Institution: University of Leeds

Unit of Assessment: UOA3 (Allied Health Professions, Dentistry, Nursing & Pharmacy)

Title of case study: Case study 5. New systems for patient self-reporting improve care and quality of life for cancer patients

1. Summary of the impact

Researchers at the University of Leeds have designed and developed new approaches and technologies for cancer patients to self-assess their symptoms and quality of life. The work focused on electronic methods for collecting patient-reported outcome measures (PROMs), developing PROMs for neglected areas of patient care, and running trials of these techniques. These approaches produced sizeable patient benefits including improved symptom control and better quality-of-life. These findings have influenced clinical guidelines in the UK and Canada, NHS policy and the endorsement of PROMs in the Health and Social Care Act (2012). Electronic PROMs systems based on the Leeds research have been implemented locally, nationally and internationally, making measurable improvements to patient welfare and health, such as a reported significant increase in completion of chemotherapy treatment.

2. Underpinning research

The diagnosis of cancer leaves patients having to shoulder a huge burden and they face an uncertain future. Before the mid-1990s cancer clinicians typically focused their attention on survival, rather than their patients' quality of life. In 1996, researchers from the University of Leeds set out to see whether cancer patient care could be improved by using routine patient-centred assessment of their clinical symptoms, as well as psychosocial issues and their quality of life. The team wanted to know if patient self-reporting could make the detection, recording and management of the disease and treatment-related problems more effective. Could the introduction of self-reporting into cancer services enhance patient quality of life and satisfaction with care, as well as inform and support more effective service evaluation? With funding from the NHS [grant a], a program of research was launched to develop and evaluate systems and questionnaires to collect PROMs and assess their implementation in practice. The team developed an electronic system for patient self-reports, overcoming logistical challenges of large volume real-time data collection in clinical practice. The research focused on (i) technical development, (ii) clinical implementation and (iii) the assessment of the social impact of cancer, detailed below.

Technical development

In 1996, **Peter Selby** (Professor of Cancer Medicine, 1989–present), **David Forman** (Professor of Cancer Epidemiology, 1994-2010) and colleagues from Leeds developed a stand-alone computer touchscreen system to deliver standard questionnaires to assess quality of life in cancer patients [grant a]. Evaluations of the touchscreen system, which were run in Leeds and in collaboration with Ann Cull (University of Edinburgh) and Ann Gould (Scottish Cancer Intelligence Unit) in an Edinburgh hospital, demonstrated its feasibility, acceptability and reliability in the clinical setting; the researchers also demonstrated the validity of the system and the score equivalence of paper versus electronic questionnaires [1-2]. Over five years the system was enhanced with funding from the Imperial Cancer Research Fund and Cancer Research UK. A version was integrated into the electronic patient records system of the Leeds Cancer Centre. An online standalone version was developed between 2010 and 2013 [grants b, c, d, e].

More recent developments and evaluation research have shown how a secure web-based questionnaire system allows clinicians to monitor patients. Studies have also shown how self-reported data can be linked to national cancer registration systems, helping clinicians to perform epidemiological outcome assessments [grant d] [3].

Clinical implementation

Between 1999 and 2008 **Galina Velikova** (initially Clinical Research Fellow, now Professor of Psychosocial and Medical Oncology, 1996–present), **Julia Brown** (initially Director of Clinical Trials Research Unit, now Professor of Cancer Trials Research, 2006–present) and **Peter Selby** evaluated the impact of regular patient reporting on symptoms and quality of life. A proof-of-principle randomised controlled trial showed for the first time that providing regular patient self-reported data to oncologists improved patient quality of life, focused doctor-patient communication, achieved better symptom control and reduced distress, without lengthening clinic visits [4].

Assessment of the social impact of cancer

Cancer patients experience problems with everyday issues (domestic life, family care, finance, employment, relationships, etc.). Prior to the work of Leeds in this area there were no concise questionnaires for assessing the effects of having cancer on daily life. With funding from Cancer Research UK, **Penny Wright** (then Research Assistant, now Associate Professor, 1996–present) and **Selby** began developing the Social Difficulties Inventory (SDI-21) in 2000. Evaluations of this self-reporting instrument showed it was reliable and valid, and importantly had clinically meaningful interpretation of responses/scores [5,6]. Between 2007-2009, **Wright** and **Dan Stark** (Senior Lecturer in Cancer Medicine, Leeds, 2003-present) translated and evaluated SDI-21 with patients of South-Asian origin from Leeds and Bradford Teaching Hospitals NHS Foundation Trust (under the care of Chris Bradley), showing that it was culturally and linguistically acceptable [grant h].

