Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Statement of Outcomes

Report on the outcome of the public consultation on the draft health technology assessment (HTA) of C-reactive protein point-of-care testing to guide antibiotic prescribing for acute respiratory tract infections in primary care settings

May 2019

About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Office of the Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services —** Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

Acknowledgements

HIQA would like to thank all of the individuals and organisations who provided their time, advice and information in support of this health technology assessment (HTA). Particular thanks are due to the Expert Advisory Group (EAG), and the individuals within the organisations listed below who provided advice.

The membership of the EAG was as follows:

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Dr Mary Keogan	National Clinical Lead, HSE Clinical Programme for Pathology
Rosarie Lynch	National Patient Safety Office, Department of Health
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Bernie O'Reilly	Patients for Patient Safety
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Dr Conor Teljeur	(Chair), Health Information and Quality Authority
Sandra Walsh	Primary Care Division, Department of Health

Members of the Evaluation Team

Members of HIQA's Evaluation Team were: Dr Christopher Fawsitt, Dr Patricia Harrington, Karen Jordan, Desmond Lucey, Liam Marshall, Dr Patrick Moran, Dr Kirsty O'Brien, Dr Éamon Ó Murchú, and Dr Conor Teljeur.

Conflicts of Interest

There were no reported conflicts of interest for the Expert Advisory Group or Evaluation Team.

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1. Introduction

In February 2018, the Health Information and Quality Authority (HIQA) commenced work on a health technology assessment (HTA) in relation to point-of-care testing (POCT). HIQA agreed to undertake the HTA following a formal request from the Lead of the Primary Care Clinical Programme in the Health Service Executive (HSE). The aim of the HTA is to establish the clinical and economic impact of providing point-of-care testing to inform prescribing of antibiotics for patients presenting with symptoms of acute respiratory tract infections (RTIs) in primary care.

This report summarises the feedback received from the public consultation process and details HIQA's responses to the issues raised, including any changes that were made to the report as a result.

HIQA is a national representative body for the European Network for Health Technology Assessment (EUnetHTA), work by which is funded by a grant from the European Commission. Its mission is to support collaboration between European HTA organisations and bring added value to healthcare systems at the European, national and regional levels. In 2017, HIQA agreed to act as lead author for a rapid relative effectiveness assessment (REA) of an emerging medical technology as part of its commitment to EUnetHTA. To facilitate timely production of the HTA on POCT, work on one of the biomarkers relevant to this assessment, C-reactive protein (CRP), was undertaken as a REA through our work with EUnetHTA. The assessment, co-authored by colleagues from Austria with review input from five other European HTA agencies, was published by EUnetHTA in February 2019. The following sections of the HTA were adapted directly from the EUnetHTA assessment: description of the technology, burden of disease, clinical effectiveness and safety, diagnostic test accuracy, and analytical performance. The EUnetHTA assessment was subject to extensive reviews by experts and stakeholders from across Europe. The sections adapted for the HTA were based on the reviewed text.

2. The consultation process

The aim of the consultation process was to obtain feedback on any issues that may not have been adequately addressed in the report and, based on the feedback, to expand coverage of material requiring further clarification.

The draft HTA was published on the HIQA website on 7 February 2019. The public consultation period closed on 15 March 2019. The public was provided with an opportunity to give feedback through a variety of means (by post, email or online) to ensure that the consultation process was accessible. The consultation webpage

contained a link to the draft report, a link to an online submission form for feedback (Crowdsignal), and a consultation feedback form that could be downloaded.

A press release was issued at the beginning of the consultation period and the findings of the draft HTA were widely reported in the media. Individuals and organisations with expertise in the area and those who would likely be affected by the introduction of C-reactive protein POCT were targeted directly and requested to provide feedback. This included relevant departments within the HSE, Irish and international experts in point-of-care testing, clinician groups and patient advocacy groups.

All comments received were saved in an online database. Individuals or organisations who wished to submit comments confidentially were anonymised before being transferred to Microsoft Excel for analysis.

The template for making a submission was semi-structured to allow people to be as focused or wide-ranging in their comments as they wished. Character or word limits were not applied to submissions. A copy of the public consultation feedback form is provided in Appendix 1.

