

Does better quality of primary care influence admissions and health outcomes for people with serious mental illness (SMI)?

A linked patient-level analysis of the full patient care pathway

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Study Protocol

Summary of Research

Background and Rationale

Serious mental illness (SMI) is a set of chronic enduring conditions associated with poor outcomes, high healthcare costs and high levels of disease burden (1, 2). Life expectancy for people with schizophrenia and bipolar disorder is typically around 20 years less than for the general population (3-8) and the majority of premature deaths in people with SMI are attributable to preventable causes. People with SMI are at higher risk of physical ill-health and hospitalisations (9, 10). Yet primary care plays a central role in the provision of care for people with SMI, with around 31% treated solely by their general practitioner (GP) (11).

'Liberating the NHS' outlined the Government's focus on measuring health outcomes (12) and NHS England has set out its aims for improving outcomes in line with the NHS Outcomes Framework (13, 14) with a strong emphasis on mental health. NHS England has exhorted general practice to play a central role in delivering better outcomes (15) including preventing avoidable emergency hospital admissions and A&E attendances, improved access to primary care and prevention of premature mortality (13). Our research accords with this policy focus on the role of primary care in improving patient outcomes.

Our key research question is whether better quality of primary care for patients with serious mental illness (SMI) can improve a broad range of outcomes (hospital admissions, costs, morbidity and mortality). We will address the research question by creating for the first time a set of comprehensive linkages between routine datasets that can be used for large scale analysis of the full patient care pathway in mental health. Despite its considerable disease burden, poor health outcomes and high costs (2, 4, 16), there has been little empirical research on the processes of care for people with SMI (11, 17).

Aims and objectives

Nationally, the quality of SMI management in primary care is assessed by the Quality and Outcomes Framework (QOF). Introduced in 2004, the QOF provides financial rewards to general practices for achieving specific quality targets for patients with a range of chronic illnesses. The SMI quality indicators in the QOF cover both mental health care, such as monitoring lithium levels; and physical care, such as routine health promotion. The QOF however only paints a partial picture of quality and may neglect other important unmeasured dimensions (18).

Our key research question is: what effect does better management of SMI in general practice have on health outcomes and health care utilisation for people with SMI? The quality of SMI management will be measured in two ways:

- 1) by achievement on relevant SMI-specific QOF indicators for both mental and physical health care, since SMI patients are more likely to suffer from preventable physical illnesses (6, 8, 19-22); and
- 2) by non-QOF measures selected on the basis of a literature review and informed by our Study Steering Committee (SSC). Potential measures include inappropriate polypharmacy (23) and the frequency and continuity of GP consultations (11, 18).

Research Plan / Methods

The outcomes to be assessed comprise utilisation or resource use measures and health outcomes:

i) hospital admissions for SMI; ii) emergency admissions for ambulatory care sensitive conditions (ACSC) which primary care can influence (9, 24, 25); iii) costs for SMI patients in primary and secondary care; and iv) mortality rates. If further linkages are feasible, we will also examine v) the number of A&E attendances; and vi) Health of the Nation Outcome Scale (HoNOS) scores, a clinician-rated outcome measure (26).

In order to examine the association between effective primary care management and health outcomes and utilisation for SMI patients, we will take an innovative approach and construct linked data across the entire care pathway. Linking datasets produces a whole greater than the sum of the parts in that we can capture all of the important elements of the care pathway for SMI patients. To enable us to track individuals over time and across care settings we will seek to assemble four longitudinal datasets based on routine data: the first at practice level linking achievement data for QOF indicators and Hospital Episodes Statistics (HES); the second at individual patient level linking the Clinical Practice Research Datalink (CPRD) which is collected in primary care with HES and ONS mortality data; the third linking HES, CPRD, A&E data; and the fourth linking HES, CPRD, and the Mental Health Minimum Dataset (MHMDS) which covers community and social care. Two of the linkages have been done before, but the third and fourth datasets (A&E data and MHMDS data) have never been linked to CPRD before.

If the third and fourth linkages are not feasible, we will use the second linked dataset to consider an alternative research question which is to examine whether there are differences in emergency admissions for ambulatory care sensitive conditions (ACSC) for SMI patients compared to non-SMI patients based on achievement for non-SMI QOF indicators. This allows us to examine the impact of any quality differences on ambulatory care sensitive condition (ACSC) emergency admissions as we know inequalities in care provision exist (27). For example, we will match patients with diabetes and SMI, with diabetes patients without SMI to determine the extent to which QOF achievement on non-SMI indicators (e.g. management of glycosylated haemoglobin levels for diabetes patients) differs and the impact of this on emergency admissions for diabetes.

We will apply appropriate statistical and econometric methods (28, 29) that take into account the multilevel longitudinal data structure. Our aim is for findings to feed directly into policy guidance to improve NHS practice around primary care management of SMI patients through changes in indicators in the QOF and through supporting evidence based decisions on local enhanced services (LESs).

Background and Rationale

The Government's mental health strategy recognises the huge personal, social and economic costs of serious mental illness (SMI) (30). An aspiration of the NHS Mandate is to achieve 'parity of esteem' for mental and physical health, which requires timely access to effective and accessible services (13, 28). In England, general practitioners (GPs) play a central role in the care of most people with SMI, and 57% of people with schizophrenia and 38% of people with bipolar disorder are predominantly treated in primary care with little or no contact with secondary care services (11). NHS England's 'Call to Action' wants general practice, "to play an even stronger role at the heart of more integrated out-of-hospital services that deliver better outcomes,... and the most efficient possible use of NHS resources" (15). NHS England has exhorted general practice to take a central role in delivering better outcomes which include reduced emergency admissions, improved access to primary care and prevention of premature mortality (13, 15, 28).

