Assessment of asynchronous specialist dermatology services delivered by telecommunications

October 2014

MSAC application 1360

Assessment report

Electronic copies of the report can be obtained from the Medical Service Advisory Committee's Internet site at http://www.msac.gov.au/

Printed copies of the report can be obtained from:

The Secretary

Medical Services Advisory Committee

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Enquiries about the content of the report should be directed to the above address.

The Medical Services Advisory Committee (MSAC) is an independent committee which has been established to provide advice to the Minister for Health on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform government decisions about which medical services should attract funding under Medicare.

MSAC's advice does not necessarily reflect the views of all individuals who participated in the MSAC evaluation.

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Medical Services Advisory Committee – role and approach

The Medical Services Advisory Committee (MSAC) was established by the Australian Government to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Minister for Health on the evidence relating to the safety, effectiveness and cost-effectiveness of new and existing medical technologies and procedures, and under what circumstances public funding should be supported.

A rigorous assessment of evidence is thus the basis of decision making when funding is sought under Medicare. A team from Deakin Health Economics, Deakin University, was engaged to conduct a systematic review of the literature and an economic evaluation of *asynchronous specialist dermatology services delivered by telecommunications to patients with inflammatory skin conditions or skin lesions.*

Purpose of Application

An application requesting MBS listing of specialist dermatology services delivered by asynchronous store and forward technology for inflammatory skin conditions and skin lesions was received from Australasian College of Dermatologists by the Department of Health and Ageing in May 2013.

Description of the proposed intervention

The application relates to a new approach of providing specialist dermatology services. The application of store and forward technology enables patients who currently do not have access, or timely access, to specialist dermatology services to receive these services by an asynchronous specialist dermatology consultation delivered by telecommunications. As it is the current telecommunications system that allows for the provision of asynchronous consultations and not the store and forward technology per se, the application has been renamed to the 'Assessment of asynchronous specialist dermatology services delivered by telecommunications'.

There are two types of teledermatology which are defined by the patient's temporal relationship with the dermatologist; store-and-forward (SAF) and real time (RT). Store-and-forward technology is used to record a patient's clinical data and digital images of their dermatological condition (store), and to transfer this information, via the telecommunications network (forward), to a dermatologist who then responds with a diagnosis and therapeutic recommendation (asynchronous consultation) but not at the same time. RT or live interactive teledermatology uses synchronous data transfer technologies (videoconferencing) to communicate with all parties (e.g. GP, dermatologist and patient), and all parties to the consultation need to be available at the same time. This type of consultation is already provided for on the MBS. This assessment will use the terms 'asynchronous specialist dermatology services delivered by telecommunications' and store and forward teledermatology (SAF) interchangeably.

Table 1 compares the features of the two types of teledermatology.

Table 1: Feature comparison of Asynchronous and Synchronous teledermatology

Relative comparison	Store and Forward	Real Time
Virtual "hands-on" examination possible	No	Yes
Patient interactivity	None, written comments sent to referring provider	Live, by way of video link
Response time	Delayed	
Image quality	Still photos, usually higher quality	Live streaming video, usually lower quality
Bandwidth requirement	Lower	Higher
Scheduling requirement	Teledermatologist may review history and images at his/her convenience	Imager, patient, teledermatologist and patient-support must all be available at the same time
Time Requirement	Low	High
Convenience	Higher	Lower
Training	Low	Higher

Source: Levin and Warshaw, 2009 and Table 1 (IMCSF)

Is it a new intervention or an extension of use of a current intervention?

This is a new approach to providing specialist dermatology services which enables patients who currently do not have access, or do not have timely access, due to geographical or physical impediments, to receive specialist dermatology services via an asynchronous consultation and support of other health practitioners. It is not anticipated to be a substitute for face-to-face consultations, but to be used where it better serves the interests of patients and offers better use of resources. It is intended to have an impact on the delivery of specialist dermatology services and its implementation may result in a change in the relationship between a patient and their specialist.

Medical conditions being addressed by the proposed intervention

Patients with inflammatory skin conditions or skin lesions requiring specialist dermatology services are the target population for this service. These type of skin conditions include skin lesions, skin cancer eczema, psoriasis, acne, bacterial impetigo, fungal infection, varicella form eruption and amoxicillin-induced drug eruption.

Proposal for public funding

The applicant provided a proposed MBS item descriptor for the listing of asynchronous specialist dermatology services by telecommunications but did not indicate the MBS Schedule location, Table 2.

Table 2: Applicant's MBS item descriptor.

Category [category number] – [Category description]
MBS [item number] Dermatology-Asynchronous Initial Consultation Fee: $72.72 Referrer is required to complete dermatologist template and provide photos, both to a standard whereby the dermatologist can decide if asynchronous consultation is suitable
MBS [item number] Dermatology-Asynchronous Follow-up Consultation Fee: $36.36 Referrer is required to complete dermatologist template and provide photos, both to a standard whereby the dermatologist can decide if asynchronous consultation is suitable

The applicant's proposed restriction for this intervention is for currently eligible patients for MBS item 99 (those with inflammatory skin conditions or skin lesions who reside in the Eligible Telehealth Areas of Australia, or patients who are care recipients in a residential care service or Aboriginal Medical Service) and to extend eligible patient to include patients who reside in Outer Metropolitan Areas of Australia or who have a disability and who have difficulty travelling to a face-to-face specialist dermatology consultation. There are no restrictions proposed to patients due to prior interventions.

The service (consultation) will continue to be provided by specialist dermatologists. The specialist dermatologist may require training in the use of the SAF teledermatology.

The proposed MBS item descriptor in Table 3, has placed the requested intervention in Category 1 as the service that is described is a professional consultation. This is also where the MBS Telehealth items are placed.

Table 3: Proposed MBS descriptor and fee

Category 1 – Professional attendances
MBS [item number] Professional attendance on a patient by a specialist practicing in his or her speciality if: the attendance is by asynchronous telecommunications; and the attendance is for a service: the patient is not an admitted patient; and the patient: is located both: within a telehealth eligible area; and at the time of the attendance—at least 15 klms by road from the specialist; or Is a care recipient in a residential care service; or Is a patient of: an Aboriginal Medical Service; or an Aboriginal Community Controlled Health Service for which a direction made under subsection 19(2) of the Act applies; or *Resides in Outer Metropolitan Areas of Australia; or* *Resides in Major Cities and has a disability which prevents travelling. .* Fee: $72.72 Referrer is required to complete an online template, using store and forward technology, specified by the dermatologist, to a standard whereby the dermatologist can decide if asynchronous consultation is suitable
MBS [item number] Each attendance SUBSEQUENT to the first in a single course of treatment Fee: $36.36 Referrer is required to complete dermatologist template and provide photos, both to a standard whereby the dermatologist can decide if asynchronous consultation is suitable

The patient group that is proposed will be covered by this item is very similar to that for the telehealth items (see Table 4). The exception is that the application has requested that eligibility for SAF teledermatology be extended to cover people with disabilities and people who reside in Outer Metropolitan Areas of Australia who have difficulty travelling to a face-to-face consultation.

The proposed fee requested is 85% of the MBS items 104 and 105. The rationale for the requested fee is that it is a balance between increased dermatology responsibility and skills, plus risk, reduced by the time taken and convenience of the proposed store and forward technology. From the descriptor of the service it appears that the time a specialist dermatologist will be required to spend with a patient will be reduced due to the responsibility on the referrer to supply a detailed clinical history and digital images, explain to the patient the diagnosis and manage the treatment; responsibilities previously of the consultant.

The proposed MBS item descriptor has been formatted to be consistent with the current professional attendance items, in particular Items 105 and 99, which reimburse specialist consultations without specifically referring to any disease speciality.

Current arrangements for public reimbursement

Currently, there are MBS professional attendance items that cover specialist dermatology services delivered in face to face consultations with dermatologists (item 104 & 105) and telehealth items which provide for specialist dermatologist services in real-time by videoconference (item 99) but there are no MBS items available for providing these services via asynchronous specialist dermatology consultations delivered by telecommunications.

Telehealth items have a derived fee which is equal to 50% of the schedule fee for the consultation item claimed (e.g. 50% of the schedule fee for item 104) when billed with one of the associated consultation items (such as 104 or 105). A patient rebate of 85% for the derived fee is payable. In addition, new MBS item numbers were introduced to provide for an initial attendance via videoconferencing by a specialist, where the service is 10 minutes or less. These new items are stand alone and do not have a derived fee.

Table 4 summarises the current MBS Telehealth items that cover attendances for specialist dermatology services, in addition to the base MBS consultation items.

New MBS items were also introduced for Patient-end Services. These items enable GPs, other medical practitioners, nurse practitioners, midwives or Aboriginal health workers to provide clinical support to a patient during the consultation with the specialist. Table 5 lists these Telehealth MBS patient-support items.

Table 4: Current MBS consultation items providing specialist dermatology services and Telehealth specialist services

Category 1 –Professional attendances
MBS 104 SPECIALIST, REFERRED CONSULTATION - SURGERY OR HOSPITAL (Professional attendance at consulting rooms or hospital by a specialist in the practice of his or her specialty where the patient is referred to him or her) -INITIAL attendance in a single course of treatment, not being a service to which ophthalmology items 106, 109 or obstetric item 16401 apply. Fee: $85.55 Benefit: 75% = $64.20 85% = $72.75 Extended Medicare Safety Net Cap: $256.65
MBS 105 Each attendance SUBSEQUENT to the first in a single course of treatment Fee: $43.00 Benefit: 75% = $32.25 85% = $36.55 Extended Medicare Safety Net Cap: $129.00
MBS 99 Professional attendance on a patient by a specialist practising in his or her specialty if: (a) the attendance is by video conference; and (b) the attendance is for a service: (i) provided with item 104 lasting more than 10 minutes; or (ii) provided with item 105; and (c) the patient is not an admitted patient; and (d) the patient: (i) is located both: (A) within a telehealth eligible area; (B) at the time of the attendance—at least 15 kms by road from the specialist; or (ii) is a care recipient in a residential care service; or (iii) is a patient of: (A) an Aboriginal Medical Service; or (B) an Aboriginal Community Controlled Health Service; for which a direction made under subsection 19 (2) of the Act applies Telehealth Item 50% of the fee for item 104 or 105. Benefit: 85% of the derived fee Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount (See para A58 of explanatory notes to this Category
MBS 113 Initial professional attendance of 10 minutes or less in duration on a patient by a specialist practising in his or her specialty if: (a) the attendance is by video conference; and (b) the patient is not an admitted patient; and (c) the patient: (i) is located both: (A) within a telehealth eligible area; and (B) at the time of the attendance-at least 15 kms by road from the specialist; or (ii) is a care recipient in a residential care service; or (iii) is a patient of: (A) an Aboriginal Medical Service; or (B) an Aboriginal Community Controlled Health Service; for which a direction made under subsection 19 (2) of the Act applies; and (d) no other initial consultation has taken place for a single course of treatment. Fee: $64.20 Benefit: 85% = $54.60 (See para A58 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: $192.60

Table 5: Telehealth Patient-end Support Services by Health professionals

MBS 2100 Level A - Telehealth attendance at consulting rooms Professional attendance at consulting rooms of at least 5 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who: (a) is participating in a video conferencing consultation with a specialist or consultant physician; and (b) is not an admitted patient; and (c) either: (i) is located both: (A) within a telehealth eligible area; and (B) at the time of the attendance-at least 15 kms by road from the specialist or physician mentioned in paragraph (a); or (ii) is a patient of: (A) an Aboriginal Medical Service; or (B) an Aboriginal Community Controlled Health Service for which a direction made under subsection 19 (2) of the Act applies Telehealth Item Fee: $22.90 Benefit: 100% = $22.90 (See para A57 of explanatory notes to this Category
MBS 2122 Level A - Telehealth attendance other than at consulting rooms Professional attendance not in consulting rooms of at least 5 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who: (a) is participating in a video conferencing consultation with a specialist or consultant physician; and (b) is not an admitted patient; and (c) is not a care recipient in a residential care service; and (d) is located both: (i) within a telehealth eligible area; and (ii) at the time of the attendance-at least 15 kms by road from the specialist or physician mentioned in paragraph (a); for an attendance on one or more patients at one place on one occasion-each patient Telehealth Item The fee for item 2100 plus $25.95 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2100 plus $2.00 per patient. Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount
MBS 2125 Level A - Telehealth attendance at a residential aged care facility A professional attendance by a medical practitioner (not being a service to which any other item applies) lasting at least 5 minutes (whether or not continuous) that requires the provision of clinical support to a patient who is: a) a care recipient receiving care in a residential aged care service (other than a professional attendance at a self-contained unit); or b) at consulting rooms situated within such a complex where the patient is a resident of the aged care service (excluding accommodation in a self-contained unit) and who is participating in a video consultation with a specialist or consultant physician, on 1 occasion - each patient. Telehealth Item The fee for item 2100 plus $46.70 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2100 plus $3.30 per patient. Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount (See para A57 of explanatory notes to this Category)
MBS 2126 Level B - Telehealth attendance at consulting rooms

Professional attendance at consulting rooms of less than 20 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who:

(a) is participating in a video conferencing consultation with a specialist or consultant physician; and

(b) is not an admitted patient; and

(c) either:

(i) is located both:

(A) within a telehealth eligible area; and

(B) at the time of the attendance-at least 15 kms by road from the specialist or physician mentioned in paragraph (a); or

(ii) is a patient of:

(A) an Aboriginal Medical Service; or

(B) an Aboriginal Community Controlled Health Service for which a direction made under subsection 19 (2) of the Act applies

Telehealth Item

Fee: $49.95 Benefit: 100% = $49.95

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: $149.85

MBS 2137

Level B - Telehealth attendance other than at consulting rooms

Professional attendance not in consulting rooms of less than 20 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who:

(a) is participating in a video conferencing consultation with a specialist or consultant physician; and

(b) is not an admitted patient; and

(c) is not a care recipient in a residential care service; and

(d) is located both:

(i) within a telehealth eligible area; and

(ii) at the time of the attendance-at least 15 kms by road from the specialist or physician mentioned in paragraph (a);

for an attendance on one or more patients at one place on one occasion-each patient

Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount

Telehealth Item

The fee for item 2126 plus $25.95 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2126 plus $2.00 per patient.

(See para A57 of explanatory notes to this Category)

MBS 2138

Level B - Telehealth attendance at residential aged care facility

Professional attendance of less than 20 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who:

(a) is participating in a video conferencing consultation with a specialist or consultant physician; and

(b) is a care recipient in a residential care service; and

(c) is not a resident of a self-contained unit;

for an attendance on one or more patients at one place on one occasion-each patient

Telehealth Item

The fee for item 2126 plus $46.70 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2126 plus $3.30 per patient.

Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount

(See para A57 of explanatory notes to this Category

MBS 2143

Level C - Telehealth attendance at consulting rooms

Professional attendance at consulting rooms of at least 20 minutes in duration (whether or not continuous) by a medical practitioner who provides clinical support to a patient who:

(a) is participating in a video conferencing consultation with a specialist or consultant physician; and

(b) is not an admitted patient; and

(c) either:

(i) is located both:

(A) within a telehealth eligible area; and

(B) at the time of the attendance - at least 15 kms by road from the specialist or physician mentioned in paragraph (a); or

(ii) is a patient of:

(A) an Aboriginal Medical Service; or

(B) an Aboriginal Community Controlled Health Service for which a direction made under subsection 19 (2) of the Act applies

Telehealth Item

Fee: $96.85 Benefit: 100% = $96.85

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: $290.55

MBS 2147

Level C - Telehealth attendance other than at consulting rooms

Professional attendance not in consulting rooms of at least 20 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who:

(a) is participating in a video conferencing consultation with a specialist or consultant physician; and

(b) is not an admitted patient; and

(c) is not a care recipient in a residential care service; and

(i) is located both:

(A) within a telehealth eligible area; and

(B) at the time of the attendance - at least 15 kms by road from the specialist or physician mentioned in paragraph (a);

for an attendance on one or more patients at one place on one occasion-each patient

Telehealth Item

The fee for item 2143 plus $25.95 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2143 plus $2.00 per patient.

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount

MBS 2179

Level C - Telehealth attendance at residential aged care facility

A professional attendance by a medical practitioner (not being a service to which any other item applies) lasting at least 20 minutes (whether or not continuous) that requires the provision of clinical support to a patient who is:

a) a care recipient receiving care in a residential aged care service (other than a professional attendance at a self-contained unit); or

b) at consulting rooms situated within such a complex where the patient is a resident of the aged care service (excluding accommodation in a self-contained unit);

and who is participating in a video consultation with a specialist or consultant physician, on 1 occasion - each patient.

Telehealth Item

The fee for item 2143 plus $46.70 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2143 plus $3.30 per patient.

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount

MBS 2195

Level D - Telehealth attendance at consulting rooms

Professional attendance at consulting rooms of at least 40 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who:

(a) is participating in a video conferencing consultation; and

(b) is not an admitted patient; and

(c) either:

(i) is located both:

(A) within a telehealth eligible area; and

(B) at the time of the attendance - at least 15 kms by road from the specialist or consultant physician mentioned in paragraph (a); or

(ii) is a patient of:

(A) an Aboriginal Medical Service; or

(B) an Aboriginal Community Controlled Health Service for which a direction made under subsection 19 (2) of the Act applies

Telehealth Item

Fee: $142.50 Benefit: 100% = $142.50

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: $427.50

MBS 2199

Level D - Telehealth attendance other than at consulting rooms

Professional attendance not in consulting rooms of at least 40 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who:

(a) is participating in a video conferencing consultation with a specialist or consultant physician; and

(b) is not an admitted patient; and

(c) is not a care recipient in a residential care service; and

(d) is located both:

(i) within a telehealth eligible area; and

(ii) at the time of the attendance - at least 15 kms by road from the specialist or physician mentioned in paragraph (a);

for an attendance on one or more patients at one place on one occasion-each patient

Telehealth Item

The fee for item 2195 plus $25.95 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2195 plus $2.00 per patient.

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount

MBS item 2220

Level D - Telehealth attendance at residential aged care facility

A professional attendance by a medical practitioner (not being a service to which any other item applies) lasting at least 40 minutes (whether or not continuous) that requires the provision of clinical support to a patient who is:

a) a care recipient receiving care in a residential aged care service (other than a professional attendance at a self-contained unit); or

b) at consulting rooms situated within such a complex where the patient is a resident of the aged care service (excluding accommodation in a self-contained unit);

and who is participating in a video consultation with a specialist or consultant physician, on 1 occasion - each patient.

Telehealth Item

The fee for item 2195 plus $46.70 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2195 plus $3.30 per patient.

Ready Reckoner

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount

Consumer Impact Statement

In a letter to the DoH, dated 28 March 2014, the Consumers Health forum of Australia (CHF) indicated that they support Medicare Benefits Schedule (MBS) reimbursement for a specialist dermatology service using store-and-forward technology, where patient information and digital images are sent by telecommunication services to a treating specialist dermatologist for diagnosis and treatment recommendations. They note that this service has the potential to remove the disadvantages experienced by people living in regional, rural and remote parts of Australia including lack of access and choice of both diagnostic and treating options and high financial and time-related costs.

Clinical need

Australia has a widely dispersed population with the majority of the population concentrated into major cities. Patient's access to dermatology services in Australia is limited due to mal-distribution of dermatologists and specialist workforce shortage. There is a scarcity of dermatologists, and most practice in the major cities with wait times often up to six months. Rural patients face barriers to access dermatologist due to long travelling times.

Skin conditions are the third most common condition seen by GPs. Skin conditions are usually not fatal but they can be painful, uncomfortable, and disfiguring. Skin cancers are an increasing problem in fair skinned populations around the world, particularly in Australia, that has the highest age-standardised rates of melanoma of the skin 937 per 100,000 (which is more than 12 times the average world rate 93 per 100,000). The non-melanoma skin cancers, includes basal cell carcinoma and squamous cell carcinoma, and together their incidence is more than five times the incidence of other cancers combined making these cancers by far the most expensive cancers to treat.

It is estimated that in total across Australia GPs see around 21.43 million patients a year with a skin problem. Although dermatologists are not one of the main medical specialities, dermatologists are among the most frequently receiving referrals from GPs. In 2012-13 7% of patients with skin complaints were referred. However, GPs, in large rural and small rural areas refer less frequently at only 4%, indicating unmet demand by rural patients for face-to-face dermatology consultations.

Likely changes in management algorithms

Currently, patients are referred to specialist dermatology services by their GP by a referral letter. For the identified population, in the absence of asynchronous specialist dermatology consultations by telecommunications, there is unmet demand for face-to-face dermatology consultations in rural areas, as evidenced by the lower referral rate to dermatologist from rural GPs compared to metro GPs. The applicant suggested that there is also unmet demand among people residing in Outer Metropolitan areas and for people with disabilities. This unmet demand is partially met with the use of videoconferencing to deliver RT specialist dermatology services in Eligible Telehealth Areas and by GPs treating these patients.

In the proposed clinical management scenario where asynchronous specialist dermatology consultations are available, the GP will refer a patient for this type of consultation. The GP will be responsible for providing the clinical history and images to the specialist, in a format

requested by the specialist, to enable the SAF consultation to proceed. After diagnosis the GP will also take on the responsibility for communicating the diagnosis to the patient and treatment management under the specialist's guidance.

In the proposed clinical management scenario patients residing in Eligible Telehealth Areas and for patients who reside in Outer Metropolitan Areas or with disabilities SAF teledermatology will be available for a GP to refer for an asynchronous specialist dermatology consultation.

The proposed service will be restricted to specialist dermatologists who can accept or refuse a teledermatology consultation and instead request they see a patient face-to-face.

Comparator

With respect to the population residing in Eligible Telehealth areas, the proposed service, asynchronous specialist dermatology consultation delivered by telecommunications, is expected to substitute for the standard MBS Telehealth items for professional attendance of specialist dermatologist in real-time by videoconference including patient-end Telehealth items.

With respect to the population that resides in Major Cities, (either in Outer Metropolitan Areas or people with disabilities) should they be granted eligibility for SAF teledermatology services, the proposed service is expected to substitute for a proportion of face-to-face consultations by a dermatologist.

The substituted specialist dermatology services, standard MBS Telehealth items, for professional attendance and patient-level support services and face-to-face consultation items are listed on the MBS (see Table 4 and Table 5).

Scientific basis of comparison

The results of diagnostic accuracy and diagnostic concordance studies are presented with respect to the primary diagnosis. The outcomes assessed are diagnostic accuracy (defined as proportion of correct primary diagnoses using histology results as a gold standard) and diagnostic concordance (defined as proportion of correct primary diagnoses using face-to-face dermatology consultation as a reference standard). Typically diagnostic accuracy was reported in the trials of skin lesions and diagnostic concordance was reported in the trials of inflammatory skin conditions.

Primary sources of evidence

A systematic literature search identified 13 systematic reviews on the subject of teledermatology but only one Warshaw (2011) was assessed as meeting the research question and quality requirements. The results of this systematic review are replicated in the assessment.

Ten studies formed an evidence base for assessing the diagnostic accuracy of SAF teledermatology. Seven of these studies directly compared SAF teledermatology and FTF in primary diagnosis of skin lesions using histopathology as a gold standard.

We identified only one small sample size head-to-head trial that directly compared SAF and VC modalities using FTF presentation as a common reference standard (Edison, 2008).

Fifteen studies on diagnostic concordance of SAF teledermatology using face-to-face clinical consultation as the reference standard were included in the pooled analysis.

Eight studies were identified on the diagnostic concordance of VC teledermatology using FTF consultation as the reference standard.

The overall summary of the sources of the evidence is presented in Table 6.**Error! Reference source not found.**.

Table 6: Body of evidence assessment matrix—SAF compared to VC

Evidence base	Excellent	1.One systematic review of teledermatology
	Good	2. Two level II comparative studies of diagnostic accuracy with low risk of bias (SAF vs FTF)
	Satisfactory	3. One level II concordance studies with moderate risk of bias
		4. Two level III-1 comparative studies of diagnostic accuracy (comparison with SAF vs FTF)
		5. One head-to head study III-1, without consecutive enrolment. Trial is underpowered
	Poor	6. Fourteen concordance studies were level III-1 or III-2.
		7.Three III-1 comparative studies of diagnostic accuracy (comparison with SAF vs FTF)
		8. Three III-1 diagnostic accuracy studies of SAF
Consistency	Good	Most studies consistent and inconsistency may be explained
Clinical impact	Good	Diagnostic accuracy used to determine the safety and effectiveness of the intervention
Generalisability	Good	Population/s studied in the body of evidence are similar to the target population
Applicability	Good	applicable to Australian healthcare context with few caveats, in particular how the service will be configured

Safety of asynchronous specialist dermatology services.

The literature search did not locate any reports that related to studies that specifically addressed the safety of SAF teledermatology. There are no inherent safety issues with providing patient clinical history and digital images by telecommunications rather than a patient being seen face-to-face.

Safety issues can arise with any diagnostic test in the form of false positives and false negatives. There is conflicting data on the accuracy of SAF teledermatology for the diagnosis of pigmented lesions and exclusion of melanoma.

Variations in digital photographic and dermatoscopic techniques and experience are suggested as reasons for the conflicting safety data. Development of quality standard to bring together best practice and existing guidance is recommended to overcome this variation.

Key Results

The high quality systematic review assessed diagnostic performance separately by the type of lesions, and stated that the diagnostic concordance of SAF was good, although the rates for VC were higher, albeit based on the fewer patients (Warshaw, 2011). Statistical pooling of 11 primary diagnosis studies in which SAF teledermatology was used to diagnose skin lesions

reported that the weighted mean absolute difference was 11% better for FTF consultation than SAF teledermatology.

The head-to-head primary diagnosis study compared SAF and VC modalities with respect to diagnostic and management concordance (using FTF as a reference standard). More identical diagnoses were given for FTF and VC examinations than for FTF and SAF examinations (80% versus 73%) but the difference was not statistically significant. Overall teledermatology (both VC and SAF modalities) demonstrated good performance in comparison to FTF consultation for diagnostic concordance (Edison, 2008).

A meta-analysis was conducted of the identified studies comparing proportions of correct primary diagnosis obtained by SAF teledermatologist and FTF dermatologist (using histology results as a gold standard for diagnostic accuracy). Diagnostic accuracy of FTF dermatologists was superior to teledermatology irrespective of the addition of teledermatoscopy, OR 0.65[0.56, 0.76] if SAF used digital images only and 0.76 [0.61, 0.95] if SAF used dermoscopy with or without digital images.

Thirteen studies evaluated diagnostic concordance of SAF teledermatology, with digital images only, using a primary diagnosis as the outcome. The weighted average estimate of a primary diagnosis concordance of all skin conditions was 64.5% (95% CI 57.4-71.5).

Six studies evaluated diagnostic concordance of VC teledermatology using a primary diagnosis as an outcome. The weighted average estimate of a primary diagnosis concordance of all skin conditions was 70.6% (95% CI 62.4-78.9). This is higher than the weighted average estimate of a primary diagnosis concordance of all skin conditions (64.5% 95% CI 57.4-71.5), assessed with SAF teledermatology. However the evidence base of VC teledermatology is considerably smaller and of a poorer quality. These pooled results did not directly compare SAF to VC.

Economic evaluation

The objective of the analysis was to compare cost-effectiveness of interventions in two settings:

- Where SAF teledermatology is not available
- Where SAF teledermatology is available to meet unmet demand for specialist dermatology services

A number of different economic evaluations are presented in the body of the report.

1) Given the absence of evidence of statistically significant difference in diagnostic performance between SAF teledermatology and VC teledermatology the basecase economic evaluation is a cost minimisation analysis where the costs of a correct diagnosis with SAF is compared to the cost of a correct diagnosis using VC teledermatology. To undertake this analysis proportions of patients to be diagnosed by GP and FTF were set to zero.

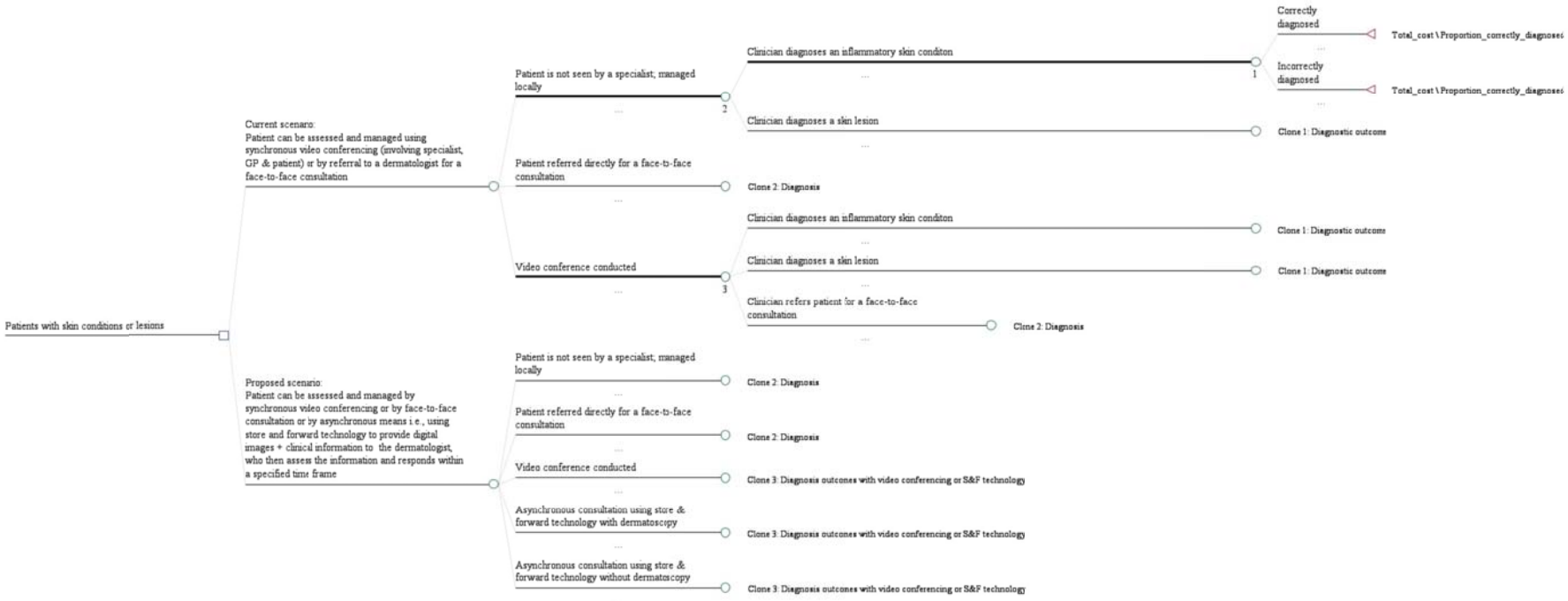
2) A variation of the basecase economic evaluation employed the full model described in Figure 1 to do the cost-effectiveness analysis in which the estimates of diagnostic performance between SAF teledermatology and VC teledermatology remains equal but the proportion of patients diagnosed by their GP reduces due to SAF becoming available. Incremental cost per additional patient correctly diagnosed based on the primary diagnosis is estimated.

The cost minimisation basecase analyses is conducted with and without the use of teledermoscopy to diagnose skin lesions. Sensitivity analysis is performed around the

assumption of equivalence in diagnostic performance between SAF teledermatology and VC teledermatology; or the introduction of a GP payment for referral for a SAF teledermatology consultation; or the cost of SAF; or the proportion of VC consultation after introduction of SAF teledermatology and the proportion of FTF consultations being averted after introduction of SAF dermatology.

The economic analysis is conducted over the time required to diagnose the patient, which is assumed to be either instantaneous (VC modality) or to arrive within one week (SAF modality). The structure of the economic model is summarised diagrammatically in Figure 1.

Figure 1. Structure of the economic analysis



The resource variables considered in the economic evaluation includes the cost of GP consultation, the cost of specialist consultation (e.g. VC, SAF), the cost of patient-support staff for videoconferencing, the cost of a digital camera, with and without a dermatoscope and the cost of software (e.g. TeleDerm). The estimates of the proportion of the population with skin lesions and inflammatory skin conditions were obtained from the literature.

Table 7 lists the probabilities used in the Model and their sources.

Table 7: Probabilities assigned in the model

Intervention & outcomes	Probabilities used in the model	Probabilities used in the sensitivity analysis	Source
Diagnostic accuracy FTF (skin lesions)	0.573		Pooled estimate from two large trials (Warshaw 2009a,b)
Diagnostic concordance FTF (inflammatory skin conditions)	1.0	1.00	Reference standard
Diagnostic accuracy GP (skin lesions)	0.23		Tran 2005
Diagnostic concordance GP (inflammatory skin conditions)	0.45		Tran 2005
Diagnostic accuracy VC (skin lesions)	0.465		Assumed the same as SAF diagnostic accuracy
Diagnostic concordance VC (inflammatory skin conditions)	0.64	0.80	In base case assumed equal effectiveness to SAF Sensitivity analysis (Edison, 2008)
Diagnostic accuracy SAF no teledermoscopy (skin lesions)	0.465		Pooled estimate from two large trials (Warshaw 2009a,b)
Diagnostic concordance SAF no teledermoscopy (inflammatory skin conditions)	0.64	0.73	Pooled estimate for basecase Sensitivity analysis (Edison, 2008)
Diagnostic accuracy SAF with teledermoscopy (skin lesions)	0.47	0.73	Pooled estimate (Warshaw 2009a,b) assumption in sensitivity analysis
Diagnostic concordance SAF with teledermoscopy (inflammatory skin conditions)	0.75	0.75	Bowns, 2006

Basecase analysis

The results of the economic evaluations are summarised in Table 8, cost-minimisation analysis (with dermatoscopy and without dermatoscopy) and Table 9, cost-effectiveness analysis.

Table 8: Results of the cost minimisation

Intervention	Total costs
Video-conferencing specialist dermatology services	$299.48
Asynchronous specialist dermatology services	
▪ Without dermatoscopy images	$185.82
Increment for SAF without dermatoscopy vs VC consultation	-$113.66
▪ With dermatoscopy images	$188.00
Increment for SAF with dermatoscopy vs VC consultation	-$111.48

As can be seen from Table 8, results from the scenario where dermatoscopy is not used, and the diagnostic performance of SAF and VC are assumed to be equal, results in SAF costing less by $113.66. Where dermatoscopy is used, and the diagnostic performance of SAF and VC are assumed to be the same, SAF costs less by $111.48, reflecting the slightly improved diagnostic accuracy with the use of dermatoscopy.

Table 9: Results of modelled economic evaluation current and proposed scenario where SAF becomes available

Intervention	Total costs	Outcome (proportion of patients correctly diagnosed)	ICER
Current scenario	$133.83	60.39%	-
Proposed scenario	$147.43	62.51%	-
Increment for SAF vs VC consultation	$13.60	2.12%	$642.22

Table 9 presents the results of an economic evaluation of the full economic model comparing the current scenario where a proportion of patients are treated by their GP (unmet demand for specialist dermatology services) or some are referred for FTF consultation or VC teledermatology with the proposed scenario where SAF teledermatology is introduced and the proportion of patients currently treated by their GP is reduced as they are referred for SAF teledermatology. Diagnostic performance between SAF and VC is assumed equal and the proportions of patients referred to FTF consultation after unsuccessful VC or SAF examination is retained. The incremental cost per additional correct diagnosis in the proposed scenario where SAF teledermatology is available is $642.22.

The applicant has requested a reimbursement for SAF teledermatology service that is based on reimbursement and not the cost of delivering the service. A cost, $141.37 for clinical services, based on ACRRM estimates, is assumed in the basecase analysis. The applicant's requested fee was determined by applying a fraction (85%) to MBS item 104 and 105. The requested fee is $72.72. Table 10 and Table 11 rerun the cost-minimisation analysis and the cost-effectiveness analysis varying the cost of SAF to equate to this requested fee.

Table 10: Cost-minimisation sensitivity analysis varying cost of SAF

Intervention	Total costs
Video-conferencing specialist dermatology services	$299.48
Asynchronous specialist dermatology services	
Without dermatoscopy images	$117.17
Increment for SAF without dermatoscopy vs VC consultation	-$182.30
With dermatoscopy images	$119.35
Increment for SAF with dermatoscopy vs VC consultation	-$180.13

Table 11: Sensitivity analysis of modelled economic evaluation varying cost of SAF

Intervention	Total costs	Outcome (proportion of patients correctly diagnosed)	ICER
Current scenario	$133.83	60.39%	-
Proposed scenario	$141.98	62.51%	-
Increment for SAF without dermatoscopy vs VC consultation	$8.14	2.12%	$384.76

The analyses presented above indicates that the model results are sensitive to the change in the cost of SAF teledermatology, with the cost minimisation estimating a saving of $180.13 and the cost-effectiveness analysis resulting in a 40% reduction in the ICER to $384.76.

Sensitivity analyses conducted shows that the results are sensitive to the variations in the estimates of the reduction in proportion of patients referred to VC (by 90%) after SAF becomes available (reduction in ICER by $200 in comparison to the basecase, although the diagnostic performance has also reduced) (Table 62).

The results are especially sensitive to the assumption that the proportion of patients currently referred to FTF will be diagnosed by SAF teledermatology (23%, Eminovich 2003). If this assumption is correct, the incremental cost per correct diagnosis marginally increases while diagnostic performance of the proposed scenario becomes inferior to the current scenario;

The results are fairly robust to the assumption of zero re-referral rates to FTF after unsuccessful SAF or VC teledermatology consultations; or to the small variation in the cost of GP consultation associated with SAF referral. The results are robust to the assumption of applying an additional cost for the GP time involved in the SAF consultation referral; the ICER was $674.69.

It was requested that the economic analysis of SAF teledermatology do a scenario analysis where patients with disabilities residing in Major Cities (outside Eligible Telehealth Areas) are able to access SAF for specialist dermatology services. In this case patients will substitute a FTF consultation for a SAF teledermatology consultation. Table 12 presents this scenario, in which it is assumed that in the current scenario, patients with profound and severe impairment to their core functioning, as defined by the ABS, will be managed by their GP, while patients with mild to moderate impairment to core functioning, will be referred for specialist consultation. In the proposed scenario, where SAF is available, 18% of patients with profound and severe impairment to their core functioning currently treated by their GP

will be treated by SAF, and 23% the other patients with moderate to mild impairment currently treated by a FTF consultation will be treated by SAF.

Table 12: Cost-effectiveness and sensitivity analyses of the SAF becoming available to people with disabilities residing outside eligible areas

Intervention	Total costs	Proportion of patients correctly diagnosed	ICER
Not including the extra time cost of GP for a SAF referral			
Current scenario (GP+FTF)	$144.63	65.76%	-
Proposed scenario (GP+FTF+SAF)			
A proportion of patient managed by GP and FTF is diverted to SAF	$156.70	64.34%	
Increment	$12.08	-1.42%	SAF is Dominated
A proportion of patient managed by GP is diverted to SAF	$155.05	67.39%	
Increment	$10.42	1.62%	$642.21
Including the extra time cost of GP for a SAF referral			
Current scenario (GP+FTF)	$144.63	65.76%	-
Proposed scenario (GP+FTF+SAF)			
A proportion of patient managed by GP and FTF is diverted to SAF	$156.70	64.34%	
Increment	$12.08	-1.42%	SAF is Dominated
A proportion of patient managed by GP is diverted to SAF	$155.58	67.39%	
Increment	$10.95	1.62%	$674.69

The cost-effectiveness analysis of two scenarios with respect to the population with disability residing in the outer metropolitan areas generally replicates the results of the cost-effectiveness analysis of the target population where is assumed that most patients referred for SAF teledermatology are currently treated by their GP. The basecase analysis assumes that a proportion of patients being managed by GPs are referred for SAF teleconsultation and produces an identical ICER ($642.21). However when the proportion of patients who are currently referred by GP for FTF consultations is assumed to be diverted to SAF, SAF teledermatology is dominated, it is both less effective and more expensive. The results are robust to whether a cost for the time for the GP to do the referral to SAF teledermatology is included.

Financial/budgetary impacts

There is a difference of 3% between the rate at which rural GPs refer their patients with skin conditions for a face to face consultation with a dermatologist (4%) and the average rate at which Australian GPs referred their patients with skin conditions to a dermatologist (7%). This difference between the current rural population referred to a specialist dermatologist

and the potential population is calculated in Table 13. It was estimated that the potential size of the population for asynchronous specialist dermatology services is likely to be the difference in the number of patients referred by rural GPs to dermatologists and the rate at which their urban counterparts refer to dermatologists.

Table 13: Number of patients referred to dermatologist from outside metropolitan areas

		2014	2015	2016	2017	2018
Rural pts referred to dermatologist	At 7%	468,013.73	475,969.96	484,061.45	492,290.50	500,659.43
Rural patients referred to dermatologists	At 4%	267,436	271,983	276,607	281,309	286,091
Difference Unmet demand for dermatologist services		200,577.31	203,987.13	207,454.91	210,981.64	214,568.33

The low rate of take up of real time specialist teledermatology services may be due to a number of reasons:

- The need for sufficient bandwidth to enable adequate vision for the dermatologist. Expert advice is that Skype is not adequate
- Difficulty of co-ordinating a time for the videoconference (Australia has 3 time zones) and to co-ordinate all the different parties
- The availability of the TeleDerm service provided by ACRRM which may address GP need for dermatology advice

Table 14 provides an estimate of the reimbursement paid in 2014-2018, for the current services, including videoconferencing, at the current demand for them. The financial implications to Medicare are estimated at between $26.2M in 2014 to $28.0M in 2018.

Table 14: Medicare Benefits paid for dermatology services to patients outside metropolitan areas, treated by specialist dermatologist & GPs

		2014	2015	2016	2017	2018
		Current nos.	Projected growth			
Benefit paid 99 services	85%	320,161	325,603	331,139	336,768	342,493
Benefits paid 104 services	85%	10,618,434	10,798,948	10,982,530	11,169,233	11,359,110
Benefits paid 105 services	85%	4,368,144	4,442,403	4,517,923	4,594,728	4,672,839
Subtotal		15,306,739	15,566,954	15,831,592	16,100,729	16,374,441
Benefits paid for GP treat 4% of patients specialist skin conditions	Average of Level B & Level C $54.38*N	10,906,391	11,091,800	11,280,361	11,472,127	11,667,153
Total $		26,213,130	26,658,754	27,111,953	27,572,856	28,041,594

Table 14 estimates the current yearly costs of treatment of dermatological conditions that require specialist dermatology services. The assumptions underlying this table are that 3% of

patients with skin conditions, in rural and remote areas of Australia, that require specialist dermatology services are instead treated by their GP. The costs of GP treatment are included. With population growth factored in the total cost to Medicare of treating skin conditions requiring specialist dermatology services is $28million in 2018.

Table 15 estimates the financial implications to the government if store and forward is available, and there is no change in demand for VC. It is assumed that 2,000 GPs take part in the first year in SAF (based on estimates from ACRRM) increasing by 1,000 GPs a year up to a maximum of 6,000 GPs, in 2018; around 60% of GPs participating in SAF. These estimates indicate that there is likely to be a small financial impact to the government from the listing of Store and Forward, approximately $900,000 in 2018 (if compared to total in 2018 in Table 14) (this figure is likely to be lower if it is assumed that SAF substitutes for VC, as it is a cheaper technology).

Table 15: Medicare Benefits paid if patients reside outside metropolitan areas and SAF is available

		2014	2015	2016	2017	2018
		Current nos.	Projected growth			
Benefit paid 99 services	85%	320,161	325,603	331,139	336,768	342,493
Benefits paid 104 services	85%	10,618,434	10,798,948	10,982,530	11,169,233	11,359,110
Benefits paid 105 services	85%	4,368,144	4,442,403	4,517,923	4,594,728	4,672,839
Subtotal		15,306,739	15,566,954	15,831,592	16,100,729	16,374,441
Benefits paid for GP treat of patients	Average of Level B & Level C $54.38*N	8,893,213	8,020,697	7,115,945	6,178,113	5,206,339
Benefits paid for SAF		2,288,525	3,491,145	4,733,993	6,018,088	7,344,475
Total $		26,488,478	27,078,796	27,681,530	28,296,931	28,925,255

**expert advice from ACRRM is that 2000 GPs out of workforce of 10,500 use service

One of the recommendations of the protocol and expert advice is that there may need to be a separate MBS item created for referrers to recognise the extra time they will incur to take an extensive clinical history, take the digital images with the requisite expertise and to upload this data to the dermatologist's SAF portal. Expert advice is that obtaining this information could take between 15-30 minutes depending on how extensive the skin involvement is. Table 16 estimates this likely additional cost to the MBS as well as the substitution of VC technology to deliver specialist dermatology services by SAF.

Table 16: Medicare Benefits paid if patients reside outside metropolitan areas and SAF is available and MBS item available for referrer

		2014	2015	2016	2017	2018
Benefits paid for SAF		2,288,525	3,491,145	4,733,993	6,018,088	7,344,475
Benefits paid for GP referral to SAF		1,782,378	2,673,294	3,593,985	4,545,207	5,527,732
Total $		28,072,285	29,550,143	31,070,135	32,633,266	34,240,565

Table 16 indicates that, under the assumptions that SAF will substitute for VC, and additional 1,000 GPs a year will refer their patients, who are currently not being referred to a dermatologist, and rural GPs will be paid an MBS item equivalent to 45.71 (average of a Level B and Level C consult) for the referral, then the costs to Medicare are likely to increase by approximately $2 million in the current year, increasing to an additional $6 million in 2018.

It was requested that the assessment try to estimate the cost of extending the delivery of specialist dermatological services via store and forward technology to people with disabilities. The ABS estimates that 18.5% of the Australian population has a disability. For people with a disability, 3.7 million (88%) had a specific limitation or restriction that meant they were limited in the core activities of selfcare, mobility or communication, or restricted in schooling or employment. Profound disability that interferes with core functioning is estimated in 3.2%, severe disability in 2.9% and moderate disability in 2.8% of the Australian population (ABS, Cat. 4430).

This additional calculation to estimate the increased cost to Medicare of extending SAF to people with disabilities is only for those who reside in Major Cities and visit their GP. People with a disability residing in rural areas are excluded from this analysis on the basis that they will already be covered under the Telehealth Eligible Items.

Table 17: Estimated cost to Medicare if asynchronous specialist dermatology services by telecommunications is extended to people with disabilities

		2014	2015	2016	2017	2018
		Current nos.	Projected growth			
Number of skin events across Australia seen by metro GP		14,743,290	14,993,926	15,248,822	15,508,052	15,771,689
Pts with profound disability	3.2%	471,785.27	479,805.62	487,962.31	496,257.67	504,694.05
Pts with severe disability	2.9%	427,555.40	434,823.84	442,215.85	449,733.51	457,378.98
Pts with moderate disability	2.8%	412,812.11	419,829.91	426,967.02	434,225.46	441,607.30
Total pts with disability visit metro GP		1,312,152.77	1,334,459.37	1,357,145.18	1,380,216.65	1,403,680.33
Assume referred to dermatologist as same rate as other patients		91,850.69	93,412.16	95,000.16	96,615.17	98,257.62
If all referred for SAF		$5,677,475	$5,773,992	$5,872,150	$5,971,977	$6,073,500
With GP referral costs		$4,198,725	$4,270,103	$4,342,695	$4,416,521	$4,491,602
Total maximum cost		$9,876,200	$10,044,095	$10,214,845	$10,388,497	$10,565,102

The estimated total additional cost to Medicare if asynchronous specialist dermatology services by telecommunications is extended to people with disabilities is $9.876M in 2014 to $10.565M in 2018, if the rates of disability, that interfere with core functioning, increases at

the same rate as population growth. These figures are likely to be at the high end and an overestimate because:

1) The estimates of people with disabilities in Major cities will include elderly people residing in residential care facilities who would be covered if SAF is listed and available in Eligible Telehealth Areas.
2) The assumption that all patients with a disability who have profound to moderate impairment to core functioning will be referred to their dermatologist using SAF technology. This is not likely to be the case. Although it may be the case that given their physical limitation people with disabilities may be referred at greater rates than their abled bodied peers, there will still remain a proportion of dermatological conditions for which only a face to face dermatological consultation can be done.
3) If people with a disability are being treated by their GP for their skin conditions then there may be a commensurate reduction in GP services to offset the increase in Medicare costs.

Costs to the State and Territory health systems

It is not anticipated that there will be any change in the costs to the State and Territory health systems from a listing of asynchronous specialist dermatology services delivered by telecommunications.

Costs to the private health insurer and/or patient

It is not anticipated that the listing of asynchronous specialist dermatology services delivered by telecommunications will have any effect on private health insurance.

Other relevant factors

If asynchronous specialist dermatology services via telecommunications is successfully listed on the MBS, it may impact the use of TeleDerm by GPs in rural and remote areas of Australia. The extent of the impact is difficult to gauge because TeleDerm provides services additional to dermatologist consultations such as GP education and support that would not be available to a GP if SAF was provided as a fee-for-service. TeleDerm is funded on a three-year basis by a fixed grant from the DoH to ACRRM. If SAF is successfully listed on the MBS then it is likely that the availability of these MBS items would be taken into consideration when then next funding round occurs. TeleDerm as provided by ACRRM is a scalable model, therefore the more that GPs use the service, the less the unit cost of clinical service delivery, making it an attractive service for widespread use. However, GPs are not reimbursed for their time.

Main issues around the evidence and conclusions for clinical effectiveness

The head-to-head study that compared SAF to VC teledermatology (Edison, 2008) was a small study that was underpowered to detect any statistically significant difference in diagnostic concordance of SAF and VC (using FTF consultation as a reference standard).

Diagnostic accuracy studies included within their population heterogeneous samples of lesions (pigmented only; non-pigmented only, all potentially cancerous lesions). A few studies that assessed the diagnostic accuracy of SAF (using histopathology as a gold standard) were identified, but most of these studies were small-sized and/or of poor quality. The exceptions were two equivalence trials (Warshaw, 2011a and Warshaw, 2011b).

Results of the assessment of the diagnostic accuracy of SAF teledermatology were aggregated by type of technology: teledermatology (digital images) vs a combination of digital images + teledermatoscopy and by the type of reported outcomes: primary vs aggregated diagnosis. Weighted averages using random effects model were estimated for each group but results should be interpreted with caution due to the significant heterogeneity.

We were unable to obtain a reliable estimate of diagnostic accuracy of VC teledermatology, therefore in the model we had to assume the diagnostic accuracy of VC to be equal to the diagnostic accuracy of SAF teledermatology.

Validity of results of the assessment of the diagnostic concordance of SAF teledermatology was compromised by the absence of the gold standard and lack of good quality trials.

Overall, there was insufficient evidence to produce a definite conclusion about the equivalence of diagnostic performance of SAF vs VC.

The evidence found that the diagnostic accuracy of FTF dermatologists was superior to teledermatology irrespective of the addition of teledermatoscopy.

Overall conclusion with respect to comparative clinical effectiveness

There are a number of uncertainties with the economic evaluation. To identify, measure and value health care resources the intervention needs to be clearly described, this is not the case with this intervention. SAF teledermatology is scalable, and has most frequently been used on an institutional basis, or alternatively among a group of dermatologists but it can be used by individual dermatologists. Institutional use of SAF teledermatology in Australia does not involve a fee-for-service model and groups of dermatologists can develop their own proprietary software. Since the applicant did not explain how SAF teledermatology will work in practice, it is assumed for the purposes of costing that an individual dermatologist will purchase a commercial software program, assumed to be TeleDerm. If SAF teledermatology is configured by dermatologists other than how it is assumed in the economic evaluation then the results of this analysis may not apply.

Little evidence was found on the proportion of patients in rural and remote areas with skin conditions requiring dermatological consultation who are managed by their GP. Referral probabilities are from a study that compared GP practice in the Bush to Urban areas (Britt, 2001). Assumptions around the proportion of rural GPs who will refer their patients to SAF if it is available are from the proportion of rural GPs who currently use the TeleDerm service. Australian data was not found on the proportion of patients who, after an unsuccessful attempt to be diagnosed by VC or SAF teledermatology consultations, will need to then go for a face-to-face examination. The corresponding parameters of the model were taken from the UK evidence (Loane 1998, 2000), which may be an overestimation of the real proportion of patients considering the technological improvements in telecommunications over the last 10 years.

As FTF examination is the reference standard in the concordance studies, diagnostic performance of FTF for inflammatory skin conditions needs to be assumed to be one in the model. This translates into the assumed linear relationship between diagnostic concordance of face-to-face consultations and SAF or VC teledermatology.

The limitation of the economic analysis of people with disabilities being eligible for SAF teledermatology was the lack of evidence on the proportion of people with disabilities that do not obtain specialist dermatology services due to difficulty in travelling to an appointment. Necessary assumptions were applied to the ABS definitions of profound,

severe and moderate disability to estimate the population of people with disabilities who may be eligible for SAF teledermatology to be able to do this analysis.

An economic analysis of patients who reside in Outer Metropolitan areas of Australia who may be eligible for SAF teledermatology was not possible. ABS population statistics and health department statistics are not disaggregated by this geographical boundary.

The result of the analysis of the financial implications for the Government estimates that there are 200,577 people in 2014 who require specialist dermatology services who currently are not able to access specialist dermatology services. The expected uptake of this asynchronous specialist dermatology services is estimated at 37,024 in 2014 increasing to 118,820 asynchronous specialist dermatology services in 2018.

The total cost to the Medical Benefits Scheme for the asynchronous specialist dermatology services is estimated to be $2,288,525 million in 2014 increasing to $7,344,475 in 2018.

Other relevant factors

If asynchronous specialist dermatology services via telecommunications is successfully listed on the MBS, it may impact the use of TeleDerm by GPs in rural and remote areas of Australia. The extent of the impact is difficult to gauge because TeleDerm provides services additional to dermatologist consultations such as GP education and support that would not be available to a GP if SAF was provided as a fee-for-service. TeleDerm is funded on a three-year basis by a fixed grant from the DoH to ACRRM. If SAF is successfully listed on the MBS then it is likely that the availability of these MBS items would be taken into consideration when then next funding round occurs. TeleDerm as provided by ACRRM is a scalable model, therefore the more that GPs use the service, the less the unit cost of clinical service delivery, making it an attractive service for widespread use. However, GPs are not reimbursed for their time in referring patient to the TeleDerm service.

Introduction

The Medical Services Advisory Committee (MSAC) has reviewed the use of asynchronous specialist dermatology services delivered by telecommunications, which is a therapeutic technology for patients with inflammatory skin conditions or skin lesions to access specialist dermatology services.

MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Scheme in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

MSAC is a multidisciplinary expert body, comprising members drawn from such disciplines as diagnostic imaging, pathology, surgery, internal medicine and general practice, clinical epidemiology, health economics, consumer health and health administration.

This report summarises the assessment of current evidence for asynchronous specialist dermatology services delivered by telecommunications for patients with inflammatory skin conditions or skin lesions.

Background

Intervention name

The intervention that is proposed for inclusion on the Medicare Benefit Scheme (MBS) and assessed in this report is asynchronous specialist dermatology services delivered by telecommunications.

The procedure / test

This application relates to a new approach of providing specialist dermatology services. Teledermatology is the use of imaging and telecommunications technology to provide dermatology services by a dermatologist to another health professional (general practitioner or nurse practitioner or other specialist) or directly to a patient. There are two types of teledermatology defined by the patient's temporal relationship with the dermatologist; store-and-forward (SAF) and real time (RT). Store-and-forward technology is used to record a patient's clinical data and digital images of their dermatological condition (store), and to transfer this information, via the telecommunications network (forward), to a dermatologist who then responds with a diagnosis and therapeutic recommendation (asynchronous telecommunication) but not at the same time. RT or live interactive teledermatology uses synchronous data transfer technologies (videoconferencing) to communicate with all parties (e.g. GP, dermatologist and patient), and all parties to the consultation need to be available at the same time. This type of consultation is already provided for on the MBS.

Table 18 compares the features of the two types of teledermatology.

Table 18: Feature comparison of Asynchronous and Synchronous teledermatology

Relative comparison	Store and Forward	Real Time
Virtual "hands-on" examination possible	No	Yes
Patient interactivity	None, written comments sent to referring provider	Live, by way of video link
Response time	Delayed	
Image quality	Still photos, usually higher quality	Live streaming video, usually lower quality
Bandwidth requirement	Lower	Higher
Relative Cost	Inexpensive	Expensive
Scheduling requirement	Teledermatologist may review history and images at his/her convenience	Imager, patient, teledermatologist and patient-support must all be available at the same time
Time Requirement	Low	High
Convenience	Higher	Lower
Training	Low	Higher

Source: Levin and Warshaw, 2009 and Table 1 (IMCSF 2012)

Teledermatology can be used in three main models of care, as a triage tool to direct patients to the appropriate service in a timely fashion, as an alternative to a face-to-face consultation or a hybrid model where a mixture of both videoconferencing and digital images is used according to patient need.

Guidelines and Standards

Implementing SAF teledermatology programs is reported to be a considerable undertaking requiring either custom built or commercially available SAF applications. Selection of a particular SAF teledermatology application will be affected by the characteristics of the dermatology practice, patient volume, the medical record filing system currently in use (requirement to be able to audit for Medicare purposes), reimbursement rates, equipment costs, hours necessary for teledermatology coordinators and financial considerations (Armstrong, 2009).

Quality standards or technical standards for use of teledermatology are not currently available in Australia. However, quality standards for dermatology, including teledermatology have been developed in the United Kingdom with an aim to bring together best practice and existing guidance. The standards produced on teledermatology, including 'store and forward' images are intended to apply to any service using teledermatology commissioned by the NHS and was a project led by the British Association of Dermatologist (Primary care commissioning, 2014).

It is reported that implementing a teledermatology program is not easy. They have been most successful in government organisation (for example, US Dept of Defence) and in closed health care systems, where the organisation have reasonable financial incentives to implement S&F teledermatology. Health care systems that have complex referral and authorisation processes can have trouble implementing an SAF program. The core purpose of teledermatology is increasing access to care and therefore teledermatology programs are generally embraced in medically underserved areas, where the community would otherwise lack access to speciality care. Where local dermatologists are available people usually have traditional face-to-face consultations (IMCSF 2012).

