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Aaron Kearsley*, Nellie Lew and Clark Nardinelli

A Retrospective and Commentary on FDA's Bar Code Rule

Abstract: Food and Drug Administration (FDA) published a final regulation in 2004 that requires pharmaceutical manufacturers to place linear bar codes on certain human drug and biological products. The intent was that bar codes would be part of a system where healthcare professionals would use bar code scanning equipment and software to electronically verify against a patient's medication regimen that the correct medication is being given to the patient before it is administered, which could ultimately reduce medication errors. In the 2004 prospective regulatory impact analysis, FDA anticipated that the rule would stimulate widespread adoption of bar code medication administration technology among hospitals and other facilities, thereby generating public health benefits in the form of averted medication errors. FDA estimated that annualized net benefits would be $5.3 billion. In this retrospective analysis, we reassess the costs and benefits of the bar code rule and our original model and assumptions. Employing the most recent data available on actual adoption rates of bar code medication administration technology since 2004 and other key determinants of the costs and benefits, we examine the impacts of the bar code rule since its implementation and identify approaches to improve the accuracy of future analyses. In this retrospective study, we use alternative models of health information technology diffusion to create counterfactual scenarios against which we compare the benefits and costs of the bar code rule. The magnitudes of the costs and benefits of the 2004 rule are sensitive to assumptions about the counterfactual technology adoption rate, with the upper-bound range of calculated annualized net benefits between $2.7 billion and $6.6 billion depending on the baseline scenario considered.

Disclaimer: The findings, interpretations, and conclusions expressed in this article are those of the authors in their private capacities, and they do not represent the views of the Food and Drug Administration.

***Corresponding author: Aaron Kearsley,** U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, Maryland, United States, 20993, e-mail: aaron.kearsley@fda.hhs.gov
Nellie Lew: U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, Maryland, United States, 20993, e-mail: nellie.lew@fda.hhs.gov
Clark Nardinelli: U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, Maryland, United States, 20993, e-mail: clark.nardinelli@fda.hhs.gov

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JEL classifications: I18; L51.

1 Introduction

In 2000, an Institute of Medicine (IOM) report, *To Err Is Human*, concluded that between 44,000 and 98,000 deaths occur annually in U.S. hospitals from preventable medical errors, including medication errors. The report identified medication errors as the most common type of error in health care. A correct medication event should involve the right drug, in the right dose, via the right route of administration, given to the right patient at the right time. A failure of one or more of these five "rights" could lead to adverse reactions, possibly including the patient's death. In response to the report, health care policy makers and professionals proposed many reforms and new practices to reduce errors, including accreditation, enhanced reporting, workforce training, and health information technology. The proposed technology that directly affected safety was the use of bar codes to administer drugs to patients.

While barcoding technology has its applications in inventory and supply chain management, bar code medication administration is an application of health information technology designed to prevent medication errors that occur during the dispensing and administration stages. This technology, also known as bedside bar code administration, is a system in which before administering medication healthcare professionals use handheld devices to scan machine-readable bar codes on a patient's identification bracelet and on a drug label to electronically verify against a patient's electronic medication record that the correct medication is being given.

Despite its potential to improve the quality of care, adoption of bar code technology was slower than anticipated. As with other types of health information technology, bar code medication administration requires investments in equipment, infrastructure, and training. Specifically, a bar code medication administration system requires bar code printers, personal digital assistants, wireless computing server technology, and software. In addition, it also requires that drug packages be labeled with a machine-readable bar code bearing identifying information.

In support of initiatives to encourage adoption of bar code medication administration as a means of reducing the number of medication administration errors, the Food and Drug Administration (FDA) issued a final regulation in 2004 that requires pharmaceutical manufacturers to place linear bar codes on certain human drug and

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biological products (Federal Register, 2004). Linear bar codes were required no later than 60 days after approval or April 26, 2006 – whichever was later – to appear on commercial product packages and unit-dose blister packages sold to hospitals and to contain the drug's National Drug Code (NDC) number, which represents the product's identifying information. By requiring commercial drug product packages and unit-dose blister packages to carry linear bar code labels, FDA anticipated that the rule would stimulate widespread voluntary adoption of bar code medication administration technology among hospitals and other facilities, thereby generating public health benefits in the form of averted medication errors.

FDA estimated the benefits and costs of its bar code requirement before issuing the rule; the key to the prospective estimate of the effects of the bar code rule was its forecast of the adoption of bar code medication administration in response to the rule. The rule requires drug labels to have bar codes but does not require hospitals to use them to administer drugs, so much of the rule's estimated benefits and costs depended on how much the rule would influence hospital investments in barcoding technology. In the years that have elapsed since the bar code rule became final, bar code technology uptake was slower than FDA predicted in 2004. For example, the regulatory impact analysis (RIA) predicted over 50% adoption by 2008 and over 90% adoption by 2010; however, survey data revealed these thresholds were not met until 2011 and 2015 (Pedersen, Schneider & Schekelhoff, 2012 and 2016). In this retrospective analysis, we recalculate the costs and benefits of the rule in light of the new data on adoption and use of bar code medication administration. We estimate that the slower adoption rate would reduce the estimated net benefits from $5.3 billion in the 2004 RIA to $2.7 billion.

In addition to using FDA's ex ante baseline, we consider alternative baselines for uptake without the rule to reassess the rule's costs and benefits. We also review and update key inputs in light of more recently available published estimates, with a focus on developing plausible bounds on the estimated impact of the rule on hospital adoption of bar code medication administration.

