Telemedicine in dermatology: a randomised controlled trial

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Executive summary

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Executive summary

Introduction

The wider availability of broadband telecommunications and the implementation of the NHS-wide network will allow healthcare providers and commercial organisations to offer a range of telemedicine services to GPs as a way of obtaining a specialist opinion.

At the start of this study, there had been few rigorous studies of the cost-effectiveness of these approaches, most published papers being descriptive. There are many feasibility studies, often in inaccessible settings: for the military, in rural areas, in nursing homes or developing countries. Others were technical or methodological studies, with only one cost-minimisation study, in the field of radiology. Reviews have also been published, indicating promise, but with little evidence.

The use of real-time teleconference technology in healthcare has developed most rapidly in non-clinical use (e.g. administrative and educational activities), orthopaedics/emergency/disaster medicine, dermatology and psychiatry. These technologies appear to have potential in dermatology, where a visual examination of the skin is often the key part of the consultant's physical examination. However, clinicians are concerned that a purely visual examination may not always be adequate (e.g. for potentially malignant lesions and some rashes), and this will be one important aspect of the evaluation. The clinical effectiveness and cost-effectiveness of these services remain largely untested. Their potential impact is considerable, not simply on the use of technology, but mainly through the consequences for the use of staff time and the impact upon clinical practice.

This study aimed to conduct a rigorous scientific comparison of two competing approaches, which the study team believed would have different profiles of cost and benefit, with the current 'gold standard' – the outpatient consultation. It was important that such a comparison was undertaken before there is widespread implementation of these technologies.

There are two possible telemedicine applications that might be considered as potential substitutes for the conventional referral of a new dermatological patient by a GP for a consultant opinion.

The first of these approaches is variously called asynchronous or 'store-and-forward' (SF), where text and digital images are prepared by the referrer and forwarded electronically to the consultant, who considers these at his/her convenience (i.e. asynchronously), and returns a diagnostic and management opinion by a similar mechanism. This approach had been the subject of descriptive studies, and appeared feasible. However, there remained concerns that the inability of the specialist to take a direct history from the patient, palpate lesions or communicate the purposes of management to the patient and referrer may lead to suboptimal care. More positively, however, this approach showed the greatest potential to reduce patient waiting (by reducing the professional time needed and allowing consultants to offer opinions on more patients), costs and inconvenience. If this technology were tested for clinical equivalence and cost reduction, considerable gains might be realised if these aspirations were confirmed.

The second approach was the use of high-quality videoconferencing, in a synchronous manner, comprising a real-time teleconsultation between patient, consultant and, importantly, GP. This technology appeared, *a priori*, to have fewer clinical drawbacks, as a three-way discussion could be held, although it still precludes the palpation of lesions by the specialist. The greatest concern with this technology was cost, not simply the cost of the equipment and telecommunications, but the frequently ignored cost of clinical time, as such teleconsultations appeared significantly slower than routine, new outpatient consultations, and because GPs would be present during the consultation. Although the unit costs of a service can vary greatly with volume, synchronous communication is likely to be the most costly alternative. However, it also had potential for some less tangible benefits, such as the greater transfer of knowledge from consultant to GP,

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factors which are more difficult to evaluate. Any technology that increases service accessibility, in itself a potential benefit, may run the risk of supply-induced demand.

In 1997, as the main SF component of this study was starting, the Department of Health introduced the '2-week wait' initiative for cancer. In principle, this policy sought to ensure that any patient suspected by their GP of having cancer had to be seen by an appropriate specialist within 2-weeks of the initial referral. Although this excluded basal cell carcinomas, other dermatological malignancies were covered. As the need for patients to be seen within this relatively (at that time) short period precluded their inclusion in the main study, a complementary study was established to examine the potential of SF telemedicine for this particular service.

Although on-line photographic libraries have been used to train clinicians in the recognition of skin cancers, and SF techniques have been applied to small numbers of suspected cancers, the performance of such approaches is highly dependent upon the nature of the patient population. A previous analysis of 52 audits and databases showed that, up to 2003, only 12% of referrals had subsequently been confirmed to have cancer (although this excluded basal cell carcinomas), and 58% of skin cancers reached hospital by other routes. There was, therefore, a strong case to consider alternative approaches to triage such referrals.

Objectives

The two key objectives of this study were:

- to compare the clinical equivalence, patient and clinician opinion of SF teledermatology with conventional face-to-face consultation in setting a management plan for new, adult outpatient referrals
- to assess the equivalence of digital photography and dermoscopy with conventional face-to-face consultation in the management of suspected cases of malignant melanoma or squamous cell carcinoma.

Design

For the SF teledermatology aspect of the study, a prospective randomised controlled trial (RCT) was carried out.

Setting

Eight general practices and a hospital dermatology department in Sheffield, England.

