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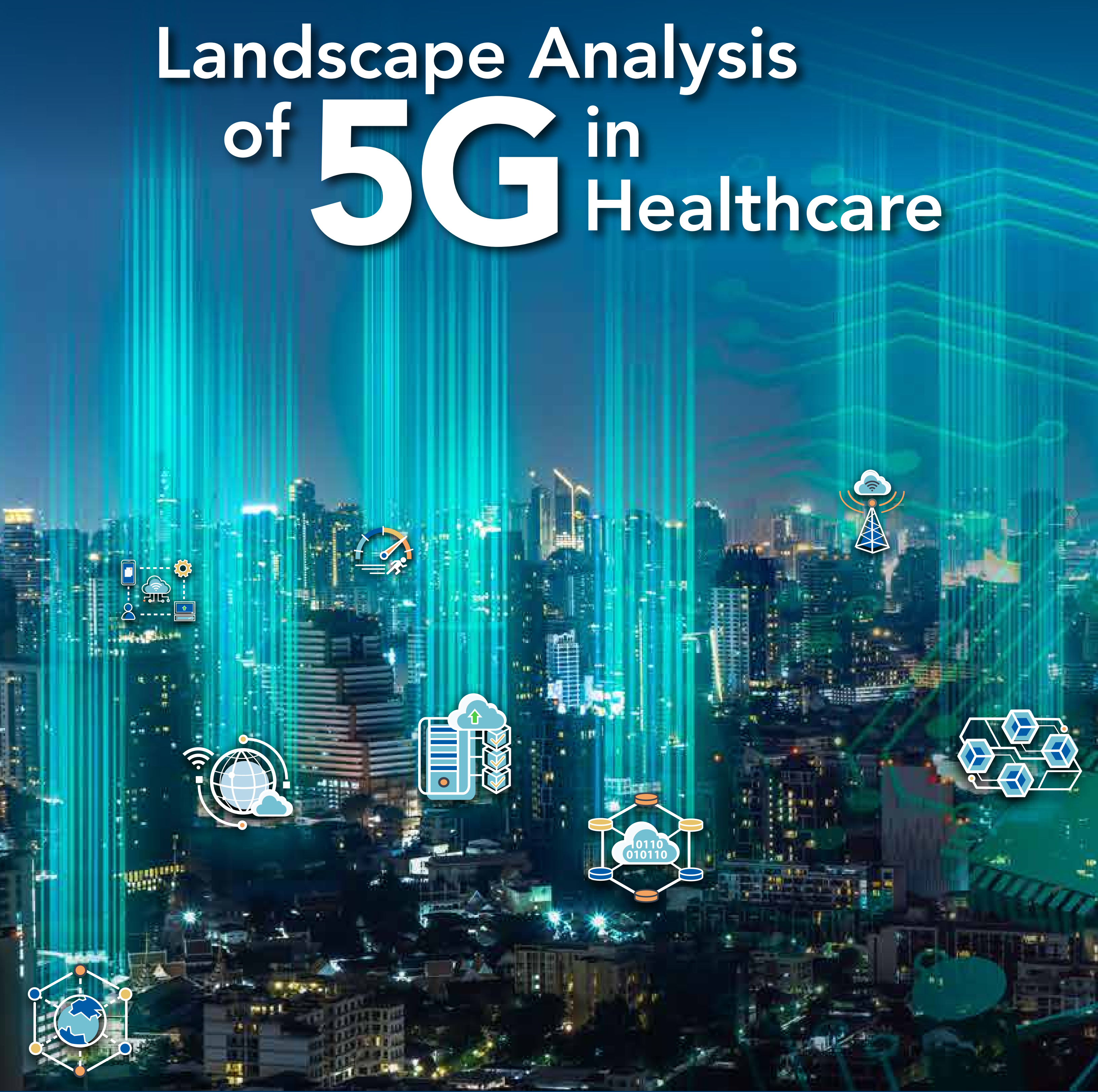
Landscape Analysis of 5G in Healthcare



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Executive Summary

As an enabler of ubiquitous connectivity, 5G will contribute to continued technical advancements in healthcare delivery by enabling novel healthcare applications or augmenting the use of existing technologies. This report surveys the role of 5G connectivity in current and future states of the continuum of care in healthcare. After an introduction of 5G technology, we provide several 5G-enabled healthcare use cases, including 5G-enabled simulation with extended reality, 5G-enabled robotics, mobile units, and remote care. Finally, some key challenges and knowledge gaps in this space are identified, bridging which would help deliver the benefits of 5G in healthcare more safely to patients.

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The Medical Device Innovation Consortium (MDIC) is the first public-private partnership created to advance the medical device regulatory process for patient benefit.

MDIC was formed in 2012 to bring the Food and Drug Administration (FDA) and industry together to share vital knowledge that can help bring safe, affordable, and effective devices to patients and providers more quickly. MDIC membership and participation is open to nonprofit, industry, and government organizations that are substantially involved in medical device research, development, treatment, or education; or in the promotion of public health; or that have expertise or interest in regulatory science.

MDIC has been designed to pursue several strategies that support its mission:

- Create a forum for collaboration and dialogue
- Make strategic investments in regulatory science, utilizing working groups to identify and prioritize key issues, and to request, evaluate, and implement project proposals
- Provide and enable implementation of tools from these projects that drive cost-effective innovation

The activities and outputs from MDIC are intended to:

- Ensure that innovative technology is readily available to U.S. patients
- Provide industry and government with methods and tools that may be used to expedite medical device development and the regulatory process
- Reduce the risk and expense of clinical research
- Reduce time and cost of medical device development

MDIC members provide guidance and leadership through collaboration to develop solutions for regulatory, scientific, health, and economic challenges within the medical device and diagnostic industry.

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01

INTRODUCTION

Over the course of the 20th century and into the start of the 21st, healthcare has increasingly been centralized into large organizations due in no small part to the increased complexity and cost of providing care. In this context, the healthcare industry has applied techniques common to many large industries taking advantage of economies of scale. However, this centralized approach has created significant inefficiencies in how and where patients receive care.

With improved technology, industrialization is now giving way to the consumerization of healthcare, where the needs of patients, not healthcare organizations, are preeminent. Over the next decade, disjointed and uncoordinated healthcare systems will move towards a continuum of care model where healthcare is provided when and where it is needed. Large healthcare centers will continue to support expensive cutting-edge therapies, but, increasingly, care will be provided in community hospitals and in patients' homes.

There is a confluence of factors making care delivery wherever patients are not only a possibility, but an imminent reality. People have come to expect convenience in their consumer experience and healthcare is no exception. The world is in the midst of a digital transformation led by the constant connectedness enabled by modern communication technology and smart devices. Contributors to this trend include the advent of cloud computing, advances in data analytics, artificial intelligence (AI), machine learning (ML), and the increased processing power of modern computers. Communication networks, especially wireless connectivity, provide the infrastructure to facilitate these advances, which will be further augmented by the growing availability of low latency and high bandwidth 5G connections.

Modern healthcare is extending to the home, with home-based and wearable medical devices to help monitor, diagnose, and provide therapies. Such devices travel with patients wherever they go. When necessary, patients can use community hospitals and larger, multidisciplinary, tertiary and quaternary care facilities based on the complexity of care needed. Patients will move between these systems as their symptoms and severity of illness dictate, with health delivery organizations recognizing that, the closer to home that care is provided, the lower the cost and the more satisfied the patient.

What is 5G?

5G is the fifth generation of cellular communication networks that offers improved data connectivity compared to previous generations such as 4G LTE. Improvements include increased throughput, lower latency, enhanced connection density, and new technologies such as software virtualization, automation, and cloud-based interfaces for rapid software integration. These facilitate an expanded use of cellular communications in several industry sectors, including healthcare, to support existing use cases and enable novel ones. 5G specifications are developed by the *3rd Generation Partnership Project (3GPP)*[1] to meet the wireless communications performance goals set by the *International Telecommunication Union (ITU)*[2] including 20 Gbps peak data rate, 100 Mbps user experienced data rate, 1 ms latency, and connection density of 1 million devices/km^2. However, realistic implementations of the 5G specifications by different equipment manufacturers and deployments by network operators result in varying achieved performance[3]. Furthermore, variables such as investment in the radio frequency (RF) spectrum that is specific to given geographies and deployed spectrum bands differ between carriers, which, in turn, contribute to the noted performance differences.

As illustrated in Figure 1, cellular networks comprise two parts: a radio access network (RAN) that facilitates the wireless (i.e., over-the-air) connection between a user and a base station and a core network, commonly relying on wired connections, with functions that include controlling the RAN, routing connections to their destinations, and interfacing with external networks like the Internet. The RAN employs base stations that use the RF spectrum to communicate with the user equipment and provide wireless coverage in a network service area.

5G expands the frequency bands commonly used by cellular networks (typically below 6 GHz) to include high band frequencies between 24 GHz—52 GHz that are collectively referred to as the *millimeter-wave [mmWave] spectrum*. The addition of the mmWave spectrum allows 5G to accommodate communication channels with significantly larger bandwidths, thus considerably increasing connection throughput. However, mmWave signals can only travel for short distances and therefore require additional network relays on buildings to propagate over larger areas. Accordingly, providing network coverage in a certain area with only mmWave requires many mmWave base stations being tightly deployed to ensure continuous coverage. Notably, the inclusion of both sub 6 GHz and mmWave signals in 5G networks provides complementary characteristics (e.g., wider coverage in sub 6 GHz, larger available bandwidth at mmWave) to address the coverage and connectivity needs of diverse service areas.

