HEALTH EVIDENCE BULLETINS WALES

A systematic approach to identifying the evidence

PROJECT METHODOLOGY 5

Weightman AL, Mann MK, Sander L and Turley RL
Cardiff: Information Services UWCM, January 2004

Division of Information Services, University of Wales College of Medicine,
Heath Park, Cardiff, CF14 4XN, UK
Tel: +2920 745142, Fax: +2920 743574, http://hebw.uwcm.ac.uk

A Project supported by the National Public Health Service for Wales & the Welsh Assembly Government

CONTENTS:

INTRODUCTION

The importance of relating clinical practice more closely to evidence, including research evidence, is increasingly influencing the thinking of health-care professionals across the world and this is changing the whole culture of information use in support of patient care. It has been shown that, where evidence is used in a methodical and properly considered way, it can change clinical practice and affect patient outcomes[i].

There is a firm commitment to improve the funding of the NHS through additional expenditure and reorganisation so as to focus resources onto care delivery[ii]. Nevertheless, choices between competing priorities and forms of treatment will still be required. Given the limited time available to health professionals[iii], the frequency with which they require information[iv] and the emerging importance of clinical governance[v,vi], these decisions need to be informed by the presentation of current and valid information which is both concise and readily accessible.

Background to the Health Evidence Bulletins - Wales

The original *Protocols for Investment in Health Gain,* written in the early 1990s, suggested areas where the introduction, or more widespread use, of certain practices could lead to worthwhile improvements in health for the people of Wales. The documents also highlighted current practices which were of questionable value. Twelve subject areas were covered.

Influential commentators, whilst welcoming the Protocols in principle, noted that the statements contained in the documents were not always clearly linked to the evidence[vii]. As new approaches to clinical effectiveness and evidence-based practice began to emerge a review of the Protocols was proposed by the Chief Medical Officer. This resulted in the Health Evidence Bulletins - Wales Project which began in June 1995 to prepare clear statements classified according to internationally recognised systems with a precise indication, for each statement, of the sources and type of evidence.

The *Bulletins* act as signposts to the best current evidence across a broad range of evidence types and subject areas. Where evidence from randomised controlled trials (and systematic reviews/meta-analyses derived from such trials) is available, it is included. However, many health issues do not easily lend themselves to investigation, or have not yet been studied, by randomised controlled trial. In these cases, high quality evidence has been sought within the other evidence types. A substantial part of this evidence, much of it qualitative, is particularly relevant to nurses and the professions allied to medicine, and within the primary care sector[viii].

The Methodology used in the project is presented in two sections. The first outlines the stages in the process from defining the task to disseminating the resultant *Bulletins.* The second section (the Appendices) contains the documents (search strategies, critical appraisal check-lists etc.) developed to support the process. This Methodology 5 has been adapted from earlier Methodologies[ix] by drawing on the experiences of all those who have worked on the project. Specific comments on the Project Methodology have been received from Margot Greer, Dinah Roberts and David Fone of the National Public Health Service for Wales (NPHS) and their help is gratefully acknowledged. The Project is co-ordinated at the Division of Information Services, UWCM under the direction of Dr William Ritchie (NPHS).

---

[i] NHS Centre for Reviews and Dissemination. Implementing clinical practice guidelines. Effective Health Care Bulletin No.8. December 1994.

[ii] Ham, C. The future of the NHS. *British Medical Journal.* 1996; **313**: 1277-1278

[iii] Sackett DL, Richardson WS, Rosenberg W, Haynes RB. *Evidence-based medicine. How to practice and teach EBM*. New York: Churchill Livingstone, 1997 pp. 8-9

[iv] Smith R. What clinical information do doctors need? *British Medical Journal*. 1996; **313**: 1062-1068

[v] *A First Class Service. Quality in the New NHS.* London: Department of Health, 1998

[vi] *Putting Patients First. Framework Document.* Cardiff: National Assembly for Wales, 1999

[vii] Gabbay J, Stevens A. Towards investing in health gain (editorial). British Medical Journal. 1994; 308: 1117-1118

[viii] Jacobson LD, Edwards AGK, Branier SK, Butler CC. Evidence-based medicine and general practice. *British Journal of General Practice*. 1997; **47**: 449-452

[ix] Barker J. *Project for the enhancement of the Welsh Protocols for Investment in Health Gain: Project Methodology.* Cardiff: Duthie Library UWCM, 1996; Weightman AL, Barker J, Lancaster J. *Health Evidence Bulletins Wales. Project Methodology 3.* Cardiff: University of Wales College of Medicine, 2000; WeightmanAL, Barker J, Lancaster J. Health Evidence Bulletins Wales. Project Methodology 4. Cardiff. University of Wales College of Medicine, 2001.

AIMS AND OBJECTIVES

- To produce documents to aid local and national planning for the delivery of health and social care.

- To produce a matrix of statements (summaries of current research and other evidence in a subject area) and the evidence supporting those statements.

- To produce *Bulletins* (in text and electronic formats) containing these statements and details of the supporting evidence to facilitate dissemination of the findings.

- To provide electronic links to the evidence from the electronic versions of the bulletins, whenever this is available freely (in full or summary form) on the Internet.

- To inform and recommend action to the Wales Office of Research & Development and other research funding bodies in the light of the findings.

