Supply Chain Management: Risk Management Redefined

Activity Overview

Managing drug shortages, assuring a safe supply chain, navigating a complex distribution and regulatory environment, and overseeing increased total pharmaceutical expenditures across the pharmacy enterprise are important challenges facing pharmacy leaders. This session will help you develop new strategies and identify evolving opportunities while managing the financial responsibilities associated with optimizing the supply chain.

Learning Objectives

After participating in this application-based educational activity, participants should be able to

- Develop a plan for optimizing the supply chain in your health system.
- Apply strategies for managing challenges related to drug shortages.
- Apply automation strategies to manage the logistics of the supply chain.
Supply Chain Management: Risk Management Redefined

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Introduction

• High level definitions of the supply chain
  – Identify some risk points
• Cleveland Clinic overview
• Vanderbilt overview
What Is a Supply Chain?

- Supply chains are the multiple processes that connect customers and suppliers
  - Sourcing and logistics
  - Getting the right materials to the right people and places at the right time and at the right cost

Pharmaceutical Supply Chain Components

- Pharmaceutical manufacturers
- Wholesale distributors
- Pharmacies
- Other
  - Group purchasing organizations (GPOs)
  - Pharmaceutical benefit managers (PBMs)

Pharmaceutical Manufacturers

- Relatively few large, multinational firms comprise the majority of brand manufacturing industry sales
  - Top 10 manufacturers account for 63% of spend
- Pharmaceutical manufacturers have the most influence on prices
  - Set wholesale acquisition cost (WAC), which is the baseline price at which wholesalers purchase drugs
Wholesalers

- Add efficiencies to the supply chain
- Transactional and logistical
- Link a manufacturer to more than 165,000 drug delivery locations
- Manufacturers ship to a small number of wholesaler warehouses in large quantities as opposed to thousands of individual outlets

3 Companies Represent 85% of All Wholesaler Business

Revenue in Billions

Smaller companies include
- Morris & Dickson
- H.D. Smith
- Smith Drug
- NC Mutual Wholesale Drug

Source: Pembroke Consulting analysis of SEC filings. Results represent calendar year 2010 although fiscal calendars may vary.

Specialty Distributors

- Specialty distributors sell specialty drugs to non-retail outlets
  - Clinics, physician offices, specialty pharmacies
  - Oncology products account for 60% of sales
  - Average specialty distributor delivers to 24,000 unique physician owned/operated clinics
Pharmacies

- There are more than 61,000 retail and mail order pharmacies in the U.S.
- Total sales of all U.S. pharmacies was $266.4 billion
- Almost 4 billion prescriptions were dispensed in the U.S. in 2010

Pharmacy Benefit Managers (PBMs)

- PBMs administer prescription insurance plans
- Over 50% of all store-based retail prescription claims were processed by 3 companies
  - CVS Caremark
  - Express Scripts
  - Medco

Group Purchasing Organizations (GPOs)

- GPOs maximize buying power mostly for non-retail customers
  - Hospitals, clinics, surgery centers
- Non-retail customers can contract at a lower rate because they are in a different class of trade (COT)
- Wholesalers "charge back" the manufacturer for the difference between the contracted rate and WAC
Pharmacy Flow of Goods and Payments

Manufacturer

Drugs

Direct Cocontract

Prime Vendor

Contract Cost or WAC

Less Prime Vendor discount

Rebates

Distribution Service Fees; Promoting Sale & Authorizing Discounts

Pharmacy Flow of Goods and Payments

Risk Points in the Supply Chain

• Product handling
• Diversion
• Recalls and shortages
• Counterfeiting
• Contracting
  – Managing those contracts
  – Rebates and market basket
• Access to LDN and payor contracts

Cleveland Clinic

Established Feb 21, 1921  
- 4 physicians  
- MD group practice

Physician led  
- Non-profit organization  
- Group practice hospital and clinics

- Bring together diverse specialists to “think and act as a unit”

Mission: “...care of the sick, investigation of their problems, and further education of those who serve.”
CC Main Campus
50 Buildings on 180-acre campus

Cleveland Clinic
Integrated Health System
serving 5.1 million patients

Additional Locations
Cleveland Clinic Florida
Weston, FL
2011 Pharmacy Purchases

$367 Million

Inpatient $135 37%
HOP/Clinic $141 38%
Other $34 9%

Source: Pharmacy Purchasing Datawarehouse YTD through Q4 2011.

