American Hospital Association

Navigating Drug Shortages in Rural Hospitals

Section for Small or Rural Hospitals

American Hospital Association

Agenda

- **Introduction** – John Supplitt, sr. director, AHA Section for Small or Rural Hospitals, Chicago, IL
- **AHA Survey of Hospitals** – Roslyn Schulman, Director, AHA Policy, Washington, DC
- **Navigating the Drug Shortage Case Example 1** – Betsy Early, Pharm.D., RMH Healthcare, Harrisonburg, VA
- **Navigating the Drug Shortage Case Example 2** – Clyde Sbravati, Director, Pharmacy Services, King's Daughters Medical Center, Brookhaven, MS
- **Questions and Discussion**

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Policy Background

- **Increasing drug shortages affecting hospitals and patients**
- **Complex issue; Many causes**
- **Policy/Advocacy Activities**
  - **AHA Hospital Drug Shortage Survey**
  - **Working with other national groups**
  - **Collaborating with HHS, espec. FDA**
  - **Working closely on Congressional legislation**

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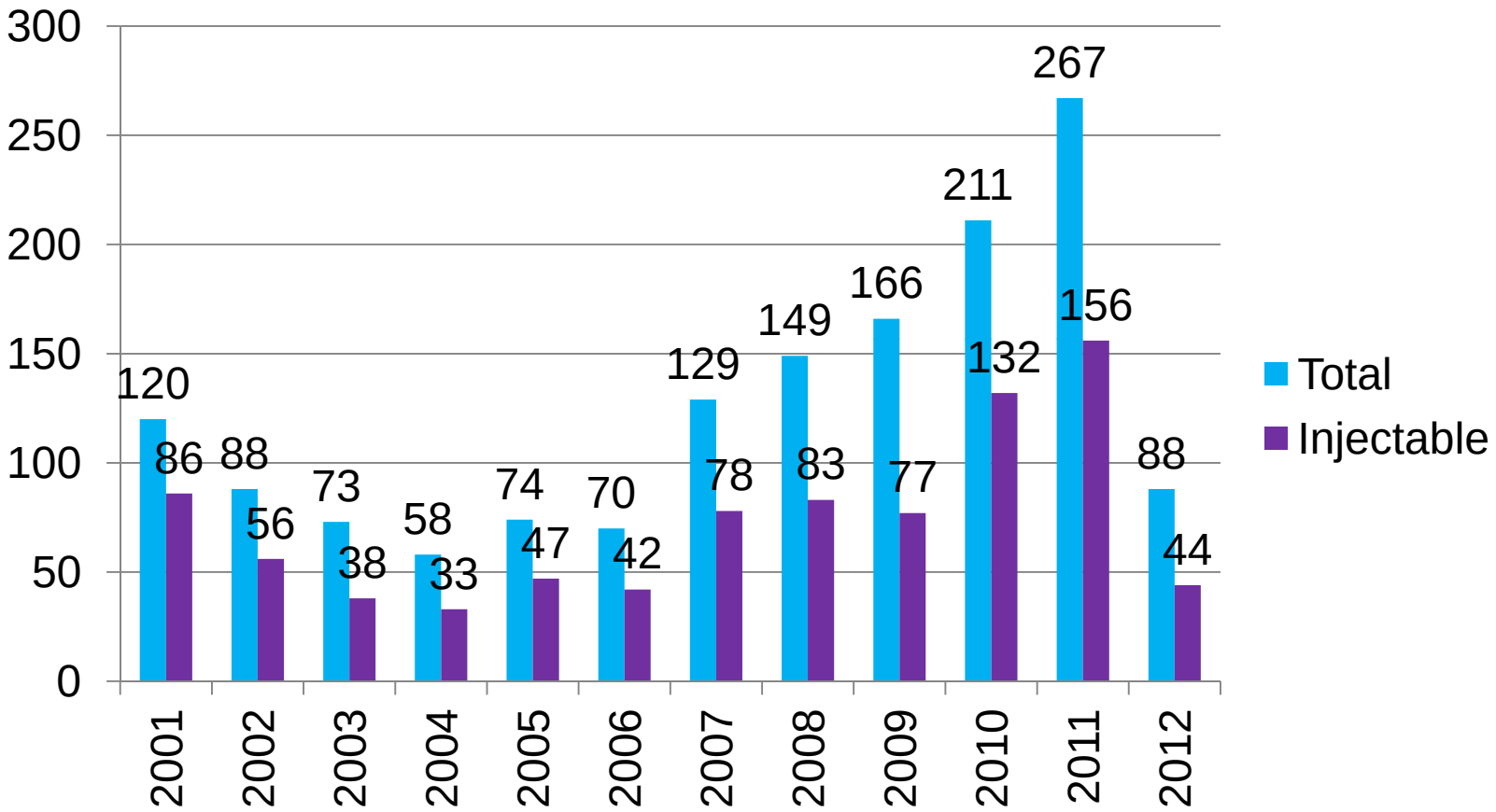
Trends in Drug Shortages



