N.B. This project was first delivered in 2012 by the then Dementias and Neurodegenerative Diseases Research Network (DeNDRoN).

MEMORY ASSESSMENT AND RESEARCH CENTRE (MARC)

RECRUITMENT STRATEGY

The Prime Minister's Challenge:
All people with dementia to be able to register their interest to be contacted about research.

"The vision is that all people with dementia and their carers will be offered the opportunity to register their interest in being contacted about research." (RAFT)

"We are not attempting to deliver an "all singing, all dancing" national system, but looking to build on current systems and make dementia services routinely collect information that is searchable for the purposes of running feasibility or recruitment queries for NIHR studies." (RAFT)

The Ministerial Advisory Group on Dementia Research (MAGDR) was formed following the Summit on Dementia Research in 2009 and their findings and recommendations were published by the Department of Health in June 2011.

The task of addressing the issue of recruitment of patients to clinical research trials was delegated to the Dementias and Neurological Diseases Research Network (DeNDRoN).

DeNDRoN is doing this by means of the Recruitment and Feasibility Tools (RAFT) project.

WHY ARE WE UP-DATING OUR LOCAL STRATEGY?

The Memory Assessment and Research Centre (MARC) founded the first memory assessment service in the (now) Southern Health NHS Foundation Trust area and it has been the primary source of recruits to clinical research trials run at MARC for the last decade.

There are now eleven memory assessment services within the Trust and the MARC memory assessment service has diminished in size as these services have been developed.

In June 2011, an audit of the origin of the referral of patients formally screened in the last three commercial trials done in the unit (n=40), showed that 52.5% of referrals came from the MARC memory assessment service, 17.5% came from outside the Trust, and 30% originated from OPMH services (other than MARC) within the Trust.

In other words, the traditional source of referrals to MARC is diminishing in size, and as things stand, local OPCMHTs are not a good source of referrals and are unlikely to make up the impending deficit in recruits.

Therefore the MARC recruitment strategy needed to be reviewed and updated to reflect these new circumstances.

MARC works closely with the DeNDRoN (South Coast) team and this seemed a good opportunity to link our project with the RAFT initiative.

The MARC team and DeNDRoN representatives decided to meet every two months to formalise an *ethical, efficient and sustainable recruitment strategy*, with a view to submitting a Research Strategy Document (RSD) to the Trust Information Governance department and the Trust Research and Development Committee for scrutiny and approval.

OBJECTIVES OF THE STRATEGY

PRIMARY OBJECTIVE

- To facilitate the efficient and ethical recruitment of patients to clinical research trials being conducted by MARC.

SECONDARY OBJECTIVES

- To increase awareness among Health Care Professionals (HCPs), that patients who participate in research benefit from the experience and are at low risk of coming to harm, and that participation in research is a valuable component of a patient's package of care.

- To explore how the advent of electronic case record systems can be used as an opportunity for facilitating recruitment to clinical research trials.
- To contribute to RAFT.

OUTCOME MEASURES (process described in section II (1)):

PRIMARY OBJECTIVE

- Compare the annual number of referrals to MARC, year on year (the figure for 1.8.11 to 31.7.12 is 164).

SECONDARY OBJECTIVES

- Compare the number of referrals from HCPs, year on year (67 for the same period, 77 if adjusted for unknowns.)
- Compare the number of referrals generated by electronic generic recruitment strategies, year on year.
- This will be determined by feedback from DeNDRoN.

CHARACTERISTICS REQUIRED OF THE STRATEGY

- It must comply with the relevant **legislation relating to research**: the principle regulations are contained in "The Medicines for Human Use (Clinical Trials) Regulations (2004)". Recruitment is also specifically mentioned in the first of two amendments made to the principle regulations in 2006, and in the only amendment made in 2008. (See addendum 1.)
- It must comply with the relevant **legislation and guidelines relating to information governance**: the main principles are contained in the Data Protection Act (1998) and the Caldicott principles. (See addendum 1.)
- It must comply with the International Committee on Harmonisation (ICH) Guidelines for **Good Clinical Practice (GCP)** (1996). (See addendum 1.)
- It must comply with the relevant **Southern Health Foundation Trust (SHFT) policies**: "RiO policy (Primary Health Records), version 1, Jan 2010", and the "General policy on conducting Research and Development- Southern Health Foundation Trust", version 1, June 2012. The latter policy is based on the "Research Governance Framework for Health and Social Care**:** 2nd edition 24 April 2005", issued by the Department of Health. (See addendum 1.)
- The strategy must be **ethically sound**.
- It must incorporate processes to **evaluate and analyse outcomes** i.e. whether the objectives are being met, and in particular, which strategies are proving to be most efficient.

- The strategy must be **flexible and subject to regular review** so that it can respond to outcome evaluations and evolve to deal with changing needs and circumstances.

