

**THE IMPACT OF ROUTINE OUTCOME MEASUREMENT
ON TREATMENT PROCESSES
IN COMMUNITY MENTAL HEALTH CARE:
APPROACH AND METHODS OF THE MECCA STUDY**

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The impact of routine outcome measurement on treatment processes in community mental health care: approach and methods of the MECCA study

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SUMMARY. Three issues characterise the background to the MECCA study: A) Throughout Europe, most patients with severe forms of psychotic disorders are cared for in the community. The challenge now is to make processes in community mental health care more effective. B) There are widespread calls to implement regular outcome measurement in routine settings. This, however, is more likely to happen, if it provides a direct benefit to clinicians and patients. C) Whilst user involvement is relatively easy to achieve on a political level, new mechanisms may have to be established to make the views of patients feed into individual treatment decisions. The MECCA study is a cluster randomised controlled trial following the same protocol in community mental health teams in six European countries. In the experimental group, patients' subjective quality of life, treatment satisfaction and wishes for different or additional help are assessed in key worker-patient meetings every two months and intended to inform the therapeutic dialogue and treatment decisions. The trial tests the hypothesis that the intervention – as compared to current best standard practice – will lead to a better outcome in terms of quality of life and other criteria in patients with psychotic disorders over a one year period. This more favourable outcome is assumed to be mediated through different treatment input based on more appropriate joint decisions or a more positive therapeutic relationship in line with a partnership model of care or both. Moreover, the study will hopefully reveal new insights into how therapeutic processes in community mental health care work and how they can be optimised.

KEY WORDS: outcome management, community mental health care, QOL, RCT, therapeutic relationships.

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COMMUNITY MENTAL HEALTH CARE

Since the 1950s, in all western industrialised countries, political reforms have substantially changed mental health care (Schmiedebach *et al.*, 2000; Fakhoury & Priebe, 2002). Former asylums have been closed or downsized, and various forms of care in the community have been established for patients with severe mental illnesses. Although the organisation and structure of services in the community vary between and within countries, most patients with severe psychotic disorders in Western Europe are now being cared for in the community. Usually, multidisciplinary teams deliver long term care for those patients in community based settings, and key working or case managing is widely regarded as a suitable method to provide co-ordination and continuity of care. In the past, several research studies addressed the question as to whether care in the community is more or less effective than previous hospital based forms of care. The result of most studies in the field suggest that care in the community does not lead to a significant improvement in psychopathology, but is associated with a more favourable quality of life and higher treatment satisfaction of the patients. This is in line with the aims of community mental health care which are no longer restricted to reducing rehospitalisation and symptoms, but now include enhancing an individual's broader role functioning, quality of life and social integration (Lehman, 1983; Kilian & Angermeyer, 1999; Awad & Voruganti, 2000).

The challenge to research now is not to establish the overall effectiveness of community care, but to find ways to improve effectiveness within community care (Priebe, 2000). On a political level, community mental health care is – to varying degrees – being criticised in some countries. Critics however rarely suggest returning to old type hospital care and resurrecting asylums. They rather look for new ways to improve care in the community and establish better practice. The question therefore is how treatment processes in community mental health care can be made more effective. Given existing economic restraints, this improvement should preferably be achieved at little or no additional cost.

Much of the debate on how to improve care has focused on service configuration and organisational issues. For example, there is the question whether functional and specialised teams for assertive outreach deliver a better service than generic community mental health teams with a general catchment area responsibility. Less emphasis has been put on how – regardless of service configuration – individual care

should be delivered and treatment processes might be optimised. In service research, the configuration of services is often directly associated with individual outcome ignoring the processes that actually link the two. There seems to be a need to investigate clinical practice in community care and test interventions that impact on how complex care packages are delivered in the community.

OUTCOMES MEASUREMENT

There have been wide spread calls to establish outcome measurement throughout mental health services. The idea is to assess individual outcome criteria and aggregate the data at the level of services and regions. This would lead to an outcome based evaluation system using routine statistics. The data can be fed back to commissioners, clinicians and managers, and inform their decisions on service development and funding. Such a process is called outcome management on a service level. Outcome management has been defined as a “technology of patient experience designed to help patients, payers and providers make rational medical care-related choices based on better insight into the effect of these choices on the patient's life” (Ellwood, 1998, p. 1551). Four techniques characterise outcome management: greater use of standards and guidelines; routine assessment of patient functioning at appropriate time intervals; pooling outcome data on a massive scale, and; dissemination of these results to relevant decision makers. The ultimate aim of outcome management is to improve clinical performance and patient outcomes (Smith *et al.*, 1997).