Leading the Pharmacy Enterprise:
Advancing Practice with Transitions in Health Care

Supply Chain Overview
Vanderbilt University Medical Center

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A Brief Overview

Vanderbilt School of Medicine
• Issued 61 MD diplomas in 1875
School of Nursing opened in 1908
Medical School integrated with the hospital in 1925
• A dispensary was part of the new model

VUMC – by the Numbers

<table>
<thead>
<tr>
<th></th>
<th>FY10</th>
<th>FY11</th>
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<tbody>
<tr>
<td>Hospital beds</td>
<td>930</td>
<td>930</td>
</tr>
<tr>
<td>Patient days</td>
<td>272,731</td>
<td>278,170</td>
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<tr>
<td>Discharges</td>
<td>51,874</td>
<td>51,538</td>
</tr>
<tr>
<td>Clinic visits</td>
<td>1,450,196</td>
<td>1,541,809</td>
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<tr>
<td>ED visits</td>
<td>108,398</td>
<td>105,487</td>
</tr>
<tr>
<td>OR cases</td>
<td>45,492</td>
<td>46,914</td>
</tr>
<tr>
<td>Total VUMC expense budget</td>
<td>$1.53 B</td>
<td>$1.65 B</td>
</tr>
<tr>
<td>Total pharmacy expense budget</td>
<td>$136 M</td>
<td>$128 M</td>
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</table>

VUMC Drug Purchases Annualized*

VUMC $121,283,592
317 FTE
125 Pharmacists
FY 11 Salary expense
28.7 mm

Clinic $50,300,235
Inpatient $46,091,126
Prescriptions $24,892,231

41%
38%
21%

*Based on Dec 2010 – November 2011 Purchases
Department of Pharmaceutical Services

- Three distinct business units
  - Inpatient (pediatrics – adults)
  - Outpatient clinic
  - Prescription business
- Why are they each unique?
  - Method of reimbursement (revenue)
  - Systems and processes
  - Each has its own business model
  - Each has its own patient care model

VUMC - Top 37 Drugs Comprise 80% of Expense

These Drugs Represent the Following Therapeutic Categories
The shortage situation is easing...

- NBC news reported an “easing crisis”
  - Fewer shortage reports vs. last year
  - FDA reporting requirement having an impact
  - FDA Safety and Innovation Act having an impact

But risk remains.....

What Is Risk?

- “The effect of uncertainty on objectives”
- Healthcare
  - Primary, secondary, tertiary prevention
- Risk management
  - Structured approach to managing uncertainty related to a threat through a sequence of activities
    - Risk assessment
    - Strategies to manage it
    - Strategies to mitigate it
  - Transfer risk (insurance), mitigate (car vs. bicycle), accept consequences of a particular risk (sailing without a life jacket)
Response of Pharmacists to Risk

- Myers Briggs
  - ISTJ – introverted, sensing, thinking, judging
- Rule following, project oriented, deadline meeting, planners who sacrifice pleasure for work
- Pragmatic response to risk...

