Inefficiencies in the current delivery of adult critical care research studies (both randomised and non-randomised) from duplication of data collection burden and for retrospective data linkage

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Abstract

Introduction

Through the hosting and co-ordination of the national clinical audit for adult critical care – the Case Mix Programme (CMP) – ICNARC has both led and facilitated the rigorous and efficient delivery of critical care research in the UK. This project included the addition of a 'Research Platform' to support efficient delivery of research through hosting the required critical care data collection/validation and through real-time prospective data linkage to the routine, ongoing collection of high-quality clinical data in the CMP. We aimed to: (i) to understand the requirements of the research platform to critical care researchers; (ii) to develop functional and technical specifications; (iii) to develop and test the Research Platform; (iv) roll-out updated IT platform to CMP units; and (v) produce user access documentation.

Methods

We convened a Research Platform User Group consisting of individuals conducting research in the critical care setting and conducted scoping workshops to understand the requirements of the Research Platform. We produced a Research Platform Functional Specification. The Research Platform was developed (and tested) as a sub-component of a full IT platform upgrade - 'Platform X'. Critical care units were 'onboarded' onto Platform X, which was carried out using duplicate upload of data to both the previous system and simultaneously onto Platform X.

Results

Sixteen individuals representing each of the 10 relevant UKCRC registered CTUs and the wider critical care research community joined the Research Platform User Group and participated in the workshops. The workshops highlighted that the Research Platform should: be accessible and responsive to all researchers; adaptable to ensure critical care data requirements for proposed research studies are met; coordinated to ensure unnecessary duplication is avoided and the burden of data collection is managed and embedded into routine collection of national clinical audit data; online data entry for trial participants and observational data on potentially eligible but not recruited patients to enhance generalisability; enable prospective observational studies, allowing

the collection of additional fields; release pages/fields to specific units at specified timepoints. The Functional and Technical Specifications for the Research Platform and the wider Platform X were signed off in November 2017. The staggered onboarding of critical care units onto using Platform X between March 2019 and June 2020. During the COVID-19 pandemic Platform X allowed the addition of critical care units and surge areas. Examples included the Nightingale Hospitals and Alder Hey Paediatric Intensive Care Unit, but also surge areas and respiratory units within existing hospitals. This expedited data collection and data entry was hugely successful, and allowed analysis and regular reporting directly from the CMP dataset. The Research Platform has been included in a number of NIHR grant applications for future multicentre randomised clinical trials.

Conclusions

A fully functional Research Platform has been developed alongside the development of the full IT platform upgrade. The system has been tested throughout the COVID-19 pandemic, which has expedited both unit onboarding and data collection. This has shown its flexibility and adaptability, which are key features for conducting research using the platform.

Introduction

In recent years, there has been a proliferation of predominantly NIHR-funded, large, rigorous, multicentre research studies (both randomised and non-randomised) in adult critical care (to which the Intensive Care National Audit & Research Centre (ICNARC) has contributed). ICNARC has, through its hosting and co-ordination of the national clinical audit for adult critical care – the Case Mix Programme (CMP) – attempted to facilitate the rigorous and efficient delivery of these research studies. Activities, to date, have included providing researchers with: analyses based on CMP data to inform sample size calculations; analyses of CMP data to inform "usual" care and outcomes (in place of observational pilot studies); and performed retrospective data linkage between CMP data and research study data (e.g. BALTI-2 (HTA)[1], HARP-2 (EME)[2], TracMan (MRC)[3], POPPI (HSDR)[4], PARAMEDIC (HTA; for trial participants admitted to critical care)[5], 65 trial (HTA)[6], REST (HTA)[7] etc.). There have been limitations to the ability to provide such facilitation, with a restrictive IT system, and with reliance on quarterly data submissions from critical care units to the CMP, which then undergo validation on our internal systems.

As part of a major upgrade (cost >£300,000), we aim to scope and specify an IT platform to meet the future needs of national clinical audit in adult critical care. The National Institute for Health Research (NIHR) Clinical Trials Unit (CTU) Support Funding to support efficient / innovative delivery of NIHR research, presented the possibility to widen the scope of our upgrade programme to address the future needs of national research in adult critical care through the addition of a 'Research Platform'. This Research Platform is to support efficient delivery of research through hosting (in whole or part) the required critical care data collection/validation and through real-time prospective data linkage to the routine, ongoing collection of high quality clinical data in adult critical care through the CMP. It would need to be accessible and responsive to all researchers (NIHR or otherwise funded), adaptable to ensure critical care data requirements for proposed research studies are met, coordinated to ensure unnecessary duplication is avoided and the burden of data collection is managed and embedded into routine collection and validation of other routine national clinical audit data

This project addressed the following aims: (i) to understand the requirements of the research platform to critical care researchers; (ii) to develop functional and technical specifications; (iii) to develop and test the Research Platform; (iv) roll-out updated IT platform to CMP units; and (v) produce user access documentation.

