Understanding how a non-National Institute for Health and Care Excellence technology appraisal drug is added to the hospital drug formulary

A. Al-Belbeisi1,2, R. Lim2, J. Fullerton1,3

1 Pharmacy Department, Oxford University Hospitals NHS Foundation Trust, UK, 2 Reading School of Pharmacy, University of Reading, Reading, UK, 3 Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, UK

Introduction: In England, only medications listed in a hospital formulary can be used to treat patients in a National Health Service (NHS) hospital. Medications approved by the National Institute for Health and Care Excellence (NICE) via technology appraisal (TA) are included in hospital formularies. Non-NICE TA medications need to be reviewed by the hospital’s drug and therapeutics committee (DTC) for inclusion in the hospital formulary. Research shows that different DTCs make contrary decisions concerning the same non-NICE TA drug request for inclusion in the hospital formulary, contributing to postcode prescribing and inequality in medication access. To understand how and why different DTCs make different decisions, it is vital to understand how a non-NICE TA drug is added to a hospital formulary.

Aim: To identify the process and variations when adding a non-NICE TA drug to a hospital formulary.

Methods: As part of a larger study, the DTC of a tertiary centre where this research was based developed and sent a questionnaire exploring DTC processes to Chief Pharmacists (via Microsoft Forms) of ten large tertiary centres in England. After completing the questionnaire, a semi-structured interview was conducted with each Chief Pharmacist to clarify ambiguity in the questionnaire responses. Only data regarding how a non-NICE TA is added to the hospital formulary was used in this study. A hierarchical task analysis (HTA) was developed; data were analysed using inductive thematic analysis to identify subgoals, tasks and subtasks required to add a non-NICE TA drug to the hospital formulary. The HTA was developed iteratively.

Results: A total of ten Chief Pharmacists (100% of those approached) completed both the questionnaire and interview. Adding a non-NICE TA drug starts with the applicant requesting and completing an application package, followed by obtaining approval to submit the application package for review. Once approval is granted, the application package goes through three review levels: initial, preliminary, and final review. The non-NICE TA drug is added to the formulary once the application package is clinically and financially approved. This process involves over 100 tasks and subtasks. The process described varied from one centre to another with the following main variations:

1. application package components,
2. how the application package is submitted for approval,
3. the depth of review the application package receives, and
4. how the final review is conducted.

Conclusion: Adding a non-NICE TA drug to a hospital formulary is complex and varied across each centre, indicating a lack of national standardisation in the process. The variations identified could contribute to health inequalities as all patients may not have equal access to the same medications. Therefore, further research is required to study the impact of these variations on patient access to medication via the NHS. Currently, there are no studies in the literature that described the process of adding a non-NICE TA drug to the hospital formulary across the tertiary centres in England. The study only included tertiary centres in England and there should be caution when considering the transferability of the findings to other types of hospitals.

References
