

THE VALUE OF MEDICAL DEVICE INTEROPERABILITY:

Improving patient care
with more than \$30 billion
in annual health care savings



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The West Health Institute is an independent, non-profit 501(c)(3) medical research organization whose mission is to lower health care costs by developing innovative patient-centered solutions that deliver the right care at the right place at the right time. This is accomplished by conducting innovative medical research, educating key stakeholders and advocating on behalf of patients. Solely funded by pioneering philanthropists Gary and Mary West, the Institute is part of West Health, an initiative combining four separate organizations – the West Health Institute, the West Health Policy Center, the West Health Investment Fund and the West Health Incubator. The Institute is located in San Diego, California, the global center for health care innovation. For more information, find us at westhealth.org and follow us [@westhealth](https://twitter.com/westhealth).



ACKNOWLEDGEMENTS

The Medical Device Interoperability Coordinating Council (MDICC) is an open forum to allow collaboration between stakeholders that are actively engaged in aspects of promoting or creating interoperable medical device systems. The MDICC formed in March 2012 to advance wide adoption of medical devices that seamlessly interoperate with other medical devices and information systems with the goal of enabling improved patient care. This analysis was prompted, in part, by MDICC's efforts, which validated the need to better quantify the value of medical device interoperability. Several individuals within MDICC deserve thanks for their contributions to this work.

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ABSTRACT

Unsustainable and ever-escalating U.S. health care costs, an estimated \$700 billion in wasteful spending and the emerging centrality of medical information and its seamless availability in the search for solutions prompt investigation into the value of creating functional medical device interoperability – the ability for medical devices to exchange information with each other and with patient data repositories such as electronic health records.

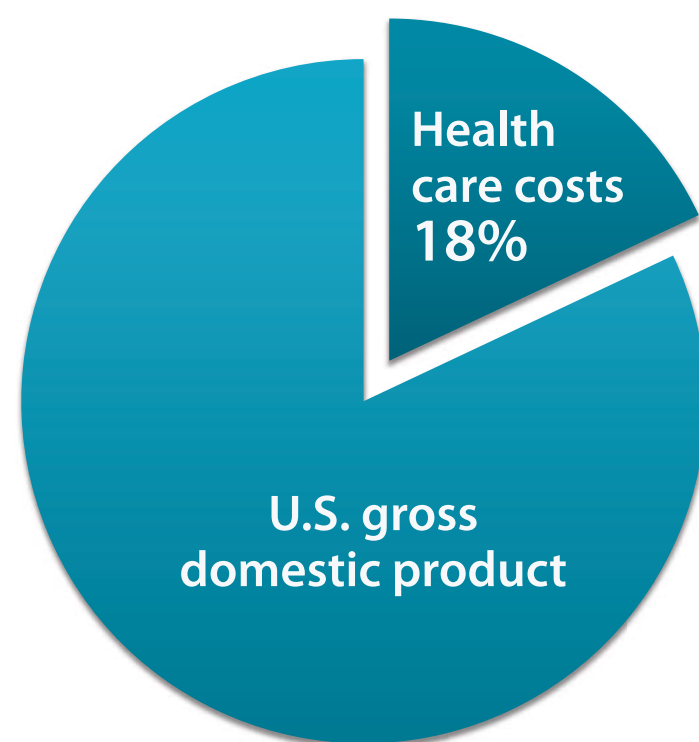
This report examines areas of waste in health care that can potentially be eliminated through greater medical device interoperability and the adoption of commonly accepted standards for interoperability. Waste reduction through greater medical device interoperability would lead to increased efficiency, improved quality and more affordable care. Commonly adopted standards can accelerate the move towards greater medical device interoperability and potentially reduce the cost of achieving interoperability. With all of the caveats associated with estimating the value of a process improvement not yet deployed, our combined top-down and bottom-up modeling suggests that **annual savings in excess of \$30 billion** may be liberated by widespread adoption of functional interoperability for medical devices.

To realize the benefits, providers, payers, medical device manufacturers and the government will need to collaborate and partner to promote the development and adoption of seamlessly interoperable devices. Industry trends are already driving providers and payers to converge and share risk through care coordination, clinical integration and improved population health management. Stakeholder collaboration is expected to provide a strong platform for accelerating adoption of medical device interoperability and realizing its associated benefits.

INTRODUCTION

Overview

Health care costs continue to consume an ever increasing proportion of U.S. spending, significantly outpacing the growth of our economy for each of the last four decades, and recently reaching as high as 18 percent of gross domestic product (GDP).¹



While both the absolute level of spending and its disproportionate growth are unsustainable, evidence indicates that as much as a third of this spending is waste (i.e., does not contribute to quality outcomes). According to recent estimates, more than \$700 billion of the \$2.4 trillion in health care spending could otherwise be avoided through improvements to the health care system.¹ Waste takes many forms, including inefficiency, unnecessary services and missed prevention opportunities, and is believed to be broadly distributed across the spectrum of health care delivery.

This study examines the sources of waste in health care that could be eliminated with medical device interoperability, as well as the waste resulting from a lack of commonly adopted interoperability standards. The report's findings suggest that increased medical device interoperability would reduce waste, lead to improvements in quality and decrease the cost of care. Additionally, comprehensive adoption of interoperability standards has the potential to reduce waste related to developing and implementing interoperability and facilitate increased interoperability.

Health IT, Medical Devices and Interoperability

Despite a nationwide push for adoption of information technology throughout the health care system and the concurrent significant advances in the technologies underlying medical devices, numerous barriers continue to impede the realization of health information technology's potential. A lack of functional medical device interoperability is one of the most significant limitations.

Medical device interoperability refers to information sharing from one device to another or between devices and Electronic Health Records (EHRs). Functional interoperability would enable clinical medical devices to communicate in a consistent, predictable and reliable way. By allowing for the exchange of data with other medical devices and with patient data sources and repositories, such as EHRs, medical device interoperability would enhance the function of the systems and devices. Exchange of data between EHRs is commonly designated as Healthcare Information Exchange (HIE) and has been analyzed in great detail elsewhere.² The reliable and seamless transfer of information through medical device interoperability can facilitate a number of improvements in efficiency and safety that can be quantified in billions of dollars of savings to the health care system, yet, despite these significant benefits, medical device interoperability is limited today.

WASTE:

Any activity that does not add value to the health care system.

FUNCTIONAL MEDICAL DEVICE INTEROPERABILITY:

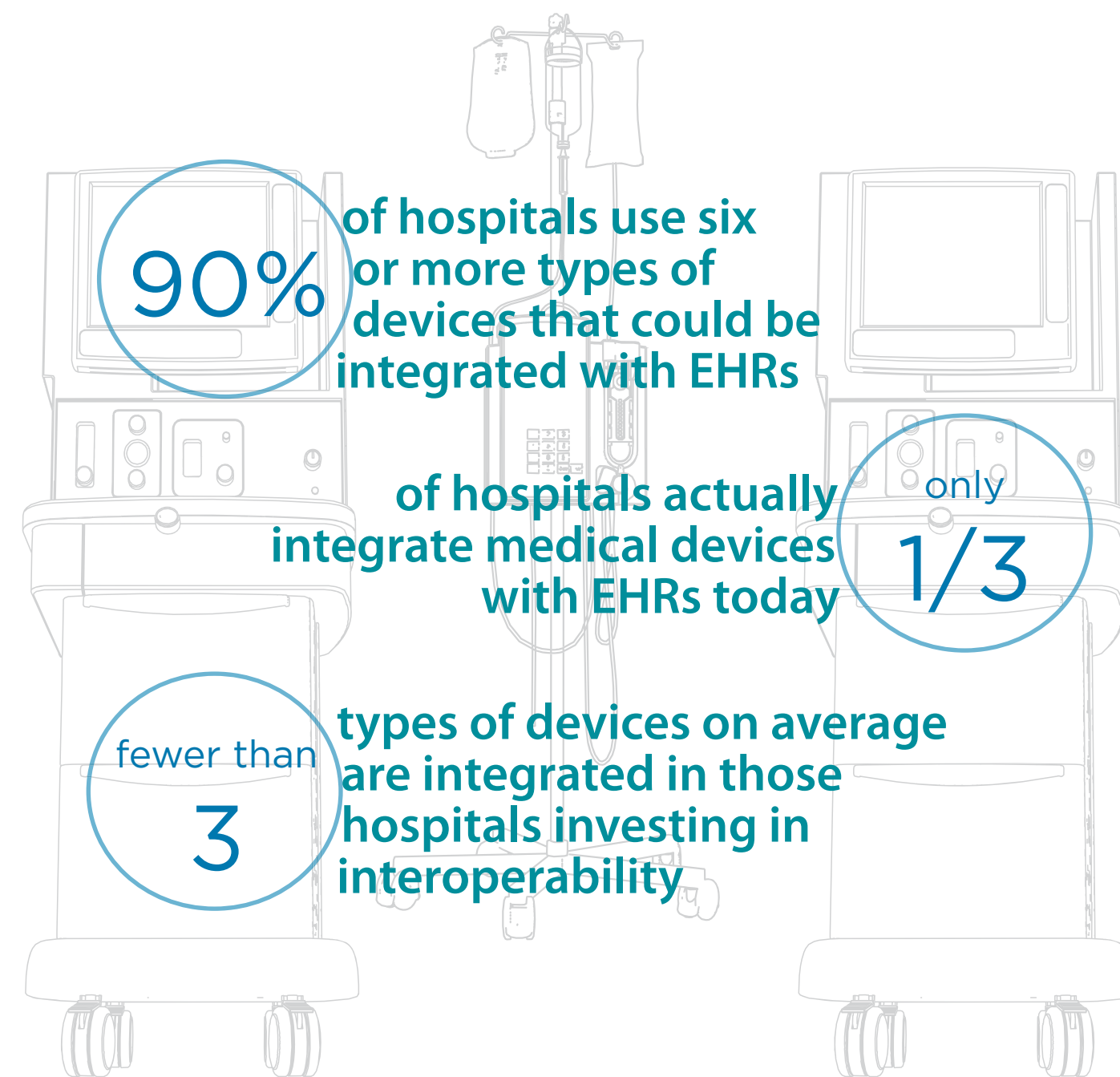
the ability for clinical medical devices to communicate in a consistent, predictable and reliable way, allowing for the exchange of, and interaction with, data from other medical devices and with patient data sources and repositories, such as electronic health records (EHRs), in order to enhance device and system functionality.

The Current State of Medical Device Interoperability and Interoperability Standards

According to a recent report by HIMSS Analytics,³ while over 90 percent of the hospitals surveyed by HIMSS use six or more types of devices that could be integrated with EHRs (such as defibrillators, electrocardiographs, vital signs monitors, ventilators and infusion pumps) only a third of hospitals actually integrate medical devices with EHRs today. Additionally, those that are investing in interoperability integrate fewer than three types of devices on average, a far cry from the six to twelve devices that may be present around an intensive care unit (ICU) bed. This lack of interoperability creates significant sources of waste and risk to patient safety because of incomplete or stale information clinicians must rely on for workflow and decision making.

