PRESCRIPTION RECORD REVIEW STUDY IN MOZAMBIQUE

MAKING MEDICAL INJECTIONS SAFER PROJECT STUDY REPORT

SEPTEMBER 2009

This publication was produced for review by the United States Agency for International Development. It was prepared by the Making Medical Injections Safer (MMIS) project.

ACKNOWLEDGEMENTS

The MMIS team is grateful to the management of the three health centers involved in this assessment for allowing the consultant access to their records and support from their staff. MMIS also acknowledges the Ministry of Health for their permission and cooperation during the time of the data collection exercise. Also, special thanks to MMIS/Mozambique for their participation in training, supervision, logistical coordination, and data collection for this study. Special thanks to the team of writers for this report: Dr. Marcelo Castrillo, Analysis and Technical Reviewer, Ms. Hanise Sumbana, Consultant Study Coordinator, and Ms. Karen Van Roekel, Senior M&E Advisor and Principal Investigator for this study. Also, thanks to other MMIS staff, particularly to Dr. Americo Ubisse, MMIS/Mozambique Country Director, Dr. Iqbal Hossain, MMIS Technical Officer, and Ms. Deepa Bhat Shanadi, MMIS Consultant, who collaborated with the report-writing team on the development of the analysis by diagnostic group, and to Dr. Castrillo, who then finalized and applied this to the analysis presented in this report. Thanks also go to Ms. Megan Noel, M&E Technical Officer, for overall support for training, technical review of the report, and institutional review board approval, to Ms. Marissa Wheeler, MMIS Consultant, for training Ms. Sumbana to conduct the data collection, and to Dr. Herman Willems of JSI, who contributed to cleaning and translating the diagnostic information used in this analysis.

MMIS thanks the US Agency for International Development (USAID) and the President's Emergency Plan for AIDS Relief (PEPFAR), whose financial support has made the survey possible.

This study would not have been complete without the prescribers who provided the information upon which the report is based. Our gratitude goes to all the informants who participated.

PRESCRIPTION RECORD REVIEW STUDY IN MOZAMBIQUE

MAKING MEDICAL INJECTIONS SAFER PROJECT STUDY REPORT

Abstract: The United States President's Emergency Plan for AIDS Relief (PEPFAR), through the US Agency for International Development (USAID), has funded John Snow, Inc. (JSI) for the implementation of the Making Medical Injections Safer (MMIS) project on injection safety in Mozambique. JSI and its partners are responsible for implementing other, similar projects in 10 other countries in Africa and the Caribbean. This report compares the results from prescription records from baseline and follow-up study periods to assess the level of unnecessary injections in three sentinel site health centers.

Recommended citation: M. Castrillo, H. Sumbana, and K. Van Roekel. *Prescription Record Review Study in Mozambique:* ***September*** *2009 Study Report*. MMIS for the Office of the Global AIDS Coordinator and the Department of Health and Human Services.

Development of this publication was supported by USAID, contract # GSA-GS-10F-0453. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of OGAC or USAID.

The Making Medical Injections Safer (MMIS) project is a five-year initiative funded by the President's Emergency Plan for AIDS Relief through the US Agency for International Development. Financial support was provided through contract # GHS-I-00-03-0026-00.

Making Medical Injections Safer is implemented by JSI Research & Training Institute, Inc. in collaboration with the Program for Appropriate Technology in Health (PATH), the Academy for Educational Development (AED), and the Manoff Group.

This page was left intentionally blank.

John Snow, Inc./Mozambique
Av. Mao Tse Tung, House 820, P.O. Box 149
Maputo City, Mozambique
Tel: 258.82.3253.330
Fax: 258.21.312544
Email: aubisse@jsi.org.mz

MMIS Headquarters
John Snow, Inc.
1616 N. Fort Myer Drive, 11th floor
Arlington, Virginia 22209 USA
Tel: 1 (703) 528-7474
Email: info@mmis.jsi.com
www.mmis.jsi.com

Office of the Global AIDS Coordinator
SA-29, 2nd floor
2201 C Street NW
Washington, DC 20522-2920 USA
Tel: 1 (202) 663-2708
www.pepfar.gov

US Agency for International Development
Bureau of Global Health
Office of HIV/AIDS
Ronald Reagan Building
1300 Pennsylvania Avenue NW
Washington, DC 20523 USA
Tel: 1 (202) 712-4810
Email: inquiries@usaid.gov
www.usaid.gov

TABLE OF CONTENTS

Acknowledgements 2

Acronyms 7

Executive Summary 9

1. Introduction 11

2. Objectives and Methodology 13
   2.1 Methods 13

3. Results 17
   3.1 Characteristics of the Sample Obtained 17
   3.2 Use of Injectable Medication 19
   3.3 Pharmaceutical Stock Data Results 21
   3.4 Supply Stock Data Results 24
   3.5 Prescriber Interview Results 24
   3.6 Study Limitations 26

4. Conclusions and Recommendations 27

Appendix A. Questionário para profissionais prescritores 29

ACRONYMS

HIV	Human immunodeficiency virus
JSI	John Snow, Inc.
MoH	Ministry of Health
MMIS	Making Medical Injections Safer
OPD	Outpatient department
PEPFAR	President's Emergency Plan for AIDS Relief
PRR	Prescription Record Review
SIGN	Safe Injection Global Network
STI	Sexually transmitted infection
WHO	World Health Organization
USAID	US Agency for International Development

EXECUTIVE SUMMARY

USAID's Making Medical Injections Safer (MMIS) project supports the Mozambique Ministry of Health to strengthen injection safety practices by replacing injections that are not medically necessary with non-injectable medications, where appropriate. The goal of this effort is to reduce the risk of accidental needle stick injuries, hence also reducing the cost of syringes and the commodity management system, eliminating the need for patients to return to the facility for follow-up injections, and reducing the amount of sharps waste to be managed.

This study was designed to collect information before and after interventions to reduce the unnecessary use of injectable medications. The main objective is to assess prescription patterns and to measure whether training and policy changes have had any effect in reducing the use of injectable medications.

The study is based on the prescription and administration of medications as recorded in three health facilities' outpatient registers. The study collected baseline information for the period from August 2005 to January 2006 and follow-up data from August 2007 to January 2008. Stock records were also collected for both study periods to assess the availability of injectable and non-injectable medications as well as injection devices. These additional data were used to assess whether shortages in these commodities could be influencing the prescription patterns for injectable versus non-injectable medications. Finally, prescribers were interviewed about their perceptions and practices related to injectable and non-injectable medications.

For this study, only outpatient department (OPD) records in three health centers (Albasine, 1 de Junho, and Polana Cimento) were assessed. Inpatient records were not reviewed because it was expected that patients admitted for inpatient treatment would be sicker, and prescribers would be less likely to have flexibility in deciding what type of medication to prescribe for them.