In addition, attendances at emergency units have been increasing over the past decade and evidence-based approaches to reduce avoidable admissions and emergency attendances are urgently needed (27, 31). Reasons for the growing pressures on A&E departments and the high number of 'avoidable' emergency hospital admissions have been the subject of a recent review instigated by the NHS Medical Director (27). The NHS Confederation has called on GPs to play a role in the provision of preventative care for mental and physical health as a means of dealing with the growing pressure on emergency care services (32). Our research will contribute to these policy goals.

SMI patients are at higher risk of hospitalisation and A&E attendance (33) than the general population, and treatment costs are typically higher for patients with SMI and a co-morbid physical health condition (34). Compared with the general population, people with SMI have double the risk of diabetes, two to three times the risk of hypertension, three times the risk of dying from coronary heart disease (35-37) and experience a ten-fold increase in deaths from respiratory disease (38, 39). Due to much higher smoking rates than the general population, smoking related diseases and heart disease are more common (19) and people with SMI are at much higher risk of obesity (37). Poor compliance with medication is common leading to relapse, poorer outcomes, and admissions.

SMI patients are predominantly cared for in community and primary care settings (11, 40). Understanding how better quality primary care can influence use of emergency secondary care services and treatment costs will help to identify how to improve the processes of care and potentially deliver improved health outcomes for individuals with SMI, as well as potentially identify ways to save NHS costs.

Our key research question is whether better quality of primary care for patients with serious mental illness (SMI) can improve a broad range of outcomes (emergency admissions, costs, morbidity and mortality). We will address the research question by creating for the first time a set of comprehensive linkages between routine datasets that can be used for large scale analysis of the full patient care pathway in mental health. Despite its considerable disease burden, poor health outcomes and costs (2, 4, 16), there has been little empirical research on the processes of care for people with SMI (11, 17).

By using patient-level data from GP practice registers we can identify the timing of patients' health checks in primary care and subsequent healthcare use including emergency admissions. The rationale is that good quality primary care and prevention may help avoid subsequent use of costly emergency secondary care services and may improve health outcomes for the particularly vulnerable SMI group.

The study will enable us to assess which indicators of primary care management of SMI used in the QOF are associated with desirable outcomes for patients and the NHS in terms of health and costs. This will have general relevance for other pay-for-performance schemes in terms of the links between target payments and outcomes. We will also examine non-QOF measures of quality that are important to service users and that could be considered for future inclusion in the QOF or for local enhanced service (LES) schemes.

Evidence explaining why this research is needed now

The health and financial burden of mental health disorders is significant, and improving outcomes and processes of care for people with serious mental illness (SMI) is a government priority (13, 30). However, there has been little empirical research examining the effects of care for people with SMI on outcomes and use of emergency

secondary care services (11). Our previous research (NIHR project (10/1011/22)) found that higher practice achievement on SMI-related QOF indicators was associated with a higher rate of emergency admissions for both mental and physical health (17). However, as this analysis was at practice level we could not identify whether individuals who were admitted to hospital had actually received care under the QOF (or, indeed any primary care), nor could we assess the direction of causality, i.e. whether achievement of QOF indicators for individual patients preceded or followed hospital admission. In addition, our previous research did not assess health outcomes. Our proposed project will therefore use patient-level data to redress these limitations, and to identify non-QOF measures of primary care quality that may reduce unplanned admissions more effectively. Our study will provide better evidence on the nature, quality and effectiveness of care for a group of vulnerable patients facing substantial health challenges.

The QOF is the most comprehensive pay-for-performance scheme in the world (41), providing financial incentives to all general practices for achieving a range of evidence-based quality targets (42). Gillam et al (18) undertook a systematic review of 94 studies on the QOF. Achievement rates for most incentivised activities initially rose following the introduction of QOF, but there was little further improvement after the third year of the scheme (2006/7) (43). Some of the observed improvement is likely due to better recording of care (44). Reductions in mortality have been modest (45), and findings on hospital admissions are mixed, particularly in cross-sectional studies (46-50). However, more recent evidence using panel data found a significant association between poorer quality care and higher emergency admissions for diabetes (51). Prescription rates for antidepressants and other drugs have increased, although this may not be attributable to the QOF (52-54) and may reflect longer courses of treatment rather than higher treatment rates (55). Gillam et al (18) also found that performance improvements for conditions not included in the QOF were significantly lower than for incentivised conditions, and that differences increased over time (43).

Our research will provide a comprehensive and timely evaluation of existing indicators for SMI patients in the QOF and will also add to the evidence base on non-incentivised areas of care by examining non-QOF quality indicators (43). 'Gaming' (for example, inappropriately exception reporting a patient who is eligible for an indicator but for whom a target has been missed), is a known risk in pay-for-performance schemes and may subvert the aim of indicators (56). We will build on the evidence base around exception reporting for SMI patients (the exclusion from QOF indicators of patients reported as unwilling, or deemed inappropriate) which is high compared with patients with other health conditions (57).

Aims and objectives

Our study objective is to examine whether better quality of primary care for patients with serious mental illness (SMI) can improve a broad range of outcomes (emergency admissions; A&E attendances; costs; morbidity; and mortality). The quality of care will be assessed with two sets of measures derived from primary care patient records: i) those used in the Quality and Outcomes Framework (QOF) which cover SMI specific indicators; and ii) other non-QOF measures.

Our six research questions are: is better quality primary care for people with SMI associated with:

1. Lower rates of SMI hospital admissions?
2. Lower rates of ambulatory care sensitive condition (ACSC) emergency admissions?
3. Reduced SMI costs in primary and secondary care?
4. Reduced mortality?

If linkages are feasible we will also examine if better quality primary care for people with SMI is associated with:

5. Lower A&E attendances?
6. Improvements in health outcomes (Health of the Nation Outcome Scales (HoNOS))?

If the data linkages which enable us to address the latter two research questions (on A&E attendances and HoNOS) are not feasible, we will address a further research question which is to compare the quality of care for SMI patients with care for a matched cohort of non-SMI patients. We will examine whether there is a difference in the quality of primary care received by patients with and without SMI who are covered by the QOF non-SMI indicators, and the impact of this difference in quality on ambulatory care sensitive condition (ACSC) emergency admissions.

