Contextual evidence in clinical medicine and health promotion

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Introduction

The randomized clinical trial (RCT) and systematic review underpin evidence-based medicine. They are perceived to provide the strongest evidence on interventions—when viewed as part of an evidence hierarchy, and are generally accepted as such, in clinical medicine. Yet, they are perceived to have limited currency in health promotion practice.1 Those trying to build bridges across these fields have often been challenged as to whether or not the RCT is the design for both.2 We argue that ‘real life’, including decision making and practice both in clinical medicine and health promotion, requires contextualized evidence; that integrated research on outcome and context is feasible and desirable, both in clinical medicine and health promotion; and that these fields could learn from each other’s approaches towards contextualization of evidence.

Clinical medicine

Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. It integrates the best external evidence with individual clinical expertise and patients’ choice.3 In generating external evidence, various research designs are applicable. The RCT and systematic review of trials are regarded as the best options for answering questions on the efficacy of interventions. Diagnostic and prognostic studies require other types of designs.

Making a clinical decision in the treatment of a specific patient requires information on the clinical profile of the patient. The clinician needs to assess whether this patient resembles the ‘average’ patient who is typically being studied in RCTs and to whom guidelines typically refer. The selection criteria in RCTs frequently exclude e.g. co-morbid conditions, younger patients or elderly. Using clinical experience, the clinician evaluates the profile of the patient and decides whether the ‘average’—approach is likely to be successful for this patient. In case of important differences between the clinical patient profile and the ‘average’ patient, the clinician should make his own decisions, based on the clinical profile of this particular patient.

Patients’ preferences and attitudes increasingly contribute to the decision making process in clinical medicine. Individualized assessment instruments enable patients to give their own definition of the clinical problem e.g. for the assessment of quality of life, functioning and disability. First, the patient describes the nature of his health-related problem(s); referring to personal experiences and using own words. The patient subsequently rates the frequency, severity or importance of the problem(s). This individualized approach towards health assessment contrasts with the traditional approach of presenting a list of professionally defined problems, which may not apply to the problem of this specific patient.

Service models such as ‘patient centred care’ and ‘collaborative care’ emphasize the patient as an active partner in the decision making process. Key elements in these models are: personalized identification and prioritisation of health problems; identification of personal strengths, resources and environmental conditions; selecting appropriate treatment based on research evidence; collaborative goal setting and agreement between clinician and patient on the implementation of treatment; treatment with a strong focus on self-management; monitoring of outcome; and adaptation of treatment, if required.4 Thus evidence-based practice in clinical medicine is heavily influenced by contextual information on specific patient profiles, on patient preferences and patient contributions to treatment.

Health promotion and analogies to clinical medicine

Evidence-based health promotion (according to the World Health Organisation) is the use of information from formal research and systematic investigation to identify causes and contributing factors to health needs and the most effective health promotion action in given contexts and populations. In health promotion (i) research evidence on health determinants informs what needs to be done; (ii) evidence on effectiveness of interventions informs what can be done in certain settings; however, (iii) what is actually done in practice depends on political and social factors; and (iv) how it is done depends on the resources, structures and stakeholders involved.5,6 Complex community interventions, typical of health promotion practice, provide challenges for applying research information on interventions because they take advantage of the existing strategies, initiatives, structures and channels in the communities7 and they do this in a participatory, empowering and ownership manner.

Where clinical medicine works on the level of individual patient, health promotion does it on the level of community (table 1). Clinical medicine typically deals with treatment and rehabilitation interventions whereas health promotion deals with community action, policies, structural and environmental changes. Clinical medicine adjusts treatment to fit the individual patient situation, community interventions proven efficient in research also need to adjust to local situations: lay values, community characteristics and priorities, culture and law. Decision making in clinical medicine happens between patient and clinician, whereas health promotion does it in a participatory way with local groups and other stakeholders.
and often with the existing resources. Similarly, in clinical medicine, the patient and clinician evaluate the outcome of the intervention together, and in health promotion only local community can answer questions like ‘did we achieve change’ or ‘does it matter to us’.

When conceptualizing ‘context’ within clinical medicine the focus is often the specific profile of the patient, patient preferences or the interaction between the patient and clinician. ‘Context’ in health promotion relates to the wider community or society, focusing on actions and changes in policies, politics and environment. Using an example of physical activity, in clinical medicine a patient and doctor can make an individually tailored plan for physical exercise, whereas health promotion would make plans to build bicycle lanes to enable people to be physically active.

### Research on outcome and context

Both clinical medicine and health promotion respect controlled designs as the preferred evidence source on outcome of interventions, wherever they are relevant. It is not so much a question of whether RCTs are valuable for developing an evidence-base—we know they are. Rather, it is a question of whether the traditional RCTs are the gold standard for gathering all types of evidence—we know they are not. The RCT has been originally developed to study outcome of interventions ‘independent of context’, emphasizing internal validity above external validity. As shown above, ‘real life’ including individual level clinical medicine and community-level health promotion is context dependent or context focused. The traditional RCT approach does not welcome patient profiles or wishes nor community values or priorities guiding and adapting intervention (bias by indication).

However, contextual information can be incorporated into the design of an RCT. This can be done e.g. by adding process evaluation to RCTs to get information on the context of an intervention; this information can be used to explore the implementation, receipt and setting of an intervention, and in the interpretation of the outcome results. Further, as Hawe et al. argue, standardization in complex interventions does not mean that all components of interventions are the same at different sites; instead, the function and process of interventions should be standardized; and intervention integrity could be defined as evidence of fit with the theory or principles of the hypothesized change process.

Thus RCTs can be complemented or adjusted to be sensitive to the context. However, the major part of the information on the context—e.g. the nature of patient’s preferences, or lay values and priorities—is best gathered in observational studies using (individualized) assessment instruments or surveys, not in a RCT. Thus, other designs than the RCT are required to adequately generate information on context.

### Sharing experience

Both clinical medicine and health promotion can contribute to the understanding of how to contextualize interventions, both in research and practice. Clinical medicine and health promotion could learn from each other’s developments. Clinical medicine has developed individualised measurement instruments—health promotion could learn and develop similar instruments for the community level. The health promotion community has advocated for well-planned process evaluation within trials. Clinical medicine could learn from these process evaluation methods. Sharing experience on contextualizing evidence will benefit both clinical medicine and health promotion.

### Conflict of interest

None declared.

### References


Received 27 May 2008, accepted 14 August 2008

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**Table 1** Analogies between clinical medicine and health promotion interventions

<table>
<thead>
<tr>
<th>Level of intervention</th>
<th>Clinical medicine</th>
<th>Health promotion</th>
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</thead>
<tbody>
<tr>
<td>Type of intervention</td>
<td>Patient treatment, rehabilitation</td>
<td>Community action, policy, structural/environmental</td>
</tr>
<tr>
<td>Needs assessment and evaluation</td>
<td>Patient preferences, goals</td>
<td>Lay values, priorities, resources, culture and laws in the community</td>
</tr>
<tr>
<td>Partners in decision making</td>
<td>Professionals</td>
<td>Local groups</td>
</tr>
<tr>
<td>Context</td>
<td>Healthcare, patient's immediate living conditions</td>
<td>Stakeholder perspective: politicians, health + other sectors' professionals</td>
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<tr>
<td></td>
<td></td>
<td>Environment, wider societal context such as policies, politics</td>
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