Although widely called for, outcome management has not been widely implemented. The reasons for this include lack of agreement about what to assess, lack of incentives to assess outcome and organisational resistance to change (Marks, 1998; Harrison & Eaton, 1999). Recently, there have been initiatives to implement outcome measurement in routine settings in various countries. This has partly been fuelled by the increasing availability of appropriate information technology that makes the aggregation and analysis of national data sets more feasible and less expensive. Despite the aforementioned hurdles, outcome management on a service or regional level – in different ways – is likely to develop in many European places rather soon. For example, the National Health Service in England is planning to implement some of the techniques of outcome management in secondary mental

health care services for all adult patients. Pilot studies to test feasibility and identify practical problems are underway. Although the precise assessment measures have not yet been decided upon, there is the expectation that every patient should have their morbidity, quality of life and treatment satisfaction regularly assessed in all mental health services throughout the country. However, routine assessment alone is likely to be perceived as just another piece of time consuming paperwork and will only happen if there is some benefit for patients and clinicians. If the results are just shelved or sent to central data managers, there will be little incentive for clinicians and patients alike to fill in questionnaires and ensure that the responses are correct. This may result in low response rates and poor quality of the data that does come in. No matter how attractive outcome management may seem as an idea and how widely supported it is, it is bound to fail in practice when response rates are poor and the validity of data doubtful. If, however, clinicians and patients can use the information that is routinely collected in a meaningful way in the therapeutic process, they are more likely to comply with the requirements of data collection, and routine outcome management is more likely to happen. Outcome management on a service or regional level may have to be combined with some form of outcome management in the individual therapeutic process in the direct clinician-patient-interaction (McCabe & Priebe, 2002).

USER INVOLVEMENT

The last fifty years have seen not just reforms of mental health care services and care systems, but also a dramatic change in the role of patients. Whatever term is used to describe patients – clients, consumers, users, and survivors being popular alternatives – they are not seen as passive objects of care anymore. They rather have an active role in care and a major influence on how health care in general and mental health care in particular are delivered. User involvement might be a political buzzword and often a matter of mere political correctness. Yet, there is no doubt that there are widespread expectations among all stakeholders that patients will get more involved in decision making processes in mental health care and that their views have to be taken into account by health care professionals. It seems relatively easy to implement such an involvement on a political and organisational level. Patients and representatives of patient groups can be appointed as members of political committees, appointment panels

and commissioning bodies. To a varying degree and in different forms, this has already happened in many services and is likely to become standard practice over time. What appears to be more difficult is how to strengthen the role of patients on the level of individual treatment processes, and how to involve patients – in particular those with severe forms of psychotic disorders – in all treatment decisions. Outcome management on the level of individual treatment processes might be a way to put the calls for user involvement into practice. This is more likely to happen if outcome criteria focus on and reflect patients' views.

CONCURRENT OUTCOME MANAGEMENT IN THE INDIVIDUAL THERAPEUTIC PROCESS

The dominant approach to measurement in outcome management is pre-post measurement of outcome, which stems from the classic pre-post design in experimental research (Brill *et al.*, 1995). This approach is in line with the emphasis on pooling outcome data on a massive scale so that managers and clinicians can evaluate the quality and effectiveness of a given treatment service or organisation (e.g., Smith *et al.*, 1997; Salvador-Carulla, 1999). However, routinely assessing treatment outcome lends itself well to assessing the impact of treatment in individual treatment cases (e.g., Brill *et al.*, 1995; Marks, 1998; Priebe, 1999; Slade, in press). Brill *et al.* (1995) call this the concurrent approach to outcome management, whereby information is gathered at multiple time points for an ongoing evaluation of treatment.

