



The Use of Essential Drugs

Model List of Essential Drugs (Seventh List)
Fifth Report of the WHO Expert Committee

This book presents and explains the seventh model list of essential drugs issued by WHO as part of its efforts to extend the benefits of modern drugs to the world's population. Intended to guide the selection of drugs in countries where the need is great and the resources are small, the list identifies a core group of prophylactic and therapeutic substances judged capable of meeting the vast majority of health needs and thus deserving priority in purchasing decisions and procurement schemes.

The first part of the report provides updated information on several components of national drug policy necessary to assure that essential drugs, corresponding to essential health needs, are available at all times in adequate amounts and in the proper dosage. Apart from advice on the selection of drugs and dosage forms and the procedures required for quality control, the report draws attention to the urgent need for better laboratory monitoring of antimicrobial sensitivity, and to the importance of post-registration studies to detect adverse drug effects and assess other indicators of drug performance. New sections discuss drug nomenclature, including the problems that arise when trade marks are derived from International Nonproprietary Names, and offer advice on the principles that should be followed when procuring or donating drugs for use in displaced communities, emphasizing the need to align essential drugs with the disease patterns commonly seen in almost every refugee settlement site.

The seventh WHO model list of essential drugs is then presented, together with an explanation

of changes made when revising the list. Organized according to therapeutic group, the list includes information on route of administration, dosage forms, and strengths, for each of 286 essential drugs. To qualify for inclusions in the list, a drug must be supported by sound and adequate data demonstrating safety, efficacy, and consistent performance in a variety of medical settings. Factors of cost, stability, quality control, and international availability were also considered. Revisions in the list, which were agreed upon by an international group of experts, reflect the availability of new drugs, new information on established drugs, and practical experiences in their use. For the first time, the list includes a selection of essential drugs needed for the palliative care of cancer patients.

A final section presents guiding principles intended to help small national drug regulatory authorities develop a system of legislative and administrative procedures that can assure quality, efficacy and safety, even when resources are limited. The report concludes with a model application form for use when requesting that a drug be included in the list.

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Structured observations of hygiene behaviours in Burkina Faso: validity, variability, and utility

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The use of observation techniques has been promoted for the study of hygiene practices; however, questions still remain about the validity and repeatability of such techniques. In this article we compare data on hygiene behaviours obtained from questionnaires with data obtained using a structured-observation approach and examine the repeatability of structured observations of behaviours and spot observations of environmental conditions.

Poor agreement between questionnaire responses and observations was found for child defecation and stool disposal practices (κ statistic: 0.25 and 0.28, respectively). There was evidence of over-reporting of "good" behaviours ($P < 0.0001$). Repeated observations of child defecation and stool disposal behaviours showed better agreement (κ statistic: 0.76 and 0.62, respectively) based on small sample sizes. These findings suggest that our questionnaire data are less valid than data obtained by direct observation. However, different approaches to questioning may be less prone to over-reporting of "good" behaviours than our approach. Further research into the validity of different forms of question is warranted.

Behaviours and conditions related to hygiene vary. Observations may be useful in determining the frequency of different behaviours/conditions in the community. However, individual practices may be too variable to assign individuals to exposed and non-exposed groups for the purpose of identifying links with health outcomes. Further studies on the variability of behaviours and the repeatability of observations are therefore needed.

Introduction

In a review of studies of the health impact of water supply and sanitation programmes in developing countries, Cairncross concluded that health benefits stem from changes in hygiene behaviour and that the measurement of such behavioural changes is likely to be easier and more reliable than the direct measurement of health benefits (1). It was, however, acknowledged that methods for the measurement of behavioural changes need to be developed.

The traditional household questionnaire, used alone, is limited in its efficacy, scope, and accuracy

(2, 3). Structured observation of behaviour has been used by psychologists (4), animal behaviouralists (5), economists, and anthropologists (6, 7), particularly over the last two decades. This type of observation is now increasingly being used also in investigations of associations between behaviour and health. For example, to measure water contact behaviour in investigations into schistosomiasis and wastewater use (8, 9); to describe water utilization practices (10-12); to describe child feeding (13); and to investigate associations between hygiene practices and diarrhoea (14, 15).