- The application of the strategy, including the evaluation and review processes, must be **efficient, repeatable and sustainable.**

STRUCTURE OF THE STRATEGY

I. PRE MARC

1. PASSIVE RECRUITMENT:
a) *GENERATING SELF-REFERRALS*
b) *GENERATING REFERRALS FROM OTHER HEALTH CARE PROFESSIONALS*

2. ACTIVE RECRUITMENT:
a) *GENERIC RECRUITMENT FROM RESEARCH CENTRE BASED CLINICS*
b) *GENERIC RECRUITMENT FROM ELECTRONIC CASE RECORDS*

II. POST MARC

1. MAKING MAXIMUM USE OF REFERRALS.

2. EVALUATING THE STRATEGY.

3. DEVELOPING THE STRATEGY.

I. PRE MARC

1. PASSIVE RECRUITMENT

a) STRATEGIES TO GENERATE SELF-REFERRALS

INTRODUCTION

Initiatives designed to generate self-referrals have mixed results.

Previous and current initiatives to recruit patients to Investigational Medical Products Trials (IMPTs) have generated recruits, but very few have made it through to randomisation. In contrast to this, recent initiatives to generate recruits to observational trials have been more successful.

The evaluation process proposed in section II (2) will start to generate objective evidence about the efficiency of these methods, and this information will help to inform the development of future strategies.

It is important to make a distinction between specific strategies to generate referrals and the broader issue of raising public awareness about dementia and dementia research.

MARC clearly needs to lead specific strategies, but the issue of who has responsibility for the broader issue of raising public awareness about dementia and dementia research needs further consideration.

PROCESSES

- INFORMATION TECHNOLOGY (1): MARC has a **web-site** which is accessed via the Trust R and D web-site. The MARC team have the expertise to maintain a basic site.

  This area is becoming increasingly relevant. Consideration needs to be given to developing the skills and resources needed to maintain an up-to-date, vibrant and interactive web-site.

- IT (2): **Study specific websites** with links from the MARC web-site are now being used to aid recruitment; for example, one of the companies conducting an IMPT with MARC have a web-site which is receiving a high number of hits. They conduct a preliminary screening procedure on prospective recruits and then forward potential subjects' names to MARC. So far, none of the 24 potential subjects generated by this process (as of mid August) have progressed to formal screening.

- PAPER (1): MARC has an A3 size poster (see addendum 2) which is suitable for display in OPMH service areas, particularly in memory clinic waiting areas. This was made available to memory assessment service personnel at the MARC education session in May 2012. The take up was poor.

  Two actions have been proposed to address this. The first is to replace the current rather disappointing picture with a more appropriate image.

  The second is to seek approval for the poster to be included in the "Standards for Information displays in OPMH (In-patient/ Community)", which would make it mandatory for the poster to displayed in all service areas. This will be done once the approval process is complete.

- PAPER (2): MARC has an information leaflet (see addendum 3) which has been in use for some time and which is well received. Again, it would be useful if this were added to the OPMH mandatory leaflet display.

- MEDIA (print, radio and television): The current Director of MARC, Professor Holmes, and the previous Director, Dr Wilkinson, are well known as authorities in this field and they have a long and distinguished record in "flying the flag" for patients with dementia and dementia research.

- TALKS TO SPECIAL INTEREST GROUPS: Talks to special interest groups such as the Alzheimers society and patient groups is an area that could be developed. In terms of the latter, giving talks at “memory matters” courses is being explored.

ADDITIONAL ISSUE

The issue of **obtaining agreement from patients to allow MARC to make a request for information from their GP notes** for the purpose of assessing whether the patient is a potential candidate for participating in clinical research trials, needs reviewing, and we would welcome advice from the Information Governance department about this. This is an issue that relates to all the areas of recruitment.

The current process relating to self-referrals is that once the subject has self-referred, the administrator receiving the referrals, (who is the “single point of referral”) phones the patient and uses a pro-forma (see addendum 4) as a prompt to gather basic demographic information **and asks the patient to give a verbal agreement for MARC to request** a summary of the patients’ medical history and current medication from their GP, which ensures that some relevant clinical information is available when the referral receives its initial review at the next fortnightly recruitment meeting.

The request for this information is made to the GP practice receptionist by telephone call. Provided the administrator or team member identifies the patient and themselves correctly and gives an assurance that faxed information will be received via a safe haven fax machine, the majority of practices will release this information, which implies that they are satisfied that this process satisfies their information governance procedures.

Occasionally practice receptionists will request that the patient phones them to confirm that they have given verbal consent, and very occasionally, the practice will only accept a signed consent letter from the patient.

CONCLUSION

The issue of developing the skills and resources needed to maintain an up-to-date, vibrant and interactive web-site needs further consideration. The Trust R and D Committee may be able to provide some guidance about this and advise us on any central, co-ordinating policies relating to this area.

If the idea to add the poster and leaflets to the OPMH mandatory display is approved, MARC will apply to the OPMH Directorate for these to be included in their policy.

