

3.4 Patient and Public Involvement Programme

3.4.1 Patient and Public Involvement Start-up Strategy

From the inception of the Co-ordinating Centre a Patient and Public Involvement (PPI) strategy was developed to ensure that DeNDRoN supports clinical research that is not only of the highest quality, but is of direct relevance to people affected by dementia and neurodegenerative diseases and that the adoption, development and delivery of clinical studies in the Network is done in partnership, with people affected by these conditions.

In 2006 Start-Up Strategy laid out principles and objectives to ensure that DeNDRoN supports clinical research that is of direct relevance, informs and actively involves people affected by the conditions at all stages of the research process both locally and nationally, and takes account of views and perspectives of patients and carers in the wider DeNDRoN strategy.

The aims of the PPI Start-Up Strategy were:

- To ensure that the views and perspectives of people affected by these conditions inform the DeNDRoN strategy
- To develop systems to inform and actively involve people affected by these conditions in clinical research at all stages of the research process both locally and nationally

The principles were:

- The views and perspectives of people affected by these conditions should inform the DeNDRoN strategy
- There should be an open and transparent system of PPI in all DeNDRoN activities. Active involvement should be at all stages and all levels of the research process
- The role of people affected by these conditions within the different components of DeNDRoN should be clearly defined

- There should be PPI on all key national and local DeNDRoN committees, with a minimum of two lay members on these committees
- There should be PPI in all DeNDRoN activities including production of information (newsletter, website etc) and attendance at conferences and events
- The timing and venues of committee meetings should take into account the needs and preferences of lay members
- Training, mentoring and support should be provided for people affected by these conditions and researchers, in relation to best practice for PPI, as well as other identified needs
- Information about DeNDRoN should be accessible to patients, carers and the public
- Duplication and fragmentation with other PPI initiatives and other organisations should be avoided (e.g., INVOLVE)
- The impact of the programme should be regularly reviewed, and should evolve as the Network's activities progress

The key objectives of DeNDRoN's initial PPI strategy were:

- To form a working party of experts (PPI Working Group; see section 3.4.2) who have experience and expertise in involving people affected by these conditions in research and service development; people affected by these conditions with some experience of active involvement in research; representatives of dementia, Parkinson's, MND and Huntington's medical research charities; and representatives of the DeNDRoN Co-ordinating Centre. The PPI Working Group was to lead on the PPI programme and its progress
- To establish and support a group of people affected by these conditions (Patient and Public Involvement Forum; see section 3.4.3) to advise and inform the DeNDRoN Directors, Operational Steering Group, Clinical Studies Groups and Study Adoption Panels on neurodegenerative disease research priorities from the perspective of those affected by these conditions
- To advise and provide support for the DeNDRoN Local Research Networks, Adoption Panels and Clinical Studies Groups on actively involving patients, carers and the public in clinical research activities
- To develop best practice guidelines about different methods and levels of active involvement of people affected by these conditions in clinical research
- To be a central resource to provide patient and carer input into the development of new research studies and lay peer review of research proposals and papers
- To organise in partnership with members of the Patient and Public Involvement Forum annual meetings in DeNDRoN Local Research Networks to inform patients, carers and the public about recent developments in neurodegenerative diseases research and Network activities (new and ongoing studies).
- To develop communication strategies to inform people affected by these conditions about neurodegenerative diseases research and DeNDRoN activities via appropriate media e.g. DeNDRoN website, newsletter, events

3.4.2 The PPI Working Group

To meet the first objective, the DeNDRoN Co-ordinating Centre established a working party. This was originally called the DeNDRoN PPI Road Map Group and first met in 2007, to lead and advise on the PPI programme and its progress. In November 2007, it became the PPI Working Group, incorporating professional representatives from each LRN, and adopting a more operational focus.

The remit of the PPI Working Group is:

- To ensure that the identified research interests and priorities of patients, carers and the public are fully taken into account
- To operate at a strategic level and assist with the development of overall DeNDRON policy in respect of improving clinical research for the benefit of people affected by these conditions
- To review and amend as necessary the aims, principles and objectives of our PPI programme
- To develop a 'road map' of how the DeNDRON Co-ordinating Centre should undertake to develop the PPI programme in order to deliver the 'aims' and 'objectives' as agreed by the Working Group

The members of the original Road Map Group were asked to consider and submit comments on the aims, principles and objectives prior to its first meeting which were then signed-off. The Group has since met several times to develop plans to achieve these and in early 2008 expanded to include Local Research Network DeNDRON staff in an increased membership. This now comprises a Chairperson, patient representatives, representatives of appropriate partner organisations, one staff representative from each of the seven Local Research Networks and from Supplementary Resources; and NEURODEM Cymru as appropriate, and also DeNDRON Assistant Director, PPI Co-ordinator and DeNDRON's MND Lead.

