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Technological Feasibility Assessment of Conducting Aeromedical Certification Exams Using Telemedicine During Public Health Emergencies

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F. Campion[1]; R. Danan[2]; L. Levine[3], B. Hayes[4] All authors from The MITRE Corporation	Product 4-5.B.1-2

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Author ORCIDs:

[1]Campion (0000-0002-0757-9305); [2]Danan (0000-0002-6312-1470); [3]Levine (0000-0002-6926-7438)
[4]Hayes (0009-0004-8101-3811)
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16. Abstract

During the Public Health Emergency (PHE) caused by the SARS-CoV-2 virus, airmen could not schedule medical exams with Aviation Medical Examiners (AMEs), necessitating the FAA to extend the duration of medical certification for several months. This situation was undesirable because it removed one of the safeguards for ensuring human reliability in aerospace operations. Accordingly, the Federal Aviation Administration's Office of Aerospace Medicine requested MITRE evaluate the feasibility of telemedicine for aeromedical certification exams in a future PHE, with the main objective of identifying validated technologies for elements of the exam. Based on interviews with senior AMEs, a telemedicine innovation challenge, and an assessment of marketplace best practices, mature telemedicine technology was identified to accomplish 19 and partially complete 10 elements of the FAA's aeromedical certification exam. Elements that can be completed via telemedicine include medical history, height, weight, ear, nose, throat, ocular motility, lungs, heart, vascular, skin, musculoskeletal extremities, spine, identifying body marks/scars/tattoos, neurologic, psychiatric, general systemic, hearing, blood pressure, pulse. Additionally, the electrocardiogram and urinalysis testing can be accomplished remotely. Elements that can be only partially assessed in the home via telemedicine include the retina, pupils, abdomen/viscera, genitourinary, vision (distant, near, intermediate), color vision, field of vision, and heterophoria. Elements that cannot be accomplished remotely include an exam of the anus and lymphatics.

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Introduction

During the Public Health Emergency (PHE) caused by the SARS-CoV-2 virus, airmen could not schedule medical exams with Aviation Medical Examiners (AMEs), necessitating the Federal Aviation Administration (FAA) to extend the duration of medical certification for several months. This situation was undesirable because it removed one of the safeguards for ensuring human reliability in aerospace operations. Accordingly, the FAA's Office of Aerospace Medicine requested that MITRE evaluate the feasibility of telemedicine for aeromedical certification exams during a PHE, with the main objective to identify validated technologies for each element of the exam described on the FAA Form 8500-8. Evaluating these technologies' operational effectiveness and suitability to accomplish an aeromedical examination was not within this project's scope.

Observations & Conclusions

Figure E1 lists key observations from an innovation challenge, interviews with the AMEs, and a literature review. Based on these, MITRE summarizes our observations and conclusions:

1. *Mature telemedicine technology is now available* to enable clinicians to complete 19 and partially complete 10 elements of the history and physical examination required for aeromedical certification exams. Two elements of the physical cannot be done with telemedicine. Electrocardiogram and urinalysis testing can be accomplished remotely.
    - Elements that *can be completed via telemedicine* include medical history, height, weight, ear, nose, throat, ocular motility, lungs, heart, vascular, skin, musculoskeletal extremities, spine, identifying body marks/scars/tattoos, neurologic, psychiatric, general systemic, hearing, blood pressure, and pulse.
    - Elements that *can be only partially assessed in the home via telemedicine* include the retina, pupils, abdomen/viscera, genitourinary, vision (distant, near, intermediate), color vision, field of vision, and heterophoria.
    - Elements that *cannot be accomplished remotely* include an exam of the anus and lymphatics.

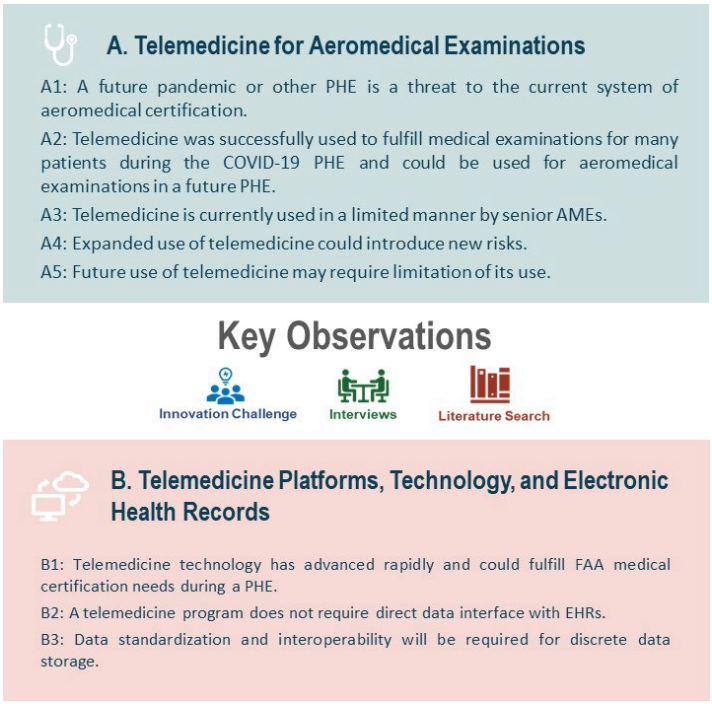

FIGURE E1: KEY OBSERVATIONS

2. *A telemedicine solution requires both a telemedicine platform and specialized medical devices*. Multiple telehealth technology platforms are now commercially available, which could provide a telemedicine option for examiners during a PHE. Interoperable medical devices are commercially available to configure a telemedicine solution with the abovementioned limitations.

Next Steps

MITRE proposes the following for consideration:

- Proceed with technology demonstration and operational effectiveness and suitability evaluation.
- Upon successful execution and results of the demonstrations, implement a policy decision on including a telemedicine provision in the national aviation preparedness plan.

INTRODUCTION

The FAA's Office of Aerospace Medicine (AAM) tasked the MITRE CAASD team to determine the feasibility of telemedicine for aeromedical certification exams, with the main objective to identify validated technologies for each exam element described on the FAA Form 8500-8. For this effort, telemedicine (i.e., telehealth) is "the use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance."[1] Preferential focus was given to exam elements with the greatest role in mitigating aeromedical risk. This report includes the results of the innovation challenge, interviews with Aviation Medical Examiners (AMEs), and other market research regarding technology solutions for the potential use of telemedicine for aeromedical certification exams.

