MASTERplans

Maximizing SLE Therapeutic Potential by Application of Novel and Systematic Approaches

MASTERPLANS Patient and Public Involvement (PPI) Strategy and Implementation Plan

Final v1.0

This document sets out MASTERPLANS strategy for patient, carer and public involvement (PPI) in order to demonstrate the importance of PPI to the project and what it involves. It also outlines an implementation plan, showing how the strategy will be operationalised.

MASTERPLANS: Patient and Public Involvement (PPI) Strategy and Implementation Plan

Introduction and purpose

This document sets out MASTERPLANS strategy (Section 1) for patient, carer and public involvement (PPI) in order to demonstrate the importance of PPI to the project and what it involves. It also outlines an implementation plan (Section 2), showing how the strategy will be carried out.

The importance of PPI in research has gained international and national recognition as being central to health care research, policy and practice and this research project has had a strong commitment to PPI from the start. Patients are the ‘end user’ / ‘consumer’ of health services and provide valuable perspectives, so health research should be ‘earthed’ in patient communities. Patients also have many skills and experiences which may come from life and from working in other sectors (e.g working with volunteers, networking, professional skills such as budgeting, communications, data information) that can prove valuable in many areas of the research process.

The NHS, the Department of Health and the Medical Research Council are committed to PPI in research. A genuine commitment to collaboration with patients was made very early in planning MASTERPLANS and was an important criterion for obtaining MRC funding.

The intended audience for this document is:

- All MASTERPLANS project personnel
- Patients and carers who are considering becoming collaborators
- The Medical Research Council as the main MASTERPLANS funding body and other funders
- Other research projects: we intend MASTERPLANS to be an exemplar of good practice with regard to PPI.

Definitions

Throughout this document, the term **patient and public involvement (PPI)** is used. In this context, PPI refers to the wider community including patients, relatives, carers and other members of the public affected by lupus. Patient and public **involvement** refers to research being carried out ‘with’ or ‘by’ patients and other members of the public, as research partners and co-workers, rather than ‘to’, ‘about’ or ‘for’ them[1]. Involving patients, carers and the public helps ensure that their concerns and aspirations are consistently understood and considered.

Public **engagement** refers to the sharing of information and knowledge about research with the public.

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[1] INVOLVE: http://www.invo.org.uk (last accessed 5th August 2015)

Individuals taking an active part in MASTERPLANS will be known as **patient collaborators** (not 'patient representatives', as they speak from personal experience and give their own views, rather than speaking for the patient group as a whole). Patient collaborators comprise patients and others affected by lupus, e.g. family members/carers. Our aim is that membership of the patient collaborators team would reflect the varied population affected by lupus.

Patient **participation** refers to patients who have consented to take part in a research study, and, as participants, provide their data and / or samples.

Background: the MASTERPLANS project

SLE is a serious autoimmune condition which often causes serious disruption in a patient's life because of the numerous debilitating symptoms and unpredictable nature of its progress. The majority of patients are women in the prime of life: the impact of the condition is often life-changing. It can lead to miscarriage, loss of employment and adversely affect some relationships.

Many patients will be prescribed steroids but these have significant side effects. The aim of treatment is always to reduce steroid use, using biologic and other therapies, but there is no clear indication of which of the various co-medications will be most effective. The time needed to ascertain efficacy can be six months, so patients may have to wait several years, risking serious damage to the body before effective treatment is found and they are able to function with some measure of 'normality'.

MASTERPLANS will investigate biomarkers (e.g. genes, chemicals circulating in the blood or present in skin or kidneys) that predict the individual patient's response to treatment with mycophenolate, rituximab and other biologic therapies. Targeting the drug to the individual patient is called stratified or personalised or precision medicine. Early results of data mining from available clinical trials will guide to a hypothesis which can then be trialled in patients with either skin or kidney involvement to establish 'proof of concept'.

The results of the study should guide doctors to the most appropriate treatment for individual patients, following an assessment of the relevant factors, thus cutting down uncertainty and delays in effective treatment. It will also give information that industry partners can use to develop better testing kits and other products.

