Medication Supply in Closed Loop Medication – Conceptual Understanding and Prerequisites

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Abstract. Closed loop medication (CLM) is an electronic supported medication management process. In addition to reducing errors, the approach provides better documentation, better traceability and better support for evaluating efficacy. Commonly today, medication information is registered in many standalone systems and manual transfer between these represents a risk of human error. To be able to discuss the CLM concept, a shared understanding is needed. In this paper, a definition of CLM is suggested and the concept is elaborated regarding prerequisites and dependencies. The definition of CLM was discussed in meetings with stakeholders regionally. Sales data from the hospital pharmacy in Trondheim (July–December 2016) were reviewed with respect to possible inclusion in a CLM. Dependencies, e.g. pharmaceutical formulation and suitability regarding repackaging into identifiable unit doses, was considered. The following definition of CLM is suggested: 'CLM is an electronically supported process for medication management where information from ordering to the point of administration is transferred seamlessly between different systems. Documentation during the process is done electronically and traceable. The CLM follows the single medication unit'. At St. Olav's hospital in the city of Trondheim, Norway, the local unit dose system repackages tablets, capsules, suppositories, ampoules, vials and more. The weekly output is about 45 000 units. Approximately 60% of total sales may be identifiable at the point of administration. For tablets and capsules, the number is about 80%. Only 14% of the medications are available as identifiable unit doses from the industry. These numbers strongly indicate that in order to reach the CLM ambitions, systems for repackaging of medications are needed.

Keywords: Closed loop medication, unit dose medication, ICT-assisted medication management, patient safety

1 Introduction

The medication (management) cycle is often defined as the processes from

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prescribing, via ordering, preparation and administration, to evaluation of (immediate) effect. In most Norwegian hospitals, the processes in the medication cycle today are supported by many standalone ICT and paper based systems, which deal with medication information separately. Manual transfer of information between these systems represents a risk of errors, hence compromising patient safety. Errors occur in all the different steps of the cycle; 20% of the reported medication related errors in Norwegian hospitals in 2014 were associated with the prescribing-phase, while approximately 80% occurred during dispensing and administration of medications [1].

The concept of closing the medication loop, as a course of action to reduce errors during medication management, was brought forward in the late 1990s [2]. Closed loop medication (CLM) is an electronic supported medication management process, see Figure 1. This concept aims to ensure; right medication, in the right dose, by the right route, at the right time and last but not least – to the right patient (the five R's). In addition to reducing errors, the approach aims to provide better documentation, better traceability and a better support for evaluating efficacy. However, to be able to discuss this concept across different hospital settings, a common basis for the understanding of CLM is needed. A conceptual understanding is further elaborated in the following paper, through examples from medication sales statistics from St. Olav's Hospital in Trondheim and a definition of CLM is suggested. Prerequisites and dependencies for the concept are brought forward, in addition to the coherency between functionalities in the systems and benefits thereof.

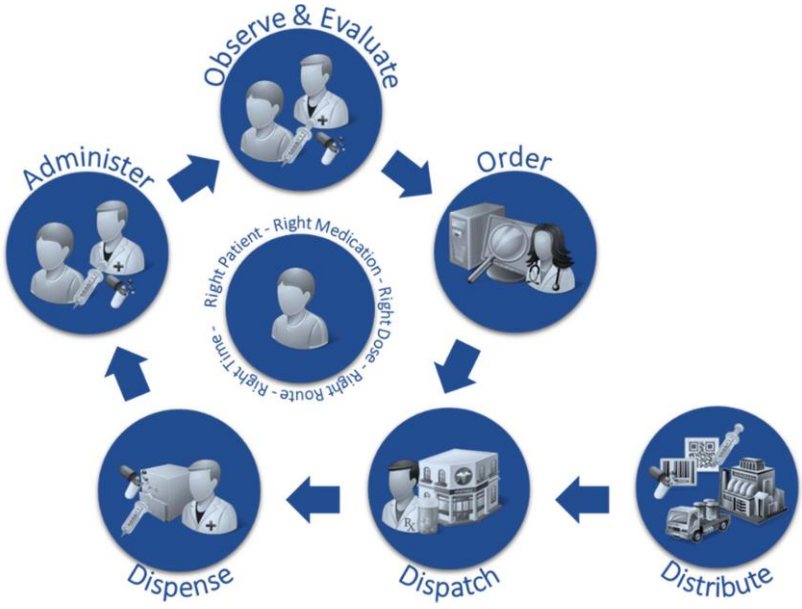

Fig. 1: Conceptual illustration of closed loop medication (modification of Figure 13, page 190 in Procurement of an EHR solution with adjacent systems and services, T Appendix 1B Functional Requirements v1.0)

1.1 Prerequisites and dependencies for CLM

At a minimum, a CLM includes an electronic ICT system for prescribing and administration of the medication, in addition to electronic identification of the health-care professional and the patient at the point of administration. In many cases, the systems also include electronic system support for dispensing as well as ordering, i.e. the supply link from hospital pharmacies is integrated into the loop.

