U.S. WOUND REGISTRY

Home | Leadership | Purpose | Data Collection | Participants | Contact

Using Registry Data in regards to Antimicrobial Dressings-Presented at the Meeting of the FDA's General and Plastic Surgery Devices Advisory Panel Sept 20, 2016

Caroline Fife, MD
Professor of Geriatrics, Baylor College of Medicine, Houston, TX
Executive Director, the U.S. Wound Registry

https://www.uswoundregistry.com/index.aspx

Key points

- RCTs in wound care demonstrate efficacy in ideal conditions
- Real world observational studies are needed to determine product safety and effectiveness
- Observational data tells us that antimicrobial dressing use is high likely because wound bacterial burden and/or infection rates are high
- The Wound Healing Index (WHI) allows wound risk stratification
- Structured data collected by >130 hospital wound centers is pooled to create the US Wound Registry which is also a Qualified Clinical Data Registry
- The USWR is the ideal way to understand patterns of practice, monitor safety and determine the effectiveness of products and devices

Real Patient

- Average wound center patient age:
  - 60.4 years
- Average wound duration at consultation
  - 189 days (6 months)
- Average number of co-morbid conditions = 6
  - 16% with CAD
  - 10% current smokers
  - 8.4% on steroids
  - 5% have renal failure or transplant
  - 26% of wounds that were not specifically diabetic foot ulcers were in patients who had diabetes

Registries provide the observational data necessary to understand real world *effectiveness.*

Image off the internet

The US Wound Registry (USWR) is a Qualified Clinical Data Registry (QCDR)

- 501(c)(3) non profit organization
  - No sponsors, no support from a specialty society, no federal grants
- Physician Quality Reporting System (PQRS) Registry since 2008
- QCDR since 2014
- Developed 21 wound care related quality measures—important types
    - Patient Reported Quality Measures
      - **Wound Quality of Life, Nutritional Screening**
      - **Patient Reported Wound Outcome**
  - Available as electronic clinical quality measures (eCQMs) for free download into any certified EHR
- Sponsors 7 "Meaningful Use" registries (CTPs, NPWT, DFU, VLU, etc.)
  - Listed on *Clinical trials.gov*; independent IRB
  - Receives data from any certified EHR under MU requirements
  - No interfaces needed; No secondary data entry

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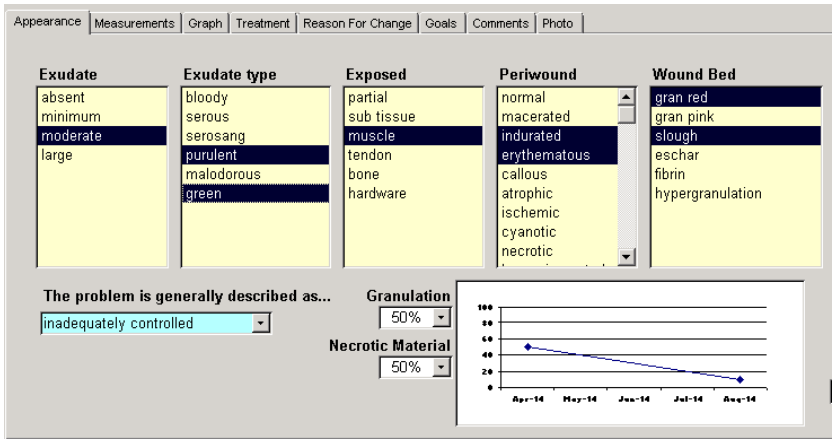
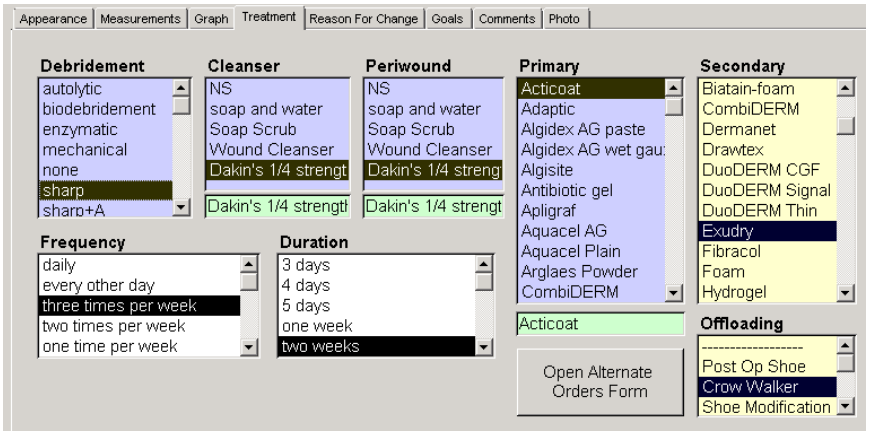
USWR Data include:

