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Journal Name:	<u>British Journal of Pharmaceutical Research</u>
Manuscript Number:	2013_BJPR_8607
Title of the Manuscript:	A Comparative Analysis of Electronic Prescribing Near Misses in King Saud Medical City, Riyadh, Saudi Arabia
Type of the Article	Original Research Article

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This journal's peer review policy states that **NO** manuscript should be rejected only on the basis of '**lack of Novelty**', provided the manuscript is scientifically robust and technically sound.

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PART 1: Review Comments

	Reviewer's comment	Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
<p>Compulsory REVISION comments</p>	<p>Results:</p> <ul style="list-style-type: none"> The total number of MEs/NMs report forms 21 was 3423 (1,025 in T1, and 2,398 in T2), and total number of reported NMs was 7415, as each form could contain more 22 than one NM. <p>Figure 2. Time-series graph of month-wise NMs rate for the year 2012 & Figure 3 & 4. Time-series graphs for NMs during the first 6-months (NMs1) and second 509 6-months (NMs2) during 2012</p> <ul style="list-style-type: none"> Time-series analysis To measure the seasonal fluctuation, and smooth the fluctuations in the data please estimate the trend of the time series; using one of these: <ul style="list-style-type: none"> <input type="checkbox"/> The moving-average method <input type="checkbox"/> Or spearman correlation <input type="checkbox"/> Logistic regression Time-series graphs 137 (Figures 2, 3 & 4) of NMs during 2012 show the different frequency of NMs between T1 138 and T2. Tables: NMs in the present report were examined during the two consecutive six-month 85 timeframes [T1 & T2]. The No. of NMs is 7415 : 2716 in T1, & 4699 in T2 (see table 1). All 	

Comment [is1]: Please put the number (and %) of reported NMs which contain more than one NM. Please put the number and % of missing values or excluded ME report from the analysis.

Comment [is2]: Figure 2 shows clearly the NMs rate wise during the T1 and T2

Comment [is3]: Not necessary to put the NMs rate in T1 and T2 separately???: to be deleted

Comment [is4]: percentage

Comment [is5]: Please put the statistical significance (p value).



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	<p>tables (except table 6, 7) have a total < 4000:</p> <ul style="list-style-type: none"> □ It is > total number of MEs/NMs report forms (3423) that could contain more than one NM, and/or more than on response for certain questions] □ it is about 1.5 times lower than the # of NM (7415). <p>→ 518 Table 2. Distribution of drug-related variables in NMs medication errors: the total is 3530: 1025 in T1 and 2505 in T2</p> <p>→ Table 3. Stages during which near miss medication errors were discovered</p> <p>→ 523 Table 4. Health professionals who committed near miss medication errors</p> <p>→ Table 5. Health professionals who identified near miss medication errors</p> <p>→ 529 Table 6. Actions taken by pharmaceutical staff in response to near miss medication 530 errors</p> <p>→ Table 8. Locations where near miss medication errors were made location</p> <p>→ Is the total # of location & gender of the patients must be equal to the total # of NM report forms?</p> <p>- Discussion, and references Mostly the same as the article of Ibrahim Abdulaziz Al-Zaagi , 2013:2 17–24. http://dx.doi.org/10.2147/IPRP.S52080 . www.dovepress.com</p>	
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Comment [is6]: Please explain

Comment [is7]: Total 3530:
In T1: 1025= # ME forms in T1
In T2: 2505: > # ME forms in T2

Comment [is8]: Total=3667

Comment [is9]: Total=3749

Comment [is10]: Total= 3429

Comment [is11]: Total= 7415: was, for every NM, an action taken?
In T1, the number of action taken was 2030 (< of number of NMs that was 2716 (see table1)); is there a modality of response " no action taken? or missing value?

Comment [is12]:
Total= 3425: The number of NM report forms in first and second half of the year were 1,025 and 2,398, respectively: lower than 1014 in T1 (are there missing value?), and 2411 in T2 > 2398 (more than one location) please explain)