The issue of obtaining consent from patients to request information from their GP requires scrutiny, as described.

The issue of who has responsibility for the broader issue of raising public awareness about dementia and dementia research needs further consideration. One model is for DeNDRoN to take primary responsibility for this, with MARC providing expertise on request.

Consideration needs to be given to how self-referrals from the general public are handled if campaigns to raise awareness result in a flood of referrals. One strategy may be to ask patients to see their GPs for a preliminary assessment, with the GP referring the patient to the appropriate team, depending on the problem identified.

b) STRATEGIES TO GENERATE REFERRALS FROM OTHER HEALTH CARE PROFESSIONALS

INTRODUCTION

The current strategy is based on arranging high quality, regular interactions with the people who run the memory assessment services in the Trust.

PROCESSES

- Identifying the target group of health care professionals: MARC has compiled a register of the people staffing the eleven memory assessment services in the SHFT, (see addendum 5.)

  The register was used to invite memory assessment personnel to the MARC teaching session held in May and attendees were asked to update the register.

  The OPMH service is going through a phase of accelerated re-configuration at the moment, (it is likely that “memory clinics” will merge back into the community teams), therefore maintaining the register is a challenge.

- Running an Education Session: Professor Holmes and Dr Wilkinson give lectures to audience’s world-wide and they agree we should be utilising this “resource” to help to achieve the objectives of the recruitment strategy.

  The first session was held on 24.5.12 under the title “An Update on Dementia Research.” Approximately x% of the SHFT memory assessment service personnel attended. Lectures were delivered by Dr Wilkinson and Prof Holmes. The feedback was overwhelmingly positive and all the attendees who completed feedback forms (17/27) were in favour of a regular Education Session.

  As a result of this feedback, MARC will run a similar high quality Education Session annually.

- Developing a newsletter: further feedback from the Education Session indicated that staff would like to have regular updates on local research and on broader developments in dementia research and their application to clinical practice. Consideration should be given to circulating the newsletter to all OPMH staff.

- Providing regular feedback to care co-ordinators about the progress of their patients.

- Visits and lectures to specific teams of HCPs will still be done on request.

CONCLUSION

It is too early to say, but based on past experience and given the ever increasing demands on clinician's time, this strategy may not be effective in terms of generating referrals from our colleagues. This situation is unlikely to change unless it becomes mandatory for clinicians to ask their patients if they are interested in being contacted about research.

However, we *are* hoping that it will help to increase awareness among HCPs that those patients who participate in research benefit from the experience and are at low risk of coming to harm, and that participation in research is a valuable component of a patient's package of care.

In contrast to the issue of raising public awareness discussed in section 1 (a), the MARC team feel that we can and should lead in this area, with assistance from DeNDRoN as required.

2. ACTIVE RECRUITMENT

a) GENERIC RECRUITMENT FROM RESEARCH CENTRE BASED CLINICS

CURRENT MARC BASED CLINIC FORMAT

- Professor Holmes runs a two session clinic offering standard care.

- Referrals to the clinic are made by the OPCMHTs and we would ask that patients remain under the care of that care co-ordinator until the outcome of the assessment is known.

- He sees two categories of patients. The first is patients who have been referred for a second opinion on diagnosis.

  The second category is assessment of patients with early objective or subjective memory loss.

- The latter group of patients will be assessed to confirm the diagnosis of MCI and to see whether they are suitable candidates for research, in particular whether they are suitable for the ICoS (Inflammation, Cognition and Stress) study, the full title of which is: "Systemic inflammatory responses to stress and its impact on cognition in Mild Cognitive Impaired subjects."

- Patients who do not have a diagnosis of MCI or who are not suitable candidates for research will remain under the care of their care co-ordinator and will not be seen again in Prof Holmes's standard care clinic.

- Suitable patients will be referred to MARC and enter the MARC referral process. These patients can then be discharged by the care co-ordinator who made the referral, and they will not be seen again in Prof Holmes' standard care clinic.

- These patients will be fast-tracked into the ICoS study and will receive 4 assessments at 6 monthly intervals, i.e. they will receive a further 18 months of follow up.

- MCI patients who convert to dementia (about 10% a year), will be referred back to the care of their OPCMHT.

- Note that the Trust is currently encouraging clinicians to discharge patients with a diagnosis of MCI back to the care of their GP. This service provides clinicians with another management option.

ADDITIONAL CONSENTING PROCESS

- If any patient seen in the clinic is a potential candidate for research and they confirm that they are interested in being contacted about suitable research trials, the patient will sign a consent form to this effect. This form (see addendum 5) has been approved by the Trust.

- The patient will be referred to MARC and their name and a summary of the assessment done to determine if they are a potential candidate for clinical research trials (diagnosis, a measure of cognitive function, relevant past medical history and current medication) will be added to a list of generic recruits.

- The patient's name will also be sent to DeNDRoN for entry onto a national list of patients who are potential candidates for research and who are interested in being contacted about suitable trials.

