

DEVELOPING OUTCOME MEASURES FOR SERIOUS MENTAL ILLNESS; USING EARLY INTERVENTION AS AN EXAMPLE

Mark Agius^{1,2}, Samir Shah², Roshelle Ramkisson², Suzanne Murphy³ & Rashid Zaman^{1,2}

¹Bedfordshire Centre for Mental Health Research in Association with the University of Cambridge,

Department of Psychiatry, University of Cambridge, UK

²Bedfordshire and Luton Partnership Trust, UK

³University of Luton, UK

SUMMARY

Developing useful outcome measures for the treatment of serious mental illness remains an important challenge for the newly re-configured Mental Health Services in the United Kingdom, towards the latter part of the ten year period covered by the National Service Framework.

The present authors have taken the opportunity to develop a method for measuring outcomes in psychotic illness while developing a service for Early Intervention in Psychosis. The results are mentioned shown, but will be discussed in detail elsewhere. This article will focus on the development of the method for outcome measurement itself. In particular, we shall argue for the need to use measurements which demonstrate functional improvement and improvement in quality of life. We shall show that, in order to measure outcomes, it is necessary to systematically record information from the first presentation of the case, so as later to be able to demonstrate what change has been accomplished. We shall also demonstrate that this activity is part of a necessary ongoing audit activity for services, but that, since there is no certain knowledge of what outcomes could have been expected prior to the implementation of new service developments, it is necessary to include a control group recruited from previous services, in order to establish meaningful benchmarks or norms to which the outcomes of a new service should be compared and judged. We argue that this methodology, despite the use of such a control group constitutes audit rather than research, but should be still amenable to statistical analysis. In order to be meaningful, and since serious mental illness may well be chronic, it is necessary that outcome measures should be carried out regularly, after specified periods of time.

We also argue for the use of appropriate rating scales, which measure both the number and the intensity of symptoms and for computer based notes in order to facilitate regular audit.

Key words: *serious mental illness - early intervention in psychosis – audit - outcome measurement*

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This paper is a re-elaboration of a paper given by Dr Mark Agius at the ISPS Slovenia Meeting in Bled, September 2006. The original paper as it was presented was eventually published as Three year outcomes of an Early Intervention For Psychosis Service as compared with treatment as usual for first psychotic episodes in a standard Community Mental Health Team-Final Results. Psychiatria Danubina 2007; 19:130-138, and so cannot be published again, however, this re-elaboration was prepared at the request of the Department of Health in England in order to demonstrate, using exactly the same clinical material as first presented in Bled, how functional outcomes in psychotic illness can be measured, an issue certainly commented on in the original presentation and repeatedly presented by Dr Agius at conferences organised by the Department of Health; Dr Agius thanks ISPS Slovenia for being the first group to hear and comment on these results and this methodology.

Introduction

Several years after the introduction of the National Service Framework for Mental Health there is still great difficulty in assessing how individual patients with serious mental illness are benefiting from the new structures which have been put in place in the community in order to provide treatment for patients. Assertive outreach teams, Crisis Intervention Teams and Early Intervention Teams for Psychosis have all been put, or are being put, in place, but it is generally not at present possible to routinely assess the effectiveness of such teams, since there are no generally agreed means of assessing the outcome of such treatment, nor any clear benchmarks against which such outcomes can be assessed. It is not simply a question of 'delivering' services which the NSF requires to be established and commissioned, but it is necessary to in-build into these services methods for showing that they are benefiting patient care to an extent greater than those services which they have replaced, and then demonstrating that they continue to provide an optimal service. These measures need to be easily available to all members of the team, as an important method of raising staff morale, and to psychiatrists and team managers, and not only to Trust Managers or Functionaries of the Department of Health, since such measures are key to justifying the existence and effectiveness of the teams, including their cost effectiveness.

Recently some of us have defined 'Serious Mental Illness' as follows:

'Patients who suffer from 'Serious Mental Illness', include all patients who suffer from such illnesses as Schizophrenia, Schizo-affective Disorder, Delusional Disorder, Bipolar Disorder (Manic Depression), Psychotic Depression, or Severe Depressive Episodes, Substance induced Psychosis, Organic Psychosis, and First or Brief Psychotic Episodes. A synonym for these illnesses is 'Psychotic Illness'. Since mental illnesses may vary in severity, even more common mental health problems, if they are judged to be severe by the treating clinician, may be treated using the same principles of health care as will be described for the patients whose illness is defined as severe in the definition above. Furthermore, illnesses which present with a high element of risk or severe disability to the patient or others would also be described as severe, so that depression with high risk of suicide, and some eating disorders (severe anorexia nervosa) and some patients with severe obsessive compulsive disorder could be defined as having serious mental illness' (Agius 2005).

