

CONCEPTUAL PAPER

Translating ethical principles into outcome measures for mental health service research

GRAHAM THORNICROFT¹ AND MICHELE TANSELLA

From the Section of Community Psychiatry (PRiSM), Institute of Psychiatry, London; and Dipartimento di Medicina e Sanità Pubblica, Sezione di Psichiatria, Università di Verona, Verona, Italy

ABSTRACT

Background. Mental health service research continues to use only outcome measures that are available rather than develop measures that are important. This paper argues that it is necessary to select and then define a set of ethical principles that can be operationalized and validated as outcome measures to provide a wider balance of information for health policy and clinical service decisions.

Methods. The method used is to adopt a five stage procedure: (i) to select ethical principles most directly relevant for mental health services and their evaluation at the local level; (ii) to propose definitions of these principles; (iii) to validate these definitions; (iv) to translate the defined principles into operationalized outcome measures; and (v) to use these outcome measures in mental health services research, within the context of evidence-based medicine.

Results. We address steps (i) and (ii) of this five-stage procedure. Nine principles are selected and defined: autonomy, continuity, effectiveness, accessibility, comprehensiveness, equity, accountability, coordination and efficiency. These principles can together be referred to as the three ACEs.

Conclusions. Of these nine principles, only two (effectiveness and efficiency) have so far been fully translated into quantitative outcome measures, upon which the evidence-based medicine approach depends. We propose that further concepts also be developed into a more complete multi-dimensional range of fully operationalized outcome measures.

INTRODUCTION

In 1850 a paper appeared entitled ‘The influence of distance from and proximity to an insane hospital on its use by any people’ (Jarvis, 1850). In describing what later became known as ‘Jarvis’s Law’, the author showed that the amount of use made of an unrestricted service by patients is inversely proportional to the distance that they live from that service. In doing so he pioneered a vital function: operationalizing an ethical principle (in this case accessibility) so that it could be quantified and

used for health service evaluation. The two aims of this paper are to take further the work of Jarvis: (i) by proposing a five-step procedure to be used in translating ethical principles into operationalized outcome measures for mental health service research; and (ii) by undertaking the first two steps of this procedure (selection and definition of principles), as a starting point for widening the range of outcome measures available to be used.

For both planning and evaluating mental health services, there is a clear need for an overall conceptual framework. We have proposed such a framework (the matrix model), which uses two dimensions, the geographical (country, local and patients levels, identified by

¹ Address for correspondence: Professor Graham Thornicroft, Institute of Psychiatry, De Crespigny Park, London SE5 8AF.

the numbers 1, 2 and 3) and the temporal (input, process and outcome phases, referred to by the letters A, B and C) (Tansella & Thornicroft, 1998; Thornicroft & Tansella, 1999). Using these two dimensions a 3×3 matrix with nine cells is constructed to bring into focus critical issues for mental health services. In the present paper we shall address the cell 2C of this matrix, that is the development of outcome measures suitable for use at the level of services for a local catchment area.

The wider context to research in this particular area is the recent explosion of interest in evidence-based medicine (EBM). This reflects the maturation of systematic reviews and other meta-analytical techniques to provide methodologically sound overviews of the strength of scientific evidence in areas of bio-medical research. The origins of EBM lie with the birth of randomized clinical trials and the increasing recognition of the importance of scientific evidence to guide the delivery of health care interventions (Cochrane, 1972; Kassirer, 1993), which have been expressed by Light (1991) as the 'Cochrane test'. This test requires clinicians and managers to respond to six challenges; (i) consider anything that works; (ii) make effective treatments available to all; (iii) minimize ill time interventions; (iv) treat patients in the most effective place; (v) prevent only what is preventable; and (vi) diagnose only if treatable.

It is notable, however, that so far the domains of outcome measures for mental health services have included, at the best, the translation of only two principles into measures, to be collected and used according to the EBM paradigm (L'Abbe *et al.* 1987; Chalmers *et al.* 1993; Cochrane Database of Systematic Reviews, 1996; Sackett *et al.* 1996). First, effectiveness of treatments and then their efficiency (the relation between effectiveness and cost) (Calman, 1994; Beecham *et al.* 1995). At worst, health economic evaluations have sometimes been conducted without answering the prior question of whether a particular intervention is actually effective. Though a treatment may be effective, it may not be cost-effective when compared with other treatments. A proper evaluation sequence is therefore first to examine effectiveness, and second to assess cost-effectiveness. This then allows health care purchasers to disinvest from

treatments that are ineffective or from those that are less efficient than their alternatives. It does not follow, however, that lack of evidence of effectiveness is the same as the presence of evidence of ineffectiveness, since many types of mental health service intervention have not been subjected to proper evaluation (Westrin *et al.* 1992; Hope, 1995). This lack of translation of further principles into measures can be understood in two ways, either because their absence has not been recognized as important, or because the process necessary to operationalize these measures has been considered to be too complex.