CONCLUSION

- The format of the clinic has been approved by the OPMH directorate and has started receiving referrals.

- The number of referrals generated by MARC based clinics, compared year on year, will give some indication about the outcome of this initiative.

b) ELECTRONIC GENERIC RECRUITMENT

DEFINITION

"The use of electronic case records to form a list of patients who are potential candidates for clinical research trials and are interested in being contacted about research."

BACKGROUND

The processes which have already been described which lead to self-referrals, referrals from health care professionals and referrals from research centre based clinics, are all forms of generic recruitment.

As described in addendum 1, there appears to be no specific mention of generic recruitment in the current research legislation.

However, this is the de facto basis for recruitment to clinical research trials in dementia research and hence there is a strong precedent for generic recruitment.

The precedent for generic recruitment has 2 key characteristics. The first is that all forms of generic recruitment must comply with the legislation and guidelines relating to **information governance and research governance**. (See addendum 1.)

The second is that the **initial approach** to a patient to ask if they would like to take part in research **must be undertaken by a clinician directly involved in the patient's care.**

The advent of electronic case records has occurred since the enactment of the current research legislation and so in addition to the fact that there appears to be no specific legislation governing generic recruitment, there is no specific mention of electronic generic recruitment, and **there is also no precedent for electronic generic recruitment** that we are aware of.

Therefore researchers undertaking electronic generic recruitment should ensure that the process being advocated satisfies the 2 key characteristics of the precedent for generic recruitment.

POSSIBLE ELECTRONIC GENERIC RECRUITMENT PROCESSES

OPTION ONE: **"THE SINGLE AGREEMENT PROCESS."**

THE AGREEMENT

- "I am interested in being contacted about research. I agree to allow NHS staff involved in research to use my electronic case records to determine whether I am a potential candidate and to record this information on a local list of potential candidates."

- The single agreement *appears* to satisfy the aims of the RAFT project:

  "The vision is that all people with dementia and their carers will be offered the opportunity to register their interest in being contacted about research." (RAFT)

  "We are not attempting to deliver an "all singing, all dancing" national system, but looking to build on current systems and make dementia services routinely collect information that is searchable for the purposes of running feasibility or recruitment queries for NIHR studies." (RAFT)

  (Note that a national list is not mentioned in these aims. Does the use of the phrase "NHS staff involved in research" entitle researchers from outside the Trust to conduct feasibility and recruitment reviews?)

- The wording *appears* to satisfy the first principle of the Data Protection Act (1998), that obtaining and recording information should be "fair and legal".

It is fair in that it is clear **why** the information is being accessed (so that researchers can determine whether the patient is a potential candidate for clinical research trials), **what** will be done with the information thus obtained (if the patient is a potential candidate for clinical research trials, the information will be put on a local list of potential candidates), and **who** will have access to the information (NHS staff involved in research.)

It is legal in that it *appears* to comply with the relevant legislation.

- The issue of **obtaining consent from patients to allow researchers to request information from their GP notes:** if this is to be a true single agreement process, this request should be inherent in the agreement.

  The question is, can it be *implied* that by asking for agreement for researchers to "use my *electronic case records* to determine whether I am a potential candidate (for research)", that this permission has been given, in that GPs use electronic case records (and some of that information is entered on the HHR) or does it need to be *explicitly* asked for, perhaps by adapting the wording of the agreement to "to use my electronic case records*, including my GP records*, to determine….", or perhaps "… to use my NHS electronic case records".

  This is a very relevant issue for researchers; mental health notes *usually do not* contain a full medical history and *seldom* contain an up to date list of medication, both of which are essential for the assessment process.

- "Are you interested in being contacted about research?" This question embodies "The Prime Minister's Challenge." Would it suffice? Patients' views on this would be enlightening.

THE PROCESS

1. An NHS staff member involved in the patient's care is meeting with the patient.

2. If the patient does, or might, lack capacity to make an informed decision to enter into "the single agreement", a legally authorised representative (LAR) must be present (this is usually the next of kin.)

3. The staff member will show the patient and LAR a paper version of the agreement form. (This will be designed if this option is approved for further development.)

4. If the patient has a mental disorder, the staff member must explain the agreement in terms the patient can understand and they must be satisfied that the patient can retain the information long enough to weigh the pros and cons relating to the agreement in the balance and reach an informed decision about whether to enter into the agreement, i.e. they must assess the patient's capacity to enter into the agreement. (Mental Capacity Act (2005).)

5. If the staff member is satisfied that the patient has capacity to enter into the agreement, the patient will be asked to print their name, sign and date the paper version of the agreement form.

6. If the staff member feels the patient lacks capacity, the LAR will be asked to make the decision on behalf of the patient and if they decide to agree, they will be asked to print their name, sign and date the relevant section of the paper version of the agreement form.

