

Evaluating the process of tailoring the global HIV/AIDS practice guidelines for use in developing countries

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Abstract

Objective. To describe a systematic procedure for adapting, or 'tailoring' the World Health Organisation's 'global guidelines for the management of HIV/AIDS in adults and children' for use in two developing countries: Malawi and Barbados.

Design. In order for these guidelines to achieve reproducibility, clinical flexibility, and clinical applicability, a systematic procedure is needed to tailor the guidelines to the local practice conditions of specific settings.

Methods. A group of local experts in each country used a nominal group process to modify the global program on AIDS (GPA) guidelines for local use. Semantic analysis techniques, known as clinical algorithm nosology (CAN), were used to compare the two modified guidelines with the global ones to determine the extent and type of differences between sets of guidelines.

Results. Standard, locally-tailored algorithm map guidelines (AMG) were developed within 4 months. CAN semantic analysis showed that guideline structure was maintained; 572/858 (66.6%) decision nodes were found to be the same in the GPA/Malawi, GPA/Barbados and Malawi/Barbados comparisons. However, different guideline versions managed patients quite differently, as evidenced by clinical algorithm patient abstraction (CAPA) scores of between 0 and 8.46 (0 = different; 8 = similar; 10 = identical). Analysis of the 197 specific differences found in these abstractions showed that 83% were in approaches to diagnosis and therapy, while the remaining 17% related to disease prevalence.

Conclusions. Standard techniques involving consensus used to develop clinical guidelines can also be employed to tailor these guidelines to local settings. Semantic analysis shows that the tailoring preserves structure but may involve significant modification to the processes of clinical care that could in turn affect care outcomes.

Keywords: clinical algorithms, guideline adaptation, HIV management, practice guidelines, semantic analysis

Using clinical practice guidelines to guide and monitor medical care requires five interdependent steps: design and development, local adaptation, dissemination and learning, implementation, and evaluation of process and of effect on outcome. Much effort has been invested recently in improving guideline design and development methodology [1,2] thus providing an increasingly firm scientific basis for guideline validity. However, it has become clear that even the most scientifically correct guideline will not be used effectively unless it is tailored for local use, disseminated to users effectively, learned thoroughly, implemented systematically

and evaluated in an ongoing fashion both as to whether it is used correctly and also as to whether it improves those health outcomes it was designed to change. Only recently has emphasis been placed on these essential, practical steps in using guidelines, and mainly in the form of quality improvement techniques [3].

Our project focused on defining how to tailor a guideline for local use and analysed how the local version differs from the generic original. Three of the attributes of good practice guidelines [2] relate to local tailoring by defining properties that enable guideline flexibility: 'reproducibility' is the extent

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to which separate groups of developers would create identical guidelines; 'clinical applicability' is the extent to which the patient population to which the guideline applies is defined; 'clinical flexibility' is the extent to which exceptions to the guidelines are defined. Clearly, a large part of a good practice guideline should be reproducible and clinically applicable, but there must also be enough clinical flexibility to suit the guideline to a particular patient or to decide that it is unsuitable.

Many clinicians and guideline developers feel that a necessary step in maintaining clinical flexibility is tailoring a guideline for use in a particular clinical practice or local environment. Does this mean that any practice guideline will have to be adapted before it is used by a clinician in a particular practice, or will guidelines only have to be adapted when applied in very different environments? We know of no studies that describe either a systematic procedure for tailoring a guideline, or the sort of changes that a guideline undergoes when such a procedure is applied.

We describe an attempt by the World Health Organisation (WHO) to systematically tailor its global program on AIDS (GPA) guidelines for management of HIV infection in adults and children [4] for use in two developing countries, Malawi and Barbados, using the same standard procedures [1] employed to develop these guidelines [5–7]. We then used new semantic analysis tools to describe the differences between the three sets of guidelines. The analysis resulted in the first description and classification of differences between a generic guideline and a local adaptation.

