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D9.6 Report on main cases study findings of main ELSIs arising from SmartHEALTH (cervical cancer screening).

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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 and to effect rapid and accurate diagnosis and monitoring in order to improve the morbidity and mortality associated with malignancy.

The aim of Workpackage 9 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 deliverables associated with WP9 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 9.4 (case studies) and is the first of two associated deliverables:

1. **D9.6** Report on case study findings of the main ELSI arising from SmartHEALTH (cervical cancer screening).
2. **D9.7** Report on case study findings of the main ELSI arising from SmartHEALTH (breast and colorectal cancer monitoring).

This deliverable focuses on WP1b and explores the perceptions of current participants eligible to participate in the UK national screening programme (women aged 25 to 64 in England and 20 to 64 in Scotland) and in the Norwegian national screening programme (women aged 25 to 69). D9.6 also refers to the findings of 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". It was noted that the views within D9.3 would benefit from the perspectives of professionals in the pathology laboratory. As a result the following two discussions were held: 1) a research seminar with six cytology staff, including a colposcopy nurse in a hospital in the North-

East of England and 2) an in-depth interview with the Head of Cytology in a hospital in Trondheim, Norway.

Eight participatory workshops (six in the UK and two in Norway) were held with groups of eligible women who explored the perceived benefits of the cervical cancer screening application of SmartHEALTH. These potential benefits were discussed within the current experiences of participants in cervical cancer screening practices. This report presents:

1. Workshop participant views of current cervical cancer screening programmes: likes, dislikes and what they would change.
2. Similarities and differences between workshop findings (screening participant views), seminar/interview findings (perceptions of cytology professionals) and D9.3 findings (partner and selected healthcare specialists' views) on the potential benefits and challenges of the SmartHEALTH cervical cancer application.
3. The implications of these findings for the development of the cervical cancer application of SmartHEALTH.

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

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. Potential ELSIs highlighted in an initial literature review (D9.2) were explored with SmartHEALTH partners and selected healthcare specialists (D9.3). Two broad research themes were highlighted for further fieldwork and were explored in the work undertaken to produce this deliverable:

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

2. SmartHEALTH: Application within current cervical screening practices

The SmartHEALTH project is exploring the potential to introduce a new DNA test into current screening practices for the high risk strains of the Human Papilloma Virus (HPV), which are found in 94.6% of cervical cancer cases (Maynard *et al.*, 2007).¹ It remains uncertain if SmartHEALTH aims to replace the current test (liquid-based cytology) or to introduce the HPV test as an adjunct to current test. SmartHEALTH is exploring three possible PoC scenarios for the cervical cancer screening application: general practitioner offices (gynaecologists), hospital outpatient departments and specialist clinics. This deliverable focuses on the most common PoC for routine cervical cancer screening in the UK: the General Practitioner's surgery.

¹ D1.5 cites nearly 100%

2.1 Current cervical cancer screening: UK and Norway studies

Cervical screening began in the UK in the mid-1960s. By the mid-1980s, although many women were having regular smear tests, there was concern that those at greatest risk were not being tested, and that women who had positive results were not being followed up and treated effectively. In 1988, the National Health Service (NHS) cervical screening programme was set up when the Department of Health instructed all health authorities to introduce computerised call-recall systems and to meet certain quality standards. Opportunistic cervical cancer screening began in Norway in the late 1950s, though the national screening programme was not established until 1992.

Currently, in Norway, all women between the ages of 25 to 70 are eligible for a free cervical screening test every three years. In England all women between the ages of 25 and 64 (20 to 64 in Scotland) are eligible for a free cervical screening test every three to five years. The UK screening programme is considered to be highly effective and, as a result, mortality rates have dropped by 7% per annum (Leeson, 2005), although the number of non-attendees in the national screening programmes is rising in the UK and Europe (Forbes *et al*, 2002)

2.1.1. Liquid-based cytology

In the UK in 2003, a new way of preparing cervical samples for examination in the laboratory was introduced: Liquid-based Cytology (LBC) (Kitchener *et al.*, 2004). Today, LBC has been introduced across the UK, while in Norway it is only operational in small areas. Only one region has introduced LBC throughout: Trondelag, in central Norway, which was the chosen site of the two Norwegian workshops.

In LBC, the sample is collected in a similar way to the conventional smear, using a special brush that collects cells from the neck of the womb. However, rather than smearing the sample onto a microscope slide, the head of the brush holding the cells is broken off into a small glass vial containing preservative fluid or rinsed directly into the preservative fluid. The sample is sent to the laboratory where it is centrifuged and treated to remove obscuring material and a random sample of the remaining cells is taken. A single layer of cells is deposited onto a slide, making visual inspection significantly easier for the cytologist than the previous 'smear test'. The slide is examined in the usual way under a microscope by a cytologist. This new method is reported to have greatly reduced stress levels for cytologists (Dowie *et al.*, 2006) and has reduced the number of cases of inadequate smears from 9% to 1-2% (Moss *et al.*, 2004). In Trondelag, the head of cytology reported that the backlog of tests had reduced by 25% and that test results were available within two weeks rather than 4 to 6 weeks.

Differences in screening practices between the UK and Norwegian studies

There were a number of differences in cervical screening practices between the two study sites, most notably:

- In the UK the participants receive test results, while in Norway the participants do not receive results unless the test was inadequate or the results were abnormal.
- In the UK the practice nurse usually takes the sample, while in Norway this is carried out by the doctor.
- In the UK the participant lies on a generic medical examination bench, while in Norway the participant sits in a gynaecological examination chair.

2.2 HPV testing in primary screening practices

Infection by HPV is now accepted worldwide as the principal causal factor and a necessary early event in cervical carcinogenesis (Walboomers *et al.*, 1999). Testing for HPV infection on a large scale is now possible, and because of its increased sensitivity compared with the traditional cytology test (commonly referred to as the Pap smear or smear test), HPV detection is now a candidate test in primary cervical screening (Cuzik, 2006).