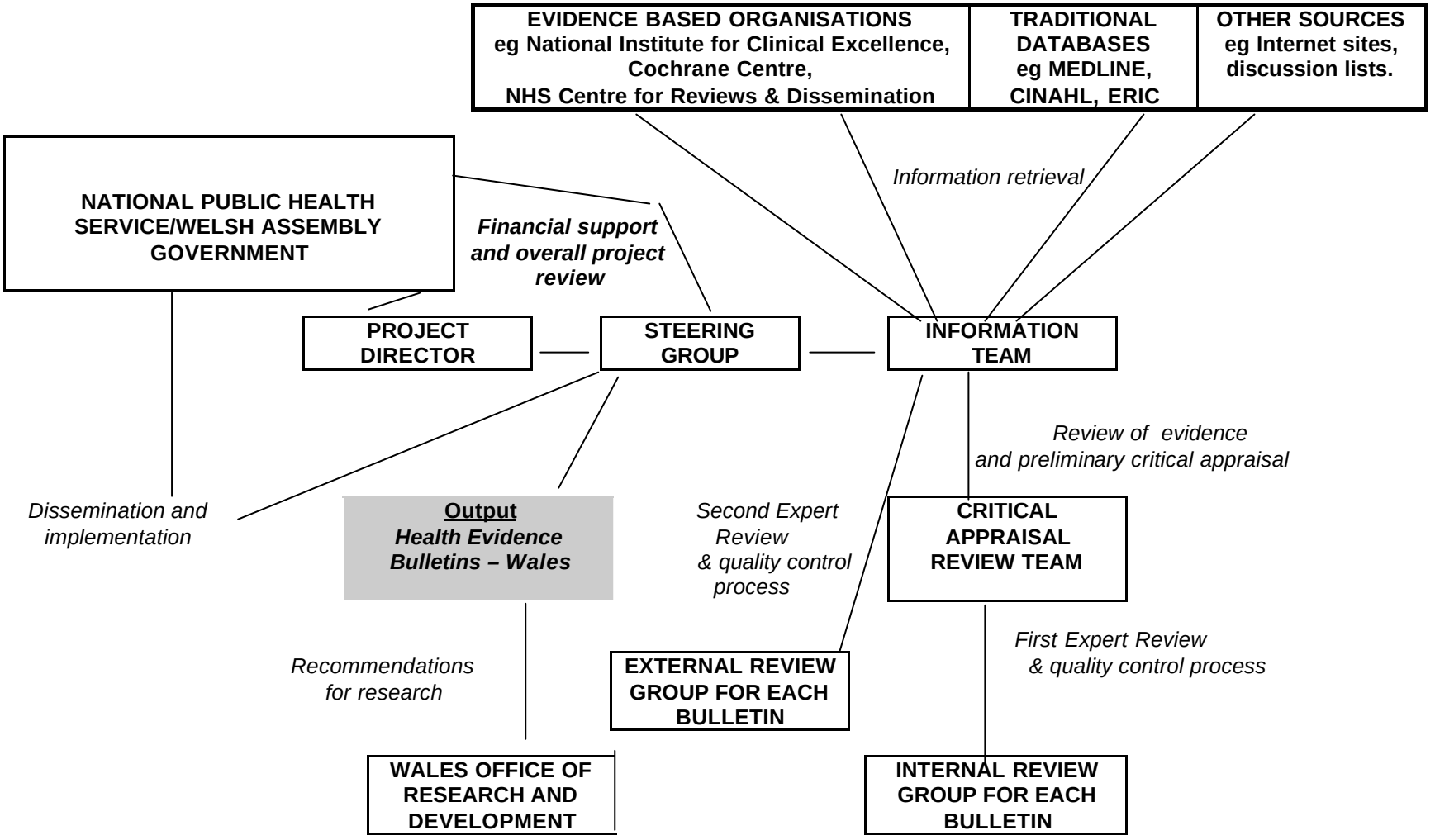
- To evaluate the Methodology and the *Bulletins* to maximise their acceptability and usability by health workers.

- To act as a catalyst for the development of evidence-based methods, information assessment and skills.

It is anticipated that the *Bulletins* will be of value in a wide variety of settings:

1. To assist Local Health Boards and the Welsh Assembly Government with the planning and commissioning of health care;
2. To inform clinical practice;
3. To identify areas for further research;
4. In continuing education and audit; and
5. In the development of educational curriculae.

OVERVIEW OF THE *HEALTH EVIDENCE BULLETINS – WALES*



METHODOLOGY

STAGE 1: DEFINING THE TASK

• Identify subject areas for searching by examining the existing bulletin or other guidance document (e.g. a National Service Framework) and on advice from the Steering Group.	*Information Manager/ Steering Group*
• Decide deadlines, and members of the critical appraisal and Internal Review Groups (Stages 4 and 5). [Each Appraisal Team should adopt a multidisciplinary approach and be aware of the information needs of medical, nursing and therapy professions as well as purchasers and consumers] [Members of the Internal Review Group should be acknowledged experts in their field. A multidisciplinary approach should be adopted to ensure coverage of all subject areas and viewpoints]	*Information Manager/ Steering Group*

STAGE 2: SEARCHING FOR INFORMATION

• Search for information in the subject areas identified in Stage 1 using appropriate sources from checklist (Appendix 1) and utilising master searches where available (Appendix 2). Carry out searches for each subject area in a stepped fashion for Types I to V evidence in a strict order (see Appendix 3 for explanation of evidence types).	*Information Officers*
• Carry out searches for a subject from the date given on the relevant chapter of an earlier bulletin if one exists. For new subject areas, search five-ten years initially depending on the amount of information in a given subject area. Search earlier dates if no systematic reviews (of randomised controlled trials (Type I) or observational studies (Type IV)) or randomised controlled trials (Type II) are found.	*Information Officers*
• Include English and non-English articles. Where the non-English abstracts seem to indicate a systematic review or a randomised controlled trial, arrange the translation of full-text documents.	*Information Officers*
• Store reference details, remove duplicates and print abstracts in a suitable format using reference management software.	*Information Officers*

STAGE 2: SEARCHING FOR INFORMATION CONT.

• Examine abstracts and, on the basis of inclusion/exclusion criteria agreed by the Steering Group, obtain relevant publications as full text. If in doubt, order document.	*Information Manager and Officers*
• Acquire full-text publications.	*Information Officers*

STAGE 3: GRADING AND SUMMARISING THE EVIDENCE

• For each full-text document supplied, attach an Evidence Form (Appendix 4) to provide the bibliographic details and indicate the type of evidence. Complete a copyright declaration for each document if required, and store in the Project Office.	*Information Officers*
• Organise the critical appraisal of each document using the appropriate Quality Appraisal Checklist as a guide (Appendices 5-11).	*Information Officers*
• Decide on the evidence to be included in the first draft of the *Bulletin*. If in doubt about inclusion, retain document and ask for advice from the critical appraisal review team.	*Information Officers/ Manager*
• Prepare the first draft of the *Bulletin* which should include a matrix of statements and the evidence which supports them (see Appendix 12). The statements should include (where appropriate): 1. the target population (e.g. age, sex); 2. quantitative information (e.g. Number Needed to Treat, % improvement); The evidence should be: 1. cited according to the Vancouver System 2. accompanied by an evidence type and any other relevant information about the research (See Appendix 13 for a summary)	*Information Officers/ Manager*

STAGE 3: GRADING AND SUMMARISING THE EVIDENCE CONT.

