

PRACTICE GUIDELINES FOR DERMATOLOGY

APRIL 2016



ACKNOWLEDGEMENTS

The American Telemedicine Association (ATA) wishes to extend its sincere appreciation to the ATA Teledermatology Guidelines Work Group and the ATA Practice Guidelines Committee for the development of these guidelines. Their hard work, diligence and perseverance are highly appreciated.

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PREAMBLE

The American Telemedicine Association (ATA) brings together diverse groups from traditional medicine, academia, technology and telecommunications companies, eHealth, allied professional and nursing associations, medical associations, government, military, regulatory and others to address and advance compliance with legal, ethical, and professional standards in the practice of telemedicine.

ATA has embarked on an organized effort to establish guidelines for the practice of telemedicine in various clinical applications to assure uniform quality of service for patients and providers, to enhance patient experience, and to enable providers to deliver appropriate care. The guidelines are developed by panels that include experts from the field and other strategic stakeholders, and are designed to serve as a standard reference and educational tool for professionals to provide appropriate care for patients. The process for developing these guidelines is based on professional consensus and a rigorous review including open public commentary period, with final approval by the ATA Board of Directors. Guidelines are reviewed and updated periodically.

The purpose of these guidelines is to assist providers in pursuing a sound course of action in providing effective and safe medical care that is founded on current scientific knowledge, technological requirements, and patient needs. Safe and effective practice requires technical training, professional knowledge and skill, and explicit processes, as described in each document. All guidelines issued by the ATA are properties of the ATA. Any modification or reproduction of the published guideline must receive prior approval by the ATA.

Compliance with these guidelines alone will not guarantee accurate diagnoses, appropriate clinical treatment or optimal outcomes. A divergence from the guidelines **may** be indicated under certain conditions, such as emergency situations in places with limited resources that call for prompt action to attend to the patient. Similarly, technological advances may alter prevailing practices or provide new and expanded opportunities.

The technical and administrative guidelines in this document do not purport to establish binding legal standards for delivering telemedicine services. They are based on the accumulated knowledge and experience of the ATA workgroups and other professionals.

• The previous ATA Teledermatology Practice Guidelines were issued in 2007. This is the revised version reflecting new knowledge in the field, new technologies, and the need to incorporate teledermatology practice in a variety of settings including hospitals, urgent care centers, Federally Qualified Health Centers, school-based clinics, public health facilities and patient homes.

SCOPE

The teledermatology guidelines apply to individual providers, group and specialty practices, hospitals and healthcare systems when providing services via information and communication technology (ICT) as a substitute for or an adjunct to in-person care.

The users of these guidelines are urged to review and comply with professional guidelines within their domain of practice as they pertain to prevention, diagnosis, treatment, and follow-up of skin disorders.

These guidelines pertain primarily to healthcare providers and patients located in the United States (U.S). When either or both parties are not within the jurisdiction of the U.S applicable local guidelines and protocols take precedence according to the rules of prevailing jurisdictions. [1,2]

The guidelines address three aspects of service delivery: clinical, technical and administrative. Under each set, the guidelines are classified according to four levels of adherence, shown in bold throughout the document:

- "Shall," indicates required action or adherence whenever feasible and/or practical.
- "Shall not" indicates a proscription or action that is strongly advised against.
- "Should" indicates a recommended action without excluding others.
- **"May"** indicates pertinent actions that may be considered to optimize the telemedicine encounter.

INTRODUCTION

The practice of dermatology is particularly suited to telemedicine because skin disorders are visible to the human eye, and clinical information can be acquired, stored, and transmitted for accurate diagnosis and appropriate treatment in the majority of cases. Cases that require biopsy can also be identified and appropriate referral initiated promptly. The practice of teledermatology can alleviate the maldistribution of specialty care, and enable patients not located in geographic proximity of expert resource to receive care. The following guidelines are designed to establish coherent, effective, safe and sustainable standards for the practice of teledermatology.

The Guidelines cover three areas, reflecting the processes associated with most teledermatology consultations: Clinical Practice, Technical Requirements, and Administration. They **may** be use together with the Core Operational Guidelines for Telemedicine Services Involving Provider-Patient Interactions, and ATA Practice Guidelines (3,4) for Live On Demand Primary and Urgent Care (2014).

