International Council of Cardiovascular Prevention and Rehabilitation (ICCPR)

International Cardiac Rehab Registry (ICRR)

Data Quality Policy

The International Cardiac Rehabilitation Registry (ICRR) is an initiative of the International Council of Cardiovascular Prevention and Rehabilitation (ICCPR), with the goal to enable assessment of cardiac rehabilitation (CR) quality in low-resource settings, with the aim of ultimately improving patient outcomes.

The ICRR is governed by a steering committee, informed by a user and research sub-committee who shall work to promote data quality. See: https://globalcardiacrehab.com/ICRR-Governance

The quality of ICRR data is fundamental to achieving our aims, including data accuracy and completeness, as well as generalizability, validity and reliability. The aim of this data quality policy is to ensure the utmost scientific integrity of the ICRR data and hence credibility of derived conclusions. Specifically, the objectives are:

1. To establish Data Quality Governance and Management processes.
2. To ensure adherence to the Data Quality Procedures.
3. To delineate Data Quality Audits, to enable assessment, periodic monitoring, maintenance and improvement of data quality.
4. To specify processes for Data Quality Improvement

It is recognized that ICRR data quality will not be 100%. Moreover, there is seldom a "gold-standard" for data accuracy, and where patients report data directly, accuracy of data cannot be checked. However, ICCR aims to use training and auditing processes to optimize registry data quality.

ICRR shall make every attempt to ensure no site shall be identified / named through enacting the processes outlined in this policy; site identity shall be restricted to only those required to enact the policy (i.e., the ICRR secretary, statistician, and research sub-committee Chair where possible), who shall respect site privacy to the greatest extent possible. Patients shall remain anonymous, identifiable only by registry ID#.

It is the goal of ICRR to work with contributing sites to identify any data quality issues early, so mitigation actions can be implemented at the program level (e.g., steward education, log review practices, capturing missing data, consideration of variable assessment protocols), but which likely are relevant to most contributing sites.

Site Training

Promotion of data quality from the outset is primary. The ICRR-Site agreements outline principles to support this.

The ICRR user sub-committee shall provide a review of the data dictionary and registry in a web meeting with all new sites. The new data stewards must participate in the on-boarding web call; Data stewards may not enter data into the registry until training is complete.

If changes are made to the ICRR (e.g., interface, variables, assessment points, procedures, system enhancements), ICRR shall engage sites to train them for change management.

Design of ICRR to Promote Data Quality

ICRR underwent a rigorous process to select variables, and to keep them at a minimum to minimize incompleteness. Any changes to variables will only be made with consultation of participating sites.

ICRR's data dictionary (https://globalcardiacrehab.com/ICRR-Variables-&-Data-Dictionary) is very explicit to reduce any potential ambiguity or variation and to ensure consistency across various contexts. All data definitions are available within the registry interface by hovering over the white bubbles with blue "i"'s.

All but one variable has discrete response options, or are continuous but have pre-specified ranges to minimize the potential of entering implausible values. There is only one "free-text" field, for patients to specify other comorbidities.

ICRR has recommendations for data stewards to ensure those entering data are qualified. The ICRR protocol specifies clearly which patients should be entered, and the site agreement specifies timelines when patient data should be entered (first entry, by assessment point, and follow-up).

To ensure follow-up assessments are completed in a timely manner, on the main "my patients" screen, patient records will appear as yellow where assessment is past due. Programs are asked to ensure all assessments are up-to-date: within 2 weeks for post-program assessments and 1 month for annual assessments.

Programs can also export their data to check it for outliers or incorrect entries.

The outcome dashboards (programs can compare themselves over time and also to all other programs in the registry; see information file on dashboards. The exact dashboard values are shown in the "activity report" log) may also alert programs to potential data quality issues. For example, if overall values are not in the expected range, this could represent a data quality issue or quality improvement need. These dashboards are available once the program duration has passed from site ICRR initiation so timeliness can work to identify any issues as early as possible, in line with our principles.

Data Completeness, and Retention (Program and Patient)

ICRR hopes to capture patient recruitment strategies through the program survey (e.g., are programs situated in institutions with inpatient units so selection bias could be assessed) and work with contributing sites to understand any environmental influences on data collection.

ICRR has a data completeness dashboard. Each site can view the completeness of each variable at each assessment point. This is compared to all sites, and color-coded. The information file on the various reports specifies how completeness at post-program and for annual assessments is calculated (i.e., where patients pass away).

For sites where patients are reporting data, there is also a "patient report log". Sites are to check it every 2 weeks, and follow-up with patients who have not yet responded. This can include collecting the information via patient interview and entering it to the registry manually.

Data completeness challenges to be expected:

Only the year of birth and gender variables are mandatory as we understand participating programs are operating in low-resource settings, and therefore they may not be able to collect all variables. This could lead to incompleteness which may not be rectifiable.

Moreover, some sites may not be able to secure approval for patient report, and even where they do, some patients will not consent to it or have the capacity to provide data (e.g., no device to receive the surveys, lack of English-language proficiency). No site will be penalized for this, but ICRR will work to minimize bias introduced to ICRR for these reasons (e.g., see policy on our website regarding translation of patient-reported items: https://globalcardiacrehab.com/ICRR-Variables-&-Data-Dictionary).

