Liaison Psychiatry: Measurement And Evaluation of Service Types, Referral patterns and Outcomes (LP- MAESTRO): WORKSTREAM 1 (WS1)

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1 Administrative information

This document describes Work Stream one (WS1) of the Liaison Psychiatry: Measurement and Evaluation of Service Types, Referral patterns and Outcomes (LP-MAESTRO) study.

It provides sufficient detail to enable an understanding of the background, rationale, objectives, population, methods, analyses, ethical considerations, dissemination plans and administration of the study; replication of key aspects of study methods and conduct; and appraisal of the study's scientific and ethical rigour from the time of ethics approval through to dissemination of the results. Every care has been taken in drafting this protocol, but corrections or amendments may be necessary.

1.1 Compliance

The Project will be conducted in compliance with the approved protocol, the Declaration of Helsinki (2008), the principles of Good Clinical Practice (GCP), the UK Data Protection Act, and the National Health Service (NHS) Research Governance Framework for Health and Social Care (RGF).

Participating sites will inform the project co-coordinator by phone or email as soon as they are aware of a possible serious breach of compliance. The Chief Investigator (CI) will assess whether or not the breach is 'serious'. For the purposes of this regulation a 'serious breach' is one that is likely to affect to a significant degree:

- The safety or physical or mental integrity of the subjects in the Study, or
- The scientific value of the Project.

1.2 Sponsor

The University of Leeds is the sponsor.

1.3 Structured project summary for WS1

Public Title	Liaison Psychiatry: Measurement And Evaluation of Service Types, Referral patterns and Outcomes (LP- MAESTRO): work stream one
Scientific Title	Liaison Psychiatry: Measurement And Evaluation of Service Types, Referral patterns and Outcomes (LP- MAESTRO): work stream one
Primary Registry and Project Identifying Number	• WS1: UK Clinical Research Network Study Portfolio ID 18727
Source of Monetary or Material Support	NIHR Health Services and Delivery Research (HS&DR) Programme number 13/58/08
Sponsor	University of Leeds
Contact for Public Queries	Dr Andrew Walker
Contact for Scientific Queries	Professor Allan House
Countries of Recruitment	UK
Area of Enquiry	Liaison Psychiatry services in the UK
Overview of LP-MAESTRO: work streams one, two and three (emboldened text indicates the remit of this protocol)	This is a complex intervention comprising the following three workstreams **1) Map and characterise services** 2) Evaluate the cost and cost effectiveness of different service models 3) Develop a commissioning framework and guidelines for service monitoring
Study Type	Work stream one (service mapping and characterization) samples liaison psychiatry services and undertakes interviews and a prospective survey of referrals, to characterize the configurations and referral patterns of services.
Target Sample Size	12 Liaison Psychiatry services
Primary Outcome(s)	1) To characterise liaison psychiatry services in the UK 2) To produce a classification system that can inform sampling for this research and also form the basis for commissioning decisions in the NHS.
Key Secondary Outcomes	None

1.4 Roles and responsibilities

1.4.1 Role of Project sponsor and funders

Name	Role
University of Leeds	Sponsor – overall responsibility for the design and management of the study
NIHR Health Services and Delivery Research (HS&DR) Programme	Funder – responsibility for project design and funding

1.4.2 Project Management Group

Name	Affiliation	Role and responsibilities
Professor Allan House	University of Leeds	Chief Investigator, Co-lead for WS3
Carolyn Czoski-Murray	University of Leeds	Co-I; Senior Research Fellow; Responsibility for PPI
Professor Mike Crawford	Imperial College London	Co-I; Professor in Mental Health Services Research; Co-lead of WS1
Matt Fossey	Centre for Mental Health	Co-I; Director of the Institute for Veterans and Familie; Co-lead of WS3
Professor Elspeth Guthrie	Manchester Mental Health and Social Care Trust	Co-I / Consultant Psychiatrist
Professor Jenny Hewison	University of Leeds	Co-I; Professor of the Psychology of Health Care; Co-lead of WS2
Professor Claire Hulme	University of Leeds	Co-I; Professor in Health Economics and Director; Co-lead of WS2
Dr Alan Quirk (or depute)	Royal College of Psychiatrists	Senior Programme Manager
Dr Chris Smith	University of Leeds	Co-I; Senior Research Fellow & Data Scientist
Dr Peter Trigwell	Leeds Teaching Hospitals Trust	Co-I; Consultant in Liaison Psychiatry; Co-lead of WS1
Dr Sandy Tubeuf	University of Leeds	Co-I; Associate Professor
Dr Andrew Walker	University of Leeds	Senior Research Fellow; Study Co-ordinator
Professor Robert West	University of Leeds	Co-I; Professor of Biostatistics

1.4.3 Study Steering Committee

Name	Position	Affiliation	Membership status
Dr Peter Aitken	Consultant in Liaison Psychiatry; Director of Research & Development, Devon Partnership NHS Trust	Department of Liaison Psychiatry, Royal Devon and Exeter Hospital	Independent Chair
Dr Chris Bates	Head of Research & Analytics, TPP	TPP	Independent Member
Ms Jennifer Bostock	PPI expert	N/A	Non-independent member
Professor Rowena Jacobs	Professor in Health Economics	Centre for Health Economics , University of York	Independent Member
Professor Allan House	Chief Investigator, Professor of Liaison Psychiatry	University of Leeds	Non-independent member
Dr Andrew Walker	Senior Research Fellow / Study Co-ordinator	University of Leeds	Non-independent member

2 Abbreviations

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CAPSS	The Child and Adolescent Psychiatry Surveillance System
CCQI	College Centre for Quality Improvement
CQC	Care Quality Commission
EOI	Expression of Interest
GCP	Good Clinical Practice
HRQL	Health Related Quality of Life
HS&DR	Health Services and Delivery Research Programme
NHS	National Health Service
LPSE-2015	Liaison Psychiatry Survey England 2015
PAG	Patient Advisory Group
PI	Principal Investigator
PIS	Participant Information Sheet

PLAN	Psychiatric Liaison Accreditation Network
PMG	Project Management Group
PPI	Patient Public Involvement
R&D	Research and Development
RAID	Rapid, Assessment, Interface and Discharge
REC	Research Ethics Committee
RCT	Randomised Controlled Trial
RGF	Research Governance Framework
RCPsych	Royal College of Psychiatrists
SSA	Site Specific Approval
SSC	Study Steering Committee
ToR	Terms of Reference
UoL	University of Leeds
URL	Uniform Resource Locator (commonly and informally referred to as a web address)
WS	Work Stream
WTE	Whole Time Equivalent

3 Introduction

3.1 Background and rationale

General hospitals have always needed access to psychiatric services [e.g. 1]. For commissioners and providers of general hospital services the question is not whether they need access to psychiatry but how that access should be arranged, and of what sort the services should be.

