THE NATIONAL GUIDELINES ON AUTOMATED MEDICATION MANAGEMENT SYSTEMS

27 April 2023

ACKNOWLEDGEMENTS

The *National Guidelines on Automated Medication Management Systems 2021* has been developed by the National Automated Medication Management Systems Taskforce (NAMMST) (see Table 1 for composition) under the National Medication Safety Committee (NMSC) 2017-2021 term (see Table 2 for composition). The NAMMST would like to thank the nominated resource persons (listed in Table 3) for their assistance in rendering their domain expertises in the development of the national guidelines and facilitating data provision for meaningful analysis of the current state.

Table 1: Composition of NAMMST, June 2019 – January 2023

Name	Institution	Designation
Mr Li Kaihui Benny (Chairperson)	NSC	Head and Principal Pharmacist, Department of Pharmacy
Ms Janice Lim Chai Huang (Vice Chairperson)	KKH	Pharmacy Practice Manager
Mr Tan Chwee Huat	AH	Senior Principal Pharmacist
Ms Angeline Liew	CGH	Principal Pharmacist (Informatics)
Mr Mark Winn	IHiS	Director, National Systems - NHIPS
Mr Wilfred Soon	IHiS	Deputy Director, Product Management & Delivery Group 2-Pharmacy
Dr Yin Shanqing	KKH	Assistant Director, Human Factors & Systems Design
Ms Wang Hui Hui	NHG Pharmacy	Deputy Director (Informatics)
Ms Puah Swee Lin	NTFGH	Senior Principal Pharmacist
Ms Ng Kai Xin	NUH	Principal Pharmacist (Clinical)
Ms Lee Soo Boon	SGH	Deputy Director, Department of Pharmacy
Mr Chan Joon Kai	SGH	Senior Nurse Manager (Nursing Informatics)
Mr Teo Yao Zong	TTSH	Principal Pharmacist
Ms Angelina Tan Hui Min	SKH	Head, Pharmacy

Name	Institution	Designation
Ms Hon Jin Shing	NHCS	Senior Principal Clinical Pharmacist
Ms Mabel Phng	ALPS	Deputy Director, Strategic Procurement (Pharmaceuticals)
Ms Choong Wei Sim	ALPS	Former Assistant Director, Strategic Procurement (Pharmaceuticals)

Table 2: Composition of the National Medication Safety Committee, July 2017 – June 2021

Name	Institution	Designation
Members		
Adj Assoc Prof Augustine Tee (Chairperson)	CGH	Chief, Department of Medicine; Deputy Chairman Medical Board (Medical Disciplines)
Mr Wu Tuck Seng	NUH	Former Director, Pharmacy Department
Dr Liew Mei Fong	AH	Director, Intensive Care Unit
Dr Chua Mei Chien	KKH	Head and Senior Consultant, Department of Neonatology; Chair of the Medication Safety Committee KKH
Dr Loh Seow Siang	KTPH	Senior Consultant, A&E
Dr Kurumbian Chandran	NTFGH	Director of Endocrinology; Co-chair of the Medication Safety Committee
A/Prof Ng Heng Joo	SGH	Senior Consultant, Department of Haematology; Director of Patient Safety
Ms Angelina Tan Hui Min	SKGH	Head, Pharmacy
Dr Tan Sze-Chin	TTSH	Senior Consultant, Department of Rheumatology, Allergy and Immunology; Chair of the Medication Safety Team
Ms Soh Lay Beng	IMH	Head, Pharmacy Department
Dr Ang Mei Kim	NCC	Senior Consultant, Division of Medical Oncology
A/Prof Ding Zee Pin	NHC	Senior Consultant, Department of Cardiology; Chairperson, Pharmacy & Therapeutics Committee

Name	Institution	Designation
Mr Li Kaihui Benny	NSC	Head and Principal Pharmacist, Department of Pharmacy
A/Prof Marcus Ang	SNEC	Consultant, Corneal and External Eye Disease Department
Ms Chua Hui Min	NCIS	Senior Clinical Pharmacist
Asst. Prof Yeo Wee Tiong	NUHCS	Consultant, Department of Cardiology
Dr Peter Moey	SHP	Clinic Director, Polyclinic Development Projects (Eunos), SingHealth Polyclinics-; Consultant Family Physician
Dr Valerie Teo	NHGP	Consultant Family Physician; Deputy Head, Ang Mo Kio Polyclinic; Chairperson, Medication Management and Usage Committee, NHGP
Dr Tan Wei Beng	NUP	Member, NUP MMUC
Ms Quek Hui Chen	JCH	Head, Pharmacy Department
Dr Colin Ngeow	YCH	Consultant, Medical Services
Dr Patrick Chia	IHiS	Director, Clinical Informatics Group
A/Prof Lita Chew	NCCS	Former Chief Pharmacist Head of Pharmacy Department, NCCS
Dr Camilla Wong	MOH	Chief Pharmacist
Secretariat: *Patient Safety & Quality Improvement (PSQI) branch, Clinical Quality, Performance &Value (CQPV) Division, MOH*		
Dr Adelina Young	MOH	Deputy Director (PSQI, CQPV)
Ms Luisa Tan	MOH	Assistant Director (PSQI, CQPV)
Ms Liu Pei	MOH	Senior Manager (PSQI, CQPV)

Table 3: List of Resource Persons

Name	Institution	Designation
Assoc Prof Lita Chew	MOH	Former Chief Pharmacist
Ms Mabel Phng Mien Hui	ALPS	Assistant Director, Strategic Procurement (Pharmaceuticals)
Mr Choong Wei Sim	ALPS	Former Assistant Director, Strategic Procurement (Pharmaceuticals)

INTRODUCTION

In our pursuit of medication safety and operational efficiency, our healthcare institutions have increasingly invested and utilised health technology and automation in the medication management and use processes. While automated medication management systems (AMMS) provide medication safety and operational efficiency benefits at the strategic level, each system is accompanied by its unique set of limitations and risks. In light of an incident involving unit-dose processing error in an inpatient pharmacy automated system and safety concerns arising from the analysis of near-miss data, the National Automated Medication Management Systems Taskforce (NAMMST) was convened to develop a set of national guidelines to facilitate the safe implementation and management of AMMS in Singapore.

This set of guidelines aims to support healthcare institutions in enhancing the safe use of AMMS for safer and better outcomes, as well as to minimise AMMS-associated errors from resulting in patient harm. It serves as a reference guide for any healthcare institution with the intention to implement a new AMMS or review its existing AMMS. While it covers the key aspects of AMMS, it is not intended to be exhaustive, particularly in the current era of rapid technological developments and innovations.

In the development of these guidelines, NAMMST has taken reference from international and best practice guidelines, and contextualised them to local healthcare settings. Site visits to local public healthcare institutions were conducted to gain insights of AMMS' operating functionalities and processes, and their respective risk management approaches and strategies. Local subject matter experts were also consulted for their expert opinions on how to approach challenges in using AMMS.

System-human interactions were found to be contributing factors to errors, near-misses and key operational issues. Guided planning, selection, and implementation of AMMS would be able to address them at the upstream level through adequate risk awareness and management in the early stages. Hence, this guideline includes strategies to minimise system-human errors and recommendations for common scenarios of system-human interactions, including medication loading into AMMS by pharmacy staff and AMMS medication retrieval and return processes by nursing staff.

As AMMS is defined as “computerised drug repackaging or storage devices/machines that allow medications to be repackaged, stored, and/or dispensed in healthcare settings”, the system-system interactions covered in this set of guidelines is limited to AMMS software to clinical systems, such as inpatient automated dispensing cabinets with electronic inpatient medication records and outpatient pharmacy automation system with pharmacy dispensing software. Although the scope of this guideline is limited, it does not negate the importance of adequate clinical risk management for system-system interactions (e.g system interfaces between prescribing software to dispensing software). AMMS are tools to improve medication safety, process reliability, and operational efficiency.

Beyond planning and implementation of AMMS, it is imperative for healthcare institutions to routinely and proactively review and redesign medication prescribing, dispensing, and administration processes to produce positive medication safety impact at the system level with AMMS being the enablers to magnify the expected benefits.

CONTENT

1 PROJECT MANAGEMENT

As AMMS involves a considerable investment by healthcare institutions to improve medication safety and operational efficiency, a robust and systematic project management process is essential to ensure its alignment to organisational priorities and the fulfilment of its expected benefits. All the project management phases, namely (i) selection and procurement, (ii) pre-implementation, (iii) implementation, and (iv) post-implementation, should facilitate the selection and optimisation of the AMMS technology/solution to achieve the intended outcomes in a sustainable manner while complying with the prevailing governance frameworks. Engagement of key stakeholders is essential at the early phases and throughout the project management process.

1.1 Selection and Procurement of AMMS

1.1.1 Establish the business case for adoption of AMMS technology/solution

Understanding organisational priorities and needs is essential in the comprehensive cost-benefit analysis of AMMS technology/solution in the identified patient care settings and/or supporting functions, and determination of “right-fit” in achieving the desired medication safety and/or operation effiency benefits. Absence of clarity in this aspect may result in the inaccurate and/or incomplete documentation of institution and/or user requirements; hence leading to the risk of inappropriate or incomplete AMMS technology/solution.

Recommendations

(a) Identify the business case or use-case based on the identified areas of concern, expected outcomes, and organisational priorities (e.g. lack of skilled manpower, improving operational efficiency, achieving zero dispensing error)

(b) Utilise data analytics to substantiate the business case in the cost-benefit analysis of AMMS technology/solution (e.g. estimated medication error reduction with automation, identification of specific process gaps that can be addressed with suitable AMMS technology/solution, potential reduction in waiting time due to improved operational efficiency)

(c) Clear documentation of institution and/or user requirements in alignment to organisational priorities

1.1.2 Identify potential AMMS technologies/solutions to address the identified organisational needs and areas of concern

A mismatch between the procured AMMS technology/solution and actual organisational priorities and needs can be a costly mistake in financial, operational, and safety aspects. Partial fulfilment of organisational needs and incomplete resolution of areas of concern may require further system enhancements or additional investments in other AMMS technologies/solutions to close these outstanding gaps in order to achieve the desired medication safety and operational efficiency benefits. Hence, it is important to identify the available AMMS technologies/solutions that can fulfil the institution and/or user requirements to minimise costs to the organisation.

Recommendations

(a) Horizon scanning to identify AMMS technologies/solutions that can best address identified organisational needs and areas of concern
(b) Request for information (RFI) in scenarios where there is absence of domain expertise in a particular specialised area

1.1.3 Shortlisting of suitable AMMS technologies/solutions

After identifying the AMMS technologies/solutions via horizon scanning and RFI process, a specific set of criteria (e.g. details of essential features and functionalities) should be used to shortlist suitable options for further evaluation. Obtaining a comprehensive understanding of each AMMS's features and functionalities facilitates streamlining of suitable options with the appropriate sizing (e.g. physical size, costs of AMMS, optional add-on modules for scalability) to achieve the intended medication safety, operational efficiency, and/or resource utilisation benefits, as well as the potential for capacity growth in the future. This allows for accurate estimation and projection of space allocation, manpower resources, and skillsets required to support the full operation of the possible AMMS options. It also facilitates prediction of the risks associated with AMMS' system design and the corresponding adverse consequences.

Inadequate space, manpower, and skillsets of staff can compromise the expected benefits in the aspects of medication safety and operational efficiency. Mismatch of appropriate site/space selection to AMMS' space requirements may result in the incomplete implementation of AMMS technology/solution and compromise its expected capabilities and benefits. For example, an Outpatient Pharmacy Automation System (OPAS) solution without adequate storage allocation for outpatient medication formulary can potentially result in the pharmacy staff performing manual medication picking and combining with OPAS output. This results in potential risk of omission errors (e.g. missing manual-picked medications or OPAS-output medications) and reduced work efficiency. System integrability with current (and/or future) IT infrastructure and other health technologies should be considered to reduce undesirable consequences that can compromise medication safety and operational efficiency benefits. Adopting a workplace safety perspective to identify suitable AMMS' system design will enable compliance to workplace health and safety regulations and promote safe working environment for staff (e.g. acceptable noise level, minimal ergonomic risks).

