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1 Introduction

The SmartHEALTH project aims to integrate a new healthcare technology into existing healthcare systems and markets, across Europe and potentially globally. To understand the impact of any new healthcare technology, upon different users, the project needs to be located within the ethical, legal and social context that accompanies the introduction of any new technology into existing infrastructures. In addition, it is necessary to speculate and explore the potential for any new and specific Ethical, Legal and Social Issues (ELSI) of SmartHEALTH applications. To an extent, the territory is already established since SmartHEALTH is operating against a background of an ageing European population and a burgeoning cancer problem. In addition, there is a common political imperative to seek effective screening programmes, rapid and accurate diagnosis and monitoring so as to improve the morbidity and mortality associated with malignancy.

The aim of Workpackage WP9 is to explore potential ELSIs associated with the nature and outcome of the implementation of SmartHEALTH technologies into existing, mainly European, healthcare systems. The aim of WP10 is to explore the gender issues and the psychological aspects influencing patients' testing intention with the new SmartHEALTH application. As each new healthcare technology evolves within its own ethical and social context, specific to the physical and cultural location, the ELSIs discussed within the WP9 deliverables relate only to the PoC applications within the current project, as shown below:

1. **WP1a:** breast cancer therapy monitoring.
 PoC: General practitioner, hospital outpatients, specialised laboratories or (possibly) home use.

2. **WP1b:** Cervical cancer screening and case findings.
 PoC: General practitioners (gynaecologists), hospital outpatients or specialised laboratories.

3. **WP1c:** Colorectal (CRC) cancer diagnosis and therapy monitoring.
 PoC: hospital outpatients or specialised laboratories.

This deliverable relates to the organisation and delivery of a research symposium on the Ethical, Legal and Social Issues of micro-systems for PoC testing under task 9.3 and task 10.4. This report outlines the content of the symposium and the main discussion points raised by participants. The title and format of the symposium were based predominantly around the ELSIs raised within the remit of WP9 and also provided a forum for WP10 to present related issues arising from their research. The symposium was also a platform for WP10 to communicate to the general population the results of the studies conducted on how gender issues relate to world views, as part of milestone M10.6. The symposium drew upon three stages of WP9 fieldwork reported in earlier deliverables:

1. D9.2 presents a literature review around potential ELSIS surrounding the implementation of the SmartHEALTH within existing healthcare systems.
2. D9.3 presents a pilot study, where the ethical and social issues raised within D9.2 are explored further with selected stakeholders (SmartHEALTH partners and external healthcare professionals) and any new potential ELSIs are highlighted.
3. D9.6 involves case studies, completed in 2008, where issues raised in D9.2 and explored in D9.3 were further explored with women (in UK and Norway) with a focus upon their perceptions of being screened for cervical cancer.

The symposium: “Integration or Disruption?: Implementing SmartHEALTH into Healthcare” was hosted by the Policy Ethics and Life Sciences Research Centre (WP9) at Newcastle University UK in collaboration with the University of Trento (WP10). The main aims of the symposium were to:

- Expose an interdisciplinary audience to the developments in SmartHEALTH technology to-date
- Clarify the nature of the specific ethical and social issues associated with integrated biodiagnostic systems
- Provide an opportunity for a cross-disciplinary discussion
- Invite participants to identify potential social and ethical questions regarding the SmartHEALTH programme to-date and potential future applications
- Disseminate relevant findings within the consortium and more widely

The symposium focused on the SmartHEALTH roadmap within the context of two applications:

- Breast cancer monitoring: moving from hospitals to General practices to patient homes
- Colorectal cancer screening and monitoring within the SmartHEALTH vision

The focus was on opening up dialogue to spark critical and creative discussions among participants with different perspectives on the technology. During the symposium, the two topics were points of departure for an open discussion and participants could redefine and challenge the ELSIs surrounding the future implementation of SmartHEALTH.

This deliverable presents:

- Rationale: participants invited and symposium content
- Methods
- Summary of Presentations
- Findings (main issues raised from symposium discussions)
- Discussion and Recommendation (new & existing questions for future development)
- Next steps for WP9 and WP10

2 Rationale: participants invited & symposium content

Within SmartHEALTH there has been an ongoing challenge to consider the potential ELSIs while the technology is itself under development. The premise behind the symposium and other fieldwork within WP9 is the recognition that the development of any new technology is socially as well as technologically determined. Technological development is influenced by people’s perceptions, and use of the actual (or near actual) technology (Mackenzie and Wajman, 2004). For example, while the trust placed in any new technology is influenced by people’s perceived risk rather than any actual risk, the technology cannot be realised or implemented if the materials or relevant knowledge does not exist to develop, for example, efficient and cost-effective biosensors. Within WP9, both approaches are considered important and therefore the SmartHEALTH technologies are explored from within healthcare and technological contexts, which in reality often merge, and from the patient/user perspective.

At the start of the project, when the technology was in the early development stage, more information was required to create a useful representation of a complex converging set of technologies. As a result, the SmartHEALTH partners were identified as the most appropriate individuals with whom to explore the technology, as they could provide more detailed

information on the technology and discuss their insights into the social and ethical issues within a more applied context. To complement the partners' views, a number of additional "sensitising" interviews were held with key informants selected from a variety of healthcare specialists within the three cancer applications. This research (D9.3) was followed up with fieldwork with health professionals in primary and secondary care (D9.7: part A). However, no interviews have been held with patients, this research is scheduled for late 2009.

The symposium participants were invited international experts, health professionals, patient representatives and selected SmartHEALTH partners (see Appendix A for complete participant list and speakers biographies). The participants who attended enabled multi-disciplinary discussions between project partners, health professionals from both secondary and primary care¹ and individuals with a patient perspective. Inevitably the chosen mix of participants informed the discussions and the issues and questions raised.

2.1 ELSIs raised in D9.2 & D9.3 and defining a 'disruption technology'

At the early stages of the project, the results of D9.2 (literature review) and D9.3 (interviews with partners and selected health professionals) produced a number of detailed questions (see table 1 below).

Table 1: Main Ethical, Legal and Social Issues for SmartHEALTH as raised in D9.2.

<p>D9.2 highlighted a number of potential ELSIs relating to both the implementation of SmartHEALTH technologies and the functionalities of these technologies.</p> <p><i>Issues related to the technology:</i></p> <ul style="list-style-type: none"> • The exact nature of these applications, in terms of screening, therapy monitoring, disease surveillance. • The sensitivity and specificity of the technology (biomarkers). • Quality control requirements for long term clinical use of these technologies. • Safety and efficacy of data handling aspects of the technologies – with particular reference to data security. • Integration with/ conflict with existing health infra-structures e.g. existing screening/ disease monitoring programmes. • The PoC location of each application and if this PoC is new or existing within current health systems. <p><i>Issues related to the implementation of the technology:</i></p> <ul style="list-style-type: none"> • Personnel - who deals with the patient/participant and in what way? • Quality of information provided – to the patient/participant user. • Counselling provided to the patient/participant user before moving through the process. • Quality of informed consent/ informed uptake. • Implications of the speed of process – from testing to results. • Managing results - quality of information and communication when disclosing results. • PoC location of each SmartHEALTH application. <p>These issues raised a number of questions for further fieldwork for WP9:</p> <ul style="list-style-type: none"> • How will this new technology fit into the existing healthcare services, in terms of more accurate tests, improved access to healthcare information for health professionals? • Will a quicker test result produce a quicker diagnosis? • Will SmartHEALTH impact on the current lack of willingness for participants to attend cervical cancer screening programmes? • Will improving the cancer screening stages and follow up stages impact on the other care services within the wider continuum? • Is the location for the tests new or existing within current practice? • How much knowledge and skill does the person using the machine require?

¹ GPs involved in the research were invited though due to last minute changes in work schedules none were able to attend.

2.1.1 Disruptive technologies: positive and negative perceptions

As the fieldwork progressed, two overriding questions guided the research:

1. What are the benefits for the possible range of users of SmartHEALTH technology?
2. Will SmartHEALTH be a disruptive technology within existing healthcare systems?

The concept of SmartHEALTH as a disruptive technology has been an ongoing discussion within the project. As highlighted in D9.3, all partners interviewed, except for two, predicted that SmartHEALTH would not disrupt existing healthcare practices. The two interviewees who perceived the technology as disruptive used the term in a positive sense and predicted that the introduction of the SmartHEALTH technology into an existing healthcare system would highlight ineffective or inefficient practices and subsequently force positive changes in current practices. A disruptive technology can be defined as a technological innovation, product, or service that employs or produces a ‘disruptive’ strategy, rather than a ‘revolutionary’ or ‘sustaining’ strategy, to replace existing dominant technologies within existing healthcare systems or markets (Christensen et al., 2006). Unlike a revolutionary or sustaining strategy, a disruptive technology does not attempt to fit into current practices in a smooth transition but instead aims to disrupt the status quo. As a result, the disruption created by the implementation of a new technology can be perceived as either positive or negative for different users. Inevitably the introduction of a new technology into existing healthcare systems creates disruption for some users while creating opportunities for change for others.