It is possible to arrange that psychiatric services to general hospitals can be delivered in the same way as they are to other parts of the health and social care services, that is - ad hoc as part of the general mental health service's response to individual requests. On the other hand it has been argued for some decades now that general hospitals have special needs by virtue of the prevalence and complexity of mental health problems that present in them and because of the special challenges that exist in trying to manage such problems in the general medical setting [2]. The usual name for the specialist services set up to respond to these needs in general hospitals is liaison psychiatry or consultation-liaison psychiatry [3]. The defining feature of general hospital liaison psychiatry services is that they are provided systematically by specifically designated psychiatric staff who have designated sessional time committed to working in general hospitals.

If it is decided that specialist liaison psychiatry provision is desirable, then a further question is raised about the exact nature of the dedicated service. When it comes to trying to answer this latter question on the basis of evidence, there are three main reasons why doing research to establish the cost-effectiveness of psychiatric liaison services is so difficult.

3.1.1 The challenge of defining and characterising liaison psychiatry services

Liaison services vary greatly in the numbers and populations of patients who are referred to it [e.g. 4]. Some undertake predominantly acute (emergency) consultation work seeing urgent referrals on the wards or in the emergency department. Typical referrals involve behaviour disturbance associated with delirium or an acute psychosis, and self-harm. Some services see referrals of all types of problem, so that in addition to emergencies they will assess and manage patients with problems of adjustment to physical illness, with multi morbidity, severe mental illness with co-morbid physical health problems, organic psychosyndromes, alcohol related problems, or with medically-unexplained symptoms. Many services restrict access based upon the age of potential referrals. These age-related services tend to see some types of clinical problem much more than others; for example in elderly liaison services [5] the case-mix is made up predominantly of the so-called 3 Ds – dementia, delirium and depression.

A classification of services should take account of these characteristics [6,7] – clinical problems accepted on referral, age of referrals, and urgency of presentation. One simple approach suggests:

Emergency services – urgent referrals from all parts of the hospital. Such services often take all ages excluding children (below 16 years of age).

Self-harm services – differ from the above in that the response needed is quick but not usually urgent, many cases are seen during or soon after physical treatment for the self-harm, and most referrals are being assessed for complex psychosocial needs rather than simply acute mental disorder.

Elderly services – treated separately because of the prevalence of delirium and dementia in the elderly and because many aspects of health and social care have different arrangements for the elderly.

Physical illness services, sometimes called psychological medicine services – seeing patients with difficulties of adjustment to physical illness especially long-term conditions or severe illness, or patients with illness that does not seem based upon physical disease at all, sometimes called somatisation or medically unexplained symptoms.

There are other considerations as well as those related to the defined clinical problem – mainly related to the structures and processes of the service.

Staffing varies [8] – from a few sessions with a single named consultant to a large team with nurses, other allied health professionals and more than one full time consultant. The question of skill and experience of staff as well as disciplinary background is important. For example, rapid assessment of inpatients is often provided by staff from a general psychiatry background who are working on a rota and may have little experience of general hospital work. Even if established for some time, not all services have stable staffing and turnover in "short-order/high throughput" services can be high.

Working practices also vary greatly, from ward-based consultation only to provision of regular specialist outpatient clinics. A few services have designated liaison inpatient beds. Such service components may be inter-dependent so that for example in Leeds some 10% of new outpatient episodes are initiated as follow-up from an acute inpatient liaison contact.

Part of the original rationale for liaison services was their educational function for non-psychiatric staff [1]: services vary in the degree to which they offer formal educational or training opportunities to non-psychiatric staff. The term "liaison" was introduced to distinguish between purely referral-based (consultation) services and those in which regular contact persisted over extended periods - the latter typically with specialist services (renal unit, oncology, burns unit etc.). This liaison function was expected to lead to improvement in skills, knowledge and attitudes among non-psychiatric staff through experiential or workplace learning rather than formal educational sessions. Because many services provide a mixture the term consultation-liaison (C-L) psychiatry has been widely used in the past. These aspects of liaison provision are important because one of the claimed benefits of liaison

services is that they improve the care and outcomes for other patients who may not be directly referred to and seen by the liaison service. Thus the main change in outcomes reported by the RAID evaluation [8] was attributed to what was called the indirect effect, on patients in the same hospital at the same time who were not seen by the service but may have benefitted from improved general care as a result of exposure of general hospital clinical staff to the RAID example.

The idea of developing a classification or taxonomy of liaison services is challenging because of the need to take into account these factors but it is nonetheless appealing. The alternative is to assume that there are enough features shared by all services that it would be possible to come up with a single framework for evaluating cost-effectiveness.

If it is possible to develop a meaningful classification of liaison services, then there are two further considerations when it comes to relating the resulting service configurations to outcomes. One is the trajectory of service development. For example the RAID service evaluation was undertaken in the first 9 months of the team's existence while Leeds has had a liaison service for 25 years. Services are changing rapidly: time in existence and history of changing structures and processes may affect referral patterns and service culture in ways that can be difficult to characterise but are likely to be important in determining outcomes.

Second, the profile of formally-designated liaison services will be influenced by patterns of local provision of other services. For example local eating disorders or addiction services may take direct referrals from the general hospital; many centres have different mental health services for the elderly however defined; self-harm assessment and aftercare may or may not be organised by the liaison service. Clinical and health psychology services are not always integrated with psychiatric liaison. Such overlapping services are in evolution in many areas, in response for example to decisions to develop integrated health and social care services for the elderly, or to develop risk-stratification models in primary care. The importance of this last point is that we need to be clear about the level of analysis when we are attempting to attribute outcomes to services – several service components (self harm, elderly and so on) may be embedded with a liaison service. Several services (liaison psychiatry, clinical health psychology, alcohol and addictions) may take referrals from a single Trust. More than one organisation may be responsible for the care of the same group of patients.

How liaison and other services work together also needs to be understood as part of the characterising of liaison services. For example – it was reported that reduced lengths of stay during the implementation of the RAID service were not accompanied by an increase in early readmission rates. Since RAID offered little in the way of follow-up services, the implication is that the change in pattern of care in the target population included the involvement of other services (in this case

especially those for the elderly) that worked to prevent those readmissions. On the other hand a recent small survey of referrals from RAID to a local CMHT indicated that only a third of referral were seen by the CMHT and only 1-2% were taken on to their caseload [11], so integrated working across the board between liaison and other mental health services cannot explain all outcomes.