Part of the reason for limited interoperability is the high cost and complexity of medical device integration, which results from the lack of incentives for medical device and HIT companies to use open interfaces to establish interchangeable interoperability. In contrast to the “plug and play” world of consumer electronics, where consumer demand for simple and seamless functionality has driven convergence on a few common standardized interfaces and platforms, providers have not required a consistent means for achieving interoperability. As a result, there is a wide range of methods used by device vendors today. Some vendors use distinct proprietary and closed communication methods even among their own devices. Additionally, some standards are loosely specified, with a number of options for configuration, meaning that even devices that use similar standards may not be able to communicate without further customization. As a result, facilitating the exchange of data between and among medical devices and EHRs currently requires hospitals to invest significant resources in developing custom interfaces and paying for middleware solutions. The cost of medical device integration has been estimated at as much as \$6,500 to \$10,000 per bed in one-time costs, plus as much as 15 percent in annual maintenance fees.⁴ These investments are a substantial undertaking for hospital systems when compared against already squeezed operating margins of less than three percent on revenue of approximately \$700,000 per bed (based on average length and cost of inpatient stays).^{5,6}

Within the current system, the medical device industry lacks the imperative to offer interoperability among devices because providers who are integrating bear these costs and do not require medical device companies to follow specific standards. Many providers continue to work without interoperability since the value proposition has not been adequately quantified to drive prioritization of the investments necessary to achieve integration over competing technology or other needs. While middleware software providers and systems integrators have issued white papers illustrating the impact of medical device integration at a hospital level,⁷ there



have been no studies to date attempting to quantify the value of medical device interoperability in addressing waste across the health care system as a whole. There has also been no detailed examination of the waste generated by the lack of commonly adopted standards. Given the efficiencies and quality assurance tools medical device interoperability offers, this report provides health care stakeholders a clear and compelling case to invest in medical device interoperability.

This paper examines the benefits of medical device interoperability in terms of the reduction of waste in health care. It also estimates the costs that could potentially be eliminated in a world where medical devices are connected in a standardized manner as computer and communications devices do today.

Methodology

This report limited the scope of its analysis to interoperability between clinical medical devices and patient data repositories such as EHRs and device-to-device interoperability. It included only those clinical devices that are potentially interoperable today, encompassing bedside monitoring devices (e.g., ECGs and physiologic monitors), imaging devices, diagnostic devices, surgical devices and therapeutic devices (e.g., infusion pumps). It focused on acute care (encompassing emergency room and inpatient settings) and did not examine the benefits of interoperability between EHRs in different health care organizations since HIEs constitute a distinct type of interoperability and have been analyzed in detail elsewhere.² Finally, while it is appreciated that the lack of functional interoperability among consumer medical devices (e.g. glucometers, weight scales and blood pressure monitors) outside the hospital and between such devices and more central EHRs is a related significant and growing challenge with its own attendant waste, the lack of conformity around the magnitude and growth of this aspect of the issue precluded it being included in this analysis, making the results of this work a more conservative estimate of the overall impact of true, functional interoperability.

This analysis followed a three-stage process:

- 1 Identification of relevant sources of health care waste
- 2 Definition and quantification of the addressable buckets of waste
- 3 Definition and quantification of the share of costs addressable by interoperability

IDENTIFICATION OF RELEVANT SOURCES OF HEALTH CARE WASTE

Relying on the Lean Six Sigma methodology as a lens to define waste as “all activity that does not add value to the health care system,” the perspective of each stakeholder within the ecosystem was examined to identify areas where waste could potentially be addressed and eliminated through interoperability.⁸ Interviews with more than 30 stakeholders from across the health care ecosystem (including providers, payers, medical device manufacturers and health IT vendors), along with secondary research, led to identifying ten areas of waste that fell into two categories: those arising from the lack of interoperability and those arising from a lack of commonly adopted standards. Of these, some were determined to be primary sources of waste

for which the impact of interoperability could be readily quantified, and others were identified as longer-term savings opportunities that were indirect (i.e., would require several additional enabling factors to address) or were difficult to measure and therefore not specifically quantified in this report (**Figure 1**).

Figure 1: Areas of Waste Identified

Quantified Areas of Waste	Primary Stakeholders Benefited			
	Providers	Payers	Patients	Device Co.
Due to Lack of Medical Device Interoperability				
1. Adverse events from drug errors, misdiagnosis and failure to prevent harm	✓	✓	✓	
2. Redundant testing resulting from inaccessible information	✓	✓	✓	
3. Clinician time spent manually entering information	✓			
4. Increased length of stay from delays in information transfer	✓			
Due to Lack of Commonly Adopted Standards for Interoperability				
5. Device testing and development costs				✓
6. Provider costs to integrate devices with EHRs	✓			
Indirect or Difficult to Quantify Areas of Waste	Primary Stakeholders Benefited			
	Providers	Payers	Patients	Device Co.
Due to Lack of Medical Device Interoperability				
7. Limited ability to collect and leverage data analytics to improve clinical decision support	✓	✓	✓	
8. Sub-optimal care driven by limited adoption and efficacy of remote patient monitoring		✓	✓	
9. Limited ability for operational maintenance and optimization of utilization/inventory management	✓			
Due to Lack of Commonly Adopted Standards for Interoperability				
10. Limited device choice, innovation and competition due to switching costs	✓			✓

DEFINITION AND QUANTIFICATION OF THE ADDRESSABLE BUCKETS OF WASTE

For each segment of waste, a reference market was established to set a maximum value of spending that could be impacted by interoperability. For example, the analysis of savings related to “time wasted manually entering information” first quantified the total value of nurses’ time nation-wide as a maximum, and then identified the portion of that time spent manually documenting information and programming devices.

DEFINITION AND QUANTIFICATION OF THE SHARE OF COSTS ADDRESSABLE BY INTEROPERABILITY

The potential impact of interoperable vs. non-interoperable devices was defined based on available clinical literature. Continuing the example of “time wasted manually entering information,” this analysis looked at the impact of medical device integration on documentation and programming time in published case studies to estimate the reduction in waste. Where an exact case study of medical device interoperability was not available, a surrogate analysis was selected based on its relationship to the activities interoperability would address. For example, “increased length of stay from delays in information transfer,” used the impact of another intervention that decreased test turnaround time - point of care testing - to estimate the impact of medical device interoperability on emergency department (ED) length of stay.

Summary of Results

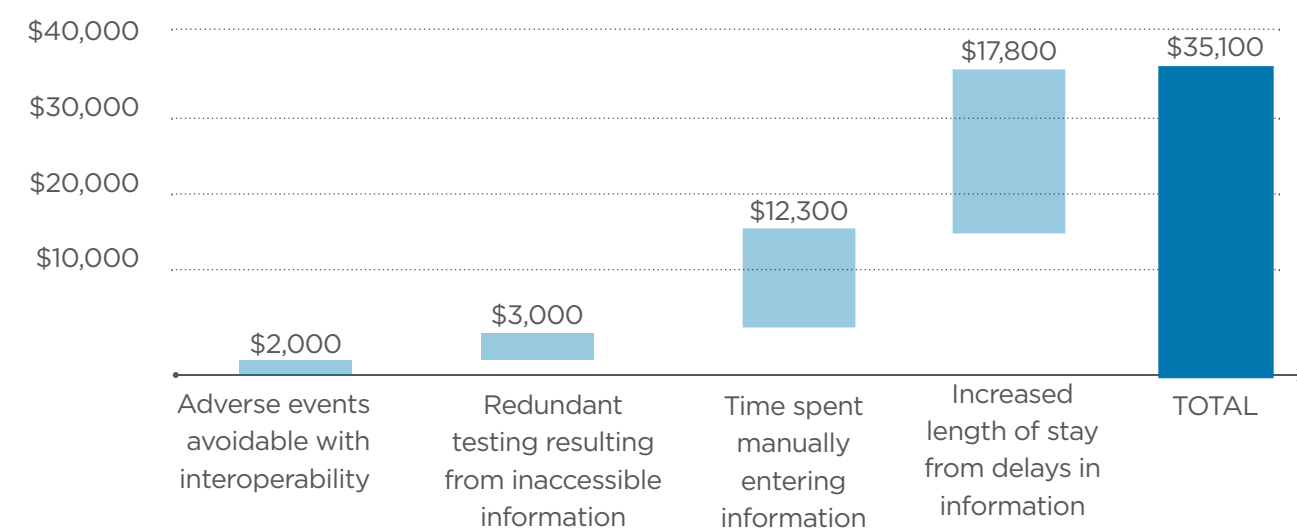
The analysis identified an estimated **\$36 billion in potential, annual addressable waste across segments of health care in the U.S.** (Figure 2). The bulk of this waste (97 percent) relates to the lack of interoperability itself, with the remainder coming from the lack of commonly implemented standards. While a lack of commonly adopted standards for medical device interoperability may result in a small amount of direct savings, it has the ability to facilitate a more rapid adoption of interoperability, which can achieve the benefits described below.

The benefits from interoperability arise from four primary activities:

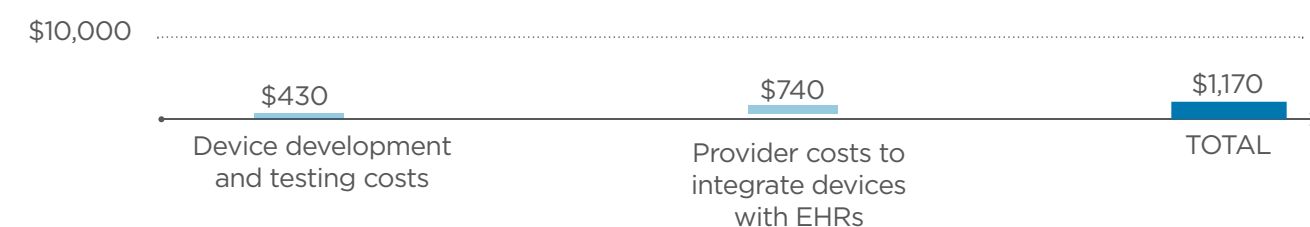
- 1) quality improvement through reduction of adverse events due to safety interlocks (**\$2 billion**)
- 2) reduced cost of care secondary to avoidance of redundant testing (**\$3 billion**)
- 3) increased clinician productivity secondary to decreased time spent manually entering information (**\$12 billion**)
- 4) increased capacity for treatment secondary to shortening length of stay (**\$18 billion**)

Benefits from common adoption of standards include reduced costs for medical device development and systems integration within a health system.

Figure 2: Estimated Addressable Waste
Estimated Waste from Lack of Medical Device Interoperability (\$M)



Estimated Waste from Lack of Commonly Adopted Standards (\$M)



*Note: Numbers rounded for clarity

For waste due to lack of medical device interoperability, the majority of benefits (93 percent) accrue to providers, followed by payers (6 percent), with initially *de minimis* direct economic benefit to patients. Additionally, device manufacturers and health IT companies are expected to gain little from medical device interoperability (Figure 3). It is important to note that differences in reimbursement policies make it difficult to precisely allocate the magnitude of benefits to each stakeholder; therefore the allocation provided below represents a reasonable estimation and allocation of those benefits. Furthermore, as patients are being asked to bear greater responsibility for the entirety of their medical costs, the savings initially attributed to providers and payors will necessarily decrease overall costs with likely proportional patient savings.

Figure 3: Savings by Stakeholder from Increased Medical Device Interoperability

Areas of Waste due to Lack of Medical Device Interoperability	Share of Total (\$ M)			
	Providers	Payers	Patients	Device Vendors
Due to Lack of Medical Device Interoperability				
1. Adverse events associated with medical device interoperability	\$1,000	\$850	\$150	
2. Redundant testing resulting from inaccessible information	\$1,500	\$1,275	\$225	
3. Clinician time spent manually entering information	\$12,300			
4. Increased length of stay from delays in information transfer	\$17,800			
Total Savings (\$M)	\$32,600	\$2,125	\$375	\$0
Total Savings (%)	93%	6%	1%	0%

*Note: Numbers rounded for clarity

For waste related to the lack of commonly adopted standards, the allocation of costs that could be eliminated was based upon interviews of stakeholders, whose views varied significantly, and was therefore a reasonable estimate based upon various expert opinions about how those costs are borne today (**Figure 4**).

