

RIGOUR AND FEASIBILITY IN TOBACCO CONTROL EVALUATION: TOWARD A SUCCESSFUL RECONCILIATION

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Abstract: The challenge of reconciling scientific rigour with feasibility is central to the goals of policy and program evaluation for tobacco control. Evaluations conducted in various settings are held to high standards of performance, and must also be considered feasible by program authorities and stakeholders. This article describes three recent examples from the field of tobacco control. Issues of context, relevance, and stakeholder participation in planning evaluation designs are central to successful reconciliation. To affect tobacco control evaluation positively, reconciliation between the goals of rigour and feasibility needs to occur on two levels: between evaluator and stakeholders, and within the evaluation plan.

Résumé : Le défi de concilier la rigueur scientifique avec la faisabilité occupe une place centrale dans les objectifs de l'évaluation des politiques et des programmes de lutte contre le tabagisme. Les évaluations, peu importe leur contexte, doivent respecter de strictes normes d'exécution, en plus de satisfaire aux critères de faisabilité des dirigeants du programme et des autres intervenants. Cet article

décrit trois exemples récents du domaine de la lutte contre le tabagisme. Le contexte de l'évaluation, sa pertinence, et la participation des intervenants à sa conception sont essentiels pour parvenir à concilier les objectifs de rigueur et de faisabilité. Pour avoir un effet positif sur l'évaluation des efforts de lutte contre le tabagisme, cette conciliation doit se faire à deux niveaux : entre l'évaluateur et les divers intervenants, et dans le plan d'évaluation même.

INTRODUCTION

In relation to the development of informed policymaking, Sylvie Stachenko states that

First and foremost, there must be a rational argument for a policy or programme based on the best available knowledge, including scientific, clinical and experiential. Any proposed policy or programme must also be feasible and practical and take into account the complexity of the socio-economic context in which it would be introduced. (Stachenko, 2008)

The same challenge—to reconcile scientific rigour with feasibility—can also be applied to the goals of policy and program evaluation for tobacco control. In conducting research syntheses, needs assessments, community surveys, and evaluations of the process, impact, and outcomes of program and policy interventions, we strive for the highest level of scientific rigour possible. Some examples include theoretical and conceptual grounding, a strong design, a representative sample, valid and reliable measures, appropriate quantitative and/or qualitative data collection and analytic procedures, attempts to minimize bias, the inclusion of ethical protocols around the provision of informed consent and participant confidentiality, and evidence-informed interpretation and reporting—the list is extensive. Though far removed from the laboratory setting, program evaluations conducted in community, clinical, or school-based settings are understandably held to high standards and expectations of competence and performance, as the results are expected to inform program and policy decisions.

As is the case with all research conducted in real-world settings (Robson, 2002), the degree to which the goals of scientific rigour in tobacco control evaluation (and program evaluation in general) can be reached is highly influenced by issues around context, feasibility, and practicality (Brownson, Chiqui, et al., 2009; Stachenko, 2008). These issues

are interrelated. Practitioners need information on design issues in order to make decisions regarding time and resource allocations, and evaluators need information on contextual and practical issues in order to finalize a design that will be both rigorous and feasible. The immediate contexts surrounding community, clinical, and school-based interventions and evaluations are invariably less predictable than researchers prefer. Public health professionals, when asked to become involved in participatory research projects in community settings, have boundaries around the amount of time and emphasis they can devote to research (Allison & Rootman, 1996). Similarly, clinicians asked to deliver counselling sessions in conjunction with their regular practice are constrained in terms of the time they are permitted to engage in training, screening for eligible participants, and documenting/tracking the interventions. Evaluation projects conducted in schools contend with a wide range of contingencies and unpredictable events (student and faculty absences, exams, policies and interventions from other sources that compete for resources) that affect the scheduling and implementation of interventions and evaluations.

In addition to these contextual issues, evaluators must identify any social, political, cultural, and economic conditions that can influence how respondents will participate in tobacco control evaluations. For example, some individuals or groups may resist participation in evaluation due to issues of trust (e.g., they may ask: How will the evaluation results be used? How will the results influence my life? Will others know my responses and challenge my opinion?). Evaluation participation may be negatively influenced by perceptions that the findings may result in removal of a program or service that the community or group perceives it needs (whether or not the program is meeting its objectives).