Current Landscape

The FAA receives and processes roughly 450,000 applications[2] for airman medical certifications annually. The majority of the medical exams are performed by physicians in private practice who have been designated as AMEs by the FAA. Senior examiners perform first-class airman exams.[2] Before the COVID-19 pandemic, there was no allowance for the use of telemedicine by AMEs for the conduct of exams or for managing the follow-up of airmen with special issuance related to specific medical problems. With the onset of the pandemic in March 2020, many physician offices were forced to close and social distancing became a public health priority to limit the spread of infection. This became problematic because, in April 2020, expiring airman medical certificates were not enforced for a time because of the challenges in conducting face-to-face aeromedical certification exams. Since the pandemic, the HIMS (Human Intervention Motivation Study) program has allowed virtual visits (visits every three months, half may be virtual) for airmen under treatment for alcohol and substance use disorder or SSRI medication management. HIMS-qualified AMEs reported that this use of telemedicine is popular among both airmen and AMEs. In this manner, the managing HIMS AME has both face-to-face and telemedicine contact with the airman during their recovery. This enables both continuity and convenience.

OBSERVATIONS

The following observations are derived from the innovation challenge, interviews with AMEs, and literature review (Figure 1). These observations summarize the current AME process and the potential role of telemedicine in a future Public Health Emergency (PHE). The conclusions and next steps are based on these observations.

A. Telemedicine for Aeromedical Certification Exams

A1: A future PHE is a threat to the current system of aeromedical certification. The COVID-19 PHE onset abruptly affected the entire nation and disrupted the provision of aeromedical certification exams using AMEs. Future PHEs, such as pandemics, natural disasters, or combinations of events, may affect all or parts of the system.

A2: Telemedicine successfully fulfilled medical exams for many patients during the COVID-19 PHE and could be used for aeromedical certification exams in a future PHE. During the COVID-19 pandemic, telemedicine rapidly gained acceptance by patients and physicians for both urgent and routine medical care. Healthcare workflows now commonly include options for the use of telemedicine, particularly in settings of constrained access to health services. Telemedicine provides enhanced safety and vital access to care for patients and providers during a PHE. Observations from current use suggest that patients would readily accept these technologies.

A3: Telemedicine is currently used in a limited manner by senior AMEs. During the COVID-19 PHE, the use of telemedicine for specific elements of AME work emerged and has become accepted practice. Telemedicine is now used for 3- and 6-month interval visits for airmen undergoing monitoring for behavioral health and substance abuse issues. AMEs serving in the HIMS program can use telemedicine at their discretion and find it quite effective and acceptable. The technology used currently is standard audio-visual connectivity with no special medical devices.

A4: Examiners are receptive to the idea of expanded use of telemedicine but also recognize the potential risks. Input from AMEs provided insights into FAA's use of telemedicine during a PHE. All the AMEs interviewed described the high value of face-to-face medical exam visits with airmen. Important information is gained by observing how an airman is dressed, walks, and presents themselves. Face-to-face office visits afford direct observation of behavior and affect, which may be more difficult to gather via telemedicine. They indicated that FAA remote examiners should be able to adopt telemedicine

technologies readily. The examiners recognize that specific training on the use of telemedicine will be needed to ensure high-quality exams, particularly for neurological and behavioral health assessments.

A5: Examiners propose the need for limits on the use of telemedicine for aeromedical certification exams during a future PHE to mitigate potential new risks of telemedicine. Several examiners indicated that if telemedicine were to be used during a future PHE, it might require some limitations. Some suggested telemedicine use should be limited to recertification exams for airmen not on a special issuance.

B. Telemedicine Platforms, Technology, and Electronic Health Records

B1: Telemedicine technology has advanced rapidly and could fulfill FAA medical certification needs during a future PHE. Examining clinicians and the airman community now have access to much of the technology infrastructure, high bandwidth internet connectivity, and smart devices needed for telemedicine. Expect continued innovation in telecommunication and remote monitoring for healthcare in the years to come, which could benefit the FAA.

B2: Potential FAA use of telemedicine during a PHE does not require direct data interface with Electronic Health Records (EHRs). The current workflow for examiners allows using local documentation and exam tools and then completing the FAA Form 8500-8 on Aerospace Medical Certification Subsystem. A telemedicine platform and approved medical devices could be used for the same workflow to complete elements of the aeromedical certification exam and remain separate from any one EHR.

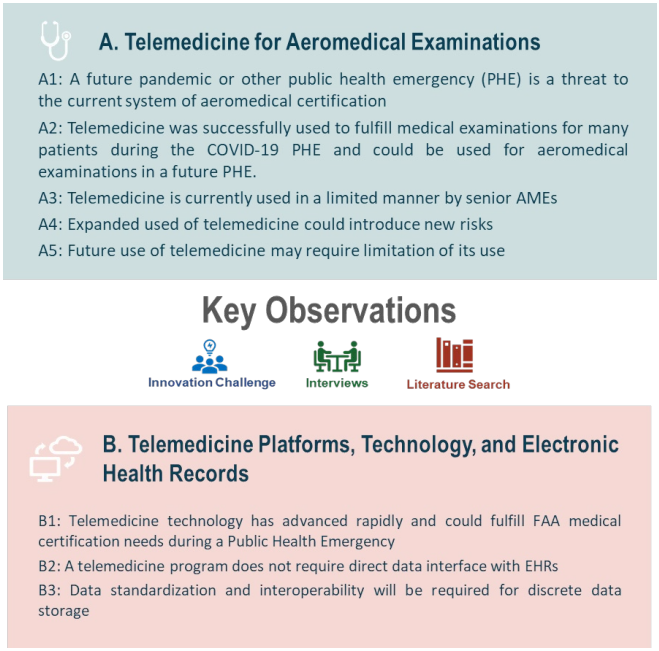

Figure 2: Key Observations by Themes

B3: Data standardization and interoperability will be required for discrete data storage. All medical devices to be considered for telemedicine must adhere to standards to allow interoperability of clinical data (e.g., blood pressure, vision metrics) and document exchange (e.g., electrocardiogram results). The Health Level Seven International® (HL7) standards, known as Fast Healthcare Interoperability Resources (FHIR), should be used to exchange data from devices. Standardized data elements using Logical Observation Identifiers Names and Codes (LOINC), Current Procedural Terminology (CPT), International Classification of Diseases, 10th revision (ICD-10), and Systemized Nomenclature of Medicine (SNOMED) coding should be used to ensure that data will be accessible for reporting individual patient trends and population-level analysis. The International Organization for Standardization (ISO) and the Institute of Electrical and Electronics Engineers provide key standards for point-of-care medical device communication fundamental for telemedicine.[3]

MEDICAL DEVICES IN THE MARKETPLACE

The COVID-19 PHE accelerated the digital transformation in healthcare, changing many aspects of clinical care.[4]This led to increased adoption of medical devices, biometrics, and wearables for screening and diagnosis using telemedicine. As such, a survey of the medical devices that could be incorporated into the aeromedical certification exam yielded promising results, as outlined in the tables below. Tables 1 provides a sampling of possible, but not exhaustive, remote solutions. The table indicates whether the device can be used to meet current FAA requirements for elements of the physical exam in a home setting, operated by an airman him/herself. "Y" indicates "yes," "N" indicates "no," and "P" indicates "partial." Exam of the anus and lymphatics require direct palpation by a skilled clinician and cannot be adequately evaluated with any current telemedicine device. Aspects of the abdominal exam and genitourinary system can be partially examined with telemedicine and a cooperative patient. Although a nearly complete eye and vision evaluation can be done with the aid of medical devices such as a retinal camera and virtual reality headset, at present, these devices cannot practically be self-operated in the home setting. A more detailed discussion of medical devices available for the physical exam, vision (Table 3, p. 15), hearing (Table 4, p. 16), and audiology testing (Table 5, p. 17), and the electrocardiogram can be found in Appendix B. A subset of physical exam elements is labeled "critical" if they relate to

potential medical conditions posing a significant safety risk. Critical aspects of the physical exam include the following elements: pulse, blood pressure, vision, hearing, eye, ear, pulmonary, cardiac, vascular, orthopedic, neurologic, and psychiatric exam. Table 2 (p. 10) provides a minimum instrument/device solution set to address overall exam requirements.

