Opportunities and challenges related to technology in supporting optimal pharmacy practice models in hospitals and health systems

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The use of technology and automation to support pharmacy practice dates back to the 1970s and has frequently been implicated as both the problem and solution for optimizing the role of the pharmacist in providing direct patient care. The increasing demand for accuracy, safety, and efficiency in medication use by regulatory authorities, manufacturers, health care professionals, and consumers has resulted in significant growth in the health information technology (HIT) market. This article examines the current state of core medication-management-supporting technologies within the context of the Institute of Medicine (IOM) and the Department of Health and Human Services (DHHS). It discusses the challenges and barriers for delivering integrated and interoperable solutions, how the technologies have performed in relation to their quality and safety claims, and, more importantly, what health-system pharmacy leaders can do to overcome current HIT challenges while optimizing the role of the pharmacist. It also identifies future technologies and trends that may affect health care delivery and provide opportunities for alternative pharmacy practice models, roles, and responsibilities. Finally, the article describes the gaps in relation to current skills and technologies and those required to reach the IOM and DHHS vision for HIT.

In 1999, the IOM report To Err is Human: Building a Safer Health System acknowledged that medication errors represented the largest single cause of medical errors in the hospital, accounting for more than 7000 deaths annually. The report made reference to several emerging technologies and systems that may be used to effectively reduce medical errors, particularly in hospital settings.

In 2001, the IOM report Crossing the Quality Chasm: A New Health System for the 21st Century was more emphatic about the use of HIT in the redesign of health care systems. The report called for automation of patient-specific clinical information within the context of an electronic health record (EHR) and integrated with computerized prescriber-order-entry (CPOE) systems, drug distribution, and medication administration systems. These systems would ideally work together (within and across organizational boundaries),...
share real-time patient information, and provide timely relevant clinical decision support at the point of care. The human as well as financial cost of medication errors and recommended solutions for improvement prompted the health care industry, large health care purchasers, and state and federal governments to promote the implementation of HIT solutions to minimize medication-related errors.

In 2003, the federal government responded to the IOM reports by adopting technical communication standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement, and Modernization Act.6,5 This provided the needed infrastructure to connect community pharmacies and insurers with health-system providers. One year later, President George W. Bush signed an executive order launching the Health Information Technology Adoption Initiative that included a 10-year plan for an interoperable health information exchange infrastructure. 6,7 The initiative provided important groundwork for developing a HIT-enabled medication-use process but more importantly heightened the awareness that HIT is vital for delivering more-cost-effective and higher-quality health care. Unfortunately, these efforts have been primarily strategic, advocacy focused, and foundational and lack the “teeth” needed to accelerate adoption. A number of professionals within the HIT community warned the federal government that a more-aggressive approach may be required to accelerate rates of adoption.7,8

In 2009, as part of the American Recovery and Reinvestment Act, Congress took a more assertive approach to advance the HIT initiative by introducing The Health Information Technology for Economic and Clinical Health (HITECH) Act.9 This legislation commits a number of resources (including Medicare subsidies for those using HIT) and requires providers who wish to participate in Medicare to obtain HIT by a specified date or pay a penalty. To be eligible for these payments that span over 10 years, hospitals and physicians are required to demonstrate meaningful use of HIT, exchange electronic health information to improve the quality of care, and report on key quality measures. The “meaningful use” rule is a significant compromise between understanding the necessity of adopting EHR technology and the challenges it creates for all health care providers.10 DHHS recently published its final rule for the first 2 years of the multiyear incentive after widespread opportunities for public and professional comment.11

The pervasive development and use of medication-management-supporting systems within the framework of an integrated EHR is inevitable. The recommendations of the IOM reports and the federal government’s financial commitment through the HITECH Act are important signals to health care organizations to continue the advancement of HIT.12 However, attaining the critical mass needed to effectively advance HIT beyond its current state will remain challenging.1,7,13,14 Reaching even higher ground with emerging and more-innovative solutions will also prove to be difficult.

