



WHO Expert Committee on Specifications for Pharmaceutical Preparations
Thirty-second Report

This report issues five sets of detailed guidelines intended to assist drug regulatory authorities in implementing a rigorous, comprehensive system for the quality control of pharmaceutical products.

The first and most extensive set of guidelines presents updated requirements for good manufacturing practices in pharmaceutical production. The requirements, which are presented in three main parts, have been considerably revised and expanded from the 1975 version to reflect advances in pharmaceutical manufacturing technology.

The second guidelines provide a step-by-step description of the procedures to be followed during the inspection of pharmaceutical manufacturing facilities in order to ascertain adherence to good manufacturing practices. Details range from advice on the frequency and duration of inspections, through basic rules for conducting an inspection, to an outline of the form and content of the inspector's report.

The third guidelines cover implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, which has also been revised and considerably strengthened. To make the certification proce-

dures better suited to rigorous control, particularly in view of the increasingly numerous reports of substandard and counterfeit drugs found on the market in developing countries, three different forms of attestation are proposed. These are a product certificate issued by the competent authority in the exporting country; a statement of licensing status, also issued by the competent authority in the exporting country; and a batch certificate, which is usually issued by the manufacturer. Models for each of these forms are also included.

Additional guidelines cover the quality of pharmaceutical and biological products prepared by recombinant DNA technology, and the validation of analytical procedures used in the examination of pharmaceutical products to ensure safety and efficacy at all stages of shelf-life, including storage, distribution and use. The remaining sections provide updated lists of available international chemical reference substances and of adopted international infrared reference spectra, and outline a protocol for a study on the quality of selected drugs at the point of use in developing countries.

The report also contains brief, updated information on several other elements of quality assurance. These include, within the development of drug quality assurance, a planned survey on products of questionable stability, priorities for the training of regulators, and arrangements for independent analysis of drug samples.

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Health, safe water and sanitation: a cross-sectional health production function for Central Java, Indonesia

D. Wibowo¹ & C. Tisdell²
PROXY
INTERNATIONAL REFERENCE CENTRE
COMMUNITY WATER SUPPLY AND
SANITATION (IRC)

The study describes the development of health production functions and their application in the evaluation of the health impacts of investments in safe water and sanitation. For this purpose, data on the morbidity of waterborne diseases and diarrhoea were collected from medical records in the province of Central Java, Indonesia. A reciprocal production function was found to fit the data best. The health production functions exhibit constant return to scale, i.e., a simultaneous m-fold increase in both safe water and sanitation coverage produces a 1-1/m decrease in morbidity. Safe water was found to be more important for health than the sanitary disposal of excreta.

Introduction

Although safe water supply and sanitation (WSS) have long been accepted as basic necessities for healthy living, measuring the health benefits that result from their availability remains controversial. Some studies indicate that improved WSS facilities are not efficacious in improving health status and not particularly cost-effective (1). In contrast, a review of 67 studies from 28 countries found that WSS investments can reduce diarrhoea morbidity and mortality rates by a median of 22% and 21%, respectively (2). Most of the studies reviewed, however, appear to have serious methodological deficiencies, e.g., inadequate health indicators and failure to control for confounding variables (3). These controversies, along with the introduction of selective primary health care (SPHC) (4), have placed greater emphasis on the use of oral rehydration therapy (ORT). WSS policies and ORT should nevertheless both be adopted, since the benefits of WSS extend far beyond its role in improving health status (4).

The health benefits resulting from investment in WSS have been measured by a number of case-control studies since the end of the 1980s. Such studies have been carried out in Malawi (5), the Philippines (6) and Lesotho (7), where it was reported

that WSS investments can produce a 20%, 20%, and 24% reduction, respectively, in the incidence of diarrhoea.

Despite these findings, doubts remain about the benefits of WSS since the 95% confidence intervals (CI) of both the crude and adjusted odds ratios in the studies in Malawi and the Philippines included the value for the null hypothesis. The 95% CI of the adjusted odds ratio in the Lesotho study also included the null hypothesis value. In other words, at the 95% CI the WSS investments may not be efficacious in reducing diarrhoea incidence.

