RESEARCH PROTOCOL: Evaluating the Use of Patient Experience Data to Improve the Quality of Inpatient Mental Health Care (EURIPIDES)

Part 1

<table>
<thead>
<tr>
<th>Aims, objectives &amp; research questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure the patient voice is heard, NHS Trusts are required to collect feedback from patients routinely. We do not know what kinds of feedback are most important or what management processes are needed to translate this into effective action plans, and we do not know if this makes any difference to patients themselves. Every Trust in the country collects patient feedback data, and in some case they have spent years setting up local systems for this. It is very unlikely that new top-down methods for collecting patient experience data would be readily and widely adopted because this would mean abandoning what Trusts are already committed to doing. So instead we view the wide range of current approaches as a natural experiment from which we can learn about what is (and isn’t) working. We believe that there are differences between organisations use of patient experience data to improve and inform service development and we are curious about the variety of ways in which this is being undertaken.</td>
</tr>
<tr>
<td>The overall research question for this proposal is “which of the many different approaches to collecting and using patient experience data are the most useful for supporting improvements in inpatient mental health care?”</td>
</tr>
<tr>
<td>This project proposes to look specifically at how patient experience and feedback is managed in inpatient mental health care settings, as this is where many mental health service users report that they have had bad care experiences. Inpatient units are very expensive to run and can be unwelcoming, disturbed and frightening places. Self-harm, suicide and violence are common, and it is well known that people of Black ethnicity are more likely than other ethnic groups to be admitted to hospital.</td>
</tr>
<tr>
<td>The proposed research has 5 work packages that are linked to the 5 study aims: After completing a systematic review to identify patient experience themes relevant to mental health care (Aim 1), we will identify, describe and classify approaches to collecting and using patient experience data to improve inpatient mental health services across England (Aim 2). We will use this information to choose 6 Trusts around the country for in-depth case studies where we will carry out interviews to find out what works for whom, and where (Aim 3). We will look particularly for evidence of meaningful service user and carer involvement, and for service improvement activity. We will present our findings to experts (including service users and carers) at a ‘consensus conference’ to agree on recommendations about best practice (Aim 4). We will ensure that our results are anchored in what is acceptable, feasible and sustainable in real-world NHS settings. Finally, we will use health economics to predict the costs that would arise (and savings that might occur) if ‘best practice’ in collecting and using patient experience data was widely adopted, and we will speak to senior NHS colleagues to explore obstacles to adopting best practice (Aim 5).</td>
</tr>
</tbody>
</table>

General information

This research is being led and sponsored by the University of Warwick. The Chief Investigator is Professor Scott Weich (s.weich@warwick.ac.uk) who is responsible for all aspects of study design and delivery. There is a research team supporting the project based at the University of Warwick, with researchers also located at the University of Birmingham and Queen Mary University London. The research is being conducted in partnership with the Mental Health Foundation who are leading on Patient and Public Involvement for the project and are involved in each Work Package (WP).
Background & rationale for EURIPIDES study

The NHS is under unprecedented pressure to deliver timely, effective and affordable care with increasingly constrained resources. At the same time there is growing concern about suboptimal care (1-5) and failure to treat patients with compassion and respect (5, 6). As a result, NICE, the NHS National Quality Board and others have re-stated the core principles of patient-centred care including dignity, compassion, choice and autonomy (4, 7-11) and called for a strengthening of the patient voice. Healthcare providers are required to collect data to assess patients’ experiences of care (12, 13). However, despite a surfeit of routinely collected patient experience data (14, 15), most are of limited value (16) either because of methodological problems (including poor or unknown psychometric properties or missing data) or because existing measures lack granular detail (17). And there is a dearth of evidence about the processes required to analyse, interpret and translate these data into tangible actions, better outcomes for patients and more efficient and cost effective care (16, 18).

It is not known whether reporting patients’ experiences is associated with improved outcomes (including clinical and functional outcomes and quality of life), reduced carer burden, or reduced costs (19, 20). Nor do we know how any effect might be mediated (e.g. via better treatment adherence), or which types of patient experience data are of most use for improving services (3, 16, 19, 21-23). The proliferation of diverse but often uncoordinated initiatives to collect and use patient experience data means that new and more theoretically coherent approaches must compete for space on operational agendas. It is unlikely that organisations which have invested in local solutions are going to jettison these readily. More needs to be known therefore about what NHS organisations are doing currently to capture and use patient experience data, and what is (and is not) working well, and why.

We believe that there will be discernible differences between organisations that demonstrate genuine commitment to, and capacity for, using patient experience data to improve services (8), and that these differences will be most clearly manifest through the existence of processes that support innovation and quality improvement (24-26), including commitment to service improvement among senior leaders, decentralised decision-making (through identifiable champions for change), role clarity within the organisation, and support for risk-taking (27, 28). We expect that organisations that set out to improve care quality will be able to evidence of methodologies for achieving this, including clear cycles of planning, implementation and reflection as opposed to small, piecemeal initiatives (8). Organisations that innovate also value information, and we anticipate that those who use patient experience data most effectively will also be the ones with the most robust data collection strategies. Finally, we believe that organisations that are genuinely patient-centred will also demonstrate investment in and adoption of co-design approaches to service improvement, and will involve service users and carers meaningfully, as partners. Feedback from patients can be perceived as critical or threatening by professionals, and may be avoided or denigrated. Co-design is a partnership approach that neutralises perceived threats through collaborative working to find mutually agreeable solutions to problems or difficulties experienced by patients when receiving care (29-30).