3.1.2 The challenge of determining patient and service outcomes

At an individual level patient benefit is of course the primary aim of liaison services. At an organisational level the beneficiaries may include other clinicians or other services.

1. Measuring patient benefit is more than usually challenging given the clinical heterogeneity of patients seen:
    a. There are too many domain or disorder-specific outcomes to be able to characterise a whole service.
    b. Some generic measures such as Health of the Nation Outcome Scales (HoNOS) may not be sensitive to change in the conditions seen in liaison work. Recent discussions about modifications to HoNOS to create a more useful measure (HoNOS–LP) are at an early stage, but informal communication suggests that no widely acceptable version is likely to emerge in the near future.
    c. The important timescales for primary outcomes will vary hugely by condition: from minutes or hours for aggressive paranoid states, a few days for delirium to months or years for chronic somatization.
    d. Relapse, recurrence or syndrome shift are common, with further presentations not always to the same part of the health service.
    e. For some patients, the goal may be to prevent relapse of their mental health problems, rather than improved outcome (e.g. patients admitted because of side effects of psychotropic drugs which then need to be switched or clozapine which is stopped and needs to be re-started etc.).

Defining and measuring patient experience is also not easy. Many who are referred acutely may subsequently remember little of their care. Some who have been referred when less impaired may disagree with how they were treated despite that treatment being in their best interests e.g. occasionally use of the Mental Health Act; refusal of further physical intervention for patients with somatoform disorder.

Nonetheless, there are efforts afoot to generate an outcomes framework that can be useful for all liaison psychiatry services, supported by the Royal College of Psychiatrists (RCPsych). Even if such a

framework can be successfully developed, implementing the recording of individual-level outcomes is a formidable task. Practical barriers arise because follow-up is so often not in the liaison services. Outcomes of interest in one setting (mortality or physical morbidity) will not be those most likely to capture the effects of liaison psychiatry intervention. More plausible in the short to medium term is the development of systems to capture domain or condition specific outcomes with which to describe outcomes in specific, necessarily narrowly defined, components of the service.

Although clinical service outcomes are usually thought of in terms of patient benefit, aspects of liaison service provision have an impact on other clinicians or the wider organisation and therefore the other service users can be thought of as general hospital clinicians. Examples of liaison work that has a direct impact on non-psychiatric clinicians include: assistance with managing problems that require different expertise such as chronic severe medically-unexplained symptoms; provision of rapid response in the emergency department or to assist with ward-based emergencies; shared involvement in follow up plans and organisation of aftercare that involve other services; communication with other service providers (secondary and primary care) to ensure co-ordinated and consistent care.

Sometimes these two aspects of outcome measurement work in unison. Shortened waits in Emergency Departments benefit distressed patients and stressed staff while they help organisations reach performance targets. Reducing inappropriate hospital stay may reduce risks or harms from potentially hazardous exposures including unwarranted investigation or treatment. However, the outcomes may be at odds if cost-saving or reduced work pressure in the general hospital comes to be seen as a priority compared with good outcomes for the patient.

3.2 Aims and objectives

The overall aim of LP-MAESTRO is to evaluate the cost-effectiveness and efficiency of particular configurations of liaison psychiatry service for specified target populations. To do this, an innovative approach based upon linking routinely collected NHS data and using economic modelling with the resulting pseudonymised case-based and/or aggregated data will be developed and evaluated.

A major challenge in assessing the cost-effectiveness of liaison psychiatry services resides in the variability in how they are configured and in the case-mix of referrals. There is also considerable heterogeneity in extraneous (demographic and other service) factors that influence outcomes for liaison psychiatry. Increasing understanding of this variability is the aim of work stream one (WS1).

3.2.1 Principal research objectives of WS1

1. To characterise liaison psychiatry services in the UK
2. To produce a classification system that can inform sampling for this research and also form the basis for commissioning decisions in the NHS

3.2.2 Secondary research objectives of WS1

There are no secondary research objectives of WS1.

3.2.3 Safety

There will be no documentation or reporting of serious or non-serious adverse events.

4 Study design

This is an observational study.

Phase 1:

Data held about Liaison Psychiatry services in acute hospitals in England by the Liaison Psychiatry Survey England 2015 (LPSE-2015)[1] includes a list of LP services in acute hospitals in England.

A purposively selected telephone interview survey will be undertaken on a subset of the respondents, concentrating on those hospitals which indicated in their responses they 'support anything other than the acute care pathway' in the original survey. The telephone survey is designed to obtain further information about specialist services provided to the acute hospital.

Phase 2: A purposively selected sample of LP services in LPSE-2015 (whether or not they took part in the telephone interviews) will be will be invited to participate in Phase 2. For liaison psychiatry services, Phase 2 involves:

1) Case study interviews of Commissioners/service-managers, key members of psychiatric clinical staff, and key members of non-psychiatric clinical staff.
2) A survey of Liaison Psychiatry clinical activity.

The results from the research activities described above, and a separate piece of LP-MAESTRO research involving the data-linkage of primary and secondary care records, beyond the scope of this document and detailed in separate research protocols, will be interpreted in the light of how the

[1] A national survey of staffing and structure in liaison psychiatry services in acute hospitals completed on behalf of the Royal College of Psychiatrists and the National Collaborating Centre for Mental Health commissioned by NHS England (Liaison Psychiatry Survey of England 2015, LPSE-2015)

service is experienced by service users and (2) how that work is understood by professional staff commissioning and delivering the service – the programme theory.

The purpose of service user participation is therefore to identify from various sources the views of people who might be or have been recipients of LP services – what works or does not work, and what they would like to see provided in an ideal world. Therefore, Phase 2 also involves:

1) interviews with service users
2) an online survey and
3) PPI expert panels.

Additionally,

4) workgroups and
5) eDiscussions including professional and PPI representatives will meet to help understand and inform the collective and emerging understanding of LP services nationally.

4.1 Phase 1

Data from LPSE-2015 will be used to form an initial characterisation of liaison services. This will be supplemented with a telephone interview survey designed to obtain further information about specialist services provided to the acute hospital.

4.2 Phase 2

Using the above initial characterisation of liaison services, LP services will be purposively sampled to ensure maximum variability based upon configuration to develop service-by-service models of liaison practice. The following activities will take place in selected LP services:

4.2.1 Case Study LP Interviews

Interview (the number of which will be determined by pragmatic factors such as availability) (a) commissioners and/or service managers, and (b) other NHS staff or associated professionals proposed by the LP Chief informant (possibly from both within and out-with the LP team) to:

a. Gain an understanding of their views on what a liaison service should provide.
b. Elicit their experience of what service the liaison service supplies locally in terms of service specification (service remit and programme theory).

