

Using the WHO/HAI Medicine Price Methodology to study a therapeutic group of medicines

Introduction and background

In 2003, the first WHO/HAI medicine prices manual (Medicine Prices – A New Approach to Measurement) was published and the methodology has been used in more than 50 surveys across almost as many countries. Most of these surveys measured medicine prices, availability, and affordability and price components of essential medicines across the whole country in the public, private and another sector.

On a number of occasions, the price, availability, affordability and price components of a medicines for specific therapeutic groups of medicines have been studied using the WHO/HAI methodology – sometimes directly, sometime adapted. Some examples including:

- Nepal and Nicaragua, John Snow International and PATH undertook a survey of commodities for reproductive health (OCP, IUD, condoms, vaccines and other medicines) using an adaptation of the WHO/HAI methodology^{1,2}
- The Non-Communicable Diseases department of WHO used the WHO/HAI methodology to survey the price, availability and affordability of 35 medicines used to treat chronic conditions (2005)³
- Medicines for Malaria Venture (MMV) undertook the first of a series of surveys in Uganda looking at the antimalarial medicines market in the public and formal/informal private sector (2007)⁴
- The Gates Foundation and the consultants advising the Board of the Roll Back Malaria Partnership on the design of an Affordable Medicines Facility for Malaria⁵ have both recognised that the WHO/HAI methodology as a useful tool to analyse the malaria medicines market (2006/7).
- In Ukraine, the methodology has been used to measure the price, availability and affordability of medicines used in palliative care (2007).
- Data from 30 surveys on 14 chronic disease medicines was analysed using data from previous surveys⁶ using the WHO/HAI Medicines Prices database⁷ (2006)

As part of the review of experiences in using the overall methodology, a second edition of the survey manual has been developed which includes the following guidance on considerations in adapting the methodology for therapeutic group studies.

Study planning and preparation

As with any survey, before commencing on the detailed planning and preparations, it is essential to determine the objectives of the therapeutic group medicine prices survey including:

- Which therapeutic group will be studied?
- Where will the survey be conducted?
- Which medicines will be studied to describe this therapeutic group?

This section presents guidance and considerations to adapt the methodology for a therapeutic group survey and should be read alongside chapter 3 (Preparation) of the manual.

1. Selecting a therapeutic group of medicines

Probably almost any therapeutic group of medicines can be studied using the WHO/HAI approach to measuring prices. Depending upon the group of medicines and where in the health system these

medicines are provided, the methodology may need varying degrees of modification. The subsequent sections discuss considerations for the study design as well as some of the implications of the choices.

Most of the medicines for the therapeutic group studies described in the introduction are usually found at all levels of the public health care system and widely in the private sector, and hence the standard WHO/HAI methodology can be applied with very few adaptations. However if the medicines for the therapeutic group that you want to study are not available at all levels of the public health care system nor widely in the private sector, then the methodology needs more adaptation through changing the sample frame to include only those levels and outlets where the medicines should be found.

2. Planning where to conduct the survey

2.1 Planning where to conduct the survey: National or regional

As with the normal medicine prices surveys, therapeutic group surveys will normally involve studying the whole country, however apart from the reasons discussed in section 3.1.1 of the manual which might result in regional surveys being done, there may be additional considerations for a therapeutic group survey – for a antimalarial medicines therapeutic group survey may decide to study prices and availability in moderate and high transmission areas only and exclude low transmission areas.

2.2 Identifying the sectors to be surveyed

The WHO/HAI Medicine Prices workbook - Part I allows easy comparison of the prices and availability of medicines in up to four sectors as is described in section 3.1.2 of the manual.

Understanding how patients obtain the medicines for the therapeutic group of medicines being studied will guide which sectors to study. It may be that the medicines being studied are obtained by patients from the same places as other essential medicines, or it could be that the situation is very different.

It is important to investigate which are the most important sectors from which patients obtain their medicines for this therapeutic group. Additionally the objectives of the survey may determine which sectors it is necessary to include within the study – e.g. the study objective may be to examine expanding the role of the private sector in the provision of medicines for HIV & AIDS, hence it would be important to understand the price and availability of the medicines in the sectors where most of the provision happens now, but also what is the current situation in the private sector.

