

Hand Hygiene Monitoring Goes High-Tech

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Editor's note: A roundtable from manufacturers in this segment is included at the end of this article.

In their quest to assess the prevalence and correlates of compliance and noncompliance with hand hygiene guidelines in hospital care, Vicki Erasmus, MSc, of the Department of Public Health at Erasmus University Medical Center in Rotterdam, The Netherlands, and colleagues determined that noncompliance with hand hygiene guidelines is a universal problem that calls for standardized measures for research and monitoring. After examining 96 empirical studies, Erasmus, et al. (2010) found an overall median compliance rate of 40 percent, with lower compliance rates in intensive care units (30 percent to 40 percent) than in other settings (50 percent to 60 percent), lower among physicians (32 percent) than among nurses (48 percent), and before (21 percent) rather than after (47 percent) patient contact.

Although hand hygiene has been the target of continuous scrutiny, study and awareness campaigns, Erasmus, et al. (2010) say that substantial and lasting effects on compliance rates has been minimal. As healthcare institutions continue to wrestle with this issue, manufacturers have stepped in to offer high-tech solutions to this perennial problem. Automated hand hygiene monitoring systems may offer a reliable method of measuring individual hand hygiene compliance, and Erasmus, et al. note, "Apart from observation and self-reporting, there are a number of other methods that may be employed as indicators of hand hygiene compliance, such as the amount of alcohol or soap used (i.e., 2 L/day), electronic monitoring (i.e., counter in alcohol dispenser), or the number of hospital-acquired infections. Each of these indirect measures has some advantages over direct observation by a trained observer—because some are much cheaper and easier to use—but they do not provide valid information on compliance. One study made a new step in this direction, however, by monitoring the entrance and exit of people from a patient's room and linking this to electronic monitoring of the alcohol-based hand rub dispenser. When someone enters without using the dispenser, this is registered as noncompliance. However, this method also has limitations, because only hand hygiene behavior when entering and exiting can be monitored, and it can only be applied to single-patient rooms."

Stewardson and Pittet (2011) answer the rhetorical question of "are new hand hygiene monitoring options needed?" by noting that although the World Health Organization (WHO)'s "My 5 Moments for Hand Hygiene" identifies opportunities that should equate to transmission of pathogens, "commonly cited limitations provide impetus to find alternative techniques, such as indirect monitoring using surrogates and automated monitoring... The potential advantages of automated systems include minimal consumption of resources once installed, provision of large data sets, and, potentially, less observation bias or Hawthorne effect. Conversely, major risks include the counterproductive temptation to monitor the wrong things because more convenient from a technical perspective, such as hand hygiene on entry/exit to wards or rooms, and a significant initial cost, which is particularly difficult in resource-limited settings. There is also the loss of an important opportunity for connection between the infection control team and HCWs, which provides an occasion for "bottom-up" promotion."

Stewardson and Pittet (2011) add, "Most healthcare workers (HCWs) know the risks posed by inadequate hand hygiene and want to improve. Yet we are notoriously poor at estimating our own performance, thus mandating the use of an alternate method. In our experience, HCWs want access to their own hand hygiene performance results. Although this may vary between countries and institutions, they dislike being observed without feedback. Moreover, to be effective, feedback should probably be immediate and individual, rather than only systematically reported compliance rates for an entire ward or department. For this purpose, automated monitoring systems able to identify specific categories of HCWs offer great benefits. And it is even better if the device is able to remind the healthcare worker to perform hand hygiene at the correct moment in a manner that does not become either excessively irritating or easily disregarded."

John M. Boyce, MD, of the Hospital of Saint Raphael in New Haven, Conn. and clinical professor of medicine at Yale University School of Medicine, emphasizes that monitoring hand hygiene compliance and providing healthcare workers with feedback regarding their performance is considered to be integral to a multidisciplinary hand hygiene improvement program. However, he adds that observational surveys conducted by trained personnel -- once considered to be the "gold standard" method for establishing compliance rates -- have their shortcomings. Instead, monitoring hand hygiene product consumption and electronic hand hygiene monitoring systems show some promise in increased hand hygiene compliance rates. Boyce (2011) notes that "Although there are many questions remaining about the practicality, accuracy, cost, and long-term impact of electronic monitoring systems on compliance rates, they appear to have considerable promise for improving our efforts to monitor and improve hand hygiene practices among healthcare workers."

Let's review current methods for hand hygiene monitoring.

1. Direct observation. Boyce (2011) says that "Direct observation of healthcare workers (HCWs) provides the most detailed information regarding hand hygiene and has the following advantages: It is currently the only method that can detect whether HCWs have performed hand hygiene during all types of opportunities with varying degrees of risk of contamination, including the five major indications for hand hygiene, in all clinical care settings and in facilities with varying levels of resources. It is the only strategy that can provide detailed information about hand hygiene technique, such as the amount of time spent using an alcohol hand rub or a soap product, the extent to which all surfaces of the hands are covered, and hand hygiene frequency before or after glove use. It is one of the few approaches that can provide compliance rates for HCWs of different types and levels of seniority and can identify specific situations that require further education of HCWs. However, direct observational surveys have several limitations, including the fact that they are time-consuming and costly. They provide information about a very low percentage (less than 1 percent to 3 percent) of all hand hygiene opportunities occurring in healthcare settings, which raises the question of the statistical validity of compliance rates generated. Direct observation of HCWs may affect their behavior and result in spuriously high compliance rates due to the Hawthorne effect ... Observational surveys are not performed in a standardized way, making realistic comparison of rates between facilities impossible. Observational surveys vary considerably among institutions with respect to the type of observers used, the level and type of training of the observers, the level of inter-rater reliability achieved (if assessed), the criteria for compliance versus noncompliance, the duration of observation periods, the level to which observations are covert or overt, and whether observations are made on all shifts or only during weekdays."

2. Self-reporting. Boyce (2011) notes that "Self-reporting of hand hygiene compliance by HCWs has been shown to be unreliable, because HCWs often tend to overestimate their level of compliance. As a result, this approach to determining hand hygiene compliance is not recommended as the sole or major method for establishing compliance rates."

