

# **Qualitative evaluation of the Health Research Support Service Pilot in Primary Care: facilitators and barriers to successful implementation at a national level**

**Final report of the independent evaluation of the  
Health Research Support Service (HRSS) Pilot in  
Primary Care**

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# 1. Overview

This report presents the findings of an independent qualitative evaluation of the Health Research Support Service (HRSS) pilot in primary care conducted in two general practices with a strong research background, one in Liverpool and one in Peterborough.

This independent evaluation of the Health Research Support Service (HRSS) specifically sought to explore the views and beliefs of all the stakeholders in the pilot project in relation to both the ethical and practical aspects of the project. We also conducted non-participant observation in meetings to set up the pilot project and at the five meetings of the Patient and Public Involvement Co-ordination Group (PPI CG). Finally we considered the views of potential stakeholders outside of the pilot project.

## 2. Background

### 2.1 Policy and academic literature

The NHS holds an extensive and invaluable electronic patient dataset, especially in primary care, but currently only limited use is made of this for research purposes. Using these data, particularly if then linked to other datasets, has the potential to improve the quality and safety of patient care. The value of linkage between routinely collected administrative data in order to answer research questions and aid clinical practice has long been established (Goldacre et al 2010). It has however been noted that record linkage studies tend to be limited to hospital data (Goldacre et al 2010). This suggests improving access to general practice patient records may be a priority.

The importance of greater access to electronic patient records for research was presented in March 2011 in The Plan for Growth (Dept for Business Innovation and Skills (BIS) 2011). It stated that the Government will build a consensus on using e-health record data to create a unique position for the UK in health research. The document went on to argue:

The NHS could offer unique opportunities for this country's international competitiveness in health research. Government can create the capacity to draw on the power of large linked data sets on a scale unprecedented here or elsewhere in the world. This would create unique opportunities for research in the UK, including more powerful uses of anonymised data sets and aggregated prescription data linked down to GP practice level. That can happen only if there is robust protection for individual patients' confidentiality and privacy. Enabling access through a managed health research data service would support clinical innovation and strengthen evidence of effectiveness, improving health outcomes. The Government will work with the National Information Governance Board and partners in the public and private sectors to publish plans by the autumn for a secure data service that is viable and affordable, and is focused on linking the data sets which do most to strengthen the international competitiveness of our life sciences research.

(BIS 2011: 93-94)

In the UK the two key pieces of legislation that impact upon the use of personal health information in research are the Human Rights Act (1998) and the Data Protection Act (1998). Baird et al (2009) argued that whilst such pieces of legislation are necessary for the protection of personal privacy and the close regulation of the use of sensitive personal information, the introduction of these Acts and the

associated requirement for the use of explicit consent may have created significant barriers to medical research.

Other protections for patients and the public in relation to the use of their health records are the common law duty of confidentiality and the Care Record Guarantee. Under the common law duty of confidentiality a healthcare provider wishing to disclose a patient's personal information to anyone outside the team providing care should first seek the consent of that patient. The Care Record Guarantee does allow for a number of exceptions for sharing health information one of which is that special permission may be given for sharing health records for research purposes (NHS 2011).

In summary it is necessary to gain informed consent before using health records for research unless special permission has been obtained. Section 251 of the NHS Act 2006 allows identifiable patient information to be used without consent in very specific circumstances. Under such arrangements patients may, for example, be required to 'opt out' of research as opposed to the normal arrangement of 'opting in'. In this respect it is useful to examine Greenhalgh et al's (2008) work on patients' attitudes to the summary care record and HealthSpace in which the consent model for the summary care record at the time was one of implied consent or 'opt out' (that is, unless a person explicitly withdrew consent, a summary care record was created). They concluded that despite an extensive information programme in early adopter sites, the public remained unclear about the current policy on shared electronic records. They further argued that people had limited understanding of what data are currently shared or what technical and access control measures are in place to protect their data. This work is important as it gives us some insights into the extent to which people engage in initiatives in relation to their health records.

Leading on from this, Buckley et al (2011) suggested that understanding the views of the public is essential if generally acceptable policies are to be devised that balance research access to general practice patients records with protection of patient privacy. They did however note that the topic is one that is recognised in the literature as being hard to grasp and about which much of the public does not feel knowledgeable (Buckley 2011), a view which is supported by Greenhalgh et al's (2008) findings presented above. Buckley et al (2011) conducted focus groups in which they found participants were positive about using names and addresses from GP records to make contact with patients in order to invite them to participate in research and in general were positive about the idea of anonymised data from GP records being used for research purposes, with a strong feeling that the outcomes of such research can be for the 'greater good'. Concerns were however expressed about data security. Finally when the use of identifiable data was discussed, all groups were positive in general about research being carried out, but felt strongly that the individuals whose information was being used should be asked for permission or at the very least told that this was happening (Buckley

et al 2011). These results from focus groups were then used to inform the development of a questionnaire. From the questionnaire 67.5% were unwilling to allow GPs to decide when researchers could access identifiable personal health information. However, 89.5% said that they would agree to ongoing consent arrangements, allowing the sharing by GPs of anonymous personal health information with researchers without the need for consent on a study-by-study basis. They concluded that their study suggested that prior consent arrangements allowing the supply by GPs of anonymous personal health information to researchers may be widely supported, and that populations willing to opt in to such arrangements may be sufficiently representative to facilitate valid and robust consent-dependent observational research (Buckley et al 2011).

To summarise, the value of using patient records for research has been noted by both Government and academia, yet this needs to be negotiated in relation to the various protections for patients in relation to the use of their data without explicit informed consent. The involvement of patients will be necessary if acceptable policies are to be devised that balance research access to general practice patients' records with protection of patient privacy.

## 2.2 The HRSS pilot in primary care

The Research Capability Programme (RCP) is a formal programme of work within the National Institute for Health Research. It was established as part of the Government's strategy, 'Best Research for Best Health' ([http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4127127](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4127127)), published in 2006. Its primary objective is to enable research to achieve its full potential as a 'core' activity for the NHS and in turn lead to improvements in the quality and safety of care. The Health Research Support Service (HRSS) is being developed as part of the RCP. The aim of the HRSS is to support researchers and enable high quality research. The HRSS is a service for researchers who need to use patient level data for research, including clinical trials. It will facilitate health research by providing high quality patient data quickly and efficiently. The HRSS aims to support research by providing:

- More timely access to better integrated information for research purposes
- More streamlined protocols for access to information
- Support for ground-breaking work on the health of the population
- Facilitation of recruitment of patients for clinical trials, for which the Primary Care system and GPs are a vital component

Almost all records in primary care are held electronically, yet only twenty percent of these records are used for research purposes. A consensus for best practice in relation to the use of patient records from general practice for research was published by the Wellcome Trust in 2009 (Wellcome Trust 2009). This consensus is upheld in the aim of the HRSS of improving access to patient level data sets for health research while ensuring that data integrity, patient confidentiality and privacy rules are upheld. This is done in a number of ways. Firstly the HRSS acts as an 'honest broker'. The honest broker function processes information from primary care records independently of both the data source and the researcher that requires the data. Secondly the HRSS operates according to strict information governance guidelines and is subject to independent audit. Finally, it is expected that the HRSS will reduce the need for researchers to use identifiable datasets by providing an advisory service and actively promoting the use of anonymised and pseudonymised datasets where appropriate.

The HRSS pilot has been set up to test the likely viability and potential benefits of the proposed service. In particular the pilot will provide insights into the challenges of acquiring, processing, linking and de-identifying data to allow researchers to have access to high quality data. As part of the pilot a limited number of research studies will be able to use the service for their research. The pilot will help identify any problems in these processes before the service is offered more widely. There will be a focus on improving the quality of data provided. The pilot study will also test how best to link data from a number of different sources to enable high quality research outcomes. GP practices involved with the pilot will work with members of the HRSS to examine the practical and ethical issues involved in providing access to electronic medical records for the purposes of research. Key issues that will need to be resolved include issues of patient consent; crucially the use of an opt out, as well as practical concerns such as the quality of the electronic data and costs involved in the transfer process.

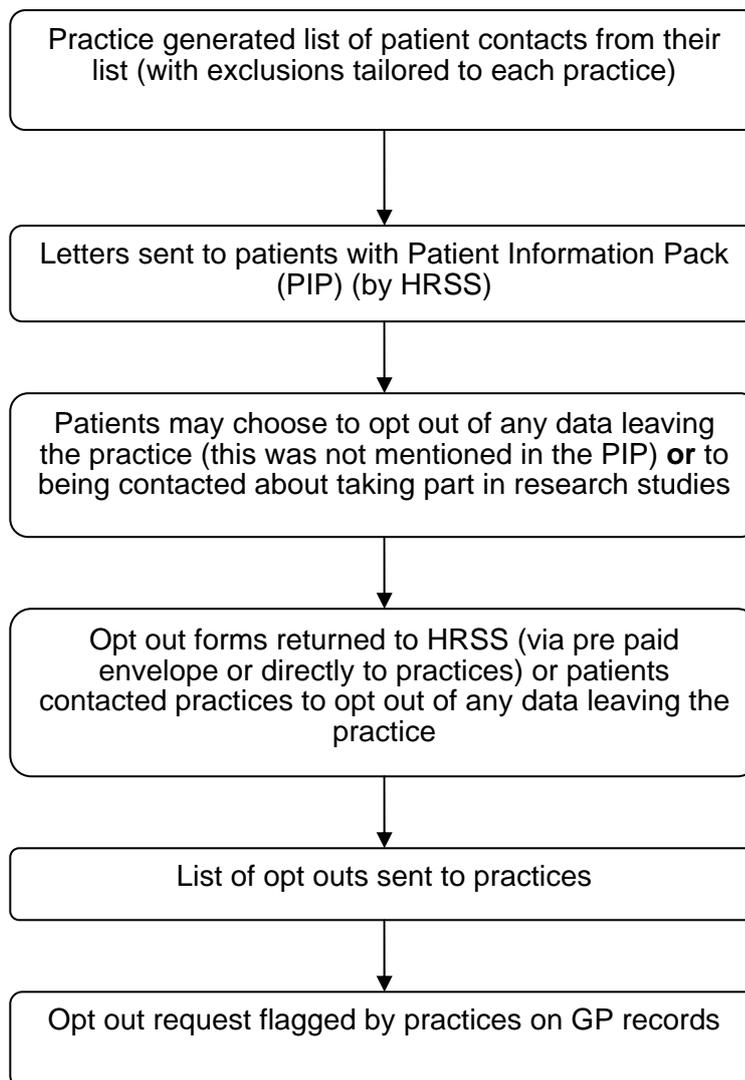
This report presents the findings of an independent qualitative evaluation of the HRSS pilot in primary care.

### 3. Implementation of the HRSS pilot in primary care

The HRSS pilot in primary care was conducted with two practices, one in Liverpool and one in Peterborough. The practices were recruited via the RCP pilot HRSS GP event held in January 2010. Representatives from these practices had shown interest in the programme and were thus self-selected. Both practices were strong research practices and are therefore atypical.

Our understanding of the process of the HRSS pilot in primary care is illustrated in Figure 1.

**Figure 1**



## **4. Independent evaluation of the HRSS pilot in primary care**

We conducted an independent evaluation of the HRSS pilot in primary care. Specifically we sought to explore the views and beliefs of all the stakeholders in the pilot project in relation to both the ethical and practical aspects of the project. We also conducted non-participant observation in meetings to set up the HRSS pilot in primary care and at the five meetings of the Patient and Public Involvement Co-ordination Group (PPI CG). Finally we also considered the views of potential stakeholders outside of the HRSS pilot in primary care. An outline of all the fieldwork conducted, with associated timelines, is given in appendix 1.

### **4.1 Aims**

To explore and describe the beliefs, views and behaviours of key stakeholders in the HRSS pilot in primary care and to identify key facilitators and potential barriers to the successful implementation of the HRSS at a national level.

### **4.2 Objectives**

- To observe and explore the interactions between participants at meetings to set up the HRSS pilot in primary care
- To observe and explore the implementation of the study processes in selected primary care settings
- To explore and describe beliefs about, and views of, the HRSS pilot in primary care of selected individuals from a range of stakeholder groups to include commissioners, patients and staff (such as GPs, nurses, practice managers and receptionists) in GP practices and people with an interest in the use of patient records for research

## **5. Methodology**

### **5.1 Ethical Approval and governance**

Ethical approval for the evaluation was sought through the Integrated Research Application System (IRAS) from the North West London Research Ethics Committee (REC) 1 (reference number 10/H0722/26), with only one non-substantial amendment to the protocol (the addition of the two freelance researchers on the project).

We also applied for Research and Development (R & D) approval through IRAS, and completed three Site Specific Assessment forms for Camden PCT, Liverpool PCT and Northamptonshire PCT. CRB checks were required and Camden PCT (NoCLOR) was our lead R&D site, completing the Occupational Health Checks for Fiona Stevenson, Louise Harrington and Nigel Lloyd, and signing off the research passports needed for access to the NHS resources. Letters of Access were then sent to us for each of these sites.

