Reprocessing at UCSF

Wins for the environment and the Medical Center

Virginia Terra Hodge, Interventional Cardiology
Chris Pollak, Performance Excellence

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“Reprocessing is one of the best things we’ve ever done. It’s a gift that keeps on giving.”

Byron Lee, MD
Director of the Electrophysiology Laboratories and Clinics
A Few Stats on UCSF

- UCSF is the only campus in the 10-campus University of California system devoted exclusively to the health sciences, and exclusively to graduate-level programs (medicine, nursing, pharmacy, dentistry).
- UCSF is the second-largest employer in San Francisco, with a paid workforce of 22,500, after the City and County of San Francisco.
- UCSF Medical Center has 495 licensed beds for adult patients.
- UCSF Benioff Children’s Hospitals, with locations in San Francisco and Oakland, has a total of 345 licensed beds.
- UCSF Medical Center and UCSF Benioff Children’s Hospitals see about 40,000 inpatients and generate more than 1 million outpatient visits per year.
UCSF’s Two Cents on Reprocessing

We Will Cover …

- Problems created by medical waste
- What reprocessing is
- Results at UCSF
- How to set up your own program
- Lessons learned
- Your questions
US Hospitals Generate 5.9 Million Tons of Medical Waste Each Year

- That does not include waste from other locations where healthcare services are provided, such as dentist offices, private physician practices, nursing homes, etc.
What Happens To All of That Waste?

15% Regulated Medical Waste

85%
What Happens To All of That Waste?

15% Regulated Medical Waste

- Pharmaceuticals
- Chemotherapy
- Pathologic Waste

1%

- Sharps
- Bio-Contaminated

14%

Incinerate

Autoclave
It Is Part of Our Professional Responsibility To Use Healthcare Resources Judiciously

Health Care Spending as Percentage of GDP

Source: OECD Health Data 2013.
Produced by Veronique de Rugy, Mercatus Center at George Mason University.
Medical Bills Are the Biggest Cause of Personal Bankruptcy in the US

- Bankruptcies resulting from unpaid medical bills will affect nearly 2 million people this year.
- Outside of bankruptcy, 56 million adults—more than 20 percent of the population between the ages of 19 and 64—will still struggle with health-care-related bills this year.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Cause of Personal Bankruptcy</th>
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<tbody>
<tr>
<td>1</td>
<td>Medical Expenses*</td>
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<tr>
<td>2</td>
<td>Job Loss</td>
</tr>
<tr>
<td>3</td>
<td>Poor/Excess Use of Credit</td>
</tr>
<tr>
<td>4</td>
<td>Divorce/Separation</td>
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<tr>
<td>5</td>
<td>Unexpected Expenses</td>
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* Represents 62% of the total; 78% of filers had some form of health insurance.

Source: Harvard University

Types of Debt Collected From Consumers in 2013

- Health care: 38%
- Student loans: 25%
- Credit cards and other financial services: 10%
- Government: 9%
- Retail: 8%
- Telecom: 4%
- Utility: 4%
- Mortgage: 2%
- Other: 1%
Medical Device Use

Devices are labeled as reusable or single use

- All devices are subject to FDA review – referred to as premarket review – before they may be legally marketed in the United States
- Decision to label a device single-use or reusable is the OEM’s
- Reusable – Manufacturer (OEM) must provide FDA with data demonstrating the device can be safely reused
- Device may be labeled single-use because:
  - OEM believes device can only be safely and reliably used once
  - OEM chooses not to conduct studies needed to demonstrate that the device can be labeled as reusable
What Is Reprocessing?

Cleaning and sterilizing a device without impairing its function

- Some devices fall into another category – they are labeled and marketed by the original manufacturer as single-use devices, but with clearance from FDA are being reprocessed for reuse
- Devices are cleaned, sterilized, and checked for functional integrity according to all of the requirements currently applicable to OEMs
- In the United States, the majority of reprocessing is performed by third-party reprocessors

<table>
<thead>
<tr>
<th>Reusing the tools of surgery</th>
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<tbody>
<tr>
<td><strong>Electrophysiology catheters</strong></td>
<td>Tube inserted in the groin or neck area and fed up to the heart; used to diagnose heart rhythm problems</td>
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<tr>
<td><strong>Endotracheal tubes</strong></td>
<td>Inserted into the tracheas to provide an open passage for air</td>
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<tr>
<td><strong>Endoscopes</strong></td>
<td>Illuminated, tubular devices used to visualize an internal organ or body cavity</td>
</tr>
<tr>
<td><strong>Laparoscopic surgical instrument</strong></td>
<td>Used to grasp or cut tissue in minimally invasive surgery</td>
</tr>
<tr>
<td><strong>Burs and shavers</strong></td>
<td>Used to grind down bone or cartilage</td>
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</table>

SOURCES: National Institutes of Health; Ascent Healthcare Solutions
Is Reprocessing Safe?

