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Integrated Digital Care
and
P4 Medicine

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Integrated Digital Care and P4 Medicine

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Introduction

"Digital health" is a buzzword that for some time has excited the healthcare world and those who invest in it. But what connotations does the term really carry and what are its true implications for impacting the three universal variables present in all healthcare discussions: Access, Quality and Cost?

This discussion examines the deployment of digital technologies in healthcare, both in the context of their potential to positively impact clinical care delivery and also to enable the meaningful patient participation in the healthcare decision and implementation process. Because data—its acquisition, curation, storage, analysis and reporting—is the byproduct of most things digital, we will also follow the data trail throughout the care delivery process with emphasis on the architecture of the health record and its evolving role in care delivery. Finally, we'll discuss predictive, preventive, personalized and participatory—P4—medicine as more than aspirational, but instead as an imminent consequence of deploying an integrated digital care platform.

Evolution of the Electronic Health Record

Widespread clinician adoption of the electronic health/medical record (EHR or EMR), spurred by the HITECH Act of 2009 and its monetary incentives, has profoundly changed the working lives of those clinicians. Design flaws adversely affecting clinical workflow have cause clinicians to devote half their time or more to documentation rather than patient care. The result is growing dissatisfaction with professional life and burnout among clinicians at a time when growing provider shortages are adversely impacting patient access to needed care. Moreover, once invested in EHR technology, a medical practice or large healthcare system finds itself literally enslaved to the particular EHR it has adopted regardless of its shortcomings. The "tar baby" nature of the adopted EHR largely results from the lack of interoperability between and among various EHRs, making the switch to a different vendor's EHR a daunting, expensive and often nearly impossible task.

Not coincidentally, the rapid and disproportionate rise in the number of IT and administrative personnel in the healthcare equation has coincided with the troves of data gathered in the use of EHRs. Yet, the supposedly valuable data stored in the relational database architecture of most EHRs is difficult to access and process by analytics engines. Either the data is insufficiently structured or lacks the semantic properties for useful analytics. A recent example is the failed attempt to extract meaningful data from M. D. Anderson's Epic® EHR for analysis by IBM's Watson supercomputer to generate clinical decision support in the treatment of cancer.[1,2]

In attempts to create data uniformity by incorporating many pull-down check boxes and cut-and-paste boilerplate clinical descriptions, it appears that EHR software developers have produced the tendency,

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[1] Jaklevic, MC. *MD Anderson Cancer Center's IBM Watson project fails, and so did the journalism related to it*. HealthNewsReview.org. 23 Feb 2017

[2] Herper, M. *MD Anderson Benches IBM Watson In Setback For Artificial Intelligence In Medicine*. Forbes. 19 Feb 2017

from a documentation perspective, to generate generic patient descriptions that miss many important clinical nuances. The results can lead to data analysis failures and even direct patient harm.[3]

Legacy EHRs may be useful and necessary for billing purposes and documentation of certain quality measures necessary to support regulatory reporting requirements. But, they are not designed to be care delivery platforms. Unfortunately, the data architecture of most current EHRs also limits their potential to become care delivery software.

Care Delivery vs. Care Documentation

The practice of medicine and the rendering of healthcare necessitates a process—one that has proven efficacious for nearly three thousand years. Moreover, that process works regardless of specialty. It is the same for primary care as it is for neurosurgery, for cardiology, for psychiatry and so on. The process of rendering medical care consists of four basic steps:

1. Evaluate: Take a patient history. Perform a physical examination. Obtain measurements, lab tests, and other studies as indicated.
2. Diagnose: Based on Evaluation, use one's training and knowledge to select the most probable cause of the patient's problem.
3. Treat: With the Diagnosis as guide, and based on knowledge of the patient, professional training and literature support, create a treatment plan and institute it.
4. Follow: Depending on the severity of the illness and the patient's expected course, see that patient at proper intervals to assess the efficacy of the prescribed treatment until the problem is cured or stabilized. If the treatment is ineffective, go back to Step 1.

Clearly, the steps described above must be followed in precise order. To do otherwise would be akin to a firing range instructor's command of "Ready! Fire! Aim!"—both are ineffective and dangerous.

An outpatient care delivery platform, whether structured as brick-and-mortar or fully digital with virtual care capabilities, is in essence a clinic. That is, earth-based or cloud-based, the "clinic" must be equipped to enable all the elements of the care process to take place, not just process documentation or video chat.

Proper virtual care, where clinician and patient are separated by indeterminate distance, is especially challenging. A virtual care platform, even one that can be used for in-person care, must be digital and must support all elements of the care process. The "virtual clinic" must allow for visual evaluation of the patient and integrated e-diagnostic devices must allow a proper physical examination, gathering and reporting of vital signs, heart and breath sounds, ultrasound inspection of the body (a surrogate for palpation), ECG and spirometry assessments and acquisition of other pertinent physiologic and mental health data. The platform must support clinical decision making, e-prescribing and/or referral for treatment, patient education and participation in the care process, and establishment of remote monitoring between follow-up visits as indicated.[4]

To serve as a care delivery platform, a modern EHR must be able to acquire and document and fulfill all elements of the care process. Unfortunately, most cannot, especially for the digitized sounds, tracings and live images acquired in the course of care. Currently, no legacy EHR alone appears to support the full process of care—virtually or in person.

