CHAPTER III
RESEARCH METHODOLOGY

This method adapted from WHO/HAI methodology developed to analyze prices, availability and affordability of essential medicines

3.1. Study Design

This study is a descriptive cross sectional study aims to analyze the prices, availability, affordability of selected essential medicines in Sudan in 6 states, comparing public, private and RDF sectors with international reference prices, using primary and secondary data,

Figure 3. 1 Conceptual framework 1

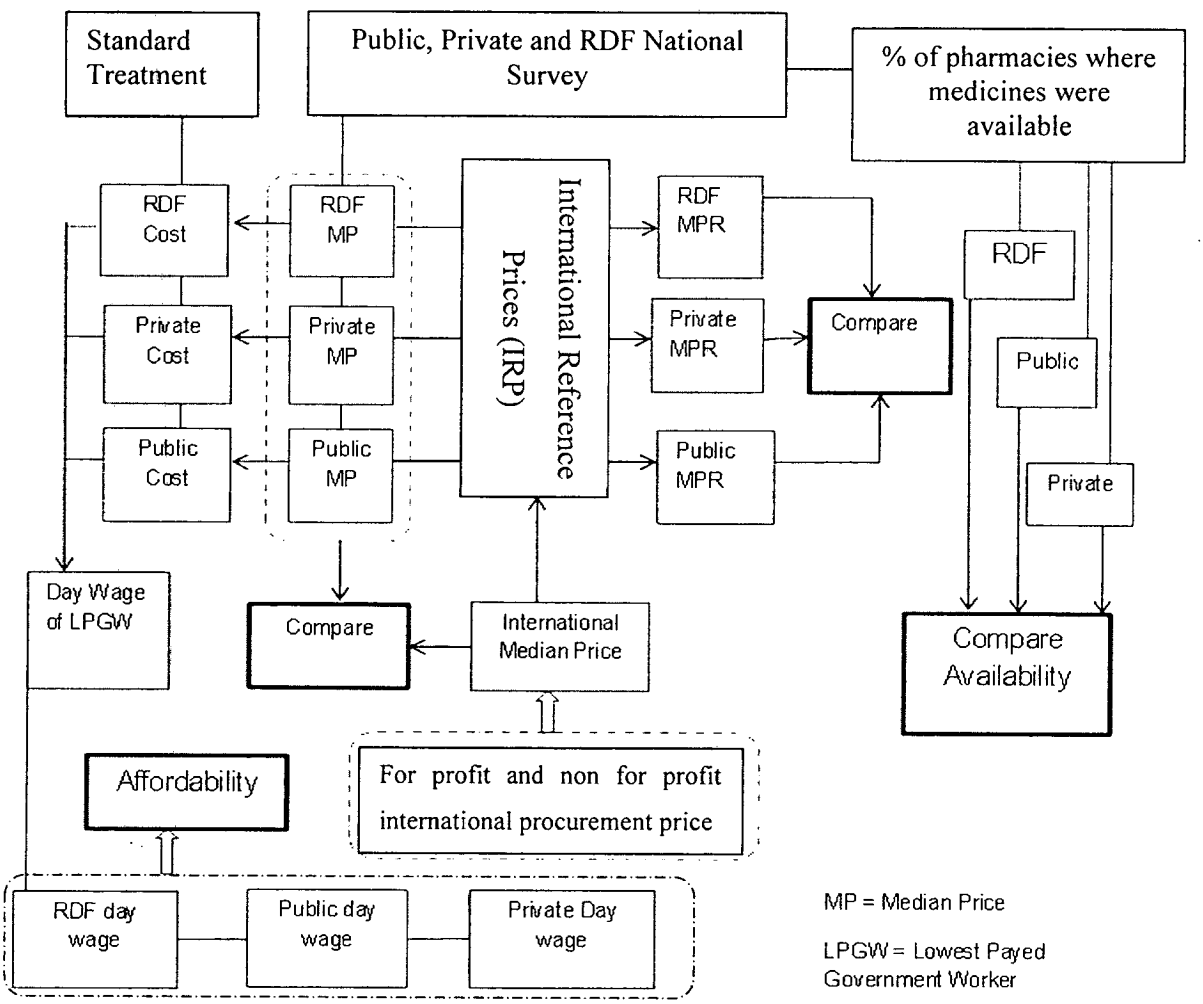
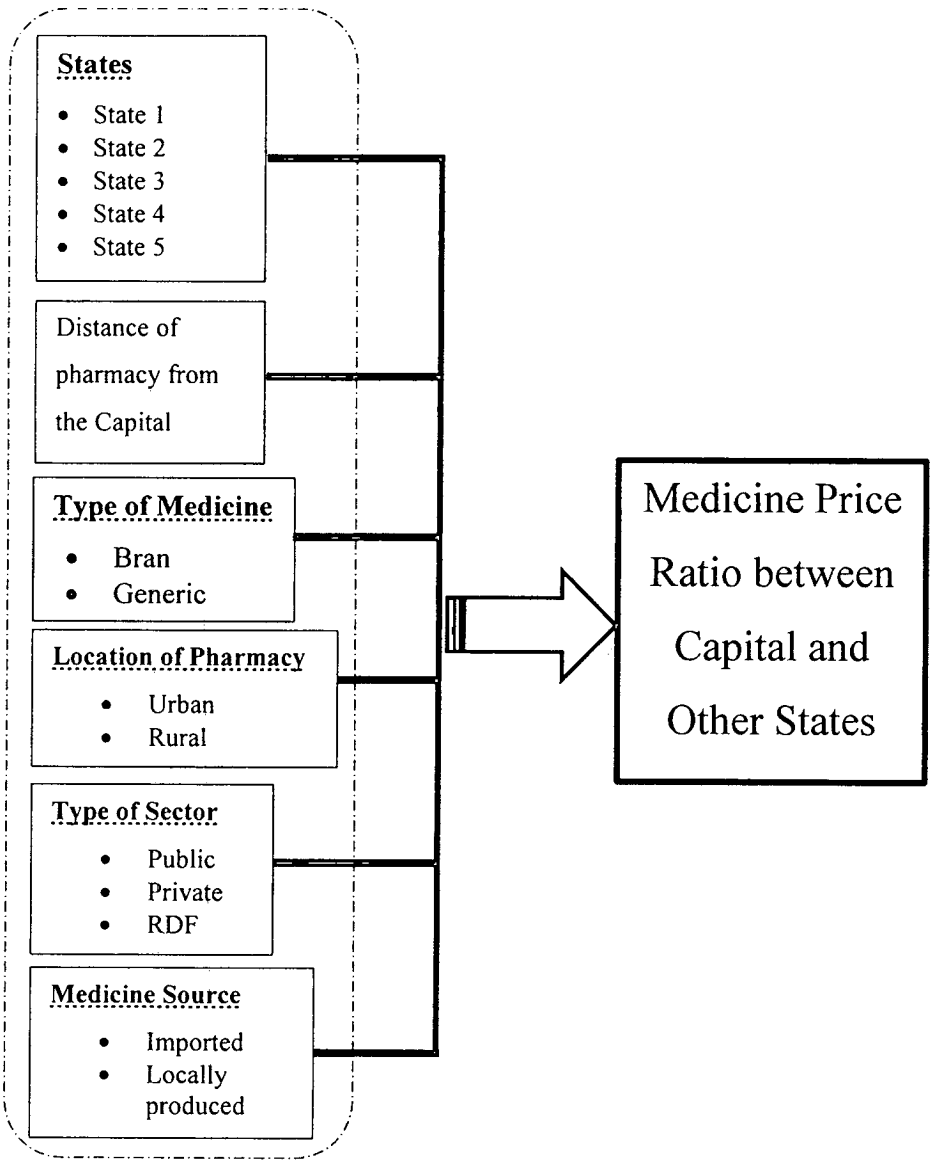


Figure 3. 2 Conceptual framework- 2



3.2. Population and sampling

Study populations is essential medicines in Sudan, 50 essential medicines surveyed in six states, across private, public and RDF sectors in each 18 medicine outlets.

