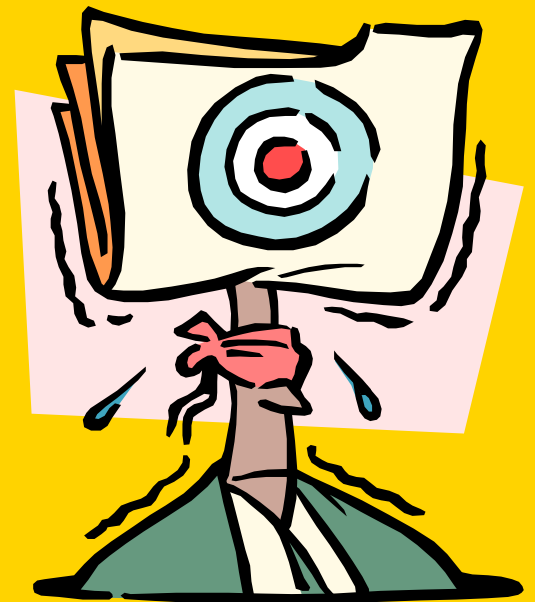




Know the Predication on No Medication: *Managing Drug Shortages in EMS*

- James Augustine, MD



What are the Safety Issues?

- The drugs are not there when patients need them, or in a form that is useful for the EMS provider (usually a paramedic)
- Safety for the provider:
 - Change in protocols
 - More training
 - More reading of packages
 - More need for documentation



Worsening Medication Shortages



- This is currently a problem at the manufacturer level
- Almost all injectable drug classes
- Non-compliance with regulatory standards and good manufacturing practices (GMPs)
- Recalls
- Regulatory issues (DEA vs. FDA)
- Issues with compounding pharmacies in some sites





Updated as of February 8, 2018; Content is Subject to Change

What are Opportunities?

- Active Inventory Management
- Protocol Changes
- Packaging
- Point of Care Support and Education
- Incident Management Team and an Action Plan

The 3 P's



Where Fire EMS Leaders are going for Safety Info



ASHP American Society of Health-System Pharmacists®
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Practice and Policy

Drug Shortages Resource Center

Welcome to the Drug Shortage Resource Center, the first stop for ASHP information and resources on drug product shortages and management.

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Resource Centers

- Anticoagulation
- Contrast Media and Medication Management
- Drug Shortages
- Emergency Care
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- Investigational Drug Services
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- Medications and Suicidality
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- Pharmaceutical Wastes
- Preceptor Skills
- Public Relations Network
- Quality Improvement
- REMS

Current Shortages

View the Current Drug Product Shortage Bulletins

Resolved Shortages

View the Resolved Drug Product Shortage Bulletins

Drugs No Longer Available

View the Drugs No Longer Available Bulletins

- [Report a Shortage to ASHP](#) and help ASHP Drug Shortage Resource Center to remain current.

Managing Drug Shortages

- [ASHP Agrees with FDA's Revised Definitions Related to Drug Shortage Reporting Requirements](#) [PDF]
- [ASHP Letter To Congressman Carney Supporting HR 3839 \(Drug Shortage Prevention Act of 2012\)](#) [PDF]

American Society of Health-system Pharmacists: <http://www.ashp.org/shortage>

State Level EMS Mgt

- Cooperation/liaison with state boards of pharmacy, health, and medicine
- Flexibility in state law, rules and regulations related to personnel capabilities
- Agency oversight allowing emergency agencies and hospitals to share stocks
- Sharing of best practices, particularly related to safety



Active Inventory Management

- Track Medication Budget
 - Look at expensive meds
 - Glucagon now about \$160 a dose
- Overall medication list prices up 91% last year