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[3] Fry, E. and Schulte, F. *Death by a Thousand Clicks: Where Electronic Health Records Went Wrong*. Fortune. 18 March 2019

[4] Knapp, TR. *A Global Medical Grid: a systems-based approach to Internet-enabled healthcare delivery*. https://www.carespanhealth.com/whitepapers January 2012

Integrated Digital Technologies

With the advent of the integrated digital care platform, a multi-disciplinary treatment plan no longer need be consigned to rare and particularly virulent problems such as complex birth deformities or cancer. Now, those afflicted with the common ailments of our society—hypertension, COPD, congestive heart failure, diabetes, anxiety and depression—which often exist as co-morbidities in the same patient—can immediately benefit from a coordinated and collaborative approach among treating clinicians. And the transparency afforded by the digital care platform allows for integration of the patient in the process, a participation that establishes an essential element of better outcome generation.

The digital care platform itself must include essential technologies integrated to work seamlessly and efficiently to optimize clinical workflow. Conceptually, a fully-integrated digital care platform is akin to a computer's operating system (OS). Just as the OS serves as a unifying platform that supports many functions and applications, the integrated digital care platform serves numerous macro functions and, in turn, supports many add-on applications that assist various areas of clinical decision support and medical specialty care. Key operating components and some sub-components of an integrated digital care platform include:

- <u>Patient Monitoring</u>—Just as sensors within an automobile's tires, brakes, suspension and engine monitor its performance historically and moment-by-moment, human physiology and behavioral/mental health functions can be monitored with an increasing array of biosensors, including attachables, implantables and wearables. For individuals with chronic diseases, *prescribed* monitoring (often called Remote Patient Monitoring or RPM) initiated by an attending clinician is becoming prevalent and reimbursable by insurers and government. Much like a car's dashboard warning signal that low tire pressure exists, data gathered in the RPM process may trigger clinical alerts when readings exceed pre-set parameters, thus allowing beneficial clinical intervention to prevent crises and avoid the exacerbation of dangerous disease conditions. RPM requires analog-to-digital sensors, presentation of sensor data to observers, and generation of appropriate signals for readings out-of-range with recognized norms. The entire monitoring paradigm requires digital implementation.
- <u>Clinical Encounter Management</u>—The clinical encounter between patient and clinician is the most important transaction in healthcare. Here, the entire process of healthcare delivery plays out, usually over a series of encounters. The clinical encounter involves a workflow that, if efficient, preserves the clinician's time and increases job satisfaction. Whether in-person or virtual, the clinical encounter also frames patient perception of the competence and empathy of the treating clinician. As the clinician's primary workshop, the clinical encounter environment must include the entire toolset that enables delivery of care and the display of actionable information necessary for executing the process, including:
    - At the patient location, a user-friendly interface that complements the provider's interface, engages the patient, and supports meaningful interactions between patient and clinician, whether in-person or at distance
    - The medical record for reference as needed
    - An Encounter Summary to capture all aspects of the session and the process of care delivery
    - Multi-channel audio-video telepresence with patients, specialist consultants, therapists and family members
    - Means to capture, display, annotate and store critical data elements, including vital signs and other sensor readings, lung, heart, bowel, and speech sounds, ECG and spirometry

tracings, laboratory data, photos, ultrasound, endoscopy, DICOM[5] images such as X-rays, MRI and CT scans, assessments including an array of behavioral and mental health queries, and legal forms including informed consent

    - Means to engage with medical Internet-of-things (IOT) hubs for biometric authentication of distant users and sensors, and transmission of sensor data under recognized standards (e.g., Continua[6]).
    - Means to annotate data and make notes with voice recognition as well as typing
    - Means to educate the patient and field questions with interactive multi-media images, videos and print libraries
    - Means to engage specialist consultants during a clinical encounter
    - Means to establish referrals
    - Means to set-up and prescribe RPM
    - Means to apply appropriate diagnostic and procedural coding (ICD-10 and CPT)
    - Means to display documents or the entire clinical interface in multiple languages

- Care Coordination—Societal mobility and the vagaries of human behavior dictate that the human factor in coordination of the complexities of medical care will always be necessary to some degree. Trained intermediaries staffing a call center can fulfill the role of care coordination, from scheduling of clinical encounters to triaging RPM alerts to lifestyle coaching and beyond. Digital information and communications technologies are the tools that facilitate such coordination.
- Data Analytics—Techniques and technologies such as natural language processing (NLP) and the application of machine learning and artificial intelligence (AI) to large data sets have the potential to predict the course of individual clinical circumstances, to enhance clinical decision-making based on evidence from the world's medical literature, and to drive continuous improvement in the healthcare delivery process based on population health experience. Syntactic data acquired from monitoring that are curated and made semantic during the clinical encounter become the essential elements for analytics. An integrated digital care platform used by many providers from multiple specialties quickly generates meaningful data for the analytics process.

Once digital care technologies are integrated, especially if those technologies exist in a cloud-based platform-as-a-service (PaaS) configuration, delivery of true medical care—especially cognitive care not requiring physical intervention (such as surgery)—is entirely possible. This makes more than 80% of outpatient care available to patients anywhere with an Internet connection. Healthcare can be scaled globally. Moreover, the transactional cost of care delivery systemically falls as the use of digital care expands. For most clinical encounters, the cost of access is nil. By often reducing the number of parties involved in the care transaction, cost is further curtailed. These savings perpetuate across populations and are additive to the savings that accrue with preventive measures and outcome management.[7]

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[5] Digital Imaging and Communications in Medicine standard. https://www.dicomlibrary.com/dicom/

[6] Continua Design Guidelines. https://www.pchalliance.org/continua-design-guidelines

[7] Knapp, TR. *Digital Healthcare Delivery and Direct Primary Care: Synergistic Impacts on the Economics of the Medical Care Transaction*. https://www.carespanhealth.com/whitepapers August 2017

