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ORIGINAL ARTICLE

What determines the (in-) efficacy of a surveillance system to reduce surgical site infections after gastrointestinal surgery?

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Abstract

A surgical site infection (SSI) is a serious and costly complication with the highest rates being reported after gastrointestinal surgery. The objective of this cross sectional study was to assess the incidence and risk factors of SSI after gastrointestinal surgery during and after hospitalization, and to evaluate the effect of the VMS (Dutch: "VeiligheidsManagementSysteem") safety programme on the SSI rate. We assessed the SSI rate from July 2008 until December 2011, according to the criteria of the Centres for Disease Control and Prevention (CDC), before and after implementation of the VMS safety programme which includes a bundle of four interventions. We differentiated between the SSI rate during and after hospitalization and between superficial, deep and organ/space infections. The incidence of SSI in relation to the wound class, risk factors for SSI, and the compliance with the programme were assessed. Data were obtained during a thirty-day follow-up period after surgery.

Surveillance after discharge significantly increased the overall SSI rate. Age higher than fifty years and contaminated or dirty wounds were risk factors for SSIs. Despite increased compliance with the safety programme, no significant decrease in SSI rate was found after implementation. The Dutch VMS safety programme did not show a significant effect on the decrease in incidence of SSI. Surveillance during and after hospitalization is essential for a reliable assessment of the SSI rate.

Keywords: Digestive system surgical, procedures and complications; Surgical wound infections and epidemiology and prevention and control; Safety management

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Introduction

A surgical site infection (SSI) is a serious and costly complication resulting in prolonged hospital stay, increased antibiotic use, increased morbidity, and even mortality.[1-4] SSIs affect up to 5% of surgical patients, with the highest rates being reported after gastrointestinal surgery.[5-9] The negative effect that SSI has on patient safety depends partly on whether the infection is superficial or deep or whether it concerns organ or space, i.e. any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure.[8,10] Since the risk of an SSI is amongst others associated with the degree of intrinsic microbial contamination of the surgical wound, wounds are classified into four wound classes.[11]

Patients with advanced stages of disease and multiple co-morbid diagnoses are often referred to a tertiary-care hospital for further treatment.[12] In addition, since shorter hospitalisation after surgery has become common practice, it is to be expected that an increased number of SSIs will be diagnosed after discharge.[11,13,14] Surveillance of SSI is an important strategy to reduce the risk for developing an SSI.[15] It consists of registration, analysis of patients' clinical data and feedback to healthcare workers.[11,16-19]

In the Netherlands, hospitals currently participate in a national programme intended at improving patient safety, i.e. the patient safety programme VMS (Dutch: *"Veiligheids ManagementSysteem"*). The programme consists of ten themes, one of which focuses on the reduction of SSI, and was developed with the aim at reducing the occurrence of preventable deaths with 50% by the end of 2012. It was initiated by the Society of Hospitals (NVZ), the Dutch Federation of University Medical Centres (NFU), and the Dutch Association of Medical Specialists and Nurses & Carers (V&VN). The theme to reduce SSI contains a bundle of four interventions. The goal is to improve the compliance with these preventive measures.[20] However, it remains uncertain which factors affect the successfulness of safety measures to reduce SSIs and whether extensive efforts result in the desired outcome, i.e. reducing SSIs.

The objective of this study was to assess the incidence of SSI after gastrointestinal surgery during and after hospitalisation, and to evaluate the (in-)efficacy of the VMS safety programme, designed at an academic medical centre, on the incidence of SSI. We performed an analysis based on a logistic regression model to determine risk factors for SSIs after gastrointestinal surgery.

Methods

Study setting and patients

The study was carried out from July 2008 until December 2011 in a 715-bed tertiary care hospital in the Netherlands, the Maastricht University Medical Centre (MUMC+). The study was divided in a pre-test period and a post-test period. In the pre-test period, from July 2008 till April 2010, surveillance was only performed during hospitalisation from July 2008 till July 2009. Half way during this pre-test period, the surveillance period was extended to a follow-up period of thirty days after surgery. The post discharge surveillance was only performed for patients visiting the outpatient clinic within the thirty days after surgery. There was no systematic follow-up of all patients over the full thirty days period. April 2010 until December 2011 was the post-test period during which the VMS safety programme had been introduced and implemented at the surgical department. The effectiveness of the VMS programme was evaluated, using the incidence of SSI as indicator parameter.

