

## JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



### Telemedicine Guidance in the Deployed Setting

This CPG is intended to be used as a guide to educate users in the deployed environment about the benefits and limitations of telemedicine.

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#### TABLE OF CONTENTS

<b>PURPOSE .....</b>	<b>2</b>
<b>BACKGROUND .....</b>	<b>3</b>
<b>OPERATIONAL TELECONSULTATION BEST PRACTICES .....</b>	<b>4</b>
Recognize .....	5
Execute .....	7
Images and Asynchronous File Transfer - Best Practices .....	8
Security - Cyber, OPSEC .....	8
Problem Solve .....	10
Documentation .....	11
<b>SUMMARY &amp; KEY POINTS .....</b>	<b>12</b>
<b>PERFORMANCE IMPROVEMENT .....</b>	<b>13</b>
<b>PI MONITORING.....</b>	<b>14</b>
<b>REFERENCES.....</b>	<b>15</b>
<b>APPENDIX A: PACE PLANNING FOR TELEMEDICINE .....</b>	<b>17</b>
<b>APPENDIX B: VIRTUAL CRITICAL CARE CONSULTATION (VC3) GUIDE .....</b>	<b>18</b>
<b>APPENDIX C: TECHNOLOGY REQUIREMENTS TO GET STARTED .....</b>	<b>20</b>
<b>APPENDIX D: TAKING GOOD PICTURES .....</b>	<b>21</b>
<b>APPENDIX E: COMMON TELECONSULTATION DEFINITIONS .....</b>	<b>22</b>
<b>APPENDIX F: INFORMATION REGARDING OFF-LABEL USES IN CPGS.....</b>	<b>24</b>

## Telemedicine Options

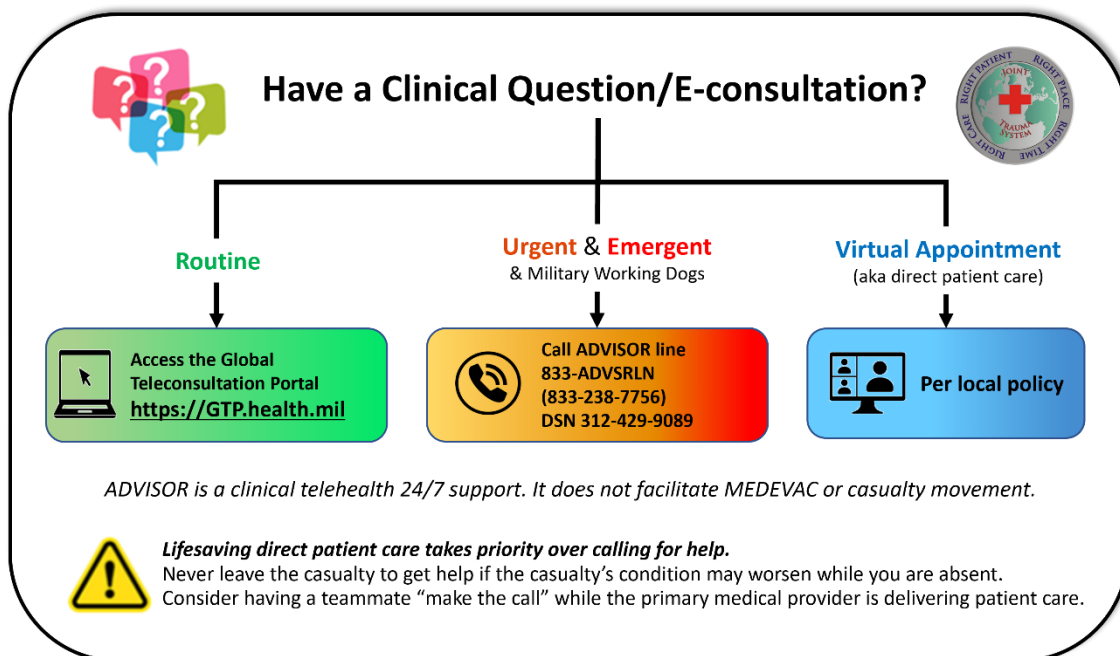


Illustration by Raymond Samonte, GTP: <https://GTP.health.mil>

## PURPOSE

Teleconsultation has been demonstrated to enhance care quality, reduce lost duty time, optimize evacuation decisions, reduce evacuation costs, and improve casualty outcome.

This Teleconsultation (TC) clinical practice guideline (CPG) is intended for use by deployed U.S. healthcare providers who are working in contingency settings outside of established Military Treatment Facilities (MTFs) and includes care of Military Working Dogs (MWDs). TC is a subset of Telemedicine (TM) or Virtual Health (VH). TM and VH are synonymous terms that refer to the overall delivery of healthcare using communications technology, usually directly to a patient with video visits. In contrast, local caregivers (LCs) who need guidance to best manage a casualty with available resources and within operational constraints use TC (sometime referred to as an eConsult) to obtain it from remote experts (REs) not physically present with the casualty. Care teams may use a variety of communications technologies to conduct TC including asynchronous solutions like text messaging, email, and web portals and synchronous solutions like chat, phone calls, and video teleconferencing. Importantly, any TM, including TC, is governed by U.S. privacy laws, including the Health Insurance Portability and Accountability Act (HIPAA).

Operational virtual health (OVH), which supports TC for deployed providers, is a collection of solutions (versus a single integrated technology platform) that have evolved over time and require specific knowledge, skills, and abilities (KSAs) for most efficient and effective use. This CPG provides this information and will be updated as the OVH system continues to evolve.

This guideline focuses on TC instead of TM because most casualties are managed by a deployed medical provider or buddy aid and, given current OVH solutions, it is more consistently available in operational settings. It is a guideline and is not intended to define a standard of care. Every deployed healthcare professional (HCP) and/or local caregiver (LC) making use of this guideline is responsible for evaluating the appropriateness of applying it in the settings of any context.

When available and used appropriately, TC is a critical enabler of better casualty care. It has been demonstrated to enhance care quality, reduce lost duty time, optimize evacuation decisions, reduce evacuation costs, and improve casualty outcome<sup>1-6</sup> but it is NOT a substitution for the deployment of necessary medical support, resources, and evacuation capabilities.

If you are a clinician expert and wish to provide TC as a RE, please contact the OVH Program Manager at the Virtual Medical Center (VMC) by sending an email from a DoD user account to [dod.advisor-office@health.mil](mailto:dod.advisor-office@health.mil). ADVISOR is ADvanced Virtual Support for OpeRational Forces.