Collectively, within a service the interviews will help understand

a. Service history – how long each element of service has been present, how staffing profiles have changed, what local determinants of service development have been.

b. Additional service detail that is not available from other sources e.g. staff meetings and protocols; academic activity such as research or education.
c. Overlapping service provision from non-liaison services.
d. Formal training activities for non-psychiatric staff.

Experience in previous projects describing old age liaison services [5] and self-harm services [13] in the UK indicates that this information can be obtained by standardised interviewing of one or two key personnel in the service such as the lead clinician or clinical service manager, and examination of formal documents such as Trust service specifications and job descriptions. During these interviews implicit and explicit views held by respondents will be elicited on how respondents understand the services remit and programme theory [14], *i.e.* what are the service's aims and how it is designed to achieve them. Interviews will be undertaken using topic guides, which will be tailored slightly for each professional group. The interviews will be audio-recorded (where possible) and transcribed before undertaking a framework analysis informed by the principles of realistic evaluation [15].

The interviews with clinicians will also generate a number of hypothetical referral sample cases regarded as typical of those they see as relevant to their service (common and routine as well as rare or challenging) and those they regard as unsuitable (outside remit or beyond the service's expertise). These hypothetical referral sample cases will help us refine our approach to service specification and will contribute to a later work stream.

Programme theories identified in eDiscussions and the expert workshops will be tested by re-interviewing the Chief Informant in each service.

4.2.2 Survey of Liaison Psychiatry clinical activity

A prospective survey of all referred cases including (for example)

a. Start time of clinical activity
b. Location of referral
c. Source of referral
d. First or repeat clinical contact
e. Main reason(s) for contact
f. Aim of contact
g. Referral to (destination)
h. Standardised measures used
i. Approximate duration of face-to-face contact

j. Comments

Similar surveys using a simple structured data collection format have been undertaken previously (e.g. European Consultation Liaison Workgroup service description [4], self-harm service project [13]).

Some LP services routinely collect data using the Framework for Routine Outcome Measurement in Liaison Psychiatry (FROM-LP)[2]. LP Services may, if they wish, provide aggregate anonymous FROM-LP data and if so this may be included in the service description.

4.3 Interviews with service users

The experience of service provision and the potential impacts it has on care pathways will be explored from the perspective of those who have used the service – either as patients or as a family member or friend who has been closely involved with an episode of care. Those parts of service models that act as potential barriers or facilitators to accessing appropriate psychiatric care will be explored, and opinions sought about how services can be improved.

4.4 Online survey

The online survey is intended to give a larger number of participants an opportunity to contribute to the research without having to commit to an interview. It also allows us to seek the views of a wider constituency – for example friends and family and those with experience of hospital admission who did and did not use LP services.

4.5 PPI expert panels

Two expert panels are planned in which members of LP-MAESTRO study team will present selected data from LP-MAESTRO to allow service users the opportunity to assist the study team with the interpretation of the data. These will be timed to be part way through the research when we expect to have some interim results and towards the end in preparation of the final report.

[2] Framework for Routine Outcome Measurement in Liaison Psychiatry (FROM-LP) has been proposed by Faculty of Liaison Psychiatry/ Royal College of Psychiatrists as a response to increasing emphasis from the NHS to routinely measure outcome data. FROM-LP focuses upon brief, simple, easy and deliverable data collection regarding Process and Outcomes such as clinician-rated clinical outcomes, patient-rated clinical outcomes, patient-rated satisfaction, and referrer-rated satisfaction).

Based upon these sources of information, expert workshop(s) will be held preceded and followed by a series of eDiscussions to agree a classification of liaison services based on structures, clinical and service processes. Selected members of the expert panel will be an integral part of this workshop.

5 Participants and recruitment

5.1 Phase 1 LP telephone interviews

5.1.1 Identification of LP services

A purposively selected telephone interview survey will be undertaken on a subset of the LPSE-2015 respondents, concentrating on those hospitals which indicated in their responses they 'support anything other than the acute care pathway'. It is anticipated that not all services contacted will respond to requests for follow-up telephone interviews and that some services may decline to participate. Reasons for non-participation, where provided, will be recorded.

5.1.2 Site approval and activation for follow-up LP telephone interviews

Unless the R&D department for a given LP service informs us no approval is required, NHS local approval (R&D) will be obtained for each liaison service selected to receive a follow-up telephone interview, and researchers will secure letters of access or honorary contracts as appropriate and determined by each NHS Trust. No follow-up telephone interviews will commence until the trial co-ordinator has provided a green-light. In most cases this will be an email, which will be sent with the (1) Chief Investigator (CI), (2) NHS Research and Development (R&D) contact, (3) Principal Investigator (PI), (4) Liaison Psychiatry Chief Informant (if different from the PI)and (4) local researchers copied in.

5.1.3 Inclusion criteria for follow-up LP telephone interviews

1) Liaison Psychiatry service in LPSE-2015

5.1.4 Exclusion criteria for follow-up LP telephone interviews

1) Not responding to an invitation to be interviewed
2) Declining an invitation to be interviewed

5.1.5 Sample size

There is no *apriori* sample size for the services identified in Phase 1.

5.2 Phase 2 LP service case studies (staff interviews and survey of LP clinical activity)

5.2.1 Identification of LP services

Services responding to LPSE-2015 (whether or not they took part in the telephone interviews) will be emailed by the LP-MAESTRO team to (1) provide information on the planned activities of LP-MAESTRO (see section 4.2), (2) request an Expressions of Interest (EoI) in Phase 2, and (3) to confirm the services meet the inclusion criteria. Based on the EOI, responses to screening questions, and a cluster analysis of the LPSE-2015 data, a sample of services will be invited to participate in Phase 2. Within the LP services that agree to take part as case studies, the names and contact details of commissioners, key psychiatric clinical staff, and key non-psychiatric clinical staff will be provided by the LP service Chief Informant. These named individuals will be sent (by post and/or email) a letter inviting them to participate in an interview along with a participant information sheet. Potential participants will be asked to contact a researcher if they are interested or to decline involvement. Individuals who do not reply will receive a follow-up telephone call, email or letter from a researcher and their services Chief Informant will also encourage a response (but he/she must not influence the decision whether or not the invitee participates).

With guidance from the LP-MAESTRO research team, the Chief Informant will nominate interviewees (commissioners/service-managers and other NHS staff or associated professionals (possibly from both within and out-with the LP team), each of whom will be invited by the research team to participate in interviews.

Two LP-MAESTRO workshops will be held to which candidate LP services for case studies will be invited. The purpose of the workshops is to provide information on LP-MAESTRO, what would be expected of participating services and what support the research team can provide.

