

The effect of user fees on prescribing quality in rural Nepal: two controlled pre-post studies to compare a fee per drug unit vs. a fee per drug item

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Summary

OBJECTIVE To compare prescribing quality with a fee per drug unit *vs.* a fee per drug item.

METHODS Prescribing data were collected prospectively over 10 years from 21 health facilities in two districts of rural eastern Nepal. In 1995, both districts charged a fee per drug item. By 2000, one district was charging a fee per drug *unit*, and the second district continued to charge a fee per drug *item* (control group). By 2002, the second district was also charging a fee per drug unit. These fee changes allowed two pre-post 'cohort' with control analyses to compare INRUD/WHO drug use indicators for a fee per drug unit *vs.* a fee per drug item.

RESULTS Charging a fee per drug *unit* increased the percentage of antibiotics prescribed in under-dosage by 11–12% ($P = 0.02$ and 0.02), decreased the percentage of patients prescribed injections by 4–6% ($P = 0.002$ and 0.02), reduced the units per drug item prescribed by 1.7 ($P = 0.02$ and 0.03), and decreased compliance with standard treatment guidelines by 11–15% ($P = 0.02$ and 0.06).

CONCLUSION A fee per unit was associated with prescription of fewer units of drugs and fewer expensive drugs (such as injections), resulting in significantly poorer compliance with standard treatment guidelines. This finding is of great concern for public health in countries where patients are charged a fee per unit of drug.

keywords prescribing quality, user fees, developing countries, evaluation

Introduction

The proportion of a population with access to affordable essential drugs on a sustainable basis is a Millennium Development Goal indicator. Public health services in many developing countries are insufficiently financed to meet patient need or demand (WHO 2003). It is estimated that one-third of the world's population may not have access to essential medicines (WHO 2002a). Despite these constraints, half of all medicines may not be used in a rational way, wasting scarce resources (WHO 2002b). Using available medicines more rationally should help to improve access.

User fees, where patients pay for medicines, are charged in many health care systems to generate revenue, to improve availability of medicines and to limit patient demand (World Bank 1993). User fees may take the form of prescription charges in publicly funded health systems or co-payments in insurance systems. Since the Bamako

Initiative, user fees for medicines have often been charged in developing countries to generate revenue to purchase more medicines and improve the quality of care in public primary health care facilities (UNICEF 1988). Although user fees may improve drug availability to a limited extent (McPake 1993), they also increase inequity (Creese 1997), and their impact on how medicines are used has rarely been studied.

A previous study in Nepal compared a flat fee per prescription (covering all drugs in whatever quantities) with a fee per drug item (covering a full course), in that patients would pay the same if they received two medicines. The study found that a flat fee per prescription, as opposed to a fee per drug item (both for a full course), was associated with polypharmacy, poorer compliance with clinical guidelines and higher costs (Holloway *et al.* 2001a; b). Qualitative investigation into reasons underlying behaviours in this same study showed that both prescribers and patients felt that it was important to try to maximise

the number of drugs for a given amount of money (Holloway *et al.* 2002). In other words, both groups felt they were not giving/obtaining value-for-money if they prescribed/received just one drug when the fee charged could cover additional items.

Increased cost-sharing lowers the numbers of both drug prescriptions and patient visits in USA (Newhouse & The Insurance Experiment Group 1993) and Zimbabwe (Chisadza *et al.* 1995). However, these studies compared level of fee rather than type of fee. Other studies examining the relationship between user fees and prescribing quality have been flawed. For example, a comparison of fee type in Tanzania (Gilson *et al.* 1993) was confounded by type of facility (private *vs.* public), one in Nepal (Chalker 1996) by drug availability, and one in Kenya (Quick & Musau 1994) by lack of a control group. Some studies were unable to evaluate the impact of user fees because of other, concurrently implemented interventions, such as decentralisation in Uganda (Anokbonggo *et al.* 2004). Prescribing quality in most of these studies was only investigated in terms of more or less use rather than being rational or appropriate.

