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Evidence based mental healthcare and service innovation: Review of concepts and challenges

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ealth provision systems in the developed western nations are currently facing major financial challenges. In order to meet these challenges, a number of new approaches used to assist the provision of health have been introduced, including the practice of health professionals. These approaches utilize specific methods of data capture and summarization such as: evidence based medicine (EBM) and practice guidelines. Evidence is generated from systematic clinical research as well as reported clinical experience and individually case based empirical evidence. All types of research though (quantitative or qualitative) have limitations. Similarly all types of evidence have advantages and disadvantages and can be complimentary to each other. Evidencebased individual decision (EBID) making is the commonest evidence-based medicine as practiced by the individual clinician in making decisions about the care of the individual patient. It involves integrating individual clinical expertise with the best available external clinical evidence from systematic research. However this sort of evidence-based medicine, focuses excessively on the individual (potentially at the expense of others) in a system with limited budgets. Evidence-based guidelines (EBG) also support the practice of evidence-based medicine but at the organizational or institutional level. The main aim is to identify which interventions, over a range of patients, work best and which is cost-effective in order to guide service development and provision at a strategic level. Doing this effectively is a scientific and statistical skill in itself and the quality of quidelines is based primarily on the quality research evidence. It is important to note that lack of systematic evidence to support an intervention does not automatically mean that an intervention must instantly be abandoned. It is also important

that guidelines are understood for what they are, i.e. not rules, or complete statements of knowledge. EBM will never have enough suitable evidence for all and every aspects of health provision in every locality. Innovation signifies a substantial positive change compared to gradual or incremental changes. Innovation using inductive reasoning has to play a major role within health care system and it is applicable to all three level of service provision: clinical practice, policy and organisation structure. The aim of this paper is to examine critically the above concepts and their complimentary role in supporting provision of health care systems which are suitable for the requirements of the population, affordable, deliverable, flexible and adaptable to social changes.

Key words: Evidence based medicine, practice guidelines, innovation

Introduction

The UK NHS (National Health System) was launched in 1948. It was seen as a major step towards the reduction of inequalities in accessing health services after the Second World War. Seventy years later, it is undergoing a period of rapid and continuous change. The UK government has made "Governance" proposals to guide organizations and maintain standards of service by the NHS and by the private/independent sector. Clinical governance can be defined as a framework through which organizations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. Health provision systems in the developed western nations are currently facing major financial challenges, which are ironically in part the result of their own success. These challenges are also consequent to other social changes, some of which have significantly improved the patients' quality of life.

In order to face these challenges, a number of new approaches have been introduced to assist, including an influence on the practice of health professionals. These approaches utilize specific methods of data capture and summarization, such as: evidence based medicine, evidence based practice, practice guidelines and a general category we might conveniently call "innovation". The aim of this paper is to explore aspects of the nature of these concepts, their potential utility and challenges in their potential implementation. Our recent experience of the introduction of some of these approaches within the UK National Health Service (NHS) will be used to illustrate some issues.

Current challenges for health care systems

Every health care system (public or independent) needs to be suitable for the requirements of the population that it serves. Reason suggests that health care systems should be affordable, deliverable, flexible and adaptable to social changes. We identify the following main challenges to the implementation of future healthcare:

- i. The demographic characteristics of the population in the western world indicate that more people survive until they are older. In the UK there is a significant increase in population over 65 years old with the prediction of a 63% increase over the next 25 years (from 2006), with the number of those aged over 85 years predicted to double.¹
- ii. Despite this increase of life expectancy, the longevity is not associated with better quality of life during those added years. Although life expectancy consistently increased during the decade 1981–1991, the years of "healthy life expectancy" actually fell during the decade 1991–2001. This means that for many people, years of added life are potentially years of increased levels of morbidity. It is also predicted that the demographic pattern of diseases will continue to change significantly, with a consequent increased incidence of chronic illness and co-morbidities often involving people having several areas of illness.²
- iii. As science progresses, new treatments are developed at a considerable rate and potential expense. These treatments usually generate new costs, which then leads to a need for increased investment for the appropriate implementation of the

treatment. Furthermore, although the previous treatments might not be as effective as some new treatments, the new treatment may actually not be cost-effective or cannot be implemented without costly adaptation of service structures and provision which then has indirect implications for total cost.

