

Patient List Protocol

Aims and Objectives of the Patient List:

1. To establish a list of people with a diagnosis of any dementia, mild cognitive impairment, Parkinson's disease, progressive supranuclear palsy, multiple system atrophy or other neurodegenerative disease willing to consider participating in research studies adopted by the Dementias and Neurodegenerative Diseases Research Network (DeNDRoN) portfolio, or approved by the Local Research Network Steering Group or executive.
2. To assist with the identification and recruitment of participants into DeNDRoN research studies. To enable early recruitment to research studies.
3. To inform people on the Patient List about research and other activities in North East DeNDRoN.
4. To promote equal access to research opportunities throughout the region.

Background

Key objectives of the North East Dementias and Neurodegenerative Diseases Research Network are to:

- To be an efficient, enthusiastic and committed Local Research Network delivering high-quality clinical research successfully, on time and to target, as part of the NIHR Clinical Research Network
- Increase involvement of local healthcare professionals, patients and their carers in studies of dementia and neurodegenerative diseases across all NHS Trusts in the North East. Increase research capacity, number of clinicians and healthcare professionals engaged in research, number of studies, number of Trusts engaged in research, and total recruitment to studies. Increase numbers of industry studies, and deliver all of these on time to target.
- Maintain a balanced portfolio with research studies in all disease categories. Encourage the development of new research initiatives appropriate for adoption by NIHR and the Dementias and Neurodegenerative Diseases Research Network.

North East DeNDRoN covers the area from the Scottish Borders to North Yorkshire and across to Cumbria. We have cooperative links with DeNDRoN Speciality Groups in the North and East Yorkshire and Northern Lincolnshire CLRN, West Yorkshire CLRN, and South Yorkshire CLRN.

Dementias and Neurodegenerative Diseases Research Network

Demographics

The North East had a population of 2.6 million people in 2010 (5% of the population of England) of whom 17.2% (450,000) were aged over 65. The population is projected to rise to 2.8 million by 2030 with 23.6% aged over 65. This is the second highest proportion of over 65's in the country after the South West (Office of National Statistics).

The population includes an estimated* 31,840 people with dementia (of whom more than half may not have a diagnosis), over 5,000 people with Parkinson's disease, 179 people with motor neurone disease, 350 people with Huntington's disease (plus at-risk individuals), and 125 people with progressive supranuclear palsy. These people need research to be integrated in their care, so participation in a clinical research study becomes a standard treatment option in our region.

The Patient List does not include people with Motor Neurone Disease or Huntington's disease as services for these groups are well integrated regional services; patients are known to the clinicians providing health care and research; and the MND Association and Huntington's Disease Association websites have facilities for people to volunteer for research. Because the services for these patients are regional and all are known to the relevant clinics, we can reach these patient groups with specific appropriate newsletters separate from the Patient List newsletters.

**data sources - Department of Health Report for The North East Dementia Regional Development and Implementation Group April 2009, 'A demographic and Service Profile'; Alzheimer's Society/Tesco "Mapping the dementia gap" 2011; North East Public Health Observatory report June 2009; Walker RW et al 2010 and Nath U et al 2001; and regional clinic records.*

Participating Trusts

Approval has been granted (under the name North East DeNDRoN Case Register) in the following NHS Trusts in the Northern region. Relevant documentation is stored in the Patient List file of ethics, R&D and Caldicott correspondence.

Trust	Approval date
Northumberland, Tyne and Wear NHS Foundation Trust	28/03/2007, Caldicott approval 18/04/2007 Approval renewed 29/11/12
Tees, Esk and Wear Valleys NHS Foundation Trust	03/02/2009, Caldicott approval 17/09/2009
Newcastle upon Tyne Hospitals NHS Foundation Trust	Caldicott approval 20/07/2007 Judged no R&D approval required
City Hospitals Sunderland NHS Foundation Trust	24/7/2007, Caldicott is part of the R&D process
Gateshead Health NHS Foundation Trust	18/02/2008, Caldicott approval 18/07/2007
Northumbria Healthcare NHS Foundation Trust	18/02/2008, Caldicott approval 25/02/2008
South Tees Hospitals NHS Foundation Trust	03/08/2007 approval including Caldicott
County Durham and Darlington NHS Foundation Trust	11/02/2009, Caldicott approval 17/09/2009
South Tyneside NHS Foundation Trust	10/09/2009 including Caldicott approval
North Tees and Hartlepool NHS Foundation Trust	08/03/2010, Caldicott approval 03/06/2009
North of Tyne Lead Research Management and Governance, (comprising Gateshead, Newcastle, North Tyneside, South Tyneside, Sunderland Teaching PCT's, and Northumberland Care Trust)	Judged no R&D approval required, and opinion from Caldicott guardian that approval is not required from Primary Care
South of Tyne and Wear including Gateshead, South Tyneside and Sunderland PCTs	Judged no R&D approval required, and opinion from Caldicott guardian that approval is not required from Primary Care
County Durham and Tees Valley Research Management and Governance Unit for County Durham PCT (comprising Darlington PCT, Middlesbrough PCT, Stockton-on-Tees Teaching PCT, Redcar and Cleveland PCT, Hartlepool PCT)	Judged no R&D approval required. Advised that Caldicott approval not needed for Primary Care
North Yorkshire and York PCT for Hambleton and Richmondshire	Judged no R&D approval required. Opinion that Caldicott approval not needed for Primary Care

