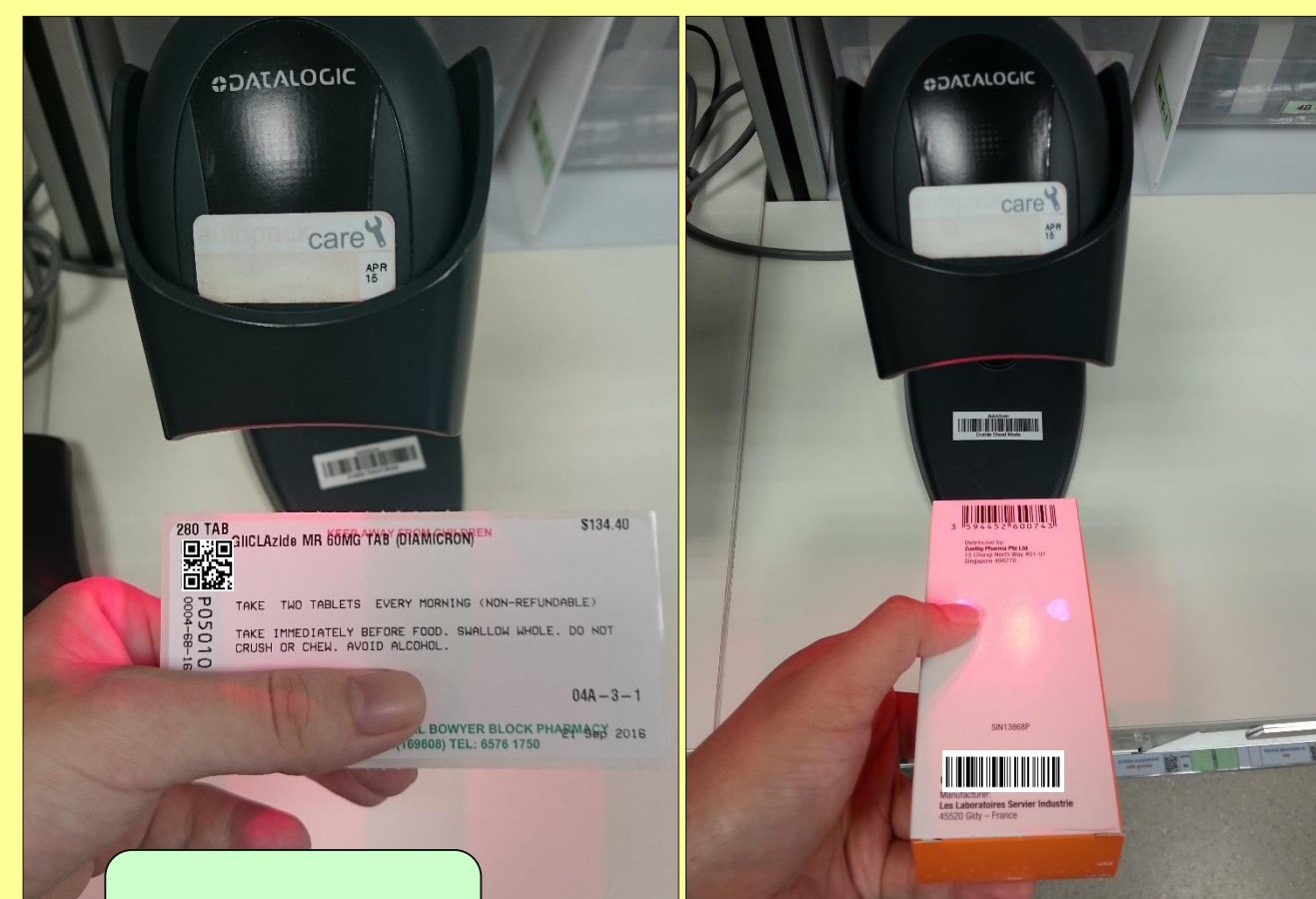


## BACKGROUND

FMEA has been used in healthcare settings to enhance medication safety effectively<sup>1-3</sup>, where potential errors during each process are proactively identified and appropriate risk reduction strategies can be proposed.