Patient Safety

- Conversion errors
  - Morphine/hydromorphone
- Adverse outcomes
- Patient care delays
- Increased length of stays
- Treatment with less effective alternative
- Evidence-based medicine attacked
- Best practice compromised
- ASHP: ≥ 15 deaths directly attributable to drug shortages¹


2011 AHA Survey
820 non-federal, acute care hospitals

Shortages by treatment category

There will be risk
Hospitals Experiencing A Drug Shortage


Risk Assessment

• Staging risk
  – Risk rating
    • Number of times event happens x severity of impact x probability event happens
  – Failure mode and effects analysis (FMEA)

• Responding to risk
  – Event analysis
  – After-action review

Drug Supply Chain
FMEA

<table>
<thead>
<tr>
<th>Step 1 Description</th>
<th>Severity Score</th>
<th>Solution Design</th>
<th>Solution Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st failure mode</td>
<td>Cause Effect</td>
<td>Severity * probability</td>
<td>Resources needed</td>
</tr>
</tbody>
</table>

**Goal**

Keep stock on shelf

**Solution**

- Design

**Evaluation**

**ISMP Response Plan**

- Maintain early warning network
  - ASHP, FDA, key manufacturer sources
- Learn reasons for and duration of shortage
- Assess inventory
- Research related drugs in short supply
- Identify therapeutic alternatives
- Prioritize patients and limit use

- Proactive FMEA – know issues with substitutes (LASA, etc.)
- Avoid temptation to hoard drugs
- Communicate with staff
- Reach out to ethics committee
- Reach out to risk management
- Maintain a shortage network with local providers
  - Including a policy for dealing with this scenario
- Proactively monitor shortage-related ADEs

**LASA** = look alike, sound alike

**Vanderbilt’s Event Analysis**

- Establish relationships with manufacturing leadership
  - Hospira
  - APP
  - Teva
  - Baxter
  - Westward
  - Bedford
- Active role in Washington, D.C.
- Relationships with media
- Bi-monthly, corporate meetings
- Layered communication plan
Vanderbilt Shortage SBAR

- Situation
  - Shortage of x, critical to care of y patient type
- Background
  - How long on the watch list?
  - Where is it used?
  - What business units affected?

SBAR = situation, background, assessment, recommendation

Vanderbilt Shortage SBAR

- Assessment
  - How long is it on backorder?
  - How much do we use?
  - How much do we have on hand?
  - Are there alternatives?
    - Therapeutic substitutions
    - Alternative sources
      - Repackagers
      - Compounders
  - How do we decide who gets what?

Vanderbilt Shortage SBAR

- Operational strategy
  - ADM system obstacles- LASA, fit
  - Communication
    - Update online formulary, weekly newsletter, add CPOE content for prescriber
  - CPOE changes for alternatives
  - Inventory control strategy (JIT/back-up inventory)
  - Policy development for critical shortages
    - Oncology
### Severity Status Follow Up

<table>
<thead>
<tr>
<th>Severity</th>
<th>Status</th>
<th>Follow Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>GREEN</td>
<td>Limited; able to maintain supply</td>
<td>Business as usual; pharmacy DO NOT LOAN</td>
</tr>
<tr>
<td>YELLOW</td>
<td>Very limited; supply unpredictable but able to maintain supply</td>
<td>Pharmacy notified; clinical and/or operational change required; P&amp;T and nursing staff notification</td>
</tr>
<tr>
<td>RED</td>
<td>Unable to obtain; low stock on shelf</td>
<td>Status notification sent to stakeholders</td>
</tr>
</tbody>
</table>

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### “The Perfect Storm”

- With no shortages, there is no gray market
- Also called the ‘black market’
- Action on Capitol Hill
- Mark-ups of 450% 1000% mark-up
- Gas price gouging during a hurricane
- Pedigree laws
Why Is Pedigree Important?

• Remember counterfeit Epogen?
  – 2002 Dear Doctor letter from Amgen
  – 40,000 unit/mL, lot P002970, exp 7/03
  – Found to contain 20x lower concentration
• Counterfeit Vicodin ES
  – March 2012 Dear Doctor letter from Abbott
• Repackaging and relabeling doesn’t require a professional!


Why Is Pedigree Important?

• Partnership for Safe Medicines
• Leaders guide in three versions
  – Doctor, nurse, pharmacist
  – Provides tips for
    • Safe sourcing
    • Evaluation of suspect medications
    • Patient education
    • Reporting

Partnership for Safe Medicines. Leader’s guide for pharmacists (URL in ref list).

What Is Going On?