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<p>Minor REVISION comments</p>		
<p>Optional/General comments</p>	<p>Well presented article (Written style and contents of all parts of the article), but:</p> <ul style="list-style-type: none"> - The data analysis is conducted on 3423 MEs/NMs report forms which contain 7415 NM. - The main total of all tables is equal to the # of report form: that is confusing for the reader. Please indicate in the methodology, or as notes in the tables on what the data analysis is conducted!! (See objective:The main assessment involves electronic prescribing 61 NMs recorded in ME report forms during the year 2012). - Some variables as (gender, location) must have the same total!! - The novelty is the comparison between the frequency of NM T1 and T2, but the significance of statistical test is absent!!! - Auto plagiarism+++ <p>Please :</p> <ul style="list-style-type: none"> - Put in the tables the total frequency (%) of missing value - Put the frequency and percentage of report forms which contain 1 or more NM. - Estimate the trend of the time series : To measure the seasonal fluctuation, and smooth the fluctuations in the data; - Do multiple regression analysis to take into consideration the confusion factors. - Avoid auto plagiarism <p>If not : the current article is considered as part 2 of the article of Ibrahim Abdulaziz Al-Zaagi , 2013 (to be published as a short communication ?)</p> <p>Ibrahim Abdulaziz Al-Zaagi , Khalid Abdulrahman Aldhwaihi, Dalal Salem Al-Dossari , Sara Osama Salem, Naseem Akhtar Qureshi . Analysis of reported e-prescribing near misses in King Saud Medical City, Riyadh. Integrated Pharmacy Research and Practice 2013:2 17-24. http://dx.doi.org/10.2147/IPRP.S52080 . www.dovepress.com The introduction, Materials and methods, data collection, results for the T1 period, and discussion are mostly the same in the above article (table 1) Auto plagiarism?!</p> <p>Title: A Comparative Analysis of Electronic Prescribing Near Misses in King Saud 5 Medical City, Riyadh, Saudi Arabia Ibrahim Abdulaziz Al-Zaagi , 2013:2 17-24.</p>	