This research proposal is for innovative work to investigate the entire care pathway for SMI patients to examine their management in primary care and the impact this has on a broad range of outcomes. Our aim is for findings to feed directly into policy guidance to improve NHS practice around primary care management of SMI patients through changes in indicators in the QOF or through informing local enhanced services (LESs) on evidence based best practice in primary care.

Research Plan / Methods

Design and conceptual framework:

To examine the association between the quality of primary care and outcomes, we will undertake secondary data analyses using multiple data sources. We will seek to construct four linked datasets based on routine data with information on the full patient care pathway (primary, community, and secondary care). These linked datasets enable, for the first time, the care received by individuals with SMI to be tracked through time and across settings. We will apply appropriate statistical and econometric methods that take into account the nature of the large and complex longitudinal or panel data structures (58) which are needed to address the research questions, including approaches for analysing multilevel or hierarchical data (28, 59). The use of longitudinal datasets helps to identify causal effects and mechanisms linking primary care management to outcomes and utilisation (58). We will carry out robustness checks to ensure our results are reliable and plausibility checks to ensure findings are meaningful in practice and can inform policy.

Quality of primary care: our key independent (explanatory) variable of interest is the quality of primary care. The national pay-for-performance scheme, the Quality and Outcomes Framework (QOF), is the principal national source of information on the quality of care for people with SMI in primary care. QOF indicators are for high-priority disease areas for which primary care has principal responsibility for ongoing care, and where there is good evidence that improved primary care will have health benefits (58). The QOF however only paints a partial picture of quality and may neglect other important unmeasured dimensions (18).

We will therefore measure the quality of care using two methods: indicators from the QOF; and non-QOF measures also derived from primary care patient records:

1. (a) *SMI-specific QOF indicators* are measured at both individual patient level and aggregated to practice level. The SMI specific indicators include measures such as monitoring of lithium levels, agreeing a comprehensive care plan and reviewing patients' physical health (35, 60). More recent indicators include recording SMI patients' alcohol consumption, blood pressure, cholesterol and cervical cytology results. A recent Cochrane Review (61) on the effectiveness of physical health monitoring for people with serious mental illness, found no published randomised clinical trials and just one ongoing study. The Cochrane Review emphasised the importance of gathering observational data on the impact of the widespread implementation of annual health checks for SMI patients in UK general practice.

(b) Should it not be feasible to link all four datasets, we will use our second linked dataset of CPRD and HES data to compare quality of care for SMI and non-SMI patients. For this analysis we will consider *non-SMI QOF indicators*, such as management of diabetes or cardiovascular disease, conditions for which SMI patients are at greater risk than the general population (8, 10).
2. We will also consider other *non-QOF measures* of SMI management which can be derived from GP practice register data and that SMI patients feel are important. These will be selected on the basis of a literature review and informed by the views and experience of our service user co-applicants and our Scientific Steering Committee (SSC). Potential measures include inappropriate polypharmacy (23) and the frequency and continuity of GP consultations (11, 18).

Outcome measures: our six research questions correspond to six different dependent variables. These comprise utilisation measures and health outcome measures: i) admissions for SMI; ii) emergency admissions for ambulatory care sensitive (ACSC) conditions (9, 24, 25); iii) mortality rates; iv) costs for SMI patients in primary and secondary care; and, if data linkage is feasible v) number of A&E attendances and vi) Health of the Nation Outcome Scale (HoNOS) scores (a clinician rated outcome scale).

All models will include year indicators to allow for common temporal trends, and a set of relevant patient, local population and practice covariates to control for confounding influences potentially masking the relationship between quality of primary care for SMI patients and outcomes.

Setting / context:

We will undertake a secondary data analysis using multiple data sources and will fine-tune our analysis plan together with PPI and our policy and clinical advisors on our Scientific Steering Committee (SSC). Our datasets include individuals with serious mental illness (SMI) seen in primary care practice within England for the study period 2001/02 to 2013/14. We can also track SMI patients through the rest of their care pathway, in hospital and community care for subsets of the full study period. We include data which is for the whole population (at practice level) and for a representative sample of practices (at patient level), making our results generalisable.

Data collection:

Data sources

Patient-level data:

Clinical Practice Research Datalink (CPRD) data:

CPRD is the world's largest computerised database of anonymised longitudinal medical records from primary care. Information includes records of clinical events (medical diagnoses), referrals to specialists and secondary care settings, prescriptions issued in primary care, records of immunisations/vaccinations, diagnostic testing, lifestyle information (e.g. smoking and alcohol status), and all other types of care administered as part of routine general practice. Currently data are collected on over 5 million active patients from over 610 general practices throughout the UK. We will use a representative sample of these practices in England based on deprivation measures and practice list size. The CPRD requires intensive data management and cleaning to produce a dataset for statistical analyses. The applicants have extensive experience of using CPRD data in quality of care related research. We will use CPRD data for 2001/02-2013/14.

Hospital Episode Statistics (HES) data:

Our main data source for hospital admissions will be HES for the financial years 2001/02 to 2013/14. HES contain a detailed record for each NHS inpatient admission to every hospital provider in England. HES contain clinical information on patients' socio-economic characteristics, diagnoses, procedures and resource use.

HES-Office of National Statistics (ONS) mortality data:

Information on patients who die in hospital can be analysed as recorded in HES, but these data alone cannot be used to identify the cause of death, or to obtain information on patients who died outside of hospital. The Office of National Statistics' (ONS) mortality data are a richer source of information on deaths than HES, with comprehensive data on place of death and underlying cause of death based on information from medical practitioners and/or coroners. Linking ONS mortality data to HES data permits the analysis of deaths in and outside hospital for all patients with a record in HES. Again, we have expertise with the linkage methodology for HES-ONS mortality data and for their analysis. Special permission is required for the ONS death fields in HES and we have experience in obtaining and analysing these data.

