Study quality and evidence of benefit in recent assessments of telemedicine

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Summary

We carried out a systematic review of recent telemedicine assessments to identify scientifically credible studies that included comparison with a non-telemedicine alternative and that reported administrative changes, patient outcomes or the results of an economic assessment. From 605 publications identified in the literature search, 44 papers met the selection criteria and were included in the review. Four other publications were identified through references cited in one of the retrieved papers and from a separate project to give a total of 48 papers for consideration, which referred to 42 telemedicine programmes and 46 studies. Some kind of economic analysis was included in 25 (52%) of the papers. In considering the studies, we used a quality appraisal approach that took account of both study design and study performance. For those studies that included an economic analysis, a further quality-scoring approach was applied to indicate how well the economic aspects had been addressed. Twenty-four of the studies were judged to be of high or good quality and 11 of fair to good quality but with some limitations. Seven studies were regarded as having limited validity and a further four as being unacceptable for decision makers. New evidence on the efficacy and effectiveness of telemedicine was given by studies on geriatric care, intensive care and some of those on home care. For a number of other applications, reports of clinical or economic benefits essentially confirmed previous findings. Although further useful clinical and economic outcomes data have been obtained for some telemedicine applications, good-quality studies are still scarce.

Introduction

Information about the benefits and costs of telemedicine is important for decision makers, but there have been few good-quality studies to date[1,2]. In a previous review[3] we considered those studies that had included comparison of a telemedicine application with a non-telemedicine alternative and that had reported administrative, clinical or economic outcomes. Only 66 scientifically credible studies of this sort were identified from searches of electronic databases between 1966 and December 2000. In the work reported here, we have given further attention to the concerns regarding the quality of most telemedicine assessments. It represents an extension of our previous review of studies of telemedicine applications[4]. We have developed a simple approach to the measurement of quality for telemedicine studies that takes into account both study design and study performance. This has been used to assess the quality of recent studies.

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Methods

Literature search

Computerized literature searches were performed using the MEDLINE, Health Star, EMBASE, PsycINFO and CINAHL databases from January 2000 to June 2002, using a similar search strategy to that described previously[3]. The HTA database (managed by the Centre for Reviews and Dissemination) was also checked for relevant studies.

Selection of publications

The abstracts identified by the search were read independently by all the authors. Relevant articles were then selected, based on the information obtained from the abstracts, and agreed in discussion between the authors. Articles were selected which compared, in a scientifically valid manner, outcomes of a telemedicine application in terms of administrative changes, patient outcomes or economic assessment with those of a conventional alternative. Articles that were limited to describing the feasibility or the technical evaluation of a certain system were excluded. When an abstract did not give sufficiently precise information about the study, the corresponding article was obtained for further review. Full-text articles obtained for closer inspection were evaluated independently by the authors, who then reached a consensus on whether they should be included in the final review, using the criteria given above.

Evaluation of study quality

The strength of evidence in selected papers was considered with regard to the study performance and study design. For *study performance*, five areas of interest were considered, as shown in Table 1. When reviewing a telemedicine study, each of these five areas was given a score of 0, 1 or 2: a score of 0 applied when relevant information was missing or was given in little detail; 1 indicated that reasonable detail was provided but there were some important limitations; and a score of 2 was allocated when the information provided had no significant limitations. Each study therefore had a possible maximum score of 10 for performance.

For *study design*, scores were assigned to four types of study. Large randomized controlled trials (RCTs), defined as those with at least 50 subjects in each arm, were given a score of 5. Smaller RCTs had a score of 3, prospective non-randomized studies 2 and retrospective comparative studies 1.

Table 1 Classification of study performance

Areas of interest	Points considered
Patient selection	Methods of randomization/selection; equivalence of intervention and control groups; drop-outs before start of intervention
Description/specification of the interventions	Adequate description for both intervention and control groups
Specification and analysis of study	Sample size; statistical methods used; clear specification of outcome measures
Patient disposal	Length of follow-up; drop-outs; compliance failures
Outcomes reported	Fullness and clarity of reporting; missing results; statistical summary; whether conclusions were consistent with data

Table 2 Quality scores and implications for decision making

Category	Overall quality score[a]	Implications for decision making
A	11.5–15.0	High quality — high degree of confidence in study findings
B	9.5–11.0	Good quality — some uncertainty regarding the study findings
C	7.5–9.0	Fair to good quality — some limitations that should be considered in any implementation of study findings
D	5.5–7.0	Poor to fair quality — substantial limitations in the study; findings should be used cautiously
E	1–5.0	Poor quality — unacceptable uncertainty for study findings

[a]Total of scores for study design and study performance.

