NHS
Health Research Authority

Call for examples of good practice in identifying patients in health research – Summary of responses

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Introduction

The revisions to the NHS Constitution have committed the health service to recognising and promoting the value of research, and the Health and Social Care Act 2012 placed obligations on NHS organisations to support this. The Caldicott 2 Review report and recent Government response agree that more should be done to increase people's understanding of the benefits of research and to inform them about how to get involved. The NHS Constitution commits the NHS to informing patients of research studies in which they may be eligible to participate. It also sets out that patients have a right to request that their confidential information is not used beyond their own care and treatment and to have that objection considered, and where that wish cannot be followed, to be told the reasons including the legal basis.

The Health Research Authority (HRA) launched a call in December 2013 for evidence to identify good practice in identifying potential participants in health research. Building on our remit to protect and promote the interests of patients and the public in health research, we asked for examples of different models for making information about research available and for identifying potential participants to health research studies. In particular, we were keen to hear about examples of patient and public engagement around models of recruitment, and evidence about patient and public expectations relating to the identification of participants. We were also interested to hear about the impact of changing recruitment strategies on recruitment and retention rates.

The HRA recognises that there is considerable variation in perspective and practice about the ways in which patients and the public are offered opportunities to take part in research. The call did not define good practice but requested examples of methods used, how patients and public were involved in designing the methods, and any feedback received on the methods. The aim of the call was enable HRA to explore the potential for providing clarity for the research community by identifying ethical, practical and efficient models for identification of potential participants. In accordance with our remit to protect and promote the interests of patients and the public in health research, such approaches should be transparent, maintain patient and public confidence in research, and protect the privacy of personal medical information.

It was anticipated that our request for information on current practice will help us to identify the need for any further advice for researchers and provide good practice examples to inform future guidance.

The call process

The call ran for seven weeks from 13 December 2013 and ended on 31 January 2014. In total we received 26 responses of varying levels of detail. In some cases we have been back to those who made the submissions for further detail. Some of the responses alerted to us to models developed by other organisations and we have had to then approach those bodies separately for their details.

The examples supplied represented a range of organisations including both primary (3) and secondary care (12) as well as national bodies. Of the 26 responses, 11 relate to generic

identification of participants, whilst 15 are condition specific. A range of conditions were represented but cancer (5) and diabetes (5) were the two main categories. A number of the responses also refer to the recruitment of healthy volunteers and controls as opposed to patients.

Activities to raise awareness of research to increase patient participation

All 26 responses cited a range of activities used to raise awareness of research. Responses submitted by organisations illustrate the many activities which they are engaged in to foster a research active culture. By way of illustration we have listed some of the awareness-raising activities undertaken by organisations below:

- 'Starter' pack for newly diagnosed patients
- "It's OK to ask" campaign
- Campaign to make new staff aware of research
- Delivering research and disease awareness sessions in schools
- All letters to patients make reference to fact that they are a research active hospital/practice
- Banner and poster displays in hospitals and general practices
- Manned display stands
- Practical demonstrations of research/open days/road shows
- Video of patients talking about research on hospital website/ Trust websites/Trust intranet
- Rolling programmes about research on Trust TV used by patients
- Staff newsletters
- Crowd sourcing
- Local media including TV, radio and newspapers
- Use of internet and websites to promote research activity.

Cited activities were as much about promoting research to NHS staff as they were to the general public and patients.

Organisations are increasingly are making use of the internet to communicate with the public about research:

- Websites to recruit healthy volunteers. For example, Sheffield Teaching Hospital have created a getinvolved@sth.nhs.uk email address which is on all research communications, and posters around Sheffield Teaching Hospitals NHS Foundation Trust. In addition they have created a webpage to advertise their clinical trials looking for health volunteers, which can be found at http://www.sheffieldclinicalresearch.org/clinical-research-activity/get-involved
- e-bulletins, emailed newsletters
- Web-based tools such as social media including Facebook and Twitter. For example, Salford Citizen Scientist project has over 400 Twitter followers.

Many organisations have been building on the the success of the NIHR led "It's OK to ask" campaign and have run events and roadshows to coincide with that campaign.

