Title: A clinical database for measuring outcomes in a low-secure service: A feasibility study


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Development of a Clinical Database for a Low Secure Service: A Feasibility Study

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Development of a Clinical Database for a Low Secure Service: A Feasibility Study

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Keywords: low secure, case register, clinical database, outcome measures

Structured Abstract

Purpose - Here we present the arguments for sustaining a clinical database, the mechanisms and resources necessary for sustainment, examine the data that can be captured and discuss what this means for practice implications and service development. We aim to demonstrate how a clinical database can provide us with information on three key areas: what patients are like before admission, what we do with them whilst they are in hospital and what happens to them when they are discharged.

Design/methodology/approach - This is conducted in the form of a feasibility study charting the development and implementation of an inpatient clinical database for a low secure inpatient service.

Findings - The feasibility of creating and maintaining a clinical database in a low secure service has been assessed and we have found that they are an invaluable source of data that all mental health services should strive to develop. They will enable services to track their own outcome measures and tailor their service and interventions according to the needs of service users.

Research limitations/implications - This is a study of the experience of one service. Ideally this research should be expanded with nationwide clinical database development.
Practical implications - This paper includes implications for the implementation of a clinical database, the resources needed for the running of this and the development of standardised outcome measures for mental health services.

Originality/value - This is potentially the first clinical database of its kind for a low secure unit and some of the first research into the feasibility of a database for the low secure population.

Implications for Practice
- All healthcare providers should endeavour to implement a clinical database for their service, particularly those providing secure mental health services for patients.
- Healthcare providers also need to ensure that appropriate patient data is being recorded accurately and consistently to enable straightforward data collection and analysis for outcome measures/service evaluation.
- Provisions should be made for a research assistant (or equivalent) to spend dedicated time on the upkeep and day-to-day running of the clinical database.
- Through the development of clinical databases throughout secure mental health services, outcome measures will become better standardised making service evaluation more meaningful and patient experience and quality of life will improve.

Introduction
Producing positive healthcare outcomes and improving the lives of patients are top priorities for both healthcare professionals and providers alike. Because of this, it can be argued that any mechanism that can be used to measure improvements to patient well-being should be utilised effectively. This is where the value of a comprehensive, centralised clinical database can truly be felt. Firstly it is important to define what is meant by a clinical database. According to Pryor et al (1985), “A clinical database is created when well-defined, discrete
Recent government initiatives have provided the impetus for developing clinical databases. For instance, the Department of Health has been examining the feasibility of developing a national, patient-based system for the collection of clinical data on patients in specialist mental health services for some time (Glover, 2000). Similarly the Council of the European Union has previously requested for member states to ensure the collection of good quality data on mental health and to develop and implement a Commission-led mental health monitoring system (Morris-Yates & Andrews, 1997). More recently, mental health services have come under increasing pressure from government initiatives to produce positive clinical outcomes and provide a high-quality treatment experience for all patients, including those residing in secure forensic mental health services (NHS Executive, 1998). One particular national driver in terms of outcome measures is the Commissioning for Quality and Innovation (CQUIN) framework, introduced by the Department of Health in 2009/10. This is a national framework for locally agreed quality improvement schemes throughout the NHS, enabling commissioners to reward excellence by linking a percentage of English healthcare providers’ income to the achievement of ambitious quality improvement goals (Department of Health, 2010). The framework reflects current government priorities with a particular focus on excellence and improvement. Achieving the goals set within the CQUIN framework is important for all services, both financially and for improvement in the quality of patient care.

It can be argued that a clinical database can make adherence to quality standards, such as those defined by government initiatives, a little more straightforward as the majority of data required can be systematically and consistently collected and stored in one central database for analysis when necessary. Such a system also has the potential to achieve greater levels of detail, accuracy and completeness that will help to satisfy the demand for proven treatment
outcomes and justification of expenditure (Black, 1998). Most importantly, outcome measures in particular are intended to identify the most effective interventions for patients and enable services to implement these successfully. Now is an ideal time to begin the development of such a database and address both the benefits, difficulties and feasibility of such a project.