Each author independently assigned scores to each study. In any case where the authors disagreed on the study design classification or where individual scores for any performance item differed from each other by more than one, the discrepancies were discussed and resolved by consensus. For each study, the mean of the authors' individual scores is reported to the nearest 0.5.

Implications for decision making

The quality of a study has implications for decision makers' appropriate use of the information from it. We assigned each study to one of five categories, based on the totals of the quality scores for study design and study performance (Table 2). High confidence can be placed in category A studies. On the other hand, those in category E, which had inadequate information for most or all of the study performance areas, and greater selection bias, provide data of unacceptable uncertainty.

Quality of economic evaluation

A further perspective was obtained for those studies that included cost or economic data by judging them against the criteria for economic analysis given by Drummond *et al*.[5]:

(1) Was a well defined question posed in answerable form?
(2) Was a comprehensive description of the competing alternatives given?
(3) Was the effectiveness of the programmes or services established?
(4) Were all the important and relevant costs and consequences for each alternative identified?
(5) Were costs and consequences measured accurately in appropriate physical units?
(6) Were costs and consequences valued credibly?

(7) Were costs and consequences adjusted for different timing?
(8) Was an incremental analysis of costs and consequences of alternatives performed?
(9) Was allowance made for uncertainty in the estimates of costs and consequences?
(10) Did the presentation and discussion of the study results include all issues of concern to users?

For each study, a score of 1 was given for each criterion that was fulfilled in a satisfactory way and, if there were no significant limitations, to provide a summary score from 0 to 10 to indicate how well the economic aspects had been addressed.

Results

Articles retrieved

From 605 publications identified in the literature search, 124 were retrieved for closer inspection. Of these, 44 papers met the selection criteria and were included in the review. Four other publications were identified through references cited in one of the retrieved papers and from a separate project, to give a total of 48 papers for consideration[6–53], which referred to 42 telemedicine programmes and 46 studies (two papers by Chua *et al*.[27,28] and two by Simpson *et al*.[23,24] referred to a single study). Some kind of economic analysis was included in 25 (52%) of the papers.

Study scores and classification

The outcomes and quality scores for the 48 publications are shown in Table 3. Further information on the studies has been presented elsewhere[4]. Thirty-five of the 46 reviewed studies (76%) concluded that telemedicine had advantages over the alternative approach, although a number also drew attention to disadvantages or uncertainties regarding the use of telemedicine. In seven studies it was unclear whether telemedicine had advantages and in four the alternative approach had advantages over telemedicine. For several applications, cost savings or clinical benefit were obtained through avoidance of travel and associated delays. Many of the studies of home care showed convincing evidence of benefit, often through use of telephone-based approaches.

Of the 46 studies, seven were based on large RCTs, 15 were based on small RCTs, seven were prospective, non-randomized trials and 17 were retrospective. The quality scores for all of the studies are given in Table 3. Twenty-four of the studies were judged to be of high or good quality (category A or B) and 11 of fair to good quality but with some limitations (category C). Of the remainder, seven studies might be regarded as having limited validity (category D) and a further four as being unacceptable for decision makers (category E); such studies at best provide an initial indication of potential effects and need follow-up with stronger assessments to provide validation.

Table 4 shows the mean performance scores in relation to study design. The data illustrate that study design is not necessarily a good indication of study quality. The mean performance scores for the large and small RCTs were similar and not substantially larger than those for the non-randomized studies. The low performance scores given to some of the RCTs indicate that relatively low confidence can be placed in their results. The high performance scores for some of the non-randomized studies indicate high quality in their performance and reporting, although confidence in their findings is limited by potential selection bias.

Economic analyses

Twenty-five of the papers included an economic analysis. In all of them this was a cost analysis. There were some high-quality cost-minimization analyses, where the effectiveness of telemedicine was taken to be equal to that of conventional care. Only two studies included health-related quality-of-life measures. The perspective of the economic analyses was mainly that of the health-care provider, although 65% included details of patients' or health-care workers' travelling costs.

Thirteen of these 25 studies met five or more of the criteria given by Drummond *et al*.[5] and were rated as good, or good to fair. Almost all the economic studies defined the research question well. About 60% valued the costs credibly and discussed the study results; 50% identified and valued the costs and effects in a satisfactory way, and 43% measured the effectiveness in an appropriate way. Timing and uncertainty were included in 30% of studies and some kind of incremental analysis interpretation could be made from 13%.

