Unit Ten: Interpretation of Results

Learning Objectives

- To be able to interpret the results from studies in order to formulate conclusions and recommendations from the body of evidence
- To understand the factors that impact on the effectiveness of public health and health promotion interventions

The following issues should be included in the discussion and recommendations section of a systematic review of a health promotion or public health intervention:

- 1) Strength of the evidence
- 2) Integrity of intervention on health-related outcomes
- 3) Theoretical explanations of effectiveness
- 4) Context as an effect modifier
- 5) Sustainability of interventions and outcomes
- 6) Applicability
- 7) Trade-offs between benefits and harms
- 8) Implications for practice and future health promotion and public health research

As those who read systematic reviews (eg. policy makers) may not have time to read the whole review it is important that the conclusions and recommendations are clearly worded and arise directly from the findings of the review.¹

1) Strength of the evidence

The discussion should describe the overall strength of the evidence, including the quality of the evidence and the size and consistency of the results. The size of the results is particularly important in population-based studies, where a small effect at the community level may have a much more practical significance than the effect of comparable size at the individual level.² Using statistical significance alone as the standard for interpretation of the results of community intervention trials is inappropriate for research at the population level.³

This section of the review should also describe the biases or limitations of the review process. Difficulties in locating health promotion/public health literature may have resulted in the inability to carry out a comprehensive search. For many reviewers, a further limitation of the review process is the inability to translate non-English articles, or search non-English electronic databases. Furthermore, interpretations may be limited due to studies missing important information relating to such factors as the implementation of the intervention, context, and methodological features (eg. blinding, data collection tools, etc) required in order to determine study quality.

2) Intervention integrity

Reviewers should discuss whether the studies included in the review illuminated the key process factors that led to effective interventions. In addition, the relationship between intervention integrity and effectiveness should be described, i.e., did studies that address integrity thoroughly show a greater impact?

An important outcome of process evaluation is the assessment of intervention 'dose', or the amount of intervention delivered and received by participants or the target group.³ Intervention dose varies markedly between community level interventions, and may be one of the factors that explain differences in effectiveness between studies. Investigators have postulated that the small effect sizes

resulting from some community interventions is a result of an insufficient intervention dose or intensity, or because participation rates were too low.³ Or alternatively, the dose of the intervention may have been inadequate relative to other forces in the environment, such as an information environment already saturated with sophisticated advertisements and product promotions.³ Mittlemark and colleagues⁴ have suggested that intervention effectiveness has been limited by the length of the intervention, recommending that for community-based interventions the intervention period be at least five years, given the time it typically takes for the community to be mobilised into action. This is because it may not be realistic to expect large individual changes in lifetime habits to occur with complex behaviours, such as eating patterns, within the timeframe of most community studies.⁴ Mittlemark et al⁴ further suggest that at the organisational or community level, additional time must be built in for "institutionalisation"; that is, the continuing process of building local, regional, and national capacity to mount permanent health promotion programs.

Information is also needed in reviews on whether it is more effective to spread a given dose out over an extended period of time, rather than to compress it into a shorter time frame to maximise the population's focus on the intervention messages.

3) Theoretical explanations of effectiveness

Although many public health interventions are planned and implemented without explicit reference to theory, there is substantial evidence from the literature to suggest that the use of theory will significantly improve the chances of effectiveness.⁵

Types of theories:

- Theories that explain health behaviour and health behaviour change at the individual level (eg. Health belief model, Stages of Change)
- Theories that explain change in communities and communal action for health (eg. Diffusion of Innovation)
- Theories that guide the use of communication strategies for change to promote health (eg. social marketing, communication-behaviour change model)
- Models that explain changes in organisations and the creation of health-supportive organisational practices (eg. theories of organisational change)
- Models that explain the development and implementation of health public policy (eg. evidencebased policy making to promote health)

Depending on the level of intervention (individual, group, or organisation) or the type of change (simple, one-off behaviour, complex behaviour, organisational or policy change), different theories will have greater relevance.⁵

Reviewers should seek to examine the impact of the theoretical framework on the effectiveness of the intervention. The assessment of theory within systematic reviews⁵:

- helps to explain success or failure in different interventions, by highlighting the possible impact of differences between what was planned and what actually happened in the implementation of the program
- assists in identifying the key elements or components of an intervention, aiding the dissemination of successful interventions.

Theory may also provide a valuable framework within which to explore the relationship between findings from different studies. For example, when combining the findings from different studies, reviewers can group interventions by their theoretical basis. Alternatively, reviewers may consider grouping interventions depending of whether they seek to influence individual behaviour, interpersonal relationships, or community or structural factors or whether they used a Program Logic or Program Theory approach.

