

1 **Simulated Medication Errors: A Means of Evaluating Healthcare Professionals' Knowledge and**
2 **Understanding of Medication Safety**

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29 **Abstract**

30 **OBJECTIVE:** To determine multi-disciplinary perceptions of the clinical significance of medication
31 errors (MEs), the responsible health professional(s), the contributing factors and potential preventive
32 strategies.

33 **METHODS:** The five simulated ME cases represented errors from five wards at a children's hospital
34 in Australia. Pre-determined answers for each case were developed through consensus among the
35 researchers. The root cause analysis (RCA) was undertaken via a questionnaire disseminated to
36 physicians, nurses and pharmacists at the study hospital to seek their opinions on the ME cases.
37 Agreement model between the participants and pre-determined responses regarding the contributing
38 factors was conducted using general estimating equation (GEE) analysis.

39 **RESULTS:** Of the 111 RCA questionnaires distributed, 25 questionnaires were returned. The
40 majority (93%) of respondents rated the significance of the MEs as either 'moderate' or 'life-
41 threatening'. Furthermore, they correctly identified two contributing factors relevant to all cases:
42 dismissal of policies/procedures or guidelines (90%) and human resources issues (87%). GEE
43 analysis revealed varied agreement patterns across the contributing factors. Suggested prevention
44 strategies focused on policy and procedures, staffing and supervision, and communication.

45 **CONCLUSION:** Simulated case studies had potential use to seek front-line healthcare professionals'
46 understanding of the clinical significance and contributing factors to MEs, along with preventive
47 measures.

48 **Keywords:** Medication error, root cause analysis, paediatrics.

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57 **1. Introduction**

58 Health service provision occurs in a complex and high-risk environment. Errors usually suggest
59 organisational system failure [1, 2]. Root cause analysis (RCA) is a form of system analysis that may
60 be used to investigate incident reports, as well as a tool for academic research or training. RCA
61 encompasses methods for retrospective, structured investigation of adverse incidents, near misses and
62 sentinel events [3]. There is broad consensus that RCA can be completed via different approaches
63 instead of a single method. One commonality between these approaches is the organisation of the
64 RCA in sequential steps [4].

65 When applied to health systems, RCA can be used to investigate all subsets of medication
66 misadventure, e.g. adverse drug events, adverse drug reactions and medication errors (MEs) [5]. In
67 Australia, medication misadventure places a significant burden on the health system, accounting for
68 2.4-3.6% of all hospital admissions in general patients, with up to 69% of these misadventures being
69 potentially preventable [6]. In the United States of America (USA), MEs account for a significant
70 proportion of errors during healthcare delivery [7]. In the United Kingdom, a 2007 National Patient
71 Safety Agency report cited over 86,000 incidents relating to ME in that year [8].

72 Some patient groups are particularly vulnerable to ME and their consequences. Studies of ME in
73 paediatric inpatients have reported incidence rates of 6% [9, 10] to 13% [11]. However, further
74 research is required to identify the medications of most concern and the children at greatest risk [12,
75 13].

76 Effective system improvement ascertains the underlying causes of ME through well-structured
77 investigations utilising RCA [5]. MEs are preventable and independent of the patient's physiology
78 and pathology, and hence are particularly suitable for RCA to prevent recurrence. Research suggests
79 that multiple health professionals, particularly those at the patient care interface, are commonly
80 implicated in the occurrence of MEs [7, 14]. However, research into the contribution of frontline
81 health professionals in preventing MEs, particularly in high-risk areas such as paediatrics, is lacking.

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83 RCA in healthcare settings such as surgery, emergency and pharmacy has been conducted using
84 authentic cases reviewed by medication safety teams [15-17]. Learning opportunities using this
85 approach are limited by the confidentiality of authentic cases. Use of simulated cases in RCA has
86 demonstrated improvements in terms of confidence and technical skills of staff, and ME reduction
87 [18]. RCA involving simulated cases may promote awareness and understanding of medication safety
88 issues including MEs without the fear of legal ramifications [18, 19].

89 This study aimed to apply RCA using a sample of simulated cases to determine multi-disciplinary
90 perceptions of the clinical significance of MEs and the responsible health professional(s).

91 Additionally, it aimed to investigate participants' views on the contributing factors for the MEs and
92 strategies to reduce error recurrence.