3.2.1. Sampling method

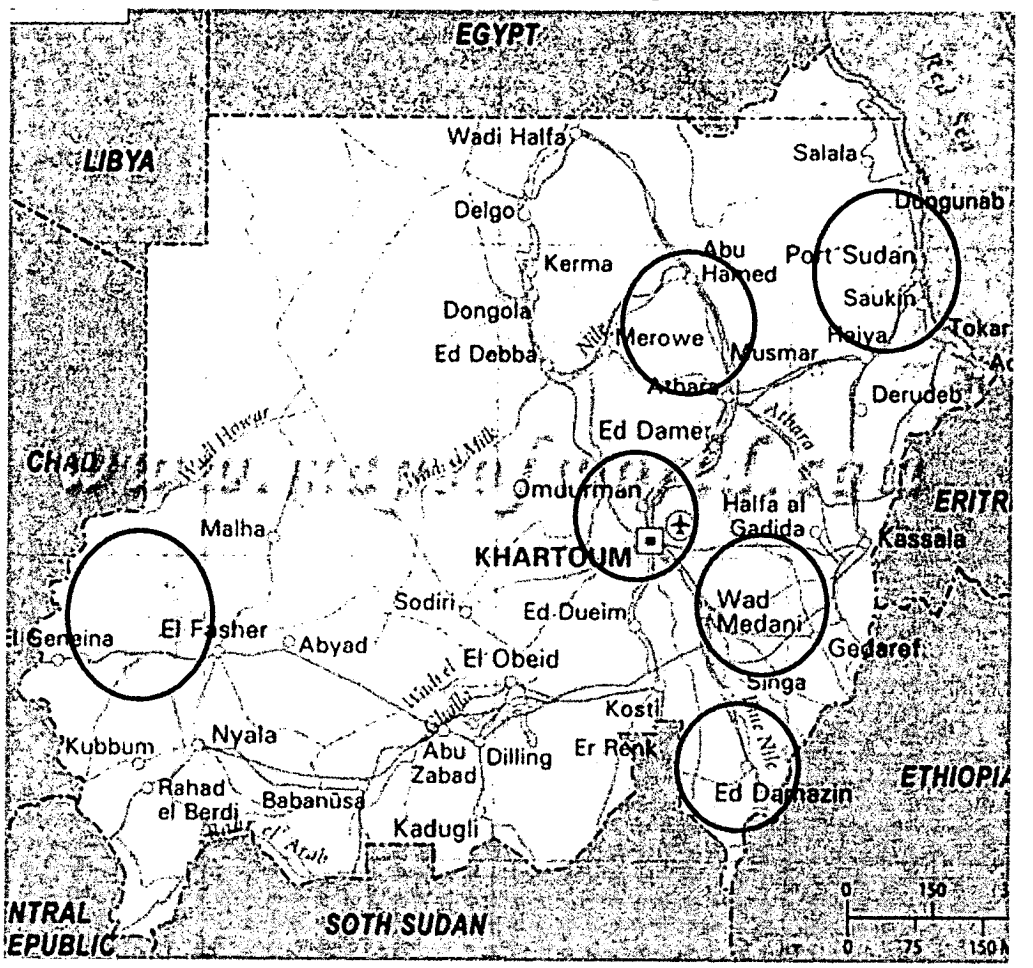
Multi stage clustered sampling method

Stage 1: State selection

State selection: state of the capital selected purposively; because it is center of Sudan, higher population more than 7 million and base for all pharmaceutical companies, local manufacturer and National Medicines Regulatory Authorities. The

country then stratified in to 5 regions, North, South, East, West and conflict area, from each one state randomly selected. (Red Sea, River Nile, Sinnar, Gazeera and West Darfur) [See the map below]

Figure 3. 3 Sudan Map



Sudan map

Stage 2: Medicine outlets selection

In each selected state in stage 1,

Sectors were clustered to three sectors, the private, public and RDF sector. Then; Public medicine outlets selection: the pharmacy of outpatient care unit in regional public hospital purposively selected, because it represent the basic and standard public sector services, expected to have all essential medicines, the rest of the 5 medicine outlets were randomly selected from created list of public pharmacies within 3 hours traveling.

