ROBOTIC REGISTRY CONSENSUS CONFERENCE
September 22-23, 2016

Florida Hospital Nicholson Center
Celebration, Florida

Summary Report
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Consensus Driven Robotic Surgery Data Registry Mission Statement and Goals

**Background:**

The new era of information science has resulted in immediate availability, analysis and sharing of real world data (RWD) that is available at the time of the occurrence - at the pace of innovation and change. However, the potential benefit of emerging technologies and innovations are slowed by the continued use of prospective clinical trials, peer-review evaluations, and the submission of research publication, which require rigorous and careful evaluation and prolonged completion time.

One solution that has emerged is the development of ‘registries’ - databases which are created in near real time and which reflect data that is available at the time of occurrence, as opposed to the traditional practice of stored data that is awaiting review and possible publication. Implementing this solution, healthcare professional communities of individual physicians, hospitals, governing bodies and societies, industry, federal agencies, etc can work together using information before it has become obsolete, allowing for real-time analysis and decisions that reflect the current status in the process of dynamic change.

One example of rapid innovation and transformation is robotic-assisted surgical devices. A real-world-data (RWD) robotic surgery registry would allow:

- Physicians to evaluate their operative performance for self-improvement
- Educators to develop standardized training programs and certification processes for ongoing education, remediation, and privileging
- Hospitals to develop quality measures, effectiveness and risk assessment to trend patient care for quality improvement
- Industry to assess the performance of their devices to promote more rapid iterations towards improved functionality and safety
- Government to maintain minimal safety and effectiveness standards and stay informed of new developments that could influence policies

All of these benefits in efficiency and greater accuracy succeed due to the rapid analysis of massive quantities of RWD.

**Mission Statement**

To design, develop, and successfully implement a RWD robotic surgery data registry that systematically collects in near real-time device-related and process-related data, is interoperable with clinical databases, and utilizes those data to improve device safety, surgeon/team performance, and public health.

**Specific Goals:**

1. To use as an exemplar, a pilot robotic-assisted surgery registry that:

   - Is open to data collection on all robotic assisted surgical device procedures performed within the US and internationally
• Collects information on robotic assisted surgical device procedures across all specialties.
• Collects, analyzes and reports data in near-real time.
• Collects data for a limited data set of core measurements that have value for distinguishing between device-related malfunctions versus non-device related events.
• Develops inter-operability by utilizing existing registry structures such as NSQIP and other society registries.
• Avoids double data entry, physician data entry, and prohibitive additional costs.
• Serves as a resource and feedback to participating institutions for patient safety, surgeons for self-assessment and self-improvement, industry partners for device tracking and research, payers, and patients in a manner that is timely and that results in improved public health.

2. When the pilot registry has accomplished the above stated goals, incrementally expand this core database to include other medical devices.

FDA’s Goals and Expectations Disseminated Prior to the Consensus Conference

FDA’s Center for Devices and Radiological Health has identified the development of real-world data collection systems as a strategic priority. Such data has the potential to support premarket regulatory decision-making and to streamline the development of innovative products to help treat patients. Important aspects of a RASD registry would be to provide information regarding real-world RASD device use and performance as part of the operating room environment, and as an individual health care provider seeks to care for their patient. Such a registry can serve as a continuous mechanism for monitoring and furthering safe innovation of RASD devices for patient benefit. We look forward to a productive dialog in September with all the attendees.

Binita S. Ashar, MD, MBA, FACS
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About the Institute for Surgical Excellence

The Institute for Surgical Excellence (ISE) is a 501(c)(3) public non-profit organization dedicated to improving surgical care and patient outcomes. ISE’s mission is to support the implementation of safer solutions to complex surgical interventions, often involving the application of emerging technologies. ISE utilizes a systems-based approach to bring together key stakeholders to identify issues, set clearly defined goals, facilitate collaboration, assess and fill gaps, and better inform healthcare consumers. For more information about ISE, visit www.surgicalexcellence.org.

ISE was responsible for the organization, management and fundraising activities of the Robotic Surgery Registry Consensus Conference. ISE has extensive experience in robotic education, training and research including conducting consensus conferences, assisting in the creation and hosting of the Fundamentals of Robotic Surgery (FRS) and the Fundamentals of Robotic Gynecologic Surgery (FRGS), providing administration for the international multi-institutional FRS validation trial, and managing the Robotic Training Network (RTN).
Meeting Participants

This landmark meeting brought together 44 key opinion leaders through a public – private partnership including:

- Robotic surgery experts
- Registry experts
- Government representatives (FDA)
- Society representatives

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- American College of Surgeons
- American Society of Colon & Rectal Surgeons
- American Urological Association
- Society of American Gastrointestinal & Endoscopic Surgeons
- Society of Gynecologic Oncologists
- Society of Gynecologic Surgeons
- Society of Laparoendoscopic Surgeons

Robotic Device Companies Represented

- Intuitive Surgical
- Stryker
- Medtronic/Covidien
- J & J/Verb Surgical
- Transenterix
- Medrobotics Corporation
- Medicaroid
- Titan Medical Inc.

Educational Grants Provided for the Robotic Registry Consensus Conference
Lectures

Introduction: Setting the Stage

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Dr. Redan showed a video of a clip falling off tissue after the use of an ultrasonic energy device with extensive bleeding following. The surgeon recovered and the patient did well after surgery. No blood transfusion was necessary.

He posed several questions for the audience:
- Did an error occur?
- Is this surgeon error or equipment/device error?
  - Did the surgeon use the device improperly?
  - Did the clip fail to hold?
  - Was the clip loaded improperly?
  - Was the ultrasonic energy device over vibrating?
- What is the responsibility of the manufacturer?
  - Did the surgeon receive adequate instructions in how to use the energy device?
  - Was the surgeon properly instructed on how to use the clip applier?
  - Do the engineers need to see these videos to invent a safer device?
- How should this be recorded in the chart?
- How do we develop safer devices?
  - Everyone must work together to make our profession safer.
  - Can we invent an instrument that will not cut until no flow is detected in a vessel?
  - Can we prohibit an instrument if urine is detected in the “tube” we are trying to cut?

He concluded with the following statement:
- “Please do not think about reasons why we cannot do this project. Instead take the position that we MUST do this project.”

**FRS Historical Perspective**

![Jeffrey S. Levy, MD](image_url)

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Interim Executive Director  
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**Fundamentals of Robotic Surgery (FRS)**

- Develop a validated multi-specialty, technical skills competency based curriculum for surgeons to safely and efficiently perform basic robotic-assisted surgery.
- Proficiency-based progression model

**FRS Consensus Conferences**
100 robotic surgeon experts, researchers, educators, and psychometricians came together to develop FRS through 4 consensus conferences.

