



# **National and Military Health System Cost Savings from Woundx**

This report estimates the cost savings that the U.S. healthcare system and the U.S. Military Health System could reap from the improved healthcare outcomes produced by Woundx

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Prepared by



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## Contents

Executive Summary .....	3
Background .....	4
DecisionQ Technology .....	4
Predictive Analytics .....	5
What Is the WoundX Project? .....	5
Research Methodology .....	7
Healthcare Outcome Data Selection .....	9
Financial Data Selection .....	10
Model Methodology.....	13
Number of Relevant Patients in the United States and MHS .....	13
Reduced Need for Surgical Debridement .....	14
Reduced Need for Secondary Wound Closure .....	17
Reduced Need for Inpatient ICU Care.....	18
Reduced Need for Inpatient General Ward Care .....	19
Reduced Need for Outpatient Rehabilitation.....	20
Reduced Exposure to Hospital-Acquired Infections during Inpatient Care .....	21
Hospital and Physician Medical Charges .....	28
Estimated Cost Savings.....	36
Future Sources of Savings .....	37
Conclusion .....	37

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## **Executive Summary**

The WoundX project uses predictive analytics to improve the medical treatment of open wounds associated with trauma. It does so by maximizing the likelihood that a wound will properly heal, thereby speeding patient recovery. That faster recovery not only improves healthcare outcomes, but also reduces medical charges related to healthcare delivery. Those lower medical charges or cost savings arise from:

1. Reduced need for surgical debridement
2. Reduced need for secondary wound closure
3. Reduced need for inpatient ICU care
4. Reduced need for inpatient general ward care
5. Reduced need for outpatient rehabilitation
6. Reduced exposure to hospital-acquired infections during inpatient care

Based on research from a thorough medical and public policy literature review as well as a survey of 24 U.S. hospitals, we estimate that the full deployment of WoundX could reduce annual medical charges in the U.S. healthcare system by \$3.4 billion.

Applying the same methodology to the U.S. Military Health System over the period from 2001 to 2014, we estimate that it could have reduced medical charges by \$873 million.

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## Background

Healthcare systems around the world are under increasing pressure to improve their performance, particularly to better manage cost growth. Growing financial pressures have compelled many hospitals in the United States to lower their cost of care—especially for the most complicated and expensive Medicare and Medicaid patients—while decreasing their reliance on cross-subsidization from commercially insured patients. The reasons are well-known. Federal and state governments, employers, insurance companies, and consumers are demanding more control over healthcare costs.

**Healthcare service providers in the United States have realized the need to improve their performance and better manage cost growth**

The Centers for Medicare and Medicaid Services (CMS) reported that in 2012 total U.S. healthcare expenditures grew by 3.7% to approximately \$2.8 trillion. CMS projected total U.S. healthcare spending to grow by 3.8% in 2013 and by an average of 5.8% annually from 2012 through 2022. Specifically, CMS projects the hospital services category to grow from its 2012 level of \$882.3 billion by at least 4.7% annually through 2022. However, at the same time, U.S. healthcare service providers have seen a slower growth in Medicare and Medicaid reimbursement rates.

The shift from commercially insured patients to more government-sponsored patients as well as the ongoing migration of procedures from inpatient care to outpatient care is putting additional financial pressure on hospitals across the United States. Indeed, there has been a move toward new and different reimbursement payment regimes to encourage the containment and reduction in the cost of medical care. Physicians and hospitals have been asked to operate more efficiently—to avoid the over or under treatment of their patients.

## DecisionQ Technology

DecisionQ is a company whose roots go back to Stanford Robotics Labs. Over the last 20 years, it has developed technology to deal with precisely the sort of data that confronts the healthcare industry today. DecisionQ's proprietary machine-learning algorithms use heuristic techniques to discover information structure and probabilities across very large and extremely complex datasets. That enables its technology to create cost-effective computational solutions for problems that previously could not be solved. Its technology is exceptionally effective at turning low sensitivity/low specificity indicators within multivariate datasets into high sensitivity/high specificity insights.

To achieve those results, DecisionQ's technology uses Bayesian belief networks. But unlike other technologies that use the same methodology, it

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**DecisionQ’s approach to predictive analytics can turn very large and complex datasets into high-sensitivity, high-specificity insights**

does not require any a priori model. No assumptions need to be made about the relationships among the variables, thus removing any human biases. All the relationships among the variables are built entirely from the input data by searching through all possible models to find the best fit. Then, the model can continuously learn from new data that is introduced, improving itself at machine speeds.

## **Predictive Analytics**

Concurrent with these economic changes, healthcare service providers have gained greater access to an ever increasing amount of digital information. That offers new ways of achieving fresh insights that can reduce the cost of healthcare delivery and improve patient outcomes. Such information within the healthcare industry falls within the category of data that has become known as “big data.” The name is merited for not only its sheer volume, but also its complexity, diversity, and timeliness.

**Predictive analytics offers a way for healthcare service providers to improve patient outcomes and reduce costs**

Although efforts to leverage “big data” in healthcare remain at an early stage, analysis of this data is already beginning to help healthcare service providers address problems related to variability in healthcare quality and escalating costs. That data is now used to understand which treatments are most effective for particular medical conditions, identify patterns related to patient outcomes, and gain other important insights that can not only help patients, but also reduce costs. Technology advances have enabled healthcare service providers to work with such data, even though the quantities of data are enormous and they often have differing structures and technical characteristics.

## **What Is the WoundX Project?**

DecisionQ’s technology has been applied to the medical treatment of traumatic open wounds. Open wounds are very common. About 3.6 million cases of all types of open wounds are reported in the United States each year. A fraction of these are the result of trauma that requires ICU care. For example, 17,414 open tibia fractures were recorded in the National Inpatient Sample for 2009.<sup>1</sup> Traditionally, open wounds undergo a process of surgical debridement and irrigation to remove necrotic tissue and foreign bodies from them. This is done as a precursor to wound closure, which if performed at the appropriate moment allows a wound to properly heal.

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<sup>1</sup> Schenker ML, Ahn J, Donegan D, Mehta S, Baldwin KD. The Cost of After-Hours Operative Debridement of Open Tibia Fracture. *J Orthop Trauma*. 2014 Nov; 28(11):626-3.

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Unfortunately, in a significant subset of these cases, wound closure fails and dehiscence occurs, in which a wound spontaneously reopens. Many factors can cause dehiscence. A patient who is undernourished or unable to eat may have a wound that is unable to heal properly or in a way that is strong enough to withstand normal stress. In other cases, a wound may be healing well, but a sudden increase in pressure could cause a wound to open. Infections can delay healing, thereby extending the amount of time where the incision is vulnerable to injury. An infection can also weaken the newly forming tissue as the body works to fight infection rather than focus on closing the wound. Of course, the longer a wound remains open for irrigation and debridement, the greater the probability that an infection occurs.

Thus, physicians have traditionally been left with a difficult decision regarding the timing of open wound closure. Among those physicians, here are proponents for early, immediate, and delayed wound closure.<sup>2</sup> Each proponent group has argued that its timing preference yields particular advantages that can produce positive medical outcomes for some segment of patients. Yet no proponent group has significantly exceeded the historic norms of success.

**WoundX project has used DecisionQ technology to develop decision support tools that improve the medical treatment of open wounds associated with trauma**

What the WoundX project has accomplished is to develop a clinical decision support tool through the combination of evidence-based clinical data with cutting-edge science to allow physicians to better understand the physiological, psychological, and physical factors that govern the body's response to trauma. WoundX will be deployed as a predictive model into which clinical and biomarker data for a specific open-wound patient can be entered. The model can then inform a physician as to when that patient's open wound should be surgically closed in order to maximize the likelihood that it heals properly. Such tools can be used to guide the management of surgical care to deliver improved patient outcomes.

Specifically, the WoundX project focused on tackling those open wounds that are often the most difficult to treat, because of the trauma that the patient has experienced. Such patients often suffer from not only their open wounds, but also the responses of their bodies' immune responses, which become chaotic when they are unable to cope with the trauma associated with those wounds.

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<sup>2</sup> Wood T, Sameem M, Avram R, Bhandari M, Petrison B. A systematic review of early versus delayed wound closure in patients with open fractures requiring flap coverage. *J Trauma Acute Care Surg*. 2012 Apr;72(4):1078-85; Lenarz CJ, Watson JT, Moed BR, Israel H, Mullen JD, Macdonald JB. Timing of wound closure in open fractures based on cultures obtained after debridement. *J Bone Joint Surg Am*. 2010 Aug 18;92(10):1921-6; Sibbald RG, Williamson D, Orsted HL, Campbell K, Keast D, Krasner D, Sibbald D. Preparing the wound bed—debridement, bacterial balance, and moisture balance. *Ost Wound Manage*. 2000 Nov; 46(11):14-22, 24-8, 30-5; Eliya-Masamba MC, Banda GW. Primary closure versus delayed closure for non bite traumatic wounds within 24 hours post injury. *Cochrane Database Syst Rev*. 2013 Oct 22;10:CD008574.

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**WoundX project can have the number of surgical debridement events and reduce the rate of wound failure to just 5% of the patient population**

*Thus, the WoundX project has sought to use hundreds of low sensitivity/low specificity clinical and biomarker data points to create high sensitivity/high specificity predictions about precisely when physicians should close open wounds in order to maximize the likelihood of proper healing and minimize the risk of wound failure in their patients. We expect that the WoundX project will halve the number of surgical debridement events that patients will require and reduce the rate of wound failure to just 5% of the patient population. Speeding the healing process through proper treatment allows patients to spend less time in ICU care and inpatient care altogether. That in turn improves healthcare outcomes across the healing arc for patients.<sup>3</sup>*

The cost savings associated with such an improvement in wound closure treatment would be substantial. We anticipate that the WoundX project will enable healthcare service providers to reap significant cost savings from six categories:

1. Reduced need for surgical debridement
2. Reduced need for secondary wound closure
3. Reduced need for inpatient ICU care
4. Reduced need for inpatient general ward care
5. Reduced need for outpatient rehabilitation
6. Reduced exposure to hospital-acquired infections during inpatient care

In short, the WoundX project helps maximize the likelihood that open wounds heal properly and thereby enable patients to recover from them faster. Those improved patient outcomes carry with them the added benefit of driving down the cost of healthcare delivery.

## **Research Methodology**

The focus of this study was to estimate the potential cost savings from the implementation of the WoundX project in the United States on an annual basis as well as the U.S. Military Health System (MHS) from 2001 to 2014. We conducted most of our research from an extensive medical and public policy literature review of over 200 peer-reviewed papers and unpublished graduate dissertations. These were largely sourced from the National Center for Biotechnology Information's PubMed and PMC databases and the U.S. Library of Congress. For our MHS analysis, we primarily used data from the U.S. Department of Defense Trauma Registry.

