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The Impact of Pre-printed Prescription Forms on Medication Prescribing Errors

in an Ophthalmology Clinic in Northeast Thailand: a Before and After Study

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Key words: medication errors, prescriptions, outpatient clinics

Word count for the abstract: 299 words

Word count for the text of the manuscript: 2468 words

ABSTRACT

Objectives: To understand the incidence and types of medication prescribing errors in a low

resource setting ophthalmology clinic, and determine the impact of a pre-printed prescription

on medication prescribing errors

Design: Nonrandomized before and after study

Setting: Ophthalmology clinic in a teaching hospital in northeast Thailand.

Participants: A total of 4349 handwritten prescriptions were collected from October to

December 2009, followed by a 1 month implementation period for the FormularyScript. A

total of 4146 FormularyScripts were collected between February to May 2010.

Interventions: Pre-printed prescription based on the hospital formulary (FormularyScript)

Primary and secondary outcome measures: All prescriptions from the handwritten and

FormularyScript groups were analyzed for medication error rates by types (legibility,

ambiguous, incomplete, abbreviation, accuracy) and subtypes (drug name, strength, which eye, route, and dispensed amount).

Results: Comparison of error rates in the 2 groups showed a 10-fold reduction in the overall error rate using FormularyScript (32.9% to 3.5%). Statistically significant decreases (p<0.001) using FormularyScripts were seen in the error types of legibility (16.1% to 0.1%), incomplete (16.1% to 0.1%), and abbreviation (3.1% to 0.3%). There was no statistically significant change in accuracy errors (0.8% to 0.6%). Ambiguous errors increased with FormularyScripts (0.6% to 2.5%), likely due to the introduction of new ways to make errors. Decreases were seen in all subtypes of legibility and accuracy errors, 4 out of 6 incomplete subtypes, and the abbreviation subtype. There were statistically significant increases in the error rates in both ambiguous subtypes using FormularyScripts, which eye (0.3% to 2.5%, p<0.001), and drug name (0.3% to 0.6%, p 0.03).

Conclusions: Outpatient medication prescribing errors are common and primarily due to legibility and incomplete information. A pre-printed prescription form can result in a decrease in the overall medication prescribing errors without changing the rate of accuracy errors, but new error types can be introduced.

ARTICLE SUMMARY

Article focus

- Little is known about the frequency and types of medication prescribing errors in developing countries, especially outpatient settings

- Computerized prescribing systems are usually not feasible in low resource settings, however a pre-printed form may be an alternative.

Key messages

- Medication prescribing errors are common in outpatient ophthalmology clinics and are primarily due to legibility and incomplete information

- Pre-printed prescription forms can significantly decease the overall rate of medication prescribing errors related to legibility, incomplete prescribing information, and use of unacceptable abbreviations without changing the overall rate of accuracy errors, but new error types can be introduced.

- A pre-printed prescription form is a viable alternative to computerized prescriptions in low resource settings for reducing medication prescribing errors by working closely with physicians and pharmacists to optimize design and by providing adequate training for users.

Strength and limitations

- The main strengths of this study is that it demonstrates that a low cost alternative to computerized prescribing exists and is effective at reducing the most common types of medication prescribing errors

- Important limitations of this study are the subjective nature of determining and classifying certain error types such as legibility, the FormularyScript did not include all necessary medications, and physicians were aware that the prescriptions were being analyzed for prescribing errors

INTRODUCTION

Accurate medication prescribing is an important process in ensuring the best possible outcomes in the treatment of diseases. Research from developed countries suggests that most prescription errors result from illegibility and incomplete prescribing information. One study in the United States found a prescription medication error rate of 7.6% in the outpatient setting, with errors in frequency and dose being the most common type[1]. A study from an ophthalmic specialty hospital in England found 45% of all medication errors occurred in the outpatient department, with errors in prescription writing being the most common[2]. A pre-

printed order sheet was shown to reduce medication errors twofold in a randomized controlled trial in a pediatric emergency department in the United States[3].

Little is known about the incidence and types of medication prescribing errors in developing countries. A review of the literature shows a handful of descriptive studies looking at prescribing errors in outpatient settings. Studies from Bahrain[4], Nepal[5], India[6-7], Saudi Arabia[8], and Nigeria[9] found a high incidence of errors in prescription writing including illegibility and incomplete prescribing information. Other issues cited were: failure to use generic medication names, non-adherence to national formulary, and inadequate medication labeling. Solutions such as computerized physician ordering systems and electronic prescription writing programs are often used to address these issues. Research in the United States has suggested that advanced computerized physician order entry systems using decision support software have the greatest impact in preventing medication errors and adverse drug reactions[1]. However, computerized prescribing systems are usually not feasible in developing countries due to resource constraints.

The goal of this study is to determine the incidence and types of medication prescribing errors in an outpatient ophthalmology clinic in a low resource setting and to evaluate whether or not a preprinted prescription with prompts for prescribing information is an effective, low cost alternative for reducing medication prescribing errors.

METHODS

This is a nonrandomized interventional study comparing medication prescribing errors before and after the intervention of a pre-printed prescription form based on the hospital formulary (FormularyScript). The FormularyScript includes names and prescribing information for selected medications. It includes prompts for all prescribing information such

dose, frequency, and route. (Figure 1)

Study site and population

The study was conducted in the outpatient ophthalmology clinic of Srinagarind Hospital, Khon Kaen University in northeast Thailand. A total of 28 ophthalmology residents, fellows, and faculty participated in the study. All prescriptions written in the outpatient ophthalmology clinic during the study period were included, unless the patient did not consent or the physician was excluded from participation in the study. Physicians were excluded if they participated in the design and implementation of the research study. Four faculty ophthalmologists elected not to participate. (Table 1)

