

1 A retrospective review of medication-related incidents at a major teaching hospital and
2 the potential mitigation of these incidents with electronic prescribing and medicines
3 administration

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28 **Abstract**

29 **Objectives:** To describe the frequency of the different types of medication-related
30 incidents that caused patient harm, or adverse consequences, in a major teaching
31 hospital and investigate whether the likelihood of these incidents occurring would have
32 been reduced by electronic prescribing and medicines administration (EPMA).

33 **Methods:** A retrospective review of harmful incidents (n=387) was completed for
34 medication-related reports at the hospital between 1 September 2020 and 31 August
35 2021. Frequencies of different types of incidents were collated. The potential for EPMA to
36 have prevented these incidents was assessed by reviewing DATIX reports and additional
37 information, including results of any investigations.

38 **Results:** The largest proportion of harmful medication incidents were administration
39 related (n=215, 55.6%), followed by incidents classified as 'other' and 'prescribing'. Most
40 incidents were classified as low harm (n = 321, 83.0%). EPMA could have reduced the
41 likelihood of all incidents which caused harm by 18.6% (n=72) without configuration,
42 and a further 7.5% (n=29) with configuration where configuration refers to adapting the
43 software's functionality without supplier input or development. For 18.4% of the low-
44 harm incidents (n=59) and 20.3% (n=13) of the moderate-harm incidents, EPMA could
45 reduce the likelihood of the incident occurring without configuration. Medication errors
46 most likely to be reduced by EPMA were due to illegibility, multiple drug charts or
47 missing drug charts.

48 **Conclusion:** This study found that administration incidents were the most common type
49 of medication-related incidents. Most of the incidents (n = 243, 62.8%) could not be
50 mitigated by EPMA in any circumstance, even with connectivity between technologies.
51 EPMA has the potential to prevent certain types of harmful medication-related incidents,
52 and further improvements could be achieved with configuration and development.

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57 **Key Messages**

58 **What is already known on this topic:**

59 One intervention shown to reduce medication errors is 'Electronic prescribing and
60 medicines administration' (EPMA) systems.

61 **What this study adds:**

62 This study found that administration incidents were the most common type of
63 medication-related incidents, most of the incidents were classified as low harm. More
64 than half of the incidents could not be mitigated by any EPMA system even with further
65 development, but EPMA could reduce the likelihood of a small number of low-harm and
66 moderate-harm incidents.

67 **How this study might affect research, practice, or policy:**

68 EPMA could lead to a reduction of harmful incidents in hospitals, and further
69 improvements can be achieved with targeted configuration and development.
70 Recommendations provided by this study can be used by hospitals to target their
71 optimisation of EPMA.

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75 **Introduction**

76 Medicines are an integral part of healthcare but there is growing evidence of the
77 importance of medicines safety and the need to prevent medication errors to improve
78 patient safety. Medication related adverse events can be the result of people either
79 experiencing adverse drug reactions (not usually preventable) or as a result of
80 medication errors (usually preventable) [1,2]. Medication errors, which are commonly
81 understood as errors throughout the process of prescribing, dispensing, administering or
82 monitoring medicines, irrespective of whether this caused harm to a patient or not [3],
83 occur frequently. Although medication error classification may differ between
84 organisations, the principles of error reduction and clinical risk management still apply to
85 the underlying risks [4].

86

87 The data collected by the National Reporting and Learning System in England indicates
88 that medicines cause around 9% of total reported incidents in the NHS [5]. Across
89 England it's estimated that 237 million medication errors occur each year, with 66 million
90 having the potential to be clinically significant [6]. Current literature shows that around
91 half of adverse drug events (ADEs) are preventable in the secondary care setting [7,8].
92 Given the consequences of ADEs there is a significant need for preventative strategies
93 that systemically target medication errors to improve patient safety and reduce costs.

94

95 EPMA can be defined as the use of electronic systems to facilitate the communication of
96 a prescription or medicine order to aid the choice, administration, and supply of a
97 medicine. Electronic prescribing and medicines administration (EPMA) systems can
98 overcome certain drawbacks of paper-based prescribing and has been shown to reduce
99 medication errors. EPMA can eliminate errors due to poor handwriting and illegibility, a
100 particular problem for paper-based prescribing [9] and can also reduce problems due to
101 data loss. EPMA ensures legibility and completeness of a prescription and most systems
102 have in-built clinical decision support functionalities that provide decision support for
103 clinicians with recommended doses, routes and frequencies [10] to decrease the

104 likelihood of the clinician writing an incorrect prescription. Kwan [11] found that the use
105 of clinical decision support systems increased the percentage of patients received the
106 desired level of care by 5.8%.