3 Methods

The symposium employed a participatory approach. Participatory workshops are a form of Participatory Appraisal (PA) technique, one of a family of research methodologies that aim to enable people to reflect on, analyse and share their knowledge of their own life experiences (Chambers, 1997). The approach allows participants to lead the research discussion and does not seek to create homogeneity or consensus of opinion.

A participatory approach is conducive to open discussions that are a necessity in mapping out the ELSIs relevant to the future implementation of SmartHEALTH technologies. Participants’ deliberations aimed to provide more strategic questions to guide the development of the technology. However, there was no attempt to create consensus of opinion as different stakeholders hold different expectations from new technologies. The challenge for the SmartHEALTH consortium is to decide which questions need to be answered within the project, which questions are directed to other parties and which questions remained unclassified at present.

The symposium was designed by an experienced participatory researcher and the symposium was based around the following structure (see Appendix B for the agenda):

Day 1: Breast cancer monitoring and SmartHEALTH

Setting the Scene: Participants were welcomed to the meeting and a broad outline of the aims and purpose of the symposium was given.

Session 1: SmartHEALTH the concept and potential future applications: Professor Calum McNeil (SmartHEALTH Coordinator) set the scene by presenting the SmartHEALTH roadmap followed by a viewing of the SmartHEALTH video which presents a near future scenario of a home-monitoring application for breast cancer. Initial questions were invited to a panel of SmartHEALTH representatives.

Session 2: Breast cancer monitoring and SmartHEALTH: Invited speakers were asked to address the symposium with a pre-prepared presentation responding to the SmartHEALTH

video and/or the SmartHEALTH roadmap from their own professional and/or personal perspective.

*Discussion*²: After the presentations, all the participants were invited to identify and discuss the technology under two main headings:

- Moving breast cancer follow-up from hospitals to GP surgeries
- Moving breast cancer follow-up from GP surgeries to patients home (video)

Day 2: SmartHEALTH and the future of CRC screening

Summarising day one: Day two began with a summary of the deliberations of day one: during morning coffee participants were invited to review written records from day one.

Session 3: SmartHEALTH and the future of CRC screening: This session consisted of four presentations, where invited speakers addressed i) ethical issues including informed consent, ii) screening participants' preferences, iii) Organisational aspects of telemedicine and iv) asking questions for organisational change.

*Discussion*³: Participants were invited to identify and discuss issues under two headings:

- What is the nature of SmartHEALTH and for whom?
- What are other potential innovations for SmartHEALTH?

Session 4: Future issues for SmartHEALTH consortium to consider: In this session, there was a shift from dialogue and understanding to debate and critical discussion (Forester, 2007). Participants were asked to imagine the year was 2015 and to propose questions that they would like SmartHEALTH to have answered by that date. Using the same methods in session 2, participants were invited to explore, discuss and record their comments under the five heading in James Cornford's presentation⁴: i) Rules and regulations ii) Roles and responsibilities, iii) Rewards & incentives, iv) Routines and habits and v) Roles and responsibilities. (A sixth category 'other' enabled additional questions and comments to be recorded.)

² To create a structure to this activity, participants were invited to write comments under 4 categories a) Opportunities/benefits; b) Challenges, c) What they would keep the same? and d) What they would change? The aim of this activity is to provide time for participants to reflect on their own and others thoughts, with the intention of stimulating a wide discussion. Records of the notes made by participants were made available on the wall during the symposium, with an opportunity for participants to view and revise their comments.

³ As with the discussion session on day 1, participants were invited to write comments for public display with the opportunity to add to or revise these during the day and to agree or challenge comments made by other participants.

⁴ Cornford's typology was chosen to provide a structure for a constructive and creative discussion around the ELSIs raised during the symposium. The benefit of these five themes is that they offered a procedural typology to categorise and subsequently organise questions and comments with a view to informing the future development of SmartHEALTH. However, this typology is not a generic model as discussed further in section 6.



Figure 1: Session 4 and wall charts from Session 2.



Figure 2: Preparing questions about 'routines and habits'.

4 Summary of Presentations

Each speaker was invited to respond to the future applications of SmartHEALTH technologies in light of their professional and/or personal experiences. This section provides concise summaries of each presentation that focused on their chosen ethical and social issue(s) and provided background information for the discussion sessions. (PowerPoint handouts and transcripts are available on request). Potential implications for SmartHEALTH are drawn together and summarised in section 6.

4.1 Setting the scene and SmartHEALTH video

This session began with an introduction by Simon Woods (on behalf of WP9 and WP10): Fionagh Thomson and Zoe Morrison briefly introduced the concept of “disruption” as neither a negative or positive concept, and invited participants to reflect on different users perceptions of a “disruptive” technology. James Cornford invited participants to reflect on the complexity of the implementation of new healthcare technologies in existing healthcare systems (see summary below). Calum McNeil (project co-ordinator) presented the SmartHEALTH roadmap and vision before showing the video of one future application of SmartHEALTH technology: home testing for breast cancer monitoring.

4.1.1 8 faces of ‘integration’ for a new healthcare technology (Dr James Cornford)

This presentation placed SmartHEALTH within the context of telecare and aimed to set the scene for the symposium by highlighting eight different issues to consider when implementing healthcare technologies into existing healthcare context. James began with the question: What does ‘integrating’ telecare mean in practice for different users? He continued: “Everyone talks about integration though they often mean something subtly (or not so subtly) different”. He proposed eight different perspectives towards integrating telecare:

1. **Service User:** a) “*Telecare is what ‘you lot’ need to do together*”. The patient user has an expectation that the “providers” of the technology, which may include the supplier, health providers, and regulators, will work together to offer a seamless and quality service; b) “*Telecare is what households also have to do*”. But the patient user must also be able to work with the providers which means that service user and their household/network have to co-operate and accommodate.
2. **Technical:** (*Telecare is a technology*). Telecare systems must inter-operate technically: suppliers of systems must address quality control of the systems and agree standards for interfaces, data structures, etc.
3. **Process:** (*Telecare is a flow of tasks that are linked and move smoothly around*). Where so much is at stake, such as monitoring serious disease then there must be high quality process mapping and process re-engineering to ensure that workflow by professionals, patients, carers or machines is co-ordinated smoothly.
4. **Practitioner:** (*Telecare is a set of innovations in, and interventions into, practice*). SmartHEALTH will need to address the practicalities of fitting into professional practice(s).
5. **Policy or vertical:** (*Telecare is policy intervention*). So SmartHEALTH will need to consider the policy implications of integration in terms of Departments of Health, European Regulation, National and International Health Policy etc.
6. **Commissioning/procurement:** (*Telecare is a commodity or service to be bought, procured or commissioned*). The process of telecare providers working together to buy the technology.
7. **Managerial:** (*Telecare is a service to be delivered*). Therefore, SmartHEALTH must consider the implications for co-ordination planning, monitoring and evaluation of telecare activities and of the targets and rewards for those involved.
8. **Organisational:** (*Telecare is a distributed organisational entity*). Therefore there are implications for co-ordination of telecare across organisational silos by managers in the health, social care arenas, e.g. between primary and secondary care.

4.2 Session 2: Breast cancer monitoring & SmartHEALTH

This session had five presentations: i) a summary of the research on breast cancer follow-up practices and the impact on patients; ii) a professional perspective from a breast cancer nurse and therapy radiologist experienced in breast cancer follow-up; iii) a patient perspective; iv) WP9's research findings: GPs and oncologist perspective of moving breast cancer follow-up from hospitals to GP surgeries and v) a medical sociological summary relevant research on telecare.

4.2.1 Comparing hospital and telephone follow-up after treatment for breast cancer: a randomized control trial (Susan Williamson)

This presentation focused on the role of patients' perspective of and attitude towards current monitoring practices. Susan presented a randomised controlled trial that compared traditional follow-up in a hospital with telephone follow-up (by specialist nurses) for women after treatment for breast cancer. The study began from three main premises:

- Current practice of hospital follow-up in the UK has little benefit for patients and health professionals
- Telephone follow-up could be more convenient for patients as there are no long waiting times in clinics, no parking problems or travel costs
- Specialist nurses have specialist knowledge/expertise, have training to meet patients' physical and psycho-social needs, can refer patients to the appropriate health professional and provide continuity of care.

