

Cross-Sectional Comparison of Electronic and Paper Medical Records on Medication Counseling in Primary Care Clinics: A Southern Primary-care Urban Research Network (SPUR-Net) Study

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Introduction: This study compared the frequency of oral counseling and written information by primary care physicians at paper medical record (PMR) clinics and electronic medical record (EMR) clinics, and assessed relationships between medication counseling and medication outcomes (knowledge, questions, reported adherence and side effects, and medication fill).

Methods: A cross-sectional study with two convenience samples of English-speaking adult patients receiving ≥ 1 prescription at the primary care index visit was conducted in two PMR clinics, with 184 (48% response) patients seen by one of 22 physicians, and in two EMR clinics, with 249 (37% response) patients seen by one of 25 physicians. Data were from medical record reviews of the index visit and 2-week post-visit telephone interviews.

Results: Three mutually exclusive counseling categories were evaluated. Patients received 1,095 prescriptions, 61% with oral counseling for indications, 21% with oral counseling for indications and side effects, and 12% with written information plus oral ("multi-mode") counseling. General linear mixed models found 1) less multi-mode counseling in PMR clinics (2%) than EMR clinics (20%); 2) PMR and EMR clinics were similar in oral counseling for indications and side effects; and 3) PMR clinics provided more oral counseling only for indications (69%) than EMR (53%) clinics. The impact of receiving oral or written counseling on patients' reports of having questions about their medications was inconclusive. Not receiving oral counseling for indications was associated with more questions, but not receiving written information was associated with fewer questions. Filling a prescription was lower when no oral counseling for indications and side effects was reported, but the absence of written information was associated with more prescriptions fills.

Conclusions: Physicians' use of EMR to print medication information did not seem to compromise their oral counseling for medication indications and side effects. This feature of the EMR was underutilized by physicians; however, future studies addressing patient recall and evaluating the quality and content of medication counseling are needed. (J Am Board Fam Med 2007;20:164–173.)

Electronic medical record (EMR) systems are only used in about 15% to 20% of US physician offices, but their use is increasing.¹ The documented benefits of such systems include listing all medications together, keeping the medication record in an eas-

ily accessible format, flagging drug interactions and allergies, and preventing medical errors and adverse drug events (ADEs).^{2,3} A study by RAND in 2005 estimated that 2 million ADEs in the ambulatory setting could be eliminated by an EMR with

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a computerized provider order entry (CPOE) component and safety features; this could save up to \$3.5 billion a year in the ambulatory setting.¹

In 1996, a working group convened by the American Medical Association (AMA) developed the Guidelines for Physicians for Counseling Patients About Prescription Medications in the Ambulatory Setting.⁴ Five key aspects for effective counseling were recommended in the guidelines: maintaining and updating the patient's medication record, discussing expectations of the treatment plan and alternatives, providing oral counseling about the medication, supplementing oral counseling with written medication information, and including follow-up evaluations to assess patients' compliance and their reported beneficial or adverse effects of the medication (see www.ama-assn.org/ama/pub/category/13610.html#table_2).⁴ Several AMA policies pertain to medication counseling: Policy H-165.896 (AMA Policy Compendium, 1998) encouraged physicians to provide medication counseling, Policy H-115.995 promoted Patient Instructional Leaflets; Policy H-120.967 approved the dispensing of computer generated drug information; H-140.975 (also an AMA Ethical Opinion) stated that the patient had the "right to receive information from physicians and to discuss the benefits, risks, and costs of appropriate treatment alternatives;" and Policy H-120.968 recommended that physicians include specific medication information on the prescriptions (eg, generic and/or brand name, dosage, frequency) rather than a vague direction on prescriptions (eg, take as directed).⁴

In its recent report, Preventing Medication Errors (July 2006), the Institute of Medicine expert committee recommended that physicians counsel patients about medications, including their indications and side effects, provide written information, and use health information technology.⁵ Reduced medication errors and ADEs have been found to be associated with medication counseling⁶⁻¹⁷ and the use of EMRs or CPOEs.¹⁸⁻²²