Part 1: MASTERPLANS PPI Strategy

1.1 Benefits of Patient and Public Involvement in the realisation of the goals of the MASTERPLANS project

PPI will help the MASTERPLANS project realise its goals, through the following anticipated benefits of PPI:

- **Improved research design** ('doing the right research'):
    - Advice on research protocols, including research priority areas and ensuring that the right questions are asked to improve health for patient benefit
    - Advice on how data and samples can be collected appropriately
    - Advice on the inclusion of outcomes important to patients
- **Improved research practice** ('making sure research is done right'):
    - External scrutiny from the end user, with insights from different perspectives, beyond those of researchers and the pharmaceutical industry:
        - Advice throughout the project on progress, risks and issues
        - Views on the research results
        - Input into plans for the sustainability and longevity of MASTERPLANS work beyond the end of the project
    - Better science through involvement of hard-to-reach participants
    - Better research impact through ensuring that the study focuses on objectives important to patients
- **Improved research governance** ('making sure that research is done legally and ethically'):
    - Ensuring that research ethics submissions, including Participant Information Leaflets and consent forms, meet patient needs and can be easily understood.
- **Improved patient recruitment and retention through easier access to patient communities**: ('spreading the word'):
    - Patients acting as champions for MASTERPLANS, including in hard-to-reach communities, by:
        - Disseminating the benefits of participation in MASTERPLANS and in research generally, while helping manage patients' expectations
        - Alerting patients on how to become involved in MASTERPLANS
        - Disseminating research progress and results
    - Potential barriers can be highlighted, which can have a bearing on patient recruitment and retention, including cultural issues

PPI is therefore vital for the successful delivery of MASTERPLANS and is interwoven through the whole Consortium.

1.2 Benefits of PPI to MASTERPLANS patient collaborators

- Being a patient collaborator and being in a network with other lupus patients will help patients increase their knowledge of lupus and of research, and may lead to patients knowing how to manage their condition better.
- Collaboration could help raise individual's confidence and give some validation to people's experience of living with a serious condition.
- Experience of committee working and other participative activities could be beneficial to patients in their career paths. Patient collaborators take responsibility to work as a team to assist with delivery of aspects of the work plan. MASTERPLANS undergoes periodic external reviews of its delivery against specified milestones, so commitment to deliver is crucial. This is another valuable skill.

1.3 Benefits of MASTERPLANS PPI to research beyond MASTERPLANS

MASTERPLANS will be an exemplar of good and possibly innovative practice in PPI in research. Patients not only bring their knowledge of living with the condition but they have other skills and experience (see above) which can enhance the Consortium's effectiveness.

MASTERPLANS PPI activities will generate a set of materials, including this document and a glossary of terms that could be used by other projects in the future.

1.4 Objectives of PPI in MASTERPLANS

The objectives of PPI within MASTERPLANS are therefore:

1. To plan the implementation of PPI in MASTERPLANS
2. To contribute towards delivery of better research, through improved research design and practice
3. To contribute towards achievement of high quality research governance
4. To act as a bridge between MASTERPLANS and patient communities, championing the project and assisting with opportunities for patient communications
5. To provide a set of resources for future projects to use

Part 2: MASTERPLANS PPI Implementation Plan

2.1 Management of PPI activities in MASTERPLANS

MASTERPLANS PPI Chair

MASTERPLANS appointed the PPI Chair, Jane Dunnage, as a co-applicant during the writing of the grant application. Jane was at that point Chair of the Trustees of LUPUS UK, and the on-going link with LUPUS UK has been very important to MASTERPLANS. The appointment of a PPI Chair before the start of the project meant that MASTERPLANS was able to embed PPI commitment into its activities from the very beginning.

