The role of Stakeholder Representation in Research Funding:

Experiences from Arthritis Research UK’s Stakeholder Panel, ‘USER’
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Summary

In early 2008, Arthritis Research UK established a joint panel of the charity’s stakeholders, USER, to review applications for its researcher-led funding schemes. Representing those who stand to benefit from the charity’s research – front line clinicians and people with musculoskeletal disease – the USER panel is the stakeholder ‘voice’ of Arthritis Research UK. Operating separately from the scientific funding panels, USER reviews a lay case for support, now a required component of all researcher-led grant applications submitted to the charity. USER considers the relevance of each proposal to the charity’s goals, and the importance of the research to its stakeholders. These opinions help to inform the scientific funding panels in their decision-making. Although other medical research funders include patient and public involvement (PPI) in their funding application review processes, Arthritis Research UK’s PPI initiative is novel; it seeks to include not only the patient voice, but the opinions of practitioners of the care and treatment of people with musculoskeletal diseases. It also provides a practical, acceptable and effective approach to stakeholder representation in the process of charitable research funding.

Background

The major funders of medical research in the UK—the Research Councils, the Wellcome Trust and other charitable funders—devolve the fate of individual applications for funding to the decision-making powers of independent scientific committees. Expert members of these committees, influenced by input from external peer reviewers, make judgments on originality, the appropriateness of the research methodology, the track record of the applicants, feasibility of the approach, and costs of the research. Committee members and external peer reviewers will also judge the relative importance of a proposal within its own particular scientific field, and clinician and clinical academic reviewers may be called upon to
consider the patient benefit that might accrue from the research. Providing the focus of the research proposal falls within the broad remit of the funder, it is likely that all applications will be considered by the scientific committees to be of equal relevance to the organisation. The committee’s decisions are based predominantly on the individual scientific strengths of the proposals, which, in the face of limited funds, may be used as the basis for priority ranking. It is almost impossible to rank the relative importance of a funding application to the funder (and by implication the funder’s stakeholders) through this approach.

As part of their strategic thinking, medical research funders aim to consider the views of the potential beneficiaries of their research, but this aspiration has been difficult to translate into action. In recent years, many funders have worked to overcome the ideological and logistical barriers to PPI within their organisations, and now have successful and well accepted PPI schemes embedded into many of their activities, including the processes employed to review applications for funding. There is no ‘gold standard’ for PPI in UK medical research funding, and the only constant appears to be the wide variety of practice, reflecting the differing functions of PPI within each organisation. Arthritis Research UK’s PPI initiative is unique in both aspiration and modus operandi; a ‘professional’ lay committee comprising both individuals with musculoskeletal disease and medical professionals, operating separately to the scientific committees, but seeking to directly influence their decision making.

**Arthritis Research UK**

For several years, Arthritis Research UK has recruited clinicians to sit on its scientific funding committees. Providing a purely clinical viewpoint, clinician members have advised these committees on the clinical importance and relevance of the research questions posed by applicants. In practice, the clinical voice has taken second place to considerations of scientific excellence, and is frequently used to address aspects of feasibility – for example, the likelihood of successful recruitment to clinical studies—rather than the broader issues of clinical need.

Continuing this practice was feasible, but Arthritis Research UK has recently revisited a number of issues that have prompted an examination of the procedures in place designed to ensure that the charity focuses on its goals and remains accountable to its stakeholder constituency:

- The diseases that form the core of our research funding are the most common arthritic conditions—rheumatoid arthritis and osteoarthritis. The charity is also committed to supporting research into several rarer disorders that, in the absence of Arthritis Research UK funding, may not be researched to a useful degree. Whilst the issue of scientific excellence, the remit of the funding committees, has always been paramount for Arthritis Research UK, the ever increasing pressures on funding allocation mean that the question of disease priority must be addressed. Generally, the funding committees do not give substantial consideration to how the support for research into different disorders should be balanced; their primary duty is to consider scientific validity.

- Arthritis Research UK operates under the financial constraints common to most medical research funders. Currently, between one in five and one in seven of applications to our researcher led schemes are funded, with most rejected due to flaws that the committee believes would significantly limit the scientific validity of the research. Although such flaws are rarely ‘fatal’, funding in such a competitive environment naturally favours those applications most likely to fulfil their research objectives, with committees showing a tendency to be risk averse. Consequently, an opportunity to address a novel research question that is also highly relevant and important to the charity may not be taken up.

- Arthritis Research UK maintains a mixed portfolio of research. Although research with a near–patient focus would appear to lend itself naturally to a conventional stakeholder input, we felt that it was important to apply the same level of stakeholder scrutiny to our significant portfolio of novel laboratory science. This type of research activity leads to the new therapies and diagnostics that stand to make real and lasting differences to the lives of people with musculoskeletal diseases.
A New Strategy

A new strategy was proposed; a process by which not only the relevance of the research to the charity’s goals could be properly considered, but the importance of the applicants’ broader research questions might be discussed in isolation of the scientific review.