Experiences of in-patient care

We have chosen to focus on inpatient mental health services because these are currently overstretched, unpopular with service users (31), expensive and where serious incidents such as suicide continue to occur. It is also the setting in which ethnic inequalities in mental health service experience are most pronounced (32). Recent reports (33-35) have highlighted a number of adverse experiences, particularly a lack of privacy and dignity (particularly on the remaining mixed sex wards), fear of assault, overcrowding, noise, lack of therapeutic activities and limited individual recovery-focused support (including preparation for discharge), and an
emphasis on coercion, control and restraint. There is consistent evidence that patients of Black ethnicity (including both African Caribbean and Black African groups) are over-represented in in-patient settings, receive higher doses of medication and experience higher rates of seclusion, physical restraint and injury (36) and suicide (37). Many people who receive inpatient mental health care do so while compulsorily detained (35). As well as the importance of studying a group that is often overlooked, identifying effective ways to obtain feedback from people who feel disenfranchised and powerless is likely to highlight robust processes.

Three notable initiatives to raise standards and improve the patient experience are Star Wards (http://www.starwards.org.uk), a third sector initiative that uses patient experience information to develop and share best practice; Productive Wards (25), led by the NHS Institute and focusing on the adoption and spread of lean working; and the Royal College of Psychiatrists' Accreditation for Inpatient Mental Health Services (AIMHS) scheme, based on evaluation against a quality standard (38). Although the great majority of NHS providers have participated (to a greater or lesser extent) in one or more of these initiatives, concerns remain about the quality of inpatient care (39). These are reinforced by recent evidence that rates of detention under the Mental Health Act are increasing among patients initially admitted voluntarily. This indicates that consent to treatment is increasingly being withdrawn among patients after being exposed to in-patient environments (35), and supports the view that inpatient mental health services remain in need of improvement. We will pay particular attention to the four domains identified by the NICE Quality Standard which apply particularly to inpatient care: shared decision-making, contact with staff, meaningful activity and use of compulsion (including control and restraint) (7).

**Study design**

There are 5 proposed work packages in this study: systematic review (WP1, Aim 1); survey of all 56 NHS providers of inpatient mental health care who are responsible for at least 50 adult mental health beds in England to populate a sampling frame for WP3 (WP2, Aim 2); in-depth case studies selected using WP2 findings, analysed using a realist approach (WP3, Aim 3); consensus conference to agree recommendations about best practice (WP4, Aim 4); and health economic modelling to estimate resource requirements and barriers to adoption of best practice (WP5, Aim 5). This work will take place across all parts of England and WP3 sites will be chosen to ensure geographic diversity.

**Methods of data collection**

After completing a systematic review to identify evidence-based patient experience themes relevant to mental health care (Aim 1, WP1), we will identify, describe and classify approaches to collecting and using patient experience data to improve inpatient mental health services across England (Aim 2, WP2). This will be achieved through conducting telephone survey interviews with Patient Experience Leads in all NHS Trusts providing adult in-patient care. We will use this information to sample diverse sites for six in-depth case studies (Aim 3, WP3), where we will undertake interviews with those who deliver and receive these services. This section details the methodology for Work Packages 2 & 3, investigating Aims 2 & 3 for which ethical approval is required.

**WP2 – survey of Patient Experience Leads in NHS Trusts**

The aim of WP2 is to generate a sampling frame for identifying and recruiting sites for WP3 case studies. We will survey providers of NHS inpatient mental health care in England and undertake telephone interviews with the identified leads for Patient Experience. We will use data from these interviews to create and populate a typology of providers based on organisational characteristics and approaches to collecting and using patient experience data to improve in patient services. We will explore their experiences of collecting and using patient experience data. We will identify which types of patient experience measures and organisational processes facilitate effective translation of these data into service improvement actions.
**Sampling and recruitment**

Our sampling frame will be all NHS providers of inpatient mental health care who are responsible for at least 50 adult mental health beds, including specialist mental health trusts. We will identify the nominated Patient Experience Lead from each provider, whom is likely to be either the CEO or a nominated senior Operational manager. In some instances more than one person may hold the portfolio for Patient Experience. In this case, the persons identified will all be interviewed. Participant information and consent forms will be sent in advance of telephone interviews. Study aims and design will be explained in the participant information sheet and will be reiterated prior to telephone interview, when participants will be asked for permission to re-contact them to discuss participation in subsequent work packages.

**Participant recruitment**

Data will be collected by means of a questionnaire and semi-structured telephone interview. The former will be used to collect information about provider organisations, including location and size (annual budget, number of staff), and inpatient services (number, location, ward type, bed numbers and length of stay). We will ask about methods for, and frequency of, collecting patient experience data from users of inpatient services) and details of ways in which these data are processed (and by whom), and fed into service improvement fora. The latter will also be the subject of telephone interviews, which will explore these areas of activity in more detail. Where appropriate, we will ask for copies of any questionnaires or other data collection tools used, as well as examples of reports arising from the collection of patient experience data. We will use the framework for classifying patient experience data collection methods developed by the Health Foundation (40), which is based on the two dimensions of ‘descriptiveness’ and ‘generalisability’.

We will explore in as much detail as possible the content of any data collected. In order to ascertain ways in which these data are used, we will ask questions about who is responsible for data collection, cleaning, analysis and reporting, and to whom these reports are passed. We will ask about how often these data are collected and their results reviewed, and whether the participant can provide us with information about any actions that have occurred in response to any patient experience findings. We will also ask whether Trusts provide support for those without fluent English to provide patient experience input.