5.2.2 Phase 2 site approval and activation

Unless the R&D department for a given LP service informs us no approval is required, NHS local approval (R&D) will be obtained for each liaison service selected, and researchers will secure letters of access or honorary contracts as appropriate and determined by each NHS Trust. No Phase 2 activities will commence until the trial co-ordinator has provided a green-light. In most cases this will be an email, which will be sent to the Liaison Psychiatry Chief Informant with the Chief Investigator (CI), NHS Research and Development (R&D) contact(s), Principal Investigator (PI) if applicable and different to the Chief Informant, and relevant researchers copied in.

5.2.3 Inclusion criteria for case study interview sites (LP staff and commissioners/managers)

1) Willing and able to provide a named person for the service who will act as our main point of contact
2) Meeting the person specification invited by the Chief Informant.
3) The LP service is largely unchanged from that reported in the Liaison Psychiatry Survey England 2015
4) The LP service was running in its current structure during the financial year 2013 to 2014

5.2.4 Exclusion criteria for case study interview sites (LP staff and commissioners/managers)

1) Unwilling or unable to provide verbal informed consent
2) Unwilling or unable to provide the time for interview without reimbursement

5.2.5 Inclusion criteria for survey of Liaison Psychiatry clinical activity sites

1) Responded to LPSE-2015
2) Unwilling or unable to provide a named person to locally co-ordinate the survey
3) Unwilling or unable to complete the survey during at a mutually agreed time

5.2.6 Exclusion criteria for survey of Liaison Psychiatry clinical activity sites

1) Unwilling or unable to participate without reimbursement

5.2.7 Sample size

A strategy to select participants based on knowledge of a population and the purpose of the study, purposive sampling, will be used to enable the capture and description of central themes and variations which are pertinent to the research aims. The categories used for sampling will be identified following Phase 1 of WS1 and by the Chief Informant for the LP service.

1. The anticipated sample of LP services for case study interviews is n=12.
2. There will be one survey (n=1) of clinical activity per service, which is anticipated to be recorded by a number of staff members.

N.B. As described above, a service may contribute to either or both of the case study interviews and/or survey of clinical activity.

5.2.8 Recruitment

Individuals identified from the LP service Chief Informant will be approached (either in person or by phone) by a researcher named on the delegation log. Potential participants will receive a participant Information Sheet (either in person, via email or via traditional postal services) and will have the opportunity to discuss the research with a researcher. Potential participants will therefore have had at least 24 hours to consider the information and ask questions before the researcher contacts the participants by phone or in person (as appropriate) for each potential interviewee to determine if she/he would like to take part. Verbal consent will be taken and audio-recorded. Interviews will last approximately 45 minutes depending on engagement.

5.3 Service user interviews

5.3.1 Sampling

Purposive sampling via sampling matrix will recruit participants with experiences of different service models from the case study sites. A sample of approximately n=20-30 service users will be recruited. The intention is to capture a detailed and comprehensive range of perspectives and participants will be identified using a pre-determined sampling frame including individuals;

- with experience of different conditions, for example, self-harm and medically unexplained symptoms,
- seen in the Emergency Department and Wards. Also, if possible, seen in an out-patient clinic,
- who are older age and working age adults,
- Seen in an emergency or less urgently.

However sampling may end when data saturation is reached.

5.3.2 Recruitment

Potential participants will either be:

1. Approached by a member of the LP clinical team involved with his/her care and provided with (i) an information sheet, (ii) a consent form with pre-paid or stamped addressed envelope, and (iii) a service-user card which will contain both the study contact details and the URL (web-link) to the online survey. The consent form will record both written informed consent and the patients preferred telephone number. The purpose of the packs is to invite the service user to be interviewed and/or participate in an online survey as outlined below. Alternatively, service users may be
2. Identified through local service-user groups.

As we are also interested in the views and opinions of family and friends of the patients with experience of attending a general hospital. We plan to use snowball recruitment techniques to include friends and family in our interview study. Participants who during their interview indicated that a friend or family member were with them during their attendance at hospital and may have views on the experience will be invited, through the participant, to contact the research team. The research team will have no access to friends or family without the express consent of participant, who has the research team contact details. These potential participants will not form part of the sampling framework as we do not anticipate recruiting more than n=5-6 friends or family.
No telephone interviews will take place before the written informed consent forms are returned to the research team and consent will be verbally re-obtained prior to interview.

5.3.3 Site approval and activation for service users interview

Where service users are identified in NHS premises, the permissions and processes detailed in 5.2.2 will apply. Where participants are obtained through local service-user groups, NHS Trust approval will not be sought. However, relevant management approval will be sought from any non-NHS organisation and indemnity confirmed.

5.3.4 Inclusion criteria for service-user interviews

1) Meeting the criteria for purposive sampling as defined in the sampling matrix
2) Being a patient seen by a LP team recruited into Phase 2 as a case study or being a friend or family member of a patient seen by a LP team recruited into Phase 2

5.3.5 Exclusion criteria for service-user interviews

1) Not fluent in spoken English
2) Unwilling or unable to provide written informed consent
3) Unwilling or unable to provide the time for interview without reimbursement
4) Meeting the criteria for a dimension in the sampling matrix that is already fully met (e.g. we have interviewed x of x service users of that type)

5.4 Phase 2 online survey

5.4.1 Sampling

It is not assumed that survey responses will be representative of the population using LP services, but rather may provide insight into the ways that patients and users experience the different ways that LP is organised across the country.

While it is hoped that the online survey will be completed only by the intended audience, this cannot be ensured without being prohibitive to genuine users (for example the use of a password or passwords was considered, but considered unfeasible). Therefore, it is accepted that individuals other than the intended audience may complete the survey and as such, no inclusion criteria at the point of participation exist.

5.4.2 Recruitment

Potential participants may become aware of the online survey from a variety of sources. These may include:

- Information given out at point of contact with LP services in a number of services (See 5.3.2).
- Where possible, the URL will appear on the web pages of relevant patient special interest and support groups. For example, BARCA-Leeds, Leeds Mind and Age UK Leeds.
- Social media (for example Facebook and Twitter) will be used to promote the opportunity for participation[3].
- Service user online support groups and blogs

Completion of the survey will be taken as consent to participate.

5.5 Phase 2 PPI expert panel

5.5.1 Sampling and recruitment

The PPI expert panels will comprise between five and eight PPI representatives which will allow for maximum participation and discussion. A presentation of the data will be made by a LP-MAESTRO researcher, and the presentations will be posted or emailed (as preferred) to the participants with any additional information to be discusses before the event to allow for any preparation they may wish.