107

108 At the time of the study, Nottingham University Hospitals (NUH) NHS Trust, a large
109 teaching Hospital in the East Midlands, relied solely on a paper-based system, except for
110 cancer patients receiving care via Chemocare (<https://www.cis-healthcare.com/>). The
111 Trust acquired funding to implement a next generation EPMA system called Nervecentre
112 (NerveCentre Software, Wokingham, UK) as the first part of a fully integrated electronic
113 patient record. Nervecentre has a range of clinical decision support and safety features
114 including the ability to build dose sentences, automatic interaction and allergy checking,
115 and barcode scanning for positive patient and medication identification
116 (<https://nervecentresoftware.com/next-gen-epr-3/epma/>).

117

118 This study investigated the different types of medication-related incidents at NUH from a
119 non-anonymous incident reporting system (DATIX [12], to 1) describe the frequency of
120 the different types of medication-related incidents that caused patient harm; 2) identify
121 and classify whether the likelihood of these incidents occurring, and associated risk could
122 have been reduced by EPMA, including clinical decision support. This research is
123 important because it identifies a novel way of determining what impact the EPMA system
124 could have on existing safety issues at the point of system selection and identifies
125 significant areas or themes relating to medication safety that cannot be solely addressed
126 by the implementation of an EPMA system.

127

128 **Methods**

129 *Study Design*

130 The study was a retrospective review of 3988 medication-related reports recorded by
131 healthcare professionals at Nottingham University Hospitals NHS Trust through the

132 DATIX incident-reporting system. This reporting system provided the framework for
133 classifying incidents in line with the requirements of the English National Reporting and
134 Learning System (NRLS) [13]. The reports represent the records of inpatients at the
135 hospital between 1st September 2020 and 31st August 2021. The study was approved by
136 the Clinical Effectiveness Department at the Trust and ethical committee approval was
137 not required.

138

139 *Data Sources/Measurement*

140 Data from DATIX included only medication-related incidents that were submitted and
141 classified by the reporter as medication related. Repeat entries were excluded and data
142 were anonymised. The incidents were classified into categories by the healthcare
143 professional that reported the incident. The DATIX categories refer to the stage in the
144 medication process where the incident occurred; these categories included:
145 Administration, Discharge, Pharmacy, Prescribing and there is also a category for Other
146 incidents. The incidents were then further categorised into more specific subcategories
147 (see Supplementary File 1).

148

149 The data extracted from each DATIX entry included the degree of harm to the patient,
150 and category and subcategory of the type of incident. The degree of harm was selected
151 by the healthcare professional reporting the incident and (except for no-harm incidents)
152 was confirmed or updated by a second person (an incident investigator within the Trust).
153 Staff are expected to assess harm in accordance with the incident reporting policy at the
154 Trust [14]. The policy defines each degree of harm and gives a non-exhaustive list of
155 examples.

156 The levels of harm were:

- 157 1. None: any unexpected or unintended event that resulted in no harm and no
158 additional treatment being required.
- 159 2. Low: any unexpected or unintended event that required extra observation or
160 minor treatment and caused minimal harm.

- 161 3. Moderate: any unexpected or unintended event that required further additional
162 treatment or an intervention of some kind and caused temporary or short-term
163 harm.
- 164 4. Severe: any unexpected or unintended event that caused permanent or long-
165 term harm.
- 166 5. Catastrophic (Death): any unexpected or unintended event that may have caused
167 death.

168

169 *Selection of Records*

170 Prior to the in-depth review of the data, any medication-related incidents identified in
171 the outpatient setting were excluded, as shown in Figure 1. From this point, all incidents
172 that were rated as no harm (3269) were removed from the review so only incidents with
173 a harm rating of low, moderate, severe, or catastrophic were reviewed (see Figure 2).
174 During the in-depth review, further exclusions were applied, as shown in Figure 2.

175

176 Insert Figure 1

177 Insert Figure 2

178

179 Some DATIX reports involved more than one incident per report. This brought the total
180 number of incidents to 387. This was the total number of incidents reviewed in-depth.

