New Medical Technology

What Do Doctors Want?

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Chair, STS Council on Health Policy and Relationships
Medical Devices

Doctors want to help patients

Devices can help patients

Doctors & manufacturers can collaborate to help pts
What Do We Want?

It really depends on who “we” is

Politico

Statesman
What Do We Want?

If “we” means practicing surgeons in the community

The standards required are not overly demanding

Evidence of benefit

Low risk of harm

Patient acceptance

Reimbursable

Specialty organizations may have higher standards
What Do We Want?

If “we” means the physician specialty organizations
The standards can and should be more stringent
  Proven efficacy - peer reviewed papers
  Proven safety - peer reviewed papers
  Economic rationale - cost effective
  Defined candidates - not off label
  Effectiveness - real world results

Patient & societal welfare are primary responsibility
Potential Collaboration

- Initial CPT code proposal
- Initial training and CME
- Long-term follow-up registry
- Practice guidelines
Potential Collaboration

- Initial CPT code proposal
- Initial training and CME
- Long-term follow-up registry
- Practice guidelines
Why Enlist Specialty?

Anyone can propose a new CPT code
  Industry
  Physician
  Specialty society

Why not just use inventors and/or investigators?
  Lack of objectivity       Too close; blind spots
  Bias is unavoidable      Academic prestige
  CPT/RUC/CMS              Financial interest
  Avoid conflict of interest

SPECIALTY PERSPECTIVE
**Why Enlist Specialty?**

Specialty societies can offer distinct advantages

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<thead>
<tr>
<th>Expertise</th>
<th>Medical knowledge</th>
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<tbody>
<tr>
<td></td>
<td>CPT / RUC rules and process</td>
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<td>CMS rules and process</td>
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<tr>
<th>Contacts</th>
<th>Practitioners</th>
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<td>AMA officials</td>
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<td>Governmental officials</td>
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<td>Specialty’s Desires</td>
<td>Communication</td>
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<tr>
<td>Lead Time</td>
<td>Fixed CPT/RUC cycles</td>
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<tr>
<td>Information</td>
<td>Device</td>
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Device Information

What does it do?
What are the risks of its use?
What, if anything, does it replace?
What competing technologies are in use?
How is it different from competing technologies?
Why is it better than competing technologies?
Is the CPT code proposal device specific?
What CPT category is appropriate - I or III?
Personnel Information

Doctor
Who is actually involved in service/procedure?
What portion of service involves physician work?
Who could serve as physician champion/advisor?

Patient
What patients should be treated with this device?
Who should not be treated with this device?
How many pts are estimated to be candidates?
Miscellaneous

Is there supportive peer reviewed US literature?

Is there a pre-existing code which may apply?

Where will the service be provided (OR, office)?

Will the service be provided in the postop period?
Potential Collaboration

Initial CPT code proposal

Initial training and CME

Long-term follow-up registry

Practice guidelines
Early Training & CME

Society of Thoracic Surgeons (STS) has sponsored training of its members for many devices:

- Thoracoscopy
- EUS and TBUS
- Endovascular stenting
- Atrial fibrillation ablation
- Off pump coronary surgery
- Stentless aortic prosthesis
- Mechanical circulatory support

Official STS Endorsement Program for industry
CME programs which meet strict criteria
Potential Collaboration

- Initial CPT code proposal
- Initial training and CME
- Long-term follow-up registry
- Practice guidelines
Registry Follow-up

STS National Adult Cardiac Database

Voluntary, audited prospective clinical database
Has been in existence for 17 years
Captures approximately 80% of all cardiac cases
Currently contains over 3,000,000 pt records
Includes >250 clinical data points per patient
Recognized by CMS, NQF, AQA and Congress
Major use to date - in hospital quality improvement
Currently negotiating with CMS and FDA to link our clinical database to the CMS administrative database to allow for long term follow-up of TMR and atrial fibrillation surgery.