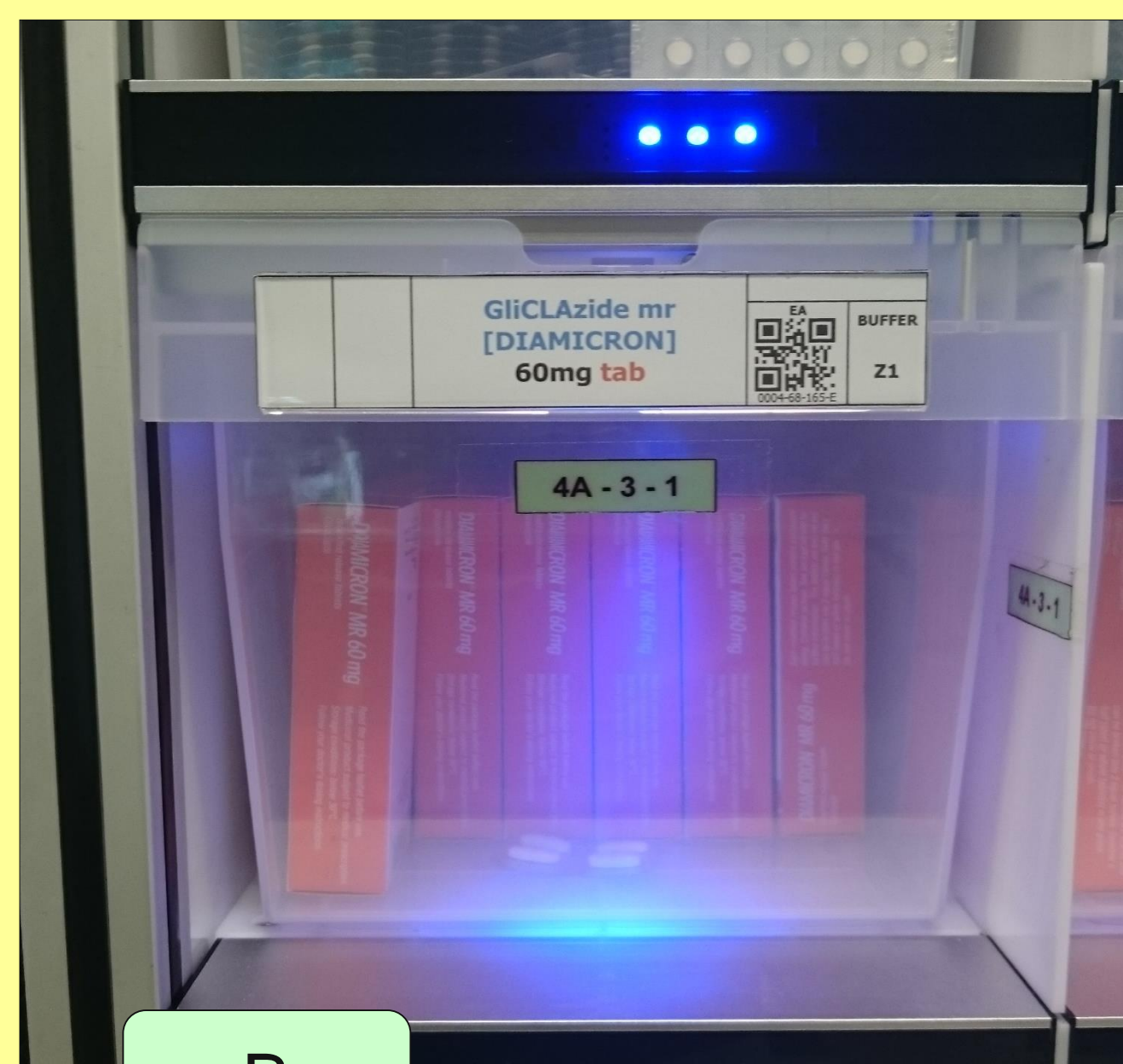


A

Scanning of quick response (QR) code on drug label or barcode on drug box triggers the Smart Bin system for picking from drug bin or loading / returning drugs to drug bin