Integrating Care, Digitally

Integrated, collaborative medical care is not a new concept. Complex diseases and conditions have required it for many decades in attempts to engineer optimal patient outcomes. Today, best practices for the care of a woman with breast cancer rely on the collaborative efforts of a geneticist, a clinical oncologist, an oncological surgeon, often a reconstructive surgeon, a nurse practitioner, a clinical psychologist and not infrequently a social worker. Family and marriage counseling are frequently indicated. Likewise, treatment planning and execution for children with craniofacial deformities involves the coordinated and collaborative efforts over many years among a variety of disciplines such as pediatric dentistry, plastic and ENT surgeons, neurosurgeons, orthodontists, pediatric nurse practitioners, geneticists, family counselors and so on. Analogies abound. And as we better understand cognitive function at the molecular level, the care of multiple co-morbid chronic disease states and the diagnosis and treatment of mental disorders that impact physical diseases and vice-versa are broad areas demanding integrated collaborative care for best outcomes.

Such collaborative care is difficult to render effectively outside of academic institutions, especially when collaborating clinicians are at disparate locations and the patient is often remote in an underserved community. But, as we introduce the concept of integrated ***digital*** care rendered by collaborating providers using a single digital care delivery platform, we find that time-and-distance constraints disappear. Moreover, the shared diagnostic instrumentation, IOT integration, data formatting and curating, and workflow conventions all foster efficient real-time collaboration that includes the patient in treatment planning and the care process.

Building the collaborative process from the ground up begins with primary care and behavioral/mental health integration.[8] Collaboration between these two inextricable disciplines establishes the framework for patient integration into the planning and treatment process even as specialists are added to the care team. Primary care providers, including physicians, nurse practitioners and advanced practice nurses[9], become patients' *ad hoc* navigators. Digital collaboration enables and optimizes the role of the primary care provider as agent and advocate for the patient—the patient's guide through the complex maze of multidisciplinary healthcare. The result: managed outcomes.

Outcomes Assessment and Management

Outcomes in healthcare may be assessed according to a number of criteria, depending on the nature of the condition. For episodic care of conditions such as a bone fracture, a flu or a skin infection, the optimal outcome is a cure achieved expediently and economically. For chronic conditions such as hypertension, diabetes, and COPD, a desirable outcome may be minimizing and controlling symptoms and adverse physiologic and mental affects to prolong quality of life and avoidance of acute exacerbations requiring emergency interventions and hospitalizations. For incurable and progressive chronic conditions, especially later in life, the desired outcome may be stabilization of the condition and optimizing quality of existence—expressed as palliative care—while the outcome for terminal conditions under hospice care usually counts success as death with comfort and dignity and the avoidance of futile care.

Assessment of outcomes for each medical care category—episodic, chronic, palliative and hospice—should address certain common questions that result from the care rendered:

- Is the patient better, worse or unchanged as the result of specific treatment?

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[8] Knapp, TR and Toney, S. *Integrated Digital Care Delivery: A Primary Care/Mental Health Example.* https://www.carespanhealth.com/whitepapers January 2019

[9] Buerhaus, P. *Nurse Practitioners: A Solution to America's Primary Care Crisis*. Am. Enterprise Inst. September 2018

- Is the economic impact of the treatment the minimum possible to achieve the desired outcome?

Optimal outcomes combine tangible improvement in the patient's condition(s) and quality of life at lowest possible cost.

Managing to optimal outcomes is not only difficult under best circumstances, it is nearly impossible without uniformity of data acquisition that generates evidence-based clinical decision support and coordinated effort by every member of the care team. Efficiency in such a process is entirely possible with a shared digital care platform that the care team utilizes to drive the desired outcome. Moreover, the results achieved for individual patients become critical elements of the data that permit population health analytics directed at driving a continuous improvement process to benefit anyone afflicted with similar conditions.

All healthcare providers are taught to be outcome-driven. We now recognize that the prevalence of comorbidity complicates the care regimen and calls for a multi-disciplinary/integrated approach. Even recently, clinical challenges for clinicians often stem from failure to understand why some patients do not respond to traditional care, even when they explain to patients the efficacy of recommended treatments and express optimism about positive outcomes. For example, when clinicians fail to appreciate the necessity for integrated physical and mental care to reach desired outcomes, it underscores shortcomings in conventional care approaches that do not account for individual risks and behaviors that can be driven by psychiatric disorders.[10] More than 68% of adults with a mental disorder also have at least one other medical condition.[11] There is bidirectional correlation with this comorbidity, meaning a mental disorder might lead to greater risk for health issues, and health problems might in turn cause greater risk of mental disorders.[12] Appreciation of these links spurs collaborative care from the outset.

It is clear that managing the course of a patient to a desired outcome not only demands an integrated digital care platform, it also demands awareness and discipline by the integrated care team.

Workflow Risk, Data Flow Integrity and Maintaining Data Chain-of-Custody

To be effective, clinicians require real-time access to actionable information. For in-person clinical encounters, legacy EHRs may provide such information, including patient vital signs, ECG tracings, spirometry readings and the like taken at the initiation of the clinical encounter, along with laboratory results, X-ray reports and other test results.

