ABHI

IBMS ROUNDTABLE DISCUSSION ON NICE GUIDANCE NG237

SUSPECTED ACUTE RESPIRATORY INFECTION IN OVER 16S: ASSESSMENT AT FIRST PRESENTATION AND INITITAL MANAGEMENT

Introduction

With antimicrobial resistance on the rise and common infections increasingly resulting in serious conditions like sepsis, there is an urgent need to take an integrated health and care approach to ARI. To achieve its objectives of becoming a global leader in infection management, the UK's approach requires improved and innovative surveillance, prevention, screening, diagnosis and treatment.

NICE Guidance NG237 aims to support healthcare practitioners in making sure that people's treatment for ARI follows the best care pathway. It sits alongside wider NHS deployment of virtual wards and the use of point of care in broader healthcare settings. As such, the guidance provides advice for remote assessments, for instance, the need to carry out these approaches in a person-centred way and to continue to refer individuals for face-to-face assessments if suspected of suffering from a serious illness. It also contains suggestions for in-person contact, where, for example, it is recommended not to offer rapid POC microbiological or flu tests to people with suspected ARI.

However, there are also limitations to the existing NG237 guidance and how it might be applied into the NHS. Led by IBMS Past President, Debra Padgett, a roundtable event took place on 22nd January 2024, inviting experts in healthcare, industry and professional bodies to discuss their thoughts on the new ARI guidance.

Roundtable discussions have led to five key recommendations for NICE on how to support the better management of ARI, aligned to the NHS's 20-year vision for achieving leadership in antimicrobial resistance. Attendees considered several factors, including remote assessment challenges, clinical decision-making, emerging pathogens, and health economic impacts. The views expressed represent the consensus developed during the roundtable.

Background

NICE Guidance NG237, covers assessment of people aged 16 and over with symptoms and signs of acute respiratory infection (bacterial or viral) at first remote or in-person contact with NHS services. It also covers the initial management of any infections. It aims to support healthcare practitioners in making sure that people's treatment follows the best care pathway. It forms part of a suite of work on virtual wards being undertaken by NICE.

NICE's suggestions for remote assessments:

- That these are approached in a holistic, person-centred way, including checking that the person is able to use any digital technology being suggested and offering alternatives, when necessary.
- The committee noted that while remote assessments can be a useful tool for identifying people without serious illness, an individual should be referred for a face-to-face assessment if a serious illness is suspected (e.g. pneumonia), they have a comorbidity, or it is not always possible to carry out a remote assessment due to difficulties communicating or because the presentation of symptoms and signs is unclear.
- Antimicrobials are not to be prescribed routinely, unless the person knows when and how to seek further medical help and there is a sound reason to prescribe remotely.
- Any decision regarding the urgency of a face-to-face assessment, and where to refer (when appropriate), should be based on severity of symptoms and rate of deterioration.

NICE's suggestions for in-person contact:

- Clinical assessment should be used to make a diagnosis and decide whether to prescribe antimicrobials, either immediately or with a back-up prescription, together with self-care advice.
- Rapid point-of-care microbiological tests or influenza (flu) tests should not be offered to people with suspected ARI to determine whether to prescribe antimicrobials.
- A point-of-care C-reactive protein (CRP) test should be considered to support clinical decision making if, after clinical assessment, it is unclear antibiotics are needed.
- If pneumonia is suspected, and a clinical diagnosis has been made, a risk assessment should be carried out using the CRB65 scoring system
- In November 2023, the guidance was amended to clarify that the threshold for treatment or referral for further assessment may be lower for people with an acute respiratory infection who are more likely to have a poor outcome, for example, people with comorbidities or multimorbidity and people who are frail.

The committee was concerned that most of the evidence considered older people, and that data for other groups (particularly those with protected characteristics) was not available. They also noted an absence of evidence about ARI during pregnancy and the post-partum period. They ensured that the specifications for the recommendations for research covered these gaps in the current evidence base.