Context may also influence the extent to which program authorities make decisions (or not) to support more rigorous evaluation designs or to act on evaluation results. Limited financial resources may preclude more costly experimental (and quasi-experimental) designs that require large numbers of participants to be recruited to measure effects. Similarly, these designs are inherently complex, and program authorities may lack sufficient resources to support evaluators to enable recruitment (e.g., in hard-to-reach or geographically dispersed populations). Changes in program mandates, leadership, funding, strategic direction, stakeholder needs, and emerging science are some of the contextual issues that influence how evaluation results may be used by program authorities.

Other challenging issues of evaluation feasibility relate to considerations of the appropriateness of various design and methodological approaches, particularly around such things as sampling strategy or the assignment of individuals or groups to specific conditions (intervention or control/comparison). Campbell and Stanley's (1963) advice to select the strongest possible designs to enhance internal and external validity is sound, although at times it is used as a rationale for selecting an experimental design (manifested in a randomized controlled trial [RCT]) in cases where it may not be the most appropriate or feasible choice.

In an important paper examining evaluation of the relevance, generalizability, and applicability of research, Green and Glasgow (2006) state that the traditional preoccupation of researchers with issues of internal validity of findings, based on the belief in the inherent superiority of the RCT, results in a lack of sufficient focus on issues around external validity, the degree to which findings can be generalized to similar groups. Thus, they argue that quasi-experimental designs may be more feasible to use for evaluation of studies conducted in community, school, and other settings. In these settings the non-equivalent comparison group design can be used to assign existing administrative units such as schools or classrooms to conditions. Also, time-series designs can be used in clinical settings to ensure that participants have access to a product/treatment deemed to have likely positive health effects, but for which sufficient exposure is required to see if these effects materialize. As well, non-experimental designs, typified by observational studies, surveys, or focus groups and other qualitative methods conducted with members of the community, patients, or groups of students can also be used when warranted. Because quasi-experimental or non-experimental designs can be seen as more appropriate than RCTs for some studies, this suggests that the type and degree of evaluation design needed is largely a function of the particular stakeholder needs and community/organizational contexts within which the study occurs (Bryman, 2000; Robson, 2002). Thus, the purpose of evaluation greatly influences the type of design and methodological approaches needed.

In tobacco control evaluations, maintaining distinctions between the goals of methodological rigour and feasibility are not useful. These goals need to and can be reconciled. An important key in determining whether the goals of both rigour and feasibility can be met is to determine if the intervention is seen as relevant to the interests of the group being studied and/or the group being asked to support the program. In other words, the inevitable discussions that occur

between researchers and practitioners concerning rigour and the feasibility of conducting evaluations in real-world evaluation settings are greatly influenced by the degree to which practitioners consider the study to be important and relevant to their goals and interests, the extent to which the evaluation can be carried out in a way that does not adversely impact relationships (e.g., with target audiences and stakeholders), and the extent to which the program authorities have the desire and ability to make decisions that result in programmatic changes. Evaluators can assist program authorities by identifying evaluation approaches that mitigate risk (financial, client, and stakeholder relationships) and optimize decision-making potential.

Evaluability assessments can be a useful strategy to help identify and sort out the most appropriate evaluation design that optimizes the reconciliation between context, rigour, and feasibility. Determining the program's objectives, the objectives of the evaluation, the potential to measure the objectives, data sources, data retrieval, and analysis potential, stakeholder involvement, program governance, and decision-making structures should be addressed before engaging in any program evaluation. In addition, participatory evaluation designs can facilitate the relationship between rigour and feasibility. Through participation of key stakeholders and clients in the evaluation strategy, we are able to determine what contextual factors influence design options and how to optimize the design in this context (Cousins, 2003).

To illustrate these points, we will consider three recent examples—an assessment of training needs for the Youth Advocacy Training Institute (YATI); a formative evaluation of the Youth Action Alliance Program (YAA); and plans to develop, implement, and evaluate a pilot intervention designed to decrease child second-hand smoke exposure (SHSe) in homes, as part of the Smoke-Free Homes and Asthma Program. Two of these examples are based on projects sponsored by the Ontario Lung Association (OLA), one was conducted by the Ontario Tobacco Research Unit (OTRU), and all have been implemented in Ontario.

CASE STUDIES

YATI Needs Assessment

The YATI needs assessment was designed to determine the current state of training needs for Peer Leaders—teens hired by Youth Action Alliances (YAAs) to advocate for tobacco control measures and to pro-

mote smoke-free communities. Needs assessment methodologies are fairly well understood, but evaluators are required to define such factors as what program authorities expect from the needs assessment; what resources are available to perform the needs assessment; what role the program authorities are able (capability, capacity, interest) to play in the needs assessment (design, implementation, interpretation, reporting); what data can be gathered to answer evaluation questions; and what sociocultural, political, economic, or other environmental factors exist that could influence the needs assessment. On the basis of this information, the evaluators determined that a survey of Peer Leaders and adult support personnel, augmented by focus groups conducted with high priority groups (those working in a highly populated urban centre, in Francophone communities, and in Aboriginal communities), would be feasible. Here we will focus on the survey component of the needs assessment project.

