Embracing Innovation: The Process of Research & Publication in Practice

Karol A Gutowski, MD, FACS
TO ADD

• How to evaluate a new product
  – Efficacy
  – Cost (use real company “estimates”)
  – Practice incorporation
• Quill experience
• Rep calling office asking about new technology
• Financial analysis
  Case studies
  Eval a product or device
  Use biomed student
Disclosures

RTI Surgical - Advisor
Suneva Medical - Instructor
Angiotech/Surgical Specialties - Advisory Board
Viora - Nonpaid Speaker & Investigator
Learning Objectives

• Understand the innovation cycle
• Resources needed to innovate
• Industry relationships & partnerships
• Regulatory issues (HIPPA, IRB)
• Presentation & publication
• Common pitfalls
General Concepts

- Scientific approach to innovation
- Ask the question
- Set up the study
- Do the study
- Spread the news!
- Consult - Contribute
The “Hype Cycle”

- Technology Trigger
- Trough of Disillusionment
- Slope of Enlightenment
- Plateau of Productivity
- Peak of Inflated Expectations

VISIBILITY vs TIME
The “Hype Cycle”

- Peak of Inflated Expectations
- Plateau of Productivity
- Trough of Disillusionment
- Slope of Enlightenment
- Technology Trigger

OK to jump on here
Technology Overlap & Overtake

- Old Technology
  - Embryonic
  - Growing
  - Mature
  - Aging
  - Discontinuance

- New Technology
Technology Overlap & Overtake

Too late to jump on?
Innovation in Plastic Surgery

- Not limited to academic practice
- Many “non-academic” innovators
- Aesthetic treatments ideal for private practice
- Most ASAPS innovators are not “academic”
Ways to Get Started

• What do I do well?
• What don’t I do well?
• What is an unmet need?
• What is the competition doing?
• What are my patient’s asking for?
• Mega-trends vs micro-trends
Time & Resources
Industry Site Assessment

- Your clinical volume
- Past industry-sponsored studies
- Clinical staff & experience
- Methods for patient recruitment
- Equipment available
- Space available
- IRB
Time Commitment

• Your time commitment
• Staff training
  – Protocols
  – Documentation
• Staff time obligations
  – Consents
  – Follow up
  – Regulatory issues
• Workflow redesign
Partnerships & Relationships
Innovation Partnerships

• Academic centers
  – Identify collaborator
  – Statistical and analytic support
  – Resident support

• Colleagues
  – Plastic surgeons
  – Other specialties

• Do not need to be local

• Define roles and responsibilities early
Project Assistants

• Undergraduate students
• Medical students
• Residents & fellows
• Nurses & physician assistants

Check background
Industry Partners

• Build relationships
• Use the product
• Discuss ideas
• Look for improvements
• Ask for resources

Proceed with caution
Avoid Pitfalls

• Disclosures
• Legal agreements
• Conflict of interest
• Intellectual property
• Confidentiality agreements

Maintain your ethics
Innovation & Research: IRBs, HIPPA, Informed Consent
Is Innovation Considered Research?

• Fine line between trying something new and conducting human research

• **Research is:**
  – Testing of drugs, devices, or products
  – Data from surveys, interviews, observation
  – Medical records
  – Bodily materials, such as cells, blood, tissues, when linked to specific individuals

• May need IRB
Role of IRB

• Protect rights & welfare of research patients
• Monitor between patient and physician
• Can suspend or terminate research
• Help researcher
  – Decrease risk
  – Improve study design
Do I Need IRB Approval for

- Chart reviews?
- Pulling data from my database?
- Studies I think are minimal risk?

YES
Avoid the IRB Pitfalls

• Play by the rules
  – Ask for guidance from IRB
  – Review every submission & revision yourself

• If you don’t
  – Not get published
  – Be sanctioned
  – Shut down research
Multicenter Trials & Local IRBs

• Expect
  – Paperwork revisions
  – Duplication of efforts
  – Inconsistencies in recommendations

• Therefore, be
  – Proactive
  – Patient
  – Prepared for long timeline
Data Safety Monitoring Boards

- Purpose: Subject safety
- Used by industry and NIH sponsored studies
- Increasingly required for investigator initiated studies

Study stopped
Waiving Requirement for Informed Consent

- Research involves no more than minimal risk
- Waiver will not adversely affect the rights or welfare of the subjects
- Research could not be practicably carried out without the waiver
- Subjects will be provided with pertinent information after participation
Informed Consent

- Provide summary page
- 6th to 8th grade reading level
- Short sentences and paragraphs
- Use of Question & Answer format (FAQs)
- Increase font size, use bold, italics, color
- Use of bullet points
- Cite major risks, append others
- Use of tables for risks
- Use graphics
- Don’t overestimate benefits or, underestimate risks
HIPPA

- Maintain study subject confidentiality
- Requires well thought out plan to gather data
- Review HIPPA guidelines
- Document all researchers HIPPA training
Medical Records & Database Research

• If the **intent** is to collect data to answer a question that may develop or contribute to general knowledge, the project is probably research

• **Rule of Thumb**: If the intent is to publish the data or present it at a professional conference, the activities probably constitute research
Preparatory to Research

• Activities that can be performed without HIPAA authorization:
  – The development of research questions
  – The determination of study feasibility (available number and eligibility of potential study participants)
  – The development of inclusion and exclusion criteria
  – The determination of eligibility for study participation of individual potential subjects

• Preparatory Research Certifications may need be filed with institution Privacy Officer
Databases

• Use of database information can constitute human subjects research

• Databases created for clinical purposes (even if they may be used at some point to answer a research question) do not require IRB review but must be registered with HIPAA Privacy Officer

• Databases created for research require IRB review & registration with HIPAA Privacy Officer
What’s Coming Next?

