Service Users and Carers as
Co-Applicants, Project Team Members and Co-researchers

This paper outlines the management, governance and ethical implications of involving service users as co-applicants, project team members and co-researchers in health and care research as well as the ethical duties of all stakeholders involved. The NHS R & D Forum Service User and Carer Working Group members (SUCWG) have generated it.

The SUCWG is working in partnership with the Health Research Authority and NIHR Involve to take this work forward through three work streams:

1. Raising awareness of public co-applicant issues for those in the research management community (to be led by the R&D Forum SUCWG);
2. Guidance for the public (to be led by HRA);
3. Guidance for researchers from funding bodies (to be led by Involve);

In order to facilitate work stream 1, the NHS RD Forum members are asked to consider the issues raised in this paper, identify any challenges not addressed in the paper and share potential solutions. They are also asked to consider what type of information or guidance would be most helpful to R and D leads working in NHS organisations.

Background

The review was driven from the personal experience of SUCWG members, and anecdotal evidence collected in discussions with other colleagues, working groups, members of the Forum, and through a discussion group held at the 2017 Forum annual conference. This had highlighted a number of challenges and issues for those fulfilling those roles.

A literature review found a lack of research in this area. The discussion, hosted by SUCWG members, at the RD Forum annual conference in 2017 found that the issues they had identified were shared by a range of research management and governance leads. A joint meeting with the Health Research Authority and Involve in July 2017 confirmed there were shared concerns. This resulted in a commitment to take a collaborative approach to considering and addressing the challenges.

Key concerns:

1. How to ensure service users and carers as project team members, co-researchers or co-applicants engaging in funding applications, are fully aware of their responsibilities in these roles and what the implications might be.

2. How sponsors, grant holding organisations, funders and other members of the research community can communicate and support service users and carers in their role.

3. Understanding the contractual and legal governance issues and responsibilities that are particular to service user and carer co-applicants, project team members, and co-researchers, from both an organisational and individual service user and carer perspective.

Introduction

There is a long history of service user and carer involvement in research, and some examples of user led health and care research. The NIHR actively supports the participation of patients in research, and the involvement and engagement of service users and carers in all aspects of the research process. This includes co-applicancy for grant funding, as members of project teams overseeing the delivery of research studies, and as co-researchers. Since the development of the NIHR there has been a drive towards a much more collaborative approach to public and patient involvement and engagement in research.

Whilst there are opportunities for service users and carers to lead research and take the role of Chief Investigator, the research infrastructure makes this challenging. The requirements of the research grant funding application process and need for academic engagement are not always easy to access for individual patients or patient groups who may not be aligned to academic institutions or research active organisations. They may also lack the experience of having been part of previous successful bids for funding or research studies.

The roles and responsibilities of service users and carers as co-applicants, project team members or as co-researchers should be recognised as being as significant as any other person similarly engaged in the research process. This means they are responsible (to a greater or lesser extent depending on their role) for the design, management, quality, conduct and integrity of that study and the safety of patients.

The terms co-applicant, project team member and co-researcher used in this paper are defined as follows:

- **Co-applicants:**
  Different funders will specify their own remit for applicants however the NIHR currently states:
  "Co-applicants are individuals with responsibility for the day-to-day management and delivery of the project. Collaborators normally provide specific expertise on aspects of the project. Co-applicants are considered part of the project team and are expected to share responsibility for its successful delivery".
  http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0005/79664/FullGuidanceNotesSAF-V1_26.pdf
- **Project team members:**
  These are service users and carers who take part in a study as part of the core project management team, as members of a steering group, on an advisory panel or similar.
- **Co-researchers:**
  Service user and carer co-researchers may undertake specific roles within the research project e.g. conducting interviews or focus groups, supporting data analysis.