3. Measuring product consumption. Boyce (2011) points to at least 13 studies that have evaluated the relationship between product consumption and observed compliance rates; 10 of these studies found that observed compliance rates increased in conjunction with increased use of alcohol handrub, while three studies did not find an association between product consumption and compliance rates. Boyce (2011) adds that monitoring product consumption has been used as a surrogate for hand hygiene compliance in a number of hand hygiene campaigns, and points to the system from McGuckin et al. who developed a system wherein the volume (mL) of alcohol hand rub and soap products used per patient-day on each nursing unit is calculated. This number is divided by 1.7 (the proposed average mL of product used per hand hygiene episode) to arrive at the estimated number of hand hygiene episodes/patient-day for the nursing unit. The resulting estimated hand hygiene rate is compared to benchmarks for ICUs and non-ICU wards. Facilities that forward their results to a dedicated website (<http://www.hhreports.com>) are provided with graphs of their hand hygiene rates over time versus proposed benchmarks. Product consumption can also be monitored by using electronic counting devices placed inside hand hygiene product dispensers that record each time a product dispenser is accessed (hand hygiene event)."

As Boyce (2011) notes, "Some of the advantages of electronic counting devices are that they can record vastly greater numbers of hand hygiene events than can be achieved by observational surveys while avoiding a Hawthorne effect, and they can provide specific data on the number of hand hygiene events occurring per patient-day. Such devices can also be used to study the effects of dispenser type, number, and location on the frequency of use to examine trends in hand hygiene frequency over time, by shift and by unit, and to evaluate the impact of interventions on hand hygiene activity."

Boyce (2011) cautions that "when considering the results obtained by either manual measurement of product usage or hand hygiene frequency rates based on electronic counting devices, it is important to keep in mind the limitations of these monitoring systems. These include the inability of either product consumption or electronic counting devices to establish the number of hand hygiene opportunities that are occurring, provide compliance rates, distinguish between product use by HCWs versus patients

and visitors, identify specific HCWs or type of HCW using the product(s), establish whether hand hygiene events are occurring at appropriate times (the WHO's "5 Moments"), evaluate hand hygiene technique, or identify specific issues that warrant further education of HCWs."

Electronic hand hygiene compliance monitoring systems are proliferating in the marketplace these days, and are differentiated by how they operate -- some include real-time locating systems (RTLS) for tracking healthcare workers' hand hygiene events, while others offer video monitoring of hand hygiene activity. A dedicated hand hygiene monitoring system can feature motion sensors that detect patient room entry and exit while sensors attached to sinks and hand rub dispensers detect hand hygiene events. Some systems feature electronic prompts such as audible beeps, flashing lights or prerecorded voice prompts if hand hygiene was not performed. Some systems provide an electronic device that functions as an alcohol handrub dispenser as well as a monitor of hand hygiene episodes on room entry and exit. With an RTLS, HCWs don badges that communicate wirelessly with dispensers and sensors located throughout the healthcare institution, and the wireless technologies used with such systems include Wi-Fi, ZigBee, ANT, active radio-frequency identification (RFID) using 433 or 915 MHz range frequencies, infrared, ultra-wideband or ultrasound. Hand hygiene compliance rates at room entry and room exit are estimated for individual HCWs and can be reported by nursing unit and time period, and can identify individuals with the lowest rates of compliance.

According to Boyce (2011), the challenge of electronic hand hygiene monitoring systems is that they are "currently not capable of detecting whether HCWs perform hand hygiene before an aseptic procedure (WHO's Moment 2) or after a potential body fluid exposure (WHO's Moment 3). However, several studies have found that WHO's Moments 1, 4 and 5, which would likely be captured by electronic systems, account for approximately 80 percent of all hand hygiene opportunities." Boyce (2011) adds that additional in-hospital trials are needed to determine how well compliance rates generated by these systems correlate with the WHO's 5 Moments. As Boyce (2011) notes, "It may be particularly important to establish how accurately detection of room entry reflects Moment 1, which requires hand hygiene before touching a patient (without touching anything outside the "patient zone" between the time they enter the room and when they touch the patient)."

While healthcare institutions may see electronic hand hygiene monitoring systems as a solid solution to hand hygiene compliance, healthcare workers may perceive these systems as intrusions and will want to know who will have access to their compliance data, how feedback will be provided, and whether compliance rates will be used in annual performance evaluations or in some other performance-related function that has the potential to be punitive in nature.

To gain better understanding of these perceptions, Katherine Ellingson, PhD, of the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention (CDC), and colleagues conducted a study at a university hospital, a Veterans Affairs hospital, and a community hospital in the Midwest. Eighty-nine healthcare workers participated in 10 focus groups whose participants reflected leadership personnel (such as chief executive officers, chief operations officers, chief medical officers, chief nursing officers, and leaders of various quality improvement departments or committees), mid-level management personnel (such as infection preventionists and unit managers), and frontline care-providing personnel (such as nurses and physicians). The researchers examined perceptions relating to awareness of hand hygiene oversight technologies; comfort level with wearable devices to monitor hand hygiene practices; situational thresholds for tolerance of monitoring; preferences for data feedback from automated hand hygiene oversight technologies; and perceptions of impact and sustainability.

Ellingson, et al. (2011) found that awareness of automated oversight technology for assessing hand hygiene practices varied by type of healthcare professional; 81 percent of leadership personnel were aware of automated hand hygiene oversight technology, which was significantly higher than awareness in frontline and mid-level groups (27 percent and 33 percent, respectively). According to the researchers, when asked to describe their comfort level with hypothetical wearable electronic devices that could measure entry and exit into patient rooms as well as hand hygiene activity, leadership personnel were significantly more comfortable compared with frontline and mid-level personnel. The most commonly cited factors influencing comfort were accuracy of data produced by the devices, lack of information about the technology, and the potential use of the data for punitive purposes. Frontline healthcare workers cited punitive use of the data as a concern more often than other professionals and were concerned about the implications of accuracy on individual hand hygiene audits. The researchers found that a majority of healthcare professionals would be open to wearing monitoring devices during an outbreak situation as long as the technology was used for identification of an outbreak source. And because many of the systems had capabilities for time-stamps and location data collection, some healthcare professionals expressed concerns about a "Big Brother" scenario that intrudes upon their privacy.