Telephone interviews will be used to review and clarify (and fill in any gaps) arising from questionnaire responses, or (where appropriate) to complete this by telephone where no postal response has been received. Participants will be asked about perceived strengths and weakness, costs, benefits and sustainability of patient experience data collection methods, about the organisational narrative and rationale for arriving at their chosen approach, about service user involvement, integration with strategic priorities and whether there is evidence of impact. We will ask about organisational processes that facilitate or hinder translation of patient experience data into tangible service gains, and about participation in national mental health inpatient service improvement programmes. Analysis of WP2 data will populate a sampling frame for WP3 (see section on data analysis).

**WP3 – six in-depth case studies in NHS Trusts**

We will survey and evaluate current approaches to collecting and using patient experience data to improve inpatient mental health services, and to study purposively selected sites in depth using a realist case study approach (41) to identify what works where and why. Ours is a deliberately bottom-up approach, in which we will treat the wide range of current approaches to collecting and using patient experience data as a natural experiment in which to learn about what is (and is not) working. We will search for evidence of service user and carer involvement and evidence of potential impacts in the form of service improvement activity.
**Site recruitment**

Our sampling frame will be the NHS service providers responding to the survey in WP2 and who consent to being re-contacted. This has several advantages: (i) we will sample based on survey responses to achieve diversity specific to the issues of interest; (ii) we have information about case study sites that will assist us in planning data collection; and (iii) providers have expressed interest in the project. We will select inpatient units within provider organisations after familiarising ourselves with WP2 findings and publically available information (e.g. Trust websites and CQC reports) and in discussion with WP2 participants. Final selection decisions will be made following initial site visits.

Our estimate of 6 case studies is based on sampling at least one of each type of case (i.e. based on the three-level provider classification developed in WP2, above). We will ensure diversity on provider size and location, including geographical spread, urban/rural setting and ethnic diversity in the population served by providers. We will focus data collection around a single inpatient ward or unit in each participating provider, to be selected in discussion with the senior operational manager.

**Participant recruitment**

For each case study site, the research team (including a service user researcher) will meet staff in charge of the inpatient unit, to explain the study and plan data collection including discussing any resources staff will need to have to hand in order to provide an informed interview (e.g. reports, meeting minutes). If the team are happy to proceed we will make plans with the team for when to start the data collection (usually within approximately 6 weeks once all Research Governance arrangements are in place) and plan details of recruitment processes for staff and patients to ensure they fit with the routines of the study site.

Service user (patient) interviews will be undertaken by a service user researcher or a member of the research team, all of whom will ensure arrangements for data collection are sensitive to inpatients’ situation and needs. Where service user (patient) and carer interviews are undertaken by service user researchers, all of the identified individuals who are service user researchers will have been trained to undertake interviews and have extensive experience of this. All interviewers will be mentored by experienced members of the project team. Interviews with service users and staff will be demanding and require considerable skill.

Data collection will usually be undertaken during approximately three weeks for each case study (spread over 4-5 weeks to allow time for initial data analysis). During this time posters and leaflets about the study will be displayed in the in-patient setting so that staff and patients are aware that the study is going on and the identity of the project team members collecting data. Data collection will continue until saturation is reached within each case study. We estimate up to 25 interviews per case study site, split between service users, staff and carers. These semi-structured interviews will be audio-recorded (with participants’ permission) and transcribed. If a participant does not wish to be audio recorded, field notes will be taken of the interview. Reflective field notes will be taken by researchers about the inpatient unit and content of interviews. Resources that support interviewee responses such as reports and meeting minutes will be collated where possible.

Interviews with staff: We will interview those working on in-patient wards (lead clinicians and team managers), operational managers and Trust leads (for Patient and Public Involvement, Inclusion, Quality and Patient Experience, as appropriate) about how patient experience data are collected and used, enablers and barriers to their collection and use, and how the wider service context (deprivation, bed shortages, rates of complaints and serious incidents, culture of service improvement) influences attempts to collect and use these data. Interview schedule...
development will be informed by the results of WP1 (to permit evaluation of the content of patient experience data being collected) and by the literature on features of health care organisations associated with quality improvement (24,25). Sampling will be purposive to ensure those with relevant knowledge and experiences are interviewed. We will timetable interviews to minimise disruption to service provision. Interviews with senior operational managers identify and explore evidence for organisational processes that support quality improvement, including decentralised decision-making, role clarity, senior support for risk-taking and existence of processes for planning, implementing and reflecting on service change. We will seek to ascertain the extent to which processes for collecting patient experience data are systematically linked with their analysis, interpretation and dissemination, and with planning and implementing service change.

Interviews with service users and carers: We will interview service users and a small number of carers to explore whether and how patient (and carer) experience data are gathered, and perceptions about how valid this is as a means of improving service delivery. Sampling will be consecutive on data collection days. Inpatients for whom discharge is planned during the data collection period and who are considered by the clinical team to have capacity will be approached for interview by a member of staff of the NHS Trust (a research nurse or member of the clinical team). If they are prepared to consider being interviewed their name will be passed to the project team who will then arrange a time and place for the interview. Interviews will be held in a private room and the confidential nature of the interview explained carefully as service users may be wary of making negative comments about their health care. We will follow an appropriate and culturally-sensitive process of obtaining the participant's signature on the informed consent form. Where required, the use of qualified and trained interpreters will be offered and provided during the interview.

Participants will be asked about opportunities they have had to tell providers about their experiences of inpatient care (or caring for someone who was an inpatient) and about their perceptions of these processes (if any) and their usefulness and perceived validity. We would expect current service users to be aware of how patient experience data is collected (where it is collected) but they may not be aware of how it is processed and whether it has had any impact. We will however enquire about whether those using services are aware of any channels through which service user feedback is shared and/or acted on, including Trust websites or social media accounts. As complaints and compliments are methods for collecting information about patient experience, we will explore the ease or otherwise of making complaints and whether and how outcomes are fed back, and whether, why and how patients give compliments. During these interviews patients may describe their inpatient experiences. This provides contextual data and will be used to aid the interpretation of their responses to the interview questions about the collection and use of patient experience data.

