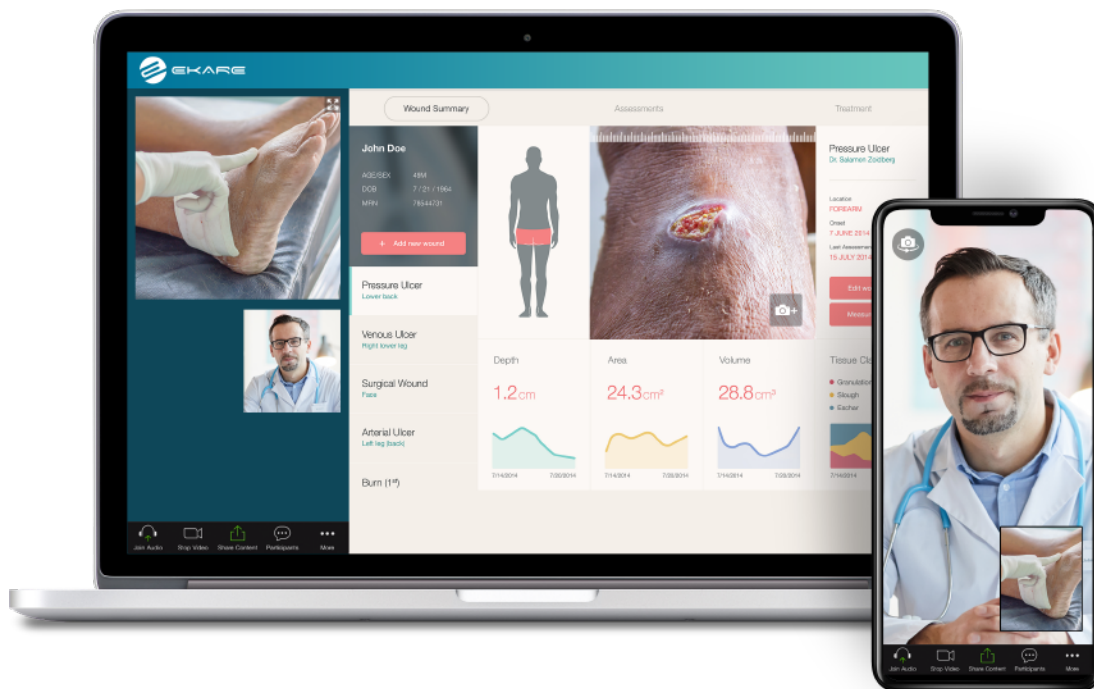




EVOLUTION OF CARE:

Enhancing the Delivery and Management of Wound Care Through Telehealth



About eKare

eKare is at the forefront of innovation in wound care. The company began as a spin-off from Children's National Medical Center (Washington, D.C.) to address the challenges with traditional wound care practice. eKare is advancing the science and delivery of wound care by leveraging mobile computing, sensor technologies and machine intelligence to improve access to care and treatment outcomes. eKare's offerings include advanced wound imaging, telehealth, business intelligence and analytics.