Hospira List- Tud	Product Description	Price Increase %	Possible Substitute Products	
			BT Item #	DESCRIPTION
0144-05	VERAPAMIL HCL INJ 2.5MG/ML 2ML FTV	387.41%		
0401-01	VERAPAMIL HCL INJ 2.5MG/ML 2ML AMP	372.00%		
0144-02	VERAPAMIL HCL INJ 2.5MG/ML 4ML FTV	370.31%		
0140-01	(SUPREL (ISOPROTERENOL HCL INJ USP) 1:5000 1ML AMP	348.32%		
0140-05	(SUPREL (ISOPROTERENOL HCL INJ USP) 1:5000 5ML AMP	324.24%		
0321-12	DIAZEPAM INJ USP CIV 5MG/ML 10ML FTV	281.66%		
0173-32	DIAZEPAM INJ CIV 5MG/ML 2ML CT LL SLMKP	214.81%		
0304-01	NITROPRUSS (SOD NITROPRUSSIDE) 50MG/2ML FTV	195.29%		
05921-01	AMINOPHYLLINE INJ USP 250MG 10ML IN 20ML FTV	173.33%		
01902-01	PROCAINAMIDE HCL INJ USP (100MG/ML) 10ML FTV	173.33%		
01639-10	FUROSEMIDE INJ USP (10 MG/ML) 10 ML ANSYR SYR	159.05%	6102-10	FUROSEMIDE 100MG, 10ML VIAL
09631-04	FUROSEMIDE INJ USP (10 MG/ML) 4 ML ANSYR SYR	158.77%	6102-04	FUROSEMIDE 40MG 4ML SDV 2048
09633-05	VERAPAMIL HCL INJ 2.5MG/ML 4ML ANSYR SYR	146.95%		
04911-34	ATROPINE SULF (0.1MG/ML 10 ML) ABI LS	143.39%	371006	ATROPINE 1MG, 10ML LUER JET 1006B 10EA/PK
06476-44	ERYTHROCI (STR ERY LACTO) 500MG ADD-V VIAL	123.72%		
04277-01	LIDOCAINE 2% HCL INJ USP 20ML FTV	126.67%		
06637-34	SOD BICARB INJ USP 8.4% 50MEQ 50ML (18GX1-1/2) LS	123.11%	371035	SODIUM BICARBONATE 8.4% 50ML LUER JET 1035B 10EA/PK
06651-06	POTASSIUM CL INJ 20MEQ 10ML IN 20ML FTV	122.50%		
05922-01	AMINOPHYLLINE INJ USP 500MG 20ML IN 50ML FTV	117.11%		
04910-34	ATROPINE SULFATE (0.1MG/ML 5 ML) ABI LS	110.37%		
01903-01	PROCAINAMIDE HCL INJ USP (500MG/ML) 2ML FTV	109.42%		
01775-10	DEXTROSE 25% INJ USP 2.5G (1ML) 10ML ANSYR SYR	100.00%		
05930-05	ATROPINE SULF INJ USP (0.05MG/ML 5ML) PED ANSYR SYR	99.88%		
01754-10	MAGNESIUM SULFATE INJ, USP 50% 10ML ANSYR SYR	99.44%	0064-10EA	Magnesium Sulfate 50% 5gm, 10ml Vial 25ea/bx 4bx/cs
07517-16	DEXTROSE 50% INJ USP 50ML ANSYR II SYR	93.98%	373301	DEXTROSE 50% 25GM 50ML LUER JET 1013B
06653-05	POTASSIUM CL INJ 40MEQ 20ML IN 30ML FTV	90.24%		
04900-34	SODIUM BICARB INJ USP 8.4%, 10 MEQ 10ML ABI SYR LS	87.11%		
01782-69	NALOXONE HCL INJ USP 0.4 MG/ML 1 ML CARPUJECT LL	86.91%		
04277-02	LIDOCAINE 2% HCL INJ USP 50ML FTV	83.48%		
01219-01	NALOXONE HCL INJ USP 4.0MG (0.4MG/ML) 10ML FTV	81.10%	373369	NALOXONE 2MG, 2ML LUER JET
06970-10	QUELIN (SUCCOLCHOLINE CL) INJ 1000MG 10ML 20ML FTV	80.82%		
12655-28	LS LF MACROBIORE EXT 20IN SC OL NON-DEHP SP	76.47%		
04279-02	LIDOCAINE 1% HCL INJ USP 30 ML FTV	71.93%		
01630-10	ATROPINE SULFATE INJ, USP (0.1MG/ML 10 ML) ANSYR SYR	71.13%	371006	ATROPINE 1MG, 10ML LUER JET 1006B 10EA/PK
04902-34	DEXTROSE 50% INJ 50ML (18GX1-1/2) LS ABOJECT	69.79%	373301	DEXTROSE 50% 25GM 50ML LUER JET 1013B
05334-34	SODIUM BICARB INJ USP 4.2% 5 MEQ 10ML ABOJECT LS	67.21%		
01631-10	CALCIUM CHLORIDE INJ, USP 10% 10ML ANSYR SYR	65.99%	373304	CALCIUM CHLORIDE 1GM, 10 ML LUER JET 1010B
06102-04	FUROSEMIDE INJ USP 40MG 4ML FTV	64.86%		
04916-34	SOD BICARB INJ USP 7.5%, 50ML ABOJECT LS	60.09%		
03414-01	METOCLOPRAMIDE INJ, USP 10MG, 2ML FTV	59.46%		
01258-30	MORPHINE SULF INJ USP CII 4MG 1ML CARPUJECT SLMKP	58.06%		
04887-20	STERILE WATER FOR INJ USP 20 ML FTV	54.76%		
06102-02	FUROSEMIDE INJ USP 20MG 2ML FTV	54.29%		

