

Teledermatology for Diagnosis and Management of Skin Conditions: A Systematic Review of the Evidence

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PREFACE

VA's Health Services Research and Development (HSR&D) Service works to improve the cost, quality, and outcomes of healthcare for our nation's veterans. Collaborating with VA leaders, managers, and policy makers, HSR&D focuses on important healthcare topics that are likely to have significant impact on quality improvement efforts. One significant collaborative effort is HSR&D's Evidence-based Synthesis Program (ESP). Through this program, HSR&D provides timely and accurate evidence syntheses on targeted healthcare topics. These products will be disseminated broadly throughout VA and will: inform VA clinical policy, develop clinical practice guidelines, set directions for future research to address gaps in knowledge, identify the evidence to support VA performance measures, and rationalize drug formulary decisions.

HSR&D provides funding for four ESP Centers. Each Center has an active and publicly acknowledged VA affiliation and also serves as an Evidence Based Practice Center (EPC) supported by the Agency for Healthcare Research and Quality (AHRQ). The Centers will each generate three evidence syntheses annually on clinical practice topics of key importance to VHA leadership and policymakers. A planning committee with representation from HSR&D, Patient Care Services (PCS), Quality Enhancement Research Initiative (QUERI), Office of Quality and Performance (OQP), and the VISN Clinical and Quality Management Officers, has been established to identify priority topics and key stakeholder concerns and to ensure the quality of final reports. Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at nicole.floyd@va.gov.

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INTRODUCTION AND BACKGROUND

Telemedicine uses telecommunication technology to transfer medical information. Due to the visual nature of a skin examination, telemedicine, specifically, teledermatology, is a potentially valuable tool in the diagnosis and management of dermatologic diseases for patients in rural areas (including rural Veterans Affairs Medical Centers [VAMCs] and Community Based Outpatient Clinics [CBOCs]) where a dermatologist may not be available. Teledermatology may also be useful in primary care settings to triage cases and limit unnecessary dermatology clinic referrals as well as to assist with follow-up care or monitoring after an in-person dermatology visit. Two particular types of teledermatology are commonly employed. Store and forward (SAF) uses asynchronous still digital image technology for communication, similar to an email system. Participants are typically separated by both time and space. Real-time or live interactive (LI) uses video-conferencing technology. Participants are separated by space, not by time. Both systems have advantages and disadvantages. SAF requires less technological sophistication and lower cost equipment than LI, permits the referring provider to submit the consultation with accompanying image(s) to the dermatologist for review at a later time, and does not require the dermatologist to be immediately available or on-call to urgently review the teleconsult while the patient is in the primary care clinic. In contrast, LI permits a more dynamic assessment of the skin condition and allows the dermatologist to obtain a real-time history from both the patient and the referring provider, to make an immediate initial diagnosis, and to provide a management plan. Owing partly to the technological simplicity of SAF and the fact that SAF allows the dermatologist to review the telemedicine consult either outside of normal clinic hours or bundled into separate time slots within an existing clinic, SAF is the more widely used form of teledermatology in the VA. An informal, unpublished survey of VA dermatology chiefs in December 2009 found that 44% (19/43) of responding VA dermatology services are utilizing teledermatology; 17 VAs are using SAF, one is using LI, and one is using both methodologies.

The diagnostic and management accuracy (match of teledermatology diagnosis or in-person dermatology diagnosis with a gold standard of histopathology or other laboratory test) and concordance (agreement between teledermatology and in-person dermatology) of these technologies, their cost-effectiveness, and their impact on clinical management and patient outcomes (including satisfaction) are not well understood. Although research demonstrating that teledermatology is accurate and cost-effective is essential, it is not sufficient. Lessons learned from mature, functioning teledermatology systems in the United Kingdom and New Zealand include that "initial concerns about the ability to diagnose and manage patients by telemedicine have turned out to be less important that the practical issues of implementation." Incorporating research findings into clinical practice requires identifying and removing structural and process barriers as well as enhancing critical components to success. Based on the work of Rogers² and a systematic review of empirical research studies, Greenhalgh et al. developed a conceptual model for considering the determinants of diffusion, dissemination, and implementation of innovations in health service delivery and organization.³ Greenhalgh et al. concluded that adoption of any health care technology increases to the degree that such technology is perceived as possessing the following qualities in relation to existing practice: relative advantage (the new technology is better than current processes); compatibility (consistency with existing values, behaviors and past experiences); low complexity (easy to understand and use); trialability (can be modified and

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experimented with on a limited basis), and observability (results of the change are visible).³

We conducted an evidence synthesis report to systematically review and summarize the scientific literature addressing: 1) teledermatology for the diagnosis of skin conditions, 2) teledermatology for the management of skin conditions, 3) clinical outcomes when teledermatology is used, 4) the cost of teledermatology compared with usual care (in-person dermatology), and 5) key elements of and barriers to successful implementation of teledermatology. We addressed the following key questions:

- 1a. How does the accuracy of teledermatology compare to usual care (in-person dermatology) for the *diagnosis* of skin conditions?
- 1b. How does the concordance of teledermatology compare to usual care (in-person dermatology) for the *diagnosis* of skin conditions?
- 2a. How does the accuracy of teledermatology compare to usual care (in-person dermatology) for clinical *management* of skin conditions?
- 2b. How does the concordance of teledermatology compare to usual care (in-person dermatology) for clinical *management* of skin conditions?
- 3. How do clinical outcomes (clinical course, satisfaction, quality of life, visits avoided) of teledermatology compare to usual care (in-person dermatology) for skin conditions?
- 4. How does the cost of teledermatology compare to usual care (in-person dermatology)?
- 5. What are the key structural and process elements associated with successful implementation of teledermatology and what are the barriers?

METHODS

TOPIC DEVELOPMENT, TECHNICAL EXPERT PANEL

This topic was nominated by the Center for Chronic Disease Outcomes Research, Minneapolis VA Medical Center in consultation with the VA Evidence Synthesis Program. Robert Dellavalle, MD, PhD; Dennis Oh, MD; and John Whited, MD, MHS agreed to serve on the Technical Expert Panel (TEP) for the project. The TEP and the VA Department of Health Services Research and Development (HSR&D) collaborated with the Minneapolis VA Evidence Synthesis Program (ESP) to identify and refine key questions including populations, interventions, comparisons, outcomes, and settings of relevance.

SEARCH STRATEGY

We searched MEDLINE (OVID) and PubMed for clinical trials, systematic reviews, cost studies, and implementation papers from 1990 to June, 2009 using standard search terms. We chose 1990 as the start date for the search based on consensus from the TEP members that studies prior to 1990 would likely not be relevant to current practice. We limited the search to articles involving human subjects and published in English language. Search terms included: remote consult/ consultation, electronic mail, telecommunications, telemedicine, telepathology, dermatology, and teledermatology. (Appendix A)

STUDY SELECTION

Titles and abstracts identified from the search were reviewed by physicians and research associates trained in the critical analysis of literature to identify peer-reviewed articles likely related to one or more of the key questions.

Specific inclusion criteria were as follows:

- 1. Controlled trial (questions 1 and 2)
- 2. Store and forward (SAF) or live interactive (LI) teledermatology

Specific exclusion criteria included:

- 1. Teledermatology involving mobile phones
- 2. Non-teledermatology settings (e.g., imaging analyses, telemedicine studies other than teledermatology, videomicroscopy studies, basic science, imaging techniques)
- 3. Dermatopathology studies
- 4. Reviews, teledermatology program descriptions, and history of teledermatology (unless

relevant to questions 3, 4 or 5)

- 5. Studies of computer-aided diagnoses only (e.g., pigmented lesions)
- 6. Survey studies addressing outcomes other than those defined in questions 1-5
- 7. Teledermatology as an educational tool for primary care physicians or residents
- 8. Technology assessment only
- 9. Remote monitoring of known diagnoses (e.g., leg ulcers, post-operative wounds)
- 10. Teledermatology involving patient generated photos and/or history (without a referring provider)
- 11. Non-English language
- 12. Case series with no control group (questions 1 and 2 only)
- 13. Commentaries, editorials or meeting abstracts (unless relevant to question 5)
- 14. Studies involving one diagnosis only (e.g., leprosy) or only acne and warts; studies of one category of skin conditions (e.g., pigmented lesions which could have multiple diagnoses) were included
- 15. Duplicate publications; if both preliminary and final reports were published, the final data analysis was utilized
- 16. Pediatric population only (as this would not be relevant to VA population); studies involving both adults and children were included.

For key questions 1 and 2 we included clinical trials of teledermatology with an in-person dermatology control group if they provided information related to diagnostic and management accuracy or concordance. For key question 3, we extracted data related to patient satisfaction and preferences. For key question 4 we obtained articles and evaluated past reviews assessing cost analyses of teledermatology programs with an emphasis on studies applicable to practice in the United States. For key question 5 we conducted a narrative review of identifiable information related to structural and process elements associated with successful implementation of teledermatology as well as barriers to implementation framing the section around the conceptual model developed by Greenhalgh et al.³

DATA ABSTRACTION

Two research associates (YH, NG) extracted data on study design, patient characteristics, lesion type(s), intervention(s), comparison(s), and outcome(s) from each included study for questions 1 to 4 (Appendix B – Data Extraction Form). The principal investigator verified all extracted data for these outcomes and also summarized data on implementation issues (question 5). Our main outcomes were diagnostic and management accuracy and concordance as defined in Table 1.

Table 1. Definitions of Outcomes

Outcome (Statistics Reported)	Definition
ACCURACY	Match of TD (teledermatology) or CD (clinical dermatology) with Gold Standard of Histopathology or other Laboratory Test
Diagnostic Accuracy – CD (% Correct, Kappa statistic, Sensitivity/Specificity)	Match of the CD diagnosis and histopathology/other lab test <u>Aggregated:</u> Match of any of the CD diagnoses (primary or differential diagnoses) with histopathology/lab diagnosis <u>Primary:</u> Match of the primary CD diagnosis with histopathology/lab diagnosis
Diagnostic Accuracy – TD (% Correct, Kappa statistic, Sensitivity/Specificity)	Match of the TD diagnosis and histopathology/ other lab test <u>Aggregated:</u> Match of any of the TD diagnoses (primary or differential diagnoses) with histopathology/lab diagnosis <u>Primary:</u> Match of the primary TD diagnosis with histopathology/lab diagnosis
Management Accuracy – CD (% Correct)	Match of the CD management plan with management based on histopathology/other lab test
Management Accuracy – TD (% Correct)	Match of the TD management plan with management based on histopathology/other lab test
CONCORDANCE	Agreement between TD and CD
Diagnostic Concordance (% Agreement, Kappa statistic)	Agreement between the TD diagnosis and the CD diagnosis Aggregated: Agreement of any of the TD diagnoses (primary or differential diagnoses) with any of the CD diagnoses (primary or differential diagnoses) Primary: Agreement of the primary TD diagnosis with the primary CD diagnosis
Management Concordance (% Agreement, Kappa statistic)	Agreement between the TD management and the CD management

QUALITY ASSESSMENT

We used the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) instrument to assess for study quality for studies pertaining to key questions 1 and 2.4 QUADAS is the first standardized, systematically developed, Delphi derived instrument used to assess methodological quality of studies of diagnostic tests. The QUADAS tool includes 14 questions that assess potential outcome bias. Items are scored as "yes," "no," or "uncertain" and can be grouped under 4 main domains: subject selection, index test, reference test, and data analysis. A summary score is not a recommended final metric of quality though we arbitrarily reported on the number of studies scored with a "yes" on at least 10 of 14 items as well the individual "yes" scores for each of the 4 domains. We believe such reporting can assist the reader in determining potential sources of study bias and encourage future researchers to adhere to these quality measures. Two extractors (EW, YH) independently reviewed all studies for quality. A third investigator (TW) resolved scoring discrepancies through review and discussion.

DATA SYNTHESIS

We reported results from each study separately for each outcome and method of outcome reporting (e.g., percent correct, kappa statistic, sensitivity/specificity, and concordance). Results were stratified according to whether the intervention was SAF or LI. We evaluated studies according to sample size, type of dermatological conditions studied, and whether they enrolled users of, and assessed outcomes in, the VA health care system. Due to considerable heterogeneity in study design, patient and lesion characteristics, and outcome reporting methods results were rarely pooled and instead displayed graphically according to teledermatology technology and sample size. If appropriate, weighted mean differences based on study sample sizes were calculated for the percentage of correct diagnoses for TD and usual care. Most pooled estimates were only possible using data from a subsample of eligible studies; caution is recommended in interpreting these pooled findings.

PEER REVIEW

A draft report was sent to TEP members and peer reviewers identified by VA HSR&D. Reviewer comments and author responses are summarized in Appendix C.

RESULTS

LITERATURE FLOW

The OVID MEDLINE search yielded 559 references with 3 duplicates for a total of 556 unique references. The PubMed search yielded 587 references. When the results from these searches were combined, 486 duplicate references were eliminated resulting in 657 titles and abstracts for review. From the 657 titles and abstracts, 473 references were excluded. The full text of 184 references was then reviewed and another 100 references were excluded. One additional reference (a recent publication) was added resulting in a total of 85 studies included in the report. Figure 1 details the exclusion criteria and the number of references related to each of the key questions.