These guidelines pertain to the three modes typically used for teledermatology: store-andforward (S&F) or transmitting digital images and associated patient data to the specialist for consultation at a later time; real-time video teleconferencing (VTC) in which providers and patients interact via live videoconferencing; and hybrid (utilizing both S&F and VTC). There is a growing body of evidence regarding the effectiveness of synchronous and asynchronous teledermatology for a variety of skin disorders that present in diverse practice settings including emergency departments, hospitals, patient homes, schools, chronic care facilities, the workplace, and the military.

Teledermatology has been found to be reliable for accurate diagnosis and treatment plans for skin disorders. (5-41). With some exceptions, the preponderance of the evidence confirms the diagnostic accuracy of teledermatology compared to in-person encounters (9, 13, 21, 28, 29, 41-48); as are, management/treatment recommendations (6, 11-13, 15, 21-23, 25, 26, 28-31, 33, 37, 43, 45, 46-53) Clinical outcomes and quality of life measures are similar as well for telemedicine and in-person care. (54-59) (60-64) Moreover, patients, referring clinicians, and dermatologists have expressed high levels of satisfaction with teledermatology, (15, 23, 33, 34, 38, 65-80) as it facilitates access to dermatologic expertise for patients who are geographically or logistically challenged.

PRACTICE GUIDELINES

In teledermatology, store-and-forward (S&F) communication typically refers to the sending or forwarding of digital images and associated patient data to the specialist for storage and consultation at a later time. For real-time video teleconferencing (VTC), providers and patients interact via live videoconferencing. These recommendations apply to S&F, VTC and hybrid (utilizing both S&F and VTC) modes for teledermatology.

CLINICAL PRACTICE GUIDELINES

Many skin conditions lend themselves to a telemedicine consult as defined in this document. Typically, these include conditions for which there is reasonable certainty of establishing a diagnosis and generating a treatment plan on the basis of visual information and access to a medical record. The ultimate decision for a teledermatology consult is made by the patient, the referring provider and the teledermatologist.

These guidelines define appropriate conditions and parameters for the safe and effective practice of telemedicine on current evidence. They are not intended to substitute for independent medical judgments that pertain to individual circumstances.

Both referring providers and consultants (hereafter referred to as providers) **shall** exercise their professional judgment regarding the appropriateness of telemedicine on a case by case basis, taking into account the presenting condition, their ability to make a definitive diagnosis, and their comfort and expertise. Providers **shall** observe relevant practice guidelines and position statements developed by the American Academy of Dermatology and other related professional organizations.

I. PRELIMINARY CONSIDERATIONS

A. Patient-Provider Relationship

Providers **shall** conform to all applicable state and federal regulations that pertain to the practice of medicine, including the establishment of a provider-patient relationship and the appropriate conditions for making diagnostic and treatment decisions - including prescribing. If the patient does not have a primary care provider, the consulting provider **should** recommend appropriate options to assure continuity of care. Practice organizations **should** establish standard operating procedures and workflows for telemedicine consults consistent with prevailing rules and norms.

B. Informed Consent

Prior to the initiation of a telemedicine encounter, the provider or designee **shall** secure patient consent to be treated, as required by local or state regulations. This can be done in writing or verbally, and it **should** include an explanation of the benefits and risks of telemedicine encounters. The language **shall** be simple and understandable by the average patient.

This explanation shall include:

- The nature of the telemedicine encounter, including any technical limitations or potential for disruption and contingency plans
- Procedures for coordination of care with other professionals, as indicated
- Protection of patient identifiable information
- Credentials of the distant site teledermatologists
- Explicit emergency plan for patients in settings without access to clinical staff
- Conditions under which telemedicine services **may** be terminated and a referral made to in-person care
- Billing arrangements, if appropriate

C. Physical Environment

The provider **shall** determine the level of distraction (e.g., noise), infringement on privacy, and other environmental conditions that **may** affect the quality of the encounter. In live-interactive encounters, the following conditions **shall** be observed:

- Both patient and provider room/environment **shall** ensure visual and auditory privacy.
- All persons in the examination room at both sites **shall** be identified prior to the consultation; and it **shall** be verified that all are visible and can be heard.
- Seating and lighting **should** be designed for both comfort and professional interaction. Background light from windows or other sources **should** be minimized.
- Cameras **should** be placed on a secure, stable platform to avoid unnecessary movement during the videoconferencing session, and **should** be placed at the same elevation as the eyes with the face clearly visible to the other person.