**Current state of medication-use-supporting technologies**

The current state of core medication-use-supporting technologies is best understood by reviewing HIT adoption and integration efforts within the framework of an EHR. The core medication-management-supporting systems representing the essential HIT infrastructure the IOM envisioned include:

- CPOE and clinical decision-support systems,
- Pharmacy systems,
- Medication reconciliation systems, and
- Medication administration systems.1-3

The overall deployment of CPOE and clinical decision-support systems in U.S. hospitals after nearly 10 years of effort is roughly 15%, with greater penetration occurring in hospitals with more than 200 beds, according to 2007 and 2009 ASHP surveys.15,16 A more-recent 2010 report found similar results, with only 14% of hospitals achieving the expected stage one meaningful use requirements; in community hospitals with fewer than 200 beds, the figure was less than 12%.17

The adoption of CPOE or e-prescribing systems in ambulatory care is considerably greater than what has been reported in hospitals, according to a Surescripts 2009 National Progress Report on e-prescribing.18 Superscripts, which operates the nation’s largest pharmacy health information exchange network, reported that one in four office-based physicians is using e-prescribing systems, nearly 70% of whom use an e-prescribing application within their EHR. The report also projected a steeper rate of growth over the past three years.
for CPOE adoption in ambulatory care as compared with the inpatient environment.

Purely electronic and integrated medication reconciliation systems are virtually absent from health care organizations today, with only 10.4% of hospitals reporting an entirely electronic process for medication reconciliation.\(^{15}\) Most facilities are still reengineering their manual processes in response to The Joint Commission’s National Patient Safety Goals and have yet to consider what the ideal functional requirements might be for a multidisciplinary integrated HIT solution.

A 2007 ASHP survey found that nearly all hospitals had implemented a pharmacy information management system; however, only half of them had systems that could interoperate within the framework of an EHR and other core medication-use systems, a clear indication that pharmacy system integration is still a work in progress.\(^{15}\) The remaining half of hospitals still utilized legacy pharmacy systems that were limited in their ability to connect or integrate with ordering and medication reconciliation systems, creating standalone medication management solutions where continuity and communication play an important role in improving medication safety. The majority of hospitals in 2007 had adopted medication distribution and storage technologies (83%) as well as repackaging automation (92%) for unit dose medications.\(^{15}\)

Despite significant progress with implementing medication administration systems, including electronic medication administration records, bar-code-assisted medication administration technology, and smart pumps, the integration of these technologies remains low, with only 20% of hospitals having all three systems in place.\(^{15}\) Integration of medication administration systems with core medication management technologies including the EHR is limited.

Data on overall EHR usage in U.S. hospitals has suggested levels of adoption ranging from 5% to 60% depending on the definition of EHR.\(^{17}\) A study commissioned by the ONC for Health Information Technology found that 8–12% of U.S. hospitals have a basic EHR and only 2% have a system that meets the federal government’s meaningful use criteria.\(^{19}\) Larger hospitals, urban hospitals, and teaching hospitals were more likely to have electronic records systems.

**Current barriers and challenges**

Despite the theoretical and demonstrated benefits of HIT, the pace of adoption remains slow. The number of real and perceived barriers for HIT adoption has become virtually insurmountable. Without any significant regulatory or financial motivation, many hospitals and health systems have chosen to wait before crossing the HIT chasm. The most significant challenges include:

- **Financial,**
- **Work force,**
- **Strategic,**
- **Cultural,**
- **Structural,**
- **Technical, and**
- **Privacy and security issues.**\(^{7,8,13,14}\)

**Financial challenges.** The cost of implementing HIT systems varies widely among physicians and hospitals, depending on the size and complexity of the operation, replacement costs, and the extent to which the organization chooses to perform its work electronically. Although a few studies have examined the cost of implementing EHRs and CPOE systems, the wide variation in practice and use and the lack of data on costs limit the value of these studies. A 2005 study, for example, estimated the costs of implementing CPOE systems at nearly $63,000 per bed—almost four times higher than that reported in previous studies.\(^{8}\)

The financial liabilities of HIT far exceed the fixed costs of the hardware and software. The resources required to implement systems and subsequently maintain them necessitate a significant long-term financial investment. The time required of hospital staff for training, temporary reductions in productivity while providers adapt to changes in workflows, and the impact on competing initiatives are significant opportunity costs. The inability of health care providers to capture immediate financial returns from their information technology (IT) investments and the costs associated with state and federal privacy and security requirements continue to constrain the widespread adoption of HIT.\(^{5,20}\)

