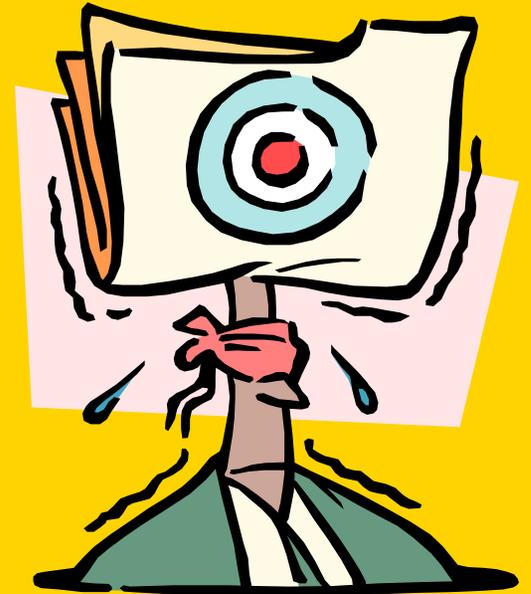


Who's Blocking the Re-Stocking? Dealing with Medication Shortages



- James Augustine, MD



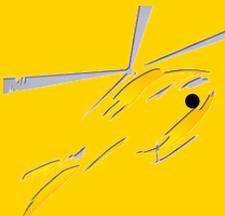
Medication Shortages



- Shortage of raw materials (disasters)
- Non-compliance with regulatory standards and Good Manufacturing Practices (GMPs)

Recalls

- Manufacturers discontinuation or shifts to other products
- Unexpected demand disrupts just-in-time supply (stockpiling) (product jumping)
- Regulatory disagreement (DEA vs FDA)