Enhanced Mobile Broadband (eMBB), Ultra-Reliable Low Latency Communications (URLLC), and Massive Machine

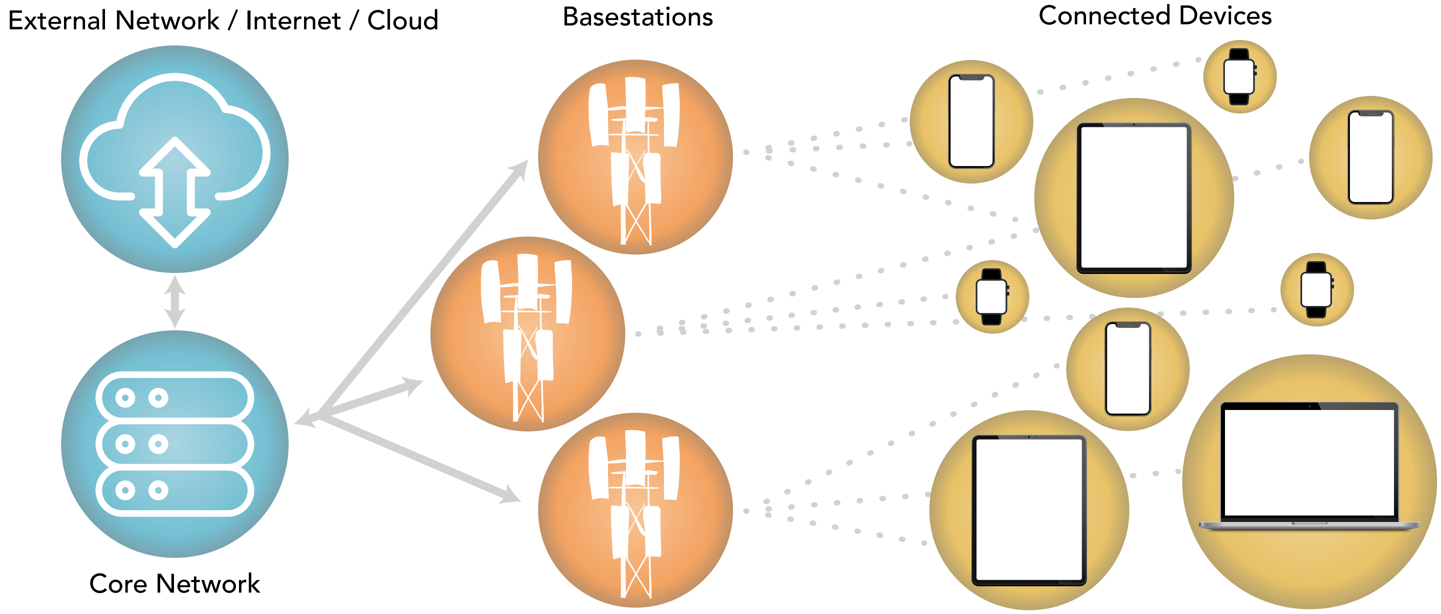

Figure 1—Simplified cellular network architecture

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[1] https://www.3gpp.org/

[2] https://www.itu.int/dms_pubrec/itu-r/rec/m/R-REC-M.2083-0-201509-I!!PDF-E.pdf

[3] See for example, https://5gobservatory.eu/5g-trial/major-european-5g-trials-and-pilots/

Type Communications (mMTC) are distinct use cases supported by 5G New Radio (NR) technology. Combining all three constitutes the 'full' 5G system[4].

eMBB provides greater data bandwidth complemented by moderate latency improvements on both 5G NR and 4G LTE and covers data-driven use cases requiring high data rates across a wide coverage area. It is an evolution of existing 4G networks which provides faster data rates. Accordingly, eMBB improvements help enable applications with intense data transmission demands like 360° video streaming and immersive virtual reality (VR) and augmented reality (AR) applications.

URLLC is intended to deliver low latency and reliable mobile services. It has strict requirements on latency and reliability to support mission critical communications, such as remote control of medical devices, industrial automation, and autonomous vehicles. Low latency allows a network to be optimized for processing large amounts of data with minimal delay. URLLC implements a quality of service (QoS) that is different from mobile broadband services, which 5G technology addresses by improvements to both the radio and core parts of the network.

mMTC supports a very large number of devices with reduced data transmission volumes in a small service area, such as Internet of Things (IoT) applications for sensing, metering, and monitoring devices. mMTC is closely linked to the IoT concept and connected wearables[5]. The distinct QoS features in eMBB, URLLC, and mMTC highlight the need to design 5G-healthcare applications with a clear understanding of what the 5G network can offer for a specific application and the tradeoffs that are inherent to the different 5G use-cases (e.g., support for transmitting large volumes of data vs. support for connecting many devices in a certain area).

An overview of 5G's unique features is presented in Appendix A—How does 5G differ from other common wireless technologies?

5G in Healthcare

As an enabler of ubiquitous connectivity, 5G can contribute to continued technical advancements in healthcare delivery. Advancements in medical image processing, sensor development, robotics, patient data information systems, and expanding use of technology by patients for their personal healthcare are all contributing factors to a meaningful integration of 5G in healthcare. Whether by enabling novel healthcare applications or augmenting the use of existing ones, 5G connectivity features can enhance the continued evolution of connected medical devices including controlling devices remotely, large image file management, and monitoring of patients both in the hospital and at home.

Expanded connectivity can also enhance the use and functionality of wearable and implantable devices and facilitate shared decision-making between physician and patient. Furthermore, 5G supports exchanging large volumes of data, contributing to collecting and aggregating diverse healthcare data streams from different sources. In turn, these can be used with AI techniques to promote a personalized and holistic patient care experience across the continuum of care. An example of communicating large volumes of data is the exchange of images (e.g., X-ray, magnetic resonance imaging [MRI], ultrasound).

The convergence of multiple technology domains (e.g., medical, communication) is enabling the envisioned applications of 5G-enabled healthcare. An example is the development of medical extended reality (XR) applications using 5G connectivity to allow the large-scale implementation of data-intensive remote training of physicians. This can facilitate the standardization of training and help overcome the collaboration, coordination, and communication challenges that arise during remote training. Similarly, robotic assisted surgery can be made available through 5G low latency communication to enable highly skilled surgeons to remotely perform procedures[6,7]. Noting that medical imaging systems play a role in planning and performing surgeries highlights the benefits of integrated connectivity across these systems. Enhanced connectivity also impacts other applications of robotics in healthcare. Examples include rehabilitation with exoskeletons, power braces for patients with paralysis, companion robots, and robots executing common logistical tasks like restocking supply and patient rooms.

The availability of 5G features supporting a massive increase in the number of devices connected to the network can enable the mass use of connected wearable devices

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[4] https://www.mediatek.com/blog/5g-what-are-embb-urllc-and-mmtc (Accessed on July 22, 2022)

[5] https://www.teldat.com/blog/5g-emmb-mmtc-urllc-fwa-smart-grid-automotive/ (Accessed on July 22, 2022)

[6] Proximie and Vodafone in successful 5G remotely assisted surgery trials (Accessed on October 25th, 2021)

[7] World's First Remote Operation Using 5G Surgery - Huawei (Accessed on October 25th, 2021)

and facilitate remote care. This use is already widespread with the help of existing local-area wireless technologies. 5G features advance this usage by enabling seamless mobility of connected devices between geographical locations. For example, a wearable device that monitors and reports a patient's vital signs during a hospital stay can continue to transmit data while in transport to the patient's home and during recovery. Such an application can further leverage a combination of 5G connectivity features (e.g., increased throughput, reduced latency, accurate positioning[8], improved reliability[9]) to create an innovative use-case integrating physician feedback, drug delivery, dosage control, and others. Notably, the widespread adoption of telemedicine methods during the COVID-19 pandemic illustrates the benefits of remote healthcare applications.

Finally, 5G is a communication technology that supports many industry sectors, including healthcare. The prospect for broad 5G adoption across many industries might incentivize telecom operators to make 5G services available in wide coverage areas with pricing models that are accessible to users in the healthcare sector. On the patient side, connected and integrated healthcare applications can provide patients with more autonomy and enable caregivers to provide care from distant locations while also facilitating the aggregation and processing of diverse healthcare data streams. Patient cost savings include time and travel expenses. Among the stakeholders sharing in the overall cost, healthcare delivery organizations (HDOs) might face upfront investments in 5G connectivity infrastructure that are weighed against the prospect for downstream cost savings due to expanded capabilities in condition prevention, management, and monitoring.

Four 5G-enabled healthcare use cases (i.e., simulation with extended reality, robotics, mobile units, and remote care) are described in more details in the Use Cases section.

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[8] 5G positioning: What you need to know - Ericsson (Accessed on October 25th, 2021)

[9] 5G Network Reliability Explained | A10 Networks (Accessed on October 25th, 2021)

02

USE CASES

Healthcare is rapidly evolving, driven by the growth of various technologies such as AI/ML, cloud computing and storage, robotics, and others, as well as an evolution of the healthcare model moving to more remote, virtual care of patients. Advances in wireless technologies play a significant role in this evolution, and 5G adoption can help bolster that role.

The first use case discussed in this document is related to the application of 5G to simulation, specifically XR telementoring and XR immersive training. Other use cases consider the deployment of 5G in robotics, mobile care unit capabilities enabled by 5G, and the expansion of remote care. All of these use cases are interrelated and can be used in multiple combinations throughout the continuum of care. Notably, 5G-enabled healthcare use cases were also presented and discussed for military use[10].

5G-Enabled Simulation with XR

XR Telementoring

Remote care commonly involves communication between patients and healthcare providers. In the U.S. and other parts of the world there is a shortage of healthcare providers outside of large cities, especially physicians and specialty care providers, XR technologies, leveraging 5G, can bring expanded expertise to providers working in underserved areas, rather than requiring the patient to travel to specialty care clinics.

An example is a mentor providing remote assistance, or mentorship, to a medical first responder (mentee). The mentor can gather greater situational awareness and provide graphical instructions to the mentee in the form of drawings or lists of information anchored in three-dimensional space. This allows the mentee to maintain field of view of the patient. Mobile medical professionals are often trained to work under adverse or hostile conditions while treating physical trauma and life-threatening wounds in the field. However, having real-time access to knowledge and expertise to assess, diagnose, and complete complex procedures and protocols to treat critical wounds could improve patient care and save lives.

Advances in XR technology can allow virtual information to be holographically inserted into the field of view of medical first responders. Delivering this virtual information from a medical specialist to the user via 5G enables high fidelity, bi-directional information to be shared at low latency. Additionally, a 5G-enabled XR telementoring solution can assist with physical interventions and interactions by adding low-latency access to health networks,

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[10] https://www.nextgov.com/cxo-briefing/2022/01/defense-officials-develop-5g-enabled-medical-applications-support-future-troops/360786/ (Accessed on April 15, 2022)

electronic health records, high-resolution digital imaging, and physiologic data from enhanced sensor monitoring.

5G systems help optimize the effectiveness and efficiencies of mobile medical personnel when operating in environments with limited access to specialized medical care. 5G capabilities can facilitate the information rendering in XR Head-mounted Displays (HMDs) and provide a real-time exchange of relevant clinical information between spatially separated mentee and mentor. A 5G-enabled XR telementoring solution can create resilient, real-time reach-back capability for mobile medical professionals by enabling real-time remote primary care support or multi-specialty access from extenders, credentialed caretakers, and specialists, thereby improving point-of-need care.

