Making the Right Choice for Sterile Processing Consumable Stock Outages

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Historically, hospital inventory systems carried a large volume of consumable supplies which offered a sense of security that vital items would always be available for patient care. Large inventories came at the cost of outdated item disposals, obsolete product disposals, and tied up funds that could have been allocated elsewhere. The introduction of Just-in-Time inventory management (JIT) across all industries in the late 1970s and early 1980s reduced inventories to minimum levels, freeing cash and reducing the impact from outdated and obsoleted supplies. The change gave rise to new challenges, such as establishing inventory levels that could anticipate normal fluctuations and responding to recalls which soon became manageable with good inventory management. Today, global supply chains face increased disruptions from disasters, pandemics, and world events which have led to significant stock outages and facilities scrambling to find substitutions. Healthcare facilities must recognize and plan a systematic approach to managing supply chain disruptions that lead to out of stock situations so that patient care can safely continue.

Learning Objectives

1. **Identify causes of product outages and when substitutions would be needed.**
2. **Establish a plan for rapid evaluation and change approval of substitution products.**
3. **Considerations when implementing a rapid deployment of a substitution product.**

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The Impact of Supply Chain Disruptions

Supply chains are complex global entities that start with raw materials. Manufacturers source raw materials from several suppliers often located in multiple countries. Manufacturing sites convert the raw materials into products. Simple products, like chemical indicators, may have a single manufacturing site. Complex products, like incubators, enlist several manufacturers to make components with the incubator's assembly relegated to a different manufacturing site.

The next step in the chain is the distributor. Distributors inventory multiple consumable products from different manufacturers. They offer healthcare facilities a straightforward way to buy multiple products from a variety of manufacturers in a single business transaction. This simplifies buying and shipping of healthcare supplies.

Disruption in the flow of materials through this chain can lead to out-of-stock situations for the healthcare facility. Not only can a disruption impact the vendor's ability to provide product, but multiple vendors sourcing the same raw material or component from the same supplier can be impacted at the same time.

Vendors have experienced out-of-stock situations from raw material shortages; machinery repairs; transportation issues; poor planning; natural disasters that affect transportation or manufacturing sites; and unforeseen spikes in demand. In most cases, the stock outage is short lived but, as the pandemic demonstrated, some are not.

Recall is the second way healthcare facilities can experience out-of-stock situations. Recalls occur when a manufacturer removes or corrects a product at the healthcare facility to protect the public health. Most recalls are voluntary manufacturer actions but when the manufacturer fails to act, the FDA may issue a mandatory recall order to the manufacturer. Recalls can be initiated from design defects, manufacturing defects, material failures, and labeling defects such as misprinted or illegible expiration dating.

Product outages have a profound impact on healthcare facilities. Facilities may postpone voluntary

procedures to preserve product inventory for urgent care. When supplies run out for extended periods of time, life preserving procedures may be cancelled. Facilities should have a means to evaluate and implement alternative solutions so that life preserving procedures are never cancelled.

What is the Plan?

It only takes one out-of-stock event to create chaos, cause delays, cancel surgeries, and potentially place patients at risk. Instead of being reactionary, developing a preventive plan that outlines roles, actions, and resources reduces the stress and chaos from product outages.

When outages are anticipated to be short term, it may be possible to source the same product from a different distributor or dealer. Facilities may also be able to obtain supplies from sister facilities or healthcare neighbors. However, when the shortage affects multiple vendors or is anticipated to be long, these options may not be available.

Ideally, all critical consumables would be second sourced. Second sourcing does not mean having two order quantities to choose from. Second sourcing is the identification and approval of a second vendor that supplies a similar product used for the same purpose. Consider creating a second source resource file that includes the ordering information, emergency reorder numbers, and quantities so there is minimal down time. When second sources are not available, facilities must quickly identify, qualify, and obtain substitutes.

