Perspectives | 2021-04-16

The individual as the foundation of healthcare data (part 1)

Realizing the true promise of the information that flows across the healthcare and life sciences continuum requires a new understanding of data management, analytics and decision-making — which a holistic approach to device connectivity can deliver.

Device connectivity and access to data are changing every aspect of healthcare. The very way that treatments and therapies are developed and deployed depends on access to dramatically increased flows of information about the human body, via networks of increasingly capable sensors.

Sensors and instrumentation provide accurate and timely data about many parameters of the human body. The data captured by these connected devices enables an increased understanding of how diseases progress and how bodies respond to various interventions.

But these physiological metrics do not exist in isolation, any more than human beings do. They are affected by personal, social, environmental and behavioral factors — and each of these domains provides a new flow of health-relevant data.

Realizing the true promise of this vast flow of data, in all of its variety, requires a new understanding of data management, analytics and decision-making. This new world is different enough from the way healthcare has typically been delivered that even those who are deeply involved in it struggle to keep up.

To demonstrate how this data will transform healthcare, a series of four articles will trace how the data that comes from a specific individual is used in different ways by different parts of the healthcare system, and how improved healthcare knowledge and treatments return to benefit an individual's and a population's health.

This initial article looks at the individual as the source of healthcare data — and as its ultimate beneficiary.

The increase in chronic conditions

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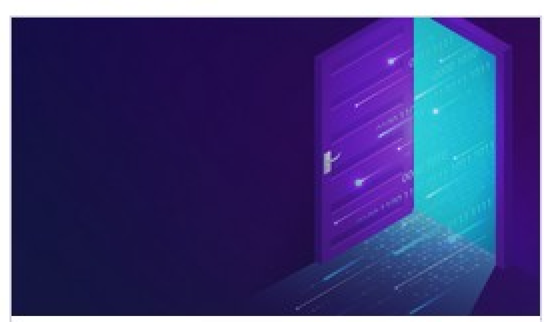

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Most care increasingly involves not discrete, acute episodes of care but chronic and long-term disease management. The prevalence of these chronic diseases is changing everything about how diseases are understood, treated and managed.

According to CDC, today, 40% to 45% of the American population has one or more chronic conditions, and 30 million people live with five or more chronic diseases. Americans with two or more chronic conditions are responsible for two-thirds of all healthcare expenditures. Further, it is estimated that by 2060 the number of people over 65 will more than double from today, to 98 million, likely increasing the burden of treating longer-term chronic disease.

Patients with chronic diseases continually generate information about their conditions, and this longitudinal data is essential to the coordination of their entire complex care teams. Chronic diseases often result in additional conditions, such as depression, a common comorbidity of chronic conditions, and an impediment to their effective treatment.

As a result of improved understanding of such correlations, information about the individual's behavioral health status has become increasingly important in treatment decisions, as has information about the individual's relationship to the people around them.

The importance of the social context

A large segment of the American population has trouble gaining access to healthcare and other forms of support. Understanding how social determinants of health (SDoH) affect health outcomes is essential to more effective healthcare delivery. Everything from access to a safe place to sleep to interpersonal relationships can play a role, and information about these aspects is another source of data.

For example, the risks of preterm birth are both physiological and socioeconomic. With certain populations, addressing only the purely medical need may result in poor outcomes. A program that uses machine learning to identify mothers at risk of preterm birth has significantly reduced the percentage of preterm births in the high-risk group.

The individual as the source and consumer of data

Over time, each individual, whether healthy or already in need of care, will throw off increasing amounts of data. Much of it will come from connected devices, some prescribed, plus the abundance of health and healthcare-related apps that provide consumers with greater insight into their personal condition.

For example, Apple Health™ and other fitness devices allow for monitoring fitness, while the VitaConnect™ Patch and Masimo SPO2 meter are among the many tools available for monitoring health conditions. These devices and others pair with an ever-growing set of apps for health, wellness and nutrition monitoring.

Over time, a baseline of an individual's physiological indicators such as their heart rate and blood pressure, as well as activity, diet and sleep patterns will develop. The consequences of any clinical encounter and resulting treatment can be viewed within the context of a particular individual's physiology.

Additional data from clinical encounters, including diagnostic imaging, lab tests, genomics, stress tests and physician notes, can be integrated with that baseline, increasing the ability to predict how this individual may respond to any particular treatment.

