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1. Introduction

In September 2007, deliverable D9.5 outlined the proposed research topics and the public engagement program in relation to the Ethical, Legal and Social Implications (ELSI) of the SmartHEALTH technology within an Australian context. Since that date there have been several changes to the research program.

Firstly, the Australian ELSI research, conducted on behalf of MiniFAB (Australia) Pty Ltd, was originally located in the Australian Centre for Emerging Technologies and Society (ACETS) at Swinburne University of Technology (SUT). In 2008 ACETS was incorporated into a Technology, Economy and Society Program in the Institute for Social Research (ISR), a Tier One Research Centre at SUT. This move has created greater synergies and capacities for Technology and Society related research at SUT.

Secondly, in consultation with the Policy Ethics & Life Sciences Institute (PEALS) at University of Newcastle upon Tyne, the public engagement program has been extended beyond a series of Café Scientifique events with the general public. SUT has chosen to conduct exploratory research regarding the application of SmartHEALTH as a means of screening for cervical cancer in General Practitioner (GP) clinics. The Australian research has followed a similar research design to that of PEALS participatory workshops on cervical cancer, with the aim of generating data in Australia which is comparable with that generated in the UK. A detailed explanation of the research conducted so far is included in Section 2 of this report.

Finally, one of the PhD students undertaking Research Topic 1 in D9.5 (p.6) regarding regulation of *in-vitro* diagnostic devices in Australia has withdrawn from the project, so this line of research will not continue. The other PhD student undertaking Research Topic 2 mentioned in D9.5 (p.6), regarding factors influencing participation in cancer screening, is ongoing, and an update from the PhD candidate conducting the research is included in Section 2 of this report.

2. SmartHEALTH research in Australia

2.1. Public engagement research programme: Cervical cancer screening in Australia

2.1.1. Background

The National Cervical Screening Programme (NCSP) commenced in 1991 as part of a joint initiative between state and federal governments of Australia (initially named the Organised Approach to Preventing Cancer of the Cervix). The primary goal of the programme is 'to reduce the incidence, morbidity and mortality of cervical cancer through organised cervical screening of women using the Papanicolaou (Pap) test (AIHW 2008: ix). The NCSP aims to: increase the percentage of eligible women being screened; establish reliable services for delivering, interpreting and reporting Pap tests; improve management of detected abnormalities; and monitor the efficacy of the program in achieving these preventative measures. (Aust Gov Dept Health & Ageing 2008a)

A national cervical cytology register has enhanced the NCSP by providing clinical information to medical practitioners as well as reminder letters to women for Pap test follow-ups (Aust Gov Dept Health & Ageing 2008c). In 2002, following similar initiatives in the UK, the Australian Government introduced the Practice Incentive Payment to further encourage General Practitioners (GPs) to improve screening uptake for women who had not been screened in the past four years or more (Morrell et al. 2005: 79; Irwig et al. 2006:1149).

A 2002/3 study to evaluate the effect of reminder letters on screening participation rates found that reminder letters were associated with higher screening participation in a population of under-screened women (Morrell et al. 2005).

Moving from Pap tests to Liquid Based Cytology (LBC)

In Australia the current method of screening remains the traditional Pap test, mostly unchanged since its invention in 1928 (PapScreen Victoria 2008b). In the UK, new guidelines accompanied the introduction of new technology (Liquid Based Cytology testing) and screening intervals were amended to every three years for women aged 25 – 49 and every five years for women aged 50 – 64 (Mullins et al. 2008). Finland and the Netherlands, both countries with very low rates of cervical cancer incidence and mortality, currently recommend screening every 5 years for women aged between 30 – 60 (WHO 2007a; WHO 2007b).

As yet, Australia has not amended screening intervals but this issue is now being raised along with discussions regarding LBC and HPV testing and requests for the long overdue review of Australian practices and procedures. There is now sufficient evidence supporting LBC testing as being superior to conventional methods due to the reduced number of unsatisfactory samples and increased detection of true abnormalities. New improvements in the sensitivity of HPV DNA testing can now broaden its use beyond just a follow-up for high grade abnormalities and make it a more useful triage tool. LBC and HPV testing are more expensive than conventional testing but improved efficiencies in the laboratory, and reducing the number of tests conducted by lengthening the screening interval, may make it a cost effective means of maintaining a low incidence and mortality rate of cervical cancer in Australia (Farnsworth 2008).

2.1.2. Uptake and understanding of cervical cancer screening

Current literature on screening behaviour indicates a lack of knowledge among women about cervical cancer screening. Recent advances in screening technology and the advent of HPV vaccination programs have served to emphasise the gaps and misunderstandings in women's knowledge. Whilst most of the literature indicates that women share a variety of reasons for lack of screening participation, ranging from cultural and language barriers to fear and embarrassment as well as physical discomfort (Fylan 1998), there is also an indication that perceptions differ between younger and older women, particularly those with children.