ICT systems for electronic prescribing in, e.g. an electronic medication record (EMR), ensures consistent and defined medication information. This information is reused in other ICT systems, along with administrative and clinical information about the patient. A continuous and comprehensive medical chart solution potentially covers all structured clinical patient information; hence the entire hospital uses the same data about the patient when moving between wards and clinics. The ICT systems and user interfaces are usually adjusted to meet the departments' unique individual needs due to information in the work flows.An electronic stock keeping ICT system for medication supply can be the link between the medication module in EMR and the production, logistics and accounting systems at the hospital pharmacy. Based on a predefined primary assortment for the individual wards, the pharmacy re stocks the medication store at the ward automatically. Scanning of the medication units by the health-care professionals at both receiving and usage is a prerequisite for good inventory management. In addition, by introducing digital systems for electronic ordering, stock status information is presented to the doctor during the ordering phase of the medication management chain.

Electronic identifiable medications at the time of administration are another prerequisite for CLM. This requires that each medication unit is identifiable, i.e. has a unique ID/barcode. There are two alternative ways to produce identifiable pharmaceuticals at unit level; unit doses in the original packaging from the industry or repackaged unit doses from hospital pharmacies or other businesses [3]. ID-marked unit doses can be supplied in two alternative ways from the hospital pharmacy; either through deliveries to medication stocks at the ward, or as patient-specific unit doses. The patient-specific doses are prescribed in the EMR to the pharmacy, labelled with the patient ID and other relevant information about the medicine before they are delivered to the ward.

Accessible and readable barcodes on the medication package assure electronically identifiable medications. Barcode labelling on the secondary packing of medication is not a requirement for marketing authorisation in Norway, only a Nordic commodity number (V.nr). Barcodes on secondary packing are suitable for identification control in processes where complete packages are included, for example by handling prescriptions at the pharmacy. Nevertheless, in CLM it is a necessity to have barcodes at unit level upon administration of the medication. In Europe, more strict regulations for barcode labelling of medications are now being introduced through the Falsified Medicine Directive (FMD) [4]. This legislation is primarily introduced to prevent counterfeiting of medications; hence, the requirement of standardised barcodes will only apply to the outer packing. Barcodes on primary packages are however introduced as a national demand through the procurement process of medications (LIS).

At the point of administration, verification of the medications should be done with

the patient present. Health-care personnel thus depend on having a mobile medication store and scanning equipment at hand bedside. Mobile storing solutions/trolleys with trays allocated for each patient, barcode readers and displays showing the actual prescription could be used. The scanning equipment or barcode readers must identify both the medication ID, the patient ID, in addition to the health personnel ID. The latter could also be solved with identification by login to the EHR-system. This fulfils the requirement of a record of who administered the medication, what was given and at what time the administration took place.
For medication that must be reconstituted before administration (e.g. powdered IV medication) or dilution of solutions for injection or infusion, to be applicable into a CLM, there should be a digital system for generating a new label or barcode that can be used for identification of the ready to use medicine at the point of administration. This applies to both when such preparations are being prepared at the hospital pharmacy and at the hospital ward.

The last prerequisite is a standardised and complete medication registry, which will ensure a common understanding regarding medication information (including barcode information) between different ICT systems in CLM. The Norwegian Medicines Agency (NoMA) is the regulatory authority responsible for medication information in Norway and provides this through the national Prescribing and Expedition Support Register (FEST).

1.2 Expected benefits of CLM

Overall, it is expected that errors occurring during medication management will reduce and patient safety improve when introducing CLM. Studies commonly show that errors during the prescribing/ordering phase and the administration phase are reduced [5–7]. The reduction of errors through patient identification by wrist-bands with barcodes at the time of administration is in itself shown to be efficient, but the outcome varies between different settings [8, 9]. Although several studies indirectly show improved patient safety, further investigations on context and cost-benefit analyses should be performed to support decision-makers in the prioritising processes [10–13].
Decision support connected to the single medication unit when ordering the medication could give patient-specific notice on allergies or whether the dose was adjusted according to blood test results. At the point of administration, the ICT system can provide guidance/support regarding, e.g. the administration route of the medication.