93 **2. Methods**

94 *2.1 Development of Simulated Clinical Case Studies and the Survey Instrument*

95 The principal researcher developed five simulated cases depicting paediatric patients, as described in
96 the Results section. The cases were based on the most common types of MEs observed in a major
97 children's teaching hospital in Western Australia [20]. Each case demonstrated one of the following
98 errors: prescribing error (setting = General Medical Ward for Infants), dispensing error (General
99 Medical Ward for Young Children), administration error (General Medical Ward for Adolescents),
100 transcribing error (Hematology-Oncology Ward) and monitoring error (General Surgical Ward). The
101 cases were constructed such that any nurse, physician or pharmacist could reflect on the scenario,
102 regardless of their specialty. Each case was reviewed by two experienced academic pharmacists for
103 accuracy of clinical information and representativeness of practice at the study hospital. For each
104 case, four or five contributing factors were pre-determined by the academic pharmacists and principal
105 researcher to allow comparison with the participants' responses. Three contributing factors were
106 common to all cases: dismissal of policies/procedures or guidelines, human resources, and
107 miscommunication (Table 1). Content and face validity of the questionnaire were reviewed by the
108 academic pharmacists.

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110 The questionnaire (available on request) was designed for self-completion by health professionals,
111 and comprised two sections. Section 1 documented participants' demographic characteristics (age,
112 gender, health profession, position, and years of experience as a health professional overall and in
113 paediatrics). Section 2 presented the five cases, followed by questions related to the ME and RCA.
114 ME-related questions required rating of the clinical significance of the error, as per methods reported
115 by the National Coordinating Council for Medication Error Reporting and Prevention/NCCMERP
116 [21] and identification of the health professional(s) perceived to have significantly contributed to the
117 error. RCA questions were adapted from the *Clinical Incident Management Toolkit* [22], whereby
118 participants identified the contributing factor(s) from six categories: specific patient issues, dismissal
119 of policies/procedures/guidelines, human resources-related issues, communication-related issues,
120 physical environment of the health service, and control/provision of medication. 'Unsure' and 'other'
121 options were also provided. Participants were also asked to suggest strategies to prevent recurrence of
122 the error. Questionnaires were produced in hard copy and code-numbered, only allowing
123 identification of respondents by health professional group (accompanying consent forms were
124 collected separately).

125 *2.2 Participants and Questionnaire Administration*

126 One hundred and eleven questionnaires were distributed during study period (July-October 2014).
127 Potential participants included all pharmacists in the hospital (n=37) and a convenience sample (20%)
128 of physicians (n=31; 5-6 physicians/ward) and nurses (n=43; 8-9 nurses/ward) from the five study
129 wards, with the intention to generate comparable numbers of responses that could be compared
130 descriptively. There is little published guidance for sampling in RCA studies; our intention was
131 exploratory analysis to compare patterns of agreement with the predetermined answers.
132 The principal researcher handed the questionnaires directly to all 37 pharmacists. To introduce the
133 study to physicians and nurses, questionnaires were distributed by the ward pharmacists or the
134 principal researcher under supervision of a ward pharmacist, using convenience sampling, to reach the
135 predefined number of potential participants per ward. Two reminders were emailed to all pharmacists
136 in August and September, while prompts to physicians and nurses were provided by the ward

137 pharmacists via email and/or ward meetings. Participants were asked to return the questionnaires and
138 the consent form by the predefined time in the envelope provided. The survey period was limited by
139 upcoming hospital accreditation.

140 *2.3 Data Analysis*

141 All data were entered into SPSS version 22.0. General Estimating Equation (GEE) analysis [23] was
142 used to develop an agreement model between the groups of participants' responses to the contributing
143 factors and the pre-determined answers for each case. The dependent variable in the GEE model was
144 disagreement regarding each factor. An odds ratio greater than one indicated greater disagreement
145 than the reference. In comparing the simulated cases, Case 5 was set as the reference. If the agreement
146 model using GEE was not able to be fitted (e.g. due to unanimous agreement), the results were
147 summarised using descriptive statistics. Participants' comments regarding the contributing factors
148 were entered into QSR NVivo version 10.0 to assist coding of emergent themes.