Some therapy areas are clearly more advanced in the promotion of clinical research as part of routine care; in cancer and paediatric diabetes there is a concerted effort to offer patients the opportunity to take part in research as part of routine clinical care. However the overall approach in cancer care is focused on approaching patients as and when in clinic as opposed to advanced models of consent. The Medicines for Children in Research Network (MCRN) talked about "the demystication of research in routine care settings which improves research opportunities for patient participation".

Some awareness raising approaches specifically applied in a primary care setting were as follows:

- One primary care research network had developed a leaflet with patient and public input for patients explaining how their data would be used in research.
- Use of a hub and spoke model with a research nurse working across a number of practices to bring patients into a study.

Many organisations are using standard NIHR leaflets to provide information about research with the public such as "It's OK to ask" and 'Understanding Clinical Trials'. Some Trusts and CCGs have gone onto develop their own material to raise aware and several made their material available which could form a useful resource for our next steps.

Consent for patients to be approached about research

We asked if organisations had developed models to allow patients (or carers) to register their details so they can be approached directly if they are suitable to be invited to join a health research study. These models range from those where some medical information is stored to allow identification of individuals meeting certain criteria who can be approached about specific projects to to those where individuals also provide consent for access to their medical records for pre-screening. The table below sets out a number of the key models for registering interest in research that are in use currently and have been brought to our attention as part of this call.

Name of scheme	Therapy area	Short description provided by respondents	Recruitment
ADDRESS 2	Diabetes Type 1	ADDRESS-2 recruits people aged between 5 and 60 who have been diagnosed with Type 1 diabetes in the last 6 months to create a national resource of people who can be approached for research studies. The project will offer these people, and their siblings, the opportunity to be involved in diabetes research studies.	Patients with type 1 diabetes are approached about the study in the first instance by their care team and they are supplied with leaflets about the project to pass onto their siblings and other close members of their family. Parents are approached if the patients are children.
Consent 4 CONSENT (C4C)	Generic	The Royal Liverpool and Broadgreen Hospital Trust has developed Consent for Consent; a system to register people willing to take part in research	Research staff target waiting areas in the hospital where they can expect to find patients with particular

Name of scheme	Therapy area	Short description provided by respondents	Recruitment
		which will allow researchers an in-depth understanding of patient groups willing to take part in research against available research studies.	conditions which will be required for imminent studies. They then approach potential participants without any prior access to their notes and ask if they would like to register their details.
Join Dementia Research	Dementia and neurological conditions	DeNDRoN (Dementia and Neurodegenerative Disease Research Network) is part of NIHR CRN and supports the development, set up and delivery of clinical research in the NHS in the dementias, Huntington's disease, motor neurone disease, Parkinson's disease, and other neurodegenerative diseases. Patients can register their contact details and their interest in taking part in research at www.dendron.nihr.ac.uk/register Through *Join Dementia Research*, DeNDRoN is developing a national system for people to provide some medical information that can be searched by approved researchers, and also provide consent for pre-screening of medical records to identify suitability for specific research projects.	Patients and carers, or anyone interested in taking part in research, can see which studies their information matches to, and can also express their interest in finding our more about any studies, which gives a good indication to researchers as to who to approach first. Registration can be offered in a variety of different ways to suit how each healthcare service operates: 1. Online at **www.joindementiaresearch.nihr.ac.uk** 2. A postal form available in selected healthcare services 3. Two telephone helplines, managed by Alzheimer's Research UK and Alzheimer's Society.
NIHR Diabetes Research Network DiaBEATes	Diabetes	Help DiaBEATes is an initiative from the NIHR Diabetes Research Network (DRN). The aim is to encourage people with diabetes to get involved with research which could help improve care and treatments for the condition. The Help DiaBEATes campaign aims to build a large consent for approach volunteer database of people willing to be contacted in the future about opportunities to take part in diabetes research. A publicity campaign has been set up to promote the campaign with the general public.	People with diabetes respond to advertisements/campaign leaflets and make contact with the NHS Contact Centre either by phone or online. NHS Contact Staff help individuals complete the registration. At the initial stage only very details are taken such type of diabetes, age and gender.