Management, governance and ethical issues relating to service user and carer roles in health and care research

Members of the SUCWG have highlighted, through personal experience, instances where they have been a signatory to successful grant awards, but were unclear what this really meant for them in terms of personal responsibility. They became aware that many other service users and carers were also lacking awareness of the legal and other responsibilities that may accompany this type of involvement. Despite this lack of clarity, members of the working group felt a strong sense of duty to ensure the success and integrity of their project *("my signature means something*"), but also had sometimes felt unable to participate as an equal member of the leadership team. In one study example, the individual consistently did not receive details of the trial steering committee meetings and therefore did not feel she could discharge her duties as a co-applicant effectively. The lack of direct communication, and demonstration of involvement in the process, led to the person feeling disenfranchised. Where the level of engagement is determined by the availability of funding for the conduct of the project and performance of the researchers, sponsors and research leads should make this clear from the outset and not set unrealistic expectations. In all cases, service user and carer engagement should be properly costed to enable the level of engagement necessary for the type of study.

This paper focuses on *how* the roles and responsibilities of service user and carer co-applicants, project team members and co-researchers might be better enabled. It looks at what experiences and lessons can be shared by the service user, research

and research management community in developing co-production and participatory research.

Responsibilities

There should be no real difference in responsibility between a service user and/or carer research team member or co-researcher and any other research team member. Systems should be in place to ensure they fully understand their legal and ethical duties when conducting good research in a health and care setting. Study-specific tasks can vary between projects, and all should be clearly documented from the outset. The reality, however, for service user and carer co-applicants, project team members and co-researchers, who may be experts because of their lived experiences but may not have the research experience and knowledge, can be more challenging where their involvement requires more facilitation and broader support.

However, there may be specific legal and governance issues in relation to service user and carer co-applicants, project team members and co-researchers. For example, the service user researcher may not be employed by any organisation that is participating in or hosting the research. The individual may wish to act as an independent researcher or consultant. This can result in some of the contractual and legal considerations outlined in this paper.

Contracts & written agreements

Service users and carers may have different roles and relationships with the organisation that is applying for grant funding or sponsoring a research study. This can vary from being registered as a volunteer to being registered as an employee. Others may be issued with an honorary contract (conferring no employment rights) and other individuals prefer to act as independent consultants. However, contracts of some kind are usually required for those who are involved in project teams or as co-researchers.

Preferred practice varies widely across organisations and the preferences of service users and carers are also equally varied dependent on their employment status and personal circumstances e.g. being in receipt of benefits. The variety of possible involvement and contracting scenarios creates confusion. This needs streamlining to strengthen the legal framework and improve the quality of involvement. The NHS Litigation Authority should clarify what level of activity and indemnity they are willing to cover in relation to the involvement of service users and carers in the research process.

A research sponsor should always make clear which duties and responsibilities they are delegating to others. This is usually done in the form of a written agreement. Scoping work could be carried out to collate information on the different types of contract, which are being issued by hosting institutions. It could be verified whether these contracts are meeting HMRC and legislative requirements and a standard template produced [based on good practice] which hosting institutions could adapt to meet their own needs. Involve guidance on payments is an important resource.

Duty of care

We argue that Sponsors have a duty of care to all members of the research team and this extends to all service users and carers engaged in research teams or as co-researchers. Some service users and carers are potentially vulnerable through the nature of their health issue, a disability or the nature of their role where they may be exposed to difficult and challenging aspects of care where data collection is taking place, or when conflicts of interest may arise. Ensuring that all research team members and organisational representatives enable all service users and carers engaged in research teams to deliver their role is an ethical issue beyond considerations of indemnity and governance. Therefore, service user and carer research team members should be included in all activities, opportunities and communications relevant to their role to prevent exclusion, which may result in an inability to discharge their duties. For Chief investigators, co-applicants and study co-researchers, who are also service users and carers, this will be most if not all the activities in the study life cycle.

Service users and carers who give their time to a project as a co-applicant or research project member or co-researcher, will take their roles seriously and it is right that they are enabled by all to meet them.

Effective involvement

There are many reasons why good involvement can be challenging and why the challenges may be heightened when service users act in a project management or co-researcher role. There is much literature available on how to involve service users and carers effectively, (for a comprehensive guide see the NIHR Involve website: (http://www.invo.org.uk/resource-centre/resource-for-researchers/) but experience can be limited. There is also significant pressure by funders to ensure applicants for research funding involve service users and/or carers in developing their application as funding is unlikely to be awarded without evidence of involvement. Lack of evidence can lead to involvement being less meaningful than it might be.

