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ORIGINAL RESEARCH

The medication process in a psychiatric hospital: are errors a potential threat to patient safety?

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Purpose: To investigate the frequency, type, and potential severity of errors in several stages of the medication process in an inpatient psychiatric setting.

Methods: A cross-sectional study using three methods for detecting errors: (1) direct observation; (2) unannounced control visits in the wards collecting dispensed drugs; and (3) chart reviews. All errors, except errors in discharge summaries, were assessed for potential consequences by two clinical pharmacologists.

Setting: Three psychiatric wards with adult patients at Aalborg University Hospital, Denmark, from January 2010–April 2010.

The observational unit: The individual handling of medication (prescribing, dispensing, and administering).

Results: In total, 189 errors were detected in 1,082 opportunities for error (17%) of which 84/998 (8%) were assessed as potentially harmful. The frequency of errors was: prescribing, 10/189 (5%); dispensing, 18/189 (10%); administration, 142/189 (75%); and discharge summaries, 19/189 (10%). The most common errors were omission of pro re nata dosing regime in computerized physician order entry, omission of dose, lack of identity control, and omission of drug.

Conclusion: Errors throughout the medication process are common in psychiatric wards to an extent which resembles error rates in somatic care. Despite a substantial proportion of errors with potential to harm patients, very few errors were considered potentially fatal. Medical staff needs greater awareness of medication safety and guidelines related to the medication process. Many errors in this study might potentially be prevented by nursing staff when handling medication and observing patients for effect and side effects of medication. The nurses' role in psychiatric medication safety should be further explored as nurses appear to be in the unique position to intercept errors before they reach the patient.

Keywords: medication safety, mental health disorders, medication errors, psychiatry

Introduction

Adverse drug events (ADEs) and medication errors (MEs) are recognized as an important quality and patient safety problem in modern hospital settings, causing harm as well as avoidable morbidity and mortality.[1–5]

There is limited evidence about these issues in psychiatric settings. Only a few studies on ADEs and MEs in psychiatric hospital settings exist. Four of these studies addressed prescribing errors and two studies addressed administration errors.[6–11]

Results from three of the studies investigating prescribing errors displayed a rate of decision-making errors which ranged from 12.5%–23.7% and a rate of documentation (clerical) errors, which ranged from 76.3%–84.5%.[7–9] The fourth study, aimed at describing errors in the prescribing phase, was based on reports

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about pharmacists' interventions.[6] In the two studies which focused on administration errors, one study was based on self-reporting by nurses and did not report any rate of error. The other study was an observational study of administration errors in elderly psychiatric inpatients where administration errors were detected in 25.9% of all opportunities for error.[10,11] Some studies have investigated several stages in the medication process, but these studies were primarily based on data collected from self-reporting of medication errors and chart reviews.[12–15] These studies measured their outcomes using different methods and denominators which makes it difficult to conduct comparisons. However, it is recognized that direct observation is the most valid method when collecting data in the dispensing stage and the administration stage.[16] It is highly important to apply reliable methods when investigating frequency and character of errors in the medication process to produce valid and precise information.[16,17]

To our knowledge, there are no studies in psychiatric hospital settings which focus on errors in more stages of the medication process, including discharge summaries, by applying the most sensitive methods of detection. A precise estimate of frequency, type, and potential severity of errors is needed to choose relevant interventions to reduce errors in the medication process. Therefore, the objective of this study was to investigate the frequency, type, and potential severity of errors in several stages of the medication process in an inpatient psychiatric setting.

Materials and methods

The medication process can be divided into prescribing, dispensing, administering, and monitoring.[18]

Furthermore, the prescription stage of the medication process can be divided into a decision-making process and a clerical process. The decision-making process concerns the physician's choice of drug, dose, and form of administration.[18] The stage of monitoring the patient for effects and side effects was not included in the study.

An error was defined as "a planned action which failed to achieve the desired consequences."[19] This means that all deviations from guidelines were considered errors; subsequently, two clinical pharmacologists evaluated all errors for potential severity, thereby separating harmless errors from errors with the potential to harm patients.

Describing proportions of errors requires a defined denominator.[20]

"Opportunities for error", defined as opportunities for active errors (omissions, mistakes, and/or conscious or unconscious rule violations), was the denominator used to calculate the proportion of errors in this study. The denominator is established by multiplying the number of handled medications with the number of requirements in the guidelines to be followed. The proportion of errors was the sum of actual errors divided by the total number of opportunities for errors.