2.1.2. The role of HPV in current cervical cancer screening practices in Norway and the UK

In 2004, the NHS completed HPV triage pilot studies and is now beginning to introduce HPV triage for borderline changes and mild dyskaryosis into the current screening programme (Moss *et al.*, 2004). For the first time in the UK, a woman with a screening test result of borderline changes or mild dyskaryosis will automatically have an HPV test performed on her sample. If the test result is HPV positive then the individual will be referred for colposcopy and, if HPV negative, she will be returned to the routine screening programme every 3 or 5 years, depending on age). However, data from the original pilot studies indicated a large initial increase in the number of referrals to colposcopy followed by a reduction in referrals, although the exact cause remains unconfirmed (Moss *et al.*, 2004). As a result, the introduction of HPV triage into a small number of centres is being monitored by the NHS. In contrast, HPV as an adjunct test to LBC in the pathology laboratory is standard practice in Trondelag.

The ARTISTIC trial: comparing LBC with HPV as a primary screening test

Comparing the social and economic benefits of LBC and HPV testing is currently problematic as research has focused on HPV and conventional Pap smears. However, in 2001 a UK trial, involving approximately 25,000 women, investigating HPV as a primary screening test alongside LBC was begun (Kitchener *et al.*, 2006). In order to determine how effective HPV testing would be in primary cervical screening, the ARTISTIC trial (a randomised trial in screening to improve cytology) was established. Women with revealed HPV results that were acted upon were compared with women whose HPV results were concealed and not taken into account in the clinical decision that followed (Kitchener *et al.*, 2004). The trial aimed to:

- Provide an estimate of the effectiveness and costs of HPV as a stand-alone test.
- Provide clear evidence on the costs, medical effects and psychosocial impact of adding HPV testing to cervical cytology.
- Determine the contribution of HPV detection to the cervical screening programme, particularly to sensitivity, specificity and inadequate smears.
- Address methodological issues in HPV testing.

The research is currently awaiting UK Health and Technology Agency approval and the findings will be available soon (S. Boyskova, personal communication).

3. Methods

This deliverable draws mainly on data collected within six participatory workshops with eligible participants in the UK national cervical cancer screening programme and two participatory workshops with eligible participants in the Norwegian national cervical cancer screening programme. 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 recognises that people's lives and ideas are complex and aims to allow the participants to lead the research discussion and does not seek to create averages or demand homogeneity or consensus.

3.1 Rationale for an exploratory approach

Currently, there are gaps in the quantitative research addressing the perceptions of participants of routine cervical cancer screening in Western Europe (Forbes *et al.*, 2002). Most research has been carried out within developing countries where cervical cancer continues to have a high mortality rate and there are significant economic and cultural barriers to women attending screening clinics (see D9.2). In contrast, Western European studies have concentrated on two areas: 1) the reluctance of certain ethnic minority groups to participate in screening (Forbes *et al.*, 2002) and 2) following interest in HPV tests, women's perceptions of being tested for HPV. This research identifies the high psycho-social morbidity associated with HPV testing (*c.f.* Waller *et al.*, 2005). However, WP9 chose not to design the research topics around women's perception of HPV, adopting instead an exploratory approach that focused on gathering participant perceptions rather than leading the discussion towards preset questions. Current cervical cancer screening practices and the implementation of the SmartHEALTH technology into existing healthcare systems could produce a variety of complex social and technical scenarios for discussion.

This participatory approach has allowed WP9 to gather relevant data on participant perceptions and has provided baseline data that raised issues for future research, as outlined in the discussion section. This research obtained approval from the ethics committee of the School of Geography, Politics and Sociology at Newcastle University.

3.2 Participatory workshops

Workshops had three specific objectives:

- To invite current participants of cervical cancer screening programmes to explore and outline their likes, dislikes and what they would change in current cervical cancer screening practices
- Within their experiences of current practices, to explore and outline their perceived likes, dislikes and what they would change about the cervical cancer screening application in SmartHEALTH.
- To provide sufficient time for participants to discuss their thoughts on current cervical screening practices.

Each workshop had six stages (though remained flexible to participant interests):

1. *Introduction*: participants ask the researcher any questions about the research project and sign a consent form;
2. *Setting the scene*: to allow participants time to think about their own screening experiences, participants were invited to identify and discuss their likes, dislikes and what they would change about current screening practices. Participants record issue of importance onto different coloured post-it notes, which are placed on a large piece of paper on the wall.
3. The *technology was presented* in two stages: i) using a second person scenario, the group mapped out their understanding of the current process of screening (from the invitation letter to receiving the final test result or, in Norway, leaving the GP office). ii) This scenario was used to highlight potential differences between the current procedures and the implementation of the technology being developed.
4. An *open debate* on the developing technology began once main participant questions were answered on the nature of the technology or noted down to be answered at a later day by a relevant expert on that subject. In this stage the researcher facilitated a shift from dialogue and understanding to debate and critical discussion (Forester, 2007). Using the same methods in stage 2, participants were invited to explore, discuss and record their likes, dislikes and what suggested changes they would propose to partners developing the technology.
5. *An initial analysis* began once all participants had no more points to add to the three categories (likes, dislikes and suggested changes). Participants were then invited to highlight which issues were of most importance using coloured dots.²
6. At the *close of workshop*, there was a final question/answer session including a discussion around how their views will inform the decision-making process within the development phase of the technology.

3.3 Presenting the technology within user screening experiences

The workshops focused on the experiences and perceptions of women regarding the current practices against which they were invited to discuss their views of the SmartHEALTH technology. For example, in one UK group four of the eight participants had breast cancer in their family and, in contrast to other groups, focussed less on the invasiveness of current tests and expressed gratitude at being offered these tests. Each participant shared their personal and professional knowledge with the group; a dentist in one group discussed the problems of providing informed consent to anxious patients. Participants were also able to draw upon knowledge from outside their professional training and experience (Chambers, 1997). For example, the husband of one UK participant was an IT specialist and she had detailed knowledge of ambient intelligent systems and current debates around health informatics, although, as mentioned below, this topic was not explored in any detail.

