

# “Natural Ground” for Medical Research Charities

## Public and Patient Involvement in Research Funding

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**Abstract:** Improving patient and public involvement in research is now an established goal of UK science policy. With many medical research charities often representing distinct patient groups as part of their broader charitable role, or having strong patient groups allied to them, patient and public involvement would seem “natural ground” for them. The Association of Medical Research Charities Natural Ground project brought together a learning set of staff and volunteers from member organizations to discuss current activities and share best practice. This article identifies 5 areas where medical research charities involve patients and discusses some of the methods used.

**Key words:** *charities, consumer involvement, Great Britain, patients, research support*

**T**HE ASSOCIATION OF MEDICAL RESEARCH CHARITIES (AMRC) is the membership organization of UK’s leading medical and health research charities. Working with our members and partners, we support the sector’s effectiveness by developing best practice, providing information and guidance, improving public dialogue about research and science, and influencing government.

Established as a charity itself in 1987, AMRC has 120 members contributing £1 billion annually to medical research aimed at tackling conditions such as heart disease, cancer, and diabetes, as well as rarer illnesses such as cystic fibrosis and motor neuron disease.

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With approximately one third of all public expenditure on medical and health research in the United Kingdom coming from charities, the sector is unparalleled, across the world, in scale and impact.

### **AMRC MEMBERS AND PATIENT/PUBLIC INVOLVEMENT**

All medical research charities support work for patient benefit, and many have close links with these beneficiaries and/or their carers. This ranges from involving patients in deciding what research to fund, using sophisticated models that put their priorities on an equal footing with those of clinicians or researchers, through to communicating research results more widely.

In parallel, an established goal of UK science policy is improving patient and public involvement (PPI) in research, as set out, for example, by the Medical Research Council in “Clinical trials for tomorrow” (Medical Research Council, 2003), which commits to “involving patients/consumers in all aspects of the clinical trials it funds.”

Although the term “PPI” is often used to summarize the way charities work with

“nonspecialists,” it is more often the case that these people are patients or carers with a specific interest in an aspect of research or policy, rather than a more general “public.” Indeed, the experiences of the AMRC’s Natural Ground project, the focus of this article, come from “disease-specific” charities and their views and experiences of collaborating with patients and carers. For this reason, the term “PI” is used throughout, denoting “patient involvement.”

It may be that as this agenda grows within both the charity sector and more widely, charities that do not have defined patient groups (such as those funding across a spectrum of conditions) develop ways to involve the “public” in what they do, and “PPI” will become a real part of the landscape.

## AMRC’S NATURAL GROUND PROJECT

### Background

As set out in the preceding section, patient involvement is very “natural ground” for research charities, hence the name given to a significant body of work carried out by AMRC over the last 2 years.

The aim of this “Natural Ground” project was to appraise the challenges and opportunities of PI, and, using best practice examples, present the different approaches that may be adopted.

There is certainly no “off-the-shelf” method for charities to involve patients in their research funding, nor is doing so necessarily the right approach for all charities at all times. This article, like the Natural Ground report itself (Natural Ground, 2009), seeks to ground PI in the experiences of our members, of what works and does not work, and the wider evidence already gathered by other organizations. By doing so, we hope it will help charities explore models of PI to enhance the science they support for patient benefit while also enlightening other interested parties.

### Methods

This project began with a request for member organizations to join a learning set that would meet 6 times over a year to share ex-

periences, discuss areas of concern, and identify topics where they felt further work was needed. Each organization was asked to bring a member of staff who managed the PI initiative as well as a patient involved in that initiative, to ensure that a rich picture of involvement was obtained.

Ten AMRC member charities thus comprised the Natural Ground “learning set”: Alzheimer’s Society; Asthma UK; Ataxia UK; Breakthrough Breast Cancer; Cancer Research UK; Juvenile Diabetes Research Foundation; Meningitis Research Foundation; Muscular Dystrophy Campaign; Parkinson’s Disease Society of the UK; and The Stroke Association.

