

Managing Medicine Shortages Toolkit



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MEDICINE SHORTAGE COPING STRATEGIES AND TACTICS - BEST PRACTICE GUIDELINES

Medical practitioners must act quickly and responsibly when faced with the shortage of an emergency care drug in order to prevent any adverse consequences and continue to provide safe, optimal care to patients. However, delivering reliably safe care must be carried out actively. Guidelines therefore must be put into place in order to meet the challenges when combating a shortage as to be able to account for providing care under difficult situations. Furthermore, these guidelines must take into account any regulations stipulating policies in clinical practice.

Providing guidelines to assist those who are actively working to manage medicine shortages as well as plan for them is a difficult task as they must be general enough to be important to a range of stakeholders (policymakers, emergency planners and medical professionals) but still fit within strict legal parameters that shall work within existing prescribed policy and legislation. Furthermore, guidelines must not be misconstrued as having legal weight; instead, they should advocate for best practices to be undertaken according to the real situation in which a shortage may occur. For this reason, these guidelines should be taken under consideration but only in accordance with existing policies that are already in place.

When evaluating healthcare documents related to risk assessment in health care, both national and local practices are found to not have sufficient guidance on the use of Proactive Hazard Analysis. The documents themselves seemingly omit risk assessment as described through individual stages. The literature shows inadequate advice provided on how to spot and identify risks. Very few documents themselves make any mention of how PHA methods may be utilized within risk assessment respective to issues within the system used. Systems do not take into account characteristics unique to the system. When conducted through a matrix based assessment, this mode of risk analysis was shown to suffer from numerous pitfalls. However, reactive and proactive risk assessment indicate there to be elements of good practices observed. There is a distinct concern related to assigning resources needed to apply PHA.

Even though there may be a strong demand among medical professionals to have PHA in practice, it is also seen as a risk since it may require additional resources which are not necessarily available. Whatever the desire to put such a system in place, there is insufficient evidence in the literature that PHA methods are widely used within established systems.

This toolkit seeks to provide a variety of good practices in risk assessment including prospective methods, which serves as informal requirements to be implemented in healthcare settings. The recommendations of, when applied in practice, must also be done in a process-driven manner.

Medicine shortages are a common issue that pharmacists frequently must manage in the scope of their daily activities. This toolkit aims to provide pharmacists, physicians and other healthcare professionals with a thorough and systematic approach applicable to all medicine shortages in order to evaluate risks stemming from them and their impact on managing patient care. It assists in:

- Offering a systematic approach that may be relied on when facing medicine shortages.
- Underscoring the importance with which healthcare professionals strive to mitigate shortages
- Educating and communicating with healthcare professionals concerning how to best manage drug therapy in the event of a shortage.
- Finding methods to best address medicine shortages by having in place sufficient but not excessive back supplies.

Step 1

Organizational assessment, which entails an overall analysis of the medicines administration process in a healthcare setting, is a primary step in clinical risk management in medicine administration and mitigating shortages. The core processes, among others, include how a medicine is prescribed, dispensed, reconstituted and administered. Particular attention should be placed on electronic prescribing features (if any) and how patient medical data are fed and extracted into/from a hospital/healthcare IT system. If paper-based, the initial assessment must take into account how medical records are screened and validated by healthcare professionals throughout the process of a medicine's administration. While conducting the initial clinical risk management stage, it is essential to acknowledge the patient population's characteristics and the major group of medicines used in the healthcare setting.

Step 2

Following organizational assessment, an **analysis of existing communication strategies among healthcare professionals**, which includes patterns of communication with patients, must be undertaken. Communication analyses are particularly important in order to have perspective on how working processes are carried out in terms of deliverables and how the information is processed among healthcare professionals. It must be clarified as to whether two-way communication exists that may facilitate feedback and regular updates among employees or if information is handled passively and does not have established timeframes.

Step 3

Historical data analysis, in terms of prior and existing shortages as well as related incidents recorded in a healthcare setting, is a tertiary process. Knowing a shortage's historical patterns facilitates subsequent stages of clinical risk assessment. This stage also provides an opportunity to focus financial and human resources where needed most, as shortages do not represent an equal threat for all medicine and patient groups affected. Only medicines most heavily and frequently affected by shortages should be treated first and incorporated in shortage-management protocols.

Step 4

Drafting treatment replacement/substitution protocols within multidisciplinary teams is the fourth step. It is essential that these protocols are created to facilitate a medicine's prescription, ordering and dispensing throughout existing hospital IT systems and facilities. Moreover, it is important that any information related to mitigating medicine shortages is provided at the point of care, taking into account that "seamless care" is only possible if information flow is continuous throughout a medicine's administration processes.

