Project IDEATE: Creating a Novel Linked Real World Data Environment in Wales for Use in an Experimental Retrospective Outcome-Based Agreement of a Breast Cancer Treatment

Burton J[1], Halsby K[1], John G[2], Selby J[2], Warburton A[2], Povey G[3], Huws D[4], Laing H[5], Sáinz de la Fuente G[1], Pijper A[6], Holloway S[6], Sloan R[6], Gogna R[6], Pearson-Stuttard J[6], Porter T[6]

1 UK Health & Value, Outcomes Innovation & Evidence, Pfizer Limited, Walton Oaks, United Kingdom,
2 Digital Health and Care Wales (DHCW), Cardiff, United Kingdom
3 ChemoCare and SACT, South West Wales Cancer Centre, Swansea Bay University Health Board, Wales, United Kingdom
4 Swansea University, Wales, United Kindom
5 Value-Based Health and Care Academy, Swansea University, Swansea, United Kingdom
6 Health Analytics, Lane Clark & Peacock LLP, London, United Kingdom

Summary

- **The linkage of real real world data and administrative datasets provides the opportunity to develop, implement and monitor innovative reimbursement mechanisms.**
- **We developed a novel, real world data environment linking diverse datasets for breast cancer patients in a trusted research environment (SeRP).**
- **Current datasets have the capability for implementing and monitoring OBAs.**

Introduction

- Outcome-based agreements (OBAs) have the potential to align the incentives of payers and providers of therapeutics around patient and population health.
- Many barriers prevent their routine implementation across healthcare systems, including the availability and quality of data to link payments to outcomes.
- Patient reported outcomes (PROMs) are of increasing interest to both clinicians and patients to measure health outcomes. Routine collection is limited to date.
- We aimed to create a novel real world data (RWD) environment with linked datasets for breast cancer patients in Wales from 2005 to 2020 to test an experimental, retrospective OBA.

Methods

- We linked datasets covering patients with incident non-operable, locally advanced or metastatic breast cancer in Wales from 2005 to 2020.
- We used the Welsh Breast Cancer Audit dataset linked across the Cancer Network Information System Cymru (CaNISC), ChemoCare, Patient Episode Database for Wales (PEDW), Admitted Patient Care (APC), Outpatient appointments (OPA), Emergency Department Dataset (EDDS), and Office of National Statistics (ONS) death datasets.
- Data were deidentified, pseudonymised, linked, and analysed within the Secure e-Research Platform (SeRP) see figure A.
- Inclusion criteria and 10 outcomes of interest were determined through multidisciplinary expert workshops.
- Missingness analyses were conducted on inclusion and outcome variables.
- Outcomes were included or excluded on the basis of data availability, easily extractable format (free-text excluded), and missingness analysis.
- Due to data limitations, PROMs were not included but outcomes deemed proxies for PROMs were included where possible and deemed appropriate by clinicians.
- All data integration and cleaning were performed in SQL.

Results

Data linkage

- We created a first of its kind linked, integrated data environment in Wales within SeRP.
- Key parameters from an experimental OBA created a unique population in the data and demonstrated feasibility.