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	<p>http://dx.doi.org/10.2147/IPRP.S52080 . www.dovepress.com. Analysis of reported e-prescribing near misses in King Saud Medical City, Riyadh</p> <p>A near miss is a medication error that happened but did not reach the patient. Near miss may also be defined as an error that reached the patient but did not result in harm.^{1 35}</p> <p>36 According to the Agency for Healthcare Research and Quality (AHRQ), a near miss is an event or situation that did not produce patient injury only because of chance.^{2 37} However, the Institute for Safe Medication Practices (ISMP) has criticized this definition.^{1 38} Near misses may occur in handwritten as well as electronic prescriptions. In the medical context, a near miss is a medication error that happened but did not reach the patient. A near miss may also be defined as an error that reached the patient but did not result in harm.²² However, according to the Agency for Healthcare Research and Quality, a near miss is an event or situation that did not produce patient injury only because of chance.²³ This definition, however, is criticized by the Institute for Safe Medication Practices (ISMP).²²</p> <p>ISMP</p> <p>39 considers a near miss as a close call, which is an event, situation, or error that took place 40 but was captured before reaching the patient. The ISMP considers a near miss as a close call, which is an event, situation, or error that took place but was captured before reaching the patient. Kessels-Habraken and colleagues</p> <p>41 extensively reviewed the literature on the definition of NM and defined three near miss incidents (Type 1-3).^{3 42} These were based on a combination of “patient reached” and 43 “patient harmed”, and focused on error handling processes in terms of detection, 44 explanation, countermeasures and their combinations. As a result, they developed a near 45 miss incident matrix. Near misses and medication errors are considered medical incidents (MIs).^{4 46}</p> <p>Further, Kessels-Habraken et al extensively reviewed the literature on the definition of near misses and defined three near miss incidents (type 1–3) based on a combination of “patient reached” and “patient harmed”, focused on error handling processes (detection, explanation, countermeasures, and their combinations), and developed a near miss incident matrix.²¹ Accordingly, near misses and medication errors are considered medical incidents.¹⁷</p> <p>An electronic prescribing system was implemented at King Saud Medical City (KSMC) in 2006 and since then no study has been carried out on medical incidents. In 2006, KSMC became the first Ministry of Health hospital to implement an electronic prescribing system.</p> <p>Materials and methods</p> <p>62 Material 62 and methods</p> <p>63 The study was conducted between 1 January to 31 December 2012 at KSMC,</p> <p>64 which is a major 1400-bed tertiary care hospital. Materials and methods</p>	
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	<p>This cross-sectional, prospective study was conducted over a 6-month period in 2012. The setting for this study was KSMC, which is a major tertiary care hospital with a 1400-bed capacity in Riyadh region. In 2006, KSMC became the first 65 Ministry of Health (MOH) hospital to implement an electronic prescribing system (EPS). In 2006, KSMC became the first Ministry of Health hospital to implement an electronic prescribing system.</p> <p>66 This tertiary care hospital serves a wide range of patients drawn from a large population 67 in and around Riyadh, many of whom present with complex medical problems and are 68 referred from different regions of KSA. The hospital's MEDI system, i.e., electronic 69 health record system, has been upgraded regularly since 2006. The EPS is connected to 70 the MEDI system. This hospital serves a wide range of patients drawn from a large population, many of whom present with complex medical comorbidities and are referred from different regions of KSA. The hospital's MEDI system (electronic health record system) has been upgraded regularly since 2006. The electronic prescribing system is connected to the MEDI system.</p> <p>Medical incidents from all divisions of the medical city are reported voluntarily to the medication safety unit of KSMC. All health care providers and consumers can report medication errors to this unit. The number of daily e-prescriptions at KSMC varies and does not</p> <p>71 include paper prescription or medication orders written on patients' charts. These prescriptions cover only electronic prescriptions and do not include paper prescriptions or medication orders written on prescription charts.</p> <p>72 Medical incidents (MIs) are reported voluntarily to the medication safety unit of 73 KSMC. All healthcare providers and consumers can report medication errors (MEs) to 74 this unit.</p> <p>Medical incidents from all divisions of the medical city are reported voluntarily to the medication safety unit of KSMC. All health care providers and consumers can report medication errors to this unit.</p> <p>Two coordinators, one from pharmacy and the other from Drug Poisoning 75 Information Center (DPIC) work on electronic MEs data collection, its entry into the 76 computer, and statistical analysis. They also produce quarterly ME reports. All MEs 77 reporters are required to complete an ME reporting form. The completed ME forms are 78 screened and reviewed by the pharmacy designee in the medication safety unit for 79 deciding whether or not the reported ME is a near miss. Thereafter, this ME form is sent 80 to DPIC for further review and statistical analysis. Sentinel errors are investigated by a 81 committee using root cause analysis (to be reported in a forthcoming paper). Two other 82 methods for reporting electronic prescribing NMs not used in this study are web and 83 telephone.</p> <p>Two coordinators, one from pharmacy and the other from the Drug Poisoning Information</p>	