Name of scheme	Therapy area	Short description provided by respondents	Recruitment
		At the heart of the campaign is the Help DiaBEATes team who are based within an NHS contact centre. The team are available to guide volunteers through the registration process, help them keep their details up to date and contact them when opportunities become available to take part in research. All volunteers registered with the campaign are waiting for an opportunity to take part in research. Over 2,000 people are registered with the campaign with a target of 5,000.	
NIHR Diabetes Research Network FARSITE	Diabetes	The FARSITE software provides a safe, convenient and effective way for the family GP to control the recruitment of their patients into clinical research, whilst allowing NHS-based researchers to run complex and powerful searches over anonymised population level health record data. The Pathfinder team has an agreement with all current FARSITE license holders to be able to view top level anonymised date for all practices using FARSITE for the purpose of completing feasibility for diabetes studies. These practices are within the following regions:- ❖ South West Peninsula ❖ Greater Manchester ❖ Cheshire and Merseyside ❖ North East Yorkshire and North Lincolnshire ❖ Cumbria and Lancashire ❖ North East London / Kent and Medway The data that is currently available is from 150 practices with a total population of 831,830 of which 41,235 have diabetes.	The FARSITE database can be used to assess the feasibility of a study by estimating the number of people that meet the feasibility conditions. Once a group of patients have identified as eligible, this information is passed back to the relevant GPs who can then look at individual patients. The GP can then decide if it is appropriate for the individual to be approached.
NIHR Diabetes Research Network	Diabetes	Linking FARSITE to the Help DiaBEATes Campaign The true potential to making improvements in recruitment to	By cross matching eligible patients found on the FARSITE system with patients who have signed up to the Help

Name of scheme	Therapy area	Short description provided by respondents	Recruitment
Pathfinder Project (encompassing both FARSITE and the Help DiaBEATes Campaign)		studies lies in the ability to link both these systems so that people who have signed up to the Help DiaBEATes campaign can be offered studies that have complex inclusion and exclusion criteria based on accurate searching against their medical record whilst also protecting their confidentiality. The links are currently being tested with the Pathfinder GP pilot sites and the outcomes will be measured over the next 6 months. The practices are currently in the process of sending the Help DiaBEATes campaign leaflets out to their patients with diabetes so we can maximise the impact of being able to use the linked systems. As part of the Pathfinder project a total of 27 GP practices have been set up to test the recruitment side of FARSITE and to allow an evaluation of the impact of the system on recruitment to time and target. All pilot practices have agreed to receive expressions of interest for new studies and to take part in a data validation exercise. The project is working with the DRN Coordinating Centre to provide:- **Early Feedback** – "*We have been able to support UK bids for studies by performing top level feasibility of potential numbers of eligible participants. We have also been able to establish when studies are not feasible in the UK and recommend where changes may need to be made to protocols to enhance feasibility*."	DiaBEATes Campaign, the NHS Contact Centre can identify individuals who have agreed to be approached **and** who are eligible for a particular study. The NHS Call centre will then telephone the relevant patients. In most cases the individual will already be familiar with the NHS Call Centre. This leads to a much higher recruitment rate than with other methods.
SHARE	Generic but pilot took place in diabetes	In Scotland the SHARE initiative has been funded by the Chief Scientist's Office (CSO)- http://www.registerforshare.org/. SHARE aims to build up a database of adults resident in Scotland who have given consent to be approached about	Not known