3. Analysis of submissions

A total of four submissions were received through the public consultation on the HTA. Three submissions were received via online feedback through the consultation webpage. Of the four submissions, three were submitted on behalf of representative organisations in the Irish healthcare setting, and one was submitted by a device manufacturer. Appendix 2 provides a full list of all the organisations that made a submission.

Each submission was read in its entirety, broken down into individual comments, and recorded to create a database of comments. The Evaluation Team identified 51 comments in total.

Amendments to the report, where applicable, were made and responses to comments were documented. The comments and responses are listed in Table 1 below.

4. Comments received and responses

This section describes some specific points raised during the consultation process and provides a brief summary of HIQA's response.

Table 1 Comments received and responses

Number	Comment	Response
1	Roche Diagnostics Limited launched a test disk for the Roche cobas b101 instrument in March 2018, an in vitro diagnostic test system designed to quantitatively determine the C-reactive protein (CRP) in human capillary whole blood and serum, EDTA K2/K3 and lithium heparin anticoagulated whole blood and plasma by photometric measurement in the point of care setting. The Roche cobas b101 is currently utilised in several sites in Ireland as part of routine CRP testing and we therefore believe that this test should be included in this health technology assessment.	Work on the list of eligible CRP POCT devices to be included in the HTA was concluded in February 2018; devices were included based on a scoping exercise, evidence from SRs and manufacturer feedback. The HTA comprises a class-based assessment for this technology, rather than findings specific to individual devices. However, the report has been amended to reflect the availability of a CRP test disk for the Roche cobas b101 instrument from Roche Diagnostics Limited in March 2018.
2	We would require some clarification on whether the costs associated with the current HSE campaigns in the antimicrobial resistance field are included in this analysis e.g undertheweather.ie or patient leaflets?	The costs for the HSE campaigns are not included in the economic evaluation. It was assumed that these are ongoing costs that will continue to accrue to the HSE with or without the adoption of CRP POCT, and hence they do not represent an incremental cost.
3	We feel that the key pieces of information are not clear enough to support clinicians given the volume of information provided. We would suggest that a short version of the assessment is produced or the results are clearly highlighted to offset against the volume of information within the full document and support readers.	HTAs are technical documents. While we endeavour to make the document readable for a general audience, we must strike a balance between readability and technical detail. The document is primarily intended to serve the needs of the decision-maker by including the relevant evidence. The development of documents that specifically support clinicians (e.g. clinical guidelines) and patients (e.g. patient information leaflets) are the responsibility of the HSE. It should also be noted that the report now contains an executive summary, a plain English summary, and an Advice section.
4	We would like to support HIQA in including the Roche cobas b101 by submitting the relevant information required as other manufacturers have. All documentation is available on request including the package insert with the product information, promotional material and site usage. The Roche cobas b101 CRP test addresses some of the points raised in the document, for example lack of pre-preparation of the patient blood sample, ease of use and room temperature storage of tests. The cobas b101 device also complies with best practice	This is noted, but there is no published formal independent evaluation or systematic review of the effectiveness of the cobas b101 CRP testing system that would support highlighting the device in the HTA report. The systematic reviews in the report included all relevant information for CRP POCT. Four separate systematic reviews were undertaken as part of this HTA. Evidence specific to the cobas b101 was not identified in any of