Situational awareness of a mentor in this scenario can be enhanced by eye tracking to inform the mentor where the mentee is gazing, allowing real-time feedback when the mentee is not on the right track. Data anchoring can allow the mentor to pinpoint locations, data, photos, video, or items in the mentee's visual space, enabling a quick way to communicate without taking eyes off the patient.

The interaction of 5G and XR technology is facilitated by the ratification of the 5G specifications 3GPP Release 16, which was finalized in July of 2020. Release 16 includes[11] XR-specific communication requirements with metrics around frames-per-second, visual motion latency, minimum level of graphical detail, upload and download speeds, device operating temperatures, and video resolution thresholds and objectives.

XR Immersive Training

Major academic healthcare institutions commonly have robust simulation centers where students practice their craft and experienced providers learn new techniques or how to use new equipment. Historically this training has been provided through cadaver labs, animal labs, and carefully supervised patient interactions.

Currently, the combined use of 5G and XR technology is deployed in specific and limited cases. One example is the immersive training of first responders in disparate locations. Other examples include immersive training in a surgical operating room supported by 5G[12]. In the future, 5G could support the deployment of XR to create immersive setups, extended to many fields and use cases.

In robot-assisted surgery, physicians often interact with the robot through actuators and a screen several feet from the patient, which highlights the room for developing novel training and simulation systems. Robotic surgery simulators are similar in function to flight simulators used to train pilots. Physicians can repeatedly practice procedures until they master the intricacies of the movements. They can also be challenged with rare and unexpected events. When incorporated in an immersive training setup, robotic simulators and XR supported by 5G communication features have the potential for expanding remote interactions between healthcare professionals, their students, and the patient.

XR offers the opportunity to train practitioners remotely in real immersive environments. It supports the creation of a mixed setting of real and virtual elements, where actions are seen in real time, with remote feedback and feeling of touch. It allows for the sharing of medical information and data before starting and allows healthcare professionals to receive support during various procedures.

While some XR immersive training use cases have been deployed, adding 5G to those mixed virtual and physical environments could bring added value in terms of data, latency, and real-time action, and help advance the use of XR from the training room to a real-life surgical room.

The training room from the trainer's perspective may include physical elements and devices, such as a manikin on which the trainer will perform and show actions to the trainees, who are virtually present thanks to telepresence. With XR, trainees are immersed in a mix of virtual and physical environment, where they get remote access to the physical devices and elements the trainer manipulates. They can feel what the trainer is doing, as if they were doing the manipulations on their own and could touch and feel the manikin as if they were in the room.

By virtualizing the training environment and placing trainees in an operating room by superposing virtual and physical elements, XR can be an alternative to traditional classroom or computer-based learning. This bridges the gaps between traditional classroom-based learning or computer based training and hands-on skill training, where trainees can get an overview of a real case situation

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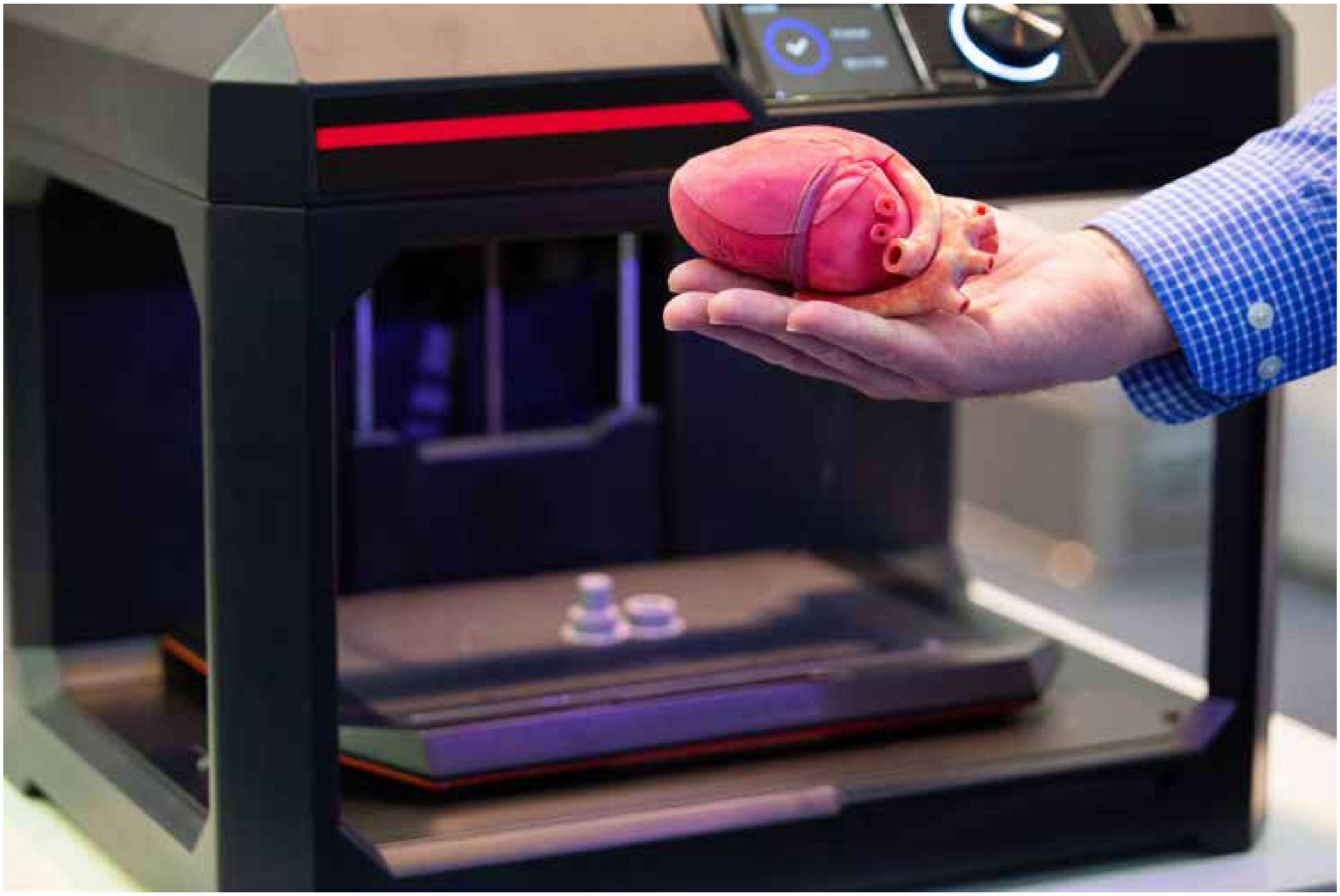
[11] 3rd Generation Partnership Project (3GPP), "Extended Reality (XR) in 5G", in 3GPP TR 26.928 version 16.1.0 Release 16, December 2020.

[12] Proximie and Vodafone in successful 5G remotely assisted surgery trials (Accessed on December 5th, 2021)



(i.e., what can happen, and how to react concretely) before being in the room with a patient.

In addition to telepresence and the use of haptic devices, shared 3D visual spaces, where trainers and trainees are not physically together, offer expanded possibilities for understanding the human body and systems. 3D visual spaces and models can provide an overview of the human body or specific organs and elements that may interact together to give an "as in real life" understanding of the human body superior to static images.

3D models of the human body inserted into an XR environment go beyond providing a two-dimensional view of one part of the human body. 3D models of different systems of the body—nervous, circulatory, skeletal, muscular, etc.—can be overlayed and dynamically simulated to present an interactive representation of the human body to a user. As that simulation becomes more complex, greater communication bandwidth can support the rendering of the model and collaboration among multiple XR users interacting with the same model. The use of such 3D visual spaces and models would foster remote collaboration in training and support more dynamic interactions.

XR enables the juxtaposition of physical and virtual elements in the same environment. It can also be used to make tools not physically present, and interactions not located in the specific location available in a specific situation for healthcare professionals. This will help support the development of new procedures that make it possible for healthcare professionals to address a situation while the relevant experts, tools, and knowledge may not be in the room.

Several key performance indicators (KPIs) are relevant when innovating 5G-enabled XR solutions in a medical context. These include evaluating how 5G connectivity evolves and contributes to improving XR solutions and ensuring that the trainees' learning experience is optimized. Accordingly, the evaluation considers metrics of the intended function, such as trainee learning, skill mastery and monitoring of pedological effectiveness. This helps demonstrate the benefit of using 5G in the use case. Therefore, an assessment platform can aggregate technical performance and human performance to capture empirical data supporting the impact of the innovation.

Additional Immersive XR Opportunities

Provided 5G power consumption and XR outdoor challenges are addressed, 5G combined with XR offers the potential to support mental health and disabled patients. XR for mental health already exists with headsets plunging the patient in an immersive and data-powered environment[13]. Incorporating 5G allows for more data introduced in real time in the patient environment and interactions with physicians if needed, with potential remote actions. This would be an extension of the telementoring, telepresence and immersive environment examples described above: patients would get virtual support and interaction with family and physicians through connected devices with XR features.

Other potential applications of 5G and XR include the hospital at home and medical planning. In the hospital at home scenario, patients in critical care could stay at home instead of going to the hospital. They would get virtual support from and interaction with physicians through connected headsets. We could imagine critical care activities performed remotely with patients getting remote medical practitioners support at home thanks to telepresence and the devices enabling XR applications. Medical planning, telementoring, telepresence, haptic devices and XR could be combined to prepare a medical procedure with participants not necessarily in the same room. This example could be applied to the planning of any medical procedure, including presurgical planning.

5G-Enabled Robotics

Remote Surgical Robots

The current state of remote robotic surgery is one of cautious excitement with reports of 5G-enabled remote surgeries starting to emerge[14]. Robots have been in use in the medical field since as early as 1985 with the PUMA 560 Robotic Surgical Arm to perform neurosurgical biopsy via a non-laparoscopic approach. The use case of robotics has been focused on making human surgeons more precise, more stable, and capable of providing surgical care that simply would not be possible using human hands. Available robotic surgical systems are provided in a variety of formats, but often include endoscopic and surgical instruments manipulated by physician-controlled actuators. Enhancements to these systems include three-dimensional visualization of the surgical field and real-time haptic feedback.

Remote robotic surgery is an anticipated leap in the context of 5G connectivity enhancements. The increased bandwidth and decreased latency of 5G allow for real-time images, device performance metrics, and critical patient data to be sent nearly anywhere. However, the technological challenges that 5G might help address are only a part of the many practical and legal challenges for this application that extend beyond the scope of this report.

