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Title	The eSMART Project: real time symptom management in the oncology setting
Author(s)	Fox, Patricia A.; Furlong, Eileen; Buick, Alison; Darley, Andrew; et al.
Publication date	2016
Publication information	Cancer Professional, Summer, 2016 : 22-24
Publisher	MedMedia Group
Link to online version	http://www.medmedia.ie/publications
Item record/more information	http://hdl.handle.net/10197/8469

Downloaded 2018-04-30T00:55:32Z

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The eSMART project: real-time symptom management in the Irish oncology setting

Patricia Fox, Eileen Furlong, Alison Buick, Andrew Darley, Jessica Walsh, Roma Maguire, Lisa McCann, Christine Miaskowski, Emma Ream, Jo Armes, Elisabeth Patiraki, Kathi Apostolidis, Nora Kearney

"It was quite reassuring; you did feel that you were being monitored. You didn't think if you put in those symptoms that you would slip through the...you know, that if you had really worrying symptoms you would have slipped through the system. Somebody would have picked it up" (Patient 11, McCann et al, 2009)

THESE ARE THE PERCEPTIONS of a patient who participated in a multicentre, randomised controlled trial (RCT) evaluating the impact of a mobile phone-based 'advanced symptom management system' (ASyMS) intervention on chemotherapy-related toxicities in UK-based patients with lung, breast or colorectal cancer. Overall, the study found that the use of the mobile phone-based intervention to monitor their chemotherapy-related symptoms was a positive experience for patients.¹

The use of ASyMS resulted in better communication with health professionals, improvements in the management of their symptoms and a reassurance that their symptoms were being monitored even when they were at home. The reported improvements in symptom management were supported by the finding that patients who were randomised to the intervention arm of the RCT had significantly lower levels of fatigue in comparison to those patients in the control arm who received standard care.²

Why is the ASyMS study relevant to the Irish oncology setting?

In 2013, European Union funding was awarded for the eSMART (Electronic Symptom Management Using the ASyMS Remote Technology) study, to evaluate the use of mobile phone technology for management of chemotherapy symptoms in a two-part, pragmatic, RCT across fourteen European clinical sites, including four in the Republic of Ireland (ROI). Over 1,100 patients are being recruited for the study across all of the sites, 162 of whom will be based in Ireland.

The primary aim of eSMART is to evaluate the short- and long-term impact of the ASyMS technology on patient reported outcome measures in patients receiving adjuvant or neoadjuvant chemotherapy for breast, colorectal and haematological cancers. In addition, eSMART will evaluate the cost-effectiveness of the technology, as well as changes in clinical practice that may follow its implementation across the different European healthcare settings (UK, ROI, Austria, Greece and Norway) over the five-year lifetime of the study.

The ASyMS intervention

The ASyMS intervention utilises mobile phone technology to enable real-time monitoring of patients' chemotherapy-related symptoms. This consists of a mobile phone device (patient handset) which contains an electronic version of the Chemotherapy Toxicity Self-Assessment Questionnaire (CTAQ).³

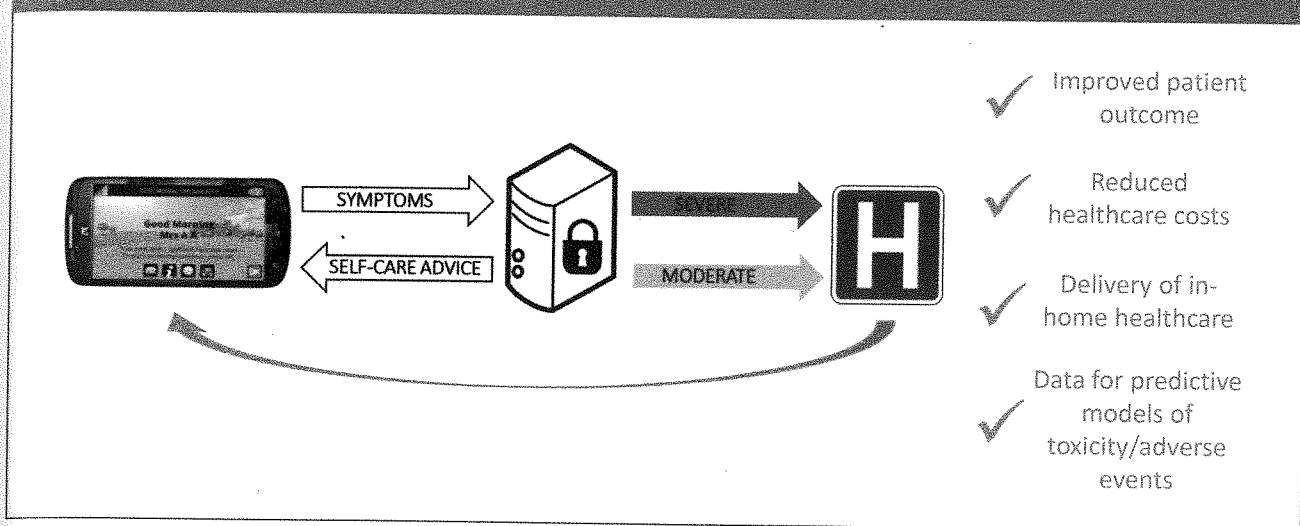
The CTAQ assesses 10 chemotherapy-related symptoms (nausea,