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## BACKGROUND

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The U.S. Military has been testing telemedicine solutions for nearly 30 years.<sup>7</sup> It was not until 2017, however, that telemedicine was recognized as an operational requirement by the Special Operations community.<sup>8</sup> Although Joint- and Service-specific requirements for telemedicine remain undefined, it is clear from experience and research that OVH can enhance management of complex casualties in austere and operational environments.<sup>3,6,9-11</sup>

Importantly, OVH provides clinical expertise to the point of need. When caregivers managing casualties reach the limit of their KSAs, two options exist for ensuring a patient receives optimal care: evacuate or call for help. Calling for help has been identified as best practice when it is uncertain if a casualty needs evacuation or when evacuation is not possible. Using TC alters evacuation plans of local caregivers in more than half of cases<sup>2,3,12</sup> and saves the U.S. Military millions of dollars annually. More importantly, these consultations have improved the care provided to casualties while simultaneously enhancing the LC's KSAs through education during the consultation and the RE's through increased understanding of austere and operational contexts.<sup>9</sup>

TC's major limitation is that it requires network resources; if the network is not available, then it is not possible to conduct TC. Still many misperceptions about this limitation exist that need to be dispelled:

- TC is widely accessible and used daily in all environments without specialized communications equipment. It uses available technology: cellular, radio, satellite phone or computer via voice, text, email, internet web portals. Encryption may enhance security or protect patient information but is not a requirement for most medical applications (see below).<sup>13</sup>
- Synchronous voice using radio or phone call is sufficient for most consultations. Voice calls plus asynchronous file transfer (i.e. images) is a highly flexible and adaptable solution for delivering consultation in very austere locations.<sup>14-15</sup> Video TC is most beneficial when LCs require tele-mentoring assistance by a RE to complete a procedure (e.g., fasciotomy, external fixation).<sup>16-17</sup>
- TC is a skill set and a tool that requires training, practice, and a PACE plan (Primary, Alternate, Contingent and Emergent). A team training in TC is able to adapt to conditions on the ground and optimize care for their patient. Last TC use when recorded sets the stage for future technologies like artificial intelligence and machine learning to produce decision support solutions that do not require network resources.

- Lastly TC takes more time than you think. Conveying information to a RE about the patient to ensure the RE has a clear understanding of the casualty's problems and the clinical questions the LC needs answered are not always straight forward. The efficiency of TC may be improved by following the best practices outlined in this CPG.

Many clinicians fear TC because of concerns about a RE who may be unfamiliar with local context may be critical of care rendered in the operational setting. While this is a valid concern, it has not born out in case reviews and after-action reports. Feedback collected from real-world and training calls about LC experience with REs has been overwhelmingly positive.<sup>3</sup> Remote military experts understand operational constraints and try hard to provide consultation in context to LCs who are often faced with nearly impossible challenges to overcome.

## OPERATIONAL TELECONSULTATION BEST PRACTICES

### Prepare - Plan and Train

Operational TC begins with the PREP mnemonic: Prepare through Planning and Training; recognize when to “make the call,” execute the consultation, and problem solve challenges. Ultimately, the safety and quality of care is the responsibility of the local caregiver and therefore telemedical support in the area of engagement (AOE) requires preparation and a PACE (Primary, Alternate, Contingency, and Emergency) plan to be successful. If a local caregiver intends to have consultation available but is unable to reach a remote consultant through one communications method, alternate methods should already have been established and tested. Thus, PACE planning takes two forms, one about when to utilize telemedicine and one for how to use telemedicine. See example in Table 1. A detailed example is in [Appendix A](#).

**Table 1. PACE Planning.**

*Examples provided of general AOE conceptual care plan and telemedical technology plan.*

*Note: the telemedicine technology PACE plan supports the alternate and contingency patient care plans. Consider the power, network, and equipment items below to be independent plans that could be “mixed-and-matched” according to need and functioning. Thus, the primary power plan could support the alternate network and contingency equipment. The technology plan should build from most reliable to least reliable.*

PACE Planning		
	Patient care plan	Telemedicine Technology
Primary	Use local assets; evacuate the patient; pre-position resources (i.e. if you expect to need a surgeon, have an OR and a surgeon available).	Power: electrical grid Network: fiber or cable internet Equipment: Dedicated telemedicine equipment (i.e. VTC exam station, camera, augmented reality device)
Alternate	Use established telemedicine relationship to support care-in-place or during evacuation	Power: solar cell battery network: 4G/LTE cellular network Equipment: cell phone/tablet +/- peripheral exam equipment
Contingency	Use ad hoc telemedicine relationships (i.e. “phone-a-friend”) to support care-in-place or during evacuation	Power: gasoline generator Network: Satellite Equipment: laptop/desktop computer, digital camera, e-mail
Emergency	Use un-approved, non-standard local solutions (i.e. local economy, high-risk care by untrained individual) to achieve “best-possible” outcome	Power: batteries Network: telephone, radio Equipment: phone, radio

Once a plan exists for when and how to perform TC, medical teams must train in realistic scenarios that require TC use to ensure this capability is available and easily utilized when needed. Given a variety of

constraints in time, Class VIII (medical material equipment, consumables, blood), funding, and personnel, most medical training focuses on managing common casualties in typical operating contexts. These scenarios rarely require LCs to engage in TC because the scenarios do not outstrip their level of training or resource availability. TC, in its current form, is an ALTERNATE care plan for prolonged casualty care (PCC) or unusual cases that exceed PRIMARY plans. Therefore, training must include unexpected scenarios that require KSAs that are unavailable to the trainees and cannot be reasonably obtained by them prior to a deployment or within their scope of practice, and thus require them to call for help from a RE. Examples include:

- Medics/corpsmen managing a burn patient over time, especially if needs include an escharotomy and advanced airway management.
- Role 1 providers managing severe community acquired pneumonia that requires mechanical ventilation or a patient with an extremity injury that requires fasciotomy.
- Role 2 surgical team managing a casualty with a head injury that requires neurosurgical input and a decompressive craniectomy or a septic patient that develops the acute respiratory distress syndrome.
- Role 3 team managing a local national with an infection caused by a highly drug resistant organism, or a patient with acute kidney injury that requires renal replacement therapy, or a burn patient with severe inhalation injury.

## RECOGNIZE

Culturally, the U.S. Military trains medical providers to succeed on their own merits; we validate individuals, not their ability to perform tasks or manage casualties as teams. Consequently, one of the hardest aspects of TC is for LCs to recognize when they should call for help. When a healthcare provider is uncertain about a casualty's diagnosis or the best management plan, s/he should consider calling for help. Because there is no single-entry point for TC within the OVH system, LCs must first determine the urgency of the consultation and then conduct TC using the appropriate technology. The OVH system is divided into routine TC and urgent/emergent TC, and direct patient care. Table 2 on the next page highlights these TC pathways and when LCs should use one or the other.

