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Operating room ventilation—Validation of reported data on 108 067 primary total hip arthroplasties in the Norwegian Arthroplasty Register

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Abstract

Rationale, aims, and objectives: The true effect of laminar airflow (LAF) systems on postoperative infection is disputed, partly due to uncertainty regarding the validity of ventilation data in register studies. The aim of this study was to validate the information on operating room (OR) ventilation reported by the orthopaedic surgeons to the Norwegian Arthroplasty Register (NAR) after primary total hip arthroplasty (THA).

Method: Forty of the 62 public orthopaedic units performing primary THA in Norway during the period 1987-2015 were included. The hospitals' current and previous ventilation systems were evaluated in cooperation with the hospitals head engineer. We identified the type of ventilation system reported to the NAR and compared the information with the factual ventilation in the specific ORs at the time of primary THA.

Results: A total of 108 067 primary THAs were eligible for assessment. None of the hospitals performed THA in true "greenhouse" (GH) ventilation. Fifty-seven percent of the primary THAs were performed in ORs with LAF and 43% in ORs with conventional, turbulent ventilation (CV). Comparing the reported data with the validated data, LAF was reported with a sensitivity of 86%, specificity of 89%, and positive predictive value (PPV) of 92%, with an accuracy of 88%. CV was reported with a sensitivity of 89%, specificity of 87%, and PPV of 84%, with an accuracy of 88%. The total, mean misreporting rate was 12%.

Conclusions: Surgeons were not fully aware of what kind of ventilation system they operated in. This study indicates that conclusions based on ventilation data reported on THA in the NAR should not be interpreted without considering the inaccuracy of the data.

KEYWORDS

conventional ventilation, laminar airflow, misreporting, operating room ventilation, The Norwegian Arthroplasty Register, total hip arthroplasty

1 | INTRODUCTION

Laminar airflow (LAF) systems have been used in operating rooms (ORs) for ultraclean surgery since the late 1950s. The intention is to reduce the incidence of postoperative infection by reducing the colony forming unit (CFU) density in the air of the OR.[1,2] The systems work by sending linear and parallel streams of clean air with constant velocity, directly on to the surgical field in order to, in theory, displace and reduce the flow of less clean air to the surgical field. In contrast, the conventional ventilation (CV) systems mostly use the dilution principle and work by creating an overpressure using turbulent air.[3] The LAF systems are, however, rarely able to create true LAF[3] and are therefore more recently designated as unidirectional airflow (UDAF or UDF) systems; but for simplicity, we will use the designation LAF in the present paper.

The existing recommendations of LAF as a prophylactic measure of postoperative infection, rest mainly on a randomized trial from a time when standards on antibiotic prophylaxis were not fully established, and was therefore not thoroughly adjusted for. The findings therefore may not apply for the current situation.[4] Subsequent observational studies from the same decade that adjusted for antibiotic prophylaxis demonstrated no influence of OR ventilation on the rate of postoperative infection.[5,6] Newer, registry-based studies have suggested that LAF actually *increases* the risk of postoperative infection.[7-9] A recent systematic review and meta-analysis in the Lancet, based partly on the above mentioned registry studies, concluded that LAF systems should *not* be installed in new ORs.[10] The conclusion is controversial and may be premature.[11,12] The Lancet review also includes a study from the Norwegian Arthroplasty Register (NAR), not studying the effect of LAF specifically, and which may be confounded by misreporting.[13]

Before concluding rigorously in systematic reviews and meta-analyses, it is of fundamental importance that ventilation data are valid and of good quality. The aim of the present study was to validate the data on OR ventilation reported on primary total hip arthroplasty (THA) cases to the NAR.

2 | MATERIAL AND METHODS

The NAR has registered individual data on primary THAs and THA revisions since 1987. The surgeon fills in a form immediately after surgery. The form contains information on patient identity, date of operation, the type of OR ventilation in addition to several other patient, and surgery-related factors. For each hospital, we used the NAR to identify the type of OR ventilation reported for the primary THA, ie, CV, LAF, or greenhouse (GH) ventilation (register form, Appendix A). The period of inclusion was 1 September 1987 to 31 December 2015.