Surgical site infection

All wounds after surgery were classified into four classes: clean, clean-contaminated, contaminated or dirty. The presence of superficial, deep and organ/space SSI was assessed according to the criteria of the Centres for Disease Control and Prevention (CDC).[8]

The index-surgery was defined as the first surgical intervention in this hospital. All SSIs diagnosed within thirty days after the index-surgery were registered according to the criteria of the CDC and the Dutch PREZIES (Dutch: *"Preventie van Ziekenhuisinfecties door Surveillance"*) national guidelines.[8,21,22] An infection was considered as an SSI linked to the index-surgery, unless a surgical intervention in another hospital had been performed at the same surgical site within thirty days before the index-surgery. Re-surgeries in this hospital, performed at the same surgical site

and within thirty days after the index-surgery, were considered to be related to this surgery, and were therefore not included in the analysis. Surgery more than thirty days after the previous surgical intervention was registered as a new index-surgery and included in the analysis. An independent experienced infection control nurse (ICN), who was trained in the assessment of SSI, collected demographic data of the patient and clinical data of the surgical procedure over the course of the study: sex, age, wound class, elective versus urgent, admission date, date of surgery, discharge date, readmission within the post discharge period, presence and type of SSI, and history of previous surgery. The inter-rater reliability (IRR) was evaluated by discussing difficult cases of SSI with independent physicians and checking print outs of the database every half year.

The sources of information were medical records and consultations of independent physicians. Post discharge surveillance (PDS) was assessed by examining patients' wounds during follow-up visits at the outpatient clinic within thirty days after surgery. This surveillance method included additional surgeon notes from the outpatient medical record to pre-existing clinical data, and was validated by the PREZIES network.[23]

The VMS safety programme

The VMS safety programme has been developed for Dutch hospitals. One of the ten themes includes a bundle of four interventions with the aim at reducing SSIs. The bundle was intended to reach a compliance rate of at least 90%, using the Plan-Do-Study-Act-cycle as developed by the American Institute for health care Improvement.[24,25] The SSI rate was measured to quantify the effect of the intervention measures. The elements of the bundle are peri-operative antibiotic prophylaxis, no hair removal before surgery, normothermia, and discipline in the operating room (OR), measured as the number of door movements during surgery.[24]

Concerning the PDSA cycle, in the 'Plan' phase we determined the number of surgical index-surgeries and the SSI rate during the study period. In the 'Do'-phase surveillance was performed to collect, analyse and interpret the relevant data. During the 'Study'-phase trends over time in SSI rate and risk factors were investigated. In the 'Act'-phase, the putative interventions which should be made to improve compliance with the infection prevention policy in the future, were determined.

Compliance with the VMS safety programme

Random observation of infection control practices was yearly performed at the OR for gastrointestinal procedures. This was done by infection control personnel, using a specifically developed checklist that consisted of infection control practices related to surgical and anaesthesia procedures. Monitoring at the OR was performed throughout all activities related to the same procedure. OR personnel were not notified in advance of which surgical procedures were about to be monitored. The number of door movements was measured from the start of the incision until the surgical wound was closed. Antimicrobial therapy was provided according to the hospital-specific guidelines of the Dutch working party on Antibiotic policy (Stichting Werkgroep AntibioticaBeleid, SWAB).[26] Cefuroxime, 1500mg intravenous, or cefazoline 500 mg with 500 mg metronidazole intravenous or 2.2 gram amoxicillin-clavulanic acid intravenous for patients who underwent colorectal surgery, within 30 minutes to 1 hour before incision. Patients who underwent other laparotomies (clean procedures) did not receive antimicrobial treatments. For a morbidly obese patient two grams of a second generation cephalosporin or one gram ertapenem was more appropriate. Hair removal was omitted, if necessary a clipper was used instead. Normothermia was defined as a body temperature between 36°C and 38°C at the end of the surgery. This was achieved with intravenous fluids and a forced-air cover.[27] Between the monitoring events no specific interventions were established to improve compliance other than increasing awareness of the guidelines.