But even those massive flows of precise data are only part of a larger picture that includes information about emotional state, social surroundings, economic circumstances, work and physical environment. An understanding of context affects both diagnosis and treatment decisions, and will inform how treatment recommendations are presented, maximizing adherence to essential treatments that might have unpleasant side effects.

Individuals with chronic conditions will likely spend a good proportion of their life managing them. Connected devices and data will allow for a more continuous, participatory, predictive health system, improving quality of life for these patients. Additionally, likely long-term costs associated with care are expected to be reduced, or shift from highly expensive acute interventions to lower-cost, long duration engagements.

Building on the foundation

Using all pertinent and available flows of information to understand the individual and their health and healthcare needs is essential. Connected devices, consumer apps and the data they generate combine to provide unprecedented visibility into the decisions and actions that lead to health concerns and ultimately disease. Connected devices will enable a more inclusive, participatory, predictive health and healthcare approach. Yet smart devices are only the first step.

When it comes to data generated by connected devices, there is a lot more going on than a short summary like this one can include.

Perspectives | 2021-04-21

Connected wellness: Rehab and home health (part 2)

By instrumenting and adding intelligence to the health monitoring process, providers and individuals can better pred
ward off adverse events. Furthermore, they can move recovery from the hospital to better equipped outpatient facilit
more comfortable locales like the patient's living room.

Clinical treatment and recovery are moving out of the hospital to outpatient facilities and, particularly, the home. Increasingly sophisticated sensors, improved bandwidth, deep-learning algorithms and automated workflows are making it possible to recover from acute events and manage chronic conditions effectively in a familiar environment.

Delivered effectively, these digitally driven improvements will enable patients to manage their healthcare, and for clinicians to build stronger relationships with their patients. To succeed, healthcare ecosystem players will need to pay close attention to patient privacy and autonomy while meeting clinical and financial requirements.

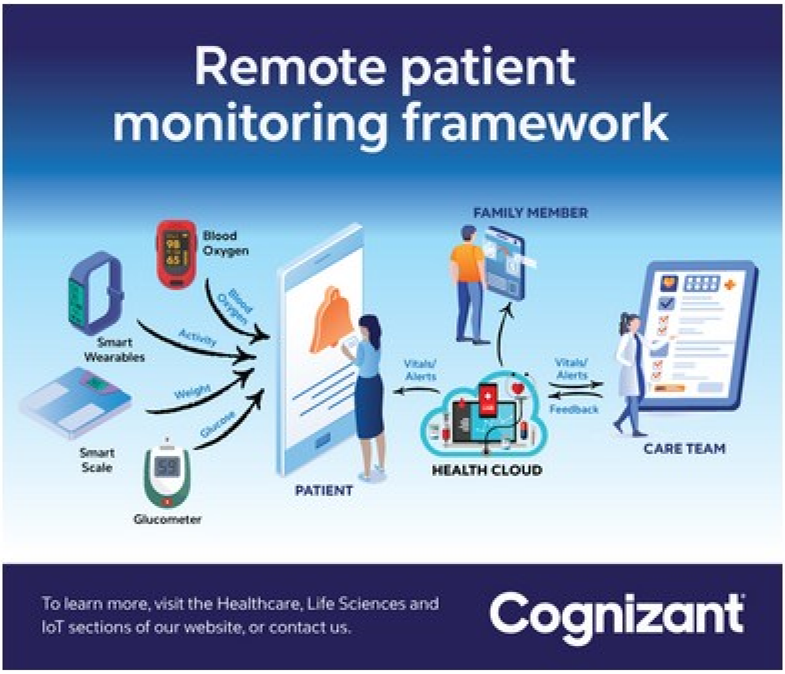
Home monitoring is already having a significant impact in applications such as postoperative care, managing chronic conditions and caring for the elderly. This installment of our connected wellness series examines the challenges and opportunities of these applications.

Postoperative care

A common need for biometric monitoring comes in postoperative care. Key vital signs may have been checked manually and infrequently by trained clinical staff simply because staff was not available for more extensive monitoring when needed. Even in the hospital ward, vital signs are checked based on staff coverage, patient loads and case severity, and infrequently after discharge.

This episodic monitoring within and outside the hospital can have major clinical and financial consequences. In some instances, complications such as infectious complications are usually preceded by early signs of hemodynamic compromise; early detection of relevant biometric signs could minimize complications and safely allow patients to return home.

