



Patient and public involvement:

**Guidance for
researchers
supported
by the BPSU**

February 2013

Foreword

Public and patient involvement (PPI) in research is recognised to improve the design, conduct and dissemination of research studies. The British Paediatric Surveillance Unit (BPSU) runs large scale surveys of paediatric conditions presenting to specialists. Questionnaires are sent only to clinicians, and no one is asked to give consent for the use of the information in their medical records. PPI is especially important in research which does not involve individual consent to ensure openness, transparency and accountability to the public.

In 2010, the BPSU commissioned an evaluation of the impact of PPI on its research activity, and one of the recommendations of the evaluation report was to produce a guide for researchers on how to involve patients and the public in their research. This guidance document is the result of a considerable amount of work by our working party chaired by Ann Seymour and TwoCan Associates, who between them have produced an accessible and practical guide which I hope you will find useful and encouraging.

Professor Alan Emond
Chair, BPSU Scientific Committee

Acknowledgements

The BPSU acknowledges the support of the Department of Health and the reporting clinician, particularly those who contributed to this guidance. Any views expressed in this publication are not necessarily those of the DH.

The BPSU would like to thank the following people for their contributions to this guidance:

- TwoCan Associates
- Ann Seymour, Lay representative, BPSU Scientific Committee
- Sue Banton, Lay representative, BPSU Scientific Committee
- Katy Sinka, Health Protection Agency
- Juliet Oerton, Lead researcher, MCADD study
- Steve Hannigan, Chief Executive, CLIMB
- Michael Absoud, Lead researcher, CNS Inflammatory Demyelination Disease Study
- Sarv Kaur, Public Involvement Officer, MS Society
- Anna Jones, Surveillance of lead in children study
- Iain Mallett, Health Protection Agency

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Introduction

About this guidance

This guidance aims to motivate and encourage researchers supported by the BPSU to involve patients and the public in their research. It offers practical advice on how to involve people, and provides examples of where PPI has been effective in BPSU studies.

Definitions

We use the term '**patient and public involvement**', (PPI) to describe the active involvement of patients and/ or members of the public as collaborators in research.

We use the term '**patients**' to describe children and their families/carers who are living with a health condition. We use the term '**patient representative**' to refer to the people working in organisations that seek to represent patient/carer interests.

The term '**public**' covers all members of the public who may have an interest in a BPSU study, but who do not have direct experience of a condition or intervention being studied. This includes children who might be screened for a condition and their parents/carers, as well as people who are the targets of health promotion research.

How this guidance was developed

This guidance was developed by TwoCan Associates (www.twocanassociates.co.uk) on behalf of the BPSU. It was informed by an evaluation of PPI at the BPSU¹ in 2011. The case studies (Section 6) were developed through interviews with the various stakeholders involved in three BPSU studies. A reference group of BPSU supported researchers helped develop the content and commented on early drafts. A BPSU working group, including staff and Scientific Committee members provided advice throughout the project.

¹ TwoCan Associates (2011) A review of patient and public involvement at the British Paediatric Surveillance Unit. Available at: <http://www.rcpch.ac.uk/bpsu/ppi>

How this guidance is structured

There are six sections to this guidance:

1. Why consider PPI
2. Who to involve and how to find them
3. When to involve patients and the public in a BPSU study
4. How to involve patients and the public
5. Resources for investigators, including;
 - completing the section about PPI in the BPSU application forms
 - how to write a lay summary
 - developing a public information leaflet
 - organisations to contact for further advice about PPI in research
6. Researchers' experiences – illustrating good practice and the benefits of PPI in BPSU studies.

Section 1: Why involve patients and the public in BPSU studies?

There is a growing body of evidence that suggests that PPI can improve the quality and relevance of health research¹. Within the context of BPSU studies, the reasons for considering involving patients and/ or the public include:

- The moral/ethical imperative
- The benefits for your research
- The requirements of funders and other research bodies
- The benefits for patients, members of the public and patient organisations

These are discussed below.

The moral/ethical imperative

BPSU studies use patient data but do not have any patient participants. Questionnaires are sent only to clinicians. Therefore no one is asked to give consent for the use of the information in their medical records. The data are anonymised and may be used without the patients' knowledge. This makes it all the more important to ensure openness, transparency and accountability to the public.

The fact that BPSU studies involve children with rare conditions also raises ethical concerns that individuals may be identified even when the data have been anonymised. PPI enables researchers to check out the acceptability of their approach with patients and the public.

Patients and members of the public can also help identify studies that are controversial or of a sensitive nature that will need to be communicated carefully, particularly if they are likely to be picked up by the media.

“ *It's a serious thing to do research without a patient's consent – so there has to be a good reason to do it. Asking patients whether they think that's acceptable – that's really important...* ”

– Researcher

¹ See for example Staley K (2009) Exploring Impact: Public involvement in NHS, public health and social care research, INVOLVE, Eastleigh. Available at: http://www.invo.org.uk/wp-content/uploads/2011/11/Involve_Exploring_Impactfinal28.10.09.pdf

The benefits for your research

Researchers undertaking BPSU studies have found that PPI has benefited their research – particularly in helping to obtain ethical approval, producing lay summaries, disseminating the results to a wider audience, obtaining media coverage and influencing policymakers to take action (Section 6 – Researchers’ experiences).

The requirements of funders and other research bodies

Public funders of research and many of the health charities now require evidence of PPI as part of their funding application process. Other research organisations, in common with the BPSU, also ask about plans for involvement e.g. research ethics committees ask about PPI in the IRAS form. Including good quality plans for involvement will make it more likely that your project will be funded and approved.

Requirements of the BPSU

As a minimum, the BPSU expects to see the following PPI in BPSU-supported studies:

- Early contact with patients/patient representative/members of the public
- Involvement in producing the lay summary for the BPSU application forms
- Involvement in producing the Public information leaflet (PIL)
- Commitment to keeping those involved informed as the study progresses
- Involvement in producing a lay summary of the findings for dissemination

This is discussed in more detail in Section 3.

The benefits for patients, members of the public and patient organisations

Involvement in a BPSU study can help individuals to acquire new skills and knowledge. It can also help patient organisations to:

- gain access to people who can help them with their work
- acquire information that will be of value to patients and their families
- gather evidence they can use to campaign to change policy or services
- establish or strengthen links that might support future collaborations.

Section 2: Who to involve and how to find them

Patient involvement or public involvement?

It's important to be clear whether it is **patients** or **members of the public** you want to involve in your study. The involvement of patients is important when direct experience or knowledge of a condition is required for the task. For example, only families affected by a health condition will know whether a particular research question is important for others like them. They can help with writing summaries of research that will be directly relevant to their peers. They might also be able to challenge assumptions made by researchers in the design of a study or in the analysis of data, based on their lived experience of the condition. Direct patient (or patient representative) involvement is therefore essential to studies of specific conditions.

The question of whether to involve a **patient** or a **patient representative** depends on the skills and experience required for the task. For example, it may be more appropriate to involve a patient representative in dissemination as they can draw on their media experience and existing communication channels to help get your message across to other audiences. However, it may be more helpful to involve patients when a lay perspective is required, for example, when producing a public information leaflet (Section 6 – Researchers' experiences).

In other studies that have wider public health implications, e.g. assessing the impact of diet on health, or with implications for national screening programmes, it will be important for the public perspective to be included. Members of the public can help with producing lay friendly summaries of your research, and importantly can comment on the public acceptability of a study. They can also help consider how best to report your findings in the media, ensuring the right messages reach the general public.

Finding patients and patient representatives

If you are studying a particular condition you will be able to find a relevant patient group (if there is one) through an internet search. Other sources of help in finding patient organisations or groups include:

- the BPSU Scientific Committee – the lay members know of a range of organisations and may well be able to signpost you to one which is relevant.
- local research design services (RDS). Each RDS has a PPI lead who will know of local patient organisations.