Participants

For the SF teledermatology part of the study, adults (aged 16 years and over) requiring a new (not seen by a hospital dermatologist within the past year) consultant opinion.

For the digital photography element of the study, adults (aged 16 years and over) requiring a consultant opinion due to suspicion of malignant melanoma or squamous cell carcinoma.

Interventions

Patients in the telemedicine intervention group were referred to the consultant and managed as far as possible using one or more digital still images and a structured, electronic referral and reply. The control group were managed by conventional hospital outpatient consultation.

Patients referred to the 2-week wait clinic were invited to have a series of digital photographs, with and without dermoscopy, immediately before their face-to-face consultation. A second consultant viewed these and outlined a diagnosis and management plan. This was compared with the actual management. Both were compared with the definitive diagnosis (either the final clinical or histological diagnosis), where undertaken.

Main outcome measures

For diagnosis and management, the outcome measure was the concordance between the consultant who had managed the case and an independent consultant who gave a second face-to-face opinion.

Results

Store-and-forward teledermatology

The study failed to achieve the recruitment target of 446 in each group. A total of 208 patients were recruited. There was also a greater loss of control cases (26%) than intervention cases (17%): difference 8% [95% confidence interval (CI): –3 to 19%, $p = 0.18$]. A statistically significant ▶

difference in ages between the two groups completing the study (mean age of intervention group 43.6 years, control group 49.7 years, $p = 0.039$) indicates that this may have introduced a bias between the two groups. A further possible source of bias is the delay (mean difference of 54 days, $p = 0.0001$) between the SF opinion and the second opinion in the SF group, whereas control patients usually received their second opinion on the same day as their outpatient appointment.

In 55% (51/92) of telemedicine cases and 78% (57/73) of control cases, the diagnosis concurred (difference –23%, 95% CI: –36 to –8%; $p = 0.002$), with the second opinion. In 55% (51/92) of telemedicine cases and 84% (61/73) of control cases, the management plan concurred with the second opinion (difference –28%, 95% CI: –40 to –14%; $p = 0.0001$). Of the 92 telemedicine cases, 53 (58%, 95% CI: 47 to 67%) were judged also to require a face-to-face consultation, mainly to establish a diagnosis and treatment plan.

Digital photography

An unexpectedly high proportion (33%, 85/256) of referrals proved to have a malignancy or a severely dysplastic lesion, with almost 22% having a malignant melanoma or squamous cell carcinoma, possibly reflecting the rise in incidence of skin cancers reported elsewhere. When both standard and dermoscopic images were employed, diagnostic concordance was modest (68%). The approach was highly sensitive (98%, 95% CI: 92 to 99%), at the expense of specificity (43%, 95% CI: 36 to 51%). Overall, 30% of cases would not have needed to be seen face-to-face, although two squamous cell carcinomas would have been missed (a number-needed-to-harm of 153). If the highest level of clinician confidence had been applied, no cancers would have been missed, but only 20% of patients would have avoided an outpatient appointment.

Conclusions

Store-and-forward teledermatology

In view of the difficulties in recruitment and the potential biases introduced by selective loss of patients and the delay in obtaining a valid second opinion in the study group, no valid conclusions can be drawn regarding the clinical performance of this model of SF telemedicine.

Digital photography in suspected skin cancer

It is unlikely that this approach can dramatically reduce the need for conventional clinical consultations whilst still maintaining clinical safety.

Research priorities

It should not be a high priority for research funding bodies to undertake similar studies of this approach to teledermatology. The RCT is particularly difficult to conduct in this area, particularly if the results are to retain any wider validity. Further study should be undertaken with more pragmatic study designs (e.g. cluster randomisation or non-RCTs). Descriptive study of past teledermatology projects would be valuable, and systematic comparative data should be collected on any future teledermatology initiatives commissioned by the NHS, possibly as a national audit project. Additional research on the assessment of diagnostic and management agreement between clinicians would be valuable in this and other fields of research.

Publication

Bowns IR, Collins K, Walters SJ, McDonagh AJG. Telemedicine in dermatology: a randomised controlled trial. *Health Technol Assess* 2006;**10**(43).

NHS R&D HTA Programme

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the 'National Knowledge Service' that is being developed to improve the evidence of clinical practice throughout the NHS.

The HTA Programme was set up in 1993. Its role 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 provide care in the NHS. 'Health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care.

The HTA Programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, service-users groups and professional bodies such as Royal Colleges and NHS Trusts.

Research suggestions are carefully considered by panels of independent experts (including service users) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or conducting a trial to produce new evidence where none currently exists.

Additionally, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme is able to commission bespoke reports, principally for NICE, but also for other policy customers, such as a National Clinical Director. TARs bring together evidence on key aspects of the use of specific technologies and usually have to be completed within a short time period.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned by the HTA Programme as project number 96/02/26. The contractual start date was in April 1998. The draft report began editorial review in May 2005 and was accepted for publication in April 2006. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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