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Implementation and quality assessment of a clinical orthopaedic registry in a public hospital department

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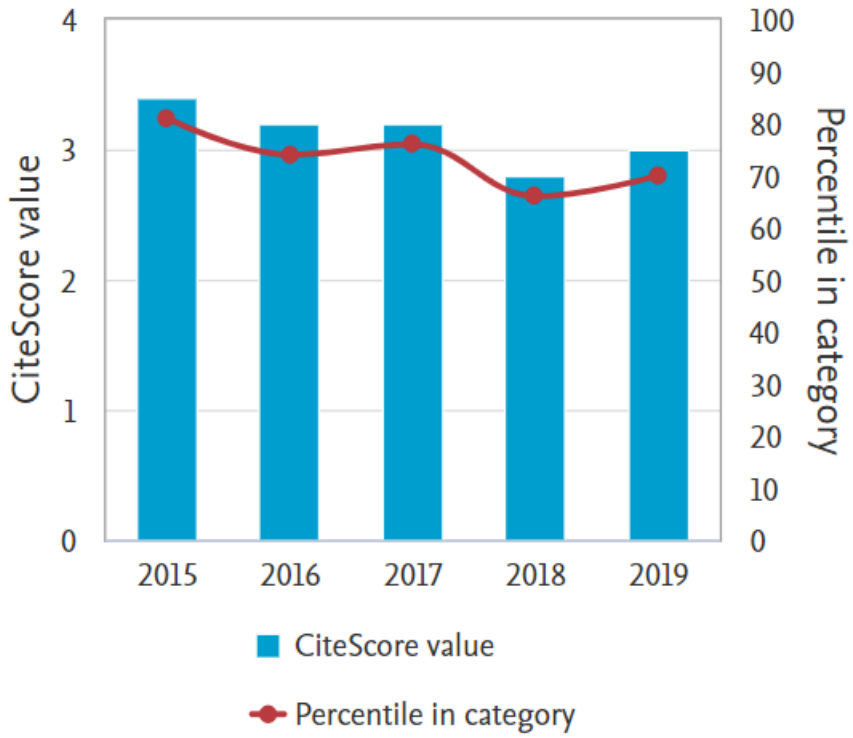

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Importants of registrie

- repositories for the collection of patient, treatment and outcomes data
- valuable tools for determining the natural history of a disease or condition
- evaluating the clinical performance and cost-effectiveness of healthcare services
- monitoring the safety and quality of patientcare.

Necessities of implementing a registry

- methodical planning
- execution and management
- clear pre-defined purpose and dataset.

Why The framework data collection and data quality assurance is necessary?

- limit bias in:
  - patient selection
  - information collected
  - Confounding
- minimise inaccurate and incomplete data.

Quality assessment of registry data:

- traditionally
  - completeness
  - Accuracy
- newer model institutional arthroplasty registry
  - adherence
  - completeness
  - Accuracy

The aims of this study were therefore threefold:

- Firstly,to report on the implementation of a quality controlled multiple-cohort clinical orthopaedic registry at a single public hospital
- secondly to describe a novel model of registry quality assessment for a multiple-cohort registry
- thirdly to report the changes in quality metrics of the registry during its initial operation.
- We hypothesise that the framework for data collection and established quality system would detect issues and contribute to quantifiable improvements in registry quality over time.

Registry implementation

Patient Recruitment

Data collection protocol

Model of quality assessment

Registry implementation

- Ethical approval for the registry by the Metro South Health Human Research Ethics Committee
- registered on the Australian New Zealand Clinical Trials Register
- A framework for the registry was established at its onset and comprised six observational, prospective cohorts consisting of shoulder and knee pathologies that were of research interest to the senior author.
- Each cohort was defined by a pathology and primary diagnosis appropriate for surgery (Supplementary file 1), as well as a research and analysis plan.
- A core dataset, comprising a minimum list of variables to be collected [4], was composed for each registry cohort (Supplementary file 2).

