

A Patient Safety Journey through 40 Years: From Clinical Challenges to Implementation of System Changes

**Stig Harthug MD, PhD
NSQH – Oslo 30.08.2024**

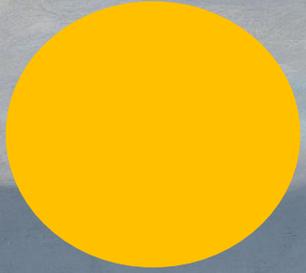


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“Far, far away Soria Moria Palace shimmered like gold”



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Head of regional unit for patient safety 2006-2020

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ORIGINAL ARTICLES

Effect of outer membrane vesicle vaccine against group B meningococcal disease in Norway

GUNNAR BJUNE E. ARNE HØBBY JON KETIL GRØNNESBY
ØYVIND ARNESEN JOHAN HOLST FREDRIKSEN
ALFRED HALSTENSEN EIRIK HOLTEN ANN-KRISTIN LINDBAK
HANNE NØKLEBY EINAR ROSENQVIST LEIF KÅRE SOLBERG
OTTO CLOSS JAN ENG L. ODDVAR FRØHOLM ARVE LYSTAD
LEIV S. BAKKETEIG BODOLF HAREIDE

For more than 15 years, Norway has had the highest incidence of meningococcal disease in northern Europe, with 80% of cases being due to serogroup B meningococci. The case-fatality has been about 10%. In this study, an outer membrane vesicle vaccine, previously been shown to be bactericidal in a

Introduction

Since 1974, Norway has had a high incidence of meningococcal disease,^{1,2} which started in the northern part of the country and slowly spread southwards. About 300 cases were being reported annually in a population of 4.2 million but since 1988 the annual number of reported cases has declined to less than 200 (fig 1). During these past 17 years, 80% of cases have been due to *Neisseria meningitidis* group B, with 75% being of serotype 15, subtype P1.16, or both.³ Genetically 70-80% belonged to the sulphonamide-resistant group of organisms of the ET-5 complex.⁴ The National Institute of Public Health (NIPH), in collaboration with the Norwegian State Serum Institute, developed a vaccine against group B meningococcal disease in 1983. Unlike the capsular polysaccharides

ME- patients:
Allegations of side
effects of the vaccine



Myalgisk encefalopati (ME)
og vaksinasjon mot
meningokokksykdom



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patients:
ons of side
the vaccine





NORDLANDSSYKEHUSET


NORDLANDSSYKEHUSET
← HOVEDINNGANG

- INNGANG PARKVEIEN**
- ✚ Akuttmottak
 - Hovedkjøkken
 - Teknisk avdeling
 - Sentrallager
 - Varemottak

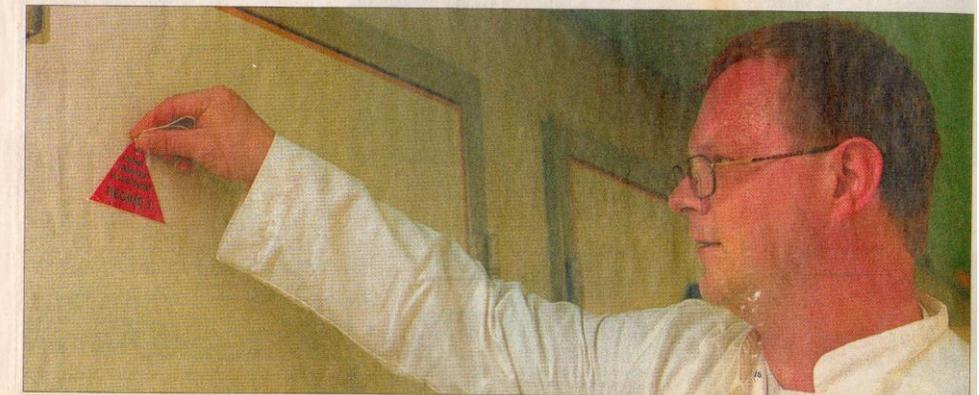

NORDLANDSSYKEHUSET
KONTAKT
• 077 20 20 20
• 077 20 20 20
• 077 20 20 20
• 077 20 20 20

>150 hospital patients infected with multiresistant enterococci at Haukeland University hospital 1995-1996

- Mostly urinary tract infection
- 1/20 died
- Failure in basic care routine
- Strongest riskfactor
 - use of broad spectrum antibiotics
- The outbreak faded slowly

Aftenposten

Farlig bakterie smittet 114



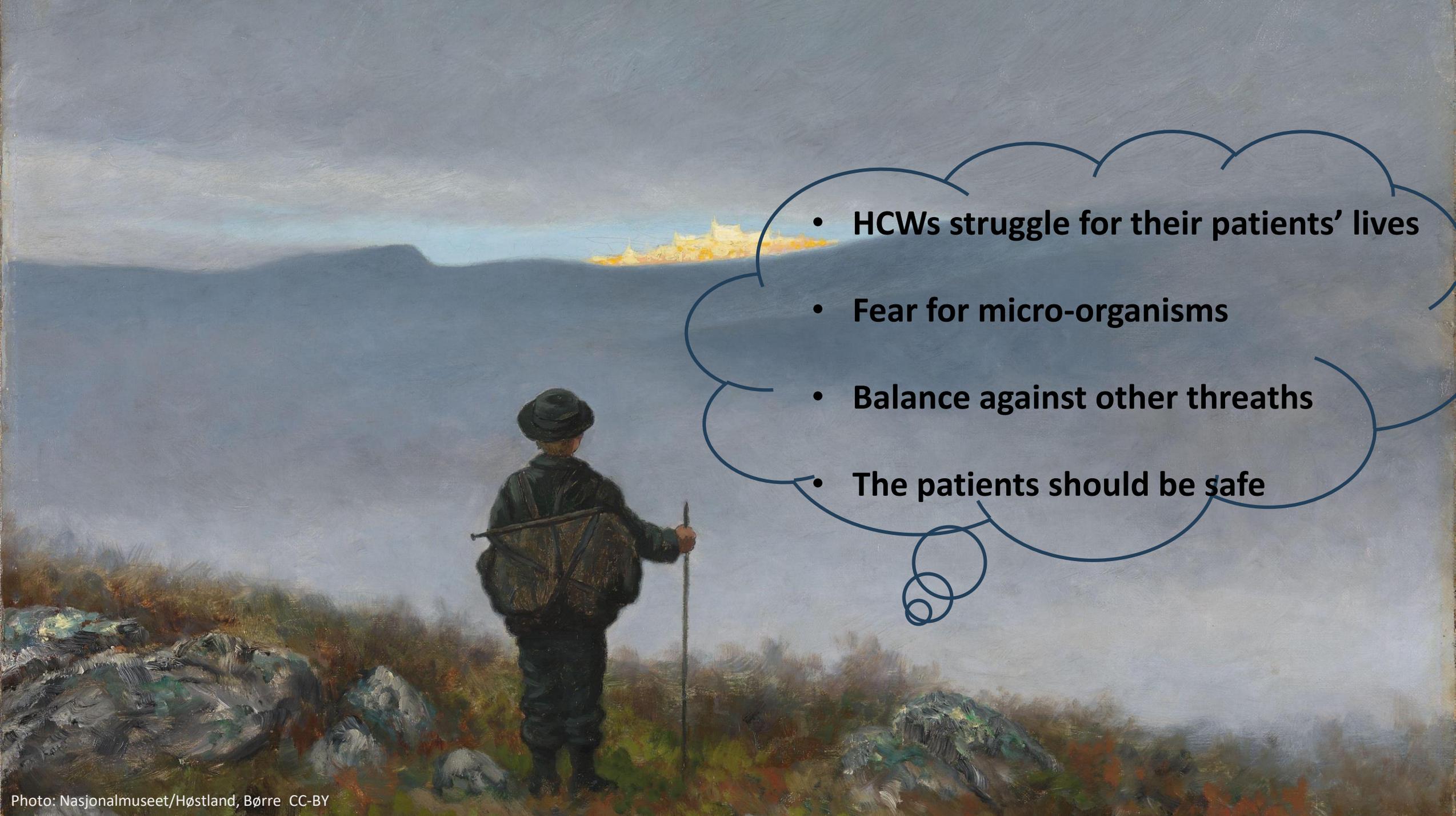
STRENGT ISOLAT: Avdelingsoverlege Stig Harthug viser den røde varseltekanten som forteller at pasienten på rommet er smittet av enterokokk-bakterier som er resistente mot antibiotikumet van-komycin. Disse pasientene blir lagt i det strengeste isolatet på Haukeland sykehus. Foto: MARIT HONMEDAL

SPRER SEG: 114 pasienter på Haukeland sykehus er det siste året blitt smittet av enterokokk-bakterier som er motstandsdyktige mot antibiotika. Fire av dem er døde. Bakteriene har spredt seg til flere avdelinger på sykehuset.