- Outcomes Measures
- Curriculum Outline
- Curriculum Development
- Validation Criteria

**Outcome Measures & Metrics**

1. Situation Awareness
2. Eye-Hand Instrument Coordination
3. Needle Driving
4. Atraumatic Handling
5. Safety of Operative Field
6. Camera
7. Clutching
8. Dissection-Fine & Blunt
9. Closed Loop Communication
10. Docking
11. Knot tying
12. Instrument Exchange
13. Suture Handling
14. Energy sources
15. Cutting
16. Foreign Body Management
17. Ergonomic Position
18. Wrist Articulation
19. Robotic trocars
20. System Setting
21. Multi-Arm Control
22. Operating Room Set-Up
23. Respond to Robot System Error
24. Undocking
25. Transition to Bedside Assist

**Modules of the FRS Curriculum**

- Module 1: Introduction to Robotic Surgery
- Module 2: Didactic Instructions
- Module 3: Psychomotor Skills Curriculum
- Module 4: Team Training and Communication Skills
7 FRS Tasks

Module 1: Introduction to Robotic Surgery

Module 2: Didactic Instructions

Module 3: Psychomotor Skills Curriculum

Module 4: Team Training and Communication Skills

Final Physical Model
Abdominal Shell
Instrument Insertion

Ring Tower Transfer
Knot Tying
Railroad Track

4th Arm Cutting
Puzzle Piece Dissection
Vessel Dissection/Division
FRS Validation Study Design

The largest proficiency-based surgical skills study with over 200 subjects
- Athens University - Athens, Greece
- CAMLS – USF - Tampa FL
- Carolinas – Charlotte, NC
- Duke University – Raleigh, NC
- EndoCAS – Pisa, Italy
- Hartford Hospital – Hartford, CT
- Imperial College - London, UK
- Lahey Clinic - Boston, MA
- Lehigh Valley – Allentown, PA
- Madigan Army – Tacoma/Seattle, WA
- MITIE - Houston, TX
- U. of Pennsylvania - Philadelphia, PA

High Stakes Examination
- ISE is in early discussion with SAGES about partnering in the development of high stakes exam for FRS

Full-Cycle Model for Emerging Technologies
- This model should really be depicted as circular for continuous improvement
Definitions are key to any scientifically valid project

1. **Data**: Quantities, characters, or symbols on which operations are performed by a computer; information in digital form
2. **Data element**: an item of data within a database or other collection of data.
3. **Data dictionary** a collection (list) of metadata describing the contents, format, and structure of a database
4. **Database**: A structured set of data held in computer storage and typically accessed or manipulated by means of specialized software
5. **Registry**: A book or volume in which important items of information of a particular kind are regularly and accurately recorded
6. **Outcome (measure)**: The result or effect of treatment. This data element describes what is to be measured—as unambiguously as possible.

7. **Metric**: A standard of measurement; a criterion/set of criteria stated in quantifiable terms. This is the unit (inches, cm, sec) that is used as the data element for the outcome measure.

8. **Likert Scale**: A scale used to measure attitudes to a particular topic or object by asking respondents to register their strength of agreement or disagreement with a number of statements about the topic or object in question, selecting from a given range of option. This scale has numbered “anchor points” which MUST be unambiguously defined.

9. **Binomial**: Consisting of only two terms (e.g., yes or no). This data element metric be used to indicate if a specific act did or did not occur, and thus the act must be unambiguously defined (by consensus).

Strategically Coordinated Registry Networks (CRNs): The Foundation of NEST

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**2016 - 2017 Center for Devices and Radiological Health (CDRH) Strategic Priorities**
- Establish a National Evaluation System for Medical Devices
- Partner with Patients
- Promote a Culture of Quality and Organizational Excellence

**FDA Investments 2011-2016**
- UDI Established a Unique Device Identification (UDI) System
- 50 Completed or engaged in over 50 inter-disciplinary initiatives, including the creation of new RWE data sources, demonstration of proof of concept for use of RWE, development and use of advanced analytics, UDI adoption, CRNs etc.
- $21,000,000 to MDEpiNet
- PB - National Medical Device Planning Board
- TF - National Medical Device Registry Task Force
Learning Medical Device Ecosystem
- Improve time from innovation product launch
- Registry data reduces premarket review time
- National Evaluation System - Faster premarket decisions with real world evidence (registry data reduces premarket review time)
- Set up “safety nets”

International Consortium of Orthopedic Registries (ICOR) – an orthopedic example
- Partnership with 29 Registries, (8 contributing data) reporting on over 5,200,000 implants
- Comparative effectiveness / safety studies (27 papers published in JBJS,)
- Use in FDA mandated PAS
- Catalyzed the development of ICOR-USA and Ortho CRN
- Informed the International Medical Device Regulators Forum (IMDRF) Registry Working Group
- Serves as a model for new International Consortia of Vascular, Transcatheter Valve, and Breast Implant registries

**Why the Coordinated Registry Networks (CRNs)?**
- Of current & emerging e-health information sources (registries, EHRs, administrative, mobile apps, etc) registries provide most robust content & operational predicates
- No single registry suffices for benefit/risk & safety for all devices
- Strategic data sharing interoperability (linking) complementary e-health sources could mitigate single source deficiencies

**Evolving CRNs**
- Ortho CRN
- Vascular CRN - VISION
- Neuro CRN - DAISI
- Robotic Surgery CRN
- HIFU CRN
- GI CRN

**Strategically Coordinated Registry Networks (CRNs): Existing Predicates of Data Sharing**
- Linked to complementary data sources
- Multiple source structured data extraction
- Distributed data networks

**MDEpiNet Efforts to Leverage Infrastructure**
- Registry Development
- National/International Consortia Development
- Electronic Device Data Capture (UDI)
- Task Force -Coordinated Registry Networks
- PASSION Initiative

**Methods**
- Active Surveillance
- Comparative Effectiveness
- Evidence Synthesis
- Claims Validation
- Linkage with other Data Sources
- Big Data Analytics

**Patient Engagement**
- Augmenting Registries with PROs and Explant Analysis for Precision Medicine
- Assessing Minimally Important Difference (MID) for orthopedics implants
• Patient and Family Engagement Committee
• Patient-led Device/Disease Specific Round Table

Think Internationally Too!
• International Consortium of Orthopedic Registries (ICOR)
• International Consortium of Cardiac Registries (ICCR)
• International Consortium of Vascular Registries (ICVR)
• International Consortium of Breast Implants Registries (ICOBRA)
• International Medical Device Regulators Forum (IMDRF) Registry WG

MDEpiNet and IDEAL

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Science and Infrastructure Center
IDEAL Framework & MDEpiNet to Advance Registry Based National System Development

IDEAL Framework describes the stages of development of surgical innovations
IDEAL Framework: describes stages of development of surgical innovations.
IDEAL Recommendations: propose appropriate methodology and reporting of research at each of these stages.
IDEAL Proposals: suggest how specific groups (publishers, funders, regulators, and professional organizations) can help to change the environment for research on surgical and interventional therapies.

