Patient Referral at the Grass-roots Level in Pakistan

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Abstract: Patient referral services constitute an integral part of any well functioning health system. In the public health sector in Pakistan, the first rung in the referral hierarchy is the Lady Health Worker (LHW) of the National Programme for Family Planning and Primary Health Care. Most independent evaluations conducted to date have given satisfactory reports of LHWs performance despite their limitations, and acknowledged the importance of their role in first level referral. However, the outcomes and consequences of referral made by the LHWs are largely unknown. One outcome, patient dissatisfaction, has been widely recognized as a measure of ascertaining how well health services are being delivered. It is imperative to learn about the referral outcomes to ascertain continuity of care, cost effectiveness of management and ensuring the appropriate case mix at the respective health facilities. Patients referred were interviewed in a cross-sectional study conducted in Karachi, Pakistan. Structured questionnaire was used to collect the data on demographic attributes, outcome of referral and satisfaction with regard to the services at the referral health facilities. About fifty six percent of patients were referred for the management of various medical and/or surgical conditions. The median cost of the treatment was 200 PKR and 1230 PKR as outpatient and in-patient respectively. About 24% of the patients reported to be cured. With regard to patients' satisfaction, 31.6% of patients were not satisfied with their management at the referral facilities. Final multiple logistic regression analysis showed that long distance to health facility (AOR, 3.54; CI: 1.36-9.19), long time to reach the referral facility (AOR, 3.72; CI: 1.06-13.04), borrowing of money for treatment (AOR, 2.14; CI: 1.18-3.89) and outcome of condition (AOR, 9.08; CI: 3.33-24.67) were significantly associated with patient dissatisfaction. LHWs are the first contact for many people with the health system in general and with the referral system in particular. However, after being referred by the LHWs, patients are left more or less unsupported by the formal system, causing in many cases, an inevitable waste of resources, unnecessary and avoidable morbidity, and social and mental stress. [Nature and Science. 2004;2(4):18-27].

Key Words: lady health workers; referral system; patient dissatisfaction; Pakistan

1. Introduction

The modern referral system was first initiated in the United Kingdom and was well established by the 1948 nationalization of hospitals. Patient referral services constitute an integral part of any well functioning health system. The goal of referral services is to ensure that patient is dealt with at the appropriate level health facility, and receive cost effective and quality management (Mariker, 1998). In addition, referral also serves to provide linkages between primary and secondary and tertiary care.

The concept of a health care hierarchy of a referral system is based on the systems notion, in which certain population within a given catchment

area is provided specified levels of care. With the realization of the importance of primary health care (PHC), the skill pyramid of the conventional health care hierarchy with the community health workers (CHWs) at the bottom and the physicians at the top has been tipped to the side (Mariker, 1998; Stefanini, 1999) with patients not only moving to higher levels (secondary or tertiary care facilities) but also to lower levels according to individual needs. Such a dynamic multi-level flow of patients between varying cadres of health care providers is seemingly complicated to manage but essential to quality and cost effectiveness. Unfortunately, in many developing countries people tend to by pass the first level care facility, which results in overburdening of higher-level facilities (Kordy, 1991).

In the public health sector in Pakistan, the first rung in the referral hierarchy is the Lady Health Worker (LHW) of the National Programme for Family Planning and Primary Health Care, which was initiated in 1999. Apart from the various other PHC activities that LHWs undertake, they also refer patients and guide individuals from the grass-roots to the appropriate health facilities (Siddiqi, 2001). No study has been identified by the authors that have studied referral rates by CHWs/LHWs. However, referral rates by the primary care physicians to specialists/consultants in well-structured health systems range from 2% to 28% (Siddiqi, 2001; Ministry of Health, 1993; Sindh Survey Report, 2002). One may assume that referral rates by community health workers would be higher than the rates by GPs. A local study conducted in Karachi, Pakistan, has reported a referral rate of 55% by LHWs, which seems to be fairly high. Some of the reasons suggested by the authors included the limitations of the LHW to manage more than very basic medical conditions and lack of resources like drugs and other medical supplies (Alper, 1994).

Independent evaluations conducted to date have given satisfactory reports of LHWs performance despite the limitations, and acknowledge the importance of their role in first level referral (Sindh Survey Report, 2002). However, the outcomes and consequences of referral made by the LHWs are largely unknown. It is imperative to learn about the referral outcomes to be able to make certain continuity of care and hence quality of care, curtailing costs and ensuring the appropriate case mix at the respective health facilities (Alper, 1994; Counter, 1989).