A number of questions remain, however, about the validity and repeatability of the structured observation approach. Stanton et al. have compared knowledge-attitude-practice questionnaires and 24-hour recall questionnaires with structured observations and found that the responses to questionnaires did not correlate with observed household practices (16). They concluded that such questionnaires should not be used as surrogates for direct observation of hygiene practices. This conclusion was, however, based on a single observation of each household and no data on the repeatability of the observations were presented. Therefore it is not clear whether the concordance between observations conducted on separate occasions would have been greater than the concordance between questionnaires and observations.

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We have carried out a study of childhood diarrhoea in Bobo-Dioulasso, Burkina Faso, which included the administration of a questionnaire on, and direct observation of, hygiene practices and environmental conditions related to hygiene. About 10% of observations were repeated and a small group of households were observed on six separate occasions. In this article we present our findings on the concordance between responses to questionnaires and direct observations of behaviour, repeated observations of environmental conditions related to hygiene, and repeated observations of hygiene practices.

Methods

A case-control study recruited all children aged ≤ 36 months from the town of Bobo-Dioulasso, Burkina Faso, who had been admitted to Sanou Sourou Hospital between 15 January 1990 and 31 March 1991. Following their discharge from hospital, the children were visited at home and each was matched with a neighbourhood control who was selected using a pre-determined set of rules. Five female fieldworkers conducted detailed interviews with the mothers of both cases and controls and observed environmental conditions in and around the house courtyards. Questions on hygiene behaviours included "Where does your child usually defecate?" and "How do you usually dispose of the stools?". Possible responses were precoded. For example, in answering the question about where the child defecated, the fieldworker could choose between "in a pot", "on the ground in the yard", "outside the yard", "in a loincloth or pants", and "other". After the interview and before leaving, the fieldworker made spot observations of various environmental conditions in and around the courtyard, including whether or not human faecal material was visible in the courtyard. Once the interviews with the case-control pairs had been completed, the questionnaires were returned to the project office. Children who had been admitted to the hospital with symptoms of diarrhoea or of acute respiratory disease were revisited for direct observation, together with their neighbourhood controls. The median interval between the interview and observation visits was 25 days (range, 2-100 days).

The three female observers were directed to households and were instructed to visit them on the evening prior to the observation in order to advise the mother that they would be returning early the next morning; surprise visits were judged to be inappropriate in this cultural setting. Mothers were told that the purpose of the visit was to follow up the health of the child and the work of the mother. The next day the observer presented herself at about

06 h 00 and continued observations until 08 h 30 to 09 h 00, or until the mother left for the market. On arrival, the observer followed the normal rules of polite behaviour, greeting other members of the family, and was generally offered a seat in the courtyard. She again explained why she had come and asked the mother or carer of the child to carry on as normal and to take no account of the observer's presence.

The range of possible behaviours was defined during a preliminary study to produce a precoded data collection form. For example, there were six numbered options to indicate where the index child's stools were thrown: "in the latrine"; "buried in the yard"; "thrown in the yard"; "thrown outside the yard"; "not thrown away during visit/child not seen to defecate"; and "other". The observer circled the number corresponding to the appropriate response as each behaviour was observed. If a behaviour was observed several times, only the first occasion was recorded. If the child was seen to defecate, the following were recorded in a similar manner: the site, the disposal, how the child was cleaned afterwards, and how and if the mother cleaned her hands after removing the stools. Most domestic activity such as washing, food preparation, and child care was carried out in the courtyard, which made observation of most behaviours relatively easy. Before leaving the courtyard, spot observations similar to those performed at the interview were made. The observers were residents of Bobo-Dioulasso who spoke the local languages and dressed in the local manner. In view of the repetitive nature of the work, women were chosen who had been educated only to primary-school level, and who had already demonstrated their patience by working as unpaid volunteers in the hospital.

Each observer received supervisory visits once a week. One in ten observations was repeated; exactly the same observation schedule was completed by the same observer after a delay of 4-60 days (average, 22 days). The observer did not have access to the first completed schedule when filling in the second. In addition, 10 households were observed on six separate occasions to examine the repeatability of the observations in greater detail.

The degree of agreement between the questionnaire responses and direct observation and between repeated observations was assessed using the unweighted kappa (κ) statistic (17). This takes into account the number of observations expected to be in accord if agreement is random, and is given by the formula:

$$\kappa = (P(A) - P(E)) / (1 - P(E))$$

where $P(A)$ is the proportion of occasions on which agreement occurs and $P(E)$ is the proportion of occasions on which agreement would be expected to occur by chance alone.

