**British Cardiovascular Intervention Society registry framework: a quality improvement initiative on behalf of the National Institute of Cardiovascular Outcomes Research (NICOR)**

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**Abstract:**

**Aims:**  The British Cardiovascular Intervention Society (BCIS) percutaneous coronary intervention (PCI) registry is hosted by the National Institute of Cardiovascular Outcomes Research (NICOR) at Bart’s Heart Centre and collects clinical characteristics, indications, procedural details and outcomes of all patients undergoing PCI in the United Kingdom. The data are used for audit and research to monitor and improve PCI practices and patient outcomes.

**Interventions:** Bespoke live data analysis and structured monthly reports are used to provide real time feedback to all participating hospitals about the provision of care. Risk-adjusted analyses are used as a quality metric and benchmarking PCI practices.

**Population & Settings:** Consecutive patients undergoing PCI in all PCI performing hospitals in the UK.

**Years:** From 1994 to present.

**Baseline data:** 113 variables encompassing patient demographics, indication, procedural details, complications and in-hospital outcomes are recorded.

**Data Capture:** Prospective data is collected electronically and encrypted before transfer to central database servers.

**Data quality:**  Data is validated locally and further range checks, sense checks and assessments of internal consistency are applied during data uploads. Analyses of uploaded data including an assessment of data completeness are provided to all hospitals for validation, with repeat validation rounds prior to public reporting.

**Endpoints:** In-hospital PCI complications, bleeding and mortality. All-cause mortality is obtained via linkage to the Office of National Statistics. No other linkages are available at present.

**Data access:** Available for research by application to NICOR at http://www.nicor.org.uk/ using a data sharing agreement

**Keywords:** Percutaneous coronary intervention, registry, data, outcomes, quality care

**Introduction:**

Percutaneous coronary intervention (PCI) is the most commonly used revascularisation modality for the treatment of coronary artery disease (CAD). There has been a significant increase in PCI activity in the UK and Europe due to increased service demand such as the treatment of STEMI by primary PCI and the associated development of STEMI (ST-elevation acute myocardial infarction) networks and increased utilisation of coronary and structural interventions(1-5). Consequently, there has been a greater emphasis from all the stakeholders to create clinical registries to advance the understanding of the clinical characteristics, care, and outcomes of patients undergoing PCI, for audit and for benchmarking of both individual operators and clinical services(6-9). In the UK, the British Cardiovascular Intervention Society (BCIS) started surveying PCI practices of a small number of hospitals in 1988(10). Further, pilot projects to collect these data electronically were undertaken by Central Cardiac Audit database (CCAD) group in 1996 which was a forerunner to the formal inception of the BCIS registry nationally in 2002(11,12). In 2011 management of the BCIS data repository moved from CCAD to NICOR, now hosted at Bart’s Heart Centre(13).

**Aims of BCIS registry:**

The mission of BCIS registry is to improve the quality of cardiovascular interventions and drive quality of care by collecting data from all hospitals providing PCI services across the UK. More specifically the BCIS registry has the following aims:

* Ongoing assessment of the availability of PCI services across the UK such as number of PCI centres and their catchment areas. These data serve as a roadmap for policymakers to evaluate the need for service expansion or restructuring.
* To assess the appropriateness and processes of clinical care provided by healthcare providers against national standards.
* To assess the procedure related complications and its impact on patient outcomes.
* Utilisation of these data for national audit and research.

**Funding and Organisation:**

The data governance of BCIS registry has evolved significantly over the years under the auspices of BCIS. The clinical leadership of data collection and analysis for national audit is overseen by the BCIS data monitoring and audit group. This group comprises several interventional cardiologists from BCIS, representatives from Medicine and Health Products Regulatory Authority (MHRA), the National Institute of Cardiovascular Outcomes Research (NICOR) and patient groups. The committee is chaired by the BCIS audit lead. The main objective of the data monitoring group is to provide strategic support, maintain and update the dataset, review of data quality within the registry, develop the analytical framework used for audit and develop internal and external collaborations to promote research. The data monitoring group has regular meetings throughout the year to ensure that the BCIS registry is meeting the needs of the clinical speciality, identify any areas of potential improvements or changes to meet the needs of changing clinical practice and review the process of the audit within the registry. Any applications for data access for research purposes are also assessed by this group. Since 2011, NICOR has been responsible for the technical and analytical support for the PCI audit along with five other national cardiac audits. NICOR’s strategic vision is to harmonising the data collection and analysis process across all domains to include not only PCI, but also the national audits of adult cardiac surgery, cardiac rhythm management, heart failure, acute myocardial infarction and congenital heart disease interventions.