Who should consider the broader relevance and importance of the proposals received by the charity? Arthritis Research UK took the view that the most important contributors are those who would benefit from answers to the research questions posed by applicants:

- People with musculoskeletal disease and their carers
- Doctors and other health care professionals who treat and advise these client groups on a day to day basis.

With this in mind, Arthritis Research UK hosted a small workshop in 2007, inviting individuals from all of these groups to consider the best strategy to achieve the charity’s PPI goals.

Stakeholder Workshop

“We have had lengthy discussions – both at our own committee meetings, and at the annual strategy days – as to whether USER’s input should inform the scientific committee’s decisions about funding, or whether USER should have the final say regarding funding, once the scientific committee has approved the science. There are pros and cons of each approach, but importantly, there have only been a few instances whereby there has been a significant disconnect between the opinions of the two committees. As USER becomes more established, and its members more experienced, it is able to flex its muscles and help to target funding towards people with arthritis.”

Clinician member

The workshop considered several models of stakeholder involvement, but concluded that representation by lay individuals or non academic clinicians on the funding panels risked ‘tokenism’. The main concern was the likelihood of the stakeholder voice not being sufficiently assertive at a table of eminent academics. It was also felt that any forum for stakeholder discussion should encourage a level of candour not possible where representatives of the research community are present. A separate panel, comprised of both lay representatives and front line clinicians, was felt to be the best solution.

Given this format, the sequence of review activities and decision making was then considered. It was agreed that initially, the stakeholder panel should meet early in the review process, and its views, on all of the applications submitted in a funding round, should inform the subsequent scientific committee decision making. This was considered wise for two reasons. Firstly, in a culture of no previous stakeholder involvement, it would help to keep a potentially sceptical scientific community onside; some researchers feel that lay stakeholders should not be entrusted with decision – making powers. As a charity, we aim to carry all our constituencies with us.

“Patient participation in medical research committees is often tokenism, plain and simple. With USER that couldn’t be further from the truth. The opinions of the lay members are highly valued and respected by the clinicians, there are no egos or personal agendas, and lay members can casually express their own views without any misplaced fear of saying something stupid.”

Lay member

Secondly, it was felt that an initial adjudication by the scientific committee on the basis of scientific merit, followed by a ranking process and final decision on funding by the stakeholder panel, would deny stakeholders the opportunity to apply their perspective to those applications that despite significant scientific flaws, ask an important research question, and might be steered towards future fundability if the scientific feedback is heeded.
The stakeholder scheme

There are five major components to the development of Arthritis Research UK’s stakeholder scheme:

• Establishment of the USER stakeholder panel
• Developing the input required from applicants – the ‘Lay Case for Support’
• Defining the process and criteria by which USER assesses the lay case for support
• Introducing the stakeholder assessment into the funding committee decision making process
• Enhanced stakeholder involvement in large awards (programme grants)

Each of the components is described in detail below.

Establishment of the USER stakeholder panel

Two groups of USER members were sought – representatives from the lay community, preferably, but not exclusively, with a musculoskeletal disease, and front line health care professionals.

Lay representatives

Recruiting lay representatives has been a challenge. The many patient support groups that exist in the field of arthritis was an obvious starting point, although we were cautious in this approach as it was thought that such individuals may disproportionately represent the view of the particular patient group to which they are affiliated. In addition to its near–patient funding schemes, Arthritis Research UK supports much basic and early translational research. It was felt (although this was not borne out by later experience) that patient group representatives may exhibit some bias towards research that offers an obvious and rapid route to patient benefit, and an ability to understand the broader potential of more basic research has become an important criterion for recruitment.

Our requirements are fairly stringent:

• We seek to recruit individuals who are able to ‘stand back’ from their own experiences of musculoskeletal disease to take a more global view, sympathetic to the wide disease remit of Arthritis Research UK. More specifically, we do not wish to recruit individuals who see membership of USER as an opportunity to air grievances or to voice support disproportionately for research in their own area of interest.
• We feel that our lay members should be equipped to read, understand and discuss science and medicine at a level equivalent to the ‘high end’ of the broadsheet news market. Members are not expected to have any specific understanding of scientific methodology or concepts (indeed we seek to exclude candidates who appear to over – analyse the limited scientific information available in the lay case for support). This requirement clearly restricts the educational and professional background of the membership, but given the material the lay members are expected to assimilate, this constraint is thought to be necessary.
• Previous experience of committee involvement is required. Lay representatives must feel comfortable voicing their own opinions as well as actively listening to others in a committee environment, assimilating the arguments and reaching an informed view.

