








Effect of the number of door openings in the operating room on surgical site infections: individual-patient data meta-analysis

Hannah Groenen^{1,2,3}, Hasti Jalalzadeh^{1,2,3}, Nathan Bontekoning^{1,2,3}, Antoinette A. A. Bediako-Bowan^{4,5}, Dennis R. Buis^{3,6}, Yasmine E. M. Dreissen^{3,6}, Anne M. Eskes^{1,7}, Jon H. M. Goosen^{3,8}, Mingyang L. Gray⁹, Mitchel Griekspoor^{3,10}, Brian L. Hollenbeck¹¹, Frank F. A. Ijpmma^{3,12}, Maarten J. van der Laan^{3,13} , Appiah-Korang Labi¹⁴ , Nina M. C. Mathijssen^{15,16}, Brett A. Miles¹⁷, Kåre Mølbak^{18,19} , Ricardo G. Orsini²⁰, Frederik J. Prakken²¹, Roald R. Schaad^{3,22,23}, Patrique Segers^{3,24} , Marius A. Stauning^{25,26}, Wil C. van der Zwet^{3,27}, Stijn W. de Jonge^{1,2} , Niels Wolfhagen^{1,2,3} , Gerjon Hannink^{28,†} and Marja A. Boermeester^{1,2,3,††} 

¹Department of Surgery, Amsterdam UMC location University of Amsterdam, Amsterdam, the Netherlands

²Amsterdam Gastroenterology Endocrinology and Metabolism, Amsterdam, the Netherlands

³Dutch National Guideline Group for Prevention of Postoperative Surgical Site Infections, the Netherlands

⁴Department of Surgery, University of Ghana Medical School, University of Ghana, Accra, Ghana

⁵Department of Surgery, Korle Bu Teaching Hospital, Accra, Ghana

⁶Department of Neurosurgery, Amsterdam UMC location University of Amsterdam, Amsterdam, the Netherlands

⁷Amsterdam Public Health, Amsterdam, the Netherlands

⁸Department of Orthopedic Surgery, Sint Maartenskliniek, Ubbergen, the Netherlands

⁹Department of Otolaryngology, Icahn School of Medicine at Mount Sinai, New York, New York, USA

¹⁰Dutch Association of Medical Specialists, Utrecht, the Netherlands

¹¹New England Baptist Hospital, Boston, Massachusetts, USA

¹²Department of Surgery, Division of Trauma Surgery, University Medical Centre Groningen, Groningen, the Netherlands

¹³Department of Surgery, Division of Vascular Surgery, University Medical Centre Groningen, Groningen, the Netherlands

¹⁴Department of Medical Microbiology, University of Ghana Medical School, Accra, Ghana

¹⁵Reinier Haga Orthopedisch Centrum, Zoetermeer, the Netherlands

¹⁶Department of Orthopaedics, Reinier de Graaf Groep, Delft, the Netherlands

¹⁷Department of Otolaryngology Head and Neck Surgery, Northwell Cancer Institute, Northwell Health, New York, New York, USA

¹⁸Department of Veterinary and Animal Science, University of Copenhagen, Copenhagen, Denmark

¹⁹Division of Infectious Disease Preparedness, Statens Serum Institut, Copenhagen, Denmark

²⁰Department of Surgery, Maastricht University Medical Centre+, Maastricht, the Netherlands

*Correspondence to: Marja A. Boermeester, Department of Surgery, Amsterdam UMC location University of Amsterdam, Meibergdreef 9, 1105 AZ Amsterdam, the Netherlands (e-mail: m.a.boermeester@amsterdamumc.nl)

†Joint senior authors; these authors contributed equally to this article

Abstract

Background: The effect of door openings in the operating room on surgical site infections remains a controversial topic and has led to strict door-opening policies. The aim of this individual-patient data meta-analysis was to evaluate the effect of the number of door openings in the operating room on surgical site infection.

Methods: MEDLINE (PubMed) and Embase (Ovid) were searched up to 2 December 2024. Authors with individual-patient data on surgical site infections and door openings were invited to collaborate. A one-stage individual-patient data meta-analysis accounting for heterogeneity was performed to examine effects overall and in subgroup analyses (wound class, implant surgery, and income level). The primary outcome was surgical site infection. The risk of bias and Grading of Recommendations, Assessment, Development, and Evaluation framework were used to determine the certainty of evidence.

Results: Individual-patient data from 8 observational studies, encompassing 4412 patients, revealed a 6.0% incidence of surgical site infection. Each extra door opening per hour was associated with increased risk of surgical site infection (odds ratio 1.012, 95% c.i. 1.005 to 1.019; $\tau^2 = 0.095$; very low certainty of evidence). This means that, for example, at a baseline infection risk of 2%, approximately 35 additional door openings per hour per surgery would be needed to cause one additional surgical site infection per 100 patients. In subgroup analyses, no differences in effect were found. The cumulative effect was more pronounced in patients with a high baseline risk of surgical site infection.

Conclusion: Very low certainty of evidence suggests a marginal increase in the risk of surgical site infection for each additional door opening per hour. Although the relative effect is minimal, the cumulative effect has an impact on patients with a higher baseline surgical site infection risk more than others. However, the certainty of the available evidence is too low and the relative effect on clinical outcomes too small to support a rigorous zero door-openings policy to reduce rates of surgical site infections.

Received: September 09, 2024. Revised: January 10, 2025. Accepted: February 27, 2025

© The Author(s) 2025. Published by Oxford University Press on behalf of BJS Foundation Ltd.

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (<https://creativecommons.org/licenses/by-nc/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact reprints@oup.com for reprints and translation rights for reprints. All other permissions can be obtained through our RightsLink service via the Permissions link on the article page on our site—for further information please contact journals.permissions@oup.com.

²¹Department of Surgery, Gelre Hospital, Apeldoorn, the Netherlands²²Department of Anaesthesiology, Leiden University Medical Centre, Leiden, the Netherlands²³Dutch Association of Anaesthesiology (NVA), the Netherlands²⁴Department of Cardiothoracic Surgery, Maastricht University Medical Centre+, Maastricht, the Netherlands²⁵Department of Clinical Microbiology, Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark²⁶Centre for Translational Medicine and Parasitology, Department of Immunology and Microbiology, University of Copenhagen, Denmark²⁷Department of Medical Microbiology, Infectious Diseases and Infection Prevention, Maastricht University Medical Centre+, Maastricht, the Netherlands²⁸Department of Medical Imaging, Radboud University Medical Centre, Nijmegen, the Netherlands

Introduction

Surgical site infections (SSIs) are frequent healthcare-associated infections, significantly contributing to postoperative morbidity, mortality, and increased healthcare costs^{1,2}. Minimizing door openings during surgery to prevent SSI is broadly recommended in clinical guidelines and SSI prevention care bundles^{3–8}. Among others, the National Institute for Health and Care Excellence⁶, the Healthcare Infection Society⁷, the European Society of Clinical Microbiology and Infectious Diseases⁷, and the Centers for Disease Control and Prevention (CDC)⁸ all recommend limiting door openings during surgery. This recommendation arises from the observed association between door openings and increased intraoperative microbial air contamination, as well as that between intraoperative microbial air contamination and SSI^{6–9}. However, conclusive clinical data examining the direct effect of door openings during surgery on SSI rates is scarce, and existing studies are predominantly retrospective or observational in nature. Notably, the World Health Organization (WHO)^{10,11} and the updated CDC guideline do not address this topic¹². Some studies^{13–16} have shown that laminar airflow reduces air contamination compared with turbulent ventilation. However, a recent systematic review and meta-analysis¹⁷ did not find that laminar airflow reduced SSI rates compared with turbulent ventilation.