Active Inventory Management

- Track Each Medication in Protocol
 - Know use of each medication, focus on meds on shortage list
 - Individual medicine plan
 - Work now to specify therapeutic alternatives
 - Check with State on any control issue
 - Keep medicines near expiration at site they are likely to be used
 - Reduce meds in box, keep more central



The Expired Medicine Issue

- Science says meds are effective beyond posted expiration date
- Especially if stored correctly (active inventory control management)



System Safety Opportunities

- Optimal use of supplies
- Expand Supply
- Don't let any go to waste in community

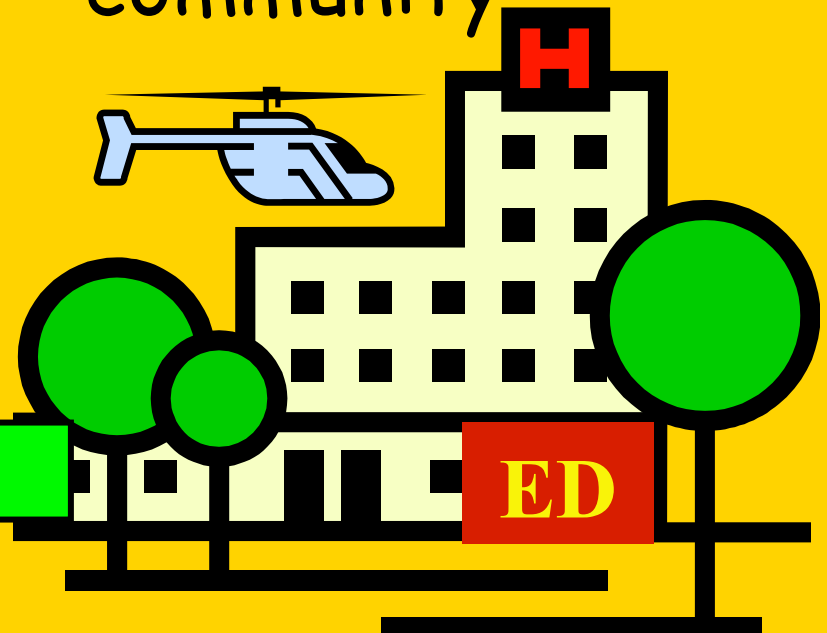


EMS Office

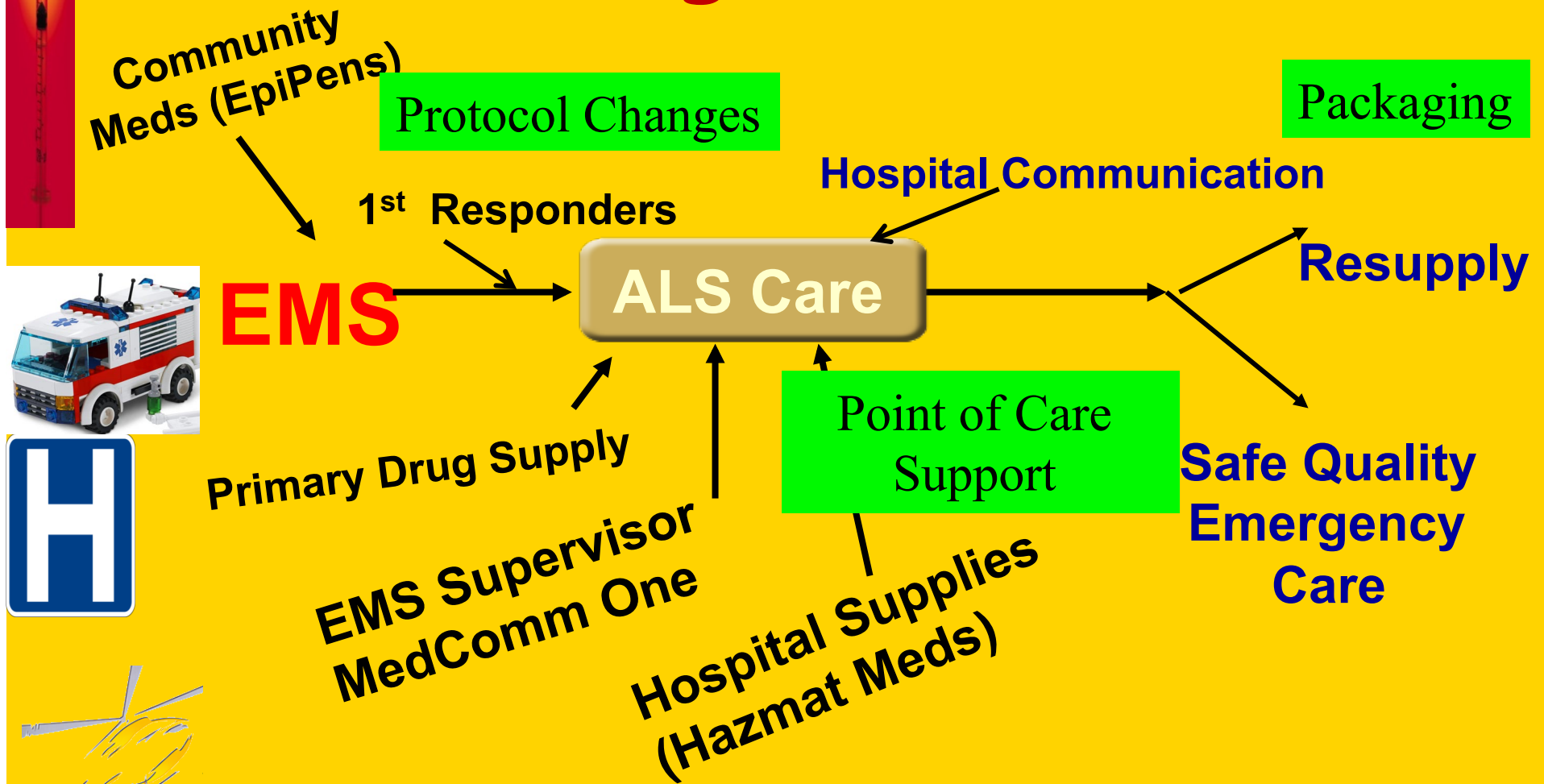
Community



Dept. of Health



Drug Shortage Safety Strategies - 3 P's



Protocol Change: Each Medication with Alternatives

Drug	Shortage Status	Where Carried	Therapeutic Substitution	Management Plan
Acetaminophen	None		Ibuprofen	None needed
Adenosine	Some versions		Verapamil	Get state approval
Albuterol	Inhalers		Levalbuterol	Get state approval
Amiodarone	Some		Lidocaine	Substitute Lidocaine now, but leave on approval list
Aspirin	None		None	None needed
Ativan	Many		Midazolam, Valium	This is drug that needs refig. Get state approval
Atropine	Many		None	Secure approval to tap hospital stocks
Calcium	Some versions		Other forms of calcium	Get state approval for all forms of calcium