KEY QUESTION 1

1a. How does the accuracy of teledermatology compare to usual care (in-person dermatology) for the *diagnosis* of skin conditions?

1b. How does the concordance of teledermatology compare to usual care (in-person dermatology) for the *diagnosis* of skin conditions?

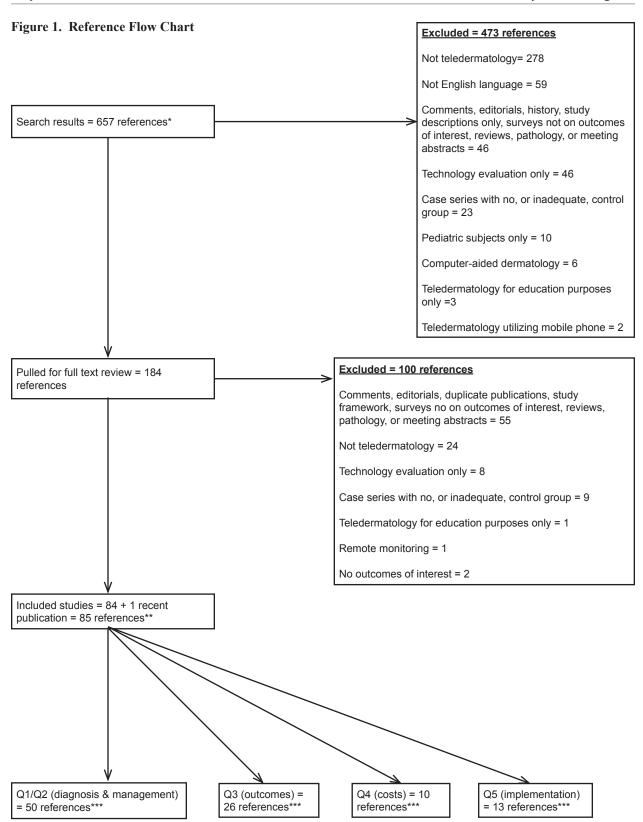
Summary of Studies for Key Questions 1 and 2 (Table 2 and Appendix E)

The study design, population and study characteristics, teledermatology characteristics, outcomes evaluated, and the quality rating for each of the included studies are presented in Appendix E.

Description of store and forward studies

Study design and location

Forty-one unique store and forward studies (reported in 42 publications) enrolling between 12 and 882 subjects met inclusion criteria for Key Questions 1 and $2.^{5,6,7,8,9,10,11,12,13,14.15,16,17,18,19,20,2}$ 1,22,23,24,25,26,27,28,29.30,31,32,33,34,35.36,37,38,39,40,41,42,43,44,45.46 The majority of these studies each evaluated fewer than 200 subjects. All studies utilized a repeated measure study design with the exception of one randomized, controlled trial (RCT). Based on location, most of the studies were conducted in the United States (n = 12), 5,6,7,23,25,26,34,36,38,42,43,44,46 followed by the United Kingdom (n = 9), $^{12,13.16,19,30,31,33,39,45}$ Italy, (n = 6), 8,9,21,22,37,40 Spain (n = 4), 10,11,14,18 Australia/New Zealand (n = 3), 15,32,41 Turkey (n = 2), 17,20 and one study each from Germany, 24 Netherlands, 25 Pakistan, 28 Brazil, 29 and Switzerland. 35



^{*}Search results from OVID MEDLINE (556) and PubMed (587) were combined, removing duplicate entries (486)

^{**}Manuscript reference list includes additional references cited for background and methods plus Web sites relevant to KQ5

^{***}Total \neq 85; many studies addressed more than one key question

Patient and skin condition characteristics

Five studies (six publications) involved U.S. military personnel and/or veterans. ^{5,6,26,27,42,43} The study by Pak also included beneficiaries of U.S. military personnel. ^{26,27} Fewer than half (19/41, 46.3%) of the studies reported mean age; of those reporting, mean age was 53 years (range of means 28 to 71 years). Thirteen studies included subjects less than 18 years of age, in addition to adults. ^{7,9,14,15,17,18,21,22,30,31,36,37,40} In 21 studies reporting gender, most of the subjects were male (57% overall, range 29% to 98%). Only 5 studies, all conducted in the United States, reported racial or ethnic characteristics. ^{5,6,7,26,27,42} The majority of subjects in those 5 studies were Caucasian (93%).

Fourteen studies included patients with a variety of skin conditions including rashes (e.g., papulosquamous, eczematous) as well as circumscribed lesions (isolated skin growths). 7,12,17,20,25,26,27, 28,32,33,36,38,42,45,46 Twenty-two studies evaluated only patients with circumscribed lesions (suspected skin cancer and/or isolated skin growths); of these, twelve studies exclusively evaluated subjects with pigmented skin lesions 5,9,14,18,21,22,24,30,31,35,37,40 and two studies enrolled only subjects with non-pigmented skin lesions. The remaining eight studies only included subjects with circumscribed lesions but did not specify pigmentation status. 10,11,13,15,16,23,34,43 Five studies did not provide details on types of skin conditions included. 19,29,39,41,44

Description of live interactive studies

Study design and location

Ten unique live interactive, repeated measure studies enrolling between 51 and 351 subjects met inclusion criteria for Key Questions 1 and/or 2.^{7,17,47,48,49,50,51,52,43,54} Two of the studies also had a store and forward component.^{7,17} One-half of the studies were conducted in the U.S. (n = 5).^{7,49,51,52,54} Two studies were performed in the United Kingdom,^{48,50} and one study each was completed in Turkey,¹⁷ Norway,⁴⁷ and New Zealand.⁵³

Patient and skin condition characteristics

One live interactive study involved U.S. veterans.⁵¹ For the six studies reporting average age, ^{7,17,47,50,52,54} the mean age (40 years; mean range 35 to 47 years) was younger and less varied compared to the store and forward studies. Seven studies included children or adolescent subjects in addition to adults. ^{7,17,47,48,50,53,54} Three U.S. studies reported racial or ethnic characteristics, ^{7,51,54} overall, the majority of subjects in these three studies were Caucasian (72%), although the study by Lowitt included a significant number of African-American participants (40%). ⁵¹ Nearly all studies reported gender (n=9), with women comprising the majority of subjects (54%; mean range 5 to 84%).

Nine studies included patients with a variety of skin conditions including rashes (e.g., papulosquamous, eczematous) as well as circumscribed lesions (isolated skin growths). 7,17,47,48,49,5 0,51,53,54 One study evaluated only patients with circumscribed lesions (suspected skin cancer and/or isolated skin growths). No live interactive studies focused specifically on either pigmented or non-pigmented lesions.

Quality assessment

Most included studies assessing accuracy and concordance (Key Questions 1 and 2) utilized methods to reduce sources of bias, particularly related to appropriate use of index and reference tests. However, the majority of studies using store and forward technology did not clearly address patient selection biases such as enrolling a representative spectrum of general dermatological patients or clearly describing exclusion criteria. Both store and forward and live interactive studies generally did not account for all patients at the end of the study or include patients with uninterpretable results (**Figures 2 and 3**). Among individual studies, 11 of 41 SAF and 3 of 10 LI publications adequately reported on least 10 of 14 quality assessment items; most lower quality studies failed to adequately describe or enroll a representative spectrum of patients or account for all originally enrolled patients in data analysis.

QUESTION 1a: Diagnostic Accuracy (Table 3, Figures 4a and 4b)

Overall Comparisons: Twenty studies (19 SAF, 1 LI) reported diagnostic accuracy defined as matching of teledermatology diagnosis with histopathology diagnosis or other lab test. Results were reported as percent match between the primary diagnosis and/or aggregated diagnoses (primary plus differential) and histopathology, kappa statistic, and/or sensitivity and specificity. Fifteen studies also reported diagnostic accuracy of usual care (in-person dermatology diagnoses), allowing for direct comparisons of accuracy rates between these two methods of care. Ten of these 15 studies found that diagnostic accuracy for usual care (in-person dermatology visit) was better than teledermatology, 5,6,8,15,24,34,37,38,40,42 3 studies reported better diagnostic accuracy for teledermatology, ^{30,35,51} and 2 reported mixed results. ^{26,27,43} The three studies which reported higher diagnostic accuracy rates for teledermatology were comprised of smaller sample sizes (n=11,⁵¹ n=51,³⁵ n= 138³⁰). In the small pilot study by Lowitt⁵¹ the difference between accuracy rates was the result of one lesion, a difference likely due to chance. In the study by Braun³⁵ involving 55 pigmented skin lesions in 51 patients, diagnoses were compared between six general dermatologists in private practice (usual care) with a dermatoscopic expert at a university pigmented skin lesion clinic (teledermatologist). The better diagnostic accuracy of the teledermatologist in this study was likely due to dermatoscopic expertise; the six general dermatologists had "different levels of experience" whereas the teledermatologist was a dermatoscopic expert. In the larger study by Jolliffe³¹ involving 144 pigmented skin lesions in 138 patients, the same dermatologist who saw the patient in clinic (and likely followed up on biopsy results) served as teledermatologist (several months later), possibly resulting in recall bias.

<u>Pooled Comparisons:</u> Statistical pooling of the six SAF studies reporting aggregated diagnostic accuracy rates found that the weighted mean absolute difference was 19% better for usual care than teledermatology. ^{5,6,26,27,34,42,43} For the 11 SAF studies ^{5,6,15,24,26,27,30,35,37,40,42,43} which reported primary diagnostic accuracy rates, the weighted mean absolute difference was 11% better for usual care than teledermatology. Similarly, the weighted mean absolute difference for primary diagnostic accuracy for six pigmented skin lesion studies was also better (5%) for usual care than teledermatology. ^{5,24,30,35,37,40} A recent unpublished analysis of teledermatology data from 1514 biopsied skin neoplasms found that teledermatology was significantly less accurate for eleven common skin neoplasms including melanoma, squamous cell carcinoma, and basal cell carcinoma.

<u>Value of Teledermatoscopy</u>: Four studies evaluated teledermatology with standard macro images and teledermatoscopy.^{5,6,8,14} In general, teledermatology accuracy rates improved up to 15% (absolute difference) with teledermatoscopy. A recent unpublished analysis found that diagnostic accuracy significantly improved with polarized light teledermatoscopy specifically for squamous cell carcinoma and basal cell carcinoma.⁵⁵

<u>Conclusion:</u> The evidence shows that diagnostic accuracy of usual care (in-person dermatology) is better than teledermatology (aggregated diagnostic accuracy absolute difference 19%; primary diagnostic accuracy absolute difference 5% and 11%). When dermatoscopy-trained teledermatologists are available, teledermatoscopy may be beneficial for isolated skin lesions.

QUESTION 1b: Diagnostic Concordance (Table 4, Figures 5a, 5b, 6a and 6b)

Overall Comparisons: Thirty-seven (27 SAF; 9 LI; 1 SAF+LI) studies reported diagnostic concordance (simple agreement without verification by histopathology or laboratory test) between usual care (in-person dermatology) and teledermatology. Thirty-five studies (25 SAF, 9 LI, 1 SF+LI) reported concordance as percent agreement for exact diagnosis (primary-see figures 5b and 6b, aggregated-see figures 5a and 6a, and/or not specified,^{7,45,46} malignant/benign status, ^{13,29,39} or diagnostic category. Seven studies in six publications reported kappa statistics^{7,11,18,29,52,53} and three studies reported sensitivity and specificity. ^{13,29,39}

Percent Concordance - SAF Lesion Study Results: Aggregated diagnostic agreement was assessed in 4 studies (Table 4, Figure 5a). Two medium-sized studies, both of which evaluated circumscribed skin lesions, found similar aggregated diagnostic concordance rates of 64% (n=109¹5) and 65% (n=163¹6). Two smaller lesion studies found higher aggregated diagnostic concordance rates, 90% (n=50³4) and 95% (n=10⁴³). Weighted average aggregated diagnostic concordance of these four lesion studies was 64.4% (230/358). Primary diagnostic concordance (Table 4, Figure 5b) was assessed in one pigmented lesion study⁴⁰ and five skin lesion studies;¹³,¹5,¹6,³4,⁴³ concordance ranged from 48% to 91%. Weighted average for these six studies was 62.3% (443/708).

Percent Concordance - SAF General Study Results: Nineteen studies involving a range of dermatologic conditions (lesions and rashes) evaluated diagnostic concordance (Table 4, Figures 5a and 5b). Aggregated diagnostic agreement was assessed in ten of these studies and ranged from 60-100%. The three highest rates were from studies in which the same dermatologist served as both clinic dermatologist and teledermatologist and did not appear to be blinded to index results (91%, ^{26,27} 96%, ³² and 100% ⁴¹). Excluding those three studies, the weighted average aggregated diagnostic agreement rate was 65.3% (703/1077). Primary diagnostic agreement was assessed in 14 studies and ranged from 46% to 88%. Excluding the three studies where the same dermatologist served as both clinic dermatologist and teledermatologist (70%, ^{26,27} 88%, ³² and 83% ⁴¹), the weighted average primary diagnostic concordance rate was 66.3% (1227/1851).

