

Barriers and success factors to the implementation of a multi-site prospective adverse event surveillance system

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Abstract

Objectives. To determine the feasibility of implementing a clinical observation method for adverse event detection.

Methods. Prospective adverse event surveillance was conducted from February to April 2012. We implemented this adverse event prospective surveillance system on the general internal medicine units of five sites within two teaching institutions and one community hospital. Following surveillance, we assembled provider and decision-maker focus groups to understand the barriers and success factors related to our implementation. We used a structured interview guide with facilitated discussion.

Results. We performed six focus group interviews in June and July 2012. In total, 31 individual participated including senior executives (15), managers (7) and care providers (9). We identified the following success factors: the overall design of the system including the clinical observer and clinical reviewer functions; the credibility of the data and the opportunity to make changes to practice in ‘real-time’. We identified the following opportunities for improvement: the need for clear guidelines on the type of information to collect for each event trigger, and for an action plan to ensure accountability and follow through on improvement efforts once the adverse event data have been analyzed.

Conclusions. This work supports a conclusion that prospective surveillance is viewed as beneficial and acceptable. For this reason, healthcare organizations should consider adopting prospective adverse event surveillance to support their local quality improvement methods.

Keywords: prospective surveillance, sentinel surveillance, safety management/methods

Introduction

Adverse events (AEs) are defined as negative medical outcomes related to the healthcare management of the patient rather than the patient’s underlying medical condition. These events represent a significant risk to hospitalized patients, with estimates from around the world estimating the risk to be as high as one in eight admissions associated with an AE [1–7]. These studies also identify that up to 50% of AEs are considered preventable by reviewers [1–7]. As a result of these statistics, it is critical to develop preventive strategies for AE reduction.

A critical step in reducing AEs is systematic measurement [8, 9]. Several AE detection methods have been developed to address this need, most commonly including voluntary reporting and administrative data surveillance [8, 10–12]. Unfortunately, these methods are hampered by several factors

including their limited accuracy. For example, voluntary incident reporting systems have been a traditional approach to AE detection, but many of the events reported do not represent AEs and >90% of AEs are not reported [13]. In addition, the use of administrative databases to generate the so-called Patient Safety Indicators is commonly used despite their well-recognized high false-positive and false-negative rates [14–16]. This method can also be limited by the lag in generating the results from these systems.

Another, more innovative approach to monitoring safety events is through the use of a clinical observer. Clinical observation is a method for prospective AE surveillance that has been used predominantly in research studies [17–23]. It relies on the investigation of potential AEs by a trained observer (‘Clinical Observer’) who is alerted by a pre-defined list of clinical event ‘triggers’. The Clinical Observer is responsible for systematically monitoring all patients within a specific area.

Clinical observation can be resource-intensive if applied to large-scale AE surveillance but is an accurate and timely method of AE detection [8] that can be well-suited to a targeted localized approach. In short, it overcomes many of the limitations of voluntary reporting and administrative database surveillance.

While a clinical observation program has worked in some research settings, there are reasons why there may not be wide-scale adoption into routine hospital operations. Sorensen *et al.* [24] identified system complexity and coordination with existing work processes as key factors affecting the implementation of prospective injury detection systems for two types of AEs; however, the authors also recognized the impact of local factors in the success of these methods [24]. In this particular case, it is possible that there are competing sources of information on AEs that diminishes the utility of the program. In addition, healthcare providers might feel threatened by the presence of the observer and may avoid interacting with them in a way to find information. Finally, managers and other hospital leaders may feel threatened by an external group preparing a report on patient safety events that will be visible to their own leaders. While these concerns are present from a theoretical point of view, it is unclear how important they might be in the successful use of this approach.

To determine the feasibility of implementing a clinical observation method for AE detection, we performed a series of focus groups after its implementation in several diverse hospitals. We chose to focus on the barriers and success factors for implementing a prospective AE surveillance system after the focus group members had experience with the measurement approach. This would give an opportunity for the stakeholders to provide their real-world experiences rather than an uninformed belief. This understanding is necessary before advocating for more widespread use of the surveillance program as it will help to overcome implementation challenges including the perceived usefulness of the information by clinicians and health system leaders.