While new health care technologies may lead to improved outcomes, they may also increase costs. The original benefit-cost analysis (BCA) attempted to include all the benefits and costs but some costs and benefits were missed. Including all the benefits and costs matters because in predicting the impact on adoption, it is important to recognize that hospitals will only adopt the technology if it is profitable from their perspective; that is, if the revenues exceed the costs of adoption, adoption will occur. Key to estimating the effect of the rule on technology adoption is to consider the mechanisms through which the rule would change either side of that equation. This exercise is challenging because the profitability of bar code

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medication administration is highly variable and heterogeneous across hospitals, with potentially fewer gains for smaller hospitals.

Because the rule requires manufacturers to place bar codes on the unit-dose packages, a direct effect of the rule is to reduce the overall cost of adoption from the hospital perspective. However, the labeling costs from the hospital's perspective associated with bar code medication administration adoption are small compared with the overall potential start-up and ongoing costs of capital and labor. Additionally, as noted by Barlas (2012), "[a]lmost every hospital in the U.S. has a drug-repackaging operation, either in-house or in a separate location, or it contracts with an outside repackager." So, cost savings likely only explain a small portion of the adoption rate. Furthermore, hospitals may have borne some or all of the costs for updating labeling from manufacturers in the form of higher prices. While our estimates of the total cost would remain the same, there may be distributional effects associated with cost pass-through that we have not explored.

Another potential mechanism through which it may affect technology adoption decisions is that the rule specifies the bar code must be in linear format. There are potential cost savings associated with a national standardized format and coding for drugs. This uniformity also likely reduced hospitals' uncertainty over the range of possible industry standards that could have arisen without the Bar Code Rule, such as alternative symbols on the labels. The rule made it safer to invest in technology systems with linear bar code scanners.

Given limitations in the available data, the focus of this retrospective BCA will be to reassess a key input – the impact of the rule on hospital adoption of bar code medication administration. While we have data on actual adoption of bar code medication administration following implementation of the rule, it is still difficult to determine the counterfactual adoption rate. Even from a retrospective standpoint, the challenge remains in isolating the effect of the rule on adoption rates from numerous confounders that may have contributed to the adoption. For example, hospital bar code systems are now frequently bundled with other technology including electronic health records. Changes in reimbursement rates for hospitals that utilize bar code technology may also have contributed to widespread adoption. We therefore explore a variety of counterfactual scenarios and discuss the assumptions and findings for each. Despite the empirical challenges with isolating the effect of the bar code rule when there are likely many other initiatives encouraging adoption of the technology occurring in parallel, it is instructive to evaluate the effectiveness of a policy after implementation as part of the regulatory review process.

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2 FDA's prospective regulatory impact analysis

In 2004, FDA estimated the regulation's effect on pharmaceutical and biologics manufacturers, hospitals, and patients. Because the final regulation required manufacturers to add linear bar codes to commercial product packages that lacked them and to the unit-dose blister packages sold to hospitals, manufacturers were estimated to incur costs ranging from five hundred to several thousand dollars per stock-keeping unit (SKU) to revise artwork, discard old label inventory and perform other compliance-related actions. Based on a report by ERG (2003), FDA estimated the total cost to manufacturers to be $48.0 million upfront and $630,000 per subsequent year (in 2004 dollars), which would be $59.1 million and $775,977 in 2015 dollars (all inflation calculations apply values from the Bureau of Economic Analysis, 2016).

The 2004 Bar Code Rule does not require that hospitals use bar codes on drug labels; however, FDA expected the bar code requirement to lead to changes in medication administration in hospitals and other health care facilities. Indeed, the principal purpose of the required labeling was to encourage use of bar code readers by requiring bar codes on labels. The largest costs of the rule, as well as its public health benefits, were therefore associated with new adoptions of bar code technology to administer medicines. Specifically, hospitals implementing bar code medication administration would need to purchase personal digital assistants with scanners for use by nurses and would also need to install wireless server computer technology throughout their facilities; they would also experience substantial nursing productivity losses, at least in the short run, as learning the new technology takes time. FDA estimated that a typical hospital adopting the technology would incur an initial cost of $448,000 (or $552,000 in 2015 dollars). Additionally, adopters would face annually recurring costs of $556,000 (or $685,000 in 2015 dollars), which captures operating and maintenance expenses, as well as productivity losses. These hospital costs could be partly offset by efficiency improvements, such as those generated by the automatic creation of medication administration records. However, the costs of acquiring bedside bar code scanners far outstripped the direct savings from reduced unit-dose labeling. ERG (2003) estimated these savings at about $11 million, or about $3,000 per hospital in 2015 dollars.

Meanwhile, any rule-induced adoption of bar code medication administration would have improved health care outcomes by reducing adverse drug events (ADEs) and acute hemolytic transfusion reactions (AHTRs) associated with medication errors and transfusion errors in hospitals. The 2004 Final Regulatory Impact Analysis (FRIA) included an estimate of the value of the resulting life years saved and pain and disability avoided. To summarize the 2004 FRIA's estimates, the

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rule was expected to result in 501,294 fewer ADEs and 693 fewer AHTRs over a 20-year period, with a weighted average value per avoided ADE of $185,800 and AHTR of $103,500 ($221,727 and $119,832 in 2015 dollars, respectively). These valuations explicitly relied on a Value of Statistical Life of $5 million (or $6.2 million in 2015 dollars).[1] The annualized value of these improvements to public health over the implementation period was estimated at $4.9 billion using a 3% discount rate or $5.2 billion using a 7% discount rate, both reported in 2004 dollars. In 2015 dollars, this amounts to $6.0 billion and $6.4 billion under the two discount-rate scenarios.