One Australian study (Siahpush and Singh 2002) used a subset of the Australian 1995 National Health Survey to examine the socio-demographic predictors surrounding Pap test uptake and knowledge. Siahpush and Singh (2002) found several socio-demographic indicators of influence including cultural background and education as well as age and marital status. In particular, women under 30 or over 49, unmarried women and women from Middle East or Asian (non-English speaking) backgrounds were less likely to be well informed on Pap smears or to accept screening opportunities. This finding is consistent with the 2005-6 AIHW report noting the decline in participation of women of between 25 – 29 years of age.

In one study of women aged 18 to 30, Giles and Garland (2006) found good knowledge amongst Australian women regarding the meaning of the term 'Pap smear' as well as a good understanding of abnormal results. However the study suffers from selection bias as participants were recruited from three groups of women likely to have an increased knowledge of cervical cancer testing and HPV: i.e. women attending a dysplasia clinic, participants of a phase 3 HPV vaccine trial, and women attending a university health service. Selection bias notwithstanding, the study still found a need for further education in relation to HPV and that the likely primary source of further information for these women would be their local GP (Giles and Garland 2006). To date there is a lack of Australian research regarding

cervical cancer screening and the possible impact of HPV screening technology and vaccinations on participation in the National Cervical Screening Programme.

2.1.3. Method

SmartHEALTH Focus Groups in Australia

There are two reasons for adopting participative focus groups in the Australian study. Firstly, the format followed the method adopted in the UK by PEALS, facilitating cross-country comparison. Secondly, the approach has been widely adopted within health research on account of its distinctive insights into lived experience.

Whilst Participatory Research is normally more long-term in nature than the Australian SmartHEALTH public engagement programme, participative focus groups have been noted as ‘an appropriate method for exploring sensitive and embarrassing subjects’ and were successfully used in research regarding the uptake of cervical cancer screening in the UK *Woman to Woman* project, 1995 – 1997 (Fong Chiu 2003). In this project, focus groups were designed from the ‘bottom up’ and around participants’ needs, rather than researcher requirements.

Participants

Initially it was envisaged that focus groups would consist of women ranging in age from 18 to 70 with experience of current cervical testing. However, the literature review indicates that age, marital status and experience of childbirth could all be significant variables in participation rates. On this account, the focus groups conducted to date have recruited women 35 years of age or older, with children, via a snowball method using the researcher’s existing social and business networks. It is anticipated that further research will be conducted with young women or adolescents, without children, under the age of 25 years.

The three focus groups conducted have each consisted of 5 women, most, but not all, of whom knew each other socially. Data from the evaluative questionnaires completed by all but one participant indicated that this method was successful in providing an atmosphere in which participants have felt comfortable expressing their opinions. (On the anonymous questionnaire participants were asked: ‘were you able to express your opinions freely and openly’. As well as space for a written answer, participants were given the option of ‘yes, completely’, ‘most of the time’, ‘not as much as I would have liked’, ‘no not at all’ and ‘don’t know’. All participants who completed the questionnaire chose ‘yes completely’).

Participant profiles from focus groups:

Focus Group	Number	Age	Professions	Education	Referred Colposcopy
1	5	35 - 54	Settlement officer; Personal Assistant; Sales Manager; Book-keeper; Home Duties	4 x secondary 1 x unknown	0
2	5	35 - 54	Administrative Consultant; Academic; Computer Trainer; Home Duties/Student; occupation unknown	2 x tertiary 2 x Masters/PhD 1 x unknown	1
3	5	35 - 54	Provisional Psychologist; Personal Assistant; Accounts Receivable Manager; Shop Assistant; Home Duties	3 x secondary 1 x tertiary 1 x Masters/PhD	1

2.1.4. Data Analysis and Status of Findings

The public engagement research programme is ongoing. Three SmartHEALTH focus groups have been conducted to date and so far support the literature as a suitable and egalitarian method of data collection. Data obtained includes notes recorded by participants during focus groups, researcher field notes and focus group conversation transcripts. Data analysis includes thematic analysis and coding, using an open coding and open grid method.

A detailed explanation of the thematic analysis and research findings will be reported as part of a dissemination report for inclusion in the SmartHEALTH Spring ELSI Symposium to be held in May 2009.