However, use of outcome measures in forensic mental health is fraught with difficulties. For instance, a severe lack of consistency has often been found in the outcome measures used in forensic mental health research, meaning that evaluating treatment outcomes can be problematic (Chambers et al, 2009). Further, Fitzpatrick et al (2010) found that domains beyond recidivism and mental health were severely under-represented in outcome measures research. The creation of a clinical database for forensic mental health is an excellent starting point from which outcome measures can be evaluated and potentially standardised. This would enable increasingly accurate comparisons of evaluative research to be conducted, resulting in a clearer picture of the most effective interventions for forensic patients (Chambers et al, 2009). It would also enable outcome measures from a wide variety of scales and domains to be evaluated, including risk assessments, occupational therapy tools and patient quality of life measures, which have been used in this study.

Further difficulties may be encountered in relation to the practicality of data collection. For instance, in a 6-month trial of data collection for a mental health database, it was found that clinic attendance was recorded as 10-20% lower in data extracted from records than in recent Department of Health returns for two Trusts (Glover, 2000). This deficit was found to be a direct result of paper records being used in some instances instead of electronic. In this way, the data inputted is somewhat limited by what data is already routinely collected in local services, how it is stored and what data collection is prioritised. Alongside difficulties in the practicality of data collection, there can also be potential issues with the completeness and accuracy of records. Work done to build previous clinical databases found that some
information was predictably incomplete and that there was sometimes a time-delay in requests for information being fulfilled. Staff did not always routinely and periodically update records when requested or when protocol stated (Glover, 2000; Kustner et al, 2002). There needs to be closely followed protocols and procedures in place for the completion of documents, which clinicians and medical staff alike are committed to completing accurately and consistently (Morris-Yates & Andrews 1997; Higgins & Howard, 2005). However, issues such as these can be identified and addressed using processes such as clinical audit.

Moving on from these data related issues, two factors in need of careful consideration when developing a clinical database are two that are intrinsically linked; staff training and costs. To set up a clinical database requires an understanding of the nature of the clinical work concerned, the organisational structure of the service, knowledge of the current data collected, why it is required and the technical and logistical arrangements for data collection (Glover, 2000). If staff with most or all of these skills are not already employed, new staff may have to be recruited or additional staff training generated to ensure that all staff involved are looking at and recording the correct data consistently (Higgins & Howard, 2005). As the complexity of an information system increases so does the cost, however at the same time so does the benefit to the service as a whole.

Because of this, conducting a feasibility study is a crucial element in the development of a clinical database to help estimate what resources will be needed to maintain the complete system and to highlight any flaws in the original design. This is the very reason we decided to conduct this particular study; to assess the feasibility and practicalities of building and running a fully operational clinical database for an expanding low secure forensic mental health service.

**Method**
Participants
This feasibility study was carried out in a low secure hospital. The sample of participants used consisted of 10 patients from the hospital’s main admissions ward. All participants were mentally disordered offenders detained under the Mental Health Act. They were all male and aged between 18-65 years old.

Tools Used
A variety of patient information and assessment tools were used to gather data on our sample of participants as follows.

- **Sample Characteristics** – Referral source, date of referral, age, gender, ethnicity, nationality, marital status, legal status.
- **Admission Data** – Admission date, admission ward, transfers between wards, discharge date, discharge destination.
- **Offending History** – Index offence, offence type, total number of violent offences across lifetime, total number of non-violent offences across lifetime, age at first offence.
- **Diagnosis** – Primary, secondary and co-morbidity diagnoses using ICD-10 categories (World Health Organisation, 1992).
- **HoNOS-Secure (Royal College of Psychiatrists, 2007)** – The Health of the Nation Outcome Scales for users of secure and forensic services comprises amended versions of the original 12 HoNOS items (items 1-12) and an additional seven-item security scale (items 13-19). This tracks clinical outcome, as well as ongoing security needs.
- **HCR-20 (Webster et al, 1997)** – The HCR-20 is a risk assessment tool for predicting the risk of future violent behaviour in criminal and psychiatric populations. It consists of 20 items relating to historical information (10 items), clinical information (5 items) and
risk management information (5 items) designed to capture relevant past, present and future considerations.