The committee was disappointed with the overall amount and quality of evidence, which meant that they were unable to make recommendations that gave clear answers about what action a healthcare practitioner should take in a specific clinical situation.

The committee considered people who had an ARI but did not have pneumonia, for example, people with influenza (flu) or a common cold. They agreed that even though many ARIs are self-limiting, some people, such as those with comorbidities or multimorbidity and people who are frail, are more likely to have a poor outcome. Because of this, the thresholds for treatment or referral might need to be lowered.

The evidence for flu testing showed that some tests were reliable at identifying people with and without flu; however, the committee did not recommend them because the decision to prescribe antivirals for flu-like illness was based mainly on seasonal advice from the UK Health Security Agency (UKHSA). They noted that flu tests could be useful for surveillance and for infection control, but that was outside the remit of this guideline.

Point-of-care microbiological tests

The evidence showed that point-of-care (POC) microbiological tests for people with suspected ARIs were not accurate enough to determine whether an infection was bacterial or viral. The economic evidence for POC single pathogen tests was sparse and demonstrated no cost effectiveness and there was no evidence for POC multi-pathogen tests.

As such, the guidance does not recommend that rapid point-of-care microbiological tests or influenza (flu) tests are offered to people with suspected ARI to determine whether to prescribe antimicrobials. Testing may be indicated for surveillance or infection control.

The committee wanted clearer data about the accuracy of POC microbiological tests to be able to give more specific advice in future, so they made a recommendation for research on point-of-care microbiological tests. In the meantime, they agreed that clinical assessment was more reliable than POC tests for making a diagnosis and determining whether antimicrobials are needed.

The committee agreed that the current evidence base for C-reactive protein (CRP) testing is limited and there are limitations of the tests, e.g. a sample taken early in the course of infection can be falsely reassuring, CRP response is unreliable for certain groups of people, for example, the very elderly, or during pregnancy and the post-partum period, who might not have typical CRP responses.

The committee emphasised that prescribing decisions should never be made on the basis of CRP testing alone. Bearing all of this in mind, they agreed that CRP testing could support clinical decision making if, after clinical assessment, a lower respiratory tract infection was suspected but it was unclear if antibiotics were needed.

The evidence showed that using a CRP test result of 100 mg/L or more as the threshold for giving antibiotics means that most people who test positive will have an infection. However, it also means that some infections may be missed. As the threshold gets lower, the chances of infections being missed reduces. However, the number of people who test positive but do not have an infection, increases. The committee agreed that a higher threshold was better in terms of antimicrobial stewardship.

The committee was concerned that antimicrobial resistance could not easily be factored into economic evaluations of ARI interventions and they made a recommendation for research on costing antimicrobial stewardship to address this.

Five Key Recommendations to Improve NICE Guidance NG237 for Better Management of ARI

1. Take account of a wider body of evidence for managing ARI with POCT

Roundtable attendees identified a need for NG237 to take account of a wider body of evidence for ARI and point-of-care testing (POCT), including real world experience and case studies, especially in the areas noted in the guidance such as elderly and pre/post-natal care.

It is vital that both NICE and NHS England provide exact references to the evidence they think is missing so that practice can be better guided. Due to a lack of clarity, it is difficult to solidify, on a national level, what is needed to collate all the different pilots and studies across England.

The guidance should explain what evidence NHS England must look at, so that we can achieve national health objectives of keeping patients in lower acuity settings unless absolutely necessary to hospitalise.

Working alongside IBMS, ABHI and key stakeholders, real world clinical evidence alongside technical sensitivity and specificity can be provided to support progression towards delivery of POCT for ARI.

2. Outline laboratory involvement in the pathway design

POCT is increasingly being used in a range of settings where laboratory medicine needs to have an input. Some of these areas fall outside the traditional remit of the laboratory, such as community diagnostic centres and virtual wards, but no less require input from laboratory professionals to provide safe care.

