EUnetHTA JA3 WP4 - Other technologies, OTCA12
Review by external experts of the draft project plan for the rapid assessment of C-reactive protein point-of-care testing (POCT) to guide antibiotic prescribing in primary care settings for acute respiratory tract infections (RTIs)

eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Collated feedback plus author's replies

Comment from *Insert your name and organisation*	**Page number** *Insert 'general' if your comment relates to the whole document*	**Line/ section number**	**Comment and suggestion for rewording** *Please insert each new comment in a new row.*	**Character of comment** • 'major'[a] =1 • 'minor'[b] = 2 • 'linguistic'[c] =3 *Please indicate your choice by writing the according number in this field, e.g. for major choose "1".*	**Author's reply**
M Cormican	6	Table 1-3	I am not familiar with abbreviation PICO	3	PICO stands for Population, Intervention, Comparator and Outcomes - it is a framework that is used to define research questions. The protocol has been updated to define this abbreviation when it is first mentioned.
M Cormican	8	13-15	The project here and elsewhere is framed primarily in terms of reducing antibiotic use to manage resistance though I do note reference to patient safety. I would think it may be better if possible to frame the issue in terms of enhancing patient safety by appropriate prescribing both ensuring that patients with bacterial infection get antibiotic and that those who do not have bacterial infection do not get antibiotic – targeting treatment to those who need it and reducing avoidable drug exposure in those who don't – this should have benefits in terms of reducing antimicrobial prescribing and resistance, but the primary goal should be better patient care. I note title of the document is to guide antibiotic prescribing not decrease it		Some of the wording throughout the document has been changed to reflect this comment. However, our principle outcome is related to the overall reduction of antibiotic prescribing with the assumption that the reduction should be in those with a low CRP level who are less likely to have a serious bacterial infection. Patient morbidity and mortality are included as safety outcomes, as the aim is to decrease prescribing of antibiotics (when they are unlikely to be of benefit) without compromising safety. However, it is acknowledged that the intervention may lead to improved care for patients with a bacterial infection. This point will be discussed in relation to the assessment findings.
M Cormican	15	Outcomes	Should patient outcomes come first ?		Patient outcomes are included as two of our primary outcomes. However, based on the title of this REA our main outcome is the effect

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					of CRP POCT on prescribing.
M Cormican	25	Checklist 1.1 Ethical	I am not certain about the No here – it seems reasonable just working through in my head if we are offering a test in a situation where a test was not previously offered (so this is POCT CRP instead of no test rather than POCT CRP instead of a conventional CRP test) does test rather than no test risk uncovering diagnoses or raising anxiety about possible diagnosis that would not otherwise have arise		The potential impact of this technology and if it raises ethical issues is debatable. After discussion of the issue, we came to the conclusion that although a high CRP could indicate a medical problem other than a serious bacterial RTI, a GP would only investigate further if other symptoms were identified on clinical examination or if treatment failure occurred. That is, a high CRP level would not necessarily impact on the GP's decision making process beyond antibiotic prescribing.
M Cormican		Checklist 2.2 Organisational	Giving what I would call an enabling prescription is already widely practiced so not a major change. I am not sure delayed prescription is a good term the prescription is given at the time (not delayed) and the intention is not to delay starting antibiotic to but avoid starting in a proportion of cases The issue of organization to ensure training, verification and quality assurance is not addressed – this is a key issue with POCT testing – most non laboratory trained healthcare workers tend to trust the supplier and the instrument- most laboratory trained health care workers take nothing for granted		Additional wording has been added to table 2-2 to explain what we mean by a 'delayed prescription'. We will include an analysis of the analytical performance of the different CRP-POCT, this will include accuracy and precision as well as usability of the instruments where this information is available.
M Cormican	24	C002 and 004	In relation to patient safety it is not clear that consideration is given to risk associated with skin puncture for testing in patients who otherwise would have a test and associated skin puncture. Skin puncture in a healthcare setting is associated with risk of transmission of blood borne virus – rare but a very significant event when it occurs – experience for example in		Additional questions around this safety issue (for patients and staff) have been added to C0008. It has also been added to the Ethics checklist.

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			acute hospitals unless there is a lot of audit glucometers tend to be blood stained and sharps may not always be safely disposed of. Skin puncture /sharps are also associated with risk for staff.		
NO'C ICGP	11	Systematic review 2: after line 16	Consideration of ease of disposing safely with minimal risk of sharps injury or exposure to blood spill. Needs to be single use item. Need to consider what healthcare risk waste disposal stream is appropriate and if this is already available in the primary care setting.	1	Additional questions around this safety issue (for patients and staff) have been added to C0008. It has also been added to the Ethics checklist. The description of the technology will describe the format of the test and the ancillary equipment / supplies required. The issue of safe waste disposal will be commented on in the discussion of the assessment findings. The disposal of these tests and what is currently available in the primary care setting are country specific and would be difficult to generalise across counties. Therefore, where relevant, it is assumed that organisational issues including the disposal of waste will be addressed in the locally adapted reports.
Orion Diagnostica	9	Table 2-2	We propose change of wording (lines 5-6): … patients who have been treated frequently with antibiotics are much more likely <u>*to be at risk*</u> *of* antibiotic resistance (instead of "more likely to have antibiotic resistance").	2	The text has been amended as follows: **….**that patients who have been treated frequently with antibiotics are at greater risk of antibiotic resistance
Orion Diagnostica	14	2.2.2	<u>Intervention</u>: Please add the registered trademark sign as follows (in the first instance the brand names are mentioned): - QuikRead go® CRP - QuikRead go® CRP+Hb - QuikRead® CRP	2	Amended

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Orion Diagnostica	20	Lines 4-7	One reference (Goossens H, Ref. 2 and Re.f 3) is listed twice	2	Corrected

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