In summary, the FDA projected that bar code medication administration would diffuse to 100% of U.S. hospitals within ten years in the presence of the rule, as opposed to 100% diffusion over twenty years in the absence of the rule. This acceleration of adoption would generate both benefits and costs in the intervening years, with annualized net benefits to society totaling $4.3 billion (with a 3% discount rate) or $4.5 billion (with a 7% discount rate), both reported in 2004 dollars. These net benefits are approximately $5.3 billion and $5.5 billion in 2015 dollars. Note that the bulk of the cost and benefit estimates described above depended not on manufacturer's direct adherence to the bar code rule but on the effect of the rule on hospital technology adoption.

3 The impact of the bar code rule on bar code technology adoption

As described earlier, one of the key parameters affecting the cost and benefit calculation in the original regulatory impact analysis is hospitals' voluntary adoption rate of bar code medication administration. The ability of bar codes to reduce medication errors depends on the ability of hospitals to scan and use the bar codes. At the time the RIA was drafted, FDA was tasked with determining a baseline adoption rate without the bar code rule and an adoption rate under the rule. The forecasts that the FDA used the in the 2004 prospective analysis (*Federal Register*, 2004) and the actual historical experience are depicted in Figure 1. The line labeled "Actual" reflects data from ASHP's National Survey of Pharmacy Practice in Hospital Settings (Pedersen et al., 2001–2017), with responses from hundreds of hospitals. The original forecast and baseline are labeled "ERG No Rule" and "ERG With Rule," since the FDA forecasts relied on a study prepared by Eastern Research Group, Inc.

1 As of May, 2015, the FDA uses a mean value of $9.5 million as its estimate of the Value of Statistical Life, with low and high estimates of $4.4 million and $14.5 million.

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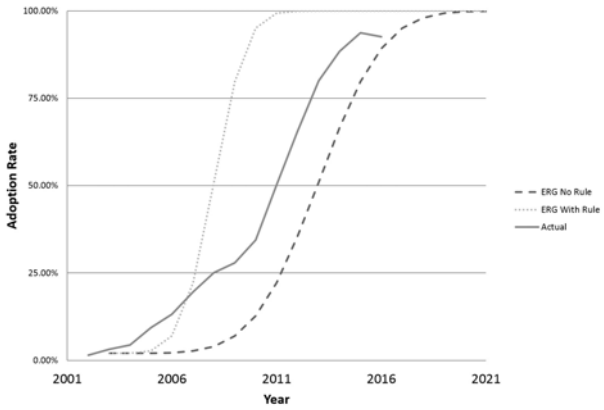


Figure 1 Adoption rate forecasts.

(ERG, 2003). The original FDA analysis, this retrospective, and the ASHP survey data all exclude federal hospitals.[2]

Note that the data show that, beginning in 2007, bar code medication administration adoption occurred more slowly than the with-rule forecast beginning in 2007. A second observation from Figure 1 is that, while adoption occurred slower than expected under the rule, bar code medication administration adoption has exceeded the "without-rule" baseline. In other words, the original projections were in retrospect overly optimistic. As a direct consequence, the predicted costs and benefits of the rule estimated in the original RIA are both overstated, even if all bar code adoption above the baseline can be attributed to the rule.

Of course, multiple factors beyond the 2004 rule influenced the adoption of bar codes, including the adoption of technology and the potential bundling of bar codes with other electronic health care technology. The bar code rule could have represented the tipping point that led to adoption, but was not the stand-alone explanation.

Although the FDA clearly overestimated the overall hospital adoption of bar code technology, there is more to investigate. If the original counterfactual adoption forecast was correct, then we can conclude the FDA overestimated the incremental effect of the FDA's bar code rule. Another possibility is that the FDA got the original counterfactual wrong. If the incremental effect of the bar code rule was estimated correctly relative to an incorrect baseline, then the final forecasted

2 We note that the exclusion of federal hospital, such as the Veterans Affairs (VA), is unlikely to impact our assessment of the incremental effect of the bar code rule because the VA hospital system was an early adopter of the technology in the 1990s prior to the Bar Code Rule.

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adoption rate would also be incorrect. Baselines always matter, especially when they are dynamic, as is the case for technology adoption. The uncertainty respecting the counterfactual adoption rate means that, although we can estimate the benefits and costs of the adoption since 2004, we are unable to estimate the incremental effects of the bar code rule since the net effect depends on an uncertain baseline. In this retrospective analysis, we therefore explore alternative baselines and their implication for the benefits and costs of the bar code rule.

4 Counterfactual bar code adoption rates without the rule

It is impossible to observe the counterfactual bar code adoption rate, or how adoption would have occurred without the 2004 Bar Code Rule. Therefore, in addition to recalculating the costs and benefits of the rule using actual adoption rate data and the original baseline forecast, this retrospective analysis also considers alternative counterfactuals as a way of bounding and creating benchmarks for the potential effects of the rule. We chose counterfactual baselines based on plausibility and the availability of data. Specifically, we consider the following scenarios:

(1) **No Trend.** At the time the prospective BCA was drafted, FDA had access to two years of data for hospital utilization of bar code technology. If the FDA had assumed that all hospitals had already made their adoption decision, the 2003 rate of 3.20% would have continued forever. Analysts often confuse the *status quo* for the appropriate regulatory baseline; however, since there was clear evidence that hospitals were adopting bar code technology without a rule, this forecast would have overstated the adoption attributable to the rule and yielded misleading results. This counterfactual scenario and cost-benefit calculations can also be interpreted as the net benefit of all hospital adoption of bar code technology since 2004.