In Pakistan, an estimated 70 to 80% of the population uses private services for their health needs, the public sector, if regulated in a structured manner, is a very important source of equity in health care (Counter, 1989) especially with regard to PHC (where the private sector has a limited role). On the other hand, reports show that LHWs cater to a significant proportion of the population in areas they serve and refer to both government and private facilities. Thus LHWs are an important link in 'private-public partnership', where both the sectors may complement each other in providing equitable

and quality health services (Sindh Survey Report, 2002). Unfortunately, in most of the developing countries, including Pakistan, the equation is tipped heavily towards the private sector and public sector utilization is dismally low (Afsar, 2003). One important reason cited for this low utilization is client dissatisfaction. Patient satisfaction in health care has been widely recognized as a measure of ascertaining how well health services are being delivered as well as accessed and utilized (Maynard, 2001). The subsequent role of the LHW within the whole system of health service delivery and its consequences on the patient need to be viewed in a holistic manner. The study presented here is part of a larger study that looked at the proportion of referrals by the LHWs and factors affecting unsuccessful referral (patients referred by the LHWs who did not visit referral site within 30 days). This study aims 1) to assess the medical and financial consequences of successful referrals (patients who were referred and visited the referral site within 30 days) to the higher-level health facilities by the LHWs and 2) to identify the factors associated with patients' dissatisfaction, attending the referral health facilities in Karachi, Pakistan. The study protocol was approved by the institutional ethics committee board of The Aga Khan University.

2. Methodology

2.1 Design and setting

This cross-sectional study was conducted from November 2000 to March 2001 in the District West of Karachi. Karachi is the largest city of Pakistan with a population of 14 million. Karachi's economic dominance has led to the massive influx of people from all areas of the country making it a multilinguistic, multi-ethnic and multi-cultural region, and has been described as 'mini Pakistan'. For administrative purpose, Karachi is divided into five districts: East, South, West, North and Malir. According to 1998 census report the total population of district West is 2105923 with 1149200 (54.6%) males and 956723 (45.4%) females (Khan, 1996). About 900 LHWs are currently providing primary health coverage in Karachi, among them 337 LHWs were based at 8 BHUs in District West, who report to the District Health Office (DHO), District West (currently Executive District Officer Health).

2.2 Recruitment of subjects

The list of LHWs providing services in District West was obtained from the District Health Officer West. LHWs were randomly selected through a random number table. Records of the last one-month (preceding the study period) of selected LHWs were reviewed; the latest eight patients referred to various health care facilities from the visited houses were selected. The study team visited and interviewed the selected individuals. Sub-set of the patients visited, who were referred to various level health facilities by the LHWs and who later attended their respective referral facilities were included in this part of the study (Figure 1).

2.3 Data collection

After obtaining informed consent, a pre-tested structured questionnaire was administered through trained staff. Parents or immediate family members who were interviewed in case subject were <15 years of age. Data were collected regarding demographic characteristics sex, monthly (age, income. employment status), process of referral (distance of the referral facility from residence, means of transportation used, visited the facility alone/with someone, cost of treatment) and patient satisfaction (with regard to services and management at the referral sites, clinical services available).

2.4 Data management and analysis

Data were analyzed according to the two objectives of the study. To observe the outcome of patient referral, descriptive statistics was carried out: mean, standard deviation and median were calculated for continuous variables, and percentages for the categorical variables. To identify factors associated with patient dissatisfaction, association between outcome variable (satisfaction versus dissatisfaction) independent variables and (patients' sociodemographic characteristics and hypothesized factors for patient dissatisfaction) were sought. Exposure variables were categorized into two or more levels, assuming as reference the category deemed to have the lowest risk of dissatisfaction. Subgroups were analyzed by using Chi-square and Fisher Exact Test.

To observe the individual effects of each exposure variable, potential mutual confounders were simultaneously controlled by means of stepwise multiple logistic regression analysis and odds ratios (ORs) with their 95% confidence intervals (CIs) were computed. After arriving at main effects model, plausible interaction terms were evaluated. The goodness-of-fit of the final multivariate model was checked by Pearson Chi-square test. An epi-info *(version 6.04. Atlanta, GA; Center for Disease Control and Prevention; 1995)* based programme was developed to enter the data, and Statistical Package for Social Sciences *(version 8.0. Chicago; IL: SPSS Inc; 1996)* was used for analysis.

