

Role of predictors in acceptance of post-exposure prophylaxis with single-dose rifampicin among contacts of leprosy in rural area of Bankura: An explanatory mixed-method study



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ABSTRACT

Background: India achieved the elimination of leprosy two decades ago although its sustenance continues to be threatened by ongoing active transmission in few remaining pockets. There is a paucity of data regarding the acceptance of single-dose rifampicin (SDR) prophylaxis among healthy contacts. **Aims and Objectives:** The aims and objectives of the study are to assess the factors influencing the acceptability of SDR among contacts. **Materials and Methods:** A community-based, sequential, explanatory mixed-method study was conducted over 6 months from September 2022 to February 2023 among 168 contacts of leprosy patients from two blocks in Bankura district, West Bengal. Quantitative analysis was done for SDR acceptance and its predictors among contacts using the Chi-square test, Mann-Whitney U test, and Logistic regression. This was followed by qualitative assessment using focus group discussions and in-depth interviews among contacts to explain the findings through a thematic approach. **Results:** Household contacts (aOR = 13.72, 95% CI = 2.09–90.19), increasing knowledge score of contacts (aOR = 3.18, 95% CI = 1.88–5.38), counseling by health workers (aOR = 11.98, 95% CI = 2.20–65.15), trust in health workers (aOR = 152.96, 95% CI = 13.17–1776.09), and not taking other medicines for comorbidity (aOR = 35.82, 95% CI = 2.94–436.02) were associated with increased SDR uptake among leprosy contacts. Barriers and facilitators of post-exposure prophylaxis (PEP)-SDR were categorized as contact, health workers, and program-related factors. **Conclusion:** SDR acceptability among contacts was 77.4%. Facilitators of SDR-PEP were awareness of side-effects, follow-up, prompt support by health workers, IEC, belief in National programs, etc. Lack of knowledge of PEP-SDR and contraindications, ineffective counseling by health workers, stigma of the disease, the increased workload of health workers, etc., were the barriers to SDR-PEP implementation.

Key words: Contact tracing; Leprosy; Post-exposure prophylaxis; Prevention and control; Rifampicin

INTRODUCTION

India's achievement of the World Health Organization (WHO) target of elimination of leprosy in 2005 is deemed as a remarkable public health success story. However,

selected endemic districts with high new case burden, Grade-2 disabilities (G2D), and child leprosy rate still remain indicating active transmission of the disease. During 2021–2022, 75,394 new cases were detected in India, with an annual new case detection rate (ANCDR)

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of 5.09/1,00,000 population.¹ Thirty-four states/UTs (out of 36 states/UTs) and 645 districts (88%) out of total 733 districts achieved elimination by March 2022.¹ A total of 1,863 G2D were detected among the new leprosy cases during 2021–2022, indicating 2.47% G2D among new cases.¹ Cases among children was 4107 (5.45%) in 2021–2022.¹ Along with the burden of undetected cases, close contacts of patients represent a high-risk group for disease transmission.² Persistence of undetected cases in the community occurs due to low voluntary reporting, lack of awareness, fear, and social stigma necessitating the development of innovative strategies in curbing disease transmission.

Post-exposure prophylaxis (PEP) to contacts of leprosy patients has been successful in arresting disease transmission and reducing the number of new cases.³ Recent evidence suggests a promising new preventive strategy with single-dose rifampicin (SDR) that reduces the risk of developing leprosy among contacts by 60% over the next 2 years.⁴ PEP is administered in India under the leprosy PEP program along with seven other countries.^{5,6}

While SDR chemoprophylaxis regimen is safe, effective, without side effects, available and affordable, with little risk of developing drug resistance, only limited studies are available regarding the factors affecting acceptance of SDR. Lack of acceptability among the healthy contacts might pose as an important barrier to compliance with PEP and successful outcomes. The findings of this preliminary study can provide useful information about the sociocultural and sociobehavioural factors that influence the implementation of SDR and suggest strategies that could be adopted to increase the acceptance of SDR and provide feedback on challenges in program implementation to identify unaddressed concerns for planning and better utilization of allocated resources.

Aims and objectives

The objectives of the study were to assess the PEP-SDR acceptability rate, to determine the factors influencing the acceptability of SDR among contacts of leprosy patients, and to explore the barriers and facilitators of SDR uptake.

