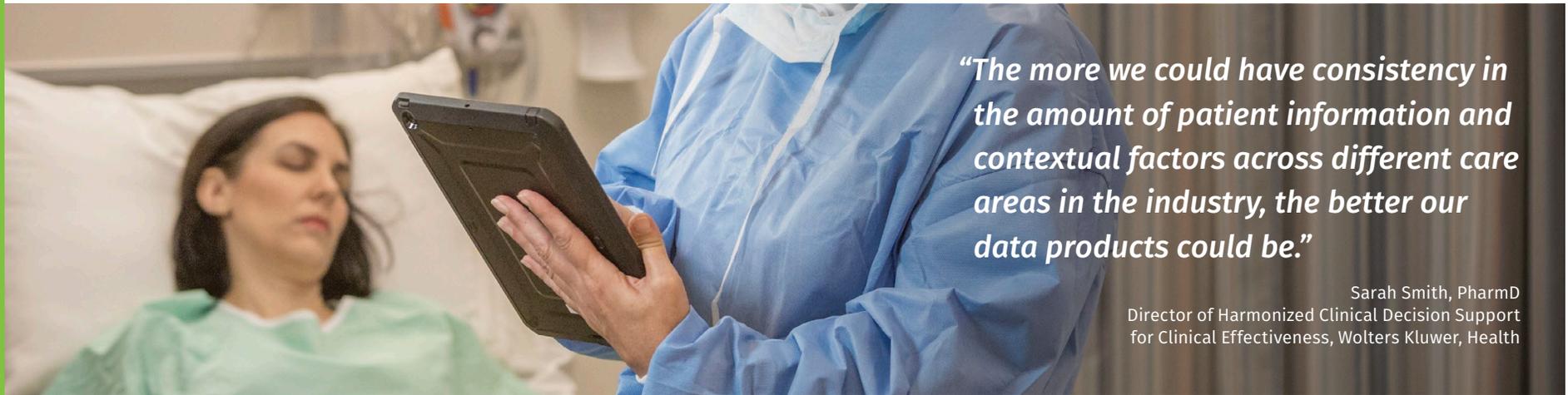


Health

Drug Data Unity:

Realistic and Idealistic Futures
for Information Exchange

Healthcare leaders have a responsibility to streamline, to innovate, but above all, to heal. It's a mandate that goes beyond the obvious – the healing of the body – to the resolution of conflicts, as industry leaders strive to build a better system for delivering care.



“The more we could have consistency in the amount of patient information and contextual factors across different care areas in the industry, the better our data products could be.”

Sarah Smith, PharmD
Director of Harmonized Clinical Decision Support
for Clinical Effectiveness, Wolters Kluwer, Health

For too long inconsistent or incompatible drug and patient data has led to business inefficiencies and harmful variances in care all over the world.

Today, information exchange is generally viewed as less than a smooth process. Despite organizations like [HL7](#) developing standards to help unify disparate pieces of machine-readable data into meaningful and usable information, for most, those data aren't being accessed and shared equally by all members of the healthcare ecosystem.

“One of the challenges we have is that we may have one (data) product, but it's not one-size-fits-all,” notes Sarah Smith, PharmD, Director of Harmonized Clinical Decision Support for Clinical Effectiveness at Wolters Kluwer, Health. Within the same industry and across industries that work with healthcare data, there are no agreed-upon blueprints, meaning each organization generally designs their solution setup and deals with their data differently. “The more we could have consistency in the amount of patient information and contextual factors across different care areas in the industry, the better our data products could be,” Smith says.

The practical vs. the impractical

Is it realistic to envision a healthcare landscape in which all players are fully interoperable, enabling consistent communication between various providers and coverage sources?

Short answer: Yes. And no.

Idealistically, we have, right now, the data and the capabilities to achieve this vision, informatics experts say. If every healthcare entity in a given region committed to adopting a set of standards for data sharing, including broadening what types of patient information is shared, and to implementing and developing a consistent interoperable technology, it could enable widespread data unity and information exchange.

Realistically, however, that doesn't happen.

In the United States, for example, where the government-sponsored HITECH act invested millions in helping hospitals and healthcare providers acquire and implement electronic health record (EHR) technology to collect and store patient data, very little of that investment has gone toward encouraging interoperability or developing unified data sharing standards, [effectively “stranding” that data.](#)¹

It seems impractical that every healthcare entity in a region would agree and consistently adhere to such standards. Additionally, they would need to be universally enforced, either by a government agency or standards body, and would require universal patient identifiers, a concept that, at least in the U.S., is often a political non-starter. Also, it would be challenging to get all healthcare providers and businesses to commit to the technological development work that would be required for such an enterprise.

