The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) Outpatient Cardiac Rehabilitation Registry

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A. REGISTRY OVERVIEW

1. Purpose of the Registry

The purposes of the AACVPR Outpatient Cardiac Rehabilitation Registry (“the Registry”) are:

1. To track and analyze aggregated clinical, behavioral, and health outcomes of patients who enroll in outpatient cardiac rehabilitation (CR).
2. To track and analyze enrollment, completion, and other measures of CR utilization across the country.
3. To monitor adverse events and hospital readmissions that occur in patients enrolled in CR.
4. To provide participating programs with aggregated data that can be used for quality improvement projects, and with comparative data for performance review.
5. To provide data that highlight CR services as a fundamental aspect of comprehensive cardiac care.

2. Background and Significance

Outpatient cardiac rehabilitation (CR) is an underutilized service with less than 20 percent of eligible patients participating. Although recognized as a standard of care by the American College of Cardiology (ACC), American Heart Association (AHA), American College of Chest Physicians (ACCP), and AACVPR, CR is not well integrated into standard medical care for patients with cardiovascular diseases, even with strong evidence to indicate improved clinical, behavioral, and health outcomes.

AACVPR is a professional society of more than 2,500 members dedicated to the advancement of cardiovascular and pulmonary rehabilitation services for patients with heart, vascular, and lung disease and to the support of professionals working in these programs. AACVPR has advocated for the collection and management of patient-centered outcomes in CR since the establishment of an Outcomes Committee in 1992. This position has been strengthened with the publication of the latest position statement on CR outcomes in 2004.

Research has shown that participation in comprehensive CR offers benefits to patients in terms of improved mortality, morbidity, physical function, and quality of life. To accrue these benefits, however, patients must be referred, enrolled, and complete the CR program. Therefore, to better promote CR’s benefits to patients, physicians, hospital administrators, healthcare payers, and regulatory agencies, it is critical to obtain real-world information on CR utilization as well as performance in attaining secondary prevention goals. In addition, outcomes data across programs can identify high-performing programs with respect to secondary prevention outcomes, and
identify procedures that lead to better outcomes. For these reasons, and to assist programs in measuring their own performance, AACVPR is developing an outpatient CR outcomes registry (“the Registry”).

The goals of the Registry will be to collect data on outcomes of patients participating in comprehensive CR, to promote research to identify disparities in performance, and to improve utilization of CR services. In particular, the data from the Registry will be used to:

1. Assess local and regional disparities in CR utilization and patient outcomes.
2. Assess CR utilization and outcomes in underserved populations, including women, minorities, and patients of low socioeconomic status.
3. Assess the long-term mortality of patients based on their CR completion status, duration of CR participation, and number of CR sessions.

Research to answer the above areas will be done with limited or fully de-identified data sets as required. Linkages to other clinical or administrative databases will be done using “indirect identifiers” (e.g., date of birth, service dates, sex) and probabilistic matching methodology whenever possible.

B. METHODS

1. Registry Design and Procedures

AACVPR will own and operate the Registry. Oversight will be provided both by the AACVPR Board of Directors and by the AACVPR Registry Committee, a subcommittee of the Clinical Applications Committee. The Registry Committee reports to the AACVPR Board of Directors. The Registry Committee will provide strategic direction for the Registry and monitor clinical activities and research, including the following:

- Set a high-level agenda for the strategic direction of the Registry.
- Advocate, promote, and influence key groups (patients, AACVPR members, hospital system administrators, corporate sponsors, professional liaison groups, healthcare payers, and healthcare regulators) regarding Registry activities.
- Identify new opportunities and strategies to further promote utilization of the Registry in CR programs.
- Establish working groups as needed to support specific projects.

The Registry data set was created under the leadership of experts in CR from the AACVPR Registry Committee and with critical input from clinicians in the field regarding the feasibility of implementation and the burden of data collection. The Registry Committee was charged with initially outlining a set of key quality metrics to measure and describe the outcomes and quality of care of patients in CR, using existing secondary prevention clinical practice guidelines as a guide. Through the evaluation of existing research and clinical experience, a comprehensive set of data elements and definitions were created in order to capture the clinical characteristics, indications, procedural aspects, and adverse outcomes of patients enrolling in CR. These data
elements and definitions were subjected to several reviews and refinements and alpha and beta site review in order to gain consensus on the final data elements and definitions.