TABLE 1: PHYSICAL EXAM ELEMENT & TELEMEDICINE/REMOTE EXAM ASSESSMENT

PHYSICAL EXAM ELEMENT	FAA FORM 8500-8 ITEM	INSTRUMENT/ DEVICE USED FOR TELEMEDICINE/ REMOTE EXAM	MEET RQMT?[1]	COMMENT
MEDICAL HISTORY	18	Standard telemedicine audio	Y	Conversational history and review of systems.
HEIGHT	21	Measuring tape	Y	
WEIGHT	22	Blue-tooth scale	Y	Multiple options in the commercial market exist.
EAR, NOSE, THROAT (CRITICAL)	25-30	TytoCare Device otoscope, tongue blade, camera	Y	Otoscope tool used to visualize ear TMs and nasal turbinates.
EYES, GENERAL (CRITICAL)	31	Standard telemedicine video	Y	
OPHTHALMOSCOPIC (CRITICAL)	32	Retinal camera/image	P	Multiple options; see Table 3: Solutions Currently in the Marketplace Identified for Eye Exams
PUPILS (EQUITY AND REACTION) (CRITICAL)	33	Standard telemedicine video, StrabisPIX Mobile Application for detailed pupillary exam	P	See Phanphruk, et al., 2019.[5]
OCULAR MOTILITY (ASSOCIATED PARALLEL MOVEMENT NYSTAGMUS) (CRITICAL)	34	Standard telemedicine video, StrabisPIX Mobile Application for detailed ocular motility exam	Y	See Phanphruk, et al., 2019.[5]
LUNGS AND CHEST (CRITICAL)	35	TytoCare or another electronic stethoscope	Y	Chest palpation and Breast exam will be limited; not commonly required.
HEART (CRITICAL)	36	TytoCare or another electronic stethoscope	Y	
VASCULAR SYSTEM (CRITICAL)	37	Electronic stethoscope, blood pressure cuff, and standard telemedicine video for inspection	Y	Consider use of blood pressure measurement of both arms and ankles as substitute for direct palpation of distal pulses.
ABDOMEN AND VISCERA	38	Standard telemedicine video	P	Abdominal exam limited to visual inspection and patient-self palpation to report tenderness.
ANUS	39	None	N	Digital rectal exam (DRE) not feasible via telemedicine. DRE is performed only at the applicant's option unless indicated by specific history or physical findings.
SKIN	40	Standard telemedicine video and TytoCare camera for close-up photo images	Y	
GENITOURINARY SYSTEM	41	Standard telemedicine video	P	Pelvic exam is not feasible via telemedicine. Exam is limited to visual inspection, performed only at the applicant's option or if indicated by specific history or physical findings.

[1] This column indicates whether the commercially available instruments or devices listed fully (Y), partially (P) or do not (N) meet the requirements to be able to conduct these at the airman's home environment.

PHYSICAL EXAM ELEMENT	FAA FORM 8500-8 ITEM	INSTRUMENT/ DEVICE USED FOR TELEMEDICINE/ REMOTE EXAM	MEET RQMT?[1]	COMMENT
MUSCULOSKELETAL UPPER AND LOWER EXTREMITIES (CRITICAL)	42	Standard telemedicine video	Y	See Laskowski et al., 2020.[6]
SPINE, OTHER MUSCULOSKELETAL (CRITICAL)	43	Standard telemedicine video	Y	
IDENTIFYING BODY MARKS, SCARS, TATTOOS	44	Standard telemedicine video, TytoCare camera for close-up photo images	Y	
LYMPHATICS	45	Standard telemedicine video and patient self-palpation	N	
NEUROLOGIC (CRITICAL)	46	Standard telemedicine video	Y	See Jj et al., 1999.[7]
PSYCHIATRIC (CRITICAL)	47	Standard telemedicine video	Y	Supplement exam with PHQ9 or other questionnaire.
GENERAL SYSTEMIC	48	Standard telemedicine video	Y	
HEARING (CRITICAL)	49	6-foot hearing test adapted for remote environment, or Hora, Noise Test for Hearing Screening, or Mimi Hearing Test	Y	See Table 4: Hearing Standards of the American National Standards Institute, 1969.
DISTANT VISION (CRITICAL)	50	Multiple device options	P	See Table 3: Solutions Currently in the Marketplace Identified for Eye Exams.
NEAR VISION (CRITICAL)	51.a	Multiple device options	P	See Table 3: Solutions Currently in the Marketplace Identified for Imaging Eye Exams.
INTERMEDIATE VISION (CRITICAL)	51b	Multiple device options	P	See Table 3: Solutions Currently in the Marketplace Identified for Imaging Eye Exams.
COLOR VISION (CRITICAL)	52	Richmond-HRR, 4th edition, printed plates in a test book	P	Color Vision Testing via specially printed plates in a test book is only method approved by FAA.
FIELD OF VISION (CRITICAL)	53	VF3 Pro Headset	P	
HETEROPHORIA (CRITICAL)	54	Screening questionnaire and Eye Cover Test using a handheld occluder and standard telemedicine video	P	See Feinberg et al., 2021.[8] Modification of current FAA standard would be needed for remote screening methods.
BLOOD PRESSURE (CRITICAL)	55	Electronic BP cuff	Y	
PULSE (CRITICAL)	56	Electronic BP cuff	Y	
URINE TEST/URINALYSIS	57	Self-administered urine dipstick test with photo image transmitted	Y	Self-administered U/A would require revised FAA standard.
ELECTROCARDIOGRAM (ECG) (CRITICAL)	58	PCA 500 portable 12-lead ECG from QT Medical	Y	