Registry implementation

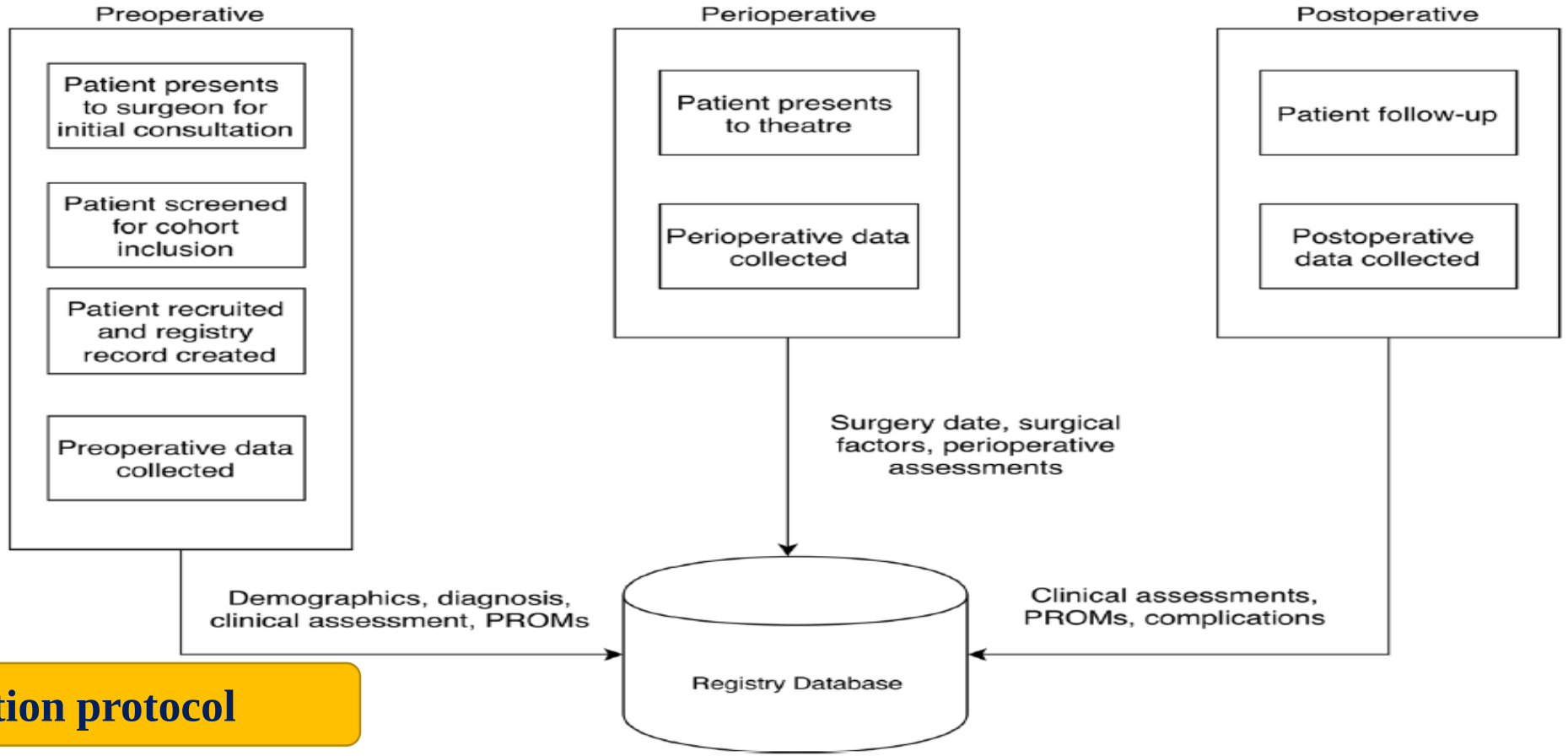
- The core dataset consisted of common variables pertaining to patient demographics, diagnosis and surgical details, clinical evaluations observed prior to, during surgery and at follow up, as well as cohort specific questionnaires to capture region, pathology and treatment related patient reported outcomes measures (PROMs). The data characteristics for each variable, including data source, timepoints for data collection, as well as allocation of responsibility for the collection and entry to registry database, were defined for the core dataset of each registry cohort.
- The data collection protocol was documented in a registry manual for reference and training purposes, and stored on a secure website accessible by key staff contributing to the registry.
- A quality assurance plan comprising a quality framework and auditing schedule (described further in the following sections) was formulated to ensure data captured to the registry was of acceptable research quality.