Delivery of the intervention

There are two participants to the proposed asynchronous specialist dermatology service, the referrer and the specialist dermatologist.

Specialist dermatologists

The proposed specialist dermatology service involves the following steps:

- The specialist dermatologist develops a standardised digital template and store and forward guidelines (this will include security measures such as encryption standards).
- The referrer accesses the dermatology template and provides to the dermatologist a completed information template and digital image (uploads this information to a telehealth portal as indicated by the guidelines).
- The specialist dermatologist accesses the clinical information and or a clinical pro-forma provided by the referrer. It is very important that this clinical information is provided according to the dermatologist's guidelines.
- After carefully reading all the clinical notes the dermatologist accesses the provided digital images and advises the referrer if they require additional information, and if the consult is unsuitable or suitable. If the proposed consult is suitable for asynchronous consult, the process basically follows the rule of classical consultation and the dermatologist provides diagnosis and management advice in a written report.

Referrer

The requirements on the referrer are that they:

- Identify a suitable patient and obtain their consent
- Contact the dermatologist and request asynchronous consult
- Document patient history, presenting complaint using dermatologists pre-prepared on-line template and capture images of relevant condition using camera and devices in accordance with store and forward guidelines developed by the dermatologist.
- Provide additional information or images if requested by the dermatologist
- If the consult is accepted, receive advice from dermatologist and treat patient accordingly.

The following is information required by the dermatologist from the referrer:

- General:
  - date & time of consult;
  - Patient details: name, Medicare number, id, phone, address, DOB, sex;
  - Referrer details: Name, site/organisation, email, health provider identifier;
  - Consultant details: Name, site/organisation, email, health provider id;
  - Urgency of response: (e.g. Within 24 hours, 2-3 days, 1 week);
- Clinical Data:
  - reason for consultation,
  - patient's chief complaint,
  - duration of condition,
  - associated signs and symptoms,
  - exacerbating factors,
  - pregnancy
  - medications, allergies,
  - investigations biopsy results/laboratory data,
  - diagnosis (provisional);
  -
- Post consultation:
  - recommendations, clinical responsibilities, management plan.

Intended purpose

This is a new approach to providing specialist dermatology services which enables patients who currently do not have access, or do not have timely access, due to geographical or physical impediments, to receive specialist dermatology services via an asynchronous consultation and support of other health practitioners. It is not anticipated to be a substitute for face-to-face consultations, but to be used where it better serves the interests of patients and offers better

use of resources. It is intended to have an impact on the delivery of specialist dermatology services and its implementation may result in a change in the relationship between a patient and their specialist. The recommendation is that a teledermatology service be part of an integrated dermatology service and that any potential compromise in quality of clinical assessment should be offset by the immediacy and convenience of service to the patient commensurate with clinical risk. There needs to be a process in place to obtain a further specialist opinion if the teledermatology consultation has not answered the clinical question.

Clinical need

Patient's access to dermatology services in Australia is limited due to mal-distribution of dermatologists and workforce shortage. Dermatology is not one of the more popular specialities, for example, it does not figure in the top 10 main specialties in Australia, and out of 2,395 new fellows (specialists) reported in 2009 in Australia, just 11 were dermatologists. Although the medical workforce has increased in rural and remote areas, doctors per 100,000 population is at least a third less than that major cities, and the component of this medical workforce that are specialists are least represented in remote/very remote areas; most specialists are employed in Major cities (Health Workforce Australia, 2012). Patients can experience long wait periods to see specialist dermatologists.

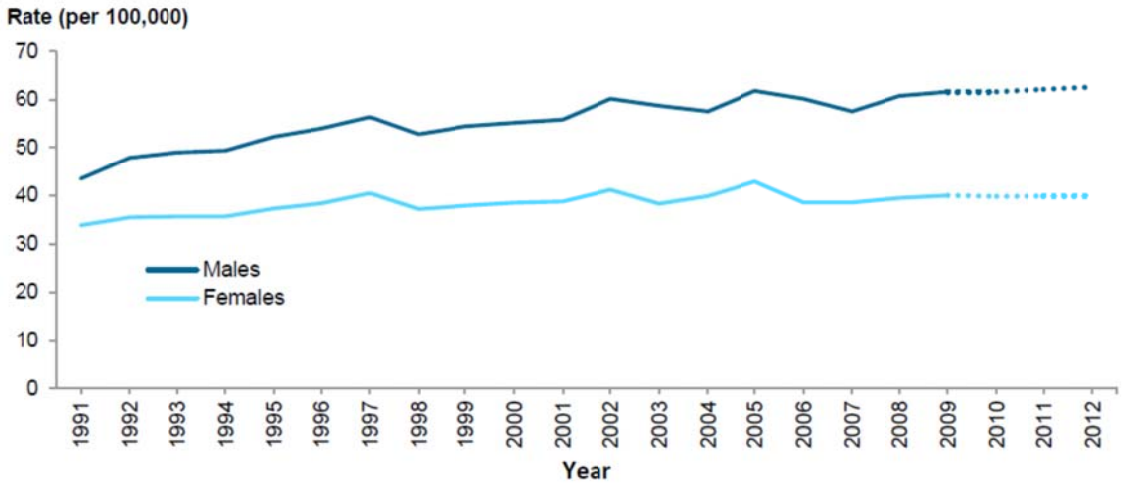
Specialist dermatology services apply to skin lesions, including skin cancer management, and inflammatory skin conditions including, eczema, psoriasis, acne, bacterial impetigo, fungal infection, varicella form eruption and amoxicillin-induced drug eruption.

Skin cancers include melanoma and non-melanoma skin cancers (NMSC), such as basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) and related lesions. They are an increasing problem in fair skinned populations around the world (Lens, 2004).

In Australia, cancer figures are robust as registration of all cancers, excluding basal and squamous cell carcinomas of the skin is required by law in each state and territory. These state based cancer registries provide data to the Australian Institute of Heath and Wealth annually, encompassing all cancer cases notified to the registry between 1982 and the most recent completed year of data. In 2012, melanoma of the skin was estimated to be the 3rd most commonly diagnosed cancer is males, 7,440 (ASR[a] 62.7, 61.3-64.2) and also the 3rd most commonly diagnosed in females 5,070 (ASR 39.9, 38.8-41.1) (AIHW & AACR 2012) (the 2012 estimates are based on 2000-2009 incidence data and rounded to the nearest 10). Figure 2 shows the increase in the incidence of melanoma.

[a] ASR=age standardised rate. The rates were standardised to the Australian population as at 30 June 2001 and are expressed per 100,000 population

Figure 2: Trends in incidence of melanoma of the skin, Australia, 1991 to 2009, with estimates to 2012



Notes

1. 2010–2012 estimates are based on 2000–2009 incidence data (see Appendix G). Estmates are displayed on the graph as a dotted line.
2. The rates were age-standardised to the Australian population as at 30 June 2001.
3. The data for this figure are in online Table D2.5.

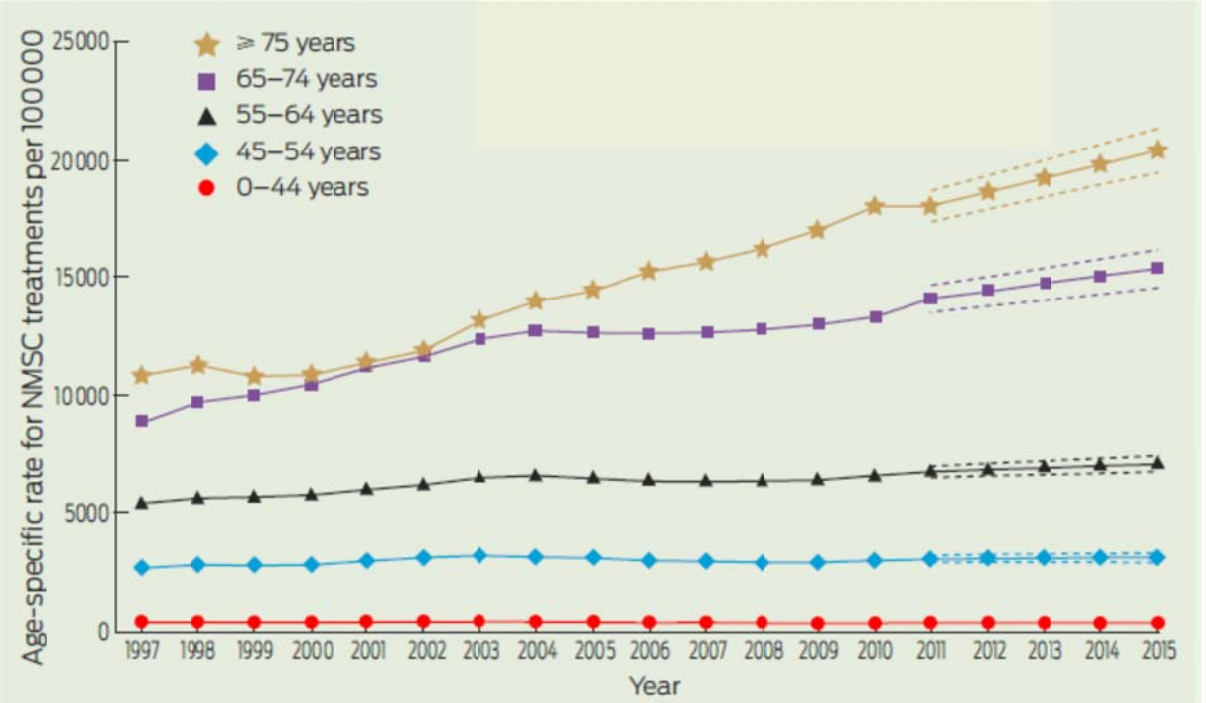
Source: AIHW Australian Cancer Database 2009.

The age-standardised incidence rate of melanoma of the skin increased for both males and females from 1991 to 2009. The increase was more marked for males–from 44 per 100,000 in 1991 to 62 per 100,000 in 2009 (an increase of 42%). For females, the incidence rate increased by 18%, from 34 per 100,000 to 40 per 100,000 over the same period. The rate is expected to remain stable between 2010 and 2012. In 2008, Australia had the world's highest age-standardised incidence rate of melanoma of the skin (37 per 100,000), which was more than 12 times the average world rate (3 per 100,000) (Askew, 2001).

Non-melanoma skin cancer (NMSC), includes basal cell carcinoma (BCC) and squamous cell carcinoma (SCC). The incidence of treated BCC and SCC in Australia is more than five times the incidence of all other cancers combined, making these cancers by far the most expensive cancers to treat (CCA, 2008; Askew, 2001). From the 2002 national survey of NMSC, the incidence rate of BCC was estimated to be 1041 per 100,000 in men and 745 per 100,000 in women, with the highest rates in northern, lower-latitude areas of Australia (Staples, 2006; NMSCWG, 2003). The risk of NMSC increases sharply with age, such that the incidence rate in people aged 70 years and over was estimated to be 193 times higher than for 20-24 years olds in 2002. Incidence rates for all NMSC were estimated to be 53% higher in males (and for SCC 75% higher in males). The ageing of the Australian population is therefore likely to increase the burden of NMSC on the Australian Health System (AIHW & CA, 2008; Fransen, 2012).

Figure 3 presents the predicted number of the annual numbers of NMSC treatments, age specific, up to 2015 based on Medicare data between 1997 and 2010 (Fransen, 2012).

Figure 3: Age-specific rate for non-melanoma skin cancer treatments, 1997-2015



The data presented in Figure 3 shows that NMSC treatment increased by 86% between 1997 and 2010, and are projected to increase by a further 22% between 2010 and 2015, based on projected population data and linear regression models fitted to the age-specific rate of services for each year extrapolated to 2015 (Fransen, 2012).

Medical management of skin conditions

Dermatological conditions represent 15.0 per 100 reasons for encounters recorded in The General Practice Activity in Australia 2012-13 (BEACH) report[b], the third most common specific reason for a GP encounter (Britt, 2013). The frequency of the problems managed by GPs (frequent individual problems) reported for skin problems was a rate of 16.9 per 100 encounters, contact dermatitis and malignant skin neoplasm being the most common. Of

[b] The BEACH program has been running since April 1998 it collects data on the characteristics of patients attending general practices, the health problems managed in these settings, and the management practices used. The BEACH report collects data on General Practice activity in Australia using a new random sample of about 1,000 GPs each year, each GP records details about 100 doctor-patient encounters of all types, the GP sample is a rolling sample, with about 20 GPs participating in any one week, 50 weeks a year (with 2 weeks break over Christmas). In general, the results present the number of observations (n), the rate per 100 encounters, and (in the case of management actions) the rate per 100 problems managed, and the 95% confidence interval. Rates per 100 encounters are used when an event can occur more than once at consultation (e.g. reason for encounter (RFE), problems managed or medications). Rate per 100 problems are used when a management event can occur more than once per problem managed. Chronic conditions are medical conditions characterised by a combination of the following characteristics: duration that has lasted or is expected to last 6 months or more, a pattern of recurrence or deterioration, a poor prognosis, and consequences or sequelae that affect an individual's quality of life. The extrapolations to the total events occurring nationally in any one year are only estimates and they may underestimate the true 'GP workload' of a condition/treatment because the extrapolations are made to GP Medicare items claimed, not to the total number of GP encounters per year (exclude DVA, state governments, workers comp, employers or not charged).

these, the rate for contact dermatitis, malignant neoplasm skin, solar keratosis/sunburn, laceration/cut, skin disease, other skin symptom/complaint, other were reported as 1.8, 1.2, 1.1, 1.0, 0.8 and 0.7 respectively (

Table 19). Of the most frequently reported new problems dealt with by GPs, there were 641 malignant neoplasms (1.1 of new problems encountered), 846 contact dermatitis (1.5 of new problems encountered), 532 solar keratosis/sunburn (0.9 of new problems).

Table 19: Patient reasons for encounter with GP and individual problems managed by GP for skin conditions

conditions	Rate per 100 encounters (95%CI)	Selected events across Australia 2012-13 (million)
Skin conditions RFE (most frequent individual reasons for encounter)	15.0 (14.4-15.6)	19.02 (18.3-19.7)
Rash	2.6 (2.4-2.8)	3.3 (3.04-3.55)
Skin symptom/complaint, other	1.5 (1.4-1.7)	1.90 (1.78-2.16)
Skin check-up	1.5 (1.2-1.8)	1.90 (1.52-2.28)
Swelling (skin)	1.0 (0.9-1.1)*	1.27 (1.14-1.39)
Laceration/cut	0.7 (0.6-0.8)	0.89 (0.76-1.01)
Frequency most frequent (individual problems)	16.9 (16.3-17.5)	21.43 (20.7-22.2)
Contact dermatitis	1.8 (1.7-1.9)	2.28 (2.16-2.41)
Malignant neoplasm, skin	1.2 (1.0-1.3)	1.52 (1.27-1.65)
Solar keratosis, sunburn	1.1 (1.0-1.3)	1.39 (1.27-1.65)
Laceration, cut	1.0 (0.9-1.1)	1.27 (1.14-1.39)
Skin disease	0.8 (0.7-0.9)	1.01 (0.89-1.14)
Other skin complaint	0.7 (0.6-0.8)	0.89 (0.76-1.01)

*LL reported as 1.0 in source. Tables 6.4 and 7.3 (Britt, 2013)

To estimate the number of selected events across Australia in 2012-13, divide the 'rate per 100 encounters' of the selected event by 100, and then multiply by the total number of GP service items claimed through Medicare, 126.8 million in 2012-13 (rounded to the nearest 100,000).

BEACH also surveys and reports the top 10 problems managed with a procedural treatment, the proportion of contacts with each problem that was managed with a procedure, and the proportion of problems managed with a procedure without medication given concurrently. Table 20 lists only the most common skin problems managed with a procedural treatment.

Table 20: skin problems managed with a procedural treatment by GP

Problem managed	% of problems with procedure (n=16,034)	Rate per 100 encounters (n=98,564)	95% LCL	95% UCL	Per of this problem	Per cent of treated problems no medications
Laceration/cut	4.7	0.8	0.7	0.9	78.9	79.9
Solar keratosis/sunburn	4.6	0.8	0.6	0.9	67.6	96.4
Malignant neoplasm, skin	3.1	0.5	0.4	0.6	43.1	94.4
warts	3.1	0.5	0.4	0.6	79.1	96.0
Chronic ulcer skin (including varicose ulcer)	2.6	0.4	0.4	0.5	71.3	79.3

Source: Table 10.5 (Britt, 2013);

Of the 10 most common problems managed with a procedural treatment by a GP, the fifth most common was for malignant neoplasm of the skin of which 94% had no medication prescribed. The most common type of procedure GPs undertook was excision/removal/biopsy/debridement or cauterisation. Extrapolating from Table 20, in 2012-13, 634,000 patients who encountered a GP for malignant neoplasm of the skin also had a procedural treatment done.

In Australia, the majority of suspicion skin lesions are managed initially by GPs and this proportion is increasing (Askew, 2007).

GPs are recommended to consider specialist referral for the following lesions:

- Recurrent lesions
- Incompletely excised lesions
- High-risk histological types, for example micronodular, infiltrating or morphoeic BCCs
- Lesions involving the central face, ears, genitalia, digits, hand or leg
- Poorly defined lesions
- Lesions fixed to underlying structures
- Lesions involving or lying adjacent to significant nerves, for example facial nerve or accessory nerve
- Trunk and extremities lesions greater than 20mm
- Cheek, forehead and scalp lesions greater than 10mm (Staples, 2006)

Although dermatologists are not one of the main specialities, dermatologists are among the most frequent specialists receiving referrals from GPs. In 2012-13, 7% of patients with skin complaints were referred, this is consistent with previous years (Britt, 2013; Tran, 2005). Of the five problems most frequently referred to a dermatologist, those most likely to be referred were acne (referred at 14.3% of GP contacts) and malignant skin neoplasm (8.5% of GP contacts) Table 21.

Table 21: The top problems most frequently referred by type of medical specialist

Problem managed	Per cent of problems referred to each specialist	Rate per 100 contacts with this problem (a)
Dermatologist	100.0	-
Malignant neoplasm	14.4	8.5
Solar keratosis/sunburn	9.9	6.2
Contact dermatitis	9.9	3.9
Acne	8.4	14.3
Skin symptom/complaint, other	7.4	7.4
Subtotal: top five problems	49.9	
General/unspecified surgeon	100.0	
Malignant neoplasm, skin	5.7	3.8

Source: Table 11.4 (Britt, 2013)
(a) The proportion of GP contacts with this problem that was referred to each type of medical specialist

However a comparison of general practice activity in metropolitan and rural areas of Australia 1998-2000, based on BEACH data, identified that in respect to referrals to dermatologists, GPs in large rural and small rural refer less frequently than GPs in Metropolitan areas, 0.4 (95%CI 0.0-0.8), 0.4 (95%CI 0.1-0.6) and 0.7(95%CI 0.6-0.8) respectively (Britt, 2001)1. Quantifying the amount of unmet demand for specialist dermatology services for people in rural and remote areas.

Table 22 presents the data collected by BEACH on the rate per 100 GP encounters that GPs refer patients to a dermatologist, include pathology, in particular skin pathology (although it is not possible to reconcile that these skin histology figures are only for patients who are recorded with a skin complaint) and those referred with a melanoma.

Table 22: referrals to a medical specialist by GP for skin conditions

Problem managed	Per cent of all referral	Per cent of referral group	Rate per 100 encounters (n=98,564)	95% LCL	95% UCL	Rate per 100 problems (n=152,517	95% LCL	95% UCL
Referrals to dermatologist	5.1	7.8	0.7	0.6	0.8	0.4	0.4	0.5
Referrals to pathology	Percent of all pathology	Per cent of group						
Tissue pathology Histology; skin	1.7 1.5	100.0 91.0	0.8 0.7	0.7 0.6	0.9 0.9	0.5 0.5	0.4 0.4	0.6 0.6
	Per cent of problems-referral links					Rate per 100 contacts with this problem		
Malignant neoplasm, skin	2.5		0.2	0.2	0.3	19.0		

Source: Tables 11.2 & 11.3 & 12.2 (Britt, 2013)

From Table 22, extrapolating to the wider Australian GP population, 887,600 (95%CI 760.800-1,141,200) had a histology of the skin performed. The number of Australians who were referred by their GP for malignant neoplasm of the skin was 253,600 (95%CI 253,600-

380,400) a likely underestimate of the incidence of malignant neoplasm of the skin as most skin neoplasms are treated by the GP and not referred on.

Existing procedures

Specialist dermatology services are provided under MBS consultation items and MBS Telehealth items (videoconferencing). It is assumed that these MBS items will remain available for patients, according to their dermatological needs and geographical isolation. Store-and-forward as a different organisational approach to delivering specialist dermatology services will augment patient's access to specialist dermatology services.

Marketing status of technology

This intervention, asynchronous specialist dermatology services delivered by telecommunications, does not require TGA approval.

Current reimbursement arrangements

On 1 July 2011, Medicare rebates and financial incentives for specialist video consultations were introduced to address some of the barriers to accessing medical services, particularly specialist services, for Australians in remote, regional and outer metropolitan areas. In many cases, these telehealth consultations provide patients in eligible areas with access to specialists or access sooner than would otherwise be the case and without the time and expense involved in travelling to major cities.

New MBS items were introduced to allow a range of existing MBS item to be provided via video conferencing. These items have a derived fee which is equal to 50% of the schedule fee for the consultation item claimed (e.g. 50% of the schedule fee for item 104) when billed with one of the associated consultation items (such as 104 or 105). A patient rebate of 85% for the derived fee is payable. In addition, new MBS item numbers were introduced to provide for an initial attendance via videoconferencing by a specialist, where the service is 10 minutes or less. These new items are stand alone and do not have a derived fee.

Table 23 summarises the current MBS Telehealth items that cover attendances for specialist dermatology services, in addition to the base MBS consultation items. There are no MBS items available for providing asynchronous specialist dermatology consultations delivered by telecommunications.

New MBS items were also introduced for Patient-end Services. These items enable GPs, other medical practitioners, nurse practitioners, midwives or Aboriginal health workers to provide clinical support to a patient during the consultation with the specialist. Table 24 lists these Teleheath MBS attendance items.

Table 23: Current MBS consultation items providing specialist dermatology services and Telehealth specialist services

Category 1 –Professional attendances
MBS 104 SPECIALIST, REFERRED CONSULTATION - SURGERY OR HOSPITAL (Professional attendance at consulting rooms or hospital by a specialist in the practice of his or her specialty where the patient is referred to him or her) -INITIAL attendance in a single course of treatment, not being a service to which ophthalmology items 106, 109 or obstetric item 16401 apply. Fee: $85.55 Benefit: 75% = $64.20 85% = $72.75 Extended Medicare Safety Net Cap: $256.65
MBS 105 Each attendance SUBSEQUENT to the first in a single course of treatment Fee: $43.00 Benefit: 75% = $32.25 85% = $36.55 Extended Medicare Safety Net Cap: $129.00
MBS 99 Professional attendance on a patient by a specialist practising in his or her specialty if: (a) the attendance is by video conference; and (b) the attendance is for a service: (i) provided with item 104 lasting more than 10 minutes; or (ii) provided with item 105; and (c) the patient is not an admitted patient; and (d) the patient: (i) is located both: (A) within a telehealth eligible area; and (B) at the time of the attendance—at least 15 kms by road from the specialist; or (ii) is a care recipient in a residential care service; or (iii)is a patient of: (A) an Aboriginal Medical Service; or (B) an Aboriginal Community Controlled Health Service; for which a direction made under subsection 19 (2) of the Act applies Telehealth Item 50% of the fee for item 104 or 105. Benefit: 85% of the derived fee Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount (See para A58 of explanatory notes to this Category
MBS 113 Initial professional attendance of 10 minutes or less in duration on a patient by a specialist practising in his or her specialty if: (a) the attendance is by video conference; and (b) the patient is not an admitted patient; and (c) the patient: (i) is located both: (A) within a telehealth eligible area; and (B) at the time of the attendance-at least 15 kms by road from the specialist; or (ii) is a care recipient in a residential care service; or (iii) is a patient of: (A) an Aboriginal Medical Service; or (B) an Aboriginal Community Controlled Health Service; for which a direction made under subsection 19 (2) of the Act applies; and (d) no other initial consultation has taken place for a single course of treatment. Fee: $64.20 Benefit: 85% = $54.60

(See para A58 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: $192.60

Notes 58 Telehealth Specialist Services

These notes provide information on the telehealth MBS video consultation items by specialists, consultant physicians and psychiatrists. A video consultation involves a single specialist, consultant physician or psychiatrist attending a patient, with the possible support of another medical practitioner, a participating nurse practitioner, a participating midwife, practice nurse, Aboriginal and Torres Strait Islander health practitioner or Aboriginal health worker at the patient end of the video conference. The decision as to whether the patient requires clinical support at the patient end of the specialist service is based on whether the support is necessary for the provision of the specialist service. Telehealth specialist services can be provided to patients when there is no patient-end support service provided.

MBS items numbers 99, 112, 149, 288, 389, 2820, 3015, 6016, 13210, 16399 and 17609 allow a range of existing MBS attendance items to be provided via video conferencing. These items have a derived fee which is equal to 50% of the schedule fee for the consultation item claimed (e.g. 50% of the schedule fee for item 104) when billed with one of the associated consultation items (such as 104). A patient rebate of 85% for the derived fee is payable.

From 1 January 2013, six new MBS item numbers (113, 114, 384, 2799, 3003 and 6004) are introduced to provide for an initial attendance via videoconferencing by a specialist, consultant physician, consultant occupational physician, pain medicine specialist/consultant physician, palliative medicine specialist/consultant physician or neurosurgeon where the service is 10 minutes or less. The new items are stand alone items and will not have a derived fee.

Where an attendance is more than 10 minutes, practitioners should use the existing item numbers consistent with the current arrangements. Normal restrictions which apply for initial consultations will also apply for these items. For example, if a patient has an initial consultation via telehealth, they cannot also claim an initial face-to-face consultation as part of the same course of treatment.

Clinical indications

The specialist, consultant physician or psychiatrist must be satisfied that it is clinically appropriate to provide a video consultation to a patient. The decision to provide clinically relevant support to the patient is the responsibility of the specialist, consultant physician or psychiatrist.

Telehealth specialist services can be provided to patients when there is no patient-end support service provided.

Restrictions

The MBS telehealth attendance items are not payable for services to an admitted hospital patient (this includes hospital in the home patients). Benefits are not payable for telephone or email consultations. In order to fulfil the item descriptor there must be a visual and audio link between the patient and the remote practitioner. If the remote practitioner is unable to establish both a video and audio link with the patient, a MBS rebate for a telehealth attendance is not payable.

Billing Requirements

All video consultations provided by specialists, consultant physicians or psychiatrists must be **separately billed**. That is, only the relevant telehealth MBS consultation item and the associated derived item are to be itemised on the account/bill/voucher. Any other service/item billed should be itemised on a separate account/bill/voucher. This will ensure the claim is accurately assessed as being a video consultation and paid accordingly.

Practitioners should not use the notation 'telehealth', 'verbal consent' or 'Patient unable to sign' to overcome administrative difficulties to obtaining a patient signature for bulk billed claims (for further information see mbsonline.gov.au/telehealth).

Eligible Geographical Areas

From 1 January 2013, geographic eligibility for telehealth services funded under Medicare will be determined according to the Australian Standard Geographical Classification Remoteness Area (ASGC-RA) classifications. A Telehealth Eligible Area will be those areas that are outside a Major City (RA1) according to ASGC-RA. Patients and providers are able to check their eligibility by following the links on the MBS Online website (www.mbsonline.gov.au/telehealth).

From 1 November 2012, there is a requirement for the patient and specialist to be located a minimum of 15km apart at the time of the consultation. Minimum distance between specialist and patient video consultations are measured by the most direct (i.e. least distance) route by road. The patient or the specialist is not permitted to travel to an area outside the minimum 15 km distance in order to claim a video conference.

This rule will not apply to specialist video consultation with patients who are a care recipient in a residential care service; or at an Aboriginal Medical Service or an Aboriginal Community Controlled Health Service for which a direction made under subsection 19(2) of the Health Insurance Act 1973 as these patients are able to receive telehealth services anywhere in Australia.

Telehealth Eligible Service Areas are defined at www.mbsonline.gov.au/ telehealth eligible areas

Record Keeping

Participating telehealth practitioners must keep contemporaneous notes of the consultation including documenting that the service was performed by video conference, the date, time and the people who participated.

Only clinical details recorded at the time of the attendance count towards the time of the consultation. It does not include information added at a later time, such as reports of investigations.

Extended Medicare Safety Net (EMSN)

All telehealth consultations are subject to EMSN caps. The EMSN caps for ART and Obstetric telehealth items 13210 and 16399 were set in reference to the EMSN caps applying to the base ART and Obstetric consultation items.

The EMSN caps for all other telehealth consultation items are equal to 300% of the schedule fee (to a maximum of $500). The maximum EMSN benefit for a telehealth consultation is equal to the sum of the EMSN cap for the base item and the EMSN cap for the telehealth items.

Aftercare Rule

Video consultations are subject to the same aftercare rules as practitioners providing face-to-face consultations.

Multiple attendances on the same day

In some situations a patient may receive a telehealth consultation and a face to face consultation by the same or different practitioner on the same day.

Medicare benefits may be paid for more than one video consultation on a patient on the same day by the same practitioner, provided the second (and any following) video consultations are not a continuation of the initial or earlier video consultations. Practitioners will need to provide the times of each consultation on the patient's account or bulk billing voucher.

Referrals

The referral procedure for a video consultation is the same as for conventional face-to-face consultations.

Technical requirements

In order to fulfil the item descriptor there must be a visual and audio link between the patient and the remote practitioner. If the remote practitioner is unable to establish both a video and audio link with the patient, a MBS rebate for a telehealth attendance is not payable.

Individual clinicians must be confident that the technology used is able to satisfy the item descriptor and that software and hardware used to deliver a videoconference meets the applicable laws for security and privacy.

A video consultation involves a single specialist, consultant physician or psychiatrists attending a patient, with the possible support of another medical practitioner, a participating nurse practitioner, a participating midwife, practice nurse or Aboriginal health worker at the patient end of the video conference. Table 24 presents information on the MBS attendance items for medical practitioners to provide clinical support to their patients, which clinically relevant during a video consultations.

Table 24: Telehealth Patient-end Support Services by Health professionals

MBS 2100 Level A - Telehealth attendance at consulting rooms Professional attendance at consulting rooms of at least 5 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who: (a) is participating in a video conferencing consultation with a specialist or consultant physician; and (b) is not an admitted patient; and (c) either: (i) is located both: (A) within a telehealth eligible area; and (B) at the time of the attendance-at least 15 kms by road from the specialist or physician mentioned in paragraph (a); or (ii) is a patient of: (A) an Aboriginal Medical Service; or (B) an Aboriginal Community Controlled Health Service for which a direction made under subsection 19 (2) of the Act applies Telehealth Item Fee: $22.90 Benefit: 100% = $22.90 (See para A57 of explanatory notes to this Category
MBS 2122 Level A - Telehealth attendance other than at consulting rooms Professional attendance not in consulting rooms of at least 5 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who: (a) is participating in a video conferencing consultation with a specialist or consultant physician; and (b) is not an admitted patient; and (c) is not a care recipient in a residential care service; and (d) is located both: (i) within a telehealth eligible area; and (ii) at the time of the attendance-at least 15 kms by road from the specialist or physician mentioned in paragraph (a); for an attendance on one or more patients at one place on one occasion-each patient Telehealth Item The fee for item 2100 plus $25.95 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2100 plus $2.00 per patient. Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount
MBS 2125 Level A - Telehealth attendance at a residential aged care facility A professional attendance by a medical practitioner (not being a service to which any other item applies) lasting at least 5 minutes (whether or not continuous) that requires the provision of clinical support to a patient who is: a) a care recipient receiving care in a residential aged care service (other than a professional attendance at a self-contained unit); or b) at consulting rooms situated within such a complex where the patient is a resident of the aged care service (excluding accommodation in a self-contained unit) and who is participating in a video consultation with a specialist or consultant physician, on 1 occasion - each patient. Telehealth Item The fee for item 2100 plus $46.70 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2100 plus $3.30 per patient. Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount (See para A57 of explanatory notes to this Category)
MBS 2126 Level B - Telehealth attendance at consulting rooms

Professional attendance at consulting rooms of less than 20 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who:

(a) is participating in a video conferencing consultation with a specialist or consultant physician; and

(b) is not an admitted patient; and

(c) either:

(i) is located both:

(A) within a telehealth eligible area; and

(B) at the time of the attendance-at least 15 kms by road from the specialist or physician mentioned in paragraph (a); or

(ii) is a patient of:

(A) an Aboriginal Medical Service; or

(B) an Aboriginal Community Controlled Health Service for which a direction made under subsection 19 (2) of the Act applies

Telehealth Item

Fee: $49.95 Benefit: 100% = $49.95

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: $149.85

MBS 2137

Level B - Telehealth attendance other than at consulting rooms

Professional attendance not in consulting rooms of less than 20 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who:

(a) is participating in a video conferencing consultation with a specialist or consultant physician; and

(b) is not an admitted patient; and

(c) is not a care recipient in a residential care service; and

(d) is located both:

(i) within a telehealth eligible area; anD

(ii) at the time of the attendance-at least 15 kms by road from the specialist or physician mentioned in paragraph (a);

for an attendance on one or more patients at one place on one occasion-each patient

Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount

Telehealth Item

The fee for item 2126 plus $25.95 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2126 plus $2.00 per patient.

(See para A57 of explanatory notes to this Category)

MBS 2138

Level B - Telehealth attendance at residential aged care facility

Professional attendance of less than 20 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who:

(a) is participating in a video conferencing consultation with a specialist or consultant physician; and

(b) is a care recipient in a residential care service; and

(c) is not a resident of a self-contained unit;

for an attendance on one or more patients at one place on one occasion-each patient

Telehealth Item

The fee for item 2126 plus $46.70 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2126 plus $3.30 per patient.

Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount

(See para A57 of explanatory notes to this Category

MBS 2143

Level C - Telehealth attendance at consulting rooms

Professional attendance at consulting rooms of at least 20 minutes in duration (whether or not continuous) by a medical practitioner who provides clinical support to a patient who:

(a) is participating in a video conferencing consultation with a specialist or consultant physician; and

(b) is not an admitted patient; and

(c) either:

(i) is located both:

(A) within a telehealth eligible area; and

(B) at the time of the attendance - at least 15 kms by road from the specialist or physician mentioned in paragraph (a); or

(ii) is a patient of:

(A) an Aboriginal Medical Service; or

(B) an Aboriginal Community Controlled Health Service for which a direction made under subsection 19 (2) of the Act applies

Telehealth Item

Fee: $96.85 Benefit: 100% = $96.85

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: $290.55

MBS 2147

Level C - Telehealth attendance other than at consulting rooms

Professional attendance not in consulting rooms of at least 20 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who:

(a) is participating in a video conferencing consultation with a specialist or consultant physician; and

(b) is not an admitted patient; and

(c) is not a care recipient in a residential care service; and

(i) is located both:

(A) within a telehealth eligible area; and

(B) at the time of the attendance - at least 15 kms by road from the specialist or physician

mentioned in paragraph (a);

for an attendance on one or more patients at one place on one occasion-each patient

Telehealth Item

The fee for item 2143 plus $25.95 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2143 plus $2.00 per patient.

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount

MBS 2179

Level C - Telehealth attendance at residential aged care facility

A professional attendance by a medical practitioner (not being a service to which any other item applies) lasting at least 20 minutes (whether or not continuous) that requires the provision of clinical support to a patient who is:

a) a care recipient receiving care in a residential aged care service (other than a professional attendance at a self-contained unit); or

b) at consulting rooms situated within such a complex where the patient is a resident of the aged care service (excluding accommodation in a self-contained unit);

and who is participating in a video consultation with a specialist or consultant physician, on 1 occasion - each patient.

Telehealth Item

The fee for item 2143 plus $46.70 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2143 plus $3.30 per patient.

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount

MBS 2195

Level D - Telehealth attendance at consulting rooms

Professional attendance at consulting rooms of at least 40 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who:

(a) is participating in a video conferencing consultation; and

(b) is not an admitted patient; and

(c) either:

(i) is located both:

(A) within a telehealth eligible area; and

(B) at the time of the attendance - at least 15 kms by road from the specialist or consultant physician

mentioned in paragraph (a); or

(ii) is a patient of:

(A) an Aboriginal Medical Service; or

(B) an Aboriginal Community Controlled Health Service for which a direction made under subsection 19 (2) of the Act applies

Telehealth Item

Fee: $142.50 Benefit: 100% = $142.50

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: $427.50

MBS 2199

Level D - Telehealth attendance other than at consulting rooms

Professional attendance not in consulting rooms of at least 40 minutes in duration (whether or not continuous) by a medical practitioner providing clinical support to a patient who:

(a) is participating in a video conferencing consultation with a specialist or consultant physician; and

(b) is not an admitted patient; and

(c) is not a care recipient in a residential care service; and

(d) is located both:

(i) within a telehealth eligible area; and

(ii) at the time of the attendance - at least 15 kms by road from the specialist or physician mentioned in paragraph (a);

for an attendance on one or more patients at one place on one occasion-each patient

Telehealth Item

The fee for item 2195 plus $25.95 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2195 plus $2.00 per patient.

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount

MBS item 2220

Level D - Telehealth attendance at residential aged care facility

A professional attendance by a medical practitioner (not being a service to which any other item applies) lasting at least 40 minutes (whether or not continuous) that requires the provision of clinical support to a patient who is:

a) a care recipient receiving care in a residential aged care service (other than a professional attendance at a self-contained unit); or

b) at consulting rooms situated within such a complex where the patient is a resident of the aged care service (excluding accommodation in a self-contained unit);

and who is participating in a video consultation with a specialist or consultant physician, on 1 occasion - each patient.

Telehealth Item

The fee for item 2195 plus $46.70 divided by the number of patients seen, up to a maximum of six patients. For seven or more patients - the fee for item 2195 plus $3.30 per patient.

Ready Reckoner

(See para A57 of explanatory notes to this Category)

Extended Medicare Safety Net Cap: 300% of the Derived fee for this item, or $500, whichever is the lesser amount

Note A57

A57 Telehealth Patient-end Support Services by Health Professionals

These notes provide information on the telehealth MBS attendance items for medical practitioners to provide clinical support to their patients, when clinically relevant, during video consultations with specialists or consultant physicians under items 2100, 2122, 2125, 2126, 2137, 2138, 2143, 2147, 2179, 2195, 2199 and 2220 in Group A30.

Telehealth patient-end support services can only be claimed where:

- a Medicare eligible specialist service is claimed;
- the service is rendered in Australia; and
- where this is necessary for the provision of the specialist service.

A video consultation will involve a single specialist or consultant physician attending to the patient, with the possible participation of another medical practitioner, a participating nurse practitioner, a participating midwife, practice nurse or Aboriginal health worker at the patient end. The above time-

tiered items provide for patient-end support services in various settings including, consulting rooms, other than consulting rooms, eligible residential aged care services and Aboriginal Medical Services.

Clinical indications

The specialist or consultant physician must be satisfied that it is clinically appropriate to provide a video consultation to a patient. The decision to provide clinically relevant support to the patient is the responsibility of the specialist or physician.

Telehealth specialist services can be provided to patients when there is no patient-end support service provided.

Collaborative Consultation

The practitioner, who provides assistance to the patient where this is necessary for the provision of the specialist service, may seek assistance from a health professional (e.g. a practice nurse or Aboriginal health worker) but only one item is billable for the patient-end support service. The practitioner must be present during part or all of the consultation in order to bill an appropriate time-tiered MBS item. Any time spent by another health professional called to assist with the consultation may not be counted against the overall time taken to complete the video consultation.

Restrictions

The MBS telehealth attendance items are not payable for services to an admitted hospital patient (this includes hospital in the home patients). Benefits are not payable for telephone or email consultations. In order to fulfil the item descriptor there must be a visual and audio link between the patient and the remote practitioner. If the remote practitioner is unable to establish both a video and audio link with the patient, a MBS rebate for a telehealth attendance is not payable.

Eligible Geographical Areas

From 1 January 2013, geographic eligibility for telehealth services funded under Medicare will be determined according to the Australian Standard Geographical Classification Remoteness Area (ASGC-RA) classifications. A Telehealth Eligible Area will be those areas that are outside a Major City (RA1) according to ASGC-RA. Patients and providers are able to check their eligibility by following the links on the MBS Online website (www.mbsonline.gov.au/telehealth).

From 1 November 2012, there is a requirement for the patient and specialist to be located a minimum of 15km apart at the time of the consultation. Minimum distance between specialist and patient video consultations are measured by the most direct (ie least distance) route by road. The patient or the specialist is not permitted to travel to an area outside the minimum 15 km distance in order to claim a video conference.

This rule will not apply to specialist video consultation with patients who are a care recipient in a residential care service; or at an Aboriginal Medical Service or an Aboriginal Community Controlled Health Service for which a direction made under subsection 19(2) of the Health Insurance Act 1973 as these patients are able to receive telehealth services anywhere in Australia.

Telehealth Eligible Service Areas are defined at www.mbsonline.gov.au/ telehealth eligible areas

Record Keeping

Participating telehealth practitioners must keep contemporaneous notes of the consultation including documenting that the service was performed by video conference, the date, time and the people who participated.

Only clinical details recorded at the time of the attendance count towards the time of the consultation. It does not include information added at a later time, such as reports of investigations.

Multiple attendances on the same day

In some situations a patient may receive a telehealth consultation and a face to face consultation by the same or different practitioner on the same day.

Medicare benefits may be paid for more than one video consultation on a patient on the same day by the same practitioner, provided the second (and any following) video consultations are not a continuation of the initial or earlier video consultations. Practitioners will need to provide the times of each consultation on the patient's account or bulk billing voucher.

Extended Medicare Safety Net (EMSN)

Items which provide for telehealth patient-end support services are subject to EMSN caps equal to 300% of the schedule fee (to a maximum of $500). This is consistent with Government policy relating to capping EMSN for MBS consultation services.

Aftercare Rule

Video consultations are subject to the same aftercare rules as face to face consultations.

Referrals

The referral procedure for a video consultation is the same as for conventional face-to-face consultations.

Technical requirements

In order to fulfil the item descriptor there must be a visual and audio link between the patient and the remote practitioner. If the remote practitioner is unable to establish both a video and audio link with the patient, a MBS rebate for a specialist video consultation is not payable.

Individual clinicians must be confident that the technology used is able to satisfy the item descriptor and that software and hardware used to deliver a videoconference meets the applicable laws for security and privacy.

Bulk billing

Bulk bill incentive items 10990 or 10991 may be billed in conjunction with the telehealth items 2100, 2122, 2125, 2126, 2137, 2138, 2143, 2147, 2179, 2195, 2199 and 2220.

Duration of attendance

The practitioner attending at the patient end of the video consultation does not need to be present for the entire consultation, only as long as is clinically relevant - this can be established in consultation with the specialist. The MBS fee payable for the supporting practitioner will be determined by the total time spent assisting the patient. This time does not need to be continuous.

Telehealth MBS items may be billed where a specialist consultation is conducted via video conferencing with a patient who is:

- not an admitted patient; and
- is eligible for Medicare rebates; and
- located in an Eligible Geographical Area (see www.mbsonline.gov.au/telehealth); or
- a care recipient at an eligible Residential Aged Care Facility (RACF); or
- in an eligible Aboriginal Medical Service (AMS)

Table 25 presents the derived fee for MBS item 99 which supports consultations of greater than 10 minutes.

Table 25: Derived fees for Telehealth item 99

	MBS Item 104		**MBS item 105**	
MBS item	Fee	85% Benefit	Fee	85% Benefit
	85.55	72.75	43.00	36.55
MBS Telehealth Item 99	Derived Fee	85% Benefit	Derived Fee	85% Benefit
	42.75	36.35	21.50	18.30
Total benefit	128.33	109.07	64.50	54.85

The Telehealth Patient-end Support Services by Health professions (listed in Table 24) allow for professional attendances a home, institution or residential care facility where multiple patients (up to a maximum of six patients), may be seen but not in a consulting room. Table 26 shows the fees that can be charged (and patient benefit) according to the duration of the attendance by a health professional not in consulting rooms.

Table 26: Fees for MBS Telehealth items that provide for multiple patients to receive clinical support during video consultations.

	Item 2122–Level A At a Home or other*		Item 2125–Level A at RACF		2137–Level B At a Home or other*		2138–Level B at RACF	
Patients	Schedule fee	Benefit 100%	Schedule fee	Benefit 100%	Schedule fee	Benefit 100%	Schedule fee	Benefit 100%
–one	48.85	48.85	69.60	69.60	75.90	75.90	69.65	69.65
-two	35.85	35.85	46.25	46.25	62.90	62.90	73.30	73.30
-three	31.55	31.55	38.45	38.45	58.60	58.60	65.50	65.50
-four	29.40	29.40	34.55	34.55	56.45	56.45	61.60	61.60
-five	28.10	28.10	32.25	32.25	55.05	55015	59.30	59.30
-six	27.20	27.20	30.70	30.70	54.25	54.25	57.75	57.75
-seven +	24.90	24.90	26.20	26.20	51.95	51.95	53.25	53.25
	Item 2147–Level C At a Home or other*		Item 2179–Level C at RACF		Item 2199–Level D At a Home or other*		Item 2220–Level D at RACF	
patients	Schedule fee	Benefit 100%	Schedule fee	Benefit 100%	Schedule fee	Benefit 100%	Schedule fee	Benefit 100%
–one	122.80	122.80	143.55	143.55	168.45	168.45	189.20	189.20
-two	109.80	109.80	120.20	120.20	155.45	155.45	165.85	165.85
-three	105.50	105.50	112.40	112.40	151.15	151.15	158.05	158.05
-four	103.35	103.35	108.50	108.50	149.00	149.00	154.15	154.15
-five	102.05	102.05	106.20	106.20	147.70	147.70	151.85	151.85
-six	101.15	101.15	104.65	104.65	146.80	146.80	150.30	150.30
-seven +	98.85	98.85	100.15	100.15	144.50	144.50	145.80	145.80

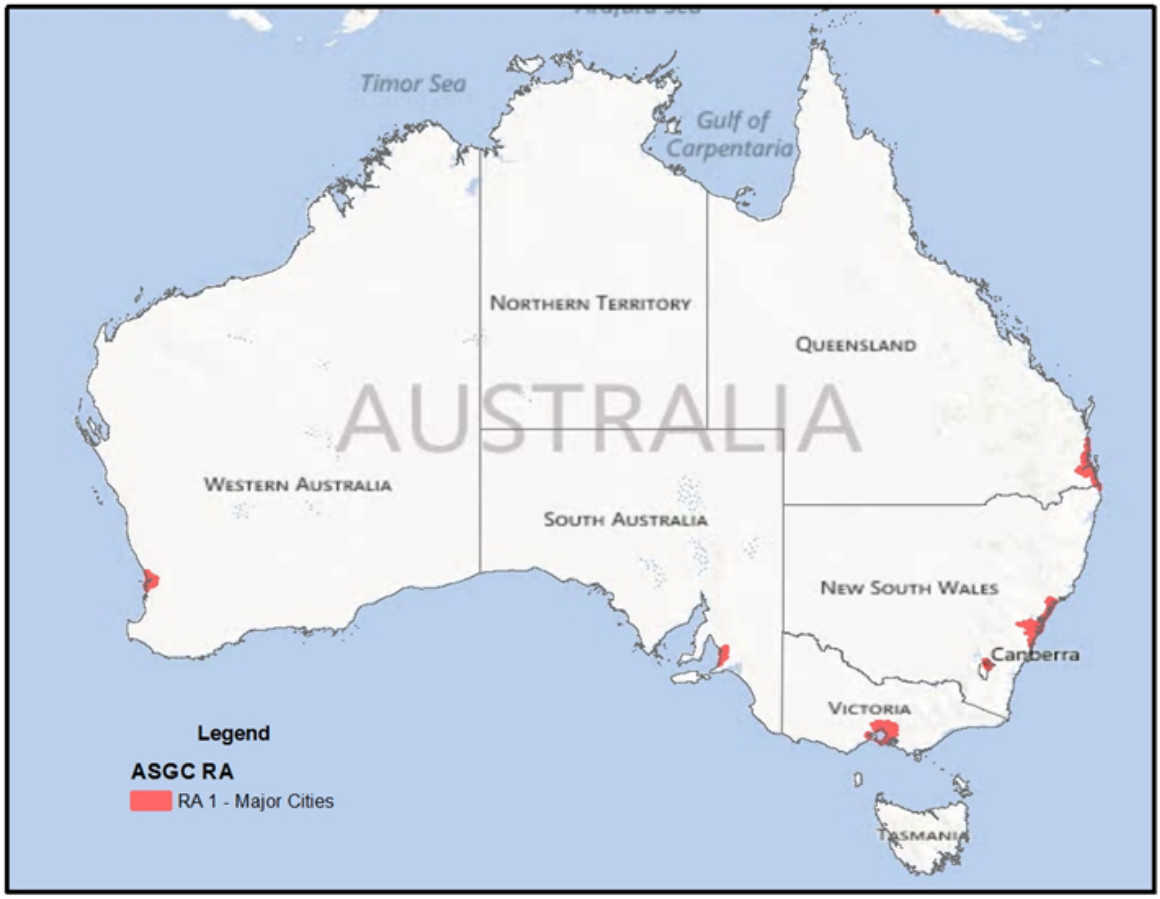
*Medical Practitioner Telehealth attendances (other than consulting rooms) at a Home or other Institution
RACF=Residential Aged Care Facility

The geographic eligibility criteria for telehealth Medicare Benefits Schedule (MBS) items changed from 1 January 2013 to align eligibility to the MBS Telehealth items with the Australian Standard Geographical Classification Remoteness Area (ASGC-RA) used by the Australian Bureau of Statistics. Under the new restrictions GPs and specialists will no longer be able to claim MBS telehealth item numbers for outer metropolitan areas. The item numbers only apply to services for patients of an Aboriginal Medical Service or a residential aged care facility in outer metropolitan areas from January 1, 2013. Rural and remote telehealth provision remains unaffected.

The application has requested that the original 2011 MBS Geographic Regions for Videoconferencing be included as a subgroup of the population, and access to asynchronous specialist dermatologist consultations be expanded to also include patients who have difficultly accessing services from outer metropolitan regions (a lack of specialist dermatologists in these areas) and for people with disabilities who may have difficulty travelling.

The National Telehealth Eligible Areas defined by the Australian Standards Geographic Classification (ASGC) RA are visually presented in Figure 4 (MBS online, 2014). Telehealth Eligible Areas are outside RA 1—Major Cities. Residents of eligible Residential Aged Care Facilities and patients of eligible Aboriginal Medical Services in all areas of Australia are eligible for specialist video consultations (telehealth items) under Medicare.

Figure 4: Telehealth Eligible Areas



All areas outside major metropolitan areas, including Darwin and Hobart, fall within this definition of Eligible areas.

The utilisation data for the MBS items listed in Table 23 and Table 24 is provided in Table 27 for the period 1 July 2011 to 30 June 2014.

Table 27: Utilisation data for specialist dermatology services* by State (01/7/11-30/06/14)

MBS item No.**	Type of Item claimed by same patient on the same day	NSW/ACT	VIC	QLD	SA	WA	TAS	NT	Total Services
99	None	648	744	2,075	298	197	173	346	4,481
	Telehealth - Lvl A or B - 5 to 20 mins	262	266	838	135	59	68	74	1,702
	Telehealth - Lvl C - at least 20 mins	142	267	866	89	77	58	218	1,717
	Telehealth - Lvl D - at least 40 mins	47	46	98	8	12	6	3	220
104	None	711,319	413,528	243,525	140,632	166,868	20,394	2,440	1,698,706
105	None	868,535	515,899	319,757	165,642	207,028	35,377	2,190	2,114,429
104 or 105	Telehealth- any level	42	96	84	17	11	7	7	264
Total		1,586,416	933,729	569,488	307,714	375,247	56,265	5,303	3,834,163

Source: DoH personal communication, number of services from 1 July 2011 to 30 June 2014, provided by derived speciality (Dermatologist specialist)
*based on provider's derived major specialty (DMS) as at 2014

** No claims found for item 113 by Dermatologists
Other = 104 & 105
Telehealth Lvl A or B -5 to 20 mins = 2100, 2122, 2125, 2126, 2137, 2138
Telhealth- Lvl C- at least 20 mins =2143, 2147, 2179
Telehealth – Lvl D – at least 40 mins =2195, 2199, 2220

The data reported in Table 27 is for three financial years, showing on average there were 1,494 claims for MBS item 99, videoconferencing, and 566,235 claims for MBS 104 item for specialist dermatology items. Qld had the highest number of claims for the videoconferencing, MBS item 99, but as a proportion of initial MBS items claimed for specialist dermatology, NT had the highest proportional use of teledermatology 14.18%.

Table 28 presents the data shown in Table 27 according to ASGS remoteness as defined by the Accessibility Remoteness Index of Australia (ARIA) Remoteness Area (ASGC, ABS)[c]. Figure 5 presents a map of these areas. Of note is that the ASGC does not have a definition for outer metropolitan area which means population data and Health Department data is not collected for this geographical boundary. In effect this means it is not possible to estimate what the demand for store-and-forward consultations might be if the eligibility criteria was widened to include patients living in outer metropolitan areas.

[c]

The Australian Standard Geographic Classification (ASGC) was developed by the Australian Bureau of Statistics (ABS) for the collection of geographic statistics. The Remoteness Structure and Accessibility Remoteness Index of Australia (ARIA) are AASGC classifications. http://www.health.gov.au/internet/publications/publishing.nsf/Content/ARIA-Review-Report-2011~ARIA-Review-Report-2011-2

http://www.abs.gov.au/websitedbs/D3310114.nsf/home/Australian+Statistical+Geography+Standard+%28ASGS%29

Figure 5: Remoteness Areas of Australia

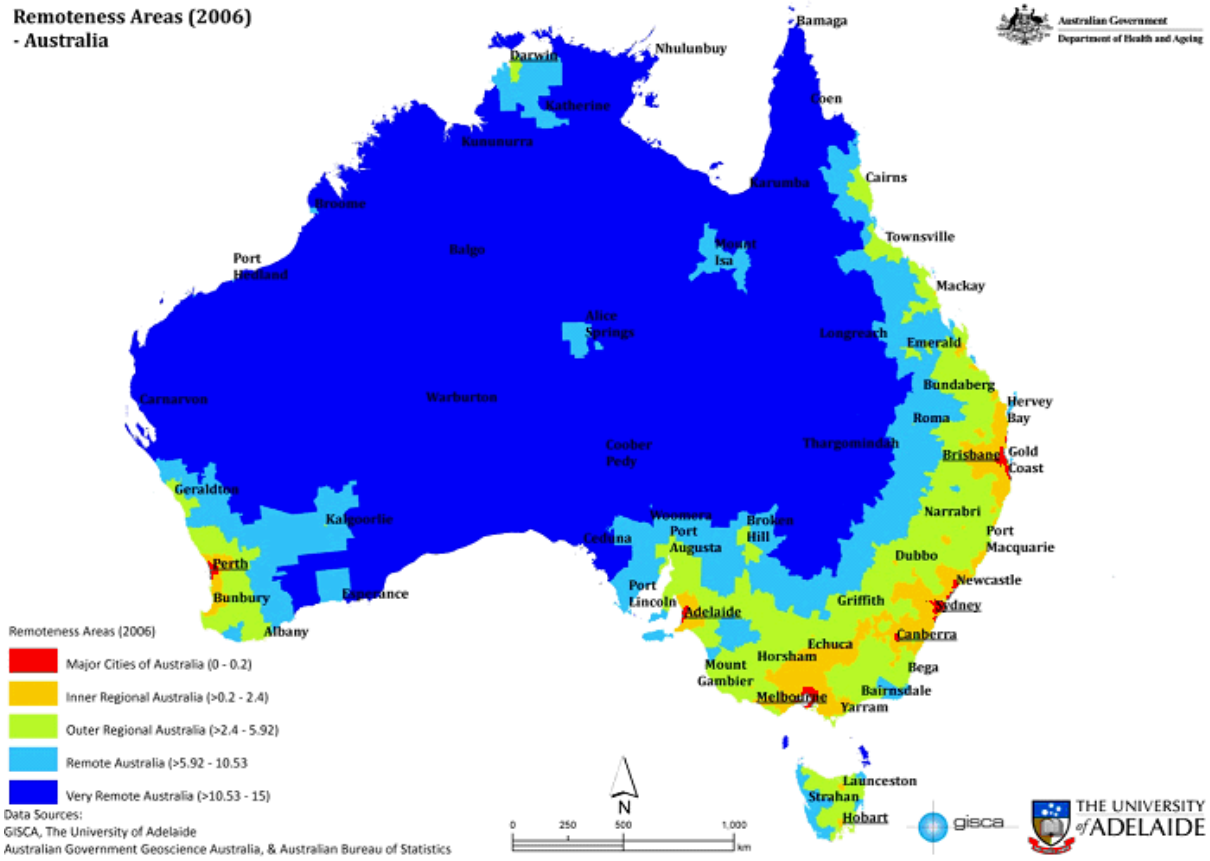


Table 28: Utilisation data for specialist dermatology services by remoteness area (01/7/11-30/06/14)

MBS item No.**	Type of Item claimed by same patient on the same day	Major cities of Australia	Inner Regional Australia	Outer Regional Australia	Remote & Very Remote	Total
99	None	872	2,125	1,304	180	4,481
	Telehealth - Lvl A or B - 5 to 20 mins	407	787	450	58	1,702
	Telehealth - Lvl C - at least 20 mins	285	859	500	73	1,717
	Telehealth - Lvl D - at least 40 mins	45	111	51	13	220
104	None	1,424,341	187,965	73,044	13,356	1,698,706
105	None	1,737,960	270,100	95,433	10,936	2,114,429
104 or 105	Telehealth- any level	59	143	53	9	264
Total		3,173,838	463,744	171,754	24,826	3,834,163

The data in Table 28 is for three financial years. Videoconferencing is most widely used in the inner regional area of Australia with on average 708 claims for MBS item 99 per year but the highest proportional use of teledermatology was in the outer regional and remote and very remote areas of Australia, as intended, at 0.79% and 0.74% respectively of total specialist dermatology services.