Over the last 15 years there has been a revolution in Information Technology (IT), potentially allowing everyone with a computer to have rapid access to a broad range of health information. As a result, there is an overwhelming plethora of scientific research, opinions, advertisements and seemingly relevant publications, which can be contradictory, conflicting and confusing to clinicians and other stakeholders. Modern clinicians (and arguably the public with access to the same information) therefore need to have appropriate appraisal skills in order to quickly and effectively critically appraise this new evidence and in the case of professionals, modify their practice accordingly.

The Royal College of Psychiatrists rapidly recognized this challenge and incorporated the relevant training (Evidence Based Medicine and critical appraisal) to its curriculum and examination schedule. By implementation of these processes, it was hoped that the research to practice gap would be reduced. A range of evidence based procedures have been designed to aid clinicians with the process of finding information, critically appraising it and to guide them towards best practice. These processes include use of IT search strategies and implementation of Evidence Based Medicine (EBM). This includes two related but ultimately different EBM processes, firstly individual decision making for a single patient and secondly guidelines for clinicians as well as purchasing bodies and management, in order to guide the treating of a patient group.

Types of evidence

Two main types of external clinical evidence feature predominantly when clinicians are considering changes to treatments or practice: (1) systematic clinical research evidence, and (2) other forms of evidence, such as reported clinical experience and individually case based empirical evidence. It is crucial to

emphasize that both types of evidence have advantages and disadvantages and can be complimentary to each other.

Research evidence has the advantage of strength in numbers, a better methodological base, and provides a standardized scientific approach to treatment. It can usefully guide service provision, but might miss an individual patient's needs and cannot be entirely prescriptive. On the other hand, clinically based empirical evidence takes into account the individual patient, the unique circumstances around him/her, and the clinical expertise of the clinician involved. However, in comparison to research evidence, clinical experience/expertise and consequent individual case effectiveness, cannot be automatically generalized to all patients and cannot or should not guide general service development as such.³ Clinical expertise in these circumstances refers to the clinician's cumulated experience, education and clinical skills. It is also recognised that the patient brings his or her own personal and unique concerns, knowledge expectations, and values to the clinical encounter. Nevertheless, overall it is recognised that the best general evidence is usually found in clinically relevant research that is systematic. There is an agreed predetermined hierarchy of quality to aid acceptance of evidence.4

Types of research methodology

Well conducted Randomised Controlled Trials (RCT) (and their resulting systematic reviews and metaanalyses) have become the gold standard for establishing treatment efficacy in the last 70 years. For issues relating to diagnosis, both RCTs and cross-sectional studies are used, whereas for issues around prognosis RCTs and cohort studies of representative patients may be considered the best sources of evidence.⁵ Qualitative research is a more recently developed type of research, originating from anthropological methodology and used mostly to explore service users' and staff experiences, attitudes and perceptions.⁶

All types of research (quantitative or qualitative) have limitations related to sample size, sample representation, rate of follow up and statistical analysis, to name just a few of them.³ Recently there has

been significant criticism regarding the reliance on RCTs as the main if not, only source of evidence for the majority of clinical issues, because it bypasses important aspects of clinical experience or service user perspectives.⁷ Qualitative research has been used to bridge this gap and several large funded studies have now included a qualitative arm in their methodology.8 Another major issue is the link between biological sciences and treatment application for human diseases. This is the topic of Translational Medicine, which aims to increase the efficiency of determining the relevance of novel discoveries in the biological sciences to human disease and to help clinical researchers to identify, through direct human observation, alternative hypotheses relevant to human disease.9

A systematic review is a review in which specified predetermined and appropriate a priori methods have been used to identify, appraise, and summarise studies addressing a defined question. It can, but does not need to involve meta-analysis. The Cochrane database (http://www.cochrane.org) is probably the most accessible and widely used for this purpose in the UK. A Meta-analysis is a statistical technique that summarises the results of several studies in a single weighted estimate, in which more weight is given to results of larger studies, and sometimes to studies of higher quality. More recently, an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses has been introduced.¹⁰

Evidence-based individual decision making (EBID)