” Vi frykter at smitten skal spre seg så mye at vi mister kontrollen over situasjonen ”

STIG HARTHUG, avdelingsoverlege Haukeland sykehus

DYSTERT. Bakterier kan utvikle motstandsdyktighet mot flere typer antibiotika. Hvis bakteriene på Haukeland går ett skritt videre i utviklingen, blir de helt umulige å behandle. Folkehelsa krever bedre kontroll. Side 3



- **HCWs struggle for their patients' lives**
- **Fear for micro-organisms**
- **Balance against other threats**
- **The patients should be safe**

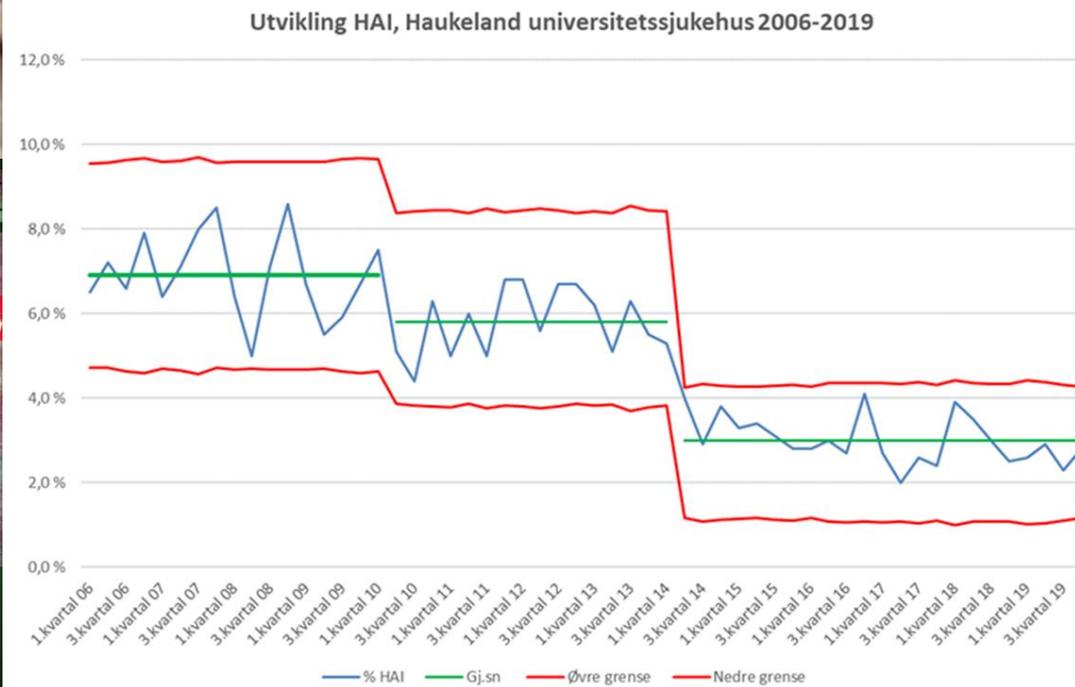
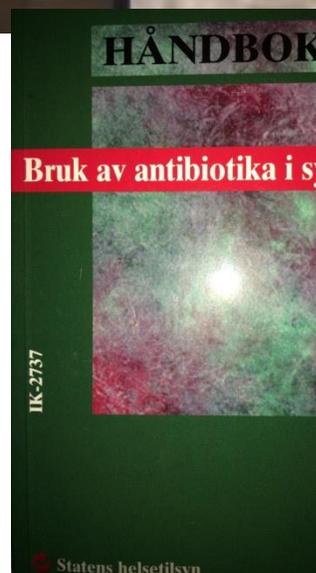


Photo: Haukeland University Hospital

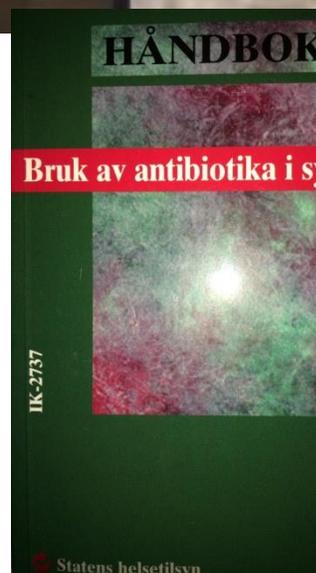


Photo: Haukeland University Hospital

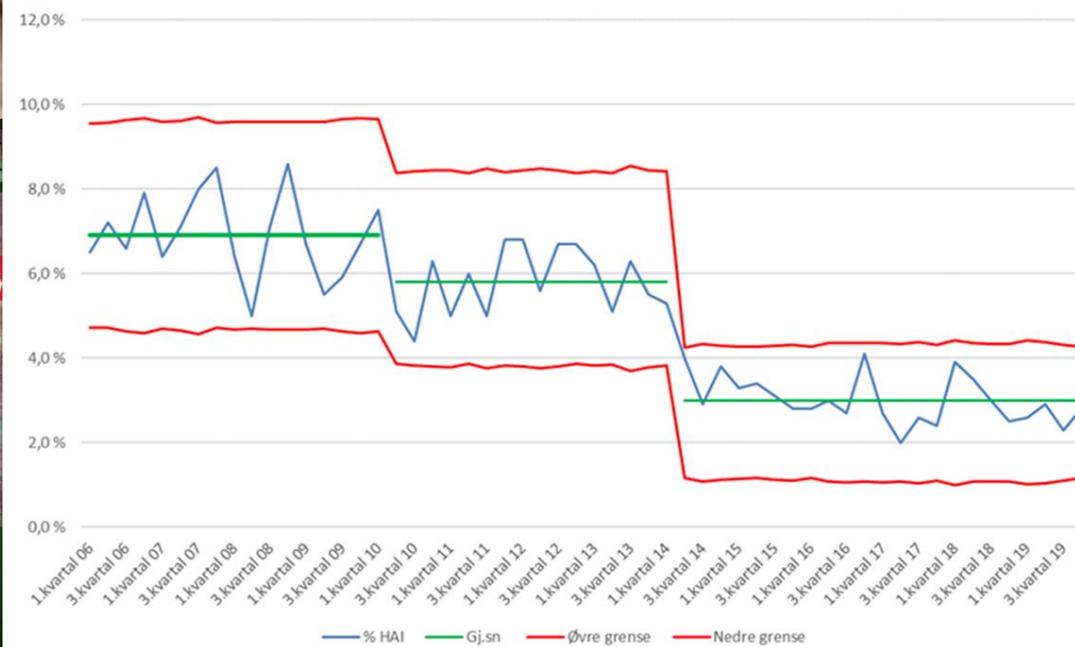
Infection control written procedures and guidelines



Infection control written procedures and guidelines



Utvikling HAI, Haukeland universitetssjukehus 2006-2019



Case: ♂ 44

- Diagnosis: bacterial spondylitis
- Treatment: kloxacillin 2 g x 4 iv (4 weeks)
+ aminoglycosid iv (2 weeks)
- Short time Central Venous Catheter required
- The patient observed:
 - Great variation in practicing the catheter care
- The patient was discharged
 - recovering but very thoughtful

The Michigan Study 2006

- From 2,7 to 0 infections per 1000 catheter days
- «Clinical Care Bundle»

The NEW ENGLAND JOURNAL of MEDICINE

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An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU

Peter Pronovost, M.D., Ph.D., Dale Needham, M.D., Ph.D., Sean Berenholtz, M.D., David Sinopoli, M.P.H., M.B.A., Haitao Chu, M.D., Ph.D., Sara Cosgrove, M.D., Bryan Sexton, Ph.D., Robert Hyzy, M.D., Robert Welsh, M.D., Gary Roth, M.D., Joseph Bander, M.D., John Kepros, M.D., and Christine Goeschel, R.N., M.P.A.

ABSTRACT

BACKGROUND

Catheter-related bloodstream infections occurring in the intensive care unit (ICU) are common, costly, and potentially lethal.

METHODS

We conducted a collaborative cohort study predominantly in ICUs in Michigan. An evidence-based intervention was used to reduce the incidence of catheter-related bloodstream infections. Multilevel Poisson regression modeling was used to compare infection rates before, during, and up to 18 months after implementation of the study intervention. Rates of infection per 1000 catheter-days were measured at 3-month intervals, according to the guidelines of the National Nosocomial Infections Surveillance System.