Concurrent outcome management may have some advantages over pre-post outcome management. Firstly, the concurrent approach – while allowing a pre-post comparison – can be used to identify the time course of improvement, i.e., when gains occurred during the course of the intervention, which is particularly useful in time-limited interventions (Brill *et al.*, 1995; Marks, 1998; Lambert *et al.*, 2001). Secondly, it may have more ecological validity in evaluating the effectiveness of treatment than pre-post outcome assessment in studies of model services (Brill *et al.*, 1995; Priebe, 1999). In other words, the findings may be more applicable to the 'real world' as opposed to the 'research world' (Harrison & Eaton, 1999) and consequently more generalisable. For example, it has been suggested that case management may be less sustainable in routine settings than under ideal conditions, but ongoing evaluation in routine practice is required to identify how it functions under the

pressures of less ideal conditions and how it can be sustained in long-term trajectories of care (Burgess & Pirkis, 1999).

WHAT OUTCOMES TO ASSESS?

Whether pre-post or concurrent outcome management is favoured, several obstacles to its implementation have been highlighted (Smith *et al.*, 1997; Marks, 1998; Salvador-Carulla, 1999; Slade *et al.*, 1999). Deciding on the criteria for assessing success is not straightforward. As Perkins (2001) notes, the list of interested parties is potentially long from politicians and pressure groups to patients and carers. Each party may have different views about the goals of treatment and, hence, the relevance and value of different outcomes. What is more, there often exist different perspectives within any of these groups. For example, different professional groups do not necessarily agree about what treatment should be provided and what outcomes are desirable. The outcomes to be assessed will also depend on the disorder being treated. People with severe forms of psychosis frequently have complex mental health problems and require support in different domains of their life, e.g., managing symptoms, housing, finances, practical skills and relationships. Hence, multiple outcome domains may need to be assessed.

In the context of outcome management, "the centrepiece and unifying ingredient of outcomes management is the tracking and measurement of function and well-being or quality of life" (Ellwood, 1988). While there is disagreement about what quality of life is (e.g., Kilian & Angermeyer, 1999; Lauer, 1999; Herrman, 2000), there is agreement that it is a complex construct encompassing many domains, at least health, social relations, family relations, work and leisure (Van Nieuwenhuizen *et al.*, 1997). There is also debate about the relative importance of subjective and objective indices of quality of life (e.g., Warner, 1999), with some expressing concern about the reliability of subjective assessments of well-being and whether they can be treated as objectively as direct assessments of pathology (Ellwood, 1998). Awad & Voruganti (2000) suggest that self-ratings about treatment outcomes by people with schizophrenia have been viewed suspiciously because their cognitive capacity may be compromised. However, cumulative findings indicate that subjective quality of life ratings are reliable and correlate to some extent with clinicians' ratings (Voruganti *et al.*, 1998). Moreover, subjective quality of life indicators in specific life

domains are much better predictors of overall well-being compared with objective indicators in the same life domains (Lehman, 1983).

Besides subjective quality of life, patients' needs and treatment satisfaction are considered important subjective evaluation criteria and are commonly used in research (Priebe *et al.*, 1998). There are numerous publications on both criteria, in particular on treatment satisfaction. Systematic research on treatment satisfaction began in the United States in the 1970s. On a group level, patients tend to be satisfied with most forms of psychiatric treatment most of the time. Yet, individual patients may well express explicit dissatisfaction with the treatment they are receiving, and in the satisfied majority, the degree of satisfaction varies. In consumer oriented health care systems, treatment satisfaction is a central outcome criterion. In many services it is routinely assessed, and the scores are used by managers and lead clinicians to make their service more attractive and appealing to patients. This is regarded as an essential element of quality management (Priebe, 2000). Comparatively little is known about how treatment satisfaction scores can be used to improve individual treatment processes. Some evidence suggests that the assessment of treatment satisfaction can be helpful if reasons for dissatisfaction are explored and patients' wishes for changes inform further treatment decisions (Priebe & Gruyters, 1999).

CLINICIAN-PATIENT COLLABORATION IN TREATMENT

In the UK, the Department of Health intends to evaluate treatment "against the aspirations and experience of its users" (Department of Health, 1997), and the National Service Framework (Department of Health, 1999) states that services should be led by the interests of its users. This is hardly surprising given that a collaborative approach in health service provision leads to better outcomes. A significant body of research in primary care has indicated that a patient-centred approach which facilitates patient participation and actively seeks the patient's perspective in the treatment interaction is associated with increased satisfaction and compliance (Stewart, 1984; Bertakis *et al.*, 1991; Roter *et al.*, 1997), less symptom burden (Little *et al.*, 2001) and fewer misunderstandings with unfavourable consequences (Britten *et al.*, 2000).