We decided to conduct two online surveys—one with the Peer Leaders and one with adult support personnel. The online surveys were seen as a potentially effective and efficient means of obtaining representative data on these groups to address the need to optimize scientific rigour. In order to enlist support for the surveys, we solicited comments on the draft questionnaire from the Peer Leaders and adult support personnel (primarily Youth Advisors). One of their key suggestions was to include opportunities for the respondents to offer general comments and suggestions regarding YATI training, materials, and support needs.

In order to enhance the representativeness of survey findings, it is important to achieve a good response rate. The challenges to accomplishing this in online surveys of the general population are even greater since the sampling frame is often not known (cases of online surveys of the general population) and there are frequently no intrinsic or extrinsic rewards or incentives for participating in the study. However, response rates in online surveys of particular groups can potentially be much higher than this, as it is often possible to obtain information on the sampling frame (basis for arriving at the denominator in calculation of response rate). Also, the intrinsic rewards attached to completing the survey may be higher for specific groups with a prior commitment to the organization sponsoring the study and/or the specific topic of study.

In the YATI surveys we took the following steps to enhance the response rates. First, the Tobacco Control Manager sent out an e-mail letter introducing the study and the research firm to Youth Advisors.

Second, we offered Peer Leaders the opportunity to participate in a draw for gifts (iPods and gift certificates to a music retailer). Third, we e-mailed periodic reminders to Peer Leaders and adult support personnel, along with the link to the online survey. Fourth, we contained the time it takes to complete the online survey questionnaire to approximately 15 minutes. Finally, we provided the respondents, through open-ended items, with several opportunities to provide comments and suggestions. These steps, several of which are outlined in Dillman's description of the Tailored Design Method (Dillman, 2000), proved to be very productive. We were able to achieve quality data from the two groups with response rates of 80.0% (Peer Leaders) and 84.8% (adult support personnel). Thus, our design and procedures proved to be rigorous, and the approach was feasible to use in the needs assessment. A key factor underlying our success was that we believe that the two groups felt that the study was highly relevant and important to their goals of further development (Peer Leaders) or facilitating development (adult support personnel). The Ontario Lung Association used the results of this study for future planning of YATI training initiatives.

Formative Evaluation of the Youth Action Alliance Program

A formative evaluation of the Youth Action Alliance Program was conducted by the Ontario Tobacco Research Unit in 2006–2007. Both the YAA program and the formative evaluation were funded by the Ontario Ministry of Health Promotion. The purpose of the evaluation was to “contribute to the performance of the Youth Action Alliance programs” by (a) describing the implementation of the intended design; (b) identifying what is working well and less well for whom, when, and why; (c) identifying positive lessons from success; and (d) identifying obstacles to success (Fiissel, Schwartz, et al., 2008). A number of phases and methodological approaches were used in the study, including a survey with adult Youth Advisors, a survey of youth Peer Leaders, and site visits. The design and findings from this formative evaluation are described elsewhere (Fiissel, Schwartz, et al., 2008).

Here we will touch on issues of rigour and feasibility in relation to the evaluation. The context of the evaluation was the Ministry of Health Promotion's need to conduct a study in a relatively short period of time to inform further program development. Limitations included the fact that the YAA program was started prior to the decision to evaluate, precluding collection of baseline data on the Peer Leaders. Funding of the evaluation precluded the identification of potential

controls, and thus experimental/quasi-experimental designs could not be used. As well, no subsequent formal or systematic evaluations were conducted (nor contemplated by the program authorities), so longer-term program outcomes could not be assessed.

Conceptual grounding and the implementation of a number of qualitative and quantitative methodological approaches of data collection and analysis were implemented to optimize scientific rigour in the design and conduct of the formative evaluation. In addition, participation in the evaluation by YAA Youth Advisors and Peer Leaders (being employees) was high and the evaluation was feasible to conduct, primarily because adequate resources were dedicated to its implementation and completion. As well, the formative evaluation projected would have been considered by study participants to be relevant to them and the future of the YAA program. Thus, there were no inherent tensions between the goals of evaluation rigour and feasibility in this case.

