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**A study of psychotropic medication prescribing patterns in prisons in
England and Wales**

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Full title of project

A study of psychotropic medication prescribing patterns in prisons in England and Wales

Research questions

1. What are the patterns of psychotropic medication prescribing in prisons in England and Wales, and how do these compare to the wider community?
2. How appropriately are psychotropic medications prescribed in prisons?
3. How acceptable are psychotropic medication prescribing decisions to patients and GPs in prisons?

Aims and objectives

1. To establish rates of prescribing for psychotropic medications (antidepressants, antipsychotics, hypnotic/anxiolytics and/or central nervous system stimulants) in prisons in England and Wales with respect to a) medication type b) dose and c) cost.
2. To compare prison psychotropic prescribing patterns with the wider community, accounting for demographic and clinical characteristics.
3. To compare prescribing patterns between different prison types and specific demographic groups, including women, older prisoners and BME groups.
4. To determine the appropriateness of psychotropic prescribing patterns in prisons.
5. To determine the perceived satisfaction and acceptability of psychotropic prescribing decisions to patients and GPs in prisons.

Background

Prisoners are entitled to the same range and standard of healthcare services as patients in the community¹. In line with this commitment, responsibility for the commissioning and provision of healthcare completed its transfer from HM Prison Service to the NHS in April 2006. It is well-established that the rate of mental illness is significantly higher in prisons than in the community^{2, 3}. A recent high-profile review⁴ noted that in the UK the number of people in prison with mental illness is higher than ever, and likely to increase; therefore, a continuing high level of need for psychotropic medication in prisons is inevitable. International studies have shown that prescriptions for psychotropic medicines, such as antidepressants and antipsychotics, are elevated in incarcerated populations in comparison to the community, and vary among different demographic groups⁵⁻⁸. Few UK studies, however, have explicitly addressed prescribing patterns in prisons.

A large survey of psychiatric morbidity among prisoners in England and Wales carried out in 1997 by the Office for National Statistics³ found that a fifth of

men and half of women interviewed were prescribed medication to act on the central nervous system, including drugs to treat mental health disorders and substance dependence. However, the study did not assess prescription costs, doses or the appropriateness of prescribing. A small-scale study of prescribing within five UK prisons by the Department of Health (DH)⁹ reported variation in drugs used and prescribing costs between establishments. Average annual prescription costs per head were £273 and £167 at local remand and high secure establishments respectively, exceeding the community average (£110). There was also higher use of medicines for mental illness in these prisons, although no inferential statistical analyses were undertaken. Whilst these studies provide interesting preliminary data on psychotropic medication use amongst prisoners, no direct comparisons with community data were made. Nor was it clear to what extent psychotropic prescribing was appropriate, safe, or acceptable to patients.

Good prescribing should maximise effectiveness, minimise risks, minimise costs and respect the patient's choices¹⁰. Assessing prescribing appropriateness in general is difficult¹⁰, made more difficult in prisons by lack of access to robust data. Unlike the community, high quality prescribing data are not routinely available from prison based prescribers. However there is reason to believe that research is needed. Mental health service users, especially when acutely ill, are a particularly vulnerable patient group: risks may be related to their own behaviour, the behaviour of others around them, as a direct result of their mental illness, or safety risks from their care or treatment¹¹. Furthermore, incidents involving mentally ill patients are particularly important because of the inherent risks posed by psychotropic medication, for example the risk of drug-drug interactions¹². One unpublished clinical audit¹³ noted that significant quantities of older antidepressants were being used in prisons when newer, safer alternatives exist. Given that overdose remains one of the most common methods of suicide among patients in contact with mental health services¹⁴, less toxic drugs should be prescribed for people at risk of suicide. A recent study by the Offender Health Research Network (OHRN) highlighted problems with continuity of care upon entry into prison. They found that half of all treatment with psychotropic medicines reported at prison reception was discontinued, often without evidence of communication with community GPs, clinical review or other recorded justification¹⁵. Indeed, serious consequences can occur from omission of medicines, although these are not well recognised¹⁶. Meanwhile, qualitative studies have indicated delays, changes to or withdrawal of psychotropic medications are a significant cause of frustration and distress to patients, to whom medicines are a valued form of support during early custody^{17, 18}.