HES Accident & Emergency (A&E) data:

These data have been collected since 2007/08 and cover attendances at major A&E departments, single specialty A&E departments, minor injuries units and walk-in centres in England. We will link A&E activity with inpatient admissions data by means of a unique pseudonymised individual patient identifier. Given the improvements in data coverage and data quality, we will seek to use data from 2009/10-2013/14. The research team has considerable expertise in the analysis of linked HES data.

Mental Health Minimum Data Set (MHMDS):

The Mental Health Minimum Data Set (MHMDS) contains record-level data on all adults using secondary mental health services in a given year. It has individual patient level information from the mental health care pathway that has been captured on clinical systems. A unique patient identifier is attached to each record making it possible to link multiple spells of care for an individual patient across different reporting periods.

The MHMDS is unique in its coverage, because it includes not only services provided in hospitals, but also in outpatient clinics and the community, where most people with SMI are treated. Over 90% of individuals in the

2008/09 MHMDS data set did not receive inpatient care and 50% had not attended a consultant outpatient clinic; consequently, HES does not capture these individuals' use of healthcare resources (40). The substantial volume of NHS care provided by community psychiatric nurses, clinical psychologists, occupational therapists, physiotherapists, and consultant psychotherapists and social workers are thus not captured in HES, but are recorded in the MHMDS. MHMDS also captures social care. MHMDS also captures a clinician-rated routine outcome measure mandated for national use, the Health of the Nation Outcome Scales (HoNOS).

MHMDS and HES records can be linked at pseudonymised patient level (62). The linkage with HES is important since mental health service users are more likely to access hospital services compared to the general population: 39% (compared to 17% in the general population) have at least one inpatient stay (62). MHMDS contains sensitive data fields such as the number of assessments under the Mental Health Act, which are subject to the approval of the Data Access Advisory Group (DAAG).

CPRD data linkage:

We will seek the requisite permissions from the ISAC (Independent Scientific Advisory Committee) at CPRD and get Confidentiality Advisory Group (CAG) approval for all CPRD linked data. Data will be linked by a trusted third party, the Health and Social Care Information Centre (HSCIC), and sent to us in pseudonymised format. Appropriate data governance will be sought, and we have considerable experience in meeting these requirements.

We will submit two data protocols to ISAC at CPRD: ISAC Protocol 1 will cover CPRD-HES-ONS data which are standard linkages; whereas ISAC Protocol 2 will cover A&E data and MHMDS data which are non-standard linkages for CPRD and have not been done before.

Practice-level data:

Quality and Outcomes Framework (QOF) data:

The Quality Management Analysis System (QMAS) provides QOF quality indicator achievement and prevalence data at practice level from the year 2004/05 onwards. A set of QOF indicators focus on care for individuals with serious mental illness (e.g. schizophrenia, bipolar disorder). The QOF indicators are based on clinical evidence, and designed to support NHS policies. The mental health QOF indicators are shown in Table 1. The QOF is reviewed annually, resulting in some existing QOF indicators being modified or dropped, and new indicators being introduced. Major changes to the set of SMI indicators were made in 2006/07 and 2011/12. Shaded cells in Table 1 indicate periods when specific SMI indicators were operative.

Table 1: QOF SMI indicators, 2004/5 to 2013/14

		QOF version; payment thresholds shown as applicable						
		2004/5 - 2005/6	2006/7 - 2007/8	2008/9	2009/10 - 2010/11	2011/12	2012/13	2013/14
Clinical indicators: Records								
MH 1	The practice can produce a register of people with severe long term mental health problems who require and have agreed to regular follow-up.							
MH 8	The practice can produce a register of people with schizophrenia, bipolar disorder and other psychoses.							
MH001	The contractor establishes and maintains a register of patients with schizophrenia, bipolar affective disorder and other psychoses and other patients on lithium therapy.							
Clinical indicators: Ongoing management								
REVIEW INDICATORS								
MH 2	The percentage of patients with severe long-term mental health problems with a review recorded in the preceding 15 mths. This review includes a check on the accuracy of prescribed medication, a review of physical health and a review of co-ordination arrangements with	25-90%						
MH 9	The percentage of patients with schizophrenia, bipolar affective disorder and other psychoses with a review recorded in the preceding 15 mths. In the review there should be evidence that the patient has been offered routine health promotion and prevention advice appropriate to their		40-90%	40-90%	40-90%			
PHYSICAL CARE INDICATORS (replace general review from 2011/12)								
MH11	The percentage of patients with schizophrenia, bipolar affective disorder and other psychoses who have a record of alcohol consumption in the preceding 15 mths.					40-90%	50-90%	
MH007	The percentage of patients with schizophrenia, bipolar affective disorder and other psychoses who have a record of alcohol consumption in the preceding 12 mths.							50-90%
MH12	The percentage of patients with schizophrenia, bipolar affective disorder and other psychoses who have a record of BMI in the preceding 15 mths.					40-90%	50-90%	
MH006	The percentage of patients with schizophrenia, bipolar affective disorder and other psychoses who have a record of BMI in the preceding 12 mths.							50-90%
MH13	The percentage of patients with schizophrenia, bipolar affective disorder and other psychoses who have a record of blood pressure in the preceding 15 mths.					40-90%	50-90%	
MH003	The percentage of patients with schizophrenia, bipolar affective disorder and other psychoses who have a record of blood pressure in the preceding 12 mths.							50-90%
MH14	The percentage of patients aged 40+ with schizophrenia, bipolar affective disorder and other psychoses who have a record of total cholesterol:hdl ratio in the preceding 15 mths.					40-80%	45-80%	
MH004	The percentage of patients aged 40+ with schizophrenia, bipolar affective disorder and other psychoses who have a record of total cholesterol:hdl ratio in the preceding 12 mths.							45-80%
MH15	The percentage of patients aged 40+ with schizophrenia, bipolar affective disorder and other psychoses who have a record of blood glucose or HbA1c in the preceding 15 mths.					40-80%	45-80%	
MH005	The percentage of patients aged 40+ with schizophrenia, bipolar affective disorder and other psychoses who have a record of blood glucose or HbA1c in the preceding 12 mths.							45-80%
MH16	The percentage of patients (aged from 25 to 64 in England) with schizophrenia, bipolar affective disorder and other psychoses whose notes record that a cervical screening test has been					40-80%	45-80%	
MH008	The percentage of women aged 25 or over and who have not attained the age of 65 with schizophrenia, bipolar affective disorder and other psychoses whose notes record that a							45-80%
LITHIUM INDICATORS								
MH 3	The percentage of patients on lithium therapy with a record of lithium levels checked within the previous 6 mths.	25-90%						
MH 4	The percentage of patients on lithium therapy with a record of serum creatinine and TSH in the preceding 15 mths.	25-90%	40-90%	40-90%	40-90%			
MH17	The percentage of patients on lithium therapy with a record of serum creatinine and TSH in the preceding 9 mths.					40-90%	50-90%	
MH009	The percentage of patients on lithium therapy with a record of serum creatinine and TSH in the preceding 9 mths.							50-90%
MH 5	The percentage of patients on lithium therapy with a record of lithium levels in the therapeutic range within the previous 6 mths.	25-70%	40-90%	40-90%	40-90%			
MH18	The percentage of patients on lithium therapy with a record of lithium levels in the therapeutic range in the preceding four mths.					40-90%	50-90%	
MH010	The percentage of patients on lithium therapy with a record of lithium levels in the therapeutic range in the preceding 4 mths.							50-90%
CARE PLAN INDICATORS								
MH 6	The percentage of patients on the register who have a comprehensive care plan documented in the records agreed between individuals, their family and/or carers as appropriate.		25-50%	25-50%	25-50%			
MH10	The percentage of patients on the register who have a comprehensive care plan documented in the records agreed between individuals, their family and/or carers as appropriate.					25-50%	30-55%	
MH002	The percentage of patients with schizophrenia, bipolar affective disorder and other psychoses who have a comprehensive care plan documented in the record, in the preceding 12 mths, agreed between individuals, their family and/or carers as appropriate.							40-90%