The audit project has been funded by central government through the Department of Health (DoH) since its inception. This funding is now managed by the Healthcare Quality Improvement Partnership (HQIP). HQIP is an independent organisation established in 2008 and led by the Academy of Medical Royal Colleges, Royal College of Nursing and National Voices. HQIP strives to enhance the healthcare system and drive the use of clinical audits to improve patient care. All participating hospitals in the project provide financial support for local data entry and validation.

**Setting:** The BCIS dataset collects information about almost every PCI procedure performed across all NHS hospitals in the UK. Although private hospitals are not obliged to participate, some of the private hospitals do also contribute to the data collection. In 2017-18 of the total 118 PCI centres in the UK, only 6 did not contribute to the registry(14). Overall, BCIS captures approximately 95% of PCI activity within the UK.

**Population and consent:** All consecutive patients undergoing PCI for treatment of coronary artery disease are recorded in the dataset. The data collected in the BCIS registry have a section 251 approval of NHS Act 2006 which allows the use of dataset for medical research and audit purposes without seeking patient consent. Full details about the data protection and security are available at (www.ucl.ac.uk/nicor/patients/security)

**Patient identification:** All patient identifiable information is encrypted before transfer to the central servers for analysis. Patients in England and Wales are tracked for survival after PCI through the Office of National Statistics by using their NHS number which is a unique 10-digit number. Tracking is not currently performed for patients in Scotland or Northern Ireland. Postcode is captured for all patients which allows linkage to assess rates of PCI per million populations in different regions of the UK. Analyses are then performed on pseudo-anonymised datasets. Details of other important variables captured within BCIS dataset are described later on.

**Start point:** The BCIS registry is designed to collect data of all consecutive adults undergoing PCI for stable angina or acute coronary syndromes in the UK from time of admission to discharge. The information about diagnostic cardiac catheterisation procedures is not collected as the main aim of BCIS registry to improve the quality of PCI activity in the UK.

**Baseline data:** There are approximately 113 variables in the BCIS dataset which capture information about patient’s baseline demographics, presentation, important cardiovascular risk factors, previous cardiac interventions, indication for PCI, details about technical aspects of the PCI procedure, pharmacology, operator details and any in-hospital adverse outcomes. The most recent dataset version is 5.6.5 supplied in the form an excel spreadsheet and is available for download from the BCIS website. The website also contains information around data standards, variable definitions and validation rules for data completeness. <https://www.bcis.org.uk/resources/bcis-ccad-database-resources/datasets-history/>

**Data capture and storage:** Participating hospitals may either enter data directly into a web-based interface provided by NICOR, or upload data that has been collected using local databases, of which a number are available. These data are exported by first converting into a specifically formatted comma separated values file, and then a NICOR provided web interface will encrypt and transfer the file for upload to central servers.

**Data quality:** The BCIS audit committee uses several approaches to optimise data quality collected in the dataset. Firstly, a comprehensive data dictionary of each variable field along with definition is provided to all the participating hospitals and is also made available for download from the BCIS website. Any changes in the data field, definition, or addition to dataset are also distributed via newsletter to all centres and published online on the BCIS website. Secondly, the help team at NICOR provides telephone support for technical issues, data definition and programme errors whereas any queries around complex clinical scenarios, case or variable definitions are addressed by BCIS audit clinical committee led by an experienced interventional cardiologist. The staff at NICOR also provide technical support and helps in answering any queries regarding clinical case scenarios, data uploads and variable field errors via telephone or a secure dropbox. A third layer of data quality assurance is added during the data upload stage to the central servers to ensure the completeness, consistency and accuracy of data submitted. During this stage, range checks are applied along with checks for internal consistency with a focus on the minimum dataset fields. Any major problems with these fields will result in failure to upload the dataset and it will be returned to the submitting centre along with an error log for further cleaning and checks before resubmission. Finally, although there is no independent external validation of the dataset at present, data from each participating hospital is rigorously audited and published in the annual audit reports. Prior to publication of the public reports of all operators and all centres, there are 2 validation rounds, during which each operator and centre has the opportunity to check and correct any inaccuracies identified. In order to improve data completeness of the key fields used in public reports of process of care and risk-adjusted outcomes reporting, BCIS have mandated minimum data completeness of greater 95% for each of 24 key variables (Table 1). The information from these variables is utilised to produce risk-adjusted outcome analyses and assess treatment delays for the management of STEMI and NSTEMI. The data entry levels for remaining fields has been generally good with greater than 80% completion rates across majority of the fields in the dataset(5).

