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Does headgear type used by the operating room staff affect postoperative surgical site infection rate?

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VÄSTRA GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

Does headgear type used by the operating room staff affect postoperative surgical site infection rate?

[Påverkar typen av operationsmössor som bärs av operationspersonalen frekvensen av postoperativ sårinfektion?]

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1. Abstract

Background: Surgical site infection (SSI) is associated with increased morbidity, mortality, and cost. Intraoperative factors may affect the risk for SSI, e.g., type of surgery, body temperature, surgical technique and the surgical staff attire. Surgical skull caps have been used since the late 19th century. Current Swedish guidelines (Vårdhandboken) require the use of caps during surgery. In certain situations (mainly implant surgery) the use of helmet type caps (hoods, covering neck, ears and all the hair) or bouffant type caps (can be worn covering all the hair and the ears) is required. Similar requirements are valid at the Sahlgrenska University Hospital operating departments where hoods are used in some, while surgical skull caps are considered sufficient in others. The basis for recommendations are early studies showing presence of bacteria in hair and on the facial skin of surgeons. In Sweden, many operating room (OR) staff members experience hoods being awkvard to use during long operations.

Question at issue: Is the use of hood or bouffant type headgear compared with the use of surgical skull caps or no hair cover associated with a reduction in mortality, sepsis, SSI, serious SSI, satisfaction with hair cover and colony forming units (CFU) in patients undergoing surgery with incision through intact skin in an operating room at a hospital?

Methods: During April 2020 two authors performed systematic literature searches in PubMed, Embase, MEDLINE, the Cochrane Library, CINAHL, and a number of HTA-databases. These authors also, independently of one another, assessed the obtained abstracts and made a first selection of full-text articles. Any disagreements were resolved in consensus. The remaining articles were sent to all authors and inclusions were finally decided in a consensus meeting. All included studies were critically appraised using checklists and certainty of evidence was defined using the GRADE system. Serious SSI was defined as deep/subfascial/organ space SSI, or infected implant.

Results: Four cohort studies reporting a total of 26,000 surgeries fulfilled our PICO and were included. Bouffant type of headgear was the intervention and was compared with skullcaps in all studies. In one of the four studies also hoods were used as intervention. In two of the studies only the surgeon, but not the other OR staff, wore bouffant type of headgear. Regarding directness, one study had no, two studies minor, and one study major problems. Regarding study limitations, three studies were considered to have some and one to have major study limitations, and three studies had some problems regarding precision.

Results per outcome:
Outcomes critical for decision-making:
Mortality and sepsis were not reported in any study.

Serious SSI (sSSI): Two studies reported sSSI and meta-analysis revealed no difference in the frequency of sSSI between headgears RR: 1.14 (95% CI: 0.91 to 1.42, p=0.25). Conclusion: It is uncertain whether the rate of sSSI is affected by using bouffant or hood type of headgear compared with surgical skull caps during surgery (GRADE ⊕◯◯◯).

Outcomes important for decision-making:
SSI: All four included studies reported the incidence of SSI. The meta-analysis showed no difference in the rate of SSI between groups. Conclusion: It is uncertain whether the rate of SSI is affected by using bouffant or hood type headgear compared with surgical skull caps during surgery (GRADE ⊕◯◯◯).

Satisfaction with hair cover and CFU were not reported in any study.

Concluding remarks: Surgical site infection (SSI) is a common and potentially devastating complication. The aetiology is multifactorial and we studied the association between the type of headgear used by the OR staff and the frequency of postoperative SSI/serious SSI as well as mortality, sepsis, satisfaction with hair cover and the concentration of CFU in the operating room air. No study reported the last four outcomes. Bouffants were the intervention in three studies while bouffants and hoods were used in one. Only the surgeon, but not the other OR staff members, used bouffants in two studies. For SSI and sSSI there were four and two observational studies respectively, with study limitations and limited precision, showing no significant differences in SSI/serious SSI rates. Conclusion: It is uncertain whether type of headgear (bouffant or hood versus surgical skull cap) used by the OR staff is associated with the rate of SSI/serious SSI (GRADE ⊕◯◯◯).

There were no studies comparing only hoods and surgical skull caps. The question whether the rates of SSI/serious SSI is associated with type of headgear used by the operating room staff is poorly studied.

2. Svensk sammanfattning – Swedish summary

Syfte: I denna HTA-rapport har vi studerat om användning av heltäckande hårskydd av heltäckande huv- eller bouffant-typ jämfört med en icke heltäckande mössa eller inget hårskydd för operationspersonalen påverkar dödlighet, frekvens av sepsis, allvarliga postoperativa sårinfektioner, postoperativa sårinfektioner, brukarnöjdhet och koncentration av bakteriekolonibärande partiklar (CFU) i operationssalen vid operationer som genomförs på en operationsavdelning med snitt genom intakt hud.

Bakgrund: Postoperativa sårinfektioner (SSI) är vanliga och potentiellt mycket allvarliga komplikationer efter kirurgiska ingrepp. Etiologin är multifaktoriell och risken för sårinfektioner kan påverkas bland annat av typen av kirurgi, patientens kroppstemperatur, kirurgens teknik och operationspersonalens skyddsutrustning. Hårskydd har använts sedan slutet av 1800-talet och i aktuella riktlinjer (Vårdhandboken) föreskrivs hårskydd under kirurgi. Vid vissa typer av operationer, företrädesvis vid implantatkirurgi, föreskrivs hårskydd av typen huva (täcker öron, hals och allt hår) eller bouffant (kan bäras så den täcker öron och allt hår). Liknande föreskrifter finns på Sahlgrenska Universitetssjukhusets operationsavdelningar och heltäckande huva används på vissa, medan på andra operationsavdelningar anses kirurgisk mössa vara tillfyllest. Bakgrunden till rekommendationerna är äldre studier som visat närvaro av bakterier i kirurgers hår och ansikte. Det finns en uppfattning bland operationspersonal i Sverige att mössor av huvtyp är obekväma att använda särskilt under längre operationer.

Metod: Med hjälp av etablerade systematiska litteratursökningsmetoder identifierades samtliga vetenskapliga studier som kunde bidra till att svara på den aktuella frågeställningen. Studiernas resultat sammanställdes. För att utreda resultatets tillförlitlighet, granskades de enskilda studiernas kvalitet och den samlade vetenskapliga kvaliteten på underlaget värderades.

Resultat: Föreliggande rapport baseras på fyra kohortstudier vilka rapporterade om 26,000 kirurgiska ingrepp. Hårskydd av bouffant-typ var intervention i samtliga studier och jämförelse var icke heltäckande mössa (C1). I en studie användes mössor av såväl huv- som bouffant-typ som intervention. I två studier bars bouffant-mössan bara av kirurgen och inte av övrig personal. De inkluderade studierna hade generellt vissa problem med överförbarhet och intern validitet och allvarliga problem med precision.

Resultat per utfall:
Utfall som bedömdes kritiska för beslutsfattande:
Mortalitet och sepsis rapporterades inte i någon av studierna.

Allvarliga postoperativa infektioner (sSSI), rapporterades i två studier. En metaanalys påvisade ingen statistiskt signifikant skillnad avseende incidens av sSSI mellan grupperna med olika huvudbonader, RR: 1,14 (95% CI: 0,91–1,42, p=0,25).
Slutsats: Det är osäkert huruvida incidensen av sSSI påverkas av operationspersonalens användning av heltäckande hårskydd av bouffant- eller huvtyp jämfört med en icke heltäckande mössa (GRADE ⊕◯◯◯).