One difficulty prisons face is the management of health and security risks associated with psychotropic medicines, including illicit use, bullying and trading, all of which pose particular safety risks. In the community, medical admissions due to adverse consequences of prescribed medication are more frequently associated with psychotropic medication than any other class of drug¹⁹. As prisoners and staff alike acknowledge, some prisoners attempt to deceive healthcare staff to obtain certain prescription drugs without medical

justification to cope, avoid reality, or relieve boredom^{17, 18, 20}. These behaviours place GPs in prisons in a difficult position, facing conflicting pressures from prisoners and the establishment influencing clinical decision making²¹. Medicines management measures used in UK prisons include formularies describing permitted medications, standardised drug regimens and supervised consumption of medication²²; however, practices vary between establishments. Research suggests that polypharmacy (two or more psychiatric medications in the same patient) and off-label prescribing (outside of recommended dose parameters, or for unlicensed indications) are common in psychiatric settings^{23, 24}. Anecdotal evidence suggests that such practices are also observed in prisons; yet there is little formal data regarding prescribing in this setting specifically. From a patient safety perspective this is an important omission; such practices could potentially increase the risk of adverse effects, increasing the requirement to screen and/or monitor patients¹¹. A recent thematic review of mental health by HM Chief Inspector of Prisons raised concerns that psychotropic medication may be over-prescribed in prisons, particularly among certain demographic groups²⁵. Indeed, particular demographic groups (e.g. women and the elderly) may present an especially complex clinical picture in prison, making prescribing decisions regarding treatment for mental disorders all the more difficult.

Reliance on paper medical records and varying pharmacy data management systems in prisons have rendered previous attempts to collect data time consuming and impractical⁹. However, the introduction of SystmOne, a new clinical IT system in common use in community primary care settings, across the prison estate will soon be completed (current coverage approx. 80%), creating a novel opportunity to examine prescribing patterns at a national level. Our current OHRN study has tested the feasibility of using secondary data held in patient clinical records on SystmOne in prisons to establish prescribing patterns in the East of England. To date, we have successfully established a data extraction methodology and secured a large sample of equivalent data from patients in the community as control data (n=30,000). Preliminary analysis has highlighted high rates of psychotropic prescribing, but with variation between prisons. The proposed study will provide a timely opportunity to build on and extend this preliminary work, producing a comprehensive, robust study of prescribing patterns in prisons across England and Wales. This work will also include a systematic exploration of the perspectives of prescribers and patients on prescribing outcomes, allowing for a more contextualised, holistic approach to assessing the appropriateness of prescribing in prisons.

Need

The NHS has fiscal and governance responsibility for providing healthcare services to prisoners, of equal range and standard as available in the wider community. A recent independent review⁴ has brought offender mental health to the forefront of the healthcare policy agenda. Prisoners represent a small proportion of the population, but their burden of mental health need is disproportionately high. For example, in Western countries, severe mental illness is seven times more common in prisoners than in the general population². Due to the increasing prison population, the number of people

with mental illness in UK prisons is higher than ever and rising⁴, thus interest in offender health is highly likely to be sustained. This work is a necessary starting point from which to improve prescribing for mental health problems in this relatively small, but socially disadvantaged population. Due to the vulnerability of patients and the types of medication used, safety issues relating to medication are a particular concern for mentally ill patients. By examining the equity, costs and appropriateness of psychotropic prescribing patterns in prisons, the aims of this study are fully compatible with those of the NHS and the HSR programme.