The first step in preparation for a rapid response to stock outages is to identify a multi-disciplinary team that includes everyone that has a role in the process affected by potential stock outages. This may include but is not limited to C-suite representatives, material's management, sterile processing leadership, surgical leadership, Biomed / Facilities, and infection control & risk management. Vendor representatives may also be needed. Each member has a defined responsibility to identify, assess, and implement a substitute product.

Unlike a change approval or new product evaluation board, this team must move quickly with less consideration on the budgetary impact and more consideration on securing a short-term substitution or process that will allow sterile processing to continue to provide services without jeopardizing patient safety.

Material management and sterile processing work together to identify potential substitute products. The substitute is reviewed against the current out-of-stock product, the specific application in the facility, and department interactions with the product.

Infection control and risk management should assess the risks to staff and patients from using the substitute product and ensure that appropriate measures to reduce new risks from the substitute are taken.

The findings, along with a financial impact assessment, are presented to the multi-disciplinary team for approval and development of an implementation plan. The implementation plan should include:

- How the product will be ordered
- Policies and procedures that may need to be temporarily changed to accommodate the substitute product
- Training and competencies of affected staff
- Implementation of any newly identified safety controls

Rapid identification, obtainment, and deployment of a substitute product is not without its challenges. At minimum, facilities should consider three basic challenges.

Lesson:

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Quiz Answers:
1. A, 2. B, 3. B, 4. B, 5. B, 6. D, 7. D, 8. A, 9. D, 10. D

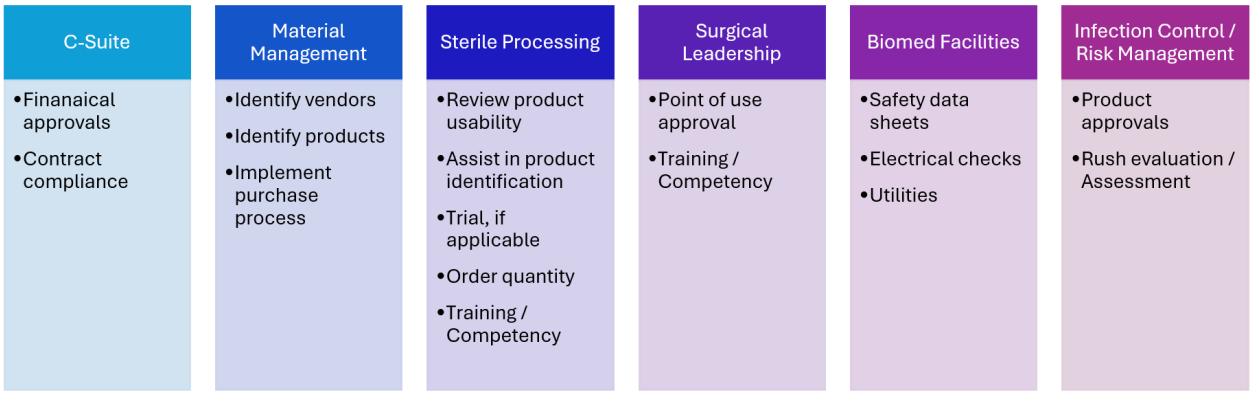

Figure 1: Example of multi-disciplinary review team responsibilities

Contracts and Purchasing Systems

Material managers work to control costs by establishing long term contracts, joining group purchasing organizations (GPO), and limiting the ability of facilities to buy products that are not on contract. These become barriers when a rapid substitution is needed. Materials management should include clauses within contracts that allow non-penalized purchases of non-contracted products in the event of a long-term product outage.

Stock outages may affect a portion of a larger healthcare group. There can be challenges adding the emergency substitute product to the healthcare system's centralized purchasing system. A plan should be in place to quickly add emergency reorder numbers, stock keep units (SKUs), or new vendors for the affected facilities.

Product Evaluation Committee approvals could slow down rapid adoption of a replacement product especially when product trials are a requirement of the product review committee. Ensure that approvals and review expectations of emergency replacement products are identified within policies and procedures. Material management may be the first to know about impending stock outages and recalls but may not have the knowledge to judge the severity. Ensure that a communication strategy is in place which includes escalation guidance in time of recall and stock outages.