RESULTS

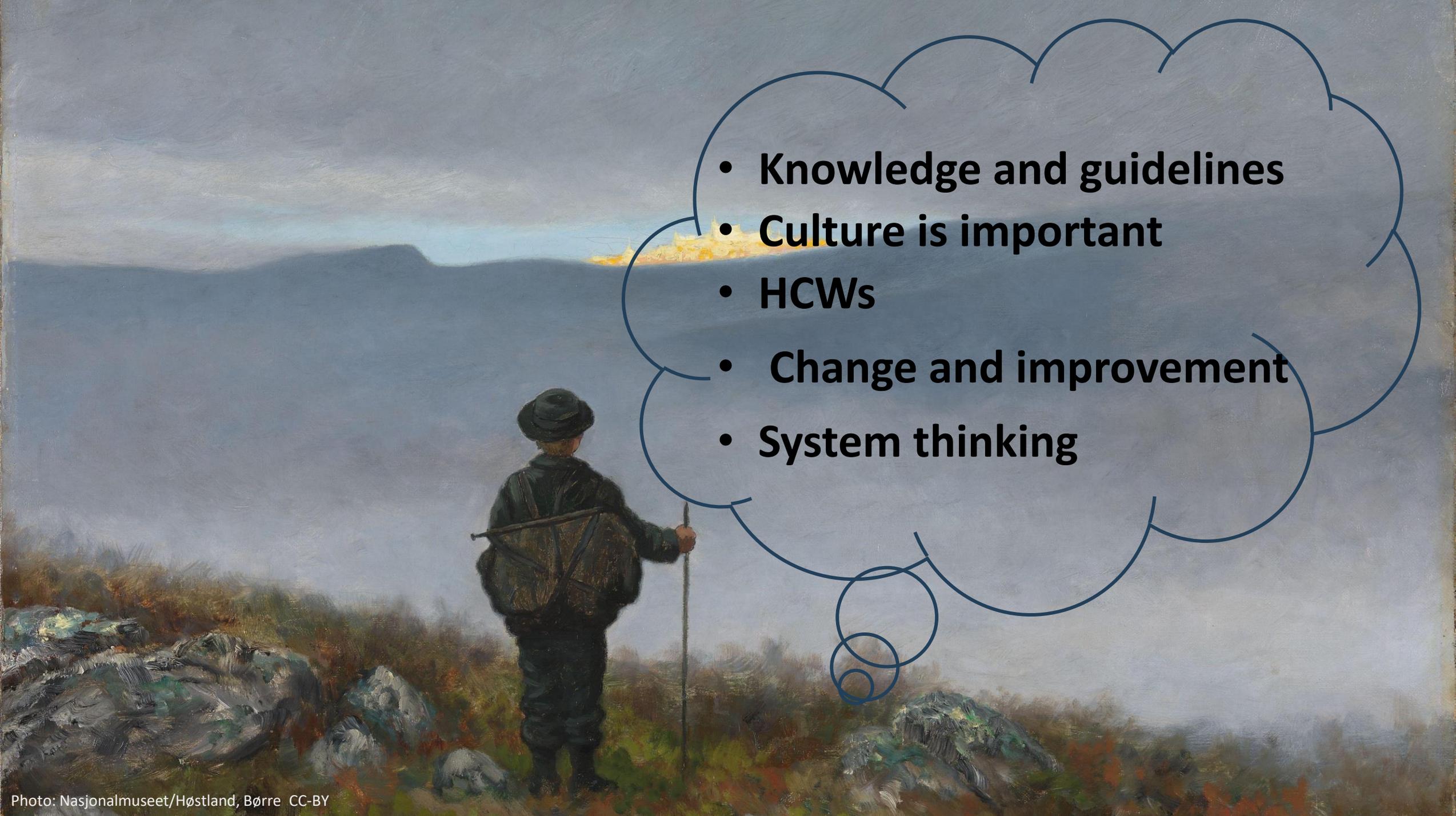
A total of 108 ICUs agreed to participate in the study, and 103 reported data. The analysis included 1981 ICU-months of data and 375,757 catheter-days. The median rate of catheter-related bloodstream infection per 1000 catheter-days decreased from 2.7 infections at baseline to 0 at 3 months after implementation of the study intervention ($P \leq 0.002$), and the mean rate per 1000 catheter-days decreased from 7.7 at baseline to 1.4 at 16 to 18 months of follow-up ($P < 0.002$). The regression model showed a significant decrease in infection rates from baseline, with incidence-rate ratios continuously decreasing from 0.62 (95% confidence interval [CI], 0.47 to 0.81) at 0 to 3 months after implementation of the intervention to 0.34 (95% CI, 0.23 to 0.50) at 16 to 18 months.

CONCLUSIONS

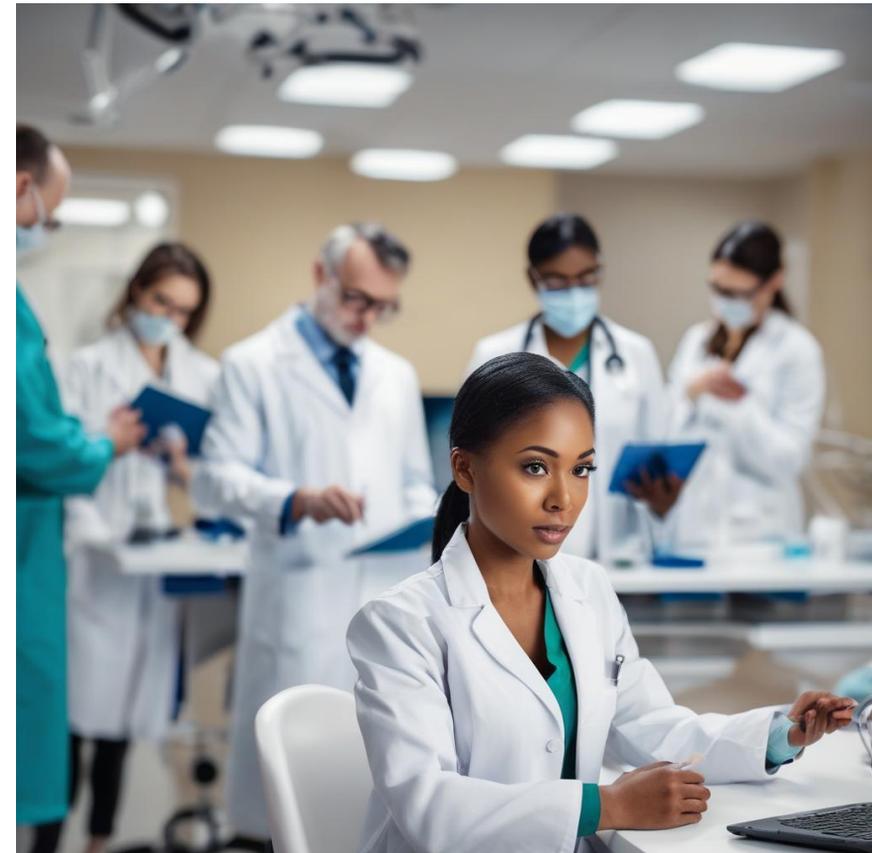
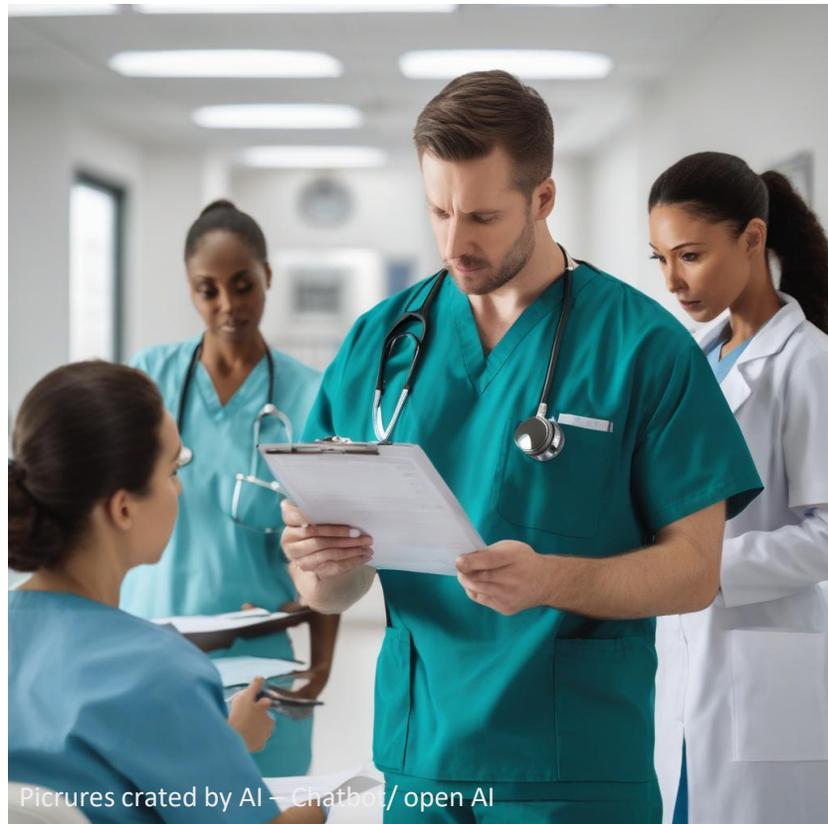
An evidence-based intervention resulted in a large and sustained reduction (up to 66%) in rates of catheter-related bloodstream infection that was maintained throughout the 18-month study period.

From the School of Medicine (P.P., D.N., S.B., S.C., B.S.), the School of Professional Studies in Business and Education (D.S.), and the Bloomberg School of Public Health (H.C.), Johns Hopkins University, Baltimore; and the University of Michigan, Ann Arbor (R.H.); William Beaumont Hospital, Royal Oak (R.W.); Ingham Regional Medical Center, Lansing (G.R.); Harper University Hospital, Detroit (J.B.); Sparrow Health System, Lansing (J.K.); and the Michigan Health and Hospital Association Keystone Center for Patient Safety and Quality, Lansing (C.G.) — all in Michigan.