If you are studying a very rare condition you might need to search for a more generic patient group. For example, CLIMB (www.climb.org.uk) is an organisation which supports families of children with a range of metabolic diseases, Rare Disease UK (www.raredisease.org.uk) supports families with rare genetic conditions and Contact-a-Family (www.cafamily.org.uk) supports families with disabled children.

If you cannot locate an appropriate patient organisation, you may need to find individual patients or families. Possible sources of help include:

- clinicians working in your field
- social media sites – some parents of children with specific conditions have Facebook pages to enable them to exchange information and offer support
- the People in Research website (www.peopleinresearch.org), where you can post an advert to find people to get involved in your study.

Finding members of the public

If you are undertaking a study that has wider public health implications there may not be an appropriate organisation to approach. In this case you could consider the following:

- Approaching a more generic organisation where you can find parents of young children to involve e.g. the National Childbirth Trust (www.nct.org.uk), NHS antenatal classes and local primary schools.
- Using a market research organisation that has a database of potential participants. This would also enable you to involve a more diverse group of people with desired characteristics e.g. families from different ethnic groups or social classes.
- Using social media sites. There are some sites that are specifically aimed at parents where you can ask for comments and feedback. For example Mumsnet will post requests for information and help from Mumsnet members. There is a charge for this (in August 2012 this was £30). See www.mumsnet.com/Talk/media_nonmember_requests
- The local research design service (RDS). Some RDS's support groups of patients and members of the public who may be able to offer comments on a study. Some RDS's may be able to help fund early involvement prior to the study being funded (for example they may fund the costs of running a focus group).
- The People in Research website (www.peopleinresearch.org), where you can post an advert to find people to get involved in your study.

What to say...

Before you approach anyone, it's helpful to prepare a clear description of:

- your research – a few sentences in plain English (see page 28) to describe the aims and methods
- your aims and expectations of the involvement – how you wish to involve people, why you want to involve them and how much time this will take
- your involvement policies – including how you will support people, for example paying for their expenses and discussing whether you will also pay for their time (see page 22).

Section 3: When to involve patients and the public in BPSU studies

All BPSU studies follow a similar format:

1. Researchers develop an idea for a study.
2. They develop their proposal and apply to the BPSU for approval. The application is a two phase process which includes preparing a lay summary and 'public information leaflet'.
3. If their study is approved by the BPSU, they then seek approval from the Ethics and Confidentiality Committee of the National Information Governance Board and from a multi-centre research ethics committee, and complete the Information Governance Toolkit. They may also need to apply for funding. Once all the approvals are in place, the study can begin.
4. The study is carried out using the BPSU 'Orange Card' system to identify cases. This card contains a list of conditions or disorders and is sent monthly by email or post to more than 3,200 consultant paediatricians and other specialists. Clinicians return the card to the BPSU notifying any cases or 'nothing to report'. Researchers contact clinicians who have reported cases and ask them to complete a short questionnaire to capture more specific information. The responses are analysed.
5. The findings are then disseminated and researchers may also seek to influence policy makers and/or service providers to ensure that action is taken in response.



British Paediatric Surveillance Unit Report Card

NOTHING TO REPORT 2012

Specify in the box number of cases seen CODE No []

- AIDS/HIV
- Congenital rubella
- Progressive Intellectual & Neurological Deterioration
- Congenital Syphilis
- Raised Blood Lead Levels
- Glutaric Aciduria 1
- End Stage Renal Disease
- Primary Congenital Hypothyroidism (UK Only)
- Autoimmune Addison's Disease
- Hypocalcaemic seizures secondary to vitamin d deficiency
- Haemolytic uraemic syndrome (excl Scotland)

PPI can be helpful at many stages, and in the remainder of this section we describe how it can be of benefit. We also highlight what the BPSU requires of researchers in terms of PPI at the different stages.

1. Developing the idea for a study

Some researchers working on BPSU studies have found that involving patients and patient groups at this early stage:

- gives them confidence that the study is important and valued by patients/the public
- confirms that patients/the public believe the research to be ethically acceptable, and helps with applications to research ethics committees
- helps to identify any topics that may be particularly sensitive and/or controversial.

“ *There is very little point in doing research unless you’re going to help the actual users. We might think we have good ideas, but it’s important to ask children and families whether they think the research is important or will make a difference in their lives or potentially could help other people if not themselves directly – because they are in the position to tell us about these things.* ”

– Researcher

“ *It can help investigators realise that they’re onto a loser or a winner – with some applications you can see that if they had actually genuinely engaged with the public and thought carefully about it, they’d have realised there’s not a lot of public interest in it.* ”

– Scientific Committee member

Requirements of the BPSU

The BPSU expects researchers to have made early contact with patients, patient representatives or members of the public (i.e. before submitting an application) in order to:

- start building the relationships necessary to support a study
- obtain feedback about the relevance of the research to children and their families and/or to gauge the level of public interest.

Example of good practice

One researcher worked with a national patient organisation, The MS Society, to run a study day for a wide range of stakeholders to help define the research question and identify the best approach:

“*The main point from the parents was that there’s a severe lack of awareness of this condition amongst clinicians. We discussed the BPSU approach and thought this would be a very good way of raising awareness because we would ask all paediatricians if they’ve seen a case and send information leaflets... We need everyone to know about this – rather than to just do a study in the few specialist centres where these patients are being treated.*”

– Researcher

This early involvement therefore helped to identify the BPSU approach as the most appropriate method from the parents’ perspective. As a consequence, the patient organisation also identified the topic as a priority within their research strategy, which eventually led to them funding this work. (See Case Studies – Section 6).

Michael Absoud, Researcher, Institute of Child Health, Birmingham Children’s Hospital, CNS Inflammatory Demyelination Disease Study.

2. Applying for funding, BPSU support and ethics approval

Some BPSU researchers have found that PPI has helped to secure funding and support from other research organisations. Early involvement in developing a research proposal can:

- reassure ethics committees that patients/the public are supportive of your research, which will allay any concerns they may have about using patient data without consent
- demonstrate to funders (and the BPSU) that your study is well thought through – it shows you have consulted all the various stakeholders about the aims and implications of your work
- help with producing a lay summary of your research for the various application forms.

Requirements of the BPSU

The BPSU expects researchers to involve patients/patient representatives/members of the public in developing the lay summary for the BPSU application form. Useful examples of lay summaries, advice on writing in plain English and guidance on completing the PPI section of the BPSU application form can be found in Section 5.

3. Developing the research materials

The BPSU asks researchers to prepare a public information leaflet about their study (see Section 5 for template and examples). The public information leaflet is not only for patients with the condition, but for the general public, and provides a brief overview of the study's aims, objectives and methodology and summarises the importance of the research. Since BPSU studies do not involve direct contact with patients, the main aim is to provide general information about the study to the public and patient groups who may be interested in the research. There will be a link to the leaflet from the BPSU website.

PPI can help with developing these leaflets by:

- making the information more relevant to people affected by a condition/issue – and ensuring it contains all the information that patients/the public want to know about
- making the information more accessible – patients/patient representatives can help with eliminating jargon. Also many patient organisations will have a lot of experience in writing for their community and may have tried and tested words or phrases that they use to explain the medical aspects of their condition
- contributing additional content – patient representatives may be able to provide statistics and/or case studies that their organisation has gathered from its members.

Patient organisations can also help with disseminating the public information leaflet via their newsletters and websites, thus ensuring a wide circulation.

“ *The first leaflet I received had lots of jargon – it's easy to forget as a researcher that lots of people don't have a scientific background, so don't understand the words you're using. Even the diagrams were very technical and scientific, so I tried to make them easier to understand and follow.* ”

– Patient representative

“ *[The patient representative] helped us to think about what should or shouldn't be in the public information leaflet. It was important to think about how much information to include about the condition (MS), because not all children with a demyelinating episode go on to develop MS. She also helped us to think about what language to use, what pictures to put in and so on.* ”

– Researcher

Requirements of the BPSU

The BPSU expects researchers to involve patients/patient representatives/members of the public in developing the public information leaflet. This is considered by the Scientific Committee when reviewing the study application.