Methods

Setting

The study took place on the general internal medicine units of five sites across two teaching hospitals and one community hospital during a 10-week period. Hospital A, located in Ontario, Canada, and Hospital B, located in Quebec, Canada, are both multi-campus academic health sciences centers offering tertiary and quaternary services as well as academic programs. Hospital C is an urban and rural community hospital offering primary and secondary care services in Ontario, Canada. This study was approved by each hospital's Research Ethics Board.

Prospective AE surveillance

Prospective AE surveillance was conducted from February to April 2012. The prospective surveillance system consisted of

active observation of all patients and providers by trained clinical observers (typically RNs or physicians) on the general medicine units at each site. Clinical observers were trained by the research coordinator. The training consisted of a didactic session followed by two weeks on site as an acclimatization period.

Providers on the participating units were informed of the activity, and posters were placed in various locations to alert staff to the triggers and the clinical observer's contact information. The clinical observers were on the units, monitoring all patients, Monday through Friday for ~7.5 h per day. Standard baseline patient information was captured on every patient monitored. The surveillance consisted of activities such as obtaining the daily census, attending shift change reports and rounds, liaising with Nurse Managers to obtain updates and incident reports, consulting nursing reports or unit log books, liaising with staff regarding specific events, reading discharge summaries and checking for abnormal lab results. When a trigger was identified, the clinical observer captured standard information describing the event. The list of triggers was developed through previous research [20] and clinical expertise. The triggers do not represent AEs necessarily but are designed to alert the clinical observer to potential problems. Triggers may include deterioration in clinical parameters, specific orders (e.g. antidotes) or patient transfers to specific clinical areas. The triggers used in this study are listed in Appendix 1.

Observations were entered into an electronic case record using the patient safety learning system (PSLS). Weekly review meetings were held between the clinical observer, the clinical reviewer (physician) and a unit nursing leader. During these meetings, the clinical reviewer was able to review the cases directly in the PSLS and document his or her opinion on whether the outcome was due to medical error or the progression of the disease. The cases were then classified by a core reviewer (a trained risk manager). This process is presented in Fig. 1, and the roles of the clinical observation team are presented in Table 1.

Data collection

Following the active surveillance period, a total of six semi-structured focus groups were conducted to elicit perspectives on key success factors and challenges related to the implementation of the surveillance program—one focus group with the surveillance team and care providers and one with decision-makers, at each participating hospital. The focus groups were selected based on a convenience sample of the decision-makers and care providers directly involved in the project implementation at the various study sites. Thus, it is possible that data saturation was not reached, which is a limitation of this study. The care providers and the decision-makers participated in separate focus groups to minimize the impact the groups could have on one another. The consolidated criteria for reporting qualitative research 32-item checklist were used to report the results of this qualitative study [25].

The research team consisted of two physicians and senior researchers (A.F. and C.V.) and a PhD nurse (C.B.). All members of the research team participated in the planning of the study. Focus groups were conducted by C.B. in June and

July 2012 in each of the participating hospitals. The surveillance team, care providers and decision-makers were invited by email to participate. A total of 31 individuals participated in the focus groups including senior executives (15), managers (7) and care providers (9). A semi-structured interview guide was developed by the research team and was used in the focus group sessions. Each session lasted ~60–90 min. The semi-structured questions and the rationale for their inclusion can be found in Appendix 2. All focus group sessions were audio-recorded and transcribed verbatim by a transcriptionist.