- CMS: Coverage with evidence development
- FDA: Post market surveillance
Other Databases

STS General Thoracic Surgery Database
STS Congenital Heart Surgery Database
ACS Nat’l Surgery Quality Improvement Project
American College of Cardiology (Interventional)
Potential Collaboration

- Initial CPT code proposal
- Initial training and CME
- Long-term follow-up registry
- Practice guidelines
<table>
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<th>SPECIALTY PERSPECTIVE</th>
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### Quality Improvement Programs

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<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>How should the device be used in practice?</td>
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<tr>
<td>Who should be allowed to use the device?</td>
<td>Training (MD, RN, PA, ANP) Certification Volume criteria</td>
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<td>Is use of the device a quality measurement?</td>
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<td>Ensuring quality would maximize the chance for patient benefit and device success</td>
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What We Don’t Want

“Me too” devices - same function at higher cost
CPT code proposals specific to a single device
CPT proposal with little supportive literature
CPT proposal for a code not widely used in US
Last minute requests for assistance/support
Unrealistic predictions regarding outcome/costs
Misleading information regarding safety/risks
What Do We Want?

To be able to collaborate with device makers
Development of new devices
Submission of CPT/RUC proposals
Initial training and CME
Short and long-term device follow-up

Collaboration between specialty societies and device makers could greatly benefit patients

To do this we need full disclosure of information both good and bad regardless of economics
The Perfect Union?

Robots doing heart surgery

By April Prince

Mighty Zeus in action
Criteria for Endorsement

1. Content based on best, most updated evidence
2. Program is fair, balanced and non-promotional
3. Content cannot disparage other products
4. Must be germane to the work of STS members
5. Content ultimately directed toward benefit of pt
STS Endorsement Program

Stipulations

1. The Workforce on Clinical Education will vet activities and presentations for which STS endorsement is sought.
2. STS must approve the objectives and final program.
3. The organization seeking endorsement must disclose the background of all speakers, including information regarding their potential conflicts of interest and STS must have an opportunity to provide comment/input.
4. A significant percentage of speakers should be STS member cardiothoracic surgeons.
5. If wet labs are to be used for demonstrating new procedures and techniques, STS member surgeons should be involved in the majority of the teaching.

6. If speakers have a potential conflict of interest (e.g. honorarium, speaker fees, project PI, grants, etc.), this must be disclosed to the program participants both orally and in meeting materials.

7. The program as offered to physicians must be in compliance with the American Medical Association's Council on Ethical and Judicial Affairs ethical opinion of Gifts to Physicians from Industry (Opinion 8.061).

8. All educational programs should include an outcomes component that demonstrates the impact of the educational activity on the clinical practice of participants.
What does the specialty get out of it?

- Further scientific advancement
- Improve patient care and outcome
- Potential additional work for members
- Fulfillment of professional responsibility
Whom to Contact

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<tr>
<th>Specialty Society</th>
<th>Billing and coding staffer</th>
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<tr>
<td></td>
<td>Coding committee chair</td>
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<td>Health policy chair</td>
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<td></td>
<td>Executive director</td>
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<td>Society president</td>
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Potential Collaboration

STS National Adult Cardiac Database

Provide trend analysis to Assess product growth
Determine market share
ID healthcare device needs

Provide STS data as a national referent group in new product development studies

Identify geographic regions with potential for clinical trial patient enrollment

Provide historical data to design clinical trials that can detect meaningful (clinical and statistical) differences
This category of CPT codes is based upon the procedure being consistent with contemporary medical practice and

- the service/procedure received approval from the Food and Drug Administration (FDA)

- many health care professionals perform the service or procedure in multiple locations across the country

- the clinical efficacy of the service/procedure has been well established and documented
Category III Codes

Emerging Technology

Temporary tracking code for new & emerging technology

Data collection
Assessment of new services & procedures
Substantiate widespread usage
Useful for FDA approval process

Used for reimbursement negotiations (CMDs, private payers)

May not conform to the usual CPT code requirements:
- the service/procedure has proven clinical efficacy
- FDA approval documented/imminent in a given CPT cycle
- performed by healthcare professionals across the country