In order to validate the information on OR ventilation reported by the surgeon, the hospitals' current and previous ventilation systems were evaluated in direct contact and cooperation with the hospitals NAR contact-surgeon and the hospitals head engineer. Six hospitals in a pilot study were visited in order to gain knowledge on the different systems and method of data collection. The factual ventilation systems in the ORs were assessed using a detailed questionnaire regarding the configuration and specifications of the ventilation systems (Appendix B). The questionnaire was used as guidance in the correspondence with the engineers. Objective, technical specifications from manuals were retrieved in cases of doubt. To be classified as a LAF system, the ventilation set-up had to be confirmed to have been installed with a unidirectional diffuser array. These criteria are not sufficient to verify true LAF conditions, but in this paper, the main issue was whether the system was installed with a unidirectional diffuser array or not, in order to do a direct comparison with the reported data.

To assess the correspondence between the reported and validated ventilation data, we did a case-to-case comparison of the OR in which each reported, primary THA was performed. The accuracy of reporting, based on sensitivity and specificity for each ventilation group, was then calculated.

If the ventilation system had been out of function, exchanged, or updated, primary THAs reported from that year were excluded. Sixty-two public hospitals reported to the register in the period. Twelve hospitals were excluded due to low numbers of primary THAs or concurrent use of ORs with different ventilation systems. Fifty hospitals were selected for inclusion. Five hospitals were excluded due to missing contact with key personnel and five due to incomplete ventilation data (Figure 1). Forty hospitals had precise information on the

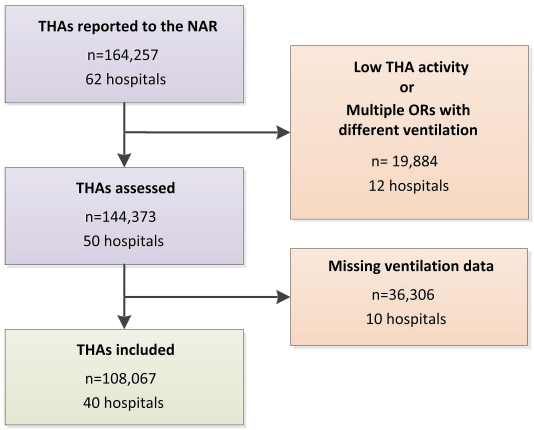

FIGURE 1 Flow chart showing hospital and total hip arthroplasty (THA) selection

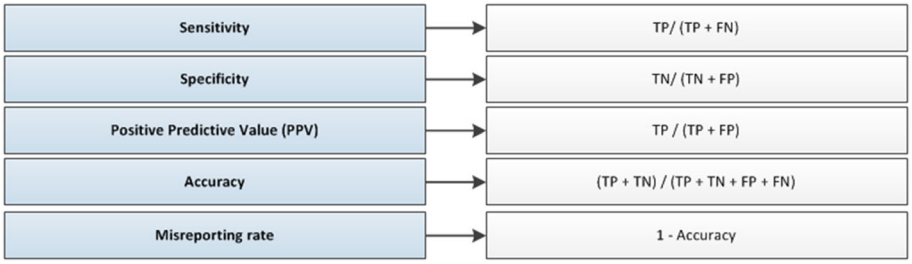

FIGURE 2 Formulas for calculating measures. FP, false positive; FN, false negative; TN, true negative; TP, true positive