TABLE 2: PROPOSED INSTRUMENT AND DEVICE FOR TELEMEDICINE & REMOTE EXAM PROTOTYPING

INSTRUMENT/DEVICE	FAA Form 8500-8 item	MEET RQMT?[2]	EXAM DOMAINS
Standard telemedicine audio and video connection	18, 31, 34, 35, 36, 37, 40, 42, 43, 44, 46, 47,48	Y	Medical History and exam elements
Standard telemedicine audio and video connection	32, 33, 38, 41,	P	Exam elements
TytoCare device with high-resolution camera, ear tip, tongue blade, and stethoscope adapters	25-30, 40, 44	Y	Ears, Nose, Throat, Skin, Identifying body marks
Electronic BP cuff	37, 55	Y	Vascular exam; Vital Signs: BP, pulse
Scale	22	Y	Vital signs: weight
EyeQue Vision Testing	50, 51	P	Vision: distant, near, intermediate
Richmond-HRR, 4th edition	52	P	Vision: color vision
VF3 Pro Headset	53	P	Vision: field of vision
Heterophoria Screening questionnaire	54	P	Vision: heterophoria screening
Handheld Occluder for the Eye Cover Test	54	P	Vision: heterophoria screening
HearScreen, *Noise Test for Hearing Screening by HearXGroup, or Mimi Hearing Test*	49	Y	Hearing screening
PCA 500 portable 12-lead ECG from QT Medical	58	Y	Electrocardiogram
Urine dipstick test	57	Y	Screening Urinalysis
Measuring tape	21	Y	Vital Signs: height

CONCLUSIONS

The COVID-19 PHE highlighted vulnerabilities in the current system for providing aeromedical certification exams. In particular, the PHE made it unsafe for face-to-face office visits for a time. The FAA did not have a contingency plan in place for remote care or telemedicine. Telemedicine is now at the point of maturity to help the FAA prepare for a future PHE. Based on research including interviews with senior FAA AMEs, the MITRE Telemedicine Innovation Challenge, and an assessment of marketplace best practices, we summarize our findings with the following conclusions:

1. Mature telemedicine technology is now available to enable clinicians to complete 19 elements and partially complete 10 elements of the history and physical exam required for aeromedical certification exams. Two elements of the physical cannot be done with telemedicine. Electrocardiogram and urinalysis testing can be accomplished remotely.
    a. Elements that *can be completed via telemedicine* include medical history, height, weight, ear, nose, throat, ocular motility, lungs, heart, vascular, skin, musculoskeletal extremities, spine, identifying body marks/scars/tattoos, neurologic, psychiatric, general systemic, hearing, blood pressure, pulse.
    b. Elements that *can be only partially assessed in the home via telemedicine* include retina, pupils, abdomen/viscera, genitourinary, vision (distant, near, intermediate), color vision, field of vision, and heterophoria.

[2]This column indicates whether the commercially available instruments or devices listed fully (Y), partially (P) or do not (N) meet the requirements to be able to conduct these at the airman's home environment.

c. Elements that *cannot be accomplished remotely* include exam of the anus (note: not a routine exam requirement) and lymphatics.

2. A telemedicine solution requires both a telemedicine platform and specialized medical devices. Multiple telehealth technology platforms are now commercially available which could be used to provide a telemedicine option for aeromedical certification exams during a PHE. Interoperable medical devices are commercially available to configure a telemedicine solution with limitations as described above.

NEXT STEPS

Telemedicine is already in use by AMEs for specific patients in the HIMS program undergoing monitoring for recertification. With a carefully planned program, the FAA could roll out an expanded use of telemedicine for contingency aeromedical certification exams. Given the above, MITRE proposes the following for consideration:

1. *Proceed with technology demonstration and operational effectiveness and suitability evaluation relative to the current in-person exam.* The FAA can start with a few Proof of Concept (PoC) demonstrations based on technological requirements, including data and device interoperability standards. Table 3 includes a complete set of medical devices that could be used to prototype a telemedicine solution for the aviation medical exam.

2. *Upon successful execution and results of the demonstrations, implement a policy decision on including a telemedicine provision in the national aviation preparedness plan.* Preparedness planners will need to determine the indications and scope of telemedicine for airman medical certification exams and the method for acquiring and providing telemedicine equipment and services. Additionally, planners should consider the likely demand for telemedicine-enabled medical certification exams during a PHE and develop FAA-designated provider staffing models to compensate for potential reduced AME availability.

APPENDICES

Appendix A: Innovation Challenge

MITRE hosted an innovation challenge to obtain perspectives on strategies to identify effective telehealth practices, including devices and methods, to improve medical history taking and physical exam documentation from the industry and stakeholders in this area. Specifically, the FAA task requested that the innovation challenge enable MITRE to :

- Elicit applicable telemedicine capabilities and leverage the industry to rapidly prototype and determine the feasibility or practicality of telemedicine for aeromedical certification exams.
- Evaluate features of the aeromedical certification exam with a preferential focus given to medical history and physical exam elements with the greatest role in mitigating safety risks. This includes emphasis on visual, auditory, cardiovascular, pulmonary, neurological, and musculoskeletal systems and evaluation of mental and behavioral health.

Seven organizations responded to the initial challenge; of these, MITRE invited five to present their solutions in Stage 2 of the innovation challenge (Figure 2):

FIGURE 3: STAGE 2 PARTICIPANTS

Mayo Clinic™, located in Rochester, MN, is one of the country's largest and most respected integrated healthcare systems. Mayo Clinic is one of the largest providers of aeromedical certification exams for the FAA. Clayton Cowl, MD, MS, himself an AME, led the development of the Mayo Clinic's proposal, "MedXPress PLUS: A Kiosk Model." Mayo invited collaborators Let's Talk Interactive® (telehealth platform), Olea Inc.® (kiosk provider), and Highmark Interactive® (behavioral health assessment tools). They demonstrated the integration of FDA-approved medical devices and an interactive telehealth platform that could be deployed through self-cleaning kiosks in high-volume locations such as flight schools or airports. The same telehealth platform and a softpack of selected medical devices can be used to provide medical certification exams in the home. In a similar configuration, Olea kiosks and Let's Talk Interactive are providing telehealth services to school systems and some universities in Florida and Texas. Web-based behavioral health assessment tools are used by neuropsychologists across the U.S. and foreign countries from Highmark Interactive. These tools could streamline and improve access to neurocognitive testing services needed by airmen to meet aeromedical certification requirements.

Medweb®, a Medical Equipment Manufacturing Company, delivers a web-enabled telemedicine platform by establishing relationships with telemedicine technology vendors and providing electronic acquisition, viewing, communications/transmission, publishing, and storage of medical data captured by various modalities and devices. Medweb's main services are the movement of radiology images across DoD and report connectivity between DoD and the VA for imaging sharing. Medweb's solutions are HL7 FHIR standards compatible. Customization is commonly needed between commercial EHR and feeder systems such as Picture Archiving and Communications Systems (PACS), scheduling, and labs. During the presentation, Medweb demonstrated how an airman and AME would use its platform and software tools using the low-code development platform from Appian®.

Tivra Health® is a start-up company based in New Jersey that aspires to build a "holistic health metaverse." This includes nutrition, fitness, sleep, health, mental, cognitive, and spiritual awareness. Tivra Health has created an interoperable platform that allows the integration of >50 medical devices using standards and reporting dashboard. It is focused on monitoring an individual's health over time and connecting them with healthcare professionals to achieve behavior change through coaching and "rewards"/recognition. Tivra Health proposes to use artificial intelligence to help personalize coaching and recommendations. The company has no active deployment and indicates that its interface and reporting tools can be tailored to meet the requirement of the aeromedical certification exam.