Recommendations

(a) Obtain a complete understanding of the features and functionalities of the various AMMS options
    (i) Benefits to medication safety, operational efficiency, and resource utilisation (e.g. demonstrated improvements in abovementioned aspects based on other users' or manufacturers' data)
    (ii) AMMS' handling capacity and throughput (e.g. number of unit doses packed per hour, ability to handle different dosage forms) for all target sites (e.g. wards, operating theatres, procedure suites, outpatient pharmacies, inpatient satellite pharmacies)
    (iii) AMMS' interoperability with other technologies (e.g. systems, devices) to facilitate care processes (e.g. care transitions, medication reconciliation)
    (iv) Manpower and skillset requirements to support AMMS technology/solution
(b) Review the important considerations in the shortlisting of suitable AMMS technologies/solutions, and examples as follows:
    (i) Desired level of automation (e.g. full automation, semi-automation)

(ii) Space availability to accommodate the hardware (e.g. machines) in the target sites (e.g. wards, operating theatres, procedure suites, outpatient pharmacies, inpatient satellite pharmacies)

(iii) Suitability of target sites to accommodate the hardware and the need to consider future proofing of these sites (e.g. ceiling height, circulation space for operators and maintenance work)

(iv) Provision for site preparation (e.g. maximum allowable floor loading/weight acoustic treatment based on machine specifications)

(v) Medication safety risks of AMMS technology/solution based on reliable information sources (e.g. user experience, published medication error/near-miss data, reputable best practice guidelines)

(vi) Adoption of similar AMMS technology/solution in other healthcare institutions (locally and/or overseas)

(vii) Frequency of AMMS machine breakdown based on historical data and/or user experience, and the downtime management processes

(viii) Establish whether a single vendor or a consortium of vendors is required to deliver the complete end-to-end AMMS solution

(ix) Consider both current and future versions of AMMS from the vendors and as well as the ability to be upgraded and/or scaled up after the initial implementation.

(x) Capability of appointed vendor to be a system integrator for the AMMS technology/solution

(xi) Considerations for system integrability with current or future IT infrastructure, systems, and health technologies, to prevent adverse consequences, such as medication safety lapses (e.g. medication errors due to inaccurate or missing order translation at system interfaces) and additional manual work processes (e.g. manual transcription)

(xii) Establish the need and costs for system integration/interfaces, particularly if multiple vendors are involved in providing the AMMS technology/solution

(xiii) Assess the workplace health and safety risks of the AMMS technology/solution based on end users' feedback, its technical operation, and prevailing workplace health and safety guidelines

(xiv) Post-implementation support provided by the vendor, including hardware/software checks/updates and replacements during preventive maintenance

(c) Identify and engage key stakeholders who are likely to be affected by AMMS technology/solution to obtain their inputs wherever relevant (e.g. patient care units, nurses, porters)

(d) Apply a systems thinking approach to understand the impact of AMMS technology/solution on upstream, downstream, and concurrent workflow processes, as well as the corresponding consequences (e.g. adverse impact of certain patient care activities, increased risk of medication errors, higher operational costs and manpower resources)

(e) Establish a comprehensive system to provide end- to- end medication management process from ordering and supply to administration of medication.

(f) Understand the possible system-system interactions and system-human interactions with the various AMMS options, as well as their benefit and risk profiles

1.1.4 Initiate a site visit to the healthcare institution(s) that has/have adopted the shortlisted or a similar variant of the AMMS technology/solution to gain insights on implementation experience

Site visit to a healthcare institution with the same or similar variant of the AMMS technology/solution provides the opportunity to understand the institution's implementation journey and the various users' experiences, particularly in the aspects of medication safety and operational efficiency. This may include sharing of new risks (e.g. safety, operational, technological, financial) that have been introduced to the existing organisational system and processes and the unintended consequences. This provides valuable insights to ascertain the suitability of this AMMS solution/technology in meeting the organisational priorities and needs.

Recommendations

(a) Arrange site visits to healthcare institution(s) with same or similar variant of the AMMS technology/solution, so that additional information can be obtained for the comprehensive evaluation of the AMMS technology/solution. The host institution(s) can conduct open sharing to facilitate in-depth understanding of the AMMS

features and functionalities, resource allocation to support AMMS, and critical safety concerns

(b) Invite all the stakeholders to join a site visit, and facilitate clarification and meaningful discussion of AMMS technology/solution

1.1.5 Request for financial resources to implement AMMS technology/solution

The implementation of the AMMS technology/solution requires the support of organisational leadership and key stakeholders, as well as the allocation of adequate financial resources to enable the effective implementation and actualisation of the intended medication safety and operational efficiency benefits. The absence of support or buy-in from institutional leadership or key stakeholders can limit the planned adoption of the AMMS technology/solution. Inadequate financial resources can lead to the implementation of an incomplete AMMS solution; hence compromising the expected attainment of the intended medication safety and/or operational efficiency benefits.

Recommendations

(a) Identify project sponsor(s) and present to senior management for endorsement prior to putting up the request for financial resources and funding, as the AMMS project typically involves multiple stakeholders and/or major changes to workflow processes

(b) Submit the AMMS project workplan during routine institutional workplan sessions and at the appropriate point in the budgeting cycle, or AMMS project funding paper to the respective funding agency (e.g. Ministry of Health) at the appropriate timeframe

(c) Engage key stakeholders, including end-user team (e.g. pharmacy, nursing, medical), IT (e.g. IHiS, health informatics), and facilities management, to collaborate on the AMMS project workplan or funding paper

(d) The AMMS project workplan or funding paper should include the following components:

  (i) Clear establishment of business case or use-case with illustrated value proposition and supporting workload and manpower projection

(ii) Number of AMMS units and supporting hardware requirements based on workload projections
(iii) Budgetary quotations from vendors
(iv) Potential costs for infrastructure and site preparation
(v) Risk assessment of the AMMS project in various risk domains (e.g. strategic, clinical safety, financial, technological, operational)
(vi) Requirements for system integration/interfaces and the estimated manpower costs to support project implementation (to be determined in collaboration with IT stakeholders, such as IHiS)
(vii) Total cost of ownership, including capital, maintenance, and operating costs
(viii) Key performance indicators, outcomes indicators, and deliverables, in consideration of the expected medication safety and operational efficiency benefits of the AMMS technology/solution
(ix) Project implementation timeline, including requirement gathering, workflow discussion, machine fabrication, delivery lead time, site preparation, installation and testing, system integration testing (SIT), user acceptance testing (UAT), and Go-Live

1.1.6 Procurement of the AMMS solution

Healthcare institutions should adhere to their respective corporate governance frameworks and procurement processes. This includes obtaining approval from the respective approving entities in accordance to the project scope and value. Failure to adhere or comply to these requirements may result in project implementation delays or project governance issues.

Recommendations

(a) Identify the corporate governance frameworks and procurements processes, approving entities, and their respective timeframes that are applicable to the proposed AMMS option(s)
(b) Advance planning for procurement processes that typically include:
(i) Preparation and review of request for proposal (RFP) or invitation to quote (ITQ)

(ii) Obtain legal advice/inputs on RFP and ITQ documents
(iii) AMMS project presentation to respective approving entities for approval to release RFP or ITQ
(iv) Release of RFP or ITQ after approval
(v) Vendor submission of RFP or ITQ
(vi) Appointment of evaluation panels

1.1.7 Nomination and appointment of technical evaluation panel to perform comprehensive evaluation of shortlisted AMMS technologies/solutions

The comprehensive evaluation of the proposed AMMS technologies/solutions by various domain experts is crucial to provide a holistic assessment for all aspects, including medication safety, IT security, facilities and infrastructure, workplace safety, and infection control. Common risks include, but not limiting to the following:

(a) Potential exposure to IT security breaches and vulnerabilities
(b) Under-sized or over-sized AMMS solution due to inaccurate requirement gathering
(c) Workplace safety hazards due to inadequate site preparation
(d) Inadequate space to implement the full AMMS solution
(e) Magnification of the scale of medication errors due to more efficient automated processes
(f) System-system interface failures
(g) System-user interface failures (e.g. machine-to-operator usage issue)

Recommendations

(a) Technical evaluation panel (TEP) to perform comprehensive evaluation can include:
(i) IT project manager
(ii) User project manager (e.g. pharmacist, nursing)
(iii) Facility and infrastructure management
(iv) Biomedical engineer
(v) Workplace safety officer
(vi) Infection control

(b) TEP members should declare conflict of interest in accordance to the prevailing governance frameworks of the healthcare institutions

1.1.8 Evaluating the shortlisted AMMS technologies/solutions using a weighted scoring evaluation checklist to reflect the order of prioritisation

A fair and consistent evaluation of all the shortlisted AMMS technologies/solutions is essential to determine their benefits and risks in the different aspects, including medication safety, operational efficiency, resource utilisation, and cost-effectiveness, in a comprehensive manner. Developing a checklist of the essential and optional features/functionalities with weighted scoring for all the evaluation components provides a structured and objective approach for the evaluation to assess all the AMMS options. It is important to assign the appropriate score weightage to the evaluation components to reflect the order of prioritisation. Higher weightage should be assigned for items that are more important.

Recommendations

(a) Evaluation should be aligned to the user requirements and weighted scoring evaluation checklist, and is applied consistently across all the proposed AMMS options

(b) The evaluation team should:

(i) Determine the acceptance criteria and key performance indicators

(ii) Schedule vendor presentation, clarification, and negotiation sessions where relevant

(iii) Request for single point of contract/vendor or system integrator in the scenario where the end-to-end AMMS solution is provided by a consortium of vendors

(iv) Determine the level of vendor support and response time for on-site and off-site support

(v) Establish the frequency of AMMS downtime (e.g. machine breakdown) based on historical data and/or user experiences, due to the increased risk of errors associated with manual processes

(vi) Assess adequacy of downtime management processes during AMMS downtime

(c) The weighted scoring checklist should include the following components:

(i) Functional score (e.g. usage, features, safety, operational aspects)

(ii) Technical score (e.g. IT security, system integration, project management risks)

(iii) Maintenance score (e.g. degree of maintenance, local/overseas support, preventive maintenance schedule, adherence to service-level agreement)

(iv) Company score (e.g. financial statuses, relevant healthcare experiences, sufficient manpower resource, past track records in similar projects)

(v) Cost reasonableness (based on total cost of ownership, including hardware, software, and maintenance costs)

(d) A comprehensive evaluation should encompass both objective evaluation (compliance to requirements) and subjective evaluation (assessment with experience).

(e) A pricing evaluation panel may be formed to review the pricing of all the vendor proposals

1.1.9 Additional considerations when evaluating AMMS vendors

Apart from evaluating the AMMS options, the evaluation committee should consider the vendors' profiles to ensure greater value proposition for the AMMS technology/solution. This is because mismatched vendor expertise, experience, and technology can compromise medication safety and operational efficient benefits.

Recommendations

(a) Evaluate AMMS vendors and their solutions/technologies in consideration of the following:

(i) Practicality of the AMMS options

(ii) Suitability of AMMS options to be deployed in local context (e.g. environmental/climate conditions, language configuration)

(iii) Risk of engaging the identified vendor

(iv) Benefits of selecting the incumbent/identified vendor

(v) Availability of measures to mitigate the risks of being locked-in

(vi) Alignment to national, cluster, and institutional strategic thrusts and directions

(vii) Long-term cost implications (e.g. comparison in consideration to expediency)

1.1.10 Awarding of contract

The awarding of contract for selected AMMS technology/solution should adhere to the prevailing corporate governance frameworks and project approval processes that typically serve as the safe-guards to manage and mitigate risks that have potential to compromise medication safety and operational efficiency. These risks may include, but not limited to the following:

(a) Under-sized or over-sized AMMS solution due to mismatch of requirements with vendor's capabilities

(b) Inability of AMMS technology/solution to integrate seamlessly with current/future IT infrastructure and systems and other health technologies

(c) High reliance of manpower and increased human error risks due to extensive manual steps in routine operation of AMMS

(d) Workplace health and safety risks (e.g. ergonomic risks) and regulatory implications

(e) Absence of single contact point (for consortium projects) for troubleshooting and solutioning can lead to delayed project implementation, lengthy machine downtime, and delivery of expected medication safety and operational efficiency benefits

(f) Inadequate downtime management procedures can lead to slower recovery to operational state

Recommendations

(a) Presentation of the recommendations of the evaluation committee to the appropriate approval entities for contract award approval

(b) Seek legal advice/inputs in the review of letter of award, contract and service-level agreement

1.2 Pre-implementation

1.2.1 Appointment of project management committee and project steering committee

Having a project management committee and project steering committee can facilitate the development of the project plan and implementation process, as well as the provision of oversight over the adherence to project plan and deliverables within the project timeframe. This will reduce the risk of project deviations and delays that can have adverse impact on the expected medication safety and operational efficiency benefits, as well as cost implications.