Methods

Understanding the requirements of the Research Platform

To understand the requirements of the Research Platform to critical care researcher in the UK, we convened a Research Platform User Group. We identified the relevant UK Clinical Research Collaboration (UKCRC) registered CTUs conducting research in the critical care setting and invited individuals to form the Research Platform User Group. The purpose of which was to help identify the requirements for the data platform to ensure that it was of the highest value to the potential users of the resource. To understand their requirement, scoping workshops to encourage discussion and identify these requirements were held.

Development of functional and technical specifications

To ensure the developers working on the Research Platform understood and could incorporate the requirements from the Research Platform User Group, a Research Platform Functional Specification was produced and discussed from a technical aspect. Once items that, from a technical standpoint, could be included t had been identified, these were incorporated into the minimal viable product (MVP) specification for the full IT platform upgrade. . It was essential this was completed prior to the commencement of building the Research Platform.

Research Platform development, testing and refinement

The Research Platform was developed as a sub-component of the full IT platform upgrade - 'Platform X'. Platform X was developed by the Development team at ICNARC, using Pentaho - a business intelligence software, consisting of a collection of tools to transform complex data. Functionality in Pentaho includes data integration; security management; dashboard display; interactive reporting; and data mining/extract. This was chosen as it could give the flexibility required in both the full upgrade and the Research Platform. Testing was carried out across the whole system against the MVP, using both internal CMP staff, and external users of the system. Any issues found were corrected and retested.

Roll-out of the IT platform

Prior to any roll-out of the Research Platform, it was vital to ensure that a representative number of critical care units were using and uploading data onto Platform X. Due to the complexities of the new system and the need to ensure all 250+ critical care units transition onto the system our Data and Business Technology team took the decision to stagger the 'onboarding' of critical care units onto Platform X . This was carried out using duplicate upload of data to both the previous system and simultaneously onto Platform X. Consistency across both the data uploaded and the validation module was carried out by the Statistics team. This ensured, that the data in Platform X remained of the same high quality and was validated in the same manner as for the previous system.

Production of user access documentation

To ensure there is a clear process detailing how to access the Platform X and the Research Platform, user access documentation to gather key information for development of study-specific pages was produced.

Results

Understanding the requirements of the Research Platform

At the start of the project we established a Research Platform User Group, which consisted of 16 individuals representing each of the 10 relevant UKCRC registered CTUs conducting research in the critical care setting and the wider critical care research community.

During the first three months of the project, we conducted scoping workshops with the Research Platform User Group. These workshops (both in person and via teleconference) successfully outlined the requirements for the Research Platform to ensure that it was of the highest value to the potential users of the resource.

The requirements of the Research Platform, highlighted at the workshops included:

- to be accessible and responsive to all researchers;
- adaptable to ensure critical care data requirements for proposed research studies are met;
- coordinated to ensure unnecessary duplication is avoided and the burden of data collection is managed and embedded into routine collection of national clinical audit data;
- online data entry for trial participants and observational data on potentially eligible but not recruited patients to enhance generalisability;
- enable prospective observational studies, allowing the collection of additional fields;
- release pages/fields to specific units at specified timepoints.

Development of functional and technical specifications

The functional specification document for the Research Platform was signed off in March 2017. At this point, the functional specification for Platform X (the full IT platform upgrade), was still in consultation. Therefore, the Research Platform functional specification could not be incorporated into the full functional specification. The Technical Specification for the Research Platform was signed off in April 2017. This confirmed that the system, which was being specified for the full IT platform upgrade to Platform X could incorporate the requirements as outlined in the functional specification. The Functional and Technical Specifications for the Research Platform and the wider Platform X were signed off in November 2017.

Research Platform development, testing and refinement

Development of Platform X alongside the Research Platform began in early 2018. Initial internal development was completed in October 2018. Testing and refinement of the system continued over November/December 2018 with initial external testing commencing in 2019. The functionality of the Platform X (including research platform) was confirmed in March 2019.

Roll-out of the IT platform

The staggered onboarding of critical care units onto using Platform X began in March 2019 with approximately 10% of the participating units, with additional units being onboarded each quarter. Due to the potential utility of the Platform X to collect expedited data during the COVID-19 pandemic, all participating units were fully onboarded

by end of June 2020. This expedited roll-out gave the opportunity to fully test the flexibility of the system, which is essential for the utility of the Research Platform.

