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SmartHEALTH

Smart Integrated Biodiagnostic Systems for Healthcare

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D9.3 Report on views of stakeholders in partner countries (interviews/surveys) on issues associated with possible use/implementation of bioanalytical microsystems for medical diagnostics.

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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, predominantly European, healthcare systems. 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 only relate to the point of care (PoC) applications within the SmartHEALTH project (see D1.4), as summarised 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 Task 9.2, which explores stakeholder views on developing an ethical framework for subsequent clinical trials. This task has two associated deliverables:

1. **D9.2** Research report on the results of exploratory study on main ethical concerns and factors affecting risk perception.
2. **D9.3** Report on views of stakeholders in partner countries (interviews/surveys) on issues associated with possible use/implementation of bioanalytical microsystems for medical diagnostics.

This report forms the second deliverable (D9.3) and explores with stakeholders the ethical and social issues raised in the first deliverable (D9.2). Both deliverables represent stage 1 and 2 of the WP9 fieldwork. The final, 3rd stage, is:

3. **D9.6:** Report on **case study findings** of main ELSI arising from SmartHEALTH. The case studies begin in 2008, and issues raised in D9.2 and explored further in D9.3 will be examined in-depth with different potential users of the SmartHEALTH technologies, from the patient to the clinician.

This deliverable (D9.3) draws upon interviews conducted with selected SmartHEALTH partners and relevant external healthcare specialists and presents:

1. The findings of exploratory discussions with partners and external healthcare specialists around the potential social and ethical issues highlighted in D9.2.
2. The implications of these findings for the next phase of the WP9 fieldwork: the case studies (D9.6)

1.1 Background: potential ELSIs highlighted in D9.2 and explored further with selected stakeholders in D9.3

As outlined in D9.2, the SmartHEALTH project can be represented in a number of ways, as an example of converging technologies, as a medical diagnostic device embedded within an informatics system, as the latest manifestation of an established automated screening and diagnostic technology or as an entirely new form of medical biotechnology. The SmartHEALTH project has a vision of innovative biomedical sensing systems combined with information technologies likely to have an immediate impact on the quality of cancer diagnosis and monitoring but with potential for much wider application. However this vision must also be seen as existing alongside other complex social processes, public interest and political agendas for health. Within this wide social context, a number of ELSIs were highlighted for further consideration, as summarised in Table 1 below.

D9.2 highlighted a number of potential ELSIs relating to both the implementation of SmartHEALTH technologies and the functionalities of these technologies.

The following ELSIs need to be clarified as SmartHEALTH moves toward the next phase of the project and trial devices are developed:

Issues related to the technology

- The exact nature of these applications, in terms of screening and monitoring, disease
- 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.

Issues related to the implementation of the technology

- 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/ communication when disclosing results.
- PoC location of each SmartHEALTH application.

Table 1 – the Main Ethical, Legal and Social issues for the SmartHEALTH project as raised in D9.2

1.2 Redefining the WP9 fieldwork questions

The potential ELSIs highlighted in D9.2 also raised a number of initial research questions for the case studies, which were redefined and refocused in light of the findings in this deliverable (see Table 2 below).

ELSI highlighted in D9.2 raised a number of fieldwork questions for WP9:

1. 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?
2. Will a quicker test result produce a quicker diagnosis?
3. Will SmartHEALTH impact on the current lack of willingness for participants to attend cervical cancer screening programmes?
4. Will improving the cancer screening stages and follow up stages impact on the other care services within the wider continuum?
5. Is the location for the tests new or existing within current practice?
6. How much knowledge and skill does the person using the machine require?

Interview findings in D9.3 redefined the initial research questions:

1. How will this new technology fit into existing healthcare services for improving:
 - a) accuracy of current tests (sensitivity of cervical cancer screening and specificity within breast cancer and CRC follow up)
 - b) improving access to health information for health professionals
2. What will be the impact of reducing the time for test results on the earlier diagnosis of cancer, within the three SmartHEALTH applications, in terms of
 - a) reducing current mortality figures and
 - b) improving patient's quality of life?
3. What impact will SmartHEALTH have on the current lack of willingness for participants to attend cervical cancer screening programmes?
4. What impact will improving the cancer screening stages and follow up stages have on other care services within the wider continuum?
5. What kinds of knowledge and skill does the person using the machine require, in terms of:
 - a) preparing high quality samples
 - b) interpreting meaningful healthcare information
 - c) communicating effectively with patients/participants?
6. What are the current skills and knowledge required for new PoC locations within current practices:
 - a) breast cancer follow up at the GP surgery and (possibly) the home?
 - b) CRC testing at the GP surgery?

These research questions will be explored within 2 broad discussions parameters:

1. Will SmartHEALTH be a disruptive technology within existing healthcare systems?
2. What are the benefits and who will benefit from SmartHEALTH technology?