Where an inpatient unit has a service user forum we will seek to interview participants. Such groups tend to have a longer term view of patient experience data collection and use, and those active in patient groups may not represent all service users. We will ask other service users that we interview about their reasons for attending (or not attending) these groups.

WP4 – Consensus conference
The aim of WP4 is to achieve expert consensus about best practice in the collection and use of patient experience data to improve inpatient mental health care, given the current state of knowledge. We will undertake a consensus conference with stakeholders where the questions will be: What are the optimal ways of collecting patient experience data, and what processes (in terms of analysis, reporting, interpretation and action planning) are necessary to ensure that patient experience data are used to deliver tangible improvements in the quality of inpatient
mental health care? Based on experience of current practices, what recommendations (for collecting and using patient experience data) would those who commission and deliver specialist mental health care be willing and able to adopt? What contextual factors are important to consider? Are there any types of activity in this area that Trusts should be advised to discontinue? Are there ways of collecting and using patient experience data that have not been attempted within the UK NHS and why haven’t they been attempted? What additional research is needed?

**Participant recruitment**

Participants will be individuals with expertise in inpatient mental health care and the use of patient experience data (clinicians, Trust Executive Directors & operational managers, commissioners, service users and carers). We will aim for 20-30 participants, to be recruited through approaches to relevant charities nationally (Health Foundation, Mind, Kings Fund as well as the Mental Health Foundation who are partners in this research), NHS Confederation, NHS England, Royal College of Psychiatrists, Picker Institute and (other) experts who have published in this field. We will provide translations of conference papers and simultaneous translation of conference proceedings on the day (if required) to enable participation of service users and carers whose first language is not English.

**WP5 – Economic modelling of costs associated with the different ways of collecting and using patient experience data to improve inpatient mental health services**

The aim of WP5 is to estimate the costs associated with different ways of collecting and using patient experience data to improve inpatient mental health services, as identified in WP3 and discussed in WP4. We will identify, for each of the case studies undertaken in WP3, the impact on health service resource use of processes for the collection and use of patient experience data. WP3 will involve the collection of data that provide a detailed description of the processes in place at each case study site for the collection, analysis and interpretation of patient experience data. This will include information on the number and grade of staff members involved in such processes, and the infrastructure in place to support them. A questionnaire will be developed for use within the semi-structured interviews with case study staff. This questionnaire will ascertain the staff time and other resources required to deliver patient experience data collection processes. All staff identified as being involved in patient experience processes will be asked to complete this questionnaire as part of the interview process. Data from the questionnaire will be used to calculate the costs associated with implementation of these processes, using standard sources of unit cost data (e.g. NHS reference costs). Qualitative data from the full interview transcripts will also be reviewed to identify additional burdens placed on service resources beyond those recorded in questionnaire responses, to achieve an estimate of the total cost associated with different types of processes. We will identify the drivers of variation in costs across case studies, and provide these findings to attendees of the consensus conference to assist their discussion of optimal approaches to patient experience data collection.

We will not have sufficient data on the long-term impact of such changes on relevant outcomes to support a formal cost-effectiveness analysis of implementing best practice processes for the collection and use patient experience data. We recognise that implementation (i.e. changing how patient experience data are collected or used) may be challenging at a local level given local objectives and resource constraints. Instead, we will develop conceptual models to represent the proximal impact of improved collection and use of patient experience data collection, and how these proximal impacts might result in long-term changes to patient health and their utilisation of health and social care.
The conceptual modelling exercise will draw on data and insights gathered from the six organisational case studies analysed in WP3. Conceptual modelling involves identifying a structured set of activities, and relations between them, that describe a system (42). We will construct conceptual models for each case study drawing on information collected during interviews conducted in WP3. This information will include details of activities that are conducted to collect patient experience data, changes that have been, or might be, implemented as a result, proximate impact on patients or the organisation of such changes, and the implications of these impacts for patient health and service organisation. The conceptual models will provide diagrammatic representation of the causal chains linking patient data collection with changes to patient experience and health outcomes, and health service resource use. These conceptual models will be further refined through discussion with operational and clinical decision-makers, so they can be used to inform selection of outcomes and data gathering activities for subsequent economic evaluations. They will be also be used as the basis of discussions with operational and clinical decision-makers at the consensus conference to capture their views on the evidence required to justify adoption of best practice processes.

Data management and analysis

Primary interview data collected from semi-structured interviews with participants will be audio-recorded (with participants’ permission) and transcribed. If a participant does not wish to be audio recorded, field notes will be taken of the interview. Reflective field notes will be taken by researchers about the inpatient unit and content of interviews. Resources that support interviewee responses such as reports and meeting minutes will be collated where possible.

Data management:
All interviews that were audio-recorded will be transcribed and anonymised (ID number only). Field notes will be transcribed and anonymised. Data from each case study site will form a dataset for analysis. Data will be uploaded into NVivo 8 software to aid with thematic analysis. The data for all WPs will be held securely at the University of Warwick.

The Chief Investigator Professor Scott Weich is the named data custodian for the study. The data will be retained for 10 years in line with the University of Warwick’s Research Data Management Policy.

Data analysis:

WP2
Analysis of WP2 data will be largely descriptive and designed to populate a sampling frame for WP3. We will classify participating service providers into four categories using ratings on two dimensions: ‘patient experience data collection’ and ‘patient experience data use’, each of which will be dichotomised as ‘limited’ or ‘extensive’. Ratings will be made independently by two reviewers and any discrepancies discussed and resolved. By definition, no providers will be classified as ‘limited patient experience data collection, extensive use’, and all providers will therefore be allocated to the remaining three categories, namely (1) ‘limited data collection, limited use’; (2) ‘extensive data collection, limited use’; and (3) ‘extensive data collection, extensive use’. We anticipate that most providers will be allocated to categories 1 and 2. To sample for WP3 we will stratify the above classification by size of provider (small, medium and large) and location (urban versus others).