Captopril	None		Lisinopril	Get state approval
Cardizem	None		Verapamil	Not seen on most protocols. Get state approval.
Dextrose	Few		Different prep	Oral glucose
Dimenhydrinate	None		Diphenhydramine	Get state approval
Diphenhydramine	Many		Dramaine, Vistaril	Get state approval
Dopamine	Many		Dobutamine	None needed
Epinephrine	Many, including important 1:10,000		None	Establish hospital relationship, request they mix 1:10,000 vials
Etomidate	Many		Propofol (also short)	Get state approval
Fentanyl, Dilaudid	Many		Morphine and each other	Get state approval
Furosemide	None		Bumetanide	Get state approval
Glucagon	Many		None	Very expensive. Substitute glucose or IN D50
Glucose (oral)	None		None	None needed
Haloperidol	Many		Droperidol	Get state approval
Heparin	Few		Different version	None needed. Not an important EMS medicine
Hydroxocobalamin	None		Lilly Kit	Assure state approval
Ipratropium	None		Straight albuterol	None needed
Ketorolac	None		None	Get state approval
Lidocaine	None		Amiodarone	None needed
Magnesium	Many		Different version	Establish hospital relationship
Metoprolol	Some		Other beta-blockers	Get state approval
Naloxone	Many		None	Establish hospital relationship
Nitroglycerine	None		None	Establish hospital relationship
Ondansetron	Acute		Promethazine	Get state approval
Promethazine	Many		Zofran, Compazine	Get state approval