**Work-force challenges.** The insufficient supply of HIT professionals who have education and training that intersects health care, computer science, and informatics has created a significant challenge for health care organizations attempting to implement integrated HIT systems. A multidisciplinary clinical informatics work force is necessary to guide integrated EHR projects and develop a comprehensive HIT-related research agenda. However, the number of training and educational programs has lagged behind demand, leaving many organizations to utilize traditional IT professionals who do not have the needed skills to effectively manage clinical information and lead technical design efforts that produce a high degree of usability.\(^{21,22}\)

**Strategic challenges.** A significant challenge often overlooked by organizations planning to implement medication management technologies is the lack of an overall vision for what an ideal technology-enabled medication-use process might look like. Health care organizations have traditionally considered their business as a group of independent departments rather than a tightly connected process for health care delivery.\(^{23,24}\) This mindset has led to fragmented
Technology solutions focused on departmental gains. Hospitals are frequently challenged with delivering quick technical solutions in response to a serious patient safety event or regulatory requirement and fail to consider the impact of their decisions on future connectivity efforts. These single-threaded departmental HIT solutions often prove to be significant barriers when trying to move toward the preferred future state.23, 24

**Cultural challenges.** Cultural challenges are often a significant barrier when implementing integrated HIT solutions. Health care professionals have traditionally practiced within their functional silos, largely due to the development of “best-of-breed” departmental systems tailored to support specific roles and responsibilities. Implementation of an integrated medication management system is a major cultural event. It requires committed leaders, an environment for innovation, and, more important, a willingness to forgo perfection in pursuing modest incremental improvements.13 The integration of HIT into existing clinical workflows has proven far more difficult and disruptive than expected.13

**Structural challenges.** Even if a health care organization was able to overcome the financial, resource, and cultural challenges and had a clear strategic plan and vision for HIT, it would more than likely fail to overcome the structural needs for system and data interoperability. Most of an organization’s data, whether recorded on paper or electronically, are secluded in departmental systems. The IOM reports mentioned earlier maintained that health information exchange or the “anytime-anywhere” access to clinical information across traditional business boundaries is essential for advancing the HIT initiative.1-3 In order for HIT systems to exchange and use health data reliably and efficiently, a number of technical and clinical semantic standards and code sets must be developed, evaluated, tested, adopted, and used, either as a result of regulation or through market forces.7 These standards are required to ensure systemic interoperability, a significant barrier for health care organizations attempting to share health care data through health information exchanges or by other means. Despite the creation of the Healthcare Information Technology Standards Panel, the process for obtaining and implementing interoperating standards has been painfully slow and still remains a significant challenge today.7

**Technical challenges.** Current HIT applications have been designed primarily to automate recurring, similar tasks, or business processes in ways that mimic existing paper processes and offer little support for the cognitive tasks of clinicians or the workflows of those using them.24 Today’s technology forces users to sort through copious transactional data among which are buried the clinically relevant information or knowledge that they are seeking. Existing HIT rarely takes advantage of human–computer interaction principles, resulting in poor application design and greater pushback from the end users.24 Current HIT architectures lack the “plug-and-play” capabilities needed to efficiently accommodate change in roles and processes or to introduce new technologies. They have been developed in isolation and are not effectively harmonized with coexisting systems, which introduces new types of errors and different safety concerns. Overcoming the operational integration problems created from current automated HIT systems remains a significant challenge.24

**Privacy and security concerns.** Concerns related to privacy and security are an additional impediment to the adoption of EHRs. The federal Health Insurance Portability and Accountability Act (HIPAA) standards were put in place to address patient confidentiality concerns.25 However, HIPPA legislation allowed more rigorous state laws to preempt the federal standards. The often conflicting interpretations of state and federal privacy policies have significantly hindered the flow of personal health information, making it difficult to gain access to data across the continuum of care. Until state and federal privacy issues are resolved, it will remain challenging to move toward the IOM’s vision for 21st century health care.7