Non-Medicare public reimbursements of dermatology services

Teledermatology has been used by dermatologists in Australia since the mid-1990's to assist in clinical education and to provide access to dermatology services to underserved communities. TeleDerm was established by the Australian College of Rural and Remote Medicine (ACRRM) in 2004 and there have also been services provided in NSW and in WA.

According to the application, specialist dermatology services receive other public funding, both State and Federal. For example Queensland Health funds the Far North Queensland and Torres Strait Program that is part of the Princess Alexandra Hospital (PAH) Outreach Teledermatology Network operated by its dermatology department as part of the Princess Alexandra Hospital Online project. Free specialist dermatology services funded by Queensland Health are provided for residents of Northern Queensland and the Torres Strait using store and forward technology. The registrar on call at the PAH takes on the case and is supervised by a consultant.

The Australian College of Rural and Remote Medicine TeleDerm program is funded by the Australian Government Department of Health and Ageing under the Medical Specialist Outreach Assistance Program (MSOAP)[d].

TeleDerm program is an online dermatology resource designed primarily for rural doctors interested in obtaining practical advice on the diagnosis and management of skin disease in general practice. Its aim is to provide ready access to specialist dermatology advice (advice is usually provided within one day). It is a national program hosted on the ACRRM's Rural and Remote Medical Education Online platform (www.rrmeo.com). Access to the program is free for ACRRM members, RRMEO subscribers and GPs who work in rural Australia. TeleDerm also provides online education using a case based approach, in addition to a consultation service. GPs are able to access online dermatological case studies, education opportunities, recommended links, and discussion forums. Educational online tutorials in basic surgical skills are also available. Subscribers can submit a digital photo of affected skin and a history (and diagnosis, if made) through the ACRRM portal. An experienced dermatologist will examine the evidence, and reports back to the medical practitioner - usually within two days - with diagnosis and or treatment options. TeleDerm also allows rural doctors anywhere in Australia to electronically submit specific de-identified cases for assessment.

TeleDerm as provided by ACCRM is a consultation service. For medico-legal reasons doctors must accept a disclaimer that TeleDerm only provides advice not treatment, that an online consultation may not be as good as a face-to-face consultation with a dermatologist and that their patient must agree to them using the service. For the same reason, TeleDerm does not provide a diagnostic service for pigmented skin lesions, but advice on management of diagnosed skin malignancy is provided. No identifying information, apart from age and sex, are sent. Minimal computer skills are needed to use the service, an internet connection, the ability to type a text message, and to attach an image, is all that is required (Muir, 2008)

An evaluation of the TeleDerm system, reported that 83% of GPs found the system easy to use and that 89% indicated that they are likely to use the system again (Ou, 2008). Anecdotally

[d] MSOAP and Visiting Optometrists Scheme (VOS) are two programs implemented to overcome some specific barriers faced by people living in rural and remote Australia. The programs are specifically targeted at facilitating access by people living in these communities to medical specialist and optometry services. They are administrated separately, but have overlapping reach.

one of the barriers to the use of ACRRM was reported as the addition of approximately 20 minutes of time to a GP consultation which is un-chargeable. The other issue with TeleDerm is the funding of a specialist to provide the service. Funding for the clinical services provided through TeleDerm is by the Federal Department of Health, for a fixed time period. This is not a fee for service model and as such currently it is not eligible for Medicare funding, so there is not guaranteed ongoing funding (Muir, 2008).

The presence of TeleDerm provided by ACRRM may have influenced the take up of the use of VC to deliver specialist dermatology services, as it can substitute for this service. If asynchronous specialist dermatology services via telecommunications is successfully listed on the MBS, it may impact the use of TeleDerm by GPs in rural and remote areas of Australia.. The extent of the impact is difficult to gauge because TeleDerm provides services additional to dermatologist consultations such as GP education and support.

Approach to assessment

Objective

To assess safety, effectiveness and cost-effectiveness of asynchronous specialist dermatology services delivered by telecommunications to patient with inflammatory skin conditions and skin lesions to inform MSAC's decision-making regarding public funding of the intervention.

The proposed intervention is an asynchronous specialist dermatology consultation delivered by telecommunications (hereafter Store-and-Forward or "SAF"). SAF teledermatology typically refers to the sending or forwarding of magnified or standard digital images and the relevant patient data to the specialist for storage and consultation. Teledermatoscopy is another form of SAF teledermatology predominately used for diagnosing skin lesions (SL). With these technologies a patient and their consultant do not need to have a face-to-face consultation and the treatment of the patient is referred back to the referrer under the consultant's direction.

Dermatoscopy, dermoscopy or epiluminescence microscopy (ELM) is a non-invasive technique for the diagnosis of pigmented skin lesions (PSLs). Dermatoscopy allows visualization of structures that are not visible by clinical examination alone, and facilitates the diagnosis of pigmented skin lesions (PSL). It uses an immersion technique to render the skin surface translucent to assist in diagnostic accuracy for PSLs, especially for malignant melanoma (Braun, 2000). Reduction of light reflection from the skin surface by eliminating surface light reflection can be achieved via contact immersion dermatoscopy (CID) or polarized light dermatoscopy (PLD). The added value of using PLD or CID is well established for clinical evaluation of pigmented lesions when performed by a dermatologist who is trained and experienced in dermatoscopy (Warshaw, 2009a). Digital epiluminescence microscopy (DELM) uses digital or digitized two dimensional pictures of PSLs, which is a main requirement in telemedicine (Braun, 2000).

The technical equipment commonly used in dermatoscopy has previously comprised expensive stereomicroscopes and digital dermoscopy systems, combined with high-end digital cameras. Recently standard pocket dermoscopy devices that are more affordable and can be attached to digital cameras and even mobile phones were also used to provide SAF teledermatology services (Kroemer. 2011).

Population

The population for who it is proposed this service will benefit are people with skin lesions or inflammatory skin conditions requiring a specialist dermatologist consultation who live outside major cities in Australia. These are people who currently reside in the eligible areas for the MBS Telehealth items; areas outside Major cities, as defined by the ASGC. Telehealth items are also eligible for elderly people living in aged care facilities and Aboriginal and Torres Strait Islander People (ATSI) people who attend Aboriginal Community Controlled Health Services (ACCSHSs).

In addition it was requested that the use of SAF teledermatology be extended to people with disabilities who may have difficulty accessing transport, and require a referral to a specialist dermatologist and people who reside in "Outer Metropolitan" areas. These groups are less likely to access specialist services if they have to travel long distances and accessing services may be costly. However, it is noted that the current geographic boundaries used to collect, collate, survey and estimate population data and health use does not include a definition of

outer metropolitan. Therefore it will not be possible to estimate the likely increase in use of dermatological services separately for people residing in "Outer Metropolitan" areas.

Disability is defined in the ABS Survey of Disability, Ageing and Carers (SDAC) as any limitation, restriction or impairment which restricts everyday activity and has lasted, or is likely to last, for at least six months. In 2012 the prevalence of disability in Australia remained steady at 18.5% compared with 2009 (when the last survey was conducted) in spite of the ageing of the population. In 2012, half of older Australians (one in seven people, 14% of the population), have a disability (1.7 million or 7.5%) (ABS, Cat. 4430, 2012)[2].

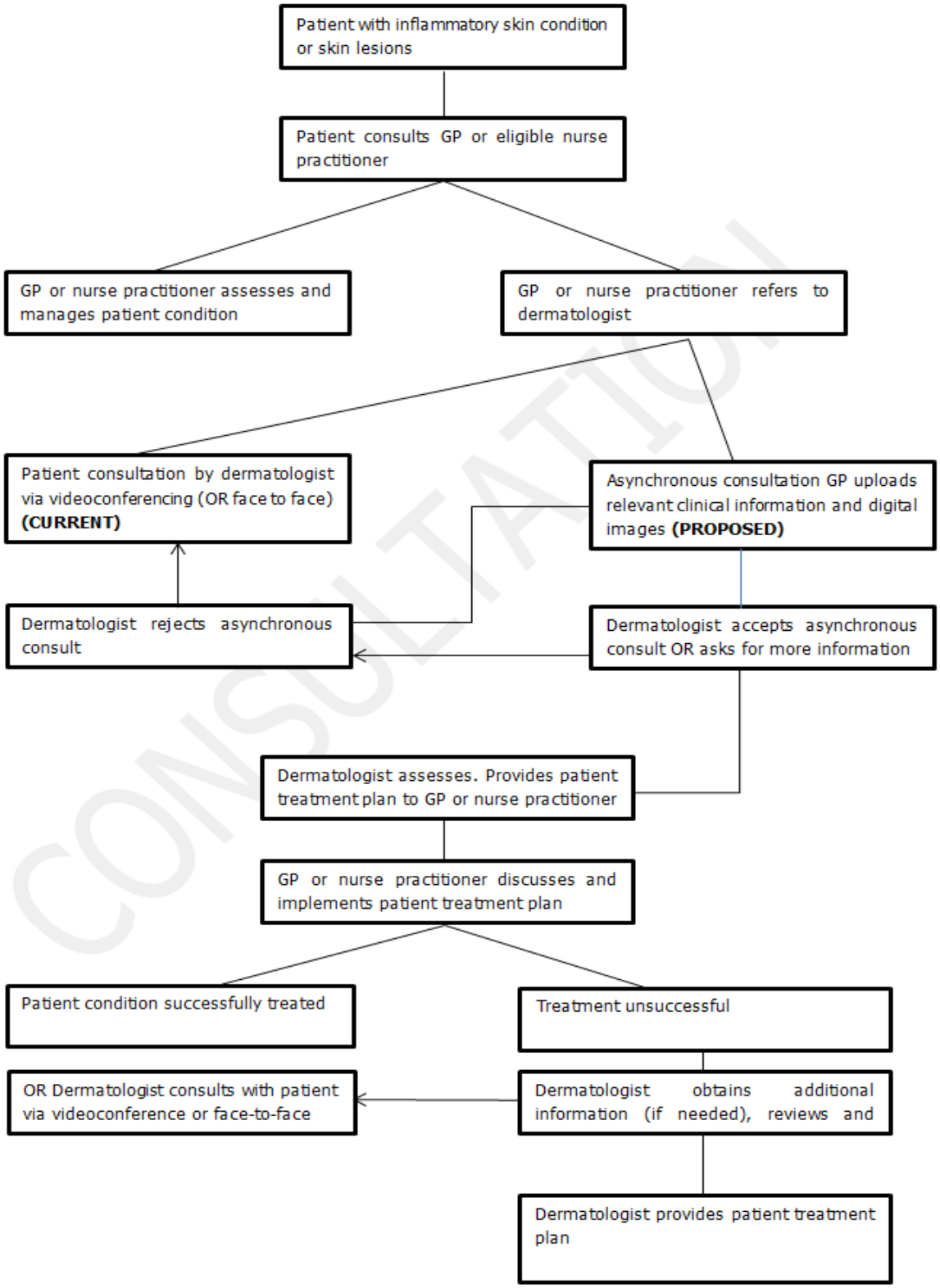
Clinical decision pathway

In the absence of teledermatology a patient will be referred to a specialist dermatologist, using a written referral, by their GP or referrer (which may be another specialist or participating nurse practitioner). The dermatologist has a face-to-face consult with the patient and provides them with a diagnosis, treatment and advice. The dermatologist sends a report to the referrer. Depending on the skin condition a follow-up appointment may be required. Patient's in rural and remote areas are more likely to have their skin conditions managed by their GP because of their geographical isolation and the lack of specialist dermatologists outside major cities. Currently, with the availability of teledermatology by videoconferencing, patients in rural and remote areas can access specialist dermatology services. A referral is sent to a specialist dermatologist but instead of a face-to-face consultation, the consultation occurs via a videoconference, in which all parties are present at the same time, referrer, patient and consultant, to discuss the patient's skin condition. Diagnosis is done by the specialist dermatologist, but ongoing treatment and management of the condition will usually be undertaken by the GP.

Under the proposed service, SAF, a patient will be referred to a dermatologist, by their GP or a referrer (which may be another specialist or nurse practitioner) after receiving patient consent. The referral will be in the form of digital images, clinical history and a completed template according to guidelines prepared by the dermatologist. The GP or referrer accesses the dermatologist's template and provides the required clinical information and digital images and then uploads to a secure portal or web. The dermatologist accesses the online information. If the specialist dermatologist determines the information and digital images are of sufficient quality they will provide an online report to the referrer with a diagnosis and treatment plan. If the information or images are inadequate the dermatologist requests additional information, after which they will provide the referrer with a diagnosis and treatment plan. If the dermatologist decides the patient is unsuitable for an asynchronous consultation they will advise the GP accordingly. Where the specialist dermatologist has provided a diagnosis and treatment plan back to the referrer the referrer then provides feedback to the patient and implements the dermatologist's advice. Similar to the current situation, depending on the skin condition a follow-up appointment may be required but instead of a videoconference or face-to-face consult it may also be done as an asynchronous consultation via telecommunications. It is proposed that patient's in rural and remote areas, including indigenous people, with the use of this service, will be more likely to have their skin conditions reviewed by a specialist dermatologist who will then be able to make a diagnosis and recommend treatment. This treatment usually can be provided by the referrer. Patients in residential care homes, or people with disabilities who are unable to travel, or have difficulty travelling will be able to have their skin conditions reviewed by a specialist dermatologist.

Figure 6 shows the clinical management algorithm with and without the proposed service.

Figure 6: Clinical management algorithm with and without asynchronous dermatology services



Comparators

The proposed service, SAF, is expected to substitute for patients who reside in Telehealth Eligible Areas of Australia (i.e. outside Major Cities as defined by ASGC, or reside in residential care homes or ATSI people who attend ACCSHSs), who require specialist dermatology services, for who a specialist dermatology consultation is available by a standard MBS telehealth items for professional attendance including patient-end telehealth items. That is a synchronous specialist dermatology consultation delivered by RT videoconference where a patient is assessed by teledermatologist in the presence and usually with assistance of GP or another referrer, such as a nurse practitioner.

In respect of the request to extend the availability of SAF teledermatology to the population of people with disabilities, who require specialist dermatology services, for who a specialist dermatology consultation is available by a standard MBS consultation item for professional attendance. That is, a face-to-face consultation with a specialist clinical dermatologist who assesses a patient in person following a written referral from a GP or another referrer.

The reference standard

Results of histopathology analysis is considered the gold-standard for diagnosis of skin lesions, either neoplastic or inflammatory (Werner, 2009). In diagnosing skin conditions, a biopsy is not always considered necessary if the more experienced dermatologist feels that clinically the diagnosis is clear-cut. Therefore, in the absence of a histological examination, the dermatologists' diagnoses are used as the reference standard (Armstrong, 2009).

For a papulosquamous condition such as psoriasis, in which distribution is more helpful than magnified images of one specific plaque, fine detail may not be important and standard images may provide adequate information for diagnosis and treatment. On the other hand, detailed, close-up photographs are likely important for the diagnosis and management of a skin neoplasm (eg, differentiation of an intradermal nevus from a basal cell carcinoma). Therefore, the diagnostic accuracy and reliability of teledermatology for one set of diseases (eczematous or papulosquamous) may not be equivalent to that of another set of conditions (skin neoplasms) when evaluated remotely using the same set of conditions (Warshaw 2009b). Therefore in assessing diagnostic performance of SAF teledermatology two reference standards were used, which correspond to the different types of skin conditions: skin lesions (also referred to as circumscribed skin lesions, skin neoplasms or isolated skin growths) for which it is standard to utilize histopathology and inflammatory skin conditions for which the reference standard is FTF presentation for a consultation with clinical dermatologist.

Primary outcomes

The *diagnostic accuracy* is an outcome measure obtained from the best available evidence that evaluates teledermatology versus clinic dermatology (FTF examination) and/or GP diagnosis using gold standard of histopathology or other laboratory test.

Diagnostic accuracy is especially important for neoplasms, for which histology is the accepted gold standard and where misdiagnosis can lead to significant morbidity and potential mortality. Histopathology is also used in diagnosis and differential diagnosis of other skin lesions.

In case of inflammatory skin conditions FTF consultations between the patient and the clinical dermatologist is assumed to be the reference standard against which *diagnostic concordance* of teledermatology is assessed.

Secondary outcomes

Management accuracy for teledermatologist (TD), clinical consultant dermatologist (FTF) and GP is where a management plan of these service providers is assessed against the management plan based on the outcomes of histopathology or other laboratory test.

Management concordance for TD and GP where a management plan of these service providers is assessed against the management plan based on the outcomes of FTF examination by a clinical dermatologist.

Patient clinical outcomes that relate to improvement in skin condition and general wellbeing of patients after a period of time (percent of patients without symptoms, quality of life etc.)

Table 29 outlines the definitions of primary and secondary outcomes evaluated.

Table 29: Definitions of primary and secondary outcomes

Outcomes	Definition
	Match of TD or CD with gold standard of histopathology
Diagnostic accuracy–CD (% Correct, kappa statistic, Sensitivity/specificity)	Match of CD diagnosis and histopathology/other laboratory test Aggregated: Match of any CD diagnoses (primary or differential diagnoses) with histopathology/laboratory diagnosis Primary: Match of primary CD diagnosis with histopathology/laboratory diagnosis
Diagnostic accuracy–TD (% Correct, kappa statistic, Sensitivity/specificity)	Match of TD diagnosis and histopathology/other laboratory test Aggregated: Match of any TD diagnoses (primary or differential diagnoses) with histopathology/laboratory diagnosis Primary: Match of primary TD diagnosis with histopathology/laboratory diagnosis
Management accuracy–CD (% Correct)	Match of CD management plan with management based on histopathology/other laboratory test
Management accuracy–TD (% Correct)	Match of TD management plan with management based on histopathology/other laboratory test
Concordance	Agreement between TD and CD
Diagnostic concordance (% Agreement, kappa statistic)	Agreement between TD and CD diagnosis Aggregated: Agreement of any of TD diagnoses 9primary or differential diagnoses) with any CD diagnoses (primary or differential diagnoses)
Management concordance (% Agreement, kappa statistic)	Agreement between TD and CD management

Source: Warshaw et al., 2011

Research questions

The research questions of interest that are addressed by this assessment are:

Diagnostic of skin conditions

- How does the *diagnostic accuracy* of SAF teledermatology (with and without teledermoscopy) compare with accuracy of diagnosis of skin condition by
    - VC teledermatology
    - FTF in person examination by clinic dermatologist
- How does the *concordance* of SAF teledermatology (with and without teledermoscopy) compare with

- VC teledermatology for the diagnosis of skin conditions

Management plan for skin conditions

- How does the *management accuracy* of SAF teledermatology (with and without teledermoscopy) compare with accuracy of management plan of skin condition by
  - VC teledermatology
  - FTF in person examination by clinic dermatologist
- How does the *concordance* of SAF teledermatology (with and without teledermoscopy) compare with
  - VC teledermatology for clinical management of skin conditions?
- How do patient clinical outcomes of SAF teledermatology compare with VC teledermatology and FTF examination by clinic dermatologist?
- Whether SAF teledermatology is cost-effective in comparison to dermatological diagnosis and management of skin condition by the alternative tele- and FTF modalities?

Review of literature

Literature sources and search strategies

A systematic search of the medical literature was conducted to identify relevant studies and reviews that could inform the assessment of clinical effectiveness and safety of asynchronous dermatologist consultation delivered by telecommunications (SAF) versus synchronous dermatologist consultation delivered by telecommunications (VC). Medline was searched for the period between 1946 – 22 June 2014 and EMBASE was searched from 1980 to 20 May 2014. Table 30 lists the electronic databases searched and the periods covered by the searches.

Table 30: Electronic databases searched

Database	Period covered
Ovid platform	
• Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)	<1946 to June 2014> <2005 to June 2014 >
• Cochrane Database of Systematic Reviews	<1991 to April 2014>
• EBM Reviews - ACP Journal Club	< 1991 to May 2014 >
• EBM Reviews - Database of Abstracts of Reviews of Effects	<3d Quarter 2014>
• Cochrane Central Register of Controlled Trials	<May 2014>
• Cochrane Methodology Register	<3d Quarter 2014>
• EBM Reviews - Health Technology Assessment NHS Economic Evaluation Database	<3d Quarter 2014> <1971 to May 2014>
EMBASE	1980 – 20 May 2014

Complete details of the literature search strategy performed using the primary databases are presented in Appendix B. In summary, the search terms included: single terms teledermatology, teledermoscopy and teledermotoscopy; as well as telehealth; telecare;

telediagnosis; telepathology, teleconferencing, web-conferencing or videoconferencing, which were combined with dermatology; dermopathology or skin disease.

Of the citations returned by electronic literature search, studies assessing diagnostic accuracy, diagnostic concordance, safety, cost-effectiveness of SAF and/or VC; impact on clinical management and patient outcomes were selected for further investigation.

The selection process firstly included screening of titles and abstracts where the following exclusion criteria were used:

- Editorials; letters; research notes; case studies;
- Pilot and feasibility studies (unless conducted in Australia);
- Conference abstracts/presentations with insufficient details;
- Non-systematic reviews;
- Publications in languages other than English;
- Not a teledermatology study

Secondly, the studies that met the initial inclusion criteria were further assessed to identify those that reported good quality data for assessing diagnostic accuracy, diagnostic concordance, safety, cost-effectiveness of SAF versus VC or FTF; accuracy or concordance of clinical management and patient outcomes against the following criteria (Table 31)

Table 31: Selection criteria

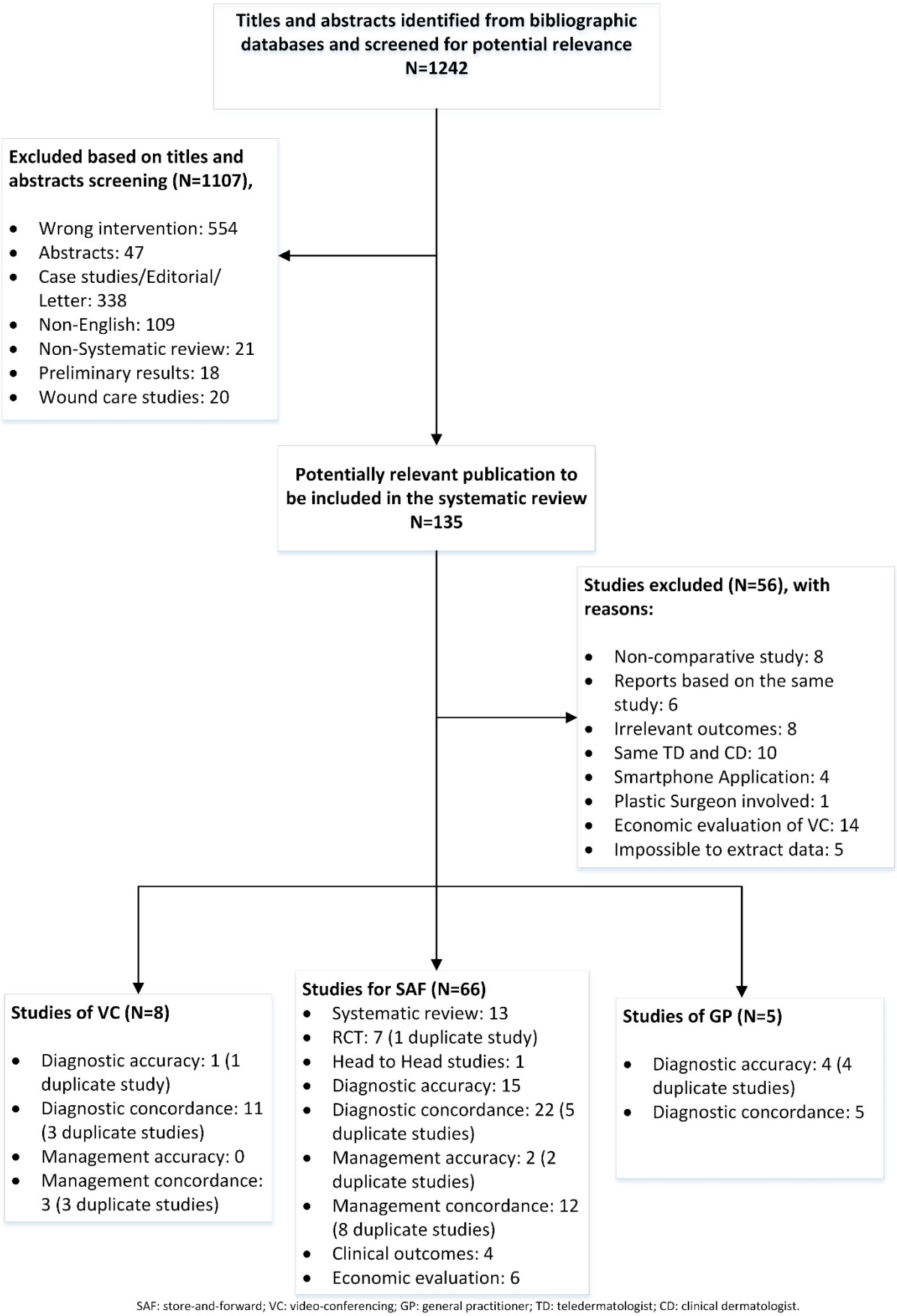
Selection criteria	Inclusion criteria	Exclusion criteria
Study design	Controlled trials (RCT and observational cohort studies assessing diagnostic and management accuracy of VC vs FTF and/or SAF vs FTF; GP vs FTF)	Studies without a control arm
Study design (quality)	Acceptable quality standards (i.e. study design, methods and reporting are sufficient to eliminate the most obvious bias and to extract the data)	Study design where concordance or diagnostic accuracy is determined by the same rather than a second dermatologist providing an independent opinion
Population	Patients presented to GP office/outpatient department or other medical facility with dermatological conditions	patients/parents patient-generating their own photographs, history, or both and searching direct advice from the Internet resources or teledermatologists (without a referring provider) and managing their disease themselves;
Index tests/Intervention	Specialist dermatology services delivered by SAF	Intervention is inconsistent with the scope of the Assessment e.g. • videomicroscopy studies, • basic science, • imaging techniques; • dermapathology • remote monitoring of known diagnoses (e.g. leg ulcers, postoperative wounds) • diagnosis made with the use of a smart phone applications • diagnosis not made by TD
Reference standard	Skin lesions with biopsy: • histopathology results Studies of all skin conditions: • face-to-face examination	Studies of skin conditions where diagnostic accuracy is assessed without a gold standard (histopathology results) or where diagnostic concordance is assessed without a standard reference (face-to-face examination)
Comparator	Specialist dermatology services delivered by VC outside Telehealth Eligible Areas specialist dermatology services delivered FTF	SAF+VC administered to the same patient sequentially
Outcomes	diagnostic accuracy; diagnostic concordance/consistency; Management plans Patient outcomes (cured, remission; died etc.)	The study outcome is inconsistent with the scope of the Assessment e.g. • only patients' satisfaction is reported; • outcomes of web-based self-management • educational outcomes for the service providers
Health economics	Study comparing the cost and/or effectiveness between SAF and VC or SAF and FTF dermatology consultations.	Study comparing the cost and/or effectiveness between VC and FTF dermatology consultations

Search results

This process of selecting good quality controlled trials that reported diagnostic accuracy, diagnostic concordance, safety, cost-effectiveness of SAF versus VC or FTF; accuracy of clinical management and patient outcomes is summarised in a Quorum Flowchart (Figure 7).

The studies are grouped by the type of technology (SAF and VC) and the type of dermatological condition. We separated studies in circumscribed lesions - isolated skin growths (skin lesions), from the studies that are not limited to skin lesions and include all skin conditions (rashes, eczemas, infestations etc.). In doing that we have followed the structure of the recent comprehensive systematic review by Warshaw (2011), however we did not separate studies in pigmented and non-pigmented skin lesions within the broader "skin lesions" category.

Figure 7: Summary of the process used to identify and select studies for the review



SAF: store-and-forward; VC: video-conferencing; GP: general practitioner; TD: teledermatologist; CD: clinical dermatologist.

Data extraction and analysis

Data on diagnostic accuracy, diagnostic concordance, and clinical management were extracted using the predesigned forms (Appendix C). Two reviewers (LG and EG) independently screened titles and abstracts of all identified studies. Disagreements were resolved by consensus. Quality of the selected studies was assessed with QUADAS-2 (Whiting, 2011) criteria which cover four key domains: participant selection, index test, reference standard, and the flow of patients through the study. Each domain was rated for the risk of bias (low, high, or unclear) and the overall quality category was assigned.

Safety of SAF teledermatology

The literature search did not locate any reports that related to studies that specifically addressed the safety of SAF teledermatology.

Systematic reviews of SAF teledermatology

Search of the literature identified 13 systematic reviews described and summarised in section "Systematic reviews".

Studies on diagnostic accuracy of SAF teledermatology

Search of the literature identified 23 full reports of diagnostic accuracy of SAF teledermatology (using histopathology as a gold standard). Six studies were excluded as not meeting the selection criteria listed in Table 31 (see Appendix C for the list of excluded studies with reasons. Two studies (Fabbrochini, 2008, van der Heijden, 2013) did not provide sufficient details to allow the data extraction. The detailed description of the selected studies is included in Appendix C)

Twelve of these studies included an FTF dermatologist consultancy as a comparator. The diagnostic accuracy of FTF was also assessed using histopathology as a gold standard allowing for the indirect comparison of diagnostic accuracy of SAF vs FTF. Nine studies assessed teledermatoscopy either as the only modality of SAF telecommunication or as an addition to teledermatology (digital images). Most of the studies enrolled only the patients with skin lesions and used skin lesions as unit of analysis. One study (Kroemer, 2011) did not report the diagnostic performance separately by histology and FTF consultancy outcomes, because not all of the suspected skin tumours were biopsied.

Six studies reported both primary and aggregated diagnoses. In the latter case estimation of the proportion of correct diagnoses takes into consideration any differential diagnoses therefore increasing the likelihood of the correct diagnosis when compared to the histopathology results. The rate of agreement between the teledermatologist and the clinical dermatologist is also higher when diagnosis accuracy is based on the aggregated outcome.

Table 32 lists the 15 included studies on diagnostic accuracy of SAF teledermatology that formed an evidence basis for assessing the diagnostic accuracy of SAF teledermatology.

Table 32: Studies included in assessment of diagnostic accuracy of SAF teledermatology

Study ID	SAF modality	Type of outcome reported	Number analysed		Quality assessment*
			Store-and-Forward	Face-to-Face	
Şenel 2013	Digital photography +dermatoscopy	Aggregated	82	82	III-1, Q3, P2
	Digital	Aggregated	82	82	

	photography				
Warshaw 2009a	Digital photography +dermatoscopy	Aggregated	542	542	II, Q1, P2
		Primary	542	542	
Warshaw 2009b	Digital photography +dermatoscopy	Aggregated	716	716	II, Q1, P2
		Primary	716	716	
	Digital photography	Aggregated	728	728	
		Primary	728	728	
Oakley 2006	Digital photography	Primary	48	29	III-1, Q3, P2
Piccolo 2000	Digital photography +dermatoscopy	Aggregated	43	43	III-1, Q3, P2
Rosendahl 2011	Digital photography +dermatoscopy	primary	463	463	III-1, Q3, P2
	Digital photography	primary	463	463	
Whited 1999	Digital photography	Aggregated	79	79	III-1, Q2, P2
		Primary	79	79	
Piccolo 1999	Digital photography +dermatoscopy	N/A	66	66	III-1, Q3, P2
Whited 1998	Digital photography	Aggregated	9	9	III-1, Q2, P2
		Primary	9	7	
Barnard 2000	Digital photography	Aggregated	25	25	III-1, Q3, P2
Braun 2000	Digital photography +dermatoscopy	Primary	55	55	III-1, Q3, P2
Coras 2003	Dermatoscopy	Primary	45	45	III-1, Q3, P2
Ferrandiz 2007	Digital photography	Primary	130	N/R	III-1, Q3, P2
Kroemer 2011	Dermatoscopy	Primary	104	N/R	III-1, Q3, P2
	Digital photography	Primary	104	N/R	
Krupinski 1999	Digital photography	aggregated	104	104	III-1, Q3, P2

*According to criteria outlined in Table 88Table 89

Studies on diagnostic accuracy of VC teledermatology

The literature search located only a single study of VC teledermatology (Lowitt, 1998). However, only a small number of patients, 11 out of 104 enrolled patients, had histopathology results available to determine diagnostic accuracy.

Studies on diagnostic concordance of SAF teledermatology

Search of the literature identified 32 full reports of diagnostic concordance of SAF teledermatology (using in person clinical presentation – FTF - as a reference standard), including one RCT (Bowns, 2006). Seven studies were excluded as not meeting selection criteria (see Appendix C for the list of excluded studies with reasons). Three studies did not report data in sufficient details to assess diagnostic concordance (Moreno-Ramirez, 2005, 2007, Rajagopal, 2009). The detailed description of the selected studies is included in Appendix C).

A subset of the studies in skin lesions (Oakley, 2006; Barnard, 2000; Whited 1998) that were included in the assessment of diagnostic accuracy (Table 32) also reported the concordance rates between teledermatologists and clinical dermatologists assessing patients during FTF consultations. Two studies, a RCT by Bowns (2006) and Mahendran (2005), used only FTF presentation as a reference standard for the patients with skin lesions.

Table 33 lists the 22 included studies on diagnostic concordance of SAF teledermatology.

Table 33 Studies included in the assessment of diagnostic concordance of SAF teledermatology

Study	SAF modality	Sample size	Quality assessment
Skin lesions			
Piccolo 1999	Digital photography +dermatoscopy	66	III-1, Q3, P2
Bowns 2006	Digital photography	230	II, Q3, P1,
	Dermatoscopy	256	
Oakley 2006	Digital photography*	189	III-1, Q3, P2
Mahendran 2005	Digital photography	163	II, Q2, P2
Barnard 2000	Digital photography	50	III-1, Q3, P2
Whited 1998	Digital photography	10	III-1, Q2, P2
All skin conditions			
Baba, 2005	Digital photography	242	III-1, Q2, P1
Ebner, 2008	Digital photography	58	III-1, Q3, P1
Heffner 2009	Digital photography	135	II, Q2, P2
Edison 2008	Digital photography	110	III-1, Q2, P1
Bowns 2006	Digital photography	92	II, Q3, P1,
Tucker 2005	Digital photography	84	III-1, Q3, P2
Oztas 2004	Digital photography	125	III-1, Q3, P1
Du Moulin 2003	Digital photography	106	III-1, Q3, P1
Rashid 2003	Digital photography	33	III-1, Q3, P2
High 2000	Digital photography	99	III-1, Q3, P1
Krupinski 1999	Digital photography	308	III-1, Q3, P2
Whited 1999	Digital photography	168	III-1, Q2, P2
Kvedar 1997	Digital photography	123	III-1, Q3, P1

Zelickson 1997	Digital photography	30	III-1, Q3, P2
Barbrieri 2014	Digital photography	50	III-1, Q3, P2
Rubegni 2011	Digital photography dermotoscopy	130	III-1, Q3, P2

*It was not clear whether digital dermoscopy was also used

Studies on diagnostic concordance of VC teledermatology

Search of the literature identified 14 full reports of diagnostic concordance of VC teledermatology (using FTF as a reference standard). One study (Oakley, 1997) was excluded as not meeting the selection criteria; three other reports related to the same study (Loane, 1997a,b Loane 1998b) that was already included; one study evaluated SAF vs VC but did not include a reference standard (FTF) for assessing a diagnostic concordance of either of these teledermatology methods (Loane, 2000). Finally, one study (Baba, 2005) did not assess a diagnostic concordance of VC against a reference standard (FTF) independently from SAF (see Appendix D for the list of excluded studies with reasons). The detailed description of the selected studies is included in Appendix C).

Table 34 lists the eight included studies on diagnostic concordance of VC teledermatology.

Table 34: Studies included in assessment of diagnostic concordance of VC teledermatology

Study	Sample size	Quality assessment
Skin lesions		
Phillips 1998	107	III-1, Q2, P2
All skin conditions		
Edison 2008	110	III-1, Q3, P1
Nordal 2001	112	II, Q2, P2
Gilmour 1998	155	III-1, Q2, P2
Lesher 1998	68	II, Q2, P2
Loane 1998a	427	III-1, Q3, P1
Lowitt 1997	130	II, Q2, P2
Phillips 1997	79	III-1, Q2, P2

*Type of agreement was not specified in the article, so it was treated as the concordance between aggregated diagnoses

Studies on management accuracy of SAF teledermatology

Literature search identified two studies of skin lesions that assessed management accuracy using histopathology or laboratory tests as gold standard (Table 35).

Table 35: Studies on management accuracy of SAF teledermatology

Study ID	SAF teledermatology	Sample size	Quality assessment
Warshaw 2009 a	Digital photography +dermatoscopy	542	II, Q1, P1
	Digital photography	542	
Warshaw 2009 b	Digital photography +dermatoscopy	714	II, Q1, P1

	Digital photography	728	

The literature search did not locate any studies that assessed management accuracy of VC teledermatology.

Studies on management concordance of SAF teledermatology

Literature search identified ten studies that assessed management concordance using FTF examination as a reference standard. Table 36 lists management concordance studies that met the inclusion criteria and contained sufficient data to extract proportion of correct diagnoses (rather than the concordance with respect to a dichotomous outcome e.g. refer/not refer or biopsy/not biopsy).

Table 36: Studies on management concordance of SAF teledermatology

Study ID	SAF teledermatology	Sample size	Quality assessment
Skin lesions			
Ferrandiz 2007	Digital photography	134*	III-1, Q3, P2
Mahendran 2005	Digital photography	163	II, Q2, P2
Shapiro 2004	Digital photography	49	III-1, Q3, P1
All skin conditions			
Heffner 2009	Digital photography	135	III-1, Q2, P1
Edison 2008	Digital photography	110	III-1, Q3, P1
Bowns 2006	Digital photography	92	II, Q3, P1,
Whited 1999	Digital photography	129	III-1, Q2, P2
Lyon and Harrison 1997	Digital photography	90	III-1, Q3, P1
Zelickson and Homan, 1997	Digital photography	29	III-1, Q3, P2
Rubegni 2011	Digital photography With dermatoscopy	130	III-1, Q3, P2

*skin lesions

Studies on management concordance of VC teledermatology

Literature search identified three studies that assessed management concordance of VC teledermatology using FTF examination as a reference standard (Table 37).

Table 37: Studies on management concordance of VC teledermatology

Study ID	Sample size	Quality assessment
Edison 2008	110	III-1, Q3, P1
Gilmour 1998	61	III-1, Q2, P2
Loane 1998	214	III-1, Q3, P1

Other studies assessing clinical effectiveness of teledermatology

Head-to-head trials

The literature search identified six head-to-head trials (Edison, 2008; Loane, 2000; Romero 2010; Romero 2014; Rajagopal, 2009; Baba, 2005). The studies by Romero (2010; 2014); Rajagopal (2009) and Baba (2005) evaluated SAF versus a combination of SAF and VC modalities and did not meet the selection criteria for the Assessment. The study by Loane (2000) was a cost-effectiveness analysis where SAF modality was directly compared with VC without involving a reference standard of any kind. This study was excluded from the analysis of diagnostic performance of teledermatology. Only the study by Edison (2008) assessed SAF and VC modalities using FTF as a reference standard and was included in the relevant sets for the pooled estimates of diagnostic performance.

Economic evaluations of teledermatology

Literature search identified 13 comparative studies. These are described in Section "Review of published economic evaluations" [120]

Studies on patient outcomes

Literature search identified 13 comparative studies assessing different types of patient benefits. Twelve of these studies assessed intermediate patient outcomes such as time to clinic attendance, time to treatment, and avoidance of unnecessary referrals. Only one RCT (Whited, 2013a) measured a change in quality of life of dermatology patients treated with and without SAF teledermatology. The different patient benefits are described below:

1. Reduced waiting times to the definitive action (either diagnosis or reassurance) for patients assessed by teledermatologist versus a conventional in-person presentation (Eminovich, 2009; Hsiao, 2008; Ferrandiz, 2007; Moreno-Ramirez, 2007; Bowns, 2006; Whited, 2002).
2. Reduction in travel time due to the reduction in FTF consultations with a clinical dermatologist (Eminovich, 2009; Hsiao, 2008; Ferrandiz, 2007; Moreno-Ramirez, 2005, 2007; Bowns, 2006; Mahendran, 2005; Taylor, 2001; Loane, 2001, Wootton, 2000; Whited, 2002). This is essentially a health-economics outcome if undertaken from the patient's or societal perspective. Although this outcome is outside the scope of the Assessment, the rate of substitution of FTF referrals for SAF diagnoses informed the modelled economic evaluation [127].

3. Speed of recovery assessed at 1 month follow-up by the self-reported measure of improvement "condition improved" or "not improved" (Eminovich, 2009); at 6 months follow-up by the self-reported "still suffer from disease" (Granlund, 2003); or by the visible change on the repeated digital images (Pak, 2007).
4. Changes in quality of life from the baseline between teledermatology patients and patients undergoing a standard referral and treatment procedure were assessed with Skindex-16 and SF-12 v2 at 3 and 9 months (non-utility based measures) in the RCT by Whited (2013a).

However, none of the studies were head-to-head studies that directly compared the benefits to patients of using SAF and VC.

Appraisal of the evidence

Appraisal of the evidence was conducted at 3 stages:

Stage 1: Appraisal of the applicability and quality of individual studies included in the review.

Reference standard

The highest level of evidence requires a blinded comparison of teledermatology diagnosis with the valid reference standard. The studies that used histopathology results (the gold standard) met this criterion (Table 32). In the highest quality trials neither teledermatologists nor clinical dermatologists were aware of histopathology results before making a diagnosis. Where teledermatology of skin conditions used trial outcomes other than histopathology (gold standard) this may compromise the validity of the comparative assessment of diagnostic performance of SAF and VC.

Diagnosis by the clinical dermatologist by FTF consultation while being masked to the diagnosis by a teledermatologist, was assumed to be a reference standard in presentations with inflammatory skin conditions. However, with respect to "difficult to diagnose" skin conditions there is a degree of disagreement in diagnostic decisions between the consultants. Discordance in clinical assessment was commented in the literature where interobserver agreement between clinical dermatologists examining patients' in-person ranged from 54% to 94% (Levin, 2009). Nevertheless it seems to be assumed that as long as the rate of diagnostic concordance between a teledermatologist and a clinical dermatologist remains as good as or better than the rate of agreement among clinical dermatologists, teledermatology is considered to be equally efficacious. For example, in 308 patients, the concordance of SAF versus FTF consultation, assessed with Cohen's Kappa coefficient (k=83%) was comparable with diagnosis concordance between clinical dermatologists (k=81%) (Krupinski, 1999). Another study of 129 patients treated by the Veteran Affairs dermatologists compared diagnostic and management agreement among patients seen by five examiners, two in the clinic and three using digital images along with a standardized patient clinical history form. Agreement on the exact diagnosis was 54% for the clinic dermatologists, 41-55% between the clinic and teledermatologists, and 49-55% among the teledermatologists (Whited, 1998; Whited, 1999). More recently the inter-observer agreement between four clinical dermatologists was 67%, lower than the 73% concordance of SAF versus FTF consultation or the 80% concordance of VC versus FTF consultation (Edison, 2008).

Some of the studies attempted to minimize the bias associated with inter-observer disagreement by using a second opinion of an independent clinical dermatologist (e.g. Bowns, 2006) or assessing the baseline rate of agreement between the examiners (Edison, 2008). However other studies did not assess the intra-group concordance as a yardstick for evaluating

the diagnostic performance of SAF or VC teledermatology when FTF presentation is used as a reference standard.

Clinical practice

Only a small proportion of the selected SAF studies used the design that followed the clinical pathway depicted in the protocol and reproduced in Figure 6. In three trials (e.g. Ferrandiz 2007, Bowns, 2006; Ebner, 2008) digital photography took place in the primary practitioner's office (usually by GP himself) uploaded together with GP's referral and patients' clinical information into a digital media and sent to the teledermatologist. Other clinical trials obtained digital images from the variety of sources (e.g. made by a medical photographer from the Hospital Dermatology Department using a digital camera (Edison 2008); made by a medical student/hospital or research staff (Oakley, 2006; Rosendahl, 2011) using a digital camera; made by a dermatologist using a digital camera, with or without dermatoscopy lens (Braun, 2000; Coras 2003). Videoconferencing was conducted at GP office (e.g. Loane, 1998a, or at the hospital when the patients were assisted by the nurse (e.g. Lowitt, 1997) or research staff (Edison, 2008). Due to the large variety in methods of obtaining digital images, the studies could not be categorized into meaningful subgroups for the separate analyses of diagnostic performance.

A limited number of studies on accuracy of teledermoscopy have taken place in a laboratory setting with a clinical photographer or a highly skilled dermoscopist with experience in taking dermatoscopic images (van der Hijden 2013, Senel, 2013). Most of the teledermoscopy studies included in the analysis used either the research staff to produce teledermoscopy images (Warshaw 2009a & Warshaw 2009b Whited, 1999) or the images were obtained by the dermatologists with various degrees of experience (Braun, 2000; Coras 2003). This limits applicability of the results to routine clinical practice.

Most of the studies included a standardized form for recording the relevant patient history and results of pathology or other tests. However some of the studies allowed a free format for recording relevant and frequently limited patient information (sex, age, the site of lesion as in Piccolo, 1999, 2000). In one study teledermatologists were not provided with clinical history (Braun, 2000). In other studies it was not possible to establish whether the clinical data that were sent to the teledermatologist together with the digital images was the same patients' clinical data that is routinely available to the consultant dermatologist assessing the patient in person. Therefore we were unable to estimate the degree of possible bias associated with the use of different technologies and different formats for recording patients' clinical data.

Design:

Most of the studies did not explicitly state that the teledermatologist was masked to the assessment made by clinical dermatologist. This may be due to poor reporting rather than poor trial design, so the data from these studies were not excluded from the analysis. However in some cases the blindness was not preserved for each of the participating consultants because the same clinician acted both as a teledermatologist and as a clinical examiner (Krupinski, 1999, Loane, 1998a). Only the studies where it was possible to apportion the results to the independent assessors were included in the analysis.

Technology:

Intervention: SAF teledermatology

The clinical trials of the store-and-forward applications of teledermatology have generally used commonly available digital cameras and varying techniques for storing and transmitting the digital photographs. Recently mobile phones with built-in cameras are used for making digital

images (Ebner, 2008). The importance of the high colour resolution of the monitors at the dermatologist's end was demonstrated in the study by Oakley (2006). Technical characteristic of the equipment used in production and transmission of digital images along with the differences in skills of the person making a photograph are likely to have contributed to the variation in the estimates of the diagnostic performance of SAF teledermatology.

Comparator: VC

The technological advances over the last 15 years resulted in significant differences in technological characteristics of VC and SAF teledermatology modalities that were employed in the identified studies. The technical characteristics during the earlier (1997-2001) clinical trials typically included digital audio (e.g., an electronic stethoscope) and/or video modalities (a digital camera with greater than 1,000-by-1,000-pixel display and 24-bit color), along with the ability to record patient history and physical examination data (in free text or captured via structured data entry from an electronic medical record). This material was transmitted using telecommunications medium. That medium might be analog telephone lines using a modem, however there was a growing proliferation of broadband services (e.g., frame relay, cable modem, digital subscriber line) that allow faster transmission. At the receiving end, consultants were likely to have access to high-powered workstations with high-resolution displays, allowing access to textual data, audio, and video in an integrated fashion (Hersh, 2001).

A comparison of the diagnostic concordance of VC teledermatology using two types of equipment (Loane, 1997a; Loane, 1997b), using FTF diagnosis as a reference standard, reported that the low-cost single-chip camera was associated with 62% of correct diagnoses vs 76% obtained with more expensive camera. Teledermatologist was unable to diagnose 14% of patients with low-cost camera and only 7% with more expensive camera. The proportion of wrong and missed diagnoses was twice as high with the low cost camera (10% compared with 5%). The study concluded that the quality of VC equipment has a direct impact on diagnostic performance. The selected VC teledermatology trials varied with respect to the technological characteristics of the video equipment and transmission (megabytes per second). The speed of transmission was also associated with the diagnostic concordance (Lowitt, 1997a & Lowitt, 1997b). The most recent trial of VC teledermatology did not report the technical specifications of the equipment or internet connectivity (Edison, 2008).

Some of the variability in diagnostic performance of VC teledermatology observed across the studies is likely to be related to the difference in technical characteristic of this modality, however the total number of studies was too small to explore this hypothesis by statistical means.

Teledermoscopy:

Teledermoscopy is a technique by which a low-power lens is used to generate a magnified image of a discrete skin lesion. In the selected studies this modality is only used for assessing diagnostic accuracy (using histology results as a gold standard). The most recent studies used the Cyber-Shot DSC-W70, SONY digital camera combined with a lens attachment Dermlite II Pro HR, 3Gen Inc (Senel, 2013); Cyber-Shot DSC-W560, SONY with 3Gen DermLite Pro II HR, 3Gen Inc, (van der Heijden, 2013).

For the study of non-pigmented lesions to obtain standard macro images (distance and close up) the authors used a digital Nikon Coolpix 4500 with a Nikon SL-1 ring flash, Nikon, Meville, NY) and PLD images (digital Nikon Coolpix 4500 with a 3Gen Dermlite lens attachment, 3Gen, San Juan Capistrano, CA) (Warshaw 2009a). For pigmented lesions a standard CID image (35-mm Minolta X 370 with a Heine dermphot lens attachment, Heine, Dover, NH) was also obtained for each pigmented lesion. The resulting 35-mm kodachrome

was scanned (Nikon Cool Scan LS-4000ED, KonicaMinolta, Tokyo, Japan) to create a digital image (Warshaw 2009b). These modern pieces of equipment were considered compatible in quality but there is uncertainty in how the technical characteristics of these equipment compares with the equipment used in the earlier studies. For example, Piccolo (2000) used a digital camera DCS 460, (Kodak, Rochester, NY, USA) with a dermatoscope Heine Delta 10, (Heine Optotechnik, Herrsching, Germany). Coras, 2003 used a hand-held 3-CCD camera (Dermogenius® ultra Rodenstock Prazisionsoptik (LINOS Co., Munich, Germany) in combination with Dermogenius Software version 1.2.

Summary of characteristics of the studies included in the analysis

Table 38 and Table 39 list selected characteristics of SAF studies included in the analysis of diagnostic performance of SAF teledermatology. For the complete description of each study see Appendix C [157].

Some of the characteristics (sample size, consecutive enrollment, blindness of the assessors, quality of images, comprehensiveness and availability of patient clinical data) are associated with the potential bias in the estimates of diagnostic performance. The selective loss of patients to the follow up was observed only in one RCT (Bowns, 2006). Other included studies were observational cohorts with repeated presentation of the same patients for teledermatology and FTF presentation, which normally occurred either on the same day or within a short period of time.

Table 38 Selected characteristics of the studies assessing diagnostic accuracy of SAF teledermatology

Study	Sample size	Population	Skin conditions	Cons-ecutive enroll-ment	Blindness of the assessors*	Who made the images	Quality of images (% rejected)	Patient data recording format
Şenel 2013	82 patients	patients referred to dermatology department	non-melanocytic skin tumors	no	yes	technician	Not reported	Standardized form
Warshaw 2009 a	542 patients with a single index lesion	patients referred to dermatology department clinic of Veteran Affairs	pigmented neoplasms	yes	yes	research staff	0%	standardized patient and lesion history collected by the research assistants
Warshaw 2009 b	728 patients	patients referred to dermatology department clinic of Veteran Affairs	nonpigmented neoplasms	yes	yes	research staff	4 unusable photos (0.5%)	standardized patient and lesion history collected by the research assistants
Oakley 2006	48 lesions	patients referred to dermatology department	skin lesions	no	yes	Medical student	Not reported	standardized patient and lesion history collected by medical student
Piccolo 2000	43 lesions	patients referred to dermatology department	pigmented difficult to diagnose skin lesions	no	yes	Not reported	Not reported	Basic clinical data sex, age, site of lesion
Rosendahl 2011	463 lesions	Retrospective analysis of consecutive biopsied lesions	pigmented skin lesions (melanocytic and non-melanocytic)	yes	yes	Clinician at the skin cancer clinic	3/466 (0.7%)	Not clear
Whited 1999	79 lesions	patients referred to veteran administration dermatology department	Skin lesions	no	yes	A research assistant (can repeat images)	Not reported	Standardized history
Piccolo 1999	66 lesions	patients referred to dermatology department	pigmented skin lesions (melanocytic and non-melanocytic)	no	yes	Not reported	Not reported	Basic clinical data sex, age, site of lesion
Whited 1998	9 lesions	patients referred to veteran administration dermatology department	suspected skin cancer.	No convenience sample	yes	Not clear: In the dermatologist's office	Not reported	History: location, duration and size of the lesion was recoded
Barnard 2000	25 lesions	patients referred to dermatology	Suspected cancer, benign	Pre-selected lesions	yes	Not reported	Not reported	patient's age, gender, location,

		department	tumour;					duration and symptoms of the skin problem
Braun 2000	55 lesions	patients selected by private dermato-logists	Pigmented skin lesions	no	yes	private dermato-logists trained in dermatosc opy	Not reported	Comprehensi ve history in the free format but not provided to TD
Coras 2003	45 lesions	patients selected by private dermato-logists	Pigmented skin lesions	no	yes	private dermato-logists trained in dermatosc opy	Not reported	Free format patient data and medical history
Ferrandiz 2007	130 patients	patients referred to cancer skin centre	Non-melanoma skin cancer or a fast-growth vascular tumor	yes	yes	A referrer (GP)	Not reported	Unspecified Clinical data
Kroemer 2011	104 lesions	patients referred to dermatology department	benign or malignant skin tumours of melano-cytic or non-melanocytic origin	Not clear	Yes	A Clinical dermatolog ist conducting FTF assessmen t	1% digital and 6% dermascopic images were not usable	Clinical data age, sex, tumour onset, location and patient history
Krupinski 1999	104 biopsied lesions	patients referred to dermatology department	Malignant premalignant benign proliferations Pigmented lesions eczema/der matitis Infections/inf estations	yes	Partly aware of the FTF diagnosis (TD=CD in 1/3 of cases) Not clear about histology results	medical students trained in the use of the camera	Not reported	Unspecified patient history

* with respect to FTF diagnosis and histology results; TD=teledermatologist

Only five of the skin lesion studies listed in Table 38 involve more than 100 units of analysis (sample size). The largest studies by Warshaw (2009a & 2009b) were also of the highest quality. Other studies are generally characterized by limitations in design, data analysis and quality of reporting. The studies differ with respect to the unit of analysis; population; skin conditions; the person responsible for producing the images and the number of produced images, which indicates a large degree of heterogeneity between the studies. For example, selecting patients from the department of Veteran Affairs resulted in significant under-representation of female patients (Warshaw, 2009a,b, Whited 1999) which limits generalizability of the results.

Very rarely consecutive enrollment was reported, and in most cases this could not realistically be excluded as a potential source of bias. Blindness of the assessors to the reference standard although rarely explicitly reported was assumed on the basis of the study design. Only a small proportion of digital and dermatoscopy images were not suitable for diagnosis, however many studies included a scale for teledermatologists to assess the quality of digital images. Variability in quality across the studies could not be estimated by statistical means due to the variety of the assessment scales used. Another potential source of bias is the comprehensiveness and

availability of patient clinical data. Some studies limited it to the age, sex, location and duration of a lesion (eg. Piccolo 1999, 2000); or did not elaborate on the content of the patient clinical data; and other studies created a standardized form to be included in the package transmitted for the teledermatology assessment (Warshaw, 2009a,b; Senel, 2013). In one study, the clinical history was collected, but was not made available to the teledermatologist (Braun, 2000).