Data analysis

The focus group sessions were analyzed using a qualitative approach with direct content analysis [26]. One researcher (C.B.) reviewed the transcripts of each focus group recorded sessions for accuracy, completeness and initial impressions. Using a

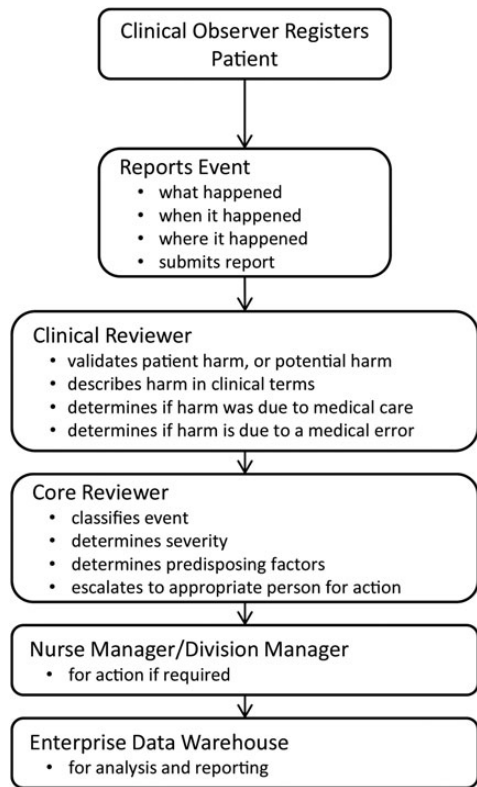


Figure 1 Clinical observation module.

Table 1 Roles of clinical observation team members

Clinical observer	A nurse or physician trained to observe specific AEs based on a pre-determined list of ‘trigger’ events. The clinical observer documents the circumstances surrounding the event and participates in weekly review meetings.
Clinical reviewer	A designated physician who reviews all cases where there was a potential for harm and documents his or her opinion on whether the outcome was due to a healthcare error or the progression of the disease.
Core reviewer	A trained risk manager who classifies the AEs according to the World Health Organization classification system.

directed content analysis approach to analyze the data [26], codes were assigned to the participants’ comments for a preliminary categorization of the transcripts. Themes were then identified to group the data based on the preliminary assessment and to facilitate comparison with emerging theory on barriers and success factors for implementation. The results were also shared with some participants to ensure accuracy. ATLAS.ti data management (Scientific Software Development GmbH, Berlin) was used to support the qualitative analysis of the data.

Results

In the surveillance team and care providers’ focus groups, participants included nurse managers, clinical reviewers and clinical observers. In the decision-makers’ focus groups, participants included division heads, directors of nursing, directors of quality, vice-presidents and a CEO.

The participants’ descriptions of the barriers and success factors to the implementation of a multi-site prospective AE surveillance system are described in two major themes: the strengths of the prospective AE surveillance system and the opportunities for improvement. The code list is available in Appendix 3.

Strengths of the prospective AE surveillance system

The general strengths of the system identified were the design of the system, with emphasis on the clinical observer and clinical reviewer functions, the credibility of the data and the opportunity to make changes to practice in ‘real-time’.

Role of the clinical observer. A clinical observer was assigned to each unit participating in the study. In some cases, the clinical observer was an existing member of the frontline staff, and known to other unit staff members. In other instances, the clinical observer came to work on the unit during the surveillance period only and was introduced to the unit staff. In both scenarios, local staff were oriented to the role of the clinical observer and encouraged to communicate regularly with them throughout the surveillance activity.

Overall, the clinical observers were seen as non-threatening to the frontline staff. Unit staff members felt positively toward the clinical observers and appreciated the questions they asked:

... [she] would come first thing in the morning and say ‘so what happened since yesterday?’ ‘Was there anything that you know

would be pertinent to the study or you know anything that I can look into sort of thing?' and she was a go getter. (P 2, 50)

Also, the participants commented that the clinical observers were visible and accessible on the unit. One of the participants explained that:

I think it was interesting when I went through the ward and observed where the clinical observer sat [...] dead centre of the ward, at the nursing station ... but that's you know like the centre of the spider web you know everything communicates through there so she hears, sees and if it's the residents or the cleaning staff, the unit coordinator, some nurses going back and forth so it was a good place to be. So she didn't, certainly didn't hide in a back room waiting for things to happen she just had all the communication lines open ... (P 1, 44)