Records were reviewed for a six-month period for both the baseline and follow-up, as described in the study protocol. Records were evenly sampled from each one of the six months. The data collector systematically selected the cases to be extracted and reviewed. After 400 records were selected from the registers, data were entered into a laptop computer using a Microsoft Access database designed by MMIS for this study.

Data were successfully collected at all three health facility sites. Overall, 2,482 patient cases were recorded in the database, including 1,263 for the baseline (August 2005 to January 2006) and 1,219 for the follow-up (August 2007 to January 2008) study periods.

Examination of the prescribers' background showed that nurses were the main care providers at outpatient clinics: 95% of all records sampled showed that nurses were providing care across all of the health facilities studied. The gender distribution of the patients was similar in both study periods and within each health facility. The patients' age distribution was similar in both baseline and follow-up groups and within each health facility.

Across the two study periods, this study found that the largest percentage of overall cases prescribed unnecessary injectable medications was 4.6% (±1.37%) at baseline, compared with 5.8% (±1.57%) at follow-up, with an odds ratio of 1.26. The slight increase was not statistically significant because the confidence intervals overlapped and the odds ratio was close to 1.

With such low rates of prescriptions for injectable medications, as well as the lack of availability of non-injectable alternative medications in Mozambique, results from data collected on stocks of medications and supplies did not impact the recommendations that resulted from this study. Prescriber interviews revealed, among other results, that 6 out of 13 prescribers stated it would be easier to prescribe orals instead of injectables if better supplies of oral medicines were available. Most prescribers also said that the

majority of injections are prescribed for patients being treated for sexually transmitted infections (STIs), and one prescriber concluded that “theoretically there are oral medications for STIs, but in practice they are still not available. That is why we still use kanamycin.” This response suggests that more emphasis is needed on supplying appropriate non-injectable medications to treat STIs, although patient data collected by this study did not identify overuse of injectable medications to treat STIs.

A general recommendation for this kind of study to be conducted in the future is to focus on only a few tracer diseases, where the diagnosis and treatment are straightforward, leaving little room for other interpretations and confounding factors. This approach would provide larger numbers of cases per tracer disease than systematically sampling records across all records recorded during the study periods.

A general, overarching recommendation for the district-level health authorities is to improve the information in patient logbooks. Health authorities need to review and supervise how logbooks are being filled out, in the columns of diagnosis or disease classification and of what procedure and treatment was provided, through quality checks and routine supervision. To this end, additional in-service training would be recommended, particularly for nurses. Stock records also showed room for improvement in stocking appropriate treatments, like those used to treat STIs in particular.

1. INTRODUCTION

According to the World Health Organization (WHO), 8–16 million cases of hepatitis B, 2.3–4.7 million cases of hepatitis C, and 80,000–160,000 of HIV infections are caused each year worldwide by the use of unsafe injections. High-risk practices include the reuse of syringes and needles as well as improper disposal of used sharps. On the other hand, over prescription of injectable medications may exacerbate the rate of transmission of blood-borne pathogens because more injections mean more injection material to be disposed of, more opportunities for accidental needle sticks, and a greater need for new sterile devices to ensure safe injections. Given these facts, WHO, particularly the Safe Injection Global Network (SIGN), and its partners developed an intervention strategy aimed at reducing injections and promoting the administration of safe injections. The SIGN core intervention areas are:

I. Behavior change of health care workers and patients to ensure safe injection practices and reduce unnecessary injections;

II. Ensuring availability of equipment and supplies; and

III. Managing waste safely and appropriately.

With the exception of vaccination programs, safe injections and waste management had not received proper attention from governments and development partners until recently. The Making Medical Injections Safer (MMIS) project, which is funded by the US President's Emergency Plan for AIDS Relief (PEPFAR) under the management of USAID and the US Centers for Disease Control and Prevention (CDC), was specifically designed to address this issue. The MMIS project under USAID supports the Mozambique Ministry of Health to strengthen injection safety practices by replacing injections that are not medically necessary with non-injectable medications and hence reducing the risk of accidental needle stick injuries, reducing the number of syringes needed and hence the costs associated with their procurement and transport to facilities, eliminating the need for patients to return to the facility for follow-up injections, and reducing the amount of sharps waste to be managed.

The MMIS health workers' training and behavior change interventions aim at the reduction of unnecessary therapeutic injections. Health prescribers and providers are trained in proper prescribing procedures, stressing that non-injectable medicines are usually easier, safer, quicker, and less expensive. On the demand side, the project aims to reduce the demand for injections among patients by explaining the availability of non-injectable medicines that are as effective as injectables.

2. OBJECTIVES AND METHODOLOGY

This study was designed to collect information before and after interventions to reduce unnecessary injections. The main objective is to determine medicine prescription patterns and to measure whether training and policy changes have had any effect in reducing the use of injectable medication.

The study is based on the prescription and administration of medicines and injectables as recorded in the three health facilities' outpatient registers. The study collected baseline information for the period August 2005 to January 2006 and follow-up data from August 2007 to January 2008. Stock records were also collected for both study periods to assess the availability of injectable and non-injectable medications as well as injection devices. These additional data were used to assess whether shortages in these commodities could be influencing the prescription patterns for injectable versus non-injectable medications. Finally, prescribers were interviewed in the follow-up assessment about their perceptions and practices related to injectable and non-injectable medications.

The analysis will also serve to enable Mozambique's MMIS project and Ministry of Health (MoH) to identify strengths and weaknesses in training and other project activities as they relate to prescribers as well as external factors, and to develop recommendations.

The study included data collection from actual prescriptions and from reviewing the information recorded in outpatient registers from the two study periods. The main objectives of the study are:

I. Compare the percentage of curative injections pre-intervention versus post-intervention across all cases and for specific illness groups that are common enough to have quantifiable results.

II. Ascertain the extent to which stockouts of non-injectable medication alternatives, injectable medications, or injection devices may affect the increase or decrease in the use of injections.

2.1 METHODS

For this study, only outpatient department (OPD) records in health centers were reviewed. The purpose of this selection criterion is to minimize the complexities inherent in analyzing cases admitted for inpatient care that might have required injectable medications for reasons that would not necessarily be fully documented in the patient registration records. Only outpatient records were used because it was assumed that the cases would be less complex (since patients with severe illness are likely to be referred for admission immediately rather than being treated in the OPD). This was intended to facilitate the analysis as to which injections were likely to be medically necessary.

2.1.1 STUDY SITES

Three health centers, Albasine, 1 de Junho, and Polana Cimento, were chosen at which to carry out the study. These sites were chosen by following a convenience sampling method based on the following criteria:

I. Willingness of senior facility management staff to participate by facilitating or permitting examination of OPD records in their facility.

II. Presence of outpatient services with at least 400 cases over a six-month period for both baseline and follow-up studies.

III. Willingness and availability of facility staff to assist with data collection at the conclusion of each study period (baseline and follow-up). For example, pharmacy staff were asked to assist MMIS

data collectors with interpreting stock register information, and OPD staff were asked to assist by transcribing patient record information from registers while eliminating identifiers from patient records.