Table 2 Initial research questions highlighted in D9.2 then redefined in the light of D9.3 interview findings

2. Rationale behind choosing partners to explore the social and ethical issues

The development of any new technology is recognised as being both technologically and socially determined; meaning that technological development is influenced by people's perceptions, and use of the technology. In addition the knowledge and materials to create the technology into a viable entity must also exist (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.

As highlighted within D9.2, the technology is still in the development stage and more information is required to create a useful representation of a complex converging set of technologies. As a result, the 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.

At this stage in the fieldwork, no interviews have been held with patients or other potential users for two reasons. First, it is not the aim of this project to invite patient opinion on the design and development of the technology until the technology is more fully developed. Indeed, to invite patients to share their views on a new technology when their views will not be taken into consideration is unethical, since interviewees may perceive that their time has been wasted and their views not taken seriously which often leads to a reluctance to be involved in future research projects (Wynne, 2001). Second, the patient groups identified will be invited to discuss the technology during the case studies when more suitable representations of the SmartHEALTH technologies have been developed. These representations will by then be sufficiently detailed to enable participants to explore how these technologies would impact upon their everyday work practice/lives, while being suitably flexible to allow participants to redefine the benefits and challenges of SmartHEALTH within existing healthcare systems.

2.1 SmartHEALTH as an EC Integrated Project

A final consideration is that SmartHEALTH is a European Commission Integrated project, which aims to explore how different disciplines work together. WP9 is one of the Workpackages that aims to work across and with all the other Workpackages. Involving partners in these research interviews prior to the case studies allows WP9 to integrate relevant social and ethical questions from the project partner network into the case studies. For example, WP7 has a number of informatics questions while WP6 is interested in how GPs perceive the hardware being developed. WP1 has developed a questionnaire for clinicians (D1.4), and relevant issues can be explored further within the case studies. Including questions raised within other work packages will enrich the case studies and also ensure that WP9 remains in line with current developments and changes that may occur during the project.

3. Methods

This deliverable draws upon data obtained from two forms of interview method:

- Semi-structured interviews with SmartHEALTH partners from across the project. Partners were regarded as both experts within their field, and therefore specialists on the functionality of the technology, and also having valuable opinions as users of their healthcare system.
- Sensitising interviews were held with a selected sample of healthcare professionals (HPs), with knowledge of the three index cancer applications: breast cancer monitoring, cervical cancer screening and colorectal cancer diagnosis and monitoring.

3.1 Partner interviews

The interviews with SmartHEALTH partners were semi-structured and had two aims:

- To provide important information on how to represent SmartHEALTH technology to a range of potential users during two case studies planned for 2008.
- To explore further the potential social and ethical issues raised in D9.2, and to raise any new issues; that will be incorporated into the case studies, and help define ethical issues to be faced in the clinical trials of SmartHEALTH.

The interview schedule had 3 stages:

1. Interviewees discussed the aims of their Workpackage within the overall project.
2. Interviewees were then invited to discuss their own perceptions of the social and ethical issues within the context of the overall project.
3. The researcher and interviewee then revisited each of the issues raised in D9.2 (Table 1) to summarise the open discussion.

The first stage of the interview allowed the researcher to clarify the WP9 understanding of the functionality of the project within that Workpackage, based upon Workpackage deliverables. These details enable WP9 to develop appropriate representations of the technology for the case study phase. For example, clarification of the fact that the biomarkers will use proteins rather than DNA may exclude the need to explore patients' anxieties about disclosure of genetic information and adverse effects of 3rd party access to this information, e.g. insurance companies. Stage 1 was also a necessary preliminary for the exploration of the next stage of the interview schedule which involved an open in-depth discussion around the social and ethical issues. The open discussion (stage 2) preceded the more structured discussion (stage 3) to allow the interviewee the freedom to discuss issues of relevance within their own work, rather than the researcher's interests, to allow differences between interviewees to arise and to provide space for new issues to be raised. Stage 3 of the interview was structured around the ELSIs raised in D9.2.

3.2 Sensitising interviews

The sensitising interviews employed three different scenarios for breast cancer monitoring, cervical cancer screening and CRC diagnosis and monitoring, to allow the interviewees to discuss the SmartHEALTH technology within their own professional field. These interviews enabled WP9 to explore the issues raised in D9.2 with a selected group of relevant healthcare professionals, not currently represented within the SmartHEALTH partnership. Sensitising interviews enable the researcher to test out the methods and questions with appropriate representatives prior to fieldwork.

4. Data Collection and Interviewee Profile

This section outlines the data collection and analysis process and the profile of the interviewees.

