PD17 Automating The Impact Reporting Of NICE Guidance

Shaun Rowark (shaun.rowark@nice.org.uk), Pall Jonsson and Seamus Kent

Introduction. The National Institute for Health and Care Excellence (NICE) intends to automate the way it monitors the uptake, impact, and value of its guidance. Traditionally this has been done by developing impact reports, long documents that, while well received, are time consuming to develop and can quickly become outdated.
Methods. We focused on a novel topic that would benefit from new data sources to examine its impact: a rapid guideline for managing the long-term effects of coronavirus disease 2019 (COVID-19). We shortlisted "measurable" recommendations within the guideline that were likely to be captured in data collections. We then reviewed available data sources that included relevant up-to-date data. Finally, we explored what existing methods were available to NICE for automating impact reporting.
Results. For long COVID-19 we accessed OpenSAFELY, a secure, transparent software platform for primary care COVID-19 data that was developed in response to the pandemic. This captured data on the management of long COVID-19 in primary care as well as onward referral to specialist clinics. In addition, we accessed data from the CVD-COVID-UK/COVID-IMPACT Consortium, which links general practice records with primary care dispensing data. This enabled us to analyze the impact of the pandemic on the prescribing and dispensing of cardiovascular disease medications. Working with our digital team we developed an automated impact reporting dashboard using Google's data studio. This enabled different views of the data, for example by region or socioeconomic status, to be presented in an automated way.
Conclusions. Automating the impact reporting of NICE guidance provides up-to-date information on its value to the health system. While we were able to collect new sources of data and automate some aspects of how these were viewed, full automation requires several enablers. These include an application programming interface between the data sources and NICE, and ensuring that NICE guidance is computer readable so that its measurement is practical in healthcare systems.

PD19 Machine Learning Modelling For Clinical Trial Design Using The National Institute for Health and Care Research Innovation Observatory's ScanMedicine Database

Ece Kavalci (ece@lindushealth.com), Jawad Sadek, Michael Young and Christopher Marshall

Introduction. Clinical trials that fail prematurely due to poor design are a waste of resources and deprives us of data for evaluating potentially effective interventions. This study used machine learning modelling to predict clinical trials' success or failure and to understand feature contributions driving this result. Features to power the modelling were engineered using data collected from the National Institute for Health and Care Research Innovation Observatory's ScanMedicine database.
Methods. Using ScanMedicine, a large dataset containing 641,079 clinical trial records from 11 global clinical trial registries, was extracted. Sixteen features were generated from the data based on fields relating to trial design and eligibility. Trials were labeled positive if they were completed (or target recruitment was achieved) or negative if terminated/withdrawn (or target recruitment was not achieved). To achieve optimal performance, phase-specific datasets were generated, and we focused on a subsample of Phase 2 trials (n=70,167). Ensemble models using bagging and boosting algorithms, including balanced random forest and extreme gradient boosting classifiers were used for training and evaluating predictive performance. Shapley Additive Explanations was used to explain the output of the best performing model and calculate feature contributions for individual studies.
Results. We achieved a weighted F1-score of 0.88, Receiver Operator Characteristic Area under the Curve score of 0.75, and balanced accuracy of 0.75 on the test set with the xgBoost model. This result shows that the model can successfully distinguish between classes to predict if a trial will succeed or fail and subsequently output the features driving this outcome. The number of primary outcomes, whether the study was randomized, target sample size and number of exclusion criteria were the most important features affecting the model's prediction.
Conclusions. This study is the first to use predictive modelling on a large sample of clinical trial data obtained from 11 international trial registries. The prediction outcomes achieved by our novel approach, which uses phase-specific trained models, outperforms previous modelling in this space.

PD20 Real-World Evidence To Support Single Arm Trials Of Oncology Interventions: Necessity or 'NICE' (National Institute for Health and Care Excellence) to Have?

Edel Falla (edel.falla@iqvia.com) and Jennifer Gaultney

Introduction. The recent National Institute for Health and Care Excellence (NICE) consultation on methods for health technology evaluation (HTE) outlined plans to include guidance on the role of real-world evidence (RWE) in HTE. This is particularly pertinent for interventions where the evidence base consists of a single arm trial (SAT) design, which is more frequently observed in oncology.

https://doi.org/10.1017/S0266462322002811 Published online by Cambridge University Press