<u>Percent Concordance - LI Studies:</u> Six LI studies reported aggregated diagnostic concordance rates ranging from 78 to 99% (Figure 6a); excluding three studies in which the same dermatologist served as both clinic dermatologist and teledermatologist for >50% of cases (78%, 48 82%, 53 82% 50), the weighted average aggregated diagnostic concordance was 86.5% (268/310). Eight LI studies reported primary diagnostic concordance rates ranging from 57-

78% (Figure 6b); excluding three studies in which the same dermatologist served as both clinic dermatologist and teledermatologist (67%, 48 75%, 53 67% 50), the weighted average primary diagnostic concordance rate was 70.5% (258/366).

Kappa, Sensitivity, Specificity

SAF Studies: Kappa values ranged from 0.71 to 0.93 for the four SAF teledermatology studies reporting this statistic.^{7,11,18,29} Excluding the one study with likely bias (same dermatologist served as both clinic dermatologist and teledermatologist, k=0.93¹⁸), kappa values varied by 16 points and values indicated substantial agreement (k=0.71,⁷ k=0.81,¹¹ k=0.87²⁹). Sensitivity and specificity was reported in three studies (utilizing the clinic dermatologist's assessment as the gold standard); all three evaluated only agreement for benign or malignant status, not specific diagnosis. Sensitivity ranged from 0.88 to 1.0 and specificity ranged from 0.39 to 0.98.

LI Studies: Three LI studies reported kappa values of 0.32,⁵² 0.62,⁵³ and 0.79.⁷ The study by Phillips⁵² had the lowest kappa value (k=0.32); this study employed a live interactive system which may not have been able to provide the detail required for the individual skin lesions evaluated. No LI studies evaluated sensitivity or specificity.

<u>LI+SAF Study Results:</u> Only one study evaluated a combination of SAF and LI teledermatology.¹⁷ In that study, primary diagnostic accuracy concordance was 82%, higher than the weighted average concordance rate of SAF studies (66.3%) and LI studies (70.5%).

Conclusion: Based on the data above, the weighted mean aggregated diagnostic concordance rates for SAF teledermatology were similar for lesion studies (64%) and general studies (65%); the rate for LI (87%) was higher, but this was based on significantly fewer patients (approximately 300 vs. >1,000). The weighted mean primary diagnostic concordance for SAF teledermatology was also similar for lesion studies (62%) and general studies (66%); the rate for LI studies was higher (71%) but based on fewer patients. In summary, diagnostic concordance of SAF is good and may be better for LI, possibly due to the ability to obtain additional history in the LI setting.

KEY QUESTION 2

QUESTION 2a. How does the accuracy of teledermatology compare to usual care (inperson dermatology) for clinical *management* of skin conditions? (Table 5)

Only two studies assessed management accuracy (expert panel consensus of management based on histopathologic diagnosis) of usual care and teledermatology.^{5,6} Both were large, utilized SAF teledermatology, were completed at the same VA, enrolled primarily older, Caucasian, men, and involved circumscribed skin lesions. In both studies, overall management was equivalent (defined as a ±10% difference) for usual care and teledermatology (macro images as well as two types of dermatoscopic images). Although the overall management accuracy rates were not significantly different, further unpublished analysis of this data provided by the lead author of this evidence report found that nine melanomas were mismanaged with teledermatology as compared to two with usual care, and management accuracy of usual care was superior to teledermatology (macro images or dermatoscopic images) not only for melanoma but also for

basal cell carcinoma, squamous cell carcinoma, and premalignant actinic keratoses.⁵⁵

<u>Conclusion:</u> While overall rates of management accuracy were equivalent $(\pm 10\%)$, for malignant and premalignant lesions, rates for teledermatology and teledermatoscopy were inferior to usual care; caution is recommended when using teledermatology in these cases. Because only two studies reported management accuracy, these results may be difficult to generalize to other populations and study settings.

QUESTION 2b. How does the concordance of teledermatology compare to usual care (inperson dermatology) for clinical *management* of skin conditions? (Table 6, Figures 7a and 7b)

SAF Studies: Fourteen SAF teledermatology studies reported management concordance (percent agreement n=13, kappa n=3, sensitivity and specificity n=2).^{7,9,10,12,13,15,16,23,26,31,42,43,45,46} Two studies evaluated concordance of the triage management decision of "refer or not refer" for pigmented skin lesions³¹ or skin lesions;¹³ percent concordance was 80%³¹ and 61%¹³ for these two studies yielding a weighted average of 75.3% (809/1075). Three studies (in four publications) evaluated concordance for the diagnostic procedure decision "biopsy or no biopsy" and found concordance rates of 100%²³ and 95%⁴³ for skin lesions (weighted average of 98.5%, 68/69) and 76% for a variety of skin conditions.^{26,27} Several studies did not describe management options but reported percent concordance rates of 55% to 94% (Figure 7a).^{7,12,15,16,45,46} Two studies evaluated concordance rates for three different management options; these rates were 96%⁹ and 72%.⁴²

Three studies reported the following kappa statistics: k=0.69 for three management options for 265 pigmented skin lesions in 18 patients; k=0.75 for planned surgical technique for 134 skin lesions; and k=0.62 for 110 skin conditions. Sensitivity/specificity ranged from 0.69/0.82 (refer or not refer³¹) to 1.0/1.0 (biopsy or no biopsy²³).

<u>LI Studies:</u> Four LI teledermatology studies reported management concordance.^{7,48,52,56} A study of 107 skin lesions in 51 patients found a concordance rate of 86% (k=0.47) for the decision "biopsy or no biopsy."⁵² Three other studies involving a wide variety of skin conditions found concordance rates of 64%, ⁵⁶ 72%, ⁴⁸ and 75%.⁷ No LI studies reported sensitivity/specificity.

<u>Conclusion:</u> Concordance rates for management were moderate to very good for both SAF and LI teledermatology.

Table 2. Summary of Study Characteristics for Teledermatology Studies (KQ1 and KQ2)

	Store and Forward (N=41)			Live Interactive (N=10)	
Characteristic	Mean and/or Range	Number of Studies Reporting	Mean and/or Range	Number of Studies Reporting	
Number of Subjects: Repeated measure studies	12 to 882 (NR in 3)	40	51 to 351	10	
Randomized controlled trials (TD arm only)	92	1	NA	0	
Studies involving US Military Personnel or Veterans: Number of subjects	129 to 728	5	102	1	
Age of Subjects in Years: All studies, weighted mean (mean range)	53 (28 to 71)	19	40 (35 to 47)	6	
Studies with children/adolescents (<18 years of age) in addition to adults	NR	13	NR	7	
Gender: Female: mean % (mean range)	43 (2 to 71)	21	54 (5 to 84)	9	
Race: Caucasian: mean % (mean range)	93 (80 to 99)	5	72 (60 to 85)	3	
Black: mean % (mean range)	5 (12 to 20)	5	27 (12 to 40)	3	
Other: mean % (mean range)	2 (<1 to 5)	5	1 (0 to 3)	3	
Study Location in U.S: Number of subjects per study	12 to 728	12	51 to 131	5	
Skin Condition Characteristics: Rashes and lesions number of subjects per study	23 to 404	14	60 to 351	9	
Lesions only number of subjects per study	12 to 882 (NR in 2)	22	51	1	
Pigmented lesions only number of subjects per study	12 to 611 (NR in 1)	12	NA	0	
Non-pigmented lesions only number of subjects per study	728 (NR in 1)	2	NA	0	
Outcomes Assessed: Diagnostic accuracy number of subjects per study	12 to 728	19	102	1	
Diagnostic concordance number of subjects per study	12 to 882	27	51 to 351	10	
Management accuracy number of subjects per study	542 to 728	2	NA	0	
Management concordance number of subjects per study	12 to 882	14	51 to 351	4	

Figure 2.

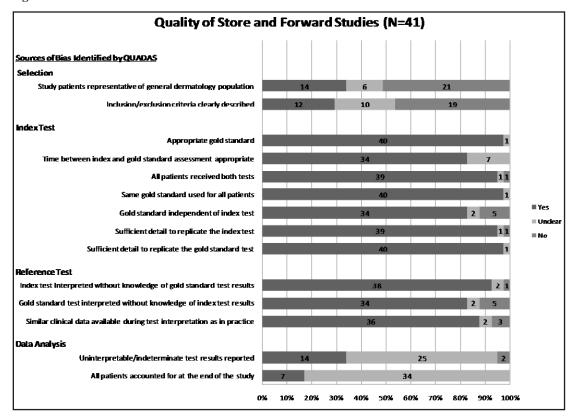


Figure 3.

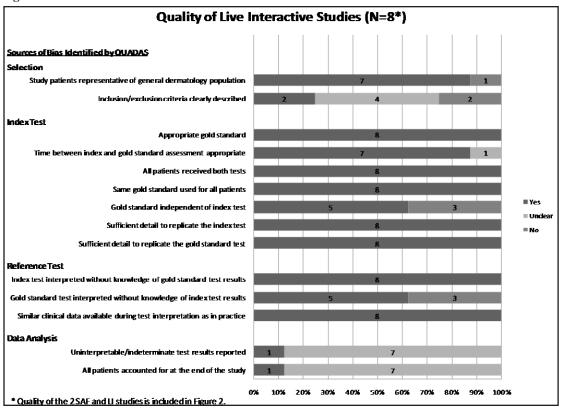


Table 3. Studies Reporting Diagnostic Accuracy using Histopathology/Lab Tests as Gold Standard (KQ1a) (See Appendix D for abbreviations)

Study	Diagnostic Accuracy - Teledermatology % Correct, Kappa, or Sensitiv- ity/Specificity	Diagnostic Accuracy - Usual Care % Correct, Kappa, or Sensitivity/Specificity	Mean Absolute Difference, % Correct
A. Store and forward p	pigmented skin lesion studies (n=10)		
Warshaw 2009 ⁵ VA 542 Pts 542 PSL	Aggregated: 52% (282/542) 65% (352/542) PLD 67% (363/542) CID Primary:	Aggregated: 80% (434/542) Primary:	-28% -9%
	50% (271/542) 47% (255/542) PLD 57% (309/542) CID	59% (320/542)	
Moreno-Ramirez 2006 ¹⁴ 61 Pts No. PSL NR	k=0.91 (95% CI 0.82, 1.00) k=0.94 TDSC (95% CI 0.88, 1.00)	NR	NA
Moreno-Ramirez 2005 ¹⁸ No. Pts NR 57 PSL	k=0.79 (95% CI 0.70, 0.89)	NR	NA
Ferrara 2004 ²¹ 12 Pts 12 PSL	Primary: 83% (10/12) TDSC	NR	NA
Piccolo 2004 ²² 73 Pts 77 PSL	Mean Sensitivity for 11 TDs: 0.91 (SD 0.09) (Range 0.83-1.00) Mean Specificity for 11 TDs: 0.95 (SD 0.04) (Range 0.92-1.00)	NR	NA
Coras 2003 ²⁴ No. Pts NR 45 PSL	Primary: 89% (40/45) TDSC For Malignant vs. Benign: Sensitivity: 0.86 Specificity: 0.92	Primary: 91% (41/45) DSC For Malignant vs. Benign: Sensitivity: 0.86 Specificity 0.96	-2%
Jolliffe 2001 ³⁰ 138 Pts 144 PSL	Primary: 47% (68/144) (95% CI 39%, 55%) TD also served as CD	Primary: 43% (63/144) (95% CI 35%, 51%) TD also served as CD	4%
Braun 2000 ³⁵ 51 Pts 55 PSL	Primary: 75% (41/55) TDSC	Primary: 64% (35/55) DSC	11%
Piccolo 2000 ³⁷ 40 Pts 43 PSL	Primary: 87% avg for 6 derms TDSC (range 81%-95%)	Primary: 91% (39/43) DSC	-4%
Piccolo 1999 ⁴⁰ 66 Pts 66 PSL	Primary 86% (57/66) TDSC	Primary 92% (61/66) DSC	-6%
B. Store and forward s	skin lesion studies (n=6)	1	1
Warshaw 2009 ⁶ VA 728 Pts	Aggregated: 56% (408/728) 65% (473/728) PLD	Aggregated: 76% (553/728)	-20%
728 SL	Primary: 43% (313/728) 47% (342/728) PLD	Primary: 56% (408/728)	-13%