Testing the IT platform during a pandemic

During the COVID-19 pandemic, all units were asked to expedite data for critically ill patients with confirmed COVID-19. Relative to the usual system of upload of a data file at the end of each quarter, units were asked to upload sequentially to Platform X (i) confirmation of a patient and their basic information (ii) 24-hour data (iii) outcome data at discharge from critical care. In addition to the expedited nature of the data submission, both additional critical care units and surge areas treating critically ill patients were taken on board at short time frames with the ability to manually enter data directly into Platform X where local hospital IT systems did not allow data export. Examples included the Nightingale Hospitals and Alder Hey Paediatric Intensive Care Unit, but also surge areas and respiratory units within existing hospitals. This expedited data collection and data entry was hugely successful, and allowed analysis and regular reporting directly from the dataset, which included:

- Daily reporting to senior figures in the NHS of number of admissions to critical care;
- Weekly analysis and reporting to critical care units and to the public;[8]
- Weekly analysis and reporting focussed on Northern Ireland and Wales;
- Risk-adjusted comparison of outcomes by critical care unit;
- Individual critical care unit reports on COVID-19 admissions;
- Publications on: the first 200 patients[9]; epidemiology and outcomes of the full cohort[10]; trends in patient characteristics and outcomes[11]; and prognostic factors for mortality[12].

Expedited data collection using Platform X has also allowed for data linkage of the critical care data to other datasets, secondary analysis and publications, including:

- Data linkage to urgent public health badged COVID-19 clinical trials, including RECOVERY[13, 14], REMAP-CAP[15, 16] and REALIST[17].
- Data linkage across the full patient pathway, from genomic datasets[18], GP practices [19, 20], Hospital episode statistics [19], NHS Digital/ONS data, Renal Registry and the National Institute for Cardiovascular Outcomes Research.

These aspects of: sequential data collection (for individual patients); more regular data upload; and the expansion to new hospitals and areas was only possible due to the flexibility of Platform X. These are key functionality aspects for the use of the Research Platform, which have now been fully tested in a real-world situation.

Production of user access documentation

Now there are a representative number of units collecting data through Platform X, user access documentation has been produced. This documentation is currently available via email, but will be available via the ICNARC website (www.icnarc.org). This contains information such as: study timelines; variables to be added; number of units and patients; and stage of funding (including resources available). This document is reviewed internally to understand the workload and resources needed.

Dissemination

As all groups carrying out research within critical care were included in the Research Platform User Group there was pre-existing knowledge regarding the plans and progress of the Research Platform. In addition, as at ICNARC we have historically linked trial data to the CMP database, critical care researchers are used to approaching ICNARC prior to submission of a grant application. At this point we have proactively discussed the possibility of using the Research Platform for primary data collection, whether it is collection of trial specific variables, or solely of the patient trial number to increase the speed of identification and data linkage. This process has led to the inclusion of the Research Platform in the following recently funded and potential future studies:

- UK-ROX, NIHR130508, Chief Investigator (CI) - Prof Daniel Martin (University of Plymouth)
- MOSAICC, NIHR129617, CI – Prof Lui Forni (Royal Surrey County Hospital)
- T4P, NIHR131822, CI – Prof Peter Watkinson (University of Oxford)
- Airways 3, NIHR131533, CI – Prof Jonathan Benger (Bristol Royal Infirmary) – *not yet funded*

In addition to this informal dissemination, which has led to the inclusion and use of the Research Platform across the aforementioned studies, we will actively disseminate the potential of the Research Platform. This will be shared, where possible, with other CTUs through Registered CTU Network events. and with the wider NIHR research community through the UK Critical Care Research Group and the NIHR CRN Critical Care Speciality Group. ICNARC is represented on all these groups.

Conclusion

This NIHR CTU Support Funding has enabled the development of a fully functional Research Platform, which has been completed alongside the development of the full IT platform upgrade. This has been completed with the input of external researchers within critical care and the understanding of their requirements. The system has been tested throughout the COVID-19 pandemic, which has expedited both unit onboarding (all units participating in the CMP are now using the new system) and data collection (uploading of contemporaneous data, rather than retrospective quarterly data). This has shown its flexibility and adaptability, which are key features for conducting research using the platform. The Research Platform is already being included within grant applications and will be used in a number of multicentre randomised clinical trials starting in 2021.

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Contribution of authors

PM (Head of Research), DH (Head Statistician), KR (CTU Director) designed, obtained funding for, and oversaw delivery of the study. AK (Data Engineer) led the technical development of the Research Platform. PM and DG wrote the first draft of the report. All authors critically reviewed and approved the report.

Conflict of interest declaration

None of the authors have declared any conflicts of interest.

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