Most prisoners serve short sentences, with all but a few eventually returning to the community. When not in custody, offenders often lead chaotic lives and contact with healthcare services is commonly sporadic and crisis-led. This type of contact is disjointed, expensive with poor health outcomes. Imprisonment represents a unique opportunity to target a socially excluded population, often unable or reluctant to participate in routine community healthcare services. Historically, research has consistently shown that the majority of mental illness remains undetected and untreated in custody^{26, 27}. Furthermore, many of those previously receiving medicines for mental illness in the community have their prescriptions stopped or changed on reception into custody due to system failures, such as poor information exchange, or fears regarding illicit use¹⁵. Thus, all too often imprisonment is experienced by patients as a disruption in care, causing significant distress^{17, 18}. An NPSA report on medication incidents recommended that prisons should review their medicines management arrangements, in particular systems for the supply of medicines¹⁶.

The Department of Health⁹ has acknowledged that there is 'a lack of reliable, easily accessible data on medicines usage' within prisons and these data were essential to managing the overall clinical, cost effective, and safe use of medicines locally and nationally. A recent thematic review by HM Chief Inspector of Prisons²⁵ made a specific recommendation that prescribing patterns for medications used to treat mental illness should be investigated. This study will explicitly address these recommendations and fill a current knowledge gap by completing the first robust examination of psychotropic medication prescribing patterns in prisons at a national level.

The timing of this funding call has provided a unique opportunity to efficiently build on our preliminary work in the East of England, capitalising on existing datasets, approvals and study management arrangements. The result will be a generalisable, robust and precise analysis of psychotropic prescribing patterns in prisons across England and Wales. We will produce a full report, complete with recommendations for practice, and circulate this amongst NHS staff who work with mentally ill offenders. This will enable NHS commissioners, service providers and offender health teams to benchmark their prescribing activity against national data, informing ongoing improvements to the equity, appropriateness and costs of prescribing and overall care for mentally ill patients in prisons.

Methods

Definition: For the purposes of this study, psychotropic medication is defined as any medication listed in Chapters 4.1-4.4 of the British National Formulary BNF28, which covers hypnotic and anxiolytic (4.1), antipsychotic (4.2), antidepressant (4.3) and stimulant (4.4) medications.

Design

The study comprises two discrete components: 1) an epidemiological survey of psychotropic prescribing patterns, using a cross-sectional design and 2) a questionnaire survey of patients and GPs in prisons to determine expectations of consultations and satisfaction with prescribing decisions.

Sampling

Samples for the epidemiological survey of psychotropic prescribing patterns will be selected using the strategy developed in the East of England study, outlined below. Two patient populations will be sampled: prisoners and GP-registered patients in the community in England and Wales. Within participating prisons, SystmOne will be used to select all patients that meet the following criteria on the 'census day': 1) aged 18 years or over; 2) in prison custody; and 3) has a valid, current prescription for psychotropic medication. The control sample will be drawn from an existing dataset of 30,000 randomly selected community-based patients from the General Practice Research Database (GPRD). The GPRD is the world's largest and most comprehensive computerised database of longitudinal medical records from primary care, collecting data on 5 million active patients from around 590 primary care practices throughout the UK. Patients in this sample have already been selected and met the following criteria: 1) aged 18 years or over on 1 February 2010; 2) alive and registered with a GP in England or Wales continuously over the period 1 Feb – 30 July 2010; and 3) prescribed psychotropic medication at any time during the period 1 Feb – 30 July 2010.

Sample size calculation: Based on our preliminary work, we expect the overall point-prevalence of psychotropic prescribing in prisons and the community to be approximately 26% and 8% respectively, generating a prevalence rate ratio of 3.25. In a comparative study of percentages, the minimum sample size needed to have a 90% chance of detecting this difference as significant ($p=.05$, two sided) is 90 per group. However, to perform the detailed subgroup analyses needed for this study (e.g. the proportion of atypical versus typical antipsychotic prescriptions among Black male prisoners), a much larger sample is required. Based on our preliminary work, we would expect 12 average sized prisons ($n=500$) to generate prescriptions for 720 hypnotics/anxiolytics, 480 antipsychotics and 1080 antidepressants. Existing data from East of England prisons could be added to this. Recruiting at least 12 prisons will therefore ensure that the study is adequately powered, even for detailed subgroup analyses.