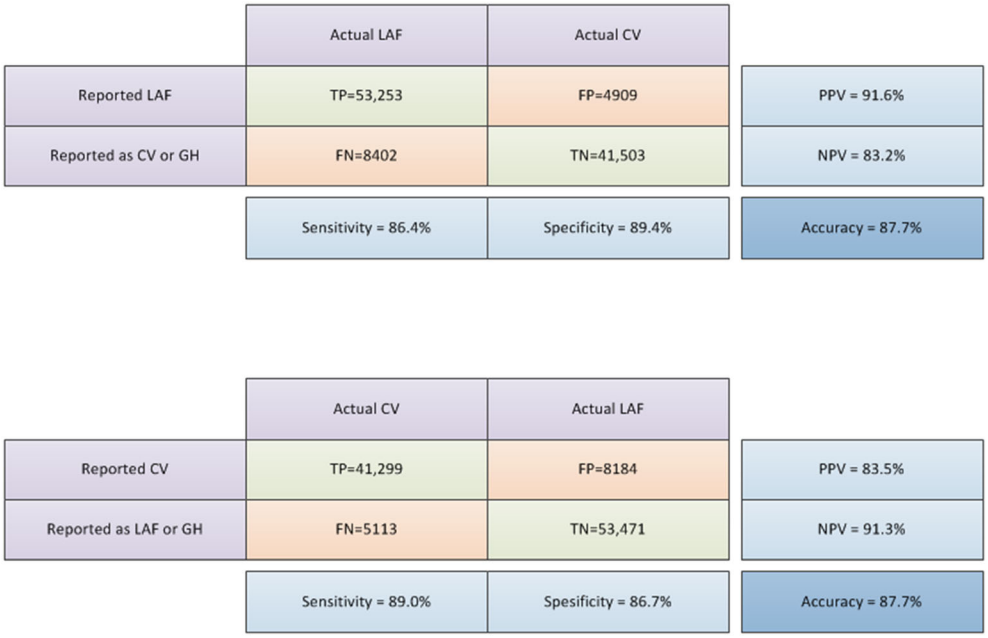

FIGURE 3 Comparison between surgeon-reported ventilation data and validated ventilation data. CV, conventional ventilation; FN, false negative; FP, false positive; GH, greenhouse ventilation; LAF, laminar airflow; NPV, negative predictive value; PPV, positive predictive value; TN, true negative; TP, true positive

OR ventilation, and these 40 hospitals reported 108 067 primary THAs available for validation.

2.1 | Statistics

The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy of reported data, and misreporting rate were calculated as presented in Figure 2. Statistical analyses were performed using SPSS version 24 (SPSS Inc, 2004).

2.2 | Ethics

The registration of data and the study was performed confidentially on patient consent and according to Norwegian and EU data protection rules.

3 | RESULTS

A total of 108 067 primary THAs were included in the further analysis. These THAs constituted 66% of the THAs reported to the NAR during the study period; 57 % of the surgeries were performed in a room with verified LAF, and 43% were performed in rooms with roof-mounted, verified CV. None of the THAs were performed in true GH conditions.

Figure 3 gives a summarized comparison between the reported OR-ventilation and the factual OR ventilation. LAF was reported with a sensitivity of 86%, specificity of 89%, and Positive Predictive Value (PPV) 92%. This gave an accuracy of 88%. CV was reported with a sensitivity of 89%, specificity of 87% and PPV of 84%, with an accuracy of 88%. This gave a total misreporting rate of 12% for both LAF and CV.

4 | DISCUSSION

We found 12% misreporting of the OR ventilation used during primary THA reported to the NAR.

Other registries have studied the preventive effect of LAF systems. All of these studies are included in the latest meta-analysis published in The Lancet.[10] Two studies based on data from The German KISS (Krankenhaus [hospital] Infections Surveillance System) registry showed an increased risk of severe surgical site infection (SSI) after THA operated in LAF conditions compared with CV.[7,9] They gathered information on the different ventilation systems by using a questionnaire, where data were provided by the surgical departments. To which degree these data were validated or from whom the data were reported remains unclear. The New Zealand Joint Registry reported an increased risk of revision due to deep infection after THA performed in an LAF theatre.[8] They validated the reported information by asking the hospitals to confirm what kind of ventilation system they used. It was not stated what kind of personnel answered these questions. Also included in the latest meta-analysis was a study from the NAR,[13] using invalidated, surgeon reported data on ventilation. In that NAR study, OR ventilation was used only as an adjustment variable in the study of time trends for revision due to infection. The relative risk of revision due to infection was found to be 1.3 (95% CI, 1.1-1.5) for LAF compared with CV. The above mentioned studies contribute to the basis for the new WHO-guidelines,[14] which recommend not to use LAF for arthroplasty. Taking the results of our study into consideration, this recommendation may be considered controversial, as the evidence is of uncertain validity and quality.

4.1 | Strengths

The validated ventilation data, presented in the present study, is based on a large, national registry, with 100% coverage and 97% completeness in the reporting of primary THA.[15-17] It offers an opportunity to validate a majority of a national cohort from a long period of time.

The validated data were based on the information retrieved from the engineers responsible for the hospitals ventilation systems, and this information was verified by the NAR contact surgeon. In addition, in order to overcome possible reporting bias, we retrieved objective, technical data from manuals and specifications on the hospitals ventilation in cases of doubt. Only indubitable information was included, and hospitals with uncertain information were excluded.