Note: Each column represents the # of new shortages identified that year

Source: University of Utah Drug Information Service

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Shortage Dynamics

Common Factors Behind Shortages

- **Product quality/manufacturing problems**
- **Not enough manufacturing capacity**
- **Discontinuation of products**
- **Problems with or shortages of raw materials or components**
- **Increase in demand due to another shortage**
- **Loss of manufacturing site**
- **Industry consolidation (fewer firms making these products)**
- **Generally not economically attractive**

ECONOMIC ANALYSIS OF THE CAUSES OF DRUG SHORTAGES – HHS, ASPE October 2011

The current class-wide shortages in the industry appears to be a consequence of a substantial expansion in the scope and volume of products produced by the industry that has occurred over a short period of time, without a corresponding expansion in manufacturing capacity.

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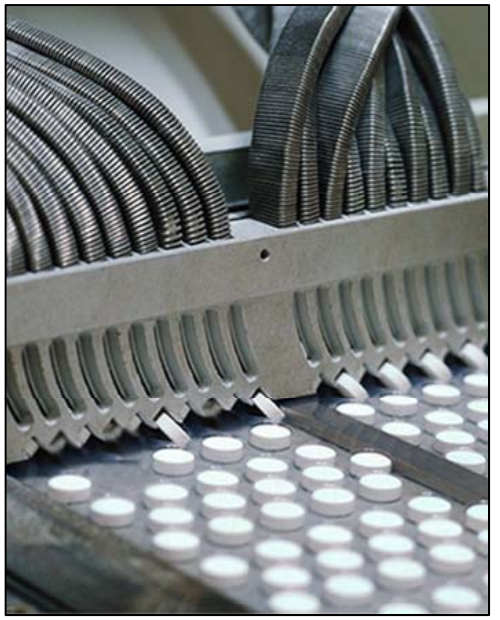
AHA Hospital Survey Results

- 820 hospitals responded
- 99% reported a shortage
- Nearly half reported >21 drugs in shortage.
- 82% of hospitals report that they have delayed treatment
- 7 in 10 hospitals reported treating patients with less effective drugs
- 77% rarely or never receive advance notification of shortage