Traditionally a PMR contains the physician's handwritten information about the patient's diagnosis, medication records, clinical assessments, and plans for therapy. Physicians write the prescriptions and give them to patients to fill at the pharmacy. In contrast, an EMR with CPOE can print the prescription, store all medication-related records in the computer, and help physicians check for patients' drug allergies, interactions, medication

use indications, and contraindications. Many EMR systems also have the capacity to provide printed medication information handouts. In theory, this should address another identified source of medication errors, namely, inadequate counseling about prescription medication indications and side effects.⁴ Written medication information can provide a useful addition to oral counseling. When used as an adjunct, written medication information reinforces specific instructions; it has been shown to be associated with improved patient knowledge of potential adverse effects but not increased patient reports of adverse effects.²³

Thus, medication counseling may provide specific information, including indications and side effects, via written or oral modes of communication. Effective physician-patient communication has been shown to contribute to patient safety and medication compliance in clinical studies.^{7,10,14-17,24-26} Yet, practice lags behind the evidence. For example, a nationwide telephone survey of patients conducted by the Food and Drug Administration (FDA) before 1980 reported that nearly 50% of surveyed individuals received information about the medication indications from their physicians, 11% reported receiving information about any medication side effects; and 19% reported not being informed at all.²⁷ Another FDA report describing findings from national telephone surveys conducted periodically between 1982 and 1994 found that receipt of oral information about medications from physicians was reported by 66% (1982 and 1984) and 70% (1992 and 1994) of surveyed individuals.²⁸ However, the receipt of written medication information from physicians was only reported by 5% (1982), 9% (1984), 14% (1992), and 15% (1994) of surveyed individuals. These data predate the use of EMR in primary care clinics. Few studies have reported the role of EMR on communication about medications during primary care outpatient visits.^{29,30}

The objectives of this study were to determine the frequency of patient-reported medication counseling by primary care physicians from PMR clinics, compared with those from EMR clinics, and to assess the relationships between medication counseling and medication outcomes (knowledge, questions, prescription fill, adverse effects, and adherence). Our hypothesis was that the EMR with printable prescriptions and an option to print medication information handouts would be associated with increased patient reports of physicians' multi-

mode medication counseling, which would have a positive impact on medication outcomes.

Methods

Study Setting and Population

This cross-sectional study was conducted within the Southern Primary-Care Urban Research Network (SPUR-Net) from January 2004 to March 2005. SPUR-Net is a practice-based research network in Houston, TX, that consists of 6 constituent member organizations affiliated with a county health system, an integrated health system, and several private practice clinics. SPUR-Net clinicians provide care to approximately 1 million patient visits per year; they serve patients from diverse ethnic and socioeconomic backgrounds. Four primary care clinics (2 PMR and 2 EMR) were selected for this observational, exploratory study because they shared similar patient visit volume and provider number. During the time of the study, in each clinic, 10 to 13 family medicine physicians each saw approximately 4 patients per hour. The PMR clinics had a total of 22 family medicine physicians, and the EMR clinics had 25 family medicine physicians. The 2 EMR clinics had used the same computer program with medication decision-support features for the previous 5 years. Human subject approvals were obtained from the Institutional Review Boards (IRBs) at each participating organization. Permission to conduct the study at each clinic was obtained from the medical director and affiliated patient advisory group.

The target enrollment was 125 patients from each of the 4 clinics. Deliberate sampling across the times of the day and the days of the week was used to recruit representative samples of eligible patients at the clinic. The patient's physician was not a factor in selection. Eligible male and female patients were 1) English speaking; 2) at least 18 years of age; 3) received ≥ 1 new or refill prescriptions at the index appointment; 4) currently using ≥ 1 other prescribed medication; and 5) provided written consent for the study, including review of their medical record and a telephone interview.

EMR and PMR Features

The EMR used in the study had the following medication safety features at the point of care: 1) printable and legible prescriptions with medication instructions; 2) space to list all medications to-

gether; 3) easily retrievable medication records; 4) available features to detect adverse drug-allergy, drug-drug, drug-nutrient, drug-vitamin, and drug-dietary supplement interactions; and 5) an option to print medication information (both indications and side-effects) handouts written at the 6th grade reading level. Physicians in the PMR clinics used the traditional method of paper-based prescription pads to prescribe medications and used any available drug information books or PDA software as medication reference source.