We describe here an alternative approach to measuring the effects of WSS on health, using a production function. Such functions have been used in agriculture and industry for some time (8, 9). Specification of the production function permits analysis of how health inputs interact to produce a particular level of health status. The importance of specifying health production functions is underlined if a cost-benefit analysis of WSS investments is carried out: failure to specify production functions is a serious methodological flaw in most health care cost-benefit analyses (10).

The present study takes the community as the unit of analysis instead of the individual or household and implicitly assumes that the health status of individuals and households is strongly affected by community environments. Community health indicators such as morbidity, mortality, infant mortality rates or life expectancy can be used as a measure of health status. In this study we have adopted morbidity as the dependent variable, based on the premise that the health benefits of safe water and sanitation are better reflected by morbidity rather than by mortality rates (4, 11). Morbidity from diarrhoea and

¹ Researcher, Centre for Policy and Implementation Studies (CPIS), P.O. Box 1520, Jakarta 10015, Indonesia. Currently: Postgraduate Fellow, Department of Economics, University of Queensland, Brisbane, Australia.

² Professor and Head, Department of Economics, University of Queensland, Brisbane, Qld 4072, Australia. Requests for reprints should be sent to Professor Tisdell at this address.

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morbidity from all waterborne diseases were taken as dependent variables.

In addition to safe water and sanitation, a number of other factors may affect diarrhoea morbidity (or mortality). Water quality is a significant determinant of diarrhoea incidence in Quindio, Colombia (12); and socioeconomic conditions, e.g., per capita income, occupation, or literacy rate, are often important factors that affect morbidity (5-7, 11).

Level of formal education can also influence the incidence of diarrhoea (13), although a specially designed education programme for personal hygiene and diarrhoea prevention seems to be more effective in this respect (12, 13). Nutritional status may affect diarrhoea mortality in developing countries, where the condition is a predominant cause of infant death (14). The following factors that affect the incidence of diarrhoeal diseases have also been identified: breast-feeding behaviour (15), food hygiene (16), cholera and rotavirus immunizations (17), measles immunization (16), and human and animal/livestock populations (12). Diarrhoea incidence increases during warm rainy seasons (5, 6, 12). Furthermore, the availability of health services in a community, as indicated by the ratio—number of health centres or medical staff: population size—can also influence measured health status (11).

The above-mentioned variables can influence morbidity from waterborne diseases and diarrhoea; however, inadequate data (either not available or inaccurate) precluded their inclusion in the study. Data on per capita income and water quality, for example, were not available for most subdistricts in the study area. In addition, data on breast-feeding behaviour and food hygiene were not readily available. Therefore we focused on safe water supply and sanitation as the only independent variables.

Methods

Model specification

The model is specified by the following general production functions:

$$MWB = f(WTR, SAN) \quad (1)$$

$$MDR = f(WTR, SAN) \quad (2)$$

where *MWB* = morbidity of waterborne diseases, including recorded incidences of diarrhoea, cholera, bacillary dysentery, typhoid fever, paratyphoid fever, and viral hepatitis A from January to December 1990 per 1000 population;

MDR = diarrhoea morbidity, i.e., the recorded incidence of diarrhoea from January to December 1990 per 1000 population;

WTR = safe water supply coverage, i.e., the percent-

age of the population with access to a safe water supply; and

SAN = sanitation (sanitary excreta disposal) coverage, i.e., the percentage of the population with access to excreta disposal facilities.

In contrast to the production functions used in industry, where output normally increases when the quantities of the inputs increase, the morbidity of disease(s) will presumably decrease as the quantities of the inputs included in the model increase. This has the following consequences: first, the expected sign of each independent variable is the opposite of that for the usual production function (Table 1); second, the marginal productivity and the elasticity of production are negative (see Annex for definitions of the production economics terms used in this article and also ref. 8, 9, 18). To avoid complications, we will use the absolute values in this article.