Recommendations

(a) The project management committee can perform the following:

(i) Produce, maintain, and execute the AMMS project plan

(ii) Oversee the project implementation process

(iii) Escalate critical issues to project steering committee (e.g. project delays, testing failures)

(b) The project steering committee can perform the following:

(i) Provide oversight, guidance, and advice to the AMMS project

(ii) Ensure the achievement of key milestones and project deliverable

1.2.2 Development of AMMS project plan

The development of AMMS project plan provides a systematic approach to the project implementation and clear objectives and focuses for each stage of build-up. Inclusion of project controls in the project plan can facilitate the achievement of the deliverables of each stage within the project timeline. This approach reduces the risk of project deviations and delays, and inappropriate project timeline.

Recommendations

(a) The AMMS project plan can include the following components:

(i) Project objectives

- Describes the aim of the project. Objectives should be specific, measurable, achievable, realistic, and time-limited

(ii) Project scope

- Describes the project's deliverables and the work required to create those deliverables. It may contain clear scope exclusions that can assist in managing stakeholder expectations and provides the baseline for assessing whether change requests or additional work are within or outside the project's boundaries

(iii) Project methodology

- The methodological approach to planning, executing, controlling and terminating the project. Different approaches and methods (i.e. LEAN, Six Sigma etc) can be employed in managing the project

(iv) Deliverables

- Describes unique and verifiable products, results, or capabilities to perform a service that is required to be produced to complete a process, phase, or project

(v) Work breakdown structure

- A hierarchical decomposition of the total scope of work to be carried out by the project team to achieve the project objectives and create the needed deliverables

(vi) Milestones

- Significant points or event in a project. Project milestones give a good overview of the progress and help communicate what is happening in the project

(vii) Project management structure

- It standardizes the project-related governance processes and facilitates the sharing of resources, tools, methodologies, and techniques. The responsibilities may range from providing project management support functions to actually being responsible for the direct management of the project. It indicates who the project sponsor and project manager are and also include stakeholders list

(viii) Risk management

- The processes of conducting risk identification, analysis, response planning, and controlling risk on a project. The aims of project risk

management are to increase the possibility and impact of positive events and decrease the possibility and impact of negative events in the project

(ix) Project resources required

- An outline of resources required for the project i.e. equipment, skilled human resources, supplies, commodities, services, material, budgets, or funds

(x) Project controls (e.g. quality assurance, configuration management, change requests)

- Involves controlling changes and recommending preventive or corrective action in anticipation of possible issues, monitoring the ongoing project activities against the plan and the project performance measurement baseline, and influencing the factors that could circumvent integrated change control or configuration management so that only approved changes are carried out

(xi) Communication and reporting

- Develop an appropriate approach and plan for project communications based on stakeholder's information needs and requirements, and available organizational assets. Lack of communications planning may cause issues such as delay in message delivery, communication of information to the wrong stakeholders, or insufficient communication to the stakeholders and misunderstanding of the message conveyed

1.2.3 Change management planning

To facilitate the smooth transition from current state to future state, it is crucial to identify the key stakeholders at early stages and address their potential change management concerns adequately. This will reduce the risk of project implementation delays due to resistance to change by key stakeholders and lengthy engagement sessions at the later stages. Early engagement of front-line users will enable them to understand the medication safety and operational efficiency; benefits of AMMS and clarify their concerns. This reduces the risks of process violations and inappropriate usage that may negate AMMS benefits and create safety/operational concerns.

Recommendations

(a) Perform organisational assessment to determine the awareness level for change management and identify the baselines for subsequent activities and measurement for change management maturity
(b) Early engagement of key stakeholders is essential for change management

1.2.4 Performing User Acceptance Testing (UAT) to ensure expected functions and scenarios are tested adequately

Comprehensive User Acceptance Testing (UAT) is essential to ensure all the expected functions and operational scenarios of AMMS solution are being tested adequately. UAT allows the detection of deviations and abnormalities in the AMMS solution, and their subsequent rectification before implementation. Inadequate UAT can lead to the risks of unexpected medication safety issues and operational problems when AMMS solution is being used for patient care activities. The rectification of these issues and problems after implementation will be costlier in terms of medication safety and operational efficiency impact.

Recommendations

(a) Detailed UAT plan with planned scenarios to test all the expected functions and operational scenarios
(b) Documentation of AMMS' behaviour during UAT
(c) Identification of deviations and unusual system behaviours for rectification
(d) Interim measures and workarounds have to be reviewed for potential medication safety risks, and risk mitigation measures need to be in place
(e) All rectifications should undergo further rounds of UAT as needed to ensure that the expected functions are achieved

1.2.5 Managing change requests systematically to reduce risk of delay in implementation and unnecessary costs

Change requests for the AMMS solution are necessary to improve medication safety and operational efficiency over time. A systematic approach is required to ensure that all the change requests have sound justifications (medication safety, operational

efficiency, and/or business needs) and are reviewed and prioritised appropriately. This reduces the risk of delayed implementation of critical changes, medication safety and operational implications, and unnecessary costs arising from inadequate review of the change requests.

Recommendations

(a) Develop a change request process to monitor new requirements or proposed changes due to UAT findings
(b) Appointment of change controller to review and assess the change requests with the vendor
(c) Analysis of the change requests should include the following components:
    (i) Impact analysis of the change (e.g. performance load, workflow, system availability, system-system interface concerns)
    (ii) Cost of change
    (iii) Implementation timeline
(d) Prioritisation and approval of the change requests by project management committee and project steering committee
(e) All change requests require a corresponding UAT plan that should include the impact analysis, test scenarios, and expected outcomes

1.2.6 User Training

A structured user training process can ensure that all the AMMS users are adequately trained and orientated to the correct procedures based on their job scopes and job functions. This will minimise the risk of medication safety and staff safety concerns arising from incorrect operation of AMMS solution.

Recommendations

(a) Develop user training guide that can include the following contents:
    (i) Standard operating procedures of the AMMS solution for the various functions
    (ii) Simple troubleshooting guide
    (iii) Management of consumables (if relevant)

(iv) Access data mining and reporting functionalities

(b) User training process can include hands-on simulation using test cases or UAT settings to enhance learning effectiveness

1.3 Implementation

1.3.1 Defining the responsibilities of project management office (PMO) in the project implementation phase

It is essential for all the members in PMO to have clear understanding of their responsibilities in the project implementation phase. This allows them to have efficient communication channels, and minimises the risks of miscommunication or inadequate communication that may have adverse impact on the project implementation. Having clear oversight and proactive monitoring enables early detection and resolution of safety and operational concerns, and their timely escalation (if required).

Recommendations

(a) Identify the essential roles and define their responsibilities:

(i) Project Manager (Informatics/IT)

- Directs and coordinates the supply, delivery, and installation of the AMMS solution
- Ensures all works and services are executed and provided by the vendor in compliance to the contract
- Oversees project administration and timeline, hardware testing and installation, technical personnel training, logistical support, operational start-up, and documentation

(ii) Project Manager (User)

- Coordinates the facility management and site preparation for installation of AMMS solution
- Handles the change management for adoption, user training, and logistics of medications
- Collaborates with project team and different user groups to review current work processes and propose workflow redesign to improve medication safety and/or operational efficiency

- Highlights medication safety and operational efficiency concerns and ensure the appropriate follow-up review and actions
- Guides the project team to develop a Business Process Re-engineering (BPR) approach to identify key clinical/business processes and document key process data (e.g. value stream mapping, activity-based costing)

(iii) Project Manager (Vendor)

- Ensures all deliverables are completed in accordance to the AMMS project plan and timeline
- Oversees the quality and consistency of work by vendor team and sub-contractors (if any)
- Ensures compliance to prevailing regulations and guidelines
- Provides adequate support staff with the appropriate expertise and skillsets for the various stages of the implementation and deployment of AMMS solution

(b) All the project managers (Informatics/IT, User, Vendor) should collaboratively manage the following tasks:

(i) Oversee the project implementation plan and timeline

(ii) Proactively highlight and escalate issues of concern (e.g. expected delays, safety and operational risks) to the relevant entities (e.g. project steering committee) via the appropriate communication channels

(iii) Develop change management plan that can include, but not limiting to, the following components:

- Engagement and communication strategies
- Sponsor roadmap
- Coaching plan
- Training plan
- Resistance management plan (to identify potential resistance to change and address the underlying concerns appropriately)

(iv) Develop measurement system to track adoption, utilisation, key performance indicators, and performance gaps

1.3.2 Staged approach for implementation of AMMS solution

Establishing a staged approach for implementation of AMMS solution allows the systematic activity planning and monitoring by all the stakeholders in accordance to the project implementation timeline. A clear implementation plan is required to enable all stakeholders to be aligned to the same approach and timeline. This will enable the smooth implementation of the various project activities and minimise the risk of project delays. Risk assessment of the implementation approach and its key activities can identify potential risks and enable the formulation of risk mitigation strategies. This will reduce the unintended adverse impact on medication safety, workplace safety, and operational efficiency.

Recommendations

(a) Staged approach for implementation of AMMS solution with a realistic timeline
   (i) Roll-out and adoption planning (preparation during the warranty delivery period)
   (ii) Early enablement roll-out (initial sites and their users for Day 1 Go-live)
   (iii) Staged roll-out (subsequent roll-out during project commissioning period)
   (iv) Post-roll-out review (further roll-out during the project warranty period)

(b) The scope of the implementation plan should include, but should not be limited to, the following components:
   (i) Hardware fabrication (e.g. machines)
   (ii) Design interface model
   (iii) Unit test specification
   (iv) System functional test plan
   (v) Volume and performance test plan
   (vi) Integration plan (for both hardware and software components that are existing and new)

(c) Perform risk assessment of the implementation approach and formulate mitigation strategies to address the identified risks

1.3.3 Establish process for management and escalation of issues identified during project implementation

Establishing the process to manage and escalate issues identified during project implementation phase enables the consistent and systematic logging, categorisation, review, and tracking of these issues. This allows the critical issues with considerable adverse impact on medication safety, workplace safety, and/or operational efficiency to be prioritised, rectified/mitigated, and monitored in a timely and effective manner. This prevents the occurrence of adverse events arising from known critical issues.

Recommendations

(a) Process for management and escalation of identified issues

(i) Establish a log of identified issues

(ii) Determine the impact of the issues on medication safety, workplace safety and/or operational efficiency

(iii) Prioritise the issues to the appropriate severity categories with the corresponding rectification timeframe requirements

(iv) Review the issues using a problem analysis mechanism and determine the underlying causes

(v) Propose the corrective measures (interim and/or permanent) with the corresponding timelines

(vi) Escalate to project steering committee, other entities and/or stakeholders whenever necessary

(vii) Monitor the log regularly to track their statuses and recurrences

(viii) Monitoring report to update the relevant AMMS committees, and/or other entities and/or stakeholders at the appropriate frequency (e.g. weekly, fortnightly, monthly) whenever necessary

1.3.4 Managing new change requests proposed during project implementation

While a robust requirement gathering process allows the inclusion of all the requirements in a comprehensive manner, it is inevitable to encounter the necessity of incoming change requests during the project implementation phase after the UAT has been completed. Hence, a systematic approach is required to ensure that these

new change requests are reviewed for sound justifications (medication safety, operational efficiency, and/or business needs) and prioritised appropriately. These new changes are tested in a rigorous manner and scheduled for implementation at the appropriate time. A change request process is needed to track and monitor the status of all the incoming change requests. This reduces the risks of introducing untested changes into the tested AMMS solution and their potential adverse impact on medication safety and operational efficiency, while catering to critical and/or urgent change requests within reasonable limits of the project implementation.

