



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL



BRIGHAM AND
WOMEN'S HOSPITAL

Using Bar Code Verification to Improve Patient Care and Tracking and Traceability



William W. Churchill MS, R.Ph.
Chief of Pharmacy Services
Brigham and Women's Hospital

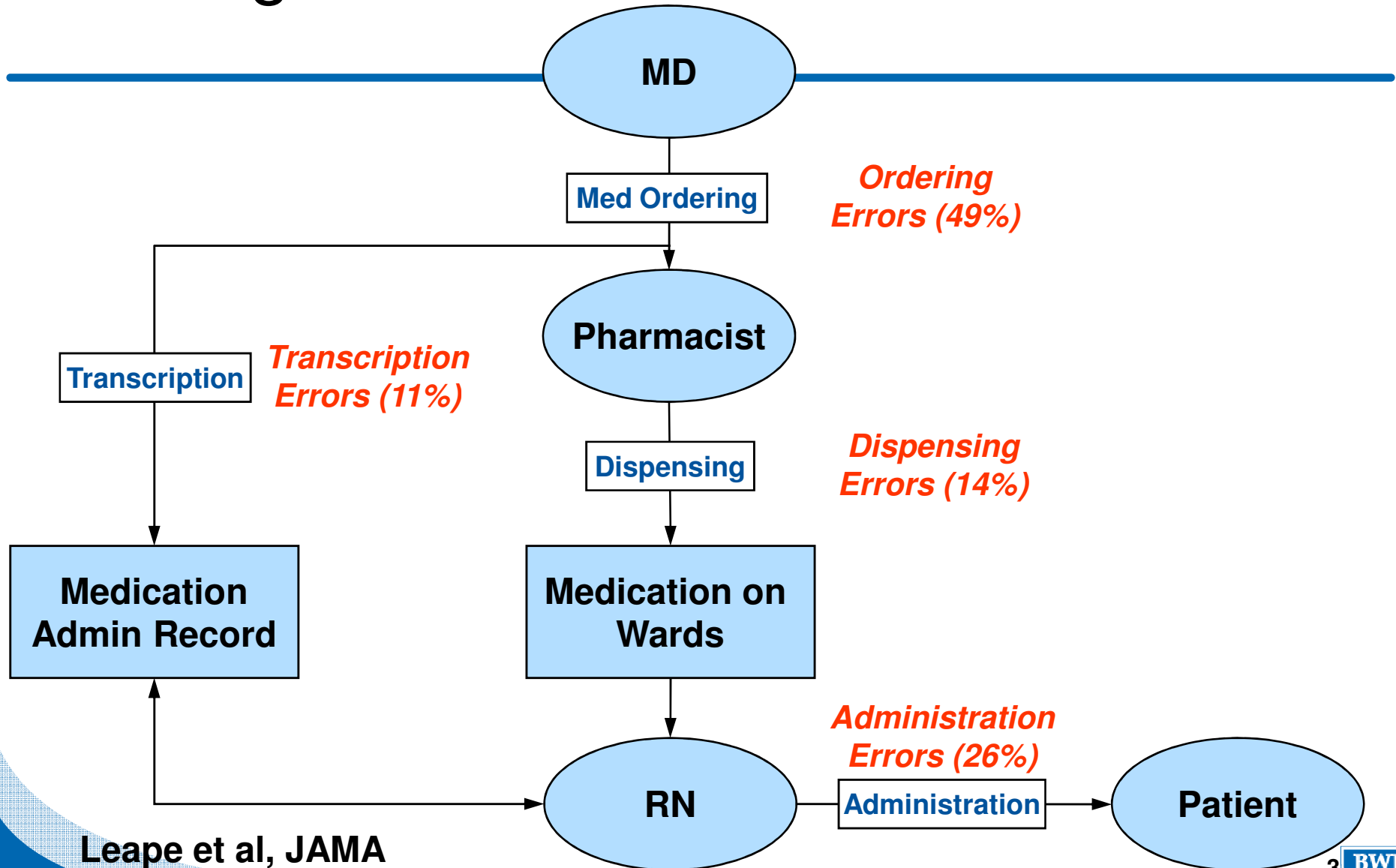


The Brigham and Women's Hospital Department of Pharmacy

- **787 bed academic tertiary medical center**
 - 57,000 annual visits to emergency room
 - 45,000 admissions
- **All medical/surgical specialties**
 - 156 ICU beds
 - Intermediate Care Units
- **2500 RN's**
- **Pharmacy staff 210 FTE's**
 - 98 full-time pharmacists
 - 101 full-time pharmacy techs
 - 11 support staff
- **Expense budget \$125 mill**
- **Revenue Budget \$410 mill**
- **Home-grown computer systems until May 31, 2015 when we will go live with Epic.**
- **Alaris Medley Smart Infusion Pump Technology**
- **Health Robotics IV Compounding Robotics**
- **ScriptPro outpatient Robotics**
- **Omnicell ADM Technology**
- **Kit Check RFID system**
- **TheraDoc ADE Surveillance System**



Background: Serious Medication Errors

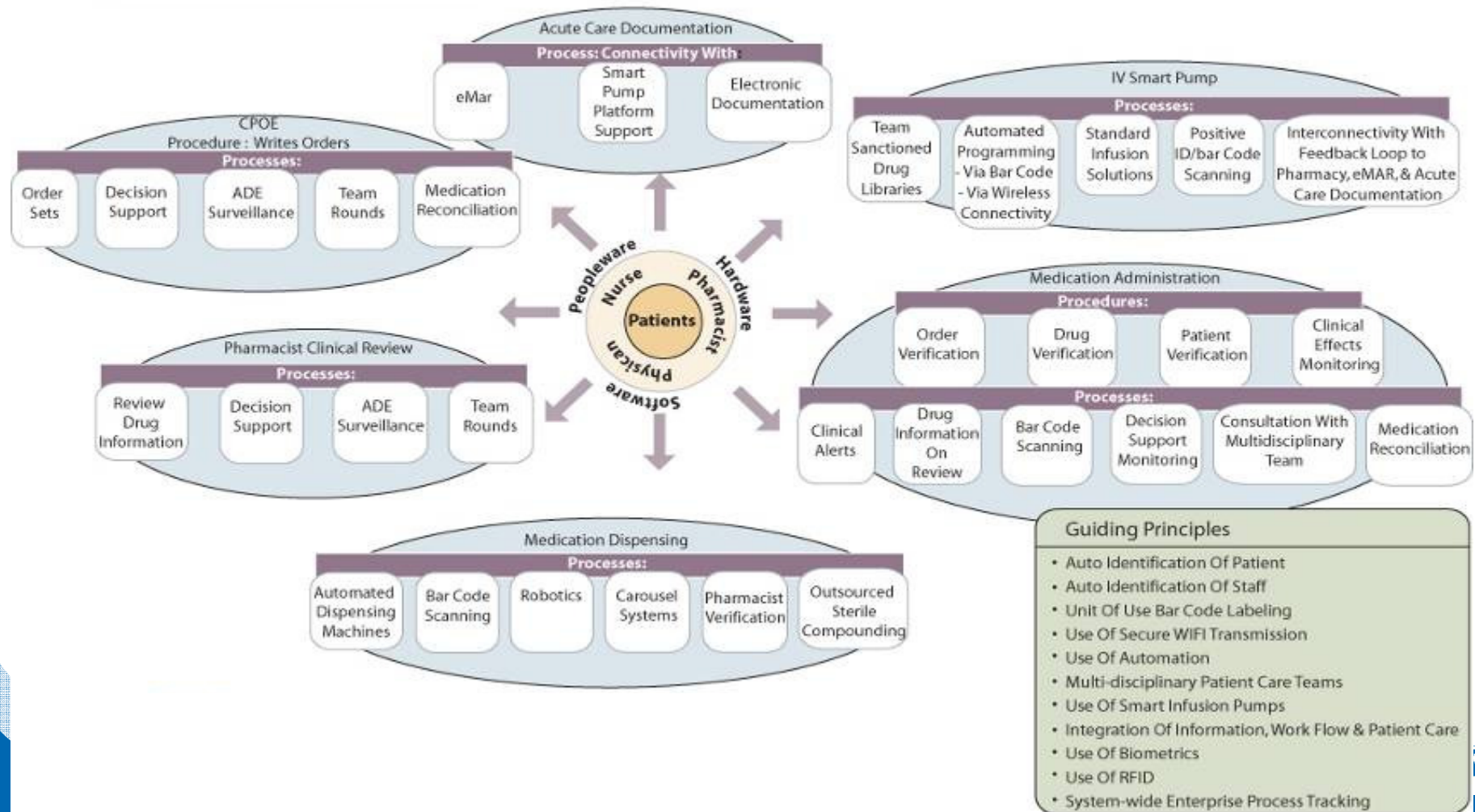


Leape et al, JAMA
1995

Ideal Gold Standard Medication Use Process

High Performance Medicine Team2: Components of the Ideal Medication Administration System

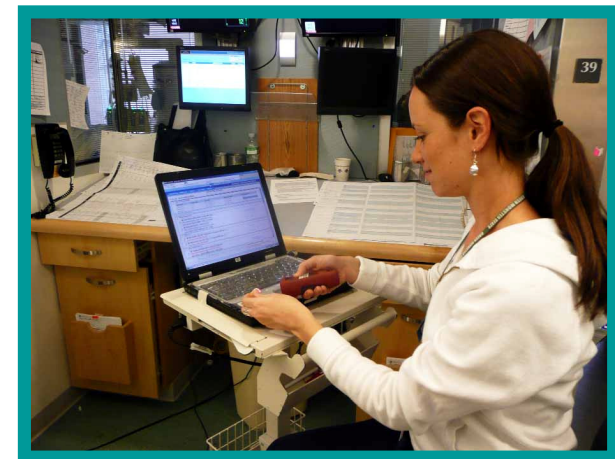
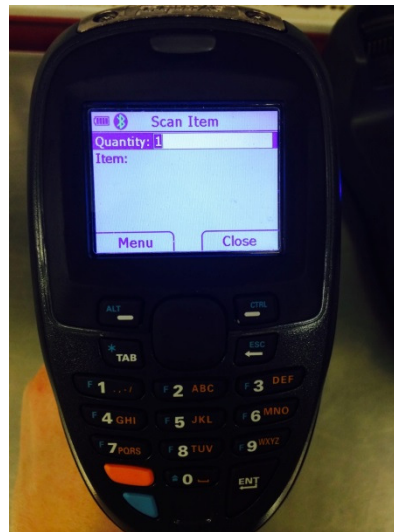
Health Care Team and System Objectives:
Right Patient, Right Medication, Right Dose
and Concentration, Right Route, Right Time



Approaches for Improving Inpatient Medication Safety

- Computerized physician order entry (CPOE)
 - Completeness and traceability of orders
 - Decision Support
 - Standardization
- Electronic clinical decision support ADE Surveillance
- Smart Infusion Pump technology
- Closed loop medication use process (MUP)
 - Medication bar code verification
 - Electronic medication administration records (eMAR)
 - Electronic flow sheets
 - RFID Technology
- Comprehensive clinical pharmacy services
- Robotic technology in the pharmacy
 - Inpatient
 - Outpatient
 - Sterile Products Suite

Bar Code Verification



Bar Code Technology

- An effective tool in many non-healthcare industries
- Provides a fail safe automated identification and feedback system in real time
- Does the “five rights” checking in one easy efficient process.
- Facilitates track and trace
- Allows nursing staff to focus more on the patient than checking “To-Do” lists.
- Allows for more effective and efficient use of pharmacy technicians.
- Frees up pharmacists from drug distribution for more patient care related responsibilities.