**Data reports and use:** The main purpose of the BCIS registry is to audit PCI activity in order to benchmark PCI practices in the UK against national standards. In order to meet these requirements, BCIS endeavours to provide as close to real time feedback as possible to the participating hospitals, treating physicians and related departments in a variety of ways. i) BCIS annual audit report is the most comprehensive, detailed analysis of the data produced on yearly basis. Within these reports, special attention is paid to the PCI service structure, data collection, appropriateness, process of care and risk-adjusted outcomes including in-hospital Major Adverse Cerebrovascular Events (MACCE), peri-procedural complications and in-hospital and 30-day mortality. The findings from these reports are also presented at the BCIS society annual meeting by the BCIS audit lead and later published on the society’s website, where they are freely available for download (https://www.bcis.org.uk/resources/audit-results/). ii) In addition to the annual report, individualised automated reports are generated for each participating centre on a regular basis with a particular focus on treatment delays and risk-adjusted outcomes. Until 2016, BCIS used North West Quality Improvement programme risk model to produce risk-adjusted analyses(15), however more recently McAllister et al(9) developed a new model to predict 30 day mortality after PCI using the BCIS dataset. A calculator is available on the BCIS web site: (https://www.bcis.org.uk/resources/pci-risk-calculator/). iii) Public reports: As part of the government’s transparency agenda, reports for every PCI operator, and every PCI centre are made publicly available each year. The reports include a description of case mix, access route, time delays to emergency PCI treatment and an analysis of risk-adjusted outcome using the 30 day mortality model. These reports are emailed to all operators and the local audit lead in each hospital to provide personalised feedback. Once they have been through a validation cycle these reports are made available for public use on the society’s website along with explanatory text to place the results in context (https://www.bcis.org.uk/patient-area/)

**Endpoints and linkage to other data:**  The dataset collects the usual set of endpoints up to the time of hospital discharge including peri-procedural complications such as stroke, myocardial infarction, bleeding and access site related complications (Table 2). Following discharge, all-cause mortality is tracked for all patients from England and Wales using the NHS number via a linkage to “Office of National Statistics”.

**Research and Impact:**  The BCIS registry has been an important source of observational research. The BCIS data monitoring and analysis group in collaboration with NICOR research committee reviews all the applications for research projects. To date over 30 different research projects around arterial access site practice, peri-procedural complications, real-world outcomes in patients presenting with cardiogenic shock and comparing different treatment in patients with stable angina have been approved. The findings from these projects have been presented at various international conferences and over 50 manuscripts have been published in high impact journals(16-26). There are further plans to expand the research impact of BCIS dataset by facilitating linkage to Hospital Episode Statistic (HES) data, and other datasets such adult cardiac surgery and Myocardial Infarction National Audit Project (MINAP) datasets within the remit of NICOR to create a longitudinal cohort of patients undergoing PCI in the UK.

**Strengths and Weaknesses:**  BCIS endeavours to collect information about every PCI procedure undertaken in the United Kingdom and the nationwide participation from all NHS hospitals in the UK adds to its national representation. It also captures all patients from a wide range of spectrum such as those with stable coronary artery disease to those presenting with haemodynamic instability. With close to a million PCI procedure records in the dataset, the BCIS dataset has allowed researchers to study some of the rare complications of PCI procedures and compare treatments/ strategies in different cohorts of patients which will not be possible in a randomised control trial(19,21,27). Public reporting of adjusted outcome analysis has allowed service providers and individual operators to compare performance against high-quality national benchmarks.

As with all other registries, BCIS registry is also subject to certain limitations. Although, almost all NHS hospitals contribute to the dataset in the UK, data collection from the private sector has been less rewarding. However, this only constitutes less than 5% of the overall PCI activity in the UK. It is also important to mention that although the mortality data is robustly tracked via linkage to ONS, cause of death is not available from this linkage. Other outcome data within the registry such as complications are self-reported and may be subject to significant under-reporting. Furthermore, as post discharge data are not collected, these complications and outcomes cannot be assessed from the dataset.