4. Carrying out the study

In other settings, there is evidence that PPI can contribute to the conduct of some kinds of research¹. However, given the constraints of the BPSU methodology, there is less room for patients/members of the public to influence this stage. You could still show people the questionnaires you plan to use, even if they are unlikely to have any comments, as then they will understand what you are asking clinicians and what the results are likely to look like.

PPI could also be useful in the interpretation of the findings from BPSU studies, as patients may have a different interpretation of the results or be able to contribute a different explanation to clinicians as to why certain findings have been observed. However there is no evidence of this impact to date. If you involve patients/the public at this stage of your work and find it to be of benefit, it would be very helpful if you could share your experience with the BPSU.

“ *When the results are in, then they ought to go back to their PPI contacts and share the results with them and get them to help interpret the results – as there may well be issues for example around delay in presentations – which a parent perspective of why that might be happening would be useful – because the doctor may have a particular view and the parent a different view.* ”

– **Executive Committee member**

Even if patients, representatives or members of the public are not involved in the conduct of the study, it is essential to keep them informed of progress and maintain contact throughout this stage. This will help them to better understand the results and be ready and willing to help with the dissemination of the findings (see page 19).

“ *Certain things might have been discussed with the paediatrician, but the parents might have relevant information or input that might be important and might completely change the look of the results – so there might be another angle on that...It could just be a minor thing that hasn't been mentioned to the paediatrician – but it's something that could be really important.* ”

– **Patient representative**

¹ See for example Staley K (2009) Exploring Impact: Public involvement in NHS, public health and social care research, INVOLVE, Eastleigh.

Requirements of the BPSU

The BPSU expects researchers to commit to keeping in contact with the people they involve throughout the lifetime of the project.

5. Disseminating and implementing results

At this stage PPI can help by:

- making reports more accessible
- making messages more powerful
- contributing patient stories/experiences that can bring the results to life – and make them more relevant to a wide range of audiences
- ensuring reports are read by policymakers
- ensuring results are made available to patients
- ensuring research findings are acted upon, where appropriate.

In particular, working with individual patients/patient representatives/members of the public can help with producing lay-friendly summaries of your results. They can also help identify which of your findings will be most relevant and important for their peers to hear about. They can help you interpret what the implications are for patients and the public and how best to communicate the findings.

Working with patient organisations may enable you to access relevant expertise and support for dissemination. They may be able to disseminate the results of your research through their website, newsletters, and at conferences. Larger patient organisations will have press teams who can help write press releases and campaign teams who can help with lobbying to ensure that results are used to influence policy or practice.

Example of good practice

One research team developed a case study of one of the children who had been included in the research. The patient was very enthusiastic about this and spoke at a dissemination event.

“ *[The patient’s] story made [the condition] real to people. You don’t understand the consequences unless you hear from someone who’s been affected by it.* ”

– Researcher

The researchers also worked with two patient organisations, who lobbied MPs and others to bring about changes in policy:

“ *It was crucially important we had the support from the directors of two patient organisations... They helped to get our research on to the right people’s desks. They knew who needed to know about the research and how to help fast track decisions. We as researchers often don’t know these things and it would have been much harder without their input.* ”

– Researcher

Juliet Oerton, Researcher, UCL Institute of Child Health, the MCADD study.

Requirements of the BPSU

As a minimum, the BPSU expects researchers to involve patients/representatives/ members of the public in producing a lay summary of the findings for wider dissemination.

Section 4: How to do it

There are different ways to involve patients and the public and the most appropriate method will depend on your particular situation – including what the task is, who you're involving, and the skills and experience of the people involved.

Within the context of BPSU studies the methods that are likely to be most useful include:

- inviting a patient, member of the public or patient representative to be on your project steering group or advisory group if you have one
- meeting informally with patients, members of the public and patient representatives
- consulting people more formally through focus groups or discussion groups
- holding workshops for larger groups of people – possibly also involving other stakeholders
- consulting individuals via email or on the phone.

There is no single right way to involve people. You're also likely to want to use different methods at different stages. For example, meeting people face-to-face is valuable when you want to have an in-depth discussion and need to be able to ask questions of each other – so this may be most useful at the beginning when discussing ideas for your research and at the end when you want to discuss the implications of your findings. You can use a simpler method (e.g. email or telephone contact) if for example you are only wanting people to comment on a draft lay summary. Other factors will influence your choice of method including:

- the preferences of the people you want to involve and whether for example they are able to travel to a meeting
- resources available – time and budget
- how much involvement you want – if you only want to get comments on a draft public information leaflet you will want to choose a different method to when you want to develop an on-going partnership with a patient organisation.

We cannot be prescriptive about which PPI method you should use for your study. However we can give you some general guidance about how to make these different methods work well and how to ensure good quality involvement.

1. Methods for involving patients/the public

PPI on a project steering group or advisory group

If you plan to involve people in a steering group you should consider:

- including the purpose of any PPI in the terms of reference for the group
- putting together a role description and person specification to help you find the right person (or people)
- recruiting two people rather than one, so that they can provide peer support
- providing guidance to the chair of the steering group on chairing meetings with PPI.

Meeting with patients/members of the public/patient representatives informally

If you plan to meet people on a more informal basis, consider:

- offering to meet people in their own environment or in a neutral environment if they prefer
- choosing a venue that will meet their access needs
- attending a regular meeting of an organisation or group
- being flexible about timings. Those who are working, have young children or who are carers might need to meet outside office hours.

Involve has produced guidance on organising meetings and recruiting lay members, which is available at www.invo.org.uk

Consulting patients/members of the public using focus groups or discussion groups

If you have never facilitated a focus group or discussion group which involves patients and/or members of the public before, consider working with a more experienced facilitator or seeking training in facilitation. There is also guidance available on running a focus group for consultation purposes available at: www.westberks.gov.uk/media/pdf/2/h/How_to_Run_a_Focus_Group.pdf.

In addition to budgeting for participants' time and related expenses (see 'How to make involvement work well' below), you'll need to budget for recording and transcribing the discussion.

Holding workshops for larger groups of people – possibly involving other stakeholders

Be aware that this may be the most expensive option for involvement and take the most time. It's almost impossible for one person to organise, facilitate and present at a meeting for a larger group, so consider working in partnership with a patient organisation or experienced facilitator. They will be able to offer advice on who to invite, timings and location and help you develop a suitable programme (see Section 6).

Consulting individuals via email or on the phone

If you are planning to consult people by phone, be prepared to contact them outside office hours. Whenever you consult people, give them plenty of time (at least two weeks) to respond. If consulting people by email, check whether they are able to receive large attachments. If you need to send out long documents, offer to print these out and send them by post. Try to minimise the costs for the people you involve (e.g. by calling people rather than expecting them to call you) and/ or reimburse them for their expenses.

2. Ensuring good quality involvement

Whichever method (or methods) you use, it's important to:

Establish a good working relationship

It can be very important to meet face-to-face when you first start working with people so as to enable everyone to build trust and confidence in working together. It will enable the patient/patient representatives/members of the public to feel more engaged and to develop a sense of co-ownership of the work. This is important to keep people motivated throughout the duration of the project.

Researchers supported by the BPSU have described how valuable their working relationships with patients have been. It has inspired and motivated them, and given them added impetus to carry out the research.