The questionnaire study will use a sample of patients attending GP clinics in prison (for any health problem) and their doctors. A subsample of at least two of the Northern prisons that take part in the epidemiological survey will be used. We will sample 1 in 4 GP consultations at routine clinics over a calendar

month at 2 male prisons (one local and one training prison) generating data on approximately 200 consultations.

Setting/context

Data will be collected from at least 12 prisons in England and Wales, comprising approximately 5-10% of the overall prison population. The prisons sampled will be selected to ensure main prisoner types are included and sites are geographically representative.

On the 30th June 2011, the prison population in England and Wales was 85,37429 . This comprised:

- 81,189 men
- 4,185 women
- 12,464 prisoners on remand
- 71,964 prisoners under sentence, of which 37,983 (53%) had four or more years left to serve (including indeterminate sentences)

We will recruit at two female prisons to the study. Although women account for only 5% of the prison population, they are particularly problematic from a mental health perspective. Women are more likely to have pre-existing psychiatric, self-harm and substance misuse problems³ and therefore have different medication needs than men. In a recent study by the OHRN, women were more likely than men to report being prescribed two or more psychiatric medications concurrently¹⁵. In addition, at least two establishments which serve young offenders (18-21) will be included. Young offenders comprise approximately 10% of the prison population and have different mental healthcare needs in comparison to adult prisoners, in particular an increased prevalence of Attention Deficit Hyperactivity Disorder (ADHD) ³⁰.

We will include an equal balance of local and training establishments. Local prisons, which serve the courts and house those awaiting trial or recently convicted, make up approximately half of the prison estate. Such establishments are likely to have different medication issues from prisons with more stable populations, which may affect prescribing patterns. For example, the increased prevalence of mental illness and suicide, the need to engage in medicines reconciliation tasks for newly received prisoners (i.e. verifying and continuing community prescriptions), and to initiate detoxification regimes for misuse of drugs, alcohol and/or prescribed medicines (e.g. long-term benzodiazepine use). In training prisons, however, where prisoners serve longer sentences and medication regimes are more stable, this should offer increased opportunities for health needs assessment, treatment and medication reviews, which may result in better prescribing.

Our preliminary work in the East of England has generated widespread support and enthusiasm and as the national Offender Health Research Network, we have an excellent national group of prison healthcare contacts and the senior management team of Offender Health at the Department of Health, which we will use to recruit prisons. At least 9 prisons nationally (including training, local and female prisons) have already indicated their interest in taking part in this study (evidence of support available on request).

Data collection

Epidemiological survey data will be collected using electronically held prisoner patient clinical records. On census days at participating prisons, we will use SystmOne to identify all patients with a current, valid prescription for at least one psychotropic medication. Prisoner populations are, by nature, transient; most prisoners serve short sentences (<6 months) and at local prisons the turnover of prisoners is high. This creates difficulty in accurately estimating population denominators over periods of time. Therefore point, rather than period, prevalence estimates for psychotropic prescribing are more achievable. 'Live' searches will be used to generate population figures for a single census day. Census days used at each prison will be dependent on access arrangements and will therefore vary across sites. We do not envisage this to be a source of bias as psychotropic medicines are not as susceptible to seasonal trends as other medicines (e.g. antibiotics).

Using SystmOne, the researcher will extract demographic, clinical and prescription data from the clinical records of individual patients that meet the inclusion criteria, including:

- Demographic data: prison, gender, legal status, ethnicity, year of birth.
- Physical and mental health diagnoses, as systematically recorded in the standard prison health screening process that every prisoner undertakes following reception into custody.
- Psychotropic prescription details: drug name, dose, frequency, formulation, indication, information recorded about anticipated drug-drug interactions or unusual doses/durations of treatment, first prescription date in custody, whether the prescription was newly initiated in this prison or continued from a previous prescriber, prescriber, drug cost (net ingredient cost).