Table 1: Description of Study Population

Number of prescriptions	Handwritten	FormularyScript
Total collected	4349	4893
Not filled at pharmacy	935 (21.5%)	246 (5.0%)
Handwritten medication on FormularyScript	Not applicable	747
Total in study population	4349	4146
% prescriptions written by physician training level	Handwritten	FormularyScript
1st year residents	23.2	26.6
2nd year residents	28.9	29.2
3rd year residents	28.9	31.7
Fellows	6.3	2.5
Attending	12.7	10.0

Data collection

During the first phase of the study, baseline data were collected on the frequency and types of medication prescribing errors on the handwritten prescription traditionally used in the clinic. The target sample size of prescriptions was 3000, based on an estimated error rate of 5% and estimated error reduction rate of 30%. Medications were recorded on the data collection spreadsheet using the name written on the prescription. Prescriptions that were written but

never filled were included in the study. Prescriptions were omitted if they were handwritten on a FormularyScript. (Table 1)

After completion of the first phase, the FormularyScript was introduced to the physicians in the ophthalmology clinic with instructions in its use. Over the next month, they were given feedback if it was not completed correctly, and design modifications were made based on the results. The second phase of the study collected data on the frequency and types of medication prescribing errors on the FormularyScript and used the same target number of prescriptions.

Prescription review process

Data for each prescription were entered into the study database along with a digital photo of the prescription and the prescribing information from the patient's chart. A 3-step review process was used on all prescriptions. The first reviewer, a recently graduated pharmacist, recorded any medication prescribing errors when the patient brought the prescription to the hospital pharmacy. The second reviewer, a pharmacy technician, reviewed all prescriptions and prescribing information from the patient chart using the digital photos. Discrepancies between the first and second reviewer were flagged. All prescriptions were reviewed a third time by one of the investigators (KEM), to make sure there was agreement in classifying errors. If necessary, a fourth investigator was consulted to resolve disagreements.

Error types and definitions

Medication prescribing errors are any type of deviation from a complete, accurate and legible prescription. They refer only to errors on the prescription, not the prescribing decision or dispensed medication. The error types and definitions were: 1) legibility: element of prescription difficult to decipher by pharmacist because writing on prescription was not clear, 2) ambiguous: element of prescription that was clearly written but could be

misinterpreted by pharmacist (e.g. use of ® for proprietary drugs could be misinterpreted as right eye), 3) incomplete: omission of required prescription element as determined by the medication, 4) abbreviation: use of unacceptable abbreviation, as determined by pharmacy, for medication name on prescription and 5) accuracy: element of prescription with different information than was written in chart or based on dosing requirements for that medication. Discrepancies between generic and trade names were not considered errors. The error subtypes, based on the required prescription elements for a given medication, were: medication name, strength, route, which eye, frequency and dispense amount. Some medications only have one form or strength, in which case these elements would not be required. The same error types were used in both handwritten and FormularyScript. However, what was considered a legibility or ambiguous error differed in the two groups. For example, a legibility error on Formulary Script occurred if the circle marked overlapped 2 medication names, and an ambiguous error on Formulary Script occurred if there was a question about the number next to drug name correlating with the prescribing information.

Data analysis

The frequency of the error types and error subtypes across all prescription elements between handwritten and Formulary Scripts were compared using a 2-sample test of proportions. A 2-sample test of proportions was also used to compare the frequency of error types on each element of the prescription. Statistical analysis was performed using Stata 9 statistical software. (StataCorp. 2005. *Stata Statistical Software: Release 9*. College Station, TX: StataCorp LP.)   Because the required elements for a prescription varied by medication, a table of the possible error types for each medication was generated. If an error type was not possible it was not included in the denominator when the error rates were calculated.

RESULTS

Error types

A total of 4349 handwritten prescriptions and 4146 FormularyScripts were included in the data analysis. The overall rate of any medication prescribing error on a prescription using handwritten prescriptions was 32.9% compared with 3.5% using FormularyScripts (p<0.001). The rates of the 5 error types on a prescription were calculated and compared for handwritten and FormularyScripts (Table 2). Statistically significant decreases (p<0.001) using FormularyScripts were seen in the error types of legibility (16.1% to 0.1%), incomplete (16.1% to 0.1%), and abbreviation (3.1% to 0.3%). There was no statistically significant change in accuracy errors (0.8% to 0.6%), but ambiguous errors increased with FormularyScripts (0.6% to 2.5%).

Table 2: Rates of Any Type of Error on Prescription in Handwritten vs. FormularyScript

Error Type	% Error Handwritten N =4349	% Error FormularyScript N =4146	Δ %	P value	CI
Legibility	16.1	0.1	16.0	<0.001	(14.9, 17.1)
Ambiguous	0.6	2.5	-1.9	<0.001	(-2.4, -1.3)
Incomplete	16.1	0.1	16.1	<0.001	(14.8, 17.0)
Abbreviation	3.1	0.3	2.9	<0.001	(2.3, 3.4)
Accuracy	0.8	0.6	0.2	0.21	(-0.1, 0.6)
Any error	32.9	3.5	29.4	<0.001	(27.9, 30.9)

Error subtypes

Error rates were calculated and compared for handwritten and FormularyScripts using the subtypes of errors based on the required fields for the different medications. (Table 3). Decreases were seen in all the subtypes of legibility errors: drug name (5.7% to 0.1%),

strength (5.8% to 0.0%), route (2.3% to 0.0%), which eye (6.5% to 0.0%), frequency (4.6% to 0.0%), and dispensed amount (1.3% to 0.0%). Decreases in all subtypes reached statistical significance with p<0.001 except for route (p 0.052). There were statistically significant decreases (p<0.001) in 4 out of 6 subtypes of incomplete error on FormularyScripts: medication name (12.3% to 0.0%), strength (6.0 % to 0.0%), route (15.3% to 1.2%), and frequency (0.5% to 0.0%). There were decreases in which eye and dispense amount but these did not reach statistical significance. The only subtype of abbreviation error, drug name, showed a decrease of 3.1% to 0.3% (p<0.001). All subtypes of accuracy error except dispensed amount showed a decrease or no change in error rates using FormularyScript, but only the decrease in which eye was statistically significant (0.5% to 0.1%, p<0.001). Dispensed amount showed an increase error rate using FormularyScript (0.0% to 0.2%, p<0.004). There were statistically significant increases in the error rates in both subtypes of ambiguous errors using FormularyScripts, which eye (0.3% to 2.5%, p<0.001), and drug name (0.3% to 0.6%, p 0.03).