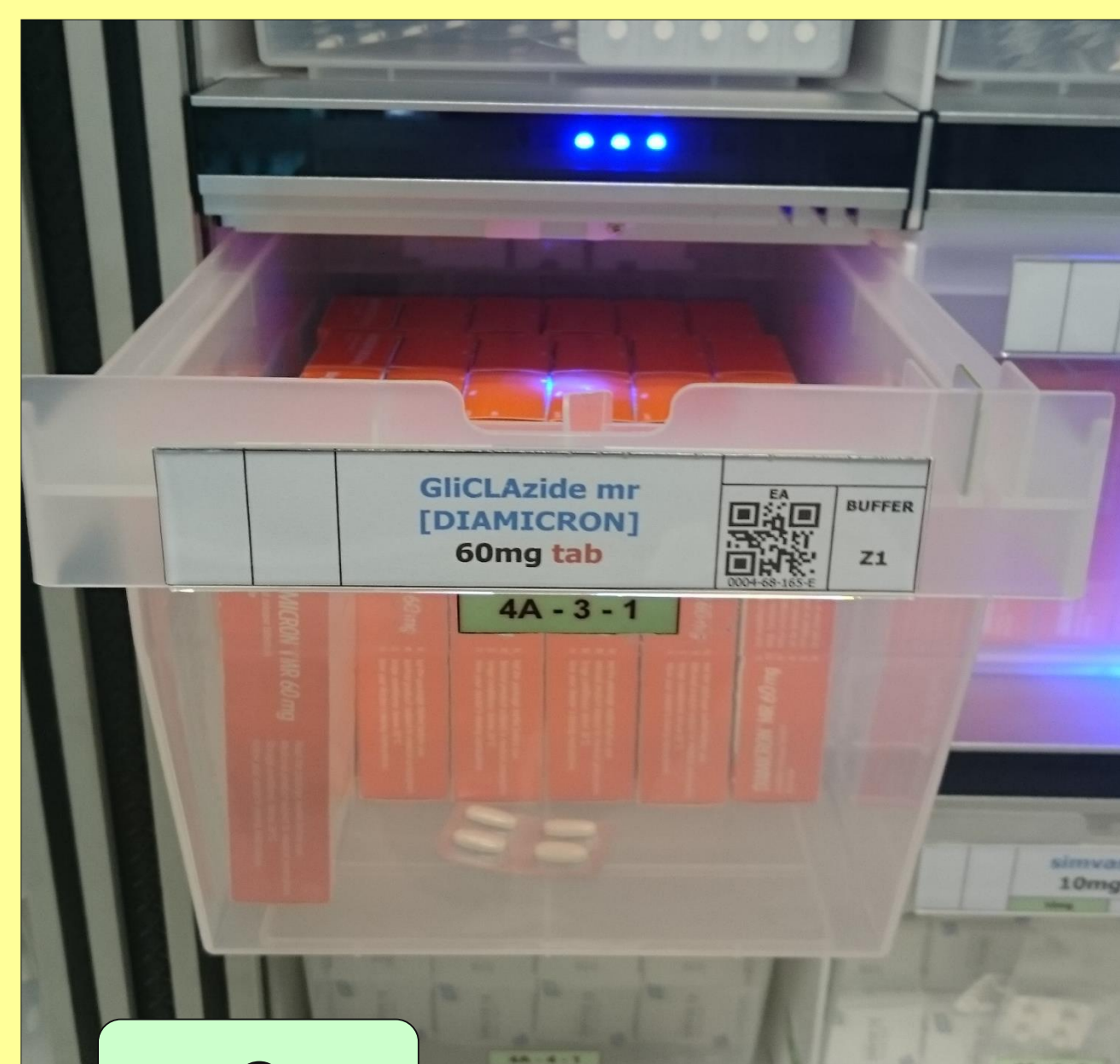
The Smart Bin system concept featuring advanced pick-to-light and locked-bin system, aimed to improve medication safety by reducing picking errors during prescription-filling. However, the efficacy of this system could be compromised as it depends on human intervention during picking, loading and returning of drugs.