The University of California Los Angeles (UCLA) eHealth Research Lab™ presented its largely experimental remote mental health monitoring platform, validated through multiple studies, and is currently in active use in ongoing research. The team proposed that this platform can be applied to remote monitoring and telemedicine, with the potential to explore alternative means of providing support to at-risk airmen, mechanisms to aid and accelerate return to duty, and potentially ensure

compliance with treatment protocols. One of the notable features of this platform is its ability to drill down to the individual (patient) level to get treatment information and obtain baseline medical data. This capability aligns with tools such as remote stethoscope, a potential tool that might be used as part of a telehealth solution. As of this writing, the research is not yet in the clinical efficacy stage and will likely not meet the target implementation within two years. While this platform is irrelevant to the current aeromedical certification exam workflow, it could apply to Special Issuances.

Zoom Communications® provides a video and communication platform that can be integrated as the key component of a telemedicine solution. It is currently in use in thousands of hospitals and physician offices in the U.S. It has standard integration tools for use with the major EHRs Epic® and Cerner®. Rest APIs (application programming interfaces) enable simple integration with existing web applications so that users are not required to download additional software. In their presentation, the Zoom team included a list of vendors that can provide the full telehealth with needed features (e.g., appointment scheduling tool, multiple providers during a session). Zoom uses industry standards for data connectivity with many medical devices to satisfy most physical exam elements. Zoom is FedRamp-certified and has contracts with the FAA and many federal agencies.

National Telehealth Networks Marketplace

The telehealth marketplace is very dynamic, with entrants of many new vendors and solutions, particularly during the COVID-19 PHE when telehealth regulations were relaxed and insurance payments increased (Figure 3).[9] This is a factor to consider when the FAA moves to the next phase and procures telehealth services and technology. Mergers and acquisitions are common as telehealth offerings mature to offer more clinical specialty services and medical devices become more sophisticated. Best practices related to remote physiologic monitoring and disease management are evolving, given changing insurance and coverage incentives. Large health systems are tailoring EHR connectivity and patient portals to create new workflows for urgent care, hospital discharge, and post-surgical care using telemedicine. Several large companies have grown as leaders in the telehealth market over the last five years as exemplified by Teladoc Health Inc. and Amwell Inc. Prior to the PHE, both companies focused on the private insurance marketplace with direct-to-employer services because Medicare and Medicaid were restrictive in their insurance coverage for telehealth services. Both companies grew rapidly during the PHE to expand service offerings, including integration with EHRs and new programs for disease management, peri-operative care, and post-hospital recovery services. These companies have also sought to build their own networks of physicians and other providers to ensure access for "on-demand" telehealth services. New health insurance products are also now promoting "digital first" service, which incentivizes patients to first seek care via telehealth before traveling to a brick-and-mortar location whenever possible.

National telehealth networks such as Teladoc and Amwell represent a potential avenue for telehealth program growth for the FAA. Integration with a national network affords streamlined technology acquisition with privacy and security agreements. Additionally, these networks have established provider networks of their own and relationships with physician organizations that could provide an opportunity to recruit future AMEs. During the PHE, most states relaxed licensure requirements so physicians could practice across state lines. Such waivers expired with the official ending of the PHE.[10]

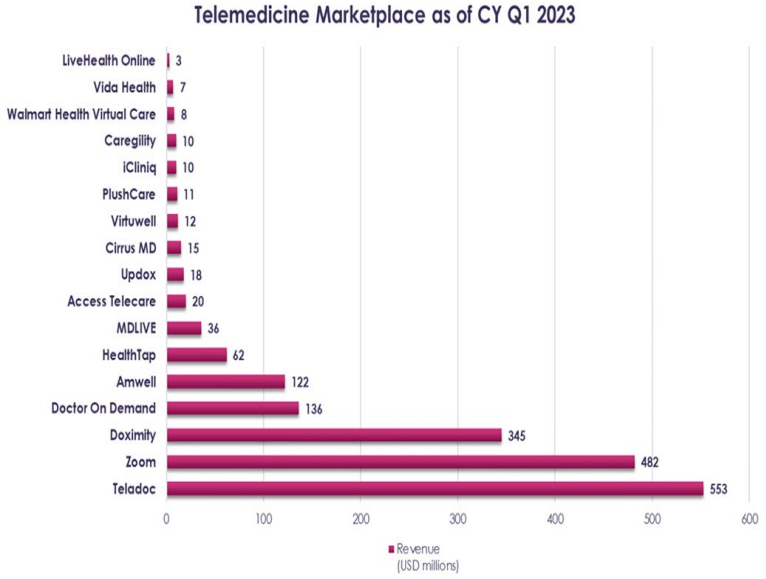

FIGURE 4: MARKETPLACE AT-A-GLANCE

Appendix B: Medical Device Research Details

Eye Exam and Vision Testing

The aeromedical certification exam includes a comprehensive vision and eye exam geared toward the dual goals of ensuring that (1) an airman is fully able to perform their duties with uncompromised vision or discomfort and (2) any signs of a degenerative and debilitating disease, discernable through an eye exam, are identified in a timely fashion.[11] The resulting exam generally falls into a physical exam to determine eye health and a series of vision tests to determine the quality of the airman's sight at different distances, along with ocular motility, color vision, and field of vision.

In the initial assessment of the eyes, the examiner looks to see if there is a general appearance of normalcy (e.g., if the sclera is normal white or injected, lids are normal or lagging). This can be accomplished with the basic telemedicine camera. The examiner typically performs the next component of a comprehensive exam of the airman's eyes using a handheld ophthalmoscope. Examiners should look for evidence of several potential maladies when conducting this exam. This exam includes examining the cornea for signs of abrasions, calcium deposits, contact lenses, dystrophy, and more. Pupils and irises are checked for the presence of synechiae and uveitis. The aqueous of the eye is examined for signs of hyphemia or iridocyclitis; the lens is observed for aphakia, discoloration, dislocation, cataract, or an implanted lens. Examiners are asked to explore the eye's vitreous and note any discoloration, hyaloid artery, floaters, or strands. An airman's optic nerve is observed for signs of atrophy, hemorrhage, cupping, or papilledema. Finally, the retina and choroid are examined for evidence of coloboma, choroiditis, detachment of the retina, diabetic retinopathy, retinitis, and more.[12]

This exam is typically performed through a close visual inspection of the airman's eyes and evaluation of the retina using a standard ophthalmoscope. However, the examiner may opt to utilize advanced imaging as well.

Examiners are given latitude regarding the precise exam modalities performed, and the standard appears to be sufficient so that the physician can confidently determine an airman's health on the conditions mentioned earlier.

Examiners are also expected to conduct a series of vision tests to determine near, intermediate,[13] and distant vision[2]; ocular motility; color; and field of vision.

