Plenary 1: Linking evidence to practice: Guidelines and alternatives
Tsuguya Fukui
‘Quality improvement by measuring and disclosing quality indicators’

Dr Gillian Leng CBE, Deputy Chief Executive
‘How effective are national strategies for getting evidence into practice?’

The evidence for driving change in healthcare indicates that it needs local ownership and leadership. This is a challenge for national organisations such as NICE (the National Institute for Health and Clinical Excellence) that produce best practice advice and guidance.

NICE was established in 1999 to produce guidance on cost-effective treatments with the aim of standardising care across the English National Health Service. NICE guidance covers a range of areas including the appraisal of new drugs and devices, clinical guidelines, and guidance on public health issues. NICE is also responsible for NHS Evidence, a service that provides a web-based portal for comprehensive access to a range of evidence for health and social care professionals.

To encourage uptake at a local level, national guideline producers need to ensure the areas covered in guidelines reflect local priorities, and are developed using robust methodology that will inspire the confidence of potential users. Despite having these key elements in place, it became clear in 2003 that the NHS was not uniformly implementing NICE guidance. NICE therefore launched an implementation strategy in 2004. The strategy is based on evidence of effective change, and informed by feedback from end users.

The presentation will cover an initial description of the evidence behind the four key elements of the NICE implementation strategy:

- raising awareness of the need to change
- motivating and inspiring people to change
- providing practical support to facilitate change
- evaluating and monitoring impact of the strategy.

The second part of the presentation will demonstrate how effective these elements have been at getting evidence into practice. This will include data on the impact of NICE recommendations on change in patient care, with a reflection on factors that are likely to have facilitated success, and those that have been barriers to change. The presentation will conclude with an assessment of what NICE might need to do in future to support the uptake of best practice guidance, in the context of an English health system that is facing significant financial challenges and undergoing substantial organisational change.

Dave Davis
‘The hidden intervention: using an effective educational strategy to ensure the uptake of best evidence in practice’
Guidelines don’t, it has been said, implement themselves. They require work and effort, and a combination of public, quality improvement, policy and professional initiatives. Hidden within them however are clear implications for education – the delivery and uptake of best evidence messages to patients, populations, policy makers – and perhaps especially to health professionals.
Using a guideline format, this presentation will focus on what we know about ‘education’ – focusing on health professionals. It will briefly review the literature, make the case that education, too, is a science worthy of study and develop recommendations about the development of an active, interventionist, educational program for guideline implementation.

Plenary 2: Guidance in the absence of evidence: what can – and cannot – be done?

Paul Glasziou
‘When are randomised trials not needed?’

Although we are wary of evidence for treatment effects other than that from randomised controlled trials, there are many examples where confident inferences about treatments have been based on other kinds of evidence. Some examples include: tracheostomy for tracheal obstruction, ether for anaesthesia, drainage for pain associated with abscesses, neostigmine for myasthenia gravis, defibrillation for ventricular fibrillation, and pressure or suturing for arresting haemorrhage. In these cases the size and rapidity of effects are larger than any plausible biases. This is simplest with stable or progressive conditions and rapid effects of treatment—for example, removing a cataract on vision or of cholinesterase inhibitors for organophosphate poisoning.

The prognosis and the treatment effect interact as noise and signal, and the ease of identification of treatment effects depends on the “signal to noise ratio”: large effects in a background of stable prognosis are convincing without randomization; small effects in a background of a fluctuating or intermittent condition are unconvincing, and randomized trials are generally required. Between these extremes, the need for trials will depend on other factors such as indirect or complementary evidence, the objectiveness of outcomes, the comparability of controls, etc.

The GRADE process for grading evidence currently allows for upgrading of observational evidence based on the size of the observed effect and on dose response relationships. Further empirical work is needed to more precisely define the risk of bias with different sizes of observed effects.