TABLE 1: Primary and secondary objectives for the eSMART project

Primary objective	To determine whether, compared to standard care, the ASyMS intervention can lead to reduced symptom burden during active chemotherapy for patients with breast cancer, CRC, HL or NHL as evidenced by a statistically significantly lower total Memorial Symptom Assessment Scale (MSAS) ^a score over all chemotherapy
Secondary objectives	<p>To determine whether, compared to standard care, the ASyMS intervention can lead to:</p> <ul style="list-style-type: none"> • A reduction in symptom burden at one-year post-chemotherapy follow-up^a • A reduction in symptom burden at mid-chemotherapy cycle (ie. peak symptom burden)^a • A significant increase in patient overall health-related quality of life compared to standard care, during active chemotherapy and at one-year post-chemotherapy follow-up^b • A reduction in overall supportive care needs during active chemotherapy and at one-year post-chemotherapy follow-up, when compared with standard care^c • Reduced levels of anxiety during active chemotherapy and at one-year post-chemotherapy follow-up, compared to standard care^d • Greater improvement in patient self-efficacy during active chemotherapy and at one-year post-chemotherapy follow-up^e • Less work limitations, both during active chemotherapy and at one-year post-chemotherapy follow-up^f <p>To carry out a costing evaluation of eSMART intervention (both total sample and country- specific)</p> <p>To evaluate changes in clinical practice as a result of the eSMART study (both site and country- specific)</p> <p>To carry out the development of predictive risk models (PRMs) for the prediction of outcomes in patients with breast cancer, CRC, HL or NHL</p>

Superscript lettering indicates measurement tool: a = Memorial Symptom Assessment Scale (MSAS);¹ b = Functional Assessment of Cancer Therapy-General (FACT-G);² c = Supportive Care Needs Survey-Short Form 34 (SCNS-SF34);³ d = State-Trait Anxiety Inventory-Revised (STAI-Y);⁴ e = Communication and Attitudinal Self-Efficacy scale for cancer (CASE-Cancer);⁵ f = Work Limitations Questionnaire (WLQ)⁶

Figure 1: The eSMART intervention



vomiting, diarrhoea, constipation, mucositis and/or oesophagitis, palmar planter erythrodysesthesia, flu-like symptoms/infection, fatigue and pain. There is also the option for the patient to report up to six additional symptoms.

A three-point scale (mild, moderate, severe) is used to evaluate symptom severity. The severity indicators have associated descriptors based on the Common Terminology Criteria for Adverse Events (CTCAE V4.0).¹⁰ Mild symptoms are defined using CTC 1 criteria, moderate symptoms CTC 2, and severe symptoms CTC 3. On completion of the questionnaire, patient 'real-time' symptom information is sent automatically via a secured connection to a secure server managed by Docobo Ltd (the software provider). In response, the software generates symptom-specific self-care advice on the patient handset.

The system is designed to empower patients undergoing chemotherapy to manage their symptoms at home through the delivery of evidence-based self-care advice via the mobile phone handset, but also to permit timely identification and rapid treatment of any potential life-threatening side-effects. If the incoming symptom reports are of clinical concern (eg. indicative of a developing infection) and require an intervention, then an immediate red alert is sent to a dedicated ASyMS clinician handset (ie. the handheld device which will be carried by a designated nurse or 'alert handler' in the hospital 24 hours a day).