Remote robot-assisted surgeries or telesurgeries could empower surgeons from multiple geographic locations

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[13] Psious | Virtual Reality Platform for Psychology and Mental Health & VR in Therapy: VR's Positive Impact on Mental Health – VRFocus (Accessed on November 25th, 2021)

[14] World's First Remote Operation Using 5G Surgery - Huawei (Accessed on December 5th, 2021)

to assist with the same surgical operation. A critical factor for the success of telesurgery applications is the ability of the surgeon to monitor the patient's vitals, other team members' tasks, the condition and location of the robotic assistant, and to maintain full audio-visual communications with team members and the patient.

KPIs of the connectivity enablers for remote robotic surgery have been investigated in the literature with various reported outcomes. For example, an Aesop 1000TS robot was used to bench-test remote surgery where a surgeon in Baltimore, MD, USA attempted to replicate a surgical procedure 9000 miles away in Singapore[15]. The bench test simulated a laparoscopic surgery and utilized cameras to send information from Singapore back to the surgeon in Baltimore. The transmission delay due to the long-distance transmission introduced significant delays in the audiovisual feeds and even induced errors in performing surgical tasks. During testing it was determined that a delay of <700 ms was needed for a remote surgeon to simply move a metal pin. Other reports referenced varying tolerable delays for 2D and 3D camera flows with the most stringent delay values of a few milliseconds attributed to the robotic control loop for haptic force and vibration feedback[16]. The difference in reported communication KPIs for enabling telesurgery can be attributed to differences in the evaluated surgical platforms, equipment, and surgical tasks. This case-specific variability highlights the need for an improved understanding of the communication KPIs and how they contribute to the overall system safety as documented in Section 03: Knoweldeg Gaps.

Compared to industrial robots, medical robots have unique requirements that can benefit from an improved communication infrastructure. An example of a unique requirement is that the human-in-the-loop control pattern requires the robot to be agile to the operator's movements, which can be communicated in terms of forces on the control device, voice commands, and the launch of a pre-programmed procedure. The robot operator (i.e., the surgeon) also relies on real-time field feedback to evaluate the surgical progress and decide on the next moves. Another point of comparison with industrial robots is the emergency stopping device, which commonly takes the form of a button that immediately stops the industrial robot to prevent further harm. However, such a mechanism is more challenging in a medical environment when considering patient safety. The returning of a surgical robot to a "safe" position after the emergency stopping device is activated may itself result in patient harm, depending on the specific task being performed.

In the context of risk management, the benefits of remote-assisted surgery depend on the overall system's safety given the practical considerations for deploying it using 5G connectivity, where the safety of patient and operator is maintained in the case of connectivity loss or degradation. These considerations include:

- Communication networks are commonly designed for "best-effort" delivery, with additional measures necessary to achieve target reliability needs.
- Bidirectional data traffic empowering the remote robotic surgery, relying on network operator's public core infrastructure to deliver consistent high bandwidth, low latency, and low jitter.
- To optimize haptic feedback sub-millisecond latency might be needed, which goes beyond current 5G capabilities.
- Safety and security improvements for data integrity, confidentiality, and availability to be addressed by the network operators and health delivery organizations to promote patient safety.

Remote Robotic Exam

Telehealth is by now established as one of the most promising uses of connected technology in the medical field. During the COVID-19 pandemic, society raced to enable remote technologies in areas not thought possible in the past. This shift to telehealth is further bolstered by new payment rules from the Centers for Medicare and Medicaid Services (CMS) in the US. Telehealth encompasses a broad range of services that not only support clinical health care but also include patient and professional health education, public health projects, and administrative initiatives[17].

The challenge of placing physicians and specialists in underserved locations is well known and documented.

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[15] Fabrlzio, M.D.; Lee, B.R.; Chan, D.Y.; Stoianovici, D.; Jarrett, T.W.; Yang, C.; Kavoussi, L.R. Effect of time delay on surgical performance during telesurgical manipulation. J. Endourol. 2000, 14, 133–138.

[16] Qureshi, Haneya N., Marvin Manalastas, Aneeqa Ijaz, Ali Imran, Yongkang Liu, and Mohamad O. Al Kalaa. 2022. "Communication Requirements in 5G-Enabled Healthcare Applications: Review and Considerations" Healthcare 10, no. 2: 293. https://doi.org/10.3390/healthcare10020293

[17] https://www.cms.gov/newsroom/press-releases/cms-physician-payment-rule-promotes-greater-access-telehealth-services-diabetes-prevention-programs (Accessed on July 22, 2022)

Robotics-assisted examination technology, with a physician or specialist assisting from a location removed from the patient, can help deliver remote care to patients. As a response to the shortage in healthcare providers, using 5G to enable remote robotic examination will make it available to a wider population. Moreover, fast and low latency 5G communication integrated with multiple innovations in AI, haptic feedback, and advanced sensors will support a sophisticated remote diagnostic system. Telemedicine and remote care are further discussed in Remote Care.

Mobile Units

With the expansion of 5G coverage, mobile medical units with 5G connections can allow an on-board medical team (e.g., paramedics, critical care nurses, other emergency medical technicians such as a CT technologist) to perform pre-hospital diagnosis and treatment on the patient while being transported to the hospital.

The advantages 5G brings to the mobile care delivery arena are improved connectivity, reliability, and high data capacity that blur the lines between in-hospital and remote care capabilities. Accordingly, this use-case can expand from inbound information gathering for better situational awareness and extending actionable care delivery to use in remote environments. Anticipated improvements include using low latency XR technology to virtually put the medical experts in the ambulance and AI-based solutions in the hands of responders.

The connected ambulance serves as a moving data hub for internal and external communication needs, e.g., collecting and transmitting the onboard data (e.g., voice, video, and/or vital signs) to the remote ER physician while receiving data from the cloud (e.g., patient medical history data and consulting for in-ambulance treatment). By utilizing 5G's mobility support and reliable connections on the move, many pre-hospital diagnoses and treatments become possible in the ambulance where emergency medical technicians (EMTs) have more options for stabilizing the patient before reaching the emergency room (ER), thereby improving the patient's healing rate. The connected ambulance relies on reliable 5G connectivity to support these communication-based services. Therefore, the standard operating procedures for connected ambulances should consider 5G service availability for the route selection process.

As 5G features and their availability continue to evolve, several technical improvements in 3GPP Release 16 will benefit connected ambulances. 5G's eMBB service supports mobile medical units in mobility classes for vehicular connectivity with speeds of 10–120 km/h and high-speed vehicular connectivity with 120–500 km/h. Fast-moving users experience frequent handovers between service cells to maintain a continuous data connection on the move. In high spectrum bands with beamforming, the handover interruption time can be longer than that of LTE (in the range of a few 10s of ms) due to beam sweeping, which may lead to more failures in the RAN and hence impair the service consistency. 3GPP NR Release 16 introduces corresponding mobility enhancement mechanisms including conditional handover and dual active protocol stack (DAPS)[18], which reduce the handover interruption time and the risk of mobile session failures.

Unlike 5G medical use cases that occur within healthcare facilities where a private 5G network might be deployed along with exclusive spectrum bands leased from the carrier, medical mobile units, such as ambulances, are deployed in the city streets and rural areas, and rely on the carrier's public network infrastructure for 5G communications. When sharing the public 5G channels with other users, mobile units can benefit from certain eMBB features in 3GPP Release 16, such as quality of experience (QoE) management and optimization mechanisms for diverse services, which can prioritize the mission-critical medical data transmissions over 5G RAN and core.

Network slicing is another key 5G feature for dedicating a set of network resources for a particular application, which enables a carrier to support specific use cases matched with a service level agreement (SLA) for the use case. In 3GPP Release 16, the network slicing function is further enhanced by introducing new procedures for reallocating network functions in the 5G core. Another added feature is Network Slice Specific Authentication and Authorization (NSSAA), which enables separate authentication and authorization per Network Slice for user data safety.

Release 16 also includes additional spectrum management mechanisms, e.g., enhanced dual connectivity (DC) and carrier aggregation (CA), for adapting the network coverage to different geographical areas, e.g., urban, suburban, and rural[19].

The ambulance's main role is to safely transport the patient to the hospital for further diagnosis and treatment. Therefore, a quick response to reach the patient and reduce transportation time to the hospital are critical to the performance of ambulance operations. 5G helps the ambulance quickly locate the patient. 3GPP Release 16 provides native positioning support by introducing radio access technology dependent positioning schemes. It improves user localization by using wide signal bandwidth in the sub-6 GHz and mmWave bands to support more stringent requirements on latency and positioning accuracy in regulatory (e.g., E911) and commercial use cases[20]. 5G can also expand assistance to the ambulance driver to reduce the patient transportation time. The driver can obtain real-time highway and local traffic information using 5G smart city applications carrying the city's IoT-based traffic data[21]. Traffic authorities can also step in to control the traffic lights to prioritize ambulances on duty. Other vehicles can yield to the ambulance when they are alerted by the ambulance via direct communication messages in addition to the siren signals.

Mobile Stroke Unit

According to the Centers for Disease Control, stroke is a leading cause of death and a leading cause of serious disability for adults in the U.S.[22] The goal of the Mobile Stroke Unit is to shorten the time between the onset of stroke-like symptoms and the delivery of thrombolytic—or "clot-busting"—drugs, which must be administered

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[18] https://www.5gamericas.org/wp-content/uploads/2021/01/InDesign-3GPP-Rel-16-17-2021.pdf (Accessed on July 25, 2022)

[19] https://www.ericsson.com/en/blog/2020/4/reducing-mobility-interruption-time-5g-networks (Accessed on July 25, 2022)

[20] The positioning requirements for regulatory (e.g., E911) and commercial applications are described in 3GPP TR 38.855. For example, Release 16 targets 1) horizontal positioning accuracy better than 3 meters (indoors) and 10 meters (outdoors) for 80% of the UEs, 2) vertical positioning accuracy better than 3 meters (indoors and outdoors) for 80% of the UEs, and 3) end-to-end latency less than 1 second.

[21] The long-term traffic data can also be used for planning EMS resources, e.g., ambulance stations, to improve service availability and response time.

[22] https://www.cdc.gov/stroke/index.htm

within three hours from when symptoms began or when the patient was last known to be well[23]. Mobile stroke units can perform pre-hospital rapid stroke evaluation and treatment, such as teleconsultation of neurological and non-neurological conditions (e.g., strokes, trauma, and respiratory, gastro-intestinal, acute pain, intoxication, labor, dysglycemia, vascular disease). During this operation, the on-board medical team communicates wirelessly with the remote support team in the hospital or the stroke center. With 5G, the Computed Tomography (CT) scans of the patient's brain can be transmitted wirelessly with very low latency to a neuroradiologist to determine the stroke type, while the test results of blood samples can be shared with the neurologist for the proper treatment protocol. With the help of the remote physician over the wireless link, the on-board staff can initiate the treatment while en route to the hospital. A remote surgery component could also be considered for mobile stroke units, if tele-operation is thought to be beneficial in situations with critical time considerations between injury and surgery.