Nicola Magrini
‘How to make weak recommendations more transparent: what we have learnt from the use of GRADE’

Hans Messersmith
‘What do you do when you have done all the easy stuff? – Developing guidelines in the absence of good quality evidence’

The Program in Evidence-Based Care (PEBC), Cancer Care Ontario, has a mandate to develop both clinical practice and organizational guidelines to assist Ontario clinicians and decision makers in providing high quality care. More recently, we have been asked to address guideline topics in areas where there is limited evidence, and yet there is a strong need for recommendations. Through example case studies of guidelines developed by the PEBC, the presenter will outline issues relevant to these circumstances including key questions to be asked; important methodological innovations that have resulted; and the key lessons we have learned.

Plenary 3: "Adapting guidelines for resource-constrained settings"

Leonila Dans
‘Experiences in the Philippines: Adapting the essential newborn care guidelines: failures and successes’
Karen Daniels
‘Translating evidence into policies and guidelines: findings from 3 southern African countries’

Getting research into policy and practice remains an important challenge in most settings. This presentation focuses on understanding the factors affecting the use of research evidence, particularly findings from randomized control trials (RCTs) and systematic reviews, in national policy and guideline development in low- and middle-income countries. In exploring this issue, the presentation draws on two cases – the use of magnesium sulphate in the treatment of eclampsia in pregnancy (a clinical case); and the use of insecticide treated bed nets and indoor residual household spraying for malaria vector control (a public health case) – across the three countries- South Africa, Mozambique and Zimbabwe. The findings suggest that translating research knowledge into policy is a complex and context sensitive process. Researchers aiming to enhance knowledge translation need to be aware of factors influencing the demand for different types of research; interact and work closely with key policy stakeholders, networks and local champions; and acknowledge the roles of important interest groups.

Hernando Gaitan
‘Adapting or de novo development of Clinical Practice Guidelines: Colombian experience’

Objective: Presenting Colombian experience regarding adapting internationally developed clinical practice guidelines.

Methodology. Current regulations governing the development of guidelines in a Colombian context were reviewed. A description of the problems faced in two cases regarding the search for available guidelines, the use of the Agree II instrument for evaluating them, mapping the evidence and the recommendations, the use of GRADE methodology as well the stakeholders’ participation is presented.

Results. Clinical practice guidelines for specific pathologies have been prioritised by central government. The guidelines form the basis for including technologies in health insurance plans. The Ministry of Health has created some methodological guidelines which should be followed by the guideline developers. Three universities having important human resources in terms of experts in methodology have formed an alliance for working as a team, providing greater transparency, ensuring greater efficiency and guaranteeing process quality. This alliance is supported by interested scientific societies which actively participate in it. The development process encountered difficulties in putting the guidelines proposed by the Ministry into practice. The AGREE II instrument has limited inter-observer agreement. The guidelines’ scope and objective, as well as mapping the evidence and following the recommendations could affect the decision to adapt good methodological quality guidelines, thus suggesting that it would be better to adopt de novo guideline development. Using the evidence summary tables proposed by the GRADE group requires training so that the users can standardise them, given that it is complex to apply them.

Conclusions: Adaptation is not always the easiest route for developing clinical practice guidelines. This requires an important work load. In spite of it being advisable to first seek the availability of international guidelines and evaluate their possible adaptation to a local context, it is sometimes more suitable to develop them in-house.
Plenary 4: "Sustainable guidelines: maintaining relevance to health policy"

Ken Kuo

‘Policy priority in sustaining guideline development’

One of the priorities of sustaining healthcare systems around the world is to improve health care quality and efficiency in facing increasing healthcare expenditure. In many clinical care areas, development of clinical practice guidelines is becoming an important issue internationally. However, the development of clinical practice guidelines consumes considerable amount of monetary and human resources. Therefore, in order to generate highest benefit with limited resources, policy decision makers of healthcare system have to identify urgent demands and set out priority based on evidence based analysis. For incidence, in Taiwan, the Department of Health decided to develop 10 most important guidelines based on the 10 top diagnosis that spend most National Health Insurance resources among all other guidelines developed by specialty societies locally. It set an example for the continuous development of guidelines in the future. On the other hand, it is also crucial to employ strict evidence-based approach in guideline development and followed by independent quality appraisal to ensure professional accountability and its later implementation. Bringing all related stakeholders to work together and the transparency during the process of guideline development can satisfy those key players with diverse interests. It paves the way for sustaining guideline development and implementation. This also provides an effective strategy in dealing with some strong advocate interest parties.