	around user and device control/access and interfacing to data management systems, as highlighted in the document.	the included studies. The HTA comprises a class-based assessment for this technology, rather than findings being specific to individual devices. It should be borne in mind that the HTA does not recommend for or against the use of any individual device.
5	We feel that it would be greatly beneficial to explore the inclusion of the Roche cobas b101 in an open discussion with the guideline committee.	This would be outside the scope of the HTA and the public consultation process.
6	The scientific evidence relating to the clinical and cost effectiveness of C-reactive protein point-of-care testing (CRP POCT) in General Practice is insufficient.	The HTA highlights the uncertainty around the clinical effectiveness and persistence of the effect of CRP POCT in primary care. Refer to comment 7 below. The cost-effectiveness of CRP POCT in primary care has been systematically reported and evaluated in the HTA report. Sensitivity and scenario analyses have been applied to the economic model and the BIA to explore the uncertainty around the benefits of CRP POCT.
7	While there is some evidence that CRP POCT with enhanced communication training can reduce anti-biotic prescribing in the short-term, the report shows that there is significant uncertainty as to what extent CRP POCT will reduce anti-biotic prescribing in the long-term. A recent randomized trial published in the Annals of Family Medicine found that "early improvement [in anti-biotic prescribing] wanes overtime, and this strategy becomes ineffective both overall and for LRTI, the only current indication for using CRP to guide decisions about anti-biotic therapy". The trial concluded that the most useful training in the long-term is enhanced communications skills. (Ann Fam Med March/April 2019 vol. 17 no. 2 125-132 doi: 10.1370/afm.2356)	The study referred to in the comment was alluded to in the discussion of the draft report; it had not been officially published at the time the draft HTA was published for public consultation. The report has been updated to include a discussion of the findings of the paper by Little et al. (2019). It should be noted that waning in improvement may be entirely attributable to the fact that CRP testing was rarely used at the 12-month audit. The continued efficacy is potentially related to the usability of CRP POCT, along with the ongoing training and quality assurance burden for CRP POCT in general practice, and this is highlighted in the conclusions of the report.
8	A useful test could support GPs in identifying patients with serious RTIs requiring hospitalisation, however there is no evidence to support the use of CRP POCT in differentiating serious RTIs nor in reducing hospitalisations.	The scope of the HTA was strictly in relation to the use of CRP POCT to guide antibiotic prescribing for acute respiratory tract infections in primary care settings. The context of using CRP POCT is as a rule-out test to support a GP decision not to prescribe an antibiotic where there is clinical

		uncertainty as to its need. The impact of CRP POCT on adverse outcomes of mortality, hospitalisations and reconsultations was evaluated and no evidence was found of an increase in these outcomes.
9	Evidence for the cost effectiveness of CRP POCT must include adequate costing of GP (or practice nurse) time spent to administer the test and to interpret and communicate the results to patients. While the report provides for the cost of the CRP devices, training and quality control, it is incorrect to assume that there will be no cost to the HSE for GP time other than an opportunity cost. It is recognised that the time to administer the test is longer than the average consultation and it is assumed that it would add an average of three minutes to a consultation. In many other jurisdictions a fee is provided for the GP to administer the test, yet no fee has been included in HIQA's HTA.	It is noted that there is a high rate of antibiotic prescribing for patients presenting with acute respiratory tract infections in Ireland. The provision of CRP POCT devices and associated training and quality control presents an opportunity to support quality prescribing of antibiotics in general practice. The cost of GP time is included in the economic model. The report has been updated to include a scenario analysis of various values of fee-per-test on the budget impact assessment (BIA) of CRP POCT implementation. We have noted the level of uncertainty around the available evidence for CRP POCT. In our conclusions, we recommend that a pilot introduction of CRP POCT is advisable. A key outcome measure would be to explore whether a fee-per-test is necessary to ensure the appropriate uptake and continued use of CRP POCT. The real economic cost per practice setting could be measured. It would also provide an opportunity to assess the viability of non-financial incentives, such as the impact of clinical guidelines and/or audits.
10	The report must take into context the signifcant under-resourcing of GP care in Ireland. FEMPI cuts of approximately 40% per GMS patient have reversed the development of General Practice over the last decade while there is an assumption that care can be shifted into General Practice and the community without the accompanying resources. Up to 2,055 additional GPs may be required over the next decade, however in the next few years almost 700 GPs are due to retire while at the same time up to 70% of recent GP graduates are intending to emigrate and almost 20% have already emigrated. GPs who have been established for a number of years are now choosing to leave Ireland and there are a growing number of GMS	There are no judgments or statements on FEMPI (Financial Emergency Measures in the Public Interest), the appropriateness of funding or future GP staffing considerations. It was considered outside the scope of the HTA. The report does consider the potential consequences for primary care in terms of additional consultation time and quantified this as displaced care. A fee-per-test scenario analysis has been included in the budget impact analysis.