Home monitoring enabled by biometric sensors that measure oxygen saturation (SpO2), heart rate, blood pressure, temperature and weight can play a large role in improving postoperative outcomes and preventing readmissions. More sophisticated sensors that detect early signs of sepsis and myocardial ischemia, which are strong predictors of 30-day postoperative mortality, are also in development.



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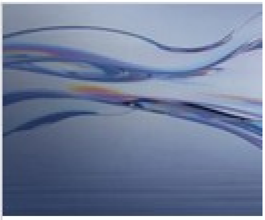

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Chronic conditions

Chronic diseases are lifelong ailments that can't be cured but only managed. Treatments can be complex and inconvenient — and may have significant side effects. Furthermore, poor self-management, particularly among new patients, can result in faster disease progression and preventable acute episodes. With continuous monitoring enabled by connected devices and an engaged and informed clinician, chronic diseases can be managed more effectively, often adding years of functional life.

Continuous biometric monitoring provides data that supports two key interventions. The first is to proactively identify patients who are likely to have trouble with adherence. The second is to customize effective interventions early on, before poor adherence becomes a long-term and intractable problem.

Predictive modeling based on known patterns of behavior, as indicated by both provider interactions and the data from connected devices, identifies patients who might require directed coaching from a specialist in disease-specific education.

Patient adherence to prescribed therapy may be low because of the lack of usable feedback on the effectiveness of health interventions for patients and clinicians. Integrating information from biometric sensors with physician analysis may provide patients with clearer, fresher insight on how treatment is affecting their condition. Patients can visualize what is improving — and what behaviors might make it worse. Self-management is easier when results can be tied to actions.

Aging

The ideal form of monitoring of elderly patients is constant and unobtrusive, not requiring deliberate self-testing on the part of the patient, and instantly detecting the first signs of developing conditions. The most effective signs of incipient health events are often not from implants or other biometric monitors, but from changes in activities of daily living (ADL), such as movement, toileting and sleep.

Passive infrared motion detectors, pressure sensors in beds and chairs, sensors for CO_2 concentration, sound (vibration) and video — anonymized as necessary for privacy — can all be used to first establish a baseline of normal variability, and then be applied to detect significant deviations from that baseline. This continuous and nearly invisible sensing can be surprisingly effective in assisting in care.

For example, the onset of congestive heart failure can be signaled by reduced use of the bed, as patients having trouble breathing at night switch to sleeping semi-upright in a recliner, while changes in toilet flushes can detect a urinary tract infection or incipient dehydration.

One in four Americans over 65 falls each year, but only half tell their doctor. Motion sensors can not only detect and alert caregivers immediately of a fall, but with proper algorithms they can also detect unsteadiness, changes in gait and balance and other issues early, enabling early intervention to prevent falls. Twenty percent of falls in the elderly result in a disruptive injury, often the first step to significant health decline.

Proactively sensing, diagnosing health problems

While sensors are becoming more pervasive, sensitive and precise, data analytics are extracting much more information from these signals, combining them, and enabling early detection of health problems.

Handheld, wearable, or patch ECGs detect arrhythmia, myocardial ischemia and some negative drug interactions. Increasingly, they can non-invasively and continuously determine blood pressure as well. Connected biometric devices in concert with deep learning are particularly useful in analyzing ECG data, which is complex and time-consuming to analyze properly, particularly if the intent is to detect signs of an approaching acute episode. Companies like Biotricity, with its beat and arrhythmia-detecting cellular IoT sensors, and Cardiolog, with its device-agnostic deep-learning ECG algorithms, are among the innovators in this area.

For orthopedics, the problem has been how to design smart joint implants containing sensors for pressure, force, strain, displacement and other parameters without compromising joint functionality. Smaller and more robust sensors are finally providing the ability to see into an implanted joint over time, providing invaluable data for early intervention before problems get serious and to individualize physical therapy regimens. Sensors and the data they collect are also assisting in developing future generations of improved joints and improved surgical techniques. Hip, knee and spine interventions will see significant evolution as a result.

According to the VA, the prevalence of Type 2 diabetes is more than twice as common among veterans than the national average, leading to a large rate of diabetic foot ulcers that can result in sepsis and limb loss. A veteran can step for 20 seconds on a foot mat from Podimetrics that measures foot temperature. The specific and longitudinal data is evaluated using an algorithm that can detect growing inflammation an average of five weeks before it evolves into an ulcer, enabling a proactive intervention.