These findings are consistent with studies in mental health care identifying the predictive validity of patient's

subjective assessments of treatment in relation to outcome. Studies by Priebe & Gruyters (1995a) and Priebe & Bröker (1999) found that schizophrenia patient's satisfaction with their treatment in long-term community care predicted time spent in hospital over the following one to two years. Among patients with depression, satisfaction with treatment predicted self-rated symptoms at discharge (Priebe & Gruyters, 1995b). Similar findings have been reported with an overlapping construct, i.e., the therapeutic relationship. A positive relationship with one's primary clinician is consistently found to predict a better outcome (cf. McCabe & Priebe, *in press*), reflected in indices such as symptomatology, time in hospital and quality of life (Frank & Gunderson, 1990; Ryan *et al.*, 1994; Neale & Rosenheck, 1995; Solomon *et al.*, 1995; Krupnick *et al.*, 1996; Gaston *et al.*, 1998; Svensson & Hansson, 1999; Tattan & Tarrier, 2000). The quality of the therapeutic relationship may be seen as both an outcome criterion in its own right – as services aim at and patients expect positive relationships – and a factor mediating other aspects of outcome. It has been argued that the therapeutic relationship is at the centre of any process in community mental health care as no care can be delivered without establishing and having some kind of relationship in the first place (Priebe, 2000; McGuire *et al.*, 2001).

THE MECCA STUDY

Assessing the patient's perspective on their quality of life, treatment satisfaction and needs for care will be at the heart of a concurrent outcomes management intervention to be tested in the MECCA study. The full study title is "Towards more effective community care of patients with psychotic disorders". The study is a European multi-centre cluster randomised controlled trial, funded by the European Commission being conducted in Granada, Groningen, London, Lund, Mannheim, and Zurich. It involves regularly assessing outcome and feeding the results back to the clinician and patient during their routine meetings. The key worker asks patients about their subjective quality of life, i.e. satisfaction with mental and physical health, accommodation, job situation, leisure activities, friendships, relationship with family/partner, personal safety, and treatment satisfaction, i.e. satisfaction with practical help, psychological help and medication. Ratings are given for each question on a simple 1 to 7 rating scale. Each satisfaction question is followed by a

question as to whether the patient wishes additional or different help in the given area reflecting subjective needs for change. If the patient expresses such a need there should be some information as to what kind of additional or different help is desired. Thus, there are only 11 regular questions, each with the complementary question on wishes for change. The assessment is done by the keyworker and patient together every two months. It is expected that the results will directly feed into the therapeutic dialogue and be discussed by the patient and key worker together. The discussion is intended to address in particular all areas where the patients expressed dissatisfaction or ratings which have changed since the previous assessment. This brief questionnaire is intended to increase feasibility. A more detailed assessment is not considered necessary or useful, since the assessment is just meant to inform the therapeutic dialogue and, if appropriate, initiate a more detailed discussion rather than replacing it.

There might be concern that social desirability will influence these ratings, i.e., that the keyworkers' presence will lead to higher ratings than the presence of an independent researcher. However, firstly, dedicated researchers are not available in routine settings to assess outcome. Secondly, Kaiser & Priebe (1999) found only a limited and inconsistent effect of the interviewer-interviewee relationship on subjective quality of life ratings.

A crucial issue for the validity of the intervention will be that the information assessed is understandable and meaningful for both clinicians and patients. According to Ellwood (1998, p. 1551), outcomes management ideally "consists of a common patient-understood language of health outcomes". Routine outcome measures should be both valid and feasible: a feasible measure should be brief, simple, relevant, acceptable and valuable to its users (Slade *et al.*, 1999). Each of the questions concerning quality of life, treatment satisfaction and needs for care are brief, simple and relevant to users' concerns (cf. Shepherd *et al.*, 1995; Angermeyer *et al.*, 2001; Lelliot *et al.*, 2001).