Table 39 Selected characteristics of studies assessing diagnostic concordance of SAF teledermatology

Study	Sample size	Population	Skin conditions	Consecutive enrollment	Blindness of assessors	Who made the images	Quality of images (% rejected)	Patient data recording format
Skin lesions								
Piccolo 1999	66 lesions	patients referred to dermatology department	pigmented skin lesions (melanocytic and non-melanocytic)	no	yes	Not reported	Not reported	Basic clinical data sex, age, site of lesion
Bowns 2006	230 patients	patients referred to dermatology department	patients suspected of cancerous skin conditions	no	yes	Clinical photographer	Not reported	a one page proforma; symptoms, signs and initial diagnosis and treatment by the GP.
Oakley 2006	48 lesions	patients referred to dermatology department	skin lesions	no	yes	Medical student	Not reported	standardized patient and lesion history collected by medical student
Mahendran 2005	163	patients referred to dermatology department	lesions suspicious of skin cancer.	yes	yes	yes	24/163 (15%)	relevant past history
Barnard 2000	25 lesions	patients referred to dermatology department	Suspected cancer, benign tumour;	Pre-selected lesions	yes	Not reported	Not reported	patient's age, gender, location, duration and symptoms of the skin

								problem
Whited 1998	9 lesions	patients referred to veteran administration dermatology department	suspected skin cancer.	No convenience sample	yes	Not clear: In the dermatologist's office	Not reported	History: location, duration and size of the lesion was recoded
All skin conditions								
Study	Sample size	Population	Skin conditions	Consecutive enrollment	Blindness of assessors	Who made the images	Quality of images (% rejected)	Patient data recording format
Baba, 2005	228 Patients 242 lesions	patients referred to dermatology department	Skin lesions & inflam-matory	yes	Yes for one out of two TDs	Nurse at the department	Not reported but could be repeated if poor quality	Comprehensive standardized clinical data
Ebner, 2008	58 patients	patients presented for urgent care in derm clinic	Skin lesions & inflam-matory	Not clear	yes	Physician made images for 86%	1 image (1.7%)	Standardized form with basic clinical data
Heffner 2009	135 pediatric patients	Children presented in pediatric dermatology clinic	either a rash or rash descriptors (eg, bumps, spots, patches)	yes	Yes for one out of two TDs	Primary investigator	4% (4 photos of the skin conditions in one patient)	Comprehensive standardized form with demographic and clinical data
Edison 2008	110 patients	Self-presented new patients in the University dermatology clinic	All skin conditions	No convenience sample	Yes	A photographer (no details)	Not reported	demographic data, basic health history, and the patient's description of the skin condition
Bowns 2006	92 patients	Selected by GP as suitable	All skin conditions except for suspected cancerous lesions	N/A RCT	yes	GPs at their practices	Not reported	a one page proforma; symptoms, signs and initial diagnosis and treatment by the GP.
Tucker 2005	84 lesions	patients	All skin	Not clear	yes	Clinic	18/84=21%	Age, sex,

		referred to dermatology clinic	conditions	retrospective data		dermatologists		Clinical history, current treatment
Oztas 2004	163 patients	patients referred to dermatology clinic	All skin conditions		yes	Not clear	Not reported	Unspecified patient history
Du Moulin 2003	117 patients	Selected by GP as suitable	All skin conditions	Not clear	yes	GPs at their practices	17/106=16 %	Unspecified patient history
Rashid 2003	33 patients	patients referred to dermatology department	All skin conditions	no	yes	Not clear	3/33=10%	Medical records
High 2000	92 patients	patients referred to dermatology department	All skin conditions	no	yes	The primary investigator	Not reported	location of the lesion(s), the temporal course, any related symptoms, medications used,relevant medical history.
Krupinski 1999	308 patients	patients referred to dermatology department	Malignant premalignant benign proliferations Pigmented lesions eczema/dermatitis Infections /infestations	yes	Partly aware of the FTF diagnosis (TD=CD in 1/3 of cases) Not clear about histology results	medical students trained in the use of the camera	Not reported	Unspecified patient history
Whited 1999	168 lesions	patients referred to veteran administration dermatology department	All types of skin lesions	no	yes	A research assistant (can repeat images)	Not reported	Standardized history
Kvedar 1997	116 patients	patients referred to dermatology department	All types of skin lesions	no	yes	A photographer	Not reported	Standardized medical history
Zelickson 1997	23 nursing	patients requesting a	All types of skin	yes	yes	A nurse	Not reported	Unspecified medical

	home patients	dermatology consultation	lesions					history
Barbrieri 2014	50 patients	Inpatients requiring dermatology consultation	All types of skin conditions	Not clear	yes	medical students trained in the use of the camera	Not reported	Medical record
Rubegni 2011	130 geriatric patients	patients referred to geriatric dermatology department	All types of skin conditions	no	yes	an unspecified "presenter"	Not reported	Standardized medical history

The identified studies were characterized by the differences in design (RCT and observational cohort studies); in populations (general population, children, the USA Veteran Administration patients, nursing home patients, geriatric patients); in skin conditions; in health care systems: hospitals and private providers in predominately privately financed health care systems (USA, India, Brazil); hospitals in publicly funded health care systems (UK, EU, New Zealand, North Ireland and Australia); and the unit of analysis (typically the diagnostic accuracy was estimated in proportion to lesions, while diagnostic concordance was estimated in relation to patients). The smallest sample size was nine (Whited, 1998) and the largest was 728 (Warshaw, 2009b). Almost all studies did not provide justification for the sample size; the exception are the studies by Brown (2006), and Warshaw (2009a,b) described in the next section. More often than not the patients were not enrolled consecutively and blindness was not preserved for some of the assessors (Krupinski, 1999; Oakley, 2006; Baba, 2005); although in the final set of studies it was possible to exclude the diagnostic accuracy data obtained from the dermatologists who assessed the same patients firstly in-person and then as a teledermatologist. Rarely the proportion of images were of such a poor quality that it rendered them unusable was reported. Where it was reported un-usability ranged from 1.7% (Ebner, 2008) to 21% (Tucker, 2005) possibly reflecting the combination of confounding factors such as skill of the person making digital/dermoscopic images and sophistication of the equipment and lighting. In some studies a provision was made for obtaining a second set of images if the first image was inadequate (e.g. Baba 2005). The standardization and comprehensiveness of the background clinical patient information varied between the studies and might have influenced variability in estimates of diagnostic performance (Oztas, 2004; Barnard, 2000).

Stage 2: Appraisal of the precision, size and clinical importance of the primary outcomes used to determine the safety and effectiveness of the intervention.

The identified studies that included patients with all types of skin conditions compared VC or SAF teledermatology diagnoses using FTF presentations as a reference standard. However, it was commented in the literature that there is a degree of disagreement between clinical dermatologists in their diagnostic decisions. In the absence of a gold standard or a baseline estimate of the intra-group concordance among the face-to-face examiners, the reliability of results suggesting an equivalent diagnostic performance of teledermatology and FTF presentations is limited (Hersh 2006). Statistical power calculations were not typically reported and the majority of the studies were apparently underpowered, so the lack of statistically significant differences, when estimated, could have been due to an inadequate sample size.

In many studies diagnostic reliability between teledermatology and the reference standard was measured using the Cohen's kappa statistic (e.g. Kroemer, 2011; Rosendahl 2011, Rubegni, 2011). The Table 40 below (Rubegni, 2011) presents K-values and suggested interpretation.

Table 40: Landis and Koch scale for the qualitative interpretation of Cohen's K coefficient

K	Interpretation
<0	No agreement
0.0-0.20	Slight agreement
0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-1.00	Almost perfect agreement

Source: Rubegni, 2011

However different studies used different thresholds and value judgements, making comparison of the reported statistic across studies problematic.

The statistically correct approach to testing clinical equivalence (non-inferiority) of SAF versus FTF consultations was first exercised in the RCT by Bowns (2006) and also used in the large good quality trials by Warshaw (2009a & 2009b). These studies tested clinical equivalence in repeated measures design using histology results as a gold standard. Bowns (2006) calculated the sample size assuming 90% of management plans being correct in the FTF group; the one-sided difference in clinical management plans between SAF and FTF within 5% was assumed to be consistent with the null hypothesis of equivalence. Diagnostic performance was a secondary outcome. The required sample size was 496 patients in each arm to ensure 80% statistical power.

In the trials by Warshaw, in both pigmented (2009a) and non-pigmented lesions (2009b) the primary statistical analyses used two-sided equivalence tests to examine the equivalence of the aggregated diagnostic accuracy of SAF teledermatology and clinic-based dermatology (FTF presentations). Diagnostic accuracy of the primary diagnosis was a secondary outcome as was the appropriateness of the selected management plan. The analysis tested the null hypothesis that the absolute difference in accuracy rates is at least 10% against the alternative hypothesis that the difference is less than 10%. This test, conducted using a significance level of .025, corresponds to assessing whether the 95% confidence interval for the difference in accuracy is entirely within 10%. To assess the equivalency of the diagnostic accuracy of SAF teledermatology and clinic based FTF examination, the required sample was approximately 520 biopsied non-pigmented lesions. The study by Warshaw (2009b) enrolled 1034 patients and selected 728 index non-pigmented lesions (one index lesion per patient). The pigmented lesions study by Warshaw (2009a) enrolled 651 patients and selected 542 index pigmented lesions.

The trials by Warshaw (2009a) and Warshaw (2009b) also assessed the incremental change in aggregated diagnostic accuracy of SAF teledermatology with the addition of polarized light dermatoscopy (PLD) and contact immersion dermatoscopy (CID). The authors compared teledermatology accuracy using just macro images and using both macro and PLD images. The McNemar test for paired observations was used (Agresti A. Categorical data analysis. New York: Wiley; 1990). McNemar test for paired proportions was also used to test whether VC and SAF-based diagnoses differed with respect to proportion of agreement with FTF clinical examination (Edison, 2008).

Other identified studies did not provide justification of the sample size and appear to be underpowered for assessing clinical equivalence of teledermatology in comparison to the reference standard. Occasionally difference in proportions of correct diagnosis between clinical and teledermatologists was statistically analyzed with Wilcoxon test (e.g. Piccolo, 1999), which may constitute an incorrect application of the test if the data were recorded in the dichotomous format (i.e. correct vs incorrect diagnosis using histology results as a gold standard).

Stage 3: Integration of this evidence for conclusions about the net clinical benefit of the intervention in the context of Australian clinical practice.

Integration of the best available evidence consisted of the following steps:

- Summary of the systematic reviews
- Narrative description of the only head-to-head trial (Edison, 2008)
- Narrative description of the eligible RCT (Bowns, 2006)
- Synthesis of the results of the included clinical trials

The studies were grouped according to the reference standard (histology results for skin lesions and FTF presentations for all skin conditions) Analysis of the accuracy and concordance data was carried out with respect to both primary and aggregated diagnoses. Diagnostic accuracy of teledermatology of skin lesions was assessed for both digital (macro) photography and teledermatoscopy.

We produced pooled estimates of diagnostic accuracy by calculating the weighted mean differences based on study sample sizes (Lipsey & Wilson, 2001). However, due to considerable heterogeneity in the study design, population and skin conditions, the results should be interpreted with caution. It was technically possible to meta-analyse the results of the diagnostic accuracy studies in skin lesions that compared SAF teledermatology with FTF examinations, however the observed high degree of heterogeneity limits the reliability of the conclusions.

Validity assessment of individual studies

The evidence presented in the selected studies was assessed and classified using the dimensions of evidence defined by the National Health and Medical Research Council (NHMRC, 2000).

These dimensions (Table 41) consider important aspects of the evidence supporting a particular intervention and include three main domains: strength of the evidence, size of the effect and relevance of the evidence. The first domain is derived directly from the literature identified as informing a particular intervention. The last two require expert clinical input as part of its determination.

Table 41 Evidence dimensions

Type of evidence	Definition
Strength of the evidence	
Level	The study design used, as an indicator of the degree to which bias has been eliminated by design.*
Quality	The methods used by investigators to minimise bias within a study design.
Statistical precision	The *p*-value or, alternatively, the precision of the estimate of the effect. It reflects the degree of certainty about the existence of a true effect.
Size of effect	The distance of the study estimate from the "null" value and the inclusion of only clinically important effects in the confidence interval.
Relevance of evidence	The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.

* NHMRC

Table 42 presents the summary of the assessment of the bias in the selected studies.

Individual studies assessing diagnostic effectiveness were graded according to pre-specified quality and applicability criteria (MSAC 2005), as shown in Table 88.

Table 42 Summary of the assessment of the bias

Study	Prospective observational cohort	Consecutive enrolment	Standardized comprehensive medical history available to the assessors	Blindness of the assessors to the reference standard	Blindness of the assessors to the alternative diagnosis	Flow of patients provided	Missed diagnoses and wrong diagnoses explained	Appropriate statistical analysis is under taken[1]	Appropriate comparison	Applicability of the population	Overall quality of the study
Diagnostic accuracy (skin lesions)											
Senel, 2013	√	?	√	√	√	-	√	-	C1	P2	Q3
Warshaw 2009a	√	√	√	√	√	√	√	√	C1	P2	Q1
Warshaw 2009a	√	√	√	√	√	√	√	√	C1	P2	Q1
Oakley 2006	√	?	√	√	√	-	-	-	C1	P2	Q3
Piccolo 2000	–	√	√	√	√	√	√	-	C1	P2	Q3
Rosendahl 2011	-	-	-	√	N/A	√	√	√	C1	P2	Q3
Whited 1999	√	-	√	√	√	√	√	-	C1	P2	Q2
Piccolo 1999	√	-	√	√	√	√	√	-	C1	P2	Q3
Whited 1998	√	-	√	√	√	√	√	-	C1	P2	Q2
Barnard 2000	√	-	√	√	√	√	√	-	C1	P2	Q3
Braun 2000	√	-	-	√	√	√	√	-	C1	P2	Q3
Coras 2003	√	?	√*	√	√	√	√	-	C1	P2	Q3
Ferrandiz 2007	√	-	√*	√	√	√	N/A	-	C1	P2	Q3
Kroemer 2011	√	-	√	√	√	√	√	-	C1	P2	Q3

Krupinski 1999	√	√	√*	√	√	√	√	-	C1	P2	Q2
Diagnostic concordance											
Skin lesions											
Bowns 2006	√	RCT	√	√	√	√	√	√	C1	P1	Q3**
Mahendran 2005	√	√	√	√	√	√	√	-	C1	P2	Q2
All skin conditions											
Baba, 2005	√	-	√	√	-	√	-	√	C1	P1	Q2
Ebner, 2008	√	-	√	√	√	√	√	-	C1	P1	Q3
Heffner 2009	√	√	√	√	√	√	√	-	C1	P2	Q2
Edison 2008	√	?	√	√	√	√	√	√	C1	P1	Q2
Tucker 2005	√	-	√	√	√	√	√	-	C1	P2	Q3
Oztas 2004	√	-	√	√	√	√	-	-	C1	P1	Q3
Du Moulin 2003	√	?	√*	√	√	√	√	-	C1	P1	Q3
Rashid 2003	√	-	√	√	√	√	√	-	C1	P1	Q3
High 2000	√	-	√	√	√	√	√	-	C1	P1	Q3
Kvedar 1997	√	-	√	√	√	√	-	-	C1	P1	Q3
Zelickson 1997	√		√	√	√	√	-	-	C1	P2	Q3
Barbrieri 2014	√	?	√	√	√	√	√	-	C1	P2	Q3
Rubegni 2011	√	-	√	√	√	√	√	-	C1	P2	Q3

Overall assessment of quality of the studies

All of the identified studies used an appropriate diagnostic performance design of prospective observational cohort with repeated diagnostic assessment, but on the summary of criteria most of them were assessed as poor quality. There were only two high quality large clinical trials (Warshaw, 2009a & 2009b) that attracted the highest rating Q1. However results of these trials had a limited generalizability as the patients were recruited from the population of the US Department of Veteran Affairs (females were underrepresented). Only six studies (4 of diagnostic accuracy and two head-to-head trials) used an appropriate statistical analysis of paired proportions but may had other limitations with respect to consecutive enrolment, description of patients' clinical data, quality of images etc. The sample size calculation based on the required statistical power was reported only in three studies (Warshaw, 2009a & 2009b, Bowns 2006).

Only six studies (Whited 1998 & 1999; Krupinski, 1999; Lesher, 1998; Bowns, 2006; Edison 2008) reported an interobserver agreement between clinical dermatologists diagnosing patients in-person (reference standard - FTF) but still appeared to be underpowered for detecting statistically significant difference. The reported results should therefore be interpreted with caution.

Strength of the evidence

The three sub-domains (level, quality and statistical precision) are collectively a measure of the strength of the evidence.

Level

The "level of evidence" reflects the effectiveness of a study design to answer a particular research question. Effectiveness is based on the probability that the design of the study has reduced or eliminated the impact of bias on the results.

The NHMRC evidence hierarchy provides a ranking of various study designs ('levels of evidence') by the type of research question being addressed (see Table 88).

Assessment of the body of evidence

Appraisal of the body of evidence was conducted along the lines suggested by the NHMRC in their guidance on clinical practice guideline development (NHMRC 2008) (See Appendix F [242]). Five components are considered essential by the NHMRC when judging the body of evidence:

- The evidence base – which includes the number of studies sorted by their methodological quality and relevance to patients;
- The consistency of the study results – whether the better quality studies had results of a similar magnitude and in the same direction ie homogenous or heterogenous findings;
- The potential clinical impact - appraisal of the precision, size and clinical importance or relevance of the primary outcomes used to determine the safety and effectiveness of the test;
- The generalisability of the evidence to the target population; and
- The applicability of the evidence - integration of this evidence for conclusions about the net clinical benefit of the intervention in the context of Australian clinical practice.

A matrix for assessing the body of evidence for each research question, according to the components above, was used for this assessment (see Table 43) (NHMRC 2008).

Table 43 Body of evidence assessment matrix- SAF compared to VC

Evidence base	Excellent	1.One systematic review of teledermatology
	Good	2. Two level II comparative studies of diagnostic accuracy with low risk of bias (SAF vs FTF)
	Satisfactory	3. One level II concordance studies with moderate risk of bias
		4. Two level III-1 comparative studies of diagnostic accuracy (comparison with SAF vs FTF)
		5. One head-to head study III-1, without consecutive enrolment. Trial is underpowered
	Poor	6. Fourteen concordance studies were level III-1 or III-2.
		7.Three III-1 comparative studies of diagnostic accuracy (comparison with SAF vs FTF)
		8. Three III-1 diagnostic accuracy studies of SAF
Consistency	Good	Most studies consistent and inconsistency may be explained
Clinical impact	Good	Diagnostic accuracy used to determine the safety and effectiveness of the intervention
Generalisability	Good	Population/s studied in the body of evidence are similar to the target population
Applicability	Good	applicable to Australian healthcare context with few caveats, in particular how the service will be configured

Expert advice

The protocol to guide this assessment of asynchronous specialist dermatology services by telecommunications was developed with the supervision of the PASC and input from experts. Membership of PASC is provided at Appendix A. [154].

Results of assessment

Is it safe?

There are no inherent safety issues with providing a patient's clinical history and digital images via telecommunications. Nevertheless SAF is a different mode to providing the clinical information required to make a clinical diagnosis. Safety issues can arise with any diagnostic test in the form of an increase in false negative or false positive diagnosis. This aspect of safety will be addressed in more detail in the clinical efficacy section of the report.

The literature reports conflicting safety data on the on accuracy of SAF teledermatology for the diagnosis of pigmented lesions and exclusion of melanoma. It appears that this conflicting safety data may reflect the variations in photographic technique, equipment and experience of referrers and reporting specialists in macroscopic and dermascopic imaging. Caution is recommended for using teledermatology and teledermatoscopy for patients with malignant pigmented lesions (Warshaw 2009a).

An additional safety concern with asynchronous specialist dermatology services delivered by telecommunications is the privacy concerns of sending confidential patient medical data via the telecommunications system and the safe storage of this data. Strong encryption standards for any platform used to send and store patient information needs to be the basis for this type of service.

One of the ways it has been suggested to overcome variations in techniques and security and privacy of patients is to develop quality standards to bring together best practice and existing guidance. This has been done in the United Kingdom. The standards produced on teledermatology, including 'store and forward' images are intended to apply to any service using teledermatology commissioned by the NHS and was a project led by the British Association of Dermatologist (Primary Care Commissioning, 2013).

Some key points discussed in this document, relevant to Australia and this requested listing, are listed below:

1) Teledermatology should not be seen as a substitute for face-to-face consultations, but as a complementary service in circumstances where it better serves the interests of patients and offers better use of resources.
2) For patients with pigmented lesions, dermoscopic images should form part of any teledermatology referral that replaces a face-to-face consultation and the specialist dermatologist needs to be trained in the interpretation of macroscopic and dermoscopic pigmented lesion images.
3) Informed consent implies that the patient is made fully aware of the potential limitations of teledermatology compared to a face-to-face consultation
4) Clinicians and healthcare professionals involved in teledermatology should be equal in terms of competence, training and experience to those involved in equivalent non-teldermatology referrals. For roles specific to teledermatology (i.e. photographing patients) it is important that training and feedback are supplied and skills audited.
5) The information (history and images) supplied as part of any teledermatology referral must be of the highest quality and as full as possible, since the patient will not be present when their condition is reviewed. Any service specification should include a

well-designed pro forma for patient history and an agreed minimum standard for images (including number and type supplied).

6) Reliable, identifiable, secure, compatible and timely communication between clinicians is central to the teledermatology process. It is important to have agreed protocols, an alert system for any breakdowns in communication and a process of feedback built in.

7) Meet security and privacy standards to the relevant legal and professional guidance on the holding, storage and transfer of patient data.

8) Patient teledermatology records are searchable for audit purposes and are accessible as part of a patient record.

Summary of Safety – There are no inherent safety issues with providing patient clinical history and digital images by telecommunications rather than a patient being seen face-to-face.

Safety issues can arise with any diagnostic test in the form of false positives and false negatives. There is conflicting data on the accuracy of SAF teledermatology for the diagnosis of pigmented lesions and exclusion of melanoma.

Variations in digital photographic and dermatoscopic techniques and experience are suggested as reasons for the conflicting safety data. Development of quality standard to bring together best practice and existing guidance is recommended to overcome this variation.

Is it effective?

- Summary of the systematic reviews
- Narrative description of the only head-to-head trial (Edison, 2008)
- Narrative description of the eligible RCTs (Bowns, 2006)
- Synthesis of the results of the included clinical trials

Summary of systematic reviews

The literature search identified 13 systematic reviews on the subject of teledermatology. The scope was often broader than teledermatology, which was one of the applications of telemedicine (Hersh, 2001 and 2006). The objectives of the reviews were not limited to the systematic assessment of diagnostic accuracy and concordance of teledermatologic modalities. The objectives included a simple overview of various dermatology techniques undertaken from the nurse-practitioner's perspective (Brown N, 2000.); survey-based overview of the state of teledermatology programs in the United States (Armstrong et al 2012); providing insights into the evolution of evaluation studies of teledermatology over the past ten years. (Eminovic et al 2006; Eminovic et al 2007); Estimating travel reduction associated with the use of telemedicine (Wootton, R., Bahaadinbeigy, K., Hailey, D., 2011). Some systematic reviews were limited in the subset of the population (the US Medicare eligible, Hersh, 2001 and 2006; rural Australian population; Moffatt, 2010); and providers (The tertiary level of teledermatology; where dermatologists are seeking the second opinion for educational or diagnostic purposes (van der Heijden, 2010)

The systematic reviews varied in their quality (Table 44) (See Appendix C for the detailed description). The reported estimates of diagnostic performance from the higher quality systematic reviews together with the conclusions of the authors are presented in Table 44. These include the results from the comprehensive high quality reviews by Levin (2009) and Warshaw (2011). Both were instrumental in organising the presentation of the data for the Assessment. The relatively poor quality systematic review by Martin-Khan, 2011 was also included as it evaluated VC teledermatology.

The added value of the remaining systematic reviews is limited due to the relatively poor quality related to the searches' strategy and inadequate reporting of the review process, and methods synthesis. This made it difficult to decide whether the author's results and conclusions are consistent with the evidence base reviewed.

The authors of all reviews used a narrative summary of the results, which was appropriate, given the underlying heterogeneity in the identified studies. Some reviews made an attempt to explore differences between the studies quantitatively, (sometimes with inappropriate statistical means Kanthraj, 2013) but made reservations about interpretation of the aggregated data.

Table 44: Results of the higher quality systematic reviews

Systematic review	Evidence synthesis	Conclusion
Levin, Warshaw 2009 Teledermatology: A Review of Reliability and Accuracy of Diagnosis and Management; Dermatol Clin 27 (2009) 163–176	Overall, teledermatologists and clinic dermatologists completely agreed with each other in 41% to 94% of cases. They had partial agreement in 50% to 100%. Within intragroup, clinic dermatologists completely agreed with each other in 54% to 95% of cases and partially agreed with each other in 90% to 100% cases. Teledermatologists demonstrated complete agreement in 46% to 83%, and partial agreement in 84% to 92%. Kappa statistics ranged from 0.22 to 0.91. Accuracy rates based on a gold standard (primarily histopathology) for teledermatology ranged from 30% to 92% for clinic dermatologists and from 19% to 95% for teledermatologists.	Teledermatology demonstrated good performance in comparison to clinic-based consultation for diagnostic agreement and diagnostic accuracy. For diagnosis, teledermatologists agreed with each other and with clinic-based dermatologists at a rate comparable to intragroup agreement among clinic dermatologists. For clinical management, the conclusions are less convincing because of the few studies on the subject.
Warshaw 2011 Warshaw, E.M., Hillman, Y.J., Greer, N.L., Hagel, E.M., MacDonald, R., Rutks, I.R., Wilt, T.J., 2011. Teledermatology for diagnosis and management of skin conditions: a systematic review. Journal of the American Academy of Dermatology 64, 759-772.	Statistical pooling of the 6 SAF skin lesions studies reporting aggregated diagnostic accuracy rates (using histology results as a gold standard) found that the weighted mean absolute difference was 19% better for clinic dermatology than teledermatology. Teledermatology accuracy rates improved up to 15% (absolute difference) with teledermatoscopy. The weighted mean aggregated diagnostic concordance rates for SAF teledermatology were similar for lesion studies (64%) and general studies (65%); The rate for VC (87%) was higher, but this was based on significantly fewer patients (approximately 300 vs >1000).	In summary, diagnostic concordance of SAF is good and may be better for VC, possibly because of the ability to obtain additional history in the VC setting. Although overall rates of management accuracy were equivalent (+/-10%), for malignant and premalignant lesions, rates for teledermatology and teledermatoscopy were inferior to clinic dermatology; caution is recommended when using teledermatology in these cases.
Martin-Khan, M., Wootton, R., Whited, J., Gray, L.C., 2011. A systematic review of studies concerning observer agreement during medical specialist diagnosis using videoconferencing. Journal of Telemedicine & Telecare 17, 350-35	The overall percentage of agreement between VC and FTF was ranged from 59% to 96%. Adding VC to SAF could improve the agreement to 90%.	10 studies using video-conferencing for dermatology consultation with FTF consultation as reference standard, were included in the systematic review. Reliability of diagnosis via video-conferencing was confirmed in all studies.
Ndegwa S, Prichett-Pejic W, McGill S. Murphy G, Prichett-Pejic W, Severn M. Teledermatology Services: Rapid Review of Diagnostic, Clinical Management, and Economic Outcomes [Internet]. Ottawa: Canadian Agency for Drugs and	The aggregated estimates of diagnostic performance from the identified reports was not produced	Teledermatology consultations — whether using SAF, VC or hybrid techniques — result in highly reliable diagnoses and management plans that compare favourably with those of conventional clinic-based care.

Technologies in Health; 2010		-Teleconsultations were statistically significantly less accurate compared with clinic-based care in diagnostic accuracy studies. Teledermoscopy may be useful in the diagnosis of skin cancers and non-pigmented skin lesions, but not for pigmented lesions or atypical lesions.

The most commonly assessed aspect of teledermatology was interobserver agreement, although management accuracy was also reported for pigmented, non-pigmented lesion and all types of skin conditions (Warshaw, 2009a & Warshaw, 2009b). The range of agreement varied widely, from 41% to 87% for complete agreement (Hersh, 2006). The most recent review that assessed diagnostic performance separately by the type of lesions, stated that the diagnostic concordance of SAF was good, although the rates for VC were higher, albeit based on fewer patients (Warshaw, 2011). The overall percentage of agreement between VC and FTF ranged from 59% to 96%. Adding VC to SAF could improve the agreement to 90% (Martin-Khan, 2011). Most of the identified studies were limited by the lack of measurement of concordance among more than one face-to-face examiner.

The studies of diagnostic accuracy typically compared the telemedicine diagnosis to some sort of gold standard, often a biopsy of a pigmented lesion. The earlier systematic review concluded that in these studies, telemedicine was nearly as good as face-to-face in correctness of diagnosis (Hersh, 2006). Statistical pooling of the 6 SAF skin lesions studies reporting aggregated diagnostic accuracy rates (using histology results as a gold standard) found that the weighted mean absolute difference was 19% better for FTF consultation than teledermatology (Warshaw, 2011). More recently it was reported that although overall rates of management accuracy were equivalent (+/-10%), for malignant and premalignant lesions, rates for teledermatology and teledermatoscopy were inferior to clinic dermatology. The systematic reviews noted the lack of corresponding studies on patients' outcomes (Warshaw, 2011).

Head-to-head diagnostic concordance trial of SAF vs VC

One of the identified studies compared VC and SAF modalities with respect to diagnostic and management concordance (using FTF as a reference standard). Four dermatologists, in random rotation among all three care modalities, examined 110 new patients (Edison, 2008). The study used ICD-9 codes for recording the diagnosis; only the first (primary) diagnosis was used in calculation of diagnostic concordance. The pilot study established 67% (95%CI 38% -88%) diagnosis concordance (exact match of the primary diagnosis) between all four dermatologists, but the sample was very small (N=15). Inter-observer diagnostic concordance for different modalities is shown in Table 45.

Table 45: Inter-observer diagnostic concordance observed in the head-to-head trial

Modality	Number	Percent	95% CI	Kappa coefficient (95% CI)
VC, SAF and FTF,	70/110	64%	54.7–72.6%	N/A
VC vs FTF	88/110	80%	72.5–87.5%	0.79 (0.75- 0.83)

SAF vs FTF	80/110	73%	64.4–81.1%	0.71 (0.67- 0.76)
SAF vs VC	77/110	70%	61.4–78.6%	0.68 (0.64- 0.73)

Source: Edison, 2008

More identical diagnoses were given for FTF and VC examinations than for FTF and SAF examinations (80% versus 73%) but the difference was not statistically significant (McNemar's test; p = 0.13). The absence of statistical significance may be due to the lack of statistical power, nevertheless, the percentage of identical diagnoses for FTF and VC examinations and for FTF and SAF examinations was higher than the baseline intragroup concordance of 64%.

Overall teledermatology (both VC and SAF modalities) demonstrated good performance in comparison to FTF consultation for diagnostic concordance.

Narrative description of the eligible RCT

The only RCT that met the selection criteria was the UK non-inferiority trial by Bowns et al (2006). The authors reported that store-and-forward teledermatology failed to achieve diagnostic and management equivalence compared with face-to-face consultations. Several trial limitations suggest that these results may not represent a valid comparison. First, the study failed to achieve the recruitment target of 892 patients as estimated based on pre-study calculations. Instead, 208 participants were recruited, that is, the study fell considerably short of recruiting the required number of patients. Apart from under-recruitment, there was a selective loss of patients and the delay in obtaining a valid second opinion in the SAF group (Ndegwa, 2010). Due to the lack of statistical power and the likelihood of a systematic bias, no valid conclusions can be drawn regarding the diagnostic and clinical management performance on SAF teledermatology from the RCT reported in Bowns (2006).

Synthesis of the results of the included clinical trials

Study ID	Tele-dermatology modality	Store-and-Forward			Face-to-Face			RD*	OR*
		Correctly diagnosed	Total number	%	Correctly diagnosed	Total number	%		
Warshaw 2009 a	Digital images +Dermatoscopy	279	541	51.6	318	541	59.0	-0.07 [-0.13, -0.01]	0.75 [0.59, 0.95]
	Digital images	273	542	50.4	318	542	58.7	-0.08 [-0.14, -0.02]	0.71 [0.56, 0.91]
Warshaw 2009 b	Digital images +Dermatoscopy	335	716	46.8	402	716	56.1	-0.09 [-0.15, -0.04]	0.69 [0.56, 0.85]
	Digital	313	728	43.0	408	728	56.0	-0.13	0.59

	images							[-0.18, -0.08]	[0.48, 0.73]
Oakley 2006	Digital images	34	48	70.8	21	29	72.4	-0.02 [-0.22, 0.19]	0.93 [0.33, 2.58]
Whited 1999	Digital images	47	79	59.5	51	79	64.6	-0.05 [-0.20, 0.10]	0.81 [0.42, 1.53]
Whited 1998	Digital images	5	9	55.6	6	7	85.7	-0.30 [-0.72, 0.11]	0.21 [0.02, 2.52]
Braun 2000	Digital images +Dermatoscopy	41	55	75	35	55	64	0.11 [-0.06, 0.28]	1.67 [0.74, 3.79]
Coras 2003	Dermatoscopy only	40	45	89	41	45	91	-0.02 [-0.15, 0.10]	0.78 [0.20, 3.12]
SAF vs FF Digital images only pooled analysis		672	1406	55.59 (48-63.19	834	1386	64.17 (59.63-68.71)	-0.11 [-0.14, -0.07]	0.65 [0.56, 0.76]
SAF vs FF Digital images plus dermoscopy pooled analysis		695	1357		796	1357		-0.06 [-0.11, 0.00]	0.76 [0.61, 0.95]

reports the proportion of correct diagnosis of primary lesions of the identified studies of SAF teledermatology in the primary diagnosis of skin lesions compared to FTF using histology as the reference standard. The results in the Tables are reported by the type of technology: teledermatology (digital images) vs a combination of digital images + teledermatoscopy.

Table 46: SAF vs FTF correct diagnosis of primary diagnosis of skin lesion (histology is reference)

Study ID	Tele-dermatology modality	Store-and-Forward			Face-to-Face			RD*	OR*
		Correctly diagnosed	Total number	%	Correctly diagnosed	Total number	%		
Warshaw 2009 a	Digital images +Dermatoscopy	279	541	51.6	318	541	59.0	-0.07 [-0.13, -0.01]	0.75 [0.59, 0.95]
	Digital images	273	542	50.4	318	542	58.7	-0.08 [-0.14, -0.02]	0.71 [0.56, 0.91]
Warshaw 2009 b	Digital images +Dermatoscopy	335	716	46.8	402	716	56.1	-0.09 [-0.15, -0.04]	0.69 [0.56, 0.85]
	Digital images	313	728	43.0	408	728	56.0	-0.13 [-0.18, -0.08]	0.59 [0.48, 0.73]
Oakley 2006	Digital images	34	48	70.8	21	29	72.4	-0.02 [-0.22, 0.19]	0.93 [0.33, 2.58]
Whited 1999	Digital images	47	79	59.5	51	79	64.6	-0.05 [-0.20,	0.81

								0.10]	[0.42, 1.53]
Whited 1998	Digital images	5	9	55.6	6	7	85.7	-0.30 [-0.72, 0.11]	0.21 [0.02, 2.52]
Braun 2000	Digital images +Dermatoscopy	41	55	75	35	55	64	0.11 [-0.06, 0.28]	1.67 [0.74, 3.79]
Coras 2003	Dermatoscopy only	40	45	89	41	45	91	-0.02 [-0.15, 0.10]	0.78 [0.20, 3.12]
SAF vs FF Digital images only pooled analysis		672	1406	55.59 (48-63.19	834	1386	64.17 (59.63-68.71)	-0.11 [-0.14, -0.07]	0.65 [0.56, 0.76]
SAF vs FF Digital images plus dermoscopy pooled analysis		695	1357		796	1357		-0.06 [-0.11, 0.00]	0.76 [0.61, 0.95]

*analysis done in RevMan

Five studies directly compared SAF teledermatology, digital images only and FTF in primary diagnoses of skin lesions using histopathology as a reference standard. Sample sizes ranged from 728 lesions to 9 (Warshaw, 2009a & 2009b; Oakley (2006) Whited (1998; 1999)). In these studies, the estimate of diagnostic accuracy of SAF with digital images ranged from 43% to 70.8%. The estimates of diagnostic accuracy of FTF presentations with digital images ranged from 56% (Warshaw, 2009a) to 86% (Whited 1998).

The equivalency of diagnostic accuracy of teledermatologists and clinical dermatologists examining patients' in-person was tested in two repeated measures adequately powered studies of pigmented and non-pigmented lesions (Warshaw, 2009a & 2009b).

In the study of non-pigmented lesions the authors concluded that the diagnostic accuracy rates (both aggregated diagnostic accuracy and primary diagnostic accuracy) of clinic (FTF) dermatologists were statistically significantly better than teledermatologists in all analyses for lesion type and teledermatology modality (macro images or macro plus PLD) (Warshaw, 2009b).

The pooled analysis in

Study ID	Tele-dermatology modality	Store-and-Forward			Face-to-Face			RD*	OR*
		Correctly diagnosed	Total number	%	Correctly diagnosed	Total number	%		
Warshaw 2009 a	Digital images +Dermatoscopy	279	541	51.6	318	541	59.0	-0.07 [-0.13, -0.01]	0.75 [0.59, 0.95]
	Digital images	273	542	50.4	318	542	58.7	-0.08 [-0.14, -0.02]	0.71 [0.56, 0.91]
Warshaw 2009 b	Digital images +Dermatoscopy	335	716	46.8	402	716	56.1	-0.09 [-0.15, -0.04]	0.69 [0.56, 0.85]

	Digital images	313	728	43.0	408	728	56.0	-0.13 [-0.18, -0.08]	0.59 [0.48, 0.73]
Oakley 2006	Digital images	34	48	70.8	21	29	72.4	-0.02 [-0.22, 0.19]	0.93 [0.33, 2.58]
Whited 1999	Digital images	47	79	59.5	51	79	64.6	-0.05 [-0.20, 0.10]	0.81 [0.42, 1.53]
Whited 1998	Digital images	5	9	55.6	6	7	85.7	-0.30 [-0.72, 0.11]	0.21 [0.02, 2.52]
Braun 2000	Digital images +Dermatoscopy	41	55	75	35	55	64	0.11 [-0.06, 0.28]	1.67 [0.74, 3.79]
Coras 2003	Dermatoscopy only	40	45	89	41	45	91	-0.02 [-0.15, 0.10]	0.78 [0.20, 3.12]
SAF vs FF Digital images only pooled analysis		672	1406	55.59 (48-63.19	834	1386	64.17 (59.63-68.71)	-0.11 [-0.14, -0.07]	0.65 [0.56, 0.76]
SAF vs FF Digital images plus dermoscopy pooled analysis		695	1357		796	1357		-0.06 [-0.11, 0.00]	0.76 [0.61, 0.95]

showed a statistically significant risk difference between SAF and FTF in correct primary diagnosis of skin lesion, in favour of FTF. Figure 8 presents a forest plot of Odds Ratio for the proportion of correct diagnosis.

Figure 8: Forest Plot of comparison of SAF and FTF in correct diagnosis of primary lesion no dermoscopy

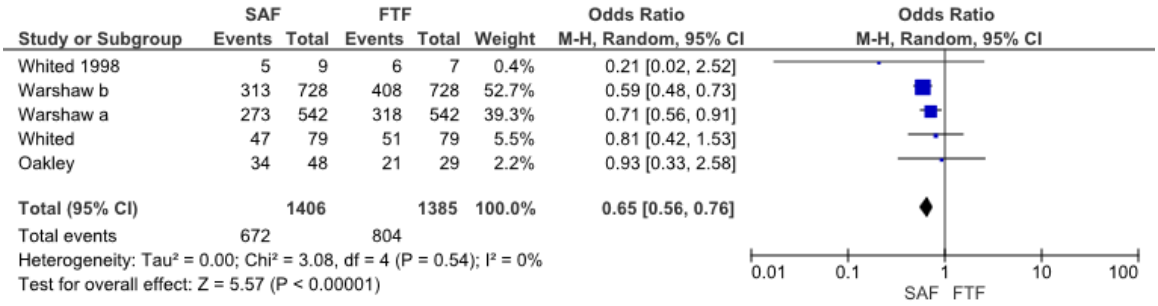


Figure 8 indicates that SAF is inferior to FTF in the correct diagnosis of primary lesions using histology as the reference standard. The heterogeneity across the studies was insignificant (I^2=0).

Four studies directly compared SAF teledermatology, dermoscopy +/- digital images, in primary diagnosis of skin lesions using histopathology as a reference standard. Sample sizes ranged from 716 lesions to 45 (Warshaw 2009a & 2009b; Braun, 2000; Coras, 2003). A small study of 55 preselected lesions (Braun, 2000) found the diagnostic

accuracy of the teledermatoscopy superior to that of the FTF examination for malignant melanocytic lesions. However, diagnoses were compared among six general dermatologists in private practice with a dermatoscopic expert at a university pigmented skin lesion clinic (teledermatologist). The better diagnostic accuracy of the teledermatologist in this study may have been a result of skin lesion and dermatoscopic expertise (Warshaw, 2011). Two of the studies added dermoscopy to digital images to assess the diagnostic accuracy of SAF compared to FTF in primary diagnoses of skin lesions (Warshaw, 2009a & 2009b). A pooled analysis does not show a statistically significant risk difference between SAF and FTF in correct primary diagnosis of skin lesion. However, the odds ratios is statistically significantly different in favour of FTF (Figure 9).

Figure 9: Forest Plot of comparison of SAF and FTF in correct diagnosis of primary lesion with dermoscopy

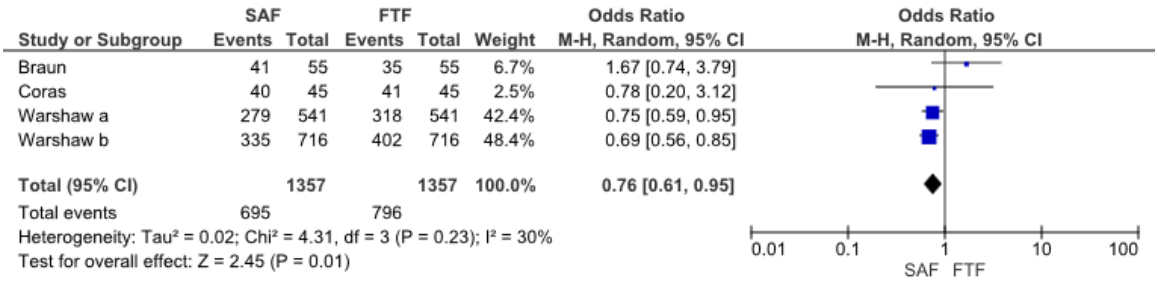


Figure 9 shows that if SAF includes the addition of dermoscopy to digital images this results in an improvement in the proportion of a correct diagnosis by the teledermatologist but SAF is still inferior to FTF consultation using histology as the reference standard. Inconsistency across the studies, in particular the results from Braun, was reflected in a degree of heterogeneity (I^2=30%).

Table 47 includes all the identified studies of SAF teledermatology and teledermatoscopy in primary diagnosis of skin lesions. Weighted averages using random effect model were estimated for each group (Lipsey & Wilson, 2001) but results should be interpreted with caution due to significant heterogeneity in the evidence base.

Table 47: Diagnostic accuracy of SAF teledermatology and teledermatoscopy in primary diagnosis of skin lesions, all identified studies (histology is reference standard)

Study ID	Teledermatology modality	Store-and-Forward			Face-to-Face		
		Correctly diagnosed	Total number	%	Correctly diagnosed	Total number	%
Warshaw 2009 a	Digital images +Dermatoscopy	279	541	51.6	318	541	59.0
	Digital images	273	542	50.4	318	542	58.7
Warshaw 2009 b	Digital images +Dermatoscopy	335	716	46.8	402	716	56.1
	Digital images	313	728	43.0	408	728	56.0
Oakley 2006	Digital images	34	48	70.8	21	29	72.4
Whited 1999	Digital images	47	79	59.5	51	79	64.6
Whited 1998	Digital images	5	9	55.6	6	7	85.7
Rosendahl 2011	Digital images +Dermatoscopy	375	463	80.1	N/R	N/R	N/R
	Digital images	320	463	69.1	N/R	N/R	N/R
Braun 2000	Digital images +Dermatoscopy	41	55	75	35	55	64
Coras 2003	Dermatoscopy only	40	45	89	41	45	91
Ferrandiz 2007	Digital images	110	130	85	N/R	N/R	N/R
Kroemer 2011	Dermatoscopy	100	104	96	N/R	N/R	N/R
	Digital images	96	104	92	N/R	N/R	N/R

*the accuracy estimates are based on a single diagnosis that needed to match the gold standard to be considered accurate
NR=not reported

Eight studies assessed the diagnostic accuracy of SAF in the primary diagnosis of skin lesions based on digital images (Warshaw (2009a&2009b); Oakley (2006); Rosendahl (2011); Whited (1998; 1999); Ferrandiz (2007) and (Kroemer, 2011). Diagnostic accuracy ranged from 43% (Warshaw, 2009b) to 82% (Kroemer, 2011). The weighted average estimate of diagnostic accuracy (using random effects) was 65.72% (95% CI 52.04-79.39). This result includes studies for which there are no FTF results.

Six studies added teledermoscopy to digital images to assess the diagnostic accuracy of SAF in diagnosing primary diagnosis of skin lesions Warshaw (2009a & 2009b) Rosendahl (2011), Braun (2000); and Kroemer (2011). Coras (2003) used teledermoscopic images alone, giving a total of six studies. Diagnostic accuracy ranged from 46.8% (Warshaw, 2009b) to 96% (Kroemer, 2011). The weighted average estimate of diagnostic accuracy (using random effects) was 73.09% (95% CI 56.86-89.31).

These estimates were obtained from the diagnostic data of the heterogeneous samples of lesions (pigmented only; non-pigmented only; all potentially cancerous lesions) examined with digital cameras and dermatoscopic equipment from different stages of technological advancement.

Addition of teledermatoscopy to digital photography in the recent studies that directly compared the two modalities resulted in the improvement of the rate of correct

diagnoses by 3.8% in Warshaw (2009b); 11% in Rosendahl (2011); and by 4% in (Kroemer, 2011). In the large study of non-pigmented lesions by Warshaw (2009b) the addition of polarized light dermatoscopy (PLD) increased the diagnostic accuracy rates for malignant lesions by 6.9% to 9.2% (P = .0088, P<0.0001), whereas the difference for diagnostic accuracy rates for benign lesions was minimal (-1% to 1%, not statistically significant). In the study of pigmented lesions Warshaw (2009a) there were no significant changes in the diagnostic accuracy of teledermatologists with the addition of contact immersion dermatoscopy (CID) images for malignant lesions to the macro images although there was a significant increase in primary, but not aggregated, diagnostic accuracy for benign lesions (6.3%, P = 0.0134).

Table 48 reports the diagnostic performance results of the identified studies of SAF teledermatology in the aggregate diagnosis of skin lesions compared to FTF using histology as the reference standard.

Table 48: SAF vs FTF comparison of aggregate diagnosis* of skin lesions

Study ID	Teledermatology modality	Store-and-Forward			Face-to-Face			OR** (95% CI)
		Correctly diagnosed	Total number	%	Correctly diagnosed	Total number	%	
Şenel 2013	Dermatoscopy+ digital images	78	82	95.1	N/R	82	-	ND
	Digital images	71	82	86.6	N/R	82	-	
Warshaw 2009 a	Dermatoscopy+ digital images	351	541	52.6	435	541	80.1	0.45 [0.34, 0.59]
	Digital images	347	542	64.0	435	542	80.3	0.44 [0.33, 0.58]
Warshaw 2009 b	Dermatoscopy+ digital images	463	716	64.7	544	716	76.0	0.40 [0.32, 0.50]
	Digital images	408	728	56.0	553	728	76.0	0.58 [0.46, 0.73]
Piccolo 2000	Dermatoscopy+ digital images	37	43	86.0	39	41	95.1	0.32 [0.06, 1.67]
Whited 1999	Digital images	61	79	77.2	67	79	84.8	0.61 [0.27, 1.36]
Piccolo 1999	Dermatoscopy+ digital images	57	66	86.4	60	66	90.9	0.63 [0.21, 1.89]
Whited 1998	Digital images	8	9	88.9	7	9	77.8	2.29 [0.17, 30.96]
Barnard 2000	Digital images	18	25	73	21	25	84	0.49 [0.12, 1.95]
Krupinski 1999	Digital images	79	104	76	93	104	89	0.37 [0.17, 0.81]
SAF vs FTF pooled analysis digital images only		921	1487		1176	1487		0.43 [0.36, 0.50]
SAF vs FTF pooled analysis Dermoscopy+/-digital images		908	1366		1078	1364		0.52 [0.44, 0.62]

*the accuracy estimates are based on a single and differential diagnoses; if either of these matches the gold standard the diagnosis is considered accurate

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Six studies directly compared diagnostic accuracy of SAF teledermatology and FTF in aggregated diagnoses of skin lesions using histopathology as a reference standard. Sample sizes ranged from 728 lesions 9 to (Warshaw, 2009a & 2009b; Bernard (2000); Krupinski, 1999; Whited (1998; 1999)). In these studies, the estimate of diagnostic accuracy of SAF with digital images ranged from 56% to 88.9%. The estimates of diagnostic accuracy of FTF presentations with digital images ranged from 76% to 89%. Two of those studies added dermoscopy to digital images to assess the diagnostic accuracy of SAF compared to FTF in primary diagnoses of skin lesions (Warshaw, 2009a & 2009b). Although, it appears the proportion of diagnoses that are correct with SAF increases when aggregate lesions are diagnosed, when compared to FTF, SAF is still statistically significantly inferior, OR 0.43 (95%CI 0.36, 0.50). Four studies added dermoscopy to digital images to assess the diagnostic accuracy of SAF compared to FTF in aggregate diagnoses of skin lesions (Warshaw, 2009a & 2009b; Piccolo, 2000 & 1999). This improved the number of correct diagnoses, but SAF still remains statistically significantly inferior, OR 0.52 (0.44, 0.62)

The equivalency of diagnostic accuracy of teledermatologists and clinical dermatologists examining patients FTF was tested in two repeated measures adequately powered studies of pigmented and non-pigmented lesions (Warshaw, 2009a & 2009b). In the study of non-pigmented lesions the authors concluded that the diagnostic accuracy rates (both aggregated diagnostic accuracy and primary diagnostic accuracy) of clinic (FTF) dermatologists were statistically significantly better than teledermatologists in all analyses for lesion type and teledermatology modality (macro images or macro plus PLD) (Warshaw, 2009b).

Similar to the estimated accuracy based on the primary diagnoses, these estimates were obtained from the diagnostic data of heterogeneous samples of lesions (pigmented only; non-pigmented only; all potentially cancerous lesions, difficult to diagnose skin lesions) examined with digital cameras and dermatoscopic equipment from different stages of technological advancement.

Diagnostic concordance of SAF teledermatology of diagnosis of all skin conditions

Table 49 lists the rates of diagnostic concordance reported in the identified studies of SAF teledermatology where FTF presentations were used as a reference standard. These studies are not limited to skin lesions and include the population with all skin conditions (lesions and inflammatory skin conditions), in which case clinical assessment by a dermatologist (rather than a diagnostic test such as histopathology) is considered the reference standard.

As in the previous section, the results were aggregated by the type of reported outcomes: primary vs aggregated diagnosis. Fifteen clinical trials assessed diagnostic concordance of teledermatology based on digital images of various quality. Only one study used a combination of digital images + teledermatoscopy and reported the highest diagnostic concordance rate (Rubegni, 2011). This study was excluded from the pooled estimates.

Table 49: Studies included in assessment of diagnostic concordance of SAF teledermatology

Study	SAF modality	Diagnostic concordance primary diagnosis		Diagnostic concordance aggregated diagnosis		Sample size
		Number Correctly diagnosed	Percent correctly diagnosed	Number Correctly diagnosed	Percent correctly diagnosed	
Heffner 2009	Digital photography	95	70	N/A	N/A	135
Edison 2008	Digital photography	80	74	N/A	N/A	110
Bowns 2006	Digital photography	51	55	N/A	N/A	92
Tucker 2005	Digital photography	47	66	67	80	84
Oztas 2004	Digital photography	88	77	N/A	N/A	125
Du Moulin 2003	Digital photography	57	54	67	63	106
Rashid 2003	Digital photography	N/A	N/A	27	81	33
High 2000	Digital photography	70	71	75	76	99
Krupinski 1999	Digital photography	256	83	N/A	N/A	308
Whited 1999	Digital photography	77	46	146	87	168
Kvedar 1997	Digital photography	77	63	85	69	123
Zelickson 1997	Digital photography	N/A	N/A	26	88	30
Barbrieri 2014	Digital photography	30	60	42	83	50
Baba, 2005	Digital photography	182	75	N/A	N/A	242
Ebner, 2008	Digital photography	43	74	N/A	N/A	58
Rubegni 2011	Digital photography +dermatoscopy	114	88	N/A	N/A	130
Weighted average estimate of primary diagnosis concordance all skin conditions		64.5% (95% CI 57.4-71.5),				
Weighted average estimate of aggregate diagnosis concordance all skin conditions		76.8% (95% CI 70.0-83.7).				

Thirteen studies evaluated diagnostic concordance using a primary diagnosis agreement that ranged from 46% (Whited, 1999) to 83% (Krupinski, 1999). The weighted average estimate of a primary diagnosis concordance of all skin conditions was 64.5% (95% CI 57.4-71.5), which is similar to the estimate of the primary diagnosis accuracy of skin lesions of 65.7% (95% CI 52.04-79.39 N=8).

The aggregated diagnosis was used in eight studies of diagnostic concordance that ranged from 63% (Du Moulin, 2003) to 88% (Zelickson, 1997), the weighted average estimate of diagnostic concordance was 76.8% (95% CI 70.0-83.7).

Results of the pooled comparisons should be interpreted with caution due to the high degree of heterogeneity associated with variations in population, settings, teledermatology skills and technology. It should also be noted that the overall quality of diagnostic concordance studies was not as good as the overall quality of diagnostic accuracy studies, which included two large non-inferiority trials by (Warshaw 2009a & 2009b).

Diagnostic concordance of VC teledermatology

The literature search identified only one study of VC teledermatology that assessed the aggregated diagnosis accuracy of skin lesions using histology results (Lowitt, 1998). The study was underpowered to detect the difference between accuracy rates, and the superior diagnostic accuracy of VC teledermatology (73% =8/11) in comparison to the clinic examination (64% =7/11) was the result of **one** lesion, a difference likely caused by chance (Warshaw, 2011). There was insufficient evidence to estimate statistical significance of the difference in diagnostic accuracy of SAF and VC teledermatology modalities.

Study	Diagnostic concordance primary diagnosis		Diagnostic concordance aggregated diagnosis		Sample size
	Number Correctly diagnosed	Percent correctly diagnosed	Number Correctly diagnosed	Percent correctly diagnosed	
Skin lesions					
Phillips 1998	63	59	N/A	N/A	107
All skin conditions					
Nordal 2001	81	72	96	86	112
Gilmour 1998	88	57	121	78	155
Edison 2008	88	80	67	N/A	110
Lesher 1998	53	78	376	99	68
Loane 1998	93	60*	118	76*	155
Lowitt 1997	N/A	N/A	61	80	130
Phillips 1997	61	77	N/A	N/A	79
Weighted average of primary diagnosis concordance all skin conditions (excluding skin cancers)			70.6% (95% CI 62.4-78.9)		
Weighted average of aggregate diagnosis of skin conditions			83.7% (95% CI 76.9-90.6)		

lists diagnostic concordance rates reported in the identified studies of VC teledermatology where FTF presentations were used as a reference standard. Most of the studies were conducted between 1997- 2001. The most recent study was head-to-head trial by Edison (2008). Only one study (Phillips, 1998) included patients with suspicious skin lesions, other studies were not limited to skin lesions and include the population with lesions and inflammatory skin conditions.

Table 50: Studies included in assessment of diagnostic concordance of VC teledermatology

Study	Diagnostic concordance primary diagnosis		Diagnostic concordance aggregated diagnosis		Sample size
	Number Correctly diagnosed	Percent correctly diagnosed	Number Correctly diagnosed	Percent correctly diagnosed	
Skin lesions					

Phillips 1998	63	59	N/A	N/A	107
All skin conditions					
Nordal 2001	81	72	96	86	112
Gilmour 1998	88	57	121	78	155
Edison 2008	88	80	67	N/A	110
Lesher 1998	53	78	376	99	68
Loane 1998	93	60*	118	76*	155
Lowitt 1997	N/A	N/A	61	80	130
Phillips 1997	61	77	N/A	N/A	79
Weighted average of primary diagnosis concordance all skin conditions (excluding skin cancers)			70.6% (95% CI 62.4-78.9)		
Weighted average of aggregate diagnosis of skin conditions			83.7% (95% CI 76.9-90.6)		

*re-calculated for the cases where a TD was not also a CD

Seven VC teledermatology studies reported primary diagnosis concordance rates ranging from 57% (Gilmour, 1998), to 78% (Lesher, 1998). The weighted average estimate of the primary diagnosis concordance of all skin conditions (excluding the study of skin cancers) was 70.6% (95% CI 62.4-78.9 N=6). This is higher than the weighted average estimate of the primary diagnosis concordance of all skin conditions assessed with SAF teledermatology 64.5% (95% CI 57.4-71.5); N=13), but the evidence base of VC teledermatology is considerably smaller and of a poorer quality to produce a definite conclusion about the equivalence of diagnostic concordance rates for these two modalities.

The aggregated diagnosis was used in five studies of diagnostic concordance that ranged from 78% (Gilmour, 1998), to 99% (Lesher, 1998), the weighted average estimate of diagnostic concordance was 83.7% (95% CI 76.9-90.6).

Secondary effectiveness outcomes

Does it change patient management?

The literature search identified two studies of management accuracy of SAF teledermatology (Warshaw 2009a & Warshaw 2009b) and seven studies of management concordance. These are presented in Table 51 and Table 52.

Table 51 Management accuracy of SAF teledermatology

Study ID	SAF modality	Store-and-Forward			Face-to-Face		
		Correctly diagnosed	Total number	%	Correctly assigned	Total number	%
Warshaw 2009 a	Digital photography +dermatoscopy	379	541	70.1	355	541	65.6
	Digital photography	382	542	70.5	356	542	65.7
Warshaw 2009 b	Digital photography +dermatoscopy	572	716	79.8	599	716	83.6
	Digital photography	574	728	78.8	608	728	83.5

Only two studies assessed management accuracy (expert panel consensus of management based on histopathologic diagnosis) of clinic dermatology and teledermatology (Warshaw 2009a & 2009b). Both were large studies of SAF teledermatology involving mostly elderly Caucasian male veterans with circumscribed skin lesions. In both studies, overall management was equivalent (defined as a +/-10% difference) for clinic dermatology and teledermatology. Although the overall management accuracy rates were not significantly different, further analysis of this data found that 9 melanomas were mismanaged with teledermatology as compared with two for clinic dermatology, and management accuracy of clinic dermatology was superior to teledermatology (with or without teledermotoscopy) not only for melanoma but also for basal cell carcinoma, squamous cell carcinoma, and actinic keratosis (Warshaw, 2010)

We were unable to identify a VC teledermatology study that assessed management accuracy.