IV. Timing of interventions to improve injection safety. Interventions should start after records have been collected for the baseline study period and should be completed by the start of the follow-up study period, unless only retrospective data collection is taking place.

V. Availability of stockroom records to obtain information on stockouts of key medications and injection devices, with dates of those stockouts, if any.

VI. Quality of patient records and stockroom registers sufficient for collecting necessary data. Records needed to be legible and to include specific dates.

VII. Location of study facilities near Maputo so that MMIS staff could provide support and follow-up to changes in record keeping that were needed to facilitate the data collection (such as recording the type of medication given and ensuring complete record keeping).

MMIS recognizes that use of these criteria introduced selection bias, but this was considered a reasonable limitation of this study given that each selected facility serves as its own control over time and given that the objective is to assess whether the MMIS interventions have been effective in these facilities.

2.1.2 SAMPLE DESIGN

The sample for this study was calculated at 1,200 cases per study period (baseline and follow-up), for a total of 2,400 cases. The total number of records needed per facility was calculated as a minimum of 400 per study period, which was divided evenly as 70 records per month (rounded) over the six-month period. The minimum sample size of 400 for each site was chosen to permit the estimation of proportions with 95% confidence bounds of ±5.0% or tighter for each site. In cases where 70 records were collected in each month, the total number per facility per time period increased to 420, allowing a 5% margin above the desired sample size for incomplete records.

For the purposes of the study, records were reviewed for the six-month period for both the baseline and follow-up. Records were evenly sampled from each one of the six months. The data collector reviewed the outpatient registers to count the total number of cases recorded for a given month. The data collector divided this number by the number of cases needed per month (i.e., 70) to determine the sampling interval. Using a random-number starting point, the data collector systematically selected the cases to be extracted and reviewed.[1] This process was repeated for each month in the six-month period to complete the sample of 400 cases that was required per facility. In cases where the records were maintained in two or more separate registers, the data collector counted the records for the month to be sampled in each register and distributed the desired sample of 70 per month proportionally across the two or more registers.

The follow-up sampling period was originally planned to begin after interventions following baseline period reporting. However, because it was noted that the number of injections for the August 2007 to January 2008 period—initially considered the baseline—was low, and because it was thought that policy changes for treatment of sexually transmitted diseases and behavior change messages at a national level might have already had an effect, it was agreed that earlier data should be collected, for August 2005 to January 2006. This period would serve as an earlier baseline before any interventions by MMIS or the MoH had begun. Thus, August 2005 to January 2006 was considered the baseline period, and August 2007 to January 2008 was the follow-up period. The same six calendar months were chosen for both baseline and follow-up periods in order to control for seasonality effects.

---

[1] Systematic selection rather than random selection was used to ensure that the cases were spread across the entire month and to minimize sampling error since the cases were recorded in a list.

2.1.3 PATIENT DATA COLLECTION

After the 400 patient records were selected from the record books, data were entered into a laptop computer using a Microsoft Access database specifically designed by MMIS for this study. The following variables were selected from each prescription record:

- Day, month, and year of patient visit
- Gender of the patient
- Age of the patient
- Primary diagnosis[2]
- All secondary diagnoses (if available)
- Names of all medications used for treatment/prescription (each listed separately in the data set in the order in which they appeared in the prescription register)
- Whether each medication listed was prescribed in an injectable or non-injectable preparation[3]
- Number of injections per prescription of injectable medication (if available)

In order to guarantee the confidentiality of the information, patients' names were not disclosed. A facility staff person who was familiar with the register books in the normal course of his/her employment at the facility was assigned to work with the consultant, and this person's task was to read aloud the information required from the register book. Before the session started, the staff person responsible for reading the information aloud signed a confidentiality form. The presence of health facility staff proved to be crucial because of the fact that they understood the medication codes used in the treatment section of the patient records. The codes used specify what medication is prescribed as well as the type of formulation (injectable or non-injectable).

2.1.4 STOCK DATA COLLECTION

Another component of the study involved analyzing the availability of medications at the health center's pharmacy by looking at stock records. The medication list was derived from the list of prescribed medications as reflected in the study database. Moreover, a list of alternative medications was developed with the pharmacy staff at each health center and was also checked to identify whether the alternative medicines were available during the same study period. In addition, the data collector inquired about the availability of injection devices such as syringes. A medication or a device was considered to be out of stock if it was not available on any day in a given month. The main objective of collecting such information was to ascertain the extent to which stockouts of non-injectable medication alternatives, injectable medications, or injection devices may have affected the increase or decrease in the use of injections.

---

[2] For each case, the diagnoses were recorded in the database using a prepared listing based on the field test of this activity in Mozambique. The diagnosis list was translated into Portuguese, and some other diagnoses were added during the data collection period. Cases with a diagnosis that did not match one of the pre-established diagnoses in the listing were reviewed and coded by the local consultant and project staff with a medical background. In some cases, the information recorded was a condition rather than a formal diagnosis, but in this report, these data will simply be referred to as diagnostic groups.

[3] It should be noted that it may not be possible to tell from the prescription record whether any substitutions were made at the time the prescription was filled. This data collection was intended to assess the prescription pattern itself, not the actual pattern of compliance or consumption by patients.

2.1.5 DATA ENTRY AND ANALYSIS

Data entry and preliminary analysis were performed using the Microsoft Access database. The database was designed by MMIS and featured separate data tables for patient records, medical stock records, and supply stock records. The format of the database was developed for use across multiple countries.

All three health centers provided an office space where the consultant would work. They also made a facility staff person available to read out the information from the register books, which was then entered into the database by the MMIS consultant. This activity was always performed on-site.

The analysis of this data set was conducted from several perspectives. These included calculating the percentage of cases that included one or more medications prescribed in injectable formulations. Data on gender, age, and prescriber type were also analyzed.

2.1.6 PRESCRIBER INTERVIEWS

In order to complement the information gathered from the record books, qualitative interviews were also conducted. Prescribers served as the interviewees. The consultant interviewed 1 medical doctor and 10 nurses. An informational recruitment letter was presented to all candidates to introduce them to the PRR study and explain the interview requirements. The letter further explained the voluntary nature of the interview. For those who consented to participate—which included prescribers employed at the study sites—interviews were conducted in a private setting. The interview consisted of 16 questions designed to capture information about how and why prescribers make their choices to prescribe injectable or non-injectable formulations when treating patients. The interview questionnaire was translated into Portuguese, the official language of Mozambique. (See Appendix A for the interview questionnaire.)

3. RESULTS

The discussion will examine the baseline and follow-up periods. Data and comparisons were stratified and analyzed by gender and age of patients as well as by facility and according to the two types of prescribers, doctors and nurses.