(2) **Linear Trend using data through 2003.** A more plausible alternative baseline would assume that the annual increase in adoption would continue at the same pace as it did from 2002 to 2003, based on the data FDA had available at the time of the RIA. Under this scenario, an additional 1.70% of hospitals adopt the technology every year, leading to universal adoption by 2060.

(3) **Linear Trend using data through 2005.** This scenario captures a counterfactual in which the FDA relied on a linear trend, but updated the baseline forecast with data available at the time the rule went into effect. Under this scenario, an additional 2.63% of hospitals would have adopted the technology every year, resulting in universal adoption by 2040.

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(4) **Canada Trend.** We also considered the experience of other countries. We looked at Canada, which has no comparable bar code requirement, which means that hospitals in Canada interested in applying bar code technology would be responsible for repackaging individual units with a bar code to make use of scanners, or pay an external repackager for this service. We chose Canada because they have made significant investments in related health information technology, such as electronic medical records (54% of hospitals in 2013–2014) (Hall & Wilgosh, 2015), and because data are available.[3]

This alternative baseline assumes that U.S. adoption would proceed at the same rate as Canada, which had 0.7% overall adoption in 2003 and 3.7% adoption in 2013, a trend of 0.3% additional hospitals adopting per year (data on Canada's adoption rate can be found in Table A1 in the Appendix). Under this scenario, we implicitly assume that bar code technology has yet to substantially penetrate the Canadian health sector primarily due to the absence of a similar bar code standard. If U.S. adoption had followed the same path as Canada, it would have been expected to fully adopt the technology in 2326.

Table 1 presents our estimates of the number of hospitals adopting bar code technology. This analysis focuses on how the rate of the adoption of bar code technology affects our understanding of the costs and benefits of the Bar Code Rule. To allow for a more direct comparison with the 2004 RIA, we hold several other factors constant. For example, in the table below, 5,040 hospitals adopting the technology corresponds to a 100% adoption rate among the 2004 RIA's estimate of 5,040 total hospitals. The column labeled "Actual" comes from annual survey results of hospital adoption rate reported by Pedersen et al. (2001–2017) multiplied by the total number of hospitals. As before, the original forecast and baseline are labeled "ERG No Rule" and "ERG With Rule," since the FDA forecasts relied on a study prepared by Eastern Research Group, Inc. (2003). Figure 2 presents these adoption rates and forecasts visually, while Figure 3 breaks down adoption rates by hospital size.

Table 2 presents a comparison of the real-world bar code medication administration adoption rate with the various forecasts and baselines. The entries in this table can be interpreted as the net effect of the rule relative to the alternative baselines, a critical figure in calculating costs and benefits. Higher percentages represent the share of hospitals that have adopted the technology faster than they would have

3 Canadian hospitals reported 33% adoption of electronic health records in 2007–2008 and 54% in 2013–2014, which can be compared to 41% in 2007 and 94% in 2014 in the United States. Canada has lagged in other technology, with 5.6% of its hospitals reporting adopting computerized prescriber-order-entry (CPOE) systems in 2005–2006 and 14% in 2013–2014. U.S. hospitals increased CPOE adoption from 3.6% in 2005 to 80.9% in 2014. Canadian figures come from Hall and Wilgosh (2015) and U.S. figures from Pedersen et al. (2016).

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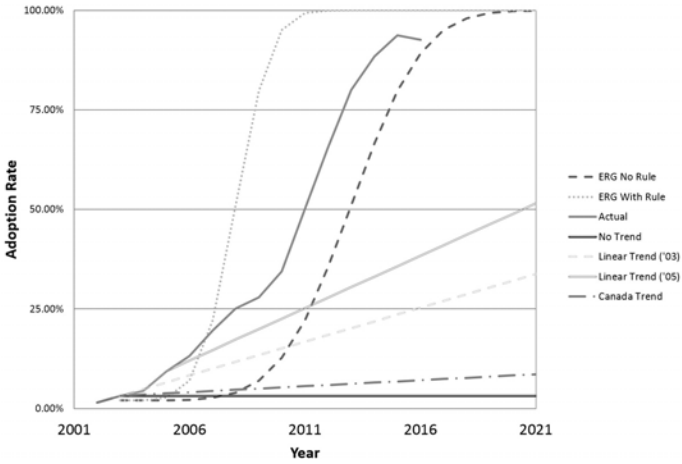


Figure 2 Alternative baseline adoption rates.

Table 1 Number of hospitals adopting bar code technology and alternative baseline forecasts.