With the lack of randomized clinical trials (RCTs) and substantial heterogeneity between studies found by previous reviews, an individual-patient data (IPD) meta-analysis (IPDMA) enables the use of all available data. An IPDMA uses raw individual-study participant-level data from the included studies, standardizes analysis to account for possible confounders for maximum statistical power, and enables detailed subgroup analyses. It seems particularly relevant to examine the potential effect of door openings in clean surgeries and implant operations, for which the association between door openings and SSI is a frequent subject of debate. This has led to a rigorous zero door-openings policy in some settings. Although exogenous contamination is believed to play a significant role in clean surgeries and operations of long duration, studies in these specialties mostly show associations with surrogates of SSI (such as increased wound contamination), rather than direct evidence of an increase in clinically relevant SSI rates^{18,19}. In implant surgeries, SSI poses additional concerns owing to the severe consequences of prosthetic infections, particularly those caused by biofilm formation on the implant²⁰.

This study presents a systematic review, IPDMA, and Grading of Recommendations Assessment Development and Evaluation (GRADE) assessment of the available evidence. The aim of the study was to investigate the potential effect of door openings in the operating room on the incidence of SSI.

Methods

Study registration

This study adhered to the PRISMA statement. The study protocol was registered with PROSPERO (CRD42022309958).

Search strategy

A systematic review and IPDMA were conducted to evaluate the effect of the number of door openings in the operating room on SSI in any type of surgery. MEDLINE (PubMed) and Embase (Ovid) databases were searched for eligible studies from inception to 2 December 2024. Additional papers were identified by backward and forward citation tracking. Moreover, all collaborators were asked whether they were aware of any other eligible studies. The complete search strategy is presented in the [supplementary methods](#).

Selection criteria

Prospective, retrospective, and randomized studies with available IPD on SSI, the number of door openings in the operating room, and procedure duration were included. In the case of studies with a before–after cohort design that investigated the number of door openings as part of a bundle of SSI prevention measures, the cohorts in the different phases were included as separate studies. Cohorts were excluded if a significant proportion of the standard SSI prevention measures, such as appropriate systemic antibiotic prophylaxis, hair removal, skin preparation, or surgical hand preparation, were not applied. These decisions were made in consultation with a senior author (M.A.B.). The analysis included only patients for whom data regarding IPD on SSI, the number of door openings in the operating room, and procedure duration were available. Unpublished and non-human studies, and studies performed outside the operating room were excluded. Furthermore, studies were excluded if the authors were unwilling or unable to contribute. There were no restrictions on the year or language of publication.

Two researchers (H.G., H.J.) individually performed title, abstract, and full-text screening, with disagreements resolved by consulting the senior author (M.A.B.).

Data extraction and validation

Corresponding authors from eligible studies were contacted. If no response was received, the co-authors were contacted. When the study met the inclusion criteria and IPD were available, the principal investigators were subsequently invited to participate in the IPDMA study group. An online collaborative meeting was organized to discuss the study protocol and the set of data items with definitions. All parties were asked to sign a data transfer agreement and to anonymize the IPD before data transfer. To guarantee data integrity, all IPD were examined for missing values or invalidities and compared with published data. In the event of potential discrepancies, the principal investigators were contacted.

Quality assessment

The risk of bias for the outcome SSI was assessed by two reviewers (H.G. and H.J.) independently using the Risk of Bias in Non-randomized Studies—of Interventions (ROBINS-I) tool for non-randomized studies²¹. The domain 'bias due to deviations from intended interventions' was not scored for studies that did

not compare interventions. Disagreements were resolved by discussion or by consulting the senior authors (M.A.B. and G.H.).

Specification of outcomes and effect measures

The primary outcome was the incidence of SSI, as defined by the authors of the original publication. No secondary outcome was analysed.

Missing data

Multilevel imputation of missing data was performed at the participant level using multiple imputation by chained equations for all studies simultaneously^{22,23}. A detailed description of the handling of missing data can be found in [supplementary methods](#), with an overview of missing data presented in [Table S1](#).

Data analysis

A one-stage meta-analysis of IPD using a random-effects framework was undertaken to determine the effect of the number of door openings per hour on SSI. Between-study differences were accounted for with mixed-effects models, with a term for random intercept and random slope for the effect of door openings per study. In addition, the relationship between the number of door openings per hour and SSI was evaluated by comparing a simple linear model with a model using restricted cubic splines.

The number of door openings was examined as a continuous variable. All analyses were adjusted for age, sex, body mass index (BMI), smoking, diabetes, the use of appropriate systemic antibiotic prophylaxis, American Society of Anesthesiologists (ASA) physical status classification, the level of wound contamination according to the CDC criteria⁸, emergency surgery, procedure duration, income level of the country where the study was conducted, and implantation of a foreign body. Confounders to be controlled for were identified using directed acyclic graphs, as shown in [Fig. S1](#)^{24,25}. Results are presented as an odds ratio (OR) with corresponding 95% confidence interval (c.i.). A two-sided $P < 0.050$ was considered statistically significant, and the results of all statistical tests are interpreted in context²⁶. Heterogeneity was assessed by the τ^2 statistic. Trial-level co-variables were accounted for in the one-step meta-analysis. An unadjusted two-step meta-analysis was also carried out.

To explore heterogeneity and test for potential effect modification, a prespecified subgroup analysis was performed based on the level of wound contamination⁸, and a non-planned subgroup analysis was conducted based on implantation of a foreign body. There may be challenges in low- and lower-middle-income countries in maintaining optimal adherence to key measures for the prevention of SSI that are considered standard in perioperative clinical care in high-income countries. Therefore, a non-planned subgroup analysis was done based on income level of the country where the study was conducted (high and upper-middle versus lower-middle and low), based on World Bank data²⁷. Furthermore, a planned sensitivity analysis was conducted after exclusion of studies with serious or critical risk of bias based on the ROBINS-I tool²¹.

Evidence appraisal

The GRADE methodology was used to evaluate the certainty of evidence using a minimally contextualized approach on the following domains: risk of bias, inconsistency, indirectness, imprecision, and publication bias²⁸. Inconsistency was assessed using τ^2 statistics. Imprecision was evaluated taking the

minimally important difference into account and, when the relative effect was large, the optimal information size approach was used by calculating the ratio of the upper to the lower boundary of the c.i. with a threshold for downgrading of 2.5^{29,30}. A more detailed description of the GRADE methodology can be found in the [supplementary material](#).