The researchers found differences among healthcare professionals when it came to deciding who should have access to the data generated by these systems. The majority of frontline care providers believed that they should be the primary recipients of the data while the majority of mid-level personnel felt that unit managers should receive the data. Most hospital leaders said that all healthcare professionals, patients and the public should have access to data.

As Ellingson, et al. (2011) emphasize, "Findings suggest that administrators considering implementation of automated hand hygiene oversight technologies should carefully consider the intended use of the data and to communicate this intended use to healthcare personnel before implementation. While these technologies have tremendous potential to overcome statistical barriers to valid hand hygiene adherence auditing by reducing sampling and observation biases, there are both real and perceived concerns about the ability of the technologies to accurately detect individual hand hygiene opportunities. Oversight technologies do, however, offer the potential of a statistical proxy for overall hand hygiene adherence.

Communicating this message to healthcare personnel will be vital to the acceptance of these technologies. Such recommendations reflect qualities characteristic of organizations that successfully implement HAI prevention initiatives, including the ability to cultivate a culture that values and understands clinical excellence, to facilitate strategic local communication before implementation for maximum ownership, and to overcome barriers by dealing directly with resistant staff." The researchers add, "As trends toward transparency and accountability continue with health reform and enhanced surveillance of HAIs, automated systems are likely to proliferate. All healthcare personnel types, but particularly frontline healthcare personnel, expressed concerns about privacy and punitive implications and suggested addressing these concerns with a clear communication strategy about the intended use of the data. Several participants advised that these automated oversight technologies be viewed as a mechanism for changing culture but cautioned hospitals to be cognizant of the perceived inaccuracies and the implications for punitive action against individuals."

While electronic hand hygiene monitoring systems will not replace observational surveys, they provide an adjunct to more traditional methods. As Boyce (2011) observes, "Because of the time required to conduct observational surveys and concerns regarding their accuracy, many facilities will continue to look for other methods to complement observational surveys." He says additional studies must address key issues such as the provision of denominator data necessary to accurately determine compliance rates, and manufacturers of these systems must conquer their limitations -- including short study periods, implementation on only several wards, failure to establish the sensitivity and specificity of electronically derived compliance rates, limited data on the systems' impact on healthcare-associated infection rates, and lack of cost-benefit or return on investment analysis. Boyce (2011) suggests that healthcare institutions take into consideration the elements of systems' design, functionality and acceptance by healthcare workers when considering purchasing such a system. He adds that more information is needed about the costs and ease of installation of the necessary infrastructure, the proportion of hand hygiene opportunities captured, ability to detect opportunities that occur during an episode of care when the patient is not in bed and when HCWs wear gloves, and the impact on compliance rates when HCWs entering the room do not touch the patient or the environment. As Boyce (2011) notes, "If further studies adequately address these issues, it seems likely that electronic hand hygiene monitoring systems will be adopted with increasing frequency in facilities with adequate resources."

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Manufacturer Roundtable

1. What is the name of your system?

BioVigil: BIOVIGIL Hand Hygiene System

HandGiene: HandGiene HHMS™ (Hand Hygiene Monitoring System)

HyGreen: HyGreen Hand Hygiene Reminding and Recording System

Proventix: nGage™

UltraClenz: Patient Safeguard System (PSS)

2. What are the components of your system?

BioVigil: There are three components of our system: The Base Station, the Badge, and the Room Sensor.

HandGiene: The components that make up the HandGiene HHMS™ include RFID – enabled dispensers and stand-alone readers, RFID badges, web-based Compliance Monitoring Software and a variety of FDA approved soap and sanitizer formulations.

HyGreen: A handwash sensor, bed monitor, badge, HyMarks software.

Proventix: The system consists of four components: (1) radio frequency identification (RFID) badges worn by healthcare workers; (2) Communication Units (CUs) located above the soap or alcohol dispenser which detect the healthcare worker's presence and tracks the hand hygiene event (or other mechanical or electrical device engagement). The CU displays important professional, performance and user-identified content through an active two-way communication display (LCD screen); (3) a wireless bridge unit that communicates messages between the nGage central server and CU; and (4) the nGage server that collects data for review. The system is built on an open architecture that allows for additional functionality through (5) active and passive RFID technology, including but not limited to (6) temperature monitoring, (7) asset tracking (active and passive RFID), (8) work flow reports (hourly nurse rounding reports for the prevention of slips and falls, housekeeping and security) and (9) monitoring of head-height angle of patients with a ventilator for the prevention of ventilator-associated pneumonia.

UltraClenz: The PSS system has several components:

- A manual or touch-free soap or sanitizer dispenser – UltraClenz's ProClenz dispensers are equipped with a monitoring interface for ease of installation. The PSS system can be adapted to be used with all commercial wall mounted dispensers by simply attaching a retrofit switch to a dispenser.
 - A Caregiver Badge – An electronic badge worn by the Healthcare worker (HCW.) The Caregiver badge is designed to present the Caregiver's hand hygiene compliance status via a series of LED's. The badge will include an audible alert when the Caregiver is non-compliant. The Badge will also transmit its current status or change of status to the Bed or Dispenser Beacon it is interacting with. The beacon will then transmit the badge's hand hygiene compliance status to the Bentley™ system (UltraClenz's Proprietary Wireless Communication System) which in turn transmits to an offsite server for reporting.
 - A Dispenser Beacon – is mounted next to the manual or touch-free dispenser being monitored. It will set the Caregiver badge to the compliant state (green LED) when the dispenser is activated. Once activated, the Dispenser Beacon will transmit the event to the Bentley system and from there up to the offsite server for storage. The event will include the badge ID, the badge hand hygiene compliance status, the dispenser ID, and a date and time stamp.
 - A Bed Beacon and Antenna – A Bed Beacon is a device mounted on or next to a patient's bed or chair that will define the proximity boundary of the patient. When a HCW approaches a patient or enters the proximity boundary, the Bed Beacon will trigger a patient contact event and will transmit the event through the Bentley system and up to the offsite server. The event will include the badge id number, the badge hand hygiene compliance status, the bed ID number and a date and time stamp. The Bed Beacon will also change the badge hand hygiene compliance status, to yellow (LED) for a first contact or red (LED) for a non-compliant contact event.
 - Bentley – A wireless network that retrieves data from the Dispenser Beacons, and Bed Beacons and transmits the data to the offsite server for data analysis and reporting.
- Components include:
- The Gateway-which gathers data from beacons and hubs and prepares information for transfer to the cellular modem and up to the offsite server.
 - Hub – acts as a repeater for the Bentley wireless network- It relays packets of information to the Gateway if the Gateway is out of range of a beacon.
 - Cellular Modem-provides a wireless connection between the Gateway and the offsite server.