This study builds on the previous study (Holloway *et al.* 2001a,b). A fee per drug unit (e.g. tablet, capsule) is common when user fees are based on a percentage of drug costs. During the study, national government policy in Nepal changed from dispensing medicines in the public sector for free, or for a small registration fee, to allowing local communities to charge patients a percentage of the drug costs in the form of a fee per unit (Ministries of Health and Local Development, Government of Nepal) and to use the collected monies to purchase supplementary drugs. In some areas, communities were allowed to charge more than 100% of the wholesale cost of the medicines. One would expect high fee levels to encourage the purchase of fewer drugs and fewer units of drugs because of patients' inability to pay, potentially resulting in the dispensing of incomplete courses of drugs. However, it is not known whether a fee per drug unit would encourage dispensing of fewer units and incomplete courses of drugs if the fee levels were set low. That is the question this study attempted to answer.

We compared the effects of a fee per drug unit *vs.* a fee per drug item (at similar below cost–price levels) on prescribing quality and cost in government primary health care facilities in rural Nepal. Our study was designed, in particular, to test the hypothesis, established in advance to preparing and analysing the data, that charging per drug unit (tablets, capsules, etc.) would result in prescribing more incomplete courses of drugs than charging a fee per drug item covering full courses of treatment.

Methods

Setting

Nepal has few roads and much of the population live without electricity, adequate access to drinking water and sanitation. Most people are engaged in agriculture; 45% live below the poverty line, and the per capita GNP in 2005 was US\$220 (WHO 2006). Per capita annual expenditure on health was US\$3–4; the health of the population was generally poor, life expectancy being 60 years and infant mortality 72 per 1000 live births (WHO 2004).

The study was conducted in the rural hilly and mountainous areas of eastern Nepal studied previously (Holloway *et al.* 2001a,b). In cooperation with the Nepal government, the Britain Nepal Medical Trust (BNMT) operated subsidized, locally revolving, essential drugs funds in these areas. About half of the essential drugs (Department of Drug Administration 1999, 2002) were supplied by the government and half by BNMT. Patients paid about 30–40% of the total drug costs through user fees. Few other sources of drugs were available in the study areas.

Study design

The study was conducted in 21 primary health care facilities in two districts (11 health posts in one district and 10 in the other) in rural eastern Nepal. Both districts were similar in terms of population, health services and other geographical factors. Data collection for auditing purposes was an integral part of the drug scheme. No patient-identifiable information was collected. Approval for the study was obtained at national and local levels from the Ministry of Health and the district health authorities.

In 1995, both districts charged a fee per drug item. By 2000, one district (Bhojpur) had changed to charging a fee per drug unit (intervention) and the other district (Taplejung) continued charging per drug item (control). By 2002, the second district had also changed to charging a fee per drug unit. The data collection infrastructure was maintained throughout this period. Two analyses to compare fee per unit with fee per drug item (for a full course), using a pre-post with control design [controlled pre-post 'cohort' design (Shadish *et al.* 2002)], were undertaken with each district acting in turn as a control for the other (Figure 1).

It was at least 5 hours' walk between health facilities within a district and two days' walk between districts, minimizing cross-contamination between facilities charging different fees. In 1995, all health facilities in each district were included. From 1998 onwards, some new sub-health posts were established in both districts as part of government policy to expand primary health care services. These facilities operated at a lower level with less-qualified

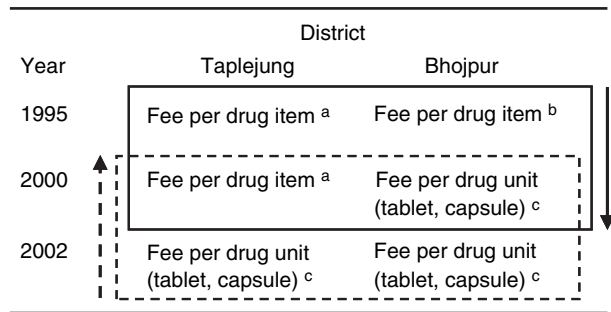


Figure 1 Two pre-post with control designs: (a) forwards in time, comparing outcomes in 2000 adjusted for 1995 baseline (solid box and arrow) and (b) backwards in time, comparing outcomes in 2000 adjusted for 2002 'baseline' (dashed box and arrow). ^aFee per drug item in Taplejung: NRs. 3 per item in health posts and NRs. 5 per item in the hospital, whether the item was cheap or expensive, covering a full course of treatment (£1 = NRs. 80–110 during 1995–2002). ^bFee per drug item in Bhojpur: NRs. 5 per expensive item (such as antibiotics and injections) and NRs. 2 per cheap item (such as paracetamol and anti-helminthics) in both health posts and hospital, covering a full course of treatment. ^cFee per drug unit: 40% of the cost price of a drug, charged by unit (tablet, capsule, bottle, injection); drug prices were listed in quantities equivalent to a full course.