WP3
Analysis stage 1: Initial analysis will be undertaken after the first week of data collection. We will examine our data, mapping processes described for collection and use of patient experience data and service users’ and carers’ awareness of and perceptions of this process. The health economics team will consider whether the data provides them with the details they require for later modelling of the resource use associated with best practice in collecting, interpreting and
acting on patient experience data (pending the outcome of WP4). We will write a summary of each case study site in relation to the collection and use of patient experience data. We will consider whether we have data on the collection and use of the range of patient experiences identified in WP1. We will then return to the site for a week to undertake further interviews. We will check our understanding of what happens at each site with staff and service users, seek to fill gaps in our understanding, probe further where appropriate, and continue sampling and interviewing until we are confident of data saturation.

Analysis stage 2: Data will then be analysed using a realist approach (43) to identify what does (or does not) work well where, when and for whom. This approach is appropriate for understanding whether and how a complex intervention (collecting and using patient experience data) is effective in achieving its desired aims (improving service quality), allowing for (and making use of) contextual variation in implementation and outcome. Analyses will seek to identify which data collection methods and which organisational processes are most effective in (i) capturing the different aspects of patient experience identified in WP1; (ii) in which types of setting; and (iii) are most likely to result in plans and actions that have the greatest potential to enhance service delivery. Data will first be analysed case by case. For each case we will:

a) Undertake thematic analysis (44) to identify the desired aims and outcomes for the intervention (collection and use of patient experience data) as perceived by staff and patients, and to explore variation within and between groups.

b) Summarise the context for each inpatient service (e.g. case mix, locality, service improvement record of the organisation). We will iteratively develop a template for summarising contextual factors.

c) Refine Stage 1 mapping of processes used for collecting and processing patient experience data through interrogation of the whole case dataset (45).

d) Identify the perceptions of staff and patients about the processes for data collection, use and impact of patient experience data through thematic analysis.

Thus for each case, we will identify contextual factors, processes for collecting and using patient experience data, including the type of data collected and the results of this collection and use including evidence of service improvement activity and its effect. We will then undertake cross case comparison to identify common and idiosyncratic configurations of what works, where, and why (41, 45).

**WP4**

Conference participants will be provided with information in advance, including the results of prior WPs and the consensus questions in a form suitable for Nominal Group Technique (NGT) (62). Mini-presentations at the start of the day will act as a reminder. A skilled facilitator (FG) will lead initial discussion. For each question, three NGTs will then be run separately, led by trained facilitators with an assistant, with different participants (9-12 participants per NGT group) to reduce the effect of variation in group composition. Participants will each take part in up to three NGT exercises. Each NGT will involve an initial round of input from the participants followed by private ranking. Rankings will be tabulated and re-presented for discussion and further ranking. Final rankings will then be tabulated. Finally, results from all of the NGTs will be presented to the whole conference for final discussion until consensus is reached. For any questions where a lack of consensus remains, NGT will be used to finalise consensus. If we are unable to achieve final consensus on the day, we will augment WP4 by employing a Delphi process after the consensus conference. We will do this within one week of the conference, to ensure issues are still fresh in people’s minds.
WP5
The first stage of the analysis for WP5 will involve reviewing initial data collection for each case study site in WP3 to determine whether sufficient details has been obtained of patient experience processes to enable them to be costed. This will include information on who is involved in these processes, what activities are involved (e.g. meetings, production of reports) and how often they occur, and whether there are specific systems or costs other than staff time involved. Any queries raised through this analysis will be passed back to the WP3 team for resolution. Once complete, health economic questionnaires will be administered as part of the interview process to all staff members involved in patient experience data processes. These questionnaires will solicit information on the time involved in patient experience activities, which will be combined with unit costs to calculate the monthly direct health service cost of patient experience data collection at each site. Data will also be obtained on patient list size at each site to allow estimation of cost per service user of patient experience activities at each site.

Qualitative data from WP3 will also be reviewed to extract information on any service changes, implemented or proposed, that resulted from patient experience data collection. This information will include the proximate aims of the service change, and the causal steps through which this would result in changes to health care resource use and/or patient health and wellbeing. The information will be used to develop conceptual models representing the pathways through which patient experience processes result in changes to cost and patient benefit, and identify service or clinical outcomes that could be measured to inform future evidence-based assessment of the effectiveness and cost-effectiveness of patient experience processes. Clinical expertise within the research team will be sought to review and extend the conceptual models produced from WP3 data by the health economics team.

Ethical considerations
This research is neither invasive nor designed to be intrusive.

WP3 involves interviews with a patients, staff, and carers (35 in total at each of the six case sites, so 210 people in the wider study). The project team is aware that all research impacts on those individuals whom are approached to participate and who do participate in it. This study is not designed to explore patients or carers experiences of inpatient services, rather it seeks to understand their experience of being asked about how they found inpatient services. It is recognised that in order to demonstrate their understanding they may draw on wider themes related to the inpatient setting and describe their experiences, however, it is not the explicit aim of the research to ask any questions of a personal or sensitive nature. Care will be taken to ensure that participants are offered the opportunity to be supported at interview by a person of their choosing (either a carer or professional) should having someone else present make them feel more comfortable. Participants will be fully briefed as to the purpose of the research and confidentiality will be assured except in the case a disclosure is made. Participants will be made aware that the research will not in any way impact their care and treatment plan.