Passing standards for vision tests are established in FAA guidelines and are based on an airman's ability to read and recite a sequence of letters of a particular size printed on a standardized chart from a set distance.

While both manual and electronic techniques exist for in-person vision testing, including the visual review of the Snellen 20-foot eye chart, or FAA Form 8500-1, a manual chart review is typically performed.

An examiner also assesses an airman's visual color acuity. FAA specifies the "use of actual color vision plates and testing machinery" and states that "[w]eb-based color vision applications, downloads, or printed versions of color vision tests are prohibited." [2] This is performed by exposing an airman to a standardized colored plate in which certain pixels are colored with slightly different hues and shades to form an object within the plate (typically a letter or number). The airman must discern the subtle color difference and recite the resulting object within the plate.

Heterophoria is a latent potential for double vision exacerbated by fatigue, hypoxia, or central nervous system depressants. Problems related to heterophoria may manifest with symptoms such as double, overlapping, or blurred vision or light sensitivity with glare or reflection. In some cases, this can affect depth perception. FAA guidance requires further testing for airmen with more than 1 prism diopter of hyperphoria, 6 prism diopters of esophoria, or 6 prism diopters of exophoria.[2] Screening for heterophoria could be accomplished using a symptom questionnaire and the eye cover test carried out with a handheld vision occluder (simply covering the vision in one eye).[8] If eye deviation is detected or concerning symptoms are elicited, consideration should be given for a complete exam by a qualified eye specialist. Finally, the examiner typically performs field of vision and ocular motility.

Numerous products in the market encompass various elements of these exams and are designed to replace or replicate the current physical exam. A subset of those is listed in Table 3. While no single solution currently exists in a mature form capable of performing all eye-related elements of the aeromedical certification exam, a combination of the products in Table 3 could potentially enable remote eye and vision exams. Advances in retinal imaging and photography now allow for images to be sent electronically to a physician for interpretation.[14] However, current technologies typically require a clinician or a medical assistant to operate and are amenable to an office or kiosk setting. Retinal imaging in the home would require a visit by a technician. Field of vision testing can be automated using a portable virtual reality headset with a report sent to the examiner.

However, this device is currently designed for use in the office setting with a technician.

These products are either operated from devices the airman is likely to have on hand or are portable and user-friendly enough that the user can self-administer the exam with limited assistance.

TABLE 3: SOLUTIONS CURRENTLY IN THE MARKETPLACE IDENTIFIED FOR EYE EXAMS AND VISION TESTING

Solution	Platform Used	Description of Test	Types of Eye Exams Performed	Comment
Eyetakes Mobile Application[15]	iOS app	Mobile app designed to directly leverage smartphone camera for fundus photography	**Detailed Eye Imaging** via portable indirect fundus and optic disc exam	Endorsed by the AAO[16] and available in the app store. *Requires clinician to operate*.
Zeiss Visuscout Handheld Fundus Camera[17]	Standalone mobile camera	Fully self-contained portable fundus camera with Wi-Fi-enabled remote transfer of images	**Detailed Eye Imaging** via comprehensive, state-of-the-art eye imaging functionality	Well-established, commercially available, clinical diagnostic device. Portable, but requires a clinician to operate the device and take the retinal photos.
Welch Allyn Panoptic Ophthalmoscope 11820 PLUS Panoptic Ophthalmoscope Smartphone Adapter[18]	Portable fundus camera that, along with associated adapter, attaches to Android and iOS devices	Camera lens and mount designed to be affixed to smartphones for professional-level fundus imaging and remote transmission	**Detailed Eye Imaging** through fundus pictures and videos	Well-established clinical diagnostic device. Portable, but requires a clinician to operate the device and take the retinal photos.
Welch Allyn Retina Vue 700 and RetinaVue Network [19]	Portable Retina Camera and Clinician network	Nonmydriatic retinal imaging uploaded to clinical network, designed for primary care office setting.	**Retinal imaging**, primarily used for annual diabetic eye screening.	Simple to use camera, no eye dilation needed, operated by support staff in office, kiosk, or potentially home.
StrabisPIX Mobile Application [5]	iOS and Android app	StrabisPIX is a HIPAA-compliant photo messaging platform that helps physicians evaluate patients' eye alignment following surgery to treat strabismus	**Ocular Motility** via mobile app	Available in the app store and in active practice at Boston Children's Hospital. Requires a second person to take photo images.
Home Acuity Test[20]	Printed on paper from downloadable PDF file	Self-administered, home visual acuity testing for those with vision better than 20/125 for use at 10 feet.	**Visual acuity test**	
EyeQue [21]	Vision test devices and smartphone and app	Vision testing devices connect physically with smartphone. App provides images and scoring of visual acuity.	20/20 Vision checker with or without glasses or contacts; automated testing for nearsightedness, farsightedness, astigmatism	Option to produce "eyeglass numbers "equivalent to a prescription.
Warby Parker Virtual Vision Test[22]	iOS and Android app	Warby Parker offers a mobile application for uncomplicated vision exams to renew eyeglass and contact lens prescriptions remotely.	**Vision Testing** via mobile app, limited to renewal of single-vision distance prescription eyeglasses and contact lenses.	In active use by popular online eyewear retailer.
Lensabl Online Vision Test[23]	Browser-based website	Lensabl provides a user-friendly online vision test to renew prescriptions remotely.	**Vision Testing** via website	In active use by popular online eyewear retailer.
Richmond-HRR, 4th edition[24]	Printed book	The HRR (Hardy Rand and Rittler) Standard Pseudoisochromatic Test, 4th Edition provides an advanced color vision test and can be administered by sending the booklet to remote patients.	**Color Vision Testing** via specially printed plates in a test book	Approved by the FAA for AME exams.

Solution	Platform Used	Description of Test	Types of Eye Exams Performed	Comment
VF3 Pro Headset	Headset device	VF3 Pro headset incorporating RAPD detection with pupillometry, active eye tracking during visual field tests	**Color Vision Testing, Field of Vision, Eye Tracking** via headset	Color vision not currently approved by the FAA at time of writing. Requires technician assistance..

Hearing and Audiology Testing

The aeromedical certification exam includes a standard hearing and audiology exam geared toward ensuring that (1) an airman has acceptable hearing in at least one ear; (2) there are no signs of disease or condition of the middle or internal of the ear, nose, oral cavity, pharynx, or larynx of the airman; and (3) there are no signs of disease or condition manifested by vertigo or a disturbance of the airman's equilibrium. This generally falls into a physical assessment where the airman demonstrates the ability to hear an average conversational voice in a quiet room, using both ears at 6 feet away, with the airman's back turned to the examiner. If an airman does not pass the 6-foot hearing test, they must take an audiology exam or a pure tone audiometric exam.

If the examiner is required to perform an audiology exam, the airman must demonstrate an acceptable understanding of speech by audiometric speech discrimination testing and score at least 70% in one ear or in a sound field environment. If the examiner is required to perform a pure tone audiometric exam, the airman is not permitted to use a hearing aid, and results must fall within the standards of the American National Standards Institute.