The Registry data set comprises approximately 180 data elements. *(A copy of the current data elements list can be found at www.aacvpr.org/CRregistry.)* HIPAA-defined patient identifiers are included in that data set: the patient’s last name, date of birth, and ZIP code; the local hospital’s medical record identifier; and dates of program-related events (enrollment, discharge, follow-up) and healthcare-related events (hospital readmissions, labs). The primary purpose for collecting these identifiers is to allow for the accurate tracking by the participating program of ambulatory performance measures that are patient level (as opposed to encounter level). To accurately assess program adherence to performance measures based on ACC/AHA clinical guidelines, the Registry must be capable of attributing multiple encounters to an individual patient, thus requiring patient identifiers. Secondary purposes include longitudinal analysis of measure compliance and outcomes, as well as future registry interoperability with existing Medicare administrative databases (thus enabling transitions of care analysis across practice setting). The ability for CR clinicians to understand their measure compliance on a patient-by-patient basis is one of the most common requests for a registry such as this.

The Registry has been developed by Cissec Corporation, a Canadian company with experience in developing clinical applications. Data entry will be either through a customized Web-based interface or via batch upload transactions from third-party ECG-telemetry applications or other electronic data systems. Industry standard security measures will be incorporated to secure data. *(See Section 3: AACVPR Data Management.)*

Participation in the Registry will be voluntary. CR programs will join the Registry by agreeing to the terms of the Participation Agreement (a contract document that outlines the obligations of each party for participation) and paying an annual subscription fee based on program size. The Participation Agreement includes a Business Associate Agreement per the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and a limited Data Use Agreement that specifies the rights and responsibilities of both the participating program and AACVPR with respect to data access and what data participating programs and AACVPR can use for performance monitoring and publication. *(The Participation Agreement is available for download at www.aacvpr.org/CRregistry.)*

The Registry is a quality assurance database and does not involve human subjects research as defined by the Office for Human Research Protections. An independent review of this protocol has been carried out by a prominent academic institution’s Institutional Review Board (IRB). In its opinion, the Registry “does not involve human subjects research subject to the regulations in 45 CFR, part 46 and would not require IRB oversight.” Individual institutions, however, may require quality assurance activities to have IRB review. Participating programs will need to verify with their administration that participation in the Registry complies with institutional requirements.
2. Data Collection

The Registry will collect data on CR utilization and outcomes of patients who enroll in CR. It will collect and monitor clinical, health, and behavioral variables at entry and discharge from CR. Participating CR programs will create a record for each patient who is referred and enrolled in the CR program, with enrollment defined as the patient having had at least one (1) billable CR exercise session. Data are collected during the routine course of CR treatment for all patients who meet the inclusion criteria as stated below (Section 4: Selection of Subjects). Additional interventions, testing, or contact with the patient outside the normal course of treatment is not required.

Initial patient demographic and medical history information, including gender, age, presenting cardiovascular diagnoses, and comorbid conditions, will be entered when the patient enters the CR program. Baseline data will include metrics of body composition, tobacco use status, medications, functional status, lipid and fasting glucose values, exercise behaviors, and the results of user-selected assessment tools in the areas of nutrition, depression screening, and health-related quality of life. These measures will be obtained again at program discharge and at one follow-up interval as designated by the participating program.

A limited number of unique patient identifiers will be collected to allow data from the Registry to be linked to Medicare/Medicaid administrative databases and other data sources. This will allow AACVPR to monitor recurrent events and long-term mortality in patients who participate in CR. Identifiers include the patient’s last name, date of birth, and hospital medical record identifier; dates of rehab enrollment, discharge, and follow-up; dates of hospital readmissions that occur while the patient is participating in CR; dates of any adverse and/or unexpected events that occur during CR; and dates of lipid and diabetes measures.

Participating programs will be able to submit data at any time. Options for data submission will correspond directly with the program’s chosen data collection mechanism. All data, regardless of the mode of collection, are uploaded to a secure server using approved encryption software with the highest encryption that is allowed. (See Section 3: AACVPR Data Management.)

Methods for data collection

The Registry offers participating programs flexible data collection solutions – a Web-based data collection tool and an Application Programming Interface (API) wherein data can be batch uploaded from on-site databases that have been reviewed and certified as compliant with Registry specifications. Data collection methods vary across programs; a survey of potential Registry users, however, revealed that most programs collect data via third-party outcomes software applications. Each program will be responsible for selecting, operating, and maintaining its own data collection mechanism.

A. Direct entry

a. Users will be able to enter data directly on an Internet-based Web site. Individual users will be provided with unique login credentials. (See Section 3: AACVPR Data Management.) Users will be required to enter or edit registry data only on
computers owned by their parent institution to ensure more complete and effective online security.