The WP9 researcher presented SmartHEALTH technology as a developing technology in the prototype phase. Once participants had discussed their views on current screening practices and mapped out a timeline of the current screening process, the researcher presented the two potential changes for current practices with the introduction of SmartHEALTH technology:

- Participants were provided with immediate test results in the GP surgery.
- Participants would be tested for HPV (the high risk strains of the virus).

² When time allowed, participants were asked to explore the question: 'how feasible do you think your suggested changes are?'

Participants were invited to ask more detailed questions although there was no attempt by the researcher to explain the intricacies of the technology unless requested. At this stage, the focus was on dialogue and understanding within the group, and between the group and the researcher. As the technology is not yet finalised this approach was a useful method to explore aspects of the technology perceived to be beneficial as well as areas of concern. Notably, issues around health informatics were not explored in depth as no participants chose to develop discussions on the ambient intelligent component of SmartHEALTH technology.

3.1.1. Sources of information used in workshops

The workshops produced detailed discussions around cervical cancer screening procedures. Each stage of the workshop was built upon participant existing knowledge of current screening practices and the development of the cervical cancer screening application. Inevitably participant knowledge about the current screening process and the cause and risks of cervical cancer differed. It was envisaged that some participants may want more information about cervical cancer and current testing procedures to extend their knowledge and/or alleviate any concerns about the risks of cervical cancer for themselves, family or friends. To address this need, during the workshop, suitable literature, websites and contact numbers were made available for participants.

The role of the researcher in the workshop was as a facilitator aiming to encourage and support open and considered discussions. An important characteristic of these workshops was that the researcher was not presented as a source of definitive scientific information (Reason and Bradbury, 2006). Inevitably the researcher drew on different sources of information during the workshop to discuss current screening practices and to present the SmartHEALTH technology.

Current practices:

As participants were held to be experts on the impact of current screening practices upon their own lives, they were invited to map out the screening process from receiving the invitation letter to receiving the final test results. It was anticipated that many participants would be unaware of, though interested in, what happens from the sample leaving the surgery to receiving the final test result. In preparation, the researcher spent a morning in a pathology laboratory in the North-East of England and was shown 1) the complete testing process from the vial entering the laboratory to the final test results and 2) the difference in slide quality between conventional smears and liquid-based cytology. Any additional information requested by participants was taken only from publically available websites: the National Health Services cervical screening programme and Cancer Research UK. For the Norwegian workshops, the researcher discussed the procedure with the Head of Cytology in the Norwegian hospital.

Presenting SmartHEALTH technology

The workshop built upon the participants' own knowledge of the potential impact of speeding up test results and the nature of being tested for HPV. Where questions were asked directly to the researcher, the information that was discussed was taken from the above publically available websites. Information on the SmartHEALTH technology was taken from non-confidential information from Workpackage deliverables.

4. Data collection and interviewee profile

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

4.1 Participant profiles

As this research is exploratory, there was no attempt to gather representative data for women eligible for screening in the UK or Trondelag, Norway. Due to the potentially sensitive research topic, each group were recruited through social/professional networks. The researcher utilised groups who already met within their everyday lives and, therefore, were accustomed to discussing social topics together (Cornwall, 2000). In the UK, ten potential groups were identified and four in Norway. This data represented six UK groups and two Norwegian groups:

Group name	Number	Age range	Professions	Experience: referral/ Colposcopies
UK				
Newcastle	5	30-50	Administrative/Research staff	0
Tyneside	9	30- 45	Chiropractor, osteopath, remedial masseur, receptionist	7
Lincoln	8	40 -50	Dentist, dental nurse, teacher, librarian	5
Bedford	7	40-60	Dancer, lecturer, shop owner teacher	4
Edinburgh No. 1	9	44-60	Social workers, GP practice nurse, gardener,	3
Edinburgh No. 2	8	30-45	Teacher, language interpreter, mature student	4
Trondelag, Norway				
Trondheim No. 1	4	30-40	Health researcher, bank workers, teachers	4
Trondheim No. 2	4	35 -45	Pathology laboratory staff	0

Table 1: Workshop group profiles: UK and Norway

Each known contact within each identified group acted as the initial gatekeeper and approached each group member informally to assess their interest. Each interested individual was provided with an information sheet by the researcher through the gatekeeper. Participants, who were contacted by post, were sent an information sheet and a covering letter with a tear-off slip to be completed by the potential participant, which provided their contact details and permission for the researcher to contact them. A suitable workshop time, date and location was agreed with the different participants by the gatekeeper and the researcher. Workshops were designed and facilitated by an experienced participatory researcher. All travel costs and child care, where needed, was covered and refreshments and food were provided.

4.2 Data analysis

As outlined in the method section, participants recorded their own data and carried out an initial analysis on each topic. The researcher produced detailed fieldnotes on the workshops process. Participant data and the researcher's fieldnotes were then subjected to thematic analysis. The themes produced were then compared with the findings of D9.3

(issues raised by interviewees) and the findings of the research seminar with the cytology professionals and the interview with the Head of Cytology in Trondheim. For this deliverable, workshop participants are not named to maintain anonymity and within the findings section are referred to by their group name.

5. Findings

The key themes emerging from the participatory workshops were remarkably similar to the issues raised by interviewees in D9.3. As a result, a similar framework to D9.3 has been adopted in this deliverable to present the workshop findings. Three broad themes emerged:

1. Workshop participant attitudes towards current cervical cancer screening practices, (likes, dislikes and what they would change).
2. Technological context: the implementation into existing healthcare systems, (The views of workshop participants and interviewees).
3. Healthcare context: perceived benefits of SmartHEALTH, (The views of workshop participants and interviewees).

5.1 Participant attitudes towards current screening practices

The main points raised by participants in regard to the screening process (from receiving the letter to receiving the test results) highlighted that participants liked that the test was available. However, three dominant themes were a dislike of:

- The gynaecological nature of the current screening test.
- Poor social skills of the nurse/doctor.
- Waiting for test results.