Table 3: Rates by Subtype of Error in Handwritten vs. FormularyScript

Error Subtype	Handwritten N (%)	FormularyScript N (%)	Δ %	P value	CI
Legibility					
Drug Name	4349 (5.7)	4146 (0.1)	5.6	<0.001	(4.9, 6.3)
Strength	1183 (5.8)	904 (0.0)	5.8	<0.001	(4.5, 7.2)
Route	564 (2.3)	161 (0.0)	2.3	0.052	(1.1, 3.5)
Which Eye	3785 (6.5)	3985 (0.0)	6.5	<0.001	(5.7, 7.3)
Frequency	4336 (4.6)	4144 (0.0)	4.6	<0.001	(4.0, 5.2)
Dispense Amount	4336 (1.3)	4144 (0.0)	1.3	<0.001	(0.9, 1.6)
Ambiguous					
Drug Name	4336 (0.3)	4144 (0.6)	-0.3	0.03	(-0.6, -0.0)
Which Eye	3785 (0.3)	3985 (2.5)	-2.2	<0.001	(-2.6, -1.6)
Incomplete					
Medication Name	4344 (12.3)	4145 (0.0)	12.3	<0.001	(11.3, 13.2)
Strength	1184 (6.0)	904 (0.0)	6.0	<0.001	(4.6, 7.3)
Route	563 (15.3)	161 (1.2)	14.1	<0.001	(10.6, 17.5)
Which Eye	3785 (0.2)	3986 (0.1)	0.0	0.70	(-0.1, 0.2)
Frequency	4346 (0.5)	4146 (0.0)	0.5	<0.001	(0.3, 0.7)
Dispense Amount	4346 (0.1)	4146 (0.0)	0.0	0.34	(-0.0, 0.0)
Abbreviation					
Drug Name	4346 (3.1)	4146 (0.3)	2.9	<0.001	(2.3, 3.4)
Accuracy					
Drug Name	4336 (0.1)	4146 (0.1)	-0.1	0.28	(-0.2, 0.1)
Strength	1187 (0.2)	911 (0.0)	0.2	0.21	(-0.1, 0.4)
Route	558 (0.2)	154 (0.0)	0.2	0.60	(-0.2, 0.5)
Which Eye	3789 (0.5)	3986 (0.1)	0.4	0.001	(0.2, 0.7)
Frequency	4349 (0.2)	4146 (0.2)	0.0	0.90	(-0.2, 0.2)
Dispense Amount	4349 (0.0)	4146 (0.2)	-0.2	0.004	(-0.3, -0.1)

Prescription elements

The data were also analysed to determine the rate of any type of error in the required

elements on each prescription. (Table 4) The presence of any type of error in that element

was counted as an error. The denominator of possible errors was determined based on the

required elements for that medication. There was a statistically significant decrease

(p<0.001) using FormularyScripts in all prescription elements: drug name (20.8% to 1.1%), route (17.0% to 1.2%), strength (11.8% to 0.0%), which eye (7.5% to 2.6%), frequency (5.4% to 0.3%) and dispensed amount (1.3% to 0.2%).

DISCUSSION

These results indicate that medication prescribing errors are common in outpatient ophthalmology clinics and are primarily due to legibility and incomplete information. This is similar to the findings of studies done in developed countries, which found that legibility and incomplete information are the most common types of medication prescribing errors[1-2]. Legibility errors, incomplete prescribing information, and use of unacceptable abbreviations were decreased using FormularyScript without changing the overall rate of accuracy errors. However, there was an increase in ambiguous type of error suggesting that new ways of creating medication prescribing errors can occur.

Table 4: Error Rate by Prescription Element in Handwritten vs. FormularyScript

Prescription Element	Handwritten N (%)	FormularyScript N (%)	Δ %	P value	CI
Drug Name	4349 (20.8)	4146 (1.1)	19.7	<0.001	(18.5, 21.0)
Strength	1188 (11.8)	911 (0.0)	11.8	<0.001	(9.9, 13.6)
Route	565 (17.0)	161 (1.2)	15.7	<0.001	(12.2, 19.3)
Which Eye	3789 (7.5)	3986 (2.6)	4.9	<0.001	(4.0, 5.9)
Frequency	4349 (5.4)	4146 (0.3)	5.1	<0.001	(4.4, 5.8)
Dispense Amount	4349 (1.3)	4146 (0.2)	1.1	<0.001	(0.7, 1.5)

An importation limitation of our study is that determining and classifying errors is a subjective process. This is especially true with legibility. We tried to address this issue through using multiple reviewers to maximize the consistency of our classification. Potential for discrepancies in error type classification is another limitation. For example, if instructions in the chart say "qid" but the prescription says every 6 hours, one person may consider this

an ambiguous frequency error and another reviewer as an accuracy error. We acknowledge that an experienced pharmacist could decipher the correct information on many of these prescriptions, but the potential for misinterpretation existed. Because of this, the anticipated impact on medication prescribing errors that could result in actually dispensing the incorrect medication is less than predicted by the study's results.

