Practical Recommendations for Implementation of Semi-Automated Healthcare-Associated Infection Surveillance in a Healthcare Facility

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Table of Contents

1. Introduction

With increased adoption of electronic health records (EHRs) in healthcare facilities, automation of the surveillance of healthcare associated infections (HAI) such as surgical site infections and bloodstream infections has become increasingly feasible. In automated surveillance (AS) manual decisions on HAI occurrence are replaced by algorithms applied to electronically stored routine care data. In semi-automated surveillance an algorithm assigns a high or a low probability that the targeted infection occurred within the surveillance period. Subsequently, cases can be ascertained by the infection prevention and control (IPC) department.[1] Over the last two decades, a number of algorithms have been published to automate HAI surveillance,[2] and – recently - a framework for the development of semi-automated surveillance algorithms for application in the local setting in a healthcare facility was validated.[3] The advantages of AS include increased standardization and reduced workload. This offers the potential to survey an increased number of HAI targets for purposes such as healthcare quality improvement or research, and IPC resources of can be directed towards interventions for infection prevention.

However, despite the numerous publications regarding the development of surveillance algorithms, successful implementation of semi-automated surveillance in practice is tedious and requires thorough preparation and sufficient knowledge of surveillance methodology to guide decision making. This document provides recommendations to guide healthcare facilities with an intention or interest to implement AS.

1.1. Background

Established within the Innovative Medicines Initiative's COMBACTE MAGNET consortium, the Epidemiology network (EPI-Net) is a network of international experts in epidemiology and surveillance of HAI and antimicrobial resistance (AMR) that aims to increase collective scientific knowledge about the distribution and determinants of serious bacterial infections, optimize and homogenize surveillance of HAI and AMR, and inform public health actions. A prior COMBACTE MAGNET EPI-Net project assessed a framework for the development of semi-automated HAI surveillance in four hospitals across Europe and concluded that using this framework, algorithms for semi-automated surveillance of SSI can be successfully developed and there is promise for standardization of surveillance on a larger scale.[3] As a follow-up project, an implementation project started, with the aim to deliver practical recommendations for implementation of semi-automated surveillance at the level of healthcare facilities.

The present implementation project is a collaboration with the PRAISE network: (Providing a Roadmap for Automated Infection Surveillance in Europe), a network project that is funded by the 7th JPIAMR joint call[4] that is developing a roadmap for large-scale implementation of automated surveillance, with a focus on the conceptual level. Within the collaboration, the present EPI-Net project aimed to provide a practical guidance document to healthcare facilities at a more detailed level, to complement the PRAISE roadmap.

Recommendations in this Practical recommendations document are based on experiences gained from the EPI-Net semi-automated surveillance implementation project, from implementation of semi-automated surveillance in the University Medical Centre Utrecht, and from an implementation project of semi-automated surveillance in three other Dutch hospitals. When drafting this document, implementation has not been finalized in most of the hospitals – due to various reasons that were not foreseen at the outset. Reasons that were related to the implementation process are addressed in the recommendations to prevent these encountered barriers in future initiatives of implementation. During these projects, obstacles encountered and lessons learned where collected and bundled to support future implementation efforts.

1.2. What is in this Practical Recommendations document?

This practical recommendations document provides, firstly, background information on semi-automated surveillance. Secondly, recommendations in the preparatory phase are reported; Important prerequisites are highlighted, including recommendations for the development of a project plan and the importance and challenges of collaboration between the IPC department and IT specialists is elaborated upon. Thirdly, recommendations are provided on how to select or develop an algorithm and validate its performance within a healthcare facility. And finally different aspects of the development of an automated surveillance system are discussed, including aspects related to data protection regulations and maintenance and sustainment. Each section formulates recommendations and subsequently provides more details or examples supporting the ratio for the recommendation.

1.3. Who is this Practical Recommendations document aimed at?

This document is aimed at local healthcare facilities that are interested in or intending to start implementing semi-automated HAI surveillance, including, but not limited to, project leaders or managers, infection control practitioners, and IT specialists working in healthcare facilities.