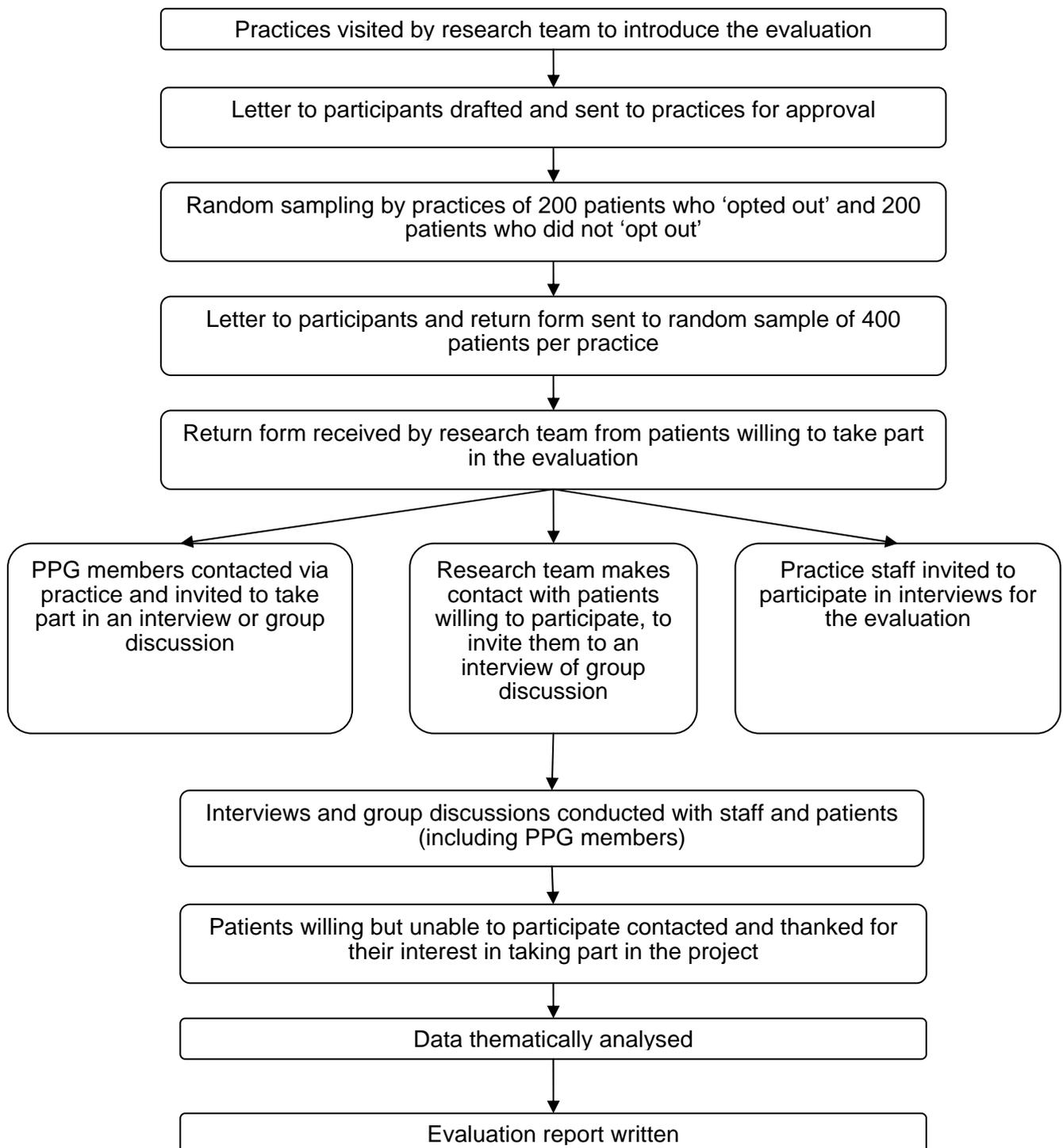
### **5.2 The steering group**

As part of our governance process we put in place a broad based steering group with an independent chair. The group comprised an academic GP (Chair), a senior academic with an expertise in policy work and a PPI representative. This group met twice and advised on the management of the project and involvement of various stakeholders.

### **5.3 Sampling of evaluation participants**

A diagrammatic overview of the methodology used in practices is presented in Figure 2.

**Figure 2 - Diagrammatic overview of methodology used in practices**



### **5.3.1 Patient participants**

Patient participants for the evaluation were recruited with the assistance of each practice. Each practice was asked to select a random sample of 400 patients - 200 patients who had opted out of their data being used to contact them to take part in research studies associated with the HRSS pilot in primary care, and 200 patients who had not opted out.

In order to invite patients to take part in the evaluation, each of the practices was provided with a letter to send out detailing the nature of the evaluation and what participation would involve. There was also a return form that patients were asked to complete with their contact details and send back to UCL (using a pre-paid envelope) if they were willing to take part in the evaluation (Appendix 2). Although we sampled equal numbers of people who had chosen to opt out and those who had not, we made the decision to send identical letters to all potential participants as we wanted to hear directly from participants what decision they thought they had made in relation to participation in the HRSS pilot in primary care. The letter invited patients to take part in their choice of an interview or group discussion at a local venue. It also stated that following participation they would receive a £20 voucher as a token of appreciation. Due to the short time-scales available to complete the evaluation, the return form stated that if they wished to participate, patients should return the form within 7 days of receiving it.

Each practice was asked to send the letter and return form to the 400 randomly-selected patients using practice headed notepaper.

#### **5.3.1.1 Return rate**

In total, of the 800 patients approached by the two practices 79 (10%) returned a form stating that they would be willing to participate in the evaluation. Response rates differed greatly between the two practices, with 57 participants from the Peterborough practice returning a response form (a response rate of 14%), and 22 participants from the Liverpool practice (a response rate of 6%).

It should be noted that although efforts were made to speak with as many patients as possible, 28 forms were received too late for involvement in the evaluation, we were unable to contact 6 patients and 2 did not attend an arranged group discussion.

### **5.2.1.2 Invitation to participate**

All of those patients who returned a form within the timescales available for the evaluation were contacted by the research team using their preferred methods of contact, and invited to participate in an interview or group discussion.

In addition to the random sample of patients from each practice, the research team were also interested in speaking with members of the 'Patient Participation Group' (PPG) at each practice. The research team worked with practice managers to make contact with representatives from each PPG, and to arrange to conduct interviews or group discussions with as many members as possible.

### **5.3.2 Staff participants**

The research team was keen to conduct interviews with as many relevant practice staff members as possible, and drew on the assistance of key staff within each practice (such as GPs and practice managers) in order to raise awareness of the evaluation, identify the most relevant staff to interview, and encourage staff members to participate. Interviews were conducted with all staff members that were available and willing to take part.

### **5.3.3 Key stakeholders outside of the practices**

We were keen to place the evaluation in context, an aim strongly supported by the steering group. To this end we decided to conduct interviews with people with an interest in the use of patient records for research and also to conduct non-participant observation at key meetings relating to the development of the HRSS pilot in primary care. A member of the project team attended a Nuffield seminar workshop on Information Governance in Health Care. The workshop consisted of a series of presentations and discussion on data linkage and anonymisation versus the use of identifiers in the context of the impact on research. It also considered legal and moral restrictions in relation to data linkage and such decisions in relation to anonymisation and identifiable data. All attendees were sent a brief outline of the HRSS pilot in primary care with a request to contact the team if they were prepared to take part in an interview. We recruited 3 people in this way. In addition we made 5 direct requests for interview, these were people either suggested by people interviewed, or identified as key figures in the academic literature. These 5 contacts finally resulted in an additional 8 interviews as we were introduced to a further 3 participants.

## 5.4 Evaluation participants

### 5.4.1 Patients

In total, 50 patients participated in interviews or group discussions across the two practices: 31 patients from the Peterborough practice and 19 patients from the Liverpool practice.

Six individual interviews and 4 group discussions were conducted with 31 patients from the Peterborough practice. Three members of the Peterborough practice's PPG participated in a group discussion for this evaluation. Eleven individual interviews and 2 group discussions were conducted with 19 patients from the Liverpool practice. Three members of the Liverpool practice's PPG participated in a group discussion for this evaluation.

Patient participants were not routinely asked to provide demographic information such as age, gender or ethnicity. However, gender of patient participants was noted and most patients also indicated their age. Available demographic information is presented in Table 1.

As Table 1 indicates, only a small number of patient evaluation participants (5) reported that they had opted out of their data being used to contact them to take part in research studies associated with the HRSS pilot in primary care, one of whom also reported having contacting the practice to request that their data not be included at all in the HRSS pilot in primary care. The vast majority of participants (40) reported they had not opted out, and the remaining 5 were unsure whether they had opted out or not. This strongly suggests, perhaps unsurprisingly, that a far greater proportion of the 400 randomly-selected patients who had not opted out of the HRSS pilot in primary care returned a form to indicate that they would be willing to take part in the evaluation, than of the 400 randomly-selected patients who had opted out of the HRSS pilot in primary care. Table 1 also shows a slightly greater number of patient participants were female (29) than male (21).

In addition, as may be seen in Table 1, older patients may be over-represented in our sample. Although the age of every patient participant is not known, the available age information suggests that very few patients under 30 took part in interviews and group discussions for this evaluation, and that at least 38% of the sample were aged over 60 (19 participants), and at least 32% (16 participants) were aged between 40 and 59 years of age. Whether or not this age distribution is broadly representative of the age distribution of those asked to take part in the HRSS pilot in primary care is unknown.

In addition, it should be noted that a number of patient participants stated that they had either a professional interest in the field of health (for example, being a current or former NHS health professional), or had a professional background in research (for instance, being a university researcher or academic), or both. In total, 9 of the 50 patient participants stated that they had either a current or former professional interest in healthcare or research.

**Table 1: Available demographic information for patient participants**

| <b>Age group</b>                       | <b>18-39</b>                          | <b>40-59</b>               | <b>Over 60</b>                                       | <b>Not known</b> |
|--|---------------------------------------|----------------------------|--|------------------|
| <b>Total number of participants</b>    | 1                                     | 16                         | 19   | 14               |
| <b>No. participants (Peterborough)</b> | 0                                     | 10                         | 14   | 7                |
| <b>No. participants (Liverpool)</b>    | 1                                     | 6                          | 5  | 7                |
|  |                                       |                            |  |                  |
| <b>Gender</b>                          | <b>Male</b>                           | <b>Female</b>              |  |                  |
|  |                                       |                            |  |                  |
| <b>Total number of participants</b>    | 21                                    | 29                         |  |                  |
| <b>No. participants (Peterborough)</b> | 14                                    | 17                         |  |                  |
| <b>No. participants (Liverpool)</b>    | 7                                     | 12                         |  |                  |
|  |                                       |                            |  |                  |
| <b>Reported opting out</b>             | <b>Reported <u>NOT</u> opting out</b> | <b>Reported opting out</b> | <b>Reported they were not sure of their decision</b> |                  |
|  |                                       |                            |  |                  |
| <b>Total number of participants</b>    | 40                                    | 5                          | 5  |                  |
| <b>No. participants (Peterborough)</b> | 26                                    | 1                          | 4  |                  |
| <b>No. participants (Liverpool)</b>    | 14                                    | 4                          | 1  |                  |
|  |                                       |                            |  |                  |

## 5.4.2 Staff

In total, 6 interviews were conducted with 7 different practice staff members (Table 2). A joint interview was conducted with a practice manager and a data manager. Interviewees included GPs and practice managers from each pilot practice, and included in each area, the members of practice staff who had been most directly involved in working with the HRSS to facilitate the practical implementation of the HRSS pilot in primary care. Despite agreement to participate in interviews from

other staff members we were unable to conduct more interviews due to unforeseen circumstances in the practices and the limited time available for the fieldwork.

**Table 2: Staff participants**

| Practice     | GP | Practice manager | Data manager |
|--------------|----|------------------|--------------|
| Liverpool    | 3  | 1                | 1            |
| Peterborough | 1  | 1                | 0            |

### 5.4.3 Key stakeholders outside of the practices

In total we conducted 8 formal interviews which were taped and transcribed and a further 3 informal discussions about which, with permission, notes were made contemporaneously. The participants consisted of people with an interest in the use of patient records for research, as well as those with a link to the HRSS pilot in primary care. Participants with an interest in the use of patient records in research could be characterised as those who worked on projects which involved the use of patient records, those that directed such projects and people who had set up and overseen large databases of patient records to be used for research. The details of participants are presented in Table 3.

**Table 3**

| Main responsibility                                    | Number of people* |
|--|-------------------|
| Worked in research using patients records for research | 7                 |
| Set up databases of patients records for research      | 3                 |
| Connection with the RCP / HRSS pilot in primary care   | 4                 |

\* Adds up to more than 11 as there is some overlap between categories.

We also attended workshops in which the HRSS pilot in primary care was presented to GPs and further meetings regarding the best way to approach research in general practice. Finally we attended all 5 of the PPI CG meetings.

## 5.5 Data collection methods

Patients who returned a form to indicate that they were happy to take part in the evaluation were contacted by the research team and invited to participate in an interview or group discussion.

All interviews and group discussions with patients took place within local, community venues. Interviews with practice staff and key stakeholders outside of the 2 participating practices took place

at their place of work. All interviews and group discussions were conducted face-to-face, and took place between the end of January and March 2011.

Prior to beginning data collection, participants were asked to read a Participant Information Sheet (Appendix 3), which outlined details such as the nature and purpose of the evaluation, how participants' interview data would be stored and for how long, and that participants views would be presented anonymously in research reports. All interviews and group discussions were voice recorded, and written consent for this, and for participation in the evaluation, was gained from each participant.

Prior to beginning the group discussion or interview, participants were asked if they would like a re-cap of the nature and purpose of the HRSS pilot in primary care. All patient participants and 7 of the stakeholders outside of the practices stated that they would. A brief re-cap was therefore given that encompassed the fact that the HRSS was an intermediary body and that patient records would be extracted from the GP system without identifiers being removed. It was stated that data would be held in a 'central repository' (safe haven) and that identifiers would be removed before being passed to any of the 5 projects involved in HRSS pilot in primary care. This was contrasted with what currently happens that researchers have to get data for research from each individual practice.

Non-participant observation was conducted at the workshops in which the HRSS pilot in primary care was presented to GPs, at further meetings regarding the best way to approach research in general practice and during all 5 of the PPI CG meetings. Contemporaneously notes were made. A brief presentation of the evaluation project was made at the workshops and at one of the PPI CG meetings. Only data for which express consent was obtained for use in the report appears here.

## 5.5.1 Interviews

All interviews were conducted with the aid of an interview topic guide developed to ensure that the key aims of the evaluation were addressed. Different topic guides were formulated for use with patients, staff, and key stakeholders outside of the 2 research practices (Appendices 4, 5, 6). A slightly modified version of the topic guide used with key stakeholders outside of the 2 research practices was used in the interviews with stakeholders directly involved in running the HRSS pilot in primary care (Appendix 7). Interviews with patients and practice staff typically lasted for between 20 and 30 minutes. Interviews with key stakeholders outside the practices varied in length from 45 minutes to 2 hours. This was an iterative process in which relevant topics raised in previous interviews were incorporated into the topic guide for subsequent interviews.