Population figures, complete with age breakdowns, will be obtained from each prison's local population database (P-NOMIS) to generate denominators for calculating prevalence rates. Each prison will also be asked to provide copies of local formularies, limited prescribing lists and all policies governing any aspect of prescribing of psychotropic medication. Finally, healthcare managers will be asked to undertake a structured telephone interview to provide information regarding the organisation and delivery of healthcare at the prison. These measures will allow us to contextualise findings with respect to current local approaches and policies on prescribing.

For the questionnaire study, patients attending prison GP appointments at selected sites will be invited to participate in the study. Over the study period, a researcher (LH) will attend prison GP clinics and ask recruited patients to complete pre-and post-consultation questionnaires (adapted from Britten et al.³¹), either themselves or as a structured interview if preferred/indicated e.g. where there are literacy problems. Questionnaires encompass patient reasons for consulting the GP, expectations about the consultation, desired outcomes and acceptability of the actual outcomes achieved. Prison-based GPs will also complete a post-consultation questionnaire, including details of drugs prescribed and indications. The researcher will review patient medical records

and extract relevant supporting information including prescription details, clinical diagnoses, medical history and referrals.

Data analysis

Analyses will be performed using Stata software. Prior to any statistical analysis, preparatory work will be completed to prepare the GPRD and prison datasets. Prison datasets will be checked for data entry errors, duplicates, range checks (to identify outliers and implausible/impossible numerical values) and consistency checks (to check for invalid combinations of values e.g. pregnancy and male gender. Where necessary, continuous variables (e.g. prescribed total daily dose) will be re-coded to form additional categorical variables (e.g. within/outside BNF recommended range).

We will also specify a list of Read/OXMIS codes for use with the GPRD dataset indicative of mental health diagnoses and other measures of co-morbidity. Where possible, we will use pre-defined, validated code lists (e.g. the Charlson Index, a popular summary measure of comorbidity, has been translated into Read/OXMIS codes³²).

Tables will be used to describe the demographic and clinical characteristics of our prison and community samples. A flow chart will be presented to describe the sampling of GPRD patients.

Our analysis strategy will attend to each of our three research questions.

1. What are the patterns of psychotropic medication prescribing in prisons in England and Wales, and how do these compare to those in the wider community?
 - 1.1. Overall rates of prescribing in prison and the community
Gender specific point prevalence psychotropic prescribing rates (percentage and 95% confidence intervals) will be generated for prison and community samples for each BNF subchapter: hypnotics and anxiolytics (4.1), antipsychotics (4.2), antidepressants (4.3) and stimulants and drugs used for ADHD (4.4). Rates will be indirectly standardised for age where appropriate, using the GPRD dataset as the standard population. Indirect standardisation is commonly used in NHS prescribing statistics. It is often more stable than direct standardisation as it minimises variance, giving smaller standard error and narrower CIs. Confidence intervals for prison estimates will be corrected for prison-level cluster effects.
 - 1.2. Subgroup comparisons
Subgroup analyses will then be performed to examine heterogeneity in prescribing rates (percentage and 95% confidence intervals) among particular subgroups, which may be masked by the overall rates yielded in 1.1. This will help to determine possible reasons for any differences between differences in prescribing patterns between prison and the community. Separate tables will describe prescribing rates, stratified by a) geographical region b) socioeconomic status c) prison type (e.g.

local, training, open) d) gender e) age group (youth offenders, adults and older prisoners), f) ethnicity and g) diagnosis (e.g. depression).