Utfall som bedömdes viktiga för beslutsfattande:

Postoperativa infektioner (SSI): Samtliga fyra studier rapporterade SSI. En metaanalys påvisade ingen statistiskt signifikant skillnad avseende incidens av SSI mellan grupperna med olika huvudbonader, RR: 1,24 (95% CI: 0,82–1,88, p=0,31). Det är osäkert huruvida incidensen av SSI påverkas av operationspersonalens användning av heltäckande hårskydd av bouffant- eller huvtyp jämfört med en icke heltäckande mössa (GRADE ⊕◯◯◯).

Operationspersonalens tillfredställelse med typ av operationsmössa, eller antalet bakteriekolonibärande partiklar (CFU), rapporterades inte i någon av studierna.

Sammanfattning: Postoperativ infektion (SSI) är en vanlig och potentiellt förödande komplikation, vars etiologi är multifaktoriell. I föreliggande HTA studerades sambandet mellan typ av huvudbonad som använts av operationspersonalen och frekvensen av allvarlig SSI (sSSI), SSI, dödlighet, sepsis, operationspersonalens tillfredsställelse med huvudbonad, samt koncentrationen av CFU i operationsrumsluften. Ingen av studierna rapporterade något av de fyra sistnämnda utfallen. Tre studier hade mössor av bouffant-typ som intervention och en hade mössor av bouffant- eller huvtyp. Avseende sSSI och SSI identifierades två respektive fyra studier, med brister avseende överförbarhet, intern validitet samt precision. Inga statistiskt signifikanta skillnader förelåg avseende förekomsten av sSSI eller SSI. Det fanns ingen studie som jämförde enbart mössor av huvtyp med icke heltäckande mössa.

Slutsats: Det är osäkert huruvida förekomsten av postoperativa sårinfektioner/allvarliga postoperativa sårinfektioner påverkas av om operationspersonalen bär mössor av bouffant-typ eller icke heltäckande mössor (GRADE ⊕◯◯◯). Det saknas bedömbart vetenskapligt underlag för utfallen dödlighet, sepsis, brukarnöjdhet och kolonibärande partiklar. Vad gäller mössor av huvtyp jämfört med icke heltäckande mössor saknas bedömbart vetenskapligt underlag. Frågan om förekomsten av sSSI eller SSI är förknippad med den typ av huvudbonader som används av operationspersonalen är bristfälligt studerad.

The above summaries were written by representatives from the HTA-centrum. The HTA report was approved by the Regional board for quality assurance of activity-based HTA. The abstract is a concise summary of the results of the systematic review. The Swedish summary is a brief summary of the systematic review intended for decision makers, and is ended with a concluding summary.

Christina Bergh, Professor, MD

Head of HTA-centrum of Region Västra Götaland, Sweden, October 28th 2020.

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Wartenberg, Constanze	Psychologist, PhD

DDS Doctor of dental surgery

MD Medical doctor

PhD Doctor of Philosophy

OD Odontology doctor

PT Physiotherapist

RN Registered Nurse

3. Summary of findings

Outcomes	Study design Number of studies	Relative effect (95% CI)	Absolute effects	Certainty of evidence GRADE*
Surgical site infection	4 Non-randomised controlled studies	RR: 1.14 95% CI: 0.91 to 1.42 p=0.25	Study 1 I[2]=3.72% (31/833) C[3]=3.98% (161/4,084) p=0.85 Study 2 I[4]=8.06% (49/608) C[3]=5.03% (47/935) p=0.02 Study 3 I[5]=5.52% (63/1,141) C[3]=5.26% (40/760) p=0.81 Study 4 I[4]=0.84% (71/8,446) C[6]=0.77% (58/7,513) p=0.63	GRADE ⊕○○○ Very low [1]
Severe surgical site infection	2 Non-randomised controlled studies	RR: 1.24 95% CI: 0.82 to 1.88 p=0.307	Study2 I[4]=1.81% (11/608) C[3]=1.07% (10/935) p=0.26 Study 3 I[5]=3.86% (44/1,141) C[3]=3.42% (26/760) p = 0.71	GRADE ⊕○○○ Very low [1]
Mortality	Not studied			
Sepsis	Not studied			
Satisfaction with hair cover	Not studied			
Concentration of colony forming units (CFU) in air	Not studied			

Footnotes: [1] Downgraded for indirectness, study limitations, and some imprecision
[2] Disposable bouffant, ears covered
[3] Surgical skull cap
[4] Bouffant, not specified if ears were covered
[5] Bouffant or hood
[6] Surgical skull cap or bouffant

* **Certainty of evidence**

High certainty, ⊕⊕⊕⊕	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty, ⊕⊕⊕○	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty, ⊕⊕○○	Confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low certainty, ⊕○○○	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

4. Abbreviations/Acronyms

ACS	American College of Surgeons
AORN	American Society of Perioperative and Operating Room Nurses
CFU	Colony Forming Units
GRADE	Grading of Recommendations Assessment, Development and Evaluation
LAF	Laminar air flow
OR	Operating Room
SR	Systematic review
SSI	Surgical Site Infection(s)
sSSI	serious Surgical Site Infection(s)
VGR	Västra Götalandsregionen (Region Västra Götaland)

5. Background

Surgical site infection (SSI) is a a serious postoperative complication, which is associated with increased morbidity and mortality, decreased quality of life and increased cost (Hollenbeak et al., 2000; Pinkney et al., 2013; Schweizer et al., 2014; Ward et al., 2014). There are many factors in the operating room (OR) that may contribute to the development of SSI such as type of surgery, intraoperative glucose control, body temperature, suboptimal surgical and sterile technique, OR ventilation and the surgical staff attire (Anderson et al., 2014).

Surgical skull caps have been used as hair cover since the late 19th century (Adams et al., 2016). The Swedish national document 'Vårdhandboken' states that the use of caps during surgery, and in certain situations (i.e. implant surgery), the use of helmet type caps (hoods) are required. Similar requirements are valid for surgery performed at the Sahlgrenska University Hospital ORs (Vårdhygien, 2019). In the Region Västra Götaland (VGR), the requirement to use hoods has been implemented in some operating departments, while surgical skull caps are considered sufficient in others.

The scientific basis for these recommendations and requirements originate from studies conducted in the 1960s, showing presence of bacteria in the operating surgeons' hair and beard (Black, 1966; Summers et al., 1965). Later studies have also shown presence of bacteria on the facial skin, especially on the forehead, nose and ears (Mastro et el., 1990; Noble, 1975; Owers et al., 2004). Results from studies, using the presence of bacteria-carrying particles, so called colony forming units (CFU), as an indicator of air contamination, are conflicting. One early study that compared the use of surgical skull cap with no headgear was unable to show a difference in CFU count in the OR air (Humphreys et al., 1991), wheras another study on the presence of CFU in air during simulated operations showed no difference between surgical skull caps and hoods, while use of no headcover increased the amount of CFU in air from 8 to 8,300 CFU/m^3 air (Taylor and Leeming, 1993). A similar setup was used by Friberg et al. (2001), who studied simulated operations in ORs with laminar air flow (LAF) ventilation. These authors found similar results as Taylor and Leeming (1993) although the difference was smaller (Friberg et al., 2001).

Altogether, these studies suggest that a difference in CFU count in air might be present between settings with the use of head cover compared with settings without head cover. Whether there is an additive effect with the use of surgical hoods or bouffants is uncertain.

Recently the American Association of Perioperative and Operating Room Nurses (AORN) published guidelines requiring the use of headgear covering hair and ears during surgery (Huston et al., 2019), whereas the American College of Surgeons (ACS) stated that the use of skull caps with minimal coverage of the hair is acceptable. These guidelines referred to the above mentioned studies demonstrating presence of bacteria in hair, beard, ear, nose and skin. As the American publicly financed health care systems (Medicare, Medicaid) required adherence to the AORN guidelines in order to finance surgery, debate between the AORN and the ACS appeared (Petro and Rosen, 2019).