With traditional interactive telemedicine based on video chat between provider and patient, such actionable information has seldom been present. However, a fully-configured digital care platform that integrates the transport and presentation of actionable clinical information about the patient using e-diagnostic equipment and biosensors can present necessary information to the clinician regardless of distance from the patient. This is critical, because without such information upon which to base a diagnosis, safe treatment becomes risky—and any injury to the patient based on adverse events associated with treatment in the absence of a credible diagnosis constitutes negligence, the grounds for malpractice.[13]

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[10] Toney, S. *Precision Care Management to Impact Comorbid Patients.* Population Health News. 2:1 January 2015

[11] Druss, BG and Walker ER. *Mental Disorders and Medical Comorbidity.* The Synthesis Project. Robert Wood Johnson Foundation. February 2011

[12] *Ibid.*

[13] Knapp, TR. *Medical Advice vs. Medical Care: A Critical Distinction for Telehealth/Telemedicine Services.* https://www.carespanhealth.com/whitepapers December 2015

But, distance and electronic diagnostic information poses its own set of challenges to assure both data and transactional integrity. The clinician must be able to trust the data presented to her. Moreover, the data consigned to the clinical record and the notations and conclusions drawn as a result, i.e. the record of the clinical transaction, must be practically and legally non-repudiable. Non-repudiation of a digital transaction and the process for achieving it are well established in online banking and other critical transactions. Supporting non-repudiation in digital healthcare delivery, whether in-person or virtual, is also essential and the criteria for doing so have been addressed.[14] All digital care platforms must incorporate these principles. Doing so enables emerging technologies such as blockchain—the maintenance of a transaction ledger—to create worldwide portability and interoperability of personal health records. Blockchain requires irrefutable demonstration of non-repudiable chain-of-custody because like any chain, blockchain is only as strong as its weakest link.

Natural Language and the Application of Artificial Intelligence

Caring for persons' medical conditions is an exercise in infinite nuance. No two people are the same and no manifestation of disease in an individual is exactly the same as its manifestation in another. Yet, capturing nuance from patient-to-patient in current EHRs, where pulldown menus, checkboxes and cut-and-paste rote phraseology are the norm, mitigates uniformity and sacrifices nuance. Over time, the records of all patients with a certain condition begin to look alike.[15] No wonder the data extracted for analytics purposes from such records fail their intended purpose as meaningful starting material for shedding insights to disease.[16]

Fortunately, artificial intelligence (AI) technologies and machine learning applied to our natural, spoken language as recorded in text and converted from audio-to-text with voice recognition technology are capable of recognizing and tagging elements of nuance that are meaningful. Natural language processing (NLP), the computerized ability to recognize meaningful words and phrases that constitute nuanced descriptions of patients and their clinical conditions, is advancing rapidly and is now practical. The application of AI in the context of diagnosis and associated treatment planning that assist clinicians in real-time with evidence-based clinical decision support is increasingly available.

Syntactic analysis and semantic analysis are the main techniques used to complete NLP tasks.[17] Syntax refers to the arrangement of data and words in a communication such that they make sense grammatically or in context, as, for example, a blood pressure of 120/80 rather than the reverse (80/120). Semantics refers to the *meaning* conveyed by the syntactical arrangement. An example is the statement "120/80 is a normal blood pressure." That statement is also termed "curating" or adding clinical nuance to a syntactic data element. A digital care delivery platform must acquire data in syntactical form and permit its conversion to semantic (curated) data by the addition of nuanced clinical observations in natural language. The curated data become meaningful *knowledge* when submitted to large data "lakes" subject to NLP by AI routines. Unfortunately, pulldown menus, checkboxes and rote cut-and-paste, though useful in limited circumstances, do not support the clinical nuances necessary to draw critical inferences sufficient to produce knowledge from big data.

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[14] Knapp, TR. *Supporting Non-repudiation in Digital Healthcare Transactions*. https://www.carespanhealth.com/whitepapers August 2017

[15] *Ibid.* Footnote #3

[16] *Ibid.* Footnotes #1 & 2

[17] Garbade, M. *A Simple Introduction to Natural Language Processing*. Becoming Human: Artificial Intelligence Magazine. October 15, 2018. https://becominghuman.ai/a-simple-introduction-to-natural-language-processing-ea66a1747b32

Engaging Patients and Integration of IOT Technologies

A powerful attribute of the integrated digital care platform is the capability to engage and integrate the patient in meaningful ways unattainable with an EHR. Creating a patient portal that provides for data acquisition and contribution by the individual independent of the actual care transaction, that generates real-time and offline interactive educational experiences, that permits family members to participate in care encounters regardless of distance, and that enables personal collaboration in treatment planning—among other facilitators to engagement— may all be incorporated in a care delivery platform that treats the patient as a key participant and decision-maker in the care process. Respecting the patient as a member of the care team is the first step. Facilitating his/her participation follows. The legacy EHR is not well architected to permit such extensive engagement. A core component of the integrated digital care platform is proactive integration of the patient.

Perhaps the most challenging aspect of patient engagement, especially in treatment of chronic diseases and multiple co-morbidities, is assuring treatment compliance. Another challenge, especially among the elderly and infirm who may live alone or with companions in like circumstances, is prevention of injury due to accidents, especially falls. Many people in such circumstances will benefit from a watchful presence that can also serve to remind the patient of medication schedules and other therapies, communicating proactively as well as responding to queries. Interactive, voice-driven Internet-of-Things (IOT) devices are beginning to fill these requirements.

The Amazon Echo ("Alexa"), Google Home, Apple Siri and Microsoft Cortina may all be purposed to assist in medical care. Timed, voice activated medication reminders and other similarly engaging communications may be easily programmed. Cameras incorporated in these devices can watch for unsteady gait and fall dangers. Appointment scheduling and initiation of virtual visits are easily accommodated. Moreover, the IOT device equipped with biometric authentication technology (fingerprint, facial recognition and/or voiceprint), coupled with device authentication using Continua[18] standards, will involve the IOT device in support of non-repudiation of the virtual visit transaction and integrity of ongoing data acquisition during remote monitoring. Of course, to realize this potential the IOT device must be coupled with an integrated digital care platform. An EHR alone will not suffice.

