

**YCFM Event #3 2010/11: “NICE and Cochrane: clinical and cost effectiveness”
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The Royal Society of Medicine**

Introduction

In modern day medicine empirical research should define the direction of the NHS in terms of treatment and care provided. However, too often, it does not.

- 10% of patients admitted to hospital experience iatrogenic harm; half could have been prevented if staff had followed good practice. (Vincent et al., 2001)
- 45% of patients fail to receive recommended care. (McGlynn et al., 2003)

The organisation of clinical research and interpretation of it has fallen primarily to a number of organisations most notably the Cochrane Collaboration and the National Institute of Clinical Excellence (NICE). This booklet aims to explore the differences and similarities between the two institutions as well as their collaborative efforts in maximising quality of care and patient involvement.

NICE

The National Institute of Clinical Excellence is a special health authority of the NHS, set up on 1 April 1999 to ensure everyone has equal access to medical treatments and high quality care from the NHS - regardless of where they live in England and Wales. It has since acquired an international reputation as a role model for the development of clinical guidelines.

NICE was established in an attempt to defuse the postcode lottery of healthcare in England and Wales; a situation where patients receive differential access to treatment due to funding decisions of the Primary Care Trust in which they live. NICE also aims to eliminate poor practice by clinicians through publishing standardised guidelines on treatment regimes for different conditions.

Guidelines are mainly published in three primary areas:

- The use of health technologies within the NHS, including new and existing medicines, treatments and procedures.
- Clinical practice: the appropriate treatment and care of people with specific diseases and conditions.
- Health promotion and preventative medicine.

Guidelines are drawn up and developed in consultation with independent committees and experts free of political influence. These include industry and health experts, academics, patients and other members of the public with a background or interest in the area. There is also input from several National Collaborating Centres, which bring together expertise from the medical colleges, professional bodies and patient/carer organisations. The centres include the National Collaborating Centre for Cancer, the National Clinical Guidelines Centre for Acute and Chronic Conditions, the National Collaborating Centre for Women and Children's Health, and the National Collaborating Centre for Mental Health.

Guidelines issued by NICE take into account clinical effectiveness and cost effectiveness. A method used to quantify this has been the Quality Adjusted Life Year or QALY for short. This allows easy comparison between different treatment options and regimes while assessing for value for money at the same time. Initially clinical effectiveness is measured. This is done so by examining how many extra months or years of life of a reasonable quality a person might gain as a result of treatment. Some of the variables used to measure quality of life include the level of pain a patient is in, their mobility and general mood. Quality of life can have a range of values from negative, considered with worse possible health, to 1, which is the best positive health. The next stage in the process is to consider cost effectiveness. This is examined by how much the drug or treatment costs per year. In the case of drugs, this is the cost of using the drugs to provide a year of the best quality of life available. Each drug is considered on a case-by-case basis. Generally, however, if a treatment costs more than £20,000-30,000 per QALY then it would not be considered cost effective.

The institution's work on clinical effectiveness guidelines often gets overshadowed by public perceptions of its role in drug rationing. Many patient and medical groups have criticised NICE for denying 'life saving' treatment to patients. The pharmaceutical and biotech industries have also heavily lobbied governments for a long time, arguing that NICE is an obstacle to innovation, delaying the introduction of new drugs into the NHS, due to the time taken for technology assessments.

The current coalition government has decreed that it intends to allow NICE to continue to write the guidelines for doctors and their patients – and has extended this role through giving NICE with the task of developing quality standards against which providers and commissioners will be held to account against – but NICE will be relieved of the controversial power it possess to recommend against the use of drugs it considers too expensive for the benefit they offer.

Instead the government wants the decision on whether a patient should get a drug to be returned to the patient's doctor, under the auspices of GPs new role as

commissioners of care in GP consortia. The cost of any new drug will be decided through a new “value based pricing” system. The NHS will negotiate with the manufacturer on a price for each new drug, taking into account not only how clinically effective it is and how it reduces the burden on a patient’s carers, but also what other treatments are available and how “innovative” the company has been in producing the drug.

Cochrane

The Cochrane Collaboration is named after a famous British Epidemiologist named Archie Cochrane who advocated the use of randomised controlled trials as a means of reliably informing healthcare practice. The Cochrane Collaboration, established in 1993, is an international network of people consisting of a mix of volunteers and paid staff who are affiliated to the organization through Cochrane entities: healthcare subject-related review groups, thematic networks, groups concerned with the methodology of systematic reviews, and regional centres.

Many of the staff are world leaders in their field of medicine, health policy, research methodology or consumer advocacy, and entities are situated in some of the world’s best academic and medical institutions. This group of dedicated staff help healthcare providers, policy makers, patients, their advocates and carers, make well-informed decisions about health care by preparing and evaluating the available evidence from randomised controlled trials. Its underlying assumption is that health care interventions will be more effective if they are based on complete and up to date evidence instead of out of date research, anecdote, and conjecture. Its eventual goals are to create a register of all completed and continuing randomised controlled trials; to combine the results of trials that meet set standards of quality; to produce regularly updated systematic reviews or meta-analyses; and to make these reviews widely available in journals, and the internet.

Research by Cochrane collaborators has found that about half the 40,000 randomised trials published since 1985 are not retrievable by expert Medline searches. This explains why the collaboration places such great emphasis in searching these journals by hand. Volunteers are hand-searching journals going back as far as 1948 which was the year the BMJ published the landmark randomised control trial of streptomycin.

Another challenge Cochrane faces is finding trials performed but subsequently never published. Certain trials that took place, especially those sponsored by industry, never ended up being published due to findings being damaging to those who sponsored them. It is also true that some journal editors are biased against publishing negative results, and studies have shown that it is largely authors who do the censoring by deciding not to submit them.

The Collaboration has its critics. Some argue that by taking randomisation as its gold standard it will miss vital data from good non- randomised studies, for which methodologies for systematic review exist. Such data are especially important in areas (such as surgery or prevention of suicide) in which randomised studies may be difficult or ethically unjustifiable. Because it limits itself to randomised studies the collaboration cannot promise answers to the most pressing clinical and policy questions, but only to those accessible through randomised trials. They do not consider cost-effectiveness.

Points for consideration:

- Should clinical effectiveness be considered in isolation from cost effectiveness? What would be the consequences of doing and not doing this?
- To what extent should clinicians be bound by clinical guidelines? When should clinicians be able to override them?
- Why, despite the efforts of NICE and Cochrane, is failure to adhere to clinical guidelines profligate? What are the consequences of this?
- Would you see NICE and Cochrane as collaborators or competitors?

Further reading

<http://www.bmj.com/content/328/7438/529.1.full>

<http://www.bmj.com/content/322/7292/943.extract>

<http://www.cochrane.org/>

<http://www.guardian.co.uk/politics/2010/oct/29/nice-to-lose-new-drug-power>

<http://www.nice.org.uk>

<http://www.bmj.com/content/309/6960/969.extract>

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626306/>

<http://www.bmj.com/content/324/7336/545.2.full>

http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/nationalcollaboratingcentres/national_collaborating_centres.jsp

<http://www.nice.org.uk/newsroom/features/measuringeffectivenessandcosteffectivenessstheqaly.jsp>