Earlier studies indicated that most problems in pre-hospital teleconsultation of neurological and non-neurological conditions, e.g., transient, and permanent signal losses, long connection reestablishment, were caused by poor wireless reception, unstable bandwidth of the legacy 3G/4G mobile network, limited high speed broadband access, and software, hardware, or human error[24,25]. Many of these problems can be improved with the adoption of 5G. Accordingly, patients transported in mobile units will have access to care coordinated by the team in mobile units and specialized care team in the hospital to improve patient outcomes. A similar case is the mobile cardiothoracic units involving the transmission of electrocardiography (ECG) data to off-site cardiologists, where an improvement in the network reliability and capacity can reduce service failures.

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[23] https://my.clevelandclinic.org/health/treatments/17242-mobile-stroke-unit (Accessed on July 25, 2022)

[24] L. Yperzeele, R.-J. Van Hooff, A. De Smedt, A. V. Espinoza, R. Van Dyck, R. Van de Casseye, A. Convents, I. Hubloue, D. Lauwaert, J. De Keyser, et al., "Feasibility of AmbulanCe-Based Telemedicine (FACT) study: safety, feasibility and reliability of third generation in-ambulance telemedicine," PloS one, vol. 9, no. 10, p. e110043, 2014.

[25] A. Itrat, A. Taqui, R. Cerejo, F. Briggs, S.-M. Cho, N. Organek,A. P. Reimer, S. Winners, P. Rasmussen, M. S. Hussain, et al., "Telemedicine in prehospital stroke evaluation and thrombolysis: taking stroke treatment to the doorstep," JAMA neurology, vol. 73, no. 2, pp. 162–168, 2016.

Remote Care

Remote care is broadly considered to include systems for remote monitoring & diagnostics, therapeutics, and telemedicine, all of which are dependent on connectivity for their functionality. Accordingly, decentralized healthcare for patients can benefit from improvements in connectivity services enabled by 5G.

Remote monitoring and diagnostics allow caregivers to monitor patient conditions while the patient is not in a clinical environment (e.g., hospital, clinic). This is commonly done through online portals that allow access to intermittently or continuously updated data streams representing patient vital signs (e.g., heart rate, pulse rate, respiratory rate, blood oxygen level, blood pressure, temperature, electrocardiogram) or other multimedia data (e.g., audio recording of cough, images/video of skin rash). 5G will improve the reliability of the connectivity infrastructure enabling remote monitoring and diagnostics, facilitating caregiver access to patient data.

Reliability is also relevant when the remote monitoring system can raise alarms for certain patient conditions to indicate the need for emergency medical care. Examples of this include wearables for detecting emergencies such as a fall or a stroke. Compared with the current communication infrastructure, 5G's support for high throughput communication and allowing network connectivity for a large number of users can improve the acquisition of detailed data from an expanded number of patients. This will enable the development of AI applications for fast healthcare pattern recognition algorithms, which require access to big data and cloud processing resources. Furthermore, connection reliability and high data throughput will enable remote intensivist support for in-hospital monitoring. In this case, HDOs will access a specific set of experts to confirm a diagnosis or consult on the patient treatment. HDOs can also expand their postoperative care services through remote monitoring systems and dedicate on-site hospital beds to the patients that need them the most.

Another application of remote care is the use of therapeutics, in which a device that delivers medicine or therapy to a patient can be controlled remotely by a caregiver, including the ability to set and adjust dosage, administer emergency therapy, or notify the patient to go seek medical attention. Examples include defibrillation therapy, drug infusion, and glucose monitoring and delivery devices. This application can benefit from the availability of wholistic patient data to the caregiver, which might be collected through remote monitoring. Similar to other remote care applications, remote therapeutics will benefit from reliable 5G connectivity to support remote clinical decisions and reduced latency for communicating alarms and acting on them.

Telemedicine is an example of remote care that became widely used during the COVID-19 pandemic to provide healthcare services to patients away from traditional healthcare delivery points, including to chronic disease patients in rural areas. Telemedicine primarily uses audio, video, and some vital sign monitors to facilitate a remote consultation with a caregiver. Prior to the COVID-19 pandemic, telemedicine was commonly used to augment in-person operations. When COVID-19 protocols shuttered healthcare facilities, telemedicine enabled healthcare providers to offer care to patients where they needed it at a reduced cost[26].

As organizations continue to use technology to enhance the way they provide care, they face challenges to ensure the interoperability of the technology and patient data and continuity between providers. A lack of interoperability between systems can be felt across healthcare organizations and by patients, manifesting as a lack of continuity in patient care and provider burnout. From the connectivity perspective, telemedicine services are limited by the network capacity required to optimally exchange the streams of health data. Thus, 5G connectivity presents an opportunity to expand the offering of telemedicine services and the possibility for integrating these services with other remote care systems to create novel mechanisms for healthcare delivery. As 5G coverage expands, planning to benefit from newly available 5G connectivity in integrated remote care systems will help promote healthcare equity by increasing patient access to healthcare, including those in rural areas.

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[26] Cigna, "Convenient, Cost-Effective, and High-Quality Virtual Care Is Here To Stay," https://newsroom.cigna.com/convenient-cost-effective-and-high-quality-virtual-care-is-here-to-stay (Accessed March 16, 2022)

03

KNOWLEDGE GAPS & PRACTICAL CONSIDERATIONS

Supply Chain and Cost

To integrate 5G network connectivity into a medical device, one must consider where to source the 5G hardware modules, the typical lifecycle of these modules, and what should be done when the modules are obsolete.

Several vendors provide 5G modules for integration in devices[27] with support for Hayes/AT command set, which facilitates the integration with existing communication stacks. However, the limited supply options at present compared to other common wireless technology modules can raise the cost of using 5G. Industry forecasts of future supply options, and how these would compare to existing offering of modules for 5G and earlier technologies, can inform device designers in their planning. Alternatively, manufacturers might consider the direct implementation of 5G modems[28] into their devices. However, that option can incur increased design and development costs.

The cost of using 5G in healthcare applications could be considered through multiple lenses. For example, one cost factor is the needed certification tests to deploy the device on a 5G network. Notably, the broad adoption of 5G in other industry verticals could potentially lower the costs of 5G integration in medical devices. Other cost factors include the cost of deploying 5G networks by service providers[29,30] and the cost of obtaining 5G service by users, whether for accessing a private or a public 5G network.

Medical device lifecycles can be longer than that for many consumer electronics, where 5G technology is prevalent. Considering the availability and obsolescence of 5G modules and the potential need for replacing them may lead to additional design, development, and verification & validation efforts. Accordingly, understanding the supply chain that supports 5G communication in medical devices can help develop design and deployment strategies that meet the device lifecycle needs.

Network Coverage

At the current stage of 5G rollout, one of the main unknowns is the availability of 5G networks globally. Network deployments vary with the availability of spectrum in different countries, which means devices would need to ensure support for the 5G spectrum available in the country of use. For mobile outdoor applications, regional differences between geographies and urban and rural areas may impact 5G availability. In particular, applications requiring low latency and high reliability and operating in the mmWave spectrum depend on a densely deployed RAN. Thus, low latency outdoor applications may initially be restricted to urban areas where mmWave cells can be deployed economically. Similarly, for campus applications, availability of 5G networks on campus plays a key role. Hospital campuses are complex environments, with needs to provide network connectivity in a variety of indoor and outdoor settings ranging across multiple buildings, and rooms with shielded walls. While 5G has the flexibility to address this degree of variability, a set of recommended practices for 5G deployment in healthcare settings is needed to help hospitals evaluate the available options that meet their unique needs.

Ongoing QoS Monitoring

Reliable, low latency communication is one of the key promises of the 5G technology, and also a requirement across many use cases in our survey of the landscape. Thus, ongoing monitoring of the quality of service will be important for safe and effective operation of medical devices and implementation of mitigating measures and fallbacks. Best practices for QoS monitoring on 5G networks will need to be developed and implemented.

Unestablished & Varying Communication KPIs

The healthcare functions that can be enabled by 5G are diverse and can have unique connectivity needs. These can be characterized by communication KPIs

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[27] Examples include FN980 from Telit and SIM8202G from Waveshare

[28] Snapdragon X50 5G Modem-RF System, https://www.qualcomm.com/products/snapdragon-x50-5g-modem

[29] https://www2.deloitte.com/us/en/pages/consulting/articles/communications-infrastructure-upgrade-deep-fiber-imperative.html (Accessed on July 25, 2022)

[30] https://www.lightreading.com/open-ran/heres-how-much-5g-wireless-network-really-costs/d/d-id/769114 (Accessed on July 25, 2022)

such as throughput and latency[31]. Understanding these KPI requirements can help the design, implementation, and evaluation of 5G-enabled healthcare applications. Medical device manufacturers approach product development through planning, design, input/output specifications, design verification & validation, and design transfer. Early in the development cycle, user needs are identified followed by an assessment of the available technologies to meet those needs. This is accompanied by a risk assessment for the device safety and business risks of using a given technology to meet user needs.

Accordingly, the use of 5G to enable medical device functions can be done when it meets or exceeds the device's connectivity needs. For example, meeting a minimum latency to enable remote control of a connected medical device or a certain bandwidth threshold to transmit quality video. Other examples of these needs are discussed in more detail in Section 02 of this document. Notably, some use cases like implantable devices might use 5G as a combination with other wireless technologies to implement a wireless link between the implant and an external device component that, in turn, connects to the network. The feasibility and benefits of directly using 5G in implantable devices remains an open question where the connectivity KPIs would extend to include energy efficiency and battery consumption.

The relevant scientific literature often discusses the communication KPIs qualitatively, which hinders the specification of quantitative KPIs that can be efficiently used to deliver the desired outcome. Also, the tradeoffs between communication KPIs and how they can be dynamically optimized to support a desired function are seldom addressed. Furthermore, there is a lack of consensus methods for documenting and reporting the communication needs of a healthcare application. Such methods have an opportunity to address the varying communication needs of different application designs, even when belonging to the same use-case category. Examples of KPI considerations include throughput, latency, packet loss, power budget, and mobility.