7. The staff member will print their name, sign and date, as the person obtaining the agreement.

8. The staff member will ensure that the signing of the agreement is confirmed on the electronic version of the agreement form held on RiO, either by making and validating the entry themselves or by validating an entry made by an administrator.

9. The Trust (information governance and research and development departments) will need to determine explicitly who will be allowed access to the patient's electronic case records. In the case of dementia research and the Southern Health Trust, it is envisaged that this will include the 9 permanent staff members of the Memory Assessment and Research Centre (MARC) and 2 permanent staff members of the Dementias and Neurological Disorders Research Network (DeNDRoN.)

10. If an OPMH patient or their LAR has signed the agreement, the Trust IT department will forward their name to MARC.

11. The named NHS staff member involved in research will access the patient's electronic case record for the purpose of assessing whether the patient is a potential candidate for clinical research trials.

12. When the researcher does the assessment they will record a summary of the assessment in the progress notes under the heading: "Research screening assessment by MARC/ or DeNDRoN (as applicable)". (The reason for including the terms MARC or DeNDRoN is that RiO has a facility for filtering and selecting progress notes which mention specific terms such as these, so that a researcher entering a patient's electronic case record for the first time can do a preliminary search to check that the assessment has not already been done, in order to avoid unnecessary scrutiny of patient records and duplication of work.)

13. If the patient is a potential candidate for clinical research trials and is interested in being contacted about research, the patients' name, contact details and the summary of the assessment will be recorded on a (paper) local list of generic recruits, which will be kept in MARC.

    The list will be subject to the same information governance requirements that would govern a paper set of patient notes.

    There is no need for an electronic record as the summary is already recorded on RiO.

14. The list must be subject to the minimum of an annual “spring clean” to ensure the information is not kept for longer than necessary, both in order to comply with principle 5 of the Data Protection Act **and** to ensure that the chance of the LAR of a deceased patient being contacted is reduced (bearing in mind dementia is a terminal disease).

DISCUSSION POINTS

- If this strategy is implemented, it will be setting a precedent.

- It requires scrutiny to see if it satisfies the first key characteristic of generic recruitment i.e. that it complies with Information and Research Governance requirements.

- It does satisfy the second key characteristic.

- This strategy will have a greater chance of success if the Trust makes it **mandatory for all OPMH care co-ordinators to ask all of their patients** whether they would like to enter into this agreement.

- One way to facilitate this is to add it to the paper form which is currently used to record the patient’s consent to allow the Trust to share information with “social services and education.” It is mandatory for care co-ordinators to record this consent electronically.

  An electronic form could be added under the icon “MCA and information sharing and consent” which is already present in the electronic case record. **This would involve a change to RiO**. This is a challenging task.

- Of interest: The SHFT IT department recently ran a pilot project with the Hampshire North OPCMHT to test a strategy in which clinicians ask patients for consent for information from their electronic case records to be transferred to the Hampshire Health Record. The project leader was Dr Lewis, clinical systems analyst.

  The consent process is recorded on a paper form and the clinician or their administrator will transfer this information to a “Consent Utility”, which is a web-based instrument which will enable the safe transfer of this information (the record of the consent) to the Hampshire Health Record.

  Note that the consent utility is being used in preference to changing the existing RiO consent to share information form, because of the difficulties in effecting changes to RiO and because the RiO system is used by other Trusts.

  A question asking the patients if they would agree to being contacted about research has been included on the paper form. This consent is reflected in the “consent utility” and then recorded in the HHR. The fact that this process has taken place is recorded in the progress notes in RiO.

  If the Trust R and D Committee approve further development of “The Single Agreement Process”, it would make sense to explore how each project could complement the other.

- The issue of liability for the Trust for any untoward events arising from this strategy needs to be discussed.

  Staff may require training in obtaining the single agreement in order to satisfy the Trust insurers. (Note that the HHR project leaders are proposing to employ 3 people to train staff in that procedure.)

  Given that this is setting a precedent, consideration could be given to seeking **a legal opinion** prior to implementing the strategy.

- **Consideration should be given to seeking patient and carer opinions** about this strategy and to involving patients and carers in the formulation of the strategy.

- DeNDRoN south coast has been identified as a site in which to develop and act as a pilot site to establish the ability of a local consent with access to RIO data can be merged with the development of a national data base.

OPTION TWO: **"ELECTRONIC CASE-LOAD MINING"**

THE PROCESS

1. The Trust Information and Research Governance departments have approved the strategy.

2. A case-load is identified.

3. An email is sent to the responsible consultant to ask them to grant permission for a named researcher to mine that case-load, and a copy of the return email granting permission is retained in a specific case-load mining folder.

4. This folder is retained in the paper case record filing cabinet in the research department and is subject to the same Information Governance procedures as a set of paper patient notes.

5. The named researcher informs the care co-ordinator that they have been given permission to mine their case-load.

6. The researcher reviews each electronic case record to assess if the patient is a potential candidate for clinical research trials.