Definitions

The definitions shown below were used in the study.

"Waterborne diseases" were taken to refer to all diseases resulting from pathogens in water that can be transmitted by direct and by indirect faecal-oral routes, for example via food prepared with or washed in contaminated water. The usual definition of diarrhoea is three or more watery stools passed in the last 24 hours.

The definitions of "safe water supply" and "sanitation" used by WHO, and adopted by the Indonesian Ministry of Health, were employed in the study. Safe water supply includes treated surface water or untreated but uncontaminated water such as that from protected boreholes, springs and sanitary wells, either in the home or within 15 minutes walking distance of it (19, 20).

Because data on sanitation facilities such as solid waste disposal were inadequate, we used only sanitary excreta disposal as the sanitation variable. Sanitary excreta disposal includes collection and disposal, with or without treatment, of human excreta and wastewater by waterborne systems or the use of pit latrines and similar installations (19).

Data collection

Data for the period January–December 1990 were collected in June–July 1991 from 14 districts (*kabupaten*) and municipalities (*kotamadya*), including 194 subdistricts (*kecamatan*) in Central Java province, Indonesia. Subdistricts were used as the unit of analysis, and there were therefore 194 observations. Data on the variables shown below were collected.

— Population.

— Recorded incidences of waterborne diseases, including diarrhoea, cholera, bacillary dysentery, typhoid fever, paratyphoid fever, and viral hepatitis A. There may have been some unrecorded cases within the community in remote villages because the villagers failed to visit medical facilities or because medical centres did not diagnose the condition accurately.

— The number of people having access to safe water facilities, both piped and non-piped systems. Piped systems supply water to various service outlets such as public taps and homes; water distributed by government enterprises and community groups is covered. Non-piped water included all other systems of providing safe water, i.e., shallow wells, deep wells, spring captations, rainwater collectors and household treatment systems.

— The number of people with access to adequate sanitation (sanitary excreta disposal) facilities, including those with access to improved pit latrines, pour-flush latrines, septic tanks with or without latrines, and public latrines.

To ensure that data of adequate quality were collected, discussions were held with the officers responsible for medical records at the district level. If inconsistencies were found (either inadequacy of definition or misrecording), the data were revised. Site visits were also made to health centres and district hospitals.

Econometric procedures

Six basic production functions (linear, quadratic, reciprocal, log-linear, reciprocal log-linear, and double-log (Cobb–Douglas)) were fitted to the data (8). The properties of each function's estimators (parameters) are shown in Table 1. The SHAZAM econometrics package was used (21).

The ordinary least square (OLS) method was employed initially. Since a plot of the data indicated both vertical and horizontal asymptotes, however, regressions without a constant term ($\beta_0=0$) were also examined. In this case, the sum of squares was calculated from zero instead of from the mean value, resulting in a raw moment of R^2 instead of the usual R^2 adjusted (21–23).

Use of cross-sectional data could result in heteroscedasticity, and in consequence the OLS estimates of the parameters β_i would no longer be the best obtainable. The tests of hypotheses would no longer be valid in this case because the OLS method produces a biased variance estimator (22, 23).

To test for heteroscedasticity, we first applied the multiplicative heteroscedasticity test. If this test

Table 1: Expected signs of estimates of the parameters, β_i , in the models

Specifications*	β_0	β_1	β_2	β_3	β_4
Linear	(+)	(-)	(-)	N.A. ^o	N.A.
Quadratic					
First alternative	(+)	(-)	(+)	(-)	(+)
or 0					
Second alternative	(+)	(+)	(-)	(+)	(-)
or 0					
Reciprocal	(+)	(+)	(+)	N.A.	N.A.
or 0					
Log-linear	(+)	(-)	(-)	N.A.	N.A.
(-)					
or 0					
Log-linear reciprocal	(+)	(+)	(+)	N.A.	N.A.
(-)					
or 0					
Double-log	(+)	(-)	(-)	N.A.	N.A.

* The general mathematical form of each specification is as follows:

Linear: $Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2$.

