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Editorial

Using GRADE to reduce the theory-practice gap

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One of the most enduring problems in nursing and nurse education is what has been referred to as the theory-practice gap. Although there is a widespread consensus that that practice and research should be more closely aligned, a solution as to how this might be achieved is less clear, particularly as this has been an issue for some considerable period of time. Simplistic approaches of "teaching more/better research" are on their own a flawed response because there are fundamental problems with applying research directly to practice which these do not address. These include: that research is done on samples to estimate the effect in populations to which individual patients may not belong; there may be differences between effects at the population and individual level; that statistical tests often do not provide the information and cannot provide the surety that people often desire; and that the uncertainty surrounding research results is not always easy to interpret or explain.

To further complicate matters there has recently been a move towards encouraging a more sophisticated use of evidence; replacing the rigid hierarchy of evidence with more dynamic approaches that allow for contextual issues to be incorporated into the assessment of a body of evidence rather than individual papers. Such an approach recognises that although RCTs are generally a higher level of evidence than observational studies, the high level of control that makes this so also means that they are less likely to demonstrate effectiveness than observational studies unless the context of the study matches that of clinical practice. Thus observational studies can, on occasions provide a higher level of evidence than RCTs (GRADE Working Group, 2013). Systematic reviews and meta-analyses are generally considered to form a higher level of evidence still, but their use introduces the additional complications of methodological, clinical and outcome heterogeneity. In addition to this there is a myriad of other factors to be taken into account when translating evidence in to a practice recommendation.

1. Using Grading of Recommendation, Assessment, Development and Evaluation (GRADE)

Many of these factors were formalised in the Grading of Recommendation, Assessment, Development and Evaluation (GRADE) guidelines which have emerged as the predominant method of assessing in a transparent manner the quality (or certainty) of evidence and translating this into a strength of recommendation. They suggest that when turning evidence into healthcare recommendations a number of criteria should be used, these include the strength of the evidence in the form of one's confidence in the magnitude of the estimate of effect, but it is not limited to that alone. Other factors to be considered include the balance between desirable and undesirable outcomes, values and preferences about treatments, and resource use (GRADE Working Group, 2013). When formulating public health, health system and health policy recommendations the World Health Organization recommend adding the importance or priority of the problem being addressed, equity and human rights considerations, the acceptability of the intervention and its feasibility to these (World Health Organization, 2014).

This approach therefore explicitly acknowledges that healthcare recommendations need to be based on factors other than a simple critique and attempted implementation of any research findings, an error that evidence-based practice courses which concentrate on research alone may make. Furthermore, the outcome of this process is more than a simple recommendation to do or not do something, it also allows for different strengths of recommendation: strong or weak for or against an intervention, or no recommendation if there is so much uncertainty that even a weak recommendation cannot be made. Importantly the defining feature of a weak recommendation is that although most people would choose or be recommended a course of action, not all would choose it or benefit from it (GRADE Working Group, 2013). This makes the existence of different responses to the same evidence explicit, and where variation is therefore likely to be appropriate.

This approach also allows for one to make stronger recommendations than one might otherwise make just based on study outcomes using an overall assessment of all of these influencing factors. For example a meta-analysis showing that exercise improved depressive symptoms compared to pharmacological treatments by an average (standardized mean difference) of −0.11 [95% CI −0.34, 0.12] which is a small and non-statistically significant difference (Cooney et al., 2013) could still result in a recommendation for this treatment based on the relative desirable and undesirable effects of the treatments (very few undesirable effects and other positive effects such as improved fitness for exercise versus the adverse events associated with the drugs),

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if patients liked an exercise regime more than drugs, and/or if it were more cost effective. Based on the same outcome data one would probably not recommend a pharmacological treatment where there might be adverse effects however. Indeed this is reflected in the new NICE Guidance Depression in adults: treatment and management, where a new recommendation is to "Consider a physical activity programme specifically designed for people with depression as an initial treatment for people with less severe depression" (National Institute for Health and Care Excellence, 2018). Note the use of the word 'consider' in this sentence which NICE use when the balance between benefits and harms is small and so the recommendation is made with less certainty. In this case there are few obvious harms, but the benefit is small and the wide confidence interval that encompasses the null value (zero) mitigate against a stronger recommendation. A weak recommendation suggests that not all individuals would choose or be best treated by the recommended course of action and so greater consideration of individual factors may be needed to help decide (GRADE Working Group, 2013).

2. Evidence to Decision Frameworks

However, even where clear evidence or guidance exists, recommendations do not implement themselves. To help with this some guideline development groups produce implementation tools, for example those produced by NICE. Although these can be helpful they may not get over the problem of applying group level guidance to individual patients in specific contexts. For this purpose Evidence to Decision Frameworks may be helpful both in making decisions and explaining any apparent contradiction between research evidence and clinical practice; remembering that under GRADE the quality of evidence in the form of an assessment of one's confidence estimate of effect supports a particular recommendation is only one factor in making a recommendation.

The GRADE Evidence to Decision Framework recognises that there are a number of different types of decision, including clinical recommendations, coverage decisions, health system and public health recommendations, and diagnostic screening and other test recommendations, which are implemented at both the individual and population levels (Moberg et al., 2018). It is important to remember the level at which evidence applies; guidance is usually produced at a population level (for example people with type 1 diabetes) but implemented at sub-group level (people with diabetes at a particular clinic) or individual level (an individual with diabetes).