• Identify areas of little or no evidence, conflicting evidence or where evidence is of poor quality in order to: either pursue the search further or make a recommendation for further research Once evidence has been assigned to statements covering a particular subject, no other types of evidence will be sought although topics covered by systematic reviews may include more recent studies.	*Information Officers/ Manager*
• Store evidence to be included and critical appraisal checklists. Evidence excluded (and appraisal checklists) should also be retained in case of query.	*Information Officers*

STAGE 4: CRITICAL APPRAISAL REVIEW

• Supply first draft and all papers under consideration to critical appraisal review team.	*Information Manager/ CA team*
• Quality check all critical appraisal work carried out by Information Team and liaise with information team to resolve any discrepancies.	*CA Team/ Information Manager/Officers*

STAGE 5: INTERNAL REVIEW

• Submit the first draft of the Bulletin to the Internal Review Group asking for the following responses: 1. Do they agree with the statements and the supporting evidence? 2. Are they aware of any better evidence than that quoted? 3. Are there any relevant topic areas that are not included? 4. Any other comments.	*Information Manager/Internal Review Group*
• Gather and expedite responses, and liaise with reviewers over queries.	*Information Manager*
• Carry out further searching, appraisal and evaluation as necessary.	*Information Manager/ Officers*
• Liaise with critical appraisal team and internal review group to draw up a final draft for external review.	*Information Manager/ CA Team/Internal Review Group*
• Seek advice from the Review Groups on the Health Gain Notation to be applied to each statement (if used) **Strength of the finding (Health Gain Notation)** 'beneficial' - effectiveness clearly demonstrated (1) 'likely to be beneficial' - effectiveness not so firmly established (2) 'trade-off between beneficial and adverse effects' - effects weighed according to individual circumstances(3) 'unknown' - insufficient/inadequate for recommendation (4) 'unlikely to be beneficial' - ineffectiveness is not as clearly demonstrated as for 6 (5) 'likely to be ineffective or harmful' - ineffectiveness or harm clearly demonstrated (6) (adapted from Enkin M, Kierse MJNC, Renfrew M and Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995)	*Information Manager/ CA Team/Internal Review Group*

STAGE 6: EXTERNAL REVIEW

• Select External Reviewers of high standing (using suggestions from the Steering Group to appraise final Bulletins for currency, accuracy and completeness.	*Steering Group/ Information Manager*
• Co-ordinate the External Review process.	*Information Manager/External Review Group*
• Give approval for dissemination of the Bulletins.	*Steering Group*

STAGE 7: DISSEMINATING THE BULLETINS

• Complete an action plan for the dissemination of each Bulletin, clearly covering: 1. Distribution list (in primary, secondary, tertiary settings); 2. World-wide publication; 3. Relevant talks and conferences	*Steering Group*
• Carry out an ongoing evaluation programme to inform the further development of both text and electronic versions to assess the value and impact of the Bulletin.	*Information Manager/ Steering Group*

CHECKLIST OF INFORMATION SOURCES
(web site addresses are provided where sites are available free via the Internet – All links accessed on 02.12.03)

A/ CORE INFORMATION SOURCES (Consulted for every subject area)

SUBJECT:
Traditional bibliographic databases:
ASSIA Applied Social Science Index & Abstracts
CINAHL Cumulated Index to Nursing & Allied Health Literature
EMBASE
HMIC Health Information Management Consortium
MEDLINE [Available free on PubMed - http://www.ncbi.nlm.nih.gov/entrez/]
SIGLE System for Information on Grey Literature in Europe
Other databases:
Best Evidence (*Evidence Based Medicine* and *ACP Journal Club*)
Cochrane Library By subscription or (abstracts only) http://www.update-software.com/ccweb/cochrane/revabstr/mainindex.htm
Clinical Evidence http://www.clinicalevidence.com
Evidence Base (Health Development Agency) http://www.hda-online.org.uk/html/research/evidencebase.html (and **HealthPromis http://healthpromis.hea.org.uk)**
NRR National Research Register. http://www.doh.gov.uk/research/nrr.htm
ReFer Department of Health research http://tap.ukwebhost.eds.com/doh/refr_web.nsf/Home?OpenForm
REGARD Social Science Research http://www.regard.ac.uk
TRIP http://www.tripdatabase.com
Systematic reviews and guidelines:
Canadian Medical Association Infobase (clinical practice guidelines) http://www.cma.ca/cpgs/index.asp
eguidelines http://www.eguidelines.co.uk
Health Technology Assessment Programme. (NHS R&D, Southampton University). http://www.hta.nhsweb.nhs.uk
National Guideline Clearing House (US guidelines including AHRQ) http://www.guidelines.gov
National Institute for Clinical Excellence (NICE) http://www.nice.org.uk
NeLH guidelines finder http://www.nelh.nhs.uk/guidelinesfinder
NHS Centre for Reviews and Dissemination systematic reviews (including *Effective Health Care* Bulletins, databases: DARE, NHSEED, HTA, etc.) http://www.york.ac.uk/inst/crd
SIGN guidelines http://www.sign.ac.uk
New Zealand Guidelines http://www.nzgg.org.nz/
EPPI Centre http://eppi.ioe.ac.uk/EPPIWeb/home.aspx

B/ EXAMPLES OF ADDITIONAL AND SPECIALISED INFORMATION SOURCES (Consulted for some subject areas)

Traditional bibliographic databases:
AMED Allied and Alternative Medicine
CareData http://www.nisw2.org.uk
CommunityWISE http://www.oxmill.com/communitywise/
Environmental Abstracts
ERIC http://www.askeric.org
Iconda http://www.cas.org/ONLINE/DBSS/icondass.html
PsycINFO Psychological literature
National Rehabilitation Information Centre (NARIC) incorporating **Rehabdata** http://www.naric.com/search
SCI Science Citation Index
SSCI Social Science Citation Index
Urbadisk http://basidati.csita.unige.it/eng/cdrom/urbadisk.php
Organisations and Publications:
Bandolier http://www.jr2.ox.ac.uk/bandolier/index.html (also covered by the TRIP database)
CompMed Bulletin
Department of Health http://www.doh.gov.uk/index.htm
Health Services/Technology Assessment http://text.nlm.nih.gov/ftrs/gateway
Her Majesty's Stationary Office http://www.hmso.gov.uk/hmso.htm
LILACS Trials in South America http://www.bireme.br, http://www.evidencias.com
MIDIRS Midwifery Information http://www.midirs.org
National Electronic Library for Health (and branch libraries) http://www.nelh.nhs.uk
World Health Organisation (WHO). http://www.who.int/home-page
Royal Colleges & Societies including:
Royal College of General Practitioners. http://www.rcgp.org.uk
Royal College of Obstetricians & Gynaecologists. http://www.rcog.org.uk
Royal College of Physicians http://www.rcplondon.ac.uk & http://www.rcpe.ac.uk
Royal College of Psychiatrists http://www.rcpsych.ac.uk
Royal College of Surgeons http://www.rcseng.ac.uk/ & http://www.rcsed.ac.uk
Royal College of Nursing http://www.rcn.org.uk/index.html
Search Engines and Discussion Lists:
BIOME http://www.biome.ac.uk
evidence-based-health evidence-based-health@jiscmail.ac.uk
Google http://www.google.com
lis-medical lis-medical@jiscmail.ac.uk
public-health public-health@jiscmail.ac.uk
systematic reviews sys-review@jiscmail.ac.uk