149 *2.4 Ethics approval*

150 Study approval was granted by the Human Research Ethics Committees of the study hospital (2923)
151 and university (PH-14-112923).

152 **3. Results**

153 Of the 111 RCA questionnaires administered to physicians, nurses and pharmacists, six (19%), 11
154 (26%) and eight (22%) were returned, respectively (overall response rate 23%). All of the returned
155 questionnaires were included in the analysis. This sample size, while low, enabled the planned
156 analysis. Most participants (52%) were aged 31 to 40 years, and the majority (84%) identified as
157 female. Each group showed a similar pattern of clinical experience (Table 2). Three of the physicians
158 were registrars and three were consultants/specialists. Four of the nurses were clinical nurses/clinical
159 midwives/clinical development nurses, and one was a clinical nurse/midwife consultant. Four of the
160 pharmacists held clinical pharmacist roles.

161 *3.1 Analysis of the Cases*

162 Case 1 hypothetically described a prescribing error involving digoxin, a high-risk drug, in a six-
163 month-old baby. The physician wrote the digoxin dose inappropriately (not including a leading zero
164 before the decimal point), resulting in a 100-fold higher dose and patient death. All but one of the
165 participants rated the error as 'life threatening'. All physicians and pharmacists perceived all three
166 health professionals (physician, nurse, pharmacist) as accountable. Nine of the 11 nurses agreed,
167 while the remaining two nurses pointed to their own profession as primarily responsible.

168 Case 2 illustrated a dispensing error where a locum pharmacist with poor vision and inadequate
169 supervision filled medication orders for a patient with a history of seizures. The dispensary was
170 arranged alphabetically by generic name, and the locum dispensed prednisolone instead of primidone.
171 All nurses and pharmacists rated the error as 'major' or 'life threatening'. The majority of the
172 physicians (83%) offered a similar assessment. Most (76%) participants identified two health
173 professionals (i.e. nurse and pharmacist) as responsible.

174 Case 3 described an error during drug administration. The patient, with a history of asthma and
175 seizures, was admitted due to asthma exacerbation. As levetiracetam was out of stock, five doses of
176 levetiracetam were omitted, triggering a seizure. All physicians and pharmacists and just over half
177 (55%) of the nurses rated the error as 'major'. There was little consensus between the groups
178 regarding who was responsible for the error.

179 Case 4 illustrated inadequate communication and documentation resulting in an anaphylactic reaction
180 in a patient with history of penicillin allergy. Over half (physicians 67%, nurses 55%, pharmacists
181 88%) assessed the error as 'life threatening', with varied perspectives about responsibility.

182 Case 5 related to a transcribing error, where an antifungal medicine was not re-charted for a newly-
183 diagnosed oncology patient. A non-oncology nurse had been deployed to this ward, and was unable to
184 identify the error. Over half of the nurses (55%) and the pharmacists (63%) rated the error as 'major'

185 in significance, whilst physicians most commonly (50%) considered it 'moderate'. All respondents
186 felt the physician had some responsibility for the error.

187 All errors were considered to have multiple contributing factors (Table 3). Dismissal of hospital
188 policies/protocols/clinical guidelines and human resources were perceived as the key issues in all
189 cases. In addition, half of the participants indicated that patient-specific issues had contributed to the
190 error in Case 1 (complexity of medical condition and young age) and Case 4 (patient's drug allergy).

191 Participants' comments relating to contributing factors identified the following themes:
192 miscommunication between staff, miscommunication between staff and the patient and/or patient
193 family, poor lighting, workspace, medication storage, documentation of administration, internal
194 transfer of medication, and staff health (only applicable to Case 2).

195 Suggestions regarding ME prevention mapped to the following themes: improved availability and
196 accessibility of clinical guidelines and strict adherence to hospital policies/protocols for high-risk
197 drugs; adequate staffing and staff supervision; adequate staff education and training/competencies;
198 effective communication between staff; patient empowerment (e.g. through education and
199 counseling); use of technology (e.g. electronic prescribing); and improving the physical environment
200 of the healthcare facilities (e.g. pharmacy layout).

201 *3.2 Agreement between Pre-Determined Contributing Factors and Participants' Responses*

202 Of the six contributing factors, two demonstrated convergence in the GEE model, due to very high or
203 complete agreement between responses from health professional groups and the pre-determined
204 factor. These factors were dismissal of policies/procedures or guidelines, and physical environment of
205 the health service.