The role of Chair is critically important to the success of PPI, if PPI is to be truly embedded into a research project. The Chair both directs the PPI contribution to the project and manages the delivery of the PPI plan. The role includes:

- Developing the PPI Strategy and Implementation Plan document (this document), PPI Communications Plan, Reward and Recognition document and other key documents, jointly with the project manager
- Identifying possible PPI group members and encouraging them to join the PPI group
- Managing the delivery of the PPI Implementation Plan, including encouraging PPI collaborators to play a valuable role in a various activities and facilitating their understanding of aspects of the research process
- Working closely with the MASTERPLANS Project Manager to provide a strong two-way communications link with the project and to plan the PPI work (weekly meetings in the early months; two-weekly thereafter)
- Maintaining contact with all members of the PPI group, by email, phone and face to face meetings
- Maintaining good, constructive relations with all members of MASTERPLANS Consortium and being a valuable member
- Preparing the PPI budget at grant application stage and managing it jointly with the Project Manager throughout the project

MASTERPLANS PPI Group

MASTERPLANS has recruited a PPI group of 18 members comprising patients and people affected by lupus, e.g. family members and who wish to contribute actively to the work of the project. The optimum size of the PPI group should be considered before recruitment starts, and will depend on the needs of the project (especially the number of committee membership positions and other roles to be filled) and the available budget for PPI activities.

Membership is encouraged from all sectors of the community affected by lupus, particularly those who may not ‘usually’ be approached. Following initial conversations with the PPI Chair about the aims and responsibilities of getting involved, individuals register with the Project Manager to join the group; this is necessary as they also sign a confidentiality agreement.

The group has responsibility for particular PPI activities such as well-written patient information, communication about the project and patient-focussed approaches. Individuals can get involved according to their interests and availability, but understand the need to commit to deadlines. Activities are undertaken in a variety of ways: by teams, at PPI workshops or at focus group meetings. Recognising that lupus is an active and often unpredictable condition to live with, patient collaborators often work in pairs so that they can support each other and provide a variety of experiences: all the committees have two patient collaborators involved.

As well as leading the group, the Chair is responsible for identification and resolution of risks and issues with regard to PPI activities and communicating risks and issues to the Project Manager. The PPI Chair's immediate contact for planning and progress reporting is the MASTERPLANS Project Manager.

PPI group meetings

The group meets face to face annually for a dedicated PPI workshop. The group may wish to convene from time to time, either by teleconference/Skype in addition to other meetings. Representation from the group will attend face to face meetings of the MASTERPLANS Consortium of academic and industrial partners.

Links with LUPUS UK

The group is linked with LUPUS UK nationally and through local groups. The charity has agreed to support MASTERPLANS, particularly by circulating information to its members and supporters and by inclusion of MASTERPLANS information on its website and social media. Several PPI members are also LUPUS UK committee members; of which one member will act as liaison between the charity and the PPI group.

Reward and recognition

Benefits for patient collaborators, including remuneration, are provided in a separate document 'PPI reward and recognition'.

Problems arising, including disputes and complaints

Problems will be referred to the PPI Chair and / or the Project Manager. Any matters / issues unsuccessfully resolved by these two people will be referred to the Chief Investigator, Professor Ian Bruce, as a final resort.

2.2 MASTERPLANS PPI responsibilities

The MASTERPLANS PPI group has the following areas of responsibility:

1. Planning the MASTERPLANS PPI work and allocating PPI roles
2. Membership of MASTERPLANS strategic and operational committees

3. Reviewing, commenting and advising on MASTERPLANS plans, outputs and results from a patient perspective:
    - Including research governance materials and planning of future work beyond the end of the MASTERPLANS project
4. Managing, preparing and undertaking communications with patients, and other stakeholders external to the project as specified in the PPI communications plan.
5. Managing and taking part in enabling activities that will help patient collaborators learn more about MASTERPLANS and lupus research generally and make meaningful contributions to the work of the Consortium.
6. Maintaining a library of MASTERPLANS PPI documents on the MASTERPLANS website.

Participation in the PLANS clinical study is outside the scope of the PPI group remit. Participation in PLANS is managed by patients' hospital clinicians, who are responsible for identifying patients as suitable for PLANS. Some patient collaborators may be invited to take part in PLANS; however their participation will be managed through their hospital Trusts in accordance with the PLANS ethical approvals.