RDF and Private sector medicine outlets selection: for each selected public medicine outlet, 1 private and 1 RDF medicine outlets were randomly selected from predefined list of RDF and private medicine outlets created at beginning.

Table 3. 1 Number of pharmacies surveyed

state	Public	Private	RDF
	Selected	Selected	Selected
Khartoum	6	6	6
West Darfur	6	5	4
Sinnar	6	6	5
Gazeera	6	6	5
Red Sea	6	6	5
River Nile	6	6	3
Total	36	35	28

Stage 3: Medicines selection

The 50 medicines surveyed:

- Global core list of 14 medicines specified by WHO, representative the global burden disease and common worldwide.
- Regional core list of 16, specified by WHO for EMRO region countries, they reflect and represent common disease treatment in the region.
- Supplementary list, 20 medicines selected according to Sudan health priority (See Appendix H).

3.3. Data collection

6 pharmacist were trained, each in one state lead the survey with other two assistant pharmacist who were trained separately, a pilot survey conducted in two states and problems may face surveyors were defined.

3.4. Type of Data

Primary data from the country national survey and secondary data from IRP from MSH price indicators guidelines (see appendix B),

3.5. Data Collection

a- Primary data

3.5.1. Data collection tool

The data collection tool designed and data were collected to the 50 selected essential medicines in

- Prices to patients (LPG and Brand) in private, public and RDF
- Government procurement prices
- The availability of selected medicines at survey time
- Manufacturers of the selected medicines
- Medicines pack size found.
- Location of the pharmacy, rural or urban
- Type of the medicine, (LPG or IB)
- Name of the medicine outlet

General information including; address, survey date, survey ID, surveyor's name, medicine outlet manager and comments

(Data available in appendix B)

3.5.2. Survey period

The survey started on February 20, 2013 and finished on March 17, 2013

b- Secondary data

3.5.3. International Reference Prices (IRP)

Median prices listed in the Management SMSH's International Drug Price Indicator Guide for 2011

3.5.4. Data for government procurement prices

Data are collected centrally from secondary data from NHIF H.Q and Health Insurance Khartoum State (HIKS).

3.6. Data management

3.6.1. Data quality

Data entered to Excel file, three trained professional were hired for this job, it took them one week to finish it. From 103 listed form were selected to check the accuracy, then data were transformed to WHO/HAI work book, expert in HAI cross check all data and he picked some errors I fixed them all before analysis.

3.6.2. Factors affecting patient's medicines price

The dependent variable: the price ratio between the state of capital and other states to estimate prices variations between them, the capital where all pharmaceutical companies and drug authorities are located, high degree of competition and higher percentage of population, accordingly; medicines prices expected to be low

Type of the sector: whether it is private, public or RDF medicines outlets they are different in their objectives, e.g. the public sector's objective is not for profit as well as qusai-private (RDF) but the last has to provide the services and revolve the budget so few profit to cover overhead expenses, while private sector's objectives is completely for profit

Source of medicines: locally produced medicines is expected to be less price than those imported, although the pricing policy may affect that but still locally produced is expected to have less price than imported.

Site of the medicine outlet: we expect that medicines in urban urea is less price than rural because the medicines warehouses and agents and the number of outlets in the urban can affect competition, also the cost transportation to the rural is higher than urban

Distance of the selected state from the capital: because all agents and local factories are concentrated in Capital, we expect that the near the state to the capital the less the prices of the medicine

Type of the medicines: brand medicines is expected to be higher in price than generic one due to cost of production which is very high at the beginning, mainly due to research and development

The expected signs of the coefficients are illustrated in table table (III-1) below

3.7. Operational definitions:

Availability of medicine is the percentage of medicines outlets where specific medicine is available at survey time.

Affordability: is the day wage of lowest paid unskilled government worker (LPGW) required to buy specific medicine, and that medicine price considered as affordable if it cost not more than one day wage.