206 Table 4 outlines the agreement model for the remaining four factors using GEE analysis. The analysis
207 showed significantly greater agreement about the contribution of patient-specific issues (i.e. low odds
208 ratios) for Cases 2 (dispensing error) and 4 (communication and documentation error) compared to
209 Case 5 (transcribing error). Case 4 was an outlier regarding human resources issues, with the high
210 odds ratio suggesting disagreement that human resources issues contributed to the communication and

211 documentation error. The participants were more likely to agree with the contribution of
212 communication in Case 3 (error during drug administration) and Case 4 (inadequate communication
213 and documentation), compared to Case 5 (transcribing error). With respect to control/provision of
214 medication as the contributing factor, the agreement with the pre-determined factors was similar
215 across all professions. The level of agreement was significantly higher for Case 4 than for Case 5.

216 **4. Discussion**

217 This study used paper-based simulated case studies; this method can reflect reality without potentially
218 identifying individuals implicated in authentic errors reported through hospital safety and quality
219 systems [18, 19]. Overall, a similar perspective was revealed among the participants across the three
220 professions on the clinical significance of the MEs, with the majority of participants rating the MEs as
221 “major” or “life threatening”, as intended in the design of the cases. However, the present findings
222 were not consistent with prior studies assessing medication-related events (i.e. MEs) either in
223 paediatric or adult patients. In such studies, physicians often rated the severity of the consequences of
224 MEs lower than pharmacists [24-26]. The observed high level of agreement in the assessment of
225 clinical significance of the MEs presented in this study might be due to less ambiguity in statements
226 of the outcomes of the MEs in the case studies, as opposed to documented interventions without clear
227 endpoints in the aforementioned studies. Furthermore, the majority of participants in this study
228 thought the MEs were the consequence of action/inaction of at least two health professionals. It has
229 been evident in this study that there was no clear pattern with each group to blame the other two
230 groups. In this sense, the health professionals substantiate the accountability of roles and
231 acknowledgment of shared responsibilities and teamwork in patient care. To some extent, the findings
232 of this study confirmed those of previous studies highlighting the nature of the healthcare process as
233 being ‘tightly coupled’ and ‘interdependent’, whereby deviations during the process were likely due
234 to the results of interactions among the care providers rather than a single person [7, 14].

235 In the present study, the varied responses to the likely contributing factors to each ME suggests
236 robustness in the simulated cases and depth of consideration by respondents. Furthermore, it
237 highlights the complexity in identifying root causes for errors, a concept recognised in the literature

238 [14, 27, 28]. Two contributing factors that were consistently identified by the researchers and
239 participants in all five cases were dismissal of policies/procedures or guidelines, and human
240 resources. As with this study, RCA of 17 critical incidents in a children's hospital in the Netherlands
241 found task and team factors were the most frequent contributing factors [14]. The task factors were
242 associated with awareness among the staff regarding the existence and implementation of clinical
243 guidelines and/or hospital protocols. Team factors referred to issues that can be resolved through
244 training [14].

245 The findings of a report on incident management (including medication-related incidents) in the New
246 South Wales public health system during 2005-2006 was in accordance with those of this study [29].
247 That study found issues related to policy and procedures, and communication (particularly
248 deficiencies in patient handover) to be the major contributing factors [29]. Consistent with this study,
249 RCA reports on adverse drug events submitted to the Veteran Affairs National Center for Patient
250 Safety in the USA in 2004 uncovered problems with policies or procedures, staff training and
251 education, communication, and equipment as common factors contributing to adverse drug events
252 [30]. Meanwhile, analysis of ME reports submitted to MedMARx (a National Medication Error
253 Reporting Program in the USA) revealed workplace distractions, staffing issues and workload
254 increases as the most frequently cited contributing factors related to MEs during hospitalization [31].
255 The similar perceptions among the health professionals collectively in our study indicated the key
256 professions are capable of identifying contributing factors to medication safety-related events.

