Innovative methods of using evidence-based medicine in patient-centred care

Andy Gray
Division of Pharmacology
Discipline of Pharmaceutical Sciences
University of KwaZulu-Natal
Outline

• Recent BMJ Head-to-head question
• From Cochrane to Sackett - the basics
• The key role of “external evidence”
• GRADING the evidence – false starts and recovery
• Translation into guidelines
• Absence of evidence
• Promoting quality use of medicines – is there room for innovation?
Head To Head

Does evidence based medicine adversely affect clinical judgment?

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Michel Accad, cardiologist1, Darrel Francis, professor of cardiology2

1 San Francisco, USA
2 National Heart and Lung Institute, Imperial College, London
Kiplingesque?

YES
“...the evidence based movement arose primarily from a desire to standardise care, not to individualise it.”

“...consider the institutions and organisations that have enthusiastically embraced EBM from the start: national health systems, private healthcare payers, regulators, drug companies, public health departments, and disease specific interest groups have all taken a keen interest in EBM precisely for its ability to formulate standards of care—that is, clinical guidelines—and to encourage, reward, or even oblige doctors to practise in accordance with those standards.”

NO
“Evidence based medicine expects doctors to choose among tweaks that have been found to do more good than harm; not just among tweaks that they or their institution like to do for financial reasons or to feel good about themselves.”

“We consistently overestimate our ability to understand biology well enough to personalise tests and treatments beneficially. Personalisation may be harmless fun and even increase the placebo effect, but we should be under no illusion that we have done anything useful.”

Oh, East is East, and West is West, and never the twain shall meet.
• Trained with Sir Bradford Hill, who pioneered the randomised clinical trial (RCT) and was the first to demonstrate a connection between cigarette smoke and lung cancer.
“It is surely a great criticism of our profession that we have not organized a critical summary, by specialty or subspecialty, adapted periodically, of all relevant randomized control trials.”


“He was a man with severe porphyria who smoked too much and was without consolation of a wife, a religious belief, or a merit award—but he didn't do so badly.”
The circle formed by two ‘C’ shapes represents our global collaboration. The lines within illustrate the summary results from an iconic systematic review. Each horizontal line represents the results of one study, while the diamond represents the combined result, our best estimate of whether the treatment is effective or harmful. The diamond sits clearly to the left of the vertical line representing “no difference”, therefore the evidence indicates that the treatment is beneficial. We call this representation a “forest plot”. This forest plot within our logo illustrates an example of the potential for systematic reviews to improve health care. It shows that corticosteroids given to women who are about to give birth prematurely can save the life of the newborn child.

DOI: 10.1002/14651858.CD004454
• Founded the world’s first department of Clinical Epidemiology and Biostatistics, at McMaster University in Ontario, Canada
• Founded and was director of the Oxford Centre for Evidence-Based Medicine
• Founding co-editor of the journal *Evidence-Based Medicine*
• Founding Chair of the Cochrane Collaboration.

David Sackett
MD, OC, FRSC, MSc, FRCP
Editorials

Evidence based medicine: what it is and what it isn't

It's about integrating individual clinical expertise and the best external evidence

\(BMJ\ 1996;312:71-72\) (13 January)

EBM defined

• “Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”

• “The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.”

• “By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centred clinical research ...”
“Evidence based medicine is neither old hat nor impossible to practice.”

“Evidence based medicine is not "cookbook" medicine. Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice, it cannot result in slavish, cookbook approaches to individual patient care.”

“External clinical evidence can inform, but can never replace, individual clinical expertise...”
Steps to practising EBM

1. Ask a focused question.
2. Track down the evidence.
3. Critically appraise the evidence for its validity, effect size, precision.
4. Apply the evidence in practice.