Over the years, Arthritis Research UK has built up a database of lay individuals recruited to read and comment on our patient information literature – this database provided an early source of potential recruits. The various charities dedicated to providing support to people with musculoskeletal diseases have also been asked to advertise the posts to their own membership. Natural turnover, a widening of USER’s activities and a need to ensure the continued high calibre of members has led to two further successful recruitment drives through the national broadsheet press.

“Looking around the table, we have an incredibly diverse panel. It’s not unusual to have a rheumatologist, an orthopaedic surgeon, a GP, the MD of a medical device company and a patient all enthusiastically debating a particular grant application. Everyone brings their own personal and professional experiences to the meeting and that allows us – we hope–to achieve a balanced consensus.”

Lay member
Clinician representatives

Clinicians are also selected according to specific guidelines. We seek representatives who are able to contribute authoritatively across the broad range of applications brought before the panel:

- Rheumatologists
- Orthopaedic surgeons
- Primary care physicians
- Allied health professionals such as physiotherapists
- Specialist nurses

It is a relatively simple task to identify lists of potential candidates from the professional societies that represent these groups and to solicit applications, but a level of stringency similar to that used for recruitment of lay members is also applied to the selection of clinician members:

- We seek to recruit clinician members not currently engaged in research. Although this helps to avoid any potential conflicts of interest, our primary goal is to ensure that clinician members assess the research proposals purely as health care professionals.

- As with lay individuals, clinicians may hold some preformed ideas about the value of research in a particular area. We are careful to select individuals who demonstrate an ability to openly consider several different views.

- An ability to engage constructively with both lay members and other clinician members is also an important consideration. One of the advantages to having clinicians as members of the panel is the opportunity it affords lay members to learn more about the clinical background to the research proposals under consideration.

The selection process

“As a practising clinician, studies addressing simple questions as to the best way to use existing medications can be appealing: relatively cheap, short timelines, and leading to effective use of scarce resources. What I was not prepared for, however, is the enthusiasm with which my lay colleagues greet basic research. There may be a study looking at an obscure molecule in a relatively rare disease, which stands perhaps a 5% chance of producing clinical benefits in 15 years’ time – and a 95% chance that it will simply add to our understanding of disease. Yet, each one of these studies could prove to be the next breakthrough – and some of my colleagues on the committee can testify how anti-TNF (an Arthritis Research UK–funded success story) has changed their lives.”

Clinician member
Selection is carried out by interview, conducted by Arthritis Research UK’s Medical Director and the Research Manager responsible for the stakeholder programme. Experienced members of USER are now routinely invited to join interview panels.

The interview is centred on the analysis of a recent example of our required Lay Case for Support, submitted with each application for funding, and provided to the candidate in advance of the interview. Where possible, candidates are interviewed in pairs—a lay representative and a clinician—and are asked to assume that the discussion is taking place during a panel meeting. The lay candidate is encouraged to discuss the lay case for support and to ask the clinician candidate for guidance where required. This allows the panel to assess both candidates’ understanding of the research, along with the performance of each in a committee situation. The candidates are then asked to summarise their thoughts on the value of the research from a stakeholder perspective, in particular raising relevant points about the importance and relevance of the research question.

**Training**

All newly recruited lay members and as many as possible of the clinicians members are required to attend an orientation and training day. Members are given an overview of the grant award process in the UK, the procedures in place at Arthritis Research UK, and the strengths and weaknesses of the peer review system. The role of USER in the review process at Arthritis Research UK is outlined, with emphasis placed on the clear difference in remit between USER and the funding committees. A ‘dummy’ committee discussion of lay cases takes place, and members of the scientific funding committees have also been invited to describe their role and to share their thoughts on the contribution of USER to the review process.

“The USER lay member selection process was more rigorous than expected. This surprised me at the time – after all, this was a voluntary gig with no commercial benefit – but in hindsight, it was absolutely necessary. Lay members must be scientifically literate, confident enough to express their views in a group setting, not have a personal agenda of any kind and also have the enduring enthusiasm to attend meetings consistently and reliably. No wonder they were so careful.”

Lay member

“I have been involved as a ‘lay/patient’ on committees before but it was often more of a token gesture and sometime very patronising. It was made very clear in what was a very thorough interview that this was not going to be the case with the USER group.”

Lay member
Developing the input required from applicants—the Lay Case for Support

Achieving a consistent quality for the non-technical lay case for support submitted with each application remains a challenge. Informed by USER’s experiences over several rounds of funding, the guidance issued to applicants for writing the lay case for support has evolved through several iterations.

What information do we ask applicants to provide in the lay case for support?

Early versions of the lay case were not heavily structured. Whilst some researchers were able to provide the relevant information in language acceptable to the USER panel, there was much inconsistency in the quality of the summaries submitted, and a more prescriptive structure that compels applicants to answer very specific questions became necessary.