257 As the contributing factors of MEs are numerous, evidence underlines the need for multiple strategies
258 for ME prevention [32]. Accordingly, analysis of the common themes of strategies proposed by
259 participants in this study identified the need for numerous strategies to prevent each ME. In line with
260 this study, the aforementioned Dutch study reported an average of five recommendations per analysis;
261 most recommendations related to task factors (36%), and required providing and/or adjusting hospital
262 protocols or guidelines (43%) [14]. The other recommendations were associated with team-based staff
263 training and technical adjustment to improve the work environment (e.g. quiet area for medication
264 preparation unit) [14]. In addition, findings of the current study correspond with strategies for ME

265 prevention in paediatrics recommended by the American Academy of Pediatrics Committee on Drugs
266 and the Committee on Hospital Care [33] and the Pediatric Pharmacy Advocacy Group [34].

267

268 As suggested by this study and other RCA studies, education of healthcare staff is an important
269 component of ME reduction [32, 35]. Pharmacists, with their knowledge and expertise of medicines,
270 are ideal educators for other health professionals, and their educator role has been shown to be an
271 effective ME prevention measure in a range of patient populations [33, 36]. Patient empowerment is
272 also recognised as a valuable strategy for ME prevention. Healthcare staff should educate patients
273 (and in the present case, families of paediatric patients) [37, 38] to improve their health literacy
274 regarding their medical conditions, medications and healthy lifestyles [39]. One common issue among
275 healthcare staff is their lack of awareness of hospital policies and procedures. In the current study, it
276 has been suggested that pharmacists are able to contribute not only to development of policies on
277 medication use (e.g. high-risk drugs, discharge medications), but also to communicate these policies
278 to other staff. Our study also confirmed the findings of previous RCA research that identified the
279 necessity of adequate communication between staff and patients and their families [40-42].

280 There are several limitations to this study. The response rate was low, possibly due to the perceived
281 time requirement to complete the task, and the study involved a single institution. A larger number of
282 participants and involvement of other paediatric institutions may reveal different trends in the data on
283 the clinical significance of the MEs, the contributing factors and participants' suggestions for ME
284 prevention. Additionally, presentation of pre-determined options could bias the results. The pre-
285 determined options were determined via consensus between the researchers, and other clinical experts
286 may give different assessments.

287

288 **5. Conclusion**

289 This is the first-known study demonstrating the use of RCA with simulated case studies in the field of
290 paediatric medication safety. RCA successfully evaluated healthcare professionals' (physicians',
291 nurses' and pharmacists') ability to assess the clinical significance of MEs, identify potential

292 contributing factors in MEs, and suggest strategies to prevent MEs. Knowledge and skills in this area
293 are critical in minimising medication misadventure in clinical practice and ensuring optimal patient
294 outcomes.

295

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300 **Conflicts of interest**

301 None declared.

302

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397 **Table 1. Researchers' pre-determined factors contributing to the medication errors**

Contributing factors	Case 1	Case 2	Case 3	Case 4	Case 5
Patient specific issues	Y	N	Y	Y	Y

Dismissal of policies/procedures or guidelines	Y	Y	Y	Y	Y
Human resources	Y	Y	Y	Y	Y
Miscommunication	Y	Y	Y	Y	Y
Physical environment of the health service	N	Y	N	N	N
Control/provision of medication	Y	Y	Y	N	N
'Other'	N	N	N	N	N

398 Y = contributing factor, N = non-contributing factor

399

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401 **Table 2. Description of participants**

Characteristics	Number of participants (%)		
	Physicians (n=6)	Nurses (n=11)	Pharmacists (n=8)
Age (years)			
21-30	1 (16.7)	3 (27.3)	0 (0.0)
31-40	4 (66.7)	4 (36.4)	5 (62.5)
41-50	0 (0.0)	2 (18.2)	1 (12.5)
>50	1 (16.7)	2 (18.2)	2 (25.0)
Gender			
Male	2 (33.3)	1 (9.1)	1 (12.5)
Female	4 (66.7)	10 (90.9)	7 (87.5)
Clinical experience (years)			
<5	0 (0.0)	2 (18.2)	0 (0.0)
5-10	2 (33.3)	2 (18.2)	2 (25.0)
11-20	3 (50.0)	4 (36.4)	3 (37.5)
>20	1 (16.7)	3 (27.3)	3 (37.5)
Paediatric experience (years)			
<5	0 (0.0)	2 (18.2)	2 (25.0)
5-10	2 (33.3)	4 (36.4)	4 (50.0)
11-20	3 (50.0)	4 (36.4)	2 (25.0)
>20	1 (16.7)	1 (9.1)	0 (0.0)