4.1 Partner interviews

Partner interviews were carried out with 13 individuals across the different Workpackages within the SmartHEALTH project, with the exception of WP3 & WP4. However, relevant aspects of these Workpackages were included in discussions with interviewees from related Workpackages such as WP2, WP5 and WP6. Most partner interviews were carried out face to face at their workplace in Germany, Switzerland and Spain, though two interviews were carried out by telephone, due to time constraints. Face to face interviews were the preferred methodology as it has a number of benefits: the interview can be flexible to fit into an interviewee's work schedule, another work colleague maybe invited into the discussion at the last minute, as in the interview with WP7 and a technological demonstration can be given, as in WP6. Participation was voluntary in all cases and in the interviews participants' consent was sought and written consent obtained. Issues of confidentiality and anonymity were included in an information sheet given to the interviewee before each interview.

All partner interviews were conducted by the WP9 researcher in the English language, since all interviewees had sufficient competency levels to discuss their perceptions of the technology adequately. The WP9 researchers are experienced in different forms of interviewing, including interviewing participants whose mother tongue is not English. The majority of the interviews were digitally recorded, with the remainder recorded through detailed fieldnotes. The recordings were listened to repeatedly and all data were subject to thematic analysis based on themes derived from the issues identified in D9.2 (Table 1), specifically addressed in the final stage of the interviews. Existing issues in D9.2 were evaluated for relevance and clarity and new issues were noted. These findings form the discussion section of this report. To ensure accurate representation of each interviewee's comments, and in line with social research ethics, each pattern of themes drawn from each interview was checked with the relevant interviewees. The initial findings were also presented to the SmartHEALTH partners at the Annual General Assembly meeting in Bilbao on 8th November 2007.

4.2 Sensitising interviews

Sensitising interviews were held with 9 healthcare professionals from different backgrounds and countries, as outlined in Table 3 below:

Profession	Area of professional knowledge (cancer)			
	Country	Breast	Cervical	CRC
Biomedical scientist	UK		Yes	
Oncology nurse	UK	Yes		
Oncologist	UK	Yes	Yes	
Oncologist (D)	Germany			Yes
Oncologist (E)	Spain			Yes
Biochemist (D)	Germany	Yes		Yes
Oncology nurse (UK)	UK			Yes
Healthcare researcher	UK			
Clinical pathologist	Antipodes		yes	Yes

Table 3 Sensitising interviews outlining the profession, country of work and cancer specialisms of the interviewees.

Overall, interviewees discussed the technology within their own professional knowledge, which is reflected in the representation of viewpoints within the findings section below. For example, the technology interviewees did not discuss the specificity/sensitivity of the biomarkers while the medical interviewees made no comments on the capability of the physical hardware. For this deliverable, interviewees are not named to maintain anonymity and within the findings section are referred to by their general area of professional knowledge:

- *Healthcare interviews* are individuals with healthcare experience
- *Technological (medical) interviews* are individuals in a technological/healthcare context
- *Technological interviews* are individuals with predominantly a technological background

5. Findings

The findings present the personal opinions of the SmartHEALTH partners and healthcare professionals interviewed and have been categorised into three broad themes, which reflect the main issues raised in D9.2.

1. Clarification of important functions of SmartHEALTH technologies to clearly represent a complex set of converging technologies.
2. Technological context: implementation into existing healthcare systems.
3. Healthcare context: perceived benefits of SmartHEALTH for different users within the healthcare context.

5.1 *The converging nature of SmartHEALTH: clarification*

During partner interviews, the nature of the technologies was clarified further in terms of the nature of the technology, difference from existing medical diagnostic systems and details of the technological process, as outlined below.

Nature of SmartHEALTH

- SmartHEALTH Integrated healthcare project is a set converging technologies which is in essence providing information for both the healthcare professional and the patient. Each healthcare user is part of an information chain of which the patient or participant is the end user.
- The technology is modular in nature and is designed to handle different sample types (blood, tissue and cells) and to be compatible to different healthcare information systems. This modularity and flexibility creates a trade off between the flexibility of the technology and the final size of the machine: the more adaptable the technology the larger the machine. In order to create a hand-held device the machines will require more specific parameters.
- This technology has the potential to be adapted and employed within other areas of healthcare, e.g. nutritional testing and further afield, e.g. environmental detection and testing of air pollutants.
- The cost benefit analysis of the technology is currently unknown though it is unlikely to be a cheap technology initially and will therefore be unviable within 'developing' countries, where, for example, cervical cancer is predominant. However, while the current costings of the forms of biosensors are expensive it is predicted that once production begins economies of scale will reduce the unit price.

Difference from current medical diagnostic systems

- The project aims to create a heterogeneous product that does not fit only one healthcare system or link to one manufacturer, as currently in place by the major medical device manufacturers. As such this heterogeneity could improve the current incompatible problems faced within current healthcare systems, in particular with the use of different information technology systems.
- The most novel aspects of this technology appear to be the potential to improve the specificity and sensitivity of current tests and the application of an ambient healthcare system (See D7.1)
- WP7 are developing a new software package to support interpretation of test results for the healthcare professional user.