• Clinical trial registration
  – Government
  – Publishers

• Trial standardization
  – CONSORT Statement
Avoiding Pitfalls

• Have a hypothesis
• Do the literature search
• Try a pilot study
• Determine sufficient sample size
• Measurable outcomes
• Overestimate time and resources needed
• Proper documentation and informed consent
• Watch for conflicts of interest
Getting Started
Know the Background

• Literature search
  – Was this already done?
  – What knowledge is missing?
  – Is the data current and applicable?

• Who is the competition?

• Ask to see industry (internal) data

• Talk with industry researches & scientific team
Design the Project

• Topic/research question
• Hypotheses
• Patient population
• Study design
• Data collection/instruments
• Analysis
• Funding sources
• Dissemination of study findings
Useful Tools

- Patient database
- Validated survey & assessment instruments
  - Wrinkle reduction scale
- Standardized outcomes tools
  - Breast-Q
  - Face-Q
- Standardized imaging & analysis
- Statistical support
  - Underpowered studies
  - Objective comparisons
Assessment Scales

Rated Numeric Kinetic Line Scale Scores for Facial Wrinkles Secondary to Hyperkinetic Function

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No wrinkles</td>
</tr>
<tr>
<td>1</td>
<td>Wrinkles not present at rest, fine lines with facial expression</td>
</tr>
<tr>
<td>2</td>
<td>Wrinkles not present at rest, deep lines with facial expression</td>
</tr>
<tr>
<td>3</td>
<td>Fine wrinkles present at rest, deeper with facial expression</td>
</tr>
<tr>
<td>4</td>
<td>Deep wrinkles at rest, deep furrows with facial expression</td>
</tr>
</tbody>
</table>

AFPS 2004
Patient Reported Outcomes Tools

**BREAST-Q and FACE-Q**

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**Measuring Quality of Life in Cosmetic and Reconstructive Breast Surgery: A Systematic Review of Patient-Reported Outcomes Instruments**

Andrea L. Pušić, M.D., M.H.S.
Constance M. Chen, M.D.
M.P.H.
Stefan Cano, Ph.D.
Annie Klassen, Ph.D.
Coleen McCarthy, M.D.
E. Dale Collins, M.D.
Peter G. Cordeiro, M.D.

New York, N.Y.; London, United Kingdom; Vancouver, British Columbia, Canada, and Lahaina, N.H.

**Background:** Patient-reported outcomes in cosmetic and reconstructive breast surgery are increasingly important for clinical research endeavors. Traditional surgical outcomes, centered on morbidity and mortality, remain important but are no longer sufficient on their own. Quality of life has become a crucial research topic augmenting traditional concerns focused on complications and survival. Given this, reliable and valid patient questionnaires are essential for aesthetic and reconstructive breast surgeons.

**Methods:** The authors performed a systematic literature review to identify patient-reported outcome measures developed and validated for use in cosmetic and reconstructive breast surgery patients. Qualifying instruments were assessed for adherence to international guidelines for health outcomes instrument development and validation.

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**Measuring Outcomes That Matter to Face-Lift Patients: Development and Validation of FACE-Q Appearance Appraisal Scales and Adverse Effects Checklist for the Lower Face and Neck**

Anne E. Klassen, D.Phil.
Stefan J. Cano, Ph.D.
Amie M. Scott, M.P.H.
Andrea L. Pušić, M.D., M.H.S.

Hull, Ontario, Canada; Plymouth, United Kingdom; and New York, N.Y.

**Background:** The FACE-Q is a new patient-reported outcome instrument to evaluate a range of outcomes for patients undergoing any type of facial cosmetic operation, minimally invasive cosmetic procedure, or facial injectable. This article describes the development and validation of FACE-Q scales relevant to facelift patients.