N Engl J Med 2006;355:2725-32.
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- A painting of a hiker in dark clothing and a hat, seen from behind, standing on a rocky mountain ridge. The hiker is holding a walking stick in their right hand and has a pack on their back. The background shows a vast, hazy landscape with distant mountains and a bright horizon. A large, blue-outlined thought bubble is superimposed on the right side of the image, containing a list of five bullet points.
- Knowledge and guidelines
 - Culture is important
 - HCWs
 - Change and improvement
 - System thinking

Teamwork or not?



Norway at the top of the world regarding rates of HCWs/capita

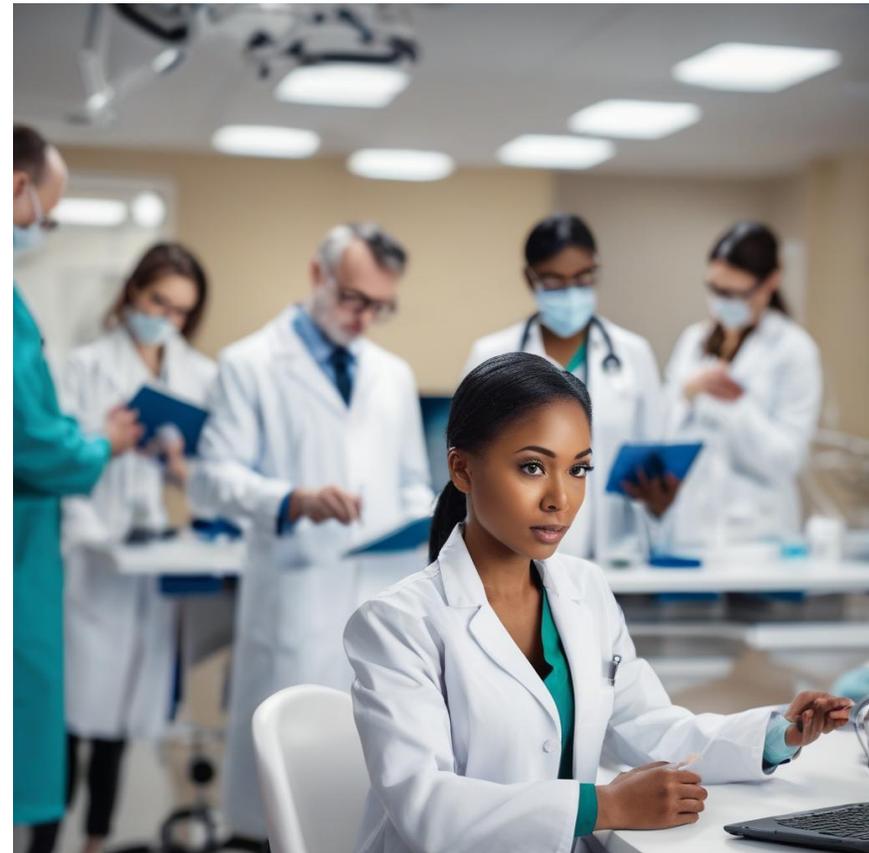
Andel av de sysselsatte i helse- og omsorgstjenestene i EØS-landene

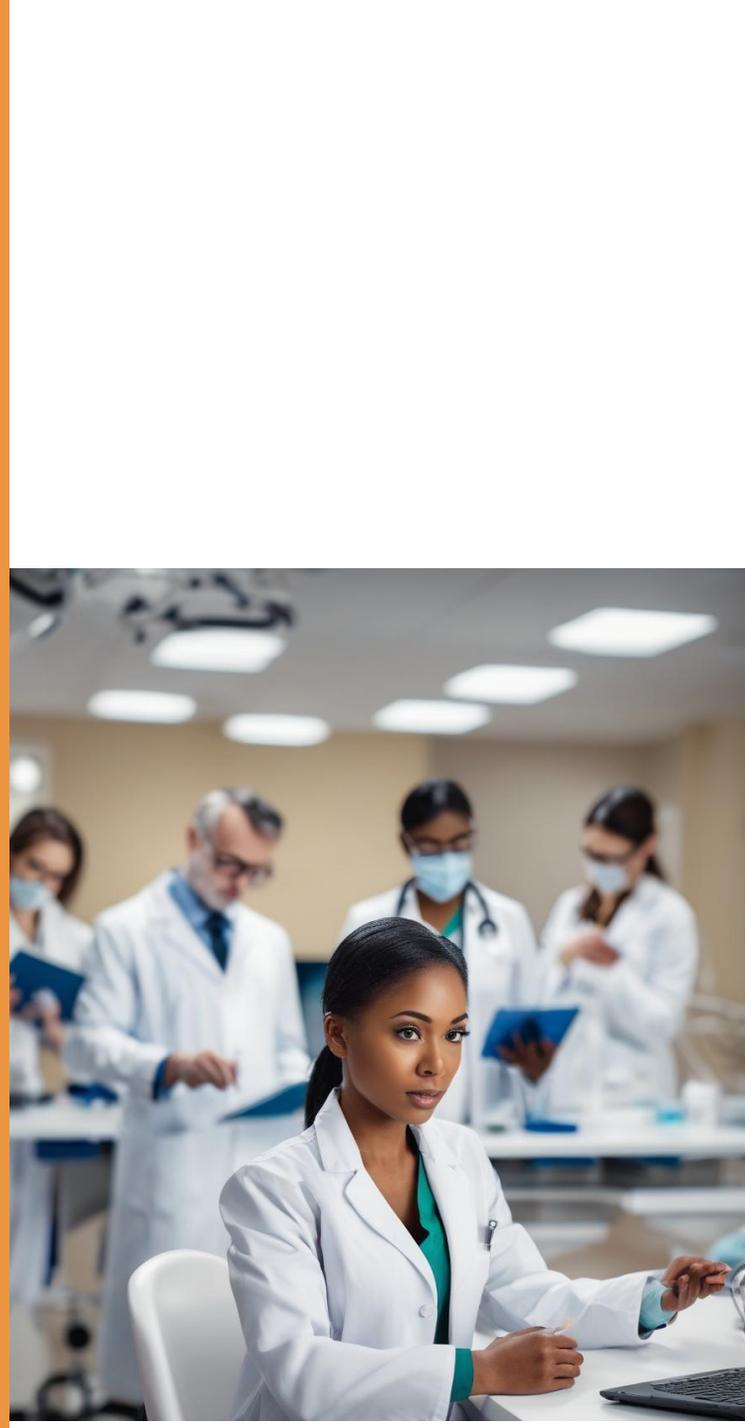


Andre land: Praktiserende leger og sykepleiere pr. 1 000 innbyggere



Kilde: Eurostat Database, State of the Health in the EU. Landhelseprofil Norge 2021 (2019-tall eller seneste tilgjengelige tall)





I trygge hender 24 7



Tidlig oppdagelse
og rask respons av
forverret somatisk
tilstand



Legemiddelrelaterte
skader



Kirurgiske
komplikasjoner



Underernæring



Urinveisinfeksjoner



Kateterassosierte
infeksjoner



Selv mord



Overdosedødsfall



God
utskrivningsprosess



Hjerneslag



Fallskader



Trykksår



Sepsis

I trygge hender

24
7



Tidlig oppdagelse og rask respons av forverret somatisk tilstand



Legemiddelrelaterte skader



Kirurgiske komplikasjoner



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Kateterassosierte infeksjoner