Recommendations

(a) Develop a change request process to monitor new changes proposed after UAT has been completed
(b) Appointment of change controller to review and assess the change requests with the vendor
(c) Analysis of the change requests should include the following components:
    (i) Impact analysis of the change (e.g. performance load, workflow, system availability, system-system interface concerns)
    (ii) Cost of change
    (iii) Implementation timeline
(d) Prioritisation and approval of the change requests by project management committee and project steering committee
(e) All change requests require a corresponding UAT plan that should include the impact analysis, test scenarios, and expected outcomes

1.3.5 Developing comprehensive checklists for implementation and deployment of AMMS solution

A systematic approach to the implementation and deployment of AMMS solution ensures the successful installation of AMMS hardware and software components and reduces the risk of disruption to routine patient care activities. Comprehensive checklists of key project implementation tasks with their respective task owners and stakeholders can allow the effective planning and monitoring of these tasks. This provides clarity to all stakeholders and reduces the risk of project delays arising from the omission of tasks essential to implementation and deployment of AMMS solution

Recommendations

(a) Develop comprehensive checklists for all the key tasks essential for the implementation and deployment of AMMS solution, as well as the stakeholders involved in these tasks
(b) Monitor the task completion in alignment to the implementation and deployment schedule in the project plan
(c) Site deployment readiness checklist can include, but need not be limited to the following components:
    (i) Minimum specifications for networks, hardware, software, and system interfaces
    (ii) Security certificate (if applicable)
    (iii) Data migration requirements
    (iv) Identified risks and constraints for deployment and their mitigation strategies
    (v) UAT completion
    (vi) Training needs identified and completed for all applicable stakeholders
    (vii) Communication with stakeholders and healthcare professionals
    (viii) Deployment schedule and guide
    (ix) Contact details for support and escalation
    (x) Measures of success for Commissioning Period

1.3.6 Maintaining essential documentation for governance and monitoring

It is important to maintain essential documentation for governance and monitoring, as well as for continuity purposes when various stakeholders handover their responsibilities and tasks.

Recommendations

(a) User Guide and Training Materials (examples)
    (i) End-user guide
    (ii) Training environment setup
    (iii) Technical services manual
    (iv) Frequently-asked questions and troubleshooting guide
(b) Project management documents (examples)

(i) Site implementation guide and acceptance test plan
(ii) Production cut-over checklist
(iii) Site implementation readiness report
(iv) UAT plan, cases, and sign-off document
(v) Milestone acceptance certificate
(vi) Integrated workflow training plan
(vii) Project closure plan
(viii) End of warranty certification

1.4 Post-implementation

1.4.1 Conduct post-implementation review and complete project closure plan

After the implementation of the AMMS solution, the PMO should conduct post-implementation review to assess the fulfilment of the expected medication safety and operational efficiency benefits, and the stipulated key performance indicators of the AMMS project. This should include the review of all the logged issues to ensure that they are resolved adequately without recurrence. This reduces the risk of medication safety, workplace safety, and operational efficiency gaps due to the inadequate optimisation of AMMS solution. Project closure plan can be completed if the AMMS solution has been reviewed to be adequately optimised.

Recommendations

(a) Conduct post-implementation review in accordance to the expected medication safety and operational efficiency benefits and the stipulated key performance indicators
(b) Review all the logged issues to ensure adequate resolution
(c) Address all unfulfilled medication safety and operational benefits, unmet performance indicators, and unresolved logged issues
(d) Complete project closure plan
    (i) Report of post-implementation review
    (ii) Documentation archival plan

1.4.2 Conduct contract scope review and complete contract closure plan

After the PMO has completed the project closure plan, it is submitted to the project steering committee that will proceed to conduct contract scope review. The contract scope review seeks to determine the complete fulfilment of the stipulated contractual deliverables, so that contract closure plan can be completed.

Recommendations

(a) Conduct contract scope review in accordance to the stipulated contractual deliverables

(b) Complete contract closure plan

(i) Roles and responsibilities of project resources

(ii) Transition plan

(iii) Major milestones

(iv) Plan and schedule for completing or handing over of outstanding tasks (if applicable)

(v) Schedule of updates (e.g. hardware, software, documentation)

(vi) Subsequent cost implications (e.g. license fees of proprietary tools)

(vii) Transition plan and schedule (for support team or new vendor to take over in a seamless manner)

(viii) Documentation archival plan

1.4.3 Establish a structure of post-implementation support and maintenance services

After the successful deployment of AMMS solution, the provision of post-implementation support and maintenance services by the vendor is essential for the continuous monitoring of key performance indicators, preventive and corrective maintenance, and new change requests. A clear structure of support and maintenance services enables the proper functioning of AMMS solution to deliver its intended medication safety and operational efficiency benefits.

Recommendations

(a) Establish a clear structure of support and maintenance services that can include, but not limiting to, the following:
    (i) Access to product specialists of the AMMS solution
    (ii) Local support centre
    (iii) Local helpdesk support
    (iv) Timely assistance to problem diagnostics and resolution

(b) Determine the processes for preventive and corrective maintenance and new change requests

(c) Establish the mechanism for continuous monitoring of key performance indicators, including measures specific to the intended medication safety and operational efficiency benefits

(d) Ensure that the essential mechanical parts required for preventive and corrective maintenance are available locally to allow timely maintenance actions

2 OPERATION OF AUTOMATED MEDICATION MANAGEMENT SYSTEMS

The operation of AMMS involves many processes with considerable impact on the medication safety and operational efficiency of medication management and use processes in healthcare institutions. Adequate management of risks at the upstream phases of AMMS operation will minimise the magnification of risks at the downstream processes of medication distribution, dispensing, and administration. Hence, it is essential to identify the intended functions of the various processes pertaining to AMMS operation and their potential risks, and formulate suitable measures to address these risks adequately.

2.1 Selection of Raw Materials

2.1.1 Review and select appropriate raw materials (including medications and consumables)

Appropriate review and selection of raw materials (including medications and consumables) before use with AMMS can prevent the occurrence of medication errors (prevent potential patient harm) and defects of repackaged products (reduce risks of re-packaging rejects).

Recommendations

(a) Develop a checklist with all the factors that must be considered in the selection of raw materials for each AMMS, and these factors can include, but are not limited to the following:
   (i) Suitability of raw materials' properties (e.g. nitrate-containing products should not undergo primary repackaging)
   (ii) Raw materials' attributes (e.g. dosage forms, dimensions, weight, product stability, package material types)
   (iii) Material handling restrictions
   (iv) Potential processing issues (e.g. blister with tablets in close proximity to one another)
   (v) Look-Alike-Sound-Alike (LASA) concerns
   (vi) High Alert Medications (HAM) concerns

(b) Determine the most appropriate modality in re-packaging and/or using the raw material after reviewing the compatibility between AMMS and raw materials
(c) Include the raw materials' attribute requirements (e.g. dosage form, blister packs, loose tablets) as part of the procurement selection and inclusion criteria
(d) Provision of actual raw materials to facilitate the assessment of raw materials' attributes and simulation/testing with AMMS for appropriateness wherever possible
(e) Comprehensive documentation of the review and selection processes and considerations

2.2 Data item Setup and Calibration Process of Raw Materials

2.2.1 Item setup of raw materials in AMMS to achieve optimal performance of AMMS

Accurate item setup of raw materials in AMMS allows the optimal performance of AMMS in achieving its intended operational efficiency and medication safety benefits. Erroneous data entry in item setup (e.g. incorrect item attributes of raw materials) can result in suboptimal performance, such as inconsistency in repackaging processes and defective final products. This is also applicable to the amendment of item attributes and deletion of raw materials in AMMS.

Recommendations

(a) Use automated item setup process (e.g. system interface item setup) where available
(b) Use central data management system of raw material attributes where available
(c) Utilise barcode scanning (e.g. manufacturer barcodes) to perform data entry where possible
(d) If manual data entry is performed, essential item attributes are verified for accuracy via independent double-checking process
(e) Access controls are put in place to limit AMMS item setup functions (including amendment and deletion) to authorised personnel
(f) Consult AMMS specialised engineers or domain expert in the item setup for complex situations

2.2.2 Calibration of raw materials using trial production batch with established production processes

Raw materials are required to be setup and calibrated appropriately in AMMS and tested using a trial production with established production processes. This verifies the appropriate setup of the essential item attributes and enables early detection of inappropriate setup/calibration and unsuitable raw materials (beyond essential item attributes). This prevents operational inefficiency arising from reworks, as well as product wastage and recall of defective final products.

Recommendations

(a) Initiate trial production batch after raw material(s) has/have been setup in AMMS to enable early detection of production issues before larger-scale production commences

(b) Trial production batch should be of an optimal production volume (smaller than routine production volume) to detect possible issues

(c) Inspection should be conducted on the trial production batch on 100% basis to ensure all issues can be identified

(d) Maintain a list of raw materials that have been successfully setup and calibrated in the AMMS, including the presence of minor defect (if any)

(e) Maintain a list of raw materials that have failed setup and calibration process in the AMMS, and use it to inform selection and procurement processes

2.3 Initiation of Batch Production Order

2.3.1 Scheduling of batch production to optimise operational efficiency and medication safety benefits of AMMS

Appropriate scheduling of batch production is essential to produce sufficient quantities of final products to match their consumption rates in patient care settings over a defined time period without incurring excessive stress on the AMMS operators. This optimises the operational efficiency and medication safety benefits of AMMS. Overproduction can result in delayed production of other final products and operational inefficiency of managing excessive quantities of the over-produced final product. Underproduction can result in the lack of barcoded final products for routine use; hence staff may resort to manual verification or workarounds that can increase risk of

human errors and compromise medication safety. Overly-tight production schedule can impose excessive stress on the AMMS operators and predispose them to commit human errors (e.g. violations) that compromise medication safety.

Recommendations

(a) Implement Just-In-Time (JIT) inventory management system to minimise waste in the production process and reduce inventory costs
(b) Optimise the production volume in consideration of AMMS processing capacity, production team, and space requirements for relevant activities
(c) Implement a verification step to check all the raw materials, production worksheets, and consumables as part of production process (e.g. independent double-check, barcode verification)
(d) Implement processes to handle scenarios that may not be adequately managed using JIT approach, and examples of such scenarios can include:
    (i) Sudden changes to demand and supply (e.g. usage surges for specific medications due to disease outbreaks)
    (ii) Raw materials of short expiry dates
(e) Adopt a proactive risk management approach to identify the potential medication safety risks in JIT system and processes, and address them adequately. Examples can include:
    (i) Review the production schedules for medication safety concerns (e.g. two LASA medications are being repackaged consecutively)
    (ii) Segregation and differentiation of different production batches of raw materials (medications) and required consumables (e.g. labels) to prevent human errors and potential mix-ups
    (iii) Establish processes to manage, segregate, and dispose defective/damaged raw materials, and to replace raw materials, with appropriate safety measures in place (e.g. independent double-checking, dedicated quarantine locations for defective raw materials)
(f) Periodical review (in accordance to prevailing policies and best practices) using data (e.g. consumption data, AMMS utilisation data, defect/reject rates) to enable optimisation of inventory management and production processes and early detection and resolution of risks

2.3.2 Data entry for each production batch

Data entry for each production batch is an important process in the repackaging of raw materials, as it involves the documentation of specific information of the production batch, and may utilise may utilise AMMS in-house softwares, customised softwares, or commercial softwares (e.g. Microsoft Excel/Access, Filemaker Pro). Correct data entry is essential for accurate batch production, efficient AMMS' operation, and prevention of errors and reworks. For instance, erroneous data entry in creation of batch job worksheets and labels may result in a systematic error for the final products where repacked medications are incorrectly labelled consistently for that batch. This can lead to patient harm if the error is not identified at the downstream care processes.

Recommendations

(a) Automate the data entry process and minimise manual process steps (e.g. data entry, quantity calculation) for production batch
(b) Usage of pre-filled fields (key item attributes), system-assigned batch number (repackaged final products), and expiration dating logic (to compute new expiry date if required) in the generation of batch job worksheets
(c) Use of standardised barcodes (e.g. GS1 barcodes) to allow data capture of essential information (e.g. GTIN, batch, expiry date) via barcode scanning and seamless usage across different systems and softwares.
(d) Use of barcode verification to initiate the batch production and data entry processes
(e) Conduct proactive risk assessment e.g. Failure Mode Effect Analysis (FMEA) of manual process steps to identify the potential risks and implement measures to address these risks adequately
(f) Where production batches are generated manually, retention labels are kept with the production worksheets as part of the audit trail, and can be retrieved easily for investigation of AMMS-related incidents

2.4 Preparation of Raw Materials

2.4.1 Deblistering of tablets/capsules from original packaging to enable repackaging process by AMMS

Deblistering is an essential process to remove tablets/capsules from the original blister packaging, in order to enable the repackaging process by AMMS. As the removal from original blister packaging will involve the removal of primary identifiers, it is essential to ensure accurate labelling and appropriate storage of the deblistered tablets/capsules before they are transferred to the AMMS for repackaging processes (e.g. unit dose packing machines). Potential risks include drug mix-up at storage areas and workstations, wrong labels affixed to the deblistered storage containers, and product quantity discrepancies.

