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Self-Reported Violations During Medication Administration in Two Pediatric Hospitals

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Abstract

Content—Violations of safety protocols are paths to adverse outcomes that have been poorly addressed by existing safety efforts. This study reports on nurses' self-reported violations in the medication administration process.

- Contributorship Statement: Alper: conception, design, acquisition, analysis, drafting, revising, and final approval
- Holden: conception, design, acquisition, analysis, drafting, revising, and final approval
- Scanlon: conception, design, acquisition, analysis, drafting, revising, and final approval
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Kaushal: conception, design, revising, and final approval

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Objective—To assess the extent of violations in the medication administration process among nurses.

Design, Setting, & Participants—Participants were 199 nurses from two U.S. urban, academic, tertiary care, free-standing pediatric hospitals who worked in: a pediatric intensive care unit (PICU), a hematology-oncology-transplant (HOT) unit, or a medical-surgical (Med/Surg) unit. In a cross-sectional survey, nurses were asked about violations in routine or emergency situations in three steps of the medication administration process.

Main Outcome Measure—Self-reported violations of three medication administration protocols were made using a 7-point 0-6 scale from "not at all" to "a great deal."

Results—Analysis of variance identified that violation reports were highest for emergency situations, rather than for routine operations, highest by HOT unit nurses, followed by PICU nurses, and then Med/Surge unit nurses, and highest during patient identification checking, followed by matching a medication to a medication administration record, and then documenting an administration. There was also a significant 3-way interaction among Violation Situation, Step in the process, and Unit, which is explained in detail in the Results.

Conclusions—Protocol violations occur throughout the medication administration process and their prevalence varies as a function of hospital Unit, Step in the process, and Violation Situation. Further research is required to determine whether these violations improve or worsen safety, and for those that worsen safety, how to redesign the system of administration to reduce the need to violate protocol in order to accomplish job tasks.

MESH Key Words

Patient safety; Compliance; Medication Administration; Violation

Keywords

Compliance; Human error; Human factors; Medical error; measurement/epidemiology; Patient safety

Introduction

Hospitalized patients may experience an average of one medication error per day.^[1] Errors at the medication administration stage of the medication use process are especially likely to result in patient harm because, with the exception of high-risk medications, no independent health care provider checks a medication before it is administered.^[23] To reduce errors in the medication administration process, protocols and technologies have been implemented.^[14] However, the success of protocols and technologies depends on compliance. Non-compliance with protocols, here referred to as violations, represents a path to medical injury that requires further study.^[5] Violations are actions that break rules, policies, protocols, or procedures.^[6] In the case of medication administration process should be carried out.

Violations in the medication administration process are known to occur,^[7-9] but to date no quantitative data exist on the extent or prevalence of violations. This study of pediatric nurses in two hospitals is the first to examine the extent to which nurses knowingly violate medication administration protocols. Because the violations are self-reported, intentional violations and unintentional violations recognized as violations after the fact are captured. Intentional violations are those committed knowing that rules, policies, or norms are being broken.^[1011] This study is also the first to examine how violations vary between two hospitals, between three types of hospital units, between three specific steps in the medication administration process, and between violations committed routinely versus in emergency situations.

Methods

This study was conducted as part of a broader study to evaluate the impact of a bar coded medication administration (BCMA) system on medication administration errors and on end users (nurses, pharmacists, and pharmacy technicians). This study analyzes cross-sectional data from a paper survey administered at two hospitals before either one implemented BCMA. The study was approved by the University of Wisconsin-Madison IRB and by the IRBs of both study hospitals.

Setting and Sample

Two urban, academic, tertiary care, free-standing pediatric hospitals participated in the study. Hospital A had 222 beds and was located in the Midwest U.S. Hospital B had 162 beds and was located in the South U.S. Three units were studied in both hospitals: a pediatric intensive care unit (PICU), a hematology-oncology-transplant unit (HOT), and a general medical/surgical unit (Med/Surg).