4.2 | Potential weaknesses

Only 40 hospitals, representing 66% of the primary THAs reported to the NAR, were eligible for validation of OR ventilation. Like the 40 included hospitals, the 22 excluded hospitals had THA activity throughout the majority of the time period and a similar distribution between local hospitals, regional hospitals, and elective centres. The excluded hospitals also had similar completeness of reporting of primary THA and OR ventilation.[16,17] Hence, we believe that the selection bias was minimal.

5 | CONCLUSION

Surgeons were not fully aware of what kind of ventilation system they operated in when performing primary THA. This resulted in a 12% misreporting rate for both CV and LAF systems. This indicates that conclusions based on ventilation data in the NAR should not be interpreted without considering the inaccuracy of the data as the subsequent evaluations of the prophylactic effect of ventilation systems against postoperative infection may turn out inaccurate.

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All authors have approved the final article. H.L., E.L., and H.D. conceived and planned the study. H.L. collected the data. H.L. and C.B.J. performed the analyses. H.L. wrote the manuscript. All authors contributed in interpretation of the analyses and critical revision of the manuscript.

We would like to thank the NAR contact surgeons and engineers at the hospitals for contributing to data collection. We also thank Norwegian surgeons for persistently and thoroughly reporting primary THAs to the NAR.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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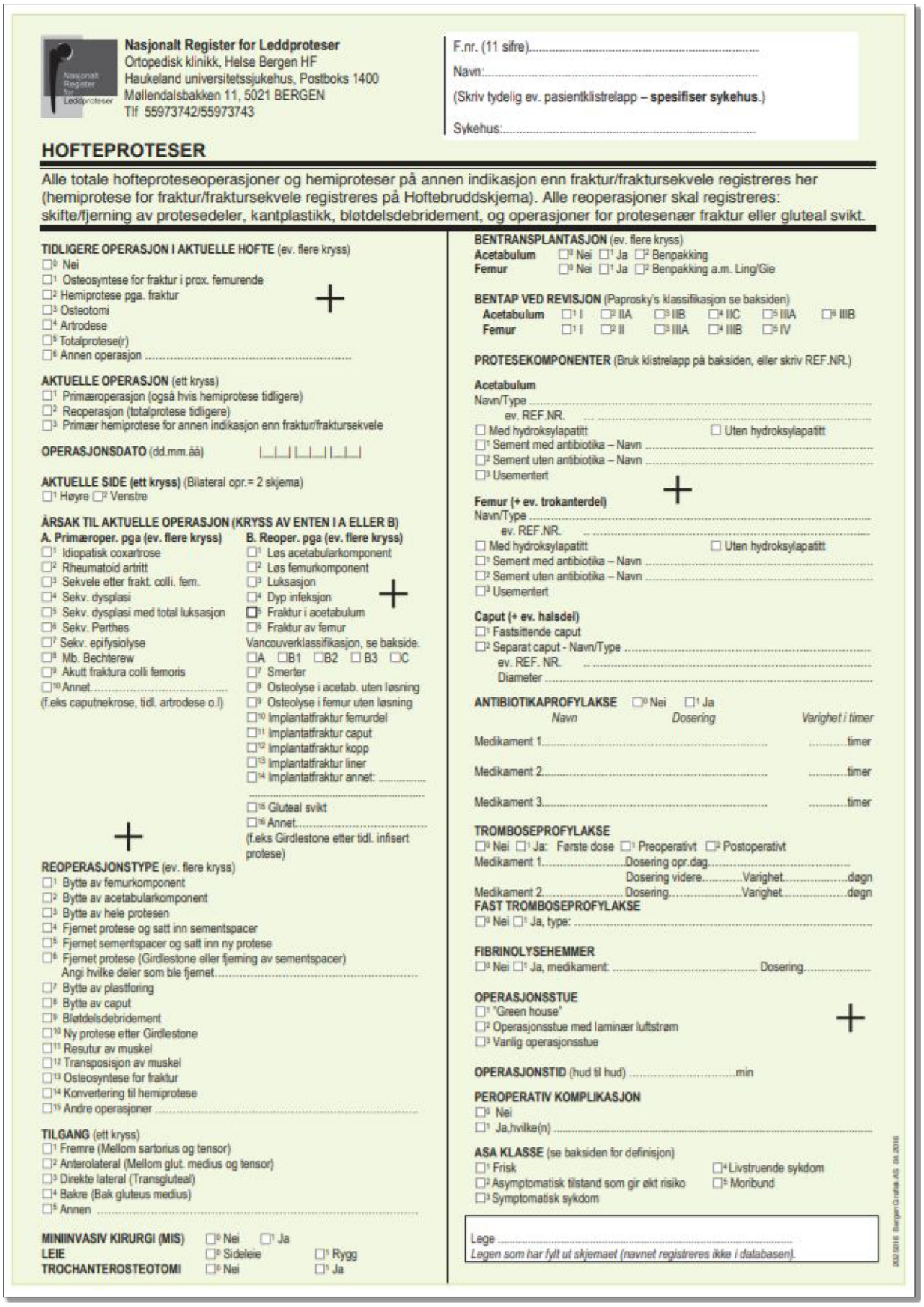
APPENDIX A