All analyses were done using R version 4.2.1 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Study selection

The initial search yielded 302 records after duplicates had been removed. Five articles were identified from citation tracking. After screening 81 full-text reports, the authors of 18 studies were contacted for IPD. Two studies^{31,32}, with 72 and 50 participants, respectively, that were identified during an update of the literature search on 2 December 2024 were not contacted for IPD retrieval because they were identified (and published) after the IPD meta-analysis had been completed. As a result, these two additional but small studies were included only in the systematic review and not in the IPDMA: the two studies would have increased the total number of patients by only 1.0% (from 4412 to 4534) and the number of SSI events also by 1.0% (from 265 to 268). Attempts to contact the authors of four studies were unsuccessful; three of these studies^{33–35} did not mention SSI data in their papers, and the fourth³⁶ dated back to 1994. The authors of five studies responded, but lacked data on SSI^{18,37–39} or were not able to share IPD (688 participants)⁴⁰. Finally, the principal investigator of one study⁴¹ responded initially, but later withdrew from collaboration without further explanation (3060 participants). Thus, the authors of 8 eligible studies^{42–49} with a potential total of 8230 patients were willing to participate in this IPDMA and provided IPD. [Figure 1](#) shows the flow chart of study and participant inclusion in the IPDMA; [Table S2](#) provides reasons for exclusion after full-text review.

Study characteristics

The characteristics of the eight studies included in the IPDMA are presented in [Table S3](#). Seven prospective comparative cohort studies^{42,44–49} and one prospective cohort study⁴³ were identified. One before–after cohort study⁴² was incorporated, implementing or strengthening multiple SSI preventive measures, involving three phases: baseline, follow-up, and sustainability. The baseline phase in that study was excluded because the authors did not adhere to the most recent standards for perioperative clinical care in a significant number of patients. The follow-up and sustainability phases were included as two separate studies. Another study was published in two separate articles^{9,49}, with one article describing surgical environment and the other SSI follow-up. Data from these studies^{9,49} were compiled into a single data set and included in the analysis and risk-of-bias assessment as a single study. One study⁴⁵ did not provide information on the number of door openings in the article; however, IPD were available for a significant proportion of patients. In addition, two studies^{46,47} did not include SSI data in the published articles, but the authors were able to share IPD on SSI outcomes. Three studies^{9,42,44} were conducted in lower-middle- or low-income countries. Primary outcomes of the original articles varied, encompassing SSI (4), colony-forming units in the air (3), and operative workflow and efficiency (1) ([Table S3](#)). Furthermore, the median number of door openings per

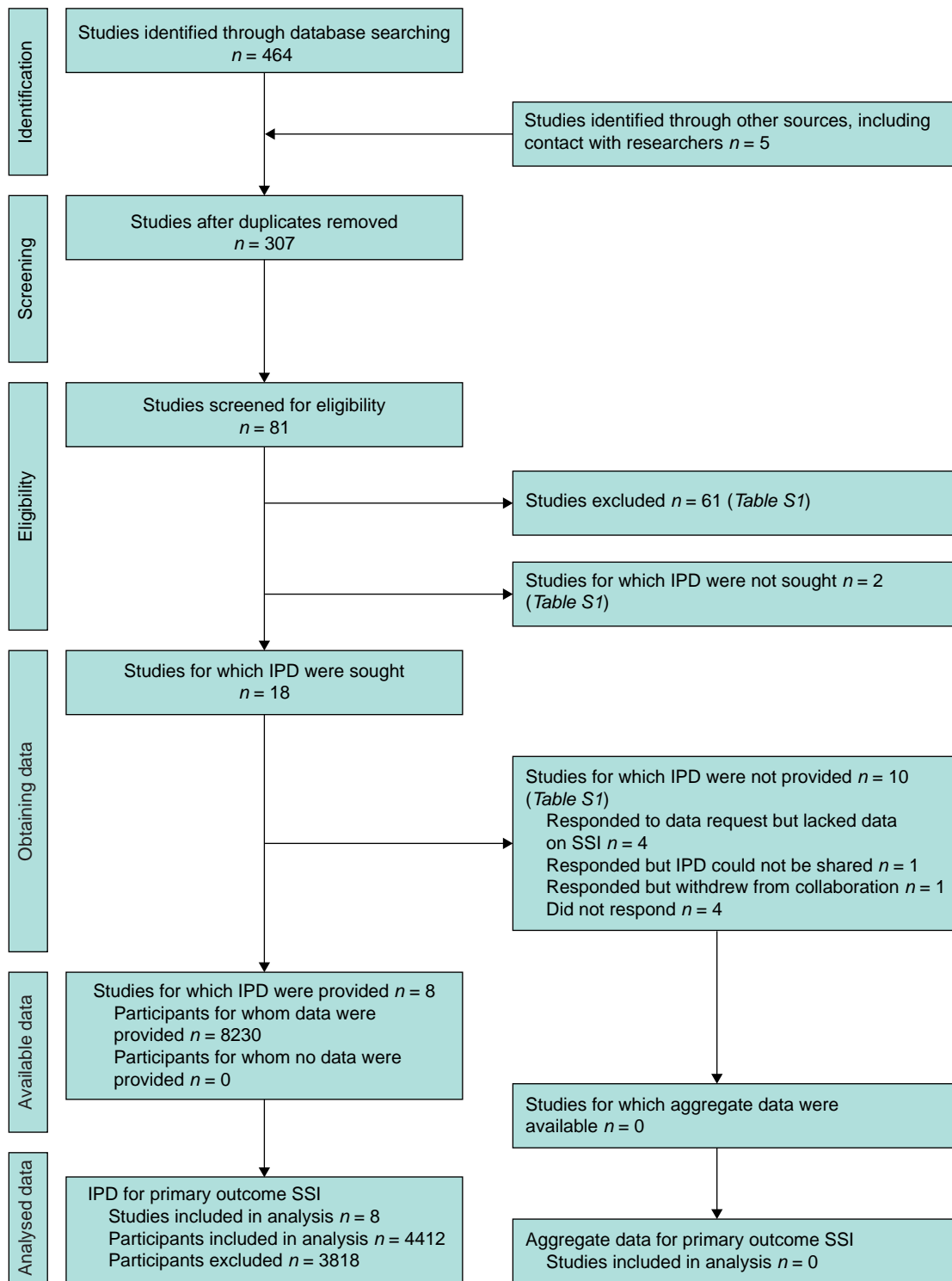


Fig. 1 PRISMA-IPD flow diagram

PRISMA-IPD, Preferred Reporting Items for Systematic Reviews and Meta-Analysis of Individual Patient Data; IPD, individual-patient data; SSI, surgical site infection. ©Reproduced with permission of the PRISMA IPD Group, which encourages sharing and reuse for non-commercial purposes.

hour (measured between incision to closure), type of surgery, and the level of wound contamination differed between studies (Table S3). The characteristics of the four studies that could not be included in the IPDMA because of challenges in IPD retrieval are presented in Table S4.