It is therefore critical to outline how appropriate stakeholders have been engaged in the review of NG237.

Furthermore, the guidance must indicate the strategies that are in place to coordinate with local laboratories for diagnostic testing, to ensure timely results and communication between healthcare providers and patients.

There is also a need to assess the integration of diagnostic test results with electronic health records managed in virtual wards. What are the challenges or successes that have been observed?

Roundtable attendees agreed that there is a need to show how diagnostics can support staff to follow the correct pathway, helping to guide those working in ward environments to develop the required level of clinical expertise for reliable tests.

When considering and introducing a point of care service, there is a requirement to understand the needs and demands of the workforce ensuring that it is in place and resourced appropriately with correct training and support to undertake all elements of the service. The wider laboratory workforce, experts in delivering high quality diagnostic services, do not need to be the operators of diagnostic testing, but must always be involved in the selection, monitoring and audit of diagnostic services. Their experience of training and education should also be utilised to ensure that those operating acquire all the knowledge, skills and competencies needed to ensure a safe service is provided at all times. Training and competence of the workforce is essential, as is the commitment to ensure training is supported alongside restricting access to only those with current competency and in-date training. As such, the guidance must be more prescriptive regarding training. It must go further to outline who will deliver this training, and who will record that tests are carried out appropriately.

3. Set out the parameters to measure health economic impact

Economic modelling was not undertaken to support the development of this guidance. There is an opportunity to set out the parameters which would impart benefits for patients and which could be measured, through a practical approach, to judge health economic impact of providing POCT diagnostics for ARI for a population cohort, particularly on vulnerable or disadvantaged groups as outlined above. This might also prompt initiatives to strengthen the existing evidence base, oversight and governance provisions, as well as highlighting funding requirements to implement POCT successfully. There is also the possibility to quantify benefit to the patient across the system as a whole.

Speaking to the intersection of virtual wards versus mainstream healthcare provision, it was highlighted that we are still very much in a hybrid model, with virtual wards not utilised to their fullest extent. There is therefore an opportunity to understand and scope the technologies that need to be deployed to support a fully-fledged virtual ward service. Calling upon real-world evidence is crucial in this context.

Real world evidence could help to identify the extent to which at-home testing can suit virtual wards for the management of respiratory infections, and the considerations that should be taken into account for accurate and reliable results.

Furthermore, roundtable attendees probed the feasibility of IBMS, as the professional body for laboratory medicine, and ABHI as the leading industry association for health technology, could support strategic research development for POCT and targeted diagnostics in ARI.

4. Provide clarity on deployment.

While the guidance provides useful advice on POCT, it doesn't categorise the situations in which a test might be used, as these should be addressed differently.

There is a need for a clear-use case for the type of tests and technologies, the performance of the technology and the applicability of the test type in the proposed clinical setting. Further work is needed to define acceptable target technical performance (TTP) characteristics for each setting that POCT is to be used to support the selection and deployment of all equipment at the point of need.

It is acceptable for the performance of testing technology to vary dependent upon the setting and the clinical question or purpose it is being used.

Whether this is at home, in surgical practices, etc, the guidance must clearly outline what is being targeted.

- Testing to treat **-** Testing to diagnose or support a clinical pathway. Diagnostic standard, with high reproducibility and precision. Laboratory standard, able to be used for diagnosis, true rule in or rule out, e.g. main laboratory tests and tests with high sensitivity and specificity to the diagnostic question.
- Testing to care **-** Testing to support a care pathway or intervention. Able to provide clear clinical guidance in terms of cut off, or low false negative performance. e.g. LFT / Rapid testing in COVID, or antimicrobial resistance (AMR) stewardship.
- Testing to monitor **-** Testing used in the home by a patient to monitor their long-term condition.
- Testing to protect and testing to control **–** Public health interventions, screening, and surveillance.

NICE also need to make room for nuances in point-of-care testing, so that staff are better informed about how to apply the guidance to their own setting.