3. References to the research

1. **Velikova G, Wright EP**, Smith AB, Cull A, Gould A, Forman D, Perren T, Stead M, **Brown J**, **Selby PJ** (1999). Automated collection of quality-of-life data: a comparison of paper and computer touch-screen questionnaires. *Journal of Clinical Oncology*, **17**(3):998-1007 http://jco.ascopubs.org/content/17/3/998.short [SCOPUS citation: 196 (24/06/13)]
2. **Wright EP, Selby PJ**, Crawford M, Gillibrand A, Johnston C, Perren TJ, Rush R, Smith A, **Velikova G**, Watson K, Gould A, Cull A (2003). Feasibility and Compliance of Automated Measurement of Quality of Life in Oncology Practice. Journal of Clinical Oncology, **21**(2):374-382. DOI: 10.1200/JCO.2003.11.044
3. Ashley L, Jones H, Thomas J, Forman D, Newsham A, Morris E, Johnson O, **Velikova G, Wright P** (2011). Integrating cancer survivors' experiences into UK cancer registries: design and development of the ePOCS system (electronic Patient-reported Outcomes from Cancer Survivors). British Journal of Cancer, **105** Suppl 1:S74-81. DOI: 10.1038/bjc.2011.424

***This study has won awards at three conferences** (UKACR & NCIN Conference 2010; Biennial Cancer Survivorship Research Conference 2012; British Psychosocial Oncology Society 2013). It is included in a systematic review (Thong, M. S. Y., F. Mols, et al. (2013). "Population-based cancer registries for quality-of-life research: A work-in-progress resource for survivorship studies?" Cancer **119 Suppl 11**: 2109-2123).*

4. **Velikova G**, Booth L, Smith AB, Brown PM, Lynch P, **Brown JM**, **Selby PJ** (2004). Measuring quality of life in routine oncology practice improves communication and patient well-being: a randomized controlled trial. *Journal of Clinical Oncology,* **22**(4):714-24. DOI:10.1200/JCO.2004.06.078 [SCOPUS citation: 339 (24/06/13)].

***This study won the International Society for Quality of Life Research (ISOQOL) paper of the year award** (2004). It is included in a systematic review (Valderas, J. M., A. Kotzeva, et al. (2008). "The impact of measuring patient-reported outcomes in clinical practice: a systematic review of the literature." Quality of Life Research **17**(2):179-193).*

5. **Wright EP**, Kiely M, Johnston C, Smith AB, Cull AB, **Selby PJ** (2005). Development and evaluation of an instrument to assess social difficulties in routine oncology practice. *Quality of Life Research,* **14**(2):373-86. DOI: 10.1007/s11136-004-5332-4 [SCOPUS citation:23 (23/-6/13)]
6. **Wright P**, Smith A, Roberts K, Selby P, **Velikova G**. Screening for social difficulties in cancer patients: clinical utility of the Social Difficulties Inventory. *British Journal of Cancer*. 2007; **97**: 1063-70. DOI: 10.1038/sj.bjc.6604006 [SCOPUS citation: 11 (24/-6/13)].

***The SDI-21 is included in a systematic review** (Muzzatti, B. and M. A. Annunziata (2012). "Assessing the social impact of cancer: a review of available tools." Supportive Care in Cancer **20**(10): 2249-2257).*

Note: All Leeds researchers in **bold**. Publications available on request from the HEI.

The inclusion of the research in peer-reviewed, high-impact publications (*J Clin Oncol*), and the publication of a range of clinical [4,6] and methodological [1,2,3,4] papers, are indicative of the quality and originality of the work.