Year	Actual	ERG No Rule	ERG With Rule	No Trend	Linear Trend ('03)	Linear Trend ('05)	Canada Trend
2002	76	–	–	76	76	76	76
2003	161	101	101	161	161	161	161
2004	222	101	103	161	247	222	176
2005	474	103	135	161	333	474	192
2006	665	111	350	161	418	606	207
2007	988	135	1119	161	504	739	222
2008	1265	201	2571	161	590	872	237
2009	1406	350	4022	161	675	1005	252
2010	1739	641	4791	161	761	1137	267
2011	2530	1119	5006	161	847	1270	282
2012	3301	1785	5038	161	932	1403	297
2013	4032	2571	5040	161	1018	1536	312
2014	4455	3356	5040	161	1104	1668	328
2015	4722	4022	5040	161	1189	1801	343
2016	4667	4500	5040	161	1275	1934	358

without the 2004 Bar Code Rule. The original "No Rule" baseline and "With Rule" forecasts are included for comparison. As an example, in 2008, this chart reads that 25.1% of hospitals had adopted bar code medication administration, which was 21.1% points higher than the FDA anticipated would adopt the technology without

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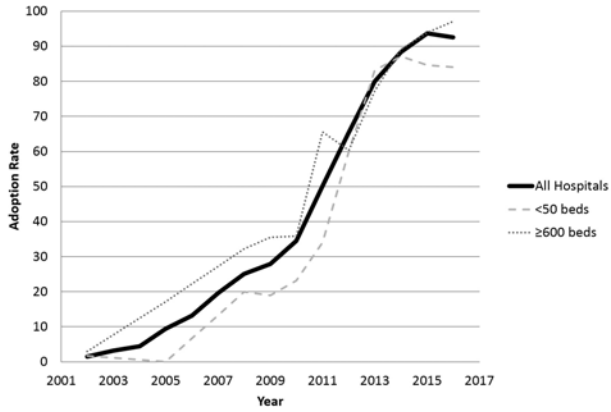


Figure 3 Adoption by hospital size.

Table 2 Actual bar code technology adoption rate and net adoption rate relative to alternative baselines.

Year	Actual	ERG No Rule	ERG With Rule	No Trend	Linear Trend ('03)	Linear Trend ('05)	Canada Trend
2002	1.5%						
2003	3.2%	1.2%	1.2%				
2004	4.4%	2.4%	2.3%	1.2%	−0.5%	0.0%	0.9%
2005	9.4%	7.3%	6.7%	6.2%	2.8%	0.0%	5.6%
2006	13.2%	11.0%	6.2%	10.0%	4.9%	1.2%	9.1%
2007	19.6%	16.9%	−2.6%	16.4%	9.6%	4.9%	15.2%
2008	25.1%	21.1%	−25.9%	21.9%	13.4%	7.8%	20.4%
2009	27.9%	20.9%	−51.9%	24.7%	14.5%	8.0%	22.9%
2010	34.5%	21.8%	−60.6%	31.3%	19.4%	11.9%	29.2%
2011	50.2%	28.0%	−49.1%	47.0%	33.4%	25.0%	44.6%
2012	65.5%	30.1%	−34.5%	62.3%	47.0%	37.7%	59.6%
2013	80.0%	29.0%	−20.0%	76.8%	59.8%	49.5%	73.8%
2014	88.4%	21.8%	−11.6%	85.2%	66.5%	55.3%	81.9%
2015	93.7%	13.9%	−6.3%	90.5%	70.1%	58.0%	86.9%
2016	92.6%	3.3%	−7.4%	89.4%	67.3%	54.2%	85.5%

the rule, but 25.9% points lower than the FDA predicted would adopt the technology under the rule. Note that, beginning in 2007, the real-world experience fell short of the original forecast, although this gap has shrunk over time.

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Table 3 Hospital adoption and costs of adoption.

				Hospital Counts and Costs (millions of dollars)		
Year	**Hospitals**	**New Adopters**	**Existing**	**Initial Cost**	**Recurring Cost**	**Total Cost**
2002	76					
2003	161					
2004	222	60	161	$33	$112	$145
2005	474	252	222	$139	$154	$293
2006	665	192	474	$106	$329	$435
2007	988	323	665	$178	$462	$640
2008	1265	277	988	$153	$686	$839
2009	1406	141	1265	$78	$879	$957
2010	1739	333	1406	$184	$977	$1160
2011	2530	791	1739	$437	$1208	$1645
2012	3301	771	2530	$426	$1758	$2183
2013	4032	731	3301	$403	$2293	$2697
2014	4455	423	4032	$234	$2801	$3035
2015	4722	267	4455	$147	$3095	$3243
2016	4667	(55)	4722	− $31	$3281	$3250

5 Recalculation of costs and benefits

5.1 Costs

We can use the alternative hospital adoption rate baselines described and presented in Section 4 to retrospectively calculate the costs and benefits of the rule. To do so, we first describe the costs hospitals adopting the technology faced to adopt and maintain bar code systems. Table 3 presents the actual number of hospitals adopting bar code medication administration (Pedersen et al., 2001–2017) in each year. New adopters, calculated as the current year's adopters minus the previous year's adopters, incur an initial cost in the first year. We rely on the 2004 RIA's estimate that a typical hospital adopting the technology would incur an initial cost of $448,000 (or $552,000 in 2015 dollars). These costs account for the installation of scanners, readers, software, and initial training. In subsequent years, adopters face an annual recurring cost of $556,000 (or $685,000 in 2015 dollars), which captures operating and maintenance expenses. These expenses also include an estimated 3% reduction in nursing productivity after implementing a bar code system, though the 2004 RIA discusses the uncertainty around this figure. To give an example calculation, in 2004, 222 hospitals had adopted bar code technology, which

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Table 4 Costs under alternative baselines.