The PPI Working Group is responsible to the DeNDRON Co-ordinating Centre Executive and has an advisory role to support the Clinical Studies Groups, Special Interest Groups, and Study Adoption processes, Local Research Networks, Supplementary Resources, and also Devolved Nations work when appropriate (see figure 3.13 and section 3.3 for description of DeNDRON Corporate Governance).

At the end of 2006, the DeNDRON Co-ordinating Centre appointed an officer to act as the PPI Co-ordinator of this programme of work. The PPI Co-ordinator is responsible with the Working Group for developing and delivering the PPI programme.

PPI priorities

The Working Group has agreed national priorities for PPI. In Feb 2008, it looked at the potential added value which PPI could bring to each of DeNDRON's processes, and the PPI methods thought to be most suitable for each process. The agreed high priority processes for PPI are:

- Strategic local and national steering groups – setting strategy and monitoring performance
- Study adoption – in particular, determining the overall feasibility of a study
- Study development – in particular, prioritising themes for research, including under-investigated themes, calling for research proposals, and working up specific practical questions into research proposals
- Patient recruitment to studies
- Communications

There are a number of issues which need to be addressed to enable people affected by neurodegenerative diseases to become more actively involved in clinical research. Although many of these issues cut across all diseases, there are those that are specific to each disease: e.g. opportunities for PPI with those with rapid disease progression are limited. Involvement of people with marked cognitive impairment is particularly challenging, and carers of people living with dementia have, in practice, been much more involved in DeNDRON discussion groups than patients themselves. There are also challenges to overcome with involving people with mobility and speech problems.

3.4.3 The Patient and Public Involvement forum

One of the initial objectives of the Patient and Public Involvement programme was to establish and support a group of patients, carers and other people affected by these conditions to provide advice.

The PPI forum is a major element in the PPI Start-Up Strategy document. The Road Map Group supported the general idea, but felt that the initial focus should be to establish links between those people who are already actively involved and was cautious about advertising widely for members of a forum. It was therefore agreed that all the individual lay members of DeNDRoN groups, locally or nationally, should be viewed as constituting this PPI Forum. The Forum can also include other individuals, but only if they are contributing significantly to DeNDRoN PPI activities, as membership needs to be as tightly focussed as possible.

The Forum is a point of referral and discussion for PPI issues, electronically or in person. The PPI Forum is supported by the PPI Co-ordinator, who ensures that the level of activity expected from PPI Forum members, and the information flow, are not excessive to avoid overloading.

The remit of the PPI Forum is:

- To act as a forum for discussion, to ensure that the identified research interests and priorities of patients, carers and the public are fully taken into account
- To provide a supportive environment in which people can become increasingly involved in all stages and at all levels of the clinical research process to improve clinical research for the benefit of patients, carers and the public
- To provide input from people affected by these conditions into the DeNDRoN Clinical Studies Groups (via CSG membership)

The PPI Forum members can receive ongoing training and support to help them fulfil specific roles, and to become as effective as possible in ensuring their views, perspectives and experience are valued and taken into account.

In 2008, DeNDRoN established an opportunity for patient and public representatives sitting on DeNDRoN's local and national committees to meet together as the PPI Forum, which also included other patients or carers not on committees but contributing in other DeNDRoN PPI activities. The PPI Forum is gradually establishing itself as a cohesive national community.

3.4.4 Appointment of lay representatives to DeNDRoN committees

All LRN Steering Groups and national DeNDRoN Clinical Studies Groups and the Methodology Special Interest Group have patient and/or carer representatives. Lay members have been chosen through a combination of consultation with medical charities and recruitment via open national advertisements.

Some Clinical Studies Groups chairs have agreed to include more than the two members formally required. Lay patient organisation membership of DeNDRoN groups is shown in figure 3.14.