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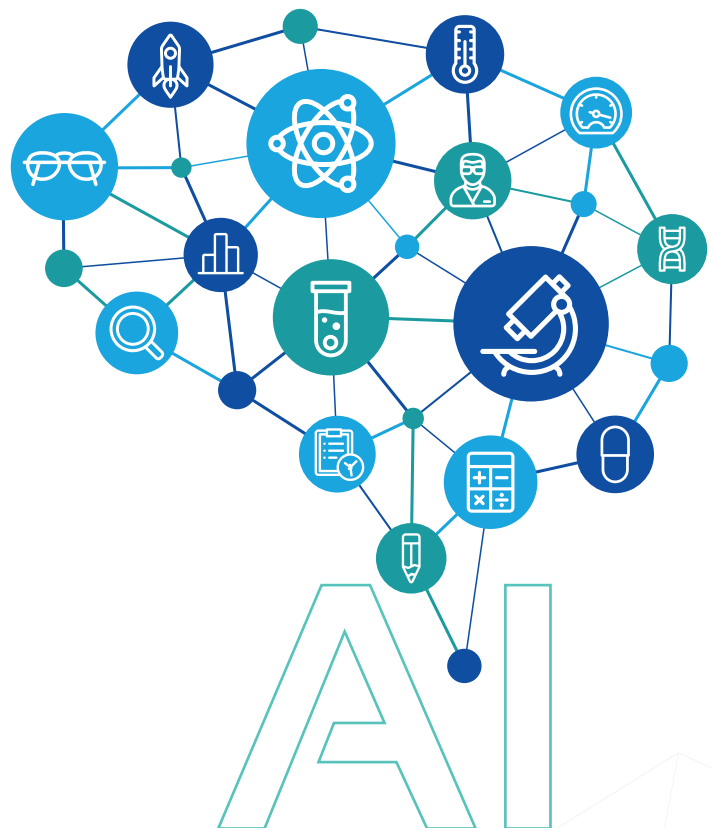
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Executive Summary

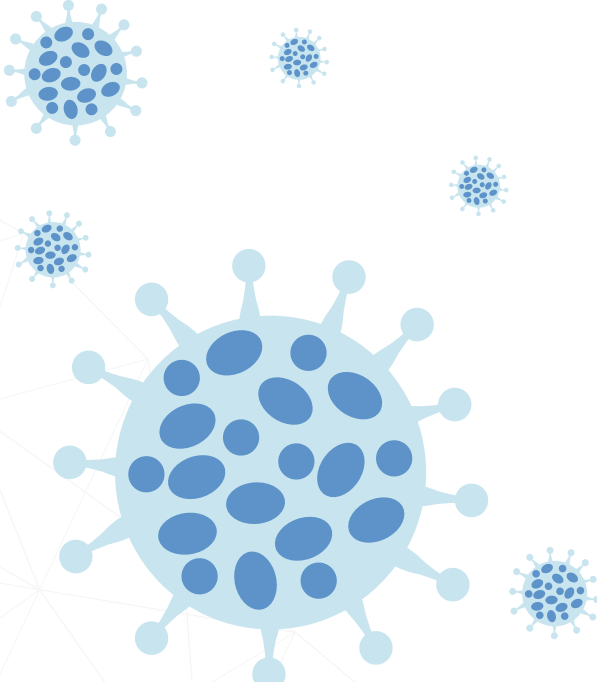
Health care delivery must continue to evolve alongside the ever-increasing challenges at the heart of our healthcare system. With a disruption in delivery of care, it became urgent and imperative for providers to leverage new solutions to reach patients. In response, providers turned to the familiar patient friendly apps, such as Skype, WhatsApp and FaceTime. While penalties for Health Insurance Portability and Accountability Act (HIPAA) violations have been waived in the US these consumer apps do not provide a sustainable platform for delivery and management of care. Public-facing apps, including Facebook Live, TikTok and Twitch are still not within the permitted domain.

Data control, integrity, security and access are among the top on both the provider and patient side. Telehealth technologies must comply with data privacy regulations while ensuring usability and data accessibility. A number of new telehealth solutions are becoming available across specialties and the use continues to expand from sharing of medical images to measuring of biological parameters remotely. This white paper examines the current challenges, regulatory landscape and application of telehealth in wound care, commonly coined telewound care.




A Catalyst for Change

With the harsh and unprecedented intrusion of the novel Coronavirus (COVID-19) pandemic, healthcare providers were hard-pressed to prioritize emergency visits and postpone elective care to mitigate the spread of the virus. As a result, important medical care has been under-utilized, putting vulnerable patients with comorbidities at great risk. Adding to the concern, patients most vulnerable to COVID-19 are those visiting wound centers.¹ Management of chronic wounds requires routine monitoring and care as these patients are prone to infection and sepsis. More than half of the patients with diabetic foot ulcers, for instance, will develop an infection during the 12-week treatment period.² For patients with chronic wounds, the situation has been detrimental. With no access to care, patients with chronic wounds are at risk for developing complications that can land them in the emergency room and further their risk of COVID-19.³

An illustration of several COVID-19 virus particles. One large, detailed particle is in the foreground, showing a spherical structure with a blue and white speckled interior and numerous light blue spike proteins protruding from its surface. Several smaller, less detailed versions of the same virus are scattered around it. The background features a faint, light gray geometric pattern of interconnected lines.