Sodium Bicarbonate	None		None	None needed
Solumedrol	Many		Dexamethasone, hydrocortisone	Get state approval
Terbutaline	Many		Albuterol	None needed. Uncommon in EMS protocols
Thiamine	Few		None	None needed. Uncommon in EMS protocols
Valium	Many		Ativan, Midazolam	Get state approval
Vasopressin	Few		Epinephrine	None needed. Uncommon in EMS protocols



Packaging for Safety

- Personnel must be confident on use of critical medicines
 - Don't discourage med use
- Package for safety



Packaging Changes

What will crews recognize easily

Pain Medications	Morphine, Fentanyl, Hydromorphone
Seizure Meds	Midazolam, Diazepam, Lorazepam
Nausea Meds	Ondansetron, Promethazine, Prochlorperazine, Droperidol
Sedatives	Ketamine, Etomidate, Propofol





Packaging for Safety

- Minimize changes in medicines
- Drugs in usable vials, carpujects and needleless forms
- Package in recognizable forms
- As medicines vary, put information right on the package
- Active inventory management
 - Less complexity for clinicians = **More complexity and cost for logistics**



Point of Care Support and Education

- At site of medicine acquisition
- In drug box
- On laptop computer



Point of Care for Clinical Providers

- Education
- Make the system error-resistant and ...
- Encourage error reporting
- Use IT help



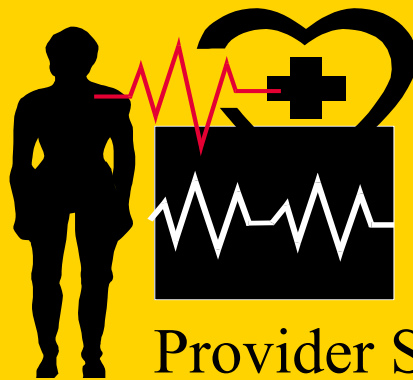
Point of Care Education: Crew Notification