The research poses ethical issues in relation to:
1. Ensuring anonymity and that adequate consent has been obtained.
2. Working with participants who may be identified as being a vulnerable group due to their mental health issues.
3. Minimising possible distress of participants when interviewing.

Management of risks:
1. We will seek to interview inpatient NHS mental health staff, mental health service users with experience of inpatient admission; and their families or carers. Confidentiality will be maintained by ensuring that any formation that could identify participants will be anonymised and the participant’s names will occur only on their consent forms. We will comply with the Data

Informed consent will be obtained from all participants. Participants will be informed at the start of the interview process and through a leaflet about their rights to withdraw from the study. Participants will further be informed that there will be no consequences of withdrawing from the study. There will be no consequences for participants of withdrawing from the study. If the participants withdraw from the study all information pertaining to them will be destroyed including any audio recordings. Audio-recorded interview data generated from this research project will be kept securely at the University of Warwick and destroyed at the end of the study. Interviews will be anonymised at transcription and given an identifier. No identifiable information will be released at any stage of the research project including dissemination of the research findings.

2. We will not include individuals who lack capacity. The reason for the exclusion criteria is that, participants need to have the capacity for reflection and be well enough to consent for themselves and participate in an interview. Participants will be initially approached by a member of clinical staff for permission to share contact details with the study team. If they agree, they will be offered the opportunity to take part; if they do not wish to do so they will not have to. There will be no coercion and potential participants will not be promised anything in return for participating, therapeutic or otherwise. Where required, the use of qualified and trained interpreters will be offered and provided during the interview. We recognise that safeguarding vulnerable adults is embedded in both good practice and subject to legislation. The research will be conducted in accordance with UK legislation and the safeguarding and whistleblowing procedures operating in each research setting. The project team recognises that not all information is confidential. Confidential information is information of some sensitivity, which is not already lawfully in the public domain or readily available from another public source, and which has been shared in a relationship where the person giving the information understood that it would not be shared with others. We recognise that confidentiality is only breached where the sharing of confidential information is not authorised by the person who provided it or to whom it relates. If the information was provided on the understanding that it would be shared with a limited range of people or for limited purposes, then sharing in accordance with that understanding will not be a breach of confidence. Similarly there will not be a breach of confidence where there is explicit consent to the sharing. Where there is concern about a vulnerable person, a refusal of consent should not necessarily preclude the sharing of confidential information. We will familiarise ourselves with the policies relevant to safeguarding, managing disclosure, and whistleblowing in the case sites, and will uphold those whilst conducting work within those sites. When obtaining consent, the researcher will explain the confidentiality and anonymity to the participant, including what will happen if there is a concern that needs to be passed on. The researcher will explain to the participant whose information may be passed on: who will see their information, why the information needs to be shared, the purpose of sharing it, and the purposes for which the agencies which receive the information might use it. We uphold the idea that it is good practice to obtain consent before sharing information, even when there is no legal requirement. Whilst in general the researcher will seek consent before disclosing information, we recognise that this is not always possible. Potential circumstances exist where it is not advisable to seek consent e.g. where to do so would:

- Place a child or young person at increased risk of significant harm
- Place an adult at risk of serious harm
- Prejudice the prevention or detection of a serious crime
- Lead to unjustified delay in making enquiries about allegations of significant harm

The participant’s interests must be the overriding consideration in making any decisions about whether or not to seek consent to disclose information. Clear guidance on this will be given to all participants at both the start of the interview and in the project information sheet to participants.
3. We recognise that when discussing the experience of being interviewed about their experience of being asked about inpatient mental health services, this may trigger an emotional response from participants during WP3. Although these interviews are not intended to elicit detailed accounts of individual service user inpatient experience, it is likely that sensitive issues like perceived coercion, lack of privacy and difficult discharge procedures will be touched upon. We will therefore provide participants with information about sources of support. If a serious risk of harm to the patient or others is identified, the researcher will discuss with a PI who will then assess and take appropriate action. A senior member of the project team (usually FG) will meet with interviewers each week for supervision. Data collection processes, interview content and personal reflections will be discussed and interview schedules and processes refined as appropriate. Professional counselling support will be available to interviewers if needed. The project team will at all times conduct themselves in a boundaried yet sensitive manner. The survivor researchers identified by the Mental Health Foundation have post-doctoral level education and have been carefully chosen for their considerable experience over many years of this type of qualitative research. Each of the researchers undertaking interviews will be trained and conversant with handling interview situations in which sensitive issues may be disclosed. Should the participant at any point appear distressed, the interviewer will offer the participant the opportunity to take time out or to terminate the interview. At the end of each interview a summary will be given by the researcher of what the main points made by the participant during the interview were. This summary will function to check to ensure understanding is correct of the points made, but will also serve to validate the participants experience and ensure that they feel heard and listened to.

Safety considerations

The study will be conducted among the 56 NHS providers of inpatient mental health care that are responsible for at least 50 adult mental health beds including 51 specialist mental health trusts. In WP2, the contact made with Trusts will be by telephone with one or two key identified members of staff. In WP3, case study research (including face-to-face interviews with staff, services users and carers) will only take place in six NHS Trusts. The research has been deliberately designed to be mindful of the burden placed on NHS Trusts and consequently will work in partnership with these organisational settings to ensure that the research complies with their internal governance arrangements. The research will take place in NHS clinical settings, and whilst there will be lone working, this will be administered in accordance with the protocols identified by each NHS setting. There will be no work outside NHS provider settings in communities.

