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

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Date	

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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, which is sponsored by University of Leeds.

It provides sufficient detail to enable an understanding of the background, rationale, objectives, trial population, intervention, 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	TBC
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

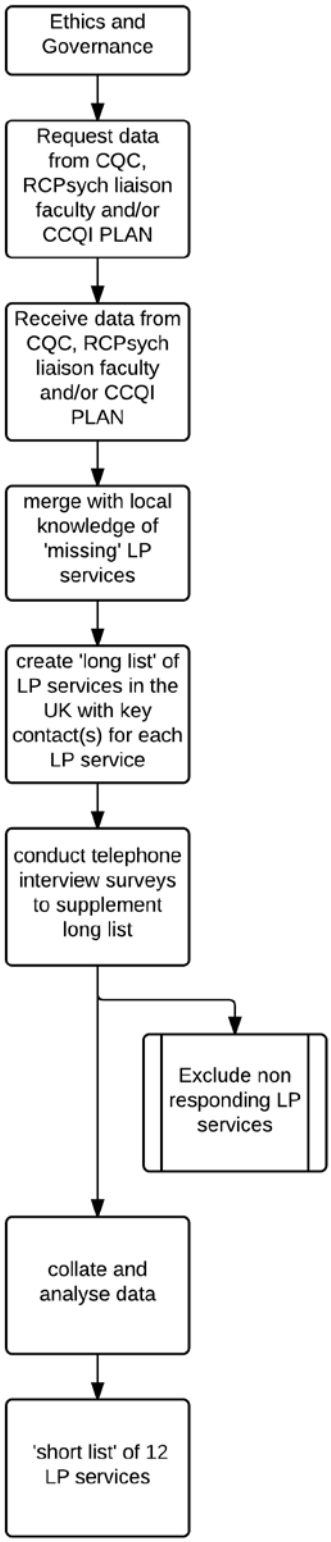
Name	Affiliation	Role and responsibilities
Professor Allan House	University of Leeds	Chief Investigator, Co-lead for WS3
Carolyn Czoski-Murray	University of Leeds	Co-I; Senior Research Fellow; Responsibility for PPI
Professor Mike Crawford	Imperial College London	Co-I; Professor in Mental Health Services 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