Quadratic: $Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_1^2 + \beta_4 X_2^2$.

Reciprocal: $Y = \beta_0 + (\beta_1/X_1) + (\beta_2/X_2)$.

Log-linear: $Y = \exp[\beta_0 + \beta_1 X_1 + \beta_2 X_2]$.

Log-linear reciprocal: $Y = \exp[\beta_0 + (\beta_1/X_1) + (\beta_2/X_2)]$.

Double-log: $Y = \beta_0 X_1^{\beta_1} X_2^{\beta_2}$.

^o N.A. = not available.

failed, the Breusch–Pagan test was used (22). If heteroscedasticity was detected, we employed the generalized least squares (GLS) method to estimate the values of β_i (21–23).

To compare specifications, we used R^2 adjusted, generalized cross validation (GCV), the Hanan and Quinn criterion (HQ), the Rice criterion (RICE), the SHIBATA criterion, the Schwarz criterion (SC), and the Akaike information criterion (AIC) (23). Preferred specifications were those having a higher value of R^2 adjusted or, if the total sum of squares was equal, a lower value of the measures of the other criteria; however, such criteria should not be used to compare specifications having a constant term with those that do not (23). In those cases where there was no constant term, the raw moment of R^2 always increases if a new variable is added to the model. Thus, we did not use this criterion to compare the goodness of fit of the quadratic function with that of the others.

Results

The data collected in this study relate to approximately 11.24 million people (about 40% of the population of Central Java). The incidence of morbid-

ity from waterborne diseases in the study area in 1990 was estimated to be about 31 per 1000, while that for diarrhoea was 23.1 per 1000 (Table 2). Thus, on average, in each subdistrict about 150 incidents of waterborne diseases and 111 of diarrhoea were recorded each month.

Diarrhoea accounted for 75% of the total recorded waterborne diseases and bacillary dysentery for about 18%. In comparison, the incidence of other diseases was very low. Although the mean incidences of typhoid fever and paratyphoid fever in most subdistricts were very low or even zero, the maximum incidences of these diseases were relatively high (Table 2). Thus these diseases pose a serious health problem in certain subdistricts.

The mean level of safe water coverage in the study sample was 56%, slightly lower than the level of 61% for the whole province of Central Java. About 39% of the population had access to sanitation facilities (excreta disposal), compared with 37% for the province as a whole. Sanitation coverage had a more uneven distribution than that of safe water, as indicated by the differences in their standard deviations.

Using the OLS method, we found that the specifications that included a constant term exhibited inferior statistical performance. This arose because the values for R^2 adjusted and the F -ratio were low, and neither safe water coverage nor sanitation coverage was statistically significant for those specifications. Application of the OLS method to specifications without a constant term indicated that reciprocal functions exhibited the best statistical performance, having the lowest values of GCV, HQ, RICE, SHIBATA, SC, and AIC. For the *MWB* and *MDR* regres-

Table 2: Summary statistics of the variables examined in the study*

	Mean	Max.	Min.
<i>Morbidity (per 1000 population)</i>			
Diarrhoea	23.1 (15.8) ^b	105.4	0.0
Cholera	0.0 (0.1)	0.5	0.0
Bacillary dysentery	5.8 (7.6)	39.1	0.0
Typhoid fever	1.2 (3.6)	38.3	0.0
Paratyphoid fever	0.6 (2.3)	24.7	0.0
Viral hepatitis A	0.2 (0.3)	2.2	0.0
Total waterborne diseases	31.0 (21.5)	146.2	0.0
<i>% of population with access to:</i>			
Safe water supply	56.3 (20.3)	100.0	14.1
Sanitation	38.9 (22.0)	98.4	3.0

* No. of observations = 194 subdistricts: population covered in the study = 11 236 798.