Emergency Drug Short

3/11

March 30, 2011 Pharmaceutical Backorder Report



BT Item #	Description	Mfctr ETA for next release	Date Mfctr expects back orders to clear	Possible sub **	Description
370067	ADENOSINE 6MG 2ML SDV 2001 10EA/BX	short dated (next lot release May)	short dated (next lot release May)	0651-02	ADENOSINE 6MG 2ML SDV 2001 10EA/BX
0409-4350-03	DILTIAZEM - CARDIZEM 100 MG ADV - NON REFRIG 10/BX	April 2011	April 2011	1171-01ea	DILTIAZEM 25 MG, 5 ML VIAL *REFRIGERATE*
371276	C2 FENTANYL 0.05MG/ML 2ML CFI 10/BX	1st Qtr 2011	1st Qtr 2011	371124	C2 FENTANYL 0.05MG/ML 2ML AMPULE 10/BOX CS24
379631	FUROSEMIDE 100MG 10ML ANSYR SYRINGE	2nd Qtr	2nd Qtr	6102-10	FUROSEMIDE 100MG 10ML SDV
0186063501	FUROSEMIDE 40MG, 4ML ANSYR SYRINGE	2nd Qtr	2nd Qtr	6102-04	FUROSEMIDE 40MG 4ML SDV
4857-10	POSPHENYTOIN 50MG/ML 10ML VIAL	June	June	No Available Sub	
1152-70	HEPARIN LOCK FLUSH 100 U/ML 10ML VIAL 25/BX	2nd Qtr	2nd Qtr	47-88815901218X <i>(while supply lasts)</i>	LV. flush syringe, 12cc, pre-fill, filled w/ 10ml 100u/ml heparin flush, terminally sterile. 30/ea
1151-70	HEPARIN LOCK FLUSH 10 UNIT/ML 10ML VIAL	2nd Qtr	2nd Qtr	No Available Sub	
372339	LABELALOL 20MG 4ML LUER LOCK CARPUJECT 1030	March 2011	March 2011	2267-54 <i>(while supply lasts)</i>	LABELALOL 5MG/ML 40ML MDV
370130	LABELALOL 100MG, 20ML VIAL 2096	late June	late June	2267-54 <i>(while supply lasts)</i>	LABELALOL 5MG/ML 40ML MDV
300-20	LABELALOL 100 MG, 20 ML VIAL	July	July	2267-54 <i>(while supply lasts)</i>	LABELALOL 5MG/ML 40ML MDV
372067	LEVOPHED 0.1% 4ML AMPULE 2067	April 2011	April 2011	No Available Sub	
1539-31	C4 LORAZEPAM 4MG/ML 1MLCFI *REFRIGERATE* 10/BX	4th QTR 2011	4th QTR 2011	371102	C4 LORAZEPAM 2MG 1ML LUER LOCKING CARPUJECT *REFRIG* CS02 10/BX
371108	C4 MIDAZOLAM **VERSED** 1MG/ML 2ML SLIMPACK CFI 10/BOX CS08	4th QTR 2011	4th QTR 2011	2305-02	C4 MIDAZOLAM 2MG, 2ML VIAL 10/BX
371128	C4 MIDAZOLAM **VERSED** 5MG/ML 1ML CARPUJECT SLIM 10/BOX	4th QTR 2011	4th QTR 2011	371111	C4 MIDAZOLAM **VERSED** 5MG/ML 1ML VIAL 10/BOX CS11
377868	C2 MORPHINE 10MG, 1ML AMP 25/BX CS18	unknown	unknown	370178	C2 MORPHINE 10MG 1ML SDV 25/BX CS25
372034	Phenytoin 250mg, 5ml vial	Late March	Late March	No Available Sub	
371483	NITROGLYCERIN 25MG/DSW 250ML BOTTLE 3031	2nd Qtr	unknown	118-1A0692EA	Nitroglycerin, in 5% Dextrose, 250 ml, injection, 25 mg (100 mcg/ml), glass bottle 12/cs
371482	NITROGLYCERIN 50MG/DSW 250ML BTL 3032	2nd Qtr	unknown	118-1A0694EA	Nitroglycerin 50mg, in 5% Dextrose, 250 ml bottle
372312	PROMETHAZINE 25MG 1ML LUER LOCKING CFI	3rd Qtr	3rd Qtr	0928-25	PROMETHAZINE 25MG/ML 1ML vial
4699-24	PROPOFOL 10mg/ml 100ml VIAL				
4699-33	PROPOFOL 10MG/ML 50ML VIAL	unknown	unknown	No Available Sub	
4699-30	PROPOFOL 200MG 20ML VIAL 5/BX				
379020	VASOPRESSIN 20U 1ML MDV 2148 <i>(only 5/11 dating is available)</i>	April 2011	April 2011	No Available Sub	
1632-01	VECURONIUM 10MG 10ML VIAL	3rd Qtr	3rd Qtr	No Available Sub	
374983	VECURONIUM 10MG 10ML	late May 2011	late May 2011	No Available Sub	

