

White Paper

Evidence-Based Wound Surveillance

A Three-Dimensional Approach
To Measuring, Imaging and
Documenting Wounds

Mark Nixon, MD and Christine Moore
2014-00050

Contents

Executive Summary	1
Part 1: The Problem	2
Part 2: Toward a Solution	8
Part 3: A 3D Wound Surveillance System	12
Summary	18
Appendix One: How Errors Accumulate	19
Appendix Two: Pro Forma Potential Savings	20
References	21

The information in this document is provided as is without warranty of any kind, either expressed or implied, including but not limited to, implied warranties of merchantability, fitness for a particular purpose, or non-infringement. ARANZ Medical Limited has used reasonable efforts to include accurate, complete and up-to-date information in this document; it does not, however, make any warranties or representations as to its accuracy, timeliness or completeness. ARANZ Medical Limited periodically adds, changes, improves, or updates this document without notice.

Executive Summary

Wounds are placing an increasing clinical, operational and financial burden on providers, particularly with the introduction of penalties associated with hospital-acquired pressure ulcers (HAPUs). Chronic wounds lead to greater risk of mortality, longer hospital lengths of stay, and readmissions. They cost a significant amount to treat, cause enormous patient suffering, can impact value-based payments, and may hurt a hospital's reputation.

Therefore, providers need to vigilantly monitor wound healing behavior so they can quickly identify wounds that are at risk of becoming chronic or reportable and take early, effective action. Inadequate wound surveillance can lead to diagnostic errors and mismanagement, resulting in higher numbers of chronic, worsening and reportable wounds.

However, it is currently very difficult to accurately monitor the development of wounds using traditional or two-dimensional (2D) digital planimetry methods. There are three main challenges to achieving the required level of wound vigilance quickly, easily, and in compliance with data security and privacy requirements. These challenges are:

- obtaining accurate measurements and reliable healing trends;
- managing image quality and logistics;
- gathering standardized documentation.

Three-dimensional (3D) wound surveillance tools provide reliable information about wounds' healing behavior, consistently high quality images, and documentation better able to withstand the scrutiny of auditors and attorneys. The combination of these features enables providers to improve and streamline the wound information gathering process.

Silhouette is an example of an automated 3D measurement, imaging and documentation system providing comprehensive wound surveillance support for multiple stakeholders.

When wound specialists and multidisciplinary teams are equipped with 3D wound surveillance, they can monitor wound progress more effectively. They use the evidence at their fingertips to influence better assessment and treatment practices, review non-specialists' stagings and assessments, and improve organization-wide wound practice. Multidisciplinary teams' wound-related communication improves.

The empowerment provided by higher quality wound information supports better treatment decisions which can improve healing outcomes, including fewer reportable wounds. Nurses can be more productive, providers can avoid penalties and costs, and patients' suffering is reduced.

Part 1: The Problem

Chronic Inaccuracy

It is estimated that up to one-third of hospital patients have a wound.¹ Treatment of this “major and snowballing threat to public health and the economy” is thought to consume around 2-4% of healthcare costs.² This pervasiveness of wounds makes them logistically complex for providers to manage.

Better wound care processes are particularly urgent in the United States as hospital-acquired pressure ulcer (HAPU) policies change.³ For instance, payers are currently penalizing providers who supply inaccurate or inadequate HAPU documentation. From 2015, the new Hospital-Acquired Conditions (HAC) Reduction Program may give reportable pressure ulcers (e.g., those worsening to stage III or IV, or hospital-acquired) the power to jeopardize millions of dollars in Inpatient Prospective Payment System (IPPS) payments for the worst-performing 25% of providers, harming their reputation as well as their bottom line.

The incidence of HAPU in Medicare hospitals averages 4.5%, leading to greater risk of mortality, longer hospital lengths of stay, and readmission within 30 days after discharge.⁴ Because of this, it is crucial that hospitals are vigilant about monitoring wound healing behavior. They must be able to provide evidence of the quality of their wound care, and be able to prove that any “preventable” pressure ulcer present on admission was not acquired on their watch.

Yet typical wound assessment practice is not well-equipped to provide robust evidence, relying on crude, centuries-old methods that are inadequate for modern health care. There are three critical issues:

- **Chronic inaccuracy in measurement**, making it difficult to effectively monitor and evidence the healing progress of wounds using traditional or two-dimensional methods;
- **Problematic wound imaging methodologies**, that are time consuming in their image acquisition and result in images of varying quality;
- **Unproductive, subjective and complicated wound documentation processes**, that fail to take into account the needs of multiple stakeholders involved in wound monitoring, documentation, communication and quality/risk management.

Dimension One: Measurement

Practitioners measure wounds to identify a healing trend, usually area reduction over time.⁵ They rely on this trend information to predict healing rates, identify factors delaying healing in a timely fashion, intervene rapidly, and provide appropriate treatment.⁶ For example, a widely accepted rule of thumb used by practitioners is that reduction of diabetic foot ulcers by 53% or more in the first four weeks is a robust predictor of complete healing within 12 weeks.⁷ As another example, the proportional relationship between one-dimensional perimeter and area measurements correlates to the healing progress of venous leg ulcers.⁸ Trends like these may determine whether or not, for instance, expensive treatments are used.

Various authors have described the qualities that a wound measurement method should possess⁹⁻¹⁰:

- **Valid** – Does it measure what it is intended to measure?
- **Reliable** – Do measurements of the same object by two or more individuals yield the same or similar results?
- **Non-invasive** – Is patient discomfort minimized?
- **Simple, accessible, and usable** – Do practitioners find it convenient, effective and easy to use in a clinical setting?
- **Cost effective** – Do the benefits of greater precision outweigh the cost?