^b Figures in parentheses are the standard deviations.

sions, the R^2 values were 0.54 and 0.55, respectively, which are reasonably acceptable for a cross-sectional analysis. In addition, only the reciprocal functions showed the significance of both the safe water and sanitation variables. The general form of the reciprocal function without a constant term is as follows:

$$Y = (\beta_1/X_1) + (\beta_2/X_2) \quad (3)$$

Multiplicative heteroscedasticity occurred in the *MWB* regression at the 2.5% significance level. For the *MDR* regression, multiplicative heteroscedasticity existed at the 11% significance level. Thus, the GLS method was used to estimate β .

Table 3 shows the regression results for the reciprocal functions obtained using the OLS and GLS methods. It is clear that the GLS method produced better specifications than the OLS method; the R^2 for the GLS specifications were higher, while those for GCV, HQ, RICE, SHIBATA, SC, and AIC were lower than those for the OLS specifications. Also, the OLS results underestimated β .

The preferred estimated reciprocal production functions (eq. (3)) for *MWB* and *MDR* are shown below:

$$MWB = 1346.6/WTR + 136.1/SAN \quad (4)$$

$$MDR = 938.5/WTR + 101.5/SAN \quad (5)$$

For the *MWB* and the *MDR* regressions, the standardized coefficients for *WTR* were about twice those for *SAN* (Table 3). This implies that increased safe water coverage can produce a greater reduction in *MWB* and *MDR* than that resulting from increased sanitation coverage, i.e., safe water has a greater effect than sanitation on the incidence of waterborne diseases and diarrhoea.

The properties of eq. (4) and (5) can be explored using an isoquant map (a set of isoquant curves). The following morbidity levels were chosen for this purpose: the mean value + 0.5 standard deviations (SD), the mean value, the mean value -0.5 SD, and the best case. The best case represents the lowest morbidity level achievable at the maximum coverage of safe water and sanitation. The isoquant maps for *MWB* and *MDR* are shown in Fig. 1 and 2, respectively. The abscissa represents safe water coverage and the ordinate, sanitation coverage. The further a curve is from the origin the lower is the morbidity level.

A number of important conclusions can be drawn from the isoquant maps, as discussed below.

- To achieve a given level of morbidity, a minimum coverage of safe water or sanitation is required. For example, to maintain the morbidity of waterborne

Table 3: Results of the regression analysis of morbidity from waterborne diseases (*MWB*) and morbidity from diarrhoea (*MDR*): reciprocal specifications

	<i>MWB</i> regression ^a		<i>MDR</i> regression ^a	
	OLS	GLS	OLS	GLS
<i>Estimated coefficients</i>				
Safe water supply	1133.7 (9.1175) ^b	1346.6 (8.6036) ^c	846.1 (9.2580)	938.5 (8.6273) ^c
Sanitation	79.8 (1.8940)	136.1 (2.1970) ^d	60.8 (1.9623)	101.5 (2.3082) ^d
<i>Standardized coefficients</i>				
Safe water supply	0.491	0.583	0.498	0.552
Sanitation	0.167	0.284	0.173	0.288
<i>Specification comparisons</i>				
R^2	0.54	0.57	0.55	0.57
F -ratio	111.92	127.93	116.07	126.15
GCV	671.00	291.02	362.45	197.91
HQ	680.14	294.99	367.39	200.61
RICE	671.07	291.05	362.49	197.94
SHIBATA	670.78	290.93	362.34	197.85
SC	693.91	300.96	374.83	204.67
AIC	670.92	290.99	362.42	197.89

^a OLS = ordinary least squares method; GLS = generalized least square method.

^b Figures in parentheses are t -statistics.

^c Significant at $\alpha = 2.5\%$.