3.1 CHARACTERISTICS OF THE SAMPLE OBTAINED

Table 1 shows that data were collected at the three health facility sites. Overall, 2,482 cases were recorded in the database, including 1,263 for the baseline and 1,219 for the follow-up study periods. Table 1 details the number of recorded cases per health facility, prescriber type, gender, and age group.

Examination of the prescribers' background showed that nurses were the main care providers at outpatient clinics: 95% overall and in all of the health facilities studied. This fact will be relevant when examining treatment provided, including injectables.

Gender distribution was similar in both study periods and across the health facilities, with slightly more female patients sampled than males.

Age distribution was also similar in both baseline and follow-up groups and within each health facility. The review of the records collected the ages of the patients already grouped into the given groups, thus not allowing any further age-group breakdown. Patients in the age group "15 and above" (≥15 years) made up about half of the records reviewed.

Table 1. Characteristics of the prescription records reviewed			
Indicator	**Baseline (*n* = 1,263)**	**Follow-up (*n* = 1,219)**	**Total (*n* = 2,482)**
Health facility			
Albasine	421	411	832
Polana Cimento	420	392	812
1 de Junho	422	416	838
Prescriber type			
Nurse	1,201 (95.2%)	1,177 (96.6%)	2,378 (95.9%)
Doctor	61 (4.8%)	41 (3.4%)	102 (4.1%)
Health facility *Prescriber type*			
Albasine			
Nurse	401 (95.2%)	382 (92.9%)	783 (94.1%)
Doctor	20 (4.8%)	29 (7.1%)	49 (5.9%)
Polana Cimento			
Nurse	386 (92.1%)	388 (99.2%)	774 (95.6%)
Doctor	33 (7.9%)	3 (0.8%)	36 (4.4%)
1 de Junho			
Nurse	414 (98.1%)	407 (97.8%)	821 (98.0%)
Doctor	8 (1.9%)	9 (2.2%)	17 (2.0%)
Gender			
Male	579 (45.9%)[a]	544 (44.7%)	1,123 (45.3%)
Female	683 (54.1%)	674 (55.3%)[a]	1,357 (54.7%)
Age group (in years)			
0–4	496 (39.3%)	434 (35.6%)	930 (37.5%)
5–14	219 (17.3%)	157 (12.9%)	376 (15.1%)
≥15	548 (43.4%)	628 (51.5%)	1,176 (47.4%)

[a] One missing case.

Table 2 shows the number of cases in each *diagnostic group* from the baseline and follow-up samples. This table is based on diagnoses recorded in the outpatient registers at the health facilities visited. The data collection form had five columns for up to five separate or concurrent diagnoses; however, it must be pointed out that the first column of the data collection form, or "*primary diagnosis*", was not consistently used by health staff recording the data in the registers for the main disease or condition. Instead, it simply represents what the health workers recorded first, without any order of prioritization. Cases actually sampled from these study facilities had no more than three diseases or conditions listed in the patient records. In the subsequent analysis, particularly of the medications given, information about all recorded diagnoses was considered for each case.

During data cleaning Marcelo Castrillo, coauthor and technical reviewer for this report, who has a medical background, supported the development of the standardized groups of diagnoses (*diagnostic groups*) in order to facilitate the quantitative analysis of the diagnostic information.[4]

Table 2 shows that about half of the cases (49.6%) were grouped with five main conditions that would not require injectable medication: malaria, bronchitis, fever, diarrheal diseases, and upper respiratory infections including influenza. It is important to note that this study controlled for seasonal variation when comparing baseline and follow-up diagnoses by sampling cases from the same six calendar months in each study period.

[4] For instance, small numbers of cases of "malaria syndrome" were aggregated under the diagnostic group "malaria", since the symptoms and medication would be the same.

Table 2. Diagnostic groups for analysis, by study period						
Diagnostic group (primary disease/condition)	**Baseline (*n* = 1,263)**		**Follow-up (*n* = 1,219)**		**Total (*n* = 2,482)**	
Malaria	303	24.0%	164	13.5%	467	18.8%
Bronchitis	129	10.2%	134	11.0%	263	10.6%
Fever	122	9.7%	111	9.1%	233	9.4%
Impetigo	68	5.4%	82	6.7%	150	6.0%
Diarrhea[a]	79	6.3%	59	4.8%	138	5.6%
Influenza/URIs[b]	77	6.1%	51	4.2%	128	5.2%
Abdominal pain	36	2.9%	88	7.2%	124	5.0%
Ache (not including heart condition)	37	2.9%	76	6.2%	113	4.6%
Pneumonia[c]	29	2.3%	68	5.6%	97	3.9%
Ear infection/sinusitis	38	3.0%	39	3.2%	77	3.1%
Ascariasis	43	3.4%	23	1.9%	66	2.7%
Candidiasis	33	2.6%	30	2.5%	63	2.5%
Dermatitis	27	2.1%	30	2.5%	57	2.3%
Dysuria/hematuria	23	1.8%	29	2.4%	52	2.1%
Arthritis	21	1.7%	25	2.1%	46	1.9%
Conjunctivitis	19	1.5%	24	2.0%	43	1.7%
Wound	15	1.2%	21	1.7%	36	1.5%
Allergy	15	1.2%	18	1.5%	33	1.3%
Asthma	27	2.1%	2	0.2%	29	1.2%
Abscess	12	1.0%	16	1.3%	28	1.1%
Herpes	6	0.5%	20	1.6%	26	1.1%
Miscellaneous group[d]	104	8.3%	109	8.9%	213	8.5%

[a] The records did not specify hydration condition.
[b] Upper respiratory infections.
[c] Lower respiratory condition, compatible with pneumonia.
[d] Includes the following diseases/conditions with too few cases to consider separately: abdominal pain and pelvic inflammatory disease amenorrhea, anemia, ascites, burn, clubfoot, contusion, diabetes, dizziness, edema, filariasis, gangrene, gingivitis, gonorrhea, heart diseases, hypertension, infected wound, intoxication, mumps (alone), myalgia, myoma, psychological conditions, seizures, STIs, syphilis, tuberculosis, tumors, vaginal bleeding, varicella, vitiligo, weakness, and weight loss.

3.2 USE OF INJECTABLE MEDICATION

Each diagnosis has a prescribed treatment in the standard treatment guidelines used in Mozambique. To analyze the pattern of prescribing behavior reflected in these records and the extent to which this behavior is consistent with the standard guidelines, each diagnosis was first checked to assess whether the guidelines included the option of an injectable medication as a treatment. Because the order in which the diagnoses were recorded was arbitrary and the goal of this study was to assess whether the general pattern of prescriptions of injectable medications was rational, the analysis of prescribing patterns by disease did not attempt to assess whether a particular medication was given for a particular disease, but rather whether the overall pattern of prescriptions of injectable medications versus non-injectable medications was consistent with the treatment guidelines. Table 3 shows 1,517 cases with diseases and/or conditions for which standard treatment does not require injectable medication. The overall unnecessary use of injectable medications was 4.6% (±1.37%) at baseline, compared with 5.8% (±1.57%) at follow-up, with an odds ratio of 1.26. The slight increase was not statistically significant because the confidence intervals overlapped and the odds ratio was close to 1.