The current guidance to applicants is shown in Appendix 2.

What issues need to be considered when asking applicants to provide a lay case?

A degree of superficiality in the information contained within the lay case for support is inevitable. Ensuring that the applicant does not ‘gloss over’ important detail or avoid answering the specific questions asked has perhaps been the greatest challenge. Applicants also have a tendency to provide unnecessary or obvious background information, particularly regarding the impact of a particular disease or the importance of developing new treatments or diagnostic tools.

The key information to be communicated by the lay case for support can be summarised as follows:

- What does the applicant want to find out?
- Why is this important?
- How will answering this question benefit people with musculoskeletal disease?

To guide the panel in assessing the importance of the research question, the applicant must explain the background evidence that has led to the question being asked. For example, it is useful to learn that the research approach has led to an advance in another disease area. The panel must also be advised on a realistic path to clinical translation; for basic laboratory research, this is often speculative, but we maintain that all applicants must be able to justify, however broadly, their requests for funding in these terms.

“I am sure that (the lay case for support) encourages researchers to think seriously of translational opportunities and stimulates more communication between clinicians and non clinical scientists.”

Project grant applicant

The language used in the lay case must be accessible to those without a scientific background, although the panel has developed knowledge and expertise with successive rounds, and is guided by a glossary of scientific terminology. Steering a path between the superficial or banal and a level of complexity that is beyond the panel is difficult. Achieving a middle ground between statements such as ‘this research aims to identify the proteins that do all the damage’ and ‘this research aims to identify the downstream signalling events following activation of molecule X’ is our aim.

The level of enthusiasm and skill showed by the majority of the applicants providing a lay case has been surprising and encouraging. Only around ten percent of lay cases submitted do not meet the required standard; the applicant is informed on receipt of the application and is provided with specific guidance to enable an acceptable re-write. If a lay case does not meet the approval of USER, even after this screening process, consideration of the proposal by both USER and the funding committee is deferred until an adequate lay case is provided.
On occasion USER has suspected a degree of subterfuge by the applicant. The patient benefits are sometimes felt to be ‘over egged’ in instances where the focus of the research is, not unreasonably, more basic in nature. In order to expose such discrepancies, the lay case is now appended with the scientific title and summary, extracted from the full application.

An exemplary lay case for support is shown in Appendix 3.

**How has the lay case evolved?**

The lay case for support has undergone several changes and will continue to evolve. The research community has accepted the new regime, and the quality of lay communication has improved greatly over the last two years. Striking a balance between over-simplification and too much detail is difficult, but as USER grows in confidence and experience, it has become more discerning about the depth of detail it requires in order to inform its judgements.

The decision was taken recently to include a brief synopsis of the research methodology within the lay case. A detailed description is not required – assessment of the feasibility or appropriateness of the methodology lies firmly within the remit of the external scientific reviewers and expert members of the funding committees. However, USER finds it helpful to know, for example, whether animal models will be used to mimic human disease, and where human subjects are to be used, USER is particularly well placed to comment on matters of recruitment, acceptability and compliance. Very basic information about the cost of the proposals is also provided to USER.

These additions were introduced after much consideration and on the understanding that they must be dealt with cautiously by USER. On a practical level, it is difficult for USER to make an informed judgement about the value for money that a particular proposal represents when science demands that some types of research are necessarily more expensive than others. Thinking more conceptually, it is important that USER’s remit remains quite distinct from that of the funding committee, for two reasons. Firstly, USER must feel that it is able to reach its conclusions on the relevance and importance of research unsullied by complicating factors such as feasibility of methodology or cost effectiveness. Secondly, overlap of remit risks loss of the goodwill, status and credibility with the funding committees that USER has worked so hard to build over the last two years.

"Over the two years, there has been a steady improvement in the quality of the lay summaries that are submitted. In the early days, some of the submissions were frankly dreadful, reminding me of the words that my A-level Chemistry teacher told me many years ago – there is no point in being a brilliant scientist if you cannot communicate effectively. There still is a noticeable range in quality, but we have all been impressed by how the scientific community has, in general, risen to the occasion."

**Clinician member**

“…..it was probably one of the more relaxed meetings that I have attended, efficient and friendly with a group of individuals who didn’t have any particularly agendas apart from making sure that what was being proposed was credible and would provide real benefits, either now or in the future for people affected by arthritis.”

