

A proposal for an evaluation model of pharmaceutical services for malaria

Uma proposta de modelo de avaliação para a assistência farmacêutica na malária

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Abstract

Malaria is a serious public health problem in over 90 countries worldwide. In Brazil the disease is prevalent in the Amazon and the control rationale is based on early diagnosis and treatment. Quality pharmaceutical services are considered a key element for control. A proposal for evaluating pharmaceutical services for malaria is presented here. A theoretical outline composed of a logical model and an indicator framework is discussed and strives to establish a basis for assessment and judgment of the way in which these services are actually delivered. The aim is to contribute to the understanding of pharmaceutical services for malaria and other endemic diseases, complying with the directives of the Brazilian National Medicines Policy.

Pharmaceutical Services; Malaria; National Drug Policy

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Introduction

Malaria is a disease limited to tropical and subtropical areas and a serious public health problem in over 90 countries. Some 515 million cases occur annually, causing 1.5 to 2.7 million deaths worldwide, mainly among children under five years of age and pregnant women ¹.

In Brazil, the National Malaria Control Program (PNCM) acknowledged 540,047 cases in 2006, of which more than 99% were from the Amazon region. Spatial distribution is heterogeneous, however. The overwhelming majority of cases happen in the states of Amazonas, Rondônia, Pará and Acre ².

The rationale for malaria control in the country is anchored on early diagnosis and adequate treatment. Treatment is specific for the type of malaria and is based on different phases of the parasite cycle ². This leads to complex treatment regimens that include multiple drugs in various combinations and which are applicable to a variety of patients – adults, the elderly, pregnant women and children of different ages.

The Brazilian National Medicines Policy (PNM) lists pharmaceutical services as one of its eight directives and four priorities ³. The main objectives of pharmaceutical services are to supply quality medicines while guaranteeing their rational use. Because activities pertaining to pharmaceutical services are linked to produce measurable management and clinical outcomes,

the different elements of pharmaceutical services (such as the organization of services, prescribing and dispensing) are deemed to have important consequences for the adherence to treatment, both by health professionals, who prescribe and dispense, as well as by patients. Therapeutic success will, in turn, influence disease prevalence in endemic areas and drug resistance.

This paper aims to propose a pharmaceutical services evaluation model for endemic diseases in the Brazilian Amazon. To our knowledge the literature has not produced an evaluation model for pharmaceutical services specifically related to endemic diseases. The development of a model based on malaria may be useful to other endemic diseases that share the same control rationale and corroborates the standards stated in the PNM.

Methods

A search of two literature databases, SciELO and PubMed, for the period January 1980 to December 2005 was conducted to investigate published information on prescribing, dispensing and adherence to malaria treatment.

Other studies on malaria treatment interventions, and further documentation of international organizations such as Management Sciences for Health (MSH), the World Health Organization (WHO), the Pan American Health Organization (PAHO) and the Amazon Antimalarials Surveillance Network (RAVREDA) were also collected.

A specialist panel, composed of researchers in pharmaceutical services and malaria, drafted the theoretical outline. A logical model was prepared, considering the following evaluation components: context, services organization and logistics, prescribing, dispensing and adherence to treatment. They were then organized according to their specific resources, activities, products and expected results.

Based on this framework, indicators for each component were identified. The issue was to consider mainly published validated indicators, in order to increase external validity. In some cases a measure of adaptation was deemed necessary. The choice of indicators was also influenced by the availability of data from the Brazilian Census Bureau (IBGE), the Brazilian Health Information System (DATASUS), the Brazilian Primary Healthcare Database (SIAB) and the Brazilian Epidemiologic Surveillance Database (SIVEP). Indicators were directed towards investigation of municipalities and health facilities within municipalities.

Results and discussion

The results of this proposal are the logical model and the indicator framework.

The logical model is shown in Table 1. It is organized to characterize inter-component relationships and the influence components have on pharmaceutical services outcomes.

It proposes four components, listing necessary resources for activities to be carried out, expected products for the activities and the evaluation outcomes. Adherence to treatment was understood to be a comprehensive result of all components. Components are referred to in studies on adherence where, in addition to the organization of services and context, prescribing and dispensing are considered as determinants for this outcome⁴.

Adequate organization of services offers a necessary structure for the clinical phases of pharmaceutical services, in health facilities and systems⁵, because drug supply and drug quality are key elements in treatment-based control models, where expected effectiveness is mandatory for success⁶. Since malaria regimens combine various medicines, all must be equally available for first-line and alternative treatments.