Full-time nurses (24 hours per week or more) who provided patient care in the study units were eligible to participate. The sampling frame was 203 nurses from Hospital A and 144 from Hospital B. Surveys were distributed to all nurses in the sampling frame. Data were collected November–December, 2005, and March–May, 2006, at Hospitals A and B, respectively. Response rates of 59.6% and 54.2% were attained in Hospitals A and B, respectively. Descriptive statistics are provided in Table 1.

Measures

The questions about violations were developed based on previous research,^[1012] and are provided in Table 2. Respondents were instructed to think of the past 30 days.

Design and Procedures

Pretesting—Questionnaire items were evaluated using expert review and cognitive interviewing.^[13] Expert reviews were completed by safety trained experts, nurse researchers, a pharmacist co-investigator, and two questionnaire design experts to assess readability, word choice, question clarity, and question content. Sixteen cognitive interviews were conducted with nurses at large teaching hospitals to appraise content validity.^[14] Through these interviews, it was determined that nurses had a shared understanding of the

protocols relevant to the questions and of the meaning of breaking protocol. In addition, nurses reported interpreting the response scale as one of frequency. That is, when asked, for example, "why did you choose to circle the 2 ("some") instead of the 3 ("moderate")" the nurses would respond that they only violated some of the time, not a moderate amount of the time.

Procedures

Publicity: The study team worked with nurse managers on the study units and with the research coordinators at each hospital to determine where to hang flyers advertising the study. One flyer provided information about the study; another listed "frequently asked questions" and answers to those questions. Some nurse managers sent emails to nursing staff encouraging them to participate in the study and/or made the PowerPoint presentation of the study available electronically.

Survey Administration: When possible, members of the research team attended staff meetings to speak with nurses and hand out surveys. All survey packets were delivered in personalized envelopes which contained the survey, an information sheet (consent form not requiring a signature), a stamped, addressed envelope in which to put the completed survey and mail it back to the survey processing center, and a \$5 cash incentive. In addition to, or in lieu of, staff meetings, the research team presented the study to nurses during the report at the beginning of the nurse's shift or during informal inservices. When few surveys remained to be delivered, the research team attempted to find each nurse to provide an individual presentation of the study and to deliver that nurse's survey. Before giving surveys to subjects, the research team endeavored to speak with each of the subjects to tell them about the study, how to participate in the study, and about measures taken to ensure their confidentiality. After the presentation, time was left for subjects' questions. Then, subjects was used to encourage nurses to complete the survey. To protect confidentiality, all nurses received identical-looking reminders.

Analysis

A four-factor mixed measures factorial model^[1516] was carried out in SPSS version 16.0 (Chicago, IL)^[17] using a 2 (Hospital: Hospital A, Hospital B) by 3 (Unit: PICU, HOT, Med/ Surg) by 3 (Step: matching the medication to the medication administration record [Match-MAR], checking patient identification [ChxID], and documenting administration of the medication [DOC]) by 2 (Violation Situation: Routine, Emergency) design. Step and Violation Situation were within-subjects variables. Hospital and Unit were between-subjects variables. Contrasts were run for significant interaction terms. The ANOVA was performed on the untransformed data and on the rank transformed data and very similar results were obtained. Therefore, based on Conover,^[18] the results of the ANOVA with untransformed data are presented here.

Interaction contrasts were carried out using Graphpad Software.^[19] A False Discovery Rate (FDR) approach was used to correct for family-wise error rate for numerous interaction contrasts. FDR is the expected proportion of false positive findings among all the rejected

hypotheses. Compared to the typical approach (e.g., Bonferroni, Sidak, etc.), FDR is not as conservative and provides a good balance between discovery of statistically significant effects and limitation of false positive occurrences (see details elsewhere^[20]).