These charities range from avowed champions and pioneers of PI, to the more skeptical. Through regular meetings over a year, experience and opinions were shared on a number of key aspects of the “mechanics” of PI. The 3 areas where most evidence was gathered were developing a research strategy, making research funding decisions, and more general involvement of patients in the “research cycle”—all aspects of how a project is designed, delivered, analyzed, and disseminated. Two further components, also reported below, covered the involvement of patients in providing information about research to others, and an analysis of evaluation methods, to reach an understanding of how the impact of PI is measured.

Each member organization had its own method of involving patients, in response to requests from patients groups or strategic decisions within the charity to increase engagement. Because these initiatives had developed organically over time, the training available to patient representatives varied, but all organizations offered patients one-to-one advice and mentoring on the kind of research supported by the charity.

### Results

#### *PI in developing a research strategy*

All AMRC members have a research strategy that defines the areas where, and how, support is focused (“AMRC: Principles of a research strategy,” 2005). The strategy also

explains where they fit within the broader field, and thus acts as a basis for developing collaborations.

While “good” research has historically been judged on scientific validity, the PI or “service user” agenda highlights that services, including research, should be consistent with patient needs. That patients themselves fund much of this research, through taxes or charitable donations, gives extra impetus to their right and reason to be involved in deciding how their money is used.

The learning set confirmed that charities tend to fund exciting science as judged by researchers and that the views of those outside the research community are not incorporated. There were tensions expressed about how this could change to support areas important to patients.

However, several charities do develop dialogue with patients and a strategy responsive to their needs and beneficial to both parties. As a staff member from one said:

It was clear that by having researchers discuss their research areas in the context of the concerns of people with asthma, views of both people with asthma and researchers changed—people with asthma gained a clearer understanding of the topics considered, while researchers developed a clearer understanding of the relevance of these topics to people with asthma.

### **Key messages**

- The importance of getting a clear mandate from trustees to take forward PI in strategy development
- The need to reach patients in ways that facilitate real discussion, which will depend on a charity’s resources as well as the type of people being involved. Is it, for example, best to involve people by asking their opinions and collating them internally, or by bringing patients, clinicians and researchers together?
- The importance of involving clinicians: they see patients, but are not always researchers, and will bring practical considerations to the table
- The final strategy should be approved by patients, accessible to lay people, written

in plain English, available in appropriate formats and become a key tool in making the charities’ work “real” to patients and the public

### **Case study**

In 2004, the Board of Trustees of the Parkinson’s Disease Society (PDS; now called Parkinson’s UK) agreed to review the society’s current research strategy and a number of key recommendations were made. This resulted in the development of a research agenda that reflected both the members’ and research community’s views on which specific areas of Parkinson’s disease research the society should focus future spending.

Thus, the research agenda was generated following input from various stakeholders, including the society’s Board of Trustees, Parkinson’s disease researchers, patients, their carers, physicians, other members of the society, and PDS staff.

The research agenda helped to prioritize the society’s research program for 2005–2009, with clear research priorities and outcomes and highlighting the importance of effective communication of research progress for the membership and fundraisers.

The priority research areas, endorsed by members at the PDS Annual General Meeting, include the following:

- slowing or halting the progression of Parkinson’s disease
- the establishment of guidelines for the clinical management of Parkinson’s disease
- the treatment of nonmotor symptoms
- evaluating the role of, and support for, carers
- evaluation of “classical” (eg, physiotherapy, speech therapy) and complementary non-drug therapies
- implementing Parkinson’s disease research findings into practice

### ***PI in research funding decisions***

AMRC members must use the transparent, independent process of “peer review” (experts from the same field assessing individual

grant applications) to choose projects to support, and operate this according to several principles including accountability, balance, independence, rotation, and impartiality (“AMRC: Use of lay reviewers in the peer review process, 2006”).