Hearing and Audiology Exams in Telehealth

The possible modalities for conducting these tests in a telehealth setting are listed in Table 5 and summarized as follows:

- **Self-administered screening tests,** such as apps on a smartphone or tablet, verify a low level of background noise, while a self-administered air conduction test is enabled with a pair of off-the-shelf headphones. A speech-in-noise audiometry test using an adaptive procedure is also available. Validated by increments of 2 dB and using a series of digits triplets, its special feature is to enable the detection of asymmetrical or conductive hearing impairments thanks to an antiphasic presentation between the two ears that invokes the principle of binaural unmasking.[25]
- **Remote access to the patient's device** involves interaction between the practitioner and the patient without a third party, where the healthcare provider remotely accesses the patient's electronic device (tele-audiometry software previously installed). Results are gathered from the patient's device and immediately analyzed. The type of tests for this mode includes pure-tone, supraliminal pure-tone, speech-in-quiet, and/or speech-in-noise, and dichotic.[25]
- **Tele-audiometry for an assisted patient**, the technician assists with installation (verifying the quality of the sound environment, launching the tele-audiometry software installed on a connected electronic device, preparing the air and bone conduction tests) and ensures that responses to auditory stimulations are correctly given.[25]

Table 4: Solutions Currently in the Marketplace Identified for Hearing Screening

Solution	Device Used	Description of Test	Air Conduction/Bone Conduction	Comment
HearScreen, Noise Test for Hearing Screening by HearXGroup[26]	Android & iOS app	Speech-in-noise	Air Conduction Only	Hearing screening but not approved by the FAA at this time. CE Certified, TGA Certified, HIPAA Self-Declared, POPIA Self-Declared, SAHPRA Registered.[27]
Mimi Hearing Test[28],[29]	Android & iOS app (more effective on iOS)	Pure-tone audiogram	Air Conduction Only	Hearing screening but not approved by the FAA at this time. Although not FDA-approved, this is free and available on the platforms listed and typically used in cases of quick and easy screening,

TABLE 5: SOLUTIONS CURRENTLY IN THE MARKETPLACE IDENTIFIED FOR DIAGNOSTIC TESTING OF HEARING

Solution	Device Used	Description of Test	Air Conduction/Bone Conduction	Comment
Koalys Confirm[30] (Shoebox company)	Android tablet-based	Pure-tone audiogram; Speech-in-Noise	Air Conduction Only	Potential use for airmen who fail screening exam, not approved by the FAA at this time. CE Mark approval in EU, listed as a Class II med device with US FDA and Health Canada. [31]
Koalys Consult[32] (Shoebox company)	Computer-based (Windows 10)	Pure-tone audiogram; Speech-in Noise; unaided and aided free field audiometry	Air Conduction & Bone Conduction	Potential use for airmen who fail screening exam, not approved by the FAA at this time. CE Mark approval in EU, listed as a Class II med device with US FDA and Health Canada.[33]
Shoebox Pro[32] (Clearwater Clinical)	iOS tablet-based	Pure-tone audiogram; Speech audiogram	Air Conduction & Bone Conduction	Potential use for airmen who fail screening exam, not approved by the FAA at this time. World's first CE-marked iPad-based audiometer, Class II medical device with FDA and Canada Health. Cleared for clinical hearing test in the EU market.[33]
eMoyo Kuduwave Plus & Kuduwave Pro[34]	Boothless computer-based	Pure-tone audiogram and suprathreshold audiometry (Stenger test); Speech-in-Noise testing	Air Conduction & Bone Conduction	Potential use for airmen who fail screening exams, not approved by the FAA at this time. ISO 13485 certified, FDA-registered, CE-mark certified for medical devices, and are compliant with all IEC, ANSI, and SANS standards for audiometry, tympanometry, and calibration.[35]
HearX HearDigits, Virtual Screening Test[36]	App for Android smartphones (tablet in the future)	Pure-tone audiogram	Air Conduction Only	Potential use for airmen who fail screening exam, not approved by the FAA at this time.

Electrocardiogram Testing

Medical certification for a first-class airman requires the individual to demonstrate an absence of myocardial infarction and other clinically significant abnormality on electrocardiogram (ECG). To satisfy this requirement, the airman must have an ECG within 60 days before the date of the application, and it must be transmitted according to acceptable standards and techniques.[2] The requirements do not specify that this should be a standard 12-lead ECG, but we assume this to be the case for this report. Although there has been substantial innovation around the use of medical devices and sensors to record and transmit heart rhythms, these are commonly limited to a single- or dual-lead ECG view. The 12-lead ECG requires the placement of multiple leads on the chest and extremities. In most scenarios, this requires trained medical personnel to place the leads. However, one vendor, QT Medical,[37] provides the PCA 500 portable 12-lead ECG equipment, automated reading, and transmission services for self-administered ECGs (Figure 4). These can be done in the home or remote center without medical personnel. The equipment is sent to the client's home, the ECG lead set is placed on the chest by the client, and the ECG is recorded and automatically uploaded to the cloud database. A cardiologist reads the ECG. The ECG image and results report are then available for download or transmission to other electronic systems.

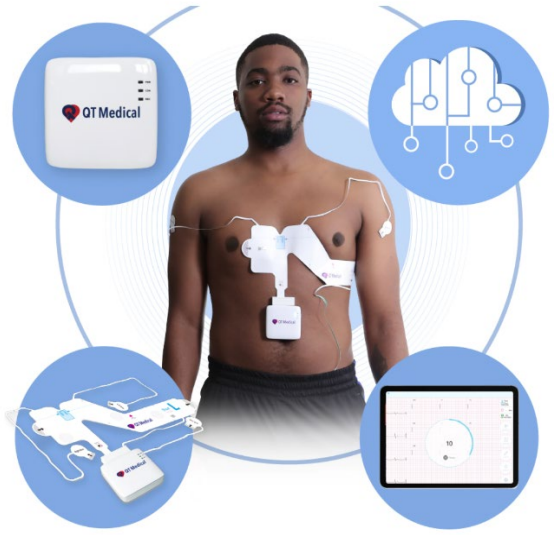

FIGURE 5: QT MEDICAL – PCA 500 PORTABLE 12-LEAD ECG

Ear, Throat, Heart, Lung, and Skin Exam

Multiple devices are available to facilitate key components of the physical exam. One manufacturer, TytoCare®, provides a single device with attachments to take images and recordings of ear, throat, lung, heart, and skin exam. The TytoCare device (Figure 5) has an ear attachment that converts it into an otoscope, a tongue depressor facilitating photos of the throat, and an auto-focusing camera for imaging skin lesions. The stethoscope attachment enables exam and recording of lung and heart sounds. The TytoCare device incorporates on-screen guiding instructions to precisely position the device in the ear, throat, chest, and above the skin to optimize the photo and audio recordings for each body part. The device is also a thermometer to allow temperature recording from the forehead or other skin surface.