181

182 *Method for Assessing the Potential for EPMA to have Prevented Incidents*

183 MC and KH (trained in the process of reviewing incident reports) reviewed each report by
184 reading the original entry and any additional information, including results of any
185 investigations. They assessed to what extent EPMA (Nervecentre) could have reduced
186 the likelihood of each incident using the mutually exclusive outcomes shown below. The
187 classification of these outcomes took account of whether:

188

- 189 A. EPMA (Nervecentre) would reduce the likelihood of this incident occurring without
190 configuration.
191
- 192 B. EPMA (Nervecentre) could reduce the likelihood of this incident occurring with some
193 configuration.
194
- 195 C. EPMA could reduce the likelihood of this incident occurring with development.
196
- 197 D. EPMA could not reduce the likelihood of this incident occurring in any circumstances.
198

199 Any uncertainties or disagreements on outcome classification were brought to the team
200 for discussion. Incidents that were classified as being avoidable with the use of the EPMA
201 system (those classified as 1 or 2 above) were further run through EPMA test scripts to
202 determine whether the medication error scenarios were correctly categorised and
203 triggered an intervention by the EPMA system. The most common themes tested were
204 barcode scanning, duplicated administration, and drug-drug interaction. For example,
205 barcode scanning involved using an iPad or phone to scan codes for both the patient and
206 the drug before being able to administer it. Alerts were displayed if the incorrect patient
207 or drug was scanned, which would reduce the likelihood of incidents involving the wrong
208 patient and/or drug at administration.

209

210 *Data Processing and Analysis*

211 The reports on the DATIX system between 01/09/2020 and 31/08/2021 were
212 downloaded and stored in a Microsoft Excel spreadsheet, including the categorisation of
213 incidents. All reports available within the period were used (no missing data), however,
214 not all reports fitted the scope of the review (see figure 1 and 2). Each incident was
215 reviewed by reading all the information provided on the report and the potential impact
216 of EPMA was recorded on a Microsoft Excel Spreadsheet using the 4-point classification
217 system shown above. Microsoft Excel was also used to process the data and analyse the
218 results. Pivot tables were used to generate frequencies for each category and
219 subcategory and to obtain the frequencies of associated harm with each category. Pivot
220 tables were also used to obtain EPMA outcomes in relation to the category and degree of
221 harm. Descriptive statistics were determined and are reported.

222 **Results**

223 Of the 387 incidents reviewed, over half (55.6%, 215 incidents) were administration
224 related. Within this category, the largest subcategory (17.3%, 67 incidents) was 'non-
225 administration / dose omitted or significantly delayed', which was often due to poor
226 communication, human error (e.g., forgetting to give drug), distractions and low staff
227 numbers. Incidents classified as 'Other' accounted for 26.4% (102 incidents) of the total
228 number of incidents. New adverse drug reaction contributed the most to this category
229 with 44 incidents (43.1%) The frequency of incidents within each category and sub-
230 category are shown in Table 1.

231
232 Most incidents reviewed were classified as low harm (83%, 321 incidents), with the
233 remaining classified as moderate harm (16.5%, 64 incidents) apart from two incidents
234 (one severe and one catastrophic). In relation to administration incidents, 89.8%
235 (n=193) were low harm and 10.2% (n=22) were moderate harm. The category 'Other'
236 consisted of all four categories of harm: 65.7% low harm (67 incidents), 32.4%
237 moderate harm (33 incidents), 1.0% severe harm (1 incident) and 1.0% catastrophic
238 harm (1 incident). Table 2 shows incidents by level of harm.

239

240 **Table 1: Frequency of Incidents Within Each Category and Subcategory**

241

Subcategory of Incidents	Number of Incidents	Percentage (%) of total number of Incidents
Administration - drug incompatibility	3	0.8
Administration - incorrect day or time	14	3.6
Administration - incorrect dose	32	8.3
Administration - incorrect drug	16	4.1
Administration - incorrect frequency	20	5.2
Administration - incorrect rate	10	2.6
Administration - incorrect route	11	2.8
Administration - non-administration / dose omitted or significantly delayed	67	17.3
Administration - self-administration error	6	1.6