- **MOHOST** (Parkinson, Forsyth, & Kielhofner, 2005) – The Model of Human Occupation Screening Tool (MOHOST) is an assessment tool designed to give an overview of the client’s occupational functioning broken down into 6 domains; Motivation for Occupation, Pattern of Occupation, Communication and Interaction Skills, Process Skills, Motor Skills and Environment. The rating scale criteria are as follows: F=Facilitates occupational participation, A=Allows occupational participation, I=Inhibits occupational participation and R= Restricts occupational participation. For the purpose of the clinical database and future analysis, the lettered scores have also been given a numeric value (F=3, A=2, I=1, R=0).

- **WHOQOL-BREF** (World Health Organisation, 2004) – This is a comprehensive survey to assess the patient’s view of their current quality of life. This includes two core questions (“How would you rate your quality of life?” and “How satisfied are you with your health?”) and four domains (Physical Health, Psychological, Social Relationships and Environment).

- **Therapeutic Activity** – Data on the number of hours in which patients participated in therapeutic activities (of any sort) was collected from patients’ weekly planners. Therapeutic activity incorporates a number of different patient activities including skill development groups, psychological interventions, work experience opportunities, activities of daily living, structured leisure time and unstructured free time. Data was collected as part of the CQUIN commissioning framework.

- **Incident Reporting** – Data on incidents committed by our sample population during their current admission was collected from the Risk Department and categorised using IR1 Form options.

- **Follow-Up Data** – Date of re-offending, re-offending type, date of re-admission, admission setting, date of death, cause of death.
Data Collection

Data was collected using a proforma designed for the purpose of this study. Data was gathered by the first author from patient clinical files, an electronic recording system (RiO) and in some cases requested from the relevant staff. For example, MOHOST assessments were obtained from members of the Occupational Therapy team, HCR-20 scores from Psychology, Incident Records from the Risk Department, ICD-10 diagnoses from Responsible Clinicians and offending histories from Police National Computer (PNC) reports/psychiatric reports/risk assessments. A quality of life survey (WHOQOL-BREF) was distributed via keyworkers and activity nurses to all patients, however only around half of patients on the admission ward wished to complete them at the time of the study. Data on therapeutic activity was gathered from the patients’ weekly planners kept on the ward.

Analytic Strategy

Data was analysed using the Statistical Package for Social Sciences (SPSS) version 19.0. Figures presented in this study are largely descriptive in nature due to this being an initial feasibility study.

Prior to carrying out the data collection for this study, approval was sought from the necessary authorities within the Trust to enable us to collect and analyse the relevant information. It is worth noting here that the clinical database is aimed at providing data for service evaluation and management statistics on patients rather than research. Therefore, ethical approval to populate the database was not required. In order to protect confidentiality an identity code was assigned to each patient so that no names would appear on the database. The list of names and corresponding identity codes are stored separately but can be accessed by specific individuals, including the authors, in the hospital.
Results

Sample Characteristics

50% of patients were referred from prison, 40% from community forensic services and 10% from other sources such as generic mental health services. The average age of participants was 27, with the youngest patient being 20 and the eldest 42 years. 70% of the patients were white, 10% were black and 20% were of other ethnic origin (Somali and Asian). 90% of participants were British, with 10% being of another nationality. 80% of participants were single and had never been married and the remaining 20% were divorced. 50% of the patients were on a Section 37 (of whom 2 were subject to a Section 41 restriction order), with 30% on a Section 48/49 and 20% on a Section 3. During the time that the feasibility study was carried out, 50% of participants were transferred from the admission ward to the rehabilitation ward within the same hospital.