The prescription is an important document, used by prescribers, dispensers and other health workers for guidance on treatment⁴. The lack of prescriptions or written instructions is viewed, by those who consider adherence to represent the patient's informed consciousness, to be a true impeditive for its occurrence⁷.

Dispensing must also present specific characteristics such as prescription checking, counseling on drug administration and use, home storage conditions, adverse effects, preventive measures and follow-up. Dispensing promotes adherence and is, in the lack of household care strategies, the last opportunity of interaction between the health system and the out-patient.

Risk-minimization during therapy is associated with quality prescribing and dispensing. In the case of malaria, misunderstanding the complexity of treatment, as well as the onset of severe adverse effects and resistance, causing and stemming from treatment abandonment, may be interpreted as consequences of faulty counseling⁴.

Adherence is the result of a process involving successive institutional and individual responsibilities. Acceptance of therapeutic guidelines by health professionals is considered to be a necessary pre-condition for patient involvement in treatment. Household follow-up is a powerful incentive to adherence outcomes⁴. In the Brazilian Amazon a theoretical 98% of municipalities are

Table 1

Logical model for evaluation of pharmaceutical services for uncomplicated malaria in the Brazilian Amazon.

CONTEXT AND ORGANIZATION OF SERVICES					
Resources	Activities	Products	Products	Results	
Budget *	Logistics	Forecasting (medicines from treatment guidelines)	Timely calculated forecast of guideline medicines	Availability of quality guideline medicines at health facility	Adequately organized pharmaceutical services for malaria, with trained staff and facilities in accordance with national guidelines
Epidemiological data		Distribution of medicines in accordance with demand	Timely delivery of guideline medicines in adequate quantities and type, according to demand		
Social and demographic data		Storing medicines in conditions so as to guarantee quality	Adequately stored quality medicines		
Treatment guidelines					
Human resources					
Distribution systems					
Storage					
PRESCRIBING					
Resources	Activities	Products	Products	Results	
Diagnosis	Prescribing in accordance with national treatment guidelines and patient specificity	Patients that leave encounter with prescription or written instruction	Prescriptions corresponding to diagnoses	Prescribing practices adjusted to the PNCM norms and to national treatment guidelines	
Treatment guidelines					
Prescription or written instruction					
Medicines (regimen)					
Trained staff					
Adequate facilities					
DISPENSING					
Resources	Activities	Products	Products	Results	
Trained staff	Assuring adequate dispensing	Drug information provided to patients	Patient informed as to correct use of all medicines supplied	Dispensing practices adequate to the needs of the PNCM and adjusted to the national treatment guidelines	
Quality medicines		Supply of complete treatment regimen			
Information for the health professional/health worker					
Educational materials for patients					
Adequate facilities					
ADHERENCE					
Resources	Activities	Products	Products	Results	
Educational materials for patients	Promoting patient adherence to treatment regimen	Information on characteristics of medicines, adverse effects, and treatment regimen known to patient		Patient and health professional/health worker adherent to treatment/treatment guidelines	
Household follow-up by trained staff		Complete treatment regimen obtained			
Adequate supply of treatment regimen		Adequate patient care			
Information for the patient		Patient follow-up at home			
Prescription or written instruction					

PNCM: National Malaria Control Program.

* In Brazil, malaria treatment is free, 100% financed by the Ministry of Health.

■ Comprehensive result.

served by the Community Health Workers Program (PACS) or Family Health Program (PSF) ⁸.

Relationships between prescribing, dispensing and adherence in the context of malaria need to be studied not only because cure depends on drug therapy, but also because presumptions and practices may be misconstrued, indicating the need for intervention strategies to correct outcomes ⁹.

The logical model gave rise to the indicator framework. Each component and sub-component was translated into one or more indicators, in order to consolidate the evaluation proposal. One guiding option was the listing of the smallest possible number of indicators. This course of action was taken in order to balance the model's theoretical consistency on one hand and the feasibility of the evaluation process on the other.

Twenty-five indicators were considered (Table 2). Sources included information databases, MSH, the PNCM and the literature ^{2,4,5,10,11,12,13}, and some had to be adapted to reflect the context and focus of the evaluation process, namely pharmaceutical services for malaria.

There is no specific way to conduct an evaluation of health services. Each proposal is somewhat dependent on the object under assessment and on the standpoint of the evaluating team ¹⁴. This proposal intends to cluster elements of a normative assessment and of evaluation research,

confronting the model with the reality of care in a "natural environment" in order to determine what is acceptable within existing parameters of care. Because investigative methods and instruments must reflect the true nature of the subject under investigation, evaluation research is useful in determining not only priorities for assessment but the best possible strategies for implementing them ⁹.