Details of the process

- The preparation of the samples is minimal except for the blood sample, which at the current stage of development requires the extraction of serum through a centrifugal process.
- The preparation of the mRNA for cervical cancer screening is still in development but may also require a simple preparation process. The current preparation time for the mRNA takes 1.5 hours but the final estimation is 15 minutes.
- The biomarkers being employed use protein and not DNA, which could impact on issues around patient's genetic disposition towards cancer.

As the technology is still being developed there are a number of following issues relevant to the social and ethical issues of SmartHEALTH that remain unclear, these include:

- The exact sensitivity and specificity of the technology, which impacts upon the accuracy of the technology, the subsequent skills required by the 'user' and the trust in the technology by the HP and the patient/screening participant.
- Acceptance of the technologies relies upon numerous factors, including the cost benefit analysis of the technologies. In addition, different European healthcare systems will have different cost benefit analysis parameters. For example, the British healthcare system is given a set amount every year, while the Germany system is based upon specialist private physicians and producing a profit-making technology may create a space for SmartHEALTH technologies. However, the following question remains unanswered:
 - What are the key determining factors underlying the cost-benefits analysis within different health-care contexts?
 - Are these factors based upon the short-term cost of the unit or the cost of time saved by the healthcare professional or the longer term cost of deaths prevented and hospital time saved?
- What will be the role of the histopathologist and clinician in the process when the SmartHEALTH technology is located within the physician's office or the patient's home? As outlined in D9.2, the UK Royal College of Pathologists state that POCT should always be managed within secondary care and the pathology labs.

This information will support the development of suitable representations within the case studies for different potential users of the SmartHEALTH technology.

5.2 Technological context: implementation into existing healthcare systems

The successful implementation of the technology within existing healthcare systems relies upon numerous factors, some are outlined above, such as the sensitivity of the biomarkers and the cost benefit analysis of the technology. Other issues highlighted in D9.2 were also raised by interviewees and can be categories into two broad themes.

1. The relevant personnel and skills required to ensure the effective and efficient implementation and running of the technology, which is sensitive to all users' needs.
2. The nature of the Point of Care location and the availability of relevant skills and personnel.

5.2.1 Relevant personnel and skills required

As outlined in D9.2, SmartHEALTH technology is part of a wider healthcare process that involves the presence of a willing patient or participant and suitable healthcare professional, the taking and preparation of a blood, cell or tissue sample. These samples will be tested, 'numerical' results produced, which are required to be interpreted into meaningful information for both healthcare professionals and patients/participants. The interpretation of test results can involve a complex web of decisions that relies upon different sources of information, such as patient's medical records and different healthcare professional's expertise. Surrounding the technological process three main social and ethical issues were also highlighted:

1. The need to provide adequate informed consent to patients to allow them to make informed decisions around treatment options and on the risks and benefits of participating in a screening programme.
2. More recently questions around the ethical aspects of health informatics and who has access to electronic records have been raised, as discussed in D7.3.
3. As SmartHEALTH promises the potential for quicker test results and, therefore, the possibility of a quicker diagnosis of a serious disease, questions were raised on the adequacy of current counselling procedures within existing healthcare systems.

Within the above technological processes and wider social contexts, interviewees highlighted three components of the process where human skill is of most importance:

- The taking and preparation of the sample
- The interpretation of the test results into meaningful information for the health professional and the patient.
- Communication between different health professionals and between health professionals and patients/screening participants.

Good quality samples: taking and preparing samples

The preparation of the sample was considered important by most interviewees, though each sample required different forms of preparation. For cervical cancer and CRC, a medically trained individual is required to take the sample, though for breast cancer, taking blood from a finger-prick may eventually be sufficient. As outlined in section 5.1, the preparation of the blood for breast cancer analysis and cells for cervical cancer screening may require basic laboratory equipment and processing.

The level of skill required by a HP such as a nurse or doctor was considered part of their current skills and was not viewed as problematic, though questions were raised on whether GPs had the available equipment or time to prepare the blood sample. In contrast, the patient's competence to play a role in these processes was questioned by all interviewees. Some interviewees raised doubts on a patient's ability to take good quality samples while others did not view this procedure as problematic. Instead they raised questions around the appropriate handling of the sample before it entered the machine, which they considered to be an important factor in the quality control of the final test result. For example, for home testing, patients may be required to refrigerate the sample immediately but a patient may be unaware that delays affect the quality of the sample and become distracted by other household activities. Interestingly, findings in D10.2 highlighted a similar concern, though from a patient's perspective and some respondents expressed anxiety over mishandling the sample and producing inaccurate test results.