### **5.5.1.2 Group discussions with patients**

Group discussions were facilitated by two researchers, and typically involved between 5 and 8 patient participants. An interactive task was used to help facilitate the group discussion, which involved participants working in two groups and writing on a piece of flipchart paper:

1. What they knew/understood about the HRSS pilot in primary care (prior to being given a re-cap by the researchers)
2. Their views and opinions of the HRSS pilot in primary care (both prior to being given a re-cap by the researchers, and following this re-cap)

Participants were given 5 or 10 minutes to complete the group task, and then the flipchart paper was displayed and each group's notes used as a basis around which to begin the discussion. The discussion was then guided by the interview topic guide (Appendix 4). Group discussions typically lasted for between 50 and 70 minutes. This was an iterative process in which relevant topics raised in previous groups were incorporated into the topic guide for subsequent groups.

## **5.6 Data analysis**

All interview and group discussion data were recorded digitally, with consent and then fully transcribed. A thematic analysis was conducted on all qualitative data collected for this evaluation. The key aims of the evaluation and the interview topic guides provided a useful framework around which to analyse the data. The analysis drew out the key themes that emerged in relation to patient and staff beliefs about, and views of, the HRSS pilot in primary care.

## 6. Results

### 6.1 Practice involvement in the HRSS pilot in primary care

Both practices stated they had initially been introduced to the idea of becoming involved in HRSS pilot in primary care through their practice's 'academic GP', who had found out about the HRSS pilot in primary care through membership of the NIHR Primary Care Research Network (PCRN). In each practice the academic GP had been instrumental in introducing the practice to the pilot and in driving the practice's involvement in it.

In both practices the majority of the day-to-day running of the pilot had been undertaken by one key staff member. Within one practice, this key practical role has been undertaken by the same GP who had led on the project, whereas in the other practice, this hands-on role had been undertaken by the data manager within the practice.

It was clear from interviews with practice staff that staff knowledge and practical involvement in the HRSS pilot in primary care was located within a small number of staff members in each practice. Staff interviewed at both practices stated that there was unlikely to be a practice-wide understanding of, or involvement with, the HRSS pilot in primary care, and this was typical of the way in which research projects were routinely managed within these practices. As one staff member commented:

*Really research is totally detached from the rest of the practice and has been up to now.*

(Practice staff)

Some staff members felt that ideally most staff would have an understanding of the research projects taking place within their practice at any one time, but in reality, research tended to sit specifically within the roles of particular staff members, and realistically, there was insufficient time for all staff to become familiar with these research projects. As a staff member explained:

*...in the ideal world you'd involve everybody so they all know what everybody is doing across the board, but it's just protected time for gleaning that information, you know, and I think those practices is the same, just isn't the hours in the day. And there isn't any protected time anymore.*

(Practice staff)

## 6.2 Patient participation in the HRSS pilot in primary care

On a pilot-wide level, practices were encouraged by the HRSS to engage members of their PPG. There were also 5 meetings of the PPI CG. One of the practices had been successful in recruiting patients to sit on this group, whilst the other practice had struggled to engage members of their PPG in this national forum. Staff at this practice felt that the reason for this lack of engagement was the fact that they had a small PPG, which was very active, but that was not interested in attending national meetings in London. As one staff member explained:

*It feels like we've almost failed on some part to engage our patient population in this, as well, so they've [the HRSS] wanted some patient engagement and there's meetings in London... and actually, our patient group are fantastic, but ....they're not interested in anything this big really.*

(Practice staff)

Discussions with members of the practice PPGs revealed that, particularly in one of the practices, the practice PPG was often consulted about the research projects being undertaken by the practice, and asked to give feedback on the planned implementation of projects or on the project patient information. PPG members at both practices stated that their PPG had been informed as a group that the HRSS pilot in primary care was taking place. This had been done by a member of practice staff who attended the PPG meeting and provided a basic explanation of the project, and its potential benefits. However, it was clear from group discussions with PPG members that they would have valued more consultation and a more active involvement in the local implementation of the pilot, and in the development of the Patient Information Pack (PIP) (appendix 8). Some patient representatives felt that in the case of the HRSS pilot in primary care, they had not had the same degree of involvement as they often had with other research projects conducted within their practices.

An interesting finding from these discussions with PPG members was that they felt strongly that the PIP provided was difficult to comprehend for most patients, and provided insufficient information about the project. The members of the PPG we spoke to felt that if they had had input into the development of the patient literature, this would have resulted in the information being more patient-friendly and comprehensive in its explanation of the HRSS pilot in primary care.

## 6.3 Impact and concerns about potential impact of the HRSS pilot in primary care for practice

Staff highlighted a number of concerns regarding the actual and potential implications of the HRSS pilot in primary care for their work. Thus, staff at one practice discussed an increased workload as a result of work carried out on the practice database preparing information for the pilot mail-out and in coding patient records for those patients who had opted out of taking part in the pilot. No issues were expressed by staff at the other practice in relation to any increased workload resulting from involvement in the HRSS pilot in primary care.

Concerns were expressed about the future potential disruption to IT systems associated with data extraction. Practice staff at one practice stated that there was a lack of clarity in relation to aspects of the extraction process, and specifically, in relation to who would take on the responsibility of developing and applying the database queries for the pilot. This resulted in concerns regarding the potential level of practice involvement and resources required. As one staff member explained:

*I suspect it's going to be us [the practice] doing the queries, but I thought they [HRSS team] could be doing the queries rather than us, so I'm confused now, how this is actually going to work.*

(Practice staff)

Reassurance had reportedly been sought from members of the HRSS team that the data extraction process for the pilot would be conducted only once, when the server was not under 'heavy demand', and that this process would not disrupt or interfere with the running of the electronic patient record system. A staff member explained as follows why s/he was concerned about the implications of the extraction process for the practice IT systems:

*..if it's done once and you have a nightmare, that's, you can live with that but if it's being done continuously, it would be a real problem.*

(Practice staff)

In addition, staff members across both practices were concerned about issues relating to confidentiality and patient consent. These staff members explained that the process of consenting patients into this research project was completely different to any previous research projects that the practices had been involved in, which always involved gaining explicit consent from patients to use

their data for research purposes. In addition, staff expressed concerns regarding the sharing of identifiable patient data with the HRSS. A staff member stated:

*...this is, you know, full identifiable patient data sitting in a warehouse. Although access to that we've been assured will be restricted when the researchers come to look at it, but the fact is that we've handed over un-anonymised patient data to sources who aren't directly involved in the patient care, which in terms of information governance is a bit of a big no-no really.*

(Practice staff)

Staff were unclear about the potential implications were the pilot to be rolled out nationally. Thus, some staff felt that there could be an increased workload for practices, in terms of conducting database queries and searches, or in running reports or pulling off data for the project. In contrast, other staff envisaged the extraction of data taking place through the use of a software package, without the need for the practice to be involved to any great extent, other than in ensuring the security of the data extraction and data management processes. A staff member explained:

*It will be a matter of a software process that we'll need to authorise and we'll extract the data without really our involvement, because obviously it's not viable to be involved in it, because you know, it's getting to be something that has to be automated, otherwise there's no point. So I think moving forward the idea is not to really know too much about what is happening except that it's happening securely. So it's not something you expect to be actively involved in any particular way other than ensuring, you know, safety, integrity, data management, so there may need to be checks for that.*

(Practice staff)

Some staff also discussed the potential for an increase in GP consultation time taken up with discussing aspects of the HRSS pilot in primary care, explaining elements of it to patients, and generally answering patients' queries regarding it. Some staff felt that this increased burden of enquiries regarding the project was likely to be greater within practices that did not generally get involved in research, where patients were not accustomed to being invited to take part in research projects. In addition, some staff felt that GP practices in areas of greater 'deprivation', or those with high levels of language and literacy issues, were more likely to receive greater numbers of enquiries from patients relating to the project and what it means for them. As a staff member commented:

*In the practices where you've got deprivation, literacy problems, you know; patients will be saying, 'what about this letter? I'm making an appointment to find out what this is about'... So it depends on the practice as well really, and what sort of area you're practising in.....*

(Practice staff)

Another said:

*You send a letter out to patients where there's literacy problems within the population; they're straight on the phone – 'I've had this letter, what's it all about?', you know, because they can't even really digest what's in it.*

(Practice staff)

However, the vast majority of staff interviewed for this evaluation stated that they had not received any queries from patients regarding any aspect of the pilot. One member of staff at one of the practices stated that s/he had had a small number of queries from patients requiring clarification of the system of opting out as they were only familiar with a system of opting in.

Some staff felt that unless the administrative work for the HRSS was conducted centrally, by the HRSS or the Primary Care Trust (PCT), there would be financial implications in terms of the remuneration to practices for the time spent coordinating patient involvement and managing the patient opt-out process, as this was unlikely to be viewed by practices as a core part of NHS work. In addition, some staff were concerned about the potential for a deterioration in practice-patient relationships if patients felt that they had not been properly informed about, or consented into, the HRSS.

## **6.4 Knowledge and understanding of the HRSS pilot in primary care**

### **6.4.1 Staff**

All 7 of the staff members who participated in interviews for this evaluation were aware that their GP practice was involved in the HRSS pilot in primary care. However, the level of knowledge and understanding about the HRSS pilot in primary care, and what involvement in the pilot meant for the practice, for patients, and for patient data, varied between staff members. The staff members with the greatest levels of knowledge and understanding were those who had had direct involvement with the

HRSS pilot in primary care, for instance by being directly involved in the data management process, or by working directly with the HRSS team to facilitate their practice's involvement in the pilot. These staff members had a clear understanding of the rationale for the HRSS, and of its aims and objectives, and also had an understanding of the practical implementation of the HRSS pilot in primary care, such as the fact that the data would be extracted from the practice in a non-anonymised form, stored within the HRSS, and drawn on by research teams.

The level of knowledge and understanding of the HRSS pilot in primary care was lower amongst staff members who had not been directly involved in the project, and it was clear from interviews with staff that detailed information about the HRSS and the practice's ongoing involvement in the pilot, was not typically disseminated amongst the whole staff team within practices. Staff who had not been directly involved in the HRSS pilot in primary care were generally aware that the practice was involved in the pilot, and that the pilot involved patient data being stored externally to the practice and used for research purposes. However, there was a lack of knowledge and understanding amongst this wider staff group, that included some GPs, about the practical aspects of the practice's involvement in the HRSS pilot in primary care, such as precisely what patient data would be extracted and how this would be done, whether or not data would leave the practice in an anonymised form, and how the data would be used. Indeed, in some cases, staff were unaware of key practical aspects of the HRSS pilot in primary care, such as that data would leave the practice in a patient identifiable form.

In addition, some of those who had been directly involved in the HRSS pilot in primary care, although generally well-informed about it, also remained unclear about some of the precise practical detail of the pilot. In particular, these staff members were unclear about issues such as the number and frequency of data extractions that the HRSS would make, and how and where the extracted data would be stored. This lack of clarity may be due in part to the fact that some of the data collection for this evaluation took place prior to the HRSS team re-visiting practices to clarify some of the practical issues related to data extraction and storage. Nevertheless, it was clear that the way in which patients' data would be extracted and stored was a key factor in whether or not practices felt that they were happy to be involved in the HRSS pilot in primary care. As one staff member stated:

*We've got some real questions... I suddenly thought, 'hang on, how does this work, are they going to do this'... are they going to come in and interrogate it, and say right, we've got a query here, we're going to interrogate that and take out the answers of the query and put it over here, or are they going to every night go right, take all the data out of your system, leave it in our system overnight, update it the next day, and every day are they going to be coming into our system, taking all the records out and putting them in their system, so they can do what they like with it when they've got it there... So*

*we have to ask that question, when they're coming up to meet us. I think if they said, 'no no, we're going to empty your data every night and update it every day', we'd be much less happy...they [the HRSS] are getting to the stage where, who's going to do it, where's it going to be stored, how's it going to be stored. That might be the end of our involvement... if colleagues aren't comfortable with the model that's been suggested, then it will go.*

(Practice staff)

## 6.4.2 Patients

Interviews and group discussions with patients highlighted a widespread lack of knowledge and understanding of what the HRSS pilot in primary care is, what it involves, and of its aims and objectives. As stated earlier, the research team provided participants with a brief overview of the HRSS pilot in primary care prior to each interview or group discussion with patient participants. The vast majority of patients had little clear understanding of the HRSS pilot in primary care prior to this overview. For example, the vast majority of patients were unaware that the pilot would involve their non-anonymised data leaving the practice to be stored externally and that this data, in an anonymised form, would then be subject to analysis by selected research teams. It was clear from interviews and group discussions, that patients had failed to understand the nature of the HRSS pilot in primary care, with patients tending to have either no understanding at all of what the HRSS was, or else a very limited understanding – for example, simply that the pilot involved 'something' about using patient data for research purposes. The following quote neatly sums up the level of understanding of the HRSS displayed by most participants:

*I didn't understand anything about the Health Research Support Society, or whatever it's called, but I had a letter, initially from the GP saying that this research was being... taking place in the future.*

(Patient)

Fewer than ten per cent of the patients who participated in this evaluation had a clear understanding of the HRSS pilot in primary care. Those patients who had the clearest understanding of the pilot were either GP practice PPG members, or had worked in health research themselves, although it is important to point out that a number of PPG members also had limited understanding of the HRSS pilot in primary care, as did the vast majority of participants who had a professional health or research background.

In addition to lacking a clear understanding of the HRSS pilot in primary care, a number of participants' had misunderstood the nature of the pilot. The most common misunderstanding was that the HRSS pilot in primary care was similar or identical to the Summary Care Record, and that the HRSS pilot in primary care would involve other health professionals gaining access to patient data, rather than research teams. Other patients had understood the HRSS pilot in primary care to be part of an existing, on-going research project that their practice was involved in, some were not aware that their data would leave the practice, and a number of others stated that they had understood that their data would leave the practice, but had understood that it would leave in anonymised form. As one patient stated:

*I think I probably thought that it was more that it was just kept at the doctors and when people wanted it, they came, sort of, to the doctors rather than being in a central place where everyone's information was*

(Patient)

Another stated:

*Yes, I think my understanding is very much that any data would be anonymised so that I couldn't be identified.*

(Patient)

It was clear then, that few patients had a clear understanding of what the HRSS pilot in primary care was. This may have been due, in part, to the information received by patients regarding the HRSS pilot in primary care. As discussed in more detail later, fewer than one-quarter of the patients who participated in this evaluation were sure that they had received the 'Information on the HRSS: Improving health through research' booklet that provided further details of the HRSS pilot in primary care, with more than half stating that they definitely had not received it, and approximately one-quarter that they were unsure whether or not they had received the booklet. However, the impact of any failure to receive the information booklet may be minimal, since lack of understanding of the HRSS pilot in primary care was apparent amongst those who stated that they had received the booklet as well as amongst those who were unsure or who stated that they had not.

