Technoleg Iechyd Cymru
Health Technology Wales

## HEALTH TECHNOLOGY WALES (HTW) GUIDANCE 020 (September 2020)

# Rapid antigen detection tests for group A streptococcal infections to treat people with a sore throat in the community pharmacy setting

**HTW Guidance:**

The use of rapid antigen detection tests (RADT) within the community pharmacy setting for the diagnosis and management of people with group A streptococcal infections is promising. Nonetheless, the current evidence is limited and does not support routine adoption.

Uncertainties remain about the clinical and cost effectiveness of the use RADT in all clinical settings. Some promising evidence has been collected on the use of RADTs in community pharmacies in Wales as part of a pilot of the NHS Wales Sore Throat Test and Treat Service but more definitive studies are required. HTW would support the accumulation of this new evidence in the setting of NHS Wales.

Further research is recommended to demonstrate the clinical effectiveness of RADT in the community pharmacy setting.

## Why did Health Technology Wales (HTW) appraise this topic?

Most cases of sore throat resolve without the need for antibiotic treatment, but a minority of cases are caused by bacterial infections (most commonly group A streptococcal infections) that may benefit from antibiotics. Rapid antigen detection tests (RADTs) are point-of-care tests that have been postulated for use in primary care to help diagnose cases of sore throat caused by group A streptococcal infections and guide antibiotic prescribing decisions.

The topic proposer requested that HTW assess the use of this test specifically in the community pharmacy setting since, if clinically and cost effective, the use of RADTs in this way may alleviate pressure on General Practices and improve the stewardship of appropriate antibiotic prescribing. This topic was submitted to Health Technology Wales by Andrew Evans, Chief Pharmaceutical Officer, Welsh Government.

***The status of HTW guidance is that NHS Wales should adopt this guidance or justify why it has not been followed. HTW will evaluate the impact of its guidance.***

## Evidence Summary

HTW identified and summarised evidence for the following question: in people who present with a sore throat, what is the clinical and cost effectiveness of rapid antigen detection tests for diagnosing and managing suspected group A streptococcal infection in the community pharmacy setting?

No studies were found on the use of RADT in the community pharmacy setting compared with other clinical settings. A recent pilot in Wales introduced RADT in sore throat consultations with antibiotic supply across 56 community pharmacies[1]. Patients presenting with sore throat were assessed using clinical risk scoring and, if indicated, were offered RADT in the pharmacy. Patients with a positive RADT were offered antibiotics. Of the 1,239 patients who underwent RADT, 350 (28.2%) tested positive. Of all patients presenting with sore throat, 19.7% (n = 340) received antibiotics.

No studies were identified which reported on the diagnostic accuracy of RADT undertaken in the community pharmacy setting, using microbiological culture as a reference standard. A review conducted as part of a previous NICE guideline (NICE DG38) assessed and reported the evidence base for the diagnostic performance of RADT in other care settings[2]. The sensitivity of RADT ranged from 68% to 100% and the specificity ranged from 73% to 100%. The Welsh pilot utilised the RADT manufactured by OSOM, which has been shown to have a sensitivity of 94% and specificity of 95%.

Two relevant studies were identified in the review of the economic evidence[3,4]. Both studies were only partially applicable as they considered healthcare systems in other countries. One of the studies was a cost-utility analysis of various diagnostic strategies for the diagnosis of group A Streptococcus pharyngitis. The analysis found pharmacist-use of RADTs to be cost-effective in comparison to other strategies. The other study was a cost-minimisation analysis which found point-of-care strep throat testing in a pharmacy setting to be cost saving in comparison to usual care in a family physician's office, walk-in clinic or an emergency room.

HTW developed a cost-utility analyses based on methodology used in an economic analysis conducted as part of NICE DG38. The analysis was adapted to reflect the use of RADTs as part of an assessment in the community pharmacy setting, based on the assumption that RADT accuracy in community pharmacy would be equivalent to the accuracy of RADT in other clinical settings. The pharmacist test-and-treat service using RADT was found to be more effective and less costly than standard GP assessment. This result was driven primarily by the lower cost associated with an assessment at pharmacy in comparison to a GP assessment as well as a reduction in antibiotic prescription.

The result was found to be insensitive to changes, with the conclusion of the analysis remaining unchanged in all modelled scenarios. In probabilistic sensitivity analysis, the pharmacist test-and-treat service using RADT was found to have a 100% probability of being cost effective at a threshold of £20,000 per quality-adjusted life-year (QALY).

The appropriate mechanism for patient engagement was determined and the patient perspective was considered where possible.

For more detail on the evidence supporting this Guidance, see Evidence Appraisal Report 020 (EAR020).