Lack of Evaluation Methods for Device Functions Enabled by 5G

When connecting to a 5G network, 5G-enabled medical devices play the role of 5G user equipment (UE)—a term that also applies to general purpose wireless equipment like smartphones. In the United Sates, UE devices need market grants from the Federal Communications Commission (FCC) in addition to certification testing, such as the program managed by Personal Communications Service Type Certification Review Board (PTCRB). Furthermore, mobile network operators (MNOs) can also impose their own acceptance testing before allowing a certain type of UE on their networks. The overall objectives of these certification tests include:

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[31] Qureshi, Haneya N., Marvin Manalastas, Aneeqa Ijaz, Ali Imran, Yongkang Liu, and Mohamad O. Al Kalaa. 2022. "Communication Requirements in 5G-Enabled Healthcare Applications: Review and Considerations" Healthcare 10, no. 2: 293. https://doi.org/10.3390/healthcare10020293

- Demonstrating the UE's adherence to regulatory spectrum rules and over-the-air behavior through quantitative measurements of its characteristics such as out-of-band emissions and radiated spurious emissions.
- Demonstrating that the UE can operate with other 5G network elements on a given carrier's network by assessing the UE's conformance to the communication protocols implemented in the network.

As described in this report, the medical device functions that can be enabled by 5G connectivity are diverse and can have diverse requirements for communication quality of service. While 5G UE certification provides evidence supporting that a 5G-enabled medical device can operate on a 5G network, the existing testing methods are not designed to address the safety and effectiveness concerns for 5G-enabled medical device functions regarding network-specific risks such as packet loss, communication delay, and link disruption[32]. Given that the information obtained by certification tests does not clarify how a medical device would safely and effectively use 5G connectivity to deliver its intended functions, novel evaluation methods are needed to bridge this gap[33].

When considering the practical aspects of evaluating 5G-enabled medical devices, there is an open research opportunity for developing a methodology for selecting the test parameters to maximize effectiveness and efficiency of test plans while meeting test objectives. 5G networks can be deployed with abundant degrees of flexibility in selecting the air interface, networking strategy, and data services. This results in a large set of test parameters that can be used to exhaust all the supported frequencies, bandwidths, modulation, and coding schemes (MCS), etc. Also considering the diversity of 5G KPIs and their varying importance in different application use cases, there is a tradeoff between the test thoroughness and efficiency (e.g., efficiently exploring test vectors that combine various operating parameters). Furthermore, medical devices can have unique data use patterns, which may deviate from the general 5G UE patterns like audio and video transmission. Therefore, an optimized and automated test strategy can help address the specific communication needs of the evaluated device, reduce the time and financial burden of the evaluation, and facilitate the timely availability of the device to users.

In addition, there is a lag between introducing new features into 5G UE solutions and making the corresponding certification tests ready and available to the vendor/integrator. The current 5G UE conformance specifications can be found in 3GPP technical specifications (TS) ranging from TS 38.508 to TS 38.533. However, 3GPP-based conformance tests are not yet available for incorporation into certification programs, such as PTCRB, leaving early technology adopters with an unclear path to certification. While this is applicable to 5G UEs in general, it expands the knowledge gap of understanding how a 5G-enabled medical device would implement a desired function. Accordingly, a coordinated effort among the various certification bodies (i.e., regulators, industry groups, MNOs) might help streamline the certification process and eliminate potential redundancies in the certification tests, which in turn can facilitate user access to novel 5G devices.

Finally, we note that large scale connectivity among diverse medical devices—like that addressed in 5G mMTC—can exacerbate any existing gaps in device interoperability. Accordingly, accelerated efforts for addressing medical device interoperability and the development of evaluation methods for assessing platform-based interoperability of medical devices are needed.

Roles, Responsibilities, and Service Level Agreements

Delivering a 5G-enabled healthcare application to the end-user requires that a multitude of stakeholders collaborate to facilitate the healthcare service delivery. Examples of the stakeholders include medical device manufacturers, HDOs, telecommunication operators/MNOs, and cloud service providers. Connected medical devices in traditional hospital deployments function as endpoints connected by a network commonly operated by the HDO. With the introduction of 5G connectivity, the hospital network operator role may shift from the HDO to

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[32] Wireless technology considerations that can have an effect on the safe and effective use of medical devices are discussed in "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff." U.S. Food and Drug Administration. [online]. Available at: https://www.fda.gov/media/71975/download

[33] Y. Liu and M. O. Al Kalaa, "Testing 5G User Equipment: Review, Challenges, and Gaps from the Medical Device Perspective," IEEE Electromagnetic Compatibility Magazine, vol. 11, no. 1, pp. 37-44, 1st Quarter 2022, doi: 10.1109/MEMC.2022.9780281.

the telecommunications service provider. This highlights the need to clearly identify the roles and shared responsibilities for ensuring communication security and QoS.

Service Level Agreements (SLAs) can serve as a framework for documenting the expectations, roles, and responsibilities of involved stakeholders[34]. Accordingly, SLAs offer an opportunity to consider the risks associated with the communication service degradation, delay, or disruption and what risk mitigation strategies can be implemented on the network side to help control those risks. For example, an SLA used with a 5G-connected ambulance might address network resource provisioning for ambulance mobility, priorities of the communications streams originating from the ambulance, and mechanisms for initiating and stopping the communication service on-demand. This can be especially challenging when the network is configured dynamically to meet evolving demands from its users and when multiple carriers or HDOs are involved. Another relevant example is the 5G-enabled device's cybersecurity, where a threat model[35] can help identify the 5G assets used by the device together with the associated cybersecurity risks and potential control measures and mitigations (e.g., software composition analysis, vulnerability scanning, penetration testing). Consequently, SLAs can help specify the roles and responsibilities for vulnerability scanning, implementation of mitigations, and the needed communication channels and protocols between the involved stakeholders (e.g., device manufacturer, vendor of software used to enable 5G functions, network provider) to facilitate those activities. Accordingly, the SLAs used for generic communication services should be upgraded (e.g., through templates, best practices) to meet the needs of 5G-enabled healthcare.

Electromagnetic Environment and Wireless Coexistence

5G extends the mobile network operation from licensed to unlicensed spectrum through 5G New Radio Unlicensed (NR-U). This follows the trend of mobile networks leveraging unlicensed spectrum bands that started in 4G with technologies like LTE-Licensed Assisted Access (LAA). Furthermore, 5G embeds a non-3GPP inter-working function to interact with non-3GPP networks and interfaces. However, operating in unlicensed spectrum bands raises concerns for wireless coexistence[36] with other band users[37] (e.g., coexistence between multiple uncoordinated 5G NR-U networks or between 5G NR-U and Wi-Fi). Wireless coexistence risks in medical devices are commonly addressed using consensus standards like the AAMI TIR69 on risk management of RF wireless coexistence for medical devices and systems[38] and the ANSI C63.27 standard for evaluation of wireless coexistence[39]. AAMI TIR69 presents a risk management framework that cites ANSI C63.27 for testing when needed[40]. However, ANSI C63.27 does not include test recommendations specific to devices using 5G NR-U or coexisting with the technology. Accordingly, there is a gap in the evaluation of wireless coexistence for devices using unlicensed 5G technology or coexisting with it.

In addition to wireless coexistence, another opportunity for additional study is the question of how 5G devices, in aggregate, change the electromagnetic characteristics of the device environment of use (e.g., hospital, home). A gap in this area is that standards[41] commonly used to test medical devices for immunity to electromagnetic disturbances do not fully cover the frequencies used for 5G transmissions.

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[34] H. N. Qureshi, M. Manalastas, S. M. A. Zaidi, A. Imran and M. O. Al Kalaa, "Service Level Agreements for 5G and Beyond: Overview, Challenges and Enablers of 5G-Healthcare Systems," IEEE Access, vol. 9, pp. 1044-1061, 2021, doi: 10.1109/ACCESS.2020.3046927.

[35] For example: Playbook for Threat Modeling Medical Devices, November 30, 2021, https://www.mitre.org/sites/default/files/publications/Playbook-for-Threat-Modeling-Medical-Devices.pdf

[36] Wireless coexistence is the ability of one wireless system to perform a task in a given shared environment where other systems (in that environment) have an ability to perform their tasks and might or might not be using the same set of rules

[37] "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff." U.S. Food and Drug Administration. [online]. Available at: https://www.fda.gov/media/71975/download

[38] AAMI TIR69:2017/(R2020) Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.

[39] ANSI IEEE C63.27-2017 American National Standard for Evaluation of Wireless Coexistence

[40] M. O. Al Kalaa, J. Guag, S. J. Seidman, Y. Ma and J. Coder, "A Case Study of Medical Device Wireless Coexistence Evaluation," IEEE Electromagnetic Compatibility Magazine, vol. 9, no. 4, pp. 47-53, 4th Quarter 2020, doi: 10.1109/MEMC.2020.9328232.

[41] IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

04

APPENDICES

Appendix A: How Does 5G Differ From Other Common Wireless Technologies?

5G includes technical and design features that differentiate it from other wireless technologies, including previous generations of cellular networks. In the following, we discuss some of these differentiating features.

Spectrum: Licensed vs. Unlicensed

The frequency band used by a wireless network impacts its communication range and network capacity. The frequency bands that can be used by 5G span a large range of frequencies and cover several access types including licensed, shared, and unlicensed bands. This allows 5G networks to serve varying coverage areas (e.g., macro cells serving large parts of a city, small cells serving a specific building), user densities (e.g., sparsely populated rural areas, a densely occupied stadium), and communication requirements (e.g., throughput, latency). The following sections provide more detail on the types of spectrum access.

Licensed Spectrum

The limited resources of the RF spectrum are regulated in each country through a designated entity. In the United States, this task falls to the Federal Communications Commission (FCC)[42]. The FCC encourages efficient spectrum use and requires spectrum license owners to have a plan for bringing their licensed spectrum to market, which is closely monitored by the FCC.

Licensed spectrum is typically used for cellular communication services to authenticate subscribers and enable user mobility in the coverage area. Licensed spectrum protections include not only the right to use that spectrum in a certain geography but also operational limits on unlicensed or other potential transmitters. Licensed spectrum also allows higher transmission power than unlicensed spectrum. Accordingly, applications in indoor and outdoor environments can benefit from the flexibility to adapt the transmission for the use case (e.g., longer range, obstacles in the environment)[43].

5G enables a new model of licensed 'private' cellular networking, where customers (e.g., a hospital) can participate in the routing control and authentication of user traffic. Using a hospital as an example, a distributed antenna system or a small cell radio can be used to create a localized cellular network deployment for the hospital. In these architectures, cellular connectivity is used like Wi-Fi for no-cost, in-building connectivity while allowing users the option to connect to a 5G carrier network when they leave the hospital.