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<sup>3</sup> Campagnolo DI, Esquieres RE, Kopacz KJ. Effect of timing of stabilization on length of stay and medical complications following spinal cord injury. *J Spinal Cord Med.* 1997; 20(3):331–34.

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**Our research involved an extensive literature review**

Our analysis pursued a straightforward methodology. First, we sought to determine the total number of patients in the United States and the MHS, respectively, who would be the most likely to benefit from the WoundX project. We defined these patients as those who experienced open wounds associated with trauma.

Secondly, we gathered data related to those patients, including the medical treatments they received as well as the outcomes of their treatments. The former included data on the number of surgical debridement and secondary wound closure events; lengths of stay (LOS) in the inpatient intensive care unit (ICU) and general ward; and number of outpatient rehabilitation visits. The latter included the percentages of patients who healed properly or experienced wound failure. We also compiled data on the prevalence of the top five hospital-acquired infections (HAI) that patients might develop during their inpatient care and the medical care needed to treat them.

Thirdly, we calculated the difference between the level of medical treatment they currently need to receive and what they might need to receive in the future with the deployment of WoundX, which is expected to reduce the wound failure rate in the relevant patient population to 5%. The faster rate of healing and recovery that WoundX could produce would naturally reduce the number of surgical debridement and secondary wound closure events, LOS in both the ICU and general ward, and number of outpatient rehabilitation visits. Given that patients would have a shorter LOS in inpatient care, WoundX could also reduce the incidence of HAIs within the relevant patient population.

**We also collected medical charge data from a broad mix of 24 civilian hospitals in the United States**

Fourthly, we sought to gather financial data related to each of the six categories of potential savings. Rather than rely on the generally incompatible financial data outlined in various medical studies, we directly collected medical charge data from 24 civilian hospitals in the United States. To obtain a representative sample, we chose a broad mix of hospitals, which ranged from Level I trauma centers to community hospitals. Though some pieces of financial data were incomplete, enough was available to ensure that data from a minimum of 19 civilian hospitals was used for each calculation.

Finally, we applied those medical charges to each category of potential savings that can arise from WoundX's improvement in patient outcomes in the relevant patient populations of both the U.S. healthcare system and MHS to determine what the cost savings for those populations could be.

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## Healthcare Outcome Data Selection

In the course of our literature review, we learned that there was significant variation in how medical investigators approached their research. We sought to aggregate comparable data across studies in order to create larger and more statistically relevant datasets. That was important, because many of the papers we reviewed contained either small datasets or data that failed to detail important attributes regarding those patients that made direct comparisons difficult. Hence, we sought out the largest pools of data available with the highest degree of data compatibility in terms of what they were intended to describe. Otherwise, we used them to simply validate our analysis.

To ascertain what the total number of patients in the United States who would most likely benefit from the WoundX project may be, we searched for studies that highlighted the number of patients who experienced some sort of open wounds associated with trauma in a specific catchment area in a given year. We sought catchment areas that were large and sufficiently diverse (but did not overlap) to be representative of the U.S. population.

That made it necessary for us to focus on papers whose healthcare outcome research was conducted in the world's developed countries. In particular, we concentrated on countries in North America and Western Europe, Japan, and Australia. We believed that the state of medical care in these countries is relatively comparable and, therefore, could provide a sufficient pool of data from which we could obtain quantitative data for our analysis.

However, such a seemingly innocuous assumption can still have potential pitfalls. Methods of medical care delivery across each country can impact how healthcare outcomes are measured. That is the case even between two countries with very similar standards of care, the United States and Canada. For example, one national Canadian study revealed that the total LOS for trauma patients is 9.4 days and that this time is, on average, divided among ICU, intermediate care, and general ward care 8.9%, 2.5%, and 88.6%, respectively.<sup>4</sup> In the United States, the time that trauma patients spend in the ICU and general ward is more balanced, due to different medical practices and incentive structures within the U.S. healthcare system.

Whenever possible we sought out studies whose patients were identified as having wounds that produced an Injury Severity Score (ISS) of 15 or above, indicating moderate or serious trauma. We did so because the

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<sup>4</sup> Moore L, Stelfox HT, Turgeon AF, Nathens A, Bourgeois G, Lapointe J, Gagné M, Lavoie A. Hospital length of stay after admission for traumatic injury in Canada: a multicenter cohort study. *Ann Surg.* 2014 Jul;260(1):179-87.

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**Patients with open wounds associated with trauma were defined as patients whose ISS was 15 or above or whose AIS was of 2 or above**

population that the Woundx project was primarily designed to address was that of American servicemen who were wounded in combat in Afghanistan and Iraq. In almost all these cases, the trauma caused by their open wound injuries required some sort of ICU care.

We then combined the data from those studies to determine the total number of relevant patients within a particular catchment area and scaled that number to approximate the total number of relevant patients in the United States each year.

The inclusion criteria for the number of relevant patients in the MHS was even more clear-cut. We obtained that data from the U.S. Department of Defense (DoD) Trauma Registry. We sought the number of patients whose Abbreviated Injury Scale (AIS) score was higher than 2, indicating moderate or serious trauma, roughly equivalent to an ISS of 15 or above. We collected that data for the period from 2001-2014.

The data we gathered on the level of medical treatment which patients have needed to receive in the past largely originated from studies that were performed on military patient populations. We found that not only did those patients meet the inclusion criteria for our research, but also their studies contained sufficient detail to meet the needs of our analysis. We assumed that the level of medical treatment which civilian patients receive mirrored that which military patients receive.

## **Financial Data Selection**

Arriving at a consistent understanding of the financial data reported in the reviewed literature was one of the most challenging aspects of our research. That was hardly surprising, because nearly all the relevant financial data that we could identify was published in medical journals, whose primary concerns revolve around healthcare outcomes, rather than forensic accounting rigor. Since our research on cost savings required insight into only one, relatively narrow, medical condition—open wounds associated with trauma—financial data related to that condition was either scant or piecemeal. Moreover, the methods by which that data was collected or estimated frequently lacked consistency, making direct comparisons across studies difficult.

**Our analysis sought to minimize the impact of confounding factors, like inflation, currency exchange rates, medical and accounting practices, and reimbursement payment regimes**

A certain degree of variation was unavoidable. Studies conducted at different times would have financial data whose totals could not be directly compared, given the vagaries that would arise from changes in the rate of medical inflation. Similarly, we found that studies conducted in different countries or regions were difficult to directly compare, given the vagaries that would arise from differences in currency exchange rates, medical and accounting practices, and medical payment regimes.

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Even studies conducted at the same time and in the same region were oftentimes difficult to directly compare, because of the differences in how specific healthcare facilities operate. Specialized healthcare facilities, such as trauma centers, may care for patients with traumatic open wounds more efficiently than general-purpose hospitals, since the former are generally better prepared to deliver such treatment. In turn, that could improve recovery time or increase the number of patients who can be treated and, in doing so, reduce the average cost per patient. Hence using trauma center financial data alone could skew our results; had we used it as a representative sample for our nationwide estimates.

More generally, financial data from medical studies often failed to correspond with our ultimate aims. For example, we initially believed that a study on the cost of surgical debridement of open tibia fractures would suit our analysis.<sup>5</sup> Open tibia fractures reflect one sort of open wound associated with trauma that we would include in our analysis.<sup>6</sup> Unfortunately for us, the study's financial data solely focused on labor costs.

For our purposes, that study fell short in three respects. First, the study did not include any facility, material, or overhead costs associated with the hospitals where the surgical debridement events took place. Second, the composition of the medical staff that the study assumed would be needed to deliver medical care (exclusively nurses and surgical technicians) was different from that which we assumed would be needed to deliver medical care (full range of medical professionals, including physicians). Thirdly, the study considered wages (i.e., what the hospitals paid their medical staff in salaries) and not professional charges (i.e., what the hospitals charged for its services or, for that matter, what the hospitals were actually reimbursed for its services).

Therefore, rather than solely rely upon financial data derived from medical studies, we chose to directly collect financial data from 24 civilian hospitals in the United States. We drew data from a wide variety of hospitals to ensure that we obtained a representative sample of such facilities in the country. These ranged from Level I trauma centers to community hospitals. While a broad geographic sample would have been desirable, we found the most accessible financial data in Ohio, where medical facilities are required to publicly release that data.

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<sup>5</sup> Schenker ML, Ahn J, Donegan D, Mehta S, Baldwin KD. The cost of after-hours operative debridement of open tibia fractures. *J Orthop Trauma*. 2014 Nov; 28(11):626-31.

<sup>6</sup> Schlitzkus LL, Goettler CE, Waibel BH, Segraves SG, Hasty CC, Edwards M, Rotondo MF. Open fractures: it doesn't come out in the wash. *Surg Infect (Larchmt)*. 2011 Oct; 12(5):359-63.

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**Cost savings were defined as medical charges rather than reimbursement payments**

Given the very large divergence between what hospitals and physicians charge and what they actually receive in reimbursement payments, one could view the latter as the better representation of true medical costs. However, the great variation in reimbursement payment regimes—including commercial, managed care, self-pay, worker's compensation, Medicaid, or Medicare—made it difficult for us to use reimbursement payments in our analysis. Depending on the regime, medical condition, and individual patient circumstances, reimbursement payments for hospital and physician charges varied widely.

Therefore, we focused on gathering hospital and physician medical charges in our survey. We sought to use financial data from the same year to avoid uncertainties regarding inflation or changes in medical practices introduced by new technology. While we could not entirely account for the inconsistencies in medical practices and cost allocation methods across hospitals, we believe the diversity of hospitals we surveyed would mitigate many of them.

We then applied those medical charges to each category of potential savings that we expect the deployment of WoundDx will deliver. We did so for our estimates of the potential cost savings in both the United States and the MHS. We used the same medical charges because we assumed that costs within the MHS are generally consistent with those in the civilian U.S. healthcare system, since most of the medical procedures and technology involved in both systems are the same.

Moreover, we did not take into account the difference in medical charges brought about by inflation from 2001-2014. To account for that difference, we would have had to have associated each year's inflation rate with the time when the relevant patients from the DoD Trauma Registry received their wounds. Since we did not know when the relevant patients received their wounds, we could not apply the appropriate inflation rates to those patients. Hence, we applied the medical charges from 2015, which we calculated in a consistent and rigorous manner, across the entire relevant patient population in the MHS over that period.

