Forslag om nasjonal metodevurdering

Viktig informasjon – se på dette først!

- Innsendte forslag til nasjonale metodevurderinger vil bli publisert i sin helhet. Dersom forslagsstiller mener det er nødvendig informasjon for utfylling av skjemaet som ikke kan offentliggjøres ta kontakt med sekretariatet før innsending.
  Forslagsstiller er klar over at skjemaet vil bli publisert i sin helhet (kryss av): ☒
- Forslagsstiller har fylt ut punkt 17 nedenfor «Interesser og eventuelle interessekonflikter» (kryss av): ☒
- Dette skjema brukes for å sende inn forslag om metodevurdering på nasjonalt nivå i Nye metoder. Skjema gjelder ikke forslag om forskningsprosjekter. En metodevurdering er en type kunnskapsoppsummering, og for at en slik skal kunne utføres behøves dokumentasjon eksempelvis fra gjennomførte kliniske studier. Manglende dokumentasjonsgrunnlag kan være en av årsakene til at Bestillerforum RHF ikke gir oppdrag om en metodevurdering.
- Hvis forslaget gjelder et medisinsk utstyr, er forslagsstiller kjent med dokumentet «Veiledende kriterier for håndtering av medisinsk utstyr i Nye metoder « (link) (kryss av): ☒

Kontaktinformasjon:

Navn på forslagsstiller (organisasjon/institusjon/foretak/produsent):

Ethicon, Johnson & Johnson MD, a division of Janssen-Cilag AS

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Dato og sted:

11.06.18 - Oslo

1. Forslagstillers tittel på forslaget:*
   *Denne kan endres under den videre behandlingen i systemet

Triclosan coated sutures for the prevention of surgical-site infection.

2. Kort beskrivelse av metoden som foreslås vurdert:

The use of triclosan coated absorbable sutures during surgery to prevent surgical site infection, and the following reduction in usage of antibiotics to treat the infections.

3. Kort beskrivelse av dagens tilbud (Hvilken metode(r) brukes nå? Status for metoden (gir kurativ behandling, forlenget levetid etc.) Vil metoden som foreslås vurdert erstatte eller komme i tillegg til dagens tilbud?)

One of the most common complications for surgical patients is surgical site infection (SSI) (WHO. The Global Guidelines for Prevention of Surgical Site Infection. 2016.)

40 – 60% of SSIs are estimated to be preventable.

(Odom-Forren J. Preventing surgical site infections. Nursing 2006; 36: 58–63)

A recent review of studies from 15 countries concluded that 9,9% of operations lead to SSI and 60% of SSIs appeared after discharge.

(Woelber et al. Proportion of Surgical Site Infections Occurring after Hospital Discharge: A Systematic Review. Surg Inf 2016; 17(5): 510-519)

One identified risk factor for SSI is the intra- and post-operative contamination of the suture thread by bacteria.

(Guo et al. Efficacy of triclosan-coated sutures for reducing risk of surgical site infection in adults: a meta-analysis of randomized clinical trials. J Surg Res 2016; 201: 105-117.)

Triclosan coated sutures with antibacterial efficacy have been developed to address this risk factor.

Triclosan coated absorbable sutures are already available as an option during surgeries. Several meta-analyses show a 26-28% reduction in SSI when using triclosan coated sutures. (Wang ZX, Jiang CP, Cao Y, Ding YT. Systematic review and meta-analysis of triclosan-coated sutures for prevention of surgical-site infection. 2013; 100:465-474.

Edmiston CE, Daoud FC, Leaper D. Is there an evidence-based argument for embracing an antimicrobial (triclosan)-coated suture technology to reduce the risk for surgical-site infections? A meta-analysis. 2013; 154: 89-100

De Jonge et al. Meta-analysis and trial sequential analysis of triclosan-coated sutures for the prevention of surgical-site infection. BJS 2017; 104: e118–e133)

In addition, the reduction of SSI can also lead to reduction in the use of antibiotics for treatment of SSI.

(Thimour-Bergström et al. Triclosan-coated sutures reduce surgical site infection after open vein harvesting in coronary artery bypass grafting patients: a randomized controlled study. Eur J Cardiothorac Surg. 2013 Nov;44(5):931-8.)

The published meta-analyses have not identified any adverse events when triclosan coated sutures have been used.

(De Jonge et al. Meta-analysis and trial sequential analysis of triclosan-coated sutures for the prevention of surgical-site infection. BJS 2017; 104: e118–e133)

Use of triclosan coated sutures are already endorsed in the guidelines for prevention of SSI, published by WHO, CDC and ACS together with SIS.