Table 52 Management concordance of SAF teledermatology

Study ID	SAF modality	Store-and-Forward		
		Correctly assigned	Total number	%
Skin lesions				
Ferrandiz 2007	Digital photography	K was reported		
Mahendran 2005	Digital photography	90	163	55.2
Shapiro 2004§	Digital photography	49	49	100.0
All skin conditions				
Heffner 2009	Digital photography	114	135	84.4
Bowns 2006&	Digital photography	51	92	55.4
Whited 1999*	Digital photography	127	168	75.3
Lyon and Harrison 1997	Digital photography	85	90	94.4

&the management decision was to refer or not refer the patient; §the management decision was to biopsy or not biopsy the skin lesion;*only the concordance on medical therapy was extracted here.

The studies that evaluated concordance management decisions based on SAF diagnosis included the triage decisions of "refer or not refer" (Bowns, 2006) for patients with

general skin conditions. The rate of concordance was modest 55%. One study evaluated concordance for the diagnostic procedure decision "biopsy or not biopsy" (Shapiro, 2004) and found a complete agreement. Other studies did not describe management options but reported percent concordance rates of 55% to 94%. The differences in population, measurement of the management agreement outcome; the study design and local practices preclude meaningful synthesis of the results that are likely to have a limited generalizability to the Australian population.

Literature search identified three studies that met the inclusion criteria and assessed management concordance of VC teledermatology using FTF examination as a reference standard (Table 53). One of these studies was a head-to-head trail (Edison, 2008).

Table 53: Studies on management concordance of VC teledermatology

Study ID	Proportion in agreement	Total number	% (95%CI)
Edison 2008	SAF with FTF 73/110 VC with FTF 82/110 VC with SAF 70/110 VC with SAF and FTF 62/110	110 110 110 110	66 (57.5-75.2) 75 (66.4- 82.7) 64 (54.7-72.6) 56 (47.1-65.6)
Gilmour 1998	44/61	61	72
Loane 1998	91/140	140	65

The success of teledermatology lies in the ability of the teledermatologist to recommend a suitable management plan. The ability to diagnose a clinical condition over the video-link or using digital images is considered different from the ability to treat the condition. There is a degree of subjectivity in assessing the management plan as a number of management plans that may be considered sub-optimum had similar clinical outcomes (Loane 1998a).

For this Assessment the value of the head-to-head trial is of a special significance. More identical management plans were given for FTF and VC examinations than for FTF and SAF examinations (75% versus 66%), which was considered clinically but not statistically significant (McNemar's test; $p = 0.15$) due to the lack of statistical power.

Diagnostic accuracy of GP treatment of skin conditions

Studies on diagnostic performance of GP's diagnosis of skin conditions

Currently, GPs in remote areas diagnose and treat skin conditions that require specialist dermatology assessment due to barriers to patients accessing these services. This unmet demand may not be able to be met by videoconferencing due to technological barriers. SAF teledermatology, should it be listed on MBS, may meet a large proportion of this unmet demand from patients requiring specialist dermatology services but whose GPs are currently treating their dermatology conditions.

A purposeful literature search of the reports on diagnostic accuracy or diagnostic concordance of GP diagnosis identified 8 full reports of diagnostic accuracy of the referrer (usually a GP). Four studies assessed diagnostic concordance of the referrer

provisional diagnosis using the outcome of SAF teledermatology as a reference standard. Three of the identified studies used a combination of histopathology results and a definite FTF dermatologist consultant's diagnosis as a gold standard for skin lesions (Bowns, 2006; Morton, 2010, Oakley, 2006). However the study by Bowns (2006) used a referral format that resulted in the majority of referred patients being suspected of having a malignant melanoma or a squamous cell carcinoma 162/256 (63.3%) and 77/256 (30.1%) respectively, which have likely underestimated the diagnostic accuracy of the referring GP to a large degree. A UK study by Morton (2010) was limited to suspected skin cancer cases and a small-size USA study by Oakley (2006) included only suspected benign and malignant skin lesions. A large Australian study (Tran, 2005) reported sufficient data with respect to both the proportion of the correct diagnoses of inflammatory skin conditions made by GP using an FTF consultation with a dermatologist as a reference standard and the proportion of the correct diagnoses of skin lesions for which biopsy results were available. The retrospectively collected data for assessing diagnostic performance only allowed a III-2, quality rank, but the population in the study reflected the characteristics of the study population (P1) and the overall quality was good (Q2).

Table 54 describes the study by Tran (2005) on diagnostic concordance and diagnostic accuracy of the referring primary care physicians.

Table 54: Study included in assessment of diagnostic performance of GP diagnosis of skin conditions

Study	Reference standard	Sample size	Number (%) of correctly diagnosed patients
Tran, 2005	Histopathology	151	36 (24%)
	FTF diagnosis	432	196 (45%)

The information provided in Table 54will be used in the economic evaluation.

Summary of effectiveness

A head-to-head diagnostic concordance trial of FTF and VC reported more identical diagnoses were given for FTF and VC examinations than for FTF and SAF examinations (80% versus 73%) but the difference was not statistically significant (McNemar's test; $p = 0.13$). The absence of statistical significance may be due to the lack of statistical power, nevertheless, the percentage of identical diagnoses for FTF and VC examinations and for FTF and SAF examinations was higher than the baseline intragroup concordance of 64%. Overall in this trial teledermatology (both VC and SAF modalities) demonstrated good performance in comparison to FTF consultation for diagnostic concordance.

A meta-analysis was conducted of the identified studies comparing proportions of correct primary diagnosis (and aggregated diagnoses) obtained by SAF teledermatologist and clinic dermatologist (using histology results as a gold standard for diagnostic accuracy). Diagnostic accuracy of clinic dermatologists was superior to teledermatology for each type of diagnosis (primary or aggregated and irrespective of the addition of teledermatoscopy).

The literature search identified only one study of VC teledermatology that assessed the aggregated diagnosis accuracy of skin lesions using histology results (Lowitt, 1998). The

study was underpowered to detect the difference between accuracy rates, and the superior diagnostic accuracy of VC teledermatology (73% =8/11) in comparison to the clinic examination (64% =7/11) was the result of one lesion, a difference likely caused by chance (Warshaw, 2011). There was insufficient evidence to estimate statistical significance of the difference in diagnostic accuracy of SAF and VC teledermatology modalities.

Pooled analysis of six VC teledermatology studies had a weighted average estimate of the primary diagnosis concordance of all skin conditions of 70.6% (95% CI 62.4-78.9 N=6). This is higher than the weighted average estimate of the primary diagnosis concordance of all skin conditions assessed with SAF teledermatology 64.5% (95% CI 57.4-71.5); N=13), but the evidence base of VC teledermatology is considerably smaller and of a poorer quality to produce a definite conclusion about the equivalence of diagnostic concordance rates for these two modalities.

Thirteen studies evaluated diagnostic concordance of SAF teledermatology using a primary diagnosis agreement. The weighted average estimate of a primary diagnosis concordance of all skin conditions was 64.5% (95% CI 57.4-71.5), which is similar to the estimate of a primary diagnosis accuracy of skin lesions of 65.7% (95% CI 52.04-79.39 N=8).

Six studies evaluated diagnostic concordance of VC teledermatology using a primary diagnosis agreement. The weighted average estimate of a primary diagnosis concordance of all skin conditions was 70.6% (95% CI 62.4-78.9). This is higher than the weighted average estimate of a primary diagnosis concordance of all skin conditions (64.5% (95% CI 57.4-71.5), assessed with SAF teledermatology. However the evidence base of VC teledermatology is considerably smaller and of a poorer quality.

Results of the pooled comparisons should be interpreted with caution due to the high degree of heterogeneity associated with variations in population, settings, teledermatology skills and technology. The overall quality of diagnostic concordance studies was not as good as the overall quality of diagnostic accuracy studies.

Summary of effectiveness – Primary effectiveness outcomes

Based on the single underpowered head-to-head trial, the difference in diagnostic concordance between FTF and SAF examinations, using FTF as the reference standard, was not statistically significant.

SAF in the primary diagnosis of skin lesions (and aggregated diagnoses lesions), using histology as the reference standard, was found to be statistically inferior when compared to face-to-face consultation.

One study found VC superior to FTF in the diagnosis of skin lesions but this was assessed as likely due to chance as the study was underpowered to assess diagnostic accuracy and the result was from one lesion.

There was insufficient evidence to produce a definite conclusion about the equivalence of diagnostic concordance rates of SAF vs VC.

Clinical management

Based on the single head-to-head trial, more identical management plans were given for FTF and VC examinations than for FTF and SAF examinations (75% versus 66%), which was considered clinically but not statistically significant (McNemar's test; $p = 0.15$) due to the small sample size of 110 patients (Edison, 2008).

Other relevant considerations

Current Model used to provide store and forward dermatological services.

- If asynchronous specialist dermatology services via telecommunications is successfully listed on the MBS, it may impact the use of TeleDerm by GPs in rural and remote areas of Australia. The extent of the impact is difficult to gauge because TeleDerm provides services additional to dermatologist consultations such as GP education and support that would not be available to a GP if SAF was provided as a fee-for-service. TeleDerm is funded on a three-year basis by a fixed grant from the DoH to ACRRM. If SAF is successfully listed on the MBS then this would be taken into consideration when then next funding round occurs. TeleDerm as provided by ACRRM is a scalable model, therefore the more that GPs use the service, the less the unit cost of clinical service delivery, making it an attractive service for widespread use. However, GPs are not reimbursed for their time.

What are the economic considerations?

Review of published economic evaluations

A review of the published economic evaluations of asynchronous specialist dermatology services (SAF) and real-time teledermatology (videoconferencing) was performed. The objective of the review of extant economic evaluation was to summarise methods and findings of existing peer-reviewed studies. (A detailed description of the studies is in Appendix E, Table 87). Twenty potentially relevant studies were identified by an electronic search of literature. Of the twenty reports, one was a conference abstract (Munn 2011) and thirteen were focused on comparing video-conferencing with FTF dermatological presentations (Armstrong, 2007; Bergmo, 2000; Burgiss, 1997; Chan, 2000; Lamminen, 2001; Lamminen, 2011; Loane, 2011i; Loane, 1999; Loane, 2001; Oakley 2000; Persaud 2005; Stensland 1999; Wootton 2000). Therefore, only six reports met the selection criteria and were included in the review.

The results and characteristics (type of economic evaluation, perspective, patient population and included costs) from one cost-benefit analysis (Loane 2000), two cost-effectiveness analyses (Moreno-Ramirez 2009, Whited 2003), and three cost-minimisation analyses (Eminovic 2000, van der Heijden 2011, Pak 2009) were summarised in Table 87.

A cost-benefit analysis conducted alongside a randomised controlled trial (Loane 2000), compared SAF with video-conferencing (VC) consultations. The costs included the costs of infrastructure for teledermatology consultations, consultation time, patient travel, and patient loss of productivity while the benefits were defined as the equivalent cost of GP's training. As a result, from the societal perspective, SAF teledermatology was cheaper (-£105.2), but associated with 20% more FTF referrals as compared to VC teledermatology.

Two cost-effectiveness studies found that SAF teledermatology was a cost-effective option from the societal (Moreno-Ramirez 2009) and Veterans Affair Healthcare System's (Whited 2003) perspectives compared with conventional Face-to-Face consultations for the management of patients with skin cancer and all skin conditions, respectively. Neither of the studies included costs of the setting up of the telecommunication infrastructure. A sensitivity analysis in the study by Whited (2003) found that the results were sensitive to the probability of a SAF patient being scheduled for a FTF presentation, the cost of FTF visit, and patient travel cost. The study by Moreno-Ramirez (2009) did not conduct a sensitivity analysis, leaving the uncertainty in the robustness of the results unexplored.

Three cost-minimisation analyses compared SAF with conventional dermatological FTF presentations. The modelled economic evaluation by Eminovic (2000) found that SAF teledermatology results in cost-savings only in two scenarios involving subgroups of the population. In the first scenario the patients treated with SAF teledermatology resided in very remote areas; the second scenario involved only the patients who, following a SAF consultation, are likely to be managed by a local GP without needing a follow-up FTF dermatological consultation. The probabilistic sensitivity analysis showed that conventional care involving FTF presentation was less expensive than SAF consultations in 89% of simulations.

Two other reports found the SAF teledermatology was the less expensive option in comparison to FTF consultations. The study by van der Heijden (2011) conducted a cost-minimisation analysis alongside a prospective cohort study from the secondary healthcare

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system perspective. The cost data collection was limited to costs of two types of consultation. The study found that the conventional FTF consultations were more expensive than the SAF consultations (by €34.94 per patient). However, the primary limitation of this study was the limited number of cost categories included in the cost analysis. The study by Pak (2009) reported results of another cost-minimisation analysis of SAF vs FTF dermatology consultations, which was conducted from the perspective of the US Department of Defense alongside a clinical trial and included a variety of hospital resources. The study found that the SAF teledermatology was more expensive than FTF consultations in terms of the direct cost per patient, however, after the higher productivity loss (indirect costs) associated with FTF dermatology was included, SAF teledermatology proved to be a cost-saving option.

Overall, the results from the identified health-economic evaluations are inconclusive and their generalizability to the Australian health care system population and geographical profiles is limited.

None of the available studies presented a comparison relative to this assessment report. Thus, a de novo economic analysis is conducted using local costing data.

Overview of the economic evaluations

A modelled economic evaluation was based on the results of pooled estimates of diagnostic performance of SAF and VC teledermatology modalities.

The analysis is, for the most part, not based on evidence from within-study comparisons of the interventions. Thus, results are likely to be confounded because the observed systematic differences in the populations assessed across studies which contributed to heterogeneity of the meta-analyses and cannot be excluded. The studies included in the meta-analyses are each associated with limitations described elsewhere.

The economic analysis and the associated sensitivity analyses presented in this assessment were conducted using TreeAge with links to an Excel workbook.

Results were generated by conducting an expected value analysis in a cohort of patients who present to their General Practitioner with inflammatory skin conditions and skin lesions, who require a referral to a specialist dermatologist and who reside in Eligible Areas of Australia for teledermatology.

Cost-effectiveness analyses estimate the incremental cost per additional patient correctly diagnosed using the primary diagnosis. When it is assumed that there is no difference in diagnostic performance between two interventions, the pair-wise comparison of the two interventions is effectively reduced to a cost-minimisation analysis.

The cost minimization analysis assumes that there is no statistically significant difference in the diagnostic performance of SAF and VC teledermatology modalities. The basecase analysis estimates the total cost per consultation using VC and SAF teledermatology modalities and then calculates the incremental difference. SAF modality is assessed separately with and without teledermatoscopy.

However, sensitivity analysis around the results of the economic analysis was conducted that assumes that differences in diagnostic performance exists across the SAF and VC teledermatology modalities as shown by the head-to-head study.

A full version of the model involves a comparison between two scenarios

- Where asynchronous specialist dermatology services are not available for patients current scenario
- Where asynchronous specialist dermatology services are available for patients, proposed scenario

The outcome assessed by the model is the proportion of accurately diagnosed patients with skin conditions requiring specialist dermatology consultation either with current scenario (SAF teledermatology not available) or with the scenario where SAF teledermatology is available.

The structure of the economic model used to conduct the analyses presented in this assessment is summarised diagrammatically in Figure 10.

Clinical effectiveness

- The parameters of comparative clinical effectiveness of the interventions used in the model are based on the best available clinical evidence. Most of the studies that provided the body of evidence had some limitations, including the studies used in the meta-analyses. The results of the modelled economic evaluation should be interpreted with caution.
- In the basecase analysis where patients present with inflammatory skin conditions, the proportion of patients accurately diagnosed with asynchronous specialist dermatology services delivered by telecommunications is assumed to be no different to the proportion of patients accurately diagnosed with real-time videoconferencing. This is based on limited evidence that found no statistical difference in the diagnostic concordance of VC vs SAF.
- Where patients present with skin lesions for asynchronous specialist dermatology services delivered by telecommunications there was insufficient evidence to establish statistically significant difference in diagnostic performance in comparison to real-time videoconferencing. Therefore the proportion of patients accurately diagnosed with SAF teledermatology is assumed to be no different to the proportion of patients accurately diagnosed with VC.
- Where patients present with inflammatory skin conditions asynchronous specialist dermatology services delivered by telecommunications is inferior in terms of proportion of patients accurately diagnosed in comparison to face-to-face consultation with a dermatologist.
- Where patients present with skin lesions asynchronous specialist dermatology services delivered by telecommunications is associated with lower proportion of patients accurately diagnosed in comparison to face-to-face consultation with a dermatologist.
- Where patients with inflammatory skin conditions present and are treated by their GP, asynchronous specialist dermatology services delivered by telecommunications is associated with the higher proportion of patients accurately diagnosed.
- Where patients with skin lesions are present and are treated by their GP, asynchronous specialist dermatology services delivered by telecommunications is associated with the higher proportion of patients accurately diagnosed.

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Population and circumstances of use reflected in the economic evaluation

Consistent with the protocol guiding this assessment, the economic analysis compares asynchronous specialist dermatology services by telecommunications to real-time teledermatology of people with skin lesions or inflammatory skin conditions who live outside Major cities in Australia, particularly in remote and very remote areas and who are underserviced by specialist dermatologists.

Structure of the economic evaluation

The objective of the analysis was to compare cost-effectiveness of introducing SAF teledermatology in two scenarios:

- Where asynchronous specialist dermatology services are not available for patients outside Major cities (i.e. residing in the Eligible Telehealth areas), current scenario
- Where asynchronous specialist dermatology services are available for patients outside Major cities, proposed scenario

The interventions are compared in the following scenarios as follows:

Current scenario where asynchronous specialist dermatology services are not available for patients residing in the Eligible areas

- Scenario where asynchronous specialist dermatology services are not available (current situation for patients residing in the Eligible Telehealth areas)
    - Patients requiring specialist dermatology services present to their GP and are treated by the GP.
        - Costs for GP consultation are assigned and patients are classified as presented with skin lesions or with inflammatory skin conditions on the basis of an Australian retrospective study (Tran, 2005)
        - For each type of skin condition the patients are then classified as having a correct diagnosis or incorrect diagnosis on the basis of an Australian retrospective study(Tran,2005)
    - Patients requiring specialist dermatology services present to their GP and are referred to a dermatologist for a face-to-face consultation. Costs incurred by the GP to refer for a FTF consult are assigned.
        - Costs for specialist consultation are assigned and patients are classified as having skin lesion or inflammatory skin conditions on the basis of an Australian retrospective study(Tran, 2005)
            - Patients are then classified as having a correct or incorrect diagnosis on the basis of pooled estimates of diagnostic concordance and accuracy using the primary diagnosis.
    - Patients requiring specialist dermatology services present to their GP and are referred to a dermatologist for a consultation by VC. Costs incurred

by the GP to refer for a VC consult are assigned. A proportion of patients will be considered unsuitable for this type of consultation and instead will have a referral for FTF consultation

- Costs for specialist consultation by VC are assigned together with cost of patient-support services. If the specialist dermatologist was unable to make a diagnosis and insisted on a face-to-face consult, a cost for specialist consultation are assigned subsequently. Patient out-of-pocket costs for specialist consultation are also assigned. All the patients either being diagnosed via VC or FTF specialist consultation are classified as having skin lesion or inflammatory skin conditions on the basis of a RCT that recruited patients from a secondary care setting (Whited 2013))
    - Patients are then classified as having a correct or incorrect diagnosis on the basis of on the basis of meta-analyses of primary diagnosis results (for inflammatory skin conditions) or assumption (for skin lesions).
    - for the proportion of non-diagnosable cases (Loane, 1998), specialist dermatologist requires to see the patient face-to-face

Scenario where asynchronous specialist dermatology services are available for patients residing in the Eligible Telehealth areas

- Scenario where asynchronous specialist dermatology services are available to patients outside Major cities (i.e. residing in the Eligible Telehealth areas),
    - Patients requiring specialist dermatology services present to their GP and are treated by the GP.
        - Costs for GP consultation are assigned and patients are classified as with skin lesions or with inflammatory skin conditions on the basis of an Australian retrospective study(Tran, 2005)
        - Patients are then classified as having a correct diagnosis or incorrect diagnosis on the basis of an Australian retrospective study(Tran, 2005)
    - Patients requiring specialist dermatology services present to their GP and are referred to a dermatologist for a face-to-face consultation. Costs incurred by the GP to refer for a FTF consult are assigned.
        - Costs for specialist consultation are assigned and patients are classified as having skin lesion or inflammatory skin conditions on the basis of a RCT recruited patients from a secondary care setting(Whited, 2013)
            - Patients are then classified as having a correct or incorrect diagnosis on the basis of pooled estimates of diagnostic concordance and accuracy using the primary diagnosis.

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- Patients requiring specialist dermatology services present to their GP and are referred to a dermatologist for a consultation by VC. Costs incurred by the GP to refer for a FTF consult are assigned.
    - Costs for specialist consultation by VC are assigned and patient-support services. If the specialist dermatologist was unable to make a diagnosis and insisted on a face-to-face consult, a cost for specialist consultation are assigned subsequently. Patient out of pocket expenses for specialist consultation are included. All the patients either being diagnosed via VC or FTF specialist consultation are classified as having skin lesion or inflammatory skin conditions on the basis of a RCT recruited patients from a secondary care setting(Whited, 2013)
        - Patients are then classified as having a correct or incorrect diagnosis on the basis of meta-analyses of primary diagnosis results (for inflammatory skin conditions) or assumption (for skin lesions).
        - Patients unable to be diagnosed by VC, the proportion required to see a, specialist dermatologist face-to-face. This proportion is from (Loane, 1998)
- Patients requiring specialist dermatology services present to their GP and are referred to a dermatologist for a consultation by SAF teledermatology. Costs incurred by the GP to refer for a SAF consult are assigned using two alternative assumptions
    - In the basecase analysis costs included are for the time of the specialist, digital camera, SAF software, and no extra time for a GP to refer for a SAF consultation
    - Costs included are for the time of the specialist, digital camera, SAF software, and the extra time a GP will require to refer for a SAF consultation

In the basecase analysis SAF consultations for skin lesions are carried out with digital images (teledermatology). In the sensitivity analysis, when equivalence in diagnostic performance is not assumed between SAF and VC modalities, cost-effectiveness analysis is conducted with and without dermatoscopy. The associated cost of dermatoscopy is included. Diagnostic accuracy for skin lesions is varied in the model according to whether dermatoscopy has been used to diagnose skin lesions or no dermatoscopy has been used to diagnose skin lesions.

The economic analysis is conducted over the time required to diagnose the patient, which is assumed to be either instantaneous (VC modality) or to arrive within one week (SAF modality).

Cost-effectiveness analysis of SAF teledermatology made available for people with disabilities residing in Major cities (Outside Telehealth Eligible areas)

Current scenario where asynchronous specialist dermatology services are not available for patients with disabilities residing in Major Cities (as defined by the AGSC)

- Scenario where asynchronous specialist dermatology services are not available (current situation for patients with disabilities residing in the Major Cities)
    - Patients, with severe interference to their core functioning who cannot travel to see the specialist dermatologist (32.97% of the Australian population with a disability, ABS, 2012), requiring specialist dermatology services present to their GP and are treated by the GP.
        - Costs for GP consultation are assigned and patients are classified as presented with skin lesions or with inflammatory skin conditions on the basis of an Australian retrospective study (Tran, 2005)
        - For each type of skin condition the patients are then classified as having a correct diagnosis or incorrect diagnosis on the basis of an Australian retrospective study(Tran, 2005)
    - Patients, with mild to moderate disabilities (67.03% of the Australian population with a disability, ABS, 2012, requiring specialist dermatology services present to their GP and are referred to a dermatologist for a face-to-face consultation. Costs incurred by the GP to refer for a FTF consult are assigned.
        - Costs for specialist consultation are assigned and patients are classified as having skin lesion or inflammatory skin conditions on the basis of an Australian retrospective study(Tran, 2005)
            - Patients are then classified as having a correct or incorrect diagnosis on the basis of pooled estimates of diagnostic concordance and accuracy using the primary diagnosis.

Scenario where asynchronous specialist dermatology services are available for patients with disabilities residing in Major Cities

- Scenario where asynchronous specialist dermatology services are available to patients with disabilities residing in the ineligible areas for Telehealth MBS items.
    - Patients, with severe or profound interference to core functioning disability who cannot travel to see the specialist dermatologist, requiring specialist dermatology services present to their GP and are treated by the GP.
        - Costs for GP consultation are assigned and patients are classified as with skin lesions or with inflammatory skin conditions on the basis of an Australian retrospective study(Tran, 2005)
        - Patients are then classified as having a correct diagnosis or incorrect diagnosis on the basis of an Australian retrospective study(Tran,2005)

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- Patients, with mild to moderate disabilities, requiring specialist dermatology services present to their GP and are referred to a dermatologist for a face-to-face consultation. Costs incurred by the GP to refer for a FTF consult are assigned.
    - Costs for specialist consultation are assigned and patients are classified as having skin lesion or inflammatory skin conditions on the basis of an Australian retrospective study (Tran, 2005)
        - Patients are then classified as having a correct or incorrect diagnosis on the basis of pooled estimates of diagnostic concordance and accuracy using the primary diagnosis.
- Patients, with severe or interference to core functioning disability, requiring specialist dermatology services present to their GP and are referred to a dermatologist for a consultation by SAF teledermatology. Costs incurred by the GP to refer for a SAF consult are assigned using two alternative assumptions
    - In the basecase analysis costs included are for the time of the specialist, digital camera, SAF software, and no extra time for a GP to refer for a SAF consultation
    - Costs included are for the time of the specialist, digital camera, SAF software, and the extra time a GP will require to refer for a SAF consultation

In the basecase analysis, SAF teledermatology is expected to partly replace GP; in the sensitivity analysis, only patients with severe or profound interference to core functioning (those who cannot travel to see the specialist dermatologist and are managed by GP currently) will be proportionally referred to SAF teledermatology consultation.

Variables in the economic evaluation

Direct health care resource costs

The resource variables considered in the economic evaluation are summarised in Table 55. To identify, measure and value health care resources the intervention needs to be clearly described, this is not the case with this intervention. SAF teledermatology is scalable, and has most frequently been used on an institutional basis, or alternatively among a group of dermatologists but it can be used by individual dermatologists. Institutional use of SAF teledermatology in Australia does not involve a fee-for-service model and groups of dermatologists often develop their own proprietary software. Since the applicant did not explain how SAF teledermatology will work in practice, it is assumed for the purposes of costing that an individual dermatologist will purchase a commercial software program, assumed to be TeleDerm. Most of the unit costs for GP consultations or specialist consultations can be derived by their relevant MBS items. Included in the direct costs is the cost for the length of time it requires a GP to collect the clinical data and digital images required for a SAF consultation. This is done in two ways. The basecase analysis assumes that MBS item 23 Level B will cover a GP's time needed to examine the patients, produce digital/dermoscopic images, and upload these together with relevant patients history. A sensitivity analysis, assumes as reported in the literature, and from expert opinion which estimates that it will take an additional 15-30 minutes to do a clinical history for SAF, that

teledermatology places additional demand on GP's time. This has been costed as a weighted average of MBS item 23 Level B and Level C. Costs of histopathology are not included in the model because it is utilised in the effectiveness side of the economic evaluation as a gold standard that determines the diagnostic accuracy of alternative teledermatology modalities

Table 55: List of health care resource items and unit costs included in the economic evaluation

Type of resource item	Natural unit of measurement	Unit cost	Source of unit costs
GP consult (for referral to FTF or VC)	Per specialist consultation	$37.05	MBS 23 Level B
GP consult (additional time for the referral to SAF)	Per specialist consultation	$45.71	0.75 Level B + 0.25 Level C
FTF consultation	Per specialist consultation	$85.50	MBS items 104
VC consultation	Per specialist consultation	45.75	MBS item 99
VC patient support staff	Per consultation item weighted average of MBS patient support items per item 99	$64.18	DoH (multiple MBS items)
SAF	Per consultation	$141.37	ACRRM
Patient out of pocket expenses on VC teledermatology consultation	Per consultation	$70	DoH (MBS 99)
Patient out of pocket expenses on FTF dermatology consultations	Per consultation	$75	DoH (MBS 104)
Cost of intervention			
Digital camera/iphone	Per consultation	$0.45	Mean cost of different modalities reported in trial
Dermatoscope	Per consultation	$2.18	Mean cost of different modalities reported in trial
Software SAF	Per consultation	$6.95	ACRRM

There is a paucity of evidence in relation to proportion of patients in rural and remote areas with skin conditions requiring dermatological consultation who are managed by their GP. Referral probabilities are from a study that compared GP practice in the Bush to Urban areas (Britt, 2001). There is only an indirect evidence of the proportion of VC teledermatology consultations of patients from rural and remote areas. No Australian data was found on the proportion of patients who, after an unsuccessful attempt to be diagnosed by VC or SAF teledermatology consultations, will need to go for an FTF examination. The corresponding parameters of the model were taken from the UK evidence (Loane 1998, 2000), which may be and overestimation of the real proportion of patients considering the technological improvements in telecommunications over the last 10 years. The proportions of patients

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managed by GP or referred to VC teledermatology in the proposed scenario were based on expert opinion.

In the diagnosis of inflammatory skin conditions, the body of evidence used FTF consultations as the reference standard. Therefore diagnostic concordance of SAF and VC is described as concordant diagnosis to FTF. The model therefore assumes that the diagnostic accuracy of FTF consultations for inflammatory skin conditions is equal to one. A necessary artefact in the model, but not a reflection of clinical evidence. A limitation of this assumption is that is assumes a linear relationship in diagnostic agreement between clinical and teledermatologist.

The clinical effectiveness variables included in the economic evaluation are summarised in Table 56.

Table 56: probabilities assigned in the model

Intervention & outcome	Probabilities used in basecase analysis	Probabilities used in sensitivity analysis	Assumptions/Source
Distribution of patients across the providers of dermatology services			
Proportion managed by FTF consultation in the current scenario	0.53	-	BEACH survey (Britt, 2013)
Proportion managed by GP in the current scenario	0.43	-	BEACH survey (Britt, 2013)
Proportion managed by VC consult in the current scenario	0.04		(0.74%, from DoH)
Proportion managed by GP in the proposed scenario	0.35		Based on the uptake of ACRRM SAF teledermatology by rural GPs)
Proportion managed by VC consult in the proposed scenario	0.04	0.0004	Based on current proportional usage Expert advice is that 90% of VC consults will be reallocated to SAF
Proportion managed by FTF consultation for patients with disability in the current scenario	0.67	-	Pts with disability ABS
Proportion managed by GP for patients with disability in the current scenario	0.33	-	Pts with disability ABS
Proportion managed by FTF consultation for patients with disability in the proposed scenario	0.52	0.67	proportion of patients being diverted to SAF teleconsultation)
Proportion managed by GP for patients with disability in the proposed scenario	0.27	-	Assumption (proportion of patients being diverted to SAF teleconsultation)
Proportion of FTF being averted by SAF consult in proposed scenario	0.23		Eminovich 2003

Proportion of patients with an inflammatory skin condition in primary care setting	0.50		Tran 2005
Proportion of patients with an inflammatory skin condition in secondary care setting	0.56		Whited 2013
Proportion of non-diagnosable cases via VC consultation	0.19		Loane 1998
Proportion of non-diagnosable cases via SAF consultation	0.14		Loane 2000
Clinical effectiveness			
Diagnostic accuracy FTF (skin lesions)	0.573		Pooled estimate across two large trials (Warshaw 2009a,b)
Diagnostic concordance FTF (inflammatory skin conditions)	1.0	1.00	Reference standard
Diagnostic accuracy GP (skin lesions)	0.23		Tran 2005
Diagnostic concordance GP (inflammatory skin conditions)	0.45		Tran 2005
Diagnostic accuracy VC (skin lesions)	0.465		Assumed the same as SAF diagnostic accuracy
Diagnostic concordance VC (inflammatory skin conditions)	0.64	0.80	In base case assumed equal effectiveness to SAF Edison, 2008 Sensitivity analysis
Diagnostic accuracy SAF no teledermoscopy (skin lesions)	0.465		Pooled estimate across two large trials (Warshaw 2009a,b)
Diagnostic concordance SAF no teledermoscopy (inflammatory skin conditions)	0.64	0.73	Pooled estimate for basecase Edison, 2008 in sensitivity analysis
Diagnostic accuracy SAF with teledermoscopy (skin lesions)	0.47	0.73	Pooled estimate Warshaw 2009a,b) assumption in sensitivity analysis
Diagnostic concordance SAF with teledermoscopy (inflammatory skin conditions)	0.75	0.75	Bowns, 2006

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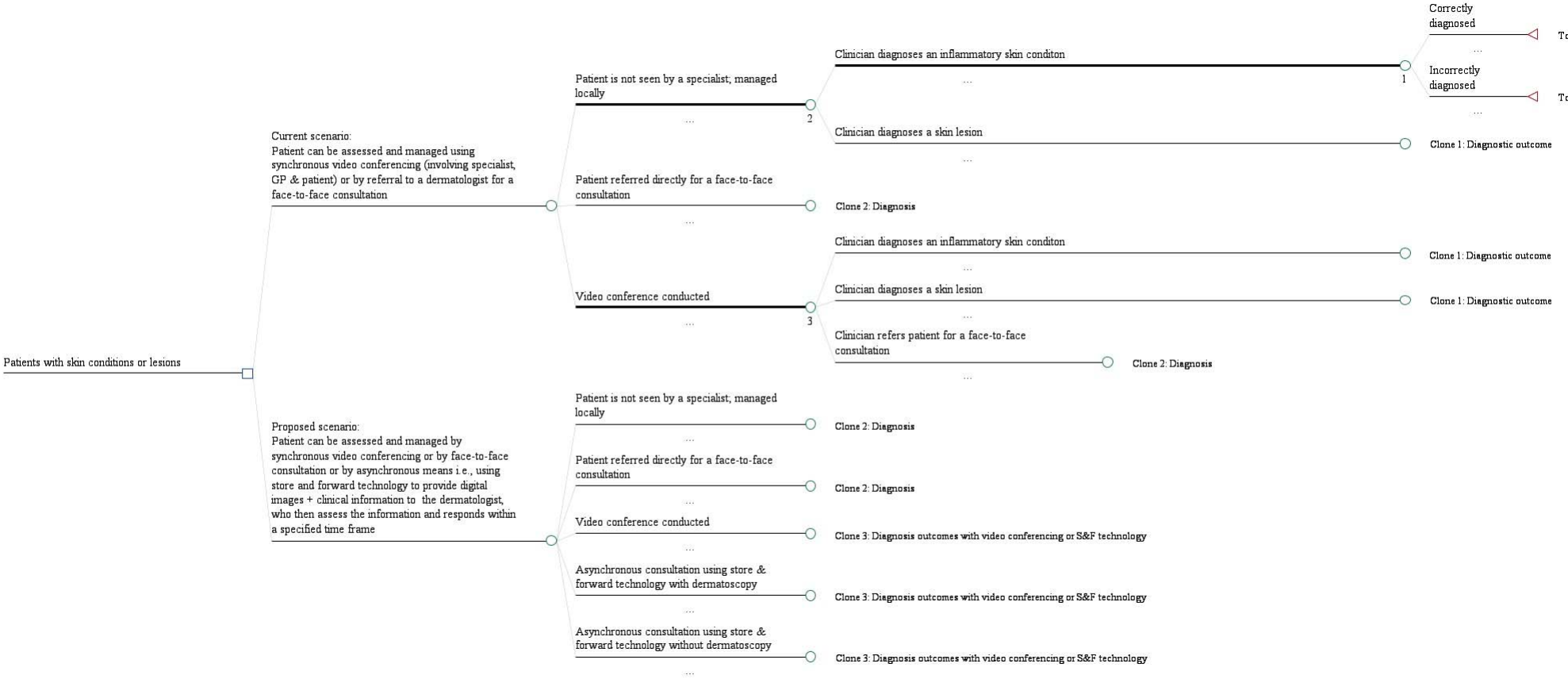
Figure 10: Structure of the economic analysis



Outcomes

The outcome assessed in the basecase analysis is the average cost per consultation using VC and SAF teledermatology modalities. The diagnostic accuracy and diagnostic concordance of SAF is assumed to be equal to diagnostic accuracy and diagnostic concordance of VC teledermatology. Sensitivity analysis is conducted where diagnostic performance of VC modality is assumed to be higher than diagnostic performance of SAF modality. SAF modality is assessed separately with and without teledermatoscopy.

The outcome assessed in the full version of the model is the proportion of patients requiring specialist dermatology consultation accurately diagnosed either with current scenario (SAF teledermatology not available) or with the scenario where SAF teledermatology is available. The diagnostic performance of SAF is assumed to be equal to diagnostic performance of VC teledermatology. SAF modality is assessed without teledermatoscopy.

Basecase analysis

Table 57 presents the results of the basecase economic evaluation that assumes no difference in diagnostic performance between SAF and VC in terms of proportion of correct and incorrect diagnosis of inflammatory skin conditions or skin lesions. Another assumption is that the proportion of secondary referrals to FTF consultation after teledermatology failed to provide a diagnosis is zero for both SAF and VC modalities.

Table 57: results of the cost minimisation analysis

Intervention	Total costs
Video-conferencing specialist dermatology services	$299.48
Asynchronous specialist dermatology services	
▪ Without dermatoscopy images	$185.82
Increment for SAF without dermatoscopy vs VC consultation	-$113.66
▪ With dermatoscopy images	$188.00
Increment for SAF with dermatoscopy vs VC consultation	-$111.48

As can be seen from Table 57 the estimate of the cost minimisation where dermatoscopy is not used, and the diagnostic performance of SAF and VC are assumed to be equal, shows in SAF costing less by $113.66. Where dermatoscopy is used, and the diagnostic performance of SAF and VC are assumed to be the same, SAF costs less by $111.48, reflecting the slightly improved diagnostic accuracy with the use of dermatoscopy.

Table 58 presents the results of the economic evaluation of the full economic model (Figure 10) comparing the current scenario where the proportion of patients are treated by GP, referred for FTF consultation or VC teledermatology with the proposed scenario where SAF teledermatology is introduced and the proportion of patients treated by GP (18%) are being referred for SAF teledermatology. The equality in diagnostic performance between SAF and VC is assumed and the proportions of patients referred to FTF consultation after unsuccessful VC or SAF examination is retained.

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Table 58: Results of modelled economic evaluation current and proposed scenario where of SAF becomes available

Intervention	Total costs	Outcome (proportion of patients correctly diagnosed)	ICER
Current scenario	$133.83	60.39%	-
Proposed scenario	$147.43	62.51%	-
Increment for SAF without dermatoscopy vs VC consultation	$13.60	2.12%	$642.22

The economic evaluation of the full model where SAF teledermatology is available estimates an incremental cost per additional correct diagnosis of $642.22

Table 59 presents the variation of the basecase analysis where diagnostic performance between SAF without dermotoscopy and VC in terms of proportion of correct and incorrect diagnosis of inflammatory skin conditions is assumed to be 0.645 and 0.706 respectively (results of the pooled estimates reported above). The diagnostic performance of SAF for all skin conditions with dermatoscopy is assumed to be 0.75 (Bowns, 2006). The proportion of correct diagnoses of skin lesions is assumed to be equal, as in the basecase analysis. Another assumption is that the proportion of secondary referrals to FTF consultation after teledermatology failed to provide a diagnosis is 0.14 for SAF (Loane, 2000) and 0.19 for VC modalities (Loane, 1998).

Table 59: Cost-effectiveness of SAF vs VC where differential diagnostic performance is assumed

Intervention	Total costs	Proportion of patients correctly diagnosed	ICER
Video-conferencing specialist dermatology services	$329.98	66.49%	-
Asynchronous specialist dermatology services			
Without dermatoscopy images	$208.29	61.33%	
• Increment for SAF without dermatoscopy vs VC consultation	-$112.68	-5.16%	-
With dermatoscopy images	$210.47	67.34%	
• Increment for SAF with dermatoscopy vs VC consultation	-$119.51	0.85%	SAF dominant

In Table 59 the diagnostic concordance of VC was increased to reflect the higher point estimate than that of SAF teledermatology reported in the literature. The costs remained as in the basecase analysis. The substitution of SAF for VC decreased the proportion of correctly diagnosed cases by -5.16%. In comparison to VC teledermatology, SAF modality is both less expensive and less effective. However, adding dermatoscopy increases the

incremental effectiveness by 0.85% in comparison to VC, while the cost remains $119.51 lower. SAF is a dominant health intervention in this scenario.

The applicant has requested a reimbursement for SAF teledermatology service that is based on reimbursement and not the cost of delivering the service. A cost, $141.37 for clinical services, based on ACRRM estimates, is assumed in the basecase analysis. The applicant's requested fee was determined by applying a fraction (85%) to MBS item 104 and 105. The requested fee is $72.72. Table 60and Table 61 rerun the cost-minimisation analysis and the cost-effectiveness analysis varying the cost of SAF to equate to this requested fee.

Table 60: Cost-minimisation sensitivity analysis varying cost of SAF

Intervention	Total costs
Video-conferencing specialist dermatology services	$299.48
Asynchronous specialist dermatology services	
Without dermatoscopy images	$117.17
Increment for SAF without dermatoscopy vs VC consultation	-$182.30
With dermatoscopy images	$119.35
Increment for SAF with dermatoscopy vs VC consultation	-$180.13

Table 61: Sensitivity analysis of modelled economic evaluation varying cost of SAF

Intervention	Total costs	Outcome (proportion of patients correctly diagnosed)	ICER
Current scenario	$133.83	60.39%	-
Proposed scenario	$141.98	62.51%	-
Increment for SAF without dermatoscopy vs VC consultation	$8.14	2.12%	$384.76

The analyses presented above indicates that the model results are sensitive to the change in the cost of SAF teledermatology, with the cost minimisation estimating a saving of $180.13 and the cost-effectiveness analysis resulting in a 40% reduction in the ICER to $384.76.

Without teledermoscopy SAF modality is both less effective and less expensive. Once teledermoscopy is added to diagnosis of inflammatory skin conditions, SAF becomes fractionally more effective although the diagnostic performance estimate is based on a single study results (Bowns, 2006).

We further addressed a number of uncertainties by conducting a set of sensitivity analyses to examine the robustness of the results to variations in parameter estimates.

Table 62 summarises results of the sensitivity analyses varying a number of inputs to the economic evaluation:

- The assumption that there is no difference in diagnostic concordance of SAF vs VC is tested;

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- The assumptions about proportions of patients attending VC; FTF or being re-referred after unsuccessful SAF or VC teledermatologies are varied;
- Costs of GP consultation associated with referral to SAF; cost of GP consultation if managing patients locally and cost of SAF teledermatology consolation varied;
- A two-way sensitivity analyses where an assumption about the proportion and one of the costs are varied simultaneously.

Table 62: Results of the sensitivity analysis

Variables altered in sensitivity analysis	Incremental costs for current scenario vs proposed scenario	Incremental proportion of patients being correctly diagnosed	Incremental cost per additional correctly diagnosed patient
Basecase results	$13.60	2.12%	$642.22
*Vary the diagnostic concordance of SAF teleconsultation without dermatoscopy**			
Apply the diagnostic concordance of 0.73	$13.60	2.49%	$545.22
*Vary the diagnostic concordance of VC teleconsultation**			
Apply the diagnostic concordance of 0.80	$13.60	2.12%	$642.22
Vary assumption that proportion of VC consultation being reduced by 90% after introducing SAF specialist dermatology services			
Apply proportion of VC consultation as 0.004 in proposed scenario	$9.22	2.05%	$448.49
Vary assumption that proportion of FTF consultation being averted after introducing SAF specialist dermatology services			
The proportion being averted by 23%	$14.91	-0.29%	Dominated
Vary assumption that no cases being re-referred to FTF after unsuccessful SAF or VC consultation			
Apply zero percent of rejection rates	$11.81	1.73%	$681.63
Assessing impact of including cost of GP's time involved in SAF consultation referral			
Weighted cost of Levels B and C of MBS item 23	$14.28	2.12%	$674.69
Vary the cost of GP's consultation if patients are managed locally by GPs			
Weighted cost of Levels C and D of MBS item 23	$10.17	2.12%	$480.54
Vary the cost of SAF consultation			
Apply the cost of $72.72 (derived from MBS item 104, sourced from DAP)	$8.15	2.12%	$384.76
Multivariate analysis			
Vary the proportions of patients reduced in VC consultation (by 90%) and including GP's time involving in a SAF consultation after SAF introduction	$10.22	2.05%	$497.12
Vary the proportions of patients being rejected by SAF or VC consultations (0%) and including GP's time involving in a SAF consultation after SAF introduction	$12.50	1.73%	$721.31

*all the other sensitivity analyses assumed the equivalent diagnostic accuracy/concordance between SAF and VC.

The results are sensitive to increasing the diagnostic concordance of SAF which is associated with improved diagnostic performance of the proposed scenario and decreased ICER by almost $100 in comparison to the basecase analysis. The results did not change when VC diagnostic concordance increased to 0.8 as this increase applied to both scenarios.

The results are sensitive to the variations in the estimates of the reduction in proportion of patients referred to VC (by 90%) after SAF becomes available (reduction in ICER by $200 in comparison to the basecase, although the diagnostic performance has also reduced). The results are especially sensitive to the assumption that the proportion of patients currently referred to FTF will be diagnosed by SAF teledermatology (23%, Eminovich 2003). If this assumption is correct, the incremental cost per correct diagnosis marginally increases while diagnostic performance of the proposed scenario becomes inferior to the current scenario;

The results are fairly robust to the assumption of zero re-referral rates to FTF after unsuccessful SAF or VC teledermatology consultations; or to the small variation in the cost of GP consultation associated with SAF referral. Reduction in the cost of SAF teledermatology consultation reduced ICER almost by half in comparison to the basecase analysis.

Two-way sensitivity analyses, demonstrated that simultaneous reduction in VC consultations and increase in the unit cost of GP consultation still produced an ICER which is $150 less than in the basecase analysis. Conversely, increasing the cost of GP consultation and assuming that no cases are re-referred to FTF would worsen cost-effectiveness results by making the referral to SAF and VC teledermatology more expensive while reducing the proportion of patients receiving the best performing diagnostic service (FTF consultation).

Limitation of the model is that evidence used in the model for skin lesion is generated from non-homogenous patients (pigmented vs non-pigmented lesions) and predominantly males. For inflammatory skin conditions, the main evidence is based on patients with widely different skin types. Costing of the different arms relied in the case of VC on MBS reimbursement but in the case of SAF on actual resource use was costed.

Cost-effectiveness analysis of the scenario where asynchronous specialist dermatology services are available for patients with disabilities residing in the ineligible areas of Telehealth

It was requested that the economic analysis of SAF teledermatology do a scenario analysis where patients with disabilities residing in Major Cities (outside Eligible Telehealth Areas but not including those in residential care housing) are eligible for SAF teledermatology consultation. In this scenario patients will substitute a FTF consultation for a SAF teledermatology consultation. Table 63 presents this scenario, in which it is assumed that currently patients with profound and severe impairment to their core functioning, as defined by the ABS, are managed by their GP, while patients with mild to moderate impairment to core functioning, are referred for specialist consultation. In the proposed scenario, where SAF is available, patients with profound and severe impairment to their core functioning currently treated by their GP will be treated by SAF, and a proportion of the other patients with moderate to mild impairment currently treated by a FTF consultation will be treated by SAF.

According to national statistics (ABS), 18.5% of the Australian population has a disability. Among them, profound disability that interferes with core functioning is estimated in 3.2%, severe disability in 2.9% and mild or moderate disability in 12.4% of the Australian

population (Australian Bureau of Statistics. Disability, Ageing and Carers, Australia: Summary of Finding, 2012. Catalogue 4430.0 Released 13/11/2013)

- In the current scenario of the sensitivity analysis, those patients with core functioning interference and severe disability will be managed by GPs [(3.2%+2.9%)/18.5%] while patients with mild to moderate disability will be referred for specialist consultation;
- In the proposed scenario of the sensitivity analysis, a proportion of patients managed by GPs or consultant dermatologist will be diverted for SAF specialist dermatology services.
  - For the proportion of patients being referred by GPs, the data is from the website for GPs' statistics (2000/10835)
  - For the proportion of patients being averted from FTF consultation, the data is from study by Eminovich 2003 (23%).

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Table 63: Cost-effectiveness and sensitivity analyses of the SAF becoming available to people with disabilities residing outside eligible telehealth areas

Intervention	Total costs	Proportion of patients correctly diagnosed	ICER
Not including the extra time cost of GP for a SAF referral			
Current scenario (GP+FTF)	$144.63	65.76%	-
Proposed scenario (GP+FTF+SAF)			
A proportion of patient managed by GP and FTF is diverted to SAF	$156.70	64.34%	
Increment	$12.08	-1.42%	SAF is Dominated
A proportion of patient managed by GP is diverted to SAF	$155.05	67.39%	
Increment	$10.42	1.62%	$642.21
Including the extra time cost of GP for a SAF referral			
Current scenario (GP+FTF)	$144.63	65.76%	-
Proposed scenario (GP+FTF+SAF)			
A proportion of patient managed by GP and FTF is diverted to SAF	$156.70	64.34%	
Increment	$12.08	-1.42%	SAF is Dominated
A proportion of patient managed by GP is diverted to SAF	$155.58	67.39%	
Increment	$10.95	1.62%	$674.69

The cost-effectiveness analysis of two scenarios with respect to the population with disability residing in the Major Cities generally replicates the results of the cost-effectiveness analysis of the target population. The basecase analysis assumes that a proportion of patients being managed by GPs are referred for SAF teleconsultation and produces identical ICER ($642.21). However when the proportion of patients who are currently referred by GP for FTF consultations is assumed to be diverted to SAF, this resulted in the current scenario being dominant. The results are robust to the variation in the cost of GP consultation associated with a SAF referral.

Costing

Costs to the Australian healthcare system overall

Costs to the Australian healthcare system overall of treatment for patients with inflammatory skin conditions or skin lesions includes the costs to the Medicare system for GP consultation, specialist consultations for dermatology services, pathology services, pharmaceuticals and hospital costs. It is not expected that the listing of asynchronous specialist dermatology services on the MBS will have a significant impact on the costs to the Australian healthcare system overall.

Treatment of melanoma and non-melanoma skin cancer in Australia places a high burden on the Australian health care system. It was reported that 2% of the Australian population are treated for NMSC (AIHW, Cat. 39). The treatment of skin cancer incurs major health costs and disfigurement. The most common and expensive cancer in Australia is non-melanoma skin cancer (NMSC), which includes basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) (AIHW, Cat. 39)). Australia experiences high demand for dermatology services, particularly out-patient, and plastic surgeons to deal with the very high rates of skin cancers (PCCC, 2013). Most skin conditions are dealt with by GPs, including skin cancers, and particularly in Queensland, skin cancer clinics have evolved to meet some of the unmet demand for medical specialists. Around 60-70% of skin cancers are treated in GP clinics. Expert advice is that the unmet demand for specialist dermatology services is mainly for patient with inflammatory skin conditions.

On 1 July 2011, Medicare rebates and financial incentives for specialist video consultations were introduced to address some of the barriers to accessing medical services, particularly specialist services, for Australians in remote, regional and outer metropolitan areas. New Medicare Benefits Schedule (MBS) items were introduced to provide for Telehealth consultations rendered by specialists, consultant physicians and consultant psychiatrists. These items allow a range of existing MBS attendance items to be provided via video conferencing, with a derived fee adding to the base item fee.

New MBS items were also introduced for Patient-end Services. These items enable GPs, other medical practitioners, nurse practitioners, midwives, Aboriginal health workers and practice nurses to provide face-to-face clinical services to the patient during the consultation with the specialist. The Patient-end items can only be claimed when the service being provided by the specialist is an Eligible Telehealth Service. On 1 November 2012, the Telehealth MBS items were amended to require that the patient and remote specialist be at least 15 kilometres apart.

A range of non-MBS financial incentives linked to the telehealth MBS items were also introduced on 1 July 2011 to encourage the change required to incorporate telehealth into everyday workflows and changes to tradition practice that will affect billing and schedule systems, IT systems, staff training and capital improvements.

Five types of incentives are available for practitioners and RACFs.

- Telehealth On-Board Incentive;
- Telehealth Service Incentive;
- Telehealth Bulk Billing Incentive;
- RACF On-Board Incentive; and

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- Telehealth Hosting Service Incentive.

This was a time-limited incentive program to encourage the support and adoption of Telehealth within the Medicare arrangement but it ceased as of 30 June 2014. Therefore these costs are not included in this section.

The listing of asynchronous specialist dermatology services delivered by telecommunications onto the MBS may have implications for the TELEDERM service delivered by ACRRM or the popularity of ACRRM may have implications for the uptake of this service. Currently, the TELEDERM budget for delivery of clinical services is $190,000 per year for which it provides around 2000 services per year to GPs. This service also includes an educational aspect for GPs, in addition to access to a dermatologist.

A 2007 report into the supply and demand of dermatologists in Australia concluded that that the supply of dermatologists is inadequate and that in particular shortages exist in rural areas and some non-capital urban areas. It is estimated that requirements for workforce for dermatologists will need to grow by a minimum of 2.6 % per year (AMWAC, 1998).

Expert advice is that the listing of asynchronous specialist dermatology services onto the MBS is likely to have positive effects on the dermatologist workforce. This is because the flexibility of store and forward technology particularly lends itself to specialists who only want to work part-time, or have family commitments, or are not able to travel. Additionally for the busy consultant teledermatology consultations can be done while travelling or after work.

Costs to the Medical Benefits Scheme (MBS)

Table 64 presents the level of use of dermatologist specialist consultation items, Telehealth items (including patient-level support items) and Table 65 shows the benefit paid.

Table 64: Number of services claimed from 1 July 2011 to 30 June 2014 provided by dermatologist specialist for telehealth items by remoteness index

MBS item No.**	Type of Item claimed by same patient on the same day	Major cities of Australia	Inner Regional Australia	Outer Regional Australia	Remote & Very Remote	Total
99	None	872	2,125	1,304	180	4,481
	Telehealth - Lvl A or B - 5 to 20 mins	407	787	450	58	1,702
	Telehealth - Lvl C - at least 20 mins	285	859	500	73	1,717
	Telehealth - Lvl D - at least 40 mins	45	111	51	13	220
104 or 105	Telehealth- any level	59	143	53	9	264
Total		1668	4025	2358	333	8384

**No claims found for item 113 by Dermatologists
Telehealth - Lvl A or B - 5 to 20 mins = 2100,2122,2125,2126,2137,2138
Telehealth - Lvl C - at least 20 mins = 2143,2147,2179
Telehealth - Lvl D - at least 40 mins = 2195,2199,2220

Table 65: Benefit paid for services claimed from 1 July 2011 to 30 June provided by dermatologist specialist for telehealth items by remoteness index

MBS item No.**	Type of Item claimed by same patient on the same day	Major cities of Australia	Inner Regional Australia	Outer Regional Australia	Remote & Very Remote	Total
99	None	$84,791	$196,929	$121,137	$16,631	$419,487
	Telehealth - Lvl A or B - 5 to 20 mins	$20,336	$37,788	$21,838	$2,769	$82,731
	Telehealth - Lvl C - at least 20 mins	$27,238	$81,353	$47,335	$6,966	$162,892
	Telehealth - Lvl D - at least 40 mins	$6,336	$15,361	$7,057	$1,847	$30,602
104 or 105	Telehealth- any level	$4,941	$10,861	$4,213	$715	$20,730
Total		$143,642	$342,292	$201,580	$28,928	$716,442

**No claims found for item 113 by Dermatologists
Telehealth - Lvl A or B - 5 to 20 mins = 2100,2122,2125,2126,2137,2138
Telehealth - Lvl C - at least 20 mins = 2143,2147,2179
Telehealth - Lvl D - at least 40 mins = 2195,2199,2220

For comparison purposes, Table 66 and Table 67 show the number of services and benefit paid for standard MBS consultation items, for dermatologist services, disaggregated by the same regions. As can be seen, the number of Telehealth items, as a proportion of total services is very small.

Table 66: Services claimed from 1 July 2011 to 30 June 2014 provided by dermatologist specialist by remoteness index

MBS item No.**	Type of Item claimed by same patient on the same day	Major cities of Australia	Inner Regional Australia	Outer Regional Australia	Remote & Very Remote	Total
104	None	1,424,341	187,965	73,044	13,356	1,698,706
105	None	1,737,960	270,100	95,433	10,936	2,114,429
Total		3,173,838	463,744	171,754	24,826	3,834,163

Table 67: Benefit paid for services claimed from 1 July 2011 to 30 June 2014 provided by dermatologist specialist by remoteness index

MBS item No.**	Type of Item claimed by same patient on the same day	Major cities of Australia	Inner Regional Australia	Outer Regional Australia	Remote & Very Remote	Total
104	None	$110,937,400	$14,156,491	$5,443,288	$986,858	$131,524,036
105	None	$72,433,908	$10,675,040	$3,714,910	$427,659	$87,251,517
Total		$183,371,308	$24,831,531	$9,158,198	$1,414,517	$218,775,553

The number of patients with skin conditions seen by rural GPs and referred to specialist dermatologists is estimated in Table 68. This estimated number of patients is assumed to refer to patients referred to dermatologist from Eligible Telehealth areas of Australia.

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Table 68: Number of patients referred to dermatologist from outside metropolitan areas

		2014	2015	2016	2017	2018	source
		Current nos.	Projected growth				
2012-13 GP medicare claims	126,800,000						A Britt (2013)
Pop growth	1.7%						B ABS
Skin conditions identified by GPs	16.9/100 encounter						C Britt (2013)
Nos of skin events seen by GPs across Australia		21,429,200	21,793,496	22,163,986	22,540,774	22,923,967	C*A*B=D
GP divide Metro Rural	 68.8% 31.2%						 E F
Number of skin events across Australia seen by metro GP		14,743,290	14,993,926	15,248,822	15,508,052	15,771,689	E*D=G
Number of skin events across Australia seen by rural GP		6,685,910	6,799,571	6,915,164	7,032,721	7,152,278	F*D=H
GPs refer skin conditions to dermatologist	7%						Britt (2013)
Rural GPs refer to dermatologist	4%						Britt, 2001 J
Rural pts referred to dermatologist	At 7%	468,013.73	475,969.96	484,061.45	492,290.50	500,659.43	I*H=K
Rural patients referred to dermatologists	At 4%	267,436	271,983	276,607	281,309	286,091	J*H=L

From Table 68 above it is assumed that due to the shortage of dermatologists in rural areas, the barrier of length of travel and ability to travel large distances and workplace commitments that as noted above, currently rural GP only refer 4% of patients with a skin complaint requiring specialist dermatology services compared to the Australian average of 7% (Britt, 2001).