Diagnosis

The most common primary diagnosis among patients was schizophrenia, with 80% being diagnosed with this disorder. The remaining 20% of patients had a primary diagnosis of schizoaffective disorder. Substance misuse was also highly prevalent as a comorbidity, with 80% of patients diagnosed with illicit drug misuse/dependence and 20% with comorbid alcohol misuse/dependence. 10% of patients had a comorbid organic mental disorder (in this instance that accounted for 1 patient). Personality issues were also relatively prevalent among these patients, with 50% diagnosed with a comorbid personality disorder (breakdown of 30% antisocial, 10% borderline, 10% paranoid).

Offending History
The majority of patients in this study had a violent index offence (60%). The mean number of violent offences committed by these patients across their life time was 3 (range 1-10), compared to a mean total of 16 for non-violent offences across their life time (range 0-64).

**Therapeutic Activity**

When data on therapeutic activity hours was averaged out across inpatient stays for our sample, we found that on average patients were offered 39 hours of structured activity per week. Patients then went on to accept and engage in an average of 27 hours of structured activity per week (excluding community leave). These are excellent results and come well above the CQUIN framework standard of offering patients a minimum of 25 hours of structured activity per week.

**Inpatient Incidents**

The most prevalent incident type reported was violence to staff with 19 incidents, closely followed by violence to patients with 10 incidents. Disruptive behaviour was the next most common incident type with 6 incidents reported. The least common incident types included clinical procedure, data protection, infection control, occupational ill health and vehicle accident.

Table 1 about here

**Discussion**

In short, a clinical database helps answer three key questions about patients admitted to hospital. Firstly, what do they look like when they are admitted? Data from our feasibility study provides a snapshot of the patient population on a low secure ward during August – September 2011. Our data has shown that our patient population were mostly white, British and single with the majority referred to us on a Section 37 or Section 48/49. Most patients
were referred from prison or community forensic services with a violent index offence and
received a primary diagnosis of schizophrenia. All patients also had some form of comorbid
substance misuse.

The second question a clinical database can help us to answer is what do we do with patients
whilst they are in hospital (in terms of therapeutic intervention)? Our study shows that on
average our patient sample were offered 39 hours of therapeutic activity a week and engaged
in an average of 27 hours, which is above the CQUIN framework standard. This involved a
variety of activities including skill development groups, psychological interventions, work
experience opportunities, activities of daily living, structured leisure time and unstructured free
time. Several assessments were also carried out to assess risk, quality of life and
occupational therapy skills. Assessments such as these are important to highlight areas of
need for patients so that correct interventions can be put in place to ensure positive progress
can be made. Such progress was seen in our patient sample as during the period of time that
the feasibility study was carried out 50% of patients were transferred from the main
admissions ward to the rehabilitation ward within the hospital.

Some of the data stored on our clinical database has been used to meet Commissioner-set
CQUIN framework targets that show quality improvement and excellence that are
subsequently rewarded financially (Department of Health, 2010). These targets include length
of stay, changes in HoNOS-secure scores and therapeutic activity hours. Although this
feasibility study simply captures one moment in time, the accumulation of data for all
inpatients during their stay in hospital using the variables we have defined here will enable
services to effectively evaluate progress and clinical outcomes in the future. These are key
areas for monitoring that have been highlighted in the literature as being of great importance
for healthcare providers (Glover, 2000; Morris-Yates & Andrews, 1997).
The final question we will be able to answer is what happens to patients when they leave hospital? Using the clinical database we can track changes in the short-term such as risk, length of stay and clinical progress as well as long-term outcomes of re-offending, re-hospitalisation and mortality. Re-hospitalisation and mortality rates can potentially be tracked using a Medical Research Information Service tracer system for discharged patients to gather data on mortality and admissions and discharges from NHS facilities. However, using this system will come at a financial cost to the service. Re-offending can be tracked using police records, but setting up an effective mechanism for this could be problematic. Being able to track patient progress using these long-term outcome measures will prove to be invaluable for service evaluation and improvement in the quality of services and treatments provided for patients. These are key areas that have been promoted as a main focus for the NHS in recent years (NHS Executive, 1998; Darzi, 2008).