As shown in Table 1, the QOF mental health indicators have upper payment thresholds of up to 90%. Therefore, practices can earn the maximum points on an indicator without necessarily achieving the target for all patients on the register. In measuring practice level performance on the QOF indicators, we will use the percentage of eligible patients (i.e. patients for whom the indicator is appropriate) for whom the indicator was achieved, rather than the QOF points earned or the proportion of maximum points earned (56). Practices can ‘exception report’ patients with the relevant condition, but for whom the targets would be inappropriate for logistical reasons (e.g. recent registration of a patient with a practice or recent diagnosis), clinical reasons (e.g. drug intolerance), or a patient is deemed unsuitable (e.g. the patient received at least three invitations for a review during the preceding 12 months but did not attend), or because of informed dissent (57). Exception reported patients are removed from official achievement calculations. We found in our previous NIHR study (17) that whether exceptions were included or excluded in computing percentage practice achievement, had marked effects on results, but we were unable to examine the reasons for exceptions. With the individual level data from CPRD we will be able to examine the role of exceptions in more detail.

Datasets

We will use these data sources to construct four linked longitudinal datasets. The research questions addressed by each dataset are shown in Table 2. The work is divided into distinct work packages. ISAC Protocol 1 which seeks to link CPRD-HES-ONS data covers work packages 3(a) and 3(b). ISAC Protocol 2 which seeks to link CPRD-HES-A&E and CPRD-HES-MHMDS covers work package 4(a). If we do not obtain approval for ISAC Protocol 2 to cover A&E and MHMDS data linkages we will undertake WP 4(b). Work package WP2 (not included in the table below) covers the identification of non-QOF indicators through the literature review.

For example, research question 4 (RQ4) (is better quality primary care for people with SMI associated with lower mortality?) is addressed by dataset 2, with the dependent variable as D4 and the key explanatory variable as Q1 under WP3(a).

Table 2: Datasets used to address the six research questions

Dataset	Research question (RQ) Is better quality primary care for people with SMI associated with:	Dependent variable (D) (outcome or utilisation measure)	Key independent variable (quality indicators) (Q)
<u>Work Package WP1</u>			
Dataset1: HES-QOF <i>Practice level</i> (2006/07-2013/14) (2006/07-2010/11) (2011/12-2013/14)	RQ1: lower SMI admissions? RQ2: lower emergency admissions for ACSCs?	D1: admissions for SMI D2: emergency admissions for chronic ACSCs D1 D2 D2	Q1: QOF achievement (SMI indicators) MH6 MH9 MH11-MH16
<u>Work Package WP3(a)</u>			
Dataset2: CPRD-HES-ONS <i>Patient level</i> (2004/05-2013/14) (2004/05-2010/11) (2011/12-2013/14)	RQ1: lower SMI admissions? RQ2: lower emergency admissions for ACSCs? RQ3: reduced costs? RQ4: lower mortality?	D1: admissions for SMI D2: emergency admissions for ACSCs D3: SMI costs in primary and secondary care D4: mortality D1,D3&D4 D1,D2,D3&D4 D1,D2,D3&D4	Q1: QOF achievement (SMI indicators) MH4,MH5,MH6 MH9 MH11-MH16
<u>Work Package WP3(b)</u>			
Dataset2: CPRD-HES-ONS <i>Patient level</i> (2001/02-2013/14)	RQ1: lower SMI admissions? RQ2: lower emergency admissions for ACSCs? RQ3: reduced costs? RQ4: lower mortality?	D1: admissions for SMI D2: emergency admissions for ACSCs D3: SMI costs in primary and secondary care D4: mortality	Q2: non-QOF indicators