	lists which are attracting few or no applicants.	
11	International evidence points to the need to shift the model of care towards General Practice and a GP-led Primary Care System and requires significant investment overtime.	It is considered outside the scope of the HTA to examine the international evidence of different models of primary care.
12	The assumption that there will be no fee for GP time spent on CRP testing devalues GP care.	The opportunity cost of GP time was explicitly included in the cost-effectiveness analysis but not in the budget impact as it does not incur a direct and immediate cost to the HSE. It is acknowledged that it displaces care. A fee-per-test scenario analysis has been added to the budget impact analysis based on reimbursement fees used in other European countries. The original omission of a scenario analysis for fee-per-test should not be perceived as HIQA making a value judgment on GP care in Ireland, but reflects the fact that GP care is funded through a combination of capitation fees and out-of-pocket payments.
13	There would be a substantial cost to the introduction of CRP POCT in General Practice with insufficient evidence of any long term impact on antibiotic prescribing.	The uncertainty is acknowledged in the report. As part of the report it is recommended that consideration should be given to a pilot introduction of the technology to assess if and how a national programme should be implemented. The decision uncertainty has been emphasised in the executive summary and the advice to the minister.
14	There is some concern that CRP POCT could potentially be used to place restrictions on GP prescribing.	The HTA of CRP POCT to guide antibiotic prescribing for acute RTIs in primary care reports that the technology should be used as a rule-out test in cases of clinical uncertainty to support a decision not to prescribe an antibiotic where the patient is unlikely to benefit. The use of the test and its interpretation rests with the GP. It should be viewed as a quality improvement measure to inform and support appropriate antibiotic prescribing and to reduce antimicrobial resistance. It should not be viewed as restricting prescribing practice.
15	With regard to anti-microbial resistance (AMR) the IMO are of the view that it would be more cost-effective to invest in: 1) better surveillance systems of both anti-biotic use and AMR	The HTA reports on the role of CRP POCT in addition to usual care in reducing antibiotic prescribing, and did not systematically evaluate the clinical or cost-effectivness of other antibiotic stewardship initiatives. It is

	2) public education programmes 3) prescriber education and communication training programmes 4) improved GP access to diagnostics to differentiate serious RTIs requiring hospitalisation.	acknowledged in the report that CRP POCT is only one of a range of antimicrobial stewardship initiatives that could be considered The absence of national-level data for antibiotic prescribing is highlighted in the report, and any pilot or roll-out of CRP POCT should be accompanied by measures to evaluate the clinical and cost-effectiveness of the initiative.
16	Summary text provided on differences between POCT and laboratory testing (1+ pages) – "POCT has the potential to pose greater risks to patients than a comparable laboratory test as it can be subject to pre-analytical, analytical and post analytical variables and is reliant on non scientific operators being fully trained in all aspects of the testing process and robust governance processes in place" concluding with a comment "An overview of Point of Care testing in general is not included as a separate section within the HTA".	The HTA addresses the distinction between laboratory and primary care-based testing, and specifically includes a review of the analytical performance of CRP POCT. As it is clearly stated in the report, internal and external quality assurance, along with appropriately trained staff, increases the likelihood of acceptable quality testing. The necessity for suitable governance structures for CRP POCT, involving medical laboratory staff, and the importance of test traceability for CRP POCT is highlighted in the report.
17	Test equipment (automation vs manual) statement "Methodologies which employ a level of automation in the sample application/ sample volume detection, timing and interpretation of the results, are less susceptible to error."	The analytical performance of CRP POCT technology has been systematically reviewed.
18	Test equipment statement "Equipment should be easily maintained, capable of IQC and EQA performance including preventing further use at failure, user friendly (ideally with on board instruction/ guidance), operation should be confined to suitably trained and competent operators through password entry, test patients should be clearly identifiable and results should be produced in a physical format which traceably identifies the patient, the operator, date time and test result. Electronic storage should also be present to provide ongoing audit of operators, results, activity and patient follow up. Connected systems provide this type of traceability." Comment concludes "the HTA does not clearly identify the importance of connectivity for complete traceability of operators and patients tests performed, to provide ongoing regulation of performance, quality and costs. It rather notes it would be "beneficial"."	The importance of internal quality control, external quality assurance and electronic storage of patient results and corresponding test batch numbers are highlighted in the report. In the context of CRP POCT, we did not find evidence to explicitly state that connectivity would ensure or improve safety for patients. However, it is now highlighted in the executive summary and the advice to the minister, that if there are connected systems between primary care and the laboratory medical information system (MEDLIS), governance of all national POCTand tracability of patient tests would be maximised.
19	The production of timely results is noted. Additionally quality and laboratory comparable	As noted in response 20, the text has been amended to emphasise the