Recommendations

(a) Dedicated workstation for deblistering purpose with line clearance to ensure one product being deblistered at any point of time
(b) Product verification process (e.g. independent double-check, verification technology/tool) to verify correct tablets/capsules and detect deviations before transferring deblistered tablets/capsules to storage locations
(c) Affix the labels immediately after deblistering is completed
(d) Review the deblistering schedules for medication safety concerns (e.g. two LASA medications being deblistered consecutively)
(e) Accurate determination of the time duration required to deblister each batch of tablets/capsules and line clearance process (avoid disruption to deblistering process and minimise time pressure on AMMS operators)
(f) Utilise weighing devices with at least 0.001gm readibility (if weight measurement is required as part of counting process)
(g) Where more than one deblistering options are possible with AMMS, assess the risks and benefits of the options and determine one fixed option as the standard process
(h) All quantities of tablets/capsules must be accounted for, including the verification of deblistered strips and deblistering machines/devices

2.4.2 Repackaging and barcode labelling of deblistered tablets/capsules to prevent medication error

Deblistered tablets/capsules are repackaged into unit dose form and accurate barcode labelling is essential to prevent medication error (wrong drug/strength/dosage form). Safety measures should be implemented to control the risks associated with this process, such as incorrect repackaging, product mislabelling, and repackaged quantity errors.

Recommendations

(a) Review the schedules for medication safety concerns (e.g. two LASA medications being repackaged and labelled consecutively)

(b) Single medication item should be repackaged and labelled in the same facility/premise wherever possible

(c) Where concurrent repackaging and labelling of different medication items are conducted in the same facility/premise, adequate segregation of the different medication items and their labels and consumables is essential to prevent medication mix-up and wrong labelling

(d) For manual repackaging and labelling processes,

  (i) Staff should focus on one single medication item at each time

  (ii) Staff handling different medications should sit away from one another with proper segregation to prevent medication mix-up

  (iii) Work environment should enable staff to carry tasks with minimal distractions and interruptions

(e) Reconcilitation of products and label quantities at the end of repackaging and labelling processes

(f) Usage of central drug database for medication images and repackaging instructions (applicable for both the task-performing staff and verification staff)

2.5 Production and Repackaging

2.5.1 Machine preparation for production and repackaging to minimise production inefficiency/wastage and occurrence of errors/defects

As AMMS seeks to deliver medication safety and operational efficiency benefits to healthcare institutions, the AMMS' outputs (e.g. unit-dose sachets, multi-dose

packages) are expected to be correct (i.e. free from defects) and be produced at a reasonable speed. Appropriate preparation of the machine for production and repackaging will minimise production inefficiency/wastage and occurrence of errors/defects with potential medication safety concerns. Examples may include incorrect raw material setup/entry in machine for specific production run, cross-contamination of medications, and loading of wrong medication into machine canister.

Recommendations

(a) Establish a protocol to guide the AMMS operators in preparing the machine for production and repackaging, including unique setup requirements for specific medications
(b) Implement a systematic verification process (e.g. barcode verification, built-in chips for medication canisters) to eliminate human errors of wrong data entry in the machine setup screen and wrong loading/placement of medication canisters in the machine
(c) Minimise manual data entry in machine setup where possible, and utilise barcode scanning to reduce transcription errors. Use of a single barcode with mulitple critical information (e.g. batch number, expiry date) can improve the process efficiency of machine setup
(d) Utilise dedicated channels from medication storage containers to sachets/packages to prevent cross-contamination risks, and limit air-flow interchange among these channels to prevent movement of drug particles
(e) Reduce the number of machine parts with the potential to trap medications (e.g. tablets) along the channels where possible, and check these parts after production to ensure no medication has been trapped
(f) Schedule teratogenic drugs and drugs with high particle generation potential as the last production run before end-of-day machine cleaning, as this minimises cross-contamination risks and enables production efficiency. Clean the machine parts that may pose cross-contaimination risks

2.5.2 Monitoring of production and repackaging processes to achieve early detection of defects and machine performance issues

Monitoring of the production and repackaging processes is important to achieve early detection of defects and machine performance issues/errors. Examples of defects/errors may include excess tablets in each unit-dose sachet, missing tablets in a multi-dose package, incomplete sealing of sachets, and printing errors on labels/sachets.

Recommendations

(a) Know the service level agreement (SLA) standard of the machine and use the SLA standard as the reference point to review the error/defect rate
(b) Establish a protocol to guide AMMS operators in the monitoring of the machine during production, including the red flags warranting a production stop
(c) Limit the AMMS operator's maximum duty duration to 4 continuous hours to minimise mental and physical fatigue

2.6 Quality Control Processes

2.6.1 Identification of non-conforming AMMS outputs to prevent their unintended use

As AMMS aims to provide medication safety benefits, only AMMS outputs that meet the required quality control specifications can be released for patient use. All non-conforming AMMS outputs are identified and segregated to prevent any unintended use.

Recommendations

(a) Establish a protocol to guide operators in the verification of the AMMS outputs and the list of components requiring verification (e.g. correct medication, strength, dosage form, quantity, printout readability, complete sealing of sachet)
(b) Establish a random sampling approach to facilitate the efficiency of the quality control check processes, and utilise higher percentage quality control check for specific production run or machines with higher error/defect rate

(c) Implement automated inspection machine to assist in the quality control check processes (e.g. verification of correct drug) where possible
(d) Utilise manual checking mechanisms (e.g. independent double-checking) for aspects that cannot be automated
(e) Store the rejected/defective sachets/packages in differentiating containers to prevent potential mix-up
(f) Implement a structured process for verification of rejected items before they are returned

2.6.2 Control of non-conforming AMMS outputs and processes to eliminate or reduce recurring errors/defects

While identifying and segregating the non-conforming AMMS outputs appropriately can prevent their unintended use, it is essential to review the root causes of the errors/defects from the system/process perspectives and implement corrective actions that are effective and sustainable in eliminating or reducing these errors/defects. Recurring errors/defects are consistent medication safety risks and increase operational costs and medication wastage.

Recommendations

(a) Implement a process for evaluating and monitoring non-conformances
(b) Identify the potential system-system and system-human interactions and formulate system-level corrective actions to address them in an effective and sustainable manner
(c) Apply human factors considerations in the analysis of process violations and non-compliance by AMMS operators
(d) Implement forcing functions where necessary
(e) Establish the mechanism to reduce errors/rejects through:
    (i) Definition of the attributes of suitable raw materials suitable to be selected for repackaging by the respective AMMS
    (ii) Optimisation of the machines through review of calibration and setup configurations
    (iii) Review of the appropriate operation of the machines

2.7 Management of Non-conforming AMMS Outputs

2.7.1 Segregation of non-conforming AMMS outputs to prevent mix-up and unintended transfer

Non-conforming AMMS outputs should be segregated to prevent mix-up and unintended transfer for patient use, as this could be a potential medication safety concern.

Recommendations

(a) Store the rejected/defective sachets/packages in differentiating containers with clear labels (e.g. rejected/defective items) to prevent potential mix-up
(b) Implement a meticulous and effective process for holding the rejected items and evaluating them for possible routing to rework or return

2.7.2 Reworking of non-conforming AMMS outputs to reduce potential wastage

Non-conforming AMMS outputs (e.g. rejected items) can be evaluated for suitability to be reworked safely using a robust rework process with control measures to manage possible risks (e.g. LASA medications, absence of original packaging, manual rework – human errors).

Recommendations

(a) Establish clear criteria to determine which rejects can be reworked safely
(b) Establish a standardised procedure for the safe reworks of rejects and manual quality control check, including control measures to manage the risks associated with manual reworks

2.8 Line Clearance

2.8.1 Line clearance of AMMS machines to ensure readiness to process new production batch

Line clearance is an important process to ensure that AMMS machines are cleared of the previous production batch and ready to process a new production batch. This

process includes the verification of machines and their components to ensure zero remnant of the previous raw materials and its particles (if any), and specific cleaning of the machines and their components (if applicable). This prevents the risks of cross-contamination and unanticipated errors.

Recommendations

(a) Establish a standardised line clearance procedure for each type of AMMS machine
(b) Develop additional protocols specific to raw materials (e.g. teratogenic, prone to generate particles)
(c) Utilise checklists to guide AMMS operators to perform the line clearance systematically

2.9 Storage/Transfer to Storage

2.9.1 Proper storage of AMMS outputs to ensure pharmaceutical stability

After passing the quality control check, the AMMS outputs are transferred to the designated storage locations. Appropriate storage and monitoring of AMMS outputs in the storage locations are essential to ensure pharmaceutical stability, minimal risks of medication errors and human errors, and minimal medication losses due to expiry dates.

Recommendations

(a) Designate storage locations with the appropriate storage conditions (e.g. cold chain) and relevant safety measures (e.g. LASA medications considerations)
(b) Implement a systematic verification process to ensure correct medications are loaded and stored in the correct storage compartments (e.g. barcode verification, verification by individual sachets or package units)
(c) Implement First-Expiry-First-Out principles (i.e. “shorter expiry date” batch should be used before “longer expiry date” batch) to the storage of AMMS outputs in the designated storage locations
(d) Consider automated processes to capture the essential attributes of AMMS outputs to reduce human dependencies and risks of human errors when transferring to

storage locations, and to trigger alerts to operators for batches that are nearing expiry dates

(e) Apply human factors considerations in designing the automated processes to error-proof against human errors (e.g. simplify and standardise process, minimise reliance on humans for manual data entry and checking)

2.9.2 Transfer of AMMS outputs to automated medication machines/cabinets

Selected AMMS outputs are transferred to the automated medication machines/cabinets in patient care settings, and it is important to ensure medication safety is established at these storage units. This minimises the risks of medication errors and human errors, and minimises medication losses due to expiry dates.

Recommendations

(a) Implement a robust verification process to ensure correct medications are loaded and stored in the correct storage compartments (e.g. barcode verification, verification by individual sachets or package units)

(b) Assess the potential risks of loading AMMS outputs in bundles and implement mitigating measures (e.g. multiple barcode scanning of items within the same medication batch to identify any mix-up that occurred in upstream processes)

(c) Implement First-Expiry-First-Out principles (i.e. “shorter expiry date” batch should be used before “longer expiry date” batch) to the storage of AMMS outputs in automated medicaiton machines/cabinets

(d) Consider automated processes to capture the essential attributes of AMMS outputs to reduce human dependencies and risks of human errors when transferring to automated medication machines/cabinets, and to trigger alerts to operators for batches that are nearing expiry dates

(e) Apply human factors considerations in designing the automated processes to error-proof against human errors (e.g. simplify and standardise process, minimise reliance on humans for manual data entry and checking)

(f) Use standardised product barcode format (e.g. GS1) that contains essential product information (e.g. expiry date, batch number) in the stock loading process

for accurate data entry to automate inventory management and monitoring of AMMS outputs

(g) Provide training to healthcare professionals (e.g. nurses, doctors) who are using automated medication machines/cabinets in patient care settings

2.10 Retrieval/Usage Process/Verification

2.10.1 Retrieval of medications from automated medication machines/cabinets

Retrieval of the correct medications from the correct storage compartments in the automated medication machines/cabinets requires the understanding of their design/features and human factors considerations in the various processes (i.e. how a healthcare staff will interact with them during different work processes). The design/features of automated medication machines/cabinets can provide both advantages and disadvantages. For example, the open-compartment drawers (with multiple medications in their own compartments in the same drawer) may predispose a staff nurse to retrieve the wrong unit-dose sachet from the wrong compartment, although it may allow greater convenience and efficiency during medication administration hours when multiple medications are required to be retrieved.