Figure 4: Maximum Potential Savings by Stakeholder due to Lack of Commonly Adopted Standards

Areas of Waste due to Lack of Commonly Adopted Standards	Share of Total (\$ M)			
	Providers	Payers	Patients	Device Vendors
Due to Lack of Medical Device Interoperability				
5. Device testing and development costs				\$430
6. Provider costs to integrate devices with EHRs	\$740			
Total Savings (\$M)	\$740			\$430
Total Savings (%)	63%			37%

*Note: Numbers rounded for clarity

Detailed Findings

LACK OF MEDICAL DEVICE INTEROPERABILITY

Costs Resulting from Avoidable Adverse Events: \$2 billion

Medical errors result in as many as three million preventable adverse events each year, driving as much as \$17 billion in excess annual medical costs and as many as 98,000 deaths per year.^{9,10} Several of the most common causes of medical errors can be substantially addressed by improved medical device interoperability, including drug errors (accounting for 20 percent of adverse events), diagnostic errors (17 percent) and failure to prevent injury (12 percent).^{9,10} Errors in technique, accounting for 44 percent, are assumed to be largely unaddressable by improved interoperability.¹⁰

Drug Errors

With and without Medical Device Interoperability

Medication errors can stem from errors in drug ordering by the physician, order transcription by various clinicians, drug dispensing by the pharmacist and drug administration at the point of care (**Figure 5**).

Medical device interoperability will facilitate the push of test results and vital signs readings to clinicians or pharmacists and automate the integration of relevant information to inform ordering decisions, thus avoiding ordering errors stemming from lack of patient information or inadequate monitoring. Interoperability can address transcription and administrative errors by allowing EHRs, physiological monitoring devices and medication administration devices to communicate in a seamless manner. Automation of these activities and functions with medical device interoperability can 1) enable automatic population of drug orders into the devices that administer these drugs, 2) transfer alerts and parameters for drug delivery from an EHR into the device and 3) provide a physiological data feed into the device. Any one of these interventions can reduce drug-related adverse events. For example, the integration of intelligent infusion devices, bar-code-assisted medication administration and electronic medication administration records has been found to reduce errors further than using these systems in a siloed manner, as it enables the automatic population of provider-ordered, pharmacist-validated infusion variables directly into the infusion device, which verifies the dose and rate against dosing limits defined in the drug library (Medical device interoperability would not address any pharmacy dispensing errors beyond those that stem from errors in transcription or ordering).

Calculations

According to a study in *Health Affairs*, adverse drug events result in an estimated \$3.8 billion in incremental medical costs annually.⁹ Ordering errors account for 39 percent of all drug errors.¹¹ There are few studies specifically examining the impact of interoperability on ordering errors, but a relevant proxy is the impact of closed-loop e-prescribing, automated dispensing, bar-code and eMAR systems, as such closed-loop systems achieve their benefits by integrating the flow of information among the subsystems which comprise them. A study in *Quality & Safety in Healthcare* found that such a closed-loop system reduced prescribing errors by 47 percent.¹²

Transcription errors account for 12 percent of all drug errors;¹¹ these errors can be addressed for all types of dosage forms, as interoperability between automated dispensing devices and computerized physician order entry (CPOE) systems can address errors for intravenous (IV) and non-intravenous drugs alike. There are few studies on the impact of interoperability between automated dispensing machines and CPOE systems specifically, but the impact of integrating bar-code medication verification with an electronic medication administration system can be used as a proxy, as the latter reduces transcription errors through a similar mechanism: by importing orders electronically from the physician's order entry or pharmacy system. Studies have found that this reduces between 50¹³ and 100 percent¹¹ of transcription errors, so an average value of 75 percent is used.

Administration errors account for 38 percent of all drug errors.¹¹ Because the mechanism for error reduction is specific to IV interoperability, the proportion of addressable errors is limited to the 60 percent that are due to intravenously administered medications.¹⁴ A study in the *American Journal of Health-System Pharmacy* found that IV interoperability resulted in a 32 percent reduction in reported monthly errors involving IV administration of heparin,¹⁵ which was used as a proxy for the impact of interoperability on intravenously administered drug errors as a whole, given that the mechanism by which interoperability addresses such errors is not specific to any particular drug.

Based on these assumptions, **potential drug error-related savings from medical device interoperability were estimated at more than \$1.3 billion annually**, or 8 percent of the \$17 billion total cost of preventable adverse events.

Diagnostic Errors

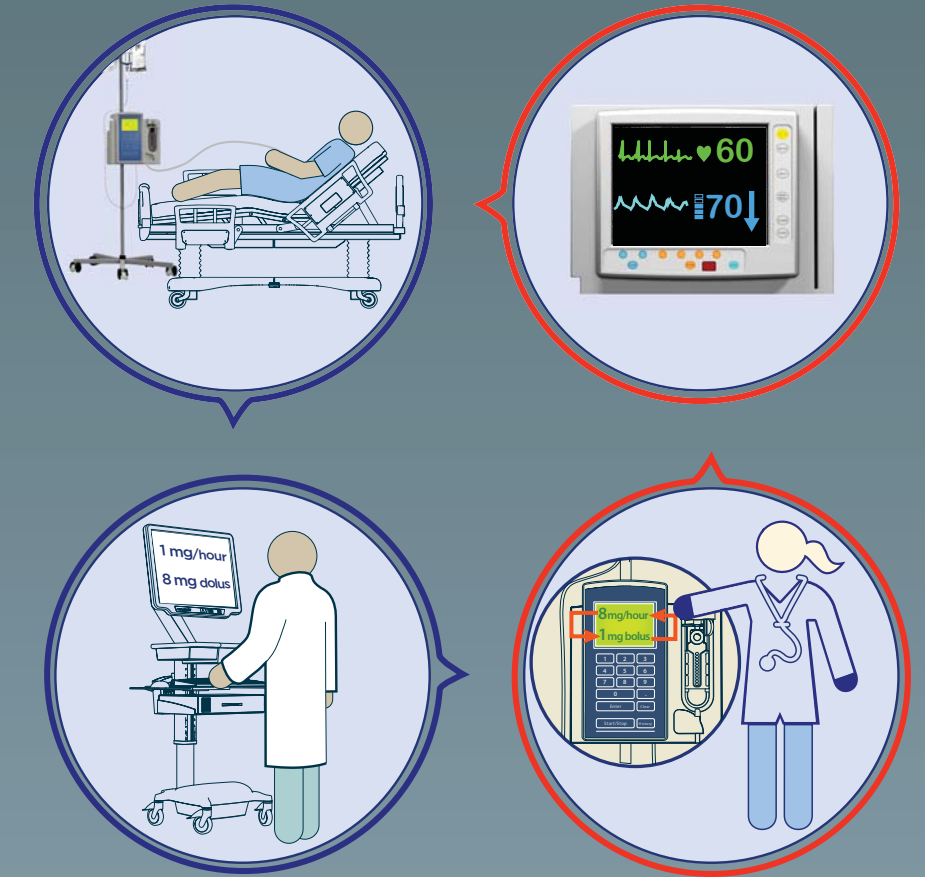
With and without Medical Device Interoperability

Diagnostic errors result from a variety of root causes, such as a failure to account for symptoms, order appropriate tests and consider all relevant diagnoses. Medical

Figure 5: Case Study: Drug Errors

Current State:

A cancer patient's pain is managed with **patient-controlled analgesia (PCA)** and has a **physician order** for a relatively low constant infusion rate of analgesia, with an intermittently high rate available when requested by the patient. As the infusion pump is being programmed, these **two rates are reversed**, resulting in over-sedation and respiratory depression. The patient's monitor **demonstrates dropping pulse oximetry**, but clinical intervention is delayed until the nurse walks back into room, resulting in anoxic brain injury.



Future State:

If the PCA pump were able to communicate with computerized physician order entry, transcription and infusion errors could be avoided. If the physiological monitoring device communicated with the pump, drug infusion would automatically be discontinued when physiological parameters move outside a predetermined range.

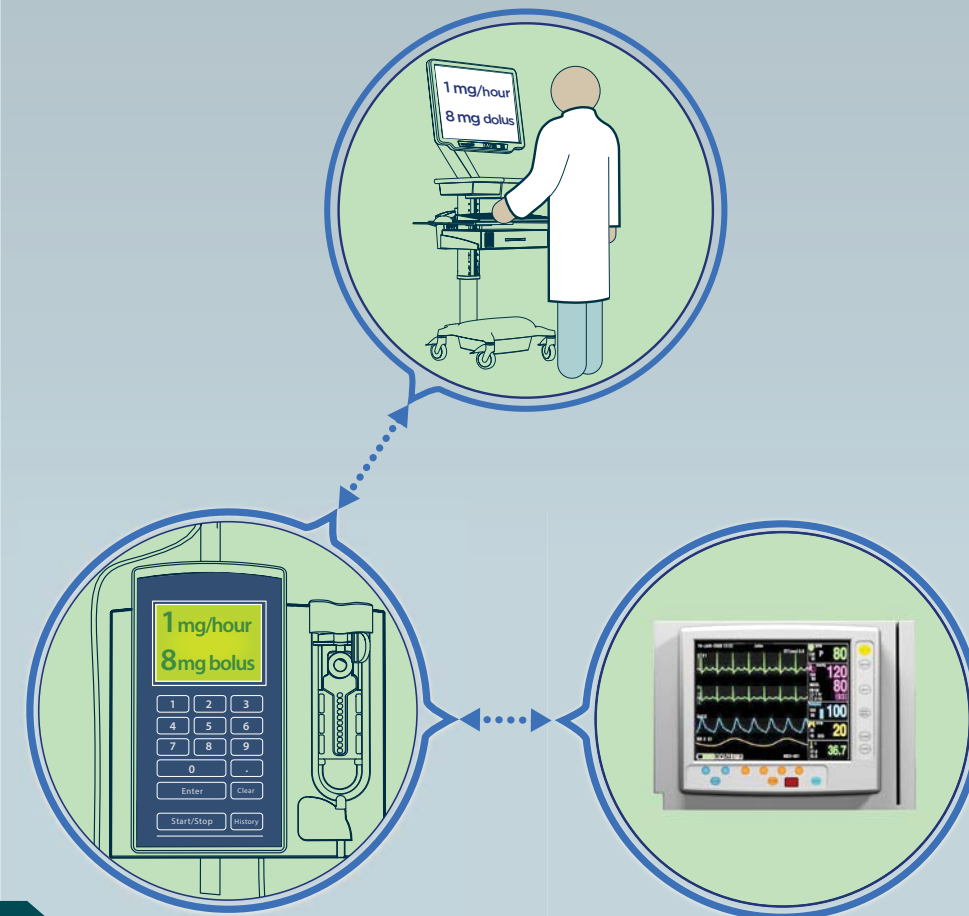
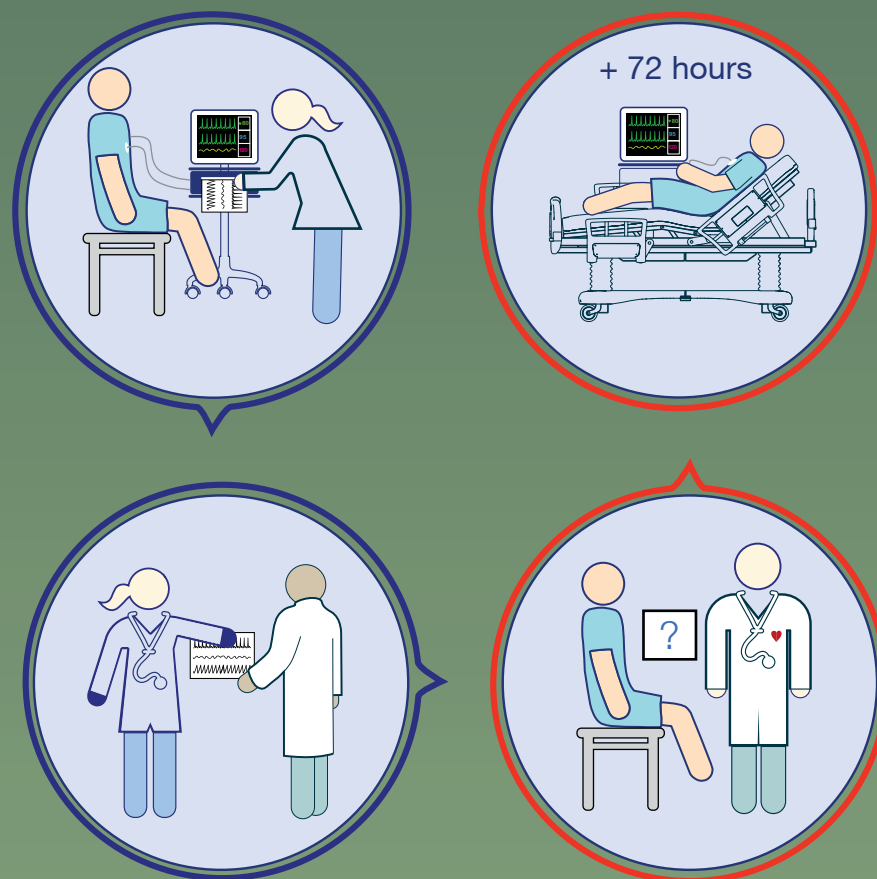