Selvmord



God utskrivningsprosess



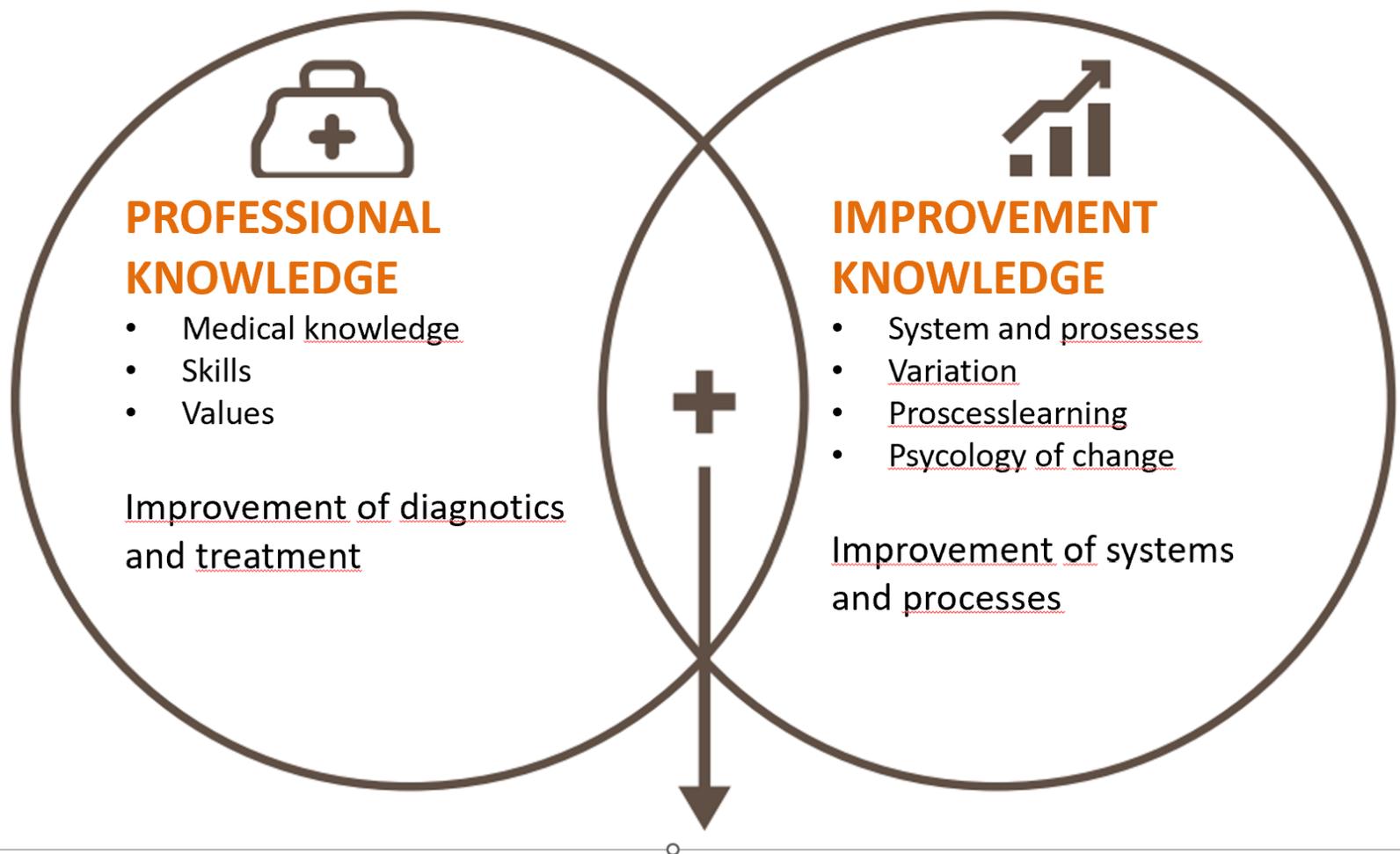
Hjerneslag



Fallskader

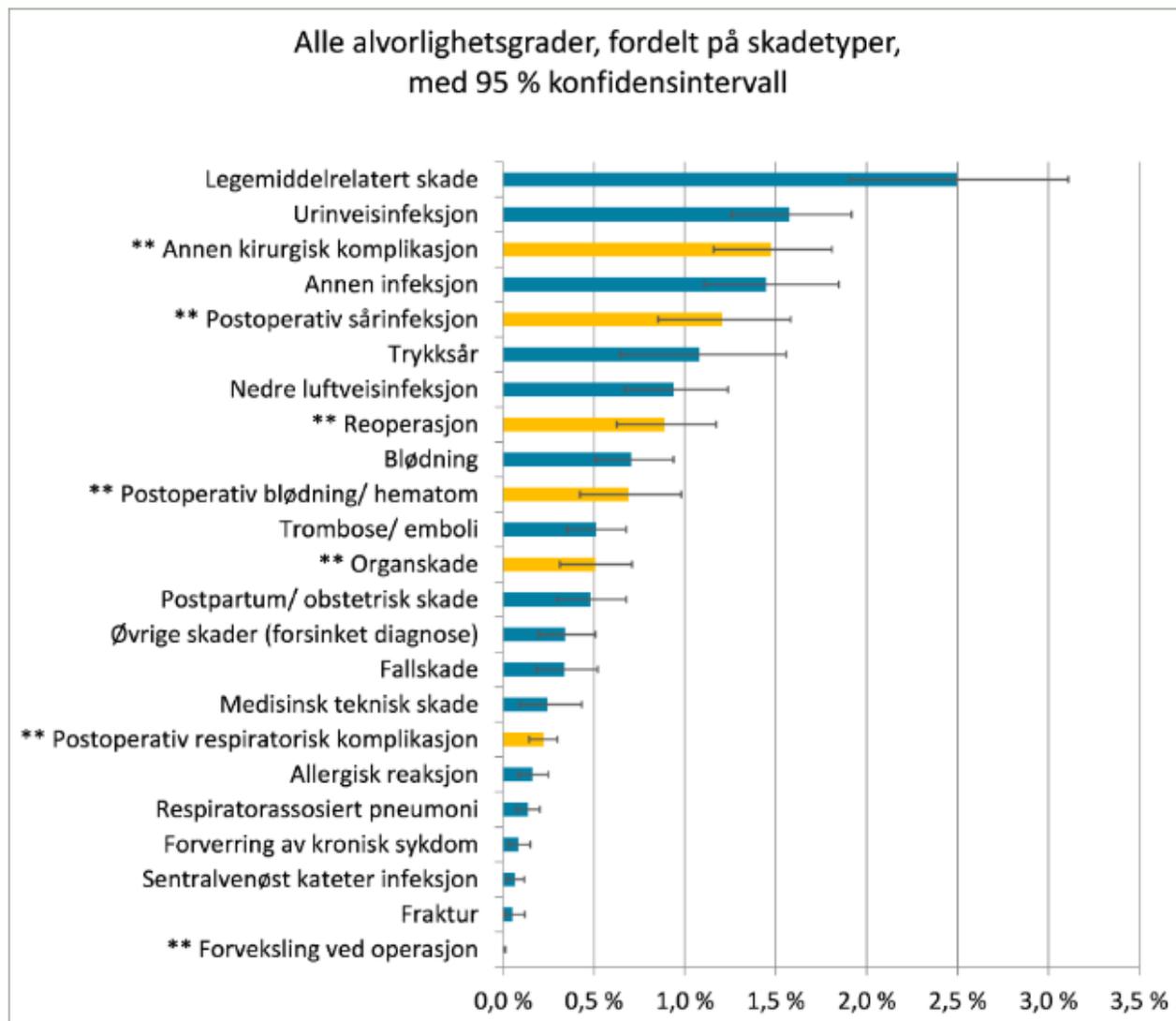


Sepsis

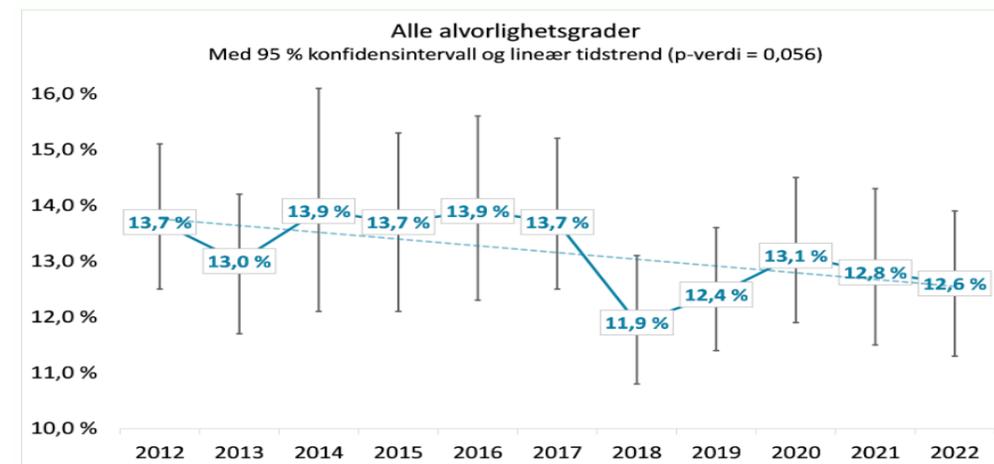


Efficient and systematic change of the health care

Modell adapted from Batalden PB and Stoltz PK (1993)



Figur 5 Andel sykehusopphold med minst én pasientskade i 2022 fordelt på skadetyper, med 95 % konfidensintervall. Alvorlighetsgrad E-I.



Figur 1 Andel sykehusopphold med minst én pasientskade for samlekategorien E-I, med 95 % konfidensintervall og lineær tidstrend for perioden 2012-2022.