It was also noted that there was merit to having frontline staff involved in the data collection. As one participant explained:

The two nurse observers were frontline nurses so they saw the data, they collected all the data and I think that was also an enabler for them collecting the data. They worked on the wards right ... so they've brought this whole experience back ... (P 6, 210)

This study enlisted local frontline nurses to conduct the clinical observation, and the clinical observers explained that they became more aware of safety issues in their own practice. After entering the triggered events and supporting information into the PSLS, the clinical observer would meet with a clinical reviewer and nursing leader on a weekly basis to review the data collected.

Role of the clinical reviewer. Clinical reviewers were physicians at each site assigned to review the patient events. Throughout the surveillance activity, the clinical reviewers worked very closely with the clinical observers. A clinical reviewer explained that during these meetings:

... we would go over that week of information that was provided which was great because then we were taking the information as it was fresh to us and we could actually think about the patient and think about how we could have done it better. (P 2, 154)

In addition, another participant agreed that the weekly review meetings were very useful. One clinical reviewer commented:

... I found that our weekly review was much more valuable to articulating what we were seeing ... (P 4, 99)

However, at the beginning, one participant explained that there was an adjustment period, where

... we found after the first meeting we were asking questions saying we're missing some bits of data and then the [clinical] observer would have those for the next one. (P 1, 150)

Also, a participant found that there was an advantage when they knew the patient, such as:

... being on the ward and knowing the patients it was a lot easier to assign preventability and other issues related to the adverse events. (P 1, 24)

Credibility of the data. The systematic approach to the collection of the events supported the credibility and timeliness of the data. A participant explained that

... the credibility of the data is much better because it's been reviewed with the team and its professional, it's very timely so you still remember the event and you get the level of detail that you need to I think act, to mobilize people to action. (P 6, 60)

This allowed, as a participant said, to ...

... take some of the issues back right away, which was helpful I think for improving. (P 2, 184)

Furthermore, the clinical observation provided a novel learning experience for the residents, who saw the value in this process. As one participant explained:

They appreciated seeing and dealing with things ahead of time in a multi-disciplinary setting. And my sense was that they appreciated the procedure. They hadn't been to this type of approach before to talk about things outside of the [Mortality and Morbidity] rounds itself and they were motivated to come even at times when they were extremely busy. (P 6, 200)

Real-time changes in practice. A unique feature of the surveillance activity was that it allowed for real-time changes to practice to address safety issues. One participant shared an improvement activity that was implemented during the study and remarked on the noticeable improvement:

... on medicine we were finding that we had a number of issues related to the wrong feeds being hung by the nurses. The bags are extremely similar and so what we did on the unit was brought it forward to the rest of the team that there were some issues with it. We did some teaching with the nursing staff in fact we created a display of the 3 types of feeds in particular that were causing us to have issues and to show the similarities and also show the differences. So we did some teaching with the staff around that and it brought great awareness and we haven't been seeing incidents related to that since we've done the teaching with the staff. So that's been quite positive. (P 2, 24)

In the same hospital, the participant explained that they addressed another issue:

... we've been really looking at some of the early warning signs in our discussion with the nurses as well you know when the heart rate's coming up, the pressure's rising or falling, that looking at some of the early warning signs that might have indicated that the patient was heading south earlier. So it's brought some focus to that too. (P 2, 28)

Also, another issue that was brought up during the review meetings is:

... that we notice a lot of medication errors in relation to our MARs [medication administration records] that was another thing that was coming up quite a bit so we kind of focused on that as well. So mak[ing] people a bit more vigilant about double-checking and transcribing stuff properly. (P 2, 32)

In addition, the timely information facilitated prompt follow-ups. On participant described:

... the patient might have still been on the unit so it was a good opportunity to take it back to the staff that were working with that patient and do teaching on the spot. So it was great that it wasn't like months later that we were reviewing the adverse events. (P 2, 156)

Overall, the surveillance program provides an opportunity to discuss the issues as they arise because the data are collected and reviewed very close to when the event happens. It also stimulates patient safety awareness and allows for prompt feedback to address any issues in a timely fashion.