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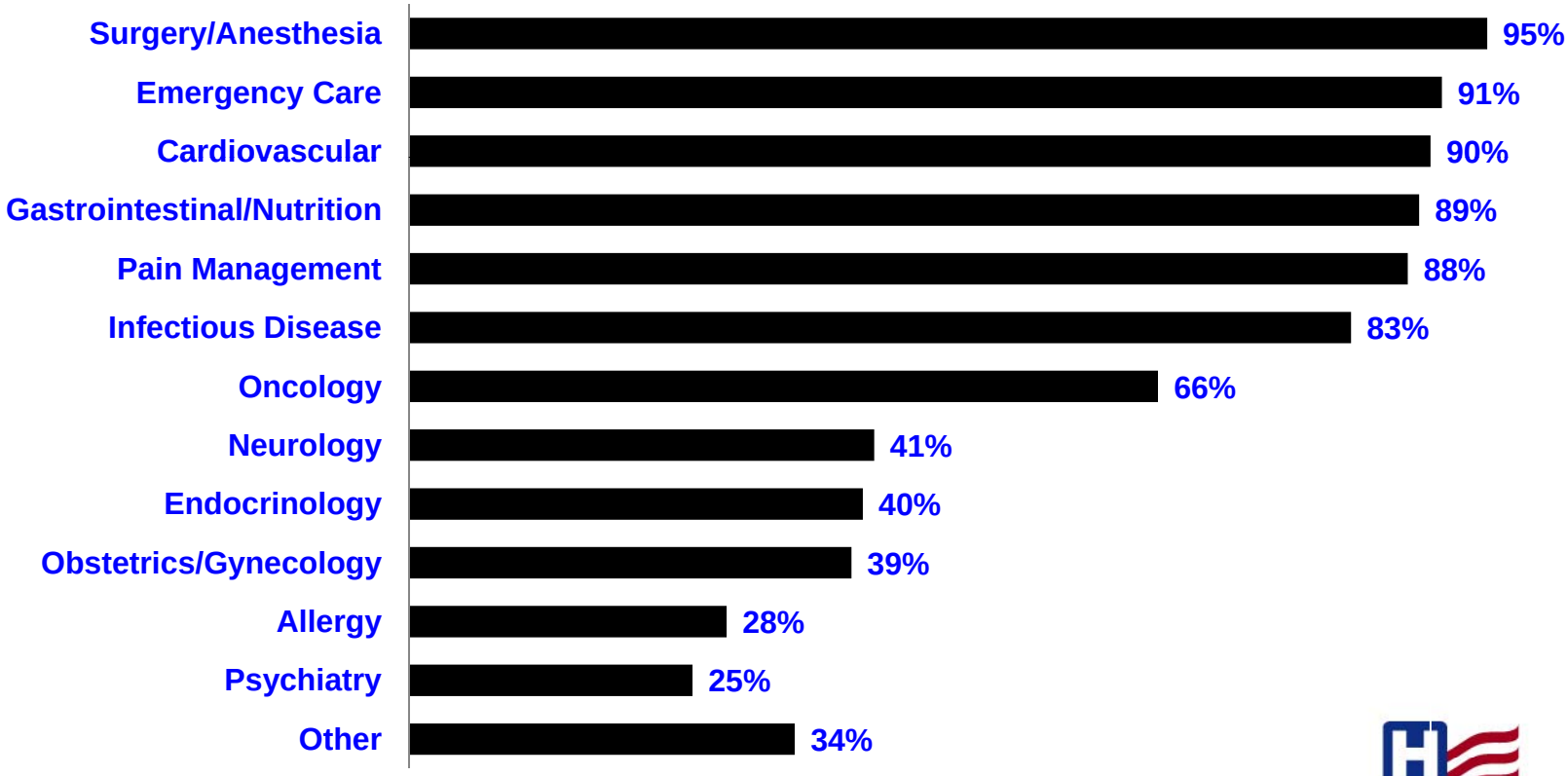
Hospital Shortages Across Treatments

Percent of Hospitals Experiencing a Drug Shortage in the Last Six Months by Treatment Category



Source: AHA analysis of survey data from 820 non-federal, short-term acute care hospitals collected in June of 2011.