Nasjonalt Register for Leddproteser
Ortopedisk klinikk, Helse Bergen HF
Haukeland universitetssjukehus, Postboks 1400
Møllendalsbakken 11, 5021 BERGEN
Tlf 55973742/55973743

F.nr. (11 sifre).....
Navn:.....
(Skriv tydelig ev. pasientklistrelapp – **spesifiser sykehus**.)
Sykehus:.....

HOFTEPROTESER

Alle totale hofteproteseoperasjoner og hemiproteser på annen indikasjon enn fraktur/fraktursekvele registreres her (hemiprotese for fraktur/fraktursekvele registreres på Hoftebruddskjema). Alle reoperasjoner skal registreres: skifte/fjerning av protesedeler, kantplastikk, bløtdelsdebridement, og operasjoner for protesenær fraktur eller gluteal svikt.

TIDLIGERE OPERASJON I AKTUELLE HOFTE (ev. flere kryss)
☐0 Nei
☐1 Osteosyntese for fraktur i prox. femurende
☐2 Hemiprotese pga. fraktur
☐3 Osteotomi
☐4 Artrodese
☐5 Totalprotese(r)
☐6 Annen operasjon .....

AKTUELLE OPERASJON (ett kryss)
☐1 Primæroperasjon (også hvis hemiprotese tidligere)
☐2 Reoperasjon (totalprotese tidligere)
☐3 Primær hemiprotese for annen indikasjon enn fraktur/fraktursekvele

OPERASJONSDATO (dd.mm.åå) |_|_| |_|_| |_|_|

AKTUELLE SIDE (ett kryss) (Bilateral opr.= 2 skjema)
☐1 Høyre ☐2 Venstre

ÅRSAK TIL AKTUELLE OPERASJON (KRYSS AV ENTEN I A ELLER B)

A. Primæroper. pga (ev. flere kryss)
☐1 Idiopatisk coxartrose
☐2 Rheumatoid artritt
☐3 Sekvele etter frakt. colli. fem.
☐4 Sekv. dysplasi
☐5 Sekv. dysplasi med total luksasjon
☐6 Sekv. Perthes
☐7 Sekv. epifysiolyse
☐8 Mb. Bechterew
☐9 Akutt fraktura colli femoris
☐10 Annet.....
(f.eks caputnekrose, tidl. artrodese o.l)

B. Reoper. pga (ev. flere kryss)
☐1 Løs acetabularkomponent
☐2 Løs femurkomponent
☐3 Luksasjon
☐4 Dyp infeksjon
☐5 Fraktur i acetabulum
☐6 Fraktur av femur
Vancouverklassifikasjon, se bakside.
☐A ☐B1 ☐B2 ☐B3 ☐C
☐7 Smerter
☐8 Osteolyse i acetab. uten løsning
☐9 Osteolyse i femur uten løsning
☐10 Implantatfraktur femurdel
☐11 Implantatfraktur caput
☐12 Implantatfraktur kopp
☐13 Implantatfraktur liner
☐14 Implantatfraktur annet: .....
.....
☐15 Gluteal svikt
☐16 Annet.....
(f.eks Girdlestone etter tidl. infisert protese)

REOPERASJONSTYPE (ev. flere kryss)
☐1 Bytte av femurkomponent
☐2 Bytte av acetabularkomponent
☐3 Bytte av hele protesen
☐4 Fjernet protese og satt inn sementspacer
☐5 Fjernet sementspacer og satt inn ny protese
☐6 Fjernet protese (Girdlestone eller fjerning av sementspacer)
Angi hvilke deler som ble fjernet.....
☐7 Bytte av plastforing
☐8 Bytte av caput
☐9 Bløtdelsdebridement
☐10 Ny protese etter Girdlestone
☐11 Resutur av muskel
☐12 Transposisjon av muskel
☐13 Osteosyntese for fraktur
☐14 Konvertering til hemiprotese
☐15 Andre operasjoner .....