**Lay member**
Defining the process and criteria by which USER assesses the lay case for support

A typical project grant round at Arthritis Research UK consists of 40 to 60 applications, all of which are reviewed by USER. The lay cases are pre-circulated to all members at least 8 weeks prior to the meeting. To bring the workload within a realistic level, each member is allocated a smaller number of lay cases for detailed scrutiny, although all members are encouraged to read as many lay cases as possible. The allocation to lay members is random, whilst allocations to the clinician members are made on the basis of expertise and experience. During the review period, members may request clarification on aspects of the research, sometimes requiring the Research Manager to refer to the full application, or they may ask questions of the applicant, again via the Research Manager. Members are asked to come to the meeting having read their allocated lay cases, armed with comments, questions and points for discussion.

A USER panel meeting seeks to reach consensus on the following:

- **Is the research within the scope of Arthritis Research UK's mission?**

  As the only true ‘voice’ of the charity in the funding decision-making process, USER is qualified to identify any proposals that they believe to be outside the charity’s funding remit. Typically, this arises when a particular disease area is not covered by the scope of the charity. For very rare disorders, or rare complications of more common disorders, USER must ‘weigh up’ the impact on the patient of the disease or complication against the likelihood that the research will lead to significant patient benefit.

- **How pressing is the clinical need for the research?**

  The importance of many of the proposals brought before USER is obvious – for example, the need to develop new drugs for rheumatoid arthritis is not controversial. USER’s clinician members, as service providers, are well placed to comment on need within their own area of clinical expertise and experience, and are comfortable in refuting suggestions of need if
they believe that current clinical practice does not suggest major gaps. The lay members approach the question from their own experiences of musculoskeletal disease, often within the context of their experiences as users of the UK's health services. For many applications, USER is the charity's most authoritative voice on matters of clinical importance.

• **Is this an important research question?**

USER must decide whether the proposal represents ‘knowledge for knowledge sake’ – for example, whether a basic science proposal would indeed lead to a clearer understanding of the biochemical characteristics of a disorder, but would not result in patient benefit of any real value, even in the long term. The onus is on the applicant to demonstrate that the question posed is a logical and promising step forward from research already completed, will lead to research that moves the field forward significantly towards patient benefit, or is a plausible extrapolation from another area of research – for example, cancer research. There are occasions where USER is unable, on the evidence provided by the lay case for support, to determine whether the research question posed in one basic science application is more important or promising in terms of patient benefit than another application in the same disease area. In these cases, USER defers to the scientific committee for its own assessment of relative importance.

• **Is the research feasible?**

Caution is exercised here – research feasibility is by and large the remit of the scientific committees, and applicants are not asked to provide detailed information on research methodology in the lay case for support. However, for proposals that involve human subjects, USER is competent to comment on issues of recruitment, compliance, acceptability and practicality.

• **Are there areas that require clarification by the funding committee?**

USER may pose questions to the funding committee, particularly in areas that they could not be expected to have adequate knowledge, even with guidance from the lay case. For example, the panel may query the novelty of the research, or the applicant’s proposed path to translation. The intention is to indicate to the funding committee that a favourable answer to these questions would increase USER’s support for the proposal (or vice versa).

**Scoring the Lay Case**

USER has experimented with several simple scoring systems. It became apparent early in the process that the funding committee had a tendency to deal, sometimes dismissively, with stakeholder input by focussing on the score given, rather than to the accompanying comment. Taking into consideration the very specific and quite disparate remit of USER, prescriptive scoring was eventually abandoned, and feedback to the funding committee focussed instead on providing thoughtful and comprehensive comment. USER input to the funding committee is provided in a formal written document. For each proposal, the document is headed with a single indicative comment, stating to what degree USER supports the research, and is followed by detailed comments and questions. The feedback sets out to:

• Indicate whether the proposal is highly supported, definitely not supported, or (as in most cases), supported in principal, dependent on the scientific critique.

• Explain the lay and clinical view of the importance of the disease or research focus.

• Voice concerns on any aspect of the proposal, on the evidence of the lay case.

“Although some applications may well be from top drawer research scientists and be scientifically robust according to the science committee, the clinicians working ‘on the coalface’ or the patients themselves may observe that even if the study succeeds, clinical practice or patient wellbeing will simply not change, for whatever reason. These grants should be a lower priority and this is where USER really earns its spurs.”

Lay member
• List the questions to the funding committee that would influence USER’s judgement.

Introducing the stakeholder assessment into the funding committee decision making process

Whilst the scientific experts on the funding committee debate the importance of an application within its own scientific field, it is the USER panel’s role to comment on the importance of the research within the context of the charity’s wider mission. Assimilating these two streams of opinion within the funding committee forum, and ensuring that the stakeholder viewpoint is not just heard, but exerts a degree of influence in the final funding decision, has been challenging.

All research funding applications submitted to Arthritis Research UK are subjected to external peer review, aiming for input from at least four experts in the field. The USER review is presented in a similar format to the external reviews. A typical example of a USER report is shown in Appendix 4. All reviews are circulated to the members of the scientific committee prior to their meeting. Scientific committee members are assigned to lead the discussion on applications within their specific area of expertise, and are expected to include consideration of both external expert and USER reviews in these discussions.