**Table 2. The operational virtual health system according to teleconsultation acuity and direct-to-patient telemedicine.**

Routine	Urgent	Emergent	Direct Patient Care
<b>Asynchronous* Support using Portals</b> <b>Global Teleconsultation Portal (GTP)</b> <a href="https://gtp.health.mil/">https://gtp.health.mil/</a>  *Asynchronous TC may be converted to synchronous TC (voice or video) depending on need and availability	Synchronous Voice* through ADVISOR 833-ADVSRN (833-238-7756) DSN 312-429-9089		<b>**Not Described by this CPG**</b> <b>Synchronous (voice/video)</b> <b>Virtual Health Appointments</b>  <b>Available only for</b>  <b>Tele-Mental Health</b> Through embedded mental health providers & <b>LRMC Catchment Area</b> DSN: 314-590-4600 Commercial: +49 (0) 6371 9464 4600
	Specialty Support for: General/Trauma Surgery Orthopedic Surgery Pediatrics Infectious Disease Toxicology Hematology/Oncology Obstetrics/Gynecology Dental	Critical Care Chemical Casualty Care Burn Center Toxicology Veterinary Medicine-Military Working Dog Ophthalmology Neonatology Emergency Department and subsequently any Specialty Not Listed#	
	<i>* Audio only TC may be converted to video or asynchronous text/email depending on need and availability</i>		
Routine Consults require a consultant response within 24 hours. Routine patients have NORMAL vital signs and are not at risk for deterioration within the next 24 hours. The consultant and casualty have time to wait for a response. Some mission requirements demand more immediate medical decisions due to short communications "windows" or operational context. Limitations due to time should encourage local caregiver to use urgent consultation systems (see above). To use GTP, you must have a username and password. To obtain a username/password go to <a href="https://gtp.health.mil/">https://gtp.health.mil/</a>	Urgent consults are all cases not routine or emergent or any questions you have about non-life-threatening conditions that require specialty medical advice and would benefit for synchronous communication between the local caregiver and the remote consultant. A good example of an urgent consult might be complex wound management. # Calls for ADVISOR Specialties not listed will be routed to the Role 4 ED within the line of evacuation to assist with connection to that specialty on call in the medical center. <b>**Importantly – ADVISOR is NOT a route of MEDEVAC and does not facilitate casualty movement or patient handoff.</b> <b>Virtual Medical Center CAC link:</b> <a href="https://info.health.mil/army/VMC/Pages/OpsMed/Operational-Medicine.aspx">https://info.health.mil/army/VMC/Pages/OpsMed/Operational-Medicine.aspx</a>	Emergent consults are for casualties with critical illness/injury. The following are some indicators: <ul style="list-style-type: none"> <li>Shock (e.g. shock index greater than 1 [HR/SBP &gt; 1])</li> <li>Respiratory failure</li> <li>Severe infection/sepsis</li> <li>Severe electrolyte abnormalities</li> <li>Encephalopathy (altered mental status)</li> <li>Severe TBI /elevated intracranial pressure (e.g., head injury with depressed level of consciousness)</li> <li>Abnormal vital signs lasting &gt; 30 min, or rapidly worsening, or other concerns:               <ul style="list-style-type: none"> <li>HR &lt; 30 or HR &gt; 110</li> <li>SBP &lt; 90 or SBP &gt; 200</li> <li>RR &gt; 30</li> <li>O2 Sat &lt; 88%</li> <li>Urine output &lt; 0.5cc/kg/hr for &gt; 2 hr; Complex/hemodynamically significant arrhythmias</li> </ul> </li> <li>Poisonings/toxicology emergencies</li> <li>Chemical Casualty Care</li> <li>Any medical emergencies, life threatening conditions, organ failure (e.g., myocardial infarction, stroke, renal failure, liver failure, severe anemia/thrombocytopenia, etc.)</li> </ul>	Mental health can be a challenging problem during deployment. TBH may be beneficial, however it must be established by trained individuals and through appropriate channels. Follow unit SOP or contact _____ to determine if TBH is available for your deployment medical plan. Units within EUCOM and or adjacent AORs may be able to take advantage of LRMC virtual support and video visits. For routine outpatient problems, call the above to obtain appointment times and instructions. *These vital signs triggers are only recommendations. Providers should initiate TC whenever they feel a patient's condition requires it*  <b>CAC enabled site:</b> <a href="https://info.health.mil/army/VMC/Pages/OpsMed/Operational-Virtual-Health-in-the-European-Theatre.aspx">https://info.health.mil/army/VMC/Pages/OpsMed/Operational-Virtual-Health-in-the-European-Theatre.aspx</a>
+ Although the ADVISOR program was originally designed for operational VH support, it may also be utilized in garrison for 2. Due to COVID-19 garrison to consult: Critical Care at n-JTCCN MTFs, Infectious Disease (adult/pediatric), Palliative Care. The caller must identify that they are requesting support for patients located in a garrison MTF.			

Global Teleconsultation Portal (GTP) is a Defense Health Agency (DHA) supported low-bandwidth web-based, secure, HIPAA-compliant, asynchronous platform used for non-urgent provider-to-provider teleconsultation, patient movement, and case management. Operational providers and consultants can access GTP and request a new account at: <https://gtp.health.mil/>

Lifesaving direct patient care takes priority over calling for help! Never leave the casualty to get help if the casualty's condition may worsen while you are absent. Consider having a teammate "make the call" while the primary medical provider is delivering patient care.

## EXECUTE

The hardest and most dangerous part of TC is for the RE to efficiently provide an accurate consultation when unable to assess a casualty themselves – inaccurate information can lead to bad recommendations and, in the worst case, bad patient outcomes, or, more commonly, confusion. Consequently, the hardest part of TC for the LC is conveying an accurate description of a patient to a RE.

LCs must possess excellent assessment skills and the ability to convey their assessment to a RE efficiently. Inaccurate and/or incomplete assessments poorly communicated to a RE makes TC inefficient because the RE will inevitably pose probing questions of the LC to better understand a casualty's condition, problems, and treatments.

To date, no adverse outcomes associated with military TC have been reported. More commonly, poorly communicated data or incomplete assessment leads to frustration, lengthy consultations, dissatisfaction with recommendations, and ultimately delayed casualty care.

To avoid this, LCs must be prepared for TC. Unfortunately, many caregivers may find conducting a TC to be anxiety provoking because they may be unsure of their assessment, uncertain about what information to provide an RE, and are worried the RE will judge them. Probing RE questions to gain further confidence in data shared may feel uncomfortable for LCs, especially if/when data is missing due to incomplete assessment. THIS IS COMMON: every caregiver has a different way of prioritizing information and not all information will be available at the time of consultation. Real world consultations take an average of three (3) synchronous TC encounters to complete, often with several asynchronous communications between synchronous touch points. Missing data may be filled in over-time and recommendations may be refined or even changed as information is updated.

The following best practice recommendations have been identified to maximize TC efficiency, information transfer, and quality of recommendations while minimizing frustration and risk of missing information necessary for best consultation in context:

1. If calling the ADVISOR line:
  - When the agent answers the phone, tell the agent if the call is real-world and deployed or in garrison or for training.
  - Indicate the specialty needed or, if unknown, ask for the emergency department.
  - Provide a good call-back number.
2. Use a script familiar to the both the local caregiver and remote consultant (see [Appendix B](#) for an example with an instruction on use).
3. Send background information using asynchronous technology ahead of synchronous TC encounters (see below).



4. Use closed loop communication that includes intentional pauses in communication for read-back and clarification.
5. Have the RE document the telemedicine encounter and send that documentation with a summary of recommendations to the LC using an agreed upon asynchronous solution.

### **Images and Asynchronous File Transfer - Best Practices**

Sending information, documentation, files, and particularly images (sometime of other files) related to casualty care before synchronous TC is a best practice because it allows the RE to consider the context of the consultation and to begin organizing thoughts ahead of the TC.