Format of Bar Code

- Bar codes are available in a variety of one dimensional formats:
 - code 128
 - UPC
 - code 39
- Bar Codes are also available in a variety of two dimensional formats:
 - Code 128 and code 39 are 1 D bar codes
 - stacked RSS is a 2D bar code
 - Data Matrix is a 2 D barcode
- Need capability of de-coding multiple formats, styles and dimensions since there is no industry standard and capability of saving and using the coded data

Two Dimensional Bar codes

■ Advantages

- 30 times smaller than a code 39 bar code
- higher degree of accuracy
 - 1 misread per 10.5 million scans for data matrix
 - 1 misread per 1.7 millions scans for code 39
- data matrix bar codes that are up to 60% damaged can be easily and accurately read
- data matrix bar code fonts can be easily printed with standard printers from MS Windows OS



■ Disadvantages

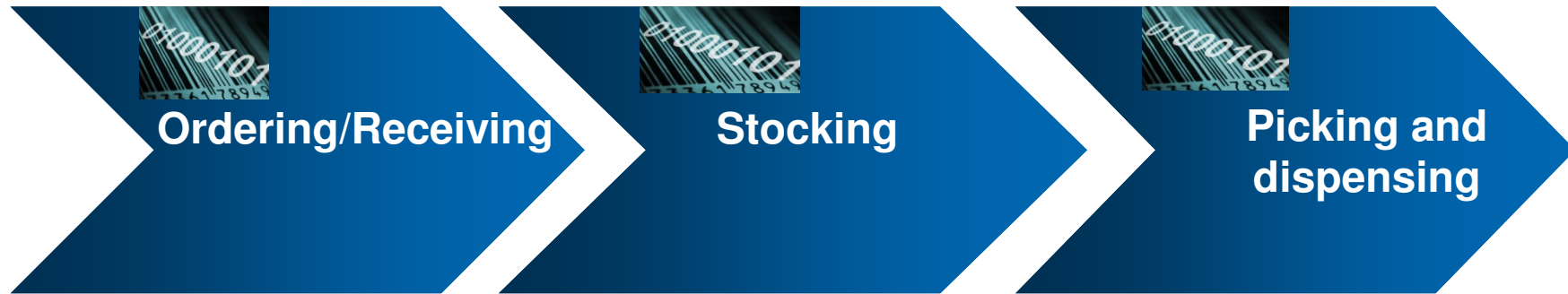
- can only be read with specially programmed imager
- not in widespread use
- Imagers are more costly.

Drug Dispensing through Automated Dispensing Cabinet Re-stock Process

- **Central Pharmacy Automation (WorkflowRx)**
- **Restocking Using Medication Storage Carousels and Batch Filling Process**