MATERIALS AND METHODS

Study design, settings, and study period

A community-based, sequential explanatory mixed-methods study was conducted in rural areas of two blocks of the Bankura District of West Bengal for duration of 6 months from September 2022 to February 2023 among contacts of leprosy patients and health workers. The study had two components, a quantitative part following an

observational cross-sectional analytical design to assess the acceptance of post-PEP with SDR among healthy contacts. The qualitative part involved focus group discussions (FGDs) among contacts and in-depth interviews (IDI) among health-care workers to assess the barriers and facilitators regarding acceptance of PEP.

Study population

Quantitative study – Adult contacts of newly diagnosed leprosy cases within the past 1 year under the Bankura (Sadar sub-division) district of West Bengal. Contacts of newly diagnosed leprosy cases who were permanent residents of the Bankura district for the past 3 years having contact (for a minimum 3 months/year) with untreated leprosy patients detected in the past 1 year and staying within approximately 100 m radius of the patient were included in the study. The exclusion criteria were age below 18 years, contacts of leprosy cases who did not give consent for disclosure of their status to their contacts, contacts who did not give consent, suspected or confirmed tuberculosis (TB) or leprosy patients, who received anti-TB treatment within the past 2 years, those with contraindications to rifampicin such as pregnancy, hypersensitivity to rifampicin, hepatic or renal disease, patients on antiretroviral drugs such as ritonavir, previous uptake of SDR, those who were taking rifampicin for any other disease or were severely ill. Standard definitions of family, household, neighborhood, and social contacts were used as per guidelines.⁷

Qualitative study – The study population was the ASHAs and ANMs of the selected areas giving their consent and being employed for more than 1 year in service and healthy contacts of newly diagnosed leprosy patients.

Sample size

Quantitative part – Assuming an SDR uptake of 71.6%,⁴ at 5% significance level, and an absolute error of 9%, the sample size was estimated to be 97 contacts. Accounting for a design effect of 1.5, the sample size required was 146, and adjusting for 20% non-response rate the total sample size was estimated at 183 participants. 183 participants were approached, but 15 contacts were not eligible, ultimately 168 contacts were included in this study.

Qualitative part – The sample size was determined by data saturation attained by informational redundancy.

Sampling technique

Quantitative part: At first, two blocks under Bankura district were selected based on ANCDR during last year, one each from high ANCDR and low ANCDR area. Based on inclusion and exclusion criteria, five leprosy cases per block were selected by simple random sampling. Contact tracing of the cases was done to get a line listing of 15–20

contacts on an average for each case of leprosy by ASHAs and ANMs and enrolled for the study till the required sample size was achieved.

Qualitative part: Purposive sampling of contacts of leprosy patients and key persons such as ASHAs and ANMs was done in the selected blocks for conducting FGDs and IDIs.

Study tools and techniques

Quantitative part – Conducted through face-to-face interviews of eligible contacts using a pre-designed pre-tested structured interviewer-administered questionnaire.

Qualitative part – Conducted through FGDs and IDIs using a semi-structured interview guide and audio recorder.

Study procedure

Quantitative assessment – The contacts fulfilling the eligibility criteria were enrolled after getting their written informed consent on participation. Data collection was done through house-to-house visits after a full explanation of the study purpose in the local language of the study purpose, risks, benefits, etc. Enrolment continued till the required sample size was obtained. Screening for leprosy cases and PEP-SDR were provided as per existing government guidelines.

Qualitative assessment – Consent was taken for audio recording from district authorities, contacts, and key informants such as ASHAs and ANMs. Four FGDs were conducted among healthy contacts using purposive sampling. Each FGD group consisted of 5–8 participants. Two IDIs were conducted among ASHAs and two IDIs among ANMs lasting for 20–30 min.

Study variables and data analysis

Quantitative data: Primary outcome was measured by the proportion of eligible contacts accepting SDR. Independent variables were sociodemographic characteristics such as age, gender, religion, educational status, marital status, and contact type. Other independent variables were knowledge score of contacts, counseling for PEP-SDR and side-effects by health workers, displayed IEC, trust in health workers, taking other medicines for comorbidity, and fear of adverse effects. Knowledge score was obtained by summing the scores obtained for 10-item knowledge questions related to the cause, transmission, stigma, and prevention of leprosy; each question was scored as 0 or 1 with total scores varying between 0 and 10. Data analysis was done using SPSS for Windows, Version 16.0. (Chicago, SPSS Inc.). Data were expressed in terms of numbers and percentages for categorical data and mean (\pm standard deviation) for continuous data. The chi-square test was done to test the association between categorical variables. Age and

knowledge scores did not follow normality; therefore, the Mann–Whitney U-test was done to assess the relation with SDR uptake. Variables with $P < 0.2$ in bivariate analysis were included in the logistic regression (LR) analysis. The statistical significance level was chosen at $P < 0.05$.