5.1.1 Likes and dislikes

Availability of the test

The majority of participants liked that the screening test was available. In particular the UK participants who had a family history of breast cancer wrote that they felt privileged/were grateful to have the test available. In the UK workshops, this discussion was often preceded or followed by a question and answer session on the reduction of mortality rates in the UK compared to high mortality rates in ‘developing’ countries where no affordable cervical screening test is available for most of the population. Some participants wrote that they did not like the procedure though they accepted it, and one participant called it “a necessary evil”. This level of emotion was not observed in the Norwegian workshops. In particular, the group with participants who had all experienced being referred for further treatment appeared unperturbed by the process. One UK participant felt a sense of security going for a smear test since having polyps diagnosed and removed. Her experiences had been positive: she had been treated well and had received “lots of information and a painless treatment”.

Most participants appreciated the reminder letter to make an appointment for the test. However in Scotland where the letter is similar to a payslip, some participants commented on the lack of privacy as “everybody knows what it’s for”. The few participants who were screened at specialist clinics liked that appointments were outside of normal GP surgery hours. In contrast, participants who were screened at their GP surgery complained about fitting their busy life schedules with surgery opening hours.

Invasive nature of the test

Participants did not like the gynaecological nature of the current test:

- The instrument was reported to be cold and “sometimes it nicks you”. One UK participant wrote she disliked the “anticipation of (is it) going to hurt”. In contrast, participants who had been screened for breast cancer, said that the Pap test was a “walk in the park” compared with having a mammogram, which was reported to be extremely uncomfortable or painful.
- A number of UK participants did not like the process of having to remove their clothes. One participant said “once you remove your knickers, you immediately feel vulnerable”. A recurring theme was the lack of dignity in being screened. All participants highlighted the importance of the social skills of the nurse or doctor. The GP of one Norwegian participant put a cartoon on the ceiling to keep screening participants occupied during the procedure, which she appreciated. However she disliked that her underwear was “on display” on a nearby chair.

Notably in the Norwegian workshops, there appeared to be a greater level of acceptance of the physical nature of being screened for cervical cancer. However, both UK and Norwegian groups expressed a preference for a non-gynaecological test.

Social skills of health professional

The character and skill of the health professional performing the test was important. The main issues raised were:

- Preference for a nurse rather than a doctor. However, two UK participants objected to “being forced” to see the nurse rather than their own female doctor, whom they knew well.
- Whether the person performing the test put them at their ease and was friendly. One UK participant appreciated when “the nurse constantly chatted” with them, although other participants found this disconcerting and wanted to be in and out as quickly as possible with no attempt by the nurse/doctor to engage them in conversation. The most positive experiences were from participants who had to be screened at specialist clinics rather than their GP clinic.

Waiting for test results

In all of the UK workshops, a common theme was the emotions attached to waiting for test results for two weeks, or more. However, some participants noted that once they had left the surgery they forgot about waiting for the results. Notably for the UK participants who had been recalled for a repeat test or referred for a colposcopy the level of worry was more intense. Several participants concluded that their level of worry was also linked to their personality.. Many UK participants who had experiences of being referred for further treatment felt reassured at the moment that they received clear test results. One participant said that the moment between receiving the sealed letter and before knowing the results was “frightening”.

Participants also discussed their dislike of being told that “the smear is inadequate and you have to go back again” or “when they find something and the letter comes back to tell you”. In Norway, participants of the cervical cancer screening programme do not receive their test results unless there is an abnormality or the quality of the sample is inadequate. All the participants in the Norwegian workshops expressed surprise that UK participants were given the test results, regardless of the outcome. All the workshops

participants agreed with the procedure in Norway: women are not informed of the result unless "something is wrong". Norwegian participants who had experiences of being referred for further treatment said that there was a mild feeling of apprehension immediately after being screened. However, often these individuals then forgot about being screened, since they knew that they would only receive a letter if something was wrong.

5.1.2 Proposed changes to current cervical cancer screening practices

The proposed changes to current screening practices were not uniform across the workshops though four main themes arose:

- a non-gynaecological test (UK and Norwegian participants).
- more information on the screening process (UK participants).
- more flexible appointment system (UK participants).
- quicker test results if the test was more specific (UK participants).

The nature of the test

All the workshop groups expressed a preference for a non-gynaecological test. One theme raised in four groups was the possibility for a blood test, though a few participants who did not like needles disagreed. One participant said she didn't care what it was, an eyeball scan or blood but not the current 'invasive' test. The emotional intensity of UK participants towards changing the current test to a non-gynaecological test varied and can be represented by the following four quotes:

- "I don't like the (invasive) procedure but it's better than no test at all".
- after a woman has given birth "you're used to it", "it's my body and I don't want to be prodded".
- "How is it possible that with all the development in technology that nobody has developed a non-invasive test. Is it because it's for women?"

Information and communication

Towards the end of the UK workshops a significant number of participants commented on their lack of understanding of the screening process and "what was happening". One UK participant wrote "we forget the facts – we are told when first tested but then 20 years later we forget. Are tests effective? Is there other updated information?". However, one UK participant wrote that "the information provided by the colposcopy clinic in ERI (Edinburgh Royal Infirmary) trials in 1995/96' was good". The Norwegian participants were less concerned about knowing what happening during the screening process. In contrast many of the UK participants requested more information on current screening practices, in particular:

- Participants who had received an 'abnormal' result wanted more information on what 'abnormal' meant.
- Participants who were experiencing/had experienced the menopause wanted to know why the test was becoming more uncomfortable or painful
- Most groups were interested in more information on LBC.

One participant who has experienced long-term gynaecological problems wanted to improve the communication between the hospitals and the GPs and wrote "ensure that all results are relayed so that women get peace of mind".

Timing of test results and appointments

Many UK participants wanted to receive their test results more quickly, though not everyone agreed. For example, some participants recommended that there should be time for reflection in case the result proved positive. However two UK participants highlighted that the current procedure of receiving a sealed letter provides limited time for reflection or is a healthcare professional present to answer any questions. Many participants wanted a more flexible appointment system that would fit into their busy life schedules while other participants wanted a friendlier atmosphere in surgeries. In each workshop, at least one participant requested that the time between undressing and dressing was decreased.