Recommendations

(a) Restrict the retrieval of medications from automated medication machines/cabinets to one medication at each time where possible

(b) Limit one medication (or one type of unit-dose sachet) in single compartment of automated medication machines/cabinets where possible

(c) Apply safety measures to address the potential risk of LASA medications (e.g. segegrate look-alike medications in different compartments with visual differentiation)

(d) Keep the medications in its original unit-dose sachets after retrieval, during storage in medication carts, and during transportation to patient's bedside

(e) Establish user access control for automated machines/cabinets to ensure appropriate access (e.g. designated healthcare staff working in patient care unit, informatics staff overseeing medication carts in the institution)

(f) Implement access control and second-user verification for selected medication classes/categories (e.g. High-Alert Medications, Controlled Drugs) in accordance to prevailing legislations and regulations and institution policies
(g) Implement medication retrieval by patient profiles where necessary to minimise errors

2.10.2 Usage Process – Storing retrieved medications in the medication carts

Prior to bedside medication administration, medications (e.g. unit-dose sachets) are retrieved from the automated medication machines/cabinets to be stored in the medication cart. The medication cart is used to bring the medications to patient's bedside for administration. Hence, it is important to ensure that the medications are stored appropriately and correctly in the medication cart with the appropriate medication safety measures in place.

Recommendations

(a) Implement mandatory barcode verification for the opening of medication storage compartment in the medication cart
(b) Complete the retrieval of one set of medications before moving on the other set

2.10.3 Usage Process – Opening of storage compartment in the medication carts for medication administration

As the opening of the storage compartment in the medication cart is the first step in the medication administration process, the opening of the wrong storage compartment may result in wrong medication administration. Some medication carts allow the manual selection option to open the storage compartment, while others require mandatory digital verification.

Recommendations

(a) Implement mandatory barcode verification for the opening of storage compartment in the medication cart
(b) Restrict the medication cart to allow the opening of one storage compartment at any point of time

(c) Establish user access control for medication carts to ensure appropriate access (e.g. designated healthcare staff working in patient care unit, informatics staff overseeing medication carts in the institution)
(d) Implement access control and second-user verification for selected medication classes/categories (e.g. High-Alert Medications, Controlled Drugs) in accordance to prevailing legislations and regulations and institution policies
(e) Implement medication retrieval by patient profiles where necessary to minimise errors
(f) Implement clear segregation of items among the compartments (e.g. unit-dose sachets should not be placed together with other items)

2.10.4 Verification of medications at patient's bedside prior to medication administration

While the verification process needs to be robust and reliable, it is essential to minimise process risks and external distractions/interruptions that can potentially compromise the safe delivery and administration of the medications to the patient. For instance, medication cart not located in close proximity to patient's bedside will result in unnecessary movement of the nurses that predispose them to potential interruptions.

Recommendations

(a) Perform patient identifier verification with patients at the point of medication administration
(b) Implement mandatory barcode verification during medication administration to verify the correct patient, correct medications, correct time and correct dosage regimens
(c) Limit the medication administration to one patient at each time to prevent correctly-scanned medications being administered to wrong patient
(d) Redesign workflow to allow medication cart to be located within close proximity to the patient's bedside during medication administration
(e) Identify the external distractions/interruptions (e.g. other healthcare staff, patients, caregivers, ringing phones) affecting the nurses who are administering medications, and formulate control measures in collaboration with the nurses

2.11 Returning Process/Management of Returned Items

2.11.1 Returning of unit-dose sachets or repacked medications

While unit-dose sachets or repacked medications can be retrieved correctly for medication administration, there are scenarios where retrieved medications may not be administered (e.g. patients refuse to take a medication). The unused items are required to be returned to appropriate storage locations via reliable and established mechanisms and processes. This is essential to prevent unintended use of the unused items, pilferage, and other scenarios with adverse consequences.

Recommendations

(a) Eliminate the returning of items directly to their original AMMS storage compartments where applicable (e.g. one-way secure return bin)
(b) Designate a secured returned location to allow returns but prevent removal, so that the returned items can be reviewed and rechanneled for reuse through a rigorous process
(c) Institute a robust process for Controlled Drugs in consideration of the additional legal requirements
(d) Implement safety measures to ensure the accurate returning of high alert medications (greater potential of harm when error actualises) and LASA medications (higher likelihood of error)

2.11.2 Management of returned items

While most returned items can be reused, it is essential to review the integrity of these items and establish a process to prevent error occurrence in the return processes. This is because the secured returned location contains different items in the same container, and this poses the risk of medication mix-up during the sorting and returning processes.

Recommendations

(a) Utilise automated functionalities/processes of AMMS where possible (e.g. automated returning of unused unit-dose sachets into the storage compartments in AMMS)

(b) Require barcode verification of the unused items to verify the correct medication to the correct compartment if the items are to be returned directly to the automated medication machines/cabinets by the staff

(c) Enable multiple barcode scanning of the items in the same bundle (to be returned) to detect any potential medication mix-up during sorting process

(d) Implement appropriate cleaning/decontamination protocols for returned items from patient care units handling patients with high infection risks, or discard all returned items if the infection risk outweighs the benefit of reducing medication wastage

3 OTHER STRATEGIES TO MINIMISE SYSTEM-HUMAN ERRORS

In addition to the outlined recommendations to minimise system-human errors in the various points of operating the AMMS e.g., sections 2.6.2 (a), 2.9.2 (a), (d), (e) and (g), other strategies to further reduce the risk of common system-human errors and safeguard patient care are reflected below.

Recommendations

(a) Clear complete, and precise prescribing instructions

(i) Healthcare professionals who are ordering medications using free-text electronic and manually written modalities should ensure that their prescribing instructions are clear, complete, and precise to minimise potential for errors. Examples may include, but not limited to:

- Clear dosage regimen (dosage, frequency, duration, PRN status)
- Inclusion of indications for PRN (when necessary) medications, particularly for medications with multiple indications
- Use of commonly used metric measures (e.g., milligrams, grams)
- Ensure that zero (“0”) precedes a decimal point (e.g., 0.25mg versus .25mg)
- Avoid usage of abbreviations and acronyms that are prone to potential misinterpretation (e.g., OD may refer to “once a day” or “oculus dexter” and this may result in wrong frequency or route of administration)

(b) Appropriate patient review during care encounters

(i) Prior to medication prescribing, dispensing, and administration, healthcare professionals should perform the appropriate patient review during their care encounters. This reduces the potential for medication-related harm. This patient review may include, but not limited to:

- Identification of potential drug-related problems (e.g., indication, adherence, safety, efficacy)
- Documentation of drug allergy and adverse drug reaction status
- Considerations of key patient’s attributes (e.g., age, body weight, hepatic function, renal function)

- Identification of drug-drug interactions and drug-disease interactions.

(c) Implement additional measures in care activities to address known medication-related risks.

Examples may include, but not limited to:

(i) Verification of patient identifiers before medication administration to ensure correct medication is administered to the correct patient

(ii) Time-out protocols before administration of high-alert medications (e.g., parenteral morphine)

(d) Review local data (e.g., incidents, errors, near-misses) to identify potential risk.

Examples may include, but not limited to:

(i) Analysis of local data (e.g., incidents, harm incidence/severity, errors, near-misses) can provide insights to healthcare institutions pertaining to new/evolving risks, potential care/process gaps, etc

4 DOWNTIME PROCESS

Similar to any automation/IT system, AMMS are subjected to both scheduled and unanticipated system downtime. Scheduled system downtime includes routine preventive maintenance and ad-hoc corrective maintenance. Unanticipated system downtime can be attributed to a variety of possible root causes; hence a thorough investigation to identify the specific root causes in order to develop the corrective actions to resolve it. While operational efficiency of clinical care processes is adversely affected by the system downtime episodes, patient care units are required to maintain medication safety standards and prevent medication-associated harm arising from preventable errors during system downtime episodes. Hence, a comprehensive set of downtime processes is essential for the duration of system downtime and the recovery phase after system downtime has been resolved. Risk assessment of the downtime processes should be performed to identify the possible vulnerabilities and control them with appropriate measures, to ensure medication safety is not compromised.

4.1 Downtime Procedures

4.1.1 Downtime procedures for unit-dose/multi-dose production

Disruption to unit-dose and multi-dose production can have adverse impact on inpatient medication administration and outpatient medication dispensing processes. Switching to manual production mode can introduce additional risks to the production proceses, and reduce the effectiveness of existing medication safety control measures. Examples include incorrect labelling of unit-dose sachets and medication excess/shortfall in multi-dose package. Downstream processes (e.g. medication administration) may be affected depending on the severity of the downtime episodes. Hence, switching to manual production mode requires risk assessment of the relevant processes, including the downstream and upstream processes, and should include relevant stakeholders (e.g. nurses performing medication administration, pharmacists dispensing multi-dose packages). The intent is to enable unit-dose/multi-dose production without compromising medication safety.

Recommendations

(a) Schedule production schedules in consideration of scheduled downtime periods (e.g. quarterly preventive maintenance)
(b) Maintain buffer stock levels of unit-dose sachets to ensure continued supply during known downtime periods
(c) Establish decision-making algorithms to determine the switch to manual production mode (e.g. severe shortage of unit-dose sachets, extended unscheduled downtime episodes) or hold-off production until after downtime episodes (e.g. short scheduled downtime episodes)
(d) Develop downtime protocol for manual production mode for both planned and unplanned downtime.
(e) Perform risk assessment on the manual processes in collaboration with relevant stakeholders and implement risk control measures for manual processes
(f) Implement mandatory independent checking at critical process steps with sufficient sampling to uphold quality control standards
(g) Schedule manual production of LASA medications away from one another (i.e. not consecutively in production queue)
(h) Automate triggering of orders to manual picking route when AMMS go into downtime mode

4.1.2 Downtime procedures for medication retrieval from automated medication machines/cabinets

Accurate and timely medication retrieval from automated medication machines/cabinets is required at all times, and disruption to the routine processes can result in medication errors (e.g. wrong drug due to LASA medications stored in close proximity, delayed medication administation due to inability of nurses to retrieve medications).

Recommendations

(a) Plan scheduled downtime periods (e.g. quarterly preventine maintenance) to be in the time periods with minimal disruptions to routine patient care activities

(b) Develop downtime procedures for manual medication retrieval from automated medication machines/cabinets
(c) Perform risk assessment on the manual processes in collaboration with relevant stakeholders and implement risk control measures for manual processes
(d) Automate order triggers to be routed from nursing units to pharmacy locations with functional medication safety mechanisms (e.g. barcode verification) where possible
(e) Apply safety measures to address the potential risk of LASA medications (e.g. segegrate look-alike medications in different compartments with visual differentiation)
(f) Implement mandatory independent checking for unit-dose sachets retrieved manually from automated medication machines/cabinets at the point of medication retrieval
(g) Implement mandatory barcode verification for unit-dose sachets retrieved manually from automated medication machines/cabinets at the point of medication administration

4.1.3 Downtime procedures for medication retrieval from medication carts

Accurate and timely medication retrieval from medication carts is required at all times, and disruption to the routine processes can result in medication errors (eg. wrong medications due to retrieval from wrong patient's drawer or medication placed in wrong patient's drawer).

Recommendations

(a) Develop downtime procedures for manual medication retrieval from medication carts
(b) Perform risk assessment on the manual processes in collaboration with relevant stakeholders and implement risk control measures for manual processes
(c) Identify sound-alike patient names in the same patient care units and separate the patients' compartments away from one another in the medication cart
(d) Implement mandatory barcode verification at the point of medication administration

4.1.4 Downtime procedures for outpatient pharmacy automation system (OPAS)

Disruption to the outpatient automated medication packing processes can have an adverse impact on the dispensing procesess. Examples include wrong medications or quantities of medications being packed and medication mix-up for different patients. Switching to manual packing modes can introduce risks to the packing and dispensing process in the pharmacy, and reduce the effectiveness of existing medication safety control measures.

Recommendations

(a) Develop downtime procedures for manual outpatient pharmacy processes (e.g. packing, verification, dispensing)
(b) Perform risk assessment on the manual processes in collaboration with the relevant stakeholders and implement risk control measures for manual processes
(c) Apply safety measures to address the potential risk of LASA medications (e.g. segegrate look-alike medications in outpatient pharmacy storage locations)
(d) Implement mandatory independent checking for all prescriptions transcribed and filled using manual processes
(e) Automate order triggers to be routed to manual packing route when OPAS machines go into downtime mode

4.2 Recovery from Downtime

4.2.1 Downtime recovery for unit-dose/multi-dose production

While downtime procedures are generally adequate in minimising disruption to patient care activities, it is essential to identify and address the risks associated with the transition from manual production processes back to automated production processes. For instance, manual production processes may produce unit-dose sachets without barcode, and this batch of unit-dose sachets should be retrieved from the patient care units to prevent the risks introduced by inability to perform barcode scanning during medication administration.