- FDA regulates the reprocessing of single-use devices and has strengthened its oversight in recent years, as the popularity of reprocessing has grown.
  - All reprocessed devices must receive 510(k) clearance from the FDA.
  - FDA inspects reprocessing companies.
  - FDA monitors reports of adverse events.
What Can Be Reprocessed?

- Expired, unused devices such as biliary stents, aneurism clips or embolization coils
- Low-risk, FDA Class I non-invasive devices
- Medium-risk, FDA Class II minimally invasive surgical devices

<table>
<thead>
<tr>
<th>Class I – Non-invasive</th>
<th>Class II – Minimally Invasive</th>
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<tbody>
<tr>
<td>Sequential compression sleeves</td>
<td>Laparoscopic graspers</td>
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<tr>
<td>Blood pressure cuffs</td>
<td>Scissors</td>
</tr>
<tr>
<td>Pulse oximeter sensors</td>
<td>Forceps</td>
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<tr>
<td>Infuser bags</td>
<td>Scalpels</td>
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<tr>
<td>Tourniquets</td>
<td>Orthopedic blades, bits, burs</td>
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<tr>
<td></td>
<td>External fixation components</td>
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<td></td>
<td>Electrophysiology cardiac catheters, cables</td>
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</table>
How Does It Work, from the Hospital’s Point of View?

- Collect at the point of use (OR, inpatient units)
- Reprocessing vendor picks up collections
- As you purchase:
  - View and order available inventory from reprocessing vendor
  - Stock reprocessed devices with (in front of) the equivalent OEM product
- If physicians have been allowed to opt out, you will need to manage a process for ensuring they get OEM only
To Buy Back, or Not To Buy Back?

- Collection is a good way to start
- Pooled versus non-pooled devices
- When the price of reprocessed vs. OEM products are essentially the same, each hospital must decide how to balance cost, risk and the environment
Results at UCSF

Less waste, more savings

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</thead>
<tbody>
<tr>
<td>Hygia</td>
<td>2,462</td>
<td>3,592</td>
<td>11,234</td>
<td>16,693</td>
<td>$78,755</td>
<td>$106,266</td>
<td>$72,628</td>
<td>$42,233</td>
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<tr>
<td>Masimo</td>
<td>-</td>
<td>5,552</td>
<td>11,163</td>
<td>11,163*</td>
<td>-</td>
<td>$21,355</td>
<td>$36,764</td>
<td>$36,764*</td>
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<tr>
<td>Stryker</td>
<td>11,863</td>
<td>14,664</td>
<td>10,349</td>
<td>16,966</td>
<td>$594,737</td>
<td>$813,904</td>
<td>$822,074</td>
<td>$962,197</td>
</tr>
<tr>
<td>Total</td>
<td>14,325</td>
<td>15,041</td>
<td>32,746</td>
<td>44,822</td>
<td>$673,792</td>
<td>$903,336</td>
<td>$931,466</td>
<td>$1,041,194</td>
</tr>
</tbody>
</table>

* Estimate. Figures for FY2015 not yet available; expectation is higher than FY2015 pounds and savings.
EP Lab: A 2-Year, Overnight Success

Through perseverance, EP Lab became the model unit

- Our first foray failed
  - Lacked the framework to support the request
  - Physician leadership
- Second time was the charm
  - Byron Lee, physician champion
  - The team worked through the logistics and physician resistance
  - Overcame OEM obstacles
- Today, the EP Lab collects and purchases everything it can
Standing Up to OEM Pressure

A strong team and dedication are required

- Reprocessing runs contrary to the interests of the OEMs
- Pressure may take several forms
  - Losing volume-related pricing discounts
  - Less favorable pricing – no longer a preferred account
  - Less support in the clinical environment
  - Reps trash-talking reprocessing to MDs
- Being aligned with your MDs is critical to holding your ground
Setting Up Your Program

1. Build the team
   - Physician champion(s)
   - Nursing champion(s)
   - Materials manager
   - Project manager
   - Buyer from Purchasing
   - We had, but you may not need:
     - Sterile Processing representative
     - Operations manager
   - We didn’t have, but you might want/need someone from:
     - Infection control
     - Value analysis
     - Greening the OR team member
Setting Up Your Program