In most cases grant awards are made to a hosting institution. Awards are sealed by a contract, and contracting for a grant as a service user and carer is a particular challenge that may bring personal liability. Each funding body will be different in their willingness to contract with individuals rather than institutions. Where an NHS organisation or University is the grant host a contract will often then need to be in place between that organisation and the sponsor, if they are not one and the same, and with the service user or carer co-applicant. Resources are usually open to scrutiny in budget sharing contracts.

Service users and carers actively involved in research may have little knowledge of research funding applications, managing a research study, or of undertaking research. Whereas sponsors are required to ensure their researchers are competent by training or experience, enabling service users to become members of project management teams or co-researchers may require a different approach whereby training and support in the roles involved in research study management or

methodology are provided during the project itself. Training and support need to be proportionate to risk and activity. Peer support could also be utilised to ameliorate risk in these circumstances.

Study teams may be inexperienced and lack confidence in involving service users and carers in their project management teams. Service user and carers may not be clear who to go to if they have a problem or feel unable to discharge their responsibilities especially if there is not a feedback mechanism to the sponsor or person who is responsible.

Sponsors role

All research in the NHS must have a sponsor to take ultimate accountability for that project but training (and funding), for those representing the sponsor organisation, is limited. Grant holders and sponsors are usually organisations and rarely individuals, meaning that service user project team members, co-researchers, or co-applicants are most often going to need to contract with a sponsor body in some way. No data was collected during the course of writing this paper to indicate that a service user or carer had ever taken on this role and what this could mean for service users and carers acting in this capacity.

Service user or carer roles may not be clearly defined in funding applications or early on in sponsor agreements; service users and carers may be included but not truly involved from the outset. They may find that rather than agreeing the role through informed discussion their role is defined for them or allocated to them. Funding applications do not always require a sponsor signature limiting the opportunity for early sponsor oversight of, and engagement with, the involvement of service users and carers in their roles. Research ethics panels may not always pick up this deficit.

Study monitoring (a means to ensure participant safety, good clinical research practice and data integrity) is not traditionally used to oversee good involvement practice, however, monitoring plans could be easily adapted to ensure service users and carers are properly enabled in their roles.

Sponsors and collaborating organisations must have policies and standard operating procedures in place for some types of clinical research and they will run internal training programmes for their staff for many of the activities to be undertaken in a health and care setting. Clinical research teams, who are employed by these organisations, are expected to have access to these courses and supervision, but this might not extend to service users and carer co-researchers.

Levels of training requirements are dependent on study type but a gap in good training or oversight from the sponsor, might lead to service users and carers engaged in project team management or as co-researchers inadvertently being both ‘a risk’ and ‘at risk’ if they do not fully understand their duties.

Examples of these might include:

- Patient confidentiality
- Data protection and information governance
- Principles of Good Clinical Practice (if a Clinical Trial of Investigational Medicinal Product/CTIMP)
- Record keeping and data integrity
- Reporting of adverse events and incidents
- Understanding standard operating procedures
- Understanding roles and responsibilities
- Recruitment and/or Consent

Any training needs to be proportionate to the role of the service user and carer in the study. Training may also be needed for researchers in how to involve service users and carers effectively in research teams or as co-applicants.

Funders role

Although the majority of research funding applications requires applicants to provide some details of co-applicants, including service users and carers, this does not always provide enough information about their roles and responsibilities. Descriptions of how applicants plan to engage team members or service users and carers throughout the study can be vague. The funding to be apportioned for involvement activity is detailed in the application but there may be no subsequent check to ensure the funding has been used for the activity detailed. Routinely collecting feedback, at the conclusion of the study, from the service user and carer representatives named in the application, would provide confirmation of engagement and the legitimate use of funding. Funders also have a responsibility to ensure that the wellbeing of those involved in the research that they fund is managed.

Service users and carers as project leads

User led research and service user and carers as research leads are still relatively rare in NHS health and care. Research managers, sponsor representatives, and other research leads, may find that they have very little experience of contracting, working with, or advising service users and carers on the issues that arise when they become the chief investigator, a co-applicant, or a study collaborator on their team. Consideration should be given to enabling greater engagement of service users and carers as research leads and ensuring the governance framework reflects this involvement.

