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Editorial

The Trigger Project: The Challenge of Introducing Electronic Patient-Reported Outcome Measures Into a Radiotherapy Service

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Quality of life is a complex concept spanning multiple domains, including physical, mental and social wellbeing. Patient-reported outcome measures (PROMs) are collected directly from the patient and are a valuable tool for collecting quality of life data without physician bias [1]. PROMs, when used in clinical practice, have been associated with improvements in quality of life, and mechanisms for their routine collection have been associated with improvements in overall survival [1–3]. The average life expectancy and the number of patients living with and beyond cancer continue to increase, but it is estimated that at least one in four suffer significant long-term side-effects after their treatment [4,5]. The breadth of choice of treatments is also growing for many patients and the decision between treatments with similar survival rates may be best served with good quality of life data collected by PROMs.

The importance of PROMs is starting to be addressed, as seen in NHS England's prioritisation of 'living with and beyond cancer' with a commitment to roll out a quality of life metric across the country, including PROMs questionnaires [6]. This will evaluate quality of life in multiple different cancers following diagnosis.

There has been a real difficulty in introducing PROMs data collection in an already overstretched National Health Service. This is probably due to the fact that traditional

quality of life questionnaires can be long, not well matched to the side-effects of particular treatments and therefore often considered time consuming and irrelevant to the patient and healthcare professional. For successful sustainable uptake of PROMs staff, 'buy in' is imperative and so far this has often been the main barrier to implementation.

Project Outline

The Royal College of Radiologists and Macmillan Cancer Support were keen to find a solution to this problem, combining a useable treatment-specific PROM for radiotherapy treatment that could be collected electronically. The electronic collection of the PROM was essential to the brief to enable national scale up and reporting. Initially the plan was to scope the addition of a PROM to one of the existing national cancer datasets, namely the radiotherapy dataset, to complement the quality of life metric [7]. However, following discussion with stakeholders this was considered unachievable as it would change the fundamental way in which the radiotherapy dataset collated its data, which was directly from radiotherapy machines.

The original concept evolved to create an electronic method of collection that would be independent of national registries but could supply the registries with data if the project successfully grew to encompass most of the country. In order to implement this project, the system had to be independent of any hospital electronic system, which

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typically vary. For the system to be successfully rolled out it had to be easy to use, set up and relevant to staff [8]. It would be patient facing to allow patients to input their own data and to gain appropriate consent for the use of their data.

Most importantly, the project needed a short treatment-specific questionnaire that would take minimal time to complete but highlighted those who needed specific help following treatment. ALERT-B is a four-point questionnaire used to screen for long-term bowel toxicity after radiotherapy (Figure 1). It is a set of questions validated against traditional PROMs tools [9]. Long-term bowel toxicity is improving following modern radiotherapy techniques but still affects quality of life in a significant proportion of people [10,11]. These symptoms are commonly not initially attributed by patients to being related to radiotherapy, and clinicians often have a poor understanding of the complex effect radiation has on bowel function. Many of the symptoms can improve dramatically and rapidly with the correct treatment, but too often these patients do not receive the most appropriate care in a timely manner. A key feature of the ALERT-B questionnaire is that the patients who are identified as being in need can more rapidly proceed to being treated according to evidence-based treatment protocols that should improve their symptoms and quality of life [12]. The new Radiotherapy Service Specification, which covers the provision of radiotherapy for adults in England, suggests that radiotherapy networks include ALERT-B as a method of collecting long-term bowel toxicity data [13].

A challenge to this project was our limited financial resources to show that this could be achieved at scale as a service evaluation project in multiple centres. Recruitment would have to be integrated into normal practice in radiotherapy departments. The model would be based around on-treat radiographers who would discuss the service with the patient at the time of radiotherapy. Limited extra resources are needed in the radiotherapy department as the patient would register for the website themselves during radiotherapy and complete the questionnaire to record initial acute toxicity. A member of staff would validate the patient online to confirm they are a real patient. The system would then invite the participant to redo the questionnaire 6 months later to collect long-term bowel side-effects. The major benefit to patients of this project is that it picks up early symptoms that may be related to pelvic radiation disease and gives patients a contact to call so that they can be linked to the most appropriate clinicians to deal with their symptoms.