## Appraisal Panel considerations

- Appraisal Panel were advised by the experts that group A streptococcal infections are currently diagnosed and managed through GP assessment using clinical risk scoring tools. A community pharmacy service using clinical risk scoring tools followed by a RADT, if indicated, provides an alternative approach to diagnosis and treatment.
- The panel heard from patient and public involvement (PPI) representatives about the views and experiences of people who have used the pharmacy test and treat service as part of the Welsh pilot. The majority agreed that using the service was more convenient than getting a GP appointment and would recommend the service to others. Furthermore, users felt that their knowledge about their condition had improved through using the service. However, some obstacles were noted such as the lack of availability of pharmacists or lack of proximity to a community pharmacy
- The clinical experts advised the Appraisal Panel that RADTs have the potential, if accurate, to reduce inappropriate antibiotic prescribing since only those patients that meet the clinical risk scoring threshold would be offered a RADT. Data from the recent pilot study in Wales showed that RADT was not clinically indicated in 28% of patients presenting to community pharmacies based on clinical risk scoring and that antibiotics were only supplied to 20% of patients with a sore throat.
- The clinical experts informed the Panel that all seven health boards in Wales have expressed interest in implementing a pharmacy-based 'test and treat service' such as the one that was used in the recent pilot project. Support for wider implementation has been agreed in principle and the Appraisal Panel considered that this provides a valuable opportunity to accumulate further 'real world' evidence about the use of such a service in NHS Wales..
- The clinical experts advised the Panel that the pilot study had not shown an increase in diagnostic seeking behaviour. They also stressed that this is an integrated service encompassing clinical scoring, testing and patient education. A key part of the service is taking the opportunity to inform patients about respiratory infections and the need for appropriate antibiotic usage and to explain to them the rationale for management decisions with the provision of reassurance when appropriate.
- Clinical experts highlighted that the pharmacy test and treat service is consistent with a broader policy objective of facilitating appropriate skill mix substitution. Specifically, this service provides an opportunity to move the management of a common and minor ailment from GPs to community pharmacies and from primary to community care.
- Clinical experts highlighted the potential for improved antimicrobial stewardship with the use of RADT in addition to clinical assessment if the testing is clinically effective.
- The experts were asked about differential and evolving clinical practice in primary and community care settings and one of the experts highlighted the results of a recent survey, which indicated that GPs preferred not to use throat swabs for bacterial diagnosis in patients with sore throats while pharmacists do. The Appraisal Panel learnt about the evolving place of point of care tests (POCTs) in primary care with the intention that POCT machines will be distributed more widely in GP surgeries this winter.
- The Appraisal Panel concluded that while the use of RADT in a community pharmacy-based care pathway has considerable promise, there is limited evidence demonstrating the clinical effectiveness, safety and diagnostic accuracy of RADTs in this setting.
- The Appraisal Panel considered the health economic evidence, most notably the new cost-utility analysis developed by HTW. The Panel concluded that while the results of the analysis highlight potential economic benefits from using RADT in community pharmacies, key uncertainties remain about clinical effectiveness, which limit the applicability of the conclusions.

- The Appraisal Panel considered the requirement for quality assurance of point of care tests. Members suggested that the service has the potential to increase the strain on health board quality assurance groups and that the cost of quality assurance needs to be considered in any assessments of cost effectiveness.
- The Appraisal Panel also considered the potential training costs that would be required to establish a wider pharmacy-based 'test and treat' service and noted that these will also needed to be considered in future economic analyses.
- Overall, the Panel concluded that the use of RADTs in the community pharmacy setting shows promise but that the current evidence is limited and does not support routine adoption. The Panel recommends that further research be undertaken to explore the clinical and cost effectiveness of the use of RADTs in a pharmacy setting for the diagnosis of streptococcal sore throat.
- The Panel noted that there is support in NHS Wales to continue the rollout of the pilot service and recommends that the opportunity be taken to acquire 'real world' clinical data from this project to contribute address uncertainties around the diagnostic accuracy and clinical effectiveness of RADT in the community pharmacy setting. Furthermore, it is proposed that this could be incentivised by developing managed access arrangements in Wales that require test manufacturers to collect evidence that is needed to demonstrate acceptable diagnostic accuracy and clinical effectiveness. This evidence will be essential for the future consideration by HTW of the potential value of RADT in this clinical context.

## Responsibilities for consideration of this Guidance

Health Technology Wales (HTW) was established by Ministerial recommendation[5,6] to support a strategic, national approach to the identification, appraisal and adoption of non-medicine health technologies into health and care settings. The HTW Appraisal Panel comprises senior representation from all Welsh boards with delegated authority to produce guidance 'from NHS Wales, for NHS Wales'. The status of HTW guidance is 'adopt or justify'. There is an expectation from Welsh Government that HTW guidance is implemented with adoption regularly audited by HTW.[7]

The guidance in this document is intended to assist Welsh care system decision makers to make evidence-informed decisions when determining the place of health technologies and thereby improve the quality of care services.

The content of this HTW guidance was based upon the evidence and factors available at the time of publication. An international evidence base was reviewed and external topic experts and HTW committee members consulted to contextualise available evidence to Wales. Readers are asked to consider the generalisability of the evidence reviewed to NHS Wales and that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. It is acknowledged that evidence constitutes only one of the sources needed for decision making and planning.

This guidance does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

No part of this guidance may be used without the whole of the guidance being quoted in full. This guidance represents the view of HTW at the date noted. HTW guidance is not routinely updated. It may, however, be considered for review if requested by stakeholders, based upon

the availability of new published evidence which is likely to materially change the guidance given.

Standard operating procedures outlining HTWs evidence review methods and framework for producing its guidance are available from the HTW website.

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Declarations of interest were sought from all reviewers. All contributions from reviewers were considered by HTWs Assessment Group. However, reviewers had no role in authorship or editorial control and the views expressed are those of Health Technology Wales.

Chair, Health Technology Wales Appraisal Panel

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