Design

The study was designed as a descriptive, cross-sectional study of errors in the medication process and potential harm. Data was collected using three methods: direct observation; unannounced visits to the wards to collect dispensed drugs for identification; and chart review. The study population included in-hospital patients aged 18 or above (n = 67), nurses and nurses' assistants dispensing and administering drugs, and physicians prescribing drugs, but the observational unit was the individual handling of medication (prescribing, dispensing, and administering). It is common in Denmark that each ward has its own stock ward system where nurses dispense drugs. The term "dispensing" refers to nurses identifying the drugs prescribed and dispensing it to medication cups. Subsequently, the nurses will administer the medications to patients. The hospital pharmacy staff undertakes monitoring the use, needs, and reordering of drugs as well as giving advice for the individual wards. In this study, regular and pro re nata (PRN) prescriptions were included, apart from discharge summaries in which PRN prescriptions were excluded. The choice of excluding PRN prescriptions in discharge summaries was made because physicians often forget or are not aware that a PRN drug deliberately not prescribed in the discharge summary must be discontinued in the computerized physician order entry (CPOE). Including this as an error type would give a distorted impression of the prevalence of errors in discharge summaries. PRN prescriptions are prescriptions not scheduled to be administered at predetermined times of the day but to be used "when needed." Errors in discharge summaries were not evaluated for potential severity, due to practical reasons. Included drug forms were tablets, capsules, mixture, suppositories, and injections.

Study site

This study was conducted in three psychiatric wards at Aalborg University Hospital, Denmark, from January 2010 to April 2010. Physicians were responsible for prescribing drugs and nurses or nurses' assistants were responsible for dispensing and administering medication. There was no

administration of drugs scheduled in the night shift. Drug prescriptions were documented in a CPOE system.

Methods for collecting data

All comparisons of observations to the CPOE were conducted by one of the authors (ALS).

Observational method

Data were collected on the wards using direct observation. The observer spent two day shifts (8 hours) and one evening shift (8 hours) on each ward, observing the nurse or nursing assistant responsible for dispensing and administering drugs. The observations covered six rounds of dispensing and administering drugs in each of the three wards. The caregiver responsible for the entire medication administration in the ward was aware of the study purpose but had no knowledge about which actions were observed and registered. The observations of dispensed and administered drugs were registered on a structured paper form and subsequently compared with prescriptions in the CPOE. Due to the tradition and rules of observing the patients' consumption of medication in psychiatric nursing, it was possible to register all administered medication. Any discrepancies between the observed and the prescribed medication in the CPOE were classified as errors, according to the criteria outlined in Table S1.

Unannounced visit to the ward

The unannounced visit to the ward was conducted approximately 3 weeks after the observational study. The dispensed medication was collected from the medication storage room before administration. The medicine collected from the medication storage room was subsequently compared to the CPOE. Any discrepancies between the identified drugs and the prescriptions in the CPOE were classified as errors, according to the criteria outlined in Table S1.

Chart review

The CPOE and discharge summaries were retrospectively screened for errors. It was assessed whether drug prescriptions were in accordance with the criteria outlined in Table S1. If a patient was sampled more than once, only new or altered prescriptions were screened for errors. Discharge summaries were also screened to identify errors, ie, discrepancies between eligible prescriptions in the CPOE and the discharge summaries, according to the criteria outlined in Table S1.

Potential clinical consequences

All registered errors in the observational study, screening of the CPOE (errors in discharge summaries excluded), and the unannounced visits to the wards to collect dispensed drugs were assessed for potential clinical consequences. The assessment was conducted independently by two senior clinical pharmacologists using a four-scale system: potentially fatal; potentially serious; potentially significant; and potentially nonsignificant.[5] The four-scale classification system can be found in Table S2.

Statistics

All data were analyzed using Stata/IC 10.0 (StataCorp, College Station, TX, USA). Frequencies were described as percentages. The kappa test was used to evaluate the inter-rater variation in the clinical pharmacologists' assessment of potential clinical consequences where appropriate. The statistical significance level was set at 0.05.