To estimate the Medicare benefits paid for dermatology services to rural patients the following assumptions are included in Table 69. The take up of delivery of specialist dermatology services by videoconferencing has been very low which may reflect a number of issues:

- The need the sufficient bandwidth to enable adequate vision for the dermatologist. Expert advice is that Skype is not adequate

- Difficulty of co-ordinating a time for the videoconference (Australia has three different time zones) and to co-ordinate all the different parties.
- The availability of the service provided by ACRRM

Table 69: assumptions used to calculate benefits

	Proportions used	MBS fee
Patients seen by dermatologist item 104	Proportion of consults to total consults=46%	Fee= $85.55*85%
Follow up visit to dermatologist Item 105	Proportion of consults to total consults=45%	Fee= $72.75*85%
Dermatologist does consult by VC	Proportion of consults to total consults =0.74%*	Fee= $128.30*85%
Patient support services as proportion of item 99 Level A or B Level C Level D Other	0.85% 0.380 0.383 0.049 0.059	MBS contribution is 100% of fee** (22.90+49.95)*0.5 96.85 142.50
GP doesn't refer patients treat themselves	4%	54.38 (average of level B and C consult)
Store and Forward		Proposed fee $72.72
GP long consult for referring to dermatologist		$105.55

Table 70 estimates the yearly costs of treating patients in Eligible Telehealth Areas for skin conditions for 2014 through to 2018.

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Table 70: Medicare Benefits paid for dermatology services to patients outside metropolitan areas, treated by specialist dermatologist & GPs

		2014	2015	2016	2017	2018	source
		Current nos.	Projected growth				
Number of skin events seen by rural GP		6,685,910	6,799,571	6,915,164	7,032,721	7,152,278	
Number of rural GPs	10,835	10,835	10,835	10,835	10,835	10,835	***
Average nos of patients with skin complaints/rural GP		617	628	638	649	660	L
Rural patients referred to dermatologists	At 4%	267,436	271,983	276,607	281,309	286,091	M
GPs treat Unmet demand for dermatologist	Diff between 4% and 7% referral	200,577.31	203,987.13	207,454.91	210,981.64	214,568.33	N
Nos of 99 services	VC services	1967	2001	2035	2069	2104	0.75%*M&
Nos of 104 services		145958	148439	150963	153529	156139	55%*M
Nos of 105 services		119511	121543	123609	125711	127848	
Benefit paid 99 services	85%	320,161	325,603	331,139	336,768	342,493	
Benefits paid 104 services	85%	10,618,434	10,798,948	10,982,530	11,169,233	11,359,110	
Benefits paid 105 services	85%	4,368,144	4,442,403	4,517,923	4,594,728	4,672,839	
Subtotal		15,306,739	15,566,954	15,831,592	16,100,729	16,374,441	
Benefits paid for GP treat 4% of patients specialist skin conditions	Average of Level B & Level C $54.38*N	10,906,391	11,091,800	11,280,361	11,472,127	11,667,153	
Total $		26,213,130	26,658,754	27,111,953	27,572,856	28,041,594	

VC=video conference

*this is the proportion of item 99, or 104 or 105 consults to total dermatology consults for remote and very remote areas these proportions differ in other ABS geographical regions (e.g. in metropolitan areas item 105 represents 54% of total consults)

**assumption is that all patient level support services provided at consulting rooms because of need for VC equipment and remote location

*** nos of rural GPs may change over the 5 year period but the direction (increase or decrease) is not clear

Table 70 estimates the current yearly costs of treatment of dermatological conditions that require specialist dermatology services. The assumptions underlying this table are that 3% of patients with skin conditions, in rural and remote areas of Australia, that require specialist dermatology services are instead treated by their GP. The costs of GP treatment are included. With population growth factored in the total cost to Medicare of treating skin conditions requiring specialist dermatology services is $28million by 2018.

Table 71: Medicare Benefits paid if patients reside outside metropolitan areas & SAF available

		2014	2015	2016	2017	2018	source
		Current nos.	Projected growth				
Number of skin events seen by rural GP		6,685,910	6,799,571	6,915,164	7,032,721	7,152,278	
Number of rural GPs	10,835	10,835	10,835	10,835	10,835	10,835	***
Average nos of patients with skin complaints/rural GP		617	628	638	649	660	L
Rural patients referred to dermatologists	At 4%	267,436	271,983	276,607	281,309	286,091	M
GPs treat Unmet demand for dermatologist	Diff between 4% and 7% referral	200,577.31	203,987.13	207,454.91	210,981.64	214,568.33	N
Average nos of patients referred per GPs at 7%		43.2	44	44.7	45.4	46.2	
Average nos of patients referred per GP at 4%		24.7	25.1	25.5	26.0	26.4	
Diff nos of patients referred per GP		18.5	18.8	19.2	19.5	19.8	O
Nos of 99 services	Assume VC	1967	2001	2035	2069	2104	0.75%*M&
Nos of 104 services		145958	148439	150963	153529	156139	55%*M
Nos of 105 services		119511	121543	123609	125711	127848	
Nos of skin conditions GPs treat	Unmet demand specialist	163,553	147,507	130,868	113,620	95,749	
Nos of GPs who adopt S&F=2000	Assume increase 1000GP/yr	37,024	56,480	76,587	97,361	118,820	ACCRM** 2000*O
Benefit paid 99 services	85%	320,161	325,603	331,139	336,768	342,493	
Benefits paid 104 services	85%	10,618,434	10,798,948	10,982,530	11,169,233	11,359,110	
Benefits paid 105 services	85%	4,368,144	4,442,403	4,517,923	4,594,728	4,672,839	
Subtotal		15,306,739	15,566,954	15,831,592	16,100,729	16,374,441	
Benefits paid for GP treat of patients	Average of Level B & Level C $54.38*N	8,893,213	8,020,697	7,115,945	6,178,113	5,206,339	
Benefits paid for SAF		2,288,525	3,491,145	4,733,993	6,018,088	7,344,475	

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Total $		26,488,478	27,078,796	27,681,530	28,296,931	28,925,255	

**expert advice from ACRRM is that 2000 GPs out of workforce of 10,500 use service

The total cost to the MBS of introducing SAF technology will be a small increase over the total costs of the current situation without SAF which is shown in Table 70. This is due to the substitution of patient currently being treated by their GP to being treated by SAF. The assumptions underlying Table 71 assumes that around 2,000 rural GPs out of a rural GP workforce of 10,500 (General Practice Statistics, 2014) will take up SAF in its first year of availability. This figure is based on the number of rural GPs who currently participate in the ACRRM run TELEDERM program. It is assumed that this proportion of GPs will refer all patients requiring specialist dermatology services to a dermatologist either for a FF consultation or a consultation via SAF; VC use will remain unchanged. The estimates in Table 71 may underestimate the costs to the GPs as they will still be required to refer the patient which incurs costs. The number of GPs that takeup SAF is assumed to increase by 1,000 GPs a year up till 6,000 rural GPs will be participating in this program. This figure is an assumption but takes into account that younger GPs are more likely to be comfortable with digital technology and over time this type of consultation may increase.

One of the recommendations of the protocol and expert advice is that there may need to be a separate MBS item created for GP referrers to recognise the extra time they will incur to take an extensive clinical history, take the digital images with the requisite expertise and to upload this data to the dermatologist's SAF portal. Expert advice is that obtaining this information could take between 15-30 minutes depending on how extensive the skin involvement is. Table 72 estimates this likely additional cost to the MBS as well as the substitution of VC technology to deliver specialist dermatology services by SAF.

Table 72: Medicare Benefits paid if patients reside outside metropolitan areas and S& F is available and MBS item available for referrer

		2014	2015	2016	2017	2018	source
		Current nos.	Projected growth				
Number of skin events seen by rural GP		6,685,910	6,799,571	6,915,164	7,032,721	7,152,278	
Number of rural GPs	10,835	10,835	10,835	10,835	10,835	10,835	***
Average nos of patients with skin complaints/rural GP		617	628	638	649	660	L
Rural patients referred to dermatologists	At 4%	267,436	271,983	276,607	281,309	286,091	M
GPs treat Unmet demand for dermatologist	Diff between 4% and 7% referral	200,577.31	203,987.13	207,454.91	210,981.64	214,568.33	N
Average nos of patients referred per GPs at 7%		43.2	44	44.7	45.4	46.2	
Average nos of patients referred per GP at 4%		24.7	25.1	25.5	26.0	26.4	
Diff nos of patients referred per GP		18.5	18.8	19.2	19.5	19.8	O
Nos of 99 services	Assume VC	0	0	0	0	0	0.75%*M&
Nos of 104 services		145958	148439	150963	153529	156139	55%*M
Nos of 105 services		119511	121543	123609	125711	127848	
Nos of skin conditions GPs treat	Unmet demand specialist	163,553	147,507	130,868	113,620	95,749	
Nos of GPs who adopt S&F=2000	Assume increase 1000GP/yr + VC	38991	58481	78621	99430	120924	ACCRM** 2000*O +VC
Benefit paid 99 services	85%	0	0	0	0	0	
Benefits paid 104 services	85%	10,618,434	10,798,948	10,982,530	11,169,233	11,359,110	
Benefits paid 105 services	85%	4,368,144	4,442,403	4,517,923	4,594,728	4,672,839	
Benefits paid for GP treat of patients	Average of Level B & Level C $54.38*N	8,893,213	8,020,697	7,115,945	6,178,113	5,206,339	
Benefits paid for SAF		2,288,525	3,491,145	4,733,993	6,018,088	7,344,475	
Benefits paid for		1,782,378	2,673,294	3,593,985	4,545,207	5,527,732	

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GP referral to SAF							
Total $		28,072,285	29,550,143	31,070,135	32,633,266	34,240,565	

Table 72 indicates that, under the assumptions that SAF will substitute for VC, and that an additional 1,000 GPs a year will refer their patients, who are currently not being referred to a dermatologist, to a dermatologist using SAF and rural GPs will be paid an MBS item equivalent to 45.71 (average of a Level B and Level C consult) for the referral, then the costs to Medicare are likely to increase by approximately $2 million in the current year, increasing to an additional $6 million in 2018.

It was requested that the assessment try to estimate the cost of extending the delivery of specialist dermatological services via store and forward technology to people with disabilities. The ABS estimates that 18.5% of the Australian population has a disability. For people with a disability, 3.7 million (88%) had a specific limitation or restriction that meant they were limited in the core activities of selfcare, mobility or communication, or restricted in schooling or employment. Profound disability that interferes with core functioning is estimated in 3.2%, severe disability in 2.9% and moderate disability in 2.8% of the Australian population (ABS Cat. 4430).

This additional calculation to estimate the increased cost to Medicare of extending SAF to people with disabilities is only for those who reside in Major Cities and visit their GP. People with a disability residing in rural areas are excluded from this analysis on the basis that they will already be covered.

Table 73: Estimated cost to Medicare if asynchronous specialist dermatology services by telecommunications is extended to people with disabilities

		2014	2015	2016	2017	2018	source
		Current nos.	Projected growth				
Number of skin events across Australia seen by metro GP		14,743,290	14,993,926	15,248,822	15,508,052	15,771,689	Table 68
Pts with profound disability	3.2%	471,785.27	479,805.62	487,962.31	496,257.67	504,694.05	
Pts with severe disability	2.9%	427,555.40	434,823.84	442,215.85	449,733.51	457,378.98	
Pats with moderate disability	2.8%	412,812.11	419,829.91	426,967.02	434,225.46	441,607.30	
Total pts with disability visit metro GP		1,312,152.77	1,334,459.37	1,357,145.18	1,380,216.65	1,403,680.33	
Assume referred to dermatologist as same rate as other patients		91,850.69	93,412.16	95,000.16	96,615.17	98,257.62	
If all referred for S&F		$5,677,475	$5,773,992	$5,872,150	$5,971,977	$6,073,500	
With GP referral costs		$4,198,725	$4,270,103	$4,342,695	$4,416,521	$4,491,602	
Total maximum cost		$9,876,200	$10,044,095	$10,214,845	$10,388,497	$10,565,102	

The estimated total additional cost to Medicare if asynchronous specialist dermatology services by telecommunications is extended to people with disabilities is $9.876M in 2014 to $10.565M in 2018, if the rates of disability, that interfere with core functioning, increase at the same rate as population growth. These figures are likely to be at the high end and an overestimate because:

1) The estimates of people with disabilities in Major cities will include elderly people residing in residential care facilities who would be covered if SAF is listed and available for Eligible Areas.
2) The assumption is that all patients with a disability who have profound to moderate impairment to core functioning will be referred to their dermatologist using SAF technology. This is not likely to be the case. Although it may be the case that given their physical limitation people with disabilities may be referred at greater rates than their abled bodied peers, there will still remain a proportion of dermatological conditions for which only a face to face dermatological consultation can be done.
3) If people with a disability are being treated by their GP for their skin conditions then there may be a commensurate reduction in GP services to offset the increase in Medicare costs.

It is postulated that the increased use of dermatologists may result in a reduction in pathology fees on the basis that GPs may be risk adverse when faced with a skin lesion and therefore excise lesions, and refer for pathology lesions that a dermatologist may not excise,

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resulting in additional savings to the MBS. This analysis has not been included in the savings to the MBS.

Costs to the State and Territory health systems

It is not anticipated that there will be any change in the costs to the State and Territory health systems from a listing of asynchronous specialist dermatology services delivered by telecommunications.

Costs to the private health insurer and/or patient

It is not anticipated that the listing of asynchronous specialist dermatology services delivered by telecommunications will have any effect on private health insurance. Currently, patients incur out of pocket expenses for the delivery of specialist dermatological services, of on average $73. This amount is not expected to vary to any significant degree if asynchronous specialist dermatology services by telecommunications is listed on the MBS.

Conclusions

Safety

The literature search did not locate any reports that related to studies that specifically addressed the safety of SAF teledermatology. There are no inherent safety issues with providing patient clinical history and digital images by telecommunications rather than a patient being seen face-to-face.

Safety issues can arise with any diagnostic test in the form of false positives and false negatives. There is conflicting data on the accuracy of SAF teledermatology for the diagnosis of pigmented lesions and exclusion of melanoma.

Variations in digital photographic and dermatoscopic techniques and experience are suggested as reasons for the conflicting safety data. Development of quality standard to bring together best practice and existing guidance is recommended to overcome this variation.

Effectiveness

Diagnostic accuracy

Overall, there was insufficient evidence to produce a definite conclusion about the equivalence of diagnostic performance of SAF vs VC.

The evidence found that the diagnostic accuracy of FTF dermatologists was superior to teledermatology irrespective of the addition of teledermatoscopy.

Economic considerations

The basecase cost minimisation analysis estimated that in a scenario where dermatoscopy is not used, and the diagnostic performance of SAF and VC are assumed to be equal, SAF costs less by $113.66. Where dermatoscopy is used, and the diagnostic performance of SAF and VC are assumed to be the same, SAF costs less by $111.48, reflecting the slightly improved diagnostic accuracy with the use of dermatoscopy.

The basecase full economic model compares the current scenario where a proportion of patients are treated by their GP (unmet demand for specialist dermatology services) or some are referred for FTF consultation or VC teledermatology with the proposed scenario where SAF teledermatology is introduced and the proportion of patients currently treated by their GP is reduced as they are referred for SAF teledermatology. Diagnostic performance between SAF and VC is assumed equal and the proportions of patients referred to FTF consultation after unsuccessful VC or SAF examination is retained. The incremental cost per additional correct diagnosis in the proposed scenario where SAF teledermatology is available is $642.22.

The analyses presented above indicates that the model results are sensitive to the change in the cost of SAF teledermatology, with the cost minimisation estimating a saving of $180.13 and the cost-effectiveness analysis resulting in a 40% reduction in the ICER to $384.76.

Sensitivity analyses conducted shows that the results are sensitive to the variations in the estimates of the reduction in proportion of patients referred to VC (by 90%) after SAF

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becomes available (reduction in ICER by $200 in comparison to the basecase, although the diagnostic performance has also reduced) (Table 61).

The results are especially sensitive to the assumption that the proportion of patients currently referred to FTF will be diagnosed by SAF teledermatology (23%, Eminovich 2003). If this assumption is correct, the incremental cost per correct diagnosis marginally increases while diagnostic performance of the proposed scenario becomes inferior to the current scenario.

The cost-effectiveness analysis of two scenarios with respect to the population with disability residing in the outer metropolitan areas generally replicates the results of the cost-effectiveness analysis of the target population where is assumed that most patients referred for SAF teledermatology are currently treated by their GP. Where the scenario assumes that a proportion of patients being managed by GPs are referred for SAF teledermatology the ICER is the same ($642.21) as in the basecase analysis. However when the proportion of patients who are currently referred by GP for FTF consultations is assumed to be diverted to SAF, SAF teledermatology is dominated, it is both less effective and more expensive. These results are robust to whether a cost for the time for the GP to do the referral to SAF teledermatology is included.

Costing

It is estimated that there are 200,577 people in 2014 who require specialist dermatology services who currently are not able to access specialist dermatology services. The expected uptake of this asynchronous specialist dermatology services is estimated at 37,024 in 2014 increasing to 118,820 asynchronous specialist dermatology services in 2018.

The total cost to the Medical Benefits Scheme for the asynchronous specialist dermatology services is estimated to be $2,288,525 million in 2014 increasing to $7,344,475 in 2018.

Appendix A MSAC membership

Member	Nomination / Expertise or Affiliation

Evaluators

Name	Organisation
Sandra Younie	Deakin University
Elena Gospodarevskaya	Deakin University
Liliana Bulfone	Deakin University
Lan Gao	Deakin University

Appendix B Search strategies

Search results of Medline (including all EBM reviews)

Date: 22/06/2014

#1 *teledermatology/ N=389

#2 (teledermatolog* or tele-dermatolog* or telederm or tele-derm or teledermatopatholog* or teledermatopatholog* or tele-dermatopatholog* or teledermoscop* or tele-dermoscop* or teledermatoscop* or tele-dermatoscop*).ti,ab. N=443

#3 1 or 2 N=445

#4 Dermatology/ N=104394

#5 exp Skin diseases/ N=810983

#6 Skin Neoplasms/ N=96275

#7 (dermatolog* or dermatopatholog* or dermoscop*).ti,ab,jn. N=68706

#8 (skin disease* or skin patholog* or psoriasis or psoriatic or skin cancer* or skin tumour* or skin tumor* or skin lesion*).ti,ab. N=80801

#9 4 or 5 or 6 or 7 or 8 N=857107

#10 exp Telemedicine/ N=15675

#11 (telehealth or tele-health or telecare or tele-care or telemedic* or tele-medic* or e-health* or ehealth*).ti,ab. N=9576

#12 (remote assessment* or rural assessment*).ti,ab. N=86

#13 (telepathology or tele-pathology).ti,ab. N=524

#14 (telemonitor* or tele-monitor* or telehome* or tele-home* or telematic or tele-matic or teleconsult* or teleconsult* or telemanagement or tele-management or teleservic* or tele-servic* or telediagnos* or tele-diagnos* or teletransmi* or tele-transmi* or transtelephonic or trans-telephonic or telefax or tele-fax).ti,ab. N=2309

#15 ((remote or wireless or mobile) adj2 (monitor* or consult* or screening or surveillance)).ti,ab. N=2094

#16 (teleconferenc* or tele-conferenc* or videoconferenc* or video conferenc* or webconference* or web conferenc* or web consult*).ti,ab. N=2343

#17 (m-health* or mobile health*).ti,ab. N-613

#18 (telemed* or eHealth).jn. N=2037

#19 9-17/or N=22644

#20 3 or (9 and 19) N=1015

#21 Limit 19 to humans N=945

Duplicate N=12

Result **N=933**

Search results of EMBASE

Date 20/5/2014

#1. 'teledermatology'/exp AND (teledermatolog*:ab,ti OR tele*dermatolog*:ab,ti OR telederm:ab,ti OR tele*derm:ab,ti OR teledermatopatholog*:ab,ti OR tele*dermatopatholog*:ab,ti OR teledermoscop*:ab,ti OR tele*dermoscop*:ab,ti OR teledermatoscop*:ab,ti OR tele*dermatoscop*:ab,ti) **N=572**

#2. Dermatology/exp/mj OR (dermatolog* OR dermatopatholog* OR dermoscop*):ti:ab OR skin NEAR/2 disease* OR skin NEAR/2 patholog* OR psoriasis OR psoriatic OR skin NEAR/2 cancer* OR skin NEAR/2 tumour* OR 'melanomalignoma'/exp/mj OR 'melanoma'/exp/mj OR pigment* NEXT/2 neoplasm* OR cell NEXT/1 carcinoma* OR solar NEXT/1 keratos* **N=665,293**

#3. 'telehealth'/exp/mj OR telehealth OR 'telemedicine'/exp/mj OR telemedicine OR e?health OR telehealth:de,ab,ti OR tele*health:de,ab,ti OR telecare:de,ab,ti OR tele*care:de,ab,ti OR telemedic*:de,ab,ti OR tele*medic*:de,ab,ti OR ehealth*:de,ab,ti OR (remote NEAR/1 assessment*):ab,ti OR (rural NEAR/2 assessment*):ab,ti OR telepathology:ab,ti OR tele*pathology:ab,ti OR telemonitor*:ab,ti OR tele*monitor*:ab,ti OR telehome*:ab,ti OR tele*home*:ab,ti OR telematic:ab,ti OR tele*matic:ab,ti OR teleconsult*:ab,ti OR telemanagement:ab,ti OR tele*management:ab,ti OR teleservic*:ab,ti OR tele*servic*:ab,ti OR telediagnos*:ab,ti OR tele*diagnos*:ab,ti OR teletransmi*:ab,ti OR tele*transmi*:ab,ti OR transtelephonic:ab,ti OR trans*telephonic:ab,ti OR telefax:ab,ti OR tele*fax:ab,ti OR ((remote OR wireless OR mobile) NEAR/2 (monitor* OR consult* OR screening OR surveillance)):ab,ti OR teleconferenc*:ab,ti OR tele*conferenc*:ab,ti OR videoconferenc*:ab,ti OR (video NEAR/2 conferenc*):ab,ti OR webconference*:ab,ti OR (web NEAR/2 conferenc*):ab,ti OR (web NEAR/2 consult*):ab,ti OR (mobile NEAR/2 health*):ab,ti OR m?health* **N=26,850**

#4. #2 AND #3 **N=770**

#5 (#1 OR #4) and [embase]/lim **N=630**

#6 [animals]/lim **N=5,939,532**

#5 NOT #6 **N=611**

After results of MEDLINE (including all EMB reviews) and EMBASE searches were combined and duplicates deleted, the final number of the identified references was **N=1107**

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Appendix C Studies included in the review

Included systematic reviews

Table 74: Assessment of the quality and results reported in systematic reviews

Systematic Review*	Objective	Search strategy	Inclusion/exclusion criteria	• Methodology	Review quality	Conclusion

Brown N. Exploration of diagnostic techniques for malignant melanoma: an integrative review. Clinical Excellence for Nurse Practitioners 2000; 4(5): 263-271	To explore the various diagnostic techniques for melanoma and to assess their usefulness in the clinical practice of nurse practitioners.	Database searched: HealthSTAR, MEDLINE, Cancerlit and CINAHL from 1952 to 1999 using the keywords 'melanoma', 'skin neoplasm', 'diagnosis', 'screening' and 'dermatoscope'. The searches were limited to studies published in the English language. In addition, the reference lists of all retrieved studies were examined.	Population – not clearly defined Intervention The specific interventions were naked-eye clinical examination alone, clinical examination with the aid of total-body photographs epiluminescence microscopy; digital ELM; computer-assisted techniques and teledermatology. Comparator: The reference standard test was histological examination after excision. Outcome Diagnostic accuracy (DA) or sensitivity and Inclusion/exclusion DA studies were eligible for inclusion. The study had to include a minimum of six melanoma lesions, and have a formal methods and results section. Studies that examined diagnostic techniques to improve accuracy for melanoma detection were eligible for inclusion. Studies that were descriptions of equipment, or that compared the DA of melanoma with another type of cancer, or were reports of first-time use of computer-aided equipment were excluded. Identified studies**: digital ELM (2 studies), and teledermatology (3 studies).	Study design The author alone selected the papers. Not clear how the data was extracted for the review, or how many reviewers performed the data extraction. Data on the author and year, the participant or clinician characteristics, and the results were extracted and tabulated. The studies were combined narratively,	The searches undertaken were of a relatively poor quality: although four databases were searched the search strategy was extremely limited. The searches were restricted to studies published in English. Overall, this was a poorly reported review in which it was difficult to assess the review process. The author's conclusions appear largely speculative in nature since almost no data on the role of nurse practitioners, and none at all on any impact of patient education, were presented in the review. The author's results and conclusions should therefore be treated with caution.	Digital ELM: neither of the studies report a DA figure, but the advantage of being able to enhance and magnify the image on the computer screen was reported in both studies. Teledermatology: 3 studies assessed the use of telephonic transmission of digital images to a remote location. However, each study focused on a different aspect of teledermatology. One study examined the concordance of diagnosis when using images from a projector and those on the Internet. The results indicated a high level of concordance between these two methods of image production. The second study confirmed the results of the first, by using two remote clinicians and comparing their diagnosis with an on-site dermatologist. Again a high level of concordance in the diagnosis was observed. The last study set up a teledermatology programme with rural sites, which were manned by physicians and nurse practitioners. The results indicated that after 10 to 12 months, the confidence levels, diagnostic ability and use of treatment plans increased significantly. Skin assessment, detection of suspicious pigmented skin lesions, and referral are part of a critically important process. The nurse practitioner also has a role in educating patients about risk factors, prevention, signs and symptoms, and the treatment of

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						melanoma.

*See the relevant entry in the Center for Review and Dissemination, University of York. **Relevant to the research question of the Assessment

Systematic Survey	Objective	Search strategy	Inclusion/exclusion criteria	Methodology	Review quality	Conclusion
Armstrong et al 2012 State of teledermatology programs in the United States, American Academy of Dermatology, 2012; 67: 939-944	To provide accurate and up-to-date information regarding the state of teledermatology programs in the United States, by conducted a comprehensive survey of the active U.S. teledermatology programs in 2011.	We used a systematic approach to identify active teledermatology programs in the U.S. First, based on a 2003 ATA survey, we identified a list of previously active teledermatology programs. In addition, we surveyed members of the ATA Teledermatology SIG and the AAD Telemedicine Task Force to identify new programs. Furthermore, we asked members from these two organizations about any additional programs not already identified by the previous two methods. Finally, we conducted an Internet search to identify any other new programs.	A total of 110 questionnaires were distributed electronically to teledermatology programs. Programs unresponsive to the initial survey were contacted at least 3 times via e-mail and at least 3 times by telephone (N=46). For programs that were identified as discontinued during the search process, we confirmed the program status with the affiliated institutions.	The questionnaire included the program contact information, availability of synchronous or asynchronous teledermatology services, service areas, accepted payment methods, and the availability of volunteer services.	The study is focused on the number; coverage and types of teledermatology programs in the USA only. It did not include the systematic assessment of comparative performance of the different types of the programs. The review cited a very limited number of publications on diagnostic accuracy of teledermatology. It effectively assumed equality in sensitivity, specificity and reproducibility of diagnosis by teledermatology in one of its specific modalities and face-to-face in-office consultations.	Overall, S&F modality was the most frequent teledermatology delivery method in 2011, which was practiced by 30 (81%) of the U.S. teledermatology programs. Specifically, 19 programs (51%) provided S&F teledermatology only, whereas 7 programs (19%) practiced both S&F and LI teledermatology for separate clinical encounters. A total of 5 programs (14%) practiced LI modality alone Teledermatology is valuable in increasing specialty-care access to various populations. This systematic study of active U.S. teledermatology programs found a decrease in total number of programs but an increase in annual consult volume per each active program. Store- and forward is the dominant delivery modality in 2011. Future efforts need to focus on means to sustain existing programs and to work alongside health policy groups to enable appropriate telehealth legislation.

Systematic Review*	Objective	Search strategy	Inclusion/exclusion criteria	Methodology	Review quality	Conclusion
Eminovic et al 2006 Ten years of teledermatology Studies in Health Technology & Informatics,2006 124; 362-367 Eminovic et al** 2007 Maturity of teledermatology evaluation research: a systematic literature review, British Journal of Dermatology 2007 156:412–419	Up to now no or limited valid scientific evidence has been found that teledermatology is beneficial for any group of users. This study aimed to perceive insight into the evolution of evaluation studies of teledermatology over the past ten years in terms of the telemedicine evaluation framework by Holle and Zahlmann consisting of four continuous phases. We added the phase "post implementation studies" that evaluate teledermatology as a fully integrated service in regular care. Aim of this review is to obtain insight in the status of teledermatology evaluation studies of the past ten years as a function of the phases defined by Holle and Zahlmann*.	Published teledermatology studies were identified by searching in the Medline database (from 1966 up to April 2005) using following search queries containing words and MeSH terms: dermatology, teledermatology, telemedicine, skin and electronic mail.	Population. Not extracted Intervention. Classified as store-and-forward S&F or real time (RT). Outcome Design of the studies provided an input for assigning it to one of the five phases. Diagnostic accuracy outcomes are not extracted Inclusion/exclusion Literature reviews, comments, abstracts, letters and editorials were excluded. Papers in other languages than English were excluded. Papers on telemedicine application for several specialties were only included if the results were separately reported for dermatology. References in literature reviews were manually searched to retrieve possibly missed references. 99 studies were identified with majority (72%) were assigned to feasibility- phase II. Only 2 papers were Phase III RCTs, in addition 4 cost studies used results from RCTs.	Two independent reviewers manually screened of the papers that met inclusion criteria. Based on the full paper, two reviewers independently assigned the studies to one of the four phases of the Holle and Zahlmann strategy (Exploratory; Feasibility; RCT; Cost-benefit or Cost-effectiveness studies; post-implementation studies) based on the pre-specified criteria. All discrepancies in classifying the selected papers between the reviewers were solved by consensus. Interobserver reliability regarding the classification into phases was calculated. The 2007 paper also reported the type of outcome for each of the included studies The studies were classified and presented using a classification typology; the outcomes of individual studies were not extracted and analysed.	The searches undertaken were of a relatively poor quality: only one database was searched the search strategy was limited. The searches were restricted to studies published in English. The reviews did not address comparative effectiveness of the teledermatology interventions; The value of the systematic review is extremely limited to the classification of the publications existed at the time of the review.	The results show that the evaluation of teledermatology takes place in different phases and that there are no clear trends over the years for certain phases, at least not by the time the study was performed. Our study shows that the majority of papers about evaluation in teledermatology reports on phase II (feasibility) studies. The number of phase II studies is continuously growing over the past ten years the number of phase III (RCT) and IV (cost-benefit & cost-effectiveness) studies is very low. The diagnostic accuracy was the most common outcome measure used in 53 studies. Earlier studies (Loane et al, 2000 showed that live interactive teledermatology was more clinically efficient than the SAF variant The push for performing RCTs in teledermatology is possibly lower than in other technical innovations since teledermatology is already implemented in regions where the benefits are straightforward (low risks and low investment costs in comparison to medical interventions). No or limited valid scientific evidence about the impact of teledermatology on clinical outcome has been found (Whitten,2002; Hailey, 2002).

*R.Holle and G.Zahlmann, Evaluation of telemedical services, IEEE Trans.Inf.Technol.Biomed. 3 (1999) 84-91.

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**The paper by Eminovich et al, 2007 is practically identical to Eminovich et al, 2006

Systematic Review*	Objective	Search strategy	Inclusion/exclusion criteria	Methodology	Review quality	Conclusion
Hersh et al 2001, 2006a, 2006b Telemedicine for the Medicare population, 2001 USA: Agency for Healthcare Research and Quality. Evidence Report/Technology Assessment; 24. 2001 Telemedicine for the Medicare population: update,Agency for Healthcare Research and Quality (AHRQ). Evidence Report/Technology Assessment No. 131. 2006 Diagnosis, access and outcomes: Update of a systematic review of telemedicine services. Journal of Telemedicine & Telecare. 2006 12 (S2) S3-31	To assess the peer-reviewed literature for telemedicine services that substitute for face-to-face medical diagnosis and treatment that may apply to the Medicare population. We focused on three distinct areas: store-and-forward, home-based, and office/hospital-based services.	MEDLINE, EMBASE, CINAHL, and HealthSTAR were searched for relevant publications using the terms telemedicine, telehealth; remote consultations (the search terms were reported). In addition, the reference lists of selected studies and relevant systematic reviews were checked. Internet sources were searched.	Population: the USA Medicare eligible adults Intervention. store-and-forward S&F telemedicine (including teledermatology) and real time clinician-patient interactive telemedicine Comparator face-to-face examination with clinical dermatologist Outcome Concordance (comparability of diagnostic decisions and recommendations for clinical management) and diagnostic accuracy outcomes; patient clinical outcomes were not reported in the identified studies Inclusion/exclusion Included studies had to be relevant to at least one of the three study areas, address at least one key question, and contain reported results. We excluded articles that did not study the Medicare population (e.g., children and pregnant adults) or used a service that does not require face-to-face encounters (e.g., radiology or pathology diagnosis). The identified studies of teledermatology (N= 5 in 2001 and N=13 in 2006) only assessed diagnosis or management decisions and not patient clinical outcomes.	Two reviewers independently selected each study for inclusion in the review. The included studies were classified according to their level of evidence (i.e. study design). In addition, for studies of diagnostic and management decisions, features of the study design which were likely to be associated with bias, such as small sample sizes (less than 10 to 20 patients), selective application of definitive diagnosis testing, and insufficiently long follow-up to determine diagnosis when a 'gold' standard test was not or could not be performed, were evaluated. One reviewer performed the validity assessment and a second reviewer checked it. The studies were presented in the narrative synthesis according to the type of telemedicine intervention being evaluated (e.g. store-and-forward) and the type of outcomes reported	The study population is limited to adults eligible to US Medicare health care program. non-English literature was not included. The validity of the included studies was assessed by a variety of ways and multiple reviewers were employed at every stage to minimise the potential for errors and bias. Given the heterogeneity of the included studies, the use of a narrative synthesis was appropriate and the authors' conclusions were appropriately cautious.	The most commonly assessed aspect of teledermatology was interobserver concordance. The range of concordance varied widely, from 41 percent to 87 percent for complete agreement to 51 percent to 96 percent for disease-category agreement. All of these studies were limited by the lack of measurement of concordance among more than one face-to-face examiner. Concordance studies assessing management decisions typically looked at decision to biopsy. While one study found complete agreement, others found lesser concordance. The studies of diagnostic accuracy typically compared the telemedicine diagnosis to some sort of gold standard, often a biopsy of a pigmented lesion. In these studies, telemedicine was nearly as good as face-to-face in correctness of diagnosis Store-and-forward services have been studied in dermatology, wound care, and ophthalmology. The evidence for their efficacy is mixed, and in most areas, there are not corresponding studies on outcomes or improved access to care. There are significant gaps in the evidence base between where telemedicine is used and where its use is supported by high-quality evidence. Further well-designed research that provides high-quality data are needed.

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*See the relevant entry in the Center for Review and Dissemination, University of York.

Systematic Review	Objective	Search strategy	Inclusion/exclusion criteria	Methodology	Review quality	Conclusion
Kanthraj, 2013 A longitudinal study of consistency in diagnostic accuracy of teledermatology tools. Indian J Dermatol Venereol Leprol 2013;79:668-78.	To observe trend in the estimates of interobserver concordance/ diagnostic accuracy (DA) between teledermatologist using a single teledermatology tool (TT) and clinical dermatologist over a period of 15 years (1997-2011) using the published evidence.	Published teledermatology studies were identified by searching in the PubMed database (from 1997 up to April 2011) using the search term "teledermatology" and "TP"	Population: 2385 patients from store and forward teledermatology (S&F) studies and 1305 patients from videoconferencing (VC) studies Intervention: teledermatology S&F and VC used by a teledermatologist Comparator face-to-face examination by clinical dermatologist Outcome Concordance (comparability of diagnostic decisions and recommendations for clinical management) and diagnostic accuracy outcomes; Inclusion/exclusion The studies were excluded if a combination of TTs used for diagnostic purpose; Studies focusing on a single clinical entity; comparison between two TTs non-English articles Studies that employed additional or special TT like teledermoscopy were excluded Studies reporting concordance/DA Between GP/nurse and dermatologist 59 studies were identified as studies of single teledermatology tool that fit selection criteria ; Studies were further assessed for quality and only those that rated in the two highest categories were included (N=35)	The author alone selected the papers. Not clear how the data was extracted for the review, or how many reviewers performed the data extraction. The author stated that all the studies included were complete feasibility studies, but this term applied indiscriminately to all studies that assessed interobserver concordance Data on the author and year, TT, clinician performing teledermatology and the presence of a comparator, and the results were extracted and tabulated. The studies were assessed for quality using author's own criteria. T-test , Chi-square statistics and non-parametric tests were used to assess the difference in DA between S7F and VC and between both vs face-to-face consultation.	The searches undertaken were of a relatively poor quality: only one database was searched the search strategy was limited. The searches were restricted to studies published in English. The author used an unvalidated criteria for assigning ranks to the identified studies according to their perceived quality. The studies were grouped by TT (S&F, VC and mobile teledermatology, online discussion forum) and by specialty Heterogeneity has neither been recognised nor explored. The use of t-Test and non-parametric statistics to assess DA and "trend over 15 years" is questionable. The author's results and conclusions should therefore be	This analysis sought to identify the DA trend was carried out by evaluating 17 S&F based and 8 VC tool-based studies in comparison with the gold-standard assessment (face-to-face clinical dermatologist consultation) The average DA was 73.35% ± 14.87% for SAFT and 70.37% ± 7.01% for VC.

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					treated with caution.	

Systematic Review	Objective	Search strategy	Inclusion/exclusion criteria	Methodology	Review quality	Conclusion
Levin, Warshaw 2009 Teledermatology: A Review of Reliability and Accuracy of Diagnosis and Management; Dermatol Clin 27 (2009) 163–176	The purpose of this article is to summarize the published literature on the reliability and accuracy of teledermatology. Diagnostic reliability of teledermatology (or reproducibility) was defined as diagnostic agreement, between dermatologists using the two different modalities. Firstly, Teledermatology wascompared with face-to-face clinic consultation; secondly, the ''intragroup'' diagnostic agreement between either clinic dermatologists or teledermatologists was assessed; lastly, the diagnostic accuracy for those studies that include definitive histopathologic diagnosis was assessed	Published teledermatology studies were identified by searching the PubMed database using the terms ''teledermatology'' and ''telemedicine and dermatology'' in the spring of 2008.	Population: population presented with various skin conditions including suspected skin cancers, pigmented lesions and neoplasms Intervention: teledermatology - S&F; live interactive (VC); teledermatoscopy Comparator face-to-face examination by clinical dermatologist, histopathology (gold standard) Outcome diagnostic accuracy - complete or partial (including differential diagnosis); management plan Inclusion/exclusion We limited this review to those studies that compared diagnosis or management; they excluded publications focused on technology, implementation, satisfaction, or economic outcomes (unless agreement or accuracy were used as outcomes of effectiveness)	Full texts of all articles published in English were retrieved and reviewed by both authors. Data on the author and year, number of patients, dermatologic conditions, numbers of clinical and teledermatologists and the diagnostic reproducibility results (% agreement) were extracted and tabulated.	The searches undertaken were of a relatively poor quality: only one database was searched and the search strategy was limited. The searches were restricted to studies published in English. The results were not separated by the type of teledermatology, although teledermatoscopy results are presented separately. An advantage of the review is a comprehensive data extraction on the diagnostic reproducibility and validity (vs gold standard if available)	Overall, teledermatologists and clinic dermatologists completely agreed with each other in 41% to 94% of cases. They had partial agreement in 50% to 100%. Within intragroup, clinic dermatologists completely agreed with each other in 54% to 95% of cases and partially agreed with each other in 90% to 100% cases. Teledermatologists demonstrated complete agreement in 46% to 83%, and partial agreement in 84% to 92%. Kappa statistics ranged from 0.22 to 0.91. Accuracy rates based on a gold standard (primarily histopathology) for teledermatology ranged from 30% to 92% for clinic dermatologists and from 19% to 95% for teledermatologists. Pairwise comparison of six clinic dermatologists and six teledermatologists demonstrated agreement rates of 68% to 80%, 56% to 74%, and 63% to 70% for diagnostic testing recommendations, recommendations for medical therapy, and recommendations for clinic-based therapy, respectively. For diagnostic testing recommendations, intragroup agreement for both teledermatologists and clinical dermatologists exceeded intergroup agreement. Teledermatology demonstrated good performance in comparison to clinic-based consultation for diagnostic agreement and diagnostic accuracy. For diagnosis, teledermatologists agreed with each other and with clinic-based dermatologists at a rate comparable to intragroup agreement among clinic dermatologists. For clinical management, the conclusions are less convincing because of the few studies on the subject

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Systematic Review	Objective	Search strategy	Inclusion/exclusion criteria	Methodology	Review quality	Conclusion
Martin-Khan 2011 Martin-Khan, M., Wootton, R., Whited, J., Gray, L.C., 2011. A systematic review of studies concerning observer agreement during medical specialist diagnosis using videoconferencing. Journal of Telemedicine & Telecare 17, 350-35	To provide a summary of comparative studies of medical specialist diagnostic agreement using videoconferencing. *Studies reported the teledermatology were commented here only.	-An electronic search was carried out of the MEDLINE, CINAHL and PubMed databases using the Medical Subject Headings (MeSH). Manual search was also performed to identify additional studies. -Search terms: 1 MeSH terms: Videoconferencing; Teleconsultation; Remote consultation. General terms: Remote consultation; Teleconsult*; Tele-consult*; videoconsult*; video consult*; VC*; remote assessment; teleass* 2 MeSH terms: Health, Diagnosis; Diagnosis, Differential; Rural Health; Rural Health Services	Inclusion criteria -a videoconference between a health professional and a patient for the purpose of diagnosis -an assessment interview with the patient which included an unstructured assessment component -usual clinical practice which involved the patient seeing the health professional Face-To-Face (FTF) -a comparison of diagnostic agreement between FTF and VC assessment with relevant reporting of statistical data -sample size equal to or greater than 20 (for each study group) Exclusion Criteria -evaluated the technical specifications of telemedicine technologies (such as bandwidth) -evaluated educational or administration applications -evaluated the economic impact or patient satisfaction -evaluated diagnostic agreement where the patient was not present to interact with the specialist, i.e. transmission of images or pathology results -evaluated monitoring devices or patient management, in which case a diagnostic assessment had already occurred -evaluated agreement of the administration of standardised assessment tools	Study characteristics summarised. Results for individual studies summarised. It is a narrative systematic review, without meta-analysis of diagnostic accuracies of all the included studies.	Poor quality Search strategy fully defined Unclear study selection and data extraction process No quality assessment of individual studies No meta-analysis Applicability concern: Only comparing FTF with video-conferencing in dermatology care	10 studies using video-conferencing for dermatology consultation while using FTF consultation as reference standard, were included in the systematic review. The overall percentage of agreement between VC and FTF was ranged from 59% to 96% while the agreement between SF and FTF was approximate 82%, and adding VC to SF could improve the agreement to 90%. The diagnostic agreement statistic Kappa was between 0.32 and 0.91 for the same diagnoses. When adding VC to SAF consultation, the agreement statistic Kappa increased from 0.71 (SAF alone) to 0.79 from one study.

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		General term: Assessment 3 Limit to English, abstract available, peer reviewed -The search was completed in June 2010	-evaluated a FTF assessment with an added VC element, but the VC diagnosis was not carried out independently, i.e. FTF assessment information by a junior specialist was given to a senior consultant via VC for verification, but no other assessments were carried out -evaluated telemedicine technologies other than VC equipment, i.e. telephone, videophone, fax Included studies: N=10			
Moffatt 2010 Moffatt, J.J., Eley, D.S., 2010. The reported benefits of telehealth for rural Australians. Australian Health Review 34, 276-281. *this study reported the telehealth benefits for Australians in a broad perspective, thus it was presented here.	To critique the quality of the studies reviewed but to elicit what the reported benefits are.	A computer assisted search of articles on Scopus (using telemedicine, telehealth, telepsychiatry, teledermatology, teleradiology, Australia, and each state and territory) since 1998 was conducted.	Inclusion criteria: Not specified. Exclusion criteria: Papers that did not report research on Australian rural, regional or remote populations	Study characteristics were summarised. Results from individual studies were not present. It is a narrative systematic review, without meta-analysis of diagnostic accuracies of all the included studies.	Poor quality Not a systematic review. Inclusion and exclusion criteria not explicitly defined. Unclear study selection and data extraction processes. No actual results reported.	Reported benefits to rural patients -reduced expense and inconvenience when compared with having to travel long distances to access a service; -the improved access to services that a locally-provided specialist service offers and the improved quality of the existing clinical services Reported benefits to rural health professionals -local access to continuing education and professional development activities, -the ability to provide an enhanced local service, and indirect benefits through experiential learning from close contact with specialists in clinical work Reported benefits to participating hospitals - ensure more appropriate patient admissions and potentially reduced length of stay or better patient outcomes Reported benefits to society -potential societal benefit of telehealth is improved productivity due to less time away from work primarily because of reduced travel. -the financial benefits to rural communities when patients remain in their community
Heijden 2010 van der Heijden, J.P., Spuls, P.I., Voorbraak, F.P., de Keizer, N.F.,	To give an overview of studies on tertiary teledermatology with emphasis on the categories of use.	A systematic literature search was performed to select any study on tertiary	Inclusion Criteria: All studies reported on the tertiary teledermatology, including original studies, comments, letters and editorials.	Two reviewers independently screened titles and abstracts of all reports	Moderate quality Search strategy fully defined Clear study selection and data	Diagnostic accuracy by comparing telediagnosis to histopathological diagnosis was approximately 78.8% in teledermatology. Studies did not report on efficiency improvement

Witkamp, L., Bos, J.D., 2010. Tertiary teledermatology: a systematic review. Telemedicine Journal & E-Health 16, 56-62.		teledermatology using the following databases: MEDLINE (1966-November 2007), EMBASE (1980-November 2007) and all databases of the Cochrane Library. Search terms: Medical records system, computerized [Mesh] OR teledermat* OR telemedicine OR teleconsult* OR e-health OR electronic mail AND (dermatol* OR skin*)	Exclusion Criteria: No referral to academic dermatologists, referring clinician was a GP, conference proceedings, fulltext not found, tertiary teledermatology not the focus of the paper, errata, abstracts, referrer was the patient. Included studies: N=11	identified by searches and discrepancies were discussed. Study characteristics summarised. Results for individual studies summarised Meta-analysis was not performed due to the significant heterogeneity across studies	extraction process No quality assessment of individual studies Applicability concerns: -It is a review for tertiary teledermatology rather than the primary care, at which GP is the referrer for specialist dermatologist. -Only 4 of included studies reported the diagnostic validity/reliability/accuracy and another 5 studies described the cost of TD.	(preventable referrals, better triage, less time spent per patient), however, added value to management of challenging skin diseases was reported.
Systematic Review	Objective	Search strategy	Inclusion/exclusion criteria	Methodology	Review quality	Conclusion
Wootton 2011 Wootton, R., Bahaadinbeigy, K., Hailey, D., 2011. Estimating travel reduction associated with the use of telemedicine by patients and healthcare professionals: proposal for quantitative synthesis in a	To summarise the information about the proportion of avoidable travel possible through use of different telemedicine applications in different contexts. *Only preliminary results were reported in this article.	Computerized literature searches will be performed using MEDLINE, HealthSTAR, EMBASE, CINAHL and the Cochrane Database of Systematic Reviews, with no date restrictions.	Inclusion criteria: (1) publications that consider travel or travel-related issues for patients, carers or health professionals, and include appropriate details on the data, methods of analysis and outcomes applicable to avoidance of travel. The proportion of avoided travel will be reported directly, or be easily calculable using the information in the paper; (2) publications reporting studies in which at least 15 patients were managed using telemedicine;	Preliminary characteristics of included studies summarised (teledermatology). Results for individual studies summarised Regression analysis was performed to	Poor quality Search strategy defined Clear study selection and data extraction process Quality assessment of included studies performed Applicability concern: -Preliminary	Use of store and forward teledermatology was associated with avoided travel for a mean of 43% of the patients. The improvement in the proportion of patients who avoided travel (67.3%) when real-time telemedicine was employed.

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systematic review. BMC Health Services Research 11, 185.			(3) publications that contain an electronic abstract; (4) publications in the English language. Exclusion criteria: (1) any paper not reporting the sample size or methodology for calculating the percentage of avoided travel; (2) articles where only anecdotal information on travel-related issues is given, without credible data and analysis; (3) single case studies and series with fewer than 15 individuals; (4) duplicate publications.	estimate the coefficient of different traveling circumstances.	results reported -Meta-analysis not performed	
Ndegwa 2010 Ndegwa S, Prichett-Pejic W, McGill S. Murphy G, Prichett-Pejic W, Severn M. Teledermatology Services: Rapid Review of Diagnostic, Clinical Management, and Economic Outcomes [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2010 (Technology report; no. 135). [cited 2010-10-12]. Available from: http://www.cadth.ca/media/pdf/H0502_Teledermatology_Re	To assess -the diagnostic accuracy and reliability of teledermatology consultations compared with current practice in remote or rural areas -the benefits of teledermatology consultations with regard to patient outcomes, wait times, avoidance of unnecessary clinic visits, patient-incurred costs, and patient satisfactions -the economic impacts of teledermatology consultation to the health care system	Electronic literature search was performed through the Ovid interface including the following databases: MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, Embase, Pubmed and The Cochrane Library. The search was restricted to English language clinical articles published between Jan 2005 and Apr 2010.	Inclusion criteria: Population/Adult patients living in remote or rural areas and needing consultation with dermatologists for medical diagnosis and treatment initiation. Intervention/Teledermatology technologies used for dermatologist consultation with patients or general practitioner. Comparator/Face-to-face consultations or usual care. Outcomes/Patient (morbidity, mortality, quality of life), efficiency (wait times, avoidance of unnecessary dermatologist visits), diagnostic accuracy, diagnostic reliability, patient satisfaction with care, provider satisfaction with teledermatology system, costs, cost-effectiveness. Study design/Systematic reviews, systematic review-based meta-	Two reviewers independently screened titles and abstracts of all reports identified by searches and discrepancies were discussed. Study characteristics summarised. Results for individual studies summarised Meta-analysis was not performed due to the significant	Good quality Search strategy fully defined Clear study selection and data extraction process No quality assessment of individual studies Not meta-analysis Applicability concerns: The comparator of this study was face-to-face consultation.	-The evidence shows that teledermatology consultations — whether using store-and-forward, live interactive, or hybrid techniques — result in highly reliable diagnoses and management plans that compare favourably with those of conventional clinic-based care. -The evidence that store-and-forward teledermatology or teledermoscopy can be used to accurately predict disease compared to gold standard tests is conflicting. -Teleconsultations were statistically significantly less accurate compared with clinic-based care in studies that exclusively used histopathology results as the reference diagnostic standard -Economic evaluations found store-and-forward teledermatology to be cost-saving from a societal perspective for the management of patients with skin cancer - It is unclear whether the implementation of teledermatology services using existing technologies

port_e.pdf		Attempt has also been made to retrieve grey literature.	analyses, randomized controlled trials (RCTs), non-randomized comparative studies, observational studies, economic studies Exclusion criteria: Exploratory, feasibility, or pilot studies; assessing chronic management outcomes including wound care (for example, leg ulcers, diabetic foot), and home monitoring of dermatologic conditions; retrospective observational studies; non-comparative; assessing technical aspects of teledermatology	heterogeneity across studies		would be cost-effective based on the specific geographic requirements in rural Canadian settings.
Systematic Review	Objective	Search strategy	Inclusion/exclusion criteria	Methodology	Review quality	Conclusion
Warshaw 2011 Warshaw, E.M., Hillman, Y.J., Greer, N.L., Hagel, E.M., MacDonald, R., Rutks, I.R., Wilt, T.J., 2011. Teledermatology for diagnosis and management of skin conditions: a systematic review. Journal of the American Academy of Dermatology 64, 759-772.	To address the (1) diagnostic accuracy/concordance of teledermatology; (2) management accuracy/concordance of teledermatology; (3) clinical outcomes of teledermatology; and (4) costsof teledermatology.	OVID MEDLINE and PubMed were searched for clinical trials, systematic reviews, cost studies, and implementation papers from 1990 to June 2009 using standard search terms. The search to articles involving human subjects. Search terms included: ‘‘remote consult/consultation,’’ ‘‘electronic mail,’’ ‘‘telecommunications,’’ ‘‘telemedicine,’’ ‘‘telepathology,’’ ‘‘dermatology,’’	Inclusion criteria: (1) controlled trial (questions 1 and 2); and (2) SAF or Video-conferencing teledermatology. Exclusion criteria: 1. Teledermatology involving mobile telephones. 2. Nonteledermatology settings (eg, imaging analyses, telemedicine studies other than teledermatology, videomicroscopy studies, basic science, imaging techniques). 3. Dermatopathology studies. 4. Reviews, teledermatology program descriptions, and historical summaries of teledermatology (unless relevant to questions 3 or 4). 5. Studies of computer-aided diagnoses only (eg, computerized pattern recognition for pigmented lesions). 6. Survey studies addressing outcomes other than those defined in	Two reviewers independently screened titles and abstracts of all reports identified by searches and discrepancies were discussed. Study characteristics summarised. Results for individual studies summarised Weighted mean difference for diagnosis accuracy studies were presented.	Good quality Search strategy fully defined Clear study selection and data extraction process Quality assessment of individual studies was conducted using QUADAS Meta-analysis was performed for diagnostic accuracy studies Applicability concerns: The comparator of this study was face-to-face consultation.	Diagnostic accuracy Statistical pooling of the 6 SAF studies reporting aggregated diagnostic accuracy rates found that the weighted mean absolute difference was 19% better for clinic dermatology than teledermatology. Teledermatology accuracy rates improved up to 15% (absolute difference) with teledermatoscopy. Diagnostic concordance The weighted mean aggregated diagnostic concordance rates for SAF teledermatology were similar for lesion studies (64%) and general studies (65%); The rate for VC (87%) was higher, but this was based on significantly fewer patients (approximately 300 vs >1000). The weighted mean primary diagnostic concordance for SAF teledermatology was also similar for lesion studies (62%) and general studies (67%); the rate for

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		and ‘‘teledermatology.’’ Hand searched references of retrieved articles was also performed and additional articles and inputs were sought via contacting our TEP members.	questions 1 to 4. 7. Teledermatology as an educational tool for primary care physicians or residents. 8. Technology assessment only. 9. Remote monitoring of known diagnoses (eg, leg ulcers, postoperative wounds). 10. Teledermatology involving patient-generated photographs, history, or both (without a referring provider).			VC studies was higher (71%) but based on fewer patients. In summary, diagnostic concordance of SAF is good and may be better for VC, possibly because of the ability to obtain additional history in the VC setting. Management concordance Concordance rates for management were moderate to very good for SA, with kappa ranging from 0.69 to 0.82 depending on different studies and sensitivity/specificity between 0.69/0.82 (refer or not refer) to 1.0/1.0 (biopsy or no biopsy) Clinical outcomes Studies suggested that clinical course was more favourable after teledermatology, for example, after 6 months of teledermatology consultation, a significantly higher percentage of teledermatology patients reported that their condition had revolved (63% vs 23%. P=0.03) Time to treatment Time from general practitioner consult to dermatology clinic (or opinion) was significantly shorter for teledermatology patients compared with clinic dermatology patients, with the difference ranging from 44 to 76.3 days (all p<0.0001) Clinical dermatology visits avoided Two studies reported the percentage of patients who did not require a dermatology clinicvisit (‘‘preventable’’ visits) after teledermatology compared with clinic dermatology patients. The differences between groups were 20.7% (39% teledermatology vs 18.3% clinic dermatology) and 28% (66% teledermatology vs 38% clinic dermatology).