Present guidelines in Sweden require the use of hoods during all implant surgery, and many surgical departments require the use of these hoods in all types of surgery (Vårdhandboken; Vårdhygien, 2019). In order to cover all hair, several staff members consider the hood to be the best headgear. On the other hand, many staff members experience these hoods being awkvard to use, impairing hearing, making the use of surgical loupes and headlights difficult, and also decreasing comfort and concentration during long operations.

Even though previous studies have shown the presence of potentially pathogenic bacteria in hair, beard, and on the skin of operating surgeons, as well as the presence of bacteria carrying CFUs in the OR air, the association between CFU levels and the incidence of SSI can be discussed. Although LAF ventilation probably reduces CFU levels in OR air (Houltz et al., 2020) no reduction of serious SSI has been demonstrated by LAF ventilation in systematic reviews (Segadal et al, 2001; Lowson et al., 2011, Gastmeier et al., 2012; Bischoff et al., 2017; Houltz et al., 2020).

At Sahlgrenska University Hospital in Gothenburg, the recommendations for the OR staff are that all staff working in the OR, also staff members that are not working within the sterile operating enviroment, are required to wear a surgical hood, covering all hair and ears.

The primary objective of the present Health Tecnology Assessment was to determine whether the choice of surgical headwear –hood or bouffant type of headgear versus surgical skull cap – is associated with the incidence of surgical site infections.

6. Health Technology at issue: Headgear in the operating room

Several types of headgear are used in the OR during surgery. At the Sahlgrenska University Hospital the following types of headgear are used: Surgical skull caps covering only hair (or even part of the hair) (Fig. 1), various types of headgear covering hair and that can be used to cover the ears (bouffants) (Fig. 2), and hood type headgear always covering all head and neck, except the face (Fig. 3).

Figure. 1
Surgical skull cap

Figure. 2
Bouffant headgear

Figure. 3
Hood type headgear

Hood headgear types are often recommended for infection sensitive surgery (mainly implant surgery), although some institutions recommend this type of headgear in all types of surgery.

7. Focused question

Is the use of hood or bouffant type headgear compared with the use of surgical skull caps (C1) or no hair cover (C2) associated with a reduction in mortality, sepsis, SSI, serious SSI, satisfaction with hair cover and colony forming units (CFU) in patients undergoing surgery with incision through intact skin in an operating room at a hospital?

PICO: P= Patients, I= Intervention, C= Comparison, O=Outcome

P: Patients undergoing surgery, in an operating room at a hospital, with incision through intact skin.

I: Personnel in the operating room using headgear covering hair, ears and neck ("bouffant" or "hood" type headgear).

C1: Personnel in the OR using non-covering headgear (i.e. "surgical skull cap")

C2: Personnel in the OR not using headgear.

O: *Critical for decision making*:
Mortality.
Serious surgical site infection (sSSI), i.e. deep/subfascial/organ infection, implant infection.
Sepsis.

Important for decision making:
Surgical site infection (SSI).
Satisfaction with hair cover.

Not important for decision making:
Concentration of colony forming units (CFU) in OR air.

8. Methods

Systematic literature search (Appendix 1)

During April 2020 two authors (TS, IS) performed systematic searches in PubMed, Embase, MEDLINE, the Cochrane Library, Cinahl and a number of HTA-databases. Reference lists of relevant articles were also scrutinised for additional references. Search strategies, eligibility criteria and a graphic presentation of the selection process are presented in Appendix 1. These authors conducted the literature searches, selected studies, and independently of one another assessed the obtained abstracts and made a first selection of full-text articles for inclusion or exclusion. Any disagreements were resolved in consensus. The remaining articles were sent to all the participants of the project group. All authors read the articles independently of one another and it was finally decided in a consensus meeting which articles should be included in the assessment.

Critical appraisal and certainty of evidence

All included studies were critically appraised using checklists and certainty of evidence was defined using the GRADE system.

The included studies and their design and patient characteristics are presented in Appendix 2. The excluded studies and the reasons for exclusion are presented in Appendix 3. The included studies have been critically appraised using the checklists for assessment of cohort studies provided by the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU). Meta-analyses were conducted using random effects model (STATA 16.1). The results and the assessed quality of each article have been summarized per outcome in Appendix 4.

A summary result per outcome and the associated certainties of evidence are presented in a Summary-of-findings table (page 7). The certainty of evidence was defined according to the GRADE system (Atkins et al., 2004; GRADE Working group). A surgical site infection (SSI) was defined as an infection that occurs after surgery in the part of the body where the surgery took place. Serious SSI (sSSI) was defined as deep/subfascial/organ space SSI, or infected implant.

Ongoing research

A search in Clinicaltrials.gov (2020-06-24) using the search terms *(hat OR hats OR headwear OR headgear OR head-wear OR head-gear OR helmet OR helmets OR bouffant OR hood OR hoods) AND (surgical OR surgeon OR surgeons OR operating OR operation* identified 201 trials. A search in ISRCTN.com (2020-06-24) using the search terms *hat OR hats OR headwear OR headgear OR head-wear OR head-gear OR helmet OR helmets OR bouffant OR hood OR hoods* identified 92 trials.

9. Results

Search results and study selection (Appendix 1)

The literature search identified 507 articles after removal of duplicates. After reading the abstracts 485 articles were excluded. Another 13 articles were excluded by two authors after reading the articles in full text. The remaining nine articles were sent to all authors, and four articles, all reporting controlled cohort studies, were finally included in the assessment (Appendix 2).

Included studies

Four cohort studies with controls were included. Three of these were follow-up studies using prospectively registered data in hospital quality registers, and the fourth study was a questionnaire mailed to operating surgeons.

A total of 26,000 surgeries were reported in the four studies. Only one study (the questionnaire) reported missing data. In all four studies, bouffant type of headgear was compared with skull caps (C1) In one of these studies, the comparator was skull caps or bouffants. In one of the studies, hoods or bouffants were used in the intervention group, and in two of the studies only the surgeon, but not the other OR staff, used bouffant type of headgear. None of the studies compared hoods alone as a surgical headgear with skull caps. Three out of the four included studies were considered to have study limitations, and one of them had major study limitations. All except one of the studies had problems with precision. The included studies also had problems with directness, since it was often unclear if the studied type of headgear was worn only by the surgeons or by all the OR staff.