Potential influence on decision making

Judgements made on reviewing the contents of the papers suggested that 19 studies appeared to have a potential to influence future decision making on telemedicine services. A further 21 reported more preliminary results, which may have been helpful to decision makers but which indicated the need for further evaluation. The possible influence of the remaining six studies was unclear. In all cases, any influence on decision making would need to be

Table 3 Indications of outcomes and quality scores

Area of application	Reference	Indications of effect of telemedicine	Performance score	Study design score	Reliability for decision makers	Economic quality score
Hospital and clinic applications						
Cardiology	6	Cost benefits from use in a prison service	7	2	C	4
	7	Effective in providing specialist paediatric advice	6	1	D	1
Dermatology	8	Cost savings, mainly to patients through avoiding travel	8.5	5	A	
	9		9	1	B	8
	10		6.5	2	C	2
	11[a]		6	1	D	5
	12	Teledermatology more costly	9	5	A	10
Geriatric care	13	Decreased hospitalization	4.5	5	B	8
	14	Lower travel costs	3.5	1	E	5
	15	Fewer falls	4	1	E	
	16	Increased case-load by geriatrician	6.5	1	C	4
Hospice care	17	Cost savings	4.5	1	D	3
Hospital referral	18	Increase in health-care productivity, improved cost-effectiveness	8.5	2	B	8
Infectious disease management	19	Reduced morbidity among HIV-positive prison inmates	7.5	1	C	3
Intensive care	20	Use of off-site intensivist gave decreased mortality and costs	8.5	1	B	6
	21	Use of Internet link to neonatal intensive care unit improved family satisfaction	8	3	B	
Mental health	22	Lower or similar costs using telepsychiatry	5.5	1	D	4
	23, 24		7	1	C	7
	25		5.5	1	D	5
	26	Outcomes better in telemedicine group	5.5	2	C	
Neurology	27, 28	Realtime teleneurology less cost-effective than conventional care	6.5	5	A	3
Ophthalmology	11[a]	Cost savings through avoidance of travel	6	1	D	5
	29	Reduction in consults for cataract surgery planning	5	1	D	
Radiology	30	Time savings in intraoperative mammography	5.5	2	C	
	31	Cost savings through avoiding transfer of trauma cases	4	2	D	6
	32	Unclear if transfer of neurosurgery cases improved outcomes	3	5	C	
	33	Improved compliance with practice guidelines	2.5	2	E	
Sleep studies	34	Telemedicine more costly than alternative approach	8.5	3	A	9
Telephone nurse triage	35	Cost savings, encouraged appropriate use of services	8.5	1	B	5
Home-care applications						
Asthma	36	Telephone intervention improved use of inhalers	7.5	3	B	
	37	Reduced utilization of health services	7	3	B	
	38		7	3	B	
Cardiovascular conditions	39	Telephone-based interventions effective for cases of heart failure	8	5	A	3
	40		9.5	5	A	
	41	Benefits unclear for heart failure	5.5	3	C	
	42	Outcomes improved for hypertensives	8	3	B	
	43		8.5	3	A	
	44	Telecardiac rehabilitation as effective as on-site intervention	9.5	2	A	
Diabetes	45	Better glycaemic control	5.5	3	C	
	46		6.5	3	B	
	47		7.5	3	B	
	48	Equal improvement in glycaemic control	7	3	B	
	49	Internet-based approach to self-management feasible but not very effective	9	3	A	
Chronic wound care	50	Improved outcomes and availability of specialist	3.5	1	E	
Obstetrics	51	Improved clinical and economic outcomes in pre-term labour	6.5	1	C	3
Epilepsy	52	Unclear if telemedicine approach to counselling produced different outcomes	7	3	B	
Spinal rehabilitation	53	Telerehabilitation can give long-term clinical and economic benefits	7	3	B	

[a]One study considered both dermatology and ophthalmology.

Table 4 Performance score and type of study design

Study design	No. of studies	Performance score data	
		Mean	Range (SD)
Large RCT	7[a]	7.1	3.0–9.5 (2.5)
Small RCT	15	7.3	5.5–9.0 (1.0)
Prospective	7	6.1	2.5–9.5 (2.4)
Retrospective	17[b]	6.1	3.5–9.0 (1.7)

[a]Using the mean for the two papers of Chua *et al.*[27,28]
[b]Using the mean for the two papers of Simpson *et al.*[23,24]
RCT, randomized controlled trial.

informed by the reliability of the studies, as indicated by their quality scores.

Discussion

For this review, we used a quality scoring system as part of the appraisal process. It was developed because we felt that earlier approaches, which placed most emphasis on study design, did not give enough information for decision makers. Our approach assesses both study performance and design, and provides an indication of study strengths and limitations. We wished to use a method of study quality assessment that could be readily applied in the field of telemedicine. Numerous other quality scales have been developed, but few of these have been directed at both randomized and non-randomized studies, a development that is comparatively recent[54]. The available quality instruments tend to focus on specific types of study design[55].