Patient Recruitment

via consultation with the senior author during outpatient clinics.
An initial diagnosis was formed on patients presenting with shoulder or knee pathologies as per the standard clinical pathway.
Patients were screened into the appropriate cohort based on primary diagnosis (Supplementary file 1) and indication for surgery.
provided written informed consent for the collection of clinical data for research purposes.
General exclusion criteria were a patient's unwillingness to participate in data collection or revocation of consent for research use of personal data.

Data collection protocol

The data collection team: clinical administrative staff, clinicians and the registry custodians
Communication between the data collection team was established using live electronic messaging.
The data collection protocol (Fig. 1) included collection of reoperative, perioperative and postoperative data as per the individual cohort-specific core dataset.
A treatment record for a patient was created by the registry custodians within the registry's database software (Socrates v3.5, Ortholink Pty Ltd., Aus) upon confirmation of diagnosis, cohort and registry recruitment.



Data collection protocol

Data collection protocol

Data collection pre- and postoperatively involved the completion of standardised patient questionnaires that were collected by the clinical team and scanned electronically to the registry custodians.

Data from the scanned forms were manually entered into the registry's software under the patient's treatment record and stored on the electronic database.

Surgical findings and procedure details were entered directly into the software on the day of the procedure.

Postoperatively, registry participants returned to the outpatient clinic for scheduled follow up. Weekly outpatient appointment lists were cross checked against treatment records by the registry custodians to identify patients who were due for data collection. These patients were flagged to the surgeon's team for collection of clinical data and questionnaires specific to the respective cohort and postoperative time point.

Model of quality assessment

The quality assurance framework consisted of three quality assessment domains, and **definitions of auditing schedule**, **roles** and **reporting lines** to assess the accuracy and quality of the data recorded in the registry.

Data were extracted at monthly to quarterly intervals by the registry custodians during the implementation of the registry as per the schedule on the quality assurance framework (Table 1).

Quality metrics were reported to stakeholders within the Registry Governance Steering Committee, which included participating surgeons and primary investigators, the registry custodian team and representatives from clinical staff or information technology personnel as needed, to identify problem areas, refine collection and organisation procedures, as well as address any gaps in datasets that could be retrieved retrospectively from clinical records.