7. When the researcher does the assessment, they will record a summary of the assessment in the progress notes under the heading: "Research screening assessment by MARC/ or DeNDRoN (as applicable)". (The reason for including the terms MARC or DeNDRoN is that RiO has a facility for filtering and selecting progress notes which mention specific terms such as these, so that a researcher entering a patient's electronic case record for the first time, can do a preliminary search to check that the assessment has not already been done, in order to avoid unnecessary scrutiny of patient records and duplication of work.)

8. If a patient is found be a potential candidate for clinical research trials, the patients' name, contact details and the summary of the assessment will be recorded on paper and filed in the case-load mining file. No electronic copy is needed as the information is already on RiO.

9. When this stage of the episode of case-load mining is complete, the researcher will meet with the care co-ordinator to review the potential candidates for research.

10. The care co-ordinator will screen the list to exclude any patients who they feel should not be approached about participating in research. Any patients that the care co-ordinator feels should NOT be approached will have this recorded and highlighted in the case-load mining folder.

11. The care co-ordinator will undertake to make the initial contact with the patient (and LAR, if the care co-ordinator deems that the patient does or may lack capacity to make this decision), to ask if the patient is interested in being contacted about research.

    The outcome of this discussion will be recorded in the progress notes in RiO and the researcher informed of the outcome.

    Any patients who are not interested in being contacted about research will have their details removed from the case-load mining folder, i.e. only the details of those patients who are potential candidates for research and who are interested in being contacted about research, would be retained in the case-load mining folder in the research department.

12. At this point these details would be added to the department's generic recruitment list, which is also kept in the same manner as a set of paper patient notes.

13. The case-load mining folder could be used as a starting point in further episodes of mining that case-load, and in so doing, duplication of work could be avoided.

14. The case-load mining folder and generic recruitment list must be subject to the minimum of an annual "spring clean" to ensure the information is not kept for longer than necessary, both in order to comply with the Data Protection Act **and** to ensure that the chance of the LAR of a deceased patient being contacted is reduced (bearing in mind dementia is a terminal disease).

DISCUSSION POINTS

- There is a precedent for case-load mining of paper patient notes.

- It is not certain that the proposed strategy will satisfy the first key characteristic of generic recruitment, the need to **comply with Information and Research Governance requirements,** (see addendum 1.)

- If it is does not, the process will need to be refined and re-submitted for approval.

- This strategy does satisfy the second key characteristic of generic recruitment, which is that the initial approach to a patient to ask if they would like to take part in research **must be undertaken by a clinician directly involved in the patient's care.**

  However, the issue of what is an acceptable way of making the initial contact e.g. face to face contact, telephone call or letter, will need to be discussed and defined.

- **Consideration should be given to seeking patient and carer opinions** about this strategy.

- This is not an ideal strategy and it is envisaged that at best it could be a stop gap measure for use until the Single Agreement Process comes into being.

CONCLUSION

In time, electronic generic recruitment could prove to be a mainstay of recruitment strategy.

However, given that there appears to be no precedents in this area, careful consideration, consultation and planning will need to take place before any actions are taken.

DeNDRoN South Coast is taking part in stage 2 of the RAFT project, and given their remit and resources, they may wish to lead the "single agreement process" project.

NOTE: The Trust "RiO policy (Primary Health Records), version 1, Jan 2010" was due for review in Jan 2011 and so must be reviewed soon. This could represent an opportunity to get any definitive procedures agreed on for generic electronic recruitment, such as the single assessment process, included as policy for Trust employees to follow.

II. POST MARC

1. MAKING MAXIMUM USE OF REFERRALS.

2. EVALUATING THE STRATEGY.

3. DEVELOPING THE STRATEGY.

1. STRATEGIES FOR MAKING THE MOST OF REFERRALS

- HAVE A SINGLE POINT OF REFERRAL:

When MARC employs another administrator, they will be the single point of referral and they will be responsible for:

1. Registering the referral on a "New Referral Data Sheet" (see addendum 6), which is in paper form at present and is kept in the case records cabinet.

2. Contacting the patient and completing the MARC Referral Proforma (see addendum 4).

3. Obtaining any relevant background information from GPs and care co-ordinators (RiO).

4. Bringing the referral to the next fortnightly referral meeting.

5. Recording the outcome of the initial review on the New Referral Data Sheet.

Until MARC has another administrator, it is the responsibility of the person receiving the referral to carry out items 2, 3, and 4 above and to bring the referral to the next recruitment meeting, when the referral and the outcome of the initial review will be registered on the New Referral Data Sheet.

- HAVE A CLEAR PATHWAY FOR PROCESSING REFERRALS

The pathway up until the referral meeting has been described.

- HAVE FOCUSED FORT-NIGHTLY REFERRAL MEETINGS

Attendance at these meetings is mandatory for all study co-ordinators and the administrator and is led by the team clinical leader.