Year	Baseline Costs Under Alternative Assumptions (millions of dollars)				
	ERG No Rule	No Trend	Linear Trend ('03)	Linear Trend ('05)	Canada Trend
2004	$70	$112	$159	$145	$120
2005	$72	$112	$219	$293	$131
2006	$76	$112	$278	$402	$141
2007	$90	$112	$338	$495	$152
2008	$130	$112	$397	$587	$162
2009	$222	$112	$457	$679	$173
2010	$404	$112	$516	$771	$183
2011	$709	$112	$576	$863	$194
2012	$1,145	$112	$636	$956	$204
2013	$1,673	$112	$695	$1,048	$215
2014	$2,219	$112	$755	$1,140	$225
2015	$2,699	$112	$814	$1,232	$236
2016	$3,058	$112	$874	$1,324	$246

amounted to an increase of 60 hospitals from 2003. Each hospital incurred about $552,000 in initial costs, for an aggregate cost of $33 million. The existing 161 hospitals each incurred $685,000 in operating and maintenance costs, which aggregates to $112 million. These costs sum to $145 million in 2004. Figures reported in the table below are presented in 2015 dollars.

We also present similar calculations for each of the alternative baselines described above. Table 4 reports the total costs for each of the baseline estimates. Note that the "ERG No Rule" and "Linear Trend ('05)" tend to have higher total costs, which directly reflects that these baselines predicted faster technology adoption than other baseline assumptions.

Finally, in Table 5, we subtract the figures presented in Table 4 from the total costs presented in Table 3 to yield the hospital costs attributable to the rule. These are the costs of hospitals actually adopting the technology minus the various forecasts of the baseline adoption rates that would have occurred without the Bar Code Rule.

5.2 Benefits

We also reconsider the benefits that accrued from the Bar Code Rule by comparing the benefits expected from the actual hospital adoption rate to the alternative

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Table 5 Costs attributable to the rule under alternative baselines.

Year	Hospital Costs Net of Baseline Costs (millions of dollars)				
	ERG No Rule	No Trend	Linear Trend ('03)	Linear Trend ('05)	Canada Trend
2004	$75	$33	− $14	$0	$25
2005	$222	$181	$74	$0	$162
2006	$359	$323	$156	$32	$293
2007	$550	$528	$302	$146	$488
2008	$709	$727	$442	$252	$677
2009	$735	$845	$500	$278	$784
2010	$757	$1,048	$644	$389	$977
2011	$936	$1,533	$1,069	$781	$1,451
2012	$1,038	$2,071	$1,548	$1,228	$1,979
2013	$1,023	$2,585	$2,002	$1,649	$2,482
2014	$815	$2,923	$2,280	$1,895	$2,809
2015	$544	$3,131	$2,429	$2,010	$3,007
2016	$192	$3,138	$2,377	$1,926	$3,004

baseline scenarios. These benefits are derived from reductions in ADEs and AHTRs avoided due to bar code technology.

The 2004 FRIA indicated that 1.25 million ADEs occur each year in the United States, of which 373,000 are preventable. In the RIA, FDA assumed that bar code system use would produce no reduction in prescribing and transcribing errors, but that its use would intercept one half of the 45.1% of all preventable ADEs that now originate in the dispensing and administration stages of the medication process.[4] Thus, if all hospitals adopted bar code systems, the number of preventable ADEs would fall by 22.6% (45.1×0.5), which would have prevented about 84,300 ADEs per year ($373{,}000 \times 0.226$). The FDA similarly calculated that 114 AHTRs could be prevented annually with full bar code technology adoption. Prior to full adoption, FDA estimated that partial adoption would translate to a proportional reduction in preventable ADEs and AHTRs.

Table 6 calculates the avoided ADEs and AHTRs implied by hospital adoption of bar code technology. In the year 2004, 222 hospitals had adopted bar

4 In a study of an academic medical center, Poon et al. (2010) found a 41.4% reduction in errors and a 50.8% reduction in adverse events associated with errors following adoption of bar code medication administration. Although this result is for a single hospital, it is remarkably close to the assumption used in the 2004 prospective analysis.

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Table 6 Avoided ADE and AHTR implied by actual bar code technology adoption.

Year	Hospitals	Avoided ADE	Avoided AHTR
2004	222	3910	5
2005	474	8458	11
2006	665	12,026	16
2007	988	18,080	25
2008	1265	23,443	33
2009	1406	26,384	37
2010	1739	33,033	48
2011	2530	48,666	72
2012	3301	64,292	96
2013	4032	79,507	121
2014	4455	88,953	138
2015	4722	95,465	150
2016	4667	95,523	153

code technology. Under the assumptions of the 2004 RIA, 1315,000 ADEs were expected to occur in a hospital setting. Of these, 394,500 were thought to be avoidable, and among these, 77,750 occurred while dispensing or administration. Based on existing literature (Yang et al., 2001; Barker et al., 2002) and discussions with industry experts, FDA expected that if all hospitals had adopted bar code technology, half of these could have been prevented, or about 88,870. Since about 4.4% of hospitals had adopted the technology in 2004, we estimate that the same percentage, or 3910 ADEs were avoided due to bar code medication administration. We continue this analysis for AHTRs, and repeat the same analysis for each of the baseline scenarios in Tables 7 and 8.

Tables 9 and 10 quantify the number of ADEs and AHTRs attributable to the rule. Similar to the hospital cost estimates presented above, these represent the difference between ADEs and AHTRs implicit from the adoption rate minus the figures for each of the baseline scenarios.