II. Telemedicine Management of the Patient

Providers **shall** determine the appropriateness of telemedicine on a case-by-case basis, and whether the patient must be seen in person and for what purpose. This information **shall** be documented in the patient's record consistent with relevant standards in evaluating the patient.

A. Patient Evaluation and Examination

The provider **shall** obtain the data necessary for making a diagnosis, differential diagnosis, workup if appropriate, and treatment plan, including:

- Identifying information (e.g., age, gender, race)
- Chief complaint(s)
- History of present illness (including location, description, size, quality, severity, duration, timing and context modifying factors such as prior treatments and responses to treatments)
- Associated signs and symptoms
- Past medical history, if pertinent
- Family history, if pertinent
- Medications
- Allergies including nature, severity of reaction, and treatment
- Adequate diagnostic quality images, as available
 Diagnostic data (e.g., obtained via self-report or access to databases) and laboratory test results

Special Considerations: The referring and consulting providers **shall** decide whether to exclude certain types of cases that require special consideration:

- Full body examination: A full body skin scan using videoconferencing (VTC) or store-and-forward (S&F) is feasible, but it may not show all skin lesions and surfaces with sufficient detail. Enhanced lighting, multiple imaging and several angles may be helpful.
- *Hair-bearing skin*: The scalp and other areas with a significant amount of hair **may** need to have hair physically displaced or removed, and special lighting **may** enhance viewing conditions.
- Pigmented lesions: Pigmented lesions may present a diagnostic challenge and should require a higher index of suspicion when interpreting. Peripheral devices such as dermatoscopes and confocal microscopy may be incorporated into teledermatology consultations (1, 27, 50, 74, 82, 93, 131).
- *Mucosal lesions*: Mucosal lesions and orifices, including genitalia, often require special attention to lighting and exposure in order to allow examination.
- *Skin color*: Lighting and background conditions **may** change the color of skin lesion captured in images.

B. Follow-up and Care Coordination

Continuity of care is a critical element in quality of medical care and patient well-being. Hence, teledermatologists **should** make every attempt to identify the patient's usual provider and local medical resources to coordinate care and make referrals as indicated.

The teledermatologist **shall** communicate results of the encounter to the patient's referring provider and/ or to the patient, using secure electronic methods in addition to verbal communication in live-interactive encounters.

A follow-up plan after the encounter **shall** be developed and communicated with the patient and/or the referring provider. This includes any required follow up, referrals, as well as clinical signs that signify a significant exacerbation. Laboratory and other diagnostics ordered **shall** be followed up in a timely manner with the patient and their providers, as indicated and necessary.

C. Documentation

Each patient encounter **shall** be documented and maintained in a secure, HIPAA (Health Insurance Portability and Accountability Act) compliant form and location. Documentation **shall** include at a minimum the diagnosis and/or differential diagnosis and recommended management/treatment plan and **shall** include a summary of the findings. Documentation **shall** adhere to all medical-legal standards of care, and, if appropriate, insurance requirements for future review and audit. Providers **shall** maintain up to date business associate agreements with technology suppliers and other vendors who have access to patient's personal health information

Language used to document the encounter **may** include: "*Based on the images and history provided, my impression is as follows.*"

Recording of live-interactive encounters is optional, unless it is required in particular settings. Patient consent is necessary when the recoding is made for quality assurance, training or research purposes. A written record of the consult **shall** be kept at least at one site (referring provider or consultant).

In store-and-forward encounters, electronic, faxed, mailed or e-mailed notes **shall** become part of the patient's medical record, including any teledermatologist annotations.

The referring provider and teledermatologist **should** establish an explicit process for patients to request copies of their telemedicine encounters.

III. Quality

Providers **shall** employ a continuous quality improvement program, including a clinical oversight process.