Although this process has traditionally received the views of scientific experts, there is increasing interest in accessing the voices of patients or carers, both for their direct interest in the outcomes of research and experience of the disease and their expertise in the feasibility of undertaking research with that patient group.

“The Alzheimer’s Society’s ‘Quality Research in Dementia’ (QRD) programme” (n.d.) was groundbreaking in this area, and, as explained, “Triage by ‘users’ of research ensures that only research which is deemed relevant to carers and people with dementia is funded by the charity.” Members of the society’s “consumer network” (a panel of carers, former carers, and people with dementia) comment on each application and score it for importance and relevance to the research priorities of the society, with only those applications that qualify at this stage being sent for scientific peer review.

An illustration of the practical importance of such assessment came from the Arthritis Research Campaign:

Our USER committee looks at the practicality of doing research and questions the assumptions of researchers. Our patient reviewer was the only person to spot that a researcher had assumed that people would only have one artificial joint—many people with arthritis have more than one replacement joint, so the suggested blood tests would provide unclear results.

Of several other charities that involve patients in research funding decision processes, Ataxia UK has patients on its scientific advisory committee receiving recommendations from peer reviewers, while, as described in “case study,” the Stroke Association uses lay member review in parallel to scientific review, having developed a plain English form asking questions important to stroke survivors.

### Key messages

- Provide adequate training, mentoring/on-going support to enable patients to contribute
- Consider if the information asked of researchers is adequate to allow patients to make decisions — this may mean training researchers to write better lay summaries, or asking for additional information. Always explain to researchers why additional information is needed, and stress the importance of doing it well
- Think about how best to ask patients to score applications to ensure their greatest involvement

### Case study

For most of its history, The Stroke Association funded research chosen solely by medical and clinical researchers. However, the arrival of a new chief executive and refocusing of the trustee board meant the time was right to examine how stroke survivors could be included in this decision-making process.

To allow meaningful lay involvement, The Stroke Association set up a service-user review process in parallel to the existing peer review process. Applicants to The Stroke Association now complete a plain English summary form, alongside a traditional research application form. The plain English summary is sent to the service user review panel, for comments. The panel is made up of 22 individuals with experience of stroke recruited via advertising in national newspapers, within The Stroke Association’s newsletter, and on the INVOLVE website. Two service user representatives attend The Stroke Association’s research awards committee, where they supply the perspective of stroke survivors and have equal status to academic and clinical members of the research awards committee.

While charities have done much of the early work in this area, public funders are now taking similar approaches, with the National Institute of Health Research committed to having members of the public on commissioning boards that make funding decisions on research supported by the Department

of Health within the National Health Service (NHS) (£116 million in 2008-2009).

By the end of the project, all organizations involved in the learning set saw the value of PI and recognized that developing a PI activity that fitted with *their* organizational need and patient views was more important than copying a model that had been successful for other funders. Implementing PI was also dependent on obtaining trustee buy-in. By sharing approaches that had been used successfully, members of charities were able to articulate the organizational benefit of PI and start to build in ongoing evaluations, to provide in-house information on the impact of PI.

### ***Involving patients in the research cycle***

The research cycle of project design, delivery, analysis, and dissemination offers many opportunities for patient involvement. Learning set members provided several examples of this "in action," the common theme being that patient/carer experience of living with a condition makes them uniquely able to assess the feasibility of planned projects or convey their importance.

This can be an invaluable "reality check," even for successfully peer-reviewed projects, including identifying practical issues that may make the project unacceptable to patients asked to participate and identifying what information patients and carers need in order to be able to comment on research. Involving patients in monitoring research can bring researchers a deeper understanding of a given condition, while involving them on committees—such as trial steering groups—can lead to better integration between those running these and the patients they need to recruit.