Emergency Drug Short 2/12

January 30, 2012 Pharmaceutical Backorder Report



Plus Three More Pages

BT Item #	NDC#	Description	release	back orders to clear	##	NDC#	Description
15023-983-02	25021-303-02	ADENOSINE 6MG, 2ML VIAL	Mid Feb	Mid Feb	0805-72	25021-0805-72	ADENOSINE 6MG, 2ML LUER LOCKING PPS 25mg/2ml
379412	00409-8234-12	ADENOCARD 5MG/2ML ANESTH SYRINGE	2nd week Feb	2nd week Feb			
1501-02	00703-1501-02	ALPROSTADIL 500MCG/ML, 1ML VIAL *REFRIGERATE* 5/BX	March 2012	March 2012	No Available Sub		
5685-23	0409-5685-23	A-Methaphed 125 mg, 2 ml Unlabeled 10ea/Bx	February 2012	February 2012	0047-22	00009-0047-22	SOLU-MEDROL, 125 MG, 2 ML VIAL 25EA/BX
AB4348-35	0409-4348-35	Amiodarone 50mg/ml 3ml amp	April 2012	April 2012	0616-03	63323-0616-03	AMIODARONE 150MG 3ML VIAL
9675-30	00143-9675-30	AMIODARONE 150 MG, 3 ML VIAL 10EA/BX	March 2012	March 2012			
6695-01	0409-6695-01	AMIDATE (ETOMIDATE) 20MG, 10ML VIAL	February 2012	February 2012	No Available Sub		
6695-02	0409-6695-02	AMIDATE (ETOMIDATE) 40MG, 20ML VIAL	February 2012	February 2012			
376029	00409-8060-29	AMIDATE 40MG 20ML LIFESHIELD SYRINGE 10KSA	February 2012	February 2012			
8061-01	0409-8061-01	AMIDATE (ETOMIDATE) 40MG, 20ML AMPULE 5/PK	February 2012	March 2012			
379494	39822-9950-02	AMYL NITRITE INHALANTS 0.3ML 12/BX *REFRIGERATION	April	April	No Available Sub		
9630-05	0409-9630-05	ATROPINE 0.15 MG 5ML ANHYD PREPILLED SYRINGE PEDIATRIC	February 2012	February 2012	374910		ATROPINE 0.5MG 5ML LIFESHIELD SYRINGE
1016-25	0517-1016-25	ATROPINE 1MG, 1ML VIAL (Am Regent)	unknown	unknown	No Available Sub		
379040		ATROPEN 2 MG/0.7 ML AUTO-INJECTOR 12EA/CS	February 2012	February 2012	379084		ATROPEN 1 MG/0.7 ML AUTO-INJECTOR
6250-30	0019-0250-30	ATROPINE 8MG 20ML VIAL	Mid Feb	Mid Feb	No Available Sub		
0500-05	5390-0500-05	BUMETANIDE 1MG, 4ML VIAL	unknown	unknown	No Available Sub		
371136	00409-1176-30	C2 DEMEROL 50MG/ML CPJ LL SLM 10/BOX CS16	March 2012	March 2012	371176	0409-1176-90	C2 DEMEROL 25MG 1ML CPJ LL SLM 10/BOX
371276	00409-1276-32	C2 FENTANYL 0.05MG/ML 2ML CARPUJECT 10/BX	February 2012	June	No Available Sub		
379094	00409-9094-22	C2 FENTANYL 0.05MG/ML 2ML SDV 25/BX	May	June			
9087-27	10019-0087-27	C2 FENTANYL 0.05MG/ML, 2ML VIAL 25/BX	February 2012	June			
371124	00409-9095-32	C2 FENTANYL 0.05MG/ML, 2ML AMPULE 10/BOX	April	June	No Available Sub		
0038-47	33019-0038-47	C2 FENTANYL 0.05MG/ML, 2 ML AMPULE 10/BOX	Late Jan	unknown			
379425	00409-9094-25	C2 FENTANYL 0.05MG/ML 5ML SDV 25/BOX	May	May 2012			
0035-72	10019-0035-72	C2 FENTANYL 0.05MG/ML 5 ML AMPULE 10/BOX	January	January			
0037-30	10019-0037-30	C2 FENTANYL 0.05 MG/ML 5 ML VIAL 25/BX	January	January			
9094-28	0409-9094-28	C2 FENTANYL 0.05MG/ML 10ML VIALS 25/PK	May	June			
9094-31	0409-9094-31	C2 FENTANYL 0.05MG/ML 20ML VIAL 25/PK	May	June			
371133	0409-9093-35	C2 FENTANYL 0.05MG/ML 5ML AMP 10/BOX	May	June			
1312-30	00409-1312-30	C2 HYDROMORPHONE 2MG/ML 1ML CPJ 10/BOX	February 2012	April	No Available Sub		
0021-25 (limited qty)	0409-0121-25	C2 HYDROMORPHONE 2MG 1ML VIAL 25/BX	February 2012	April			
377868	0178-48	C2 MORPHINE 10MG, 1ML AMP 25/BX CS18	unknown	unknown	No Available Sub		
370178	0178-44	C2 MORPHINE 10MG 1ML SDV 25/BX CS25	unknown	unknown	371125	00548-1091-00	C2 MORPHINE 10MG 10ML LUER JET 5/9 10/BOX CS25
371123	0409-1261-31	C2 MORPHINE 10MG/ML 1ML CPJ 10/BOX LL	February 2012	February 2012			
1260-60	0409-1260-60	C2 MORPHINE 8MG/ML 1ML CPJ 10/BOX LL	late Feb	April	1264-81 (exp 9/2012)	0009-1264-31	C2 MORPHINE, 15 MG, 1 ML LUER LOCK CARPUJECT, 10/BX
371121	0409-1258-30	C2 MORPHINE 4MG/ML 1ML CPJ 10/BOX LL SLM CS21	January	April	371120 (limited avail)	00409-1762-30	C2 MORPHINE 2MG/ML 1ML CPJ 10/BOX LL SLM CS20
00205310	0409-2053-10	C3 KETAMINE 50MG/ML 10ML 10/BOX / controlled	February 2012	JUNE 2012	2051-05 (limited avail)	00409-2051-05	C3 KETAMINE 100MG/ML, 5ML VIAL, 10/BOX
0001-10	67457-0001-10	C3 KETAMINE 50MG/ML, 10 ML VIAL, 10/BOX	February 2012	JUNE 2012	No Available Sub		
2051-05	00409-2051-05	C3 KETAMINE 100MG/ML, 5ML VIAL, 10/BOX	Nospire indicates limited availability		No Available Sub		
0184-30	05530-0184-01	C4 BUTORPHANOL - STADOL 2MG 1ML VIAL 10/BOX CS05	April	April	No Available Sub		
371104	0409-1273-32	C4 DIAZEPAM 5MG/ML 2ML LUER LOCKING CARPUJECT 10/BX CS04	March	March	00017-0001-70	00187-0001-70	C4 DIASTAT ACCUCIAL RECTAL VALLUM