1. Ideally, send images of patients and care context to REs before starting a TC. This helps the remote expert to provide “consultation in context” and avoids recommendations that are discordant with local capabilities. Useful images include:
  - Flowsheet and other documentation like the TC script
  - Patient wounds
  - Imaging – pictures or video of collected imaging studies (ultrasound, x-ray, etc.)
  - Whole patient
  - Special equipment
  - Facility or aid station
2. Image quality is important ([Figure 1](#)). Photographs that are less than 500KB are often of insufficient quality to convey information to a remote consultant.
3. Be mindful of patient privacy and operational security (OPSEC):
  - Images should be compliant with HIPAA. Do not include personally identifiable information in the image like full face images and unique tattoos unless they are essential for communicating injury or disease state to the remote expert in which case the image must be encrypted before sending. Best practice is to use the GTP to send these images.
  - Similarly, do not include images of the environment that could cause a safety issue for the local care team by exposing their location or affiliation or other information that could be used against them (consider, for example, media implications of the image).
4. Note that digital photos may also contain “geotags” which can provide an exact location where it was taken. This feature can be disabled if there are security concerns. The easiest way to do so is to disable location services on your device before taking pictures.

### **SECURITY - CYBER, OPSEC**

- DO NOT DELAY teleconsultation due to an unsecure connection unless operational requirements dictate otherwise.
- Traditional teleconsultation is UNCLASSIFIED; the local caregiver should maintain normal rules of operational security when utilizing unclassified networks. Most RE consultants DO NOT have access to SECRET communications, but this may be established in special circumstances after UNCLASSIFIED communication is established first.
- Maintaining patient privacy should be a priority, and many available tools for communication meet patient privacy requirements.



- When sending patient information or images by open communication methods, limit patient identification to sex and age. Location can be generic by addressing temperature (hot/warm/cold), surroundings (urban/rural), or environments (desert/tropical).
- Location to the level of continent or region can be useful for the consultant/expert to better identify diseases specific to certain areas (e.g., hemorrhagic fevers, malaria, etc.).

Figure 1. Telescript examples

**Panel A: Large Script Form**

1 SEE  
20  
403-94  
45112

Try to e-mail images/supporting documentation before calling  
State that you are calling for a critical care consultation  
If unable to provide the information due to operational security, state so

This [redacted] I am a [redacted] E-EMT

My best contact info is [redacted]

Intensivist number: [redacted]

Alternate e-mail or SMS: [redacted]

**CALL SCRIPT "read-back please point"**

I am in/at (location): [redacted]

My patient's name/DOB/SSN are [redacted]

Anticipated evacuation time is (range): [redacted]

I have a 30 yo M (sex)

With (injury, problem, etc.): 2nd Degree Burns on both legs 70%

That occurred (time/hours ago): 0730

Who is (prior) stable / getting better / getting worse / getting worse rapidly

Pertinent past medical/surgical history is: NONE

I need help with (be specific if possible, i.e. "I need help reading this ECG," or "I don't know why this patient is getting worse," etc.):

**KNOWN/POTENTIAL PROBLEMS/INJURIES**

2nd Degree Burns 10% Both Legs - Hypothermia  
Compartment Syndrome - Infection  
Shock

Other Consultants have recommended:

**"read-back please point" then VITAL SIGNS**

HR	112	BP	98/66	UOP	None
RR	16	SpO2	99%		
Temp		MS			

**EXAM**

Neuro	N/A	Ext/MSK	
Heart		Pulses	

**Panel B: Concise Script Form**

This is [redacted] I am a [redacted] 140

My best contact info is [redacted]

Intensivist number: [redacted]

Alternate e-mail: [redacted]

**"read-back please point"**

I am in/at (location): [redacted]

My patient's name/DOB/SSN are [redacted]

Anticipated evacuation time is (range): 4/10/2 I have a 30 year old male

With (injury/problem/etc.): 2nd Degree Burns/Infection 70% on both legs

That occurred (time) hours ago: (12:30, 12:00, 1:00)

Who is (prior) stable / unstable, getting better / getting worse / getting worse rapidly

Pertinent past medical/surgical history is: None

I need help with (be specific if possible, i.e. "I need help reading this ECG," or "I need help stabilizing this patient," etc.):

Thyroid nodule / infection in leg

**KNOWN PROBLEMS/INJURIES** 9/10/2 11:00 AM in 6th Street / 10th Street

17th Street / 10th Street 10:00 AM - 11:00 AM after being notified / 10:00 AM - 11:00 AM

10th Street / 10th Street 10:00 AM - 11:00 AM

Other Consultants have recommended:

**"read-back please point" then VITAL SIGNS**

HR	102	BP	115/55	UOP	None, Urine 92cc/6hr
RR	16	Temp	100.0	MS	None

**EXAM**

Heart	PMT	Ext/MSK	
Lungs	Clear	Pulses	Weak Bilateral
ABG	Normal	Skin/Wounds	

**INTERVENTIONS DONE**

wound care, (gaiter/skin)  
ETT / resp / ACV tube / Foley  
Catheter (R side)  
Analgesia / sedation (Fentanyl, Mid)  
Pain management, then recommendations

Call Early, Call Often

**Panel C: SFMS Prolonged Field Care Card**

3,150cc

750ml

1000ml

The provided examples in the above figure are examples of call scripts sent ahead of the teleconsultation (TC) with a remote expert (RE). Panel A (size 2.17MB) is larger, takes more time to send,

but is of sufficient quality to be read. Panel B (size 36.4kb), transmits easily, but is uninterpretable and of no utility. A reasonable file size that balances transmissibility and legibility is 500-1000kb (0.5-1MB). Panel C is a great example of legible and functional transmission of a vital sign flow sheet with the interventions sent to the RE prior to the initiation of TC.

## PROBLEM SOLVE

A general understanding of the capabilities and limitations of the various TM and TC technologies available is important. Intentionally using different technologies during training, especially switching between them, and limiting network resources during an encounter, helps LCs and REs become flexible in their use of technology and its limitations for delivering casualty care with TC support. ***Not all questions can be answered with TC; sometimes the best recommendation is simply to evacuate the casualty or experience the consequences.*** Still, TC may help mitigate risks if/when evacuation is no possible or available quickly.

Synchronous video helps make TC more efficient because REs can see what is happening in real time, but it is rarely required if TC does not involve tele-mentoring a procedure. Preliminary data from a small study presented in abstract<sup>10</sup> demonstrates that key aspects of procedural quality may suffer when voice only TC is utilized for procedural tele-mentoring compared to video. When not performing a procedure, sending image asynchronously and/or providing detailed description by text or during synchronous audio TC can convey the same information as real-time video with significantly less network consumption. Indeed, some procedures can be completed with frequent asynchronous “chats” that include images (often with the RE sharing annotations on the image).