Opportunities for improvement

Two opportunities for improvement to enhance or refine the surveillance system emerged from the discussion. The first was the need for clear guidelines on the type of information to collect for each event trigger in order to facilitate the clinical review process. The second was the need for an action plan to ensure accountability and follow through on improvement efforts once the AE data have been analyzed.

Need for clear guidelines on the type of information to collect for each event trigger in order to facilitate the clinical review. The participants suggested that the list of event triggers be further clarified to help with the data collection.

A participant suggested that

... the different triggers require perhaps different kinds of additional information. And you sort of start getting back to the clinical observer and saying well if we've got these parameters we need to know what's happening before so we're trending upwards or downwards or all over the place to make that decision. And it wasn't clear in their data collection procedures to do that. So I think we had to train them to do, to tell us what information we needed to make that decision, the actual decision on the event. (P 1, 150)

In addition, a participant suggested that some of the triggers:

... could perhaps be automated like if it is a trigger that is one of the, a lab test or a parameter that you fill in the previous 3 or something like time sequence so that people can know 'okay it's always been 2 for the last week so what?' you know. (P 1, 154)

Similarly, another participant suggested:

Some of those triggers are excellent and they're not built into our information system. I'll give you an example is creatinine goes up >25% or then another example is a particularly severe adverse event is heparin-induced thrombocytopenia where it has to fall by 50%. Now 50% may still bring it within the normal limits but there's no trigger built into the lab to say that this has gone up by >25% or this has gone down by 50% so you have to actually be alerted to that. (P 1, 158)

Another participant felt that we could integrate other systems to maximize the data collection.

... the inclusion of MDROs [multidrug resistant organisms] as an adverse event is sort of an extra step that is already being monitored elsewhere. So it just seems that it's doubling up information that is collected very assiduously by another group. And then

assigning it to preventable or not preventable didn't really seem all that useful at that point. (P 1, 18)

Given the challenges to collect the relevant data for each trigger, a clinical reviewer described that

... there were times when it was very difficult to decide whether something was caused by an underlying condition versus the medical cause ... (P 1, 30)

In addition to refining the data collection process, some participants felt that a follow-up plan be developed to ensure that proper actions are taken based on the results found from the surveillance activity.

Need for an action plan to ensure accountability and follow through on improvement efforts once the adverse event data have been analyzed. A participant explained that:

... if anything I'd say that comes out of this is we need a process to sit down in a systematic review fashion of the overall picture ... We've got all this data that's sort of sitting there in this lovely little black box and how do we actually move forward to look at it (P 3, 310)

Similarly, another participant explained the need to be

... reviewing the data, deciding on the important factors and then implementing change I haven't yet seen that done properly and yeah I think that that's most important. (P 5, 223)

The participants identified the need to define appropriate actions to address the results from the observation activity.

Discussion

In this study, we measured provider and administrator opinions related to the use of prospective surveillance for detecting AEs. Clinical observation is a powerful tool for identifying incidents and errors in medical care, especially when compared with self-report or voluntary reporting mechanisms [8, 19, 21, 27]. In particular, clinical observation generates data on AEs that are rich in detail, which in turn facilitates improved classification of severity and cause of AEs. The resulting data are of high quality and produced in a timely manner [8]; however, the success of this methodology also depends on the uptake of the approach and results by key stakeholders, including front-line staff and hospital decision-makers. Overall, the feedback received on the implementation of the prospective AE surveillance activity in several hospitals was positive, and suggestions to improve the system were useful.