Conceptual choices for medication supply at St. Olav's Hospital/Trondheim Hospital Pharmacy
In 2004, at St. Olav's Hospital it was decided to introduce automated medication supply and, with a time horizon, CLM. Consequently, the hospital pharmacy in Trondheim started to repackage medication into unit doses in 2012. The stock keeping and ordering system at St. Olav's Hospital (Delta) was introduced at the same time as

the unit doses.

The unit dose packaging system at the hospital pharmacy can repack tablets, capsules, suppositories, ampoules and vials. In addition to the automated dispensing and labelling of unit doses, pharmacy personnel manually barcode multi-dose packages (e.g. mixtures and ointments) and other medications that are not suitable for repackaging. This manual approach also assures traceability in the supply chain for these medications. The unit dose facility at the hospital pharmacy in Trondheim has a production flexibility that allows it to dispense medications for a day's consumption for the individual patient at a 750-bed hospital. The actual medications are then collected on a plastic ring with a patient tag (Figure 2). This functionality is currently not in production, awaiting introduction of electronic ordination through the electronic health record (EHR) procurement-project (Helseplattformen). Meanwhile, the unit doses (without patient labelling) are supplied to local storage at the hospital wards and allocated into patient-specific trays in medication trolleys.

Fig. 2: Unit dose with patient tag (left) and barcode on bag (right), produced at the hospital pharmacy in Trondheim

2 Method

Based on our knowledge regarding the current state of CLM, we have identified both a need for a deeper conceptual understanding and a thorough investigation of the prerequisites for potentially achieving the goal. Accordingly, the research questions for this work were:

- What is CLM?
- To which extent could CLM be achieved based on the current supply model at St. Olav's Hospital?

The concept of CLM was discussed during meetings with stakeholders regionally. The discussions were arranged in conjunction with two regional project meetings, with staff from the pharmacy and the hospital, as well as technical resources. Relevant literature, reports over the topic from other health regions and ongoing projects were studied to give input to the regional discussion [2, 14]. Different views, about which work processes and system support are included in a CLM, were taken into account. A common conclusion was in the end summed by agreeing on a definition of CLM.

Sales statistics from medication supply at St. Olav's Hospital
Sales statistics for medications from the hospital pharmacy in Trondheim to all departments organised under St. Olav's Hospital Health Trust in the period 1.3.2016–31.8.2016 were retrieved from the internal pharmacy enterprise resource planning (ERP)-systems, FarmaPro. The data were categorised and reviewed to give a complete picture of the types of medications supplied to a large university hospital in Norway, as well as to highlight the proportion of the total medication delivery that could potentially be included in the CLM on the basis of the conceptual choice made. Dependencies for the latter, e.g. pharmaceutical formulation and suitability for repackaging into identifiable unit doses, were considered based on the types of medicines already repacked into unit doses from the hospital pharmacy. To categorise preparations, subheadings were linked to package type in the FEST register. These package types are then merged into more general groups, e.g. all vials in one category, and all blister packages in another category (See Table 1).

Potential for single dose units from the pharmaceutical industry
An estimate of the proportion of medications that can be delivered as unit doses from the industry was also made. The available unit dose medicines (tablets and capsules) were identified with package type 'ENDOSE' in FEST for each product. In addition, medications ready to use as unit doses were considered single dose in this context. This applies, for example, to Metronidazole Inf 5mg/ml 100ml infusion bottles. These medications were also identified using known package types from FEST.

3 Results and Discussion

Based on the discussion with stakeholders regionally, the following definition of CLM is suggested: 'CLM is an electronically supported process for medication management where information from ordering to the point of administration is transferred seamlessly between different ICT systems. Documentation during the process is done electronically and traceable. The CLM follows the single medication unit'.

This definition is not very different from the other definitions found, but an important statement is added in the last sentence: 'CLM follows the single medication unit' and not the whole list of medications. This means that one of the patients' medications may be included in a CLM while others are not. When it comes to

knowledge and clinical decision support in CLM, only support for correct management of the single medication is included in the process-support. This means that, e.g. interaction support is not included in a CLM.