Figure 6: Case Study: Missed Diagnoses

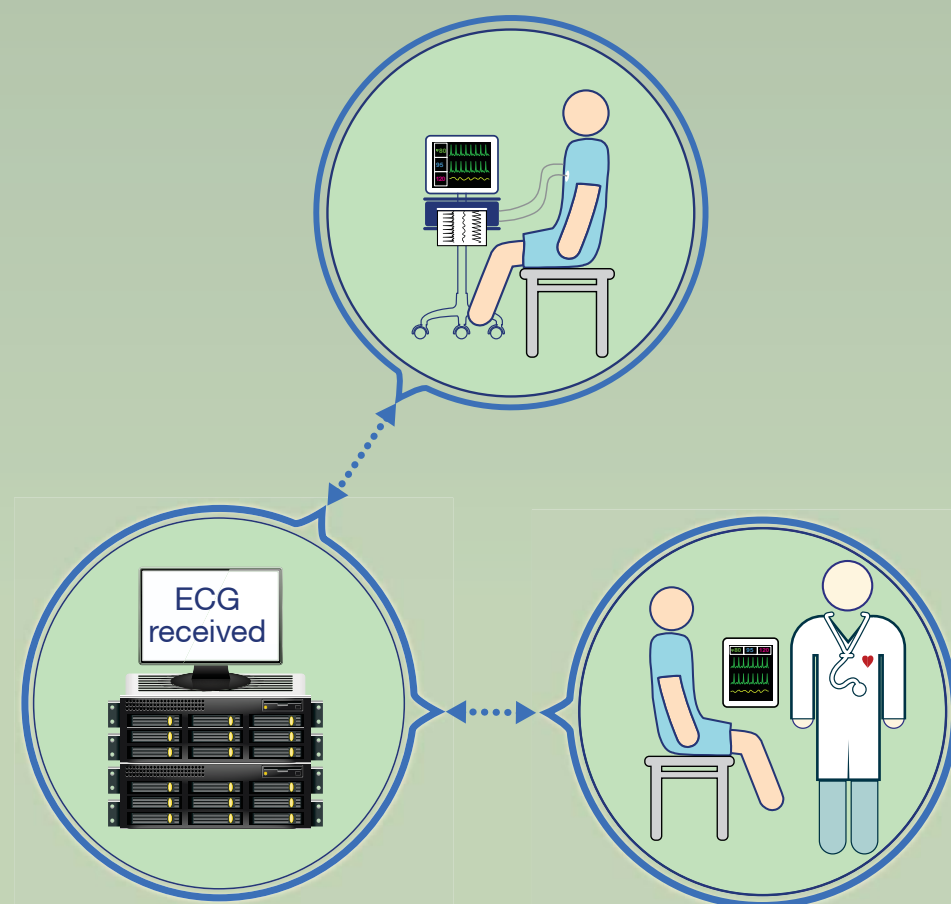
Current State:

A 35 year-old male presents to the Emergency Department with weakness. **A nurse notes an abnormal heart rhythm based on bedside monitoring. The printed heart rhythm strip is reviewed by an ER physician, who admits the patient for observation and cardiology consultation.** The next day, a cardiologist sees the patient, **but the diagnostic rhythm strip is unavailable.** Repeated ECGs are non-diagnostic. Additional testing is undertaken to reproduce the arrhythmia, all without effect. The patient is discharged without intervention, and **returns in 72 hours with worsening symptoms.**



Future State:

Automated push of information to the EHR would save an electronic version of heart rhythm monitoring results and present it to the cardiologist at the appropriate time, enabling the correct diagnosis and treatment.



device interoperability can reduce such errors by making symptom readings available in real time and pushing test results to a care provider in a timely and clear manner (Figure 6).

Calculations

Joanne Callen and colleagues found that 16.5 percent of missed Emergency Department (ED) diagnoses that harmed patients were due to a breakdown at the step of transmitting test results to the provider.¹⁶ This was applied here as a proxy for the improvement that could be realized by medical device interoperability facilitating the immediate “push” of test results to the EHR so that the care provider has the right information to make appropriate diagnoses.

Based on this assumption, as well as the aforementioned estimates for the costs of preventable adverse events (\$16.6 billion) and the percentage due to diagnostic errors (17 percent), it was estimated that interoperability could result in nearly \$466 million in annual savings related to addressing diagnostic errors, about 3 percent of the total cost of preventable adverse events.

Failure to Prevent Injury

With and without Medical Device Interoperability

“Failure to prevent injury” encompasses a variety of potentially preventable conditions. A primary example is ventilator-associated pneumonia; interoperability can reduce its incidence by automating and facilitating the monitoring of physiological parameters and matching the ventilator support needed by individual patients (Figure 7). This is particularly important for managing ICU patients with dynamic vital signs and lung capacity in accordance with best practice guidelines. Interoperability supports clinicians in performing frequent “ready to wean” assessments, which leads to fewer ventilator days and thus fewer cases of pneumonia.

Postoperative shock can also be addressed by improved interoperability, as integrating continuous vital signs monitoring with alarm systems has been shown to reduce its incidence by allowing earlier intervention in patients whose condition is deteriorating.

Calculations

A study in *Quality & Safety in Health Care* found that the incidence of ventilator-associated pneumonia decreased by 57 percent in response to a bundle of interventions, which included the examination of a number of “trigger tools” to initiate a search for root causes.¹⁷ Based on insights from industry experts who have studied patient safety and device interoperability, interoperability was conservatively

assumed to contribute about 25 percent of the value of these interventions. Applying this to the approximately \$1.1 billion in health care costs from ventilator-associated pneumonia¹⁸ would result in **total potential savings of more than \$163 million.**

A study in *Anesthesiology* found that continuous pulse-oximetry surveillance reduced “rescue events” (events necessitating the activation of code blue, STAT airway, or HERT teams) by 65 percent.¹⁹ The study indicates that having timely access to information about changes in a patient’s clinical status allows providers to intervene and prevent medical injury. A similar rationale can be applied to the prevention of postoperative shock through the increased accessibility of information created by medical device interoperability. Currently, more than \$35 million is spent in excess medical costs due to postoperative shock annually.¹⁹ A predictable reduction of 65 percent in postoperative shock cases was implied through improved medical device interoperability, **resulting in potential savings of almost \$23 million.**

Together, the **impact of interoperability on ventilator-associated pneumonia and postoperative shock totals \$186 million**, or about 1 percent of the total \$17 billion cost of preventable adverse events.

In total, with nearly \$1.3 billion in savings related to adverse drug events, \$466 million related to diagnostic errors and \$186 million related to failure to prevent injury, the analysis suggests that **medical device interoperability could save more than \$2 billion in medical costs across all preventable adverse events**, or more than 11 percent of the \$17 billion cost of all preventable adverse events.

Additional Factors to Consider

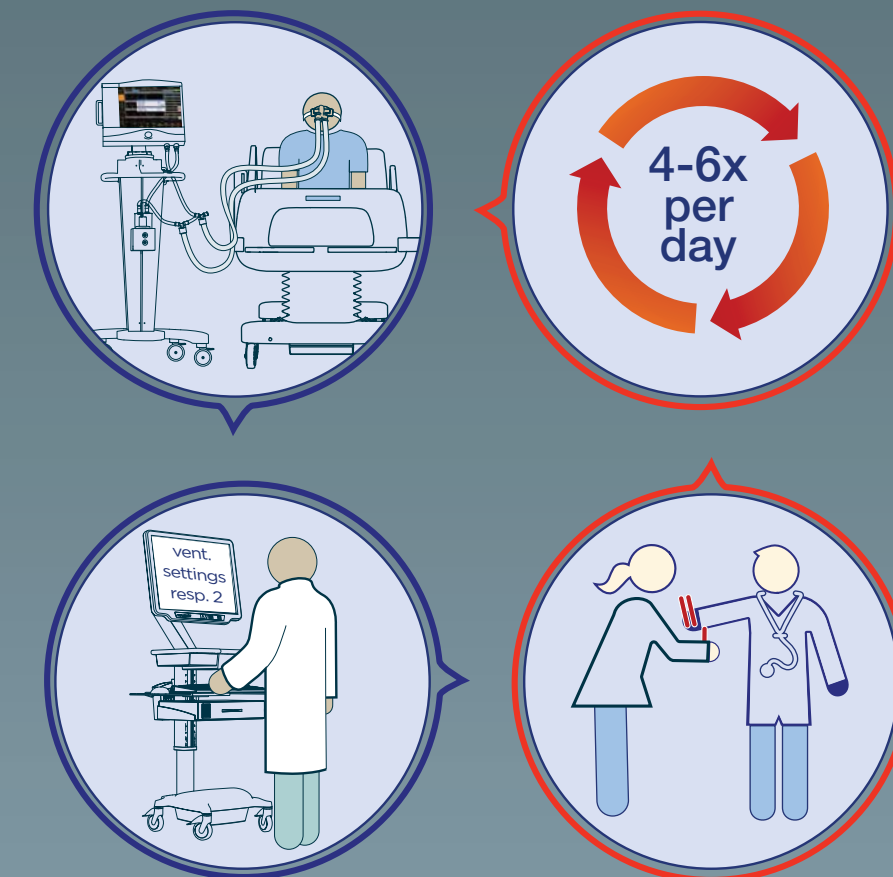
The estimated \$2 billion total savings is a conservative estimate focused only on reportedly preventable adverse events. Preventable adverse events, defined as adverse events resulting from medical errors,²⁰ make up \$17 billion in costs. There is reason to believe that some proportion of adverse events typically deemed unpreventable today could be prevented through greater medical device interoperability, as mechanisms discussed above, such as timely and contextual data display and smart alarms. This could move care past current best practices (reliable estimates of the percentage of unpreventable errors that could be addressed by interoperability are not currently available, so they were not included in the estimates for this paper). Studies also suggest that adverse events may be susceptible to underreporting. For example, a recent study in *Health Affairs* even found that common methods of adverse event detection miss 90 percent of adverse events, suggesting the incidence could be as much as ten times higher than reported.²¹

While interoperability can further reduce adverse events in the aforementioned ways, it also poses the risk that, in certain instances, an interoperable system could result in magnified systemic errors. For instance, an incorrect drug formulation in a clinically integrated IV system could automatically push to all related infusion pumps hospital-

Figure 7: Case Study: Failure to Prevent Injury

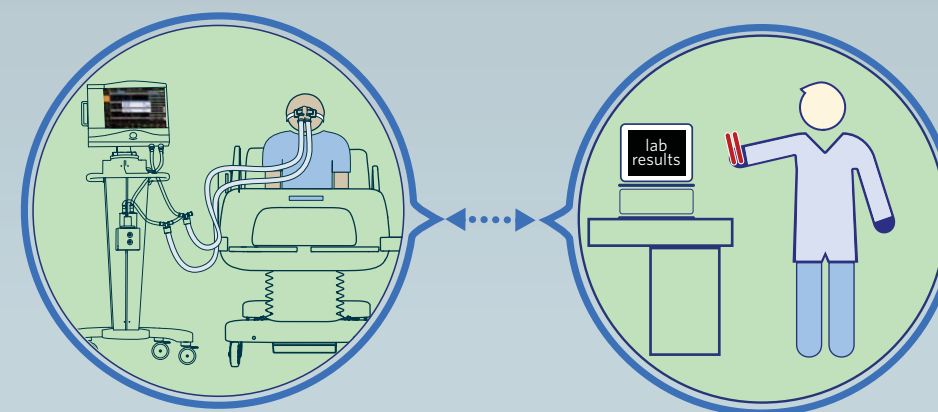
Current State:

A patient is intubated and on a ventilator in the ICU for brain injury. **The physician orders a ventilator setting with specific physiological parameters** per evidence-based guidelines. Repeat blood gas testing is ordered to maintain these specific parameters. The nurse notifies a respiratory therapist, who **draws blood and sends it to the lab.** The nurse receives results and calls the physician with findings, which requires a change in the ventilator settings. **This cycle occurs four to six times a day** based on the patient’s dynamic clinical status.