The study was carried out in two centres in the Northwest of England. The control group involved hospital follow-up where patients are seen frequently by junior doctors though nurse-led clinics are increasing. The new intervention was a telephone follow-up by specialist nurse that: i) focused on information giving rather than searching for recurrence; ii) questions evolved from previous research on women with breast cancer and their information needs; and iii) builds upon and develops the skills of breast cancer nurses. The study conclusions were that:

- Specialist nurses can deliver a high quality follow-up service over the telephone
- women in the telephone follow-up group showed high levels of patient satisfaction
- Telephone follow up:
 - shifts focus away from clinical examinations with little value to meeting the information needs of patients
 - reduces the burden on hospital outpatient clinics
 - is suitable for patients with long travelling distances

4.2.2 Future for nurse-led monitoring (A. Walshe & C. Downs)

This presentation represented the professional and personal reflections of a senior breast cancer nurse and a therapy radiologist in running follow-up clinics for women living with breast cancer:

- Emotional support for women to alleviate anxiety about their cancer treatment and how it affects their lives
- Notably, the patient's anxiety levels increase significantly before their clinic appointment
- Health professionals must be able to assess the coping and psychological needs of patients beyond their treatment plan and into their everyday personal and family lives

In reflecting on the potential impact of the SmartHEALTH technology and moving breast cancer follow-up from hospitals to the home, they ask three questions:

1. How will the technology fit into the process of managing patient care?
2. What is the likely role of specialist nurse in preparing patients for this type of technology?
3. What are the challenges in terms of the development of patient information and education?

4.2.3 The Clinic in the Kitchen (Lynne Stobbart)

This presentation was from the perspective of an experienced social researcher who shared her experiences of living with breast cancer and being monitored post-treatment. Lynne's presentation outlined her personal thoughts on the video (the full transcript is in Appendix C). Below are key phrases and questions from 16 points presented by Lynne:

1. Who will be eligible to use the SmartHEALTH technology?
2. Is there perhaps an over emphasis on the idea that "early monitoring will keep the disease under control?"
3. Does early detection equate to early treatment? And more importantly, will it make a difference to outcome?
4. Is it possible that this screening technology (whether at home or in healthcare facilities) may also lead to unnecessary or equally damaging treatments?
5. A cynical view maybe that this initiative is less to do with patient benefit and more to do with minimising the workload on healthcare professionals and thus reducing costs.
6. The idea of simultaneous updating of medical records is very appealing. However, this assumes a level of compatibility, compliance and competency that isn't always evident within NHS data management systems.
7. What are the implications of over-testing? (For example over-anxious patients carrying out more tests than instructed/required).
8. Conversely, what about (patients) who are too anxious/frightened to perform the test, or simply forget?
9. If test results are positive the GP will give the patient an appointment - will the patient also be aware that the test is positive? If not, and the appointment system fails for some reason, how will the patient know?
10. The proposed system for managing home testing raised some questions regarding patient/professional relationships. Having had an initial breast cancer episode I wonder whether (it would be better) if all future communication/management was via Breast Cancer Team rather than the GP.
11. The video opens with a statement that SmartHEALTH technology ensures that the patient is at the centre of disease management. For me, this raises two questions: a) what does it actually mean for the patient to be at the centre of disease management? b) And is this where they want to be?
12. With choice and control comes an obligation to act responsibly. Who will monitor whether or not I've been doing the test regularly?
13. I have a concern that patients may become obsessive about their condition, treatment and lifestyle and that regular self-monitoring may exacerbate this.
14. Even though the rest of my treatment is over (or soon will be) this daily medication, is a constant reminder that although I am 'cancer free' and I feel absolutely fine, I am still 'not quite normal'. Whilst I am sure that home testing would indeed be more convenient in every practical sense. When I first watched the video and saw the equipment I wondered, '*where would I keep it?*'

15. I have some concerns that by bringing this complex testing process into such a mundane space this might trivialise the condition and detract from its seriousness.
16. Because home testing would remove the need for the patient to attend a clinic it might prevent them from reporting other ad hoc symptoms which they may consider too trivial to warrant making a specific appointment for but which may be important and which they may have reported in a face to face consultation.

Lynne concluded with the following comment: I believe that this system does indeed provide an opportunity to ensure that the patient is at the centre of disease management, but being at the centre of disease management does not necessarily mean ‘do-it-yourself’. Patients will be at the centre of their own disease management if they are given the choice of how that disease is to be managed:

“More personally for me, the clinic is the place to be a patient, and I don’t want a clinic in my kitchen”.

4.2.4 Disruption or Integration? Using social ecology approach to understand interactional conventions in Telehealthcare (Yannis Pappas)

Yannis drew on the theory of the social “ecology” as a framework for understanding change in healthcare systems. He proposed that the implementation of new healthcare technologies creates change within four basic components of the healthcare “ecosystem” (organisational, medical, technical and psychosocial) that affect and disrupt the system as a whole. This concept framed a study (using conversational analysis) that explored the effect of video-mediated, real-time telemedicine on the communication (between GP and patient in primary care settings with a consultant in a hospital).

The study began on the premise that while common themes in e-health research are optimisation of planning and enhancement of implementation, and ‘we know a good deal about bandwidths and resolutions, (we know) little about the human dimensions that make practice possible’ (Whitten et al, 2000: 112). Yannis stressed that telemedicine is an unfamiliar terrain which requires constant negotiation of communication skills and roles.

Study findings identified four types of change which had an effect on: a) interprofessional communication; b) organisation of the encounter; c) power distribution between the participants; and d) health professionals’ required skills:

- Telemedicine greatly affects institutional interaction between participants and has a destabilising effect on the skills that consultants employ in producing and maintaining an asymmetry between their role and the role of the patients
- Telemedicine produces conflicts of agendas between healthcare professionals, takes the communicative floor away from the consultant and affects patient participation
- Telemedicine greatly affects the way physical examination is conducted
- Training to acquire telemedicine-specific skills is important

He concluded with the following comment on the concept of disruption within current healthcare research: “Perhaps we should be thinking of disruption and integration as inevitable products of change, which need to be studied through appropriate research methods. Several qualitative research methods, including various analyses of interprofessional communication have been proven effective in identifying issues of change and disruption in healthcare.”

4.3 Session 3 SmartHEALTH and the future for CRC screening

This session included four presentations based on invitations to researchers from different disciplines (bioethics, psychology, social studies and organisational change) to present a

chosen topic related to the SmartHEALTH applications: i) ethical aspects of SmartHEALTH vision; ii) implementation of telecare and current challenges; iii) qualitative research in WP10 on factors affecting users uptake of screening tests; iii) informed consent and screening practices; and iv) questions for organisational change.

4.3.1 Screening: Do healthcare standards change from the “individual” to the “public health”? a bioethical viewpoint (Rouven Porz)

Rouven’s presentation revolved around three phrases (underlined below) in a SmartHEALTH statement:

“The Smart HEALTH Integrated Project is developing the next generation of smart diagnostic systems fully integrated into healthcare systems in Europe. Driven by key applications in cancer diagnostics, SmartHEALTH will enable enhanced medical diagnosis leading to earlier and more precise results and thus contributing to an increased quality of life.”

Based on these phrases, Rouven posed three questions: 1) Do we know what we refer to when we argue for a better quality of life? 2) Do scientific results make sense for everyone? and 3) what if SmartHEALTH leaves the “medical” domain?

He began by asking: What is Quality of Life? How do we put this into practise and how do we measure it? Are we talking about a vision here, a value, a virtue, or are we talking about a concrete tool in social management? He concluded that the notion “quality of life” only makes sense as a relational measurement, and not as an abstract idea, that seems unbeatable (though empty) in every discussion in the healthcare arena. He proposes that clarifying “quality of life” will be important in future communication about the implementation of SmartHEALTH. He then explored the question: What is a “result” (and from whose perspective)? He outlined that a “medical result” primarily means to assess a patient’s health status. “Results” arising from a scientific world assume that we live in a scientifically based world and, therefore, a scientific interpretation of “a result” presumes that science can give meaningful explanation of our bodily functions and our life-world. He problematised this viewpoint by referring to a study that explored patients’ perception of genetic testing in Switzerland (see transcript details). The findings highlighted that different people find different ways to make meaning of their lives and diseases that do not always begin from or even include a scientific narrative.