“ *We were very influenced by the families and buoyed up by the fact that they were so supportive of what we were planning to do.* ”
– Researcher

Ensure good communication

This helps to keep people interested and motivated for continued involvement throughout your project, which could take years. You can't expect an individual/organisation to help you with disseminating the results of your research if you haven't been in touch with them since the time you asked them to comment on a public information leaflet years earlier. So you will need to keep people informed of the progress of the study every few months (or as often as you have agreed to do so). Ways to do this include:

- sending regular email updates to the people who have been involved
- using Twitter, Facebook or other social media. Many patient organisations have at least one Twitter account which they could use to alert people to news and updates about your research. Parents of children with rare conditions often use Facebook to communicate and may allow you to use their Facebook page to give updates
- offering to attend meetings or other events organised by patient groups to talk about the research
- ensuring you send patients and members of the public who have been involved at any stage a lay summary of the results of the study.

Example of good practice

Our experience of PPI was with a specific patient/parent group, the Histiocytosis Research Trust (HRT), a charity which has strong links with research. The Trust Secretary was kept fully informed of the study while it was running and results were presented informally to parents at a conference, and on the HRT website. Some clinical members of the study team are Trustees and several are involved in patient 'road shows'. At these evening events, sponsored by the HRT, a series of short talks is given by doctors, patients and parents and participants are then able to quiz the individual doctors about their condition or ongoing research.

Jane Salotti, Researcher, Newcastle University, Langerhans Cell Histiocytosis study

Be open and accessible

This is important to ensure that people feel they can contact you and ask questions. Keeping an open dialogue may also benefit your research, in opening up new opportunities for involvement and expanding the ways you work with individuals/organisations (see Section 6).

“ *The key thing was communication. [The patient representative] felt he could ring up and ask how it was going at any time and we felt we could call him and ask for his views.* ”

– Researcher

Give feedback to the people you involve

It's essential to tell people how their involvement has made a difference to your study.

“ *You have to keep in touch, and you have to be prepared to feedback and give back. That's extra work – but that's what we're here for. I'm not being negative about it. It's actually the more rewarding part of what we do as researchers – to see the effect on real people. But it's an extra thing to do that you have to factor in, in terms of the work to do on a study. It's vital – I don't think we should be doing the research unless we're prepared to engage with those people.* ”

– Researcher

Follow good practice guidance when planning meetings or events

INVOLVE has produced guidance on how to plan meetings and events, available at: www.invo.org.uk/getting-started

Pay people for their time and cover any out-of-pocket expenses

INVOLVE has produced guidance on paying people and how much to pay them, which is available at: www.invo.org.uk/posttypepublication/payment-for-involvement.

Section 5: Resources for researchers

1. Completing the section about PPI in the BPSU application forms

The BPSU application forms ask you to describe PPI in the proposed study, as well as what PPI has taken place to date. You should ensure you describe:

- who you have involved to date and how. For example, if you met with patient representatives to discuss your plans, say who you met with and what they said.
- how PPI has influenced you so far – has anything in your plans changed as a result of PPI? If so, say what these changes are.
- who you will involve if the project is supported, and how you will involve them. For example, will a patient representative sit on a steering committee for the project? Will patients/ members of the public be invited to help write the public information leaflet?
- how you have budgeted for PPI. This might include travel and child care costs to enable people to attend a meeting or event to discuss the project, and a fee for people's time if you are asking them to attend a meeting or event. You can find more information about payment on the INVOLVE website – see page 26.

2. Writing a lay summary

During the course of developing and carrying out a BPSU study, it's likely that you will need to produce a number of lay summaries. These will include:

- a few sentences that describe your plans, to use when you initially approach patients or members of the public
- a lay summary of your proposed study, for the BPSU application form
- a public information leaflet, to ensure patients and the wider public can easily find out about the study
- a summary of the results.

There are two essential features of a 'good' lay summary:

1. It contains the information that patients/the public want to hear about – i.e. it is relevant and useful to them.
2. It is written in plain English and is easy to read.

The best way to achieve this is to work with patients/members of the public to produce your lay summaries.

In terms of making your summary easy to read, you might also find it helpful to think about¹:

- your writing style
- the layout and presentation

These are discussed below.

¹ Mellor E, Raynor D and Silcock J. (2003) Writing information for potential research participants. In: Manual for Research Ethics Committees 6th Edition. Cambridge University Press, Cambridge.

Your writing style

● Think about your audience

Write as if you are explaining your work to a friend or family member who has no scientific background. This will help you keep it simple. You will be writing for a mixed audience with a range of reading ages and levels of education. Some may have little medical or scientific knowledge. Those with a better understanding will not be offended by simple, direct language.

● Talk directly to your reader

As you are writing, imagine you are talking to your reader and write the way you would speak to them. Refer to the researchers as 'we'. For example, 'we will look for...'

● Use simple words and avoid scientific jargon and acronyms

Your vocabulary should be as simple as possible. Try to use everyday alternatives to jargon. For example, use 'give' instead of 'administer'. If technical terms must be used, then provide a simple definition. Avoid acronyms unless you are sure that they are very widely known (e.g. it's fine to use 'NHS' but not 'BPSU'). Consider using pictures or diagrams if these can help to explain complex issues.

● Be positive and direct

Try to write in a positive and direct style. Make sentences short and without too much punctuation. If more than one comma or connecting word seems necessary, then consider using more than one sentence or a bulleted list. Make sure your main point is in the first part of a sentence and/or paragraph.

● Use active verbs rather than passive ones

Clear writing describes people doing things, not people having things done to them. Use active verbs not passive ones. For example, use 'we will look for the effects on quality of life' rather than 'the effects on quality of life will be observed'. It's usually clearest to keep 'subject verb and object' in that order.

● Don't turn verbs into nouns

This is often done in formal documents. It doesn't help people's understanding. For example, 'When your blood has been tested, a decision will be taken with respect to your continued participation' could read 'We will test your blood and decide if you should stay in the trial.'

● Test your writing with patients and patient representatives/members of the public

This is the only foolproof way to find out if your writing can be read and understood. Ask patients/patient representatives/members of the public to comment on drafts of any information you prepare for the public and policymakers.

Layout and presentation

● Guide your reader

In a long document, a short introduction can be used to highlight important points and guide the reader through detailed text. Make an effort to select and use clear sub-headings. Group related points together under a clear heading.

● Format and style

This is always a matter of personal preference, but since some people may have problems with their sight, it is often best to:

- use Arial font, minimum point size 12 or 14
- use line spacing of 1.5
- align text to the left (justified text is harder to read)
- use italic, bold and underlined styles sparingly
- highlight headings by additional space rather than underlining
- leave plenty of clear space in your document – particularly around bullet points and lists.

Further advice is available from the Royal National Institute of Blind people (RNIB):

www.rnib.org.uk/professionals/accessibleinformation/text/Pages/clear_print.aspx

3. Public information leaflets: template and examples

Template for a BPSU public information leaflet

● Design

A4 folded to A5 – 4 pages.

● Front page

Heading – British Paediatric Surveillance Unit

Title – Public information leaflet

Who/what is this information leaflet for?

Suggested text: This leaflet provides information about a new study of XXXXX. It aims to provide information about the condition, why this study is important and what we hope to show by doing it. It also provides contact details of the researchers undertaking the study and a link to the website where the results will be published.

Subject of study

To include:

- What is condition?
- Why does it develop?

● Inside pages

Information about the study – to include:

- why it is being undertaken
- who is funding the work
- what it is investigating
- where it is taking place
- time period
- how the information will be collected
- what are the possible risks and benefits ? – to include assurance of anonymity and confidentiality
- who should be contacted if there are any questions about the study

● Back page

Information about the BPSU

CHYLOTHORAX STUDY IN INFANTS AND CHILDREN

www.rcpch.ac.uk/system/files/protected/page/PATIENTINFORMATIONSSHEET.pdf

BRITISH PAEDIATRIC SURVEILLANCE UNIT

WHAT IS THE BRITISH PAEDIATRIC SURVEILLANCE UNIT (BPSU)?
The aim of the BPSU is to encourage the study of rare conditions in children. It was founded in 1986 by the Royal College of Paediatrics and Child Health, the Health Protection Agency and the Institute of Child Health (London).