## **6.5 Patients' knowledge and understanding of their role in the HRSS pilot in primary care**

Interviews and discussions with patients also highlighted a lack of understanding of what involvement in the HRSS pilot in primary care would or might mean for them. For instance, very few patients understood what would be done with their health data once it was extracted by the HRSS – at most, that it would be used for ‘research’.

The vast majority of patients had no clear understanding of what would be done with their data once it left the practice, who would have access to it, or their potential level of future involvement in the HRSS. In particular, very few patients were clear that once their data was stored within the HRSS it might be analysed by a research team, that they might be invited to take part in a research project, or both. Typically, those who had some understanding of what might be done with their data once it was extracted to the HRSS and what their future involvement in the HRSS might be, felt that it would either involve a ‘number-crunching’ exercise on patients data with no future involvement from them, or else that the HRSS pilot in primary care was ‘another’ research project similar to ones they might have participated in in the past, and that they might be called on to take part in a research project at a later stage. Within this group there was a lot of discussion about the fact that the data would be held by an intermediary body (a ‘safe haven’) which was part of the NHS, and that the research teams would not have access to non-anonymised data. Although the term ‘safe haven’ was not used the concept seemed well understood.

It was clear also, that there was a lack of understanding regarding the ‘opt-out’ of the HRSS pilot in primary care, and what this opt out meant. The ‘opt-out’ process is described further in section 6.9 of this report. However, it was clear from this evaluation that few participants who had opted out of the pilot had understood that they were simply opting out of being contacted to take part in a research project, and instead felt that by ‘opting-out’ they were opting out of participation in the HRSS pilot in primary care as a whole, and thus were unaware that their data would still be included in the data extracted for the HRSS pilot in primary care.

## **6.6 Participants’ perspectives on the HRSS pilot in primary care**

### **6.6.1 Staff**

All of the staff who participated in interviews and group discussions were supportive in principle of the HRSS pilot in primary care. Staff who had a good knowledge of the aims and objectives of the HRSS pilot in primary care, and in particular those who had been directly involved in the implementation of the pilot within their practices, tended to be especially positive about the potential benefits of the

HRSS, with those staff members who were less well-informed about the HRSS still feeling that it was a good idea in principle and to be encouraged and supported. As one staff member stated:

*We're seeing it as a very important project. So we've always, kind of, wanted to use data efficiently and been frustrated that the NHS doesn't generally use data efficiently, so you know, it's certainly ticked the box as far as what we believe should happen about the appropriate use of data.*

(Practice staff)

GPs in particular, highlighted a number of potential benefits that a nationally implemented HRSS would bring about, in particular, the positive impact that a successfully-run HRSS could have on health research. For example, GP's saw the potential of the HRSS to greatly increase the pool of patient data available to health researchers, as well as enabling a more representative sample of participants to be involved in clinical trials. For GPs, this greater pool of data and more representative sample of participants would help to facilitate more robust research and help health professionals to make more effective clinical and healthcare planning decisions, thus benefiting patients. As one GP stated:

*...you've got an opportunity with a research project to say that we can do some higher quality studies that are more representative in terms of the participants, so that when we do a randomised controlled trial, we know that we've actually got a wider perspective of the population with that condition who've been studied, so we've got a more accurate and more reliable answer as to how likely it is that the individual sitting in front of us would benefit from that treatment. That, I would have thought would be good, for the individuals to know that when they go to their doctor, that the recommendations are being made about how that care is going to be managed would be better, because we've developed more efficient and effective mechanisms to recruit a more representative population sample.*

(Practice staff)

Another stated:

*The more information we have about how illness works, the better we can obviously plan how to deal with those things and the implications for patients individually. But also, a practice population of saying 'okay, we've got this many patients who have this problem or who are this heavy or who are, you know, their blood pressure is this high*

*and that means that we need to have X amount of money set aside because we know this many of them will have a stroke. This many of them will have a heart attack’.*

(Practice staff)

Cost benefits of the HRSS were also highlighted by GPs. For example, the centralisation and automation of data analysis processes was highlighted as a factor that would allow health research to be conducted more efficiently and at lower cost. GPs also highlighted the potential cost savings that could be made through basing clinical decisions about treatments on better quality research evidence. As one GP stated:

*As a clinician, I know, I’m never quite sure why I stopped doing certain things and starting using something new and more expensive, because I didn’t really see that there was much wrong with what I was using before, and I’m not convinced that they’d ever been put head to head. But a new ulcer drug comes out, we stop using the old one, and although in theory it’s supposed to be better, has anyone ever actually put a thousand patients through a direct comparison and said well, it works better for this, but not necessarily for that. Because it might cost, you know, we’re in an expensive world, if we could save money in some areas we could spend more in others.*

(Practice staff)

Although most staff members were supportive of the HRSS pilot in primary care, most also stated that they had previously had, or continued to have, some concerns about the pilot. These concerns typically revolved around the safety, security, and confidentiality of patient data. For instance, some staff members stated that when they had found out about their practice’s involvement in the HRSS pilot in primary care, they had been concerned about factors such as how the data would be held, where it would be held, in what format it would be held, who would be allowed to gain access to the data, and whether the data would be anonymised or not. These staff members typically stated that a visit from the HRSS team helped to allay these concerns, and that they were now satisfied that patient data would be stored and accessed in an appropriate manner.

In addition, interviews with staff members highlighted that within practices, there had been some disquiet amongst staff members about the practice’s involvement in the HRSS pilot in primary care. Interview data suggest that different staff members within practices held differing views on sharing patient data and on consenting patients into research projects, with some having a more ‘liberal’ approach to data-sharing than others, and that there was some concern that the consent and data-sharing procedures in place for the HRSS might conflict with practices’ established principles and

practices in relation to consent and confidentiality. Interview data, as well as discussions with staff within practices, suggest that some of these concerns persist within practice teams.

## 6.6.2 Patients

Although patients who participated in interviews and group discussions for this evaluation generally had a poor understanding of the HRSS pilot in primary care, they nevertheless indicated widespread support for the pilot, once the researchers had explained its nature and purpose. The vast majority of patients stated that they felt the HRSS was a good idea and a number highlighted potential benefits that they felt the HRSS would bring about. Patients with a health service or research background tended to cite more specific potential benefits of the HRSS, seemingly through having a more detailed knowledge of the area. The majority of patients, however, were broadly supportive of the HRSS because of its focus on improving health and health outcomes. As one patient said:

*I haven't got any qualms about it [the HRSS] anyway, its health, how are you going to get progress if somebody doesn't look into it, do you know what I mean, so I'm not worried about that really.*

(Patient)

Another stated:

*If somebody can make a breakthrough, you know, with something, a piece of research, I mean, isn't that what it's all about?*

(Patient)

In a number of cases, the potential benefits of the HRSS cited by patients were similar to those highlighted by staff members. For instance, some patients highlighted the potential of the HRSS to provide health researchers with a greater pool of data on which to draw, and larger research sample sizes. They also felt that the HRSS could encourage greater numbers of GP practices to become involved in research. One patient stated:

*If you did it [implemented the HRSS] and had a wider range, sort of, all over England, then you'd have a very good, sort of, base to pull stuff out of.... So yes, I think it would be a good thing and as I say, with so many people coming from different places, there's going to be issues that affect certain communities, which perhaps they've not really sort of looked at at the moment, or don't know much about at the*

*moment...You'd be getting a much wider range of, sort of, different races, different ethnicities, because obviously certain groups have different issues don't they?*

(Patient)

A number of others saw the benefits of the HRSS primarily in terms of the 'streamlining' of health research processes, for instance feeling that the HRSS had the potential to help speed up health research by centrally storing patient data, and helping to better coordinate research. As one patient said:

*[The HRSS might] cut out, avoid unnecessary duplication of information. It might speed things up in terms of research processes.*

(Patient)

Another said:

*In terms of research, it's probably going to be helpful because having data sort of collated from different areas already is obviously going to facilitate things, it might speed processes up.*

(Patient)

A number of patients then, highlighted the potential of the HRSS to help streamline and facilitate the research process. This was often discussed in the context of the HRSS benefiting patients, by helping health professionals to build health-related knowledge, better understand of diseases, improve diagnosis, and develop more effective treatments. These patients tended to view the streamlining role of the HRSS as potentially important in helping research to be conducted more efficiently, both in terms of time and money, and thereby speeding up the time it takes to develop new treatments. As one patient said:

*I mean, because I know that when you develop a drug it can take years and years and years to go through all the trial stages. If that could potentially make things quicker, and you get an anti-cancer drug or something for someone who hasn't got that time for it to become licensed then it's... it's only going to be beneficial*

(Patient)

Another stated

*I think if you're going to do something like treat cancer, treat something, eczema, allergies, something that affects one in five people you need the huge samples in order to do it... the time it takes for a researcher to do that going by surgery to surgery, it's just not economical and it's not a good way of resources in this climate; when we've got such short resources you need to make the most of it.*

(Patient)

Although there was widespread support for the HRSS amongst patients, two patients voiced concern about the HRSS and felt that it was not a good idea for a central, intermediary body such as the HRSS to hold patient data and facilitate research. One of these patients was particularly concerned about the fact that non-anonymised patient data would be held by a body that was detached from the patient whose data was being held, and that had no personal relationship to the patient. For this patient, the storage of such data within a body like the HRSS was fraught with risk, and this patient far preferred for patient data to remain 'within' the practice. This patient commented:

*The fact that it's there in an unanonymised way, with a large number of people who have nothing to do with that patient, who have no duty of care individually to that patient, having access to that data is problematic and could cause problems in the future.*

(Patient)

Similarly, the other patient who voiced concerns about the HRSS in principle, stated that it seemed too impersonal and detached from the patient, and that she preferred the more direct, personal approach, where health data was stored locally. This patient said:

*I suppose it makes it easier for you, or whoever's doing it. But it just strikes me as like all part of the... this big, anonymous world, you know, where individuals don't seem to... you know, not be respected as much... My gut feeling is no, I don't, I wouldn't be happy with it. I don't see why it can't be as it was, a more direct, personal approach.*

(Patient)

## **6.7 Participants' views and feelings about data being shared**

### **6.7.1 Patients' feelings about their data being used in the HRSS pilot in primary care**

The vast majority of patients who participated in this evaluation were happy for their GP practice to share their patient data with the HRSS pilot in primary care. However, for the majority of these patients, their support for the sharing of their data with the HRSS pilot in primary care was not absolute, and they highlighted a number of restrictions and parameters that they felt needed to be in place in order for them to be completely happy with their data being shared. For example, most participants were happy for their data to be shared with the HRSS pilot in primary care so long as these data were 'protected' and stored safely and securely, and restrictions were placed on who was allowed to have access to it. In addition, a smaller number of patients also felt that that they were happy for their data to be shared, so long as only data that were necessary and relevant were shared with the HRSS pilot in primary care. The following quotes, sum up the views and feelings held by most patients about their health data being shared with the HRSS pilot in primary care:

*It's the misuse and, you know, and who was really looking at it. That's my only sticking point and I kind of think that will be a sticking point for a lot of people.*

(Patient)

And:

*I would also want a reassurance as well, though, that if, for argument's sake, my data were used for a specific clinic or whatever project, that only that which was required for that project would be released, such as I wouldn't want companies to know what I do for a living, anything, you know, that sort of stuff because it's not relevant... So it's limited to only that which is required.*

(Patient)

The notion that only 'necessary' and 'relevant' data should be shared with the HRSS was also a theme that was highlighted during patients' discussions of issues around the sharing of non-anonymised patient data. When the nature of the HRSS was explained to patients by the researchers, there was often also an assumption amongst patients that their data would be anonymised before it was shared with the HRSS. A number of participants were concerned about their data being shared in identifiable form, and were particularly concerned about the possibility of it being shared with details of their names or addresses attached to it. Some of these participants failed to see the relevance of such personal identifiers, and why data that left the practice could not be in anonymised form. These patients, although still willing for their data to be shared with the HRSS, were clear that they would have far preferred it to be shared in anonymised/non-identifiable form, and particularly without names and addresses attached to records, typically because of concerns about data security.

In addition, a small number of patients stated that, although they were happy for their data to be shared with the HRSS, they would have liked more information about their practice's sharing of their data with the HRSS, in order to be completely at ease. This additional information included, detail about precisely what data would be shared, in what format, and how it would be transferred.

Very few of the patients who participated in this evaluation were completely opposed to their data leaving the practice in identifiable form, and those who were stated that they felt this way because of concerns over data security. One such patient stated:

*I personally feel very strongly that we should not go in as identified data. And there are ways of doing that which, you know, can identify... the practice can identify the patient, and follow up anything if need be, but Joe public in the HRSS can't identify the patient*

(Patient)

Whilst the majority of patients who participated in interviews and discussions were happy for their health data to be shared with the HRSS, it was clear that the HRSS being part of the NHS, and patients' shared data being kept within the NHS, was important to many patients' willingness for their data to be shared. Many patients voiced some concern about the sharing of their health data, particularly in non-anonymised form, with organisations external to the NHS.