Median price ratio: is the median retail price patient paid by patients or government procurement median price divided by median price of (IRP) from the MSH to see how far the medicine price is high or less depend on the ratio, e.g. if MPR is equal 2 that means the local price is high from international one by 2 fold.

3.8. Data analysis

I will use WHO/HAI standard workbook developed by WHO/HAI to analyze the data (Measuring medicine prices, availability, and affordability and price components) it is Excel Computerized Workbook can be downloaded from this website: http://haiweb.org/medicineprices/manual/documents.html, for the first part of analysis. While OLS to estimates coefficients of factors affecting medicine prices.

Unit price per tab/cap/ml/dose according to the specific medicine dosage form will be calculated considering the package size of the medicines.

3.8.1. Availability

$$Availability = \frac{All\ Medicine\ outlet\ where\ medicine\ available}{Total\ number\ of\ surveyed\ medicine\ outlets} \times 100$$

Availability of individual medicine was calculated, then the availability in each individual sector was calculated, then different sectors were compared.

d. Avalability in the public sector

$$= \frac{Public\ Medicine\ outlet\ where\ medicine\ available}{whole\ public\ outlets\ surveyed}$$

e. Availability in the private sector

$$= \frac{Private\ Medicine\ outlet\ where\ medicine\ available}{whole\ private\ outlets\ surveyed}$$

f. And availability in RDF sector

Then *(d),(e)* and *(f)* were compared

3.8.2. Medicines prices

- ***International comparison of the MPRs***

1. We picked up 2013 as base year for comparison, using MSH reference price 2011

2. MPR converted to Sudan specific prices

a. Multiply the appropriate MSH reference price to get the price in U.S. Dollar (USD)

b. Multiply (2a) times the relevance exchange rate used in the survey to obtain the local currency unit price.

3. Convert local currency to US dollars, this can be done by divide the local currency from (2b) by the official exchange rate for the U.S dollar in the time of the survey conducted (the period average exchange rate).

4. Adjust for inflation/deflation: (because the different source of prices and difference in the times, e.g the survey in 2013, using MSH 2011 reference price, different prices from different countries for the comparison)

$$a1.\,Deflation\ factor = 1 - \frac{\text{SurveyYearUSCPI} - \text{BaseYearUSCPI}}{\text{BaseYearUSCPI}}$$

$$a2.\,Inflation\ factor = 1 + \frac{\text{SurveyYearUSCPI} - \text{BaseYearUSCPI}}{\text{BaseYearUSCPI}}$$

b. Multiply (4a1 or 4a2) times the price from (3) above

5. Recalculate MPR

Divide adjusted country prices from (3) or (4) above by the MSH reference price

Inter-sectoral and regional variation in prices

Compare between the MPR between the public private and RDF

- ***For the price comparison***

Calculate the MPR in each sector

$$a.\,Median\ Price\ Ratio\ (MPR) = \frac{Median\ unit\ price\ from\ the\ Survey\ (public)}{Reference\ unit\ price\ from\ MSH}$$

$$b.\,Median\ Price\ Ratio\ (MPR) = \frac{Median\ unit\ price\ from\ the\ Survey\ (Private)}{Reference\ unit\ price\ from\ MSH}$$

Then compare [a] and [b] the individual medicines' price in the two sectors

- ***For government procurement prices***

$$MPR\ for\ government\ procurement\ prices = \frac{Government\ median\ procurement\ price}{International\ Rfeference\ Prices}$$

3.8.3. Treatment affordability

Affordability of a disease treatments calculated based on lowest paid unskilled government worker.