It is not possible to abandon the theoretical basis of pharmaceutical services, even if certain criteria may apparently not be applicable to the context of malaria. An example of this issue is the prescription form. Because prescribing for malaria is not usually carried out by physicians, the evaluation proposal was obliged to incorporate context, allowing for the existence of written instructions as an acceptable alternative. This counterbalance between theory and reality eases the evaluation process, albeit limiting its scope.

The therapeutic use of antimalarials may lead to non-adherence, enhancing resistance and disease prevalence. The challenge of pharmaceutical services is to provide services and medicines in order to counter avoidable health problems and help resolve established ones. The development of an evaluation model of pharmaceutical services for malaria can also contribute to the understanding of this key control strategy for other endemic diseases in Brazil.

Resumo

A malária é um grave problema de saúde pública em cerca de 90 países. No Brasil, a Amazônia congrega o maior número de casos. No país, o racional de enfrentamento se baseia em diagnóstico precoce e tratamento. A assistência farmacêutica de qualidade é considerada elemento-chave para o controle da doença. Apresenta-se uma proposta de avaliação da assistência farmacêutica, composta por um modelo lógico e uma grade de indicadores, discutidos de modo a estabelecer uma base de comparação e julgamento da forma na qual os serviços são ofertados. O objetivo é contribuir para o entendimento da assistência farmacêutica na malária e em outras endemias, atendendo às diretrizes da Política Nacional de Medicamentos.

Assistência Farmacêutica; Malária; Política Nacional de Medicamentos

Contributors

C. G. S. Osorio-de-Castro coordinated proposal, development and results, draft and review. G. C. Chaves collaborated on the proposal, development and results, and review. A. M. Ruiz collaborated on the proposal, development and results. E. S. Miranda collaborated on the proposal, development and results, draft and review. M. R. Campos collaborated on the proposal, development, results, and draft. M. C. Suárez-Múti collaborated on the proposal, development and results, and review. L. F. Freitas collaborated on the proposal, collaborated in development and results.

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Table 2

Indicator framework for evaluation of pharmaceutical services for uncomplicated Malaria in the Brazilian Amazon.

CONTEXT AND ORGANIZATION OF SERVICES (CO)			
Component	Indicator	Detail	Reference
CO1	% of literate individuals in municipality	Data from DATASUS, IBGE, SIAB and RAVREDA	Santos & Natal ⁵
CO2	% of households served by water supply from municipal network	Data from DATASUS, IBGE, SIAB and RAVREDA	Santos & Natal ⁵
CO3	% of households served by municipal garbage collection	Data from DATASUS, IBGE, SIAB and RAVREDA	Santos & Natal ⁵
CO4	Municipal coverage by PACS or PSF	Data from DATASUS, IBGE, SIAB and RAVREDA	Adapted from Santos & Natal ⁵
CO5	Number of cases of uncomplicated malaria (estimated and confirmed) in the municipality	Data from municipal health secretariats	Adapted from Santos & Natal ⁵
CO6	% of resistance to first-line treatment regimen of most prevalent form of malaria in the municipality	Data from the PNCM	Adapted from World Health Organization ¹⁰
CO7	Number of antimalarials on the national guidelines that progressed to Phase III clinical trials in Brazil	Assesses adequacy of national treatment guidelines to published evidence	Freitas et al. ¹¹
CO8	Availability of the MTM or of official prescriber guidance material for malaria from the Ministry of Health at the health facility	The MTM is published by the Ministry of Health and includes the official treatment guidelines. At least one perfectly readable copy of the 2001 version should be present in the facility. Other official guidance material from the Ministry of Health is alternatively accepted	Adapted from Fundação Nacional de Saúde/Ministério da Saúde ² , and World Health Organization ¹²
CO9	Number of available complete treatment regimens for uncomplicated malaria caused by <i>Plasmodium vivax</i> and/or <i>P. falciparum</i> at the health facility	In order to fill out this indicator, prevalence data from the municipality, number of cases per month at the health facility and stock of medicines are needed	Adapted from World Health Organization ¹²
CO10	Good Storage Practices	A checklist for storage conditions and practices is suggested, composed of mandatory structural elements, hygiene conditions, storage practices, organization and stock control	Adapted from Management Sciences for Health ¹³
CO11	Existence of expired antimalarials at the health facility	Stock for antimalarials composing regimens for the most prevalent type of malaria in the municipality should be investigated as to expiry date in each health facility	Adapted from World Health Organization ¹⁰ and Santos & Natal ⁵
CO12	Uninterrupted supply of first-line antimalarials at the health facility	The health facility must follow some procedure of stock control. Uninterrupted supply for regimens for the most prevalent type of malaria in the municipality should be checked, from forecasting forms and supply dates	Adapted from World Health Organization ¹²
CO13	% of encounters in which diagnosis occurs before prescription of treatment regimen	An encounter is characterized by a patient meeting a health professional/health worker for diagnosis/treatment/counseling, at the health facility or at home. Diagnosis involves the determination of the type of malaria from a blood sample, according to the PNCM. The date of diagnosis and the date of treatment assignation will be investigated	Adapted from Fundação Nacional de Saúde/Ministério da Saúde ² and World Health Organization ¹⁰