Unfortunately, not only are methods commonly used in clinical practice difficult to use, they are often poorly validated, and subject to serious question in terms of accuracy and precision¹¹:

- **Rulers:** The standard area formula *length x width* is inaccurate, and typically over-estimates true wound area by 44%.¹² This method is also not precise, with practitioners often using different ways to calculate length and width, resulting in measurements with poor reproducibility (Figure 1);
- **Planimetry**, such as tracing a wound onto acetate film and calculating the area, has been estimated to have an up to 22% error rate¹³;
- **Digital planimetry**, which involves using software to estimate the area within a user-drawn outline on a digital image, requires a number of conditions to be met to ensure accuracy is not compromised. For an ideal outcome, the wound must lie in a flat plane; a scaled calibration target, such as a ruler, must be in a plane; the wound and the target must be in the same plane; the camera lens must be parallel to the wound and the target; and the target must be identified accurately. For instance, slightly altering the angle of the camera so it is no longer perpendicular to a wound can distort measurements by 10%¹⁴ to 35%¹⁵;

- **Geometry:** Errors compound on any method that involves determining an area based on a linear measure. This not only involves rulers, but also digital planimetry. Appendix One shows how easily errors of $\pm 20\%$ can be introduced, even when measuring a wound of a regular shape;
- **Wound depth and volume** measurement are even more problematic. For instance, wound volume measured using alginate casts produces errors of 5%-40%¹⁶, and the Kundin method is considered to be very subjective.¹⁷

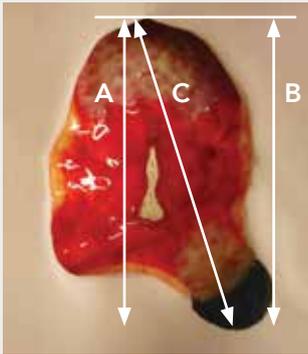
Imprecise Trends

The next step is for practitioners to graph the measurements they have made over time in order to look at healing trends. Many practitioners assume that wound measurements contain a systematic (non-random) deviation from the true value – in other words, they are “uniformly inaccurate,” and can therefore form a trustworthy healing trend. However, this is not the case. As wounds are measured by many assessors, the inaccuracies are random, making the resulting error bars of their measurements too wide to be clinically useful. Rating variability ranges from 16% to more than 50%.¹⁸⁻¹⁹

There seems to be widespread acceptance of inaccuracy without an acknowledgment of its adverse implications for clinical practice. Figure 2 shows how lack of precision in healing trend data can affect clinical decision making. If error bars are too broad to confirm if a wound is getting smaller or larger, a facility is less able to detect and respond promptly to meaningful changes in wound size, or to provide valid evidence supporting healing outcomes.

Practitioners skilled at wound care combine their measurements with clinical judgment about the wound to assess change and make sound decisions. However, the health care system is moving towards higher levels of precision, demanding not just quality care, but evidence of quality care.

Precise measurement is important, and inaccuracy is costly. It has been estimated that the measurement-related portion of the US health care budget ranges from 10%-15%, and error-related spending (re-work, quality tests, etc.) accounts for 30%.²⁰ As technology developments make measurement in health care easier and more precise, payers can demand more accurate measurement data as a basis for reimbursement and shift the costs of inaccuracy to providers. Wound measurement is not exempt from this trend.



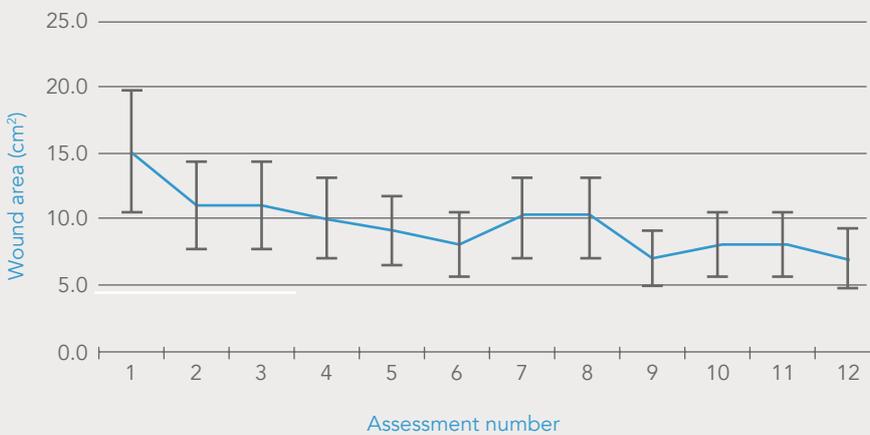
What is the area of this wound?

There are different methods for making length and width measurements, such as (1) the longest length and largest perpendicular width method; and (2) the so-called clock method which requires a superior to inferior (or 12 o'clock to 6 o'clock) measurement, and a medial-lateral (or 3 o'clock to 9 o'clock) measurement.

But even when practitioners are using the same method, they can obtain very different results. For example, if the clock method is used, the length may be the longest distance in the superior-inferior direction (A), or the length of the extent of the wound in the superior-inferior direction (B). Or – even though practitioners are trained not to do this – they often tilt the measurement from the strict 12 o'clock to 6 o'clock orientation (C). In this example, the largest length is 15% longer than the shortest.

Figure 1

Wound healing progress



Clinical decision-making is adversely affected by measurements with large errors and the resulting imprecise trends that are based on those measurements. For instance, if the error rate on a weekly assessment is $\pm 30\%$ as shown above, and the wound is making a 10% change each week, it will take three weeks before any improvement or deterioration can be objectively proven. Note that in this example, deterioration and improvement in the wound are undetectable between assessments 2 and 9.

Figure 2

Dimension Two: Wound Imaging

Images are useful for wound documentation. However, if the images are not standardized or of high quality, they add risk and introduce error to the documentation. Wound photo transfer can cause local storage and security issues and photos are difficult to transfer to an electronic medical record (EMR). Guidelines are often complicated, and the cost of ownership of cameras can escalate.

Shaw and Bell sum up the drawbacks of digital photography: “Digital imaging takes considerable time and studies seldom show the total time to capture the image, transfer the image from the camera to the computer, and then calibrate and measure the wound... Many additional factors also require management such as lighting, environment and the distance of the camera from the [foot].”²¹ A busy nursing team with high turnover and multiple demands would struggle to deliver consistently high quality images under these circumstances.