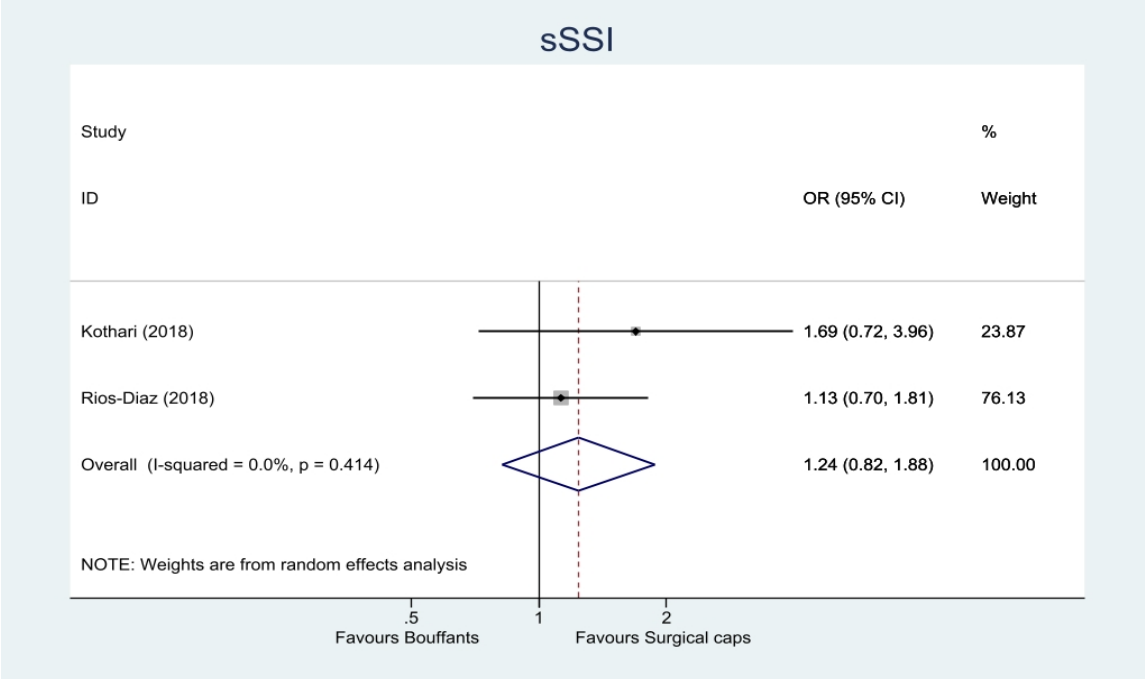
Results per outcome

Outcomes critical for decision making:

Mortality and sepsis: No study reported the outcomes mortality and sepsis.

Serious surgical site infections: Two studies reported the frequencies of sSSI, including 1,543 and 1,901 patients respectively, with an endpoint at 30 days. Meta-analysis revealed no difference in the frequencies of sSSI between the studied headgears (Fig 4).

Figure. 4 Meta-analysis of studies comparing bouffant-type of headgear with surgical skull cap. *Outcome: Serious SSI*



Study	RR (95% CI)	% Weight
[1]Kothari (2018	1.69 (0.72 to 3.96)	23.87
[2]Rios-Diaz (2018)	1.13 (0.70 to 1.82)	76.13
D+L pooled RR	1.24 (0.82 to 1.88)	100.00

Heterogeneity chi-squared = 0.67 (d.f. = 1), p = 0.414
I-squared (variation in RR attributable to heterogeneity) = 0%
Estimate of between-study variance Tau-squared = 0.0000
Test of RR=1: z= .02, p = 0.307

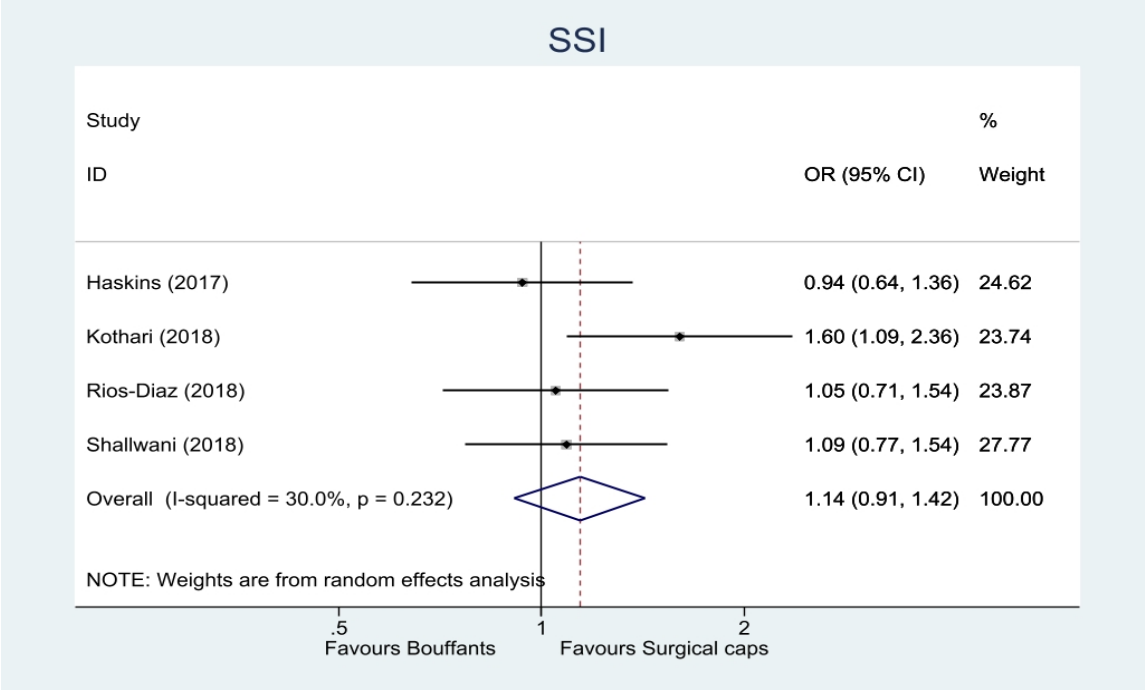
[1] Bouffant, not specified if ears were covered. Control: surgical skull cap
[2] Bouffant or hood. Control: surgical skull cap

Conclusion: It is uncertain whether the rate of serious SSI is affected by using hood or bouffant headgear compared with surgical skull caps during surgery.
Very low certainty of evidence (GRADE ⊕◯◯◯).

Outcomes important for decision making:

Surgical site infections: All four included studies reported the incidence of SSI. In three studies the endpoint was SSI within 30 days and in the fourth study, time to endpoint was not stated. One study (n=1,543) reported a significant difference in SSI between the bouffant group (8.06%) and the surgical skull cap group (5.03%, p=0.02). No other significant differences were reported. The meta-analysis showed no significant differences between the groups (Fig. 5).

Figure. 5 Meta-analysis of studies comparing bouffant-type of headgear with surgical skull cap. *Outcome: SSI*



Study	RR (95% CI)	% Weight
[1] Haskins (2017)	0.94 (0.64 to 1.36)	24.62
[2] Kothari (2018)	1.60 (1.09 to 2.36)	23.74
[3] Rios-Diaz (2018)	1.05 (0.71 to 1.54)	23.87
[4] Shallwani (2018)	1.09 (0.77 to 1.54)	27.77
D+L pooled RR	1.14 (0.91 to 1.42)	100.00

Heterogeneity chi-squared = 4.28 (d.f. = 3), p = 0.232
I-squared (variation in RR attributable to heterogeneity) = 30.0%
Estimate of between-study variance Tau-squared = 0.0155
Test of RR=1: z= 1.15, p = 0.250

[1] Disposable bouffant, ears covered. Control: Surgical skull cap
[2] Bouffant, not specified if ears were covered. Control: Surgical skull cap
[3] Bouffant or hood. Control: Surgical skull cap
[4] Bouffant, not specified if ears were covered. Control: Surgical skull cap or bouffant

Conclusion: It is uncertain whether the rate of SSI is affected by using a hood or bouffant headgear compared with surgical skull caps during surgery. Very low certainty of evidence (GRADE ⊕◯◯◯).

Satisfaction with hair cover was not reported in any study

Outcomes not important for decision making:

No studies using CFU as outcome were identified.

10. Ethical aspects

The selection of headgear during surgery might affect the risk for postoperative sSSI or SSI and could thus have an impact on health-related quality of life and even life expectancy for the patient, if a difference in infection rate would exist between different types of headgear.

There is a substantial cost difference between surgical skull caps and hood caps, considering the large volume of these disposable garments used. A reduced incidence of SSI using hood caps might justify a higher cost, but the present HTA concludes that it is uncertain whether there is any difference in the incidence of postoperative SSI and sSSI, regarding the type of surgical headgear worn in the OR.