Work Package WP4(a)			
Dataset3: CPRD-HES-A&E <i>Patient level</i> (2009/10-2013/14)	RQ5: lower A&E attendances?	D5: A&E attendances	Q1: QOF SMI indicators Q2: non-QOF indicators
Dataset4: CPRD-HES-MHMDS <i>Patient level</i> (2011/12-2013/14)	RQ6: better outcomes?	D6: HoNOS scores	Q1: QOF SMI indicators Q2: non-QOF indicators
Work Package WP4(b)			
Dataset2: CPRD-HES-ONS <i>Patient level</i> (2004/05-2013/14) (Matched cohort SMI and non-SMI patients)	RQ2: Does quality of care differ for SMI and non-SMI patients and is it associated with differences in emergency admissions for ACSCs?	D2: emergency admissions for ACSCs	Q1: QOF achievement (non-SMI indicators, e.g. diabetes)

Notes:

ACSC: Ambulatory Care Sensitive Condition
A&E: Accident and Emergency
CPRD: Clinical Practice Research Datalink
HES: Hospital Episodes Statistics
MHMDS: Mental Health Minimum Dataset
ONS: Office for National Statistics (mortality data)
QOF: Quality and Outcomes Framework
SMI: Serious Mental Illness

Dataset1: A national practice level dataset covering around 8000 English general practices, using data from the QOF and HES. We will extract HES data on all emergency spells for individuals with a primary or secondary diagnosis of SMI. The definition of SMI corresponds to ICD-10 diagnostic codes F20-F31 and matches the inclusion criteria for SMI registers that are used in primary care as part of the QOF. Admissions will be aggregated to practice level. This dataset will cover the period 2006/07 to 2013/14, providing around 80,000 practice-year observations. Dataset1 has the advantage that it covers all practices and we can know the identity of the practices (and the proportions of patients in different small areas or Lower Super Output Areas (LSOAs)) and can therefore attach a very large set of covariates.

This dataset will be used to address research questions 1 and 2.

Dataset2: A longitudinal patient level dataset from 2001/02 to 2013/14, linking CPRD data with data from HES and ONS mortality data. We will select a nationally representative random sample of around 134 practices that have remained continuously in the CPRD dataset from the 610 practices currently contributing to CPRD. Using an appropriate list of Read codes (a coded version of clinical terms used in general practice) we will identify people with SMI. From each practice we will extract all patients with a diagnosis of SMI that are eligible for linkage to HES and ONS data giving a sample of around 33,000 SMI patients.

We will re-calculate QOF achievement for individual patients in CPRD from the Read codes. We will use the CPRD data to construct measures of individual patient morbidity and management in primary care, including prescriptions received, and referrals to secondary care. HES data - linked by CPRD to individual patient records - will provide detailed information on the reason for admission and co-morbidities. ONS data - linked by CPRD to individual patient records - will provide information on mortality.

To analyse the impact of quality on costs, we will use national NHS Reference Costs to assign costs to activity such as inpatient days and outpatient attendances. We will cost activity recorded in CPRD by attaching unit costs to activities such as consultations, pharmaceuticals, tests and referrals. We already have the algorithms for costing care for these various activities.

This dataset will be used to address research questions 1 and 2 (as a cross-check to Dataset1), as well as research questions 3 and 4. Dataset1 (the national practice level dataset with rich covariates) and Dataset2 (the patient level dataset with rich individual patient morbidity data but in

a smaller sample and with fewer practice level covariates) each have strengths and we will compare the two approaches (triangulate) to see how sensitive results are.

Dataset3: This dataset will be as the above Dataset2 linking HES and CPRD data at patient level for SMI patients. It will however include a linkage to A&E attendances. This dataset will run from 2009/10 to 2013/14.

This dataset will be used to address research question 5.

Dataset4: This will link patient level HES, CPRD, and MHMDS which includes community and social care. MHMDS is only available from 2011/12 onwards as a consistent panel (version 4) and we will therefore link HES, MHMDS, and CPRD for 3 years up to 2013/14.

This dataset will be used to address research question 6.

This will be the first time these comprehensive linked routine datasets (in particular Dataset3 and Dataset4) have been created and used for large scale analysis of the full patient care pathway in mental health. The linkage across datasets will enable us to cross-check and triangulate data, thus enhancing the robustness of the study. The linkage will be done by HSCIC on behalf of CPRD, but all the data cleaning and coding will be done by the research team.

Quality of care

Our key independent (explanatory) variable of interest is quality of primary care as measured by:

- 1) QOF achievement, using SMI-specific (Table 1) QOF indicators. The QOF indicators require GP practices to monitor mental state, medication (use, adherence, and side effects), social isolation, access to services, and occupational status of SMI patients. Given the increased health risks associated with SMI and the medications used in its treatment, physical health monitoring is also important. The recent National Audit of Schizophrenia found that just 29% of people with schizophrenia receive an annual physical health check (35). GPs are paid to record measures such as weight and BMI, alcohol consumption, blood pressure, glucose levels and cholesterol (35, 60). SMI patients should also have a care plan developed jointly between primary care and secondary mental health services.

The QOF indicators will be at practice level for Dataset1 (direct from QMAS) and we will calculate QOF achievement from Read codes for patient-level Dataset2, Dataset3 and Dataset4. We will examine not just whether and when QOF indicators were achieved for individual patients, but the actual levels of the relevant parameters (e.g. blood pressure). Achievement rates will be calculated with and without exception reported patients (i.e. patients deemed inappropriate for the quality indicator by their practice).

- 2) Non-QOF measures will be selected on the basis of a literature search, PPI and clinical input, and informed by the Scientific Steering Committee (SSC). These may include measures such as inappropriate antipsychotic polypharmacy which can lead to greater side-effects with no clinical benefit (63). There are particular concerns around possible adverse effects of antipsychotic medication (6, 7, 64). The US Agency for Healthcare Research and Quality uses a performance measure for inpatients discharged on two or more antipsychotic medications (23). There are 952 drug-dose combinations with antipsychotic properties within CPRD data and the count of oral and depot drugs for SMI patients within practices is a potential quality indicator. We will be able to explore when treatment was initiated e.g. whether antipsychotic polypharmacy prescribing was started within a primary care consultation. Another possible indicator is the frequency of GP consultations, since regular check-ups may help ensure continuity of care and prevent relapse (11). Continuity of care can be measured as the proportion of recorded consultations within a given time frame which were with the same practitioner (18).