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	<p>Center, work on electronic medication error data collection, its entry into the computer, and statistical analysis. They also produce a medication error report. Notably, all medication error reporters are required to complete a medication error reporting form. The completed medication error forms are screened and reviewed by the pharmacy designee in the medication safety unit for deciding whether or not the reported medication error is a near miss. Thereafter, this medication error form is sent to the Drug Poisoning Information Center for further review and statistical analysis. Sentinel errors are investigated by a committee using root cause analysis (a related separate paper is forthcoming on this). Two other methods for reporting near misses not used in this study are web and telephone.</p> <p>Data collection 101 Data collection 102 All medication error report forms were evaluated by the pharmacist and Drug 103 Poisoning Information Center staff. The relevant data were abstracted from these forms. 104 The variables examined were gender, medication-related variables such as drug types, 105 dose, frequency of administration, route of administration, dosage form, concentration, 106 and duration, details on reporters and interveners, types of errors, causes of errors, stages 107 of electronic prescribing NMs made, settings where NMs were made, actions taken to 108 avoid the occurrence of NMs, and suggested recommendations for preventing electronic 109 prescribing NM errors in the future. In addition, real practice MEs safety/prevention 110 programs at KSMC were also identified. For this purpose, key pharmaceutical care 111 managers of KSMC were consulted. This study was approved by the Academic 112 Department of KSMC that gave permission to analyze and publish our findings regarding 113 electronic prescribing NMs. Data collection All medication error report forms were evaluated by the pharmacist and Drug Poisoning Information Center staff. The relevant data were abstracted from these forms. The variables examined in this study were gender, medication-related variables (such as drug type, dose, frequency of administration, route of administration, dosage form, concentration, and duration), details on reporters and interveners, types of errors, causes of errors, stages of near misses made, setting where near misses made, actions taken against near misses, and suggested recommendations for preventing near miss errors in the future.</p> <p>From an ethical perspective, the research team submitted the required documents to the academic department of KSMC that gave permission to analyze and publish the reported near misses.</p> <p>Discussion Unlike 186 the female predominance in MEs, males were slightly overrepresented (1772 males vs</p>	
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	<p>1651 females) in this and our previous study^{18 187} despite the fact that in ambulatory care 188 females tend to utilize more healthcare services.. Unlike in medication errors, males were overrepresented in this study despite the fact that, in ambulatory care, females tend to utilize more health care services than males.</p> <p>Hence females who utilize more health care services paradoxically tend to have fewer near misses as evidenced in this study.</p> <p>This finding diverges from other reports²⁴ and therefore needs further study.</p> <p>Other important sites for NMs were pediatric and adults</p> <p>202 emergency and maternal ambulatory care services, which is consistent with other studies.^{5-6,12,18,20 203} Other important observed sites where near misses were made were pediatric and adult emergency service settings and maternal ambulatory care services, which is consistent with other studies.^{11-12,19,25}</p> <p>In general, factors such as patient's age, weight, diagnosis, prescribed medications, ²¹⁰ experience of health care providers, practice setting, and the presence or absence of EPS have a strong impact on the prevalence of MEs.^{16-17,21 211} Interestingly, similar factors predict the occurrence of NMs,^{22 212} an important aspect of medication errors. In general, multiple factors, including gender of patient, age, weight, diagnosis, prescribed medications, experience of health care providers, practice setting, and the presence or absence of an electronic prescribing system have a strong impact on the prevalence of medication errors.^{9,10,24} Similar factors tend to predict the occurrence of near misses.²⁶</p> <p>Tanaka and colleagues examined predictors ²¹⁴ of NMs and ²¹⁵ adverse events and found that those for NMs and adverse events are quite similar. Years ²¹⁶ of experience, frequency of night shifts, ward location, and time pressure were all ²¹⁷ significantly related to both NMs and adverse events. Tanaka et al²⁶ examined the predictors of near misses and adverse events, including age, gender, years of nursing experience,</p> <p>The predictors of near misses and adverse events in this study were quite similar, although years of experience, frequency of night shifts, ward location, and time pressure were significantly related to both near misses and adverse events.</p> <p>²¹⁸ According to this study, there was little difference between the causes of NMs and those of adverse events.²² Thus, it probably makes little difference whether near misses or adverse events are chosen for identifying possible causes of adverse events.²</p> <p>In a systematic review of ²²⁶ medication errors, Lisby and colleagues reported prevalence of MEs ranged from 2% to</p>	
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	<p>227 75%, with no association found between how MEs were defined and their prevalence. However, the majority of studies reported prevalence rates below 10%.²⁶</p> <p>In a systematic review of definitions and characteristics of medication errors, Lisby et al included 45 studies that reported prevalence of medication errors ranging from 2% to 75%, with no association found between definitions and prevalence. However, the majority of studies reported prevalence rates below 10%, despite a wide variation in rates reported.³⁵</p> <p>228 Approximately 35% of MEs are potentially preventable adverse events/near misses.^{27 229} Approximately 35% of medication errors are potentially preventable adverse events/near misses.³⁶</p> <p>These findings argue for the 242 presence of electronic checks in the process of prescribing and dispensing medications 243 throughout the year in order to prevent these medical incidents and the adverse health consequences and economic losses involved.³²⁻³³²⁴⁴ Therefore, there should be electronic checks in the process of prescribing and dispensing medications in order to prevent medication errors and the adverse health consequences and economic losses involved.^{1,2}</p> <p>The correct and complete documentation of medication-related variables in electronic prescriptions is mandatory ²⁴⁵ and strongly ²⁴⁶ recommended in clinical and pharmaceutical practice worldwide. Only when this is ²⁴⁷ accomplished will patient safety, quality care, cost reductions and decreased morbidity and mortality be ensured across the healthcare system.¹⁶⁻¹⁷ The correct and complete documentation of patient, health provider, and medication-related variables in electronic prescriptions is strongly recommended in clinical and pharmaceutical practice worldwide. Only then will patient safety, better quality care, and cost reductions, together with decreased morbidity and mortality be ensured across the health care system.^{9,10}</p> <p>This has been substantiated in 249 at least one study of NM events on labor and delivery, in which medication and patient identification errors were the most common near miss events.^{5 250} In another study of 251 perceptions of perioperative nurses, personal factors reflecting “communication between 252 team”, “inconsistent information,” and “incorrect monitoring” were the most frequently identified causes of near misses.⁷ This claim has been substantiated in one study of near miss events in labor and delivery, in which medication and patient identification errors were the most common near miss events.¹¹ In another study of perceptions of perioperative nurses, factors reflecting</p>	