	results should be noted, as timely is only one aspect of the result.	importance of quality assurance.
20	"Reliable CRP test results" should be "quality assured results" in all sections.	The text of the report has been amended.
21	The test equipment overview should include identification of connectivity, patient and operator identification and reagent traceability in the descriptors.	Connectivity and data storage functionality on devices are included in Appendix A (technical features of the device). If connectivity is present, it is assumed that this detail can be recorded in the electronic health record (EHR) of the patient.
22	Reagent storage and traceability statements "Correct reagent storage conditions are critical. A system for documenting lot numbers, expiry dates and monitoring of same to prevent outdated stock are required – Pg24. Additionally the ability to vertically trace/ link lot numbers to patient tests is required. The equipment should be capable of providing for reagent lot number storage traceability".	Vertical integration is acknowledged in the first paragraph on page 24. This refers to scanning or uploading batch/lot numbers and linking to EHR. The SOPs and systems of governance that should be incorporated at a practice level for POCT to ensure that the tests are used in accordance with best practice are also highlighted in the description of technology and organisation chapters. Connectivity and data storage functionality on devices are included in Appendix A (technical features of the device). If connectivity is present, it is assumed that this detail can be recorded in the patient's EHR.
23	It is likely some form of documented refrigeration monitoring would be required. This may already be in place in some sites however, provision does not appear in the costings where it may be required.	Documented refrigerator monitoring is standard practice in primary care (for example, for vaccines). This was not considered relevant for inclusion in the economic evaluation.
24	"Basic training" As outlined previously there is a significant level of risk for non scientific staff performing testing and training needs to be comprehensive and include ongoing competency assessment structures. Any training should be governed by Point of Care/ Scientific staff and not reliant/ supplied solely by commercial interests. It would be necessary to ensure that commercial interests have adequate suitably trained and experienced personnel to provide training to the level required. Later in the document operators were noted to improve performance with practice and participation in EQA programmes – pg. 151; pg.159; pg160	The intention is to emphasise that a certain minimum level of training would be required. The word "basic" has been removed. All other concerns raised are addressed in the organisation chapter. We included a statement that "It would be appropriate for the POCT national steering committee to make recommendations on the potential role for medical scientists, as community POCT teams, in delivering the training programme and governance structures for CRP POCT in primary care".

25	"Support from laboratories may be needed" For all POCT testing the laboratory remains the reference point and methodology. Laboratory/ dedicated Point of Care Specialist support and governance are essential to any service.	It would be essential for a CRP POCT roll-out that dedicated laboratory medical scientists would provide support and governance. At implementation stage, the POCT national steering committee would be able to make specific recommendations on the potential governance role for medical scientists as community POCT teams, which may require input from the chief medical scientists in hospitals. This has been acknowledged on page 17 of the report (as detailed in the response to comment 24).
26	A complete section should be added concerning quality service provision as is currently envisaged in several European countries (Scandinavia, Wales, France etc.) where all testing at POCT will be specified to ISO 22870. The use of the year should be removed for both standards as there are newer versions (15189:2012; 22870:2016). This could include reference to participation in EQA e.g. pg. 160 "adequate levels of precision and accuracy maintained over time". Reference is made to best practice initiatives in Wales on pg 224. Also Section 9.3 Pg. 229 – 235.	Points raised are covered in the organisation chapter as acknowledged in the comment. The HTA report was reviewed and edited for consistency in the reference years for ISO standards.
27	Section 4.6 (key messages) does not include reference to the commentary within the section on studies describing older adult versus younger adults and the absence of studies from long term facilities or out of hours attendances.	A relevant key point has been added to the end of chapter 4 and also highlighted in the advice section.
28	Section 5.3: studies using data where laboratory staff performed the testing should not be used. All references suggest that where laboratory staff perform testing on a POCT device the performance is consistent with the manufacturer's data or acceptable percentage coefficient of variation (CV) is obtained (pg150). However, the reality as outlined previously is that the testing performance by non scientific test staff may be less quality assured and in some cases sub optimal. While not always the case, with proper governance, training and ongoing competency assessment, improvements in performance were demonstrated as noted previously.	While the first review documents the realised impact of CRP POCT on antibiotic prescribing, the second review is concerned with the distinct question of the ability of the test to distinguish between viral and bacterial infections. For this question the level of proficiency of the staff is less relevant. The review answers the question of "can it work?" The third review examines the analytical performance of the test and addresses the association between proficiency and training of staff and test performance.
29	Additionally many studies in Table 5.2 (10/15) used standard laboratory measurement. Perhaps include a reference to Section 6.3.1 where this is stated.	Table 5.2 refers to studies examining diagnostic test accuracy, while section 6.3.1 refers to studies that evaluated analytical performance. The former is important to determine whether CRP