However, as a postscript to this study, funding for the YAAs by the Ontario Ministry of Health Promotion was discontinued in August 2009, not because of the formative evaluation results conducted earlier, but perhaps largely due to two limitations of the YAA program design—the plan to rely on developing large numbers of youth volunteers to sustain the program and expand its reach, and the plan to involve primarily at-risk Peer Leaders as opposed to “mainstream” youth in communities. As it transpired, relatively few youth volunteers were recruited to augment Peer Leader efforts, perhaps because Peer Leaders were paid staff of the YAAs (up to 10 hours per week) and there may have been little incentive for other teens in the community to volunteer (although Ontario secondary students need to devote hours to community service activities as part of their requirements for graduation). Nor were there structures and mechanisms in place to differentiate between paid staff and volunteer roles. As well, though it was possible to recruit more at-risk youth as Peer Leaders in some communities (large urban communities in Toronto; aboriginal youth), most YAAs were unable to do so. As these were two central features of the Ministry of Health Promotion’s vision and plan for the YAA program, the fact that there was only limited evidence of their implementation put continuation of program funding in jeopardy. As a result of the formative evaluation findings, the Ministry of Health Promotion modified the program to require that at least 25% of peer leaders be hired from at-risk populations. But the period following the formative evaluation was a time of substantial instability for the YAA program, as the Ministry of Health Promotion questioned its cost-effectiveness.

In this case, then, despite a high degree of reconciliation between the goals of tobacco control evaluation rigour and feasibility, funding was discontinued. As mentioned earlier, no subsequent evaluation to examine cost effectiveness and track program outcomes over time was conducted. Thus it is possible that some program impacts and outcomes may have emerged after the formative evaluation, which was based solely on performance in the initial year of YAA implementation.

Smoke-Free Homes and Vehicles Pilot Project

The goal of the Smoke-Free Homes and Asthma Program of the Ontario Lung Association is to reduce SHSe through the promotion of smoke-free homes and vehicles. In an initial step, a research synthesis—focusing on epidemiological profiles of the groups most at risk, some of the behavioural and social factors influencing these patterns, and a review of existing evidence for the effectiveness of various intervention approaches—was undertaken (Allison, 2008). A number of recommendations were provided in the final report of this research synthesis, including the need to develop, implement, and evaluate specific interventions designed to reduce SHSe and promote smoke-free homes and vehicles among those most at-risk—children and adolescents.

To address this need, OLA embarked on the development of a pilot project to be conducted in conjunction with Primary Care Asthma Programs (PCAPs) in Ontario. The PCAP sites, themselves located mainly in clinical locations and Community Health Centres (CHCs), provide a unique setting and opportunity to conduct a rigorous pilot study within an organizational framework and mandate consistent with the goal of reducing SHSe. The findings from the pilot project will inform decisions to consider a more rigorous trial to examine intervention effectiveness in comparison to an alternative (usual) program. If the findings of the fuller evaluation suggest that the intervention is effective, this would suggest that PCAPs can serve an important role as community settings for provider-delivered programs in the future.

The specific intervention being used in the PCAP pilot project is based on the use of a coaching and motivational interviewing (MI) approach (Emmons, Hammond, et al., 2001; Hovell, Meltzer, et al., 2002; Resnicow, Dilorio, et al., 2002) delivered by trained Certified Asthma Educators or Certified Respiratory Educators (staff members of PCAPs). In our initial discussions with PCAP coordinators about the feasibility of conducting the pilot project, we outlined a design

that would include screening for eligible clients (target parents [adult smoker or their spouse] living in homes in which one or more children below age 5 are exposed to SHS); an initial 10–15 minute intervention counselling session with a follow-up counselling session; and two follow-up telephone calls for assessment of their progress and to provide a counselling booster at monthly intervals. In addition, a “Smoke-Free Homes Kit” and brief visit with a physician will be incorporated into the intervention. Proxy measures of child SHSe, provided by the target parent, will be used. Nicotine monitoring of homes will also be used in order to assess the validity of self-report measures.