Data Collection

Recruitment by research assistants occurred at the clinic before the patient saw the doctor. A brief interview was conducted after the patient had seen the doctor to obtain contact information and to verify the receipt of at least 1 prescription. Two weeks after the index visit, a research assistant completed a chart review and a primary care research fellow conducted a telephone interview with each patient participant. We designed the study for a 2-week call-back time to allow sufficient time to assess whether patients had filled their prescription or had developed any adverse effects. No information that identified the patients or the clinic providers appeared in the research datasets. All research staff completed human subjects protection training certification and adhered to Health Insurance Portability and Accountability Act (HIPAA) regulations.

Measures

Counseling Outcomes

The primary outcome of this study was the number of patients reporting medication counseling by their primary care physicians grouped by EMR and PMR clinics. The data collection questions used in this study were adapted from questions previously developed (see acknowledgment).³¹ For each medication, information on oral counseling for medication indications and side effects were elicited with the following questions: "When you received your prescription, did your doctor tell you what this medication was for?" (yes or no), and "Did your doctor tell you about the possible side effects?" (yes or no). To assess written counseling for each medication, we asked: "Did you get printed information about this medication from your doctor?" (yes or no). Based on the distribution of responses to these

3 questions, we examined 3 mutually exclusive forms of medication counseling for analysis: 1) oral counseling for indications, 2) oral counseling for indications and side effects, and 3) written information plus oral (multimode) counseling.

Medication Outcomes

For each medication, patients were asked an additional set of questions: “What do you take this medication for?”, answers were compared with the FDA-approved medication indications (correct/incorrect). The accuracy of medication indications was used to indicate patient’s knowledge. The question “Do you have any questions about this medication for your doctor?” (yes/no), was used to assess patient understanding of the prescribed medication. The question “Did you fill this prescription?” (yes/no) was used to evaluate patient action after receiving their prescription. The question “Are you still taking this medication” (yes/no), was used to assess the patient’s self-reported adherence. If the answer was no, we asked “why not?” Patients chose 1 reason from the following list: completed therapy, changes by physician, ran out of medication, medication not available, did not need the medication, and side (adverse) effect. We selected these outcomes because published evidence suggested that medication counseling, either oral or written, was associated with increased patient knowledge,³² understanding,^{16,32} medication fill,^{11,25,26} and medication adherence^{11,25,26,33}; counseling did not increase reported adverse effects.²³

Covariates

We selected covariates that published evidence had suggested were associated with medication counseling by physicians, including gender,¹⁷ age,^{17,34} race/ethnicity,¹⁶ educational level,¹⁷ continuity of care by the same or a different physician,³⁵ number of medications,¹⁶ and the type of medications (new or continued).^{16,35} (Table 1) We also postulated that the type of chief complaint at the index visit (acute, chronic, or health maintenance) might affect medication counseling; therefore, we also included this covariate in our analyses.

Statistical Analysis

Frequencies for medication counseling were calculated for the three mutually exclusive counseling groups. Descriptive statistics were used to examine

characteristics of the study sample. Generalized linear mixed models (GLMM) using PROC GLIMMIX in SAS 9.1 were used to take into account the nested design and adjust the estimates for the number of medications per patient. ORs and 95% CIs were estimated from the GLMM.

Our primary analyses examined factors associated with the 3 categories of counseling. First, we examined whether significant variability in medication counseling occurred in the 2 clinics within each clinic type (EMR, PMR). Because no variability was detected, we did not model individual clinic differences. χ^2 and *t* tests were used to assess differences between EMR and PMR clinics for all patient-level covariates. A value of $P \leq 0.05$ was considered statistically significant (2-tailed test). Next we conducted univariate analyses to examine the association between clinic type and each covariate with each outcome. Our final multivariable analyses examined whether the type of medication counseling differed by clinic type even after controlling for any significant covariates.

Our secondary analyses examined whether medication counseling affected medication outcomes. Descriptive statistics were used to assess the distribution of responses across medication outcome variables. For variables with adequate variance, we conducted univariate analyses to examine the association between medication outcomes and each covariate and clinic type. Our final multivariable analyses examined whether medication outcomes were associated with different types of medication counseling after controlling for any significant covariates including clinic type.