Patient & Public Involvement

Patient and public input is integral to the design of this project, and is led by the Mental Health Foundation (MHF). Informal discussions about this research were held with service user researchers and the National Survivor User Network (NSUN) (http://www.nsun.org.uk). The response has been positive since this work resonates with MHF and NSUN priorities. Both organisations have lobbied for better understanding of the purpose, process and impact of patient experience feedback and both are active in articulating the patient view in mental healthcare and research.

Mental health service users (and carers) will be involved in all aspects of this research. We will use standards for service user involvement in research developed by NSUN and the MHF (and co-authored by David Crepaz-Keay of the MHF). Service user researchers (SURs), all of whom have experience of working for or with the MHF, will be involved in WP2 (survey of mental health inpatient providers), WP3 (case studies) and WP4 (consensus conference). In WP2, SURs will advise on the questionnaire and topic guide and on the development of the WP3 sampling frame. In WP3, SURs will conduct interviews with service users. In WP4, SURs will help in recruiting service user and carer participants and will act as facilitators at the consensus conference itself.
In addition to recruiting and supporting SURs, the MHF will also co-ordinate and facilitate an advisory panel of ‘ordinary’ mental health service user and carers comprised of individuals with experience of using (or caring for people who use) services but not of research per se. This panel will meet four times during the project lifetime and will advise on key decisions as the project develops, for example, design, methods and questions. The Service User & Carer Advisory Group will be recruited from MHF and NSUN’s existing networks (which were originally established to advise on mental health policy and service development). We will recruit 8-10 members using selection criteria designed to ensure that members have direct, recent experience of using or caring for someone who has used inpatient services. We will ensure diversity within the Advisory Group in respect of gender, ethnicity, age and geography. Members of the Advisory Group will not be eligible to participate in the WP4 consensus conference. All service users and carers taking part in Advisory Group meetings or the consensus conference will be paid honoraria reflecting the value of their contribution in addition to being reimbursed for travel expenses.

Follow-up

WP2: The research may involve follow up to the telephone survey with identified members of staff within NHS Trusts in order to gather data or resources about Patient Experience monitoring in their particular settings which they did not have to hand during the first interview. This will be planned with the staff member take place within 2-3 working weeks of the initial interview.

WP3: Once data collection from each site is complete (usually within a 5 week time period) there will be no follow up. We will not retain the personal information of participants. All participants will have been given details of the study web page and email address of project researcher if they wish to access further information about the project as it proceeds.

Expected outcomes of the study

Our results will provide the first comprehensive overview of current approaches to collecting and using patient experience data to improve inpatient mental health care in England. We aim to examine and understand how organisations collect and use these data, and how they mobilise and use this potential source of new knowledge to improve services. We will examine these processes in depth at case study sites chosen to reflect the diversity of approaches, and we will identify the organisational characteristics that enable and constrain these processes. We will seek evidence of changes to services and to patient outcomes, and we will identify what is and is not working, where and why. The research, and our recommendations, will be grounded in the real world NHS, and we will conduct a consensus conference of experts (including service users and carers) at which we will review the study findings and agree recommendations based on what is judged feasible, acceptable and sustainable in NHS settings according to commissioners, service providers and service users and carers (WP4). We will extend this by modelling variation in resources (costs) associated with adopting new ways of collecting and using patient experience data and associated service improvements, the obstacles to this, and the value (i.e. cost) of evidence required to convince NHS commissioners and providers to substantially alter the way they deliver inpatient mental health care (WP5).

Dissemination of results and projected outputs

The outcome of the consensus conference meeting (WP4) will form the basis of the outputs to be disseminated to NHS providers. This meeting will produce:

1. A dissemination report, with an executive summary. This will include research results; will offer an analysis of the range of existing inpatient experience tools currently used in relation to collection, management and monitoring of this data; will suggest future innovations or where possible disinvestment strategies for methods or mechanisms that are not proving fruitful; and will make recommendations.

3. Practical recommendations for implementation and change management for NHS organisations wishing to take this forward.

The NHS Trusts that enter into the study will have findings from the study disseminated to them by the project team. This research has been designed to be used and useful. Whilst the objective is not to create a product or output such as a toolkit, it is expected that the learning gleaned from this research will be made as widely available as possible for adoption where appropriate. The results of the Consensus Conference will be reported and widely circulated to all participating Trusts. The project website will provide links to the published project outputs. The project will send a summary of the results of the study to all Patient Experience leads across England as identified and contacted as part of WP2. In addition to these outputs, further academic dissemination will take place through publications and presentations at relevant conferences. Any new data generated by this study and the Intellectual Property within it, will be owned by the University of Warwick.

### Quality Assurance

This research has received ethical approval from [insert name of NHS REC here] and is sponsored by the University of Warwick. The research project is funded by the National Institute of Health Research’s Health Services and Delivery Research Programme.

Protocol compliance: Accidental protocol deviations can happen at any time. Any protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately. If any amendments are made to either the protocol or the recruitment materials associated with the EURIPIDES project the Chief Investigator will seek appropriate approvals from NHS R&D departments and where necessary the NHS REC. Any substantive changes will be communicated to the relevant stakeholders i.e. RECD, R&D, regulatory agencies. All sites engaged in research will be issued with the most recent protocol version.

### Ethics

This project has received proportionate independent peer review by external experts, and has received ethical approval from [insert ethics committee name here].

### Informed Consent Forms

This project has approval for [insert name and version number of consent forms here].

### Duration of the Project

The project commenced on the 01.12.15 and is due to be completed by the 01.12.18, spanning a three year period.