Laws, Rules and Regulations

Healthcare is the most regulated industry in the U.S. and likely worldwide. The laws, rules and regulations that govern healthcare delivery, as with most elements of the social contract, are prone to be rapidly outdated by technological advances. This is certainly true with digital care, telehealth and telemedicine as well. Here are a few examples, discussed in the context of an integrated digital care delivery platform:

- *HIPAA/HITECH*—The Health Insurance Portability and Accountability Act (HIPAA) was passed in 1996. Core provisions of the Act were directed at protecting the security, privacy and confidentiality of protected health information (PHI)—the personal medical information of U.S. citizens. In 2009, the security requirements for protection of PHI, along with enforcement provisions, were significantly reinforced under the Health Information Technology for Economic and Clinical Health (HITECH) Act. These laws have particular relevance to digital health where PHI evolves at disparate locations and is transmitted among many devices, streamed through cyberspace and stored in cloud-based systems. To protect PHI and assure its chain-of-custody,

[18] *Ibid.* Footnote #5

strategies, policies and procedures must be created and implemented to avoid legal violations not common to brick-and-mortar care.[19]

- *Medical Licensure*—With its telemedicine and telehealth capabilities, digital care can functionally obliterate geographic barriers between patients and providers. While providing convenient or even lifesaving healthcare access to many people, current medical licensure laws and associated ancillary legislation often prohibit providers not licensed in a particular jurisdiction (state) from engaging and caring for individuals residing within said jurisdiction. To many individuals faced with need for care in health professional shortage areas and who might receive appropriate digital care, these licensure laws become detrimental. State medical boards, responsible for licensing, oversight and enforcement of state medical practices have been reluctant to yield to proposals for national licensure that would allow fluid practice across state lines. Recently, a series of interstate "compacts" has arisen that permit cross-state care using digital technologies. A national license, based on national Medical Specialty Board certifications, which is already the norm, would eliminate the hurdle and leave State Boards of Medicine oversight and enforcement authority.

- *Telemedicine/telehealth constraints*—Perhaps the greatest gap between the law and technological capability resides in the current flux in laws governing the practice of and reimbursement for care delivered at distance using telehealth and telemedicine. Technically, telemedicine may be deemed anything from a text message, e-mail or phone call to a video chat to full blown medical care with a digital care platform. Well intentioned laws often fail to address the policies necessary to assure that legitimate care is being delivered based on legislators' lack of familiarity with what constitutes safe care that supports the traditional care process.[20,21]

  For example, a Florida statute passed in May 2019 states "*If a telehealth provider conducts a patient evaluation sufficient to diagnose and treat the patient, the telehealth provider is not required to research a patient's medical history or conduct a physical examination before using telehealth to provide health care services.*" Pursuant to this wording in the statute, the Florida legislature is permitting violation of basic tenets of clinical care. That is, if one is to diagnose and treat, there must be a knowledge of patient history and one must have done a (directed) physical exam in order to (i) not miss key findings upon which a diagnosis may rest and (ii) have knowledge of past history that could prevent disastrous consequences of a specific treatment such as prescribing a drug to a patient with history of past allergies to it.

Quality Metrics and Quality Reporting

In attempts to assure that clinicians are rendering quality care to patients and not simply quantities of care, CMS (Medicare/Medicaid) and various insurers have created putative quality metrics that impact providers of care. The implementation of quality methods, measures and reporting has contributed not only to the administrative burden placed on clinicians but has also to the rise in administrative personnel in healthcare. Many of the quality measures that, increasingly, "value-based" clinician reimbursement is based upon are reasonable and as enacted may foster good care. However, the most salient indices of effective clinical care are seldom, if ever, requested—namely, *is the patient getting better, getting worse*

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[19] Knapp, TR, Walter, J and Renaudin, C. *Property Rights and Privacy Principles*. J Healthcare Info Mgmnt. 14:4 83-89. Winter 2000

[20] Knapp, TR. *Legislative and Policy Recommendations for Telehealth, Telemedicine and Digital Healthcare Delivery in the United States*. delivered to U.S. congressional representatives. https://www.carespanhealth.com/whitepapers December 2016

[21] *Ibid*. Footnote #13.

or staying the same? Accurate reporting of individual patient outcomes is the precursor to accurate population outcomes analysis. An integrated digital care platform whereby multiple collaborating providers gather clinical data uniformly in a format conducive to measurement, analysis and reporting becomes efficient and more quickly meaningful—whether the data concerns quality measures or outcomes reporting.

Supporting P4 Medicine: Predictive, Preventive, Personalized and Participatory

In the December 23, 2013 issue of *Genome Medicine*, Dr. Leroy Hood of the Institute for Systems Biology (Seattle) and Dr. Charles Auffray of the European Institute for Systems Biology (Lyon, France) co-authored an editorial entitled "*Participatory Medicine: a driving force for revolutionizing healthcare*."[22] In that editorial, the two authors coined and discussed the term "P4 medicine", which stands for **p**redictive, **p**reventive, **p**ersonalized and **p**articipatory.