The quality improvement program includes:

- technical or administrative failures
- appropriateness of virtual encounter
- patient and/or provider satisfaction
- patient outcomes
- pathology or imaging results
- recommendations for follow-up

IV. Ethical Considerations

Telemedicine practice **shall** conform to the same professional ethics that govern in-person care. Telemedicine providers **shall** incorporate ethical statements and policies and legal/regulatory requirements into their standard operating procedures, including:

- An explicit code of ethics.
- Compliance with federal, state, and jurisdictional laws and regulations, and institutional policies.
- Non-discrimination clause regarding denial of service to individuals on the basis of location, socio-economic status, disease or disability, gender, gender preference or sexual orientation, ethnicity, national origin or religious affiliation.
- Provision of service **should** not be conditional upon receipt of payment by the patient

V. Direct-to-Patient Care

Based on the limited data available from the emerging practice of direct-to-patient teledermatology and some potential concerns regarding quality, third-party benefits, follow-up, and disclosures, anyone practicing direct-to-patient teledermatology **shall** develop and implement an explicit quality assurance plan and proper disclosures. The disclosure can be posted on a Website, software application or other information source, and **should** include basic information on professional qualifications, credentialing and privileging; the nature of the service provided (such as consultations, referrals and follow-up); participation in networks or health systems; and patient-relevant information such as quality assurance mechanism in place and patient access to their records.

TECHNICAL GUIDELINES

I. Communication Modes and Applications

All efforts **shall** be taken to use appropriate ICT modalities with authentication, verification, confidentiality, and security arrangements and with full compliance with HIPAA laws. Software platforms **should** not be used when they incorporate social media.

II. Devices and Equipment

Devices **shall** have up-to-date antivirus software and a system-wide firewall with security patches and updates on the operating system and third party applications.

Providers/organizations **shall** use device management software to provide consistent oversight of applications, devices and data configurations and security.

Organizations and providers **shall** ensure that equipment and connectivity are functioning properly with regular testing and maintenance.

III. Image Quality

Image quality is essential for providing teledermatology service. This applies to both synchronous and asynchronous encounters. The following technical specifications **shall** be observed:

A. Requirements for Real-time Videoconferencing (synchronous encounters)

The technology **shall** meet the following specifications:

- H.264 video compression standard or higher
- H.323 compliant
- H.261 video compression standard compatibility
- G.711 audio compression standard or higher
- Live video resolution 4CIF (704x480) or higher
- Content resolution XGA (1024x768) or higher
- Capability of connecting at 384kbps running 4CIF @ 30fps
- Minimum of 384 kbps connection speed between referral and consultant sites
- Different technologies **may** render different video quality at the same bandwidth; hence each end point **shall** use bandwidth sufficient to achieve clinical quality.
- Where practical, providers **may** recommend preferred video conferencing software and/or video and audio hardware to the patient, as well as providing any relevant software and/or hardware configuration considerations.
- The providers and patients **may** use link bandwidth test tools to determine connectivity before starting the session to ensure sufficient quality of service.
- Wired links provide the most reliable connectivity on the Internet, and they **should** be used when available.
- The videoconference software **should** adapt to changing bandwidth availability without losing the connection. If feasible, redundant systems **should** be in place.

Lighting

Background lighting **should** be minimized, and additional indoor lighting using fluorescent daylight or full spectrum bulbs **may** be needed to augment the illumination device on the examination cameras.

Views

The imager **should** hold the camera at a distance to show the general distribution of the skin lesion(s) before obtaining close-up images (usually about 24" for most body areas). When moving the camera to show the distribution and other details, the imager **should** request feedback regarding the speed of camera movement from the dermatologist to ensure adequate image quality. Oblique views **may** be included to show skin surface changes.

Positioning

If the camera does not contain an image viewer, it is important to position the patient (as feasible) in between the camera and the videoconference monitor in one line of sight.

Verbalization of Body Regions Being Examined

The imager **shall** identify the part of the body being imaged, noting important characteristics such as size, color, and appearance of skin.

Focus

Camera angle must be perpendicular to the skin for close-up images, noting the distance to the skin lesion(s), and the camera must be held as still as possible.