Perfect agreement between observations arises when $\kappa = 1$, while $\kappa = 0$ indicates that the agreement is no better than that which would arise by chance. By convention, values for κ in the range 0.01-0.39 are taken to indicate poor agreement, those in the range 0.40-0.75 good agreement, and those >0.76 excellent agreement.

The data were also analysed using χ^2 tests for general associations and trends and also McNemar's test.

Results

A total of 2775 home interviews, were performed with the mothers of hospitalized children and with those of neighbourhood controls (follow-up rate, 70% for the hospitalized children). In addition, 548 of the households were visited for the purpose of direct observation. The follow-up rate for all children who fulfilled the selection criteria for observation was 61%. Of the observation households, 57 (10%) were revisited for a repeat observation, and 10 households were observed on six separate occasions.

Comparison of questionnaire and observation data

Table 1 summarizes the distribution of questionnaire responses to selected questions and of observations about environmental conditions for all the households visited. Shown also are the corresponding data from the 549 initial observations. A high proportion of mothers interviewed (75%) reported that their child defecated in a pot, while 66% of the 277 children, when they were observed, actually did so. Similarly, a high proportion of mothers (67%) reported disposing of their child's stools in the latrine, while rather fewer (56%) were actually observed to do so. The majority of mothers (78%) reported purging their child (30% every day and 48% from time to time); however, during the 2.5-hour period of observation, only 11% of mothers were actually observed purging their children. Human faeces were observed relatively rarely in the courtyard or on the slab of the latrine.

A paired analysis of the mother's response to the question "Where does your child defecate?" and direct observation of the child's behaviour in the same household is shown in Table 2. Of the children observed, 277 (51%) were seen defecating, 271 were not seen defecating. There was no evidence that those seen defecating differed from those not seen

Table 1: Distribution of responses to questions about hygiene practices and observations of environmental conditions and of hygiene behaviours

	No. of households	
	Questionnaire (n=2775)	Observation (n=548)
<i>Behaviours: questionnaire versus observation</i>		
<i>Where did the child defecate?*</i>		
Pot	2058 (75) [†]	183 (56)
On the ground	183 (7)	22 (8)
In a loincloth or pants	415 (15)	61 (22)
Outside the yard	98 (4)	3 (1)
Other	4 (0)	8 (3)
<i>Where did the mother dispose of the child's stools?*</i>		
In the latrine	1855 (67)	154 (56)
Buried in the yard	11 (0)	2 (1)
Thrown away in yard	186 (7)	25 (9)
Thrown outside yard	716 (26)	44 (16)
Other	0 (0)	7 (2)
Not disposed of		45 (16)
<i>Does the mother purge the child?*</i>		
Yes	2151 (78)	61 (11)
No	616 (22)	487 (89)
<i>Does the child eat earth?*</i>		
Yes	737 (27)	42 (8)
No	2028 (73)	501 (92)
<i>Environmental conditions: questionnaire versus spot observation</i>		
<i>Were faeces present on the latrine slab?*</i>		
Yes	333 (14)	95 (19)
No	2128 (86)	404 (81)
<i>Were faeces present in the yard?*</i>		
No	337 (12)	148 (27)
Yes, animal only	2057 (74)	344 (63)
Yes, human only	27 (1)	11 (2)
Yes, animal - human	346 (13)	44 (8)
<i>Was stagnant water visible in the yard?*</i>		
Yes	910 (33)	225 (41)
No	1856 (67)	323 (59)

* Figures in parentheses are percentages.

† The denominator for these behaviours is 277, since 271 children were not observed to defecate.

defecating in terms of their mother's response to the questionnaire ($P > 0.5$). Among the 277 children for whom a comparison was possible, there was agreement between the questionnaire reply and the observation results for 187 (68%); $\kappa = 0.25$ (95% confidence interval (CI): 0.14, 0.35), i.e., agreement between the questionnaire and the observation was poor.

Table 3 shows a paired comparison of the mother's response to the question "Where do you dispose of the child's stools" with the direct observation of her behaviour. Again, there was no evidence that those children seen defecating differed from those not seen defecating in terms of the mother's response to the question ($P > 0.40$). Among the 277 children who were seen defecating, the mother's action was in accord with her response to the questionnaire for 161 (58%). Exclusion of those mothers who did not dispose of the stools during the observation period increased the proportion of agreements to 69%. If the mothers of children not seen to defecate and those recorded in the category "other" are excluded and the categories "thrown away in the yard", "buried in the yard" and "not disposed of" are grouped into a single category "in the yard", the resulting κ statistic is 0.28 (95% CI: 0.19, 0.36); if

mothers who did not dispose of the stools during the course of the observation are excluded κ increases to 0.38 (95% CI: 0.27, 0.48).