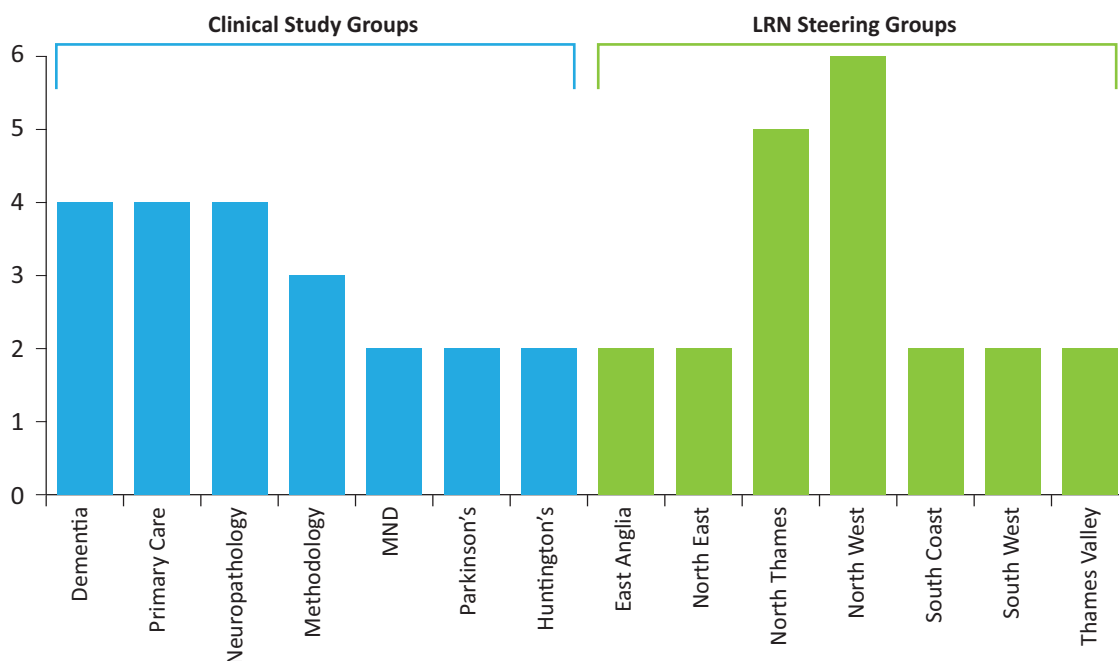


Figure 3.14: Patient and carer representative numbers on DeNDRON CSGs and LRN Steering Groups

Mentoring and training of patient and public representatives

The Working Group recognised that good support lay members would attract a broader range of people, and supported a proposal by the PPI Co-ordinator to develop mentorship mechanisms to focus on scientific understanding and general confidence in the role. However, mentoring for lay members in DeNDRON is seen as part of a two-way support system, where lay members can opt to link up with a professional member of the same committee. The DeNDRON Co-ordinating Centre consulted about support mechanisms. A DeNDRON focus group of patients and carers held in the North West LRN on this topic felt strongly that it must mean mutual support. The system uses an initial checklist and a follow-up checklist, and lay members can use these checklists in the same way to support 'professional' members of the group, including advice about joint working and patient and/or carer perspectives, and discussing the professional member's continuing development.

The initial checklist comprises discussing each other's expectations of support, exploring the purpose of DeNDRON and role of the Group, clinical understanding and research methods, avenues for relevant background reading, training needs and other support. The follow-up support checklist looks at areas where both lay and professional member might wish to improve skills, and increase patient and public involvement.

A twin-track approach to PPI

The PPI Working Group supports a twin-track approach to involvement, i.e. that formal representation on committees exists alongside mechanisms for broader PPI engagement, and that the engagement with medical charities runs alongside engagement with individual patients and carers not connected to any organisation. However, at least initially, the PPI Working Group recommended that efforts should concentrate on developing patient and carer representation on DeNDRON's committees rather than a wide-ranging assortment of involvement methods, although these will be useful as supportive mechanisms, both locally and nationally. The Group stressed that it was more important that DeNDRON should tap into the existing knowledge within all the medical charities and their wealth of expertise in consulting around often complex issues, together with expert input from PPI professionals, rather than 'reinventing the wheel' (see figure 3.15).

