RESEARCH ARTICLE

Effect of Closed Loop Medication Administration on Drug Returns in Inpatient Facilities

Authors
Eceberil Ozturk, Ilker Kose, Beytiye Ozge Elmas
Istanbul Medipol University

Affiliations

Ilker Kose
Istanbul Medipol University
Email: ikose@medipol.edu.tr

Abstract
Medication management in inpatient facilities is a crucial issue for patient safety. In inpatient conventional drug management, a common problem relates to drugs prescribed and delivered to patients being returned to the pharmacy without reason for the return. When reasons are given, they are not often regularly and correctly recorded. Closed Loop Medication Administration (CLMA) protects patient safety by managing all processes, including intake of the drug to the hospital's stock, administering the drug to the patient, and disposal of unused drugs using technology. CLMA is known to contribute positively to patient safety. However, there is no study on the effect of CLMA on the return of non-administered drugs. This study aims to analyze the effect of CLMA on drug return rates and investigate the data quality of reasons for drug returns. The research was carried out in three inpatient clinics of a Turkish state hospital (Bolu İzzet Baysal Public Hospital) where the CLMA was implemented in May of 2017. The data set obtained from the hospital information system (HIS) is anonymized. The study showed a significant increase in drug return rates after CLMA, and the data quality of drug return reasons is also significantly improved. These results show that CLMA contributes positively to drug return rates and the data quality of drug return reason records.

Keywords: Closed Loop Medication Administration, Drug Return, Digital Hospital, EMRAM

Introduction

Closed Loop Medication Administration System

Inpatient treatment processes involve more significant risks for patient safety than outpatient treatments (Agrawal, 2009). One of the high-risk aspects of treatment relates to drug safety (Vural,Çiftçi and Vural, 2014). There are different risks at every stage, from the hospital's supply management to drug administration to the patient (Törüner, Kılıçarslan and Erdemir, 2010). The Closed Loop Medication Administration (CLMA) model was developed to reduce these risks (Bowles and Lu, 2007; Henderson¸ Lunak, Markiewicz, Tobin et al., 2003). CLMA is the management of all processes from the drug intake to the hospital's stock, to the administration or return and disposal of the drug, using technology that prioritizes patient safety (Bowles and Lu, 2007). CLMA can facilitate the systematic and reliable implementation of a very long and complicated process (Skiba, 2006). CLMA's basic workflow consists of the following steps (Theal and Yang, 2016);

1. Stock Management:

a) Medicines are verified with technology (barcode, RFID, etc.) and added to the hospital's stock.

b) Stock is managed by monitoring the name, type, amount, expiration date of the drugs and storing them under appropriate conditions.

c) Expired drugs are disposed of using an established procedure.

2. Order:

a) The physician orders medication electronically.

3. Pharmacist Approval:

a) The pharmacist evaluates the details of the prescription and approves it if appropriate.

b) Approved drugs are packaged and labeled (barcode, RFID, etc.) in the pharmacy as a unit dose (tablet, ampoule, etc.).

c) The pharmacist verifies unit dose drugs with the help of technology and sends them to the patient's ward.

4. Medication Administration, Return, and Disposal:

a) The nurse administers the medication to the patient according to the five rights of medication administration (right patient, right medication, right time, right dose, right route).

b) Drugs that are not administered to the patient for any reason are verified with technology (barcode, RFID, etc.) and returned to the pharmacy, again as a unit dose. The reason for the return should also be recorded.

c) Drugs that are unusable for any reason are disposed of according to a drug disposal procedure.