Many of these patients live in rural areas with limited healthcare services, which further intensifies their situation. Physical and emotional isolation is common among this demographic.^{4,5} Factors such as limited mobility, pain, high level of exudate, malodor, leakage onto clothing can cause patients to be socially withdrawn.⁶ An overwhelming majority of patients report a negative emotional impact on their lives, including social isolation, depression, negative self-image and fear.^{7,8} Furthermore, fear of being judged or feelings of embarrassment due to stigma can be a deterrent for seeking care. Often patients wait until their condition has taken a turn for the worse.




Caring for patients with chronic wounds presents a unique challenge. Usually at admission or transfer to wound clinic, there is a lack of information on prior treatment, diagnostic studies, previous communication regarding potential recovery or plan of care. Non-compliance to treatment visits and plan is another difficult aspect of wound care management. For patients living with chronic illness, the non-compliance rate is 50%.⁹ Missed appointments, poor compliance with the treatment plan or medications lead to complications, higher morbidity, mortality and increased health care costs. For patients living in rural areas, limited caregiver availability, lack of transportation and lack of access to specialty services add to the problem.

Amid the COVID-19 pandemic, there is an opportunity to rethink our model of care. The healthcare must evolve to improve access, affordability and delivery of care. The enormous pressure and constraint placed on the healthcare system is becoming a catalyst for change. We have witnessed a decade's worth of transformation advance in a few short weeks. This has been one of the most challenging and exciting times as our healthcare system is being ushered into a new era. Providers must embrace new technology, leveraging recent advances in telehealth modalities, sensors, wearable and connected devices, to reach, treat and empower patients.

The Regulatory Landscape

As part of the emergency response, the Centers for Medicare & Medicaid (CMS) temporarily expanded benefits to telehealth services (Table 1). This policy and regulatory flexibility are part of the broader efforts of the White House Task Force to ensure access to healthcare, particularly for those at high-risk of complications during the pandemic.¹⁰ The US Department of Health & Human Services (HHS) granted a blanket waiver to enable providers to deliver services to patients in another state, however, states needed to waive these restrictions. We are likely to see this trend continue beyond the COVID-19 pandemic (Fig 1).



At the time of this writing, all 50 states plus Washington, D.C have introduced licensure flexibilities.¹¹ Additionally, parity payment is being provided across 38 states plus Washington, D.C., allowing providers to be reimbursed at the same rate as in person visits.^{11,12} 20 states have released guidance to waive or lower telehealth copays for the Medicaid population (Table 2). Many states are moving to pass legislation that would permanently expand access to telehealth. New York recently signed the senate bill to law, expanding telehealth services.¹³ Idaho has also made telehealth permanent through an executive order.¹⁴ Most recently, President Trump issued an executive order to expand telehealth, modernize regulations and reform payments. Specifically, the order calls HHS to launch a sustainable model for rural communities and extends part of Medicare’s broader coverage of telehealth beyond the current public health emergency.¹⁵