Even within a sector, it could be that the medicines being studied are supplied in different ways from different funders, follow different supply chain routes, are managed separately or are provided to patients in different places. In the study design, these different routes and dispensing points may want to be studied as separate sectors to enable a comparison to be made. An example could be with medicines for HIV and AIDS, where different donor/grant programs supplies are managed completely separately.

2.3 Identifying survey areas

Apart from excluding certain areas because the survey objectives limit the geographical scope of the survey e.g. only studying prices and availability of antimalarial medicines in moderate and high transmission areas of the country only, the selection of study areas should follow the process described in section 3.1.3 of the manual.

3. Selecting the sample

The approach to selecting a sample of outlets described in section 3.2 of the manual should be followed unless the therapeutic group of medicines being studied is not generally provided, or the policy is that they are not provided, at all facilities and outlets in the sectors being studied.

For some medicines, like medicines for HIV and AIDS, TB, and cancer, these are often only provided at designated or accredited treatment centres. Unless the sampling approach is adapted, applying the

standard approach would underestimate the availability, and perhaps collect an insufficient number of data-points to be able to properly analyse the price data - as many of the facilities/outlets visited should not have the medicines. This is easily overcome by selecting the facilities from a sample frame that only includes the designated facilities/outlets which would enable the price, availability and affordability in designated or accredited centres. Different approaches may be deemed necessary if the designation/accreditation policy differs by sector – what is important to consistently apply is the approach in that all sectors are selected using the same principle. It may also be that the clinical outlets are accredited, but there is no accreditation for the retail pharmacies – hence in this case, the designation/accreditation criteria may be used to select these outlets and the criteria described in section 3.2 of the manual for private sector medicines outlets is used (closest to the public medicines outlet selected).

However if the designation or accreditation is not widely respected, a selection from all outlets as described in section 3.2 may be more appropriate as the findings would inform on the actual availability and prices rather than availability and prices from those outlets supposed to supply those medicines.

4. Deciding how many medicines to study

The WHO/HAI Medicine Prices workbook - Part I allows easy comparison of the prices and availability of up to 50 medicines as is described in section 3.3 of the manual.

Surveying all therapeutic alternatives for a particular condition provides a more accurate representation of availability than if one or two medicines are surveyed when alternative products exist. However, for conditions with a large number of treatment alternatives, the list of medicines can become quite long, each medicine, dosage form and strength permutation counts as one medicine in terms of the survey design. The time and resources required to conduct a survey with an extensive medicine list should be considered carefully.

Depending upon how many medicines it is desired to study in the therapeutic group survey, the survey can either, be managed within a normal medicines prices survey, or as a stand alone survey. Whichever option is chosen, it is recommended that the study include at least the 14 global core medicines, and where possible the 16 regional core medicines. – This will enable the price and availability dynamics of the therapeutic group of medicines to be compared to those of other essential medicines which may be very meaningful in the interpretation of the findings and development of recommendation and strategies related to your surveys objectives. It will also enable the publicly accessible global data base of important global and regional prices and availability to expand.

Therapeutic group medicines studied as the 20 medicines of supplementary list

Providing all the geographic areas are included within the process of selecting geographic areas and if there are 20 or fewer different medicine/dosage form/strength permutations in the therapeutic group of medicines to be studied then these medicines can become the supplementary list⁸ and the survey carried out as described in the normal way using the standard workbook (Part I).

If the geographic areas being studied excludes certain areas of the country because of the objectives of the therapeutic group study (as previously discussed), then the standard approach can still be taken with the limitation that the findings of the prices and availability of the other medicines only reflect the findings in those geographic areas rather than, for example to the whole country.

More than 20 therapeutic group medicines to be studied

If there are more than 20 medicine/dosage form/strength permutations are included within the therapeutic group then there are two options to consider in how to design the survey:

- a) Exclude the regional core list of medicines, enabling up to 36 therapeutic group medicines to be studied within a single workbook (Part I)⁹. Note that the 14 global core medicines should always be surveyed for the reasons described above.
- b) Use more than one workbook; 50 medicines per workbook can be studied, so using 2 workbooks for example would enable the 30 global/regional core medicines to be studied plus 70 other medicines from the therapeutic group. Note that the use of multiple workbooks refers to Part I of the workbook only, and does not refer to Part II which is reserved for price components data entry and analysis.

Excluding the regional core list will have the disadvantage of not being able to compare the findings of price, availability and affordability of medicines for the therapeutic group being studied to other essential medicines and will also not contribute to the publicly available global database of findings from medicine prices surveys.