EXAMPLES OF SEARCH STRATEGIES USED IN THE PROJECT

SEARCH FILTERS FOR MEDLINE (OVID)

GUIDELINES

Developed by the Evidence Based Informatics Project at McMaster University, Canada

01 guideline.pt.
02 practice guideline.pt.
03 exp guidelines/
04 health planning guidelines/
05 or/1-4

RANDOMISED CONTROLLED TRIALS

from the Evidence Based Informatics Project at McMaster University and a discussion with Sam Vincent (*Clinical Evidence,* London:BMA).
NB The *Cochrane Library* Controlled Trials Register now includes all the controlled trials in Medline plus many other trials, and they are currently adding trials from Embase.

Set Search
---
01 random:.tw,sh,pt. or placebo:.tw,sh.
02 (clinical trial or controlled clinical trial).pt.
03 ((single or doubl: or tripl: or treb:) and (blind: or mask:)).tw,ab
04 or/1-3

SYSTEMATIC REVIEWS AND/OR META-ANALYSES - FILTER 1

From Boynton J *et al.* Identifying systematic reviews in Medline. Developing an objective approach to search strategy design. *Journal of Information Science* 1998; **24(3)**: 137-157
Strategy sensitivity = 98%, precision=20%

01 (meta or synthesis or literature).ab
02 (randomized or trials or controlled).hw
03 (published or extraction or search or medline or selection).ab
04 meta-analysis.pt
05 (sources or trials or review).ab
06 (articles or reviewed or english or language).ab
07 **or/1-6**

/ = subject heading
ab = word contained in abstract
hw = word contained in title, abstract or subject heading
pt=publication type
sh = word contained in subject heading
tw = word contained in title or abstract

SEARCH FILTERS FOR MEDLINE (OVID) cont.

SYSTEMATIC REVIEWS AND/OR META-ANALYSES AND OTHER STUDIES – FILTER 2

A more specific, but less sensitive, filter from the Evidence Based Informatics Project at McMaster University.

Set	Search	
01	meta-analysis.pt,sh.	
02	(meta-anal: or metaanal:).tw.	
03	(quantitativ: review: or quantitativ: overview:).tw.	
04	(systematic: review: or systematic: overview:).tw.	
05	(methodologic: review: or methodologic: overview:).tw.	
06	(integrative research review: or research integration:).tw.	
07	quantitativ: synthes:.tw.	
08	**or/1-7**	**'Quick' search for systematic reviews/meta-analyses**
09	(medline or medlars).tw,sh. or embase.tw.	
10	(scisearch or psychinfo or psycinfo).tw.	
11	(psychlit or psyclit).tw.	
12	(hand search: or manual search:).tw.	
13	(electronic database: or bibliographic database:).tw.	
14	(pooling or pooled analys: or mantel haenszel).tw.	
15	(peto or der simonian or dersimonian or fixed effect:).tw.	
16	or/9-15	
17	review.pt,sh. or review:.tw. or overview:.tw.	
18	16 and 17	
19	**9 or 18**	**Most systematic reviews**
20	random:.tw,sh,pt. or placebo:.tw,sh.	
21	(clinical trial or controlled clinical trial).pt.	
22	(single or doubl: or tripl: or treb:) and (blind: or mask:)	
23	**or/20-22**	
24	**19 and 23**	**Systematic reviews/meta-analyses of therapies**

Search Filter to be added to the Systematic Reviews of Therapies Filter above to look for Observational Studies (Type IV evidence)
(under development for the *Health Evidence Bulletins - Wales* project)

024	**= systematic reviews of therapies filter (as above)**	
025	comparative study.sh	
026	exp evaluation studies/	
027	follow up studies.sh	
028	prospective studies.sh	
029	(single group pre-post or cohort or time series or case-control:).tw	
030	or/25-29	
031	**30 not (19 or 23)**	**Observational studies**

SEARCH FILTERS FOR EMBASE (OVID Internet)

RANDOMISED CONTROLLED TRIALS

Developed for use in the *Health Evidence Bulletins – Wales* from the McMaster Medline strategy and as a result of discussion with Sam Vincent (*Clinical Evidence,* London: BMA, NB The NHS Centre for Reviews and Dissemination is currently developing strategies for use with Embase)

1. exp Randomized Controlled Trial/
2. randomi?ed controlled trial.mp
3. (random: or placebo: or double-blind:).mp
4. or/1-3
5. controlled clinical trial.mp
6. **4 and 5**

SYSTEMATIC REVIEWS AND/OR META-ANALYSES

Developed for use in the *Health Evidence Bulletins – Wales* from the McMaster Medline strategy

1. exp meta analysis/
2. meta-anal:.mp
3. metaanal:.mp
4. quantitativ: review :.mp
5. quantitativ: overview:.mp
6. systematic: review:.mp
7. systematic: overview:.mp
8. methodologic: review:.mp
9. methodologic: overview:.mp
10. integrative research review:.mp
11. research integration:.mp
12. quantitativ: synthes:.mp
13. (medline or medlars or embase).mp
14. hand search:.mp
15. manual search:.mp
16. (pooling or pooled analy:).mp
17. mantel haenszel.mp
18. (peto or der simonian or dersimonian or fixed effect:).mp
19. (scisearch or psychinfo or psycinfo or psychlit or psyclit).mp
20. (electronic database: or bibliographic database:).mp
21. **or/1-20 SYSTEMATIC REVIEWS AND/OR META ANALYSES**

SYSTEMATIC REVIEWS/META-ANALYSES OF THERAPIES

If the randomised controlled trials filter is added to the end of the systematic reviews filter as lines 22-26 and lines 21 and 26 are combined then: **027 21 and 26 = systematic reviews of therapies**

SEARCH FILTER FOR CINAHL (OVID)

SYSTEMATIC REVIEWS AND/OR META-ANALYSES

Developed by the NHS Centre for Reviews and Dissemination. This search has a high recall but a low precision. The NHS CRD plan to develop the strategy into a tiered approach with the most precise search terms listed first.