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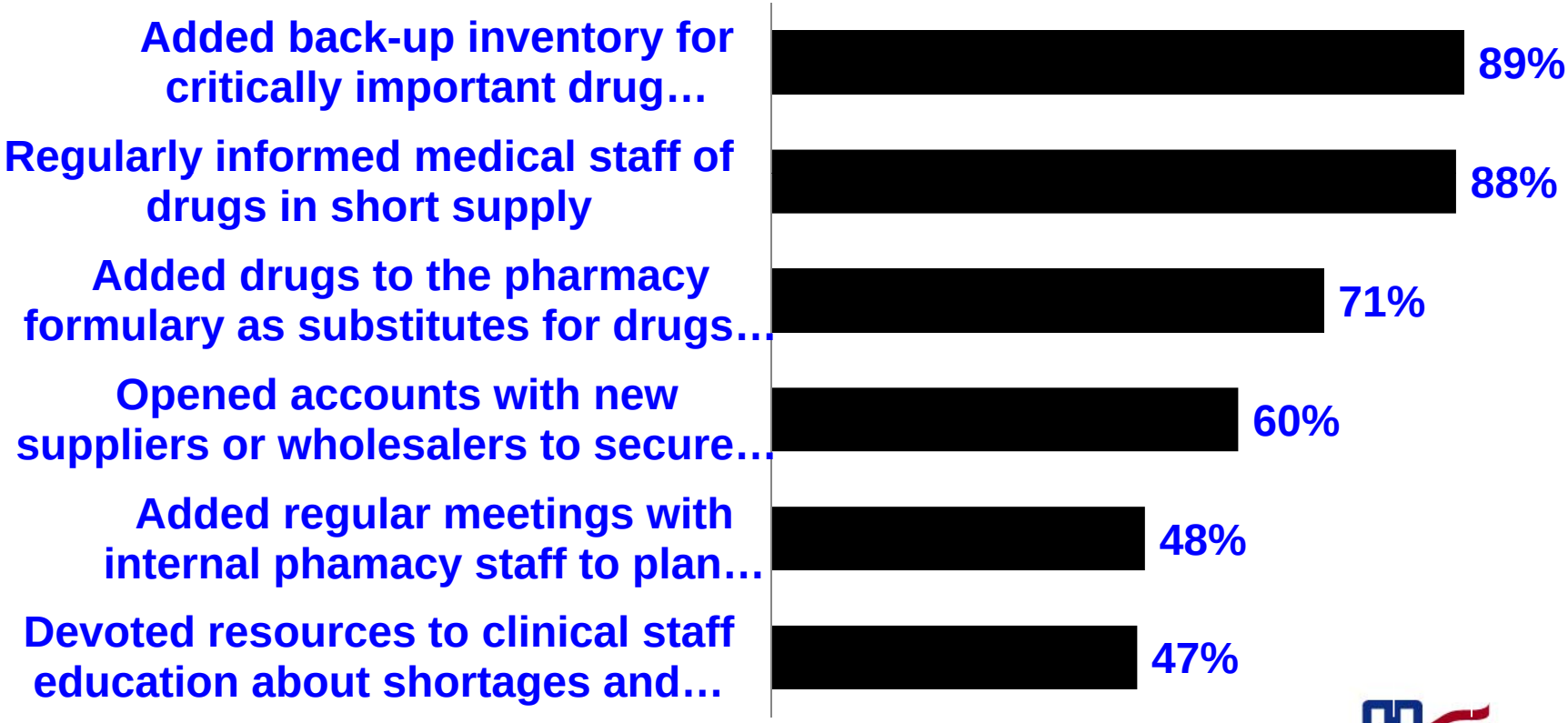
Hospital Actions to Reduce Impact

Percent of Hospitals Taking Actions to Improve Patient Safety and Reduce Financial Impact of Drug Shortages



Source: AHA analysis of survey data from 820 non-federal, short-term acute care hospitals collected in June of 2011.

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FDA Action on Shortages

- FDA's activities and actions have prevented nearly 300 additional drug shortages since 2010.
  - Collaborating and communicating with industry, health professionals, and patients
  - Requiring mfgrs of "medically necessary" sole source drugs to provide early notification of discontinuances/interruptions
  - Working with manufacturers to find ways to mitigate quality issues (e.g. use regulatory flexibility)
  - Asking other firms to increase production
  - Expediting review of applications/inspections
  - Importing shortage drugs
- President's Executive Order (Oct. 31, 2011)
  - Letter urging all mfgrs to report
  - Increased FDA drug shortage program staffing
  - Fighting price gouging and gray market

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Legislative Developments

- **House and Senate User Fee legislation includes drug shortage provisions**
  - **May 25, Senate passed the FDA Safety and Innovation Act (S. 3187)**
  - **May 31, House passed the FDA Reform Act (H.R. 5651)**
- **Next step, need to resolve differences in bills**
  - **House and Senate leaders plan to enact legislation by end of June**
  - **Supported by Obama Administration**

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Legislative Developments, cont.

