Title **HTA Molecular Diagnostics in Belgium**

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Aim

To evaluate the transient solution whereby molecular diagnostics were introduced into the Belgian healthcare system based on funding of 18 Centers for Molecular Diagnosis (CMDs). To develop a framework to evaluate and introduce new molecular tests.

Conclusions and results

The CMDs introduced 94 molecular tests, while the yearly CMD health insurance budget remained fixed at 6.5 million Euros. Over the years, the volume of tests for microbiology (117 139 tests in 2004) and hemato-oncology (29 611 tests in 2004) has increased. Using new real-time polymerase chain reaction (PCR) technology, the cost per test decreased to an average of 33 Euros for a PCR test performed in duplicate. Most of the tests are performed using in-house PCR methods ("home-brew"), and most of these methods have not been validated. Standardization of the tests and evaluation of their clinical or diagnostic efficacy are not well documented. Non-CMD hospitals express the need for more efficient communication and a faster turn-around time for specific tests. In contrast to Europe, molecular testing kits in the US must undergo pre-market evaluation, and GMP standards are also required for components of in-house tests. The proposed model for test evaluation was applied to several molecular tests: detection, quantification in genotyping of HCV-RNA (of clinical use and cost effectiveness); PCR enterovirus in meningitis (technical accuracy insufficient); PCR t(14;18) in follicular lymphoma (at diagnosis, diagnostic performance of FISH is superior versus PCR); PCR Factor V Leiden (clinical impact has not been demonstrated unequivocally).

Recommendations

A model to evaluate (novel) molecular tests is being proposed. The model consists of a 6-point scale to judge the diagnostic efficacy of a test and several conditions to arrive at test effectiveness under routine conditions. These include appropriate requesting of tests, test quality (compulsory ISO accreditation and participation in external quality assessment programs for all tests is recommended), and service requirements (maximum turn-around time and standardized reporting). Health authorities should build the necessary expertise to evaluate individual tests. Where needed, appropriate studies to evaluate diagnostic efficacy should be financed. Microbiology tests with proven clinical utility and a large volume can be reimbursed as other laboratory tests. Rare microbiology tests are best performed at one or a few reference centers for reasons of expertise and quality. Molecular tests in hemato-oncology are best performed in laboratories that also perform the cytogenetic testing since there is a need for stepwise testing and integrated interpretation of these complex tests.

Methods

Test characteristics were documented using CMD financial reports, activity reports, reports of CMD quality assurance rounds, CMD standard operating procedures and questionnaires completed by the CMDs. Documentation on kits was received from the manufacturers. Interviews were conducted with requesting physicians in non-CMD hospitals. Databases were searched for HTAs and systematic reviews. A pilot assessment was conducted for selected tests.

Further research/reviews required

A systematic review or HTA was identified for only a small fraction of molecular tests, which limits evidence based decision making.

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