A PROCEDURE TO TRANSLATE PRINCIPLES INTO OUTCOME MEASURES

We propose a five-stage procedure to translate principles into outcomes. First, key principles for a particular area of health practice need to be identified. Such a selection will need to consider their direct relevance and how to avoid repetition, or overlap between principles. Secondly, the selected principles will need to be specifically defined. Thirdly, the selection and definitions initially proposed will require external validation by, for example, a consensus expert validity process, such as a Delphi exercise. Fourthly, the principles need to be operationalized through scale construction and standardization. Finally, the scales, once developed may be implemented in research studies, to provide a multi-dimensional assessment of mental health service outcomes, within the paradigm of EBM. Here we address the first two of these five stages.

To propose this selection of ethical principles we have reviewed the literature and drawn upon our own clinical and research experience to identify those which we consider to be the most relevant to mental health service research, and which are mutually independent. In relation to biomedical ethics as a whole, the approach of 'principlism' has been best set out in the 'Principles of Biomedical Ethics', in which four principles are described as the basis for medical ethics: respect for autonomy, non-maleficence, beneficence and justice (Downie & Calman, 1987; Beauchamp & Childress, 1994; Holm, 1995). In more particular relation to quality at the service level, Maxwell (1984) has recognized

Table 1. *Nine ethical principles to translate into operationalized outcome measures for mental health service research: the 'three ACEs'*

Principle
1 Autonomy
2 Continuity
3 Effectiveness
4 Accessibility
5 Comprehensiveness
6 Equity
7 Accountability
8 Coordination
9 Efficiency

that quality of care cannot be reduced to a single measure, and has described six dimensions access to services, relevance to need, effectiveness, equity, social acceptability, and finally efficiency and economy. Building upon this, we have selected nine principles, which are shown in Table 1. While some degree of overlap still remains, we regard these particular nine principles as largely conceptually distinct, and as exerting the most impact upon mental health services in economically developed countries.

Since the definition of terms is an important starting point for scientific enquiry, in the second stage of our suggested procedure for the development of quantified measures, we put forward in the indented paragraphs below our own proposed definition for each principle in turn, and also draw upon the etymological roots of each word taken from the *Shorter Oxford Dictionary*.

DEFINING PRINCIPLES FOR USE AS OUTCOME MEASURES

Autonomy

Autonomy has been defined as 'personal freedom', or the 'doctrine of the self-determination of the will'. This is not a characteristic of a health service, but rather of what the service does. It refers to the capability of the service to preserve and promote independence by positive experiences, and to reinforce the strengths or healthy aspects of each patient, especially the most severely disabled, while controlling symp-

toms (Hall, 1992; Jinnett-Sack, 1993). There is a balance between this principle and continuity of care, in that over-intrusive or over-frequent follow-up can effectively interrupt the processes of recovery and rehabilitation. Autonomy is closely associated with another of our key principles: accessibility. The ability to exercise autonomy through choice is relatively unimportant unless a real choice is possible between actual alternatives that are both available and seen to be relevant by patients.

'Autonomy' we define as 'a patient characteristic consisting of the ability to make independent decisions and choices, despite the presence of symptoms or disabilities. Autonomy should be promoted by effective treatment and care.'

Continuity

Continuity has been defined as 'a continuous or connected whole', or 'coherence'. These definitions are pertinent to our purpose here in that they stress the ongoing need by many patients for reliable sources of treatment and social support. Johnson *et al.* (1997) distinguished the longitudinal and cross-sectional dimensions of continuity of care. 'Longitudinal continuity' refers to the ability of services to offer an uninterrupted series of contacts over a period of time. 'Cross-sectional continuity' includes continuity between different service providers.

The implementation of this principle may also be a way of increasing efficiency, for example the avoidance of multiple or overlapping interventions can reduce costs and adverse effects. At the same time there are disadvantages from a too compulsive stress upon continuity, which can encourage patients to develop an unhealthy degree of dependence on a particular service, which in turn may foster a chronic sick role (Dickenson, 1997). For these reasons we consider that for long-term illnesses an appropriate balance is needed to provide variable continuity.

We define 'continuity' as 'the ability of the relevant services to offer interventions, at the patient or at the local level, and: (i) which refers to the coherence of interventions over a shorter time period, both within and between teams (cross-sectional continuity); or (ii) which are an uninterrupted series of contacts over a longer time (longitudinal continuity)'.

Effectiveness

The Cochrane database defines effectiveness as ‘The extent to which a specific intervention, when used under ordinary clinical circumstances, does what it is intended to do’ (Cochrane Database of Systematic Reviews, 1996). In this sense effectiveness applies to routine clinical settings, as compared with ‘efficacy’, which means how far a specific intervention achieves its intentions under ideal, experimental conditions, such as those which are required for randomized controlled trials (Adams *et al.* 1996).