Included RCTTable 75: Flow of participants in the included RCT

Trial	Number recruited	Excluded (missing data, consent withdrawal etc.)	Lost to follow up (e.g. transferred to another hospital)	Analysed
Bowns, 2006	A total of 500 patients per group needed to be recruited based on a standard outpatient treatment plan concordance of 90% with an independent specialist, using a one-sided significance level of 0.05 and allowing a loss to follow-up of 10% of patients. Research IDs were randomised prior to recruiting. Teledermatology N=111; clinical dermatology N=98	Teledermatology out of N=111 Withdrew before data collection began (n = 4) Formally withdrew later (n = 3) Failed to attend second opinion (n = 11) Clinical dermatology out of N=98 Withdrew before data collection began (n = 3) Formally withdrew later (n = 8) Failed to attend second opinion (n = 3)	Teledermatology Lost to follow-up (n = 1) Clinical dermatology Lost to follow-up (n = 10)	Teledermatology N=92 Clinical dermatology N=73 Of these, 92/111 (83%) of the intervention group and 73/98 (75%) of the control group had sufficient data for the analysis of the main study outcomes

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Table 76: baseline characteristics of the participants of the included RCT

Study	Age (mean, SD)	Gender N, % male	Ethnicity/ Skin type	No. of rural residency (%)	Skin cancer history (%)	Other dermatological history (%)	Duration of current skin disease (acute, subacute, chronic)
Bowns, 2006 TD N=92 CD N=73	43.6 (17.8) 49.7 (19.8)	34 (37) 28 (38)	N/R	N/R	N/R	Acne vulgaris 7 Eczema/dermatitis 11 Malignant lesions 3 Melanocytic naevi 5 1 Other benign lesions 8 Hair/nail disorders 3 Psoriasis 8 Infections 4 Urticaria 5 Venous ulcer/eczema 2 Other 11 No diagnosis given 25 Acne vulgaris 4 Eczema/dermatitis 6 Malignant lesions 9 Melanocytic naevi 10 Other benign lesions 12 Hair/nail disorders 2 Psoriasis 3 Infections 3 Urticaria 3 Venous ulcer/eczema 1 Other 16 No diagnosis given 4	N/R

Table 77: Included RCT

Author, year, country	Study design, objective	Intervention		Comparator	Reference standard	Technology	Photographer	Population	Measure of clinical outcome	Outcomes reported	Histopathology outcomes	Safety outcomes	Results (management)	Conclusions from the study
Bowns I R, Collins K, Walters S J, McDonagh A J G. Telemedicine in dermatology: a randomised controlled trial. Health Technology Assessment 2006; 10(43): 1-58 United Kingdom	A prospective parallel group randomised controlled trial for assessing equivalence of store-and-forward (SF) teledermatology to face-to-face clinical consultation at eight general practices and a hospital in UK. The aim of this trial is to compare the clinical equivalence (% agreement), in the clinical management decision (diagnosis and treatment	Patients in the Store-and-forward (SF) intervention group were referred to the teledermatologist and managed using one or more digital still images and a structured, electronic referral and reply.		The control group was managed by conventional face-to-face hospital outpatient consultation.	Patients from either group were seen face-to-face by another clinical dermatologist for a second opinion. The reference standard: the definitive diagnosis (either the final clinical or histological diagnosis, where undertaken)	The Nikon CoolPix 900 digital camera, to give the highest quality close-up pictures of skin when used by a GP with limited training. A standard Pentium II personal computer (PC) used in general practice, with an improved graphics card and the unusual 17-inch monitor running at super VGA level. Images were transferred directly from the camera's memory card using a proprietary card reader	GPs at their practices	Adults (aged 16 years and over) requiring a new (not seen by a hospital dermatologist within the past year) consultant opinion. The patients suspected of cancerous skin conditions were included in the non-RCT study	diagnostic concordance	In the intervention group, diagnostic agreement was achieved in 55% (51/92) of cases vs 78% (57/73) of cases in the control group where the diagnosis was agreed between the two consultants. Difference -23% (95% CI: -36% to -8%; p = 0.002)	Not reported/not applicable for non-cancerous conditions	In the intervention group N=53/92 or 57.6% were found not to be suitable for management by TD and referred to CD. Naturally, no patient was transferred in the control group. A high proportion of TD group 33 (36%) could not be reliably diagnosed and needed a	The number of days between referral and diagnostic opinion was 13 (SD=11.5) in TD and 67 (SD=27.6) in the control group The study's primary measure of clinical efficacy is the adequacy of the initial treatment plan. The adequacy of this plan was assessed by an independent dermatologist, blinded to the nature of the original consultation group. In the intervention group, management agreement	analysis of the data available SF TD failed to achieve diagnostic and management equivalence with face-to-face clinical dermatology. We believe that under-recruitment, selective loss of patients and the delay in obtaining a valid second opinion in the TD group mean that no valid conclusions can be drawn regarding the clinical performance on SF TD.

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	plan) between the consultant who had managed the case and an independent blinded consultant who gave a second conventional face-to-face consultation in setting.					(CardPort Swift) and viewed using Piccolo software at the dermatology department on two similar PCs, with 19-inch monitors					clinical presentation.	was achieved in 55% (51/92) of cases vs 84% (61/73) of cases in the control group. Difference -28% (95% CI: -40% to -14%; p = 0.0001) Excluding 53 patients from TD group who were not suited for TD management agreement was achieved in 67% (26/39).	

Table 78: Inclusion/exclusion criteria in observational cohort studies

Study	Inclusion criteria	Exclusion criteria
Store-and-Forward teledermatology with diagnosis accuracy based on histological analysis as an outcome		
Barnard et al. Evaluation of an asynchronous teleconsultation system for diagnosis of skin cancer and other skin diseases. Telemed J E Health 2000;6:379-84.	Not reported	Not reported
Braun, et al. Teledermatoscopy in Switzerland: a preliminary evaluation. J Am Acad Dermatol 2000;42:770-5.	Skin lesions that had already been scheduled for routine excision because of suspicion of malignancy or patients' demand	Not reported
Bowns et al. Telemedicine in dermatology: a randomised controlled trial. Health Technology Assessment 2006; 10(43): 1-58	Patients comprised new (referred with a new problem or not seen by a hospital dermatologist in the last 12 months), adult (aged 16 years and over) patients for whom the GP felt there would normally be a need for a conventional outpatient consultation with an NHS consultant dermatologist	*two main reasons for exclusion: first, the nature of the dermatological problem (these will be rare and mainly related to the anatomical site, e.g. genital lesions); *second, reasons unrelated to the skin problem, such as an inability to understand the nature of the study for reasons of language barrier, mental illness or handicap, wish to consult privately, refusal of consent and so on. *Although that was not intended by the original study design, the patients suspected of cancerous skin conditions were included in the parallel observational study
Coras et al. Teledermatoscopy in daily routine - results of the first 100 cases. Curr Probl Dermatol 2003;32:207-12.	100 pigmented lesions available for assessment in 3 private dermatological offices.	Not reported
Ferrandiz, et al 2007 Teledermatology-based presurgical management for non-melanoma skin cancer: a pilot study. Dermatol Surg 2007;33:1092–1098	Patients were {retrospectively?] included in the TD-based surgical referral system had to present with a clear-cut diagnosis of nonmelanoma skin cancer, or a fast-growth vascular tumor (i.e., pyogenic granuloma), suitable for surgery under local anesthesia after the evaluation of the teleconsultation.	Patients with lesions expected to need a major reconstruction (i.e., large grafts or flaps) after the telemedical evaluation represented formal contraindications for this procedure; Patients showing lesions highly suspicious for malignant melanoma were also excluded

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Kroemer et al. Mobile teledermatology for skin tumour screening: diagnostic accuracy of clinical and dermoscopic image tele-evaluation using cellular phones. British Association of Dermatologists 2011 164, pp973–979	Men or women with benign and ⁄or malignant skin tumours of melanocytic or nonmelanocytic origin referred or self-referred to the Department of Dermatology at medical University	Not reported
Krupinski et al. Diagnostic accuracy and image quality using a digital camera for teledermatology. Telemed J 1999;5:257-63.	Patients referred for specialty consultation by either primary care providers or general dermatologists	Not reported
Oakley et al. Diagnostic value of written referral and/or images for skin lesions. J Telemed Telecare 2006;12:151-8.	Patients who were referred to the departments of dermatology and plastic surgery for diagnosis and management of one or more skin lesions were invited to take part.	Known inflammatory dermatoses, infections and lesions that had resolved were excluded from the study, as were lesions in which all images were considered of inadequate quality.
Piccolo et al. Face-to-face diagnosis vs telediagnosis ofpigmented skin tumors: a teledermoscopic study. Arch Dermatol 1999;135:1467-71.	Patients with pigmented skin lesions, which were subsequently excised.	Unclear
Piccolo et al. Teledermoscopy- results of a multicenter study on 43 pigmented skin lesions. J Telemed Telecare 2000;6:132-7.	Patients from the region around Graz were studied over three months. All lesions included in the study were selected because of their diagnostic difficulty and were subsequently excised for a histopathological evaluation.	Unclear
Rosendahl 2011	Consecutively selected biopsied pigmented skin lesions	N/A
Şenel 2013	Patients who presented to the dermatology outpatient clinic at the Ankara hospital and had a non-melanocytic skin tumour on clinical examination.	Unclear
Warshaw et al. Accuracy of teledermatology for pigmented neoplasms. J Am Acad Dermatol 2009a;61:753-65.	High-risk patients included patients already enrolled in the Minneapolis Veterans Affairs Medical Center dermatology clinic who required (or requested) removal of one or more skin neoplasms; low risk patients were	(1) individuals requesting or referred for skin tag removal only; (2) individuals presenting for excision or treatment of a neoplasm previously biopsied; (3) individuals requiring biopsy for papulosquamous or eczematous conditions (non-neoplastic); and (4)

	participants who were referred to dermatology by non-dermatology healthcare providers for evaluation of a skin neoplasm via a consult to dermatology	inability to comprehend and give informed consent.
Warshaw et al. Accuracy of teledermatology for nonpigmented neoplasms. J Am Acad Dermatol 2009b;60:579-88.	High-risk patients included patients already enrolled in the Minneapolis Veterans Affairs Medical Center dermatology clinic who required (or requested) removal of one or more skin neoplasms; low risk patients were participants who were referred to dermatology by non-dermatology healthcare providers for evaluation of a skin neoplasm via a consult to dermatology	(1) individuals requesting or referred for skin tag removal only; (2) individuals presenting for excision or treatment of a neoplasm previously biopsied; (3) individuals requiring biopsy for papulosquamous or eczematous conditions (non-neoplastic); and (4) inability to comprehend and give informed consent.
Whited et al. Reliability and accuracy of dermatologists' clinic based and digital image consultations. J Am Acad Dermatol 1999;41:693-702.	Patients with skin lesions being referred for a diagnostic question were included.	Patients with previously diagnosed skin conditions referred for management.
Whited et al. 1998	Subjects were a convenience sample of patients at the Veterans Affairs Medical Center who were referred to The dermatology clinic for a suspected skin cancer.	Unclear
Store-and-Forward teledermatology with diagnostic concordance as an outcome		
Barbieri, 2014 The reliability of teledermatology to triage inpatient dermatology consultation. JAMA Dermatol. 2014;150(4):419-424.	Participants were recruited from the population of inpatient dermatologic consultations requested at the Hospital of the University of Pennsylvania between September 1, 2012, and April 31, 2013. Participants were eligible for the study if they were older than 18 years and capable of providing written informed consent.	Not reported
Du Moulin, et al. The reliability of diagnosis using store-and-forward teledermatology. J Telemed Telecare 2003;9:249-52.	Patients presenting a dermatological problem to their GP could be included in the study. All skin conditions were eligible	Patients for whom the referral was clearly indicated were excluded

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	for inclusion.	
Ebner, et al Mobile teledermatology: a feasibility study of 58 subjects using mobile phones. Journal of Telemedicine and Telecare 2008Volume 14 Number 1, p2-7	Patients attending the outpatient clinic for an urgent-care dermatology visit: adults with visible skin lesions; willing to participate; and able to provide informed consent.	Children, subjects with skin lesions that could not be visibly documented (e.g. phlebothrombosis) or subjects who were not willing to provide informed consent
Edison, 2008 Diagnosis, diagnostic confidence, and management concordance in live-interactive and store-and-forward teledermatology compared to in-person examination Telemedicine Journal & E-Health, 2008, 14 (9) 889-95	Head-to-head trial Enrolled subjected were a convenience sample of new patients who self-scheduled and subsequently presented to the dermatology clinic on a "study" day. Every patient was invited to participate	Not reported
Heffner VA, Lyon VB, Brousseau DC, Holland KE, Yen K. Store-and-forward teledermatology versus in-person visits: a comparison in pediatric teledermatology clinic. J Am Acad Dermatol 2009;60:956-61.	Consecutive patients enrolled to the pediatric dermatology clinic with a rash or rash descriptors (bumps, spots, patches)	Not reported
High, et al Assessment of the accuracy of low-cost store-and-forward teledermatology consultation. J Am Acad Dermatol 2000;42: 776-83.	Patients presented for FTF consultation at the Dermatology department. No specific inclusion criteria	No specific exclusion criteria
Kvedar et al. The substitution of digital images for dermatologic physical examination. Arch Dermatol 1997;133:161-7.	Adult patients presenting with dermatologic symptoms in a university-based practice who consented to have their skin conditions documented with a still digital camera according to a standardized protocol.	Patients with a presenting complaint of acne or warts were excluded because these conditions pose no diagnostic challenge and would favourably bias the study.
Tucker 2005	New patients agreed to have a digital photograph taken of their lesions or a representative area of their eruption.	Unclear
Mahendran 2004	Patients with suspicious skin lesions being referred by GP to a dermatology department.	Unclear
Oztas 2006	Randomly selected outpatients from the department of dermatology	Unclear
Rashid 2003	Selective patients from the outpatient department of dermatology	Unclear

Zelickson 1997	All nursing home resident consultations requests from the Walker Methodist Health Care Centre	Unclear
Videoconferencing with diagnostic accuracy as an outcome		
Lowitt et al. Teledermatology and in-person examinations: a comparison of patient and physician perceptions and diagnostic agreement. Arch Dermatol 1998;134:471-6.	Consecutive dermatology patients at the Veteran Affairs Medical Centre	Patients transported by stretcher and those who refused to participate
Videoconferencing with diagnostic concordance as an outcome		
Edison, 2008 Diagnosis, diagnostic confidence, and management concordance in live-interactive and store-and-forward teledermatology compared to in-person examination Telemedicine Journal & E-Health, 2008, 14 (9) 889-95	New self-scheduled patients presented at the Dermatology Clinic.	N/R
Gilmour et al Comparison of teleconsultations and face-to-face consultations: Preliminary results of a United Kingdom multicentre teledermatology study The British Journal Of Dermatology 1998 Jul; Vol. 139 (1), pp. 81-7;	N/R	N/R
Lesher JL Jr, Davis LS, Gourdin FW, English D, Thompson WO. Telemedicine evaluation of cutaneous diseases: a blinded comparative study. J Am Acad Dermatol 1998;38:27-31.	Patients at least 18 years of age with a skin problem were recruited randomly from among patients enrolled in the health system	N/R
Loane et al. Diagnostic accuracy and clinical management by real real time teledermatology: results from the Northern Ireland arms of the UK multicentre teledermatology trial. J Telemed Telecare 1998;4:95-100.	Patients with dermatological conditions requiring a specialist referral	N/R
Lowitt et al. Teledermatology and in-person examinations: a comparison of patient and physician perceptions and diagnostic agreement. Arch Dermatol 1998;134:471-6.	Consecutive dermatology patients at the Veteran Affairs Medical Centre	Patients transported by stretcher and those who refused to participate
Phillips 1997	Patients referred to the dermatology clinic	N/R

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	and willing to sign a consent form	
Phillips 1998	Convenience sample. Patients were enrolled in the screening through flyers distributed at the hospital and physician offices in the community. The screenings were held on four days in the winter and spring of 1996.	N/R
Nordal 2001	Consecutive not previously diagnosed patients from municipality of of Sør-Varanger referred to teledermatology consultations at the hospital in Kirkenesand and giving consent.	Patients needing surgical treatment for tumours, most of the patients with nevi and emergency cases were excluded

Table 79: Flow of participants

Trial	Number recruited	Excluded (missing data, consent withdrawal etc.)	Lost to follow up (e.g. transferred to another hospital)	Analysed

Store-and-Forward teledermatology				
Barnard, 2000	N of patients is not reported; 50 lesions were selected	N/A	N/A	50 lesions
Braun, 2000	N of patients is not reported; 58 lesions were collected.	Three lesions were excluded because they were not eventually removed or because the histopathologic report was not accessible.		51 patients and 55 lesions
Coras, 2003	100 pigmented lesions	N/R	55 lesions	45 excised lesions
Ferrandiz, 2007	N=134	N/R	N/R	130 patients
Kroemer, 2011	88 patients 113 skin tumours	9 lesions from 8 patients were excluded due to the poor image quality	N/A	80 patients with 104 skin tumours
Krupinski, 1999	N=308 N=104 histology diagnoses	N/R	N/R	N=308 N=104 histology diagnoses
Şenel 2013	150	N/A	N/A	82[1]
Warshaw 2009 a	2152	878	N/A	542
Warshaw 2009 b	2152	878	N/A	732
Oakley 2006	N/A	N/A	N/A	73[3]
Piccolo 2000	N/A	N/A	N/A	40
Whited 1999	N/A	N/A	N/A	129[4]
Piccolo 1999	N/A	N/A	N/A	66
Rosendahl 2011	463 lesions	3/463 (0.7%)	N/A	463
Whited 1998	N/A	N/A	N/A	12[5]
Barbieri, 2014	N=50	0	0	N=50
Du Moulin, 2003	N=117	N=11	0	N=106

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Ebner, 2008	N=83	N=13 showed no clearly visible skin lesions; N=4 children; N=7 declined to participate N=1 could not provide a consent	0	N=58
Edison, 2008	N=115 N=5 declined to participate	0	0	N=110
Heffner, 2009	N= 137 One family and one patient was removed, having been seen in-person by the dermatologist before	N=1 refused to participate; N=1 contamination of the results	0	N=135
High, 2000	N=92 with 106 skin conditions	0	0	N=92 with 106 skin conditions
Kvedar, 1997	N=116 with 128 skin conditions	Seven image sets were excluded because of clerical errors in data collection or in image acquisition.	0	121 images from non- reported number of patients
Tucker 2005	N/A	N/A	N/A	75
Mahendran 2004	N/A	N/A	N/A	163
Oztas 2006	N/A	N/A	N/A	125
Rashid 2003	N/A	N/A	N/A	33
Zelickson 1997	N/A	N/A	N/A	29
Videoconferencing				
Gilmour, 1998	N=126; 155 skin conditions	0	0	Diagnosis concordance N=126; 155 skin conditions Management plans N=61

Lesher, 1998	N=60; 68 skin conditions	0	0	N=60; 68 skin conditions
Loane, 1998	N=427	0	0	N=427
Lowitt, 1998	N=139	N=6 first pilot stage patients were excluded; N=9 refused to participate; 29 patients had only FTF examination*	58 conditions were not assessed either by TD or in- person	N=102 patients 130 conditions
Phillips 1997	N=60 patients	0	0	N= 60 patients with 79 evaluable cutaneous problems
Phillips 1998	51 patients	0	0	N=patients not reported 107 lesions
Nordal 2001	121 patients	9 failure to fill the clinic examination form (N=8) or missed diagnosis on the form (N=1)	0	112

N/A=not applicable; N/R not reported

[1]Only 82 patients had the histopathologic results of the skin lesions.

[2]64 cases were selected from 300 eligible cases by dermatology specialist depending on the completeness of the data.

[3] 73 patients had a total of 109 skin lesions.

[4] 129 patients had a total of 168 skin lesions.

[5] 13 skin lesions from 12 patients.

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Table 80: Baseline characteristics of the participants in SAF trials

Study	Age (mean, SD)	Gender N, % male	Ethnicity/ Skin type	No. of rural residency (%)	Skin cancer history (%)	Other dermatological history (%)	Duration of current skin disease (acute, subacute, chronic)
Barnard[a] 2000	N/R	N/R	N/R	N/R	25 tested lesions included 8 cancer cases	N/R	N/R
Braun, 2000	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Coras, 2003	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Ferrandiz, 2007	70.25 (95% CI, 63.11–77.39)	82 (61.2%)	N/R	N/R	Non-melanoma skin cancer (73%)	N/R	N/R
Kroemer, 2011	median age 69 years, range (3–93)	41 (46%)	N/R	N/R	113 skin tumours	N/R	Median duration 52 months
Krupinski, 1999	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Barbieri, 2014	55.2 (16.2)	18 (36%)	N/R	N/R	N/R	N/R	N/R
Du Moulin, 2003	47 years	N/R	N/R	N/R	N/R	N/R	N/R
Ebner, 2008	median age of 41 years (range 18–85 years)	34 (59%)	N/R	N/R	N/R	N/R	N/R
Edison, 2008	Mean=42 (range 7 -92)	34 (31%)	94 (85%) white, 13 (12%) African-American, 2 (2%) Asian, 1 (1%) Hispanic/Latino	N/R	N/R	N/R	N/R
Heffener 2009	6.17 years (range 3 months-	81 (60%)	43%Caucasian , 38% African American; 13%	N/R	N/R	N/R	N/R

paediatric	18 y.o.)		Hispanic, 5% Asian, and 1% other				
High, 2000	39.7 (range of 10 months to 81 years)	48 (52%)	Fitzpatrick classification N=103 skin types I-IV, N= 3 patients classified as type V or VI.	N/R	N/R	N/R	N/R
Kvedar, 1997	40 years (range 18 to 84)	61 (51%)	N/R	N/R	N/R	N/R	N/R

TD=teledermatology; CD=clinical dermatology; N/R not reported

[a]the unit of analysis was a lesion, not a patient

Table 81 Baseline characteristics of the participants in SAF trials (cont.)

Study	Number of subjects	Age (years)	Gender (Female %)	Ethnicity (Caucasian/ white %)	No. of rural residency (%)	Skin cancer history (%)	Other dermatological history (%)	Duration of current skin disease (acute, subacute, chronic)
Şenel 2013	150*	55	49%	N/A	N/A	6%	N/A	Mean duration 1.7± 0.3 years
Warshaw 2009 a	728	71	2.2%	98.9%	N/A	37.9%	11.5%	< 3 month 11.0%
								3-12 month 31.7%
								1-2 year 20.2%
								2-5 year 16.2%
								5-20 year 10.9%
								Other 9.9%
Warshaw 2009 b	542	66	4.2%	97.1%	N/A	33.4%	11.8%	< 3 month 3.5%
								3-12 month 14.2%
								1-2 year 8.5%
								2-5 year 14.2%
								5-20 year 11.1%

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								Other 43.4%
Oakley 2006	73	59	64%	N/A	N/A	N/A	N/A	N/A
Piccolo 2000	40	39.5	48%	N/A	N/A	N/A	N/A	N/A
Rosendahl 2011	389 With 463 lesions	75 (SD=17)	32.6%	N/A	N/A	N/A	N/A	N/A
Whited 1999		61	2.3%	79.8%	N/A	N/A	N/A	<1 month 9.5%
								1-12 month 41.7%
								>12 month 48.8%
Piccolo 1999	66	41.2	51.5%	N/A	N/A	N/A	N/A	N/A
Whited 1998	12	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Tucker 2005	75	3-87	72%	N/A	N/A	N/A	N/A	N/A
Mahendran 2004	163	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Oztas 2006	125	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Rashid 2003	33	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Zelickson 1997	29	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 82: Baseline characteristics of the participants in VC trials

Study	Age (mean, SD)	Gender N, % male	Ethnicity/ Skin type	No. of rural residency (%)	Skin cancer history (%)	Other dermatological history (%)	Duration of current skin disease (acute, subacute, chronic)
Gilmour, 1998	Range (3 month – 83 years)	64 (51%)	N/R	N/R	N/R	N/R	N/R
Lesher, 1998	N/R	N/R	N/R	N/R	N/R	N/R	N/R
Loane, 1998	43 years (SD 24) Range (5 months - 89 years)	92 (45%)	N/R	N/R	N/R	N/R	N/R
Lowitt, 1997	Median 65 (range 23-85)	124 (95%)	White 79 (60%) 52 (40%)	98 (75%) within 45 min driving distance 33 (25%) outside 45 min driving distance	N/R	N/R	N/R 28 (21%) initial visit 103 (79%) follow-up
Phillips 1997	The average age was 37 years (range, 1 to 68 years).	24 (40%)	Black 15 (25%), white 44 (73%) "other."=1 (2%)	100%	N/R	N/R	N/R
Phillips 1998	The average age was 46.7 years.	N=8 (16%)	White 38 (75%), non-white 3 (6%) 10 (20%) N/R	N/R	N/R	N/R	N/R
Nordal 2001	mean age 40	57/116= 49%	N/R	N/R	N/R	N/R	N/R

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	years; range was 17–82 years						

Table 83: Characteristics of the included SAF studies

Author, year, country	Study design, objective	Intervention	Comparator	Reference standard	Technology (camera, IT system, quality of pictures, pixels)	Who made the images	Population (skin conditions)	Outcomes reported	Accuracy based on histopathology outcomes	Safety outcomes (safety, repeated requests (%), refusals, misdiagnosis)	Results (management)	Conclusion as reported in the paper
Store-and-Forward teledermatology with diagnosis accuracy based on histological analysis as an outcome												
Barnard, 2000 Evaluation of an asynchronous teleconsultation system for diagnosis of skin cancer and other skin diseases. Telemed J E Health 2000;6:379-84. USA	A study designed to assess the ability of dermatologists to evaluate digital images of skin cancers as well as other skin diseases using a store-and-forward application.	SAF TD (the same images assessed by 5 TDs)	In person FTF consultation (by one of three dermatologists selecting the case)	Results of biopsy, culture, or wet mount results	Nikon-FujixDS505 digital camera with a 105-mm lens. A CD-ROM contained all 50 clinical cases. Each case was presented through a self-executing software application. It contained a number of digital images along with relevant text; the recipient opened and viewed the application on their personal desktop computers (Pentium 133MHz or	N/R	8 cancer cases The noncancer cases include a variety of viral, fungal or bacterial skin infections, inflammatory dermatoses, reactive dermatoses, benign tumors, systemic diseases with skin manifestations, vascular reactions, and one disorder of keratinization	Concordance was determined by comparing primary and differential diagnoses made by the teleconsultants on all 50 cases with those made by the dermatologists who originally examined the patients in person. For eight skin cancers, the diagnostic accuracy for the in-person dermatologist was 88% versus 90% (range, 75–100%) for the teleconsultants. The concordance between the in-person and teleconsultant diagnoses were in agreement 77% of the time (90% if differential diagnoses were	For the 25 cases (including the 8 skin cancers) confirmed by either biopsy (20), culture (1), or wet mount (4), the in-person accuracy was 84% compared to 73% (range, 65–88%) for the teleconsultants.	Not a part of the study	Not a part of the study	The results show that this application allows levels of accuracy and concordance equivalent to those obtained with live interactive teleconsultation systems

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					greater) with a 15-inch or larger colour VGA monitors for evaluating the images. This permitted full screen displays of 24-bit colour with 480 X 640-pixel resolution.			included).				
Braun et al. Teledermatoscopy in Switzerland: a preliminary evaluation. J Am Acad Dermatol 2000;42:770-5. Switzerland	To evaluate the feasibility and the benefit of teledermatoscopy in diagnosis of pigmented skin lesions as a form of telemedicine under routine conditions in private practice.	Teledermatoscopy performed by the hospital-based physician experienced in teledermatoscopy.	FTF in person consultation, including DELM	Histological diagnosis	Epiluminescence microscopy (ELM) is a noninvasive technique for the diagnosis of pigmented skin lesions (PSLs). commercially available as "dermanet" system (Arpage AG, Zürich, Switzerland) Digital epiluminescence microscopy (DELM) uses digital or digitized two-dimensional pictures of PSLs. The system is based on a commercially	6 private practice dermatologists trained in DELM	Pigmented skin lesions	The diagnostic accuracy of the teledermatoscopic approach for benign melanocytic lesions was superior to the conventional diagnosis (68% vs 53%). For the malignant melanocytic lesions it was 100% compared with 78% for the conventional approach The diagnostic accuracy for suspect melanocytic skin lesions for both approaches was 67%. Cohen's κ. For the agreement of FTF diagnosis, we obtained a K value of 0.565	Teledermatoscopy diagnosis accuracy was 75% (41/55) vs 64% of FTF (35/55)	Picture quality was evaluated to be good or very good in 90% of the DELM pictures and in 95% of the macroscopic pictures. 9 benign lesions were misdiagnosed by a teledermatoscopy assessment vs 13 in FTF assessment; no malignant lesions were misdiagnosed by a teledermatoscopy	Not a part of the study Clinical history was not made available to teledermatologists	We have identified the feasibility of a consultation by teledermatoscopy but consider our study as exploratory for any other extrapolation, because it lacks many appropriate controls in this respect. Because clinical information such as age, sex, risk factors for melanoma, and phototype was only available in 15% of all cases, we are unable to comment on the impact of this on our study. Experience in the field

					available PC (166 MHz MMX Intel Pentium processor, 32 MB RAM, 4 GB hard disk) that was equipped with a standard PCI graphic card (4 MB ram, 24-bit color depth at 600 × 800 resolution). A Mitsubishi CCD camera was added to the system. It has a physical resolution of 768 × 567 pixels and allows macro pictures as well as DELM examination.			compared with 0.742 for teledermotoscopy diagnosis.				of ELM seems to have more impact on the diagnosis than clinical information, particularly for nonpigmented lesions
Coras B et al. Teledermatoscopy in daily routineeresults of the first 100 cases. Curr Probl Dermatol 2003;32:207-12. Germany and Switzerland	To assess the possibility [diagnostic accuracy] of teledermatoscopy with computerized dermatoscopy system with video camera	SAF (dermatoscopy images) sent to the Department of Dermatology of the University by one of 3 experiences dermatologists in private practice	FTF with dermatoscopy diagnosis by private practice dermatologists	Histology diagnosis	Hand-held 3-CCD camera (Dermogenius ® ultra) with resolution of more than 700 TV lines and 512x512 pixels. The pictures are stored using Dermogenius Software on the IBM-	Dermatologists made the digital (clinical) pictures and dermoscopic images	45 of 100 pigmented lesions that were excised the diagnosis according to the protocol was benigh, atypical melanocytic nevi; malignant melanocytic skin lesion.	teledermatoscopy Primary: 89% (40/45) For malignant vs benign: Sensitivity: 0.86 Specificity: 0.92 Face-to-face plus dermatoscopy Primary: 91% (41/45)	In 45 lesions excision was performed See primary outcome Teledermatoscopy vs histology 5 incorrect diagnoses Face-to-face	10% of digital images were rejected	Not a part of the study	Results demonstrated similar sensitivity and specific for teledermatoscopy and FTF consulations. The procedure of teledermatoscopy is simple and may be in high demand in the future

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					compartible PC.			For malignant vs benign: Sensitivity: 0.86 Specificity: 0.96	plus dermatoscopy vs histology 4 incorrect diagnoses			
Ferrandiz, et al 2007 Teledermatology-based presurgical management for non-melanoma skin cancer: a pilot study Dermatol Surg 2007;33:1092–1098 Spain	Teledermatology (TD) allows a clear-cut diagnosis of skin cancer and even an accurate planning of the surgical treatment. To date, however, no previous experiences on TD as a preoperative management facility have been published. This study describes the preliminary results of a SFTD system aimed at the presurgical management of nonmelanoma skin cancer patients	Primary care provider cooperating with a hospital-based TD via SAF in preparation of non-melanoma cancer skin patients for surgery. Blood and coagulation testing are performed at the PCC and patients directed to the surgery bypassing outpatient dermatological FTF visit. The GP also managed the withdrawal of the drug in patients taking blood thinners.	A random sample of N=92 patients managed through the conventional surgical referral system (FTF) for the outcome "difference in waiting time"	Histological diagnosis	Two digital pictures are taken (Coolpix 4300, 1600x1200 pixels, Nikon, Tokyo, Japan) at the Primary care centre: a panoramic view of the anatomic area where the lesion arises, and, a macro picture to describe all the morphologic features of the lesion; inserted in a Word document (Microsoft Word) sent via the Andalusian Public Health System Intranet to the e-mail account of the skin cancer clinic.	A GP	Non-melanoma skin cancer (73% ; N=134) and or a fast-growth vascular tumor (i.e., pyogenic granuloma) suitable for surgery Diagnoses: basal cell carcinoma, squamous cell carcinoma, keratoacanthoma, hypertrophic actinic keratosis, fast-growth vascular lesion (pyogenic granuloma), and other tumors	The effectiveness of SFTD as a diagnostic tool was measured in terms of accuracy. For the accuracy evaluation, the agreement rate between the clinical diagnosis yielded through teleconsultation and the final histopathologic diagnosis	Primary diagnosis 85% (110/130) (Warshaw, 2011) k = 0.86 (95% CI 0.83-0.89)	Patients managed through TD were operated on within a mean interval of 26.10 days (95% CI, 24.51–27.70 days) since the first visit to the GP, with only one visit to the hospital. The mean waiting interval of patients operated on through the conventional referral system was 60.57 days (95% CI, 56.20–64.93 days; n = 92; po.001)	Agreement rate between the surgical technique planned through teleconsultation and the surgical technique finally performed were measured. k = 0.75 (95% CI 0.71-0.79)	SAF has demonstrated to be effective and accurate as a pre-operative tool for non-melanoma skin cancer. It avoids unnecessary visits to the hospital and shortens waiting intervals.

Kroemer et al. Mobile teledermatology for skin tumour screening: diagnostic accuracy of clinical and dermoscopic image tele-evaluation using cellular phones. British Association of Dermatologists 2011 164, pp973–979 Austria	To assess the diagnostic accuracy of clinical image tele-evaluation and teledermoscopy for mobile skin tumour screening.	SAF: a board-certified dermatologist with clinical expertise in teledermatology and dermoscopy reviewed digital images and dermoscopic images separately with one month interval (two separate outcomes were assessed vs FTF and histology as a mixture of reference standards)	FTF consultation	Histology diagnosis in suspicious lesions (not reported separately)	Up to three clinical (autofocus mode) and dermoscopic (macro mode) images were made using a mobile phone camera (Nokia N73 with a built-in 3.2-megapixel camera; Nokia, Helsinki, Finland). dermoscopic images were taken by applying the camera lens on a pocket dermoscopy device (DermLite II PRO HR; 3Gen LLC, Dana Point, CA, U.S.A.). stored in JPEG format and transferred via virtual private network for teleconsultation.	Images were obtained by the FTF consulting dermatologist	104 lesions (skin tumours) were grouped into four diagnostic categories (benign melanocytic, benign nonmelanocytic, malignant melanocytic and malignant nonmelanocytic skin tumours)	Teledermatology 92% (96/104) Teledermatoscopy 96% (100/104) Digital images and dermatiscopic images were assessed by the same dermatologist Clinical and dermoscopic tele-evaluations demonstrated strong concordance with the gold standard (k=0.84 for each) and similar high sensitivity and specificity for all diagnostic categories. With regard to the detailed diagnoses, clinical image tele-evaluation was superior to teledermoscopy resulting in 16 vs. 22 discordant cases.	78 (69%) lesions were excised and histology diagnoses obtained. The accuracy is not reported separately vs FTF and histology results Together, 78 correct telediagnoses and 26 mismatches were observed using either clinical and ⁄or dermoscopic images for tele-evaluation	9 lesions from 8 patients were excluded due to the poor image quality. 11 (11%) of 104 lesions were misdiagnosed vs combined standard of FTF and histology FTF examination.	Not a part of the design	Clinical image tele-evaluation might be the method of choice for mobile tumour screening
Krupinski et al. Diagnostic accuracy and image quality	to compare the diagnostic concordance of a dermatologic diagnosis	SAF made at a specialised Dermatology Dept after an in person	FTF in person consultation with a	Histology diagnosis when available (n=104)	the patient's skin lesions were photographed with the	All images were made at dermatol	N=308 Malignant or premalignant Benign proliferations	Using FTF as a reference standard (N=308) The three dermatologists had	N=104 Primary: 76% average for	Out of the 104 cases, there were 11 cases (11%) that	Not a part of the study design	Digital photography for store-and-forward teledermatology produces high

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using a digital camera for teledermatology. Telemed J 1999;5:257-63. USA	based on in-person physical exam with a diagnosis based on still photo images acquired using a digital camera and displayed on a computer monitor.	presentation	dermatologist		Canon PowerShot600 digital camera. The images had a spatial resolution of 832 3 608 pixels, with 24-bit colour resolution and were transferred to a Gateway 2000 computer (Gateway; North Sioux City, SD) with a Gateway CrystalScan color monitor (1024 x 768, resolution). The software program PhotoImpact Album version 3.0 was used to file the images.	ogy department. The photos were taken by one medical students trained in the use of the camera	Eczema/dermatitis Pigmented lesions Infections/infestations Papulosquamous disorders Urticarial & allergic Collagen/vascular Miscellaneous	84%, 85%, and 81% correctly matching decisions (average 83%), with 16%, 15%, and 19% mismatches respectively. Some TDs were also CDs (see the same patients in person)	3 TDs FTF vs histology Primary/aggregated: 89% average for 3 CD	received a mismatch diagnosis during the in-person examination compared to the biopsy results. Overall, 83% of the cases were rated as having excellent or good image sharpness, with 4% being rated as poor.		quality images and diagnostic concordance rates that compare favorably with in-person clinical diagnoses.
Şenel 2013 Turkey With dermatoscopic images	Observational, cohort study To investigate if the reliability of diagnosis and management in non-melanocytic skin tumours would be increased by the addition of	Macros images, dermatoscopic image and standard information form.	FTF	Histopathology	Cyber-Shot DSC-W70, SONY (3072*2304 pixels)a lens attachment (Dermlite II Pro HR, 3Gen Inc).	Technician	Outpatients from department of dermatology of a tertiary hospital with non-melanocytic skin tumour.	Diagnostic accuracy (Mean): -Without dermatoscopy 71/82 (86.5%) -With dermatoscopy 78/82 (95.1%) Diagnostic reliability (Kappa, 95%CI) -Without	SCC: N=26 BCC N=2 Vascular tumour N=8 Dermatofibroma N=32 Kaposi sarcoma N=4	Missed diagnosis Without dermatoscopy TD A:4 SCC, 3 KS, 1 BCC TD B: 3 SCC, 1 KS -With	Management concordance κ (95%CI) Without dermatoscopy TD A: 0.67 (0.55-0.80) TD B: 0.70 (0.59-0.82) -With	The results confirm that teledermatology is a reliable technique for the diagnosis and management of non-melanocytic skin tumours and that the addition of dermatoscopic images increases

	dermatoscopic images to SAF teledermatology.							dermatoscopy: TD A: 0.77 (0.69-0.85) TD B:0.75 (0.67-0.83) -with dermatoscopy TD A: 0.85 (0.79-0.91) TD B: 0.86 (0.80-0.93)		dermatoscopy TD A:2 SCC, 1 KS TD B:1 SCC	dermatoscopy TD A: 0.73 (0.62-0.85) TD B: 0.76 (0.66-0.87)	the reliability and the accuracy of teledermatology.
Warshaw 2009a United States N=542 With dermatoscopic images	Observational, cohort study compare conventional, in-person clinical dermatology with store-and-forward teledermatology for pigmented skin neoplasms, using the outcomes of diagnostic accuracy and appropriateness of management	Clinical photographs and the standardized patient and lesion history	FTF	Histopathology	Nikon Coolpix 4500	Unclear	Patients being referred to dermatology by nondermatology health care providers for evaluation of a pigmented skin neoplasms.	Aggregated: SAF=282/542 (52%) FTF=434/542 (80%) -Primary: SAF=271/542 (50%) FTF=320/542 (59%)	Benign keratosis N=125 Dysplastic nevus N=115 Benign nevus N=82 Melanoma N=36 BCC N=66 SCC N=18 Dermatatofibroma N=12	Misdiagnosed melanoma Without dermatoscopy: SAF N=7 FTF N=1 With dermatoscopy (PLD) SAF N=3 FTF N/A With dermatoscopy (CID) SAF N=6 FTF N/A	Management accuracy SAF:383/542 (71%) PLD: 380/542 (70%) CID: 401/542 (74%) FTF:356/542 (66%) PLD: 356/542 (66%) CID: 357/542 (66%)	The diagnostic accuracy of clinic dermatologists evaluating 542 veterans with pigmented skin lesions was superior to teledermatologists and the addition of dermatoscopic images did not significantly increase the diagnostic accuracy of teledermatologists. Despite the superiority of clinic dermatology for diagnostic accuracy, the two methods of care had overall equivalent rates of appropriate management; however, 7 index melanomas (19%) would have been mismanaged via teledermatology.

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Warshaw 2009 United States N=728 Dermatoscopy was used	Observational cohort study To assess the equivalence of conventional, in-person clinical dermatology with SAF teledermatology for the diagnosis of skin neoplasms.	Standardized patient and lesion history and clinical digital photographs, including dermatoscopic images.	FTF	Histopathology	Camera Nikon Coolpix 4500	Research assistant	Patients at high and low risk for developing skin neoplasms from dermatology department requiring removal of one or more skin neoplasms (high risk) and those were referred to dermatology department by non-dermatology professionals (low risk).	Diagnostic accuracy Single and differential diagnoses -Without dermatoscopy SAF 408/728 (56%) FTF 553/728 (76%) -with dermatoscopy SAF =463/716 (65%) FTF=544/716 (76%) Single diagnosis -Without dermatoscopy SAF 313/728 (43%) FTF 408/728 (56%) - with dermatoscopy SAF 335/716 (47%) FTF 402/716 (56%)	BCC N=237 SCC N=148 Premalignant /non-melanocytic N=81	Misdiagnosis of SCC Without dermatoscopy N=1 With dermatoscopy N=0	Management plan appropriateness Without dermatoscopy SAF 574/728 (79%) FTF 608/728 (83%) with dermatoscopy SAF= 570/714 (80%) FTF= 597/714 (84%)	Using macro images, the diagnostic accuracy of teledermatology was inferior to in-person dermatology, but accuracy of management plans was equivalent. The addition of polarized light dermatoscopy yielded significantly better aggregated diagnostic accuracy, but management plan accuracy was not significantly improved. For the important subgroup of malignant lesions, the addition of polarized light dermatoscopy yielded equivalent diagnostic accuracy between teledermatologists and clinic dermatologists.
Oakley 2006 New Zealand	Observational cohort study To evaluate an asynchronous (store-and-forward) telemedicine referral system to see whether text, images or both would enable a dermatologist to make a diagnosis	Medical records, clinical pictures and dermatoscopic images	FTF	Histopathology	Camera Nikon Coolpix 995	Medical student	Patients referred to the department of dermatology and plastic surgery for diagnosis and management of one or more skin	Diagnostic accuracy -Single diagnosis SAF 34/48 (71%, 95%CI 56-83%) FTF 21/29 (73%, 95%CI 53-87%) Diagnostic concordance: SAF vs FTF -single diagnosis 100/189 (53%)	BCC N=10 SCC N=8 Melanoma N=4 Benign Naevus N=3 Seborhhoeic ketatosis N=3 Dermatitis N=1	Missed SCC diagnosis SAF N=0 FTF N=4	Management concordance SAF vs FTF 208/252 (82%)	The teledermatology management plan was more likely to include biopsy, excision or review than was the case at the FTF consultation. Teledermatology may result in an increase in follow-up appointments and surgical procedures.

	and categorize the referral.						lesions.	-single and differential diagnoses 64% (number not reported)				
Piccolo 2000 Italy Dermatoscopy was used	Observational cohort study To evaluate the agreement between the teledermoscopic diagnosis and the conventional, face-to-face diagnosis	Medical records, clinical pictures and dermatoscopic images	FTF	Histopathology	Camera DCS 460, Kodak Dermatoscopy Heine Delta 10, Heine Optotechnik	Unclear	Selective patients from the region around Graz	Diagnostic accuracy: SAF (mean)=37/43 (85%) FTF=39/41 (91%)	Melanoma N=11 Melanocytic naevus N=23 BCC N=3 Seborrhoeic keratosis N=2	Missed diagnosis of melanomas SAF (mean) N=3 FTF N=3	N/A	Teledermoscopy can be a reliable technique for the diagnosis of pigmented skin lesions. Doctors with experience in dermoscopy can provide an accurate telediagnosis of pigmented skin lesions.
Whited 1999 USA N=79* *only 79 out of 168 lesions had a definitive diagnostic test	Observational cohort study To assess and compare the reliability and accuracy of dermatologists' diagnoses and management recommendations for clinic-based and digital image consultations	Medical records and macro images of skin lesions	FTF	Histopathology	Camera Fujix DS-515 (1280*1000 pixels)	Research assistant	Patients being referred to the dermatology consult service with skin lesions. (those with previously diagnosed skin conditions referred for management were excluded)	Diagnostic accuracy: -Complete agreement (mean) SAF 47/79 (59%) FTF 51/79 (65%) -partial agreement (mean) SAF 61/79 (77%) FTF 67/79 (85%) Diagnostic concordance (all 2 clinical dermatologists and 4 teledermatologists) -complete agreement κ=0.63 TD1 41% (95%CI	N/A	N/A	Management concordance (mean) Medical therapy Partial 75% Complete 68% clinical procedure Partial 70% Complete 70% diagnostic tests Partial 69% Complete 67%	Diagnostic reliability among clinic-based examiners and teledermatologist examiners is comparable. Diagnostic accuracy does not differ between clinic-based dermatologists and digital image examiners. Teledermatology consultation is a clinically useful technique that provides comparably reliable and accurate diagnostic conclusions when used for referrals of

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								34-49%) TD2 44% (95%CI 36-52%) TD3 52% (95%CI 45-60%) Mean=46% -complete +partial agreement TD1 84% (95%CI 79-90%) TD2 83% (95%CI 78-89%) TD3 95% (95%CI 92-98%) Mean=87%				dermatologic conditions.
Piccolo 1999 Italy Dermatoscopy was used	Observational cohort study To verify the diagnostic concordance of pigmented skin lesions using dermatoscopic devices between clinical dermatologist and teledermatologist.	Medical records and clinical images, including dermatoscopic pictures.	FTF	Histopathology	Camera DXC 930P, SONY	Unclear	Patients being referred to the dermatology department and having the pigmented skin lesions excised.	Diagnostic accuracy SAF=57/66 (86%) FTF=60/66 (91%) Diagnostic concordance SAF vs FTF 60/66 (91%)	Melanoma N=1 BCC N=4	Missed cancerous diagnosis: SAF N=0 FTF N=0 Number of discordant diagnosis vs histopathology SAF N=9 FTF N=5	N/A	Teleconsultation of clinical and dermatoscopic images via SAF technology represents a valuable tool for the diagnosis of pigmented skin lesions when expert counselling is not available for FTF diagnosis.
Rosendahl 2011 Australia	A retrospective analysis of consecutively biopsied pigmented skin lesions diagnosed with digital and dermatoscopic images	Digital and dermatoscopic images. Not clear whether medical records were provided. Dermatoscopy –based diagnosis used a pattern analysis	N/A	Histopathology	Canon EOS (SLR) using a macro lens (60-mm f2.8 macro) Dermatoscopic images were nonpolarizing, Dermlite Fluid or Dermlite Foto and Heine	clinicians at the specialised skin cancer clinic	Patients with pigmented lesions (463 lesions)	Diagnostic accuracy SAF -a diagnosis digital image only 320/463 (69.1%) -Single diagnosis digital image and dermatoscopy 375/463 ?? (80.1%) (P<0.001) McNemar test	Dermoscopy sensitivity of 98.6% for BCC, 86.5% for pigmented squamous cell carcinoma, and 79.3% for	3 lesions excluded due to poor image quality	N/A	Dermatoscopy improves the diagnostic accuracy for nonmelanocytic lesions. A simple algorithm based on pattern analysis is suitable for the detection of melanoma and nonmelanoma skin cancer.

					Delta 20				melanoma			
Whited 1998 United States	Observational study Compared the precision and accuracy of digital image consultations with conventional consultations.	Medical records and clinical images	FTF	Histopathology	Camera Fujix DS-515 (1280*1000 pixels)	Unclear	Convenience sample of patients at the Veterans Affairs Medical Center who were referred to the dermatology clinic for a suspected skin cancer.	Diagnostic accuracy -Single diagnosis SAF TD1 7/9 (78%) TD2 2/9 (22%) FTF=6/7 (67%) -Single and differential diagnoses SAF TD1 8/9 (89%) TD2 7/9 (78%) FTF=7/9 (78%) Diagnostic concordance SAF vs FTF -Single diagnosis TD1 8/10 (80%) TD2 6/10 (60%) Mean=70% -Single and differential diagnoses TD1 9/10 (90%) TD2 10/10 (100%) Mean=95%	BCC N=3 SCC N=2 Keratoacanthoma N=2	Missed diagnosis for cancerous diseases (including differential diagnosis) TD 1 N=0 TD 2 N=0	Management concordance (vs FTF): TD1 10/10 (100%) TD2 9/10 (90%)	This study suggest that teledermatologymay be a viable consultative technique for providing accurate diagnoses.
Store-and-Forward teledermatology with diagnostic concordance as an outcome												
Barbieri, 2014 The reliability of teledermatology to triage inpatient dermatology	To evaluate whether a store-and-forward teledermatology system is reliable for the initial triage of inpatient	Teledermatology consultations by two independent teledermatologists based on the information	In-person consultation by a dermatologist	Diagnostic and management plan by the in-person dermatol	AccessDerm smartphone platform (Vignet), with images captured by a smartphone camera.	A fourth-year medical student	Inpatients of the US hospital Generalized lesion 22 (44%)	The primary study outcomes were concordance of the triage plans and the decision to biopsy. Secondary outcomes included diagnostic	N/A	Concordance in a biopsy decision between in-person teledermatologist and teledermatol	In-person dermatologist assigned 66% of consultations for the next day or later, with	Regarding triage decisions, the teledermatologists rarely failed to triage a consultation to be seen the same day when the in-person

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consultations JAMA Dermatol. 2014;150(4): 419-424. USA	dermatology consultations	from the medical record and patient using the prompts in the AccessDerm smartphone platform (Vignet), with images captured by a smartphone camera. The form from the AccessDerm platform was filled by a medical student. in-person dermatologic consultation note		ogist			Most common dermatologic diagnoses: Drug reaction 7 (14%) Stasis dermatitis 4 (8%) Graft vs host disease 3 (6%)	agreement between the in-person dermatologist and teledermatologists. There was complete, partial, and no agreement for 64%, 20%, and 16% of the consultations, respectively, between the in-person dermatologist and teledermatologist1 and for 56%, 26%, and 18% of the consultations, respectively, between the in-person dermatologist and teledermatologist 2. Comparing two teledermatologists, there was complete, partial, and no agreement between teledermato-logists for 58%, 30%, and 12% of consultations, respectively. Thus, there was 82% to 88% complete to partial diagnostic agreement.		ogists 1 and 2 was 94% and 96% respectively.	18% triaged to outpatient care. Teledermatologist 1 triaged 60% of consultations to the next day or later, with 12% deferred to outpatient care. Teledermatologist 2 triaged 60% of consultations to the next day or later, with 8% triaged to outpatient care. Concordance in a biopsy decision between in-person teledermatologist and teledermatologists 1 and 2 was 94% and 96% respectively. Concordance in a biopsy decision between in-person teledermatologist and	dermatologist believed it was necessary (<10% of cases). On determining whether to biopsy, the teledermatologists rarely failed to request a biopsy when the in-person dermatologist requested one (<5%of cases).

											teledermatologists 1 and 2 was 94% and 96% respectively.	
Du Moulin, et al. The reliability of diagnosis using store-and-forward teledermatology. J Telemed Telecare 2003;9:249-52. Netherlands	To examine the reliability of diagnoses made using store-and-forward teledermatology using ICD-9-CM or ICD-10 codes.	SAF	FTF (by one of 8 dermatologists other than telederматologist)	FTF in-person consultation	A digital camera (Ricoh 5000). The resulting images were 1200x1800 pixels in size, at a colour depth of 24 bits/pixel.	A GP	117 patients Malignant or pre-malignant lesions Benign proliferations Eczema Pigmented lesions Infections Follicular eruptions Papulosquamous;Urticarial/allergic Collagen/vascular	Diagnostic concordance in primary diagnosis: 54% (57/106) When differential diagnosis is added the concordance became: 63% (67/106) Discordance with respect to one (1/6=17%) malignant; 6/11=55% benign lesions and 9/12=75% other skin condictions	Not a part of the study	Either the FTF dermatologists or the teledermatologist made no (useful) diagnoses for 11 patients (the pictures were of poor quality or the FTF dermatologist was not able to see any skin problem at all)	An additional to TD diagnostic procedures were required to make a definitive diagnosis in 39 cases (33%).	In the present study, concordance was lower than in most other studies of SAF teledermatology. For some diagnostic groups it seems that teledermatology could only supplement a conventional dermatological consultation.
Ebner, et al Mobile teledermatology: a feasibility study of 58 subjects using mobile phones Journal of Telemedicine and Telecare 2008Volume 14 Number 1,	The purpose of the present study was to examine the feasibility of teledermatology consultations using mobile phones with built-in cameras. We assessed the agreement between the diagnoses from	Two dermatologists independently provided a TD consultation	FTF in-person consultation	FTF in-person consultation	Each subject was given a mobile phone (Nokia 6230i, Nokia, Espoo, Finland) with a built-in camera (1280x1024 pixel resolution). The captured images were stored in	Either a patient or a physician at the outpatient hospital department for 50 (86%) of patients	58 patients with dermatitis/eczema; herpes zoster; soft tissue infections; scalded or burned skin; facial dermatoses; urticaria/drug reactions and	In 41 cases (71%), the diagnosis provided by TD1 was the same as that given in the FTF examination (full agreement). In 15 cases (26%), the diagnosis differed, but was in the same diagnostic category (relative agreement). In only two cases (3%) did	Not a part of the study	In one case that could not be evaluated due to poor image quality,	The 48 subjects in the FTF-Standard Group were managed by TD1 according to the teletriage as follows: 31 subjects (65%) were in ambulatory treatment; 14	In a real setting, TD1 could have treated31(53%) remotely, TD2 could have treated 34 subjects (59%) remotely; also in the FTF group, 10 subjects (17%) were advised about further procedures. In contrast, 17 subjects (29%)

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p2-7 Austria	teledermatology and those from face-to-face (FTF) consultations. We also investigated the potential of mobile teledermatology for triage: ambulatory treatment; immediate admission; another visit for a surgical procedure				JPEG format and transferred to a PC via the Nokia Connectivity Wire DKU-2. Each image was re-sized to 800x600 pixels using a standard package (Image Viewer version 1.0). Images were stored on a database and were evaluated using a proprietary web application designed for telediagnosis.		arthropod reaction. pityriasis rosea acne and acneiform dermatitis ulcus cruris; ulcus durum in syphilis; epidermis cyst; infected scar; stasisdermatitis clavus; erythema migrans; Sweet syndrome; and psoriasis vulgaris;	the diagnoses conflict (disagreement). The diagnosis provided by TD2 showed complete agreement with the FTF examination in 44 cases (76%) and relative agreement in eight cases (14%). In six cases (10%), the diagnoses provided by TD2 disagreed with those provided by the FTF examination. There was complete agreement between TD1 and TD2 in 43 cases (74%) cases and relative agreement in nine cases (16%). There was disagreement in six cases (10%).			subjects (29%) were given a recommendation to consult a dermatologist and two subjects (4%) were advised immediately for admission. TD1 and TD2 were in full agreement (100%) with the FTF consultation, in advising the six subjects to go to for admission and four subjects to consult a dermatologist to perform elective surgery	diagnosed by TD1 and 14 subjects (24%) diagnosed by TD2, would have needed an additional dermatology visit.
Edison, 2008 Diagnosis, diagnostic confidence, and management concordance in live-interactive and store-and-forward	To compare LI and SF teledermatological diagnostic decisions with FTF consultations for diagnostic and management agreement, and diagnostic confidence.	Four dermatologists provided consultations in a random rotation among SAF;VC (and FTF control) consultations	FTF in-person consultation	FTF in-person consultation	Not reported	A photographer (no details)	110 new patients with Actinic keratosis; Acne Intradermal nevus; Psoriasis Seborrheic keratosis	Diagnostic self-reported confidence was rated on a Likert scale from 1 (no confidence) to 5 (complete confidence). Inter-observer diagnostic agreement FTF, VC, and SF:	Not a part of the study	5 cases had a complete disagreement between 3 dermatologists	Complete management agreement among FTF, SF, and VC, resulting in an identical primary treatment, occurred in 62 of 110 (56%)	The highest confidence rating (5) was given for 87% of FTF examinations, 59% for VC, and 54% for SF. Diagnostic confidence ratings for SF and VC were not significantly

teledermatology compared to in-person examination Telemedicine Journal & E-Health, 2008, 14 (9) 889-95 USA							Verruca Contact dermatitis; Rosacea Melasma Dyshidrosis Atopic dermatitis Tinea versicolour; Benign neoplasm; Urticaria Congenital nevus; Androgenic alopecia; Alopecia areata; Dermatosis papulosis Nigra Pilar cyst Atypical nevus Perioral dermatitis etc.	70/110 (64%) FTF and VC: 88/110 (80%) K = 0.79 (95% CI 0.75- 0.83) FTF and SF: 80/110 (73%) K = 0.71 (95% CI 0.67- 0.76) SF and VC: 77/110 (70%) K = 0.68 (95% CI 0.64- 0.73) There were no significant differences (p = 0.13) in diagnostic reliability between VC and SF modalities with respect to FTF standard. Inter-observer complete diagnostic confidence FTF 96/110 (87%) VC 65/110 (59%) SF 60/110 (54%)			cases. (95% CI 47.1% - 65.6%)	different from each other (p = 0.50); however, diagnostic confidence ratings for VC and SF were both statistically lower than for FTF (p < 0.0001).Results suggest comparable diagnostic and management agreement with VC or SF and FTF.
Heffner, Store-and-forward teledermatology versus in-person visits: a comparison in pediatric teledermatology clinic. J Am Acad	The objective of the study was to determine the ability of a board certified pediatric dermatologist to correctly diagnose rashes by history and digital images alone compared with direct	SAF diagnosis and management plans provided by two paediatric dermatologists	FTF in person clinical presentation CD is the same as one of the TDs;	FTF Clinical presentation	Canon Powershot SD450, a 5-megapixel camera in digital macro mode without flash. This camera was chosen for its ease of use and	A dermatologists without training in photography	N=135 Eczema/atopic dermatitis Molluscum contagiosum Seborrheic dermatitis Flat warts Insect bite or sting	the primary outcome is the intrarater agreement between in-person FTF visits and diagnosis based on SAF images; the secondary outcome was to evaluate interrater agreement of SAF images, between the two	Not a part of the study design	The 24 cases of dis-agreement In 6 cases (25%), it was thought that a whole-body photograph, instead of only close-up	the comparison between an in-person visit and a photographic diagnosis by another dermatologist became 84% after removing	Teledermatology appears to have a useful role in the care of children with rashes

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Dermatol 2009;60:956-61. USA	visualization of the patient. Our hypothesis was that SF digital photography combined with a brief patient history and rash description would provide sufficient information for the pediatric dermatologist to make the same diagnosis when compared to an in-person clinic visit.				highquality image reproduction. The camera was set in fine detail with image size at 1200 31600 pixels. The light source was overhead fluorescent with some natural light through examining room windows. The dermatologist had no formal photographic training.		Contact dermatitis Nevus Perioral dermatitis Scabies Tinea capitis Viral exanthem Vitiligo	teledermatiologist and between CD and the second teledermatiologist; Primary diagnosis agreement between clinical dermatologist and second (independent) dermatologist: 70% (94/135) (95% CI 60%-77%) k = 0.65 (95% CI 0.58-0.73)		images, would have made the diagnosis easier. In 4% of cases (n = 1) poor photographic quality was identified as the cause of the missed diagnosis. All cases were reviewed to determine the types of dermatoses that were missed. The only scenario represented more than once was three cases of scabies misdiagnosed as atopic dermatitis	clinically irrelevant disagreement. 84% (114/135) k = 0.82	
High et al Assessment of the accuracy of low-cost store-and-forward teledermatology consultation.	The purpose of this study was to compare the diagnostic results from two types of dermatology consultations: telemedicine using SAF technology	SAF diagnosis and management plans provided by 2 or 3 dermatologists (the cases where TD was also CD were exluded)	FTF in person clinical presentation	FTF Clinical presentation, or histology in 69 cases (results are not reported)	Images were created with a Sony DSC-F1 digital camera (Sony Corporation), downloaded to a PC workstation using a serial	the primary investigator, who was neither a dermatologist nor a photogra	N=92 with 106 skin conditions. The vast majority of patients were of Fitzpatrick classification skin types I-	Aggregated: TD1 vs CD 85% (84/99) TD2 vs CD 64% (49/77) TD3 vs CD 77% (76/99) Primary:	69 biopsies were obtained 100% consistent with FTF diagnosis, consistency with SAF is not reported	In only 6 (6%) of 106 cases did all SAF diagnoses submitted differ from the corresponding FTF	Not assessed	Our results suggest that relatively inexpensive equipment can render a high-quality teledermatology consultation. For the overall data set, the percent agreement between SAF and

J Am Acad Dermatol 2000;42: 776-83. USA	and traditional face-to-face (FTF) office visits. Criteria for comparison included overall accuracy of diagnosis, as well as accuracy based on diagnostic confidence, image quality, and the type of skin lesion involved				port interface and accompanying software. The Sony DSC-F1 camera displayed 640 × 480 pixel resolution with 24-bit colour. a PC with a Sony Trinitron Multiscan-15sf colour monitor set to display 24-bit colour at 864 × 480 pixels	pher, created all images.	IV, with only 3 patients classified as type V or VI. The study population contained a wide variety of dermatologic conditions. Most frequent Acne,dermatitis Nevus, keratosis	TD1 vs CD 70% (69/99) TD2 vs CD 64% (49/77) TD3 vs CD 77% (76/99)		evaluation.		FTF final diagnoses was in excess of 81% for each of the 3 teledermatologists.
Kvedar et al. The substitution of digital images for dermatologic physical examination. Arch Dermatol 1997;133:161-7. USA	To investigate the diagnostic accuracy of clinicians viewing a patient's history and static digital image set compared with clinicians who conducted office based physical examinations of the same patients.	SAF diagnosis provided by 2 dermatologists independently; Patient record	FTF consultation by one of 13 dermatologists	FTF	a digital camera (Kodak DCS 420) equipped with a macro lens (Nikkor 50 mm). The digital images were stored on optical disks as PICT files and viewed using a software program (Adobe Photoshop,Adobe Systems Inc, San Jose, Calif) on a Macintosh computer (Apple Macintosh PowerMac	Two professional photographers	Malignant or premalignant (non-pigmented) Eczema/dermatitis Pigmented lesions Infections/infestations Papulosquamous disorders	2 TDs aggregated diagnoses : 70% 67% Primary diagnoses: 61% 64%	Not a part of the study design	27% of the images taken by this method had a Q-index rating of less than 4, indicating a significant number of unacceptable images interspersed with the high-quality images.	Not a part of the study design	Still digital images can substitute for the dermatologic physical examination in up to 83% of cases. This study provides validation of the store-and-forward concept of telemedicine as applied to dermatology.

