Surveillance WHO guideline 'Global guidelines for the prevention of surgical site infection, second edition. 2018'1

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Surgical site infection surveillance: definitions, methods and impact

The surveillance of healthcare-associated infections (HAI) is one of the core components of an effective infection prevention and control (IPC) program (WHO, 2009A; Zingg, 2015). However, defining, detecting, reporting, and interpreting HAI, including surgical site infections (SSI), is challenging and requires expertise, time, and resource dedication.

Definitions of surveillance and SSI

Surveillance is defined as "the ongoing, systematic collection, analysis, interpretation and evaluation of health data closely integrated with the timely dissemination of these data to those who need it" (CDC, 1988).

There are many definitions of SSI and a systematic review identified as many as 41 different definitions (Bruce, 2001). However, only five were described as being standardized definitions created by multidisciplinary groups. More than one third of included studies used the Centers for Disease Control and Prevention (CDC) definitions, either 1988 or 1992 (Garner, 1988; Horan, 1992). While the authors of the review suggest that a single definition allows longitudinal analysis and benchmarking, they conclude by stating that "there is no single, objective gold standard test for surgical wound infection" (Bruce, 2001). Currently, many countries use the HAISSI protocol developed by the European Centre for Disease Prevention and Control (ECDC) (ECDC, 2012).

Aims of surveillance

The primary aim of surveillance is the collection of data on SSI rates in order to obtain a measure of the magnitude of the problem. These data must then be analyzed to identify and investigate trends, including a careful interpretation of results. Finally, surveillance data should guide the identification of improvement actions and evaluate the effectiveness of these interventions. In this context, the feedback of SSI rates to relevant stakeholders is important.

Should surveillance be conducted?

The positive impact of HAI surveillance was first described in the landmark study on the efficacy of a nosocomial IPC program conducted in the United States of America (USA) in the 1970s. In this trial, it was shown that an IPC program with both surveillance and control components could lower SSI rates significantly (Haley, 1980). Importantly, surveillance of SSI is part of the WHO safe surgery guidelines (WHO, 2009B). Many countries have introduced mandatory surveillance of HAI, including SSI, such as the United Kingdom and certain states in the USA, whereas other countries have voluntary-based surveillance, such as France, Germany, and Switzerland. However, there are considerable differences related to the length and type of surveillance (Wilson, 2012; NICE, 2011). Increasingly, national networks and "networks of networks" are being created, such as the CDC National Healthcare Safety

Network (NHSN), the ECDC HAI Surveillance Network (HAI-Net) and the International Nosocomial Infection Control Consortium (INICC).

By using standardized definitions of HAI and specifically SSI, these networks allow inter-hospital comparisons and benchmarking. An essential component of these surveillance networks is feedback to individual hospitals, as discussed below.

It has been postulated that a "surveillance effect" might occur, similar to the Hawthorne effect in clinical trials, that is, the simple fact of being conscious that one is being observed may independently lead to improved practices or improved adherence to guidelines (Gastmeier, 2009).

Another way in which a successful surveillance program may decrease SSI rates is that the feedback given to the institution may prompt investigation of why its rates are higher than the benchmark. Certain process indicators (if not already collected) may then identify the reason for "underperformance" and prompt local initiatives to improve performance on these indicators. There is conflicting evidence that conducting surveillance as part of a network has a positive impact on SSI rates (Table 1). Some studies report a successful reduction of SSI rates after participation in a surveillance network (Astagneau, 2009; Brandt, 2006; Geubbels, 2006; Haley, 1985; HPA, 2009; Manniën, 2008), while others report no effect (Staszewicz, 2014). However, there is an important methodological issue that could "dilute" the reduction in the time trend of SSI rates, which is the fact of adding smaller hospitals in a network without taking into account their year of participation in the network. This obstacle was overcome in an analysis of German data where hospitals were stratified by year of participation (Gastmeier, 2009) and in an analysis of Dutch (Geubbels, 2006) and Swiss (Staszewicz, 2014) data where SSI rates were stratified by surveillance time to operation in consecutive one-year periods using the first year of surveillance as a reference. The Dutch and German studies reported decreasing time trends of SSI rates after surveillance, whereas the Swiss study did not.

Table 1. Temporal trends of SSI rates after surveillance in selected networks (adapted from Astagneau, 2010)¹

 1 The study by Manniën, 2008 was not included in the WHO table. As it was mentioned in the text, the working group decided to add the data to Table 1.