Evidence-based individual decision (EBID) making is the commonest evidence-based medicine as practiced by the individual clinician. Evidence based individual decision making is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It involves integrating individual clinical expertise with the best available external clinical evidence from systematic research. For the treatment of an individual patient the process involves six steps (table 1). In these circumstances, evidence based practice starts and ends with the needs of an identified patient and takes into account individual clinician's skills. However, there is managerial and budgetary

concern that this sort of evidence-based medicine focuses excessively on the individual (potentially at the expense of others in a system with limited budgets), even though it has been conducted using sound scientific methodology.¹¹

Evidence based medicine guidelines

Evidence-based guidelines (EBG) are also the practice of evidence-based medicine but in an organizational or institutional level. This process includes the production of guidelines, policy, and regulations. This approach has also been called evidence based healthcare. Evidence-based health care extends the application of the principles of Evidence-Based Medicine to all professions associated with health care, including commissioning and management. EBM at this level remains the practice of integrating the best available research evidence with clinical expertise and patient values in making decisions about the care of individual patients, but uses the information to inform service provision in terms of patient groups, using guidelines, protocols and care pathways. In order to achieve this, the guidelines utilize a synthesis of a broad range of research studies and opinions. Doing this effectively is a scientific and statistical skill in itself and the quality of quidelines is based primarily on the quality research evidence as already identified above. The processes used in this "service delivery" form of Evidence Based Medicine (EBM) still share some of the characteristics of Individual Evidence Based Practice, but there are

Table 1. Steps of evidence-based individual decision making (EBID) (Sackett et al 1996)

- i. Start with the patient a clinical problem or question arises from the care of the patient
- ii. Construct a well built clinical question derived from the case
- iii. Select the appropriate resource(s) and conduct a research
- iv. Appraise that evidence for its validity (closeness to the truth) and applicability (usefulness in your clinical practice)
- v. Return that evidence to the patient-integrate with your clinical expertise, this patient's preferences and apply it to practice
- vi. Evaluate your performance with this patient

fundamental differences. The main aim in this type of EBM is to identify what interventions, over a range of patients, work best and what is cost-effective in order to guide service development and provision at a strategic level.

Economic analysis is a set of formal, quantitative methods used to compare two or more treatments, programs or strategies, with respect to their resource use and their expected outcomes. If two strategies are analyzed but only costs are compared, this comparison would inform only the resource-use half of the decision and is termed a cost analysis. Comparing two or more strategies only by their consequences (such as in a randomized trial) informs only the outcomes portion of the decision. A full economic comparison requires that both the costs and consequences be analyzed for each of the strategies compared. A cost benefit analysis assesses whether the cost of an intervention is worth the benefit, by measuring both in the same units (usually monetary). A cost effectiveness analysis measures the net cost of providing a service as well as the outcomes obtained. Outcomes are reported in monetary units per Absolute Risk Reduction (AAR) (single unit of measurement). A costutility analysis converts effects into personal preferences (or utilities) and describes how much it costs for some additional quality gain (e.g. cost per additional quality-adjusted life-year or QALY).

Examples of guidelines in the UK include those in the Cochrane database and the National Institute of Health and Clinical Excellence (NICE) technology appraisals, which are compulsory for the NHS and clinical guidelines, which are not compulsory, though adherence to their recommendations is a strong indicator of high quality service provision. NICE guidelines are developed independently from commissioners, providers and politicians and guide the provision of evidence based practice. Therefore, they provide easy access to quality evidence, promote the scientific approach in clinical practice, reduce political interference in service provision and promote quality and accountability.5 There are examples of NICE guidelines that have not been implemented because of adverse press coverage, such as the implementation of Contingency Management in substance misuse. There are also instances of examples in which guidelines have been reviewed and revised without

the required evidence base, due to pressure by professionals or service users, such the guidelines on the use of medication in Alzheimer's disorder.¹²

Despite their importance, Guidelines have potential limitations, because they can only base their recommendations on quality of pre-existing research, 13 i.e. what has been looked at already. It is important to note that lack of systematic evidence to support an intervention does not automatically mean that an intervention must instantly be abandoned. It may just mean that this intervention or clinical issue has not been researched adequately. Some therapeutic techniques, for instance those requiring specific human attachments such as psychotherapy, cannot be randomized, blinded or be subject to RCTs. Also factors such as the complexity of design (Simple trial designs being more readily performed), current research trends and available methodologies, affect what research is actually carried out, analyzed and ultimately published. RCTs in psychosocial interventions in particular are more methodologically challenging and expensive than pharmacological interventions.¹⁴ In fields such as the psychological field individual and manualised interventions are easier to study than dynamic, group or unstructured humanistic interventions.