Administration - extravasation	36	9.3
SUBTOTAL ADMINISTRATION INCIDENTS	215	55.6
Discharge - delay in Pharmacy processing of TTO	4	1.0
Discharge - delay in prescribing of TTO	2	0.5
Discharge - patient discharged with incomplete set of medication or no medication	8	2.1
SUBTOTAL DISCHARGE INCIDENTS	14	3.6
Other - clinical trial error (prescribing, dispensing, administration, protocol violation)	4	1.0
Other - contraindication to the use of the medicine	16	4.1
Other - discrepancy in medication documentation records (CDs, drug chart, etc.)	4	1.0
Other - drug wastage (financial loss)	6	1.6
Other - faulty medicinal product	2	0.5
Other - incorrect injectable drug preparation: prescribing, administration, manufacturing (incorrect concentration/diluent, incorrect volume, incorrect drug /dose, incorrect label/ details missing on label)	4	1.0
Other - incorrect monitoring / failure to monitor therapeutic levels	7	1.8
Other - mismatching between patient and medicine (misidentification)	2	0.5
Other - missing medication or drug chart	5	1.3
Other - new adverse drug reaction / unexpected response / oversensitivity to drug	44	11.4
Other - patient with known allergy prescribed or administered a drug they are allergic to	4	1
Other - storage or transportation issues	2	0.5
Other - wrong expiry / omitted expiry / passed expiry date	2	0.5
SUBTOTAL OTHER INCIDENTS	102	26.4

Pharmacy - clinical pharmacist screening error	2	2.6	242
Pharmacy - incorrect directions on label	1	0.3	
Pharmacy - incorrect information or pharmacy advice (endorsement on chart, verbal or written information)	1	0.3	
Pharmacy - significant delay in supply or failure to supply (not TTOs)	1	0.3	
Pharmacy - transcription error	1	0.3	
Pharmacy - Unavailable Medication Stock	4	1.0	
SUBTOTAL PHARMACY INCIDENTS	10	2.6	
Prescribing - failure to prescribe a planned prescription	10	2.6	
Prescribing - incorrect day or time	3	0.8	
Prescribing - incorrect dose	19	4.9	
Prescribing - incorrect drug	10	2.6	
Prescribing - incorrect frequency	3	0.8	
Prescribing - incorrect rate	1	0.3	
SUBTOTAL PRESCRIBING INCIDENTS	46	11.9	
GRAND TOTAL	387	100	

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245 **Table 2: Frequency and Type of Reported Incidents Associated With Harm**

Category of Type of Incident	Level of Harm associated with Incident (row % of each category)				Total (column % of total incidents in category)
	Low	Moderate	Severe	Catastrophic	
Administration	193 (89.8)	22 (10.2)	0	0	215 (55.6)
Discharge	14 (100)	0	0	0	14 (3.6)
Other	67 (65.7)	33 (32.4)	1 (1.0)	1 (1.0)	102 (26.4)
Pharmacy	8 (80.0)	2 (20.0)	0	0	10 (2.6)
Prescribing	39 (84.8)	7 (15.2)	0	0	46 (11.9)
Total (% of total incidents)	321 (83.0)	64 (16.5)	1 (0.3)	1 (0.3)	387 (100)

246

247 Of the 33 incidents in the 'Other' category that were of moderate harm, 24 (72.7%)
 248 were due to a new adverse drug reaction, unexpected response to a drug or
 249 oversensitivity to a drug. Most of these incidents relate to opioid sensitivity.

250

251 In 18.6% (n = 72) of all incidents, the likelihood of the incident occurring could have
 252 been reduced by EPMA without configuration, 18.1% (13 incidents) of these were in the
 253 moderate harm category with none in the severe or catastrophic category. Nearly two
 254 thirds (65.3%, n = 47) of the incidents that would have been reduced by EPMA without
 255 configuration were in the category 'administration', which included drug-drug interaction
 256 and duplicate administration. A further 7.5% (n = 29) of the incidents could have been
 257 reduced by EPMA with configuration, 20.1% (6 incidents) of these were in the moderate
 258 or severe harm categories (5 moderate harm incidents and 1 severe harm incident). The
 259 vast majority of these incidents (79.3%, n = 23) were administration and prescribing,
 260 most of these were due to an incorrect dose. In 11.1% (n = 43) of all incidents, the
 261 likelihood of the incident occurring could have been reduced by an EPMA system with
 262 further development, 9.3% (4 incidents) of these incidents were in the moderate harm

263 category, with none in the severe or catastrophic category. Nearly 50% (21 out of 43)
264 were administration related, mostly within the subcategories of incorrect dose, frequency
265 and non-administration. Development needed to prevent the incorrect dosing was mostly
266 linking the system with infusions (including guard rails) and integration with laboratory
267 data. Half (10 out of the 21) of the administration incidents were neonatal related, with
268 8 of these involving gentamicin dosing (within incorrect frequency, dose or day or time
269 subcategories).