Quality assessment

The risk-of-bias assessment of the individual studies for the outcome SSI is presented in Table S5. Using the ROBINS-I tool²¹, four studies^{45,46,48,49} were scored as having a moderate risk of bias. Another four studies were rated as having a serious risk of

Table 1 Baseline and surgical characteristics of participants included in the primary individual-patient data analysis

	Total (n = 4412)	SSI (n = 265)	No SSI (n = 4147)
Age (years), median (i.q.r.)	43.0 (30.0–60.0)	50.5 (35.0–64.0)	43.0 (30.0–60.0)
Missing	76 (1.7)	1 (0.4)	75 (1.8)
Sex			
Male	1549 (35.1)	114 (43.0)	1435 (34.6)
Female	2790 (63.2)	150 (56.6)	2640 (63.7)
Missing	73 (1.7)	1 (0.4)	72 (1.7)
ASA grade			
I	1830 (41.5)	75 (28.3)	1755 (42.3)
II	1815 (41.1)	125 (47.2)	1690 (40.8)
III	557 (12.6)	54 (20.4)	503 (12.1)
IV–V	70 (1.6)	7 (2.6)	63 (1.5)
Missing	140 (3.2)	4 (1.5)	136 (3.3)
BMI (kg/m²), median (i.q.r.)	25.1 (22.5–28.3)	26.3 (22.7–29.8)	24.9 (22.5–28.1)
Missing	3197 (72.5)	140 (52.8)	3057 (73.7)
Smoking status			
Active smoking	363 (8.2)	32 (12.1)	331 (8.0)
Not smoking	852 (19.3)	98 (37.0)	754 (18.2)
Missing	3197 (72.5)	135 (50.9)	3062 (73.8)
Diabetes			
Yes	117 (2.7)	23 (8.7)	94 (2.3)
No	1201 (27.2)	113 (42.6)	1088 (26.2)
Missing	3094 (70.1)	129 (48.7)	2965 (71.5)
Appropriate systemic antibiotic prophylaxis			
Yes	3858 (87.4)	240 (90.6)	3618 (87.2)
No	89 (2.0)	7 (2.6)	82 (2.0)
Not indicated	280 (6.3)	13 (4.9)	267 (6.4)
Missing	185 (4.2)	5 (1.9)	180 (4.3)
Implantation of a foreign body			
Yes	693 (15.7)	39 (14.7)	654 (15.8)
No	3373 (76.5)	203 (76.6)	3170 (76.4)
Missing	346 (7.8)	23 (8.7)	323 (7.8)
Procedure category			
Abdominal	2351 (54.4)	183 (69.1)	2168 (53.4)
Vascular	164 (3.8)	12 (4.5)	152 (3.8)
Trauma and/or orthopaedic	691 (16.0)	28 (10.6)	663 (16.3)
Head and neck	274 (6.3)	7 (2.6)	267 (6.6)
Breast	366 (8.5)	15 (5.7)	351 (8.7)
Gynaecology	215 (5.0)	7 (2.6)	208 (5.1)
Hernia repair	226 (5.2)	10 (3.8)	216 (5.3)
Other	36 (0.8)	3 (1.1)	33 (0.8)
Missing data	89 (2.1)	0 (0.0)	89 (2.1)
Emergency surgery			
Yes	1222 (27.7)	82 (30.9)	1140 (27.5)
No	3133 (71.0)	183 (69.1)	2950 (71.1)
Missing	57 (1.3)	0 (0.0)	57 (1.4)
Contamination level*			
Clean	1828 (41.4)	64 (24.2)	1764 (42.5)
Non-clean	2525 (57.2)	201 (75.8)	2324 (56.0)
Missing	59 (1.3)	0 (0.0)	59 (1.4)
No. of door openings per hour, median (i.q.r.)	13.9 (3.4–31.7)	22.4 (6.1–46.7)	13.1 (3.3–31.0)
Missing	0 (0)	0 (0)	0 (0)
Procedure duration (min), median (i.q.r.)	75 (49–120)	107 (65–164)	73 (48–119)
Missing	0 (0)	0 (0)	0 (0)

Values are n (%) unless otherwise stated. *According to the Centers for Disease Control and Prevention wound classification. SSI, surgical site infection; i.q.r., interquartile range; ASA, American Association of Anesthesiologists; BMI, body mass index.

bias, owing to missing data⁴², confounding^{43,47}, or selection of reported results⁴⁴. The IPD provided additional insights into confounding and selection of the reported results, resulting in the risk of bias being reduced from serious to moderate for three studies^{43,44,47}.

Participant selection

All 1605 patients from the baseline phase of the before–after cohort study⁴² were excluded because a significant proportion of the standard SSI prevention measures, such as systemic antibiotic prophylaxis, were not achieved. Furthermore, an

additional 2213 patients were excluded because IPD on SSI, procedure duration, or door openings were missing, resulting in the inclusion of 4412 patients in the IPDMA.

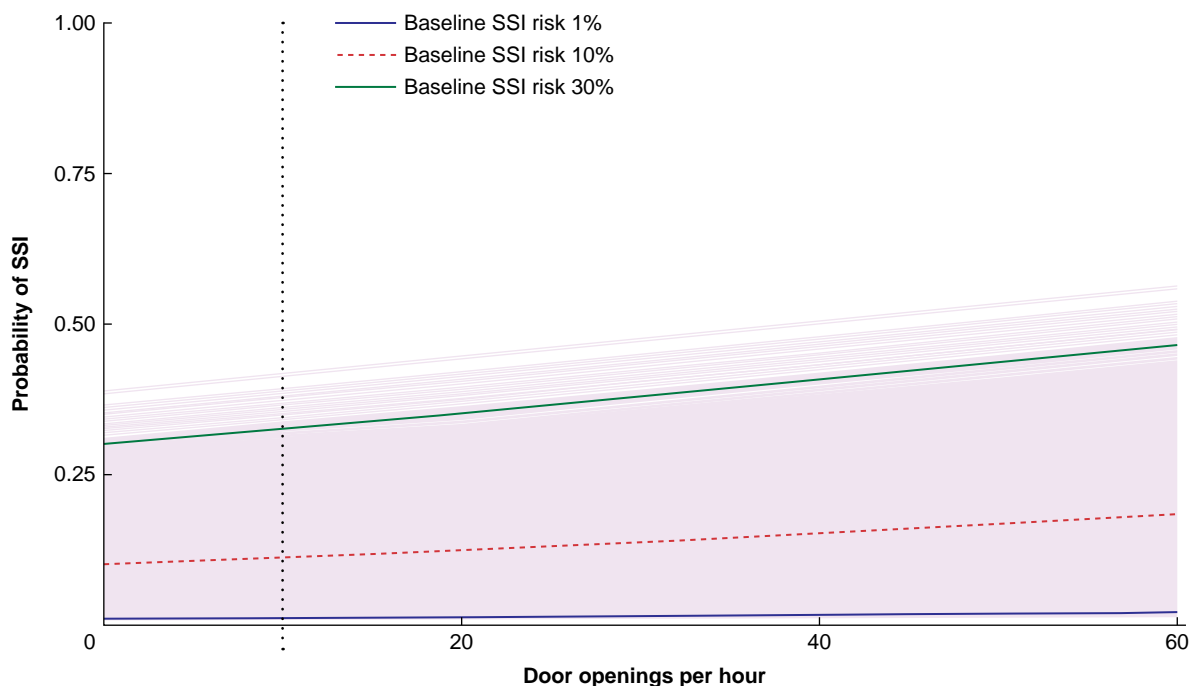
Results of syntheses

The overall incidence of SSI was 6.0% and the median number of door openings per hour was 13.9 (interquartile range 3.4–31.7) (Table 1). In addition, there was an increased duration of surgery and a higher number of door openings per hour in the SSI group compared with the non-SSI group (Table 1).