(continues)

Table 2 (continued)

CONTEXT AND ORGANIZATION OF SERVICES (CO)			
Component	Indicator	Detail	Reference
CO14	Average period from blood sample to diagnosis	Diagnosis involves determination of type of malaria for adequate treatment assignment. The date of blood sampling and the date of result/diagnosis will be investigated	Adapted from Fundação Nacional de Saúde/Ministério da Saúde ² and World Health Organization ¹⁰
CO15	% of trained health professionals/ trained health workers (in diagnosis and treatment) attending to malaria patients	Training involves receiving the patient, collecting patient history, blood sampling and lab work, interpretation of results, diagnosis, indication of treatment and adequate dispensing (including counseling)	Adapted from Santos & Natal ⁵
CO16	Existence of specific facilities for patient encounter (for prescribing and dispensing)	Locale where patient is received and where encounters (including prescribing and dispensing) take place	Adapted from Santos & Natal ⁵ and Osterberg & Blaschke ⁴
PRESCRIBING (P)			
Component	Indicator	Detail	Reference
P1	% of patients with uncomplicated malaria that report at dispensing with a prescription or written instructions	Patients, having searched for diagnosis and treatment, may have been provided with a prescription or written instructions on their treatment regimens. Written instructions may also be in the form of pre-printed flyers, pamphlets etc and are given out by health professionals / health workers. The investigation is to be done when the patient exits the dispensing area	Adapted from Osterberg & Blaschke ⁴
P2	Average number of medicines in the prescription or in written instructions originating from the same encounter, apart from the ones from MTM	In theory, any patient might receive a prescription for different ailments at the same encounter when he or she is being treated for malaria. The patient will be asked for his or her prescription or written instruction received in order to assess whether other medicines, (apart from antimalarials), were prescribed and how many. A group of patients will characterize a health facility and the group of facilities will characterize a municipality	Adapted from Fundação Nacional de Saúde/Ministério da Saúde ² , World Health Organization ¹² and Osterberg & Blaschke ⁴
P3	% of encounters for uncomplicated malaria treatment in which prescribing (or indication) is done in accordance with MTM	Certain criteria must be followed: if the prescription/ written instruction is done in accordance with the diagnosis; if the treatment regimen is part of the official guidelines; if prescribed by generic name; if the complete treatment regimen is prescribed	Adapted from Fundação Nacional de Saúde/Ministério da Saúde ² , World Health Organization ¹² and Freitas et al. ¹¹
DISPENSING (D)			
Component	Indicator	Detail	Reference
D1	% of dispensing encounters in which patients/caregivers receive information on the treatment regimen	Dispensing is observed for assessment of: existence of prescription or written instructions; delivery of complete treatment regimen; information relayed to patient (at least: dosing information, household storage, common adverse effects); available literature for health professionals/workers	Adapted from Osterberg & Blaschke ⁴
D2	% of medicines adequately labeled for patient delivery	Dispensing is observed to assess labeling of delivered medicines. Minimally accepted are name of medicines on labels to coincide with the one on the prescription/instruction and dosing	World Health Organization ¹²

(continues)

Table 2 (continued)

