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Editorial

The challenges of designing and evaluating complex interventions

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Complex interventions are widely used in the health service and in public health practice, and are increasingly so in the realm of oral health and dentistry (e.g. Bradley *et al*., 1999; Bonetti *et al*., 2003; Blair *et al*., 2004; Renz *et al*., 2007; Shaw *et al*., 2009). The Medical Research Council (2008) describes them as interventions that contain several interacting components although the complexity may arise through several dimensions. Designing, implementing and analysing complex interventions can pose many challenges because they are generally multi-centred and always multi-faceted, involving multiple aims, targets, processes, and impacts. Not all of the facets or their interactions can be easily defined, predicted, or assessed, particularly when these interventions take place within the relatively uncontrolled environs of an existing organisation or health care system.

Often, the first challenge we meet is deciding on the intervention target(s). Identifying what requires intervening in or what exactly you want to change is not always straightforward. For example, the overall aim might be to improve patient oral health outcomes. However, oral health systematic reviews (www.thecochranelibrary.com) show that oral health outcomes can be influenced by changing many different behaviours, among which are improving oral hygiene, increasing the application of fissure sealants, increasing fluoride use by professionals and patients. To begin designing a complex intervention, decisions have to be made about the specific behaviour you want to target to achieve your overall aim. For example, improving oral hygiene may mean that your intervention targets the behaviour of patients (helping them perform better toothbrushing, or enabling them to request the dentist to fissure seal their children's teeth or provide advice on the optimum use of fluoride), the behaviour of dentists (encourage them to provide oral hygiene advice, or to focus more on preventive care in their patient management such as applying fluoride varnish or fissure sealants), and/or the behaviour of the system (inform policy change to provide greater financial incentives, or to provide required training/education). Decisions regarding the intervention target behaviour are usually pragmatic and based on what is currently generating personal, public or government interest, available expertise, and research and funding opportunities.

However, a study may have many aims that may influence the design of your intervention. For example, in one of our studies (Clarkson *et al*., 2009) we designed a complex intervention to improve oral health outcomes by changing patient behaviour, targeting how often as well as how thoroughly patients brushed their teeth. However, in addition to our aim of improving oral hygiene, we also had an aim to address a common criticism in research - that complex intervention development is often difficult to replicate. This influenced the design of our intervention as the content had to be evidence-based and have a transparent and replicable derivation, as did the intervention's framing (based on a behavioural change model), and format (that it could be delivered by any dentist within the time constraints of a primary care consultation). Another one of our aims for this study was to further an understanding of the impact of different trial designs on intervention effects. To that end we had to ensure that our intervention design was robust enough to be tested in independent trials of different designs (patient –randomised and cluster-randomised).

Similarly, theoretical aims can shape your intervention design. In many of our studies we use theories from different disciplines, particularly economic and psychological models (e.g. Bonetti *et al*., 2009; Chalkley *et al*., 2010), to inform the design of complex interventions and to help further our understanding of intervention effects, as well as the performance of target behaviours.

However, recognising that interventions can have multiple aims, and taking care to design your intervention so that its behavioural targets will help you achieve those aims, is only the first challenge in designing, implementing and evaluating complex interventions. The next challenge is to identify the process by which the intervention is to generate the desired change in the behavioural target(s). The original MRC (2000) guide to developing and implementing complex interventions calls this identifying the active ingredients of an intervention.

Take for example audit and feedback. It is one of the most common interventions in primary care, yet there is rarely a full description in the literature of the active ingredients in either process (Foy *et al*., 2005). What is known is that the success rate of an audit and feedback intervention is highly variable. However, without identifying the active ingredients within each process (e.g. is the focus on changing behaviour through upward and downward comparisons, positive or negative reinforcement, persuasion, confidence-building, education), it is not actually possible to either replicate an intervention's development or understand why it succeeded or failed.

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The MRC (2000, 2008) guides to developing complex interventions recommend using a theoretical model to define the active ingredients of change which can be included in an intervention. The challenge is in choosing the theoretical model. For example, The Theory of Planned Behaviour (Ajzen, 1991) is a psychological model which suggests that a behaviour is related to intention to perform it, attitude about it, perceived social pressure to do it, and perceptions about the difficulty of performing it. An intervention framed using this model would have these variables as its active ingredients, and so attempt to change a target behaviour by changing them. However, the active ingredient of an intervention framed using an educational model might focus on changing behaviour by changing knowledge. The active ingredient of an intervention framed using an economic model might be monetary incentives. The active ingredient of an intervention framed using a sociological model might be organisation structure or culture. Even within disciplines, the active ingredients of an intervention will differ. Another Psychological model, Implementation Intention Theory (Gollwitzer, 1999) specifies action plans about when and how a behaviour is to be performed as the means of influencing it. There is no set criteria to help you in choosing among the available models, since many of them have been successfully applied to understanding health-related outcomes including dentists' decision-making (Grimshaw *et al*., 2001; Eccles *et al*., 2005; Bonetti *et al*., 2010). Yet, no single theory or intervention design can be thought of as a magic bullet for enabling professional behaviour change (Oxman, 1995), and using any one or combination of theoretical models to frame the content and delivery format will result in very different interventions.

