Systematic Review Protocol (updated December 9th 2010)

What are the effects of interventions to improve the uptake of evidence from health research into policy in low and middle income countries?

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Background

The evidence-base for improving health continues to grow. However, concerns remain that the translation of this evidence or knowledge into appropriate policies and practice is partial and slow (Aaderud et al, 2005). Knowledge translation in healthcare has been defined by the Canadian Institutes of Health Research (http://www.cihr-irsc.gc.ca/e/39033.html) as a "dynamic and iterative process that includes the synthesis, dissemination, exchange and ethically sound application of knowledge to improve health, provide more effective health services and products and strengthen the healthcare system" (Strauss et al, 2009). This definition is also used by the World Health Organization (WHO, 2006).

In recent years, common factors affecting the use of evidence by policy makers and clinicians have begun to emerge, from theory (Brazil et al, 2005), and from observational or experimental studies on translation, thus creating an evidence-base itself. Graham and colleagues (2006), for example, have developed a conceptual framework called the "knowledge-to-action cycle", based on a review of 30 planned-action theories and their common elements. A wide range of potential influences and determinants have been identified from organisational to individual actor levels, and including key contextual elements, such as local leadership (Stetler et al, 2009)**.** Aaron et al (2009), for example, argue that organisational support is a malleable factor in facilitating the use of evidence, and that greater attention should be paid to organisational influences that can facilitate the dissemination and implementation. Most of the discourse agrees that the most effective strategies to bridge the gap between research and practice, will have at their heart, effective academic practice – policy maker partnerships (Brownson and Jones, 2009). Others place great responsibility on researchers, arguing that they need to be more aware of factors influencing the demand for different types of research; to interact and work closely with key policy stakeholders, networks and local champions; and to acknowledge the roles of important interest groups (Woelk et al, 2009).

Better communication is suggested as fundamental to increasing the use of research evidence in policy. Four strategies to assist in increasing the use of research in policy: making research findings more accessible to policy makers; increasing opportunities for interaction between policy makers and researchers; addressing structural barriers such as research receptivity in policy agencies and a lack of incentives for academics to link with policy; and increasing the relevance of research to policy (Campbell et al, 2009).

Intervening to increase the extent to which health policies are informed by research has long been one of the rationales for reforming health research systems. In recent years, the benefits of reform are reflected in: (a) growing understanding by researchers of the value of adopting a collaborative approach with policymakers in setting research agendas; (b) the expansion of the pool of knowledge relevant for policy making; (c) the generation of capacity to conduct systematic reviews of that evidence; and (d) the growing attention given to the policymaking structures necessary to absorb and use research evidence (Hanney and Gonzalez-Bloc, 2009). Others argue that the time-consuming nature of an evidence-based approach to policy decision-making suggests the need for more efficient production processes that are quick and clean enough (Lavis et al, 2008), including for example a role for knowledge brokering. The latter has become a popular knowledge translation and exchange strategy to promote interaction between researchers and end users, as well as to develop capacity for evidence-informed decision making. Knowledge-brokering can be carried out by individuals, groups and/or organisations, as well as entire countries. In each case, the knowledge broker is linked with a group of end users and focuses on promoting the integration of the best available evidence into policy and practice-related decisions. The novelty of the knowledge broker role in public health provides a unique opportunity to assess the need for and reaction to the role and its associated activities (Dobbins et al, 2009). Such an evaluative perspective is also warranted for other interventions aimed at improving health research uptake.

Several earlier systematic reviews have summarised policy-makers perceptions on barriers and facilitators to knowledge translation (IDRC 2003; Innvaer et al, 2002; Mitton et al, 2007). The following table summarises the main factors identified:

Barriers	Facilitators
Individual level • Lack of experience and capacity for assessing evidence • Mutual mistrust • Negative attitude towards change and research	Individual level • Ongoing collaboration • Values research • Networks • Building of trust • Clear roles and responsibilities
Organisational level / environment • Unsupportive culture • Competing interests • Frequent staff turnover • Interest group pressure on decision makers • Issues of censorship and control • "Anti-intellectualism" in government against use of research • Importance of indigenous knowledge (religion and cultural differences)	Organisational level / environment • Provision of support and training (capacity building) • Sufficient resources (money, technology) • Authority to implement changes • Readiness for change • Collaborative research partnerships • Community pressure or client demand for research
Related to communication • Poor choice of messenger • Information overload • Traditional, academic language • No actionable message (information on what needs to be done and the implications)	Related to communication • Face-to-face exchanges • Involvement of decision makers in research planning and design • Clear summaries with policy recommendations • Tailored to specific audience • Relevance of research • Knowledge brokers • Opinion leader or champion (expert, credible sources)
Related to time or timing • Differences in decision makers' and researchers' time frames • Limited time to make decisions	Related to time or timing • Sufficient time to make decisions • Inclusion of short-term objectives to satisfy decision makers