		levels can be used to support prescribing decisions (given that it measures a surrogate biomarker). The latter is important to determine whether the POCT devices can accurately and precisely measure CRP levels.
30	"Diagnostic test accuracy may vary between patient subgroups" this should have the following added "and testing methodologies and equipment" as various methodologies and equipment were used.	The report text has been amended.
31	In Table 5.6: SD – Is this one standard deviation or the number of patients ??	SD refers to standard deviation. The list of abbreviations under the table has been amended to clarify this point.
32	It is unclear if the equipment provision is in the cost per test or additional as shown in Table 8.9.	The table title has been amended to reflect that it is the unit cost per test carried out.
33	Section 8: Costs do not appear to include the performance and purchase or IQC material. This may need to be performed daily.	Internal quality assurance (IQA) is considered an important aspect of ensuring that a POCT device will return accurate and reliable results. We have added text to the end of the discussion section in chapter 8 to elaborate on the opportunity costs associated with IQA.
34	Section 8: There is no cost provision for repeat testing or failed tests. Without connectivity it would be impossible to track/ audit this	This is addresed by including a test failure rate of 6% (page 183). There are univariate sensitivity analyses carried out for CRP and CRP + comms in figures 8.9 and 8.10 (using 0.06 to 0.09).
35	Section 8: No costing has been included for governance of the proposed service. It would be necessary for Laboratories to have additional specialist resources to liaise with GP practices for training and other ongoing quality issues and supervision either nationally or within the group setting. The absence of connectivity would seriously hamper remote monitoring of any POCT service performance.	Costs are included for an IQA/CRP training scheme (Table 8.18), but not for this level of governance from medical scientists in the suggested structure of community POCT teams with a supervisory role for chief medical scientists for POCT in hospital. It will be acknowledged in the caveats in the report that this level of governance and support will require additional funding. Real-world evidence of costs can be gathered via pilot implementation.
36	Currently there is no system of governance for any POCT testing that may be performed in a GP practice or out of hours clinic. Additionally there is no system of inspection to audit any testing that is ongoing and there is little to no participation in existing EQA programmes.	These deficits are acknowledged in the organisation chapter with potential suggestions offered for consideration.

37	Healthcare assistants may indeed be commencing performance of POCT testing pg. 221. However is there documented evidence of training and ongoing competency assessment and has the training within the relevant courses had some laboratory scientific staff oversight and includes limitations of POCT equipment ??	The training and EQA options for the users of CRP POCT are outlined in the organisation chapter.
38	POCT INR services provided in the community must have laboratory reference points and specialist governance. A generalised reference to this practice incorrectly suggests some form of quality service and ongoing governance; however, without careful supervision by scientific staff there is significant patient risk. The recently identified global calibration error for Roche INR strips attests to this. This error was identified by the WEQAS EQA programme, reported to HPRA and required HPRA intervention, reversion to laboratory INR testing in certain circumstances and patient strip replacement. There are other ongoing firmware issues in relation to patient self testing meters for INR	The example of the global calibration error with CoaguChek® XS PT Test Strips manufactured by Roche Diagnostics and the need for batch recall and re-examination of test results emphasises the importance of test tracability. This emphasises the importance of an EQA scheme with an essential requirement for the involvement of hospital laboratory staff in the user training, quality management and governance of an national CRP POCT programme. The report has been amended to ensure that the importance of EQA is clearly stated.
39	Pg 223-4. The availability of connectivity is not solely a requirement for accreditation, but rather more importantly allows monitoring of testing performance, operators, activity, follow up and governance, which will otherwise be untraceable.	This was clarified in further detail as suggested on page 226.
40	POCT connectivity would be essential to this programme for the reasons outlined previously. It is likely that POCT Middleware will not be an “aspiration” but rather central to proving quality assured services.	Text has been added describing this as the "ideal approach" for a national POCT governance programme to maximise governance and tracability for patient test results.
41	Section 9.3 page 253 (stakeholders): The wording “governance” should be included as quality assured testing goes well beyond protocols, training and IQC. This section might include the development of community POCT specialist teams.	This section reports on quality assurance and details the training and supervision of end users, regular quality control and proficiency testing by participating in an EQA scheme as key to providing reliable results for CRP POCT in routine care. Governance of a CRP POCT is now addressed in sections 10.5.2 and the executive summary. See points 42 and 43.
42	Section 10.5.2: There is an opportunity to reiterate that only a quality assured / governed service will achieve the desired outcomes.	Text has been added in the discussion chapter to reiterate that only a quality-assured and appropriately governed CRP POCT service will achieve the desired outcomes.
43	Section 11.8: Again there is an opportunity to refer to a quality assured and governed service.	Text has been added in the executive summary to reiterate that only a