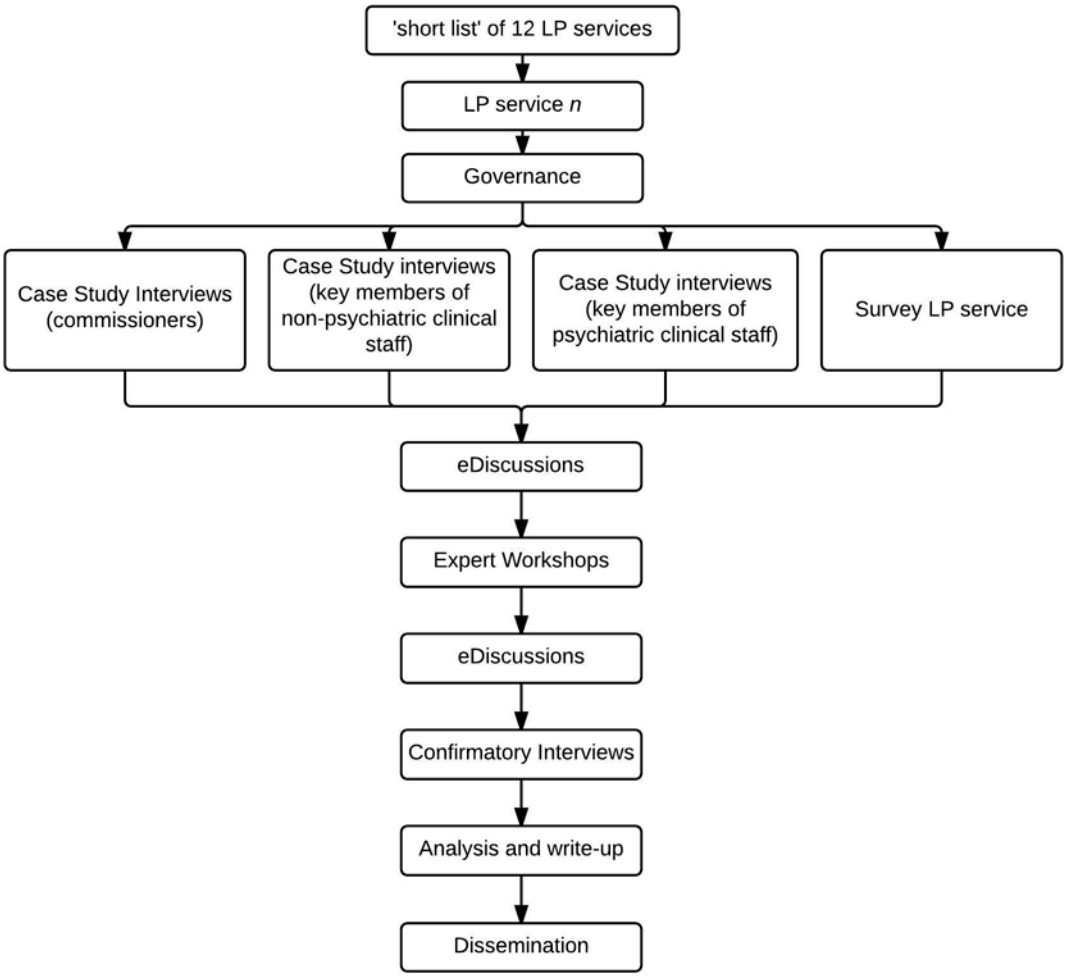
Name	Position	Affiliation	Membership status
Dr Peter Aitken	Consultant in Liaison Psychiatry; Director of Research & Development, Devon Partnership NHS Trust	Department of Liaison Psychiatry, Royal Devon and Exeter Hospital	Independent Chair
Dr Chris Bates	Head of Research & Analytics, TPP	TPP	Independent 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
Ms Claire Seymour	Director of Research	West Yorkshire and Bassetlaw CSU	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 LP-MAESTRO WS1 diagrams

2.1 LP-MAESTRO WS1 process diagram: Phase 1



2.2 LP-MAESTRO WS1 process diagram: Phase 2



3 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
GCP	Good Clinical Practice
HRQL	Health Related Quality of Life
HS&DR	Health Services and Delivery Research Programme
NHS	National Health Service
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
WS	Work Stream
WTE	Whole Time Equivalent

4 Introduction

4.1 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.

4.1.1 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.

4.1.2 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.

- 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.

4.2 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).

4.2.1 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.

4.2.2 Secondary research objectives of WS1

There are no secondary research objectives of WS1

4.2.3 Safety

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

5 Study Design

This is an observational study.

Phase 1 of WS1 comprises:

1) Follow-up telephone interviews

The study will target all liaison psychiatry services in the United Kingdom. The setting will be Liaison Psychiatry (LP) services within the United Kingdom which will be identified from data held in CQC, the RCPsych liaison psychiatry faculty and/or CCQI PLAN and selected by purposive sampling as described below.

Data held about all UK Liaison Psychiatry in CQC, by RCPsych liaison faculty and/or CCQI PLAN will be reviewed. These data will be supplemented with expert knowledge to identify LP services that may exist, but that are not, or are poorly, described in the identified databases. For example, (1) LP services may be known to the study team but not included and (2) geographical areas or NHS Trusts conspicuous by their absence and suggestive of services suspected to exist. Information on these 'missing sites' will be obtained through publically available or co-investigator knowledge. This will create a 'long list' of LP services.

A purposively selected sample of responding sites will be telephoned to obtain further background information on the service and to gauge their willingness to participate further in LP-MAESTRO. Data from the identified databases and follow-up telephone interviews will be merged and analysed to allow the purposive sampling of LP services into a 'short list' of 12 LP services.