Statistical Analysis

The incidence of SSI was defined as the number of SSIs per number of surgical procedures and was calculated for the pre-test and the post-test periods. The SSI rate during hospitalisation in the post-test period was compared to that of the pre-test period, using the Pearson's chi-square test. The univariate relationship between each independent variable and SSI was evaluated using a logistic model for continuous variables. Variables with the lowest infection risk were taken as reference group (clean wounds, age less

than thirty years and elective procedures). Logistic regression was performed to assess the impact of a number of factors on the likelihood that an SSI during hospitalisation in the pre-test and post-test periods occurred. The model contained ten independent variables: sex (female or male), age groups (< 30 year, 30-50 year, 50-70 year or >70 year), wound classes (clean-contaminated, contaminated or dirty), previous surgery and urgency of surgery (acute or emergent). Results were considered to be significant at a *P* value of ≤0.05. Unadjusted, adjusted odds ratios (OR) and the 95% confidence intervals (CI) were calculated for each independent variable. All statistical analysis of the data was done using the SPSS programme for Windows, PASW Statistics 18.

Results

Study population

Of the 2546 surgical procedures (including 390 re-surgeries within thirty days), 2156 index-surgeries were included in the analysis. The gender ratio was 1067 (49.5%) male and 1089 (50.5%) female. The patients' ages ranged from 18 to 98 years with a mean of 63 years for male and 62 years for female patients. Surgical procedures were classified as clean (n=254, 11.8%), clean-contaminated (n=857 39.7%), contaminated (n=518, 24.0%) and dirty (n=413, 19.2%). The wound class of 114 procedures (5.3%) was unknown.

In total, 485 SSIs were diagnosed (22.5%) during and after hospitalisation, of which 243 (50.1%) were superficial, 216 deep (44.5%) and 26 organ/space

Table I. Patient characteristics with SSI and without SSI during hospitalisation, Pre-test versus Post-test

	Pre-test (N=1224)			Post-test (N=932)		
Characteristics	**SSI (+)**	**SSI (-)**	***OR, 95%CI***	**SSI (+)**	**SSI (-)**	***OR, 95%CI****
Number	177 (14.5)	1047 (85.5)		179 (19.2)	753 (80.8)	
Sex			1.30, 0.94-1.79			1.30, 0.94-1.81
Female	81 (45.8)	547 (52.2)		79 (44.1)	382 (50.7)	
Male	96 (54.2)	500 (47.8)		100 (55.9)	371 (49.3)	
Age			0.78, 0.52-1.17			0.57, 0.36-0.91
≥50	143 (80.8)	803 (76.7)		155 (86.6)	593 (78.8)	
<50	34 (19.2)	244 (23.3)		24 (13.4)	160 (21.2)	
Wound class**			1.54, 1.11-2.13			1.54, 1.10-2.15
1+2	79 (44.6)	554 (52.9)		78 (43.6)	400 (53.1)	
3+4	95 (53.7)	433 (41.4)		93 (52.0)	310 (41.2)	
Previous operation***			0.84, 0.54-1.30			0.79, 0.52-1.22
Yes	28 (15.8)	142 (13.6)		32 (17.8)	111 (14.7)	
No	149 (84.2)	905 (86.4)		147 (82.1)	642 (85.3)	
Procedure			1.13, 0.81-1.57			0.85, 0.61-1.18
Emergency	63 (35.6)	402 (38.4)		72 (40.2)	273 (36.3)	
Elective	114 (64.4)	645 (61.6)		107 (59.8)	480 (63.7)	
Hospitalisation (days)	28.9 ± 21.5	23.4 ± 29.2		25.5 ± 23.7	14.0 ± 18.5	

* Characteristics of patients with SSI: comparison between the Pre-test and Post-test.
** Wound class: 1 (clean), 2 (clean-contaminated), 3 (contaminated), 4 (dirty)
*** Previous operation within 30 days at the same surgical site

Table II. Patient characteristics with SSI and without SSI during hospitalization, Pre-test versus Post-test