3. Does your system use RFID or WiFi? Are there issues with interference of the RFID signal caused by other electronic equipment?

BioVigil: We do not use RFID technology but we could link to such technology. Our system utilizes a low-power RF communication protocol and a mesh network.

HandGiene: The HandGiene HHMS™ uses both RFID and Wi-Fi. There has been no interference of the RFID signal experienced.

HyGreen: No.

Proventix: nGage utilizes wireless infrastructure and active and passive RFID technology. nGage can co-exist with many other wireless networking standards given the correct setup. Facility testing has not identified interference with medical devices or other technology. The system is FCC, IC and UL certified.

UltraClenz: PSS does not use RFID or WiFi. Badge and beacon communications are proprietary, secure and very robust in noisy RF and RFID environments. The proprietary Bentley wireless network was specifically designed so the use of WiFi could be avoided. This allows the PSS to be installed in a health care facility without the need to interact with the facility's IT or communications infrastructure.

4. How does your system work?

BioVigil: The Room Sensor is a small unit that mounts at the doorway of any monitored area. Working with the BIOVIGIL Badge, the Room Sensor identifies when a healthcare worker enters or exits a room. The healthcare worker's Badge flashes red and green and emits a reminder tone, prompting the worker to sanitize his or her hands. Any alcohol-based sanitizer can be used, from any type of dispenser. The healthcare worker presents his or her hands to the Badge. A green light means clean. The BIOVIGIL Badge is small, lightweight and unobtrusive. Using a low power, ZigBee protocol, infrared receiver and a metal-oxide alcohol sensor, it works with the other BIOVIGIL components to detect and ensure compliance. The Base Station is a small appliance that automatically connects with the BIOVIGIL Badges that are within its range to offload compliance data and push updates and other instructions to the Badge.

HandGiene: The HandGiene HHMS™ monitors the movements of covered staff and employees as they move about the facility, in and out of patient rooms, patient treatment areas or the bathroom. Our HHMS™ records all instances of compliance or non-compliance with the facility's established hand hygiene protocols and provides real-time feedback, compliance recording and report functions. Monitoring occurs down to bed level. The HandGiene HHMS™ utilizes real-time web-based compliance monitoring software that provides a wide range of user customizable report and analysis functions.

HyGreen: The HyGreen system reminds healthcare workers to wash their hands. After cleaning their hands with soaps or gel, healthcare workers place them under the HyGreen sensor that sends a wireless "all clean" message to a badge worn by the healthcare worker. A wireless monitor above the patient bed searches for the message. If it's absent, the badge vibrates, reminding the healthcare worker to wash. All interactions are recorded in the HyMarks database in real-time.

Proventix: The nGage system is a point-of-care compliance monitoring system that motivates healthcare workers to follow hand hygiene standards set by healthcare regulatory agencies. With nGage, the healthcare worker, while washing his or her hands, receives professional, performance and user-identified content through an intuitive and interactive display located above the dispenser. Communication Units are installed in each patient room in close proximity to the soap or alcohol dispenser and in hallways next to sanitizer dispensers. As a healthcare worker wearing an RFID badge enters a room, the Communication Unit detects the presence of the RFID Tag through a secure wireless network and the system records whether or not the tagged healthcare worker had the opportunity to perform a cleansing event. nGage not only measures the number of times a specific wearer of the Tag cleanses, but also knows how many opportunities there were to cleanse. The data is recorded on a central server via a secure wireless network.

UltraClenz: PSS was designed to protect the patient. All HCWs are assigned a Caregiver Badge. After the HCW washes or sanitizes their hands, the Dispenser Beacon will send a signal to turn their Badge green and send the data to the Bentley System including the location of the dispenser that was used, the date and time stamp of the dispense event, and who activated the dispenser. When the Caregiver approaches a bed, the Bed Beacon will identify the HCW and send a signal to the Caregiver badge to turn the badge to the yellow cautionary state. The Caregiver will remain in a yellow state until one of the following four events occur:

- If the caregiver walks away from the patient bed, and returns (re-contacts) after 1 minute, the badge will turn red. This will be a non-compliant event for not washing after leaving a patient and not washing before re-contact.
- If the caregiver walks away from the patient bed, the Badge will time out within 5 minutes and automatically turn red. This will be a non-compliant event for not washing after patient contact.
- If the caregiver walks away and approaches a second patient area before washing, the patient Bed Beacon will turn the Badge to red non-compliant state, warning the employee that they are out of compliance and to wash their hands immediately.
- If a caregiver leaves a patient area and sanitizes their hands, the Dispenser Beacon will record the event and change the Badge status from the yellow cautionary state to green.

5. What have been the results of real-world testing and/or use in hospitals? Provide references to studies.

BioVigil: A study, published in and directly excerpted from: *Journal of Hospital Infection* 76 (2010) 354–372: The setting was a 35-bedded inpatient orthopedics ward, VCU Medical Center. In the first study phase, 1646 hand hygiene opportunities (HHO) for all healthcare workers were observed [using direct observation and no BIOVIGIL Badge] with an overall compliance of 66%. In the second phase, 6831 electronic observations were made [this time using the Badge] and overall compliance was 93%. Segmented regression analysis revealed that immediately following the intervention, hand hygiene compliance increased by 23%. In phase 2, individual compliance ranged from 72% to 100% with a median compliance of 92%, and a mean compliance of 91%. Nearly half (47%) of the nurses had compliance rates of 95%. Compliance on room entry was 90% and on room exit 94%. Twelve felt that the alcohol sensor badge improved their compliance; one felt it had no effect; and one felt that it did not improve compliance. Ten respondents felt that all healthcare workers should wear the Badge.

