A novel methodology using direct patient contact and UK national registries to collect long-term data from randomised trials: Extended follow up of the TARGIT-A trial of intraoperative radiotherapy for breast cancer (TARGIT-X)

Full paper in press at NIHR Journals Library

Professor Jayant S Vaidya[1]*, Professor Norman R Williams[1], Professor Max Bulsara[1,2], Ms Chris-Brew Graves[1], Dr Ingrid Potyka[1], Mr Nicholas J Roberts[1], Ms Julie Lindsay[3], Dr Siobhan Laws[4], Dr Sanjay Raj[4], Professor Michael Douek[5,7,8], Dr Mary Falzon[6], Dr Gloria Petralia[6,8], Dr Sarah Needleman[9], Dr Anu Malhotra[7], Ms Marcelle Bernstein[10], Professor Jeffrey S Tobias[6].

111

Introduction: Many diseases including breast cancer have a long natural history. Therefore, longer-term effects of treatments are important for patients and for their full evaluation. However, trial follow up data are collected by specific staff and funded for a relatively short duration. We evaluated whether we could collect follow up information for patients in a breast cancer randomised clinical trial by direct patient contact and data from national registries.

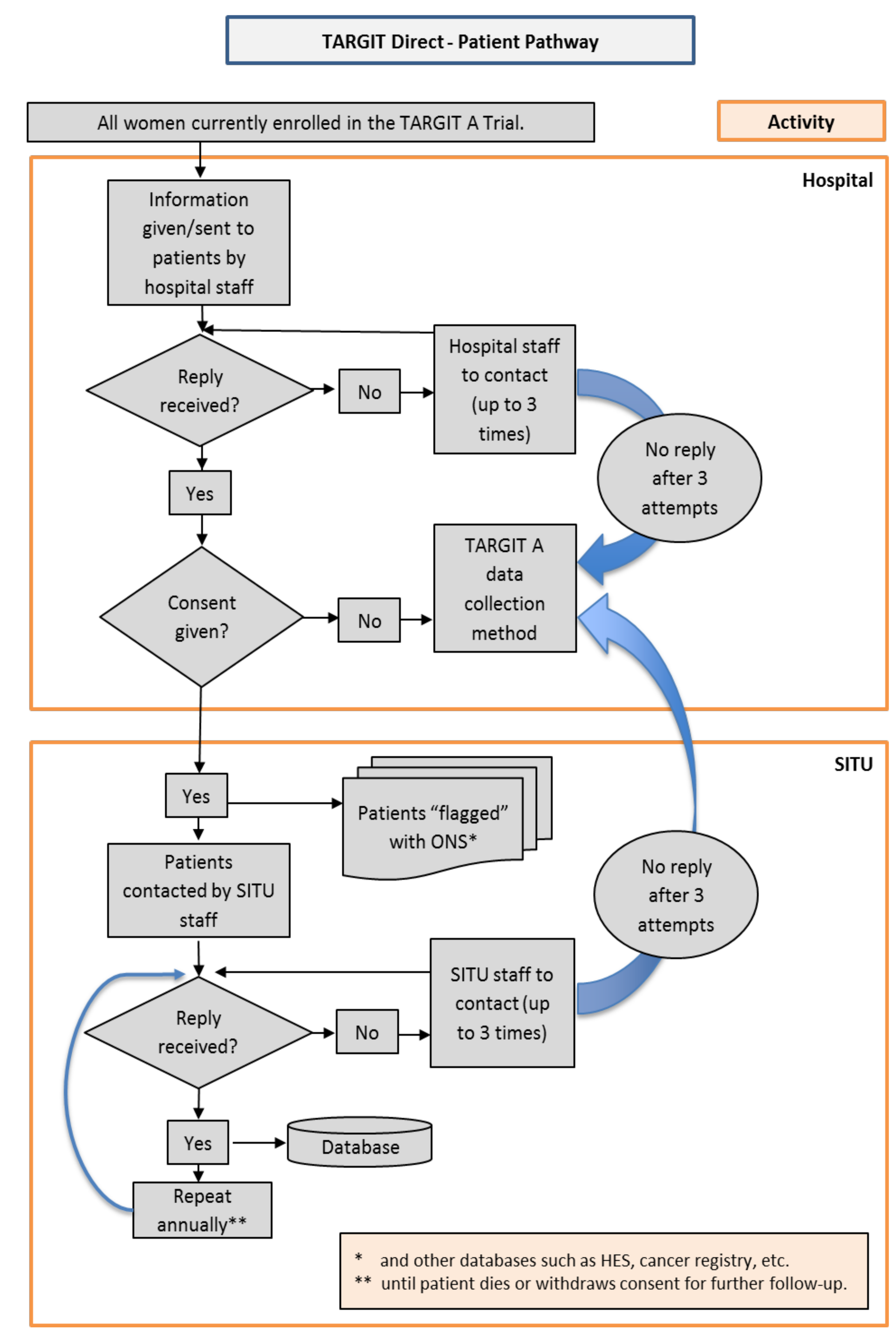
Setting: The TARGIT-A randomised clinical trials of targeted intraoperative radiotherapy during lumpectomy (TARGIT-IORT) vs whole breast radiotherapy (EBRT_ and delayed TARGIT-IORT vs EBRT (n=1153), recruited women with early breast cancer diagnosed in 33 centres in 12 countries, between March 2000 to June 2012.
We planned to recruit all UK patients from the TARGIT-A trials for extended follow-up. This was the first randomised trial of intraoperative radiotherapy for breast cancer.

