

# Enterprise Risk Management on Drug Shortage in KK Women's and Children's Hospital, Singapore

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## Introduction:

World-wide drug shortage is becoming a challenge in the healthcare system. As such, it is crucial for KKH Pharmacy department to conduct an Enterprise Risk Management (ERM) to manage drug shortages through identification of the risk associated with critical drug shortage and come up with mitigation controls and monitoring as well as a good communication plan to better prepare for this risk.

## ERM Methodology:

Drug shortage data over the last 1 year in 2012 was gathered to better understand the extend of the drug shortage problem in KKH as well as to identify the leading contributing factors for the drug shortage in the past year.

Other risks were identified through scenario planning to identify failure points, literature search and from analysis of the organizational and external environment risks through a risk and control self-assessment (RCSA).

Role	R Responsible	A Accountable	C Consulted	I Informed
Director of Allied Health Specialties				X
Chief Pharmacist		X	X	
Purchasing Pharmacist	X			
Drug Information Services Pharmacist			X	
Inpatient Pharmacy Head			X	
Outpatient Pharmacy Head			X	
Pharmacy Store Coordinator	X			
Pharmacy Storekeeper	X			

The risks that will be put into consideration will include the following:

- Reputational risk
- Regulatory risk
- Human capital risk
- Credit risk
- Competitor risk
- Operation risk
- Supplier risk
- Terrorism risk
- Natural hazard risk
- Black swan

AS/ NZS 4360 Semi-Quantitative analysis is used to grade each risk identified and come up with mitigation plans through a comprehensive risk register.

## Results:

Key performance and risk indicators dashboard are developed for effective risk and performance monitoring. These identified risks and key performance and risk indicators will be reviewed biannually to ensure that they are kept up to date. This ERM will also be discussing change management challenges and strategies, communication plan and crisis management plan in preparation for the worse if mitigation plans fail.

Key Performance Indicators (KPIs) monitor changes in performance of the business/ operational activities/ processes that have an impact on specific business objectives. They are linked to the critical success factors of the organization/ department. Key Risk Indicators (KRIs) relate to a specific risk and demonstrate a change in the likelihood or impact of the risk event occurring. Key Control Indicators (KCIs) relate to monitoring controls' application and effectiveness.

## Communication and Consult:

The completed plan will be communicated across the department, shared at Ministry of Health, Chief Pharmacist meeting and upload into the internet for sharing purposes.

In conclusion, one should keep in mind the key ERM implementation success factors below to ensure successful implementation of ERM in your organization. This includes:

- Implementation of ERM framework within the risk maturity level of the organization
- Gain support of leadership and develop a clear vision
- Build a strong risk aware corporate culture
- Acquire strong project management capabilities
- Ensure adequate resource allocation and team involvement
- Build your organization network
- Provide the right ERM knowledge, skills and training
- Link rewards system to ERM objectives
- Go for quick wins, communicate about ERM success and share knowledge
- Use External consultants effectively

## Setting Key Performance and Risk Indicators Dashboard for Effective Risk and Performance Monitoring

Risks	Control	KPI	KRI	KCI
a) Critical drugs not available to treat patients resulting in serious patient outcome and media release of news b) Purchase of counterfeit drugs especially unregistered source from overseas supplier c) Medication errors due to frequent change in drug packaging/formulation as a result of drug shortage	a) Identify the list of critical drugs where there are no alternatives available. Buffer stocks of 3 months should be kept for this group of drugs on top of the par level. b) Identify suppliers with frequency stock supply issues and look for alternative vendors c) Establish good communication and network system with drug suppliers so that we can be informed ahead of stock shortage situation and work with other vendors to increase production. d) Drug ration and patient prioritization e) Good network system with other healthcare institutions to establish collaborative arrangements for drugs to be shared/ loaned. To come up with a guideline to check on suppliers and drug source. Using ASHP guideline to identify counterfeit drugs f) Establish a system within hospital to inform staff of change in drug appearance, strength and formulation g) Work with Risk managers to identify possible risks and work out mitigation plans	No. of cases where patients are deprived of critical drugs No. of medication errors related to change in drug appearance, strength and formulation as a result of drug shortage	No. of vendors with frequent stock out situations No. of cases unable to loan from other hospitals in the event of stock out. No. of cases where drugs are recalled due to counterfeit reasons	No. of inventory days for identified critical drugs
Drug approval rejected by Health Sciences Authority (HAS) due to safety concerns over drug stability, packaging, patient information leaflet	Work with HSA to establish an urgent approval process for critical drugs		No. of cases of drug shortage due to delay in regulatory approval process	
Attrition of experience purchaser or storekeeper in pharmacy affecting drug inventory and purchase Fraud or bribery at procurement process	a) Staff retention scheme to ensure staff needs are met b) Ensuring staff benefits are competitive to attract staff with good values and experience c) Robust training program to develop human capital d) Review of procurement processes to ensure good procurement processes are in place e) Regular audits to ensure system in place and well complied.	% of staff attrition in Purchasing and Pharmacy Store	No. of critical audit issues raised during internal/ external audits	
Improper inventory process resulting in drug shortage	a) Regular review of par level to ensure up to date b) Establish a system for storekeepers to check their stocks daily and activate procurement process as early as possible when stocks fall below par. c) Set up pharmacy system trigger to alert when stocks fall below par level to trigger ordering d) Avoid "Just in time" inventory management for critical drugs			No. of out of stock situations or last minute ordering of drugs due to poor inventory control
Unreliable suppliers who failed to deliver drugs on time	Regularly review vendors performance			Vendors performance Evaluation every quarterly and % grade below average
Pandemic diseases like H1N1 resulting in shortage of high demand drugs	Follow MOH Emergency stock piling procedure. Ensure drugs to be stock piled are stock up accordingly with good expiry			% of drugs kept below par level or expired during quarterly review