The data we gathered from various studies in our literature review proved to be primarily useful to validate our data selection process. Whenever possible, we used direct comparisons to determine whether the data we selected to use in our calculations was generally consistent with those from other studies. Unfortunately, the data from most studies were insufficiently comparable with one another so that we were unable to aggregate them into statistically relevant datasets.

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## Model Methodology

As outlined earlier, we believe that the improvement in patient outcomes from the WoundDx project would produce potential outcome savings in the following six categories:

1. Reduced need for surgical debridement
2. Reduced need for secondary wound closure
3. Reduced need for inpatient ICU care
4. Reduced need for inpatient general ward care
5. Reduced need for outpatient rehabilitation
6. Reduced exposure to hospital-acquired infections during inpatient care

For each of first four categories, we used the expected reduction in the rate of wound failure to 5% of the patient population in our calculations. Our criteria for wound failure included wound dehiscence, flap failure, graft rupture, etc., but not wound infections. We then used the results of those calculations to determine the results of the last two categories.

The last area, which deals with the associated reduction in HAIs during inpatient care, required a more elaborate approach. That entailed first developing a model to determine the daily incidence of HAIs in the inpatient population.

We then combined the results of our calculations for each of the six categories above with the number of relevant patients from the United States and MHS to arrive at our estimates for the cost savings from the WoundDx project. That is encapsulated in the following equation:

$$\text{Number of relevant patients} * \text{Outcome savings from the six categories} * \text{Medical charges associated with the six categories} = \text{Cost savings from WoundDx}$$

### Number of Relevant Patients in the United States and MHS

To determine the relevant patient population is in the United States, we sought to find the number of severe trauma cases that required ICU stays within the largest possible catchment area. The biggest and most-recent study we identified through our literature review revealed that within a catchment population of 20,500,000, there were 7,080 cases of “severe traumatic injury” from April 1, 2006 to March 31, 2007 in North America (drawn from an international sample of three sites in Canada and six sites in the United States). From these cases, we eliminated those who died before reaching an ICU and those who died while in ICU care, since

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WoundDx would have made no difference in those cases. That left 4,477 cases, which is representative of 70,100 cases of severe traumatic injury within the U.S. population of 321,000,000 in 2015.<sup>7</sup>

From the 2002 Nationwide Inpatient Sample of the Healthcare Cost and Utilization Project, we learned that an estimated 272,278 injury-related acute wounds occurred in the United States that year. Of that number, 263,837 cases or 96.9% included an open wound.<sup>8</sup>

**Number of relevant patients in the United States is 67,930**

Given that 70,100 cases of “severe traumatic injury” were projected to occur in the U.S. and 96.9% of “injury-related acute wounds” are likely to have an open wound, we could calculate the number of patients who were likely to have an open wound associated trauma. Hence, we estimate that the relevant patient population in the United States each year to be 67,930. Those are also the patients that we believe WoundDx is well suited to benefit.

**Number of relevant patients in the MHS from 2001-2014 is 18,256**

To determine what our relevant patient population is in the MHS, we turned to the DOD Trauma Registry. With assistance from U.S. military health officials, we learned that the MHS treated 18,256 patients between 2001 and 2014, who could have benefited from the deployment of WoundDx. Of these relevant patients, 6,212 were U.S. active-duty military personnel and 12,044 were either foreign allied military personnel or foreign civilians.

While U.S. active-duty military personnel naturally received the full spectrum of medical care, we assumed that foreign patients received only acute treatment. That included surgical debridement, secondary wound closure, and inpatient ICU and general ward care. As a result, for foreign patients treated by the MHS, we assessed the potential savings only from the reduced need for acute treatment and not from the reduced need for outpatient rehabilitation care.

## **Reduced Need for Surgical Debridement**

Surgical debridement is widely recognized as an important part of the successful treatment of open wounds, particularly those associated with some sort of trauma.<sup>9</sup> But how extensive surgical debridement needs to be

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<sup>7</sup> Minei JP, Schmicker RH, Kerby JD, Stiell IG, Schreiber MA, Bulger E, Tisherman S, Hoyt DB, Nichol G. Severe traumatic injury: regional variation in incidence and outcome. *Ann Surg.* 2010 Jul; 252(1):149-57.

<sup>8</sup> We estimate the U.S. population was 287,600,000 in 2002. Hostetler SG, Xiang H, Gupta S, Sen CK, Gordillo, GM. Discharge patterns of injury-related hospitalizations with an acute wound in the United States. *Wounds.* 2006; 18:340-51.

<sup>9</sup> Sathiyakumar V1, Thakore RV, Stinner DJ, Obremskey WT, Ficke JR, Sethi MK. Gunshot-induced fractures of the extremities: a review of antibiotic and debridement practices. *Curr Rev Musculoskelet Med.* 2015 Sep; 8(3):276-89; Diefenbeck M, Haustedt N, Schmidt HGK. Surgical debridement to optimise wound conditions and healing. *Int Wound J.* 2013; 10 (suppl. 1):43-47.

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is less clear. Hence, we sought to better define the need for surgical debridement and the impact WoundDx would have on that need.

Our first task was to complete our understanding of the patient outcomes under the current state of medical treatment. We focused our research on a 2010 study performed by many of the same investigators who are current involved in the development of WoundDx. The study provided data on patients who best fit our inclusion criteria. It revealed that the average number of surgical debridement events required for patients who healed properly to be 3.0 and the average number of surgical debridement events required for patients who experienced wound failure to be 7.6.<sup>10</sup> A smaller study of patients with traumatic lower-extremity injuries seemed to validate that average number of surgical debridement events that were required for patients who healed properly. It reported an average of 2.9 surgical debridement events per patient.<sup>11</sup> Even a study of deep sternal wound infections found that an additional 2.9 surgical debridement events per patient were needed in conjunction with other surgical procedures to successfully close those wounds.<sup>12</sup>

The 2010 study also revealed that the percentage of patients who experienced wound failure was 23.7%.<sup>13</sup> Another study, which concentrated on traumatic lower limb injuries, reported a wound failure rate of 23.9%.<sup>14</sup> That seemed to confirm the data we chose to use. One should note, however, that a different study on traumatic lower limb injuries reported a wound failure rate of only 14.3%.<sup>15</sup> Other studies that more narrowly concentrated on specific types of wounds and wound failure exhibited similar wound failure rates. For example, one focused only on wound dehiscence and found its rate to be 16.5% (from its control group which had a lower average ISS of 12.1).<sup>16</sup> Two other studies on moderate-to-severe open tibia fractures focused on flap failure and found their rates to be 9.5% in the United Kingdom and 9% in the United States.<sup>17</sup>

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<sup>10</sup> Utz ER1, Elster EA, Tadaki DK, Gage F, Perdue PW, Forsberg JA, Stojadinovic A, Hawksworth JS, Brown TS. Metalloproteinase expression is associated with traumatic wound failure. *J Surg Res.* 2010 Apr; 159(2):633-9.

<sup>11</sup> Erdmann D, Lee B, Roberts CD, Levin LS. Management of lawnmower injuries to the lower extremity in children and adolescents. *Ann Plast Surg.* 2000 Dec; 45(6):595-600.

<sup>12</sup> Phan TQ, Depner C, Theodorou P, Lefering R, Perbix W, Spilker G, Weinand C. Failure of secondary wound closure after sternal wound infection following failed initial operative treatment: causes and treatment. *Ann Plast Surg.* 2013 Feb; 70(2):216-21.

<sup>13</sup> Utz ER1, Elster EA, Tadaki DK, Gage F, Perdue PW, Forsberg JA, Stojadinovic A, Hawksworth JS, Brown TS. Metalloproteinase expression is associated with traumatic wound failure. *J Surg Res.* 2010 Apr; 159(2):633-9.

<sup>14</sup> Lo CH, Leung M, Baillieu C, Chong EW, Cleland H. Trauma centre experience: flap reconstruction of traumatic lower limb injuries. *ANZ J Surg.* 2007 Aug; 77(8):690-4.

<sup>15</sup> Liu DS, Sofiadellis F, Ashton M, MacGill K, Webb A. Early soft tissue coverage and negative pressure wound therapy optimises patient outcomes in lower limb trauma. *Injury.* 2012 Jun; 43(6):772-8.

<sup>16</sup> Stannard JP, Volgas DA, McGwin G 3rd, Stewart RL, Obrebsky W, Moore T, Anglen JO. Incisional negative pressure wound therapy after high-risk lower extremity fractures. *J Orthop Trauma.* 2012 Jan; 26(1):37-42.

<sup>17</sup> Parrett BM, Matros E, Pribaz JJ, Orgill DP. Lower extremity trauma: trends in the management of soft-tissue reconstruction of open tibia-fibula fractures. *Plast Reconstr Surg.* 2006 Apr; 117(4):1315-22; Naique SB, Pearse M, Nanchahal J. Management of severe

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Given the percentage of patients who experienced wound failure and the respective numbers of surgical debridement events required for patients who healed properly and experienced wound failure, we could use the following equation to calculate the weighted-average number of surgical debridement events across the patient population. We calculated that number to be 4.1. One should note, however, that a study of massive pelvic and extremity wounds found that 7.9 surgical debridement events using vacuum-assisted closure and 4.1 surgical debridement events using vacuum-assisted closure with silver dressing were needed to treat open-wound patients.<sup>18</sup>

Number of surgical debridement events (for patients who healed properly) \* Percentage of patients who healed properly + Number of surgical debridement events (for patients who experienced wound failure) \* Percentage of patients who experienced wound failure = Weighted-average number of surgical debridement events for the patient population

Our second task was to determine what the impact of WoundX's deployment would have on the number of surgical debridement events under the future state of medical treatment. Since we expect that WoundX's deployment will halve the current weighted-average number of surgical debridement events for the patient population, we could simply calculate the future weighted-average number of surgical debridement events for the patient population to be 2.0.

**WoundX could reduce the need for surgical debridement for the 95% of patients who heal properly from 3.0 to 1.8**

However, given the marked improvement we expect to see in the patient population, we also sought to understand what impact WoundX might have on the number of surgical debridement events for patients who healed properly. We did so by using the same equation above, but with new inputs. Those inputs included the percentages of patients who heal properly and of those who experience wound failure after the deployment of WoundX, which we expect to be 95% and 5%, respectively. With this data and the average number of surgical debridement events required for patients who experienced wound failure, we calculated the number of surgical debridement events for patients who healed properly would fall from 3.0 to 1.8. (See Table 1.)

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open tibial fractures: the need for combined orthopaedic and plastic surgical treatment in specialist centres. *J Bone Joint Surg Br.* 2006 Mar; 88(3):351-7.