2. Introduction on semi-automated HAI surveillance

In traditional HAI surveillance, all patients or surgical procedures in the surveillance population are manually reviewed for the presence of HAI according to predefined case-definitions. In semi-automated HAI surveillance an algorithm classifies patients or surgical procedures into a high or a low probability that an infection occurred. Only patients classified as having a high probability that a HAI occurred are manually reviewed to ascertain whether criteria of a HAI definition were met. Cases assigned a low probability are classified as free-of-HAI without chart review. Subsequently, HAI incidence can be calculated, that is the number of HAI (e.g. surgical site infections or blood stream infections) divided by the total surveillance population (e.g. all patients who underwent cardiac surgery or the total number of days at risk) within a certain time period. Figure 1, originally published by Sips et al,[5] graphically displays this process and for more background information see [van Mourik CID 2018[1]]

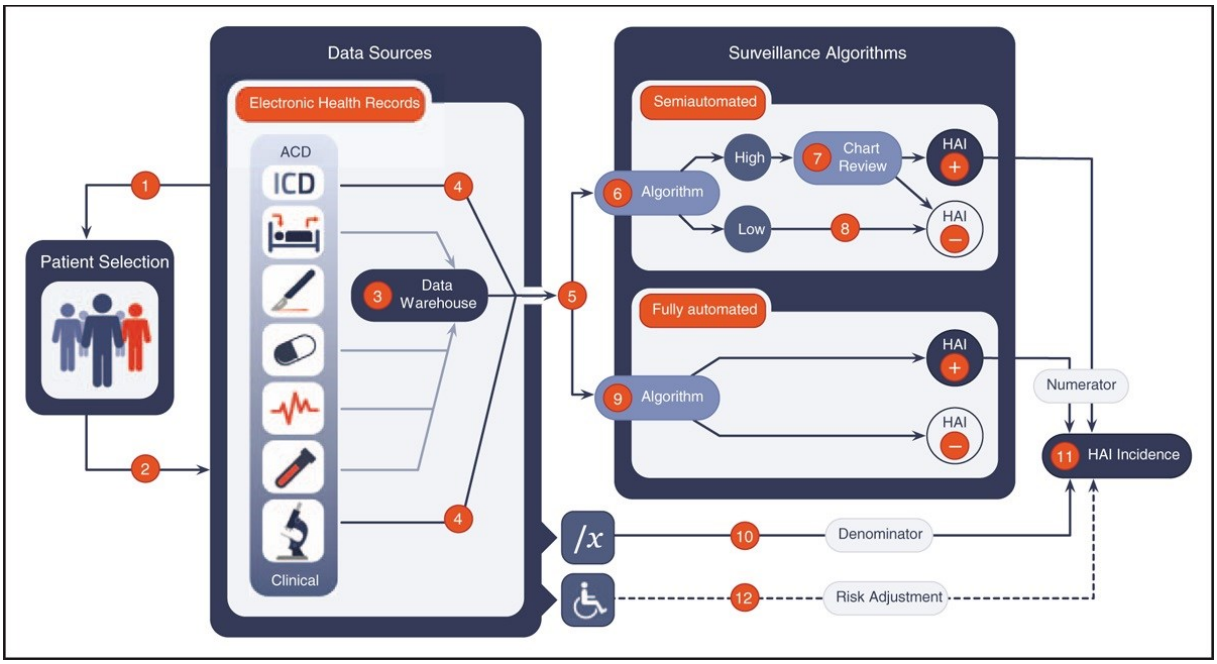

Figure 1. An overview of semi-automated and fully automated surveillance of healthcare associated infections (originally published by Sips et al, CID 2017) Patients are included in surveillance based on administrative records (e.g. admission records or procedure codes) (1). For these patients, the required administrative and/or clinical data are extracted from EHRs (2). Some data may be obtained through data warehouses (3), whereas other data may need to be extracted directly from unlinked EHRs (4). Some data sources require cleaning or preprocessing before they can be incorporated in an algorithm (5). In the case of semiautomated surveillance, the algorithm classifies patients as having a low or high HAI probability (6). Medical charts of high-probability patients are manually evaluated by an infection control practitioner to assess HAI status (7), whereas low-probability patients are assumed not to have developed an HAI (8). In the case of fully automated surveillance, the algorithm classifies patients according to their HAI presence or absence without manual confirmation (9). Finally, denominator data (number or time at risk) are obtained (10), either manually or electronically, and combined with the numerator (HAI cases) to determine the HAI incidence (11). For unbiased interpretation of the incidence, determination of risk adjustment variables (e.g. surgical wound class, American Society of Anesthesiologists (ASA) score, prior surgery) is indispensable, and should ideally be collected electronically as well (12). EHRs, electronic health records; HAI, healthcare-associated infection.