Ethics

Approval of the study was obtained from the Danish Data Protection Agency. The investigator was ethically obliged to intervene in the case of observing an error. If the investigator had to intervene, it was registered as an error.

Results

Patients

The study included 67 eligible patients (24 men [36%] and 43 women [64%]) with a mean age of 46 years (20–79 years). The most common reason for admission was schizophrenia and other psychotic disorders (22/67;33%), followed by bipolar disorders (11/67;16%).

Frequency of errors

A total of 189 errors were detected in 1,082 (17%) opportunities for errors. The frequency of errors in the different stages of the medication process is shown in Table 1. The majority of errors were detected in the administration stage with errors in 142/340 (42%) opportunities for error. This was followed by discharge summaries with errors in 19/84 (23%) opportunities for error. Nine (47%) errors in discharge summaries were due to eligible prescriptions in the CPOE, which were not prescribed in the discharge summary.

The intention behind investigating the dispensing stage using two methods was to examine the validity of the results obtained in the observational study. There were errors in 9/324 (3%) opportunities for error of the dispensed drugs in

Table 1 Frequency of errors in the different stages of the medication process

Prescribing, CPOE n/N_{total} (%)	Dispensing, observational study n/N_{total} (%)	Dispensing, unannounced visit n/N_{total} (%)	Administration n/N_{total} (%)	Discharge summaries n/N_{total} (%)
10/267 (4)	9/324 (3)	9/67 (13)	142/340 (42)	19/84 (23)

Notes: N_{total}, the total number of opportunities of errors in each stage (prescription and doses); n, the total number of detected errors in each stage of the medication process. The difference in number of dispensed medications and number of administered medications in the observational study was due to incidents where staff had administered medicine without the investigators' presence.
Abbreviation: CPOE, computerized physician order entry.

the observational study and in (9/67) 13% of the dispensed drugs in the unannounced control visit of which the majority was associated with one nurse assistant. Fewest errors were detected in the prescribing stage.

Frequency of error types

The identified errors were distributed by error types which are shown in Table 2. The most frequent error types were lack of identity control (135/142; 95%) and concordance with drug prescription (10/142; 7%). The error type lack of identity control occurs when the patients' identity is not established before administering drugs. The clinical guideline states that the person administering the drugs must identify the patient by having the patient say his full name and Social Security number, or by using the obligatory wristband to identify the patient. The error type concordance with drug prescription occurs if already-dispensed drugs are delegated to another staff member; this person must compare the drugs to be administered with the prescriptions in the CPOE. Error types in the administration stage could be mutually dependent. This occurred with the following error types: "lack of identity control;" "wrong time;" and "lack of correct labeling." The dependency arises because each of the aforementioned error types affects all doses which were delivered to the patient in that particular incidence. Analysis of these error types showed that "lack of identity control" occurred in 49 of 137 (36%) deliveries. "Wrong time" occurred in four of 137 (3%) deliveries. Finally, "Lack of correct labeling" occurred in three of 137 (3%) deliveries.

Assessment of potential clinical consequences

The assessment of the potential clinical consequences was carried out in a worse-case scenario, meaning that whenever the clinical pharmacologists disagreed on the severity of an error, the most severe assessment was included in the analysis. Results from the assessment are displayed in Table 3; definitions are outlined in Table S2. The inter-rater agreement (measured by the test statistic kappa) for errors in prescribing, dispensing, and administration varied from good to perfect (0.54; 0.75; 0.82; and 1.0, respectively).[21]

The pharmacologists assessed 84/998 (8%) errors as potentially serious or potentially fatal. The number of opportunities for error in this part of the study was reduced to 998 because assessment of potential clinical consequences did not include errors in discharge summaries. The four potentially fatal errors were related to the error types: "omission of PRN dosing regime" (n = 2) and "lack of identity control" (n = 2). There were errors in 142/340 (42%) of all opportunities for errors in the administration stage, and it was assessed that 75/142 (53%) of these errors had the potential to harm patients.