His final comment focused on the concept of enhanced medical diagnosis and he presented three future possible scenarios for SmartHEALTH:

- Post-treatment monitoring: as people grow older and morbidity rates change to rates of multi-morbidity, older people may be monitoring for a variety of diseases.
- Screening: If SmartHEALTH enters the area of lifestyle, individuals could monitor themselves before going (e.g.) hiking and ask: Am I fit for my hiking trek tomorrow?
- Screening/monitoring results and social networking: as joggers share their heart rate results on network sites, in the future people may share their test results.

From the third scenario he asks the question: What are the implications for people obsessed with their health and/or hypochondriacs if SmartHEALTH changes from the medical domain to a leisure time lifestyle activity.

4.3.2 The world of telecare: what we think we know (James Cornford)

This presentation expanded the consideration of SmartHEALTH telecare and proposed five main barriers and attendant questions to be addressed in order to move forward:

1. **Rules:** based on the assumption that people are ‘rule following creatures’, current rules (various) prevent the development of telecare. In order to move telecare forward, telecare needs to be mandated. The question is: who can mandate telecare?
2. **Roles:** based on the assumption that people act within well established roles, key roles which underpin the successful operation of telecare are lacking. The questions are: which roles are missing and who should create/develop the roles?
3. **Rewards:** based on the assumption that people are rational maximisers, the current structure of incentives/benefits is preventing the promotion of telecare. The questions are: who should change the structure of incentives and who are the incentives for?
4. **Routines:** based on the assumption that people are habitual creatures, existing routines block the development of telecare as a habitual activity. The questions are: how do you break up ineffective existing routines, create new ones and who should do it?
5. **Relationships:** based on the assumption that people are social and political animals, current telecare does not have sufficient committed allies and/or has too many enemies. The questions are: how do we recruit more allies and/or neutralise the enemies and who should do this?

4.3.3 Intelligent technologies for quick and easy colorectal cancer detection: A boost for screening behaviours?" (Lucia Savadori)

Lucia presented the results of the University of Trento’s quantitative study in Poland, Italy and the UK that explored the factors affecting patient’s change in testing intent due to the introduction of a new diagnostic test such as SmartHEALTH. She highlighted that as early cancer detection is among the most relevant factors impacting on morbidity and mortality, new technologies such as SmartHEALTH could improve early detection rates and increase the chances of survival. However, patients must choose to be tested and uptake of colorectal cancer screening is currently less than 50% since patient’s testing intent is determined by the availability of the test and by a complex mix of socio-demographic and psychological factors. Respondents were asked to complete a questionnaire about their attitudes towards three scenarios for colorectal cancer diagnosis: a) Colonoscopy; b) SmartHEALTH; and c) a Home-kit test. The SmartHEALTH test was described as a new test with the following features: a sophisticated technology for sample analysis (highly technological); a quick diagnosis (15-30 minutes); easy to use (by family doctor and/or at every point-of care); non-invasive (blood sample taken from a finger) and all three tests were said to have 99.9% of accuracy.

Their findings showed that the offer of a Lab test greatly increased the intent for testing, moving it from 28% of people answering yes to colonoscopy to 77% of the people answering yes to the Lab test. The Home kit test, instead, did not offer a greater advantage compared to the Lab test and Lucia concluded that the convenience of implementing this type of home testing is therefore questionable. The main conclusions were:

- Lack of trust in a cancer diagnosis test appears to be one of the most critical variables in refusing to use a new test such as SmartHEALTH.
- Additional critical variables were individualism and the optimism toward technology: respondents were more favourable towards SmartHEALTH when they agreed with the statement that “if people have the vision and the ability to acquire property they should be allowed to enjoy it.”

4.3.4 Raising Questions for change (Zoe Morrison)

This presentation centred on Zoe’s research into change in the workplace. The talk used two case studies (the stocking frame in the 19th century and military helicopters in the 21st century) to illustrate how innovation in the development of technology can have unintended

consequences and consideration of such consequence must be factored into development. In conclusion, Zoë emphasised the need for deep consideration of simple questions regarding the application of innovative and disruptive technologies. Questions raised for discussion included:

- Questions of information and communication, for example. Healthcare staff, other agencies and Patients.
- Issues relating to inclusion, such as accessibility, acceptability and choice for different SmartHEALTH users.
- The potential for innovation and the potential for other applications of the technologies being discussed.

5 Symposium Findings

The section summarises the key issues and questions recorded by participants under the headings below during the discussion sessions:

- Moving follow up from hospitals to GP practices
- Moving follow-up from hospitals into patients homes
- Future directions for Smarthealth: suggested questions to address (Routines, Roles, Relationships, Rewards and Rules)

Under each heading, participants recorded their thoughts into four broad themes: i) Opportunities/benefits; ii) Challenges; iii) What to keep the same? and iv) What to change? (See Appendix C for participants' verbatim comments and questions).

5.1 Moving follow-up from hospitals to GP surgeries

5.1.1 Opportunities/benefits and Challenges

Opportunities and benefits included:

- Greater accessibility, in particular for rural communities (though this was questioned as in some areas transport is limited)
- A less threatening environment in their GP surgery
- Continuity of care could be improved (if assigned the same GP)
- Speed of results would reduce anxiety of waiting for results
- GPs know co-morbidity and medication and, in an ideal situation, know the patients and family situation
- Practice nurses could also be competent to give this care (as shown by randomised controlled trials in lung and colorectal cancer)

Challenges included:

- Patients maybe 'locked into one GP's care and they may need fast access to secondary care
- Would patients trust results taken by the GP?
- Could GPs provide the emotional support for patients and the education for other GPs and patients?
- How would the new workflow be managed?

5.1.2 What to change and what to keep the same?

- The role of the specialist doctors and nurses and other health professionals.

- If hospital personnel can provide women with the psychosocial support then follow up should stay in hospitals.
- Change might include the creation of a specialist healthcare team in primary care.

5.2 Moving follow-up to patients' homes

5.2.1 Opportunities/benefits and Challenges

Opportunities and benefits for patients included:

- Greater autonomy and self-determination giving patients greater control in their care
- The technology could offer an alternative option for patients who do not want to go to support groups
- The technology was seen to be potentially cheaper in terms of: a) less organisation and b) less private costs, though questions were raised on the cost of rolling out the technology and, as the technology advanced, subsequent updates.

Challenges included:

- Could the weight of personal responsibility may be too much since many cancer patients are over 65 years old?
- Patients are seeking greater autonomy in their healthcare and may wish for direct access to results without involvement of his/her doctor. As in other home monitoring contexts, such as blood pressure monitoring, leaving the patient to contact the doctor when needed.
- Could the technology trivialise testing and, therefore, the significance of the results, with the possibility of false reassurance.
- How to effectively control the quality of self-monitoring and manage human error. (Who would service, identify faults and failure? How would robust quality standards be maintained in a non-hospital test? How would be patient data be kept private?)
- Is the technology designed for an 'idealised home or a chaotic home? (is the technology being designed for the home or household/the family?)
- How to address new workflow challenges [defined as the 'design part of the process that lie outwith the technology']: (Who will explain the technology to patients, ensure compliance and manage speedy referrals back to hospitals? What new skills will clinicians need? How will the technology become acceptable to GPs, patients and 'others'?)
- While locating the test in the home was seen as been beneficially for rural populations and could address current inequality through improving access to healthcare, the technology seems inaccessible to the blind and individuals who are less technologically able and, therefore, could discriminate against individuals who may benefit the most: chronic disease, disable and multiple morbidity.

5.2.2 What to change and what to keep the same?

Only one issue was raised under the heading of what should stay the same:

- Patient support and reassurance with a dominant focus on the continuing and increasing role of the breast cancer nurses.

5.3 Future direction for SmartHEALTH

In the final session, participants recorded the questions they want SmartHEALTH to have answered by 2015, under Cornford's typology to implementing healthcare technologies:

i) Routines and habits; ii) Rules and regulations; iii) Rewards and incentives; iv) Relationships; v) Roles and responsibilities.

5.3.1 Routines and Habits

The main issues were:

- As in other fields of innovation, new needs and habits are produced (particularly for new organisational routines). New habits would need to be learnt by and be acceptable to health professionals and patients.
 - For home testing, patients would need to “learn” a different way of coping with their health problems and to reconfigure their everyday working practices (e.g. taking a test every day after morning with coffee).
 - For hospital based testing, on one day a patient is tested first with SmartHEALTH then, if positive, more test are immediately carried out.
- Is the system uniform across a health system?
- How prescriptive is the testing process for patients? (How intensive are the reminders to test and what are the reminders?)
- What happens if one of the people in the health care routine fails to comply?
- Will this new routine be restricted by hospital office hours or can patients test at their own convenience?
- What are the implications on workflow for testing in acute routines?