Joining the Patient List

Clinicians send the patient's contact details, by letter, telephone or email, after raising the issue of research with them. DeNDRoN sends out the patient information sheet and follows this up with a phone call to arrange a home visit if they are interested.

Patients or carers are able to contact us directly, by personal contact during a DeNDRoN visit to a community group or public event, by phone, letter, email or through the website www.dendron.nihr.ac.uk/northeast and request information sheets.

Clinicians may ask patients about joining the List during consultations, or write to them following confirmation of their diagnosis, providing them with the patient information sheet and inviting them to consider participation in the Patient List.

A member of DeNDRoN staff follows up all patient approaches (whether direct or via clinician) with a telephone call after a few weeks, allowing time for the patient and their carer/informant/personal consultee to read the information sheet, to arrange a home visit if they want to go ahead. A home visit is dispensed with if there is no doubt that the patient has capacity to understand the Patient List fully and to agree to DeNDRoN holding information about them. In this case the Patient List Consent and Data Collection Form are completed by post and telephone.

Every effort is made by DeNDRoN staff to maximise understanding of the Patient List. Informed consent to retaining information about the patient or the affirmative opinion of the personal consultee is obtained for all Patient List participants. The agreement of a family member, carer, next of kin or trusted representative to be an informant for the patient in relation to the Patient List is obtained where possible.

Processing the Consent and Data Collection Forms

Once consent and / or the positive opinion of the personal consultee is obtained, DeNDRoN staff complete the Data Collection Form in consultation with the patients and their informant, with reference to medical records if necessary. All completed Data Collection Forms will be processed by the DeNDRoN Administrator, Data Manager or designated member of the DeNDRoN team.

1. Consent and personal consultee forms and other documentation checked and date-stamped to acknowledge receipt and completeness.
2. Consent and personal consultee forms are copied (1 copy retained, 1 sent to patient or consultee, 1 sent to GP and/or clinician).
3. Data is entered on Patient List database.
4. Data collection forms, consent and personal consultee forms are filed securely in locked metal filing cabinets.
5. All parties to receive copies of the information sheet and patients receive a welcome pack containing a letter of thanks, a copy of their consent and/or personal consultee form, a recent DeNDRoN newsletter and DeNDRoN contact details *a change of circumstances form*.
6. GPs are sent a form to keep on file and complete if they become aware of a change in the patient's circumstances (eg moving to a new address, death).

Identification and selection of clinical study participants

The Patient List is used for identification of potential study participants. Only DeNDRoN staff (normally the Data manager, Administrator, or another designated member of the DeNDRoN team) will search the Patient List following requests from researchers working on approved studies.

The Patient List searches are made by running data queries in the database to produce lists of potential participants based upon the recruitment criteria of the specific studies. Each study on the DeNDRoN portfolio has a member of staff identified either as working on that study directly, or linking to the research team. Such identified members of the DeNDRoN team contact the individual Patient List members by telephone or letter to tell them about the study and ask them if they may be interested in joining. If the Patient List member agrees then the patient information sheet for the study will be sent out. After the patient has had time to read the patient information sheet then the DeNDRoN team member will telephone again, or visit at home, to explain further or answer any questions. With the Patient List member's agreement their name and contact details will be passed to the study research team, who will then recruit them or invite them for a screening visit. Depending on the arrangements for the study, the DeNDRoN staff member may be responsible for taking patient consent and carrying out the clinical study.

The clinician(s) caring for the patient will be informed if they join a clinical study. If the patient is in the care of a clinician in a Trust where there is no R&D approval (or Patient Identification Centre (PIC) status) for the study in question, then the patient would be unable to join the study unless the clinician is of the opinion that that patient's clinical care would best be served by referral to a clinician who is a Principal Investigator for the study.

The Patient List database keeps a record of Patient List members screened for suitability for studies, and a record of all Patient List members approached about joining studies, and the outcome. The DeNDRoN team keep a record of the studies notified to each patient in order to avoid over loading any individual with repeated requests. Preferences expressed by Patient List members when they are approached about studies (e.g. not wishing to consider brain imaging studies) will be recorded so as not to approach them with subsequent similar requests.