In Phase 2 of WS1, a representative with decision-making authority of each 'short listed' LP service will be approached to consider the LP service taking part in the study. Consenting LP services will be asked to participate in:

1) Case study interviews of Commissioners, key members of psychiatric clinical staff, and key members of non-psychiatric clinical staff.

2) A 28 day survey of practice.

Workgroups and eDiscussions including professional and Patient/Public representatives will meet to help understand and inform the collective and emerging understanding of LP services nationally. Members of the eDiscussions and work-group will not be recruited through their involvement in LP Services as service users.

5.1 Phase 1

Data from CCQI PLAN [12], other identified databases, and local expert knowledge derived from the research team and the Royal College of psychiatrists' Liaison Psychiatry Faculty will be used to form an initial characterisation of liaison services. CCQI PLAN holds some details of the majority of services currently identified in the UK. Staffing profile and size of general hospital Trust will be used as proxies for complexity. This will be supplemented with

1. Follow-up telephone interviews.

Combining these resources we will obtain an overview of the main models of liaison psychiatry service provision. This will be the basis of the next Phase of WS1.

5.2 Phase 2

Using the above initial characterisation of liaison services, 12 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 the selected services:

5.2.1 Interviews

Interview (a) commissioners, (b) non-psychiatry clinical staff (the number of whom will be determined by pragmatic factors such as availability) and (c) psychiatric clinical staff 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 CCQI PLAN 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 will be elicited on how respondents understand the services remit and programme theory [14].

During these interviews views held by respondents will be elicited to help understand the service's remit and programme theory, *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.

5.2.2 Prospective survey

Undertake a 28 calendar day prospective survey of all referred cases including (for example)

a. Case mix.
b. Source of referral.
c. Number of new and follow-up patient contacts.
d. Discharge plan from liaison service.
e. Timing of contact.
f. Aim of contact.

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]).

Interview data will be triangulated with data from the survey to develop service-by-service models of liaison practice.

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 service users group will be an integral part of this workshop. For each service type (here, service also refers to discrete components of service) a service model or service programme theory will be formulated.

The programme theories will be tested by conducting a follow-up interview with each service's Chief Informant (defined below) using the associated logic model as the framework.

6 Participants

6.1 Phase 1

6.1.1 Identification of LP services to form a 'long list'

Liaison services will be identified by data from CQC, the RCPsych liaison psychiatry faculty and/or CCQI PLAN and supplemented with local expert knowledge.

6.1.2 Phase 1 site approval and activation

6.1.2.1 Follow-up 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.

6.1.2 Inclusion criteria for 'long list'

1. Liaison Psychiatry service in the UK

6.1.3 Exclusion criteria for 'long list'

1. Children only service.
2. Prison only service.
3. Armed Forces only service.
4. Non response to follow-up telephone interview.

6.2 Phase 2

6.2.1 Identification of LP services to form a 'short list'

LP services will be identified from Phase 1 of WS1. An initial and reserve list will be obtained and LP services will be initiated until 12 LP services agree to participate. LP services will be excluded if they are unwilling to participate in all the activities of Phase 2.

6.2.2 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 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.

6.2.3 Inclusion criteria for interviews

1) Meeting the person specification (service commissioner, key member of non-psychiatric clinical staff, or key member of psychiatric clinical staff).

6.2.4 Exclusion criteria for interviews

1) Unwilling or unable to provide the time for interview without reimbursement.

7 Interventions

This is a non-interventional study.

8 Outcomes

8.1 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.

8.2 Secondary Outcomes

None.

8.3 Study Closure

LP-MAESTRO WS1 will close 3 months after the last confirmation interview.

8.4 Recruitment

8.4.1 Phase 1 Recruitment

Data held about all UK Liaison Psychiatry in CQC, by RCPsych liaison faculty and/or CCQI PLAN will be reviewed. These data will be supplemented with expert knowledge to identify LP services that may exist, but are not described in the identified databases. For example, (1) LP services may be known to the study team but not included and (2) geographical areas or NHS Trusts may be conspicuous by their absence and suggestive of services suspected to exist. Information on these 'missing sites' will be obtained through publically available sources or co-investigator knowledge. This will create a 'long list' of LP services.