**Current state of HIT quality and safety claims**

The IOM and HIT Adoption Initiative recommended applications of technology that required the use of all facets of HIT, including automation, connectivity, decision support, data mining, and analytics.24 The significant number of HIT challenges and the continuing concern about the incidence of adverse drug events has driven most health care organizations to make modest HIT investments that involve only automation. They have focused on automating specific tasks of the medication-use process rather than committing to significant investments in first-generation, multifunctional, interoperating HIT systems.24 Although a number of published studies have found benefits with CPOE, clinical decision support systems, bar-code-assisted medication administration and dispensing systems, and smart pumps,26-35 the deployment of nonintegrated automated solutions has contributed to unintended consequences, including changes in communication patterns, new and different kinds of errors, overdependence on technologies, more and new work for physicians, and complex workflows (particularly at patient care interfaces).36 The mixed safety performances from a number of automation initiatives, including CPOE, emphasize the importance of investing in medication-
use-supporting technologies that enable connectivity across the medication-use process and provide real-time clinical decision-support capabilities as described by the IOM reports.\textsuperscript{1,3,24,37} Health care organizations making more-significant HIT investments, primarily through improved connectivity and clinical decision support, have been able to garner more-encouraging improvements in quality and safety.\textsuperscript{24,30-32} However, these technologies have been built primarily around tightly integrated, all-encompassing systems that have been successful in solving current problems but lack the needed flexibility to reach the preferred future state.\textsuperscript{24}

**Summary of the current context for HIT**

The HIT chasm confronting health care organizations today is comparable in size and scope to the quality chasm described by IOM 10 years ago.\textsuperscript{3} Despite a number of successful quality initiatives, the overall improvements in health care outcomes have missed the mark. Environmental scans of HIT initiatives today, including medication management systems, have revealed similar marks for improvements.\textsuperscript{12-14} Although some automated solutions have produced incremental advancements, the results have fallen short of expectations, unable to deliver what is needed to achieve the vision of 21st century health care.\textsuperscript{7,8,12-14,36,37} This has created a great sense of urgency among all health care leaders and the government to move the HIT initiative beyond discussions of potential benefits, conceptual framework, and infrastructure requirements.\textsuperscript{7,8,24}

**Overcoming HIT challenges**

The dramatic infusion of HIT funding and the government’s shift from persuasion and encouragement to regulation (including financial incentives and penalties) are clear indications that HIT is no longer optional for improving the quality of health care. This realization has profound implications for pharmacy practice leaders, who should not allow themselves to be deceived by the slow rate of adoption and the poor performance of current HIT solutions.

To avoid diminished opportunities for ongoing innovation, we believe that pharmacy practice leaders—individually and collectively—should adopt a set of attitudes and pursue a set of actions along the following lines:

1. Recognize that HIT will have a major impact on pharmacy practice.
2. Accept that current and emerging technologies could supplant roles traditionally performed by pharmacists.
3. Resist waiting for the perfect solutions to become available before pursuing any HIT applications.
4. Continue to seek HIT solutions that yield incremental gains and ensure that those gains are aligned with institutional goals and ideal HIT strategic objectives.
5. Articulate an ideal vision and strategy for an IT-enabled medication-use process.
6. Influence regulatory groups, HIT vendors, and health-system leaders to pursue sound methods for achieving optimal HIT approaches to medication management systems.
7. Work collaboratively with community and health-system pharmacy leaders to achieve a higher level of medication-system connectivity and integration by advocating for technical and semantic medication standards that support system interoperability.
8. Build and strengthen relationships with internal and external stakeholders that influence HIT development.
9. Pursue leadership positions within the HIT industry.
10. Advocate for new professional roles for pharmacists in informatics and clinical analytics.

**The preferred future state of pharmacy information technology**

Any discussion of the future state of technology is somewhat perilous, recognizing that the truly transforming technologies of the past have not necessarily been known about in advance. Such discussion must also recognize that these technologies are not ends in themselves but are tools to facilitate achievement of a new practice model. As a result, the most productive way to discuss these technologies is to focus on the roles they will support and the features those technologies will require to support those roles. The following discussion is informed primarily by the vision statement on technology-enabled practice issued by the ASHP Section on Pharmacy Informatics and Technology (Table 1).\textsuperscript{38}