IDEAL Collaboration
Open network directed by an international Steering Group of surgeons, methodologists, statisticians, journal editors and translational experts.

Three main areas of activity:
1) Research to validate and develop the Framework and Recommendations.
2) Education to spread knowledge of the best research/reporting methods.
3) Advocacy for initiatives to improve the environment for surgical research.

http://www.ideal-collaboration.net/

Stage 1: IDEA
- Initial report
- Innovation may be planned, accidental or forced
- Focus on explanation and description

Stage 2a: DEVELOPMENT
- “Tinkering” - (rapid iterative modification of technique and indications)
- Small experience from one center
- Focus on technical details and feasibility

Stage 2b: EXPLORATION
- Technique now more stable
- Replication by others
- Focus on adverse effects and potential benefits
- Learning curves important
- Definition and quality parameters developed

Stage 3: ASSESSMENT
- Gaining wide acceptance
- Considered as possible replacement for current treatment
- Comparison against current best practice (RCT if possible)

Stage 4: LONG TERM MONITORING
- Monitoring late and rare problems, changes in use & quality of surgical performance
Registry Components

“Organized system that continuously and consistently collects relevant data in conjunction with routine clinical care, evaluates meaningful outcomes and comprehensively covers the population defined by exposure to particular device(s) at a reasonably generalizable scale (e.g. international, national, regional, and health system)’ with a primary aim to improve the quality of patient care”

1. DEVICE DATA: The registry contains sufficient information to uniquely identify the device. Ideally, the unique device identifier would be included, but when the UDI is not available, the registry would include a combination of identifiers (catalog, number, manufacturer, description).

2. QUALITY IMPROVEMENT SYSTEM: Is part of a health care delivery quality improvement system or evolving into one as device technologies are diffused into practice and need continuing evaluation (including outlier identification).

3. BENEFICIAL CHANGE: Has established mechanisms to bring about beneficial change in health care delivery through stakeholder participation, ownership and integration into the relevant health care systems.

4. EFFICIENCY: The registry is embedded in the health care delivery system so that data collection occurs as part of care delivery (i.e., not overly burdensome, not highly complicated, not overly costly) and integrated with workflow of clinical teams.

5. ACTIONABLE DATA: The registry provides actionable information in a relevant and timely manner to decision makers.

6. TRANSPARENCY: The governance structure, data access, and analytical processes of the registry are transparent.

7. LINKABILITY: Information in the registry can be linked with other data sources for enhancement including adequate follow up achievement.

8. TOTAL DEVICE LIFE-CYCLE: The registry can serve as infrastructure for seamless integration of evidence throughout the device life cycle.

Implications

- If a new implantable device is completely novel and requires learning then all IDEAL stages in a consecutive order including an RCT in Stage 3 are justified

- If a registry were set up for these devices from stage 1 to 4, subsequent “me too” devices could join it via ‘nested RCT design’

- For devices which have already bypassed IDEAL Stages 1-3 without assessment, (e.g. robotic surgery, hips, knees) a population registry with minimum data may be needed, similar to international joint replacement registries

IDEAL Framework & MDEpiNet Infrastructure in USA

- MDEpiNet Infrastructure building focus is to facilitate building systems that provide timely information on performance of specific medical devices for decision making by patients, physicians, regulators and all other stakeholders

- Approach is to facilitate and/or leverage national investments in registries and other relevant data systems (dual purposing) to create ‘National Medical Device
Introducing CRN as Realistic Vision for Efficient Registry System Development (need to integrate relevant data)

- Major ‘Quality and safety’ registries initiated by professional societies, states, healthcare systems, NIH/AHRQ, other
- CMS claims including Part A,B,C,D
- Commercial claims
- PCORI CDRNs
- All payer State databases
- Comprehensive EHRs (if possible)

Distributed CRN

Key Points for Discussion

- Even with optimistic expectations about registry and related data maturity our efforts should be scaled up to be powerful and timely enough to address particular device-related questions (e.g. outlier performance)
- For effective CRN timely and seamless access to key national data sources must be achieved and stakeholder alignment and support is critical
  - The process has to be efficient/not burdensome to justify data sacrifices made compared to direct data collection
- Sufficient device and clinical outcome data will always be a challenge and we have be able to make decisions based on pragmatically generated CRN data
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Current Dysfunctional Clinical Data Ecosystem

Limited data liquidity due to:
- Lack of interoperable data standards/API data infrastructure
- Limited business case for improved data flow and better quality for care
MACRA: MIPS vs. APM

- Building an APM
  - Individual Episodes
  - Episode clusters
  - Attribution of episode to provider (e.g. Patient relationship category – PRC)
  - Linkage to quality
  - Risk mitigation (risk adjustment)
  - Risk/Opportunity assessment
  - Gainsharing

Start with Concept Defined in Q-ORD

- Domains and Phases of Care
  - Preoperative evaluation
  - Immediate preoperative
  - Intraoperative
  - Postoperative
  - Post-discharge

- Surgeon’s Responsibilities: Preoperative Evaluation Phase of Care
  - Appropriateness for surgery
  - Major medical conditions
  - Specific medications
  - Hi-risk patients- risk calculators
  - Informed consent
  - Institution specific elements of surgical work-up
  - Review of preoperative labs
  - Coordination of care

Define Work Flow: Use Case Replicates Phases of Care

<table>
<thead>
<tr>
<th>Data FROM</th>
<th>Stage</th>
<th>Surgeon Record</th>
<th>Data TO</th>
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<tr>
<td></td>
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<td>Referring</td>
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<tr>
<td>1</td>
<td>Initial Assessment</td>
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<td>2</td>
<td>Therapeutic Plan Devised</td>
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<td>3</td>
<td>Risk Calculation</td>
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<td>4</td>
<td>Risk Review/Documentation</td>
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<td>5</td>
<td>Counseling/Consent</td>
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<td>6</td>
<td>Pre-Surgery Care</td>
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<td>7</td>
<td>Pre-op evaluation/review</td>
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<td>8</td>
<td>Intra-operative Care</td>
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<tr>
<td>9</td>
<td>PACU Care</td>
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</table>
The Surgical Care Continuum

To care for a patient the surgeon must:

- Understand the patient’s problem
- Review the patient’s history
- Verify active medical problems
- Review medications
- Examine patient
- Define therapeutic options
- Calculate risks
- Counsel patient/family
- Define pre-op preparation (optimization)
- Comply with relevant MEASURES
- Reassess on day of procedure
- Redetermine risk
- Assess compliance with optimization Rx
- Coordinate team activity Checklist
- OR checklist
- Operative Procedure
- Procedure Documentation (Attestation /Attribution)
- Manage PACU transition from team to surgeon
- Post operative care
- Coordinate peri-operative Rx
- Disposition
- Follow up