In the following sub-sections 5.2 and 5.3, the workshop findings are discussed with reference to the findings of D9.3 and similarities and differences are highlighted. In the following sections, the eight groups of women are referred to as *workshop participants*, the partners and selected healthcare specialists interviewed for D9.3 are referred to as *interviewees* and participants from the cytology research seminar as *cytology professionals*.

5.2 Technological context: implementation into existing healthcare systems

Interviewees in D9.3 highlighted that the successful implementation of the technology within existing healthcare systems relies upon numerous factors, such as the sensitivity of the biomarkers. Both workshop participants and interviewees discussed the following two broad themes.

1. The availability of relevant skills and personnel within the Point-of-Care location.
2. The relevant personnel and skills required to ensure the effective and efficient implementation and running of the technology.

5.2.1 Point-of-Care location and relevant skills required

During the workshops, the suitability of the current location for cervical cancer screening (GP surgeries) was raised by only a few individuals, who quickly concluded that “there didn’t seem to be a better option”. However, one participant in four of the groups raised the possibility of opting for a home-test. The immediate reaction by other participants was of disbelief, and some amusement. Despite the challenges that this location would present to current practices, one participant, a chiropractor, argued strongly for home-testing. In three other groups, this option was rejected for three reasons, which mirrored interviewee concerns over home-testing for breast/CRC monitoring:

- Participants were uncertain on how to take a sample and most participants disliked the idea of collecting a sample themselves.
- Questions were raised on whether individuals should receive a positive test result without a nurse/doctor present to ask questions.
- Unlike a pregnancy/diabetic test result that provides a yes or no result, a positive result for a cervical cancer test often leads to a number of possible decisions.

Cytology professionals’ perspective: suitable as adjunct test to LBC in hospitals

Healthcare interviewees predicted that the SmartHEALTH technology would not change the current location of point of care for cervical cancer screening. In contrast, the cytology professionals did not support the introduction of the SmartHEALTH technology into GP surgeries due to concerns over the potential lack of skills and knowledge held by

GPs to perform HPV tests. Instead, the head of cytology in the hospital in Trondheim proposed that the technology could be a useful adjunct test to LBC if it was located in the pathology laboratory.

Workshop participants also discussed the relevant personnel and skills required by the health professional carrying out the test, though this topic was more dominant in the UK workshops.

5.2.2 Relevant personnel and skills required

In D9.3, interviewees highlighted two main social and ethical issues surrounding the effective implementation of the technology:

- Adequate informed consent for participants to allow informed decisions on the risks and benefits of participating in a screening programme.
- Ethical aspects of health informatics and who has access to electronic records.

Interviewees also highlighted three professional skills that are important in developing and maintaining an effective and efficient cervical cancer screening process:

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

The themes raised by workshop participants were similar to themes raised by interviewees, with the exception of health informatics and inevitably communication skills focussed only on the interaction between participant and health professional. The importance of good communication and social skills of the health professional performing the test was a common theme across all groups, as outlined in section 5.1. There were three differences between the workshop findings and the interview findings: 1) less emphasis on technical details, such as preparation of samples, 2) increased focus on informed consent and 3) lack of information on the current screening processes.

Good quality samples: taking and preparing samples

For both interviewees and workshop participants, the level of skill required by the health professional was considered part of their current skills and was not perceived as problematic. However, questions were raised as to whether GPs had the available equipment or time to prepare the sample. Interviewees viewed the preparation of the sample as important, in particular for cervical cancer, where a medically trained individual is required to take a good quality sample. Unsurprisingly, workshop participants discussed the importance of the sample quality less than interviewees, except for the participant who is a nurse in a GP practice. She praised the introduction of LBC, including the higher quality of samples taken. However, her main issue of concern was that the appointment time was too short to inform participants about the screening process in order to obtain informed consent.

Quality of the interpretation of test results into meaningful information

All the interviewees and workshop participants predicted that the handling of negative test results could be managed by any doctor with little psycho-social impact on the

participant, assuming that the new technology (biomarkers) were of sufficient accuracy to provide confidence in the test results. In addition, as with healthcare interviewees, many workshop participants recognised that the interpretation of positive test results may lead to a number of decision pathways. A 'positive' result may lead to an individual (participant) moving into a further stage of assessment and investigation that relies upon different healthcare specialists. Interviewees strongly recommended that the SmartHEALTH technology should be embedded into a support system that would address the needs of both health professionals and participant/patient. As the cervical cancer screening application aims to develop a highly sensitive test for HPV not cancer, interviewees predicted that results would produce fewer choices for interpretation and, therefore, there was less potential for misinterpretation than with the results in the breast and CRC monitoring applications.

Workshop participants also recognised the potential simplicity of the 'yes or no' results for different strains of HPV. However, the lack of specificity in HPV testing raised concerns and the majority of participants often asked "so what happens next if you get a positive result?" or "what does a positive result mean exactly?". Seven of the eight workshops concluded that the HPV test alone appeared no different from the current test, in terms of providing assurance to the screening participant and reducing their chances of referral to the next stage of assessment. Most participants who had experience of being referred for further investigation concluded that if the HPV test was no more specific than the current LBC test then they did not want a new test. Instead participants recommended improving current procedures.

As outlined in D9.3, interviewees working within WP1 stressed that this Workpackage has recognised the need to develop a range of guidelines on different decisions pathways for the health professionals handling positive test results. However, at this stage in the development of the SmartHEALTH prototype these decision pathways remained unexplored.

Informed consent/uptake: knowledge of HPV and the current screening process

The need for informed consent and informed uptake was recognised by most interviewees, in particular the medical interviewees who raised one area of concern:

- 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.

In seven of the eight workshops the topic of HPV was introduced by the researcher during the presentation of the technology, though only the two Edinburgh groups chose to discuss this topic in detail. The two groups raised and discussed three main questions:

- What was the difference between the many strains of HPV and the high risk strain of HPV present in cervical cancer?
- What were the benefits of HPV over current LBC tests?
- Why did there appear to be a lack of public knowledge about the virus?