Drug categories and errors

Errors with the potential to harm patients were most often associated with drugs related to the patients' psychiatric condition (Table 4). The drug category most often associated with these errors was psycholeptics. The type of drug most often involved in potential harmful errors was atypical antipsychotics, followed by anxiolytic-sedative drugs and mood stabilizers. The errors assessed to be potentially fatal were related to prescribing and administration of medication and were associated with analgesics (opioids) (n = 2) and psycholeptics (atypical antipsychotics) (n = 2). Nonpsychiatric drugs associated with potential harmful errors constituted 7/77 (9%). The majority of these errors were anti-inflammatory and antirheumatic drugs, including nonsteroidal anti-inflammatory drugs (NSAIDs).

Discussion

There were errors in almost one-fifth of all handlings of medication of which the vast majority occurred in the administration stage. The main type of errors was lack of identity control. The prevalence of potentially harmful errors was 8%, of which 0.3% errors were considered potentially fatal. The potentially fatal errors involved drugs from the categories of analgesics and psycholeptics. A few other studies in psychiatry have examined administration errors and identified

Table 2 Frequency of error types in the different stages of the medication process

Stage in medication process	Total number of doses or prescriptions affected with at least one error in each stage of the medication process (N)	[a]Total number of error types in each stage (n/N)
Prescribing, CPOE	N = 10	
Drug name		0
[b]Drug prescription		2/10
[c]Omission of PRN dosing in CPOE		8/10
Dispensing, observational study	N = 9	
Drug prescription		0
Omission of dose		3/9
Wrong dose		1/9
Unordered dose		0
Contamination		1/9
Lack of correct labeling		4/9
Dispensing, unannounced control visit	N = 9	
Drug prescription		0
Omission of dose		6/9
Wrong dose		2/9
Unordered dose		1/9
Administration	N = 142	
Omission of dose		0
Wrong dose		1/142
Unordered dose		0
Contamination		0
[d]Lack of correct labeling		0
[e]Wrong time		8/142
Wrong route		0
Wrong administration technique		0
[f]Lack of identity control		135/142
Wrong patient		0
[g]Concordance with drug prescription		10/142
Discharge summaries	N = 19	
Drug name		1/19
Drug prescription		9/19
Omission of drug		9/19

Notes: [a]One dose or prescription affected by an error could be associated with more than one error type; [b]drug prescription: means one or more errors (including omissions) in strength per unit, route of administration, form of administration, dose, frequency of administration, signature, date, duration of treatment (only antibiotics was included in this study); [c]omission of PRN dosing regime in CPOE: means one or more errors (including omissions) in strength per unit, route of administration, form of administration, dose, frequency of administration, signature, date, duration of treatment; [d]lack of correct labeling: means that all drugs administered to patients must be marked with the patient's full identity; [e]wrong time: means the drugs were administered ±60 minutes off the scheduled time; [f]lack of identity control: means that the patient's identity has not been established by having the patient state full name and Social Security number or using the obligatory wristband; [g]concordance with drug prescription: means that when dispensed drugs are delegated to another staff member, this person must compare the drugs to be administered with the prescriptions in the CPOE.
Abbreviations: CPOE, computerized physician order entry; PRN, pro re nata.

the error types mismatching between medication and patient and wrong patient. One study found mismatching between medication and patient to occur with the second highest frequency; whereas, the second study found wrong patient to constitute 4/108 (3.7%) of all administration errors.[10,14] These results emphasize the importance of systematically identifying patients to secure the right medication for the right patient. We found that administration errors constituted 142/340 (42%) of all errors, which is in contrast to a USA study of several stages in the medication process, which demonstrated that 10% of all medication errors were identified in the administration stage.[15] This disparity is most likely due to variation in error types. In an observational study of administration errors in elderly psychiatric patients, errors were identified in 369/1423 (25.9%) of opportunities for error. However, this result is not entirely comparable, because the aforementioned study did not include the error type lack of identity control or any of the related error types, such as wrong patient or mismatching between medication and patient.

