ACCP Clinical Administration PRN (CADM)

Summary of CADM Roundtable on Drug Shortage Management

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**Introduction/background**

Thank you to the 40+ participants in our inaugural Roundtable discussion. This was started as a result of a meeting of the CADM officers and committee chairs at the 2017 ACCP Annual Meeting. Seeing the success of this session, future Roundtables will be planned. Topics will be chosen by the PRN officers and committee chairs, focusing on timely topics but also those that have general applicability to the membership.

A Roundtable discussion on drug shortage management was chosen for its timeliness and how all pharmacies and pharmacy departments are being challenged to develop or change approaches.

It is hoped that all members receiving this summary are able to identify best practices and new items to consider as they develop strategies within their own organizations.

**Results of survey**

A survey was sent to the CADM listserve on 12/29/2017. It was requested that members provide details on various aspects of how drug shortages are managed within their institutions. Results as of 1/3/2018 were presented during the Roundtable discussion. As of that date, there were 27 responses from 19 different states. As of 1/9/2018, a total of 35 responses have been submitted. The results as of 1/9/2018 are being sent out as a separate attachment with this summary. A general list of learnings is listed below.

* Approximately 40% of respondents state that there is a current **formal** drug strategy management strategy in place.
* By far the majority of respondents state that the pharmacy stakeholders involved in **development** of drug shortage strategies involve pharmacy operations leaders, pharmacy buyers, and pharmacy clinical leaders. The majority also include IT and frontline pharmacists.
* Drug shortage management strategies are most often **led** by pharmacy operations leadership.
* **Non-pharmacy stakeholders** engaged in strategies most often include medical and nursing staff. Less often, IT and senior leadership are included.
* **Formal approval** for strategies is most often done by medical staff, e.g. P&T Committee. Nearly ½ also require nursing leadership approval.
* The plan is **communicated** primarily by email and pharmacy department staff meetings. Other means include a pharmacy department newsletter and staff meetings. Less often, communication is done via intranet postings, nursing department staff meetings, organization-wide newsletter, and EHR alerts.
* The **frequency of communication** is, in the vast majority of responses, as changes occur. Some provide weekly updates. Some, though only a minority, communicate specifically at the resolution of the shortage.

**Other discussion items**

Survey respondents recommended additional topics. These were discussed individually.

* Gray-market distributors
	+ No participants admitted using these.
	+ These sources are highly unreliable, with major concerns over sourcing (i.e. DSCSA compliance), storage conditions, and price gouging.
* Compounding pharmacies to make dosage forms normally available commercially
	+ Several participants described processes for formal review of compounding pharmacies. This includes review of quality monitoring, regulatory compliance records, and an onsite inspection.
	+ One participant stated that only 503A FDA-approved traditional compounder pharmacies are used.
* Using non-sterile ingredients for sterile dosage forms
	+ No participants admitted doing this in-house.
	+ Several participants stated that as long as the compounding pharmacy had been fully reviewed and inspected by organization representatives, non-sterile to sterile compounding is allowed.
* Process to track costs
	+ No one admitted having a robust process in place.
	+ One organization has been forecasting cost impacts as part of the planning process.
	+ One organization is planning to track adherence to the strategy, e.g. therapeutic substitution, and provide individualized feedback to providers.
* Restricted-use protocols
	+ Many organizations have put these into place to prioritize use of limited stock on the highest priorities.
	+ Many organizations have built alerts and/or hard stops to direct providers to therapeutic alternatives.
	+ Some organizations have found success in putting limits on duration, i.e. alerts or “time-out” procedure. Examples given were parenteral opioids and antimicrobials.
	+ Some organizations require that providers that want to use a shortage item for a non-approved indication seek P&T Committee approval.
	+ Many organizations rely on pharmacists to apply the approved criteria of restricted-use protocols. Some organizations require escalation to leadership for requests to override non-adherence to restricted-use protocols.
	+ There was some discussion on staff challenges in implementing
* Definition of “sufficient” quantity
	+ Defining “sufficient” is necessary for organizations to keep stock that will meet patient-care needs and to know which medications to target interventions.
	+ Many organizations use a flexible definition, especially in light of the expected severity of the shortage, duration, and impact on patient care.
	+ Some organizations try to keep 1 month supply on hand. Once the supply is down to 2 weeks, a management strategy discussion is triggered.
	+ One institution balances allocations within a therapeutic classes. The example given was small-volume parenterals. The supplier has allocated a certain number of dosage forms that can be purchased within the therapeutic class. The organization has calculated the number of weeks onhand for all. Purchasing under the allocation is prioritized for those dosage forms with the least number of weeks on hand.
* Substitution process
	+ Discussed criteria for pharmacy approval vs. P&T Committee approval.
	+ Some institutions will allow the pharmacy to approve as long it is selecting between/among the same or similar dosage form from different manufacturers.
	+ Some institutions require P&T Committee approval for all changes.
* Error/event reporting
	+ One organization has been encouraging staff to report medication errors and events related to drug shortage strategies. This is done through the voluntary reporting system.
	+ It is important to ensure that the reporting system has a discrete field to identify drug shortage as a causative/contributing factor.
	+ Regular review of event reporting should be done and inform any changes to the drug shortage management process.

**Additional information**

ASHP has a guideline document on this topic. <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/managing-drug-product-shortages.ashx>.

**Future topics**

Within the survey, the following items were recommended for future Roundtable discussions. As stated before, the CADM officers and committee chairs will take these into consideration as Roundtable discussions are scheduled.

* Scheduling of clinical staff
* Multiantibiotic prescribing in community/clinic setting
* Management of high cost generics such as calcitonin, ethacrynic acid, isoprotetenol
* Measurement of clinical pharmacy productivity