This study reviewed the influence of RWE submitted as part of the evidence base for NICE oncology appraisals.
Methods. A search for NICE HTEs was conducted for interventions supported by SATs from January 2017-November 2021. Evidence was stratified by submission packages with SAT evidence alone or in combination with randomized controlled trial (RCT) evidence, with or without RWE.
Results. Thirty-two decisions for interventions supported by SATs were made by NICE between 2017-2021, all in oncology indications. Fifty percent were supported by SAT evidence and fifty percent by RCT plus SAT evidence, both with or without RWE. A lower proportion of RCT/ SAT HTEs submitted RWE compared to SAT HTEs (fifty vs ninety four percent). Seventy five percent and nineteen percent of SAT HTEs received a positive recommendation, with and without restrictions, irrespective of submitting RWE. One negative decision was observed for SATs supported by RWE. Sixty three percent and thirty eight percent of RCT/ SAT HTEs received a positive recommendation, with and without restrictions. Overall, the proportion of positive recommendations were lower for HTEs submitting RWE (ninety six percent) compared to HTEs not submitting RWE (one hundred percent), which is in contrast to recent findings specific to orphan oncology HTEs (one hundred versus seventy eight percent).
Conclusions. RWE was more commonly submitted to support SAT HTEs, than RCT HTEs. The use of RWE seems to be established as a necessity to supplement a SAT evidence base, whereas RWE is more generally a nice to have in RCT HTEs. However, RWE appears to positively influence decision-making for orphan oncology indications with a more neutral influence for non-orphan indications.

PD21 Data Sources And Real-World Data On Medical Devices In The Brazilian Scenario

Leidy Anne Teixeira (leidyunb@gmail.com) and
Fotini Toscas

Introduction. The Brazilian government has made efforts in systems to generate data from medical devices (MD). This work explores the main systems and data sources in the perspective of contributing as a source to generate real world data (RDW).
Methods. Document review of relevant national data sources for MD. In addition, a structured search was carried out in EMBASE using key descriptors for RWD applied to the regulatory context and to the management of health technologies, without date or language restrictions.
Results. Eighteen primary federal government data sources for MD were identified. Not all sources are publicly accessible. Of the articles, the search returned 1,185 results, of which 29 titles were selected and 8 met the protocol's objective. Included articles were from Europe, the United States and Canada. As in other countries, Brazil initially systematized DM administrative data to meet commercial and financial demands. With the evolution of health technology assessment methods, the use of RDW has become imperative to assess the value of MD to society. Common examples from these countries are implantable MD databases. Current challenges focus on data linkage and quality, in addition to standardized naming. The adoption of the Unique Device Identification (UDI) is one of the promising initiatives to facilitate traceability throughout the lifecycle proposed in the International Medical Device Regulators Forum (IMDRF) of which Brazil is a member. Among the systems, the following stand out: i) ConectSUS, which intends to provide access to health information centered on the patient, anywhere and at any time; ii) National implant registry that generates data on implanted prostheses and stents, surgical techniques used, the profile of patients and the health services involved.
Conclusions. This work showed the similarities between Brazil and other countries in the management of MD data throughout its life cycle, as well as mapped the national primary data sources for MD.

PD22 Exploratory Analysis of a Brazilian Real-World Open Database Applied to Prostate Cancer

Lucilena Rebelo Monteiro, Mércia Liane Oliveira,
Mario Olímpio Menezes and
Lorena Pozzo (lorenapozzohta@gmail.com)

Introduction. Prostate cancer was the second most frequent cancer and the fifth leading cause of cancer death among men in 2020. The incidence rates vary substantially in countries with different Human Development Indexes (HDI), while the mortality rates decrease with improved access to the health system, availability of therapies and earlier detection. Worldwide, population-based cancer registries are important tools for planning and managing health systems. The Fundação Oncocentro de São Paulo (FOSP) is responsible to collect, clean and publicize data from cancer treatment institutions. This study aimed to describe retrospectively the demographic and clinical profile of prostate cancer (PC) in Brazil using this database. It is not an incidence study as data is representative only from specific institutions.
Methods. This was a retrospective observational study of the years 2000 to 2020 from analysis of the publicly available FOSP database (http://www.fosp.saude.sp.gov.br).
The records were extracted, merged, and cleaned using a fully documented and validated data process. Only patients included on the register with a primary PC diagnosis were considered.
Results. From January 2010 to June 2020, there were 943,660 patients diagnosed with C61 in FOSP database for the considered time period. The majority of the FOSP database records are from patients who live and/or were born in SP (91.8 and 58.4%, respectively) or MG (2.8 and 10.5%, respectively). The mean age of PC at baseline was 69 years. Considering the stage of the disease, the mean ages are 55, 70, 67, 66 and 61, for stages 0, 1, 2, 3 and 4, respectively. This cohort was also analyzed in relation to treatments received, and status at the end of treatment (51.3% are disease-free, 18.4% are alive with cancer, and 30.3% are dead).

https://doi.org/10.1017/S0266462322002811 Published online by Cambridge University Press