Name of scheme	Therapy area	Short description provided by respondents	Recruitment
		healthcare research, with a target of 1 million over 5 years. To date 16,000 adults registered in the last 6 months. Patients register for SHARE either by completing a registration leaflet or online. The online registration takes less than 1 minute and they then receive a letter confirming their name, community health index number and preferred method of contact (irrespective of which enrolment method used). Patients give their name, date of birth and postcode – from this information they can be linked to their electronic health records.	
Scottish Diabetes Research Network	Diabetes	The CSO-commissioned Scottish Diabetes Research Network has also set up a research register - http://www.sdrn.org.uk/?q=patient/researchregister	Not known
Sheffield Teaching Hospital NHS Trust (STH)	Example supplied of approach used in respiratory medicine.	Sheffield Teaching Hospital explained that several of their departments have set up their own databases to register interested patients. They gave the example of the process used in the Respiratory department Over 300 local patients have joined the respiratory research database which is seen as a valuable resource for undertaking locally-led research studies and in addition for undertaking feasibility assessment when participating in commercial or industry clinical research.	Prior to a Consultant appointment, patients visit the Respiratory Physiology department for respiratory assessments. At this appointment patients are provided with a generic information sheet. At their next appointment the clinician obtains the patient's consent to use their information in two ways: Firstly by using anonymous clinical information for research - Respiratory test results and information is used to improve understanding of disease and effectiveness of treatment, to maintain high standards for respiratory testing, and to generate ideas for future research. The information used is anonymised and patients are not identified in any way.

Name of scheme	Therapy area	Short description provided by respondents	Recruitment
			Secondly by finding patients willing to be contacted about being actively involved in research studies. Staff record if patients are happy to be contacted every now and then to see if they are interested in taking part in suitable future studies or clinical trials. Recruitment is aided by Research Ethics Committee approved advertising Posters and information on the Sheffield Teaching Hospital research website. Over 300 local patients have joined the respiratory research database which is seen as a valuable resource for undertaking locally-led research studies and in addition for undertaking feasibility assessment when participating in commercial or industry clinical research.

The table above demonstrates that there is variety of approaches across the UK but also within individual hospitals.

In addition to the examples cited above, Imperial College reported that they are in the process of implementing an electronic patient data management system that might allow patients to register their interest in research. In addition some Trusts are also routinely seeking consent for the use of tissue for research purposes at the same time as consenting for surgery.

Interestingly although we received responses from primary care, we did not receive any examples of approaches for consent models initiated by primary care research networks in England for use by primary care researchers. All examples supplied by primary care focused on the GP seeking consent in the consultation setting. Whilst some models do involve accessing GPs records such as FARSITE, these are condition specific and have not been initiated in primary care or used by primary care researchers.

Scotland has developed an innovative model (SHARE) to acquire consent for patients to be approached directly about research studies. SHARE is still at an early stage of implementation but

the impact of the pilot stage has been marked. The pilot project which involved the diabetes population (10,000 patients with diabetes have been registered as willing to participate in research) has resulted in a screen failure rate for studies of <1% and has resulted in sites receiving top recruiter status and first global patient in several commercial studies. Since the diabetes pilot register began in 2007, recruitment to diabetes trials has gone from 2,655 to more than 11,000 in 2012. The team report that SHARE should be able to do the same for many disease areas.

In addition to the models above, patients are routinely approached on completion of a study for permission to contact them for future studies.

It was suggested by some respondents that an approach of registering interest or consenting to access to medical records would be a valuable way of ensuring that participant recruitment targets are met in a timely fashion. Guidance on when and how to introduce these models would be welcomed by respondents.

Barriers to implementation

Most respondents were unable to identify specific barriers encountered in establishing systems for registers of interested patient or healthy volunteers. Some respondents confirmed that they had experienced problems with IT systems in previous years in terms of developing general research patient databases but these problems seem to have been mostly overcome. Most of the identified barriers were IT related:

- Worried that flagging patients might overload the system
- One Trust had attempted to implement a patient database for general research two years ago but resources and data systems could not accommodate the practice.

Lessons learnt

Similarly only a few respondents were able to report lessons learnt. Key messages identified in responses included:

- Keep it simple
- Ensure a simplified approach to collecting the details of individuals
- Make people who have already completed a study feel welcome to come back
- Need more robust data systems
- If developing a database of patient details, ensure that the correct questions are asked initially to aid screening
- Ask the public what they want and be open, transparent and honest with everything you do.
- A database of interested patients cannot exist in isolation; it requires agreed policies and governance structures to be in place.