For the data in Tables 2 and 3 there was strong evidence that in the event of a disagreement between the questionnaire response and the behaviour observed, the discrepancy was more likely to arise through the reporting of a "good" behaviour (i.e., defecation in a pot, stools thrown in the latrine) and the observation of some other behaviour, rather than vice versa ($P < 0.0001$, McNemar's test).

The apparent levels of agreement between the questionnaire and observation for the questions "Does the child eat earth?" and "Do you purge the child?" were poor ($\kappa = 0.16$ and 0.04 , respectively). In interpreting these results, however, it should be recalled that the child was observed for only 2.5 hours; many of the children not observed eating earth, for example, may nevertheless have been regular earth eaters. Some support for the accuracy of the mother's responses to these questions may be drawn from the observation that 17% of children reported to eat earth were observed doing so, compared with 4% of those reported not to do so ($P < 0.001$). Similarly, of those mothers who stated that they never purged their child, only 1 (1%) was observed doing

so. of those who stated that they sometimes purged their child, 5% were observed doing so; and of those who said they purged their child every day, 27% were observed doing so (χ^2 test = 51.9, $P < 0.0001$).

The levels of agreement between the observations of environmental conditions at the time of the interview and that at the time of observation were generally poor (Table 4). The presence of excreta on the slab of the latrine appeared to be relatively rare, and the repeatability of this observation was little better than might be expected to occur by chance. Conversely, the presence of faecal matter (usually animal) in the yard was relatively common, but again the repeatability was poor. The presence or absence of stagnant water in the courtyard was more consistent than the presence or absence of excreta.

Comparison of two consecutive observations

Table 5 summarizes the comparisons of consecutive observations of behaviours related to hygiene, ranked in order of decreasing κ statistics. Because not all behaviours were observed at all visits, the effective sample size for each behaviour varies. For some of the behaviours the sample size was very small, and thus the results should be interpreted with caution. The place where the child defecated, how the stools were disposed of, and whether or not the child ate earth, all had higher κ statistics than for the comparison between the questionnaire and observation data. Observations of other behaviours showed moderate-to-good repeatability, except for the mother's action after going to the latrine, for which the agreement was no better than chance. This finding is, however, based on a very small sample size. In addition, the observer could not record whether the mother went to the latrine to defecate or urinate, and part of the variability in the mother's behaviour may have arisen because of this.

The inter-observation agreement for various environmental conditions, recorded at successive observation visits, was generally poor; whether the yard had been swept, whether meal plates had been washed, how food was covered, and how drinking-water was stored each had κ statistics < 0.4 , indicating poor repeatability. Better agreement was obtained between two observations of whether and how the latrine hole was covered (κ statistic = 0.59; 95% CI: 0.39, 0.80).

Comparison of six consecutive observations

In 10 households the observation schedule was repeated on six separate occasions. Three children behaved consistently, using a pot only on at least four occasions. Four children were not observed defecating more than once, and thus contributed no information about behaviour variability. The behaviour of the remaining three children varied: two used a pot on early visits but defecated on the ground at later visits. Such a pattern is consistent with the concept of "reactivity": at first the mother makes an effort to appear hygienic in front of the observer but as she becomes used to the observer's presence she reverts to her normal behaviour.

The manner in which the mother disposed of the child's stools was fairly consistent. For only one mother were two different methods of stool disposal observed. Four mothers consistently threw stools in the latrine, while the stool disposal practices of the remaining mothers were observed at most once.

Analysis of the results for these 10 households revealed a pattern of repeatability consistent with that suggested by a comparison of two observations. The presence of stools on the latrine slab was rare and occurred at random. For four of the households faeces were never observed on the latrine slab, while for another four the faeces were observed on only

Table 2: "Where does the child usually defecate?" Comparison of the questionnaire responses with direct observation of the same households

Questionnaire	Observation					Total
	Outside yard	Loincloth/pants	Pot	In yard	Other	
Outside yard	2	0	1	1	0	7
Loincloth or pants	0	19	14	1	3	44
Pot	1	39	163	17	5	208
In yard	0	3	5	3	0	12
Other	0	0	0	0	0	0
Total	3	61	183	22	8	271

Table 3: "Where does the mother usually dispose of the child's stools?" Comparison of questionnaire responses with direct observation of the same household