3. Results

Of the 247 patients who attended the referral site, 155 (62.8%) were females and 92 (37.2%) were males. The mean age of the patients was 37.6 ± 21.2 SD, and majority 140 (56.7%) of them were of age >35 years. About 60% of the patients were married. More than half 126 (51.0%) of study subjects had no formal schooling. On the basis of mother tongue, we categorized the ethnicity into four groups, majority 140 (56.7%) of them were Mohajirs. Only 54 (21.9%) patients had reimbursement/insurance facility for their medical bills. Table 1 describes the socio-demographic characteristics of the referred patients.

3.1 Referral outcome

Among patients who attended the health facility, 140 (56.6%) were referred for the management of various medical/surgical and gynecological/obstetrical conditions, 61 (24.7%) for investigations, 35 (14.2%) for diagnosis and 11 (4.5%) on patient request. Only 4% of patients visited government facilities, the rest having visited private physicians (61.5%) and in-formal practitioners 63 (25.5%). One hundred seventeen (47.4%) patients were prescribed 0-3 drugs, 78 (31.6%) 4 to 6 drugs and 52 (21.1%) more than 6 drugs. One hundred and seventy-seven patients (71.7%) were treated as outpatients, while 70 (28.3%) were treated as in-patients. The median cost of the treatment was 200 PKR and 1230 PKR as out-patient and in-patient respectively. One hundred and two (41.3%) patients had borrowed money to finance their treatment. Due to the current episode of ill health, 59 (23.7%) of patients stayed away from their work for 2-8 days. About 25% of patients reported improvement in their conditions with the management they received at the referral facilities.

3.2 Factors associated with patient dissatisfaction

Seventy-eight (31.6%) patients were not satisfied with the management they received from the referral health facilities. When asked about reasons for dissatisfaction, 28 (11.3%) cited that they did not get better, 18 (7.3%) said that the treatment was too expensive, 12 (4.9%) complained about the long waiting time, 12 (4.9%) said that they were not given any medications and 8 (3.2%) complained the rudeness of the health facility staff.

We found no difference in the socioeconomic and demographic profile of satisfied and dissatisfied patients groups (p>0.05). Univariate analysis for the factors associated with dissatisfaction in patients who attended the referral health facilities is given in Table 2. Final multiple logistic regression analysis (Table 3) revealed that long distance to referral facility (>3 km vs <1 km, Adjusted OR, 3.54; CI: 1.36-9.19), long time to reach the referral facility (>60 minutes vs <30 minutes, Adjusted OR, 3.72; CI: 1.06-13.04), borrowing of money for treatment (Yes vs No, Adjusted OR, 2.14; CI: 1.18-3.89) and outcome of condition (never got better vs cured, Adjusted OR, 9.08; CI: 3.33-24.67) were significantly associated with referral patient dissatisfaction. The final multivariate model fitted well as confirmed by the Pearson goodness-of-fit test (p=0.813).

4. Discussion

The present study set out to assess the outcome of patient referral and to identify the factors associated with dissatisfaction in patients attending the referral health facilities. We found that the major clienteles of LHWs were women and children. Considering that women are often restricted to visit a health facility by themselves in most of the sociocultural settings in Pakistan, LHWs are an important source of PHC at the grassroots-level. Other important groups of patients being catered to by the LHWs were adolescents (11 to 19 years) and the elderly (>60 years), both groups of which often have less access to health services.

4.1 Referral outcome

The majority of patients were referred for the management of various medical and/or surgical conditions, which is consistent with other research work (Barker, 1991; Majumdar 1997; DCR, 1998).

Among total patients referred substantial number of referrals (28.3%) were consequently admitted as inpatients. This proportion may be significantly reduced if LHWs were better trained and supplied to manage acute conditions and provide first aid.

One may argue that the less number of referred patients visiting government facilities reflects failure of the LHWs programme to increase government facilities usage. However, without the necessary improvements in quality of these health facilities, LHWs can do little to improve utilization. On the contrary, LHWs may face embarrassment and loss of credibility when the patients they have referred return disappointed and dissatisfied from these health facilities (Nordberg, 1996).