Table 2 Effect sizes of door openings and door openings–variable interactions (unadjusted and adjusted results) on surgical site infections

	Unadjusted analysis		Adjusted analysis*	
	Odds ratio	P	Odds ratio	P
Per one additional door opening per hour	1.009 (1.002, 1.015)	0.010	1.012 (1.005, 1.019)	< 0.001

Values in parentheses are 95% confidence intervals. Results are for a one-step meta-analysis of individual-patient data using a random-effects framework to test the effect of the number of door openings per hour on surgical site infections. *Variables included in the model were: age, sex, body mass index, smoking, diabetes, the use of appropriate systemic antibiotic prophylaxis, American Association of Anesthesiologists grade, level of wound contamination according to Centers for Disease Control and Prevention criteria, emergency surgery, procedure duration, income level of the country where the study was conducted, implantation of a foreign body, and study as a random effect.

**Fig. 2** Effect of door openings on the rate of surgical site infections

The plot shows the effect of the number of door openings per hour on the rate of surgical site infections (SSIs) from a one-step meta-analysis of individual-patient data using a random-effects framework, and corrected for confounders. The pink lines show the absolute increase in SSI risk for every extra door opening per hour (odds ratio 1.012, 95% c.i. 1.005 to 1.019) for every possible scenario in the model. The absolute increase in SSI risk is shown for three baseline SSI risks: 1, 10, and 30%. Variables included in the model were: age, sex, body mass index, smoking, diabetes, the use of appropriate systemic antibiotic prophylaxis, American Association of Anesthesiologists grade, level of wound contamination according to the Centers for Disease Control and Prevention criteria, emergency surgery, procedure duration, income level of the country where the study was conducted, implantation of a foreign body, and study as a random effect. The vertical dotted line represents the commonly recommended threshold of 10 door openings per hour, as often suggested in guidelines^{5–8}.

Restricted cubic splines did not benefit model fit. Therefore, the non-spline approach was used. Effect estimates with corresponding 95% confidence intervals for the primary outcome are presented in Table 2. After adjustment for confounding, a difference in SSI risk was found for every extra door opening per hour (OR 1.012, 95% c.i. 1.005 to 1.019). This means that, for example, at a baseline infection risk of 2%, approximately 35 additional door openings per hour per surgery would be needed to cause one additional surgical site infection per 100 patients. The cumulative effect of door openings was more pronounced in patients with a high baseline risk of SSI than in patients with a low baseline risk of SSI (Fig. 2). Unadjusted two-step meta-analysis is presented in Fig. S2 (OR 1.007, 0.994 to 1.019). Low between-study heterogeneity was found ($\tau^2 = 0.095$).

Subgroup and sensitivity analyses

The SSI incidence was 3.5% in clean surgeries (64 of 1828 patients) and 8.0% in non-clean operations (201 of 2525 patients). The association between the number of door openings per hour and

SSI did not differ between non-clean and clean surgeries (OR interaction term 0.996, 95% c.i. 0.982 to 1.009). For implant surgeries, which consisted of 298 clean (43.0%) and 395 non-clean (57.0%) operations, the SSI incidence was 5.6% (39 of 693 patients), compared with an incidence of 6.0% for non-implant surgery (203 of 3373 patients). Within clean implant surgeries, the types of procedure varied, and included 188 abdominal operations (27.1%), 27 vascular procedures (3.9%), 205 trauma and/or orthopaedic surgeries (29.6%), two head and neck operations (0.3%), 183 gynaecological procedures (26.4%), 78 hernia repairs (11.3%), and six surgeries classified as other (0.9%). Consequently, associations between the number of door openings per hour and SSI were comparable for implant and non-implant surgeries (OR interaction term 0.980, 0.952 to 1.008). Regarding income levels, the incidence of SSI was 8.1% in high-income countries (101 of 1251 patients) and 5.2% in low-income countries (164 of 3161 patients). The association between the number of door openings and SSI also did not vary between high- and low-income countries (OR interaction term 0.991, 0.979 to 1.004).

Table 3 GRADE assessment for outcome surgical site infections

Certainty assessment							Certainty
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	
8	Observational studies	Not serious	None	None	None	Publication bias suspected	⊕○○○ Very low

GRADE, Grading of Recommendations Assessment, Development, and Evaluation.

A sensitivity analysis excluding studies at serious or critical risk of bias, comprising 1726 patients *versus* 4412 patients in the main analysis, revealed comparable results to the main analysis (OR 1.012, 1.002 to 1.022).

Certainty of evidence

The starting certainty of evidence was low, because all included studies had an observational design. One study had a serious risk of bias, but sensitivity analysis excluding this study revealed comparable results to those of the main analysis, so downgrading for risk of bias was not necessary. Furthermore, no downgrade for inconsistency was needed ($\tau^2 = 0.095$). All studies provided IPD on the primary outcome SSI, so indirectness was not serious^{50,51}. There was no imprecision, because the confidence intervals did not overlap thresholds of interest, and the ratio of the upper and the lower boundary of the confidence intervals was < 2.5 ³⁰. Previous research has indicated that publication bias is potentially more significant in observational studies than in RCTs^{52,53}. Therefore, the risk of publication bias was considered substantial because of the observational design of the included studies and the fact that data were often collected for previous study. Overall, the certainty of evidence for the primary outcome was downgraded by one level, resulting in a very low overall certainty of evidence for SSI (Table 3 and Table S6).

Discussion

This systematic review and IPDMA examined the effect of the number of door openings in the operating room on SSI in any type of surgery. The findings indicate, with very low certainty of evidence, that each additional door opening per hour is associated with an increase in the risk of SSI. Although the relative effect is minimal, the cumulative impact may be clinically more noteworthy in patients with a higher baseline risk of SSI owing to patient- or surgery-related factors.

A restriction on the maximum number of door openings in the operating room to reduce SSI risk has been a controversial topic for many decades⁵⁴. Restricting the maximum number of door openings is incorporated into guidelines and care bundles on the prevention of SSI, even though the clinical evidence to support this recommendation is limited^{3-8,19,55}. The underlying assumption about the impact of door openings on SSI risk is grounded in the theory that door openings disrupt airflow in the operating room, potentially introducing contaminants into the operating field and wounds. To date, available studies have presented low-quality clinical evidence with inconclusive results.