A purposively selected sample of responding sites will be telephoned to obtain further background information on the service and to gauge their willingness to participate further in LP-MAESTRO.

It is anticipated that not all services contacted will respond to the follow-up telephone interviews. Services that do not respond (even after repeated attempts, see below), will not be considered for Phase 2 on the rationale that they are not willing to participate. We will only consider LP services where there is an identified Chief Informant who has in indicated interest.

8.4.2 Phase 2 Recruitment

8.4.2.1 Services

LP services 'short listed' in Phase 1 of WS1 will be approached to participate in the study.

Invited LP services must be prepared to allow members of the LP service to be interviewed and to provide 28 days of consecutive survey data. No patient identifiable data will be collected or recorded; all survey data will be pseudonymised case-based and/or aggregated.

LP service level approval for the LP service to participate is anticipated to be provided by either the lead consultant or clinical service manager as appropriate for each service. This person will be the LP service Chief Informant.

The recruitment and interviews of commissioners, non-psychiatric clinical staff and psychiatric clinical staff can occur in any order and may be before, after or in parallel with the 28 day survey data.

8.4.2.2 Interviewees

Within the 'short listed' LP services that agree to take part, the names and contact details of commissioners, psychiatric 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, key members of non-psychiatric clinical staff and key member of psychiatric clinical staff), each of whom will be invited by the research team to participate in interviews.

Twelve services will be included in which at least one representative from each professional group will be interviewed. Shortlisted services will be replaced with a reserve if they are unable to provide this. This expectation will be made clear to services.

9 Data Collection, Management and Analysis

9.1 Data Collection Methods: Phase 1

9.1.1 Follow-up telephone interviews

Data held about all UK Liaison Psychiatry in CQC, by RCPsych liaison faculty and/or CCQI PLAN will be reviewed.

The Chief Informant at selected services will receive a telephone call to request further information about their LP service. An interview guide 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, but the interviewer will make notes under headings within by the interview guide. 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.

9.2 Data Collection Methods: Phase 2

9.2.1 Interviews

9.2.1.2 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).

9.2.1.3 Sample

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.

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 the 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. There will be a tailored version of the interview topic guide for each of the three professional groups, and a further interview guide for the confirmatory interview (see below).

9.2.1.4 Interview 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):

- Views on what a liaison service should provide.
- What service the LP service supplies locally.
- Why the service is configured in the way it is.
- Who delivers the service.
- Where the service is delivered.

9.2.1.5 Interview 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), who will sign a confidentiality agreement.

Framework analysis will be used to develop themes from the interview data. The transcripts of the semi-structured interviews will be analysed by a researcher. In order to improve validity (closeness to truth) [15] a sample (defined in the analysis plan) will be analysed independently by a second researcher with triangulation and where agreement cannot be reached arbitration will be sought.

9.2.2 Survey of Practice

Survey data will be collected for 28 consecutive calendar days prospectively and directly by the participating LP service staff. All data will be pseudonymised case-based and/or 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 routinely collected pseudonymised case-based and/or aggregated data. Every effort will be made to minimise burden to the LP services.

9.2.3 eDiscussions and Expert Workshop

Using information obtained in Phases 1 and 2, expert workshop(s) will be held preceded and followed by eDiscussion(s) to agree a classification of liaison services based on structures, clinical and service processes. Members of the expert service users group will be an integral part of this workshop. For each service type a service model or service programme theory will be formulated – what the service's aims are and how it is designed and run to achieve them.

9.2.4 Confirmatory Interviews

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.