We also understand that contact information for all patients, and perhaps more so for those in low-resource settings is subject to change. Therefore, retention for the annual follow-ups will not be optimal, but we will work together to optimize it as possible.

Finally, CR programs may have changes in staffing etc. which may render it difficult to complete continued annual assessments. ICRR will work with programs to find work-arounds where possible.

ICRR-Level Data Quality Audits

Due to geographic and financial limitations, ICRR cannot visit participating sites to audit data quality and review adherence to registry protocols. Also due to privacy considerations, external chart review is not possible.

Nevertheless, participating sites will be engaged to assess data quality over-and-above site-level best practices outlined above. ICRR's research sub-committee shall centrally, with support of the Secretary and statistician, also audit data quality through several mechanisms as outlined below every 6 months.

a. Completeness reports shall be monitored, with particular consideration of where incompleteness maybe systematic rather than random and where retention may be problematic. Programs in the lowest 15% for data completeness at each

assessment point shall be contacted (percentage may change as the registry matures).

b. The research sub-committee shall also examine internal consistency of data (e.g., patient reported as expired post-program but annual data provided, or large increases in LDL values from pre to post-program).

c. Random audits of coverage / representativeness and data accuracy shall be undertaken proactively by ICRR. Two sites shall be selected every 6 months; sites providing data through electronic upload shall also be considered. Selected sites will be ineligible for reselection until/unless all participating sites have been audited.

   One patient ID shall be randomly selected by ICRR from the site's roster. Selected program data stewards shall be contacted and asked to arrange for another party (potentially another data steward who did not enter data for the specific patient, but if no other data stewards are available and independent third party who complies with all privacy and access requirements) to independently (blinded to entered data) extract each program-reported variable for the patient at each assessment point available and provide this to the ICRR research sub-committee. Level of agreement between entered data and provided data shall be computed.

   The local independent auditor shall also be engaged to audit registry coverage at the site level. ICRR shall randomly select a specific month of all months in which the site has been a member of the ICRR. First, where the site has an inpatient cardiac unit, the local auditor will be invited to determine the number of CR-eligible inpatients discharged during the month under consideration. Second, the local auditor will also be asked to investigate the number of referrals received by the program in the given month, to consider the proportion of these patients that meet ICRR inclusion/ exclusion criteria (see protocol at: https://globalcardiacrehab.com/ICRR-Governance), and to search for some of the patients by year of birth and sex.

Responses shall be determined based on findings, with several avenues outlined below.

Data Quality Rectification: Corrective and Preventive Actions

Results of data completeness and quality audits shall be fed back to program stewards. The program data steward shall be engaged where data inaccuracy or incompleteness has been identified as a potential issue to explore types, causes and frequencies of data discrepancies, through a structured interview. Sites will be asked to verify data issues, revise data as applicable (including removal of potential duplicate entries), and document. The site will be engaged to explore the root causes of sub-optimal data, and set goals for rectification with a mutually-agreed timeline.

Where warranted, remote audits of site data may be performed using videoconferencing, while maintaining participant anonymity.

Some data quality issues may be considered more urgent, and timely action initiated.

The research sub-committee shall share findings of audits with the user sub-committee, again without site identification. The user sub-committee shall consider learnings from the findings (e.g., need to revise training, need to educate participating programs) and whether corrective and preventive actions could be warranted at a registry-level. Where applicable to other sites, the sub-committee shall communicate them with all participating programs; This could be achieved through several means, including email (e.g., helpful tips, troubleshooting FAQs) or webinars.

The ICRR Steering Committee reserves the right to terminate relationship with sites with thirty (30) days prior written notice, if there are serious and continuing problems with data quality that are modifiable, and the site fails to engage in data quality rectification (both corrective and preventive actions) in good faith where feasible. Upon termination of the Site Agreement for the above reason, with recommendation from the research sub-committee, the ICRR Steering Committee will decide whether to retain some or all, or destroy all data received from the site to ensure the utmost integrity of ICRR data. This precludes any data that has already been aggregated into currently circulating datasets.

Some issues identified could be prevented with ICRR system enhancements or policy. We will also work with the broader CR community to pursue electronic upload of variables where possible.

Data Quality Reporting

The ICRR research sub-committee shall annually report to the ICCPR steering committee their data quality activities and findings. ICRR recognizes that the way the registry is designed may also need revising to reduce data entry errors; findings shall be considered in this light.

Each ICRR annual report shall include information on data quality for transparency. Data quality and missingness shall be considered in all analyses. Procedures for handling missing data shall be stated fully in all reports. Any known data quality issues shall be transparently reported as limitations.

ICRR may also enter into discussions about data quality learnings with other CR registries through the liaison sub-committee. ICRR will also inform applicants securing access to ICRR data regarding data quality, support them to mitigate it through analytic approaches as possible, and promote transparent reporting.

ICRR aims to consider generalizability as a means to reveal how well we meet our defined purpose.

SOURCES:

1. https://bmjopenquality.bmj.com/content/8/3/e000490
2. Available data quality policies from other CR registries.