(WHO. The Global Guidelines for Prevention of Surgical Site Infection. 2016.

Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017

American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update)

A national guideline for the use of triclosan coated sutures would:

- **Improve patient outcomes**
- **Reduce health care costs**
- **Reduce the use of antibiotics**

(De Jonge et al. Meta-analysis and trial sequential analysis of triclosan-coated sutures for the prevention of surgical-site infection. BJS 2017; 104: e118–e133

D. J. Leaper, C. E. Edmiston Jr and C. E. Holy. Meta-analysis of the potential economic impact following introduction of absorbable antimicrobial sutures. BJS 2017 Jan;104(2):e134-e144

Thimour-Bergström et al. Triclosan-coated sutures reduce surgical site infection after open vein harvesting in coronary artery bypass grafting patients: a randomized controlled study. Eur J Cardiothorac Surg. 2013 Nov;44(5):931-8.)

4. Hva gjelder forslaget?	Ja	Nei
En helt ny og innovativ metode?	☐	☒
Et nytt bruksområde, eller en ny indikasjon for en etablert metode?	☐	☒
En sammenligning mellom flere metoder?	☒	☐
Er metoden tatt i bruk?	☒	☐
Hvis ja – metode tatt i bruk i klinisk praksis?	☒	☐
Hvis ja – metode tatt i bruk innen forskning/utprøving?	☒	☐
Re-evaluering av metode som er tatt i bruk i klinisk praksis?	☐	☒
Er metoden relevant for utfasing?	☐	☒

The proposal suggests the use of triclosan coated absorbable sutures in any type of surgery for the reduction of surgical site infection (SSI), and the following reduction in Length of Stay (LOS), usage of antibiotics, hospital costs, and socioeconomic costs.

World Health Organization, WHO advocates: ”The panel suggests the use of triclosan-coated sutures for the purpose of reducing the risk of SSI, independent of the type of surgery.”

(WHO. The Global Guidelines for Prevention of Surgical Site Infection. 2016.)

5. Hva omfatter metoden (flere kryss mulig)?

Legemiddel	☐
Medisinsk utstyr/IVD medisinsk utstyr som er CE-merket*	☒

*Hvis metoden er CE-merket: Hva er den CE-merket som og til hvilket bruksområde?

The first triclosan-coated suture, VICRYL* Plus, was CE marked in 2004 as a class III product. It was followed by MONOCRYL* Plus (2008) and PDS* Plus (2010), also class III.

Medisinsk utstyr/IVD medisinsk utstyr som ikke CE-merket	☐
Prosedyre	☐
Screening	☐
Høyspesialiserte tjenester/nasjonale tilbud	☐
Organisatorisk oppsett av helsetjenesten	☐
Annet (beskriv)	☐

"Klikk her og beskriv. Inkluder eventuelt hvem som er ansvarlig for utvikling av metoden"

6. Metodens bruksområde:

Forebygging	☒
Utredning og diagnostikk	☐
Behandling	☐
Rehabilitering	☐
Spesialisthelsetjenesten	☒
Primærhelsetjenesten	☒

The triclosan coated sutures are used to prevent SSIs. Triclosan coated sutures are indicated for general soft tissue approximation and/or ligation. Triclosan coated sutures may be used for most types of surgery, but their safety and effectiveness have not been established in cardiovascular tissue, ophthalmic surgery nor neurological tissue.

7. Finansieringsansvar

	Ja	Nei
Har spesialisthelsetjenesten et finansieringsansvar for metoden i dag	☒	☐
Vil spesialisthelsetjenesten kunne få finansieringsansvar for metoden?	☐	☐

The speciality care service has the funding responsibility for purchase of sutures. But also for the raised costs connected to surgical site infections. According to documentation and data a decrease in numbers of surgical site infections can be expected, and the reduction in cost following that.

(D. J. Leaper, C. E. Edmiston Jr and C. E. Holy. Meta-analysis of the potential economic impact following introduction of absorbable antimicrobial sutures. BJS 2017 Jan;104(2):e134-e144)

8. Er metoden omtalt i nasjonale faglige retningslinjer eller handlingsprogrammer utarbeidet av Helsedirektoratet?

No, not to our knowledge. But three globally recognized health authorities have recently added triclosan coated sutures to their SSI prevention guidelines. The use of the triclosan coated sutures are mentioned in Folkehelseinstituttets web page, with references to the well documented results from the use of these sutures, and due to the updated global guidelines from WHO, American College of Surgeons (ACS) and Surgical Infection Society (SIS), Center for Disease Control and Prevention (CDC).

https://www.fhi.no/kk/forbedringsarbeid/pasientsikkerhet/farre-infeksjoner-med-impregnert-operasjonstrad/

References 1. Berríos-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. JAMA Surg. doi:10.1001/jamasurg.2017.0904. 2. Global guidelines on the prevention of surgical site infection. World Health Organization website. http://www.who.int/gpsc/ssi-prevention-guidelines/en/. Accessed April 4, 2017. 3. Ban KA, Minei JP, Laronga C, et al. American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update. J Am Coll Surg. 2016;224:59-74.