Quality of the interpretation of test results into meaningful information

All interviewees predicted that the handling of negative test results could be managed by any doctor with little psycho-social impact on participant/patient, assuming that the biomarkers were of a sufficient accuracy to provide confidence in the test results. In contrast, in particular within healthcare interviews, interviewees recognised that the interpretation of results which were not negative could involve a complex web of potential decision pathways. For each of the index cancers future management and treatment will be contingent upon careful staging of the disease and assessment of the patient. Therefore a "positive" result may mean that the patient moves into a further stage of assessment and investigation that relies upon a multi-disciplinary team of healthcare specialists. SmartHEALTH technology should therefore be embedded into a support system that addresses both the doctor's and patient's needs.

In the case of the cervical cancer screening application which tests for participant HPV status, rather than cancer, when the qPCR process is predicted to be a highly sensitive test then results would produce fewer choices for interpretation, and therefore potential misinterpretation, than results for breast and CRC monitoring. Interviews within WP1 highlighted that the Workpackage has recognised that a range of guidelines on different decisions pathways for HPs handling positive test results will need to be developed. At this stage of the development, these decisions pathways have not yet been explored.

Home testing

The interpretation of results by patients in home testing raised a number of concerns. All interviewees were highly sceptical of the patient viewing the test results for 3 reasons;

1. There was concern that patient's anxiety would increase when dealing with the test results with no HP support. One interviewee referred to this situation as the 'white coat syndrome' where a patient requires the presence of an HP for comfort and reassurance.
2. The participant/patient was viewed as having insufficient skills to make accurate sense of the information.
3. The interpretation of test results is likely to be part of a highly complex decision-making process, involving different professionals, that does not always lead to a clearly defined diagnosis or prognosis.

Healthcare interviewees highlighted the complexities involved for HPs in making the correct clinical decision on the basis of test results and other clinical findings. These interviewees emphasised again the complexity of the decision-making process within which the SmartHEALTH technology would be embedded. However, in contrast to most technological interviewees, healthcare interviewees also stressed the importance of the role of patient/participant in the process, the need for appropriate communication and information giving and the necessity of making decisions with their full consent.

Communication between different HPs and HPs and patients/participants

During discussions on the communication skills required by healthcare professionals, interviewees highlighted 3 main issues: informed consent/informed uptake, the ethical issues around the health informatics component of SmartHEALTH and the relevance of counselling services to accompany screening and monitoring.

Informed consent and uptake

The importance and need for informed consent and informed uptake was recognised by most interviewees, though only medical interviewees and two technical (medical) interviewees discussed this topic in detail. Medical interviewees highlighted two main issues:

- Within cervical cancer screening there was concern around the public's lack of knowledge of HPV as a common viral infection among sexually active adults and the potential negative impact of informing participants of their HPV status and its link with cervical cancer.
- Within breast cancer follow-up, there was concern that the technology added to the current debate within breast cancer follow-up where recent research has identified the lack of an evidence base to support clinical follow-up (see D9.2:16). Interviewees also recognised that monitoring of disease may be problematic if this was not supported by a range of suitable treatment options, as discussed further in section 5.3.2.

The technological (medical) interviewees stressed the need for SmartHEALTH to ensure that both patients and participants were made aware of the ability and limitations of the technology and to explain in accurate detail the process involved. Both interviewees also suggested that issues around informed consent and uptake should be addressed as part of the implementation of the SmartHEALTH technology. However, one question raised was: who should be responsible for implementing and monitoring appropriate informed uptake for screening participants? Placing this responsibility upon GPs, within a public healthcare sector, was considered to be inappropriate since many GPs were overworked and, therefore, should not/could not be held responsible for providing and monitoring patients' understanding of the issues surrounding cervical cancer screening.

Health informatics

Most interviewees recognised the importance and need for addressing the ethical aspects of the health informatics aspects of SmartHEALTH, though few discussed this topic in detail with the exception of WP7 interviewees who have written extensively on this issue (see D7.3). For example, concerns over access to sensitive issues within a patient's medical record, such as mental health problems were also raised by most technological (medical) interviewees. One potential topic not covered within D7.3 is the patient's perception of molecular biomarkers and anxieties around the potential for revealing a patient's genetic disposition towards cancer. All technological (medical) interviewees stated that while in theory this information could be accessed by trained specialists, in

practice it would be unlikely that the health professionals carrying out the tests would have the skills or intention to extract this information. All interviewees predicted that the current health informatics systems were adequate to protect patient's medical records within the SmartHEALTH applications.

Speeding up results and counselling for bad news

All interviewees recognised that speeding up the test results increased the potential of a participant or patient being given a positive diagnosis earlier. As such, all highlighted the importance and need for appropriate counselling, though the majority of interviewees believed that the counselling procedures within existing healthcare system would be suitable for the implementation of SmartHEALTH. The health interviewees in the UK highlighted the current focus in the National Health Service Cancer Plan and training courses for HPs on 'how to give bad news' based upon extensive research into the psycho-social welfare of patients. Two healthcare interviewees also highlighted that delays are sometimes required by the both patient and the HP. As also raised in D9.2, an HP may require a delay to make a well-informed diagnosis while patients/screening participants may require time to assimilate the information given, when the test results prove 'positive'.