11. Organisational aspects

Various types of surgical caps have been used since the late 19th century. Until the 1970s these were almost exclusively textile surgical caps. After the pioneering studies by Charnley (1972), showing a reduction of surgical SSI when isolating the patient from the surgical team, using an aspirated helmet system, headgears covering more of the head were introduced.

At present disposable bouffants and hood type headgears are commonly replacing the previously used surgical caps, especially in implant surgery.

Time frame for the putative introduction of the new health technology

Hoods/bouffants are already used in many operation departments.

Present use of the technology in other hospitals in Region Västra Götaland

Mandatory use of hoods was introduced in several operation departments at the Sahlgrenska University Hospital in 2018 as a new operation department with laminar flow ventilation in all ORs was opened. In most operation departments in the VGR surgical caps are allowed during surgical procedures that are not considered infection sensitive, although the use of hoods is recommended.

Consequences of the new health technology for personnel

No education or training is necessary.

Time frame for the putative introduction of the new health technology

Surgical hoods have already replaced surgical caps in some departments.

Consequences for other clinics or supporting functions at the hospital or in the Region Västra Götaland

None.

12. Economic aspects

Present costs of currently used technologies

The total amount of headgear used annually at the Sahlgrenska University Hospital was (in 2019) 520,600 with a total cost of 892,148 SEK. The current use includes a mix of “bouffant” or “surgical hoods” type headgear and surgical skull caps.

The cost for the most commonly used surgical hood type headgear was 3.8 SEK/unit (but with some models priced up to 5.95 SEK/unit) and the cost of the most used surgical skull cap was 0.8 SEK/unit.

Expected costs of the new health technology

The total cost per year, if surgical hoods would be used in all surgeries and by all OR staff members, would be between 1.98 and 3.1 million SEK depending of hood model.

This can be compared with a total cost per year, if surgical skull caps would be used in all surgeries and by all OR staff members, which would be about 0.42 million SEK.

Total change in costs

If all surgeries and all OR staff members at the Sahlgrenska University Hospital would use surgical hood type of headgear, the total annual cost would increase from the current cost of 892,148 SEK to about 1.98 and 3.1 million SEK, i.e. an increase by about 1.1 to 2.2 million SEK. On the other hand, if all staff members would use skull caps only, the annual cost would decrease to 468,540 SEK, a reduction of SEK 418,748 from the current cost.

If the type of headgear would affect the risk of SSI or sSSI, this could have large cost consequences, but considering the absence of evidence in favor of such effects this scenario was not taken into consideration in the economic analysis.

Possibility to adopt and use the new technology within the present budget

It is not possible to implement surgical hood type of headgear in all surgeries and for all OR staff members within the present budget since it would increase the total direct costs. Hence, such a decision would require increased resources/budget or some other health services to be displaced.

Available economic evaluations or cost advantages/disadvantages

No published economic evaluations or budget impact analyses were identified in the literature search.

13. Discussion

Summary of main results

This HTA report, based on a systematic review and meta-analysis, identified only four controlled cohort studies. The outcomes SSI and sSSI were reported in four and two studies, respectively. Meta-analyses showed no significant differences in the incidences of SSI and sSSI between the surgeries where hood or bouffant type headgear was used compared with where surgical skull caps (in one of these studies surgical skull caps or bouffants) were used. For both outcomes, the conclusion was that it is uncertain whether the incidence of SSI and sSSI is affected by the use of hood or bouffant headgear compared with surgical skull caps during surgery (GRADE ⊕◯◯◯). None of the included studied addressed the use of hood caps alone as intervention (Fig. 3). Bouffant caps were used as intervention in three studies, and bouffant or hood caps were used in one study. In all four studies, surgical skull cap was used as comparison (C1), and in one of these studies surgical skull caps or bouffants were used. The specificity of the intervention was limited, since in two of the studies only the surgeon, but not the other OR staff, wore bouffant type of headgear, and also since bouffant caps can be worn with or without covering all the hair and the ears. Moreover, because of the retrospective design of the four studies it was unclear which headgear the surgeon was in fact wearing before the introduction of the bouffant. Three of the four included studies were considered to have some study limitations and one to have major study limitations, and all but one study had problems regarding precision.

None of the studies reported the outcomes mortality, sepsis, satisfaction with hair cover or CFU. The use of CFU as a surrogate endpoint evaluating actions aimed at a reduction of postoperative infections can be questioned. The use of CFU is mainly based upon the results of the MCP study (Lidwell et al., 1982). This study was performed as a multicenter trial investigating the effect of laminar air flow on sSSI in 39 hospitals in England and Sweden during the years 1974 to 1979. Lidwell and coworkers presented a correlation analysis showing a strong correlation (r^2=0.79 and $p<0.02$) between CFU levels and the rate of sSSI in 8000 patients. This result has been interpreted as strong evidence of causality between CFU levels and sSSI. However, a major limitation of the MCP trial is the use of prophylactic antibiotics. Antibiotics were given “at the discretion of the surgeon” leading to almost all patients being treated with antibiotics in some hospitals and none in others. If only the results from the hospitals where > 90% of the patients received prophylaxis (as in most hospitals today) are extracted from Lidwell’s data, this group consists of 4096 patients.

If the correlation between CFU and sSSI is analysed in this group, r^2 becomes 0.016 and p is close to 1. These and other problems with the MCP trial made the authors of another systematic review (Segadal et al, 2001) suggest that the correlation between CFU and sSSI presented by Lidwell et. al. is not valid for surgery performed after antibiotic prophylaxis, i.e. to surgery performed today in Sweden. In support of this notion, a recent systematic review (SR) from HTA-centrum concluded that although vertical LAF ventilation probably substantially reduces CFU levels in the OR air (GRADE ⊕⊕⊕◯), it may not be associated with a reduction of sSSI (GRADE ⊕⊕◯◯) in orthopedic implant/non-implant and GI/vascular/mixed surgery (Houltz et al., 2020).

All the included studies in the present HTA were published in the USA between 2017 and 2019, questioning whether headgear covering hair and ears, e.g. bouffant (Fig. 2) or hood (Fig. 3) type of caps, was associated with less SSI or sSSI, compared with the traditional surgical 'skull cap' covering only the top of the hair (Fig. 1).

In the included studies, the underlying issue, to compare headgears of the surgical 'skull cap' type with headgears covering all hair and ears, is only partly addressed. The results are not immediately applicable to the present clinical setting in Sweden, since the most commonly used types of surgical headgears are either surgical 'skull caps' or hood caps.

All included studies were non-randomized controlled studies. In three studies the hospital quality management system was used, and in the fourth study a questionnaire was sent to operating surgeons, making all data observational. This study design may incorporate various sources of bias, difficult to adjust for. As it was unclear how and by whom the hospitals had identified and reported the SSIs into their quality management systems, whether this was made by a blinded observer, or not, e.g., detection bias cannot be excluded. Only the questionnaire study reported missing data, with a response rate of 70%. A further limitation of the included studies was the time to follow-up, which was 30 days in three of the four studies, and unclear in the fourth study. Many SSIs are detected within 30 days, but may, especially regarding sSSIs following implant surgery, occur much later. Precision was also a problem in the included studies, since the frequency of SSI, usually around 3.5-5%, would require a sample size of approximately 10,000 patients to reach a clinically relevant and significant difference (Evans, 2011). Only one of the present studies included more than 2,000 patients. The total number of patients in the four studies was 25,613.

We did not identify any previous systematic review on the association of various types of headgear with the incidence of SSI. In order to evaluate the impact of different headgear on SSI a large scale randomized controlled trial would be required.