Our approach to the appraisal of study quality relies on summing values from two scales, one related to performance and the other to study design. The scales are orthogonal, but both assess the quality of the study and generate implications for decision making. Both scales are considered to be ordinal. We assume that each of the five attributes specified in the study performance scale (Table 1) has the same influence on the quality of a study. Study design is also scored using a kind of ordinal scale, which is considered to have interval properties. The scale is valued to reflect increasing confidence in the study results and their relevance for decision making.

Ordinal scale values of dimensions can be summed if they are somehow comparable. Adding scores from the two scales has validity since both types of measure are linked to study quality and reliability, although in different ways. Overall reliability of a study for decision making will depend on both performance and design. Both poor design of studies and lack of rigour in their execution may result in biased estimates of effects[55]. Taking a decision on a study's worth on the basis of these features implies some sort of additive process, be it implicit or explicit. We adopted an explicit approach, which seems to us to have value in specifying the contributions of the different study attributes.

We chose to place greater weight on study performance than on study design (two-thirds and one-third weight, respectively). Both aspects are important, but the scheme we used gives higher scores to well conducted non-randomized studies than to poorly performed (or at least poorly described) RCTs. Our estimates of quality showed that there was considerable variation in performance scores for all study design groups for the reports that we reviewed, which indicates the importance of considering how competently a study has been performed and reported. We found, for example, large RCTs with relatively low performance scores and non-randomized studies with high performance scores.

For study design, there would be general agreement on the order of preference (large RCTs, small RCTs, prospective studies and retrospective studies), although the scores allotted to each type of study design might be debated. For example, we may have been too generous with the value given to very small RCTs. Also, the cut-off of 50 subjects per arm in defining a large RCT is arbitrary. In principle, power calculations might be used to determine the design quality score for an RCT. However, such calculations have not been done in most telemedicine studies and would be difficult to apply routinely. No consideration was given in this work to inclusion of meta-analyses, a point for future consideration should such studies become more common in telemedicine assessment.

A more detailed and rigorous approach to the appraisal of quality of randomized and non-randomized studies, such as that of Downs and Black[54], might be considered but would be less easy to apply (and less likely to be used in practice). We hope both that the approach taken will be helpful to decision makers in telemedicine insofar as it draws attention to the need to consider both study quality and study performance, and that others will be encouraged to apply and refine this method.

The results of our review were consistent with earlier findings that there is still relatively little good-quality information in the literature on the efficacy, effectiveness and cost-effectiveness of telemedicine. About 8% of the articles identified in the literature search reported a controlled comparison of a telemedicine application with a conventional means of providing services. However, a number of the selected papers described further findings from studies that had

been included in the earlier review[3] — comparatively few new telemedicine assessments were identified.

Over half the reviewed studies were judged to be of high or good quality. Also, more than half the economic studies were judged as good, or good to fair, although the scope of economic analysis was limited. The selected studies included several good-quality cost-minimization analyses that provided sound information for decision making. It should be borne in mind, however, that even within this highly selected sample of the telemedicine literature there were a number of studies that were of limited or even unacceptable quality.

Convincing new evidence on the efficacy and effectiveness of telemedicine was given, for example, by studies on geriatric care and some of the studies on home care, such as those on the management of asthma. There were also useful reports on applications in intensive care. In a number of other applications, reports of clinical or economic benefits essentially confirmed previous findings of benefits through avoidance of travel or of patient transfer, rather than breaking new ground. The economic analyses indicated that several telemedicine applications were cost saving, especially if all cost implications were considered. Benefits from telemedicine were not demonstrated in studies on neurological consultations (where the services were feasible but not cost-effective), in sleep studies, or in the home care of persons with epilepsy.

As with our previous review, it was notable that services based on use of the telephone were beneficial in many areas, including nurse triage and telecare for patients with asthma and cardiovascular disorders. In many cases telephone services should be considered as an alternative to conventional care. This simple technology (which has been available for decades) is often cost-effective and in some cases superior to more complex telemedicine approaches.

While there is emerging evidence of the benefits of telemedicine in some new areas of application, in many cases evidence is provided by only a few preliminary studies. Harder evidence of benefit is still confined to a few applications that have been studied in more detail and in several centres. Because the implementation of telemedicine applications varies between sites and especially between countries, there is a need for multiple studies showing the benefits of telemedicine before an application can be recommended. Even then, local conditions should be considered carefully in the implementation of a programme. For example, the introduction of telemedicine may affect both the organization and the health-care process, and this may determine the success of the programme, but these issues were rarely discussed in the articles we reviewed.

Few papers considered the long-term or routine use of telemedicine and there was little in the way of follow-up data on clinical outcomes or the health status of patients. The lack of good-quality outcome measurement and economic studies is a weakness in the field. In a previous review[3] we concluded that 'Useful data are emerging on some telemedicine applications, but good-quality studies are still scarce and the generalizability of most assessment findings is rather limited'. From the results presented here, the picture is still much the same.

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