However, to make further inferences from the data presented in Table 3, two facts need to be examined. Candidiasis accounts for most of the unnecessary use of injectable medicines, and the injectable antibiotic most used was kanamycin. Another trend which can be interpreted from Table 3 is that there are only 4

STI cases meaning that most likely some candidiasis cases were wrongly classified and were actually STI cases mixed with true candidiasis (leucorrhea and vaginal discharge).[5] When the candidiasis row is removed, the overall percentage of unnecessary use of injectable medicines drops to 1.9% (1.4% for baseline and 2.4% for follow-up).

On the basis of this finding, there appears to be a trend of unnecessary use of injectables, but it is confined to sexually transmitted diseases, if indeed some candidiasis cases were actually STIs. In any case, evidence from this study suggests that further examinations are needed to clarify those issues and that more attention is needed to the syndromic management of STIs.

Table 3. Distribution of diseases and/or conditions for which standard treatment does not require injectable medication, by study period

Disease and/or condition	Baseline			Follow-up			Total		
	Total cases	Used injection		Total cases	Used injection		Total cases	Used injection	
Malaria	291	1	0.3%	151	5	3.3%	442	6	1.4%
Bronchitis	125	3	2.4%	131	1	0.8%	256	4	1.6%
Impetigo	68	2	2.9%	81	1	1.2%	149	3	2.0%
Diarrhea	78	0	0.0%	57	0	0.0%	135	0	0.0%
Influenza	77	2	2.6%	50	0	0.0%	127	2	1.6%
Pneumonia	27	1	3.7%	63	9	14.3%	90	10	11.1%
Ear infection, sinusitis, and URI	37	1	2.7%	38	0	0.0%	75	1	1.3%
Ascariasis	43	0	0.0%	23	0	0.0%	66	0	0.0%
Candidiasis	**33**	**27**	**81.8%**	**29**	**24**	**82.8%**	**62**	**51**	**82.3%**
Dermatitis	27	1	3.7%	30	0	0.0%	57	1	1.8%
Herpes	6	0	0.0%	20	0	0.0%	26	0	0.0%
Hypertension	6	0	0.0%	4	0	0.0%	10	0	0.0%
Tuberculosis (no meningitis)	2	0	0.0%	6	0	0.0%	8	0	0.0%
Filariasis	3	0	0.0%	2	0	0.0%	5	0	0.0%
Mumps (alone)	1	0	0.0%	3	0	0.0%	4	0	0.0%
Amenorrhea	2	0	0.0%	1	0	0.0%	3	0	0.0%
Gingivitis	1	0	0.0%	1	0	0.0%	2	0	0.0%
Total	827	38	4.6%	690	40	5.8%	1,517	78	5.1%

[5] The outpatient records in Portuguese classified the conditions as leucorrhea, candidiasis or vaginal discharge, and also oral candidiasis, hence some males were also counted.

Baseline		Follow-up		Odds ratio
Average	Confidence interval	Average	Confidence interval	
4.6%	±1.37%	5.8%	±1.57%	1.26

Disease and/or condition	Baseline			Follow-up			Total		
	Total cases	Used injection		Total cases	Used injection		Total cases	Used injection	
Total without candidiasis	794	11	1.4%	661	16	2.4%	1,455	27	1.9%

Once the list of diseases or conditions for which injectable medication is not recommended was established, the next step of the analysis was to obtain the number of injectables used overall and by four independent variables (health facility, prescriber type, age group, and gender).

Cross-tabulating by independent variables shows that the health facility 1 de Junho prescribed the most unnecessary injectable medications at both baseline and follow-up. Nurses provided treatment for these types of cases sampled from all three health facilities, with a slightly higher percentage during the follow-up study. Overall, the oldest age group (≥15 years) was prescribed more unnecessary injectable medication compared with the younger groups, and overall, female records showed a slightly higher rate of prescriptions for unnecessary injectable medications (Table 4).

Table 4. Distribution of diseases and/or conditions for which standard treatment does not require injectable medication, by independent variable and by study period

Independent variable	Baseline (*n* = 826)	Follow-up (*n* = 690)	Total (*n* = 1,516)
Health facility			
Albasine	1.0%	5.7%	3.1%
Polana Cimento	2.9%	4.3%	4.3%
1 de Junho	11.8%	7.7%	7.5%
Prescriber type			
Nurse	4.8%	6.1%	5.2%
Doctor	0.0%	0.0%	0.0%
Age group (in years)			
0–4	0.3%	4.3%	1.7%
5–14	4.1%	1.1%	2.7%
≥15	11.1%	9.5%	8.6%
Gender			
Male	1.3%	3.5%	3.6%
Female	7.6%	8.2%	6.2%