14. Future perspectives

Scientific knowledge gaps

Even though the decision of which type of headgear that should be used in various types of surgeries may have medical and economic consequences, the scientific base for decision-making in this matter is absent.

Ongoing research

We have not been able to find any ongoing research addressing the questions addressed in this HTA. Such studies would have great impact on the possibility of making informed decisions and are thus warranted.

15. Participants in the project

The question was nominated by

Christina Svärd, senior consultant, M.D., PhD, Head of Department of Hybrid and Intervention, Region Västra Götaland, Sahlgrenska University Hospital, Gothenburg, Sweden.

Participating healthcare professionals

Anders Thornell, M.D., PhD., Region Västra Götaland, Consultant Surgeon, Department of Endocrine Surgery, Sahlgrenska University Hospital, Researcher, Institution of Clinical Sciences, Department of Surgery, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden.

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Declaration of interests

None of the authors declared any conflict of interest.

Project time

The HTA was accomplished during the period of 12/03/2020 to 28/10/2020.
Literature searches were made on 07/04/2020.

Appendix 1: PICO, study selection, search strategies, and references

Question(s) at issue:

Is the use of hood or bouffant type headgear compared with the use of surgical skull caps (C1) or no hair cover (C2) associated with a reduction in mortality, sepsis, SSI, serious SSI, satisfaction with hair cover and colony forming units (CFU) in patients undergoing surgery with incision through intact skin in an operating room at a hospital?

PICO: (*P=Patient I=Intervention C=Comparison O=Outcome*)

P: Patients undergoing surgery, in an operating room at a hospital, with incision through intact skin.

I: Personnel in the operating room using headgear covering hair, ears and neck ("bouffant" or "hood" type headgear).

C1: Personnel in the OR using non-covering headgear (i.e. "surgical skull cap")
C2: Personnel in the OR not using headgear.

O: *Critical for decision making*:
Mortality.
Serious surgical site infection (sSSI), i.e. deep/subfascial/organ infection, implant infection.
Sepsis.

Important for decision making:
Surgical site infection (SSI).
Satisfaction with hair cover.

Not important for decision making:
Concentration of colony forming units (CFU) in OR air.

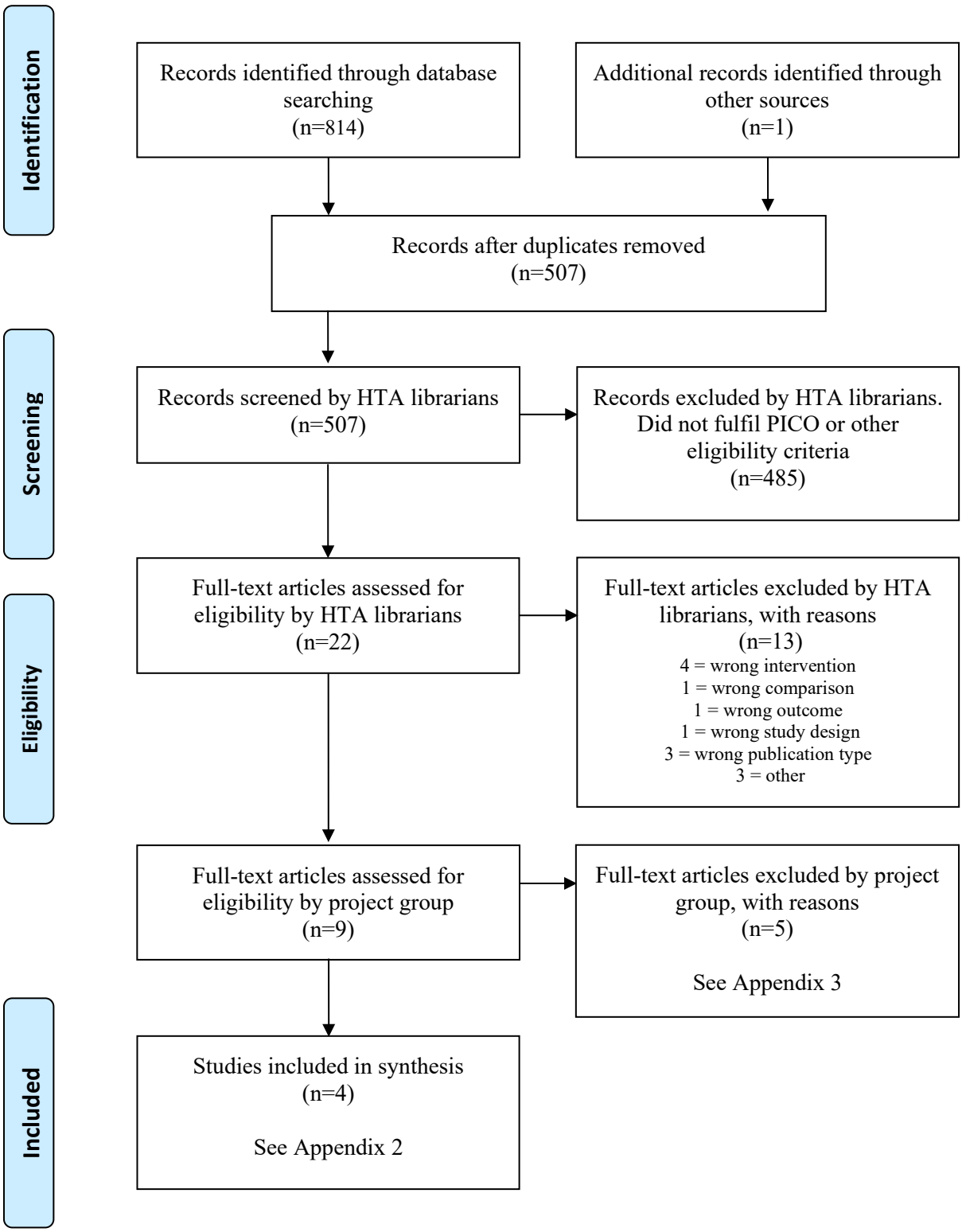
<u>Eligibility criteria</u>

Study design:
Systematic reviews
Randomised controlled trials
Non-randomised controlled studies, > 100 patients per group
Qualitative studies regarding satisfaction with hair cover

Language:
English, Swedish, Norwegian, Danish

Publication date: 1990-

Selection process – flow diagram



Modified from Moher et al., 2009

Search strategies

Database: PubMed
Date: 07 Apr 2020
No. of results: 174

Search	Query	Items found
#17	**Search #15 NOT #16 Filters: Publication date from 1990/01/01; Danish; English; Norwegian; Swedish**	**174**
#16	Search (Editorial[ptyp] OR Letter[ptyp] OR Comment[ptyp]) Filters: Publication date from 1990/01/01; Danish; English; Norwegian; Swedish	1510657
#15	Search #13 NOT #14 Filters: Publication date from 1990/01/01; Danish; English; Norwegian; Swedish	177
#14	Search ((animals[mh]) NOT (animals[mh] AND humans[mh])) Filters: Publication date from 1990/01/01; Danish; English; Norwegian; Swedish	2861800
#13	Search #5 AND #6 Filters: Publication date from 1990/01/01; Danish; English; Norwegian; Swedish	177
#8	Search #5 AND #6 Filters: Publication date from 1990/01/01	180
#7	Search #5 AND #6	181
#6	Search pubmednotmedline[sb]	3214395
#5	Search #3 AND #4	1912
#4	Search #1 OR #2	1089834
#3	Search hat[tiab] or hats[tiab] or cap[tiab] or caps[tiab] or headwear*[tiab] or headgear*[tiab] or head-wear*[tiab] or head-gear*[tiab] or helmet[tiab] or helmets[tiab] or bouffant*[tiab] or hood[tiab] or hoods[tiab]	64788
#2	Search surgical[tiab] or surgeon[tiab] or surgeons[tiab] or operating room*[tiab] or operation room*[tiab] or operating theat*[tiab] or operation theat*[tiab]	1084841
#1	Search Operating Rooms[mh]	13592