	Pre-test	Post-test	
Characteristics	**SSI (+)**	**SSI (+)**	***OR, 95%-CI****
Number	177 (14.5)	179 (19.2)	*1.41, 1.12-1.77*
Superficial	88 (49.7)	88 (49.2)	*0.98, 0.65-1.48*
Deep/Organ space	89 (50.3)	91 (50.8)	*1.02, 0.68-1.55*
Sex			
Female	81 (45.8)	79 (44.1)	*0.94, 0.62-1.42*
Male	96 (54.2)	100 (55.9)	*1.07, 0.70-1.62*
Age			
>70	76 (42.9)	76 (42.4)	*0.98, 0.64-1.49*
50-70	67 (37.9)	79 (44.1)	*1.30, 0.85-1.98*
30-50	26 (14.7)	21 (11.7)	*0.77, 0.42-1.43*
<30	8 (4.5)	3 (1.7)	0.36, 0.09-1.38
Wound class**			
1	2 (1.1)	6 (3.4)	*3.03, 0.60-15.2*
2	77 (43.5)	72 (40.2)	*0.87, 0.57-1.33*
3	49 (27.7)	36 (20.1)	*0.66, 0.40-1.08*
4	46 (26.0)	57 (31.8)	*1.33, 0.84-2.11*
Previous operation***	28 (15.8)	32 (17.9)	*1.16, 0.66-2.02*
Emergent procedure****	63 (35.6)	72 (40.2)	*1.22, 0.79-1.87*
Proportion PDS SSI*****	29 (27.6)	100 (35.8)	*1.46, 0.89-2.40*

* Characteristics of patients with SSI: comparison between the Pre-test and Post-test.
** Wound class: 1 (clean), 2 (clean-contaminated), 3 (contaminated), 4 (dirty)
***Previous operation within 30 days at the same surgical site
****Not elective
***** *In the Pre-test PDS was only performed from July 2009 – Apr 2010, 76 inpatient SSIs and 29 outpatient SSIs*

(5.4%). Most superficial and deep SSIs were classified as clean-contaminated wounds (47.7% and 37.5% respectively). The organ/space SSIs were mainly classified as dirty wounds (65.4%). We observed an overall trend towards a higher incidence of SSI when progressing from clean to dirty wound procedures: 7% (clean), 24% (clean-contaminated; OR 4.0, 95% CI 2.4-6.7), 23% (contaminated; OR 1.0, 95% CI 0.7-1.2) and 32% (dirty; OR 1.6, 95% CI 1.2-2.1).

For statistical analysis, 1224 surgical procedures in the pre-test period and 932 procedures in the post-test period were examined (Table I). SSI rates of contaminated and dirty wounds were significantly higher than in clean and clean-contaminated wounds, both in the pre-test as well as in the post-test period. In the post-test period patients aged fifty and higher were more likely to get an SSI. In both periods a significant longer duration of hospitalisation was found in patients with an SSI compared to those without an SSI (mean additional length of stay (LOS): 11.5 and 5.5 days respectively).

Observation of practice at the OR was performed for twenty-three randomly selected gastrointestinal surgeries. In the pre-test period the non-compliance rate for the four measures was less than 90%. In the post-test period a significant increase of compliance with the measures regarding antibiotic prophylaxis, shaving policy and the number of door movements was observed. No increase in compliance with normothermia measures was found. Despite this increase, compliance with measures regarding the number of door movements remained low. Overall

Table III: Comparison of patients with superficial and deep/organ space SSI during hospitalization, Pre-test versus Post-test