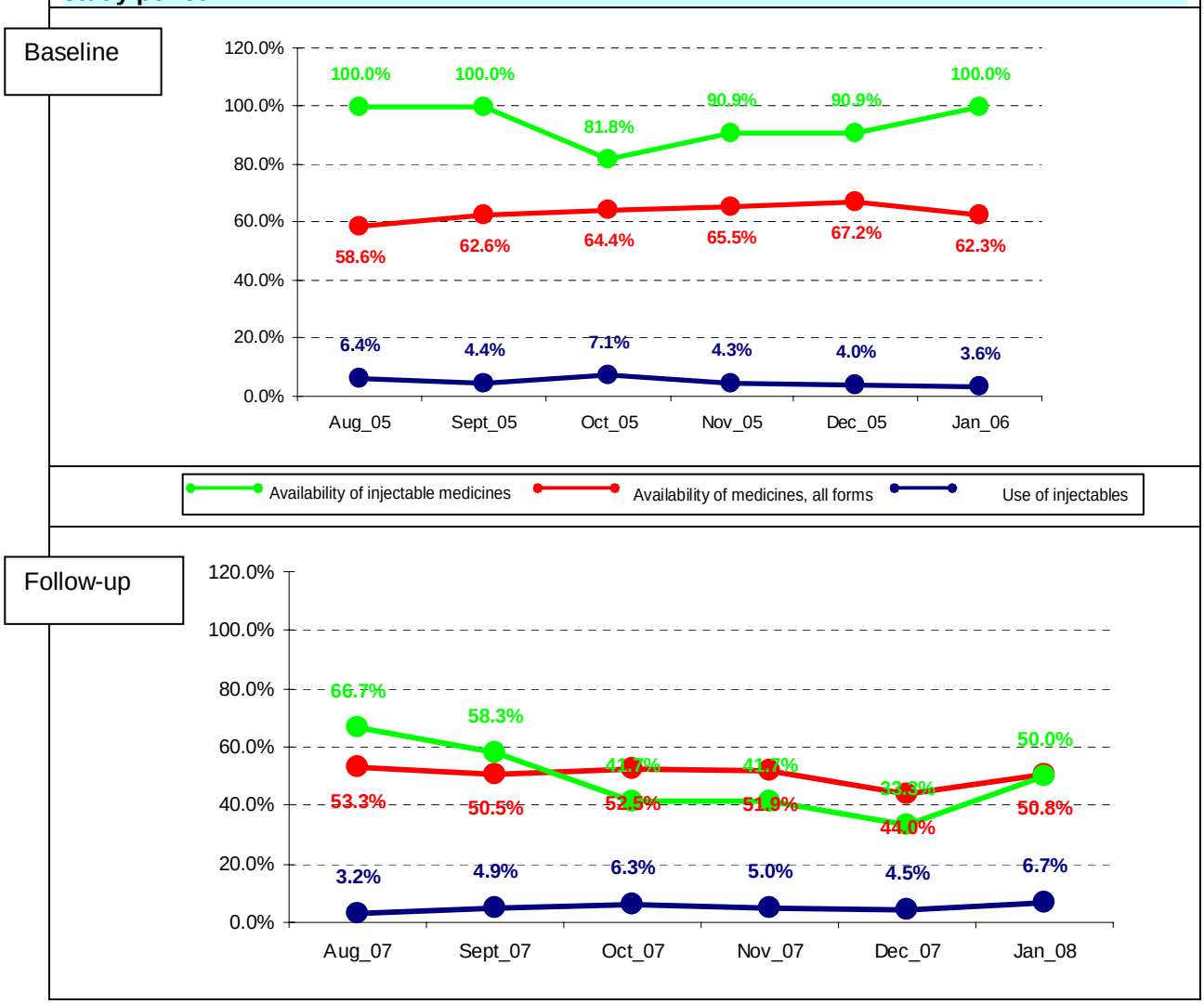
3.3 PHARMACEUTICAL STOCK DATA RESULTS

One of the objectives of this study was to ascertain the extent to which stockouts of non-injectable medication alternatives, injectable medications, or injection devices may affect the increase or decrease in the prescription of injectable medications. To this end, the consultant collected information from the pharmacy to establish the availability of all medications that had been prescribed in the sample cases. Records were taken from the pharmacy register books and/or stock cards.

Records showed whether specific medications were available during each month of the study periods. If a medication had not been available on any one day in a given month, it was considered to be out of stock for that month.

Figure 1 depicts the overall availability of medicines at study facilities (red line), the availability of injectable medications (green line), and the use of injectable medications (blue line) for the two study periods. In general, Mozambique has an overall shortage of medicines of all forms, which was found to be even more pronounced during the follow-up period. The availability of injectable medications was less than that of overall medicines at follow-up study period and decreased from baseline to follow-up. The use of injectable medication (blue line) remained the same during baseline and follow-up periods. The fact that injectable medications were as available or less available during the follow-up study period apparently did not have any relationship to the use of injectables. Further exploration is needed to determine whether health providers maintain the same use of injectables over time because they do not want to modify their treatment practices and they have sufficient supplies to sustain them, or whether the use of alternative, non-injectable medications is still not well understood and more sustained efforts are needed to standardize it.

Figure 1. General comparison of patterns of availability and use of injectable medication, by study period



An additional component of this section was the collection of information on the availability of alternative medication. From the information collected, it was possible to determine that the alternative for a non-injectable medication was always a non-injectable medication. In addition, the pharmacy staff person mentioned that in most cases the injectable medication did not have a non-injectable substitute. The justification was that if an injectable medication was prescribed, it was because a "weaker" version of the medication (oral, in this case) was not the most appropriate one because the condition may be more serious.[6]

It is important to note that a standard supply of medication is provided on a monthly basis to all health facilities. However, some medications from the standard list (known as Kit A) are almost never used, so the pharmacy has to return them. And some are frequently used and are therefore always out of stock or available in very low quantities. Given this, it is important to advocate for increasing the stock of these frequently used drugs in the monthly standard supply provided so that facilities do not have stockouts of appropriate treatments.

[6] The examples cited were cases requiring Fansidar and quinine injectable medications.

3.4 SUPPLY STOCK DATA RESULTS

According to information obtained from the injection book at each of the facilities, the most commonly used syringes are the 5 ml and 10 ml **auto-disposable syringes** although in some cases the 3 ml as well as the 2 ml syringes were reported to have been used.

The register book does not specify which type of syringes were in stock (reference is made only to size), but in conversation with the health staff it was found that the book refers to auto-disposable syringes, which are the most commonly used. Because the most-used sizes are the 5 ml and the 10 ml, the consultant inquired about availability of these syringes during the study period. For Albasine health center, the 5 ml syringes were out of stock in August 2005 (baseline period) and in August, September, and November 2007 (follow-up), whereas the 10 ml syringes were out of stock in August and September 2005 (baseline period) and in August, September, and November 2007 (follow-up). At Albasine health center, the only stockout registered was for the 5 ml auto-disposable syringes. Polana Cimento health center also registered stockout of the 5 ml auto-disposable syringes for the baseline months of October and December 2005.

Although this study observed some stockouts in regularly used syringe types over both study periods, it is not likely that this had an effect on prescribing patterns, because most injectable medications had no non-injectable alternative. If the correct device was not in stock, the prescriber had the choice of either prescribing nothing at all or using another size or type of device to administer the injection; this study did not explore the extent to which these options were used. This evidence does suggest the need to ensure adequate stock levels of new sterile injection equipment to meet the demands of prescribers and providers. Given no alternative to injectable medications, stockouts could lead providers or patients to turn to other harmful practices, such as reusing injection equipment.

3.5 PRESCRIBER INTERVIEW RESULTS

Qualitative interviews were conducted with prescribers as part of the data collection process during the follow-up study only. Overall, all but one of the prescribers interviewed were nurses (the other was a medical doctor). A total of 13 prescribers were interviewed across the three health centers (3 at Albasine, 4 at 1 de Junho, and 6 at Polana Cimento). All interviews were conducted in Portuguese.

All prescribers reported that they always provide prescriptions to patients because they feel that the patient cannot leave the consultation “empty-handed”. As one prescriber describes it, “Even if the patient does not have anything, I have to give a prescription, so that they are happy when they leave the health center.” Prescribers further mentioned that patients leave the consultation without a prescription only when they are transferred to another health facility or when they are referred to a doctor.

When asked how many patients out of 10 are likely to receive a prescription with at least one injectable medication, the majority reported a low number of prescribed injections. Those who reported high numbers (two prescribers reported 4, and one reported 7) justified this by stating that it was because they see a number of STI cases on a daily basis. Prescribers also mentioned that the decision to give injectable medications to patients depends: (a) on the severity of the problem, (b) whether it is possible to solve the problem through oral medication, and (c) whether it is an STI case. One prescriber also mentioned that the decision about the type of medication also depends on what is available at the pharmacy, but the evidence presented here shows that this may not be a general practice among health providers. Most prescribers pointed out that injectable medications are usually prescribed for STIs, discharge, infections, severe malaria, and severe pneumonia. Prescribers mentioned dehydration, frequent vomiting, convulsions, and coma as conditions for which an injectable medication is advisable.