270

271 Our study suggests that EPMA would not be able to reduce the likelihood of the incident
272 in 62.8% (n = 243) of all incidents where harm was identified (see Table 3), 53.9% (n
273 =131) of these incidents were classed as 'Administration' and 29.6% (n = 72) were
274 'Other'. Just over half (60.9%, 131 out of 215) of the administration incidents could not
275 have been prevented by EPMA under any circumstance. Most of these incidents were due
276 to lack of communication, distractions, or shortage in staff – where EPMA has no impact.
277 For prescribing incidents, 45.7% (21 out of 46) could not have been prevented by EPMA
278 with many falling in the 'failure to prescribe' and 'incorrect dose' categories, where the
279 latter is not always preventable by EPMA systems that do not have clinical decision
280 support capabilities. For the vast majority of 'Other' incidents (70.6%, 72 out of 102),
281 EPMA could not have reduced the likelihood of the incident occurring, with all incidents
282 classified as new adverse drug reaction having this outcome.

283

284 Table 3 shows that in about 20% of incidents associated with low harm (18.4%, n = 59)
285 and moderate harm (20.3%, n = 13), EPMA could have reduced the likelihood of the
286 incident occurring without configuration. In contrast, 62.3% (n = 200) of low harm
287 incidents and 65.6% (n = 42) of moderate harm could not have been prevented with
288 EPMA.

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Table 3: Degree of Harm and associated EPMA Outcome

Degree of Harm of Incidents	EPMA Outcome* (row % per degree of harm)				Grand Total (column % of total)
	A	B	C	D	
Low	59 (18.4)	23 (7.2)	39 (12.2)	200 (62.3)	321 (83.0)
Moderate	13 (20.3)	5 (7.8)	4 (6.3)	42 (65.6)	64 (16.5)
Severe	0	1 (100)	0	0	1 (0.3)
Catastrophic	0	0	0	1 (100)	1 (0.3)
Grand Total (% of total)	72 (18.6)	29 (7.5)	43 (11.1)	243 (62.8)	387 (100)

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* Outcomes:

- A. EPMA (Nervecentre) would reduce the likelihood of this incident occurring without configuration.
- B. EPMA (Nervecentre) could reduce the likelihood of this incident occurring with some configuration.
- C. EPMA could reduce the likelihood of this incident occurring with development.
- D. EPMA could not reduce the likelihood of this incident occurring in any circumstances.

300 Discussion

301 *Summary of Findings*

302 This study found that administration incidents were the most common type of
303 medication-related incidents that caused patient harm (n = 179, 46.3%). Most of the
304 incidents that caused patient harm were classified as low harm (n = 321, 83.0%) with
305 64 (16.5%) classified as moderate harm. In 18.6% of all harmful incidents (n=72), the
306 likelihood of the incident occurring could have been reduced by EPMA without additional
307 configuration, and a further 7.5% (n=29) of incidents would have been reduced with
308 configuration. Most of the incidents (62.8%, n =243) could not be mitigated by EPMA in
309 any circumstance, even with integration with other technologies. For 18.4% of the low-
310 harm incidents (n=59) and 20.3% (n=13) of the moderate-harm incidents, EPMA could
311 reduce the likelihood of the incident occurring without configuration. Most of the low-
312 harm (n=200, 62.3%) and moderate-harm (n = 42, 65.6%) incidents could not be
313 reduced under any circumstance, which provides scope for further development of EPMA
314 systems.

315

316 *Strengths and Limitations*

317 Reporting systems in hospitals, such as DATIX, will inevitably involve underreporting
318 given that reporting is voluntary and time consuming, which means that reporting bias is

319 a limitation of our study. Therefore, the DATIX reports in this study may not be fully
320 representative of all incidents occurring. We analysed reported incidents, which means
321 that incidents that could not have been prevented by any EPMA system, such as new
322 adverse drug reactions, were included in our analysis, and is a limitation of our study.
323 This study reviewed only harmful incidents, thus focusing on what might be regarded as
324 the most important incidents, but potentially missing out on learning from no-harm
325 incidents that had the potential to cause harm.