Other examples include soft contact lenses containing strain gauges that measure intraocular pressure to manage glaucoma (SENSIMED Triggerfish), seizure-preventing electrical pulse generators (Neuropace), and closed-loop systems for diabetics that detect blood sugar levels to aid in self-management and support regulated doses of insulin (Medtronic SmartGuard).

Home health in an institutional context

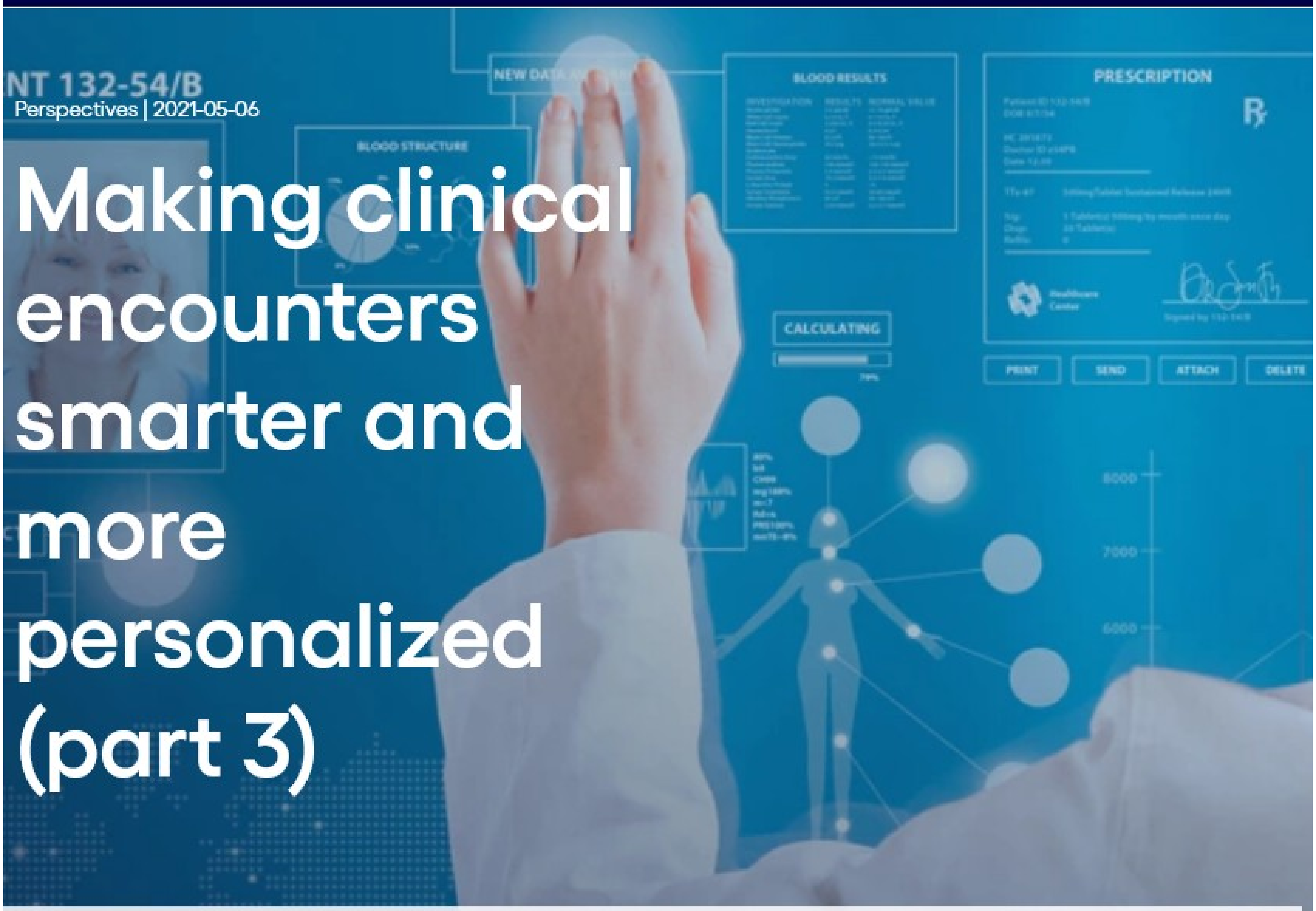
Evolving systems that optimally share risk and reward among the complex network of stakeholders, comprising the modern healthcare system, is as important to ensure the best therapeutic outcomes of home health as any blood pressure detector or insulin pump.