WHAT DOES THE BPSU DO?
It allows doctors and researchers to find out how many children in the UK and the Republic of Ireland are affected by the particular disease or condition each year - this is called epidemiological surveillance. Doctors can also gather information about all the cases of a particular rare condition so they can begin to understand what might have caused it and how to diagnose and treat.


On receiving the card, the BPSU informs the investigation team, who send the reporting doctor a short confidential questionnaire for more information about the affected child. BPSU researchers never contact families or children and surveillance studies don't ever affect a child's treatment. The purpose is ONLY to collect information to learn more about the condition.


HOW DOES THE BPSU WORK?
Each month the unit sends a distinctive orange card to over 2400 consultant paediatricians; the card lists the rare conditions currently being studied. If a doctor has seen a child affected by one of these conditions they tick a box on the card and return it to BPSU.

WHAT HAS THE BPSU ACHIEVED?
PUBLIC HEALTH IMPACT
The BPSU has now helped to undertake surveys of over 60 rare conditions which may affect children. These have helped to increase understanding of why the conditions occur and can help to provide better diagnoses and treatments.


(From the BPSU Public Information Leaflet – 'Investigating rare childhood conditions for the future health of the nation')

For further information contact:
British Paediatric Surveillance Unit
Royal College of Paediatrics & Child Health
5-11 Theobalds Road, London WC1X 8SH
Tel: +44 (0) 207 0926173 / 74
E-Mail: bpsu@rcpch.ac.uk
Website: <http://bpsu.inopsu.com>

University Hospitals Bristol 
NHS Foundation Trust



BRITISH PAEDIATRIC SURVEILLANCE UNIT



PUBLIC INFORMATION SHEET

CHYLOTHORAX STUDY IN INFANTS AND CHILDREN

**TOWARDS BETTER TREATMENT AND MANAGEMENT OF
INFANTS AND CHILDREN WHO DEVELOP A CHYLOTHORAX**

WHAT IS A CHYLOTHORAX ?

A **chylothorax** is a condition that results in a build-up of fluid in the space around the lungs. The fluid, called chyle, is a normal fluid that is made when the body digests fat and is usually transported in lymph vessels. If this fluid builds up around the lungs it puts pressure on them and makes breathing more difficult.

WHY DOES A CHYLOTHORAX DEVELOP ?

Sometimes the vessels that transport the chyle become damaged and leak and then the fluid builds up around the lungs. The most common causes for a chylothorax to develop include:

- a congenital cause
- trauma caused by thoracic surgery
- lymphoma (cancer of the lymph system)

ost BPSU feedback Phase 2.doc

THE CHYLOTHORAX STUDY

The treatment and management of infants and children with a chylothorax is varied and it is currently difficult to know how best to manage children with this condition.

A study has been designed to gain information about infants and children who develop a chylothorax with the aim of improving understanding of the condition and how best to treat it.



The British Paediatric Surveillance Unit (BPSU) is supporting this study (see back page of leaflet), as well as the Paediatric Intensive Care Society (PICS) and the British Congenital Cardiac Association (BCCA) and we hope this information leaflet provides you with the necessary information about the study.

WHERE IS THIS STUDY HAPPENING

The study is being led by medical and nursing staff at Bristol Royal Hospital for Children and will be taking place in all hospitals across the United Kingdom, Northern Ireland and the Channel Islands.

HOW LONG WILL THE STUDY GO ON FOR?

The study will continue for 13 months.



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ACUTE PANCREATITIS IN CHILDHOOD

www.rcpch.ac.uk/system/files/protected/Doc9-%20Public%20information%20leaflet%202012.pdf

BRITISH PAEDIATRIC SURVEILLANCE UNIT

WHAT IS THE BRITISH PAEDIATRIC SURVEILLANCE UNIT (BPSU)?

The aim of the BPSU is to encourage the study of rare conditions in children. It was founded in 1986 by the Royal College of Paediatrics and Child Health, the Health Protection Agency and the University of London-Institute of Child Health.

WHAT DOES THE BPSU DO?

It allows doctors and researchers to find out how many children in the UK and the Republic of Ireland are affected by the particular disease or condition each year - this is called epidemiological surveillance. Doctors can also gather information about all the cases of a particular rare condition so they can begin to understand what might have caused it and how to diagnose and treat. BPSU studies can benefit future patients with rare conditions.

HOW DOES THE BPSU WORK?

Each month the BPSU sends an orange card to almost 3500 consultant paediatricians and specialists; the card lists the rare conditions currently being studied. If any doctor has seen a child affected by one of these conditions they tick a box on the card and send it back. The BPSU informs the research team who send the doctor a short confidential questionnaire asking for more information. Researchers are not told the names and addresses of patients, and families are not contacted.

WHAT HAS THE BPSU ACHIEVED?

The BPSU has now helped to undertake surveys of over 90 rare conditions which may affect children. These have helped to increase understanding of why the conditions occur and can help to provide better diagnoses and treatments.

For further information contact:
British Paediatric Surveillance Unit,
Royal College of Paediatrics & Child Health
5-11 Theobalds Road, London WC1X 8SH
Tel: +44 (0) 207 0926173 / 74
E-Mail: bpsu@rcpch.ac.uk
Website: www.rcpch.ac.uk/bpsu

Doc9 - Public information sheet for the web - Acute Pancreatitis in Children V2



BRITISH PAEDIATRIC SURVEILLANCE UNIT



PUBLIC INFORMATION SHEET –

INFORMATION FOR THE WEB

ACUTE PANCREATITIS IN CHILDHOOD

INFORMING BETTER TREATMENT AND MANAGEMENT OF CHILDREN WHO DEVELOP ACUTE PANCREATITIS

WHAT IS ACUTE PANCREATITIS?

ACUTE PANCREATITIS IS A RARE CONDITION IN CHILDHOOD IN WHICH THE PANCREAS, WHICH IS SITUATED IN THE ABDOMEN, BECOMES INFLAMED AND VERY PAINFUL. CHILDREN DEVELOPING PANCREATITIS OFTEN NEED ADMISSION TO HOSPITAL AND MAY REQUIRE SURGICAL INTERVENTION.

WHY DOES PANCREATITIS DEVELOP?

There are many causes for this condition including:

- Viral infections
- Trauma
- Gall-stones
- Congenital abnormalities in pancreatic anatomy (formation)
- Inherited genetic conditions

WHO SHOULD BE CONTACTED IF YOU HAVE ANY QUESTIONS ABOUT THIS STUDY?

Please contact the British Paediatric Surveillance Unit of the Royal College of Paediatrics and Child Health, London (see over page) or E-mail the researchers at J.P.H.Shield@bristol.ac.uk.

WHAT ARE THE AIMS OF THIS STUDY?

The treatment and management of children with pancreatitis is varied as the condition is quite rare in childhood and it is currently difficult to know what constitutes the best management strategy for this condition for any given child.

This study has been designed to examine the causes, investigations, treatments and complications of acute pancreatitis with the aim of improving understanding of the condition and how best to treat it.

The British Paediatric Surveillance Unit (BPSU) is supporting this study (see overleaf), as well as the British Association of Paediatric Surgeons (BAPS) and we hope this information leaflet provides you with the necessary information about the study.

WHERE IS THIS STUDY HAPPENING

The study is being led by the University of Bristol and Bristol Royal Hospital for Children and will be taking place in all hospitals across the United Kingdom, Northern Ireland and the Channel Islands.

HOW LONG WILL THE STUDY GO ON FOR?

The study will continue for 25 months.

Doc9 - Public information sheet for the web - Acute Pancreatitis in Children V2

HOW WILL THE INFORMATION BE COLLECTED?