Dimension Three: Documentation

The problems described above are compounded by the ineffective and inefficient collection and management of critical information about wounds. While there is a lot of literature about “wound management” in the context of clinical guidelines, very little has been written about the complexity of the overall wound management effort. Systemic factors include:

- **Risk management:** Many quality, risk and legal managers have experienced the challenges of putting together pieces of ad hoc documentation when there is an adverse event such as a hospital-acquired pressure ulcer. With the spotlight on a potential legal case or penalty, the lack of standardization of wound documentation is exposed and there is a higher risk of an unfavorable outcome.²² Practitioners are not necessarily adept at gathering accurate measurement data or conforming with strict documentation standards, resulting in different interpretations of measures or levels of reporting.²³
- **Multidisciplinary team communication:** It is being recognized that success in chronic wound care requires an integrated chronic disease management methodology²⁴ rather than siloed thinking. Disciplines involved in the wound care effort may include nursing, nutrition, occupational therapy, orthotics/prosthetics, physical therapy, general practice, podiatry, social work, pharmacy, and specialists²⁵, often in multiple organizations. Under these circumstances, care teams need high-quality communication based on readily available wound information that is accurate, easy to access, and comprehensive.

- Lack of specialist competency:** There are recognized issues with the accuracy of wound assessment by non-specialized staff.²⁶ This extends to treatment decisions. In a retrospective analysis, 78.5% of patients treated by a board certified wound care nurse healed in comparison to the 36.3% of those treated by non-certified nurses.²⁷ Wound specialists are a crucial part of the wound care system, but are typically stretched to capacity managing the wound care effort and an increasing documentation burden. Often, they are required to travel to patients, further consuming time and effort.²⁸ The consequences of this disparity of skill include unnecessary patient suffering, readmissions, penalties and litigation risks, rework and extra costs. For instance, hospital admissions and extended hospital stays typically consume 37%-49% of the total cost of wound care.²⁹
- Litigation:** Up to 20% of all US legal medical claims and more than 10% of settlements are wound related³⁰, and there are more than 17,000 pressure ulcer-related lawsuits filed annually in the United States.³¹ Settlements average \$279,000 each.³² Documentation is a critical success factor in pressure ulcer litigation.³³ If documentation can prove no neglect occurred, a lawsuit is less likely to proceed; however, many out-of-court settlements have been forced on providers because of a lack of evidence of care, not necessarily the absence of care itself.³⁴

Part 2: Toward a Solution

The Form of a Solution

Practitioners use information to help make decisions that improve the quality of care, and to fulfil their administrative obligations. The regulatory changes in wound policies and the need for accountability and proven outcomes justify a new approach to wound surveillance innovation.

A suitable solution would address both measurement and clinical process challenges currently experienced in wound care. Outcomes would include comprehensive wound surveillance, streamlined processes, better communication and decision support for multi-disciplinary teams, and reduced risk exposure.

An ideal solution would provide:

- accurate and precise measurements;
- reliable healing trends;
- high quality images;
- objective and relevant documentation satisfying legal and regulatory requirements;
- integration into existing processes and EMR;
- ease of use;
- conformity with regulations and standards such as protected health information (PHI), Health Insurance Portability and Accountability Act (HIPAA), HL7 and DICOM.

Accurate Wound Surveillance

Any wound surveillance program used for clinical decision support (CDS) must be built on a foundation of accuracy. As the National Quality Forum reports, "CDS enables better care by increasing the provision, documentation, measurement, and reporting of services recommended in quality measures and clinical guidelines. CDS can help deliver 'the right information to the right person in the right format through the right channel at the right time'."³⁵

Critically, traditional wound measurement modalities result in measurements with large errors and unreliable trends. However, three-dimensional (3D) methods can accurately measure area, along with the important indicators of depth and volume. Until recently, these systems were prohibitively expensive and cumbersome, but there are now commercially-available 3D measurement systems that overcome many of the limitations of traditional wound measurement techniques.

These systems are typically based on laser triangulation or stereo-photogrammetry methods. Such 3D systems account for both the curvature of the body and the irregular nature of wounds. Therefore, accurate measurements can be taken from the 3D models that these systems generate.

These systems do, however, share some of the limitations of traditional techniques. For example, surface-based 3D systems cannot quantify the degree of undermining or tracking in a wound. Circumferential wounds can be difficult to assess, although some systems do allow for accurate measurements of extensive wounds.³⁶ 3D systems do not offer diagnoses or replace good clinical judgment; rather, they equip an organization to achieve better wound outcomes by supplying precise measurement and trend data, and supporting more effective wound surveillance and communication between wound stakeholders.

The Case for Innovation

To date, providers have spent most of their wound care budgets on treatments and labor costs,³⁷ and have paid a price – often hidden – for decreased productivity, reimbursement penalties, and the costs associated with litigation brought about by inaccuracy and inconsistency.

Precise measurement forms the foundation for better wound assessment practices and creates downstream value. Practitioners equipped with better tools make fewer errors and produce better clinical outcomes, stronger evidence, more efficient and effective processes, more targeted treatment, less reimbursement leakage, and greater patient satisfaction.

However, if an organization is contemplating a new approach to wound surveillance, other stakeholders such as finance and value analysis, multidisciplinary team members, 'C-suite' decision-makers, and the IT department are likely to be involved. These stakeholders may be less aware than those at the front line of the hidden costs and challenges of achieving effective wound outcomes, and may require a clear justification for investing budget and/or time in an improvement.

While this white paper is designed to provide the basis of a case for innovation in precision-based wound surveillance, the case is strengthened when the organization's specific costs can be quantified. It is beyond the scope of this document to describe how to prepare a formal business case, but the following steps are helpful:

1. Define the core issue the innovation is addressing: The organization may be exposed to the risk of hospital-acquired pressure ulcers; it may need better quality management systems to prove wound outcomes; it may not have

robust documentation to demonstrate evidence of care. Multidisciplinary team communication may need improvement; there may be too much dependence on non-specialist staff; or the organization may wish to leverage the knowledge of wound specialists. Wound logistics may be too complex or wound-related productivity may be low. The organization may wish to open up a new wound clinic or establish a wound telehealth service. There may be a combination of factors.

2. What are the costs of the issue? Table 1 offers some prompts to help identify areas where change may prove worthwhile, and shows how direct, risk and opportunity costs all contribute to the case for innovation.
3. Define metrics that will indicate improvement. Based on the answers from Table 1, how will you know when the implementation is working?
4. What should be the scope of innovation? Does it combine a technology with a change in processes? Or does the organization simply need to equip practitioners with better tools?
5. Determine how to implement the innovation appropriately, perhaps starting with a single point of care device, or a pilot in a single facility
6. When the improvements are realized, what will be the return to the organization?