5.3 Monetizing Benefits

The 2004 FRIA included an estimate of the value of the resulting life years saved and pain and disability avoided; in the analysis FDA estimated that each ADE and AHTR resulted in additional direct medical costs of $2257. Additionally, the

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Table 7 ADE avoided under baseline scenarios.

Year	ERG No Rule	No Trend	Linear Trend ('03)	Linear Trend ('05)	Canada Trend
2004	1790	2844	4355	3910	3110
2005	1847	2879	5939	8458	3419
2006	2013	2915	7562	10,963	3735
2007	2472	2952	9225	13,529	4059
2008	3721	2989	10,928	16,158	4390
2009	6575	3026	12,672	18,850	4728
2010	12,174	3064	14,458	21,607	5075
2011	21,523	3102	16,287	24,430	5429
2012	34,758	3141	18,159	27,320	5791
2013	50,687	3180	20,075	30,279	6162
2014	67,010	3220	22,037	33,307	6541
2015	81,306	3260	24,044	36,406	6928
2016	92,108	3301	26,099	39,578	7324

Table 8 AHTR avoided under baseline scenarios.

Year	ERG No Rule	No Trend	Linear Trend ('03)	Linear Trend ('05)	Canada Trend
2004	2	4	6	5	4
2005	2	4	8	11	5
2006	3	4	10	15	5
2007	3	4	13	19	6
2008	5	4	15	23	6
2009	9	4	18	27	7
2010	18	4	21	31	7
2011	32	5	24	36	8
2012	52	5	27	41	9
2013	77	5	31	46	9
2014	104	5	34	52	10
2015	128	5	38	57	11
2016	148	5	42	63	12

suffering and death resulted in quality-adjusted life year (QALY) losses valued at $185,500 per adverse drug event (ADE) and $101,200 per acute hemolytic transfuction reaction (AHTR). These valuations explicitly relied on a Value of Statistical

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Table 9 ADE avoided due to the rule.

Year	ERG No Rule	No Trend	Linear Trend ('03)	Linear Trend ('05)	Canada Trend
2004	2121	1066	(444)	–	800
2005	6611	5579	2519	–	5039
2006	10,013	9111	4464	1063	8291
2007	15,608	15,128	8856	4551	14,021
2008	19,722	20,454	12,515	7285	19,053
2009	19,809	23,358	13,712	7534	21,656
2010	20,859	29,969	18,575	11,426	27,958
2011	27,144	45,564	32,379	24,236	43,237
2012	29,534	61,151	46,133	36,972	58,501
2013	28,819	76,326	59,431	49,228	73,345
2014	21,943	85,733	66,916	55,646	82,412
2015	14,159	92,204	71,420	59,058	88,537
2016	3415	92,222	69,425	55,945	88,199

Table 10 AHTR avoided due to the rule.

Year	ERG No Rule	No Trend	Linear Trend ('03)	Linear Trend ('05)	Canada Trend
2004	3	1	(1)	–	1
2005	9	7	3	–	7
2006	14	12	6	1	11
2007	21	21	12	6	19
2008	28	29	17	10	27
2009	28	33	19	11	31
2010	30	43	27	17	40
2011	40	67	48	36	64
2012	44	91	69	55	88
2013	44	116	90	75	112
2014	34	133	104	86	128
2015	22	145	112	93	139
2016	5	148	111	90	141

Life of $5 million (or $6.2 million in 2015 dollars). By multiplying these values by the ADEs and AHTRs avoided due to the rule, we can monetize these benefits, which appear in Table 11.

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Table 11 Monetized benefits due to avoided ADE and AHTR (Millions of 2015 $).

Year	ERG No Rule	No Trend	Linear Trend ('03)	Linear Trend ('05)	Canada Trend
2004	$394	$198	− $83	$0	$149
2005	$1229	$1037	$468	$0	$937
2006	$1861	$1694	$830	$198	$1541
2007	$2901	$2812	$1646	$846	$2607
2008	$3666	$3802	$2327	$1354	$3542
2009	$3683	$4342	$2549	$1401	$4026
2010	$3878	$5571	$3453	$2124	$5198
2011	$5046	$8471	$6020	$4506	$8038
2012	$5491	$11 369	$8577	$6874	$10,876
2013	$5358	$14,190	$11,049	$9152	$13,636
2014	$4080	$15 939	$12,441	$10,346	$15,322
2015	$2632	$17,143	$13,278	$10,980	$16,461
2016	$635	$17,146	$12,908	$10,402	$16,398

Table 12 Annualized net benefits under alternative baseline assumptions (millions of 2015 $).

Baseline	ERG No Rule	No Trend	Linear Trend ('03)	Linear Trend ('05)	Canada Trend
Benefits	$3376	$8054	$5812	$4438	$7659
Hospital Costs	$656	$1482	$1064	$807	$1408
Manufacturer Costs	$9	$9	$9	$9	$9
Net Benefits	$2711	$6563	$4739	$3622	$6242

5.4 Net Benefits

With costs and benefits calculated, we can now combine these to recreate the net costs and benefits. Table 12 reports the net benefits of the rule under the various baseline assumptions discussed earlier. Across each scenario, drug manufacturers incur regulatory costs that are annualized as $9 million, and are reported by year in the appendix. All figures are reported as millions of 2015 dollars, annualized over the 2004 to 2016 time period using a 3% discount rate.