New Referral Data Sheet to be up-dated at all meetings.

The outcome of the initial review will be recorded.

This will be one of four outcomes:

1. The patient is not a suitable candidate for taking part in clinical research trials. The person who received the referral must feed this decision back to the patient and carer AND feed back this outcome to the referrer.

2. Patient is suitable for research, but there are not suitable trials for this patient at present. The patient's information will be kept in a "Potentials" box which is also kept in the case records cabinet. The person who received the referral must feed this decision back to the patient and carer AND the referrer and tell the patient that their case will be reviewed regularly, especially when new trials are due to start, and they will be informed when a suitable trial is identified.

3. Patient is suitable for a specific trial. The study co-ordinator for that trial will take responsibility for the referral from that point.
4. It is possible that there is insufficient information to triage the case. In this instance the person who received the referral will be asked to obtain more information and bring the referral back to the next meeting, when one of the above three outcomes can be recorded in the outcome section of the New Referral Data Sheet.

The “potentials” box will be reviewed regularly at this meeting.

Study co-ordinators will feed back on their case-loads at this meeting.

- ENCOURAGE ACTIVE MANAGEMENT OF REFERRAL CASE-LOADS

  The Clinical team leader will also meet with study co-ordinators on a one-to-one basis to offer advice and assistance with “active referral case-load management.”

- TEAM MEMBERS TO CONSIDER VISITING PATIENTS AT HOME

Recent experience has shown that home visits by team members, including principal and sub investigators, to discuss trials and even to obtain consents, can improve the likelihood of patients entering trials.

- WORK CLOSELY WITH DeNDRoN

The process for assisting DeNDRoN to compile a national list of potential candidates for dementia research trials has been referred to in section I.

Compiling a “national list” is the principle aim of phase 2 of the RAFT project.

In time it is hoped that referrals will in fact also come to us from DeNDRoN in addition to us sending them referrals.

It is envisaged that DeNDRoN will gradually assume a central role in matching recruits to trials.

2. ONGOING EVALUATION OF THE STRATEGY

- ONGOING SURVEY OF THE SOURCES OF NEW REFERRALS

  The survey of new referrals for the period of 1.8.11 to 31.7.12 needs to be seen in the light of the fact that the system for recording these figures during this period was not in the format we are using now and so the source of referrals is not known in some cases and the total number is unlikely to be totally accurate, but is about +/- 5% out at most, and so the figures are still useful for identifying trends.

  The number of new referrals: 164.
  Referrals from MARC based clinics: 30, (34)
  Self-referrals: 43, (49)
  Referrals from other Health Care Professionals: 67, (77)
  Electronic recruitment: nil yet.

  Unknown: 24, note that the figure in brackets above represents the actual figure plus the relative proportion of actual in each category to total x 24, to give us working figures.

CONCLUSION:

A robust system for recording new referrals and the origin of the referral is now in place and the data will be collated annually.

- A ROLLING AUDIT OF WHICH TYPE OF REFERRALS END UP IN ACTUAL SCREENING FOR TRIALS

This project began with a survey of the source of referrals of the cases which actually progressed to formal screening. The results of the original audit in 2011 were:

The number patients formally screened: 40
Referrals from MARC based clinics: 21
Self-referrals: nil
Referrals from other Health Care Professionals: 19
Electronic recruitment: nil

A re-audit for the period 1.8.11 to 31.7.12 (the same as the period for the survey of new-referrals) gave these results:

Number of patients formally screened: 61, (47 randomised.)
Referrals from MARC based clinics: 23
Self-referrals: 3
Referrals from other Health Care Professionals: 35
Electronic recruitment: nil

CONCLUSION: The trend for the number of patients screened referred from MARC based clinics to drop, relative to the number of patients screened who have been referred by other HCPs, has continued.

It is difficult to draw conclusions beyond that, because the time periods were different for each audit. The time periods will be the same for future audits.

The process will be refined for the next re-audit to reflect the changing profile of the trials being conducted at MARC.

This will involve recording two separate outcomes, namely patients screened for CTIMPs (drug trials) and patients screened for observational studies, but the sub-analysis will still be division into the same 4 categories of referrals.

The reason for this refinement is that different recruitment methods may be more suitable for the 2 different styles of study, for example, the above figures confirm that encouraging self-referrals is not an efficient way of recruiting to drug trials, but early signs are that advertising for self-referrals for the ICOS (observational) study that started in August is proving to be effective and efficient.

- COMPARISON OF THE ANNUAL SURVEY AND RE-AUDIT FIGURES

Comparison of these figures should enable us to draw conclusions about patterns of referral and which referral strategies are proving to be effective, as reflected by the total number of referrals from that referral group, and which strategies are efficient as reflected in the ratio of number being screened versus total number per category.

These figures will be reviewed at an annual Recruitment Strategy review to be held each October, once the figures have been collated and analysed.