Mitton et al. (2007) also reviewed studies implementing knowledge translation strategies. Ten of the 18 studies they identified satisfied their quality criteria. Eight of these studies were from Canada and two were from the UK. The studies examined the following strategies: face-to-face exchange (consultation, regular meetings) between decision makers and researchers, education sessions for decision makers, networks and communities of practice, facilitated meetings between decision makers and researchers, interactive multidisciplinary workshops, capacity building within health services and health delivery organisations, web-based information and electronic communications, steering committees (to integrate views of local experts into design, conduct and interpretation of research). The message communicators included researchers, decision makers and knowledge brokers. However, most of the studies did not include clearly defined outcome measures and the focus of most studies was to describe the transfer and exchange of the information rather than a formal

evaluation of the knowledge translation strategy and no firm conclusions regarding the effectiveness of the strategies could be drawn. They do however summarise under "grey literature" one randomised controlled trial that has been published in full since (Dobbins et al., 2009). In this trial, the effectiveness of three knowledge translation strategies were tested in Canadian public health decision making in programmes related to the promotion of physical activity and healthy body weight in children. The interventions included access to an online registry of research evidence, tailored messaging, and a knowledge broker. Some evidence of a positive effect on decision-making was only seen for targeted messaging. The knowledge brokering intervention was affected by the value placed by public health organisations on research evidence. In those organisations placing less value on research evidence, knowledge brokering was more effective, whereas it was less effective in organisations already recognising the importance of evidence-based decision making.

Several systematic reviews are currently underway to address the effectiveness of knowledge translation strategies. Ciliska et al.[1] in Canada are conducting a systematic review on the effectiveness of knowledge translation strategies used to promote evidence informed decision making among public health practitioners in community or public health settings. While a strong emphasis of this review is on translation of research to public health practice, policy making at the local level is also included and outcomes include strategic changes in terms of research knowledge being transferred to public health policy and programme development. The review includes a broad range of study types (practitioner randomised controlled trials, cluster randomised controlled trials, non-randomised cluster controlled trials, controlled before and after studies, interrupted time series designs, qualitative studies) and includes studies both from high and low and middle income country settings.

Armstrong et al.[2] in Australia are conducting a systematic review on the effectiveness of knowledge translation strategies from research to public health decision making. The review also includes a range of study designs including qualitative evidence; both studies from high and low / middle income countries are included, but the review is not in the public domain yet.

We have not identified any systematic reviews specifically about the translation of health research into health policy in developing countries. The present review will therefore focus on knowledge translation into both local and higher level policy decision making in low and middle income countries only. The primary rationale for this relates to the importance of context to strategies for knowledge translation, in terms both of the wider health system and the major burden of ill-health (Nutley et al, 2007; Carden, 2009). These influences vary across the continuum from the poorest to richest country, but grouping together low & middle income countries provides some contextual homogeneity. In global terms, these countries also bear a disproportionate share of communicable and non-communicable diseases, are those most unlikely to achieve many of the Millennium Development Goals by 2015 (UNDP, 2010), and thus represent the focus of interest for bi-lateral agencies, such as DFID, in terms of development assistance (Greco, et al 2008). Lessons from this systematic review on strategies for increasing policy uptake of evidence on effective interventions have the potential to support efforts to accelerate health improvement in low and middle income countries.