Results

Table 3 provides means and standard deviations for each Step of the medication administration process in each Hospital, each Unit within each hospital, overall for both hospitals, and for each type of unit across hospitals. Additionally, the percentage of nurses reporting ever violating (a response > 0) is reported. Appendix 1 shows the raw distributions of responses in a mosaic plot; the plot provides the complete distribution of responses on the 7-point response scale for: both Violation Situations, both Hospitals, the three types of Units, and the three Steps of the edication administration process.

Significant Effects (Main Effects)

The main effects (testing for the effects of individual variables, without regard for interactions or moderating effects) for the variables of Unit (F (2, 1158) = 3.47, p<0.05), Step in the process (F (2, 1158) = 17.52, p<0.05) and Violation Situation (F (1, 1158) = 77.63, p<0.05) were significant. Effect sizes for significant effects, based on Cohen's D, were 0.26 for Unit, 0.26 for Step, and 0.49 for Violation Situation. For Unit, violations scores were highest for HOT, followed by the PICU, and then Med/Surg. For Step, violation scores were highest for ChxID, then Match-MAR, and finally DOC. The main effect for Violation Situation showed that violations scores were higher in emergency situations. The main effect for Hospital was not significant (F (1, 1158) = 2.80, p=0.096).

Significant Effects (Interaction Effects)

Interactions effects, which test the hypothesis that the effect of variable A on the outcome differs depending on the level of some variable B, are more illuminating than the main effects as they test whether and how main effect are moderated by another variable. The four-way interaction among the four main effects was not significant. There was a significant Unit by Step by Violation Situation interaction (F (4, 1158) = 3.24, p<0.05). To ease discussion of the three-way interaction, the two-way interaction between Unit and Step is discussed for each level of Violation Situation. Figures 1a and 1b show the 3-way interaction.

Routine Situations

Contrasts for the three-way interaction show that there were no differences among the three units for DOC or Match-MAR for routine violations (Figure 1a). However, for ChxID, the HOT units had significantly higher routine violation scores than the PICUs and Med/Surg units. In both the PICU and HOT units, routine violations in ChxID were reported more than violations in Match-MAR. Across units, significantly more violations were self-reported in ChxID than in DOC.

Emergency Situations

In emergency situations (Figure 1b), there were significant Unit differences for all three Steps of the medication administration process. For Match-MAR, the PICUs and HOT units had significantly higher emergency violation scores than the Med/Surg units. For ChxID, all three units significantly differed from each other; the HOT units had higher violation scores than the PICUs and Med/Surg units; the PICUs had significantly higher violation scores than the Med/Surg units. Finally, for DOC, the HOT units had significantly higher violations scores than both the PICUs and Med/Surg units.

Across units, there were no significant differences between reported violations in Match-MAR and ChxID. In both the PICUs and HOT units, there were fewer reported violations in DOC than in either Match-MAR or ChxID; in the Med/Surg units, there were no differences between steps.

Discussion

This study provided the first attempt at quantifying violations in the medication administration process. The results show that, based on nurses' self reports, depending on the Unit of care, the Violation Situation, and the Step of the medication administration process, violations were reported by as few as 33.3% to as many as 90.8% of nurses (defined as any non-zero response); reports of violations were not limited to one or two aberrant scenarios. This study also provided the first assessment of the extent to which violations vary by structure and process variables; violations do vary depending on the Violation Situation, the care Unit, and the particular Step of the medication administration process.

The study confirms findings from qualitative studies that show violations of protocols and technology use policies occur in the medication administration process.^[7-92122] This study extends prior findings by showing the extent of the violations and the structure and process variables that contribute to varying violation rates.

Significant Effects (Main Effects)

Main effects were found for Unit, Step, and Violation Situation, but not for Hospital. The null finding for Hospital is as important as the significant main effects. Not finding hospital differences demonstrates that our findings were not isolated to what might otherwise have been labeled a problematic hospital. Instead, we found similar self-reported violation levels at two highly regarded pediatric hospitals. We cannot say for sure if other pediatric hospitals have similar levels of violations, but our findings do not rule out that violations in medication administration are a systemic phenomenon.