Systematic reviews would also be greatly enhanced if in the discussion attention was paid to the gaps in theoretical coverage of interventions. For example, many interventions seek to focus on single level changes rather than seeking to change the environment within which people make their choices.

4) Context as an effect modifier

Interventions which are effective may be effective due to pre-existing factors of the context into which the intervention was introduced.

Where information is available, reviewers should report on the presence of context-related information⁶:

- social and political factors surrounding the intervention, eg. local/national policy environment, concurrent social changes
- time and place of intervention
- structural, organisational, physical environment
- aspects of the host organisation and staff, eg, number, experience/training, morale, expertise of staff, competing priorities to the staff's attention, the organisation's history of innovation, size of the organisation, the status of the program in the organisation, the resources made available to the program;
- aspects of the system, eg, payment and fee structures for services, reward structures, degrees
 of specialisation in service delivery; and
- characteristics of the target population (eg. cultural, socioeconomic, place of residence).

The boundary between the particular intervention and its context is not always easy to identify, and seemingly similar interventions can have a different effect depending on the context in which it is implemented.

5) Sustainability of interventions and outcomes

The extent to which the intended outcomes or interventions are sustained should be an important consideration in systematic reviews, as decision-makers and funders become increasingly concerned with allocating scarce resources effectively and efficiently.⁷

It is believed that interventions which isolate individual action from its social context would be unlikely to produce sustainable health gain in the absence of change to the organisational, community and institutional conditions that make up the social context.⁷

Reviewers may choose from a number of frameworks which describe the factors that determine sustainability⁸⁻¹⁰

- Bossert⁸ suggests that both contextual (eg. political, social, economic and organisational) factors and project characteristics (eg. institution management, content, community participation) are related to sustainability.
- Swerissen and Crisp⁹ propose that the relationship between the intervention level (individual, organisational, community, institutional) and strategies (eg. education, policies, social planning, social advocacy) indicates the likely sustainability of programmes and effects.
- A framework outlining the four integrated components of sustainability has also been produced.¹⁰

6) Applicability

Applicability is a key part of the process of summarising evidence, since the goal of systematic reviews is to recommend interventions that are likely to be effective in different settings.

Reviewers should use the RE-AIM model¹¹ (Reach, Efficacy, Adoption, Implementation, and Maintenance) for conceptualising the potential for translation and the public health impact of an intervention. The user can then compare their situation to the RE-AIM profile of the included studies or the body of evidence.

RE-AIM:

Reach – the absolute number, proportion, and representativeness of individuals (characteristics that reflect the target population's characteristics) who are willing to participate in a given initiative, intervention, or program. Individual levels of impact.

Efficacy/Effectiveness – the impact of the intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes. Individual levels of impact.

Adoption - the absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate a program. Comparisons should be made on basic information such as resource availability, setting size and location, and interventionist expertise. Organisational levels of impact.

Implementation – at the setting level, implementation refers to the intervention agents' integrity to the various elements of an intervention's protocol, including consistency of delivery as intended and the time and cost of the intervention. At the individual level, implementation refers to clients' use of the intervention strategies. Organisational levels of impact.

Maintenance – The extent to which a program or policy becomes institutionalised or part of the routine organisational practices and policies. At the individual level, it refers to the long-term effects of a program on outcomes after 6 or more months after the most recent intervention contact. Both individual and organisational levels of impact.

Example – taken from <u>www.re-aim.org</u>

A school-based intervention that has a large impact in terms of reach and efficacy at the individual-level but is only adopted, implemented and maintained at a small number of organisations (with specific resources that are not available in typical 'real-world' schools) could potentially be described as an intervention that has a large potential for impact (if the RE-AIM model was not used). In reality, when considering organisational-level impact, in addition to individual –level impact, this intervention would have little hope of resulting in a large public health impact because it could not be adopted, implemented and maintained in real-world settings.

This is also true of the converse situation where an intervention has systemic organisational adoption, implementation, and maintenance, but little reach, efficacy or maintenance at the individual level. So if only one level was assessed (i.e. the organisational level) the impact of the intervention would be considered large even though there is no individual-level reach, efficacy or maintenance.

Case study - The Victoria Council on Fitness and General Health Inc. (VICFIT)

VICFIT was established through the Ministers for Sport and Recreation and Health to provide advice to government and to coordinate the promotion of fitness in Victoria. One of VICFIT's initiatives, the Active Script Program (ASP), was designed to enable all general practitioners in Victoria to give consistent, effective and appropriate physical activity advice in their particular communities. The evaluation of the initiative utilised the RE-AIM framework, which is available at http://www.vicfit.com.au/activescript/DocLib/Pub/DocLibAll.asp.