In the Edinburgh group No. 2, the topic of HPV was introduced by one of the participants as the workshop began. Before arriving at the workshop, the participant had read about HPV on the internet and discovered that the virus was classed as an STD (sexually

transmitted disease).³ Her comments started a discussion on the nature of HPV and the link with sexual practices and questions were raised as to whether HPV is linked to herpes. One participant initially appeared anxious that she knew little about HPV and wanted to understand all the details of the virus. Other participants in this group were less anxious about their lack of knowledge of HPV and agreed with the participant who wrote that “unless their HPV status was directly linked to cancer then they didn’t want to know about it”. One individual did want to know her HPV status, though her interest was scientific to the different strains of HPV. Notably, in the other seven groups, where HPV was introduced by the researcher when presenting the technology, participant discussions focussed less on HPV as a sexually transmitted disease and more on the accuracy of the HPV test (specificity and sensitivity) and what the test was revealing.

In contrast to varying levels of discussions on HPV, a recurring theme in all workshops was that available knowledge on current screening processes was partial or missing, in particular:

- The meaning of ‘abnormal cells’ in a test result.
- The nature of cervical cancer as a relatively slow growing cancer over 10 years.
- The replacement of Pap test by LBC and the subsequent reduction in inadequate samples and the subsequent reductions of recalls for repeat tests.
- Women’s risk of cervical cancer and how this risk differs with age.

Both the interviewees in D9.3 and the UK workshop participants strongly suggested that issues around informed consent and uptake should be addressed as part of the implementation of the SmartHEALTH technology. The Norwegian participants were less concerned around issues of informed uptake, though all the Norwegian participants were aware of the introduction of the HPV vaccine in Norway. In contrast, most of the UK participants were unaware of the introduction of the same vaccine into the UK in 2008. The head of cytology also stated that being infected with HPV in Norway does not hold the same social stigma as in other European countries.

Who should be responsible for informed consent/uptake?

In D9.3, the interviewees raised the question: who should be responsible for implementing and monitoring appropriate informed uptake for screening participants? There was general consensus that placing this responsibility upon GPs was inappropriate since many GPs were overworked, in particular in the public healthcare section. As a result, many GPs should not/could not be held responsible for providing and monitoring participants’ understanding of the issues surrounding cervical cancer screening. The workshop participant who is a GP practice nurse discussed at length her concerns that insufficient appointment time is currently allocated to informing women about the process of screening. In her personal opinion, many screening participants were involved in a screening process that they did not fully understand and therefore informed consent was not being obtained. Both the Head of Cytology in the hospital in Trondheim and the cytology staff in England expressed doubts about GPs having sufficient time or understanding of HPV to ensure informed uptake by screening participants.

Within the SmartHEALTH project, the HPV specialists have highlighted that there is also significant misunderstanding about HPV within the medical profession. This statement is supported by recent research on current knowledge of the HPV vaccine by Sherris *et al.*

³ One participant, an osteopath, questioned the negative connotations associated with HPV as a sexually transmitted disease as presented in her medical training and within the public domain.

(2006) that there are “stark gaps in knowledge on HPV at all levels- among policymakers, healthcare providers, parents, and teens – in both the industrialized and developing worlds” (2006:210).

5.3 Healthcare context: benefits

Workshop participants discussed two of the potential benefits offered by the introduction of the SmartHEALTH technology:

- The speeding up of test results from weeks to minutes can alleviate patient/participant 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.

5.3.1 Speeding up test results for earlier diagnosis

In D9.3 many of the technological 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 healthcare interviewees, in particular an oncologist who stressed that delays in diagnosing of cancer are multiple along the chain of care. This point was also raised by the workshop participants who worked in the healthcare system or had experience of being referred for further investigation after an abnormal smear test. The cytologist interviewed for D9.3 highlighted that 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.

A key theme raised in all eight workshops was the desire for quicker test results. The interviewees and the workshop participants highlighted the benefit of providing quicker test results when test results were negative and patient/participant anxiety was reduced.⁴ However, this majority benefit was outweighed by the disadvantage of receiving an immediate HPV positive result that would lead to further referral and therefore a similar sense of uncertainty on leaving the surgery. In five of the six UK workshops, many participants were disappointed - then indignant - that the new test was not more specific. For the Norwegian and UK participants there was confusion on the perceived benefits of the technology since the test was not more specific. In addition, a number of participants raised the issue that a different test was being introduced, which they currently had limited information on. Interestingly, one UK participant, a lecturer, highlighted the similarities between the sound of the acronym ‘HPV’ and ‘HIV’, which could be “scary if you misheard”. However, most participants expressed limited anxiety about being given an HPV positive result.

Appropriate counselling for immediate positive test results

Interviewees recognised that speeding up the test results increased the potential for participants to receive a positive diagnosis in the GP surgery. As a result, all the interviewees had highlighted the importance and need for appropriate counselling. The majority of interviewees believed that the counselling procedures within existing healthcare systems would be suitable for the implementation of the SmartHEALTH technology. Workshop participants also suggested counselling for positive results, though a few participants highlighted that in current practice “nobody is with you when you open the letter” and discussions returned to the lack of knowledge of current screening

⁴ With the exception of women who would receive HPV negative results and still develop cervical cancer

procedures. During workshop discussions, participants also raised questions on the need for immediate test results for a relatively slow growing cancer when compared with a heart attack or in Accident and Emergency departments of hospitals where the speed of test results is paramount.

Positive delays in receiving test results

In the Lincoln group, the dentist highlighted a point raised by health interviewees: professionals 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 proved 'positive'. The dentist and dental nurses explained that in their experience an anxious patient may appear to be listening but often does not hear what is being said to them. They stressed that an individual's ability to assimilate knowledge and make informed choices is not only based on the information provided but on "the state of mind at the time". This issue was also stressed by the practice nurse in the Edinburgh group No. 2, a breast cancer oncologist interviewed for D9.3 and the Head of Cytology in the hospital in Trondheim.