The severity of administration errors in psychiatric settings has been assessed less severe when compared

Table 3 Categories of potential clinical consequences of errors in the medication process

	Nonsignificant n (%)	Significant n (%)	Serious n (%)	Fatal n (%)	Interrater variation
Prescribing, CPOE	0	4 (40)	4 (40)	2 (20)	$\kappa = 1,0^a$
Dispensing, observational study, n (%)	0	6 (66)	3 (33)	0	$\kappa = 0.82^a$
Dispensing, unannounced visit, n (%)	4 (44)	5 (56)	0	0	$\kappa = 0.75^a$
Administration, n (%)	29 (20)	38 (27)	73 (51)	2 (1)	$\kappa = 0.54^a$

Notes: [a]Kappa test for interrater agreement; the highlighted areas represent errors with the potential to harm patients.
Abbreviation: CPOE, computerized physician order entry.

to administration errors in somatic hospital settings.[11,15] However, this study assessed more than one-half of all administration errors to be potentially serious. Many hospitals have introduced wristbands as a means to control patients' identity, including the psychiatric hospital where our study was carried out. In a study of how and whether nurses identify patients in a psychiatric hospital setting, it was found that the use of wristbands was erratic and influenced by a psychiatric nursing culture rooted in the belief that (good) nurses know who the patients are.[22] The inconsistency in using the patient's wristband for identification has also been addressed in somatic settings, and it has been shown in simulation tests that as many as 61% of nurses do not discover an unexpected identity error.[23,24] This raises a question about how and when nursing culture plays a role in patient safety and whether this brings advantages or barriers. Nurses are involved in many errors, but nurses also prevent many errors from happening.[25] It needs to be considered that nurses are the professionals spending most time with the patients and, therefore, function as gatekeepers, where they can prevent errors and harm from reaching the patient. Nurses are coordinating several aspects of care to patients, including the care delivered by other health care professionals, and this is a major contribution to patient safety.[26]

Errors in discharge summaries constituted 10% (19/189) of all errors detected in the study. It is not possible to compare these results directly to other studies due to definitions and categorizations; however, earlier studies of errors in discharge summaries in general hospital settings have found discrepancies in 2%–76% of the prescribed drugs.[5,27,28]

It has been asserted that surgery and psychiatry are associated with the highest rate of dispensing errors and, therefore, it appears reasonable to consider psychiatry a high-risk specialty, in regards to dispensing errors.[29] We investigated dispensing errors using observation and unannounced control visit, which showed a difference in results. When using observation and unannounced control visit to identify dispensing errors the rate of errors was 9/324 (3%)

Table 4 Categories of drugs involved in errors with potential to harm patients

Drug category	Prescribing	[a]Dispensing (observational and unannounced control visit)	Administration
N Nervous system			
N02 Analgesics	2	0	0
N03 Antiepileptics	0	0	9
N05 Psycholeptics			
– Atypical antipsychotics	3	3	20
– Typical antipsychotics	0	1	9
– Anxiolytic-sedative	1	0	17
– Other	0	0	3
N06 Psychoanaleptics			
– Mood stabilizers	0	0	9
N07 Other nervous system drug	0		1
M Musculoskeletal system			
M01 Anti-inflammatory and antirheumatic products			6
H Systemic hormonal preparations, excluding sex hormones and insulins			
H03 Thyroid therapy			1

Notes: Drugs are categorized according to the Anatomic Therapeutic Chemical (ATC) Classification System (World Health Organization Collaborating Centre for Drugs Statistics Methodology [WHOCC]). [a]In this table, the observational and unannounced control visit in the dispensing stage have been collapsed.

and 9/67 (13%), respectively. The difference in identified errors is caused by dependency in data, which arises due to the few nurses and nurses' assistants involved in dispensing and administering medication. When pooling the results from the dispensing stage, the error rate was 18/391 (5%). This result is supported by other studies not depending on unit dose systems which found error rates <1% and up to 5%.[5,29,30] The most common error type in the dispensing stage was omitted dose, which is in accordance with a previous study using similar methods of error detecting but in a general hospital setting.[5]

In this present study, the clinical pharmacologists assessed three errors in the dispensing stage to be potentially serious, and no errors were assessed as potentially fatal. To our knowledge, there are no other studies in psychiatry where observed dispensing errors have been assessed for severity.