Fig 1. Summary of Policy Changes Influencing Expanded Telehealth Use

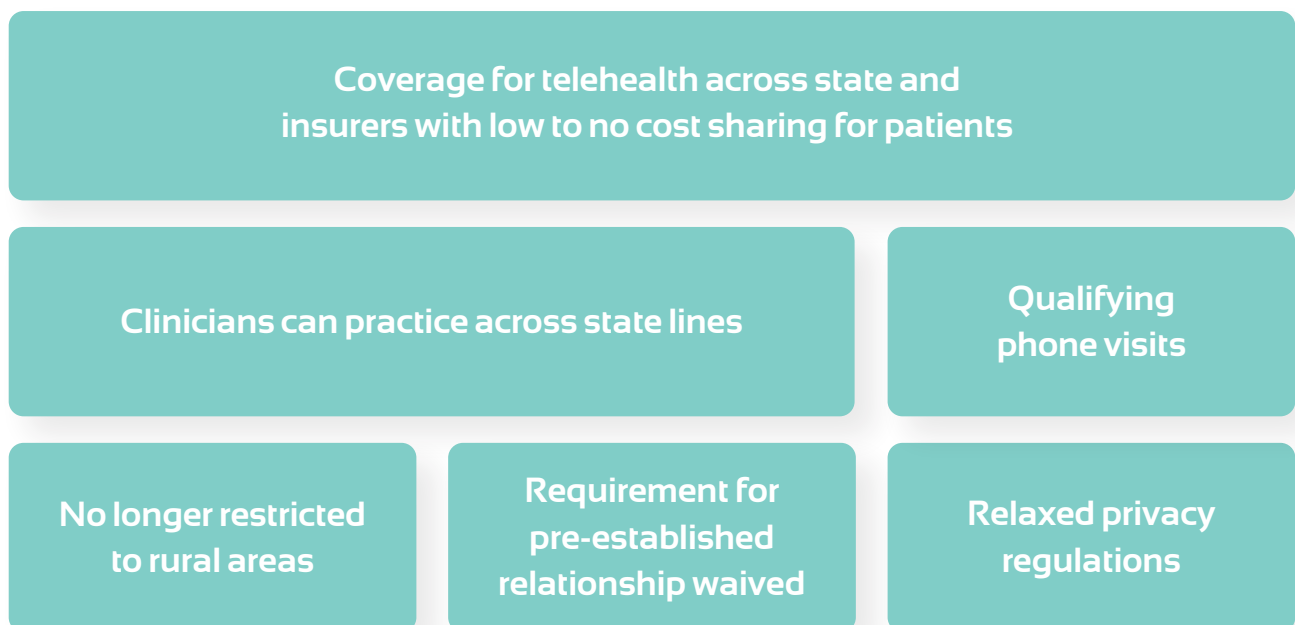


Table 1. Medicare Telehealth Services Allowed During Public Health Emergency

Evaluation and Management (E/M)	99201-99215	Office outpatient
	99221-99223	Initial hospital
	99231-99233	Subsequent hospital
	99304-99306	Initial nursing facility
	99307-99310	Subsequent nursing facility
	99281-99285	Emergency department
Telehealth-Specific Codes	99444	Online medical evaluation by provider to patient
	99441	Telephone evaluation 5-10 minutes
	99442	Telephone evaluation 11-20 minutes
	99443	Telephone evaluation 21-30 minutes
	99446	Interprofessional telephone or online assessment by consulting provider 5-10 minutes
	99447	Interprofessional telephone or online assessment by consulting provider 11-20 minutes
	99448	Interprofessional telephone or online assessment by consulting provider 21-30 minutes
	99449	Interprofessional telephone or online assessment by consulting provider 31+ minutes