01 meta analysis/
02 meta-analysis research/
03 metaanaly:.tw.
04 meta-analy:.tw.
05 cochrane:.tw.
06 nursing interventions.pt.
07 (review: or overview:).ti.
08 literature review/
09 literature searching/
10 computerized literature searching/
11 synthes:.tw. adj3 (literature: or research: or studies or data).tw.
12 (medline or medlars or embase or scisearch or psycinfo or psychinfo or psyclit or psychlit).tw,sh.
13 pooled analy:.tw.
14 ((data adj2 pool:) and studies).tw.
15 ((hand or manual: or database: or data base: or computer:) adj2 search:).tw.
16 reference databases/
17 ((electronic: or bibliographic:) adj2 (database: or data base:)).tw.
18 review.pt.
19 (review: or overview:).ab.
20 (systematic: or methodologic: or quantitativ: or research: or literature: or studies or trial: or effective:).ab.
21 18 and 20
22 19 adj10 20
23 or/1-17,21,22
24 editorial.pt.
25 letter.pt.
26 case study.pt.
27 record review/
28 peer review/
29 (retrospective: adj2 review:).tw.
30 (case: adj2 review:).tw.
31 (record: adj2 review:).tw.
32 (patient: adj2 review:).tw.
33 (patient: adj2 chart:).tw.
34 (peer adj2 review:).tw.
35 (chart: adj2 review:).tw.
36 (case: adj2 report:).tw.
37 exp case control studies/
38 exp prospective studies/
39 case studies/
40 animal studies/
41 (rat:or mouse or mice or hamster: or animal: or dog: or cat: or rabbit: or bovine or sheep).tw.
42 or/24-41
43 42 not (42 and 23)
44 23 not 43 = SYSTEMATIC REVIEWS AND/OR META ANALYSES

SEARCH FILTER FOR PSYCLIT/CLINPSYC/PSYCINFO

Used in the *Health Evidence Bulletins Wales* project.

1	meta analysis.sh	
2	meta-anal:.tw	
3	metaanal:.tw	
4	meta analysis.id	
5	(systematic: and (review: or overview)).tw	
6	(critical: and apprais:).tw	
7	(critical: and review:).tw	
8	or/1-7	
9	literature review.sh	
10	literature review.id	
11	9 or 10	
12	8 or 11	
13	case report.sh	
14	8 not 13	
15	12 not 13	
16	limit 14 to human	**SYSTEMATIC REVIEWS AND/OR META ANALYSES**
17	limit 15 to human	**Systematic reviews/meta-analyses and some other reviews**
18	treatment effectiveness evaluation.sh	
19	(random: and trial:).tw	
20	(random: and allocat:).tw	
21	double blind.tw	
22	single blind.tw	
23	or/18-22	
24	limit 23 to human	
25	clinical trial.id	
26	clinical trial:.tw	
27	(singl: or doubl: or trebl: or tripl:) adj5 blind.tw	
28	(clin: adj25 trial:).ti,ab	
29	placebo:.tw	
30	placebo:.id	
31	placebo:.ti,ab	
32	random:.ti,ab	
33	methodology.sh	
34	experimental design.sh	
35	experimentation.sh	
36	experimental methods.sh	
37	or/25-36	
38	limit 38 to human	**RANDOMISED CONTROLLED TRIALS**
39	effectiveness.id	
40	followup studies.sh	
41	posttreatment followup.sh	
42	treatment outcomes.sh	
43	longitudinal studies.sh	
44	(control: or prospectiv: or volunteer:).ti	
45	comparative study.tw	
46	or/39-45	
47	limit 46 to human	**CONTROLLED PROSPECTIVE AND OTHER STUDIES**

TYPE OF EVIDENCE CLASSIFICATION FOR THE HEALTH EVIDENCE BULLETINS - WALES*

I Evidence from a systematic review (which includes at least one randomised controlled trial and a summary of all included studies).

Examples include those published by the Cochrane Collaboration, the NHS Centre for Reviews and Dissemination and NICE. The evidence from such a review requires careful appraisal as, if well done, the evidence is powerful.

II Evidence from a well designed randomised controlled trial of appropriate size.

III Evidence from a well designed intervention study without randomisation.

Evidence in this category will only be included if no category I or II evidence is available. A common research design is the before-and-after study.

IV Evidence from a well designed non-experimental study e.g. cohort, case-control or cross-sectional studies. (Also include studies using purely qualitative methods)

Evidence in this category will only be included if no category I, II or III evidence is available. Economic analyses (cost-effectiveness studies) are also classified as Type IV evidence.

V Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert consensus committees.

* This classification is based on the Bandolier system (http://www.jr2.ox.ac.uk/bandolier/band6/b6-5.html) adapted to include the NHS Centre for Reviews and Dissemination criteria for a systematic review (see the *Database of Abstracts of Reviews of Effectiveness* in the *Cochrane Library*).

EVIDENCE FORM

Author(s):

Title:

Source:

What type of evidence is represented by this document?

I	Systematic review (including at least one RCT)	☐
II	Randomized controlled trial	☐
III	Other experimental study	☐
IV	Observational study or economic analysis	☐
V	Expert opinion	☐

Select appropriate Quality Appraisal Checklist.

Accept after quality appraisal? Yes ☐ No ☐

Suggested statement:

.....

.....

.....

.....

Comments:

.....

.....

.....

Document provided for: ..... Date: .....

The above is for my own research or private study purposes only

Signed: ..... Date: .....

(Please sign yellow copy or British Library form – as attached - and return to Project Office

Health Evidence Bulletins - Wales: Questions to assist with the critical appraisal of a systematic review [including at least one randomised controlled trial] (Type I evidence); [including at least one non-randomised intervention study] (Type III evidence); or [of observational studies] (Type IV evidence)

Adapted from the CASP questions (taken from Oxman AD *et al.* Users' guides to the medical literature. VI How to use an overview. *Journal of the American Medical Association.* 1994; **272(17)**: 1367-1371) and Barker, JM. Project for the enhancement of the Welsh Protocols for Investment in Health Gain. Project Methodology. Cardiff: Duthie Library. UWCM, 1996. HEBW systematic review definition is based on the criteria used by NHS CRD for Database of Abstracts of Reviews of Effects (DARE.) http://agatha.york.ac.uk/faq4.htm

Paper details **Authors:**

Title:

Source:

A/ What is this review about, and does it meet the systematic review criteria?