staff and a small essential medicines list, and hence were excluded from the study.

Fee systems

The fees, irrespective of the system, were set in a way that patients would pay about 40% of the drug costs if they were treated in full courses in accordance with guidelines (requiring on average one expensive and one cheap drug) (Figure 1). Two slightly different types of item fees, 1-band and 2-band, were in use in different districts in 1995; the 1-band fee charged the same fee for each drug and the 2-band fee charged two fees – one for cheaper drugs and another for expensive drugs. For the purposes of this study, the 1-band and 2-band item fees were regarded as being the same because the previous study had shown little difference between the two (Holloway *et al.* 2001a,b). In the fee-per-unit facilities, drug prices were set at 40% of the wholesale cost price. Prices were publicly listed for quantities equivalent to a full course.

The Britain Nepal Medical Trust and government staff implemented fee per drug unit throughout a district over a few months. Implementation involved two visits to the facility, to ensure adequate supply of drugs and related materials and to train the staff in the new fee system, and a limited publicity campaign involving posters and talks in schools and bazaars on market days.

Outcomes and potential confounding factors

Indicators of general (WHO 1993) and specific prescribing quality, including compliance with national standard treatment guidelines (Department of Drug Administration 1999), were collected in 1995, 2000 and 2002 from carbon copy prescriptions. The average drug cost per prescription was estimated for the prescription sample for each facility using 1995 drug prices for all years. This refers to the estimated cost of all drugs in a prescription and not the fee charged to patients. It was calculated by multiplying the unit price of each drug as purchased in 1995 (baseline year for this evaluation) by the number of units prescribed.

Possible confounding factors were also measured in all time periods. Such factors included patient age, sex and diagnosis from carbon copy prescriptions, patient attendance from health facility records and drug availability from regular observations (twice yearly on average) at the health facilities by BNMT staff.

On average, 200 numbered carbon copy prescriptions were sampled per facility per year. A starting number was chosen randomly and every *n*th prescription was sampled, with '*n*' chosen to provide a sample size of about 200, taking into account the number of prescriptions per health facility. Data were entered into an Epi Info (v6.03) database. Averages for all prescribing indicators in each health facility were calculated and constituted the dataset for analysis. Averages were based on at least 100 prescriptions per facility per year, except for the percentage of prescriptions compliant with standard treatment guidelines (*n* = 30), which required individual prescriptions to be assessed against a set of *a priori* criteria (Holloway 1999, 2001a,b). Averages were never close to zero or one, and so all variables could be treated as continuous. Data were entered by the same BNMT staff for all three study years. The first author checked a random sample of the data and, overall, found mistakes in less than 5% of data entered.

Analysis

Indicators of prescribing quality for the two fee systems were compared by multiple linear regression modelling of averages at the level of the cluster (health facility), thereby taking account of any lack of independence between patients within facilities. For the purposes of our analysis, the 1-band and 2-band item fees were regarded as being the same because the previous study had shown little difference between them (Holloway *et al.* 2001a,b). All results are presented with fee per drug item as the reference fee system.

For the period 1995 to 2000, the comparison between fee per drug unit and fee per drug item in 2000 was

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adjusted using baseline data from 1995, when both districts used fee per drug item, i.e. a conventional pre-post with control design. For the period 2000 to 2002, the comparison between fee per drug unit and fee per drug item in 2000 was adjusted using data from 2002, when both districts used fee per drug unit, i.e. a pre-post with control design *backwards in time*. Confounding by case-mix was investigated by calculating changes in potential confounding factors over time (i.e. between 1995 and 2000, and between 2000 and 2002).