<sup>18</sup> Siegel HJ, Herrera DF, Gay J. Silver negative pressure dressing with vacuum-assisted closure of massive pelvic and extremity wounds. *Clin Orthop Relat Res.* 2014 Mar; 472(3):830-5.

Table 1.  
Reduction in Surgical Debridement Events from WoundX Deployment

	Surgical Debridement Events, Proper Healing (patient percentage)	Surgical Debridement Events, Wound Failure (patient percentage)	Surgical Debridement Events, Weighted Average (patient percentage)
Current treatment without WoundX	3.0 (76.3%)	7.6 (23.7%)	4.1 (100.0%)
Future treatment with WoundX	1.8 (95.0%)	7.6 (5.0%)	2.0 (100.0%)
Improvement from WoundX	1.2	0.0	2.0

## Reduced Need for Secondary Wound Closure

Patients whose wounds heal properly after primary wound closure have no need for a secondary wound closure procedure. But patients who do experience wound failure are likely to require a secondary wound closure procedure. Wound failure rates can be as high as 53.4% in some lower-extremity wound cases.<sup>19</sup> As mentioned above, we expect that the use of WoundX will increase the percentage of patients who heal properly 76.3% to 95% of the relevant patient population.

That means 18.7% of the relevant patient population, who would otherwise have experienced wound failure, would have had their open wounds heal properly as a result of the insight that WoundX can provide. Those patients would naturally have no need for secondary wound closure. Assuming that every patient who experiences a wound failure would require one secondary wound closure event, we could determine the number of secondary wound closure events that WoundX is likely to avoid from the difference between the number of patients who experience wound failure in the current state of medical treatment without WoundX and the future state of medical treatment with WoundX.

**WoundX could reduce the number of secondary wound closure events by 12,702 in the U.S. healthcare system and 3,414 in the U.S. Military Health System**

In the U.S. healthcare system that equates to at least 12,702 secondary wound closure events that could be avoided each year. In the U.S. Military Health System that equates to at least 3,414 secondary wound closure events that could have been avoided from 2001-2014. (See Table 2.) Of course, even more wound closure events might have been avoided, because some number of secondary wound closure events performed under the current state of medical treatment without the benefit of WoundX may also have failed, prompting the need for tertiary wound closure events.

<sup>19</sup> Stankiewicz M, Coyer F, Webster J, Osborne S. Incidence and Predictors of Lower Limb Split-Skin Graft Failure and Primary Closure Dehiscence in Day-Case Surgical Patients. *Dermatol Surg.* 2015 Jul; 41(7):775-83.

Table 2.  
Reduction in Secondary Wound Closure Events from WoundX Deployment

	U.S., annual (patient percentage)	MHS, 2001-2014 (patient percentage)
Current treatment without WoundX	16,099 (23.7%)	4,327 (23.7%)
Future treatment with WoundX	3,397 (5.0%)	913 (5.0%)
Improvement from WoundX	12,702 (18.7%)	3,414 (18.7%)

## Reduced Need for Inpatient ICU Care

Similar to our analysis of the reduced need for surgical debridement, our estimate of the reduced need for inpatient ICU care was based on the ability of WoundX to reduce the rate of wound failure to 5% of the patient population. That reduced need for inpatient ICU care was captured in terms of a reduction in the ICU LOS.

However, the medical literature could not provide sufficient data regarding inpatient ICU care to allow us to make a direct estimate. Instead, it was necessary for us to derive that data from the total LOS—the combination of the ICU LOS and general ward LOS—which would, in turn, enable us to make an estimate.

Fortunately, the 2010 study we earlier referenced revealed that the total LOS for patients who experienced wound failure was 60.0 days and the weighted-average total LOS for its patient population was 31.0 days.<sup>20</sup> One should note, however, that four other studies on patients with what appeared to be similarly complicated injuries reported average total lengths of stay of 19.0 days, 21.0 days, 24.6 days, and 25.3 days.<sup>21</sup> We elected to use the data from our chosen study, because it also provided sufficient detail on patient injury severity and other aspects of medical care that were needed for our analysis. We combined these new pieces of data with the percentages of patients who either healed properly or experienced wound failure to calculate the total LOS for those patients who healed properly under the current state of medical treatment using the following equation:

<sup>20</sup> Stojadinovic A, Eberhardt J, Brown TS, Hawksworth JS, Gage F, Tadaki DK, Forsberg JA, Davis TA, Potter BK, Dunne JR, Elster EA. Development of a Bayesian model to estimate health care outcomes in the severely wounded. *J Multidiscip Healthc.* 2010 Aug 16; 3:125-35.

<sup>21</sup> Siegel HJ, Herrera DF, Gay J. Silver negative pressure dressing with vacuum-assisted closure of massive pelvic and extremity wounds. *Clin Orthop Relat Res.* 2014 Mar; 472(3):830-5; Enninghorst N, McDougall D, Hunt JJ, Balogh ZJ. Open tibia fractures: timely debridement leaves injury severity as the only determinant of poor outcome. *J Trauma.* 2011 Feb; 70(2):352-6; Verma H, Ktenidis K, George RK, Tripathi R. Vacuum-assisted closure therapy for vascular graft infection (Szilagyi grade III) in the groin—a 10-year multi-center experience. *Int Wound J.* 2015 Jun; 12(3):317-21; De Caridi G, Serra R, Massara M, Barone M, Grande R, Butrico L, Mastroberto P, de Francis S, Monaco F. VAC therapy for the treatment of complex wounds after cardio-thoracic surgery. *Int Wound J.* 2014 Sep 17.

Total LOS for patients who healed properly \* Percentage of patients who healed properly + Total LOS for patients who experienced wound failure \* Percentage of patients who experienced wound failure = Weighted-average total LOS for the patient population

Given that calculation, we could then determine the weighted-average total LOS for the patient population under the future state of medical treatment without WoundX. To do so, we used the total LOS for patients who healed properly, the total LOS for patients who experienced wound failure, and the percentages of both types of patients under the future state of medical treatment with WoundX.

Using the same equation above, we calculated the weighted-average total LOS for the patient population under both the current and future states of medical treatment. By subtracting the latter from the former, we arrived at the weighted-average total LOS savings that could result from the deployment of WoundX. That total LOS savings was 7.1 days or 22.9% of the total LOS needed under the current state of medical treatment.

**WoundX could reduce the need for ICU care by 1.3 days**

Only then were we ready to determine the ICU LOS savings. From the same 2010 study we used earlier, we learned that the ICU LOS under the current state of medical treatment is 5.6 days.<sup>22</sup> That appeared to be corroborated by a different study of patients with acute physiology scores above 45 at the time of their ICU admission that revealed an ICU LOS of between 4.8 and 7.2 days.<sup>23</sup> Given the ICU LOS from our chosen study and the total LOS savings, we calculated the ICU LOS under the future state of medical treatment to be 4.3 days. Thus, the ICU LOS savings is 1.3 days. (See Table 3.)

Table 3.  
Reduction in Inpatient ICU LOS from WoundX Deployment

	Inpatient ICU LOS (days)
Current treatment without WoundX	5.6
Future treatment with WoundX	4.3
Improvement from WoundX	1.3

**Reduced Need for Inpatient General Ward Care**

<sup>22</sup> Stojadinovic A, Eberhardt J, Brown TS, Hawksworth JS, Gage F, Tadaki DK, Forsberg JA, Davis TA, Potter BK, Dunne JR, Elster EA. Development of a Bayesian model to estimate health care outcomes in the severely wounded. *J Multidiscip Healthc.* 2010 Aug 16;3:125-35.

<sup>23</sup> Zimmerman JE, Kramer AA, McNair DS, Malila FM, Shaffer VL. Intensive care unit length of stay: Benchmarking based on Acute Physiology and Chronic Health Evaluation (APACHE) IV. *Crit Care Med.* 2006 Oct; 34(10):2517-29.

Similar to our analysis of the reduced need for inpatient ICU care, our estimate of the reduced need for inpatient general ward care was based on the ability of WoundX to reduce the rate of wound failure to 5% of the patient population. We captured that reduced need for inpatient general ward care in terms of a reduction in general ward LOS.

Having already found through our research the ICU LOS and total LOS for the current state of medical treatment, we could directly determine the general ward LOS for the current state of medical treatment without WoundX. Likewise, having already calculated the ICU LOS and total LOS for the future state of medical treatment, we could directly determine the general ward LOS for the future state of medical treatment with WoundX.

**WoundX could reduce the need for general ward care by 5.8 days**

Then, we subtracted the future from the current general ward LOS for the patient population to arrive at the general ward giving us a calculated LOS savings of 5.8 days. (See Table 4.)

Table 4.  
Reduction in Inpatient General Ward LOS from WoundX Deployment

	Inpatient ICU LOS (days)
Current treatment without WoundX	25.4
Future treatment with WoundX	19.6
Improvement from WoundX	5.8

### **Reduced Need for Outpatient Rehabilitation**

Similar to our analyses of the reduced need for inpatient ICU and general ward care, our estimate of the reduced need for outpatient rehabilitation was based on the ability of WoundX to reduce the rate of wound failure to 5% of the patient population. That reduced need for outpatient rehabilitation was captured in terms of outpatient rehabilitation events.

Peer-reviewed medical literature on outpatient rehabilitation of patients who experienced open wounds associated with trauma is sparse. As a result, data related to the number of outpatient rehabilitation events was spotty, at best.

Given that the severity of an open wound is often positively correlated with the level of inpatient ICU and general ward care needed, we believed it was logical that the level of outpatient rehabilitation is also positively correlated. With no evidence to the contrary, we assumed that the need for inpatient ICU and general ward care was directly related to the need for outpatient rehabilitation. Hence, we assumed the same savings for

outpatient rehabilitation as we calculated for inpatient ICU and general ward care.

**WoundX could reduce the need for outpatient rehabilitation by 2.9 events**

One of the few peer-reviewed studies to quantify the number of rehabilitation events needed for patients who had undergone an open wound of sufficient severity to require an amputation cited an average of 12.7 rehabilitation events.<sup>24</sup> Given an assumed savings of 22.9%, the number of rehabilitation events that could be saved is 2.9.

We summarized the improvements in healthcare outcomes between the current state of medical treatment without WoundX and a future state of medical treatment with WoundX below. The faster healing and recovery in patients whose treatments are informed by WoundX could produce meaningful improvement in their healthcare outcomes. (See Table 5.)