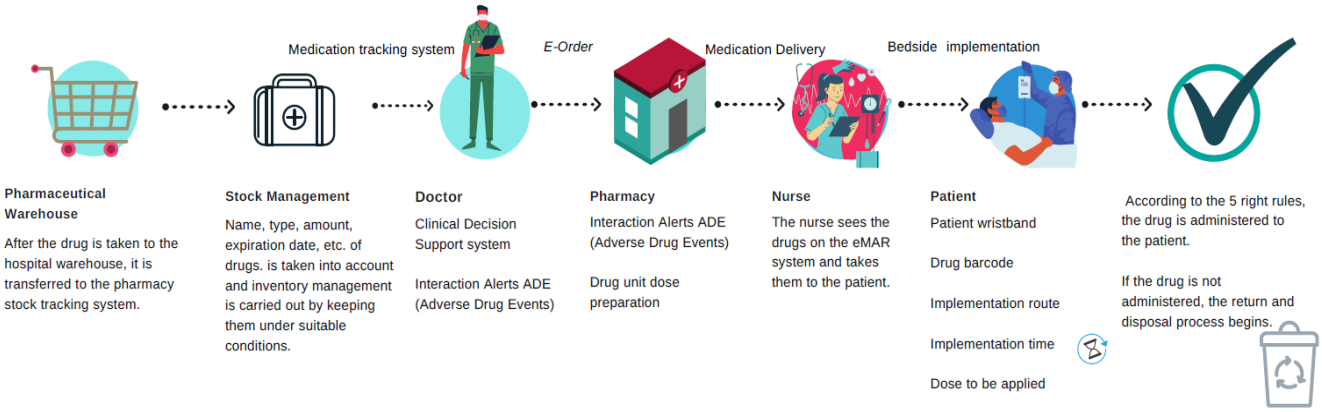

Figure 1: CLMA process

As seen in Figure 1, almost every step of the CLMA is carried out electronically, incorporating the clinical decision support system (CDSS). Besides, drug verification is performed with the help of technology (barcode, RFID, etc.). Thus, an error or inconsistency in any one step will prevent proceeding to the next step.

CLMA and Medication Safety

Medication errors are among the most threatening factors for patient safety. A study conducted by the American Pharmaceutical Institute in the USA stated that more than 1.5 million people are harmed every year due to medication errors (Yöntem, Güntürkün, Tokem, 2019). In a patient safety report published by the U.K. National Reporting and Learning System (NRLS) stated that 9.6% of security violations were medication errors (Thomas et al., 2011). In another study conducted in the USA in 2005, it was stated that medication errors caused 218,000 deaths and cost 130 billion dollars, while the same study revealed that 400,000 preventable errors harmed at least 1.5 million patients. The U.K. National Patient Safety Agency (NPSA) shows that errors occur primarily during the drug administration phase. 71% of the severe or fatal harm in medication errors consists of wrong posology, wrong medication, and neglected or delayed drugs (National Patient Safety Foundation, 2017). Global studies suggest that for every 100 people admitted to a hospital, 6.5 patients will experience drug interactions (Adverse Drug Events (ADE) that can lead to death or disability, reflecting similar results from the USA, U.K., and Australia (Aygin and Cengiz, 2011). The most common causes of medication errors continue to be the wrong dose, wrong route, and wrong time (Hillin and Hicks, 2010). Within the scope of CLMA, these errors are significantly reduced when the nurses apply the five-right rules at the bedside with the help of technology (barcode, RFID, etc.) (Wu, Kuo, 2005). In one study, the contribution of warnings received during drug administration to the overall process in a closed-loop hospital was examined. When the most received warnings were examined, it was seen that 1.22% of the system included false dose warnings (Hwang, Yoon, Kyoung, 2016).

Medication Application is seen as one of the healthcare processes with the highest

error rates. Some studies observed that the most common medication errors related to the incorrect or incomplete entry of prescriptions. (Hillin and Hicks, 2010). As part of the CLMA process, e-order significantly reduces these errors (Bates, Boyle, Vliet, Schneider, Leape, 1995). It has been shown that CLMA reduces drug administration errors and is a systematic and safe complement to drug administration, not only during the ordering phase but also during drug administration to patients (Bowles and Lu, 2007; Burkoski et al., 2019).

CLMA increases the interaction between the doctor and the pharmacist and ensures that the prescription is verified by both (Burkoski et al., 2019). According to a study conducted by Bates et al., effective communication between the physician and the pharmacist during the drug order reduces medication errors (Bates, Boyle, Vliet, Schneider, Leape,1995). The literature states that the double-checking method before drug administration reduces the risk of medication errors (Evans, 2009).

Aside from the clinical benefits, CLMA also has some economic effects. A very recent study on the effect of CLMA on drug billing leakage showed that CLMA decreased the drug invoice leakage from 4.4% to 0.5%, which represents a decrease of 83.8% (Eraltug et al., 2020).

Studies in the literature reveal various benefits of CLMA regarding medication errors. However, there is no study in the literature about returned drugs that are ordered but not administered to the patient for any reason. Whereas unreturned and unused drugs can lead to consequences that threaten patient safety, such as misuse or accidental use of unsuitable medicines, as well as financial losses. This study investigates the effect of CLMA on drug returns and the quality of drug return records.

METHODS

This study was carried out at Bolu İzzet Baysal Public Hospital, which was certified as Stage 6 according to HIMSS EMRAM criteria on 12.05.2017. The data obtained in the study were obtained from three clinics (internal medicine, neurology, and cardiology). The data belong to the year before CLMA implementation (May 2016-April 2017) and the year following CLMA implementation (May 2017-April 2018) was compared to analyze the change in drug return rates. All patients from all age groups and all genders were gathered anonymously from the database, and returned drug records were filtered separately.