(see overleaf for criteria)

	Yes	Can't tell	No
1. Is the review relevant to the needs of the Project?	continue		discard
2. Did the review address a clearly focused issue? In terms of: • the population studied • the intervention given • the outcomes considered.			
3. Did the authors look for the appropriate sort of papers? Did the studies address the review's question and have an appropriate study design?			
4. Were the important, relevant studies included? • Databases searched, reference list follow-up, • Personal contacts, unpublished work • Non-English publications • Are the inclusion, exclusion criteria stated? • Has a funnel plot been included to check for publication bias?			
5. Did the authors assess the quality (rigour) of the included studies?			

Is it worth continuing?

B/ What are the findings and can they be trusted?

	Yes	Can't tell	No
6. If the results of the review have been combined, was this reasonable? • Were the studies sufficiently similar in design and results? • Are the results of included studies clearly displayed? • Are the reasons for any variation in the results discussed?			

7. What is the overall result of the review? Include a **numerical result** with the **confidence limits** if available.	

C/ Are the results relevant locally/to me?

	Yes	Can't tell	No
8. Can the results be applied to the local population? • Cultural and/or sociodemographic differences? • Genetic differences? • Differences in medical practice?			
9. Were all important outcomes considered? Consider reliability. Are outcome measures objective (i.e. a direct measure of change) or subjective (e.g. self reported).			
10. Is any cost information provided?		N/A	
11. Accept for further use as a systematic review* (Type I, III or IV evidence)?		Refer to Team Leader	

Comments:

* To be classified as a systematic review, the review should meet the criteria used by the NHS CRD for the Database of Reviews of Effectiveness (DARE):
1) Are inclusion/exclusion criteria reported that address the review question?
2) Is there evidence of a substantial effort to search for all the relevant research literature;
3) Is the validity of the included studies adequately assessed?;
4) Is sufficient detail of the individual studies presented?;
5) Are the primary studies summarised appropriately?
http://agatha.york.ac.uk/faq4.htm [accessed 23.09.03]

Health Evidence Bulletins - Wales: Questions to assist with the critical appraisal of a randomised controlled trial (Type II evidence)

Adapted from the CASP questions (taken from Guyatt *et al.* Users' guides to the medical literature. II How to use an article about therapy or prevention. *Journal of the American Medical Association.* 1993; **270**: 2598-2601 and **271**: 59-63; Barker, JM. Project for the enhancement of the Welsh Protocols for Investment in Health Gain. Project Methodology. Cardiff: Duthie Library. UWCM, 1996; Egger *et al.* How important are comprehensive literature searches and the assessment of trial quality in systematic reviews? *Health Technology Assessment* 2003; **7(1)**

Paper details **Authors:**

Title:

Source:

A/ What is this trial about and can I trust it? Screening questions.

	Yes	Can't tell	No
1. Is the trial relevant to the needs of the Project?			
2. Did the trial address a clearly focused issue? in terms of: • the population studied, • the intervention given, • the outcomes considered.			
3. Was there concealment of allocation? Note whether: • the randomisation process was described explicitly eg the use of random number tables or coin flips; • there was some form of centralised randomisation scheme eg central allocation or use of sealed opaque envelopes.			
4. Were all the patients who entered the trial properly accounted for at its conclusion? • Was follow-up obtained for 80-100% of subjects? Note % follow-up. • Were patients analysed in the groups to which they were randomised?			
5. Were patients, health workers and study personnel 'blind' to treatment? • Patients? • Health workers? • Study personnel?			
6. Were the groups similar at the start of the trial? In terms of all the factors that might be relevant to the outcome: age, sex, social class, life style etc.			
	Yes	Can't tell	No

7. Aside from the experimental intervention, were the groups treated equally?			

Is it worth continuing?

B/ What did they find?

8. How large was the treatment effect? • What outcomes were measured? • Take a note of the result(s) (eg odds ratio, number needed to treat) if provided.	**Result(s):**
9. How precise was the estimate of the treatment effect? • What are the confidence limits? • Do you feel confidence in the authors' use of statistics?	

C/ Are the results relevant locally/to me?

	Yes	Can't tell	No
10. Can the results be applied to the local population? Do you think the patients covered by the trial are similar enough to your population? Consider culture, geography etc.			
11. Were all important outcomes considered? If not, does this effect the conclusion(s)?			
12. Is any cost information provided?		N/A	
13. Accept for further use as Type II evidence?		Refer to Team Leader	

Comments:

In the draft statement Remember to include the relevant target group (age range, sex etc.);the duration of the study, the measured outcomes/benefits with quantitative information if available and whether: 1. Treatment allocation was concealed; 2. An intention-to-treat analysis was carried out (include % follow-up); and 3. The trial was double (or triple) blind.

Health Evidence Bulletins - Wales: Questions to assist with the critical appraisal of an interventional study without randomisation (Type III evidence)

Sources used: Critical Appraisal Skills Programme (CASP, Anglia and Oxford RHA) questions, NHS Centre for Reviews & Dissemination, Guidelines for those carrying out or commissioning reviews. CRD report No. 4, 1996. Polgar A, Thomas SA. Chapter 22. Critical evaluation of published research in Introduction to research in the health sciences. 3rd edition. Melbourne: Churchill Livingstone, 1995.

Paper details **Authors:**

Title:

Source

A/ What is this paper about?

	Yes	Can't tell	No
1. Is the study relevant to the needs of the Project?			
2. Does the paper address a clearly focused issue? Are the aims of the investigation clearly stated?			

B/ Do I trust it?

	Yes	Can't tell	No
3. Is the choice of study method appropriate? • Has an acceptable method been chosen (eg interventional without randomisation, before-and-after study)? • Are the inclusion/exclusion criteria given? • Is the choice of control group (if included) adequate?			

C/ What did they find?

	Yes	Can't tell	No
4. Are tables/graphs adequately labelled and understandable?			
5. Are you confident with the authors' choice and use of statistical methods, if employed?			
6. What are the results of this piece of research? Are the authors' conclusions adequately supported by the information cited?			

D/ Are the results relevant locally?