The data also show that violations during emergency situations are more likely to be reported than routine violations, that violations are more likely to be reported in the hematology units (HOT), followed by the intensive care units (PICU), and then by medical-surgical units (Med/Surg), and that violations are more likely to be reported in the checking identification (ChxID) process, followed by matching medication to MAR (Match-MAR), and then by documentation (DOC). The significant 3-way interaction between Unit, Step,

and Violation Situation provides a more accurate picture of those variables than the main effects, and is discussed next.

Significant Effects (Interaction Effects)

In routine situations, violations of the protocol for ChxID are reported more often on the HOT units than on the other two units. Greater reporting of ChxID violations in HOT compared to in other units may be partially explained by longer patient stays in HOT units due to the nature of those patients' diseases. Because patients are on the unit for a long time, nurses are better able to get to know the patients and may perceive that following the protocol for checking identification of these more familiar patients is less necessary. There may be a misunderstanding of the need for the identification check as per protocol: the check goes beyond verifying that the nurse knows the patient; it also ensures the medication in hand matches the patient. A nurse could accidentally take the wrong medication for the right patient, or have the "right" medication, but get distracted and go into the wrong patient's room—in both cases, simply recognizing the patient in the room may not prevent the misadministration.

In emergency situations, the picture is different. Typically, the HOT units had the highest reported levels of violations in emergency situations, followed by PICUs, and then Med/ Surg. Why the HOT units had the highest reported levels requires further investigation. The reason for their reporting of higher levels of violations of Match-MAR may be related to patients having long lengths of stay, but it is not clear why violations of DOC would be higher.

Interestingly, in emergency situations, violations of Match-MAR were reported more than violations of ChxID and DOC in all units (though not significantly more in all cases). This differs from routine situations, in which violations of ChxID were most-reported. This may be because the MAR was located in a patient's chart and not necessarily available at bedside, unlike the patient identification. Another possibility is that the MAR may be less relevant during an emergency; emergency medications may be ordered and administered without first being entered into the MAR.

Violations in Healthcare Settings

Rules, policies, and procedures assume a work environment that is favorable to compliance. In contrast, healthcare delivery, especially in inpatient PICUs and HOT units, is characterized by time pressure, high acuity patients, and a need for problem solving. In those environments, medication administration is highly complex and filled with interruptions to manage and challenges to resolve.^[23-26] When the reality of a clinical environment does not match the environment assumed by designers of rules or policies, violations are to be expected—because there is not enough time to comply with protocols, because the cost of compliance is perceived as higher than the cost of violating, or because different protocols may conflict.^[582728] The presence of conflicting goals is common in complex systems like health care^[29] and makes it more likely that violations will occur regularly.

Importantly violations do not imply less safety; violations may reduce, have no impact on, or even improve safety.^[103031] While violations may increase the likelihood and severity of

adverse events,^[1132] violations can also be necessary or even desired (by a patient or family) such as when compliance would slow down a process that requires speed to save a life.^[33] In such cases, it is the clinician who, while technically violating a rule, might be in fact making "the difference between total disaster and a small accident, or no accident at all."^[34]

Limitations

This study has four main limitations. First, the questions captured self-reports of violations rather than the actual number of violations. Therefore, we cannot report actual rates of violations. Our data only give a sense of the extent of intentional violations that nurses were able and willing to self-report. Violations committed unknowingly would not have been captured in this analysis. While observing violations is possible, and may have provided a more accurate count of violations, differentiating between intentional and unintentional violations is impossible because the observer cannot know the subject's intentions. Further, nurses may choose not to violate while being observed because violations are socially undesirable.