2.3 MASTERPLANS PPI activities in more detail

2.3.1 PPI planning

The main PPI planning phase (2014 to October 2015) comprised:

- Identification of members of the MASTERPLANS PPI group
- Development of the PPI Strategy (this document) and supporting documents
- Development of the PPI Communications plan
- Appointments to PPI roles (committees, Communications Team Leader)

2.3.2 Committee membership and project oversight

Two members of the PPI group sit on each of the following committees, so that members can support each other. The Project Manager met with patient collaborator members before the first meeting of each committee in order to brief them. Further pre and post-meeting briefings can be held with the PPI Chair if the patient collaborators feel that is helpful to their participation. The Glossary is available to explain terminology.

MASTERPLANS committees:

- Consortium Management Board (CMB)
- Project Steering Group (PSG)
- Scientific Advisory Board
- Access Committee
- Longevity Committee
- Commercialisation and Knowledge Transfer Committee
- Analysis Group

Patient roles on committees

Patients will contribute to committees in their role as experts with lived experience often in touch with other lupus patients, and in a more general role according to the expertise required by the committee.

The following benefits are anticipated from patient committee membership: perspectives independent of researchers and industry; better communication between patients and scientists and health professionals; specialist expertise and lived experience; improved research design and practice; knowledge of how lupus affects others; understanding of barriers to involvement.

Method of appointment to committees

A document was made available to enable PPI collaborators to choose committees that they would be interested in joining. The document covers the commitment for being a committee member of each committee and an outline job specification for committee members. Patient collaborators were invited to send an expression of interest in membership of particular committees to the PPI Chair and Project Manager. Where there were still vacancies, the PPI Chair approached individuals.

2.3.3 Reviewing, commenting and advising on MASTERPLANS plans, outputs and results

Patient collaborators will generally review project plans, outputs and results as part of their membership of committees and through attendance at face to face Consortium meetings. Reviews of research governance materials (see Section 2.3.4) will take place outside formal meetings, often by email and teleconference, in collaboration with the Project Manager.

Results: Project results on specific biomarker discovery are amongst the most sensitive information generated by the project and will be disseminated on a very limited basis prior to publication. However, every effort will be made to share project results with patient collaborators, even if the names of particular markers cannot be divulged.

Future work beyond the end of the project: MASTERPLANS anticipates follow-on clinical trials testing the emerging algorithm and any kits for testing biomarkers in clinic. Patient input into the planning of this research will be important. This will be primarily through patient collaborator membership of the Longevity Committee, Project Steering Group and Consortium Management Board.

2.3.4 Contributions to MASTERPLANS research governance

Members of the PPI group work closely with the Project Manager in the development of the research ethics applications for the new ('prospective') PLANS study in Work Strands 2 – 4. It is possible that a research ethics application may also be required in Work Strand 1 (existing data and sample sets).

Patient roles in research governance

Members of the PPI group are invited to review parts of the Research Ethics Committee (REC) application (which comprises many documents) including:

- Patient Information Sheet(s)
- Consent Form(s)
- Posters and other advertising materials to attract patients to participate in the studies
- Certain parts of the main application and parts of the research protocol (both of which are long documents)
- The lay summary

There are a number of other related applications to different regulatory committees, and it is possible that patients may be invited to comment on parts of any of these. All applications may be subject to amendments due to changes in the research, so patients may be asked to comment on amendments as well.

The following benefits are anticipated: better research design, including data and sample collection processes; improved readability and attractiveness to patients of the Patient Information Sheet, posters and other advertising materials; sensitivity to cultural/religious aspects, improved patient recruitment with wider reach to some groups and retention through management of patients' expectations.

Commitment

This will depend on the length of the document. Approximately one to two hours will be needed for commenting on short documents such as Patient Information Sheets and associated consent form(s) and as long as possible will be allowed for this to be done. Reviewing parts of the main application and research protocol may take substantially longer.

2.3.5 Management of communications to patients and the public

Working closely with the MASTERPLANS Project Manager, the Communications Team will lead communications with patients and the public. Work will comprise:

- Development of a patient / public communications plan. This will be a sub-plan of the main communications plan for the whole project.
  - The plan will be based around 'triggers' for communication and how to address various stakeholders and to reach those who are able to influence decision-makers.
- Preparing and reviewing communications at trigger points and releasing communications in the most appropriate media. This may include:
  - Providing advice on the most appropriate media to use in order to reach other patients.