Unlicensed Spectrum

Many wireless technologies commonly used in medical devices and healthcare environments operate in unlicensed spectrum bands, such as the 2.4 GHz industrial, scientific, and medical (ISM) and the 5 GHz unlicensed national information infrastructure (UNII) bands. Examples of unlicensed band technologies include Wi-Fi and Bluetooth. The free access to unlicensed bands facilitates the availability and affordability of these technologies, which contribute to their ubiquity in enabling local area communications between medical devices and other systems and networks. However, this comes at the cost of managing wireless coexistence with other users of the wireless channel, which can lead to communication delay, disruption, or loss.

Devices can transmit in unlicensed spectrum bands without a license if they follow certain rules. One key area is the limitation placed on transmission power, antenna gain, and effective isotropic radiated power (EIRP)[44]. For example, Part 15 of the FCC rules indicates that systems using digital modulation in the industrial, scientific, and medical (ISM) band at 2400—2483.5 MHz, such as Wi-Fi devices, have a maximum EIRP of 36 dBm[45]. The difference in power limits between licensed and unlicensed spectrum is a major contributor to the difference in feasi-

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[42] The FCC table of frequency allocations can be found by following this link

[43] Limits on transmission power are commonly expressed in decibel watts [dBW] or decibel milliwatts [dBm] and are determined by each country. For example, the FCC transmission limits are detailed in 47 CFR 101.113.

[44] The sum of the transmit power and antenna gain.

[45] 47 CFR 15.247(b)

ble communication range between wireless technologies (e.g., Bluetooth in the 2.4 GHz ISM band vs. cellular communication in the 900 MHz frequency range).

Shared Spectrum

The RF spectrum can also be shared between users with differing access priorities. This is done in the Citizens Broadband Radio Service (CBRS) in the 3.5 GHz band[46], where three access tiers are specified: incumbent, priority, and general authorized access. This sharing is facilitated by a spectrum access system. Shared spectrum is also used by 5G service providers to supplement their licensed spectrum for 5G deployments like private 5G networks.

Range

The communication range of a wireless network is influenced by the signal transmission power, signal wavelength with its unique propagation characteristics, and physical obstructions. In 5G, transmission frequencies are commonly categorized into three 'bands': the low, mid and high bands. Figure 2 illustrates the different RF spectrum bands used in 5G. The mid and low bands, often referred to as the sub-6 GHz band, have the longest communication range. Propagation characteristics and signal range attenuation caused by physical obstacles such as trees, walls, and pollution have a lower impact in sub-6 GHz bands compared to the high band. The high band—often referred to as mmWave—has a considerably shorter range. mmWave signals are commonly transmitted from small cell radios on the sides of walls or the top of utility poles.

Assuming an unobstructed line of sight for communication, the expected range of the 5G bands can be:

- Low band 5G (e.g., 600-700 MHz) radio tower transmissions cover hundreds of square miles
- Mid band 5G (e.g., 2.5/3.5 GHz) radio towers cover a radius of several miles
- High band (mmWave, e.g., 24/39 GHz) radio covers one mile

In short, the higher the frequency band at which the radio operates, the less range it has. In realistic applications, high bands such as mmWave only propagate in a line of sight for a few thousand feet, while the mid band range covers a few miles and low band covers tens of miles. Communication range is further limited by the endpoint device, which must be able to transmit for that same distance back to the network.

As illustrated in Figure 3, the spectrum band used is an essential consideration for network deployments. Therefore, mid to lower bands are deployed using network towers to offer wide area coverage. Mid bands and the mmWave high band are used for targeted outdoor locations as well as indoor environments. Unlicensed spectrum bands and mmWave are commonly used indoors.

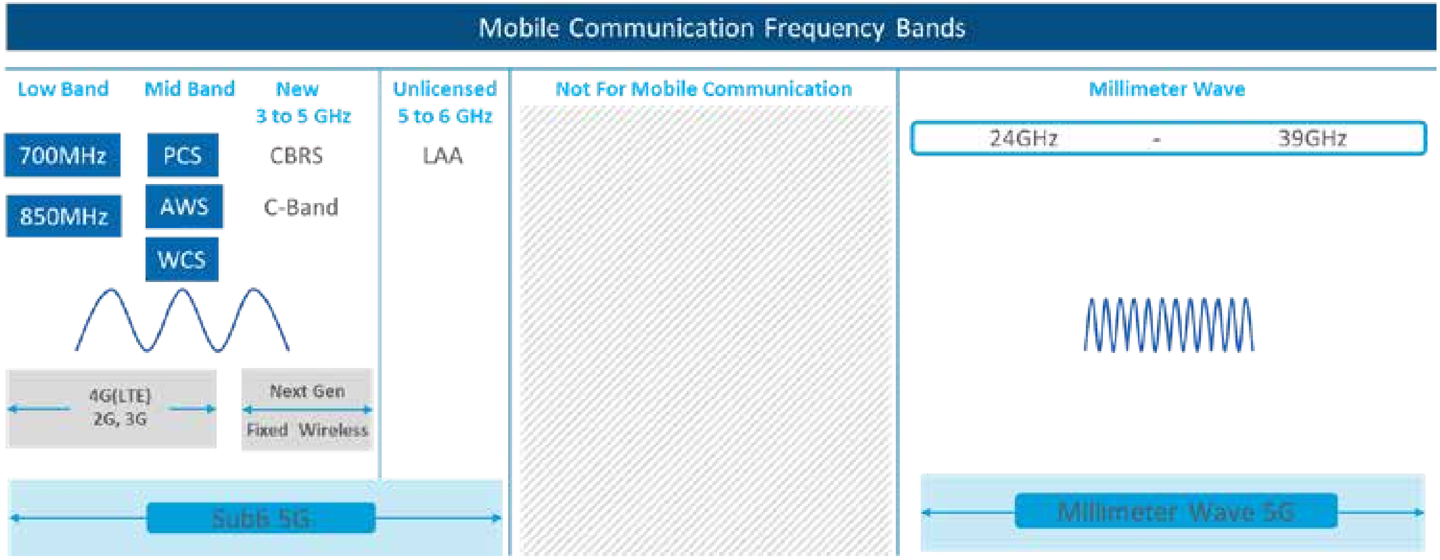

Figure 2—5G use of RF spectrum

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[46] More information is available on https://www.fcc.gov/35-ghz-band-overview

Figure 3—Common 5G deployment scenarios when considering the used RF spectrum

Capacity

The number of connections that a wireless technology can service is referred to as capacity. The previous generation of mobile networks, 4G, is limited to around 5000 reliable connections. Unlicensed Wi-Fi radios can theoretically connect a few hundred; however, in reality, that number can be less because of coverage limits and available hardware resources. 5G aims to achieve a capacity of one million devices per square kilometer.

Security

5G offers the potential for more secure and private communication than previous generations by providing greater network controls, improved security protocols, and improved user privacy. 5G communications are secured using features in the 5G technical specifications, together with security add-ons commonly deployed by 5G service providers[47]. Together, these features help strengthen the cybersecurity of 5G-enabled applications while offering the flexibility to tailor the network support for certain application needs in network slicing scenarios. However, 5G's unique features (e.g., high throughput, greater device density, virtualized infrastructure) may amplify the potential impact of new and previously known threats. Additional security measures (e.g., Network Slice Security, Software Supply Chain Hardening, automatic threat triage) may be needed to address these threats and deliver 5G-enabled health care services safely, privately, and securely. The following presents a list of some 5G security and privacy features.

5G Standards-Based Security and Privacy Features

- Over-the-Air Protection: 5G has stronger encryption requirements for over-the-air communication *(enforce 128-bit AES until 256-bit AES[48])*. Not only does 256-bit encryption make the data-at-rest and data-in-motion more private and secure, but 5G networks ensure that the subscriber's unique identity and location are also encrypted, making them more difficult to identify or locate from the moment they join the network. This feature also helps protect users and organizations from "man-in-the-middle" (MITM) attacks where a malicious actor, positioned between communicating parties/ devices, may eavesdrop, manipulate data, or drain the battery.
- 5G Subscriber Identity Privacy: Subscription Concealed Identifier **(SUCI)** is used to conceal/ protect the Subscription Permanent Identifier **(SUPI)**.

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[47] TS 133 501–V15.2.0–5G; Security architecture and procedures for 5G System (3GPP TS 33.501 version 15.2.0 Release 15) (etsi.org)

[48] https://www.etsi.org/deliver/etsi_ts/133500_133599/133501/15.01.00_60/ts_133501v150100p.pdf

- Security Edge Protection Proxy (SEPP): 5G Roaming or Network-to-Network Protection allows roaming users the same security and privacy protections as if they were on their home network.
- Increased Home Network Control for Authentication: This allows a 5G home network to help verify the mobile device when requesting service from the serving network.
- Unified Authentication Framework: 5G offers unified authentication methods for both 3GPP (cellular) and non-3GPP (e.g., Wi-Fi) access networks. This makes the transition from 3GPP networks to non-3GPP networks more secure by removing a potential threat vector during authentication.
- Security Anchor Function (SEAF): This is used for re-authentication of the mobile device when it moves between different access networks without having to run the full authentication protocol. SEAF is collocated with the Access Management Function (AMF) and is a 'middle-man' during the authentication process that can reject an authentication request from the UE[49].

5G Cybersecurity and Privacy Considerations

As enterprises use 5G networks and develop 5G-enabled applications, cybersecurity and privacy should be woven into network architecture from the beginning to provide a unified platform that is able to provide maximum security and privacy to all users.

Some of the unique cybersecurity considerations of 5G stem from specific use cases. For example, a use case such as telerobotic surgery relies on ultra-low latency communication, and an attack to interrupt or degrade the signal (i.e., bidding down) would have a greater potential impact than a use case that used 5G's high bandwidth to routinely transmit large medical files such as MRIs. Additionally, some of the unique cybersecurity considerations result from 5G's infrastructure (e.g., the blurred network boundaries decrease the visibility of individual users), where threat actors may attempt to infiltrate the hybrid-cloud network by exploiting vulnerabilities within such virtualized infrastructure (e.g., infrastructure as a code) that make 5G networking possible. Finally, there are cybersecurity considerations that stem from certain 5G features (e.g., 5G's lower latency, increased throughput, and high device density) that can increase the efficacy of Distributed Denial of Service [DDoS] attacks.