Product Instructions for Use

No two products' instructions for use (IFU) are the same. An important consideration is reviewing the substitute product's IFU. Identify differences between the out-of-stock product and the proposed substitute. Identify substitute product constraints and contraindications. Consider things like reactions between chemicals, compatibility with devices, water incompatibility, test result interpretation differences, etc.

Review the IFU of the equipment, medical devices, and accessories that the substitute product will be used on or with. When conflicts between the substitute product's IFU and other products' IFU exists, vendors should be contacted to help reconcile these differences. If the vendor approves the use of the product despite the differences within IFU, request the approval in writing on company letterhead. This should be included in the risk assessment for the emergency use of the substitute product.

Review facility processes, policies, and procedures that are specific to current product and may not be compliant with the replacement product IFU. Facilities should have a plan for incorporating temporary changes to policies and procedures. Also consider the incorporation of educational tools such as wall charts and interpretation guides when necessary.

Off Label Use

The search for replacements may also require verification of intended use by reviewing the product's market clearances. If the clearance is in line with the facility's intended use, no further action is required. If, however, it is not in line with the facility's intended use, the use becomes an "off label" use.

Off label use is only considered acceptable when a healthcare professional at their clinical discretion determines that using a device in a way not explicitly approved by the regulatory agency is the best course of action for a patient's specific condition especially when there are no other suitable treatment options available. It is crucial to always consider the potential risk and benefits involved by performing a risk assessment to support the decision of off label use, the benefit must outweigh the risk.

What is the decommission process?

Returning to the normal state should be as methodical as it was to rapidly deploy a substitute product. Consider:

- Disposition of substitute product inventory
- Deactivating reorder numbers/SKU
- Reimplementing former policies and procedures
- Training needs and removal of product use tools

Conclusion

Supply chain disruptions are improving as manufacturers turn towards second sourcing and regional sourcing and use advanced planning and scheduling software. Inventories, initially raised to counter the disruptions from the COVID pandemic, are beginning to drop. Now is the time for healthcare facilities to identify the emergency substitution team and shore up the emergency substitution policies and procedures before the next great supply chain disruption happens. **HPN**

Reference:

1. Alicke, K. and Foster, T. (14, October 2024) Supply Chains: Still vulnerable. McKinsey & Company. https://www.mckinsey.com/capabilities/operations/our-insights/supply-chain-risk-survey#/

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Making the Right Choice for Sterile Processing Consumable Stock Outages - Practice Quiz

1. **Which is not part of a supply chain?**
   A. Transportation
   B. Material supplier
   C. Manufacturer
   D. Distributor
2. **How can two different vendors be affected by a material shortage?**
   A. Source different suppliers
   B. Source the same supplier
   C. Sell to the same customer
   D. Sell to the same distributor
3. **What FDA action can cause stock outages?**
   A. Clearance
   B. Recall
   C. Rebranding
   D. Sale
4. **All recalls are mandated by FDA.**
   A. True
   B. False
5. **What is the best prevention for long term stock outages?**
   A. Large volumes of inventory
   B. Second sourcing critical items
   C. Vendor penalties for stock outages
   D. In-house manufacture
6. **What is infection prevention's role on the rapid response team?**
   A. Find substitutions
   B. Price negotiation
   C. Training
   D. Risk evaluation
7. **What should be included in the implementation plan?**
   A. Ordering instructions
   B. Product training
   C. Temporary changes to policies and procedures
   D. All of the above
8. **This should be in purchasing agreements to protect against stock outages.**
   A. Non penalized off contract purchasing
   B. Second source items
   C. Noncontracted purchase prevention
   D. Recalled items list
9. **Which instruction for use should be reviewed against the substitute product's IFU?**
   A. None
   B. Out of Stock product IFU
   C. Medical Device IFU.
   D. Both B and C
10. **What should be done when the old product is back?**
    A. Removal of substitute product
    B. Deactivating reorder numbers in purchasing systems
    C. Returning to former policies and procedures
    D. All of the above

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