Secure Data Storage

The Patient List database is only accessible by members of North East DeNDRoN team. The database is password protected on a secure NHS network (Northumberland, Tyne and Wear NHS Foundation Trust). Computer users must abide by IT Security Guidelines, and have a personal username and a password changed every month. Only the NE DeNDRoN Data Manager and Administrator and appointed DeNDRoN staff member have the database password and authority to make data available to researchers provided that the the data requests have been approved and patients have indicated an interest in the specific studies.

Paper copies of consent forms and forms containing patient details are stored securely in locked metal filing cabinets in the DeNDRoN office at St Nicholas Hospital. The key to the cabinet is kept in a locked drawer, and the office is locked when unoccupied.

Withdrawing from the Patient List

Should patients withdraw from the List or die, or in the opinion of their personal consultee should leave the Patient List, then contact information (addresses and telephone numbers) for both them and their personal consultee and informant is removed from the computer database, in addition to the personal consultee and informant names. This measure is to minimise the chances of these patients being accidentally selected as potential participants for future studies whilst still allowing us to keep records of Patient List activity and recruitment to studies. Following withdrawal or death, complete paper records are retained but marked as “consent withdrawn” or “deceased” and stored in a different filing cabinet drawer to the active Patient List members’ files. Appropriate GPs and clinicians are advised that the patient is no longer participating in the Patient List. Letters of thanks are sent to patients and informants and personal consultees of people who withdraw, thanking them for their involvement.

Data Analysis

The Patient List recruitment statistics are analysed from time to time to ascertain progress and confirm balance between disease groups, and that the Patient List is fulfilling the stated aims. Analysis and results of analyses are expressed so data is completely anonymous. We are aware that records of deceased patients are accessible by relatives under the Access to Health Records Act 1990.

Consent

Our consent procedures are compliant with the principles of the Mental Capacity Act 2005. Every effort is made by DeNDRoN staff to provide clear and simple explanations about the Patient List to enable patients to understand as fully as possible. Potential Patient List members may lack capacity, either because they cannot understand the information provided; cannot retain the information; cannot weigh the information as part of a decision making process; or cannot communicate their decision by any means.

A member of the NE DeNDRoN team (all appropriately trained) or an independent doctor will complete a mental capacity assessment form for all patients to confirm that there has been an assessment of the patient’s capacity to consent.

The patient List uses three forms:

Form A: All patients who are capable of giving consent themselves use this form. Some patients with physical or other disabilities may only be able to give verbal or indicated consent (e.g. nodding their head) and in these cases we will ask a witness to sign their consent form to confirm that they have observed this consent.

Form B: Patients who lack capacity to consent and are therefore unable to sign or verbally express their intention to consent will only be included in the Patient List if a Personal Consultee (as defined in the Mental Capacity Act as a person who, as a result of an existing relationship with the person who lacks capacity, can advise the researcher about that person’s participation in the project) gives their opinion that to their knowledge the patient has not refused to participate, advises on what the patient’s wishes and feelings

would be about taking part, and that they believe participation to be in the patient's best interests. The advice of the Personal Consultee is recorded on Form B.

Form C: All informants of patients will be asked to sign this form to confirm that they are happy for us to store their contact information within the Patient List. The informant is often the partner, main carer or next of kin and may be the same person as the Personal Consultee (if there is one) or not.

Consequently patients with capacity sign form A and their informant Form C. Patients lacking capacity have their Personal Consultee sign Form B, and their informant (who may or may not be the same person as the Personal Consultee) signs form C

Maintaining accuracy, consistency of consent and tracking and recording of deaths

Consent cannot be assumed to be enduring. We update information held in the Patient List by sending out a 'Change of Circumstances' form with each Patient List newsletter and inviting Patient List members to contact us by phone, letter or email if there have been any changes in their diagnosis, living arrangements, GP or medication, or if they are interested in any of the studies described in the newsletter. When any member of the DeNDRoN team has contact with a Patient List member e.g. in connection with possibly joining a study, they update the information we hold if there are any changes. We phone Patient List participants (or informants or Personal Consultees) biennially, asking them if there have been any changes in their circumstances, if they have been receiving Patient List newsletters, and to update us on their position relating to consent and to notify us if they wish to withdraw or whether they feel that the consent procedure needs re-visiting with the patient or Personal Consultee. This may be required if a patient's mental capacity has changed and Form B needs completing.

GPs are sent a 'change of circumstances' form to keep on file and complete and return to us if they become aware of e.g. a new address, death of the patient.

Avoiding re-contacting patients who have refused participation

To avoid re-approaching patients who decline participation in the Patient List, a minimum electronic dataset comprising patient name, date of birth and consultant details will be retained.

Communication

We send newsletters to Patient List members regularly, at least 3 times a year. These contain news about DeNDRoN, let patients and their informants or carers know about the studies that are taking place, about studies in development, and about completed studies and their results. We also give updates on how many people have joined the Patient List. Newsletters do not contain any patient identifiable details. Enclosed with the newsletters is a 'change of circumstances' form and encouragement to contact us.