Results

Description of the Sample

Of 2568 patients (1,097 PMR and 1471 EMR) approached at the clinics during their index visit, 1054 patients (386 PMR and 668 EMR) met inclusion criteria; and 594 patients—267 PMR (69%) and 327 EMR (49%)—consented. Telephone interviews were completed 2 weeks after the index visit by a total of 433 patient participants—184 PMR (48%) and 249 EMR (37%). The main reason patients gave for declining participation was lack of time. A total of 161 patients could not be reached by phone after 3 calls placed by the research staff and were considered lost to follow-up. Three other patients in the PMR group withdrew from the study.

Table 1. Patient Characteristics by Clinic Type (N = 433 Patients)

Variable	PMR Clinic	EMR Clinic	Total	χ^2 *	P Value
	N (%)	N (%)	N (%)		
Gender	184 (42%)	249 (58%)	433		
Female	137 (74%)	180 (72%)	317 (73%)	0.25	.66
Age (mean \pm SD)	52.1 \pm 11.5	53.2 \pm 17.4	52.7 \pm 15.2	$t = 0.77$.44
Race/ethnicity				4.62	.33
White	106 (58%)	150 (60%)	256 (59%)		
Hispanic	25 (14%)	31 (12%)	56 (13%)		
Black	47 (25%)	62 (25%)	109 (25%)		
Asian and other	6 (3%)	6 (2%)	12 (3%)		
Education				67.23	<.001
Less than high school	43 (24%)	13 (5%)	56 (13%)		
High school	43 (24%)	35 (14%)	78 (18%)		
Some college	72 (40%)	85 (34%)	157 (37%)		
College graduate	21 (10%)	84 (34%)	105 (24%)		
Post-graduate	5 (3%)	32 (13%)	37 (8%)		
Chief complaint type				0.83	.66
Acute	87 (47%)	131 (53%)	218 (53%)		
Chronic	54 (29%)	74 (30%)	128 (31%)		
Health-maintenance	23 (12%)	42 (17%)	65 (16%)		
Duration of care				15.67	.001
<1 year	72 (40%)	55 (22%)	127 (30%)		
1 to 2 year(s)	19 (10%)	39 (16%)	58 (13%)		
2 to 3 years	24 (12%)	37 (15%)	61 (14%)		
>3 years	68 (38%)	118 (47%)	186 (43%)		
Number of prescribed medications taken per patient (mean \pm SD)	6.35 \pm 4.26	4.84 \pm 3.08	5.48 \pm 3.70	$t = 4.30$	<.001

* χ^2 unless otherwise specified.

More than two thirds of the sample were female; the average age of the surveyed patients was early fifties (Table 1). EMR and PMR clinic patients differed on educational attainment, duration of care, and average number of prescribed medications (Table 1).

Medication Counseling

Counseling for each of the 1090 medications prescribed to the 433 patients at the index visit was reported in the mutually exclusive categories as follows: oral counseling for indications, 659 (60%); oral counseling for indications and side effects, 226 (21%); and written information plus oral counseling, 129 (12%). We excluded from the analysis 73 (7%) medications that had missing data for one or more counseling categories. Of the potential covariates, gender and race/ethnicity were significantly associated with receiving written information and were included in the final analysis with

clinic type. Findings from the models adjusting for design effects and statistically significant covariates indicated differences between PMR and EMR clinics for 2 types of counseling (Table 2). Medications prescribed at PMR clinics included more patient reported oral counseling for indications (69%), compared with EMR clinics (53%), but there were no differences in oral counseling for indications and side effects. For medications prescribed at PMR clinics, multimode counseling was provided less often (2%) than it was provided in EMR clinics (20%). Additionally, women were offered multimode counseling less often (9%) than men (21%), regardless of the type of medical record used in the clinic.

Medication Outcomes

In PMR clinics, 13 (2.55%) medications were stopped as a result of adverse effects, and in EMR clinics, 6 (1.03%) medications were stopped (total

Table 2. ORs and 95% CIs from General Linear Mixed Models Reporting Statistically Significant Differences in Counseling (N = 1090 Medications)

	Oral Counseling for Medication Indications		Oral Counseling for Medication Indications and Side Effects		Written Information plus Oral (MultiMode) Counseling	
	OR	CI	OR	CI	OR	CI
PMR vs EMR	1.75	1.18 to 2.59	1.22	0.77 to 1.94	0.47	0.24 to 0.92
Female vs male	—	—	—	—	0.12	0.05 to 0.25
Non-Hispanic vs Hispanic	—	—	—	—	2.94	0.96 to 9.00