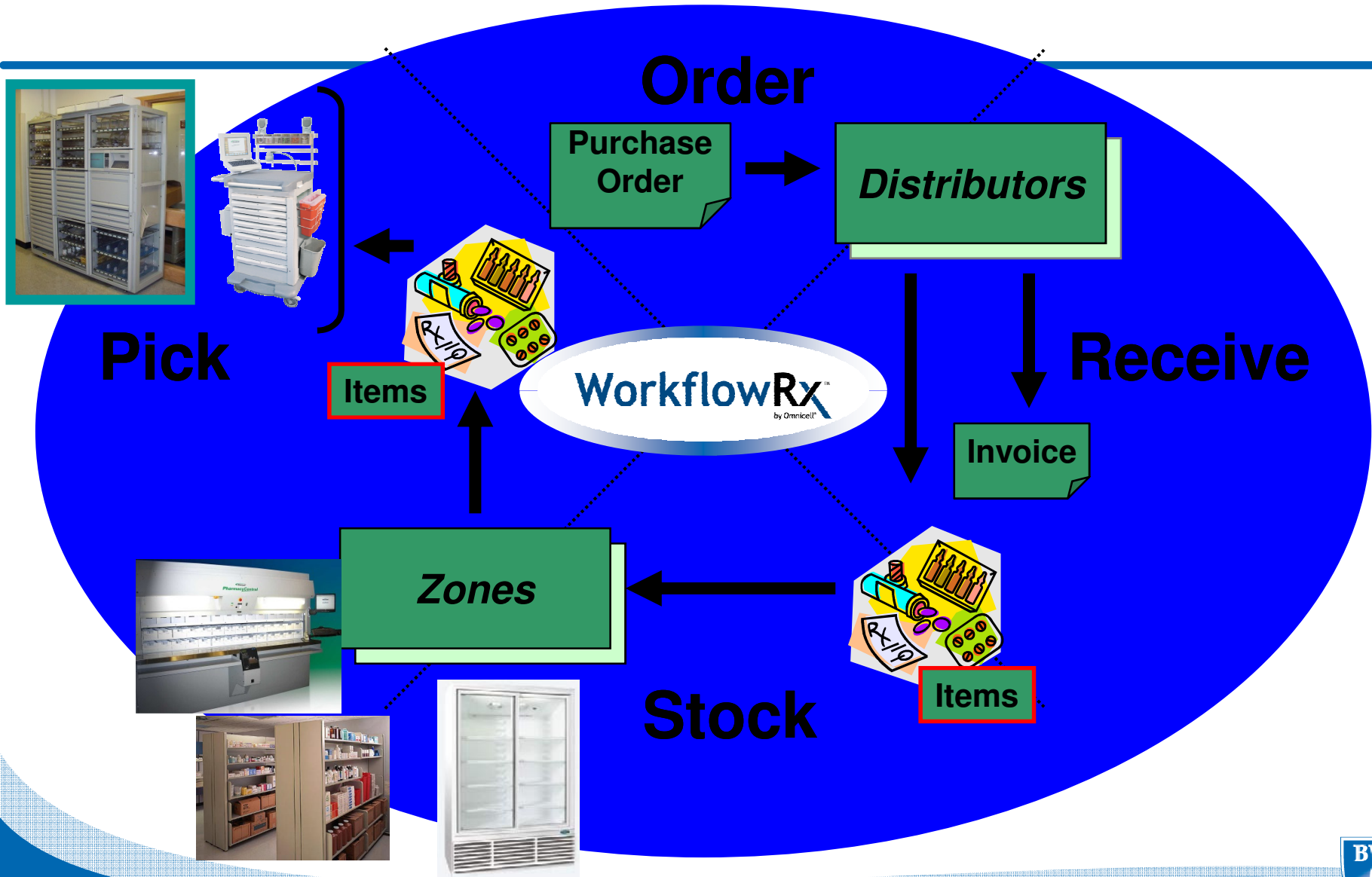


WorkflowRx Overview



Reporting, Inventory management, billing, bar-code verification, guiding lights

Pharmacy Workflow

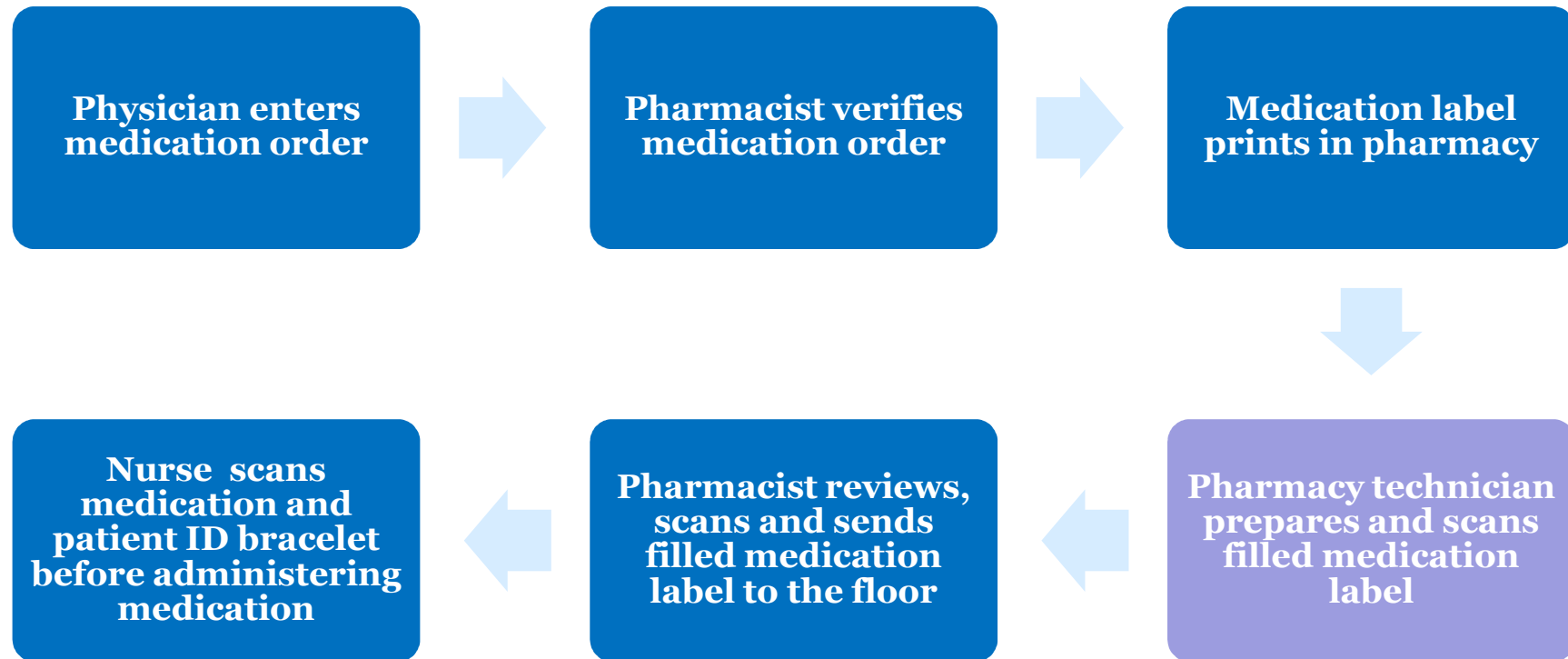


Use of Safety Stock

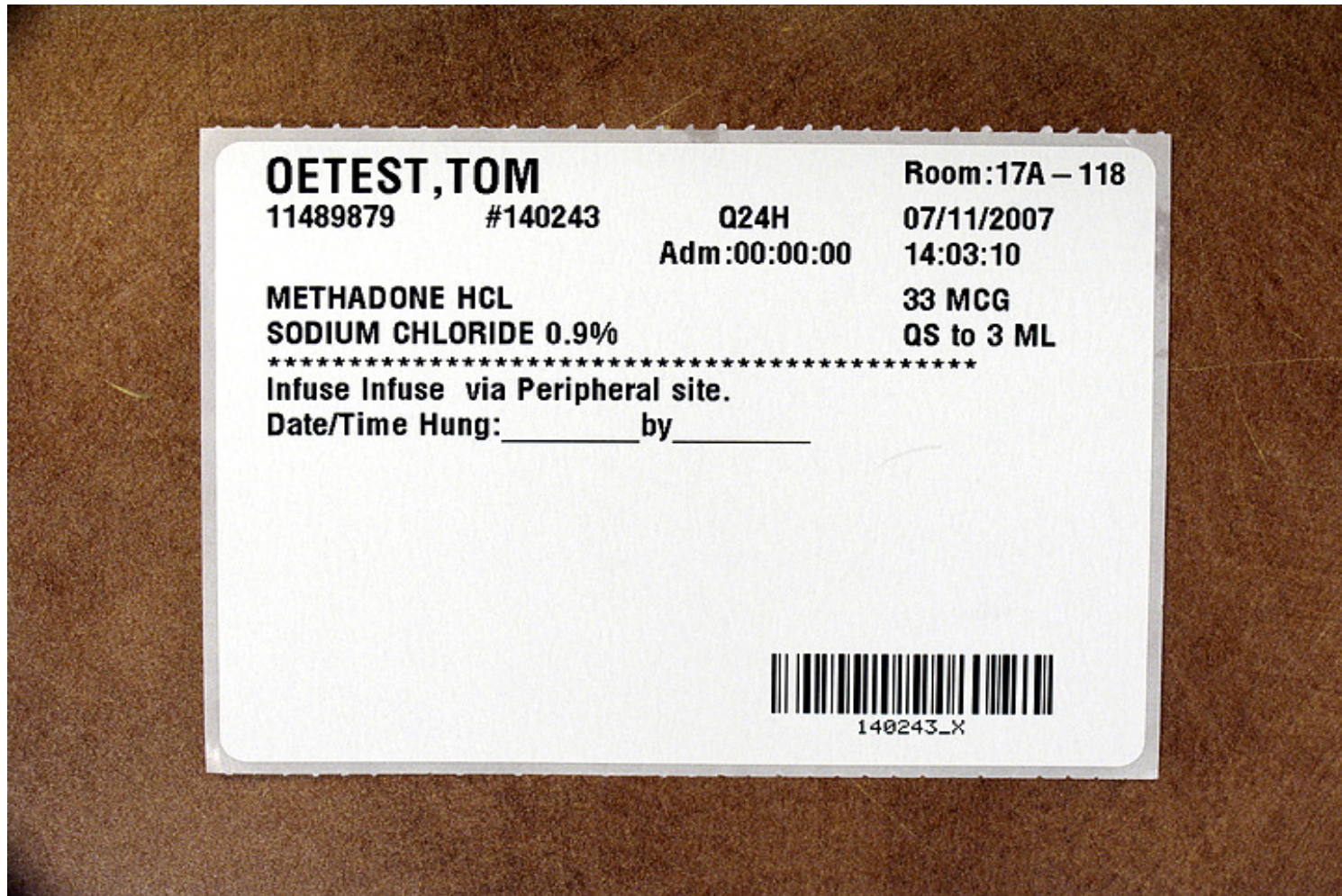
- **Bar code confirmation on:**
 - Restock
 - Issue
 - Return
- **Restock efficiency and accuracy**
- **Insure “Right Drug, Right Location”**
- **Distinguish “look alike/sound alike” medications**



Medication Distribution Process



Patient Specific Label Prints



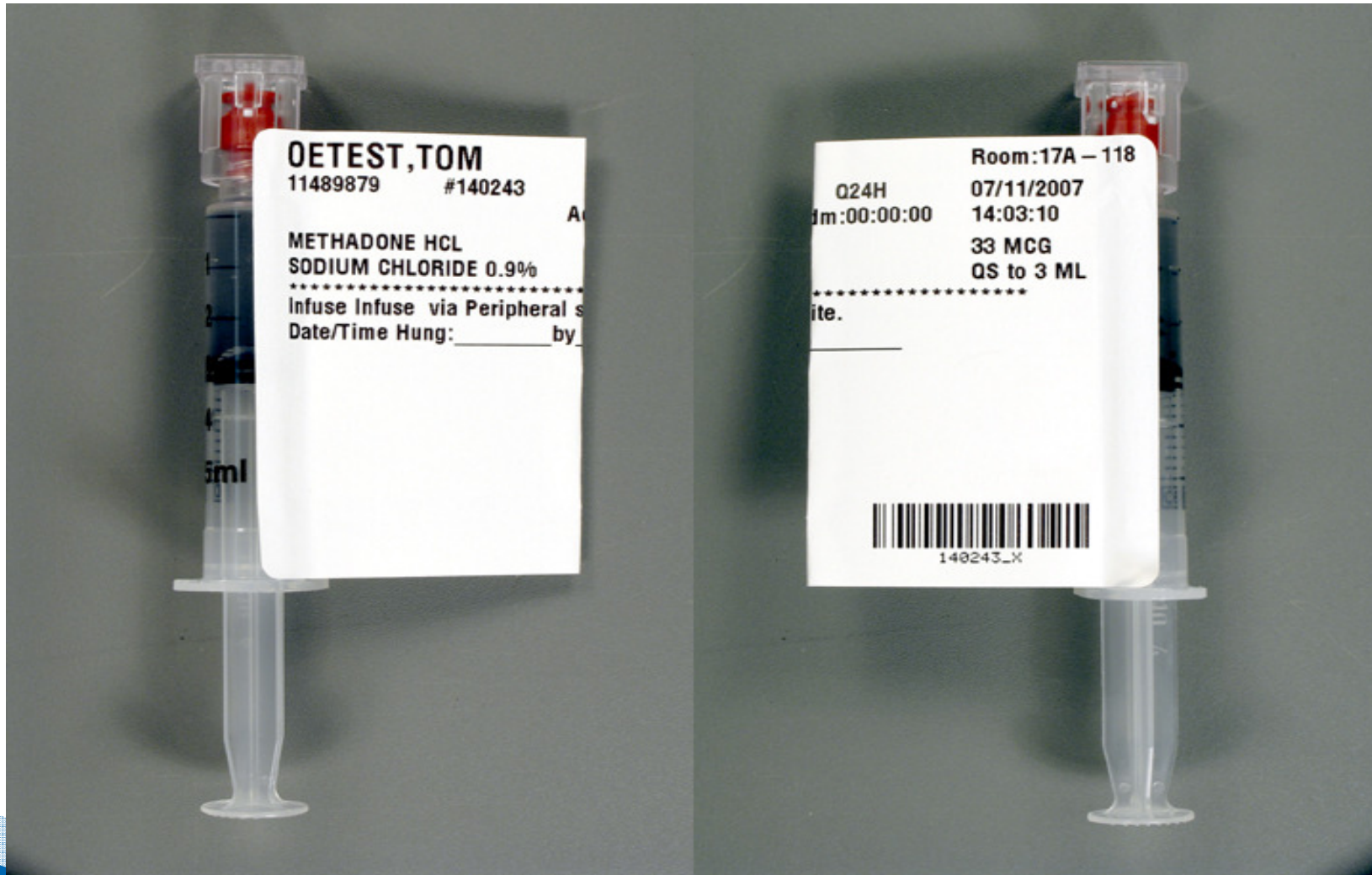
Scan Patient Label



Verify the Medications



Final Patient Specific Product Safely Labeled, Prepared and Administered



Bar Code Track and Trace Capabilities

FLOOR LABEL DISTRIBUTION **FILL**			LAST PRINT: 09:57:52			PEND SESSIONS: 141	
SESSION NUMBER: <input type="text"/>		Open session	Refresh	Report	MENU	Send	
Patient	Session	Approved	Printed	Prepared	Checked	Sent	Deliv'd
	R8 74987571		04:42	04:55	04:57	05:24	
	R1 75171869		02:35	03:54	03:56	05:24	
	R7 75015049		00:42	01:10	01:13	05:24	
	R1 75175224		07:21	09:50			
	R1 75172993		04:09	04:44	04:57	05:24	
	X X22097811		07:58				
	R8 M22083341		04:31	09:23	09:37	09:39	
	75200253	07:30	07:35	08:36	08:38	08:39	
	R52 M22103707		07:27	07:36	07:37	07:40	
	75201789	08:18	08:21	09:31	09:33	09:36	
	R48 M22109769		07:14	07:39	07:39	07:40	
	X X22107594		07:16	07:46	07:48	07:49	
	R63 M22086599		06:54	07:34	07:37	07:40	
	X X719440		08:17	09:26?			
	R6 M22144133		07:41	07:54	07:57	07:57	
	75100872	06:04	06:07	06:21	06:23	06:24	

User: GILLIS,CHRISTINE M [New User](#)