Sample

Medication	Expected date of release	Reason for shortage
Calcium Chloride 1gm/ 10mL vial	Unknown	Manufacturing delay
Diazepam 5mg/ml in 2mL luer locking carpject	March, 2012	Manufacturing delay, next delivery 2/12
Diphenhydramine 50mg luer locking carpject	June, 2012	Manufacturing delay, next delivery 6/12; PROBLEMS WITH SYRINGE
Dopamine 400mg/ 5mL single dose vial	Unknown	Manufacturing delay
Lasix 40mg/4mL syringe		Manufacturing delay depending on manufacturer used; next delivery 3/12
Magnesium Sulfate 5mg/10mL single dose vial	Unknown	Increased demand for product; product is being released
Magnesium sulfate 5mg/10mL syringe	March, 2012	See above
Promethazine 25mg/ 1mL luer locking carpject	Product suspended until 2013	Manufacturing delays, estimated delivery date of 2013
Midazolam (Versed) 5mg/2mL vials	April, 2012	APP manufacturer- increased demand so company will release as it becomes available. Bedford manufacturer- temporary suspension of manufacturing; release date unknown. Hospira manufacturer-withdrawal of product in order to improve quality activities; will be available in 2013 West-ward manufacturer-increase in product demand;

American Society of Healthcare Pharmacists, <http://www.ashp.org/shortage>

Solutions

- Read, 'rite, 'rithmetic
- Management at state level
- Management at regional level
 - Incident Management System
 - Mutual Aid
 - Liaisons
 - Safety Official
 - Documentation



Reading: Information Sources

- American Society of Health-Systems Pharmacists(ASHP)
- FDA
- Suppliers
- Manufacturers
- Your Dept of Health



Date: February 24, 2012 14:21:14 CST

To: jgoodloemd@aol.com

Subject: Drug shortage information from TMB

Reply-To: leigh.hopper@tmb.state.tx.us

Having trouble viewing this email? [Click here](#)

State Support



Texas Medical Board Update and Links February 24, 2012

Drug shortage information

Recently, a Texas physician related a situation in which doctors had to resort to the use of expired emergency resuscitation drugs. Would the Texas Medical Board consider the use of expired drugs a violation of the standard of care?

The short answer is, if TMB investigates a complaint involving expired drugs, it will consider the drug shortage as well as storage conditions in making a determination.

Texas physicians across all specialties are coping with widespread drug shortages. A shortage of an important leukemia drug is making headlines now. Manufacturing delays, scarcity of raw materials, increased demand contribute to the problem. According to the National Cancer Institute, the trend is expected to worsen.

Most of what is known about drug expiration dates comes from a study conducted by the Food and Drug Administration at the request of the military. With a large and expensive stockpile of drugs, the military faced tossing out and replacing its drugs every few years. What they found from the study is many of the drugs, both prescription and over-the-counter, were good to use years after the expiration date. But the key was proper storage.