- **Both bills (with differences…):**
  - **Expand mfgr early notification requirements (no CMPs!)**
  - **Expedite inspections and reviews**
  - **Collect and share additional information (studies, reports, drug shortage list expansion)**
  - **Require FDA to issue regulations**
  - **Expand/clarify policy on repackaging of drugs**
  - **Create generic drug user fee program**
- **Senate bill would:**
  - **Allow FDA to add biologics to early notification req.**
  - **Create Task Force that would formulate strategy**
  - **Codify FDA's use of enforcement discretion**
- **House bill would:**
  - **DEA: Raise mfgr quotas for controlled substances**
  - **Use better approach to non-notifying mfgrs**

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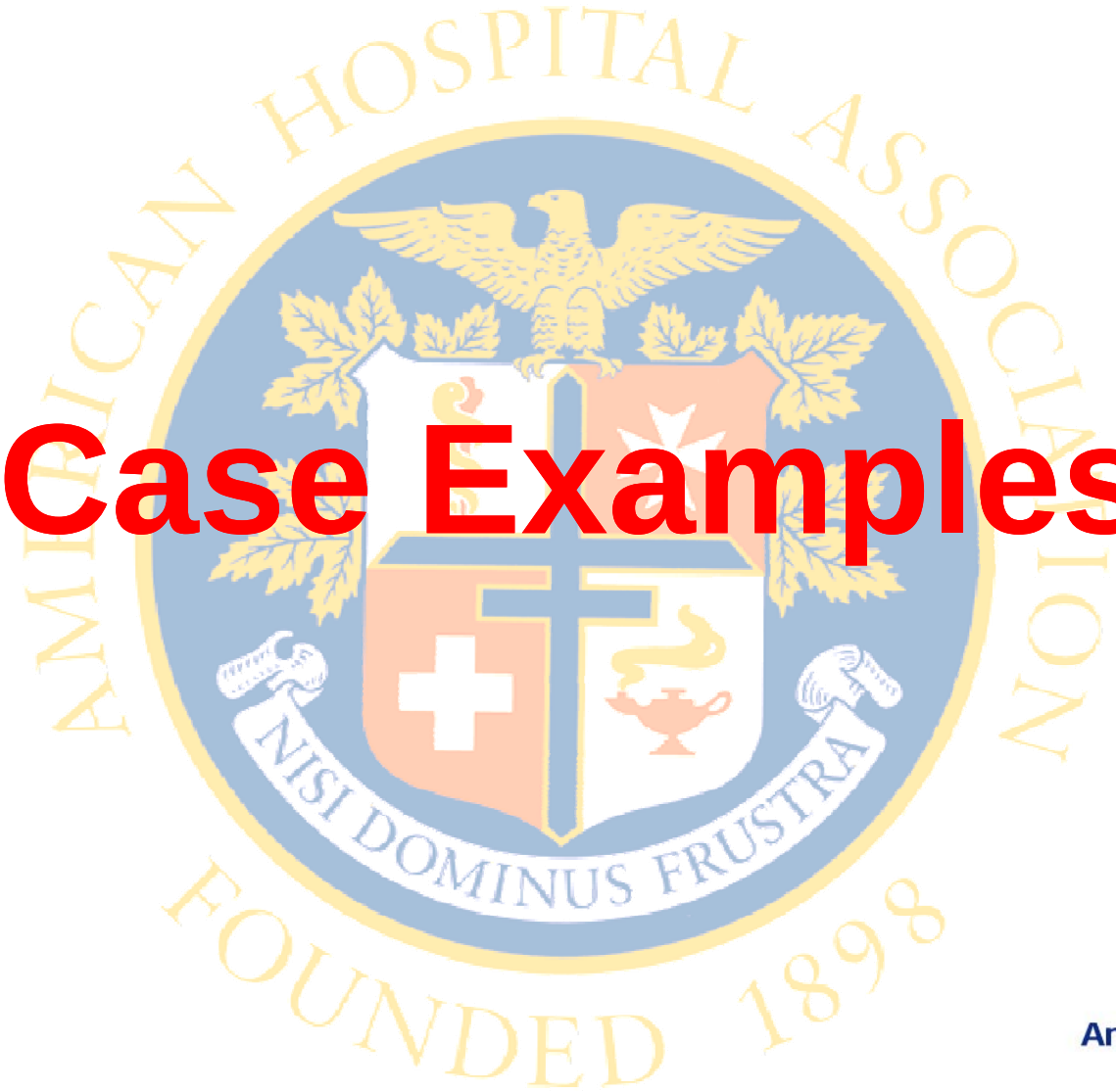
Case Examples



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Rockingham Memorial Hospital