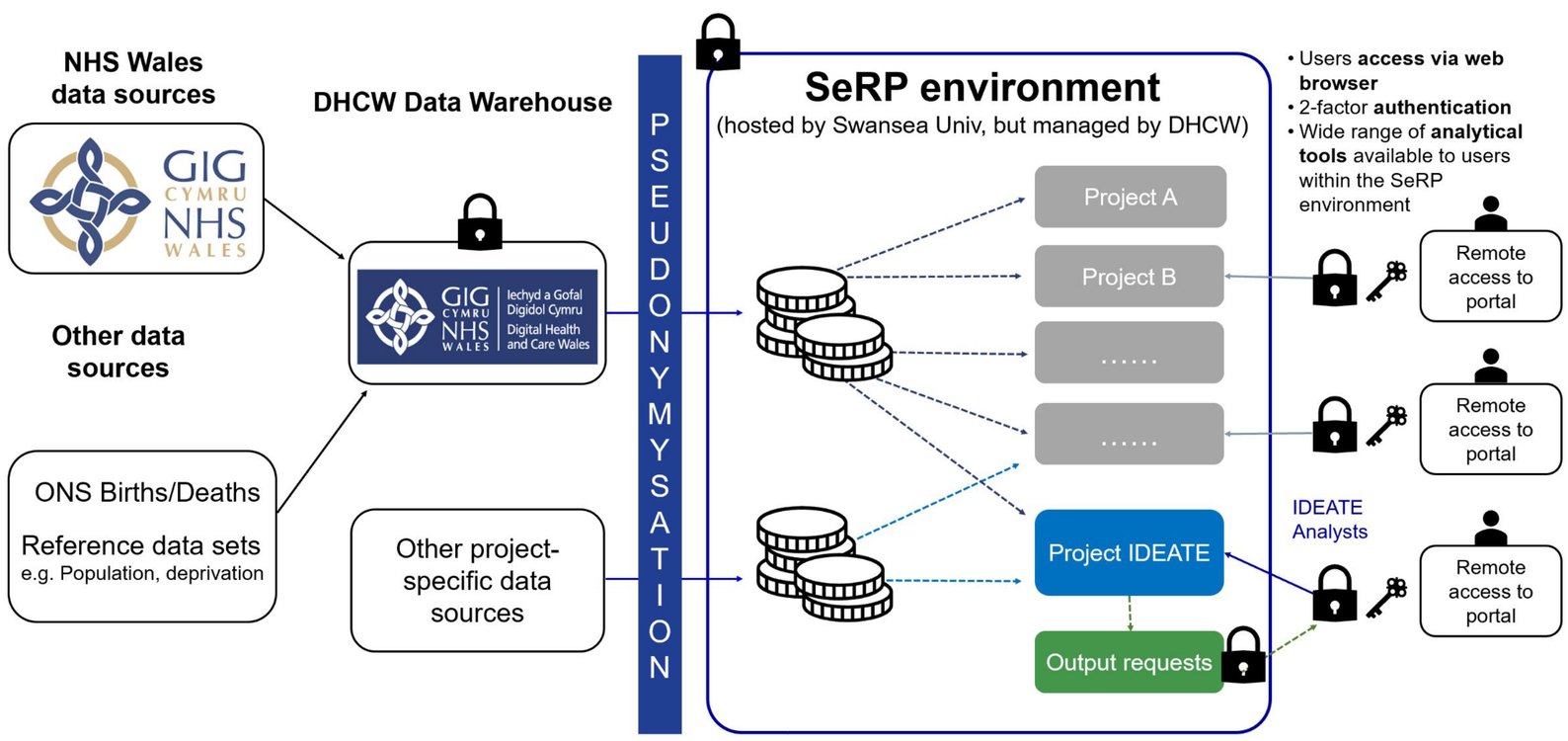
OBA Population

- The unique population is comprised of 696 patients with incident non-operable, locally advanced or metastatic breast cancer from 2014 to 2020; 99% female with median age of 72 years at inclusion.

Outcome development

- We defined and standardised five outcomes:
  - 1-year survival;
  - 30-day mortality;
  - intolerance to treatment;
  - spinal cord compression; and
  - days disrupted by care.
- The remaining 5 of the 10 outcomes (e.g progression free survival) were not included due to lack of dataset access, free-text format, and/or high missingness.
- Spinal cord compression was excluded due to the low incidence observed within the study population
- 30-day mortality was excluded following further discussion with clinicians who determined that it is not a feasible outcome measurement for inclusion in an OBA.

Figure A – Data process to deidentify, pseudonymise and link data within SeRP



All **analysis are carried out in-situ within the SeRP environment** with no data removed as a default. Users may **request to output data** to their local PCs/environments, but this is only possible following **sign-off by DHCW-based SeRP administrators.**

Conclusion

- RWD will be vital to enable implementation and monitoring of OBAs.
- Integration with additional datasets, more consistent data capture to enable inclusion of outcomes most relevant to stakeholders, a cost-effective method to extract data from free-text fields, and reduced missingness are future developments needed.

Financial disclosure: This study was sponsored by Pfizer

Acknowledgements

We thank Julie Francis, Alex Percival, and Allison Roblin at DHCW- Commercial Services, Cora Suckley at DHCW – Information Governance, James Pearson and Ellen Collins at Pfizer Ltd- Legal, and Kate Steel at LCP- Legal for significant contributions to the complex multi-organization information governance, compliance, and data privacy requirements facilitating IDEATE.