There were other study limitations that deserve mention. We elected to include medications lost to follow up (prescriptions written but not filled at the hospital pharmacy) because our calculations with and without them showed similar results. We acknowledge that 21.5% of handwritten and 5.0% of FormularyScript medications did not receive the second review by the pharmacy technician. We believe that the design of the FormularyScript contributed to some ambiguous and accuracy errors as up to 3 medications could be written on one FormularyScript. Using a preprinted prescription with only one medication per page could eliminate some of the ambiguous and accuracy errors. Some physicians wrote some prescriptions on the FormularyScript even though the medications were pre-printed. These were excluded from analysis but this may have created some selection bias. The physicians in the study were aware that the prescriptions were being analyzed for error rates, although the exact types and details were not disclosed. We acknowledge this could have resulted in modification of their behavior, or Hawthorn effect, which may have affected overall error rates in both handwritten prescriptions and FormularyScripts.

In conclusion, we found that a pre-printed prescription form can significantly decease the overall rate of medication prescribing errors related to legibility, incomplete prescribing information, and use of unacceptable abbreviations without changing the overall rate of accuracy errors. However, introducing new error types can occur. By working closely with physicians and pharmacists, design and process modifications can be made to minimize this concern, in addition to providing adequate training for users. By adhering to this strategy,

FormularyScript is a viable alternative to computerized prescriptions in low resource

settings.

Contributorship statement:

Thuss Sanguansak: PI, project design, oversight, implementation and manuscript preparation

Michael Morley: Co-Investigator - project design, oversight, data analysis

Yosanan Yospaiboon: Co-Investigator - project oversight and implementation

Alice Lorch: Project design and implementation

Bethany Hedt: Statistical analysis and manuscript preparation

Katharine Morley: Co-investigator - project design, oversight, data analysis, manuscript

preparation

Competing interests: None

Data sharing: There are no additional data available

Trial registration: None

Ethics approval: All procedures and protocols were approved by the Khon Kaen University Ethics Committee for Human Research and the Research Ethics Review Committee of the World Health Organization.

Patient consent: Informed consent was obtained from all patients and staff participating in the study.

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Tables

Table 1: Description of Study Population

Table 2: Rates of Any Type of Error on Prescription in Handwritten (HW) vs. FormularyScript (FS)

Table 3: Rates by Subtype of Error in Handwritten vs. FormularyScript

Table 4: Error Rate by Prescription Element in Handwritten vs. FormularyScript

Figure legends

Figure 1: Reproduction of the FormularyScript. Patient demographic and accounting information is in Thai. Final version used in study had prescribing information in Thai. Three medications can be written on one form. A number is written next to each medication and corresponds with the prescribing information. Medications not listed can be written in blank spaces

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โรงพยาบาลศรีนครินทร์ คณะแพทยศาสตร์ มหาวิทยาลัยขอนแก่น

HN. _____	ใบสั่งยาผู้ป่วยนอก

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ส่วนนี้ใช้ติด sticker ราคายาและข้อมูลผู้ป่วย

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_____ pred forte 1% drop
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_____ dexamethasone 0.1% drop
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_____ travatan 0.004% drop
_____ alphagan-P 0.15% drop
_____ xalacom drop
_____ azopt 1% drop
_____ cosopt drop
_____ combigan drop
_____ diamox 250mg tab
_____ 50%glycerine soln
anti allergy
_____ hista oph drop
_____ spersallerge drop
_____ alomide 0.1%
_____ vividrin drop
_____ zaditen drop
antibiotic + steroid
_____ dexoph drop
_____ trobradex drop
_____ maxitral oint
other
_____ atropine.........% drop
_____ NaCl ....% drop
_____ paracetamal ....mg tab
_____ solcoseryl 20% gel

Drug 1 _____

Dose	Route	Times/day	Every # hours	จำนวน
◯ 1 หยด ◯ ตาขวา	1	1	6	ขวด
◯ 1 เม็ด ◯ 2 ตา	2	2	8	หลอด
◯ 2 เม็ด ◯ ตาซ้าย	3	3	12	เม็ด
◯.........cc ◯ กิน ◯ ac ◯ pc	4	4		กล่อง
◯............ ◯ เปลือกตา	◯ prn	◯ hs		

Drug 2 _____

Dose	Route	Times/day	Every # hours	จำนวน
◯ 1 หยด ◯ ตาขวา	1	1	6	ขวด
◯ 1 เม็ด ◯ 2 ตา	2	2	8	หลอด
◯ 2 เม็ด ◯ ตาซ้าย	3	3	12	เม็ด
◯.........cc ◯ กิน ◯ ac ◯ pc	4	4		กล่อง
◯............ ◯ เปลือกตา	◯ prn	◯ hs		

Drug 3 _____

Dose	Route	Times/day	Every # hours	จำนวน
◯ 1 หยด ◯ ตาขวา	1	1	6	ขวด
◯ 1 เม็ด ◯ 2 ตา	2	2	8	หลอด
◯ 2 เม็ด ◯ ตาซ้าย	3	3	12	เม็ด
◯.........cc ◯ กิน ◯ ac ◯ pc	4	4		กล่อง
◯............ ◯ เปลือกตา	◯ prn	◯ hs		

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แพทย์_____

เลขที่ใบอนุญาตประกอบวิชาชีพเวชกรรม _____

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จัดยา_____ ตรวจสอบยา_____ ส่งมอบยา_____
ผู้รับยา_____

ยื่นใบสั่งยา-คิดราคา-รับเอกสารแล้ว ดำเนินการ ดังนี้

● ผู้ป่วยบัตรจ่ายตรงหรือชำระเงินเอง ติดต่อ ห้องการเงิน หมายเลข **33-38**

เมื่อดำเนินการเรียบร้อยแล้ว นำเอกสารนี้ไปนั่งรอรับยา

(เจ้าหน้าที่การเงิน กรอกข้อมูล) ....

....