And the word "evolve" is deliberate. Such a system cannot be designed and imposed. But it can certainly be guided and nurtured. This evolution is further aided by the connectivity of biometric sensors generating continuous data that combines with computer intelligence and clinician insight to improve patient outcome on an ongoing basis.

Part 3 of this series examines ways to make sense of all the information that flows into the clinical encounter, including patient physiological data as well as the patient's health history, social context, genetics and individual treatment responses. Part 4 will assess how specific treatments will be created, starting from patient data, clinical trials and real-world evidence and progressing through the control systems of the

Perspectives | 2021-05-06

Making clinical encounters smarter and more personalized (part 3)



Instrumenting patient and provider interactions with connected devices that provide continuous data can result in better therapies, treatments and understanding, improving our collective wellbeing.

The clinician-patient encounter is the crucial interaction in care delivery. However, current clinical technologies, in the form of electronic health record (EHR) screens and claims processes can create friction between physicians and patients. The current clinical environment and supporting technology infrastructure is exposing physicians to stress and burnout, while patients feel like mere objects to be processed as quickly and efficiently as possible.

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The cure for bad technology can be better technology — if it focuses on the relationship between clinician and patient. While patients are generating increasing amounts of data, care teams can improve care and reclaim their patient relationships with the support of advanced technologies. Artificial intelligence (AI), intelligent information filtering and voice recognition all serve to make the trove of patient generated data intelligible and useful, leading to better patient outcomes. The race is on to better connect patients and providers with data that can elevate the wellbeing of us all.

While technology has overpromised in the past, the next generation of intelligent assistants is poised to remove the burden of administration from physicians. At the same time, these assistants are giving them increased power to find and apply available knowledge and, concurrently, help patients understand and manage their health.

Information management for the busy clinician

The healthcare industry generates 30% of the world's data volume, and its rate of growth will only increase. Methods for managing and integrating those data flows will need to dramatically improve.

Patient data is already contained in systems of record that include medical histories, lab results, clinical images and outcomes, as well as recorded health habits and shared personal circumstances. The addition of genomic and other data will enable the development and delivery of targeted treatments based on a patient's specific physiology and disease state.

Increasingly, data is generated from connected sensors, whether wearable, implanted, or in the patient's therapeutic equipment that generate real-time and real-world data. The clinician can have a contextual, longitudinal and real-time view of a patient's vital signs, including heart rate, blood pressure, blood sugar and sleep patterns.

Additional data from research and population data in the form of clinical practice guidelines, randomized clinical trials (RCTs), journal articles and real-world data (RWD) further enhance individualized understanding. However, the volume of data generated from patients and clinical activities can easily overwhelm the most dedicated clinician. Natural language processing (NLP) and other methods will extract essential clinical insights converting those insights into real-world evidence, which in turn enhances clinical decision-support tools powered by NLP and AI.

Understanding workflows

Information from connected sensors supports clinical workflows at every point. Sensors at the bedside and in the bed aid in identifying at-risk patients, by monitoring vital signs and detecting the early signs of an upcoming problem.

The need to enter encounter data into EHRs is a time-consuming workflow that clinicians desperately want to automate. The most workable solution to documenting exams as they occur, rather than requiring hours of later work, has been to rely on a human medical scribe — an expensive solution with limited scalability. Increasingly, though, voice-driven computerized virtual assistants, such as Dragon Ambient eXperience from Nuance Health and 3M™ M*Modal Fluency Direct are finally delivering scalable solutions for clinical environments.

Remote presence technologies, including telehealth, increase the range of possible clinical encounters and scale it suitably for the treatment regimen. Remote care demonstrated its value during the pandemic. Sometimes a longer in-person visit is necessary, but often the best solution is a quick video chat supported by data from sensors, or even a quick set of questions from an app and a clickthrough to a prescription.