Methods

Guideline development

In 1989, GPA convened a group of experts to develop clinical guidelines for managing AIDS/HIV infection in adults. After the text versions of the guidelines had been written, most of them were translated into flow chart guidelines (algorithm maps) over 9 months using published techniques [1] for algorithmic analysis and standard construction of algorithmic guidelines. The GPA guidelines address the following clinical areas in map format: (i) recognition of symptomatic HIV infection; (ii) laboratory evidence of HIV infection; (iii) chronic diarrhoea; (iv) oral thrush; (v) respiratory conditions; (vi) lymphadenopathy; (vii) headache; (viii) fever; and (ix) HIV-associated skin diseases. Management of the HIV-infected asymptomatic person is presented in text format. The algorithm maps are innovative in specifying three levels of care for almost all the main complications. These levels, termed A, B and C, are designed to take into account the differing socio-economic realities and medical resource levels across countries, and thus map the approaches to care with no laboratory support, with minimal laboratory support and with the support of tertiary care laboratory and radiological facilities, respectively.

Development of the paediatric algorithm maps began in March, 1990, and the penultimate drafts were completed in

a workshop over a 5-day period using nominal group process and Delphi [8,9] techniques. The workshop, led by two of the authors (CZM and RW), included seven expert participants from developed and developing countries. The paediatric guidelines [10] closely parallel the adult ones both in format and content, except for three problems unique to children (neurological abnormalities, failure to thrive, and abnormal chest X-ray in a child with no respiratory symptoms), and include a prose chapter on counselling.

Tailoring guidelines for use in developing countries

Workshops were held in Malawi (July 1991) and Barbados (January 1992), building on the authors' experience with tailoring guidelines for use in the health centres of Harvard Pilgrim Health Care (HPHC) in the USA [3], and based on the observation that local consensus processing engenders a sense of guideline ownership. The workshops used nominal group process to enable local experts to modify the GPA guidelines for local use, and to begin planning implementation. A stepwise process was used to determine the composition of the workshop groups. The first step was to determine the target of the guideline application, e.g. university hospital, health centre, etc. This decision was influenced by a number of factors, including the state of the HIV epidemic and the existing infrastructure. It was generally agreed to develop guidelines for health facilities where patients would most likely go (urban versus rural), and where access to health facilities would be simple. Guidelines in Barbados, a small country with a good infrastructure, including public transport, focused on the major hospital and polyclinics; while guidelines for Malawi were developed to improve HIV care at the central, regional and community levels.

Once the target institutions for application of the guidelines were defined, the second step involved identifying the professional categories (e.g. doctors, nurses, medical school/nursing teachers), programmes and departments (essential drug programme, hospital administration, etc.) that would be involved in application of the guidelines. The third step involved the actual selection of participants, which further took into consideration the preferred group size for consensus building (15–20 participants) and sought to maintain a distribution of two-thirds medical or nursing staff and one-third administrative staff. In order to minimize personal selection bias, an external consultant facilitated the first three steps. However the final decision was taken by WHO's counterpart in the Ministry of Health. None of those selected for the Malawi and Barbados workshops refused to participate, however attendance at the workshops was not always complete.

Additional consensus workshops were held in Burundi (using French versions of the GPA guidelines), in Thailand, and in Trinidad for the 17 English-speaking Caribbean countries, but these do not form a part of this study.

Workshop process goals included: summarizing essential international and local epidemiological data on AIDS, describing local care facilities and mechanisms, familiarizing the

Table 1 Summary of participants' questionnaire responses from Malawi and Barbados workshops

Questions	Malawi (n=28)			Barbados (n=12)		
	Yes	Un	No	Yes	Un	No
GPA clinical guidelines sound?	26	0	2	12	0	0
GPA guidelines cover management of HIV?	26	0	2	12	0	0
GPA guidelines useful for reaching national consensus?	23	2	3	12	0	0
Nominal group process efficient?	17	4	7	12	0	0
Workshop succeeded in modifying guidelines in Barbados/Malawi?	23	3	2	12	0	0
Workshop succeeded in developing implementation plans?	15	10	3	12	0	0
Guidelines useful for guiding clinical care?	23	0	4	12	0	0

Un, undecided.

participants with guideline content, and performing consensus procedures on all of the GPA guidelines. The intended outcome of the workshop was a complete draft of local clinical guidelines for the management of AIDS/HIV infection and its complications within a month of the end of the workshop.