Questionnaire	Observation							Total
	In yard	Buried	Outside yard	In latrine	Other	Not disposed	Not seen	
In yard	1	1	4	5	0	3	21	35
Buried	0	0	0	0	0	0	0	0
Outside yard	8	0	26	15	4	13	60	126
In latrine	16	1	14	134	3	29	190	387
Total	25	2	44	154	7	45	271	548

Table 4: Comparison of spot observations of environmental conditions recorded at the time of the questionnaire interview and at the time of the observation

Questionnaire	Observation					
	Excreta on the slab of the latrine		Excreta visible in the yard		Stagnant water in the yard	
	Yes	No	Yes	No	Yes	No
Yes	15	41	380	120	143	60
No	78	351	17	27	82	263
κ statistic	0.07 (-0.03, 0.16) ^a		0.18 (0.10, 0.26)		0.46 (0.38, 0.53)	

^a Figures in parentheses are the 95% confidence intervals.

Table 5: Repeatability of observations of behaviours performed on two separate occasions

Behaviour	% incidence of behaviour at first observation (n = 549)	Effective sample size	κ statistic
Where child defecates			
Pot	33	16	0.76 (0.48, 1.05)*
On ground	4		
Loincloth/pants	11		
Outside yard	1		
Other	2		
Child eats earth			
Yes	8	55	0.73 (0.38, 1.08)
No	92		
How child's stools are disposed of			
Latrine	28	16	0.62 (0.28, 0.96)
In yard	5		
Outside yard	8		
Other	1		
Not disposed of	8		
Child given infusions			
Yes	12	55	0.56 (0.20, 0.94)
No	88		
Child bathed			
No	46	55	0.48 (0.30, 0.68)
Water	6		
Soap	35		
Infusion	14		
Hands washed before food handling			
Not washed	32	18	0.45 (-0.01, 0.91)
With water	13		
With soap	2		
Child purged			
Yes	11	57	0.44 (0.07, 0.82)
No	89		
How mother cleans her hands after cleaning child			
Nothing	17	17	0.33 (-0.11, 0.78)
Rinsed fingers	25		
Washed water	2		
Washed soap	4		
Wiped	1		

(continued on next column)

(Table 5, continued)

How child is cleaned after defecating			
Nothing	2	16	0.33 (-0.07, 0.74)
Water only	37		
Soap	4		
Wiped	8		
Mother washes hands after latrine			
Not washed	21	11	-0.03 (-0.46, 0.40)
With water	18		

* Figures in parentheses are 95% confidence intervals.

one of the six visits. In one household, faeces were observed on the latrine slab twice, while in the remaining household they were observed three times. The presence of faecal material in courtyards was much more common: for six households such material was observed every visit; for two households, on five of six visits; and for two households on only one visit. The presence of stagnant water in the courtyards did not vary at all over six visits: for three households stagnant water was always observed, while for the other seven it was never observed.

Inter-observer variation

Inter-observer variation was difficult to assess since the allocation of observers to households was not random but was based largely on the geographical location of the households. Thus, differences between observers could have arisen because of socio-economic and cultural variations between different areas of the town. Comparison of the initial observations made by each of the three observers indicated that there were no differences for reports about the child's defecation site ($P > 0.10$) and child purging ($P > 0.40$). For earth eating the differences approached statistical significance ($P = 0.06$), with one observer (A) reporting about twice as often as the other observers (B and C) that children ate earth. Observer B saw the mother disposing of the child's stools in the latrine or outside the courtyard more often than observers A or C, and in the courtyard less often than A or C ($P < 0.01$). Observer A reported excreta on the latrine slab more often than observers B or C ($P < 0.001$), while observers A and C reported excreta in the courtyard and stagnant water in the yard more often than observer B ($P < 0.0001$ in both cases).

Discussion

Health researchers may be interested in studying behaviours for several reasons. They may wish to understand and describe what occurs within a particular community, and why; also they may wish to understand the links between these behaviours and health, and to plot changes in behaviours over time. Among the techniques available for this purpose are the following: participant observation, focus group discussions, key informant interviews, structured interviews of a sample of the population, and structured observations of a sample of the population. Each technique can contribute to an understanding of behaviour but all have shortcomings in identifying and quantifying what occurs in practice. Two areas of difficulty can be identified: the validity of the method of measurement and the variability of the behaviour itself.