Results

Tables 1 and 2, respectively, show means of cluster averages for all prescribing indicators for each fee type, together with changes in the indicators, for the two study comparisons (i.e. 1995 to 2000 and 2000 to 2002). Table 3 shows the mean differences in indicators between fee systems for the two comparisons adjusted for baseline data, i.e. the regression coefficients. These are the differences in prescribing outcome between fee per unit district and item fee district:

- in 2000 taking into account baseline differences in prescribing indicators in 1995 when all health facilities used fee per drug item (comparison 1), and
- in 2000 taking into account baseline differences in prescribing indicators in 2002 when all health facilities used fee per drug unit (comparison 2).

Tables 1 and 2 show that, for both comparisons, fewer units per drug item and fewer injections were prescribed in those facilities charging a fee per drug unit than those charging a fee per drug item. The reduction in units per

drug item constituted deterioration in prescribing quality, rather than an improvement, because a greater percentage of patients received medicines, both antibiotics and other drugs, in under-dosage in facilities charging a fee per drug unit as compared to facilities charging a fee per drug item. The overall indicator of prescribing quality, the percentage of patients treated in compliance with standard treatment guidelines, was low in all facilities in all time periods, being 36–51%, but was lower in those facilities charging a fee per unit. Other prescribing indicators were similar in all time periods and both districts. The average drug cost per prescription was similar in both districts but appeared to increase over the period 1995–2002, even though the 1995 drug prices were used for all time periods.

Compared to charging a fee per drug item, Table 3 shows that charging a fee per drug unit significantly increased the percentage of patients prescribed antibiotics in under-dose by 11–12% (comparison 1, $P = 0.02$; comparison 2, $P = 0.02$), decreased the percentage of patients prescribed injections by 4–6% (comparison 1, $P = 0.002$; comparison 2, $P = 0.02$), decreased the number of units per drug item prescribed by 1.7 (comparison 1, $P = 0.02$; comparison 2, $P = 0.03$), and decreased compliance with standard treatment guidelines by 11–15% (comparison 1, $P = 0.02$; comparison 2, $P = 0.06$). Other prescribing indicators did not change significantly.

There was no substantive change in any potential measured confounding factor across the study period. Patient attendance, age, sex and case-mix remained similar, and more than 90% of all key drugs were available throughout the study. Consequently, indicators were not standardised for case-mix as in the previous study (Holloway *et al.* 2001a,b).

Prescribing indicator	Fee per item (1995) vs. fee per unit (2000)			Fee per item (1995 and 2000 control)		
	Bhojpur district			Taplejung district		
	1995	2000	Difference	1995	2000	Difference
Average number of drug items per prescription	2.1	2.2	+0.1	1.8	1.9	+0.1
% prescriptions with antibiotics	54.4	55.2	+0.8	54.6	53.4	-1.2
% prescriptions with injections	17.6	5.4	-12.1	15.3	10.9	-4.4
% prescriptions with vitamins/tonics	15.8	14.8	-1.0	8.4	10.7	+2.3
Average number of units per drug item	14.4	12.6	-1.8	15.7	14.4	-1.3
% antibiotics prescribed in under-dose	15.8	26.6	+10.8	11.4	14.8	+3.4
% other drugs prescribed in under-dose	23.9	28.8	+4.9	12.4	20.9	+8.5
% prescriptions compliant with STGs	47.7	36.3	-11.4	45.0	51.2	+6.2
Average cost per prescription (NRs.)	23.7	30.5	+6.8	26.0	30.8	+4.8

Table 1 Prescribing indicators: comparing fee per drug unit vs. fee per drug item in 1995–2000

STGs = Standard Treatment Guidelines; NRs. = Nepalese Rupees

K. A. Holloway *et al.* **Effect of user fees on prescribing quality****Table 2** Prescribing indicators: comparing fee per drug unit *vs.* fee per drug item in 2000–2002

