VIRTUAL CLINICAL OUTCOME ASCERTAINMENT IN A PROSTATE CANCER TREATMENT TRIAL

Athene Lane[1], Michael Davis[1], Eleanor Walsh[1], Peter Holding[2], Grace Young[1], Chris Metcalfe[1], David Neal[2], Jenny Donovan[1], Freddie Hamdy[2]

[1]University of Bristol, [2]University of Oxford

Background and aim:

The ProtecT randomised trial (Prostate cancer testing and treatment trial) compares active monitoring, radiotherapy and surgery for localised disease. The primary outcome is prostate cancer mortality with secondary clinical outcomes of disease progression and metastasis. The primary outcome was comparable between groups for the 10-year median analysis in 2015 (based on 1643 randomised men) so follow-up was extended to a median of 15 years (November 2020) (Figure 1).

Research nurses at 9 UK hospitals completed annual paper Case Report Forms (CRFs) for clinical secondary outcomes in the 10 year analysis. NHS routine data (from Public Health England) was to have identified men with potential disease progression to target site visits by a central research nurse/data manager using a REDCap eCRF (Figures 2 and 3). Disease progression and metastases outcomes were derived as previously.

The COVID-19 pandemic stopped site visits and so we developed three virtual data collection methods and aimed to assess their relative effectiveness.

Methods:

In March 2020 a 2-page eCRF collecting essential outcome data was created and in July 2020 site PIs agreed to help collect data at a virtual investigators meeting (Figure 4).

Ethical approvals were gained by December 2020 for a protocol amendment and updated study end date (due to COVID delays). In addition, GDPR terms in site agreements were updated which delayed the central research nurse renewing their NHS Research Passport to access data.

Fig 2 Case note reviews before March 2020

Results:

We used 3 different data collection methods tailored to site capacity and IT access. Staff at four sites completed eCRFs supported remotely by the trial data manager and research nurse through training, emails and virtual calls. The central research nurse gained remote access to hospital electronic health records (EHR) at 3 sites by April 2021 after extensive governance approvals, IT training and installing EHR software on multiple laptops. At two sites, site staff interrogated their EHRs during virtual calls (planned around clinical commitments) while trial staff completed the eCRFs without access to the EHR. An average of 15 note reviews were completed during a 2-hour call.

Table 1 Comparison of remote data collection methods

Data Capture Method	Sites (n)	Completion (participants/ Site total)	Percentage completion	Comments
Site staff	4	575/600	95.8 %	• First method established and easiest to set up • More data cleaning as site staff completing CRFs
Remote EHR access	3	594/601	98.8%	• Last method established and complex for trial • Less data cleaning as trial staff completing CRFs
Virtual calls	2	266/272	97.4%	• Time/staff intensive, sometimes out of office hours • Less data cleaning as trial staff completing CRFs

All methods had comparable data collection rates (Table 1) at over 95%. Less data cleaning was required if trial staff completed eCRFs remotely or with virtual calls with site staff. Other benefits included travel and accommodation savings, reduced carbon footprint, and that site staff could obtain information from outside their hospital EHR. However, the shortened CRF did not have all the data items in the longer eCRFs.

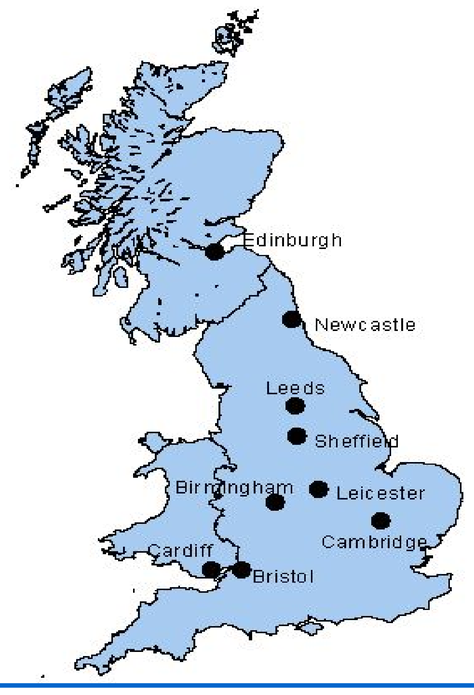
Fig 1 10-year median outcomes

Patient-Reported Outcomes after Monitoring, Surgery, or Radiotherapy for Prostate Cancer Donovan et al. New England Journal of Medicine Oct 2016

10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer Hamdy et al. New England Journal of Medicine Oct 2016

Fig 3 eCRF system

Fig 4 ProtecT sites



Conclusions:

Three remote clinical outcome capture methods were successful after site visits ceased due to the COVID-19 pandemic with different benefits and challenges. However, enabling remote data capture and governance delayed the 15 year analysis by 18 months from November 2020 to May 2021.

This study/project is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme, HTA 96/20/99; ISRCTN20141297. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. We thank ProtecT PIs and site staff for their contributions.

Poster design by Tom Steuart-Feilding