HandGiene: The HandGiene HHMS™ has been beta tested in multiple facilities, however the results of these beta tests have not yet been published.

HyGreen: Miami Children's Hospital in Miami has maintained a hand hygiene compliance rate in the high 90s. They also did a six-month study that was presented at SHEA 2012 showing an 89% reduction in infections with HyGreen being their only change in practice.

Proventix: At the seven-month mark of an installation with Princeton Baptist Medical Center of Birmingham, Ala., healthcare-associated infections (HAIs) decreased by 22.0 percent overall on the unit as compared to the same months during the previous year. The number of patient admissions was accounted for during this study with very little difference in total admits to the pilot unit (2,602 versus 2,652) over the seven months, with only slight month-to-month variation. The cost studies for the hospital over the seven-month period on just 2,652 patient admissions reflected a decrease of 159 patient days and reduced hospital net losses of over \$133,386. At the six-month mark of another pilot unit consisting of 21 beds at Princeton, HAIs decreased by 35.1 percent as compared to the same months during the previous year, reflecting a decrease of 239 patient days and reduced hospital net losses of over \$200,079. The system was also validated by the University of Chicago Medical Center and the University of Maryland School of Medicine which also conducted their own study looking at the accuracy of an automated hand hygiene monitoring solution.

UltraClenz: The PSS system components have undergone the successful completion of several beta tests. We expect the successful completion of the remaining beta tests during the first quarter of 2012 with a clinical trial to follow shortly thereafter.

6. Does your system also include product-usage monitoring in any way?

BioVigil: The BIOVIGIL system does not measure volumetric usage of soaps or sanitizers. We measure whether a healthcare worker has used a sufficient amount of hand sanitizer to meet the sensing requirements.

HandGiene: The HandGiene HHMS™ monitors the volume of product used and instantly notifies appropriate staff when a particular dispenser is running low on soap or sanitizer. Should that dispenser run out of soap or sanitizer, a constant signal is sent for it to be refilled as the dispenser itself makes user customizable audio and/or visual alerts. The HandGiene HHMS™ compliance software allows administrators to produce reports focused on soap and sanitizer usage. These reports can further differentiate between specific types of products that were dispensed, including soap or sanitizer; with or without alcohol; liquid, gel or foam.

HyGreen: No.

Proventix: nGage monitors the number of dispenses that occur at each soap or sanitizer dispenser. In addition, Proventix can power touch less auto dispensers, allowing them to become battery free with a patent pending technology. This technology incorporates dispenser solution level reporting that notifies environmental services staff when solution needs to be replaced, saving time and avoiding waste of soap and sanitizer.

UltraClenz: The PSS system has the capability to monitor usage by counting dispense events and estimating low chemical volume levels.

7. What are the disadvantages to traditional hand hygiene observation and monitoring and why does technology provide a better solution to hand hygiene compliance?

BioVigil: Truthfully, there is no comparison between the BIOVIGIL system and observation. Observation does not produce consistently accurate results – it is subject to human error and results can be subjective in nature. Beyond that, it is costly, time consuming and labor intensive. There is a need for a solution that can capture compliance accurately, provide feedback and record data for use by supervisors and administrators. Put simply, nothing can produce 99.9 percent accuracy like BIOVIGIL can. A solution to the spread of HAIs cannot tolerate false positives and guesswork.

HandGiene: Traditional hand hygiene observation and monitoring is limited in a myriad of ways specifically related to the methods used, areas covered, time of the day, etc. It is very infrequently conducted 24/7/365 and almost never facility wide at all times. Lastly, the opportunity for human bias and the possibility for compilation errors exist and have to be considered. The HandGiene HHMS™ operates every day, all day and is not affected by interpersonal relationships. It monitors everyone in the same manner and holds everyone accountable to the same requirements as determined by the administration. Further all monitoring is done without any HIPPA concerns while providing monitoring down to the bed level.

HyGreen: Many facilities gauge their hand hygiene through observation or “secret shopper” programs. Many infection preventionists have said their secret shopper programs are reporting high compliance numbers when they know that is not true. You can’t watch every interaction and human bias is always a contributing factor. A recent Japanese study really brings this point home. This study showed that typical observation techniques – meaning a secret shopper with a clip board – reported a 77 percent compliance rate. Unbeknownst to the staff and the secret shopper, and done at the same time, 24/7 direct observation was done via web cam. And it showed that compliance was actually 22.5 percent. After this, they told the staff that they were being observed by a web cam, and the compliance rate only went up to 33.8 percent. [Reference: H Kunishima, K Tokuda, M Meguro, T Kobayashi, J Chiba, T Aoyagi, M Hatta, M Kitagawa, Y Honda and M Kaku. Assessment of hand hygiene adherence using a web camera. Presentation at the International Conference on Prevention & Infection Control (ICPIC). BMC Proceedings 2011, 5 (Supplement 6):P104doi:10.1186/1753-6561-5-S6-P104.] So if secret shoppers don’t work, and 24/7 web cam monitoring doesn’t work – what does? We believe and are seeing in our installations that reminding is the key. People get busy and they forget to wash. Having the reminder system helps healthcare workers to wash every time.

Proventix: Current hand hygiene compliance methods, such as periodic surveillance, self-reporting, and aggregate volume measurements, are often inaccurate. Healthcare workers often overestimate the frequency and quality of their hand washing, making self-reported practice an inaccurate way to measure hand hygiene compliance. Traditional hand hygiene observation and monitoring practices are inaccurate because these methods lack the ability to track and measure compliance across a hospital. Periodic surveillance only captures a fraction of the hand hygiene events performed and cannot provide an accurate compliance number. Technology provides a better solution because it is completely objective in its measuring functionality and capability. The nGage system also accurately measures hand hygiene events on a continual, around-the-clock basis and provides real-time feedback to healthcare workers, which traditional methods are unable to accomplish. Technologies like nGage that are expandable provide multi-functional capabilities and can be leveraged to create operational efficiencies.