Problems of validity arise when study techniques do not represent accurately actual behaviours. This is particularly likely when the behaviour being investigated is socially sensitive, e.g., sexual behaviour. Some techniques may reflect more accurately than others what actually happens; for example, in a study of sexual habits in the Gambia, Pickering concluded that structured interviews with prostitutes produced less valid data than those obtained from key informant interviews (18). Although the social sensitivity of different behaviours varies from society to society, in most cultures defecation behaviour is probably less socially sensitive than sexual behaviour. Women in Burkina Faso appear, in general, to be less reticent about revealing personal habits than women in some Asian societies, although certain ethnic groups in West Africa, such as the Peulh and the Dogon, have particular social codes that forbid any reference to defecation.

Agreement between the questionnaire responses and observations on child defecation and stool disposal practices were relatively poor when chance agreement was taken into account ($\kappa = 0.25$ and 0.28 , respectively). A higher proportion of mothers than were actually observed to do so reported that their child used a pot and that they then disposed of the faeces in the latrine. This suggests a tendency to over-report those practices that were perceived to be "good", although some of the disagreement could have arisen if the defecation and stool disposal practices changed according to the time of the day or because of the long interval between the two observation visits. In Bangladesh, Stanton et al. also found evidence of over-reporting of "good" hygiene practices on questionnaires compared with the distribution of observed practices (16).

A higher degree of concordance was found between repeated observations of child defecation and stool disposal behaviours than between the questionnaire response and the initial observation. For the site where the child defecated, the confidence intervals around the κ statistics did not overlap ((95% CI: 0.14, 0.35) for the questionnaire versus observation results and (95% CI: 0.48, 1.05) for the observation versus observation results). However, because this behaviour was not observed at every visit, the sample size for the comparison of the two observations was very small and the κ statistic is therefore highly sensitive to changes in one or two observations. For the method of stool disposal, the two observations showed a greater degree of concordance than the questionnaire results and the initial observation but here the confidence intervals around the κ statistics did overlap ((95% CI: 0.19, 0.36) for the questionnaire versus observation results and (95% CI: 0.28, 0.96) for the observation versus observation results). These findings together with the suggestion of over-reporting of "good" practices on the questionnaire are consistent with the hypothesis that the questionnaire responses were less valid than the data obtained by direct observation. It should be noted, however, that our questionnaire asked the mother what "usually" happened when the child defecated. Other forms of question, e.g., "What happened the last time the child defecated?", might have produced more valid responses than the form of question we used.

In addition to the problem of validity, the variability of behaviours (and of the environmental conditions derived from those behaviours) causes difficulties in investigations designed to identify associations between behaviours and health. The use of a single observation to identify behaviours or conditions that are risk factors for a poor health outcome assumes that the behaviour is largely habitual (or the condition is largely constant). Thus, if there are two groups of mothers, one of which always throws the child's stools in the latrine, while the other throws them in a corner of the courtyard, a single observation can discriminate between them and a study relying on a single observation (or a good questionnaire) will be able to detect whether one of these behaviours carries a higher risk than the other. If, instead, mothers cannot be divided into two distinct groups, but behave in a similar fashion, sometimes throwing stools in the latrine and sometimes in the corner of the courtyard, a study relying on a single observation will have little power to detect a risk behaviour and may seriously underestimate the magnitude of the risk associated with that behaviour. Questionnaire responses can vary considerably according to the precise form of the question.

Our findings suggest that hygiene behaviours and environmental conditions in Burkina Faso lie somewhere between the two extremes outlined above. There appears to be some consistency in most of the observed behaviours and conditions but it is clearly not absolute, and the degree of consistency may vary substantially from behaviour to behaviour and from condition to condition.

The potential effect of this variability is considerable. For example, consider 2000 courtyards which can be divided into "clean" and "dirty" groups (1000 each). Suppose that in the 1000 "clean" courtyards faecal matter is only rarely present (and observed) on 20% of days and that in the 1000 "dirty" courtyards faecal matter is commonly present on 80% of days. If all the courtyards are visited on two separate occasions and we record whether faecal material is present, the expected value of the κ statistic for the two observations would be 0.36^a—higher than the value we obtained in our study.