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	<p>“communication between team”, “inconsistent information”, and “incorrect monitoring” were the most frequently identified causes of near misses.¹³ Medical incidents (MIs) can occur at any one of the five stages of medication administration, including medication prescribing.^{18,28 255}</p> <p>To address this issue further, a ²⁵⁶ study found that the phase affected by the most medication errors in all three models was ²⁵⁷ transcription and the least affected phase was administration, but prescription errors were the worst in single-dose systems.^{34 258}</p> <p>In another study, nurses reported that medication ²⁵⁹ administration and transcription errors were the most frequent types of NMs caused by ²⁶⁰ personal factors rather than by institutional factors. Medication errors can occur at any one of the five stages/phases involved in the process of medication administration: prescribing the medicine; dispensing the medicine;</p> <p>the phase affected by the most errors in all three models was transcription; and the least affected phase was administration, except for the single-dose system, in which prescription was the worst.</p> <p>The causes of near misses were more likely to be personal factors rather than institutional factors, This study emphasized that education ²⁶¹ to avoid personal errors, including STAR, i.e., stop, think, act, review, and verification of proper procedures, was imperative for nurses to avoid NMs.¹⁰ Top techniques to mitigate near misses included STAR (stop, think, act, review) and verification of proper procedures. In conclusion, education about mitigating techniques for near misses is imperative for nurses.¹⁶ Henneman and Gawlinski proposed that nurses manage medical errors by identifying and correcting them.^{37 285} Evidently, health professionals often do not report near misses for many reasons including fear and blame.³⁸²⁸⁶ Henneman and Gawlinski proposed how nurses as operators can manage medical errors by identifying and correcting them.³⁹ Evidently, health professionals often do not report near misses because of lack of understanding, fear, blame, ...⁴⁰</p> <p>In psychiatric settings, ²⁶³ medication administration errors are the most common errors, and distraction, poor communication and being unfamiliar with the ward are common contributory factors.^{11 264} ²⁶⁵ These results underscore the importance of double checking, training of health professionals, and focusing on physician entry in reducing near misses.^{10-11,18} In the psychiatric</p>	
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	<p>setting, medication administration errors were the most common errors (88.8%) and distraction, poor communication, and being unfamiliar with the ward were common contributory factors.¹⁸ These results are consistent with those reported in the present study and underscore the importance of double checking, training health professionals to avoid making such errors, and focusing on physician entry are recommended in order to reduce near misses.</p> <p>Physicians and nurses tend to make the most near misses, whereas 275 pharmacists 276 and nurses are those most likely to identify and report NMs. According to this study, physicians and nurses made the most near misses, whereas pharmacists and nurses identified and reported the most near misses.</p> <p>Furthermore, pharmacists are most likely to intervene in order to prevent medication errors.^{18, 29–31} Pharmacist interventions result in the prevention of up to 89% of medication errors.^{30, 31, 36} Pharmacists were most likely to intervene in order to prevent these errors, as many other studies have also found, and this role and the related tasks of clinical pharmacists have been discussed in the literature.^{29–31} Similarly, pharmacist interventions were those most likely to prevent medication errors (11%–89%).^{30,31,38}</p> <p>Evidently, health professionals often do not report near misses for many reasons including fear and blame.^{38 286} Evidently, health professionals often do not report near misses because of lack of understanding, fear, blame,</p> <p>According to our previous study¹⁸²⁸⁹, antibiotics, cardiovascular drugs, CNS agents, 290 nutritional products, GIT agents and coagulator modifiers were the most frequent 291 medications involved in NMs. According to the present study, anti-infective, cardiovascular, and central nervous system agents, nutritional products, gastrointestinal agents, and coagulator modifiers were the most frequent medications involved in near misses.</p> <p>Globally, antibiotics are prescribed most frequently and are the most common source of adverse drug events.^{39-40 292} As we found in the present study, antibiotics are prescribed most frequently in hospitals and are the most common source of adverse drug events.⁴⁵</p> <p>IV medications from multiple drug groups have been 295 associated with up to 54% of potential adverse drug events/near misses and 56% of medication errors.^{41 296} In addition, intravenous medications from multiple drug groups have been associated with up to 54% of potential adverse drug events/near misses and 56% of medication errors.⁴³</p> <p>It has been emphasized that the counseling of patients regarding medication use 302 and the documenting of details in e-prescriptions by physicians are key to preventing</p>	
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	<p>medication errors⁴⁵ 303 including near misses. Researchers have suggested that the counseling of patients regarding medication use and the documenting of details in e-prescriptions by physicians are key in preventing medication errors.⁴⁶ The advantages and techniques of patient counseling have been discussed.^{18, 46-47}³⁰⁴ Patient counseling is clearly 310 underused in this tertiary care setting. Counseling of patients regarding medication use 311 needs to be mandatory as it tends to reduce medical incidents and facilitates patient safety 312 and improves quality of life. On the other hand, the importance of patient counseling from several perspectives by trained clinical pharmacists is gaining ground globally.⁴⁷</p> <p>Patient counseling has multiple advantages, including prevention of medication errors, enhanced concordance and adherence, and improved outcomes.^{46,47}</p>	
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Note: Anonymous Reviewer