Another challenge that is relevant to the intervention process is choosing how to test your intervention once its content, framing, and delivery format have been determined. The gold standard method for testing complex interventions is a randomised controlled trial, but that may not be pragmatically possible. For example, your intervention may require context level adaptation, such as adjusting educational materials to suit various local learning styles and literacy levels. Since the trial of your intervention must take place within an existing organisation or health care system, it may only be possible to have quasi-experimental designs. You can also be faced with operational issues related to obtaining enough power to be able to answer your research questions. You may want to include a number of outcomes or test the influence of moderating variables (such as gender, years in practice, patient mix) but to do so in a randomised control trial may require recruiting numbers equating to national populations to power it.

The next challenge is to determine how to evaluate the impact of a complex intervention. This actually entails several challenges. Decisions have to be made about how the active ingredients are to be assessed, particularly if there are no standardised measures. In addition, it is not always possible to assess the outcome of interest and a proxy variable has to be created or employed. Related to this, decisions have to be made about how success is to be defined. For example, success could be defined as any significant change in outcome or proxy outcome or even any change. Decisions also need to be made about an appropriate analysis method (qualitative, quantitative, mixed methods) as well as the statistics themselves (e.g. descriptive matrices, t-tests, regressions). Many of these decisions will have to be made at the design stage, stemming from how the research questions are formulated.

Given that a complex intervention is multifaceted and usually operating within an existing health care system, it can be extremely difficult to identify exactly which element of the intervention is having the effect you record. Evaluating impact involves the challenge of identifying and collecting whatever information you can to understand the intervention effects. If it was successful, did it work through the mediating mechanisms (the active ingredients) as hypothesized? Did any of its components interact? Can the intervention be adopted on a wider scale or was success context specific? Will different doses or formats be required for it to be more successful or to enable it to be adopted service-wide? If the intervention was unsuccessful, was it because the intervention was faulty (in terms of the concept or theory), or problems with its delivery (i.e. control group contamination). Also, the larger environment may need to be assessed in some way, since intervention effects may be influenced by external health services reform and development.

Another evaluation challenge is separating out how your conducting the trial affected the results of that trial. This can happen in many ways. Influencing (or even trying to influence) the behaviour of a patient may also impact on the dentist in unexpected ways and vice versa. Also, when inviting people to participate in a trial we are ethically obligated to fully inform them of the subject of that trial. By agreeing to participate, the dentist or patient is immediately sensitised to that subject and may change their behaviour in unexpected ways, which may mask intervention effects - having it appear much more or much less effective than it actually is.

Related to the ethics of informed consent, is the seeking of ethical approval of your overall study**.** Research conducted within UK Universities and within NHS jurisdiction requires approval from ethic committees to ensure that a study does not infringe on the rights, safety, dignity and well-being of research participants. However, keeping to a protocol that does not contaminate trial results and yet matches a requirement of full disclosure for participants can sometimes be problematic. Furthermore, interventions for the purpose of research and interventions to enable service development have different ethical requirements that need to be taken into account. At present, this is challenging as there is lack of consistency in how ethics committees define research and service development.

Then there is the challenge of funding your research. Complex interventions are expensive to design, run, test and evaluate. Ensuring adequate funding for the running of your study is one of the most taxing aspects of research today – particularly in these times of full economic costing and limited funding resources. The application process itself can be a daunting task, and act as a barrier to undertaking research, even for experienced researchers. Sometimes it will be necessary to make subtle changes to your intervention design and target outcomes in order to meet the requirements of a particular funding body.

Finally, research results have to be disseminated if they are to be of wider value. The main challenge here is how best to communicate your results and their implications to stakeholders. Without engaging them, your results are unlikely to be translated into policy decisions with service-wide

implications. A related challenge is disseminating your results in a timely fashion to enable them to be synthesized into accumulating evidence-bases, such as systematic reviews. In an ideal world, this means publishing your study in scientific journals, whether your intervention was successful or not. However, sometimes it can be difficult to find journals who are willing to publish null results.

While there are references that can guide you in designing, implementing and evaluating complex interventions (e.g. MRC, 2008), there is no denying that there are challenges within challenges in ensuring a complex intervention has the greatest likelihood of success, that you have the greatest chance of understanding its effects, and enabling its implementation and adoption beyond your study. Nevertheless, meeting these challenges can help our colleagues and our patients provide and receive the best evidence-based care possible.

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