Recommendations

(a) Develop protocols to ensure seamless transition from manual production processes to automated production processes
(b) Perform risk assessment on the transition protocols to identify and address the risks associated with the transition
(c) Retrieve unit-dose sachets produced by the manual processes (if they lack the medication safety features present in those produced by automted procesess)
(d) Limit the supply of unit-dose sachets for patient care units based on the estimated usage for the expected downtime duration (to enable ease of retrieval)
(e) Reconcile the downtime manual records/logs with the prescriptions and inventory system

4.2.2 Downtime recovery for automated medication machines/cabinets

The transition from manual processes to automated processes in patient care units should ensure medication safety and prevent the occurrence of the patient care issue arising from the transition period. Inventory management aspects should also be considered to ensure that there is continued supply of unit-dose sachets available in patient care units for timely medication administration.

Recommendations

(a) Develop protocols to ensure seamless transition from manual processes to automated processes
(b) Perform risk assessment on the transition protocols to identify and address the risks associated with the transition
(c) Automate order triggers to revert to automated medication machines/cabinets
(d) Reconcile the downtime manual records/logs with the inventory and medication management system
(e) Perform stock count/check for automated medication machines/cabinets to reconcile stock levels and identify any wrong items in the storage compartment

4.2.3 Downtime recovery for medication carts

During the downtime recovery period, it is important to ensure that the correct medications are present in the patients' drawers and that timely medication administration are maintained. The complete emptying of medication carts and reassignment of patients' drawers may be required depending on the downtime processes and the extent and impact of downtime.

Recommendations

(a) Develop protocols to ensure seamless transition from manual processes to automated processes
(b) Perform risk assessment on the transition protocols to identify and address the risks associated with the transition
(c) Maintain timely medication administration in patient care units during downtime recovery
(d) Implement mandatory removal of all medications in the medication carts as part of downtime recovery protocol if applicable
(e) Implement mandatory removal of all labels on medication carts or drawers as part of downtime recovery protocol if applicable

4.2.4 Downtime recovery for outpatient pharmacy automation system (OPAS)

During the downtime recovery period, it is important to ensure that the prescriptions are being processed accurately and there is no lapse during the manual-to-automated transition process. Inventory management aspects should also be considered to ensure that there is continued supply of medications available in OPAS for timely prescription processing.

Recommendations

(a) Develop protocols to ensure seamless transition from manual processes to automated processes
(b) Perform risk assessment on the transition protocols to identify and address the risks associated with the transition

(c) Automate order triggers to revert to OPAS when downtime is over

(d) Reconcile the downtime manual records/logs with the prescriptions and inventory system

(e) Perform stock count/check for OPAS to reconcile stock levels

5 MONITORING

As AMMS are expected to achieve appropriate, accurate, safe, timely, and secure distribution of medications in healthcare settings, healthcare institutions should have a comprehensive plan for the monitoring of AMMS and the medications accessed through them, as well as the supporting mechanisms for risk management, patient safety, and quality improvement. It should include a systematic process of monitoring patient safety and operational efficiency, managing risks, incidents, and errors, and continuous quality improvement.

5.1 Proactive Risk Management

While AMMS can be designed to improve patient safety and operational efficiency, that same design can possess inherent vulnerabilities with safety, accuracy, security, and data confidentiality concerns. System-system and system-human interactions can contribute to additional vulnerabilities that may lead to potential opportunities for errors and inefficiency. Early detection and management of risks can prevent and mitigate the adverse effects and costs of the actualised risks. Hence, it is essential to initiate proactive risk management at early stages to identify and address risks pre-emptively. Proactive risk management measures (e.g. enterprise risk management, failure modes and effects analysis) can be employed at different levels (concept, system, design, and process) wherever applicable. On-going proactive risk management can continue to assess the various risk domains (e.g. clinical, operational, technological) and emerging risks (e.g. cybersecurity, information/data security) on a periodical basis.

Recommendations

(a) Initiate proactive risk management to identify and address risks pre-emptively prior to implementation and major changes to systems and processes
(b) Select the appropriate risk management approaches and tools at the appropriate levels, and in alignment to the institutional risk management framework
(c) On-going proactive risk management to assess known risks and consider emerging risks on a periodical basis

(d) Consider the following aspects of medication management and use during the risk management process of AMMS (where relevant):
   (i) Selection and procurement of medications
   (ii) Storage of medications
   (iii) Prescribing of medications
   (iv) Preparation of medications
   (v) Dispensing of medications
   (vi) Administration of medications
   (vii) Monitoring of medications
   (viii) Research medications
   (ix) Sample medications
   (x) High Alert Medications
   (xi) Look-alike-sound-alike (LASA) medications
(e) Periodical review of international and local AMMS-associated incidents/near-misses as part of the on-going proactive risk management to identify opportunities for proactive prevention of harm and incidents

5.2 Continuous Quality Improvement

A continuous quality improvement process should be included as part of the monitoring of AMMS, and feedback loops to the relevant stakeholders should be established for timely and effective follow-up actions. Opportunities for improving medication safety and operational efficiency should be identified and investigated with the aid of data analytics and clinical reviews, so that the suitable strategies can be developed, implemented, and reviewed subsequently. Healthcare institutions could review their AMMS on a periodical basis (e.g. annually, biennially) for systematic improvement in medication safety and operational efficiency, in consideration of the evolving national and organisational priorities, local/international medication safety data and concerns, and current best practice guidelines. Appropriate improvement tools, such as Plan-Do-Study-Act (PDSA), LEAN, and Six Sigma, may be used to facilitate the continuous quality improvement process.

Recommendations

(a) Include a continuous improvement process with feedback loops to stakeholders for timely and effective follow-up actions
(b) Use of data analytics and clinical reviews to develop, implement, and review suitable strategies
(c) Periodical review of AMMS in consideration of priorities, local/international medication safety data, and best practice guidelines
(d) Use of appropriate improvement tools

5.3 Monitoring for Medication Safety

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professionals, patient, or consumer (NCCMERP, 2001). As AMMS are expected to deliver medication safety benefits and prevent medication errors, specific benefit measures should be monitored. Examples can include reduction in missed/delayed dose and errors involving wrong medications, wrong dosage forms, and wrong strength. AMMS-associated medication errors should be monitored and reported in accordance to the prevailing regulations and institutional policies. Control charts may be used to provide additional system-level insights on the reliability of AMMS over time. While near-misses may not have reached the patient despite its occurrence, it will be important to understand the nature and occurrence frequency of these near-misses and determine their possibilities of actualising into actual errors and the corresponding impact.

Recommendations

(a) Monitor the expected and specific medication safety benefits of AMMS
(b) Systematic process of monitoring and reporting AMMS-associated errors
(c) Use of control charts to monitor system-level reliability of AMMS over time
(d) Analysis of near-misses to identify and address risks proactively

5.4 Monitoring for Operational Efficiency

AMMS are expected to have high availability and minimal system downtime to achieve the operational efficiency benefits, as it will reduce the risk for errors arising from manual workflow and alternative workaround processes to cope with system downtime. In addition to the medication safety parameters, specific operational efficiency benefit measures should be monitored. Examples can include order processing turnaround time and reject/defect rate. Downtime operations should also be monitored to ensure adequate support is in place to ensure safe continuation of care delivery. Parameters may include care delivery delays, errors during downtime, as well as time spent to clear backlog and complete reconciliation after AMMS is back online.

In scenarios where AMMS are integrating with other health technologies (e.g. electronic health records, laboratory information system, barcode medication administration), the common objective is to eliminate the risks of human errors by reducing the number of manual entry steps (risk of transcription errors) and preventing workarounds (unsafe acts) by healthcare staff. Hence, system-system interoperability between AMMS and other health technologies is important to enable seamless system-system interfaces and bilateral system communication. Error detection measures, such as automated matching of medication orders (e.g. prescribed versus dispensed/administered) and discrepancy alerts (e.g. medication order mismatch and failure to actualise order), can be considered to enable early detection of technological lapses at the system interfaces.

Recommendations

(a) Monitor system availability/downtime rate/incidence of AMMS
(b) Monitor the expected and specific operational efficiency benefits of AMMS
(c) Monitor the effectiveness of back-up operations during AMMS downtime
(d) Monitor system-system interoperability between AMMS and other health technologies
(e) Consider measures for early detection of technological lapses at system interfaces

5.5 Incident Management

Despite best intentions and proactive efforts to design a perfectly safe AMMS and its accompanying processes, incidents often continue to occur in unanticipated manner. This could be attributed to the complexity of healthcare processes and the near-impossible challenge to establish a perfect understanding of all the possible system-system and system-human interactions associated with AMMS. Hence, it is essential to have a comprehensive incident management approach with supporting mechanisms to manage AMMS-associated incidents.

5.5.1 Incident Reporting and Investigation

AMMS-associated incidents should be reported in accordance to the incident management processes of the healthcare institutions, clusters, and/or national entities whenever applicable. The incident report should provide sufficient details to enable the comprehensive investigation and analysis of the incident. The investigation outcomes should include the detailed process flow of the actual incident, identification of failed processes, and any deviations from the intended process steps.

5.5.2 Incident Analysis

A systematic analysis of the incident can identify the root causes and related contributory factors (e.g. environmental conditions, technology limitations) that have led to the incident occurrence. As healthcare processes are largely human-dependent and comprise system-human and human-human interactions, it is essential to apply human factors considerations in analysing the nature of error occurrences and factors contributing to the errors and their eventual consequences. Human factors frameworks, such as Human Factors Analysis and Classification System (HFACS), can be applied in the incident analysis process as a structured approach to identify human factors considerations in the incidents.

System-level corrective actions should be formulated and implemented to address the identified root causes and contributory factors, and be monitored for effectiveness and sustainability. As investigation and analysis require time to be completed, immediate

corrective actions should be implemented to mitigate any potential immediate patient harm. In scenarios where system-level corrective actions require considerable timeframe for development and implementation, interim measures should be implemented to minimise the incident recurrence. Interim measures and corrective actions should be monitored for effectiveness and sustainability, and PDSA approach may be used if appropriate.

Corrective Actions / Interim Measures should achieve at least one of the following outcomes:

(a) Prevent incident recurrence
(b) Reduce the frequency of occurrence
(c) Improve detection of incident when it recurs
(d) Mitigate the severity of patient harm when incident recurs

Root cause analysis (RCA) shall be conducted in accordance to the prevailing regulations and institutional policies, or whenever deemed necessary by the respective governance entities (e.g. patient safety committee, quality assurance committee). This provides a systematic approach for organisational learning from the AMMS-associated incidents, and a structured formulation and implementation of corrective actions to prevent incident recurrence. During the RCA process, it is crucial to uphold the Just Culture approach to avoid the occurrence of “second victim” situations, and incident decision tree models may be used as the systematic approach to determine the culpability of the erroneous or unsafe acts by different individuals.

Recommendations

(a) Systematic incident management processes (reporting, investigation, analysis, and formulation/implementation of corrective actions)
(b) Incident management process should be multi-disciplinary and include relevant stakeholders (e.g. pharmacists, nurses, doctors, informatics staff, patient safety officer, medication safety officer)
(c) Invite domain experts (e.g. pharmacist, nurses) from other healthcare institutions with similar AMMS to provide independent expert opinions in the incident management process where relevant and appropriate

(d) Apply human factors considerations in incident analysis and formulation of system-level corrective actions
(e) Interim measures should be implemented if system-level corrective actions require considerable time and resources to be implemented
(f) Interim measures and corrective actions should be monitored for effectiveness and sustainability
(g) Conduct RCA whenever necessary for organisational learning
(h) Adopt incident decision tree models to uphold Just Culture and minimise risk of "second victim" occurrence

5.6 Data Management and Analytics

Many AMMS have the capacity to produce data in addition to the standard reports, and their data mining capabilities may be explored to provide data reviewing opportunities for continuous monitoring and improvement of medication safety and operational efficiency. This may provide greater insights on actual occurrences and avoid total reliance on self-reported incident reports.