TILGANG (ett kryss)
☐1 Fremre (Mellom sartorius og tensor)
☐2 Anterolateral (Mellom glut. medius og tensor)
☐3 Direkte lateral (Transgluteal)
☐4 Bakre (Bak gluteus medius)
☐5 Annen .....

MINIINVASIV KIRURGI (MIS) ☐0 Nei ☐1 Ja
LEIE ☐0 Sideleie ☐1 Rygg
TROCHANTEROSTEOTOMI ☐0 Nei ☐1 Ja

BENTRANSPLANTASJON (ev. flere kryss)
Acetabulum ☐0 Nei ☐1 Ja ☐2 Benpakking
Femur ☐0 Nei ☐1 Ja ☐2 Benpakking a.m. Ling/Gie

BENTAP VED REVISJON (Paprosky's klassifikasjon se baksiden)
Acetabulum ☐1 I ☐2 IIA ☐3 IIB ☐4 IIC ☐5 IIIA ☐6 IIIB
Femur ☐1 I ☐2 II ☐3 IIIA ☐4 IIIB ☐5 IV

PROTESEKOMPONENTER (Bruk klistrelapp på baksiden, eller skriv REF.NR.)

Acetabulum
Navn/Type .....
ev. REF.NR. .....
☐ Med hydroksylapatitt ☐ Uten hydroksylapatitt
☐1 Sement med antibiotika – Navn .....
☐2 Sement uten antibiotika – Navn .....
☐3 Usementert

Femur (+ ev. trokanterdel)
Navn/Type .....
ev. REF.NR. .....
☐ Med hydroksylapatitt ☐ Uten hydroksylapatitt
☐1 Sement med antibiotika – Navn .....
☐2 Sement uten antibiotika – Navn .....
☐3 Usementert

Caput (+ ev. halsdel)
☐1 Fastsittende caput
☐2 Separat caput - Navn/Type .....
ev. REF. NR. .....
Diameter .....

ANTIBIOTIKAPROFYLAKSE ☐0 Nei ☐1 Ja

	Navn	*Dosering*	*Varighet i timer*
Medikament 1			timer
Medikament 2			timer
Medikament 3			timer

TROMBOSEPROFYLAKSE
☐0 Nei ☐1 Ja: Første dose ☐1 Preoperativt ☐2 Postoperativt
Medikament 1.....Dosering opr.dag.....
Dosering videre.....Varighet.....døgn
Medikament 2.....Dosering.....Varighet.....døgn

FAST TROMBOSEPROFYLAKSE
☐0 Nei ☐1 Ja, type: .....

FIBRINOLYSEHEMMER
☐0 Nei ☐1 Ja, medikament: ..... Dosering.....

OPERASJONSSTUE
☐1 "Green house"
☐2 Operasjonsstue med laminær luftstrøm
☐3 Vanlig operasjonsstue

OPERASJONSTID (hud til hud) .....min

PEROPERATIV KOMPLIKASJON
☐0 Nei
☐1 Ja,hvilke(n) .....

ASA KLASSE (se baksiden for definisjon)
☐1 Frisk ☐4 Livstruende sykdom
☐2 Asymptomatisk tilstand som gir økt risiko ☐5 Moribund
☐3 Symptomatisk sykdom

Lege .....
Legen som har fylt ut skjemaet (navnet registreres ikke i databasen).

30/5016 BergenGrafisk AS 04.2016

APPENDIX B

Nasjonalt Register for Leddproteser

Nasjonalt Register for Leddproteser
The Norwegian Arthroplasty Register

Spørreskjema – Ventilasjon av operasjonsstuer

Stuenummer: .....

Periode i bruk: fra..... til.....

1) Ventilasjonstype/luftstrømstype: Laminær (LAF) ☐ Konvensjonell ☐ Greenhouse ☐ Annet:.....

2) Stuens areal: .....m^2

3) Stuens takhøyde: .....m

4) Luftens utgangshastighet: .....m/s

5) Anleggets nominelle innluftsmengde: .....m^3/h Friskluftsandel.....

6) Hvilken type filter/filterklasse er installert?: .....