Objectives
To assess the effects of interventions to improve health research uptake into health policy in low and middle income countries. This will include studies to:
- evaluate the effects in different settings and among different end-user groups, including both positive and negative effects
- explore the contextual and enabling factors most closely associated with these effects

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[1] Professor at McMaster University (Hamilton, Ontario), School of Nursing and Scientific Director of the National Collaborating Centre for Methods and Tools; review expected to be available by the end of the year
[2] Senior Research Fellow in knowledge translation and exchange at the School of Population Health, University of Melbourne, and Cochrane Public Health Group; review expected to be available by the end of the year

- better understand which combination of interventions is associated with optimal evidence-informed decision making outcomes, and whether the combination changes in different settings and among different end-users

Inclusion criteria

Types of studies

The following types of studies will be eligible for inclusion:

- Randomised controlled trials, controlled trials
- Observational studies with a comparison group
- Prospective longitudinal before and after studies
- Systematic reviews (of interventions to facilitate knowledge transfer into health policy and of barriers and facilitators to knowledge transfer)
- Qualitative and quantitative studies of barriers and facilitators of knowledge transfer

Where relevant systematic reviews are identified, these will be summarised and results will be supplemented with results from relevant primary studies not included in the reviews. In the case of systematic reviews including both studies from high and low / middle income countries, only the evidence from low / middle income countries will be summarised; if this is not possible and the majority of studies in the review is from high income countries (or the provenance of the studies is unclear), the review will be excluded.

Types of interventions

Any knowledge translation strategy directed at health decision makers and aimed at promoting or facilitating the use of research evidence into policy and policy implementation.

This could include, for example:
- Education / workshops / reminders / tailored messaging for decision-makers
- Capacity building for decision makers to access and demand for research evidence
- Deliberative processes for priority setting
- Knowledge brokers
- Establishment of networks linking research and policy
- Policy dialogues
- Platforms for exchange between decision-makers and health researchers
- Health research studies commissioned by decision-makers and aiming at improving practice in a certain area of health care

We will consider interventions in terms of the different stages of the knowledge-to-action cycle developed by Graham et al (2006) mentioned earlier, which includes the following steps:
1. Identify a problem that needs addressing: a) identify need for change, b) identify change agents, c) identify target audience, d) link with appropriate individuals or groups with vested interests in the project.
2. Review the evidence or literature.
3. Adapt the evidence and/or develop the innovation.
4. Assess barriers to using the knowledge.
5. Select and tailor interventions to promote the use of knowledge.
6. Implement the innovation.
7. Develop the plan to evaluate the use of knowledge: a) pilot test, b) evaluate the process to determine whether and how the innovation is used.

8. Evaluate the outcomes or impact of the innovation.
9. Maintain change & sustain ongoing knowledge use.
10. Disseminate results of the implementation process.

Types of participants

The interventions included will be aimed at those involved in health policy making at local, sub-national, national or global levels in low and middle income countries. These will interact, for example, with health care professionals using health research evidence for practice, researchers generating evidence, funding agencies, knowledge brokers etc. All areas of health care relevant to public health and health policy will be included.

The World Bank definition of low and middle income countries will be used.

Exclusion: studies targeted directly at clinicians and other healthcare practitioners for translation of research evidence into practice.

Types of outcomes

For policy and policy implementation, a broad range of outcomes from interventions will be sought along the continuum from policy-maker to population beneficiaries. To be included, studies have to report at least one policy-related outcome.

Primary outcome:
- Change in health policies based on uptake of research evidence

Other outcomes may include:
- Policy-related outcomes:
  - New government directives and other policy documents
  - Increased resource commitments, financing of evidence-based health programmes
  - Planning and implementation reports for health strategies, services, and programmes
  - Mass media materials (e.g. government news releases)
  - Organisational change (either in institutions related to health practice or to health policy, e.g. establishment of public health ministry etc.)
  - Indicators of sustainability
- Practice-related outcomes:
  - Evidence-based clinical guidelines
  - Rules and regulations
  - Process indicators of availability and utilisation of new practice
- Behavioural and psychosocial outcomes:
  - Stakeholder / policy-maker knowledge and attitudes
  - Acceptability and views of policy-makers regarding interventions
  - Barriers and facilitators of uptake of research into policy
- Health outcomes [only if policy changes are also reported]
  - Any health-related outcomes relevant to the policy (hard patient-oriented outcomes)
- Adverse effects of any interventions (e.g. such as disproportionate disruption of policy priorities or increased under- and mis-reporting of practices)

Methods

Search strategy

The following electronic databases will be searched for relevant studies:
- WorldCat
- MEDLINE / PubMed
- EMBASE
- CINAHL
- POPLINE
- The Cochrane Library (all databases)
- Google Scholar
- Campbell Collaboration
- World Health Organisation and other UN agencies
- Database of promoting health effectiveness reviews (DoPHER)
- African Index Medicus (AIM)

If time permits, other more region- or subject-specific databases may also be searched.