Freeze-frame Capture

Most video cameras are equipped with a freeze-frame feature, which is useful for diagnosis, especially when bandwidth (connectivity speed) is low. Freeze-frames allow the dermatologist to appreciate fine features of skin lesions and minimize image degradation that occurs when scanning with the camera.

Color

Viewing devices may be color calibrated. A MacBeth color chart may be useful.

Other

Avoid distracting jewelry and clothing. Use measurement tools to show size and distribution, appropriate.

B. Requirements for Asynchronous Imaging

Digital Cameras

Digital cameras **shall** be used for image acquisition, with a minimal resolution of 1024x768 pixels (0.8 megapixel), preferably 3264x2448 pixels (8-megapixel) or greater

Macro mode

Macro mode capability is ideal (close-up mode or "flower" image).

Background

Use a solid, neutral color with a non-reflective surface

Lighting

Diffuse, indirect light is optimal, using fluorescent daylight or full spectrum bulbs (avoid incandescent). If outdoors use well-lit areas, or evenly shaded areas if sunny.

Flash

Use flash to help eliminate shadows, but it **may** cause white out if too close.

Compression

Use JPEG medium or low setting (no more than 20:1).

Focus

Adjust camera and patient to have camera angle perpendicular to the skin lesions being imaged. Use autofocus with area of interest in center of frame. If not possible, focus first on the area of interest, depress shutter button half-way to focus, and then move the camera to center the image before fully depressing shutter button.

Color

Viewing devices may be color calibrated. MacBeth color chart may be useful.

White Balance

The imaging device **shall** be calibrated for white balance by taking a picture of white or gray card. The image can be used to set the white balance by accessing custom white balance (typically available under camera settings). The white balance calibration **should** be recalibrated if there is a change in the physical location of the imaging device or lighting in the room.

Views

A chaperone or legal guardian **should** be used as required or appropriate.

If more than one area is involved, all regions involved **should** be included. Take images to show location and arrangement of lesion(s). Take several views.

- Far entire body or obvious region
- Medium include an anatomical landmark such as the navel or hand
- Close-Up if the camera has a macro capacity (the "flower" image) an image can be taken within 18 inches from the skin; otherwise use the optical zoom, if available for a close-up. Use perpendicular and oblique views for close-up.

Complementary views **should** be included. For example, if the hands are involved, take photos of the feet, knees and elbows (additional examples located in the ATA Quick Guide to Store-and-Forward Teledermatology for Referring Providers) (See Appendix)

Peripheral devices such as dermatoscopes and confocal microscopy **may** be incorporated into teledermatology consultations. Images **should** be obtained using a hybrid or polarized dermatoscope.

Dermoscopy_images **may** be taken with a dermatoscope less than 2 inches from the skin (non-contact mode) and touching the skin after cleaning the instrument and skin with alcohol pads (contact mode) to improve luminance.

Distracting jewelry and clothing **should** be removed prior to imaging.

Lesions **should** be identified. Identification markers **should** be placed adjacent to the lesion without covering any portion of it. *On the skin*: Lesions can be identified using adhesive labels, surgical tape, washable markers or other removable tools. Before sending the image, the user **should** add a digital circle, box or arrow to the image. A ruler **should** be included in each image (general and close-up) in close proximity to the lesion so that size/extent can be determined from the image.

Images shall not be altered in any way after taken.

Images, transmitted text and teledermatologist response **shall** become part of a secure, retrievable medical record.

Images **should** be reviewed during the acquisition process to ensure acceptable quality. Send only helpful and clear images to the consultant.

C. Mobile Device Use

Device Camera

All image acquisition details described above for digital cameras apply to mobile device cameras.

Applications/Software

Applications (apps) **shall** allow for images and medical information to be uploaded in a secure, HIPAA compliant and encrypted protocol, such as the Advanced Encryption Standard (AES), accessible only by secure registration and password; **may** include a protocol for reimbursement, and downloadable to an electronic patient record.

IV. Image Display

Monitors for viewing images **shall** have a minimum of 1024x768 pixel resolution, minimum contrast ratio of 500:1, minimum luminance of 250 cd/m² and minimum dot pitch of 0.19. A dedicated monitor or set of monitors **may** be used. Color calibration **may** be used to ensure the reliable color rendition.