The IPDMA approach is necessary because of the substantial heterogeneity of earlier studies on this topic and the lack of clinical data. All the available evidence was aggregated by using raw individual-level data from original studies, which allowed the inclusion of individual patients and unpublished data, the performance of detailed subgroup analyses, and standardization of the analysis for maximum statistical power.

Conducting subgroup analysis based on wound contamination levels is crucial, because wound contamination is an important predictive factor for SSI. Clean and implant surgeries, in particular, have been key topics of ongoing debate because of the association between the number of door openings in the operating room and surrogates of SSI^{18,19,47}. Moreover, SSI presents additional concerns in implant surgeries due to the potential for the formation of implant biofilm²⁰. This has prompted the implementation of strict zero door-openings policies in some settings. Although previous studies have frequently demonstrated a significant association between door openings and increased bacterial air or wound contamination¹⁹, it is important to emphasize that the present study focused specifically on the clinical outcome of SSI. Consequently, associations between the number of door openings per hour and SSI were comparable among wound contamination levels or implant status.

The limitations of this study stem primarily from the nature of the individual studies and their inherent clinical heterogeneity. Although IPDMA allows more detailed adjustment for confounders, the possibility remains of residual confounding owing to unmeasured or imperfectly measured variables, which may not be consistently available across all studies. Multiple imputation was used to increase precision and avoid bias during the analysis²². Still, the high rate of unavailable data may have limited the accuracy of the imputed values, possibly affecting the findings to some extent. However, even with a high percentage of missing data, multiple imputation has been shown to result in unbiased estimates if the missing data are missing at random and the imputation model is well specified^{22,56}.

It is worth noting that studies conducted in lower-income countries may not strictly adhere to the most recent standards for perioperative clinical care. Therefore, a subgroup analysis was performed based on country income level, which revealed no differences in the association between the number of door openings per hour and SSI for high-income countries compared with low-income countries. Furthermore, several studies did not report a definition for SSI or used definitions other than the diagnostic criteria outlined by the CDC⁸.

After obtaining IPD, the risk of bias for most studies initially assessed as having a serious risk of bias was fortunately reduced to a moderate risk, thereby enhancing the robustness of the findings. However, one study remained at serious risk of bias⁴². Notably, a sensitivity analysis excluding that study yielded results comparable to those of the main analysis, further supporting the reliability of the conclusions.

Finally, IPD was not retrieved from four eligible studies, resulting in their inclusion in the systematic review only, and not in the IPDMA. These studies reported conflicting results. One of these⁴¹ was a two-phase neurosurgery study including 3060 patients, whose authors unexpectedly withdrew from the collaboration without providing a clear reason. The authors of that study concluded that the potential benefit of restricting operating room traffic in reducing SSI rates is minimal at best,

and possibly non-existent. Another study⁴⁰ in cardiac surgery, which included 688 patients, was unable to share IPD. That study reported an association between an increased mean door opening frequency and a higher risk of SSI in both univariable and multivariable analyses; however, some methodological weaknesses, such as the possibility of unmeasured confounders, may have influenced these results⁴⁰. Two studies identified in the updated search were not contacted for IPD retrieval because they were identified (and published) after the IPD meta-analysis had been completed. One orthopaedic study³¹ with 72 patients demonstrated that implementing an informational sign reduced the number of door openings. The study suggested that this reduction also influenced SSI rates, because fewer SSIs occurred with the sign in place. However, it did not present data on the number of door openings per SSI patient, making it impossible to draw conclusions about the relationship between door openings and SSI³¹. The other study³², a paediatric neurosurgery investigation involving 50 patients, quantified foot traffic but found no cases of SSI.

Interestingly, door openings in the operating room may also have a potential non-infectious impact¹⁹. Some studies have suggested that a decrease in door openings increases attention in the operating room³⁸. In addition, door openings are believed to be a surrogate marker for operating room discipline and hygiene. Given that lapses in operating room discipline have been strongly associated with the occurrence of SSI⁵⁷, decreasing the number of door openings could possibly be of value^{38,58}.

This IPDMA presents the first cumulative clinical data on the effect of the number of door openings in the operating room on SSI in any type of surgery. A marginal increase in SSI risk for each additional door opening per hour was found, which may affect patients with a higher baseline SSI risk more than others. However, the certainty of the available evidence is too low and the relative effect on clinical outcomes too small to support a rigorous zero door-openings policy to reduce SSI rates.

Funding

This systematic review was funded by the Dutch Stichting Kwaliteitsgelden Medisch Specialisten (SKMS, Foundation Quality Funds Medical Specialists).

Acknowledgements

The authors thank B. Allegranzi (WHO Infection Prevention and Control Global Unit) for providing data for this IPDMA; H. Graveland (Dutch National Guideline Group for Prevention of Postoperative Surgical Site Infections) for critical advice; and all the authors, co-authors, and collaborators in each study included in this IPDMA.

Author contributions

Hannah Groenen (Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Software, Validation, Visualization, Writing—original draft), Hasti Jalalzadeh (Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Software, Validation, Writing—review & editing), Nathan Bontekoning (Writing—review & editing), Antoinette Bediako-Bowan (Resources, Writing—review & editing), Dennis Buis (Writing—review & editing), Yasmine Dreissen (Writing—review & editing), Anne Eskes (Writing—review & editing), Jon

Goosen (Writing—review & editing), Mingyang Gray (Resources, Writing—review & editing), Mitchel Griekspoor (Writing—review & editing), Brian Hollenbeck (Resources, Writing—review & editing), Frank IJpma (Writing—review & editing), Maarten van der Laan (Writing—review & editing), Appiah-Korang Labi (Resources, Writing—review & editing), Nina Mathijssen (Resources, Writing—review & editing), Brett Miles (Resources, Writing—review & editing), Kåre Mølbak (Writing—review & editing), Ricardo Orsini (Writing—review & editing), Frederik Prakken (Resources, Writing—review & editing), Roald Schaad (Writing—review & editing), Patrique Segers (Writing—review & editing), Marius Stauning (Resources, Writing—review & editing), Wil van der Zwet (Writing—review & editing), Stijn de Jonge (Resources, Writing—review & editing), Niels Wolfhagen (Methodology, Writing—review & editing), Gerjon Hannink (Conceptualization, Formal analysis, Methodology, Resources, Supervision, Writing—review & editing), and Marja Boormeester (Conceptualization, Funding acquisition, Methodology, Supervision, Writing—review & editing)

Disclosure

A.A.A.B.-B. reports having received funding from DANIDA through the HAI-GHANA Project. The funder had no role in study design, data collection, analysis, or preparation of the manuscript. A.M.E. received a European Wound Management grant outside the submitted work. M.L.G. has received Northwell Grand Rounds honoraria outside the submitted work. M.A.B. has received grants from J&J and 3M, as well as speaker and/or instructor fees from J&J, 3M, BD, Gore, Smith & Nephew, TelaBio, Angiodynamics, GDM, Medtronic, and Molnycke, outside the submitted work. The authors declare no other conflict of interest.