The median cost incurred by the patients attended as out-patients was 200 PKR, constituting 6% and 3% of the monthly income of the lowest and the next higher income groups respectively, a large proportion of the monthly wage to spend on a single episode of illness. On admission as an in-patient, the total treatment cost rose to six times i-e 1230 PKR. The immense economic burden can be judged by the fact that a large number (41.3%) of people had to borrow money in order to finance their treatment. There was also appreciable loss of productive workdays. Hence, the monetary consequences of referral are significant enough to emphasize on curtailing unnecessary referrals.

With current emphasis on identification and symptomatic treatment, a visit to a health care provider inevitably results in prescription of multiple drugs even if they may not be medically justified (Harold, 1996; Halm, 1997). In our study, almost one third (31.6%) of patients were prescribed 4 to 6 drugs and about one fifth (21.1%) more than 6 drugs. The outcomes of such 'apparent' injudicious prescription of drugs results in increasing appearance of resistant strains of infections, undesired side-effects, lack of patient compliance and a waste of valuable resources (Sturm, 1997; Das, 2001). Ironically, one reason for dissatisfaction with management was that patients were not given any medications. This typifies the cultural paradigm of the communities' expectations of a health care provider in which some medication given, usually in the form of drugs or injections, is perceived as a sign of quality (Afsar, 2002). The physicians may be partially responsible for this induced demand for drugs. The LHW in her role as a

health educator can help create awareness in this regard. LHWs contacted majority (92.7%) of their referred patients afterwards to enquire about outcome of their referrals. This practice is in line with the process of feedback and continuity of care, and augments well for the LHW-client relationship.

4.2 Factors associated with patient dissatisfaction

One third of the patients reported to be dissatisfied with the management at the referral sites, which is similar to studies done in other settings (Das, 2001; Millar, 2001). Final model showed that long distance and long travel time to health facility were significantly associated with patient dissatisfaction. In Pakistan, despite an extensive network of primary health facilities, quite often individuals with ailments that could easily be managed at lower level tend to bypass and visit tertiary care institutions and thus over-burden the outpatient departments of major hospitals (Sturm, 1997; Siddiqi, 2001). Inevitably, these patients spend more time to travel longer distances and have to wait longer to be seen by the physician. In developing countries including Pakistan, the effect of distance on service utilization becomes stronger, when combined with the dearth of transportation and poor roads, as a cause of dissatisfaction (Coulter, 1995; Khan, 2000; Kersnik, 2001). The importance of a well-established transport mechanism has been cited as an essential part of a referral system (Bhuiya, 1995). Even though lack of resources may limit the possibility of developing and maintaining such a mechanism, the author has come across a Community Based Organization (CBO) in a remote desert area (Therdeep) in Pakistan that has developed a system whereby the community contributes towards a pool of money reserved for transportation costs for patients in need of serious medical attention. Local health authorities may replicate such novel initiatives wherever possible.

Our study showed that people spend a large proportion of their income on health care, even if they have to borrow money. In our study, borrowing of money for treatment was found associated with patient dissatisfaction. This may be partly explained by the fact that borrowing of money not only increases the financial burden but also compromises self-esteem. One could hypothesize that these people then, would avoid visiting the facilities at the start of their illness and delay seeking care until complications force them to do so. This inevitably raises treatment cost further while at the same time increasing the morbidity and mortality (Janse, 1999).

Our data showed that patients who 'did not get better' were more likely to be dissatisfied compared to patients who reported to be cured with the management they received. This is understandable; though we are not in a position to comment on why their conditions did not improve. In our study 3.2% patients reported 'rudeness of the health facility staff', a reason for dissatisfaction. Staff attitude has been reported as an important factor for patient satisfaction (Katung, 2001). It is hypothesized that the success of informal sector (unregistered practitioners and quacks) in attracting patients may be attributed to their good interpersonal skills and clientprovider relationship (Campbell, 1997; Aljunid, 1996; Sharaf, 2003). Other important factors for patient dissatisfaction such as absence of insurance, repeated visits to referral site and visiting referral facility alone were not found significant in the multivariate analysis.

Our study does have some important limitations. Firstly, we could not assess the appropriateness of the referrals made by the LHWs. Secondly, due to limited scope of the design and the large number of different referral sites clients were referred to, we did not study the provider-client interaction at referral health facilities which we believe could have strengthened our discussion with regards to patient dissatisfaction.