Causes and Consequences
(Gottlieb, American Enterprise Institute)

• Don’t mistake one for another
• “Complex and multifactorial”
• Common threads
• Regulatory in nature
  – Manufacturing
  – Pricing and profitability
  – Branding and manufacturing limitations

American Enterprise Institute. Solving the growing drug shortages (URL in ref list).
• ‘Zero tolerance’ policy
• Recall increase
  – 45/year, 5 due to particulate matter
  – 100/year, 20-30 due to particulate matter
• Hospira experience
  – Letter 483 (45% of inspections result in a Letter 483)

Causes

Pricing / Profitability / Productivity
• Medicare Modernization Act (MMA 2003)
  – Medicare Part B reimbursement changes
  – AWP to ASP + 6% on prior 6-month data
  – Physician-administered medications
  – Limits price increases
  – Can force practice to use more expensive branded products

Causes

• Older manufacturing processes
• Ineffe GMP
• Margins too thin to reconcile a Warning Letter or Letter 483
• FDA backlog
  – Working thru new drug applications backlog
  – Addressed any applications that could alleviate drug shortages
  – Prescription Drug User Fee Act (PDUFA)
• Active pharmaceutical ingredient (API) shortage
Consequences

- Patient care is threatened
  - Best practice
  - Oncology discussion
  - Canceling surgery
  - Focus from patient to logistics
    • Clinical, operational and administrative resources
- Financial impact (ASHP Survey)
  - $200 million spent in purchasing therapeutic alternative
  - $216 million in additional labor costs
  - 8-12 hours/wk of additional labor impact

Capitol Hill Response

- Preserving Access to Life-Saving Medications Act
  • Amy Klobuchar (MN) and Robert Casey (PA)
  • Requires early notification by manufacturer of any incident that would cause interruption
  • 16 months to get signed into law

‘Drug Shortage Prevention Act’

- John Carney (DE) and Larry Bucshon (IN)
- ASCO, ASPEN, AZ, HOPA
- Mandates expedited review of drugs vulnerable to shortage
- Requires more refined FDA regulatory process that addresses manufacturing issues without instigating a shortage
Presidential Executive Order

- First Executive Order involving the FDA in years
- October 31, 2011
- Broadened reporting requirements for potential shortages and instructed FDA to accelerate reviews of new applications for marketing purposes
- Increased communication staff by 4 people
- More robust shortage information

Resources for Managers: Reading List

- ASHP guidelines on managing drug shortages
- Impact of drug shortages on U.S. health systems
- National survey of the impact of drug shortages on acute care hospitals
  - http://www.ahp.org/content/11/19/2015.short (accessed 2012 Sept 4)
- American Hospital Association survey on drug shortages
  - http://www.ahajournals.org/content/11/1/drgshrsurveys.pdf (accessed 2012 Sept 4)
- Drug shortages, an approach to managing the latest crisis
- Anything by Erin Fox
“A license to market lifesaving medications should entail a public obligation to meet demand”
- Family Cancer Center Foundation

Leading the Pharmacy Enterprise: Advancing Practice with Transitions in Health Care

Drug Diversion: Risks to the Supply Chain

Mark Sullivan
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“These people who get addicted are extremely good at what they do, and if you’re not one step ahead of them, you’re going to have a problem.”
- John Burke, President
National Association of Drug Diversion Investigators
Tennessee ranks second in the nation for prescriptions per capita

- 15.7 million controlled substance prescriptions written between 2006 and 2007
- In 2006 …
  - 323 deaths from prescription drug overdoses
  - 73 deaths from illicit drugs

Risk Assessment Response

- Would you rather stage and mitigate or respond?
- Get ready to do both

Risk Assessment

- Staging risk
  - Risk rating
    - Number of times event happens x severity of impact x probability event happens
  - Failure mode and effects analysis (FMEA)
- Responding to risk
  - Event analysis
  - After action review
Opioid Pain Reliever Sales, Deaths, Treatments
CDC 1999 thru 2008 MMWR 2011