A small number of patients stated that they would be less happy for their data to be shared with the HRSS, if the HRSS were a commercial company. These patients were typically suspicious of the use that a private company might make of their health data, and of whether a private company would act completely in the public interest. A larger number of patients also voiced concern about the possibility of private organisations, and especially insurance companies, gaining access to their data, now or in the future. For these patients, the fear appeared to be that insurance companies gaining access to this data might result in patients being refused health, travel or life insurance, or their claims being refused. Patients tended to be clear that patient health data was a potentially valuable resource for private companies, and many were keen that their data should not be allowed to fall into their hands. As one patient stated:

*One of my fears was if it somehow goes astray from there and somebody, for instance, like insurance companies, get hold of it they could use it to their advantage and the patient's disadvantage.*

(Patient)

Another said:

*...there's a lot of information that companies would be very eager to purchase that would... you know, they'd be able to target people or refuse certain people benefits or claims, or whatever.*

(Patient)

Another commented:

*...once it's held, you know as well as I do, what's to stop, in the fullness of time, insurance companies coming up and saying oh, we'll give you... buying data; and they do*

(Patient)

In addition, interviews and discussions also highlighted the concerns held by a number of patients, about their freely-given health data being accessed and sold on for commercial gain, or used for profit, by profit-making pharmaceutical companies. These patients tended to feel that their data should be used for the public good, and were generally keen that it should not be used for the financial benefit of commercial companies, or at least that if this were the case, patients should be fully aware of this. As one patient stated:

*I would have a reservation about my personal information being used for the profit of a private drug company... I'm very happy to support the NHS. I think the drugs companies make enough profit themselves to... and are probably one of the primary factors in driving up the cost of the NHS. So for them to get free information... If the NHS wants to charge them for it and get something back, that might be different.*

(Patient)

Another said:

*if people have access to information which they're going to use for their own shareholders or commercial purposes I have questions about that. I'm not saying I don't want them to do the work. But I want to be clear and I want to know what they're putting back in, because I can see that they could take out quite effectively, from a national service set up, at our tax payers' expense and get commercial benefit from it, it ought to be clarified.*

(Patient)

## 6.7.2 Factors identified as important in influencing patients' feelings about their data being shared with the HRSS

Through qualitative analysis of interviews and group discussions with patients, a number of factors emerged as potentially important in influencing whether or not patients were happy for their data to be shared with the HRSS. Whether or not a patient's medical record contained 'sensitive' information and whether they had experienced or were experiencing a 'sensitive' or 'embarrassing' health condition, was highlighted as likely to influence their views on their data being shared with the HRSS. For instance, a number of patients stated that they were happy for their data to be shared as they had 'nothing to hide' or their patient records did not contain particularly sensitive information, and some of these patients highlighted the fact that they might feel less happy with their data being shared if their patient records contained 'sensitive' information, and that those who had 'embarrassing' or 'sensitive' health conditions would be likely to show greater opposition to their medical records being shared. 'Sensitive' or 'embarrassing' information and conditions included sexually transmitted infections, HIV, having had an HIV test, or having experienced mental ill-health. Typically, the reasons given for those with such information on their health records being less likely to want their data shared with the HRSS were related to concerns about who might have access to this data now or in the future, and the notion that it might be used to the disadvantage of patients. As one patient commented:

*But, like, if people did have sensitive information that they've shared with their GP or, you know, mental health problems or something that they may think might affect jobs and insurance and things like that, then they may feel uncomfortable having their information in an intermediary group to then be sent on to various companies.*

(Patient)

At the same time, having experienced a health condition was also highlighted as a factor that was important in some patients wanting their data to be shared with the HRSS. For some patients, and particularly some who had experienced a relatively uncommon condition, participation in the HRSS pilot in primary care through data-sharing and the possibility of taking part in a clinical trial, provided an opportunity to try to help others. Some patients, for example, felt that the NHS had helped them greatly when they were unwell, and that they wanted to 'give something back' to the NHS. As one patient said:

*I think the people who are more likely to respond to that in a positive way are people who have problems with their health...*

(Patient)

'Giving something back' to the NHS also emerged as an important motivation for participating in the HRSS pilot in primary care for some patients who had not experienced particular health conditions, but who were committed to the NHS and felt that they had benefited from it during their lives, and wanted to help it. A number of patients stated that they were committed to the NHS, and that this was a key reason why they were happy to participate in the HRSS pilot in primary care.

Another factor that appeared to be important in patients being happy for the data to be shared with HRSS pilot in primary care was the age of the patient, with a number of patients stating that they felt that people who were older, were more likely to be happy to participate in a project such as the HRSS pilot in primary care, than younger people. The reasons given for this included that older people are more likely to appreciate and be aware of the potential health benefits of participation than younger people, and also that, because of their age, they are more likely to have a long-standing relationship and a greater level of contact with their practice. One patient stated:

*So I really... when I was younger I probably wouldn't want my information [to be shared]... but now I couldn't give a damn, if it helps them... if it helps them....[When I was younger] I would've been pretty bullish about it and thought, no, I'm not going to, you know, but now I realise that even if it's not a benefit for me, it will probably benefit somebody, okay.*

(Patient)

### **6.7.3 General attitudes to data being shared**

The vast majority of patients' feelings about their health data being shared with the HRSS largely mirrored their feelings about non-health data held about them by, or example, private companies and public bodies. Thus the vast majority of patients were unconcerned on a day-to-day basis about the personal data that existed about them and generally happy for it to be held and shared. However, as with their health data, many patients were keen that appropriate safeguards were in place to govern storage and access to their personal data, and were happy for it to be shared so long as these safeguards were in place. For most patients, health data was no more 'sensitive' than other forms of data held about them, for example by private companies and public bodies

A key theme that emerged from the analysis, was that patients had grown accustomed to data being held about them, and for many, this meant that they had become less concerned about data being held and shared. For a number of patients, a large amount of their data being held and shared had become a 'fact of life' and so was not something that they felt was generally worth concerning themselves with. As one patient stated:

*One of the things about society these days, everyone gets terribly hung up, don't they, about the privacy of their data? And I just feel if you've got nothing to hide, what's your problem? And then all the business about identity cards, for heaven's sake! You know, everyone knows everything about you, anyway, but you just don't realise it.*

(Patient)

Another said:

*And I think they [the Government] know enough about me anyway, because I don't believe for one minute, you know, all this doctor confidentiality. I think these days the Government know enough about you anyway...the way I view it is they already know about me.*

(Patient)

Interestingly, some of these patients were dubious about the extent to which data could be kept confidential or held securely, and felt that despite safeguards, legislation and protocols that might be in place around data protection and security, it was inevitable that data might be lost or accessed by unauthorised individuals. For these patients, the fact that 'people' had access to their data meant that there was a risk of loss or misuse. However, most of the patients who voiced concerns about the ability of organisations to keep data secure appeared resigned to the fact that this was the case, and were largely unconcerned, often as they felt that there was little data that existed about them that might be used to harm them. As one patient stated,

*There isn't any data security these days...somebody will be able to get into any database in the country if they are so minded – if they can hack into the Pentagon, they can get into our GP information. The NHS medical system, well, that's a joke...I think you've got to accept that people will get your information.*

(Patient)

Another patient commented:

*A guarantee is only as good as the people providing the service, if you like, you know. Yes, you can have all these guarantees, but if you've got individuals that are just throwing records around...*

(Patient)

Findings suggest that high-profile media reports of government employees and bodies losing individuals' personal data had not led to most patients who participated in this evaluation becoming cautious about their personal data being held and shared. Although a number of patients mentioned high-profile data losses and security lapses without prompting from the researchers, this was usually discussed in terms of their inevitability, and tended not to be a major cause for concern amongst patients. Some staff members who participated in this evaluation, however, stated that they were aware of patient concerns over data-security that had been fuelled by media reports of data losses, and that dealing with these concerns by convincing patients of the security of the HRSS would be a key challenge in the future.

During interviews and group discussions for this evaluation, patient participants were asked whether they had ever seen the Care Record Guarantee document, which has the potential to allay patients' concerns about data-sharing by detailing how NHS information is protected and the safeguards that are in place within the NHS around the protection of patient health records. However, none of the patients involved in this evaluation, including those who previously or currently work within the NHS, had ever seen this document.

A minority of patients did state that they were concerned about the amount of data that was generally held and shared about them. These patients typically felt that too much data was held about individuals, and for some of them, the routine nature of data gathering and sharing had made them more guarded about their personal data. For a small number of these patients, health data was also seen as more 'sensitive' than most other forms of data that might be held about an individual. As one patient stated:

*I think your health data is a lot more personal; it's potentially... it could be potentially embarrassing for different patients with different conditions, you know. ... I mean, smoking status, that kind of thing or, you know, alcohol consumption; those things, I suppose, I'm not overly concerned about that. But if I've approached a GP with anxiety problems or, you know, if I needed counselling at any point or... I suppose I would be more concerned about that information being freely available to Joe Public.*

(Patient)

## 6.8 The Patient Information Pack (PIP)

Interview and group discussion data suggested that not all patients who participated in this evaluation had received the full Patient Information Pack (PIP) (Appendix 8). In particular, a large number of patients stated that they had not received the 'Information on the HRSS: Improving health through research' booklet. More than three-quarters of patients who participated in this evaluation recalled receiving the letter and opt-out form that were part of the PIP, with approximately ten per cent stating that they were unsure whether they had received these documents or not, and three patients stating that they had not received them. However, fewer than one-quarter of the patients who participated in this evaluation were sure that they had received the 'Information on the HRSS: Improving health through research' booklet, with more than half stating that they definitely had not received it, and approximately one-quarter that they were unsure whether or not they had received the booklet.

Many patients then, in commenting on the PIP during interviews or group discussions, stated that they were seeing the full PIP for the first time, as they had not received the 'Information on the HRSS: Improving health through research' booklet.

### 6.8.1 Views on the PIP

#### 6.8.1.1 Staff

All but one of the 7 staff members who participated in this evaluation felt that the PIP required improvement so that it provided clear, accessible information to patients about the HRSS pilot in primary care. In particular, there was a perception amongst most staff that the language used in the PIP, and particularly in the 'Information on the HRSS: Improving health through research' booklet, was too 'wordy' and 'technical' to allow many patients to be able to gain a good understanding of what the project was about, and what their potential involvement in it might be. As one staff member stated:

*...for me to read it was understandable because I knew the project, but I think if you're somebody who didn't know about it then... that didn't know anything about research or anything then it would have been quite difficult to understand really...Literacy as well; not all of our patients can read, and we do have a diverse population...*

(Practice staff)

For these staff members, information provided to patients about the HRSS pilot in primary care needed to strike a balance between providing enough information for them to make an informed decision about whether or not to become involved in the project, and at the same time be accessible to a diverse range of people, and not overly technical or too lengthy. Staff members appreciated that this was a difficult task, particularly given the often diverse nature of communities served by practices. As one stated, describing the shortcomings of the PIP:

*That's comfortably beyond the reading age of a significant chunk of our patients. I don't know how you'd give enough information without having that amount on a page. But that for a large number of our patients would actually be very daunting and probably they would just kind of look and think, well, either they're going to think, well, doctor knows best, fine carry on. Or for some of them it would be a case of there's no way I'm wanting to because I don't understand it. I don't know what you're going to do with my information and I don't want to be part of it.*

(Practice staff)

Another stated:

*...from some patients who are very, very aware and want to, kind of, be sure they'll know exactly what's happening to their data, to other patients who are wondering why everybody doesn't know about their data anyway, they assume that everybody knows everything, you know, and they're really surprised, doesn't everybody know? So I think, you know, we're dealing with quite a wide population perception, and that's in a way why it can be difficult to produce the information, because you don't know who you're talking to.*

(Practice staff)

Most staff members then, felt that the information that was sent to patients to inform them about the HRSS pilot in primary care required simplification, in order to ensure that patients were able to grasp in simple terms what the HRSS pilot in primary care is, and understand what their participation will involve. As one staff member, who felt that patients did not really understand the information provided in the PIP, commented:

*...whether we were actually able to give something that patients really understood, I'm not entirely convinced. I think we needed something much simpler, I think. We needed something which on a piece of A4, someone can just read a couple of lines and know*

*what it is, you know, they need to know what it is straight away, rather than having to read through two or three pages, because people don't do it.*

(Practice staff)

### 6.8.1.2 Patients

Opinion was split amongst patients about the PIP and whether or not it was accessible and understandable. A number of patients felt that the PIP gave an adequate explanation of the HRSS pilot in primary care and an appropriate level of information for them to understand what the HRSS pilot in primary care was about. However, some of these patients also felt that although the PIP was appropriate for informing them about the pilot, it was not necessarily appropriate for use with the general public, who might find the level of detail in the 'Information on the HRSS: Improving health through research' booklet in particular, daunting, and not fully understand the nature of the HRSS after reading the letter and booklet. These patients tended to feel that the PIP required simplification in terms of language, to make it more accessible and meaningful to patients.

A key theme that emerged from a number of discussions about the PIP was that the majority of patients felt that the PIP failed to fully inform patients about key details of the HRSS pilot in primary care. Patients generally felt that appropriate information about the HRSS pilot in primary care was required for them to make an informed decision about whether or not to become involved in it, and a number felt that the PIP failed to clearly address some key information about the pilot. This included details such as exactly who the HRSS was, what data will be shared between practices and the HRSS, how data would be extracted and in what form (for example anonymised or non-anonymised), and exactly what patient data would be used for. As one patient commented:

*But from what I can see, it [PIP] doesn't sort of say, 'this is how we store it', 'this is how we will distribute it to the researcher'. And, I suppose, you don't know if... you don't know what information they're passing on. If they want to do research into X drug and whatever effect, you don't know if they're only going to receive, what, the relevant parts of your medical record or the entire medical record.*

(Patient)

Another patient, who felt that the PIP was vague and failed to fully inform patients about the HRSS pilot in primary care, said:

*It wasn't that clear who was going to collect it, who they were going to give it to...*

(Patient)

Another stated:

*...the clarity isn't in this letter even, about the anonymity; there's nothing mentioned there about your data will go out identifiable.*

(Patient)

Interviews and group discussions also highlighted the importance for many patients, of the covering letter from their GP introducing the HRSS pilot in primary care, and it was clear that this letter was crucial to many patients feeling confident that they were happy to participate in the HRSS pilot in primary care. However, a small number of patients also discussed the need for the GP letter and information leaflet to more clearly outline the potential benefits of the HRSS pilot in primary care, in order to encourage greater patient involvement. For these patients, the PIP required more detail in this area. As one said:

*...it [PIP] fails to make the benefits clear - that was its first problem – of this kind of research of people being able to do this, that it's a very difficult one for them to get the kind of data they need and there's an awful lot to be learned from studying people's data.*

(Patient)

It was also clear from interviews and group discussions that very few patients had read the PIP in any depth. Notwithstanding the fact that a large percentage stated that they had not received the information booklet, this suggests that there may be a need to amend the literature that is sent to prospective HRSS patient participants in the future, to encourage their engagement with it.