Potential economic benefits

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. Some workshop participants concluded that the HPV test may be beneficial if it was significantly cheaper than the current smear tests. In contrast, the cytologist interviewed for D9.3 had raised questions around the viable cost of HPV screening tests within the UK, since current tests can cost up to £80 a test. The cytologist 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. Independently, participants in four of the workshops suggested investing in research on how to improve the current visual inspection of smear tests rather than introducing HPV tests.

5.3.2 Improving accuracy of test results (sensitivity & specificity)

In D9.3, interviewees stressed that within the field of cervical cancer screening improving the sensitivity of tests was considered important due to the

- Current high percentage of false positives and subsequent recalls for repeat tests.
- The subjectivity of the visual inspection of cervical cells by pathologists.

Workshop participants also requested a reduction in unnecessary repeat screening. However, most of the workshop participants perceived the role of the cytologist in the interpretation of test results as a positive aspect. All the participants, except one individual in the Newcastle group, expressed a preference for a human being to hold the key role in the interpretation of test results. The presence of a cytologist in the interpretation of test results was held to be important as the participants believed that the cytologist brought an 'experienced eye' into the process. However there was no aversion to the implementation of new technologies that supported, but did not replace, the role of a cytologist.

5.3.3 Perceived Benefits: differences between project partners, cytology staff and workshop participants

In D9.3, all the interviewees focused on the benefits of improving sensitivity of current cervical cancer screening tests over increasing the speed of the results. In contrast, many participants did not view the increased sensitivity of the test to be beneficial unless the specificity was improved and the number of referrals was reduced. Overall, participants perceived few benefits for themselves with the introduction of the HPV test. There was general confusion about the rationale behind developing the technology for cervical cancer screening with an undercurrent of suspicion and cynicism in three of the UK workshops. In four of the UK workshops participants raised questions as to why the project had not focused on other more serious diseases, such as prostate cancer. The most cynical response arose in the Bedford group when one participant asked “did a bunch of men develop this new technology? ... did they have a piece of kit and wonder now what shall we do with it?”.

However, the cytology staff and participants supported the use of the SmartHEALTH technology as an adjunct test in the pathology laboratory alongside LBC. As outlined on page 16, the Head of Cytology in the Trondheim hospital was positive about the future of the technology as an adjunct test in cervical cancer screening; in particular as the technology offered a closed/robust testing environment that minimised contamination. The cytologist believed that the future of cervical cancer screening was in the use of both cytology and molecular biology in the pathology laboratory.

6 Discussion

The eight participatory workshops engaged a small number of participants and therefore do not claim to represent all women eligible for the current UK or Norwegian cervical cancer screening programmes. However, these workshops have produced important in-depth data which echo the potential ethical and social issues surrounding the implementation of SmartHEALTH raised by interviewees in D9.3. Seven of the eight groups also raised a new and challenging issue for the SmartHEALTH project by questioning the rationale behind the focus on HPV testing to improve current screening practices. The workshop findings are discussed further within the two broad research themes presented on page 5.

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

6.1 *What are the benefits of SmartHEALTH for participants?*

Overall participants highlighted only a few perceived benefits of SmartHEALTH, such as 1) the technology would be useful “if it picked up the other 25% of cervical cancer that is currently missed”⁵ and 2) test results could be given with a health professional present to answer questions. However, seven of the eight workshop groups were sceptical about the benefits of replacing LBC with HPV tests. Within their understanding of current

⁵ NHS websites state that “early detection and treatment can prevent 75 per cent of cancers developing but like other screening tests, it is not perfect.” (NHS, 2007).

screening practices, participants did not support the introduction of this new technology as a primary screening test.

Participants in the Norwegian and UK Workshops raised the following two questions:

- Why introduce a new test that does not aim to improve the experience of undergoing cervical screening or reduce referral for further investigation?
- Could an HPV test be performed after the LBC detected abnormal cells?

However, in regard the second question, one participant in the Lincoln group and one in the Bedford group wanted an immediate referral for a colposcopy since immediate treatment could be given if needed. WP10 found a similar attitude with respondent perceptions of colorectal cancer screening (see D10.3).

Participants in the UK workshops raised three additional questions:

- Why did the HPV test continue to be gynaecologically invasive, despite “leaps and bounds” in other areas of healthcare technology? (And had any money been invested in exploring this issue?).
- Why did there appear to be limited information on HPV testing in the public domain?
- What was the rationale for investing money into cervical cancer rather than, for example, prostate cancer?

The scepticism and confusion expressed by the workshop participants towards the cervical cancer screening application of SmartHEALTH is explored within the second question.

6.2 Will SmartHEALTH be a disruptive technology in existing healthcare systems?

In D9.3, 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, the SmartHEALTH technology would fit into the existing systems in terms of current medical skills available, counselling services and health informatics systems. However, two interviewees presented a contrasting perspective and predicted that SmartHEALTH would be a disruptive technology as it would:

1. Change the current nature of health care diagnosis.
2. Highlight current inadequacies within existing systems in terms of: current levels of cancer treatment, health care records and communication between different healthcare staff.

The above comments relate predominantly to the implementation of the breast and CRC applications of SmartHEALTH. However, the potentially disruptive nature of the cervical screening application was a dominant theme for workshop participants.

6.2.1 Disruptive technology: positive and negative perceptions

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. The two interviewees in D9.3 used the term *disruptive* in a positive sense as they 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. Inevitably the introduction of a new technology into existing healthcare systems creates disruption for some users while creating opportunities for change for others.

Discussions in five of the six UK workshops highlighted a desire by participants to change and ‘disrupt’ existing current practices of cancer screening practices, in particular:

- Replacing the current gynaecological test with another form of test, such as a blood test.
- Producing quicker test results that are more specific and sensitive.
- Improving the behaviour of the health care professionals performing the smear test.
- Designing a surgery layout that offers adequate privacy for participants.