Step 5

Risk management must incorporate **follow-up and patient monitoring** as well, as a fifth step, which includes multidisciplinary patient supervision after a substitute has been introduced. Monitoring records must also address a medicine's adverse effects, health outcomes, the duration of a hospital stay, any delays in care and emerging drug-drug interactions. Furthermore, follow-up and patient monitoring is based on continuously checking laboratory parameters, which may signal health deterioration due to a medicine's substitution.

Step 6

The final step of clinical risk management in shortages is dedicated to **sharing risk-assessment outputs with representatives from other healthcare settings as well as national healthcare and regulatory authorities**. Even when fully completed up to stage five, clinical risk management for a particular patient and healthcare setting is not yet fully complete if not shared and properly stored in a database of the risk assessments conducted. Therefore, it is crucial that this final stage of clinical-risk management be conducted in cooperation with all stakeholders involved in shortage management within the respective healthcare system.

Answer these questions as part of risk assessment in medicine shortages:

1. Do you have hospital formulary list of medicines?

YES

Having one will allow pharmacists (and other medical professionals) to more quickly assess substitutes for the medicine(s) affected by shortages with those available via the formulary. Furthermore, examining the formulary will assist in estimating the extent to which shortages may affect patient care, as based on available treatment options.

NO
(why needed?)

Having a formulary helps to facilitate a better comprehension of the medicines used in a healthcare setting. It provides quick access to seeing the availability of a pharmacological group of medicines that may be used for a particular disease. Moreover, a formulary plays a central role in applying therapeutic protocols based on available treatments approved by a Drug and Therapeutic Committee (DTC). Formularies are also needed in order to carry out regular clinical audits based on patient-care assessment, entailing potential treatment pathways in relation to the medicines available for use in a healthcare setting.

2. Do you have an electronic prescribing system in your hospital/healthcare setting?

YES

An electronic prescribing system allows information to be fed on shortages from a hospital IT system so all healthcare professionals involved in prescribing medicines may be aware of what treatments are affected by a shortages and what treatments could be used as alternatives/substitutes.

NO
(why needed?)

The literature conclusively agrees that there is a distinct benefit of having an electronic prescribing system in place within healthcare settings. In shortages, electronic prescribing provides synchronization to disseminate data on available substitutes to all healthcare professionals simultaneously, thereby reducing the need to frequently contact and confirm with other healthcare professionals. Electronic prescribing not only allows the healthcare professional to be promptly aware of any medicine affected by a shortage, but to track and monitor how the substitution took place and who approved it. Furthermore, depending on the electronic prescription platform, it serves to assess potential interactions that may occur after the initial treatment was terminated and an alternative introduced.

3. Does the prescribing system link to a hospital pharmacy IT system?

YES

If a prescribing system is linked to the hospital pharmacy IT system, it provides a well synchronized platform for information exchange when the information is fed automatically into a prescribing system, in relation to the medicine's availability in a hospital pharmacy.

NO
(why needed?)

When a hospital pharmacy's IT system maintains up-to-date information on the medicines available, the hospital pharmacy is both able to keep track of all shortages and notify healthcare professionals as needed. If linked to a prescribing system, such information is automatically fed from the hospital pharmacy and interpreted by a prescriber. If this is not the case and several information systems operate simultaneously in a hospital, it is much more complex to transfer the information quickly in a "seamless care" fashion, so everyone may have access to the medicines available to prescribe. However, if the data on shortages is not promptly fed into the "prescribing" system, errors may occur when notifying healthcare professionals on the medicines affected as well as those medicines still available. Not linking the prescribing system to the hospital pharmacy IT system also introduces the needless risk of transcribing errors and adds further complications throughout patient treatment due to medication errors.

4. Do you have a dedicated Drug and Therapeutics Committee (DTC) in your hospital/healthcare setting?

YES

A DTC will allow for a multidisciplinary environment in which potential solutions to medicine shortages may be discussed. A DTC will also facilitate the decision-making process on therapeutic or generic substitutions, which must take place when a shortage occurs.

NO
(why needed?)

A DTC is needed in every healthcare setting in order to assure patients receive the best treatment based on inter-professional and multidisciplinary co-operation. DTCs have tremendous importance as an overarching body that provides support to hospital pharmacies conducting alternative treatment assessment throughout a shortage. Moreover, DTCs and hospital pharmacies work together in creating contingency plans on how to react to some shortages, particularly those which possess the greatest clinical impact on patients. With the support of a DTC, it is possible to facilitate the decision-making process on treatment substitution when a shortage occurs and disseminate information on them throughout a healthcare facility in a quickly and formal fashion.