When implementing semi-automated surveillance, all steps from selection of the surveillance population to calculation of HAI incidence and collection of data for risk-adjustment need to be addressed and integrated in the workflow, irrespective of the method or approach chosen. The recommendation below address some practical aspects encountered throughout the implementation process.

3. Preparatory phase: Recommended steps before implementation of an automated surveillance system

Key recommendations preparatory phase

√ Commitment of all stakeholders before starting implementation of semi-automated surveillance is important to prioritize the project and generate funding and human resource capacity

√ The development of a project plan is pivotal to manage expectations, define the scope, and define the project management

√ Clear communication between the IPC and IT department - together with basic understanding of IT concepts and semi-automated surveillance methodology - will enhance collaboration between both departments

√ When contracting IT consultants or software suppliers, clear functional and technical specifications need to be defined by the IPC department and IT department, both for the development phase and maintenance phase

3.1. Stakeholder support, priorities, and capacity

A hospital department, for example the microbiology or IPC department, may take the initiative or may be remitted to automate the HAI surveillance. It is recommended to assign a project manager or coordinator. Before starting implementing semi-automated surveillance, it is important to have a clear view of all stakeholders and departments that are involved and obtain their support for the project. Approval of the hospital management board is essential to arrange agreements with internal and external parties, provide funding, and generate capacity, but as well to prioritize the project. This explicit prioritization is important since simultaneous developments in IT systems may conflict the development of automated surveillance. Priority and allocation of staff members from IT departments is essential for successful and timely completion of the project.

Further, early involvement of all related parties in project development will enhance the success of the project. Stakeholders' understanding of the objectives and benefits of automated HAI surveillance is a minimum requirement to obtain support. In our experience, achieving this understanding requires extensive explanation and active involvement along with a clear picture of expected benefits in terms quality of surveillance and resources required and saved. Suggested roles and departments involved in automated surveillance are listed below, although this may vary between healthcare facilities and is dependent on how the system will be implemented.

- Department of microbiology and infection control
- Management board
- Patient safety, Healthcare quality, or Risk management department
- Medical specialists performing procedures under surveillance
- IT department
- Data managers
- Epidemiologists
- Data protection officer

3.2. Project plan: managing expectations, defining the scope, and organisation

A project plan is indispensable to align expectations on the project results, roles, and responsibilities. Within this plan, the scope of the project needs to be defined, as well as a timeline and budgetary plan. Some specific recommendations on the content of a project plan for implementing semi-automated surveillance are summarized here:

- **Target and algorithm selection:**

Implementation of an automated surveillance system may be focused on a specific surveillance target. When developing a surveillance system it is recommended to consider a generic design that is also applicable to other types of HAI. This will facilitate future expansion and updates, and favour long term commitment by stakeholders. In addition, a robust and sustainable system should be pursued with respect to algorithm selection, system development, and maintenance. Specific considerations with regard to these topics are described in subsequent chapters.

- **Descriptions of automated surveillance system:**

A description of the automated surveillance system including expected functionalities are to be defined a priori in a list of requirements of the system. Although this description may seem straightforward, without explicit specification requirements may be interpreted differently or may be forgotten. Some examples of requirements:

- automated selection of the targeted surveillance population and possibilities for manual correction
- creating a selection of cases with a high probability of an HAI
- registering the final ascertainment of HAI cases, both in cases with high- and low probability (e.g. documenting that a case was assigned a low probability).
- support validation of ascertainment of HAI cases by second reviewer
- allowing for regular updates to coding systems or procedures
- an infrastructure that supports adding new surveillance targets in the future
- dashboard to provide feedback or a possibility to extract numerator and denominator data.

Second, explicit descriptions of what is in and out of scope will manage expectations and support in the development of solutions. For instance, the data selection and functionalities needed for retrospective surveillance differ from outbreak monitoring. Keeping outbreak monitoring is out of scope may facilitate implementation as data can be collected retrospectively in periodic intervals and real-time analysis is not required (e.g. algorithms can be applied at one time point 90 days after surgery).

Third, roles and responsibilities of parties involved should be formalized, since expectations may differ between roles or wards involved in the surveillance system. Implementation of an automated surveillance system will also have different consequences for different parties. For example, the contribution of infection control practitioner towards generating surveillance data will partly move towards IT or data management and data managers or IT specialists will play a new role in surveillance.

Finally, it is important to be aware of and document assumptions, dependencies, and constraints, such as availability of data sources with good quality and (human) resources (assumptions), validation results of algorithm performance (dependencies); EHR developments or other projects running in parallel (dependencies); requirements of participation in regional or national surveillance networks (constraints).