Database: Embase 1974 to 2020 April 03 (OvidSP)
Date: 07 Apr 2020
No. of results: 271

#	Searches	Results
1	exp operating room/	35949
2	(surgical or surgeon or surgeons or operating room* or operation room* or operating theat* or operation theat*).ab,kw,ti.	1473881
3	(hat or hats or cap or caps or headwear* or headgear* or head-wear* or head-gear* or helmet or helmets or bouffant* or hood or hoods).ab,kw,ti.	88730
4	1 and 3	180
5	((surgical or surgeon or surgeons or operating room* or operation room* or operating theat* or operation theat*) adj6 (hat or hats or cap or caps or headwear* or headgear* or head-wear* or head-gear* or helmet or helmets or bouffant* or hood or hoods)).ab,kw,ti.	438
6	4 or 5	564
7	limit 6 to yr="1990 -Current"	526
8	limit 7 to (danish or english or norwegian or swedish)	496
9	**limit 8 to (embase or medline)**	**271**

Database: CINAHL (EBSCOhost)
Date: 07 Apr 2020
No. of results: 82

#	Undran	Resultat
S6	**S2 N6 S3** **Avgränsare - Publiceringsdatum: 19900101-20201231; Språk: Danish, English, Norwegian, Swedish**	**82**
S5	S2 N6 S3	84
S4	S1 AND S3	41
S3	TI (hat or hats or cap or caps or headwear* or headgear* or head-wear* or head-gear* or helmet or helmets or bouffant* or hood or hoods) OR AB (hat or hats or cap or caps or headwear* or headgear* or head-wear* or head-gear* or helmet or helmets or bouffant* or hood or hoods)	12,961
S2	TI (surgical or surgeon or surgeons or "operating room*" or "operation room*" or "operating theat*" or "operation theat*") OR AB (surgical or surgeon or surgeons or "operating room*" or "operation room*" or "operating theat*" or "operation theat*")	228,528
S1	(MH "Operating Rooms")	8,856

Database: Ovid MEDLINE(R) ALL 1946 to April 06, 2020 (OvidSP)
Date: 07 Apr 2020
No. of results: 238

#	Searches	Results
1	exp Operating Rooms/	13592
2	(surgical or surgeon or surgeons or operating room* or operation room* or operating theat* or operation theat*).ab,ti.	1081460
3	(hat or hats or cap or caps or headwear* or headgear* or head-wear* or head-gear* or helmet or helmets or bouffant* or hood or hoods).ab,ti.	65852
4	1 and 3	67
5	((surgical or surgeon or surgeons or operating room* or operation room* or operating theat* or operation theat*) adj6 (hat or hats or cap or caps or headwear* or headgear* or head-wear* or head-gear* or helmet or helmets or bouffant* or hood or hoods)).ab,ti.	254
6	4 or 5	290
7	limit 6 to yr="1990 -Current"	259
8	**limit 7 to (danish or english or norwegian or swedish)**	**238**

Database: The Cochrane Library
Date: 07 Apr 2020
No. of results: 49
Cochrane reviews 1
Trials 48

ID	Search	Hits
#1	MeSH descriptor: [Operating Rooms] explode all trees	208
#2	(surgical or surgeon or surgeons or operating room* or operation room* or operating theat* or operation theat*):ti,ab,kw (Word variations have been searched)	107341
#3	(hat or hats or cap or caps or headwear* or headgear* or head-wear* or head-gear* or helmet or helmets or bouffant* or hood or hoods):ti,ab,kw (Word variations have been searched)	6496
#4	#1 AND #3	2
#5	(surgical or surgeon or surgeons or operating room* or operation room* or operating theat* or operation theat*):ti,ab,kw NEAR/6 (hat or hats or cap or caps or headwear* or headgear* or head-wear* or head-gear* or helmet or helmets or bouffant* or hood or hoods):ti,ab,kw	48
#6	**#4 OR #5**	**49**

The web-sites of **SBU** and **Folkehelseinstituttet** were visited
07 Apr 2020
Nothing relevant to the question at issue was found

Reference lists
A comprehensive review of reference lists brought 1 new record

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Reference lists

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Project: HTA - Does headgear type used by the operating room staff affect postoperative surgical site infection rate?
Appendix 2 – Characteristics of included studies

Author Year Country	Study Design	Study Duration	Study Groups; Intervention vs control	Surgical procedures studied	Patients (n)	Mean Age (years)	Men (%)	Outcome variables (relevant for PICO)
Haskins, 2017, USA	Cohort Questionnaire	30 days	I=Disposable bouffant, ears covered C=Disposable surgical skull cap, or cloth surgical cap	Ventral hernia repair surgery	6,210	57	I=103 (41) C=2,909 (49)	Surgical site infection
Kothari, 2018, USA	Cohort before-after	30 days	I=Bouffant cap C=Skull cap	Colon/intestinal, hernia/other, hepatobiliary, and foregut surgery	1,543	I=59 C=56	I=572 (94) C= 862 (92)	Surgical site infection Serious surgical site infection
Rios-Diaz, 2018, USA	Cohort before-after	30 days	I=Bouffant or helmet C=Surgical skull cap	Clean or clean-contaminated surgery: e.g. colectomy, pancreatectomy, and ventral hernia repair. Not vascular surgery	1,901	I=60 C=58	I= 644 (44) C= 306 (40)	Surgical site infection Serious surgical site infection
Shallwani, 2018, USA	Cohort before-after	Unclear	I= Bouffant C=Surgical skull cap	Clean (class I) surgery, spinal surgery, and neurosurgery craniotomy/craniectomy	15,959	Not reported	Not reported	Surgical site infection

Project: HTA - Does headgear type used by the operating room staff affect postoperative surgical site infection rate?
Appendix 3: Excluded articles

Author, year	Reason for exclusion
Hubble, 1996	Wrong intervention, no patients
Markel, 2017	No patients
Sjol, 2002	No outcomes reported
Spruce, 2017	No outcomes reported
Wills, 2020	Wrong (mixed) interventions

Project: HTA-Does headgear type used by the operating room staff affect postoperative surgical site infection rate?
Appendix 4.1
Outcome variable: sSSI

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Kothari, 2018, USA	Cohort before-after	1,543	Not reported	Bouffant cap n=608, sSSI=11 (1.81%)	Skull cap n=935, sSSI=10 (1.07%) p=0.26*	Endpoint SSI 30 days Not specified if bouffant caps were used with ears covered * p-value calculated from data with Fisher's exact test.	+/?	?	?/-
Rios-Diaz, 2018, USA	Cohort before-after	1,901	Not reported	Bouffant or hoods n = 1,141 sSSI=44 (3.86%)	Surgical skull cap n = 760 sSSI=26 (3.42%) p=0.71	Endpoint SSI 30 days Not specified if bouffant caps were used with ears covered sSSI including deep, and organ/space infections * p-value calculated from data with Fisher's exact test.	+/?	?/-	+/?