Table 5.  
Reduction in Outpatient Rehabilitation Sessions from WoundX Deployment

	Outpatient Rehabilitation Sessions
Current treatment without WoundX	12.7
Future treatment with WoundX	9.8
Improvement from WoundX	2.9

**Reduced Exposure to Hospital-Acquired Infections during Inpatient Care**

The application of WoundX to the medical treatment of open wounds associated with trauma cannot directly prevent hospital-acquired infections. But WoundX can do so indirectly in two ways. First, since it enables the optimum treatment of open-wound patients that speeds their healing and recovery, it can shorten the amount of time that patients must spend in the hospital as well as reduce the number of surgical procedures that patients must undergo. In doing so, WoundX can reduce the likelihood that patients would contract HAIs. Secondly, the presence of HAIs has been linked to wound closure complications. Hence, any reduction of the likelihood that patients might contract HAIs would also reduce the possibility that they will experience wound closure complications.<sup>25</sup> That is particularly relevant, because the incidence of

<sup>24</sup> Christiansen CL, Fields T, Lev G, Stephenson RO, Stevens-Lapsley JE. Functional Outcomes After the Prosthetic Training Phase of Rehabilitation After Dysvascular Lower Extremity Amputation. *PM R*. 2015 May 12. pii: S1934-1482(15)00234-8.

<sup>25</sup> Vogel TR, Diaz JJ, Miller RS, May AK, Guillaumondegui OD, Guy JS, Morris JA. The open abdomen in trauma: do infectious complications affect primary abdominal closure? *Surg Infect (Larchmt)*. 2006 Oct; 7(5):433-41.

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HAI has been repeatedly demonstrated to be correlated with injury severity and surgery.<sup>26</sup>

Among the most common categories of HAI are: blood stream infection (BSI), urinary tract infection (UTI), pneumonia, gastrointestinal infection, and surgical site infection (SSI). Together, these five types of HAI represent over 90% of the HAIs that occur in the United States today.<sup>27</sup> Hence, we chose to focus our research on them.

Within each category of HAI, there are particular forms that are noteworthy. These include central line-associated bloodstream infection (CLABSI), catheter-associated urinary tract infection (CAUTI), ventilator-associated pneumonia (VAP), and *Clostridium difficile* infection (CDI). Oftentimes, the number of studies performed on these particular forms of HAI exceeds that performed on the broader categories of HAI.

Given that our research sought to quantify the degree to which faster patient healing and recovery can influence the number of HAIs, it was important for us to determine the daily incidence of each HAI category in our relevant patient population. However, how we could make this determination was not immediately evident. Even after accounting for the difference in injury severity between those patients who experienced open wounds associated with trauma and all other patients, we found that the methods used across various HAI studies often lacked consistency. That made compiling results across those studies problematic, especially when the severity of patient wounds or the conditions under which they were treated varied or were poorly defined.

Moreover, the vast majority of HAI studies did not approach them in a holistic fashion. Rather, they were largely focused on either a single HAI or a subset of them. For example, one large group of HAI studies exclusively focused on device-associated HAIs, such as CLABSI, CAUTI, and VAP. They ignored the respective broader categories of HAIs, like BSI, UTI, and pneumonia. Similarly, another group of HAI studies focused only on CDI to the exclusion of all other gastrointestinal infections. A third group of HAI studies focused on HAIs that were

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<sup>26</sup> Melsen WG, Rovers MM, Groenwold RH, Bergmans DC, Camus C, Bauer TT, Hanisch EW, Klarin B, Koeman M, Krueger WA, Lacherade JC, Lorente L, Memish ZA, Morrow LE, Nardi G, van Nieuwenhoven CA, O'Keefe GE, Nakos G, Scannapieco FA, Seguin P, Staudinger T, Topeli A, Ferrer M, Bonten MJ. Attributable mortality of ventilator-associated pneumonia: a meta-analysis of individual patient data from randomised prevention studies. *Lancet Infect Dis*. 2013 Aug; 13(8):665-71; Lazarus HM, Fox J, Lloyd JF, Evans RS, Abouzelof R, Taylor C, Pombo DJ, Stevens MH, Mehta R, Burke JP. A six-year descriptive study of hospital-associated infection in trauma patients: demographics, injury features, and infection patterns. *Surg Infect (Larchmt)*. 2007 Aug; 8(4):463-73; Jamulitrat S, Narong MN, Thongpiyapoom S. Trauma severity scoring systems as predictors of nosocomial infection. *Infect Control Hosp Epidemiol*. 2002 May; 23(5):268-73.

<sup>27</sup> Magill SS, Edwards JR, Bamberg W, Beldavs ZG, Dumyati G, Kainer MA, Lynfield R, Maloney M, McAllister-Hollod L, Nadle J, Ray SM, Thompson DL, Wilson LE, Fridkin SK. Multistate point-prevalence survey of health care-associated infections. *N Engl J Med*. 2014 Mar 27; 370(13):1198-208.

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acquired only in the ICU, rather than during all of inpatient care. A fourth group of HAI studies focused on HAIs that were the product of either primary or secondary infections, but not both. These sorts of approaches to HAI research, when combined with the variability in their methods and definitions of terms, substantially limited our ability to use the results of most smaller-scale studies.

**Our HAI research focused on  
BSI, UTI, pneumonia,  
gastrointestinal infection, and  
SSI**

With an appreciation of such complexities involved in HAI research, we began our study by bounding the parameters of what we would investigate. We focused our research on only the top five categories of HAIs and used them to represent all HAIs. All other categories of HAIs suffered from not only the same issues as those associated with the top five listed above, but also the lack of either patient outcome or financial data on them.

We also had to make a number of assumptions. First, we made no distinction between primary, secondary, or tertiary HAIs. Methodologically, we did so because we sought to capture the daily incidence of all HAIs, rather than that of any particular sort. From a practical standpoint, we did so because there was a lack of consistent data across primary, secondary, or tertiary HAIs. While the incidence of follow-on infections may be meaningful, we lacked enough data on follow-on infections to seriously consider them in our analysis.<sup>28</sup>

Secondly, we assumed that patients who experienced either general surgery or trauma would have similar incidences of HAIs. We justified our assumption on the basis that both patient populations, given a comparable ISS, are likely to have open wounds that are equally susceptible to HAIs. Recent research on HAIs among critically ill trauma and general surgery patients seem to validate our assumption.<sup>29</sup>

Thirdly, in the absence of any contrary data, we assumed that the medical research on the ratio of HAIs that are acquired from devices and those that are acquired from other means within the same category of HAI could be applied equally across the entire inpatient LOS. Thus, we assumed in our analysis that the ratio of how HAIs are acquired remained the same between patients who acquired them in an ICU and those who acquired them in a general ward. That said, the data we used did account for the differences in the overall incidences of HAIs between the ICU and general ward.

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<sup>28</sup> Becerra MB, Becerra BJ, Banta JE, Safdar N. Impact of *Clostridium difficile* infection among pneumonia and urinary tract infection hospitalizations: an analysis of the Nationwide Inpatient Sample. *BMC Infect Dis*. 2015 Jul 1; 15:254.

<sup>29</sup> Kelly KB, Banerjee A, Golob JF, Fadlalla AA, Claridge JA. Where's the difference? Presentation of nosocomial infection in critically ill trauma versus general surgery patients. *Surg Infect (Larchmt)*. 2014 Aug; 15(4):377-81.

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**Daily incidences for CLABSI, CAUTI, and VAP were calculated from National Healthcare Safety Network data**

The data we used for our analysis was principally gleaned from three sources. The first of these was a multiyear program managed by the Centers for Disease Control and Prevention (CDC). In 2005, the CDC organized the National Healthcare Safety Network (NHSN) to collect data on certain HAIs across the United States. About 2,500 hospitals now contribute data to the program annually. The NHSN's data on three forms of device-associated HAIs—CLABSI, CAUTI, and VAP—for the years 2007, 2009, 2010, and 2012 were published in a series of reports in the *American Journal of Infection Control*.<sup>30</sup>

The data we used for our analysis of CLABSI, CAUTI, and VAP came from these reports. Since the NHSN segregated its HAI data according to the type of facility or department where an infection took place, we selected data from those settings where we believed patients who were most likely to have ISSs comparable to those in our relevant population would have been treated. For ICU settings, we selected data from the following settings: Medical/surgical - Major teaching; Medical/surgical - All other, ≤ 15 beds; Medical/surgical - All other, > 15 beds; Surgical - Major teaching; Surgical - All other; and Trauma. For the general ward, we selected data from the following settings: Medical, Medical/surgical, Orthopedic trauma, and Surgical.

From the raw data on the number of HAI cases and its corresponding number of patient days across 2007, 2009, 2010, and 2012, we calculated a weighted average of the HAI incidence per patient day for both ICU and general ward care with the following formula:

HAI cases / Number of patient days = HAI incidence per patient day

We focused on the HAI incidence per patient day, rather than per device day, because patients may not require a device during every day on his or her stay. That incidence figure was particularly important in our analysis, because WoundX is expected to inform the selection of treatments that produce LOS savings, regardless of device usage.

Determining the daily incidences for the broader categories of BSI, UTI, and pneumonia required us to ascertain the incidences of all the other HAIs within the same categories, but were not associated with a device.

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<sup>30</sup> Dudeck MA, Edwards JR, Allen-Bridson K, Gross C, Malpiedi PJ, Peterson KD, Pollock DA, Weiner LM, Sievert DM. National Healthcare Safety Network report, data summary for 2013, Device-associated Module. *Am J Infect Control*. 2015 Mar 1;43(3):206-21; Dudeck MA, Horan TC, Peterson KD, Allen-Bridson K, Morrell G, Pollock DA, Edwards JR. National Healthcare Safety Network (NHSN) Report, data summary for 2010, device-associated module. *Am J Infect Control*. 2011 Dec; 39(10):798-816; Dudeck MA, Horan TC, Peterson KD, Allen-Bridson K, Morrell GC, Pollock DA, Edwards JR. National Healthcare Safety Network (NHSN) report, data summary for 2009, device-associated module. *Am J Infect Control*. 2011 Jun; 39(5):349-67; Edwards JR, Peterson KD, Andrus ML, Dudeck MA, Pollock DA, Horan TC. National Healthcare Safety Network (NHSN) Report, data summary for 2006 through 2007, issued November 2008. *Am J Infect Control*. 2008 Nov; 36(9):609-26.

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To do so, we turned to a second source of data—a recent paper in the *New England Journal of Medicine* which conducted a nationwide survey of HAIs.<sup>31</sup> Since that paper’s survey of 183 hospitals adhered to the NHSN’s criteria on how HAIs are defined, we could confidently combine its results with those from the reports in the *American Journal of Infection Control*.