Fabbrocini 20078	k=0.44	k=0.52	
No. Pts NR	k=0.45 CID	k=0.70 CID	NA
44 SL			
Ferrandiz 2007 ¹⁰	Primary: 85% (110/130)		
134 Pts	k=0.86 (95% CI 0.83, 0.89)		
No. SL NR (73% NMSC)		NR	NA
Oakley 2006 ¹⁵	Primary: 71% (34/48)	Primary: 72% (21/29)	-1%
No. of Pts NR	(95% CI 56, 83)	(95% CI 53, 87%)	-1/0
29 SL	38 TDs including 6 residents	5 CDs including 2 plastic	
29 SL	38 TDs including 6 residents		
		surgeons	
Barnard 2000 ³⁴	Aggregated: 73% avg for 8TDs	Aggregated: 84%	-11%
25 "cases"	(range 54%-80%)		
Whited 1998 ⁴³	Aggregated average: 84%	Aggregated: 78% (7/9)	6%
VA	Aggregated (2 TDs):		
9 SL	89% (8/9)		
	78% (7/9)		
	Primary average: 59%	Primary: 67% (6/7)	-8%
	Primary (2 TDs):		
	78% (7/9)		
	22% (2/9)		
C. Store and forward go			
	T	1.600/	100/
Pak 2003 (part II) ²⁶	Aggregated: 78% (No. NR)	Aggregated: 60%	18%
DoD	D: 100/	D : 520/	5.40/
119 Pts	Primary 19%	Primary: 73%	-54%
119 Conditions			
Krupinski 1999 ³⁸	Primary: 76% Avg for 3 TDs	Primary/Aggregated: 89% Avg	-13%
104 Pts		for 3 CDs	
104 Conditions		(Combo 58% Primary; 42%	
		Aggregated)	
Whited 1999 ⁴²	Aggregated average: 77%	Aggregated: 85% (95% CI 77%,	-8%
VA	Aggregated (3 TDs):	93%)	
No. Pts NR	68% (95% CI 58%, 78%)		
79 Conditions	78% (95% CI 69%, 87%)		
	85% (95% CI 77%, 93%)		
	Primary average: 59%	Primary: 59% (95% CI 48%,	0
	Primary (3 TDs):	70%)	
	53% (95% CI 42%, 64%)	'	
	63% (95% CI 52%, 74%)		
	62% (95% CI 51%, 73%)		
Weighted mean difference	for aggregated diagnosis studies		
(range of mean difference		100/ (29 to 190/) 6 studios > 5.6.26	5.34.42.43
		-19% (-28 to 18%; 6 studies) ^{5,6,20}	-,,
	for primary diagnosis studies (range		
of mean differences; # stu	dies)	-11% (-54 to 11%; 11 studies) ^{5,6,5}	15,24,26,30,35,37,40,42,43
Weighted mean difference	for primary diagnosis pigmented skin		
lesion studies (range of me	ean differences; # studies)	-5% (-9 to 11%; 6 studies) ^{5,24,30,35}	5,37,40
D. Live interactive stud	ies (n=1)		
	T	A	00/
Lowitt 1998 ⁵¹	Aggregated: 73% (8/11)	Aggregated: 64% (7/11)	9%
VA No. Dta ND			
No. Pts NR			
11 Conditions			

Aggregated Diagnostic Accuracy of Store and Forward Studies

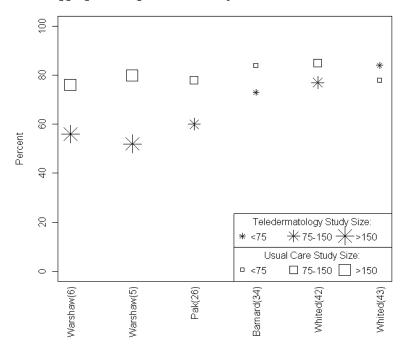


Figure 4a

Primary Diagnostic Accuracy of Store and Forward Studies

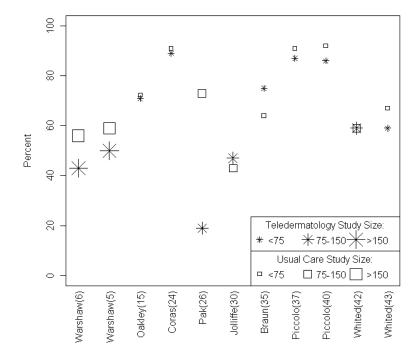


Figure 4b.

Table 4. Studies for Reporting Diagnostic Concordance between Teledermatology and Usual Care (In-Person Dermatology) (KQ1b)*

Study No. of subjects No. of skin conditions	Percent concordant	Kappa statistic	Sensitivity and Specificity
A. Store and forward pig	mented skin lesion studies (n=2)		
Moreno-Ramirez 2005 ¹⁸ 108 Pts No. PSL NR	NR	k=0.93 (95% CI 0.87, 0.98) TD = CD	NR
Piccolo 1999 ⁴⁰ 66 Pts 66 PSL	Primary: 91% (60/66) DSC	NR	NR
B. Store and forward ski	n lesion studies (n=6)		
Moreno-Ramirez 2007 ¹¹ 882 Pts 882 SL	NR	k=0.81 (95% CI 0.78, 0.84)	NR
Bowns 2006 ¹³ 256 Pts 256 SL	Primary: 69% (159/230) agreement on specific diagnosis TDSC: 75% (193/256) agreement on benign or malignant	NR	TD: Sensitivity=0.98 (95% CI 0.92, 0.99) Specificity= 0.39 (95% CI 0.32, 0.47) TDSC: Sensitivity=0.98 (95% CI 0.92, 0.99) Specificity=0.43 (95% CI 0.36, 0.51)
Oakley 2006 ¹⁵ 73 Pts 109 SL	Aggregated: 64%, No. NR Primary: 53% (100/189) (95% CI 46, 60%) TD=38 dermatologists including residents CD=3 dermatologists and 2 plastic surgeons	NR	NR
Mahendran 2005 ¹⁶ 163 Pts 163 SL	Aggregated: 65% (106/163) Primary: 48% (78/163)	NR	NR
Barnard 2000 ³⁴ 50 "cases"	Aggregated: 90%, No. NR (range for 8TDs 86-96%) Primary: 77%, No. NR (range for 8 TDs 67%-84%)	NR	NR
Whited 1998 ⁴³ VA 12 Pts 10 SL	2TDs - Aggregated: 90% (9/10) 100% (10/10) Primary: 80% (8/10) 60% (6/10)	NR	NR
C. Store and forward gen	neral studies (n=19)		
Edison 2008 ⁷ 110 Pts 110 Conditions	Primary: 73% (80/110) (95% CI 64, 81%)	k=0.71 (95% CI 0.67, 0.76)	NR
Bowns 2006 ¹² 92 Pts 92 Conditions	Primary: 55% (51/92)	NR	NR

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Baba 2005 ¹⁷	Primary:		
228 Pts	TD also served as CD: 81% (197/242)	NR	NR
242 Conditions	TD not the same as CD: 75%		
T. 1 200510	(181/242)		
Tucker 2005 ¹⁹ 75 Pts	Aggregated: 68% (57/184)	ND	ND
84 Conditions	Primary: 56% (47/84)	NR	NR
Oztas 2004 ²⁰	Primary: 70% (88/125) Average of 3 TDs		
125 Pts	111111ary. 7070 (88/123) Average 013 11Ds	NR	NR
125 Conditions		1110	1111
Du Moulin 2003 ²⁵	Aggregated: 63% (67/106)		
106 Pts	Primary: 54% (57/106)	NR	NR
106 Conditions			
Pak 2003 ²⁷	Aggregated: 91% (366/404)		
DoD	Primary: 70% (283/404)	NR	NR
404 Pts	TD also served as CD (included		
404 Conditions	residents)		
Rashid 2003 ²⁸			
33 Pts	Aggregated: 81% (27/33)	NR	NR
33 Conditions			
Oliveira 2002 ²⁹		1 007	g
92 Pts	98% (88/90) for benign vs. malignant	k=0.87	Sensitivity=1.00
No. Conditions NR	1 060/ N NB		Specificity=0.98
Lim 2001 ³² 23 Pts	Aggregated: 96%, No. NR	ND	ND
27 Conditions	Primary: 88%, No. NR TD also served as CD	NR	NR
Taylor 2001 ³³			
188 Pts	Aggregated: 60%, No. NR Primary: 50%, No. NR	NR	NR
No. of Conditions NR	1 11111ary . 3070, 110. 111X	IVIX	INIX
High 2000 ³⁶	Aggregated:		
92 Pts	85% (84/99)	NR	NR
106 Conditions	64% (49/77)		
	77% (76/99)		
	Primary:		
	70% (69/99)		
	64% (49/77)		
** * 1:400029	77% (76/99)		
Krupinski 1999 ³⁸	3 TDs (some also served as CD)	ND	ND
308 Pts 308 Conditions	Primary: 81%, No. NR	NR	NR
508 Conditions	81%, INC. INK 84%		
	85%		
	Average of all 3: 83%		
Lewis 1999 ³⁹	93% No. NR		Sensitivity=0.88
56 Cases	(likelihood of benign vs. malignant on 1-5	NR	Specificity=0.80
	scale)		(benign vs. malignant)
Tait 1999 ⁴¹	Aggregated: 100% (30/30)		
30 Pts	Primary: 83% (25/30)	NR	NR
No. of Conditions NR	TD also served as CD		
Whited 1999 ⁴²	3 TDs - Aggregated:		
VA	84% (95% CI 79%, 90%)	NR	NR
129 Pts	83% (95% CI 78%, 89%)		
168 Conditions	95% (95% CI 92%, 98%)		
	Primary: 41% (95% CI 34%, 49%)		
	41% (95% CI 36%, 49%) 44% (95% CI 36%, 52%)		
	52% (95% CI 45%, 60%)		
	Average = 46%		
	1		I.

Kvedar 199744	2 TDs - Aggregated:		
No. of Pts NR	70%	NR	NR
123 Conditions	67%		
	Primary:		
	61%		
	64%		
Lyon 1997 ⁴⁵			
100 Pts	93% (93/100)	NR	NR
100 Conditions	TD staff; CD resident		
Zelickson 1997 ⁴⁶			
29 Pts	88% (53/60)	NR	NR
30 Conditions	Combination of 2-3 TDs		
D. Live interactive st	udies skin lesion studies (n=1)		
Phillips 1998 ⁵²			
51 Pts	Primary: 59% (63/107)	k=0.32	NR
107 SL			
E. Live interactive ge	oneral studies (n=8)		
	inerui studics (n=6)		
Edison 2008 ⁷	000/ (00/110)	1 0.70	ND
110 Pts 110 Conditions	80% (88/110) (95% CI 73%, 88%)	k=0.79 95% CI 0.75, 0.83)	NR
		9376 C1 0.73, 0.83)	
Nordal 2001 ⁴⁷	Aggregated: 86% (97/112)		
112 Pts	Primary: 72% (81/112)	NR	NR
112 Conditions			
Gilmour 1998 ⁴⁸	Aggregated: 78% (121/155)		
126 Pts	Primary: 57% (88/155)	NR	NR
155 Conditions	TD also served as CD in 51% (79/155) of		
	cases		
Lesher 1998 ⁴⁹	Aggregated: 99% (67/68)		
60 Pts	Primary: 78% (53/68)	NR	NR
68 Conditions			
Loane 1998 ⁵⁰	Aggregated: 82% (352/427)		
351 Pts	Primary: 67% (285/427)	NR	NR
427 Conditions	TD also served as CD in 63% (226/427)		
	of cases		
Lowitt 1998 ⁵¹			
VA	Aggregated: 80% (104/130)	NR	NR
102 Pts	Agreement for diagnostic category		
130 Conditions			
Oakley 1997 ⁵³	Aggregated: 82% (110/135)	k=0.62 (TD not the	
104 Pts	Primary: 75% (101/135)	same as CD)	NR
135 Conditions	TD also served as CD in 79% of cases	k=0.91 (TD also	
		served as CD)	
Phillips 1997 ⁵⁴			
60 Pts	Primary: 77% (61/79)	NR	NR
79 Conditions			
F. Live interactive an	d store and forward studies (n=1)		
Baba 2005 ¹⁷	Primary:		
228 Pts	90% (218/242) TD also served as CD	NR	NR
242 Conditions	82% (199/242) TD not the same as CD		
			i .

 $^{{\}bf *Results\ for\ staff\ dermatologists\ unless\ otherwise\ reported}.$

Aggregated Diagnostic Concordance of Store and Forward Studies

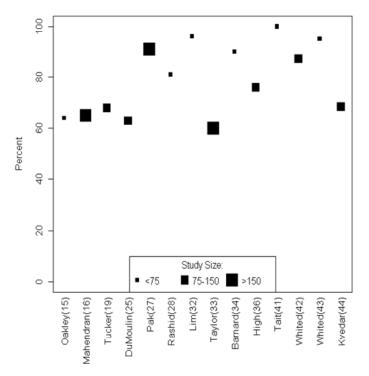


Figure 5a.

Primary Diagnostic Concordance of Store and Forward Studies

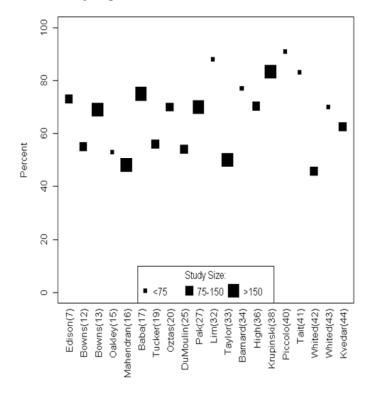


Figure 5b.

Aggregated Diagnostic Concordance of Live Interactive Studies

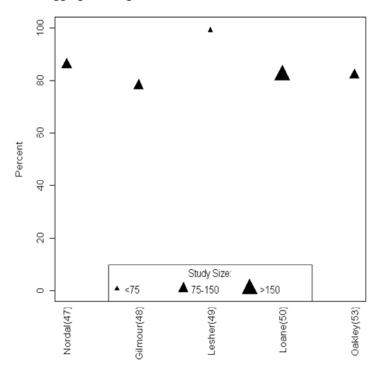


Figure 6a.

Primary Diagnostic Concordance of Live Interactive Studies

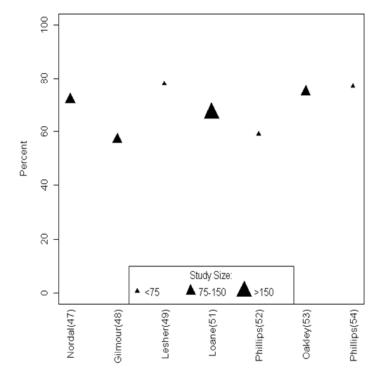


Figure 6b.