- **Evaluation of the automated system and acceptance criteria**

It is recommended to predefine how and when the surveillance system will be evaluated. During the developmental phase, parts of the system can be evaluated, such as data quality and integrity, and consistency of automated selection of the surveillance population as compared to manually selected population. Acceptance criteria can be defined, both for data quality and availability of specific functionalities, and use cases assembled to test all possible scenarios when applying the automated surveillance system in regular surveillance, both at a global and detailed level.

- **Organizational structure and planning**

Thorough preparation and implementation of semi-automated surveillance requires a substantial investment of time and man-hours and may need to be aligned with or prioritized over regular activities and other development projects. The exact amount of time required is difficult to estimate as it depends on the pre-existing situation and type of approach; in general the investment is considerable – project leadership likely involves one or more days a week for several months. Further, procurement procedures (see paragraph 3.4) imply a certain lead time. Efficiency of implementation is increased by a clear description of project management, roles and responsibilities and a time frame: who is doing what and when. Moreover a budgetary plan should be included, both for getting approval and

subsequent project management. If possible, agreements on roles, responsibilities, and monetary requirements for maintenance are ideally also included within the implementation project plan.

3.3. Collaboration and communication infection control team and IT specialists

An automated surveillance system cannot be developed without a close collaboration and clear communication between the IPC team and IT specialists. Both parties should have a clear understanding of automated surveillance, the workflow and the needs of an automated surveillance system. Because of differences in background between specialties, similar interpretation of what is needed is not self-evident. Without having an understanding of automated surveillance and basic understanding of each other specialty, communication will be complicated and potentially obstruct the implementation process. If an IPC project member has a basic understanding of some IT concepts and awareness of differences between the user interface of EHR and the back-end, this would facilitate explaining the needs in performing surveillance and in functionalities of an automated system to the IT specialists. Subsequently, the IT department needs to be able to translate these needs in IT concepts to develop functional solutions, serving both front end EHR users and back end data managers. To enhance efficiency in algorithm implementation, a consultant or other person with sufficient knowledge can serve as a link between departments, translating needs and questions that arise during the project.

3.4. External parties

Depending on the capacity and budget of the health care facility, external parties can be contracted, such as IT consultants or developers during the process of development, or software suppliers, implementing automated surveillance in their software packages. Contracting external parties may be bounded to regulations, such as procurement procedures, with demanding processing time. Clear technical and functional specifications need to be defined, in close cooperation with the IT department. Moreover, a strategy for maintenance of the system should be defined upfront, including the assignment of the responsibility (locally or with the external party) and engagement of the necessary human and financial resources. Data processing by a third party further requires appropriate (legal) agreements.

4. Algorithm selection and validation

Key recommendations algorithm selection and validation

√ Ideally, a semi-automated surveillance system starts with simple targets with clear surveillance definitions, where diagnosis follows standardised clinical procedures, and that can be detected with algorithms requiring limited data sources.

√ Algorithms need to be compatible with case-definitions, local data availability, and clinical procedures

√ An existing framework can be applied to develop algorithms that are applicable to the local setting

√ It is recommended to design algorithms that are not too specific to optimize sustainability

√ It is recommended to create insight in availability and quality of structured routine care data prior to algorithm selection or development

√ Algorithm performance always needs to be validated in the local setting

4.1. Algorithm selection

An initial step before algorithm development is the selection of the surveillance target for automated surveillance. This selection is dependent of many considerations, for which we refer to the PRAISE Roadmap (not published yet). In general, it is recommended to start with simple targets, with 1) clear surveillance definitions, 2) clinical practices following well standardized clinical procedures, and 3) that can be detected by algorithms requiring limited and generally available data. For these targets development of semi-automated surveillance will be easiest and with gained experience the method can be expanded to other targets.