Approaching the general public about research

Whilst the consent to be approached model can work well for patients with long term conditions, it is not necessarily applicable to other disease areas. In response some parts of the country are developing innovative approaches to identifying members of the public who would be willing to assist with health research studies. This cohort approach lends itself survey type research and public health interventions but also permits a wide range of methodologies including clinical trials. Some of the suggested models are shown in the table below. This list is by no means exhaustive but gives an idea of some the approaches that were suggested to us.

Model	Short description	Recruitment
Citizen Scientist http://www.citizenscientist.org.uk/research-opportunities/	The Citizen Scientist project was launched in Sept 2012 and is a public engagement in research initiative. The web based system makes it easy for people to find out about health research in their local area and to seek opportunities to take part in research studies. These opportunities range from participation as a study volunteers to patient representation on steering committees or	Self-selected Over 600 people have signed up to mailing lists and there are over 400 Twitter followers plus 700 users of the website per month. Individual studies are

	just having a voice about local research. This unique approach allows people to investigate for themselves about research that might suit them and to self refer into the studies by approaching their clinician or the researchers directly. ***It puts the choice with the individual.*** The project also recognises the research carried out by local community groups and in time will offer opportunities for researchers to volunteers their support and expertise. "*By making research more accessible in this way we aim to increase awareness, understanding and acceptance of our research. As a result we will build a community that is fully engaged with health research and improve on the way we recruit volunteers to studies.*" The website has link to a range of studies including • healthy volunteer studies • clinical trials • surveys and questionnaires • patient and public involvement opportunities.	not recruited to directly, rather researchers can showcase their individual studies on the website and interested people can then go direct to the research study websites if they wish to.
South Yorkshire Cohort http://clahrc-sy.nihr.ac.uk/south-yorkshire-cohort.htmlhttp://clahrc-sy.nihr.ac.uk/south-yorkshire-cohort.html	The South Yorkshire Cohort (SYC) run by the Yorkshire & Humber CLAHRC offers an opportunity to initiate a programme of research and employs a cohort multiple RCT approach. Initially collecting data through postal self-completed questionnaires. So far more than 10 research studies have recruited participants via the cohort.	A two stage sampling process, initially using a random sample recruited via GP practices and invited to participate
The Exeter 10,000 http://www.exeter.crf.nihr.ac.uk	NIHR Exeter Clinical Research Facility is advertising for 10,000 volunteers – both patients and healthy volunteers. Volunteers have to attend an appointment where they give samples of blood and urine and complete health questionnaires.	Self-selected

Healthy Volunteer databases

We were informed of a number of databases which had been set up specifically to recruit healthy volunteers. Examples given include:

- Oxford Vaccine Centre Healthy volunteers database (including a quarterly email newsletter)
- Liverpool Consent for Consent model
- Sheffield Teaching Hospital NHS Foundation Trust: http://www.sheffieldclinicalresearch.org/clinical-research-activity/get-involved

- NHSCR identifying healthy controls using the NHS Central register in Scotland: http://www.gro-scotland.gov.uk/national-health-service-central-register/about-the-register/index.html
- Salford Citizen Scientist has a gateway to sign up online to opportunities for healthy volunteers.

Training and other Initiatives

Reported training initiatives tended to have focused on informing clinical staff about research so that they can talk to patients and their families about research with confidence and knowledge when delivering clinical care. Those that have implemented training of this kind, report that it has raised awareness of research amongst staff and has led to a perception that research is part of routine care and helps to ensure that all eligible patients will be approached.

The Medicines for Children Research Network (MCRN) focuses training on Paediatric GCP, obtaining consent and general research skills, and ensures that clinical staff are prepared and equipped to consider potential for involvement in studies when a child is receiving clinical care. In addition, study specific training is also provided, alongside numerous approaches to raise awareness of the research currently ongoing in departments (for examples, posters, leaflets, update sessions). This is particularly pertinent in some clinical settings, for example A&E and Intensive care, where staff numbers are large, recruitment is often 'out of hours' and creative models of recruitment are needed. Through such initiatives and joint working the MCRN has been able to support complex interventional studies with very large numbers of children in emergency settings, e.g. MAGNETIC, CHiP and CATCH.