Future State:

If blood gas measurements were integrated in real time into ventilator settings to maximize gas exchange, device interoperability could eliminate unnecessary steps and potential delays, minimizing time on a ventilator and thus reducing the duration of hypoxia, the impact of acid-base disturbances and the risk of ventilator-associated pneumonia.



wide, though this would be mitigated by the ability to centrally identify and rapidly respond to and correct such errors. However, this risk is a primary reason any device-to-device interactions or device controls based on information from another system will need to be carefully analyzed to ensure safety and effectiveness.

Costs Resulting from Redundant Testing: \$3 billion

Redundant laboratory and radiology testing account for more than \$8 billion in direct health care costs per year, according to a study in Health Affairs.⁹

With and without Medical Device Interoperability

Redundant testing stems from numerous factors, including “defensive medicine” driven by lack of trust in tests conducted in other institutions and fear of liability, but it is often simply the result of misplaced, delayed or illegible hard-copy test results (Figure 8).

Greater interoperability would allow test results to flow directly into an EHR, eliminating the problem of misplaced or illegible results. Redundant tests due to liability or other hospital policy-related justifications would not be impacted.

Calculations

According to a study in *Quality & Safety in Healthcare*, errors in reporting results to the physician and charting or filing errors made up an estimated 39 percent of testing process errors.²² This was used as a proxy for the share of redundant tests, which could potentially be attributed to lost or illegible information (as opposed to hospital policy, potential liability or other reasons). Assuming 95 percent these issues could be resolved with improved medical device interoperability that allows for pushing data to the EHR and potentially to physicians (using picture archiving and communication systems (PACS) as a proxy, as it provides interoperable digital storage and transmission of medical images and is measured as high as 99 percent effective),^{23, 24} medical device interoperability could create savings of \$3 billion annually, related to avoiding redundant tests from lost information-37 percent of the total costs of redundant testing.

Costs Resulting from Clinician Time Spent Manually Entering Information: \$12.4 billion

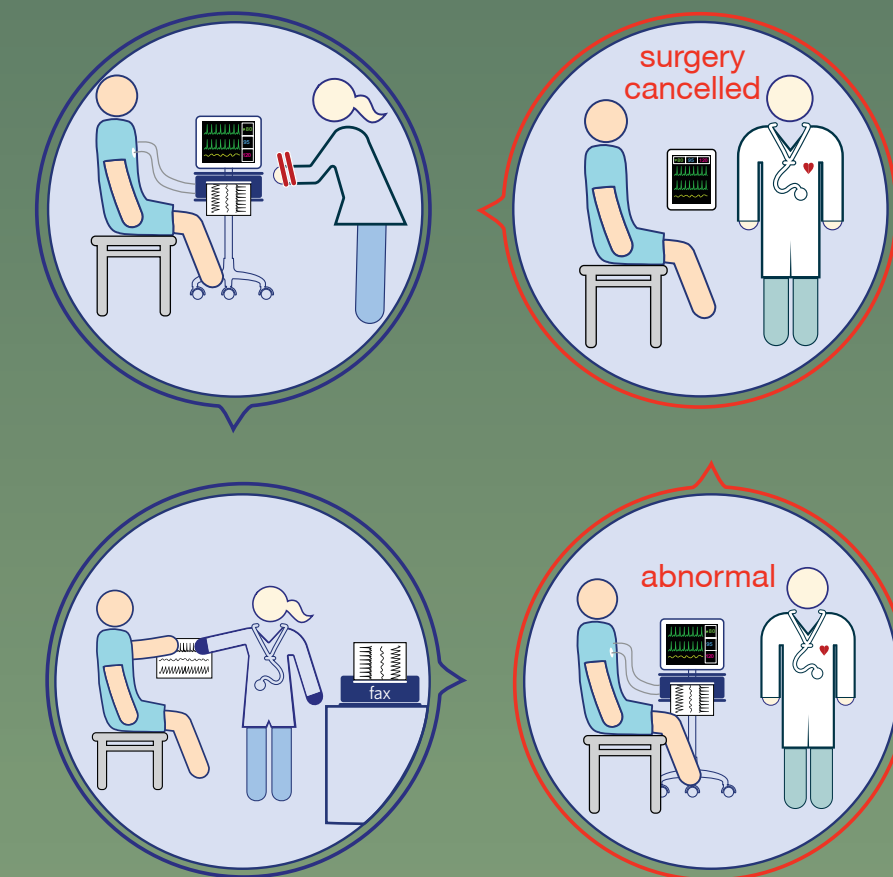
Nurse time is a valuable and scarce resource, with nurse salaries accounting for an estimated \$173 billion in health care spending per year²⁵ and various studies predict a future nursing shortage, resulting from the aging and retiring nurse population and the increasing health care needs of aging baby boomers.²⁶ Through seamless

Figure 8: Case Study: Redundant Testing

Current State:

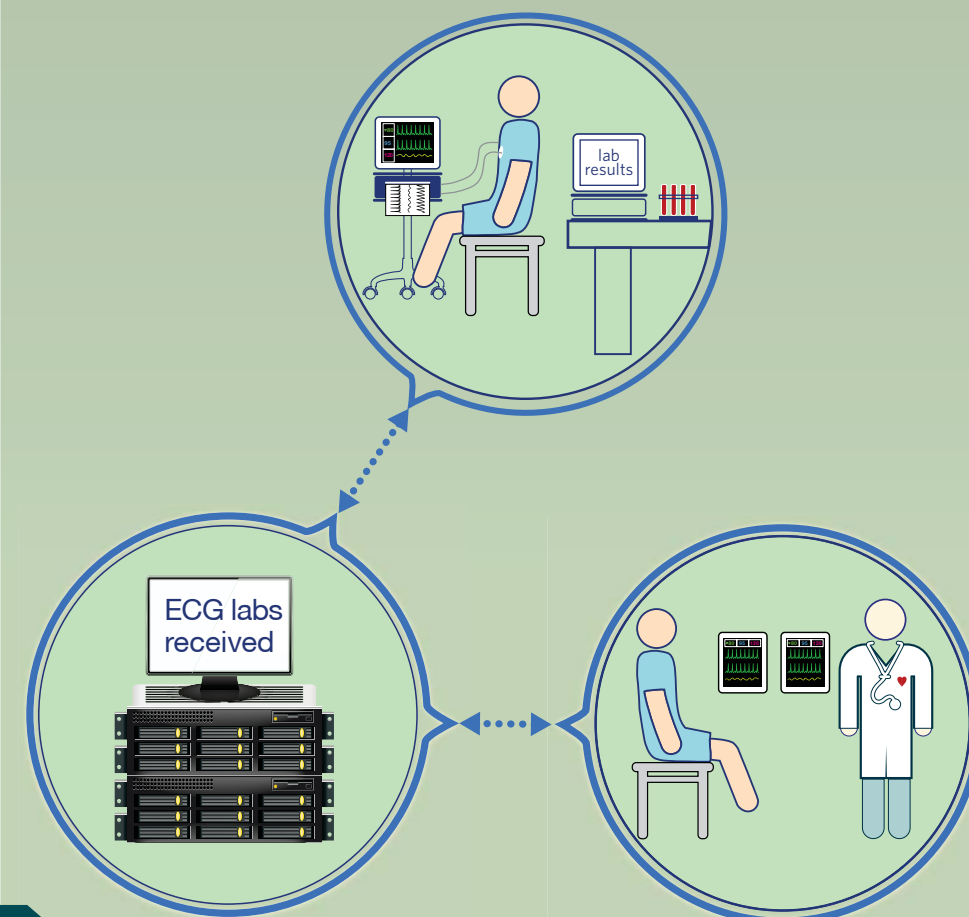
A 50-year-old has **all preadmission testing completed prior to surgery** in an associated outpatient center. **Results are faxed to the pre-admission testing unit and a copy is given to the patient.**

The patient loses the paperwork, and the fax never arrives, **so the patient must have all labs and ECG repeated on the day of surgery. The ECG is abnormal, without the previous version for comparison. The surgery is delayed and finally cancelled** for cardiology evaluation of the abnormality.



Future State:

If lab testing devices populated the EHR directly, information would not be lost. This would avoid repeat testing as well as surgical case cancellation by providing the previous ECG for comparison, allowing the provider to evaluate existing versus new abnormalities.



communication between devices and EHRs, interoperability can reduce the manual verification and documentation activities nurses must currently perform and allow them to use their time more effectively caring for patients.

With and without Medical Device Interoperability

Studies estimate that about 35 percent of a nurse's shift time is spent on documentation.²⁷ A significant proportion of this time is spent simply manually entering vital signs readings onto paper charts or into EHRs. Interoperability eliminates this time by automatically sending readings from devices to EHRs.

Another source of inefficiency is time spent manually programming devices (e.g., infusion pumps), which is a complex, cumbersome process today. Interoperability significantly reduces this time by enabling the automatic population of provider-ordered and pharmacist-validated infusion variables directly into the infusion device.

Calculations

With regards to manually entering vital signs readings, studies on the impact of medical device integration find that it eliminates a significant proportion of documentation time. The literature relied on for this analysis suggested a conservative 20 percent reduction in documentation time.²⁸ When extended across the 1,612,000 registered nurses in U.S. hospitals,²⁹ paid an average of \$106,500 a year,^{30,31} this would amount to **more than \$12 billion in annual savings**.

Regarding manual programming of devices, a study in the *American Journal of Health-System Pharmacy* found that IV interoperability reduced the time to program "smart" infusion pumps by 23 seconds per setup.¹⁵ Extending this over the nearly 750,000 smart pumps estimated to be in use across U.S. hospitals today without EHR integration,³² assuming two pump setups per day, and the same nurse salary used above, this amounted to nearly \$175 million in annual savings (see the Appendix for step-by-step calculations).

In total, widespread interoperability could save nurses' time valued at nearly \$12.3 billion, or 7 percent of total nurse salaries, representing the cost of over 115,000 nurses.