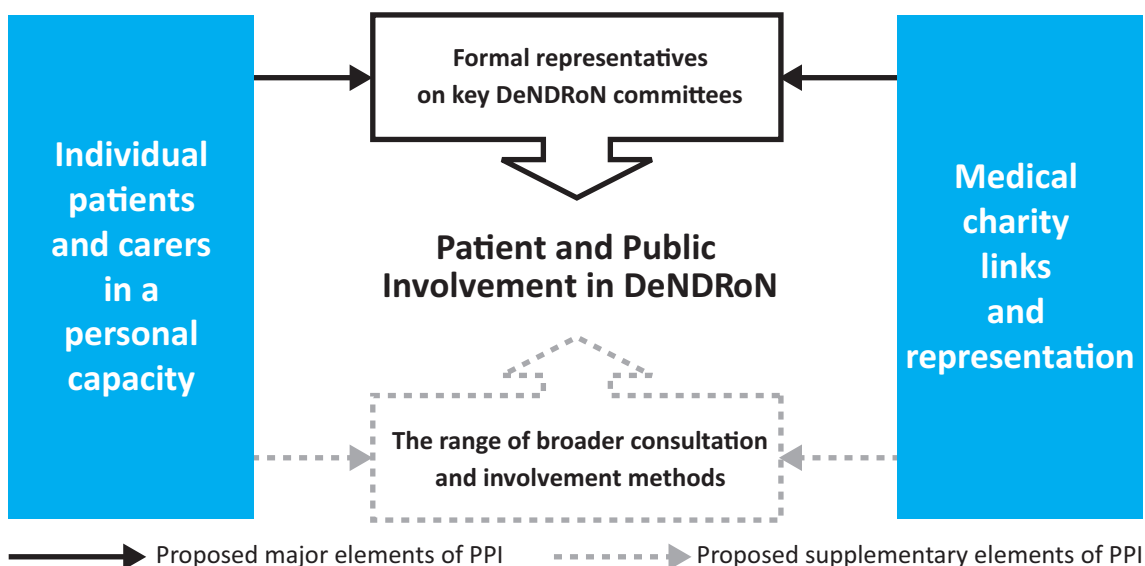


Figure 3.15: 'Twin-track' approach to patient and public involvement.

3.4.5 Communication

The Co-ordinating Centre has established a dedicated PPI area within the DeNDRON website and Portal and a newsletter to inform patients, carers and the public about neurodegenerative disease research. The PPI Co-ordinator leads on the development of these communication channels with the input of the PPI Working Group, and support of the UKCRN PPI Lead. The PPI Co-ordinator and DeNDRON Co-ordinating Centre work closely with the national press offices and local branch networks of the relevant patient and carer disease-specific charities to develop appropriate communications with these partner organisations.

There have been nationally organised focus groups and discussions around the barriers to participation in research (addressing dementias, HD, and PD so far). These have allowed individuals not formally on any committees to be involved in PPI outputs, and see themselves as part of the Forum. The PPI pages of the NIHR DeNDRON Portal are being developed to allow Forum team discussions and document reviews. Patients co-chaired sessions of the 2008 Annual Conference.

Figure 3.16 describes the relationships between the various components of PPI in DeNDRON. Communication between these components is by formal meeting minutes and informal channels described above.

3.4.6 PPI structure

The structure of patient and public involvement is described in figure 3.16 and the model of PPI in DeNDRON study development is shown in figure 3.17.