This wider group of PPI representatives will be recruited from local user groups who have expressed an interest in our research. We will endeavour to invite individuals with a range of experiences of Liaison Psychiatry including addiction referrals, self-harm, and medically unexplained symptoms. We

[3] Facebook allows advertising much in the same way as small ads in a newspaper might appear. Advertisers pay a small sum per 'click' if an individual clicks on the link to your page. In this case the page would be the online survey. The study team would have no way of tracing or identifying individuals who use this method to link to the survey. We would include a short explanation about the study. We will target the age range 18years to 70 years and Facebook users in England.

also plan to encourage input from patients who have found the experience of being admitted to hospital a distressing experience that may have had more lasting effects on their wellbeing.
Written Informed consent will be obtained on arrival and prior to participation in the panel discussions.
It is anticipated that some individuals will wish to share their personal experiences in the context of the presented information and elicitation process. Therefore, a briefing on confidentiality and respect will be part of the introduction to the panel.

6 Interventions

This is a non-interventional study.

7 Outcomes

7.1 Primary outcomes

1. To characterise liaison psychiatry services in the UK
2. To produce a classification system that can inform sampling for this research and also form the basis for commissioning decisions in the NHS.

7.2 Secondary outcomes

None.

7.3 Study closure

LP-MAESTRO WS1 will close 3 months after either,

(i) the last psychiatric clinical staff interview,
(ii) the last non-psychiatric clinical staff interview,
(iii) the last commissioner/service-manager interview,
(iv) the last confirmatory interview,
(v) the last service user interview,
(vi) the last PPI expert panel,
(vii) the end of the last LP survey of clinical activity, or
(viii) the closing date of the online survey

dependent upon which of i to viii occurs last.

8 Data collection and management

8.1 Data collection: Phase 1

8.1.1 Follow-up telephone interviews

Data held about all UK Liaison Psychiatry in LPSE-2015 will be reviewed.

The Chief Informant (LPSE-2015 respondent, or alternate if advised), at selected services will receive an email to request further information about their LP service. A telephone interview record form will be designed prior to any interviews commencing and will be agreed by the PMG. Explicit verbal consent to participate will be sought from the interviewee. The telephone calls will not be recorded and this will be made clear to the interviewee at the beginning of the conversation, before their verbal consent is sought.

These follow-up telephone interviews will provide further context in helping to understand what the service does and why it does it. All questions will relate to the service provision and no patient identifiable data will be requested or recorded.

8.2 Data collection: Phase 2

8.2.1 Case study Interviews

8.2.1.1 Setting

Semi-structured interviews will be conducted in the LP service, by telephone, or at a mutually agreed location nominated by the respondent (as long as local governance approval is in place if needed).

8.2.1.2 Topic guides

The interview topic guides will be developed based on Phase 1 and may draw upon previously held examples and will be approved by the PMG before being used. For example, the topic guides for interviews may contain questions to elicit (N.B. these are exemplars only and may not be part of the final topic guides):

- Checking and updating the information we have on the service
- Understanding the types of clinical work undertaken
- Influences on what the service does and why
- Summing up and looking to the future

8.2.1.3 Data collection

The interviewers will be researchers involved in the LP-MAESTRO study and interviewees will be informed (both verbally and on the participant information sheet) that their comments will be pseudonymised.

The researcher will be responsible for digital audio recording of the interviews (where possible) and taking of field notes. Transcription will be carried out by experienced audio-transcriber(s).

8.2.2 Survey of LP clinical activity

All data will be pseudonymised and aggregated before being sent to the research co-ordinator at the University of Leeds.

Instructions on what to include in the survey will be agreed by the PMG and will be operationalised at a site-by-site level. In some cases it is anticipated that services will not be required to undertake any additional work other than the selection and sharing of pseudonymised and aggregated data. Every effort will be made to minimise burden to the LP services.

8.2.3 Confirmatory Interview

Programme theories identified in eDiscussions and the expert workshops will be tested by re-interviewing the Chief Informant in each service, using the associated logic model as the framework for our confirmatory interviews.

Verbal informed consent from each LP service Chief Informant will be obtained prior to the confirmatory interview.

8.2.3.1 Setting

Semi-structured interviews will be conducted in the LP service, by telephone, or at a mutually agreed location nominated by the respondent (as long as local governance approval is in place if needed).

8.2.3.2 Confirmatory Interview guide

The confirmatory interview guide will be informed by the information obtained about that case study site detailed elsewhere in this protocol and will be agreed by the PMG before use.

8.2.3.3 Data collection

The interviewers will be researchers involved in the LP-MAESTRO study and interviewees will be informed that their comments will be pseudonymised.

8.2.4 Service user interviews

8.2.4.1 Setting

The interviews will be conducted by telephone where possible, with face-face interviews in the service users' home as needed. The University of Leeds lone Working standard[4] will be adhered to. The researcher will be responsible for digital audio recording of the interviews (where possible) and taking of field notes. Transcription will be carried out by experienced audio-transcriber(s).

8.2.4.2 Topic guides

The researchers will use a semi structured topic guide informed by PPI co-applicants. The researcher will probe pertinent questions with participants and expand on issues raised.

Time will also be scheduled for participants to suggest alternative service attributes and models for which they may have a preference. This will ensure that participants have the freedom to highlight and discuss the aspects/attributes of LP care that are important to them regardless of whether or not those attributes exist in currently provided service models. Participants will also be to think about their attitudes to psychological/psychiatric care provided by the NHS in general.

8.2.4.3 Data collection

The interviewers will be researchers involved in the LP-MAESTRO study and interviewees will be informed (both verbally and on the participant information sheet) that their comments will be pseudonymised.

The interviews will be digital audio recorded and notes taken. Transcription will be carried out by experienced audio-transcriber(s).

8.2.5 PPI expert panels

8.2.5.1 Setting and expenses

The venue is likely to be on University of Leeds premises. All expenses incurred will be reimbursed and participants will be offered a choice of voucher at the start of the panel.

8.2.5.2 Data collection

The PPI groups will be facilitated by experienced researchers.

The interviews will be digital audio recorded and notes taken. Transcription will be carried out by experienced audio-transcriber(s).

[4] http://wsh.leeds.ac.uk/info/194/lone_working/116/lone_working
Accessed 23/05/2016

8.2.6 Online survey

8.2.6.1 Hosting, design and testing

The survey will be hosted by Bristol Online Surveys (BOS) and be open for up to one year to provide maximum participation while allowing time for analysis and reporting.