Table 1 Quality Domain assessments

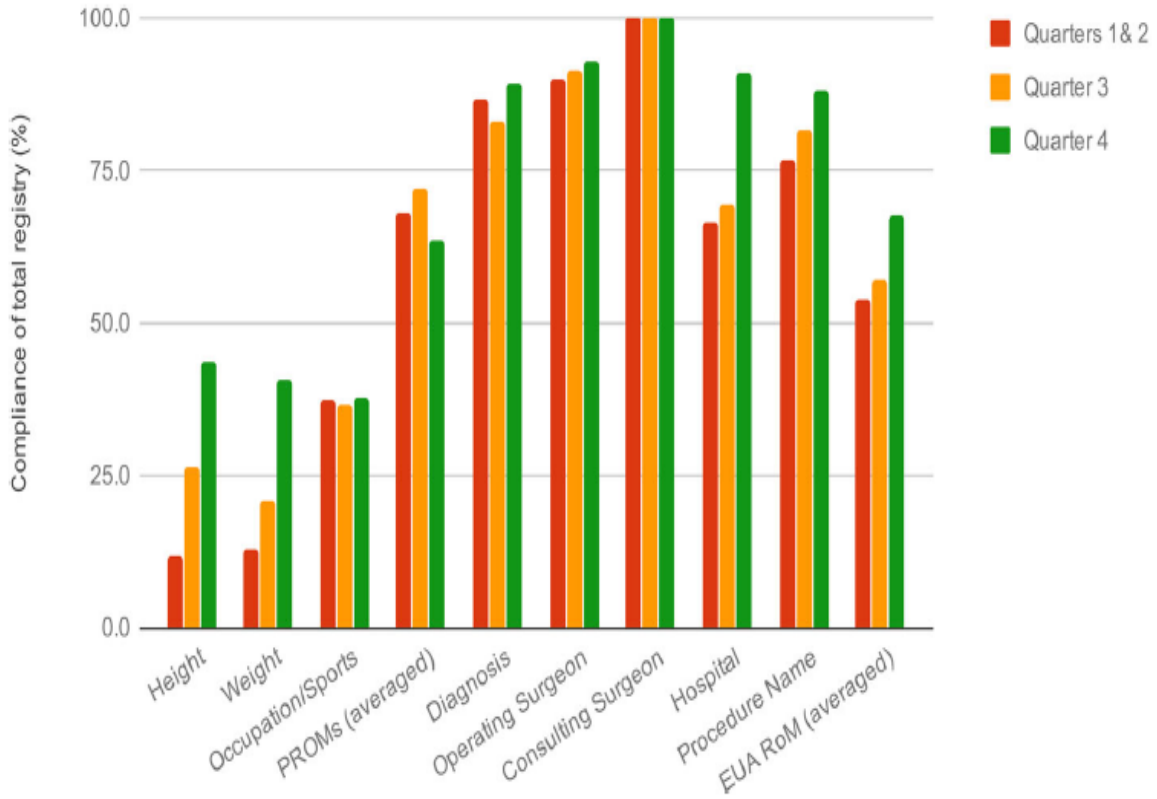
Quality domain	Completeness		Consistency	Validity	
Level of assessment	Registry	Cohort	Registry	Internal	External
Domain objective	Assess the capture of participants to the registry	Assess the capture of data within specified cohorts	Assess the accuracy of placement of patients into correct cohorts; identify issues with data capture and entry (e.g. transcription errors)	Assess the accuracy of patient-specific data records as a true reflection of individual clinical data and reported outcomes	Assess the reliability of aggregated cohort data against benchmarks determined from evidence based literature
Method of assessment	Ratio of treatment records in the registry to number of patients eligible for participation in the registry. Calculated by checking archived consult lists containing patients assigned to a cohort against treatment records stored in the electronic database.	Ratio of data captured for patients' treatment records compared to the total number of variables within the CDS for each cohort. Calculated by dividing the number of patients at time (x) with data (i) available, by the number of patients eligible for collection of (x)(i). Assessed for all treatment records entered into the registry.	All treatment records were retrieved and diagnosis was checked against cohort inclusion and exclusion criteria. Any cohort assignment that did not match the diagnosis was flagged and the contributing surgeon notified. Outlier analysis utilising quartiles method was performed on current age, age at surgery, height and weight. Assessed for all treatment records that had a diagnosis entered into the registry.	Validate individual patient data records to original data / patient submitted forms. Determined by comparing source data and data transcribed to the registry software. Data validation performed by a registry custodian member who was independant to data entry. Assessed for all treatment records entered into the registry.	The highest quality evidence of appropriate patient outcomes were used to benchmark aggregated cohort PROMs data. Assessed for all treatment records with PROMS data captured to the registry.
Audits performed during pilot period (July 2017 - Aug 2018)	12	6	6	4	4
Benchmark	90% [9, 13]	90% [9, 13]	95% set internally by registry custodian team	90% [9, 13]	Varied depending on PROM

registry completeness

- Quality auditing of registry completeness against source lists from the hospital revealed an overall capture rate of 96.8 and 94.3% treatment records in the first and second quarters, respectively. Discrepancies in registry completeness were detected by an internal validation audit revealing a lack of registry record for these patients, despite complete records for PROMs retrieved.
- Once these missing patients were accounted for, a capture rate of 100% was achieved in the third and fourth quarters.

cohort completeness

- Individual patient cohort completeness for the predefined data sets was less accurate, ranging from 10 to 100% for common patient information across the registry such as height, weight and occupation/sport status and PROMs (Fig. 2). There was an upward trend in the rates quarter by quarter, with only a reduction in Quarter 4 for the PROMs.
- Validation of digital registry records against source data was completed for patients returning paper forms (100% return rate) for PROMs (Fig. 4).
- Through Quarters 1 and 2, 3.1 and 14.1% of returned paper forms were not entered into the registry. Additionally, comparison between paper and software records indicated that by Quarter 1, 10.4% of surveys were transcribed incorrectly into the digital record, which increased to 14.1% by Quarter 2.