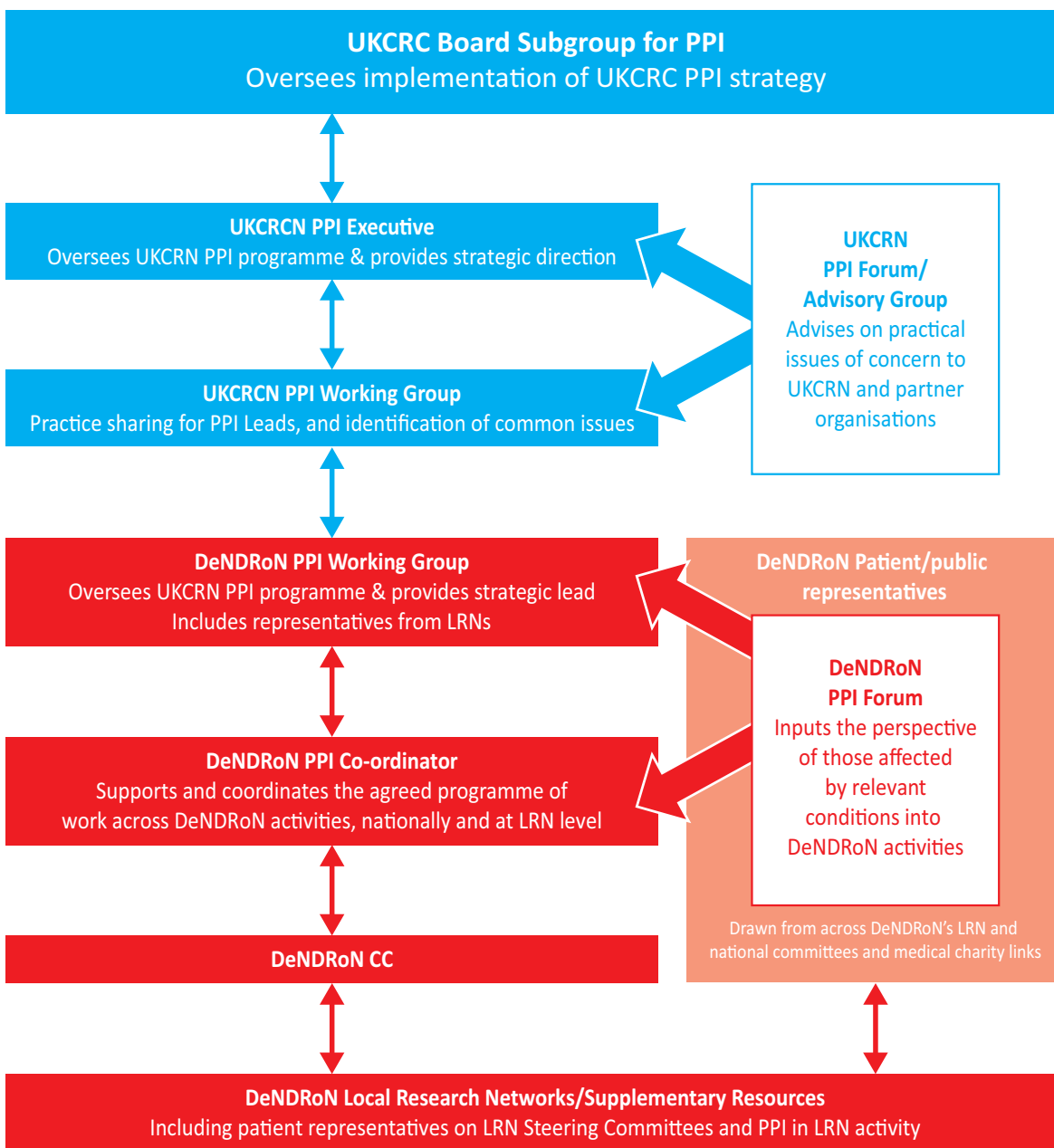


Figure 3.16: Diagrammatic representation of PPI structure and key relationships

3.4.7 PPI contributions to DeNDRoN outcomes

Lay membership across all the CSGs has enhanced DeNDRoN's relevance to patients and discussions in CSGs have changed in terms of clarity and relevance to patients and carers. The PPI impact from strategy setting through to designing research questions and adoption is mainly at national CSG level, whereas study management and delivery are mainly at LRN level.

For example, as a direct result of patient input, the Parkinson's Disease CSG is working up large-scale research into patient priorities for clinical research. In addition, a lay member who is a patient with early dementia presented a report to the Dementias CSG around barriers to recruitment to dementia research. This drew ideas from two DeNDRoN focus groups which had explored the topic in the North East. This prompted the CSG to investigate potential ideas for developing clinical research into models of care for dementia.

Figure 3.17 describes the study development cycle. Examples of PPI in the cycle are given below.