A red alert (to be addressed within 30 minutes) is generated for symptoms that are severe or life-threatening (eg. fever). An amber alert (to be addressed within four hours) is of moderate concern and will be generated in response to symptoms that have the potential to become more serious (CTC 2) and which would be responsive to early interventions. All clinicians have access to their patients' information through the secure eSMART web-based system, therefore on receipt of an alert the clinician can view the patient's 'real-time' symptom reports before contacting the patient to initiate the appropriate symptom management.

The alert handler will provide appropriate, standardised care as per normal hospital policy, document the actions/interventions performed, and sign off the alert on the eSMART website.

Connected health in Ireland

We believe that the eSMART study is very timely given the relatively recent investment in the area of connected health in Ireland; the eHealth Strategy for Ireland¹¹ was published in 2013,

the first chief information officer for the Health Services Executive was appointed at the end of 2014 to lead the new eHealth Ireland group, and the website (*eHealthIreland.ie*) was launched in 2015. Ireland's progression and investment into eHealth is further evidence of the commitment to delivering innovative, high-quality healthcare.

The benefits of an intervention such as ASyMS are evident for patients and their healthcare providers. Self-empowerment is enhanced through the use of personalised in-home healthcare while regular communication between patients and their healthcare providers is more easily facilitated. ASyMS enables real-time, remote monitoring of patients' symptoms, thereby facilitating early intervention where appropriate.

The eSMART study will result in a vast dataset through tracking large numbers of patients with breast, colorectal and haematological cancers throughout their chemotherapy regimens. This information will be particularly beneficial for the development of predictive risk models that have the ability to equip patients and their healthcare providers with personalised predictions of the risks of developing chemotherapy-related symptoms, an advancement which should significantly aid decision-making in the context of symptom management.¹²

The key to the success of eHealth is the multidisciplinary aspect,¹³ taking into account the involvement of patients and clinicians, the IT industry and researchers. Bringing modern technology in line with current clinical practice involves the collaboration of doctors, nurses and other members of the clinical care team.¹⁴

Recognising this, the eSMART project utilised clinician and patient advisory groups to ensure the smooth integration of the eSMART protocol into the clinical setting. Oncology clinicians' at all four Irish sites (St James's Hospital, St Vincent's University Hospital, St Vincent's Private Hospital and University Hospital Waterford) have been actively involved in the development of the eSMART project (ie. giving feedback on clinical issues and attending training sessions) and are centrally involved in the day-to-day co-ordination of the project at their respective clinical sites.

This level of engagement from Irish clinicians made it possible to integrate the eSMART project into the existing clinical structures; all four Irish clinical sites have completed the feasibility

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phase of the study and it is estimated that the RCT will commence in April 2016.

While acknowledging the challenges we have already encountered and those we are likely to encounter over the coming years, this research collaboration with our Irish clinical colleagues, patients and international research colleagues has been very rewarding and we believe it will make a significant contribution to cancer care in Europe.

Patricia Fox is an eSMART co-investigator and lecturer/programme co-ordinator, Graduate Diploma in Cancer Nursing, University College Dublin (UCD); **Eileen Furlong** is an eSMART co-investigator and lecturer/programme co-ordinator, Advanced Nursing Practice and Health Assessment programmes, UCD; **Alison Buick** is an eSMART postdoctoral research fellow, UCD; **Andrew Darley** is an eSMART research assistant, UCD; **Jessica Walsh** is an eSMART research nurse, UCD; **Roma Maguire** is an eSMART deputy chief investigator and professor of eHealth, University of Surrey (US), UK; **Lisa McCann** is an eSMART co-investigator and senior lecturer in cancer care and lead for eHealth, US, UK; **Christine Miaskowski** is an eSMART co-investigator and senior lecturer in nursing, University of California (UC), USA; **Prof Emma Ream** is an eSMART co-investigator and director of Health Sciences Research, US, UK; **Jo Armes** is an eSMART co-investigator and senior lecturer in nursing, King's College London, UK; **Elisabeth Patiraki** is an eSMART co-investigator and associate professor in nursing, National and Kapodistrian University of Athens, Greece; **Kathi Apostolidis** is an eSMART co-investigator and vice president of ECPC, European Cancer Patient Coalition, Belgium, and **Prof Nora Kearney** is an eSMART chief investigator, professor in nursing, US, UK

Funding: The eSMART project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement No. 602289

Chief investigators: Prof Nora Kearney and Prof Roma Maguire, University of Surrey

Corresponding author: Dr Patricia Fox. Email: patricia.fox@ucd.ie

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