As one moves from the individual patient level to the treatment programme level, the amount of evidence from controlled studies decreases rapidly, as does its quality, and the primary issue becomes one of effectiveness rather than efficacy. To make research useful in practice we need to move from efficacy to effectiveness, that is, to extend research from selected patient groups to more representative patient samples taken from ordinary clinical settings.

We define ‘effectiveness’ at the individual patient level as ‘the proven, intended benefits of treatments provided in real life situations, and at the treatment programme level as the proven, intended benefits of services provided in real life situations’.

Accessibility

Accessibility can be understood as ‘capable of being entered or reached’ or ‘get-at-able’. This relates directly to the central point, which is that patients should be able to reach and ‘get at’ services where and when they are needed. Accessibility remains a complex concept. It is used in relation to geographical distance or to travel times from patients’ homes to health services sites, to delays in how long it takes for patients to be accessed or treated, and to selective barriers or filters, which reduce the uptake of services by all patients (such as stigma), or for some subgroups of the population (such as ethnic minorities).

There may be disadvantages associated with too much accessibility. If specialist services or hospitals are too easily available, then patients may have a low threshold to consult when in difficulty, may bypass primary care services where these exist, and may expect specialist attention when suffering from relatively minor,

brief, and self-remitting conditions. Such contacts may divert time and resources away from more severely disabled patients, and access may be delivered at the expense of equity. Secondly, if accessibility is too high, then efficiency may reduce as minor disorders are seen in the more expensive specialist services. Accessibility, therefore, cannot be unlimited, and services may need to encourage self-limited use by patients, for example, in relation to night-time emergency services.

We define ‘accessibility’ as ‘a service characteristic, experienced by patients and their carers, which enables them to receive care where and when it is needed’.

Comprehensiveness

A central dilemma for health services is the balance between offering more intensive care to fewer patients or less intensive care to more. The degree of comprehensiveness of a service, therefore, raises the key question: comprehensive for whom? Taking mental health as an example, psychiatric disorders will affect about a third of the general adult population in any year, and since the capacity of the specialist mental health services, even in most economically developed countries, means that they can provide a service usually to between 2% and 6% of the adult population, these services will necessarily be limited to only a minority of those suffering from mental illnesses. The question then becomes one of quality or quantity. Services that selectively treat first the more severely mentally ill, such as in Britain, will provide a relatively poor service for the majority of patients who have neurotic illnesses. Many of these cases remain untreated if they are not recognized by primary care staff. This lack of treatment, in turn, may increase the risk of chronicity and of developing subsequent disabilities and handicaps. Similarly, in other areas of medicine, services given to people with lesser degrees of severity may replace those given with more severe forms of illness.

We define ‘comprehensiveness’ as ‘a service characteristic with two dimensions. By “horizontal comprehensiveness” we mean how far a service extends across the whole range of severity of mental illnesses, and across a wide range of patient characteristics. By “vertical comprehensiveness” we mean the availability of the basic

components of care, and their use by prioritized groups of patients’.

Equity

Commonly defined as ‘fairness’, the application of the principle of equity implies that the distribution of money for health services should be made according to criteria that are specified, transparent, and which have widespread acceptance as being fair. There is a need to adapt and apply such rational and explicit approaches to resource allocation in settings where historical and inequitable patterns may predominate (Chodoff, 1981; Mooney, 1986; Westrin *et al.* 1992).

In our view there is a useful distinction between explicit and implicit equity in allocating resources to health services. Implicit methods are often based on decisions taken by restricted groups of people that are not transparent, since the criteria used are not in the public domain. These decisions may be defined as equitable by using *post hoc* independent procedures. We believe that the basis upon which resources are allocated should be made explicit be based upon a process of needs assessment.

We define ‘equity’ as ‘the fair distribution of resources: the rationale used to prioritize between competing needs, and the methods used to calculate the allocation of resources, should be made explicit’.

Accountability

At the individual patient level the principle of accountability refers to the element of responsibility within the relationship between staff and individual patients, a relationship that needs to be based upon confidence and trust. Each patient has a legitimate expectation that the clinician will offer treatment based upon a ‘duty of care’, and will do this in accordance with accepted standards of professional practice. For example, one aspect of direct accountability to the patient is that clinical information remains confidential. This type of direct patient accountability may be challenged by requests from family members (or others), who express the need for services also to be accountable to them. At the treatment programme level, a wider set of considerations apply, and health services operate in a way that offers dual accountability: both to the patient and to the wider society. In practice, health

services are held accountable by the public to act in a way that maintains public confidence in their viability.

We define ‘accountability’ as ‘a function that consists of complex, dynamic relationships between mental health services and patients, their families and the wider public, who all have legitimate expectations of how the service should act responsibly’.