Bar Code Trace by Individual Patient Order

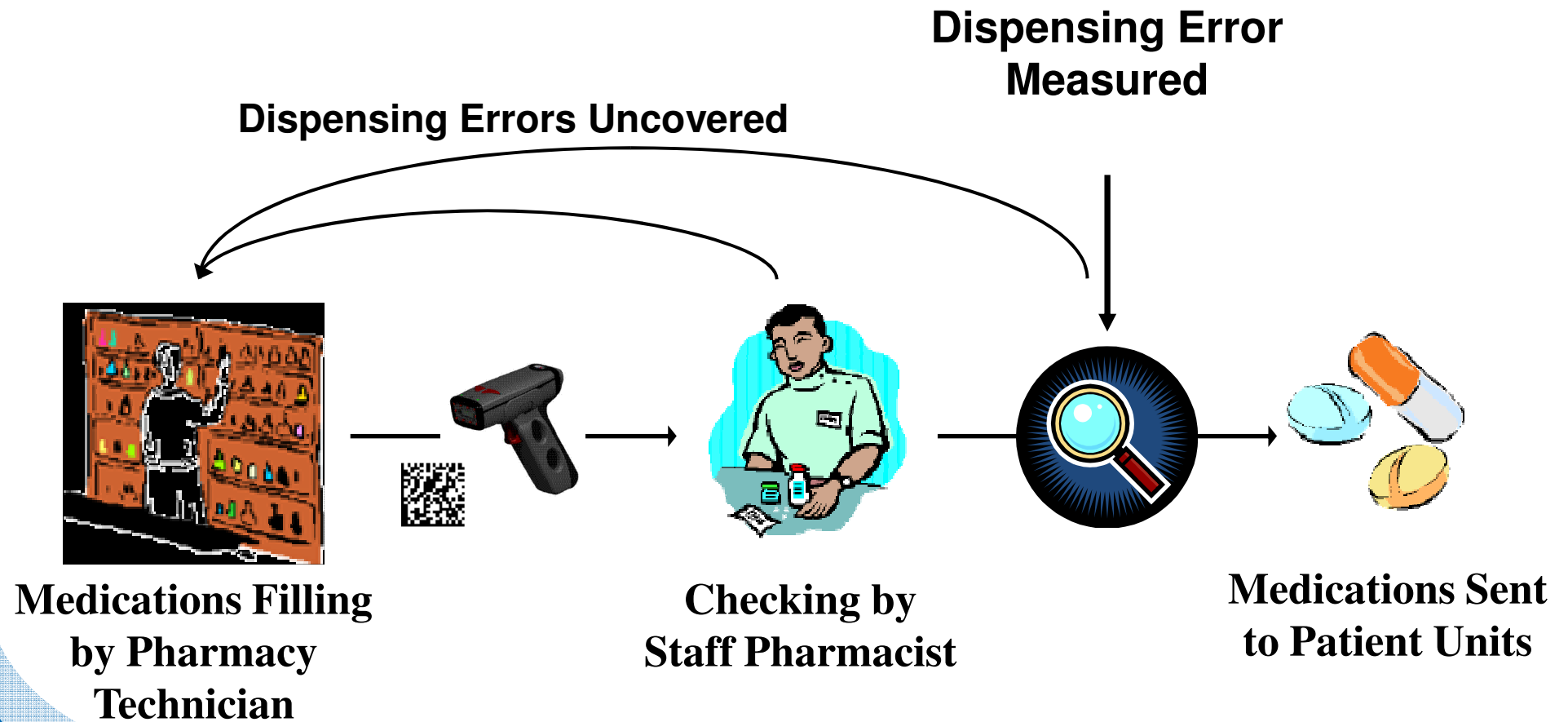
http://clinical.partners.org/scripts/phsweb.mwl?APP...

Order distribution history Mar 18, 2015
TAMIFLU 75 MG PO Q12H X 10 doses RX#22170530

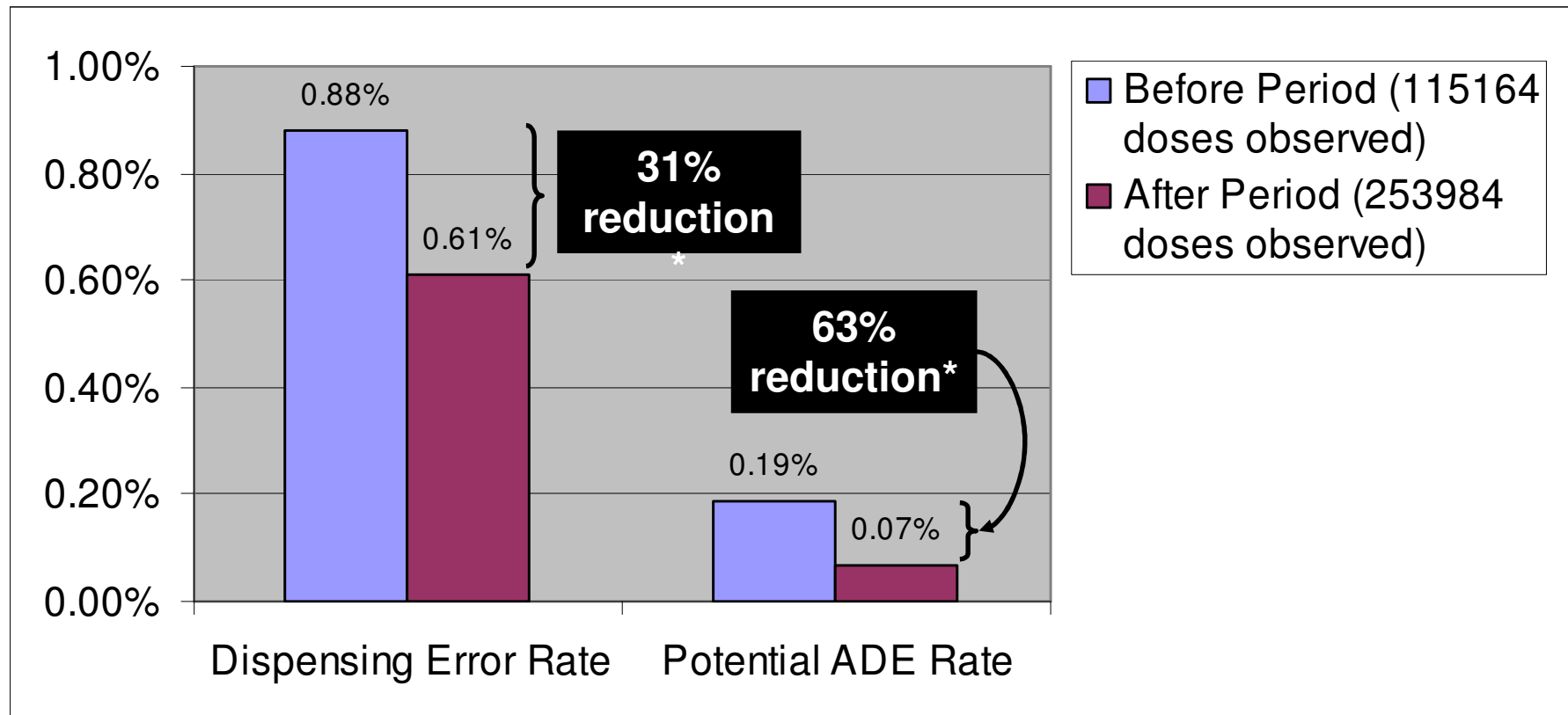
PROCESS	##	QTY	TIME	KEY
APPROVED			09:57AM	by JJYm
PRINTED	0	4	10:01AM	by ISI
PRINTED	0	4	10:14AM	by ISM
PREPARED	0	4	10:22AM	by TWpc
CHECK	0	4	10:23AM	by JHJl
SENT	0	4	10:24AM	by JHJl

CANCEL

Pharmacy Dispensing Process: Ensuring High Reliability with Barcode Technology



Dispensing Errors and Potential ADEs: Before and After Barcode Technology Implementation



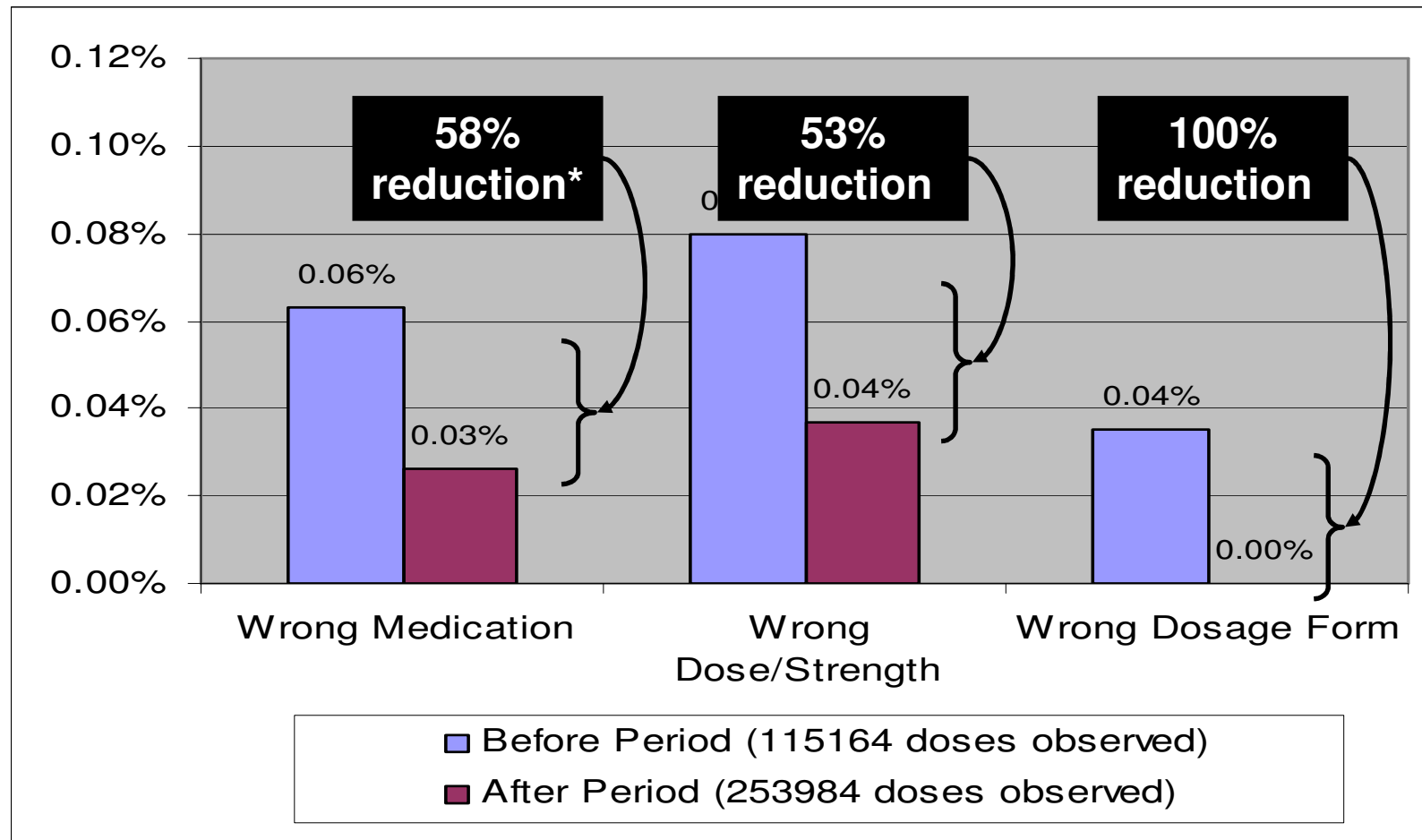
* $p < 0.0001$ (Chi-squared test)

Poon, et al. *Annals of Internal Medicine* 2006

2006



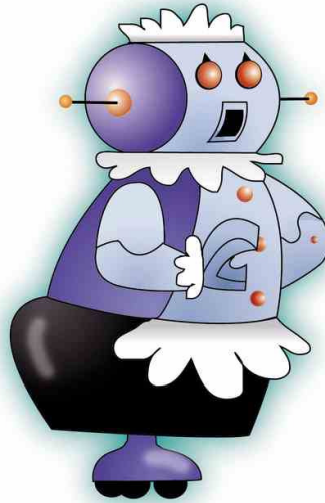
Effect of Barcode Technology on Target Potential ADEs



* $p < 0.001$ (Chi-squared test)

Poon, et al. *Annals of Internal Med* 2006

Robots, Robots, Robots!