The Mayo Clinic's presentation on a telemedicine solution using a medical kiosk included the potential to use over 45 different connected devices in the kiosk. Figure 6 displays a selection of devices for completion of the aeromedical certification exam for use in a medical kiosk. The digital stethoscope allows the patient to listen to their heart and lung sounds while simultaneously transmitting them to the physician during the virtual visit.

FIGURE 6: TYTOCARE DEVICE FOR REMOTE PHYSICAL EXAM IN THE HOME

FIGURE 7: EXAMPLE DEVICES FOR REMOTE PHYSICAL EXAM IN A KIOSK

Appendix C: Methodology

This project used the AME Guide and FAA Form 8500-8 to define scope. The exam requirements were tiered based on the criticality of exam elements to detect conditions with a high risk for pilot incapacitation. MITRE then generated ideas for potential requirement solutions based on an innovation challenge, AME interviews, and a market survey (Figure 7). The MITRE Telemedicine Innovation Challenge allowed innovators to demonstrate how a physician or other healthcare provider can use telehealth technologies to conduct a standardized medical history and physical exam. Participants were asked to share their knowledge and determine the feasibility and practicality of telehealth for aeromedical certification exams. The challenge was promoted to large and small commercial vendors, healthcare provider organizations, and the start-up community through the American Telemedicine Association, Digital Medical Society, and MITRE networks. The team also performed a detailed literature search of peer-reviewed and scholarly articles on telemedicine, focusing on the best practices and technologies that evolved during the COVID-19 PHE. This helped augment any gaps identified and validate the observations gleaned from the interviews and vendors' presentations.

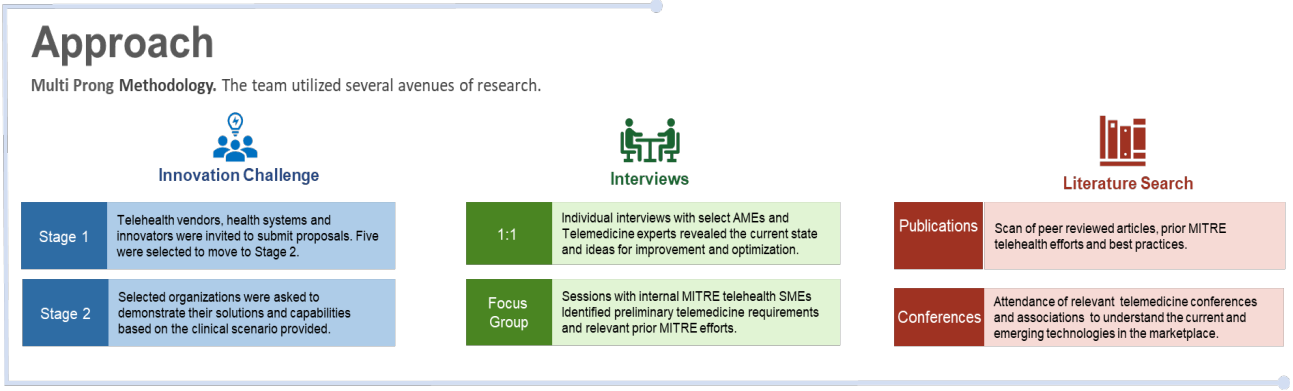

FIGURE 8: METHODOLOGY

The interviews with AMEs enabled the team to obtain their experience on the current state and insights into the technical feasibility of telemedicine. Interviews with Dr. Tvaryanas (AAM-600) and eight physician leaders representing the major clinical specialties were completed at the project's outset. The interviews were followed by one-on-one interviews with an additional group of experienced AMEs from across the U.S. Figure 8 below shows the breakdown of the participants and their respective specialties.

Total Interviewed:	**15**
Affiliation: FAA	11
Affiliation: Private Practice Or Other	4
HIMS Certified	3

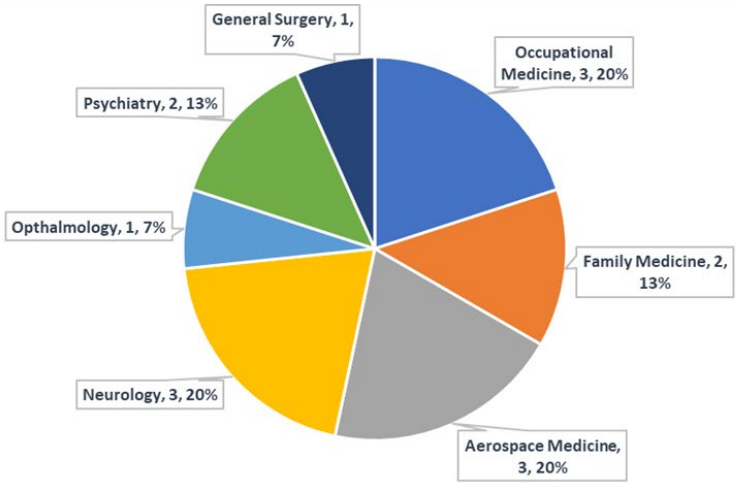

FIGURE 9: FAA AND SENIOR AMES INTERVIEWED - AT A GLANCE

ACRONYMS, ABBREVIATIONS, AND DEFINITIONS

AAM	Office of Aerospace Medicine
Air conduction [38]	The transmission of sound vibrations to the eardrum through the external auditory meatus (opposed to bone conduction)
Airman/Airmen	Airman/Airmen refer to pilots and air traffic controllers who are required to undergo aeromedical certification exams
AME	Aviation Medical Examiner – a physician designated by the FAA and given the authority to perform airman physical exams for issuance of second- and third-class medical certificates (NOTE: Senior AMEs perform first-class airman exams.)
Bone conduction [38]	The transmission of sound vibrations to the internal ear through the cranial bones (as opposed to air conduction)
CE Mark	Stands for "Conformite Europeenne" which certifies that a product has met EU health, safety, and environmental requirements therefore ensuring consumer safety.
DoD	Department of Defense
DOT	Department of Transportation
DRE	Digital Rectal Exam
ECG	Electrocardiogram
EHR	Electronic Health Record
FAA	Federal Aviation Administration
FHIR	Fast Healthcare Interoperability Resources
HIMS	Human Intervention Motivation Study
HIMS AMEs	AMEs who are trained in evaluating airmen for substance- or alcohol-related conditions or other mental conditions
HIPAA	Health Insurance Portability and Accountability Act
HL7	Health Level Seven International
ISO	International Organization for Standardization
PHE	Public Health Emergency
POPIA	Protection of Personal Information Act (POPI Act). https://popia.co.za/
SAHPRA	South African Health Products Regulatory Authority
SSRI	Selective Serotonin Reuptake Inhibitors
Telemedicine	Also referred to as telehealth. The use of telecommunications and information technology provides access to health assessment, diagnosis, intervention, consultation, supervision, and information across distance.[1]

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