Table 5. Studies Reporting Management Accuracy using Histopathology/Lab Tests as the Gold Standard (KQ2a)

Study	TD Management Accuracy, % Correct	CD Management Accuracy, % Correct	Absolute Mean Difference, % Correct
A. Store and forward	studies		
Warshaw 2009 ⁶ VA	79% (574/728)	84% (608/728)	-5%
728 Pts 728 SL	80% (581/728) PLD	84% (609/728) PLD	-4%
Warshaw 2009 ⁵ VA	71% (383/542)	66% (356/542)	5%
542 Pts 542 PSL	70% (380/542) PLD	66% (356/542) PLD	4%
	74% (401/542) CID	66% (357/542) CID	8%
Weighted mean differences; No. studies)	rence for studies (range of mean differ-	-0.6% (-5 to 5%;	2 studies) ^{5,6}
Weighted mean differ ferences; No. studies)	rence for PLD studies (range of mean dif-	-0.2% (-4 to 4%;	2 studies) ^{5,6}
B. Live interactive st	udies		
No studios			
No studies			

Table 6. Studies Reporting Management Concordance between Teledermatology and Usual Care (In-Person Dermatology) (KQ2b)

Study	Percent concordant	Kappa statistic	Sensitivity and Specificity
A. Store and forward p	igmented skin lesion studies (n=2)		
Di Stefani 2007 ⁹ 18 Pts 465 PSL	TD1 96% TDSC TD2 96% TDSC Denominator: # of lesions For 3 Management Options (Annual follow-up, Short term follow-up, Biopsy)	TD1 k=0.68 TD2 k=0.70	NR
Joliffe 2001 ³¹ 611 Pts 819 PSL	80% (652/819) Concordance for refer or not refer	NR	Sensitivity=0.69 Specificity=0.82 Calculated on 82% of refer or not refer
B. Store and forward sh	kin lesion studies (n=5)		
Ferrandiz 2007 ¹⁰ 134 SL (73% NMSC)	NR	k=0.75 (95% CI 0.71, 0.79) Agreement on planned surgical technique	NR
Bowns 2006 ¹³ 256 Pts 256 SL	61% (157/256) Concordance for refer or not refer	NR	NR
Mahendran 2005 ¹⁶ 163 Pts 163 SL	55% (90/163)	NR	NR

Shapiro 2004 ²³ 49 Pts 49 SL	100% (49/49) Concordance for biopsy vs. no biopsy	NR	Sensitivity=1.0 (95% CI 0.87, 1.00) Specificity=1.0 (95% CI 0.85, 1.00)
Whited 1998 ⁴³ VA 12 Pts 10 SL	TD1 100% (10/10) TD2 90% (9/10) Concordance for biopsy or no biopsy	NR	NR
C. Store and forward go	eneral studies (n=7)		
Edison 2008 ⁷ 110 Pts 110 Conditions	66% (73/110) (95% CI 58%, 75%)	k=0.62 (95% CI 0.55, 0.69)	NR
Bowns 2006 ¹² 92 Pts 92 Conditions	55% (51/92)	NR	NR
Oakley 2006 ¹⁵ 73 Pts 109 Conditions	82% (208/252) TDSC Denominator: # of responses from up to 38 TDs and 5 CDs, including 2 plastic surgeons	NR	NR
Pak 2003 ²⁶ DoD 404 Pts 404 Conditions	76% (307/404) Concordance for biopsy or no biopsy	NR	NR
Whited 1999 ⁴² VA 129 Pts 168 Conditions Denom- inators for Management Types NR	3 TDs Medical Therapy: Aggregated: 71%, 75%, 80% Primary: 67%, 68%, 69% Clinical Procedures: Aggregated: 64%, 73%, 74% Primary: 64%, 73%, 74% Diagnostic Tests: Aggregated: 70%, 69%, 69% Primary: 67%, 66%, 68%	NR	NR
Lyon 1997 ⁴⁵ 90 Pts 90 Conditions	94% (85/90) CD=resident TD=staff	NR	NR
Zelickson 1997 ⁴⁶ 29 Pts 30 Conditions	90% (54/60) Combination of 2-3 TDs	NR	NR
D. Live interactive stud	ies (n=4)		
Edison 2008 ⁷ 110 Pts 110 Conditions	75% (82/110) (95% CI 66%, 83%)	k=0.71 (95% CI 0.64, 0.78)	NR
Gilmour 1998 ⁴⁸ 61 Pts 61 Conditions	72% (44/61)	NR	NR
Loane 1998 ⁵⁶ 214 Pts 252 Conditions	64% (160/252) TD also served as CD in 44% of cases	NR	NR
Phillips 1998 ⁵² 51 Pts 107 SL	86% (92/107) Concordance for biopsy or no biopsy	k=0.47 Biopsy or no biopsy	NR

Management Concordance of Store and Forward Studies

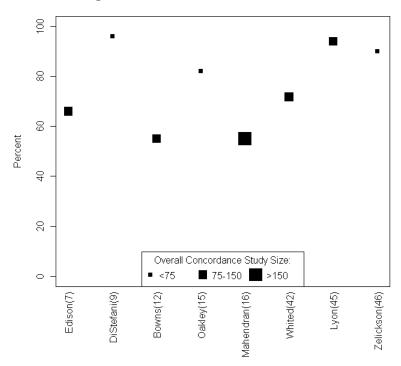


Figure 7a.

Management Concordance of Live Interactive Studies

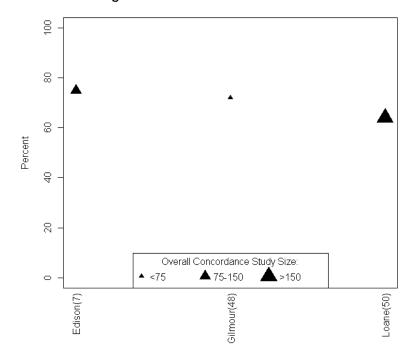


Figure 7b.

KEY QUESTION 3

How do clinical outcomes (clinical course, satisfaction, quality of life, visits avoided) of teledermatology compare to usual care (in-person dermatology) for skin conditions? (Tables 7, 8, and 9)

<u>Clinical Outcomes:</u> We identified three studies that reported clinical course for patients evaluated with either teledermatology or usual care (in-person dermatology) (Table 7).^{57,58,59} Although two of the studies suggested that clinical course is more favorable following teledermatology, the three studies used different methods for determining clinical course and assessed clinical course at different time points.

Eminovic et al.⁵⁷ reported a notable difference in the percentage of patients improved at one month after referral in the teledermatology group (20%) compared to the usual care group (4%). The assessment was done by a dermatologist during an in-person dermatology consultation. However, it is important to note that the teledermatology group was treated during the one month period, as needed, based on the results of the teledermatology consultation while the usual care group had yet to see a dermatologist. In the Pak et al.⁵⁸ study involving DOD and veterans, the assessment was done for both groups at four months after the initial visit (either teledermatology or in-person dermatology) using photographic images. There was no significant difference in clinical course rating (improved, no change, or worse) between the two groups. Granlund et al.⁵⁹ assessed outcomes at six months using a questionnaire. The response rate was 60%. A significantly higher percentage of teledermatology patients reported that their condition had resolved (63% vs. 23%, p=0.03).

Table 7. Clinical Course Outcome for Teledermatology Studies (KQ3)

Study	Intervention	Clinical Course	
Country Number of Subjects for Clinical Course Outcome/Total Number of Subjects Design		Teledermatology Care	Usual
A. Store and forward systems studies (n=2)		1	
Eminovic 2009 ⁵⁷ Netherlands N=369 evaluable (total N=605 pts) RCT; general practitioners randomized to TD or UC Clinical outcome assessed at time of CD appointment	Teledermatology group: SAF TD followed by CD visit at 1 month Usual care group: referred for CD visit (approximately 1 month waiting time)	40/200 (20%) judged to not need CD visit because condition had improved	7/169 (4%) judged to not need CD visit be- cause condition had improved
Pak 2007 ⁵⁸ United States VA and DoD N=508/698 Clinical outcome assessed by photographs (baseline compared to four months)	Teledermatology group: baseline SAF TD with repeat imaging at 4 months Usual care group: CD visit (baseline) with imaging for outcome assessment only; repeat imaging at 4 months	64% improved 33% no change 4% worse n=272	65% improved 32% no change 3% worse n=236 (p=0.57)
B. Live interactive studies (n=1)			
Granlund 2003 ⁵⁹ Finland N=29/48 Non-randomized; same dermatologist for TD and UC Clinical outcome assessed via questionnaire at six months (29 of 48 pts responded)	Patients from first clinic had TD consultation Patients from second clinic had CD consultation Both groups: follow-up as needed after initial consultation	63% "still suffer from disease" 63% "resolved" n=16	85% "still suffer from disease" 23% "resolved" n=13 (p=0.03)

<u>Patient Satisfaction:</u> Seven SAF and four LI studies reported patient satisfaction (Table 8). Assessment tools ranged from a single question to surveys with over 50 items. As a result of the wide discrepancy in assessments used, we focused our report on overall satisfaction measures rather than satisfaction with specific elements of teledermatology or usual care (in-person dermatology).

SAF Studies: In the four SAF studies that included both teledermatology and usual care groups, satisfaction ratings were comparable with a mean satisfaction rating of 3.8 out of 5,⁵⁷ or greater than 75% of patients reporting satisfaction with both teledermatology and usual care.^{12,18,60} In the three studies with no comparison group, teledermatology was rated as "excellent" or "good" by 42% of the patients;⁶¹ 93% reported they were "happy" with teledermatology;^{62,63} and at 4 to 6 weeks after teledermatology, 64% reported they were satisfied.⁶⁴ Three of the studies included VA or DoD populations.^{60,61,64}

LI Studies: Four LI studies reported patient satisfaction. In the one study that included teledermatology and usual care groups (non-randomized), a significantly greater number of patients (96% vs. 83%, p=0.03) reported they were satisfied with teledermatology than with usual care.⁵⁹ The median satisfaction rating (on a scale of 0 to 10) was also higher for the teledermatology group (9.6 vs. 9.0, p=0.03). Of the three studies without a comparison group, the reported satisfaction ratings were 44%,⁴⁷ 88%,⁶⁵ and 92%.⁶⁶ Only one of these studies was completed in the United States.⁶⁵

Overall: Of the five studies that included both teledermatology (either SAF or LI) and usual care groups, patients expressed comparable levels of satisfaction in three of the studies (all of which were randomized, controlled trials; one included a veteran population). One non-randomized study reported greater satisfaction with teledermatology. One repeated measures study reported greater satisfaction with usual care, however, the usual care patients in that study had already been seen via SAF teledermatology. Response rates for the satisfaction assessments ranged from 58% to 100%.

<u>Patient Preference</u>: Four SAF and eight LI studies reported patient preference (Table 8). A total of four of these studies (2 SAF, 2 LI) were conducted in the United States.

SAF Studies: With the exception of one study that reported that 76% of patients preferred teledermatology over waiting for a usual care appointment, ¹² preferences for teledermatology or usual care were similar. In one VA study, 42% preferred teledermatology over usual care while 37% preferred usual care over teledermatology. ⁶⁰ A study from the United Kingdom reported that 40% preferred usual care over teledermatology with 68% responded that teledermatology was "as good as" usual care. ^{62,63} A DoD-based study reported that 42% preferred teledermatology and 38% preferred usual care when asked 4 to 6 weeks after their initial appointment. ⁶⁴

LI Studies: In one study, patients experienced both SAF and LI sessions. Although 85% "accepted" SAF teledermatology, 82% of those patients felt that the LI session was also needed.¹⁷ Reported preferences for teledermatology ranged from 69%⁶⁵ to 38%.^{47,48} Reported preferences for usual care ranged from 28%⁴⁷ to 43%.⁶⁷ In two studies, approximately one-third of the patients surveyed expressed no preference.^{47,53} In two studies, teledermatology was rated "as good as" usual care by 54%⁵³ and 66%⁶⁷ of patients.

Overall: Preference for teledermatology ranged from 38% to 86%. One study reported slightly higher satisfaction with usual care but 76% of the patients preferred teledermatology over waiting to see a dermatologist. A VA study reported that patients were more likely to respond "strongly agree" to statements about satisfaction with usual care and more likely to respond "agree" to statements about satisfaction with teledermatology yet "most" patients preferred a teledermatology appointment rather than driving 2 hours to see a dermatologist. It appears that other factors, such as waiting time for a in-person dermatology appointment and the need to travel long distances (involving both expense and time off from work), influence patient preference for usual care or teledermatology.