5.3.2 Rules and regulations

The rules and regulations focused on: i) data use and storage; ii) quality assurance; iii) support services for users; iv) costs incurred for patients; and v) policy issues.

Data Use and storage:

- Who will have access to the data (health professionals and patients), who will own the data and how will the data be transferred between relevant services?
- What else can the data be used for?
- Should this technology be a ‘public’ technology?

Quality assurance:

- What are the Quality standards CE mark?
- How will quality control of home based kit be managed? (e.g. non qualified users)

Support services:

- What can users (patients and health professionals) expect from system support?
- What is the turn around time to deal with emergencies and joined up services, e.g. ambulances and GPs with call centres?
- Home testing will need to adhere to national ethical guidelines

Costs:

- For the home test, who pays if the machine breaks, or is stolen?
- How will payment reimbursement be managed?

Policy:

- To accommodate this new technology, the health care model will have to change and therefore new health policies need to be developed.

- One participant wrote: “the rules topic is not relevant for SMARTHEALTH (since) none of its characteristics will introduce novelties when compared with alternative technologies”.

5.3.3 Rewards and incentives (benefits)

The main issues raised were:

- Patients must perceive the new technology as something ‘positively increasing’ their quality of life:
 - The home test allows the patient to work with no need to take days off for hospitals tests and the test could be taken on holiday
- What are the implications for patient’s health insurance?
- Can the patient choose to opt in or out?
- GPs will need to be reimbursed if the test is moved to GP practices
- A national health service (e.g. the UK NHS) may invest more money into a new technology if the uptake is high

5.3.4 Relationships

Key relationships to considered at different levels are:

- Health professional needs and procurement dept guidelines
- Secondary & primary care (current poor relationship need to change)
- Patient, GP and the secondary care consultant (in a real-time situation)
- Patient and the technology (will I trust my SmartHEALTH monitor? How will this relate to other test results?)

Additional questions raised were:

- Is this aimed at consumers or patients?
- Is there a need for a new ‘profession’ of experts in this area? (how will these new professions fit with other health care professionals?)
- Are there issues of ‘deprofessionalisation’ and therefore of trust between patient and health professional?
- Disruption (for better or worse) of power dynamics between patient & professional?

5.3.5 Roles and responsibilities

In terms of roles and responsibilities, questions to be addressed by the SmartHEALTH consortium focused predominantly on the following organisations and individual professions:

- **Royal colleagues:** Are the various medical royal colleges playing catch up to the technology?
- **Pathology dept:** (when) should pathology departments start to gear up for SMART/molecular diagnostics and what happens to staff with microscopes etc?
- **Pharmacists:** train pharmacists in use of SmartHEALTH kit. What is the role for community pharmacy?
- **Patients:** responsibility shifts much more on the users for the applications which allow telecare (home kit)
- **Specialist nurses:** could use specialist nurses roles remain but be developed further developed (e.g. work with specialists nurse to develop hardware that is suitable for their workflow)

- **Service providers:** Provide different options for different patients so they have as little or as much support as they want?
- **Procurement department:** compromise between what the technology buyers (NHS procurement) and the users want (patients & health professionals)
- **General:** Who will be responsible for giving results? Who distributes & collects & maintains the machines?
- Create a SmartHEALTH spokesperson and personalise the technology (testing for trust?)

6 Discussion and recommendations

Discussions around social and ethical issues frequently highlight the complexity of the socio-technological context and raise a myriad of questions that cannot always be answered. However the aim of raising social and ethical questions is not always to address them but to remain mindful of them during the complex process of implementation. During the presentations, the speakers raised a number of potential implications for SmartHEALTH as summarised below.

6.1 *Potential implications raised by speakers*

James Cornford highlighted that implementation is multi-faceted and warned against any attempt to simplify this process. Yannis Pappas equates the healthcare setting to an ecosystem with four symbiotic components (organisational, medical, technical and psychosocial) and therefore changes in one component creates a domino effect upon the other three components. Zoe Morrison highlighted the complexity of change and advocates an ongoing process of asking the right questions for change though she warned that no amount of planning can avoid unintended consequences.

Inevitably, the nature of the questions raised will be moulded by the position of the stakeholder within the healthcare system (e.g. procurement department, NHS manager, secondary care consultant, practice nurse or patient):

- Amanda Walshe and Carole Downs in their role as health professionals in breast cancer follow-up raised questions around their duty of care for patients in providing sufficient levels of psychosocial support for patient and the need for health professionals to be retrained to continue providing this support.
- WP9 research presented the views of select oncologists and GPs who also raised concerns about the effective flow of knowledge and responsibilities between primary and secondary care and in maintaining their duty of care to patients.
- Rouven Porz as an applied bioethicist based in a Swiss hospital raised questions on defining ‘quality of life’ and recommended that the project’s chosen definition should be clearly communicated during the implementation of SmartHEALTH.
- WP10 research raised issues of trust between participants in a screening programme and the perceived reliability and accuracy of the technology.
- Lynne Stobbart raised numerous challenging questions based on her personal experience as a patient and her rejection of the home monitoring system in her everyday life as she stated: “I don’t want a clinic in my kitchen”.

6.1.1 **Managing questions for Change: existing/ new questions raised by Participants**

As a myriad of questions arise from different stakeholders, suitable typologies need to be identified in order to effectively categorise and subsequently manage questions for change.

For the purposes of the symposium, the facilitators chose Cornford's typology to categorise participants' questions in the session 4. However, the most suitable typology must be guided by the vision, aims and level of social accountability within the SmartHEALTH consortium that are beyond the remit of this deliverable. In this section, the aim is to highlight which questions raised by participants have been identified within the project, which questions are being addressed and which questions are new to the project.

Existing questions raised within the Project

A majority of the questions raised by participants mirrored the ethical and social issues raised by WP9 (see table 1) and WP10, and reinforces the ELSIs identified within the project. One ELSI raised by WP9 (see D9.3) not raised in the symposium: should patients be tested for diseases where there is no effective treatment?

Within the project, other Workpackages have begun to address some of these questions:

- WP1 have acknowledged the need for decision pathways to be developed for health professionals across the different care pathways (see D9.3)
- WP7 have written extensively on data security methods (see D7.3)
- WP12 are exploring European regulation laws

New Questions to consider

A number of questions raised in the symposium had not been raised within the project:

- As the technology becomes part of routine care, what new needs and habits will arise?
- What is the role of the pharmacists and the Royal colleges in the implementation of SmartHEALTH?
- How to compromise between health professionals' needs and procurement guidelines?
- From the macro to the micro: how to address the complexity of workflows and multiple level relationships between humans and technologies?
- Is the aim to move the process into the home (the place) or the household (family)?
- Should SmartHEALTH create a spokesperson to create understanding of the technology, open dialogue and personalise the technology?

Inevitably, a significant number of questions remain unanswered at this stage, the most notable being questions around relationships:

- How to address potential changes in patient and health professionals' routines and the multiple relationships within the care pathways between organisations, health professionals, the patient and the 'machine'.

The different stakeholders act as powerful agents who can provide support for or set up barriers against the future implementation of new healthcare technologies. A number of participants suggested that SmartHEALTH take a lead in developing these multi-level relationships as there is a "complex interaction among many potential agents depending upon each specific application of the SmartHEALTH platform".

In conclusion, this symposium created a space for discussions that produced numerous ELSIs in the form of future questions for the SmartHEALTH project. Once the Steering Committee has agreed a suitable typology for managing strategic questions (around potential ELSIs) raised by different stakeholders, the challenge that the Consortium faces is agreeing which questions should be considered by the project, which questions are to be set aside for other external parties to consider and which questions remain uncategorised and shelved for the immediate future.

7 Implications for fieldwork

The implications of the symposium findings for the final phase of the fieldwork, the case studies (D9.6) support the focus on the patient perception of the SmartHEALTH technology. (As also requested by the EC during the Technical Review in February 2009.)

7.1 Next research steps for WP9 and WP10

D9.7: Report on case study findings of main ELSIs arising from SmartHEALTH

As outlined in the presentations, WP9 have completed the research with oncologist and the next step is to set up workshops with (breast and CRC) patients to explore their perceptions of SmartHEALTH vision (the video). Workshops will be set up towards the end of 2009 and patients will be invited to watch the SmartHEALTH video and share their thoughts on the SmartHEALTH technology in their everyday lives in terms of: i) opportunities/benefits; ii) challenges; iii) what they would change? iv) what they would keep the same?