In studies of the effects of health care, the main types of bias arise from systematic differences in the groups that are compared (selection bias), the care that is provided, exposure to other factors apart from the intervention of interest (performance bias), withdrawals or exclusion of people entered into a study (attrition bias), or how outcomes are assessed (detection bias). Reviews of studies may also be particularly affected by reporting bias, where a biased subset of all the relevant data is available. High quality guidelines are developed in a way that minimises the risk of bias. The quality of such development can itself be subject to guidelines and critical appraisal.

It is important to note that guidelines emanating from different professional bodies with separate aims use different methodologies (for example NICE and Cochrane are analyzing data from the original studies, whereas Canadian Network for Mood and Anxiety treatments (CANMAT) or British Association for Psychopharmacology (BAP) use existing meta analysis studies and are written for different pur-

poses in different systems. It should come as no surprise that different guidelines differ from or even contradict each other. For example, the BAP and the CANMAT do not take cost factors into account, whereas NICE does. BAP does not take complimentary medicine into account, whereas CANMAT does. Comparing NICE, BAP and to CANMAT guidelines for depression therefore, an increasing range of medications is supported.^{15–17}

It is also important that guidelines are understood for what they are, i.e. not rules, or complete statements of knowledge. They are based on a statistical abstraction of what happens in the 'population' with that diagnosis. They only apply to individuals in a probabilistic way.¹⁸ This challenge increases when evidence originates from a different country. Ethnic, local and cultural differences can make evidence implementation impractical or too expensive. This challenge is well recognized with psychosocial interventions.¹⁴ Novice doctors base their prescribing decisions on guidelines, whereas senior doctors base their management on a sophisticated holistic assessment of the individual patient that goes far beyond "diagnosis". 19 Because of the impracticality of providing guidelines covering all the important patient characteristics (independent variables), guidelines can only be a highly generalized starting point. Expert doctors adapt guidelines to the individual patient in the consultation; this is a complex, partly automatic and unconscious activity that is developed through years of study, training and practice.

Innovation

Within the UK, NHS innovation has been defined as an "idea, service or product, new to the NHS or applied in a way that is new to the NHS, which significantly improves the quality of health and care wherever it is applied". Innovation is more than simply an improvement in performance. The NHS definition acknowledges two further important aspects of innovation:

- 1. It refers to the whole process of development, implementation and diffusion of innovations into widespread use.
- 2. It needs to be replicable.

Innovation signifies a substantial positive change compared to gradual or incremental changes. In the NHS organizational context, innovation may be linked to positive changes in quality of care, efficiency or safety. The simplest form of health service innovation is where a local team alters a component/practice of the local care system, according to local needs. A team develops an innovation for their own (in-house) use, because existing systems or products do not meet their needs. Such an example is the development of a preparation for detoxification Cognitive Behaviour Therapy group intervention, part of a three stage community treatment programme for alcohol dependence, as a response to local needs despite the lack of existing evidence.21

EBM and associated guidelines will never have enough suitable evidence for every aspect of health provision in every locality. Innovation using inductive reasoning has to play a major role within the NHS and any other health care system.²² It is applicable to all three levels of service provision: clinical practice, policy and organisation structure.²³

Innovation in clinical practice attempts to cover the gaps in scientific knowledge and provide pragmatic solutions with suitable implementation challenges. However, it can be risky, especially if untested or untried. It is crucial for any innovative practice to be monitored for adverse effects to the individual (relevant also to innovation in psychosocial interventions), and negative effects on service provision such as exclusion of vulnerable patients or unacceptability to patients and staff. It is also important for innovation to be evaluated for effectiveness and cost-effectiveness, using robust research methods audits or other techniques.²⁴