5.2.2 Point of Care testing: new or existing locations

As outlined in D9.2, some SmartHEALTH applications are proposing new locations for testing, while others will fit into the existing healthcare systems. For PoC technologies within primary care, good communication between secondary and primary care is essential in effectively introducing and operating these types of technologies. However, historically communication between the two care services has been fraught with problems.

Only interviewees working within a healthcare context raised issues around PoC as outlined below:

- The cervical cancer testing at the physician's office was viewed as no different from current practice, unless the technology improved accuracy, which would be highly beneficial as outlined within the healthcare context.
- Breast cancer monitoring at home was recognised as completely new and was not initially recommended by any interviewee with the main concerns being highlighted on page 13. One breast cancer specialist was concerned about patients monitoring at home and recounted their own observations of patients plotting a change in the presence of certain biomarkers, which they subsequently misinterpreted and created undue anxiety. However, one CRC specialist, after a discussion around the current breast cancer debate changed his mind and concluded that some of his own patients were capable of monitoring their disease at home without undue anxiety. S/he stated that a good doctor would know which patients' characters made them suitable to monitor at home and which patients would have less anxiety by being monitored at a clinic.
- CRC monitoring at the GP is an uncommon practice within many European public healthcare systems. All three oncologists raised concern over GP's monitoring CRC or breast cancer patients since many GPs have few patients with these cancers and have neither the time nor the knowledge to provide a high quality care service.

5.3 Healthcare context: benefits.

During interviews, SmartHEALTH was presented as having three main benefits, which are also highlighted in the DoW:

- Speeding up of test results from days or weeks to minutes that will alleviate patient anxiety from current waiting times and lead to confirmation of a negative result or the quicker referral to the next stage of testing or diagnosis.
- Improving accuracy (sensitivity and specificity) of current tests.
- Providing ambient healthcare systems, which will allow health professionals using the SmartHEALTH technology to download patient's medical health records and also consult with other health specialists.

Interviewees' reflections on these three benefits are outlined below.

5.3.1 Speeding up test results for earlier diagnosis

Some technological interviewees highlighted the cost benefits associated with quicker tests that led to increased number of tests being performed in one day and a saving of time. Significantly, most interviewees equated reducing the time taken for test results, to reducing the time taken for the interpretation of test results and subsequently, where relevant, the earlier diagnosis of cancer or recurrence. This assumption was questioned by the oncologist specialist as the delays in diagnosing of cancer are multiple along the chain of care. In addition, reducing the delay in testing does not then alleviate the pressure for a busy pathology laboratory that may need to be involved in validating the test results. Earlier test results were uniformly viewed as positive when test results were negative and the patient could be informed immediately. However, all interviewees recognised that in reducing the time for speeding up the cancer testing when test results are positive can raise a number of social and ethical issues around adequate information giving and counselling.

5.3.2 Improving accuracy of test results (sensitivity & specificity)

All healthcare interviewees praised the benefits associated with improving the sensitivity and the specificity of current test results. A specific focus was placed on:

- Improving the sensitivity of cervical cancer screening
- Improving the specificity of breast cancer monitoring.

Within cervical cancer screening, improving the sensitivity of current testing was considered to be key in the screening of a disease that currently has a high and unacceptable level of false negatives, where current tests relied upon visual subjective inspection of cells by trained pathologists and the profile of the individual being screened had one wide parameter: a female aged between 23 and 55. A cervical cancer specialist highlighted the positive impact of cervical cancer screening programmes in the West that have significantly reduced the mortality of the disease. Interestingly, one cervical cancer clinician raised questions around the viable cost of HPV screening tests within the UK, since current tests can cost up to £80 a test. The clinician also highlighted the current focus within the UK on automating pathology tests, and a move away from molecular biomarkers such as current HPV testing due to the high cost.

Moral dilemma: improving test accuracy when no curative treatment is available

Within breast cancer monitoring the accuracy of the biomarkers was also identified as something which may contribute to developing a more nuanced and sophisticated diagnosis and subsequent treatment options. Two oncologists noted that if personalising treatment plans for patients could be improved then this would be an important future development. However, interviewees working in a healthcare context recognised the ethical problem of improving the monitoring of cancer where this had no impact on treatment options and long-term outcomes. Amongst the issues explored by those working with breast cancer and CRC was the concern that much is not understood about these diseases, raising the question: **is it ethical to improve the accuracy of tests when there is no suitable treatment response?** In this situation, improving the accuracy of diagnosis would not reduce overall mortality rates but would result in a patient being told the certainty of their death rather than being provided with treatment options. However, one oncologist speculated on the controversial topic that this form of monitoring technology could provide some patients the choice to opt out of aggressive treatment in preference for palliative care, recognising that their disease was now a terminal condition. The oncologist spoke from experience that for some women stopping life extending treatment may have the benefit of improving their quality of life because they would no longer be suffering the iatrogenic effects of chemotherapy. S/he provided several examples of patients who chose to stop treatment with subsequent improvement to their health, both mental and physical.