Imperial College Healthcare NHS Trust, Brighton and Sussex University Hospitals NHS Trust and Velindre University NHS Trust were chosen to give a diverse spread of sites, with a lead clinician and a radiographer at each department and administration support at Imperial. The aim of this 1-year project was to see how many patients registered and then went on to complete the 6-month questionnaire, against the denominator of those receiving radical pelvic radiotherapy at that particular centre.

Assessment of Late Effects of RadioTherapy-Bowel

ALERT-B Screening Tool

Date:

Your specialist has asked you to complete this screening tool to pick up any bowel or tummy problems you may have developed following radiotherapy treatment.

Please answer Yes or No to the following questions:

1. Do you have difficulty in controlling your bowels (having a poo), such as:

- Having to get up at night to poo	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
- Having accidents, such as soiling or a sensation of wetness ("wet wind")	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

2. Have you noticed any blood from your bottom recently? (any amount or frequency)

Yes No

3. Do you have any bowel or tummy problems that affect your mood, social life, relationships or any other aspect of your daily life?
(e.g., do you avoid any activities or situations- travel, work, social life or hobbies? Do you take continence supplies or spare clothing with you when you go out? Have you made any dietary changes? Do you need to allow for frequency or urgency of needing the toilet?)

Yes No

If you have any other problems your doctor will be happy to discuss this with you.

Fig 1. ALERT-B screening tool [9].

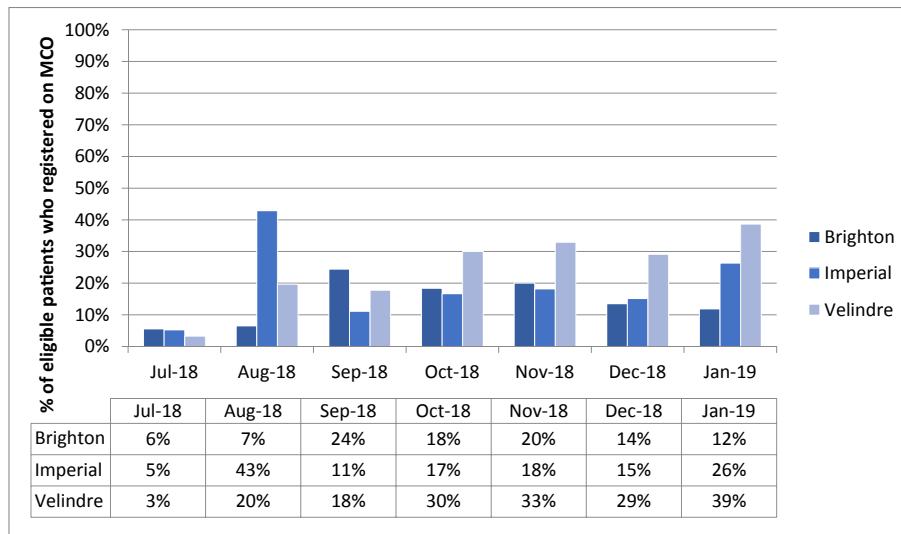


Fig 2. Recruitment over time across the three centres.

The Experience So Far

At the 6-month mark of this year-long feasibility project, about 250 patients have registered with the Trigger project using an electronic platform hosted by My Clinical Outcomes [14]. Of those who have answered the initial questionnaires, 55% had answered 'yes' to one or more of the ALERT-B questions that probably represents acute gastrointestinal toxicity. We are now beginning to see the return of the 6-month post-radiotherapy questionnaires. This will give us a tangible measure of the burden of long-term side-effects actually experienced by patients receiving pelvic radiotherapy. It may also allow further correlation of tumour type with side-effect burden, as all patients receiving pelvic radiotherapy are eligible. Another benefit could be to identify patients for research projects in this disease area.