Cancer Research UK recognises that given the active nature of research in cancer care, the consent to be approached model is not appropriate and rather, they promote research opportunities directly to patients through their online CancerHelp UK clinical trials database. This contains trial summaries that are written primarily for a lay audience – the standard lay summary is reviewed and revised specifically for patients and carers . Each summary provides accessible information to patients and carers on

- the aim of the trial
- eligibility and exclusion criteria
- trial design
- information about hospital visits
- side effects
- list of locations of trial sites
- name of the chief investigator and details of organisations supporting the trial.

Comments received from other respondents stressed the need to look at the recruitment of patients outside of secondary care:

- Work closely with Local Authorities and local carer organisations plus CCGs.
- Now that care of diabetic patients is increasingly transferring to primary care, identification has to take place in primary care rather than secondary care.

Patient identification following a review of notes

Using patient notes to identify patients will be more appropriate for certain conditions and for certain types of trials. Using patient notes as a way of identifying suitable participants is the norm in many areas where the option of being in a study is an integral part of the therapeutic options on offer, for example in cancer care. Research nurses described arrangements in many cancer studies where multi-disciplinary teams including the research nurse review opportunities for participation in research as part of the treatment decision, and review medical records to assess eligibility for current studies.

The response from the Medicines for Children Research Network (MRCN) identifies some complexity around the balance between privacy and sensitivity of medical information against the opportunity to take part in research: *The vast majority of studies within the MCRN portfolio have required review of medical notes to assess eligibility of potential participants. The key question is therefore when this is undertaken and by whom. In the opinion of the MCRN, Trusts and network research support staff employed by those hospitals, have variably interpreted guidance on access to notes. Some have taken a strict view of prohibiting access to staff not directly involved in the clinical care of potential participants, others have permitted or not actively prohibited such access. For many or most disorders, there are currently no databases or registries available to identify participants.*

The approach of the MCRN has been to ask network staff to encourage investigators who are involved in care to assess the eligibility of potential participants at an early stage to facilitate such participants' early access to a study once all approvals are in place. They support investigators with data management in such situations, for instance of non-identifiable data. This approach has been one of the factors in enabling the MCRN to support international commercial studies that have, in around 30% of studies since 2009, achieved first global recruits in the UK.

The MCRN note that the review of patient notes is an extremely sensitive area and they support an open discussion with patients and public. Possible options are to actively seek informed consent from all patients for accredited research staff to review their records in the context of potential research studies or, subject to broad public approval, use an opt-out approach.

Finally we noted that six of the responses submitted to us, described research nurses or researchers having direct access to patient notes, admission lists or theatre lists all containing identifiable information in order to screen for suitability. However, these examples did not describe whether patient or public views had been sought, or what information or publicity had been given about use of medical records, or how effective these methods had been in recruitment of participants.

Scotland

A response from Scotland an approach to identifying potential participants after reviewing patient notes using NHS analytical staff as a go between GPs and researchers. The system works in the following way:

National Services Scotland (NSS) is a non-departmental government body with close links, including Caldicott Guardian and Medical Advisor, with the National Records of Scotland (NRS). NSS is custodian of many of Scotland's health administrative datasets, and NRS custodian of Scotland's civil registers, including NHS Central Register (NHSCR). Both organisations report to have sound

expertise, experience and appropriate governance in place to facilitate the identification of potential participants, whether as individuals with the condition of interest to a proposed investigation, or as healthy controls. These are described below:

1. Identification of study participants with a condition of interest

Skilled and trained analytical staff run a query against the appropriate health administrative dataset to identify individuals with the condition of interest. Using registered deaths information from NHSCR, this output is checked to remove the data of the deceased. By querying against Scotland's Community Health Index (CHI) for those against whom a death has not been registered, the current registered General Medical Practitioner for the individual is identified. NSS can then send recruitment information on behalf of the researcher to the General Medical Practitioner of the identified individuals. Based on their knowledge and understanding of both the research proposal and their patient, the GP then decides whether or not to pass on the recruitment information to the identified individual. The GP is also asked to confirm that the patient has the condition of interest. At no point during this process is any identifiable patient information disclosed to the researcher. The first contact the researcher receives is from those individuals who, having received the recruitment information from their GP, are happy to participate in the proposed research. "*Our experience has shown that the response rate varies considerably when this method is used, from 19% in one case to between 60% and 70% in another."* The focus of the studies and the patient population involved were different in the two studies.