Healthcare is increasingly a team enterprise — including not only physicians, nurses,

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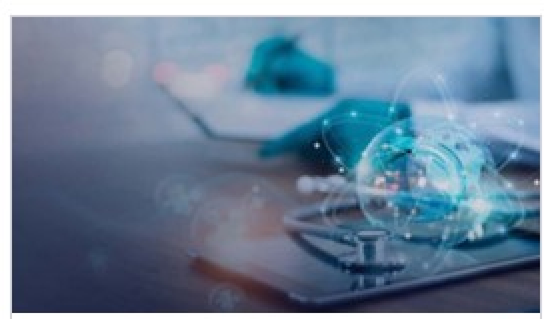

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allied health staff and technicians but also increasingly capable AI-enabled equipment. Connected sensors enable every member of the team to have access to real-time data relevant to their task. Well-functioning communication between clinical and consumer sensors along with data aggregation, security, compliance and analytics that facilitate team communication during crucial care handoffs can significantly improve outcomes. Communication errors, particularly during handoffs, [contribute to 50% to 80% of significant adverse events](#).

The most important member of the care team is the patient, who can be in charge of their own health outcomes. Progressively capable apps can guide patients through symptoms and issues, taking them step by step through self-checks that increase their understanding of their health status and enable the physician to focus directly on whatever issues are most important.

The smart hospital

When a patient has a more serious health problem and must be admitted to a hospital, the degree of care intensifies dramatically, as does the need for data gathering, exchange and analysis. A smart hospital with a [real-time health system](#) (RTHS) that leverages sensors collects data widely, distills and analyzes it — and then quickly distributes curated findings to users.

An RTHS improves operations, clinical tasks and patient experience. For example, providers that improve operational effectiveness typically rely on a wide range of IoT-enabled asset management solutions that locate mobile assets, monitor equipment operating condition, and track inventories of consumables, pharmaceuticals and medical devices. This improves equipment utilization, reduces waste, improves equipment uptime and ensures optimal inventories. The right equipment and supplies, based on patient needs and clinician preferences, will always be available when needed.

Once clinicians and support staff can view how long various steps take in their workflows, where delays occur, and what patients experience as a result, they can then evolve solutions based on a combination of their intimate day-to-day knowledge and data on how that workflow interacts with or is used by other functions.

A smart hospital ensures that patients are aware of who is on their care team, where they are and what is happening next to move them toward discharge — giving them a valuable sense of control in the often confusing and intimidating environment of a modern hospital.

The renewal of the physician-patient relationship

The changes to this relationship have happened mostly by accident, driven by institutional imperatives, including the need for measuring performance and outcomes, often impelled by reimbursement and regulation.

What happens to this relationship will now be more deliberately planned. As a result of the **21st Century Cures Act**, patients, who have been the passive partner in this relationship, are gaining new control over their healthcare data and will be expected to be more informed and active participants in their treatment. And physicians, with access to distilled and organized data, and able to rely on automated data and voice recording, can direct their full, informed attention on the complete human being before them.

Perspectives | 2021-06-02

Improving therapeutic effectiveness by tying treatment development to manufacturing (part 4)

Connectivity and sensors are transforming how clinical information supports the development, manufacture and application of new treatments that improve patient wellbeing.

Today's life sciences and healthcare continuum is fully enhanced by an ever more connected array of sensors and machines. In this setting, pharmaceuticals and medical devices are developed and manufactured in facilities that are fully monitored by sensors. Devices used by clinicians, researchers and patients alike are monitored by an increasing number of sensors. Medication adherence will also be further managed and monitored by sensors. In aggregate, the capture of data from patients provides real-world data of use, misuse and treatment response, on an individual basis.

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Data for treatment development

The randomized clinical trial (RCT) has been the gold standard for the efficacy of medical interventions. RCTs, however, face two main obstacles: recruitment and retention. Recruitment requires identifying patients who meet a set of specific criteria, which is difficult and time-consuming.

Between a quarter and two-thirds of trials fail to recruit their required number of participants. Access to larger pools of patient-generated health data (PGHD) — much of it derived from connected sensors and health and wellness apps — enables the identification and recruitment of suitable study candidates.

Once patients participate, data from wearables and other monitors provide closer contact with the study team, while reducing the need for the subject to travel to a research center for periodic evaluation, which improves retention.

Such monitoring also provides more precise information about adherence to the study protocol. Efficacy numbers can then reflect the actual use of a medication, as well as reveal the full impact of side effects or other obstacles to proper use, providing novel insights to effectiveness. Engaging patients in managing their own care in trials may also streamline future clinical development workflows.