Six out of 13 prescribers stated that the suggestion they have for making it easier to prescribe orals instead of injectables is to have better supplies of oral medicines. Most prescribers said that the majority of injections are applied for patients being treated for STIs, and one prescriber concluded that “theoretically

there are oral medications for STIs, but in practice they are still not available. That is why we still use kanamycin." It is important to mention that a new protocol for STIs was approved in 2006, but all prescribers stated that they still do not have the oral alternatives for STIs that are presented in the new protocol. This information was confirmed by the MoH professionals.

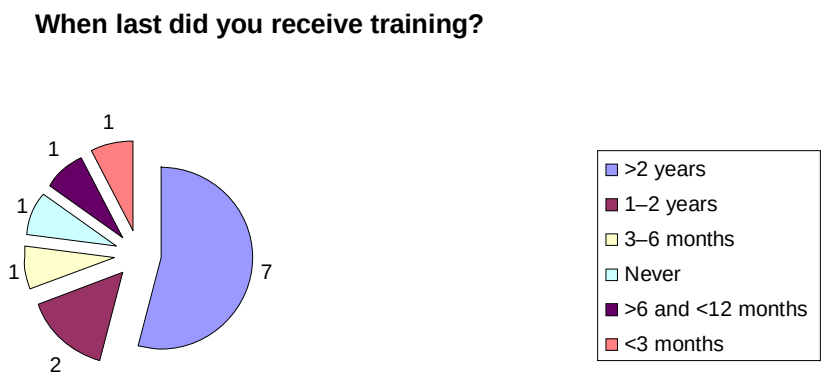
When asked how many patients out of 10 are likely to request an injection, the majority of prescribers mentioned that very few (ranging between 0 and 2) are likely to request an injection. However, three prescribers stated that large numbers (5, 6, and 9 respectively) request an injection. Almost all prescribers (12 out of 13) stated that they were unlikely to give the patient an injection, even if they asked for it, when they originally were going to prescribe another formulation. The only prescriber who said otherwise justified this by stating that it depends on the disease the patient has, and that she could respond to the request if there was an injectable alternative.

Prescribers stated that in the event of a patient with fever requesting an injection when they had previously prescribed an oral medication they would, in response, do or say the following to convince the patient otherwise:

- Explain that there is no need for injections.
- Explain the risks/consequences of injections.
- Explain that the prescribed (oral) medication is as effective.
- Explain that it is the best option.
- Explain that oral medication will be effective as long as the patient follows the prescription.
- Explain that the medication being provided is appropriate for the diagnosis.
- Explain when orals are given and when injectable medications are given.
- Explain that the effect of the medication is the same.

When asked when they last received training about prescribing different medicines to treat patients (including deciding between injections and other routes of administration), the majority responded that it had been more than two years ago (Figure 2). Only one responded that he/she had received training less than three months earlier.

Figure 2. Responses of prescribers to the interview question "When last did you receive training?"



3.6 STUDY LIMITATIONS

This was a retrospective study using data collected from outpatient logbooks at three health centers in Mozambique. The study only considered the diagnoses or classifications recorded in the logbooks, as well as treatment provided. The logbooks did not contain any additional information about the signs and symptoms, lab results (if samples were taken at all), onset of symptoms, physical conditions, severity of the illness, demand for injections, cultural beliefs, or access to services. Nevertheless, the purpose of the study was not to assess the quality of care received or the accuracy of the diagnosis, only the use of injectable medications. In that regard, the study focused only on the number of injections provided, comparing baseline and follow-up study periods. Hence, the conclusions and recommendations address only that issue.

From simple observation (not a real evaluation standard), the medicine and supply stock record system was not well maintained, particularly in Polana Cimento, where it was not possible to obtain access to the information.

It was not possible to interview as many prescribers as expected, and only one medical doctor was available for the interview. Furthermore, there was no way to interview the prescribers about their perceptions and practices at baseline since this was a retrospective study.

During data collection, the consultant had to skip some records and take the next well-written one, because of prescribers' poor handwriting. Also problematic was the fact that some prescribers had used codes from a very old system with which the person reading out the information was not always familiar. In such cases (and where it was possible), the consultant needed to call the prescriber to verify the information.

Patients do not have a specific identification number. Therefore, there was no way to follow up or cross-check these data with further information stored elsewhere in these facilities.

The study's purpose was to focus exclusively on OPDs. However, it was evident from the data, as well as from prescribers' accounts, that the pediatric section/department hardly ever has curative injections for children. This may have contributed to a low number of cases collected that received curative injections.

This study was conducted solely in health centers where MMIS is working. It is possible that other levels or types of facilities in the Mozambican system, such as hospitals or private-sector facilities, may have higher numbers of injections or more overuse of injections.

CONCLUSIONS AND RECOMMENDATIONS

The original plan of the Mozambique PRR study was to conduct a baseline study, which would be followed by interventions and then a follow-up study. However, during the data collection process and upon preliminary data analysis, the team realized that the number of injections was already very low, and it might be very difficult to lower it further. It was thought that earlier events such as the MoH change in policy for treating STIs with non-injectable medications and behavior change communication might have already had an effect that would only be seen in comparing these data with those from an earlier time period. For this reason, it was decided that the data collected August 2007 to January 2008 would be the follow-up data and that a retrospective data collection for an earlier baseline period (August 2005 to January 2006) would be conducted.

The strategies to reduce the unnecessary use of injectable medications ranged from managerial measures to training health providers about the use of oral medications and standard treatment guidelines. However, the study did not show any decline in the use of injectables, and the rate was very low to begin with. It seems that heath workers use injectables in cases where the diagnosis was clear and where injectable treatment is, in fact, needed, such as syphilis. In comparison, they avoid using injectables medicines during diarrhea episodes. In the case of STIs, overall patients do not need injectable treatment, but this depends on how providers classified a disease or condition. Evidence from this study does suggest that STI syndromic management still needs further investigation and training, because there is confusion about classifying STIs. One example of this is misclassification and possible inappropriate treatment of cases of candidiasis.

It is recommended to focus on only a few tracer diseases, where the diagnosis and treatment are straightforward and clear, leaving little room for other interpretations. This approach would serve to increase the number of cases per tracer disease for more-quantitative analysis as opposed to the current approach, which provides an overview of all types of diseases and conditions with smaller numbers of cases in each one.

A general recommendation for the district-level health authorities is to improve the adherence to standard protocols and quality of care, and also improve the quality of the data in the logbooks. Health authorities need to supervise and monitor the quality of service delivery and how logbooks are being filled out, in the columns of diagnosis or disease classification and of what procedure and treatment was provided, through quality checks and routine supervision. More in-service training would be needed, particularly for nurses.