Prescribing indicator	Fee per item (2000) <i>vs.</i> fee per unit (2002)			Fee per drug unit (2000 and 2002 control)		
	Taplejung district			Bhojpur district		
	2000	2002	Difference	2000	2002	Difference
Average number drug items per prescription	1.9	1.8	-0.1	2.2	2.4	+0.2
% prescriptions with antibiotics	53.4	52.4	-1.0	55.2	62.6	+7.4
% prescriptions with injections	10.9	7.2	-3.8	5.4	5.3	-0.1
% prescriptions with vitamins/tonics	10.7	9.0	-1.7	14.8	22.0	+7.2
Average number of units per drug item	14.4	13.7	-0.7	12.6	12.8	+0.2
% antibiotics prescribed in under-dose	14.8	19.8	+5.0	26.6	26.9	+0.3
% other drugs prescribed in under-dose	20.9	27.9	+7.0	28.8	34.6	+5.8
% prescriptions compliant with STGs	51.2	47.8	-3.4	36.3	40.3	+4.0
Average cost per prescription (NRs.)	30.8	28.2	-2.6	30.5	33.5	+3.0

STGs, Standard Treatment Guidelines; NRs., Nepalese Rupees.

Table 3 Estimates of the effects on prescribing indicators of changing from fee per drug item to fee per drug unit

Prescribing indicator	Comparison 1: 1995–2000†			Comparison 2: 2000–2002‡		
	B coeff	95% CI	P	B coeff	95% CI	P
Average number of drug items per prescription	+0.03	-0.25 to +0.30	0.84	-0.29	-0.64 to +0.06	0.10
% prescriptions with antibiotics	+1.86	-2.97 to +6.69	0.43	+0.63	-6.00 to +7.26	0.84
% prescriptions with injections	-6.03	-9.59 to -2.46	0.002	-4.10	-7.52 to -0.68	0.02
% prescriptions with vitamins/tonics	-4.53	-12.0 to +2.98	0.22	-3.18	-14.0 to +7.59	0.54
Average number of units per drug item	-1.71	-3.12 to -0.30	0.02	-1.68	-3.17 to -0.19	0.03
% antibiotics prescribed in under-dose	+10.9	+1.58 to +20.1	0.02	+12.0	+2.02 to +21.9	0.02
% other drugs prescribed in under-dose	+8.50	-3.33 to +20.3	0.15	+4.75	+5.13 to +14.6	0.33
% prescriptions compliant with STGs	-15.4	-28.2 to -2.51	0.02	-10.6	-21.76 to +0.67	0.06
Average cost per prescription (NRs.)	+1.96	-0.95 to +13.9	0.73	-4.07	-13.42 to +5.27	0.37

†Prescribing indicator 2000 = a + b1 (prescribing indicator1995) + b2 (fee per unit) + error

‡Prescribing indicator 2000 = a + b1 (prescribing indicator2002) - b2 (fee per item) + error (Note: the sign for b2 was reversed so that the fee per drug item represented the reference fee system, see Methods.)

Discussion

A fee per drug unit was associated with significantly poorer prescribing quality than a fee per drug item across a range of prescribing indicators. Poorer prescribing quality in fee per unit districts arose mainly from a small but significant reduction in the number of units prescribed per drug, resulting in a higher proportion of patients receiving antibiotics in under-dose. Because standard treatment guidelines specified full courses of treatment, under-dosing, in turn, resulted in poorer compliance with guidelines.

The impact on compliance with standard treatment guidelines would almost certainly have been greater but for the counter-effect of a greater reduction in the prescription of injections in fee-per-unit districts than in fee-per-item districts. Because it was common that more injections were

used than necessary, the greater reduction in the prescription of injections in fee-per-unit facilities contributed to improved compliance with standard treatment guidelines. However, because prescription of injections was rare as compared to prescription of oral antibiotics and other drugs, the improvement in compliance arising from the prescription of fewer injections only partly offset the overall finding of poorer compliance with standard treatment guidelines in fee-per-unit facilities that arose from the prescription of drugs in under-dose.