Supplementary material

[Supplementary material](#) is available at *BJS Open* online.

Data availability

Deidentified individual participant data obtained via data sharing agreements were used in this analysis. The decision to share data with third parties is that of the authors of the original studies.

References

- Gillespie BM, Harbeck E, Rattray M, Liang R, Walker R, Latimer S *et al*. Worldwide incidence of surgical site infections in general surgical patients: a systematic review and meta-analysis of 488,594 patients. *Int J Surg* 2021;**95**:106136
- Badia JM, Casey AL, Petrosillo N, Hudson PM, Mitchell SA, Crosby C. Impact of surgical site infection on healthcare costs and patient outcomes: a systematic review in six European countries. *J Hosp Infect* 2017;**96**:1–15
- Crolla RMPH, van der Laan L, Veen EJ, Hendriks Y, van Schendel C, Kluytmans J. Reduction of surgical site infections after implementation of a bundle of care. *PLoS One* 2012;**7**:e44599
- van der Slegt J, van der Laan L, Veen EJ, Hendriks Y, Romme J, Kluytmans J. Implementation of a bundle of care to reduce surgical site infections in patients undergoing vascular surgery. *PLoS One* 2013;**8**:e71566

5. Koek MBG, Hopmans TEM, Soetens LC, Wille JC, Geerlings SE, Vos MC et al. Adhering to a national surgical care bundle reduces the risk of surgical site infections. *PLoS One* 2017;**12**:e0184200
6. Excellence National Institute for Health Care. *Surgical Site Infections: Prevention and Treatment*. <https://www.nice.org.uk/guidance/NG125> (accessed 10 January 2024)
7. Humphreys H, Bak A, Ridgway E, Wilson APR, Vos MC, Woodhead K et al. Rituals and behaviours in the operating theatre—joint guidelines of the Healthcare Infection Society and the European Society of Clinical Microbiology and Infectious Diseases. *J Hosp Infect* 2023;**140**:165.e1–e165.e28
8. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee. *Am J Infect Control* 1999;**27**:97–132
9. Stauning MA, Bediako-Bowan A, Bjerrum S, Andersen LP, Andreu-Sánchez S, Labi A-K et al. Genetic relationship between bacteria isolated from intraoperative air samples and surgical site infections at a major teaching hospital in Ghana. *J Hosp Infect* 2020;**104**:309–320
10. WHO. *Global Guidelines for the Prevention of Surgical Site Infection* (2nd edn). Geneva: World Health Organization, 2018
11. Allegranzi B, Zayed B, Bischoff P, Kubilay NZ, de Jonge S, de Vries F et al. New WHO recommendations on intraoperative and postoperative measures for surgical site infection prevention: an evidence-based global perspective. *Lancet Infect Dis* 2016;**16**:e288–e303
12. Berrios-Torres SI, Umscheid CA, Bratzler DW, Leas B, Stone EC, Kelz RR et al. Centers for Disease Control and Prevention guideline for the prevention of surgical site infection, 2017. *JAMA Surg* 2017;**152**:784–791
13. Birgand G, Toupet G, Rukly S, Antoniotti G, Deschamps M-N, Lepelletier D et al. Air contamination for predicting wound contamination in clean surgery: a large multicenter study. *Am J Infect Control* 2015;**43**:516–521
14. Diab-Elschahawi M, Berger J, Blacky A, Kimberger O, Oguz R, Kuelpmann R et al. Impact of different-sized laminar air flow versus no laminar air flow on bacterial counts in the operating room during orthopedic surgery. *Am J Infect Control* 2011;**39**:E25–E29
15. Erichsen Andersson A, Petzold M, Bergh I, Karlsson J, Eriksson BI, Nilsson K. Comparison between mixed and laminar airflow systems in operating rooms and the influence of human factors: experiences from a Swedish orthopedic center. *Am J Infect Control* 2014;**42**:665–669
16. Hirsch T, Hubert H, Fischer S, Lahmer A, Lehnhardt M, Steinau H-U et al. Bacterial burden in the operating room: impact of airflow systems. *Am J Infect Control* 2012;**40**:E228–E232
17. Bischoff P, Kubilay NZ, Allegranzi B, Egger M, Gastmeier P. Effect of laminar airflow ventilation on surgical site infections: a systematic review and meta-analysis. *Lancet Infect Dis* 2017;**17**:553–561
18. Birgand G, Azevedo C, Rukly S, Pissard-Gibollet R, Toupet G, Timsit JF et al. Motion-capture system to assess intraoperative staff movements and door openings: impact on surrogates of the infectious risk in surgery. *Infect Control Hosp Epidemiol* 2019;**40**:566–573
19. Birgand G, Saliou P, Lucet JC. Influence of staff behavior on infectious risk in operating rooms: what is the evidence? *Infect Control Hosp Epidemiol* 2015;**36**:93–106
20. Zimmerli W, Trampuz A, Ochsner PE. Prosthetic-joint infections. *N Engl J Med* 2004;**351**:1645–1654
21. Sterne JA, Hernan MA, Reeves BC, Savović J, Berkman ND, Viswanathan M et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ* 2016;**355**:i4919
22. van Buuren S. *Flexible Imputation of Missing Data*. Boca Raton: CRC Press, 2018
23. van Buuren SGO, Groothuis-Oudshoorn K. mice: Multivariate imputation by chained equations in R. *J Stat Softw* 2010;**45**:1–67
24. VanderWeele TJ. Principles of confounder selection. *Eur J Epidemiol* 2019;**34**:211–219
25. Shrier I, Platt RW. Reducing bias through directed acyclic graphs. *BMC Med Res Methodol* 2008;**8**:70
26. Wasserstein RL, Lazar NA. The ASA statement on p-values: context, process, and purpose. *Am Stat* 2016;**70**:129–133
27. Hamadeh N, Van Rompaey C, Metreau E, Eapen SG. *New World Bank Country Classifications by Income Level: 2022-2023*. <https://blogs.worldbank.org/en/opendata/new-world-bank-country-classifications-income-level-2022-2023> (accessed 10 January 2024)
28. Schünemann H, Brożek J, Guyatt G, Oxman A (eds). *GRADE Handbook*. <https://gdt.gradepro.org/app/handbook/handbook.html> (accessed 11 March 2025)
29. Zeng L, Brignardello-Petersen R, Hultcrantz M, Siemieniuk RAC, Santesso N, Traversy G et al. GRADE guidelines 32: GRADE offers guidance on choosing targets of GRADE certainty of evidence ratings. *J Clin Epidemiol* 2021;**137**:163–175
30. Zeng L, Brignardello-Petersen R, Hultcrantz M, Mustafa RA, Murad MH, Iorio A et al. GRADE guidance 34: update on rating imprecision using a minimally contextualized approach. *J Clin Epidemiol* 2022;**150**:216224
31. Erivan R, Villatte G, Haverlan A, Roullet CA, Ouchchane L, Descamps S et al. Does a sign restricting operating room access reduce staff traffic in the surgical department? *Orthop Traumatol Surg Res* 2024;**110**:103843
32. Saleh M, Lasha E, Nichols CS, Shimony N, Dugan JE, Vaughn B et al. A prospective observational study of operating room traffic during shunt surgery: who comes in and why? *J Neurosurg Pediatr* 2024;**35**:167–173
33. Knudsen RJ, Knudsen SMN, Nymark T, Anstensrud T, Jensen ET, La Mia Malekzadeh MJ et al. Laminar airflow decreases microbial air contamination compared with turbulent ventilated operating theatres during live total joint arthroplasty: a nationwide survey. *J Hosp Infect* 2021;**113**:65–70
34. Scaltriti S, Cencetti S, Rovesti S, Marchesi I, Bargellini A, Borella P. Risk factors for particulate and microbial contamination of air in operating theatres. *J Hosp Infect* 2007;**66**:320–326
35. Von Dolinger EJ, Brito DV, Souza GM, Melo GB, Gontijo Filho PP. Air contamination levels in operating rooms during surgery of total hip and total knee arthroplasty, hemiarthroplasty and osteosynthesis in the surgical center of a Brazilian hospital. *Rev Soc Bras Med Trop* 2010;**43**:584–587
36. Ratkowski PL. Traffic control. A study of traffic control in total joint replacement procedures. *AORN J* 1994;**59**:439–448
37. Taafe K, Lee B, Ferrand Y, Fredendall L, San D, Salgado C et al. The influence of traffic, area location, and other factors on operating room microbial load. *Infect Control Hosp Epidemiol* 2018;**39**:391–397
38. Roberts ER, Hider PN, Wells JM, Beasley SW. The frequency and effects of distractions in operating theatres. *ANZ J Surg* 2021;**91**:841–846
39. Anderson RL, Lipps JA, Pritchard CL, Venkatachalam AM, Olson DM. An operating room audit to examine for patterns of staff entry/exit: pattern sequencing as a method of traffic reduction. *J Infect Prevent* 2021;**22**:69–74

