



Using Registry Data in
regards to Antimicrobial
Dressings-Presented at the
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<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

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

USWR Data include:

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

The screenshot shows the 'Appearance' tab of the USWR data entry form. It contains several dropdown menus for wound characteristics:

- Exudate:** absent, minimum, moderate (selected), large
- Exudate type:** bloody, serous, serosang, purulent, malodorous, green
- Exposed:** partial, sub tissue, muscle (selected), tendon, bone, hardware
- Peri wound:** normal, macerated, indurated, erythematous, callous, atrophic, ischemic, cyanotic, necrotic
- Wound Bed:** gran red, gran pink, slough, eschar, fibrin, hypergranulation

Below these are fields for 'The problem is generally described as...' (inadequately controlled), 'Granulation' (50%), and 'Necrotic Material' (50%). A line graph shows the trend of granulation from April 14 to August 14, with a downward arrow indicating a decrease.

The screenshot shows the 'Treatment' tab of the USWR data entry form. It contains several dropdown menus for treatment details:

- Debridement:** autolytic, biodebridement, enzymatic, mechanical, none, sharp (selected), sharp+A
- Cleanser:** NS, soap and water, Soap Scrub, Wound Cleanser, Dakin's 1/4 strength (selected)
- Peri wound:** NS, soap and water, Soap Scrub, Wound Cleanser, Dakin's 1/4 strength (selected)
- Primary:** Acticoat (selected), Adaptic, Algidex AG paste, Algidex AG wet gauze, Algisite, Antibiotic gel, Apligraf, Aquacel AG, Aquacel Plain, Arglaes Powder, CombiDERM
- Secondary:** Biatain-foam, CombiDERM, Dermanet, Drawtex, DuoDERM CGF, DuoDERM Signal, DuoDERM Thin, Exudry, Fibracol, Foam, Hydrogel
- Frequency:** daily, every other day, three times per week (selected), two times per week, one time per week
- Duration:** 3 days, 4 days, 5 days, one week, two weeks (selected)
- Offloading:** Post Op Shoe, Crow Walker, Shoe Modification

There is also a button for 'Open Alternate Orders Form'.

- 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

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.

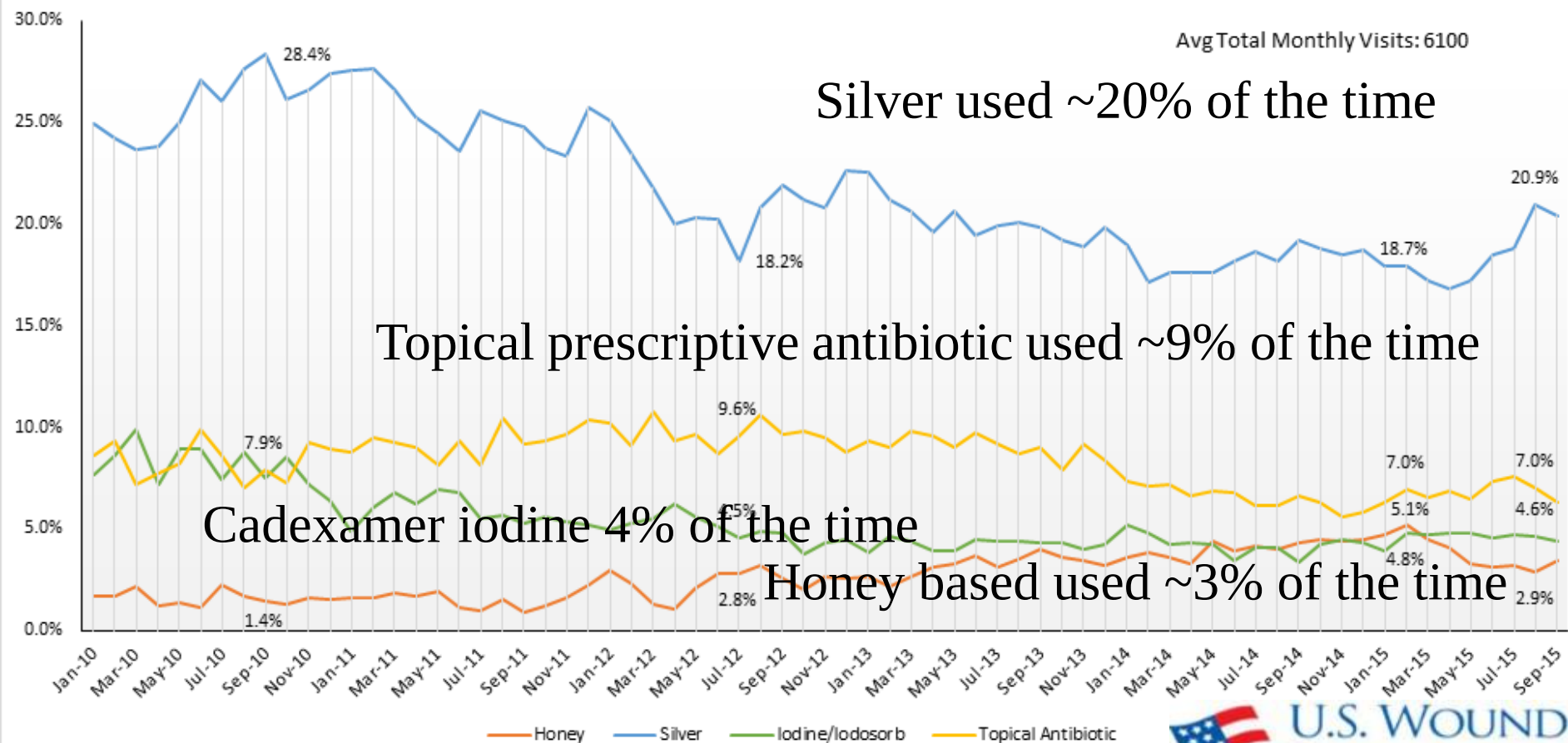
Distribution of Dressings by Category

(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%

Antimicrobial product usage over time



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.**