Studies suggest that the nursing shortage (estimated at 135,000 vacancies in 2008)³³ may have temporarily abated due to the economic downturn, but the shortage is likely to return as the economy recovers and more Americans gain health insurance (with estimates predicting a shortage as high as 500,000 nurses by 2025).³⁴ Rather than resulting in staff reductions or avoidance of additional hires, these efficiency gains would likely translate into the ability to serve an increasing volume of patients with the current number of nurses, avoiding a future shortage. It could also allow

hospitals to increase the amount of nurse time devoted to direct patient care, which has been shown by numerous studies to have a positive impact on patient outcomes and could generate potentially larger savings for the system.³⁵

Additional Factors to Consider

The \$12.4 billion value calculated above represents a conservative estimate of the clinician time saved through greater interoperability for several reasons. First, the calculations only examined the impact on nurses' time saved, as this was the impact most widely measured in the clinical literature, but Rausch and Judd suggest that greater interoperability could save time for support staff as well.²⁸

Physicians also waste time collecting information from disparate sources while making rounds. Thus physician time could be saved by consistent and comprehensive presentation of data generated by medical devices. Both physicians and nurses could potentially save additional time from streamlining operating room and other patient safety checklists by automatically populating information from the relevant medical devices. Furthermore, the 20 percent time savings used represents a low estimate of the time savings found in the literature, with several studies finding time savings of 40 percent or more.^{36,37}

It is worthwhile to note that the gains associated with interoperability's effect on nursing time may differ greatly by region, as nurse wages show significant regional variation. Another conservative limitation to the estimate above is its calculations of device programming time looked only at smart pumps, omitting other programmable devices (e.g. ventilators), though given that most devices do not require nearly the same level of programming, the additional impact of this may be relatively small. These several factors suggest that the actual value created in this category could be two to three times as large as that estimated in this analysis.

Costs Resulting from Increased Length of Stay: \$17.8 billion With and without Medical Device Interoperability

Delays in receiving test results hinder decision making, unnecessarily extending the length of ED visits and inpatient hospital stays. Medical device interoperability, by pushing test results to the clinician, would accelerate decision making, reducing length of stay and providing opportunities for "right-sizing" of departments or avoidance of future staff augmentation.

Calculations

Within the ED, the impact on length of stay of reduced test turnaround time due to satellite point-of-care testing was used as a proxy for the impact of greater interoperability, given that interoperability is expected to reduce length of stay

through a similar mechanism – increased speed of test results. A study in the *Archives of Pathology and Laboratory Medicine* found that by decreasing test turnaround time by an average of 87 percent, ED point of care testing decreased length of stay by 41 minutes.³⁸ Extending this across the more than 136 million ED visits per year, each with an average stay of approximately 3.5 hours,³⁹ would result in a total reduction in length of stay equal to more than 26 million additional ED visits eliminated each year. Valuing each visit at an average cost of \$380⁴⁰ would yield **potential savings of nearly \$9.9 billion annually**, or 19 percent of total ED spending.

Hospitals could realize these savings in a variety of ways, such as reducing or repurposing ED resources. Alternatively, given that nearly 3 percent of attempted visitors currently leave without being seen,⁴¹ hospitals might use the additional capacity to better serve this cohort, potentially resulting in increased throughput and revenue of as much as \$1.5 billion, but for the sake of this analysis, the impact was captured as savings.

With regards to inpatient stays, the impact of reduced test turnaround time due to combining computerized physician order entry (CPOE) with electronic medication administration records was used as a proxy for the impact of greater interoperability because it looked at the impact of faster test results on length of stay, this time through the integration of clinical systems. A study in the *Journal of the American Medical Informatics Association* found sizeable reductions in radiology procedure completion and lab result reporting times which resulted in a decrease from 3.91 to 3.71 days in severity-adjusted length of stay in one hospital, and no significant impact in the other.⁴² Using this as a proxy for the impact of medical device interoperability yields an average impact of 0.1 day reduction in length of stay. Extending across more than 39 million annual inpatient stays,⁶ each averaging 4.6 days⁶ and \$9,200 in cost,⁶ yields **estimated reduction in inpatient stays worth \$7.9 billion**, or 2 percent of total inpatient spending.

In total, the value of reduced length of stay due to medical device interoperability comes to \$17.8 billion, or 4 percent of total ED and inpatient costs.

Additional Factors to Consider

In addition to reducing length of stay, the timely transfer of information provided by medical device interoperability would improve the quality of care by enhancing clinical decision-making through the presentation of comprehensive, up-to-date information to clinicians. For example, medical device integration at St. John's Medical Center increased its vital sign charting frequency from every 15 minutes to every five minutes, which helped to improve patient outcomes and overall quality of care.⁴³

Detailed Findings

LACK OF COMMONLY ADOPTED STANDARDS

The preceding section discusses waste in the health care system due to the lack of interoperability - the inability for devices to electronically share data and information with each other and with hospital information systems and to enable clinicians to act upon this information. As discussed in the introduction, the most common solution to addressing these issues today is the development of customized interfaces between devices, as the diverse implementations and limitations of currently adopted standards do not allow “plug-and-play” interoperability. But this lack of commonly adopted standards itself results in further waste, as device manufacturers must incur testing and development costs to facilitate interoperability with a diverse range of systems, and health care providers must, in addition, invest resources to integrate devices with EHRs and other information systems. These costs, in turn, inhibit a move to greater interoperability across the health care system.

Device Development and Testing Costs

In interviews conducted with device manufacturers, estimates of the costs of developing and testing devices to facilitate interoperability with EHRs varied by manufacturer, averaging \$740,000 per device per EHR.⁴⁴ An estimated 235 potentially interoperable devices are approved by the FDA each year,⁴⁵ but interviews with manufacturers suggested that, at most, half of the devices released each year involve additional investments to facilitate interoperability. These assumptions result in an estimated \$87 million in development and testing costs across the industry to achieve interoperability with each EHR vendor. Using the conservative assumption that device manufacturers seek to achieve interoperability with six other systems on average (the top six EHR vendors account for 80 percent of market share,⁴⁶ making them the most likely candidates for interfacing) yields annual industry-wide testing and development costs more than \$520 million today. While adopting standards will include short-term increases in costs, in the longer term, overall industry testing and development related to interoperability would likely decline relative to the expenses incurred today. If vendors only had to achieve interoperability with one common set of standards, these costs could drop to \$87 million, **saving approximately \$430 million in device development and testing costs industry-wide**, or nearly 2 percent of total industry research and development (R&D) spending.⁴⁷

Provider Integration Costs

It is important to note that a substantial proportion of the costs of interoperability are also passed on to providers, with device companies in some cases supporting

interoperability between their device and hospital systems on an as-requested basis. Hospitals spend billions of dollars annually on EHR implementation⁴⁸ and hospital development and integration, a portion of which is invested in achieving medical device interoperability.

Starting with one-time integration costs of \$10,000 per bed per year,⁴ and assuming 7 percent of hospitals integrate devices to EHRs per year (based on the percentage of hospitals moving into advanced stages of EHR adoption each year⁴⁹), and 15 percent annual maintenance costs for the 33 percent of hospitals with a level of current interoperability,³ annual provider investment in interoperability is estimated at \$1.1 billion. Assuming that 66 percent of these costs could be reduced with commonly adopted standards, as hospitals go from using three different sets of interfaces (based on the HIMSS Analytics finding³ that hospitals integrate an average of three types of devices today) to one set of interfaces would yield an [estimate of nearly \\$740 million in potential annual savings](#).

Given the substantial costs of integration, reducing these costs through convergence on common “plug-and-play” standards could greatly accelerate the move to medical device interoperability among providers, much as convergence on the USB standard revolutionized interoperability for computer peripherals and other electronics, with more than six billion USB-enabled products sharing information today.⁵⁰

Who Benefits?

A high-level analysis suggests that the majority of benefits related to increased medical device interoperability and improved adoption of common standards for interoperability may accrue to providers (93 percent), followed by payers (6 percent) and patients (1 percent) (**Figure 9**).

Savings from avoidance of adverse events would accrue in part to providers, payers and patients. While payers and patients typically bear the costs of treatment, payers are increasingly penalizing providers for preventable adverse events by limiting or denying reimbursement. The extent to which each stakeholder bears costs and accrues benefits varies by payer and by type of event (e.g., never events), making it difficult to quantify the precise proportion of savings accruing to each stakeholder. To provide a directional estimate, it was assumed that the benefits are split in half with providers gaining roughly \$500 million. The remaining \$500 million is divided between payers and patients based on the ratio of national health expenditure for each, 85 percent (\$425 million) and 15 percent (\$75 million) respectively.

As with adverse events, reimbursement for redundant testing varies based on payer contracts, and reimbursement trends are moving to deny payment for tests already performed. For reasons similar to those above, providers have been assumed to bear

Figure 9: Savings by Stakeholder

Areas of Waste due to Lack of Medical Device Interoperability	Share of Total (\$ M)			
	Providers	Payers	Patients	Device Vendors
Due to Lack of Medical Device Interoperability				
1. Adverse events avoidable with medical device interoperability	\$1,000	\$850	\$150	
2. Redundant testing resulting from inaccessible information	\$1,500	\$1,275	\$225	
3. Clinician time spent manually entering information	\$12,300			
4. Increased length of stay from delays in information transfer	\$17,800			
Total Savings (\$M)	\$32,600	\$2,125	\$375	\$0
Total Savings (%)	93%	6%	1%	0%

**Note: Numbers rounded for clarity*

Areas of Waste due to Lack of Commonly Adopted Standards	Share of Total (\$ M)			
	Providers	Payers	Patients	Device Vendors
Due to Lack of Medical Device Interoperability				
5. Device testing and development costs				\$430
6. Provider costs to integrate devices with EHRs	\$740			
Total Savings (\$M)	\$740			\$430
Total Savings (%)	63%			37%

half the costs of such testing, and therefore capture 50 percent of the savings. The remaining 50 percent was again allocated to payers and patients based on the ratio of national health expenditure for each.

Savings from decreased length of stay are assumed to accrue entirely to providers, who are typically paid a flat fee for visits regardless of length of stay. Likewise, providers bear the full costs of nurse salaries, and therefore capture the entirety of the savings relating to time wasted manually entering information.

Medical device companies accrue all benefits that may result from the reductions in research and development resulting from common adoption of standards for interoperability, and providers accrue the related reductions in capital and development expenditure and maintenance created by avoiding custom integration solutions.

Additional Benefits Not Quantified

LACK OF MEDICAL DEVICE INTEROPERABILITY

The benefits discussed above form the core case for interoperability, representing benefits that could be realized directly. However, there are a number of additional benefits enabled by interoperability which are more difficult to quantify or require additional enabling factors to be realized.

Greater medical device interoperability could enable rapid advances in clinical decision support, as the continuous flow of patient-specific physiologic information (e.g., vital signs) to data repositories would enable advanced data analytics. This combination of real-time patient data can help to achieve clinical workflow improvements not realizable today and result in improved affordability of medical care, the impact of which cannot be quantified prospectively.

Stakeholders would also see benefits of interoperability when using remote patient monitoring systems with the EHRs, which would facilitate viewing of patient-generated data alongside clinically generated data. Remote patient monitoring has been shown to reduce costs and improve outcomes in a number of studies,⁵¹ and by integrating data into providers' workflow, interoperability could encourage provider adoption and further improve efficacy. Additionally, the interoperable transfer of non-clinical device data (e.g., battery status, need for software updates, device location, etc.) would enable the automation of device maintenance currently managed manually, as well as improve inventory and utilization management.

Patients would benefit through reduced premiums and improved care, as well as improved experiences in the system. First, they will spend less time on medical care, as patient time wasted due to redundant tests, extended length of stay and redirects from overcrowded emergency rooms to available hospitals effectively represents foregone wages. Additionally, preventable adverse events result in not only increased medical costs but also increased mortality. While these are significant sources of value, these productivity and mortality benefits are not typically included in the \$700 billion estimates of waste in the health care system, and therefore have been excluded from this analysis.

Lack of Commonly Adopted Standards

Commonly adopted standards would also create several additional sources of value beyond the savings estimated above. According to interviews with health system engineering experts, the custom interfaces required today pose the risk of a high volume of systematic medical errors if developed incorrectly, and writing and

maintaining these interfaces to a high level of reliability is difficult and expensive for device manufacturers, particularly as the supply of qualified labor becomes increasingly scarce. By reducing the need for custom interfaces, commonly adopted standards would lessen these costs and risks.

