

Executive summary

A review of near patient testing in primary care

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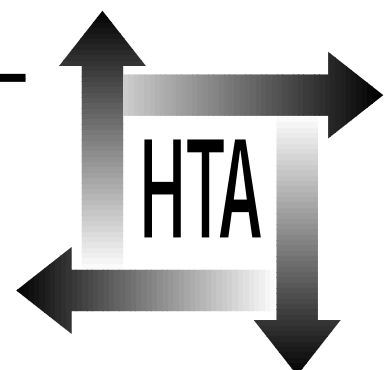
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Health Technology Assessment
NHS R&D HTA Programme





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Aims and objectives

The aim was to identify publications relating to near patient testing (NPT), the use of alternative delivery systems between laboratory and general practice, including electronic data interchange (EDI), and computerised diagnostic decision support (CDDS), in the primary care setting to answer the following questions.

- What is the availability of NPT for primary care?
- What evidence is available to support the clinical effectiveness of NPT?
- What evidence is available on the accuracy and reliability of NPT within primary care?
- What evidence is available on the cost-effectiveness of different NPTs?
- How may CDDS improve the effectiveness of NPT?
- What evidence is available that compares NPT and existing laboratory services?
- What evidence is available on the cost-effectiveness of EDI or alternative delivery systems?

How the research was conducted

Eight databases were searched, and the bibliographies from relevant publications checked for completeness. Unpublished work and publications not included in the databases were obtained by personal contact with collaborators, and from a postal survey sent to heads of academic departments of general practice and clinical chemistry and to researchers active or interested in the field worldwide. Questionnaires were also sent to 150 commercial organisations.

Publications that met agreed definitions and reported original data were included in the systematic review. Of the 1057 publications identified, 102 (92 related to NPT, eight to CDDS, and two to EDI) were passed to the reviewers for appraisal of validity.

The limited amount of published research relating to any particular NPT prohibited meta-analysis. Scoring systems to assess the validity of evaluations were also difficult to apply.

Research findings

A wide variety of NPT systems have been developed. In general, the quality of the methods reported in

the literature was poor. The issue of patient convenience and acceptability has not been adequately addressed.

No evaluations of alternative delivery systems met the review criteria.

No studies have evaluated the telephone or fax machine as a means of reporting results. For EDI, the majority of papers were descriptive.

EDI and alternative delivery systems are not a replacement for NPT when the provision of an immediate result might have an impact on the quality of care. EDI may have clinical and cost advantages over traditional means of communication, but this has not been evaluated.

The advisory role of the laboratory can be supported by CDDS. The use of CDDS and NPT has not, however, been fully evaluated.

Few economic analyses have been conducted, and most were simple cost analyses. There are insufficient data for conclusions to be drawn on the cost-effectiveness of NPT in primary care.

Recommendations

Further systematic reviews

Subject-specific systematic reviews are required that include laboratory and secondary care studies, and consider the potential for altering current management and patient acceptability.

Priority topics include:

- biochemistry profiles on desktop analysers
- cholesterol testing
- urinalysis for the diagnosis of urinary tract infection
- anticoagulation control
- NPTs for the identification of acute infection.

Assessment of NPT and EDI

A research programme to assess NPT in primary care would be appropriate:

- Phase one – initial reliability and safety
- Phase two trials – in selected populations (These could result from partnerships between

the research community, technology manufacturers and licensing authorities.)

- Phase three trials in unselected populations and cost-effectiveness and impact studies.

None of the EDI programmes currently being used in the NHS has been rigorously evaluated. Controlled trials against existing practice should be undertaken.

Guidelines for the evaluation of NPT

Evaluations should be preceded by an assessment of clinical practice to determine the need for and required performance of each diagnostic test in each particular clinical situation. Where the impact of a test is uncertain, or little is known about potential management strategies, the evaluation will need to begin by using qualitative methods and the collection of audit data to define the clinical problem itself. The problem, and the potential role of the test, should be structured in the form of a decision tree and utility assessments should be undertaken, together with some preliminary cost analyses to define the range of clinically-useful performance characteristics.

Once this information is available, studies can be designed to evaluate the performance of an NPT in the primary care setting (see full report for details of methodological issues).

Proposed research priorities

(Note: A modelling exercise to demonstrate the potential for health gain should be considered before embarking on a full-scale evaluation.)

Further primary research, if the quantitative systematic review indicates that knowledge is incomplete. Likely topics are those identified above for further systematic reviews.

Primary research into NPTs or EDI where promising evidence exists but where there is insufficient material to justify a further quantitative review. For example:

- screening for iron deficiency in the child development clinic
- NPT for the exclusion of deep venous thrombosis
- NPT for HbA_{1c} in the practice diabetic clinic
- NPT for microalbuminuria in the practice diabetic clinic
- home monitoring of blood glucose by patients in tight control of diabetes
- NPT for cardiac muscle damage in the diagnosis of acute chest pain

- comparison of EDI for routine results with current practice
- comparison of CDDS with EDI and specialist advice.

The evaluation of newly-developed NPTs for which there is little evidence of their effectiveness.

Modelling/scoping exercises to assess the potential for NPT or EDI to provide clinical benefit to patients.

Conclusions

There is little evidence to support the general introduction of NPT in general practice in preference to existing laboratory services, other than as part of a rigorous, controlled evaluation.

There may be specific clinical areas where NPT may provide additional value to patients, particularly in the areas of early diagnosis, screening, and monitoring of chronic disease. The provision of additional diagnostic information during a consultation may enable primary care physicians to improve the quality and accuracy of their diagnoses, with potential benefit to patients. Such selective introduction of NPT should only take place after evaluation.

Even if there is a substantial increase in NPT in primary care, the laboratory service will continue to provide its existing service, and may need to expand its role in support of quality control and training of practice staff. Although unevaluated, one potential means of introducing NPT into primary care is through laboratory outreach.

Specific practice protocols that give details of the clinical indications for testing, staff training and the necessary quality control procedures may be required to support the introduction of NPT.

There is evidence to suggest that desktop multi-analysers for the analysis of 'routine' samples, and urine multi-test strips for confirming the diagnosis of urinary tract infection in the presence of dysuria, are of limited value in general practice.

EDI may present advantages over traditional means of communication, but its introduction should be subject to evaluation.

Publication

Hobbs FDR, Delaney BC, Fitzmaurice DA, Wilson S, Hyde CJ, Thorpe GH, *et al.* A review of near patient testing in primary care. *Health Technol Assessment* 1997; 1(5).

NHS R&D HTA Programme

The overall aim of the NHS R&D Health Technology Assessment (HTA) programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health.

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