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Tucker 2005 United Kingdom N=75 (number of lesions=84) Skin Lesion	Observational cohort study To test the efficacy of the teledermatology screening of referrals, and thereby to triage the patients to appropriate care.	Medical records and clinical images	FTF	N/A	Camera Fujifilm MX-1700 zoom	Dermatologist *two dermatologists took pictures for two batches of patients separately and then the pictures were read by the other dermatologist	Patients seeing in general dermatology clinics.	Diagnostic concordance SAF vs FTF -complete 37/84 (44%) -partial 47/84 (68%)	N/A	Quality of images Poor N=18	N/A	Teledermatology is not likely to have a great impact on reducing waiting lists. It is possible that it may help to prioritize referrals from remote areas.
Mahendran 2004 UK N=163 *unclear that if the TD1 was the served as the clinical dermatologist. Skin Lesion	Observational cohort study To investigate the value of a store-and-forward teledermatology system in the diagnosis and management of lesions suspicious of skin cancer.	Medical records and clinical images	FTF	N/A	Camera Nikon Coolpix 950 (1200*1600 pixels)	GPs	Patients with suspicious skin lesions referred by GPs to dermatology department.	Diagnostic concordance TD1 vs FTF 78/163 (48%) TD2 vs FTF 72/163 (44%)	N/A	Missed diagnoses including BCC, melanoma, dermatofibroma, basal cell papilloma. Quality of image Insufficient quality N=24	Management concordance TD1 90/163 (55%) TD2 85/163 (52%)	This study illustrates that the store-and forward type telemedicine system has limited diagnostic accuracy for skin lesions. However, our results suggest that store-and-forward teledermatology may be suitable and safe for screening out clearly benign lesions but the study casts doubt on its efficiency.
Oztas 2006 Turkey	Observational cohort study	Medical records and	FTF	N/A	Camera Cannon	Unclear	Randomly selected	Diagnostic concordance:	N/A	N/A	N/A	A Web-based system appears to

N=125 General patients	To investigate the accuracy and reliability of teledermatology using a Web-based store-and-forward system.	clinical images			PowerShot 70 (800*600 pixels)		patients being referred to the department of dermatology.	Mean -with clinical information88/125 (70%) -without clinical information 72/135 (57%)				be reliable for teledermatology. A single well trained teledermatologist may give better results than a group of less well trained clinicians.
Rashid 2003 N=33 General patients	Observational cohort study To compare the accuracy of store and forward method of teledermatology with the traditional face-to-face consultation.	Medical records and clinical images	FTF	N/A	Camera Unclear	Unclear	Selective patients being referred to dermatology department of a tertiary hospital.	Diagnostic concordance: SAF vs FTF 27/33 (81%)	N/A	Quality of image Insufficient quality N=3	N/A	This study concludes that store and forward method of teledermatology is reliable and can provide a means of increasing access to dermatological care in rural and under-served areas.
Rubegni 2011 N=130 geriatric Italy	Observational cohort study The aim of this study was to determine the efficacy of store-and-forward teledermatology vs face-toface consultations in elderly patients	Medical records and clinical and dermotoscopic images	FTF 3 dermatologists	N/A	A standardized record sheet for medical three digital photographs and sometime1 or two dermoscopic images using a Cyber-shot W350 14.1 camera and a DermLite II pro HR (3Gen, San Juan Capistrano, CA, USA).	Medical student collected medical history data The presenter??? took photos	130 new geriatric patients at the dermatology clinic of the university department	Diagnostic concordance SAF vs FTF 114/130 (87.7%) Cohen's kappa coefficient 0.863 (0.800–0.926)	N/A	N/A	Management concordance SAF vs FTF 69.6% (Cohen's k= 0.640)	Store-and-forward teledermatology can improve diagnostic and therapeutic care for skin disease in elderly who lack easy and / or direct access to dermatologists.
Zelickson 1997 N=29 Nursing home	Observational cohort study To examine a still-image store-and-forward	Medical records and clinical images	FTF	N/A	Camera Video Camera Recorder High 8 model CCD-TR400, Sony	Nurse	All nursing home resident consultation requests from the	Diagnostic concordance SAF vs FTF 53/60 (88%) *combination of 2-3	N/A	N/A	Management concordance SAF vs FTF 54/60 (90%) *combination	This study provides evidence that nursing home teledermatology consults may replace some onsite

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patients	teledermatology system for use in the care of nursing home residents.						Walker Methodist Health Care Center.	TDs			of 2-3 TDs	consultations by offering quality care in a cost-effective manner.

Table 84:Characteristics of the included VC studies

Author, year, country	Study design, objective	Intervention	Comparator	Reference standard	Technology (camera, IT system, quality of pictures, pixels)	Who made the images	Population (skin conditions)	Outcomes reported	Accuracy based on histopathology outcomes	Safety outcomes (safety, repeated requests (%), refusals, misdiagnosis)	Results (management)	Conclusion as reported in the paper
Videoconferencing with diagnostic concordance as an outcome												
Gilmour et al Comparison of teleconsultations and face-to-face consultations: Preliminary results of a United Kingdom multicentre teledermatology study The British Journal Of Dermatology 1998 Jul; Vol. 139 (1), pp. 81-7; UK, North Ireland	The objective of this multicentre study was to undertake a systematic comparison of face-to-face consultations and teleconsultations performed using low-cost videoconferencing equipment.	TD consultancy in GP's office over VC	FTF TD also served as CD in 51% (79/155) of cases	N/A	Videoconferencing units VC7000 camcorder Sharp VL-H400H, images were transmitted at full CIF resolution (352pixels, 288 lines)	GP or a trained assistant operated a videocamera	126 patients and 155 skin conditions (diagnoses) Diagnoses: eczematous, psoriasis, infections, tumours, acne and other	Aggregated: 78% (121/155) Primary: 57% (88/155)	Not a part of the study design	Wrong diagnoses were made by TD in 4% of cases. in 18 (11%) cases no useful diagnosis were made by TD 12/44 TD could not manage over VC in 5 cases the TD management plan was suboptimum. No misdiagnosis of tumour has occurred	Concordance in 72% (44/61) of management plans N=61 patients; 13/44 had to have a hospital surgery; 31 (50%) of patients (n=61) could have been managed by VC alone	This study illustrates the potential of telemedicine to diagnose and manage dermatology cases referred from primary care.
Lesher JL Jr, Davis LS, Gourdin FW, English D, Thompson WO. Telemedicine evaluation of	We attempted to determine the percentage of encounters in which two different dermatologists, one using telemedicine and	VC without any demographic or medical history details	FTF in-person consultation with independent CD	diagnosis of FTF consultation	Sony Trinitron (PVM-2030) colour monitors with a standard resolution of 560 TV lines. The cameras	Not applicable	60 Patients 68 Conditions Diagnoses: eczematous, psoriasis, infections, tumours,	Aggregated: 99% (67/68) Primary: 78% (53/68)	Not a part of the study	14/68 (21%) partial disagreement; 1 (1%) is complete disagreemen	Not a part of the study	A greater proportion of patients fell into the "partial agreement" category

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cutaneous diseases: a blinded comparative study. J Am Acad Dermatol 1998;38:27-31. USA	one on-site, could independently arrive at the same primary diagnosis		immediately after the VC session		used included a single chip JVC TK-1280U remote-controlled room camera with a Computar TV zoom lens H1020812 MP with focal length of 8 to 80 mm, and a three-chip Panasonic WV-E550 remote-controlled patient camera with a Fujinon TV zoom lens S16 ´ 6.7 BMD-D24 with focal length of 6.7 to 107 mm.		acne Dermatofibroma Actinic keratosis Cutaneous horn Actinic keratosis Seborrheic dermatitis Basal cell carcinoma Eczema Vitiligo Furunculosis Hidradenitis Scabies Seborrheic dermatitis			t		when examined with telemedicine; specifically, with telemedicine evaluation, 21% of the cutaneous problems or lesions fell into a partial agreement category, compared with 6% of lesions examined on-site by both investigators in person to establish inter-rater reliability.
Loane et al. Diagnostic accuracy and clinical management by real real time teledermatology: results from the Northern Ireland arms of the UK multicentre teledermatology trial. J	Prospective observational cohort to assess clinical effectiveness of VC versus clinical face-to-face consultation. Two hospital dermatology departments that were linked to two health centres	VC at the health centre in presence of GP	hospital consultation by the dermatologist in the outpatient department of a hospital	Gold standard was assumed to be a diagnosis and management plan of FTF consultation	For the realtime teledermatology, low-cost videoconferencing units (VC7000, BT) connected by basic-rate ISDN lines at 128 kbit/s were installed at each of the participating sites. An additional videocamera	Not applicable	N=351 with 427 diagnoses; Most patients N=226 were seen at the hospital by the same dermatologist who provided a TD advice. Diagnostic concordance decrease when a different	Concordance in primary diagnosis between VC and FTF was 71% when the same dermatologist was involved or 60% with a different dermatologist, Concordance in treatment plans between VC and FTF was 62% when the same dermatologist was involved or 65% with a different	Not a part of the study	Patients were seen FTF on the same day as VC. Wrong or missed diagnosis was recorded in 10% of cases. Inability to give a treatment plan or inappropriate plan was	Management plans N=214 with 252 diagnoses	These findings suggest that the Clinical management of dermatological conditions can be carried out satisfactorily via real time teledermatology using low-cost telemedicine

Telemed Telecare 1998;4:95-100. North Ireland					was connected to the video-conferencing unit at each health centre to enable the general practitioner (GP) to transmit close-up images to the dermatologist. (JVC KY-F55B)		dermatologist assessed the patients in a FTF consultation.	dermatologist		recorded in 29% of 252 cases		equipment
Lowitt et al. Teledermatology and in-person examinations: a comparison of patient and physician perceptions and diagnostic agreement. Arch Dermatol 1998;134:471-6. USA	To compare physician and patient impressions and inter-physician diagnostic agreement between live teledermatology and in- person examinations.	Nurse-assisted videoconferencing with a dermatologist	FTF interview with another dermatologist	Histology diagnosisfor every biopsy performed N=11	VC were conducted over a dedicated data line (T1) at the rate of 1.554 megabytes per second (64% of patients) and at ¼ T1 (384 kBT per second) for the 36% of patients	Nurse assisted in VC	N=104 Acne, dermatitis fungal papulosquamous Benign tumour premalignant tumour Malignant tumour	Aggregated: 80% (104/130) 84% for T1 and 78% for ¼ T1. See Table 4 in the paper for diagnostic agreement by condition	VC Aggregated: 73% (8/11) FTF Aggregated: 64% (7/11)	On 6 occasions a premalignant or Malignant tumour was mentioned by TD but not CD or vice versa	Not a part of the study	Physicians and patients were satisfied with teledermatology examinations. Diagnostic agreement between in-person and video dermatologists was high.
Phillips 1997	Prospective, observational study. To determine the reliability of videoconferencing in evaluating skin tumors, the impact of the technology on the clinician's degree of suspicion that a	Diagnosis was made by on-site physician and teledermatologist via videoconferencing.	N/A	FTF	CLI CODEC (Panasonic 3-chip or Canon 1-chip) plus digital camera with dermatoscopic camera.	Not applicable	Patients enrolled in the screening at the community hospital or physician offices with suspected skin tumors.	-Diagnostic concordance: Primary diagnosis 63/107 (58.9%) -Decision to biopsy the lesion: Agreement κ=0.47, p<0.025	N/A	N/A	N/A	The concern about the malignancy of a particular skin lesion and the recommendation whether to do a biopsy were not significantly affected by telemedicine

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	skin tumor is malignant, and the recommendation to do a biopsy.											technology.
Phillips 1998	Prospective, observational study. To measure the degree of concordance between a dermatologist seeing a patient in a clinic and another dermatologist seeing the same patient over a commercially available videoconferencing system	Diagnosis was made by on-site physician and teledermatologist via videoconferencing.	N/A	FTF	Picture Tel System 4000 plus digital camera (Elmo model MN401X).	Not applicable	Patients being referred by another physician.	Diagnostic concordance: -Primary diagnosis 61/79 (77.2%) -Type of problem Lesions 82.7% Rashes 74.1% Other 75%	N/A	N/A	N/A	There was a reasonable degree of agreement between the two examining physicians. Despite the relatively high degree of concordance the teledermatologist had a significantly lower degree of confidence in his diagnoses.
Nordal 2001	Prospective, observational study. The aim of the present study was to evaluate teledermatology in a comparative study of videoconferences versus face-to-face consultations	The same patients underwent a teledermatology consultation and then a face-to-face consultation.	N/A	FTF	The same videoconferencing systems were used at both sites (Titan, Philips); they were connected at 384kbit/s. The magnified still images had a resolution of 720 pixels6576 lines. A three-chip CCD camera (DXC-930P, Sony) was used for patient	Not applicable	Patients from primary care being referred for dermatology consultations.	Diagnostic concordance: -Primary diagnosis 81/112 (72.3%) -aggregated diagnosis 97/112 (86.6%) Dermatologist evaluation -favour VC= 14% -favour face-to-face consultation= 22% Average duration of consultation (minute)	N/A	N/A	N/A	Videoconferencing with a participating general practitioner may be useful in dermatology, but the technique should be used only for selected patients.

					video and still images			VC=9.45 -FTF=10.16				

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Appendix D Excluded studies

Table 85: Excluded RCT with reasons

Study	Reason
Baba et al, 2005 A comparison of teledermatology using store-and-forward methodology alone, and in combination with Web camera videoconferencing; Journal of Telemedicine & Telecare, 11(7) 354-60	Wrong comparator. The study compared the diagnostic accuracy of SF teledermatology with SF in combination with video conferencing teledermatology.
Bergmo et al, Web-based consultations for parents of children with atopic dermatitis: results of a randomized controlled trial, Acta Paediatrica, 2009; 98:2: 316-20	The study population is inconsistent with the scope of the Assessment: parents of children with atopic dermatitis (AD), who were educated and trained at the baseline, communicated with teledermatologists and self-managed AD, although the GP consultations and hospital visits were not excluded
Chambers et al, Patient-centered online management of psoriasis: a randomized controlled equivalency trial, Journal of the American Academy of Dermatology,2012;66:6:948-53	The study population is inconsistent with the scope of the Assessment: patients with psoriasis, from both intervention and control groups received initial assessment in person during a consultation with clinical dermatologist. Only the follow up of psoriasis treatment was randomised and investigated.
Collins et al, 2004 Patient satisfaction with teledermatology: quantitative and qualitative results from a randomized controlled trial, Journal of Telemedicine & Telecare, 2004;10:1:29-33	The study outcome is inconsistent with the scope of the Assessment (e.g. only patients' satisfaction is reported)
Leggett, et al A randomized controlled trial using instant photography to diagnose and manage dermatology referrals. Family Practice 2004; 21: 54–56	The study intervention is inconsistent with the scope of the Assessment (instant photograph sent by post rather than digital images sent by Internet-based system)
Loane, 2000 A randomized controlled trial to assess the clinical effectiveness of both real time and store-and-forward teledermatology compared with conventional care. Journal of Telemedicine and Telecare 2000 (6) S1:1-3	The SAF arm of the trial was excluded as Polaroid rather than digital photographs were used

Table 86: Excluded observational cohort studies with reasons

Study	Reason
Piccolo D, Soyer HP, Chimenti S, Argenziano G, Bartenjev I, Hofmann-Wellenhof R, et al. Diagnosis and categorization of acral melanocytic lesions using teledermoscopy. J Telemed Telecare 2004;10:346-50.	Wrong outcome: interobserver variability among 11 dermatologists evaluating teledermoscopy images with known diagnosis
Chen, 2010 Pediatric teledermatology: Observations based on 429 consults J Am Acad Dermatol 2010;62:61-6.	Concordance between GP's provisional diagnosis and teledermatologist's diagnosis is assessed without a standard comparison (face-to-face examination) of another dermatologist (second opinion)
Eastman et al, A teledermatology care management protocol for tracking completion of teledermatology recommendations. Journal of Telemedicine and Telecare Volume. 2012; 18 (7) 374-9	The study design (follow-up on protocol and management practices of the TD program) and outcome (number of consultations, procedures, medications, etc) is inconsistent with the scope of the Assessment
Eminovich, et al Potential effect of patient-assisted teledermatology on outpatient referral rates. Journal of Telemedicine & Telecare, 2003; 9 (6)321-7	The images were supplied by patients rather than GPs or other health professional. Pilot study
Griffiths WA, Improving melanoma diagnosis in primary care--a tele-dermatoscopy project. Journal Of Telemedicine And 2010; Vol. 16 (4), pp. 185-6	Non-comparative study. Not clear how accuracy was assessed if at all.
Grimaldi, et al Digital epiluminescence dermoscopy for pigmented cutaneous lesions, primary care physicians, and telediagnosis: a useful tool? Journal of Plastic, Reconstructive & Aesthetic Surgery.2009 62 (8) 1054-8	Wrong outcome: triage, non-comparative study. study; histology was used on a very small number of lesions
Granlund H, Thoden CJ, Carlson C, Harno K. Real-time teleconsultations versus face-to-face consultations in dermatology: immediate and six-month outcome. J Telemed Telecare 2003;9:204-9.	Neither control (gold standard) for diagnostic accuracy was used nor concordance rates were reported
Hockey, A. D. Wootton, R. Casey, T. Trial of low-cost teledermatology in primary care. Journal of Telemedicine & Telecare, 10 Suppl 1; 44-7	Neither control (gold standard) for diagnostic accuracy was used nor concordance rates were reported
Jolliffe et al. Can we safely diagnose pigmented lesions from stored video images? A diagnostic comparison between clinical examination and stored video images of pigmented lesions removed for histology. Clin Exp Dermatol 2001;26:84-7.	Inappropriate study design where concordance or diagnostic accuracy is determined by the same dermatologist reassessing the digital images after conducting in-person consultation
Jolliffe et al. Can we use video images to triage pigmented lesions? Br J Dermatol 2001;145:904-10.	Inappropriate study design where concordance is determined by the same dermatologist reassessing the digital images after conducting in-person consultation. Outcome: no a diagnostic accuracy, but the agreement on refer or not refer to the dermatological consultancy
Kaliyadan, F et al. Mobile teledermatology--patient satisfaction, diagnostic and management concordance, and factors affecting patient refusal to participate in Saudi Arabia. Journal of Telemedicine & Telecare, 2013 19(6) 315-9	Wrong intervention. Both teledermatologists used a mobile phone to take and assess the images
Lamel, et al Impact of live interactive teledermatology on diagnosis, disease management, and clinical outcomes, Archives of Dermatology; 148 (1) 61-5	Wrong intervention. Digital photographs were taken with a mobile phone enabled with Application to facilitate remote diagnoses
Lasierra, N. Lessons learned after a three-year store and forward teledermatology experience using internet: Strengths and limitations. International Journal of Medical Informatics.2012;81 (5) 332-43	Inappropriate study design where concordance is determined by the same dermatologist reassessing the digital images after conducting in-person consultation.
Lim, D. Oakley, A. M. M. Rademaker, M. Better, sooner, more convenient: A successful teledermoscopy service Australasian Journal of Dermatology (2012) 53, 22–25	Neither control (gold standard) for diagnostic accuracy was used nor concordance rates were reported

Loane et al.Preliminary results from the Northern Ireland arms of the UK Multicentre Teledermatology Trial: effect of camera performance on diagnostic accuracy. J Telemed Telecare 1997;3 Suppl1:73-5.	Inappropriate study design where concordance is determined by the same dermatologist reassessing the outcome of the VC by conducting in-person consultation.
Loane MA; et al Effect of camera performance on diagnostic accuracy: preliminary results from the Northern Ireland arms of the UK Multicentre Teledermatology Trial. Journal Of Telemedicine And Telecare 1997; Vol. 3 (2), pp. 83-8;	Inappropriate study design where concordance is determined by the same dermatologist reassessing the outcome of the VC by conducting in-person consultation.
Loane et al. Preliminary results from the Northern Ireland arms of the UK Multicentre Teledermatology Trial: is clinical management by realtime teledermatology possible? J Telemed Telecare 1998;4 Suppl1:3-5.	Companion paper
Head-to-head Loane MA, Bloomer SE, Corbett R, Eedy DJ, Hicks N, Loter HE, et al. A comparison of real-time and store-and-forward teledermatology: a cost-benefit study. Br J Dermatol 2000;143: 1241-7.	Neither control (gold standard) for diagnostic accuracy was used nor concordance rates were reported. VC was compared directly to SAF
Lozzi et al, The additive value of second opinion teleconsulting in the management of patients with challenging inflammatory, neoplastic skin diseases: A best practice model in dermatology? Journal of the European Academy of Dermatology and Venereology. 1997. 21 (1) 30-34	No proper control. Teledermatologist assisted a face-to-face consultant dermatologists in diagnosis difficult cases (no blindness)
Moodie, T., Rademaker, M., Oakley, A., 2013. Non-melanocytic lesions diagnosed by teledermoscopy-retrospective review. Australasian Journal of Dermatology 54, 1	Retrospective study and conference abstract
Pak, H.S., Harden, D., Cruess, D., Welch, M.L., Poropatich, R., National Capital Area Teledermatology, C., 2003. Teledermatology: an intraobserver diagnostic correlation study, Part II. Cutis 71, 476-480.	Patients were evaluated by the same dermatologist
Pak, H.S., Harden, D., Cruess, D., Welch, M.L., Poropatich, R., National Capital Area Teledermatology, C., 2003. Teledermatology: an intraobserver diagnostic correlation study, part I. Cutis 71, 399-403.	Patients were evaluated by the same dermatologist
McKoy, K.C., DiGregorio, S., Stira, L., 2004. Asynchronous teledermatology in an urban primary care practice. Telemedicine Journal & E-Health 10 Suppl 2, S-70-80.	Patients were evaluated by the same dermatologist
Moreno, D., Ferrandiz, L., Perez-Bernal, A.M., Rios, J.J., Carrasco, R., Camacho, F., 2005. [Evaluation of a screening system for patients with pigmented lesions using store-and-forward teleconsultation]. Actas Dermo-Sifiliograficas 96, 222-230.	Non-English, only abstract available
Moreno, R., 2007. Erratum: Store-and-forward teledermatology in skin cancer triage: Experience and evaluation of 2009 teleconsultations (Archives of Dermatology (April 2007) 143, 4, (479-484)). Archives of Dermatology 143, 886.	Erratum
Moreno-Ramirez, D., Ferrandiz, L., Bernal, A.P., Duran, R.C., Martin, J.J., Camacho, F., 2005. Teledermatology as a filtering system in pigmented lesion clinics. Journal of Telemedicine & Telecare 11, 298-303.	Companion paper to "Moreno-Ramirez, D., Ferrandiz, L., Nieto-Garcia, A., Carrasco, R., Moreno-Alvarez, P., Galdeano, R., Bidegain, E., Rios-Martin, J.J., Camacho, F.M., 2007. Store-and-forward teledermatology in skin cancer triage: Experience and evaluation of 2009 teleconsultations. Archives of Dermatology 143, 479-484."
Moreno-Ramirez, D., Ferrandiz, L., Galdeano, R., Camacho, F.M., 2006. Teledermatoscopy as a triage system for pigmented lesions: a pilot study. Clinical & Experimental Dermatology 31, 13-18.	Companion paper to "Moreno-Ramirez, D., Ferrandiz, L., Nieto-Garcia, A., Carrasco, R., Moreno-Alvarez, P., Galdeano, R., Bidegain, E., Rios-Martin, J.J., Camacho, F.M., 2007. Store-and-forward teledermatology in skin cancer triage: Experience and evaluation of 2009 teleconsultations. Archives of Dermatology 143, 479-484."

Oakley, A.M., Astwood, D.R., Loane, M., Duffill, M.B., Rademaker, M., Wootton, R., 1997. Diagnostic accuracy of teledermatology: results of a preliminary study in New Zealand. New Zealand Medical Journal 110, 51-53.	Preliminary results to study "Oakley, A.M., 2001. Teledermatology in New Zealand. Journal of Cutaneous Medicine & Surgery 5, 111-116."
Pak, H.S., Welch, M., Poropatich, R., 1999. Web-based teledermatology consult system: preliminary results from the first 100 cases. Studies in Health Technology & Informatics 64, 179-184.	Preliminary results from 100 cases.
Piccolo, D., Peris, K., Chimenti, S., Argenziano, G., Soyer, H.P., 2002. Jumping into the future using teledermoscopy. SKINmed 1, 20-24.	Non-systematic review.
Rao, B.K., Mateus, R., Wassef, C., Pellacani, G., 2013. In vivo confocal microscopy in clinical practice: comparison of bedside diagnostic accuracy of a trained physician and distant diagnosis of an expert reader. Journal of the American Academy of Dermatology 69, e295-300.	Wrong intervention: Confocal microscopy was utilised in the study, which is outside of the scope of the asessment
Rashid, E., Ishtiaq, O., Gilani, S., Zafar, A., 2003. Comparison of store and forward method of teledermatology with face-to-face consultation. Journal of Ayub Medical College, Abbottabad: JAM	Only 30 patients were enrolled. Pilot study
Ruiz, C., Gaviria, C., Gaitan, M., Manrique, R., Zuluaga, A., Trujillo, A., 2009. Concordance studies of a web based system in teledermatology. Colombia Medica 40, 259-	The same dermatologist provided FTF and SF consultations within five minutes. The dermatologist was not blind to the previous diagnosis.
Sheraz, A., Halpern, S.M., 2011. Influence of additional dermoscopy images on teledermatology screening of skin lesions. British Journal of Dermatology 165, 136.	Conference abstract
Taberner Ferrer, R., Pareja Bezares, A., Llambrich Manes, A., Vila Mas, A., Torne Gutierrez, I., Nadal Llado, C., Mas Estaras, G., 2009. Diagnostic reliability of an asynchronous teledermatology consultation. Atencion Primaria 41, 552-55	Non-English
Tadros, A., Murdoch, R., Stevenson, J.H., 2009. Digital image referral for suspected skin malignancy--a pilot study of 300 patients. Journal of Plastic, Reconstructive & Aesthetic Surgery: JPRAS 62, 1048-1053.	Diagnosis was made by plastic surgeon rather than the dermatologist.
Tan, E., Jameson, M., Yung, A., Rademaker, M., Oakley, A., 2009. Successful triage of patients referred to a skin lesion clinic using teledermoscopy (Molemap program). Australasian Journal of Dermatology 50, A24-A25.	Conference abstract
Tan, E., Oakley, A., Soyer, H.P., Haskett, M., Marghoob, A., Jameson, M., Rademaker, M., 2010. Interobserver variability of teledermoscopy: an international study. British Journal of Dermatology 163, 1276-1281.	Wrong outcome: Reported only an Interobserver (teledermatologists) variability, which is outside the scope of the assessment
Tan, E., Rademaker, M., Oakley, A., 2009. Inter-observer variability of teledermoscopy. Australasian Journal of Dermatology 50, A61.	Wrong outcome: Reported Interobserver (teledermatologists) variability, which is outside the scope of assessment Conference abstract
Tan, E., Yung, A., Jameson, M., Oakley, A., Rademaker, M., 2010. Successful triage of patients referred to a skin lesion clinic using teledermoscopy (IMAGE IT trial). British Journal of Dermatology 162, 803	Same dermatologists reviewed the patients' dermatoscopic images
Taylor, P., Goldsmith, P., Murray, K., Harris, D., Barkley, A., 2001. Evaluating a telemedicine system to assist in the management of dermatology referrals. British Journal of Dermatology 144, 328-333.	Same dermatologists reviewed the patients images
Trindade, M.A., Wen, C.L., Neto, C.F., Escuder, M.M., Andrade, V.L., Yamashitafuji, T.M., Manso, V.L., 2008. Accuracy of store-and-forward diagnosis in leprosy. Journal of Telemedicine & Telecare 14, 208-210.	For the diagnosis of leprosy
Tucker, W.F.G., Lewis, F.M., 2005. Digital imaging: A	Same reviewing dermatologist took the image for patients.

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diagnostic screening tool? International Journal of Dermatology 44, 479-481.	
Warshaw, E., Lederle, F., Grill, J., Gravely, A., Bangerter, A., Fortier, L., Bohjanen, K., Chen, K., Lee, P., Rabinovitz, H., Johr, R., Kaye, V., Bowers, S., Wenner, R., Askari, S., Kedrowski, D., Nelson, D., 2009. Accuracy of teledermatology for pigmented neoplasms. Journal of Investigative Dermatology 129, S66.	Conference abstract
Warshaw, E.M., Gravely, A.A., Nelson, D.B., 2010. Accuracy of teledermatology/teledermoscopy and clinic-based dermatology for specific categories of skin neoplasms. Journal of the American Academy of Dermatology 63, 348-352.	Letter to editor
Wolf, J., Moreau, J., Ferris, L., Akilov, O., 2013. Diagnostic accuracy of smartphone application in evaluating pigmented skin lesions. Journal of the American Academy of Dermatology 68, AB151.	Evaluation of smartphone application in diagnosing pigmented skin lesions. Conference abstract
Wolf, J.A., Ferris, L.K., 2013. Diagnostic inaccuracy of smartphone applications for melanoma detection--reply. JAMA Dermatology 149, 885.	Reply to "Wolf, J.A., Moreau, J.F., Akilov, O., Patton, T., English, J.C., 3rd, Ho, J., Ferris, L.K., 2013. Diagnostic inaccuracy of smartphone applications for melanoma detection. JAMA Dermatology 149, 422-426."
Wolf, J.A., Ferris, L.K., 2013. In reply. JAMA Dermatology 149, 884-885.	Reply to "Wolf, J.A., Moreau, J.F., Akilov, O., Patton, T., English, J.C., 3rd, Ho, J., Ferris, L.K., 2013. Diagnostic inaccuracy of smartphone applications for melanoma detection. JAMA Dermatology 149, 422-426."
Wolf, J.A., Moreau, J.F., Akilov, O., Patton, T., English, J.C., 3rd, Ho, J., Ferris, L.K., 2013. Diagnostic inaccuracy of smartphone applications for melanoma detection. JAMA Dermatology 149, 422-426.	Evaluation of smartphone application in diagnosing pigmented skin lesions.
Yassaee, M., Albrecht, J., Hutchins, S., Okawa, J., Bonilla Martinez, Z., Moghadam-Kia, S., Taylor, L., Coley, C., Werth, V., 2009. Diagnostic accuracy of using telemedicine to evaluate vesicular or pustular rash illnesses. Journal of Investigative Dermatology 129, S49.	Conference abstract
Zelickson, B.D., 2003. Teledermatology in the nursing home. Current Problems in Dermatology 32, 167-171.	Pilot study. Only 30 patients were recruited in the study
Zelickson, B.D., Homan, L., 1997. Teledermatology in the nursing home. Archives of Dermatology 133, 171-174.	Non-systematic review
Oztas, M.O., Calikoglu, E., Baz, K., Birol, A., Onder, M., Calikoglu, T., Kitapci, M.T., 2004. Reliability of Web-based teledermatology consultations. Journal of Telemedicine & Telecare 10, 25-28.	The diagnostic accuracy of SAF teledermatology was compared to the results of histopathology only. No comparator arm.

Appendix E Review of economic literature

Economic evaluations

Table 87: Review of economic evaluations

Author /year country	Objective*	Population	Perspective/ time horizon/ discounting	Interventions/ comparators	Type of economic evaluation	Resource use/ outcomes	Results	Comments*
Eminovic 2010	The objective was to investigate the economic implications of using store-and-forward telederm atology to provide a	Patient from primary care in Netherlands	-The authors stated that a societal perspective was adopted. -The time horizo	The interventions were store-and-forward telederm atology and the usual care. Store-and-forward telederm atology consisted	The Cost-minimisation analysis was based on a decision-tree model.	-The effectiveness data were mainly from the Primary care Electronic Referrals: Focus on Efficient Consultation using Telemedicine in Dermatology (PERFECT	-The total mean costs were EUR 387.0 (95% CI 281.0 to 502.5) for teledermatology and EUR 354.0 (95% CI 228.0 to 484.0) for usual care; a difference of EUR 32.5 (95% CI -29.0 to 74.7). -When the	Interventions: The selection of the comparators was appropriate and the usual care was included. The interventions were well described. Effectiveness /benefits:

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	skin assessment for patients who did not need an urgent consultation with a dermatologist.		n was six months.	of the general practitioner (GP) uploading two to four digital images and a description of the skin problem to a secure website. The dermatologist received an email and consulted these images and then provided the GP with advice on further		D) trial. This was a cluster randomised trial of 631 patients, with 85 GPs, and five dermatologists. From this trial, the authors determined that there was no difference in the clinical outcomes between the interventions. This was supported by another published study. The main clinical effectiveness estimate was patient recovery. - No	distance to a dermatologist is greater (75km or more) or when more consultations can be prevented by teledermatology (37% or more), teledermatology resulted in cost savings. -The probabilistic sensitivity analysis demonstrated that usual care was less expensive than teledermatology in 89% of simulations. Authors' conclusions The authors concluded that	The effectiveness data were from a randomised trial, which appears to have been of good quality. The authors assumed equal effectiveness for the two interventions based on this trial and validated this assumption using the results of another study. Costs: The perspective was clearly stated and the cost categories were consistent

				procedures or referral. The usual care consisted of a GP referral to a dermatologist for a face-to-face consultation.		summary benefit measure was used because the interventions were assumed to be clinically equivalent. A cost-minimisation analysis was carried out. -The economic analysis included the costs of GP care, dermatology care, out-of-pocket expenses for patients including travel costs, and productivity losses due to	teledermatology was unlikely to be cost saving, unless patients had to travel long distances to see dermatologists or they were likely to be able to be treated in a GP practice without needing a face-to-face dermatological consultation.	with this perspective. The unit costs and quantities of resources used were clearly and separately presented. The sources of costs were reported and appear to have been of good quality. The price year was not reported, making it unclear if the costs were adjusted for inflation. Discounting was not required as the time horizon was six months. Analysis and

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						GP or dermatologist visits. The cost of investments, including the digital camera, website, and training for the GPs and dermatologists, was included for teledermatology. The resource use was based on data from the PERFECTD trial. The unit costs were mainly from the Dutch Manual for Costing, while market prices and expert opinion		results: A synthesis of costs and benefits was not carried out, as a cost-minimisation analysis was conducted. The authors justified this type of analysis on the grounds of the equal efficacy of the two interventions. The sensitivity analysis used both a deterministic and a probabilistic approach and extensively investigated the uncertainty. The authors compared their findings

						were used for some investment costs. All costs were presented in Euros (EUR).		with the results of another published study and discussed some limitations of their study.
Loane 2000	To evaluate the clinical efficacy and cost-effectiveness of real-time and store-and-forward telederm atology along with a clinical trial.	Patients with dermato logical conditio ns requirin g a specialis t referral in the view of their treating GP.	-Societa l perspe ctive -Time horizo n: the same as the length of the clinical trial	Store-and-forward telederm atology versus real-time telederm atology for patients with all skin condition s.	Cost-benefit analysis .	The effectiveness and cost evidences were both from a part of randomised controlled trial conducted in the first 12 months of the UK teledermatol ogy trial. Patient clinical outcomes and costs of the RT consultation	Diagnostic concordances: -Primary diagnosis 51/84 (60.7%) -Aggregated diagnosis 74/84 (88.1%) Clinical outcomes (hospital appointment required) Real-time: N=43 SAF: N=66 Consultation time (mean±SD) Real-time:	Comparator: The selection of the comparator was appropriate. Validity of estimate of measure of effectiveness The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The

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						were compared with patient clinical outcomes and costs of the SAF consultation. The concordance between the diagnostic and management decisions made at both consultations was determined later by the third consultant dermatologist. Costs	15.7±4.6 SAF: 1.6±0.7 Costs: -Variable costs Real-time: £39.25+29.83+5.99+1.89= £76.96 SAF: £4+9.5+4.76+1.89= £20.15 -Fixed costs Real-time: £49456*50 SAF: £2380 -Savings (non-referrals) Real-time: £9.74 SAF: 0 -Benefits (equivalent cost of GP training)	use of a randomised trial is able to ensure a high internal validity. Validity of estimate of measure of benefit The benefit measure was specific to the intervention considered in the study. However, it is not comprehensive enough to reflect all the benefits derived from the intervention (e.g. saved waiting time to receive treatment).

						-variable cost: (1).determined by consultation time (2) cost of travel (not reported in the current study) -fixed cost: Equipment cost for real-time and store-and-forward teleconsultations. Benefits: Avoided dermatological hospital referrals by GPs.	Real-time: £ 60.04 SAF: 0 -Net societal cost Real-time: £132.10 SAF: £26.90 Authors' conclusions The store-and-forward consultation was cheaper, but less clinically efficient, compared with the real-time consultation. The absence of interaction in a store-and-forward consultation limits the dermatologist's ability to obtain clinically useful information in order to diagnose	Validity of estimate of costs The authors stated explicitly the perspective that was adopted in the study. Detailed information on the cost items included was provided, although the cost for travelling was published in previous study (the detailed results were not reported here). Sensitivity analysis was not

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							and manage a patient satisfactorily.	performed.
Moreno-Ramirez 2009	To conduct an economic analysis of a store-and-forward telederm atology system for the routine triage of skin cancer patients. A cost-identification, cost-effectiveness and sensitivity analysis under a societal perspecti	Patients being referred from primary care centres with suspected skin cancers.	- Societal perspective -Time horizon: between March 2004 and July 2005.	Store-and-forward telederm atology versus conventional care for patients with suspected skin cancers.	Cost-effectiveness analysis.	The effectiveness evidence was from a non-randomised comparative study conducted between March 2004 and July 2005. Cost components include fixed costs (Equipment, e.g. computer, digital camera) and variable costs (Preparation and submission of	Average total cost per patient SAF teledermatology: €79.78 Conventional: €129.37 ($p < 0.005$) Average cost for travel per patient SAF teledermatology: €6.01 Conventional: €13.2 Average lost productivity cost per patient	Comparator: The selection of the comparator was appropriate. Validity of estimate of measure of effectiveness The effectiveness evidence came from a clinical trial, which was appropriate for the study question. Validity of estimate of measure of benefit

	ve was used to compare telederm atology with the conventi onal care alternativ e.					teleconsultat ion at primary care centre, evaluation of teleconsultat ions by dermatologis t, FTF visit at local dermatologis t, FTF visit at skin cancer clinic, travel to skin cancer clinic by patient, working time lost by patient. *Telecommu nication cost over the intranet considered negligible and not included in the cost	SAF teledermatology: €12.6 Conventional: €27.5 Statistically significant inverse relationship between average unit cost of teleconsultation and the number of teleconsultations ($p < 0.001$). Average waiting interval (days) SAF teledermatology:1 2.31 Conventional:88.6 2 ICER	The benefit measure was specific to the intervention considered in the study. However, it is not comprehensiv e enough to reflect all the benefits related to those two interventions. Validity of estimate of costs The authors stated explicitly the perspective that was adopted in the study. Detailed information

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						analysis.	Cost-saving of €0.65 per waiting day avoided. Authors' conclusions SAF teledermatology is cost-effective for managing referrals in skin cancer clinics in a public health system equipped with an intranet.	on the cost items included was provided.
van der Heijden 2011	This study prospectively investigated the effect of telederm atology on efficiency, quality	The study population comprised patients referred for a dermatology consulta	-The secondary healthcare system perspective -time horizo	Store-and-forward telederm atology versus conventional care for patients with all skin	Cost-analysis	The efficiency data were from the prospective cohort study. Efficiency of SAF was measured by	Efficiency Teledermatology prevented 74% (n=19741/26596) of physical referrals. Quality -A TDC was performed for	Comparator: The selection of the comparator was appropriate. Validity of estimate of costs

	and costs of care when integrated in daily practice and applied following patient selection by the general practitioner (GP).	tion with all skin conditions	n was not clearly defined	conditions.		the number of physical referrals prevented. Quality was expressed as the number of TDCs performed for second opinion, as physical referrals resulting from these teleconsultations, response time of the dermatologists and the educational effect experienced by the GP. Costs: Cost of physical	second opinion in 29% of the cases (n=10611). Among those, 16% (n=1723) were referred to the dermatologist on the dermatologist's advice. -mean response time TDC 4.6 h (median 2.0, range 1.5 min-49 days) -GP's learning experience A lot (17%)/substantial (39%)/slightly (29%)/not at all (15%) -helpfulness to dermatologist	The authors stated explicitly the perspective that was adopted in the study. Only the consultation costs were included in the cost analysis. The cost components included were not comprehensive enough.

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						consultation, cost of teledermatology consultation, and cost of TDCs for referral prevention.	A lot (25%)/substantial (42%)/slight (20%)/not at all (13%) Costs (weighted average costs per patient) -conventional €192.00 -TDC €157.06 Authors' conclusions Teledermatology can lead to efficient care probably at lower cost. We are therefore of the opinion that teledermatology following GP selection should be considered as a possible pathway	

							of referral to secondary care.	
Whited 2003	To incorporate the clinical outcomes from a clinical trial with cost estimates to report a cost analysis and a cost-effectiveness analysis to compare a conventional dermatology consult	The study population comprised patients referred for a dermatology consultation.	-The Veteran Affair Health Care system perspective -The setting was secondary care. The economic study was performed in the USA.	A store-and-forward telederm atology (TD) service for patients referred for a dermatology consultation was examined. The consultant dermatologist reviewed a digital image and a standardised history,	Clinical trial based cost-effectiveness analysis. -The study sample comprised 275 patients, of which 140 were in the UC group and 125 in the TD group. Other inform	-The effectiveness evidence came from a prospective, randomised clinical trial that was carried out at a single centre. Of the 110 TD patients who were scheduled for a clinic visit, 21 (19.1%) did not present for their visit. One patient was not scheduled but showed for a clinic visit anyway. Of the 140	-In the base-case analysis, the median time to initial definitive intervention was 137.5 days for UC and 50 days for TD (p=0.0027). This resulted in an incremental effectiveness of 87.5 days. Variations performed in the sensitivity analysis did not alter substantially the base-case results, and the incremental effectiveness of TD ranged from 86 to 87.5 days. -Cost results In the base-case analysis, the	Selection of comparators The selection of the comparator was appropriate as it reflected the conventional approach to patient management. The authors made an extreme comparison in the model, because exclusive use of TD was compared with exclusive use of UC. Validity of estimate of

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	with a store-and-forward telederm atology system.			in addition to a text-based electroni c request, and then evaluated whether to schedule the patient for a clinic-based evaluatio n or to relay a diagnosis and treatment plan back to the referring clinician.	ation on the study sample was not provide d.	UC patients, 27 (19.3%) did not present. Further details on the study design were not reported.(W hited 2002) -The analysis of the clinical study used actual clinic visit data. These data were derived from clinic visit occurrences and accounted for no-show rates or non-compliance with clinic visit recommenda tions.	annual cost of treating 5,440 patients was $198,016 with TD and $116,416 with UC. Thus, the average cost per patient was $21.40 for UC and $36.40 for TD. The incremental cost per patient was $15. The sensitivity analysis showed that the incremental cost per patient did not vary substantially in the alternative scenarios (the incremental cost varied from $10.50 to $13.85).	measure of effectiveness The effectiveness evidence came from a clinical trial, which was appropriate for the study question. However, the study had been published already and limited information on the methods, study sample and results was provided. The use of a randomised trial ensures a high internal validity. However, it was not

						-The summary benefit measure was the median time to the initial definitive intervention. This was obtained using a modelling approach. -Indirect cost was only accounted for in the sensitivity analysis. -It was assumed that a dermatology clinic visit would take a	Similarly, unrealistic variations in the base-case model inputs were required for TD to be cost-saving over UC. The two-way sensitivity analysis revealed that the three variables that showed the potential of having cost-savings thresholds (although at very extreme values) were the probability of a TD patient being scheduled for a clinic visit, clinic visit cost, and travel cost. The inclusion of	possible to draw any conclusions on the robustness of the estimate measures, owing to the lack of information. Validity of estimate of measure of benefit The summary benefit measure was specific to the intervention considered in the study and is not comparable with the benefits of other health care interventions.

						half-day off from work for the patient or a family member. The price year was 2001 in US dollars.	indirect costs did not alter the base-case results, although the TD costs were more comparable with UC costs. -An incremental cost-effectiveness ratio was calculated to combine the costs and benefits of the alternative diagnostic strategies. In the base-case analysis, the incremental cost per patient per day of time to initial definitive intervention saved with TD over UC was $0.17. The results of the sensitivity analysis did not vary in comparison with the base-case	Validity of estimate of costs The authors stated explicitly the perspective that was adopted in the study. Detailed information on the cost items included was provided, although the costs were presented as macro-categories. Therefore, the unit costs were not given. This reduces the possibility of replicating the analysis. Similarly,

							results (ranging from $0.12 to $0.16 per patient per day saved). Authors' conclusions The teledermatology service decreased the time to initial definitive intervention, but was more costly than usual care (UC) for a dermatology consultation. TD could be considered cost-effective in settings requiring long waiting periods for routine dermatological care.	information on the source of the costs was limited for some items. Some costs were estimated in 2001 but the price year was not reported, which makes reflation exercises in other settings difficult. The costs were treated deterministically in the base-case, but extensive variations of the base-case costs were investigated in the sensitivity analysis. The indirect costs were also included in the sensitivity

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								analysis and the method of calculation was explicitly reported. The authors noted that the variable costs could have been underestimated because the time spent by clinicians for other duties was not taken into consideration.
Pak 2009	The aim of this study was to perform a cost minimization analysis of store-and-forward	Participating subjects who were being referred from a Primary Care Clinic to a Dermat	- Department of Defence perspective -Time horizon: 4 month	SAF telederm atology versus conventional care.	Cost-minimisation analysis (a part of a randomised controlled trial)	Effectiveness From a previously published randomised controlled trial Direct Costs	Average direct cost per patient SAF: US$294 Conventional: US$283 Average lost	Comparator: The selection of the comparator was appropriate. Validity of estimate of costs

	telederm atology compare d to a conventi onal dermatol ogy referral process (usual care). Because compara ble clinical outcome s were found, a cost-minimiza tion analysis comparin g incurred costs between competin g, yet	ology Clinic with various dermato logic conditio ns.	s			Dermatolog y consultation, teledermatol ogy consultation, primary care visit, laboratory tests, laboratory preparations, procedures (including biopsies, laser therapy, UV therapy, and surgery), radiological tests, and medications. Indirect Costs Lost productivity cost for seeking	productivity cost per patient SAF: US$47 Conventional: US$89 Total cost per patient SAF: US$340 Conventional: US$372 Sensitivity analysis Not performed	The authors stated explicitly the perspective that was adopted in the study. A series of cost components were included in the analysis. However, the start-up fee, on-site training, internet access fee and annual maintenance fee were not considered.

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	equally effective, strategies is the analytic strategy employed for this study.					treatment was included as a cost borne directly by the department.	Authors' conclusions From a Department of Defense perspective, SF teledermatology is a cost-saving strategy compared with conventional consultation when costs associated with lost productivity are considered.	

*sourced from the Centre for Review and Dissemination, University of York, United Kingdom.

Appendix F Assessment of the body of evidence

Table 88 Designations of levels of evidence according to type of research question (including table notes) (NHMRC 2008).

Level	Intervention [1]	Diagnostic accuracy [2]	Prognosis	Aetiology [3]	Screening Intervention
I [4]	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard,[5] among consecutive persons with a defined clinical presentation[6]	A prospective cohort study[7]	A prospective cohort study	A randomised controlled trial
III-1	A pseudo randomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard,[5] among non-consecutive persons with a defined clinical presentation[6]	All or none[8]	All or none[8]	A pseudo randomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: ▪ Non-randomised, experimental trial[9] ▪ Cohort study ▪ Case-control study ▪ Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-control study
III-3	A comparative study without concurrent controls: ▪ Historical control study ▪ Two or more single arm study[10] ▪ Interrupted time series without a parallel control group	Diagnostic case-control study[6]	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: ▪ Historical control study ▪ Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)[11]	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series

Table notes

[1] Definitions of these study designs are provided on pages 7-8 How to use the evidence: assessment and application of scientific evidence (NHMRC 2000b).

[2] The dimensions of evidence apply only to studies of diagnostic accuracy. To assess the effectiveness of a diagnostic test there also needs to be a consideration of the impact of the test on patient management and health outcomes (Medical Services Advisory Committee 2005, Sackett and Haynes 2002).

[3] If it is possible and/or ethical to determine a causal relationship using experimental evidence, then the 'Intervention' hierarchy of evidence should be utilised. If it is only possible and/or ethical to determine a causal relationship using observational evidence (ie. cannot allocate groups to a potential harmful exposure, such as nuclear radiation), then the 'Aetiology' hierarchy of evidence should be utilised.

[4] A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence. Systematic reviews of level II evidence provide more data than the individual studies and any meta-analyses will increase the precision of the overall results, reducing the likelihood that the results are affected by chance. Systematic reviews of lower level evidence present results of likely poor internal validity and thus are rated on the likelihood that the results have been affected by bias, rather than whether the systematic review itself is of good quality. Systematic review quality should be assessed separately. A systematic review should consist of at least two studies. In systematic reviews that include different study designs, the overall level of evidence should relate to each individual outcome/result, as different studies (and study designs) might contribute to each different outcome.

[5] The validity of the reference standard should be determined in the context of the disease under review. Criteria for determining the validity of the reference standard should be pre-specified. This can include the choice of the reference standard(s) and its timing in relation to the index test. The validity of the reference standard can be determined through quality appraisal of the study (Whiting et al 2003).

[6] Well-designed population based case-control studies (eg. population based screening studies where test accuracy is assessed on all cases, with a random sample of controls) do capture a population with a representative spectrum of disease and thus fulfil the requirements for a valid assembly of patients. However, in some cases the population assembled is not representative of the use of the test in practice. In diagnostic case-control studies a selected sample of patients already known to have the disease are compared with a separate group of normal/healthy people known to be free of the disease. In this situation patients with borderline or mild expressions of the disease, and conditions mimicking the disease are excluded, which can lead to exaggeration of both sensitivity and specificity. This is called spectrum bias or spectrum effect because the spectrum of study participants will not be representative of patients seen in practice (Mulherin and Miller 2002).

[7] At study inception the cohort is either non-diseased or all at the same stage of the disease. A randomised controlled trial with persons either non-diseased or at the same stage of the disease in both arms of the trial would also meet the criterion for this level of evidence.

[8] All or none of the people with the risk factor(s) experience the outcome; and the data arises from an unselected or representative case series which provides an unbiased representation of the prognostic effect. For example, no smallpox develops in the absence of the specific virus; and clear proof of the causal link has come from the disappearance of small pox after large-scale vaccination.

[9] This also includes controlled before-and-after (pre-test/post-test) studies, as well as adjusted indirect comparisons (ie. utilise A vs B and B vs C, to determine A vs C with statistical adjustment for B).

[10] Comparing single arm studies ie. case series from two studies. This would also include unadjusted indirect comparisons (ie. utilise A vs B and B vs C, to determine A vs C but where there is no statistical adjustment for B).

[11] Studies of diagnostic yield provide the yield of diagnosed patients, as determined by an index test, without confirmation of the accuracy of this diagnosis by a reference standard. These may be the only alternative when there is no reliable reference standard.

Note A: Assessment of comparative harms/safety should occur according to the hierarchy presented for each of the research questions, with the proviso that this assessment occurs within the context of the topic being assessed. Some harms are rare and cannot feasibly be captured within randomised controlled trials; physical harms and psychological harms may need to be addressed by different study designs; harms from diagnostic testing include the likelihood of false positive and false negative results; harms from screening include the likelihood of false alarm and false reassurance results.

Note B: When a level of evidence is attributed in the text of a document, it should also be framed according to its corresponding research question eg. level II intervention evidence; level IV diagnostic evidence; level III-2 prognostic evidence.

Source: Hierarchies adapted and modified from: NHMRC 1999; Bandolier 1999; Lijmer et al. 1999; Phillips et al. 2001.

Table 89 Grading system used to rank included studies

Validity criteria	Description	Grading System
Appropriate comparison	Did the study evaluate a direct comparison of the index test strategy versus the comparator test strategy?	C1 direct comparison CX other comparison
Applicable population	Did the study evaluate the index test in a population that is representative of the subject characteristics (age and sex) and clinical setting (disease prevalence, disease severity, referral filter and sequence of tests) for the clinical indication of interest?	P1 applicable P2 limited P3 different population
Quality of study	Was the study designed and to avoid bias? High quality = no potential for bias based on pre-defined key quality criteria Medium quality = some potential for bias in areas other than those pre-specified as key criteria Poor quality = poor reference standard and/or potential for bias based on key pre-specified criteria	Q1 high quality Q2 medium Q3 poor reference standard poor quality or insufficient information

Quality

The appraisal of intervention studies pertaining to treatment safety and effectiveness was undertaken using a checklist developed by the NHMRC (NHMRC 2000a). This checklist was used for trials and cohort studies. Uncontrolled before-and-after case series are a poorer level of evidence with which to assess effectiveness. The quality of this type of study design was assessed according to a checklist developed by the UK National Health Service (NHS) Centre for Reviews and Dissemination (Khan et al 2001). Studies of diagnostic accuracy were assessed using the QUADAS quality assessment tool (Whiting 2003).

Statistical precision

Statistical precision was determined using statistical principles. Small confidence intervals and p-values give an indication as to the probability that the reported effect is real and not attributable to chance (NHMRC 2000b). Studies need to be appropriately to ensure

Size of effect

For intervention studies of intervention name it was important to assess whether statistically significant differences between the comparators were also clinically important. The size of the effect needed to be determined, as well as whether the 95% confidence interval included only clinically important effects.

Relevance of evidence

The outcomes being measured in this report should be appropriate and clinically relevant. Inadequately validated (predictive) surrogate measures of a clinically relevant outcome should be avoided (NHMRC 2000b).

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Glossary and abbreviations

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