UltraClenz: The basic disadvantage to traditional monitoring is that HCWs are often aware they are being observed and therefore make an extra effort to do the proper washing during the observation period. This bias can create the Hawthorne Effect and can result in inaccurate data. When HCWs are not being observed their behavior reverts back to pre-observation behaviors. With a technology system, hygiene activity can be monitored constantly 24 hours a day. The PSS system can give supervisors a real-time, 24-hours-a-day look at compliance. Additionally, PSS focuses primarily on patients and the HCW interaction with patients. With regular feedback and coaching, supervisors have a tool that can help increase their compliance rating and change HCW behavior. The system is also a tool for the HCW. By providing real-time feedback, the HCW is immediately made aware of non-compliant hand hygiene. This allows the HCW to “self-correct” which will ultimately lead to behavior modification. Even the product-usage systems have important disadvantages. Those systems generally show how much soap or sanitizer is being used but ignore the critical factor of when it is being used. Our system is patient centric and focuses on when the HCW washes in an attempt to be consistent with the Five Moments of Hand Hygiene established by the WHO.

8. How does your system contribute to standardized measuring instrument and standardized reporting?

BioVigil: The system is specifically designed to provide intervention and standardized reporting and audit data- generation capability. BIOVIGIL clients access their data via cloud-based apps with a range of analytics and reporting capabilities.

HandGiene: The HandGiene HHMS™ operates in a very simple manner that can readily be adjusted by a facility’s administration. All reports are user customizable and can be saved for later use. Everyone is held to the same standard, as the system in its monitoring activities does not differentiate by type of staff or their respective position within the facility. In the report functions, administrators can create, save and print reports based on the specific criteria created for their specific query.

HyGreen: Our HyMarks reporting system records all hand hygiene events in the hospital in real time. We even have a one-click Joint Commission report that can be generated. You can view by individual, floor, unit or hospital and get accurate numbers on true hand hygiene compliance.

Proventix: The nGage system captures all hand hygiene events and opportunities 24 hours a

day, seven days per week, and 365 days per year. Because there is no bias in technology, continual monitoring and consistent reporting allows the healthcare worker to know his/her hand hygiene compliance level. Researchers from the University Chicago Medical Center and the University of Maryland School of Medicine presented a poster in October 2011 at IDSA, "Validation of an Automated System for Monitoring Hand Hygiene Compliance."* Their study evaluated nGage™ to manual observations of caregiver hand hygiene behavior. Highlights of the team's conclusion:

- The monitoring system's accuracy for the detection of caregiver entry into and exit from patient care areas was 100 percent
- There was no interference with medical devices or other technology detected at either site

*Emily Landon Mawdsley MD, Heather M. Limper MPH, Lisa Pineles, Stephen G. Weber MD MSc, and Daniel Morgan MD. University of Maryland School of Medicine and University of Chicago Medical Center.

UltraClenz: The PSS system meets three out of the five WHO moments of hand hygiene including, before touching a patient, after touching a patient and after touching a patient surroundings. The PSS system has a number of basic reports that can report compliance based on date, badge number, room number or employee type. These reports can detail a chronological list of events including hygiene events, patient contacts and compliance status during the course of a day or shift.

9. How does your system provide validation for accuracy and reliability overall?

BioVigil: Each Badge is assigned to an individual and is 99 percent-plus reliable at detecting zone entries and exits and compliance with hygiene protocol via direct sensing.

HandGiene: The HandGiene HHMS™ is fully integrated transmitting all data in real-time. Each hand hygiene opportunity and the compliance or non-compliance is recorded and verified in real-time. The RFID tag worn by monitored individuals is an active RFID tag, which transmits a signal that can be read through multiple layers of clothing by the stand-alone readers and the soap or sanitizer dispensers. Every effort was made during the development of the HandGiene HHMS™ to eliminate opportunities for monitored individuals to "fool" the system or for false readings to occur. In fact should any dispenser run out of soap or sanitizer, a constant signal is sent in real-time and email and/or text alerts are sent to the responsible parties to refill the dispenser. Anyone who is read by that dispenser as trying to dispense soap or sanitizer while the dispenser was empty does not get credit for a compliant hand hygiene event.

NyGreen: We test our system constantly. And Miami Children's hospital also tested the system independently and found it extremely accurate. This data was also presented at SHEA 2012.

Proventix: The system has an inherent ability for validation of accuracy and reliability by way of the display on the control unit (CU). Because the healthcare worker is badged, the system captures the person's name upon each hand cleansing opportunity as well as each actual event. Upon dispensing soap or sanitizer, the healthcare worker sees his/her name appear on the display of the CU. During training of the system, the healthcare worker is coached to watch for his/her name to show up on the CU as confirmation that the system has captured the event appropriately.

UltraClenz: The PSS system can be validated through the traditional means of observation. For example, sending an observer to observe HCW's and comparing these observations to data recorded in the PSS. The PSS system is not capable of auditing itself. However, it will reduce the number of physical observations typically done. Additionally, every time a HCW comes in contact with a patient, PSS records the event. The hand hygiene status of the HCW is also recorded. For the first time, UltraClenz has developed a system that can validate both the numerator (HCW hand hygiene) and the denominator (patient interaction).

10. How does your system handle limitations such as capturing hand hygiene opportunities and behavior beyond entering and exiting/situational context of hand hygiene opportunities, and multiple-patient rooms?

BioVigil: The system is capable of creating control zones within a room to detect multiple hand hygiene events within the same room. The system is also configured to dynamically set the context of any control zone via a mesh network to allow administrators to require different hygiene protocol in different zones. For example, the context can be dynamically adjusted to drive a more stringent protocol for specific behavior in a high-risk patient's room or control zone vs. a standard room. Or when an HAI is detected in an area, protocol can also be dynamically modified to increase awareness and decrease risk of transmission.

HandGiene: The HandGiene HHMS™ provides monitoring to the bed level so it is not limited to just entering and exiting a patient room or treatment area. Through the use of multiple stand-alone readers in a multiple-patient room staff interaction with each patient and compliance with requisite hand hygiene protocol in these varied situations is properly and efficiently handled.