**Access to data:** Applications for access to BCIS registry for research and audit purposes are welcomed by NICOR, who in close collaboration with BCIS research executive group reviews all applications at their Data Access Request Group (DARG) meetings. The data application forms can be downloaded from HQIP website(<https://www.hqip.org.uk/national-programmes/accessing-ncapop-data/#.XGaBazP7RPY>), and submitted electronically via email.

**Conclusion:**  The BCIS registry has evolved from a survey of interventional practice derived from a small number of hospitals to a national programme collecting data from almost every single PCI procedure performed in the UK. Consequently, it has allowed high-quality national benchmarking of PCI practices both at the institution and operator level, thus improving overall care and outcomes of patients. In addition to being a useful audit tool, the BCIS registry has provided an important platform for observational research.

**Conflicts of interest:** none

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 Table 1: Minimum data standard fields requiring over 95% completion for successful data uploads.

|  |  |  |
| --- | --- | --- |
| **Variable field** | **Description**  | **Reason** |
| 1.03 | NHS number ( England & Wales) | For linkage to ONS and HES |
| 1.06 | Date of Birth | For age calculation required for risk adjusted outcome calculation |
| 1.07 | Sex | For risk adjusted outcome calculation |
| 2.03 | Procedural urgency  | For risk adjusted outcome calculation |
| 2.04 | Pre-admission cardiogenic shock | For risk adjusted outcome calculation |
| 2.07 | Date/time of symptoms onset | For delays to treatment calculations |
| 2.08 | Date/time of arrival at first hospital | For delays to treatment calculations |
| 2.13 | Prior Myocardial infarction | For risk adjusted outcome calculation |
| 2.16 | Diabetes | For risk adjusted outcome calculation |
| 2.18 | Weight | For risk adjusted outcome calculation |
| 3.02 | Consultant responsible for procedure (Name) | Used to assign procedures to the operator for the operator outcomes reporting |
| 3.09 | Number of vessels attempted | For risk adjusted outcome calculation |
| 3.26 | Date/time of first balloon inflation  | For delays to treatment calculations |
| 4.01 | In-hospital PCI outcome | To identify in-hospital complications |
| 4.03 | Status at discharge  | For in-hospital mortality  |
| 4.04 | Discharge date | For length of stay |
| 5.05 | History of CVA | For risk adjusted outcome calculation |
| 5.06 | History of renal disease | For risk adjusted outcome calculation |
| 5.26 | Date/time of arrival at PCI hospital | For delays to treatment calculations |
| 5.27 | Date/time of call for help | For delays to treatment calculations |
| 5.30 | Location of patient at onset of STEMI | For delays to treatment calculations |
| 5.31 | Consultant responsible for procedure ( GMC number) | Used to assign procedures to the operator for the operator outcomes reporting |
| 5.35 | Creatinine | For risk adjusted outcome calculation |

Table 2: In-hospital complications captured in BCIS dataset

|  |  |  |
| --- | --- | --- |
| Variable field | Complication  | Description  |
| 4.01 | PCI hospital outcome | * Q wave myocardial infarction (stable angina & NSTEMI patient only
* Non Q wave myocardial infarction (stable angina patients only)
* Elective CABG-patient stable and decision to send for elective CABG after failed PCI.
* Emergency CABG- as a result of complication.
* Arterial complication-not related to access site.
* Cerebrovascular event (embolic)
* Cerebrovascular event (Bleed)
* Transient ischemic attack/ Reversible ischemic neurological deficit
* Re-intervention PCI
* Re-catheterization (no PCI)
* Re-infarction (ACS patients only
* Blood transfusion
* Renal failure/ dialysis
* Cardiac Tamponade
* Platelet transfusion
* Gastrointestinal bleed
 |
| 4.03 | Status at discharge  | * In-hospital mortality
 |
| 5.19 | Arterial complications | * False aneurysm- conservative management
* False aneurysm- compression required
* False aneurysm- thrombin injected
* False aneurysm- surgical management
* Haemorrhage-no haematoma
* Haemorrhage- delayed discharge
* Haemorrhage-requiring surgery
* Haemorrhage-retroperitoneal
* Arterial occlusion
* Arterial dissection
* Any other surgical intervention
 |
| 6.02 | In-hospital bleeding | * BARC In-hospital bleeding Type 0-5
 |