NIHR Research Design Service for Yorkshire and the Humber Public Involvement in Grant Applications Funding Award Report

Introduction

Cardiovascular disease and diabetes are a significant cause of ill-health and death in England. The Yorkshire and Humber region have some of the highest levels of death due to heart disease and stroke in England, and levels of diabetes higher than the average for England. As a result, health promotion and ill-health prevention is a priority for the National Health Service.

In Yorkshire Ambulance Service (YAS), one of the ways to 'make every contact count' has been the introduction of an incidental findings guideline. Incidental findings are abnormal results found during medical tests, for example x-rays or blood pressure checks, which are unexpected. If you have a face-to-face assessment by a member of ambulance staff, you will nearly always have your pulse, blood pressure and blood sugar checked. The incidental findings guideline, provides advice to ambulance staff about what to do in the event that they find that a patient's blood pressure or blood sugar is raised above a certain value, or if the patient has an irregular heartbeat. The most common advice provided by the incidental findings policy, is to advise the patient that they should see their own GP about the abnormal finding, unless it is very high, or associated with other symptoms, such as dizziness, shortness of breath or chest pain, in which case the patient is likely to be taken to hospital, or the ambulance staff member will speak to the GP directly for advice.

No research undertaken about the impact on patient's health or primary care services when ambulance service introduce such guidance. A recent audit conducted in YAS has estimated that if the incidental findings guidance was followed by all staff, an additional 90,000 GP appointments would be required in Yorkshire and Humber region each year.

However, we do not know what happens when ambulance staff advise patients to see their GP as a result of an incidental finding. For example, patients might ignore the advice. Alternatively, they may visit their GP only to find that the incidental finding of concern to the ambulance staff has resolved. It is also possible that the GP will agree that further investigation is needed, or treatment commenced. If GP practices are overwhelmed with patients who have been advised by the ambulance staff to contact their GP, it may make it more difficult for other patients to access their GP.

Aim

The grant application was made to assist in developing a research proposal to address this knowledge gap. There were several important aspects to the research proposal that required advice from PPI groups:

1. Do service users want to know about incidental findings, when they have likely called the ambulance service for something completely unrelated?
2. Which is the most acceptable way to obtain consent and collect the data needed for the study?
3. How best to explain what this study is about and, once the study has been completed, how best to communicate the findings?

Method

Patient and public representatives were identified from members of the Sheffield Emergency Care Forum (SECF), which I sit on as an ambulance service advisor, and several other patient involvement (PI) groups with specialist expertise in cardiovascular disease, including stroke, and diabetes.

I held two meetings with approximately 20 PI representatives in total, with representatives from several PI groups. Prior to the meetings, I sent out a copy of the plain English summary requested that those attending to consider the 3 questions outlined above.

At the meetings, I briefly introduced the project and clarified any points that were not clear to attendees. I did have 2 fictitious case studies to help highlight the kind of patient encounter that were pertinent to the research study and these helped initiate discussion. There was also time to enable those attending to provide their own lived experience.

Having outlined when the incidental findings policy would be applied, I ask those attending what they thought about the current incidental findings policy and whether in their view it was an appropriate public health activity for ambulance services to be undertaking.

Next, I explained the three main methods by which the necessary permission to collect the data could be undertaken:

1. Confidentiality Advisory Group approval is obtained. Eligible patients are identified from the ambulance service electronic patient records and matched to their primary care record stored in one of two primary care databases, CPR-D or Research One.
2. Confidentiality Advisory Group approval is obtained. Eligible patients are identified from the ambulance service electronic patient records and the patient's GP contacted. The GP writes to the patient explaining about the study and providing an opportunity for the patient to opt-out of taking part if they wish. Primary care data relating to patients who do not opt-out is returned back the ambulance service with an anonymous identifier
3. The paramedic who sees patient obtains consent for their GP records to be accessed. The GP practice is informed about the patient, allocates a unique identifier and sends back an anonymised dataset having looked up the patients record

I outlined the benefits and drawbacks associated with each method and asked the group to order each of these methods in order of preference.