PICO(T) question

P – patient, problem or population
I – intervention
C – comparison, control or comparator
O – outcome
(T) – time/type of question/type of study design
HARLOT plc: an amalgamation of the world’s two oldest professions

David L Sackett, Andrew D Oxman on behalf of HARLOT plc

Tired of being good but poor, the authors have amalgamated the world’s two oldest professions in a new niche company, HARLOT plc, specialising in How to Achieve positive Results without actually Lying to Overcome the Truth

“The HARLOT team together with some of our satisfied customers on the road to riches. We can fabricate the results you need and, for a small extra fee, we can fabricate the photos you need too, showing you chumming with selected stars of science and cinema. The truth is in the eye of the beholder, and we can plaster whatever you want them to see directly on their retinas.”
### Table 1. Levels of medical evidence to support treatment guidelines used by the Scottish Intercollegiate Guidelines Network (SIGN)

<table>
<thead>
<tr>
<th>Level</th>
<th>Type of evidence</th>
<th>Grade of recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ia</td>
<td>Meta-analysis of randomized controlled trials</td>
<td>(A)</td>
</tr>
<tr>
<td>Ib</td>
<td>At least one randomized controlled trial</td>
<td></td>
</tr>
<tr>
<td>IIA</td>
<td>At least one well-designed controlled study without randomization</td>
<td>(B)</td>
</tr>
<tr>
<td>IIIB</td>
<td>At least one other type of well-designed quasi-experimental study</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>Well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>Expert committee reports or opinion and/or clinical experience of respected authorities (in the absence of level I-III evidence)</td>
<td>(C)</td>
</tr>
</tbody>
</table>

*Source: Scottish Intercollegiate Guidelines Network*
### Suggested Walkovers Between Taxonomies for Assessing the Strength of a Recommendation Based on a Body of Evidence

<table>
<thead>
<tr>
<th>SORT</th>
<th>CEBM</th>
<th>BMJ’s Clinical Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Recommendation based on consistent and good-quality patient-oriented evidence</td>
<td>A. Consistent level 1 studies</td>
<td>Beneficial</td>
</tr>
<tr>
<td>B. Recommendation based on inconsistent or limited-quality patient-oriented evidence</td>
<td>B. Consistent level 2 or 3 studies or extrapolations from level 1 studies</td>
<td>Likely to be beneficial</td>
</tr>
<tr>
<td>C. Recommendation based on consensus, usual practice, disease-oriented evidence, case series for studies of treatment or screening, and/or opinion</td>
<td>C. Level 4 studies or extrapolations from level 2 or 3 studies</td>
<td>Likely to be ineffective or harmful (recommendation against)</td>
</tr>
<tr>
<td>D. Level 5 evidence or troublingly inconsistent or inconclusive studies of any level</td>
<td>D. Level 5 evidence or troublingly inconsistent or inconclusive studies of any level</td>
<td>Unlikely to be beneficial (recommendation against)</td>
</tr>
</tbody>
</table>

SORT = Strength of Recommendation Taxonomy; CEBM = Centre for Evidence-Based Medicine; BMJ = BMJ Publishing Group.
ASSESSING THE QUALITY OF REPORTS OF RANDOMIZED CLINICAL TRIALS: IS BLINDING NECESSARY?

Alejandro R. Jadad, MD, DPhil; R. Andrew Moore, DPhil; Dawn Carroll, RGN; Crispin Jenkinson, DPhil; D. John M. Reynolds, DPhil; David J. Gavaghan, DPhil; and Henry J. McQuay DM

Oxford Regional Pain Relief Unit (A.R.I., R.A.M., D.C., H.J.M.); Nuffield Department of Anaesthetics (A.R.I., R.A.M., D.C., D.J.G., H.J.M.); Department of Public Health and Primary Care (C.J.); and University Department of Clinical Pharmacology (D.J.M.R.); University of Oxford, Oxford, UK

ABSTRACT: It has been suggested that the quality of clinical trials should be assessed by blinded raters to limit the risk of introducing bias into meta-analyses and systematic reviews, and into the peer-review process. There is very little evidence in the literature to substantiate this. This study describes the development of an instrument to assess the quality of reports of randomized clinical trials (RCTs) in pain research and its use to determine the effect of rater grading on the assessments of quality. A multidisciplinary panel of six judges produced an initial version of the instrument. Fourteen raters from three different backgrounds assessed the quality of 36 research reports in pain research, selected from three different samples. Seven were allocated randomly to perform the assessments under blind conditions. The final version of the instrument included three items. These items were scored consistently by all the raters regardless of background and could discriminate between reports from the different samples. Blind assessments produced significantly lower and more consistent scores than open assessments. The implications of this finding for systematic reviews, meta-analytic research and the peer-review process are discussed. *Controlled Clin Trials* 1996; 17(1–12

**Jadad score**

1. Was the study described as randomized (this includes the use of words such as randomly, random, and randomization)?
2. Was the study described as double blind?
3. Was there a description of withdrawals and dropouts?