TARGIT-IORT website

TARGIT-IORT literature

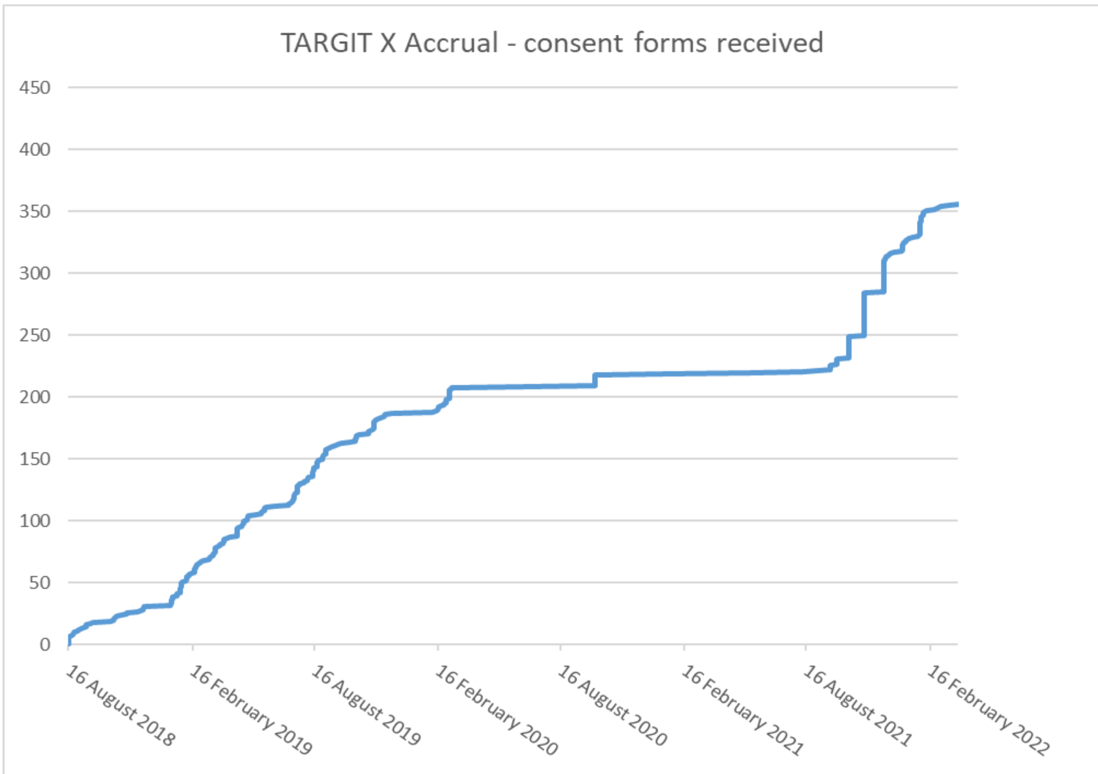
TARGIT-IORT BMJ paper

TARGIT-IORT BJC paper



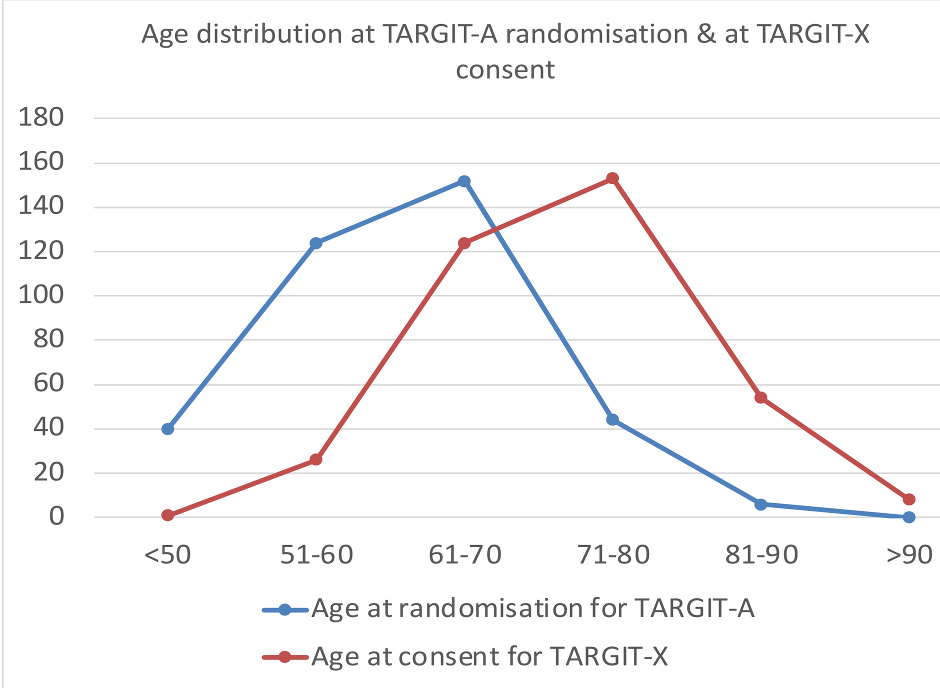
Methods:

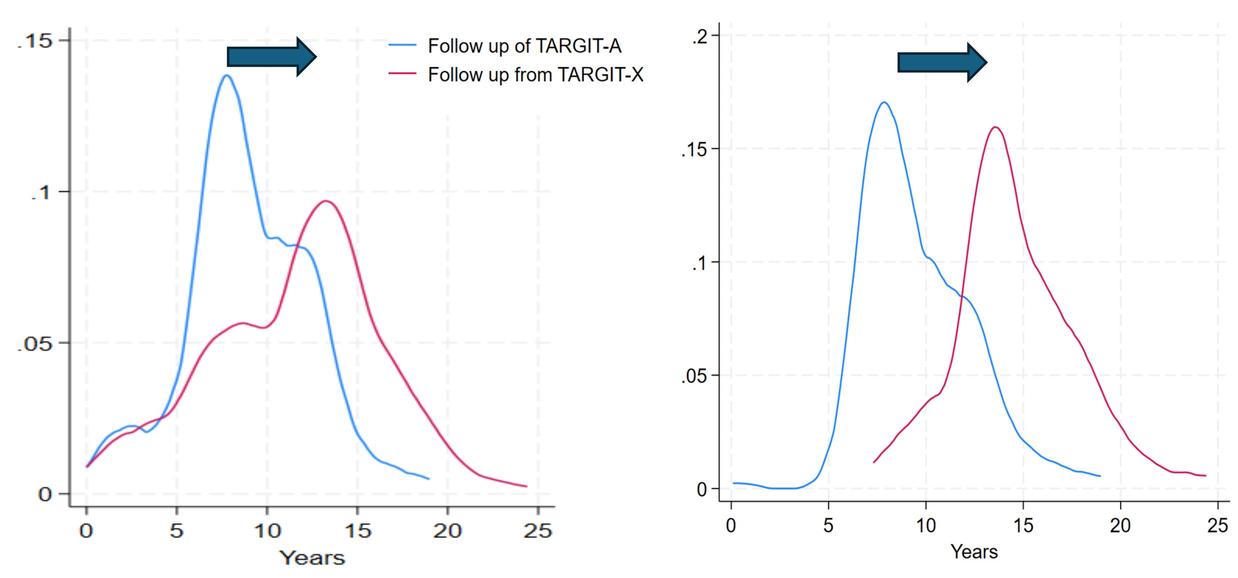
- We assessed the feasibility of recording whether patients are alive and their current health status including events related to breast cancer, and effects of radiotherapy such as lung cancer diagnoses, by direct patient contact and data from NHS Digital (health episodes, diagnoses and death).
- Patients were consented in collaboration with the recruiting site and then contacted annually, if appropriate, directly by the trial centre.
- We calculated the proportion of eligible patients whose status could be ascertained, contacted, consented and provided follow up information via direct patient contact and/or NHS Digital data. We estimated the additional years of follow up and its cost.