Reviewers should describe the body of evidence with respect to the main domains relevant to the applicability of public health and health promotion interventions to the users' needs – see Table Two.

Table Two. Evaluation of the applicability of an individual study or a body of evidence

RE-AIM	Domain	Characteristic	Data to be collected from	Applicability to the user's
evaluation factor			the study*	needs*
Reach	Sample	Sampling frame	How well the study population resembles the target population the authors indicate they would like to examine Inclusion and exclusion criteria	Does the study population resemble that of the user's with respect to relevant characteristics, eg., disease risk factors?
		Sampling method	Participation rate The representativeness of the study population to the target population, eg., volunteers, provider/researcher selected, random sample Characteristics of the non- participants	If the study population was selected (i.e. not a random sample with a high participation rate), how might the user's population differ? Might they be less receptive to the intervention?
	Population	Age	Age of the population	What age of population do the data likely apply to, and how does this relate to the user's needs?
		Sex	Percentage of each sex in the population	What sex do the data likely apply to, and how does this relate to the user's needs?
		Race/ethnicity	Race/ethnicities are represented in the study population	Are the data likely specific to a specific racial/ethnic group, or are they applicable to other groups?
		Health status and baseline risk	Percentage of the population affected at baseline by diseases or risk factors	How does the baseline health status of the user's population compare to that of the study population?
		Other	Other population characteristics that are relevant to outcomes of this intervention	Are there other population characteristics that are relevant to outcomes of this intervention?
Efficacy	Internal validity	Internal validity	Assess internal validity for the study	Can the study results be attributed to the intervention or are there important potential confounders?
	Outcomes	Process and intermediate outcomes	Process (eg., number of telephone calls to clients) and intermediate outcomes (eg., dietary change) examined in the study	Are the outcomes examined in the study relevant to your population? Are the linkages between more proximal (intermediate and process) outcomes based on sufficient evidence to be useful in the current situation?
		Distal health and quality of life outcomes	Health and quality of life outcomes examined in the study	Are the outcomes examined in the study relevant to user's population?

		Economic	Economic outcomes: cost,	Is economic efficiency part of the
		efficiency	cost effectiveness, cost-	decision-making process? If so,
		cinciency	benefit, or cost-utility	are the data on cost or economic
			centerity of cost diamety	efficiency relevant to the user's situation?
		Harms	Any harms from the	Are these harms relevant to the
			intervention that are	user's population?
			presented in the data	Are there other potential harms?
			-	How is the user balancing
				potential benefits with potential
				harms?
Adoption	Intervention	Provider	Who delivered the	Are the described interventions
			intervention	reproducible in the situation
			Training and experience of	under consideration? Is the
			the interventionists	provider expertise and training
			If the intervention is	available?
			delivered by a team,	
			indicate its members and	
			their specific tasks	
		Contacts	Number of contacts made	Is the frequency of contacts in
			between the providers and	the study feasible in the current
			each participant	situation?
			Duration of each contact	
		Medium	Medium by which the	Is this medium feasible in the
			intervention was delivered:	user's situation?
			in-person, telephone,	
			electronic, mail	
		Presentation	To individuals or groups	Is this format feasible in the
		format	With family or friends	current situation?
			present	
		Content	Based on existing tools and	Is this feasible in the current
			materials or developed de-	situation?
			почо	
			Tailoring of the intervention	
			to individuals or subgroups	
	Setting	Infrastructure of	Organisational or local	Is the needed infrastructure
		the health care	infrastructure for	present in the current situation?
		delivery system or	implementing the	
		the community	intervention	
		Access to the	Access to the intervention	Does the current situation
		intervention	among the target	provide the resources to ensure
	T 1	A 17	population	access to the intervention?
Implementation	Individual	Adherence	Individual rate of adherence	Are there barriers to adherence
	level		to the intervention	in the current situation? Are
			Attrition rate from the	their local factors that might
	D	Total	program	influence the attrition rate?
	Program level	Integrity	The extent to which the	Are there barriers to
			intervention delivered as	implementation in the current
N.C. Co.	T. 1: 1 1	Control 1999 C	planned	situation?
Maintenance	Individual	Sustainability of	Change in behaviour or	What is the relative importance
	level	outcomes	other important outcomes in	of short- versus long-term
	D 1	C	the long term	outcomes to the user?
	Program level	•	Facets of the intervention	Is the intervention feasible in the
		the intervention	that were sustainable in the	long term in the user's setting?
			long term	Does the necessary
			Infrastructure that	infrastructure exist? Are there
			supported a sustained	available resources? What

		intervention	barriers to sustainability might
		Barriers to long-term use of	be anticipated?
		the intervention	

^{* &}quot;Data to be collected" and "applicability" can be applied to the individual study or to the body of evidence

7) Trade-offs between benefits and harms

Reviewers should discuss whether there were any adverse effects of the interventions, or describe if there were certain groups that received more/less benefit from the interventions (differential effectiveness). If cost data is provided for the interventions studies this should also be reported.