There was also some concern amongst a small number of patients that these omissions may have meant that patients were not fully aware of what they were 'opting-in' to by default by not completing the opt out form that was sent to them. As one patient stated:

*...quite a high percentage of people who have, as I say for whatever reason, opted in or haven't opted out, would be totally unaware of what they've opted out of or opted in to...*

(Patient)

## **6.9 Reasons concerned with the opt out**

The vast majority of participants viewed the HRSS as a positive development, which they felt would generally be beneficial to research and to the NHS. Even those participants who opted out of the HRSS pilot in primary care, acknowledged the potential benefits of it.

## **6.9.1 Reasons for not opting out**

Participants provided a range of reasons as to why they had not opted out of the HRSS pilot in primary care, with many participants giving multiple reasons for their involvement. These reasons have been categorised into the following:

- To help contribute to research knowledge and progress
- To contribute to improvements in the NHS and the development of treatments and cures
- Feeling that they 'have nothing to hide'
- To 'give something back'
- Opting in by default

In addition, a very small number of participants were unsure as to whether or not they had opted out of the HRSS pilot in primary care, as they could not remember receiving the PIP. However these participants felt that, should they receive the pack now, they would be happy to take part, as they felt that in order for progress to be made, people need to be prepared to help by taking part in projects like this one.

### **6.9.1.1 To help contribute to research knowledge and progress**

A number of participants stated that they wanted to participate in the HRSS pilot in primary care as they felt that their involvement could 'help' by contributing to research, and could potentially contribute to developments within research. This was often related to previous positive involvement in research projects and clinical trials. Some participants stated that they were generally 'pro-research' and felt that research projects should be supported.

A number of participants highlighted the fact that the HRSS pilot in primary care would enable research to be conducted in a more streamlined, more efficient and cost effective manner, which they felt could only be a positive development. Some participants who worked within the field of research were very supportive and positive about research. They acknowledged the importance of it, as well as the potential difficulties faced in involving people in it. They felt that available data should be utilised for research purposes in order for progress to be made. As a participant explained:

*Well I think the, I think obviously the data source is there to be used; it would be senseless not to use it.*

(Patient)

### **6.9.1.2 To contribute to improvements in the NHS and the development of treatments and cures**

Most participants were clear that any research that could potentially lead to improvements in health services and the NHS, and assist in the identification and development of potential cures, therapies and treatments, could only be positive. Some participants stated that they had opted to take part in the HRSS pilot in primary care as they felt that all patients could benefit from this project, which could potentially help in improving treatments for both common and unusual conditions.

Participants who stated that they were living with chronic health conditions or those who said that they had received medical treatment for illnesses, welcomed any research which might result in developments in treatment and care for these conditions, and these participants stated that their illnesses had been a factor influencing their decision not to opt out of the pilot, as they wished to help people with similar conditions.

### **6.9.1.3 Feeling that they ‘have nothing to hide’**

Many participants who did not opt out of the pilot stated that a key reason for them taking part was that they ‘had nothing to hide’. These participants stated that they had nothing in their medical history that they were embarrassed about or that they felt needed to be kept secret. However, some of these participants acknowledged that some people may wish to opt out because they had experienced what could be considered as embarrassing illnesses, or conditions that they may not want people to know about.

### **6.9.1.4 To ‘give something back’**

A large number of participants were keen to be involved in this pilot as a way of ‘giving something back’ to either the NHS or to their GP Practice, for the treatment they had received over the years.

Some participants felt that they had a responsibility to society to take part in such projects in order to benefit society as a whole. A participant explained his point of view in the following way:

*And I think we seem to neglect, sometimes, the fact that if we live in a democratic society, we have obligations to the society as a whole. So for something like this it's only right that one should agree to take part*

(Patient)

Many participants were keen to be involved in the pilot as a way of 'giving something back' to the NHS, in order to help other people and support the NHS, which they felt had served them and their families well. A participant stated:

*I'm very much a child of the welfare state...What I am today, I owe very much to the welfare state and, on that basis, I feel it's only right that I should give something back.*

(Patient)

Some participants stated that they had not opted out of the pilot because the letter of invitation had come from their GP practice, which they trusted. This trust meant that they were happy to take part in a project which was being undertaken by their GP practice, which they had faith in, and believed would only be involved in projects it viewed as of benefit to the practice and its patients.

### **6.9.1.5 Opting in by default**

A small number of participants stated that they had opted in by default, as they had either put the letter aside and not got around to reading it, or had forgotten to return the form to opt out. These participants were unhappy about the fact that they were now in the pilot even though they had not wished to be.

## **6.9.2 Reasons for opting out**

A small number of participants (5) stated that they had opted out of being involved in the pilot, and these participants gave the following reasons.

- Personal reasons
- Concerns about data security
- Insufficient information about the HRSS

### **6.9.2.1 Personal reasons**

Some of the those who opted out stated that a key reason was that they had health issues, or were undergoing treatment at the time that they received the invitation letter, and did not feel in a position at that time to take part. These participants stated that if they were to receive the invitation letter now, they would be happy to take part, as they have since recovered from their illnesses and are no longer receiving treatment.

Other participants stated that they were not happy to share their health records for personal reasons. Interestingly, some of these participants either currently worked, or had previously worked, within the NHS and/or within health research. One of these participants thought that the HRSS letter that she received related to sharing medical records for clinical reasons, under the Summary Care Record initiative, and had opted out of participating because of this. However, this participant stated that s/he was not happy to share her records under any circumstances, including for research purposes, so would still have opted out of the pilot, had she understood what it was about.

### **6.9.2.2 Concerns about data security**

Some participants, including those who stated that they either currently or previously worked within the field of health research and/or the NHS, stated that they had opted out of taking part in the pilot because they lacked confidence in the NHS' ability to maintain control over data and over who has access to it. These participants felt that they lacked trust in the NHS in terms of its ability to hold confidential data securely, and some participants felt that the potential for human error was too great for them to risk being involved.

### **6.9.2.3 Insufficient information about the HRSS**

A very small number of participants stated that they opted out because they felt that the information they had received regarding the project was unclear and that they did not know enough about the HRSS to be happy to be involved. As a participant explained:

*So I felt hang on a minute I don't want my data to be shared with other bodies that I don't know anything about.*

(Patient)

## 6.10 Views on the opt-out

### 6.10.1 Staff

The evaluation found that staff views were split on the issue of the opt-out process used for the HRSS pilot in primary care. Staff expressed both positive and negative views related to the fact that the HRSS pilot in primary care employed an opt-out system for patient involvement, meaning that patients had to actively opt out of taking part in the pilot, otherwise they would automatically be included. These views are discussed below:

#### 6.10.1.1 Positive views on the opt out system

Some staff members felt that having a system whereby patients had to actively opt out of taking part was the best way of gaining the greatest number of patients involved in the pilot. These staff members felt that it made sense to maximise the numbers involved. A staff member explained why s/he felt it was beneficial to have an opt-out system for the pilot:

*...if you want to increase uptake I think having it as an opt-out is the sensible thing to do because only those who actually have an issue with that are going to take the trouble to opt out.*

(Practice staff)

On a number of occasions when discussing the merits of an opt-out system over an opt-in, staff likened the situation to the debate around whether organ donation should be an opt-in or opt-out system, given that the aim in both cases is to increase uptake.

Some staff expressed the concern that if the system were an opt-in, the pilot would not be able to gain a representative sample, because the sample of opted-in patients would more than likely be skewed. These staff felt that the opt-out system allows for a less biased sample to be generated. A staff member explained the situation s/he often encounters in conducting research using an opt-in system:

*We get very biased samples in the studies that we do, so you can write to 500 people and 30 say yes.*

(Practice staff)

Another said:

*If you do an opt in.... you get much lower participation rates and I think you get biased samples...Now, if you have an opt out, where you can get to a much wider group of the population, I still like to believe you're more likely to get people who you wouldn't have anticipated would take part, who will actually take part.*

(Practice staff)

### **6.10.1.2 Negative views on the opt out system**

*They [the practice] signed up to certain principles, one of which was about consent and confidentiality. So we have had some questions about, so, to what extent is this project in conflict with what we said we'd sign up to, which is, we do nothing with the patient without explicit consent. Now we're saying, this project takes us into where there's implicit, not explicit, consent, because it's an opt out system.*

(Practice staff)

As the quote above from a staff member highlights, some staff members expressed concern about, or stated that they were uncomfortable with, the use of an opt-out system for the pilot, as they felt that it contravened commitments made by their practice related to patient confidentiality and the need to gain explicit consent from patients. In addition, some of these staff members felt that this approach to research was completely different to the way in which they had always conducted research, and that active, explicit, written informed consent had always been crucial to involving patients in any previous research conducted by the practice. As a member of staff explained:

*I'm quite uncomfortable with it [the opt-out] really, for me, just because all the research that we've ever done before has always been with the explicit consent of the patient.*

(Practice staff)

The majority of staff explained that they would feel more comfortable about the pilot if patients had to sign and return a form to say that they were opting to take part. This, they felt would be more in line with standard practice for conducting research projects. A staff member explained how s/he felt the opt-out system could cause problems for the practice as follows:

*If you get a patient who hasn't really understood the opt-out, or automatic opt-in, who then decides to do something about it, I think it could be something that blows up in their face really.*

Another reason presented by staff for an active opt-in system related to the fact that the opt-out system employed left room for doubt, in terms of whether patients had actively consented to take part, or whether they had simply not received the information pack, had forgotten to return the opt-out form, had misunderstood the process required to opt out, or had literacy or language issues which meant that they had not understood the significance of not returning the opt out form. Staff at one of the practices in particular, which experienced a high rate of transience within its patient population, felt that an opt-out system was a particular problem in that area, where they were less confident than they would be if the practice had a different practice population, that patients had seen the letter and were actually happy for their data to be used in the HRSS pilot in primary care. As a staff member explained:

*So when we write out to our registered population, and we don't get an answer back, we're probably less confident than many other sites, actually, they've seen the letter, read it, and said yes. They may never have got the letter because they've moved. Now we don't know, until people come in and say oh, I don't live there anymore, that they've moved.*

(Practice staff)

Some staff also dismissed the argument often given in support of having an opt-out system, of being able to obtain a more representative sample. Whilst they felt that this was likely to be true, they also felt that not opting out of data entering the HRSS did not necessarily guarantee that patients would get involved in specific trials conducted through the HRSS further down the line.

Staff working at one of the practices stated that they felt that an opt-in system would also provide a decent sample, as a result of the research-active nature of the practice, and the low levels of transience in the population, as one staff member explained:

*They're [the patients] aware that it has been a research practice for many years and very loyal patients, you know; it's very GP family friendly. Patients that are with the practice have been with the practice years; you know; we haven't got a transient population. And they know that we have been a heavily research practice, you know; so I think they would have every confidence and every faith in the practice.*

(Practice staff)

### 6.10.1.3 An alternative view to the opt out

Some staff felt that patients should have had to return the form regardless of whether or not they wished to opt out of the pilot. They felt that this would have provided more certainty about patients' intentions. This is illustrated below:

*So I mean certainly, you know, philosophically I would've felt more comfortable with that [return form to opt in and opt out], because then for me there's no doubt and that data can be very properly used, because it's been a positive decision.*

(Practice staff)

Another stated:

*...for me in an ideal world, I would've wanted a yes or a no, that they should do something positive, that was my preference right from the beginning, just because I think that would leave us in a really strong position that you actually know who has opted in and you'll know who's opted out, and then there are a few others that have not replied. But that to me just means that you've covered all your bases and you can't be criticised.*

(Practice staff)

## 6.10.2 Patients

Most patient participants were either positive about the use of an opt out system for the HRSS pilot in primary care, or else did not view it as a particular problem. The following sections outline patients' views on the opt out system.

### 6.10.2.1 Positive views about the use of an opt out system

Most patients who voiced arguments in favour of having an opt-out system for the pilot, stated that they felt this to be the best system as it was likely to result in a higher level of patient involvement, a greater amount of data to draw on, from a wider cross-section of people, and it would help to reduce the possibility of obtaining a heavily skewed sample. One participant explained as follows:

*Well, you'll get less people opting out... Not that I think we should do it by stealth, but the more information there is gathered, the better, so it's not bad.*

(Patient)

Another stated:

*...in terms of getting a wider response, greater proactivity, I suppose it's quite a good way of doing it from your point of view.*

(Patient)

A number of people who stated that they felt that the opt-out system was the best way to conduct the HRSS pilot in primary care, made comparisons to the benefits of having an opt-out system for organ donation, rationalising their arguments for this system in this way.

Some participants discussed their belief that, in addition to leading to the widest potential pool of participants, the opt-out system was likely to be more cost-effective than the opt-in approach, which some participants felt was an important consideration in the current economic climate.

### **6.10.2.2 Negative views about the use of an opt out system**

Patient participants in this evaluation who were unhappy with the use of an opt out system, highlighted a number of reasons why they were unhappy about its use. These are discussed according to the following themes.

- Issues regarding a lack of active, informed consent to participate
- Issues regarding the use of identifiable patient data

#### **6.10.2.2.1 Issues regarding a lack of active, informed consent to participate**

A number of participants felt very strongly that anyone wishing to participate in the HRSS pilot in primary care should have had to complete and return a form to actively give their consent to participate, as the following quote highlights:

*...patients should be asked to return the form if they want to opt in, rather than assuming if you don't reply....*

(Patient)

Another participant said:

*...this should have been done the other way round. If you wanted to opt in you returned the letter with your signature on, i.e. you are signing to opt in, and if you didn't return it then whoever was dealing with it assumed that you did not want to take part.*

(Patient)

These participants raised concerns over the opt-out process as they felt that patients who had not fully understood the information they had received, or had not grasped the consequences of the project or of not actively opting out, would be included in the pilot, even though they may not have wished to be included. This, they felt had potential repercussions, as these patients may, at a later date feel that they were not informed about the project, or that they lacked sufficient information to be able to make an informed decision about their involvement, resulting in them potentially feeling that they have been 'coerced' into participating. One participant explained as follows why s/he felt that a lack of active consent could have implications in the future:

*I think the NHS has a duty of care for people's information. I think one of the things that is very live in the public's imagination and understanding is the concept of doctor/patient confidentiality.... whoever is running these projects, both the research database and just the day to day management of NHS patient information, need to be very careful because all it takes is ...one case that is taken up by the media where a patient comes to harm because of a breach of confidentiality and the repercussions can be quite catastrophic.*

(Patient)

Many participants also disagreed with the use of an opt out because they felt that the information provided to patients in the PIP was not clear enough or sufficient enough to be able to assume that anyone who did not opt out had actively decided to take part. These participants felt that the information provided needed to be shorter and simpler, explaining the benefits and the full implications of participation. In addition, some concerns were voiced about whether the opt-out system was appropriate for gaining 'informed' consent into the project from participants unable to understand the letter, such as those with literacy or language skills, as the following quote highlights:

*I think there are potentially some vulnerable people that may not have fully understood what was going on and would've just probably binned it and they've automatically been opted in...*

In addition, a small number of participants felt that if an opt out system were to be used, it was necessary for there to be a system in place to allow patients to opt out of the HRSS pilot in primary care at any time, and to clearly communicate this to patients.