Either give a score of 1 point for each “yes” or 0 points for each “no.”

Give 1 additional point if: For question 1, the method to generate the sequence of randomization was described and it was appropriate (table of random numbers, computer generated, etc.)

and/or: If for question 2 the method of double blinding was described and it was appropriate (identical placebo, active placebo, dummy, etc.)

Deduct 1 point if: For question 1, the method to generate the sequence of randomization was described and it was inappropriate (patients were allocated alternately, or according to date of birth, hospital number, etc.)

and/or: For question 2, the study was described as double blind but the method of blinding was inappropriate (e.g., comparison of tablet vs. injection with no double dummy)

Final score ranges from zero (very poor) to five (rigorous)
Guidelines for the management of chronic asthma in adolescents and adults

Laloo U; Atkinson G; Wang M; Abdool-Gautier S; James E; McK H; Feldman C; O’Brian J and Jack C
Working Group of the South African Thoracic Society

Correspondence to: Prof Ulrika Laloo; E-mail: laloo@uc.ac.za

Introduction

Asthma prevalence is increasing worldwide and surveys indicate that the majority of patients in developed and developing countries do not receive optimal care and are therefore not well controlled. The aim of these guidelines is to promote a better standard of treatment based on advances in the understanding of the pathobiology and pharmacotherapy of asthma and to encourage uniformity in the management of asthma.

The South African Thoracic Society first published guidelines for the management of chronic persistent asthma in 1992 and the second revision in 2000. The current revision is prompted by:

- The revised classification and new evidence on the safety and optimal use of asthma medication.
- An ongoing need to emphasize the use of anti-inflammatory medication as the foundation of asthma treatment.
- The positioning of neuromuscular blockers in the maintenance treatment of chronic asthma.
- An emphasis on defining and achieving control of asthma.

EVIDENCE

The strategies recommended in these guidelines are classified according to the Evidence Category in Table 1 and denoted as “Evidence A, B, C and D.”

For details about these see Table 10 in the Additional Materials section.

Table 1: Categories of evidence for management strategies in asthma

<table>
<thead>
<tr>
<th>Evidence Category</th>
<th>Sources of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Randomised controlled trials. Rich body of data.</td>
</tr>
<tr>
<td>B</td>
<td>Randomised controlled trials. Limited body of data.</td>
</tr>
<tr>
<td>C</td>
<td>Nonrandomised trials. Observational studies.</td>
</tr>
<tr>
<td>D</td>
<td>Panel consensus judgment.</td>
</tr>
</tbody>
</table>

METHOD

The 2007 asthma guidelines update was developed following a meeting with a working group constituted by the SA Thoracic Society. The working group is chaired by Prof U.L. Laloo. The contribution by the working group is generally acknowledged.

Meetings were held with the working group on the 2-3 July 2006, subsequently the editorial board was convened and met on the 30 March 2007 to develop and finalize the guidelines. The SA Thoracic Society, SA Asthma Education Program (SA-NEP) of the SA Thoracic Society, and the National Asthma Education Program (NAEP) of the SA Thoracic Society contributed to the guidelines. The guidelines were endorsed by the SA Thoracic Society.

The document is issued as a living document that will be updated periodically.

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Table 1: Categories of evidence for management strategies in asthma (Reproduced with permission from Global Initiatives for Asthma, 2006)
The introduction of this tool, as a critical appraisal mechanism, is an important advance in the use of evidence-based medicine principles (in its true sense) in the development and publication of practice guidelines in SA. Through ensuring the application of sufficient rigour in the development process, there is a firm belief that a clinician’s ability to make informed clinical decisions will be enhanced, ultimately leading to improved patient care through discouraging the use of ineffective and wasteful interventions. This, in turn, will result in more efficient resource utilisation, will elevate the level of trust in the guideline itself, and is likely to impact on the ability and willingness to implement such a guideline in practice.
RATING QUALITY OF EVIDENCE AND STRENGTH OF RECOMMENDATIONS

GRADE: an emerging consensus on rating quality of evidence and strength of recommendations

Guidelines are inconsistent in how they rate the quality of evidence and the strength of recommendations. This article explores the advantages of the GRADE system, which is increasingly being adopted by organisations worldwide.