Arising in the early 2000s, the appellations *predictive*, *preventive* and *personalized* characterized emerging trends in medicine and projected potential associated with analysis of large data sets unique to each individual. In short, because the human being is being digitized—including one's genomic, proteomic, microbiomic and other –omic data, along with metabolic and molecular reactions and their effects on the individual's state of being, coupled with fitness data, sociological interactions and related stress elements—a predictive model of one's health future is possible, especially if personal data acquisition and analyses are cradle-to-grave propositions. Consequently, analysis of an individual's big data cloud will make it possible to predict that individual's health future. If that future carries high risk of certain diseases, then it will often be possible to avoid disease by instituting preventive measures. And if disease does occur, for example a cancer having certain genomic differences from the host genome, then highly personalized and targeted treatments become realistic.

Hood and Auffray added the fourth P—participatory—to arrive at P4 medicine, because they believe that systems medicine, big data and associated analytics are not enough to trigger a true health care revolution. The necessary added ingredient is direct involvement of patients in their own healthcare through social networks. Further, in addition to the technological challenges of P4 medicine, which are relatively straightforward with solutions advancing rapidly, these authors concede that significant societal challenges must be overcome. They list eight. We will briefly discuss them in the context of integrated digital care.

Like Hood and Auffray, we believe that to realize a vision of P4 medicine there must be integration of technology, of patients, of caregivers, of the ethics, policies, laws, rules and regulations that form society's social contract. We also believe that an integrated digital platform for healthcare delivery and patient engagement—one that serves as both an ecosystem and an operating system for the "apps" that will enhance and advance the healthcare milieu—is a necessary foundation for the revolution that is health and medicine's future.

As quoted and paraphrased in italics below, Hood and Auffray delineate eight societal challenges to P4 medicine. Let's summarize this discussion by briefly addressing them in relation to an integrated digital healthcare platform:

1. *How do questions related to the ethical, legal, societal, security, privacy, policy, regulatory aspects and economics of P4 medicine that deal with individual patients get answered in a cogent and cohesive manner?*

[22] Hood, L. and Auffray, C. *Participatory Medicine: a driving force for revolutionizing healthcare*. Genome Medicine. 5:110. 23 Dec 2013. https://genomemedicine.biomedcentral.com/articles/10.1186/gm514

The architecture and features of a properly integrated digital care platform take into account each of these issues proactively. First, the sovereign entity in healthcare delivery is the patient. Once that frame of reference is incorporated into the delivery platform, matters of societal import—ethics, the law, regulatory policy, privacy, confidentiality and primacy of engagement—may be hard coded into the fabric of the system. Every digital care platform should be judged against these concepts.

2. *Who is included in the term 'participatory'? Including patients is obvious because a core idea of 'personalized' medicine also involves patients increasingly taking control of their own health. But how do we include physicians and other healthcare workers, other members of the healthcare system (payers, providers)?*

   Patient primacy in the care delivery system does not mean that others are excluded. It simply means that *participation is a matter or permission* with respect to the privacy of the patient. With patient permission, any stakeholder in the healthcare process may participate. Family members from afar may attend a clinical encounter. New members of the care team may be added. A payer's case managers may be granted access to critical personalized information. All with patient permission. Thus, *permission management* is a critical element of an integrated digital care platform.

3. *How do we bring an appropriate understanding of P4 medicine to all participants in the healthcare system? And how do we systematically obtain their feedback for guidance in developing new wellness products and services?*

   Public awareness of the paradigm shift to P4 medicine is best accomplished by demonstrating its benefits both to individuals and to society at large. People look to their care providers for guidance. That is unlikely to change regardless of how deeply involved with one's own care a patient becomes. Why? Because when illness strikes, when one feels sick and threatened, going it alone is not a pleasant or reasonable approach. When ill, we all seek a human touch in the form of a trusted clinician. Those clinicians require indoctrination in the concepts of P4 medicine. Teaching medical and nursing school students the art and science of care delivery on an integrated digital care platform is a critical component of promulgating the principles of P4 medicine.

4. *A key to the continuous improvement of P4 medicine is the ongoing mining of the personal data clouds of billions of individuals. For this will allow rapid progress in our understanding of the complexities of disease and wellness—and profoundly change healthcare. Hence after appropriate de-identification, it is essential that each patient's data cloud be available for mining for the predictive medicine of the future. How can we educate patients regarding the value of their data and how it can advance biomedical science without injury to them?*

   Again, the architecture of the integrated digital care platform can facilitate de-identification of clinical data from billions of individuals. The methodology is inherent to security measures that automatically segregate personal demographic information from clinical information with strong encryption keys mating the two databases, thus facilitating de-identification of clinical data subject to the analytics process. For analyses that require matching clinical data with individuals, two facilitators can be enacted in platform architecture: permission management and incentivized disclosure (paying people for use of personalized data under informed consent).

5. *Decentralization of medicine is an important aspect of the emerging P4 medicine focus on wellness. Many disease-oriented social networks (for example, PatientsLikeMe, Breast Cancer*

Alliance, Multiple Myeloma Research Foundation) are already beginning to alter how clinical trials are carried out. These social networks illustrate that healthcare and wellness can move away from hospitals and into foundations and even the home.

Decentralization and distribution of healthcare seamlessly and economically is a hallmark of an integrated digital care platform. The 'knowledge of the crowd' becomes an important aspect of health improvement, especially for promoting effective wellness strategies and providing supportive approaches to chronic illness, palliative care and hospice programs.