Appendix 2 offers a pro-forma ROI calculation showing examples of potential financial and productivity impacts.

Wound cost, risk and opportunities

Costs can be calculated in terms of lost revenues, penalties, costs of inappropriate or ineffective treatments, and lost productivity if tasks must be repeated due to inaccurate, inefficient, and inconsistent wound assessments.

Costs

Here are some examples of indicators of unnecessary costs in the current environment. Calculate over a given period:

1. The number and cost of inaccurate wound stagings that could have been avoided with better measurement, imaging, trend data, monitoring, specialist reach, or expert supervision;
2. Productivity lost due to wound reassessment;
3. Reimbursement lost or repayments required due to inaccurate assessments;
4. Reimbursement lost or penalties paid due to reportable or hospital-acquired pressure ulcers (HAPU);
5. Opportunity cost of bed days lost due to HAPU;
6. Wound-related readmission penalties;
7. Legal settlements.

Risk and quality management

1. What is the extent and cost of wound-related error in the organization?
2. To what extent can it be proven that pressure ulcers were not acquired at a particular facility?
3. What is the organization's exposure to wound-related litigation?
4. How accurate is the wound assessment capability of the generalist nursing staff? Are the facility's wound specialist/s overwhelmed with work? What risks are associated with these issues?

Opportunities

1. How would treatment outcomes improve if multidisciplinary teams had instant, precise wound healing data, imaging, and documentation at their fingertips?
2. To what extent can the organization prove wound healing outcomes and be ready for pay-for-performance/evidence-based reimbursement of wound care?
3. What difference would it make if patients could see their wound healing progress and the consequences of non-compliance?
4. What are the current logistical costs associated with wound care? What value could be placed on a more streamlined and accurate process?
5. What telehealth and other opportunities are available for wound care if assessments can be accurately measured, documented, and reviewed remotely?

Table 1

Part 3: A 3D Wound Surveillance System

Recent three-dimensional electronic wound measurement methods can accurately measure wounds, accounting for both the curvature of the body and the irregular nature of the wounds. Such methodologies not only measure area more accurately, they can also measure volume, depth and perimeter³⁸, and generate reliable healing trend evidence.

One such 3D-based system is the Silhouette wound imaging, measurement and documentation system (Figure 3).



Figure 3: Non-invasive 3D electronic wound measurement, imaging and documentation.

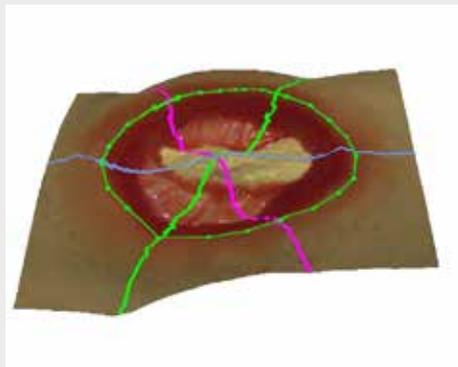


Figure 4: Behind the scenes, SilhouetteConnect creates a 3D model of the wound.

Figures 3 and 4

The key components of Silhouette are:

- SilhouetteStar™ point-of-care camera and 3D capture device;
- SilhouetteConnect™ software, which creates a 3D model of the wound (Figure 4), based on the data acquired by SilhouetteStar, derives accurate area, perimeter, depth and volume measurements from the model, and records standardized notes. This runs on a Windows device (tablet, laptop, workstation);
- SilhouetteCentral™, a secure Internet-based database that stores and consolidates the information obtained from the organization's SilhouetteStar + SilhouetteConnect devices, sharing data with the EMR (Figure 5).