B. Batch upload via API
   a. Cissec has developed an API that allows third parties to connect to the Registry. One-way communication with the Registry will be allowed. The party uploading data to the Registry will be responsible for the development of procedures to ensure that the uploaded data is valid and meets Registry definitions. Cissec will provide API documentation to assist developers and will work with third parties to test the API interface. Batch uploads will be able to be performed at any time.

3. AACVPR Data Management

Data security measures

Safeguards are in place to protect the security of AACVPR data. These safeguards include a combination of physical, technological, and administrative security measures.

The following physical safeguards protect AACVPR data:

- The AACVPR Registry is hosted on servers that reside in a facility that is secured with an alarm system.

The following technological safeguards protect AACVPR data:

- A 2048 bit SSL Certificate is used to provide RC4 128 bit encryption to encrypt information in transit when participating healthcare organizations are accessing the AACVPR Registry through a Web-based viewer.
- Each individual user is assigned unique login credentials.
- The following password controls safeguard the AACVPR data:
  - Passwords must be eight (8) or more characters in length;
  - The eight (8) most recent expired passwords may not be repeated;
  - Passwords expire every 90 days;
  - Passwords cannot be the same as the UserID;
  - Users are locked out after three (3) failed login attempts;
  - Administrator intervention is required to unlock a locked user account; and
  - There are uppercase, lowercase, and special character requirements for password complexity.
- The network that houses the AACVPR servers is protected with firewalls (all unnecessary ports are blocked). Servers are monitored with intrusion detection, antivirus, and antimalware software.
- The server housing the Registry resides in a state-of-the-art colocation facility.
- Backups will be conducted on a daily basis.
The server that hosts the AACVPR Registry is set up as a Virtual Server that is isolated from other servers and applications.

A full audit trail is in place in the AACVPR application to monitor access and use of the AACVPR Registry. The audit trail captures the username, time of access, what was accessed, where the access occurred, and how the access occurred.

Application errors encountered in the AACVPR Registry are automatically e-mailed to the AACVPR application administrators at Cissec. Errors are also logged in the database itself and added to the Windows server error logs.

AACVPR uses role-based access to ensure data security.

Passwords are encrypted in the AACVPR iMIS database.

Passwords are one-way encrypted. Physical access to the database will not provide an individual with a user password.

Sensitive data held within the AACVPR Registry are encrypted using a TRIPLE_DES algorithm. Physical access to the database will not provide an individual with access to sensitive information.

The password to access the server and the instance of the database in the SQL server is known only to software developers and hardware technicians that are working on the AACVPR project.

The MSSQL database server is separate from that of the webserver, and is not accessible from outside of the secure network.

The AACVPR application safeguards regarding inactivity; a logged in user will automatically be logged out after 15 minutes of inactivity.

The following administrative safeguards protect AACVPR data:

- The system that hosts the AACVPR Registry application has an extensive audit trail of all activity. The audit trail is reviewed by the Master Administrator upon request. As part of the Participation Agreement, all participating programs are aware of the audit trail capability. Participating programs can initiate requests to review their audit trail by contacting AACVPR.
- Cissec employees are required to sign a contract that includes a clause that addresses confidentiality requirements.
- Cissec employees have extensive experience working in a healthcare environment with regulated privacy and security requirements. New employees at Cissec are provided with training prior to starting an assignment that has privacy and security requirements.

4. Selection of Subjects

To be included in the Registry, patients in participating Registry programs must 1) have at least one diagnosis that makes them eligible for CR services; 2) be referred from a physician involved in their care; and 3) be enrolled in the CR program. Eligible diagnoses include documented coronary artery disease (CAD) (as indicated by a prior acute coronary syndrome, including ST elevation [STEMI] or non-ST elevation myocardial infarction [NSTEMI]), coronary revascularization procedure such as coronary artery bypass surgery (CABG) or percutaneous
coronary intervention (PCI), surgery to repair or replace a cardiac valve, heart transplant, or medical management of stable angina pectoris. Patients referred for management of heart failure, either medically or through the use of ventricular assist devices (VAD), may also be included in the Registry. Enrollment is defined as having participated in at least one (1) billable CR exercise session. All patients meeting the above criteria will be entered into the Registry. Patients will undergo CR services based on the procedures and policies of the participating programs and the patients’ healthcare insurance plans. There will be no discrimination or bias with respect to inclusion on the basis of sex, race, socioeconomic status, or religion.