Second, only two hospitals participated. This limits the generalization of the findings. However, most published patient safety studies have occurred in a single institution. The lack of a main effect for Hospital suggests that the extent of the violations is not limited to one hospital. A related point is that we did not adjust for the demographic differences between the hospitals so we do not know if any of the existing results could be explained by differences in, for example, job experience. This should be addressed in future research. Third, because of the question wording, we do not know the specific violation behaviors that respondents had in mind when they reported committing violations, generally. For example, we do not know if a reported violation of ChxID meant only checking one patient identifier instead of two, checking no identifier at all, or violating the protocol in some other way. Future research will need to obtain such specifics.

Fourth, there could be response bias. The response rates were acceptable, but we do not know how non-respondents differed from respondents. The response rate is high enough, however, that even if all non-respondents reported not violating at all, the data would show high levels of reported violations. Finally, though not a limitation per se, this study does not explain how to address violations. There exists general knowledge about violation causes in work domains,^[27] and there is emerging evidence from healthcare,^[782235] but more research is needed.

Conclusion

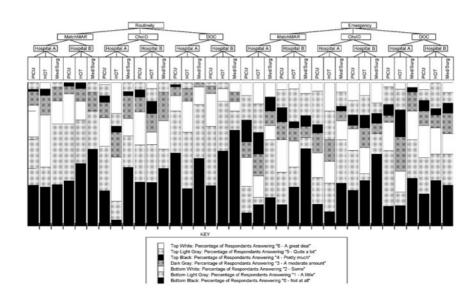
This study demonstrates that violations occur in the medication administration process across Hospitals, Units, and Steps in the process. Importantly, factors such as the Unit in which a nurse works, whether or not a nurse is in an emergency Violation Situation, and the Step of the medication administration process all interact to influence intentional violations. This finding is important as it provides empirical evidence that structural and process variables influence intentional violations. Just as safety scientists urge a shift from blaming people for medical errors to studying the causes of errors, we strongly advocate not blaming

clinicians for violations, but rather searching for a more systems-oriented causal explanation. It is, after all, the causes of violations that need remediation.

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Appendix



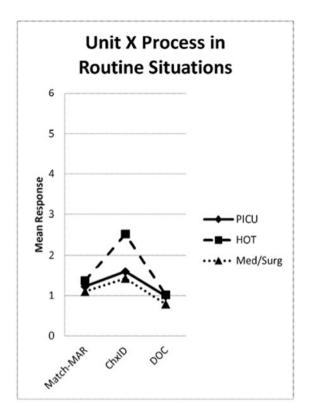
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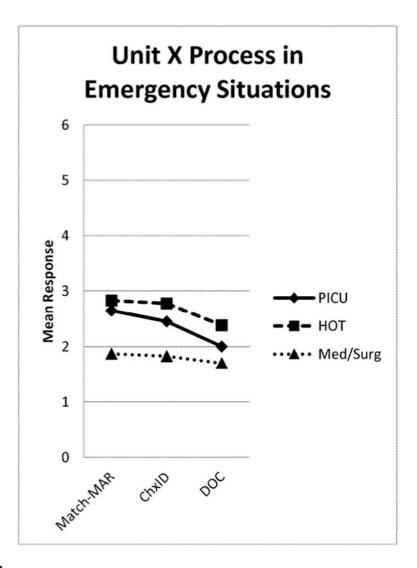


Figure 2.

a and b show the 3-way interaction of Unit \times Process \times Situation. Figure 1a shows how Unit and Process vary within Routine Situations and Figure 1b shows how Unit and Process vary within Emergency Situations.

Table 1

Descriptive statistics.