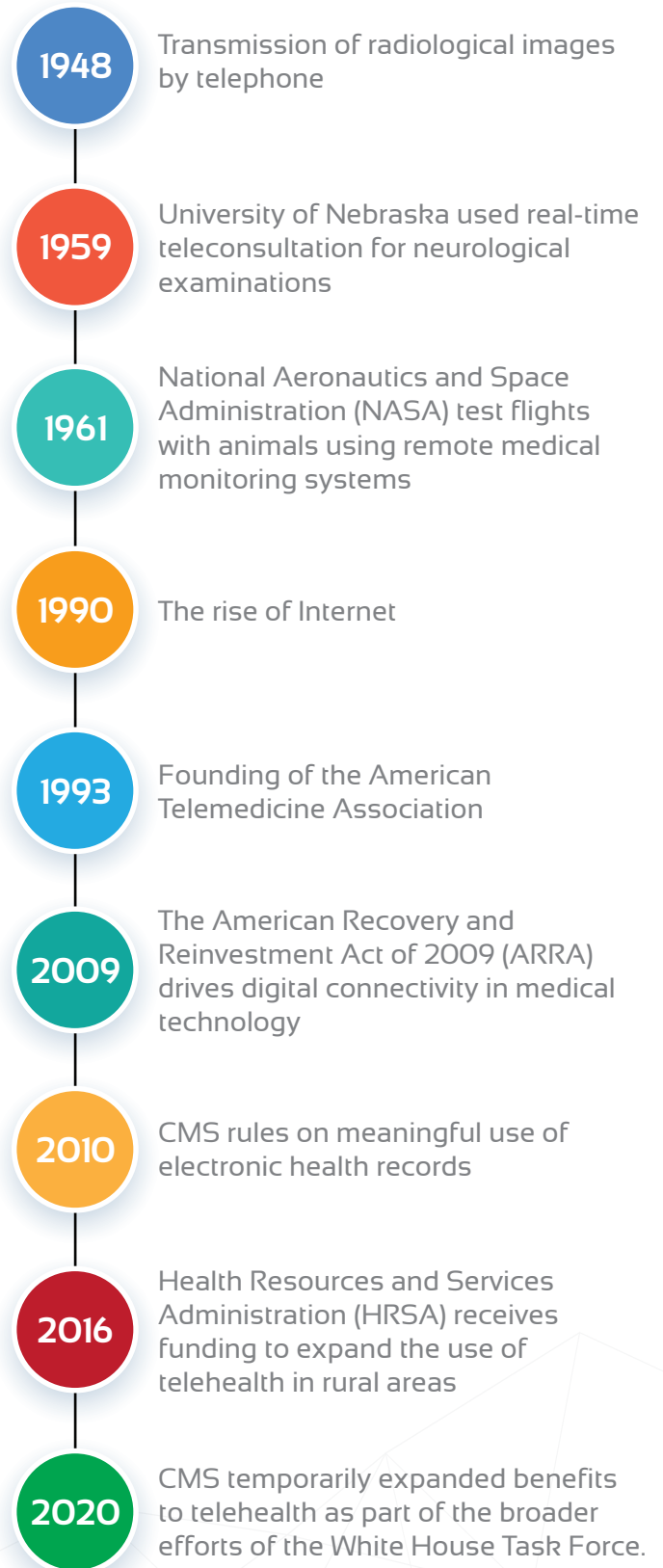
Table 2. State Level Trends

State	Key Changes
Alaska	Requires insurance carriers to cover mental health benefits via telehealth.
California	Telephone is allowed and reimbursed at the same rate as in-person visit.
Colorado	Waived requirement for pre-established patient-provider relationship. Requires state Medicaid program to reimburse at the same rate as in-person services.
Idaho	Temporarily waived restrictions on telehealth were made permanent.
Iowa	Set forth requirements for schools to provide behavioral health services via telehealth in school setting.
Louisiana	Requires health plans issued on and after Jan 1, 2021 to provide coverage for telehealth. Expanded definition of telehealth to include behavioral health services.
Maine	Case management services covered by MaineCare program can be delivered via telehealth without requiring risk of hospitalization or admission to emergency room as a qualifying criterion.
Maryland	Telehealth services to be held at the same standards of practice that are applicable to in-person care. Requires the Maryland Medical Assistance Program to provide mental health services via telehealth in patient's home setting.
Massachusetts	Providers can deliver clinically appropriate and medically necessary services via telephone and live video.
Michigan	Prohibit insurer from requiring face-to-face contact between provider and patient for services appropriate for telehealth. Cover telehealth under medical assistance program and Healthy Michigan program if the originating site is an in-home or in-school setting.
North Carolina	Increase public access to professional psychological services by allowing telehealth practice across state lines.
New York	Expanded definition of telehealth to include audio-only.
Texas	Cover audio-visual and audio-only at the same rate as in-person.
Utah	Required certain health benefits plans to provide coverage parity and commercially reasonable reimbursement for telehealth services.
Washington	Providers offering telehealth services to be reimbursed at the same rate as in-person visit.