The field names in the data set are as follows: Drug name, number of unit dosages, application date, return date, and return reason. The calculation was done using Microsoft Excel.

RESULT

The study showed numerical and proportional changes before and after CLMA implementation, as given in Table 1.

Table 1: Change in drug returns before and after CLMA

Clinic	Before CLMA			After CLMA			Change	Change Rate
	# of Drugs	# of Returned Drugs	Return Rate	# of Drugs	# of Returned Drugs	Return Rate		
Internal Medicine	42,804	1,434	3.35%	34,188	1,333	3.9%	0.55%	16.4%
Neurology	31,224	875	2.80%	28,632	1,036	3.6%	0.82%	29.1%
Cardiology	8,448	289	3.42%	10,476	507	4.8%	1.42%	41.5%
Total	82,476	2,598	3.15%	73,296	2,876	3.9%	0.77%	24.6%

As seen in Table 1, the drug return rates before CLMA are 3.35% in internal medicine, 2.80% in neurology, and 3.42% in cardiology. On average, this rate is 3.15%. On the other hand, the return rates after CLMA were 3.9% in internal medicine, 3.6% in neurology, 4.8% in cardiology, and 3.9% on average. Thus, there is an increase in drug returns in all clinics varying between 0.55% and 1.42%, which corresponds to 0.77% on average. Similarly, the increased return rates vary between 16.04% and 41.5%. The study suggests an increase of 24.6% in drug return rates after the CLMA application.

Table 2 represents the distribution of return reasons for unadministered drugs before and after the CLMA application.

Table 2: Change in distribution of drug return reasons before and after CLMA

Reasons for Return	Return Drug Numbers		Change Ratio
	Before CLMA	After CLMA	
Death	20	100	**400%**
Wrong Drug Entry	52	71	**36.54%**
Drug Stopped	285	924	**224.21%**
Referral to Intensive Care	401	771	**92.27%**
Discharge	556	910	**60.78%**
Treatment Change	1,274	101	**-92.07%**
Standard Deviation	460.66	429.42	**-6.8%**

As seen in Table 2, all the return reasons after CLMA increased except "treatment change". The standard deviation of the return reason distribution has also decreased by 6.8%. This situation can be interpreted to mean that nurses did not carefully record return reasons before the CLMA application and that they tended to select the "treatment change" option

over other options. The considerable change in the return reasons suggests that the unit dose packaging approach and step-by-step process of CLMA increased the return rates and increased the nurses' awareness to record the return reason more carefully.

To compare the number of returns before CLMA implementation with the number of returns after CLMA implementation, the normality of the rate differences was examined with Kolmogorov Smirnov and Shapiro Wilk tests. Since the normality condition could not be achieved in the test result, the values before and after CLMA implementation were analyzed with the Wilcoxon test. (A = 0.05) was used for the significance level.

Table 3: Pre-CLMA and post-CLMA refund rates comparison (3 clinics over 12 months)

	N	Mean(Median)±SS	Z	p
Number of returns before CLMA	216	13,333 (0.00)± 32,6865	-2,376	0.017*
Number of returns after CLMA	216	13,792 (3.00)± 21,7948		

**p<0.05*

The comparison of the number of returns before and after CLMA implementation was made using a Wilcoxon test. Since there is a test probability value (p <0.05), it is understood that there is a significant difference. Accordingly, the number of drug returns after CLMA [13.792 ± 21.7948] was higher than the number of returns [13.792 ± 21.7948] before the CLMA system. According to the test, it is a claimable indicator that CLMA increases the number of drug returns.

Comparison of the number of drug return reasons reported before and after CLMA (3 clinics, 12 months, six reasons) is given in Table 4.

Table 4: Before and after CLMA drug return reasons

Return reason	N	Before CLMA	After CLMA	p
		Mean (Median)±SS	Mean (Median)±SS	
Death	36	0.6(0.0) ±3.3	3.9(0.0) ±11.8	0.115
Incorrect Drug	36	1.4(0.0) ±3.0	2.0(0.0) ±3.1	0.295
Drug Stopped	36	7.9(0.05) ±13.9	25.0(19.0) ±20.4	0.000**
Referral to ICU	36	11.1(0.0) ±24.9	21.9(9.50) ±28.6	0.009**
Discharge	36	15.8(2.50) ±30.8	27.0(14.5) ±26.8	0.050*
Treatment change	36	43.1(16.0) ±59.2	2.9(0.0) ±8.5	0.000**

**p<0.05 **p<0.01*

Comparing the returns before and after CLMA, which are divided according to the reasons for the return, it was determined that there was no significant difference between the reason of death and wrong drug entry ($p > 0.05$). There was a significant difference in the reasons for the stop, referral, discharge, and treatment change ($p < 0.05$).