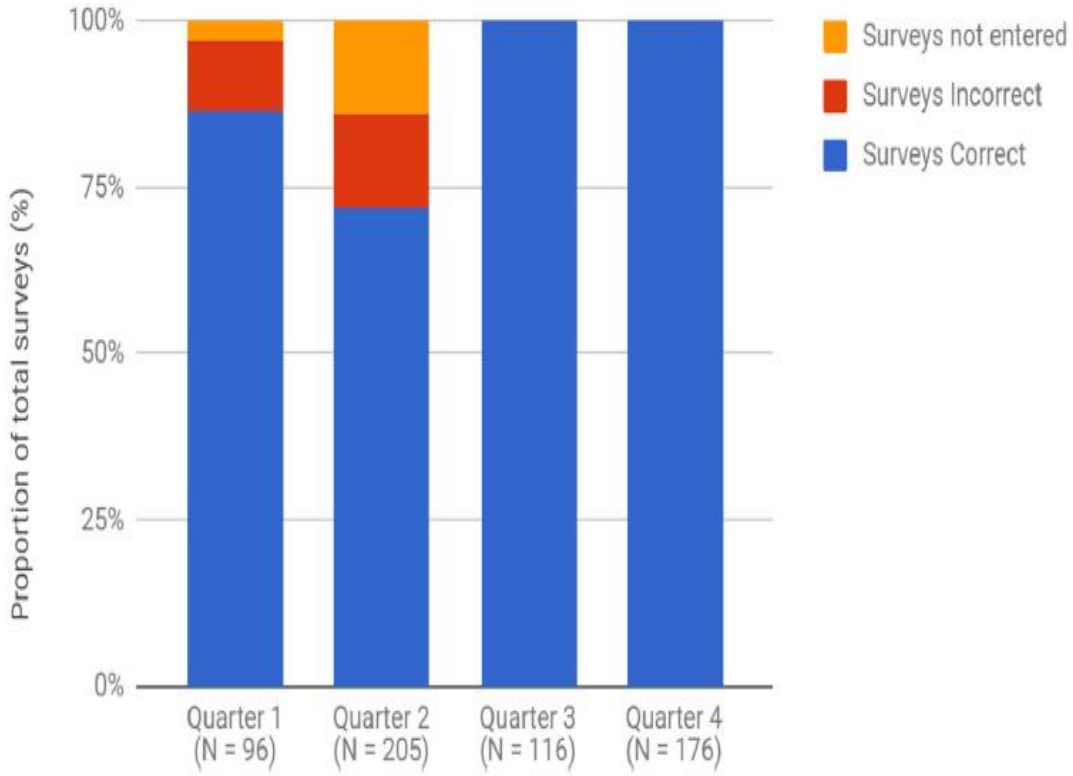


Fig. 4 Internal validity of PROMs over the pilot period

Procedure evolution

- A team approach was used to implement changes to the patient and clinical data capture processes.
- The first concerned the uploading of patient surveys to the registry. While patient questionnaires were initially scanned into the registry, the audit analysis indicated inadequate print quality, insufficient scan resolution and failure to follow the correct response format by patients were likely contributors to poor data quality.
- The process was altered from Quarter 3, where by clinical staff scanned patient forms to a mutually accessible folder, with the research custodian team **transcribing the data to the registry** software.