APPENDIX A: QUESTIONÁRIO PARA PROFISSIONAIS PRESCRITORES

Data_____ Nome da unidade sanitária _____

1. Na sua opinião, ao tratar um paciente com um simples caso de febre, o medicamento tomado por via oral é MAIS eficaz, TÃO eficaz quanto ou MENOS eficaz do que o medicamento tomado por injecção?
    1. Por via oral é MAIS eficaz
    2. TÃO eficaz quanto a injecção
    3. Por via oral é MENOS eficaz
    4. Não sei
    5. Outro (especificar) _____

    Instruções: Apenas uma resposta.

2. Ao receitar um tratamento para os seus pacientes, dá-lhes quaisquer informações sobre medicamentos tomados por via oral e/ou injecções? Caso sim, quais informações?
    A. O medicamento oral é igualmente eficaz
    B. As injecções fazem efeito com mais rapidez do que os medicamentos orais
    C. Como fazer o acompanhamento – próximos passos
    D. Efeitos colaterais
    E. Como tratar os efeitos colaterais
    F. O que fazer em caso de reacções adversas
    G. Outro, especificar_____
    H. Nenhum

    Instruções: Se o profissional prescritor responder "não", marcar a opção H "nenhum". Respostas múltiplas são aceitáveis. Marcar todas as mencionadas espontaneamente pelo inquirido. ***Não ler.***

3. De cada 10 pacientes ambulatórios que examina, para cerca de quantos (em média) receita algum medicamento?

    _____

    Instruções: Registar o número mencionado. Deve ser um número entre 0 e 10. Utilizar o número citado aqui para fazer a próxima pergunta.

4. Dentre esses _____, quantos recebem uma receita que inclua pelo menos uma injecção?

    _____

5. Como decide se um paciente deve receber uma receita para um medicamento injectável em vez de apenas medicamentos orais?

_____

_____

_____

_____

Instruções: Anotar a resposta dada nas palavras do próprio profissional prescritor.

6. Na sua opinião, para que condições especificamente, se houver alguma, a necessidade do medicamento injectável é maior?

_____

_____

_____

7. Que factores, se houver algum, incentivam os médicos ou outros profissionais de saúde a receitar tratamentos que incluam injecções em vez de um medicamento oral? (*Explorar: algum outro?)*
   A. Falta de medicamento oral
   B. Os pacientes querem injecções
   C. Não há directrizes
   D. Não há tempo/pacientes demais
   E. O paciente não concluirá (cumprirá) o regime de tratamento com medicamentos orais
   F. As injecções são mais lucrativas
   G. As injecções são mais eficazes
   H. Outro, especificar _____
   I. Nada/Não sei

   Instruções: Respostas múltiplas são aceitáveis. Marcar todas as mencionadas espontaneamente pelo inquirido. ***Não ler.***

8. O que sugere para que se torne mais fácil receitar medicamentos orais em vez de injectáveis?
   A. Melhor aprovisionamento de medicamentos orais
   B. Pacientes que aceitem a sua decisão quanto ao tipo de receita
   C. Mais formação/supervisão
   D. Mais tempo para aconselhar
   E. Pacientes que concluam (cumpram) o regime de tratamento
   F. Menos agulhas/seringas/medicamentos injectáveis
   G. Chamadas de atenção/guias profissionais/directrizes
   H. Outro, especificar _____
   I. Nada/Não sei

   Instruções: Respostas múltiplas são aceitáveis. Marcar todas as mencionadas espontaneamente pelo inquirido. ***Não ler.***

9. De cada 10 pacientes que NÃO recebam uma receita de injecção, cerca de quantos solicitam uma injecção? _____

10. Seria provável que desse uma injecção ao paciente, se este pedisse, quando a sua inclinação inicial era de receitar outra medicação?

_____

_____

11. Imagine que eu seja um paciente com febre. Receitou-me um medicamento oral embora eu tenha pedido uma injecção. O que diria ou faria em resposta?

_____

_____

12. De que fontes recebeu informações sobre injecções ou vantagens dos medicamentos orais nos últimos 6 meses?
    A. *Workshop* de formação
    B. Supervisor
    C. Colegas
    D. Cartaz
    E. Folheto
    F. Guia de bolso
    G. Boletim
    H. Vídeo
    I. Calendário
    J. Revistas/publicações
    K. Associação profissional (especificar) _____
    L. Outro (especificar) _____
    M. Nenhuma

    Instruções: Respostas múltiplas são aceitáveis. Marcar todas as mencionadas espontaneamente pelo inquirido. ***Não ler.*** *Explorar, perguntando "Algum outro?"*

13. Quando começou a trabalhar nesta unidade sanitária?

    Mês: _____ Ano : _____ (99 Não me lembro)

    Instruções: Se a pessoa não se lembrar da data exacta, pedir uma estimativa. A data é anterior ao início das intervenções _____
    1. Sim
    2. Não

14. Quando foi a última vez que recebeu formação sobre a prescrição de medicamentos para tratar os seus pacientes (incluindo a escolha de injecções ou outras formas de administração)?
    1. Há menos de 3 meses
    2. De 3 a 6 meses atrás
    3. Entre 6 e 12 meses atrás
    4. Entre 1 e 2 anos atrás
    5. Há mais de 2 anos
    6. Nunca
    7. Não sei/não me lembro

    Instruções: Ler as opções em voz alta e marcar a mais próxima à experiência do inquirido.

15. Que materiais de IEC em injecção segura estão disponíveis nesta unidade sanitaria? *(MOSTRAR IMAGENS DE MATERIAIS RELACIONADOS COM PROFISSIONAIS PRESCRITORES OU OS PRÓPRIOS MATERIAIS)*
    A. Cartaz
    B. Folheto
    C. Guia de bolso
    D. Boletim
    E. Vídeo
    F. Calendário
    G. Nenhum → *Encerrar a entrevista*
    H. Não sei → *Encerrar a entrevista*

    Instruções: Respostas múltiplas são aceitáveis. Marcar todas as mencionadas espontaneamente pelo inquirido. ***Não ler.*** *Explorar, perguntando "Algum outro?"*

16. Quais destes materiais considera úteis para si e/ou os seus pacientes?
    A. Cartaz
    B. Folheto
    C. Guia de bolso
    D. Boletim
    E. Vídeo
    F. Calendário
    G. Nenhum

    Instruções: Respostas múltiplas são aceitáveis. Marcar todas as mencionadas espontaneamente pelo inquirido. ***Não ler.*** *Explorar, perguntando "Algum outro?"*

Obrigado pelo tempo que dedicou a esta entrevista. Os seus comentários são de grande utilidade.

For more information, please visit www.mmis.jsi.com.

Making Medical Injections Safer (MMIS)

John Snow, Inc.

1616 North Ft. Myer Drive, 11th Floor

Arlington, VA 22209 USA

Phone: 703-528-7474

Fax: 703-528-7480

www.mmis.jsi.com