About the ICEBP

The International Consortium for Evidence-Based Perfusion (ICEBP) is a truly international effort aimed at incorporating evidence-based principles into extracorporeal perfusion practices. There are currently 17 member organizations:

1) Australian and New Zealand College of Perfusion
2) Belgian Society of Extra Corporeal Technology
3) Connecticut Society of Perfusion
4) Florida Perfusion Society
5) German Society of Cardiovascular Engineering
6) Japanese Society of Extra Corporeal Technology in Medicine
7) Minnesota Perfusion Society
8) Dutch Society of Extra Corporeal Circulation
9) Scandinavian Society of Extra Corporeal Technology
10) Spanish Association of Perfusionists
11) The American Academy of Cardiovascular Perfusion
12) The American Society of Extra Corporeal Technology
13) The Canadian Society of Clinical Perfusion
14) The European Board of Cardiovascular Perfusion
15) The Missouri Perfusion Society
16) The Society of Clinical Perfusion Scientists of Great Britain and Ireland
17) The Turkish Society of Perfusionists.

The ICEBP has created the following mission and vision statements to guide our work:

Mission

The International Consortium for Evidence-Based Perfusion (ICEBP) is a partnership and collaboration between perfusion societies, medical societies, clinicians and industry to improve continuously the delivery of care and outcomes for our patients.

Vision

To achieve this mission, we will focus our energies in two principle areas:

Registry

- Create an international perfusion registry and facilitate its implementation
- Identify gaps between current and evidence-based clinical practice

Guidelines

- Review, comment, and/or endorse evidence-based guidelines concerning the practice of cardiopulmonary bypass
- Collaborate with medical societies in the development of guidelines concerning the practice of cardiopulmonary bypass

In order to succeed, the ICEBP will foster communication amongst its membership through a web portal, scientific conference, and internal and external publications.
This document serves as a white paper describing the International Consortium for Evidence-Based Perfusion (ICEBP) International Perfusion Registry.

**Purpose:**
To collect patient, procedural, and outcomes-level data on patients undergoing cardiopulmonary bypass (CPB), and report information back to the front-line workers caring for these patients for the purpose of continuously improving the process of care delivered to our patients.

**Introduction:**
Few robust clinical registries exist to collect data regarding the practice of CPB. In addition, most of these do not have sufficient validation to reflect confidently and accurately the volume or practice of cardiopulmonary bypass care. Also, such registries typically do not afford users to link to databases such as the Social Security Administrative File\(^1\) to determine long-term survivorship.

On a separate note, these registries are often not controlled by those charged with practicing cardiopulmonary bypass, and therefore may not fully address the needs of the perfusion profession. As a consequence, the perfusion community does not control the content and subsequent analysis of these data. These registries may have limited opportunity for providing information for benchmarking and tracking performance of CPB practice over time.

The development of a dedicated perfusion registry would fill this void. Additionally, collection of unique patient identifiers within this registry would facilitate linkage with cardiothoracic surgical registries, as well as those from other professional bodies.

We provide a schematic for collecting and analyzing data related to CPB, and subsequently feeding back information to the clinicians. We have developed over the last several years a data form, along with definitions, that seeks to address focused aspects of CPB practice. This data form encompasses patient, procedural and clinical outcomes, as well tracks guideline indicators. We have focused our attention on the following areas of perfusion:

1. Patient demographics (to adjust for potential patient-level confounders)
2. Compliance with published perfusion guidelines
3. Cell processing and filtration
4. Renal Management
5. Factors that influence low ejection fraction among patients presenting with normal ejection fraction

In this design, a single medical center would contribute data to a dedicated server, which would plot this data over time (Figure 1). The data would be housed at The Dartmouth

\(^1\) http://www.ssa.gov/
Institute for Health Policy & Clinical Practice.\(^2\) Data will be the property of each participating medical center. External benchmarks, if they exist, would be plotted on the same graph as the actual data from this medical center.

**Figure 1. One Center’s Experience**

As shown in Figure 2, just as a single medical center may contribute data, so may many centers. The additional centers’ experiences provide a more comprehensive view of the world.

**Figure 2. The Profession’s Experience**

Through data contribution from many centers, we allow ourselves the opportunity to understand more concretely variation in clinical practice. By quantifying this variation, we are able to identify those medical centers that may serve as benchmark institutions (Figure 3).