### Supporting pharmacists as clinical medication managers

Presuming that the intended practice model places pharmacists in the role of primary medication therapy managers with oversight (but not hands-on control) of the medication distribution system, it is clear that technologies will be required to gather, organize, and present both clinical and operational information in meaningful ways. This implies the following requirements:

1. Patient information is contained in a single, addressable, longitudinal EHR with a standardized format that can be electronically scanned for situations that require the pharmacist's attention.
2. Terminology and key metrics are standardized to permit interoperability of data between systems.
3. Operational systems are derived from clinical systems and are constructed in a way that drives behavior around clinical care, not around products. Drug distribution should be derived from clinical care as opposed to the situation with current systems that tack clinical issues onto what is fundamentally a product-need forecasting system.
### Table 1.
**Preferred Future State of Pharmacy Information Technology: Gap Analysis**

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<tr>
<th>Future State</th>
<th>Current State</th>
<th>Gap Analysis</th>
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<tr>
<td><strong>Clinical Medication Management</strong></td>
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<tr>
<td>Patient information is contained in a single, addressable longitudinal EHR with a format that can be electronically scanned for actionable situations.</td>
<td>Current EHR deployment is relatively small (less than 20% of institutions) and there are no standards by which the data within those EHR products are represented. Development and standardization of tools that survey them is therefore difficult.</td>
<td>A standardized, best-practice EHR (or at least a view) needs to be developed to permit appropriate implementations of decision support and analysis tools.</td>
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<td><strong>Terminology and key metrics</strong></td>
<td>Systems are highly proprietary, as are the tools that provide analysis.</td>
<td>Standards for data representation are needed to permit standardized tools to provide decision support.</td>
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<td><strong>Operational systems are derived from clinical systems and are constructed in such a way as to drive behavior around clinical care, and not around products.</strong></td>
<td>Pharmacy systems are product-driven with data architectures that are better oriented to product distribution than clinical management.</td>
<td>Clinically oriented systems are needed that can also derive the information necessary to drive drug product selection, preparation and distribution.</td>
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<td>Decision-support systems are present that can maintain appropriate context and apply the correct actions to the right person at the right time in the right context.</td>
<td>Current decision support systems are almost exclusively limited to alerts at order entry and operate independent of clinical context. These systems require considerable maintenance and customization at each site.</td>
<td>A richer data set based on best practices that can use clinical information as context to refine systems is needed, as is CDSSs that are more than order-entry alerts. Some standards that permit sharing and creation of best practices are needed to enable more-rapid deployment and more appropriate use.</td>
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<td>Provides on-line access to standard references as well as known literature.</td>
<td>While these databases are available, few systems currently take advantage of them and, when they do, they primarily provide on-line representations of published references.</td>
<td>Databases that incorporate contextually relevant links to reference literature are needed so that contextually relevant information can be accessed.</td>
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<td>Permits oversight of the medication distribution system.</td>
<td>Current operational systems have little audit trailing and virtually no clinical context with which to evaluate the medication use process.</td>
<td>Operational systems need to be able to trace medication use processes both through the pharmacy distribution process and the clinical medication use process.</td>
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<td><strong>Management of Medication Preparation and Distribution</strong></td>
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<td>Medication products are marked with a machine-readable code that reliably identifies medication products in terms of their clinically-relevant contents.</td>
<td>Pharmacies currently spend considerable manpower and time maintaining a current list of bar codes/NDCs so that automated systems can identify the products.</td>
<td>Central, reliable database of known codes that systems can query is needed. Database needs to support identification down to the therapeutic entities and amounts in products.</td>
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<td>Medication products are packaged in containers that are “automation-friendly” to permit the application of robotics to the selection, preparation and distribution of medication products.</td>
<td>Pharmacies currently spend considerable time and effort packaging doses for machine manipulation. Robotics for i.v.’s have speed issues directly related to the nature of current i.v. containers.</td>
<td>Containers that are easily manipulated by robotics, with labeling that is easily and reliably read, are needed. Containers need to facilitate speedy robotic manipulation.</td>
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<th>Future State</th>
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<td>Medication selection and preparation activities are processed to the extent possible by robotic devices with extensive in-process controls to assure correct and consistent processing steps.</td>
