOLUTE RATES

One way of assessing public health issues is to select the risk involved in intervention for a particular disease and effectiveness of that intervention. A study will support to look at the risk for disease A, community-based disease. Three risk factors (X, Y, and Z) each play their role independently in the likelihood of death due to the disease [8, 9]. There may be a chance of larger associations of any of the risk factors i.e., association of X higher than Y, more than that the scientists are much more concerned with the relative importance of the risk factor which will help in the decrease of the disease if the intervention gets implemented. From the below Table the risk factor A had the highest relative risk for disease X. Though it is assumed that the risk factors are statistically significant, factors Y and Z are of less importance. Further details of the study will show that 2% of the population studied was exposed to risk factor X, and 50% of the population affected by the risk factors Y and Z. A measure of impact, attributable or etiological risk show results using the formulas described below. It concluded that near about 7% of the deaths can be potentially preventable if the effect of risk factor X can be omitted. Factors Y and Z cannot be ignored and proved to be of far higher importance to the community. The attributable risk measures both the relative risk and also the risk factors common in the population. Higher relative risk concludes identification of real factors and not the adulterated ones derived from various factors. The risk factor became of high importance to the community when the attributable risk is high. At the end this is a hypothetical example that shows that these kinds of results are applicable in many situations [10].

CONCLUSION

The RCT framework is not as limited as many health researchers think it is, and it offers certain advantages that should not be cavalierly forfeited. With minor modifications certain obstructions of RCT

design can be overcome. Any design that has the combination of cluster randomization with phased intervention delivery, which has been previously implemented in studies or trials, can be set as an example of a modified RCT design. RCT, if avoided for unknown reason will only weaken health promotion and stymie its potential benefits. To ameliorate a current public health catastrophe - obesity, a convoluted health challenge will be a precursor through developing randomized designs that are appropriate for community based health promotion research. The global casualty rate from tobacco continues to be assessed as successful tools for tobacco control remain ambiguous. So, rather than circumscribing against randomization and efforts to expand alternative research evaluation methods, arduous effort should be there to develop randomized designs that are both canonical and feasible, which will accelerate the goals of current health issues and disease prevention. The International Union for Health Promotion has been far more prolific and its message to the health promotion researchers in 1999 stating that Randomized controlled trials or any experimental designs should be avoided to measure health promotion intervention effectiveness. There is an axiom that health promotion as a field harmed by such designs. Hence, in that case both the philosophical and the practical situations that underlie the rejection of RCTs are taken into consideration. With time, researchers diverted themselves to randomized controlled trials (RCTs) in an effort to increase the validation of their developed designs. The priority to have quality standards in clinical research has led to the Movement for Evidence-Based Medicine5 and the establishment of the Cochrane Collaboration ,resulting in important improvements in methods and the acceptable quality of evidence. The fortune of these efforts has invigorated the extension of RCT designs to the fields of public health and health policy.

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