Conversely, as shown in clinical trials, intensive surveillance may lead to the detection of higher SSI rates than under standard surveillance conditions. As an example, in a recent clinical trial comparing skin antiseptic agents for caesarean section, the SSI rate was 4.0% in one arm and 7.3% in the other (Tuuli, 2016). These rates seem higher than the most recently available data from the ECDC, which show an SSI rate of 2.9% (inter-country range: 0.4%-6.8%) (ECDC, 2013).

Establishing a surveillance system

According to the US Association for Professionals in Infection Control and Epidemiology (APIC), there is "no single or "right" method of surveillance design or implementation" (Lee, 2007). However, the

following minimal requirements for ensuring quality of surveillance have been identified by the Association (Lee, 2007):

- A written plan that states goals, objects and elements of surveillance process;
- Constant rigor of intensity of surveillance;
- Consistent elements of surveillance (for example, definitions, calculation methods);
- Adequate human resources (professionals trained in epidemiology);
- Informatic services, computer support;
- Evaluation methods.

For a surveillance program to be successful, there should be a method of data validation to ensure that data are accurate and reliable (Manniën, 2007), particularly for benchmarking purposes (Haustein, 2011).

Methods for conducting surveillance

In the field of SSI, most surveillance systems target colorectal surgery and total hip and knee arthroplasty. The most common outcome indicator is the cumulative SSI incidence (or SSI rate). Detecting SSI using prevalence methods is less reliable given the high proportion of SSIs that manifest after discharge.

For any given period, denominator data represent the total number of procedures within each category. The number of patients can be used also as the denominator, but it is less precise because more than one infection can occur in the same patient. Numerator data will be the number of SSIs in that same period. Demographic data (age, sex, timing and choice of antimicrobial prophylaxis, American Society of Anesthesiologists (ASA) score, duration of the operation and wound contamination class) are recorded for all patients, including the site of infection and type of SSI (superficial, deep, organ/space) for those with SSI. Linkage with microbiological data may also be useful.

The gold standard is prospective direct surveillance, although it is time- and labor-intensive and costly (Anderson, 2014). The CDC recommendations describe indirect methods of surveillance (sensitivity of 84-89%; specificity 99.8%) as a combination of:

- 1. Review of microbiology reports and patient medical records.
- 2. Surgeon and/or patient surveys.
- 3. Screening for readmission and/or return to the operating room.
- 4. Other information, such as coded diagnoses, coded procedures, operative reports or antimicrobials ordered.

The importance of post-discharge surveillance

It is estimated that a significant proportion of SSIs are detected following patient discharge. This proportion varies across settings and according to different definitions, but it has been estimated to be between 13% to 71% (Holtz, 1992). The fact that hospital length of stay has been steadily decreasing over the past decades has probably contributed to shifting the burden from inpatient to outpatient infections. Moreover, implant-associated infections may not become apparent until one year after the procedure. For this reason, many surveillance networks recommend the practice of post-discharge surveillance. There is no known gold standard procedure for post-discharge surveillance and a systematic review identified only seven reports of studies comparing different surveillance methods (Petherick, 2006). Due to variations in data collection and classification, as well as missing information regarding diagnostic criteria, no synthesis of post-discharge surveillance data

was possible. The authors concluded that more research is required regarding the measurement of SSI after hospital discharge.

There has been controversy regarding the CDC decision to shorten post-discharge surveillance to 90 days instead of one year after certain procedures (CDC, 2013). This change was aimed at simplifying post-discharge surveillance and reducing delayed feedback, but it has not been universally adopted as yet (ECDC, 2012). A report compared historical prospective SSI surveillance data from a USA network to the retrospective application of the updated CDC definitions (Dicks, 2014). The authors found that 9.6% of SSIs detected by the former definition went undetected with the new definitions; 28.8% of these undetected SSIs concerned hip and knee prostheses. The proportion of missed SSIs varied by procedure, but they were high for hip (8.8%) and knee prostheses (25.1%). Another report from the Dutch SSI surveillance network analyzed the influence of the duration and method of postdischarge surveillance on SSI rates in selected procedures (Koek, 2015). The proportion of missed SSIs was variable, but they were 6% and 14% for hip and knee prostheses, respectively. More importantly, the study showed that the updated CDC method of performing post-discharge surveillance was associated with a higher risk of not detecting a SSI when compared with the former method.

How to report surveillance data

Although most surveillance systems report SSI rates, there has been debate in the literature regarding the best choice of outcome indicator. Some authors argue that the incidence density of inhospital SSI is a more suitable choice of outcome indicator by taking into account different lengths of hospital stay and different post-discharge surveillance methods (Wilson, 2007). This indicator requires recording the date of patient discharge.