9. Involverer metoden bruk av stråling (ioniserende/ikke-ioniserende)?

Ja	Nei
☐	☒

"Klikk her og beskriv kort beskrivelse type strålekilde, utstyr og stråleeksponering"

10. Hvilke fagområde(r) gjelder metoden, og hvilke pasienter berøres? (Får metoden evt. også konsekvenser for andre grupper (som personell, pårørende?)

Triclosan coated sutures can be used in all surgical procedures, for all patients, but their safety and effectiveness have not been established in cardiovascular tissue, ophthalmic surgery nor neurological tissue. No adverse events have been reported with the use of triclosan coated sutures. Using triclosan in sutures represents a one-time use of triclosan, which minimizes the risk of possible negative effects linked to continuous use of antibacterial substances. The personnel will not be exposed to triclosan in sutures due to use of gloves. The use of triclosan in sutures will not increase the ecological risk (Pellinen J. The use of triclosan in surgical sutures from the environmental perspective. 2009).

11. Hvilke aspekter er relevante for vurderingen? (flere kryss mulig)

Klinisk effekt	☒
Sikkerhet/bivirkninger	☒
Kostnader/ressursbruk	☒
Kostnadseffektivitet	☒
Organisatoriske konsekvenser	☐
Etiske	☐
Juridiske	☐

12. Foreslå hva som bør være hovedproblemstilling(er) for metodevurderingen, samt eventuelle underproblemstillinger (i samsvar med pkt. 10). For deg som er kjent med «PICO (Patient, Intervention, Comparator, Outcom) -begrepet»)- inkludere gjerne tentativt forslag til PICO.

The main issue is patient outcomes; the occurrence of surgical site infections after surgery. SSIs may also lead to increased hospital costs typically exemplified by increased length of stay, as well as increased use of antibiotics and patient morbidity. Studies and meta-analysis classified as level 1A evidence show a decrease in these aspects compared to sutures without triclosan coating.

13. Gi en kort begrunnelse for hvorfor det er viktig at metodevurderingen som foreslås bør gjennomføres:

An evaluation of the triclosan coated sutures on a national level, with a following national guideline would benefit both the patients and the national healthcare service, due to the reduction of SSI (and the decreased hospital costs, decreased usage of antibiotics, better patient outcome).

14. Kommenter metoden som forslås vurdert mht. følgende punkter:

Alvorlighetsgraden på tilstanden metoden er ment for

SSI is the most common complication after surgery and counts for 37% of all healthcare-associated infections. SSI take a significant clinical and economical toll. Patients with SSI are likely to be 5x more likely to be readmitted (1), up to 10 additional days hospitalized (2), 2x as likely to die (1). Because SSIs interrupt the natural healing process, they are also strongly correlated to other wound complications. Patients with SSI are 2x more likely to develop incisional hernia, are 6x more likely to suffer wound dehiscence following abdominal surgery (4).

Triclosan coated sutures have been shown in multiple meta-analysis to reduce the risk of SSIs by 26-28% (5-7).

References:

1. Berríos-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. JAMA Surg. doi:10.1001/jamasurg.2017.0904.

2. Global guidelines on the prevention of surgical site infection. World Health Organization website. http://www.who.int/gpsc/ssi-prevention-guidelines/en/. Accessed April 4, 2017.

3. Ban KA, Minei JP, Laronga C, et al. American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update. J Am Coll Surg. 2016;224:59-74.

4. Van Ramshorst GH, Nieuwenhuizen J, Hop WC, et al. Abdominal Wound Dehiscence in Adults: Development and Validation of a Risk Model. World J Surg. 2010;34:20-27

5. Berríos-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. JAMA Surg. doi:10.1001/jamasurg.2017.0904.

6. Global guidelines on the prevention of surgical site infection. World Health Organization website. http://www.who.int/gpsc/ssi-prevention-guidelines/en/. Accessed April 4, 2017.
7. Ban KA, Minei JP, Laronga C, et al. American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update. J Am Coll Surg. 2016;224:59-74.