Evolution of Telehealth

While telehealth is just now beginning to take center place in wound care, it has been in existence since the late 1940s. It began on landline telephones with sharing of radiological images & medical documentation over long distances.¹⁶ The rise of internet and digital revolution followed by a wave of advancements in science and technology shaped a new era for remote health care.

It is now transforming the future of health care delivery and solving one of the health care's biggest challenges - access to care. Telehealth is improving continuity of care during the pandemic and closing the care gap. It provides a more efficient way to utilize limited staff and resources to deliver point of access care for specialty consults, triage for emergent conditions, medical education, and chronic care management.



Studies have shown that telehealth visits can significantly lower health care costs. The US department of Veterans Affairs (VA) attributed a saving of \$2,000 per year, per patient to its telehealth strategy; there was a notable reduction in hospital days (59%) and reduction in hospital admissions (32%).¹⁷ A study by Bashshur et al. highlighted that telehealth has the potential to reduce congestive heart failure-related hospital visits by as much as 56 percent.¹⁸ A pilot study, involving the exchange between a wound care clinician at the University of Virginia and patient at a long-term care facility, reported a cost savings of \$13,650 for 21 visits.¹⁹ There have been a limited number of studies on the use of telehealth technologies in wound care.

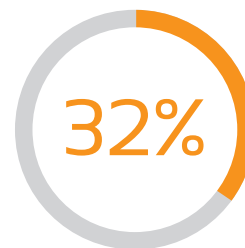
VA Telehealth Study



**\$2,000 Annual
saving per patient**



**Reduction in
hospital days**



**Reduction in
hospital admission**

Telehealth Use Cases

Telehealth continues to proliferate and expand into diverse platforms. These services can be broadly classified into two main categories: 1) direct-to-patient, 2) provider-to-provider (Table 3).

Direct-to-Patient (DTP)

DTP includes synchronous & asynchronous technologies such as videoconferencing, email and remote-patient monitoring, data storage-and-forwarding. DTP services allow patients to access high quality care from the comfort of their homes. At this time, patients are in a state of heightened anxiety and fear, which has led to an increase in missed appointments and poor compliance with treatment plans or medications.

For patients living in rural areas, limited caregiver availability, lack of transportation and lack of access to specialty services continues to be a problem. DTP telehealth modalities have the potential to cut health care costs, improve patient compliance and satisfaction, as well as reduce the burden on emergency departments and doctor's offices.



Provider-to-Provider (PTP)

PTP services involve synchronous or asynchronous interprofessional consultations, health assessment and management. This enables health care professionals across the continuum of care to review and share data, make assessments and recommendations through a secure portal. In wound care, it's not uncommon to see a lack of accurate or complete information for referred patients. This often leaves questions about past interventions and outcomes unanswered. PTP exchange has the potential to drastically improve care coordination, early diagnosis and treatment. Furthermore, it can strengthen transitions of care between referring providers and long-term/post-acute care providers.

Table 2. State Level Trends

	Use Cases	Type of Service	Modality	Data Accessed or Shared
Direct-to-Patient	Teleconsultations	Synchronous	Real-time audiovisual	Medical record and images
	Remote patient monitoring	Asynchronous	Mobile apps, wearable devices and/or connected devices	Continuous data via connected devices Patient reported data
	Patient education	Synchronous or Asynchronous	Real-time audiovisual and/or secure messaging or notifications	Medical record and images
	Decentralized Clinical trials (DCT)	Synchronous or Asynchronous	Real-time audiovisual, mobile apps, wearable devices and/or connected devices	Continuous data via connected devices Patient reported data
Provider-to-Provider	Interprofessional consultations	Synchronous	Real-time audiovisual	Medical record and images

The Challenge

Clinical trials are the mainstay for advanced treatment for chronically ill patients. In wound care, patients often present with complex etiologies, have had little or no success with standard care and are usually underinsured; some may even have waited a long time to qualify for the study. The abrupt clinical hold caused by COVID-19 left many patients without care, leaving them at risk of complications, infection and sepsis.