The U.S. Food and Drug Administration maintains an extensive website devoted to the issue. For more information, visit <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>. The American Society of Health-System Pharmacists also has a useful list: <http://www.ashp.org/DrugShortages/Current/>
<http://www.ashp.org/DrugShortages/Current/>

To read past news releases, updates and past issues of the TMB Bulletin, please

State Level Management

- Cooperation/liaison with State Board of Pharmacy
- Flexibility in state law, rules, and regulations related to personnel capabilities
- Agency oversight allowing emergency agencies and hospitals to share stocks
- Information distribution
- Sharing of best practices, particularly related to safety

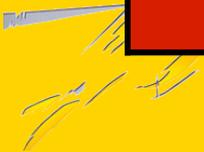


Drug	Shortage Status	Where Carried	Therapeutic Substitution	Management Plan
Acetaminophen	None		Ibuprofen	None needed
Adenosine	Some versions		Verapamil	Get state approval
Albuterol	Inhalers		Levalbuterol	Get state approval
Amiodarone	Some		Lidocaine	Substitute Lidocaine now, but leave on approval list
Aspirin	None		None	None needed
Ativan	Many		Midazolam, Valium	This is drug that needs refrig. 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	Very limited use, not 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	Need opportunity to tap hospitals, and have hospitals 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	Assure approval to tap hospital stocks
Metoprolol	Some		Other beta-blockers	Get state approval
Naloxone	Many		None	Assure approval to tap hospital stocks
Nitroglycerine	None		None	Assure approval to tap hospital stocks
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

Writing: Look at Protocols, Meds, Shortages and Therapeutic Substitutions

'Rithmetic: ED/EMS Med Cost Per Patient

"Thinners" = Heparins, Eptifibatide, Lytics	\$1.81 Per Patient
All Antibiotics	\$1.99 per Patient
Everything Else (Ondansetron #1 Used Med)	\$1.77 per Patient
Total Medication/IV Cost	\$5.57 per Patient



EMS Meds Strategies

Meds that have no substitutes	Exchanges with hospitals, ration
Meds short on critical forms	Formulate, therapeutic subs
Meds with therapeutic substitutes	Substitutions
Education, Packaging, Logistics	Personnel and Supply \$\$\$\$



Handwritten signature or scribble.