Related components include data sources, ACS services, areas for interoperability and compliance with MACRA

**Clinical Workflow/Documentation**

- **Pre-op**
  - A: Entry:
    - Dx, planned CPT, Risk Data
  - B: Patient Counseling (SDM)
    - Optimization plan
    - Understanding
    - Consent
    - Advanced Directives

- **Immediate Pre-op**
  - C: Pre-op assessment
    - Optimization results
    - Measures
    - Clinical pathways
    - Team coordination

- **Intra-op**
  - D: Operative
    - Note (synoptic?)
    - Metrics
    - Attestation (Attribution)

- **Post-op**
  - E: Post-operative
    - SSR
    - Protocol care
    - Patient Satisfaction CPIA

- **Post D/C**
  - F: Follow-up
    - Release

**Robotic Registry**

- Absolutely necessary
- Disparate parts housed in a single entity
- Will demand interoperability
- Standardization of data structure

*Projected Risk Link to CDS Pre-op classification*

*Better go*

*Worse - optimize*

*Way Worse - reconsider*

*High mortality - palliate?*

*SSR (QCDR) -> MIPS NSQIP*

"Charge" Resource consumption

**QPP**

- MIPS: Quality 50%
- QRUR 10%
- CPIA 15%
- ACI 25% (MU)
• Back end driver: Adverse Events
  o Operator
  o Robot
• Front end:
  o Safety
  o Efficacy
  o Efficiency
  o Cost
  o Innovation

Lessons Learned from an Alternative Approach to Surgical QI Registry Development: The SCOAP Example

David Reed Flum, MD MPH
Department of Surgery
University of Washington

What We Built in Washington State...10 Things We Wished We had Known
  1. Authoritative vs coercive
  2. The boogeyman helps you build it, but can kill it too
  3. Stakeholders matter (really)
  4. The natural order is un-natural - Process and Outcomes first, then Safety (and only after success can you get to Appropriateness)
  5. Leaders of these initiatives-not your traditional leaders
  6. Sustainability means providing real value
  7. Data integrity is a journey and not a destination
  8. QI kills research-research kills QI
  9. Roving spotlight better than a glaring sun
  10. Not about data collection, but behavior change
Airline Industry Follow Up
Southwest Airlines Flight 812 suffered rapid depressurization at 34,400 ft (10,485 m) near Yuma, Arizona, leading to an emergency landing at Yuma International Airport, on April 1, 2011. The incident caused minor injuries to two of the 123 aboard.
- Within 6 Hours the US fleet was “grounded”
- Within 6 Days the world’s fleet examined
- Cut the required “cycle time” for inspection in half to 6 months

Medical Device Industry Follow Up
“The unacknowledged incidence of laparoscopic stapler malfunction” (published in Surgical Endoscopy 2012)
- It took 6 years to get the stapler recalled

SCOAP Developed
- Learning system: focus on process of care
  - Surveillance
  - Structural Process and Outcome Metrics
  - Evidence-based Interventions
- Impact behavior through
  - Policy
  - Peer to peer networking
  - Checklists
  - Education and public health initiatives

Growing a Learning System
- Spread across the interventional space
  - Spine, urology, general/pediatric surgery, vascular
  - Cross disciplines
  - Target conditions
- Inclusion of Pre & Post-hospital care
- Focus on metrics that matter most to our patients
- Disease-based, more than interventions-based
- Overlay research on the data sharing platform
Working Groups

Group 1: Clinicians - Structure and Metrics for Current Data Repositories (Facilitator: Martin Martino, MD and Richard Satava, MD)

- Describe current data repositories and types of metrics used
- Integration of proposed registry with existing registries “Databases must talk to each other”
- Data security and integrity – Database protection under Patient Safety Organization
- Prompting questions:
  - What are the important outcomes measures that we must define in order to decide on what data to collect?
  - What metrics (numerical, unambiguous defined qualitative, etc)?
  - Define an error and/or a malfunction unique (and common) to robotic surgery
  - What data do we need to collect to help determine Device, versus training, versus surgeon training deficiency (i.e. surgical errors)?
  - How do we collect “near miss data” (i.e. 3000 ml blood loss but outcome was excellent, ureter cut but recognized, repaired and no sequela)?
  - Understand what is already collected by NSQIP as to not duplicate
  - Surgical team/education errors
  - What skills and judgement testing is required to allow a clinician to perform safe robotic surgery?

Group 2: Clinicians and Researchers - Measurement Methods for the RSDR (Co-Facilitators: Art Sedrakyan, MD and Roger Smith, PhD)

- Define known/potential device malfunctions and surgeon errors
- Determine methodology to discriminate between malfunction vs error
- Prompting questions:
  - What data entry format is best?
  - How is the quality of the data guaranteed (data assurance)?
  - Who will enter the data (data acquisition)?
  - How do we leverage existing knowledge, database systems, data entry processes, work flow, and data extraction tools?
  - How do we add new questions/data points after the registry is launched?
  - Can data entry be automated from Electronic Medical Records and claims data?
  - How easy is it to extract data, run reports and query the database?
  - Data dictionary development
  - How do we collaborate and share data with other registries (interoperability)?
  - How do we support the needs of patients, payers, and providers with the registry?
  - How do we work closely with the FDA to leverage their resources and help them strengthen a national system for medical devices?
  - How do we get longitudinal safety/outcome data?
  - How can FRS scores be linked to surgical errors or not?
Group 3: Industry, Academia, Other Registries: How will the RSDR be implemented? (Co-Facilitators: Jay Redan, MD and Sean Hagen)

- Determine data the robotic systems are capable of ‘reporting’ (e.g. malfunctions vs errors?)
- Determine which data does industry want to make available – are there proprietary issues?
- Define how data will automatically be reported to the registry database
- Prompting questions:
  - How can surgical teams/surgeons contact industry for notifications of device failure
  - How can surgeons make suggestions for improvement and get IP for their idea?
  - What information do engineers need to know about a device dysfunction?
  - What processes during innovation can industry collaborate with “end users.”
  - What simulation would be helpful to prevent errors?
  - How is Return on Investment calculated for device innovation and how will it help or hinder product development?