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OPD 801-ยาน้ำ update 26-01-53

Reproduction of the FormularyScript. Patient demographic and accounting information is in Thai. Final version used in study had prescribing information in Thai. Three medications can be written on one form. A number is written next to each medication and corresponds with the prescribing information. Medications not listed can be written in blank spaces

209x297mm (300 x 300 DPI)

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
Outcome data	15*	Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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The Impact of Pre-printed Prescription Forms on Medication Prescribing Errors in an Ophthalmology Clinic in Northeast Thailand: A Nonrandomized Interventional Study

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The Impact of Pre-printed Prescription Forms on Medication Prescribing Errors in an Ophthalmology Clinic in Northeast Thailand: A Nonrandomized Interventional Study

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Key words: medication errors, prescriptions, outpatient clinics

Word count for the abstract: 291 words

Word count for the text of the manuscript: 2225 words

ABSTRACT

Objectives: To understand the incidence and types of medication prescribing errors in a low

resource setting ophthalmology clinic, and determine the impact of a pre-printed prescription

based on the hospital formulary (FormularyScript) on medication prescribing errors.

Design: Nonrandomized interventional study

Setting: Ophthalmology clinic in a teaching hospital in northeast Thailand.

Participants: 4349 handwritten prescriptions collected from October 2009 to December

2009, and 4146 FormularyScripts collected from February 2010 to May 2010.

Primary and secondary outcome measures: All prescriptions from the handwritten and

FormularyScript groups were analyzed for medication error rates by types (legibility,

ambiguous, incomplete, abbreviation, accuracy) and subtypes (drug name, strength, which

eye, route, and dispensed amount).

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Results: Comparison of error rates in the 2 groups showed a 10-fold reduction in the overall error rate using FormularyScript (32.9% to 3.5%, p<0.001). FormularyScripts were associated with statistically significant (p<0.001) decreases in the following error types: legibility (16.1% to 0.1%), incomplete (16.1% to 0.1%), and abbreviation (3.1% to 0.3%). There was no statistically significant change in accuracy errors (0.8% to 0.6%, p=0.21). Ambiguous errors increased with FormularyScripts (0.6% to 2.5%, p<0.001), likely due to the introduction of new ways to make errors. Decreases were seen in all legibility, abbreviation, and accuracy error subtypes, and 4 out of 6 incomplete error subtypes. There were statistically significant increases in both ambiguous error subtypes: which eye (0.3% to 2.5%, p<0.001) and drug name (0.3% to 0.6%, p=0.03).

Conclusions: In our study population, outpatient medication prescribing errors were common and primarily due to legibility and incomplete error types. A pre-printed prescription form has the potential to decrease medication prescribing errors related to legibility, incomplete prescribing information, and use of unacceptable abbreviations without changing the overall rate of accuracy errors. However, new error types can occur.

INTRODUCTION

Accurate medication prescribing is an important process in ensuring the best possible outcomes in the treatment of diseases. Research from developed countries suggests that most prescription errors result from illegibility and incomplete prescribing information. One study in the United States found a prescription medication error rate of 7.6% in the outpatient setting, with errors in frequency and dose being the most common type[1]. A study from an ophthalmic specialty hospital in England found 45% of all medication errors occurred in the outpatient department, with errors in prescription writing being the most common[2]. A pre-printed order sheet was shown to reduce medication errors twofold in a randomized

controlled trial in a pediatric emergency department in the United States[3].

Little is known about the incidence and types of medication prescribing errors in developing countries. A review of the literature shows a handful of descriptive studies looking at prescribing errors in outpatient settings. Studies from Bahrain[4], Nepal[5], India[6-7], Saudi Arabia[8], and Nigeria[9] found a high incidence of errors in prescription writing including illegibility and incomplete prescribing information. Other issues cited were: failure to use generic medication names, non-adherence to national formulary, and inadequate medication labeling. Solutions such as computerized physician ordering systems and electronic prescription writing programs are often used to address these issues. Research in the United States has suggested that advanced computerized physician order entry systems using decision support software have the greatest impact in preventing medication errors and adverse drug reactions[1]. However, computerized prescribing systems are usually not feasible in developing countries due to resource constraints.

The goal of this study is to determine the incidence and types of medication prescribing errors in an outpatient ophthalmology clinic in a low resource setting and to evaluate whether or not a preprinted prescription with prompts for prescribing information is an effective, low cost alternative for reducing medication prescribing errors.

METHODS

This is a nonrandomized interventional study comparing medication prescribing errors before and after the intervention of a pre-printed prescription form based on the hospital formulary (FormularyScript). The FormularyScript includes names and prescribing information for selected medications. It includes prompts for all prescribing information such dose, frequency, and route. (Figure 1)

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Study site and population

The study was conducted in the outpatient ophthalmology clinic of Srinagarind Hospital, Khon Kaen University in northeast Thailand. A total of 28 ophthalmology residents, fellows, and faculty participated in the study. All prescriptions written in the outpatient ophthalmology clinic during the study period were included, unless the patient did not consent or the physician was excluded from participation in the study. Physicians were excluded if they participated in the design and implementation of the research study. Four faculty ophthalmologists elected not to participate. (Table 1)

Table 1: Description of Study Population

Number of prescriptions	Handwritten	FormularyScript
Total collected	4349	4893
Not filled at pharmacy	935 (21.5%)	246 (5.0%)
Handwritten medication on FormularyScript	Not applicable	747
Total in study population	4349	4146
% prescriptions written by physician training level	Handwritten	FormularyScript
1st year resident physicians	23.2	26.6
2nd year resident physicians	28.9	29.2
3rd year resident physicians	28.9	31.7
Fellows (subspecialty training after residency)	6.3	2.5
Faculty physicians	12.7	10.0

Data collection

During the first phase of the study, baseline data were collected on the frequency and types of medication prescribing errors on the handwritten prescription traditionally used in the clinic. The target sample size of prescriptions was 3000 to achieve 80% power to detect a 30% reduction in rate of errors, and assuming an error rate of 5% under the current system (alpha

=0.05). Medications were recorded on the data collection spreadsheet using the name written on the prescription. Prescriptions that were written but never filled were included in the study. Prescriptions were omitted if they were handwritten on a FormularyScript. (Table 1) After completion of the first phase, the FormularyScript was introduced to the physicians in the ophthalmology clinic with instructions in its use. Over the next month, they were given feedback if it was not completed correctly, and design modifications were made based on the results. The second phase of the study collected data on the frequency and types of medication prescribing errors on the FormularyScript and used the same target number of prescriptions.