What's in these IV Bags?



Rationale for Robotic IV Admixture Preparation

- The medical literature has defined the risks associated with improper preparation of Compounded Sterile Products (CSP) by humans
- USP <797> requires sterile product preparation to be completed in an appropriate sterile environment.
- The Joint Commission, requires all non-emergent IV admixtures to be prepared by the Pharmacy department.
- Need to limit staff exposure to potential carcinogenic and teratogenic medications.
- Need to improve the utilization of limited pharmacy resources.
- Volumetric process is less accurate than Gravimetric process

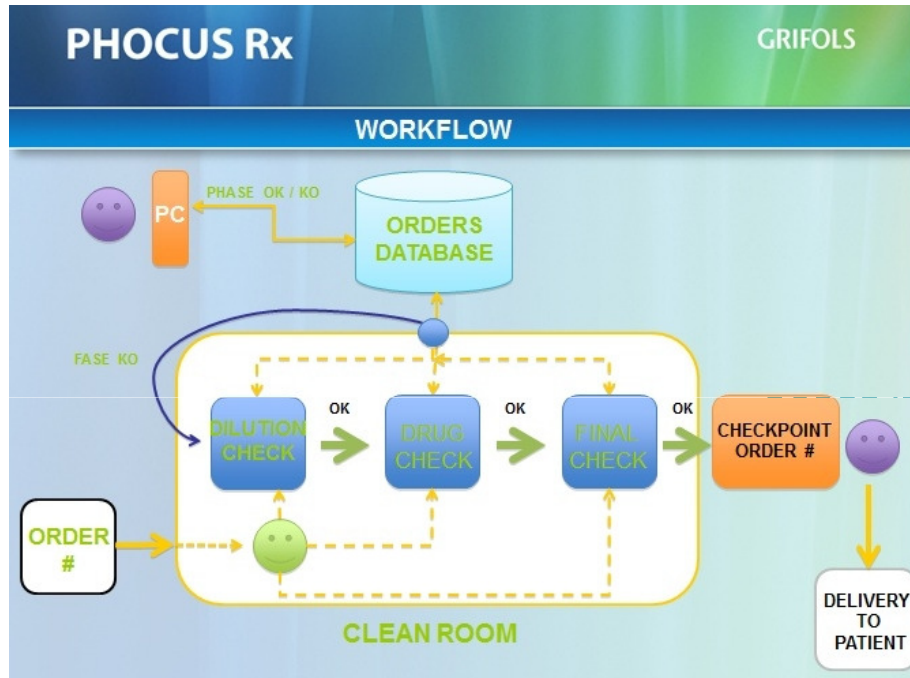


Robots Provide Us With:

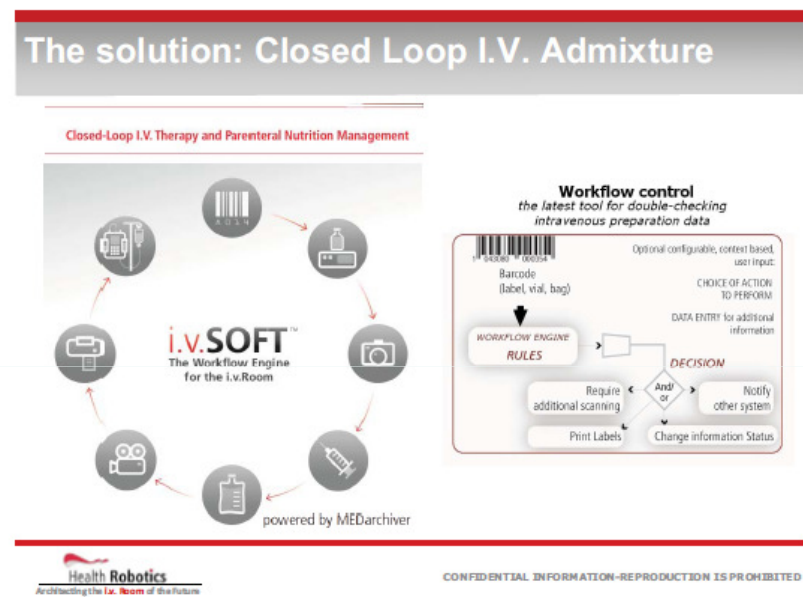
- Bar code verification
- Specific gravity and gravimetric verification
- Optical scanning
- Central data storage
- High degree of accuracy and precision
- Efficient work flow
- Workload prioritization and tracking
- Interfaces
- Limits human involvement in the compounding process
 - **NOTE -humans are the primary source of contamination!**



Searching for the Gold Standard for a Compounded Sterile Products Service



With permission of Grifols



With permission of Health Robotics

Centralized Electronic Data Storage and Database Management

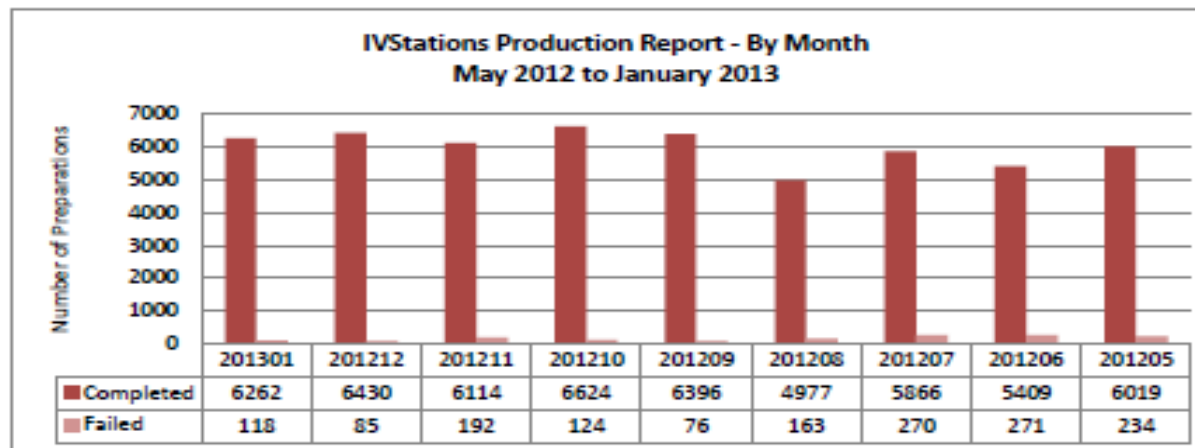
- We need the capability to electronically store all data associated with the preparation of CSPs.
 - Date/time
 - Source of preparation (Human/Robot)
 - All ingredients with lot numbers and exp. Date
 - Accuracy of final product
 - Production time for efficiency
- We need the capability to analyze and utilize the data to continuously improve the process and staff productivity, efficiency and accuracy.



Central Database Tracking of all Gravimetrically Prepared CSPs-Total Volume

IVStations Production Report - By Month
May 2012 to January 2013

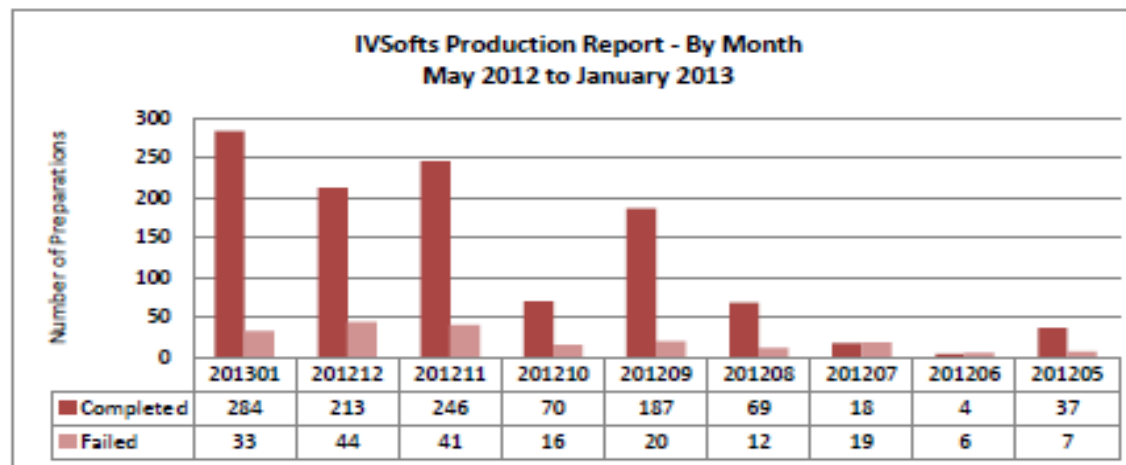
StatusName JobStartYearMonth	Completed			Failed			Total by ROWS		
	Request Count		Average Minutes	Request Count		Average Minutes	Request Count		Average Minutes
	Value	Percents by ROW	Value	Value	Percents by ROW	Value	Value	Percents by ROW	Value
201301	6262	98%	14,511	118	2%	306	6380	11%	14,816
201212	6430	99%	14,496	85	1%	195	6515	12%	14,691
201211	6114	97%	14,374	192	3%	461	6306	11%	14,835
201210	6624	98%	15,663	124	2%	273	6748	12%	15,936
201209	6396	99%	15,910	76	1%	261	6472	12%	16,171
201208	4977	97%	11,366	163	3%	317	5140	9%	11,683
201207	5866	96%	13,250	270	4%	746	6136	11%	13,996
201206	5409	95%	12,858	271	5%	961	5680	10%	13,820
201205	6019	96%	13,724	234	4%	935	6253	11%	14,660
Total by COLUMNS	54097	97%	126,153	1533	3%	4,456	55630	100%	130,608



Central Database Tracking of all Gravimetrically Prepared CSPs –Total Volume

IVSofts Production Report - By Month
May 2012 to January 2013

atusName ibStartYearMonth	Completed			Failed			Total by ROWS		
	Request Count		Average Minutes	Request Count		Average Minutes	Request Count		Average Minutes
	Value	Percents by ROW	Value	Value	Percents by ROW	Value	Value	Percents by ROW	Value
11301	284	90%	877	33	10%	1,519	317	24%	2,395
11212	213	83%	761	44	17%	174	257	19%	935
11211	246	86%	871	41	14%	132	287	22%	1,003
11210	70	81%	203	16	19%	1,497	86	6%	1,700
11209	187	90%	609	20	10%	126	207	16%	736
11208	69	85%	181	12	15%	074	81	6%	255
11207	18	49%	055	19	51%	184	37	3%	238
11206	4	40%	011	6	60%	010	10	1%	021
11205	37	84%	099	7	16%	010	44	3%	110
Total by COLUMNS	1128	85%	3,668	198	15%	3,725	1326	100%	7,393