5. Subject Recruitment and Compensation

No active recruitment will take place at Registry programs except that CR programs may contact physicians of patients who are eligible for CR services but who have not yet been formally referred. No compensation will be offered to patients, families, or physicians for patients’ participation in the Registry.

6. Consent Process

There will be no consent required of patients to have their data entered into the Registry. All patients will complete an informed consent process for participating in CR as dictated by local regulations or hospital policies. No testing, time, risk, or procedures beyond those required by routine care provided in CR will be imposed on patients as a result of this project. Furthermore, no data beyond that collected in the course of routine care will be collected.

7. Subject’s Capacity to Give Legally Effective Consent

This is an observational data registry. Information will be collected during the course of routine care of the patient while in CR. Due to the large national scope of the Registry, seeking consent from individual patients is not feasible.

8. Study Interventions

No additional interventions will be performed outside of the normal course of care. Data collection will be done from patients’ existing medical records.

9. Risk/Benefit Assessment

There should be no added procedural risk to patients through involvement in the Registry. No testing, time, risk, or procedures beyond those required for routine care will be imposed. The primary risk associated with this project is the potential for a breach of patient confidentiality. AACVPR has established a robust plan for ensuring that appropriate and commercially
reasonable physical, technical, and administrative safeguards are in place to mitigate such risks, as described in the Data Management section (Section 3) of this protocol.

10. Costs to the Subject and Compensation

There are no costs or compensation to the patient for participation in the Registry.

11. Data Analysis and Statistical Considerations

Upon receipt of the Registry data submission the Web-based application reviews the data electronically and reports back coding errors. Such electronic checks verify consistency and completeness and allow participants to have ample opportunity to edit data until it satisfies schema criteria. The electronic checks are predicated on a series of validation rules that assesses individual data for format, completeness, and range consistency.

Once the data meets the data quality thresholds, it is saved to the database. Users will be able to view several pre-formatted reports that display pre and post outcomes of individual patients, aggregated program outcomes, and aggregated outcomes compared to national evidence-based guidelines or benchmarks. (Examples of registry reports can be found at www.aacvpr.org/CRregistry.)

AACVPR understands the need to ensure that the data submitted to the Registry is accurate. Accepted data verification methods used with paper data collection (chart abstraction, on-site audits) appear less relevant for electronic systems and is not something AACVPR can feasibly do at this time. Moving forward, AACVPR is committed to the development of innovative and reliable data quality assurance and validation enhancements, including the establishment of electronic audit trails in the Registry, novel auditing procedures as appropriate, enhanced capabilities for data resubmission aimed at ensuring completeness, and statistical anomaly analysis.

AACVPR also intends to use the Registry data to further study this patient population in large aggregated numbers. The Participation Agreement signed by Registry participants includes a Data Use Agreement that permits AACVPR to conduct research using a limited data set; this research may include combining a limited data set of the Registry with limited data sets from other sources (e.g., other registries, private insurance company claims records, publicly available insurance claims records from the Centers for Medicare and Medicaid Services) using probabilistic matching methodology. This research may be used to 1) inform the practice of care, but not directly impact patient care by virtue of participation in the Registry; 2) revise the data elements collected on the patient populations; and 3) develop resources to support the practice of care, but that are independent of participation in the Registry. AACVPR will contract with data analytic centers or individuals to conduct such analyses. As mentioned in the Data Management section of this protocol, such data analytic centers or individuals will be required to sign a contractual instrument that holds them to the same standard regarding protection of PHI as are outlined in the Business Associate Agreement between AACVPR and each Registry Participant.
The AACVPR Research Committee will be responsible for accepting research proposals, reviewing proposals for scientific merit, signing Data Use Agreements, and coordinating the dissemination of Registry data with the principal investigators and AACVPR. It will be the responsibility of the principal investigator(s) to obtain appropriate institutional review through their local institution. Fully de-identified or limited data sets will be provided to the researcher as defined in the Data Use Agreement. Data from individual programs may be used for internal and external research or quality control; however, the programs will not be identified to the researcher unless given written permission by the programs to be specifically identified. In all cases, the specific data required for the research and the procedures used to maintain security and confidentiality of the data will be documented and agreed to by AACVPR and the researcher in the Data Use Agreement.

12. Data Storage and Confidentiality

Please refer to Section 3: AACVPR Data Management for details regarding how data captured in the Registry is stored and how the confidentiality of such data is maintained.
References