Prescription review process

Data for each prescription were entered into the study database along with a digital photo of the prescription and the prescribing information from the patient's chart. A 3-step review process was used on all prescriptions. The first review was done by a pharmacist, who recorded any medication prescribing errors on the prescription when it was brought to the hospital pharmacy. Agreement between medication information on the prescription and in the chart was done by a research assistant trained as a pharmacy technician at the time of entry into the study database. The second reviewer, a pharmacy technician, reviewed all prescriptions and prescribing information from the patient chart using the digital photos. Discrepancies between the first and second reviews were flagged. All prescriptions were reviewed a third time by one of the investigators (KEM), to make sure there was agreement in classifying errors. If necessary, a fourth investigator was consulted to resolve disagreements.

Error types and definitions

Medication prescribing errors are any type of deviation from a complete, accurate and legible prescription. They refer only to errors on the prescription, not the prescribing decision or

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dispensed medication. The error types and definitions <u>used in this study were based on the prescription error classifications used at Srinagarind Hospital. They are as follows:</u> 1) legibility: element of prescription difficult to decipher by pharmacist because writing on prescription was not clear, 2) ambiguous: element of prescription that was clearly written but could be misinterpreted by pharmacist (e.g. use of ® for proprietary drugs could be misinterpreted as right eye), 3) incomplete: omission of required prescription element as determined by the medication, 4) abbreviation: use of unacceptable abbreviation, as determined by pharmacy, for medication name on prescription and 5) accuracy: element of prescription with different information than was written in chart or based on dosing requirements for that medication. Discrepancies between generic and trade names were not considered errors. The error subtypes, based on the required prescription elements for a given medication, were: medication name, strength, route, which eye, frequency and dispense amount. Some medications only have one form or strength, in which case these elements would not be required. The same error types were used in both handwritten and FormularyScript. However, what was considered a legibility or ambiguous error differed in the two groups. For example, a legibility error on Formulary Script occurred if the circle marked overlapped 2 medication names, and an ambiguous error on Formulary Script occurred if there was a question about the number next to drug name correlating with the prescribing information.

Data analysis

The frequency of the error types and error subtypes across all prescription elements between handwritten and Formulary Scripts were compared using a 2-sample test of proportions. A 2-sample test of proportions was also used to compare the frequency of error types on each element of the prescription. Statistical analysis was performed using Stata 9 statistical software. (StataCorp. 2005. *Stata Statistical Software: Release 9.* College Station, TX: StataCorp

LP.)   Because the required elements for a prescription varied by medication, a table of the possible error types for each medication was generated. If an error type was not possible it was not included in the denominator when the error rates were calculated.

RESULTS

Error types

A total of 4349 handwritten prescriptions and 4146 FormularyScripts were included in the data analysis. The overall rate of any medication prescribing error on a prescription using handwritten prescriptions was 32.9% compared with 3.5% using FormularyScripts (p<0.001). The rates of the 5 error types on a prescription were calculated and compared for handwritten and FormularyScripts (Table 2). Statistically significant decreases (p<0.001) using FormularyScripts were seen in the following error types: legibility (16.1% to 0.1%), incomplete (16.1% to 0.1%), and abbreviation (3.1% to 0.3%). There was a statistically significant increase in ambiguous errors with FormularyScripts (0.6% to 2.5%, p<0.001). There was no statistically significant change in accuracy errors (0.8% to 0.6%, p=0.21).

Error subtypes

Error subtype rates were calculated and compared for handwritten and FormularyScripts based on the required fields for the different medications. (Table 2). Key findings from this analysis were statistically significant (p<0.001) decreases in all legibility, incomplete and abbreviation error subtypes, except for legibility route, and incomplete which eye and dispensed amount. All accuracy error subtypes except dispensed amount showed a decrease or no change in error rates using FormularyScript, but only the decrease in which eye subtype reached statistical significance (0.5% to 0.1%, p<0.001). There were statistically significant increases in the error rates in both ambiguous error subtypes using FormularyScripts, which eye (0.3% to 2.5%, p<0.001), and drug name (0.3% to 0.6%, p=0.03).

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Table 2: Rates by Error Type and Subtype in Handwritten vs. FormularyScript