Initial Strategies

- 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



Safety of Care



Provider Satisfaction



Finance and
Logistics



Shared Drug
Sources: Right Place,
Right Time

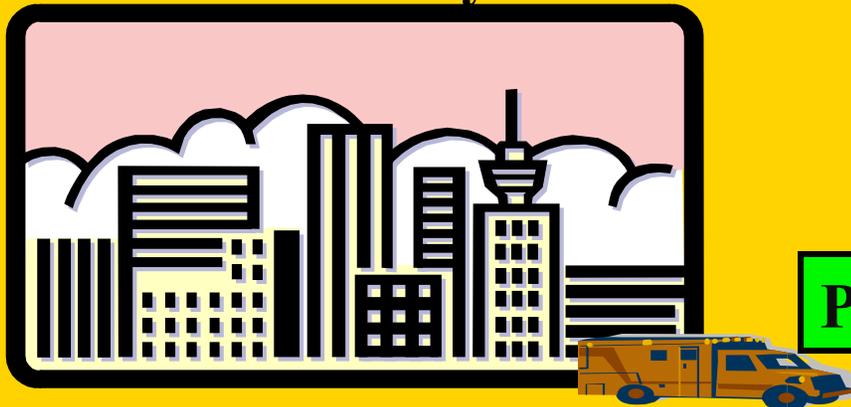
Local System Priorities

- Optimal use of Supplies
- Patient Service
- Safety

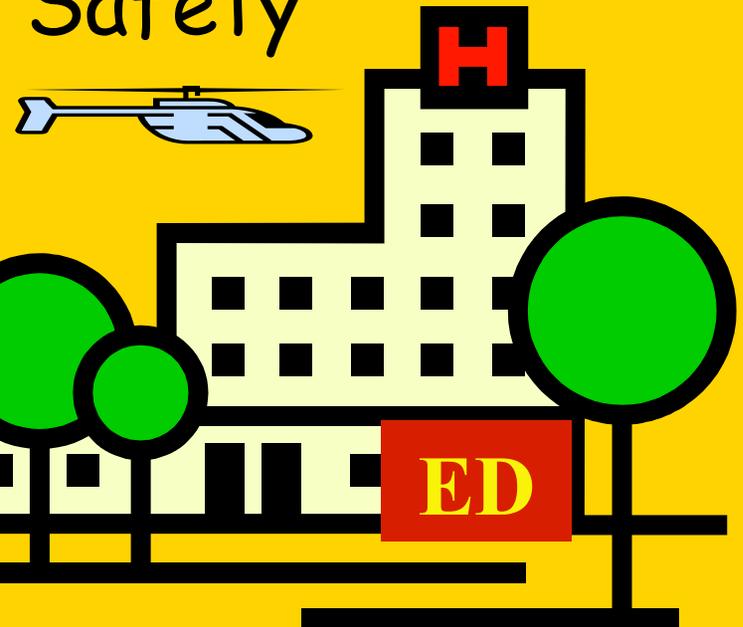


EMS Office

Community



Dept of Health

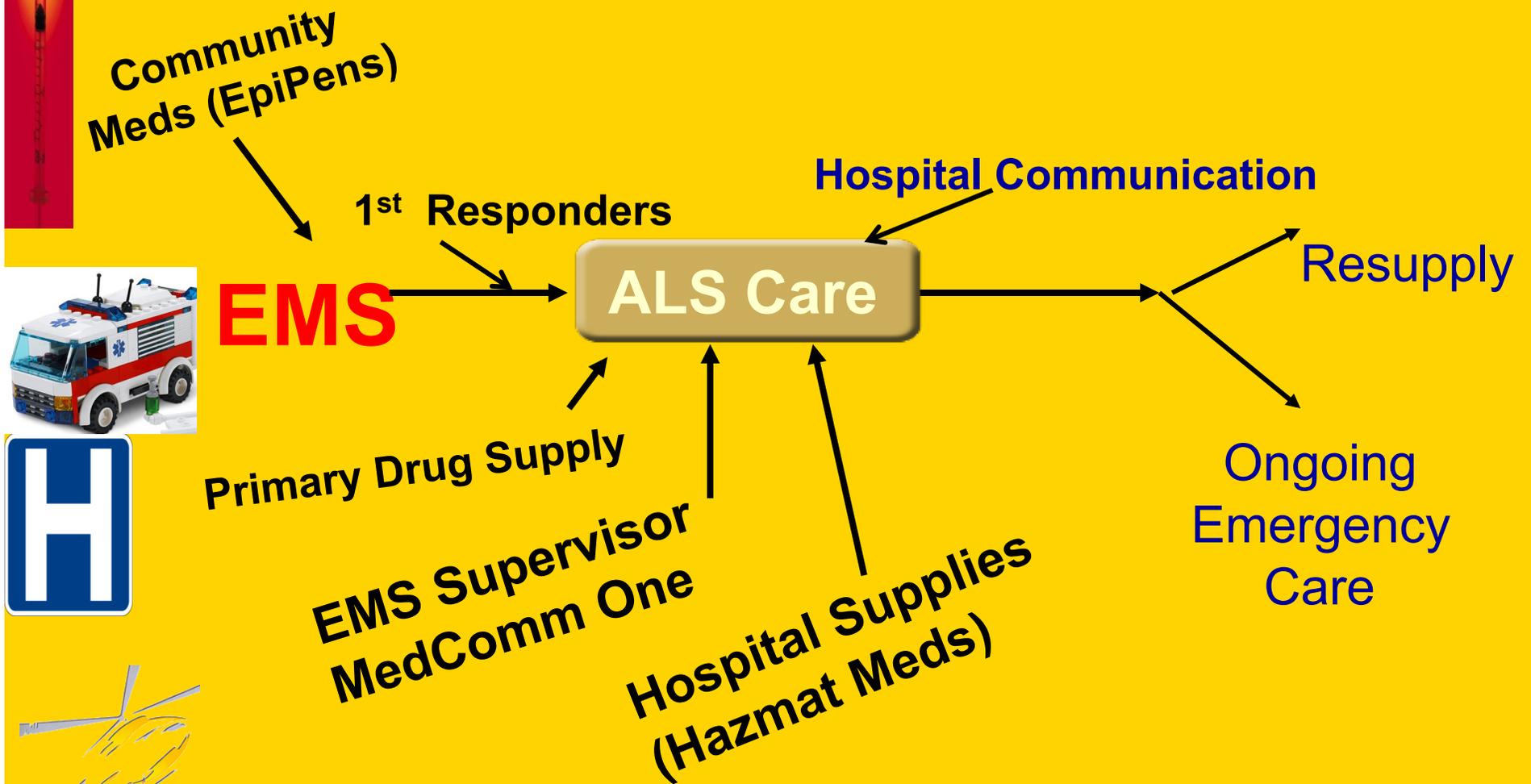


Safety Mandates

- Focus on critical medicines
 - Don't discourage med use
- Package for safety



Patient Safety Strategies



EMS Clinical Providers

- Education
- Make the system error-resistant, and....
- Encourage error reporting



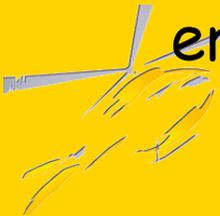
IT help



Safety Considerations for the Patient

- For the Providers

- Change in regulations
- Change in protocols
- More training
- More reading of packages
- More need for documentation
- Repercussion-free error reporting
- Minimize changes in medicines
- Drugs in usable vials, carpujects, 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**