From the perspective of the healthcare professionals and senior leaders, the information provided by this AE detection approach was much better than existing data available from voluntary reporting or administrative data. Specifically, the feedback indicated that from the perspective of stakeholders, the surveillance data were timely, believable and actionable, which provided a great opportunity for implementing changes to practice and facilitating targeted education. These opinions are consistent with published research, which confirms the limitations of voluntary reporting and administrative data

[13, 28, 29]. It is likely that the surveillance data can fill an important void in the opinion of those interviewed.

However, simply measuring AEs does not lead to any meaningful changes. It is clear that we need to develop a strategy that focuses on the implementation of improvement efforts derived from the AE data analysis. Local clinical teams need guidance on the interpretation of the results, prioritization, the monitoring of progress and the implementation of improvement efforts. This prospective surveillance methodology combined with a variety of quality improvement methods such as the Plan-Do-Study-Act model [30], LEAN methodologies or the Comprehensive Unit-Based Safety Program [31] should be studied in order to better understand whether it can be a component of an overall approach to generate sustainable improvements.

Caution must be exercised when drawing conclusions beyond the focus group participants, as their experiences with this approach may not be universal. Processes were put in place to maximize participation and to avoid any power imbalances within the groups by organizing separate groups, one for healthcare professionals and another for senior leaders in each participating organization. Another limitation included the potential bias of having only one coder review the focus group transcripts. A final consideration is that this assessment was only from the user perspective and did not explicitly evaluate psychometric properties. This study was not designed to evaluate the reliability and validity of the surveillance, but another assessment performed by other investigators of these characteristics for other surveillance methods shows that the clinical observer method is, if anything, more accurate than other surveillance methods [10]. The fact that the people interviewed in our study stated that the information in the reports was high quality likely reflects this higher accuracy, compared with other sources of AE information. Of course, we need to evaluate reliability and validity in future studies.

Despite these methodological limitations, the study presents the overall strengths of having a prospective surveillance system. It has been successfully implemented in multiple hospitals involving participants from the frontline staff to senior leaders. Furthermore, senior leaders across the five sites studied agreed that this method was extremely useful in providing a systematic approach to measuring AEs. This feedback lends support to other organizations adopting this approach to systematically detect AEs.

Conclusion

This work supports a conclusion that prospective surveillance is viewed as beneficial and acceptable. For this reason, healthcare organizations should consider adopting prospective AE surveillance to support their local quality improvement methods. Future research will need to focus on systematic 'responses' to the data generated from AE surveillance.

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Appendix I

Table A1 Triggers used by clinical observers

Laboratory based triggers		
INR > 5	Glucoscan > 18 * 2	Mg < 0.4
K < 2.8	WBC < 3.0	Mg > 5.0
K > 6.0	WBC > 18	pH < 7.25
Na < 120	Hb decrease > 20%	pH > 7.5
Na < 150	Plt decrease > 50%	Positive HIT assay
Cr > 25% change	Calcium < 1.5	Positive blood culture
Ck > 500	Calcium > 3.0	Positive c. difficile toxin
Glucoscan < 3.0	Phosphate < 0.4	
Patient based triggers		
Respiratory distress/Dyspnea	New DVT/PE	CV Line complication—arterial injury
Chest pain	New Pressure Ulcer	CV Line complication—difficult insertion (>3 attempts)
O ₂ sat < 90%	Fall resulting in injury	CV Line complication—other
Systolic BP < 100	Pneumothorax	Family/patient dissatisfied with care
HR > 110	Return to OR	Altered Level of consciousness
Temp > 39 C	New gastric/duodenal ulcer	
Temp < 35 C	Surgical Wound Complication	
Rash	Compartment Syndrome	
Nausea/Vomiting	CV Line infection	
Unexpected death	CV Line complication—pneumothorax	
System based triggers		
Line complication	Transfer to ICU	Unable to obtain MD in a timely manner
Foley complication	IV pump error	Unable to obtain consultant in a timely manner
Stat ECG	Delay in therapy	Unable to obtain critical care bed in a timely manner
Portable X ray on floor	OR cancelation	Equipment unavailable in emergency situation
New Isolation Precautions	Diagnostic error	
Use of physical restraints	Order for blood products	
RACE call	Medical equipment problem	
Code Blue call	Medication administration error	
Pharmacy based triggers		
Order for Flumazenil		
Order for Vitamin K		
Order for Nalaxone		
Order for Protamine		
Order for FFP		