Box 2 | Quality of evidence and definitions

High quality—Further research is very unlikely to change our confidence in the estimate of effect

Moderate quality—Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate

Low quality—Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

Very low quality—Any estimate of effect is very uncertain
Box 2 Examples of implications of strong and weak recommendations

**Strong recommendation for intervention**

*For patients*—Most people in this situation would want the recommended course of action and only a small proportion would not

*For clinicians*—Most people should receive the intervention

*For quality monitors*—Adherence to this recommendation could be used as a quality criterion or performance indicator. If clinicians choose not to follow such a recommendation, they should document their rationale

**Weak recommendation for intervention**

*For patients*—Most people in this situation would want the suggested course of action, but many would not

*For clinicians*—Examine the evidence or a summary of the evidence yourself and be prepared to discuss that evidence with patients, as well as their values and preferences

*For quality monitors*—Clinicians’ discussion or consideration of the pros and cons of the intervention, and their documentation of the discussion, could be used as a quality criterion.

**No specific recommendation**

The advantages and disadvantages are equivalent

The target population has not been identified

Insufficient evidence on which to formulate a recommendation
https://gradeapro.org/
WHO guidelines

4 main factors:
• the confidence in the estimates of effect of the evaluated evidence (i.e. the quality of the evidence)
• values and preferences related to the outcomes of an intervention or exposure
• the balance of benefits and harms
• resource implications

Also:
• the importance or priority of the problem being addressed
• equity and human rights
• acceptability
• feasibility
RESEARCH METHODS & REPORTING

The Cochrane Collaboration’s tool for assessing risk of bias in randomised trials

Flaws in the design, conduct, analysis, and reporting of randomised trials can cause the effect of an intervention to be underestimated or overestimated. The Cochrane Collaboration’s tool for assessing risk of bias aims to make the process clearer and more accurate.

Julian P T Higgins senior statistician¹, Douglas G Altman director², Peter C Gotzsche director³, Peter Jüni head of division⁴, David Moher senior scientist⁵, Andrew D Oxman senior researcher⁶, Jelena Savović postdoctoral fellow⁷, Kenneth F Schulz vice president⁸, Laura Weeks research associate⁹, Jonathan A C Sterne professor of medical statistics and epidemiology⁹, Cochrane Bias Methods Group, Cochrane Statistical Methods Group

¹MRC Biostatistics Unit, Institute of Public Health, Cambridge CB2 0SR, UK; ²Centre for Statistics in Medicine, University of Oxford, Oxford, UK; ³The Nordic Cochrane Centre, Rigshospitalet and University of Copenhagen, Denmark; ⁴Institute of Social and Preventive Medicine, University of Bern, Switzerland; ⁵Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, Ontario, Canada; ⁶Department of Epidemiology and Community Medicine, Faculty of Medicine, University of Ottawa, Canada; ⁷Preventive and International Health Care Unit, Norwegian Knowledge Centre for the Health Services, Oslo, Norway; ⁸Department of Social Medicine, University of Bristol, Bristol, UK; ⁹Phd, Research Triangle Park, North Carolina, USA
<table>
<thead>
<tr>
<th>Bias domain</th>
<th>Source of bias</th>
<th>Support for judgment</th>
<th>Review authors’ judgment (assess as low, unclear or high risk of bias)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection bias</td>
<td>Random sequence generation</td>
<td>Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups</td>
<td>Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence</td>
</tr>
<tr>
<td></td>
<td>Allocation concealment</td>
<td>Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrolment</td>
<td>Selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment</td>
</tr>
<tr>
<td>Performance bias</td>
<td>Blinding of participants and personnel*</td>
<td>Describe all measures used, if any, to blind trial participants and researchers from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective</td>
<td>Performance bias due to knowledge of the allocated interventions by participants and personnel during the study</td>
</tr>
<tr>
<td>Detection bias</td>
<td>Blinding of outcome assessment*</td>
<td>Describe all measures used, if any, to blind outcome assessment from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective</td>
<td>Detection bias due to knowledge of the allocated interventions by outcome assessment</td>
</tr>
<tr>
<td>Attrition bias</td>
<td>Incomplete outcome data*</td>
<td>Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomised participants), reasons for attrition or exclusions where reported, and any reclusions in analyses for the review</td>
<td>Attrition bias due to amount, nature, or handling of incomplete outcome data</td>
</tr>
<tr>
<td>Reporting bias</td>
<td>Selective reporting</td>
<td>State how selective outcome reporting was examined and what was found</td>
<td>Reporting bias due to selective outcome reporting</td>
</tr>
<tr>
<td>Other bias</td>
<td>Anything else, ideally prespecified</td>
<td>State any important concerns about bias not covered in the other domains in the tool</td>
<td>Bias due to problems not covered elsewhere</td>
</tr>
</tbody>
</table>