Results:

- 607 of 714 UK patients originally recruited in the TARGIT-A trials were initially eligible (dead/withdrawn not eligible).
- Of these, 94.5% (574/607) status / reason for non-participation was ascertained.
- Of these, 87% (502/574) patients' health status could be determined.
- Of these, 73% (366/502) or 60.3% of the total (366/607) were found to be in good health, provided valid consent for TARGIT-X and their health status.
- **Less than 5%(25/502) patients were unwilling to participate: 23 declined and 2 withdrew.**
- An additional 103 deaths recorded: doubling the initial number to 203.
- **A 65% overall survival at 15 years shows that unlike other PBI trials, TARGIT-A was NOT a low-risk cohort**
- The quality of data returned by patients was very good (e.g., mismatch rate for recording date <0.1%(1/1470 forms).
- **Patients who participated increased their follow up by a median 6 years (to 14 years (IQR 13 to 16)).**
- **The cost, including research funds, was < £60/patient/year of follow up.**
- Limitations included difficulties in receiving data from NHS Digital due to their due to repeated organisational changes, plus unexpected price rises in the costing of data download**.**

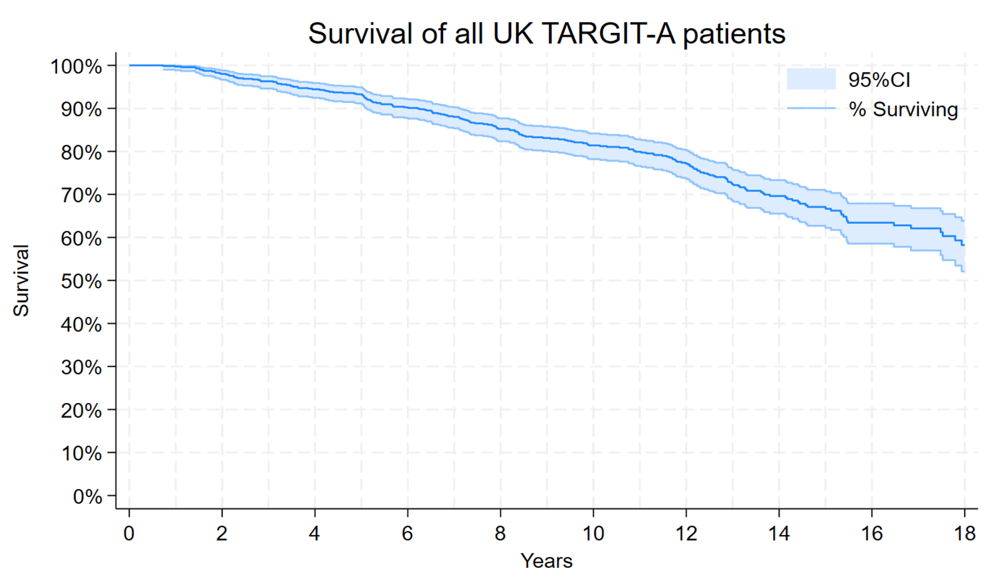




Recommendations for future research: To investigate why treatments proven in large international randomised trials showing patient benefit and are cost-effective, are not widely adopted in the UK whilst they are included in almost every other country's clinical practice guideline and widely adopted worldwide, to assess the influence of preconceived notions, conflicts of interest, and improve NICE processes.

Conclusion:

- In the UK, 95% patients are willing to be followed up long-term.
- It is feasible to collect follow up data for long-term health conditions accurately from patients with direct patient contact together with NHS Digital.
- It leads to a substantial increase in the length of follow up and number of relevant events, at a low cost.
- Our new approach could be adopted as an efficient method of obtaining long-term follow up data from patients in randomised clinical trials.



FUNDED BY NIHR National Institute for Health Research

UCL

British Association of Surgical Oncology ~ Association for Cancer Surgery
BASO~ACS ` Conference, November 2025

Affiliations: 1. University College London, 2. Institute for Health Research, University of Notre Dame, Fremantle, Australia, and UCL 3. Ninewells Hospital, Dundee, 4. Royal Hampshire Hospital, Winchester, 5. University of Oxford, Oxford, 6. University College London Hospital, 7. Guy's Hospital, London, 8. Oxford University Hospital, Oxford, 9. Royal Free Hospital, London, 10. Patient advocate, London, UK