Pre-test			Post-test			
Variables	Number with superficial SSI (n=88)	Number with deep/organ space SSI (n=89)	Number with superficial SSI (n=88)	Number with deep/organ space SSI (n=91)	OR, 95%-CI Superficial SSI	OR, 95%-CI Deep/Organ space SSI
Sex						
Female	39 (44.3)	42 (47.2)	37 (42.0)	42 (46.2)	*0.91, 0.50-1.66*	0.96, 0.53-1.72
Male	49 (55.7)	47 (52.8)	51 (58.0)	49 (53.8)	*1.10, 0.60-1.99*	*1.04, 0.58-1.87*
Age						
>70	41 (46.6)	35 (39.3)	38 (43.2)	38 (41.8)	*0.87, 0.48-1.58*	*1.11, 0.61-2.01*
50-70	38 (43.2)	29 (32.6)	39 (44.3)	40 (44.0)	*1.05, 0.58-1.90*	*1.62, 0.89-2.98*
30-50	7 (8.0)	19 (21.3)	11 (12.5)	10 (11.0)	*1.65, 0.61-4.48*	*0.46, 0.20-1.04*
<30	2 (2.3)	6 (6.7)	0	3 (3.3)	*0.49, 0.43-0.57*	*0.47, 0.11-1.95*
Wound class**						
1	0	2 (2.2)	3 (3.4)	3 (3.3)	*0.49, 0.43-0.57*	*1.48, 0.24-9.09*
2	41 (46.6)	36 (40.4)	43 (48.9)	29 (31.9)	*1.10, 0.61-1.98*	0.69, 0.37-1.27
3	29 (33.0)	20 (22.5)	23 (26.1)	13 (14.3)	*0.72, 0.38-1.38*	*0.58, 0.27-1.24*
4	17 (19.3)	29 (32.6)	51 (58.0)	42 (46.2)	*5.76, 2.92-11.34*	*1.77, 0.97-3.25*
Previous operation***	14 (15.9)	14 (15.7)	11 (12.5)	21 (23.1)	*0.76, 0.32-1.77*	*1.61, 0.76-3.40*
Emergent procedure****	28 (31.8)	35 (39.3)	33 (37.5)	39 (42.9)	*1.29, 0.69-2.40*	*1.16, 0.64-2.10*

** Comparison of superficial and deep/organ space SSI between the Pre-test and Post-test.*
*** Wound class: 1 (clean), 2 (clean-contaminated), 3 (contaminated), 4 (dirty)*
**** Previous operation within 30 days at the same surgical site*
***** Not elective*

compliance with all four preventive measures increased in the post-test period with 10% (data not shown).

Number of SSI in the Pre-test versus post-test period

The number of SSI diagnosed during hospitalisation significantly increased in time, from 14.5% in the pre-test period to 19.2% in the post-test period (OR 1.41, 95% CI 1.12-1.77, Table II). The proportion of SSIs diagnosed after discharge slightly increased in the post-test period, from 27.6% to 35.8%. The LOS of all patients (with and without an SSI) was lower in the post-test period than the pre-test period (16.2 days and 24.2 days respectively). The number of superficial SSI classified as dirty was higher in the pre-test period as compared to the post-test period (OR 5.76, 95% CI 2.92-11.34, Table III).

Results from the logistic regression analysis showed that in the pre-test period three independent variables contributed significantly to get an SSI. The strongest predictor being dirty wounds had a 23.6 times higher chance to develop an SSI than clean wounds.

In the post-test period only two of the independent variables contributed significantly to get an SSI, i.e. patients older than seventy years and wounds classified as dirty. The strongest predictor for developing an SSI was again a dirty wound class which had a 4.8-fold higher risk for developing an SSI compared to clean wounds.

Discussion

To evaluate the factors determining the effect of the VMS safety programme on the SSI rate after

gastrointestinal surgery, we compared the incidence during the pre-test period with the incidence during the post-test period. We showed that for a reliable assessment of the SSI rate, surveillance during and after hospitalisation is crucial. Surveillance only during hospitalisation would result in an underestimation of SSI, as in our study the SSI rate that was diagnosed after discharge increased from 27.6% in the pre-test period to 35.8% in the post-test period. We further confirmed that older age and contaminated or dirty wounds were risk factors for developing an SSI. However, despite a trend of increasing mean overall compliance with the measures of the infection preventive bundle, no association was found with a significant decrease in SSIs.

Similar observations were found by others monitoring their SSI rates.[28-30] Crolla *et al.*[31] implemented a comparable safety bundle and found higher compliance rates above 60% with a significant reduction of the SSI rates by 36%. However, they used a zero-tolerance approach, a warning system for personnel who did not adhere to the prevention measures.

The safety bundle of the present study had been implemented from the second half of the pre-test period. The lowest compliance rate was observed with the number of door movements (39%). Although discipline is considered important in terms of infection control, it is difficult to measure. Therefore, we decided to count the number of door movements as being representatives for discipline at the OR. The highest compliance rate was found with the shaving measures (87%), but still not reached 90% as was the primary aim of the VMS programme. Our low overall compliance with the complete safety bundle can partly be explained by the complexity of the health care environment, the difficulty to change behaviour, and insufficient priority for infection prevention.[24,32]