Table 8. Patient Satisfaction and Patient Preference for Teledermatology Studies (KQ3)

Study	Patient Satisfaction		Preference
Country Satisfaction Assessment Number of Patients for this Outcome Preference	Teledermatology	Usual Care	
A. Store and forward systems studies (n=7)	,		
Eminovic 2009 ⁵⁷ Netherlands RCT - GPs randomized to TD or UC 20/43 items from short-form Patient Satisfaction Questionnaire III (mean score, 5 point scale - 5 indicating greatest satisfaction) N=350/605 (57.8% response rate)	3.8 n=191	3.8 n=159	NR
Bowns 2006 ¹² United Kingdom RCT 51 items from Patient Satisfaction Questionnaire III plus 9 items specific to SAF N=147/208 (70.7% response rate)	satisfied overall: 84% n=80	satisfied overall: 87% n=67 (p=0.59)	preferred TD over waiting for UC: 76%
Moreno-Ramirez 2005 ¹⁸ Spain, Pigmented Lesions Repeated measure design Question "Are you satisfied with this way of being attended by a specialist?" N=219 TD; 108/219 "selected" for additional UC	very satisfied: 86% n=219	very satisfied: 98% n=108 (all had TD before UC)	NR
Whited 2004 ⁶⁰ United States; Durham, NC VAMC RCT Telephone Survey UC: Visit-Specific Satisfaction Questionnaire TD: Related questions plus specific TD items BOTH: 5 point scale (Excellent to Poor) N=194/275 (70.5% response rate)	excellent or very good: 79% n=101	excellent or very good: 78% n=93	preferred TD over UC: 42% preferred UC over TD: 37%

Weinstock 2001 ⁶¹ United States; Togus, Maine VAMC TD Cohort Telephone Survey (10 questions) 5 point scale (Excellent to Poor) Mean 14 months after TD (range 2.5-30.5) N=100/148 (67.6% response rate) randomly selected from 1030 consults	excellent or good: 42% ability of TD to treat skin disease: good/excellent 41% fair/poor 46%	no comparison group	NR
Williams 2001 ^{62,63} United Kingdom TD Cohort Survey of 15 items developed for SAF TD 5 point scale (strongly disagree to strongly agree) N=123/141 (87.2% response rate)	"happy" with TD: 93%	no comparison group	prefer UC to TD: 40% believed TD as good as UC: 68%
Pak 1999 ⁶⁴ United States, DoD TD Cohort Survey (details NR) at baseline and 4-6 weeks N=77/100 (baseline; 77% response rate) N= 55/100 (4-6 week; 55% response rate)	baseline: satisfied with TD: "most" 4-6 weeks: satisfied with TD: 64%	no comparison group	at 4-6 weeks: prefer UC: 38% prefer TD to wait- ing for UC: 42%

B. Live interactive studies (n=9)			
Granlund 2003 ⁵⁹ Finland Open, non-randomized TD vs. UC Survey of 5 questions: Completed after encounter and 6 months 5 point scale (very good to very bad) Linear analog scale of 0 to 10 Completed after encounter and 6 months N=48 immediately after encounter N=29 at 6 months	satisfied with TD: 96% n=23 Linear analog scale: Median=9.6 after consultation Mean=7.4 at 6 months n=16	satisfied with UC: 83% n=25 (p=0.03) Linear analog scale: Median=9.0 after consultation (p=0.03) Mean=6.6 at 6 months (p>0.05) n=13	NR
Baba 2005 ¹⁷ Turkey Combined SAF + LI Cohort Questions: 1) Acceptance of TD or UC 2) Need for LI in addition to SAF N=228	overall satisfaction NR	no comparison group	would accept TD: 85% (of these, 82% felt LI+SAF was needed rather than just SAF)
Hicks 2003 ⁶⁵ United States TD Cohort Survey of 8 questions: Completed after each visit, ≥1 survey per pt 7-point scale (very unsatisfied to very satisfied) N=321 TD pts	very satisfied or satisfied: 88% n=258	no comparison group	felt TD much better/ better than UC: 69% n=255

Nordal 2001 ⁴⁷ Norway Repeated measures design Survey of 9 items:	very satisfied with TD: 44% unsatisfied with TD:	no comparison group	for a future dermatol- ogy consult: prefer TD: 38% prefer UC: 28%
4 point scale (very satisfied to unsatisfied) N=116/121 (95.9% response rate)	10%		indifferent: 34% general preference: prefer TD: 18% prefer CD: 16% indifferent: 66%
Lamminen 2000 ⁶⁶ Finland TD Cohort Survey (details NR) N=25	TD "excellent or good": 92%	no comparison group	NR
Gilmour 1998 ⁴⁸ United Kingdom Repeated measures design Survey of 16 items: 5 point scale (strongly disagree to strongly agree) N=122/126 (96.8% response)	overall satisfaction NR	no comparison group	prefer TD: 38% prefer UC: 42% TD as good as UC: 43%
Lowitt 1998 ⁵¹ United States, Baltimore VAMC Repeated measures design Survey of 7 items: 4 point scale (strongly disagree to strongly agree) N=124/139 (89.2% response rate)	overall satisfaction NR	overall satisfaction NR more "strongly agree" responses for UC vs. more "agree" responses for TD (p=0.001)	"most" prefer TD close to home rather than UC 2 hours away
Loane 1998 ⁶⁷ Northern Ireland Repeated measures design Survey of 15 items: 5 point scale (strongly disagree to strongly agree) N=292/334 (87.4% response rate)	overall satisfaction NR	overall satisfaction NR	prefer TD: 41% prefer UC: 43% TD as good as UC: 66%
Oakley 1997 ⁵³ New Zealand Repeated measures design Survey (details NR): 5 point scale (strongly disagree to strongly agree) N=98/104 (94.2% response rate)	overall satisfaction NR	overall satisfaction NR	TD as good as UC: 54% undecided: 31%

<u>Time to Treatment:</u> Four SAF studies and no LI studies addressed the question of time to treatment (Table 9). One study included both time to treatment and time to teledermatology results; one additional study included only time to teledermatology results.

In all four studies, the time to treatment was shorter for patients who were initially seen by teledermatology. Time from general practitioner consult to dermatology clinic (or opinion) was significantly shorter for teledermatology patients compared to usual care patients in the three studies that reported this outcome^{11,12,68} with the difference ranging from 44 days to 76.3 days (all p<0.001). Time to biopsy was 19 days shorter (p=0.03).⁶⁸ Time to surgery or definitive intervention was significantly shorter in the three studies that reported this outcome.^{10,68,69} The difference ranged from 21 to 86 days (all p<0.01). Two of these studies^{68,69} were conducted

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at VA medical centers. It is important to note that although times to treatment experienced by teledermatology patients in the VA studies were shorter than those for usual care patients, the reported times are not reflective of current VA practices; all veterans now are scheduled within 30 days. Two studies reported time to teledermatology results. Mean times were 61.1 hours¹¹ and 44 hours.¹⁸

<u>Clinic Dermatology Visits Avoided:</u> The number of in-person dermatology visits avoided was reported in 11 SAF and 3 LI studies (Table 9). Two SAF studies reported the number of dermatology visits required. Teledermatology patients required a mean of 0.98 visits in one study⁶⁸ and 1 visit in another study.¹⁰ In the same two studies, usual care patients required a mean of 1.13 or at least 2 visits, respectively.

Two SAF studies reported the percentage of patients who did not require a dermatology clinic visit ("preventable" visits) following teledermatology compared to usual care patients. The differences between groups were 20.7% (39% teledermatology vs. 18.3% usual care)⁵⁷ and 28% (66% teledermatology vs. 38% usual care). Two live interactive studies reported a similar outcome with a difference of 14% (44% teledermatology vs. 30% usual care) in one study and a difference favoring usual care of 1% (54% teledermatology vs. 55% usual care).

Seven additional SAF studies and one additional LI study reported visits avoided with no comparison group. The percentage of visits avoided ranged from 12.8% to 72%. 11,16,18,33,64,66,69,72 The study that reported 12.8% clinic dermatology visits avoided also reported that 33.1% required clinic dermatology surgery. 16

<u>Conclusions:</u> There was insufficient evidence to conclude whether teledermatology had an effect on clinical course, although a VA/DoD study with over 500 patients reported comparable outcomes. Patient overall satisfaction with and preference for teledermatology or usual care were comparable in VA/DoD and other studies. Patients noted waiting time for an appointment and travel time/distance as factors when considering preference. Time to treatment was significantly shorter and clinic dermatology visits can be avoided when patients have an initial teledermatology visit.

Table 9. Time to Treatment and Clinic Dermatology Visits Avoided for Teledermatology Studies (KQ3)

Study	Time to Treatment (Average)	CD Visits Avoided*				
A. Store and forward systems studies (n=11)					
Eminovic 2009 ⁵⁷ Netherlands Cluster RCT N=369/605	NR	CD visits "preventable" for: TD 39.0% (N=200) UC 18.3% (N=169) Difference 20.7% (95% CI 8.5, 32.9)				
Hsiao 2008 ⁶⁸ United States Retrospective review of veterans treated for skin cancer N=149/169 46% UC, 54% TD	Consult to (days): Opinion (TD or CD): TD 4 vs. UC 48 (p<0.001) Biopsy: TD 38 vs. UC 57 (p=0.034) Surgery: TD 104 vs. UC 125 (p=0.006)	Mean number of CD visits: TD 0.98 vs. UC 1.13 (p=0.02) NOTE: 14% of TD did not require any CD visits prior to surgery; all UC required ≥1 visit				
Ferrandiz 2007 ¹⁰ Spain Pilot study of SL needing regular surgical excision N=226 (134 TD compared to random sample of 92 UC	Consult to surgery (days): TD 26.1 vs. UC 60.6 (p<0.001)	TD: 1 CD visit needed UC: ≥ 2 CD visits needed Difference: ≥ 1 visit				
Moreno-Ramirez 2007 ¹¹ Spain Repeated Measure, Historical Control N=2539 (2009 TD compared to 530 UC	Consult to CD clinic (days): TD 12.3 vs. UC 88.6 (p<0.001) Time for TD results 61.1 hrs NOTE: N unclear for this outcome	51.2% (n=1029) of TD did not need CD visit				
Bowns 2006 ¹² United Kingdom RCT N=165/208	Consult to opinion (days): TD 13 (n=85) vs. UC 67 (n=72) p<0.0001	No follow-up visits needed: TD 66% vs. UC 38% (p=0.0003)				
Knol 2006 ⁷² Netherlands N=306 intent to refer consultations and 505 TD No comparison group	NR	53.3% (n=163) did not need CD				
Mahendran 2005 ¹⁶ United Kingdom Repeated Measure N=163	NR	12.8% (n=21) did not need CD (reassurance only) 33.1% (n=54) did not need CD consult visit but did need CD surgery				
Moreno-Ramirez 2005 ¹⁸ Spain Cohort, PSL N=219	Time for TD results 44 hrs	51% (n=111) did not need CD				
Whited 2002 ⁶⁹ United States RCT of Veterans N=275 (TD=135, UC=127)	Consult to definitive intervention (days, median): Intent to Treat: TD 41 vs. UC 127 p=0.0001 Actual Visit: TD 50 vs. UC 137.5 p=0.0027	18.5% of TD did not need CD				
Taylor 2001 ³³ United Kingdom TD Reliability Study N=188/194	NR	31% of TD did not need CD (based on 376 assessments, 188 cases X 2 consultants) NOTE: CD diagnosis differed from TD diagnosis in 14% of these 188 cases				

Pak 1999 ⁶⁴ United States Department of Defense Cohort, no comparison group N=100	NR	45% did not need CD	
B. Live interactive studies (n=3)			
Loane 2001 ⁷⁰ United Kingdom RCT TD vs. UC N=274 (126 TD, 148 UC)	NR	44% of TD and 30% of UC did not need follow-up visit	
Wooton 2000 ⁷¹ United Kingdom RCT TD vs. UC N=204 (102 TD, 102 UC)	NR	54% of TD and 55% of UC did not need follow-up visit	
Lamminen 2000 ⁶⁶ Finland Cohort, TD N=25	NR	72% did not need follow-up visit	

^{*}Does not include TD visit(s). Number of CD visits avoided

KEY QUESTION 4

How does the cost of teledermatology compare to usual care (in-person dermatology)? (Table 10)

Cost data were reported in three studies involving SAF teledermatology, six studies of LI teledermatology, and one study that included both SAF and LI teledermatology (Table 10). Due to differences in factors included in cost assessments and the various perspectives (societal, health service, or patient), it was difficult to summarize these findings.

SAF Studies: Whited et al.⁷³ used a micro-costing approach with a VA perspective and found that teledermatology was cost-effective but not cost-saving for decreasing time to initial definitive dermatologic care. It was assumed that VA centers had both on-site primary care and dermatology clinics. Definitive care was achieved in 50 days using teledermatology compared to 138 days with usual care. The long-duration to achieve definitive dermatologic care, particularly for the usual care population, is no longer consistent with current VA practice (appointments within 30 days) and may result in an overly favorable estimate of teledermatology. Pak et al.,⁷⁴ based on a DoD population, reported cost savings of \$32 per patient if lost productivity was considered. Moreno-Ramirez et al.⁷⁵ reported that teledermatology was cost-effective for patients referred to a skin cancer clinic.

SAF and LI Study: A comparison of SAF and LI teledermatology found store and forward to be less expensive but less efficient clinically than live interactive teledermatology.⁸⁰ This analysis considered the educational benefit to general practitioners obtained during the live interactive sessions.

LI Studies: Six studies assessed LI versus usual care including two studies conducted in the United States. Studies had marked differences in design and settings. Most indicated that

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teledermatology either cost less or was cost efficient compared to usual care, particularly if patients had to travel long distances or certain criteria were met for referral volume and costs.