On receiving the card, the BPSU informs the investigation team in Bristol who send the reporting doctor a short confidential questionnaire for more information about the affected child. BPSU researchers never contact families or children and surveillance studies don't ever affect a child's treatment. The purpose is ONLY to collect information to learn more about the condition.

They will also provide details of the child's progress, one year later.

Through analysing this information we hope to increase understanding of the causes and development of pancreatitis and improve treatment.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS

BPSU studies also use patient records in this way and do not directly contact patients. The care and treatment that children and young people with Acute Pancreatitis are receiving will not change during this study.

However we hope that by learning more about the condition, diagnosis and care will improve in the future. The information collected will not identify individual children and patient confidentiality will be maintained at all times.

The NHS uses medical records for audit or research to improve future health and care. Hospitals and health professionals record when a patient does not want their notes to be used for audit or research (known as dissent), so you must let your doctors or hospital know if you wish to dissent. If a patient (or legal guardian) dissented from their medical notes being used for research, their data would also not be used in BPSU studies.

4. Organisations to contact for further information and advice about PPI

If you'd like further information or advice, you might find the following organisations helpful:

BPSU Scientific Committee lay members

There are two lay members of the BPSU Scientific Committee, both with extensive experience of involvement in research affecting children and young people. For more information on the BPSU Scientific Committee lay members, visit: www.rcpch.ac.uk/bpsu/patientsandpublic

INVOLVE www.invo.org.uk

INVOLVE is a national advisory group that supports PPI in NHS, public health and social care research. INVOLVE is funded by and part of the National Institute of Health Research (NIHR). The INVOLVE website has lots of useful information – for example there is a guide for researchers about PPI (www.invo.org.uk/resource-centre/resource-for-researchers/) and guidance on payments and expenses is updated regularly. You can also sign up to receive a regular newsletter and obtain information about events.

Medicines for Children Research Network www.mcrn.org.uk

The NIHR Medicines for Children Research Network (MCRN) aims to improve the co-ordination, speed and quality of randomised controlled trials and other well designed studies of medicines for children and adolescents. The MCRN has a PPI lead and can offer advice on involving parents as well as children in research.

People in Research www.peopleinresearch.org

People in Research connects members of the public to researchers who want to involve them in their work. You can use this website to advertise opportunities for involvement and for advice on how to recruit people to get actively involved in research.

Plain English Campaign www.plainenglish.co.uk

The Plain English Campaign works to ensure that everyone has access to clear and concise information. They offer training, editing and a kite marking system (the Crystal Mark). The Plain English Campaign website features a number of free brochures, including one on how to write in plain English (see www.plainenglish.co.uk/files/howto.pdf).

Research Design Service www.nihr.ac.uk/research/Pages/ResearchDesignService.aspx

The NIHR Research Design Service (RDS) supports researchers to develop and design high quality research proposals for submission to NIHR and other national, peer-reviewed funding competitions for applied health or social care research. There are ten NIHR Research Design Services. All have a PPI lead who can offer advice about PPI at the design stage. Some also offer grants to enable researchers to develop PPI in research before they have obtained funding. Some have a PPI group – members may be able to offer 'public' input at the design stage of a study.

Section 6: Researchers' experiences

The MCADD study

About the study

MCADD is a serious inherited metabolic disease which can lead to neurological damage and in some cases death. The MCADD study aimed to generate evidence to support the introduction of screening into the New-born Bloodspot Screening Programme. The study had four parts:

1. A pilot screening phase, which aimed to assess the effectiveness and feasibility of the screening test. This was to ensure that screening would detect affected babies, which could then help prevent episodes of the disease occurring in later life.
2. Concurrent surveillance through the BPSU and the six screening laboratories with the aim of identifying any children up to the age of 16 who were newly diagnosed with MCADD either through screening or clinical presentation. This phase also enabled researchers to study the age at which children were presenting with MCADD, the severity of the disease and what genes were involved. It also aimed to ascertain whether the screening programme would be cost effective.
3. A two year follow-up phase where researchers contacted clinicians to find out what happened to children.
4. A final implementation phase – the results of the study led the Department of Health in England to mandate screening for MCADD in 2009.

This case study focuses on phases 2-4.

Juliet Oerton was the lead researcher on the MCADD study with Professor Carol Dezateux who was the Principal Investigator. **Steve Hannigan** was involved in the study as a patient representative: he is chief executive of the charity CLIMB – Children Living with Inherited MetaBolic disease. CLIMB supports families of children with MCADD.

Juliet's experience

How did you find people to involve?

We approached CLIMB and Contact-a-Family right at the beginning of the project.

How were they involved?

Steve Hannigan from CLIMB joined our Scientific Steering Group and came to all of the meetings. He worked with families affected by MCADD to comment on information aimed at families.

We worked hard to keep families informed – we presented the study at the CLIMB annual conference and wrote two articles for the CLIMB newsletter about the study.

We also worked with CLIMB and with Genetic Alliance UK¹ to ensure that our research led to full implementation of screening for MCADD.

How did the involvement make a difference?

At a very early stage, when we presented the study at the CLIMB annual conference, we were very influenced by the families and buoyed up by the fact that they were so supportive of what we were planning to do.

Members of the Scientific Steering Group valued Steve's perspective – he offered a very down to earth view and reminded us that there were people out there who had suffered. There was a lot of mutual respect between him and the clinicians on the steering group.

Once we had the results, it was crucially important that we had the support from the directors of the two patient advocate organisations (CLIMB and Genetic Alliance UK). They gave added impetus to the lobbying. They helped to get our research on to the right people's desks. They knew who needed to know about the research and how to help fast track decisions. We as researchers often don't know these things and it would have been much harder without their input.

Our experience of working with Steve encouraged us to involve CLIMB in another project looking at a different metabolic condition.

What helped to make the involvement work?

Steve's involvement in the Scientific Steering Group was very important. The key thing was communication. I hope Steve felt he could ring up and ask how it was going at any time and we felt we could call him and ask for his views.

¹ Genetic Alliance UK is a national charity of over 150 patient organisations supporting all those affected by genetic conditions.

How did you work with patients?

At the dissemination stage we used a case study of one of the patients who was identified via the BPSU study – a child called Katy. She was reported to us anonymously through the study. She had become exceptionally ill very quickly aged 11 and did nearly die. But she had recovered.

When we were looking for a good case study, and we knew this patient was doing well, the clinician who was caring for her approached her directly to ask if she would be prepared to share her story and speak to the press. Once her story had come out, we kept checking with her to make sure she was happy to remain involved. For example, the Chief Medical Officer wanted to use Katy's story in his annual report, so we checked with her again then. She was even more excited to be involved.

Katy's story made MCADD real to people. It's difficult to understand the consequences of the condition unless you hear from someone who's been affected by it. Katy was a really good advocate. When we launched the screening programme at the Houses of Parliament, she came along with her Mum and was star of the show.

What would you do differently next time?

CLIMB are based in Crewe and we didn't ever visit them at their headquarters – although we did go to their conferences. In retrospect I don't think that caused a problem. But I suspect that if we'd gone there early on, we might have developed stronger relationships with staff and volunteers which would have been a good thing to have done. The only two people we communicated with were Steve and Pam. It would have given us a better understanding of how the organisation works, how they are funded – what you can reasonably expect – and how much support we should also be offering them – rather than simply expecting them to always help us with the study. We ought to step outside of our London bubble more often to see what it's like for these organisations that are struggling to raise funds so we can try to offer more to them.

What are the downsides to involvement?

You can't just do it once and think you've done it. You need to keep in touch, and you have to be prepared to provide information and feedback. That's extra work – but that's what we're here for. I'm not being negative about it. It's actually one of the more rewarding things we do as researchers – to see the positive impact of what we are doing for real people. But it's an extra thing to do which has to be factored in, in terms of time and the work to be done on a study. It's vital – I don't think we should be doing the research unless we're prepared to engage with these organisations and the people they support.