Error Type and Subtype	Handwritten N (%)	FormularyScript N (%)	Δ %	P value	CI
Legibility	**4349 (16.1)**	**4146 (0.1)**	**16.0**	**<0.001**	**(14.9, 17.1)**
Drug Name	4349 (5.7)	4146 (0.1)	5.6	<0.001	(4.9, 6.3)
Strength	1183 (5.8)	904 (0.0)	5.8	<0.001	(4.5, 7.2)
Route	564 (2.3)	161 (0.0)	2.3	0.052	(1.1, 3.5)
Which Eye	3785 (6.5)	3985 (0.0)	6.5	<0.001	(5.7, 7.3)
Frequency	4336 (4.6)	4144 (0.0)	4.6	<0.001	(4.0, 5.2)
Dispense Amount	4336 (1.3)	4144 (0.0)	1.3	<0.001	(0.9, 1.6)
Ambiguous	**4349 (0.6)**	**4146 (2.5)**	**-1.9**	**<0.001**	**(-2.4, -1.3)**
Drug Name	4336 (0.3)	4144 (0.6)	-0.3	0.03	(-0.6, -0.0)
Which Eye	3785 (0.3)	3985 (2.5)	-2.2	<0.001	(-2.6, -1.6)
Incomplete	**4349 (16.1)**	**4146 (0.1)**	**16.1**	**<0.001**	**(14.8, 17.0)**
Medication Name	4344 (12.3)	4145 (0.0)	12.3	<0.001	(11.3, 13.2)
Strength	1184 (6.0)	904 (0.0)	6.0	<0.001	(4.6, 7.3)
Route	563 (15.3)	161 (1.2)	14.1	<0.001	(10.6, 17.5)
Which Eye	3785 (0.2)	3986 (0.1)	0.0	0.70	(-0.1, 0.2)
Frequency	4346 (0.5)	4146 (0.0)	0.5	<0.001	(0.3, 0.7)
Dispense Amount	4346 (0.1)	4146 (0.0)	0.0	0.34	(-0.0, 0.0)
Abbreviation	**4349 (3.1)**	**4146 (0.3)**	**2.9**	**<0.001**	**(2.3, 3.4)**
Drug Name	4346 (3.1)	4146 (0.3)	2.9	<0.001	(2.3, 3.4)
Accuracy	**4349 (0.8)**	**4146 (0.6)**	**0.2**	**0.21**	**(-0.1, 0.6)**
Drug Name	4336 (0.1)	4146 (0.1)	-0.1	0.28	(-0.2, 0.1)
Strength	1187 (0.2)	911 (0.0)	0.2	0.21	(-0.1, 0.4)
Route	558 (0.2)	154 (0.0)	0.2	0.60	(-0.2, 0.5)
Which Eye	3789 (0.5)	3986 (0.1)	0.4	0.001	(0.2, 0.7)
Frequency	4349 (0.2)	4146 (0.2)	0.0	0.90	(-0.2, 0.2)
Dispense Amount	4349 (0.0)	4146 (0.2)	-0.2	0.004	(-0.3, -0.1)
Any Error	**4349 (32.9)**	**4146 (3.5)**	**29.4**	**<0.001**	**(27.9, 30.9)**

Prescription elements

The data were also analysed to determine the rate of any type of error in the required elements on each prescription. (Table 3) The presence of any type of error in that element was counted as an error. The denominator of possible errors was determined based on the required elements for that medication. There was a statistically significant decrease (p<0.001) using FormularyScripts in all prescription elements: drug name (20.8% to 1.1%), route (17.0% to 1.2%), strength (11.8% to 0.0%), which eye (7.5% to 2.6%), frequency (5.4% to 0.3%) and dispensed amount (1.3% to 0.2%).

Table 3: Error Rate by Prescription Element in Handwritten vs. FormularyScript

Prescription Element	Handwritten N (%)	FormularyScript N (%)	Δ %	P value	CI
Drug Name	4349 (20.8)	4146 (1.1)	19.7	<0.001	(18.5, 21.0)
Strength	1188 (11.8)	911 (0.0)	11.8	<0.001	(9.9, 13.6)
Route	565 (17.0)	161 (1.2)	15.7	<0.001	(12.2, 19.3)
Which Eye	3789 (7.5)	3986 (2.6)	4.9	<0.001	(4.0, 5.9)
Frequency	4349 (5.4)	4146 (0.3)	5.1	<0.001	(4.4, 5.8)
Dispense Amount	4349 (1.3)	4146 (0.2)	1.1	<0.001	(0.7, 1.5)

DISCUSSION

These results indicate that medication prescribing errors are common in the outpatient ophthalmology clinic at Srinagarind Hospital and are primarily due to legibility and incomplete information. This is similar to the findings of studies done in developed countries, which found that legibility and incomplete information are the most common types of medication prescribing errors[1-2], and error rates of 7.6-21% [1, 10-11]. Legibility errors, incomplete prescribing information, and use of unacceptable abbreviations were decreased using FormularyScript without changing the overall rate of accuracy errors. However, there

was an increase in ambiguous type of error suggesting that new ways of creating medication prescribing errors can occur.

As a nonrandomized single site interventional study, we acknowledge this study is limited in its conclusions and is not generalizable. In addition, there are several other important limitations that need to be mentioned. Determining and classifying prescribing errors is a subjective process, especially legibility errors. We tried to address this issue through using multiple reviewers to maximize the consistency of our classification. We acknowledge that an experienced pharmacist could decipher the correct information on most of these prescriptions, but the potential for misinterpretation existed. Because of this, the anticipated impact on medication prescribing errors that could result in actually dispensing the incorrect medication is less than predicted by the study's results. Another limitation is that medications lost to follow up (prescriptions written but not filled at the hospital pharmacy) were included in our calculations, so that 21.5% of handwritten and 5.0% of FormularyScript medications did not receive the second review by the pharmacy technician. We elected to include them because our results with and without them were unchanged. We believe that the design of the FormularyScript contributed to some ambiguous and accuracy errors as up to 3 medications could be written on one FormularyScript., and having only one medication per page may reduced some of the ambiguous and accuracy errors. While most physicians found the FormularyScript design acceptable and easy to use, occasionally some physicians wrote some prescriptions on the FormularyScript even though the medications were pre-printed. These were excluded from analysis but this may have created some selection bias. The physicians in the study were aware that the prescriptions were being analyzed for error rates, although the exact types and details were not disclosed. We acknowledge this could have resulted in modification of their behavior, or Hawthorn effect, which may have affected overall error rates in both handwritten prescriptions and FormularyScripts.

In conclusion, we <u>believe this study suggests that a </u>pre-printed prescription form <u>has the potential to </u>decrease medication prescribing errors related to legibility, incomplete prescribing information, and use of unacceptable abbreviations without changing the overall rate of accuracy errors. <u>Additional investigation is indicated to determine whether or not these benefits can be realized in other settings. Even though there are several important limitations to this study, we feel it brings attention to an important opportunity to address medication prescribing errors in low resource settings where electronic prescribing systems are not feasible. Our finding that new error types occur highlights the need to monitor any new medication prescribing system for unintended consequences. </u>By working closely with physicians and pharmacists, design and process modifications can be made to minimize this concern, in addition to providing adequate training for users.