- 3.4.7.1 Point 1, 'Strategy setting at CSG level'**, is the proposed CARE-DEM trial of care co-ordinators in dementia. This arose out of strategic priorities of both the Primary Care CSG and Dementias CSG with particular involvement of patient representatives (see section 5.9).
- 3.4.7.2 Point 3, 'Designing research questions'**. The PD Get-UP study was first developed in the South West with a large amount of patient input at the design stage and shows that PPI at LRN level can enhance the design of research questions locally as well as nationally.
- 3.4.7.3 Point 4, 'Designing and submitting proposals'**, is exemplified by the LiCALS study. All professional and lay members of the MND CSG wholeheartedly supported the demand for a study of efficacy of lithium and contributed to the rapid submission and adoption of the study into DeNDRoN (see section 5.9).
- 3.4.7.4 Points 5, 'Study management at LRN level' and 6, 'Study delivery at LRN level'** are exemplified by patients and carers in South West, East Anglia and Thames Valley LRNs who participated in discussion groups looking at specific studies exploring a tool kit of processes to enhance accrual rates to these studies. Other DeNDRoN LRN patient and carer groups which have addressed LRN study management more generally, suggesting methods for how PPI can help to open up new research sites.
- 3.4.7.5 Point 6, 'Study delivery at LRN level' PPI Tool kit**

A basic off-the-shelf tool kit of PPI involvement methods is under development by the PPI Co-ordinator to facilitate LRN engagement around study development, delivery and, in particular, accrual to studies. A series of discussions and focus groups with patients and carers has looked at what tools can help LRNs to address challenges around specific studies. The tool kit will include items to help with gaining ethical approval for disseminating information about studies, working with local patients to develop new sites for studies and tackling obstacles to accrual. Practical checklists to support exercises such as focus groups and templates and guidelines for surveys have already been developed. The tool kit has been developed through the PPI forum and a series of workshops including two at the 2008 DeNDRoN conference (see section 6.7 for an example of where PPI is used in study delivery).