42% reduction of all surgical complications

ANNALS OF SURGERY
A MONTHLY REVIEW OF SURGICAL SCIENCE SINCE 1885

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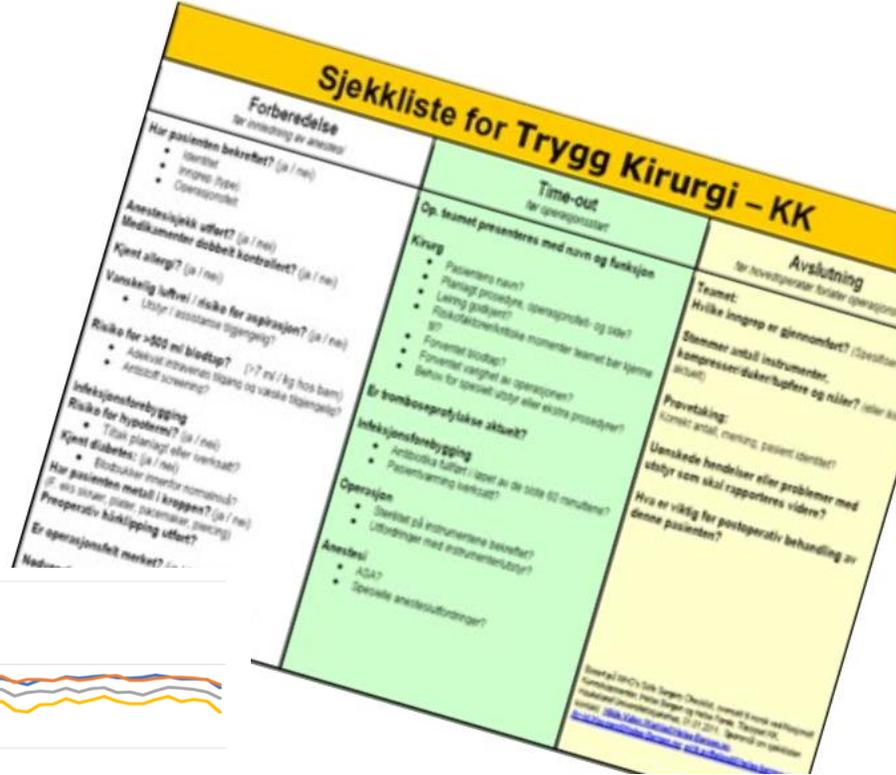
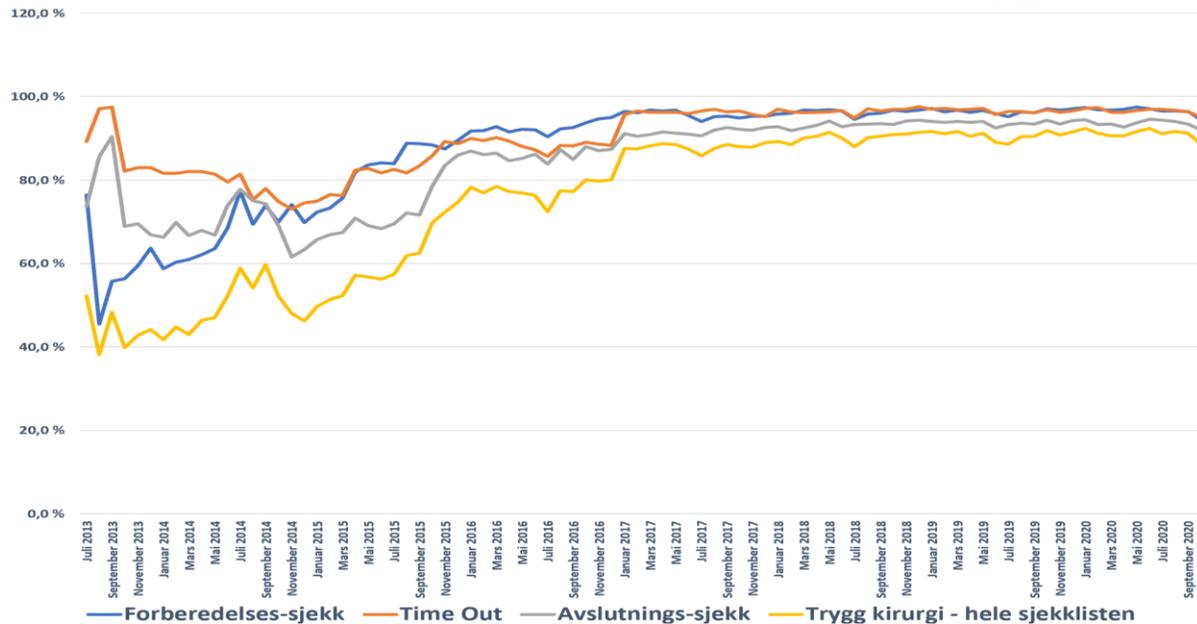
Annals of Surgery:
May 2015 - Volume 261 - Issue 5 - p 821–828
doi: 10.1097/SLA.0000000000000716
Features

Effect of the World Health Organization Checklist on Patient Outcomes: A Stepped Wedge Cluster Randomized Controlled Trial

Haugen, Arvid Steinar MSc^{*,†}; Sjøteland, Eirik MD, PhD^{*}; Almeland, Stian K. MD[‡]; Sevdalis, Nick PhD[§]; Vonen, Barthold MD, PhD[¶]; Eide, Geir E. PhD^{1,***}; Nortvedt, Monica W. PhD^{**}; Harthug, Stig MD, PhD^{**,*}



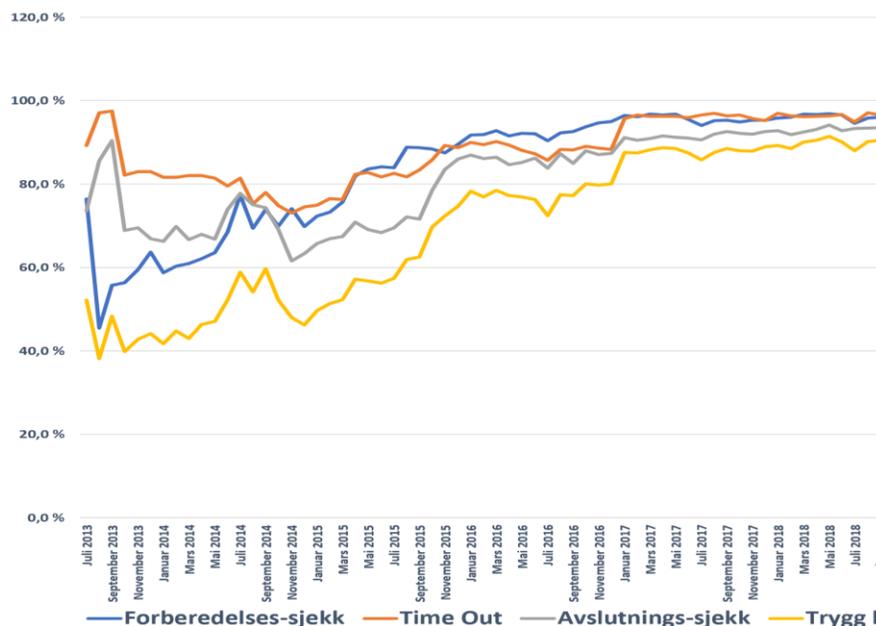
Utilisation of Safe Surgery Checklist at Haukeland University Hospital 2013-2020 (N = 240 000)



Utilization of Safe Surgery Checklist at Haukeland University Hospital 2013-2020 (N = 240 000)

Patients Safety Checklist (PASC) in Surgery

Implementation of a Stepped Wedge Cluster RCT - Effects on Patient and Implementation Outcomes