We have recently been involved in developing a new service for Early Intervention In Psychosis in Luton, Bedfordshire.

Because of the relative novelty of this service, we felt that it was necessary to develop a system for measuring the outcomes of this service, and having this system in-built into the processes of the new team.

We faced the difficulty that there were no clear evidence based guidelines in the literature as to which outcomes to measure, what changes we were to expect in the outcomes of care as opposed to treatment as usual, and no clear benchmarks to measure such changes.

It did appear, from reports from the Leo Service in Lambeth, that there should be a number of changes in the quality of life of the patients, (Craig 2004), and this view was also supported by the aspirations of such guidelines as the IRIS guidelines (North Birmingham Trust 1999) but we were uncertain as to the degree of change in outcome that we were to expect in our patients compared with what we had been used to in working with the Community Mental Health Teams. Therefore, we set about identifying Standards which could be used for measuring both process and outcome.

Our pilot early intervention service was set up in 2001 (Agius 2007). We based our entry criteria for choosing patients for admission to the service on those of McGorry's EPPIC service in Melbourne. These have become the standard criteria for all Early Intervention in Psychosis services (Edwards 2002) and are:

- All clients aged 14-35 and will have psychosis of any diagnostic category.
- All clients will receive intervention from the service for 3 years.
- Clients will not be engaged with any other service.
- Clients who have only received anti-psychotic medication for less than a month are included.
- Learning disabled and brain injury clients are excluded.

Assessment of the patient for entry into the service was carried out by the Psychiatrist with input from at least one member of staff, and then discussed with the whole team. Each patient was assigned a care co-ordinator from among the nurses and social workers on the staff. The care co-ordinator would work with the Psychiatrist to devise the care plan for the client, and would ensure its implementation for the duration of time that the patient was in the service. Psychoeducation

and Family interventions, and the identification of early signs of relapse, as well as some Cognitive Behavioural work, was also delivered by the care-coordinator.

There was a staff of psychologists who would deliver complex Cognitive Behavioural Interventions and Family Interventions and carry out neuro-cognitive testing where necessary. Medication was managed by the attached two doctors.

At the end of three years, it was considered necessary to develop some standards which would ensure that an appropriate package of care had been delivered with good results. These standards have been audited at regular intervals (Agius 2004).

The Outcome standards for our service are as follows:

1. Client's mental state will improve (By BPRS, PANSS, or KGV).
2. Client's social needs (i.e. housing, support, food etc) will be met.
3. Post Psychotic Depression will be addressed.
4. Clients will return rapidly to employment or education.
5. Clients will continue taking medication throughout the three years of the intervention.
6. Medication use will be optimised, including due care of side effects and early use of clozapine if appropriate.
7. Relapse rate will be reduced.
8. Suicide rate will be reduced.
9. Use of the mental health act will be reduced.
10. Clients and families will have an increased understanding of psychosis and how to prevent it.
11. Families and carers will receive the support they need and high EE will be reduced.
12. Illicit drug use is reduced.

The import of the last three standards (10, 11, 12.) is that clients and their families will have learnt enough about the illness to be able to manage it themselves by the time that they will have left the service- this would be analogous to education for patients with other chronic diseases such as diabetes, who nowadays receive training in how to manage their diabetes from diabetes training centres.

Methods (Theory of Measuring Outcomes)

Having developed the standards or outcome measures above, we considered ways in which they could be measured. Our considerations have led us

to a number of rules regarding the measurement of outcomes, which are listed below:

1. Outcome measures are only valid if they have been mutually agreed with the patients, as it is the patients who can best define what recovery means

We needed a set of outcome criteria which we could monitor for each patient who was to be discharged, so that we could see that the service was achieving what it had set out to do. We also needed a set of measures with which we could measure that we were achieving our goals. However, we also needed to know that the client and ourselves were agreed as to what we wanted to achieve.