  - Identifying opportunities and events which can further the work of MASTERPLANS.
  - Presenting MASTERPLANS work at hospital open days.
  - Provide regular information on progress of the study in the LUPUS UK News & Views magazine.
  - Social media postings about MASTERPLANS.
  - Developing and updating the MASTERPLANS PPI web pages.

The following benefits are anticipated: championing MASTERPLANS in the patient community; disseminating ways to become participants in PLANS; advising on appropriate and sensitive ways of reaching patients; patient-focussed measures' dissemination of results; educating patients and the public concerning the benefits of research participation and regarding lupus generally, including better management of the condition by patients and health professionals.

Commitment

Development of the communications plan will take many hours and will be supported by the Project Manager. Preparing communications such as articles could take around three hours per communication, though social media communications would be much quicker. Reviewing communications will take around 1 hour per communication.

2.3.6 Enabling activities

Some PPI activities will assist patient collaborators by providing training and resources to enable them to play a full role in MASTERPLANS. Activities will include:

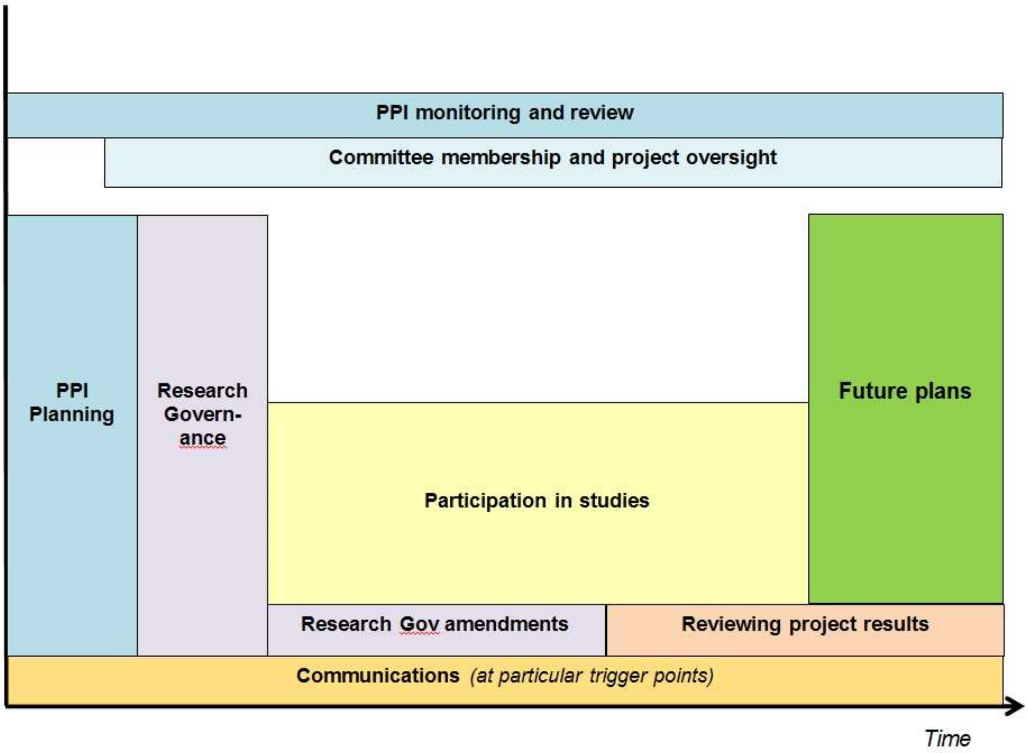
- Development of a glossary of terms used in MASTERPLANS and lupus research
- Training activities at PPI and Consortium meetings
- Circulating information on other training courses, articles, websites etc.

2.3.7 Maintaining a library of documents on the MASTERPLANS PPI website

To meet the MASTERPLANS PPI objective of being an exemplar to other projects, the MASTERPLANS website will include key PPI documents and other information about MASTERPLANS PPI.