While most patients who take on work of this sort do not do it in such an all-encompassing way, some do. Readers may be interested in the work of Lester Firkins, a former banker hurled by tragedy into the "research cycle" when his son died of variant Creutzfeldt-Jakob disease. Firkins chaired the Human BSE Foundation for 2 years, the PRION-1 trial for quinacrine in Creutzfeldt-Jakob disease, now chairs the steering group

of clinician/patient collaboration the James Lind Alliance (n.d.), and is a member of INVOLVE, which provides advice and support to patients, researchers, and funders on how best to support and encourage PI in the research cycle (INVOLVE, n.d.). Devoting significant time to "lay involvement" as a business consultant for the Medical Research Council, Firkins says, "I just never thought it needed formalising. In a sane society, doctors would take patients' and carers' views into account" (Petit-Zeman, 2005).

### **Case study**

Breakthrough Breast Cancer funds research programs at its own research center and satellite units and utilizes PPI in some of its research management processes. Opportunities mainly exist on specific committees for ongoing projects, for example, 2 participant representatives sit on the Breakthrough Generations Study Advisory Committee and 1 patient representative sits on the steering group for the Breast Cancer Clinical Outcome Measures project, an audit of symptomatically detected breast cancer. Breakthrough's scientific advisory committee is attended by a lay trustee. Breakthrough is also working with partner organizations, such as the National Cancer Research Institute, to enable women with breast cancer to participate in the governance of clinical trials, via being on trial steering committees.

### ***PI in providing information about research to patients and the public***

There are 2 main reasons why charities need to clearly convey the work they fund to patients and the public. First, as set out in this article, increasing patient involvement in research funding requires their intimate understanding of it, while second, the value of ensuring general public understanding of charity-funded work is crucial if they are to support it.

While research grant applications often contain a "lay" summary or abstract, designed to allow a nonexpert to understand a study's aims and implications, many funders find that researchers are apparently unable to

“translate” their work to make it meaningful to nonspecialists. And it is increasingly patients who make this clear, such as members of the Stroke Association’s Service User Review Panel.

Developed to allow stroke survivors and carers to comment on research funded by the association, a key first step for the panel was to develop questions to ensure the “lay summary” provided the appropriate information and incorporate these into a plain English summary form as part of the grant application pack.

Members of Arthritis Research Campaign’s USER committee of people with arthritis and nonresearch-active clinicians were discontented with information provided in application abstracts, leading them to restructure the form, asking for more specific information within this section including objectives, background, and a statement on why the research is novel and its endpoints. Applicants who do not provide adequate information must resubmit.

The experience of the Alzheimer’s Society is also encouraging:

Lay summaries and the need to write these clearly was the first hurdle. [These] have improved enormously over the years. With the aid of innovative diagrams, it is possible for a good communicator to get across to us the most complex concepts and explain where their project fits in the jigsaw of Alzheimer’s.

### Key messages

- Providing more detailed lay-friendly information was a culture change for researchers. They require guidance on what information should be provided, clarity on what will happen if they do not comply and reassurance that providing a truly “lay” abstract will not lead to their application being marked down by scientific peer reviewers as being simplistic.
- Information provided to lay members should be relevant to their needs and the task they are being asked to do.
- Different groups of lay people will require information in different formats, or even different information. They must be in-

involved in deciding what information is relevant to them and how it should be presented.

### Case study

CancerHelp UK is the patient information website of Cancer Research UK. The website provides an information service about cancer and cancer care that is available to all and written in a way that people can easily understand. As part of this service, the CancerHelp UK team provides summaries of ongoing clinical trials and of trial results, written in plain English. They have found that clinical researchers often do not have the necessary skills to write in lay terms and employ a team of people with defined skills and training in writing for a lay audience.

### *Evaluation: Measuring the impact of PI in research*

Just as the UK health care system sets much store by “evidence-based” medicine, so we need to find ways to gather *evidence* that involving patients makes for “better” research. But it is early days for PI in this respect: as a relatively new way of working, it should not be assumed that lack of studies providing evidence of effectiveness is the same as lack of effectiveness.