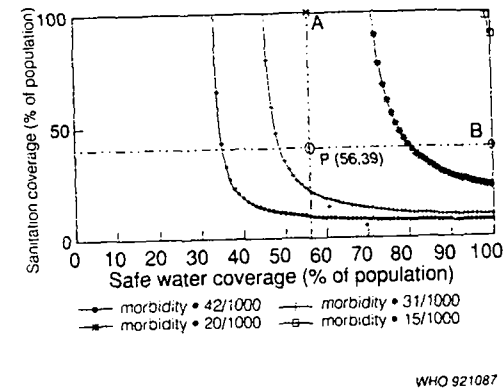
^d Significant at $\alpha = 0.5\%$.

diseases at a level of 31 per 1000 (the mean value of our data), it is necessary to have a safe water coverage of 45% at a sanitation coverage of 100% or a sanitation coverage of 8% at a safe water coverage of 100%. These minimum values can be seen in Fig. 1 by drawing a perpendicular from the 45% point on the abscissa, indicating the minimum value of safe water coverage, or a horizontal line from the 8% point on the ordinate, indicating the minimum value of sanitation coverage. Table 4 shows the minimum values of safe water and sanitation coverage for the four morbidity levels selected.

- There is a limit to the reduction in the morbidity of waterborne diseases and diarrhoea that can be produced by safe water supply and sanitation interventions only. These limits are illustrated by the isoquants that are furthest from the origin (15 per 1000 for *MWB* and 10.5 per 1000 for *MDR*).

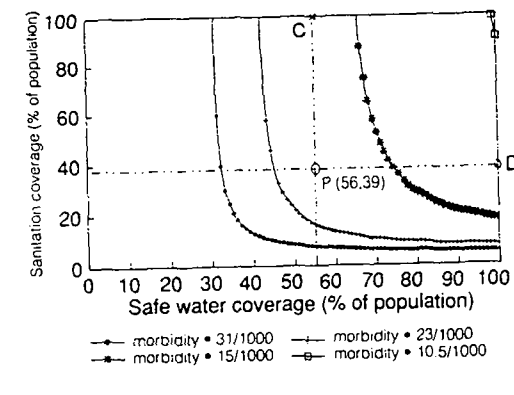
- If any one input is held constant at the current coverage level, i.e., at the mean value of *WTR* or *SAN*, it is impossible to reach the most distant isoquant curve (the lowest morbidity level) by increasing the coverage of the other variable to 100%. Fig. 1 (points A, B, and P) and Fig. 2 (points C, D,

Fig. 1. Isoquant curves of morbidity from waterborne diseases (points A, B, and P are explained in the text).



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Fig. 2. Isoquant curves of morbidity from diarrhoea (points C, D, and P are explained in the text).



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and P) show that the existing mean coverage (*WSS*: 56%; and *SAN*: 39%) is well below the level needed to minimize morbidity if the only controlled variables are provision of safe water and sanitation.

To illustrate how morbidity declines if the levels of the inputs changes, we show below the expressions for the elasticity of production. For *MWB* the elasticity of production with respect to safe water supply ($\xi_{WTR-MWB}$) is given by:

$$\xi_{WTR-MWB} = 1346.6SAN / (1346.6SAN + 136.1WTR)$$

Table 4: Minimum requirement for the coverage of safe water (WTR) and sanitation (SAN) at four morbidity levels

Morbidity level	% coverage for:	
	WTR	SAN
Waterborne diseases (MWB)		
41.7/1000 (mean + 0.5 SD)	33	5
31.0/1000 (mean)	45	8
20.2/1000 (mean - 0.5 SD)	71	20
15.0/1000 (best case)	99	89
Diarrhoea (MDR)		
31.0/1000 (mean + 0.5 SD)	31	5
22.1/1000 (mean)	42	7
15.2/1000 (mean - 0.5 SD)	66	17
10.5/1000 (best case)	99	91

while the elasticity of production with respect to sanitation ($\xi_{SAN-MWB}$) is given by:

$$\xi_{SAN-MWB} = 136.1WTR / (1346.6SAN + 136.1WTR)$$

For MDR the elasticity of production with respect to safe water is given by:

$$\xi_{WTR-MDR} = 938.5SAN / (938.5SAN + 101.5WTR)$$

and the elasticity with respect to sanitation by:

$$\xi_{SAN-MDR} = 101.5WTR / (938.5SAN + 101.5WTR)$$

From these expressions it can be seen that the values of ξ_{WTR} and ξ_{SAN} for both morbidity of waterborne diseases and diarrhoea are always <1. In other words, if the coverage of either WTR or SAN is mul-

tiplied by a positive constant, m , while the coverage of the other is held constant, the morbidity of waterborne diseases and diarrhoea decline by less than $1-1/m$. For example, doubling the sanitation coverage while holding WTR constant less than halves the morbidity.