Incident Management

**Incident
Command**

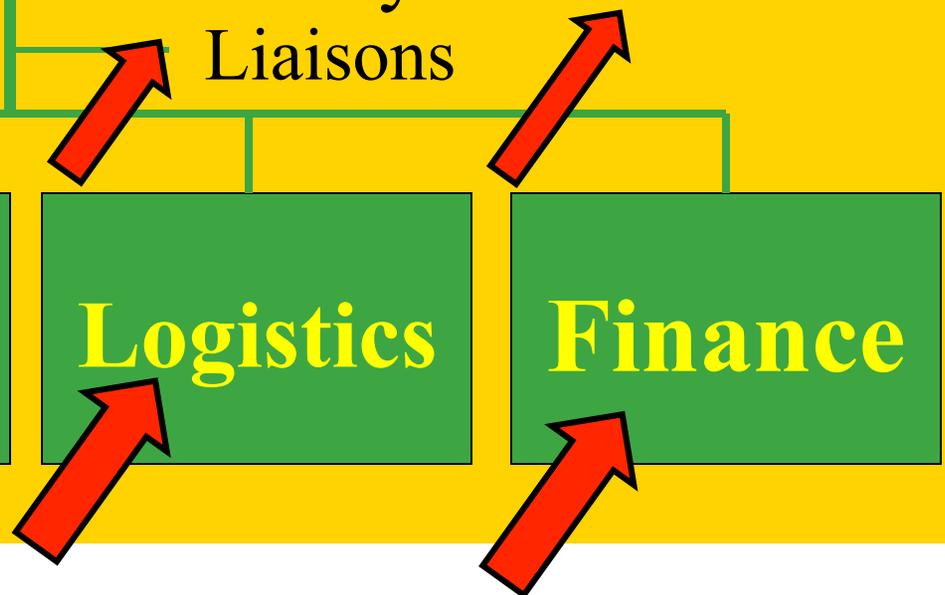
Public Information
Safety Officer
Liaisons

Operations

Planning

Logistics

Finance



IAP Elements

- Logistics
 - Supplies, Storage, Allocation
 - Mutual Aid Exchanges
 - Creation of new Supply Chain "MedComm One"
- Finance
 - Accounting for exchanges
 - Budgets
- Liaisons
 - State EMS Office and State Pharmacy Board
 - Local Dept of Health
- Safety
 - Patient Safety
 - Hospital Pharmacy



Innovative Steps



- Science says meds are effective beyond posted expiration date
- Especially if stored correctly (ACTIVE INVENTORY MGT)
- “Compounding” of certain medicines in EMS-friendly packaging
- <http://www.pcab.info/find-a-pharmacy.shtml>
- Dept of Health supplies and info exchange systems



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

Af termath

Active medicine inventory management with overall less budget impact

Saf er medicine packaging and “No Risk” rpti

Expanded protocols and JIT education progr