<u>Conclusions:</u> Cost studies were limited by variations in parameters included and perspectives chosen for the analyses. The majority of studies (including both SAF and LI technologies) found teledermatology to be cost effective if certain critical assumptions were met; the most important included patient travel distance, teledermatology volume, and costs of usual care.

Table 10. Teledermatology Studies Reporting Cost Outcomes (KQ4)

Author/Year/Country Funding	Participants Age, race, gender	Sites Providers	Cost Outcomes/Utilization Outcomes (US\$, except as noted)			
Design	Skin Conditions	Assumptions	(****, ********************************			
Store and Forward vs. Usual Care (I	N=3)					
Whited 2003 ⁷³	N=275 (135 TD, 140 UC)	On-site primary care clinic and on- site dermatology clinic	-Average cost (\$) per pt (base-case): TD: 36.40 UC: 21.40			
U.S. Veterans	age: NR race: NR	Providers: primarily dermatology	Incremental cost per pt: 15.00 (sensitivity analysis range: 10.50 to 15.00)			
VA HSR&D	gender: NR	residents	-Median time to initial definitive intervention: TD: 50.0 days UC: 137.5 days			
RCT TD vs. UC	Conditions: NR	Micro-costing approach, VA perspective	Incremental effectiveness: 87.5 days Incremental cost-effectiveness ratio for TD: \$0.17 per pt per day (sensitivity analysis range: \$0.12 to \$0.17) Conclusion: TD not cost-saving but was cost-effective for decreasing time to initial definitive dermatological care			
Pak 2009 ⁷⁴ U.S. Army Personnel	N=698 (351 TD, 347 UC) age: NR	Military primary care and dermatology clinics	-Costs (\$, average per pt) TD UC Total Direct 103,043 (294) 98,365 (283) Lost Productivity 16,359 (47) 30,768 (89)			
U.S. Army Telemedicine and Advanced Technology Research Center RCT TD vs. UC	race: NR gender: NR Conditions: NR	Providers: NR Cost-minimization, DoD perspective	Total Cost 119,402 (340) 129,133 (372) Conclusion: TD cost-saving, if lost productivity is considered			
Moreno-Ramirez 2009 ⁷⁵ Spain	N=4018 (2009 TD, 2009 UC) age: NR race: NR	12 primary care clinics/ 1 central skin cancer clinic Providers: NR	-Waiting interval for skin cancer clinic: TD: 12.3 days UC: 88.6 days Incremental effectiveness 76.3 days -Unit cost (\$) per pt:			
Instituto Carlos III Non-randomized comparison of consecutive TD and UC pts	gender: NR Conditions: suspected skin cancer	Societal perspective	TD: 119.67 UC: 194.06 (p<0.005) Incremental cost savings of TD \$74.39 -Cost-effectiveness: \$0.98 saved per waiting day avoided by TD			
			Conclusion: SAF TD is cost-effective for referrals to skin cancer clinic			

Store and Forward vs. Live Interact	ive (N=1)				
Loane† 2000 ⁸⁰ United Kingdom NHS R&D, Southern Health and Social Services Board, Glaxo, Steifel Repeated measure – both SAF and LI TD Anonymous economic questionnaire after LI consultation	N=96 /102 randomized to TD (see Wootton 2000) age: mean=38.9 years race: NR gender: 47% male Conditions: Most common - eczema, psoriasis, acne, and tumors	4 primary care centers (2 rural, 2 urban) and 2 dermatology centers Providers: 2 dermatologists (1 for SAF and 1 for LI)	-Dermatologist consultation time (mean): SAF: 1.6 min LI: 15.7 min -Total pt time (wait, consult, travel) (mean): SAF: 41.5 min LI: 52.2 min -Variable costs per pt		
			Conclusion: SAF cheaper, but less clinically efficient, than LI		
Live Interactive vs. Usual Care (N=6	(i)				
Burgiss 1997 ⁷⁶ U.S. Funding: NR	N=87 (119 visits) age: NR race: NR gender: NR	2 rural primary care centers and university dermatology clinic Providers: 1 dermatolo- gist	-Total Costs \$ (per Pt) Primary care* TD		
Before and after TD comparison	Conditions: dermatitis, infectious, acneiform, papulosquamous, tumors		Conclusion: TD can decrease costs of dermatological care		
Wootton† 2000 ⁷¹ United Kingdom UK Multicentre Teledermatology Trial NHS R&D Southern Health and	N=169/204 (102 TD, 102 UC) age: mean=38.6 yrs race: NR gender: 42% male Conditions: NR	4 primary care centers (2 rural, 2 urban) and 2 dermatology centers Providers: NR	-Costs per Pt		
Social Service Board, Glaxo, Steifel RCT TD vs. UC Anonymous economic questionnaire after TD consultation			Conclusion: TD not cost-effective in setting evaluated (average distance to dermatology clinic 26km); TD would be cost- effective if distance >78km		

Loane 2001 ⁷⁷ New Zealand New Zealand Ministry of Health and Health Informatics Foundation, V-Tel, B&H Ltd, Digital Equipment Corporation, Leo RCT TD vs. UC	N=203 (109 TD, 94 UC) age: mean=41 yrs	2 rural primary care centers and 1 dermatology department Providers: NR Societal perspective	-Costs (\$): Fixed Costs Variable Costs Total Unit Cost Conclusion: From socie than UC	15	D	13,53 13,53 127.	6.60 71
Patient questionnaire							
Bergmo 2000 ⁷⁸ Norway Funding: NR Case Series comparison of TD to 3 alternatives: 1. combination of pt travel and visiting dermatologist 2. pt travel to central dermatologist 3. hiring local dermatologist	N=375 TD pts (actual workload for 1 yr) age: NR race: NR gender: NR Conditions: NR	1 primary care clinic and 1 central dermatology clinic Providers: NR Assumed health outcomes for TD = UC Societal and health-care sector perspective	-Fixed Costs (\$) TD: 43,866.35 Pt Travel/Visiting: 35,052.60 Pt Travel: 0 Local Dermatologist: 105,452.60 -Variable Costs (\$) per Pt TD: 21.12 Pt Travel/Visiting: 66.33 for 1st 240 pts* Pt Travel: 479.60 Local Dermatologist: 0 *Maximum workload for visiting dermatologist - 240 pts; remaining pts travel to clinic at cost of \$339.90 per pt Conclusion: TD was less costly than the three alternatives if >195 pts per year				
Loane†	N=274 pts (126 TD, 148 UC)	1 urban and 1 rural pri-	-Total Costs/Benefits(\$)		an_	<u>Rural</u>	
2001 ⁷⁰ UK	254/413 (62%) questionnaires completed age: mean=39.7 years	mary care clinic and 1 dermatology department	Variable Fixed	TD 7025 10527	<u>UC</u> 7226 0	<u>TD</u> 4747 8605	<u>UC</u> 3062 0
Funding :NR	race: NR	Providers: General prac-	Total	17552	7226	13352	3062
RCT TD vs. UC	gender: 44% male TD pts: 61% urban, 39% rural	titioners and dermatolo- gists	Savings Societal* Marginal**	1084 16468 77	0 7226 69	459 12893 88	0 3062 71
Patient questionnaire after each visit	UC pts: 71% urban, 29% rural Conditions: NR	Health service and pt perspectives	Unit*** *(Fixed+Variable)-(Sa **(Variable-Savings)/(***(Societal)/(#Pts) Conclusion: Overall, tot Sensitivity analysis four	(#Pts)			71 UC

Armstrong	N=451 TD visits (301 new, 150 follow-	1 Primary care center	-Costs (\$) per hour	<u>TD</u>	<u>UC</u>	
200779	up) and 47,434 UC visits	and 1 dermatology clinic	TD equipment	4.75	0.00	
U.S.			Facility and personnel	143.88 1	93.04	
	age: NR	Providers: 1 nurse prac-	Physician compensation	125.00 1:	53.00	
Funding: NR	race: NR	titioner (trained in der-	Total	273.63	346.04	
	gender: NR	matologic procedures); 1				
Non-randomized comparison of TD		dermatologist	Conclusion: Hourly costs higher for UC than TD			
and UC visits	Conditions: Top 5 conditions: actinic		One-way Sensitivity Analyses found TD = UC costs if:			
	keratosis, eczema, acne, benign neo-	Provider perspective;	a. technology cost \$44/hr			
	plasm, viral infection	cost-minimization	b. physician compensation was \$197/hr			
			c. clinic space cost was \$57/hr (rather than \$12.50-TD			
			and \$100-UC)			
			Reimbursement for TD: per visit=\$122, per hour=\$487			

[†]UK Multicentre Teledermatology Trial

^{1.} Post-operative wound care, and chronic dermatitis.

KEY QUESTION 5

What are the key structural and process elements associated with successful implementation of teledermatology and what are the barriers? (Table 11)

As summarized above, most research in teledermatology has focused on the accuracy and reliability to diagnose and manage skin conditions in a research setting. However, lessons learned from mature, functioning teledermatology systems include "...that the successful implementation of teledermatology as a routine service requires understanding of and paying great attention to the interplay between social and technical aspects of teledermatology."⁸¹ Finch and colleagues conducted a longitudinal qualitative study based on in-depth semi-structured interviews of dermatologists, nurses, administrators, patient advocates, primary care providers and technologists in 12 teledermatology services in the UK and concluded that "the original... vision of how teledermatology would be utilized, as a technological fix for long waiting lists and consultant shortages, failed to be realized."⁸²

Several publications have described key elements for successful implementation of teledermatology. 83,84,85,86,87,88,89 We summarized these recommendations in Table 11. We attempted to categorize success facilitators using the definitions of Greenhalgh et al. We categorized implementation barriers according to administrative, clinical, patient and technical factors. We emphasized factors likely to play a role in VA specific settings. Detailed information on specific equipment, training in photography, and computerized medical record applications are beyond the scope of this review and are available on the World Wide Web. 90,91,92 Because store and forward is the method used almost exclusively for dermatology in the VA system (informal survey December, 2009), we focused on this form of teledermatology in this section. Readers interested in lessons learned from live interactive teledermatology programs are referred to Oakley et al. The following summary of key elements of facilitators and barriers to implementation are based on a review of the literature and the authors' experience with teledermatology within the VA.

Evaluate the Implementation Setting:

Prior to implementing a teledermatology program, a thorough evaluation of organizational issues for the specific VA setting is critical. Most Veterans Integrated Service Networks (VISNs) have at least one larger medical center with dermatology services whereas smaller VAMCs and Community Based Outpatient Clinics (CBOCs) usually do not have on-site dermatology services. There are three likely scenarios for implementing teledermatology in a VA setting:

Intrasite Service: Teledermatology services for a site which already has an onsite VA dermatology service. The main purpose of this type of service is usually triaging dermatology consults.

Intersite Service: Teledermatology services for a site which has no onsite VA dermatology services but a VA with a dermatology clinic is within reasonable driving distance.

New Service: Teledermatology services for a site which has no VA dermatology services. In this scenario, dermatology services are usually either provided by community dermatologists (fee basis or contract), by other VA specialties (surgery, ophthalmology, plastics, infectious diseases, etc), or by primary care without specialty support.

Define Objectives:

The objectives for these three VA scenarios may be very different. As described by Pak, 83 common objectives of teledermatology programs include: to improve access to dermatology, to optimize dermatology resources, to reduce dermatology costs, and/or to improve quality of health care (including educating primary care physicians). Identifying specific objectives will help determine the type of teledermatology service best suited for the program's goals. Because new systems require significant effort, it is crucial that key players (dermatologists, primary care providers, and administrators) perceive that the benefits outweigh the effort and commitment to learning a new system. In the framework of Rogers² this would be considered determining the relative advantage of teledermatology versus existing services.

Understand Organizational Issues:

Understanding how the VISN or specific medical center delivers dermatological care is important. This is consistent with the Greenhalgh et al.³ recommendation that implementation of teledermatology must be compatible with medical center's existing values, behaviors and past experiences. Lessons learned from teledermatology in the United Kingdom include that teledermatology is "not a quick nor simple fix for long waiting times in dermatology." Revenue models for Intrasite and Intersite situations are relatively simple as the main dermatology service already provides dermatology care. In these situations, the main goal is often to decrease waiting times and eliminate unnecessary visits to the dermatology clinic; physician workload generally remains stable for dermatology but may increase for primary care. For the New Service scenario, workload for both the dermatology hub site and remote primary care site increase. In this situation, fee basis/consultation costs for the remote site generally decrease; if the two sites have different operating budgets, there will need to be some type of transfer of funds to support the extra workload by the dermatology service. It is also important to realize that not all skin conditions are treatable via teledermatology, so some fee basis/consultation by the referring site to community dermatologists will continue in the New Service scenario and therefore, it is unlikely that these costs will be completely eliminated.