Outcome and utilisation measures

Our key dependent (response) variables of interest correspond to our six research questions, and comprise the following outcome and utilisation measures:

- 1) Hospital admissions for SMI care;

- 2) Emergency admissions for ambulatory care sensitive conditions (ACSC), where better primary care may help avoid unplanned admissions (24, 25). These conditions have been shown to be either more prevalent in an SMI population or to carry a higher relative risk of mortality; SMI patients are also at higher risk of hospitalisation for such conditions (9, 10). ACSC conditions include: diabetes, asthma, hypertension, congestive heart failure, epilepsy, chronic obstructive pulmonary disease and pyelonephritis (1). Rates of emergency admissions have been rising steadily and are under increasing scrutiny; it is argued that many could be avoided by better quality primary care (65).
- 3) Costs of SMI care in primary, secondary and community settings; and
- 4) Mortality which is a key outcome indicator for SMI patients (3-5, 7, 64, 66, 67).

If data linkages are feasible, we will also examine:

- 5) Number of A&E attendances: 43% of mental health service users in England visited A&E at least once in 2012/13, double the rate (21%) of the general population, and 20% of people treated in A&E could have been treated in primary care (33, 62); and
- 6) Health of the Nation Outcome Scale (HoNOS) scores, the most widely used routine 12-item clinical outcome measure of health and social functioning which provides a measure of morbidity and is particularly applicable to individuals with severe and enduring mental illness (26). HoNOS items are each scored from 0 (no problem) to 4 (severe problem) yielding a total score in the range of 0 (best) to 48 (worst) and outcome is measured by comparing a change in patients' scores at two points in time.

Covariates

Socio-economic data on deprivation and small area characteristics at Lower Super Output Area (LSOA) will be attributed to GP practices for Dataset1 using the Attribution Data Set which contains information on the number of patients in each practice who are resident in each LSOA. GP and practice characteristics from General Medical Statistics (GMS) data will be included. We will also calculate measures of distance from the GP practice to acute and mental health hospitals to control for variations in access.

For the individual-level datasets, CPRD will not provide information on the LSOA of the patient but will attach socio-economic measures derived from LSOA data such as deprivation deciles. We will also seek to obtain permission for HSCIC to derive measures of distance to provider based on patient postcode (or their LSOA centroid) and provider site postcodes.

The enclosed Gantt chart demonstrates the planned steps in the execution of the study.

Data analysis:

These large and complex datasets will require an array of quantitative approaches. The team has considerable experience in the analysis of these types of data. Each dataset will consist of a panel of observations covering a number of years [Dataset1: 2006/07-2013/14; Dataset2: 2001/02-2013/14; Dataset3: 2009/10-2013/14; Dataset4: 2011/12-2013/14]. Dataset1 has annual observations, while the patient level Dataset2, Dataset3 and Dataset4, have repeated observations at irregular intervals. For example, we know the dates of primary care use, hospital admissions, and A&E attendances, and will make use of the timing of events to code the sequence of observations within a year for each SMI patient.

The longitudinal element to the data will allow us to more robustly identify the impact of the practice-level indicators on our outcome measures than cross-sectional data would permit. There are three important elements to this: (i) longitudinal data afford better control for unobserved characteristics, at either the individual or practice level that plausibly impact both practice performance and patient outcomes (for example, practice style and culture) and hence otherwise would confound important relationships; (ii) repeated observations at practice or patient level allow us to investigate lags in the relationship between performance measures and outcomes as we are able to observe the timing of events. Both these factors are crucial in trying to move beyond revealing associations (a limitation of cross-sectional analysis) to identifying causal effects and mechanisms linking practice management to outcomes.

The data are hierarchical, reflecting, for example, that activities are 'nested within' patients with SMI who in turn are nested within practices, hospitals and small areas within which they receive community services. Where appropriate, analyses will take into account this multilevel and hierarchical structure.

The key dependent variables which correspond to our six research questions, are binary categories (died/alive), counts (e.g. number of hospitalisations, A& E attendances etc.), proportions (e.g. proportion of practice patients admitted to hospital), and expenditures (cost of primary and secondary care of SMI patients). The nature of the dependent variable has consequences for the approach to modelling (e.g. cost data at an individual level are non-negative, highly skewed, and leptokurtic; count data are non-negative, often with a spike at zero and highly dispersed). All are best modelled as non-linear (e.g. exponential) functions of covariates. Our analyses will take into account the nature of the dependent variable, and hence the appropriate regression approach. The size of the respective datasets will ensure relationships are estimated with great precision. Findings will be presented in terms of both statistical significance and effect size, to allow judgements of clinical and policy relevance. The richness these data provide will ensure we can investigate important relationships at an appropriate level and with sufficient granularity to inform policy making.

All models for the six research questions will include year indicators to allow for common temporal trends, and a set of relevant patient, local population and practice covariates where possible to control for confounding influences potentially masking the relationship between SMI management and outcomes. In particular we will control for patient case-mix through diagnosis codes derived from practice Read codes as well as HES records. We will carry out a variety of robustness checks to ensure our results are reliable and plausibility tests to ensure findings are meaningful in practice and can inform policy.

Plan of investigation and timetable

Based on the detailed GANTT chart with key milestones for the project (supplementary file), we report here the key research activities in 6-monthly intervals. Some activities are scheduled across longer than 6-months, but we highlight the key activities which commence within each 6-month block.