Procedure evolution

- The second change was in response to survey packs missing data variables (such as height and weight) and a reduction in PROMs data quality by Quarter 4. This was rectified by directly scanning the clinic pre-admission screening form, which contained these fields, for subsequent patients from Quarter 3.
- Data entry processes were also changed for Quarter 4, with restrictions placed on transcription of ambiguous responses and formalisation of the definitions of ambiguous patient responses.
- This was particularly problematic for PROMs containing visual analogue scales or questions with tables of responses.
- Both clinicians and patients were given updated instructions and additional education with regards to the PROMs forms.The instructions and layout of the forms were also modified to guide patients in completing the surveys more accurately.

Procedure evolution

- **Thirdly**, mismatches were observed for some patients between the cohort they were placed within the registry and their recorded diagnosis in Quarter 3.
- Analysis revealed that the addition of new diagnoses to the registry software had not been updated simultaneously in the quality audit framework.
- In addition, outlier analysis revealed discrepancies in age at surgery and weight consistency in Quarter 3, which were caused by a defect within the registry software, which was subsequently addressed with the vendor.
- Messaging also allowed for real time alerts from clinicians regarding new patients to be added to the registry.

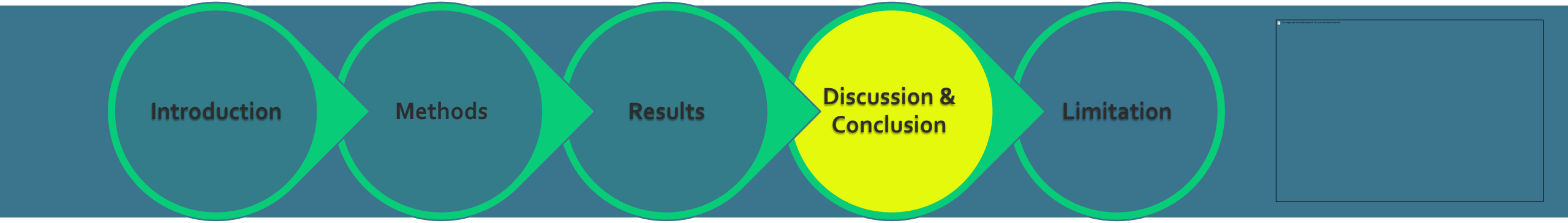
Table 3 Novelty of auditing methods introduced relative to contemporary literature. *CDS - core dataset*

Quality Audit	Completeness		Consistency	Validity	
Level of Assessment	Registry	Cohort	Registry	Internal	External
Definition as per current study	Ratio of treatment records in the registry to number of patients eligible for participation in the registry	Proportion of data captured for patients' treatment records compared to the total number of variables within the CDS for each cohort	Accuracy of placement of patients into correct cohorts	Accuracy of data in registry validated against original data / patient submitted forms	Reliability of data against evidence based literature benchmarks
Current study	✔	✔	✔	✔	✔
Bautista et al. 2017 [13]	✔ "adherence"	✔ "completeness"		✔ "accuracy"	
Torre et al. 2017 [7]	✔ "Completeness" or "quality rate"				
Seagrave et al. 2014 [8]	✔ "registry completeness"	✔ "Cohort completeness" (Demographic, administrative, medical history, procedure and acute care details only. PROMs were not audited.)		✔ ("accuracy")	
Barr et al. 2012 [9]	✔ "completeness"			✔ "accuracy"	
Espehaug et al. 2006 [10]	✔ "Completeness"				
Arthursson et al. 2005 [12]	✔ "Completeness"			✔ loosely described	
Fender et al. 2000 [11]	✔ "Completeness"			✔ "inaccuracies"	

- Our model of quality assessment is a novel three-pronged approach to evaluate the completeness, consistency and validity of patient data captured within a clinical registry. In essence, our completeness assessment covered both the “adherence” and “completeness” assessments proposed by Bautista and colleagues [13], while our appraisal of “accuracy” via a combination of consistency and validity auditing could be considered a more robust method.
- We believe that these two additional auditing methods, not previously considered in the literature, lead to a more comprehensive assessment of registry data quality. Consistency of the data contained in the registry provided timely indications on the accuracy of data transfer or problems with data entry that may render the data unusable for analysis.