Furthermore, the costs of proprietary interfacing with a variety of EHRs and other hospital information systems limits innovation among device manufacturers, particularly smaller players, who lack the scale to recover these fixed interoperability costs. As has been seen in other industries with the adoption of USB and wireless communication standards, commonly adopted standards allow small companies to quickly and efficiently create and bring new technologies to market. This not only lowers the barriers to innovation for small device manufactures and start-up companies, but can also be a major influence in fueling the economic growth.

This increase in innovation and competition would, in turn, allow providers to choose from a broader range of devices and potentially result in reduced prices paid for devices and greater innovation in new devices – benefits difficult to quantify, but repeatedly mentioned by provider interviewees. These benefits would be further bolstered by a reduction in switching costs, compared to the current situation where investments in interoperability with a given vendor's devices create substantial barriers to a hospital buying devices from different vendors in the future.

Conclusion

SUMMARY

This study estimates that **widespread medical device interoperability can eliminate \$36 billion of waste in the health care system**. Functional interoperability leads to increased efficiency, lower costs and better quality of care through four primary drivers: 1) quality improvement through reduction of adverse events due to safety interlocks (**\$1.9 billion**), 2) reduced cost of care secondary to avoidance of redundant testing (**\$1.5 billion**), 3) increased clinician productivity secondary to decreased time spent manually entering information (**\$12 billion**) and 4) increased capacity for treatment secondary to shortening length of stay (**\$18 billion**).

Impact on Efficiency

The reduction in clinician time spent manually entering information allows providers to improve workflow and optimize staffing models. Physicians and nurses can redirect time saved for value-added activities such as direct bedside care, patient education and care coordination. In addition, providers can allocate time to fulfill the requirements established by value-based purchasing and hospital readmissions reduction programs. With an aging population and expansion of insurance coverage

leading to increased demand for services, providers are more prepared to respond to the call to provide better care at a lower cost.

Through timely access to relevant and complete clinical information, medical device interoperability can shorten length of stay and create additional capacity without an increase in cost. Shorter length of stay is attained by improving the quality of care for existing patients. Increased capacity creates an opportunity for providers to right-size their departments, achieve appropriate bed utilization and management metrics and expand access to care for patients not currently being served in the system.

Impact on Costs and Quality

Interoperability drives direct cost savings by decreasing the number of procedures completed through avoidance of redundant testing and adverse events. The “data push” capabilities enabled by functional interoperability will help overcome the latency or inaccuracy of reporting test results that often result in redundant testing today. A reduction in adverse events driven by safety interlocks enabled by interoperability also results in direct savings by removing the cost of care associated with treating patients who experience these events. The distribution of these cost savings will depend on the contracts established between payers, providers and patients.

A system-wide improvement in quality of care is achieved through automation of processes and reduction of the number of opportunities for human error. Adverse events decline as clinical work flow is simplified and the number of steps to diagnose and treat a patient is reduced. Avoiding redundant testing also improves the patient experience and overall quality of care by reducing the number of procedures a patient must endure and the time the patient spends in the system.

Limitations and Areas for Further Research

This analysis was undertaken to estimate the magnitude of potential health care delivery cost savings resulting from the availability and widespread adoption of true, functional medical device interoperability. As there are few examples of such plug-and-play interoperability, a variety of assumptions and extrapolations from surrogate circumstances were employed, referenced as appropriate to guide the reader. Nonetheless, the nature of this work does not afford absolute precision, but rather an order-of-magnitude estimate. Additionally, the current cost of achieving medical device interoperability and, in turn, the potential savings from common adoption of standards are less certain than the estimates of waste addressed by interoperability itself. There is limited research available on the costs of provider integration and limited consensus from stakeholders on the proportion

of device development and testing costs and provider integration costs that would be eliminated with commonly adopted standards. This remains an important area for further research, as the substantial costs of achieving interoperability represent a significant barrier to realizing the efficiency, cost and quality benefits detailed above. Experience in other industries suggests that commonly adopted standards would indeed have the desired impact of accelerating adoption and potentially reducing costs of integration, and this should be further examined as a potential solution for medical device interoperability.

Call to Action

Given the opportunity to improve patient care and reduce health care spending by more than \$30 billion per annum, the question that follows is how to drive a shift from the current state with a lack of widespread medical device interoperability to a fully networked health care system where the substantial benefits of interoperability can be realized.

Current Efforts towards Increased Interoperability

A number of organizations are working to further medical device interoperability in the clinical environment by promoting various means of standardization. However, no single effort has reached critical levels of adoption. One approach, developing prescribed profiles to facilitate consistent implementation of communication standards, is being led by Integrating the Healthcare Enterprise (IHE), a broad initiative of health care and health information technology stakeholders. This group creates profiles based on existing standards bodies such as IEEE and HL7. The North American branch of IHE facilitates an annual connect-a-thon to validate profiles and hosts a number of demonstrations through an Interoperability Showcase at the HIMSS national meeting. Other efforts include the Medical Device “Plug-and-Play” (MD PnP) Interoperability Program, which has “been working to accelerate the adoption of medical device interoperability by providing interoperability building blocks (use cases, standards, a neutral lab environment and open research tools) and by changing clinical and market expectations of what can be achieved.”⁵² Most recently, the *Association for the Advancement of Medical Instrumentation* (AAMI) announced a partnership with the testing, certification and standards development organization Underwriters Laboratories (UL) to develop a suite of standards on medical device interoperability, aiming “not to supplant existing standards or profiles,” but rather “to map them into a framework and address further safety issues where applicable.”⁵³

In the consumer medical device realm, the Continua Health Alliance is promoting the adoption of common standards for interoperability. Meanwhile, a number of consumer-driven medical device companies are taking a market-wide approach to interoperability through the use of Application Programming Interfaces (APIs),

with companies such as Fitbit using APIs to share data between activity sensors, smartphones, computers and applications. The clinical device sector has seen limited application of this type of approach. Additionally, in the clinical medical device realm, purchasing behavior of providers has yet to require this level of “plug-and-play” interoperability now common among consumer electronics. There are several efforts that provide requirements guidance for medical device interoperability. For example, Medical Device “Free Interoperability Requirements for the Enterprise” (MD FIRE)⁵² comprises a white paper and sample RFP and contracting language. The IHE Patient Care Device User Handbook also describes how and why to acquire and implement systems and devices for device interaction. However, these efforts and efforts by many individual hospital systems have yet to be utilized on a broad scale. While consumers quickly drive technology to common standards for ease of use and rapid adoption, hospitals have yet to share a common voice related to requirements for medical device interoperability.

Who Will Lead the Way?

Despite the numerous activities promoting standardization for medical device interoperability, no common approach has been adopted widely. The value proposition presented above suggests that it is unlikely medical device and IT companies will proactively move towards standardized “plug-and-play” device interoperability, and that providers may have the most significant burning platform for promoting medical device interoperability as a solution to the efficiency, capacity and cost issues they are currently facing, supported by pressure from payers changing to more value-based payment models.

Device Manufacturers

In order to drive rapid adoption of medical device interoperability, incentives for device companies, who will bear the cost to develop the capability within devices, must be aligned with those of the remaining health care stakeholders, who reap the benefits of increased interoperability and adoption of standards. Discussions with medical device industry leaders highlight the fact that although technology to generally enable interoperability exists, market forces today do not create the aligned incentives to produce devices with consistent modes for interoperability.

As discussed previously, device manufacturers are unlikely to see substantial benefits from either increased interoperability or commonly adopted standards. The latter would likely be viewed as diminishing the competitive advantage of large companies who currently tout integration among their own closed system of devices as a benefit of purchasing their bundled device solutions. Moreover, interviewees expressed concerns that the development and testing costs involved in moving to consistent industry-wide standards would be substantial in the short-term relative to the longer-term gains in development costs avoided through convergence on standards. As

a result, device manufacturers may not have strong incentives to organically lead the charge towards common adoption of open, plug-and-play interoperability standards until their customers – health care providers – coordinate to provide clear requirements consistently, perhaps even fully integrated with their procurement processes.

Providers

Providers accrue the vast majority of benefit from medical device interoperability at \$33 billion, or 93 percent of the total, primarily due to productivity gains from improved workflow. However, few, if any, providers have achieved functional interoperability, and those that have typically created customized closed systems that are not scalable solutions for the rest of the industry. A *2010 HIMSS Analytics* study suggests that more than two-thirds of providers have entirely forgone the investment required to obtain any level of benefits from functional interoperability to date.³

Interviews indicated that the benefits of interoperability are not well documented and are currently superseded by other decision-making criteria, such as current regulation and limited budgets for competing projects. Many providers are currently most concerned with meeting the immediate, Stage 1, requirements for Meaningful Use of EHRs, incentivized by deadlines for funding from the Centers for Medicare and Medicaid Services (CMS). Stage 1 requirements create minimal standards for sharing selected and prescribed information among stakeholders – an important first step, but a far cry from the interoperability requirements needed to realize the benefits detailed above. Based on the recent Stage 2 requirements and proposals for Stage 3, Meaningful Use is missing an opportunity to advance medical device interoperability. Although Meaningful Use requirements can establish important prerequisites for collecting device information, they do not currently drive functional medical device interoperability.

Aside from their current focus on basic Meaningful Use, an additional challenge for providers is that they too could incur an appreciable investment of resources to build the infrastructure and replace legacy medical devices to demonstrate interoperability. However, as identified above, the productivity gains and cost savings created by the improved workflow facilitated by medical device interoperability can create a substantial return on these investments.

To realize these returns, providers need support of technology and device companies to address the workflow integration, as well as financial incentives to prioritize interoperability over other investments. If providers begin to consistently require interoperability as a key component in request for proposals (RFPs) for new equipment, they can steer the device and technology industries to resolve the workflow needs and adopt more standard means for implementation of interoperability. This would require increased coordination and collaboration among the various parties currently focused on developing standards and guidelines for

interoperability. Additionally, a continued shift toward capitation models by payers will put pressure on providers to aggressively manage limited resources and create a sense of urgency around investments that can improve productivity, such as medical device interoperability.