*Assessments should be made for each main outcome or class of outcomes.
The medical use of cannabis for reducing morbidity and mortality in patients with HIV/AIDS (Review)

Lunge EE, Gray A, Siegfried N

Figure 1. Flow diagram depicting screening process.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.
Absence of evidence is not evidence of absence

Douglas G Altman, J Martin Bland

The non-equality of statistical significance and clinical importance has long been recognized, but this error of interpretation remains common. Although a significant result in a large study may sometimes be clinically important, a large population arises from minimization of non-significant findings. By convention, a P value greater than 0.05 (P = 0.05) is called "not significant." Randomized controlled clinical trials that do not show a significant difference between the treatments being compared are often called "negative." This term wrongly implies that the study has shown that there is no difference, whereas usually all that has been shown is an absence of evidence of a difference. There are quite different meanings.

The sample size of controlled trials is generally inadequate, with a consequent lack of power to detect real, and clinically worthwhile, differences in treatment. At a 5% level, only 50% of a sample of 50 trials published in the New England Journal of Medicine in 1997 showed a significant difference at the 0.05 level, although we would have had a 50% chance of detecting even a 5% difference if the difference existed and the trials being compared, and they found no improvement in a similar sample of trials published in 1966. To interpret all these "negative" trials as providing evidence of the inefficacy of new treatments is clearly wrong and fallacious. The term "negative" should not be used in this context.

A recent example is given by a trial comparing paroxetine and amitriptyline in patients with varicella zoster. The study was carried out on a sample of only 100 despite a reported calculation that suggested that 1800 patients were needed. This trial had only a 50% chance of getting a statistically significant result if the studied clinically worthwhile treatment difference really existed. One consequence of such low statistical power was a wide confidence interval for the treatment difference. The authors concluded that the two treatments were equally effective despite a 95% confidence interval that included differences between the cured rates of the two treatments of up to 20 percentage points.

The absence of evidence of the dangers of administration of non-significant results is found in numerous meta-analyses (averages) of published trials, when few, if any, of the individual trials were statistically large enough. A dramatic example is provided by the overview of clinical trials evaluating fibrinolysis treatment (intravenously or intracoronarily) for preventing infarction after acute myocardial infarction. The overview of randomized controlled trials found a modest but clinically worthwhile (and highly significant) reduction in mortality of 22%, but only if five of the six trials had shown a statistically significant effect with P = 0.05. The lack of statistical significance of most of the individual trials led to a large study before the true value of the treatment was appreciated.

While it is usually reasonable not to accept a new treatment unless there is positive evidence in its favor, when issues of public health are concerned we must question whether the absence of evidence is a valid enough justification for inaction. A recent publicized example is the suggested link between some sudden infant death and enteric in utero infections. Forensically the absence of evidence can be seen, for example, in relation to the possible link between violent behaviour and exposure to marijuana and violence, the possible harmful effects of prolonged exposure to magnetic fields, the association between electromagnetism and leukemia, and the possible association between hormone replacement and depression from cows. Can we be confident that the absence of such evidence in such cases means that there is no risk or only a negligible one?

When we are told that there is no evidence that A causes B we should first ask whether evidence means simply that there is no information at all. Others are data we should look for quantification of the association rather than just a P value. Where these are small P values may yield conclusions concerned with the existence of a relationship, but specific examples are likely to be wide, including considerable uncertainty. While we can never prove the absence of a relationship, when necessary we should seek evidence against the link between A and B—for example, from case-control studies. The importance of carrying out such studies will be related to the seriousness of the proposed effect and how widespread is the exposure in the population.

1. National Statistics Laboratory, Imperial Cancer Research Fund, London WC1, U.K.
3. Correspondence to: D Altman.

1968, the New England Journal of Medicine.