COMPARISON OF 2011/2012 FIGURES:

This comparison will not provide definitive indicators of efficiency of recruitment methods, because the patients being screened have not all come from the pool of new referrals received in that year; some will have come from the "potentials box " generated from referrals received prior to this period and some will have been in previous trials.

However the figures can give some indication of trends and they will become increasingly reliable if we compare longer time periods as the process continues.

The ratio reflecting effectiveness of recruitment categories and by extension the strategies targeting those groups is: Number of patients screened from that category/ number of patients referred in that category.

- MARC referrals ratio: 23/34 = 68%
- Self-referrals Ratio: 3/49 = 6%
- Other HCPs ratio: 35/77 = 45%

CONCLUSION: As one would expect, recruiting patients from MARC based clinics is the most efficient method of recruitment, HOWEVER this can only ever provide a finite number of referrals and if we remove the referrals that arose from Dr Wilkinson (who no longer does a clinic), to leave the number of screened patients who were referred by Prof Holmes alone in the last year under consideration, then the figure for patients originating from MARC who were screened, drops to 15.

The self-referrals ratio suggests that strategies aimed at generating self-referrals for drug trials in the last year have been very inefficient and should be used with caution in the future.

The "other HCPs" ratio is not definitive, but it does suggest that recruiting patients via other HCPs is reasonably efficient.

Of greater significance is that the potential for generating more referrals from this source is greater, but is likely to require sustained engagement with our colleagues, using strategies such as the teaching day and newsletters.

The "great unknown" is the issue of electronic recruitment. Some thought will need to be given as to how we measure efficiency with regard to these processes, if they are instituted, so as to compare fairly with these figures. Initial thoughts would suggest that "e-pre-screening" may be quicker than how we pre-screen referrals from other HCPs, hence a lower ratio may not mean it is a less productive use of time overall.

3. FURTHER DEVELOPMENT OF THE STRATEGY

- General Principles:

1. The overall time spent by the team on implementing strategies, evaluating strategies and refining and developing the MARC recruitment strategy should be proportionate and boundaried.
2. At the same time the process must not stall and regular recruitment strategy meetings with the whole MARC team will be continued.
3. The "committee" structure has worked well and once this stage of the project has reached completion (which will be marked by the final implementation of a Recruitment SOP, Standard Operating Procedure), the position of chair-person will be re-allocated on an annual basis.
4. The chairperson will have responsibility for allocating specific tasks to team members and co-ordinating implementation, evaluation and development. As part of this they will arrange a mid-year review meeting in April and a longer annual review meeting in October.
5. Maintain links with DeNDRoN and the Trust R and D department.
6. The team must aim to maintain an awareness of "best recruitment practice" by maintaining links with the wider research community.

- **CURRENT ACTION PLAN**

SHORT TERM

1. **Submit the Research Strategy Document to the Trust R and D committee on 25.9.12.**
2. **Incorporate any amendments recommended by the committee.**
3. **Allocate the tasks identified in the strategy and any new tasks arising from the committee recommendations. It is envisaged that the tasks will fall under the categories of INTERNAL (relating to MARC) and EXTERNAL, whereby the RSD will be handed over to interested parties such as DeNDRoN and perhaps the Trust R and D department, with a view to those bodies using the RSD to inform their development of national strategies in the former case and a Trust strategy in the latter case.**
4. **Reduce the RSD to a Standard Operating Procedure.**
5. **This document will be re-submitted to the Trust R and D committee for final Research Governance approval.**
6. **The SOP will be submitted to the Trust information governance department for scrutiny and approval.**
7. **The MARC team will attend a training session to make sure everyone is aware of their responsibilities as proscribed by the SOP.**
8. **Full implementation of policy.**

MEDIUM TERM

1. **Accurate monitoring of outcomes.**

2. **Annual team review of outcomes, brainstorming and re-formulation of an Action Plan.**
3. **Make amendments to the SOP as they arise, keep it a dynamic document.**
4. **Maintain an awareness of "best practice" regarding recruitment within the research community.**
5. **Maintain awareness of the work being done around recruitment by other organisations.**
6. **In particular, keep track of the progress of any process regarding RiO.**
7. **Continue to develop the educational role of MARC with regard to memory assessment personnel in the Trust.**

LONGER TERM

1. **A thorough knowledge of best recruitment practice should aid the MARC team in making applications to the Regional Ethics Committee for approval of Clinical Research Trials.**
2. **By gathering reliable evidence of a successful recruitment strategy, and given that this is so often a rate –limiting step in trials, MARC will be in a position to use this evidence to attract good quality trials AND INVESTMENT to the unit.**

REFERENCES

1) **The Ministerial Group on Dementia Research- headline report (Department of Health, June 2011.)**
2) **DeNDRoN South Coast- Interact Report, "Overview of the dementia clinical services (Memory Services.)" April 2011.**
3) **The references to the relevant legislation, guidelines and policies are part of addendum 1.**