Real-world data (RWD), gathered from regular monitoring of a wide range of patients over long periods of time, provides detailed information about how treatments work in daily life for more patient types than could be included in an RCT and, once analyzed, becomes real-world evidence (RWE) that enhances therapeutic effectiveness. RWE is also used to monitor post-market safety and adverse events for both biopharmaceuticals and medical devices, improving care decisions and therapeutic guidelines.

Precision medicine emerges

RCTs can fail to provide meaningful insight when some part of the population responds strongly to a treatment while others don't. RWE can help stratify patients into subpopulations that are more susceptible to a particular disease or have a specific treatment response. Additional data, such as genomics and other biomarkers, may help identify the mechanisms behind these responses. Combined, these expanding sets of clinical and ambient data allow for more specific targeting of patients for the appropriate trials.

Many diseases are increasingly seen as a complex of several diseases with similar symptoms, which can be divided up and defined by mechanistic pathway (endotype), specific clinical presentation (phenotype), and individual patient susceptibility (genotype).

This growing knowledge of diseases can enable a more precise balancing of interventional benefits and risks. For example, Herceptin is a breast cancer drug that is an effective treatment for women with too many Her2 protein receptors in their tumors, which are caused by an overexpression of the Her2/neu gene. Herceptin works less well for tumors without excess Her2 receptors, but for all patients it increases the risk of heart dysfunction. So, a test for the Her2/neu gene enables targeting this treatment for maximum benefit while minimizing exposure of some patients to unnecessary risk.

A more granular understanding of disease states leads to better-defined RCTs and more narrowly defined and targeted treatments. Such precise therapies will increasingly challenge manufacturing processes as they demand low-volume production runs of specialized therapies aimed at specific populations at the same time as overall capacity is kept high.

Even narrower are personalized therapies that use the patient's own cells as the basis for treatment. An example is autologous CAR-T cancer therapy, which extracts T cells from a patient's blood, genetically reengineers them to recognize and kill cancer cells, and then infuses those cells back into the patient. Currently, these processes can't be carried out in the same location and require a complex supply chain with strict

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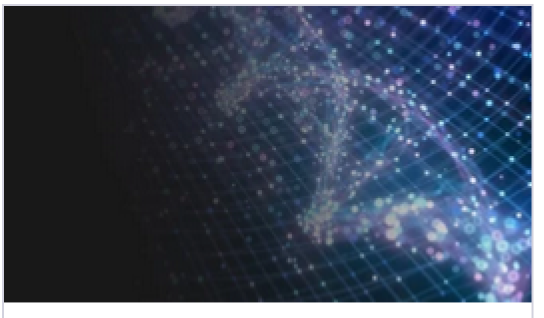