Finally, I asked for feedback on the plain English summary, and advice on how best to disseminate the findings from the study, before closing with a request for some of the attendees to provide PPI assistance and guidance should I be successful in obtaining a research fellowship to undertake the study.

Contributions made by patients and the public

Six of the attendees at the PI events kindly agreed to give their time and expertise in shaping the fellowship application to ensure that it remained patient focused and have offered to provide ongoing PI support should the fellowship application be successful.

Specific examples of their involvement in developing this proposal include:

1. Confirming that the study question is important and relevant to patients, and providing enthusiastic support for the early detection of cardiovascular disease and diabetes
2. PI members consulting with myself and their peers to seek clarification on terminology, and current awareness about how information is collected and shared between the ambulance service and primary care. They also explored their feelings around whether patients should be informed when an incidental finding is discovered. This was were subsequently included in the text of the application as they (and their peers) felt strongly that patients should know
3. PI members reviewed numerous drafts of the application and provided advice on the detailed research plan and plain English summary. In addition, they were able to provide guidance on how PI can assist with the planning, conduct and dissemination of the research study.

Evaluation of PI involvement

I evaluated PI involvement using questions based on the RDSYH PI feedback form. All 6 members of the PI group responded to the survey, although did not necessarily answer all questions. Table 1 provides a summary of responses.

Table 1: PI responses to survey

Question	**Response**		
	Yes	No	Did not answer
Did the researcher tell you how they would use your input in their grant application?	6	0	0
Do you know if your contribution has made a difference to the research application?	3	1	2
Did you enjoy the experience of assisting the researcher with their research?	4	0	2
Thinking about your experience, would you be willing to take part in similar activities in the future to help other researchers develop their ideas and their research proposals?	4	0	2

Four participants provided responses to the question: Can you let us know in what ways, if any, the researcher could have improved your experience? and Can you let us know in what ways, if any, the researcher could have improved your experience? (Appendix B). The following is a short account of the experience of one of the PI group:

> *"Richard involved lay people very early in his research plans. I think he has always been aware of the usefulness of service users and lay people in research plans. I was present at his presentation at a Sheffield Emergency Care Forum meeting, The proposed study was outlined and questions asked and answered by the forum members. He asked for volunteers to form part of a small PPI group to assist throughout his study. Two members volunteered and others were keen to assist later if necessary.*
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> *The two members met with three other people who had experienced pre-hospital care given by ambulance service paramedics.In my opinion, based on my own experiences, it is extremely important to patients, that symptoms picked up and recorded by paramedics, can help diagnose conditions which otherwise might not be picked up until much later when the condition might have become serious and treatment more intense and expensive. If these "incidental findings" can be recorded and used by other clinicians, then there should be more than on e satisfactory outcome i.e. :*
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> *one good/better outcome for the patient; one for the GP who can treat earlier; one for the emergency department and ambulance service clinicians and perhaps a financial saving for the NHS where an early diagnosis could prevent/avoid complications and possibly expensive surgery.*
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> *My experience of being part of the PPI group has been both interesting and rewarding. I have gained knowledge about the workings of the ambulance service and have felt that my contributions have been welcomed and thought useful. The group has been kept in close touch throughout the application process and we hope to continue to meet and give our input in funding is given to this very worthwhile research study."*

Overall, the feedback was positive. However, there were a couple of areas for improvement. While I had provided some feedback relating to changes to the application as a result of the PI input, this was not picked up by all members. On reflection, I should have checked to ensure if there were any outstanding queries or concerns.

The timelines for CDRF applications are quite protracted (the application took around 12 months to prepared), so it was no surprise that some members had difficulty keeping track. While I did try to keep everyone up-to-date, perhaps more frequency reminders and progress updates would have been helpful.

Patient and public involvement going forward

In the event that the CDRF is awarded, the six members of the study PI team will meet with myself approximately every 6-months, although they have all agreed to additional ad hoc communication as the study progresses. The PI team have kindly allowed their email addresses to be shared, allowing asynchronous group discussions on relevant study issues. This will also provide an opportunity to keep the team informed of progress, and to assist with the various applications that are required for the study. The PI team have a wealth of experience with study applications, including ethics and confidentiality advisory group approvals, which will be necessary to obtain.