	Yes	Can't tell	No
7. Can the results be applied to the local situation? Consider differences between the local and study populations (eg cultural, geographical, ethical) which could affect the relevance of the study.			
8. Were all important outcomes/results considered?			
9. Accept for further use as Type III evidence?		Refer to Team Leader	

Comments:

Draft Statement (if appropriate):
(Remember to include the relevant target group (age range, sex etc.); the measured outcomes/benefits with quantitative information if available; and the health gain notation)

Health Evidence Bulletins - Wales: Questions to assist with the critical appraisal of an observational study eg cohort, case-control, cross-sectional. (Type IV evidence)

Sources used: Critical Appraisal Skills Programme (CASP, Anglia and Oxford RHA) questions and Polgar A, Thomas SA. Chapter 22. Critical evaluation of published research in Introduction to research in the health sciences. 3rd edition. Melbourne: Churchill Livingstone, 1995; Undertaking systematic reviews of research on effectiveness. University of York: NHS Centre for Reviews & Dissemination, 2001; Weightman AL, Barker, JM, Lancaster J. Health Evidence Bulletins Wales Project Methodology 3. Cardiff: UWCM, 2000.

Paper details Authors:

Title:

Source

A/ What is this paper about?

	Yes	Can't tell	No
1. Is the study relevant to the needs of the Project?			
2. Does the paper address a clearly focused issue? in terms of • the population studied? • (case-control study only) Is the case definition explicit and confirmed? • the outcomes considered? • are the aims of the investigation clearly stated?			

B/ Do I trust it?

	Yes	Can't tell	No
3. Is the choice of study method appropriate?			
4. Is the population studied appropriate? • (cohort study) Was an appropriate control group used – ie were groups comparable on important confounding factors? • (case-control study) Were the controls randomly selected from the same population as the cases?			
5. Is confounding and bias considered? • Have all possible explanations of the effects been considered? • (cohort study) Were the assessors blind to the different groups? • (cohort study) Could selective drop out explain the effect? • (case-control study) How comparable are the cases and controls with respect to potential confounding factors? • (case-control study) Were interventions and other exposures assessed in the same way for cases and controls? • (case-control study) Is it possible that overmatching has occurred in that cases and controls were matched on factors related to exposure?			

6. (Cohort study) Was follow up for long enough? • Could all likely effects have appeared in the time scale? • Could the effect be transitory? • Was follow up sufficiently complete? • Was dose response demonstrated?			

C/ What did they find?

	Yes	Can't tell	No
7. Are tables/graphs adequately labelled and understandable?			
8. Are you confident with the authors' choice and use of statistical methods, if employed?			
9. What are the results of this piece of research? Are the authors' conclusions adequately supported by the information cited?			

D/ Are the results relevant locally?

	Yes	Can't tell	No
10. Can the results be applied to the local situation? Consider differences between the local and study populations (eg cultural, geographical, ethical) which could affect the relevance of the study.			
11. Were all important outcomes/results considered?			
12. Is any cost-information provided?			
13. Accept for further use as Type IV evidence?		Refer to Team Leader	

Comments:

Draft Statement (if appropriate):
(Remember to include the relevant target group (age range, sex etc.); the measured outcomes/benefits with quantitative information if available; and the health gain notation)

Health Evidence Bulletins - Wales: Additional questions to assist with the critical appraisal of a qualitative study.

Adapted from the Critical Appraisal Skills Programme questions (CASP, Anglia and Oxford RHA, adapted from Mays N & Pope C. Rigour and qualitative research. *British Medical Journal.* 1995; **311**: 109-112); North Thames Research Appraisal Group (NTRAG): 1998 Critical review form for reading a paper describing qualitative research and Barker, JM. Project for the enhancement of the Welsh Protocols for Investment in Health Gain. Project Methodology. Cardiff: Duthie Library. UWCM, 1996.

Paper details Authors:

Title:

Source

A What is this paper about?
Screening questions

	Yes	Can't tell	No
1. Is the study relevant to the needs of the Project?	continue		discard
2. Does the paper address a clearly focused issue? Are the aims of the investigation clearly stated?			

B/ Do I trust it?

	Yes	Can't tell	No
3. Is the choice of a qualitative method appropriate? • What was this study exploring (eg behaviour/reasoning/beliefs)? • Do you think a quantitative approach could have equally/better addressed this issue?			
4. Was the author's position clearly stated? • Has the researcher described his/her perspective? • Has the researcher examined his/her role, potential bias and influence?			
5. Was the sampling strategy clearly described and justified? Check to see whether: • the method of sampling is stated or described • the investigators sampled the most useful or productive range of individuals and settings relevant to their question • the characteristics of those included in the study are defined (and are comparable to the wider population)			
6. Was there an adequate description of the method of data collection given? • Is the method of data collection described and justified? • How were the data collected (eg audiotape/videotape/field notes)? • If interviews were used, were the questions pre-tested? • If observation was used, is the context described and were observations made in a variety of circumstances?			

	Yes	Can't tell	No
7. Were the procedures for data analysis/interpretation described and justified? Check to see whether: • a description is given of how the themes and concepts were identified in the data • the analysis was performed by more than one researcher • negative/discrepant results were taken into account • the data were fed back to the participants for comment			

C/ What did they find?

8. What are the primary findings? Consider whether the results: • address the research question • are likely to be clinically important			
	Yes	Can't tell	No
9. Are the results credible? • Were sequences from the original data presented (eg quotations) and were these fairly selected? • Is it possible to determine the source of the data presented (eg numbering of extracts)? • How much of the information collected is available for independent assessment? • Are the explanations for the results plausible and coherent? • Are the results of the study compared with those from other studies?			

D/ Are the results relevant locally?

	Yes	Can't tell	No
10. Can the results be applied to the local situation? • Consider differences between the local and study populations (eg cultural, geographical, ethical) which could affect the relevance of the study.			
11. Were all important outcomes/results considered?			
12. Accept for further use?		Refer to Team Leader	

Comments:

Draft Statement (if appropriate):
(Remember to include the relevant target group (age range, sex etc.); the measured outcomes/benefits and the health gain notation if appropriate)

Health Evidence Bulletins - Wales: Questions to assist with the critical appraisal of an economic analysis (Type IV evidence)

Sources used: Greenhalgh T. How to read a paper: Papers that tell you what things cost (economic analyses). *British Medical Journal* 1997; 315: 596-599; Drummond MF *et al.* Users' guides to the medical literature. XIII. How to use an article on economic analysis of clinical practice. A.. Are the results valid? *Journal of the American Medical Association* 1997; 277: 1552-1557; O'Brien BJ *et al.* Users' guides to the medical literature. XIII. How to use an article on economic analysis of clinical practice. B. What are the results and will they help me in caring for my patients? *Journal of the American Medical Association* 1997; 277: 1802-1806.