Consideration of the USER review during scientific committee meetings took some time to establish. To begin with, committee members often required prompting by the Research Manager or the committee chair to voice USER’s comments. This problem has now diminished. As the process has developed, stakeholder input has become less of an afterthought, with committee members actively incorporating USER’s contribution during discussion and using it to influence the decision making process.

To the surprise of many, particularly the research community itself, stakeholder assessment at Arthritis Research UK has proved as supportive of basic and underpinning research as it has of clinical research projects. In practice, a USER statement of support (or otherwise) that agrees with the scientific committee decision is viewed as a validation of the stakeholder contribution. Despite the fact that the USER review is based on a quite distinct set of criteria to that used by the funding committee, this is by far the most frequent outcome. Whilst reassuring for both parties, there is also a significant minority of proposals that fall outside of this neat resolution. Prior to the existence of USER, ‘excellence in science’ was generally a sufficient basis on which to award funding (or otherwise) to proposals; a strong directional steer from USER now complicates this process somewhat.

When entirely valid points about the clinical importance of the research, or its relevance to the charity, have been raised, USER sends a strong message to the scientific committee in one of two directions:

• The application is outside the remit of the charity and should not be funded, irrespective of the quality of the science. Typically, the disorder is not within the charity’s remit, the knowledge gain for a rare disorder is minor,

“It will be a brave scientist who underestimates the genuine depth of understanding this committee has and thinks that a few well chosen words will distract from the rigour needed to persuade the group to recommend an application.”

Lay member
or the relevance of the research to a specific disease is tenuous.

- The application poses questions of major importance to stakeholders. If the science does not merit funding, the applicant should be given appropriate feedback to enable the resubmission of an improved application. However, in practice, where the proposal carries serious methodological flaws, re-submission is not encouraged by the scientific committee. The revision required to enable this would be unfeasible for most applications, and the culture amongst most funding committees can be summarised by the statement: ‘it is not our job to write successful applications for applicants’. However, USER will push for ultimate support if appropriate modifications are achievable.

For the very small number of proposals where USER’s opinion is diametrically opposed to that of the funding committee, the proposal will be deferred for further consideration. This situation has not yet arisen, but it is envisaged that a small panel comprising representatives of both USER and the scientific committee will be convened to reconsider the proposal and reach a final consensus decision. Such strong disagreements are infrequent, in part reflecting the growing influence of USER. This is an evolving area, and remains under review.

**Enhanced stakeholder involvement in large awards (programme grants)**

Arthritis Research UK also supports large programmes of work, providing substantial support over a longer period to established groups of investigators. The application process has two stages:

- A brief letter of intent, used to shortlist those to be invited to submit a full application
- Full application by the shortlisted applicants, subjected to a full peer review process

Given the level of investment for the charity, the bar for funding these applications is very high. It is appropriate that consideration of the importance and relevance of the research is included in the assessment process for these grants, and in 2009, the decision was taken to involve USER in programme grant review.

All programme grant applicants at the first stage of the process were required to give a 10 minute presentation to USER, setting out the justification for their proposals in terms of the relevance and importance of the research to the charity’s stakeholders. Applicants then fielded questions from the USER panel. USER’s final assessments were submitted to the programme grant short-listing panel. USER’s views on the merits of each application were remarkably similar to those of the short-listing committee, with full agreement on which applications should be invited for full submission. The exercise was felt by both USER and the applicants to be very successful.

Minor changes are planned for 2010. There will be limited USER representation on the short-listing panel, whose brief will now be simplified to consider the suitability of the research for

“Presenting to the USER committee definitely made me think in a different way about our research and what makes it worthwhile. I did a trial run in front of two articulate and knowledgeable lay people and that was extremely helpful. In fact I changed the presentation dramatically after that trial run.”

**Programme grant applicant**
programme funding and whether its broad aims are convergent with the charity’s goals. Shortlisted applicants will then present their proposals to USER, whose reviews will inform the final awarding committee.

**The future of stakeholder assessment at Arthritis Research UK**

At present, USER’s involvement is restricted to review of project and programme grant applications. The committee has matured to the point where its contribution to the review process for Fellowship schemes is now under consideration, and is likely to be introduced in 2011. Recruitment to the panel is carried out on a regular basis, and membership has recently grown to nine lay members and six clinician members in anticipation of this increased activity.

“**So one year on, how has my USER committee experience been?** Well I’ve met some genuinely bright people, who care, want to make a difference and want Arthritis Research UK to use donor money correctly and wisely, so that it’s effective and beneficial to those most in need of support.”

Lay member

We aim to continue the steady improvement in the quality of the lay case for support, revising both its structure and the guidance we provide to applicants in order to ensure that it meets the needs of USER. Applicants who have particular difficulties with non-technical writing are offered tutorials to improve their skills.