- Calculate the minimum day's wage of unskilled government worker required to purchase disease's treatment using the National (MPR) as medicine price.
- We will calculate the affordability of treatment to the following disease in figure (III-1) where 10desease will be assessed for affordability

Table 3. 2 Standard Treatment affordability calculation

	Condition	Medicine	Strength	Dosage Form	Treatment schedule
1	Asthma	Salbutamol	0.1mg/dose	inhaler	1inhalor of 200 doses
2	Diabetes	Glibenclamide	5mg	cap/tab	1cap/tab×2/day×30days = 60
3	Hypertension	Atenolol	50mg	cap/tab	1cap/tab×30days = 30
4	Hypertension	Captopril	25mg	cap/tab	1cap/tab×2/day×30days = 60
5	Hypercholesteromia	Simvastatin	20mg	cap/tab	1cap/tab×30days = 30
6	Depression	Amitriptyline	25mg	cap/tab	1cap/tab×3/day×30days = 90
7	Adult RTI	Ciprofloxacin	500mg	cap/tab	1cap/tab×2/day for 7days = 14
8	Pediatric RTI	Co-trimoxazole	8+40mg/ml	suspension	5ml×2/days×7days = 70ml
9	Adult RTI	Amoxicillin	500mg	cap/tab	1cap/tab×3/day ×7days = 21
10	Adult RTI	Ceftriaxone	1g/vial	injection	1 injection
11	Anxiety	Diazepam	5mg	cap/tab	1cap/tab×7day =7
12	Arthritis	Diclofenac	50mg	cap/tab	1cap/tab×2/day×30days = 60
13	Pain/inflation pediatric	Paracetamol	24mg/ml	suspension	child1year: 120mg(=5ml)×3/day×3days=4
14	Peptic ulcer	Omeprazole	20mg	cap/tab	1cap/tab×30days = 30

Source: (WHO/HAI, 2008b)

3.8.4. Government procurement prices

Compare the generic government purchase price with IRP (MSH 2011), calculating the MPR

$$\text{Government Median Price Ratio} = \frac{Government\ Median\ Procurement\ Price}{International\ Refernce\ Price}$$

3.8.5. Factors affecting patient's medicines prices

Use ordinary least square (OLS) for simple regression to analyze factors affecting patient's medicine price

The regression model:

$$\left(\frac{P_{State}}{P_{Capital}}\right)_i = \beta_0 \pm \beta_1 Sit_i \pm \beta_2 sector1_i + \beta_2 sector2_i \pm \beta_3 sour_i \pm \beta_4 typ_i \pm \beta_5 dist_i + \beta_6 state1_i + \beta_7 state2_i + \beta_8 state3_i + \beta_9 State4_i + \beta_{10} state5_i + \varepsilon_i:$$

Where:

$\left(\frac{P_{State}}{P_{Capital}}\right)_i$ = *the price ratio between medicines price in other states and medicine price in the capital of the ith medicine*

β_0 : Constant term

$\beta_1 - \beta_{10}$: the coefficients of the explanatory variables.

sit_i : is dummy variable =1 if the site of the pharmacy is urban site, = 0 if rural site.

$sec1_i$: is dummy variable =1 if the sector is private; otherwise = 0

$sec2_i$: is dummy variable = 1 if the sector is RDF; otherwise = 0

$sour_i$: is dummy variable = 1 if the medicine is imported, = 0 if locally produced

typ_i : is dummy variable = 1 if the medicine is generic, = 0 if it is brand

$dist_i$: Distance of the state from the capital in km

$state1$: is dummy variable = 1 if the state is West Darfur; otherwise = 0

$State2$: is dummy variable = 1 if the state is Gazeera; otherwise = 0

$State3$: is dummy variable = 1 if the state is Sinnar; otherwise = 0

$State4$: is dummy variable = 1 if the state is Red Sea; otherwise = 0

$State5$: is dummy variable = 1 if the state is River Nile; otherwise = 0

ε_i : is error term

Table 3. 3 Expected signs of the coefficients

type of sector			**source of med.**		**site of outlet**		**Distance**	**type of medicine**	
private	Pubic	RDF	import	local	Urban	Rural		Brand	Generic
+	+	+	+	+	+	+	+	+	+
State 1	State 2	State3	State4	State5					
+	+	+	+	+					

Sector type expected to have (+) sign, because moving from Khartoum out site to other state, medicine price will increase comparing Khartoum to other states and all other factors follow this expectation

Factors affecting patient's medicines price

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