Workflow Assist Technologies

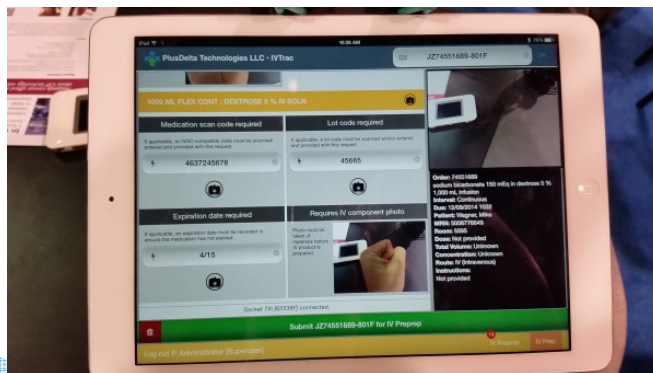
DoseEdge®



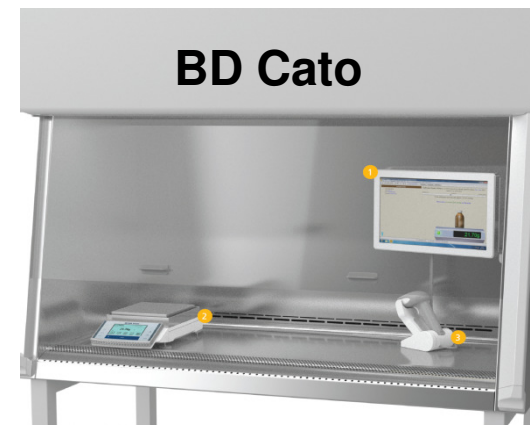
IVsoft Assist®



Phocus RX

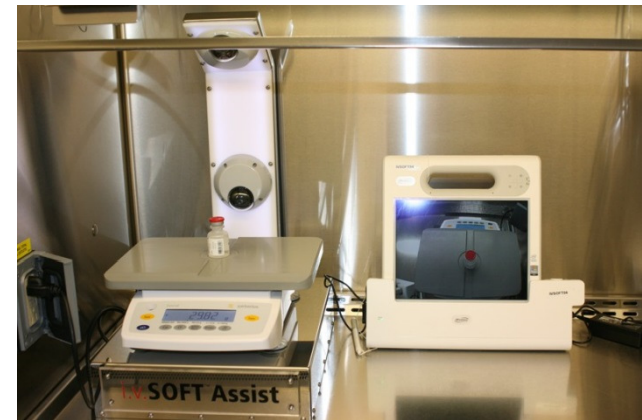


BD Cato



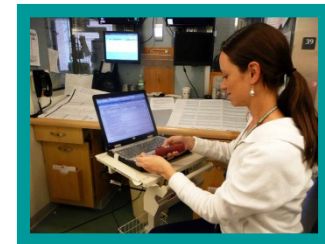
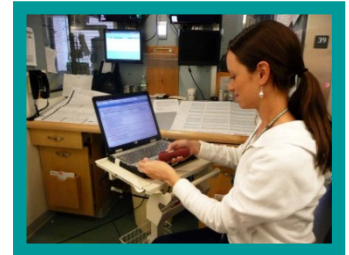
Work Flow Assist Technology

- IVSoft Assist (BWH has 4 Devices)
 - Checks human preparation process at each step using gravimetric checking.
 - Fully interfaced via “Worklist”.
 - Efficiency (1.5 – 3.5 minutes per dose).
 - Not as product dependent as robotics.
 - Patient specific doses.
 - Vials/materials that do not meet robot specification.
 - Non-standard, non-premade doses.

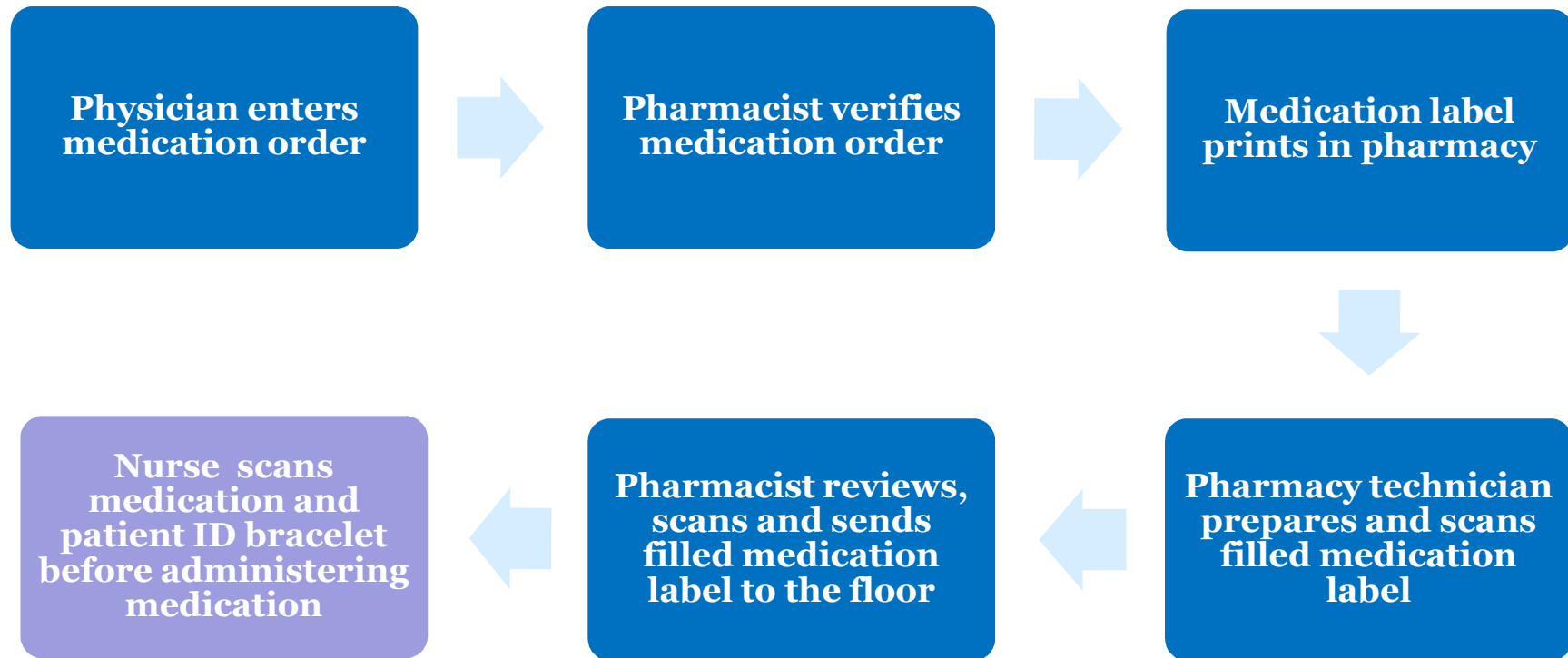


Bar Code Med Administration (BCMA)

- Orders flow electronically from CPOE through pharmacy order verification to an electronic medication administration record (eMAR)
 - Eliminates transcription entirely
 - Nurses have laptops or hand held devices with eMAR and use this to track what medications need to be administered
- Nurses use barcode verification of the medication and the patient to verify that the drug they are administering matches the physicians' orders
 - Right drug, right patient, right dose, right time
 - eMAR alerts if any of these is incorrect
 - Reduces administration errors



Medication Distribution Process



Impact of Bedside Barcode Verification on Potential Adverse Drug Events of Various Severity

	No Barcode Scanning (n=6712)	Barcode Scanning (n=7314)	Relative Reduction (p-value)
Potential Adverse Drug Events	3.1%	1.6%	51% (p<0.001)
Significant	1.82%	0.94%	48% (p<0.001)
Serious	1.30%	0.60%	54% (p<0.001)
Life-threatening	0.03%	0.01%	54% (p=0.52)

Poon et al, N Engl J Med 2010;362:36-45

Impact of Barcode Verification and eMAR on transcription errors

	Manual Transcription (n=1799)	Automatic Transcription (n=1283)	Relative Reduction (p-value)
Transcription Errors	6.1%	0%	100% (p<0.001)
Potential Adverse Drug Events due to transcription Errors	3.0%	0%	100% (p<0.001)
Significant	1.6%	0%	100%
Serious	1.3%	0%	100%
Life Threatening	0.06%	0%	100%

Potential Medication Safety Impact at a Tertiary Care Teaching Hospital

- The pharmacy barcode verification system currently in use is preventing per year:
 - >13,500 medication dispensing errors (31% reduction)
 - >6,000 errors with potential for harm (63% reduction)
- The eMAR bar code verification system intercepts nearly 7700 potential errors per month:
 - Wrong drug 7107
 - Wrong patient 192
 - Expired med 360

Financial Benefits of Barcode Technology in the Pharmacy

- Medical costs saved through adverse drug event reduction, *per year*
- Increased on-time medication availability on nursing units
- Improved inventory control
- Formal cost benefit analysis showed break-even within first year after go-live
 - 5-year cumulative net benefit = \$3.3M

Maviglia, S et al. Archives of Internal Medicine 2007

Bar code Verification is needed everywhere not just for inpatient areas!



Radio Frequency Identification (RFID)

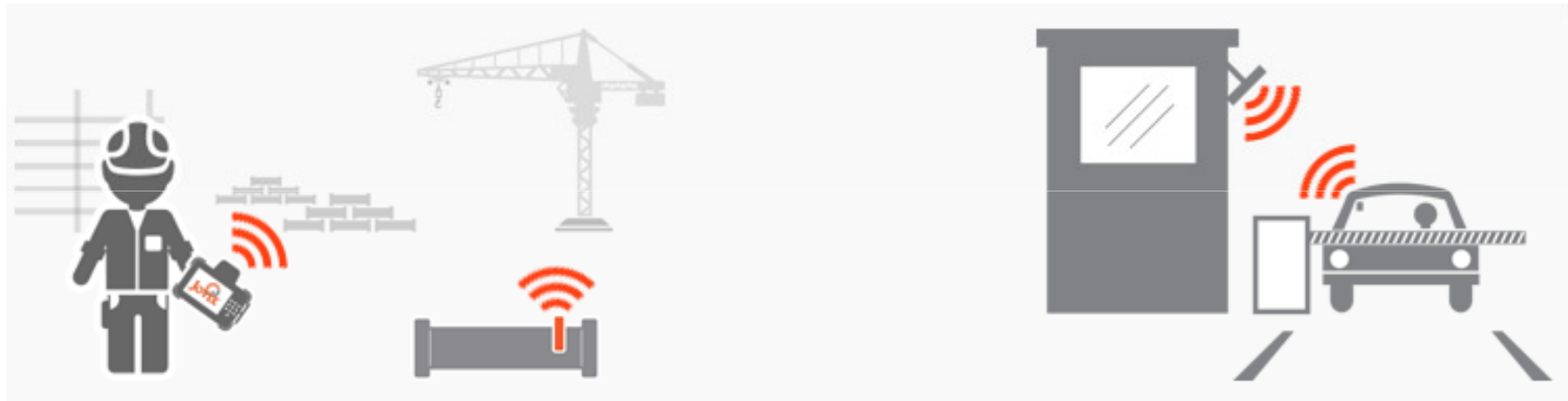
- Form of wireless communication that uses radio waves to identify and track objects
 - Track multiple objects at once
 - Different practice settings
 - Transportation, healthcare, animal tracking
- Components
 - Tag (active vs. passive)
 - Reader
 - Database tracking objects