In order to adjust for variations in case-mix, it is recommended to present risk-adjusted SSI rates in addition to crude rates (O'Neill, 2009). The most commonly used method of risk adjustment is the NNIS risk index whose aim is to predict the occurrence of an SSI in a given patient (Culver, 1991). This risk index has been updated and includes procedure-specific factors that improve its predictive power, but it is not widely used (ECDC, 2012; Mu, 2011). Of note, collecting data for the NNIS risk index may be difficult in settings with limited resources where very limited information is reported in patient records. As an example, in a systematic review conducted by WHO, only 14 of 231 SSI surveillance studies from developing countries reported using the NNIS risk index (WHO unpublished data).

Some surveillance systems report standardized infection ratios, which is the ratio between the observed and the expected infection rates (Rioux, 2006; Gaynes, 2001). A ratio higher than 1.0 indicates that more SSIs occurred than were expected, whereas a ratio lower than 1.0 indicates the opposite (Gaynes, 2001). The simplest manner to calculate the expected number of SSIs is by multiplying the number of operations in each procedure category by the SSI rate and dividing by 100. This accounts for the case-mix and is therefore a risk-adjusted summary measure (Gaynes, 2001).

Other surveillance systems (UK, Switzerland) use a funnel plot to improve the precision of the estimates of SSI rates, which are dependent on the number of operations performed. SSI rates are plotted against the number of procedures for each hospital and 95% CIs are drawn. In this manner, outliers (hospitals with unusually high rates) can be easily identified (Spiegelhalter, 2005). *Difficulties associated with surveillance*

Active surveillance is a resource- and time- consuming activity. Constraints can be both in financial terms and/or in the availability of trained and dedicated staff. Surveillance data need validation and interpretation by supervising IPC professionals and/or epidemiologists. The correct collection of clinical data (preferably electronically) is essential for a successful surveillance system. Based on some interesting publications (Aiken, 2013), the WHO has developed an adapted approach to SSI

post-discharge surveillance by issuing pre-discharge instructions to the patient to allow him/her to recognize signs of infection and maintain follow-up through telephone calls. The presence of effective infection control programs and societies (local and national) is essential for introducing a sustainable surveillance system.

Use of surveillance for benchmarking

The use of HAI surveillance data, including SSIs, has been advocated for benchmarking purposes (Haustein, 2011). Benchmarking can be used for several purposes, including for the publication of "league tables" as in the UK and USA (Jarvis, 2003). In addition, it is also used in the USA as the basis for modifying hospital payments to facilities paid by Medicare (Anderson, 2014). There are advantages and disadvantages of benchmarking as there are important pitfalls that should be actively avoided. There is a possibility that surveillance systems with more intensive and sensitive surveillance methods that result in higher SSI rates may be unfairly penalized.

Even in the presence of uniform standardized definitions, several studies have shown that inter-rater agreement for SSI is rather low (Hedrick, 2015; Birgand, 2013; Wilson, 2004). One study evaluated inter-rater agreement by submitting 12 case-vignettes of suspected SSI to IPC physicians and surgeons from ten European countries (Birgand, 2013). It was found that there was poor agreement regarding SSI diagnosis and the type of SSI, with variations between and within countries. An analysis of data submitted from 11 countries to the ECDC HELICS (Hospitals in Europe for Infection Control through Surveillance) network showed that there was a substantial variation not only in terms of case-mix (as measured by the NNIS risk index score), but also in the reporting of SSI (highly variable inter-country proportions of superficial SSI ranging from 20-80%) and the length and intensity of postoperative follow-up (Wilson, 2007).

An audit of SSI surveillance methods in England showed that differences in data collection methods and data quality were associated with large differences in SSI rates (Tanner, 2013). What is striking is that even in the presence of mandatory surveillance with a clearly defined national protocol, a substantial proportion of responders (15%) used alternative definitions.

Conclusions

Ideally, surveillance of SSI should be an integral part of IPC programmes of health care organizations and priorities for public health agencies worldwide. However, caution must be exerted when interpreting SSI data, especially when making comparisons, due to a possible heterogeneity of definitions used, surveillance methods, risk stratification and reporting.

Further studies are needed to determine the most sensitive methods of diagnosing SSI, both for inpatients and as part of PDS, and the most efficient methods of collecting data. It is of the utmost importance to develop and test reliable adapted definitions and surveillance methods for settings with limited resources. The role of automated computerized algorithms needs to be also further evaluated. Similarly, the role of SSI surveillance data for benchmarking purposes needs to be clarified, especially when public reporting is involved.

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