The nature of the discussions in the Norwegian workshops was notably different from the UK workshops. Norwegian participants began discussing current screening practices as a routine and accepted medical procedure, though as each workshop progressed the preference for a non-gynaecological test became increasingly evident.

However, most UK and Norwegian workshop participants perceived the implementation of the SmartHEALTH application to offer few benefits over current practices. Any disruptions to current practices were perceived negatively. Once UK participants began to ask further questions on the exact nature of HPV test results and what the test result meant, they became disappointed. Replacement of the current test by HPV testing was not perceived as an improvement since while the test may be more sensitive than current tests it was not more specific. As a result, a positive result remained inconclusive and further referrals were required. Participants with a positive test result would still leave the surgery with little reassurance.

Workshop participant understanding of and attitudes towards a new HPV test

Workshop participants acknowledged that their knowledge of HPV was limited, in particular in the UK workshops. However, the range and quality of the discussions within the workshops suggest that participants’ attitudes towards HPV testing are more nuanced than current research suggests. For example, Wardle *et al.* (1995), Waller *et al.* (2003), Massi *et al.* (2004) and Kitchener *et al.* (2008) focus on levels of participant anxiety on receiving a HPV positive test. In contrast, the frustration, or anxiety, expressed by the UK participants when discussing HPV appeared to be created by the realisation that they had limited knowledge of HPV, and the screening process. This awareness of their lack of knowledge became heightened during discussion in the workshops on the recent introduction of the HPV vaccine. However, notably these responses were not created by the introduction of a new technology but rather by the lack of information on HPV that they perceived to be readily available.

In contrast, the public’s distrust in and subsequent rejection of new technologies is frequently assumed to be a fear of the technology itself. For example, the halting of the GMO crops by the British public is often based on this assumption (*c.f.* Marchant, 2001). This perception of the Public has been labelled as a myth by Marris *et al.* (2004), who

have criticised the common interpretation of the public reaction towards the GMO debate. They proposed that the backlash was based not on fear but on anger and frustration at the lack of information provided, the lack of trust in the source of the information and, as more widely discussed, the late invitation into the consultation process. If the developers of new technologies assume that the Public fear the introduction of a new technology, and this assumption proves to be unfounded, then irreconcilable misunderstandings can develop between the potential users of the technology and the technology developers.

In addition, although current research frequently states that HPV is a topic that creates anxiety for screening participants, the workshop data does not inevitably support this proposition. Instead workshop findings raise questions on the relationship between participant perceptions of the virus and how HPV is presented and subsequently discussed. For example, presenting HPV as a common virus rather than as an STD may create more open discussions on the different strains of HPV, of which only a few are linked to cervical cancer. Currently there is no evidence of any social research on the link between the representation of HPV employed in a study and how this representation moulds participants' perceptions of the virus and associated benefits and risks.

7 Implications for SmartHEALTH

SmartHEALTH Integrated healthcare project is a set of converging technologies, which are in essence providing information for both the healthcare professional and the patient and screening participant. One challenge for the implementation of SmartHEALTH is to identify the different information needs for the various end users of the technology, which includes healthcare professionals and patients/participants. A further challenge is for health professionals to obtain informed uptake from patients/participants. Although legal definitions of informed consent exist it remains a difficult concept to measure as this process is a complex interaction that is often intuitive in nature. One health professional has described the process as “you must feel assured that the patient is capable of participating in the discussion, both receptively and expressively, and that she can make a sound and reasoned decision.”(Nelson, 2007). The moral requirement to obtain informed uptake of cervical cancer screening raises questions about the most appropriate way for health professionals to present and discuss with participants the nature of the high risk strains of HPV in cervical cancer.

In D9.3 interviewees recognised that participants/patients must be made aware of the ability and limitations of the technology and to explain in accurate detail what the process involves. The nature of this information (the ability and limitations of the technologies) must include participant perceptions of the technology and address their expectations of how a new screening technology could change current practices for them. For screening participants, the key questions raised in the workshops and to be addressed in the future development of the SmartHEALTH project are:

1. What happens after a positive test result for screening participants? [Interviewees in D9.3 partially address this issue by highlighting the need to develop a range of guidelines on different decision pathways for the nurse/doctor handling positive test results. At this stage of development, these decisions pathways have not been explored.]
2. Why current practices will not change significantly (in particular why the test continues to be gynaecological)?

3. What are the benefits of HPV testing over LBC in terms of both sensitivity and specificity?
4. What will be the positive impact of replacing LBC with HPV within the current chain of care?

Finally, if the project is committed to developing the cervical cancer application then it is recommended that SmartHEALTH:

- Explore with screening participants and relevant health professionals new and innovative methods of presenting and discussing HPV; in order to address the current misunderstandings of the nature of the virus within the healthcare profession and the wider Public domain.

7.1 Future steps for SmartHEALTH

WP9 has begun fieldwork for the next deliverable: D9.7 Report on case study findings of main ELSI arising from SmartHEALTH (breast and colorectal cancer monitoring). There are two small study sites:

- UK study: 4-5 interviews with GPs and 4-5 interviews with secondary care health professionals currently involved in breast and colorectal cancer monitoring.
- Norwegian study: 4 interviews with health professionals involved in breast and colorectal cancer monitoring.

The Norwegian study has been completed. In the UK study, WP9 received the final paperwork from the NHS on 23 December 2009 and have begun the main interviews in primary and secondary care. The interviews are expected to be completed towards the end of January 2009.

In May 2009, an interdisciplinary symposium will be held on the Ethics, Legal and Social Issues (ELSIs) of micro-systems for PoC testing. This event aims to bring together individuals from within the SmartHEALTH project, as well as invited international experts from relevant disciplines including healthcare ethics and social science with a view to exploring the social and ethical aspects of the developing SmartHEALTH converging technologies. The symposium will focus on 2 research topics 1) breast cancer monitoring and 2) colorectal cancer screening. The topics relate to the research of WP9 (PEALS), and WP10 and WP9 (SUT formerly ACETS) respectively. The symposium proceedings will be made available on relevant websites. This symposium is being organised jointly between WP9 and WP10 (gender issues).

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