HyGreen: We excel at multi-patient rooms. Each bed would have a bed monitor over it creating its own zone of protection around that patient bed. Therefore, if you washed your hands and went to the

first bed – got your compliant hand wash and then moved to the second bed without washing – the bed monitor over the second bed knows you haven't washed your hands. It will give you vibration to remind you to go and wash. Our system is unique in this – as it's the only system that goes to the bed level and can give you such a level of detail.

Proventix: 24/7 monitoring allows for significant population-based analysis and understanding of operational requirements. Understanding is the first step to developing compliance models that take situational context into consideration. nGage does not modify workflow but simply measures events and compels compliance by providing value during the hand hygiene event.

UltraClenz: The PSS system will track not only hygiene events but patient contacts as well. Once a HCW washes or sanitizes their hands, the badge will turn green. If the HCW approaches patient (A) the badge will be turned to yellow, a cautionary state. If the HCW approaches a second patient (B) either in the same room or a different room while in the yellow state, their badge will immediately turn red and report a non-compliant event. In addition to the above, if the patient leaves patient A for more than 5 minutes, the HCW's badge will turn red to a non-compliant state.

11. If your system requires the wearing of a badge/tag, is there an optimal location on the healthcare worker to improve accuracy?

BioVigil: The BIOVIGIL Badge can be worn on the upper torso, outward facing, and can be worn at least half a dozen other ways for convenience and integration with other badges and ID cards that the worker may already be carrying.

HandGiene: The RFID tag utilized as an integral part of the HandGiene HHMS™ is an active tag. It can be worn under multiple layers of clothing such as when clipped to a shirt pocket of a staff member who is also wearing a suit jacket and a lab coat. In fact the HandGiene tag can be in the monitored persons pocket and still be accurately read by the HandGiene HHMS™.

HyGreen: Each healthcare worker wears a HyGreen badge, optimally worn on the upper torso.

Proventix: For best results and accuracy, the optimal location to affix the badge is at breast-pocket height and on the side of the arm with which the healthcare worker normally dispenses.

UltraClenz: The HCW badge is an electronic radio frequency (RF) badge. The badge can be worn on a belt, pocket, on a lanyard around the neck or even inside a pocket. The badge does not rely on line of sight or IR to activate. The badge is very flexible with regards to where it can be worn.

12. How do you address the perception by healthcare workers that hand hygiene technology is intrusive and constitutes a "Big Brother" approach to monitoring compliance?

BioVigil: This is a challenge that we feel confident can be tackled by messaging. We like to cite a recent article in New York Times: Health that indicates a similar sentiment: "Changing the Message from "Wash Your Hands to Protect Yourself" to "Wash Your Hands to Protect Your Patients," the study found, could motivate some doctors and nurses to wash their hands more frequently. Indeed, there will always be naysayers, and that is to be expected, but if we emphasize the rationale behind the system, we are confident we can meet any negativity with logic: the patient is the reason behind this technology. Our system is designed to be minimally invasive and avoid interruptions to workflow. BIOVIGIL believes that the peace of mind the system brings to patients will significantly offset reservations of workers regarding intrusiveness and burden. The most important focus of our system is to provide real-time intervention to protect patients. The monitoring and tracking of compliance is a secondary benefit of the system.

HandGiene: The HandGiene HHMS™ was developed with input from healthcare professionals during multiple rounds of research. These results were integrated into the function of the HandGiene HHMS™. For example, the HandGiene HHMS™ has both visual and audio alerts to remind healthcare workers to comply with hand hygiene protocols. Proactive steps were taken to remove the patient from the function of being the "handwash police." All monitored individuals are given access to the web-based compliance software so they can review their own hand hygiene compliance rate and compare them to certain benchmarks, which are set by the administration. Further, the HandGiene HHMS™ does not require the monitored individual to add any additional steps to the hand hygiene protocol such as placing their hand under or next to something in order for the presence of alcohol to be detected.

HyGreen: The thing that healthcare workers really like about this system is that it's not a "gotcha" kind of system. It's there to help. We all know how busy healthcare workers are. It's inevitable that people forget. And that's where HyGreen really shines. It helps you help your patient by reminding you to wash before patient contact.

Proventix: The nGage system is a tool to increase the quality of care provided in hospitals. Nothing about the system is secretive or intrusive as the "Big Brother" comparison suggests. In fact, it is the

opposite. The system gives workers the ability to know their individual compliance and make improvements when necessary. Healthcare workers want to do a good job and know that hand hygiene is the best way to eliminate the spread of infections. However, healthcare workers often overestimate the frequency and quality of their handwashing, making self-reported practice an inaccurate way to measure hand hygiene compliance. nGage helps create improvement by sharing information with healthcare workers at the point of care without disrupting workflow. This information encourages healthcare workers to wash their hands. The system is a partner in achieving better patient outcomes and assuring the safety of patients, visitors and staff.

UltraClenz: We believe that HCWs care deeply about the safety and health of their patients and that they will look favorably upon any system that can improve patient outcomes. In that respect, we feel that we are partnering with the HCW to reduce infection. The PSS system does not monitor HCW private space or habits. PSS monitors when HCW's wash or sanitize their hands and their hygiene status when they come into contact with a patient under their care. Theoretically, if the HCW washed prior to coming into contact with patients and after contact with patients there would be a clean report. The PSS system is not meant to violate a HCW's private space but to remind them to perform proper hand hygiene prior to coming into contact with patients as required by their job to protect their patient's safety (and their own safety). The patient Safeguard System was designed to protect the patient. The HCW can also benefit from the system and is a secondary advantage of the system.

13. How do you help users address the potential punitive use of the data produced?

BioVigil: It is not BIOVIGIL's job to create policy. We provide highly secure, confidential and serialized (anonymous) data to clients. From there, the client can choose to punish, incentivize, etc, based on their own standards.

HandGiene: HandGiene helps users address the potential punitive use of collected data by making them active participants in the process. Each user can setup email and/or text alerts to let them know if their own compliance rate falls below a certain threshold set by that user. HandGiene believes that "Education is the Key, but Monitoring and Accountability is the Answer™". By making each user an active participant and giving them all open access to their own data, they are all equally empowered to self-monitor and take proactive steps before their supervisors or Infection Control administrators become involved.