What advice would you offer other BPSU researchers about involvement?

Do some background digging to find out which are the support organisations for families affected by the condition you are studying. That's an important first step – to find out what range of information and support is already out there.

Then it's a sit back and reflect moment, about how what you're doing will dovetail or not with what's already out there. It's very important to make contact with the key support organisations and to try to have a dialogue with them. We've found in the two studies we've done since MCADD – that to have endorsement from bone fide established support groups has been really beneficial in terms of showing that we've established a link and are working with them – but also to push through an ethics application – it's part of a broader assessment of how well an application has been thought through and worked up – not just as an add-on but as integral part of the research and beyond. So it's a good thing to get that perspective early on.

It's very useful to know what information is already out there – then you can use it. And you need to make sure you're not going to put information out that may be conflicting and could confuse people. It also helps you as a researcher understand the condition. These organisations are very good at providing information in layman's terms. Any new researcher won't necessarily have an in-depth understanding, so it's very useful.

Usually these support groups are easy to find using the internet – they pop up straight away when you start searching for a condition.

Steve's experience

How were you involved?

I was involved from an early stage – I joined the project in 2001 and was a member of the Scientific Steering Group. I was very involved at the implementation stage – we helped with information and training. And I remain involved as a member of the National Programme Board for Screening.

What could have been done better?

I wish the project had happened faster!

How did your involvement make a difference?

It's very hard to say – we were part of the process and are still part of the monitoring. We got a lot of useful information as a result of being involved. It was a partnership and felt very positive.

One of the clinicians on the Scientific Steering Group became very involved with CLIMB as a result of our involvement with the MCADD study. He helped us to draft new publications and to make medical information more accessible (e.g. dietary guidelines).

What advice would you offer other BPSU researchers about involvement?

Make effective use of patient organisations – bring us on at an early stage. Come and talk to us. We don't bite. Or we're quite happy to come to you, if we're in your area. We're out and about all the time.

Patient groups may well have worked on other research projects, so they can offer support and information that would help the project move forward. Patient groups can also give information about a study on its website and can also suggest other avenues, other ways of reaching people.

Use social media and the web. Patient groups are likely to reach many more people than a researcher (for example the CLIMB website gets between 120,000 and 140,000 hits per year) and by using social media you can get an immediate response.

At the end of the day 99% of researchers have never come across a family with a metabolic disease. We understand the devastation. Go and meet the families, understand the reality for the families.

CNS Inflammatory Demyelination Disease Study

About the study

Inflammatory demyelinating diseases are a rare group of illnesses which affect the central nervous system (which is made up of the brain and spinal cord). Many children recover well from these conditions. However, some have longer-term problems and may even have another bout of illness. It was not known how often these conditions occur in children in the UK and Ireland, or what the future holds for children who are affected. This study aimed to:

1. Find out how many children are affected by a new demyelinating event (incidence) in the UK and Ireland each year.
2. Find out what happens to these children in the longer-term, for example how many children have a disability or a second episode.
3. Describe treatments currently being used in the UK and Ireland.

Michael Absoud was the lead researcher on this study. **Sarv Kaur** was involved as a patient and a patient representative – she is the Public Involvement Officer at the MS Society. The MS Society was one of the funders of this study.

Michael's experience

How did you find people to involve?

We approached the MS Society and asked them to help.

How were they involved?

Before we applied for any funding the MS Society organised a study day, because they felt that there was a lack of information about this topic. Families with children with CNS demyelinating diseases attended, as well as adult neurologists and psychologists. One of the main things that came from it was that research studies were needed to find out how common these conditions are, how they present at the early stages and what are the predictors of subsequently developing MS. So this was a strong endorsement for our study. After this, the MS Society funded the research in partnership with Action Medical Research.

The MS Society was also very involved at the dissemination stage. One of the first things we did was to publish an article in an Open Access journal. That was supported by the MS Society and the University – it required extra funding which we didn't have at the beginning, but we managed to get that. We felt it was important to make the results accessible to everybody online – not just to the select few. The input from the users was also that this would be an important aspect of disseminating research to the public. The MS Society will also carry a link to the paper from its website.

The MS Society wanted to raise awareness of the finding that MS can also affect children – even though this is rare. So they released a press release which was picked up by the BBC and we then did an interview for a breakfast show. It was also featured online¹.

We are hoping to carry on doing more studies and Sarv is going to nominate someone else to take on the longer term aspects of this work. So in terms of building on our partnership, we want to continue involving people, to help us think about future projects.

How did the involvement make a difference?

It made a difference at all the stages. At the beginning, the involvement reassured us that this was an important topic for people affected by MS. It helped us to identify other collaborators and it helped to secure funding. The concept of doing a surveillance study came from the study day organised by the MS Society. The main issue raised by parents at the study day was that there's a severe lack of awareness of this condition amongst clinicians. We discussed the BPSU approach and everyone thought this would be a very good way of raising awareness because we ask all paediatricians if they've seen a case. So that was where the idea of working with the BPSU came from.

¹ Available at: <http://www.bbc.co.uk/news/health-18461778>

People who came to the study day also recommended we collaborate with adult MS researchers, because there may be similar factors around causes, and so findings from studies in children might have wider relevance. This led us to collaborate with groups that we hadn't thought of before.

Before the study day this topic wasn't seen as a priority by the MS Society. After the day, paediatric MS became part of the Society's research strategy. Applicants for MS Society research funds are encouraged to show how their proposal fits with the Society's research strategy. So PPI helped to secure funding for the study.

The involvement also helped to make sure our information was lay-friendly and that patients knew about our study. Sarv helped us to think about what should or shouldn't be in the public information leaflet. It was important to think about how much information to include about MS, because not all children with a demyelinating episode go on to develop MS. Sarv also helped us to think about what language to use, what pictures to put in and so on.

And it also helped at the dissemination stage. Sarv was important in linking us to other parts of the MS Society – for example the research leads and the media office. It was useful for us because it made us think about things we wouldn't normally think about with dissemination – the Open Access and the wider public awareness. The MS Society gave us a different perspective on how to put rare diseases on the map a bit. That may not be something researchers think about – they tend to focus on how do we write this paper, how do we present this at a conference. Linking in with other people from the MS Society helped a lot.

At the end of the study, Sarv didn't just say that's it – your job is done. She asked what we were planning to do next and suggested we get someone else involved very early on – even at the very early stages of an idea before writing outline applications etc. It is useful to have that – instead of having an idea and then looking for someone to involve.

What helped to you to get started with PPI?

It's been nearly four years since we first put in the BPSU application. Perhaps when we started we weren't as aware of the different avenues that user involvement could provide – we're getting better at it now. The reason we thought about it was because the BPSU mentioned it as an essential requirement – so that was a nice push to help us think about it. That was the initial driver for us and helped us to take the first steps.

How are you developing your PPI?

We have contacted the Medicines for Children Research Network about other studies. They now have the resources to advise on, for example, on how to carry out focus groups with young children and families as a way of consulting them and feeding into the research design. So they could give advice to support any activity around involvement – how to access users'

views and record it in a more methodical way and help with the logistics of that. So it's an extra layer of support.

What are the downsides to involvement?

A research group that's new to involvement may see it as an extra layer of work and see it as a tick-box activity – which it shouldn't be. So people need to understand the benefits of it and see how it benefits research.

What advice would you offer other BPSU researchers about involvement?

There is very little point in doing research unless you're going to help the actual users. We might think we have good ideas, but I think it's important to ask children and families whether they think the research is important or will make a difference in their lives – or potentially could help other people if not themselves directly – because they are in the position to tell us about these things.

A lot of unsuccessful research happens because sometimes we can miss pretty central things – but users will think about them.