Results

Questionnaire for workshop participants

A questionnaire aimed at assessing whether workshop participants felt that the main workshop goals had been achieved was given to all participants in the two workshops. Answers to key questions from the questionnaire, shown in Table 1, indicate that participants felt that the goals of learning the GPA guideline content and tailoring the guidelines to local conditions had been achieved.

Workshop outcomes

Both Malawi and Barbados produced local versions of the GPA guidelines (available on request from WHO) within 4 months, thus showing that this goal was attainable. The clinical algorithm nosology (CAN) semantic analysis technique [11], including clinical algorithm patient analysis (CAPA), for determining the extent and nature of differences between practice guidelines, and the clinical algorithm structural analysis (CASA) for quantifying structural differences, was used to compare the GPA guidelines and their adaptations in Malawi and Barbados. In summary, these techniques begin with clinical rule analysis, which translates the clinical logic of each individual step between algorithm boxes into a set of 'If...then' conditional statements. Thus, each algorithm map is transformed into a list of specific rules of logic which serve to pinpoint the patient management differences identified by the algorithm comparison process. The CAPA technique then defines a hypothetical patient for each pathway, beginning at the first node of the algorithm and continuing until a particular terminal 'action' node is reached. The

patients of one version of an algorithm map are then managed using the other version of the map. For example, one hypothetical patient on the GPA algorithm for respiratory conditions (see Figure 1) is defined by the boxes 1,2,4,5,6