Data analytics allow healthcare institutions to interpret, inform, communicate, and prioritise the key concerns of AMMS for effective decision-making process, and aid in continuous quality improvement for both medication safety and operational efficiency. The data analytics approach should be aligned to the organisational data governance arrangements (e.g. data security, data access/use, data extraction/reporting capabilities, periodical audits) to minimise any unintentional breach of data governance policies and downstream issues. Business intelligence capabilities can be employed (wherever applicable) to support the effective analysis of multi-source datasets and to obtain a comprehensive picture of the areas of concern, so as to facilitate successful continuous quality improvement.

Recommendations

(a) Exploring data mining capabilities of AMMS can provide data reviewing opportunities for continuous monitoring and improvement

(b) Use of data analytics to prioritise decision-making and facilitate continuous quality improvement

(c) Data management and analytics approaches should be aligned to the organisational data governance arrangements

(d) Business intelligence capabilities can be employed for effective analysis of multi-source datasets

6 GOVERNANCE OPERATING MODEL

Having a governance operating model will enhance the healthcare insitutions' ability to implement and exercise the appropriate governance and oversight over the AMMS and their associated functions. The governance operating model provides clarity in the organisation of the operational, financial, technological, human resources, risk management, performance reporting, and compliance aspects. This enables the translation of governance frameworks and policies into operational processes and practices, and establishes the connection and communication loop between governance and operational processes. Additionally, it will provide oversight over essential aspects of AMMS, including procurement, health informatics/technology, staff qualifications and education, occupational health and safety considerations, and management of outsourced functions.

6.1 Establishing a governance operating model

The governance operating model of AMMS should be aligned to the national, cluster, and institutional governance frameworks and processes, and be integrated as part of the overall corporate governance, rather than having different governance frameworks and structures. This allows the appropriate oversight of the AMMS in a consistent manner as other aspects of the healthcare institutions.

Recommendations

(a) Develop the AMMS governance operating model of AMMS in alignment with the prevailing national, cluster, and institutional governance frameworks and processes

(b) Components of AMMS governance operating model should take reference from the prevailing governance frameworks, and can include, but not limited to, operational, financial, technological, human resources, risk management, performance reporting, compliance, and occupational health and safety aspects

(c) Establish the AMMS-related entities, committees, and/or workgroups with clear reporting structures and terms of reference (e.g. roles, responsibilities, authority, accountability) in consideration of the institutional, cluster, and national governance frameworks and processes

(d) Develop clear performance reporting and management processes (e.g. service-level agreement, key performance indicators, clinical quality/safety measures, audits), and escalation processes (e.g. incidents of considerable severity or recurrence frequency), including periodical communication to the relevant stakeholders (e.g. committees, departments, vendors)

(e) Establish performance standards for medication safety, accuracy, timeliness, and costs (where relevant)

(f) Appoint suitable representatives with domain expertise to enable holistic coverage of the various governance aspects

(g) Consider the inclusion of relevant medication management and use following aspects as part of AMMS governance (where applicable to AMMS solutions/technologies used in the healthcare institutions)

(i) Selection and procurement of medications
(ii) Storage of medications
(iii) Prescribing of medications
(iv) Preparation of medications
(v) Dispensing of medications
(vi) Administration of medications
(vii) Monitoring of medications
(viii) Research medications
(ix) Sample medications
(x) High Alert Medications
(xi) Look-alike-sound-alike (LASA) medications

6.2 Staff qualifications and education

Operationalising an AMMS has considerable impact on healthcare staff in both direct patient care activities and patient care support activities. Healthcare insitutions require appropriately qualified/skilled personnel to operate and handle the various aspects of AMMS, so that the intended medication safety and operational efficiency benefits can be achieved. It is essential to identify the qualifications, knowledge, and/or skills required of the healthcare staff whose work responsibilities are directly or indirectly affected by AMMS use, which may be beyond their conventional pre-professional

education or clinical training (e.g. automation, robotics), and provide adequate training to them. This also enables these healthcare staff to operate the AMMS safely in the healthcare institutions.

Recommendations

(a) Develop a staffing plan/strategy to enable appropriate staff-workload complement for the safe and efficient use of the AMMS in the various settings
(b) Define the job scope and description of healthcare staff who are operating and handling the various aspects of AMMS, as well as the appropriate education, knowledge, and skills in alignment to their job responsibilities
(c) Develop an evaluation process to determine the suitablity of the healthcare staff for a particular jobscope related to AMMS operationalisation and his/her continued proficiency over time
(d) Provide the appropriate orientation and training required for healthcare staff to operate and handle the AMMS, including on-going training for enhanced features implemented over time
(e) Train healthcare staff to perform basic troublshooting to resolve simple AMMS issues, as well as to triage and identify scenarios where escalation is needed
(f) Include a higher-level user group (e.g. super-users, user leads) capable of managing and supporting AMMS and the healthcare staff using AMMS

6.3 Occupational health and safety considerations

Healthcare institutions have the obligations to provide a safe working environment for all staff and vendors working in their premises, and to minimise their exposure to occupational health risks through appropriate risk assessment and implementation of control measures. This can be done by both proactive occupational health risk assessment of the routine AMMS operating processes and continuous improvement arising from actualised safety incidents/near-misses. Public health occurrences (e.g. pandemic, infectious disease outbreaks) may warrant the implementation of additional safety measures to ensure patient safety and staff safety in the relevant AMMS-related processes.

Recommendations

(a) Identify the prevailing occupational health and safety regulations relevant to the AMMS solution/technology implemented in the healthcare institution

(b) Incorporate best practices from international/national guidelines and healthcare institutions with similar AMMS solution/technology

(c) Conduct proactive occupational health risk assessment of AMMS operating processes to identify and address the risks (e.g. provision of ear plugs to cope with loud noises from machines, addition of noise-reduction interventions in the machine setup)

(d) Manage all occupational health and safety incidents/near-misses in alignment to the prevailing regulations and institutional quality and safety framework

(e) Establish processes for periodical occupational health and safety reviews (e.g. audits, walkarounds) to identify new risks and risks that may not be adequately managed by existing measures in view of evolving occupational health and safety regulations and best practices

(f) Engage relevant domain expertise (e.g. public health, infection control) in recommending additional measures to ensure patient safety and staff safety in AMMS-related processes during public health occurrences (E.g. pandemic, infectious disease outbreaks)

(g) Implement a communication feedback process for healthcare staff to speak up on occupational health and safety concerns experienced during AMMS-related work activities (e.g., ergonomic hazards) and identify opportunities to improve their well-being at workplace

6.4 Outsourcing of functions

Healthcare institutions outsource various functions for purposes of operational cost savings, manpower optimisation, and/or risk transference. Hence, it is essential to ensure that the vendors can provide these outsourced functions that meet the minimum quality standards that are clearly understood by all parties. Mechanisms and processes are required to be put in place for monitoring of quality standards and management of unexpected occurrences or deviations.

Recommendations

(a) Ensure that the outsourcing of AMMS-related functions is aligned to the AMMS governance operating model, as well as the prevailing institutional, cluster, and national governance frameworks for the management of outsourced services
(b) Develop clear contracts that include scope of services, expected service-level agreements and performance indicators, mechanisms for monitoring quality standards and management of unexpected occurrences and deviations, and ensure that the contractual clauses are aligned to the prevailing legal and contract management requirements

6.5 Information and System Security

Adequate information and system security are required in AMMS to protect patient data and reduce potential of medication diversion from AMMS storage. This is important in minimising data/information security risks in AMMS with profiled functionalities (with patient information), as well as ensuring adequate control of medication stocks in AMMS.

Recommendations

(a) Implement security functions and processes in managing the AMMS' accessibility and user access matrix in alignment to the prevailing health informatics regulations and institutional and cluster IT policies
(b) Define user access/privileges and the need to limit access to specific medications or AMMS locations, or by specific healthcare staff types
(c) Develop policies to provide guidance of scenarios where AMMS system overrides are allowed (e.g. medical emergencies) and the required safety measures (if any) to minimise the risk of error
(d) Perform independent double-check for medications retrieved via AMMS system overrides and document the rationale for system overrides
(e) Review the AMMS system overrides to evaluate these deviations from routine process steps and the need to introduce strategies to reduce risk of error when system overrides are used

(f) Implement strategies to ensure adequate control of medication stocks in AMMS (e.g. periodical stock counts, random audits)

6.6 Considerations for AMMS use during pandemic and disease outbreaks

While AMMS improves medication safety and operational efficiency of medication-related processes in healthcare institutions, it is essential to ensure that additional measures are implemented to ensure patient safety and staff safety during pandemic and disease outbreaks, particularly in the patient care units handling confirmed or suspected cases. Domain expertise (e.g. infection diseases, infection control, public health) should be consulted to ensure adequacy of the measures.

Recommendations

(a) Seek domain expertise (e.g. infection diseases, infection control, public health) to evaluate the nature of pandemic or disease outbreak and provide recommendations for additional measures

(b) Maintain “clean hands” approach while removing or filling medications at AMMS machines/cabinets

  (i) Perform hand hygiene before and after accessing AMMS machines/cabinets

  (ii) Provide disinfectants (for cleaning) and hand sanitisers near AMMS machines/cabinets to allow the healthcare staff to disinfect common touchpoints and perform hand hygiene conveniently

  (iii) Review the possibility to disable fingerprint authentication technology (as gloves may interfere with the fingerprint scanner) and switch to username/password access or other contactless biometric authentication (e.g., retinal scanning)

(c) Minimise human traffic and limiting cross-contamination to patient care units (particularly those managing confirmed or suspected cases)

  (i) Increase the medication stock levels in AMMS machines/cabinets to reduce restocking frequency and human movements to AMMS

  (ii) Review medication lists and stock levels in AMMS machines/cabinets to optimise them for the routine usage (e.g. including medications used for treatment or symptom management of specific infectious disease)

(d) Restrict returning of unused medications to original compartments in AMMS machines/cabinets

(i) Provide a common secured, one-way return bin to allow healthcare staff to return unused medications

(ii) Implement a cleaning process for returned medications using the appropriate cleaning disinfectant before re-allocating them to be restocked into AMMS machines/cabinets

(iii) Discard unused medications from patient care units managing confirmed or suspected cases or brought into patient rooms, if deemed as a necessary measure by the domain experts

(e) Providing medication information to support safe medication use

(i) Implement alerts to provide healthcare staff with critical medication information of new or unfamiliar medications used during pandemic or disease outbreaks when retrieving medications from AMMS machines/cabinets

(f) Implement periodical cleaning of AMMS machines/cabinets using the appropriate cleaning disinfectants, including the common touchpoints in surroundings

GLOSSARY

Term	Description
Automated Medication Management Systems (AMMS)	Computerised drug repackaging or storage devices/machines that allow medications to be repackaged, stored, and/or dispensed in the healthcare settings. They may possess patient-profiled functionalities and/or medication distribution tracking capabilities.
Closed Loop Medication Management System (CLMM)	Automated medication management system that integrates systems and automation to close the inpatient medication management, dispensing, and administration loop and to improve safety and efficiency in inpatient medication handling and use.
High Alert Medications	Medications that bear a heightened risk of causing significant patient harm when used wrongly
LEAN	Lean methodology is a way of optimizing the people, resources, effort, and energy of your organization toward creating value for the customer.
Outpatient Pharmacy Automation System (OPAS)	Automated medication dispensing systems that are deployed in outpatient pharmacy settings to improve safety and efficiency of medication packing and dispensing processes via automation (e.g., robotics).
Six Sigma	A disciplined, statistical-based, data-driven approach and continuous improvement methodology for eliminating defects in a product, process, or service.
Unit-Dose	One discrete pharmaceutical dosage form of a medication in a single package.

ABBREVIATIONS

Abbreviations	Full term
AMMS	Automated Medication Management Systems
BPR	Business process re-engineering
CLMM	Closed Loop Medication Management System
GS1	Global Standards 1
GTIN	Global Trade Item Number
HAM	High Alert Medications
HFACS	Human Factors Analysis and Classification System
IHiS	Integrated Health Information Systems
IT	Information technology
ITQ	Invitation to quote
JIT	Just-In-Time
LASA	Look-Alike-Sound-Alike
NAMMST	National Automated Medication Management Systems Taskforce
OPAS	Outpatient Pharmacy Automation System
PDSA	Plan-Do-Study-Act
PMO	Project management office
RCA	Root cause analysis
RFP	Request for proposal
SIT	System integration testing
SLA	Service level agreement
TEP	Technical evaluation panel
UAT	User acceptance testing

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