ISHLT Mechanically Assisted Circulatory Support Registry (IMACS)

Policies and Standard Operating Procedures

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The ISHLT Mechanically Assisted Circulation Support Registry (IMACS) is an international database that will enroll patients who have received a mechanical circulatory support device (MCSD). IMACS is being created and will be administered by the University of Alabama, Birmingham under a contract with ISHLT. Enrollment of patients may occur via an individual hospital or via a collective. A collective is defined as an existing database that records data on patients through a national database or a scientific society database. This document contains the initial description of the governance and standard operating procedures for IMACS. All IMACS documents and data entry will be in English.

I. Governance

A. Ownership: The IMACS Registry is owned by the ISHLT. The actual governance of IMACS is by the IMACS Board which is appointed by the ISHLT Leadership. The ownership of the data remains with the submitting hospital or collective.

B. Board: The IMACS Board will provide oversight of the registry and all standard operating procedures will be approved by this board. For a current list of the board members, go to the ISHLT website http://www.ishlt.org/boardsAndCommittees/mcsdDatabase.asp.

C. Committees: With the approval of the IMACS Board, several committees will be established to oversee specific components of IMACS. For example, a data access, analysis and publications committee will be formed and whose purpose will be to solicit, evaluate and manage specific requests for research. A hospital standards committee will produce and implement policies for assessing data compliance from individual hospitals and collectives.

II. Patient, Hospital and Collective Enrollment

A. Patient inclusion/exclusion criteria: The goal of IMACS is to enroll and follow patients who receive durable mechanically assisted circulatory support devices (MCSD) in all countries and hospitals that wish to participate. Durable devices are defined as those devices that are capable of allowing a patient discharge with the device in place. Devices are defined on a country by country basis. Devices that have been approved by the relevant regulatory body will be included and also investigational devices will be included. The only exclusion criterion is patients who receive a non-durable MCSD. Note that pediatric patients are to be included in IMACS.

B. Hospital enrollment: An individual hospital may directly enroll into IMACS. The web based data entry system will be completed during the fall of 2012 and will allow direct entry of data at the local hospital.

C. Collective enrollment: IMACS will also allow the enrollment of collectives. The collective will not be asked to enter data directly into the web based data entry system, but will be asked to provide electronic datasets that will be transferred securely to IMACS. It will be the task of the IMACS staff to provide the translation of the data elements in the collective data to the data elements in IMACS.

III. Regulatory Considerations

A. Ethics Board: Each hospital will be asked to comply with the requirements of their local ethics board. The local ethics board may or may not require informed consent. IMACS will only require documentation of approval for the hospital's participation in IMACS. For collectives, IMACS will require documentation of whatever regulatory procedures are required of the collective.

B. Informed consent: As stated above, IMACS will require documentation of the requirement for informed consent or the waiver of informed consent.

IV. Data to Be Collected

A. Patient Health Information: IMACS will require the collection of detailed data elements for each patient including pre-implant, post implant and adverse event data. Some of this data will fit the US definition of protected health information (PHI). IMACS will minimize the collection of PHI and IMACS will work individually with hospitals and collectives that have specific issues.

B. Device Brand identifiers: IMACS will ask for the device brand, but our reports will likely only provide statistical summaries according to device type, e.g. continuous flow pumps.

C. Hospital identifiers: For individual hospitals that enroll into IMACS, we will ask for a hospital code. For collectives that submit data to IMACS, we would also like a hospital code but it can be a code that does not convey the hospital name. This is an optional requirement. We will need this code so that we can communicate with the collective when we have data quality issues for a specific hospital. The collective would then have to communicate with the hospital. The IMACS data managers will have access to these hospital identifiers; however, this information will not be part of any public reports.

D. Web based data entry for enrolled hospitals: The web based data entry system is robust and will allow analyses of the important patient and device characteristics along with detailed information on the 7 most important adverse events. The web based data entry system is being programmed by the same group at UNOS who programmed the data entry system for INTERMACS. This system has proven to be stable, robust and as user friendly as is possible for this complex medical field.

E. Data downloads from collectives: We will require annual downloads of data from the collectives. We will ask the collectives to give us the correct subset of patients based on the enrollment date of the collective. The IMACS staff will perform the mapping of the collective data into the IMACS data elements and structure. While we intend to minimize the required effort by the collective, we fully expect that many interactions will be required for the IMACS staff to understand the data collection definitions, data structure and follow-up requirements of the collective database. The data mapping algorithms will be provided to the collective for verification.

F. Data downloads to collectives: If requested by a collective, the IMACS staff will send the mapped data for the collective back to the collective.

V. Data Quality

A. Data entry quality checks: For both the hospital entered data and the collective data, we will perform quality checks to ascertain internal consistency and to identify outliers. The results of these efforts will be included in reports back to the hospitals and the collectives.

B. Audits: This audit strategy includes telephone audits to verify the key data elements (e.g., patient status, implant date, device brand, date and cause of death, date of transplant, date of explant recovery, device malfunctions, infections, bleeding events, etc). We also intend to perform 'for cause' audits when a hospital's follow-up compliance drops below 70%. These 'for cause' audits will likely be extended phone audits.

C. Hospital/Collective Evaluation: Each hospital and collective will receive a report card that will evaluate the quality of the data. This will include summaries of follow-up compliance, timeliness of data entry, and completeness of patient capture. Two of the major VAD companies have agreed to provide IMACS with implant counts by calendar quarter for all hospitals in the world. This will allow our assessment of patient capture.

VI. Data Policies and Information Security

A. Security: IMACS will follow the basic information security requirements that are required by the US Federal Government. This will include a secure system for electronic transfer of data and reports. This also includes policies that provide secure handling of sensitive data.

B. Data Access: Each hospital/collective will have access to the data that has been submitted by that hospital/collective. No hospital/collective will have access to the data from another hospital/collective. No PHI will be provided to any entity outside of the IMACS Data Center

C. Quality Reports: The ISHLT will provide a semi-annual report to the hospitals and Collectives that summarize the data from that entity.

D. Data Research Requests: Hospitals and Collectives may make data requests to the ISHLT. These requests will be accepted and prioritized by the IMACS board.

VII. Periodic Reports

A. Policies: Reports and scientific analyses that will be produced by IMACS will provide no hospital specific information, will provide no country specific information and will provide no patient specific information.

B. Annual Report: An annual report on the status of the IMACS Registry and summaries of the enrolled patients will be provided at the annual ISHLT meeting and this report will be published in the Journal of Heart and Lung Transplantation (JHLT).

C. Annual Reports to hospitals/collectives: Each year a report will be provided to each individually enrolled hospital. The hospital specific statistical summaries will be benchmarked against the entire IMACS database. An annual report will also be provided to each collective. The collective specific statistical summaries will be benchmarked against the entire IMACS database.

VIII. Research

The primary goal of IMACS is to better understand outcomes in patients who receive MCSDs. This includes an emphasis on improving patient outcomes and on moving the MCSD field forward.