5. Do you have a dedicated medicine-shortage task-force group (MSG) with participating healthcare professionals (such as pharmacists, quality in healthcare officers, physicians, nurses ...) in your hospital/healthcare setting?

YES

A MSG allows for shortages to be efficiently assessed and for decisions on therapeutic substitutions to be made more effectively since it will better incorporate all levels of the healthcare setting.

NO
(why needed?)

A MSG is often not fully formed and functions within a DTC. However, due to the complexity of a DTC's tasks, it is recommended that a healthcare facility has a separate body on shortages, which can provide only a synthesis to the DTC when further elaboration on shortage mitigation is needed. Moreover, with a dedicated group of healthcare professionals focused on shortages, it is possible to mitigate passing the buck (i.e., "not claiming responsibility for oneself and one's tasks"), which is more likely to occur if no one assumes responsibility for managing and tracking shortages in a healthcare setting.

6. Are there any internal procedures in place to manage medicine shortages in your hospital/healthcare setting?

YES

Depending on the type of a shortage and patient population affected, internal procedures provide straightforward directions to HCPs on how to manage shortages. Having such procedures also facilitates a follow-up of the conducted procedures as well as a thorough analysis of what has been done.

NO
(why needed?)

Having internal procedures in place within a healthcare setting not only defines responsible HCPs who will perform the initial data assessment on shortages, but it will also establish the groundwork for multidisciplinary collaboration that is required to mitigate shortages. Moreover, internal procedures help in setting high standards of quality in healthcare as they are living documents that are able to be actively evaluated and amended to better achieve the desired health outcomes in a healthcare setting. Procedures also facilitate quickly modifying hospital information systems so they may process information flows faster on available and non-available medicines, delivering this information to those who are prescribing the medicine(s) to a patient. More importantly, by following such procedures, an HCP may more easily measure how effective the procedures are on overcoming or mitigating a shortage in real time. Moreover, due to their active nature, these procedures allow for tracking of progress made against a drug shortage to be better monitored throughout the year. Finally, these procedures help an HCP distinguish critical from non-critical shortages and may significantly impact the time needed to respond to one. Given that time is one of the most crucial factors when managing a shortage, these procedures are of extreme importance in emergency teams and in intensive care.

7. Do you have a list available of high-risk medicines affected by previous shortages?

YES

Having a list of high-risk medicines enables an HCP to tailor a list of substitutes for each high-risk medicine should a shortage occur. Depending on the number of high-risk medicines affected by a shortage, an HCP may thereby quickly assess the potential impact on providing health services in their healthcare setting.

NO
(why needed?)

Having a list of high-risk medicines available that bear a major therapeutic impact on patients is a necessity for an HCP in order to improve readiness when facing increased shortages. While a medicine deemed critical for one hospital may not be as critical for another, by evaluating the number of high-risk medicines, it is still possible to approximately establish the threshold below which healthcare services may be managed under the current supply. To illustrate, if an abundance of high-risk medicines is affected by a shortage and only a limited number of substitutes is available, then the healthcare services they need to be proactively checked against supply. Managing a shortage, these procedures are of extreme importance in emergency teams and in intensive care.

8. Does a pharmacist validate medicine's prescription after a physician prescribes?

YES

By having a hospital pharmacist evaluating/validating prescriptions, chances of information transfer among HCP and providing a quick feedback on alternatives, their potential for adverse effect and emerging new drug-drug interactions are much higher.

NO
(why needed?)

Interdisciplinary approach is inevitable in order to provide best possible care to a patient. This is particularly important when it comes to managing shortages. Validation conducted by a pharmacist allows a prospective assessment of patients medical records and how appropriate a substitute is for a patient, especially when a prescriber is not aware of a shortage, or when a hospital information system does not support automatic substitutes suggestion to a prescriber. The same stands for drug-drug interaction assessment, which is of great importance when an alternative is introduced to a patient, especially when no automatic interaction checker is integrated within hospital information systems.

9. Does your healthcare professionals have timely two-way communication (email; phone call)?

YES

Two-way communication is of a great importance in managing shortages, as a HCP needs to confirm if all the information on shortages and potential substitutes is well transferred and to provide feedback on efficiency of shortages mitigation measures taken.

NO
(why needed?)

Regardless of the means of communication available in a healthcare setting, of outmost importance is that it is two way communication. Timely information is useless if not well received and contemplated. In other words, knowing a substitute for a medicine in a shortage is only enough when it is provided on time and when feedback on proposed solutions is provided among HCP. This is not only important from prescribing and dispensing point of view, but also from the administration point of view, as nurses have to be well aware of substitution made in patient medical record and alternative's administration patterns in order to achieve optimal health outcomes in times of shortages.