Group Participants

<table>
<thead>
<tr>
<th>GROUP 1</th>
<th>GROUP 2</th>
<th>GROUP 3</th>
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<tbody>
<tr>
<td>Martin Martino, MD</td>
<td>Art Sedraky, MD</td>
<td>Jay Redan, MD</td>
</tr>
<tr>
<td>Richard Satava, MD</td>
<td>Roger Smith, PhD</td>
<td>Sean Hagen</td>
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<tr>
<td>Roberto Bergamaschi, MD</td>
<td>Sarfraz Ahmad, PhD</td>
<td>Leila Bahreinian, MD</td>
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<tr>
<td>Linda Bradley, MD</td>
<td>Karen Ariemma</td>
<td>Jennifer Brennan</td>
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<tr>
<td>Farid Gharagozloo, MD</td>
<td>Ellen Axelson</td>
<td>Jack Bonasera</td>
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<tr>
<td>Rob Holloway, MD</td>
<td>Roberto Bergamaschi, MD, PhD</td>
<td>Myriam Curet, MD</td>
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<tr>
<td>Mario Leitao, MD</td>
<td>Luciano Mazzaro</td>
<td>Stephanie Fitts, PhD</td>
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<tr>
<td>Gaby Moawad, MD</td>
<td>Danica Marinac-Dabic, MD, PhD</td>
<td>John Hart, MBA</td>
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<tr>
<td>Deborah Nagle, MD</td>
<td>David Flum, MD</td>
<td>Colleen Riley</td>
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<tr>
<td>Vip Patel, MD</td>
<td>Jim Hu, MD</td>
<td>Sachin Sankholkar</td>
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<tr>
<td>Ajita Prabhu, MD</td>
<td>Myoung Kim, PhD, MA, MBA</td>
<td>Ken Turner, PhD</td>
</tr>
<tr>
<td>Phil Shaddock, MD</td>
<td>Steve Knych, MD</td>
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<tr>
<td>Li-Ming Su, MD</td>
<td>Shilpa Mehendale</td>
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<tr>
<td>Patricia Sylla, MD</td>
<td>Keith Nahigian</td>
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<tr>
<td>Joe Uddo, MD</td>
<td>Dimitrios Stefanitis, MD, PhD</td>
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<tr>
<td>Emily Weber LeBrun, MD, MD</td>
<td>Joseph Tepas, MD</td>
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<tr>
<td>Paul Wetter, MD</td>
<td>Erika Wolff, PhD</td>
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Major categories of device malfunction

<table>
<thead>
<tr>
<th>System Errors</th>
<th>Covers or Elec. Arcing</th>
</tr>
</thead>
<tbody>
<tr>
<td>System error codes and faults</td>
<td>Electrical arcing, sparking, charring</td>
</tr>
<tr>
<td>System transferred into a recoverable or non-recoverable safety state</td>
<td></td>
</tr>
<tr>
<td>Video/</td>
<td>Unintended Instrument</td>
</tr>
<tr>
<td>Loss of video</td>
<td>- Unintended or unstoppable movements started without the surgeon’s command</td>
</tr>
<tr>
<td>Imaging Problems</td>
<td>Operation</td>
</tr>
<tr>
<td>Display of blury images at surgeon’s console or assistant’s touchscreen</td>
<td>- Instruments not recognized by system</td>
</tr>
<tr>
<td>Broken</td>
<td></td>
</tr>
<tr>
<td>Burnt/broken parts and components</td>
<td>- Instruments not working, open/closed</td>
</tr>
<tr>
<td>Pieces</td>
<td>Other</td>
</tr>
<tr>
<td>Fell into surgical field or body cavity</td>
<td>- Cable, wire, tube, or instrument damages and breakages</td>
</tr>
<tr>
<td>Failing Into Patients</td>
<td>- Issues with electrosurgical units, power supplies/cords, patient-side manipulators, etc.</td>
</tr>
<tr>
<td>Broken Tip</td>
<td>- Other events reported as “Malfunction”</td>
</tr>
<tr>
<td>- Tears, burns, splits, holes on tip cover</td>
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</tr>
</tbody>
</table>


Generic Surgeon Errors

- Organ/visceral injury
  - Burn/puncture/avulsion/ transection
  - Number of reversible/ non-reversible complications
- Device Use Error
  - Collisions arms/ instrument
  - Excess force
- Pedal confusion
- Off-site injury/lack of device visualization

**Specialty Specific Surgeon Errors**

- Should we pick 2 errors from each specialty performing robotic-assisted surgery that are unique to their specialty?

**Case Descriptors**

- Time of surgery/time of day/# of prior surgeries that day
  - Fatigue
- Faults
- Level of Surgeon Experience
- Demographics of team training
- Approach (eg. hybrid)
- Emergency vs Elective
- Alerts (improper/not enough)

**Team based Errors**

- Inadequate experience with handling emergency situations
- Lack of training with specific system features
- Inadequate troubleshooting of technical problems
- Inadequate system/instrument checks before procedure
- Incorrect port placements/docking errors
- Incorrect electro-cautery settings
- Incorrect cable connections
- Inadequate manipulation of robot master controls
- Inadequate coordination between hand & foot movements
- Incorrect manipulation or exchange of instruments
- A more comprehensive analysis of multi-dimensional causes of incidents is the topic of the future research.

**Next Steps**

- Implementation of a questionnaire/form to efficiently see if any of these occurred intraoperatively.
- Possible partnership with ACS/ACS-AEI

**Questions to be Resolved**

- If we are able to discriminate between device error and surgeon error through evidence in the database, and it is determined that a preventable surgeon error occurred, how do we then provide a method for remediation (evidence-based education and training)? This is probably a separate project requiring separate funding.
Desirable Data that can be Leveraged from Secondary Data Sources

- Ideal: Reach clinical area consensus on common data items
- Categories of Data: Discharge with Comorbidities and Procedures, Cancer Stage or Some Disease Severity, Discharge Disposition, Length of Stay, Reoperation, Anesthesia Time, ...
  - (18 sources were listed)
- Time Lag: 6-18 months

Linkable Databases

- NSQIP
- STS
- SGO
- SAGES
- AHSQC
- NCDB
- OPTUM ($, unclear)
- United ($, unclear)
- Premier (special action)
- Medicare
- State Claims
- SEER Medicare

Information to Relay to Group 1

- Group 1: Need a second module for readmission to hospital
  - Currently limited because patients don’t come back to same hospital
  - Linkage with claims can validate whether sicker patients return to same or other hospital
  - MACRA will require return to same provider
Getting Started

- Do we build a large complete data set? Or do we create something small and easy to implement first?
  - Ask stakeholders what they need (surgeons, hospitals, payers, government, industry)
  - Identify level of effort to enter a record

Group 3 Report

Determine Data the Robotic Systems are Capable of ‘Reporting’

- System Make/Model
- Time and Date of Procedure
- Surgeon ID – Surgeon Metrics for the Case
- Instruments Selection
- Time Stamps of All Reported Events (automated)
- Maintenance History
- Instrument Life, Use History, Reuse History, Duty Cycle
- Accidental Actuation (eg. Mono no vs. bipolar activation)
- Deviation from plan (Robot Specific)
- How Often a Feature is used (workflow)
- Ergonomic Indicators
- Camera Specification and Manipulation
- Shutdowns and Halts
- Surgeon Engagement Time at the Console
- Total OR Time, Case Time, Console Time
- Energy and Setting of Energy Device
- Energy Use History
• Insufflator time and Amount of Gas Used
• Dock and ReDock
• Device Implant Registry (Robot Specific)
• Light Source Time
• Inputs to the Instruments
• Power Source Errors
• Robotic Arm Failure
• Registration Error (Robot Specific)

Determine Data that can be Facilitated but Sourced Outside the Device

• Surgeon Profile, Experience, License Number, Glove Size
• Biometric ID
• Cloud Source of Video and Audio
• Patient Profile
• Tissue Condition
• Procedure Type
• Inform Verification Spec
• Was it Used as Intended
• Pre and Post Data to Augment Automatically Collected Data
• Time Between Events
• Inform Customer Training
• Manual Time Stamps
• Complete Ratio – include denominator

What are the Concerns?