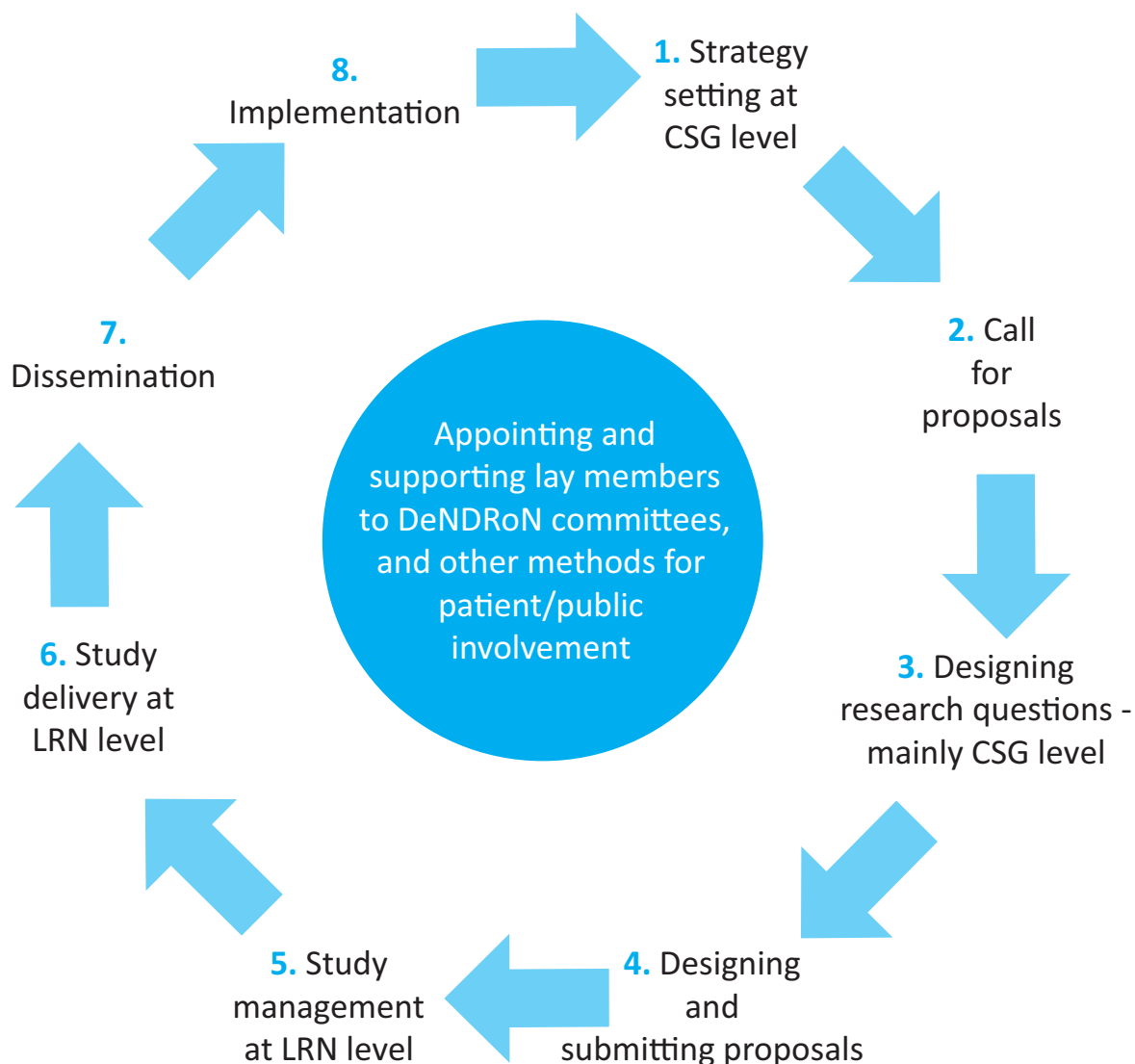


Figure 3.17: Model of PPI involvement in DeNDRON study life cycle

3.4.8 Evaluation PPI

The PPI Working Group supports a pragmatic approach to evaluation, following on from the earlier discussion about ethical and strategic principles underlying PPI. Initially, the process indicators are documenting involvement in all of DeNDRON's key committees and measuring whether the actual activities (e.g. number of lay member representatives on a committee) matches the planned targets. The PPI working group felt it was important to allow sufficient time to develop and implement PPI in DeNDRON before attempting to formally evaluate it. It was decided in mid 2008 that a survey of attitudes to PPI in research should be concluded to provide a baseline against which future progress can be measured. This will be conducted early in 2009. In addition a 360° appraisal of PPI activities will be conducted in mid 2009 to identify areas of focus for the next period of the DeNDRON contract.

3.4.9 PPI in Local Research Networks

LRNs are taking every opportunity to raise public awareness of what the network can offer to support clinical research, and at the same time patients and carers are increasingly helping to shape LRN projects and steer LRN developments. All LRNs have a cohort of patients interested in involvement in DeNDRON management and general activity. All LRNs have had attendance of patients/carers at their local launches.



3.4.8.1 – NIHR DeNDRON Co-ordinating Centre Review 2008

There is a growing recognition that all staff members are responsible for mainstreaming patient and public involvement in LRN activity and that raising public awareness is a basic starting point for building cohorts of patients and carers interested in research. For example, East Anglia DeNDRoN's 2008 conference included presentations from patients and carers, and charity display stands. It was publicised in local libraries and clinics. North East DeNDRoN held a successful first conference attended by over 100 people which included patients and medical charity representatives. Most LRN launches have included prominent speeches given by patients and carers, including some powerful accounts of patients' experiences and views on clinical research. In North Thames DeNDRoN a comprehensive scoping exercise of all relevant PPI stakeholders was completed in spring 2008. One identified action from this was a full day conference attended by over 40 patients and carers to map out further opportunities for PPI involvement in the LRN's work. From this group five people stepped forward to sit on the North Thames DeNDRoN steering committee.

Publicity has not been limited to launches. LRN staff members have visited many local charity patient and carer groups to speak. This outreach has not only involved DeNDRoN research staff; in the South West, for example, senior Clinicians have addressed local groups on behalf of DeNDRoN. Other outreach has included an LRN providing financial support for patient representative events in return for DeNDRoN exhibition space.

3.4.9.1 Building systematic local involvement

Many LRNs are systematically mapping their local communities, and building up cohorts of interested patients and carers. For example, Thames Valley DeNDRoN has scoped the type and remit of organisations in the Thames Valley which are involved with dementia, motor neurone disease, Parkinson's disease or Huntington's disease. This will enable future contact by Research Nurses or investigators to provide information to groups and will provide an opportunity to involve patients and carers at an early stage of research development. South West DeNDRoN is also mapping the local patient groups, and North Thames DeNDRoN has made considerable effort to understand the general organisation of the constituent NHS trusts and the individuals, both professionals and patients, who are associated with them. Rather than being limited to an ad hoc resource, North Thames DeNDRoN is building on this approach to develop a PPI Panel, as part of their PPI strategy.