Unpublished studies will be identified through the following databases:
- ISI Web of Knowledge (includes Conference Proceedings, BIOSIS Previews, and Journal Citation Reports)
- ZETOC
- Databases of ongoing studies – such as http://www.ClinicalTrials.gov and http://www.who.int/trialsearch/

Other search strategies will include:
- Examination of reference lists from relevant studies
- Citation searching
- Contacting experts in relevant research centres or specialist libraries e.g. SUPPORT network; CIHR; etc

The International Development Research Centre (2003) has identified a range of networks that could play a role in research translation in low and middle income countries, and their websites will be searched for relevant information. These networks include (only the ones still active are listed here):
- Afro-Nets (http://www.afronets.org/)
- The Bellanet Alliance (http://www.bellanet.org/)
- The Development Gateway (http://www.developmentgateway.org/)
- Global Development Network (http://www.gdnet.org/)
- Global Knowledge Partnership (http://www.globalknowledgepartnership.org/)
- The Health Systems Trust (http://www.hst.org.za/)
- Equinet Africa (http://www.equinetafrica.org/)
- Sustainable Communications Development Network (http://www.sdcn.org/)
- Trade Knowledge Network (http://www.tradeknowledgenetwork.net/)
- Pragmatic Trials in Health Care (http://www.practihc.net)
- Different WHO programmes, e.g. the Alliance for Health Policy and Systems Research (http://www.who.int/alliance-hpsr/en/), Tropical Disease Research (http://apps.who.int/tdr/) and the Human Reproductive Programme (http://www.who.int/hrp/en/)

Other relevant networks active in the field and website to consult include:
- The SUPPORT Collaboration (http://www.support-collaboration.org)
- EVIPNet (the Evidence-Informed Policy Network, http://www.evipnet.org)

- International Health Partnership (http://www.internationalhealthpartnership.net)
- Knowledge Utilization, University of Laval (http://kuuc.chair.ulaval.ca/english/index.php)
- McMaster KT+ Database (http://plus.mcmaster.ca/kt/)
- The Knowledge Brokers' Forum (http://www.knowledgebrokersforum.org/)
- Health Systems Evidence (McMaster University) (http://www.healthsystemsevidence.org/)
- J-PAL initiative (Massachusetts Institute of Technology) (http://www.povertyactionlab.org/)
- Source – International Information Support Centre (http://www.asksource.info/)
- Centre for Global Development (http://www.cgdev.org/section/topics/global_health)

The following search terms (PubMed, to be adapted for use with the other databases) will be combined (terms within columns to be combined with "OR", columns to be combined with "AND"):

Knowledge translation	Policy	Study type	Geographic region
best practices adoption	decision-making	trial*	"developing country"
adoption of best practices	policy	outcome*	"developing countries"
change implementation	policies	effect*	"middle income"
dissemination	program*	evaluate	"low income"
evidence uptake	strateg*	evaluation*	"third world"
evidence-based decision-making		implement*	poverty
evidence-based policy-making		improve *	"resource poor"
evidence-informed policy-making		intervention*	"poor country"
evidence to policy		measure*	"poor countries"
implementation research		cohort	"Developing Countries"[Mesh]
implementation science		compare*	"Poverty"[Mesh]
information utilisation		comparison	"Africa"[Mesh]
information utilization		comparative	"Caribbean Region"[Mesh]
knowledge broker*		controlled	"Central America"[Mesh]
knowledge translation		randomised	"Latin America"[Mesh]
knowledge transfer		randomized	"South America"[Mesh]
knowledge transformation		qualitative	"Asia"[Mesh]
knowledge utilisation		"Clinical Trial "[Publication Type]	
knowledge utilization		"Epidemiologic Studies"[Mesh]	
knowledge exchange		"Comparative Effectiveness Research"[Mesh]	
knowledge adoption		"Comparative Study "[Publication Type]	
knowledge mobilisation		"Evaluation Studies "[Publication Type]	
knowledge mobilization		"Meta-Analysis "[Publication Type]	
knowledge to action		"Multicenter Study "[Publication Type]	
research utilization		"Validation Studies "[Publication Type]	
research utilisation		"Empirical Research"[Mesh]	
research to policy			
research transfer			
research translation			

Due to time constraints, the search will be limited to studies published in English language from 1990 onwards (when the Cochrane and Campbell Collaborations became established). The two journals Implementation Science (2006 to Oct 2010) and Health Policy and Planning (2000 to Oct 2010) will be hand-searched.