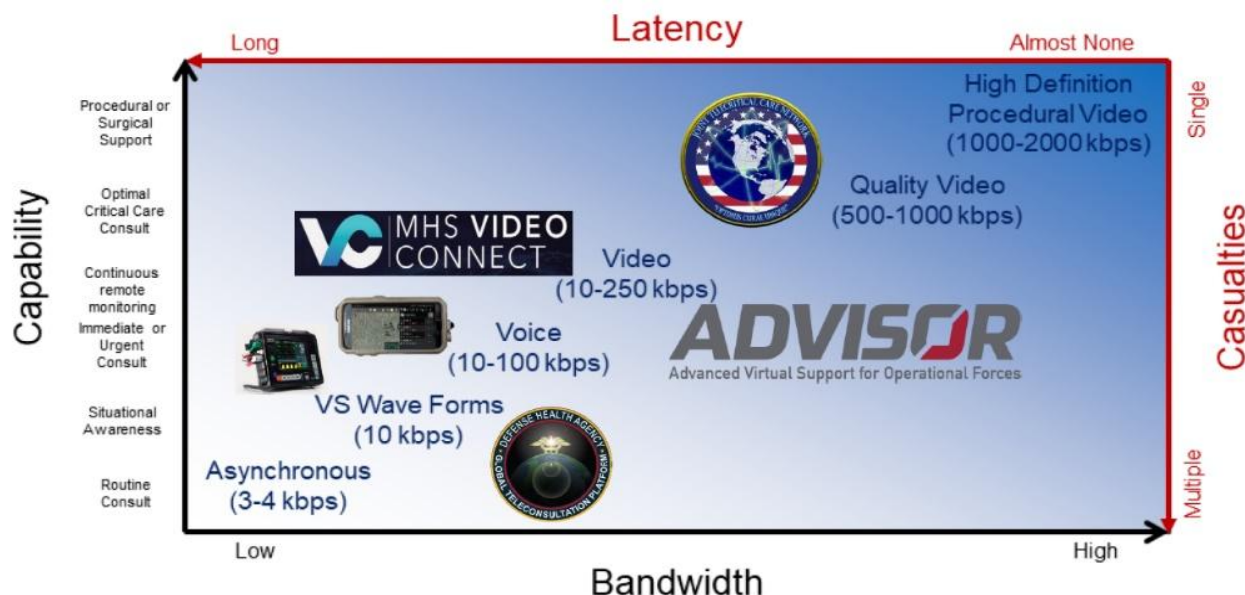
Because the telemedicine capability is a function of network resources matched to the number of casualties or encounters ([Figure 2](#)), understanding this relationship is important for mission planning.

Always use the most appropriate technology to optimize the consultation. Do not waste time establishing a network heavy video TC if lesser or more available technology (i.e. a radio or phone call) is sufficient. Also, it may be possible to increase the technology (i.e. go from an asynchronous consultation to a video consultation) if resources (hardware, software, and network) are available and the TC would benefit.

Understand the limitations of your technology and how to maximize its utility. It is difficult to complete a physical exam or part of a physical exam virtually without the correct digital equipment (e.g., stethoscope, ophthalmoscope, otoscope, etc.). Similarly, if bandwidth is limited, but video is needed by the RE for understanding, consider turning off the RE’s video (thus decreasing bandwidth needs by approximately half).

If utilizing TC for casualty care, always have a back-up means of communication – a second radio/frequency, a second phone-line/cellphone (on both ends of the encounter – LC and RE), an alternate computer – whatever your pace plan states. At the beginning of an encounter, always ensure that call back numbers and second options are discussed at the beginning of the consultation (this is included in the example call scripts in [Appendix B](#)). Train to use back-up options.

**Figure 2. Telemedicine capability is a function of network resources, particularly bandwidth and latency, matched to the number of casualties or encounters.**



While network resources may be robust and able to support multiple continuous remote monitoring encounters, they may rapidly diminish when supporting a real-time, high quality video teleconference to facilitate a procedure. Similarly, asynchronous modes of communication (texting, email) require little bandwidth making it possible for many local caregivers to consult remote experts simultaneously, but it will take longer to receive responses. Increasingly synchronous and higher quality modes of communication require increased amounts of bandwidth but deliver shorter latent periods and increased capabilities to support local caregiver needs. Increasing network resources increased capability or encounter volume or both.

## DOCUMENTATION

Documentation of the TC encounter is important for process improvement and lessons learned as teleconsultation continues to develop and inform future CPG development.

Documentation of casualty care is ultimately the responsibility of the LC providing direct care. All theater and local command documentation requirements should be completed by the LC. Best practice, however, is for REs to also document their consultation and recommendations and to send them to the LC as soon as possible. For routine consultations, this is automatic within the GTP. For TC not utilizing the GTP (urgent/emergent consultation), asynchronous communication between LCs and REs is on an ad hoc basis (using HIPAA compliant messaging applications or using encrypted email).

Additionally, REs document all OVH encounters using the Operational Virtual Health Report (OVHR) available at:

<https://info.health.mil/army/VMC/Lists/OperationalVirtualHealthReport/Item/newifs.aspx?source=/army/VMC/Pages/VMC/ADVISOR.aspx> (must have CAC enabled computer/mobile device).

If a TC is for a casualty who is a Military Health System beneficiary, and at least two of the following patient identifiers are available and can be provided by the LC managing the casualty, REs should document the encounter in MHS Genesis or other electronic medical record:

- Patient name
- Social Security Number
- DoD Identification Number
- Date of Birth

Best practice is to copy information from the OVHR into the appropriate note in the EMR.

TC encounters for patients who are NOT MHS beneficiaries or for whom identifiers are not available/cannot be provided cannot have documentation in the EMR. REs will complete OVHRs and send recommendations to LCs as described above.

LCs utilizing ADVISOR for TC are also asked to complete an Operational Virtual Health Evaluation (OVHE) available at:

<https://info.health.mil/army/VMC/Lists/OperationalVirtualHealthEvaluation/Item/newifs.aspx?source=/army/VMC/Pages/VMC/ADVISOR.aspx>.

When deployed LCs need to follow up with the appropriate medical theatre POCs on where they should document the patient encounter.

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## SUMMARY & KEY POINTS

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While Joint requirements documents for OVH continue to process, military medical providers have increasingly utilized formal and informal OVH capabilities to solve real-world problems. This is a natural evolution of casualty care secondary to continuous improvements in communications technologies, the process of healthcare delivery learnt during medical training, and the specialization and sub-specialization of the medical profession that occurs with the march of scientific discovery in medicine.

This guideline has focused on TC as a tool for increasing LC's KSAs in real-time through care coordination with a RE, effectively increase scope of practice to manage complexities of casualty care created by operational constraints (like delayed evacuation). The CPG highlights the PREP mnemonic as a model for maximizing the benefit of TC and minimizing risks.

The following best practices for TC in resource limited, austere, and operational environments are summarized as follows:

1. **PREPARE:** Telemedicine is a skill that must be practiced by both local caregivers and remote experts to prepare for efficient and effective interactions. Ideally, this care team should train together using simulated patients to optimize their communication and ensure their technology choices match their clinical needs. Utilize PACE planning to harden your TC capabilities ([Appendix A](#)).
2. **RECOGNIZE:** Local caregivers must recognize when TC is necessary (i.e. "when to make the call") and what process to use based on the acuity of casualty. Conceptually, the more "acute" a

patient is, the earlier and more frequently the LC should engage with the remote expert. “Call early, call often” is a saying used often by REs when casualties are severely ill or injured. Routine, Urgent, and Emergent TC should be conducted using the resources outlines in [Table 2](#).