HyGreen: We discuss this with hospitals and all have agreed that this is to be used as a reward system for employees who excel at hand hygiene and as a way to retrain individuals who are having issues.

Proventix: The nGage system compels healthcare workers to comply through behavioral modification. The goal is to change the process and to use the data produced as a guide to facilitate understanding of how hand hygiene can be improved. Compliance information is provided to each healthcare worker using the nGage screen to encourage self-improvement and appropriate education to create maximum results. Proventix trains and encourages managers to recognize high performing employees for their efforts and progress to encourage everyone to success.

UltraClenz: The intent of the PSS system is to be a real-time reminder for HCW to wash or sanitize their hands. The badge worn by the HCW is the primary reminder with a real-time report as the secondary means of a reminder. The compliance reports can be used by infection control to review compliance status with nurse managers. If data is collected, it should be reviewed and feedback given. What the user does with the data after review is up to the user. Data can be saved, archived or purged after feedback.

14. How do you educate users about the function of the system and to maximize its operation?

BioVigil: Implementation is comprised of: physical installation and training and immersion, where we educate wearers of the functions of the system and the importance of how our system can assist them in benefitting their patients and themselves.

HandGiene: The HandGiene HHMS™ uses web-based compliance software that every monitored user can access. Each user can actively monitor their own respective performance and compliance with the facility's protocols. Reports are easy to generate, save and share by email, printing or fax so that proactive discussions can occur, enhancing the staff and administrations' movement towards improved hand hygiene compliance rates.

HyGreen: We have a wonderful training program run by nurse clinical educators.

Proventix: The Proventix Clinical Team provides training to nurse managers and staff regarding the system, why it is in place, and how it should be used through training videos, educational materials, and in-person sessions. Proventix strongly encourages leadership from the highest levels within the organization, as this tends to promote and encourage end users to be supportive and accepting of the system. Proventix also encourages leadership to be judicious with the data that is generated to

prevent the data from being used in a punitive way.

UltraClenz: UltraClenz markets its system to full service manufacturers and distribution facilities. Our customers will determine the best way to train their customers and hospital staff. The system should be presented as a Patient Safeguard System.

15. What is the cost of your system?

BioVigil: BIOVIGIL has a Managed Service Model where clients pay a subscription price per badge per month. Price is based on duration of the contract and number of badges deployed. There are no capital acquisition costs for our system.

HandGiene: The HandGiene HHMS™ is a very reasonable all encompassing solution to the dilemma of monitoring the hand hygiene compliance of staff throughout a facility. The approximate cost of equipment for a private and semi-private patient room is \$2,000 and \$2,300, respectively. Firm pricing, including installation costs is determined after a site visit and evaluation. There is an initial software setup fee. After installation, the only on-going cost is for soap and sanitizer, which a transfer cost as the facility is already purchasing both soap and sanitizer, and the annual replacement of the RFID tags, which need to be replaced on a schedule based on projected battery life. There are no annual software fees, or maintenance fees or equipment charges. Once the HandGiene HHMS is installed the facility owns it. The projected ROI is six months or less for any installation of the HandGiene HHMS.

HyGreen: It varies by configuration. Our team goes in to determine how many bed monitors, badges and hand wash sensors are needed for that specific hospital's layout.

Proventix: Negotiated with specific healthcare system based on need.

UltraClenz: UltraClenz designed PSS from the ground up with its primary focus being to monitor hand hygiene compliance. One of the primary focuses behind PSS was cost. PSS costs a fraction of what is currently being distributed in the market.

16. How do you help infection preventionists make the business case for its purchase?

BioVigil: We believe, and emerging data shows, that technology-enabled hand hygiene systems will significantly reduce HAI incidence rates, resulting in major cost avoidance for hospitals ranging from \$20,000 to 50,000 per case. Further, the BIOVIGIL system frees up healthcare personnel who are tasked with tracking and auditing of hand hygiene resulting in direct cost reallocation. Thirdly, we believe as consumer awareness grows and anxiety surrounding HAIs increase, the BIOVIGIL system will provide a competitive advantage for hospitals in the consumer marketplace.

HandGiene: Governmental requirements and regulations and insurance company mandates, including Medicare/Medicaid has made a healthcare facility's utilization of some form of hand hygiene monitoring system a necessary reality. The facility-wide deployment of the HandGiene HHMS™ is a reasonable, justifiable business expenditure. Assuming a conservative cost of treating each HAI is \$30,000. Then the cost of one HAI covers the installation of the HandGiene HHMS in approximately 15 patient rooms. A 100-bed hospital has an estimated 210 HAIs/year at an approximate cost to treat of \$6.3 million non-reimbursed. This same facility could install the HandGiene HHMS for an approximate, exaggerated cost of less than \$500,000 including the installation of additional dispensers in all hallways, bathrooms, treatment areas, labs, etc. and food service areas and cafeterias. Assuming that the HandGiene HHMS only reduces the HAI rate by 50 percent, the facility still saves 3.15 million less the cost of the system or 2.6 million or an ROI of two to three months.

HyGreen: We talk to them about infection reduction, patient safety and also protecting healthcare workers from HAIs, too. We also talk about return on investment. At Miami Children's Hospital, their ROI was less than 60 days.

Proventix: nGage's hand hygiene monitoring is what sells infection control, but when Proventix demonstrates the system's flexibility to meet a variety of quality monitoring capabilities such as temperature monitoring, asset tracking and nurse rounding, nursing and quality managers want it too. nGage also appeals to information technology because the system's open architecture philosophy meets so many of their challenges. nGage reduces the manual tasks clinicians, physicians and administration perform so that they can focus on the business of improving patient care and outcomes. Financially, the nGage system has a demonstrable ROI. Typically, a 200-bed facility can have a cash neutral investment with the system by preventing slightly over two infections per month. To date, with installs across the country, nGage is proven to accomplish this financial threshold. We work with each of our clients and build a financial model on an institution-by-institution basis.

UltraClenz:

1. Low cost
2. Focuses on the patient and not on the HCW

3. Reduces the need for physical observation
4. Automates and streamlines data compilation analysis
5. Differentiates between type of healthcare worker
6. Lower infection rates
7. Lower cost of infections
8. Decrease in published infection rates
9. Marketing opportunities