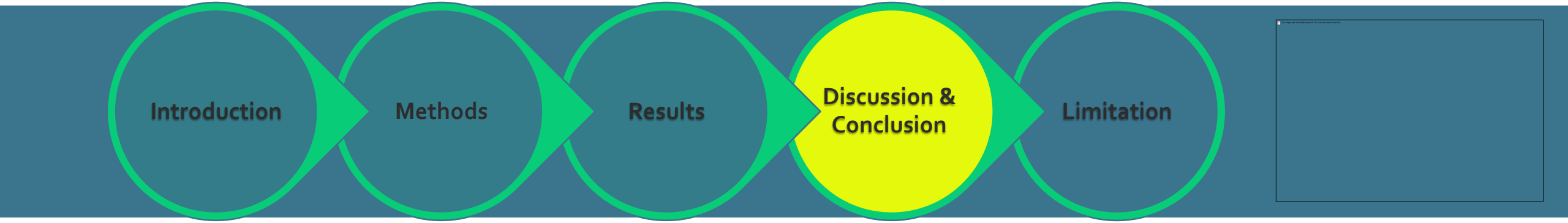
- External validation provides verification that PROM scores are being administered as intended, and determines whether the aggregated outcome of a treatment reflects broadly across all patients. However, comparison of present quality metrics to previously established registries requires careful consideration due to inconsistencies and disparity in the definition of terms referring to the completeness, adherence and accuracy of data (Table 3).

- Despite the lack of gold standard for completeness,consistency and validity in orthopaedic registries, rates above 90% [9, 13] or 95% [8] have been described as acceptable in the literature.
- This study reports a 100% capture rate at one year with respect to registry completeness, consistency and internal validation after deficiencies in data capture processes were addressed.
- Reports on registry completeness, in relation to the capture of eligible patients for participation in a clinical registry, are varied in the literature, ranging from 50 to 98.7% [7–9, 13]. Registry completion was determined to be highly dependent on the participation of both patients and staff to the collection of clinical data for monitoring purposes.



- The present findings demonstrate the importance of detailed and regular auditing and reporting for data quality. The novel quality assessment methods proposed within this study enabled identification of causative issues such as problematic data entries, transcription errors and ambiguous patient responses to questionnaires, and facilitated the implementation of strategies to improve data collection processes, with demonstrable improvements in data quality.
- Ongoing audits also provided a feedback mechanism to assess the effectiveness of changes to registry data entry processes, leading to improvements in internal validation and registry completeness.
- Furthermore, non-quantifiable changes such as improving communication, education and training led to improvements in data quality as reflected by the high registry completeness rate observed, confirming communication as a key factor in the success of a quality controlled registry