1.3. Univariate analyses

Prevalence rate ratios (PRRs) and appropriate univariate statistical tests will be used to test group differences (established in 1.1. and 1.2) for statistical significance. Chi-squared tests will be used for categorical data and t-tests will be used for continuous data.

1.4. Multivariate analyses

Log-binomial modelling will be used to examine multivariate relationships, and to control for any confounders identified. Relationships between a range of prescription outcomes (e.g. drug type, multiple prescriptions) and demographic, clinical and criminological variables. An empirical approach using automated backwards stepwise procedures, or manual backwards elimination, will be used to compile sets of variables for inclusion in multivariate models.

For example, if the proportion of antipsychotic prescriptions which were newer generation (atypical) was 90% in the community and 60% in prison, the PRR would be 1.5. Log binomial regression would then be used to adjust PRRs for potential confounders such as ethnicity, sex and comorbidity. Using PRRs will help to convey findings to clinicians and patients simply, rather than using odds ratios, which can be difficult to interpret and/or be misleading³³.

2. How appropriately are psychotropic medications prescribed in prisons?

2.1. The Prescribing Appropriateness Indicators (PAI)

The proportion of prescriptions issued in prison that meet each of the indicators in the PAI will be used to analyse appropriateness. The PAI is a standardised, validated tool^{34, 35} that is applied to prescribing data held in medical records, so it is suited to assessing appropriateness in larger scale studies. The PAI was chosen as it is a set of explicit indicators requiring comparison with a set of published standards (the BNF) within the context of the individual patient, enhancing both validity and reliability³³. The PAI will be completed for each separate psychotropic medication prescription (excluding indicator 9, about hypertension) and we will report the percentage of prescriptions that meet each indicator:

1. The indication for the drug is recorded and upheld in the BNF
2. The reason for prescribing a drug of limited value is recorded and valid
3. Compared with alternative treatments in the same therapeutic class, which are just as safe and effective, the drug prescribed is either one of the cheapest or a valid reason is given for using an alternative
4. A generic product is prescribed if one is available
5. If a potentially hazardous drug-drug combination is prescribed, the prescriber shows knowledge of the hazard
6. If the total daily dose is outside the range stated in the BNF, the

- prescriber gives a valid reason
- 7. If the dosing frequency is outside the range stated in the BNF, the prescriber gives a valid reason
- 8. If the duration of treatment is outside the ranges stated in the BNF, the prescriber gives a valid reason

In order to guide clinicians, we will not only describe the percentage that did not meet each criterion, but also describe the nature of common 'errors' in prescribing. These will depend on the nature of the errors observed, but may include:

- The drugs most frequently associated with no recorded indication, or an inappropriate indication
- The most commonly prescribed hazardous drug-drug combinations
- The most commonly prescribed drugs with a total daily dose a) above and b) below the range stated in the BNF

2.2. Other guidelines (inc. NICE)

We will also review up-to-date relevant NICE guidelines to identify any other appropriate, measurable standards that may be applied to prescribing, including guidelines for anxiety, depression, bipolar disorder and schizophrenia³⁶⁻³⁹. During the preparation phase of our timescales (months 1-4), the team will decide which NICE guidelines are relevant, review the most up-to-date versions of these and, where possible, extract measurable standards to include in our data extraction sheet.

For example, NICE guidance clinical guideline 82 (Schizophrenia³⁸) states: "Do not initiate regular combined antipsychotic medication, except for short periods (for example, when changing medication)." Therefore, the data extraction sheet could measure adherence by including:

- Is the patient receiving more than one antipsychotic medication?
- Is this documented as a changeover period?
- How long has the patient been receiving more than one antipsychotic medication?

We will also identify the proportion of older adults (aged 65 and over) in prison prescribed potentially inappropriate medication using the Beers criteria⁴⁰. The Beers criteria, a list of medications potentially inappropriate for older adults, was developed on the basis of expert consensus and extensive literature review, and has been widely used to survey clinical medication use and to decrease health problems associated with prescribing in older adults.