According to this;

• The average return after CLMA due to the drug being stopped [25.0 (19.0) ± 20.4] is higher than the mean return before CLMA [7.9 (.05) ± 13.9]. With CLMA, the number of returns made because the drug was stopped has increased.

• The average return after CLMA due to referral [21.9 (9.50) ± 28.6] is higher than the average return rate before CLMA [11.1 (.0) ± 24.9]. With CLMA, the number of returns made because the patient was referred to the ICU has increased.

• The average return after CLMA due to discharge [27.0 (14.5) ± 26.8] is higher than the average return rate before CLMA [15.8 (2.50) ± 30.8]. With the CLMA system, the number of returns made because the patient was discharged has increased.

• The average return after CLMA due to treatment change [2.9 (.0) ± 8.5] is lower than the average return rate before CLMA [43.1 (16.0) ± 59.2]. With the CLMA system, the number of returns made because the treatment plan was changed has decreased.

The number of drugs may vary over the years, so this was examined to see if this change statistically affects our result. To compare the ratio of the number of returns to the number of drugs for a year before CLMA implementation and the ratio of the number of returns for the year after CLMA implementation to the total number of drugs, the normality of the ratio differences was performed with the Shapiro Wilk's test. Still, since the test result's normality condition could not be achieved, pre-post ratio values were analyzed using the Wilcoxon test. (A = 0.05) was used for the significance level.

Table 5: Number of returns/number of drugs rates before and after CMLA implementation

	N	Mean(Median)±SS	Z	p
Number of return /Number of drug (pre-CMLA)	36	0.03353(0.03400) ±0.02531	-2.153	0.031*
Number of return /Number of (post-CMLA)	36	0.04450(0.03800) ±0.02477		

**p<0.05*

Since there is a test probability value ($p < 0.05$), it is understood that there is a significant difference. Accordingly, the percentage of returns before the CMLA system is 33.5 ± 2.5%, and the percentage of return after the CMLA system is 44.5 ± 2.4%. Therefore, it is understood that there is an increase in the percentage of return after CMLA implementation.

DISCUSSION

The literature shows that CLMA disciplines hospital information systems and provides a significant decrease in the incidence rates of failure to control physician requests and patient identity and significantly reduce medication administration errors (Chandak, 2016). Besides, the CLMA supports recording of the entire process from stock intake of drugs to the hospital to the delivery of drugs to the patient. Based on the disciplined step by step process and unit dose packaging approach, it can be suggested that CLMA is capable of reducing wrong drug entries and drug losses, which can prevent drug waste. The increase in drug return rates that we achieved in our study supports this suggestion. Additionally, CLMA is also capable of increasing the data quality of drug return reasons on HIS.

Based on this study's outcomes, it can be claimed that the implementation of the CLMA application in inpatient facilities is crucial not only for patient safety but also for cost-savings. Thus, policymakers should encourage CLMA applications in hospitals.

Even though there is no study about drug return in the literature directly related to CLMA, studies show that increasing the process discipline is positively affecting drug management. In one study, the relation between drug returns and automatic dispensing machine (ADM) were examined. (Deliberal, Barreto, Menezes and Bueno 2014). This study compares the ADM with the central pharmacy. Here, the drug return rate was high since the central pharmacy sends medicines for 24 hours, and some of the drugs are sent on demand. Thus, drug return rates were relatively high. The study showed that using ADM decreased drug return rates since the pharmacy started to send the drugs as unit doses and as ordered. In our case, the pharmacy was sending the drugs as ordered but not as a unit dose. But the unadministered drugs were not returned to the pharmacy regularly. The usage of CLMA disciplined the drug return process and increased drug return rates.

Another study claims that standardizing the drug return reasons is beneficial to drug management (Ling, MeiLing, Yi, YuMei, 2013). This claim is consistent with our study's result since CLMA increased the data quality of drug return reasons.