- Educational brochures, posters
- Email blasts
- Text messages



Incident Action Plan

- Create a management group
- Get resource persons together in-house
- Need state cooperation from EMS and pharmacy boards
- Initiate cooperation with other agencies and hospitals



Provider Satisfaction



Safety of Care



Finance and
logistics



Shared drug
sources: Right place,
right time

Incident Management

**Incident
Command**

Public Information
Safety Officer
Liaisons

Operations

Planning

Logistics

Finance



LEVEL 1 ADVISORY

Advisory and Preparatory Activities

Hospitals

Intel and Feedback on shortages
Design and approve agreements for sharing meds with each other and EMS

County EMS and Fire Agencies

Develop therapeutic equivalent list
Make appropriate protocol changes to allow substitutions

Using paramedic input design:

- Packaging solutions for safety
- Safety program
- Needed just in time educational programs

DOH

Assist in study of tracking program for typical and atypical meds
Study sources for atypical meds

Planning Team

Study legal and regulatory challenges and develop recommendations
Design medication tracking program and what elements of DOH program that can be applied
Create the process for declaring shortage and allowing compounding
Design a “no risk” safety reporting program
Study the central sourcing program
Publish “Drug Shortage Status Bulletin” for Command Team, state, local hospitals and providers
Develop LEVEL 3 elements and props

Finance

Budget projections on the impact of this program
Purchase Order process for timely and emergency acquisition, and designate a compounding pharmacy
Study reliable sourcing and pricing programs

LEVEL 2 MODERATE SHORTAGES

Medication shortages affect availability and patient care in emergency operations, with Life Threatening Risk

Trigger: When multiple therapeutic substitutions are being used, and multiple medicines are in shortage status at hospital and EMS sources

Hospitals approve agreements for sharing meds with each other and EMS

County EMS and Fire Agencies

Implement protocol changes to allow substitutions
Using paramedic input design initiate:

- Packaging solutions for safety
- Safety program
- Just in time educational programs

First stage of “Medication Command” utilization

DOH implements elements of tracking program for typical and atypical meds
Initiate sourcing for atypical meds

Planning Team

Implement needed legal and regulatory changes
Finalize state “releases”
Implement process for declaring shortage and start needed compounding program
Implement medication tracking program and elements of DOH program
Implement “no risk” safety reporting program
First stage implement central sourcing program
First stage of drug quality management program
Final design LEVEL 3 elements and props

Finance

Purchase Order process for timely and emergency acquisition

LEVEL 3 SEVERE SHORTAGES

Many medication shortages affect patient care, with Life Threatening Risks

Trigger: When many medicines are in therapeutic substitutions at hospital and EMS

Hospitals actively sharing meds with each other and EMS

County EMS and Fire Agencies

Implement protocol changes to allow substitutions
Implement:

Full complement of packaging solutions for safety
Safety program
Just in time educational programs
Uniform use of “Medication Command” program, with core group of designated personnel and distribution program

Make full use of DOH tracking program for typical and atypical meds
Implement program for use of atypical meds

Planning Team

Implement needed legal and regulatory changes
Declare shortage and fully utilize compounding program
Implement central medication sourcing program and elements of DOH program
Convert to drug quality management program doing active analysis of the “no risk” safety reporting program
Design the “all clear” criteria
Integrate Finance and timely emergency acquisition

Aftermath

Active medicine inventory management with overall less budget impact
Safer medicine packaging and “No Risk” rpting
Expanded protocols and JIT education program

Safety Aftermath

- Active medicine inventory management with overall less budget impact
- Safer medicine packaging
- “No Risk” reporting
- Just in time educational process



Safety Summary

- Drug Shortage has Big Impact in Emergency Care
- Safety Impacts for Patients and Providers
- Credibility Impact for all leaders and suppliers
- Financial Impact
- Regulatory Challenge for all aspects of the system