Appendix 2 Focus group questions

Review teams and convenience sample of front-line clinicians

‘(NB: Review teams and Front-line clinicians will participate in separate focus groups to minimize the impact the groups might have on one another)’

Introduction/research objectives:

- A brief summary of the purpose of the focus group will be discussed with participants; procedures of the focus group will be reviewed.
- Participants will be asked to introduce themselves and provide a brief summary of their role during the study

Q1: How was your overall experience with the AE surveillance activity?

‘Rationale: We want to get an overall understanding of the review teams’ and front-line clinicians’ experiences with the AE surveillance activity. We wanted to keep the first question very broad and high level so as not to influence the participants’ responses’.

Q2: How did the staff on the wards react to the presence of a clinical observer? Do you feel as though the staff readily cooperated with data collection? Do you feel that staff were threatened by the presence of the observer? Please elaborate.

‘Rationale: We want to fully understand the impact of the observers on the staffs’ behavior, from both the staff and the review team’s perspectives’.

Q3: How do you feel senior decision makers at the hospital felt about the information collected? Do you feel they appreciated the information regarding AEs? Do you think the information derived from the surveillance will be useful? Please elaborate.

‘Rationale: We want to understand how the review teams and clinicians perceive the data will be used. We want to evaluate the level of provider buy-in that exists for the system’.

Q4: Were there any specific incidents that you consider a great success to the implementation of this AE surveillance system? Were there any specific incidents that you consider a great barrier to the implementation of this AE surveillance system?

‘Rationale: We want to identify major challenges we may encounter in the broader implementation of this system. However, we wanted to keep the question very broad and high level so as not to influence responses’.

Q5: Do you feel that the survey instrument is a valid way to evaluate the adverse event surveillance program? What changes, if any, do you think would make the survey more accurate or easier to understand? Please elaborate.

‘Rationale: We will use a portion of the focus group time to evaluate the survey instrument. This validation will enable us to ensure the content validity of our survey and allow its’ use in future studies’.

Decision makers

Introduction/research objectives

- A brief summary of the purpose of the focus group will be discussed with participants; procedures of the focus group will be reviewed.

Q1: How much of a priority is it for you to identify and reduce AEs at your institution/on your ward? Why or why not?

‘Rationale: We want to understand how much the decision makers know about AEs that occur in their institutions and what types of priorities they have with regards to the detection and/or prevention of AEs’.

Q2: What did you think about the reports you were provided as a result of this AE surveillance system?

‘Rationale: We want decision makers to volunteer information about the reports they received. We hypothesize that they will think the reports generated from our system will contain more useful information than previous reports, but we did not want to suggest so in the question at the risk of biasing the answers or leading the conversation too much’.

Q3: Do you think this system is something you would like to implement on a more permanent basis at your institution/on your ward? If so, what issues do you think need to be addressed in order to make this possible?

‘Rationale: We want to identify major challenges we may encounter in the broader implementation of this system. However, we wanted to keep the question very broad and high level so as not to influence responses’.

Q4: Do you feel that the survey instrument is a valid way to evaluate the adverse event surveillance program? What changes, if any, do you think would make the survey more accurate or easier to understand? Please elaborate.

‘Rationale: We will use a portion of the focus group time to evaluate the survey instrument. This validation will enable us to ensure the content validity of our survey and allow its’ use in future studies’.

Appendix 3 Code list

Role of the clinical observer
 Role of the clinical reviewer
 Credibility of the data
 Changes in practice
 Type of information needed for each trigger
 Closing the loop