REFERENCES

1. Agrawal, A. (2009). *Medication errors : prevention using information technology systems*. 681–686. https://doi.org/10.1111/j.1365-2125.2009.03427.x
2. Ana Paula Deliberal, Daniela Vescia Menna Barreto, C. P. M. D. B. (2014). *Patient safety: analysis of the impact of implementation of automated dispensing cabinets on drug return in an university hospital*. *40*(1), 124–129. https://doi.org/http://dx.doi.org/10.4322/2357-9730.76692
3. Aygin D, C. H. (2011). *İlaç Uygulama Hataları Ve Hemşirenin Sorumluluğu," Şişli Etfal Hastan. Tıp Bülteni*. *45*, *n*, 110–114.
4. Bates , Deborah L Boyle BA, Martha B. , Vliet RN, Schneider, L. (1995). Adverse Drug Events. *Journal of General Internal Medicine Volume*, *199–205*.
5. Burkoski, Yoon, Solomon, Hall, Karas, Jarrett, C. (2019). Closed-Loop Medication System: Leveraging Technology to Elevate Safety. *Nurs. Leadersh.*
6. Chandak, A. (2016). Adoption of Medication Management Technologies by U.S. Acute Care Hospitals after the HITECH Act. *Theses & Dissertations.*, *175*. https://digitalcommons.unmc.edu/etd/175
7. Eraltug, Z., Uzumoglu, G., Bolat, O., Ozkan, E., Aydin, N., & Kose, I. (2020). *Effect of closed-loop medication administration on medication billing leakage : A case study*. *15*.
8. Evans, J. (2009). Prevalence, Risk Factors, Consequences and Strategies for Reducing Medication Errors in Australian Hospitals: A Literature Review. *Contemp. Nurse*, 31:176-189,.
9. National Patient Safety Foundation (2017). https://ipfs.io/ipfs/QmXoypizjW3WknFiJnKLwHCnL72vedxjQkDDP1mXWo6uco/wiki/National_Patient_Safety_Foundation.html date of acces:15.10.2020
10. H. Thomas, L., Cordonnier-Jourdin, C., Benhamou-Jantelet, G., Diviné, C., & L. L. (2011). Medication errors management process in hospital: a 6-month pilot study. Fundamental & Clinical Pharmacology. *Fundam. Clin. Pharmacol.*
11. Henderson, D., Lunak, R., Markiewicz, E., & Tobin, C. C. (2003). *Closed loop medication use system and method*. *2*(12). https://patents.google.com/patent/US8478604B2/en
12. Hillin, Hicks. (2010). Medication errors from an emergency room setting: safety solutions for nurses. *Am. Care Nurs. Clin.*
13. Kılıçarslan, & Erdemir. (2010). Prevention of Medication Errors in Pediatric Patients. *Hacettepe Üniversitesi Sağlık Bilimleri Fakültesi Hemşirelik Dergisi*, 63–71.
14. Ling, MeiLing, Yi, YuMei, Z. (2013). *Process management of drug returns to the inpatient dispensary*. https://doi.org/https://en.cnki.com.cn/Article_en/CJFDTotal-YXFY201304019.htm
15. M. Bowles and J. Lu. (2007). Systemic Closed Loop Electronic Medication Management Approach. *Int. J. Innov. Res. Sci. Eng. Technol.*, An ISO, vol. 3297, no. 9.
16. Skiba. (2006). Strategies for identifying and minimizing medication errors in health care settings. *Heal. Care Manag.*, 70–77. https://doi.org/10.1097/00126450-200601000-00010
17. Theal J, Y. L. (2016). *Reduce Medication*

Errors With Closed-loop Medication Administration System. 1–18. https://www.himss.org/sites/himssorg/files/reduced-medication-errors.pdf.

18. Vanessa Burkoski, Jennifer Yoon, Shirley Solomon, Trevor N.T. Hall, Albert B. Karas, S. R. J. and B. E. C. (2019). Closed-Loop Medication System: Leveraging Technology to Elevate Safety. *Canadian Journal of Nursing Leadership*, *32*.
19. Vural, F., Çiftçi, S., & Vural, B. (2014). *Sık Karşılaşılan İlaç Uygulama Hataları ve İlaç Güvenliği*. 271–275.
20. Wang, Yoon, Kyoung, Hwang, W. (2016). *Provider risk factors for medication administration error alerts: analyses of a large-scale closed-loop medication administration system using RFID and barcode*. *Volume25,*. https://doi.org/https://doi.org/10.1002/pds.4068
21. Wu , Kuo, L. (2005). *The application of RFID on drug safety of inpatient nursing healthcare*. *85–92*. https://doi.org/https://doi.org/10.1145/1089551.1089571
22. Yöntem,Güntürkün,Tokem, K. (2019). İlaç Hatalarına Yönelik Hemşirelerin Bilgi ve Tutumlarının İncelenmesi. *İzmir Kâtip Çelebi Üniversitesi Sağlık Bilimleri Fakültesi Dergisi*, *4*(2), 51–59.