<td>The application of robotics is primarily limited to compounding processes and unit-dose cart filling and tends to stand alone. Robotic devices continue to be expensive to install, manage, and maintain. They tend to be large, multi-purpose devices that attempt to provide a variety of services that, like a Swiss Army Knife, do many things but none of them well or quickly.</td>
<td>Robotic technologies will continue to mature and improve in speed and reliability; integration is needed to further remove reliance on human performance. It remains to be seen whether these devices remain large, multi-functional products or become a collection of tools from which those operating the dispensing function select the most appropriate one.</td>
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<td>Medication selection, preparation, and distribution systems that capture significant amounts of data about these processes that can be used to both audit the process and drive various analytical processes and metrics regarding the effectiveness of these processes.</td>
<td>Work flow software is available from a few vendors for the sterile compounding space; more is needed for other manual dispensing activities.</td>
<td>A well-articulated vision for the role of robotics in medication selection, preparation, and delivery is needed, as is the development of technologies to better automate checking activities including smart vision systems for detecting defects and measurement errors.</td>
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<td>Medication delivery systems that trace the course of any medication supply to its current location.</td>
<td>Currently available devices capture extensive logs, but the integration of the data from those logs to view an entire medication use process is not currently practical. Manually performed processes tend to remain largely undocumented, except for some emerging work flow management products.</td>
<td>Metrics need to be defined and devices need to develop support for, and reporting of these metrics.</td>
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<td>Medication selection, preparation and delivery systems that limit activities to those users who are trained and, where appropriate, credentialed to perform those activities.</td>
<td>There are a few product tracking products on the market as standalone products; integration with clinical systems is poor.</td>
<td>These features will need to become integrated into clinical systems for full traceability.</td>
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<td>Medication selection, preparation and delivery systems that capture logging data as a byproduct of the performance of the required duties (as opposed to becoming steps someone must remember to do).</td>
<td>Most systems currently available offer permission-based control of access to critical functions.</td>
<td>These permission-based approaches will need to be continued.</td>
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<tr>
<td>Medication selection, preparation and delivery systems that capture logging data as a byproduct of the normal operation of the devices.</td>
<td>Most automated systems do this currently; large amounts of data are captured as a by-product of the normal operation of the devices.</td>
<td>This approach will need to be continued as more automation devices are developed.</td>
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<th>Informatics</th>
<th>Future State</th>
<th>Current State</th>
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<td>Informatics practice must embrace data models that drive clinical practice as a primary requirement and distribution practice as a benefit of that clinical knowledge. Informatics practice must start from a well-articulated statement of best practices to be enabled and enforced within the informatics infrastructure.</td>
<td>Informatics tends to accept current offerings as a base point and to request incremental changes to those features. Informatics does not envision what systems should look like unconstrained by “what is” with the result that there is no clear vision of “what should be.” Dissatisfaction with current commercial offerings abounds, but there seems to be little consensus regarding what should replace it.</td>
<td>Informatics must develop an ideal operational model for the application of technology, and articulate that vision as a set of requirements to the industry. Informatics must drive requirements as opposed to awaiting the next gift from industry. Focus must move away from incremental modification of “what is” to consideration of “what should be.”</td>
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Informatics as a practice will know as much or more about the realities of work flow as the providers who participate in it, and will constantly and critically look for ways to apply appropriate automation tools to improve the safety, efficacy, and efficiency of those processes. Practice is largely uncharacterized in any meaningful way. Informatics tends to layer automation on top of current processes without considering how practice should change. Informatics needs to be developed as a subspecialty within pharmacy practice that develops new knowledge about both clinical and distributive practice, and guides the development of new technologies that meet the current and future needs of the profession.

The practice must develop a data model for representing drug entities that is designed primarily for clinical purposes but also generates data necessary for drug distribution. Current formulary data structures are primarily aimed at inventory management and product distribution. This organization often confounds clinical decision-making, which ordinarily occurs at the level of therapeutic entities (drugs) rather than their commercial presentation (products). One such structure might maintain the concept of a drug as an entity that can be used for specific therapeutic purposes at one level while recognizing that those drugs must be delivered using commercially available or pharmacy-prepared products. Therapeutic decision support would be based on these drug entities and drive the selection and use of specific products that contain these entities.