		quality-assured and appropriately governed CRP POCT service will achieve the desired outcomes.
44	It would be useful to include the wording "experts in Point of Care Testing" as part of list of people contributing to this document as Paudy O' Gorman is the Chief Medical Scientist in Point of Care at the Mater Hospital, seconded to the MEDLIS project for POCT connectivity and I chair the ACSLM POCT Advisory Body. We both are members of the National POCT Steering Group.	Nominating body or representative group has been recorded for both EAG members.
45	There is interchangeable reference to Laboratory Technicians and Biomedical Scientists within the document. I understand this may be a direct reference to the relevant papers as different job descriptors are used within Europe. Within Ireland the correct term is Medical Scientist.	We double-checked the use of terms. Our understanding is that the terms were appropriately used in a context and country-specific manner.
46	National educational campaign would be required to educate patients with regards to the service and their expectations from the service, e.g clinical response times.	We have referred to the need for a national educational campaign to educate patients regarding the service and their expectations from the service in the organisation chapter of the report.
47	Funding would need to be in place for GP Practices which should include equipment, consumables, calibration and repairs and patient education equipment.	We have referred to the funding of CRP POCT in primary care in the organisation chapter of the report.
48	Staff training would be vital to ensure quality assurance. Currently there are no Professional Development Co-ordinators in 4 regions nationally to roll out training and no educational resources in place for Practice Nurses, so this would need to be addressed.	The importance of staff training for quality assurance has been addressed in section 9.1.2. Although the educational resources for practice nurses falls outside the scope of the HTA, a sentence has been included to highlight any potential regional variation in training and educational resources for practice nurses.
49	There is the potential to have the patient flow in the GP practice hindered, however it is recognised that Practice Nurses are adapt at managing individual caseloads whilst also supporting the GP so it is perceived that this would be at a minimum.	We have referred to the potential impact of CRP POCT on patient care and healthcare practitioner workflow in primary care in section 9.1.1 of the organisation chapter.
50	There are concerns amongst Practice Nurses that the POC testing would be used for other clinical manifestations than Respiratory conditions. Controls would need to be in place to ensure that the POC testing is not inappropriately implemented or results evaluated.	We have referred to the potential for indication drift following the introduction of CRP POCT in primary care in the organisation chapter. There is the potential for such drift to be partly controlled through clinical guidelines. This has been emphasised in the executive summary and the key

		points informing the advice to the Minister for Health and to the HSE.
51	Interpretation of results must also be the primary responsibility of the GP.	Figure 9.1 illustrates a possible treatment pathway for the use of CRP POCT. If the test is undertaken by the practice nurse, it may involve the patient having the initial consult with the doctor followed by the POCT with the nurse, and a subsequent reconsult with the GP to review the test results, a prescription (if necessary) and communication around the test result. It is acknowledged that for registered nurse prescribers, this latter step could be simplified with the prescription (if necessary) and communication around the test results delivered by the nurse.

5. Changes to the report from the consultation process

Based on the feedback received from the consultation, a number of edits were made to clarify or reword text in the report. A new section was added to the economic analysis (section 8.3.5) that provides a scenario analysis in relation to providing a reimbursement fee to GPs carrying out CRP point-of-care tests.

In addition to the changes made above, a plain English summary has been added to the final report. Every attempt has been made in the plain English summary, the Executive Summary and the Advice to the Minister to provide clarity on issues identified as part of the consultation that were commonly misinterpreted.