Coordination

We can distinguish between cross-sectional and longitudinal types of coordination. The first refers to the coordination of information and services within an episode of care (both within and between services). The latter refers to the inter-relationships between staff and between agencies over a longer period of treatment, often spanning several episodes.

We define ‘coordination’ as ‘a service characteristic that is manifested by coherent treatment plans for individual patients: each plan should have clear goals and include interventions that are needed and effective, no more and no less’. By ‘cross-sectional coordination’ we mean ‘the coordination of information and services within an episode of care’. By ‘longitudinal coordination’ we mean ‘the inter-linkages between staff and between agencies over a longer period of treatment’.

Efficiency

There will never be ‘enough’ resources allocated for health services in the eyes of patients, their carers or staff. If we accept this scarcity as the basic condition, our starting point is therefore the narrower question of allocation. The pursuit of efficiency can mean, therefore, reducing the costs for a given level of effectiveness (outcome), or improving the level of effectiveness or the volume and quality of outcomes achieved from fixed budgets (Knapp, 1995).

Three types of economic efficiency have been defined by Drummond & O’Brien (1997). ‘Technical efficiency’ is ‘achieving maximum physical output from resource use’ (without considering the costs implications). ‘Productive efficiency’ means ‘achieving maximization of output for a given cost’. ‘Allocative efficiency’ is defined as ‘achieving maximization of the value attached to the output for a given cost’. In terms of the patient level, Cochrane (1972) described ineffi-

ciency in two senses: the use of ineffective therapies and the use of effective therapies at the wrong time.

We define 'efficiency' as 'a service characteristic, which minimizes the inputs needed to achieve a given level of outcomes, or which maximizes the outcomes for a given level of inputs'.

CONCLUSIONS

The nine principles enumerated in this paper, which from their initials could be termed 'the three ACEs', have been described in relation to the individual patient, and to the treatment programme levels. We do not suggest that all nine are relevant to every type of mental health service evaluation across cultures. In fact, the principles that we describe are specifically intended to be translated into a range of outcome measures suitable for services for those suffering from long-term and severe mental illnesses, within the context of a public health care system of care (Goldberg & Tantam, 1991). The choice of which principles are accorded high social value will vary over time. In the 1970s, for example, a higher importance would have been attached to autonomy, accessibility and equity, while in the current decade our decision to include continuity, accountability and coordination reflects, within economically developed countries, a re-emerging concern to control deviant behaviour. Time will also matter in terms of the clinical condition of individual patients. High levels of autonomy may be appropriate for some patients at one point in time, and high levels of continuity, requiring a reduction in autonomy, may be essential for the same patients times. In this case, the aims of the clinical treatment plan would change over time, and the effectiveness of the different clinical interventions could be assessed if specific outcome measures, and their context-specific calibration, were available.

Conflicts can occur between the views of different parties on which principles should predominate, or between the consequences of different principles which apply simultaneously to any given situation. In the first case, there may be a clear division between the views of the wider public on how far patients with a history of violence, for example, should be afforded

autonomy, and the views of the patients themselves. In the second case, an example of the conflict between autonomy and the absence of informed consent on one side, and the principle of beneficence on the other has arisen in relation to the use of regional or national case registers for investigating potential health risks of the working environment (Westrin *et al.* 1992). Indeed the moral imperative to balance counterposing principles is central to medical ethics (Holm, 1995).

Our point is that, if a wider array of measures were available, then a more sophisticated and specific set of questions about the effects of mental health interventions could be answered. For example, where improving continuity of care is the primary aim of a service intervention, this should be measured directly (Goldman *et al.* 1994). Within Europe, some aspects of continuity, for example, within mental health services research, have already been operationalized to compare two different treatment programmes in Italy and the Netherlands (Sytema *et al.* 1997). We expect that translations of other principles into operationalized measures will also occur to address specific research questions, especially in relation to longer-term mental disorders, in part because it is often true that only a limited impact can be made by treatment upon the primary symptoms.

The future development of methodologies for mental health service research should also consider another point. The application of the EBM paradigm to the planning and organization of mental health care may induce a systematic bias. This bias will be toward those treatments and those services for which there is good evidence of effectiveness. However, as Hope (1995) pointed out, we should consider that there are at least two factors that influence whether such good quality evidence is available: the amount of effort and resources which are put into research (for example, drug treatments, generously funded by pharmaceutical industry, are likely to be supported by more evidence for effectiveness compared to other treatments); and the ease with which desired outcomes can be operationalized and quantified (some types of outcomes, especially those at the service level, are more difficult to measure than others).

The procedure and the definitions we have proposed here can be considered as the first two

stages towards the development of quantitative measures to evaluate a broader range of health services outcomes, and so to further the work of Jarvis (1850).

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