Payers and Government

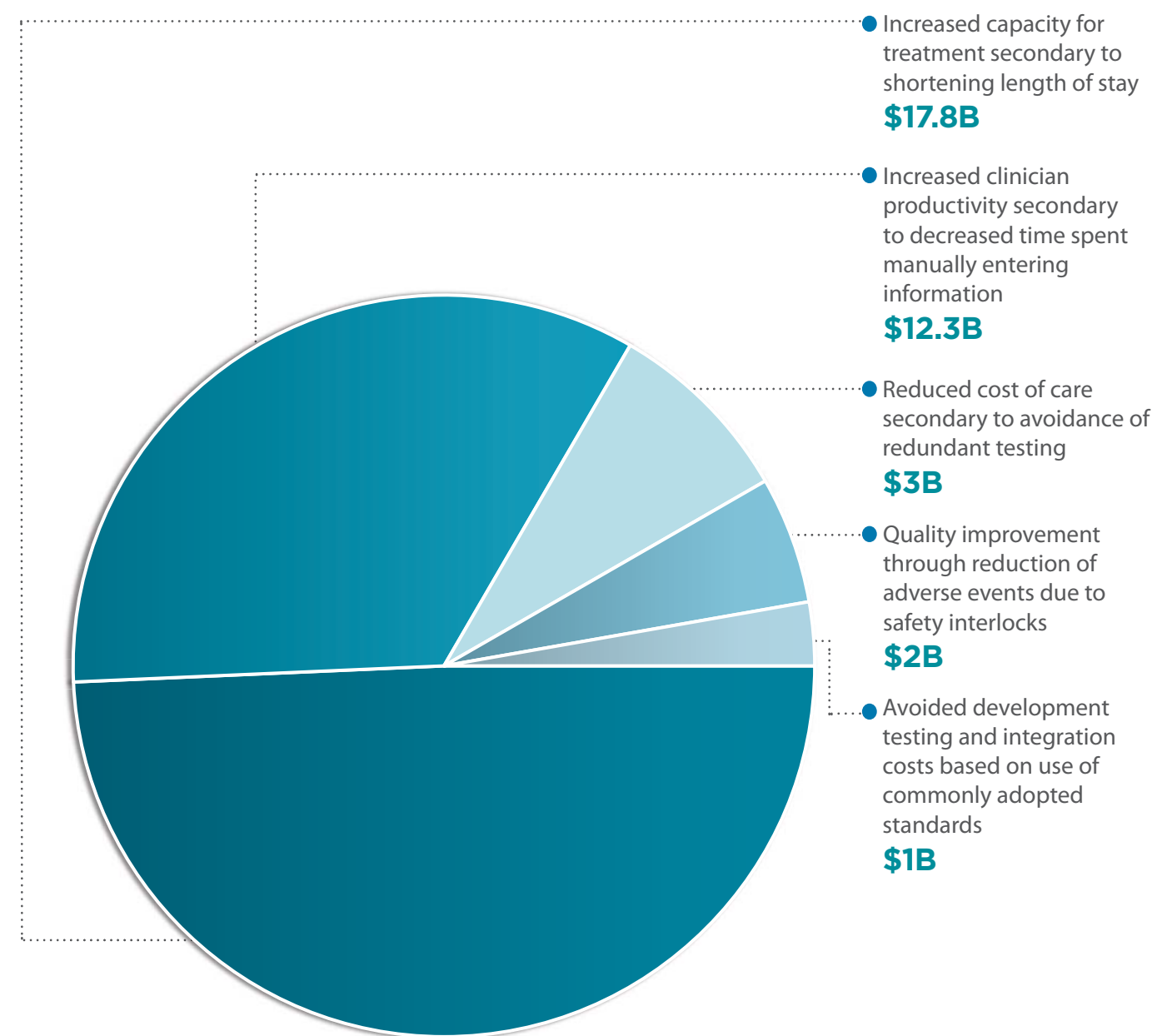
Payers and the government (both in its role as a payer through Medicaid and Medicare and more broadly in its position as a regulator with the responsibility to address market failures) are also poised to influence the speed of medical device interoperability. While the analysis in this paper suggests that payers capture a much smaller proportion of benefits from interoperability than providers, payers will secondarily benefit from the reduced cost of services and improved health outcomes associated with the efficiency gains of providers. Additionally, many of the benefits not quantified in this analysis, such as improved adoption and efficacy from remote patient monitoring and the ability for advanced data analytics would result in reduced costs to payers. A continued shift in the payment system from fee-for-service to capitation or other value-based approaches will accelerate the need for providers to improve workflow to achieve better outcomes with fewer resources.

The federal government is already taking steps to incentivize greater interoperability. Broadening Meaningful Use requirements to incorporate functional medical device interoperability could play a crucial role in driving greater interoperability throughout the health care system; however, it would be about five years before this incentive took effect. Government and private payer reimbursement practices will need to be primary drivers to promote provider implementation of medical device interoperability in order for the system to more rapidly realize the savings estimated in this report, similar to how future payments to providers will be tied to complying with Meaningful Use, readmission and other emerging performance standards.

The continued convergence of payers and providers will create a strong platform for accelerating medical device interoperability. Accountable Care Organizations (ACOs), for example, could be a driver of medical device interoperability, given their need to achieve cost savings while integrating large and disparate networks across EHRs and HIEs. Although ACO participation is currently low, with only 13 percent of hospitals reporting current participation in an ACO or plans to do so within a year according to the Commonwealth Fund, other models of care coordination and collaboration for improved population health management will drive similar needs for the efficiency and quality improvements that can be provided by medical device interoperability.⁵⁴

Coupling this convergence with the systemic capacity challenges providers already face due to increasing demands on the system from 30 million new consumers entering the health insurance market, a rapidly aging population and predicted clinician shortages, providers are finding themselves on a burning platform that requires them to do more with less. This creates a strong case to redirect investment toward medical device interoperability due to its significant impact on clinician productivity and cost reduction.

Breakdown of Estimated Benefits from Medical Device Interoperability



Appendix

DETAILED CALCULATIONS

Lack of Interoperability

Adverse Events: Drug Errors

	Metric	Value	Notes
	Value of adverse event costs attributable to drug errors (\$K)	\$3,800,000	[9]
x	% of drug errors due to ordering errors	39%	[11]
x	% preventable by interoperability	47%	[12]
=	[A] Value of reduced ordering-related adverse events (\$K)	\$702,000	
	Value of adverse event costs attributable to drug errors (\$K)	\$3,800,000	[9]
x	% of drug errors due to transcription errors	12%	[11]
x	% preventable by interoperability	75%	[11] [13]
=	[B] Value of reduced transcription-related adverse events (\$K)	\$342,000	
	Value of adverse event costs attributable to drug errors (\$K)	\$3,800,000	Calculated above
x	% of drug errors due to administration errors	38%	[11]
x	% due to intravenous medications	60%	[14]
x	% preventable by integrated infusion pumps	32%	[15]
=	[C] Value of reduced administration-related adverse events (\$K)	\$277,248	
	[A] + [B] + [C] = Total potential drug error-related savings from interoperability (\$K)	\$1,321,248	

Blue numbers indicate inputs

Adverse Events: Diagnostics Errors

	Metric	Value	Notes
	Total cost of preventable adverse events (\$K)	\$16,600,000	[9]
x	% of adverse events due to diagnostic errors	17%	[10]
=	Value of adverse event costs attributable to diagnostic errors (\$K)	\$2,884,050	
x	% of diagnostic errors addressable by device interoperability	17%	[16]
=	Potential diagnostic error-related savings from interoperability (\$K)	\$465,630	

Blue numbers indicate inputs

Adverse Events: Failure to Prevent Injury

Ventilator-Associated Pneumonia

	Metric	Value	Notes
	Total annual cost of ventilator-associated pneumonia (\$K)	\$1,140,000	Estimates range from \$780M to \$1.5B; midpoint used [18]
x	Reduction in ventilator-associated pneumonia due to bundle of interventions	57%	Ventilator-assisted pneumonia reduced from 7.5 to 3.2 per 1000 ventilator days [17]
x	% attributable to device interoperability	25%	Based on industry interviews
=	Potential ventilator associated pneumonia savings from interoperability (\$K)	\$163,400	

Blue numbers indicate inputs

Postoperative Shock

	Metric	Value	Notes
	Total number of postoperative shock incidents caused by errors annually	748	[9]
x	Medical cost per error (\$K)	47	Mortality cost per error (\$46,584) not included [9]
=	Total medical cost of postoperative shock errors (\$K)	\$35,230	Based on industry interviews
x	% Reduction due to device interoperability	65%	Continuous pulse ox surveillance reduced "rescue events" from 3.4 to 1.2 per 1000 patient discharges [19]
=	Potential postoperative shock-related savings from interoperability (\$K)	\$22,796	

Blue numbers indicate inputs

Redundant Testing

	Metric	Value	Notes
	Direct costs of redundant tests in U.S. hospitals (\$K)	\$8,172,000	[9]
x	% of duplicative tests due to lost information	39%	14.5% of testing process errors due to charting or filing errors; 24.6% due to failure to report results to physicians [22]
x	% avoided due to interoperability	95%	99% number from [23] corroborated by qualitative commentary in [24]. 95% value used to be conservative
=	Potential cost saved by medical device interoperability (\$K)	\$3,035,489	

Blue numbers indicate inputs

Wasted Clinician Time Manually Entering Vital Signs Readings

	Metric	Value	Notes
%	of time spent on documentation	35%	Assumed to be constant for hospitals with and without EHRs (studies find varying effects) [27]
x	Average annual salary for nurse	\$106,500	\$50/hour total compensation for hospital RNs [31], x 2130 hrs worked/year [30]
x	Total number of registered nurses (RNs) in U.S. hospitals	1,612,000	2.6M licensed RNs employed in nursing, 62% of those work in hospitals [29]
=	Total value of nurse time spent on documentation per year (\$K)	\$60,602,334	
x	% of time saved due to interoperability	20%	[28]
=	Total potential annual savings in nurse salaries (\$K)	\$12,120,467	

Blue numbers indicate inputs

Manually Programming Devices

	Metric	Value	Notes
	Reduction in programming time per smart pump setup (min)	0.4	23 seconds per setup [5]
x	Number of infusion setups per smart pump per year	730	Assumption - 2 readings/day x 365 days/yr
=	Hours saved in setups per smart pump per year	5	
x	Number of smart pumps in use across U.S.	805,560	5,754 U.S. hospitals [] x 50% using smart pumps x 280/hospital [3]
x	% of hospitals not interfacing smart pump with EHR today	93%	[3]
=	Hours saved in pump setups across U.S. per year	3,497,806	
x	Average hourly salary for nurse	\$50	[31]
=	Total potential annual savings in nurse salaries (\$K)	\$174,890	

Blue numbers indicate inputs

Increased Length of Stay Emergency Department

	Metric	Value	Notes
	Total number of ED visits	136,072,000	[39]
x	Reduction in ED time (hours)	0.68	[38]
=	Maximum hours of ED time gained	92,982,533	
/	Average length of ED visit (hours)	3.5	[39]
=	Number of ED visits saved	26,266,252	
x	Average cost of ED visit	\$380	\$52B total ED expenses and 136M visits [40]
=	Value of ED visits reduced (\$K)	\$9,883,046	

Blue numbers indicate inputs

Inpatient

	Metric	Value	Notes
	Total inpatient stays	39,400,000	[6]
x	Reduction in length of stay (days)	0.1	[42]
=	Total days of inpatient time gained	3,940,000	
/	Average length of inpatient stay (days)	4.6	[6]
=	Number of inpatient stays saved	856,522	
x	Average cost per inpatient stay	\$9,000	[6]
x	Value of inpatient stays reduced (\$K)	\$7,880,000	

Blue numbers indicate inputs

Lack of Commonly Adopted Standards Device Development and Testing Costs

Metric	Value	Notes
Testing and development costs per EMR interface, per device (\$K)	\$740	Estimates from vendor interviews ranged from \$350K to \$1.2M; midpoint used
x # of potentially interoperable devices developed per year, industry-wide	235	Based on FDA 510k approvals data
x % of devices with interoperability-related development	50%	Based on vendor interviews
= Costs per EMR interface (industry-wide) (\$K)	\$86,827	
x Average # of EMR interfaces required today (per device)	6	[46]
= [A] Total testing and development costs today (\$K)	\$520,960	
Costs per EMR interface (industry-wide) (\$K)	\$86,827	From line 4 above
x Average # of EMR interfaces required in future state	1	Based on vendor interviews
= [B] Total testing and dev. costs in future state (\$K)	\$86,827	
[A] - [B] = Savings on testing and dev. costs (\$K)	\$434,133	

Blue numbers indicate inputs

Provider Integration Costs

Metric	Value	Notes
One-time integration cost to EMR, per bed (\$K)	\$10	[4]
x Average number of staffed beds nationwide per hospital	164	[55]
= Average integration costs per hospital (\$K)	\$1,637	
x Number of hospitals nationwide	5,754	[55]
x % with integrated devices (installed base)	33%	[3]
x Annual maintenance as % of one-time integration	15%	Industry standard, based on interviews
= [A] Annual maintenance costs nationwide (\$K)	\$466,288	Calculated
Average integration costs per hospital (\$K)	\$1,637	From above
x Number of hospitals nationwide	5,754	From above
x % of hospitals integrating devices to EMR per year	7%	[49]
= [B] Annual one-time costs nationwide (\$K)	\$649,977	Calculated
[A] + [B] = Estimated total integration spending (\$K)	\$1,116,264	Calculated
x Share reduced by implementation of common standards	66%	Standardized from
= Total potential savings (\$K)	\$736,734	3 to 1 interfaces (average number of integrated devices today is 3, according to [3])

Blue numbers indicate inputs

Notes

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