PRESCRIBING/DISPENSING (PD)			
Component	Indicator	Detail	Reference
PD1	% of patients/caregivers that exit the health facility adequately informed as to the treatment regimen	Acceptable minimal information depends on: receipt of complete treatment regimen; capacity to relay to interviewer how to take the medicines; household storage and common adverse effects. If information given by patient has been sub-optimal, interviewer is to complement it	Adapted from World Health Organization ¹²
ADHERENCE (A)			
Component	Indicator	Detail	Reference
A1	% of patients receiving care for malaria at home from community/family health program workers	Household visit by health workers is investigated in the municipality in order to assess if worker is adequately trained for diagnosis and treatment, if worker relays relevant information to the patient on antimalarials and adverse effects, if physical assessment of patients is done, if blood sampling and counseling are carried out, if educational materials are made available	Adapted from Santos & Natal ⁵
A2	% of patients that declare having completed their treatment in accordance with prescription/written instruction	A statistically established fraction of patients interviewed exiting the dispensing area that present a prescription or written instruction, that received a complete treatment regimen, and that live in an accessible location (< 1 hour from the health facility) are followed at household after 2 or 5 days of treatment (depends on regimen). Adherence is assessed through the self-reported method (report of daily treatment progress and experienced problems, including adverse effects). In case of sub-optimal adherence, the patient will be referred back to the health facility	Adapted from Osterberg & Blaschke ⁴
A3	% of patients that at household visit present difference between expected number of pills/capsules (dosage forms) and those actually presented to interviewer	A statistically established fraction of patients interviewed exiting the dispensing area that present a prescription or written instruction, that received a complete treatment regimen, and that live in an accessible location (< 1 hour from the health facility) are followed at household after 2 or 5 days of treatment (depends on regimen). The researcher will demand to see the medicines received at encounter to treat malaria. Dosage forms will be counted for comparison with expected number. In case of sub-optimal adherence, the patient will be referred back to the health facility	Adapted from Osterberg & Blaschke ⁴

DATASUS: Brazilian Health Information System; IBGE: Brazilian Census Bureau; SIAB: Brazilian Primary Healthcare Database; RAVREDA: Amazon Antimalarials Surveillance Network; PACS: Community Health Worker Program; PSF: Family Health Program; PNCM: National Malaria Control Program; MTM: National Malaria Treatment Guideline.

References

1. Snow RW, Guerra CA, Noor AM, Myint HY, Hay SI. The global distribution of clinical episodes of *Plasmodium falciparum* malaria. *Nature* 2005; 434:214-7.
2. Fundação Nacional de Saúde/Ministério da Saúde. Manual de terapêutica da malária. Brasília: Fundação Nacional de Saúde/Ministério da Saúde; 2001.
3. Brasil. Portaria nº. 3.916/MS/GM. Aprova a Política Nacional de Medicamentos. Diário Oficial da União 1998; 30 out.
4. Osterberg LMD, Blaschke TMD. Drug therapy: adherence to medication. *N Engl J Med* 2005; 353:487-97.
5. Santos EM, Natal S, organizadores. Dimensão técnico-operacional. Unidade didático-pedagógica: modelo teórico de avaliação. Rio de Janeiro: ABRASCO; 2006. (Série Ensinando Avaliação, 2).
6. Luiza VL, Osorio-de-Castro CGS, Nunes JM. Aquisição de medicamentos no setor público: o binômio qualidade-custo. *Cad Saúde Pública* 1999; 15:769-76.
7. Farmer P. Social scientists and the new tuberculosis. *Soc Sci Med* 1997; 44:347-58.
8. Departamento de informática do SUS. Sistema de Informação de Atenção Básica – cadastramento familiar – Brasil. <http://tabnet.datasus.gov.br/cgi/deftohtm.exe?siab/cnv/SIABFbr.def> (accessed on 05/Aug/2005).
9. Uchimura KY, Bosi MLM. Qualidade e subjetividade na avaliação de programas e serviços em saúde. *Cad Saúde Pública* 2002; 18:1561-9.
10. World Health Organization. Monitoring and evaluation toolkit: HIV/AIDS, tuberculosis and malaria. Geneva: World Health Organization/The Global Fund/The United Nations Joint Programme on HIV/AIDS/United States Agency for International Development/Centers for Disease Control and Prevention/United Nations Children's Fund/World Bank; 2006.
11. Freitas LF, Chaves GC, Wannmacher L, Osorio-de-Castro CGS. Malária não-complicada por *Plasmodium vivax* e *P. falciparum* no Brasil: evidências sobre fármacos isolados e associações medicamentosas empregados em esquemas terapêuticos recomendados pelo protocolo terapêutico oficial. *Cad Saúde Pública* 2007; 23:2285-94.
12. World Health Organization. How to investigate drug use in health facilities: select drug use indicators. Geneva: World Health Organization; 1993.
13. Rational Pharmaceutical Management Project, Management Sciences for Health. Rapid pharmaceutical management assessment: an indicator-based approach. Arlington: Management Sciences for Health; 1995.
14. Silver L. Aspectos metodológicos em avaliação dos serviços de saúde. In: Gallo E, organizador. Planejamento criativo: novos desafios em políticas de saúde. Rio de Janeiro: Editora Relume-Dumará; 1992. p. 195-209.

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