• Cloud Sourcing Data
• Hardware/Software Malfunction (IP Issue)
• Robotic Coordinator or Industry Rep Entering Data

Training Issues

• FRS or FLS Should be Completed to Validate Use of the Device
• Maintenance of Certification on the Device

Integrated Robotic Data Set from the Three Working Groups

Please see APPENDIX 1: ROBOTIC PROCEDURE INFORMATION (DATA SET). Each data element will undergo the Delphi process to create a consensus driven final data set.
Potential Registry Data Collection Model

Possible Registry Partners
- ACS
  - NSQIP*
  - NCDB
- STS
- SGO
- AHSQC
- Other societies

Other Data Sources
- EMR
- PCORI Database
- OPTUM
- United
- Premier
- Medicare
- State Claims
- SEER Medicare

*Insert Robotic Data set into NSQIP as a pilot study

Next Steps
1. Send out final draft of Mission/Goals Statement for group approval - Done
2. Summary report sent within 4 weeks - Done
3. Finalize data form (OR point of care) - Done
   a. Delphi process online (Months 2-3)
4. Create the following working groups
   a. IRB (month 2)
   b. IT Platform and website (month 2)
   c. Outreach to ACS, NSQIP to investigate collaboration (month 2)
   d. Outreach to other societies to investigate collaboration (month 2)
   e. CRF development, skip logic and definitions (month 2)
   f. Determine elements the robot collects that can be shared (month 2)
   g. Investigate data elements in major surgical databases (month 3)
5. Start pilot for OR point of care module
   a. Develop budget for pilot study (month 3)
   b. Develop inclusion/exclusion criteria for participating institutions (month 3)
   c. Determine which specialties should be involved in the pilot study (month 3)
   d. Outline QI incentive for participating institutions (month 3)
   e. Secure funding for pilot (month 4-6)
   f. Recruit 12-20 hospitals (month 4-6)
   g. Start pilot (month 9)
Appendix 1: Robotic Procedure Information (Data Set)

Robotic Database
The list below is a draft of a comprehensive list of data elements related to robotic-assisted surgery. The final list of “essential” data elements (minimal data set) will be developed through the Delphi consensus process and will probably be half the size or less of the list below. The final consensus-driven list of data elements will be inserted into a more general surgical database like NSQIP.

Background Information
1. Procedure type (see time breakdown below)
   - Robotic assisted
   - Hybrid
     - Amount of time on robot – Time _____________
     - Amount of time not on robot – Time _____________
2. Robot information
   a. System Make ___________________________________________________________
   b. Model _________________________________________________________________
   c. Maintenance History ______________________________________________________
   d. Instrument Life, Use History, Reuse History, Duty Cycle ___________________________
3. Robotic instruments used during procedure (choose all that apply)
   - Scissors
   - Monopolar scissors
   - Bipolar Maryland
   - Large needle drivers
   - Double fenestrated graspers
   - Long tip forceps
   - Pro Grasper
   - Cobra
   - Radiologic, ultrasonic, molecular or other imaging (Firefly, etc)
   - Other ___________________________________________________________________
4. Surgeon robotic experience
   a. Completed formal robotic training with documentation
      - Robotic device familiarization training
        1. Yes
        2. No
      - Structured clinical skills training, mentoring, etc
        1. Yes
        2. No
   b. Completed annual simulation robotic maintenance of certification
      - Yes
      - No
   c. Total Number of robotic cases
      - 0-5
      - 6-25
      - 26-50
      - 51-100
5. **Procedure Times**
   a. Patient in room – Time ________________________
   b. Anesthesia induced – Time ________________________
   c. Robot docked – Time ________________________
   d. Trocar insertion completed – Time ________________________
   e. Trocar removed – Time ________________________
   f. Procedure complete – Time ________________________
   g. Time of day for surgery
      o Morning 6 am to 10 am
      o Mid-day 10 am to 2 pm
      o Mid Afternoon 2-6 pm
      o Evening 6- 10 pm
      o Night 10 pm to 6 am
   h. # of prior surgeries that day
      o 1
      o 2
      o 3
      o 4
      o 5
      o 6 or more
   i. Hours of prior surgeries that day
      o None
      o 0-2
      o 2-4
      o 4-6
      o 6-8
      o >8

6. **Audiovisual information**
   a. Was Video recorded
      o Yes
      o No
   b. Was Audio recorded
      o Yes
      o No

**Preoperative Adverse Events** (check all that apply)

7. Positioning of the equipment and robot setup
   □ None
- Incorrect positioning of equipment, patient bed, or OR staff that leads to preventable collisions
- Incorrect positioning of the console so there is not an adequate view of the operative field by the surgeon
- Failure to orient the robotic arms in the recommended stowing position prior to moving the cart base
- Inadequate sterile prepping the operative site

8. Positioning of patient (check all that apply)
   - None
   - Incorrect positioning of patient resulting in patient movement during the procedure
   - Moving the operating table (purposefully or inadvertently) after docking

9. Systems check (check all that apply)
   - None
   - Inadequate system/instrument checks before procedure
   - Incorrect electro-cautery settings
   - System Faults (recoverable or not recoverable)

10. The Ergonomic positioning errors (check all that apply)
    - None
    - Incorrect positioning of equipment, patient bed, or OR staff that leads to preventable collisions
    - Incorrect positioning of the console so there is not an adequate view of the operative field by the surgeon
    - Failure to orient the robotic arms in the recommended stowing position prior to moving the cart base