The strengths of our study were the surveillance of SSI by a trained independent infection control nurse over the course of the study and the definitions of SSIs as well as the duration of the surveillance period that were defined according to the criteria of the CDC. According to the literature the assessment by an independent qualified person is the most reliable method for surveillance of SSI.[33] Correlation between the assessment by a surgical team involved in the operating procedure or the patients themselves and the infection control nurse were found to be low.[33,34]

For the post discharge surveillance we assessed the surgical wounds during follow-up visits at the outpatient clinic. Using this "passive" PDS method the proportion of SSI diagnosed after discharge on the total percentage of SSI was 33.6%. This percentage is higher than the 14% as described by Medina *et al.*[14] Others who used active surveillance, which not only included the results of the patients' visits to the outpatient department, but also telephone calls to the patients and the general practitioners, found percentages of post discharge SSI up to 46%.[13] Surveillance after discharge will substantially contribute to the overall SSI rate, especially as there is an overall tendency to a decrease in hospitalisation periods resulting more often in diagnosis of an SSI after hospitalisation.

However, some limitations of this study should be mentioned, that could explain the inefficacy of our surveillance system. The wound class of 114 procedures was unknown and therefore not included in the analysis. Another limitation was that some important risk factors were not included in the regression analysis, such as operative procedure, NNIS (National Nosocomial Infections Surveillance) risk index, duration of surgery and ASA score. Instead, we used the older wound classification according to the CDC, as it also predicts the risk of SSIs based on the bacterial load at the time of the operation. We acknowledge that for a good evaluation of a surveillance method, stratification using standard risk factors is crucial to be made. Regarding our SSI rate, we only calculated an overall incidence of SSI and did not differentiate between the different surgical gastrointestinal procedures. It is to be expected that the proportion of different procedures, with different risk factors, will influence the overall incidence. Furthermore, the number of patients between the pre- and post-test differed with 24%. The lower number in the post-test period can be explained by the fact that in the post-test period patients were more intensively monitored in multidisciplinary meetings and therefore fewer patients needed to undergo an operation. Finally, the compliance with the bundle measures were based on a small number of OR observations , which might

have influenced the reliability. However, it is not very likely that increasing the number of observations will result in a higher observed compliance rate. A more stringent approach (such as a zero-tolerance) is necessary to improve the compliance and to result in an improvement of patient safety.

Large variation, from 5% to 39%, in the incidence of SSI has been reported.[19,35] Our overall SSI rate was 22.5%. Narong *et al.* found an overall SSI rate of 5.8%.[36] However, the authors missed some infections, especially in patients who were discharged early and lost to follow-up. In the study by Suljagic *et al*., the SSI rates ranged from 0% to 14.3%.[5] Inter-study variation is further explained by different types of hospitals a study is based on, e.g. tertiary or local community hospitals,[37] and definitions of surgical site infections that are used by researchers.[38-40] Some authors diagnosed an SSI only when the bacteriological culture of the wound was positive[41], whereas we used the CDC criteria.[8]

There is also variation between studies in reported incidence of SSI within the different wound classes. The National Nosocomial Infection Surveillance (NNIS) system reported an incidence of 2.1% for clean wounds, 3.3% for clean-contaminated, 6.4% for contaminated and 7.1% for dirty wounds.[8] Lichtenfels *et al.* showed incidences of 1.5-2.9% for clean wounds, 2.8-7.7% for clean and clean-contaminated, 6.4-15.2% for contaminated, and 7.1-40% for dirty wounds.[42] Similar figures were also described by others.[5,43,44] Likewise, we found a progressively higher incidence of SSI from clean to dirty wound procedures.

In conclusion, with this study we identified factors for the (in-)efficacy of a surveillance method, as it is difficult to predict an effect on SSI after gastrointestinal surgery in our academic hospital. We tried to point out that documentation of certain important factors is required and that compliance with safety measures is ensured to consume considerable resources that might be more effectively directed to other quality initiatives. Despite a slight increase of compliance with the measures of the VMS safety programme, the number of SSI did not show a reduction over time. Also, the too short period after implementation might have contributed to the lack of observed effect. Still, interventions to improve compliance with infection prevention guidelines should be enhanced, since other studies have shown a reduction of SSI rate after bundling interventions into a programme and thereby an improvement in the compliance of healthcare workers.[31,45,46] Most important is that resources and expenditures should be well considered according to the setting.

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