Betsy Early, PharmD MBA

Navigating the Drug Shortages

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DRUG SHORTAGE POLICY & PROCEDURES

Identification

- **When identified, medications are added to our drug shortage list**
- **Our drug shortage list is on the pharmacy department SharePoint site and is available real-time to pharmacy staff and is uploaded to our pharmacy webpage every week for all hospital staff**
- **A link is emailed to managers of clinical areas of the hospital every week**
- **This shortage list only contains drug shortages that are affecting RMH, the current status of product at RMH, and any action plans that we are implementing**

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Drug Shortages List: RMH

Description of Medication: Empty PCA vials

Description of Shortage: Pre-Filled PCA vials have been released by manufacturer. Empty PCA vials have been delayed for another 5-6 weeks

Action Plan: Sterile vials unavailable. We are down to the last box and the compounding pharmacy can no longer supply premade PCA's. Conservation education has been sent out

Last updated: 5/1/12

Priority: 1

ASHP Drug Shortages Link:
http://www.ashp.org/DrugShortages/Current/Bulletin.aspx?id=890

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DRUG SHORTAGE POLICY & PROCEDURES

Notification

- **Pharmacists and all pharmacy staff are notified Clinical pharmacists on the nursing units are notified/educated on situation**
- **Affected Medical staff members are notified**
- **Pharmacy communicates with nursing staff including signage posted at the automated dispensing machines to alert them of the change in products**
- **An emergency therapeutic interchange from Pharmacy & Therapeutics Committee and Medical Executive Committee (as outlined in our formulary policy) is activated**

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DRUG SHORTAGE POLICY & PROCEDURES

Interventions

- **Monitor our supply and attempt to obtain alternate sizes/strengths as shortage became known**
- **Work with nurses and physicians on utilization and alternatives**
- **Educate pharmacists of the shortage and alternatives available**

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DRUG SHORTAGE POLICY & PROCEDURES

Actions

- **Clarify orders for medications and suggest alternate routes as necessary and appropriate**
- **Add new strengths/sizes to our automated dispensing machines**
- **Obtain product from a compounding pharmacy**
- **Increased stock of alternatives**

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DRUG SHORTAGE POLICY & PROCEDURES

Resolution

After the shortage resolves:

- **Communicate availability of product**
- **Update drug shortage list**
- **Alternate stock is removed from all areas and automated dispensing machines**
- **Remove signs and notices**
- **Replace with the original strength/size**

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EXAMPLE - 1

Furosemide injection (Lasix)

- Added furosemide injection to our drug shortage list
- Increased stock of bumetanide as an alternative
- Notified pharmacists to begin clarifying orders for IV furosemide and suggest alternate routes whenever possible
- Added bumetanide to our automated dispensing machines
- Communicated to nursing staff included signage posted at the machines to alert them of the change in products in the automated dispensing machine
- Sought an emergency therapeutic interchange from Pharmacy & Therapeutics Committee and Medical Executive Committee as outlined in our formulary policy

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EXAMPLE - 2

Midazolam and lorazepam injection shortage

Midazolam, lorazepam, and diazepam injections were all on shortage at the same time. When our supply began dwindling, we implemented several measures:

Midazolam and lorazepam injection shortage

- We added these medications to our drug shortage list
- We notified pharmacists to begin clarifying orders for IV doses of these medications and suggest alternate routes whenever possible
- We added new strengths/sizes to our automated dispensing machines
- Communication to nursing staff included signage posted at the machines to alert them of the changes in strength. We also use auxiliary labels whenever possible to alert staff to the different strength/size
- We notified our clinical pharmacists that round in the critical care unit to convert all patients possible to propofol infusions instead of Midazolam or Lorazepam infusions
- We notified our pulmonologists of the need to use propofol infusions and avoid benzodiazepine infusions whenever possible
- We investigated alternatives in case we were faced with having no benzodiazepine injection in stock and worked with neurologist to define an action plan. (Luckily we never had to implement this)
- After the shortage resolved, we removed the alternate stock from all areas and automated dispensing machines and replaced with the original strength/size

Navigating the Drug Shortages

LESSONS LEARNED:

- **You can't over-communicate the issue**
- **Engage the medical staff quickly**
- **Get the information out in a user-friendly format**
- **Make the information easily accessible**
- **Communicate your efforts**