Innovation in policy, although pragmatically necessary due to the accumulation of new evidence (evidence based policy), can also be problematic. Whenever an innovative policy is required, either because of gaps in evidence or because of convenient political choices, there is a risk of a service embarking in a rollercoaster of trying to generate the

missing "supportive" evidence post hoc at all costs (policy based evidence).²⁵

Evaluations of medical innovations in practice suggest that success is more likely where interventions are relatively simple and well-designed and where there is strong evidence of the clinical benefits.²⁶ Compare, for example, prescribing a new psychotropic medication with what is involved, with say the introduction of Early Intervention Teams. In practice innovations require significant organisational effort to overcome inertia and fear, in order to succeed and become embedded in routine.²⁷ Bearing these factors in mind, the following summarises some of the main challenges in service innovation in mental healthcare:

- 1. Innovations will not always meet conventional standards of evidence criteria consistent with an EBM model. This is particularly the case with values based service innovations, such as the introduction of the Recovery Approach into a local service, where the evidence supporting is equivocal or still emergent. Such service innovations raise the questions of the type of evidence that is appropriate, what criteria should be applied and what procedures does this involve.
- Many service innovations are not primarily concerned with the application of technical interventions. All innovations have service implications, but some of them can be highly complex and involve equally complex approaches to be successfully implemented.
- 3. A further challenge is that many innovations are not uni-professional. Their successful implementation involves multi-disciplinary team members working jointly. This requires an organisational approach to change, including high quality leadership.¹⁸
- 4. Service user experiences and user priorities for their own care and treatment should increasingly impact on both the focus and process of service innovations. Approaches to service innovation need to develop effective ways of involving service users in informing agendas and the processes of innovation.

Implementing EBM and Innovation in the NHS and other health care systems

Commitments to improvement and excellence and ever increasing financial challenges have lead to innovations and changes of service delivery and philosophy. Some of these changes in the NHS have appeared to be political and driven by aspiration rather than scientific evidence, resulting in division of opinion between professionals, service users and carers. These changes at times have appeared "populist", or only superficially rational and as not necessarily having satisfactory evidence based grounds. In our view, although EBM and Innovation look potentially contradictory, they may be combined productively and compliment each other in order to promote better health services for the population, if judiciously monitored.

For example, the early stage in the implementation of a recovery orientated approach in substance misuse services had given the false impression that recovery is related only to exit from substitution treatment. In other words, recovery could only be achieved when people get "detoxified" from their medication. This created a deep division between substitution treatment services and recovery and community re-integration innovations. This has been modified by the acceptance of the evidence based harm minimization interventions within the overall recovery orientated treatment system.²⁸

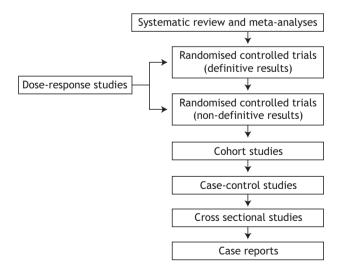


Figure 1. Hierarchy of evidence (Greenhalgh 2010)

A major factor in innovation failure can be information and change overload. There may be concerns about ethical implications of change and parallel concerns about legal implications. These need to be identified, addressed and overcome. Crucially, not innovating also carries potentially grave risks. It is easy for clinical staff and administrators to be complacent and carry on, as they have done for a long time, in the belief that this provides best and most cost effective care when, in fact, better alternative ways of doing things have emerged.

One means by which EBM has been promoted in the NHS has been through top down implementation in the form of clinical guidelines and standardised protocols, sometimes underpinned by a strong policy imperative. Although such guidelines are important, the evidence of their routine application is less certain.²⁹ There is often limited time for decision making. Often there is a lack of political power in a locality. There may also be a lack of resources and skills for policy analysis and evaluation and a lack of consensus. Identified evidence is sometimes not fully relevant to the case in hand and evidence is only part of the basis of any decision. There may be an inability to release resources from current budgets.

A recent poll of the Royal College of Psychiatrists showed that 64% of responding UK psychiatrists agreed that NICE or Scottish Intercollegiate Guidelines Network (SIGN) guidelines have improved the quality of mental health care for their patients. The question of whether EBM or innovation as described above have had any positive influence on the quality of care provided and whether they have increased patients satisfaction, is a major topic for further debate. This is definitely linked with the major issue of the definition of patient-centred services and the potential conflict between patients' and professionals' definitions of good care and their associated expectations.