Subsequently, algorithms can be selected from the literature but applicability in the local situation is dependent among others, on case definitions, data availability, and local clinical procedures. Validation in the local situation is thus important (see paragraph 4.3). Alternatively, an algorithm, applicable to local clinical and surveillance practices can be pre-emptively developed by applying the framework that was evaluated in the prior EPINET study[3]. Steps of the framework are presented in box 1. For detailed information, we refer to this manuscript. Based on the results of this prior study, it is recommended not to include too specific elements that are heavily dependent on clinical practice or registration procedures to optimize robustness and sustainability. Specific algorithm components, such as specific types of antibiotics run the risk being replaced in clinical procedures, with consequences for algorithm performance. Further it appeared that the performance of algorithms tailored to specific clinical procedures in local settings did not outperform algorithms that could be standardized across hospitals, given that data was available and validated in each individual center.[3]

Framework for pre-emptive algorithm development in semi-automated HAI surveillance

1) Collect detailed information regarding current manual surveillance methods and clinical diagnostic and treatment practices, by survey and interview
2) Pre-emptively design an algorithm to fit clinical practice and availability of data stored in EHRs; by using a previously developed algorithm or by new development
3) Apply pre-emptively designed algorithms to data stored in EHRs and classify patients as having a high or low probability of HAI
4) Assess performance of the algorithm compared to manual chart review (reference standard)
5) Refine algorithms, data extraction or data analyses methods in a series of validation steps.

Box 1. Steps of a framework for pre-emptive algorithm development in semi-automated surveillance. Originally published by van Rooden et al. (Infect Control Hosp Epidemiol. 2020 Feb;41(2):194-201. doi: 10.1017/ice.2019.321).

4.2. Data availability

In an automated surveillance system routine care data will be extracted from EHR systems for the selection of the surveillance population, algorithm application, and possibly additional variables for case mix corrections. An overview of available relevant data is thus important. Communication between the IPC team and the IT specialists is needed for insight in availability of structured data and interpretation of registered information. For instance, elective procedures and emergency procedures may be registered differently; some EHR fields may have a specific meaning in clinical practice; to select information from specific specialties selection by wards may not be valid. Data from ICU departments is often stored in separate systems and not all data may be always accessible. Results from the studies, including the EPINET study[3,6] show that algorithms not including ICU data on antibiotics had acceptable performance. Thus, it is not necessarily a prerequisite to collect all data from the ICU, also depending on the targeted procedure, on local clinical procedures, and on local registration procedures.

When selecting data sources, it is recommended to include original data sources where information is stored in structured fields and registered by standardized codes, for example surgical procedures or antibiotic prescriptions. Some information, e.g. microbiology results, are recorded in a laboratory information management system (LIMS), and subsequently this information is imported in the EHR. However, results in the EHR may be a summary of the original information and not always stored in structured fields. Ideally, information is registered in standardized codings or format (such as ICD10 codes or ATC codes). In order to combine data from various data sources, availability of unique variables identifying patients, admissions, procedures, or samples is essential.

The IPC team plays an important role in verification of quality and applicability of extracted data and selection criteria for source data, an indispensable step before algorithm development and application. If possible, clinical registration procedures in medical records may be improved to improve data quality. As mentioned before, some data sources require cleaning or preprocessing before they can be incorporated in an algorithm. In this process, infection control teams may require data management support.

4.3. Algorithm validation

Evaluation of algorithm performance in the local situation, based on local clinical procedures and local data availability, should be the first step of algorithm implementation. In semi-automated surveillance, high sensitivity is important not to miss any cases, together with an optimal positive predictive value for efficiency. [7] To obtain reliable results, sufficient data should be analysed. In most cases this implies analysis of historical data. However, results should be representative of current clinical and surveillance procedures and of data availability, registration procedures and electronic systems in use. Hence, it is recommended to include only data from recent years that are considered representative. A clinical epidemiologist may support analyses on algorithm performance as compared to traditional surveillance. In addition, especially when the availability of validation data is limited, a plan for ongoing post-implementation validation can made upfront.

5. Development of an automated surveillance system

Key recommendations Development of an automated surveillance system

√ High quality data management and version control is important to integrate data sources and reproduce surveillance outcomes

√ The feasibility of automated selection of the surveillance populations is dependent on the definition of the population

√ The possibility of selecting cases with a high probability of an infection in an automated surveillance system facilitates manual ascertainment

√ Integrating an automated surveillance system within an EHR system may have advantages for consultation or registration of surveillance outcomes, but increases vulnerability to malfunctioning of the system due to EHR (re-)development or contracting.