Study selection

- Stage 1: The titles and abstracts of identified studies will be screened by two researchers for relevance to the topic. Those studies considered not to be relevant on the grounds of topic will be excluded. Studies involving the topic, but perhaps not relevant on the grounds of population will be passed to the team for consideration
- Stage 2: Full text/papers will be sought for all studies appearing to meet the inclusion criteria and a final selection will be made by two independent reviewers.

A flow chart will be produced to facilitate transparency of the process.

Data extraction

Data will be extracted from the studies identified using a structured data extraction form. Given the limited time and resources available for the review, this will be a simple text based form in the word processing package MS Word. The data will be entered on to the form electronically to facilitate data summarisation and the writing of the final report. A sample data extraction form is shown in Appendix I. Where possible, authors of primary studies will be contacted to provide essential missing or additional data. A second researcher will independently check the data extraction forms for accuracy and detail. Disagreements will be resolved by consensus or by consulting a third reviewer, if necessary.

Data will be extracted wherever possible to enable strategies for translation of health research into health policy to be considered according to the characteristics of the decision-making environment as defined by Carden (2009), including:
- The nature of the decision-making regime: 1. routine; 2. incremental; 3. fundamental.
- Type of research and policy interaction: 1. clear government demand; 2. government interest in research, but leadership absent; 3. government interest in research, but with a capacity shortfall; 4. a new or emerging issue activates research, but leaves policymakers uninterested; 5. government treats research with disinterest or hostility.
- Contingencies: 1. stability of decision-making institutions; 2. capacity of policy-makers to apply research; 3. decentralisation or tight central control; 4. special opportunities for countries in transition; 5. economic crisis and pressures on government.
- Communication and research management strategies; timing.

Quality assessment

Study quality will be assessed using the methods recommended for public health guidance by the UK National Institute for Health and Clinical Excellence (NICE, 2009). Quality will be assessed by one reviewer and a proportion of the assessments will be double-checked by a second reviewer. Disagreements will be resolved by consensus or by consulting a third reviewer, if necessary.

Quantitative intervention studies:
1. Population
    1.1. Is the source population or source area well described?
    1.2. Is the eligible population or area representative of the source population or area?
    1.3. Do the selected participants or areas represent the eligible population or area?

2. Method of allocation to intervention (or comparison)
    2.1. Allocation to intervention (or comparison). How was selection bias minimised?
    2.2. Were interventions (and comparisons) well described and appropriate?
    2.3. Was the allocation concealed?
    2.4. Were participants and/or investigators blind to exposure and comparison?
    2.5. Was the exposure to the intervention and comparison adequate?
    2.6. Was contamination acceptably low?
    2.7. Were other interventions similar in both groups?
    2.8. Were all participants accounted for at study conclusion?
    2.9. Did the setting reflect the country's usual practice?
    2.10. Did the intervention or control comparison reflect the country's usual practice?
3. Outcomes
    3.1. Were outcome measures reliable?
    3.2. Were all outcome measurements complete?
    3.3. Were all important outcomes assessed?
    3.4. Were outcomes relevant?
    3.5. Were there similar follow-up times in exposure and comparison groups?
    3.6. Was follow-up time meaningful?
4. Analyses
    4.1. Were exposure and comparison groups similar at baseline? If not, were these adjusted?
    4.2. Was intention to treat (ITT) analysis conducted?
    4.3. Was the study sufficiently powered to detect an intervention effect (if one exists)?
    4.4. Were the estimates of effect size given or calculable?
    4.5. Were the analytical methods appropriate?
    4.6. Was the precision of intervention effects given or calculable? Were they meaningful?
5. Summary
    5.1. Are the study results internally valid (i.e. unbiased)?
    5.2. Are the findings generalisable to the source population (i.e. externally valid)?