6. *Patients are beginning to question whether they want to have physicians who do not know anything about their genomes, or nutrition or wellness. Patients are beginning to move to more recently trained physicians knowledgeable of the new technologies and strategies that are transforming the practice of medicine. A challenging question is how to generate the patient-activated social networks that will trigger the healthcare systems to accept P4 medicine.*

   Medical schools are inherently tradition-bound with respect to the way in which healthcare is taught and delivered. Change will occur as teaching faculty and curricula are exposed to a cohesive methodology for taking advantage of rapidly emerging digital technologies in healthcare. Analog, brick-and-mortar-centered methods will give way to integrated digital care platforms only as such platforms are available to medical schools. Already, schools of nursing are leading the way by incorporating telehealth/telemedicine technologies and techniques into certified simulation laboratories that teach nurse practitioners and advanced practice nurses the proper approaches to digital care. Creators of digital care platforms have a responsibility to incorporate faculty and students of academic medical institutions into their cohorts of users. Once the providers of the future are schooled in the philosophies, features, benefits (and yes, risks) of integrated digital care, the patient-activated social networks that complement the P4 approach will become accepted attributes of the system.

7. *The participatory aspect of P4 medicine is extremely dependent upon first class IT for healthcare capable of managing and integrating millions to billions of personal data clouds—that is aggregating, mining, integrating them and finally producing models for each patient that are predictive and actionable—thus defining the future architecture of P4 medicine. In addition, it is essential that there be a 'trusted third party site' that contains up-to-date and accurate information on systems medicine and P4 medicine.*

   This is an aspirational statement that is being realized today. The advent of the properly-architected, integrated digital care platform creates a milieu that supports all aspects of P4 medicine. There is no need for a separate 'trusted third-party site' if proper credentialing and accreditation of the integrated digital care platform is provided by existing trusted third parties such as NCQA.

8. *It is clear that if the information from patient data clouds is to be used effectively to optimize their wellness and minimize disease, there needs to be a trusted interpreter of these data clouds for each patient. It is our view that a new healthcare professional, which we (Hood and Auffray) term a healthcare and wellness coach, will need to be created who can look at the patient's data cloud and present it to them in a way that encourages them to use their data to improve their health. We believe that nursing and general medical practice would be an ideal starting background from which to train such individuals.*

   We fully agree with Hood and Auffray that primary care, including the integrated mental/behavioral health component, is the nexus upon which P4 medicine must be built.

Reliance on large data lakes as starting material for identifying vulnerable individuals is one key to prevention. For example, predictive modeling and risk stratification methodologies are useful in the identification of individuals at risk for treatment failure and poor outcomes. Individuals who suffer from multiple comorbidities with identified psychosocial issues/barriers have increased health risks and costs that are far greater than those who do not appear to have associated psychopathology or psychosocial factors.[23] Transforming traditional reactive medicine to proactive/preventive and integrated care is a cornerstone in the P4 medicine approach—and critical in our current complex environment.

The role of the primary care provider (PCP)—the nurse practitioners and the family practice physicians—will rapidly evolve to the benefit of the individual patient as digital tools and workflow efficiencies provide more time to spend on the needs of patients and their families. Today, studies show that the legacy EHR consumes 50% or more of provider time documenting care.[24] An EHR as part of an integrated digital care platform should dynamically and automatically assist with documentation. Moreover, clinical decision support and quality reminders can now assist in many heretofore labor-intensive aspects of care. The PCP practicing digital P4 medicine will serve as clinician as well as *advocate* and *agent* for the patient in the journey to achieve and maintain wellness as well as to combat disease.

Summary

The human being is being digitized—from genome to capture of the activities of daily life with wearable sensors to characterization of mental status at any given time to continuous monitoring of metabolic processes with external or internal biosensors. From cradle to grave, we will each produce many terabytes of analyzable information, which, used correctly, will help us *predict* what our individual health future may have in store, will help us *prevent* many of the adversities that are predicted, will help *personalize* strategies and treatments to maintain or restore wellness, and will permit us to *participate* in our own health and, with data sharing, the health of humanity. We are on the cusp of P4 medicine.

But, we must not lose sight of the fact that healthcare delivery carries risk for both clinician and patient. Surgery is injury. Most medications have side effects, some potentially fatal. Provider acts of commission or omission, most often inadvertent, may engender harm. And, digital care interposes new risks that must be addressed in the design of the delivery platform, the policies that govern care delivered via the medium, and the operating procedures from data management to provider credentialing to practice standards and the like. Managing risk utilizing the product development principles of a quality system such as ISO 9000 is a necessary exercise, otherwise the shift to P4 medicine will be disrupted and delayed. With proper forethought, that need not be the case.

To realize the promise of a P4 future for medicine and healthcare in general, an integrated digital care platform—an ecosystem and operating system for digital health—must evolve rapidly with risk management in mind. Such a platform must be designed and engineered to embrace the entire P4 medicine paradigm, especially with respect to patient participation. Legacy EHRs are unsuited to serve as the foundational elements of integrated digital care due to their inherent design limitations. Instead, the digital care platform must integrate technologies, emerging applications, users (particularly, patients) and clinical care collaboration.

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[23] Toney, S. *Care Coaching, An Alternative Approach to Managing Comorbid Depression*. J. Prof. Case Mgmnt.15:3 May 2010

[24] *Ibid.* Footnote #3

If we are careful, if we solicit input from all stakeholders, if we adhere to the principles and process of medical care delivery, subordinating technology to those principles, then P4 medicine is an aspiration we can all embrace and, together, achieve.

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Glossary of Terms

AI (**A**rtificial **I**ntelligence)—the simulation of human intelligence by computer systems, characterized by the ability of computers and their software to quickly accomplish tasks usually requiring human intelligence such as data analysis, visual perception, speech recognition, and decision-making

Authentication—the process of confirming the identity of a person or device communicating or interacting with a system

Biometric—refers to measurements or characteristics of a human body. Biometric authentication refers to confirmation of identity using a unique aspect of the body, such as a fingerprint, voice print or iris scan.