V. Connectivity

VI. Privacy

All patient identifiable information (protected health information) **shal** be treated as confidential and protected from unauthorized use and **shall** meet recognized standards. Individuals in charge of technology **shall** familiarize themselves with the technologies available regarding computer and mobile device security.

When using a mobile device, special attention **shall** be placed on the privacy of information being communicated or stored.

Devices **shall** be configured to utilize an inactivity timeout function that requires a password or re-authentication to regain access. This timeout **should** not exceed 15-20 minutes. Mobile devices with patient information **should** be kept in the possession of the provider when traveling or in an uncontrolled environment.

Providers **should** have the capability to remotely disable or delete stored information on their mobile device if lost or stolen.

Patients **should** be informed that some software and mobile apps designed for patient use separately and permanently store or create copies of images on equipment or device, creating a possible security/privacy risk.

Access to videoconferencing sessions **shall** be limited to authorized users.

Whole disk encryption (FIPS 140-2, known as the Federal Information Processing Standard, **shall** be used when storing protected health information on the hard drive of the providers' computers.

Patients **should** be informed regarding the best ways to protect their devices and data, especially when using software, web-based or mobile apps on their own.

Providers and patients **shall** discuss any intention to record encounters or images, the purpose or use of the recording, how the information will be stored, and how privacy will be protected. Recordings **shall** be encrypted for maximum security. Access to the recordings **shall** be limited strictly to authorized users.

ADMINISTRATION GUIDELINES

I. Security

Teledermatologists **shall** keep a record of all users of electronic records to assure that only those with legitimate clinical need can have such access as stipulated by law. Use of such records for administrative, research or teaching **shall** be defined and approved by appropriate bodies, such as Institutional Review Boards.

System administrators **shall**: Keep database files in encrypted form at rest and in transit.

• Have the vendor pass a security audit and sign a Business Associate Agreement if data storage is cloud-based,

II. Privacy

III. Licensing and Credentialing

Providers **shall** follow federal, state and local regulatory and licensure requirements related to their scope of practice, and **shall** abide by state board and specialty training requirements. A provider **shall** ensure that he/she is duly licensed and credentialed in a jurisdiction in which the patient is physically located. Providers **shall** practice within the scope of their licensure and **shall** observe all applicable state and federal legal and regulatory requirements regulations related to the use of telemedicine.

The practice of medicine **shall** be defined as occurring where the *patient* is located at the time of the physician-patient encounter. As such, the provider **shall** be under the jurisdiction of the state medical board where the patient is located.

Providers who wish to be licensed in multiple states, or "interstate medical licensure" **shall** be aware of regulations and options. For example, the Federation of State Medical Boards (FSMB) has drafted the "Interstate Medical Licensure Compact" to provide an expedited licensure process for eligible physicians. The compact is expected to ease the process of gaining licensure in multiple states.

According to the Compact, eligible physician designates the *state of principal licensure* and selects the other member states where a medical license is desired. The state of principal licensure would verify the physician's eligibility and provide credential information to the Interstate Commission, which collects any applicable fees and transmit the physician's information and licensure fees to the additional states. Subsequently, the physician would be granted a license. The Compact does not change the state's existing definition of a physician within its Medical Practice Act nor the requirements for state medical licensure. The enactment of the Compact in additional states is a dynamic process, and the practitioners **should** refer to www.licenseportability.org for the latest updates.

IV. Liability

Teledermatologists **shall** be cognizant of the liability that is incurred in medical practice, whether in-person or via electronic means.

Providers **should** verify that their medical liability insurance policy covers telemedicine services, including services provided across state lines, if applicable.

APPENDIX

DEFINITIONS

Teledermatology refers to the delivery of dermatology specialty services (advice, diagnosis, treatment planning, and education) to patients and other healthcare providers remotely using information and communication technology.

Synchronous teledermatology refers to the remote provision of services online or with both provider and patient communicating at the same time.

Asynchronous (or store-and-forward) teledermatology refers to the remote provision of service at different times.

Hybrid teledermatology refers to utilizing both store-and-forward and videoconferencing modes for teledermatology.

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