√ Technical and organizational measures need to assure data and privacy protection

√ A clear maintenance plan, including documentation and validation of the system and data sources, supports the sustainability of the automated system

5.1. System development and integration of data sources

Data that will be used in automated surveillance are often extracted from multiple systems and need to be integrated to exploit them for automated surveillance. A data warehouse can be supportive, but is not a prerequisite. In any case, it is important to verify data integrity, to validate correct and complete attributions of all relevant information with the same episode, such as all antibiotic prescriptions or all microbiology results belonging to one sample. High-quality data management and version control performed by the IPC department with sufficient knowledge on this topic and/or by a dedicated data management or IT department are pivotal to validate and reproduce surveillance outcomes. In addition, involving data management in early phases of the development of a surveillance system can be supportive to guarantee similar interpretability both at the back end and the front end. For example, registration forms to ascertain infections should be designed such that the interpretation of each question field is always the same and pre-defined answers are unequivocal.

5.2. Automated selection of surveillance population

A surveillance population is usually defined by a national or regional surveillance system, often based on definitions from the CDC[8,9] or ECDC[10,11]. This includes criteria on selection of surgical procedures, medical devices or days of admission. How and how well the surveillance population can be selected automatically is dependent on these definitions and on whether and how target procedures, like surgical procedures or presence of a medical device, are registered. In the first place, procedures need to be registered in a fixed place within EHRs, e.g. insertion and extraction of central vascular catheters, and can be registered with different coding systems. Further, automated selection or extraction of the population may be complicated if procedures are included or excluded differently under specific circumstances. For example, in- or exclusion of procedures with any prior surgery in the same area or urgent procedures will complicate automated extraction if this information is not documented in structured fields. Hence, identification of some target populations is more straightforward than others. It can be recommended to start with feasible targets with clear and simple definitions of which the criteria are well documented. To ascertain a correct population selection, it is essential that automated selections of the surveillance population are validated before implementation.

5.3. Algorithm results and registration of case ascertainment; integrated or separated from the EHR system

In semi-automated surveillance algorithms indicate for each patient a high or low probability that a HAI occurred. An automated surveillance system needs to be developed such that the selection of cases with a high probability become available for the infection control practitioners to manually evaluate whether cases fulfil the definitions of an infection; cases assigned a low-probability of HAI should be documented as such. Subsequently this ascertainment needs to be registered and potentially validated by a second person. Finally, an overview of all confirmed cases and the complete surveillance population need to become available to perform analyses on incidence numbers.

These functionalities of an automated surveillance system may potentially be integrated in an EHR or can be built in a separate system. Advantages of integrating these functionalities in an EHR system include the direct availability of all information from the patient when verifying cases with a high probability of an infection, including letters and (radiologic) reports. Secondly, HAI can directly be recorded in the patients' medical file and easily related to individuals.

On the other hand, EHR systems generally are under development and will have regular updates or hotfixes. Further, a new company may be contracted to supply the EHR in the future, jeopardizing (home built) surveillance systems integrated in EHR systems. To reduce dependencies of EHR developments and related risks of malfunctioning of the automated system, building or contracting a separate system to automate the surveillance can be considered. Updates to EHRs will still affect data connections and extractions, but the impact on infrastructure and algorithms will be reduced.

5.4. Data protection

In the process of data extraction, integration, algorithm application, case ascertainment, and data analyses, different roles will handle medical data. Privacy and data protection need to be assured at all stages. In semi-automated surveillance, all cases with a high probability of an HAI need to be reviewed by the infection control practitioners. Thus, access to patient identifiers is essential. For data managers or researchers on the other hand access to identifiable data is not required. Hence, a system may be developed such that only certain roles have access to identifiable data. Overall, the system needs to be compliant with laws, regulations, and policies that apply, and it is recommended to consult local data protection officers early in the development phase. Additionally, IT specialists may be consulted to advice on technical measures.

5.5. Maintenance and sustainment

Maintenance is essential for a sustainable system. A clear documentation of the automated system, including data sources and selection criteria is pivotal in maintaining an automated surveillance system. If external parties are contracted, hospital employees may need to be trained to employ and maintain the surveillance system without or with limited support.

With regular (for instance yearly) evaluation of selection of data sources codes used in clinical practice, the system can be kept up to date. Moreover, random samples of procedures can be evaluated to validate the algorithm.

6. Conclusions

This document provides recommendations for developing and implementing a semi-automated surveillance system in a healthcare facility, based on experiences with development and implementation of such systems in several hospitals in recent years. It can be used by other hospitals embarking on semi-automated surveillance. However, this may also be considered as a living document: the experience of more hospitals move towards automation of surveillance in this is an evolving field will supplement these recommendations. We recommend formal monitoring and evaluation of implementation of automated surveillance systems from the initial phase to finalization in multiple hospitals..

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