CHAPTER TWO

METHODOLOGY

2.1. Study Design

The study was a cross-sectional descriptive study based on historical data, interviews and meetings with key players and direct observation of current practice. The study was therefore both quantitative and qualitative. For the quantitative aspect, questionnaires, one for Facility Managers (See Annex 2) and another for the Hospital Pharmacy (See Annex 3 of number of facilities), were used to collect the data. This data collection tool was a structured questionnaire based on policies and procedures contained in the drug supply management workshop manual.[10] The Facility questionnaire tool also entailed a drug prescribing tool, which has indicators for measuring key parts of the drug use process.[17] This tool deals with rational prescribing, dispensing and use of drugs. The Facility questionnaire also assesses the tracer Drug Items and tracer Standard Operational Procedures. The data collection tools were based on those developed by the WHO[18] and the Health Systems Trust (HST) [19, 20] with some adjustments and adaptation. The researchers administered the structured questionnaires. Initially the questionnaires were to be self-administered. However, the pilot study indicated that there was a tendency by respondents to avoid questions they did not understand and those they were not comfortable with.

The qualitative part of the study used in-depth interviews with key players in the Drug Supply Management System. These key informants were Hospital Superintendents, Community Pharmacists and Provincial Pharmacy Directorate staff. These interviews were semi-structured. A compiled list of items, on which information was to be gathered, was used during the meetings. This was not a questionnaire, but an interview guide, which itemised points, or aspects that were to be covered during the meeting/conversation. The meeting was to inform or strengthen the administered questionnaires. During these meetings, the key informants were interviewed on how they perceived Drug Management and also on problems relating to drug problems in the district. The observational part of the study also formed part of the qualitative aspect of the study. The researched physically took part in the observation of current practice with regard to the Drug Management practices. What was observed was carefully written down and dated, and the analysis was performed at the end of the data collection period. This analysis was again seeking to really understand what was going on in the Drug Management Chain. Reviewing of historical data (e.g. Prescription indicators and SOPs) was very informative on this aspect.

At the time of the study, the researcher was working at Mopani as a site facilitator for the Initiative for Sub-district Support (ISDS) of the Health Systems Trust in the Mopani District. As part of the researchers' responsibilities, a number of interventions were facilitated aimed at improving the quality of care provided in PHC facilities in Mopani District. One of these interventions was to assist the district to implement the use of the District STI (Sexually Transmitted Illnesses) Quality of Care Assessment (DISCA) Tool to strengthen the management of STI in Mopani District. The DISCA is a tool for evaluating and monitoring the quality of STI care at facility level.[21] The

data collection phase took place in one month (March 2004). The data collection phase involved the completion of the DISCA Tool as part of data collection. It also included interviews with senior clinicians, inspecting facilities, equipment and supplies, and examining the laboratory specimen register and patient medical records. Each sub-district had a team that spearheaded the completion of the DISCAs at facilities. The ISDS facilitator was part of these teams.

The study was also a cross-sectional analytic study. It was cross-sectional because it investigated both the exposure (factors) and the outcome (drug shortages) at the same time.[22] The analytical component of the study was used to establish the link between the exposure and the outcome.[23]

2.2. Study Population

The study focussed on PHC facilities and the Drug supplying hospitals. The respondents were professional nurses and pharmacy personnel in charge of the PHC facilities and the pharmacy at the day of the interview. Key informants for the in-depth interviews were selected hospital superintendents and the Provincial Pharmaceutical Directorate. All superintendents were qualified medical doctors, who also practised at the hospitals they were managing.

2.3. Sample Size

The target was to evaluate all the four sub-districts that form the Mopani District. The PHC Facilities are distributed as follows: Ba-Phalaborwa Sub-district has 1

Community Health Centre and 7 Clinics; Greater Letaba Sub-district has 20 clinics; Giyani Sub-district has 2 Community Health Centres and 20 Clinics; Greater Tzaneen Sub-district has 4 Community Health Centres and 27 clinics. In total, Mopani District has 81 PHC Facilities. Each Sub-district is divided into Local Health Areas. The clinics are evenly distributed across the Local Health Areas. For the primary study, a stratified (by region) random sampling method was used to select a sample of 45 PHC facilities comprising fixed clinics and health centres. The selection criteria were to select 50 % of PHC facilities in each local area. However, where the total of the facilities was an odd number 50 % plus 1 were selected. In Ba-Phalaborwa, all PHC facilities took part in the study. This was because the sub-district has only 7 PHC facilities. All selected clinics were approached, through the District Manager, Sub-district Managers and Local Health Area Managers, to participate in the study. Of all the 45 selected PHC Facilities selected, 45 questionnaires were successfully completed, translating to a coverage rate of 55.6 % (i.e. 45 out of 81 facilities) and a response rate of 100 %.

Of the 6 hospitals supplying clinics with drugs, 6 questionnaires were successfully completed, translating again to a response rate of 100 %. Of the total 6 supplying hospitals, only 2 in-depth interviews were successfully completed, reflecting a 33 % response rate. The main reason for failure to obtain a successful interview was the unavailability of the suitable respondent at the time of the interview due to other work commitments.