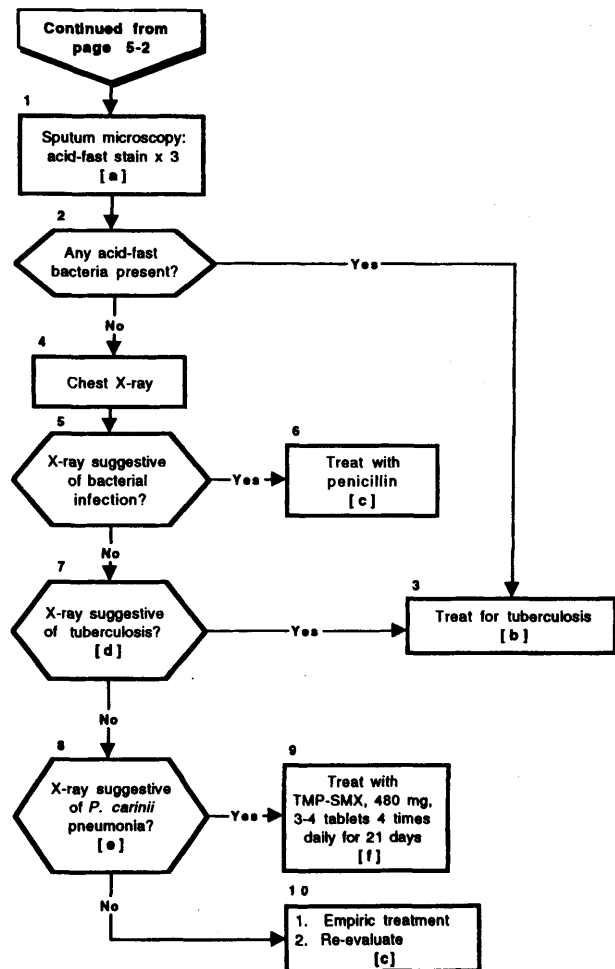


Figure 1 GPA algorithm for respiratory conditions

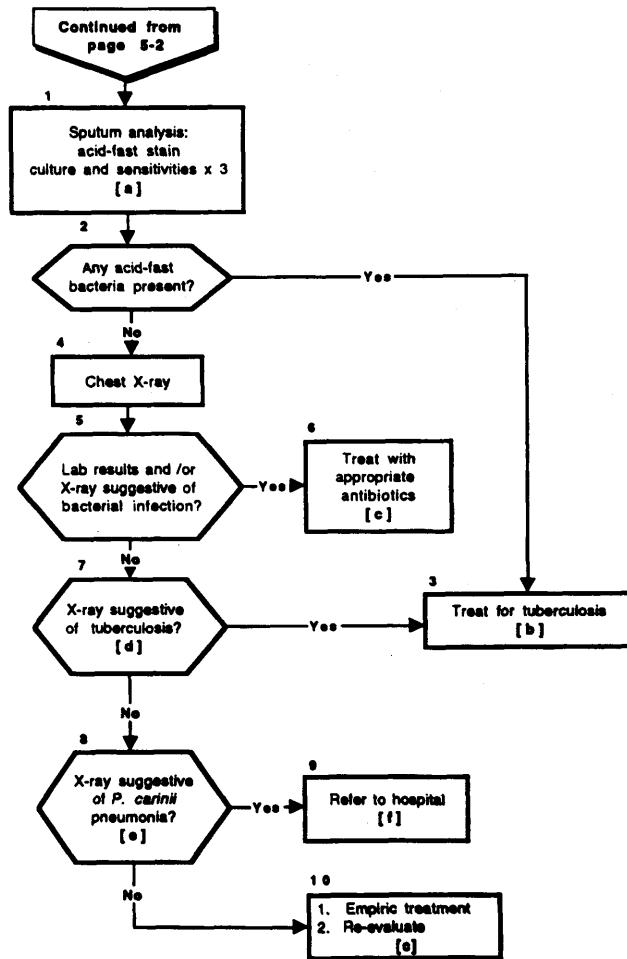


Figure 2 Barbados algorithm for respiratory conditions

(1 = sputum microscopy: acid-fast stain × 3; 2 = no acid-fast bacteria present; 4 = chest X-ray; 5 = X-ray suggestive of bacterial infection; 6 = patient treated with penicillin). This hypothetical patient follows nearly the same pathway on the Barbados algorithm (see Figure 2, boxes 1,2,4,5,6), except that the sputum analysis includes culture and sensitivities (box 1), so that both the bacterial cultures and X-rays are used to determine whether or not the patient has a bacterial infection (box 5); the patient is then given appropriate antibiotics based on sensitivity testing (box 6). The success of the second version of the map in managing each of the patients defined from the pathways of the first version is judged as identical, similar, or different (scored 10, 8 and 0 respectively). This process is then reversed, and the patients defined for all pathways of the second version are managed using the first version.

If one compares visually the structure of any two algorithm maps, they appear similar (see parallel parts of the maps in Figures 1 and 2). This similarity is due to the number of decision nodes that remain the same across versions. Specifically, 65% (186/285) of the nodes in the 11 comparable GPA and Malawi guideline maps, 76% (328/427) of the nodes in the 13 comparable GPA and Barbados guideline

Table 2 CASA complexity scores¹ for the GPA, Barbados and Malawi algorithms for the clinical management of HIV infection in adults

Algorithm	GPA	Barbados	Malawi
Suspected symptomatic HIV infection	19	24	19
Positive initial test for HIV antibodies	9	12	16
Chronic diarrhoea	68	43	52
Oral thrush	60	23	29
Respiratory conditions	58	47	35
Lymphadenopathy	51	22	40
Headache	56	39	–
Fever	67	53	32
HIV-associated skin disease	71	71	–
Mean	51	37.1	31.9
Range	9–71	12–71	16–52

GPA and Barbados $t=1.449$ (non-significant); GPA and Malawi $t=0.954$ (non-significant).

¹ CASA complexity score = $2(n_1D_x) + 1(n_2D_o) + \sum_{i=1}^x (L_p)_i$, where:

n_1D_x = number of decision boxes

n_2D_o = number of all other boxes

$\sum_{i=1}^x (L_p)_i$ = the number of boxes in the pathways between the origin and re-entry of a loop, with D_x boxes weighted × 2.