Active vs. Passive Tags

Tag Type	Active	Passive
Power Source	Battery operated	Requires energy transfer from reader
Communication Range	High (>100 M)	Low (10 M)
Relative Cost	\$15.00-100.00	\$0.15-\$5.00
Examples at Brigham and Women's Hospital	Alaris Pump	KitCheck



Active vs. Passive Tags

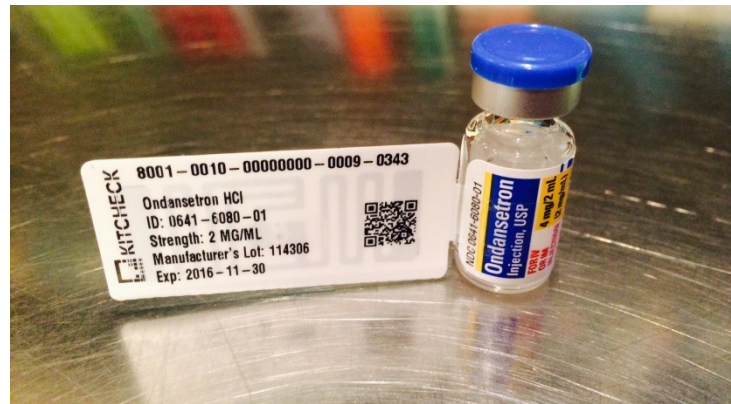


Active Tag

Passive Tag

Active vs. Passive Tags

Passive Tag



Active Tag

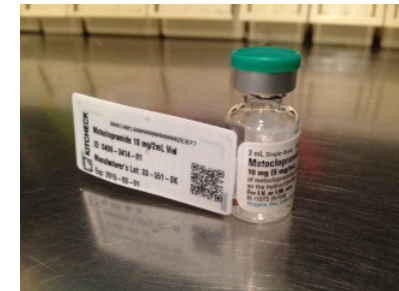


RFID Refrigerator & Passive Tags Blood Clotting Factors



Enhanced Medication Safety for OR Medication Dispensing - Kit Check RFID Scanning Station

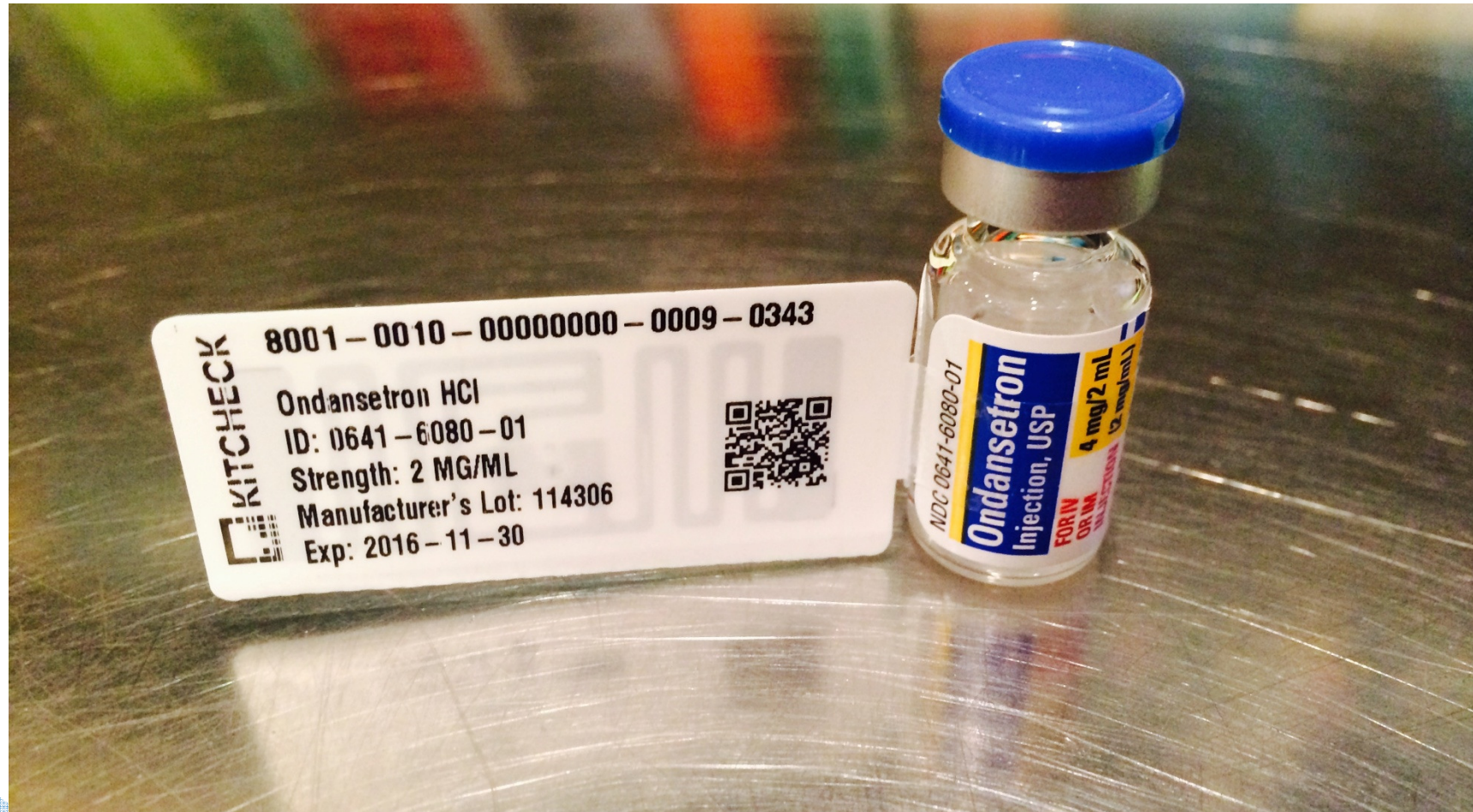
- System uses passive RFID technology with base station reader.
- Checks all contents of our OR medication kits in seconds for:
 - Dating (both outdated and soon to be outdated)
 - Proper quantity
 - Correct medication
 - Missing medications
- Since installation:
 - **1.1 million** medications have been scanned for accuracy and expiration checking in kits with **zero** errors leaving the pharmacy.



Kit Check



Kit Check



Kit Check



Kit Check

The screenshot shows the top navigation bar of the Kit Check application. On the left is the 'KITCHECK' logo. Next to it is a blue 'SCAN' button with a scanner icon. To the right are navigation links for 'Inventory', 'Tags', and 'Reports'. Further right is the user name 'Audrey Kivlehan' followed by icons for a user profile, settings, and a help/question mark. Below the navigation bar is a blue header bar with the text 'Welcome, Audrey!' and a question mark icon. The main content area contains three paragraphs of text: 'Use the SCAN button above to start the scanning process.', 'Please make sure all items are in the scanning station and the doors are securely closed.', and 'You can set a default start page for Kit Check so that every time you log in, you will see that screen by default. This preference can be changed in the User Settings screen at any time.'



View Inventory

Understand and manage your inventory by reviewing all kit scans and creating kit masters and formulary items.



Print Tags

Begin the process of tracking your inventory by printing tags for kits and items.







Run Reports

Use a wide range of reports to gain better visibility into your tagged items and operational activity.



Kit Check

KITCHECK [SCAN](#) [Inventory](#) [Tags](#) [Reports](#) Audrey Kivlehan   

11 Items **Thoracic Surgery Kit** ID: TH01 Scanned on Mar 18, 2015 at 10:30 by Audrey Kivlehan 

0 EXTRA **1** MISSING **0** EXPIRED **0** EXPIRING **Bupivacaine w/ Epi on Feb 01, 2016** [Dispatch Kit](#)

[Scan Summary](#) [Scan Details](#)

Missing Items [Print Billing Sheet](#)

Shortage	Segment	Expected	Actual
1	Bupivacaine 0.5% w/Epi, 30ml vial	1	0



Kit Check

The screenshot displays the KITCHECK software interface. At the top, there is a navigation bar with the KITCHECK logo, a 'SCAN' button, and menu options for 'Inventory', 'Tags', and 'Reports'. The user's name, 'Audrey Kivlehan', is visible in the top right corner. The main content area shows a 'Thoracic Surgery Kit' with 11 items. A modal dialog box titled 'Scan Kit and Items' is open in the center, displaying a loading spinner and the text 'Scanning your items. Please wait.' Below the dialog, there are buttons for 'Dispatch Kit' and 'Print Billing Sheet'. A table at the bottom shows 'Missing Items' with columns for 'Shortage', 'Segment', 'Expected', and 'Actual'. The table contains one row for 'Bupivacaine 0.5% w/Epi, 30ml vial' with a shortage of 1, an expected quantity of 1, and an actual quantity of 0.

Shortage	Segment	Expected	Actual
1	Bupivacaine 0.5% w/Epi, 30ml vial	1	0

Kit Check

The screenshot displays the KITCHECK application interface. At the top, there is a navigation bar with the KITCHECK logo, a SCAN button, and menu items for Inventory, Tags, and Reports. The user's name, Audrey Kivlehan, is shown along with user, settings, and help icons. Below the navigation bar, a header section identifies the kit as a "Thoracic Surgery Kit" with 12 items and ID: THO1. It also shows the scan date and time: "Scanned on Mar 18, 2015 at 10:31 by Audrey Kivlehan".

A summary row below the header shows the status of various components: 0 EXTRA, 0 MISSING, 0 EXPIRED, and 0 EXPIRING. A note indicates "Bupivacaine w/ Epi on Feb 01, 2016". A "Dispatch Kit" button is visible on the right.

Below the summary row, there are two tabs: "Scan Summary" (selected) and "Scan Details". The main content area features a large green banner with a white checkmark icon and the text "You're done! This Kit is complete." Below this banner, a white box contains the instruction: "Use the **Dispatch Kit** button above to put the Kit in use!"