The online survey will include questions similar to those in the service-user interviews and will include both open (free text) and closed questions. Feedback and support from colleagues with experience of conducting online surveys has been obtained and the online survey has been extensively piloted with several PPI groups to refine the questions and usability.

8.2.6.2 Data collection

The online survey will identify the status of the respondent (e.g. user of LP services, friend or family of service user, person with long term conditions but no experience of liaison psychiatry service use etc.)

The survey will be anonymous. Survey users will be advised not to provide their name or other identifiable information, but should an individual submit identifiable information (such as a name) this will be deleted by the research team.

At analysis any entries considered to be spam will be excluded and the mechanisms for doing so will be agreed by the PMG.

8.3 Data management

The project will utilize 10 datasets:

1. Operational database for the project, which will include: names of LP services, key contacts and contact details, etc.
2. Data received from 2015. The dataset will retain references to individual staff members, sites and services to allow (a) identification of sites interested in participating in Phase 2 (b) follow-up non-responding sites without inconveniencing responding sites and (c) understand the geographical and clinical landscape of the services
3. Follow-up telephone interview data which may include, for example: staffing data (e.g. numbers and number of disciplines), infrastructure data (e.g. access to secretarial or administrative support), the general hospital data (e.g. number of beds), referral practice data (e.g. referral mechanisms) and data relating to follow-up practice and rates of follow-up (e.g. arrangements for referral). For analogous reasons to Dataset 2, references to individual staff members, sites and services will be retained.

4. Clinical activity survey data from services. The data will contain a site ID number that references the LP service from which it was obtained and the initials of the person who clinician who completed the survey.
5. Transcribed staff interview data (clinical, non-clinical and commissioner/service manager). The dataset will retain (a) the name of service from which they were collected and (b) the professional group of the interviewee.
6. Service user contact details and characteristics.
7. Transcribed service-user interview data.
8. PPI expert panel contact details and characteristics.
9. Transcribed PPI expert panel data.
10. Service-user survey data. Data obtained from the online survey will be checked for any information potentially de-anonymising the data.

All data will be considered to be potentially identifiable and/or sensitive.

Electronic data held at both the University of Leeds or the Royal College of Psychiatrists will be stored in encrypted format, and access will be restricted to specified members of the study team. Any data that must be electronically communicated between these institutions for processing and analysis purposes will be transmitted in encrypted format. The electronic data held at each institution will be subject to the back-up policies of that institution.

Audio-recordings of interviews will be digital and will be transferred directly from the audio-device to a secure location at the University of Leeds or the Royal College of Psychiatrists (depending on where/by whom the interview was conducted) as soon as possible after the recording has been taken. Once transferred and checked, the audio recording on the audio device will be deleted. Any audio-device containing an interview will kept in a locked location or on the researcher's person until the recording can be transferred to a server.

Any personal data required to be held on paper will be securely stored in a locked filing cabinet in a lockable room in the Leeds Institute of Health Sciences (University of Leeds), or the Royal College of Psychiatrists for the duration of the study and archived as detailed elsewhere.

9 Analysis

9.1 Telephone interviews

Descriptive, and if appropriate quantitative, statistical tests will be applied.

9.2 Case study interviews and service user interviews

The number of potential service configurations, individual experiences and budget constraints necessitate a broad, 'Framework' approach. Framework analysis is useful for a structured exploration of participants' perspectives and provides an advantage because findings are induced from their original accounts [16]. This approach provides less detail than other methodologies (e.g. Grounded Theory), but it will enable the gathering of data from a range of services, and an understanding of the service user experience.

Following the Framework approach [16], data analysis will comprise five stages:

i) familiarisation with the data;

ii) identifying the thematic framework;

iii) indexing;

iv) charting; and,

v) mapping and interpreting.

The process of familiarisation enables the researcher to identify emerging themes or issues in the data. Little is known about the impact on patients from the commissioned care pathways and so we will rely on published literature and our patient and clinical co-applicants to help refine the thematic framework (Identifying the thematic framework). All of the data generated from the interviews will be indexed numerically according to the particular theme to which it corresponds (Indexing). Data will then be lifted from its original text and placed under subheadings derived from the framework (Charting). The analysis of the concepts identified in early interviews will inform revisions to the interview guides for subsequent interviews (Interpretation). The themes are flexible and can be modified in the light of new data, and a process of constant comparison will be used to examine across themes and cases.

The goal of the analysis will be to develop a better understanding of the patient experience of the models of service delivery offered across England and to feed these results into the case studies. In addition an insight into how patients perceive their care pathway and whether they have opinions and ideas that could bring about improved care will be sought.

9.3 Online survey

Descriptive statistical tests will be applied to collate and organise the data. The free text will be analysed using similar methods to the service-user interviews described above, as appropriate.

9.4 PPI expert panel

The data will be analysed using content analysis, with data analysed for patterns and themes, to develop categories and sub-categories of attributes and arrive at a comprehensive set of attributes.

Data will be analysed iteratively using constant comparative methods [17]. Data analysis will follow the standard methodology for thematic content analysis as appropriate.

Close reading of the data to identify words that capture thoughts or concepts. Labels/codes are attached to these data and become the initial coding frame. Codes are then sorted into categories based on how they relate to one another, and grouped into meaningful clusters. Data will be charted to organise the categories into a meaningful structure and definitions for each code and subcategory developed.

The outputs from these work packages will be incorporated into the quantitative findings providing a framework for the interpretation of the results.

10. Data monitoring

10.1 Data Monitoring Committee

As detailed in section 11.2.2, a Data Monitoring Committee (DMC) will not be convened.

11 Quality assurance and control

For the purposes of both Phase 1 and Phase 2 of WS1, the study will be organised and managed as follows.

11.1 Monitoring

There will be no study monitoring other than central monitoring of

1. Response rates to follow-up telephone interviews (Phase 1).
2. Recruitment of LP services (Phase 2).
3. Number of clinical activity surveys completed (Phase 2).
4. Number of staff interviews completed (Phase 2).
5. Number of service user interviews completed (Phase 2).
6. Response rates to the online survey (Phase 2).

11.2 Project oversight and PPI

Project oversight is intended to preserve the integrity of the project by verifying a variety of processes and prompting corrective action where necessary. The processes reviewed relate to response rates, recruitment and adherence to protocol and Good Clinical Practice; completeness, accuracy and timeliness of data collection.

Annexe one shows the relationship between project oversight bodies and depicts the possible lines of communication to and from the sponsor and funder.

11.2.1 Project Management Group

A Project Management Group (PMG) will be set up to assist with developing the design, co-ordination and strategic management of the project. The membership, frequency of meetings, activity (including project conduct and data review) and authority will be covered in the PMG terms of reference.

