

Input from external experts on the draft **Project plan - “Antibacterial-coated sutures versus non-antibacterial-coated sutures for the prevention of abdominal, superficial and deep, surgical site infection”** - with author's replies

EUnetHTA JA3 WP4 - Other technologies

Comments from external experts on the Project plan “Antibacterial-coated sutures versus non-antibacterial-coated sutures for the prevention of abdominal, superficial and deep, surgical site infection” with author's replies

November 2016



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<p>Comment from <i>Insert your name and organisation</i></p>	<p>Page number <i>Insert 'general' if your comment relates to the whole document</i></p>	<p>Line or section number</p>	<p>Comment and suggestion for rewording <i>Please insert each new comment in a new row.</i></p>	<p>Character of comment <ul style="list-style-type: none"> • 'major'^a =1 • 'minor'^b = 2 • 'linguistic'^c =3 <i>Please indicate your choice by writing the according number in this field, e.g. for major choose "1".</i> </p>	<p>Author's reply</p>
<p>Stephan Kriwanek, Austria</p>	<p>8</p>	<p>Table 3</p>	<p>The study includes Polyglactin, Polyglecaprone and Polydioxanone sutures. The incidence of complete abdominal wound dehiscence within 30 days and the rate of incisional hernias will be analyzed. The current recommendation for closure of the abdominal wall does not include Polyglactin. Therefore, suture material represents a confounding factor for the analysis of wound dehiscence and incisional hernias. For these reasons wound dehiscence and incisional hernia should only be analyzed after use of Polydioxanone sutures.</p>		<p>Thank you, but we should assess all antibacterial-coated sutures according the CE mark and approved Instructions for use. Systematic literature search will be done and synthesis and reporting of the evidence will be provided according the current methodological standards.</p>



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Ivana Mareković, Croatia	8	Table 3. Project Scope: PICO/3.0	Beside defining population, it should be specified which criteria were used to define surgical site infection (SSI). There are criteria from Centers for Disease Control and Prevention (CDC) http://www.cdc.gov/nhsn/PDFs/pscManual/9pscSSIcurrent.pdf?agree=yes&next=Accept and also the criteria used by European Centre for Disease Prevention and Control (ECDC) in a context of Surveillance of surgical site infections in European hospitals – HAISSI protocol cdc.europa.eu/en/publications/Publications/120215_TED_SSI_protocol.pdf . Both criteria classify surgical site infections in three main groups superficial incisional, deep incisional and infection of organ/space but the descriptive criteria are different.	1	Thank you, specification was made: “Incidence of superficial and deep incisional surgical site infections (SSIs), according to the US Centre for Disease Control and Prevention (CDC) criteria [6,12] in patients undergoing abdominal surgery”.
Ivana Mareković, Croatia	9	Table 3. Project Scope: PICO/3.0	Incidence of SSI (superficial and deep) in patients undergoing abdominal surgery is suggested for being used as an outcome indicator. The following should be more clearly explained: <ul style="list-style-type: none"> - surgical site infections include superficial, deep and organ/tissue infections; the reason why only the first two types of SSI is included in outcome evaluation should be explained; - according to ECDC there are two indicators used to express the incidence of SSI: <ol style="list-style-type: none"> 1. cumulative incidence includes SSI diagnosed during hospital stay as well as SSI diagnosed after the discharge from the hospital; it is expressed as a the number of SSI per 100 specific operations 2. incidence density only includes SSI diagnosed during hospital stay and is the number of SSI per 1 000 post-operative days. <p>Maybe the cumulative incidence is more appropriate because it includes also SSI after the discharge from the hospital and for some coatings (for example triclosan) it is demonstrated that it provides prolonged protection against colonization of the tissue around the sutures because its effects last for approximately 1 month.</p>	2	Abdominal <i>superficial and deep incisional</i> surgical site infections were specified clearly in the title and through the whole text. This was requested by national decision maker. Systematic literature search will be done and synthesis of the evidence will be provided according reported outcomes.
Ivana Mareković, Croatia	13	Table 4b. Preliminary Evidence/4.0	Antibiotic prophylaxis is named in the list of patient characteristics, but perhaps it should be more defined regarding the timing, dosing and the antimicrobial agent given.	1	Accepted. Change made. Thank you.

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Ivana Mareković, Croatia	13	Table 4b. Preliminary Evidence/4.0	<p>Glycemic control should be named in the list of patient characteristics. Patients with poorly regulated hiperglycemia had a significantly increased risk of infection. Glycemic control in individual patient could impact the outcome and could mislead the assessment of antibacterial-coated sutures significance.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Kwon S, Thompson R, Dellinger P, Yanez D, Farrohki E, Flum D. Importance of Perioperative Glycemic Control in General Surgery: A Report From the Surgical Care and Outcomes Assessment Program. <i>Ann Surg.</i> 2013 January ; 257(1): 8–14 2. Kiran RP, Turina M, Fazio Victor MB. The clinical significance of an elevated postoperative glucose value in nondiabetic patients after colorectal surgery: evidence for the need for tight glucose control? <i>Ann Surg</i> 2013 Oct;258(4):599-604 3. Kao L, Phatak UR. Glycemic control and prevention of surgical site infection. <i>Surg Infect</i> 2013 Oct;14(5):437-44 <p>Also, all other risk factors for SSI should be included in the analysis (obesity, hypothermia, duration of operation, presence of drainage etc.) in order for antimicrobial-coated suture assessment to be adequate.</p>	1	Accepted. Change made. Thank you.
Ivana Mareković, Croatia	13	Table 4b. Preliminary Evidence/4.0	<p>The results of microbiological cultures should be included in the analysis. The efficacy of some compounds used for coating of sutures (for example triclosan) has limited efficacy to gram-negative pathogens.</p> <p>Mattavelli I, Rebora P, Doglietto G, et all. Multi-center randomized controlled trial on the effect of triclosan-coated sutures on surgical site infection after colorectal surgery. <i>Surg Infect</i> 2015;16:226-235</p>	1	Accepted. Change made. Thank you.