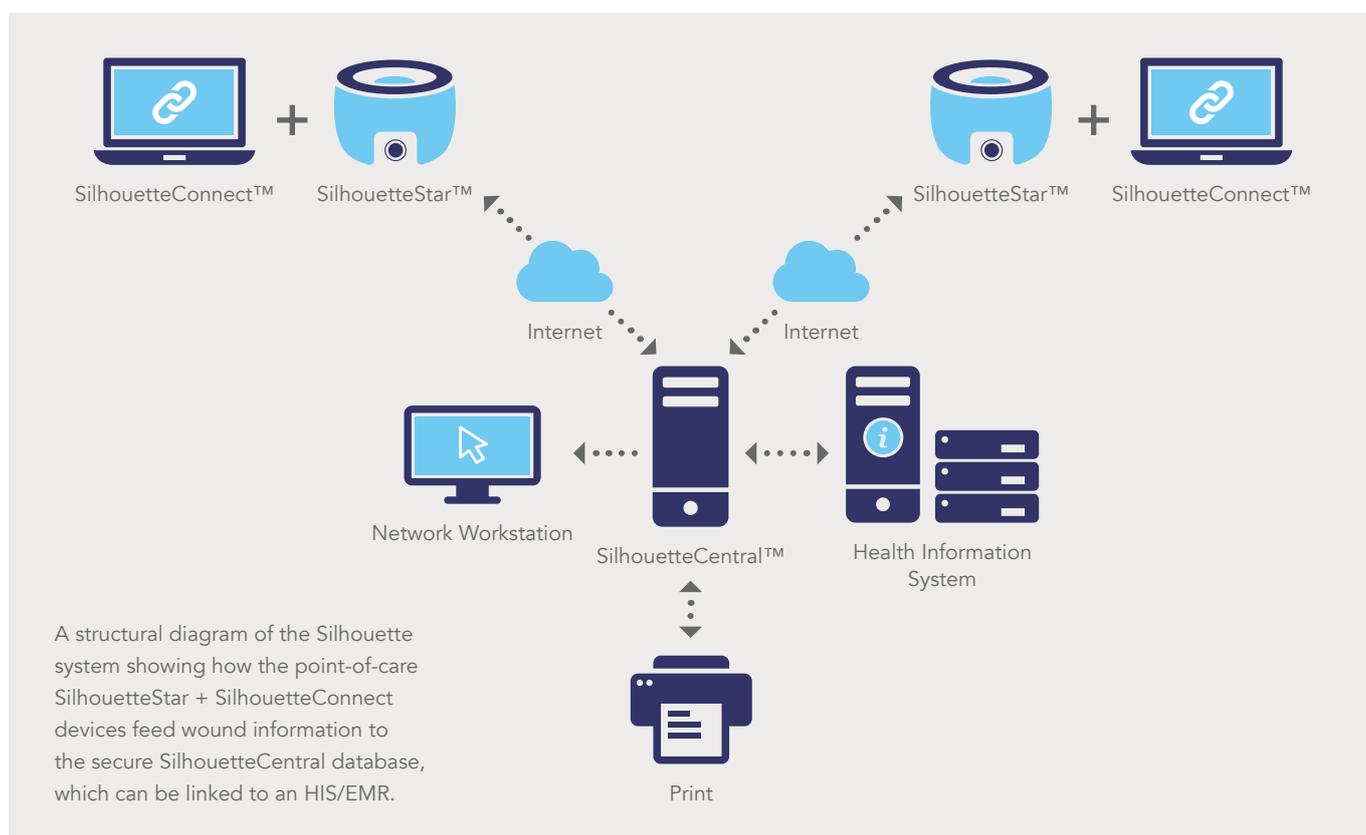


Figure 5

Accurate Measurement and Precise Healing Trends

Silhouette enables clinicians to capture accurate and precise measurements and derive reliable healing trends. A recent study found that any single Silhouette-derived measurement is likely to be within approximately 2% for area, 1% for perimeter, 5% for average depth and 5% for volume³⁹ (95% confidence interval). Inter- and intra-rater variability is extremely low – <1% for area and perimeter, and <2% for average depth and volume. This indicates that repeated measurements over time, even by non-specialist assessors, will detect small differences as a wound changes in size and dimensions. The healing trends presented are statistically meaningful (Figure 6).

Silhouette therefore meets the requirements as previously defined for a quality wound measurement method.⁴⁰

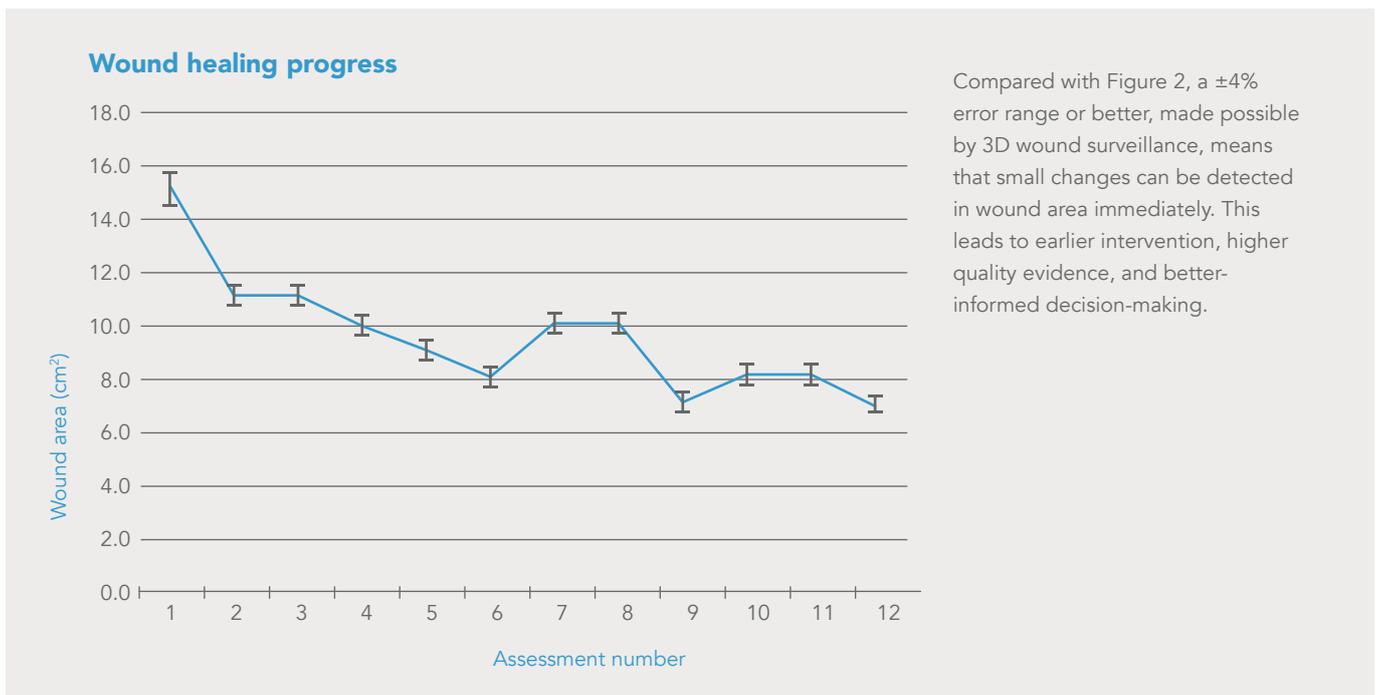


Figure 6

Wound Imaging

Silhouette addresses typical wound image management issues, producing high quality images at the point-of-care. The SilhouetteStar device has no user-adjustable settings – the camera has its own light source, and the laser lines position the camera for optimum focus and composition. There is only one moving part – the button which captures the wound image.

Silhouette assessments are recorded directly into the patient record. Images are not stored on the camera because image data is transferred in real-time to the SilhouetteConnect software. The wound photographs and measurement information are displayed together so the practitioner, or any authorized stakeholder logged in remotely, can compare the image with healing trends and other clinical information.

Documentation

Silhouette provides reliable documentation for reimbursement, defense and audit purposes.

At the point of care, customized wound notes fields in Silhouette enable practitioners to record standardized and free text documentation about the wound and the patient (Figure 7). These are exported into Wound Assessment Reports combining measurements, graphs

displaying the latest healing trends, images, and documentation. Upon synchronization, this data is transferred to SilhouetteCentral via an Internet connection, enabling other authorized stakeholders to view the assessment information. Here, reports can be generated based on aggregated patient data. Using this facility, clinical managers can, for instance, track whether assessments are occurring as often as required, identify outliers and review wound outcomes metrics. If SilhouetteCentral is integrated to the EMR, the wound information can also be transferred here automatically.



Figure 7a



Figure 7b

Figures 7a and 7b: Examples of SilhouetteConnect wound documentation, which is entered directly into the patient record.