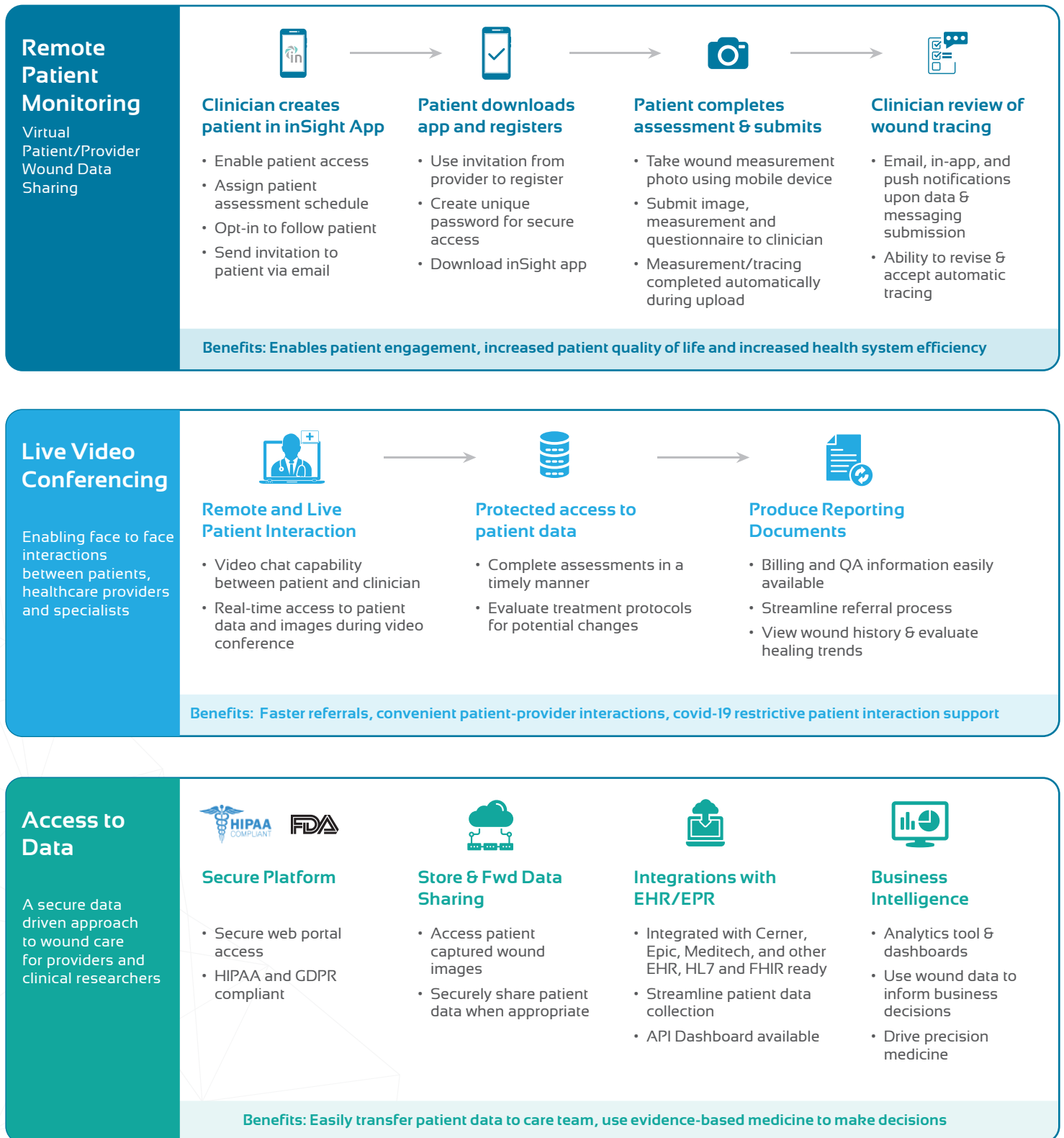
The Solution

The technology must comply with data privacy and security regulations while ensuring usability and data accessibility that are continuously evolving. While there are limitations to delivering care via live video streaming, safety evaluations, risk assessments and measurement of wounds can be done remotely. eKare's telehealth solution includes video conferencing, secure messaging and a patient app built on artificial intelligence (AI) to measure wounds, streamline data collection and facilitate remote monitoring (Figure 2). The clinical workflow is streamlined and enables the provider to review, accept or revise automated wound recognition and the resultant measurement tracing. The platform is HIPAA, General Data Protection Regulation (GDPR), and 21 CFR Part 11 compliant.

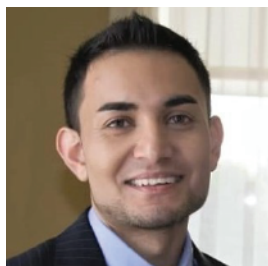
The Benefits

eKare's telehealth solution promises to improve care coordination across practice and clinical research, allowing providers to communicate with patients more frequently. This can emphasize adherence to complex treatment protocols and medication management, enhance management of chronic wounds, and significantly increase patient satisfaction. It also provides new opportunities for patient education and engagement. Moreover, this technology has the potential to enable hybrid or full DCTs in wound care, minimize recruitment and retention barriers without compromising study design, quality or data integrity.

Figure 2. eKare Telehealth Solution



About the Authors



Raphael A. Yaakov, MS

Raphael's experience spans across public health, clinical research and technology. He has helped support key initiatives in patient communication, pediatric and adult cancer education programs, global epidemiological surveillance of micronutrient deficiencies to managing phase I-IV multinational drug and device studies. He is interested in developing disruptive approaches and technologies that address gaps in clinical practice and integrate patient's voice in clinical decision-making. Raphael's work has appeared in a number of peer-reviewed journals, including *Advances in Skin & Wound