Table 1: Categorisation of medicines according to original package and unit type in CLM

Formulation	Original package	Unit type in CLM*	Example	Specification/comment
Tablets and capsules	Blister	SDU	Remeron-S® Orally Disintegrating Tablets	Blister card is cut into single units and repackaged
		SDU	OxyNorm® Capsules	Converted to bulk before repackaging
	Bulk	SDU	Metoprolol® Tablets	Box (bulk) from manufacturer
	Box	WP	Amoxicillin® Capsules	Box (bulk) from manufacturer with antibiotics/cytotoxic that cannot be repacked into unit dose
Powder sachets		SDU	Movicol® Powder for oral solution	
Oral drops	Bottle	MDU	Laxoberal® Oral drops	
Inhalation	Single dose inhaler	SDU	Ventoline® Solution	1ml and 2 ml ampoules for inhalations.
	Multi-use inhaler	MDU	Ventoline@ Inhalation aerosol	Multi-dose inhalator
Pre-filled pen/syringe	Single use pen/syringe	SDU	Prolia inj® Pre-filled syringe	Single dose syringe
	Multi-dose pen/syringe	MDU	Insulatard FlexPen® Pre-filled pen	Multi-dose syringe
Injections	Multi-dose vial	MDU	Marcain-adrenalin inj.®	Multi-dose vials that can be used for 24h
	Single dose vial or ampoule	WP/SDU	Pneumovax inj®	Single dose ampoule
Infusions	Multi-dose vial	MDU	Morfin NAF 40mg/ml 10ml®	Multi-dose vials that can be used for 24h
	Single dose vial	SDU	Inflectra® Powder for infusion	Single use vials

Liniment	Bottle	MDU	Locoid Crelo®	Multi-dose liniment that can be shared between several patients
Ointment and creams	Bottle	MDU	BetnovatChinoform®	Multi-dose creams that can be shared between several patients
Oral spray	Bottle	MDU	Nitrolingual®	Multi-dose spray
Nasal spray	Bottle	MDU	Instanyl®	Single dose
Nasal drops	Bottle	SDU	Flutide nasal®	Single use nasal drops
Ear drops	Bottle	MDU	Cilox®	
Eye drops	Bottle	MDU	Blocadren Depot®	Multi-dose eye drops
	Minims	SDU	Oxibuprocain Minims®	Single use eye drops
Implants		WP/SDU	Zoladex® implant	Single dose
Mixtures	Bottle	MDU	Mycostatin® mixt.	Multi-dose bottles
Suppositories		SDU	Voltaren® sup.	Single dose
Vagitories		SDU	Dalacin® vag.	Single dose
Skin patches		WP	Norspan® Depot patch	Single dose

*SDU = single dose unit, MDU= multi-dose unit, WP= whole package

In the period from 1.3.2016–31.8.2016 (six months), a total of 2 001 671 single units were produced at the facility in Trondheim Hospital Pharmacy, corresponding to about 45 000 single dose units weekly. From this, 61% are potentially electronically identifiable at the point of administration.

Regarding tablets and capsules, the figure is 83%. For the same period, we could identify only 14% of medications available as unit doses from the industry. The proportion of these unit doses branded with barcodes is unknown.

The remaining medicines which could not be electronically identifiable at unit level at the point of administration are: ointments, creams, syrups and tablets/capsules distributed in boxes. For this group of substances, additional labelling is a possible solution to increase the availability of barcode branded medicines.

Based on the analysis of sale statistics, we realise that CLM may be difficult or not possible to establish for all groups of medications. This supports our definition of CLM that it follows the single medication unit.

To summarise, the above suggested definition opens for a qualitative approach to the area and the following is made possible:

- Overview of the share of total medications delivered as identifiable and hence eligible for CLM
- Comparison of CLM status between units and hospitals
- A more thorough understanding of the link between pharmacy dispensing and CLM
- Measurable goals regarding CLM for a unit or hospital

4 Summary and Conclusion

Only a low proportion of medications were available as identifiable unit doses from the pharmaceutical industry at the time of the study and with the defined prerequisites; this is based on medications sold as unit doses with the correct package type indicated in FEST. In real life, the number might be higher but not anywhere close to the 80–90% that can be delivered based on preparation of unit doses in the hospital pharmacy. These numbers strongly indicate that in order to reach the CLM ambitions, systems for repackaging of medications are needed. Further investigation regarding medication error status, cost-effectiveness and an optimised ICT-supported work-flow should be done in the present context as a basis for future decision support.

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