The first column reports the benefits and costs if the original forecast of hospital adoption without the rule had been correct. Under this scenario, the rule would have generated $3.4 billion in annualized benefits, while hospitals would incur $656

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million in annualized costs to adopt and maintain bar code technology. Subtracting these costs and the manufacturing costs yields $2.7 billion in annualized net benefits.

To put these estimates into context, the 2004 RIA estimated the annualized net benefits of the rule to be $4.3 billion in 2004 dollars, using a 3% discount rate. This is equivalent to $5.3 billion in 2015 dollars. These net benefits are calculated as the difference between $6.0 billion in annualized benefits and $747 million in annualized costs, again in 2015 dollars. As a consequence of hospitals adopting bar code technology slower than predicted under the rule, the benefit and cost estimates from the 2004 RIA are both too high when applying the original baseline. We next consider how net benefits change in light of the alternative baseline scenarios described earlier.

The second column again uses real hospital data, but diverges from the original ERG baseline by assuming that no new hospitals would have adopted bar code technology without FDA's bar code rule. Relative to column 2, the benefits and hospital costs both increase. Column 6, which assumes that U.S. adoption would have followed Canada's gradual trajectory without the rule, yields similar results.

The third column adopts a baseline where U.S. adoption would continue at its 2003 trend, reflecting the most up-to-date data available to FDA at the time the original RIA was drafted. This alternative baseline suggests that, without the rule, hospitals would have continued to adopt bar code technology more rapidly than ERG's baseline through 2011, with a relatively slower adoption rate following this point. This translates to relatively lower benefits and costs through 2011 and relatively higher benefits during 2012–2016.

The fourth column uses a linear trend through 2005, the last year prior to the rule taking effect. An additional two years of data predicts more aggressive adoption of bar code medication administration by hospitals, although this may be due to hospitals adopting the technology after learning about the rule.

Our retrospective analysis presents a wide range of annualized net benefit estimates, between $2.7 billion and $6.6 billion. This uncertainty stems from different assumptions about what the adoption rate of bar code technology would have been in absence of the 2004 Bar Code Rule. These should be considered upper-bound estimates of the net effect of the rule, since many other initiatives affected the adoption of bar code technology in hospitals. Alternatively, these estimates can be considered a joint BCA of the Bar Code Rule and all other contemporaneous initiatives that pushed for bar code technology adoption. The 2004 RIA explored other sources of uncertainty in these estimates, including the effectiveness of bar codes at intercepting medical errors, and the mortality probability following an ADE. In a sensitivity analysis, the 2004 RIA yielded a range of estimated annualized net

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benefits between $862 million and $9.3 billion, when updated to 2015 dollars. All the net benefit calculations included in this retrospective fall in this range.

6 Reassessment of hospital costs

In addition to re-estimating the costs and benefits of the 2004 Bar Code Rule based on real-world data and considering several alternative counterfactual baselines, we also reconsidered our assumptions about the role of hospital costs. In the original analysis, the Bar Code Rule induced hospitals to speed up adoption of bar code technology, causing them to incur costs, which are included in the RIA. However, as mentioned earlier, the rule did not mandate adoption by any hospital. If we use a common assumption that hospitals aim to maximize profits, then any hospital that voluntarily adopted bar code medication administration must therefore have expected that doing so would either reduce other costs, or increase its revenue. Following through with this argument, this suggests that the costs we calculate are overstated, as hospitals should have offsets at least as large as their costs. More research could be done to investigate whether hospitals were motivated to adopt bar code technology because of reimbursement incentives for improved outcomes.

7 Conclusions

This retrospective BCA of the 2004 Bar Code Rule gives an overview of the FDA's original regulatory impact analysis, describes how the real-world experience differed from forecasts, and attempts to understand the actual impacts of the rule. While access to new data allows us to better understand what happened, uncertainty remains over the counterfactual – at what rate hospitals would have adopted bar code technology without the rule. As we are unable to observe what the adoption rate would have been in the absence of the rule and thereby retrospectively measure the benefits and costs with certainty, we considered several alternative scenarios, and gave cost and benefit calculations based on each of those scenarios. The different scenarios based on actual adoption rates and other evidence, however, show that the benefits greatly exceeded the costs, with high benefit-cost ratios, under any plausible counterfactual adoption rate. However, it is unclear what portion of the adoption can be claimed by the Bar Code Rule. Given the number of and credibility of competing theories that explain adoption, the original ERG baseline, which attributes most of the technology uptake in hospitals to other forces besides the 2004 rule, remains our preferred counterfactual.

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In this retrospective, we also briefly discussed an alternative approach toward costs to industry with voluntary investments in technology. Additional extensions of the analysis could include reconsidering other parameters, such as the effectiveness of bar code technology in reducing errors, or the likelihood that an error leads to an adverse health event. There are, however, potential costs that were not included in this analysis. Specifically, by setting the standard as a linear bar code, the Rule may have induced hospitals to make investments in technologies that are not "future proofed." A better understanding of the state of hospital technology would be a logical next step in addressing this concern.

Appendix

Table A1 Canadian adoption of bar code medication administration.

Year	Canada	USA
2002		1.5%
2003	0.7%	3.2%
2004		4.4%
2005	1.4%	9.4%
2006		13.2%
2007	1.2%	19.6%
2008		25.1%
2009	3.8%	27.9%
2010		34.5%
2011	4.2%	50.2%
2012		65.5%
2013	3.7%	80.0%
2014		88.4%

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