4. Decision-support systems are present that can maintain appropriate context and apply the correct actions to discovered relationships.
   a. Real-time, continuous monitoring detects the need for interventions based on documentation in the clinical record, qualifies its evaluation based on those data, prioritizes the indicated interventions based on acuity of illness, and schedules the appropriate actions.
   b. Drill-down capability that permits “digging into” individual problems or patterns of problems.
   c. Tracing functions that permit review of a particular medication process for a particular patient within a particular period of time using both clinical and operational data to display both operational and clinical outcomes.

5. Provides online access to standard texts as well as the primary literature.
6. Acquires and reports utilization data according to changing user needs without requiring vendor modification.
7. Permits oversight of the medication distribution system.
   a. Operational systems maintain sufficient audit trails and reporting to permit oversight and analysis of the effectiveness of the medication distribution system in terms of efficiency, timeliness, cost, and safety.
   b. Drill-down capability that permits “digging into” individual problems or patterns of problems.
   c. Tracing functions that permit review of a particular medication process for a particular patient within a particular period of time using both clinical and operational data to display both operational and clinical outcomes.

In the ideal system described above, pharmacists would find on their computers a work queue containing the following types of information:

1. A list of patients who require immediate attention because their medi-
1. A list of patients who require attention because they are demonstrating declining renal or hepatic function and are taking medications that might require dosage adjustment.

2. A list of patients who require attention because they are demonstrating declining renal or hepatic function and are taking medications that might require dosage adjustment.

3. A list of patients who require attention because their medication profile indicates that they could experience a drug interaction.

4. A list of patients who require attention because their medication profile indicates that they could experience a drug interaction.

5. A list of patients who require attention because their therapy could be converted from the i.v. to the oral route.

6. A list of new patients to be seen because they require a medication history and medication reconciliation.

As pharmacists begin working through the interventions on their lists, they begin to make adjustments in medication therapy. The software presents current clinical information about the patient for whom an order is being entered, adding or deleting information depending on the medication being ordered. Warnings occur only when ordered therapy is extremely likely to be harmful; less-serious issues precipitate automatically scheduled follow-up assessments. Occasionally, the pharmacist needs to review references, which he or she accesses in context. A pharmacist may note that a medication ordered the previous day has not yet been administered, so he or she will inspect both operational and clinical records; if operational records indicate that the medication has not yet been received in the pharmacy, the pharmacist orders alternate therapy; the staff responsible for distribution is notified that the medication originally ordered is no longer needed.

Management of medication distribution. In the ideal future, the medication distribution system is overseen by a pharmacist but is exclusively operated by advanced technical practitioners who are appropriately trained and credentialed. The medication selection and distribution process is governed by in-process quality-assurance steps; standardized practices minimize the opportunity for errors in product selection, preparation, and distribution.

To the extent practical, medication selection, preparation, and distribution activities are completely automated to remove opportunities for human error, effectively automating the checks that are now mandated by law to be performed by pharmacists. This implies the following requirements:

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Table 1 (continued)

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<tr>
<td>Therapeutic formularies must operate in the context of a national (if not international) encoding scheme for drugs and products that supports automated maintenance of new drugs and products without requiring the validation of each new product as it comes into the facility. This implies that a coding system (such as the NDC) would be maintained as a nationally available, reliably current data set whose contents were set by an authoritative and neutral body from which any system could reliably identify not only the description of the product for supply chain purposes, but also enough clinical information to determine whether or not that product was suitable to fulfill the requirements of any particular medication order.</td>
<td>Globally, coding is highly fragmented both in structure and data content. Within United States, the NDC represents this coding with a variety of problems: • There is no authoritative list of codes and the products to which they refer. The FDA database is updated every 6 months and is not heavily policed. • There are multiple permitted formats and code lengths without reliable crosswalks between them. • Only the vendor identifier portion of the code is controlled, one cannot look at an NDC and tell from the NDC what drug it represents. • Generation of the drug and package code in the NDC is completely at the whim of the vendor and the decision to invent a drug code versus a package code is not uniformly applied by all vendors. • NDCs are allowed to be reused, defeating their usefulness in longitudinal health records.</td>
<td>There is a need for a “smarter” numbering system than currently exists, and one whose contents are more centrally controlled than the current NDC. The coding of any particular product must be reliably unique within the longitudinal electronic health record (e.g., codes cannot be reused). The coding should permit a software system to identify the contents of the package irrespective of vendor (e.g., the drug code for a cefazolin 1 gm vial should be the same irrespective of who made it).</td>
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EHR = electronic health record, CDSS = clinical decision-support system, NDC = National Drug Code.
1. Medication packages are marked with a machine-readable code that reliably identifies medications in terms of their clinically relevant contents.

