Institution: University of Derby
Unit of Assessment: Biological Sciences
Title of case study: Improvements to cancer treatment

1. Summary of the impact (indicative maximum 100 words)

Collaborative research conducted by the Biological Sciences Research Group (BSRG) has brought considerable benefits for the treatment of cancer patients. Experimental research has shown that the shelf-life of the biological cancer drug Herceptin can be greatly extended thereby bringing significant economic benefit through cost savings. A clinical trial has demonstrated that yoga benefits the health and well-being of patients with gynaecological cancer leading to prospects of improved cancer survivorship. Sowter provides research-informed oncology training for NHS clinical trials staff throughout the National Institute of Cancer Research UK network (NCRN), and has supervised two senior registrars through their MD qualifications.

2. Underpinning research (indicative maximum 500 words)

Extending shelf-life of medicines

Herceptin is a humanised monoclonal antibody belonging to a new class of cancer drugs known as biologics, and current recommendations state that it must be discarded 24 hours after initial dilution. The summary of product characteristic (SmPC) states that Herceptin must be used within 24 hours after dilution to a patient-specific concentration (based on mg/kg) in an infusion bag. Extending this shelf-life would enable a more efficient use of the drug and save money that could be released for other NHS services; however aggregation of the drug could lead to loss of biological activity and unforeseen immunogenic effects. Results from a study by Wilkinson (Senior Lecturer), Sowter (Reader) and Shropshire (PhD student) demonstrated that Herceptin diluted to a clinically relevant dose (0.5mg/ml) in an infusion bag and aged for up to 119 days at the recommended storage conditions showed no significant difference to fresh Herceptin in terms of biological activity or physico-chemical condition. Funding was provided by the University and BUPA; Quality Control North West (QCNW) NHS supplied Herceptin and the compounding unit for infusion bags (Jackson).

Improving the well-being of cancer patients.

Sowter was the chief investigator of the first UK-based randomised controlled clinical trial (RCT) into the effects of yoga for gynaecological cancer patients. After consultation with patient groups, the trial ran at the University between 2011 and 2012. Bali, senior consultant gynaecologic oncology surgeon and associate member of the Biological Sciences Research Group (BSRG) oversaw patient recruitment at the Royal Derby Hospital, whereas Sowter and Archer (PhD student) oversaw the yoga classes and data analysis. The Cancer Reform Strategy, launched by the government in 2007, sets a clear aim to improve the experience of people living with and beyond cancer. Previous research has demonstrated several therapeutic benefits of yoga. Participants in the control group (n=25) and yoga intervention group (n=19) filled out EORTC QLQ C30 questionnaires at baseline and finish, and scored pain, anxiety, fatigue and quality of life (QoL) weekly on a visual analogue scale (VAS). Analysis of longitudinal data suggested that when time and intervention (yoga) are combined, yoga significantly contributes to the quality of life of patients. Focus group data also strongly indicated that Yoga classes had a positive impact on the QOL of this group of patients.

Impacts on practioners and services

Sowter has co-supervised two NHS senior registrars through MD projects at the University of Nottingham Medical School between 2009-2013. Both projects described potassium channel expression in ovarian cancer for the first time, and two putative ovarian cancer oncogenes (Eag and TREK 1) were identified. The Director of studies (Khan) advised on channel biology, Sowter provided all oncology input and provided ovarian cancer tissue microarrays (validated in previous research).

All research by Sowter described in this section has informed and underpinned training courses that she delivers to NHS clinical trial staff across all National Cancer Research Network areas in England.

3. References to the research (indicative maximum of six references)

Health and well-being of gynaecological cancer patients.

One Voice: For gynaecological cancer patients past, present and future. Eds: S.archer & G.Shawcroft. Published by Bali Publications, Ballymena, UK (2013)

Impacts on practitioners and services.