LOOKING FORWARD:

- **Hope for a resolution….**
- **Utilize system for other issues**

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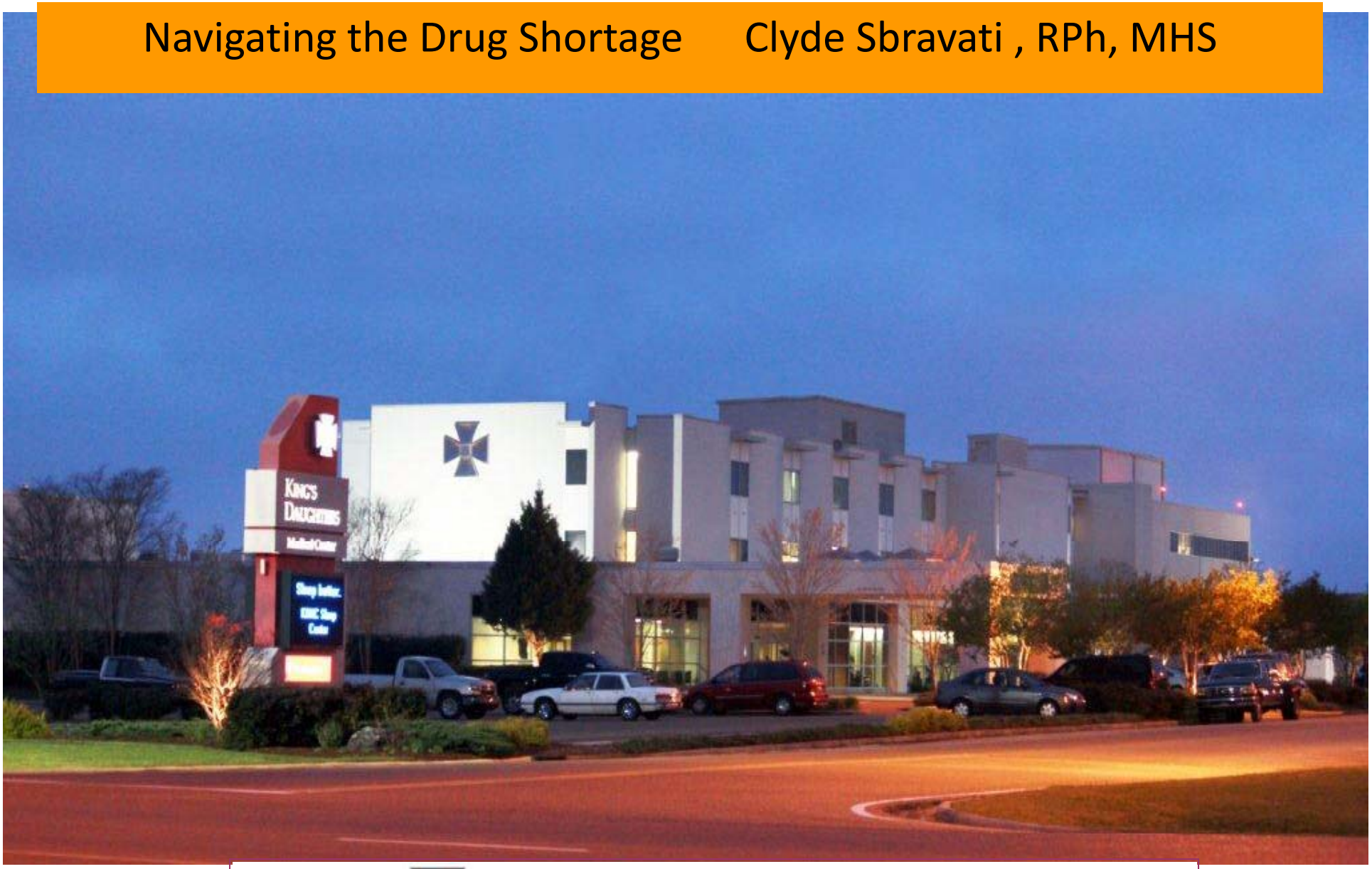
Navigating the Drug Shortage

Clyde Sbravati , RPh, MHS



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Mississippi's #1 Rated Hospital