The U.S. [Department of Health and Human Services'](#) Commission on Systemic Interoperability (CSI) wrote that our siloed healthcare landscape leads to “injury, wasted resources, and lost lives,” and that the barrier to connectivity “is not a lack of technology, but a lack of attention and a lack of will.”²

However, with even a little bit of attention and will, every step forward pays dividends in creating a stronger digital health infrastructure to help connect different departments, organizations, regions, and even countries, and turn data into meaningful information that can improve patient safety.



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of global hospital
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Patient safety and the data input gap

Medication errors can have a devastating impact on patients, leading not only to patient harm, but to high care costs and drains on staff resources:

- In England, more than 237 million medication errors are reported every year costing the NHS upwards of £98 million and resulting in more than 1,700 lives lost, according to a 2020 report³
- According to a 2019 report, the U.S. FDA receives more than 100,000 reports every year of medication errors⁴
- Ten percent of U.S. hospital patients are subject to a medication error, while U.S. community pharmacies have an estimated dispensing error in 1.5% of all prescriptions⁵
- Globally, the WHO estimates 6 to 7% of hospital admissions in some countries to be medication-related⁶

“Drug errors, it’s pretty clear, cost society a lot,” says Steven Hart, MD, a clinical informatics expert. “That includes the individual patients who might be harmed and maybe have a longer hospitalization or become permanently impaired or die. That’s a big deal to that patient, but it’s also a big deal to the insurance company that has to pay for the ramifications and to the hospital, potentially. That’s where it becomes a systemic issue. If you can reduce adverse drug events, the net benefit to society would be quite large financially.”

With the advent of electronic health systems and the increasing digital maturity in many developed healthcare ecosystems, professionals turn to clinical decision support (CDS) to help prevent medication errors.

In a hospital setting, healthcare professionals have access to a wealth of inputs from which to draw context for clinical drug safety screenings: lab data, current patient weight, problem lists, demographics, and more.

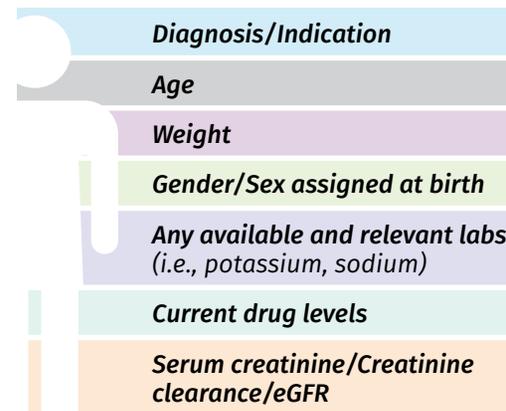
But then, that patient and their prescription leave the hospital and head out into the wide world of retail pharmacies, clinics, outpatient care, and insurance counseling services.

“The whole role of the pharmacist is to monitor drug therapy and make sure it’s right for the patient and then bring anything to the physician’s attention if it’s not,” Smith explains. “It’s that second level of thorough check.” But retail pharmacists and other providers outside the admitting hospital only have access to a small fraction of the demographic and diagnostic data that prescribers consult, she says. “In some ways, the community pharmacist these days is working in the dark.”

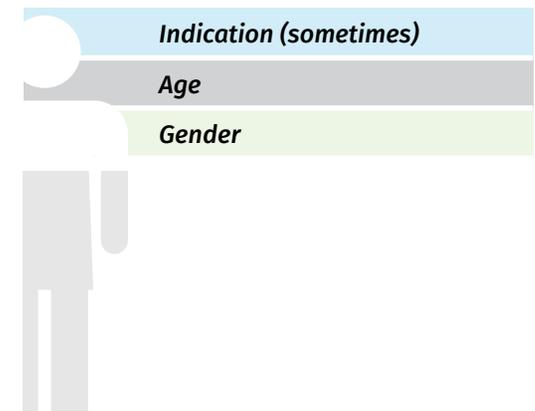
“The pharmacist, ideally, would have all the same information the physician has when making decisions,” Hart agrees.