Lisa Askie

‘International collaboration, individual patient data and prospective meta-analysis - the best evidence base for sustainable guidelines’

For guidelines to be of relevance to users they must be valid, reliable and current. There are challenges in sustaining the effort needed to ensure all guidelines meet these criteria. Methodologies that may help guideline developers better achieve sustainability include individual patient data and prospective meta-analysis and the international collaboration that is needed for these techniques to be used successfully.

Systematic reviews utilising all the available evidence are the backbone of high quality guidelines. However, there are several potential sources of bias that can be introduced into systematic reviews: bias within individual randomised trials, a biased selection of trials included in the review and a biased selection of treatment questions. Possible ways of overcoming these potential biases include improving the quality of individual trials; improved subgroup and sensitivity analyses via individual patient data meta-analysis; prospective registration of trials to reduce reporting biases and prospective meta-analysis to minimise bias in question selection.

Individual patient data (IPD) meta-analysis involves the central re-collection and analysis of the raw, line-by-line data from each participant in each trial included in a systematic review. This requires the formation of a collaborative group comprising the trialists whose data will be used and a management / data analysis team. The full collaborative group have direct input into the data to be collated, the methods of analysis and reporting of results. This level of collaboration between reviewers and trialists does not often occur with aggregate data systematic reviews.

A prospective meta-analysis (PMA) is a meta-analysis of studies (usually randomized trials) that were identified, evaluated and determined to be eligible for the meta-analysis before the results of any of those studies became known. Prospective meta-analyses enable hypotheses to be specified in advance of the results of individual trials; enable prospective application of study selection criteria; and enable a priori statements of intended analyses.
Collaboration is crucial to the success of both these methodologies and it is this collaboration that enables the results of both the individual trials and the meta-analysis of the trial results to be incorporated into relevant guidelines sooner, for example, by meta-analysing accumulating data as they emerge. The full involvement of all the relevant trialists from the outset (in a PMA) also encourages the earlier development of additional questions that can be addressed with the combined datasets and results in better dissemination and endorsement of the meta-analysis results and the development of subsequent guidelines.

Ilkka Kunnamo
‘Implementing guidelines on populations by means of clinical decision support’

Guidelines are not always implemented during clinical encounters even if the professional is aware of the guideline and it is readily available. Clinical decision support systems (CDS) integrated with electronic health records (EHRs) are used to remind the professional at the right time when decisions are made. They have been shown to modestly improve care, particularly preventive care and drug safety.

The full impact of evidence-based care can only be realized if interventions are provided to all people who are expected to benefit. Considerable potential for improving the health is implied in contacting people who have been lost to follow-up after a health problem has been identified. The Virtual Health Check (VHC) is a procedure where the structured data of all people in a population (e.g. the panel of a general practitioner) are sent to a CDS system that applies a set of decision support rules to each person. A list of patients with reminders how to improve their care is created.

Simultaneously, also statistics on patients who are eligible to an intervention and on whom the intervention has been implemented are recorded. Eligibility takes into consideration e.g. contraindications to drugs so that people on whom the intervention could not be applied are excluded from the denominator in the quality statistics. If individually tailored targets and care plans are included in the EHR, accuracy of the CDS feedback will be further improved.