40. Roth JA, Juchler F, Dangel M, Eckstein FS, Battagay M, Widmer AF. Frequent door openings during cardiac surgery are associated with increased risk for surgical site infection: a prospective observational study. *Clin Infect Dis* 2019;**69**:290–294
41. Bohl MA, Clark JC, Oppenlander ME, Chapple K, Budde A, Lei T et al. The Barrow Randomized Operating Room Traffic (BRITE) trial: an observational study on the effect of operating room traffic on infection rates. *Neurosurgery* 2016;**63**:91–95
42. Allegranzi B, Aiken AM, Zeynep Kubilay N, Nthumba P, Barasa J, Okumu G et al. A multimodal infection control and patient safety intervention to reduce surgical site infections in Africa: a multicentre, before–after, cohort study. *Lancet Infect Dis* 2018;**18**:507–515
43. Bahethi RR, Gold BS, Seckler SG, Kinberg E, Stepan KO, Gray ML et al. Efficiency of microvascular free flap reconstructive surgery: an observational study. *Am J Otolaryngol* 2020;**41**:102692
44. Bediako-Bowan AAA, Molbak K, Kurtzhals JAL, Owusu E, Debrah S, Newman MJ. Risk factors for surgical site infections in abdominal surgeries in Ghana: emphasis on the impact of operating rooms door openings. *Epidemiol Infect* 2020;**148**:e147
45. de Jonge SW, Boldingh QJJ, Koch AH, Daniels L, de Vries EN, Spijkerman IJB et al. Timing of preoperative antibiotic prophylaxis and surgical site infection: TAPAS, an observational cohort study. *Ann Surg* 2021;**274**:e308–e314
46. Mathijssen NMC, Hannink G, Sturm PDJ, Pilot P, Bloem RM, Buma P et al. The effect of door openings on numbers of colony forming units in the operating room during hip revision surgery. *Surg Infect (Larchmt)* 2016;**17**:535–540
47. Perez P, Holloway J, Ehrenfeld L, Cohen S, Cunningham L, Miley GB et al. Door openings in the operating room are associated with increased environmental contamination. *Am J Infect Control* 2018;**46**:954–956
48. Prakken FJ, Lelieveld-Vroom GM, Milinovic G, Jacobi CE, Visser MJ, Steenvoorde P. Meetbaar verband tussen preventieve interventies en de incidentie van postoperatieve wondinfecties. *Ned Tijdschr Geneesk* 2011;**155**:A3269
49. Stauning MT, Bediako-Bowan A, Andersen LP, Opintan JA, Labi AK, Kurtzhals JAL et al. Traffic flow and microbial air contamination in operating rooms at a major teaching hospital in Ghana. *J Hosp Infect* 2018;**99**:263–270
50. Guyatt GH, Oxman AD, Kunz R, Woodcock J, Brozek J, Helfand M et al. GRADE guidelines: 8. Rating the quality of evidence—indirectness. *J Clin Epidemiol* 2011;**64**:1303–1310
51. Schunemann HJ, Mustafa RA, Brozek J, Steingart KR, Leeflang M, Murad MH et al. GRADE guidelines: 21 part 1. Study design, risk of bias, and indirectness in rating the certainty across a body of evidence for test accuracy. *J Clin Epidemiol* 2020;**122**:129–141
52. Guyatt GH, Oxman AD, Montori V, Vist G, Kunz R, Brozek J et al. GRADE guidelines: 5. Rating the quality of evidence—publication bias. *J Clin Epidemiol* 2011;**64**:1277–1282
53. Schunemann HJ, Mustafa RA, Brozek J, Steingart KR, Leeflang M, Murad MH et al. GRADE guidelines: 21 part 2. Test accuracy: inconsistency, imprecision, publication bias, and other domains for rating the certainty of evidence and presenting it in evidence profiles and summary of findings tables. *J Clin Epidemiol* 2020;**122**:142–152
54. Sadrizadeh S, Aganovic A, Bogdan A, Wang C, Afshari A, Hartmann A et al. A systematic review of operating room ventilation. *J Build Eng* 2021;**40**:102693
55. Calderwood MS, Anderson DJ, Bratzler DW, Dellinger EP, Garcia-Houchins S, Maragakis LL et al. Strategies to prevent surgical site infections in acute-care hospitals: 2022 update. *Infect Control Hosp Epidemiol* 2023;**44**:695–720
56. Madley-Dowd P, Hughes R, Tilling K, Heron J. The proportion of missing data should not be used to guide decisions on multiple imputation. *J Clin Epidemiol* 2019;**110**:63–73
57. Beldi G, Bisch-Knaden S, Banz V, Muhlemann K, Candinas D. Impact of intraoperative behavior on surgical site infections. *Am J Surg* 2009;**198**:157–162
58. Wheelock A, Suliman A, Wharton R, Babu ED, Hull L, Vincent C et al. The impact of operating room distractions on stress, workload, and teamwork. *Ann Surg* 2015;**261**:1079–1084