Evaluate and Provide Required Resources:

It is important to evaluate the resources (primary care, dermatology, and other specialty resources) at each site. For the Intrasite and Intersite situations, resources are usually a minor concern because any services not available in primary care are usually available in dermatology, which is either on site (Intrasite) or within driving distance (Intersite). There may be some simple resources needed in primary care (e.g., liquid nitrogen for treatment of warts and actinic keratoses) that will enhance management of common skin conditions in primary care without requiring a dermatology visit. If these additional resources are not created, teledermatology will simply function as a triage tool, eliminating only consultations for straightforward benign growths or treatment for simple skin rashes.⁷³ For the New Service scenario and the Intersite scenario, additional manpower will be needed for follow-up of teledermatology recommendations at the referring site. Often this is a primary care physician, physician assistant, or nurse practitioner who serves as a "local dermatology champion," someone who is willing to perform skin biopsies, microscopic examinations for fungus, bacteria and scabies, and other relatively minor procedures. If this creates extra workload for that individual, it is important that

this be recognized, and if needed, adjustments made to their schedule. Because approximately 50% of VA dermatology visits are related to skin neoplasms, it is important to identify surgical specialties at the referring site for excisions of biopsy-proven skin cancers (e.g., ophthalmology, plastics, general surgery, ear/nose/throat). A key component is whether the implementation scenarios developed are of relatively low complexity and easy to understand and use for both the dermatology and the referring primary care services. In an informal survey of VA dermatology service chiefs in December 2009, three sites volunteered information regarding reasons why they discontinued providing teledermatology services which included that teledermatology: was an ineffective use of physician time, resulted in suboptimal images, and that most patients ultimately needed to come to the dermatology clinic (unpublished).

Conduct Cost Analysis and Assess Alternatives to Teledermatology

One of the most common mistakes in planning teledermatology programs is to focus primarily on the cost of teledermatology equipment. Store and forward teledermatology equipment generally consists of an off-the-shelf, moderate quality digital camera. Personnel, not equipment costs, are the most important costs in a teledermatology program and all alternatives to teledermatology should be explored. In the New Service scenario, the major alternative is outsourcing (fee basis, consultation). Other common options include hiring a part-time dermatologist or a physician extender with dermatology training. Cost comparisons of teledermatology with these alternatives should include evaluation of the number of consults, number of dermatology visits typically required per patient, average cost per consultation, and the types of services typically provided by community dermatologists. For example, if the major services provided by community dermatologists are procedures, teledermatology is unlikely to yield cost savings because these procedures cannot be performed remotely unless a VA provider is hired or trained to perform these procedures.

Prepare a Business Model

The business model needs to incorporate support at the remote site for both obtaining and uploading photographs and dermatologic-specific medical history and for follow-up of teledermatology recommendations. This "teledermatology technician" is often a nurse practitioner, physician assistant, nurse, or other medical personnel. While one study found that it took an average of 12 minutes for a primary care physician to take pictures, upload the images, and subsequently implement advice, 93 for consistency of photo quality and efficiency of physician time, we do not advocate that primary care physicians function as imagers and/ or technicians. Collins and colleagues⁹⁴ collected data from 36 general practitioners (who were responsible for obtaining photographs and uploading information) participating in a randomized controlled trial of SAF teledermatology in the United Kingdom; 47% stated that they were not satisfied with teledermatology (21% were satisfied and 32% were unsure) and 50% identified increased workload as a key problem. In his review of teledermatology in the military, Pak stated that "teledermatology has not been embraced by primary care providers because it requires additional resources at the referring site (although less total resources for the higher organization). Most clinics were short on personnel and primary care providers did not have time to take photos."85 Implementation is more likely to succeed if the teledermatology technician is not the referring provider and has flexible duties so that he/she is available to perform

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teledermatology services when needed so that the patient does not have to return for imaging. Alternatively, patients can be scheduled at a later time into a teledermatology clinic at the remote site for imaging by the teledermatology technician.

A process for follow-up of teledermatology patients is also critical. In some situations, the teledermatology technician also serves as a coordinator, notifying patients of teledermatology recommendations, coordinating medication recommendations, suggested procedures and appropriate follow-up visits. In all three scenarios (Intersite, Intrasite, and New Service), teledermatology involves a shift from a dermatology referral model to a co-managed/consult model and more workload for primary care providers. Unless support for this increased workload is provided, the system is likely to fail.

Obtain Organizational Support

It is important to obtain support from key opinion leaders at both the referring site and the dermatology site. Medical center leadership, primary care, surgical subspecialties, dermatology, and pharmacy are important. If the referring site does not perceive a need for teledermatology, there will be minimal incentive to allocate space and resources. For the Intersite and New Service scenarios, the remote pharmacy may need to stock additional dermatology-specific medications and create quick pharmacy orders in the VA Computerized Patient Record System (CPRS). "Marketing" teledermatology to both dermatologists and primary care providers also requires creativity. As emphasized above, if workload increases for either or both services, incentives and support are critical for success. Benefits to primary care providers are often greatest in the New Service scenario. Providing education and quick consultative services to rural primary care physicians can be important motivators. Dermatologists and primary care providers must be involved in program planning from the outset to provide insight on the business model and workflow issues. It is also important to incorporate teledermatology into regular clinic procedures. For example, one teledermatology program failed, in part, simply because it took the dermatologist 15 minutes each way to walk to the telemedicine area. ⁸⁶

Provide Teledermatology Specific Training

The teledermatologist often provides hands on training for the teledermatology technician. Several helpful resources are available on dermatology-specific photography and recommended medical histories for teledermatology. 83,90,91,92 It is ideal if the teledermatology technician and local dermatology champion learn basic dermatology terminology, common skin conditions, and criteria for appropriate teledermatology consults. Periodic refresher training should also be included.

Table 11. Key Elements for Success and Barriers to Implementation

Facilitators for Implementation

Determine Relative Advantage

Define objectives

Evaluate alternatives to teledermatology

Clarify if relative risk of implementation is manageable

Conduct initial cost analysis and estimate

Assess Compatibility

Involve all parties in the planning and implementation process

Understand organization layout

Obtain buy-in from key players

Research resources available (primary care, specialty care, community)

Design Low Complexity System

Create easy to use system

Provide onsite technology support

Provide support at referring site (technician/consult manager)

Provide support for additional workload at dermatology site

Incorporate teledermatology into usual processes

Minimize patient waiting time

Ensure Trialability

Reconceptualize professional roles/duties and ensure high levels of flexibility

Provide training and feedback for teledermatology technician/consult manager

Analyze business process and refine

Demonstrate Observability

Determine if objectives are met, disseminate findings and evaluate improvement steps

Barriers to Implementation

Administrative:

Lack of initial administrative support

Lack of *ongoing* support

Clinical:

Insufficient training of primary care and dermatology in use of teledermatology

Single person trained who may not be available

Inertia among potential users (patients, primary care, dermatology)

Increased workload for primary care and dermatology without additional support

Lack of clinical follow-up

System does not fit objectives of the site

Emphasis on technology rather than practical implementation and ongoing support

Patient:

Patient inconvenience

Lack of education of participants (patients and providers)

Patient preference to see "in-person" dermatologist

Technical:

Software problems

Purchase of general teledermatology equipment rather than standard digital camera

Poor photo quality

Lack of standardization

SUMMARY AND DISCUSSION

This report summarizes a large body of evidence regarding: 1) teledermatology for the diagnosis of skin conditions, 2) teledermatology for the management of skin conditions, 3) clinical outcomes when teledermatology is used 4) the cost of teledermatology, and 5) key elements of and barriers to successful implementation of teledermatology. Differences in study settings, skin conditions, trial methodology, and outcomes weaken the strength of the evidence. When appropriate, we calculated weighted pooled estimates for similar studies. Summarized evidence indicates that diagnostic accuracy of usual care (in-person dermatology visit) is 5 to 19% (average absolute difference) better than teledermatology. When dermatoscopytrained teledermatologists are available, teledermatoscopy improves diagnostic accuracy of circumscribed skin lesions, although generally not to a level exceeding usual care. We found that diagnostic and management concordance of usual care (in-person dermatology visit) and teledermatology is good for SAF and may be better for LI, likely due to the ability to obtain additional history in the LI setting. Limited data from two SAF studies, both from the same VA medical center, show that while overall management accuracy rates are equivalent for SF teledermatology and usual care, teledermatology is significantly less accurate for malignant skin lesions including squamous cell carcinoma, basal cell carcinoma, and melanoma. While this finding needs to be confirmed in other settings and in other study populations, awareness of this potential limitation of teledermatology in a VA population is important.

Our search found very little evidence on clinical course, an important limitation also noted in a 2006 report from the Agency for Healthcare Research and Quality (AHRQ). Studies evaluating visits avoided uniformly showed that teledermatology can decrease the number of dermatology clinic visits. While studies of patient satisfaction were generally positive, factors such as distance to the dermatology clinic and wait times for an in-person appointment play important roles in patient satisfaction. Cost analyses were limited by broad variations in cost assessment parameters and perspectives. The majority of studies found teledermatology to be cost effective if certain critical assumptions were met; the most important included patient travel distance, teledermatology volume, and costs of usual care.

While evaluation of accuracy and reliability of a new technology is important, many more factors become important in evaluating clinical outcomes. Especially for SAF teledermatology, if recommendations are not communicated to the patient or not implemented by the referring provider, patient outcome is likely to be poor, despite a highly accurate and reliable technology. Because teledermatology involves a shift in workload, ongoing support (i.e., funding for a teledermatology technician, training for primary care physicians, additional dermatology staff) is critical. Barriers to implementation and key factors for success are highly dependent on the intended setting. Identifying site-specific barriers is critical to successful implementation.

CONCLUSIONS

In general, diagnostic accuracy of usual care (in-person dermatology care) is better than SAF teledermatology. Both SAF as well as LI teledermatology appear to have acceptable diagnostic and concordance compared to clinic dermatology. SAF is currently more widely used in the VA. Little information exists on the impact of teledermatology on clinical outcomes and management compared to management provided by in clinic dermatologists. This may be particularly

important for dermatologic conditions with potentially serious outcomes (e.g., malignant and premalignant lesions). Patient satisfaction with teledermatology is relatively high though there are individuals who have strong beliefs for a particular approach and little information exists from non-research settings regarding patient satisfaction. Cost analysis studies are limited in number and relevance to current VA practice. Identifying and removing barriers to successful implementation is essential. Studies are needed to compare teledermatology with primary care to inform decision making about the best way to provide dermatology in areas without reliable access to in-person dermatology (e.g., rural areas). Given the results of this review, the potential benefits of teledermatology (e.g., decreased patient travel, shorter time to intervention, primary care provider education) need to be evaluated in the context of its limitations including inferior diagnostic accuracy and management accuracy, especially for malignant skin neoplasms.

FUTURE RESEARCH RECOMMENDATIONS

Additional research is needed to determine the long-term effectiveness, feasibility, satisfaction, and cost-effectiveness of teledermatology (especially store and forward methodologies) integrated into primary care settings with outcomes related to the impact of teledermatology on patient management and clinical outcomes. Standardized reporting of diagnostic, management, and outcome accuracy and concordance are needed. Future studies should attempt to distinguish between lack of concordance between two in-person dermatologists and lack of concordance between teledermatology and in-person dermatology. Studies that blind assessors to the patient/lesion are preferred to reduce bias in outcome assessment. Additional outcomes could assess the impact on primary care practice, referring provider satisfaction, and follow-up patterns. Barriers to successful implementation need to be identified that incorporate differences in patient populations, lesion severity, and acuteness; distance traveled and availability of local dermatologists; and other clinical setting issues in order to determine the relative feasibility and effectiveness of different teledermatology strategies in different settings (e.g., Intrasite, Intersite, New Site).

Importantly, while this review suggests that diagnostic accuracy of teledermatology is inferior to in-person dermatologic care, teledermatology may still be superior to dermatologic care provided by a non-dermatologist; studies are needed to compare teledermatology with primary care. Additional research is needed to determine the long-term outcomes and cost-effectiveness of teledermatology (especially store and forward methodology) in the VA setting. We are aware of one randomized controlled study in progress (Impact of Teledermatology on Health Services Outcomes in the VA HSRD IIR05-278, PI John Whited) which will assess quality of life and nine-month clinical course outcomes in two VA SAF teledermatology programs.

We recommend prioritizing studies which address the following outcomes:

1. Comparison of teledermatology with dermatologic care by a VA primary care provider or a dermatology trained nurse practitioner: This study setting is very relevant to remote/inaccessible locations where no in-person dermatologist is available (e.g., Hawaii, Alaska, remote rural clinics). Relevant outcomes include diagnostic accuracy and concordance, management accuracy and concordance, long-term outcomes, cost-effectiveness, and patient/provider satisfaction.

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- 2. Comparison of teledermatology with in-person care by a dermatologist in a VA setting: Long-term clinical outcomes, patient and provider satisfaction, and cost analyses are needed. Additional outcomes should assess the impact of teledermatology on primary care practice and follow-up patterns. Barriers to successful implementation need to be identified that incorporate differences in patient populations, skin condition severity and acuteness, distance traveled, and availability of on-site dermatologists.
- 3. Comparison of specific imaging techniques to enhance teledermatology accuracy: More research is needed to understand the limitations of teledermatology (e.g., malignant skin neoplasms) and whether specific techniques (e.g., polarized light dermatoscopy, contact immersion dermatoscopy, and confocal microscopy) can overcome these limitations.
- 4. Evaluation of teledermatology to provide follow-up dermatologic care: Clinical outcomes, feasibility, and cost analyses are needed to evaluate chronic skin conditions which require frequent monitoring such as leg ulcers, post-operative wound care, and chronic dermatitis.

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