- Detailed description each wound at each visit
  - Drainage amount, odor, granulation, size, etc.





- Every dressing used by brand (130 hospital clinics)
  - Currently there are >200,000 discrete patients with >500,000 wounds and >2 million visits (34 US States and Puerto Rico), including all co-morbid conditions, demographics, eRx, wound treatments, outcomes, etc.
- Duration of use of every dressing
- Debridement details if performed
- Whether the appearance of the wound changed in response to the dressing

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Real World Use of Antimicrobial Dressings

- 5,240 patients (7,099 wounds)
- Only 66% of wounds healed
- Average time to heal: 15 weeks (107 days)
  - 10% of wounds took >33 weeks to heal
- 71% of wounds treated with antimicrobial dressings
  - 4.7% of wounds received 4 or more different episodes of care with antimicrobial dressings
- Wounds present for 6 months on average before antimicrobial dressing was used
- Antimicrobial dressings were used longer when:
  - The patient had multiple co-morbidities
  - The wound was non healing
  - Systemic antibiotics were used
- Antimicrobial dressings were used an average duration of 4 weeks

A Retrospective Data Analysis of Antimicrobial Dressing Use in 3,084 Patients. Fife, et al, OWM 2010: 56(3); 28-42.

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Distribution of Dressings by Category

(since dressings can be comprised of more than one component, the total is more than 100%)

Dressing	Chronic Ulcer	Diabetic Foot Ulcer	Pressure Ulcer	Venous Ulcer
Silver	17.9%	18.5%	18.4%	20.4%
Hydrogel	4.5%	4.3%	2.9%	2.8%
Absorbent	80.7%	86.9%	77.8%	81.3%
EnzymaticAgents	7.8%	7.7%	9.9%	6.8%
Collagen	8.3%	10.2%	9.1%	8.6%
Hydrocolloid	1.6%	1.0%	4.4%	0.6%
Iodine/Iodosorb	10 %	13.6 %	7.3 %	8.6 %
TopicalAntibiotic	7.5%	5.7%	5.1%	4.5%
Film	10.0 %	7.8 %	14.9 %	4.8%