Conclusions

In the second decade of the 21st century it is imperative that health systems aspire to meet both patients' and society's needs. Health care delivery

systems consequently need to be suitably flexible and adaptable. Emphasis on the provision of critically appraised evidence-based medicine is recommended. This is an approach that aims to reduce unnecessary variation in treatment, promote costeffective interventions and support national health services to meet the health needs of the population. The role of high quality clinical guidelines is considered central for its implementation. Every effort should be made to reduce unnecessary idiosyncratic (and therefore prone to mistakes) practice and meet the justifiable request for patient choice and public accountability of managing public health system resources. A judicious mixture of evidence based practice, evidence based medicine and guidelines with local tailoring and innovation, combined with strong clinical expertise and patient's values, is recommended.

The medical profession has tended to emphasise profession-specific training and clinical leadership. However, a more holistic approach is essential for successful service innovation and the need to consider transforming organisational contexts and promoting cultural change, in turn creating an environment conducive to transformation of practice. The nursing literature has been helpful in relation to service innovation in evaluating evidence to inform a 'practice development' model of service change and innovation, which takes such an holistic approach.³¹ The evidence suggests that successful practice development approaches apply equal importance, not just to the innovation itself and the evidence supporting its efficacy, but also to two other components of service innovation: the context of the environment into which the innovation is to be introduced and, secondly, facilitation of the process of introducing and implementing the innovation. It is the process of implementation that addresses the components of service innovation which are associated with successful implementation.

Note

This paper is based on the presentation entitled "Adapt and Survive: Innovation in Mental Health Services in the National Health Service in England", given by CK at the 21st Pan-Hellenic Congress of Psychiatry, Athens, May 2011.

Τεκμηριωμένη ψυχιατρική φροντίδα και καινοτόμες υπηρεσίες: Ανασκόπηση των εννοιών και αμφισβητήσεων

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Τα συστήματα υγείας των αναπτυγμένων χωρών καλούνται να αντιμετωπίσουν μεγάλες οικονομικές δυσκολίες. Νέοι τρόποι συγκέντρωσης και σύνθεσης δεδομένων, όπως η «τεκμηριωμένη ιατρική πράξη» και η χρήση «κλινικών οδηγιών», χρησιμοποιούνται για την αντιμετώπισή τους. Η τεκμηρίωση στηρίζεται στη συστηματοποιημένη κλινική έρευνα, στα δημοσιευμένα περιστατικά και στην προσωπική κλινική εμπειρία. Η τεκμηρίωση μπορεί να στηρίξει τις ατομικές αποφάσεις του κάθε κλινικού στη θεραπεία του κάθε ασθενούς. Οι κλινικές οδηγίες από την άλλη, χρησιμοποιούνται σε επίπεδο οργάνωσης και σχεδιασμού παροχής υπηρεσιών. Σκοπός τους είναι να υποδείξουν ποιες παρεμβάσεις και για ποιες πληθυσμιακές ομάδες είναι πιο αποτελεσματικές και οικονομικές. Δεν υπάρχει όμως τεκμηρίωση για όλα τα ζητήματα που αφορούν στην παροχή υπηρεσιών. Καινοτομίες βασισμένες σε λογικά βήματα μπορεί να παίξουν σημαντικό ρόλο. Καινοτομίες μπορούν να εφαρμοστούν και στα τρία επίπεδα παροχής υπηρεσιών υγείας: κλινική πράξη, πολιτική και φιλοσοφική κατεύθυνση και οργανωτικές δομές. Σκοπός του παρόντος άρθρου είναι να εξετάσει κριτικά τις παραπάνω έννοιες και τον συμπληρωματικό τους ρόλο στην ανάπτυξη συστημάτων υγείας τα οποία ανταποκρίνονται στις ανάγκες του πληθυσμού, είναι οικονομικά, εφαρμόσιμα, ευέλικτα και προσαρμόσιμα στις κοινωνικές αλλαγές, χρησιμοποιώντας παραδείγματα από την εμπειρία μας στη Μεγάλη Βρετανία.

Λέξεις ευρετηρίου: Τεκμηριωμένη ιατρική πράξη, κλινικές οδηγίες, καινοτομίες

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