ARI is a very wide and diverse area, requiring a wide range of clinical and pathological tests, so the document could better explain the approach with respect to clinical and pathology testing. Seasonal variations must also be considered with respiratory infections, to provide better clarity for clinicians and to allow for virtual wards to adapt quickly to new or emerging pathogens, considering seasonal variation as a key factor.

5. Link to existing POCT guidance document

The accuracy of POC microbial tests is always improving. However, the real concern lies with how the tests are being used, and if a user is carrying out a test correctly. There is a patient safety imperative that quality standards and good governance are maintained in this complex area of diagnostics, especially as it moves into new and novel domains, with more complex oversight models needing to be developed.

There are worries around introducing POCT to clinical environments, where training in areas like false positives and false negatives would be vital for ARI. Experience dictates that high performing POCT services are enabled by allowing for the services to be covered by the existing laboratory quality management system, providing for regular audit, monitoring, provision of training and quality assurance by the most appropriate healthcare experts, in addition to technical and procurement support.

As such, there is a need for governance and digital structures, to ensure the quality and appropriateness of testing. This can be achieved in the guidance by linking to the existing Professional Body POCT document drawn together by the IBMS, ALM and RCPath (Point of Care Testing: National Strategic Guidance for at Point of Need Testing - Institute of Biomedical Science (ibms.org)), which outlines device sourcing, governance, management and assurance and should be considered in parallel with all of the above recommendations.

IBMS RECOMMENDATIONS FOR NICE GUIDANCE NG237: A SUMMARY

1. Take account of a wider body of evidence for managing ARI with POCT

There is a need for NG237 to take account of a wider body of evidence for ARI and point-of-care testing (POCT), including real world experience and case studies.

2. Outline laboratory involvement in the pathway design

The guidance must include strategies that are in place for coordinating with local laboratories for diagnostic testing, and assess the integration of diagnostic test results with electronic health records in virtual wards. NG237 must show how diagnostics can support staff to follow the correct pathway.

3. Set out the parameters to measure health economic impact

NG237 should set out the parameters that would impart benefits for patients and that could be measured to judge the health economic impact of providing POCT diagnostics for ARI.

4. Provide clarity on deployment

There is a need for the guidance to categorise the situations in which POCT might be used, by demonstrating a clear-use case for the types of tests and technologies, the performance of the technology, and the applicability of the test type in varied clinical settings.

5. Link to existing POCT guidance document

By linking to the existing POCT document, drawn together by the IBMS, ALM and RCPath, the guidance could help to ensure the appropriateness and quality of testing.

Roundtable Attendees

Attendee Name	Job title	Organisation
Debra Padgett (Chair)	Past President	Institute of Biomedical Science
Nishan Sunthares	Managing Director, Diagnostics	ABHI
David Wells	CEO	Institute of Biomedical Science
Jayne Bailey	Senior Director Government Affairs & Market Access EMEA	Cepheid
Shabana Malik	Director of Access UK&I	bioMérieux
Steve Lee	Director of Diagnostics Regulation	ABHI
Jennifer Collins	IBMS NE Region,	Institute of Biomedical Science
Robyn Wilson	Point of Care Deputy Manager POCT-for-Scot Joint Director	NHS Tayside
Michael Palmer	Laboratory Manager, National Mycology Reference Laboratory Chair of IBMS Medical Microbiology Specialist Advisory Panel.	UK Health Security Agency IBMS
Joy Allen	Health Economics Manager	Roche Diagnostics, UK & Ireland.
Ian Cocking	Pathology Service Manager	Leeds Teaching Hospitals NHS Trust

Observers

Lynda Rigby, Executive Head of Marketing and Membership, IBMS

Ayesha Pindoria, Communications Officer, IBMS

References

Point of Care Testing: National Strategic Guidance for at Point of Need Testing - Institute of Biomedical Science (ibms.org),