2.4. Outline timeline of MASTERPLANS PPI activities

The following diagram outlines the different PPI activities over the duration of the project. For convenience, 'participation in studies' is also included, even though (as noted above) it is outside the remit of the PPI group. The timing of most activities after the initial planning / set-up phase is driven by activities elsewhere in the project.



2.5 Barriers and enablers of MASTERPLANS PPI

Barriers

There are a number of difficulties and barriers to PPI[2]. For MASTERPLANS PPI to be successful, an awareness of possible barriers is needed. For lupus patients, barriers to involvement include:

- Difficulties finding out about opportunities for involvement
- Patient's health can be unpredictable
- Not used to taking part in meetings/reading papers
- Formal recruitment processes can be off-putting
- Learning the language of a specialised discipline (glossary being provided to help with this, also plan for support from scientific 'buddy')
- Uncertainty about what is expected of patient collaborators in different activities
- Changes in personal circumstances which re-define priorities e.g. birth of a child, change in career
- Not receiving feedback on what the patient has contributed
- Need to concentrate on complex issues for extended periods.
- Difficulties with teleconferences: hearing and recognising who is speaking, breaking into the conversation
- Personal difficulties: physical, emotional and fatigue because of their condition;
- Caring responsibilities for children and other family members

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[2] http://www.healthtalk.org/peoples-experiences/improving-health-care/patient-and-public-involvement-research/difficulties-and-barriers-involvement

- Organisational barriers: timing and location of meetings; having to take time off work to attend meetings
- May prefer to have a less structured approach to involvement
- Disillusionment about the process and the length of time involved
- Unable to sustain initial interest

Enablers

The above barriers are addressed in Section 9 (Operational guidelines).

To underpin work in the PPI group's areas of responsibility, patient focus groups will take place to provide a better shared understanding of patients' views on key issues, including measures of improvement in their condition.

2.6 Operational Guidelines Supporting MASTERPLANS Public and Patient Involvement

The following guidelines for good practice should be considered during planning of any PPI activity:

1. MASTERPLANS will be conducted to the highest ethical standards, and the dignity and rights of PPI members will be respected at all times.
2. If there is PPI attendance at any committee or other activity, at least two PPI members will allocated.
3. Patients will be suitably trained for their roles:
    - Training will be provided on important topics as part of the focus group meetings
    - Patients will be briefed by the Project Manager before attending meetings
    - Support will normally be provided by the PPI Chair in the first instance
    - A glossary of key terms will be provided.
4. When planning meetings, consideration will be given to:
    - Distance and transport links between the venue and patients' homes, including, where applicable, provision of taxis to the nearest station.
    - Access to the building, meeting room, toilets and refreshment area, for people with limited mobility.
    - Provision of appropriately accessible information *eg* large print versions of papers
    - Provision within the agenda of adequate breaks for patient collaborators.
    - Post-meeting evaluation from the perspective of patient participants.

    Every effort will be made to facilitate involvement arrangements for patient collaborators:

    - Appropriate refreshments will be provided during the activity.
    - The length of time for which patients are out of pocket following a MASTERPLANS activity will be minimised:
    - The University of Manchester provides a service for booking and pre-paying for hotel accommodation and travel.

- The MASTERPLANS Project Manager will process patients' expense forms promptly and will inform the patient when the form has been submitted to the University financial administration system. NB It is not possible to fast-track expense forms.

6. MASTERPLANS website:
   - The public website will include PPI information in order to inform current and future patient collaborators and help engage with the general public.
   - The PPI group will have its own private work area within the MASTERPLANS website, in which members can share public documents.
7. The Project Manager and Chair of the PPI group jointly control the budget for PPI activities, and all anticipated expenditure must be authorised in advance, ideally by both individuals.

2.7 Monitoring and review of PPI activities

The PPI Chair and the MASTERPLANS Project Manager will routinely review progress, risks and issues in their weekly meetings. In addition, PPI activities will be reviewed in the same way as all other parts of the MASTERPLANS project. Project Steering Group and Consortium Management Board patient members will report PPI-related progress, risks and issues verbally in the regular committee meetings. The PPI Group will also feed into the six-monthly reporting to the Medical Research Council (MRC).