Research grants

a. **Selby P.** NHS Executive.1996-1999. £324,150.
b. **Selby P.** Imperial Cancer Research Fund Programme. 1999-2002. ≈£375,000.
c. **Selby P.** Cancer Research UK. (Two awards) 2001-2008. ~£1M.
d. **Wright P.** Macmillan Cancer Support. Title- Survivors of adult cancer: a feasibility cohort study 2010-2012. £409,131.
e. **Velikova G**. NIHR (National Institute for Health Research) Programme Development grant. Title-Towards safer delivery and monitoring of cancer treatments. **E**lectronic patient self-**R**eporting of **A**dverse-events: **P**atient **I**nformation and a**D**vice (eRAPID) (Grant ref: RP-PG-

1209-10031). Dec 2010- Dec 2012. £99,986.

f. **Velikova G.** Cancer Research UK Clinician Scientist grant. Implementation of quality of life assessment in the care of individual cancer patients through strategies for changing clinical practice (Ref C7775/A2941). 2003-2008. £591,928.
g. **Velikova G**. Cancer Research UK programme grant. Title-Routine assessment of symptoms, functioning, social difficulties and quality of life of cancer patients to improve the process and outcomes of care (Ref C7775/A7424). 2007-2013. £1,682,500.
h. Bradley C and **Wright P.** NIHR RfPB. Title- The social impact of cancer on people of south Asian origin: patient interview study (Ref PB-PG-0706-10284).2007-2009; £80,472.

4. Details of the impact

Contributing to clinical practice guidelines

The Leeds research has influenced clinical guidelines internationally. For example, the trial demonstrating patient benefits from routine measurement of quality of life using automated measurement significantly contributed to clinical practice guidelines published in 2011 by the International Society for Quality of Life Research [A]. The SDI-21 was referenced in pan-Canadian clinical practice guidelines published in 2009 by the Canadian Partnership Against Cancer (Cancer Journey Action Group) and the Canadian Association of Psychosocial Oncology (information on downloads available only from Canadian Partnership Against Cancer 2012-June 2013 = 45) [B]. The National Cancer Survivorship Initiative Vision, published in 2010 referenced SDI-21 as a questionnaire for assessing the quality of life of cancer survivors [C] (Google analytics unique page views www.ncsi.org.uk: PAGE: /?s=vision+document 01/02/10-14/08/13: 59,688 document downloads) [C].

Change in policy

NHS policy and the Health and Social Care Act 2012: The Health and Social Care Act 2012 endorses the use of PROMs to put patients at the centre of the NHS. **Sir Michael Richards**, National Cancer Director (1999-2013) said: *“Health services must become more patient centred. We urgently require methods to measure this aspect of care. Leeds researchers have provided us, not only with technologies for this purpose but also evaluated their measurements in a positive randomised controlled trial. This was very influential in development of policy and the incorporation of Patient Reported Outcome Measures as a central theme within the NHS”* [D]. Since 2010 **Velikova** and **Wright** have been members of a Department of Health/Macmillan National Cancer Survivorship Initiative advisory group on metrics. This group reviews research on PROMs; it made recommendations on which PROMs should be included in the pilot and full NHS PROMs survey (see later).

Changes in practice

Adoption of electronic self-reporting tools in clinical practice: In 2012, the Leeds Cancer Centre and the Yorkshire Cancer Network pioneered electronic Holistic Needs Assessment within routine patient care; the self-reported data are integrated into electronic patient records. This facility allows nurses to assess quality of life issues, leading to an agreed care plan in discussion with patients. The web-based questionnaire system is undergoing quality assurance testing prior to application for kite marking for use as a medical device.

In 2012 Electronic Holistic Needs Assessment (eHNA) was piloted by the Department of Health/Macmillan National Cancer Survivorship Initiative at four sites in England. A larger scale rollout is currently underway at 25 sites using a new prototype system in 2013. This software implements the 2007 National Cancer Action Team’s guidelines, which, were strongly influenced by Leeds research into the social impact of cancer. The eHNA tool included the Leeds-developed SDI-21 as one of the assessment measures [E]. **Velikova** and **Wright** are both members of the eHNA steering committee as experts in such electronic systems. The Leeds team provides on-going advice regarding electronic assessment to the eHNA project [E].

The SDI-21, one of three validated questionnaires, has been used in national evaluations of the quality of life of cancer patients and survivors: in 2011 it was used to collect data for the Department of Health national pilot PROMs survey of 4,992 cancer survivors [F]**;** it is also being used in the full national PROMs survey of 50,000 cancer patients during 2013. Internationally, the SDI-21 is being used in routine cancer practice in Canada as part of an electronic Distress Assessment and Response Tool (DART) for assessing, monitoring and supporting cancer outpatients. Between October 2009 to December 2012 47,661 DART assessments were undertaken with 13,672 assessments including the SDI-21. The use of DART has led to significant improvements in patient well-being (see below) [G].