5. Conclusions

The LHWs are providing invaluable services with regards to PHC and support to patients. Our current analysis and earlier work suggest that despite an inevitable large referral rate, the LHWs are effectively functioning as the first contact of many people with health system in general and specifically with the referral process. Beyond this, there is currently little data available to argue against our hypothesis that the patient after being referred by the LHWs from the grass root level is left unguided and not sufficiently supported by the heath system, causing in many cases, an inevitable waste of resources, unnecessary and avoidable morbidity and social and mental stress. More research is needed to follow patients as they interact with various levels in the health system so that loopholes causing wastage and delays are minimized and the health system be structured to provide efficient, effective and equitable health services to all.

Acknowledgements

The authors thank the study patients. We acknowledge Dr. Saqib Ali Shiekh (District Coordinator, District West) and Ms. Zahida Hussain Shah (Health Education Officer and Assistant coordinator, District West) of the National Programme for Family Planning and Primary Health Care for their invaluable support.

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Table 1. Characteristics of the patients (referred by the Lady Health Workers) who attended the referral health care facilities in Karachi, Pakistan (n=247).

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A sec (second stard second)	#	%0	
Age (completed years)	25	14.0	
<15	35	14.2	
15-35	12	29.1	
> 35	140	56./	
Gender			
Male	92	37.2	
Female	155	62.8	
Ethnicity			
Mohajir	140	56.7	
Sindhi	21	8.5	
Pathan	48	19.4	
Punjabi	21	8.5	
Baloch and others	17	6.9	
Education of the donor			
Illiterate	126	51.0	
Primary to Secondary	96	27.9	
Intermediate and above	52	21.1	
Marital status			
Single	24	9.7	
Married	148	59.9	
Divorced/widowed/separated	32	13.0	
Not applicable (age less than 15 years)	43	17.4	
Household income (PKR*/month)			
≥ 6000	67	27.1	
3000-<6000	120	48.6	
< 3000	32	13.0	
Not applicable (age<15 years)	28	11.3	
Number of household			
≤5	73	29.6	
6-10	137	55.5	
>10	37	15.0	
Beneficiary status (Insurance)			
Yes	54	21.9	
No	193	78.1	

* Pakistani Rupee (1 \$= 58 PKR)

Associated factors	Dissatisfied	l Patients	Satisfied	Patients	OR [†]	95% CI‡
Age (years)						
> 35	43	(55.1)	97	(57.4)	1.00	-
15-35	24	(30.8)	48	(28.4)	1.03	0.61-2.07
<15	11	(14.1)	24	(14.2)	1.13	0.47-2.29
Gender						
Male	26	(33.3)	66	(39.1)	1.00	-
Female	52	(66.7)	103	(60.9)	1.28	0.73-2.25
Ethnicity						
Mohajir	53	(67.9)	87	(51.5)	1.00	-
Punjabi	2	(2.6)	19	(11.2)	1.49	0.59-3.75
Pathan	10	(12.8)	38	(22.5)	0.43	0.19-0.94
Sindhi	10	(12.8)	11	(6.5)	0.17	0.04-0.77
Baloch and others	3	(3.8)	14	(8.3)	0.35	0.09-1.28
Education						
Intermediate & above	13	(17.3)	39	(24.2)	1.00	-
Primary - secondary	24	(32.0)	45	(28.0)	1.61	0.72-3.56
Illiterate	38	(50.7)	77	(47.8)	1.45	0.69-3.0
Marital status						
Single	22	(28.2)	45	(26.6)	1.00	-
Married	47	(60.3)	101	(59.8)	0.95	0.51-1.76
Separated\Divorced	9	(11.5)	23	(13.6)	0.80	0.32-2.02
\Widowed		()				
Beneficiary Status						
Ves	18	(23.1)	36	(21.3)	1.00	_
No	60	(25.1) (76.9)	133	(21.3) (78.7)	0.90	0 47-1 72
Monthly Income**	00	(70.5)	155	(70.7)	0.90	0.17 1.72
> 6000	6	(9.0)	26	(17.1)	1.00	_
3000 - <6000	43	(64.2)	20	(17.1)	2 42	0 92-6 34
<3000	18	(26.9)	49	(30.7) (32.2)	1 59	0 56-4 49
	10	(20.9)	19	(32.2)	1.09	0.00 1.19
Ever been referred before			0.5		1.00	
Yes	40	(56.4)	85	(50.3)	1.00	-
No	34	(43.6)	84	(49.7)	0.88	0.49-1.57
Attended the referral site						
Same day	19	(24.4)	77	(45.6)	1.00	-
Within a week	44	(56.4)	64	(37.9)	2.79	1.48-5.24
After one week	15	(19.2)	28	(16.6)	2.17	0 97-4 84
	10	(1))	-0	(10.0)	,	0.57
~						
Someone accompanied						
Yes	60	(76.9)	145	(85.8)	1.00	-
No	18	(23.1)	24	(14.2)	1.81	0.92-3.58
Want to referral site by						
Walk	24	(30.8)	64	(37.0)	1.00	_
Transnort	2 4 54	(60.0)	105	(57.7) (62.1)	1.00	- 0 78-2 /3
Transport	57	(09.2)	105	(02.1)	1.57	0.70-2.43