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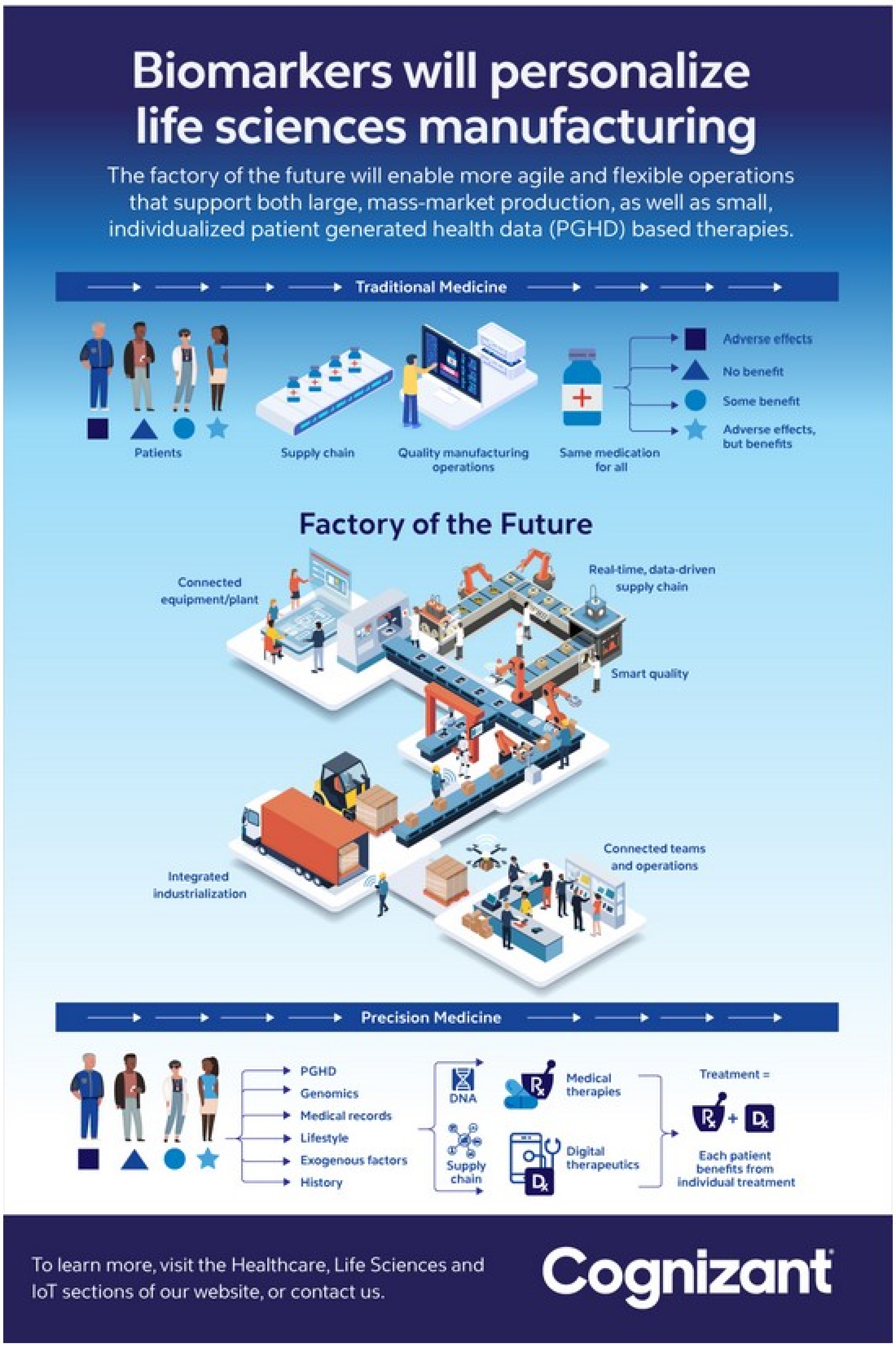

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Advanced drug manufacturing

Sensors and intelligent machines are also transforming biopharmaceutical manufacturing by providing visibility into the process rather than just the equipment. Connectivity to devices by industrial control systems has been around for a while but was difficult to modify and required the attention of a large, skilled staff. This new level of connectivity and automation makes it possible to improve manufacturing system efficiency, quality and reliability, increasing yield capacity and driving revenue.

For example, previously, measuring cell density in a bioreactor required taking a sample to quality control and waiting for the result before deciding to add more glucose substrate. A closed-loop control using a **Raman spectral probe** to continuously measure cell density enables the precise addition of glucose multiple times daily to maintain the optimum density and maximize yield.

Currently, there can be significant quality and yield variance from one facility to another and from one batch to another in the same facility. These variances stem from a number of factors including employee procedures, equipment maintenance, raw material quality, facility environment and other causes. Connected sensors that measure every parameter can finally provide a view into every process step and its downstream consequences.

For example, recording the exact time that a bioreactor is inoculated with a culture and then being able to tie that time to downstream results, combined with knowledge of all other varying inputs, provides a previously unavailable context and enables understanding of the root causes of variance in quality and yield. Those causes can then be addressed to minimize variance.

This real-time closed-loop control data has a positive effect on R&D as well, as information about manufacturing constraints affects initial pharmaceutical research and design. For example, mammalian cells are susceptible to shear. Various processes in a bioreactor, such as agitator ramp-up speed, gas sparging to provide oxygen, and foaming that leads to bubbles bursting, can all result in shear. These parameters of the manufacturing process, along with many others, need to be taken into account to design maximum productivity into a therapy from the beginning. This links drug development to the GMP manufacturing facility, and also generates the data that aids in regulatory compliance.

This real-time and contextual manufacturing data enables changes up and down the supply chain, optimizing end-to-end throughput, and meeting the increasing challenge of smaller batches required by precision medicine.

Back to the patient

As indicated in our **initial installment of this series**, the information flowing up from individuals finally returns to them in the form of more effective and easily used treatments, enabling patients to benefit from treatments that are effective, timely and personal. The interconnected world of sensors and machines is transforming all aspects of the healthcare and life sciences industry.