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404 **Table 3. Factors perceived to contribute to the medication error**

Factors	Number of participants, N=25 (%)				
	Case 1	Case 2	Case 3	Case 4	Case 5
Patient specific issues	13 (52)	1 (4)	8 (32)	22 (88)	11 (44)
Dismissal of policies/ procedures or guidelines	24 (96)	25 (100)	23 (92)	20 (80)	20 (80)
1. Error/omission in medication reconciliation	8 (32)	14 (56)	15 (60)	4 (16)	15 (60)
2. Clinical guidelines	15 (60)	15 (60)	8 (32)	0 (0)	3 (12)
3. Coordination of care	9 (36)	11 (44)	19 (76)	12 (48)	3 (12)
4. Medical record documentation	15(60)	1 (4)	2 (8)	12 (48)	7 (28)
5. Level and frequency of monitoring of patient	7 (28)	0 (0)	4 (16)	2 (8)	1 (4)
Human resources issues	22 (88)	24 (96)	23 (92)	16 (64)	24 (96)
1. Staff workload and inadequate staffing	10 (40)	19 (76)	15 (60)	2 (8)	24 (96)
2. Recruitment	0 (0)	0 (0)	0 (0)	1 (4)	4 (16)
3. Staff training and competencies	20 (80)	14 (56)	15 (60)	12 (48)	9 (36)
4. Staff supervision	14 (56)	14 (56)	7 (28)	1 (4)	6 (24)
Miscommunication	13 (52)	8 (32)	22 (88)	24 (96)	9 (36)
1. Miscommunication between staff	13 (52)	5 (20)	22 (88)	15 (60)	8 (32)
2. Miscommunication between staff and patient and/or family	2 (8)	5 (20)	7 (28)	20 (80)	6 (24)
Physical environment of the health service	1(4)	23 (92)	0 (0)	0 (0)	0 (0)
Control/provision of medication	11 (44)	20 (80)	21 (84)	3 (12)	9 (36)
1. Medication storage	1 (4)	14 (56)	4 (16)	0 (0)	0 (0)
2. Labeling	1 (4)	9 (36)	1 (4)	1 (4)	0 (0)
3. Documentation of administration	5 (20)	1 (4)	3 (12)	1 (4)	9 (36)
4. Internal transfer of medication	3(12)	6 (24)	17 (68)	0 (0)	0 (0)
'Other'	9 (36)	14 (56)	6 (24)	4 (16)	10 (40)

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407 **Table 4. Agreement between researchers and participants regarding contributing**
 408 **factors**

Variables	Odds ratio of contributing factors (p-value)*			
	Patient-specific issues	Human resources	Communication	Control/provision of medication
Case study [#]				
Case 1 (Prescribing error)	0.702 (0.406)	3.290 (0.160)	0.501 (0.318)	2.299 (0.191)
Case 2 (Dispensing error)	0.027 (0.003)	1.000 (1.000)	1.205 (0.763)	0.439 (0.206)
Case 3 (Administration error)	1.748 (0.369)	2.093 (0.568)	0.067 (<0.001)	0.334 (0.132)
Case 4 (Communication and documentation error)	0.090 (0.001)	13.744 (0.006)	0.020 (<0.001)	0.238 (0.034)
Case 5 (Transcribing error)**	1	1	1	1
Participants' role ^{##}				
Physician	1.114 (0.865)	1.677 (0.541)	0.299 (0.030)	0.522 (0.382)
Nurse	3.719 (0.039)	1.044 (0.954)	0.402 (0.125)	1.068 (0.900)
Pharmacist**	1	1	1	1

409 *Using General Estimating Equation analysis

410 **Set as a reference

411 [#]High agreement across the four contributing factors was seen in Case 4.

412 ^{##}Nurses shared less agreement with pre-determined answers regarding the contribution of patient-specific
 413 issues. Physicians were more likely to agree with researchers signifying communication as the contributing
 414 factor. No agreement with pre-determined answers for human resources and control/provision of medication as
 415 contributing factors of MEs.

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