Care*, *Chronic Wound Care Management and Research*, and *Wound Repair and Regeneration*. He completed his undergraduate course work in life sciences at the Pennsylvania State University and holds a MS with a concentration in pharmacoeconomics and outcomes research from the University of the Sciences in Philadelphia. Raphael currently serves as the VP of Clinical Development at eKare, Inc.



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Martha Kelso is the Chief Executive Officer of Wound Care Plus, LLC, the largest mobile wound care provider in the Midwest. With over 20 years' experience in advanced wound care, Martha is a visionary and entrepreneur in the field of mobile medicine. Martha is a published author and a member of several national advisory boards. She is frequently called upon as a legal expert witness and has been a featured speaker at hundreds of education events. Martha is currently the Principal Investigator for a CMS funded Clinical Research study on the efficacy of Platelet Rich Plasma, and is widely recognized as being a pioneer in the advanced wound care arena who works tirelessly to shape the future landscape of healthcare.



Brian McManus

As the Vice President of Clinical Research Operations, Brian McManus is invested in working with clients to collect high quality data for clinical trials. Prior to joining the eKare team, Brian spent nearly 15 years administering research studies across the US and Europe. During this time, he also managed a wound imaging core lab for a multitude of studies with a focus of streamlining data collection processes.



Emmanuel Wilson, MS

Emmanuel Wilson is a biomedical engineer by training with a keen focus on customer support and logistics since joining eKare in 2016. Prior to this, he was at the Sheikh Zayed Institute for Pediatric Surgical Innovation at the National Children's Hospital as a staff scientist, where he developed and tested tools for minimally invasive surgery and computer-assisted interventions. Emmanuel received his MS in Biomedical Engineering from The Catholic University of America in Washington, D.C.

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