In a model scenario, informatics experts say pharmacists both inside and outside of hospital settings should have access to the following data for every patient in order to screen for medication safety:

Model data inputs that would follow each patient are:



Actual data inputs that follow a prescription for dispensing are:



More complete sharing of information would lead to more precise drug safety screenings, and ultimately, fewer drug errors, Smith predicts. However, the financial value of implementing a substantial change to information sharing standards would be difficult to quantify, and Smith says it would be challenging to draw a straight line from cause to effect.

“It’s not straight-forward, black-and-white ROI (return on investment),” she says, and therefore would be a difficult case to pitch to decision makers in charge of standards, interoperability, and technology infrastructure. But, she believes, it would result in less predictable, indirect cost savings, such as fewer hospital readmissions or fewer lawsuits associated with negative outcomes related to drug prescribing errors.

When it comes to data, location matters

Your data sharing is often affected by your latitude. In Germany, for example, medical information sometimes cannot be shared even across different departments of the same hospital due to data protection regulations.⁷

The data gap Smith and Hart describe that exists between the inpatient provider and the outpatient provider is not a universal phenomenon. It is a common conundrum in the U.S., the Kingdom of Saudi Arabia, the United Arab Emirates, and other healthcare ecosystems in which organizations have the ability to purchase their own healthcare information system and patients have the choice of private insurers, either through their employers or out-of-pocket purchase. This economic choice, for all its arguable benefits, also creates data silos. Each system or business owns its own data, and patients and professionals must rely on government regulations or standards bodies to develop and enforce interoperability.

Those countries all have achieved a higher level of digital maturity. However, data silos also exist in some countries where healthcare infrastructure is lacking. Informatics experts describe similarly siloed situations in less developed regions where healthcare professionals have compensated for lack of resources by supplementing paper charting with homegrown EHRs of their own design.

The barriers to information sharing are lower in countries with national health systems, which strive to create equal access to care – and thus data – for all citizens. But nothing in healthcare is an absolute: Even when a national identification system for patients helps enable information sharing between a country’s provider organizations, there are still barriers to interoperability, including gaps in technology infrastructure and data quality in different regions and hospital locations.



The financial value of updated standards would be difficult to quantify, and it would be challenging to draw a straight line from cause to effect.

Improving how and what we share

Experts agree, the key to improved data sharing and interoperability lies in two areas of investment:

1. Standardized, sophisticated technology infrastructure
2. Quality data delivered in sharable format

The worldwide push to adopt EHR technology over the last two decades represented a first step in the global digitization of healthcare. Although disparate systems cannot always share information smoothly and different regions operate at vastly different levels of technological maturity, we now have a global consensus toward electronic records and information sharing. Newer technologies like [SMART on FHIR](#) help further streamline app development and enhance decision support with [CDS Hooks](#).

Except in cases where a platform or type of data is mandated nationwide by a ministry of health, there will always be a mix of choices from hospital to pharmacy and beyond. Interoperability and data sharing will depend on standards, quality, and our willingness to adhere to them.

When it comes to setting standards for information exchange, generally, whichever body steps up to propose a standard becomes the standard bearer, Hart explains, even if that standard is ambiguous or less well-defined than the industry may have hoped. Once a standard has been set and starts to become implemented, it is complex and costly to change it, Smith adds. The investment of time and money to undo or redo an established health data vocabulary or standard identifier that is implemented and entrenched throughout a major health system, retail chain, benefits provider, or national health organization's information system – let alone thousands of such entities – would be substantial, and in some cases daunting enough to discourage the endeavor.

Future-proof

To be as prepared as possible, Smith suggests investing in a data system that is “future-proof,” or able to map to variety of standard concepts and identifiers so as to adapt to unexpected industry demands. By contrast, Hart notes that many data systems designed with finite digit structures have been caught unprepared when they arrived at the unforeseen moment when they would soon run out of possible digit combinations.

American healthcare organizations are facing just such an issue with the FDA's identifier, the National Drug Code, or NDC, which is anticipated to run out of potential 10-digit combinations within the next decade, requiring a switch to 11 or 12 digits. Another example would be the first time a drug was ever priced at \$1 million – data systems unequipped to handle the extra digit place in their pricing fields needed to quickly adapt.