Blockchain—in medicine, a ledger of healthcare transactions that are validated and immutable, available via the Internet, and subject to patient privacy and access controls

CMS (**C**enters for **M**edicare and Medicaid **S**ervices)—is an Agency of the federal government under the Department of Health & Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid

Comorbidity—the simultaneous presence of two or more chronic conditions in a single person

COPD (**C**hronic **O**bstructive **P**ulmonary **D**isease)—a medical term used to describe progressive lung diseases that cause difficulty in breathing, such as emphysema, chronic bronchitis and non-reversible asthma

DICOM (**D**igital **I**maging and **C**ommunications in **M**edicine)—a standard for handling, storing, printing and transmitting information for medical images

Digital care/digital health—the convergence of digital technologies that affect healthcare delivery including the engagement of individuals and society, measurement of individual conditions, storage, analysis and reporting of data, all intended to make medicine more efficient and precise

ECG (**E**lectro**c**ardio**g**ram)—a spatial recording of the electrical activity of the heart over a period of time, usually about 30 seconds

EHR/EMR (**E**lectronic **H**ealth **R**ecord/**E**lectronic **M**edical **R**ecord)—a digital version of a patient's healthcare and medical record, designed to make medical information available instantly and securely to authorized users

Genomic data—the information that characterizes the specific DNA sequence of an individual

HIPAA (**H**ealth **I**nsurance **P**ortability and **A**ccountability **A**ct of 1996)—a U.S. law that provides for the privacy, security and confidentiality of personal health data

HITECH Act (**H**ealth **I**nformation **T**echnology for **E**conomic and **C**linical **H**ealth Act of 2009)—a U.S. law that requires and provides monetary incentives to healthcare providers to adopt electronic health records and supporting technology

Hospice care—is comprehensive, supportive and collaborative end-of-life care without continued attempts to cure the terminal condition

Integrated digital care—is the use of digital technologies to facilitate a combination of patients and collaborating medical providers in a highly interactive form of medical and social care delivery and care reception designed to create measurably better outcomes

ISO 9000—a set of quality management systems standards from International Organization for Standardization that are designed to help organizations and companies ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to a product or service

IOT (**I**nternet **o**f **T**hings)—a network of Internet connected objects able to collect and exchange data. In digital care, a medical IOT "hub" can connect patients and devices to the digital care platform and can relay reminders and instructions to patients depending n input from the patients or their connected devices

IT (**I**nformation **T**echnology)—the study or use of systems (especially computers and telecommunications) for storing, retrieving, and sending information

Microbiomic data—information that characterizes all the microbes (bacteria and viruses) and the full collection of their genetic composition in a "community" such as the human body

NCQA (**N**ational **C**ommittee for **Q**uality **A**ssurance)—an independent, nonprofit organization in the United States that works to improve health care quality through the administration of evidence-based standards, measures, programs, and accreditation

NLP (**N**atural **L**anguage **P**rocessing)**—**a branch of artificial intelligence that helps computers understand, interpret and manipulate human language

Non-repudiation—a legal concept that is widely used in information security, which refers to any service that provides proof of the origin of the data and the integrity of the data, i.e., that the data, message or transaction was not forged or corrupted in any way

OS (**O**perating **S**ystem)—a software platform that manages computer hardware and software resources and provides common services for computer programs. An OS for digital medicine implies a platform that manages devices and software resources that contribute to the process of medical care delivery.

Outcome analytics—measurement, analysis and reporting of changes in the health of an individual, group of people, or population that are attributable to an intervention or series of interventions

P4 medicine—stands for Predictive, Preventive, Personalized and Participatory. It is the clinical face of systems medicine, which is an ongoing, data-driven journey to health involving all aspects of one's life, one's environment, one's mind and one's body.

PaaS (**P**latform **a**s **a** **S**ervice)—a cloud computing model in which a third-party provider delivers hardware and software tools—often those needed for delivery of a service—to users over the Internet. A PaaS provider hosts the hardware and software on its own infrastructure.

Palliative care—specialized medical care for people living with serious illness. This type of care is focused on relief from the symptoms and stress of the serious illness with a goal to improve quality of life for both the patient and the family.

PCP (**P**rimary **C**are **P**rovider)—a medical doctor (MD), nurse practitioner (NP) or physician's assistant (PA) who cares for patients using health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses in a variety of health care settings

Permission management— (i) access controls and what a user or group of users is allowed to see and do in a protected PaaS system; (ii) the creation and custody of a user's authorizations (permissions) for personal data disclosure and use, and for various types of informed consent, in a protected (medical) PaaS system

Predictive analytics—the use of data mining, statistics, modeling, machine learning, and artificial intelligence to analyze current and past patient data to make predictions about the patient's medical future

Proteomic data—the information concerning the entire set of proteins that is produced or modified by an organism or system

RPM (**R**emote **P**atient **M**onitoring)—the use of digital technologies to collect medical and other forms of health data from individuals in one location and electronically transmit that information securely to health care providers in a different location for assessment and recommendations

Semantic data—structured data that is represented in a specific logical way. The semantic data model includes information that adds a basic meaning to the data and the relationships that lie between them, allowing for easy development of application programs and easy maintenance of data consistency when data is updated.

Spirometry—a common test used to assess how well the lungs work by measuring how much air is inhaled, how much is exhaled and how quickly it is exhaled. Spirometry is used to diagnose asthma, chronic obstructive pulmonary disease (COPD) and other conditions that affect breathing.

Syntactic data—standardized packaging and transmission mechanisms for data that serves as a prerequisite for semantic data interoperability and analysis

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