The problem with the VHC is that it can only record information based on structured patient data. A key task is to create national or international standards for each country of structuring patient data in all EHR systems. Initiatives for data structuring and sharing include the Continuity of Care Document (CCD) in the USA and epSOS in Europe. Multiple coding systems (like ICD-10, ICD-9 CM, ICPC-2 or SNOMED CT for diagnoses) and different measurement units (centimeters, inches) can be handled on the side of the CDS so that reminders can be created and quality statistics produced from different EHR systems and different countries. In some countries like Finland, all EHR data will be in a central repository, and not only professionals treating the patients but also the patients themselves will have access to the data.

An ideal setting for population-based guideline implementation is the chronic care model and a system where the primary care team is responsible for both preventive and medical care of a panel of patients. One such model is the Patient-Centered Medical Home model of the U.S. A legal and ethical problem on confidentiality may arise if the patient has never visited the professional who reviews the results of the VHC, and does not know that a professional is going to review his/her data. There are at least two solutions: First, every person could be informed in advance that VHCs will be performed and that they can opt out. Second, the results of the VHC could be sent directly to the citizen via text messages, automatically created letters, or via a...
personal health record (PHR) application, with decision aids and advice to contact a health care professional when appropriate.

Providing feedback from the VHC directly to the citizen has additional advantages. The citizen can check that the data are correct, and he/she can add and update information on e.g. diet, exercise and smoking. In Finland almost 20 percent of the population have performed an electronic health check for themselves inspired by a reality TV program and web-based questionnaire that estimated the number of life years to come and suggested ways to increase the number of healthy years.

Guideline developers should be actively involved in developing CDS. Via tools like VHC, guidelines can be implemented and their impact evaluated on populations, and resources can be directed where maximum health gains are achievable. Involving citizens directly will make them key actors in their care, while saving health care professionals time to do their part.

Plenary 5: "Promoting quality of evidence and guidelines in the international community"

Tamara Kredo

‘Agreement and Alignment - guidelines for five priority diseases in the Southern African Development Community’

Background: Reducing the burden of disease relies on availability of evidence-based clinical practice guidelines (CPGs). There is limited data on availability, quality and content of guidelines within the Southern African Development Community (SADC). This evaluation aims to address this gap in knowledge and provide recommendations for regional guideline development.

Methods: We prioritised five diseases: HIV in adults, malaria in children and adults, pre-eclampsia, diarrhoea in children and hypertension in primary care. A comprehensive electronic search, supported by email contact with SADC Ministries of Health was used to locate guidelines. The AGREE II tool was applied by independent reviewers to evaluate 6 quality domains reporting the guideline development process. Individual domains were scored and percentages calculated. Alignment of the evidence-base of the guidelines was evaluated by comparing content with key recommendations from accepted reference guidelines, identified with a content expert, and percentage scores were calculated.

Findings: The search was conducted between June and October 2010. We identified 30 guidelines from 13 countries, publication dates ranging from 2003-2010. Overall the ‘scope and purpose’ and ‘clarity and presentation’ domains of the AGREE II instrument scored highest, median 58%(range 19-92) and 83%(range 17-100) respectively. ‘Stakeholder involvement’ followed with median 39%(range 6-75). ‘Applicability’, ‘rigour of development’ and ‘editorial independence’ scored poorly, all below 25%. Alignment with evidence was variable across member states, the lowest scores occurring in older guidelines or where the guideline being evaluated was part of broader primary healthcare CPG rather than a disease-specific guideline.

Conclusion: This review identified quality gaps and variable alignment with best evidence in available guidelines within SADC for five priority diseases. Future guideline development processes within SADC should better adhere to global reporting norms requiring broader consultation of stakeholders and transparency of process. A regional guideline support committee could harness local capacity to support context appropriate guideline development.
Richard Shiffman
‘Can the New IOM Standards for Guideline Development Improve Guideline Quality?’

Philip van der Wees
‘Promoting quality of evidence and guidelines: what is G-I-N's role?’