And it is important, too, that we heed the “sanity” of listening to patients and carers: there is a strong and simple case that PI makes for better medical research because those with direct experience of a condition are invaluable to deciding on the best strategies to understand and tackle it.

Many government funders in health and social care now see PI as a key mechanism for ensuring that services are “fit for purpose” and responsive to recipients’ needs. Similarly, charities increasingly agree with this philosophical basis of PI. But, as more adopt it in some way into how they work, so their keenness to evaluate its effectiveness in helping publicly donated funds be best used grows. A recently published report exploring the impact of public involvement in clinical research revealed that this improves research design

as well as recruitment to studies. However, it is clear that the evidence base could be improved by having more consistent and robust ways of assessing impact, as well as providing researchers with guidance on reporting this (Staley, 2009).

One important point here is that robust evaluation (of any "intervention," including PI) requires that its purpose be clearly defined at the outset so that its impact can be measured. Indeed, the UK Clinical Research Collaboration, which brings together diverse partners to promote high-quality clinical research, recently evaluated the use of PI within its advisory groups and highlighted exactly this (TwoCan Associates, 2009).

Natural Ground participants were aware of the dearth of academic literature to evaluate PI and the need to integrate such evaluation into its development and rollout.

### **Case study**

Among members that have attempted evaluation, two approaches taken by the Alzheimer's Society to evaluate the QRD are interesting.

First, the Society compared research funded since the program was set up with that prior to 2000 and found that PI led them to fund treatment research but stop funding service evaluation studies. A second, longer-term evaluation is looking at the influence of the QRD program on members of scientific and lay panels and has already reported that the ability of researchers to communicate about science has been enhanced: "Applicants have slightly simplified their presentations because of consumer involvement. This has meant that they are also easier for the scientists to understand, as they are unlikely to be specialists in the particular field that the applicant is working in."

It remains important to ground PI in an evidence base if it is to become part of "mainstream" research processes. Ultimately, evidence of its efficacy will encourage researchers to engage with charity requirements for them to outline how their work benefits patients.

### **THE FUTURE AND CONCLUSIONS**

The future of PI in medical research rests in the ability of individual organizations to identify whether and in what way it has value for them, how it fits with their existing activities, and whether their patients want to and can undertake it. To succeed, PI needs to be seen as integral to a given organization, not an add-on.

While adopting PI needs collective organizational will, some may not "buy-in" at the beginning but become convinced of its merits only as tangible benefits become apparent. For researchers, this can turn them from seeing PI as an additional burden to truly valuing working more closely with patients. There are already strong examples of how, by developing significant conversations with patients about living with medical conditions, researchers have begun to pursue fruitful new avenues.

While much can be learned by organizations from one another, the Natural Ground project reinforces the importance of PI being tailored to fit. That said, a growing range and number of organizations train and support patients who want to become involved in medical research in ways outlined here, and detailed in the full Natural Ground report ("AMRC: Principles of a research strategy," 2005).

Of those patients who do seek involvement, or welcome it once offered, not all want to help in the same way. Furthermore, patient populations include people with diverse mental and physical issues, which can make engagement especially challenging, and working with "hard to reach groups" is a perennial problem.

PI is thus "Natural Ground" for medical research charities. Through their strong connection with patients they are uniquely placed to develop useful PI that is not tokenistic. PI helps funders demonstrate the relevance of their research to donors and supporters and ensure that this portfolio is focused on areas important to people with a given condition.

However, medical research charities are not unanimously wedded to PI, and while clearly

here to stay, and growing, its evaluation must be robust. This will both ensure organizations are devoting time, energy, and resources to an activity that enhances their research and help others see what approaches might—or indeed might not—work for them.

Natural Ground has achieved its primary aim of lifting PI off the page, making it feel real

and possible for organizations understandably hesitant about such an undertaking. But this is only the beginning: we will now work to support charities who are having discussions about PI to find models and ways of working that suit them best and add clear value to their funding of research for patient benefit.

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