Wiley
...national random sample mail survey of 599 primary care physicians and 600 psychiatrists from November 2007 to August 2008. Physicians were presented with 14 drug-indication pairs (e.g., gabapentin [Neurontin] for diabetic neuropathy) that varied in their FDA-approval status and levels of supporting evidence.

There was a strong association between physicians’ belief that an indication was FDA-approved and greater evidence supporting efficacy for that use (Spearman’s r 0.74, p<0.001).

However, 41% of physicians believed at least one drug-indication pair with uncertain or no supporting evidence (e.g., quetiapine [Seroquel] for dementia with agitation) was FDA approved.
But how do we change practice?

- Devised for undergraduate medical students
- Applied more widely – e.g. PHC nurses
- Intended to also reach postgraduate students and practitioners

The P-drug process

Step 1: Define the patient’s problem
Step 2: Specify the therapeutic objectives
Step 3: Make an inventory of effective groups of medicines
Step 4: Choose an effective group according to criteria
Step 5: Choose a P-drug

The P-treatment process

Step 1: Define the patient’s problem
Step 2: Specify the therapeutic objectives
Step 3: Verify the suitability of your P-treatment
Step 4: Start the treatment
Step 5: Give information, instructions, warnings
Step 6: Monitor (and stop?) treatment
WHO/DAP/93.1 Detailed methodology for simple surveys
Widely applied and used to guide quality improvement activities

**Indicator design - Core indicators**

**Prescribing**
- Average number of drugs per encounter
- Percentage of drugs prescribed by generic name
- Percentage of encounters with an antibiotic prescribed
- Percentage of encounters with an injection prescribed
- Percentage of drugs prescribed from EML or formulary

**Patient care**
- Average consultation time
- Average dispensing time
- Percentage of drugs actually dispensed
- Percentage of drugs adequately labelled
- Patient’s knowledge of correct dosage

**Facility**
- Availability of EML or formulary
- Availability of key drugs
Public sector – not measured nationally since 2003
Private sector – mostly treated as proprietary information
Intervening to improve medicines use is challenging. A wide array of health-system stakeholders with legitimately different objectives, functions, and incentives influence medicines use. Coordinated and sustained attention to priority medicine use problems is also undermined by a range of factors: the almost singular focus on the part of many international donors, non-governmental organisations, and development agencies on access to medicines for AIDS, tuberculosis, and malaria; fragmented and frequently competing priorities across stakeholders; and operating environments with weak legal and regulatory structures, lack of awareness of the problem, or inadequate political will to tackle it.
Figure 11: Evidence from high-quality systematic reviews about effectiveness interventions targeting use of medicines by health professionals

Figure 12: Evidence from high-quality systematic reviews about effectiveness of different types of interventions targeting patients and consumers
Making Australia more medicinewise, through digital health and data insights, health professional education and reliable health information for consumers.

Managing GORD with PPIs in primary care

Proton pump inhibitors (PPIs) are commonly prescribed and often used long term, even when stepping down in dose or stopping may be more appropriate.

This program aims to encourage patients and doctors to consider stepping down PPI treatment for GORD, where possible.
Panel 18: Improving quality use of medicines by Australian providers and consumers

NPS MedicineWise is an independent, not-for-profit, evidence-based organisation that works across the Australian health sector and broader community to deliver improved medicines use, better health outcomes, and more efficient health care.

NPS MedicineWise involves stakeholders, develops key messages, and produces a mix of publications, products, and interventions designed to achieve these specific outcomes.

An in-house evaluation team assesses NPS MedicineWise and its activities. As part of its evaluation process, NPS MedicineWise conducts regular general practitioner, pharmacist, and consumer surveys of knowledge, attitudes, awareness, and behaviours around medicine use and NPS programmes.

<table>
<thead>
<tr>
<th></th>
<th>2014 Target</th>
<th>2014 Actual</th>
<th>2015 Target</th>
<th>2015 Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported Pharmaceutical Benefit Scheme savings (AUS million)*</td>
<td>69.26</td>
<td>70.44</td>
<td>69.28</td>
<td>69.24</td>
</tr>
<tr>
<td>Reported Medical Benefit Scheme savings (AUS million)†</td>
<td>5.0</td>
<td>N/A</td>
<td>45</td>
<td>33.05</td>
</tr>
<tr>
<td>Number unique general practitioner participants</td>
<td>14,000</td>
<td>13,129</td>
<td>14,000</td>
<td>14,447</td>
</tr>
<tr>
<td>Number consumer interactions</td>
<td>200,000</td>
<td>942,436</td>
<td>200,000</td>
<td>1,732,635</td>
</tr>
</tbody>
</table>

*Pharmaceutical Benefit Scheme savings reported for a particular year are on the basis of the evaluation report completed during the year, based on the previous year’s data. †Medical Benefit Scheme savings reported in 2015 covers savings for both 2014 and 2015.