2.3. Prescribing costs

Costs of prescribing will be assessed by calculating the Net Ingredient Cost (NIC) for each individual psychotropic medicine using the prices in the NHS Drug Tariff. Analyses will examine:

- The mean NIC per prescription and patient
 - The proportion of prescriptions where generic products are prescribed (PAI, Indicator 4)
 - The prevalence (%) of 'unnecessary' prescriptions (i.e. those without a documented indication) that are prescribed (PAI Indicator 1).
3. How acceptable are psychotropic medication prescribing decisions to patients and GPs in prisons?

The questionnaire study specifically attends to this aim . We will identify:

- The proportion of patients that prior to the consultation wish to start, change or stop a psychotropic prescription.
- The proportion of patients that following the consultation: received a prescription; were satisfied with the consultation; and were happy with the prescribing decision.
- The proportion of doctors that following the consultation: were satisfied with the consultation; felt pressured to write a prescription; and felt comfortable with the prescribing decision (including the decision to prescribe nothing).
- The proportion of prescriptions that were unwanted (by the patient); and not strictly indicated (in the doctor's opinion).

For all of the above, differences between consultations involving psychotropic versus other types of medication will be compared (chi squared tests) and multivariate predictors of satisfaction will be identified (using univariate and multivariate log-binomial regression).

Contribution to collective research effort and research utilisation

The main output of this research will be a detailed report describing prison prescribing patterns compared to community practices, filling a significant and widely recognised knowledge gap and adding to the limited body of knowledge around prescribing in prisons. The final report will include the following sections:

- Background literature on policy and research relating to prescribing and the treatment of mental illness in prisons
- Rates of psychotropic prescribing in prisons, nationally and within regional and demographic subgroups
- Equity of prescribing between prison and the community
- The appropriateness of psychotropic prescribing in prisons
- Common errors in psychotropic prescribing in prisons
- Acceptability of prescribing to patients and GPs in prisons
- Discussion of implications for patient safety, equivalence and quality of prescribing
- Recommendations for practice, audit and research

The report will be made available for download (free of charge) on the OHRN website. Findings will be reported in a clear yet robust style, accessible to practitioners and academics alike. The report is intended for use as a resource to assist policy-makers and practitioners with planning, comparing

and benchmarking prison prescribing activity. We will publicise and disseminate this report widely amongst OHRN's extensive network of contacts, including the senior management team of Offender Health at the Department of Health, with whom we have established links.

Five regional seminars will be delivered throughout the UK to disseminate findings amongst prison clinicians and the NHS offender healthcare management community. The seminars will be run free of cost to delegates (50 places per seminar) to maximise attendance and will be run at University, NHS or HM Prison Service sites. Seminars will include presentation of key findings with dedicated time for questions, open discussion and ideas for improving practice.

Appropriate versions of the report will be produced for different audiences including NHS managers, pharmacists and academics. Summaries will be prepared especially for patients (with help from patient representatives at the Mental Health Research Network). Findings will also be disseminated via scientific papers in peer-reviewed journals, at conferences, and other relevant stakeholder events.

The study is supported by the Offender Health Research Network (OHRN), which has an excellent track record of engaging NHS stakeholders, delivering and disseminating research outputs, contributing to policy debate and impacting directly on NHS practice and service delivery in this area. In this context, there is a real opportunity for this study to inform improvements in care. Notably, OHRN research informed the recent high-profile Bradley Report⁴ and resultant DH offender mental health strategy⁴¹ developed in response which made the case for offender mental health service reform. Currently Offender Health are in the process of forming themed workstreams to support the ongoing modernisation of offender mental healthcare post-Bradley. These workstreams are likely to include themes such as mental health services and primary care, which the findings of this project could directly inform and contribute towards.