Intraoperative Adverse Events

11. Adverse event capture
    a. Number of reversible complications
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
        - 6 or more
    b. Number of non-reversible complications
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
        - 6 or more
    c. System error codes during procedure (check all that apply)
        - None
        - Error type captured (Get list from industry of 6-8 most common types)
d. Failure to recognize and address system error notifications
   - Yes
   - No

e. Time stamp for adverse event
   - Done automatically
   - Done manual
   - Not done

f. Manufacturer informed of error
   - Yes
   - No

12. Other device, system, instrument errors
   a. System shutdown
      - Yes
      - No
   b. System transferred into a recoverable or non-recoverable safety state
      - Yes
      - No
   c. Robotic Arm Failure (check all that apply)
      - None
      - Unintended or unstoppable instrument movements started without the surgeon’s command
      - Instruments not recognized by system
      - Cable, wire, tube, or instrument damages and breakages
        - Instruments not working, stuck open or closed
        - Burnt/broken parts and components
        - Pieces fell into surgical field or body cavity
        - Pieces fell into surgical field or body cavity requiring an additional procedure
        - Broken tip or holes on the tip cover causing tears or burns
   d. Power Source or Display Errors (check all that apply)
      - Issues with electrosurgical units, power supplies/cords, patient-side manipulators
      - Display of blurry images at surgeon’s console or assistant’s touchscreen
      - Loss of video

13. Docking Errors (check all that apply)
   - None
   - Insufficient separation of working arms from camera resulting in arm collisions
   - Failure to insure that all the arms are free of collision with the patient - Injury (bruising, etc.) to the patient
   - Not checking for the appropriate position of the trocars prior to docking robotic arms
14. Trocar insertion (check all that apply)

- None
- Injury to a major organ or vascular injury
- Not visualizing the tip of the trocar during insertion
- Not checking the port site and operative site for bleeding, injury, etc. after insertion
- Trocars placed too close together resulting in robotic arm collisions or making reaching operative site difficult (this may not be the case in single site surgery)
  - If possible measure distance between ports

15. Instrument Insertion (check all that apply)

- None
- Clutching the arms during instrument exchanges (this deactivates the safety mechanism that the robotic system uses to remember the instrument position and allow for the new instrument to go back to the exact location of the removed instrument)
- Clutching the robotic arm during instrument exchange without monitoring the new instrument tip during reinsertion
- Instrument not completely inserted through trocar so its wrist is not visible past the cannula and it is not ready for surgical control (this is done by the assistant, not the console surgeon)
- Not maintaining view of instrument during its insertion
- Collision of instrument with tissue upon insertion

16. Other instrument usage issues (check all that apply)

- None
- Overpowering the master controls preventing master/slave alignment and instrument activation
- Attempting to remove the instruments when they are still attached to tissue or crossing inside the patient
- Applying too much pressure on the controllers that generates a temporary locking of the instrument
- Taking fingers off the controllers after activating instruments that results in uncontrollable movement

17. Preventing Injury (check all that apply)

- None
- Failure to establish a safe working space for the bedside assistant when placing assistant ports
- Not turning on the console speaker so that the assistant can hear intentions of the console surgeon

18. Organ/tissue injury (check all that apply)

- None
- Burn
- Puncture
- Avulsion
- Transection

19. Device Use Error (check all that apply)

- None
- Collisions arms/ instrument
- Excess force
- Pedal confusion (Accidental Actuation - Mono vs. bipolar activation)
Off-site injury/lack of device visualization
  □  Electrical arcing, sparking, charring

20. Emergency undocking had to be performed
  o  Yes
  o  No

**Postoperative Adverse Events**

21. Safe Removal of Instruments (check all that apply)
  □  None
  □  Attempting to remove instruments when they are still attached on tissue or crossing inside the patient
  □  Undocking the ports before the instruments are removed
  □  Clutching the robotic arm before instruments are removed, which could cause advancing the instruments towards the patient during removal
  □  Dropping instruments or other equipment during removal
  □  Discarding camera mount while removing drapes (mount is reusable)

22. Undocking (check all that apply)
  □  None
  □  Moving the OR table before robot is undocked
  □  Patient injury by the robot due to repositioning of the patient before undocking
  □  Collision with the patient or other OR equipment
  □  Not turning the robot off before attempting to move the patient from OR table to the gurney
  □  The robot cart running over cables and crushing them
  □  Falls resulting from the OR team tripping on a cable

**OR Team Information**

23. Team experience
  □  The OR team did not complete a formal team training course
  □  All members of OR team are not familiar with the setup and basic operations of the robotic system
  □  Lack of training with specific system features
  □  Type of bedside assistant
    □  PA
    □  MD
    □  RNFA
    □  CSTFA
    □  Resident
    □  Fellow
  □  Experience of the bedside assistant (total number of robotic cases as an assistant)
    o  0-5
    o  6-25
    o  26-50
    o  51-100
    o  101-500
    o  >500
Number of cases the assistant has worked with the console surgeon
- 0-5
- 6-25
- 26-50
- 51-100
- 101-500
- >500

24. Team-based errors (check all that apply)
- None
- Inadequate troubleshooting of technical problems
- Positioning of OR team does not take into consideration potential problems that may occur during surgery
- Paths are not clear for personnel to move freely about the room
- Errors while handling emergency situations

25. Team STEPPS Protocol errors
- None
- No call-back (The surgeon and assistant not repeating instructions) before conducting a specific action (instrument change, suture insertion, energy activation, repositioning, etc)
- No CUS (Concerned, Uncomfortable, Safety issue)
- No SBAR (Situation, Background, Assessment, Recommendation)
- No Pre- or Post-op Checklist
Appendix 2: Agenda

Robotic Surgery Data Registry Consensus Conference Agenda

AGENDA Day 1: Thursday, September 22, 2016

7:00am - BUS FROM BOHEMIAN HOTEL AND MELIA HOTEL TO FLORIDA HOSPITAL NICHOLSON CENTER

7:15-8:00am - BREAKFAST & REGISTRATION

8:00-8:10am - Welcome Jay Redan, MD, Richard Satava, MD, Jeffrey Levy, MD

8:10-8:20am - Introductions & Administrative Announcements Jeffrey Levy, MD

8:20-8:30am - Objectives of the FDA ‘Robotic Surgery Data Registry’ (RSDR) Rick Satava, MD

8:30-8:45 - History and Definitions Rick Satava, MD
- Identify specific products to be created during this event. (Data dictionary, repository, etc)
- Definitions: What will be measured (outcomes measures)? How will it be measured (metrics)?

8:45-9:45 - PANEL: Background Developing the RSDR Jeffrey Levy, MD (Chair)
- Discriminating System Malfunction vs Surgeon Error Tony Gallagher, PhD
- The FDA’s Needs Danica Marinac-Dabic, MD, PhD
- MDEpiNet and IDEAL Art Sedrakyan, MD, PhD
- ACS Surgical Quality Database Initiatives – NSQIP, SSR, PQRS Joseph Tepas, MD

9:45-10:00am - BREAK
10:00-11:30am - BREAKOUT SESSIONS

- Group 1: Clinicians – Structure and Metrics for Current Data Repositories
- Group 2: Clinicians and Researchers - Measurement Methods for the RSDR
- Group 3: Industry, Academia, Other Registries: How will the RSDR be Implemented?