**Methods:** The FACE-Q was developed by following international guidelines for patient-reported outcome instrument development. For outcomes following...
Is this Product or Device Approved? Know the FDA
501K Clearance

• FDA does not “approve” medical devices
• FDA “clears” them for sale
• FDA clearance does NOT imply level of efficacy
• A device may be cleared for a different use
  – RF fat reduction devices are cleared for tissue warming
• Starts with Premarket Notification to FDA
  – FDA determines if similar to device in 1 of 3 classes
  – Class I: Exempt due to minimal risk (tongue depressor)
  – Class II: Some risk
  – Class III: Support or sustain human life
“Off-Label” Use of FDA Cleared Device

• May use cleared device “off-label” to treat
• May NOT use for research unless IRB approved
• Is this device approved?
Tissue & Cell Therapies

- FDA regulates HTCP (Human cells & tissue products)
- Excludes “autologous cells recovered & implanted during the same surgical procedure”
- No premarket approval if tissue:
  - Minimally manipulated
  - Homologous use
  - Not combined with another article

Controversial:
Proceed with Caution
Working with Industry: The Pitfalls
Negative Press

• More government & public oversight

Senate Launches Investigation of Medtronic Spine Fusion Device
June 22, 2011
By JOHN FAUBER, Milwaukee Journal Sentinel/MedPage Today

• Association with “bad” product

Spine Experts Repudiate Medtronic Studies
By BARRY MEIER and DUFF WILSON
Published: June 28, 2011 | 59 Comments

• Ghostwriting by Industry

Report Urges More Curbs on Medical Ghostwriting
By NATASHA SINGER
Published: June 24, 2010

The New York Times
Open Payments

Creating Public Transparency of Industry-Physician Financial Relationships

The Official Website for Open Payments (Physician Payments Sunshine Act)

Open Payments creates greater transparency around the financial relationships of manufacturers, physicians, and teaching hospitals. The program requires that the following information is reported annually to CMS:

- Applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report payments or other transfers of value they make to physicians and teaching hospitals to CMS.
- Applicable manufacturers and applicable group purchasing organizations (GPOs) to report to CMS certain ownership or investment interests held by physicians or their immediate family members.
- Applicable GPOs to report to CMS payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest at any point during the reporting year.
Intellectual Independence

• Institutional guidelines
  – Preserve independence & control

• Identify common goals with industry
  – Win-win situation
  – Funding and resources for your research
  – Favorable results with a product
  – Identify contraindications/flaws with products

• Conflict of interest

• Don’t be a “Hired gun”

• Bias towards positive results
  – Study design
  – Result reporting
Intellectual Property

• Institutional guidelines
  – Protect your and institutions IP

• Document everything
  – Signed & dates notebook
  – Archive emails
  – Unopened certified letters
  – Nondisclosure agreements
  – Patent issues

• Have these discussions early in the process
Funding for your Innovation
Funding Sources: Industry

- More complex
- More restrictions
- Perception of bias
- May provide products or device
- May provide statistical & analytic support

- Need established relationship and track record
Funding Sources: Professional Organizations

• Formal grant process
• Consider grant writing workshop
• Partner with established researcher
Funding Sources: Institutional

• Hospital grants
• Academic center grants
  – Include residents
  – Need faculty member
• Start-up and pilot-study grants
• Institution may benefit
  – More external grants
  – Public relations
Other Funding Sources

- Philanthropy organizations
- Service organizations
- Grateful individuals & patients
Presenting, Publishing and Disseminating your Innovation
Disseminating Innovation

- Public education & relations
- Paper presentations
- Trade publications
- Journal publications
Public Education & Relations
Paper Presentations

• Hospital Conferences
• Local & Regional Societies
  – Consider non-plastic surgery organizations
• National societies
  – More formal applications
  – Competitive
  – Long lead time
  – Industry exposure
Trade Publications

• Less science, more trends and opinions
• Industry exposure
• Patient PR tool
Professional Journal Publications

- More science, less opinion
- Best industry exposure
- Need to plan before staring the project
- Time intensive if doing it alone
- Consider partnerships
The Components

• Abstract
• Introduction
• Methods
• Results
• Tables and Photos
• Discussion
• References
Authorship

• Explicit assigning responsibility & credit
  – Conception
  – Design
  – Execution
  – Analysis & interpretation

• NOT a right to inventorship or copyright

• Be able to explain & defend the study

• Define upfront with industry & other partners
Embracing Innovation: The Process of Research & Publication in Practice

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Course Information & Objectives

Monday, April 28
4:30pm – 6:30pm

716 From Hot Topics to a Hot Practice – How Innovation Can Drive a Thriving Practice
2 CME credits — Discounted pre-registration fee: $140 On-site fee: $190
Joe Gryskiewicz, MD, Karol Gutowski, MD and Brian Kinney, MD

Level: Basic/Comprehensive
Organization: Panel

Who is allowed to attend Surgeons/Spouse/Physician’s Assistants/Registered Nurses/Office Personnel/Exhibitors

Course allowed to be recorded: Yes

Any additional AV requirements beyond basic set up (basic includes 1 screen, LCD projector, microphone, laser pointer): No

3-5 goals or objectives for the course:

• Develop expertise in surveying the tech environment and identifying ideas for development
• Creating a successful business plan, dealing with investors and managing money wisely
• Navigating the FDA and establishing preclinical designs
• Evaluating scientific success and business success, what works, what doesn’t
• Establishing relationships with companies, working as a team and maintaining independent credibility
• How to evaluate and compare competing products (toxins, energy devices, etc.)
• Developing clinical expertise with new products, best practices
• Differences and challenges in practice setting type (Private Practice, Academic, Group Employed)
• Presenting & publishing
• Marketing your innovative practice
• Assess scientific success and business success, deciphering what works and what does not