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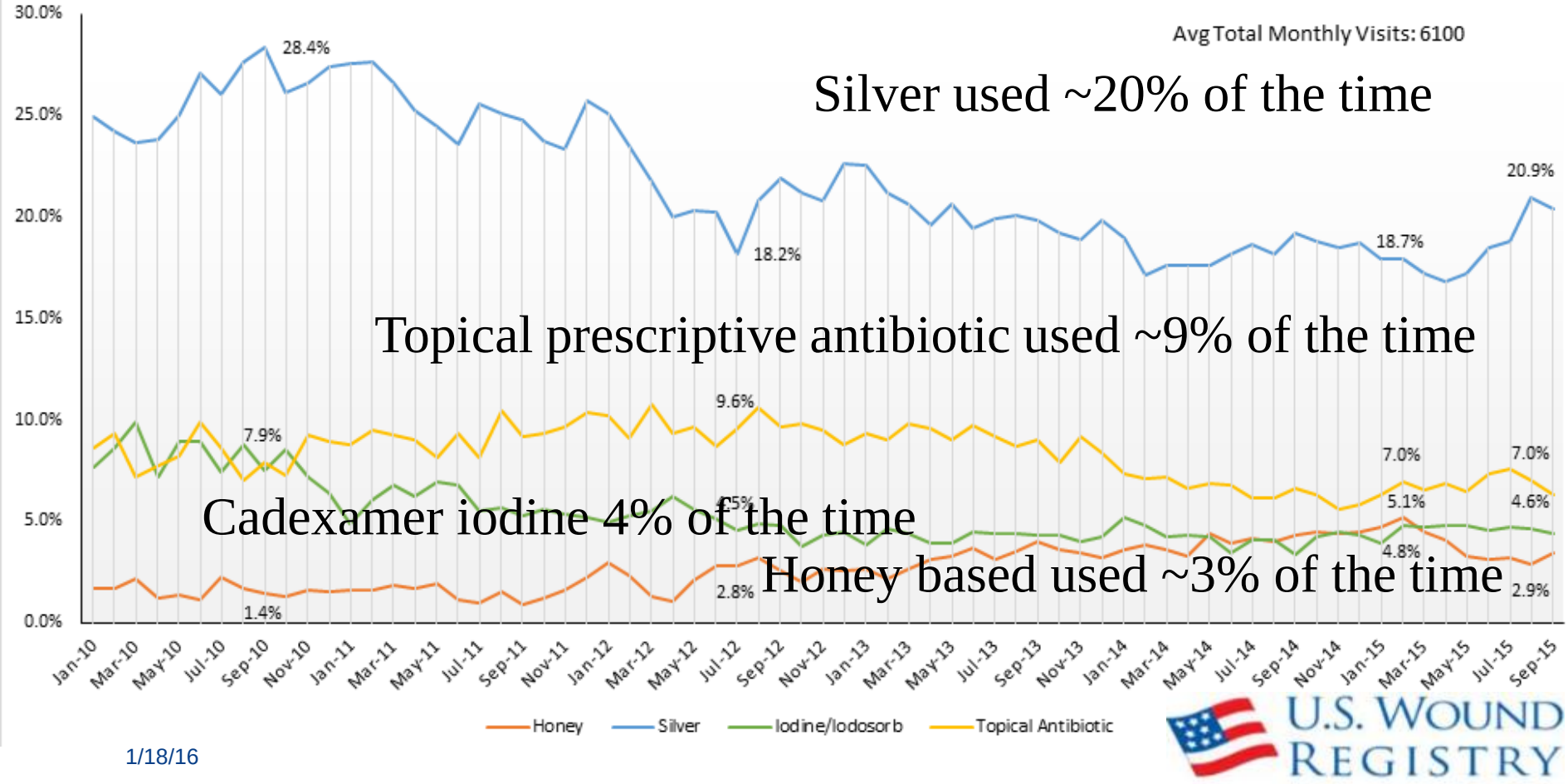
Antimicrobial product usage over time



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How the USWR Can Be Used

- Validated Risk Stratification with Wound Healing Index (WHI) allows the creation of matched cohorts
  - 7 predictive mathematical models based on different wound types
- Comparative Effectiveness Research and SAFETY studies are possible with real world data on CTPs, antimicrobials, wound dressings, NPWT
- **Antimicrobial dressing use is high because these wounds appear to need it**
  - 80% of wounds encounters document moderate to large drainage
  - **52% of wound care patients are prescribed systemic antibiotics**, most patients more than one course, and many intravenously
- We have the ability to monitor response to treatment including:
  - Changes in wound healing parameters
  - Systemic antibiotic practices (likely of much greater risk)
  - Possible surrogates for resistance
  - **We could determine if topical antimicrobials decrease the need for or use of systemic antibiotics, hospitalization rate, amputation rate, healing rate.**

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