So we spend a lot of time explaining to each client what we could do for him, and coming to a series of individualised agreed goals for each client. As a consequence, we found that we needed to accept that if we do help the client to achieve what we have *jointly agreed*, then this is a success, and leads to client satisfaction, even if those agreed objectives do not always meet what we might consider the ideal outcome from the point of view of medical opinion or public health or indeed our own personal objectives.

2. In order to measure outcomes, the first important measurement is the baseline measurement, which must take place as soon as the patient presents to the service, this will enable proper assessment of how the patient's condition will improve in the future.

To be able to measure outcomes, we need to first measure how patients were when they first joined the service, i.e. have a baseline, so the first measurement needs to be at the first assessment, when the patient is most unwell. This was often seen as onerous by our staff, who would feel that carrying out formal assessments using rating scales at the first assessment might be unnecessarily intrusive, but against this must be balanced that, if information is not gathered, then it cannot be used to assess future progress.

3. Methods of information gathering need to be standardised, so that later, comparisons can be made. This is achieved by the use of standard rating scales

We used a set of instruments, which we used at regular intervals during our work with the client. Ideally, we tended to use the instruments once every 6 months, or when we consider it necessary. Many of these instruments are rated by the patients themselves, and so are easy to administer. One key advantage of rating scales is that they enable the

intensity of symptoms, as well as their presence, to be monitored, so it is possible to observe symptom improvement over time.

Instruments used in Luton EI Team:

- PANSS (Positive and Negative symptom Scale);
- Beck Depression Inventory (self administered);
- Beck Anxiety inventory (self administered);
- Lunsers (for side effects- self administered);
- HoNOS (Health of the Nation Outcome scale);
- CANSAS (Camberwell Assessment of need short version);
- EUROQOL (for quality of life- self administered);
- Trust CPA document for Risk Assessment.

4. Outcome Measurement must be time limited

To be able to measure outcomes in ongoing conditions, we need to establish what the time-span of the measurement shall be, i.e. what have we achieved in x years. In this way, the outcomes may be compared to those of other patients by the same time. It is easy to achieve this in Early Intervention Services, since the time period during which they work with patients is three years. Thus all outcomes should be measured over a three year period. With other services, such as Assertive Outreach or Community Mental Health Teams, it will be necessary to fix a time limit, so that 'two, or three, year outcomes may be audited in an assertive outreach team'. Since it is possible for patients' mental state or social situation may deteriorate over time, this 'rule' is necessary so that like is compared with like.

5. As well as measuring outcomes, in order to properly manage a service, it is also necessary to audit process measures

These may be issues like:

- What medication and dosage are we using?
- What psychological interventions have been applied?
- What side effects are occurring?
- What is the change in mental state?

This latter issue the measure of process back to the measure of outcome. One other important issue that arises with regard to process is that it is possible that throughout the period being audited, more than one team may look after the patient, thus, for example, a home treatment team or an in-patient unit may have to look after a patient of the Early Intervention Service. It is important to

develop audit to show that there is consistency of care no matter which team is involved.

6. To be able to measure outcomes in ongoing conditions, we need to establish what the expected outcomes are likely to be

It is important that such expected outcomes are not based on theoretical aspirations, but on what outcomes have been expected up till now with similar groups of patients in the real world under local conditions.

Often, with a new service, no such realistic outcomes are known, so for this audit, we need a comparator group to act as a benchmark. The comparator group could be a similar group of patients who have either been treated in the same location previously for the same period of time, or one treated simultaneously in a neighbouring location where no 'new service' exists for the same condition, so that such a group represents 'treatment as usual'. We see such a comparator group as providing a benchmark for audit purposes under these circumstances, rather than a 'research project'. This is because we see this process as essential to the development of new services, and therefore part of standard care. The two groups should be able to be compared using standard statistical methods.

7. In order to facilitate the Audit process, we strongly recommend that in each team a computer program be set up, to which all members of the team have access, which will hold basic clinical data on patients. Notes, including all rating scales should also be kept.

In the Early Intervention Service in Luton, we used an ACCESS based database to record basic data on patients, medication, and the data derived from several rating scales. This enabled us to easily publish yearly audits on the progress of our patients.