#### **6.10.2.2.2 Issues regarding the use of identifiable patient data**

Some participants felt very strongly that the HRSS pilot in primary care should definitely take an active opt-in approach, given the fact that the patient information leaves the practices in an identifiable format. These participants were especially concerned about this aspect of the pilot as they felt that this was not clearly outlined in the information provided to patients in the PIP. As a result, the vast majority of participants stated that they were unaware that this was the case, and that they had assumed that the data was anonymised before it left the practices. The following quote highlights why some people felt that an opt-in system was important in these circumstances:

*I'd understood that it was unnamed usage. If they were going to track back to individuals, I think they ought to have the chance to opt in creatively.*

(Patient)

## **6.11 Factors important in the success of the HRSS**

The following sections outline the key factors that this evaluation identified as important to the successful implementation of the HRSS in primary care, and which are likely to be important to any wider roll-out of the initiative.

### **6.11.1 Trust in the GP practice**

It was clear from interview and group discussion data analysis that patients' trust in their GP practice was a crucial factor in them deciding to participate in the HRSS pilot in primary care. The importance of 'trust' was highlighted by most patients and also some practice staff.

For instance, the letter within the PIP was sent from the GP practice, and a large number of patients highlighted the importance of this letter in their decision to participate in the HRSS pilot in primary care. For some patients, their trust was invested in the practice as a whole, whilst for others it tended

to be more closely related to trust in a specific GP. Patients typically discussed having high levels of trust in their GP practice, both in terms of the level of care they received and also in terms of the way in which the practice stored and held their health data. This trust in the practice typically meant that patients felt that their GP had their best interests at heart, was unlikely to suggest that they become involved in any project that might be risky or detrimental to them, and that if their GP was suggesting involvement in the HRSS pilot in primary care, then 'it must be okay'. Practices were therefore seen as 'validating' patient involvement in the HRSS pilot in primary care. As one patient stated:

*Because the practice that we're in is quite forward thinking and if they're, if they're passing it along to us and that they've had a look at it and they're assured us that it's, you know, it's nothing that is going to be detrimental to us, then we're quite happy, you know, not to opt out...*

(Patient)

Another patient commented:

*...you feel that your doctors are going to be acting in your best interests, so they're not likely to put forward something that they think is rubbish*

(Patient)

Staff also highlighted the importance of trust in the practice in patients' decision to participate in the HRSS pilot in primary care. As one staff member stated:

*...patients have got great respect for [the doctor], would go along with anything that [the doctor] thinks is okay. They would think, well, if [the doctor]'s involved with that, it must be all right, you know.*

(Practice staff)

## **6.11.2 Trust in the NHS and the NHS 'brand'**

A related factor, highlighted by a number of patients, was their level of trust in the NHS. It was clear that their decision to participate in the HRSS pilot in primary care was based in part on the fact that the HRSS documentation that they received through the post had been sent by the NHS, and that the HRSS was perceived to be within the NHS. As highlighted earlier, a number of patients stated that they were committed to the NHS, and for these and other patients, the NHS 'seal of approval' meant that they were happy to participate, as they felt that the NHS was a trusted institution. As one patient stated:

*If it's under the umbrella [of the NHS], it's been quality tested and I'm happy with that.*

(Patient)

Some patients contrasted receiving a letter from the NHS with receiving the same document from a private organisation, and most of these patients stated that without the apparent NHS endorsement, they would have been more suspicious and more likely to opt-out. One patient, who had misgivings about the HRSS but decided to participate, said:

*For me, I'm wary about it [the HRSS], but the fact that it has the... it's under the auspices of the NHS rather than, if you like, Bloggs whatever; if it was Bloggs whatever, as I said before, I wouldn't do it...*

(Patient)

Another stated:

*I mean, I trust the NHS. I trust an institution that is ours, you know, not some private sector outfit.*

(Patient)

### **6.11.3 A research-active practice**

Another, related factor that both patients and staff felt had the potential to influence the success of the HRSS pilot in primary care was whether or not a practice was 'research-active', and whether or not patients were used to being asked to become involved in research projects. Both of the HRSS pilot practices were strong research practices and it was clear that most patients who participated in the evaluation were aware of this. For a number of both staff and patients, the fact that a practice has a history of conducting research is likely to mean that patients are more likely to participate in a project like the HRSS. As one staff member stated:

*I think that the majority of our patients are quite keen to be, you know, and happy to be in a practice involved with research that they know is going to improve patient care. So I think – but I do think our practice is very different and I think that's because it's quite a new practice and, you know, that's [research] always been part of the ethos. I think it might be quite different for a practice that had never been part of anything and then started sending information about research...*

(Practice staff)

Similarly, as one patient stated:

*... we are part of a GP practice that regularly does research, so we're used to getting letters saying, 'we're doing some research at the moment'. So I've already gone through the thought process that I like research and I'd like to support the practice in doing research so I don't opt-out. So it wasn't a specific decision about this it was kind of part of another decision, if you see what I mean.*

(Patient)

Interestingly, although analysis of qualitative data from this evaluation suggests that being part of a research-active practice, and having been asked to participate in research before, may act to encourage participation in projects such as the HRSS pilot in primary care, it also suggests that a potential risk may be that in some cases, patients may be less likely to scrutinise information on new research projects such as the HRSS pilot in primary care, feeling for instance, that they are part of an existing research project.

#### **6.11.4 Publicity and information**

It was clear from this evaluation that good-quality publicity and information about the nature and purpose of the HRSS, the practical implementation of it, and its implications for practices and patients, is an important factor in practices and patients engaging with the initiative. Although evaluation findings suggested that high-level knowledge of the details of the HRSS was not apparent amongst all practice staff, they also suggested that the input of the HRSS team had been important in helping GPs and other staff who were to be directly involved in the local implementation of the HRSS, understand the project and its implications for the practice. For some staff members, face-to-face explanation of the practicalities of the HRSS by the HRSS team had been vital to their initial concerns being allayed and them becoming comfortable with their practice's HRSS involvement. As one staff member stated:

*I mean obviously as a pilot we got sort of visit from the researchers [HRSS team]. So in that regard we actually got I think quite good quality information. We were able to ask questions and we were, you know, given good quality information about it. So you know, we had the chat, I had concerns. I asked them and they were addressed. I can't really ask for better than that.*

(Practice staff)

Patients too, felt that good quality information about the HRSS would help patients to make informed choices about whether or not they wanted to be involved. Some patients felt that details related to the

security and sharing of data might be particularly important for encouraging those patients with ‘sensitive’ information in their health records to participate in the HRSS initiative by allaying any concerns they might have about the security of, and access to, their health data. Both patients and staff highlighted the need for better patient information about the HRSS, with one patient who opted out of the HRSS pilot in primary care stating that she would have opted in if she had had clearer, more detailed information.

## 6.12 Barriers and potential barriers to HRSS success in the future

The following sections outline the perceived actual and potential barriers to the success of the HRSS initiative identified through interviews and discussions with staff and patients.

### 6.12.1 Staff

Staff highlighted relatively few barriers to the success of the HRSS initiative, and those barriers that were highlighted tended to be raised by a small number of interviewees. One interviewee, for example, highlighted the potential difficulties for the HRSS of ensuring accurate data was available for research teams to draw on. For this interviewee, whilst data might be accurate at the time of extraction, where practices have a highly transient population, extracted snapshot data could very quickly become out-of-date – possibly within a matter of weeks. This staff member felt that this issue provided a key challenge for the HRSS, and that although one solution to this might be to take multiple data extractions from practices at regular intervals, this might not prove feasible or appropriate for all GP practices. As this staff member stated:

*I can't believe that this [the HRSS] has never happened in the past because it makes such sense. To have a database of information that you interrogate, this is fantastic, it should happen. But then when you think about the data just taking up a snapshot of time and how immediately that data is completely out of date in every sense of the data...*

(Practice staff)

In addition, for some staff, the potential and actual burden of the HRSS pilot in primary care on the workload and daily operation of the practice, was another perceived barrier to further roll-out of the HRSS. One staff member felt that practices might be reluctant to participate if they felt that, for

example, HRSS data extraction processes were likely to disrupt their own use of IT systems. An additional potential barrier highlighted by a small number of staff members, was that participation in the HRSS would require the provision of specialist IT support to assist practices in preparing their data for extraction to the HRSS, since not all practices have this expertise in-house.

Another staff member highlighted suspicion amongst some practices about the use that their patients' data might be put to if they participated in the HRSS, as a potential barrier to the wider roll-out of the initiative. For this staff member, practices might be wary that their patients' data might be analysed or utilised for purposes other than 'health research', and this might be a reason for practices being reluctant to participate. For instance, this interviewee felt that some practices might be suspicious that HRSS data might be accessed in order to check up on a practice's work, the profiles of patients, or the incidence of certain condition within a practice's patient population. As this staff member stated:

*I think people don't trust the government, them, the PCT, not to use something like this to actually also quietly check what else you've been up to...So I think there's that, so how confident can we be that it really has got absolute firewalls around it and nobody else is allowed into this data.*

(Practice staff)

Another related, potential barrier that emerged from qualitative analysis of staff interviews, was whether or not practices were satisfied that the processes and procedures used by the HRSS around patient consent, anonymity of data, and the extraction and storage, were acceptable, and whether or not they fitted with established practice-level processes and protocols. Where this was not the case, some staff felt that some practices might be reluctant to participate in the HRSS.

### **6.12.1 Patients**

In general, patients were unsure about what the potential barriers to wider HRSS roll-out might be. However, the most frequently-cited potential barrier to HRSS success was the financial cost of attempting to encourage a large number of practices and their patients to become involved in the initiative. Some patients, for example, highlighted the potentially high cost of a campaign, be that local or national, to appropriately inform patients about the HRSS. These patients tended to feel that the cost of a publicity campaign similar to the one that had been conducted through their practice, with a PIP sent to patients and posters placed in GP practices, might prove prohibitive, especially in the context of current Government austerity measures.

A small number of patients also felt that there were likely to be difficulties in encouraging a diverse range of practices to become involved in the HRSS, and in particular, in encouraging practices without a history of research activity. These patients commented that non research active practices and the patients that they serve, might prove difficult to engage as they were not used to being involved in research and they might not understand the potential implications of a project like the HRSS. Patients saw this issue as having potential implications both for the HRSS in terms of the quality and range of patient data that the HRSS would be able to access, as well as for non-research practices in terms of the need to take additional steps to explain the HRSS to their patients. As one patient stated:

*The two practices that have been chosen [for the pilot] have got a research background. What about practices that are sort of last century? We've still got them. How do we get a widespread mix that is representative, and if a particular practice is in a leafy suburb where there's only a single demographic, or not very much, we need the mix... So I think the only danger is if we don't get that rich spectrum of information.*

(Patient)

Another patient said:

*I would guess if you were doing this with a surgery that didn't habitually do research, it would be very different because, from the surgery's point of view, this was the first time any of their patients had received a letter about doing research. That could generate an awful lot of anxiety and questions, ringing up, asking, explanation, which just won't go on for us.*

(Patient)

## 6.13 Interviews with key stakeholders

Interviews were conducted with 11 people. People interviewed varied from people involved in working on datasets using patient records, to those who had set up databases of patient records, people who had an interest in the use of patient records for research as well as people directly involved in the RCP / HRSS. Results are discussed in relation to the following themes;

- Views of the HRSS as a concept
- Potential barriers to the effectiveness of the HRSS

- Views of the opt out.
- The importance of communication and engagement

### 6.13.1 Views of the HRSS as a concept

The general view held was that setting up the HRSS was very important and that despite the cost it would be an absolute disaster if it did not go ahead. It was suggested it was a good opportunity to develop research infrastructure for the future and therefore should not be passed by. Furthermore that it would be negligent not to make use of the wealth of data that has been and continues to be collected as part of the NHS.

*...it would be an absolute disaster if it [the HRSS] was pulled. This has to be the future for research in this country ... I know funding is tight but this, to me, is one of the future infrastructure opportunities that we can't let pass by*

(Stakeholder 1)

The fact that databases allowing data linkage have previously been set up was noted, but it was suggested that the potential scale of the HRSS was important for the economy in terms of attracting researchers and industry to focus their Research and Development work in the UK, as well as in relation to the types of questions and quality of work that would be made possible by the existence of such a service. Moreover in relation to the data it would make available, the ability to use records to conduct observation studies was seen as particularly valuable as conditions and medications can be seen in relation to the real world as opposed to clinical trials in which patients do well as they get a greater level of care by virtue of participation in a trial.

It was suggested that if the HRSS were to achieve its full potential it needed to be securely funded, not a piecemeal service supported and determined by grants. Moreover, in line with comments made by patients about the importance of the 'NHS brand' it needed to have a public element to ensure accountability.

*You know if you gave this to a private sector company then I think there'd be war*

(Stakeholder 8)

All this was not to say that the HRSS wasn't seen as potentially problematic. In particular concerns were raised about the potential problems for the HRSS in relation to the transfer of identifiable information into a safe haven due to the lack of clarity in the common law duty of confidentiality,

together with the need to take account of The Data Protection Act, the European Human Rights Act and the Care Records Guarantee.