D10.4: Report on study of psychological factors influencing patients' informed choice in non-invasive tests

WP10 stressed the importance of patients' informed choice, that is, patients must choose what test to do together with their doctors. However, in clinical practice often patients simply comply with a status quo (for example, they do an exam because it is in the normal guidelines, but they do not fully understand the meaning of it). There is a chance that hi-tech instruments such as SmartHEALTH might increase this tendency. In Task 10.5 (Study on psychological factors influencing patients' informed choice in non-invasive tests), UNITN will study this aspect to understand whether non-invasive tests that are automatically performed by a computer along with routine-blood tests might reduce patient's awareness of doing the specific test. Patients might comply with the doctor's request simply because the test is "included in the package" (automatically performed by the computer). But they might not be prepared for the very dramatic results (potential cancer diagnosis). This tendency is a famous effect in psychology, known as the "status quo bias" that demonstrates that people are willing to keep a particular option in the insurance if already included in it, but they would never include that same option if not present at the choice moment (Hershey, Johnson, Meszaros, and Robinson, 1990).

Appendix A: Symposium Participants

SmartHEALTH Symposium, May 18-19th 2009, “Integration or Disruption?: Implementing SmartHEALTH into Healthcare”

	NAME	AFFILIATION	BACKGROUND	LOCATION
1.	Calum McNeil Calum.mcneil@ncl.ac.uk	Newcastle University medical school (SmartHEALTH Coordinator)	Biological sensor systems	Newcastle, UK
2.	Stephan Kiefer stephan.kiefer@ibmt.fraunhofer.de	Fraunhofer Institute, SmartHEALTH participant	Ambient healthcare systems	Saarland, Germany
3.	Simon Woods Simon.woods@ncl.ac.uk	PEALS, Newcastle, SmartHEALTH participant	Bioethicist	Manchester, UK
4.	Fionagh Thomson Fionagh.thomson@ed.ac.uk	PEALS, Newcastle, SmartHEALTH participant	Social & Ethical Issues	Edinburgh, Scotland
5.	Lucia Savadori lucia.savadori@unitn.it	University of Trento, SmartHEALTH participant	University researcher in Psychology	Trento, Italy
6.	Luigi Mittone luigi.mittone@unitn.it	University of Trento, SmartHEALTH participant	University professor of Economics	Trento, Italy
7.	James Cornford james.cornford@ncl.ac.uk	KITE, Newcastle University	Research fellow	Norfolk, England
8.	Tony Branson Tony.Branson@nuth.nhs.uk	Northern Centre for Cancer Care, Newcastle	Director of research/oncologist	Newcastle, UK
9.	Carole Downs Carole.Downs@nuth.nhs.uk	Northern Centre for Cancer Care, Newcastle	Therapy radiologist	Newcastle, UK
10.	Amanda Walshe Amanda.walshe@nhct.nhs.uk	Northern Centre for Cancer Care, Newcastle	Senior Macmillan Breast cancer nurse	Newcastle, UK
11.	Rouven Porz Rouven.Porz@insel.ch	Bern hospital	bioethicist	Bern, Switzerland
12.	Gary Player Gary.Player@cddft.nhs.uk	Durham hospital	Cytology	Durham, UK
13.	Zoe Morrison Zoe.morrison@hw.ac.uk	Herriot Watt University	Former manager in primary and secondary care	Scottish Borders
14.	Lynne Stobbart lynne.stobbart@ncl.ac.uk	Newcastle University	Patient perspective	Newcastle, UK
15.	Elsie Grinsell	Chair, patient group	Patient perspective	Northumbria, UK
16.	Greg Maniatopoulos gregory.maniatopoulos@ncl.ac.uk	Newcastle University	ELSI of telecare	Newcastle, UK
17.	Susan Williamson Susan.williamson@man.ac.uk	Manchester University	Nurse researcher	Manchester, UK
18.	Lorraine Cowley Lorraine.cowley@ncl.ac.uk	PEALS, Newcastle University	Genetic counsellor	Newcastle, UK
19.	Victoria Hamilton (VEHAMILTON@groupwise.swin.edu.au)	Swinburne University Melbourne	PhD: participants’ attitudes to CRC screening	Melbourne, Australia
20.	Christine Campbell christine.campbell@ed.ac.uk	Edinburgh University		Edinburgh, Scotland
21.	Ruth Jepson Ruth.jepson@stir.ac.uk	University of Stirling		Scotland
22.	Philip Bowe Philip.bowe@dcu.ie	Dublin City University, SmartHEALTH participant		Dublin, Ireland

Appendix B: Symposium Agenda

Day 1	
12:00- 13:00	<i>registration and welcome buffet lunch</i>
13:00- 13:40	<p>Setting the Scene Simon Woods: welcome and aims of Symposium. Fionagh Thomson/Zoe Morrison: ‘disruptive’ new technologies: the good, the bad & the unknown James Cornford, the 8 faces of ‘integration’ for a new healthcare technology</p>
13:40- 14:40	<p>Session 1: SmartHEALTH and the video Dave Wenn/Calum McNeil: introduction to SmartHEALTH Vision. <i>New & existing Points of care: from hospitals to GP surgeries to patients’ homes</i> Questions from participants to a panel of SmartHEALTH project</p>
14:40 – 15:40	<p>Session 2: Breast cancer monitoring and SmartHEALTH: participants’ responses</p> <ol style="list-style-type: none"> 1. Susan Williamson: Comparing hospital and telephone follow-up after treatment for breast cancer: a randomized control trial 2. Amanda Walshe (Senior MacMillan nurse)/Carole Downs (Therapy Radiologist): future for nurse-led monitoring 3. Lynne Stobbart: The Clinic in the Kitchen
15:40- 16:00	<p>afternoon break</p> <ol style="list-style-type: none"> 4. Fionagh Thomson/Tony Branson: the social, ethical & practical: moving breast/colorectal cancer follow up from hospitals to GP practices. 5. Yannis Pappas: Disruption or Integration? Using a social ecology approach to understand interactional conventions in telehealthcare.
16:30 – 17:30	<p><u>Discussion</u> <i>Pre-dinner drinks and Symposium dinner</i></p>
19:00	
Day 2:	
9:00	Simon Woods: introduction to day 2 & summary of issues raised in day 1
9:20 – 10:30	<p>Session 3: SmartHEALTH and the future of CRC screening</p> <ol style="list-style-type: none"> 1. Rouven Porz :. Screening: Do health care standards change from the "individual" to "public health"? A bioethical point of view" 2. James Cornford: the world of telecare in the UK: what we think we know? 3. Lucia Savador: Intelligent technologies for quick and easy colorectal cancer detection: A boost for screening behaviors?" 4. Ruth Jepson: Issues affecting informed choice in cancer screening, with particular reference to colorectal cancer screening 5. Zoe Morrison: raising questions for change
10:30 – 10: 50	Morning break
10:50 – 11:50	<u>Discussion</u>
11:50 – 12:15	Session 4: Future issues for SmartHEALTH consortium to consider
12:15 – 13:15	SmartHEALTH panel: final questions on SmartHEALTH technologies
13:15 – 14:15	lunch
14:15 – 15:15	Break out discussion groups: the main issues for SmartHEALTH to consider?
15:15 – 15:30	plenary discussion session on feedback from each group
	Close of Symposium.

Appendix C: Full transcript of ‘The Clinic in the Kitchen’ (Lynne Stobbart)

1. Who will be eligible to use the SmartHEALTH technology? Will home monitoring be optional or compulsory? Will consideration be taken of the patient’s social circumstances e.g. emotional issues, support network? Someone living alone, technophobic and/or with high anxiety levels may be very apprehensive about using this technology. Will they need assistance or even just ‘moral support’ when conducting the test?
2. The GP in the video acknowledges that screening may be anxiety provoking. This may be related to a) using the equipment (technophobes), b) waiting for the result, c) waiting time till appointment if indicated. (Although some of these may apply even if the test were to be conducted in the GP’s surgery or hospital clinic.) He attempts to reassure the prospective user that the benefits of early detection/treatment outweigh the stress of regular testing. Is there perhaps an over emphasis on the idea that “early monitoring will keep the disease under control?” Perhaps a more realistic statement would be that regular testing offers a better chance of keeping the disease under control.
3. Does early detection equate to early treatment? And more importantly, will it make a difference to outcome? Concerns have been raised about the recent stroke awareness campaign in that as well as raising awareness it raises expectations regarding the availability of treatment interventions, which currently cannot be met at a national level. Whilst such a lack of resources is not a good enough reason not to continue with the campaign, or in this case to offer home testing, full and proper consideration of the implications is crucial.
4. In the light of recent reports that cancer screening ‘blights ten lives for every one life saved’ (a view I do not share) is it possible that this screening technology (whether at home or in healthcare facilities) may also lead to unnecessary or equally damaging treatments?
5. A cynical view maybe that this initiative is less to do with patient benefit and more to do with minimising the workload on healthcare professionals and thus reducing costs. But where will funding come from for self testing - primary or secondary care?
6. The idea of simultaneous updating of medical records is very appealing. However, this assumes a level of compatibility, compliance and competency that isn’t always evident within NHS data management systems. Users would require considerable reassurance regarding confidentiality and data security issues, particularly in the wake of recent fiascos.
7. What are the implications of over-testing? (For example over-anxious patients carrying out more tests than instructed/required).
8. Conversely, what about those who are too anxious/frightened to perform the test, or simply forget?
9. If test results are positive the GP will give the patient an appointment - will the patient also be aware that the test is positive? If not, and the appointment system fails for some reason, how will the patient know? However, if the patient is alerted to the positive result in advance of the appointment, the intervening period of uncertainty may be very stressful (although admittedly this situation is not necessarily exclusive to the home testing situation). (See further note below, post-symposium).