### Project Management

There is a project management group formed of co-applicants, research fellows, administrators, and Patient and Public Involvement representation from the Mental Health Foundation. The project management team consists of:

- **Chief Investigator**: Professor Scott Weich (s.weich@warwick.ac.uk)
- **Co-investigator**: Dr Sophie Staniszewska (sophie.staniszewska@warwick.ac.uk)
- **Co-investigator**: Professor Frances Griffiths (f.e.griffiths@warwick.ac.uk)
- **Co-investigator**: Professor Kamaldeep Bhui (k.s.bhui@qmul.ac.uk)
- **Co-investigator**: Dr Michael Larkin (m.larkin@bham.ac.uk)
- **Co-investigator**: Dr Elizabeth Newton (e.k.newton@bham.ac.uk)
- **Co-investigator**: Dr David Crepaz-Keay (dcrepaz-keay@mentalhealth.org.uk)
- **Co-investigator**: A/Professor Jason Madan (j.j.madan@warwick.ac.uk)
- **Co-investigator**: Dr Charlotte Croft (c.croft@warwick.ac.uk)
- **Co-investigator**: Ms Tracey Wrench (tracey.wrench@cowparkt.nhs.uk)
- **Co-investigator**: Mr Prince Adeyinka Ade-Odunlade (ade.odunlade@cowparkt.nhs.uk)
- **Senior Research Fellow**: Dr Carole Mockford (carole.mockford@warwick.ac.uk)
- **Research Fellow**: Dr Alastair Canaway (a.canaway@warwick.ac.uk)
The project management team will meet at regular intervals (every six to eight weeks) throughout the project. These meetings will have a different configuration of participants in relation to the different work packages as appropriate throughout the project. At each meeting the leaders of each work package and sub-package will present a project and work package status update including future plans, progress and any initial results or feedback.

Independent Study Steering Group
In addition to these individuals listed who make up the project management team, this project is monitored by an external expert Steering Group. This steering group will meet three times during the lifespan of the project, at 6, 12, 18, and 24 months. This group will review the project progress and provide an expert outside perspective. As this is a multi-sit research study, a Study Steering Committee (SSC) will be appointed by the HS&DR programme as per the NIHR SSC Guidance. The role of the SSC is to provide overall supervision for a project on behalf of the Project Sponsor and Project Funder and to ensure that the project is conducted to the rigorous standards set out in the Department of Health’s Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. It should be noted that the day-to-day management of the project will remain the responsibility of the Chief Investigator Professor Scott Weich. The composition of the SSC will comprise: an independent chair; an independent statistician; a health economist; a clinician; at least one person with relevant expertise to inpatient mental health and NHS settings; a PPI representative; a representative of the sponsor and a representative from the research network meetings. The SSC will meet three times during the course of the project. The NIHR HS&DR Programme Director will review the nominees and appoint the Chair and members.

Project plan and timetable
This project plan indicates the monthly schedule for the work packages.

<table>
<thead>
<tr>
<th>Work package (WP)</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WP2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WP3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WP4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WP5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Diagram key
Activity (outlined colour)
Pre-activity (paler non-outlined colour)

References
3. Black N, Varaganum M, Hutchings A. Relationship between patient reported experience (PREMs) and patient reported outcomes (PROMs) in elective surgery. BMJ Quality & Safety. 2014.


The Evaluating the Use of Patient Experience Data to Improve the Quality of Inpatient Mental Health Care project is funded by the National Institute for Health Research’s Health Services and Delivery Research Programme.


Part 2

**Budget**

| Total research costs (not including NHS Support & Treatment costs): £719,524.89 |
| Total NHS Support & Treatment costs: £1,014.00 |

**Other support for the Project**

This project is supported by CRN West Midlands who are the lead network. There is further Service Support from the Clinical Research Network (CRN), to help identify key contacts in WP2 and to support recruitment of study participants in WP3.

**Collaboration with other scientists or research institutions**

This project is a collaboration between the University of Warwick, The University of Birmingham, Queen Mary University London, and the Mental Health Foundation.

**Curriculum Vitae of investigators**

Chief Investigator Professor Scott Weich is Professor of Psychiatry and an honorary Consultant Psychiatrist, and is an experienced health services researcher. Professor Weich will lead WP2. Sophie Staniszewska brings experience of designing and leading research into patient experience, and chaired the panel responsible for recent NICE Clinical Guidance on patient experience. She will lead WP1. Professor Frances Griffiths is a senior qualitative researcher with expertise in research design, including realist approaches to data analysis. She will lead two WPs, namely WP3 (case studies) and WP4 (consensus conference). She has conducted similar conferences previously, and is expert in the Nominal Group Technique that will support the final content of study recommendations. Dr Jason Madan is Assistant Professor in Health Economics and has led economic evaluations using a wide range of methodologies in a number of clinical areas including mental health. He will lead WP5. Professor Kamaldeep Bhui is skilled in both qualitative and quantitative mental health services research, and has an international reputation for leading many policy-relevant studies. As Editor of the British Journal of Psychiatry he will provide expert guidance on dissemination. Michael Larkin and Elizabeth Newton are research psychologists with expertise in participatory research and implementation science. They are experts in qualitative research and have undertaken research applying co-design methodology to mental health. There is guidance and input from the partnership with Coventry & Warwick Partnership NHS Trust through Mr Prince Adeyinka Ade-Odunlade who is the Acting Assistant Director for Acute Services, and Ms Tracey Wrench who is the Director of Nursing. David Crepaz-Keay is Head of Inclusion at the Mental Health Foundation and will lead on PPI.

**Financing and Insurance**

This project is sponsored by the University of Warwick. The University has in force a Public and Products Liability policy and a Clinical Trials Insurance Policy which provides cover for claims for “negligent harm” and the activities here are included within that coverage subject to the terms, conditions and exceptions of the policy. This research is funded by the National Institute of Health Research’s Health Services and Delivery Research Programme.