**Daily incidences for BSI, UTI, and pneumonia were calculated from ratios using daily incidences for CLABSI, CAUTI, and VAP, respectively**

The paper in the *New England Journal of Medicine* revealed the specific ratios between HAIs associated with devices and those generated from all other sources. That enabled us to use the quantitative data from the larger NHSN dataset to calculate the daily incidences of BSI, UTI, and pneumonia that arose from all other sources other than devices. Together with the daily incidences of CLABSI, CAUTI, and VAP, they represent the total daily incidences of BSI, UTI, and pneumonia.

Gastrointestinal infections posed a different data challenge for us. Despite the fact that they are the third largest category of healthcare associated infection in the United States, they have been excluded from many of the device-focused studies of HAIs, because their incidence is not linked to any specific device. Hence, we could not use the same methodology to examine gastrointestinal infections as we used for BSI, UTI, or pneumonia. The attention gastrointestinal infections have received is often centered on CDI, the most frequent cause of healthcare-associated infectious diarrhea.<sup>32</sup>

Like many other HAI studies, the NHSN reports did not include data on CDIs. Therefore, we could not benefit from their large quantitative sample. Instead, we used the smaller dataset from the paper in the *New England Journal of Medicine*. It provided us with an estimate of the total number of CDI cases in the United States. However, to determine the daily incidence of CDI required us to know the total number of patient-days for the population at risk. Fortunately, a study in *JAMA Internal Medicine*, whose researchers conducted a systematic review of CDI literature, provided that figure.<sup>33</sup> Combining the data from those two papers, we determined the daily incidence rate of CDI in patients who experienced open wounds associated with trauma.

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<sup>31</sup> Magill SS, Edwards JR, Bamberg W, Beldavs ZG, Dumyati G, Kainer MA, Lynfield R, Maloney M, McAllister-Hollod L, Nadle J, Ray SM, Thompson DL, Wilson LE, Fridkin SK. Multistate point-prevalence survey of health care-associated infections. *N Engl J Med*. 2014 Mar 27; 370(13):1198-208.

<sup>32</sup> Tabak YP, Zilberberg MD, Johannes RS, Sun X, McDonald LC. Attributable burden of hospital-onset *Clostridium difficile* infection: a propensity score matching study. *Infect Control Hosp Epidemiol*. 2013 Jun; 34(6):588-96.

<sup>33</sup> Zimlichman E, Henderson D, Tamir O, Franz C, Song P, Yamin CK, Keohane C, Denham CR, Bates DW, “Health Care-Associated Infections: A Meta-analysis of Costs and Financial Impact on the US Health Care System,” *JAMA Intern Med*. 2013; 173(22):2039-2046.

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**Daily incidence for gastrointestinal infection was calculated from the combination of data from two broad studies**

Together with the ratio between gastrointestinal infections associated with CDI and those generated from all other sources that we gleaned from the paper in the *New England Journal of Medicine*, we could calculate the daily incidence of gastrointestinal infection that arose from all other sources other than CDI.

Within specific patient populations, we should note that the daily incidence of CDI could be much higher. One nationwide study put the daily incidence of CDI at 1.11% for those patients who already suffer from pneumonia and at 1.19% for those who already suffer from an UTI.<sup>34</sup>

Finally, we examined SSIs. This category of infection is unlike any of the other four categories of infection. The occurrence of SSIs is directly linked to a specific event, surgery, rather than exposure over a period of time either in a hospital setting or to a particular device. That distinction is an important one for how we calculated the reduction of SSIs from the deployment of WoundX. That is because however much a WoundX-informed treatment method may reduce a patient's number of debridement events or his LOS in inpatient care, he will still require at least one surgical procedure to close his open wound. Thus, rather than determine the daily incidence of SSIs, we sought to understand their prevalence (or the likelihood that patients would contract a SSI) within our relevant patient population.

Given the wide range of open wounds associated with trauma as well as the surgical procedures that could be used to treat them, we chose not to narrow our data collection on SSIs to those connected with specific types of surgical procedures. Instead, we chose to use an aggregate number of SSIs that covered the widest number of surgical procedures to determine their prevalence.<sup>35</sup>

We then multiplied the prevalence of SSIs with the number of patients that we estimate could benefit from WoundX to determine the number of cases that it could help to avoid. We chose that patient subset, because WoundX could not impact the number of surgical procedures of those patients who healed properly, since they would receive the same number of surgical procedures in any case. Similarly, WoundX could not impact the number of surgical procedures of those patients who experienced wound failure after the deployment of WoundX, because they would also receive the same number of surgical procedures in any case.

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<sup>34</sup> Becerra MB, Becerra BJ, Banta JE, Safdar N. Impact of *Clostridium difficile* infection among pneumonia and urinary tract infection hospitalizations: an analysis of the Nationwide Inpatient Sample. *BMC Infect Dis*. 2015 Jul 1; 15:254.

<sup>35</sup> Leaper DJ. Risk factors for and epidemiology of surgical site infections. *Surg Infect (Larchmt)*. 2010 Jun; 11(3):283-7.

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**Though Woundx does not reduce the prevalence of SSIs, it can reduce the number of secondary surgeries where SSIs are acquired**

But Woundx could reduce the number of surgical procedures associated with those patients who healed properly, but would have experienced wound failure after the deployment of Woundx. These patients would have avoided secondary surgery to treat their wound failures. That reduced number of surgeries also reduces their exposure to SSIs.

But whether they are SSIs, BSIs, UTIs, pneumonia, or gastrointestinal infections, HAIs as a whole are an international problem. An international consortium of hospitals that has collected extensive data on HAIs that mirrors the efforts of the NSHN reports that HAI incidence rates are generally higher outside of the United States, even in Europe.<sup>36</sup> The closest study that approximated our holistic research approach was one performed in five ICUs from two northern European university hospitals. It reported 431 HAI cases during ICU care over the course of 28,498 patient days.<sup>37</sup> That equates to an incidence of HAIs of 1.51%. Excluding SSIs, our incidence of HAIs in ICU care totaled 0.83%. Given that the European study took place over a decade ago, the results are not surprising.

**Woundx is estimated to avoid 2,655 HAI cases in the United States each year**

We totaled the results from our individual calculations of the daily incidences of HAIs below. (See Table 6.) The table also shows the cumulative incidences of HAIs over the periods of related inpatient LOS savings that we expect Woundx will deliver. We then multiplied these cumulative incidences of HAIs with the appropriate patient populations to calculate the number of HAI cases that Woundx could help to avoid. The appropriate patient populations differed between those HAIs which result from daily exposure and SSIs which are linked to a surgical procedure. Hence, we only used the patient population that would have avoided secondary wound closure as a result of Woundx when we calculated the number of SSI cases that it could avoid.

In total, we expect that Woundx's deployment would lead to 2,655 fewer HAI cases in the United States each year and would have led to 714 fewer cases in the MHS from 2001-2014.

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<sup>36</sup> Rosenthal VD, Bijie H, Maki DG, Mehta Y, Apisarnthanarak A, Medeiros EA, Leblebicioglu H, Fisher D, Álvarez-Moreno C, Khader IA, Del Rocío González Martínez M, Cuellar LE, Navoa-Ng JA, Abouqal R, Guancho Garcell H, Mitrev Z, Pirez García MC, Hamdi A, Dueñas L, Cancel E, Gurskis V, Rasslan O, Ahmed A, Kanj SS, Ugalde OC, Mapp T, Raka L, Yuet Meng C, Thu le TA, Ghazal S, Gikas A, Narváez LP, Mejía N, Hadjieva N, Gamar Elanbya MO, Guzmán Siritt ME, Jayatilleke K; INICC members. International Nosocomial Infection Control Consortium (INICC) report, data summary of 36 countries, for 2004-2009. *Am J Infect Control*. 2012 Jun; 40(5):396-407; Rosenthal VD, Maki DG, Mehta A, Alvarez-Moreno C, Leblebicioglu H, Higuera F, Cuellar LE, Madani N, Mitrev Z, Dueñas L, Navoa-Ng JA, Garcell HG, Raka L, Hidalgo RF, Medeiros EA, Kanj SS, Abubakar S, Nercelles P, Pratesi RD; International Nosocomial Infection Control Consortium Members. International Nosocomial Infection Control Consortium report, data summary for 2002-2007, issued January 2008. *Am J Infect Control*. 2008 Nov; 36(9):627-37.

<sup>37</sup> Grundmann H, Bärwolff S, Tami A, Behnke M, Schwab F, Geffers C, Halle E, Göbel UB, Schiller R, Jonas D, Klare I, Weist K, Witte W, Beck-Beilecke K, Schumacher M, Rüden H, Gastmeier P. How many infections are caused by patient-to-patient transmission in intensive care units? *Crit Care Med*. 2005 May; 33(5):946-51.

Table 6.  
Reduction in Hospital-Acquired Infection Cases from WoundX Deployment

	Prevalence within HAI Category	Daily HAI Incidence	Total HAI Incidence Saved with WoundX*	Reduced Cases U.S. (annual)	Reduced Cases MHS (2001-2014)
<i>ICU Care</i>			1.3 days		
Blood stream infection – CLABSI	84.0%	0.062%	0.079%	54	14
Blood stream infection – Other	16.0%	0.012%	0.015%	10	3
Urinary tract infection – CAUTI	67.7%	0.137%	0.175%	119	32
Urinary tract infection – Other	32.3%	0.065%	0.084%	57	15
Pneumonia – VAP	39.1%	0.077%	0.099%	67	18
Pneumonia – Other	60.9%	0.120%	0.154%	104	28
<i>General Ward Care</i>			5.8 days		
Blood stream infection – CLABSI	84.0%	0.015%	0.087%	59	16
Blood stream infection – Other	16.0%	0.003%	0.017%	11	3
Urinary tract infection – CAUTI	67.7%	0.030%	0.172%	117	31
Urinary tract infection – Other	32.3%	0.014%	0.082%	56	15
Pneumonia – VAP	39.1%	0.004%	0.023%	15	4
Pneumonia – Other	60.9%	0.006%	0.035%	24	6
<i>Inpatient Care</i>			7.1 days		
Gastrointestinal infection - CDI	70.9%	0.251%	1.787%	1,214	326
Gastrointestinal infection - Other	29.1%	0.103%	0.733%	498	134
Surgical site infection			1.964%**	249	67
<b>Total</b>				<b>2,655</b>	<b>714</b>

\* Total HAI Incidence Saved with WoundX is defined as the daily HAI incidence multiplied by the LOS saved with WoundX.

\*\* SSI prevalence in the secondary wound closure patient population.

## Hospital and Physician Medical Charges

Hospital and physical medical charges attributable to a particular disease or form of treatment were among the most challenging to acquire. That is because one must not only gain access to broadly comparable data regarding charges, but also obtain sufficiently detailed data to segregate the charges for a particular disease or treatment from those for all other diseases or treatments.