	Hospital A	Hospital B
Response Rate	59.6% (n=121)	54.2% (n=78)
Gender (% female)	97.5	96.2
Race (% white, not Hispanic)	93.4	94.9
Education (% completing college)	93.4	97.4
Age*		
18-29	33.1	56.4
30-39	32.2	20.5
40-49	24.8	15.4
50+	9.9	7.7
Shift		
Day	43.0	43.6
Evening / Afternoon	32.2	2.6^{\dagger}
Night	24.8	37.2
Other (e.g. weekends)	10.7	16.7
	Mean (SD)	Mean (SD)
Hours / week **	31.3(7.8)	37.3 (6.8)
Job tenure ^{**}	8.9 (8.1)	4.4 (5.7)
Unit tenure ^{**}	8.1 (7.6)	3.9 (5.4)
Employer tenure **	9.2 (8.2)	4.8 (5.9)
Occupation tenure**	11.6 (9.4)	7.7 (8.0)

* p 0.05 (Pearson chi-square)

** p 0.05 (t-test, equal variances not assumed)

 $^{\dagger}\text{Hospital B}$ had limited options for evening shifts; the majority of nurses were allowed only 12-hour shifts

Table 2

Questions and response scale used in study. Numbered Questions in Table 2 correspond to numbered Violation Situation / Steps in Table 3.

Alper et al.

1In actual practice, to what extent do your find yourself routinely having to beeak protocol for matching medications to the MAR/medication profile?012345602In actual practice, to what extent do your find yourself routinely having to medications?012345603In actual practice, to what extent do you find yourself routinely having to beeak protocol for checking patient identification in order to administer medications?012345604In a mergency situation, to what extent do you find yourself having to beeak protocol for metaling administered medications?012345605In an energency situation, to what extent do you find yourself having to beeak protocol for checking patient identification in order to administer dencinacións?012345606In an energency situation, to what extent do you find yourself having to beeak protocol for checking patient identification in order to administer dencinacións?012345606In an energency situation, to what extent do you find yourself having to beeak protocol for checking patient identification in order to administer0123345606In an energency situation, to what extent do you find yourself having to beeak protocol for checking patient identification in order to administer0123345<			Not at all	A little	Some	Not at all A little Some A moderate amount Pretty much Quite a lot A great deal Don't know	Pretty much	Quite a lot	A great deal	Don't know
In actual practice, to what extent do you find yourself routinely having to medications?0123345603In actual practice, to what extent do you find yourself routinely having to be ake protocol for documenting administered medications?012345604In actual practice, to what extent do you find yourself having to be ake protocol for matching medications to the MAR/medication profile?012345605In amergency situation, to what extent do you find yourself having to medications to the MAR/medication profile?012345606In amergency situation, to what extent do you find yourself having to medications?012345606In amergency situation, to what extent do you find yourself having to medications?012345606In amergency situation, to what extent do you find yourself having to medications?012345607In amergency situation, to what extent do you find yourself having to medications?012345608In amergency situation, to what extent do you find yourself having to medications?012345609In amergency situation, to what extent do you find yourself having to medications?0123<	1	In actual practice, to what extent do you find yourself routinely having to break protocol for matching medications to the MAR/medication profile?	0	1	2	3	4	5	6	0
3In actual practice, to what extent do you find yourself routinely having to break protocol for documenting administered medications?012345604In an emergency situation, to what extent do you find yourself having to break protocol for matching medications to the MAR/medication profile?012345605break protocol for matching medications to the MAR/medication profile?012345606break protocol for checking patient identification in order to administer medications?012345606In an emergency situation, to what extent do you find yourself having to medications?01234560	2	In actual practice, to what extent do you find yourself routinely having to break protocol for checking patient identification in order to administer medications?	0	1	2	3	4	5	6	0
4In an emergency situation, to what extent do you find yourself having to break protocol for matching medications to the MAR/medication profile?012345601In an emergency situation, to what extent do you find yourself having to medications?012345606In an emergency situation, to what extent do you find yourself having to medications?012345606In an emergency situation, to what extent do you find yourself having to break protocol for documenting administered medications?01234560	3	In actual practice, to what extent do you find yourself routinely having to break protocol for documenting administered medications?	0	1	2	3	4	5	9	0
In an emergency situation, to what extent do you find yourself having to break protocol for checking patient identification in order to administer012345606In an emergency situation, to what extent do you find yourself having to break protocol for documenting administered medications?01234560	4	In an emergency situation, to what extent do you find yourself having to break protocol for matching medications to the MAR/medication profile?	0	1	2	3	4	5	9	0
6 In an emergency situation, to what extent do you find yourself having to 0 1 2 3 4 5 6 0 break protocol for documenting administered medications?	5	In an emergency situation, to what extent do you find yourself having to break protocol for checking patient identification in order to administer medications?	0	1	2	3	4	5	6	0
	9	In an emergency situation, to what extent do you find yourself having to break protocol for documenting administered medications?	0	1	2	3	4	5	6	0