maps, and 41% (60/146) of the nodes in the five comparable Malawi and Barbados guideline maps, remained the same. Structural similarity was confirmed by CASA, which scores different decision nodes and the presence of loops. As shown in Table 2, there were no significant differences between overall CASA scores for the three versions, though there was a trend for the GPA version to be more complex than either the Malawi or Barbados versions. This is primarily due to the fact that the GPA version was designed to be inclusive of a broad spectrum of socio-economic and medical resource levels, while the Malawi and Barbados versions were tailored for use within the specific socio-economic and resource levels of these countries. Thus, all differences greater than 10 for maps 3–8 indicated that the GPA version, which contained three levels within each of these maps, was more complex. Malawi, with severely limited resources and a severe AIDS problem, generally only developed algorithm maps for levels A and B (care with no laboratory support, and care with minimal laboratory support, respectively); and Barbados, which is a middle-income country with a more focal AIDS problem, generally only developed algorithm maps for levels B and C (care with minimal laboratory support, and care with tertiary laboratory and radiological facilities, respectively). Both Malawi and Barbados algorithm maps were therefore less complex than those for the GPA.

The CAPA analysis measured the extent to which any two maps function differently when used to manage patients. Of a total of 699 pathways from the two-way comparisons of the three guideline sets (GPA/Malawi, GPA/Barbados and Malawi/Barbados), 17% (118) were identical, 6% (40) were

Table 3 Combined CAPA scores comparing the nine GPA, Malawi and Barbados algorithmic treatment guidelines for HIV-infected adults (Levels A, B, and C)

Guideline	Combined CAPA scores								
	GPA–Malawi			GPA–Barbados			Malawi–Barbados		
	A	B	C	A	B	C	A	B	C
Recognition of symptomatic HIV infection ¹		0.00			0.00			0.00	
Laboratory evidence of HIV infection ¹		0.00			0.00			0.00	
Chronic diarrhoea	0.00	3.33	–	–	0.00	4.00	–	0.00	–
Oral thrush	0.00	–	–	–	–	6.92	–	–	–
Respiratory conditions	0.00	0.00	–	–	0.00	8.46	–	0.00	–
Lymphadenopathy	1.80	0.00	–	–	–	1.37	–	–	–
Headache	–	–	–	3.71	–	5.00	–	–	–
Fever	0.00	0.00	–	–	0.00	0.00	–	0.00	–
HIV-associated skin diseases ¹		–			8.00			–	
Overall score		0.47			2.88			0.00	

¹ Single algorithm map for this subject, no development of different levels.

Scores based on a scale of 0–10 (0 = completely different; 10 = completely identical); – indicates no matching algorithms for comparison.

similar, and 77% (541) were different. The calculated CAPA scores for the three inter-country comparisons, shown in Table 3, confirm that these algorithm maps function quite differently. The GPA and Barbados guidelines showed the most similarity, with an overall combined CAPA score (averaging the scores for all three guideline maps) of 2.88 (range: 0–8.46). The GPA and Malawi guidelines managed patients differently, for the most part, with an overall combined CAPA score of 0.47 (range: 0–3.33) and the Malawi and Barbados guidelines managed patients very differently, with an overall combined CAPA score of 0.

The clinical rule analysis pinpointed the reasons for the differences in patient management between the three sets of guidelines. One hundred ninety-seven specific management differences were identified. These fell into 12 categories, which were either of a disease-related, diagnostic or therapeutic nature. The breakdown of differences across the 12 categories is shown in Table 4. The Appendix contains examples of these differences from the comparisons of the GPA, Malawi and Barbados guidelines. Diagnostic and therapeutic differences accounted for 83.7% (165/197) of the differences, while differences in disease prevalence accounted for the remaining 16.3% (32/197).

In summary, the three different AIDS guideline versions are structurally similar, but differences in local conditions or resource levels result in many differences in patient management.

Implementation

Although implementation was discussed repeatedly, sometimes in detail, no systematic AIDS guidelines implementation plan was produced in any of the countries.