7) Hvor ofte foretas: Filterbytte.....pr. år

Rengjøring.....pr. år

8) Hvordan og hvor ofte foretas CFU-måling?: ...../.....pr. år

Ingen rutiner ☐

9) Har CFU-verdien vært målt til ≤ 10CFU/m^3: Ja ☐ Nei ☐ Vet ikke ☐

10) Ventilene for ut-luft er plassert: Gulv ☐ Vegg ☐ Tak ☐

11) Benytter systemet underkjøling?: Ja ☐ Nei ☐ Vet ikke ☐

<u>For LAF-tak:</u>

12) Takets størrelse .....m x .....m

13) Takets luftstrøm er definert som: Delvegg ☐ Helvegg ☐ Spesifisering:

14) Takets luftstrøm er: Vertikal ☐ Horisontal ☐ Skrå ☐

15) Er det montert sidevegger/skjørt?: Ja ☐ Nei ☐ Lengde:

16) Er det installert spesial-operasjonslamper for LAF?: Ja ☐ Nei ☐

17) Er det sonemarkering i gulvet?: Ja ☐ Nei ☐

Spørreskjema - Ventilasjon av operasjonsstuer - forklaringer

Stuenummer og Periode i bruk: Den aktuelle operasjonsstuens romnummer og perioden den ble brukt i intervallet 1987-2015. (dd.mm.åååå, mm.åååå, åååå eller dd (dagens dato)).

1) **Ventilasjonstype:** Laminær luftstrøm (LAF), Konvensjonell (turbulent) overtrykksventilasjon, «Greenhouse»-ventilasjon eller annet spesifisert tak (Allander, Weiss, Trox etc).

2) **Stuens areal:** Stuens areal i kvadratmeter (m^2).

3) **Stuens takhøyde:** Stuens takhøyde i meter (m).

4) **Luftens utgangshastighet:** Snittverdi av luftens utgangshastighet i meter per sekund (m/s). For sonedelte tak er det også ønskelig at det oppgis én snittverdi. Størrelsesorden 0,15 - 0,5 m/s.

5) **Anleggets innluftsmengde:** Luftvolumet som systemet tilbyr per time (m^3/h) (Størrelsesorden 1000-16000 m^3/h) samt friskluftsandel (primærluft).

6) **Filtertype/-klasse:** Filtertype for innløpsluften. Det er ønskelig med informasjon om alle steg. For eksempel HEPA, 3 stage, Last H13.

7) **Filterbytte og rengjøring:** Frekvens for filterbytte (alle steg) og rengjøring av ventilasjonssystemet; 1 x -, 2 x pr. år etc.

8) **CFU-målinger:** Gjøres målingene under pågående kirurgi («**intraoperativt**») og i nærheten av operasjonsfeltet, eller på «**tom stue**»? Frekvens for CFU-målinger; 1 x -, 2 x pr. år etc.

9) **CFU-verdien:** Har CFU-konsentrasjonen noen gang vært målt til å være ≤ 10CFU/m^3 slik kravet fra statens helsetilsyn om ultrarene operasjonsstuer tilsier? Dette vil spesifiseres i korrespondanse med smittevernavdelingen.

10) **Ventiler for ut-luft:** Er slusene for luften som forlater rommet plassert langs gulvet, på veggen (eventuelt som langstrakte sluser fra gulvet og opp på veggen), tak eller en kombinasjon (sett da flere kryss eller spesifiser)?

11) **Underkjøling:** Benyttes det underkjøling av innløpsluft?

12) **Takets størrelse:** Mål på selve ventilasjonsflaten (lengde x bredde)

13) **Takets luftstrøm:** Er det snakk om et helveggssystem med nokså jevn snitthastighet for luftsøylen i hele taket, eller er det snakk om et delveggssystem med ulike hastighetssoner. Ved delvegg er det ønskelig at prinsippet spesifiseres: eksponensiell LAF e.l.

14) **Takets luftstrøm:** Er det vertikal luftstrøm, horisontal luftstrøm eller skrå luftstrøm?

15) **Sidevegger/skjørt:** Er det montert sidevegger/skjørt ned langs innløpet? Hvis ja: oppgi helst lengde på disse/dette.

16) **Spesiallamper:** Er det montert spesial-operasjonslamper til bruk sammen med laminær luftstrøm for å hindre dannelse av turbulens?

17) **Sonemarkering:** Er det markeringer i gulvet på stuen som indikerer luftsonen(e)?