Kristen Parker – Hep C video

Oct. 20, 2008: Kristen Parker is counseled by a Rose Medical Center employee health nurse. Parker is told about her hepatitis C results. The nurse counseled Parker about health care precautions to prevent the transmission of the disease at work.
March 2009: Denver police, working with the DEA, began investigating suspected theft and diversion of controlled substances at Rose Medical Center.
April 13, 2009: Kristen Parker caught in area she was not assigned, triggering an immediate suspension and another drug test.
April 21, 2009: Results of second drug test returned with positive drug test. She had tested positive for fentanyl. She was informed on April 21 to report to Human Resources. On April 22, she did not show and was sent a certified letter of termination.
April 24, 2009: Rose informs State Health Department, DEA, and State Board of Pharmacy about termination of an employee for cause.
May 4, 2009: Parker began working at Audubon Surgical Center in Colorado Springs.

Colorado anesthesiologist being sued defends practices that defy guidelines
Posted: 12/12/2011 01:00:00 AM MST
By Michael Booth
The Denver Postdenverpost.com

The chairman of a major anesthesiology department at St. Anthony Hospital will testify that doctors don’t have a duty to lock drugs like fentanyl at all times, serving as an expert witness in support of defendant Dr. Sherry Gorman, records show.

Gorman also maintains she did not have that responsibility and that she considers drug diversions an “urban legend,” in a lawsuit brought against Gorman by an infected patient.
Drug Supply Chain

Diversion Risks in the Supply Chain

• Loss prevention and asset protection
  – Instilling a sense of responsibility in training
  – Identification of gaps to limit incidents
  – Insuring controls exist to protect the supply chain
  – Profiling
• Narcotics, muscle relaxants, steroids, high cost drugs

What needs to be included in diversion event analysis?
Diversion Risks in the Supply Chain

- Diversion
  - Pharmacy
  - Nursing
  - Anesthesia
  - Other
- Diverters need motivation, rationalization, and opportunity

Health Professionals

- 30% of arrests are health professionals
- Average health professional arrest every 6 days
- Almost 70% of those arrests are nurses
- Average nurse arrest every 8 days
- Approximately 15% of health care professionals will struggle with substance abuse during their career

The drugs most often listed on Tennessee death certificates

Methadone
Alprazolam
Hydrocodone
Fentanyl
Morphine
Diazepam
Oxycodone
Carisoprodol
Amitriptyline
Drugs on the Street

- Hydrocodone, oxycodone ($7)
- OxyContin ($1/mg)
- Diazepam, alprazolam ($1-3)
- Carisoprodol ($3)
- Methylphenidate ($10)
- Hydromorphone ($40)
- Methadone ($25), suboxone ($10)

Economic Implications

- Nearly half a million emergency department visits in 2009 were due to prescription pain medication abuse.
- Non-medical use of prescription pain medication costs health insurers up to $72.5 billion annually in direct health care costs.

Types of Diversion

- Theft
- Breakage and waste
  - Commonly used method, naïve coworker
- Omission
  - Sign out of inventory, did not chart on MAR
- Substitution
  - Remove drug, replace with saline, water, talcum powder, look-alike tablet
Who has started?

• How to start?
• People, process, systems
  – What people are needed to manage this?
  – What process is needed to guide this?
  – What systems are needed to support this?
    • Physical security
    • Monitoring
    • Information technology

How to Start

• Broaden beyond the pharmacy
  – Engage nursing, HR, legal, risk management, security, IT, others
• Divide the work
  – Education, policy development, steering team, operations team
• Participate in the work
  – Monitor the data, maintain engagement, maintain reporting

Processes to Limit Loss

• Background checks, drug screening
• Processes for inventory from wholesaler vs. order
• Entry of inventory into automated inventory tracking system
  – Carousel, ADM, robot
• Video capability for pharmacy, external and internal
  – Controlled access
• Internal audit process
Profiling the Diverter