11:30am-12:00pm - REPORTS OF GROUPS 1, 2 & 3

12:00pm-1:00pm - LUNCH

1:00pm-3:45pm - BREAKOUT SESSIONS (CONTINUED)

- Group 1: Clinicians – Structure and Metrics for Current Data Repositories
- Group 2: Clinicians and Researchers - Measurement Methods for the RSDR
- Group 3: Industry, Academia, Other Registries: How will the RSDR be Implemented?

3:45pm-4:00pm - Short Refresher BREAK

4:00-5:00pm - INTEGRATION REVIEW (ALL ATTENDEES)

- Integration Process of the Three Reports

5:30pm - BUS TO HOTEL

7:00-9:00pm - GROUP DINNER AT THE COLUMBIA RESTAURANT

AGENDA Day 2: Friday, September 23, 2016

7:00am - BUS FROM BOHEMIAN HOTEL AND MELIA HOTEL TO FLORIDA HOSPITAL NICHOLSON CENTER

7:15-8:00am – BREAKFAST

8:00-8:30am – Continued Background for Developing the RSDR

- Lessons learned from an alternative approach to surgical QI registry development
  - the SCOAP example
  - David Flum, MD, MPH

8:30-10:00am - BREAKOUT SESSIONS (CONTINUED)

- Group 1: Clinicians – Structure and Metrics for Current Data Repositories
- Group 2: Clinicians and Researchers - Measurement Methods for the RSDR
- Group 3: Industry, Academia, Other Registries: How will the RSDR be Implemented?

10:00am-10:15 - SHORT BREAK

10:15am – 12:00pm - FINAL INTEGRATION SESSION
Do the errors or malfunctions need to be validated?
Define the reports that need to be generated for malfunction vs error.
Is it possible for the surgeon to cause the robot to malfunction (improper use)?
For surgeon errors, who is notified (hospital, surgeon, industry, etc.)?
Is there suggested remediation for surgeon error (further training, mentor/proctor, etc.)?
How is the RSDR maintained and updated (longer term follow-up and longitudinal studies)?
The Role of Patient Safety Organization for Error Reporting

12:00-1:00pm - LUNCH

1:00-2:00pm - Wrap up Session and Next Steps
- Compile and review Consensus of Skills and Measurement Methods
- Give assignments to specific members
- Distribute Summary Report in 4 weeks
- Set dates and agenda for follow-up

2:00pm - DEPARTURE FROM NICHOLSON CENTER
- Transportation to airport available
Appendix 3: Pictures from the Consensus Conference

Lecturers
Appendix 4: FAQs Addressed Prior to the Consensus Conference

What issues will the consensus conference address? (See attached Agenda)

1) Developing a robotic surgery data repository based on experience with other existing surgical registries (ie, NSQIP, SCORE, etc.)
2) Meeting the needs of the FDA in developing this registry
3) Determining the metrics and structure of this registry
4) Assuring data security
5) Defining device malfunction, training error, and surgeon error
6) Determining the methodology used to differentiate a malfunction versus an error
7) Developing a registry design that can be a template for future registries
8) Determining educational and training remediation needed when a surgeon/surgical team error is discovered
9) Making the database entry process easy and usable to extract information from the submitted information

What is the structure and leadership of the registry?

The Robotic Registry Consensus Conference originated from a requirement within the FDA to create a registry that can support the mission of continuous monitoring of device safety (including innovation) of robotic-assisted surgical devices for patient benefit. A secondary FDA objective of the consensus conference is to create a registry template that can be used for other devices to improve comparison of device data with clinical outcomes data.

ISE will be responsible for the organization, management and fundraising activities of the Robotic Surgery Registry Consensus Conference and the development of a Robotic Registry. ISE has extensive experience in robotic education, training and research including conducting consensus conferences, assisting in the creation and hosting of the Fundamentals of Robotic Surgery (FRS) and the Fundamentals of Robotic Gynecologic Surgery (FRGS), providing administration for the international multi-institutional FRS validation trial, and managing the Robotic Training Network (RTN). Members of the leadership of ISE constitute the Organizing Committee for Robotic Registry Consensus Conference, and have appointed Drs. Jeffrey Levy, Jay Redan, and Richard Satava as facilitators of the conference.

What role do you envision for the specialty societies?

One of the main purposes of this consensus conference is to determine the most appropriate structure and outcome measures for the registry. Specialty society experience and input will be crucial for this component of the conference. Since many societies have their specialty-specific registries, the societies’ participation is essential in creating this registry in a manner that it can be both independent and interoperable with other clinical outcomes registries. Please note that this is a device registry and not a procedure specific registry, so a broad representation of surgical societies utilizing robotic assisted surgery is necessary.

What societies have confirmed participation?

- American College of Surgeons
How will this registry integrate with other specialty society registry efforts?

Part of the answer to this question will be determined through the consensus conference and that is why it is so important to have diverse society and surgical registry representation and input at this meeting. As indicated above, it is important to create a registry for the FDA that is independent yet interoperable with other registries. This is a complex process, which federal agencies know well in their data sharing with other agencies. One of the challenges for the conference will be to define how to integrate the federal FDA database with the civilian (surgical societies) database. The FDA’s Center for Devices and Radiological Health (CDRH) has the responsibility of receiving medical device safety data from industry. On the other hand, societies, such as the American College of Surgeons (ACS) have developed patient outcomes registries, such as National Surgical Quality Improvement Program (NSQIP) registry. Thus, another major objective of the conference will be to develop a method to correlate the robotic device registry data with the clinical outcomes data, in a de-identified, HIPAA compliant manner, in order to determine if an adverse clinical outcome in robotic surgery is due to device malfunction or to surgeon (or non-surgeon) cause.

What robotic device companies have confirmed participation?

- Intuitive Surgical
- Stryker
- Medtronic/Covidien
- J & J Verb Surgical (Google)
- Transenterix
- Medrobotics Corporation
- Titan Medical Inc.

Specifically, what role or access to data will industry have?

Seven robotic companies (listed above) will be participating in this conference, all of which have FDA approved commercially available systems, or emerging robotic surgery systems. These companies will define the device data which they can provide to the CDRH to include in the FDA registry database about the robotic devices. As indicated above, the two databases will be independent – FDA device database, and specialty society clinical outcomes database(s). The challenge is to determine how to correlate the data in order to resolve whether errors are robot malfunction or surgeon related.

None of the robotic device companies will have access to individual clinical data. The conference will help determine how to capture and provide data in a useful way, while preserving patient privacy, to improve patient safety and surgical outcomes on an ongoing basis.
Appendix 5: Meeting Slides and Reading Materials

Please go to the Dropbox link to find the meeting slides and reading materials.

https://www.dropbox.com/sh/i9gv4rembt7cw5b/AAATLh_Hkw4gEe06rTiFtPkSa?dl=0