8. At the end of the Audit Period, a final set of evaluations is carried out. In order to assess functional outcome, we have found that the most relevant data is not the mental state of the patient per se, (patients may function despite still having positive symptoms of psychotic illness), but a series of psychosocial observations which include the following outcome standards

- Client's social needs (i.e. housing, support, food etc) will be met.
- Post Psychotic Depression will be addressed.
- Clients will return rapidly to employment or education.

- Clients will continue taking medication throughout the three years of the intervention.
- Medication use will be optimised, including due care of side effects and early use of clozapine if appropriate.
- Relapse rate will be reduced.
- Suicide rate will be reduced.
- Use of Client’s mental state will improve (By BPRS, PANSS, or KGV).
- The mental health act will be reduced.
- Clients and families will have an increased understanding of psychosis and how to prevent it.
- Families and carers will receive the support

they need and high EE will be reduced.

- Illicit drug use is reduced.

The import of the last three standards (10, 11, 12) is that clients and their families will have learnt enough about the illness to be able to manage it themselves by the time that they will have left the service- this would be analogous to education for patients with other chronic diseases such as diabetes, who nowadays receive training in how to manage their diabetes from diabetes training centres.

When the patients are discharged at the end of three years, we record our outcomes in a specially designed chart which is based on our outcome measures.

OUTCOME CRITERIA FOR ASSERTIVE CASE MANAGEMENT / EARLY INTERVENTION CLINICS

Client’s mental state will improve (by BPRS, PANSS or KGV)	
Client’s social needs (i.e. housing, support, food, etc) will be met	
Post Psychotic Depression will be addressed	
Clients will return rapidly to employment or education	
Clients will continue taking medication throughout the three years of the intervention	
Medication use will be optimised, including due care of side effects and early use of clozapine if appropriate	
Relapse rate will be reduced	
Suicide rate will be reduced	
Use of the metal health act will be reduced	
Clients and families will have an increased understanding of psychosis and how to prevent it	
Families and carers will receive the support they need and high EE will be reduced	
Illicit drug use is reduced	

Figure 1. Chart used to measure outcomes for individual patients in the Luton Early Intervention Service

Results

We have used this methodology in order to compare our outcome measures for the first 62 patients who we have treated to the same outcome measures for 62 patients treated by a neighbouring CMHT. Detailed Statistical Analysis of the results is to be published elsewhere, but the following is a table which summarises the results:

CMHT Patients	62	CMHT Patients Average age (in years)	25.40
EI Patients	62	EI Patients Average Age	24.61
CMHT Patients Male	46	CMHT Patients Mean Age	25.40
EI Patients Male	47	EI Patients Mean Age	24.61
CMHT Patients Female	16	CMHT Patients Median Age	28.50
EI Patients Female	15	EI Patients median Age	25
		CMHT Patients Modal Age	23
		EI Patients Modal Age	25
		CMHT Patients Average DUP (in months)	23.02
		EI Patients Average DUP	23.19
		CMHT Patients Mean DUP	23.02
		EI Patients Mean DUP	23.19
		CMHT Patients Median DUP	10
		EI Patients Median DUP	24