6. Conclusions

We received extensive feedback from a diverse range of organisations. As a result, we have updated various sections of the report to include additional information or to clarify certain aspects of the evaluation. This document will also serve as a useful companion report to the HTA of CRP POCT to guide antibiotic prescribing for acute RTIs in primary care, as it clarifies issues that were identified in the public consultation.

We received many suggestions and queries regarding the operational issues that will need to be addressed during the planning and implementation phase of introducing a CRP POCT programme. While some of these details are outside the scope of the assessment, many elements were already discussed in the organisation chapter of the report. Where possible, they are provided here for the benefit of those involved in any future work in this area.

We would like to thank all those who made submissions as part of the consultation process and express our gratitude for their contribution to ensuring that this assessment benefited from the views of people from all backgrounds and experiences.

7. References

1. Little P, Stuart B, Francis N, Douglas E, Tonkin-Crine S, Anthierens S, et al. Antibiotic Prescribing for Acute Respiratory Tract Infections 12 Months After Communication and CRP Training: A Randomized Trial. Annals of family medicine. 2019;17(2):125-32.

Appendix 1: The public consultation feedback form

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health technology assessment on C-reactive protein point-of-care testing to guide antibiotic prescribing for acute respiratory tract infections in primary care settings

For public consultation

Consultation Feedback Form

Your feedback is very important to us. We welcome responses to all questions as well as any additional comments you would like to make.

When commenting on a specific section of a document, it would help if you can identify which element you are commenting on and the relevant page number.

The closing date for consultation is 5pm on Friday, 15 March 2019.

You may email or post a completed form to us. You may also complete and submit your feedback online at www.hiqa.ie.

About you

Name	
Address	
Contact details	
Date	

Page 1 of 5

General Information and Questions

You may provide us with feedback on the specific questions (see questions that follow), or alternatively you may provide us with general comments.

Part 1

Are you replying in a personal capacity or on behalf of an institution or organisation?

☐ Personal capacity

☐ On behalf of an institution

☐ On behalf of an organisation

Part 2

Please outline any general or specific feedback on the documents. In your response, where applicable, please specify the section to which you are referring.

Question 1
The report contains scientific evidence regarding the epidemiology of acute respiratory tract infections, clinical effectiveness, safety and cost-effectiveness of C-reactive protein point-of-care testing. Do you have any suggested alterations or additions to the scientific evidence included in the report?

Please comment

Question 2
The report includes contextual information that supports our understanding of the applicability of the scientific evidence to the Irish setting, and the organisational challenges that might arise. Do you have any suggested alterations or additions to the contextual information included in the report?

Please comment

Question 3
The combination of the scientific evidence and contextual information underpins our interpretation of the data. Do you have any suggested alterations or additions to the interpretation of the evidence included in the report?

Please comment

Question 4
If you had any issues with the clarity or presentation of the report, can you identify the sections that caused difficulties?

Please comment

Question 5
Do you have any general comments you would like to make about this document?

Please comment

Thank you for taking the time to give us your views.

After the closing date, we will assess all feedback and use it to finalise our documents. The final documents and the Statement of Outcomes (a summary of the responses) will be published on http://www.hiqa.ie.

If you wish to do so, you can request that your name and/or organisation be kept confidential and excluded from the published summary of responses. Please note that we may use your details to contact you about your responses. We do not intend to send responses to each individual respondent.

Please return your form to us either by email or post:

consultation@hiqa.ie

Health Information and Quality Authority
HTA on C-reactive protein point-of-care testing to guide antibiotic prescribing for acute respiratory tract infections in primary care settings
George's Court
George's Lane
Dublin 7

If you have any questions you can contact the consultation team by calling (01) 814 7463.

Please return your form to us either by email or post before 5pm on Friday, 15 March 2019.

Please note that the Authority is subject to the Freedom of Information Acts and the statutory Code of Practice regarding FOI.

For that reason, it would be helpful if you could explain to us if you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

Appendix 2: List of organisations that made submissions

The Academy of Clinical Science and Laboratory Medicine (ACSLM)

Irish Medical Organisation (IMO)

Irish Practice Nurses Association (IPNA)

Roche Diagnostics Ltd

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