3. **EXECUTE:** Effective and efficient teleconsultation takes practice, but can be improved by
  - Using a script familiar to the both the local caregiver and remote consultant ([Appendix B](#)).
  - Sending background information using asynchronous technology ahead of synchronous telemedicine encounters.
  - Using closed loop communication that includes intentional pauses in communication for read-back and clarification.
  - Having the remote expert document the telemedicine encounter and sending that documentation with a summary of recommendations to the local caregiver.
4. **PROBLEM SOLVE:** Understand the capabilities and limitations of available TC technologies and what types of TC can be performed using them. Be able and willing to switch between technologies when appropriate and have back-up communications solutions.

<https://prolongedfieldcare.org/telemed-resources-for-us-mil/> offers some excellent information about operational TC from an experienced group of clinicians.

Additional information about the GTP and ADVISOR programs can be found at:

<https://info.health.mil/army/VMC/Pages/Home.aspx> or by emailing [dod.advisor-office@mail.mil](mailto:dod.advisor-office@mail.mil)

When utilized effectively, TC can improve casualty care, reduce evacuation costs, and optimize casualty outcomes in many challenging deployment contexts.

When in doubt, call early and call often.

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## PERFORMANCE IMPROVEMENT

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JTS is a performance improvement (PI) organization which employs a systematic approach to determine the acute and long-term outcomes of all casualties, the quality of care, improvements in prevention and treatment and logistical implications. The JTS supports U.S. military PI initiatives by identifying, tracking, and making recommendations on PI measures to ensure the appropriate evaluation and treatment of injured Service members across the continuum of care and improve patient transition between phases of care.

The JTS PI Branch coordinates all PI activities across the spectrum of DoD trauma care and resolves trauma system patient care issues. JTS PI work relies on data collected in the DoD Trauma Registry. The data enables JTS to conduct gap analyses for medical capabilities to direct ongoing and future combat casualty care research, trauma skills training, and direct combat casualty care.

OVH utilizes encounter and summary statistics collected from the GTP, ADVISOR call center, OVHRs, and OVHEs to monitor the “health” of the system. Metrics tracked from these sources include:

- Number of Routine, Urgent, and Emergent TCs
- Location origin by Combatant Command



- Number of missed calls and failed connections
- Time from call to connection with RE (urgent/emergent calls) or time to receive recommendation from RE (routine)
- Quality of LC consultations (quality of presentation, appropriateness of questions, ability to provide appropriate recommendations)
- Quality of RE consultations (quality of the interaction, quality of the recommendations, and ability to implement recommendations)
- Casualty outcomes when available
- Evacuations avoided or downgraded
- % of OVHR/OVHE completion

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## PI MONITORING

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### POPULATION OF INTEREST

Patients in resource-constrained operational environments requiring teleconsultation using the GTP and ADVISOR platforms.

### INTENT (EXPECTED OUTCOMES)

- Local caregivers develop and maintain a teleconsultation PACE plan as part of mission planning.
- Local caregivers utilize call scripts when communicating with remote experts on ADVISOR.
- ADVISOR remote experts forward written guidance to local caregivers as a supplement to verbal advice.
- Teleconsultation details are documented with the encounter in the patient's health record. Details include consultant's name, specialty, and recommendations.
- Local caregivers submit an Operational Virtual Report Evaluation when using ADVISOR.
- Remote experts submit an Operational Virtual Health Report when using ADVISOR.

### DATA SOURCES

OVH utilizes encounter and summary statistics collected from the GTP, ADVISOR call center, OVHRs, and OVHEs to monitor the "health" of the system.

### SYSTEM REPORTING & FREQUENCY

The above constitutes the minimum criteria for CPG compliance. The system review and data analysis are performed by the OVH program.

## RESPONSIBILITIES

The OVH program manager and deployed unit is responsible to ensure familiarity, appropriate compliance, and PI monitoring with this CPG.

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## APPENDIX A: PACE PLANNING FOR TELEMEDICINE

The below tables provide examples and considerations for developing your teleconsultation PACE plan.

**Table 1. The patient care and teleconsultation plan will depend on mission analysis.**

	Patient Care Plan
Primary: Normal operations	Patient care and evacuation according to doctrine, roles of care, evacuation. If uncertain about the need for evacuation of a routine casualty, and unable to determine this using local resources (e.g. battalion surgeon, regional support medic, etc.), engage the TC routine or urgent system. If a casualty evacuation is delayed beyond planning purposes outstrips LC KSAs +/- local supplies or resources. ENGAGE TC urgent or emergent system through communications plan.
Alternate: Failed communication to one planned expert	If unable to contact the preferred TC solutions, use alternate solution. <ul style="list-style-type: none"> <li>▪ If unable to contact the GTP for a routine TC case, call the ADVISOR line.</li> <li>▪ If unable to contact the ADVISOR line for an urgent/emergent TC case, send message through the GTP.</li> </ul>
Contingency: Unable to use established TC solutions	Use ad hoc telemedicine relationships (i.e. "phone-a-friend") to support care-in-place or during evacuation. This could take the form of a phone call, radio transmission, or email. Identify these individuals and contact method beforehand. Consider use of internet-based information to help manage casualty.
Emergency: No network or communications so no TC available	Use un-approved, non-standard local solutions (i.e. local economy, high-risk care by untrained individual) to achieve "best-possible" outcome. Identify hospitals and medical assets in the local area of operation and their contact information. Consider establishing relationships early. Identify manuals, textbooks, how-to-guides for when/if there is no internet and no communications.

**Table 2. Telecommunications Technology Plan will depend on mission analysis.**

	Technology Plan
Primary	<b>To Local Support:</b> Radio per SOP. <b>To DoD OVH systems:</b> <ul style="list-style-type: none"> <li>▪ <b>Power:</b> Electrical grid</li> <li>▪ <b>Network:</b> Fiber or Cable internet</li> <li>▪ <b>Equipment:</b> Dedicated telemedicine equipment (i.e. VTC exam station, room camera, augmented reality device, peripheral devices)</li> </ul>
Alternate	<b>To Local Support:</b> Operational Chat <b>To DoD OVH systems:</b> <ul style="list-style-type: none"> <li>▪ <b>Power:</b> Solar Cell Battery</li> <li>▪ <b>Network:</b> 4G/LTE Cellular Network</li> <li>▪ <b>Equipment:</b> Mobile Phone/Tablet +/- peripheral exam equipment</li> </ul>
Contingency	<b>To DoD OVH systems:</b> <ul style="list-style-type: none"> <li>▪ <b>Power:</b> Gasoline generator</li> <li>▪ <b>Network:</b> Satellite</li> <li>▪ <b>Equipment:</b> Laptop/desktop computer, digital camera, e-mail</li> </ul>
Emergency	<b>To DoD OVH systems:</b> <ul style="list-style-type: none"> <li>▪ <b>Power:</b> Batteries</li> <li>▪ <b>Network:</b> Telephone, radio</li> <li>▪ <b>Equipment:</b> Phone, radio</li> </ul>