Now suppose that on days when there is no faecal material in the courtyard a child has a 2% risk of developing diarrhoea, and on days when there is faecal material the risk is 6%, i.e., the presence of faecal material is associated with a risk ratio of 3.0. On any given day we then expect 28 children from clean households ((1000 × 0.8 × 0.02) + (1000 × 0.2 × 0.06)) and 52 children from dirty households ((1000 × 0.2 × 0.02) + (1000 × 0.8 × 0.06)) to develop diarrhoea. If these 80 children are observed on another day, we would expect to classify 47.2 ((28 × 0.2) + (52 × 0.8)) as living in dirty courtyards and 32.8 as living in clean courtyards. Thus the expectation of the risk ratio estimated from a study based on a single observation on any day other than that on which transmission occurred is 1.22 (47.2/32.8), which is substantially less than the true risk ratio (3.0). Hence, even a slight degree of variability in the behaviour/condition being measured can result in a serious bias towards unity in the estimate of the risk ratio.

Methods for the measurement of behaviour are a subject for much debate among epidemiologists and public health specialists who are attempting to improve health promotion activities. Structured observations have been promoted as one of the tools that seem best adapted to the measurement of hygiene behaviours. Some questions, however, remain to be answered. First, can hygiene behaviours be measured and summarized in a useful way? If so, can structur-

ed observations perform this task? If structured observations can perform this task, are they the best way of doing so?

The results of our study provide tentative answers to some of these questions. Behaviours and conditions related to hygiene in Bobo-Dioulasso vary, both within and between individuals, and the within-individual variability may be substantial. In such circumstances, measurement of these behaviours and conditions may be useful for certain purposes, but not others. For example, measurement may be useful to determine the incidence/prevalence of different behaviours/conditions in the community. Investigations designed to monitor changes in hygiene behaviours, perhaps by means of an education programme, could then use a series of cross-sectional studies to do so. Individual hygiene practices may, however, be too variable to assign individuals to exposed and non-exposed groups for identifying links with health outcomes. Further studies on the variability of behaviours and on the repeatability of structured observations, with larger sample sizes and in other settings, are needed before any firm conclusions can be drawn.

Our findings are consistent with, but do not prove, the hypothesis that, in Burkina Faso, data collected through direct observation of hygiene-related behaviours have greater validity than those obtained through questionnaire interviews, which may tend to overestimate the frequency of good practices. Studies whose aims is to describe the range and relative frequencies of different hygiene-related behaviours in Burkina Faso should perhaps then be based on direct observation rather than on questionnaire interviews. Structured observations are, however, expensive. In our study, 549 households were observed for a total of about 1400 hours and data were gathered on child defecation behaviours on 277 occasions. Thus, approximately 5 hours were required to observe each event. Our questionnaire related to what "usually" happened. A different approach to questioning, e.g., "What did you do the last time...", may be less prone to over-reporting of good behaviours. Further research into the validity of different forms of question is warranted.

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Resume

Observation structurée des habitudes d'hygiène au Burkina Faso: validité, variabilité et utilité

On a déjà souligné l'intérêt des observations structurées comme moyen d'étude des habitudes d'hygiène. Toutefois, la validité et la reproductibilité de ces observations soulèvent encore des questions, tout comme la variabilité des habitudes d'hygiène elles-mêmes. Dans le présent article, nous avons comparé les données obtenues à l'aide de questionnaires à celles recueillies par la méthode des observations structurées; nous avons également examiné la reproductibilité de ces observations et d'observations ponctuelles portant sur l'environnement domestique.

Au total, 2775 mères d'enfants âgés de 36 mois ou moins ont été interrogées à Bobo-Dioulasso, au Burkina Faso. Lors de l'entrevue, des questions ont été posées à la mère sur les habitudes de défécation de son enfant et sur la façon dont elle se débarrassait des excréments. A la fin de l'entrevue, les conditions régnant dans la cour de la maison ont été observées. En outre, des observations structurées portant sur les habitudes d'hygiène ont été faites en début de matinée dans 549 de ces maisons où l'état des lieux a également été noté une nouvelle fois. Enfin, 57 maisons ont fait l'objet d'observations structurées répétées.