2.2. Factors Influencing participation in cancer screening: Testing the path structure of a cognitive, emotive and social model of colorectal cancer screening decisions

(PhD candidate: Victoria Hamilton; Supervisors: Prof Susan Moore, Dr Denny Meyer)

Colorectal cancer (CRC) is the second leading cause of cancer-related death (after lung cancer) in Australia, and is the most frequently diagnosed non-cutaneous cancer (AIHW & AACR, 2004). National bowel screening initiatives are being piloted or implemented in Australia, the United Kingdom, the United States, and in many European nations. However, screening uptake remains consistently and internationally low at around 45-50% (DHA, 2005). Compared to screening programmes for other serious disease such as mammography or cervical screening, this rate is beneath optimal uptake for a programme to be both economically viable and to ease the health system burden (less than 40% of bowel cancers are detected at an early stage) (DHA, 2007, retrieved 29 January 2008). National screening programmes attract considerable research interest, particularly in relation to understanding the malleable, psychosocial factors involved in screening decision-making.

Health behaviour models (e.g. the health belief model, theory of planned behaviour and theory of reasoned action, precaution adoption process model, protection motivation theory) attempt to explain screening behaviour within a rational decision-making framework. However, a large proportion of variance remains unexplained by any single theoretical model.

Furthermore, when the desired preventive health behaviour is considered relatively simple and infrequent (for example, a non-invasive screening test to establish one's health status in relation to a particular disease), decisions to decline a screening opportunity appear to be driven by processes not yet identified in major health models. The aims of the project outlined here are to examine the social influences and cognitive-emotive cues that individuals may incorporate into uncertain and consequential medical decision-making for bowel cancer screening. The model will be guided by a dual-processing framework (experiential and deliberative processing modes) and will investigate specific screening-related heuristics based on the work of Kahneman and Tversky on representativeness, availability, and anchoring and adjustment (1973).

Emotion has received little attention in major health behaviour models, though it is increasingly being realised as an indispensable component of the decision-making process in neuropsychological and decision-making fields of research. The discrete emotions most commonly examined in the literature include anxiety and fear. However, findings are incongruous and have suggested negative, positive, and curvilinear relationship patterns (Hay, Buckley, & Ostroff, 2005). These conflicting findings merit further investigation and refinement of the role that fear and anxiety play in screening decisions. Fear will therefore be examined in relation to different aspects of the screening experience, including procedural aspects, cancer and mortality-related fear, and a fear of embarrassment. Emotions such as disgust and embarrassment, which may be particularly salient in the context of bowel health, have been identified frequently as barriers in qualitative research, but have received less consideration in quantitative research. While individual disgust sensitivity and trait embarrassability scales have been developed, measures of situational disgust in a medical context could not be found (while a medical embarrassment scale has only recently been published, see Consedine, Krivoshekova, & Harris, 2007). The role of emotion in screening decision-making remains a fertile area for exploration, particularly with low rates of screening uptake and the recent decision to gradually phase in a national bowel cancer screening programme in Australia.

Social support and normative beliefs about screening are also expected to shape screening decision processes, and have been examined in cognitive-social models (for example, see Honda & Kagawa-Singer, 2006), and in psychosocial studies of screening decision processes (Magai, Consedine, Neugut, & Hershman, 2007). Trust in one's GP and in the medical system will also be examined for its potential moderating role.

Key components from these three areas of research have not yet been tied in to a cohesive model of screening decision processes. The proposed research will begin to examine the interface between these three major areas in the formation of intentions to screen for colorectal cancer.

2.2.1. Progress

A preliminary study has been completed to establish relationships amongst key variables and to explore the psychometric properties of a range of cognitive, emotive and social measurement scales. This study was conducted in order to inform the design of a large-scale community study to be carried out in 2009 in an Australian sample. The primary research question asks whether discrete emotions and heuristics can significantly contribute to the variance in bowel cancer screening decisions, and if these relationships are moderated by social factors.

237 participants from a convenient population sample took part in the preliminary study and the researcher is currently in the data preparation and analysis stage which includes correlation, regression and confirmatory factor analytic statistical techniques. These results

are expected to direct the design of a shorter community-based survey, the results of which will be analysed by structural equation modelling at the end of 2009.

3. Conclusion

Research conducted by the PhD candidate on a cognitive, emotive and social model of colorectal cancer screening decisions has been planned and is now ongoing. Further progress will be reported in 2009. This research is expected to continue beyond 2009 and a final technical report will be provided by the PhD candidate.

The public engagement research program in relation to cervical cancer screening and the implementation of SmartHEALTH in GP clinics is also ongoing and further exploratory research is planned. This research is expected to be completed in the first half of 2009, with a final technical report provided at the end of 2009.

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Website Resources:

National Cervical Screening Program: www.cancerscreening.gov.au/

Papscreen Victoria: www.papscreen.org.au

National HPV Vaccination Program: www.australia.gov.au/cervicalcancer

Gribbles Pathology www.vic.gribbles.com.au/info/general/Home/get/0/0/

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