To overcome these hurdles and ascertain the charges that are attributable to the patient outcome improvements that WoundX is expected to deliver,

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we gathered medical charge data from 24 hospitals. Generally, hospital charges included the amounts hospitals billed for the use of facilities, supplies, non-physician staff, and other normal resources required for care. We used that data to determine the average hospital charges are for certain medical treatments, including surgical debridement, secondary wound closure, inpatient ICU and general ward care, and outpatient rehabilitation. While only a limited number of hospitals provided us with data, we sought to survey a sufficiently wide variety of them in order to gain a representative sample of hospitals across the United States.

**Surgical debridement event medical charges.** Surgical debridement events require the use of a hospital's operating room facilities as well as the services of physicians. Hence, to determine the medical charges associated with a surgical debridement event, we had to independently consider the medical charges of hospitals and physicians when such a medical procedure is performed.

We learned from a study on the impact of injury severity and transfer status on reimbursement payments for femur fractures what total physician medical charges are for transfer and non-transfer patients with an ISS of 18 or above and injuries similar to open wounds associated with trauma. Such an ISS is consistent with the level of injury severity that our report seeks to analyze. The study was particularly fortuitous for our report, because it was performed at one of the 24 hospitals in our survey, ensuring the compatibility of our respective financial data.<sup>38</sup>

To ascertain how much physician medical charges are for a surgical debridement event, we assumed that the key driver of physician medical charges is time. However, the study above only provided the total physician medical charges for transfer and non-transfer patients. Hence, we began by calculating the weighted-average total physician medical charges for both transfer and non-transfer patients.<sup>39</sup> That total was \$29,035.

Then, we sought to determine the physician medical charges per minute for patients with open wounds associated with trauma. We did so using the following equation:

Total physician medical charges / Weighted-average minutes for needed medical procedures = Physician medical charges per minute

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<sup>38</sup> Nahm NJ, Patterson BM, Vallier HA. The impact of injury severity and transfer status on reimbursement for care of femur fractures. *J Trauma Acute Care Surg.* 2012 Oct; 73(4):957-65.

<sup>39</sup> *Ibid.*

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But to calculate the weighted-average minutes for needed medical procedures, we first had to define what those medical procedures are likely to be for patients with open wounds associated with trauma. Hence, we sought the opinions of those medical practitioners from Walter Reed National Medical Center and the Uniformed Services University of the Health Sciences who have been directly involved with WoundDx to understand the range of medical procedures needed to treat patients who experienced open wounds associated with trauma, the likely occurrence of those medical procedures, and the average length of time required for each of them. Given the current standard of care in the United States, we expect that all the patients who meet our inclusion criteria will receive surgical debridement. The most likely wound closure procedures they will receive include: primary closure, split-thickness skin graft, local or rotational flap coverage, free flap coverage, and amputation. (See Table 7.)

Given that we already (a) determined the weighted-average number of surgical debridement events for the patient population; (b) determined the percentages of the patient population who either healed properly or experienced wound failure; and (c) could safely assume that patients who healed properly would receive one wound closure event and those who experienced wound failure would receive two wound closure events, we calculated the weighted-average minutes for needed medical procedures using the following equation:

$$\{ \text{Percentage of patients who healed properly} * \{ [\text{Number of surgical debridement events (for patients who healed properly)} * \text{Minutes per surgical debridement event}] + \text{Weighted-average minutes for needed medical procedures (for patients who healed properly)} \} + \{ \text{Percentage of patients who experienced wound failure} * \{ [\text{Number of surgical debridement events (for patients who experienced wound failure)} * \text{Minutes per surgical debridement event}] + \text{Weighted-average minutes for needed medical procedures (for patients who experienced wound failure)} \} \} = \text{Weighted-average minutes for needed medical procedures}$$

With that result, we could then calculate the physician medical charges per minute for patients who experienced open wounds associated with trauma. Finally, we multiplied that result with the number of minutes needed for a surgical debridement event to determine the physician medical charges for a surgical debridement event.

To examine hospital medical charges, we turned to our survey of 24 hospitals. Most of them described the medical charges that they bill in terms of operating room set-up and usage, typically in 15-minute increments. Differences in a patient's injury severity or surgery complexity can influence hospital billing. Unsurprisingly, the more severe

the injury or complex the surgery is, the greater the associated medical charges are.

Given that our relevant patient population was defined as having experienced open wounds associated with trauma, we naturally assumed that their injuries would generally be more severe and would require more complex surgery than the norm. That said, if one considers a normal distribution of such injuries, more of them would still be clustered near the mean, rather than the tail.

Therefore, when compelled to select a level of injury severity or surgery complexity to identify the appropriate medical charges, we generally chose the ones that were slightly above the norm in terms of injury severity or surgery complexity. When there was an odd-numbered scale, we selected the midpoint, for example 2 on a 3-point scale or 3 on a 5-point scale. When there was an even-numbered scale, we selected the option slightly above the midpoint, for example 4 on a 6-point scale or a 5 on an 8-point scale. When only qualitative descriptors were given, we selected “major procedure.”

**Each surgical debridement event requires medical charges of \$14,681**

Since we learned that each surgical debridement event requires about 90 minutes of time in an operating room, we added the medical charges for operating room set-up to those for 90 minutes of operating room usage (at the appropriate level of injury severity or surgery complexity) for the 20 civilian hospitals from our 24-hospital survey to determine the hospital medical charges for each hospital. Then we calculated the average hospital medical charges across all 20 civilian hospitals. Finally, we added that to the physician medical charges that we calculated earlier to determine that the average medical charge was \$14,681 per surgical debridement event. (See Table 7.)

Table 7.  
Hospital and Physician Medical Charges for Medical Procedures Needed to Treat Patients Who Experienced Open Wounds Associated with Trauma

	Percentage of Patient Population	Operating Room Time (minutes)	Hospital Medical Charges	Physician Medical Charges	Total Medical Charges
Debridement		90	\$9,574	\$5,106	\$14,681
Primary closure	42.5%	90	\$9,574	\$5,106	\$14,681
Split-thickness skin graft	42.5%	90	\$9,574	\$5,106	\$14,681
Local or rotational flap coverage	9.0%	180	\$16,221	\$10,213	\$26,434
Free flap coverage	3.0%	600	\$47,237	\$34,043	\$81,280
Amputation	3.0%	180	\$16,221	\$10,213	\$26,434

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**Secondary wound closure event medical charges.** Given the hospital and physician medical charges that we collected to calculate the total medical charges associated with surgical debridement events, we could use a similar methodology to calculate the total medical charges associated with secondary wound closure events.

As in the earlier case of our calculation of surgical debridement medical charges, we separately determined the hospital and physician medical charges. But rather doing so for only one medical procedure, we did so for each of the possible wound closure medical procedures, including primary closure, split-thickness skin graft, local or rotational flap coverage, free flap coverage, and amputation. We expect these wound closure medical procedures require three different lengths of time in the operating room.

Then, we added the medical charges for operating room set-up and those for the three different lengths of time of operating room usage (at the appropriate level of injury severity or surgery complexity) for the 20 civilian hospitals from our 24-hospital survey to determine the hospital medical charges for each hospital. Then, we took the average of the hospital medical charges for each of the three lengths of time in the operating room, in order to determine the hospital medical charges for each of the possible wound closure medical procedures.

From our earlier calculation of medical charges per surgical debridement event, we already determined the physical medical charges per minute for patients who experienced open wounds associated with trauma. Thus, we multiplied the physical medical charges per minute and the three lengths of time in the operating room to determine the physician medical charges for each of the possible wound closure medical procedures.

**Each secondary wound closure event requires medical charges of \$18,089**

Then, we combined the hospital medical charges with their respective physician medical charges for each of the possible wound closure medical procedures. Already having the likelihood of each of the possible wound closure medical procedures in our relevant patient population, we calculated the weighted-average medical charge was \$18,089 per secondary wound closure event.

**ICU and general ward LOS medical charges.** To understand the medical charges associated with ICU and general ward lengths of stay, we began by recording the daily medical charges for inpatient ICU and general ward care from the hospitals in our survey. Nineteen hospitals provided the needed financial data for inpatient ICU care and 22 hospitals provided it for inpatient general ward care.

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**Daily medical charge was  
\$4,100 for ICU care and  
\$1,210 for general ward care**

We then averaged the medical charges for ICU and general ward care for each hospital in our survey. The average daily medical charge was \$4,100 for inpatient ICU care and \$1,210 for inpatient general ward care. A nationwide study of medical charges from 2002 seemed to validate our calculations. It revealed an average daily medical charge for inpatient ICU care, which required mechanical ventilation, of \$2,193.<sup>40</sup> According to the U.S. Department of Labor's medical-cost data CPI subset through 2014, we can estimate that to be \$3,342.

**Rehabilitation event medical charges.** Since medical facilities offer a range of rehabilitation services, we chose to focus our financial data collection effort on one service, neuromuscular reeducation. We did so because many of the patients who experienced open wounds associated with trauma—particularly those whose wounds involved extremities or resulted in amputations—would require that sort of rehabilitation. For those hospitals whose list of rehabilitation services was insufficiently detailed to cite neuromuscular reeducation, we chose therapeutic exercise (and, in one case, manual therapy) as an alternative; they are the sorts of rehabilitation that are useful for the same patient population.

**Each rehabilitation session  
requires medical charges of  
\$945**

Most of the hospitals in our survey priced their rehabilitation services in 15-minute increments. We assumed that a single rehabilitation session would require 120 minutes. We then tallied the medical charge per rehabilitation session for each hospital and averaged the medical charges across the 24 civilian hospitals in our survey that provided us with the needed financial data. The average medical charge was \$945 per rehabilitation session.

**HAI treatment medical charges.** Since the costs linked to HAIs can be high, reducing the number of patients who contract HAIs can have a meaningful impact on the total cost savings that the WoundX project can generate.

Given that our research focused on five different categories of HAIs—BSI, UTI, pneumonia, gastrointestinal infection, and SSI—we sought to ascertain the cost for treating each of them. While many studies have documented the additional costs brought about by HAIs, most of those studies are now dated, were focused on single HAIs (making it difficult to compare across HAIs), or were performed in countries with different currencies and reimbursement regimes.<sup>41</sup>

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<sup>40</sup> Dasta JF, McLaughlin TP, Mody SH, Piech CT. Daily cost of an intensive care unit day: the contribution of mechanical ventilation. *Crit Care Med.* 2005 Jun; 33(6):1266-71.