10. The proposed system for managing home testing raised some questions regarding patient/professional relationships although I realise that this is based on my own personal experience of the system here in Newcastle. Having had an initial breast cancer episode I wonder whether it would not be better if all future communication/management was via the Breast Cancer Team rather than the GP. My initial visit to the GP when I found my breast lump was only the second time I'd seen a GP since registering with the practice 5 years earlier, and the first time I'd seen this particular doctor. Since having surgery and adjuvant therapies I've had much more contact with the Breast Care Team and feel that they know more about me. Unless the delivery of treatment is also likely to change, GPs may not have the level of specialist knowledge required and therefore the proposed procedure would only be adding an extra step before referral back to the Breast Cancer Team. Personally, I think this may be an ideal application for nurse led clinics (particularly in the light of discussion during the symposium).
11. The video opens with a statement that SmartHEALTH technology ensures that the patient is at the centre of disease management. For me, this raises two questions: a) what does it actually mean for the patient to be at the centre of disease management? b) And is this where they want to be? As with other 'patient centred' systems and approaches, this system appears to offer the patient some degree of choice and control, for example where they do the test, and when (within a defined time frame). At first sight it does indeed appear to offer an element of convenience which is not usually associated with attending a busy outpatient clinic. My outpatient follow-ups probably last no more than 10 minutes, (and they're only this long because they incorporate my clinical trial follow up) but it will take me at least half an hour to get there and then to get back to work. All of my appointments in this particular clinic have been at least 50 minutes late. So the element of choice and control does have some appeal.
12. With choice and control comes an obligation to act responsibly. For example, performing the test on time, following the instructions precisely and taking seriously the test, its outcome and other matters that may affect my health. If I do something wrong or do my test a day or a week late and it turns out to be positive, is that my fault? Almost *certainly not* - but what will be the psychological affect of wondering if it is? And what if I choose not to do the test at all, even just for one month? Who will monitor whether or not I've been doing the test regularly? If I miss a test, or indeed several, and then perhaps have a positive test, will treatment options be withheld because I failed to take responsibility for my own health? (Based on similar rationale to suggestions that we should refuse smokers the option of vascular surgery or heart/lung transplants.)
13. I have a concern that patients may become obsessive about their condition, treatment and lifestyle and that regular self-monitoring may exacerbate this. Whilst this may more commonly be the case for chronic illnesses, anticipated recurrence may give rise to similar issues. During the course of my treatment I have come into contact with women who are almost 'professional patients' and who have made themselves thoroughly miserable, for example, by trying to stick to some of the more extreme and rigid 'cancer prevention' diets. *In my own opinion, although I have tried to maintain a reasonably healthy lifestyle, there is no point in being 'cured' if you can't enjoy your life.*
14. Most women breast cancer survivors I've had contact with, especially those who had the whole gamut of treatment options, just want to regain a sense of normality. For me, one of the most difficult aspects of my treatment regime (although by far the most straightforward!) has been the prospect of 5 years of tamoxifen treatment. Even though the rest of my treatment is over (or soon will be) this daily medication, is a constant reminder that although I am 'cancer free' and I feel absolutely fine, I am still 'not quite

normal'. Whilst I am sure that home testing would indeed be more convenient in every practical sense, I wonder whether conducting a clinical test, particularly one with such potentially serious consequences, would have a similar effect of reinforcing patient status. When I first watched the video and saw the equipment I wondered, '*where would I keep it?*' I don't want it in the intimate space of my bathroom or bedroom where I am my 'personal self'; I don't want it in my kitchen, along with the pots and pans or my recipe books, where I am my 'domestic self'; or in my study where I work and am my 'professional self'. Because I am well, I do not consider myself to be a cancer patient when I'm in those spaces. I am only a cancer patient when I'm in the clinic having my herceptin. To have the testing equipment at home seems like making my home a surrogate clinic, bringing the disease into the home rather than keeping it in the hospital/clinic, where it belongs and I'm not sure that the physical convenience of testing at home would be a worthwhile 'trade'.

15. I wonder whether this drive for home testing is perhaps a backlash against the medicalisation of normality? It seems paradoxical to me that when other 'normal' life events such as birth, death, the 'terrible twos', and general disappointment are being medicalised, this seems to be an attempt to 'normalise' breast cancer, which is, after all a potentially life threatening disease, by bringing its surveillance into the home. Undoubtedly this may have some positive effects. By giving the patient some degree of control and by removing testing from the sometimes intimidating clinical environment it may reduce the fear that many people still associate with 'the C word'. By presenting this testing technique as something that the patient can manage themselves perhaps the condition itself will become less of a taboo subject. Perhaps the psychological impact of a diagnosis of breast cancer may be minimised by promoting such openness. However, is the flipside to this potentially raised awareness complacency? I have some concerns that by bringing this complex testing process into such a mundane space this might trivialise the condition and detract from its seriousness. If testing and early diagnosis is perceived to be easier, perhaps one might not be so concerned about maintaining a healthy lifestyle as a preventative measure (a situation which could impact upon general health status, not just cancer recurrence). Patients may become blasé or complacent. In conversation with a patient at the herceptin clinic I was surprised to learn how she felt that public (and other patients') attitudes towards breast cancer have changed over a number of years. She is currently receiving treatment for her third episode of breast cancer, over a period of about 20 years. Whilst she is pleased that because of improvements in treatments people no longer immediately think that breast cancer is a death sentence, she worries about what she sees as an extreme alternative view; patients affected by a different cancer have reacted to her diagnosis quite nonchalantly, with comments such as 'Oh, there's loads they can do for that now'. But people still die from breast cancer.

16. Because home testing would remove the need for the patient to attend a clinic it might prevent them from reporting other ad hoc symptoms which they may consider too trivial to warrant making a specific appointment for but which may be important and which they may have reported in a face to face consultation.

Lynne concluded with the following comment: I believe that this system does indeed provide an opportunity to ensure that the patient is at the centre of disease management, but being at the centre of disease management does not necessarily mean 'do-it-yourself'. Patients will be at the centre of their own disease management if they are given the choice of how that disease is to be managed. More personally for me, the clinic is the place to be a patient, and I don't want a clinic in my kitchen.

Appendix D: Summary of Participants' comments and questions from session 2 and 4

Table 2: Summary of opportunities/benefits, challenges, things to change and what to keep the same if follow up was moved from a) hospitals to GP surgeries and b) from hospitals to patients home.