For clinical decisions at the population level there are twelve criteria to be considered, while at the individual level there are ten (Alonso-Coello et al., 2016); the individual level criteria being:

- Is the problem a priority (from the perspective of individual patients)? Healthcare professionals are used to prioritising care; but it is important to remember that patients may not attach the same priorities to problems as those treating them.
- How substantial are the desirable anticipated effects? A treatment with greater desirable effects is more likely to receive a stronger recommendation and be acceptable to patients. This assessment should include both frequency and magnitude of effect, using absolute numbers where possible (for example what proportion is likely to have the effect?) and the likely importance of the outcome.
- How substantial are the undesirable anticipated effects? Using the same rationale to that above, a treatment with greater undesirable effects is less to receive a stronger recommendation and be acceptable to patients.
- What is the overall certainty or quality of the evidence of effects? This requires an assessment of the certainty attached to outcome estimates, both negative and positive. This can be assessed using the main GRADE criteria for quality of evidence; and uncertainty would reduce the strength of any recommendation.
- Is there important uncertainty about or variability in how much people value the main outcomes? If there is uncertainty about how much patients or carers value the outcomes or if those with different values would make different decisions, this would reduce the strength of any recommendation.
- Does the balance between desirable and undesirable effects favour the intervention or the comparison? This should take into account the previous four questions (magnitude of desirable and undesirable effects, certainty of the evidence of these, and the value attached to the outcomes) and seek to make a judgment on the overall balance between desirable and undesirable effects.
- Does the cost effectiveness of the intervention (the out-of-pocket cost relative to the net desirable effect) favour the intervention or the comparison? There is a difference here between individual and group-level decisions as to whether this is assessed as the costs to the service, costs to the patient, or both. The nature of this assessment is also likely to depend on the way that healthcare costs are allocated between patient and provider, but in most circumstances the greater the costs the less likely a strong recommendation is. In some cases costs are critical to a recommendation.
- What would be the impact on health equity? Interventions should always seek to reduce inequity; for example by reducing barriers to access by cost or geography.
- Is the intervention acceptable to patients, their care givers, and healthcare providers? Acceptability can be influenced by many things, most commonly it is a mixture of the balance between the balance of desirable and undesirable effects, and associated financial costs.
- Is the intervention feasible for patients, their care givers, and healthcare providers? Feasibility may differ according to settings, for example what might be possible in an RCT conducted in a large tertiary centre might be wildly different to a small local hospital or an uncontrolled treatment as might be given in a general clinic. Patients may also not be able to comply with the treatment.

The main difference between the individual and population perspectives are that in the latter cost effectiveness is broken down into the size of resource requirements, the certainty of the evidence of resource requirements, and the cost effectiveness of intervention at a population level rather than focusing on the individual (Alonso-Coello et al., 2016).

Other considerations that might be used include:

- Any other evidence that may be useful but which is outside of the normal evidence hierarchy
- Plausible consequences even when evidence is lacking, for example effects on equality or access, or likely difficulties with implementation
- Explanation of any assumptions made
- Clear explanation of the reasons for a judgment if this does not clearly reflect research evidence
- The need to document the voting results or any discussions by the panel that affects the decision (Alonso-Coello et al., 2016).

Thus it is clear that clinicians and patients might make different decisions based on contextual and individual factors, which while informed by research evidence is not dependent on that alone. Additionally it emphasises the importance of how the application of group level guidance to individuals is carried out.

3. An Example – Fever in Children

One area where there is considerable variation from recommended practice is in the treatment of fever in children with antipyretic medicines. Guidance around the world recommends this only for distress (National Institute for Health and Care Excellence, 2013) or to improve the child's comfort (Sullivan et al., 2011), yet they use is much more

Table 1
Explaining theory-practice gap using the GRADE evidence to decision framework.

Criterion	Application to fever
Is the problem a priority (from the perspective of individual patients)?	Although fever does not need treating itself, both parents and professionals worry about it
How substantial are the desirable anticipated effects?	Reduction of fever may ease discomfort and pain
How substantial are the undesirable anticipated effects?	Use of antipyretics may exacerbate anxiety by implying that fever needs treatment, small possibility of adverse effects
What is the overall certainty of the evidence of effects?	Strong evidence for reduction in fever and pain
Is there important uncertainty about or variability in how much people value the main outcomes?	Clear evidence that parents and professionals value fever reduction
Does the balance between desirable and undesirable effects favour the intervention or the comparison?	No clear difference
Does the cost effectiveness of the intervention (the out-of-pocket cost relative to the net desirable effect) favour the intervention or the comparison?	Some cost associated with medicines, although in the UK on prescription it is free to children. On a population level this cost may be substantial if widely prescribed.
What would be the impact on health equity?	No significant impact
Is the intervention acceptable to patients, their care givers, and healthcare providers?	Antipyretics are popular medicines among parents and professionals
Is the intervention feasible for patients, their care givers, and healthcare providers?	Yes, the medicines are relatively straightforward.

widespread among parents and professionals. Although there appears to be a clear gap between theory and practice, application of the Evidence to Decision Framework explains why this may be the case and demonstrates the complexity of theory behind the practice and the decision-making processes may be occurring (Table 1). There is therefore probably less of a theory-practice gap than it might first seem, it is just that practice includes things other than research evidence. Once students and staff understand that research itself is full of uncertainty, these contextual issues become clearer.

Declarations of Interest

None.

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