<sup>41</sup> Becerra MB, Becerra BJ, Banta JE, Safdar N. Impact of *Clostridium difficile* infection among pneumonia and urinary tract infection hospitalizations: an analysis of the Nationwide Inpatient Sample. *BMC Infect Dis.* 2015 Jul 1; 15:254; De Lissovoy G, Fraeman K, Hutchins V, Murphy D, Song D, Vaughn BB. Surgical site infection: incidence and impact on hospital utilization and treatment costs. *Am J Infect Control* 2009; 37:387-97.

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To clarify which data we should use, we adopted criteria that would compensate for these confounding features. We sought the most recent data sources; we selected studies which had a uniform data collection methodology across all major HAIs; and we used only those studies conducted in the United States.

Moreover, we chose not to consider the additional costs related to secondary or tertiary infections, even though they sometimes carry a significant cost. One recent study put the additional cost of a single HAI at \$14,561. But when methicillin-resistant *Staphylococcus aureus* is already present, a second case of HAI could cause the additional treatment cost soar to between \$60,000 and \$63,810.<sup>42</sup> But to make use of such secondary and tertiary costs, we would need to use similarly detailed patient outcome data, which was unavailable to us.

Among the most extensive studies was *The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention*.<sup>43</sup> Published in 2009, its data was based on an extensive review of the medical literature on HAIs. But it too has become dated. It also focused on the narrow forms of HAIs (i.e., CLABSI, CAUTI, VAP, CDI, and SSI), rather than the wider categories of which they are parts. Nor could the study fully reconcile the reasons behind the broad range of costs for each form of HAI. For example, the costs per infection for CLABSI ranged from \$5,734 to \$22,939 (in 2003 dollars); those for VAP ranged from \$11,897 (in 1999 dollars) to \$25,072 (in 2005 dollars); and those for SSI ranged from \$10,443 (in 2005 dollars) to \$25,546 (in 2002 dollars). Apart from the broad range of costs that it reported, the study did not account for the impact of inflation or the varying breadth of the data sources of its surveyed papers, nor reconcile how costs were defined across those surveyed papers.

Due to these inconsistencies we focused on a study published in the *JAMA Internal Medicine* in 2013. The study provided data on the widest categories of HAIs, including BSI, UTI, pneumonia, gastrointestinal infection, and SSI. While the study used the same literature review methodology to collect its data as *The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention*, the study used more recent data. Even so, it still reported a wide range of costs. For example, the costs per infection for CLABSI

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<sup>42</sup> Henson G, Ghonim E, Swiatlo A, King S, Moore KS, King ST, Sullivan D. Cost-benefit and effectiveness analysis of rapid testing for MRSA carriage in a hospital setting. *Clin Lab Sci*. 2014 Winter; 27(1):13-20. Anderson DJ, Kaye KS, Chen LF, Schmader KE, Choi Y, Sloane R, Sexton DJ. Clinical and financial outcomes due to methicillin resistant *Staphylococcus aureus* surgical site infection: a multi-center matched outcomes study. *PLoS One* 2009; 4:e8305.

<sup>43</sup> Scott, R Douglas. *The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention*. Atlanta: Centers for Disease Control and Prevention, March 2009.

ranged from \$30,919 to \$65,245; those for VAP ranged from \$36,286 to \$44,220; and those for SSI ranged from \$4,005 to \$82,670.<sup>44</sup>

Using a Monte Carlo simulation, the study generated point estimates and 95% confidence intervals for the attributable costs. The study found that the cost per infection for CLABSI was \$45,814, that for UTI was \$896, that for VAP was \$40,144, that for *Clostridium difficile* infection was \$11,285, and that for SSI to cost \$20,785.<sup>45</sup> Since the treatment for a particular infection was unlikely to be substantially different from the treatment for the whole category of infections, we assumed that the cost associated with a particular infection, such as CLABSI, was the same for the cost associated with all blood-stream infections.

We converted those estimated costs into medical charges to make them consistent with our other financial data. To perform that conversion we used the cost-to-charge ratio, which the *JAMA Internal Medicine* study suggested, of 0.5. We then accounted for inflation of those charges from 2012, when the study collected its data, to 2015, when the rest of the financial data that we used in our analysis was collected. That financial data originated from our 24-hospital survey.

Finally, we calculated the rate of inflation over that period from the Producer Price Index data for general medical and surgical hospitals from the U.S. Bureau of Labor Statistics. For our calculation, we assumed that the study’s data was collected in December 2012 and we adjusted it for inflation through September 2015, which is the most recent data available to us. Our consolidated attributable hospital and physician medical charges follow.<sup>46</sup> (See Table 8.)

Table 8.  
Attributable Hospital and Physician Medical Charges

	Cost (2012)	Charges (2012)	Charges (2015)
Surgical debridement event			\$14,681
Surgical wound closure event			\$18,089
Inpatient ICU care, daily			\$4,100
Inpatient general ward care, daily			\$1,210
Outpatient rehabilitation event			\$945

<sup>44</sup> Zimlichman E, Henderson D, Tamir O, Franz C, Song P, Yamin CK, Keohane C, Denham CR, Bates DW, “Health Care-Associated Infections: A Meta-analysis of Costs and Financial Impact on the US Health Care System,” *JAMA Intern Med.* 2013; 173(22):2039-2046.

<sup>45</sup> *Ibid.*

<sup>46</sup> Producer Price Index. Industry Data, General medical and surgical hospitals (series ID PCU622110622110), <http://www.bls.gov/ppi/home.htm>.

Hospital-acquired infections				
Blood stream infection	\$45,814	\$91,628		\$94,212
Urinary tract infection	\$896	\$1,792		\$1,843
Pneumonia	\$40,144	\$80,288		\$82,552
Gastrointestinal infection	\$11,285	\$22,570		\$23,206
Surgical site infection	\$20,785	\$41,570		\$42,742

## Estimated Cost Savings

Returning to the equation at the start of this analysis, we now have sufficient data to calculate the cost savings for each of the six categories of potential outcome savings. After we totaled the cost savings from all six categories, one could see how substantial the combined cost savings could be for not only the U.S. healthcare system, but also the MHS. The U.S. healthcare system could reduce annual medical charges by \$3.4 billion and, over the period from 2001-2014, the MHS could have reduced medical charges by \$873 million. (See Tables 9 and 10.)

Table 9.  
Potential Annual Cost Savings from WoundX Deployment in the United States (\$ millions)

	Relevant patient population	Saving per patient day	Saving per event or session	National savings per year
Savings from surgical debridement	67,930		\$14,681	\$2,039.5
Savings from surgical wound closure	12,702		\$18,089	\$229.8
Savings from inpatient ICU care	67,930	\$4,100		\$357.6
Savings from inpatient general ward care	67,930	\$1,210		\$478.4
Savings from outpatient rehabilitation care	67,930		\$945	\$187.0
Savings from avoided hospital-acquired infections				\$81.1
<b>Total</b>				<b>\$3,373.4</b>

Table 10.  
Estimated Cost Savings from WoundX Deployment in the Military Health System, 2001–2014 (\$ millions)

	Relevant patient population	Saving per patient day	Saving per event or session	MHS savings (2001-2014)
Savings from surgical debridement	18,256		\$14,681	\$548.1
Savings from surgical wound closure	3,414		\$18,089	\$61.8
Savings from inpatient ICU care	18,256	\$4,100		\$96.1
Savings from inpatient general ward	18,256	\$1,210		\$128.6

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care			
Savings from outpatient rehabilitation care	6,212	\$945	\$17.1
Savings from avoided hospital-acquired infections			\$21.8
Total			\$873.5

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## Future Sources of Savings

**Woundx project also offers the potential for cost savings from chronic open wounds, like diabetic, pressure, and vascular ulcers**

Open wounds are very common. About 3.6 million cases of open wounds are reported in the United States each year.<sup>47</sup> Many are of the acute and traumatic variety that we address here. However, the majority of open wounds in the United States are chronic. They are the result of ailments such as diabetic, pressure, and vascular ulcers. About 10-15% of the estimated 26 million Americans with diabetes are at risk of developing lower-extremity diabetic ulcers. About 7% of these will require an amputation. Another 1.3 to 3 million Americans are believed to have pressure ulcers.<sup>48</sup> Both sorts of ulcers are susceptible to infection. In the case of diabetic foot ulcers that infection rate may be as high as 50%. The estimated cost to treat a diabetic foot ulcer ranges from \$4,595 to over \$28,000 over the course of two years. Many of these individuals are over 65 and about 3% of the total Medicare budget is annually spent on open wound care.<sup>49</sup>

Eventually, Woundx could be applied to not only acute and traumatic open wounds, but also those that are chronic. That would further expand the potential cost savings from the technology, given the even larger relevant patient population pool that suffers from those types of wounds.

## Conclusion

The big-data revolution is still growing, and most of the potential for value creation is still unclaimed. But it has set the healthcare industry on a path of rapid change and new discoveries. Healthcare service providers, which are committed to this sort of innovation, will likely be the first to reap the rewards. Hence, initiatives such as Woundx that provide decision support tools based on analysis of these extremely large and varied datasets have the potential to transform healthcare. In addition to reducing patient LOS and hospital costs, the use of Woundx to determine optimum treatments

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<sup>47</sup> "Statistics about Open Wound," WrongDiagnosis.com, [http://www.rightdiagnosis.com/o/open\\_wound/stats.htm](http://www.rightdiagnosis.com/o/open_wound/stats.htm) (accessed on Sep. 20, 2015).

<sup>48</sup> Lyder CH. Pressure Ulcer Prevention and Management. *JAMA*. 2003; 289(2):223-226.

<sup>49</sup> Sheehan P, Jones P, Giurini JM, Caselli A, Veves A. Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial. *Plast Reconstr Surg*. 2006 Jun; 117(7 Suppl):239S-244S.

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can improve patient outcomes and save lives. Increased hospital capacity would further benefit the national healthcare system, which has suffered from the closure of many hospitals. That benefit would have an even bigger impact on increasing the capacity and operating efficiency of ICUs, which represent 10% of inpatient beds, but 20 to 35% of hospital operating costs.<sup>50</sup> Healthcare service providers that invest and promote predictive analytic capabilities would not only gain a competitive advantage, but also lead their industry into a new era.

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<sup>50</sup> Krell KE. Critical care medicine growth requires dealing with our 'perfect storm' of manpower shortage. *Crit Care Med.* 2010 Jul; 38(7):1613; Halpern NA, Pastores SM. Critical care medicine in the United States 2000-2005: an analysis of bed numbers, occupancy rates, payer mix, and costs. *Crit Care Med.* 2010 Jan; 38(1):65-71.