— Variable not included in the model.

of 19 (1.74%) medications; Fisher's exact *P* value = 0.065). These frequencies were too small to be included in the final GLMM analysis. Two other outcomes, knowledge about medication use (95% answered correctly) and whether the patients were still taking medications regardless of reason (74% still taking medications), did not have adequate variance across counseling type to be included in the final GLMM analysis. Descriptive statistics identified 2 variables (question for doctor and medication fill) with adequate variance to assess their association with types of medication counseling. Multivariable models indicated significant effects of counseling on medication outcomes after adjusting for design effects and covariates (Table 3). We found that prescriptions were less likely to be filled (92%) when there was no oral counseling for indications and side effects, compared with 98% when oral counseling was reported. Not having oral

counseling for indications was associated with a higher rate of asking doctors questions (15%), compared with 8% with oral counseling. In contrast, having multimode counseling was associated with a higher rate of asking questions (10% no multimode vs. 21% with multimode). Furthermore, having multimode counseling was associated with a lower likelihood of filling the prescription (87%), compared with no multimode counseling (94%).

Discussion

Our hypotheses about the association of medical record type and the 3 counseling categories were partially supported. Overall, our data showed that a higher proportion (20%) of our surveyed patients from the EMR clinics reported having obtained written information from their primary care physicians, compared with previously reported data (5%

Table 3. ORs and 95% CIs from General Linear Mixed Models Reporting Adjusted Effects of Counseling on Medication Outcomes (N = 1090 Medications)

	Question for Doctor		Medication Fill	
	OR	CI	OR	CI
Oral counseling for indications (none vs some)	2.11	1.29 to 3.47	1.05	0.57 to 1.95
Age	0.98	0.96 to 0.99	—	—
PMR vs EMR	—	—	2.03	1.06 to 3.89
Oral counseling for medication indications and side effects (none vs some)	0.59	0.34 to 1.04	0.15	0.04 to 0.54
Age	0.98	0.96 to 0.99	—	—
PMR vs. EMR	—	—	2.05	1.08 to 3.91
Written information plus oral counseling (none vs some)	0.36	0.18 to 0.73	2.64	1.21 to 5.77
Race/ethnicity (Hispanic vs non-Hispanic)	0.41	0.20 to 0.84	—	—
Age	—	—	0.98	0.96 to 1.00

— Variable not included in the model.

to 15%).²⁸ The use of EMR with the option to print medication information handouts to supplement physicians' oral counseling seemed to be a feasible practice, which is consistent with the AMA guideline recommendations.⁴ Nevertheless, EMR with a printable written information feature may be underutilized based on these findings. We found that those patients who did not receive written information plus oral counseling asked fewer questions but filled more prescriptions. It is possible that patients who were not given written information did not know what to ask in regard to their medication, whereas patients given written information, which may provide substantially more information than was discussed during the index visit, may become confused and concerned by the information provided. Having too much information may deter some people from filling their prescription. The negative relationship between written information and prescription filling could also be interpreted as physicians who were confident that the patient would follow through may have decided that giving the written information was unnecessary. Future studies should assess the usefulness of written information when supplemented with oral counseling in patient's health literacy level and in medication decision making.

Our data also show that oral counseling for medication indications was lower (69% in PMR clinics and 53% in EMR clinics) when compared with previous national findings of up to 70% published in the 1980s and the 1990s and 84% found in an AMA survey.^{4,27,28} The difference is likely due to the inclusiveness of previous studies compared with our mutually exclusive counseling groups. In fact, when we pooled all counseling outcomes, we found that 97% of surveyed patients reported receipt of oral counseling for medication indications in both the PMR and EMR groups in our study. Our finding that not having oral counseling for indications was associated with increased questions for the doctor lends support to the importance of oral counseling in helping patients understand their medications.

Regarding oral counseling for medication indications and side effects, our data show that a similar proportion (approximately 20%) of surveyed patients seen at the selected PMR and EMR clinics reported having obtained oral counseling for medication indications and side effects. Previously published national findings reported a lower propor-

tion (11%),²⁷ but the AMA survey reported a higher proportion (68%)⁴ of oral counseling for medication side effects. Even when we reanalyzed our data using nonmutually exclusive groupings, oral counseling for medication side effects was only 24% at PMR clinics and 31% at EMR clinics. Furthermore, we found that not having oral counseling for indications and side effects was associated with increased prescription fills. We postulate that having more information, including side effects, may make some people hesitant about filling their prescriptions.