Innamaa A., Jackson, L., Asher, V., Bali, A., Sowter, H. and Khan R. (2013) The Expression of the K2P Channels TREK 1 and TREK 2 in Epithelial Ovarian Cancer and Effect of TREK 1 and 2 modulating agents on Cell Proliferation of SKOV 3 and OVCAR 3 Cells. Clinical and Translational Oncology (published on-line)

Innamaa A., Jackson L., Asher V., Bali A., Sowter H. and Khan R. (2013) The Expression of the oncogenic K2P Channel KCNK9 (TASK3) in ovarian carcinoma. Anticancer Res. 33:1401-1408

Asher V., Khan R., Warren A., Shaw R., van Schalkwyk, G., Bali, A. and Sowter, H.M. (2010) The Eag potassium channel as a new prognostic marker in ovarian cancer. Diagnostic Pathology 5:78

4. Details of the impact (indicative maximum 750 words)

Extending the shelf-life of biologic cancer drugs

In 2010 The National Institute for Clinical Excellence (NICE) recommended that Herceptin (trastuzumab) be available for women with HER2 positive advanced breast cancer. The cost of implementing this guidance in England and Wales is estimated at £17 million. Our study demonstrated that the shelf life of Herceptin can be safely extended, and significant financial savings have been made by QCNW NHS who changed their protocol accordingly in 2012. The cost saving for the Clatterbridge Hospital which is just one hospital in the North West Region was £1.1M in one year based on the Trastuzumab study data. Initial results have been published as poster presentations at the National Cancer Research Institute conference in November 2012. In the short term future the impacts of this study will extend nationally and internationally.

Health and well-being of gynaecological cancer patients

Participants continued to want Yoga classes at the UoD post-trial (funded for 1 year by the gynaecological cancer research fund and now paid for by patients; currently there is an average of 8 patients in each weekly class) and have put together a book of their positive experiences during the trial and during their cancer experience (published May 2013). This research was highlighted in an interview with Sowter for GEM FM (average weekly audience figures 453,000) which ran on every news bulletin on 01.02.11. A participant of the Yoga trial (Gill Shawcroft) appeared on Radio Derby (139,000 viewers per week) to discuss her experiences on the trial.

Impacts on practitioners and services.

Beneficiaries of Sowter's research are two NHS senior registrars who completed MD projects under her supervision: Mr Viren Asher (Eag and HERG potassium channels as novel therapeutic targets in ovarian cancer) and Ms Anni Innamaa (The Expression and function of the K2P Channels TASK 3, TREK 1 and TREK 2 in Epithelial Ovarian Cancer). Sowter's cancer research background helped inform the project design and training in techniques (such as immunohistochemistry and TMA analysis). The director of studies for both projects was Dr Khan (Obstetrics researcher, Associate Professor, University of Nottingham). Asher and Innamaa have now taken consultant posts as a result of successfully gaining this qualification. Sowter is also a key trainer of NHS clinical trials in all networks across England, and was successful in a nationwide tender to bid for NCRN training contracts (2013). Her courses (Introduction to Oncology and Cancer Treatment) are aimed at trials nurses and administration staff who work in the area of

oncology, although have also been accessed by GPs. These courses have run 4-6 times a year since 2010, and been delivered to staff from all areas of the National Institute for Health Research Cancer Research Network in England (reaching approximately 500 NHS staff so far). In feedback collected after each training day (by the NCRN), 95-100% of participants stated that this training would benefit their working practice. The content of these courses is informed by research conducted by Sowter, specifically her expertise as a clinical trial chief investigator and basic research into therapeutic target development.
Some comments at feedback refer specifically to elements based on Sowter's research such as "Contextual information. i.e. what we have/nave not achieved with other courses."

5. Sources to corroborate the impact (indicative maximum of 10 references)

View from a Yoga patient: Mrs Gill Shawcroft 19 Broadway, Ripley, DE5 3LJ. Telephone 01773744580 or 07803602681. Email gshawcroft@btinternet.com. Mrs Shawcroft had appeared on Radio Derby to talk about her experiences on the Yoga trial and, along with other participants, and has written a book to highlight the positive aspects of Yoga for gynaecological cancer patients

Clinical Trials teaching can be verified by Ann Courtman, Research Administrator, Peninsula Cancer Network, West Yarner, Dun Cross, Dartington TQ9 6DX. Tel: 01803 860660

Herceptin project with QCNW NHS
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Supervision of MD students can be corroborated by Dr Raheela Khan, University of Nottingham Medical School at Derby, Royal Derby Hospital.