Figure 1 demonstrates the Smart Bin system drug picking, loading and returning processes at our Pharmacy.



B

Light-Emitting Diode (LED) lights up, guiding staff to the correct drug bin



C

Locking mechanism unlocks, enabling staff to pick from drug bin or to load / return drugs to drug bin

Figure 1: Smart Bin system workflow

## METHOD

The potential failure modes and effects occurring in the processes were studied in January 2016 prior to implementation of the Smart Bin system. Each failure mode was evaluated using three 10-point scores: severity of effect, likelihood of occurrence, and probability of detection. Risk priority numbers (RPNs) were calculated using the product of these three scores. We identified steps with high scoring RPNs and proposed risk reduction strategies. The RPNs for pre-implementation and one-month post-implementation of the Smart Bin System were compared. Comparative analysis of medication near misses was also conducted 5-months before and after implementation of the Smart Bin system on a weekly basis. Independent sample t-test was performed via SPSS version 20.0

## RESULTS AND DISCUSSION

A 10-step process map was developed with 79 failure modes, 104 potential failure effects and 159 potential causes.

## RESULTS AND DISCUSSION

Process steps	Total failure modes	Sum of RPNs before FMEA	Sum of RPNs after FMEA
Picking	5	2821	1931
Loading	14	3601	3441
Returning	11	6981	4161
Verification	9	3789	2529
Removing expiring drugs	10	3551	2631
Enquiry	8	2254	1234
Checking	5	1154	874
Unloading	7	1311	1311
Assign / unassign drug	6	304	304
Assessing fridge / open shelves	4	2336	1156

Table 1: Number of process steps and failure modes identified in the Smart Bin system processes

Failure modes identified	Process steps
Scanning multiple drug labels concurrently	Picking
Entering wrong expiry date	Returns
Performing verification in system without first verifying contents	Verification
Use of inappropriate system module or bypassing of the Smart Bin system, resulting in inaccurate transaction records	Loading, returning, verification, picking

Table 2: Failure modes with the highest RPNs

Risk reduction strategies were targeted to the failure modes with the highest RPNs and therefore, highest risks.

Process steps	Risk reduction strategies
All processes	Develop the Smart Bin system Standard Operating Procedures (SOP) based on FMEA findings
All processes	Conduct staff training, with emphasis on strict compliance to SOP and consequences of deviating from SOP, through mass briefing and hands-on sessions
All processes	Administer the Smart Bin system competency assessment for all staff before they are certified to work independently
Picking	Set configuration transition time between multiple drug label scans for same staff
Picking	Review drug location and ensure multiple strengths are located in different gondolas
Loading	Educate staff to check and verify expiry date of all drugs
Returns	Review drug returns workflow, include printing of QR codes from drug list for return of loose blisters to the Smart Bin system
Verification	Educate staff on importance of verification process
All processes	Conduct random checks to ensure staff select appropriate system module

Table 3: Recommended risk-reduction strategies targeting failure modes with highest RPNs

The RPNs were recalculated post-implementation of the Smart Bin system and a 30% reduction in RPN was observed. After implementation, the number of medication near misses due to wrong drug picked from Smart Bin was reduced by 94.0% from 5.19 to 0.31 per 10,000 items picked per week ( $P < 0.001$ ).

## CONCLUSION

FMEA is a useful tool to evaluate new systems, and resulted in a 30% reduction in RPN in our study. The proposed risk-reduction strategies proactively reduced risks associated with human error.

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