326

327 It was noted that DATIX reports often varied in detail and sometimes this meant it was
328 down to the reviewer's interpretation to decide where in the medication process the error
329 occurred when assessing the potential impact of EPMA. To overcome this problem, any
330 uncertain or ambiguous reports were taken to the wider team to discuss; in some cases,
331 reports were excluded due to insufficient detail (see Figure 2).

332

333 Nervecentre was used as the EPMA system for this study. Other systems implemented in
334 different hospitals may offer different benefits and liabilities, but the experience of our
335 team suggests that our assessments are applicable to other EPMA systems used in the
336 NHS.

337

338 The classification system we use for medication incidents was based on the DATIX
339 reporting system which is commonly used in the UK. We acknowledge that this makes it
340 difficult to make comparisons with international studies of incident reporting, although
341 the World Health Organisation recognises that there are several different systems for
342 classifying patient safety incidents and the data from them are not directly comparable
343 [15]. Also, we note that the main purpose of the study was to assess the preventability
344 of incidents by EPMA, and here we have been able to make some comparisons with the
345 international literature.

346

347

348 *Comparison with Existing Literature*

349 The findings show that administration incidents are the most common type of patient
350 harm incidents reported at the Trust. Although this is consistent with current national
351 estimates [6], the national figures show that administration incidents contribute an even
352 higher proportion of total incidents. The reduction of incidents by EPMA shown in this
353 study is supported by studies that have looked at error rates before and after EPMA
354 implementation, which found that error rates were reduced [16-20]. For example,
355 Franklin [20] found that the introduction of an electronic prescribing system reduced the
356 percentage of prescribing errors by 47%.

357

358 Gates [21] concluded that although electronic systems significantly reduced prescribing
359 errors, he found no significant effect of electronic prescribing systems on patient harm.
360 Westbrook [22] also found that an electronic medication management system reduced
361 prescribing error rates, but there was no evidence of a reduction in harm. In contrast,
362 our research found that 37.8% of low harm incidents (n=121) and 34.4% of moderate
363 harm incidents (n=22) could be reduced by EPMA, on its own, with configuration or with
364 development, which agrees with Holdsworth [23] who found that EPMA reduced
365 medication errors that caused harm.

366

367 *Implications for secondary care*

368 This study has identified the potential impact of EPMA on medication-related harm in one
369 NHS Trust, but the findings are likely to be relevant to secondary care in the UK and
370 beyond. It is important to recognise that while certain types of incidents can be
371 prevented by EPMA, others are less amenable to electronic solutions. This includes
372 incidents where the predominant causes are communication failures, distractions,
373 inadequate staff numbers, and failures such as drug extravasation; strategies in addition
374 to EPMA are needed to address these types of incidents. In a survey of chief pharmacists
375 in NHS Trusts, Shemilt [24] found that although electronic prescribing systems enforced

376 policies through the use of mandatory fields, staff would sometimes bypass these fields
377 in order to expedite workflow.

378

379 In addition, it is important for healthcare providers to be aware that there can be
380 unintended adverse consequences from EPMA [25,26], although the benefits generally
381 outweigh the risks. Negative consequences can include an increase in clinician workload
382 and changes in clinical workflow [25]. Discrepancies between the structured and free-
383 text portions of the electronic record can lead to adverse drug events [26].

384 Understanding the adverse consequences of EPMA will enable developers to improve
385 their systems.

386

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390 **Author Contributions**

391 TA, TH, TD, AK and BI designed the study. MC and KH conducted and analysed the study
392 with support from all the other authors. MC and KH wrote the work up and BB wrote the
393 first draft of the publication. All authors reviewed and commented on the draft
394 publication and BB edited the final manuscript.

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396 No financial support was provided.

397 **Competing Interests**

398 The authors report no competing interests.

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401 **Ethical Approval**

402 The study was approved by the Clinical Effectiveness Department at the Nottingham
403 University Hospital NHS Trust; ethical committee approval was not required.

404

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484 **Figure 1: Flowchart showing the number of incidents identified in the**
485 **outpatient setting and excluded before the in-depth review of incidents**

486 **Figure 2: Flowchart showing the change in number of incidents during the in-**
487 **depth review.**

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