Preliminary discussions with PCAP coordinators consisted of an initial in-person meeting, several teleconferences involving all PCAP coordinators in the province, teleconferences with PCAP coordinators from those sites being considered for participation in the pilot study, and site visits. An online survey was conducted with PCAP coordinators, Certified Asthma Educators, and Certified Respiratory Educators in order to obtain additional information about their availability for counselling, the smoking status of clients, and frequency of contact. Subsequent discussions with the smaller number of PCAPs (those under consideration for being selected for the pilot) have allowed for much more in-depth coverage of the potential factors affecting feasibility. In the initial discussions, PCAP coordinators identified a number of important issues affecting the feasibility of conducting this pilot project:

1. The proposed length of the intervention period (months) and the length of the initial counselling session (minutes).
2. How the eligibility of participants will be determined, how they will be screened, and who will do it. For example, if client records will be used, who will be responsible for this activity? What are the resource implications if PCAP administrative staff are asked to do this?
3. The number of individuals that will be included in the sample.
4. Whether or not individuals with specific pre-existing conditions (e.g., chronic obstructive pulmonary disease [COPD]) will be eligible to participate in the study.

In these discussions, members of the evaluation team have identified a number of issues affecting the decisions regarding the design of the pilot study:

1. The number of Certified Asthma Educators and Certified Respiratory Educators (or similar roles) in Ontario PCAPs and the number available from those PCAP sites under consideration for participation in the pilot study.
2. The number of eligible individuals likely to attend the PCAP for a visit within a particular period of time.
3. The feasibility of having trained Certified Asthma Educators conduct initial screening in order to recruit clients to the study during a regular visit to the PCAP.
4. The feasibility of having the Certified Asthma Educators conduct the necessary follow-up sessions and documentation.

To briefly summarize progress in planning this pilot project, discussions have been productive and worthwhile. Much of the discussion of interest to both parties dealt with the important issues of rigour and feasibility. The evaluation team has met with PCAP coordinators from the PCAP sites under consideration to facilitate additional discussions. Informed decisions regarding design issues were facilitated by insight into the context of PCAP operation. For example, it was not immediately clear that many of the PCAP staff who would be conducting the intervention were not permanent employees of the OLA. Thus, transfer payments to PCAPs to cover additional time of Certified Asthma Educators and Certified Respiratory Educators needed to be taken into account. The necessary trade-offs to be made between rigour and feasibility will be a result of continuing discussions between the parties involved. A key factor in providing the impetus to a successful resolution of the issues under discussion is the relevance of the project to PCAP coordinators, staff, and clients. Their active engagement in this process increases the likelihood that the pilot study will be successfully implemented and evaluated (Allison & Rootman, 1996; Fielden, Rusch, et al., 2007).

DISCUSSION

Our article has attempted to address how context, rigour, and feasibility are interrelated and how this relationship sets boundaries on the potential for successful program evaluation studies that accurately measure programs (processes, impacts, and outcomes). From the examples described above, a number of lessons are learned about facilitating the link between rigour and feasibility: (a) understanding of context is essential, (b) understanding of client needs and expectations are also essential, (c) understanding of different data collection strategies are important in matching information needs with “real

world” context, and (d) assessment of the likelihood of the respondent pool to respond to different data collection strategies is useful.

Despite these considerations, attempts to ensure that the goals of rigour and feasibility are reconciled do not guarantee a successful program outcome. Zakarian and colleagues previously described the failure of an intervention conducted in a clinical setting to decrease SHSe among study participants (Zakarian, Hovell, et al., 2004). A central explanation for that finding focused on organizational changes during the course of the intervention. A large number of supervisory and clinical staff involved in the study left to take other positions before it was completed. This change in the environmental context of the study may have affected the degree of organization and staff commitment, consistency of intervention delivery, and therefore study quality. So precedents exist where things can go wrong. A rigorously designed study originally believed to be feasible and relevant may have failed to demonstrate intervention effectiveness due to factors beyond the control of evaluators or the organizations they partner with. There are also, in a different context, challenges to evaluating more macro-level policy interventions, such as natural experiments (Ramanathan, Allison, et al., 2008).

To affect tobacco control evaluation positively, reconciliation between the goals of rigour and feasibility needs to occur on two levels: between the evaluator and stakeholders, and within the evaluation plan. On the first level, reconciliation may be partly a function of tradeoffs and negotiation. On the second level, reconciliation is more a function of informed decisions by the evaluator regarding the priorities and weights attached to these goals, based on in-depth consultations with program authorities, including a discussion of the risks and benefits of measuring or not measuring various program goals. We have also seen, in the examples described, that the perceived relevance of a specific approach can serve to help overcome obstacles to reconciliation. It is clear that adopting participative models of evaluation planning in addressing issues of rigour, feasibility, and relevance is an important step in the process. Finally, comparable to Robert Groves’ (1989) description of the goals of survey research, in tobacco control evaluation evaluators should attempt to influence all of those design and contextual factors over which they have some control.

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