2. Identification of healthy controls

NHS Central Register is an administrative register managed by the National Records of Scotland http://www.gro-scotland.gov.uk/national-health-service-central-register/about-the-register/index.html . Thus it is a quality controlled register which contains basic demographic details of everyone who was born, or have died, in Scotland plus anyone else who is (or has been) on the list of a general medical practitioner in Scotland. It has been used successfully in a research study to assist in the identification of 'healthy' controls by an applicant who had already used the on-line electoral roll for this purpose. Appropriately matched controls having been identified by NHSCR staff, the method involved the sending out of recruitment information (prepared by the researcher) by NHSCR with a covering letter from the then Registrar General of Scotland. No demographic information was disclosed to the researcher. Those individuals who wished to participate sent their recruitment details directly to the researcher, who reported a response rate of 21.6 %. The findings arising from this work have been published in the Journal of Clinical Epidemiology and demonstrate the importance of methodological rigour and prior assessment in choosing sampling frames for case-control studies (J Clin Epidemiol [2013,66(6):675-680]).

Advantages are of this method of recruitment are:

1. Researchers only receive the identifiable information of individuals who wish to participate in their study, thereby alleviating the challenges of getting 'consent for consent';
2. Welfare considerations of how a research invitation might affect an individual can be taken on board by the GP;

3. Quality checks to minimise the risk of recruitment information being sent to the deceased or to individuals who do not in fact have the the condition of interest are integral;
4. Use of flags on NHSCR against those to whom a questionnaire has been sent prevents their inclusion in future cohort extracts.

Patient and Public Involvement

We asked respondents to tell us what patient and public involvement had taken place in the development of the models used to identify potential participants. Only three responses gave any details of patient and public involvement in the development of the model and that included:

- the Salford Citizen Scientist project,
- the Liverpool Consent for Consent model, and
- the Medicines for Children Research Network (MCRN).

The Salford Citizens Scientist project consulted with a group of 60 people about how it should provide information to the public about research and what would encourage people to take part. Twelve people were recruited to become members of the Citizens Scientist Advisory group.

The Liverpool Consent for Consent model involved patients in the initial development of the model and more recently appointed a patient representative to the governance team.

The NIHR Medicines for Children Research Network (MCRN) has developed and established a Patient and Public Involvement/Engagement model that encourages children and families to be actively involved in the design and delivery of research projects. A key role for children and families is to work with researchers to ensure research meets the needs of patients and this involves commenting on the design of studies to make it more practical for patients to participate and this includes the design of age appropriate information sheets to support children and families to take part in research. It is difficult to measure the impact of this involvement on patient recruitment as there are no validated tools to measure such impact. However, research staff responsible for recruitment have reported that the input of children and families in the development of research protocols and information aids the recruitment process. Children and families represent the MCRN as ambassadors to promote research to other children and families. Parents talk to other parents about studies and this has resulted in parents enrolling their children into clinical trials.

Other respondents mentioned that they had plans to undertake patient involvement or set up panels but overall patient and public does not seem to be a high priority despite the relevance to this specific issue.

Conclusions

The HRA are not proposing 'a one size fits all solution'. Clearly appropriate models for recruiting participants will depend on the research study in question and should be sensitive to the situation of the potential participant. It was clear that the creation of systems that allow patients to register their interest in clinical trials in advance and allow researchers to make contact with them when a suitable study arises, are increasingly being developed for various long term conditions. Feedback indicated that the resources and effort required to implement these systems should not be under-estimated, and it would appear that there is need for guidance on developing such approaches and shared learning which others can benefit from.

However in other disease areas it is necessary to approach patients directly in the consultation setting. So, for example, in oncology, it is standard practice to consider research options as part of clinical care. Cancer Research UK pointed out that it is important to appreciate that the recruitment of an oncology patient to a phase III trial as part of their treatment or to a phase I trial when their treatment options have run out, is, and should be, very different from studies that recruit patients with non-life threatening, long-term conditions or healthy members of the public.