Quantitative studies reporting correlations and associations:
1. Population
    1.1. Is the source population or source area well described?
    1.2. Is the eligible population or area representative of the source population or area?
    1.3. Do the selected participants or areas represent the eligible population or area?
2. Method of selection of exposure (or comparison) group
    2.1. Selection of exposure (and comparison) group. How was selection bias minimised?
    2.2. Was the selection of explanatory variables based on a sound theoretical basis?
    2.3. Was the contamination acceptably low?
    2.4. How well were likely confounding factors identified and controlled?
    2.5. Was the setting relevant to low and middle income countries?
3. Outcomes
    3.1. Were outcome measures and procedures reliable?
    3.2. Were all outcome measurements complete?
    3.3. Were all the important outcomes assessed?
    3.4. Was there a similar follow-up time in exposure and comparison groups?
    3.5. Was follow-up time meaningful?
4. Analyses
    4.1. Was the study sufficiently powered to detect an intervention effect (if one exists)?
    4.2. Were multiple explanatory variables considered in the analyses?
    4.3. Were the analytical methods appropriate?

4.4. Was the precision of intervention effects given or calculable? Were they meaningful?
5. Summary
   5.1. Are the study results internally valid (i.e. unbiased)?
   5.2. Are the findings generalisable to the source population (i.e. externally valid)?

Qualitative studies
1. Theoretical approach
   1.1. Is a qualitative approach appropriate?
   1.2. Is the study clear in what it seeks to do?
2. Study Design
   2.1. How defensible/rigorous is the research design/methodology?
3. Data collection
   3.1. How well was the data collection carried out?
4. Trustworthiness
   4.1. Is the role of the researcher clearly described?
   4.2. Is the context clearly described?
   4.3. Were the methods reliable?
5. Analysis
   5.1. Is the data analysis sufficiently rigorous?
   5.2. Are the data 'rich'?
   5.3. Is the analysis reliable?
   5.4. Are the findings convincing?
   5.5. Are the findings relevant to the aims of the study?
   5.6. Adequacy of Conclusions
6. Ethics
   6.1. How clear and coherent is the reporting of ethics?
7. Overall assessment
Items will be rated as suggested by the NICE methodology guide.

Assessment of systematic reviews will be based on the PRISMA statement (Moher et al, 2007):
- Inclusion criteria described (study design, participants, interventions, outcomes)
- Details of literature search given (databases, dates, keywords, restrictions)
- Study selection described
- Data extraction described
- Study quality assessment described
- Study flow shown
- Study characteristics of individual studies described
- Quality of individual studies given
- Results of individual studies shown
- Was the statistical analysis appropriate?

Data synthesis

The types of interventions being evaluated in this review will be diverse in settings, mechanisms and methods of measuring outcomes. This will result in significant heterogeneity and thus pooling will not be possible. Findings will thus be summarised narratively, using text and tables. Qualitative and quantitative studies will be reported separately. If possible, interventions will be grouped be a) type of knowledge translation intervention, b) setting (e.g. low income, middle income country), c) area of care (e.g. primary care etc.).

This will follow the CRD recommended approach of tabulating study type, interventions, number of participants, summary of participant characteristics, outcomes and outcome measures. A separate table may be used to record study quality or risk of bias. Given the variety of study designs and the limited timing

available, synthesis will most likely to be through a narrative approach. To explore generalisability, qualitative evidence relating to the underlying factors that determine or hinder the effectiveness of interventions will be examined. Quantitative and qualitative components of the review will be compared from different study contexts.

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APPENDIX I – **Sample data extraction sheet for primary studies**

Study / design	Participants	Interventions / Outcome measures	Quality
Study ID year **country:** **medical field:** **focus:** **design:** **setting:** **single/multi-centre** **duration:** **follow-up:** **funding:**	**type of participants involved:** **total number / number in any** **comparison groups:** **inclusion criteria:** **exclusion criteria:** **baseline practice to be addressed:** *Information about government:* **type of government:** **category of receptivity (Carden):** *Information about decision makers,* *such as:* **position of decision maker:** **discipline of decision maker:** **years in current position:** **years in public health:** **subgroups:**	*Interventions:* **intervention:** **control:** **both groups:** *Outcome measures* **primary:** **process evaluation:** **implementation in policies:** **implementation in practice:** **knowledge:** **attitudes:** **views:** **other:** **timing of assessment:**	*Use quality checklist as per "assessment of quality section"*