## APPENDIX B: VIRTUAL CRITICAL CARE CONSULTATION (VC3) GUIDE

VIRTUAL CRITICAL CARE CONSULTATION (VC3) GUIDE – 2 2017 (v3.1) To be used with Prolonged Field Care Card	
<p><b>Don't skip Pause points! Use them to ensure that key information is communicated.</b></p>	<p>1. Before calling, email image of the casualty (wounds, environment, etc.), "capabilities" (back of page), &amp; vital signs trends, to <a href="mailto:dod.advisor-office@health.mil">dod.advisor-office@health.mil</a></p> <p>2. If call not answered: a) call next number on PACE or call back in 5 – 10 min.</p> <p>3. If unable to provide information due to operational security, state so.</p>
<p><b>Hours since injury/start and anticipated EVAC time:</b></p> <p><b>**IMPORTANT**</b> <b>DO NOT USE your time of injury.</b> Consultants are often in different time zones. State the <i>hours since the injury</i> occurred or the amount of time you have been caring for the casualty. Give estimate of anticipated time until evacuation.</p>	<p>This is _____ I am a (job/ position) _____</p> <p>My best contact info is: _____</p> <p>YOUR best contact info is (Consultant's number): _____ Alternate e-mail: _____</p> <p><b>*** PAUSE POINT, CONFIRM CONTACT INFO ***</b></p> <p>I have _____ (number) of casualties to discuss with you.</p> <p>The _____ (1st, 2<sup>nd</sup>, 3<sup>rd</sup>, ...) is a _____ year-old _____ (sex) _____ (active duty/foreign national/OGA, etc.), who has the following:</p> <p>Mechanism of Injury or known diagnosis(es) _____ that occurred in (location) _____</p> <p>The injury/start of care occurred _____ hours ago. Anticipated evacuation time is (range) _____</p> <p>Injuries/Problems/Symptoms: _____</p> <p>Treatments: _____</p> <p>He/she is currently (circle) stable/ unstable, getting better/ getting worse/ getting worse rapidly</p> <p>Known Medication Allergies/Past medical/Surgical history is: _____</p> <p>I need help with (be specific if possible, i.e. "I need help reading this ECG," or "I need help stabilizing this etc.) _____</p> <p>Other Consultants have recommended: _____</p> <p><b>*** PAUSE POINT Remote Consultant to ask clarification questions ***</b></p> <p><b>VITALS</b> (current &amp; trend as of _____): HR _____ BP _____ RR _____ SpO2 _____ EtCO2 _____</p> <p>Temp _____</p> <p>UOP(ml/hr) _____ over _____ (# hours) Mental Status (GCS/ AVPU) _____</p> <p><b>EXAM:</b> Neuro _____ Ext/ MSK _____</p> <p>Heart _____ Pulses _____</p> <p>Lungs _____ Skin/ Wounds _____</p> <p>Abd _____</p> <p><b>LABS:</b> ABG: _____ Lactate: _____ Other: _____</p> <p><b>*** PAUSE POINT Remote Consultant to ask clarification questions ***</b></p>
<p><b>If you have called other consultants, describe what they have recommended thus far.</b></p>	<p><b>DO NOT Write PII</b> (personally identifiable information) on the call script if you intend to send a digital copy (completed/photograph) via e-mail. Just be prepared to give this information during the call.</p> <p><b>Patient history: BRIEFLY tell the patient's story using a modified MIST format:</b></p> <p><b>Mechanism of Injury/Illness</b></p> <p>Known Injuries/Problems</p> <p>Current Symptoms</p> <p>Treatments Rendered.</p> <p>Describe mechanism of injury or history of present illness (when symptoms started, what were they, how they progressed, etc.). List the known problems <i>explicitly</i>. Provide assessment of patient stability or clinical trend. Provide any known past medical history/surgical history/allergies.</p> <p>Describe what you need the consultant to help you with. Be as specific as possible.</p>

Use these sections to organize notes/ thoughts from the consultant back to you.

Plans/Recommendations							
PRIORITY	SYSTEM/PROBLEM		RECOMMENDATION				
	Neuro or problem #1						
	CV or problem #2						
	Pulm or problem #3						
	GI or problem #4						
	Renal or problem #5						
	Endocrine or problem #6						
	MSK/ Wound or problem #7						
	Tubes, lines, drains or problem #8						
	Prophylaxis/prevention or prob#9						
	Other						

TO-DO/ FOLLOW-UP/TO-STOP	NOTES
1.	
2.	
3.	
4.	
5.	

Perform a READBACK!

*** PAUSE POINT, for Medic/Local Caregiver to ask clarification questions ***							
Available "kit" (supplies, equipment, medications) !! IF POSSIBLE PHOTOGRAPH AND SEND VIA EMAIL BEFORE CALLING !!							
IV access:	IV	Central line	IO (location)	Other: _____			
Monitor:	Propaq	Tempus	Foley	Graduated urinal	PulseOx only	Exam Only	
	Other: _____						
Commo:	Tempus i2i ID: _____ THIAB: _____ SAT# _____ Local Cell# _____						
	Web VTC Address _____						
	Other (e.g. "FaceTime, VSee, Skype, etc.): _____						
IV Fluids:	Plasma-Lyte	LR	Normal Saline	3% saline	Other: _____		
Colloids:	Hetastarch	Albumin	Other: _____				
Blood products:	Whole blood	PRBC	Plasma	FDP	Platelets	Other: _____	
Medications:	Antibiotics: name/route/dose _____						
	Morphine IV/ PO		Other opioid (name/ IV/ PO): _____				
	Fentanyl IV/ PO (pop)		Ketamine				
	Midazolam		Diazepam (IV/ PO)				
	TXA		Other(s): _____				
Airway supplies:	ETT	Cric kit	LMA	Ventilator	BVM	O2	Suction
Misc:							

Use this section to describe what **equipment** you have. Preferably send a picture of this section ahead of the call. If possible, also take a de-identified picture of the **casualty**, an image of the **care environment** (if OPSEC permits), and an image of **flow sheets** ("ECCF" images) to send ahead of the call. **MINIMUM IMAGE SIZE** is 500 KB for text/flow sheets)

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## APPENDIX C: TECHNOLOGY REQUIREMENTS TO GET STARTED

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### **Bring this to your J6, S6 to share what you need....**

Using technology in a deployed environment may be a challenge to conduct in an area of operations (AO). Electricity and internet connection, while taken for granted in day-to-day life, are often limited resources in the AO and must be considered in the planning process for telemedical support. Technology should not limit teleconsultation but should augment it.

Ultimately, the type of technology you use should match the clinical question at hand and will be limited by the power, network, and equipment available.

- Use photographs and asynchronous technologies (e.g., e-mail, text) for routine problems or simple updates to a remote expert for their situational awareness. Slow internet connections will delay transmission of images especially ones of sufficient quality to be used. Dermatologic problems, for example, are well suited for using asynchronous technology to make diagnoses and care plans.
- Use synchronous technologies (i.e. phone) to discuss problems like diagnostic dilemmas, care plans with complex risk-benefit tradeoffs, problem solving for management of scarce resources, or timing of patient transport.
- Use video-teleconsultation for procedural telementoring or virtual direct patient care.
- Remote monitoring technology (i.e. telemetry) allows remote experts to help local caregivers identify trends in patient physiology. Using this technology, tele-critical care teams can help local caregivers by monitoring multiple casualties and facilitate better situational awareness. These services may also be utilized to help diminish task saturation (i.e., reduce documentation burden) and enable work-rest cycles.