10. Do you have “shortages issue” as part of hospital procurement process?

YES

When potential for a shortage, based on defined set of criteria, is introduced into healthcare setting’s procurement procedures, it provides a chance to take into account not only offered price of a medicine, but also the number of suppliers for a medicine and manufacturers dependence on one API supplier.

NO
(why needed?)

Due to increasing shortages globally, prudent tendering procedures are needed more than ever. Taking into account number of suppliers for a medicine with a major therapeutic impact when in a shortage; number of manufacturers API suppliers; history of shortages and how quickly a shortage was resumed provide more certainty that the best offer will be selected via tenders and shortages if happen will be well and quickly managed.

10. Do you have ethics framework for patient prioritization during medicine shortages before allocating substitutes?

YES

Having an ethics framework for prioritizing patients for treatment, during shortages, helps HCP to take decision more quickly on treatment pathways and select patients. By that they are able to share responsibility for patient's health outcomes with a healthcare setting.

NO
(why needed?)

Shortages bring a great deal of uncertainty and by having an ethics framework for patient prioritization in providing treatment during shortages, HCP have support in deciding and providing treatment to certain group of patients first. Framework based on interdisciplinary consensus within a healthcare setting, allows HCP and patients to follow a transparent way for selecting patients and treatments when treatment options are limited and patients' lives are in danger due to interrupted treatments..

A WAY FORWARD

As soon as the pharmacy department has assembled all the information required, its respective Drug Shortage Task Force must meet in order to provide an evaluation on the total projected impact the shortage may have on patient care as well as create an applicable action plan. Any differences in therapy must be identified as well as changes in distribution and prescription must also take into account any and all budgetary restrictions. Risk assessments targeting the patients affected must also be performed. Any other changes pertinent should also be included. The final action plan must then be communicated to all staff for them to be informed and educated on the situation and solutions available to them and the patient. All medical staff (physicians, pharmacists and nurses) will likely see their practice and workflow change as it relates to the therapeutic alternatives provided. The drafted action plan must be given to all pertinent medical staff and it must contain all details on the medicine shortage itself. This phase demands a close working relationship where members may freely interact and cooperate with one another as well as with local health systems.

Should any changes prove to be inadequate from any previous stage of implementation, it might be useful to consider a contingency phase as well to address any potential risk management which would include liability from the healthcare institution and prioritizing patients. Patients must also be educated on their treatment, which necessitates that expected outcomes of any suboptimal therapy be communicated to them. Patient dialogue must also involve, if applicable, risk management teams and legal representatives should there arise an extenuating circumstances. If there is a higher total number of patients expected to be directly impacted or that the shortage itself will carry onward for an extended time, it may also prove necessary to prioritize the drug. Where relevant, national bodies / organizations and their guidelines may also serve as a further resource that may be used to analyze what patients are most in need. At present, the majority of national guidelines, however, do not recommend therapeutic alternatives in the event of a shortage. Several action items may deem necessary in order to mitigate shortages, targeting different areas already assessed through risk assessment.

Action 1 - Increase Supplies

The most commonly-used medications and classes that would be in immediate high demand must be examined prior to a shortage in order to be ready in the event of one. Improved supply of critical medications, especially low-cost items and analgesics, sedatives, antimicrobials, pulmonary, behavioral and medicines used at Intensive Care (IC) must be carried out in advance so that, should a shortage occur, there will be a ready supply to mitigate it throughout.

Action 2 - Use Alternatives and Alternative Ways of Supply

Medications need to be obtained through alternative wholesalers or distributors. Stemming from the intricacies of supply chains as well as uneven demand, not all pharmacies may have the medicine, but have all the ingredients, including active principle ingredients (API) to compound it. Therefore, compounding pharmacies are a potential source of medicines undergoing a shortage. A common error in shortages is also that some medicine alternatives are overlooked. Metered-dose inhalers, for example, may be readily used instead of nebulized medications as they both deliver the same medication.

Action 3 - Restrict, Reduce and Rationalize Use of Medicines

Increasing stocks and diversifying supply chain may not fully remedy shortages. Reduction and restriction of medicines may deem needed. Therefore, certain medications must be restricted based on merely their prophylactic use as opposed to their therapeutic use. Antibiotics must only be given under therapy and not as a preventative measure when needed.

Action 4 - Change Administration of Medicines

Use subcutaneous, oral or nasogastric routes of administering medicine if possible. Administer medicines by gravity drip instead of IV pumps. Consider extensions of medicines' expiration dates in cooperation with regulatory bodies.

Action 5 - Reallocate and Prioritize

Reallocate medicines locally within healthcare setting or regionally/nationally taking into account the current epidemiological data, priority patients and limited stocks.