**Conclusions**

There is no doubt that USER has succeeded in bringing the stakeholder voice right to the heart of the decision making processes at Arthritis Research UK. If establishing and maintaining stakeholder representation was an end in itself, the charity has achieved its goal. But the driving force behind the USER project was, and still is, a desire to influence funding practice, helping to steer the research agenda along a path set by both the charity’s goals and the aspirations and needs of the individuals who support the charity and hope to benefit from its research.

In these terms, how should the impact of USER be measured? A quantitative analysis is a challenge in a system where the stakeholder panel does not have either a vote or the power of veto, and we will continue to assess the panel’s influence by comparing USER assessment and scientific committee outcome on a round – by – round basis. Analysis of Arthritis Research UK’s funding profile – the distribution across all levels from underpinning research through to treatment development and health services research – before and after USER involvement, may be informative, although the charity will continue to be equally supportive of all levels of research activity.

It is reasonable to suggest that the requirement to justify the importance of their research in terms that were not required two years ago may influence researchers’ thinking and approach to writing their applications. We will continue to collect anecdotal evidence of any such culture change from researchers themselves, as well as listening to USER’s own perspectives on how the character and quality of applications may have changed to reflect the panel’s influence.

“**I find it a privilege to be involved in making sure that the voices of practitioners, patients and particularly donors are heard. USER will grow in importance as its role develops further and I look forward to being a part of it.”**

Lay member
Appendix 1: USER membership

Lay members

Alison Allam
Post-graduate student in Social Policy.
Joined March 2010

David Chandler
Chief Executive, Psoriasis and Psoriatic Arthritis Alliance.
Joined March 2009

Martin Eve
Post-graduate student of English literature and a technical director of the Professional Association of Clinical Coders
Joined March 2010

Michael Green
Chief Executive of a healthcare company
Joined March 2009

Maureen Grossman
Retired deputy head-teacher and science teacher with a research background
Joined March 2009

Matt Homfray
Veterinary surgeon and associate of a consultancy to the pharmaceutical industry
Joined March 2009

Philip Knowles
Business consultant and academic
Joined March 2010

Mark Ranson
Safety Manager for a harbour towage operator
Joined March 2008

Jane Taylor
Retired University lecturer and tutor
Joined March 2010

Clinician members

Steven Cannon
Consultant Orthopaedic Surgeon
Joined March 2009

Patricia Cornell
Senior Rheumatology Practitioner
Joined March 2008

Nicola Goodson
Senior Clinical Lecturer and Consultant Rheumatologist
Joined March 2009

John Halsey
Consultant Rheumatologist
Joined March 2008

Robert Marshall
Consultant Rheumatologist
Joined March 2008

Janet Suckley
Consultant Physiotherapist and Registered Osteopath, registered for a Professional Doctorate in Health and Social Care
Joined March 2010
Appendix 2: The lay case for support – guidance to applicants

Arthritis Research UK now requires all applicants to its response mode grant schemes to provide a lay case for support with their application. For some schemes, the purpose of the lay case is to allow assessment of the application by representatives of Arthritis Research UK’s stakeholders; people with musculoskeletal diseases and healthcare providers. Lay cases for all funded studies will be posted on Arthritis Research UK’s website, and may form the basis of a press release or be used for fundraising and marketing activities.

The lay case will be reviewed by the USER panel, comprising front-line healthcare professionals and informed lay members.

USER’s remit is to consider the potential clinical benefit of all applications within a particular scheme; those of a more basic nature but which may offer important future benefit for patients will be assessed using the same criteria as those that promise direct or immediate clinical benefits. USER’s assessment is considered formally by the funding committees, and forms an important part of the decision-making process.

The lay case should be written at the level of a science feature in a broadsheet newspaper. It must specifically answer the questions set out below, structured within each sub-heading. Minimal use of jargon or acronyms is important; where this is unavoidable, please provide explanations. Terms such as ‘pathway’, ‘expression’, and ‘signalling’ should be avoided or fully explained. There is no need to explain at length the generic importance or impact of the disease area you plan to investigate. The use of non-scientific analogies to explain complex ideas is encouraged. Images and diagrams are also acceptable as an aid, not an alternative, to narrative explanation.

Please follow the link to view an example of a well-written Lay case for Support.

It is crucial that your lay case conveys relevant information in a form comprehensible to a lay readership. Arthritis Research UK will request re-submission of lay cases that fall short of this standard, and your application may be deferred to subsequent funding rounds if an adequate lay case is not submitted.

We strongly advise that you “test” your lay case with an informed lay reader before submission.