Table 6: NPS MedicineWise operating results reported in the 2015 Director’s Report.
The start of something good ..... or a cost-saving measure?
In the last decade, hundreds of initiatives that send health information messages through mobile phone networks have emerged in low-resource countries. Most of these have been small in scale, with only five having scaled to >1 million beneficiaries: Kilkari and mMitra in India; Healthy Pregnancy, Healthy Baby Text Messaging Service (Wazazi Nipendeni) in Tanzania; Aponjon in Bangladesh; and MomConnect in South Africa. Of these programmes, MomConnect has attained the highest population-level coverage, reaching >60% of pregnant women attending their first antenatal care appointment in 2017.
Clinical Decision Support Systems for the Practice of Evidence-based Medicine

Ida Sim, MD, PhD, Paul Gorman, MD, Robert A. Greenes, MD, PhD, R. Brian Haynes, MD, PhD, Bonnie Kaplan, PhD, Harold Lehmann, MD, PhD, Paul C. Tang, MD

Recommendations for Policy Makers

- Develop financial and reimbursement policies that provide incentives for health-care providers to implement and use CDSSs of proven worth.

- Develop and implement financial and reimbursement policies that reward the attainment of measurable quality goals, as might be achieved by CDSSs.

- Promote coordination and leadership across the health care and clinical research sectors to leverage informatics promotion and development efforts by government, industry, AMIA, and others.
Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success

Kensaku Kawamoto, Caitlin A Houlihan, E Andrew Balas, David F Lobach


What is already known on this topic

Clinical decision support systems have shown great promise for reducing medical errors and improving patient care. However, such systems do not always result in improved clinical practice, for reasons that are not always clear.

What this study adds

Analysis of 70 randomised controlled trials identified four features strongly associated with a decision support system’s ability to improve clinical practice—(a) decision support provided automatically as part of clinician workflow, (b) decision support delivered at the time and location of decision making, (c) actionable recommendations provided, and (d) computer based.

A common theme of all four features is that they make it easier for clinicians to use a clinical decision support system, suggesting that an effective system must minimise the effort required by clinicians to receive and act on system recommendations.
Computerised decision support systems for healthcare professionals: an interpretative review

Kathrin Cresswell
Research Associate, eHealth Research Group, Centre for Population Health Sciences, University of Edinburgh, UK

Azeem Majeed
Professor of Primary Care, Global eHealth Unit, Department of Primary Care & Public Health, Imperial College London, UK

David W Bates
Professor of Medicine, Department of Medicine, Brigham and Women’s Hospital, and Harvard University, Boston, MA, USA

Aziz Sheikh
Professor of Primary Care Research & Development, eHealth Research Group, Centre for Population Health Sciences, The University of Edinburgh, Edinburgh, UK

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Conclusions Whilst the potential of clinical decision support systems in improving, in particular, practitioner performance is considerable, such technology may also introduce new risks resulting not only from technical challenges (such as data inaccuracy) but also from disruption of clinical workflows. Moving forward, there is a need for system development, procurement and implementation to be characterised by a user ‘pull’ and then tailor systems to the needs of users.
Use of Electronic Health Records and Clinical Decision Support Systems for Antimicrobial Stewardship

Graeme N. Forrest,1 Trevor C. Van Schooneveld,2 Ravina Kullar,3 Lucas T. Schulz,4 Phu Duong,3 and Michael Postelnick5

1Division of Infectious Diseases, Portland Veterans Affairs Medical Center, Portland, Oregon; 2University of Nebraska Medical Center, Omaha; 3Global Medical Affairs, Cubist Pharmaceuticals, Lexington, Massachusetts; 4University of Wisconsin Hospital and Clinics, Madison; and 5Northwestern Memorial Hospital, Chicago, Illinois