2. Start with collections

- Get the head of the department on board (e.g., Chief of Surgery)
- Choose a reprocessing vendor(s)
- Train the staff
  - Reprocessing rep will inservice and get bins in place
  - Make it easy with photos on the collection bins
  - No space in the OR? Use the case carts
- Create a way to report waste avoidance and dollar savings to staff

Advantages to starting with collections: There is less resistance to collections and – for non-pooled devices – you begin to build an inventory to repurchase
Setting Up Your Program

3. Purchase reprocessed devices

- Prioritize products to begin purchasing – UCSF started with harmonic scalpels
- Create an information packet for physicians and others
- Work through purchasing process with Materials team (so reprocessed is purchased first, then OEM when reprocessed is not available)
- Communicate to physicians – from the most senior influencer (e.g., Chief of Surgery) and physician champion
  - Is opting out allowed? Will savings be shared with the departments?
- Identify the physician users of targeted products and speak with them, ideally one-on-one, to gain support (physician champion)
Reprocessing Website

Website acts as an information clearinghouse

Shared Documents

- UCSF's Reprocessing Program
- Reprocessing Documents (White Papers, Articles, etc)
- Government-Regulatory
- Device-Specific Information
- Ascent-Stryker General Information
- S10(k)'

Links to Useful Reprocessing Websites

- FDA Site for Reprocessing
  U.S. Food and Drug Administration's "Device Advisor: Comprehensive Regulatory Assistance for Reprocessing of Single-Use Devices"
- S10(k) Database - Third party Reprocessors of Single-use Devices
  FDA issues S10(k) Premarket Notification when a third-party reprocessor has been given approval to reprocess a specific device. This site contains a searchable database, to find the S10(k) for a particular device.
- List of S10(k)s Known To Be Reprocessed or Considered for Reprocessing
  The U.S. Food and Drug Administration publishes its "List of S10(k)s Known To Be Reprocessed on Confidence for Reprocessing" (Attachment 1 of the September 25, 2012 Federal Register Notice).
- MAUDE - Manufacturer and User Facility Device Experience
  - MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1996, and manufacturer reports since August 1996. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 CFR 803.14. - This online search allows you to search CDRH database information on medical devices which may have malfunctioned or caused a death or serious injury.
- MedWatch
  MedWatch is the FDA Safety Information and Adverse Event Reporting Program. This is the website for reporting serious problems to FDA.
- Association of Medical Device Reprocessors
  AMDR is the Association of Medical Device Reprocessors, a trade-based association representing third party reprocessors of medical devices. AMDR members perform an estimated 60 percent of the third party reprocessing done in the United States.
- ECRI
  ECRI is a non-profit health services research agency that maintains medical device safety reports in a searchable database.
- Association for Healthcare Resource & Materials Management
  Association for Healthcare Resource & Materials Management has a Reprocessing Advisory on its website.
- CADTH - Reprocessing Single-use Medical Devices in Canada
  Funded by Canada’s federal, provincial, and territorial governments, CADTH is an independent, not-for-profit agency that delivers information about health technologies, including reprocessed SUDs.

Content Editor Web Part
Edit this page to modify your web part content.
Reprocessing Website

- List of reprocessed devices purchased by UCSF, with 510(k) #s
- Reprocessing overview, and why UCSF has a program
- UCSF Policy statement
- Chief of Surgery’s letter

Shared Documents

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<td>UCSF’s Reprocessing Program</td>
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<td>Reprocessing Documents (White Papers, Articles, etc)</td>
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<td></td>
<td>Government-Regulatory</td>
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<td></td>
<td>Device-Specific Information</td>
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<td></td>
<td>Ascent-Stryker General Information</td>
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<td></td>
<td>510(k)’s</td>
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<td>(More Documents...)</td>
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- What CMS surveyors look for
- FDA, GAO reports and studies
- Federal Register – list of SUDs
- AORN guidance statement
Lessons Learned

- Your physician champion needs to be passionate and influential
- Think through the logistics
  - Where will the collection bins go? How does purchasing reprocessed devices fit in with the way we currently purchase?
- Plan ahead for how to counter physician resistance
- Dedicate time to monitoring collections and physician use, and use the opportunity to educate and encourage
- Make the savings public
- Identify who will carry the torch post-launch, when the team disbands
“We were successful because the team that championed the idea was able to overwhelm the expected skepticism and resistance with great enthusiasm.”

Byron Lee, MD
Director of the Electrophysiology Laboratories and Clinics
Questions?

We are happy to answer your questions, now and in the future

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