Plan of investigation and timetable

Month Activities

- 1-4
 - Establish study steering group
 - Update prison prescribing data extraction sheet to include standards from NICE guidelines
 - Obtain NIGB approval to collect prescribing survey data without patient consent
 - Adapt patient and doctor questionnaires developed by Britten et al (2003) for use in prison
 - Update NHS, ethics and NOMS (Prison Service) approvals to include changes to protocol
- 5-13
 - Recruit prisons
 - Prescribing data collection
 - Input prescribing survey data
- 10-13
 - Recruit prisons to questionnaire survey
 - Questionnaire survey data collection

- Input questionnaire survey data
- 14-18 • Data analysis
- Report writing
- Develop patient and practitioner summaries
- Dissemination of findings (inc. regional seminars)
- Preparation of journal papers and conference abstract.

Approval by Ethics Committees

The East of England prescribing study has been approved by Northern and Yorkshire REC (Ref: 09/H0903/54), including approval to use GPRD data in combination with prison prescribing data, confirming the feasibility of our current proposal. We will submit the additions and improvements to the study protocol as amendments to our existing approvals (1 and 2) or as a new application (3):

1. The addition of further prison sites throughout England and Wales.
2. Additional data items on prescribing to the epidemiological survey (prescribing appropriate indicators and standards from NICE guidelines) to improve assessment of quality.
3. A new questionnaire survey component to address acceptability of prescribing to patients.

In addition, we will apply for National Information Governance Board (NIGB) approval (under Section 251 of the NHS Act 2006) to access patient identifiable data without consent as part of the epidemiological survey. It is not practicable to seek consent from individuals for this part of the study for two reasons: the large sample sizes involved (whole prisons) and the difficulty in accessing a transient population. Previously, prison healthcare staff completed the data collection and sent anonymised data to the research team; however, we feel collecting it ourselves would improve the speed, efficiency, quality and completeness of data collection, without increasing costs or impact on NHS services. We hold NIGB approval for 4 previous offender health research projects and are thus experienced applicants. NIGB have confirmed that a fast track application would be possible (approx 2 weeks); we will apply for this for the East of England study to confirm feasibility of procedures, guaranteeing a smooth start to the work if funded (HSR will be informed of any outcomes shortly).

Project management

The steering committee will meet in the first month of the study and quarterly thereafter to monitor progress and assist with troubleshooting, if required. Members will advise on the questionnaire adaptation, application of the PAI tool, analysis strategy, interpretation of the findings, study final report and dissemination. The committee will comprise the applicants, advisers and a minimum of 2 service user representatives. The latter will be drawn from contacts within the OHRN and/or MHRN.

Service users/public involvement

Involving service users in offender research in a meaningful way is challenging and has, historically, been uncommon. One of the principal goals of the MHRN is to actively promote the involvement of service users, carers and frontline

staff in mental health research. The East of England study has been adopted by the MHRN and has provided help with producing lay summaries of the study protocol and advice on involving service users. We will continue to draw on their wealth of experience, contacts and resources to develop a strong sense of service user involvement in this study.

Service users at HMP Kennet reviewed our preliminary East of England study and their suggestions were incorporated into the protocol at the design stage. We have sought advice from a MHRN service user development officer regarding a model of involvement for the current study. On their advice, we will establish a service user reference group of 3 individuals with personal experience of mental health problems and/or imprisonment. These will be drawn from MHRN and/or OHRN's network of contacts and existing service user groups – members of the North West Service User Research Panel have already expressed an interest in participating. The reference group will meet on a quarterly basis, prior to steering committee meetings, to review study procedures, help design study materials (patient questionnaires and information sheets), write summaries of findings and assist with dissemination. Representatives from the reference group will attend the steering committee group to feedback as and when required. This combination will empower service users to make focused contributions in an informal setting, without necessarily having to attend every steering group meeting. Service users will receive payment for participation within these groups in line with MHRN and INVOLVE guidance. We will also visit established 'patient forums' in participating prisons (which meet regularly to give feedback on healthcare services) as a means of consultation, communication and dissemination among prisoner patients.

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