• “Best nurse”
• “Above reproach”
• Works extra”
• “Stays late”
• “Prefers nights”
• “ICU/surgical”
• “Access for others”
• Agency employee
• Divorce
• Child custody
• Recent surgery
• Family stressors
• Personal stressors

Obtaining the Data

• Spreadsheet or database of transactions
• Sorted by unit, service line
• Sorted by drug
• Sorted by highest to lowest
• Will reveal areas for investigation

Tools Available

• User-created spreadsheets or databases
• Commercial products
  – Pharmacy or ADC system vendor analytics
  – “Bolt on” analytics products
    • Medacist (RX Auditor), Omnicell (Pandora)

Pharmacy Diversion

- Typically CIII and CIV drugs
- Greater opportunity if no perpetual inventory process in place
- Many instances where single person in a work area with little oversight
- Self impairment, impaired, or trafficking
- Diversion of waste during compounding
Operating Room Diversion

• Typically manual documentation processes, chart vs. narcotic documentation
• Short-acting narcotics
• 1 death per month in the U.S.
• Screening of waste returns
  – Chain of custody
• Audit of documentation

Investigation

• Circumstantial evidence
• Generally lack direct proof
• Review
  – ADM transaction data
  – MAR and chart documentation
  – Time and attendance
• Perform patient and staff interviews

Possible Findings

• High transactions
• Charting gaps, variance from other caregivers
• Frequent bathroom breaks, especially if diverting and using IV drugs
• Video evidence helpful but not always possible
Typical Findings

- Using scheduled injectables
  - Hydromorphone, morphine, fentanyl, sufentanil, remifentanyl
- Self addicted
- Not trafficking
- BOLO atypical findings

Where will you go from here?

- Risk management for
  - People
  - Process
  - Systems

Other Resources

- National Association of Drug Diversion Investigators
- DEA
- CMS Medicaid Integrity Group
  - [http://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/MedicaidIntegrityProgram/Downloads/drugdiversion.pdf](http://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/MedicaidIntegrityProgram/Downloads/drugdiversion.pdf)
Leading the Pharmacy Enterprise: Advancing Practice with Transitions in Health Care

Leveraging Automation to Manage the Supply Chain

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Cleveland, Ohio

ASHP Pharmacy Practice Model Initiative (PPMI)

- Identify emerging technologies
  - Identify available technologies to support implementation of the practice model and identify emerging technologies that could impact the practice model

Complicated Distribution
What automation is available today to help you manage your ordering, distribution, monitoring, and administration processes?

- AGVs (Frog®)
- EMR (EPIC®)
- Workload and inventory management software / hardware
  - PHACTS®
  - MedBoard®
  - Dose Edge®
  - Chemotherapy robotics (Apoteca®)
System Automation (cont.)

- ADMs (Pyxis®)
- Smart pumps (Baxter®)
- BCMA (EPIC®)

Automated Medication System

Electronic Medication Administration Record (EMAR)

- Recognized as a best practice
  - Preventing medication errors
  - Decrease in adverse drug events
- Eliminates transcription by pharmacists
- Improves turn-around time
EMAR and CPOE

- Wireless
- Decentralized order verification
- Round – enter orders
- MAR electronic

CPOE = computerized physician order entry

EMAR

- How many?
  - Under 100 beds
  - 1 – 300 beds
  - > 300 beds
- Epic®
- Cerner®
- What else?

Automated Guided Vehicles (AGVs)

- Largest U.S. deployment in health care (80 units, $80K each)
- 3000 trips / day
  - 700 miles / day
- From service center to depots
  - Supplies, waste removal, linen, food, pharmacy
  - Product moved from depot to end users
Technology for Pharmacy

- Creates a sound foundation for pharmacy operations
- Enables pharmacists to better interact with patients and caregivers
- Safety
  - Barcoding
  - Pick to light
- Efficiency
  - Decrease turn-around time
  - Increase inventory turns

Automated Central Pharmacy

- 6 Carousels
  - 4 standard
  - 2 refrigerated
- High speed packager
- 100% Bar-coded