Velikova provided professional advice leading to the adoption of the Leeds approach in a new clinical programme for lung-heart transplant patients monitoring in Edmonton (Alberta, Canada) [H]. Clinicians developed specific guidelines on the use of PROMs to individualize patient care and the monitoring has become standard practice. By 2010, 172 lung-heart transplant patients participated, 98% were happy to complete the assessments regularly; 91% of clinicians endorsed the use of PROMs in routine practice [H]. **Velikova**'s work and professional advice significantly influenced the decision to launch the Patient Outcomes Program to promote patient-centred care at Cancer Treatment Centers of America (CTCA) at Midwestern Regional Medical Center (Zion, IL, USA; private cancer hospitals in USA) [I]. The current quality of life database of CTCA consists of 12,000 patients; the data are being used by the clinical teams providing supportive care to patients on cancer treatment [I].

Changes in health outcomes

Enhancement of the patient experience, improved well-being and clinical outcomes: In Canada the evaluation of DART has provided evidence of improved patient well-being (measured by reductions in SDI-21 scores over four consecutive outpatient appointments) [G]. SDI-21 items are strong predictors of suicidal thoughts [J]; use of the tool alerts clinicians to patients with these ideas so they can offer appropriate support to prevent harm. Overall, DART enhanced the patient experience with measured improvement of patient's perception of treatment and support. A differential benefit of DART was demonstrated for low income patients ($p=0.046$). Clinical outcomes also improve with the use of DART. Clinician assessment of high distress scores was associated with an increase in patient's ability to complete chemotherapy from 50% to 85%. This improvement in compliance was achieved with no change in health service burden (clinic length or workload). Staff felt DART improved systematic inquiry about concerns. Most patients (88%) felt DART improved communication of symptoms and concerns with the health care team [G].

5. Sources to corroborate the impact

A. User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice. Version: November 11, 2011. Produced on behalf of the International Society for Quality of Life Research. Available at http://www.isoqol.org/research/isoqol-publications

B. Howell, D., Currie, S., Mayo, S., Jones, G., Boyle, M., Hack, T., Green, E., Hoffman, L., Simpson, J., Collacutt, V., McLeod, D., and Digout, C. A Pan-Canadian Clinical Practice Guideline: Assessment of Psychosocial Health Care Needs of the Adult Cancer Patient, Toronto: Canadian Partnership Against Cancer (Cancer Journey Action Group) and the Canadian Association of Psychosocial Oncology, May 2009. Available at http://www.partnershipagainstcancer.ca/wp-content/uploads/2.4.0.1.4.6-AdultAssesmentGuideline122109.pdf

C. Department of Health. Macmillan Cancer Support. NHS Improvement (2010). National Cancer Survivorship Initiative Vision. London, Crown. Available at http://www.ncsi.org.uk/wp-content/uploads/NCSI-Vision-Document.pdf

D. Individual corroboration: the National Clinical Director for Cancer, Department of Health, 2013.

E. Individual corroboration: Chief Executive, Macmillan Cancer Support and co-director National Cancer Survivorship Initiative, 2013.

F. Department of Health - Quality Health (2012). Quality of Life of Cancer Survivors in England: report on a pilot survey using Patient Reported Outcome Measures (PROMS). London, National Institute for Health Research. Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/127273/9284-TSO-2900701-PROMS.pdf.pdf

G. Individual corroboration: Physician lead for DART, Psychosocial Oncology and Palliative Care, University Health Network - Princess Margaret Cancer Centre, Toronto, Canada, 2013.

H. Individual corroboration: Senior researcher, Lung Transplant programme, Edmonton, Canada, 2013.

I. Individual corroboration: Vice president of Outcomes Research at Cancer Treatment Centers of America at Midwestern Regional Medical Center, Zion, IL, USA regarding the contribution of the Leeds approach to electronic assessments in clinical practice in North America, 2013.

J. Y. Leung, M. Li, G. Devins, C. Zimmermann, C. Lo, G. Rodin. Routine Screening for Suicidal Intention in Patients with Cancer. Psycho-Oncology, *in press*. DOI: 10.1002/pon.3319. http://www.ncbi.nlm.nih.gov/pubmed/23878040