Electronic health records (EHRs) and clinical decision support systems (CDSSs) have the potential to enhance antimicrobial stewardship. Numerous EHRs and CDSSs are available and have the potential to enable all clinicians and antimicrobial stewardship programs (ASPs) to more efficiently review pharmacy, microbiology, and clinical data. Literature evaluating the impact of EHRs and CDSSs on patient outcomes is lacking, although EHRs with integrated CDSSs have demonstrated improvements in clinical and economic outcomes. Both technologies can be used to enhance existing ASPs and their implementation of core ASP strategies. Resolution of administrative, legal, and technical issues will enhance the acceptance and impact of these systems. EHR systems will increase in value when manufacturers include integrated ASP tools and CDSSs that do not require extensive commitment of information technology resources. Further research is needed to determine the true impact of current systems on ASP and the ultimate goal of improved patient outcomes through optimized antimicrobial use.
Computerised provider order entry combined with clinical decision support systems to improve medication safety: a narrative review

Sumant R Ranji, Stephanie Rennke, Robert M Wachter

BMJ Qual Saf 2014;23:773–780

Results We included five systematic reviews, one narrative review and two controlled trials. The existing literature consists mostly of studies of homegrown systems conducted in the inpatient setting. CPOE+CDSS was consistently reported to reduce prescribing errors, but does not appear to prevent clinical ADEs in either the inpatient or outpatient setting. Implementation of CPOE+CDSS profoundly changes staff workflow, and often leads to unintended consequences and new safety issues (such as alert fatigue) which limit the system’s safety effects.

Conclusions CPOE+CDSS does not appear to reliably prevent clinical ADEs. Despite more widespread implementation over the past decade, it remains a work in progress.
The impact of pharmacy computerised clinical decision support on prescribing, clinical and patient outcomes: a systematic review of the literature

Jane Robertson\textsuperscript{a}, Emily Walkom\textsuperscript{a}, Sallie-Anne Pearson\textsuperscript{b}, Isla Hains\textsuperscript{b}, Margaret Williamson\textsuperscript{c} and David Newby\textsuperscript{a}

\textsuperscript{a}Discipline of Clinical Pharmacology, School of Medicine and Public Health, The University of Newcastle, Newcastle, Australia, \textsuperscript{b}UNSW Cancer Research Centre, University of New South Wales and Prince of Wales Clinical School, Sydney and \textsuperscript{c}National Prescribing Service, Sydney, Australia

IJPP 2010, 18: 69–87

Conclusions Our study demonstrated greater effectiveness of safety-focused compared with QUM-focused CDSSs. Medicine safety issues are traditional areas of pharmacy activity. Without good communication between pharmacists and physicians, the full benefits of QUM-focused CDSSs may not be realised. Developments in pharmacy-based CDSSs need to consider these inter-professional relationships as well as computer-system enhancements.
Decision time for clinical decision support systems

Authors: Dympna O’Sullivan, Paolo Fracaro, Ewart Carson and Peter Weller

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Medicine is a long established, highly regulated discipline, whereas no licence is required to practice computer science, but computer system errors could have a direct impact on patient safety. Although the US Food and Drug Administration has developed guidance regarding medical software and other safety-critical healthcare IT systems, software validation is not usually subject to protocols as stringent as other healthcare interventions (eg randomised controlled trials for new therapies).

Furthermore, computer scientists usually work in teams who collectively develop software, whereas an individual clinician is often solely responsible for medical decisions related to their patients’ health. Questions therefore arise about the legal risks to clinicians when relying on decisions generated by a CDSS, particularly when these systems use complex ‘black-box’ methods.
Living systematic review involves modifications to review production and publication, enabled by improved production efficiency and adherence to the norms of scholarly communication.

Together with emerging innovations in the reporting of primary research and in the creation and use of evidence in health systems, living systematic review contributes to a new evidence ecosystem in which health knowledge and practice are efficiently and rigorously entwined.
Concluding thoughts

• Evidence-based medicine is critical to the sustainability of universal health coverage.
• The opportunities to improve the quality of medicines use – at all levels (prescriber, dispenser, user) – are myriad, and depend on a more judicious application of evidence-based principles.
• South Africa has been slow to adopt technological tools that enable more innovative evidence-based interventions, such as CPOE and CDSSs, partly because of fragmentation in the health system, but also because of an almost complete focus on billing as the driver of IT systems design.
• mHealth shows some promise, at scale, but is insufficient on its own to ensure quality of care.
Surely not (any more)!!