Using more than one workbook (Part I) means that you can potentially study as many medicines as is desired, however the workload in managing the data and analysing the findings becomes more challenging. More analysis needs to be done manually as the automatic analyses within the workbook only apply to those medicines within that particular workbook and not all the medicines across the multiple workbooks. The number of workbooks to be used should be as limited as possible and preferably not greater than two.

In determining the number of medicines from the therapeutic group to be studied, it needs to be considered how comprehensive the study needs to be – in line with the objectives and remembering that each medicine, dosage form and strength permutation counts as one medicine. The list of medicines can therefore be quite quickly used up.

5. Selecting the actual medicines to be studied

As previously discussed it is strongly encouraged to include the global core list of medicines, and if possible to include the regional core list of medicines, in the survey, and as is discussed in section 3.3.1 of the manual, medicines should only be deleted if the medicine is not registered in the country.

Selection of the supplementary list of medicines for the therapeutic group of medicines being studied.

Previously it has been discussed the limitations of expanding the list of medicines too much and ideally no more than 2 workbooks (100 medicines) should be used.

It is quite likely that if all the medicines/dosage form/strength permutations for the therapeutic group under consideration are listed that you may have hundreds of items - for example greater than 180 medicine/dosage form/strength permutations of antimalarial medicines are registered in Uganda.

It is therefore likely that there will need to be some prioritization of which of the medicines to select to study in the therapeutic group. Section 3.3.2 advises on how to select supplementary medicines in general and most of these considerations and some others are relevant for prioritization for a therapeutic group survey:

- a) Not all of the medicines registered may be marketed in the country – sometimes medicines are registered prior to being launched in a country and at other times, medicines may remain on the register even if they are no longer marketed; identifying these items may reduce your list of medicines. For those medicines which are not familiar, this information can be obtained from the market authorization holder, importer and/or wholesalers
- b) National treatment guidelines or local treatment practices - medicines that are recommended on local or national treatment guidelines should be included. Additionally medicines commonly prescribed as alternatives to the recommended treatments, whether rational or irrational, cost effective or not effective can be included so that comparisons of the price, availability and

affordability of the recommended and commonly used medicines for the same condition can be compared

- c) Expected availability at all the levels being studied – to ensure that there is enough data for robust analysis
- d) Existence of an international reference price. In the standard methodology, it is essential that all the medicines being studied have an international price to allow a proper analysis using an external standard (the international reference price) can be made. This is discussed in Chapter 3, Box 3.5, as are the different sources of international reference prices – the MSH International Reference Price being the most comprehensive, relevant and commonly used.

Before deciding which international reference price source to use, an analysis across the options listed in Box 3.5 should be made to identify the source with the greatest matches with your list of medicines¹⁰.

However, in a therapeutic group analysis where most of the commonly used medicines, dosage forms and strengths are be studied, it is unlikely that they will all have an MSH international reference price – and if another source is used, unlikely that they will all have that international reference price.

As mentioned above, it is very likely that there will be some medicines which you want to study that do not have international reference prices, in this case the analysis of the medicines needs to be two-fold: 1) using Median Price Ratios (see Manual section Chapter 8, Box 8.1) for those medicines with an international price; and 2) using the median price in local currency. The median price in local currency is automatically calculated and presented in the last column of the individual Field Data Consolidation pages, in data entry view with ratios turned on to display summary data for individual medicines(see manual section 7.4.1)¹¹, but is not presented on the “sector summary” or “product summary” pages.

An alternative approach , if you are using the MSH prices as the international reference price (for those medicines that have an international reference price) is to use the “other unit price” column on the reference prices page of the workbook (Part I). If in this column for each medicine the value of $[1 \div (\text{exchange rate})]$ is entered as the unit price for each medicine, e.g. if $1\text{US} = 1680$ Uganda Shillings, enter for each medicine in the in “other unit price” column¹² $[1 \div 1680] = 0.000595$. What this will do is, when the “MSH/Other Prices” button on the reference prices page is pushed, will result in all the analyses throughout the workbook will be in local currency for all the medicines where it is labelled MPR (regardless as to whether there is an international reference price or not). Pressing the button again will return the analysis to the MSH reference prices and what is labelled MPR will be MPR (for those medicines with an international reference price).

The analysis of availability and affordability of medicines does not rely on the international reference price and is therefore unaffected by the existence or not of an international reference price.