<p>Målet med sjekklisten er å forebygge komplikasjoner som kan oppstå i operasjonsforløpet</p> <p>Bruk sjekklisten aktivt ved å krysse av på JA eller NEI på sjekklisterpunktene.</p> <p>Har du spørsmål når du går gjennom sjekklisten, skriv dem ned og ta med til sykehuset. Hvis nødvendig kontakt sett inn avdelings kontakt informasjon her.</p> <p>Viktige punkter du bør tenke igjennom før operasjonen</p> <p>1. Bruker du medisiner? <input type="checkbox"/> NEI, gå til punkt 4 <input type="checkbox"/> JA, lær deg navn, utseende, tidspunkt du tar medisinene og hvorfor du tar dem</p> <p>2. Bruker du blodfortynnende medisiner? <input type="checkbox"/> NEI <input type="checkbox"/> JA, er du informert om du skal stoppe eller når du skal stoppe med dem før din operasjon? Hvis ikke, ring 2 uker før operasjonen og avklar med avdelingen</p> <p>3. Har du en medisinaliste, med siste endringer? <input type="checkbox"/> JA, husk å ta den med til sykehuset <input type="checkbox"/> NEI, bestill time hos fastlegen og be om en ny medisinaliste</p> <p>4. Har du diabetes, høyt blodtrykk, hjerte- og karsykdommer, sår som ikke gror eller blir du behandlet for andre kroniske lidelser? <input type="checkbox"/> NEI <input type="checkbox"/> JA, hvis du ikke har hatt kontroll for dette de siste 12 månedene bestill time hos fastlegen.</p> <p>5. Har du vært i utlandet de siste 12 månedene og hatt tannbehandling, medisinsk behandling, vært innlagt eller jobbet på sykehus? <input type="checkbox"/> NEI <input type="checkbox"/> JA, bestill time hos fastlegen og få tatt bakterieprøver av deg før innleggelse, ring avdelingen og informer</p> <p>6. Er du informert om at opphør/avhold av røking og inntak av alkohol og andre rusmidler i god tid før operasjonen kan forebygge komplikasjoner? <input type="checkbox"/> JA <input type="checkbox"/> NEI, be om informasjon fra fastlege <input type="checkbox"/> Ikke aktuelt</p> <p>7. Er du informert om at det å være aktiv og ha et næringsrikt kosthold før operasjon kan redusere sjansen for komplikasjoner? (avklar med fastlegen om aktivitetsnivå) <input type="checkbox"/> JA <input type="checkbox"/> NEI, be om informasjon fra fastlege</p> <p>Ta kontakt med din tannlege hvis behov</p> <p>8. Går du til tannlege hvert år? <input type="checkbox"/> JA <input type="checkbox"/> NEI, tannlegekontroll anbefales før en operasjon</p>	<p>Bruk sjekklisten aktivt ved å krysse av på JA eller NEI på alle sjekklisterpunkter.</p> <p>Hva trenger du å være informert om før du reiser hjem? Les gjennom spørsmålene under før du snakker med legen og sykepleieren som skal skrive deg ut. Be om skriftlig informasjon ved behov.</p> <p>Komplikasjoner</p> <p>28. Er du informert om komplikasjoner som kan oppstå? <input type="checkbox"/> JA <input type="checkbox"/> NEI, be om informasjon fra legen som skriver deg ut</p> <p>29. Er du informert om hva du skal gjøre hvis du får komplikasjoner eller blir akutt syk? <input type="checkbox"/> JA <input type="checkbox"/> NEI, be om informasjon fra legen som skriver deg ut</p> <p>30. Er du informert om at du skal bruke støttestrømper? <input type="checkbox"/> NEI <input type="checkbox"/> Ikke aktuelt <input type="checkbox"/> JA, avklar med sykepleieren din eller legen som skriver deg ut hvor lenge du skal bruke dem</p> <p>Aktivitet og restriksjon</p> <p>31. Er du informert om når du kan kjøre bil igjen? <input type="checkbox"/> JA <input type="checkbox"/> NEI, avklar med lege/sykepleier som skriver deg ut</p> <p>32. Er du informert om at det er viktig at du er i aktivitet og når du kan begynne å trene? <input type="checkbox"/> JA <input type="checkbox"/> NEI, avklar med lege/sykepleier som skriver deg ut</p> <p>33. Er du informert om aktivitetsrestriksjoner? <input type="checkbox"/> JA <input type="checkbox"/> NEI, avklar med lege/sykepleier som skriver deg ut</p> <p>34. Er du informert om når du kan dusje igjen? <input type="checkbox"/> JA <input type="checkbox"/> NEI, avklar med lege/sykepleier som skriver deg ut</p> <p>Medisiner</p> <p>35. Skal du begynne med nye medisiner? <input type="checkbox"/> NEI, gå til punkt 40 <input type="checkbox"/> JA, bruk sjekklisterpunktene under og be om en gjennomgang med legen som skriver deg ut</p> <p>36. Er du informert om mulige bivirkninger til de nye medisinerne? <input type="checkbox"/> JA <input type="checkbox"/> NEI, avklar med legen som skriver deg ut</p> <p>37. Er du informert om hvem du kan kontakte hvis du opplever bivirkninger? <input type="checkbox"/> JA <input type="checkbox"/> NEI, avklar med legen som skriver deg ut</p> <p>38. Er det medisiner eller mat du ikke kan spise sammen med de nye medisinerne dine? <input type="checkbox"/> NEI <input type="checkbox"/> JA, avklar med legen som skriver deg ut og skriv ned navnene</p>
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- **Research**
- **Knowledge and skills**
- **Interdisciplinary teamwork**
- **Measurements**



Virtual pictures generated by AI – ChatGPT



RESEARCH ARTICLE

Open Access

Investigating the use of patient involvement and patient experience in quality improvement in Norway: rhetoric or reality?

Siri Wiig^{1*}, Marianne Storm¹, Karina Aase¹, Martha Therese Gjesten¹, Marit Solheim^{2,3}, Stig Harthug^{4,5}, Glenn Robert⁶, Naomi Fulop⁷ and QUASER team

Abstract

Background: Patient involvement in health care decision making is part of a wider trend towards a more bottom-up approach to service planning and provision, and patient experience is increasingly conceptualized as a core dimension of health care quality.

The aim of this multi-level study is two-fold: 1) to describe and analyze how governmental organizations expect acute hospitals to incorporate patient involvement and patient experiences into their quality improvement (QI) efforts and 2) to analyze how patient involvement and patient experiences are used by hospitals to try to improve the quality of care they provide.

Methods: This multi-level case study combines analysis of national policy documents and regulations at the macro level with semi-structured interviews and non-participant observation of key meetings and shadowing of staff at the meso and micro levels in two purposively sampled Norwegian hospitals. Fieldwork at the meso and micro levels was undertaken over a 12-month period (2011–2012).

Results: Governmental documents and regulations at the macro level demonstrated wide-ranging expectations for the integration of patient involvement and patient experiences in QI work in hospitals. The expectations span from systematic collection of patients' and family members' experiences for the purpose of improving service quality through establishing patient-oriented arenas for ongoing collaboration with staff to the support of individual involvement in decision making. However, the extent of involvement of patients and application of patient experiences in QI work was limited at both hospitals. Even though patient involvement was gaining prominence at the meso level – and to a lesser extent at the micro level – relevant tools for measuring and using patient experiences in QI work were lacking, and available measures of patient experience were not being used meaningfully or systematically.

Conclusions: The relative lack of expertise in Norwegian hospitals of adapting and implementing tools and methods for improving patient involvement and patient experiences at the meso and micro levels mark a need for health care policymakers and hospital leaders to learn from experiences of other industries and countries that have successfully integrated user experiences into QI work. Hospital managers need to design and implement wider strategies to help their staff members recognize and value the contribution that patient involvement and patient experiences can make to the improvement of healthcare quality.

Keywords: Patient experience, Patient involvement, Quality improvement, Multi-level study

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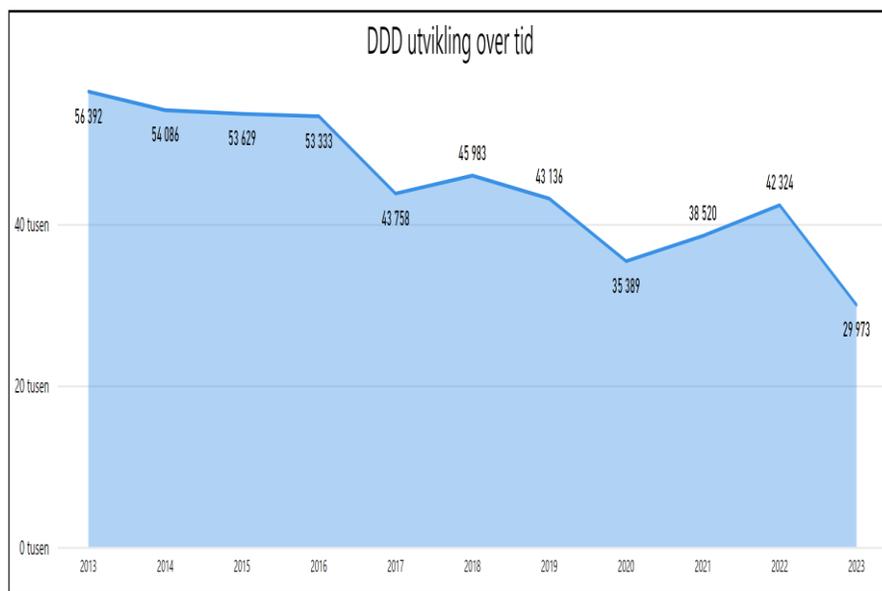


Do not forget the patients

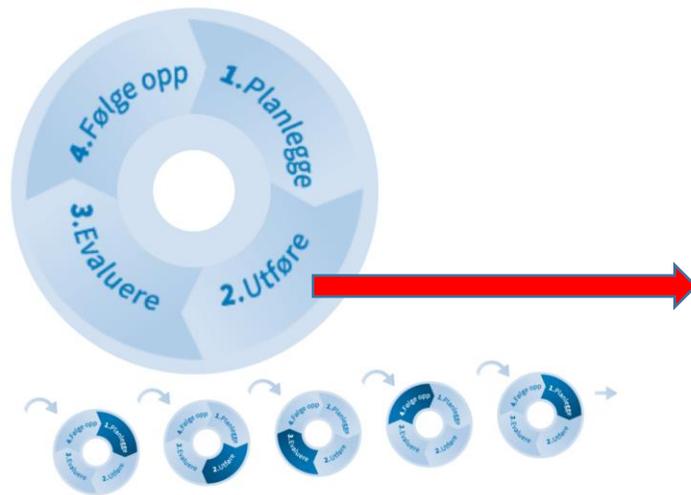
Listen to them

Interdisciplinary teams

Reduction in utilisation of broad spectrum antibiotics in the Norwegian hospitals achieved for a significant period



www.antibiotika.no



1. Planlegge **2. Utføre** 3. Evaluere 4. Følge opp

Antibiotikastyring i sykehus



Etter å ha erkjent behovet for forbedring, satt seg mål, valgt måleverktøy og tiltak, skal tiltak implementeres. I forbedringsarbeid bl.a. innen smittevern har man sett nytten av å samle all denne informasjonen i en tiltakspakke, slik at alle involverte skal kunne vite hva målet er og hva som skal gjøres. Vi foreslår at man prøver ut tiltakene på en post, for så evt. å implementere samme tiltak på andre poster/ avdelinger som har satt seg samme mål.