It was also questioned as to whether there really was a need for larger numbers to participate in trials on the basis that international medical research thus far has generally been based on smaller numbers and that statistical techniques are able to deal with missing data:

*There is a big difference between what a researcher would like to have and what they actually need to have, and all that they need to have is numbers adequate to derive a reasonable probability ... most medical research is living with a huge drop out rate, either dropping, won't go in, or go in and drop out. And nobody is saying ... how terrible all this medical research is. So all I'm saying is that the research world has to come to terms with a, what I believe is a kind of cultural reality that you can't get everybody all the time. ... and then some of the new statistical adjustment techniques and imputed data and all that stuff are really clever ways of coping with missing data and data sets.*

(Stakeholder 11)

### **6.13.2 Potential barriers to the effectiveness of the HRSS**

A key concern shared by a number of stakeholders was the quality of data that would form part of the HRSS. In addition concerns were expressed that people may become less critical of the source data once the value of a data linkage service was evident:

*linkage of data like this becomes an enormously valuable resource. The more valuable it becomes, the less likely people are to be critical of the source data*

(Stakeholder 1)

Interestingly, one person commented on the quality of the data in relation to the potential sustainability of the HRSS with the comment that if only rubbish appeared to come out of studies based on data from it then people would no longer wish to input their data. The quality of medical notes in secondary care was identified to be a particular potential barrier to the development of the HRSS. Yet it was also suggested that the UK needed to be careful not to undersell itself in that the worst data in the UK is better than most other countries' best data.

*The UK has to be extremely careful. Our worse data is better than most other countries' best data .. we shouldn't kick ourselves in the foot*

(Stakeholder 2)

It was felt different data sources have different strengths and weaknesses and the concern was expressed that if researchers were given a linked dataset directly from the HRSS they may be less likely to take the limitations of the original datasets into account than they would have done if they had been more directly involved in acquiring and linking the data. The question was also raised about data cleaning, with the concern expressed about potentially losing control over this process as a researcher.

*I think a potential disadvantage is data cleaning, possibly, that we all have our concerns about the quality of the data and we'll all go through our own processes of trying to make it better because we don't ... we can't rely on what we get*

(Stakeholder 7)

The evaluation focused on primary care and it was felt a potential barrier to the development of the HRSS was the belief among GPs that they are the custodians of patients' data and they must protect it at all cost. The issue of time was also raised, about which it was commented that GPs would not feel they had time to discuss the HRSS with patients and if they did so they would expect to be paid for it. This view about the need for payment was not universally held by all the interviewees. Finally, in line with interviews with practice staff and patients, it was noted that practices which are not research forward may form a challenge to a future roll out.

### **6.13.3 The opt out**

Using an opt out as opposed to an opt in was seen as a contentious issue. It was suggested that maybe it was acceptable for a pilot but beyond that it was thought it would be politically unpalatable.

*Pilots are pilots, trying to do it for 55 million people is a different kettle of bananas*

(Stakeholder 3)

It was suggested that the process of getting a form to sign and envelope to return the response was generally associated with opting in and therefore was potentially confusing. One person suggested that it should be started with an opt in and if that proved uncontroversial then you could move to a system of opt out. An opt out was thought to be more acceptable for the summary care record as:

*There is an obvious, direct patient benefit from it.*

(Stakeholder 3)

Finally it was suggested that an opt out may be seen to go against the spirit of 'nothing about me without me', as an opt out does not constitute active consent.

The use of an opt out was not seen to be as problematic if the communication concerning it was of a high quality. It was however noted that just because people don't respond does not mean they are happy to have their data included. When talking about non-response to the opt out one stakeholder said:

*I think we've got to be extremely careful. And I think we've got to summarise it by saying it would include a range of people who would go from pretty near opt in to pretty near opt out ... and then to draw the assumption that that is acceptance, that is a significant step. It may be necessary in a modern society, with all the pressures on everybody, we understand that. But I think it is more of a compromise is what I am saying, than a specific opt in.*

(Stakeholder 11)

In summary, concerns were raised as to the extent to which people's decisions about the opt out constituted informed consent.

#### **6.13.4 Communication and engagement**

Communication and engagement were thought to be important at all levels. The complexity of the central message of the HRSS was nicely paraphrased by the statement that what people needed to be told was that their identifiers were taken to minimise the use of identifiers:

*we take your identifiers to minimise the use of identifiers, which is a complex message to get across.*

(Stakeholder 9)

Issues of ethics and governance were mentioned throughout the interviews. This was not just in relation to the importance of its existence but also of communicating it to all the stakeholders. It was felt that if the HRSS was to succeed then it needed a strong senior sponsor who was respected and trusted by the key stakeholders, engagement of peer networks, as well as strong PPI engagement.

The importance of patients' perspectives was raised in relation to the development of the service. It was felt it would be important for any future development of the HRSS to focus on communicating the

benefits of the HRSS both for themselves, others and future generations through a range of media such as a big advertising campaign, as well as more locally based avenues such as local newspapers. Another idea suggested was the integration into popular media such as soap opera story lines. A key idea was trying to get a mind shift so that clinical care and research were seen as linked in people's minds and in this way making the use of clinical data for research seem more obvious. The idea of running sessions in practices about the HRSS was raised, but countered by the idea that this may prove too time and resource intensive.

It was also thought to be important to stress what is not happening to the data, for example it is not being sold to insurance companies.

*What we don't do is we don't articulate what we don't use data for, for example, so we we don't give it to insurance companies*

(Stakeholder 8)

In relation to data safety it was felt that despite concerns following reports of losses of data from Government, that in this respect human interactions are more of a problem than technology.

## **6.14 Observations at the Patient and Public Involvement Co-ordination Group (PPI CG)**

The PPI CG met 5 times between December 2010 and April 2011 for four hours on each occasion. Attendance and commitment to the tasks were high, interestingly the only members who did not consistently attend were the representatives from the two practices; one practice was never represented and the representative from the other practice resigned following attendance at two meetings. All the other representatives, aside from those associated with the HRSS pilot in primary care, had gone through an application and selection process while these two representatives had been appointed by virtue of their practice's involvement in the primary care pilot project. The commitment may have proved too demanding.

Presentations at the meetings stressed the strong commitment to research governance in the RCP and by default the HRSS pilot in primary care. A key theme running through the PPI CG was the importance of PPI representation in relation the RCP/HRSS, both in terms of conceptual development of the RCP/HRSS as well HRSS project material. Of particular concern was that the group were only shown the patient information pack (PIP) that had been sent out to patients after it had been sent. The PPI CG was highly critical of the leaflet and its lack of clarity in relation to what people were being

asked to opt out of. Their feelings about the pack could be summed up by the comment made by one member that “*I wouldn't start from here*”. There was a concern that the PIP tried to do too much in presenting (1) the HRSS (2) the opt out (3) information on research and (4) clinical trials. It was felt it was not clear from all this information what people were being asked to do. Another comment was that the letter accompanying the PIP was so blandly worded so as to discourage people from engaging. In line with comments made in the external stakeholder interviews, it was noted that just because people don't respond that does not mean they are happy for their data to be included. Indeed one member of the PPI CG suggested that prior to using the data the HRSS should put up posters explaining what was about to happen to people's data if they had not completed an opt out form. The PPI CG were offered the opportunity to engage with making changes to the PIP but the general feeling seemed to be of disappointment that they had been unable to have a role in what was seen to be a very central part of the project.

## 7. Discussion

### 7.1 Overview

A key finding of this evaluation was that there was widespread support for the concept of the HRSS. Patients, staff and stakeholders outside of the practices identified a number of potential benefits of the HRSS feeling that the initiative had the potential to positively contribute to health research and assist in the development of new knowledge, understanding, services, and treatments.

The majority of patients were willing for their data to be shared with the HRSS so long as there were adequate and appropriate safeguards in place to ensure the security of their health data. For most patients sharing of their health and other personal data was not a major concern. Patients who were concerned about their health data being shared for the HRSS pilot in primary care were typically wary because of concerns about data-security, storage and access, with some patients voicing concerns about their data leaving the practice in an identifiable format. Once explained, the concept of a 'safe haven' was widely understood.

The fact that the HRSS was perceived to sit within the NHS was an important factor in many patients' willingness to be involved in the HRSS pilot in primary care, as was the fact that the project had the endorsement of their GP practice. In addition, the research active nature of the practices involved and patients' awareness of this were also factors that emerged as important in patients' willingness to be involved in the HRSS pilot in primary care.

It is however important to note that detailed knowledge about the pilot was limited to a small number of staff members. The vast majority of patients had little clear understanding of the HRSS pilot in primary care and were unaware, prior to the brief explanation provided by the researchers, of key aspects of it such as the fact that the pilot would involve patient data leaving the practice in a non-anonymised form, and that data would be stored externally within the HRSS.

The PIP was the principal route through which patients became aware of the existence and nature of the HRSS pilot in primary care. Staff, patients, PPGs and the PPI CG were all critical of the PIP. They highlighted a need for the PIP to be amended. A number of participants raised concerns that the PIP did not clearly inform patients about the nature, purpose, and implications of the HRSS, and thus was not successful in providing patients with the information required to allow them to make an informed decision as to whether or not to opt out of the HRSS pilot in primary care. In keeping with

this, a key theme which ran through all the interviews with stakeholders from outside the practice was the importance of maintaining good communication and engagement with all stakeholders.

The majority of patients who were sent information about the HRSS pilot in primary care chose not to opt out of the pilot project. The use of an opt out was perceived by both patients and staff to increase participation and reduce bias in the sample. However, there were concerns raised in interviews with all the groups involved in this evaluation about the use of an opt out system for consenting patients into the pilot. Participants were concerned about whether or not implicit consent to a research project such as the HRSS pilot in primary care is acceptable. It is important to note that it was necessary to read the Frequently Asked Questions section of the website for information on how to opt out of any data leaving the practice and that this may have acted as a barrier to people expressing such a decision.

In relation to any future roll out, concerns were expressed by staff about the impact on workload and potential need for additional resources and support. Concerns were also expressed by staff and stakeholders outside of the practices about the accuracy of data. Patients were concerned about the potential cost of publicity and how easy it would be to recruit from non-research practices given the patients were at a different starting point, a concern echoed in the interviews with stakeholders from outside the practices.

## **7.2 Strengths and limitations**

### **7.2.1 Strengths**

We have gained the views of 50 patients and 7 key members of staff. These included patients who stated they had opted out of being contacted about taking part in research. We have also spoken to 11 stakeholders with an expertise and interest in the use of patient records for research and have observed at key groups involved with setting up the HRSS pilot in primary care and in relation to patient and public involvement (PPI CG).

### **7.2.2 Limitations**

There were only two practices involved in the pilot and these were strong research practices. This means the practice staff were used to dealing with research projects and the patients were aware of research, even if they had not previously taken part in it. Moreover the patients who participated were

self-selected and were generally older and educated to a high level. It may be more difficult to engage both staff and patients in non-research practices.

Short time scales due to the delays in receiving funding for the evaluation meant the fieldwork within the practices was conducted over a six week period. This meant we were unable to speak to some staff who were unavailable on the agreed day due to unforeseen circumstances in the practices.

Delays in the implementation of the HRSS pilot in primary care means the evaluation has not been able to take account of the data extraction. This is the period when the perceived feasibility of the project in relation to the effect on IT systems and any perceived effect on workload would have come to the fore.

## 8. Key findings and recommendations

- National Implementation of the HRSS

There was widespread support for the concept of the HRSS. The vast majority of patients stated that they felt the HRSS was a good idea and a number highlighted potential benefits that they felt the HRSS would bring about. 'Giving something back' to the NHS emerged as an important motivation for participating in the HRSS pilot in primary care. The majority of patients who participated in this evaluation were happy for their GP practice to share their patient data with the HRSS pilot in primary care.

**We recommend the national implementation of the HRSS programme in primary care**

- Patient and staff understanding of the project

Levels of understanding about the detail of the HRSS varied and very few people had a good understanding. One patient who opted out of the HRSS stated that she would have opted in if she had had clearer, more detailed information about the HRSS pilot in primary care.

**We recommend substantial review of the HRSS communication processes.**

- The Patient Information Pack (PIP)

All of the participants interviewed in relation to the PIP were critical of it and most felt it was too 'wordy' and 'technical.' Moreover, there was a feeling expressed by both the national Patient and Public Involvement Co-ordination Group (PPI CG) and the local Patient Participation Groups (PPGs) based in the practices that failure to get their feedback prior to the PIP being sent out had been a missed opportunity.

**We recommend a review of the Patient Information Pack (PIP) to ensure patients in participating practices are provided with a clear account of the HRSS and implications of involvement.**

- Role of the HRSS Team

The input of the HRSS team was important in helping GPs and other staff to understand the project and its implications for the practice. The need for clarity is likely to be even more important with non-research active practices.

**We recommend that frequent contact between the HRSS and the participating GP practices is built into plans for moving forward.**

- Acceptability of the opt out system

Both staff and patients acknowledged that the use of an opt out increased patient participation, thus reducing potential sampling bias. There was however concern about the use of a system of opt out which was widely seen to be an 'opt in by default' and could not be said to form the basis of active informed consent.

**We recommend re-consideration of the opt out processes.**

- Patient and public involvement:

Patient representatives in the Patient Participation Groups (PPGs) in the practices and on the national Patient and Public Involvement Co-ordination Group (PPI CG) did not feel their skills had been fully utilised in the implementation of the HRSS.

**We recommend greater involvement by patient representatives at both the local and the national level.**

- Involvement of the private sector

Many patients voiced concern about the sharing of their health data, particularly in non-anonymised form, with organisations external to the NHS. This was echoed in some interviews with practice staff and interviews with stakeholders external to the HRSS pilot in primary care.

**We recommend any involvement of the private sector, even as a partner, in the HRSS in the future would require careful consideration and negotiation.**

## 9. References

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## 10. Glossary of terms:

**HRSS** – Health Research Support Service

**NIHR PCRN** – National Institute for Healthcare Research Primary Care Research Network

**PCT** – Primary Care Trust

**PIP** – Participant Information Pack

**PPI CG** – Patient and Public Involvement Co-ordination Group

**PPG** – Patient Participation Group

**RCP** – Research Capability Programme

# 11. Appendices

- 1) Gantt chart
- 2) Letter about evaluation
- 3) Participant information sheet
- 4) Interview/focus group schedule (patients)
- 5) Interview schedule (staff)
- 6) Interview schedule (key stakeholders)
- 7) Interview schedule (commissioners)
- 8) Patient Information Pack (PIP)