Involve people at an early stage before applying for funding. With surveillance studies, it's necessary to involve at an early stage to find out if patients think the study is important. The fact that you don't have to ask people for their consent is a good reason for involvement. It's a serious thing to do research without a patient's consent, so there has to be a good reason to do it. Asking patients whether they think that's acceptable is really important.

If you can show the patients think this is the best design to do the study – this can help with ethics review – as the ethics committees will ask why you are doing it without consent.

Get involvement in developing the public information leaflet, and then in publicising your research on as many websites as possible – it's important, because then you've tried as much as possible to let children and parents know this work is going on.

Keep users updated and involved and engaged. If funding is available, get them to the conferences where you are presenting the research.

It does help if a user is attached to a patient organisation or group because that gives them a framework to fall back on in terms of getting advice about a question – it helps the user feel more empowered to approach the researcher and feel they can be more proactive.

Sarv's experience

How were you involved?

I helped Michael put together lay-friendly information for parents of children with MS-like symptoms. I also looked at the website and the leaflets he was intending to circulate.

Michael presented information about the study to the parents with children with MS at four hospitals. I looked at his PowerPoint presentations to make sure they were lay-friendly. I also attended one of the presentations.

At the end of the study, I put together a news story for the MS Society website. This enabled us to tell people affected by MS about the results of the study, but also to tell them about the next phase of the study.

What difference did your involvement make?

I had a good understanding of what the project was about – before I started working for the MS Society I was actively involved in this study – so I knew what I needed to tell the MS community.

It was a new area of research – we needed to make parents aware that MS can manifest at a young age, with varied symptoms. Many people affected by MS thought it was an adult condition. It was a very good piece of research which helped us understand the development of MS-like symptoms in early childhood and it was this information which needed to be shared widely across the MS community. We made sure to inform our own staff as well which meant that the findings were quickly incorporated into the advice we give out to patients.

Michael was fairly new to involvement at the beginning of this study – he didn't know what to expect. I hope my involvement has helped him and made him think about involving people in all future studies.

What helped to make it work well?

My research background helped. It meant I could do that middle work – I could understand the researcher's point of view and then communicate that to people affected by MS in a lay-friendly way.

Michael and I kept each other up to date – there's always something that can come out of that. For example Michael mentioned he was developing a website and I said I would be willing to help with that – which might not have been something he would have considered. If both patients and researchers are enthusiastic and keen, if they keep that communication channel open, there might be new opportunities that can emerge which can help ease the researchers' workload just that little bit. It also helped that I had got to know Michael well.

We had met at various conferences, so he was always able to update me on progress and whether he required any further input.

What could have been done better?

It would be nice to have an open and clear process, especially around timescales. Even a rough outline of what's planned at the next stage can help you manage your time and suggest areas where you can help again. It is always good to know what has been done in response to PPI – what has changed and what hasn't changed in order to understand what impact you have made.

What advice would you offer other BPSU researchers about involvement?

Get people affected by the condition involved as early as possible. Don't wait for the application stage – I want the involvement to be even earlier than that, at the development stage of the project. Then you can get input on whether this is a strong application – from the perspective of people affected by the condition. This could give researchers a boost of confidence, but also help them think about what else might need to be considered.

If you involve people at an early stage it develops the relationship and helps with involvement in the next stages. In the long run it saves time, because you get it right the first time – with the funding application and ethics. PPI can ensure that the project is relevant and important to the people who will be most affected. It also gives the patients an understanding of what's involved in the different stages of research which can make them more patient and understanding of the perspective the researcher, which again can make this relationship stronger.

Please consider the language you use and make sure all scientific words are explained. You also need to be prepared for some criticism as this will benefit and prepare you in the long run if the same point is highlighted at a later stage of your research.

You need to get input from a wide range of people affected by the condition – don't just involve people at one particular stage or with a particular form of the condition.

You need to make sure that you are clear about what you are asking people to do. And you need to be open to comments and then feedback what you will do in response to those comments.

Surveillance of lead in children (SLIC) study

About the study

Lead poisoning in children is associated with a range of effects, including reduction in IQ and disruptive behaviour. Changes in the law have led to the removal of many sources of lead from the environment, and this has led to a decrease in blood levels of lead in the population. However, it is known that a small number of children are still being exposed to harmful levels of lead, for example from old lead paint.

This study aimed to:

- investigate the incidence of clinically diagnosed blood lead concentrations in children aged 0-15 years in the UK and Republic of Ireland
- describe the treatment and health outcomes for children one year after diagnosis
- report the proportion of cases where a lead source was identified and to describe these sources
- raise awareness among paediatricians about the possibility of lead poisoning
- provide support in managing children with elevated blood lead concentrations.

Anna Jones was a public health specialist registrar at the HPA who worked on the study.
Iain Mallett works at the Health Protection Agency.

Anna's experience

How did you assess the importance of this research to parents and families?

I became interested in how lead affects children following the publication of a case series which demonstrated the barriers that families and health services face in dealing with lead exposure in childhood. Later, I arranged to sit in on sessions at the toxicology clinic at Guys Hospital and this helped me to understand the issues for families and parents of affected children.

How did you involve members of the public?

We worked with Iain – he set up a focus group of members of the public to comment on the information for the public included on the study website.

How did the involvement make a difference?

Listening to the experiences of parents and children at the toxicology clinic helped inform my thinking. Hearing about the barriers parents face in getting lead removed and the length of time it had taken to get to that stage was useful in strengthening the collaboration we developed between researchers.

What helped you to get started?

We worked with the BPSU from the beginning and we found that really helpful. The contacts were really constructive.

What were the challenges?

What's difficult is that lead exposure in childhood is about exposure to a toxin rather than a discrete illness or syndrome – people therefore don't necessarily form support groups. We talked about that a lot with the BPSU – that there wasn't a group that we could involve.

What advice would you offer other BPSU researchers about involvement?

Think about it early. You don't necessarily need to do any PPI early on, but you need to think about it. Think about possible ways in and get advice from the BPSU at an early stage too.

I think it's about being very clear and definite about what you want the involvement to be. It's about making sure that it's not tokenistic, it's not just about having a parent on a steering group for the sake of having a parent on the group.

Iain's experience

How did you involve people?

I work in patient and public engagement at the Health Protection Agency, within the communications division. One of our core objectives is to provide information for the public that is understandable, and to test the quality of any information for the public. The SLIC study team approached me to ask about what sort of advice they could give to people that was practical and useful and understandable. They wanted to include this on a website they were putting together for the SLIC study.

So we decided to run a focus group. The Health Protection Agency has a pool of 1,000 people we can draw on to run focus groups. We chose to recruit people who live in the North East, because we've run groups there before. We wrote to about 200 people asking them if they were parents, and if so, whether they'd be interested in taking part in a discussion about lead poisoning and advice about lead. Three men and four women agreed to take part in the focus group. We offered them a small one-off payment to cover travel and to recognise that they have given their time. We also offered additional money to cover carer costs.

One of the SLIC study team attended so that they could answer any technical questions. People looked at the website and commented on the information. They were surprised that GPs and nurses weren't very aware of signs and symptoms and they wanted to be reassured that training about this topic would be considered in future.

What advice would you offer other BPSU researchers about involvement?

Focus groups work very well to test information for the public. They stimulate good discussion and I think that helps people who feel they don't necessarily have an opinion. And the participants enjoy it, they have a good time.

To have a good discussion you need to take people on a journey. When people first arrive they may feel that they have nothing to say about the subject or they know everything about the subject. Don't be frustrated or disappointed by that. People get up to speed surprisingly quickly. It is about managing the group. I put a lot of store by what we say at the beginning of a discussion – we use Chatham House rules, everyone has the right to have their say and we respect that. You've got to feel confident enough that if someone's dominating or putting over a view that is inaccurate, that you can handle that.



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