Process Improvement

Silhouette addresses the process-related challenges described in Part One of this paper.

With Silhouette, communication improves because all stakeholders can monitor wound assessments and healing trends remotely, review the images and measurements of the wound, review the assessment practice of others, and obtain second opinions and consensus on diagnosis and treatment decisions.

Wound specialists can extend their reach using Silhouette, as it enables them to gather the information they need from non-specialists at the point-of-care, supervise and review these assessments, and focus their efforts on outliers and urgent cases. Wound specialists can improve the assessment capability of non-specialists using Silhouette information for feedback and training.

Silhouette has the ability to record wound treatment decisions and link this information to wound stage and healing progress. This means facilities can monitor the relationship between treatments, wound healing progress and other factors, and clinicians can justify the use of more expensive treatments if necessary.

Silhouette gives organizations oversight of the entire wound care effort. Clinical managers can use aggregate reporting to review important trends, key areas of focus and wound outcomes metrics.

They can choose how prescriptive their Silhouette assessment processes will be. If strict protocols are required, Silhouette offers a "protocol engine" with a configurable structured workflow.

If there is an adverse event such as a suspected hospital-acquired pressure ulcer, the whole "story" of the wound is provided in one place, avoiding the scramble for piecemeal documentation when a particular wound outcome is under scrutiny.

Privacy, Safety, Data Security and Compliance

Silhouette mitigates risks associated with the handling of patient information.

Because images and assessment information are recorded directly in the patient record, the risk of error is minimized. Silhouette also supports a variety of protocols and functionality, including HL7 patient demographic information exchange, DICOM image transfer, DICOM Encapsulated PDF report creation and transfer, and data exchange via web service APIs. Silhouette is designed to support PHI, HIPAA and Health Information Technology for Economic and Clinical Health Act (HITECH) compliance.

The Silhouette system is compliant with all major accreditation marks. Regulatory clearance includes an FDA Class 1 approval (US), along with CE Mark (Europe), Health Canada – Therapeutic Products Directorate (Canada), TGA approval (Australia), Health Services Authority (Singapore) and WAND registration (New Zealand).

Does evidence-based wound surveillance improve outcomes for patients?

The link between a support tool like Silhouette – which offers no diagnostic or preventative capability – and improved patient outcomes, is not explicit. However, providers using the Silhouette system report that it contributes to better patient outcomes:

- Because Silhouette improves communication, decisions are better-informed – particularly in the quality of interaction between members of multidisciplinary teams;
- Because measurements are precise and trustworthy, practitioners can have confidence in the healing trends being displayed and intervene promptly;
- Because Silhouette enables real-time review, wound stagings and other diagnoses can be monitored and fast intervention made if stagings are incorrect. This reinforces the important role played by a WOC nurse in the overall solution;
- Silhouette information can be used to illustrate the status of the wound to patients, often motivating them to improve compliance. Silhouette also provides useful communication for families;
- Because the point of care assessment process is non-invasive and efficient, patients are more comfortable and infection risk is mitigated.

Summary

To date, the wound care community has been resigned to inaccurate measurement and complex, inconsistent processes that rely too much on the human factor to obtain evidence of quality care.

Electronic 3D wound measurement, imaging and documentation systems signal the advent of rigorous clinical decision support for wound care.

Jacqui Fletcher, Clinical Editor of Wounds UK, in reviewing the Silhouette system, concluded: 'Clinicians, managers and clinical commissioners will be interested in considering these systems as important tools to improve delivery, reporting of care, and outcomes for patients with wounds, in a range of care settings'.⁴¹

Systems like Silhouette free practitioners from the burden of documentation so they can provide best-practice wound care for patients. This not only leads to a better patient experience, it can also increase the likelihood of patient engagement and compliance.

With innovative wound surveillance, providers can better manage hospital-acquired pressure ulcers and other chronic wounds, and improve targeting of treatment. Defensive documentation is available at the fingertips. New opportunities such as wound telehealth can be explored.

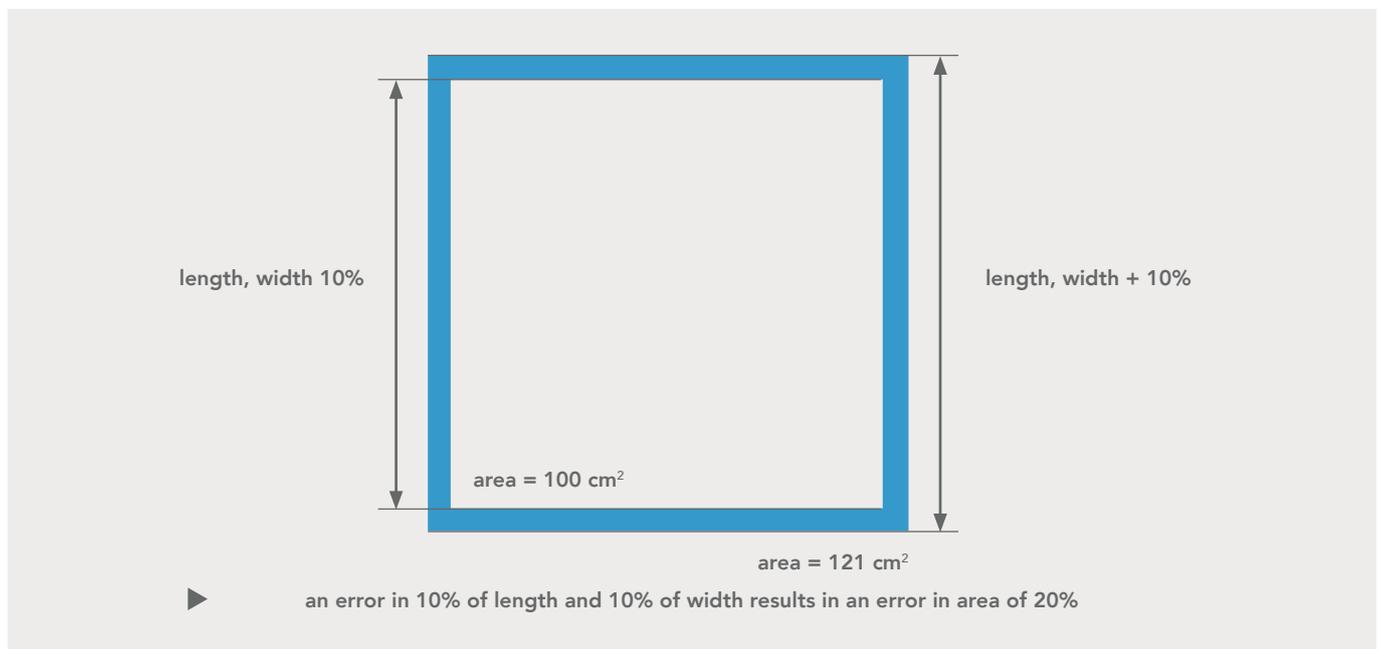
As wound care becomes more sophisticated, those holding providers to account such as payers and attorneys will increasingly be able to demand a higher standard of care, and the costs and consequences of not doing so will become greater.