Identifiers and concepts

Interoperability and data sharing require your system to map information to a variety of essential and useful standards, depending upon your use case and location. These include:

- Drug concepts
- Allergen concepts
- Immunization codes
- Additional concepts for e-prescribing certification
- Disease and conditions concepts
- Additional concepts for procedures and therapies



Economic choice in healthcare, for all its arguable benefits, also creates data silos.

In regions where there isn't a national health system, informaticists continue to raise the somewhat controversial issue of a standard medical record identification system – in other words, a patient ID which would be used to access a universal medical record for that individual regardless of where or by whom they were treated within their country of residence.

The argument in favor of a standard medical ID, explains Bonnie Briggs, RPh, Associate Director at Clinical Effectiveness, Wolters Kluwer, Health, is that in countries like the U.S., “patient medical record information is scattered in different physician offices, their dentist, their pharmacy, and their weight or medication lists may not be consistent at all because they were recorded at different times.” With the issuance of a national patient identification system to support real-time exchange of information across systems, Briggs argues that all of that individual's providers would have access to more accurate information and more context to inform decision making.

Yet, she also notes, it is an idea that fails repeatedly to take hold with policy makers due to concerns over data security (would a central patient database be vulnerable to hacking?) and objections based in policy and politics that may be unlikely for some regions to overcome.

With similar, but still disparate technologies and identifiers the reality for most healthcare professionals, the best way to ensure smart and smooth exchange is to arm organizations with high quality data that not only serves their immediate goals but aligns them with the demands of their partners in communication – whether they be direct care providers

and health systems, retail pharmacies, labs, health benefits businesses, or research organizations. If drug data is flexible and robust enough to be trusted by partners throughout the industry, it enhances the efficiency and effectiveness of transfer of information and reduces the likelihood of data confusion.



Approximately one-third of drugs screened by retail pharmacies can be affected by renal function.

Steven Hart, MD, clinical informatics expert

With the script

Additionally, in order to ramp up drug safety and harmonize drug decision making between the various parties that handle a prescription along the journey from diagnosis, to dispensing, to administration and claims processing, there are essential data that informatics experts recommend be included in a patient profile. These data may not currently be standard information transfer with a prescription, but pharmacy experts recommend them as the safety data healthcare organizations, data vendors, and CDS systems should be equipped to process for ideal medication safety review.

Patient age and weight

While age is “fairly reliably transmitted” with prescriptions, due to it being necessary for claims processing, Smith says, “weight is hit or miss.” As patient weight can alter standard dosing recommendations, it is a seemingly simple but necessary input that can be troublingly absent from pharmacist safety screenings.

Renal function measurement

Renal values, such as creatinine clearance and estimated glomerular filtration rate (eGFR), are key inputs to effectively screen for safe dosing and are often missing from patient profiles outside of hospital settings. Hart estimates that approximately one-third of drugs screened by retail pharmacies can be affected by renal function, but without those values, the pharmacists simply forego that portion of the safety check. Even if it isn't an available or shared input in all settings, being prepared for kidney function and renal dosing data is drug safety best practice.

Indication/Diagnosis

Patient diagnosis is an important contextual factor in evaluating appropriateness of a drug, as well as the appropriate dose of a drug. Diagnosis or indication for use of a drug can also be used for medication therapy management and population health studies.

Problem list/Comorbid conditions

Beyond the indication, with each prescription, pharmacists benefit from an understanding of a patient's constellation of conditions and treatments to make a fully informed assessment of how a drug will affect them and of its efficacy, says Hart.



The future of data can start right now

Data unity may still, in many ways, be an ideal, but our reality is a more interoperable, interactive healthcare information technology landscape than we had even a decade ago.

“I personally see this problem as an opportunity,” says Hart. Instead of looking at health information exchanges and only seeing the gaps where information isn't being shared, he advises that the healthcare industry and innovators instead ask themselves, “can we provide a product or a mechanism where we can pull that information into the system, and all of a sudden, you can provide better results.”

¹ <https://www.statnews.com/2020/11/18/interoperability-untapped-tool-fight-against-covid-19/>

² <https://endingthedocumentgame.gov/report.html>

³ <https://qualitysafety.bmj.com/content/30/2/96>

⁴ <https://www.fda.gov/drugs/information-consumers-and-patients-drugs/working-reduce-medication-errors>

⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6173242/>

⁶ <http://www.who.int/mediacentre/news/releases/2017/medication-related-errors/en/>

⁷ <https://www.nature.com/articles/s41746-019-0158-1>