The nature of keyworking involves clinicians meeting their patients in a variety of settings, including the patient's home, the mental health team office or the hospital. Regularly assessing outcome across these settings must be practicable. Recent advances in information technology mean that paper and pencil measures can be replaced by computerised assessments using mobile technologies. To this end, a software application has been developed so that the assessment can be completed using a mobile hand-held computer.

The application allows the ratings to be entered by the patient and/or keyworker into a database. The results of the assessment are processed by the application and presented to the keyworker and patient there and then. The results are also passed on to other clinicians involved as is appropriate.

The quality of life and satisfaction scores, along with needs for additional care, rated in the current and the previous assessment are presented in a graphical colour display. The feedback highlights (a) change over time (b) dissatisfaction with life domains and aspects of treatment and (c) needs for additional or different input. This may prompt explicit discussion about the reasons for any changes and the action to be taken. Information about ratings over time and how they change according to a person's circumstances can facilitate a discussion about expectations and progress, or lack of progress, in treatment. The mechanism of action might be fine-tuning or increasing the number of appropriate treatment decisions. As a result of the discussion, the clinician and patient might decide on practical support to change a person's objective circumstances (e.g. housing) or a more psychological approach to change a person's subjective view of their life situation and treatment. In the latter case the clinician might apply elements of cognitive therapy depending on his or her qualification and training. The intervention might also affect the therapeutic relationship and – because of the necessary focus of the dialogue on patients' ratings and views – foster a partnership model of care as opposed to a more paternalistic relationship. The intervention is meant to be a clinical one and not just a component of quality management.

The MECCA study is a cluster randomised controlled trial comparing the new intervention with standard community mental health care as practised in the given centre. Inclusion criteria for key workers are a professional qualification in mental health and a minimum of one-year professional experience in an outpatient setting. Key workers are randomised to either the experimental or the control condition. The cluster randomisation prevents transfer effects from the intervention to the control group in patients from the same key worker. Out of the caseload of each key worker, patients are randomly selected who fulfil the following criteria: living in the community and treated as outpatients by community mental health teams; a history of at least 3 months of continuous care in the current service; fulfilling DSM-IV criteria for 295, i.e. schizophrenia and other psychotic disorders; aged between 18 and 65 years of age; having at least one

contact with their key worker every two months; capable of giving informed consent; and sufficient knowledge of the language of the host country. Exclusion criteria are: living in 24 hour supported hostel type of accommodation; severe physical handicap, organic psychiatric illness or primary substance abuse (however, dual diagnosis as such is not an exclusion criterion); expectation to discharge the patient from the service within the next 12 months. At baseline and 12 month follow up, all outcome criteria are assessed by an independent researcher using established instruments. Treatment costs are recorded on an ongoing basis.

The trial tests the hypothesis that the intervention will – over a 12 month period – lead to better outcome in subjective quality of life, i.e. the main outcome criterion, and also in treatment satisfaction, needs, the quality of the therapeutic relationship, and patients' empowerment. Changes in psychopathology are not hypothesised to differ between the two groups. Concerning treatment costs in the two groups, the study is exploratory. One might expect higher as well as lower costs in the experimental group. Higher costs could occur due to additional input as a result of patients' wishes and joint decisions. The intervention could be associated with lower costs when it helps to prevent costly hospital admissions or emergency interventions. If the one year outcome will indeed be more favourable in the intervention group, we further hypothesise that the positive outcome will be mediated through more appropriate therapeutic interventions as decided by the clinician and patient or a better therapeutic relationship in line with a partnership model of care or both.

OUTLOOK

It will take some time before the MECCA study will yield final results. A positive outcome in line with the hypothesis would provide essential information on how to implement outcome measurement and outcome management in routine care. It would also help to persuade clinicians – and patients – to engage with outcome management and to regard regular assessments as useful, and not just another administrative burden. Beyond that, however, we hope that the study will reveal new insights into processes in community mental health care. The trial follows the same study protocol in six different countries with different traditions, health care systems and therapeutic cultures. The experiences, some of which will be captured by qualitative assessments methods, will hopefully tell us more about how

community mental health care can be made more effective and more therapeutic. The trial does not just test a new treatment component that may or may not be applied in an individual case, but a mechanism to improve best practice within the still developing field of community mental health care.

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