2. Utføre

- > Tiltak innen antibiotikastyring
- > Tiltakspakker
- > Kommunikasjonsplan
- > Tids- og aktivitetsplan

Nasjonale føringer	Verktøy	Kunnskapsgrunnlag
<ul style="list-style-type: none">> Handlingsplan mot antibiotikaresistens i helsestjenesten (2016)> Nasjonal strategi mot antibiotikaresistens 2015-2020> Forskrift om ledelse og kvalitetsforbedring i helse- og omsorgstjenesten (2017)	<ul style="list-style-type: none">> Retningslinje for bruk av antibiotika i sykehus> e-læringskurs: Antibiotikabruk i sykehus> E-bok «Antimicrobial stewardship – from principles to practice» (må lastes ned)> Fordypningsoppgaver: Sykepleiers oppgave i antibiotikastyring	<ul style="list-style-type: none">> Kunnskapsgrunnlag antibiotikastyring

< 1. Planlegge **3. Evaluere** >

Praktiske råd og verktøy til hver fase



We do just partly succeed in implementation of patient safety measures

We need a practical approach based on scientific evidence and experience



Implement it!

Investigating implementation of patient safety interventions in primary and specialised health care



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159 studies on implementation of rapid response systems, antibiotic stewardship and medication reconciliation

- Multiple activities reflect mainly
 - method-based improvement science
 - determinant frameworks from implementation science
- Unexploited potential for continuous adaptation of implementation activities to address changing contexts
- Research-informed guidance on how to make such adaptations could advance implementation in practice



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Rapid response systems, antibiotic stewardship and medication reconciliation: a scoping review on implementation factors, activities and outcomes

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ABSTRACT

Introduction Many patient safety practices are only partly established in routine clinical care, despite extensive quality improvement efforts. Implementation science can offer insights into how patient safety practices can be successfully adopted.

Objective The objective was to examine the literature on implementation of three internationally used safety practices: medication reconciliation, antibiotic stewardship programmes and rapid response systems. We sought to identify the implementation activities, factors and outcomes reported, the combinations of factors and activities supporting successful implementation; and the implications of the current evidence base for future implementation and research.

Methods We searched Medline, Embase, Web of Science, Cumulative Index to Nursing and Allied Health Literature, PsycINFO and Education Resources Information Center from January 2011 to March 2023. We included original peer-reviewed research studies or quality improvement reports. We used an iterative, inductive approach to thematically categorise data. Descriptive statistics and hierarchical cluster analyses were performed.

Results From the 159 included studies, eight categories of implementation activities were identified: *education; planning and preparation; method-based approach; audit and feedback; motivate and remind; resource allocation; simulation and training; and patient involvement*. Most studies reported activities from multiple categories. Implementation factors included: *clinical competence and collaboration; resources; readiness and engagement; external influence; organisational involvement; QI competence; and feasibility of innovation*. Factors were often suggested post hoc and seldom used to guide the selection of implementation strategies. Implementation outcomes were reported as: *fidelity or compliance; proxy indicator for fidelity; sustainability; acceptability; and spread*. Most studies reported implementation improvement, hindering discrimination between more or less important factors and activities.

Conclusions The multiple activities employed to implement patient safety practices reflect mainly method-based improvement science, and to a lesser

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Many patient safety practices can reduce risk of harm to patients, but are often not implemented routinely.
⇒ Insights from implementation science may help address this challenge.

WHAT THIS STUDY ADDS

⇒ This review provides an overview of the strategies and factors reported to influence implementation of three commonly used safety practices: rapid response systems, antibiotic stewardship and medication reconciliation.
⇒ The included studies lacked active mapping of implementation factors and continuous adaptation of practices and activities to these.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

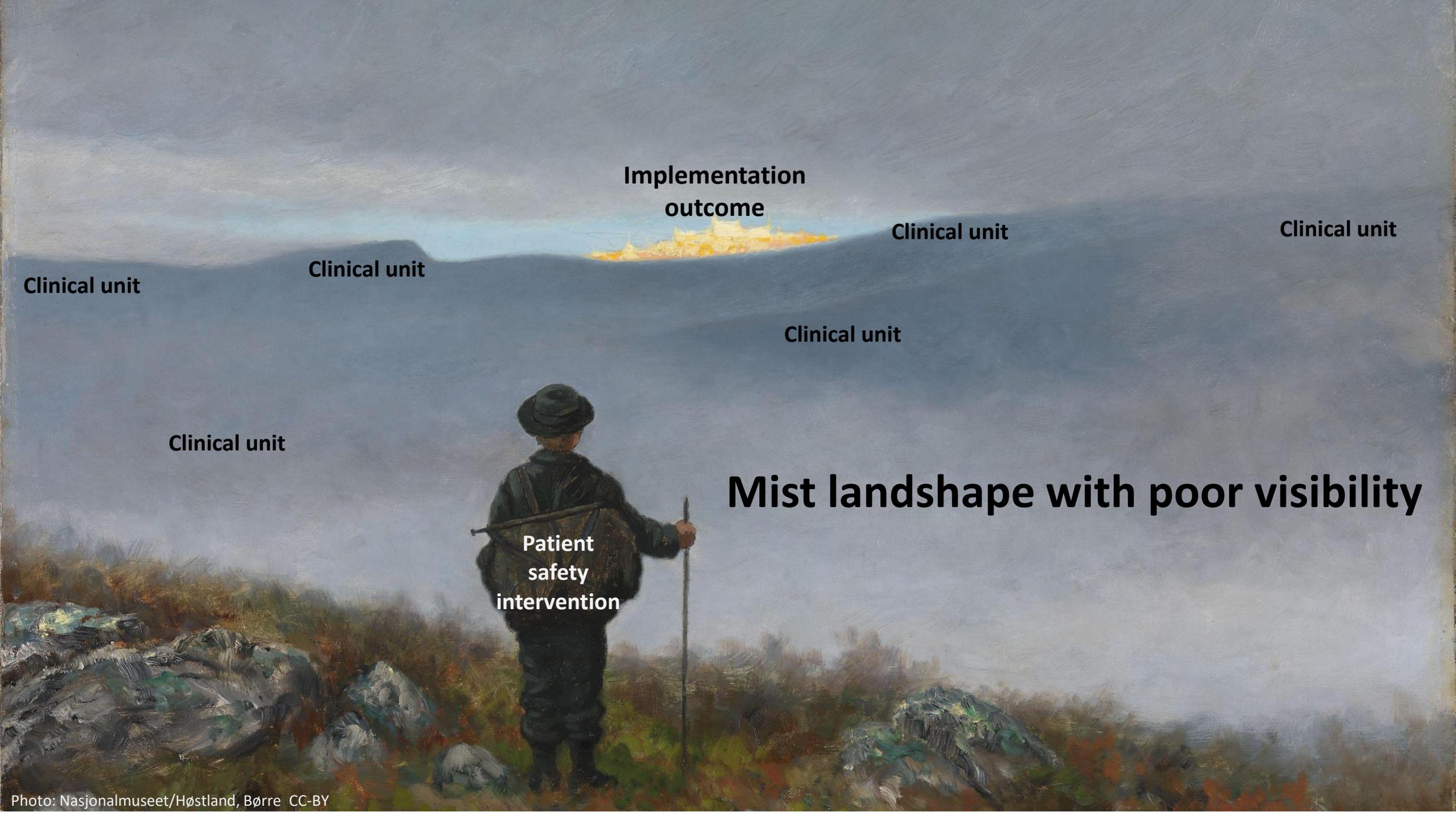
⇒ Practitioners may benefit from our findings to inform themselves of current implementation practice as well as potential context factors to be aware of.
⇒ Future research could inform implementation practice by exploring the relation between specific implementation activities and the factors they aim to address.

degree determinant frameworks from implementation science. There seems to be an unexploited potential for continuous adaptation of implementation activities to address changing contexts. Research-informed guidance on how to make such adaptations could advance implementation in practice.

Reported from the included studies

categories based on thematic condensation

Activities	Factors	Outcomes
Education	Collaboration	Fidelity or compliance
Planning and preparation	Resources	Proxy indicator for fidelity
Method-based approach	Readiness and engagement	Sustainability
Audit and feedback	External influence	Acceptability
Motivate and remind	Organisational involvement	Spread
Resource allocation	QI competence	
Simulation and training	Feasibility of innovation	
Patient involvement		



**Implementation
outcome**

Clinical unit

Clinical unit

Clinical unit

Clinical unit

Clinical unit

Clinical unit

Mist landshape with poor visibility

**Patient
safety
intervention**



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