Drug Supply Chain Security Act (DSCSA)





Summary Requirements for DSCSA Starting Jan 1, 2015

- DSCSA requires tracing, verifying and identifying products across ALL changes of ownership from Manufacturer to Dispenser
- DSCSA compliance is based on three core regulatory requirements:
 - *Tracing*: Send or receive Transaction History (TH), Transaction Information (TI) and Transaction Statement (TS) on change of ownership
 - *Verification*: Retrieve, analyze, verify and provide TH, TI, TS and serialized identifiers during suspect product investigations and recalls
 - *Serialization*: Serialize drug products at the unique package and case level for originally manufactured and repackaged product

• DSCSA High-level Deadlines

2015	2017-20	2023
Lot-level traceability Product and transaction verification Tracing and Verification archival	Serialization (package, case) Verification (SNI of package) Serialization archival	Package-level traceability

- A company's DSCSA compliance depends on Operations, Transactions, Network Relationships, Products:

Manufacture and introduce saleable drugs into commerce	Purchase saleable drugs from another company	Repackage saleable drugs and sell into the supply chain	Sell products to patients outside of the supply chain
 Manufacturer Requirements	 Wholesaler Requirements	 Repackager Requirements	 Dispenser Requirements



Product Tracing Requirements

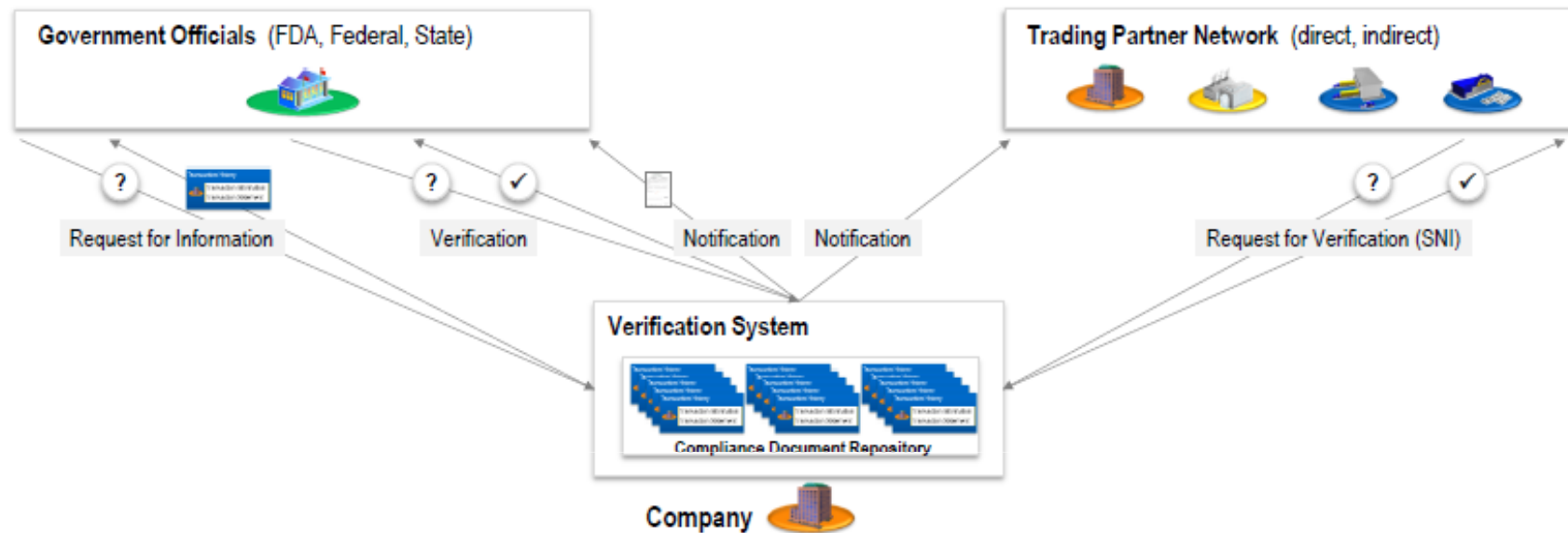


- Acquire or provide on each change of ownership:
 - **Transaction History + Transaction Information + Transaction Statement**
- Starts as a single document from the manufacturer
- Different forms of TH, TI, TS required depending on product source and transaction history
- TH, TI, TS for products purchased or sold must be retained in a record repository for 6 years past date of transaction
- DSCSA DOES NOT DEFINE A SPECIFIC DATA EXCHANGE METHOD

Transaction History (TH)	Transaction Information (TI)	Transaction Statement (TS)
<p><u>Single</u> document starting with manufacturer</p> <ul style="list-style-type: none"> • Includes Transaction Information for each change of ownership going back to the manufacturer • Special versions of Transaction History created during certain wholesale distribution scenarios <p>Electronic or paper (initially)</p> <ul style="list-style-type: none"> • Electronic format at point of manufacture required starting in 2017 	<ul style="list-style-type: none"> • NDC • Product Name • Strength • Dosage Form • Container Size • Number of Containers • Lot Number (optional in certain scenarios) • Transaction Date (optional in certain scenarios) • Shipment Date (if >24 hrs. from Trans Date) • Transfer From Party (business name & address) • Transfer To Party (business name & address) • Wholesaler Contact Information (for Drop Shipment) 	<p>Statement attesting that party transferring ownership:</p> <ul style="list-style-type: none"> • Is authorized and registered • Received product from authorized, registered party • Received Transaction Information and a Transaction Statement from the prior owner • Did not knowingly ship suspect or illegitimate product • Had systems and processes in place to comply with verification requirements • Did not knowingly provide false transaction info • Did not knowingly alter the transaction history

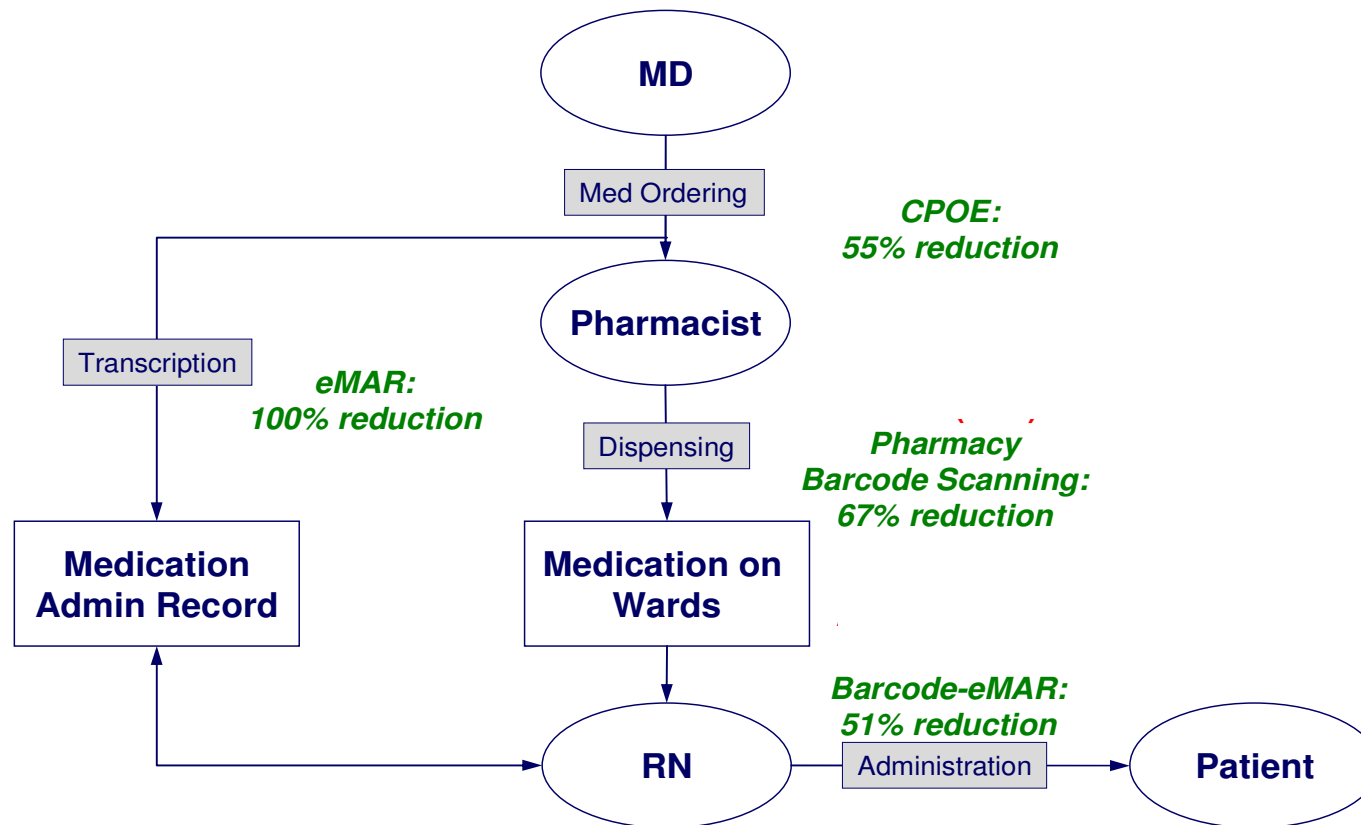


Product and Transaction Verification Requirements



Regulation	Date	Requirements
Request for Information	Jan 2015 (M, R, W) July 2015 (Dispenser)	If receive request for information from government official in the event of a recall or suspect product investigation: <ul style="list-style-type: none"> • Provide TH, TI, TS for requested products in one (1) business day (not to exceed 48 hrs.) [dispensers have 2 business days]
Verification	2015 (all) *2017-2020 (mfg, repack, wholesaler, dispenser)	If receive verification request from gov't official in suspect product investigation or if company determines it has suspect product: <ul style="list-style-type: none"> • Conduct investigation in coordination with trading partners; quarantine such product • Validate TH, TI of identified products • *Verify SNI of identified products
Request for Verification	2017 (mfg) 2018 (repack)	If receive request for verification of drug product from supply chain participant (direct, indirect trading partners): <ul style="list-style-type: none"> • Verify product identifier/SNI of the products queried against product identifier/SNI affixed by manufacturer/repackager • Notify trading partner of results within 24 hours
Notification	2015 (all)	Notify gov't officials of cleared product subject to investigation Notify FDA and all immediate trading partners if determine a product in their possession or control is illegitimate (w/in 24 hours) Manufacturers: Notify FDA and Immediate trading partners if reason to believe at high risk of possession of illegitimate product Notify trading partners of investigation termination
Archive	2015 (all)	Archive suspect product investigation and illegitimate product documentation for 6 years past investigation closure

What's the Overall Benefit of Medication Safety Technology and Automation?



Some Final Thoughts...

- ✓ **Technology can never replace the critical thinking of clinicians but it can serve as a key safety and productivity tool for the staff.**
- ✓ **Track and trace capability has the potential to help improve drug preparation, drug distribution, and medication administrations processes based on review of real-time objective data analytics.**
- ✓ **Bard code scanning technology is the current benchmark, but RFID technology may be the future of track and trace.**