Forventet effekt

Reduction in the rate of SSI by 26-28%.

According to “Sykehusinfeksjoner, raport av omfang og kostnader” from 2015, hospital infections count for 2,1 billion NOK based on the cost of bed days. Approximately 37% of all hospital infections is SSI, equivalent 777 million NOK.

By reducing the SSI with 26%, this can potentially lead to a 202 million NOK saving for the Norwegian Hospitals.

In addition, a reduction in the use of antibiotics can be expected, and consequential improved patient outcome, which will be positive in the light of the increased occurrence of multi-resistant bacteria.

http://docplayer.me/26169757-Sykehusinfeksjoner-rapport-av-omfang-og-kostnader-utarbeidet-av-computas-as-november-2015-sykehusinfeksjoner-rapport-av-omfang-og-kostnader.ht

Sikkerhet (beskriv kort opplysninger om kjente risikoforhold, sikkerhetsaspekter og bivirkninger)

There are no adverse events described in the documentation with the use of triclosan coated sutures. Nor any environmental impact. Using triclosan in sutures represents a one-time use of minimal amounts of triclosan.

Totalt antall pasienter i Norge metoden er aktuell for

All surgical patients that are given absorbable sutures, excluding use in ophthalmic surgery and in cardiovascular and neurological tissue.

Konsekvenser for ressursbruk i helsetjenesten

Cost reduction related to the reduction of SSI due to reduction in LOS, fewer readmissions, and smaller use of antibiotics.

Behov for revisjon av eksisterende nasjonale faglige retningslinjer, evt. utarbeidelse av nye

Yes. An evaluation of the triclosan coated sutures on a national level, with a following national guideline would benefit both the patients and the national healthcare service, due to the reduction of SSI (and the decreased costs, decreased usage of antibiotics, better patient outcome, reduction in LOS).

15. Oppgi referanser til dokumentasjon om metodens effekt og sikkerhet (eks. tidligere metodevurderinger). (Inntil 10 sentrale referanser oppgis. Ikke send vedlegg på dette trinnet i prosessen.)

WHO. The Global Guidelines for Prevention of Surgical Site Infection. 2016.

Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017

American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update

De Jonge et al. Meta-analysis and trial sequential analysis of triclosan-coated sutures for the prevention of surgical-site infection. BJS 2017; 104: e118–e133

Wu X et al. Antimicrobial-coated sutures to decrease surgical site infections: a systematic review and meta-analysis. Eur J Clin Microbiol Infect Dis 2017;36:19-32

Renko et al. Triclosan-containing sutures versus ordinary sutures for reducing surgical site infections in children: a double-blind, randomised controlled trial. Lancet Infect Dis. 2017 Jan;17(1):50-57

Thimour-Bergström et al. Triclosan-coated sutures reduce surgical site infection after open vein harvesting in coronary artery bypass grafting patients: a randomized controlled study. Eur J Cardiothorac Surg 2013 Feb 22.

16. Oppgi navn på produsenter/leverandører vedrørende metoden (dersom aktuelt/tilgjengelig):

Johnson & Johnson Ethicon, represented in Norway by Johnson & Johnson MD, a division of Janssen-Cilag AS

17. Status for markedsføringstillatelse (MT) eller CE-merking: Når forventes MT- eller CE-merking? Eventuelt opplysning om planlagt tidspunkt for markedsføring).

The triclosan coated sutures have had CE mark since 2004 on the Norwegian market.

18. Fritekstrubrikk (Supplerende relevant informasjon, inntil 300 ord.)

On a European level, the rate of SSI remains high despite the decrease in the rate other type of infections. The contamination of suture material by bacteria is identified as one of the most common risk factors for SSI. As the largest manufacturer of surgical sutures, we at Johnson & Johnson Ethicon believe it is our responsibility to develop products that minimizes the risks and improves patient outcomes.

19. Interesser og eventuelle interessekonflikter

Beskriv forslagstillers relasjoner eller aktiviteter som kan påvirke, påvirkes av eller oppfattes av andre å ha betydning for den videre håndteringen av metoden som foreslås metodevurdert. (Eksempler: Forslagsstiller har økonomiske interesser i saken. Forslagsstiller har eller har hatt oppdrag i tilslutning til eller andre bindinger knyttet til metoden eller aktører som har interesser i metoden.)

Johnson & Johnson Ethicon is a global manufacturer of sutures. Ethicon is represented in Norway by Johnson & Johnson Medical Devices, a division of Janssen-Cilag AS.