Overall Hospital, Medical, & Surgical Care

Selected by CARECHEX® A Rating Service of The Delta Group

KDMC Policy : Key points

- We use The American Society of Health-System Pharmacists (ASHP) definition. A shortage is “a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent.”
- Medical staff helped developed the substitution hierarchy: brand, product size, strength, alternate agent
- Safeguards are in place prior to distribution of product

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KDMC Procedures

Identification of shortage

- Staff review national shortage lists (ASHP, FDA, buying group) daily
- Vendor relationships nurtured: Hospira notices, Baxter emails, Pfizer updates,
- Local Networking: weekly Director of Pharmacy phone calls to define issues
- “Gray” market solicitation: they often call soliciting sales when some supplies are still available through normal channels.
- Prediction of pending shortages because of collateral impact from actual shortages (expect bumetanide shortage when furosemide supply is short, or famotidine supply impacted by ranitidine shortage)

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KDMC Procedures

Assessment of impact

- Duration of shortage, allocation possibility, usage history of product
- Availability of substitutes, possibility of compounding, implication of restrictions. Possibility of alternative routes (PO vs IV)
- Patient population affected. Is usage elective? Critical care drug?
- Restriction barriers: non-24 hour pharmacy. Is medication urgently needed after hours
- Cost: purchasing compounded or gray market items increases cost tremendously. Prescribers, COO, CFO notified of cost impacts

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KDMC Procedures

Develop management plan

- Review impact with primary users (Hospitalist, Anesthesiologist)
- Review possibility of purchases of formulary to weather the storm
- Review generic equivalents; different sizes, strengths, compounding issues?
- Evaluate possibility of restriction of distribution after pharmacy consult
- Develop necessary safeguards: ADM notifications, e-mail to hospital staff, personal contact on rounds with all providers, labeling enhancements, changes to order sets, formulary updated to reflect stock outages.

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KDMC Procedures

Communicate plan

- Pharmacy maintained internal alert board
- Order administration notes on eMAR
- Shortage added to Hospital e-Bulletin board list of shortage products
- Reports to Safety Committee, Patient Care (P&T), Medical staff
- Daily reminders on rounds and in Physician lounges
- Alerts added to ADM, restricted access in ADM
- Follow up review of use of substitute products with nursing to assure good understanding of use.

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Case example: Ranitidine injection

- **IDENTIFY**
  - Identified shortage during ordering process
- **ASSESSMENT**
  - Evaluated current stock
  - Ran history of usage to determine: inventory movement, physician prescribers, patient type
  - Reviewed alternatives: oral, famotidine, restrictions to critical need, other therapeutic substitutes
- **Plan**
  - Substitute famotidine (intravenous push). Pharmacy automatic substitution approved by P&T Committee and medical staff
  - Restrict available ranitidine injection to patients identified by physician staff as medical necessity

Case example: Ranitidine injection

- **Communication of Plan**
  - Notify medical staff through staff meeting, email, visits to offices
  - Attach substitution explanation to all ranitidine orders with substituted famotidine
  - Edited all order sets with ranitidine orders to famotidine
- **Implementation and follow up**
  - Substitutions began after all order sets changed and staff notified
  - Administration variance on eMAR followed to assess nursing issues
  - Weekly discussions with primary users to identify any problems

Epilogue: Subsequent increased usage of famotidine vials lead to shortage. We had to revise plan/order sets/implementation again to convert to famotidine pre-mixed product given IVPB !!

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Safeguards

- Alerts on ADM. Warnings of size/concentration/packaging variances
- Administration notes on eMAR showing differences in administration rates or monitoring issues
- Labeling
- Barcode administration
- Restricted distribution
- Direct user contact to nurses and physicians for patient specific substitutions
- Order set changes, formulary notes
- IV pump medication library changes

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Lessons

- Don’t shy away from overkill on safeguards
- Don’t be surprised (impact of Maalox type antacids)
- Some hospitals will have supplies.
- Use only reliable suppliers
- Physicians and nurses need to be assured you are doing all you can to obtain safe medications. Stand by your policy on obtaining products.
- Re-enforce established patient safety procedures (multiple doses from single dose vials)

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Questions and Discussion

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