La concordance entre les réponses au questionnaire et l'observation des habitudes de défécation des enfants et d'élimination des excréments par la mère est relativement mauvaise si l'on tient compte des coïncidences dues au hasard (indice κ : 0.25 et 0.28 respectivement). Le nombre de "bonnes" réponses était manifestement trop élevé ($P < 0.0001$), beaucoup de mères déclarant que leur enfant utilisait un pot et qu'elles jetaient les excréments dans une latrine, alors que l'observation a montré que ce n'était pas le cas. L'accord a été meilleur entre les observations successives portant sur les habitudes de défécation des enfants et l'élimination des excréments par la

mère (κ : 0.76 et 0.62 respectivement), mais ces comparaisons ont porté sur de petits échantillons. Ces résultats sont compatibles avec l'hypothèse selon laquelle les réponses aux questionnaires sont moins fiables que les données obtenues par observation directe, mais sans en apporter la preuve. S'il en est bien ainsi, il est peut-être préférable que les études destinées à décrire l'éventail et la fréquence des différents comportements liés à l'hygiène au Burkina Faso fassent appel à l'observation directe plutôt qu'à des questionnaires. Toutefois, il est possible de poser les questions de façon différente (par exemple: "Qu'avez-vous fait la dernière fois où...?") et d'éviter ainsi un nombre excessif de bonnes réponses. Il serait bon de poursuivre les recherches sur la validité des différentes façons de formuler les questions.

Cette étude met en relief la variabilité, parfois importante, de la plupart des pratiques et des conditions d'hygiène à Bobo-Dioulasso. L'observation peut être utile pour déterminer l'incidence ou la prévalence de différents comportements ou de différentes conditions, par exemple dans le cadre d'une série d'études transversales sur les changements de comportement d'une communauté. Toutefois, les pratiques d'hygiène personnelle sont peut-être trop variables pour que l'on puisse répartir les individus entre groupes exposés et non exposés en vue d'établir des liens entre ces comportements et leurs conséquences sur la santé. D'autres études devront être entreprises dans ce domaine.

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^a The number of courtyards expected to be observed clean on both occasions = (1000 × 0.8 × 0.8) + (1000 × 0.2 × 0.2) = 580. The entries for the other cells of the 2 × 2 table are calculated similarly.

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A vaccination survey using the EPI methodology to evaluate the impact of a child health outreach programme in an urban area of South Africa

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A community-based survey of the vaccination status of children aged 12-23 months was conducted to evaluate the impact of a child health outreach programme on vaccination coverage in Alexandra township, South Africa. The EPI cluster sampling technique was adapted for this purpose. The sample size, including the number of clusters and the number of units per cluster, was increased to permit stratification of the data and comparison of the results with those obtained in a study conducted prior to the introduction of the outreach services in 1988.

At the time of the survey interview, 67% of the children were fully vaccinated (78% against measles) and by 1 year of age, 58% were fully vaccinated (69% against measles). The increase in coverage since the introduction of the programme was statistically significant only for measles (Student's t-test, $P < 0.01$). A total of 75% of children living in formal dwellings, compared with 51% living in informal dwellings, were fully vaccinated by interview (Fisher's exact test, two tailed, $P < 0.0001$). Mothers from informal dwellings had a 1.88 times greater chance of not knowing about the outreach services ($P < 0.001$). Children whose mothers knew where vaccinations were given, attended postnatal clinics, used the outreach services, possessed a road-to-health card from the Alexandra Health Centre, and who resided in a formal dwelling all had a higher chance of being vaccinated.

Introduction

Alexandra township is situated 15 km from the centre of Johannesburg. Estimates of its current population range from 150 000 to 250 000, a three-fold increase since the census of 1985 (1). Approximately 33% of the population live in informal dwellings or shelters, 15% in new developments, 8% in three large single-sex hostels, and the remainder in old houses. The already poor socioeconomic conditions have been aggravated by rapid urbanization and its associated problems, unemployment, and the 3-year state-of-emergency in South Africa.⁴ Inadequa-

tely maintained sewage, sporadic refuse removal, the absence of storm-water drainage, and overcrowding in the township are predisposing factors for infectious disease and concomitant poor nutritional status.

Most of the health services for the community are provided by Alexandra Health Centre and University Clinic (AHC), a privately funded facility. In its efforts to provide comprehensive health care to all the people, AHC is attempting to create a model for health care for the urban poor (2). Curative services, including 24-hour emergency and maternity services, and preventive and promotive services are provided. An outreach service is also operated by AHC. A total of 17 general practitioners provide primarily curative care, a number of traditional healers are active in the area, and a state clinic provides services to deal with tuberculosis, chronic psychiatric problems, and some vaccinations.

Vaccination is provided by both AHC and the state health clinic according to the following schedule: BCG and monovalent oral poliovirus vaccine at birth, diphtheria-pertussis-tetanus (DPT) and oral trivalent poliovirus vaccine 1, 2, and 3 at 3, 4 1/2 and 6 months of age, respectively; and measles vaccine at 9 months of age. Administration of monovalent

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