2. Medications are packaged in containers that are “automation friendly” to permit the application of robotics to the selection, preparation, and distribution of medication packages at speeds and with certainty that cannot be achieved with human handling.30

3. Medication selection and preparation activities are processed to the extent possible by robotic devices with extensive in-process controls to ensure correct and consistent processing steps.

4. When medication selection and preparation activities must be performed by hand, they are governed by applications and processes that provide extensive in-process controls to minimize the opportunities for error. This may include automatic identification of selected products, vision systems that detect appropriate product selection or correct measurement of liquid medications, vision systems that can detect the appearance of inappropriate inclusions (e.g., particulates) in liquid doses, intelligent scheduling of activities to ensure that medication doses will be effective when they are finally administered, enforced use of appropriate containers, and audit trails.

5. Medication selection, preparation, and distribution systems capture data about these processes that can be used to both audit a process and drive various analytical steps and metrics regarding the effectiveness of these processes.

6. Medication delivery systems trace the course of any medication supply to its current location.

7. Medication selection, preparation, and delivery systems limit activities to those personnel who are trained and, where appropriate, credentialed to perform those activities.

8. Medication selection, preparation, and delivery systems capture detailed audit trails as a byproduct of the performance of the required duties (as opposed to becoming extra steps someone must remember to do).

In order to convince regulatory bodies that it is safe to delegate drug distribution tasks to a technical work force, it will be necessary for (1) the work force to be appropriately trained and credentialed and (2) the majority of the work be done by automated systems that apply in-process controls and capture extensive audit trail documentation.

Informatics infrastructure. The technology described above will require an informatics infrastructure that is considerably different from what is currently available, though ongoing development is showing promise. For example:

1. Informatics practice must be built on a foundation of best practice models. This requires that the profession actively describe best practice in clear terms.

2. Experts in informatics practice must stop building clinical functionality on top of drug distribution systems and start building systems that support clinical practice with drug distribution as one outcome of a system. This requires, among other things, that the fundamental structure of data change to first support clinical practice in terms of drug entities and formulations and then manage the distribution of drug products that provide those entities and formulations.

3. Informaticists will study and know as much or more about the realities of workflow as do the workers who provide patient care. Informatics experts will constantly and critically look for ways to apply appropriate automation tools to improve the safety, efficacy, and efficiency of workflow processes.

4. Changes required to enable a future pharmacy practice model will require significant change in HIT and informatic experts must develop change management processes to cope with this reality.

5. A drug- and drug-product-coding system must be developed that meets both clinical and supply-chain needs. The current National Drug Code is inadequate for the task.

Conclusion

Current application of technology in health care, especially in acute care, must be viewed as a set of experiments that informs our need for future systems but has failed to improve the quality of the health care services we provide. Future technology needs to be (1) standardized around models other than those that have evolved in the current marketplace, (2) better integrated and interoperable to permit successful clinical use of acquired data, (3) driven by consistent product-coding structures, and (4) designed by informaticists who understand technology both from a technical and a human perspective. Health-system pharmacists need to actively pursue the adoption of well-integrated (as opposed to best-of-breed) technology solutions centered on an EHR to provide them the clinical infrastructural within which to practice.

The pharmacy profession needs to immediately begin to research and articulate requirements for automated systems that meet the needs of new practice models. Pharmacists should drive the development of systems that meet those requirements rather than merely accepting the least offensive of the current commercial offerings.

Health-system pharmacists need to advocate at the federal level for the adoption of a better-controlled and more clinically relevant drug-product-coding system than the national Drug Code. Specifically, that system needs to unambiguously describe the content of any pharmaceutical package.

Health-system pharmacists need to immediately begin to research and describe the change management techniques and processes that will facilitate the transition from current
IT systems to the systems that will enable and drive our future practice models.

References