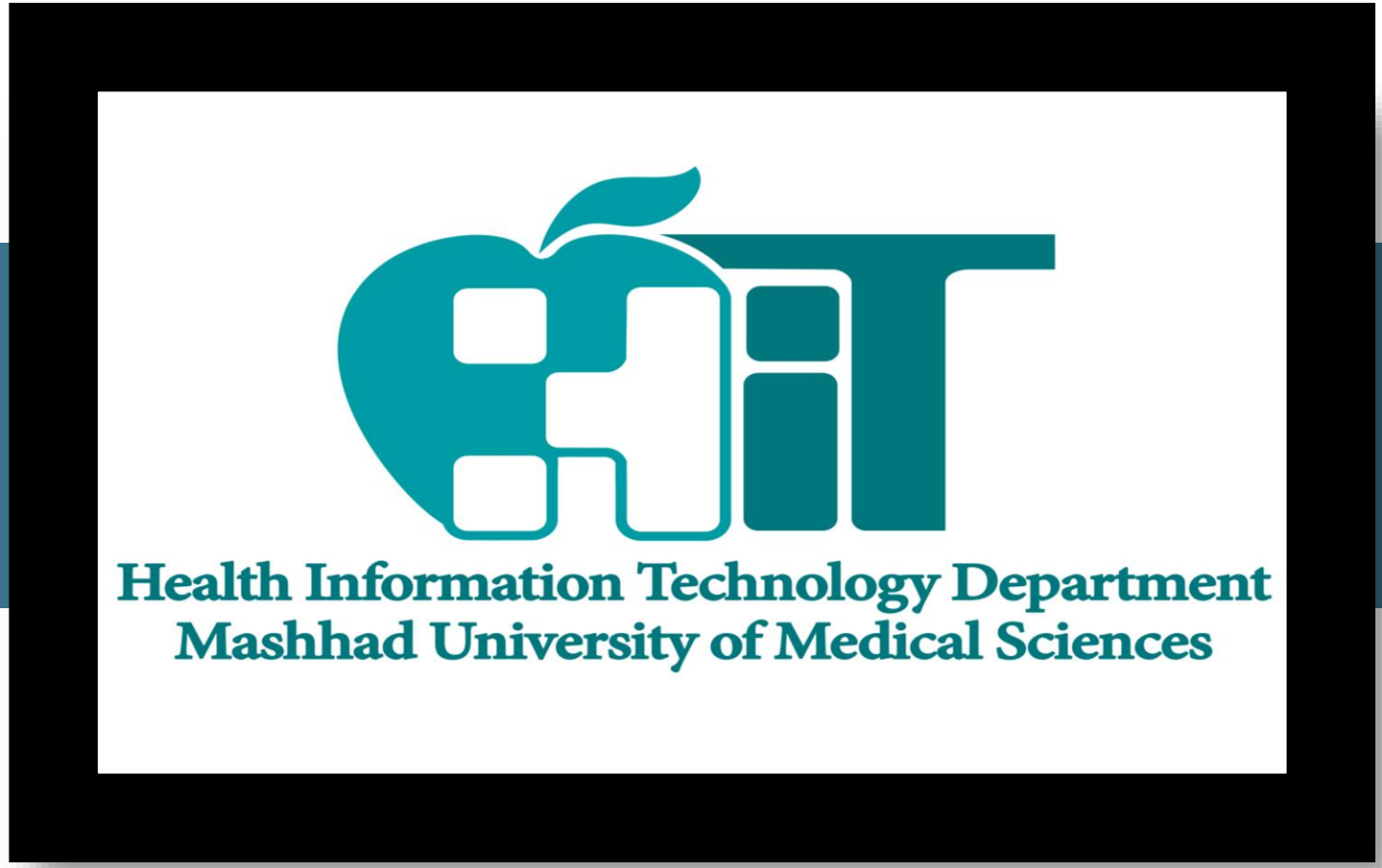
- In the future, the registry will transition to the use of electronic surveys which should assist with automating quality assessment and subsequently improve data quality.
- There is an emerging body of literature indicating the strength of mixed-mode capture of PROMs, with greater reliance on electronic methods [15–17].
- With the advent of digital hospitals, we may also see data populated in accessible systems as a by-product of normal clinical activity.
- Additionally, a research nurse may also be of benefit serving as permanent personnel responsible for coordination of the registry.
- Ensuring PROMs surveys are completed accurately prior to a patient's departure from the clinic would also have a large impact on cohort completeness.
- With time and refinement, more surgeons and other cohorts will be added to expand the registry within the department.



- A unique framework targeting multiple aspects of data completeness, consistency and validity paired with comprehensive, regular auditing and feedback contributed to superior data quality in a short time period.
- Improvements in registry quality over time can be clearly observed.
- This model can be replicated in other registries to improve clinical impact and ensure applicability of the data to aid clinical decisions, especially in newly implemented registries.

- Firstly, our study was conducted over a relatively short period of about 12 months.This limited the improvement seen over the pilot period, especially with respect to cohort completeness, despite improvements made to the registry framework and its processes.
- A longer period of study could identify additional errors and allow more substantial improvements in data quality to be observed.
- Additionally, manual quality assessment on all records is not feasible for a larger cohort, so the approach listed above would need to be adapted once a newly implemented registry has been operating for some time.

Thanks for Your Attention



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