Carousels: More than Hardware

- Enterprise management
  - Hardware
  - Software
  - Standardized item master
- Oversight and visibility across the enterprise
  - Standardized system reporting and metrics
50% reduction in floor space
25% reduction in inventory

Space Reduction

Automated storage and retrieval
- Reduced travel time
- Reduced labor fatigue
- Improved work quality

Workflow

Lessons Learned: Inventory Management Software
- Cycle counts
  - Only as good as the perpetual inventory data
  - Drug jail
- Process for holidays, wholesaler inventory days, etc...
- Downtime
  - Everything can break
  - Hardware, software
Who is?

- Using robots?
- Using carousels?
- <100 beds
- 100 – 399 beds
- > 400 beds

Carousels and Robots Used in 30% of Facilities


Single Hospital Distribution Model with Carousel

Enlarged on page 51
Quality

• Patient safety
  - Pick to light
  - Barcoding
  - Eliminate look-alike, sound alike (LASA) errors

Cost

• Cost reductions
  - Increase inventory turns
  - Decrease carrying cost
  - Reduce labor costs (re-allocate)
  - Smaller pharmacy footprint

Scan Points Flow Chart

Order processed

Ready for RPh check

Sent via tube

Ready for delivery

Picked up at window

On cart

Delivered to location

On delivery

Hand delivered to nurse
IV Workflow Management


Who Has?

- IV workflow software?
  - Dose Edge?
  - Simplify 797?
  - IV Soft?
  - Homegrown?
  - Other? If so, what?
Sterile Product Robotics

• Improve safety and efficiency
  – High risk and high cost
• Batch products
  – Syringes
  – Piggybacks and large volumes
• Patient specific

Chemotherapy Compounding

Who Has?

• Sterile products robots?
  - Intellifill?
  - RIVA?
  - CytoCare?
  - IV Station?
  - Apoteca?
Automated Dispensing Cabinets

Nursing units: 1 Setup for every 17 Beds
ICU: 1 Setup for every 10 beds

Intelligent Infusion Devices

• “Smart pumps”
  – Drug library
    • List of all medications entered into the pump software
    • Dosing limits
  – Automatic dose calculation by the pump
  – Wireless communication
  – Data capture

Smart Pumps

• Hospital-specific drug libraries
• Safety software and rule sets for high risk drugs
• Data gathering of infuser event and alarm logs - PI
• Pre-population of infusion programming parameters into final confirmation screen
• Reduces number of steps and potential for programming errors
• Can integrate with EMAR
Smart Pumps

- Who has them?
  - LV
  - Syringe
  - PCA
- Who is …
  - Getting good wireless quality assurance data from them?
  - Using barcoding with them?

BCMA

Medication Error Reduction (UW)

Overall medication error rate

<table>
<thead>
<tr>
<th>Error Type</th>
<th>Pre Admin-Rx (%)</th>
<th>Post Admin-Rx (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong Dose</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Wrong Dosage Form</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Omitted doses</td>
<td>92%</td>
<td>92%</td>
</tr>
<tr>
<td>Wrong time</td>
<td>77%</td>
<td>77%</td>
</tr>
<tr>
<td>Wrong drug</td>
<td>51%</td>
<td>51%</td>
</tr>
</tbody>
</table>
Other Stuff to Automate...

- Wireless temperature monitoring
- Repackaging
  - Outsourced
  - High speed repackagers
- Automated compounding devices
  (Baxa)

What are we missing?

Leading the Pharmacy Enterprise:
Advancing Practice with Transitions in Health Care

Specialty Pharmacy: Opportunities and Challenges

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What is Specialty Pharmacy?

- Oral and self-injectable pharmaceuticals
- Treat chronic, high cost diseases
- Requires dedicated clinical and administrative resources for complex "high touch" therapies
- Requires special access
  - Specific drugs
  - Insurance contracts and reimbursement
- Accreditation will be required for key payor contracts

Specialty pharmacy business has become a $100B market and is expected to grow twice as fast as the overall drug market.