The main difficulties of building a clinical database were in the data collection, particularly with assessments such as the MOHOST (Parkinson, Forsyth, & Kielhofner, 2005) and HCR-20 (Webster et al, 1997) which were not always complete for all patients. However, as this study was done on the main admission ward with a particularly high turn-over of patients compared with other wards in the hospital, this is fairly understandable. Finding complete and accurate offending histories was also difficult at times as not all patients had a PNC report and other reports were not always detailed enough. Having all patients complete the quality of life questionnaire also proved challenging as inpatients are often asked to complete a range of other questionnaires during their stay in hospital. As a result the questionnaire will be substantially shortened for future use to make it more feasible for patients to complete.

Previous research has highlighted similar issues (e.g. Glover, 2000) as the data inputted into the database can only be as good as the original data recorded. We found that all too often there were gaps and assessments weren’t always available electronically. This resulted in
additional time taken to chase paper records from individual members of staff, which often proved to be frustrating and very time consuming. Similarly, staff did not always periodically update patient records and requests for information were not always fulfilled promptly. Kustner et al (2002) also experienced this problem in the development of their case register for schizophrenia.

However, the implementation of the clinical database will hopefully improve this situation as staff are now regularly reminded to complete records and assessments promptly for input onto the database. Protocols and mechanisms for these processes are being reinforced with staff regularly. Morris-Yates & Andrews (1997) and Higgins & Howard (2005) recognised this as being vital for the development of clinical databases and for the efficiency of healthcare services in general. Black (1998) also highlighted this improvement in accuracy and completeness as an invaluable benefit of implementing a clinical database.

Higgins & Howard (2005) and Glover (2000) documented the importance of employing staff with an understanding of the clinical framework, the data collected and the structure and mechanism of the database itself. Having completed this feasibility study we cannot stress enough the importance of having a permanent research assistant (or similar) in position to have time dedicated to the upkeep of a clinical database. Otherwise it would be all too easy to let data collection and input become less of a priority for other members of staff to complete.

Another benefit of carrying out this feasibility study is that it has helped to standardise the outcome measures we use as a service and reminded staff of the importance of ensuring assessments are regularly completed and recorded. In the long-run it is hoped that this will go some way towards creating a clearer picture of the most effective interventions for forensic patients. This is a view also held by Chambers et al (2009) from their article on outcome measures used in forensic mental health research.
Some minor alterations were made to the database during the course of the feasibility study, for example an extra category was added to referral source to account for those who were recalled from Community Treatment Orders and data on offending histories was altered to only include formal convictions. Self-reported incidents that didn’t result in a conviction have been removed as they are very problematic to track reliably. Some other alterations may need to be made as data collection increases across all inpatient wards and includes community patients in the future.

Now the feasibility study is complete and we have found that there is a need and the resources for such a development, the clinical database will be rolled out across all inpatient wards and data collection will begin retrospectively. In terms of future plans, in the shorter term it is envisaged that extending the clinical database to all inpatient wards would allow more sophisticated analytic strategies to be used to analysis the data. For instance, looking at changes in outcome measures over time and whether certain variables such as the length of stay correlate with measures of risk, occupation and psychopathology. In the longer term, the aim is to collect outcome data in relation to rates of re-hospitalisation, re-offending and mortality among the patient population of our low secure service.
References


Darzi, A. (2008) High Quality Care for All NHS Next Stage Review Final Report, Department of Health,

Department of Health (2010) Using the Commissioning for Quality and Innovation (CQUIN) payment framework – A summary guide,


### Table 1: Tools

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<td>Impairment Subscale</td>
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<td>Delusions/Hallucinations</td>
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<td>Depression Subscale</td>
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<td>Social Subscale</td>
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<td><strong>Total</strong></td>
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<td><strong>HCR-20</strong></td>
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<td>Risk Management Items</td>
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<td><strong>Total</strong></td>
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<td><strong>WHOQOL-BREF</strong></td>
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<td>How would you rate your quality of life?</td>
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