11.2.2 Data Monitoring Committee

Consideration was given to the avoidance of the three main causes of potential harm:

a) Physical harm caused by the intervention. As there is no intervention this risk is not applicable.

b) Mental harm caused by the intervention. As there is no intervention this risk is not applicable.

c) Harm caused by the research design. As the study is observational and does not involve the collection of identifiable patient data, this risk is minimal.

In light of the above, a Data Monitoring Committee (DMC) will not be convened. The following considerations further justify this decision:

1. The Study is not a Randomised Controlled Trial.
2. No participant will undertake any clinical procedures or tests other than as part of their routine care
3. No identifiable NHS patient data will be collected
4. Adverse Event and Serious Adverse event data will not be collected.

11.2.3 Study Steering Committee

The Study Steering Committee (SSC) is the independent group responsible for oversight of the project in order to safeguard the interests of study participants and the funder, and reports directly to the funder. The SSC provides advice to the PMG, funder and sponsor on all aspects of the project through its independent Chair. The membership, frequency of meetings, activity (including project conduct and data review) and authority will be covered in the SSC terms of reference.

11.2.4 Sponsor

The role of the sponsor is to take on responsibility for securing the arrangements to initiate, manage and finance the study. University of Leeds is the sponsor.

11.2.5 Public and Patient Involvement (PPI)

A number of LP-MAESTRO co-applicants have developed groups of committed and informed members of the public who are all people with experience of long term physical illness and awareness of mental health issues. They are drawn from patient organisations such as Diabetes UK, Breatheasy and Heartline and have experience of membership of steering committees, development of participant information resources, research websites, patient interventions and dissemination of research findings. The study team has experience of training and supporting PPI members new to these roles.

A budget is held for PPI consulting fees. A number of consultation reference groups will be established to advise on materials and choice of outcomes. All PPI work will be reimbursed at INVOLVE [18] recommended rates as well as covering out-of-pocket expenses.

The Public Involvement Impact Assessment Framework will be used to shape and evaluate PPI involvement in the proposed research [19].

Service users and members of the public will be involved throughout the project, and have had input into this ethical review application as well as the original grant application. The wider Patient Advisory Group (PAG) are a virtual group who we have contact with via email. The PAG will be engaged with at a number of points during the study to share materials. In the course of the study, PPI co-applicants will continue provide input into the study. The group have already provided practical input into topic guides, information sheets, consent forms, and the online survey.

Two members of the PAG co-applicant and are full members of the research team. One of the PPI co-applicants is also a member of the Study Steering Committee.

A team member with considerable experience of PPI will support the PAG and provide research mentorship to facilitate meaningful involvement in the project. PAG members will be reimbursed for their time and travelling expenses will be paid. Training will be offered to PAG members to develop their skills and knowledge of research.

12 Ethics and dissemination

12.1 Research Ethics approval

Before initiation of the study at any site, the protocol, all informed consent forms and any material to be given to the prospective participants will be submitted to the relevant REC for approval (or a decision that REC approval is not required). Any subsequent amendments will be submitted for further approval.

The rights of any participant to refuse to participate in the study without giving a reason must be respected.

12.2 Other approvals

Please see sections 5.1.2 and 5.2.2.

12.3 Protocol amendments

Substantial Protocol amendments will be co-ordinated by the LP-MAESTRO project co-ordinator after approval by the PMG. Investigators and other relevant parties will be notified of amendments in a timely manner so as to ensure appropriate regulatory and ethical principles are met. A summary of protocol amendments will be maintained.

As this protocol details WS1 only, further applications detailing later work streams will be submitted for approvals as appropriate.

12.4 Consent

12.4.1 Phase 1

Consent will be "implicit" by any service participating in a follow-up telephone interview.

12.4.2 Phase 212.4.2.1 Case study interviews

All participants (NHS staff) who participate in the interviews will provide written informed consent.

12.4.2.2. Clinical survey of clinical activity

Patients will not be asked to provide consent for use of pseudonymised and/or aggregated data.

This meets ethical standards for the following reasons:

1. There is no intervention.
2. NHS patient level data will be pseudonymised and/or aggregated.
3. The study follows accepted practice.

12.4.2.3 Service-user interviews and PPI expert panels

All participants (service-users) who participate in either interview or expert panels will provide written informed consent.

12.4.2.4 Online survey

Consent will be "implicit" by electronic submission of the survey.

12.5 Confidentiality

All interview transcripts and published quotes will be pseudonymised.

12.6 Other ethical issues

The NHS staff interviews will not be exploring highly sensitive issues and therefore the study has no material ethical issues. LP services involved in Phase 1 will not be anonymous so as to facilitate purposive selection of sites in Phase 2.

12.7 Declaration of interests

The investigators named on the protocol and grant application have no financial or other competing interests that impact on their responsibilities towards the scientific value or potential publishing activities associated with the project.

12.8 Indemnity

University of Leeds indemnity applies for the management and design of the research, NHS indemnity applies for the conduct of the research.

12.9 Finance

The LP-MAESTRO studyis fully funded by National Institute for Health Research Health Services and Delivery Research (NIHR HS&DR) Programme (13/58/08).

12.10 Archiving

The investigators agree to archive and/or arrange for secure, password protected storage of LP-Maestro study materials and records for periods corresponding to the type of material.

- The results of the service characterisation will be held securely at the University of Leeds for 15 year after end of study.
- The pseudonymised interview transcripts and files used in the analysis of qualitative data will be held securely at the University of Leeds for 15 year after end of study.
- Pseudonymised aggregated clinical activity survey data will be held securely at the University of Leeds for 15 year after end of study.
- The non-anonymised interview recordings will be archived at the University of Leeds for 12 months after the submission of the final report to allow for any data or follow-up queries to be resolved.

- Personal identifiable information which is solely for the identification and contact details of LP service Chief Informants and those consenting for interview in the project will be stored securely at the University of Leeds for 12 months after the submission of the final report to allow for any data or follow-up queries to be resolved.

In all cases at the end of the archive period the data will be securely destroyed.

12.11 Access to Data

Requests for access to study data will be considered, and approved in writing where appropriate, after formal application to the PMG and SSC.

12.12 Publication Policy

12.12.1 Study Results WS1

The results of the study will be disseminated regardless of the findings.

12.12.2 Authorship

During the first 6 months the PMG will agree a publication and dissemination strategy consistent with the NIHR publication strategy and HS&DR requirements. The SSC will endorse the publication and dissemination strategy.

13 Ancillary studies

None at present.

14 Protocol amendments

This is version 1.2 of the protocol: the first substantial amendment.

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Annexe one: LP-MAESTRO project oversight structure.