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Table 3

Means, standard deviations, and percent self-reporting ever violating for questions about violations. Numbered Violation Situation / Steps in Table 3 correspond to numbered questions in Table 2.

Violation Situation Step		Hospital A	PICU	НОТ	Med/Surg	Hospital B	PICU	нот	Med/Surg	Hospital A and B	PICU	НОТ	Med/Surg
1 Danting Match MAD	Mean (SD)	1.39 (1.31)	1.37 (1.30)	1.73 (1.52)	1.19 (1.17)	1.04 (1.15)	1.08 (1.00)	1.00 (1.17)	1.00 (1.51)	1.25 (1.26)	1.26 (1.20)	1.36 (1.38	1.13 (1.28)
1. Kouune /Match-MAK	Percent	71.6	71.4	72.7	71.0	60.5	68.4	56.5	46.7	67.2	70.3	64.4	63.0
2 Barting Cherlin	Mean (SD)	1.89 (1.74)	1.69 (1.57)	3.17 (1.92)	1.38 (1.54)	1.60 (1.59)	1.49 (1.43)	1.87 (1.89)	1.47 (1.55)	1.78 (1.69)	1.62 (1.52)	2.52 (2.00)	1.40 (1.53)
2. ROULINE / CITALD	Percent Mean (SD)	75.0	75.4	95.7	59.4	67.5	69.2	69.69	60.0	72.1	74.4	71.8	59.6
2 Bouting DOC	Mean (SD)	0.89 (1.08)	0.83 (1.11)	1.30 (1.22)	0.72 (0.81)	0.97 (1.22)	1.15 (1.06)	0.74 (1.14)	0.87 (1.68)	0.92 (1.13)	0.95 (1.10)	1.02 (1.20)	0.77 (1.15)
3. Koutine/DOC	Percent	55.0	49.2	73.9	53.1	57.1	71.8	47.8	33.3	55.8	57.7	59.2	46.8
Emmont Match MAD	Mean (SD)	2.72 (1.94)	2.92 (1.87)	3.30 (2.03)	1.90 (1.84)	2.28 (1.97)	2.38 (1.79)	2.36 (2.08)	1.85 (2.38)	2.55 (1.96)	2.71 (1.85)	2.81 (2.09)	1.88 (1.99)
4. Elliergency /Match-MAK	Percent	87.0	8.06	85.0	80.0	74.7	85.0	78.7	46.2	82.1	88.6	78.6	69.8
G. T	Mean (SD)	2.55 (2.02)	2.71 (1.95)	3.15 (2.16)	1.80 (1.94)	2.20 (2.17)	2.20 (2.14)	2.41 (2.13)	1.86 (2.41)	2.41 (2.08)	2.51 (2.03)	2.76 (2.15)	1.82 (2.07)
J. Elliergency / ClixIL	Percent	81.7	84.6	0.06	70.0	68.4	75.0	68.2	50.0	76.4	81.0	78.6	63.6
	Mean (SD)	2.02 (1.71)	2.03 (1.71)	2.86 (1.77)	1.40 (1.45)	1.96 (1.81)	1.98 (1.76)	1.91 (1.87)	2.00 (1.96)	1.99 (1.75)	2.01 (1.72)	2.37 (1.86)	1.59 (1.63)
0. Emergency / DOC	Percent	81.0	86.2	85.7	66.7	73.7	77.5	68.2	71.4	78.1	82.9	76.7	68.2