CMHT Patients Modal DUP	0.25	CMHT Patient Psycho-education recorded in notes	12
EI Patients Modal DUP	12	EI Patient Psycho-education recorded in notes	57
CMHT Patients Caucasian	43	CMHT Family Psycho-education recorded in notes	7
EI Patients Caucasian	25	EI Family Psycho-education recorded in notes	32
CMHT Patients African/Caribbean	8	CMHT Family Work recorded in notes	4
EI Patients African/Caribbean	10	EI Family Work recorded in notes	25
CMHT Patients South Asian	11	CMHT Pts who originally used illicit drugs	23
EI Patients South Asian	25	EI Pts who originally used drugs	35
CMHT Patients Chinese	0	CMHT Pts who-used drugs in 3 yr	17
EI Patients Chinese	2	EI Pts who used-drugs in 3 yrs	12
CMHT Unemployed	34	CMHT Pts who Stopped drugs	6
EI Unemployed	21	EI Pts who stopped drugs	23
CMHT on Jobs Market	4	CMHT Pt who know early signs (done systematically)	8
EI on Jobs Market	7	EI Pts who know early signs (done systematically)	46
CMHT Part time Work	5	CMHT Pts used MH ACT	41
EI Part time Work	4	EI Pts used MH ACT	24
CMHT Full time work	16	CMHT total use MH act	43
EI full time work	17	EI total use MH act	26
CMHT College/vocational courses	6	CMHT total admissions	137
EI College/ vocational courses	8	EI total admissions	77
CMHT at University	3	CMHT total relapses	92
EI at university	12	EI total relapses	129
CMHT Lives with Family	31	CMHT relapses treated outside hospital	16
EI lives with Family	46	EI relapses treated outside hospital	63
CMHT Lives Alone	23	CMHT Post psychotic depression treated with antidepressants	29
EI lives Alone	16	EI Post psychotic depression treated with antidepressants	15
CMHT sheltered accommodation	7	CMHT Post psychotic depression treated with CBT	4
EI sheltered accommodation	0	EI Post psychotic depression treated with CBT	1
CMHT in Prison	2	CMHT poor compliance with medication	22
EI in prison	0	EI poor compliance with medication	8
CMHT Atypicals oral	14	CMHT Full compliance with medication	22
EI Atypicals oral	34	EI full compliance with medication	41
CMHT typicals oral	8	CMHT partial Compliance with Medication	17
EI Typicals oral	0	EI partial compliance with medication	2
CMHT Clozapine	2	CMHT medication considered unnecessary	1
EI Clozapine	3	EI medication considered unnecessary	11
CMHT Depots Typical	24	CMHT complete remission	33
EI Depots Typical	3	EI Complete remission	40
CMHT Risperidone Consta	2		
EI Risperidone Consta	3		
CMHT Poly-pharmacy	8		
EI Poly-pharmacy	1		
CMHT Total Atypicals	18		
EI Total Atypicals	40		
CMHT Nil Medication	4		
EI nil Medication	17		
CMHT Patients suicidal attempts	8		
EI Patients suicidal attempts	4		

CMHT partial remission	13
EI partial remission	14
CMHT ongoing full psychosis	2
EI ongoing full psychosis	6
CMHT relapsing	10
EI relapsing	0
CMHT Negative symptoms	11
EI Negative symptoms	2
CMHT Positive symptoms	11
EI Positive symptoms	15

It appears that in many respects, outcomes in the Early Intervention Service were better in many respects than those of the neighbouring CMHTs.

Most of these results were statistically significant by χ^2 test.

In particular, more of our clients appear to return to Work and Education $p=0.09$, that is near significance.

More of our clients continue to comply with medication for three years, compared to the CMHT group $p=0.015$. This is statistically significant. This is likely to be because we have agreed joint goals with our patients. The Early Intervention Clients appear better able to identify relapse early and have it treated in the community. This is also statistically significant at value $p<0.0001$. They and their families are more likely to continue living together, again statistically significant at value, $p=0.007$, and both they and their families have received better psycho-education about their condition. The Early Intervention Clients are less likely to be admitted to hospital significant at value $p<0.0001$, and the Mental Health Act is less likely to be used with the Early Intervention Clients, again statistically significant, at value $p=0.004$. The Early Intervention Clients are less likely by three years to have been put on Depot and Typical Anti-psychotic Medication, and more likely to be taking Atypical Anti-psychotic Medication. This is also significant at value $p<0.001$. They are less likely to suffer from Negative Symptoms of Psychosis, but some continue to function despite the continuing presence of positive psychotic symptoms. Finally, we found that we were able, through our assertive approach and offering of psycho-education to show that we were able to persuade clients who entered the service using illicit drugs to stop using illicit drugs. This was

significant at value $p=0.003$. In this we were more successful than the CMHT (Agius 2007).

Conclusion

In this article, we have only briefly discussed the results of our service, as we have only used them as an illustration of what can be done with regards to outcome measurement within a developing mental health service.

We believe that the use of the above described methodology for measuring outcomes has greatly contributed to both the success of our team and the measurement of this success. If we had not measured what we were doing constantly, we would not have been able to intervene appropriately to ensure optimal treatment to our patients or to adjust our treatment policies so that they had optimal effect.

We recommend that all mental health teams, both in the community and in wards should use a similar methodology to ensure optimal outcome for their patients.

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Correspondence:

Mark Agius MD, Early Intervention Service
Charter House Alma Street Luton LU12PJ, UK
E-mail: ma393@cam.ac.uk