Competing interests: None

Ethics approval: All procedures and protocols were approved by the Khon Kaen University Ethics Committee for Human Research and the Research Ethics Review Committee of the World Health Organization.

Patient consent: Informed consent was obtained from all patients and staff participating in the study.

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Tables

Table 1: Description of Study Population

Table 2: Rates by Error Type and Subtype in Handwritten vs. FormularyScript

Table 3: Error Rate by Prescription Element in Handwritten vs. FormularyScript

Figure legends

Figure 1: Reproduction of the FormularyScript. Patient demographic and accounting information is in Thai. Final version used in study had prescribing information in Thai. Three medications can be written on one form. A number is written next to each medication and corresponds with the prescribing information. Medications not listed can be written in blank spaces

โรงพยาบาลศรีนครินทร์ คณะแพทยศาสตร์ มหาวิทยาลัยขอนแก่น

HN. _____ | ใบสั่งยาผู้ป่วยนอก

ส่วนนี้ใช้ติด sticker ราคายาและข้อมูลผู้ป่วย

ชื่อ_____ อายุ _____
วันที่_____ สิทธิผู้ป่วย _____

◯ ค่าบริการ 50 บาท | ผู้ป่วยบัตรทองหรือประกันสังคม หลังการพบแพทย์แล้วให้ตรวจสอบสิทธิที่ช่อง 13-18 ก่อนติดต่อห้องจ่ายยา

antibiotic
_____ poly oph drop
_____ vigamox drop
_____ chlor oph drop
_____ kemicitin oint
_____ terramycin onit
_____ amphotericin B 0.3% drop
_____ ketoconazole 2% drop
_____ natamycin 5% drop
_____ zovirax 3% oint
_____ cloxacillin.........mg cap
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anti inflammation
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_____ pred forte 1% drop
_____ efemolin drop
_____ dexamethasone 0.1% drop
_____ flucithalmic gel
_____ restasis drop
_____ voltaren drop
_____ nevanac drop
tear
_____ genteal drop
_____ systane drop
_____ tear naturale free drop
_____ vislube drop
_____ genteal gel
_____ vidisic gel
_____ lac oph

anti glaucoma
_____ pilocarpine 2% drop
_____ glauco oph 0.5% drop
_____ alphagan 0.2% drop
_____ lumigan0.03% drop
_____ xalatan 0.005% drop
_____ travatan 0.004% drop
_____ alphagan-P 0.15% drop
_____ xalacom drop
_____ azopt 1% drop
_____ cosopt drop
_____ combigan drop
_____ diamox 250mg tab
_____ 50%glycerine soln
anti allergy
_____ hista oph drop
_____ spersallerge drop
_____ alomide 0.1%
_____ vividrin drop
_____ zaditen drop
antibiotic + steroid
_____ dexoph drop
_____ trobradex drop
_____ maxitral oint
other
_____ atropine.........% drop
_____ NaCl ....% drop
_____ paracetamal ....mg tab
_____ solcoseryl 20% gel

Drug 1 _____

Dose	Route	Times/day	Every # hours	จำนวน
◯ 1 หยด ◯ ตาขวา	1	1	6	ขวด
◯ 1 เม็ด ◯ 2 ตา	2	2	8	หลอด
◯ 2 เม็ด ◯ ตาซ้าย	3	3	12	เม็ด
◯.........cc ◯ กิน ◯ ac ◯ pc	4	4		กล่อง
◯............ ◯ เปลือกตา	◯ prn	◯ hs		

Drug 2 _____

Dose	Route	Times/day	Every # hours	จำนวน
◯ 1 หยด ◯ ตาขวา	1	1	6	ขวด
◯ 1 เม็ด ◯ 2 ตา	2	2	8	หลอด
◯ 2 เม็ด ◯ ตาซ้าย	3	3	12	เม็ด
◯.........cc ◯ กิน ◯ ac ◯ pc	4	4		กล่อง
◯............ ◯ เปลือกตา	◯ prn	◯ hs		

Drug 3 _____

Dose	Route	Times/day	Every # hours	จำนวน
◯ 1 หยด ◯ ตาขวา	1	1	6	ขวด
◯ 1 เม็ด ◯ 2 ตา	2	2	8	หลอด
◯ 2 เม็ด ◯ ตาซ้าย	3	3	12	เม็ด
◯.........cc ◯ กิน ◯ ac ◯ pc	4	4		กล่อง
◯............ ◯ เปลือกตา	◯ prn	◯ hs		

....
....
....

แพทย์_____
เลขที่ใบอนุญาตประกอบวิชาชีพเวชกรรม _____

คิดเงิน_____ ติดฉลากยา_____
จัดยา_____ ตรวจสอบยา_____ ส่งมอบยา_____
ผู้รับยา_____

ยื่นใบสั่งยา-คิดราคา-รับเอกสารแล้ว ดำเนินการ ดังนี้

● ผู้ป่วยบัตรจ่ายตรงหรือชำระเงินเอง ติดต่อ ห้องการเงิน หมายเลข **33-38**

เมื่อดำเนินการเรียบร้อยแล้ว นำเอกสารนี้ไปนั่งรอรับยา

(เจ้าหน้าที่การเงิน กรอกข้อมูล) ....

....

● ผู้ป่วยบัตรทอง/ผู้ป่วยประกันสังคม ให้ถือเอกสารนี้นั่งรอรับยา

ส่วนนี้ใช้ติด sticker ราคายาและข้อมูลผู้ป่วย

OPD 801-ยาน้ำ update 26-01-53

Reproduction of the FormularyScript. Patient demographic and accounting information is in Thai. Final version used in study had prescribing information in Thai. Three medications can be written on one form. A number is written next to each medication and corresponds with the prescribing information. Medications not listed can be written in blank spaces

209x297mm (300 x 300 DPI)

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
Outcome data	15*	Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.