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

9.3 Data Management

The project will utilize 5 datasets:

1. Operational database for the project, which will include: names of LP services, key NHS employee professional contact details and process data such as whether an interview has been scheduled and taken place etc.
2. Data received from CQC, by RCPsych liaison faculty and/or CCQI PLAN will include, for example: name of LP service contact, name of this liaison psychiatry service, name of the acute hospital served, and services provided. 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 will 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. Transcribed interview data, which will include: assessment (e.g. location and urgency), main problems seen (e.g. adjustment to illness, medically unexplained symptoms, or cognitive impairment), main reason for request (e.g. advice about diagnosis and management), and actions taken (e.g. medication review). The dataset will retain (a) the name of service from which they were collected and (b) the professional group of the interviewee.
5. 28 day survey data from services, which will include pseudonymised patient-level data: main problem associated with referral (e.g. adjustment to illness, medically unexplained symptoms, or cognitive impairment), reason for request (e.g. advice about diagnosis and management), actions taken (e.g. medication review) and follow-up and communication arrangements made. The data will contain a pseudonym that references the LP service from which it was obtained. All LP services will be given a unique pseudonym and a separate database will hold the mapping from this pseudonym to the identifiable details of the service (see 1).

All data will be considered to be potentially identifiable and/or sensitive, and will be managed in accordance with the Data Management Plan, agreed by the PMG.

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 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.

9.4 Analysis

9.4.1 Sample Size

9.4.1.1 Phase 1

- There is no *apriori* sample size for the 'long list' of services identified in Phase 1.
- The anticipated 'short listed' sample size after service selection is n=12.

9.4.1.2 Phase 2

1. The sample size for interviews will be:
    - Service commissioner (1-2 per service).
    - Key members of non-psychiatric clinical staff (2-6 per service).
    - Key members of psychiatric clinical staff (1-2 per service).
    - Confirmatory interviews with LP service Chief Informant (1 per service).

    In total there will be between 5 and 11 interviews per service, and 60 and 132 interviews in total.
2. The sample size for service surveys will be 12 (1 per service).

9.4.2 Analysis Plan

A detailed analysis plan for WS1 will be produced by the PMG prior to the analysis of any data.

Analysis of interviews will be undertaken using Framework Analysis.

9.5 Data Monitoring

9.5.1 Data Monitoring Committee

As detailed in section 10.2.2, a Data Monitoring Committee (DMC) will not be convened.

9.5.2 Interim Analyses

There is no plan for an interim analysis of data derived from LP-MAESTRO WS1.

10 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.

10.1 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 audits completed (Phase 2).
4. Number of interviews completed (Phase 2).

10.2 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 of LP services and Staff 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.

10.2.1 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.

10.2.2 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.

10.2.3 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.

10.2.4 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.

10.2.5 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 [13].

A budget is held for PPI consulting fees. A number of consultation reference groups (expert workshops) will be established to advise on materials and choice of outcomes. All PPI work will be reimbursed at INVOLVE [16] 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 [17].

11 Ethics and Dissemination

11.1 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.

11.2 Other Approvals

Please see sections 6.1.2 (Phase 1 site approval and activation) and 6.2.2 (Phase 2 site approval and activation).

11.3 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.

11.4 Consent or Assent

11.4.1 Phase 1

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

11.4.2 Phase 2

Patients will not be asked to provide consent for use of pseudonymised case-based 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 case-based and/or aggregated.
3. The study follows accepted practice.

All participants (LP service staff) who participate in the interviews will provide "explicit" verbal Informed Consent.

11.5 Confidentiality

All interview transcripts and published quotes will be pseudonymised.

11.6 Other ethical issues

The 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. No identifiable information will be collected on any NHS patients.

11.7 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.

11.8 Indemnity

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

11.9 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).

11.10 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 case-based and/or aggregated 28 day 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.

11.11 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.

11.12 Publication Policy

11.12.1 Study Results WS1

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

11.12.2 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.

12 Ancillary Studies

None at present.

13 Protocol Amendments

This is version 1.0 of the protocol: no substantial protocol amendments have been made.

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Annexe one: LP-MAESTRO project oversight structure.