6. Data entry

Chapter 7 describes data entry and is only slightly different if more than one workbook is used – in which case, special care needs to be taken in the entering of the outlet identification codes correspond between the workbooks (row 7 of the data entry grid on the Field Data Consolidation pages).

7. Analysis of the findings

Chapter 8 of the manual discusses how to analyse and interpret the data. For therapeutic group surveys much of this advice can be followed as is described there. There are however a few special considerations.

- a) As previously discussed, if more than one workbook is used, then the analysis becomes more challenging in that the work is spread over more than workbook and the automatic analyses only apply to a subset of those being studied (i.e. only the ones in that workbook). If analyses of the entire basket of medicines across all the workbooks are necessary, then these would need to be done manually.
- b) In all analysis of medicines price information, the comparison of the price of an individual medicine between and within sectors, and between regions and countries is more statistically sound than comparing a basket of medicines across and within sectors; and between regions and countries. With therapeutic group surveys the analysis of the findings of a basket may be completely irrelevant. For example in a therapeutic group survey of medicines for tuberculosis, you may study the first line recommended treatment as well a number of the non-recommended medicines for your country for TB – presenting the price and availability information of the basket of recommended and not recommended medicines would have little meaning in that a high “basket” availability would indicate the stocking of non-recommended medicines – which is not the desirable outcome – it would however be completely relevant to present the price and availability information drug-by-drug. “Basket” comparisons of the entire list of medicines therefore only make sense when it is desirable for all the medicines to be stocked. An alternative way to de-select some medicines in the basket comparison using the “include in analysis” column on each sector data entry page (column D of the data entry grid on the Field Data Consolidation pages) (see manual Section 8.5).
- c) If the alternative approach described under 5d) above is used, care needs to be taken to know when the MSH international reference price is being used to calculate a Median Price Ratio and when the “other price source” is being used to calculate the price in local currency

8. Measuring the components of the final (patient) price

As with the normal medicine prices survey, understanding the components of the final (patient) price completes more of the picture on understanding the prices of medicines. Conducting a price components study as is described in chapter 9 is therefore highly recommended. Like with the selection of medicines described above, it is meaningful to study a small proportion of essential medicines outside the therapeutic group being studied so as to see whether there are major differences between the therapeutic group and essential medicines in general.

IF YOU ARE CONSIDERING UNDERTAKING A THERPAEUTIC GROUP SURVEY THEN CONTACT HAI (info@haiweb.org) OR WHO (medicineprices@who.int) TO DISCUSS YOUR PROPOSED PROTOCOL BEFORE UNDERTAKING TRAINING OR FIELD WORK.

¹ Rao R, Thapa D. Nepal: reproductive health commodity pricing survey. Understanding access, equity, and affordability of essential reproductive health commodities. 2005. USAID/DELIVER.

http://www.haiweb.org/medicineprices/related/12012006/NepalRHPrising_final%20rpt.pdf

² Beitz J. and Romero D. Prices of reproductive health medicines in Nicaragua. March 2006. PATH

http://www.haiweb.org/medicineprices/related/09062006/NicaraguaPricingStudy_Final.pdf

³ Mendis S, Fukino K, Cameron A, Laing R, Filipe A, et al. The availability and affordability of selected essential medicines for chronic diseases in six low- and middle-income countries. Bull World Health Org 2007; 85(4): 279-87

<http://www.who.int/bulletin/volumes/85/4/06-033647.pdf>

⁴ https://www.mmv.org/article.php3?id_article=392

⁵ <http://www.rollbackmalaria.org/globalsubsidytaskforce.html>

⁶ Gelders S, Ewen M, Noguchi N, Laing R. Price, availability and affordability An international comparison of chronic disease medicines, WHO/EMRO and HAI <http://www.haiweb.org/medicineprices/30052006/CHRONICANN.pdf>

⁷ www.haiweb.org/medicineprices

⁸ A standard medicine prices workbook contains room for 50 medicines, if some of the 14 global core and 16 regional core medicines have been deleted because they are not registered in the country (see section 3.3), then more than 20 spaces may be available for supplementary medicines

⁹ Medicines can be deleted as described in section 3.4 of the manual

¹⁰ Note that the same set of reference prices must be used for all the survey medicines, i.e. cannot combine two types of international reference price.

¹¹ Column "E"

¹² Column "J"