8) Implications for practice and future health promotion and public health research

Public health and health promotion reviewers are in an ideal position to determine the implications for practice and future research to be conducted to address any gaps in the evidence base. For example, where evidence is shown to be lacking, reviewers should clearly describe the type of research required, including the study design, participants, intervention details and contexts and settings. If the reviewed evidence base is flawed due to particular methodological issues (eg. outcome assessment tools, allocation bias, etc) these quality issues can be addressed in future studies.

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ADDITIONAL READING

Rychetnik L, Frommer MS. Schema for Evaluating Evidence on Public Health Interventions; Version 4. National Public Health Partnership, Melbourne 2002.

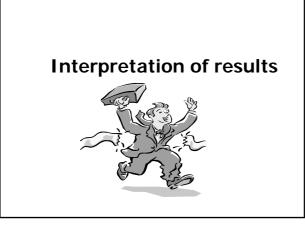
Visit http://www.re-aim.org for information relating to generalising the results from primary studies.

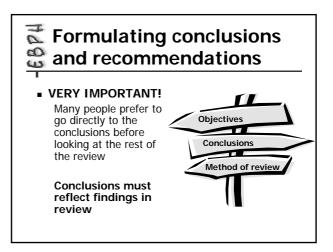
Glasgow RE, Lichtenstein E, Marcus AC. Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. Am J Public Health. 2003 Aug;93(8):1261-7.

Dzewaltowski DA, Estabrooks PA, Klesges LM, Bull S, Glasgow RE. Behavior change intervention research in community settings: how generalizable are the results? Health Promot Int. 2004 Jun;19(2):235-45.

EXERCISE

1. In small groups, list the types of information required from studies to help you determine the applicability of the results to other settings and the transferability of interventions to other settings. Do **not** use the table provided.







Issues to consider

Conclusions should be based on:

- Strength of evidence
- Biases/limitations of review
- Applicability and sustainability of results
- Trade-offs between benefits and harms
- Implications for public health and future research



Strength and biases

- Strength
 - How good is the quality of evidence?
 - How large are the effects?
 - Consistent results?
- Biases / limitations of review
 - Comprehensive search?
 - Quality assessment?
 - Appropriate analysis?
 - Publication bias?



Applicability

- Applicability relates to:
 - Study population characteristics
 - Validity of the studies
 - Relevant outcomes (incl. efficiency), interventions, comparisons
 - Integrity of intervention details of intervention (provider, adherence, medium, setting, access, infrastructure)
 - Maintenance of intervention/sustainability



Factors relating to the interpretation of effectiveness

- Theoretical frameworks
- Integrity of the intervention
- Influence of context



🔓 Theory

- Change in behaviour at individual, community, organisational, policy level
- Examine the impact of the theoretical framework on effectiveness
 - Group studies according to theory
 - Assists in determining implementation (integrity of interventions)
- Discuss theoretical frameworks used (all single level?)





Context

VERY IMPORTANT IN HP/PH REVIEWS

- Influences effectiveness of intervention
- Social/cultural, political, organisational
- Affects ability to pool results
- Affects applicability



Context

- Time and place of intervention
- Local policy environment, incl. management support for intervention
- Broader political and social environment, concurrent social changes
- Structural, organisational (aspects of system), physical environment
- Training, skills, experience of those implementing the intervention
- Characteristics of the target populations (eg. culture, literacy, SES)

DATA OFTEN NOT PROVIDED!!



Trade-offs

- Trade-offs
 - Adverse effects / potential for harm
 - Costs of intervention



Sustainability

- Sustainability of outcomes and/or interventions consider:
 - Economic and political variables
 - Strength of the institution
 - Full integration of activities into existing programs/curricula/services, etc
 - Whether program involves a strong training component
 - Community involvement/participation



Implications for PH/HP

- Not good enough to simply say "more research is needed"
- State what type of research should be done and why
 - What specific study design or quality issue should be addressed in future research?