Table 1: Distribution of Health Facilities Evaluated Using Questionnaire

Supplier	Sub-district	No. of Clinics	No. of CHC	Total
Maphutha Malatji	Ba-Phalaborwa	6	1	**7**
Khensani Hospital	Greater Giyani	11	1	**12**
Kgapane Hospital	Greater Letaba	10	0	**10**
Dr C.N. Phatudi	Greater Tzaneen	5	3	**8**
Van Velden Hospital	Greater Tzaneen	4	0	**4**
Letaba Hospital	Greater Tzaneen	3	1	**4**
Total		**39**	**6**	**45**

For the STI evaluation, each sub-district did a random sample of its PHC facilities, except Ba-Phalaborwa where the DISCA Tool was used to collect data from all 7 PHC facilities. In Greater Letaba, data collection was done in 15 of 20 facilities, in Giyani it was 15 of 22, whilst in Greater Tzaneen it was 15 of 32 PHC facilities. In

total 52 of the 81 facilities were sampled for the DISCA, indicating a sample of 64%. It was agreed that clinics identified for the STI study would be excluded from the administered questionnaire, except in the Ba-Phalaborwa Sub-district because of the few facilities there. To make sure the sample size was big enough for this study 2 clinics in Greater Letaba, 2 in Giyani and 1 in Greater Tzaneen had to be included in the drug management study, meaning that they were included in both the STI study and the drug supply study.

2.4. Pilot Study

A pilot study was done at three clinics in the Greater Tzaneen Sub-district in order to identify sources of information, the suitability of the tools and estimate of the time required to collect data per facility using the structure questionnaire. This was testing face and content validity. Face validity refers to the extent to which the measure or the question makes logic and common sense, whereas content validity refers to the extent to which the measure includes all elements of a variable being investigated.[24] Experts in the field of drug management were consulted and participants were asked for feedback on the data collecting instruments. Adjustments were made, as appropriate to the research process and questionnaires. For example, it was agreed that Patient Care Indicators be excluded because they were not necessary in determining factors related to drug shortages. They are mainly used to measure the quality of care. Such indicators include average consultation time, average dispensing time, and patient's knowledge of correct dosage. The questionnaires piloted in three facilities were not included as part of the results of the study.

2.5. Data Collection

The most important data for this study were collected between March and July 2004 (i.e. 5 months), in which the author participated and literally administered the tools in 3 of the sub-districts. In the Giyani Sub-district, two field workers who had received training on the data collection tools and had participated in the pilot study did data collection. One of the field workers is a Chief Professional Nurse and HIV/AIDS Coordinator for Giyani Sub-district. The other is a Professional Nurse and STI Coordinator for the Giyani Sub-district.

Prescribing encounters were sampled retrospectively by drawing random encounters from historical medical records over a period of three months from date of survey. At least 30 encounters were randomly selected per facility.

Observation of current practice regarding the Drug Management Practices provided a rich source of information, which the structured questionnaire could not provide, especially practices that could be avoided by respondents.

The in-depth interviews with Hospital Superintendents and the Acting Provincial Pharmaceutical Director were important in understanding the Drug Management System and the context of the current system in place. These key informants, through their experience and knowledge, gave a perspective that the professional nurses could not provide.

For the DISCA evaluation, the data collection phase, as already indicated, took place in one month (March 2004). The data collection phase involved the completion of the

DISCA Tool as part of data collection. It also included interviews with senior clinicians, inspecting facilities, equipment and supplies, and examining the laboratory specimen register and patient medical records. Each sub-district had a team that spearheaded the completion of the DISCAs at facilities. The ISDS facilitator was part of these teams.

Also consulted for this study, from 2003 to 2005, were a number of unpublished contemporary research studies on issues related to Drug Management. These data were supplemented with published sources on Drug Management issues. These books, articles and journals appear as part of the references.

2.6. Data Measurement

The tools which were used to collect the data were based on those developed by WHO[18] and the HST[19, 20], with some adjustments and adaptation. Tracer drugs items and tracer SOPs were used to assess the Drug Supply Logistics Indicators. Questionnaires, one for Facility Manager or sister in-charge and another for Hospital Pharmacy Manager, were used. According to HST, these tools are standard measures that have been applied with success and can therefore be used with confidence.[20] The observation of current Drug Management Practices and the in-depth interviews with key players complemented the structured data collection tools.

2.7. Validity and Reliability

The validity and reliability of the data collection tools were ensured during the primary study. The questionnaires were piloted in three clinics to test face and content validity. Face validity refers to the extent to which the measure or the question makes

logic and common sense, whereas content validity refers to the extent to which the measure includes all elements of a variable being investigated.[23] Inter-observer variation was limited by the training and supervision of field workers during data collection. A statistician was consulted during questionnaire design and data analysis in order to eliminate analysis and interpretation errors. Selection bias of PHC Facilities was eliminated through stratified random sampling.

2.8 Ethical Consideration

Permission to conduct the study was granted by the University of the Witwatersrand's Ethics Committee (on the 26th February 2003) and the Limpopo Province's Research and Quality Improvement Directorate (on the 27th March 2003). The data was handled with strict confidence within the premises of each facility. Information obtained is reported as a group, and no results are attached to facility name. Whilst names of Facilities appear on the questionnaires, for purposes of identifying questionnaires, efforts were made to ensure that results couldn't be traced back to an individual PHC facility or respondent. Respondents were kept anonymous; no names were attached to questionnaires and patient records. The information was gathered with informed consent from participants. Participation was voluntary, and respondents were assured that the information was not going to be used against them. They were also informed of their right not to participate in the study, with no negative consequences to follow.[24]

2.9. Data Analysis

The data were analyzed using the Epi Info 6 program, which is software developed by the Centre for Disease Control, Atlanta, Georgia. Descriptive statistics such as means,

frequencies, standard deviation and 95% confidence intervals was used to organize, present and summarize quantitative data. Excel spreadsheets were used for tabular and graphical presentations. For the qualitative part of the research (i.e. in-depth reviews), content analysis on similar and different themes was done. Complex analytical tools such as logistic regression were used to determine predictors of drug shortages.

For the DISCA evaluation, the data analysis was done manually. There is a step-by step tool in the manual that explains how to do the data analysis. The tool is very straight forward and user-friendly. It was done manually so that health providers could be able to conduct their DISCA evaluation on their own instead of relying on the ISDS Facilitator.