Activities 01/15-06/15:

- Application to UoY ethics committee
- Application to ISAC for Protocol 1 (CPRD-HES-ONS linkage)
- Establish Scientific Steering Committee (SSC)
- WP1: Collate Dataset1
- WP1: Practice level analyses
- WP2: Literature review to ID non-QOF measures
- WP2: Consensus to finalise non-QOF measures
- WP2: Write up literature review
- Progress report 1: 1 July 2015
- First meeting of Scientific Steering Committee (SSC)

Activities 07/15-12/15:

- Application to ISAC for Protocol 2 (CPRD-A&E-MHMDS linkage)
- WP3(a): Familiarise with CPRD data
- WP3(a): Calculate QOF data in CPRD from Read codes
- WP3(a): Check linkages with HES & ONS
- WP3(a): RQ1 and RQ2 admissions analyses
- WP3(b): RQ1 and RQ2 admissions analyses
- Progress report 2: 8 January 2016
- Second meeting Scientific Steering Committee (SSC)

Activities 01/16-06/16:

- WP3(a): RQ4 mortality analysis
- WP3(b): RQ4 mortality analysis
- Progress report 3: 1 July 2016
- Third meeting of Scientific Steering Committee (SSC)

Activities 07/16-12/16:

- WP3(a): Collect Reference Costs and PSSRU costs and merge
- WP3(a): RQ3 cost analysis
- WP3(b): RQ3 cost analysis
- Progress report 4: 10 January 2017
- Fourth meeting of Scientific Steering Committee (SSC)

- Workshop for GPs in Hull

Activities 01/17-06/17:

- WP4(a): Check linkages with A&E & MHMDS
- WP4(a): RQ5 A&E analysis
- WP4(a): RQ6 HoNOS analysis
- or WP4(b): RQ2 matched cohort analysis
- Progress report 5: 1 July 2017
- Fifth meeting of Scientific Steering Committee (SSC)

Activities 07/17-12/17

- Robustness checks
- Finalise analyses
- Report writing
- Final meeting of Scientific Steering Committee (SSC)
- Progress report 6: 10 January 2018

Activities 01/18-06/18

- Dissemination - open access journal publications
- Dissemination - lay summaries, newsletters
- Final draft report circulated for comments
- Submit draft final report: 13 July 2018

Throughout the project, we will undertake dissemination activities such as presentations at conferences and publications in open access journals.

Project management

A project co-ordinator will assist with: data requests, funder requirements, administrative support of team meetings, Scientific Steering Committee (SSC) meetings, organisation of workshops and seminars.

The core team of analysts will meet every fortnight throughout the project to maintain continued progress on key milestones. The full team will meet monthly although input will be provided by them as needed at other key stages of the research. Meetings will be in York and those who are not based in York, will join via Skype or teleconference, or in person, as appropriate. The PI and other team members will have Skype and teleconference meetings to provide support to our service user team members on the quantitative analysis, as needed.

The project timeframe is for a project lasting 3.5 years of which 3 years will be active research time and the final 6 months will be devoted to dissemination activities with staff inputs tapered accordingly. The project will be managed by ensuring work is focused on agreed key milestones and within defined work packages. A Gantt chart is attached. Financial management will be provided by one of the two dedicated financial administrators at CHE, who will handle the financial accounting and processing of all income and expenditure and will provide the PI with quarterly financial updates.

We will establish a Scientific Steering Committee (SSC) with an independent chair, to ensure our study makes a difference for patients and the NHS. In our previous NIHR project (10/1011/22), the advisory group has proven invaluable in ensuring the project has generated results that have the best chance of having an impact. The advisory group members have agreed to continue in this capacity and we have sought to boost the group with additional members with fresh perspectives. The SSC will meet every 6 months (6 times over the course of the project), with the PI and two or three people from the research team also in attendance, depending on the analysis to be discussed. The project co-ordinator will provide administrative support to the SSC. SSC meetings will be chaired by an independent chair. Costs for these meetings, including PPI have all been budgeted for.

Approval by ethics committees

NHS Ethics approval is not required: this type of study is classed as low risk due to minimal burden or intrusion for participants, as it is based on the analysis of anonymised secondary data. We will nevertheless seek an opinion from the University of York Research Ethics Committee to confirm this.

The use of CPRD data is subject to approval by the ISAC ethics committee run by the MHRA. There are formal processes in place for gaining access to Clinical Practice Research Datalink (CPRD) and linked data which require provision of guarantees on data use and security, all of which CHE has considerable experience of undertaking. The research will comply with the University of York's data protection guidelines (www.york.ac.uk/recordsmanagement/dpa/). The linkage of CPRD will require permission from the Health Research Authority Confidentiality Advisory Group (CAG), but this is done through CPRD and the linkage is undertaken by a trusted third party, the Health and Social Care Information Centre (HSCIC). The application for data access and linkage will be made through CPRD who will sub-contract the linkage requests to HSCIC.

Patient and Public Involvement

Two of our research team co-applicants have lived experience of serious mental illness. They have participated in team discussions to shape and clarify our research questions.

PPI involvement will benefit the research by ensuring that:

- (i) we address questions which matter to service users;
- (ii) interpretation of results and findings are plausible, and
- (iii) dissemination is in an appropriate format.

This strategy builds on our track record of engaging service users in conceptually challenging areas of mental health services research, in particular very quantitative work and we have been congratulated by the NIHR on our model of service user involvement (17).

With regard to (i), two of our team, will play a pivotal role in our research team, but will also sit on our Scientific Steering Committee (SSC). In our previous NIHR project (10/1011/22), they successfully played this dual role and they said they felt genuinely engaged as part of the team. They will actively participate in the research to identify relevant quality measures in primary care and be involved in the literature review and will further help inform the research at all stages. They will receive support and training from other team members through regular discussions on the quantitative components as needed and will attend an MHRN National Scientific Meeting to build links with other service user researchers.

With regard to (ii), our service users on the team will be updated on emerging research results and their input into the plausibility of these findings from the perspective of a user of mental health care services will be sought.

With regard to (iii), we will share our findings with service users and mental health charities. We will utilize the extensive network of contacts that the York Mental Health Research Group (MHRG) has built up. We will disseminate our results making use of newsletters produced by MHRN.

All service user payments are based on INVOLVE guidance.

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