5.3.3 Ambient healthcare system: access to medical record and other professional knowledge

The benefits of the ambient healthcare component of the SmartHEALTH project were predominantly raised by interviewees working on WP7 and WP12 and healthcare interviewees external to SmartHEALTH.

The healthcare interviewees expressed doubts regarding the viability of implementing this component of the technology because of the generally poor state of healthcare records and problems of incompatibility among current information technology systems. However, within the breast cancer and CRC applications, there was a clear opinion that an ambient health system that provided access to medical health records and other healthcare professionals would be highly beneficial for both the HP and the patient. In contrast, a biomedical scientist involved in the UK cervical cancer screening programme, discussed the under use of the telepathology¹ technology within their hospital. Anecdotally, s/he stated that many clinicians preferred face to face meetings and/or to post slides with a covering letter to colleagues to ask for their professional opinions. However, the same interviewee predicted that this ambient healthcare system would be useful in remote locations where the patient could not easily travel to a hospital outpatient department though they raised doubt over the practical uptake of this component of the technology within urban settings.

¹ Telepathology is the electronic transmission of pathological images, usually derived from microscopes, from one location to another, for the purpose of interpretation and diagnosis.

6. Discussion

What emerged from the findings is that many issues highlighted in Table 1 were also raised by interviewees during open discussions on their perceptions of the ethical and social issues surrounding the implementation of SmartHEALTH. Within these findings, two broad questions for future discussion evolved, one within the technological context and the second within the healthcare context:

1. Will SmartHEALTH be a disruptive technology within existing healthcare systems?
2. What are the benefits and who will benefit from the SmartHEALTH technology?

6.1 *Will SmartHEALTH be a disruptive technology?*

Within the context of implementing the technology, two main themes arose: the relevant personnel and skills required for the effective implementation and whether the technology was similar to existing technologies or whether it would be a new kind of point of care location.

Most interviewees, with a technology background, viewed SmartHEALTH to be a new diagnostic device to add to the existing tool bag of diagnostic devices. As such, this technology would fit into the existing systems in terms of current medical skills available, counselling services and health informatics systems. In contrast, one interviewee, with extensive experience in developing these systems stated that this technology was a disruptive technology that would change the nature of healthcare diagnosis. One healthcare expert agreed that SmartHEALTH would be a disruptive technology as it would highlight current inadequacies within existing systems in terms of: current levels of cancer treatment, healthcare records and communication between different healthcare staff.

6.2 *What are the benefits and who will benefit from the SmartHEALTH technology?*

As highlighted in section 5, the technology is perceived to have three main benefits:

- Speeding up of test results.
- Improving accuracy (sensitivity and specificity) of current tests.
- Providing ambient healthcare systems and access to medical health records and other healthcare professionals for the user of the diagnostic medical device.

Interviewees highlighted the benefit around reducing the speed of test results in terms of reducing patient anxiety when test results were negative. However, overall this benefit was considered to be more important by most technological interviewees and less by healthcare interviewees. In particular, doubts were raised on the assumed symbiotic link between reducing the time taken for testing and the time taken for diagnosis. In contrast, the focus on accuracy of test results held a higher profile during discussions, in particular the sensitivity and specificity of tests.

Within cervical cancer screening, improving the sensitivity of tests was considered important due to the current high percentage of false negatives and the subjectivity of the visual inspection of cervical cells by pathologists in current tests procedures. Within breast cancer follow-up, the specificity of the tests was highlighted as important for

developing more nuanced diagnosis and therefore more personalised treatment plans for patients. However, two external healthcare interviewees questioned the rationale behind developing this new diagnostic technology for breast cancer follow-up. They pointed to the change of practices regarding clinical follow-up and monitoring, moving to less intensive follow-up following treatment and more emphasis on psycho-social care than clinical monitoring. They also questioned whether the technology would have an impact on length and /or quality of life in a way that would be considered an improvement on current treatment options. In addition, one CRC specialist highlighted the need for a less invasive blood test rather than an invasive tissue test, since by the time the cancer has progressed to be present in the colon tissue there is no curative treatment currently available. Instead, they argued that CRC screening through a blood test that tested for earlier stages of CRC should be the main focus rather than CRC diagnosis or monitoring.

A healthcare scenario based on all three benefits

Inevitably each interviewee highlighted the benefits of the technology based upon their own professional technical and/or healthcare knowledge, though there was a notable lack of widespread discussions around the third benefit: the ambient healthcare system. One healthcare professional, an oncologist, presented a scenario based on all three benefits and recognised that if the technology allowed for a real-time link between the patient, GP and a specialist in a remote clinic then this might build upon the increasing focus on both primary and secondary care's involvement in cancer diagnosis, (see D9.2:5):

- *The scenario:* the patient or participant is tested at the GP's office who, ideally, knows the individual, their character and can provide suitable emotional support. If the interpretation of test results are not negative and provide a number of different interpretations outside the GP's professional comfort zone, the GP, with primary care skills and knowledge, has immediate access to a pathologist or oncologist, with secondary care skills and knowledge, at a centralised hospital through the ambient healthcare system.