The reduction in use of injections with a fee per unit may be because of the fact that they are very expensive in comparison with other medicines, and the cost to the patient would have risen significantly with each injection given. Our finding that fewer injections were used with a fee per unit (where the charge to the patient was likely to

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be much greater than with a fee per drug item covering a full course) was similar to other findings, where higher drug charges to patients resulted in decreased use (Foxman *et al.* 1987; Newhouse & The Insurance Experiment Group 1993; Chisadza *et al.* 1995). By contrast, the percentage of patients being prescribed antibiotics did not fall with a fee per drug unit, suggesting that the extra fee for an extra tablet with the fee per unit system (much smaller than for an extra injection) did not deter providers from prescribing antibiotics.

Although fewer injections were used in fee-per-unit districts than in fee-per-item districts, fewer injections were prescribed in all districts across the study period. This overall decrease in injection use did not invalidate the evaluation of different fee systems because of controlled before–after study design. This district-wide decrease was likely to have been due to other nation-wide policy changes to reduce injection usage at primary health care level, including a change in the national essential medicines list. The fee-per-drug unit was introduced, despite the likelihood of poorer prescribing, because it was the government policy to do so throughout the country. It was not introduced by the investigators as an ‘intervention’ to reduce injections. We hypothesised that this policy would reduce compliance with standard treatment guidelines overall, as observed, and persuaded the local authorities to stagger the introduction of fee-per-drug unit in order to evaluate its impact. As shown during the study period, there were other ways to reduce the use of injections, such as deleting injections from the essential drugs list, so reducing their availability in government health facilities.

The results support the hypothesis that charging per drug unit (tablets, capsules, etc.) is associated with the prescription of more incomplete courses of drugs as compared with charging a fee per drug item covering full courses of treatment. The size of effect of any intervention is important because small effects, although statistically significant, may be too small to justify the effort of implementation. According to a review of all intervention studies aimed at improving rational use of medicines, a change of 11–12% with regard to the percentage of patients being prescribed antibiotics in under-dose, and 11–15% with regard to compliance with guidelines represents an important effect of moderate size (Ross-Degnan *et al.* 1997; WHO 1997).

We made an effort to minimise the risks of patients being prescribed and dispensed medicines in under-dose, or incomplete courses, by listing the prices of all medicines at the health facilities only in terms of quantities consistent with guideline recommendations (i.e. in full course) and not by individual unit (e.g. per tablet or capsule). This action, together with the relatively low level of fees, may

have limited the negative consequences on under-dosing of charging a fee per unit.

The average cost per prescription was not significantly different between the two districts or between the two fee systems, even though one might have expected a lower cost per prescription with the fee-per-unit district, where fewer units and fewer injections were being prescribed. We have no explanation to this.

The use of pre-post with control designs for two staggered comparisons gives the study high internal validity. Both comparisons, using different fee systems as the baseline, showed very similar results. Although the study was conducted in only two districts, we believe the results should apply to other rural districts in Nepal and, possibly, to other rural settings operating low-cost-fee systems. Taking into account the low overall prescribing quality and the fact that both fee systems were easily implemented, the findings from this study have important policy implications. User fees are often charged but usually without consideration of their impact on prescribing quality.

In poorer countries, patients often have to purchase drugs by unit from private shops and pharmacies. In such circumstances, there is a financial incentive for the retailer to try to sell more expensive drugs in greater quantity. However, patients often cannot afford to pay the prices charged and so they buy drugs in smaller quantities, often in under-dose. In this study, health workers had no financial incentive to sell expensive drugs in greater quantities because all monies collected were used to purchase more drugs and not to supplement the health workers' incomes. Thus, the impact of the fee system could be investigated in isolation, without the complicating effect of financial gain. The prices charged to patients for drugs were fixed at a very low rate by the district health committees. Even so, the fee per unit system carried a perverse financial incentive with regard to rational use of medicines because patients bought drugs in under-dose as it was clearly cheaper for them to do so.

In conclusion, this study evaluated the impact of a fee per drug item *vs.* a fee per drug unit on prescribing quality. Charging a fee per unit is clearly associated with prescription of fewer units of drugs and fewer expensive drugs (such as injections), resulting overall in significantly poorer compliance with standard treatment guidelines. In this setting, the use of relatively low level of fees and listing of prices only in terms of full-course quantities may have limited the potential negative consequences of charging a fee per unit, such as under-dosing. Because fees are often charged for medicines, these results are of major public health importance and should be taken into account by policy makers.

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