Your lay case must be structured as follows:

1. Objectives (50 – 80 words)
Briefly state the objective(s) of your project.

2. Clinical benefits (150 – 200 words)
Provide a full explanation of how achieving your research objectives will benefit patients, either as a direct result of your findings, or to inform future research that may result in clinical benefit. If your research fits into the latter category, please suggest a research pathway towards direct patient benefit.

3. Background
   a. Context (100 – 150 words)
Briefly and clearly explain the context of your research: the disease and its clinical impact, the particular area(s) that your project seeks to address, and the need for further understanding or treatment options.
   
   b. Questions (150 – 200 words)
What questions do you want to answer? Summarise the evidence that led you to formulate your questions and objectives.
   
   c. Experimental plan (100 – 150 words)
USER’s remit is not to consider the scientific strengths or feasibility of research proposals, but a general understanding of the researcher’s experimental plan is helpful. Please give a brief overview, using minimal scientific jargon, of what you plan to do. If applicable, this should include information about the experimental approaches to be employed, the types of samples to be analysed and how they will be sourced, rationale for the use of animal models, and how human subjects will be used.
   
   d. Novelty (100 – 150 words)
Explain why your research is novel.
Appendix 3: Exemplary lay case for support

Project Title: Does Wnt16 support the regeneration of cartilage?

Objectives: We have recently discovered that the molecule Wnt16 is produced by cartilage soon after injury and in the early phase of cartilage healing, and that this molecule protects cartilage from injury. In this study, we wish to test whether the production of Wnt16 may also be important for cartilage healing, with the longer term goal of using Wnt16 to induce cartilage regeneration and prevent the development of osteoarthritis (OA).

Clinical Benefits: With this research, we aim to lay the initial experimental groundwork for the future development of a Wnt16 preparation that can be delivered directly into the affected joint through a small fibre optic cable, either as a solution or within an injectable carrier that delivers the drug slowly. This would be a major advantage over current therapies, which require invasive and sometimes multiple interventions.

The development of such strategies will prevent severe and permanent disability in patients suffering from cartilage loss, and reduce the high costs associated with such conditions. Such costs are not limited to the treatment of the condition itself, but also to its associated disabilities and the side-effects of the current treatments.

As with all developmental work of this nature, we expect patient benefit from this research to be some years away.

Background

Context: Cartilage damaged through trauma has a limited repair capacity, particularly in older people, and small lesions can become larger, resulting in OA. Strategies to heal cartilage lesions are therefore important in order to relieve symptoms and prevent the need for joint replacement. The two options currently available for the treatment of isolated cartilage defects, micro-fracture and autologous chondrocyte implantation (ACI), both require surgical intervention and, particularly in the case of ACI, are invasive and costly, and results are inconsistent.

In younger patients, the cartilage can heal spontaneously, suggesting the existence of molecular mechanisms that activate and support cartilage healing. This project stems from a study supported by Arthritis Research UK and published in 2008, revealing that injured cartilage activates many repair genes, including Wnt16. Wnt molecules are known to induce regeneration and wound healing in other tissues, so it is likely that Wnt16 supports cartilage repair. Testing this hypothesis is the scope of this application.

Questions: Is the production of Wnt16 in the joint necessary for healing of cartilage defects?

Experimental plan: We have obtained a new mouse mutant lacking the Wnt16 gene, and have recently generated a model system to study cartilage regeneration in adult mice. These models will allow us to understand in more detail the importance of Wnt16 in cartilage repair.

Novelty: Most studies on cartilage have focussed on limiting cartilage destruction, not on inducing repair. This has been partly due to a lack of information regarding the molecules that play a role in regeneration, and partly because we were missing models that were suitable to investigate regeneration in adult mammals. Through our own research to identify the potential role of Wnt16, and the development of new mouse models in collaboration with colleagues at Harvard University, we now have a unique opportunity to pursue this exciting area of research.
Appendix 4: Example USER report to funding committee

Project title: Does Wnt16 support the regeneration of cartilage?

USER Grade: Broadly supportive

Patient and clinician members of USER made the following comments on the importance of this project from a stakeholder viewpoint:

Current treatment options for osteoarthritis are unsatisfactory, and drugs to slow degeneration of cartilage have had little impact. Research offering a realistic prospect of regenerative therapy is welcome.

USER was persuaded by the lay case that, compared to existing technologies, this early research offers a novel approach that would be acceptable and practical, but accepts there is no guarantee of success.

USER raised the following questions to be addressed by RSC:

1. The applicant emphasised that the main application of this research is to prevent progression of early cartilage lesions – is it known how likely these lesions are to progress to osteoarthritis?
   Is there a possibility of unnecessary (and counter-productive) intervention in some patients?

2. USER had concerns about the applicability of this research. As many patients with osteoarthritis only become symptomatic when joint damage is already well-established, how would eligible patients with early osteoarthritis be identified?