3D-based systems like Silhouette give providers confidence in their ability to evidence a suitable standard of wound assessment, readying them for the accountable pay-for-performance environment.

To find out more, visit www.aranzmedical.com

Appendix One: How Errors Accumulate

Simple math demonstrates how errors can accumulate. Consider for example a simple shape like a square, with sides of 10 cm. The area of this square is 100 cm². With an error of just 10% in the length and width measurements (1 cm) in both directions, the area of this new square is 10 ± 1 cm by 10 ± 1 cm which is 81 – 121 cm². So by introducing 10% of error into a length and width measurement, there is an error of ±20% in area.



Appendix Two: Pro Forma Potential Savings

This table describes the sorts of savings that could be achieved with investment in a 3D wound surveillance solution like Silhouette. The assumptions on which these figures are based are as follows:

- This scenario is for a hypothetical 300-bed acute hospital system of which 10% of patients have wounds and 4.5% of all wounds are hospital acquired pressure ulcers.⁴²
- There are 75 nursing staff, including 2 wound specialists. Average length of stay (ALOS) is calculated at 5 days and \$8,030 is allocated per Hospital Acquired Pressure Ulcer for lost reimbursement that would have been paid by CMS if the wound was not hospital acquired.⁴³
- Nurses earn on average \$33 per hour.⁴⁴
- A bed day cost is calculated at \$1960.⁴⁵
- This hypothetical facility makes one out-of-court pressure ulcer settlement averaging \$279,000⁴⁶ every three years, settled on the basis that documentation does not provide adequate evidence of care, rather than there being poor quality care per se.
- This scenario is based on wound specialists using a wound surveillance system like Silhouette to critique the wound staging of non-specialists, and using feedback from the system to improve assessment capability across the hospital. It assumes that, with higher quality information, the hospital is able to make decisions that will halve the number of reportable hospital acquired pressure ulcers.
- The wound surveillance solution in this scenario has no diagnostic capability, but its clinical decision support enables practitioners to achieve more effective wound surveillance and to improve overall staging capability. This is because the precision in the data supports more effective intervention. Note that return on investment depends on the quality of the implementation and its alignment to the originating issue, and is likely to be part of a wider program of wound care.
- Pro forma savings are based on a hypothetical hospital and the above assumptions. Actual results will vary from case to case.

Indicator	Savings		
	Before 3D wound surveillance innovation	After innovation	Saving
Hours lost repeating inaccurate wound assessments per year (75 nurses)	2190 hours	91.25 hours	2098.75 hours
Reimbursement lost to hospital acquired pressure ulcers (HAPU) per year	\$2,637,947	\$1,348,284	\$1,289,663
Opportunity cost of bed days lost with incidence of HAPU per year	\$2,575,440	\$1,316,336	\$1,259,104
Total potential financial savings in a year			\$2,548,767

References

1. Gottrup F, Henneberg E, Trangbæk R, Bækmark N, Zøllner K, Sørensen J. Point prevalence of wounds and cost impact in the acute and community setting in Denmark. *J Wound Care*. August 2013; 22(8):413-4, 416, 418-22.
2. Chandan K. Sen et al. Human Skin Wounds: A Major and Snowballing Threat to Public Health and the Economy. *Wound Repair Regen*. Nov–Dec 2009; 17(6):763–771.
3. Susan Reinach-Lannan, BSOM. Mission possible: Getting Medicare reimbursement for wound care in acute-care settings. *Wound Care Advisor*. September/October 2012; 1(3).
4. Lyder, C, Wang, Y, Metersky, M, et al: Hospital-Acquired Pressure Ulcers, Results From the National Medicare Patient Safety Monitoring System Study. *J Am Geriatr Soc*. 2012;60(9):1603-1608.
5. F. Gottrup (chair). Outcomes in controlled and comparative studies on non-healing wounds: recommendations to improve the quality of evidence in wound management. *Journal of Wound Care* June 2010;19(6).
6. Flanagan M. Improving accuracy of wound measurement in clinical practice. *Ostomy Wound Management*. 2003 Oct;49(10):28-40.
7. Sheehan P, Jones P, Caselli A, Giurini JM, 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. *Diabetes Care*. 2003 Jun;26(6):1879-82.
8. Cardinal, M, Eisenbud, D, Armstrong, D. Wound shape geometry measurements correlate to eventual wound healing. *Wound Repair Regen*. 2009 (17)173–178.
9. Romanelli, M. MD, PhD: Wound assessment: Clinical and instrumental (presentation), Wound Healing Research Institute, Department of Dermatology, University of Pisa (2006).
10. Fette, A. A clinimetric analysis of wound measurement tools. *Worldwide Wounds*, January 2006. <http://www.worldwidewounds.com/2006/january/Fette/Clinimetric-Analysis-Wound-Measurement-Tools.html> Accessed 02/20/2014
11. Pillen H., Miller M, Thomas J et al. Assessment of wound healing: validity, reliability and sensitivity of available instruments. *Wound Practice and Research* November 2009;17(4):208.
12. Romanelli, M. Wound assessment.
13. Shaw, J, Bell, P. Wound Measurement in diabetic foot ulceration, from *Global Perspective on Diabetic Foot Ulcerations*”, edited by Thanh Dinh, ISBN 978-953-307-727-7 December, 2011: under CC BY 3.0 license
14. Mayrovitz, H. Documenting wound areas via digital photography: effect of camera angle on area accuracy, Presented to WOCN Society 40th Annual conference, June 2008.
15. Rennert, R, Golinko, M, Kaplan, D, et al. Standardization of wound photography using the wound electronic medical record. *Advances in Skin and Wound Care* 22(1).
16. Plassmann, P, Jones, T. MAVIS: a non-invasive instrument to measure area and volume of wounds. *Medical Engineering & Physics*, July 1998;20(5):332-338.
17. Richard, J, Daures, J, Parer-Richard, C, et al. Of Mice and Wounds: Reproducibility and Accuracy of a Novel Planimetry Program for Measuring Wound Area. *Wounds*. 2000;12(6).