The sum

$$\xi_{WTR-MWB} + \xi_{SAN-MWB}$$

is equal to the elasticity of production of MWB (ξ_{MWB}), and the sum

$$\xi_{WTR-MDR} + \xi_{SAN-MDR}$$

to the elasticity of production of MDR (ξ_{MDR}).

We can easily see that both ξ_{MWB} and ξ_{MDR} are always equal to one. Thus, the production functions for MWB and MDR exhibit constant returns to scale. Therefore if we multiply safe water and sanitation coverage by a positive constant, m , the morbidity of waterborne diseases or diarrhoea decreases by $1-1/m$. For example, if the coverage of both safe water and sanitation are simultaneously doubled, the morbidity of waterborne diseases and diarrhoea will be halved. Table 5 shows the potential morbidity reduction resulting from various levels of input.

Along an isoquant one input can be substituted for another to maintain the same morbidity level. The elasticities of substitution between safe water and sanitation (η) are constant (0.5) for both the MWB and the MDR production functions.^a Hence at any level of morbidity, safe water and sanitation exhibit a low and constant substitutability.

^a Mathematical proof available upon request.

Table 5: Expected reduction in morbidity if the sanitation (SAN) and water (WTR) inputs are increased simultaneously or if one input is held constant while the other is changed

% inputs increase	Both inputs changed			SAN held constant			WTR held constant		
	% MWB reduction	% MDR reduction	% MDR reduction	% WTR increase	% MWB reduction	% MDR reduction	% SAN increase	% MWB reduction	% MDR reduction
1	1	1	1	1	1	1	1	0	0
50	33	33	50	29	29	29	50	4	5
75	43	43	75	37	37	37	75	5	6
100	50	50	100	44	44	44	100	6	7
200	67	67	200	58	58	58	200	9	9
300	75	75	300	65	65	65	300	10	10
400	80	80	400	70	69	69	400	10	11

Discussion

This study has provided additional evidence that safe water and sanitation are efficacious in improving health status (5-7, 11). The health production functions that fit the data best have a reciprocal form, and both safe water and sanitation are significant regressors for morbidity from both waterborne diseases, as a whole, and for diarrhoea in particular.

Some workers have suggested that provision of sanitation may be more efficacious than safe water in reducing morbidity from waterborne diseases (2, 24); our findings, however, indicate that a safe water supply is more important than sanitation (sanitary excreta disposal) in this respect. If there are budget constraints, investment in provision of safe water should therefore be given higher priority than investment in sanitation.

The above suggestion does not mean that investment in sanitation is unimportant. First, safe water and sanitation have a low substitutability, making it relatively difficult to replace one input with another while maintaining the same morbidity level. Second, a reduction in morbidity is unlikely to be maximized (in relation to increased investment) if an increase in safe water coverage is not accompanied by an increase in sanitation coverage. Finally, if the sanitation coverage falls below the minimum level required to achieve a particular targeted morbidity level, this target will not be achieved even if safe water coverage is increased to 100%. Consequently, if health policy aims at maximizing health status in relation to investment, i.e., minimizing morbidity levels, the coverage of safe water and sanitation facilities must both be increased simultaneously.

We estimated the reduction in morbidity resulting from a given increase in safe water and/or sanitation coverage. This differs from the case-control approach (5-7), which estimates the reduction in morbidity caused by a shift from "not being exposed to safe water/sanitation facilities" to "being exposed to such facilities". Thus, the case-control method implies an increase from zero to 100% coverage, which was not necessarily the situation in our study.

We calculated a larger reduction in morbidity than that reported by other workers (5-7). The 20% morbidity reduction reported in these studies requires an increase from zero to 100% coverage. In our study, the same reduction was produced by a 25% increase in safe water and sanitation coverage.