Table 2. Univariate analysis of the factors associated with patient dissatisfaction at the referral health facilities in Karachi, Pakistan.

Continue Table 1:

Time to reach the referral site						
(minutes)						
<30	30	(38.5)	88	(52.1)	1.00	-
30 - 60.	38	(48.7)	75	(44.4)	1.49	0.84-2.62
>60	10	(12.8)	6	(3.6)	4.89	1.64-14.59
Number of visits to the referral site						
0 - 2						
3 - 5	26	(33.3)	51	(30.2)	1.00	-
> 5	32	(41.0)	66	(39.1)	0.95	0.51-1.79
	20	(25.6)	52	(30.8)	0.75	0.38-1.52
Total cost (Runees)						
<100	20	(25.6)	38	(22.5)	1.00	_
100-<500	20	(23.0) (30.8)	50	(22.3) (30.2)	0.89	- 0.43-1.85
500-2000	20	(25.6)	44	(26.0)	0.86	0.41-1.84
>2000	14	(17.9)	36	(20.0)	0.74	0 33-1 68
Borrowed money	17	(17.7)	50	(21.5)	0.74	0.55-1.00
No	36	(46.2)	109	(64.5)	1.00	_
Ves	42	(53.8)	60	(35.5)	2 12	1 23-3 66
Admitted as innatient	f <u>/</u>	(33.0)	00	(33.3)	4.14	1.25-5.00
No	55	(70.5)	122	(72.2)	1.00	-
Ves	23	(29.5)	47	(27.8)	1.08	0 60-1 96
Staved away from work/school		(2).5)	17	(27.0)	1.00	0.00 1.70
(days)						
0-2	23	(30.7)	44	(27.3)	1.00	-
3-8	11	(14.7)	45	(28.0)	0.45	0.19-1.02
>8	41	(54.7)	72	(44.7)	1.13	0.61-2.12
Outcome of condition		· · /		~ /		
Cured	9	(11.5)	52	(30.8)	1.00	-
Under consultation	44	(56.4)	98	(58.0)	2.59	1.18-5.72
Never got better	25	(32.1)	19	(11.2)	7.59	3.01-19.17
Distance from the referral site		· · · ·				
(Kilometer)						
< 1	10	(12.8)	48	(28.4)	1.00	-
1-3	31	(39.7)	65	(38.5)	2.29	1.02-5.12
> 3	37	(47.4)	56	(33.1)	3.17	1.43-7.04

• Statistically significant ** 28 refused to answer the question [†] Confidence interval ‡Odds ratio

 Table 3. Multivariate regression analysis of the factors associated with patient dissatisfaction, who attended the referral health facilities in Karachi, Pakistan.

Associated factors	Adjusted OR [†]	95 % CI [‡]
Distance from the referral site (kilometer)		
< 1	1.00	-
1-3	2.23	0.93-5.34
> 3	3.54	1.36-9.19
Time to reach the referral site (minutes)		
<30	1.00	-
30 - 60.	0.85	0.41-1.73
>60	3.72	1.06-13.04
Borrowed money		
No	1.00	-
Yes	2.14	1.18-3.89
Outcome of condition		
Cured	1.00	-
Under consultation	2.58	1.10-6.06
Never got better	9.08	3.33-24.67

[†] Confidence interval [‡] Odds ratio

Total number of patients visited by the selected LHWs in 1 month



*Data of 18 patients were incomplete and not included in the analysis

Figure 1. Schematic description of enrollment of study subjects