7. Implications for Fieldwork

The findings have two main implications for the final phase of the fieldwork, the case studies: the presence of any new issues and the redefinition/refocusing of the current research questions (Table 1)

7.1 Redefining existing fieldwork questions

Within D9.2, six broad questions were raised to be explored within the case studies and further fieldwork (see section 5):

1. 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?
2. Will a quicker test result produce a quicker diagnosis?
3. Will SmartHEALTH impact on the current lack of willingness for participants to attend cervical cancer screening programmes?
4. Will improving the cancer screening stages and follow up stages impact on the other care services within the wider continuum?
5. Is the location for the tests new or existing within current practice?
6. How much knowledge and skill does the person using the machine require?

All ethical and social issues raised by interviewees are embedded within the above six fieldwork questions. However, notably question 1 became more prominent within discussions in terms of improving sensitivity and specificity of tests, while question 2 was rarely mentioned: ‘will a quicker test result produce a quicker diagnosis?’

As the aim of D9.3 was to explore further issues raised in D9.2, no fieldwork questions will be rejected prior to the case studies. However, in light of the findings, as presented here, questions 1, 2, 5 and 6 have been redefined, as outlined below, while questions 3 & 4 remain the same at this stage of the research:

1. How will this new technology fit into existing healthcare services for: a) improving accuracy of current tests (sensitivity of cervical cancer screening and specificity within breast cancer and CRC follow up); and b) improving access to health information for health professionals?
2. What will be the impact of reducing the time for test results on the earlier diagnosis of cancer, within the three SmartHEALTH applications, in terms of: a) reducing current mortality figures; b) improving a patient’s quality of life?
3. What impact will SmartHEALTH have on the current lack of willingness for participants to attend cervical cancer screening programmes?
4. What impact will improving the cancer screening stages and follow up stages have on other care services within the wider continuum?
5. What kinds of knowledge and skill does the person using the machine require, in term of: a) preparing high quality samples; b) interpreting meaningful healthcare information; and c) communicating effectively with patients/participants?
6. What are the current skills and knowledge required for new PoC locations within current practices: a) breast cancer follow up at the GP surgery and (possibly) the home; and b) CRC testing at the GP surgery?

7.2 Next research steps

D9.6: Report on case study findings of main ELSIs arising from SmartHEALTH

Current plans are to carry out two case studies in two European countries (one in the UK and the second in another European country, possibly Norway or the Netherlands). The first case study will be in the UK because UNEW, the WP9 leaders, are based in the UK and have links with suitable healthcare professionals in the National Healthcare Service (NHS), which is a crucial factor in accessing different users and developing quality case studies. The rationale behind the location of the second case study is not yet finalised but will be based around two main criteria: a) a healthcare system that has the potential to implement SmartHEALTH in the near future; and b) the presence of healthcare partners who have suitable links within their healthcare system to aid setting up the case study. The latter is the deciding criteria and one current possibility is Norway. This rationale was discussed during relevant interviews and supported by interviewees. Each case study will be embedded within a complex social context and, as a result, there will be no attempt to contrast the two case studies, though different aspects can be compared. The exact nature and fieldwork details of both case studies are still under discussion and will be detailed in a subsequent report.

Based on the information gathered during interviews with partners (D9.3), different key users of the SmartHEALTH technologies will be invited to discuss their perceptions of

the SmartHEALTH technologies and predict how these technologies will impact upon their current work practices or/and their everyday lives. These case studies will include the following three components:

- Ongoing public dialogues during the development of the SmartHEALTH technologies.
- Different users, from the patient to the clinician, will be invited to discuss the SmartHEALTH technologies within suitable SmartHEALTH applications.
- A specific focus on exploring how SmartHEALTH technologies could impact on the current debates around breast cancer follow-up services.

Note: it is expected that the different users will re-interpret the potential benefits and challenges of SmartHEALTH technology, as outlined in this report or presented by SmartHEALTH partners (D9.3), in line with their own work practices and lives. These different interpretations and meanings of SmartHEALTH technologies will be an important part of the WP9 research findings and, as a result, will inevitably impact on the relevance of the 6 research questions presented at the end of 7.1. Some questions will gain prominence while others may become obsolete within the final findings presented in D9.6. These research questions will be explored within 2 broad discussions parameters:

1. Will SmartHEALTH be a disruptive technology within existing healthcare systems?
2. What are the benefits and who will benefit from the SmartHEALTH technology

8. References

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