	Opportunities/benefits	Challenges	What would stay the same	What would change
Secondary care to GP	<p>For patients: may appear more accessible (local) possibly less threatening/serious for patient potential to improve continuity of care <u>IF</u> able to see same person results are quicker and therefore reduce anxiety of waiting for results increased equity for users: access to NHS services is not influence by the place where the users live (2 yellow dots) could reduce/eliminate invasive diagnostic techniques Available local rather than travel a distance</p> <p>GPs : know co-morbidities, and medications know the patients and family situation (in an ideal world) for breast & bowel RCT evidence of equivalence the nurse can do it</p>	<p>Patients: - maybe 'locked in' to one GP's care - need fast access to secondary care if needed -will they trust results or will they ask doctor to re-do the exam? Who will provide emotional support for patients/education for patients/ HP? contact if recalled anxiety provoking in all follow For primary care healthcare team lack specialist knowledge <u>ensure are 'up to the task' – information in psychosocial needs</u> where would the 'shift' (for follow-up) stop? what other conditions would be moved to GP for follow up and with what impact? specific workflow challenges (who monitors? is it voluntary/optional? <u>-who maintains the systems?</u> Better communication between primary & secondary General: -Who would fund it? -need to integrate IT systems (is this possible in NHS?) -Sufficient quality control - training/certification - make the system one of choice (red dot)</p>	<p>role of the specialist Breast cancer nurse (holistic one) If hospital provider what women need in terms of psycho social support then keep hospitals follow up Keep (follow-up) relationship driven not technology driven</p>	<p>specialist healthcare team (but specialist in what?) every type of cancer is different, so this Question is too generic! (depends on system) as Health care systems differ - identification of named professional, to ensure continuity of care - clear quality assurance (blue dot)</p>
GP to home	<p>could change the 'balance of care' from GP to (patient) self care & increase autonomy and empowerment increase patient control and competency alternative for patients who dont want to go to support groups "easy to do when i have 5' of spare time"</p> <p>the informed patient: he/she wants to see the results of a measurement immediately without involvement of his/her doctor - he/she monitors the cancer markers by himself/herself. like, blood pressure monitoring in the home and gets in contact with his/her doctor in case of need. Question: what is more important or where is the balance: - benefits for the patient - (cost) benefits for the healthcare system - benefits for doctors/hospitals Cheaper in terms of 1) less organisation 2) less private costs</p>	<p>"I do it correctly?" lack of emotional/psychosocial support if frequency of testing increases increased period of anxiety a) prior to test and b) awaiting follow up appointment potentially trivalising test (therefore significant of results) <u>weight of personal responsibility - too much? [most cancer patients (more than sign) 65 years]</u> <u>cancer can still be life-threatening - diabetes can be controlled by cancer not yet fully comprehensive treatment - a dance of false reassurance</u> <u>could discriminate</u> against those who may get most benefit. chronic disease, disabled, multiple morbidity and not (technologically able) How do we maintain robust quality standards in non-hospital based testing <u>how expensive is this technology to roll-out? (1 yellow dot)</u> who services the technology/identifies faults/failure? what happens when the technology moves forward? cost implications <u>acceptable to Gps and patients (and others)</u> <u>was the data kept private</u> <u>workflow challenges (design part of the process that lie out with the technology): who will explain technology to patients/manage speedy referrals back to hospitals/ patient compliance?</u> What new skills will clinicians need?</p>	<p>patient support and reassurance</p>	<p>could change the demographics of inequalities increasing rural access good rural populations - (arrow for decreasing) people who are disable, blind availability of helpline/support systems (technological issues) allow patient choice 'opt in' or 'opt out' of system opportunity to address 'ad hoc' issues If the patient becomes the 'system user' which new support will be provided? Relationship between the patient and the NHS (perceived) is the aim to move the process into the home or household?</p>

Table 3: Summary of participants questions in session 4 under Cornford's typology of five headings (routines, rules, rewards, roles and relationships).

Routines and Habits	Rules and Regulations	Rewards & Incentives
<ul style="list-style-type: none"> • Like many other fields of innovation, new needs & habits are produced. • New organisational routines especially for platform pplications addressed towards telemedicine • for users (patients/ health professionals): • new habits for the users who should "learn" a different style of coping with their health problems Reconfiguration of everyday working practices (e.g. taking a test every day after morning with coffee) • "supply produces demand": as the technology becomes part of routine care, new needs and habits will appear • Exams could become "day hospitals" exams where you are tested 1st with SmartHEALTH then, if positive, do immediately more testing. • Questions raised: • is it a uniform process across any health system, or different locally? • (what you are monitoring/etc with affect the answer to the above) • how does it fit with patient's other habits and routines? how prescriptive is the process? how will they (patients) feel about this habit? • What happens if someone in the routine doesn't do it? • How intensive are the reminders to test? What are the reminders? • Who follows up non-compliance by patients? • Will this new routine be restricted by hospital 'office' house or can patients do testing at their own convenience? • What are the implications for testing acute routines? 	<p><i>Data Use and storage:</i></p> <ul style="list-style-type: none"> •Data protection (needs to stay the same) •How will you know whose blood is being tested? •Patients' access to their own data? •What else can/will the data be used for? •Who will 'own' the data? (may need to create new users.) •How will date get passed to the relevant services? •Who will have access to the data? •Should it be a 'public' technology e.g. NHS date protection remain the same <p><i>Quality assurance, Quality standards, CE mark?</i></p> <ul style="list-style-type: none"> • How will you manage external quality control of home based kit? •Non qualified users <p><i>Support services:</i></p> <ul style="list-style-type: none"> • What can I expect from system support (for user/patient/healthcare professional?) • What is the quality of: call centre/triage/management/turn around time to deal with emergencies/joined up services, e.g. ambulances, GPs with call centre <p><i>Costs: Who pays if it breaks it /needs to retest/is stolen?</i></p> <p>Payment reimbursement (1 green)</p> <p><i>Policy and healthcare model:</i></p> <ul style="list-style-type: none"> • Policy development around the service/•Health care model will have to change • Ethics need to adhere to guidelines/•Could I sell tests of my friends & neighbours? • Rules topic is not relevant for SmartHEALTH -as none of its characteristics introduce novelties from this point of view when compared with alternative technologies 	<ul style="list-style-type: none"> •Rewards for the users they must perceive the new technology as something "positively increasing" their quality of life (not just doing it because its possible). •Reward GPs (-ve concern) •For patients: can do work, no need to take "sick days" or holidays . can go on holiday if necessary. What are the implications for health insurance (+ve/-ve?) What if patient chooses not to take SmartHEALTH - is their care compromised? Will it be a system where patients 'opt-in', or do they need to know how to opt out to receive conventional healthcare? (need alternative methods to SmartHEALTH) Will there be a post code lottery on SmartHEALTH technology. (some maybe smarter than others) NHS needs to save money after initial outline: need decent update Need to get procurement department to buy the technology while creating a technology that patients/HPs want. identify immovable barriers in procurement guidelines & what you can change). different ways of selling technology beyond simple cost-benefit analysis may spend more money if uptake is high

Roles & Responsibilities	Relationships	Other/ Carparking
<p><i>Royal colleges:</i> Are the various medical royal colleges playing catch up (when) should pathology departments start to gear up for SMART/molecular diagnostics. what happens to staff with microscopes etc?</p> <p><i>Pharmacists:</i> train pharmacists in use of SmartHEALTH kit. What is the role for community pharmacy?</p> <p>Patients: responsibility shifts much more on the users for the applications which allow telecare (home kit)</p> <p><i>Specialists nurses:</i> could use specialist nurses (telephone F.U.)/specialist nurse roles remain but further developed (work with specialists nurse to develop hardware that fits into their everyday work)</p> <p><i>Service providers:</i> quality assurance are misunderstood level? can you maintain standards? provide different options for different patients so they have as little or as much support as they want?</p> <p>compromise between what the technology buyers (NHS procurement) and the users want (patients & health professionals)</p> <p>who will be responsible for giving results?</p> <p>who distributes & collects & maintains the machines?</p> <p>SmartHEALTH: •create a SmartHEALTH spokesperson (a marketing role? testing for trust?) personalise the technology. Decide who you want to please & who you don't (cant please everyone) and then be open and honest about it in the business plan/statement.</p>	<ul style="list-style-type: none"> • Is this aimed at consumers or patients? (either will affect relationship with healthcare and the consumer model may work with some applications.) • Is there a need for a new 'profession' of experts in this area? where will they fit in with other health care professionals - what will the relationship be? • Are there issues of deprofessionalisation and therefore of trust? ('Tupperware' sales model) • <i>Relationship changes between:</i> <ul style="list-style-type: none"> • Health professionals and procurement dept. • Secondary & primary care need to change as well as their relationship with patients • Patient & GP & secondary care (real-time) • Patient (?constantly testing) and the rest of the family cant go on holiday this week potential heart attack blowing in from the east.. • Patient and technology - will i trust my SmartHEALTH monitor? How will this relate to other test results? • Disruption (for better or worse) of power dynamics between patient & professional? • Complex interaction among many potential agents depending upon each specific application of the SmartHEALTH platform (a leadership for SmartHEALTH?) 	<ul style="list-style-type: none"> • patient support and reassurance • could change the demographics of inequalities increasing rural access good rural populations - (arrow for decreasing) people who are disable, blind • availability of helpline/support systems (technological issues) • allow patient choice 'opt in' or 'opt out' of system • opportunity to address 'ad hoc' issues • If the patient becomes the 'system user' which new support will be provided? • Relationship between the patient and the NHS (perceived) • is the aim to move the process into the home or household?