**Minimum:** Voice telephone connection with/without asynchronous media to call **ADVISOR** hotline (**1-833-238-7756 DSN: 314-429-9089**) and read from the TCCC card or other form of documentation.

**Better:** Voice connection WITH concurrent email or photo exchange (i.e., send a photo of the call script, vital signs flowchart, the casualty/care environment, and available kit) closely followed by a phone call. Use a telemedicine report such as the Prolonged Casualty Care (PCC) flowsheet ([Appendix B](#)).

**Best:** Synchronous, real-time audio/video feeds with/without remote diagnostic equipment using the teleconsultation as a guide. If required use the Virtual Critical Care Consultation guide ([Appendix B](#)) and send a picture of casualty, capabilities, and vital sign trends to the consultant via email or text using operational security and protections of patient privacy.

### **SOFTWARE**

At a minimum, if possible, the local caregiver (LC) and if required, the patient will need access to a secure platform to send messages (picture), make a call or conduct a VTC. There will be times that access to a secure platform is not possible. However, do not delay teleconsultation unless operational situations dictate otherwise (extremely rare). The LC should carefully balance the risk and benefits of waiting for a more secure platform.

### **HARDWARE**

Many HCP/LCs can access TM through secured mobile devices.

- A computer (MC4/NIPR or any CPU) or mobile device
- An integrated or external microphone
- An integrated or external camera

### **INTERNET**

Having a solid internet connection is a crucial piece of successfully accessing telemedicine, especially for telehealth visits conducted by the LC and the patient that require high definition (HD) pictures or a VTC. For Role I/II Access to **NIPR with at least 512kb upload and download speed (1MB preferred)**, or **ISP Wi-Fi connection w/same**. Ideally, internet speeds should be at least **15Mbps download and 5Mbps upload**. While video streaming can happen with slower connections and lower definitions (LD), these are the recommended speeds needed to have a clear video experience for the majority of platforms.

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**APPENDIX D: TAKING GOOD PICTURES**

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1. Use a well-lit area.
2. Avoid flash photography, if possible.
3. A solid, uniform background is preferred.
4. Have someone else besides the patient take the photograph.
5. If using a cellular phone, use the main (rear-facing) lens, not the "selfie" lens.
6. Make sure the area of involvement is well focused; don't get too close if this makes the image out of focus.
7. For individual lesions, make sure the whole lesion is in the picture.
8. Use a ruler in the image (or, if a ruler is not available, a common object such as a coin) to demonstrate the size of the lesion.
9. For rashes, get a distance view that shows the pattern of the rash and a close-up view that shows the character of the rash.
10. More in-depth training for medical photography on JKO: DHA-US472 Virtual Medical Digital Photography

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## APPENDIX E: COMMON TELECONSULTATION DEFINITIONS

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**Asynchronous Communication** - unidirectional information flow (i.e., text, e-mail), sometimes known as store and forward, refers to telemedicine that is delivered at a later time from when the patient or another healthcare provider requests it. This could be text-based interactions, a specialist reviewing labs or records at a later time, or a patient conducting an online assessment for medications.

**Bandwidth** - the amount of information that may move through a network at any point in time. Think of it like a door or a turnstile: only one or two people can fit through at a time. Similarly, packets of digital information flow through wires and those wires, or their connections, are limited in size and thus only allow a certain amount of information to pass through them at a time. Thus, packets must “get-in-line” such that some arrive to their destination before others. If the network is not “point-to-point” and serves multiple users, then these users must share the bandwidth. Some information on the network can be considered “higher priority” than other information. Quality of services protocols allow certain types of information or information from a particular source/user to move more freely (i.e. may go to the “head of the line”) than other information.

**Consultant/Expert**- the clinician who receives the consult from the local caregiver. This may be a designated consultant in a formal system, or a validated and/or trusted expert provider chosen by the local caregiver

**Distant Site**- a distant site is the location the telemedicine provider is in at the time of remote patient service. Sometimes this is referred to as the consulting site.

**Extended consultation**- emergent consultation is for patients with critical illness or injury. This concept reflects clinical engagement more than communication modality. This refers to a consultant/expert who remains engaged with the care of a local patient or local patients over time by monitoring physiologic vital signs, audio channel(s), video feed(s), or combinations of these technologies.

**Latency** - the amount of time it takes information to travel from origination to destination. Most of the time, digital information travels quickly, even across hundreds of miles of distance. Still, using satellite communication to move from one side of the globe to the other, or from the moon to the earth, delays receipt of information. Information may also be slowed if it must pass through filters, firewalls, or scanning software.

**Local Caregiver**- the person (not necessarily someone with medical training) who is taking care of a patient and who initiates teleconsultation.

**Originating Site**- the originating site is the location the telemedicine patient is in at the time of remote patient service.

**Remote Patient Monitoring**- remote patient monitoring refers to technology and programs that help track patient health data at a distant site outside of the hospital or clinic and send that data to care providers in real time. This technology could be in the form of connected healthcare devices like a smartwatch or heart monitor, health monitoring and wellness apps, or connected home devices. Remote monitoring patient data can include vital signs, weight, blood pressure, blood sugar, and other inputs like mental health data or symptoms.

Routine consultations are those that do not require immediate assistance. Routine consultations may take many hours to receive a response from a specialist (4-24 hours; median response time is approximately 4 hours).



**Synchronous Communication**- bidirectional information flow (i.e. voice, video, both). Synchronous telemedicine refers to telemedicine that is performed in real-time via video or phone consult. In practice, this looks like an urgent care provider assessing symptoms of a sore throat and fever, a psychiatrist managing a patient's medication, or a primary care provider conducting a follow-up visit with a patient.

**Telemedicine**- remote evaluation, diagnosis, treatment, and/or consultation using telecommunications technologies. Telemedicine is a subset of telehealth referring to the specific delivery of clinical healthcare services through telecommunications platforms. Examples of telemedicine could be video consults, phone consults, or patient-provider communication through text messages or a patient portal.

**Teleconsultation – or “eConsult”** is a caregiver to remote expert discussion about a patient's diagnosis, diagnostic plan, treatment, or management plan using telecommunications technology such as a call, text, video consult, etc.

**Urgent non-critical care specialty consultations** are those in which remote consultants need to speak with a specialist in order to best manage a patient within hours. This could be a patient related need (i.e. the patient may worsen in the next several hours) or mission specific need (i.e. there is a short communications window or there is a mission essential decision to make like “does this casualty need to get on the evacuation platform that is leaving in the next hour or can he/she continue mission until the next available evacuation time”).

**VTC – video teleconferencing** is the ability to share audio and video signal between two locations to conduct real-time communication. This includes point-to-point (one location communicates to only one other location at a time) and multi-point (multiple locations communication with multiple other locations simultaneously).

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## APPENDIX F: INFORMATION REGARDING OFF-LABEL USES IN CPGS

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### PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of “off-label” uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

### BACKGROUND

Unapproved (i.e. “off-label”) uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing “investigational new drugs.” These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

### ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the “standard of care.” Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

### ADDITIONAL PROCEDURES

#### Balanced Discussion

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

#### Quality Assurance Monitoring

With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

#### Information to Patients

Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.