Fig. 1 and 2 show that if safe water and sanitation coverage are maximized (equal to or almost equal to 100% coverage), total eradication of waterborne diseases and diarrhoea is unlikely. Other parameters such as habitat and socioeconomic factors also influence their incidence.

The approach used in our study is not intended to be a substitute for the case-control method; rather both are complementary. The case-control method permits in-depth observation of an individual's health status with greater capability for controlling the confounding variables; however, the possibilities for model exploration are limited because of its binary-dependent variable. Our approach uses community observations and has a greater potential for model exploration (a quantitative dependent variable is used); however, its ability to control the confounding factors was lower because of data limitations.

The study demonstrates how proper medical records and/or surveillance data can be used to assess the relationship between health inputs and community health status. The quality of medical records and/or surveillance data, particularly morbidity records, plays an essential role in this case. As discussed above, the morbidity data collected may be an underestimate, even though strenuous efforts were made to obtain complete data. Thus, it is necessary to develop an improved medical or surveillance record system that incorporates data from all medical facilities, including health centres, clinics, hospitals, and private practitioners. This will not only be beneficial for research purposes, but also for health planning and policy-making.

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Résumé

Santé, eau saine et assainissement: fonction de production transversale à Java Central, Indonésie

Cet article décrit l'application des méthodes économétriques et de la théorie de l'économie de production au calcul de fonctions de production en santé. Les fonctions obtenues ont été utilisées

pour examiner l'impact de la fourniture d'eau saine et des investissements dans le domaine de l'assainissement sur l'état de santé. Les données ont été recueillies à partir des registres officiels de la province de Java Central, en Indonésie, qui couvre 194 sous-districts. L'étude a été réalisée entre janvier et décembre 1990. Les fonctions de production en santé qui s'adaptent le mieux aux données sont des fonctions inverses, et les résultats montrent que la fourniture d'eau saine et l'assainissement (évacuation des excréta) sont des facteurs de régression significatifs pour la morbidité due aux maladies transmises par l'eau et à la diarrhée. La fourniture d'eau saine est un facteur plus important que l'assainissement pour réduire la morbidité. Les fonctions de production que nous avons obtenues montrent des régressions constantes, c'est-à-dire que si la couverture de la fourniture d'eau saine et de l'assainissement est multipliée simultanément par une constante positive m , la morbidité due aux maladies à transmission hydrique et à la diarrhée baissera d'un facteur de $1-1/m$. Si la couverture de l'assainissement est constante, une augmentation d'un facteur m de la couverture de la fourniture d'eau saine réduit la morbidité d'un facteur inférieur à $1-1/m$, et inversement. De plus, une faible valeur de l'élasticité entre les variables eau saine et assainissement a été trouvée. L'emploi de ces seules interventions pour réduire la morbidité a un impact limité, ce qui montre la nécessité d'utiliser d'autres programmes sanitaires. La connaissance des fonctions de production en santé est un préalable indispensable à la bonne exécution des analyses coût/avantages des investissements réalisés dans les domaines de la fourniture d'eau saine et de l'assainissement.

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Annex

Explanation of the production economics terms used in the text

- The *Production function* expresses the maximum output that can be produced as a mathematical function of a set of variable inputs, at a given technological level.
- Marginal productivity* is the variation in total output if the quantity of an input is increased infinitesimally, holding the quantity of other inputs constant.

- An *isoquant curve* represents all combinations of inputs that yield the same level of output.
- The *elasticity of production* measures the proportionate change in output relative to the proportionate change in all inputs. The elasticity of production with respect to an input measures the proportionate change in output relative to the proportionate change in that input, holding other inputs constant.
- Constant returns to scale* occur when the output increases m -fold if all inputs are multiplied by a positive constant. m , i.e., the value of the elasticity of production is equal to unity.
- Elasticity of substitution* is a measure of how "easy" it is to substitute one input for another along an isoquant. Low substitutability between inputs occurs if the value of the elasticity of substitution is below unity.