18. Wendelken, M. et al: Wounds Measured From Digital Photographs Using Photodigital Planimetry Software – Validation and Rater Reliability. *Wounds*. 2011;23(9):267-275.
19. Koel, G. Reproducibility of current wound size surface measurement, Conference proceedings, EWMA, May 2008
20. May, W. E-Health and Technology: Empowering Consumers in a Simpler, More Cost Effective Health Care System. Before the Committee on Commerce, Science, and Transportation, Subcommittee on Science, Technology and Space, United States Senate. July 2001.
21. Shaw and Bell. Wound Measurement in Diabetic Foot Ulceration
22. Bicandi, C, Hawkins, M. When Bad Pressure Ulcer Documentation Happens to Good People. Presented at Idaho Health Care Association – Idaho Center for Assisted Living 46th Annual Convention & Tradeshow, January 2012.
23. The Health Foundation (editorial) <http://www.health.org.uk/news-and-events/newsletter/measuring-quality-a-complicated-task/> Accessed 02/20/2014
24. Hurd, T. Understanding the financial benefits of optimising wellbeing in patients living with a wound. *Wounds International*, June 2013;4(2).
25. Association for the Advancement of Wound Care (AAWC) Statement on Comprehensive Multidisciplinary Wound Care, 2005. <http://aawconline.org/wp-content/uploads/2011/07/AAWCMulti-disciplinarystatement.pdf>. Accessed 02/20/2014
26. 'Assessing Your Pressure Ulcer Knowledge' WoundSource, Dec 2012 K Zulkowski, <http://www.woundsource.com/blog/assessing-your-pressure-ulcer-knowledge>
27. Bolton, L, McNeese, P, Van Rijswijk, L. Wound healing outcomes using standardized assessment and care in clinical practice. *Journal Wound Ostomy Continence Nursing*. March 2004;31(2):65-71.
28. Khan, A. Pressure ulcer prevalence: hospital-wide monitoring and management. http://www.woundcarenurses.org/uploads/7/6/6/7/7667574/pressure_ulcer_prevalence.pptx (presentation). Accessed 02/20/2014
29. Drew P, Posnett J, Rusling L. The cost of care for a local population in England. *Int Wound J*. 2007;4(2):149-155.
30. Henderson, K. The 'rapid track' to improved wound outcomes. *Today's Wound Clinic*, October 2012: 24-25.
31. AHRO. Preventing pressure ulcers in hospitals: A toolkit for improving quality of care. <http://www.ahrq.gov/professionals/systems/long-term-care/resources/pressure-ulcers/pressureulcertoolkit/putoolkit.pdf>
32. Bader, D et al. *Pressure Ulcer Research: Current and Future Perspectives*, Springer. 2010.
33. Rosenfeld, J. Legal Perspectives: The Significance of Charting in Litigation Involving Pressure Sores. August 2012. <http://www.woundsource.com/blog/legal-perspectives-significance-charting-litigation-involving-pressure-sores>
34. Ibid.
35. National Quality Forum (NQF). Driving quality and performance measurement—a foundation for clinical decision support: A consensus report, Washington, DC: NQF; 2010.

36. Nixon, M, Rivett, T, Robinson, B. Assessment of accuracy and repeatability on wound models of a new hand-held, electronic wound measurement device Presented at the Symposium for Advanced Wound Care (SAWC), Atlanta, Georgia, 2012.
37. Hurd, T. Evaluating the costs and benefits of innovations in chronic wound care products and practices. Ostomy Wound Management, June 2013.
38. Nixon et al. Assessment of accuracy and repeatability.
39. Ibid.
40. Romanelli, M. Wound assessment.
41. Fletcher, J. The use of electronic data capture devices in wound care settings. Wounds UK 2012;8(4).
42. Lyder, C, Wang, Y, Metersky, M, et al: Hospital-Acquired Pressure Ulcers , Results From the National Medicare Patient Safety Monitoring System Study. J Am Geriatr Soc. 2012;60(9):1603-1608.
43. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html?redirect=/HospitalAcqCond/06_Hospital-Acquired_Conditions.asp
44. http://www.bls.gov/oes/current/oes_nat.htm#29-0000
45. <http://kff.org/other/state-indicator/expenses-per-inpatient-day/#table>
46. Bader, D et al. Pressure Ulcer Research: Current and Future Perspectives, Springer. 2010.

About the authors

Mark Nixon, MD, is Chief Medical Officer and co-founder of ARANZ Medical Ltd with a background in internal medicine and a BS in physics and mathematics. He is the author of *Laser Scanning for Three-Dimensional Imaging of the Body Surface* (1995), and is recipient of the SAWC 2009 Wounds Annual Young Investigators Award.

Christine Moore is Marketing Manager of ARANZ Medical Ltd. She has a background in health innovation marketing, particularly in medical devices and home health.

Terms of use

All rights reserved. No part of this report may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording, faxing, emailing, posting online or by any information storage and retrieval system, without written permission from the authors. All trademarks and brands referred to herein are the property of their respective owners.

Legal notices

The contents of this publication are for informational purposes only. While all attempts have been made to verify information provided in this publication, neither the authors nor the publisher assumes any responsibility for error, omissions or contrary interpretations of the subject matter contained herein.

The purchaser or reader of this publication assumes responsibility for the use of these materials and information. Adherence to all applicable laws and regulations, both referral and state and local, governing professional licensing, business practices, advertising and all other aspects of doing business in the United States or any other jurisdiction, is the sole responsibility of the purchaser or reader. The authors and publisher assume no responsibility or liability whatsoever on the behalf of any purchaser or reader of these materials. Any perceived slights of specific people or organizations are unintentional.

Document Number

2014-00050

aranZmedical