Methodology for the development of NHS Plus evidence-based guidelines

In a further bid to encourage the improvement of the quality of OH practice in the UK, NHS Plus has created a Clinical Effectiveness Unit in occupational health. The unit has been set up in partnership with the Royal College of Physicians and the Faculty of Occupational Medicine. The main functions of the unit will be to oversee the completion of the current evidence-based guidelines under development, to develop further guidelines and to
develop a national audit programme to ensure the implementation of the guidelines.

In order to maintain consistency between the guidelines, a common methodology was developed by the project leader based on Scottish Intercollegiate Guideline Network (SIGN) [1] methodology. The methodology for the systematic review and study selection process is based on CRD report 4, NHS Centre for Reviews and Dissemination, University of York [2]. The criteria for development, implementation and evaluation of guidelines are as recommended by the AGREE collaboration [3] The project was widely publicized among UK occupational health professionals via professional newsletters and individuals or groups were invited to submit topics and proposals for development. The applicants were asked to submit their review protocol with key questions broken down into a series of structured primary and secondary questions using the PICO format (population to be studied, intervention, comparison, outcomes and study designs to be included in the review) [4].

In developing the new guidelines, a stakeholder group was formed with representatives from the Health and Safety Executive, Health and Safety Commission, Trades Union Congress, Royal College of Nursing, British Medical Association, Faculty of Occupational Medicine, Department for Work and Pensions, Institute of Personnel Management, Association of NHS Occupational Physicians and Association of NHS Occupational Health Nurses. The stakeholder group assessed the proposals and the decision on whether or not to fund the proposal was based on the quality of the submission and the following criteria:

(i) Evidence of variation in practice, which affects management or clinical outcomes.
(ii) A strong research base providing evidence of effective practice.
(iii) The potential benefit to employees/employers must be sufficient to justify the resources invested in the development and implementation of the guidelines.

Successful applicants were asked to form and lead a multidisciplinary guideline development group (GDG). Selection of members of the GDG was dependant on the guideline under development and included a human resources representative, a manager, an academic (with expertise in the topic), an occupational physician, an occupational nurse (or other specialist nurse depending on the topic), a patient, a union representative, a general physician/surgeon or general practitioner with a special interest in the topic under development. All members of the GDG were asked to disclose conflicts of interest.

The GDG further refined the key questions, which then formed the basis of the strategy for the literature search. A wide number of databases were searched including as a minimum, OVID Medline, Embase, BNI Cochrane Library, CINAHL, PsycInfo (for reviews of psychological issues), Faculty of Occupational Medicine dissertation library and other databases relevant to the topic under investigation. The GDG decided on the scope of the search, including if language restrictions should be applied and what time period the search should cover. A research librarian undertook the literature search. Study inclusion and exclusion criteria were set by the GDG and the study selection process followed that recommended by CDR4.

In order to ensure consistency, a bespoke critical appraisal form based on the Critical Appraisal Skills Programme critical appraisal tools was devised [5]. Members of the GDG underwent a training session in critical appraisal skills and use of the critical appraisal form. Following the training session, selected members of the GDG with previous experience in epidemiology were assigned into pairs and given papers to critically appraise. Each person from the pair individually appraised each of their papers using the revised SIGN grading system (Table 1).

In the event that a pair or appraisers could not reach agreement on the SIGN grading, the paper was passed on to the GDG leader for final decision. Guidelines published after 2006 used the algorithm in Table 2 to classify studies [6].

Once all the papers had been appraised and the evidence level assigned, the results were tabulated. In line with National Institute for Clinical Excellence methodology [6], papers that had a high risk of bias or confounding (i.e. had been assigned a minus in their grading) were excluded from the evidence. Draft recommendations were drawn up and discussed by the GDG and levels of evidence were assigned as per Table 3.

Good practice points were assigned to practical points, which the GDG wished to emphasize, but for which there was not and is unlikely to be any research evidence.

Draft guidelines and A4 summary leaflets for employers, employees and health professionals were drafted. The guidelines follow a standard format and include suggested audit criteria and research recommendations for further research.

The draft guidelines were assessed by two independent expert referees who were asked to comment on the comprehensiveness and accuracy of interpretation of the evidence-based supporting the recommendations in the guideline. The comments were given to the GDG to address any points raised by the external reviewers. The final draft was circulated to members of the stakeholders group for collation of comments. Each member of the GDG formally approved the final version of the guideline prior to publication. A distribution and implementation plan was devised for each guideline depending on the principal target groups.
Table 1. Scottish Intercollegiate Guideline Network (SIGN) grading

Levels of evidence

1++
High-quality meta-analyses, systematic reviews of RCTs (randomized controlled trials), or RCTs with a very low risk of bias.

1
Well-conducted meta-analyses, systematic reviews of RCTs or RCTs with a low risk of bias

1−
Meta-analyses, systematic reviews of RCTs or RCTs with a high risk of bias

2++
High-quality systematic reviews of case–control or cohort studies. High-quality case–control or cohort studies with a low risk of confounding, bias or chance and a high probability that the relationship is causal

2+
Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2−
Case–control of cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is causal

3
Non-analytic studies, e.g. case reports, case series

4
Expert opinion

Table 2. NICE algorithm for classifying primary study—designs about effectiveness
Table 3. Assignment of grades of evidence to recommendations

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<thead>
<tr>
<th>Grades of recommendation</th>
<th>Description</th>
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<tbody>
<tr>
<td>A</td>
<td>At least one meta-analysis, systematic review or RCT rated as 1++ and directly applicable to the target population. A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results.</td>
</tr>
<tr>
<td>B</td>
<td>A body of evidence including studies rated as 2++, directly applicable to the target population and demonstrating overall consistency of results. Extrapolated evidence from studies rated as 1++ or 1+.</td>
</tr>
<tr>
<td>C</td>
<td>A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results. Extrapolated evidence from studies rated as 2++.</td>
</tr>
<tr>
<td>D</td>
<td>Evidence level 3 or 4. Extrapolated evidence from studies rated as 2+.</td>
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References