

## Drug Shortage

### Busy Day Tool Kit Preceptor Instructions

**Learner level:** IPPE and APPE Students

**Estimated time to complete:** May take several hours/days and can be done intermittently

**Preceptor Instructions:** Provide student with a current ongoing drug shortage that your institution is currently faced with. Using this module ask the student to formulate a drug shortage action plan.

**Student Instructions:** Read through the module and read the 2018 ASHP Guidelines on Managing Drug Product Shortages. Identify the key stakeholders in each step of managing the drug shortage and work through possible ways to mitigate the risk to the facility. Research the cause/contributing factors of the shortage, clinical implications, and possible changes to workflow and processes caused by the shortage. Formulate a communication plan and implementation plan for the shortage item. your preceptor about the topics/activities you completed.

### Operational/Clinical Assessment

1. Validate details of drug shortage
  - a. Products affected
  - b. Reason for shortage
    - i. FDA/ASHP websites
    - ii. Manufacturer
    - iii. Distributor
  - c. Estimated product availability date
2. Identify severity of shortage for your institution
  - a. Stock on hand
    - i. Historical use
    - ii. Days supply on hand
  - b. Supply from institution's primary distributor
  - c. Supply from predetermined alternative distributors
  - d. Supply direct from Manufacturer
3. Therapeutic Assessment
  - a. Identify Patient population affected
  - b. Identify Therapeutic alternatives
  - c. Restriction strategies
4. Determine supply of alternatives
  - a. Stock on hand of alternatives
    - i. Historical use
    - ii. Days supply on hand

## **Shortage Impact Analysis**

1. Identify the therapeutic differences between the shortage item and the alternatives
2. Analyze the prescribing differences
  - a. Formulary status
  - b. Order sets
  - c. Clinical decision support
  - d. Drug information
3. Analyze distribution process changes
  - a. Automated dispensing cabinet
  - b. Unit dose
  - c. IV preparation
  - d. Stability
4. Analyze administration process changes
  - a. Bar code medication administration
  - b. Infusion pumps
5. Financial Ramifications
  - a. Cost analysis
    - i. Cost of shortage item vs alternative

## **Communication and Implementation of process changes**

1. Who needs to be included in communication?
  - a. External communication (FDA, Center for Drug Evaluation and Research)
  - b. Medication safety team
  - c. Informatics specialists
  - d. Pharmacists
  - e. Pharmacy technicians
  - f. Nursing staff
  - g. Prescribers
2. Draft a communication
  - a. shortage details
  - b. effective date
  - c. identified therapeutic alternative
  - d. temporary guidelines and procedure
3. Describe changes in information systems for implementation
  - a. ADC
  - b. HER
  - c. Infusion pumps
4. Describe changes in inventory systems for implementation
5. Describe new procedures that will be implemented

## **Identify Shortage Resolution Tasks**

1. Formulary changes
2. Information system changes
3. Inventory system changes
4. Procedure changes

## References

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2. FDA Drug Shortages - <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>
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4. Severity and Impact of Sterile Injectable Drug Shortages - <https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-Sterile-Injectable-Drug-Shortages-March2022.pdf>
5. ISMP Special Issue: Drug Shortage Survey Reveals High Levels of Frustration, Low Level of Safety - <https://www.ismp.org/resources/special-issue-drug-shortages-national-survey-reveals-high-level-frustration-low-level>
6. ASHP Drug Shortage Roundtable Report - <https://www.ashp.org/drug-shortages/shortage-resources/roundtable-report>
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8. Drug Shortages and Labor Cost - <https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129>
9. Injectable Opioid Survey Report - <https://www.ashp.org/drug-shortages/shortage-resources/injectable-opioid-survey-report>
10. ASHP Drug Shortage Statistics <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>
11. FDA Drug Shortage statistics - <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm>
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13. Management of Shortages of CBER-Regulated Products - <https://www.fda.gov/media/83301/download>
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15. Sterile Water for Injection Shortage - <https://www.ashp.org/drug-shortages/shortage-resources/sterile-water-for-injection-faq>
16. 2018 ASHP Guidelines on Managing Drug Product Shortages <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/managing-drug-product-shortages.pdf>

*Last Updated May 2023 by the Section Advisory Group (SAG) on Medication Management*

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