Developing best practice

Good involvement practice in patient and public involvement is well documented, by the NIHR and Involve, however the RD Forum Service User and Carer working group recommends some additional areas of good practice in order to:

1. Address the problem of ensuring clarity in roles and responsibilities of service users as co-applicants, project team members or co-researchers.
2. Understand the legal and contractual governance issues that are particular to service user and carer co-applicants, project team members and co-researchers, from both an organisational and individual service user perspective.

Good practice:

- Excellent communication is critical. As with any project communication is key and sponsors, collaborating organisations, and service users and carers, should agree from the outset how best to ensure this occurs. This includes how to ensure good communication between research team members. A written communication plan is a good idea.
- Ensuring contact details and methods of accepted communication are made clear and are available to service users and carers in research studies. The ability to report to the sponsor, if they do not feel able to discharge their roles and responsibilities, should be clear.
- Ensuring early and ongoing advice, support and training for service users and carers in the fundamentals of research management and study leadership roles where required. These needs should be assessed before and during the study and reflected upon at the end. A clear job description with guidance could be agreed in support of the role
- Ensuring other training needs that would otherwise be provided to clinical research staff (as listed above) are identified for the service users and carers engaged in similar roles, and that they are enabled to access this training as necessary with similar support.
- Ensuring service users and carers in research teams are involved in the agreed delegation of responsibilities. This might be between sponsor and Chief Investigator, between sponsor and co-applicants or collaborators (and the organisations responsible for them) and between chief investigators and study teams. These should be written and agreed in a way that is understood between all concerned, including the service user and carer, with a clear explanation of terms.
- Including involvement in sponsor monitoring plans to ensure that it is happening effectively. Monitoring the involvement of their service user and carer research team members and co-applicants should occur throughout the life of a study, in order to support involvement, and this should be explicit. Monitoring activity might include conversations or face to face meetings with service user and carer research team members to check they feel able to meet their responsibilities rather than just a question to the research teams to confirm that they have included them.
- Ensuring training for sponsor representatives and other researcher leads about enabling involvement and service users and carers in a co-applicant or research team role.

Areas to be explored further

In scoping this paper, the following areas were identified for further consideration.

Contracts and written agreements:

- Consideration should be given to the different sorts of agreement that exist for service user and carer project team members or co-researchers and the risks and benefits of each type should be assessed. They could be analysed to see if they are adequate and proportionate and to identify examples of good practice.
- Consideration should be given to whether agreements should be in the form of a personal honorary contract, alongside a separate matrix to make clear the specific roles and responsibilities, or whether should this be more of a collaboration agreement. If the latter, how would the indemnity cover for the service user and carer be provided and is this covered by the NHSLA for service user and carer partners if an honorary agreement is in place?

Liability:

- Consideration should be given to the liabilities and personal risks for an individual who takes on specific roles and responsibilities on a project, for a grant, with and without an agreement in place with the sponsor and/or grant holding body.
- Consideration should be given to the liabilities for a sponsor/grant holding body conducting a study without written agreement with individuals undertaking activities within the study. Within this an examination of how the different sorts of agreements mitigate this risk should be undertaken.
- Sponsors need to be provided with clarity on legal and indemnity issues relating to service users and carers.

Grant funding awards

- Grant funders should consider the role of service users and carers as potential grant holders and incorporate this into their award literature. This guidance should include whether they are willing to award funding to individuals who are not based within an institution.
- A template needs to be created for the form of an agreement between a host institution and a service user or carer member of a research team or co-applicant where the institution holds a grant award for or with a service user or carer lead but is not the Sponsor.

Intellectual Property, publication rights,

- Guidance is needed on whether service user and carer research team members, co-applicants, and co-researchers are being considered equally for Intellectual Property and publication rights.
- Clarification is needed on whether different contracting arrangements impact on this.

Next steps:

To work with HRA and Involve on the three work streams identified. The R&D Forum SUCWG has agreed to lead work stream 1.

Please go to our online survey to support this work.

https://www.surveymonkey.co.uk/r/PBHVDS5

Thank you

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