Rationale to Keep Your Specialty Pharmacy Business

- Improve quality of care
  - Continuity of care
  - Leverage integrated delivery model and medical record
  - Improve patient adherence
  - Patient experience (one-stop shopping)
  - Eliminate "white bagging"
- Capture incremental revenue and margin
- Improve physician office efficiency and satisfaction

Source: IMS Health; AIS; Express Scripts 2010; Health Strategies Group; Industry Overview & Assessments of Leading SP Companies, 2010; Booz & Company analysis.
Why Is This important?

Current significance
• Losing revenue to outside pharmacies
• These drugs are replacing office infused therapies

Future significance
• Significant revenue loss as market grows
• Value-based operation
  – Control over cost
  – Pharmacists influence pharmaceutical management of patients

Strategic Alignment
• Patient experience
  – Entire cycle of care managed by your health-system
  – Service offerings very patient focused
• Quality and patient safety
  – Enhanced visibility within the medical record
  – Specialized drug education and adherence programs
  – Accreditation standards consistent with Joint Commission
• Enterprise growth
  – Large potential source of revenue and growth
  – Offset loss from office-infused to self-administered therapies
• Operating excellence
  – Integration with existing ambulatory pharmacies and mail order service
  – Economies of scale
    • Consolidate with home care
    • Do you outsource TPN / Cardioplegia

Risks
• Limited distribution networks
• Payor carve-outs
• Infrastructure
• Accreditation
• Physician buy-in
• You better execute…
Cleveland Clinic

- Total opportunity
  - 2013: $194,000,000
  - 2017: $412,000,000
- Conducted a thorough analysis and business plan to identify realistic revenue and associated expenses
- Bigger margin if 340B

Specialty Pharmacy

- Factors affecting financial performance
  - Number of specialists in the system
  - Payor mix
  - Number of prescriptions per patient
  - Revenue per prescription
  - Capture rate from system
  - Staffing levels and labor costs
  - Delivery logistics

Options

- Build it
- Buy it
- Hybrid
Build it
• Significant start-up costs
• Easier for large integrated systems to do this
• Distribution
• Call center
• Back office
  – Pre-authorization
  – Patient assistance
  – Billing
• Disease state specialists

Buy it
• Partner with third party
  – UHC® is creating a UHC® specialty branded program
  – Excelera® from Fairview (University of Minnesota Medical Center)
  – Premier® (Commcare®)
  – Consultants
    • Therigy®
    • Armada®
    • Focused Solutions Inc.®

Hybrid
• You fill the prescription and your business partner operates the back office
• Diplomat®
  • Giant Eagle
  • Costco
What Can You Do?

• Work with your C-suite
  – Develop business plan
  – Build infrastructure

• Work with your contracting team
  – Eliminate “carve outs”
    • Manufacturer / payor

• Work with your physicians
  – Identify strengths and weaknesses of competition
  – Send you business
Single Hospital Distribution Model with Carousel

Pharmogistics

Satellite, MD office, and department browser ordering

Larger hospital

Static shelving and refrigerators

Carousels with PC and scanner

ADUs  Patient carts

Returns PC

PhIS PC

Buyer PC

Mobile PC

ADU Console

PhIS PC

Mobile ADU Console

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Patient carts
SELECTED REFERENCES


OTHER RESOURCES

Drug Shortages
ASHP guidelines on managing drug shortages

Impact of drug shortages on U.S. health systems

National survey of the impact of drug shortages on acute care hospitals
   – http://www.ajhp.org/content/61/19/2015.short (accessed 2012 Sept 4)

American Hospital Association survey on drug shortages
Drug shortages, an approach to managing the latest crisis
  (accessed 2012 Sept 4)

Erin R. Fox, Pharm.D. Manager, Drug Information Service, University of Utah Health Care
– Excellent resource for information related to drug shortages

**Drug Diversion**
National Association of Drug Diversion Investigators

DEA

CMS Medicaid Integrity Group

**Automation**