Evidence from the call for good practice suggests that one of the areas which must be addressed at an early stage is patient and public involvement. It appears that many of the responses submitted to us, so far, are weak in the area of patient and public involvement despite the fact that their views are integral to developing and implementing many of these approaches successfully. Patient and public involvement in the development of recruitment approaches and databases is essential to the success of these models and any future guidance will need to suggest ways in which this can be achieved. There is some controversy over of who should have access to patient notes in order to screen them for suitability for inclusion in future studies. In particular the debate focuses on the role of the research nurse in relation to the clinical care team. We have been told that researchers would welcome an open discussion with patients and the public focusing on this topic to inform the development of future guidance on this issue.

It is also helpful to think about ways of improving recruitment to health research studies which are not clinical trials. There appears to be a trend in the recruitment of cohorts of the general public which can be used to feed into a variety of different studies reflecting a range of methodologies. These may also lend themselves particularly to public health and lifestyle interventions/research, but are also being used to recruit into clinical trials.

The internet is increasing the accessibility of research; both in terms of making people aware of opportunities to take part in research, as well as the ability to sign up and register their interest in taking part. This might include consenting online to being approached, or to access to medical records, when suitable studies arise.

Examples given to us from Scotland provide a clear demonstration of how electronic systems can be used to identify suitable patients for studies using an intermediary that already has lawful access to do the searching, thus easing the burden placed on general practice staff and allowing researchers access to identifiable data only with the consent of the individual. Diabetes research seems to be leading the way in the development of innovative approaches to identification and recruitment of

potential research participants in England. The most sophisticated model appears to be combining the use of technology to screen anonymised records combined with consent for approach. This is known as the Pathfinder project which encompasses both the Help DiaBEATes Campaign and the FARSITE project.

Information supplied about the information governance aspects of establishing databases of patients and public willing to be contacted about research has been limited, and this is an area for future consideration.

From the responses received, it is evident that a number of innovative approaches to identification of potential participants are being explored. As anticipated, a range of views about access to medical records were received. Disappointingly there was little feedback on patient and public engagement on this issue, or the success rate of using this approach.

Appendices

Appendix 1 – HRA Call for good practice models for identifying potential participants for research studies

Job role: (please select)

☐Researcher ☐University research management

☐Research nurse ☐Clinical staff

☐Research network staff ☐NHS research management

☐Other

1. Have you or your organisation been involved in the development or implementation of activities to raise awareness of research in order to increase patient participation in research activities? If yes, please describe this, including the impact this had on patient recruitment.

2. Please provide examples of the information provided to patients to help improve their awareness of participating in research. If possible, please provide any information on how successful it has been.

3. Have you or your Trust/organisation developed a model to allow patients (or carers) to register their details so they can be approached directly if they are suitable to be invited to join a health research study?

3a. If so, please describe the model, how patients registered or opted out, and how the approach to potential participants was made.

3b. Please give details of any patient and public involvement in developing the model.

3c. Please provide details of feedback from patients, public or clinical staff on its use.

3d. What barriers have you encountered in establishing systems for advance consent to identify suitable participants? (Please include here any technological barriers such as software not allowing the creation of additional flags attached to patient notes)

3e. What are the lessons learnt from implementing such an approach?

4. Please describe any other models of advance consent that you are involved in or aware of. (Please include here model for obtaining consent, their advantages, disadvantages, barriers to implementation and lessons learnt).

5. What examples of initiatives or training are you aware of to increase the role of direct care teams in including potential participation in research as part of the treatment decision with patients?

6. Please give examples of situations where potential participants have been approached following a review of medical records. Please give details of how you decided who could review the medical records, what identifiable information was visible, and how you provided transparent information to patients about this use of their medical records. How successful were such methods in recruiting participants?

7. We might want to contact you in order to seek further detail or seek your consent to use your contribution as an example of good practice. If you are willing to be contacted please complete your details below:

Title:	
Name:	
Role:	
Organisation:	
Work address:	
Email:	
Telephone:	