\(^2\) http://tdi.dartmouth.edu/
These benchmark institutions may serve as sources of key information for institutions who wish to learn how to redesign care to transition to a more optimal level of performance. We can see how this framework allows us to move from theoretical to tangible benchmarks. Additionally, this feedback of data may also serve to bring the cardiac surgery community closer, and offer opportunities to build collaboration across professionals and institutions. Efforts to make inroads in improving care would be supported by the International Consortium for Evidence-Based Practice (ICEBP).

**Functionality:**
Data would be submitted in any number of ways. Medical centers would have the option of:
- Submitting data from a “home-grown” or vendor-supported data registry by developing a harvest file with the pre-specified fields
- Submitting data vis-à-vis a web-based form.

In either case, data submitted to the registry would be transmitted over a dedicated encrypted ftp server, or similar manner. The ICEBP has developed a web-based data form that encompasses specification for each of the fields. Validation rules have been established to maximize the integrity of the data submitted in this manner. If data is submitted from a different source, validation will occur prior to merging with the larger registry.
We recognize that individuals will not wish to collect data in duplicate, as medical centers often submit data to other registries, whether regional, national or international in nature, such as the Society of Thoracic Surgery National Database. These registries would likely provide patient demographics and disease characteristics, as well as postoperative data [albeit we have limited the core dataset to focus our efforts on the aforementioned 5 areas]. The registry will also communicate with electronic perfusion data management system files, as an increasing number of perfusion programs are using these products to improve their practice. This latter feature will provide a great portion of the fields pertinent to the intra-operative management of the patient. We have begun working with industry to create an export file from their heart-lung machine data management programs.

The registry functions more than just as a data repository. For those using the web-based data entry forms, the registry will provide an online query tool. This feature will empower individuals to understand their practice, as well as how ascertain how they perform relative to their peers. In addition, formal reports will be generated for all users twice per year to each participating medical center. More frequent, or customized, reports will afford a revenue stream for the registry.

In order to participate in the registry, contractual agreements will be made with each institution to validate the case counts submitted to the registry. This validation will be made against that medical center’s billing data. Any procedures found in this process not to have been submitted to the registry will be requested. By doing this, the registry will have a complete picture of all procedures performed and data collected at each participating medical center. We recognize that some international programs will not allow protected health information to be submitted to the registry. Validation will then occur within the country of origin. However, protected health information can be collected within the United States of America, as evidenced by New York State or within the Northern New England Cardiovascular Disease Study Group.

The registry will be linked to death records on a periodic basis to quantify long-term survivorship subsequent to each procedure. In the United States, these records are publicly available through the Social Security Administration (for a nominal fee). We will make every effort to identify similar data sources within other countries.

**Short and Mid-term Goals:**
In the short-term, the ICEBP seeks to embed its registry within state, region, or country-based quality collaboratives. The benefit of this strategic plan is to have the registry be used among groups that are accustomed to collecting, reflecting, and using data for the quality assurance and improvement.

---

3 http://www.sts.org/sections/stsnationaldatabase/
5 http://nnecdsg.org/
With this in mind, the ICEBP has agreed to collaborate with the Michigan Society of Thoracic and Cardiovascular Surgeons\(^6\) to pilot the ICEBP registry within the state of Michigan. These two entities have targeted a Fall 2009 start date. A certified STS vendor (Armus Corporation, http://armus.com) has been selected to develop a web-based portal and database structure to meet the ICEBP’s needs. All sites within Michigan are STS users. The ICEBP has initiated dialogue with a number of its industry partners (Maquet, Terumo Cardiovascular, Medtronic, and Sorin Group) regarding how we might collaborate to assist in pulling data from electronic data sources. These partners have agreed to work with our vendor on such an endeavor. The ICEBP will help facilitate these discussions through a web-based project management tool.

Beyond the pilot phase, we have been approached, or have approached, a number of quality collaboratives regarding future sites for the registry.

Additional Questions:

Donald S. Likosky, Ph.D.
Theron A. Paugh, B.S., C.C.P.
International Consortium for Evidence-Based Perfusion (ICEBP)
Email to: registry@icebp.org
www.bestpracticeperfusion.org

\(^6\) http://www.mstcvs.org/qc