Discussion

An early example of clinical guideline use was published by Tuddenham [12], who used a flow chart to guide radiology technicians in interpreting the results of barium enemas. However, although flow chart diagnostic accuracy was greater than 80%, its purpose was mainly for teaching and it is not clear to what extent it was used for patient care. In 1970, Tufo described a medical guideline system for office aides [13]. In 1973, Sox *et al.* [14] demonstrated that clinical algorithms in protocol chart format could be used by untrained clinical personnel, called Medex's, to guide and monitor care for common primary care problems. These studies and another by Margolis *et al.* [15] demonstrated that algorithm-based guidelines are effective for teaching clinical management. Algorithm-based guidelines have also been proven safe and feasible, at least in the short term, for guiding care provided by nurse practitioners and other paraprofessionals [16], physicians [17], and patients [18], in a variety of settings, including primary care [14, 16–18], telephone [19], hospital [20] and home [18,21]. In all of these attempts to use clinical guidelines, either the guidelines were designed by their developers for use in a particular clinical environment, or it was assumed that in order to transfer a guideline to a new environment, it had to be tailored for use in that environment. However, the tailoring process has hardly been described.

We developed the GPA guidelines using the standard method for algorithm map guideline development recently described by the Society for Medical Decision Making [1] and recommended by the Office of the Forum for Practice Guidelines of the Agency for Health Care Policy and Research [22]. We then assumed that the same procedure used for

Table 4 Summary of meaningful differences between GPA, Malawi and Barbados algorithms for the clinical management of HIV infections in adults

Criteria	GPA– Malawi	GPA– Barbados	Barbados– Malawi	Total (%)
Disease-related differences				
Different management of condition because of local disease prevalence	10	9	3	22 (11.16)
Difference in definition of clinical condition	4	4	2	10 (5.07)
				Subtotal: 32 (16.24)
Diagnostic differences				
Difference in diagnostic criteria	6	4	6	16 (8.12)
Different diagnostic tools used	6	14	10	30 (15.22)
Diagnosis confirmed by laboratory test, not clinical findings	7	2	2	11 (5.58)
Test results evaluated differently	2	2	2	6 (3.04)
				Subtotal: 63 (31.97)
Therapeutic differences				
Difference meaningful to patient	0	10	2	12 (6.09)
Different treatment for same condition	4	5	4	13 (6.59)
Medications chosen on basis of sensitivity testing	0	2	2	4 (2.03)
Different evaluation period/criteria	6	4	4	14 (7.10)
Further instructions given regarding follow-up/on-going supervision of treatment	10	8	4	22 (11.16)
Referral to another facility/consultation with other medical personnel	7	18	12	37 (18.78)
				Subtotal: 102 (51.77)
Total	62¹	82²	53³	197 (100%)

¹Total from 11 two-way algorithm comparisons (Levels A and/or B) of seven matching treatment guidelines.

²Total from 13 two-way algorithm comparisons (Levels A, B and/or C) of nine matching treatment guidelines.

³Total from five two-way algorithm comparisons (Levels A or B) of five matching treatment guidelines.

achieving consensus during guideline development, a combination of the modified nominal group process and the Delphi process, could be used to tailor the generic GPA AIDS guidelines for use in a particular country.

Questionnaire data (see Table 1) indicate that the algorithm map format and most of the content were highly acceptable to participants in the national workshops. Local versions of the GPA AIDS guidelines were produced within a reasonable time period and were demonstrated by semantic analysis to provide clear definitions for use in the local medical environment. We do not conclude either that the local (Malawi or Barbados) adaptations of the GPA guidelines were used by clinicians, or that these adaptations are effective in the sense that they changed outcomes of AIDS management. However, production of local adaptations of the guidelines within several months indicates that consensus methods in a workshop setting can be used not only for deriving the expert version of a guideline, but also for tailoring the guideline to local conditions.

Tailoring can be achieved not only at facilities in which care can be expected to be similar, such as health centres within the same health plan, but also across national and socio-economic boundaries. Key elements determining success with national tailoring of the GPA guidelines were the broad

representation of clinical approaches in the GPA expert group and the resulting flexibility of having three levels of care defined for each branch of the GPA guidelines. Based on the experience of conducting consensus workshops (including those that do not form a part of this study), the global programme on AIDS has also developed a short manual describing how countries or institutions can carry out a local tailoring workshop [23].