Paper details Authors:

Title:

Source

A/ What is this paper about?

	Yes	Can't tell	No
1. Is the study relevant to the needs of the Project?			
2. Is the analysis based on a study that answers a clearly defined clinical question about an economically important issue? • Costs and benefits (outcomes) should be compared for two or more strategies			

B/ Do I trust it?

3. Whose viewpoint are costs and benefits being considered from? • The patient, the hospital, the drug company, the treasury, and/or society in general?			
	Yes	Can't tell	No
4. Have the interventions being compared been shown to be clinically effective? • Is there evidence of effectiveness from one or more randomised controlled trials or other compelling studies?			
5. Are the interventions sensible and workable in the settings where they are likely to be applied? eg • Is the ownership of a necessary piece of expensive equipment assumed? • Is likely compliance and/or the requirement for additional time considered?			
6. Was an appropriate method of analysis used? • eg Cost-benefit, cost-utility (see Greenhalgh, 1997) Method used: ……			

C/ What did they find?

	Yes	Can't tell	No
7. How were costs and benefits measured?			
8. Were incremental rather than absolute benefits considered? • ie Consider cost per patient who benefits rather than cost per individual treatment eg where NNT = 10, one patient will benefit per 10 treated.			
9. Was the "here and now" given precedence over the distant future? • Where future, rather than immediate, health benefits are assumed most analyses use a discount figure of around 5% per year.			
10. Was a sensitivity analysis performed?			
11. Were "bottom line" aggregate scores overused? • Are unfamiliar units used with little explanation of the consequences in plain language?			
12. What are the results of this piece of research? Are the authors' conclusions adequately supported by the information cited?			

D/ Are the results relevant locally?

	Yes	Can't tell	No
13. Can the results be applied to the local situation? Consider differences between the local and study populations (eg cultural, geographical, ethical) which could affect the relevance of the study.			
14. Accept for further use as Type IV evidence?		Refer to Team Leader	

Comments:

Draft Statement (if appropriate):
(Remember to include the relevant target group (age range, sex etc.); the measured outcomes/benefits with quantitative information if available; and the health gain notation)

Health Evidence Bulletins - Wales: Questions to assist with the critical appraisal of guidelines.

The **AGREE guidelines** for the critical appraisal and evaluation of guidelines are currently being used in the Project.

http://www.agreecollaboration.org/

Some background to the project (from the AGREE web-site is given below):

What is AGREE?

AGREE is an international collaboration of researchers and policy makers who seek to improve the quality and effectiveness of clinical practice guidelines by establishing a shared framework for their development, reporting and assessment.

Who are the participants?

The collaboration has the participation of a core of European countries: Denmark, Finland, France, Germany, Italy, the Netherlands, Spain, Switzerland and the United Kingdom as well as Canada, New Zealand and the USA.

What is contained in the research programme?

AGREE is an integrated research programme currently funded by the BIOMED-2 Programme of the European Union. Project: PL96-3669

It comprises several research projects, including:

1. The creation of an appraisal instrument (AGREE) to assess the quality of clinical guidelines
2. The development of standard recommendations for guideline developers
3. A comparison of guideline development programmes.
4. A content analysis of guidelines on asthma, diabetes and breast cancer
5. An appraisal of individual recommendations.

How to contact AGREE?

The AGREE collaboration is co-ordinated by the Health Care Evaluation Unit at St George's Hospital Medical School in London. Contact: Françoise Cluzeau (email: f.cluzeau@sghms.ac.uk)

HEALTH EVIDENCE BULLETINS - WALES

Bulletin Title:	
Chapter Title:	**Literature search completed on:** **..../...../.....**

This document is a supplement to, not a substitute for, professional skills and experience. Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation	
The Statements	***The Evidence***

Health Evidence Bulletins - Wales: Reference page for Critical Appraisal Teams

Statements should include a brief summary of the supporting evidence including, where possible:

- The relevant target group - age range, sex etc.
- The measured outcomes/benefits with quantitative information where results are statistically significant (eg. % improvement, odds ratio etc. - and the confidence interval, if available)

Caveats should include any potential source of bias or other concerns about the quality and/or generalisability of the study.

Evidence should be cited:

- using the Vancouver system (see below)
- with an indication of the type of evidence (see below) and other relevant information as appropriate (eg "no. of patients in the trial = ...", "systematic review, literature search to December 2002, using Medline and Embase only" etc.)

Guidance on Vancouver System

Standard periodical article:
You C H, Lee K Y, Chey R Y, Menguy R. Electrogastrographic study of patients with unexplained nausea, bloating and vomiting. *Gastroenterology* 1980; **79**: 311-4.
(NB List all authors when six or less; when seven or more, list only first three and add et al)

Book or monograph:
Eisen H N. *Immunology: an introduction to molecular and cellular principles of the immune response*. 5th ed. New York: Harper and Row, 1974: 406.

Published proceedings:
DuPont B. Bone marrow transplantation in severe combined immuno-deficiency with an unrelated MLC compatible donor. In: White H J, Smith R, eds. *Proceedings of the third annual meeting of the International Society for Experimental Hematology.* Houston: International Society for Experimental Hematology, 1974:44-6.

World Wide Web page (no author)
High blood pressure in pregnancy [online]. 2001 [cited 2002 Oct 21]. Available from: URL: http://www.nhlbi.nih.gov/health/public/heart/hbp/hbp_preg.htm
(Author/editor (surname initials). Title [online]. Year [cited year month day]. Available from: URL:)

Type of evidence

'Type I evidence' - at least one good systematic review (including at least one randomised controlled trial).
'Type II evidence' - at least one well designed randomised controlled trial
'Type III evidence' - well designed other trials
'Type IV evidence' - well designed non-experimental studies
'Type V evidence' - expert opinion

Example

The Statements	***The Evidence***
1.25g. Standard **self-help** materials may increase quit rates compared to no intervention, but the effect is likely to be small. In 11 trials of self-help compared to no intervention there was a pooled effect that just reached statistical significance (odds ratio 1.24, 95% CI 1.07-1.45). No evidence was found that self-help interventions had an additional benefit when used alongside other interventions such as advice from a health care professional or nicotine replacement therapy[i].	i. Lancaster T, Stead LF. Self-help interventions for smoking cessation. (Cochrane Review). In: The Cochrane Library, Issue 1 2003. Oxford: Update Software. (most recent update 11 April 2002) http://www.update-software.com/abstracts/ab001118.htm [accessed 15.10.03] (Type I evidence - systematic review, literature search to March 2002, of 51 trials)