PI is central to this study as it centres around a process that currently relies upon a patient being motivated to contact their GP. Having an ongoing dialogue with the PI team will help ensure that the analysis, conclusions and recommendations take clear account of patient behaviours and decision-making. In addition, since the PI team are also members of a wider community of patients and society, they have agreed to provide a broader perspective beyond just their own opinions.

Several members of the PI team have indicated that they wish to assist with the data analysis, as they have previous expertise in this area. However, all members will be involved in more general aspects of the study analysis, to ensure that patients remain the focus of attention, despite this being a data-only study, and providing advice on which simulations should be undertaken.

The PI team have also suggested that they can assist with planning the dissemination, by acting as the 'target audience' for the dissemination strategy and content. One example that has already been provided is to frame the results in terms of a fictitious patient.

From a personal perspective, the PI team who have already invested their time in supporting this application, has given me confidence as a novice researcher that I can successfully undertake this PhD with their support.

Challenges

The only obstacle that occurred during this process, was the processing of expenses, due to the bureaucratic finance procedures in place at the Trust. However, while laborious, these do ensure financial transparency.

Application outcome

I was successful in getting an interview and I am now just waiting to hear the results from the panel.

Appendix A: Funding breakdown

Item	Amount (£)
Love2Shop vouchers for PI attendees	289.00
Payment to Sheffield Emergency Care Forum refreshments	40.00
Payment to Sheffield Teaching Hospitals for PI refreshments	28.00
Total	**357.00**

Appendix B: Free text responses from the PI group

Please describe briefly what you were asked to do by the researcher

We met when required following showing an interest in the research topic. We were given information on what the research was about and what was expected of us. We gave feedback verbally or written on several stages of the applications about jargon any unclear information. Patient consent forms outcomes etc.
We reviewed the project summary (by email) at various stages of the research development. We also reviewed other documents by email.

During face-to face meetings, Richard gave us explanations about the purpose of the research, current Ambulance Guidelines procedure, and the concepts of the link to NHS data (which returns an anonymised data-set for use in further modelling), and the link of this data to further data-sets such as medical condition prognosis based on varying and various factors.

As a group, we also discussed the usefulness of the research, the relevance of the current guidelines and the ethical and data privacy considerations of asking patients to consent to their data being used in this research.

From refining his research proposal, attend a focus group, lay/plain English review.

I, together with others, were asked to comment and advise on how the researcher could develop his research idea. From that point on, a small group of interested service users were asked to further comment and advise on the proposal. The group confirmed that the research was important to patients, clinicians and to the NHS. The PPI group advised on the plain English summary, general terminology, data use and protection, and how the results might be later disseminated and used for patient benefit. At all stages the group was kept informed and involved in the progress of the application.

Can you let us know in what ways, if any, the researcher could have improved your experience?

I felt Richard kept us very up to date it was difficult with time lines and Christmas etc to always give speedy responses but that was circumstances beyond the control of Richard it was just logistics. My experience was a very positive one and I felt Richard was a very

considerate and knowledgeable researcher in his field. He was very considerate of our needs and asking what if any information we required to efficiently do the job.

Personally, I would like to be given some references to (completed) research which has used either a link to NHS-E data or to this type of modelling. I don't know how Richard has used our contributions, but until now (being asked about this) it did not detract from my experience. I don’t know whether he has kept a record of specific contributions from our group which have influenced him or which have been explicitly incorporated. If so, I would be interested to get this feedback.

Only in so much as the process is so long winded, maintaining familiarity with the proposal was very difficult - plenty of revision required!

My opinion, as one of the lay people involved from the outset, was sought and recorded and used in the application. I, and others, have been thanked for our continuing interest in the research planned. I have been made to feel that my contribution is worthwhile and useful. I don't think the researcher, Richard Pilbery, could have improved my experience - it has been/is excellent.