Reports of adverse effects were less frequent in our study than at least 1 earlier study.³¹ In this other study, in addition to a phone call to patients at approximately 2 weeks, the investigators also called patients again at 3 months after the index visit. It is also difficult to define an acceptable side effect. Because of the low frequencies of reported adverse effects, we could not further analyze the association between counseling and reported adverse effects. Previously, Gibbs et al found that written information plus oral counseling was associated with improved knowledge, but not increased reports, of adverse effects.^{23,36-38}

Safe use of medications may be promoted by using written medication information. Because of the enhanced clarity of printed prescriptions compared with handwritten prescriptions, EMRs and CPOEs can provide benefits such as legible prescriptions, formulary compliance,³⁹ and decreased prescribing errors.^{20,40-51} Despite its many benefits, most studies show that CPOE could actually slow down the patient's care management process, increase the time needed by physicians to complete their work, and inhibit the patient-physician interaction.^{52,53} In 2 hospitals, the implementation of CPOE was associated with unintended consequences such as increased adverse drug reactions and medication ordering and delivering errors.⁵³

Our study results should be interpreted in the context of several limitations. First, our estimates of medication counseling, by either oral or written modes, may be imprecise because our definition of counseling may have been overly inclusive of simple information giving. In addition, because our survey questions were designed to measure several outcomes such as prescription fill and adverse effects in addition to medication counseling, we waited for 2 weeks to call patients. Therefore, study participants' memory recall about medication

counseling 2 weeks after their index visit may be inaccurate. We cannot confirm whether or not those who reported receiving counseling actually obtained the counseling. Future studies including audiotaped encounters between patients and physicians could provide verification of self-report data and assess the duration, quality, and content of medication counseling. Future studies would also benefit from defining acceptable side effects. In addition, including patients' understanding of medication indications and side effects would be helpful in assessing the effectiveness of bidirectional communication between physicians and patients regarding safe medication use. Counseling alone is not sufficient to reduce medication errors.

Second, because of privacy concerns raised by one of the IRB boards, we used a convenience sample instead of identifying patients using randomized sampling methods as originally proposed. Nevertheless, we recruited patients by using deliberate sampling across time of day and across days of the week to increase the representativeness of patients selected from the 4 group practice clinics. We had a low response rate due to lack of time indicated by most patients who declined participation. Because of HIPAA concerns, we did not collect information from nonrespondents and therefore could not assess how they might have differed from those who participated in the study. Thus, this study cannot provide population estimates.

Third, even though we enrolled multiethnic participants from both the PMR and the EMR clinics, we only had sufficient resources to conduct the study for English-speaking patients. This study cannot provide population estimates. Future studies should examine whether differences in the primary language used by patients influence physicians' medication counseling styles.

Fourth, future studies should also assess the effect of physician-level characteristics such as gender and number of years in practice; physician-level information was not collected in this study. Assessing the effect of collaborative practice with pharmacists and nurses would be helpful.

Despite these limitations, our findings showed an increased provision of written information to supplement oral counseling with the use of EMR. This finding suggests that the use of EMR is feasible in busy primary care clinics and does not negatively affect or substitute oral counseling for medication indications and side effects as has been

suggested by a much earlier finding in a meta-analysis.⁵⁴ Our study was conducted in a practice-based primary care network with both private and public clinics; therefore, our study findings may be more easily translated into clinical practice. This exploratory study provides some understanding of how medication counseling received by primary care patients is affected by EMR and how counseling may affect medication outcomes. How an EMR affects medication counseling is important because a growing number of primary care clinics and other health-care organizations face the challenge of implementing or upgrading their EMR systems. Provider-directed interventions are needed to increase the use of EMR features that may improve medication-related communication among primary care physicians and patients.

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Contributorship: GMK conceived of the study, designed the survey questionnaires, coordinated and managed the data collection process, initiated and evaluated data analysis, and drafted the manuscript. PDM provided the direction for the study and helped drafted the manuscript. AM performed statistical analyses and helped drafted part of the manuscript. PRS directed the data analyses. JR contributed in the overall direction of the paper and in reviewing the manuscript. All of the authors approved the submitted draft.

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