Project: HTA-Does headgear type used by the operating room staff affect postoperative surgical site infection rate?
Appendix 4.2
Outcome variable: SSI

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Haskins, 2017, USA	Cohort Mail questionnaire	6,210	79% response rate	Disposable bouffant, ears covered Disposable bouffant, ears covered Total SSI, n=834 31 (3.72%)	Disposable surgical skull cap OR 0.884 95% CI: 0.5 to 1.56 Cloth surgical cap OR 1,136 95% CI: 0.53 to 2.44 Total SSI, n=4,084 161 (3.94%) p=0.84 *	Endpoint SSI 30 days Disposable bouffant, ears covered n=834, SSI=31 Disposable surgical skull cap, n=3,433, SSI=137 Cloth surgical skull cap, n=615, SSI=24 * p-value calculated from data with Fisher's exact test.	?/-	+/?	?/-
Kothari, 2018, USA	Cohort before-after	1,543	Not reported	Bouffant cap, n=608 SSI=49 (8.06%)	Skull cap, n=935 SSI=47 (5.03%) p=0.02	Endpoint SSI 30 days	+/?	?	?/-
Rios-Diaz, 2018, USA	Cohort before-after	1,901	Not reported	Bouffant or helmet, n=1,141 SSI=63 (5.52%)	Surgical skull cap, n=760 OR 1.12 95% CI: 0.73 to 1.71 SSI=40 (5.26%) p=0.81	Endpoint SSI 30 days	+/?	?/-	?
Shallwani, 2018, USA	Cohort before-after	15,959	Not reported	Bouffant, n=8,446 SSI=71 (0.84%)	Surgical skull cap, n=7,513 SSI=58 (0.77%) p=0.63	SSI, endpoint time unclear	+	+/?	+/?

OR: Odds ratio, SSI=Surgical site infection

Innehållsdeklaration

Denna HTA-rapport är baserad på följande moment:

- ☑ Metodbeskrivning
- ☑ PICO
- ☑ Uttömmande litteratursökning
- ☑ Flödesschema
- ☑ Urval relevans
- ☑ Kvalitetsgranskning
- ☑ Tabelldata
- ☑ Sammanvägning av resultat
- ☑ Metaanalys
- ☑ Evidensgradering enligt GRADE
- ☑ Sammanfattning
- ☑ Ekonomi
- ☑ Organisation
- ☑ Etik
- ☑ Pågående studier
- ☑ Exkluderade artiklar
- ☑ Expertgrupp deltar
- ☑ Extern granskning
- ☑ Kunskapsluckor identifierade
- ☑ Jävsdeklaration inhämtad från projektdeltagarna

Region Västra Götaland, HTA-centrum

Health Technology Assessment
Regional activity-based HTA

HTA

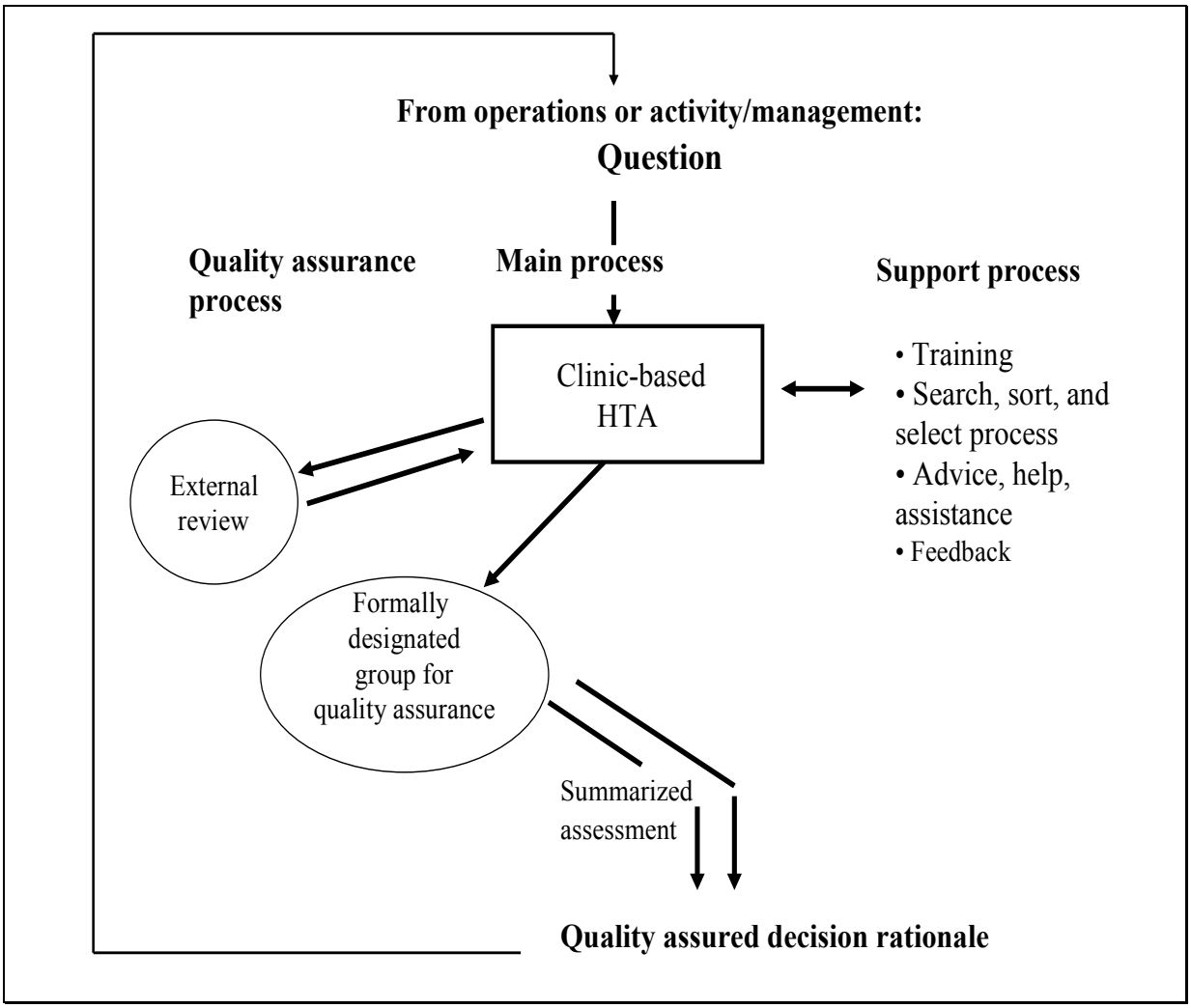
Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technologies, i.e. interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care.

To evaluate the certainty of evidence the Centre of Health Technology Assessment in Region Västra Götaland is currently using the GRADE system, which has been developed by a widely representative group of international guideline developers. According to GRADE the level of evidence is graded in four categories:

High certainty of evidence	= (GRADE⊕⊕⊕⊕)
Moderate certainty of evidence	= (GRADE ⊕⊕⊕O)
Low certainty of evidence	= (GRADE ⊕⊕OO)
Very low certainty of evidence	= (GRADE ⊕OOO)

In GRADE there is also a system to rate the strength of recommendation of a technology as either “strong” or “weak”. This is presently not used by the Centre of Health Technology Assessment in Region Västra Götaland. However, the assessments still offer some guidance to decision makers in the health care system. If the level of evidence of a positive effect of a technology is of high or moderate quality it most probably qualifies to be used in routine medical care. If the level of evidence is of low quality the use of the technology may be motivated provided there is an acceptable balance between benefits and risks, cost-effectiveness and ethical considerations. Promising technologies, but a very low quality of evidence, motivate further research but should not be used in everyday routine clinical work.

Christina Bergh
Professor, MD
Head of HTA-centrum


From operations or activity/management:
Question
Quality assurance process
Main process
Support process
Clinic-based HTA
• Training
• Search, sort, and select process
• Advice, help, assistance
• Feedback
External review
Formally designated group for quality assurance
Summarized assessment
Quality assured decision rationale

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