Examples of the types of attacks against 5G networks include:

- Signal Jamming – Like all wireless technology, 5G is still susceptible to signal jamming. This can be physical jamming of the physical downlink / uplink control channel, physical broadcast channels, etc., as well as signal degradation. Signal jamming attacks increase latency or interrupt critical use cases.
- MITM attacks – MITM is a common strategy to intercept data and potentially disseminate malicious commands to connected devices/ receivers. For example, a bad actor could send signals that rapidly drain the batteries of critical connected medical devices, potentially causing physical hazards (e.g., during surgical operations).
- Mobile Network Mapping (i.e., device fingerprinting) – Wireless devices connected to a private network can "sniff" identifying data of other devices connected to the network and ascertain potentially sensitive information about those devices (e.g., manufacturer, capabilities, etc.)
- DDoS – 5G supports a greater number of connected devices on a high-speed network. This capability may be leveraged by threat actors to conduct crippling DDoS or weaponized IoT botnet attacks. DDoS attacks are attempts to disrupt normal traffic by overwhelming a network, server, or service with a flood of internet traffic, using compromised computer systems or IoT devices.
- Authentication and Key Agreement (AKA) Attack – An AKA attack exploits a vulnerability in the 5G "Authentication and Key Agreement" security protocol. The attack enables a malicious actor that compromised the long-term key of a user to then impersonate that user to a Serving Network.
- Dynamic Spectrum Sharing (DSS) Attack – 5G networks require several physical short-range cell towers and support DDS and "network slicing." However, an attack on one of these

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[49] X. Zhang, A. Kunz and S. Schröder, "Overview of 5G security in 3GPP," 2017 IEEE Conference on Standards for Communications and Networking (CSCN), 2017, pp. 181-186, doi: 10.1109/CSCN.2017.8088619.

physical devices, or the virtualized infrastructure, may allow a bad actor to jam the network, or access as well as move between network slices.

- Bidding Down – This attack causes devices to "bid down" to lower-quality network protocols, causing a degradation in the quality of their service, which can significantly disrupt time-sensitive and carefully scheduled operations.

Common Telecommunications Carrier 5G Security Feature Add-Ons

The following security features are commonly implemented by cellular network operators in addition to those that are part of the 5G specifications. They might be applicable to implement when deploying medical device applications to address particular risks.

- Security Monitoring – Continuous monitoring for data exfiltration/leakage and logging. Threat analytics using data insights, AI, and ML. 5G mMTC supports extremely large numbers of devices with various functions, consequently automated management and security monitoring might help fortify confidentiality and integrity[50].
- Identity & Access Management (IAM) – Multi-factor authentication, Role Based Access Control (RBAC), Network Access Management.
- 5G Edge Cloud Security – Virtual firewalls, secure Operations, Administration and Maintenance (OAM), secure cloud infrastructure, storage encryption, security scanning, secure Virtual Private Networks (VPNs), access control lists (ACLs).
- 5G RAN DDoS Security – Inherent 5G RAN DDoS Detection and Mitigation functions, closed-loop automation based on Open Network Automation Platform (ONAP) (i.e., ECOMP-on-ONAP)

Additional Layers of Security and Privacy

- Automated Threat Triage – The exponential increase in the number of devices accessing the network will lead to an increase in the amount of security alerts. To prevent Security Analyst fatigue, organizations should consider implementing tools (e.g., automated threat triage) that increase the efficiency of Security Operations Centers (SOCs).
- Broad Network Monitoring and Slice Security – Remotely monitor and track individual subscriber and slice IDs on the 5G network, and secure 5G slices with individual virtual firewalls that enable dynamic security requirements for each slice.
- Software Supply Chain Hardening and Third-Party Risk Management – The proliferation of interconnected medical devices and applications may necessitate integrating cyber supply chain risk management (C-SRM) across the organization. C-SRM may include appraising third party businesses and vendors of acceptable cybersecurity practices. Additionally, software composition analysis tools (SCA) may be used to prevent vulnerable opensource or third-party software from exposing the network.
- Network Redundancies – When considered during the network design and deployment in a coverage area, redundancies can protect against network performance and availability attacks as well as build resiliency by implementing geographic redundancy (GR) and high availability (HA) and storing data in numerous locations with a surplus of servers to exceed peak demand.
- Secure Access Service Edge (SASE) – Combines wide area networking and security into a single cloud service directly at the edge. Offering protection from connected medical device botnet attacks and compromised devices through layers of remote wireless monitoring. Security is based on identity, real-time context, and compliance policies, allowing a continuous assessment of risk / trust throughout an entire user session

Deployment

5G permits flexible network deployment options by facilitating the introduction of 5G features while continuing to leverage existing 4G network infrastructure, enabling communication over diverse spectrum bands, and using software to customize the functions of network equipment and dynamically control those functions.

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[50] Liyanage, M., Ahmad, I., Okwuibe, J., de Oca, E.M., MAI, H.L., Perez, O.L. and Itzazelaia, M.U. (2018). Software Defined Security Monitoring in 5G Networks. In A Comprehensive Guide to 5G Security (eds M. Liyanage, I. Ahmad, A.B. Abro, A. Gurtov and M. Ylianttila). https://doi.org/10.1002/9781119293071.ch10

5G specifications were designed to facilitate the gradual deployment of 5G networks while maximizing the utility of existing 4G LTE infrastructure. Accordingly, 5G non-standalone (NSA) deployments are implemented by augmenting a 4G LTE network with some 5G network elements to offer limited 5G service while most of the network control remains over 4G LTE. Conversely, 5G standalone (SA) deployments are implemented solely with 5G network elements.

5G offers flexible control over the network (e.g., authenticating users, routing traffic), which allows for custom network deployments that are tailored for the connectivity needs of customers like hospitals. Accordingly, network service providers can share the network control with private customers and make available some of the operator's licensed spectrum to enable the customer's private network. Alternative spectrum arrangements are also possible over licensed spectrum acquired directly by the customer, unlicensed spectrum, or shared spectrum (e.g., CBRS).

Private 5G deployments can be done in tandem with other existing wireless technologies. For example, Bluetooth can be used to connect medical devices to patients' and caregivers' smartphones, which in turn connect to the cloud through the private 5G network. A private 5G network or an existing Wi-Fi network can be used to provide connectivity for devices within a hospital, while 5G is used to maintain connectivity when the device is taken away from the hospital. The flexibility of 5G deployment options can help organizations use the wireless connectivity that best fits their needs and the communication requirements of the devices they use while managing the performance and cybersecurity aspects of the chosen scenario. Security considerations for private 5G deployments include the security of the equipment providing network connectivity and the security of end points on the network. Securing the private 5G deployment contributes to the overall security of the 5G network.

5G Coupled with Cloud distribution

5G deployments use edge computing to improve connectivity performance for end users, such as reduced latency. This is done by including data storage and processing units closer to where data is generated and processed – at the edge of the network. Edge compute nodes then become a part of a distributed cloud where workload balancing policies can be implemented to optimize the service delivery (e.g., medical imaging data routed and processed internally in a hospital instead of being uploaded to and then queried from a distant server).

Network providers vary in how they adopt edge computing in their 5G networks. For example, network-based edge compute involves placing compute infrastructure in cell tower shelters, central offices, or commercial data centers that connect the network equipment and network users. An alternative to this model is premise-based edge compute, where hardware solutions can be installed on a customer's premise and are designed for integration with 5G edge nodes offered by the cellular network provider. These cellular edge nodes allow the identification and routing of desired network traffic so that all data transmission and processing remain at the customer's premise. This model allows the cellular network to be used like Wi-Fi and commonly hold what is referred to as a 'zero rate' data plan. Having localized 5G access to on-premise compute resources helps achieve an end-to-end latency around 5 ms in one direction[51]. The introduction of standalone 5G core networks is expected to further help reduce the latency.

Other deployment options that cellular network providers can implement include providing direct gateway routes to cloud providers through 'dynamic exchange' segmentation and routing within the network. In this deployment, the network provider and customer agree on specific performance targets to facilitate the customer's access to desired cloud provider services.

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[51] Gino, Carrozzo and M. Shuaib, Siddiqui and Kevin, Du and Bessem, Sayadi and Oscar, Carrasco and Fotis, Lazarakis and Janez, Sterle and Roberto Bruschi. Definition and Evaluation of Latency in 5G with Heterogeneous Use Cases and Architectures. Accessed on: Jan 12, 2022 [Online]. Available: https://www.5gcity.eu/wp-content/uploads/2020/05/Definition-and-Evaluation-of-Latency-in-5G-with-Heterogeneous-Use-Cases-and-Architectures.pdf

Appendix B: Glossary

3G	the third generation of cellular communication networks
3GPP	3rd generation partnership project
4G	the fourth generation of cellular communication networks
5G	the fifth generation of cellular communication networks
AAMI	association for the advancement of medical instrumentation
ACL	access control list
AES	advanced encryption standard
AI	artificial intelligence
AKA	authentication and key agreement
AMF	access management function
ANSI	American national standards institute
AR	augmented reality
CA	carrier aggregation
CBRS	citizens broadband radio service
CMS	centers for Medicare and Medicaid services
C-SRM	cyber supply chain risk management
CT	computed tomography
DAPS	dual active protocol stack
DC	dual connectivity
DDoS	distributed denial of service
DSS	dynamic spectrum sharing
ECG	electrocardiography
EIRP	effective isotropic radiated power
eMBB	enhanced mobile broadband
EMT	emergency medical technician
ER	emergency room
FCC	federal communications commission
FDA	united states food and drug administration
GR	geographic redundancy
HA	high availability
HDO	healthcare delivery organization
HMD	head-mounted display
IAM	identity & access management
IoT	internet of things
ISM	industrial, scientific, and medical
ITU	international telecommunication union
KPI	key performance indicator
LAA	licensed assisted access
LTE	long term evolution, also refers to 4G
MCS	modulation and coding scheme
MITM	man-in-the-middle
ML	machine learning
mMTC	massive machine type communications
mmWave	millimeter-wave
MNO	mobile network operator
MRI	magnetic resonance imaging
NR	new radio
NR-U	new radio unlicensed
NSSAA	network slice specific authentication and authorization
OAM	administration and maintenance
ONAP	open network automation platform
PTCRB	personal communications service type certification review board
QoE	quality of experience
QoS	quality of service
RAN	radio access network
RBAC	role based access control
RF	radio frequency
SASE	secure access service edge
SCA	composition analysis tools
SEAF	security anchor function
SEPP	security edge protection proxy
SLA	service level agreement
SOC	security operations center
SUCI	subscription concealed identifier
SUPI	subscription permanent identifier
TS	technical specifications
UE	user equipment
URLLC	ultra-reliable low latency communications
VPN	virtual private network
VR	virtual reality
XR	extended reality

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