How and why did the tailored versions differ from the generic GPA original? By uncovering the micro-anatomy of guideline logic, CAPA analysis clarifies the many clinical differences between the GPA, Malawi and Barbados guidelines. The general architecture of how one would go about taking care of a patient, as reflected in the major subdivisions of the guidelines and the general approach to a complication, is preserved, so long as assumptions regarding disease prevalence and socio-economic/medical resource levels remain the same. Of course if disease prevalence is different, e.g. Barbados has no malaria, then the part of the GPA original guiding this care is dropped. However, even when disease prevalence remains the same, the details of care, which are determined by socio-economic and political realities and affect the availability of diagnostic procedures and drugs, are different enough so that a clinician practising in Barbados or

Malawi might have to spend at least several days to weeks adapting a general guideline to local conditions. This type of analysis fills an important gap in our ability to compare practice from one location to another. In the future, assuming that guidelines for care are available at a particular clinical location, we should be able to use this methodology to determine what sort of differences account for practice variation between cities, neighbourhoods or even practitioners.

In contrast to guideline tailoring, guideline implementation was not addressed at the national workshops. Work at the Institute for Healthcare Improvement and at HPHC has shown that quality improvement techniques for improvement of industrial processes can be adapted for use in a clinical quality improvement program aimed at implementing clinical practice guidelines [3]. Using the Institute's designing care course [24] as a model, WHO held an international workshop for training AIDS clinician experts in both tailoring and implementing HIV guidelines.

This study should increase awareness among guideline developers and users that the use of guidelines is a complex process that only begins with guideline development. Guideline tailoring is an important step in this process, enabling a generic guideline or one developed for use at a particular site to be tailored for use elsewhere. Semantic analysis data show that tailoring may affect both the general approach to diagnosis and therapy, as well as the details of care. Tailoring can thus be seen as recalibrating clinical applicability and flexibility for a particular medical and socio-economic environment. Without this sort of modification, a guideline may not be implementable.

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Appendix

Examples of differences between GPA, Malawi and Barbados algorithms for management of symptomatic HIV infection in adults

(1) Different management of condition because of local disease prevalence

Fever

Malawi

History and physical exam
 Consider antipyretic treatment
 Maintain hydration
 Anti-malarials
 IF improved THEN follow-up as needed
 IF not improved
 Choose appropriate level (A,B,C)

Barbados

History and physical exam
 Consider antipyretic treatment
 Maintain hydration

 Choose appropriate level (A,B,C)

(3) Different diagnostic criteria

Suspected symptomatic HIV infection

GPA

IF herpes zoster and tuberculosis¹
 THEN symptomatic HIV infection

¹ Two or more characteristic findings lead to diagnosis of symptomatic HIV infection.

² One cardinal finding leads to diagnosis of symptomatic HIV infection.

Malawi

IF herpes zoster²
 THEN symptomatic HIV infection

(5) Disease confirmed by laboratory tests; not presumed from clinical findings

Lymphadenopathy/Level A

GPA

Papulosquamous skin rash and/or
 evidence of recent genital ulcer

THEN presumed syphilis

Benzathine penicillin 2.4 million IU
 i.m. single dose

Malawi

Papulosquamous skin rash and/or
 evidence of recent genital ulcer

THEN do VDRL

IF positive

THEN Syphilis

Benzathine penicillin 2.4 million IU
 i.m. single dose

(6) Different evaluation of test results

Positive initial test for HIV antibodies

GPA

Perform alternative (ELISA) test
 IF positive

THEN definite evidence of HIV infection

IF alternative (ELISA) test negative

THEN perform conventional supplementary
 testing (WB, IFA, RIPA)

IF negative

THEN no HIV antibodies present

Barbados

Perform alternative (ELISA) test

IF positive

THEN perform supplementary (innolia) test

IF positive

THEN positive test for HIV infection

IF alternative (ELISA) test negative

THEN negative test

(10) Different evaluation criteria/period

Oral thrush/Level A

GPA

IF presumed oral thrush only

THEN local application of 1% aqueous
 solution of Gentian Violet twice daily;
 or Nystatin 100000 IU oral suspension
 three times daily for 7 days

Malawi

IF presumed oral thrush only

IF severe

THEN nystatin suspension or pessaries

IF not severe

THEN local application of 1% aqueous
 solution of Gentian Violet twice daily;
 or Nystatin suspension or pessaries according
 to STG