The 248 patients currently registered with the Trigger project represent, as of January 2019, 12% of the eligible patients at Brighton & Sussex, 26% at Imperial and 39% at

Velindre (Figures 2 and 3). We are hoping to reach the 60% sign up of eligible patients.

The registration level so far has been low and shows the challenges to implement a project like this without designated resources in the National Health Service. There is considerable variability between the three sites. This variability has also been found in the NHS England Quality of Life Metric pilot study. We continue to use a learning in practice approach through surveys of staff and by speaking to sites directly. The higher levels within Velindre could be predicted due to their specialist interest in pelvic radiation disease for more than 5 years [15]. Staff shortages are seen across the National Health Service and this means that already overstretched staff do not have time to take on the extra effort required for the Trigger project. This may be evident in Brighton and Imperial, who have smaller teams of on-treat radiographers/nurses.

This system is designed to help those patients significantly affected by pelvic radiation disease after 6 months and point them to the right help more effectively and

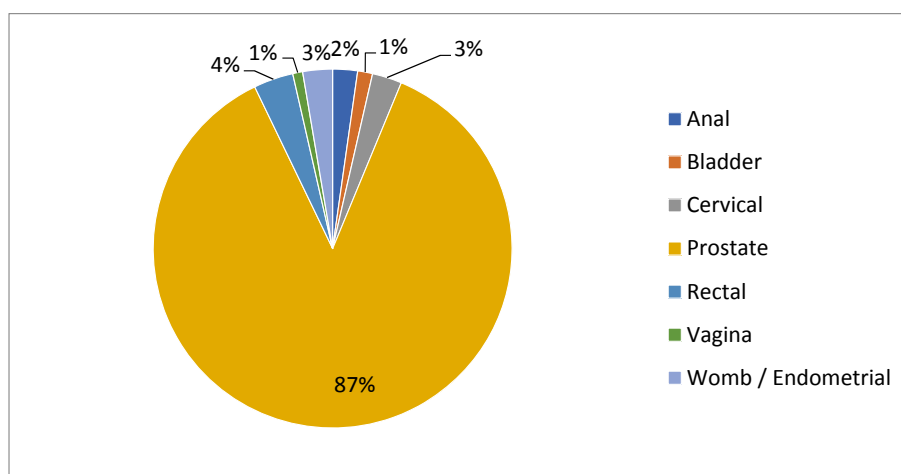


Fig 3. Rates of patients registered on the platform by cancer type.

quickly. Therefore, patients may not sign up as they do not see the relevance of the project at the time of registration. A lesson of the project is how we can build the system to give more perceived benefits for the patient at registration.

We continue to implement measures to try to combat some of the issues and raise awareness to all staff. Examples of these are a promotional video filmed at the Royal College of Radiologists and at all three radiotherapy centres to promote patient and staff engagement with the project and a monthly newsletter, including sign-up rates, with a breakdown of cancer type and highlighting effective practice, aiming to inform clinicians and promote further engagement.

If these initiatives are effective then this project will have been one of the first of its kind to implement the routine collection of entirely electronic PROMs, in a scalable manner, without dedicated funding for sites. This could significantly improve the experience of patients undergoing treatment in the future, as in light of ongoing resource and workforce constraints, electronic collection of these data could provide stratified follow-up of patients with cancer, detecting those with toxicities and supporting remotely those who are not currently experiencing side-effects. A national roll-out of a project similar to Trigger is feasible using the same low-resource model, and requires adoption by the National Health Service for full uptake and increased patient engagement.

Conflicts of Interest

J. Staffurth reports grants from Tenovus Cancer Care, during the conduct of the study; non-financial support from Bayer, personal fees from Janssen, outside the submitted work. L. Smith is an unpaid trustee of the Pelvic Radiation Disease Association. D. Bloomfield was Medical Director Professional Practice, Royal College of Radiologists when this project was initiated.

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