There were few prescription errors, but the prescription stage represented one-half of the potential fatal errors. Most of the prescribing errors were of the type "lack of PRN regime," which is a type of prescription error that nurses are capable of intercepting. On the other hand, it also places nurses in a situation where they possibly make independent decisions as to whether a PRN medication is appropriate. The use of PRN medication is often solely the nurses' decision and, perhaps, due to a lack of research into the use of PRN medication as an intervention in mental health care, the practice varies considerably.[31]

Strengths and weaknesses in the study

The majority of studies on medication errors and psychopharmacotherapy have been conducted in general hospital settings, and very few studies include a psychiatric population. Thus, this study is an important contribution to the current knowledge, as it focuses on errors in several stages of the medication process by applying the most sensitive method to each stage in a psychiatric hospital setting. There were 67 patients included in the study, which is a relatively small sample and a potential weakness in the study. Observation as a method of detecting errors is considered a valid and well-tested method; in this study, we sought to substantiate the validity of observing for errors with the unannounced control visit.[17,32] The difference in errors identified by observation and the unannounced control visit is solely due to the dependency in data caused by the few nurses and nurses' assistants participating in the study. In this study, dispensing of drugs was done by nurses and nurses' assistants, which might complicate comparisons with other hospitals and settings where hospital pharmacies undertake the dispensing of drugs. It appears the study has a good internal validity, but the study was carried out in a single university hospital, thus producing a limited external validity. However, it is evident that psychiatric university hospitals – in comparison with somatic hospitals – are equally challenged in improving the quality of the medication process.

Conclusion

Errors were found in almost one-fifth of all handlings of medication, and a proportion of these errors had the potential to harm patients. In this study, the majority of errors involved psycholeptics, but potential fatal errors also involved analgesics. Most errors were found in the administration stage, and studies suggest that both nursing culture as well as an irregular practice regarding the patient's identity wristband could be a risk factor for not checking the patient's identity. This could lead to the error type "wrong patient." It might be beneficial to address nursing culture as well as awareness of existing clinical guidelines. Further studies are needed to investigate how and whether nurses influence medication safety for in-hospital psychiatric patients and how nurses can improve the quality of medication and medication safety for psychiatric patients.

Disclosure

The authors report no conflicts of interest in this work.

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Supplementary tables

Table S1 Criteria and definitions for error types

Stage in medication process	Definition	Error types
Prescribing	Unambiguous prescription	Omission of drug name, drug formulation, route, dose, dosing regime, date, signature, length of treatment time where required
Dispensing	Dispensed medication is concordant with prescribed drug in electronic medication chart	Wrong drug, unordered dose, omission of dose, wrong dose, wrong drug formulation, contamination (ie, touching tablets without gloves), control of prescription (ie, controlling that only prescribed drugs are dispensed), ambiguous labeling of medication
Administering	The right medication to the right patient in the right way and at the right time	Wrong: dose, administration technique, route, time (±60 minutes), unordered drug, unordered dose, omission of dose, lack of identity control, wrong patient (one or more medications administered to the wrong patient), contamination, concordance with drug prescription
Discharge summaries	Eligible prescriptions in medical record are identical to prescriptions in discharge summaries	Discrepancy in: drug name, drug formulation, route, dose, regime, omission of drug, unordered drug

Note: Adapted with permission from Lisby M, Nielsen LP, Mainz J. Errors in the medication process: frequency, type, and potential clinical consequences. *Int J Qual Health Care*. 2005.
Abbreviation: CPOE, computerized physician order entry.

Table S2 Definition of potential clinical consequences

Category	Definition	Definition of keywords
Potentially fatal	Errors judged to imply a potential clinical risk for causing the death of the patient	Fatal refers to errors that could lead to the death of the patient
Potentially serious	Errors judged to imply a potential clinical risk of injuring the patient	Injury includes errors that would require active treatment to restore the health of the patient. A potentially serious error would lead to either permanent or temporary disability
Potentially significant	Errors judged to imply a potential clinical risk of being "inconvenient" for the patient – without causing any harm or injury	"Inconvenient" refers to unpleasant consequences of wrong dose/drug omission of dose/drug that could lead to pain, dizziness. It also refers to any monitoring of the patient, such as extra blood test, measurement of blood pressure
Potentially nonsignificant	Errors judged to be without any potential clinical risk for the patient	Without clinical risk refers to errors that did not lead to any injury or inconvenience for the patient

Notes: The highlighted areas represent errors with the potential to harm patients. Adapted with permission from Lisby M, Nielsen LP, Mainz J. Errors in the medication process: frequency, type, and potential clinical consequences. *Int J Qual Health Care*. 2005.

Reference

1. Lisby M, Nielsen LP, Mainz J. Errors in the medication process: frequency, type, and potential clinical consequences. *Int J Qual Health Care*. 2005;17(1):15–22.