Qualitative data: Audio records were transcribed verbatim and translated into English. Thematic analysis was used for data analysis.⁸ The codes generated were assembled into probable categories that were continually revised to further generate and improve each theme. The conflict of opinions was resolved by discussion with experts. Data collection was stopped when theoretical saturation was reached and no original themes emerged. Finally, categorization into appropriate concept names of themes was decided by consensus of all researchers and applied to data. To ensure the validity of the data, the help of two researchers experienced in qualitative research was sought and member checking with health workers was done as a triangulation method. Integration of mixed-methods study was done at the design, analysis, and interpretation stage. Good reporting of a mixed-methods study reporting guidelines were followed.⁹

Ethical considerations

Ethical clearance was obtained from the Institutional Ethics Committee, Bankura Sammilani Medical College, West Bengal. Necessary permission to conduct the study was obtained from State, District, and Zonal leprosy officers and other concerned authorities. Written informed consent was obtained from respondents. Anonymity and confidentiality were maintained.

RESULTS

The mean age of the contacts was 37.4 ± 12.60 years (varying from 18 to 72). The majority of the contacts were female (51.8%), Hindu (91.1%), educated below middle school level (61.3%), married (64.9%), and neighborhood contacts (52.4%). The mean knowledge score of the contacts was 3.96 ± 1.98 , varying from 0 to 7. More than three-fourths (77.4%) of contacts had consumed PEP-SDR.

Factors affecting the uptake of SDR using bivariate analysis have been shown in Tables 1 and 2. Sociodemographic factors such as age, gender, religion, education, and marital status were not associated with the uptake of SDR. In bivariate analysis, factors such as type of contact, knowledge score of contacts, counseling regarding PEP-SDR and its side-effects by health workers (ASHAs/ANMs), trust in health workers, intake of other medicines for comorbidity, and fear of adverse drug reactions were found to be significantly

Table 1: Association between sociodemographic characteristics and SDR uptake among contacts of leprosy patients (n=168)

Variables	Sub-variables	SDR taken n (%) 130 (77.4)	SDR not taken n (%) 38 (22.6)	Test statistics χ^2 , df, p value
Age in years (Mean±SD)		37.2±12.65	37.9±12.56	Mann-Whitney U=2392.5, Z=-0.294, P=0.769
Gender	Male	59 (72.8)	22 (27.2)	1.843, 1, 0.175
	Female	71 (81.6)	16 (18.4)	
Religion	Hinduism	120 (78.4)	33 (21.6)	1.080, 1, 0.299 Fisher exact test P=0.334
	Islam	10 (66.7)	5 (33.3)	
Education	Below VIII	78 (75.7)	25 (24.3)	0.415, 1, 0.519
	VIII and above	52 (80.0)	13 (20.0)	
Marital status	Married	83 (76.1)	26 (23.9)	0.270, 1, 0.603
	Others	47 (79.7)	12 (20.3)	
Type of contact	Household	70 (87.5)	10 (12.5)	8.935, 1, 0.003
	Neighbor	60 (68.2)	28 (31.8)	
Knowledge score (Mean±SD)		4.50±1.78	2.1±(1.49)	Mann-Whitney U=772.5, Z=-6.529, P≤ 0.001

Bold values indicate p value <0.05 (statistically significant)

Table 2: Association between other variables and SDR uptake among contacts of leprosy patients (n=168)

Variables	Sub-variables	SDR taken n (%) 130 (77.4)	SDR not taken n (%) 38 (22.6)	Test statistics χ^2 , df, P value
Counseling for PEP-SDR by health worker	Done	95 (89.6)	11 (10.4)	24.592, 1, <0.001
	Not done	35 (56.5)	27 (43.5)	
Counseling for side-effects of PEP-SDR by health worker	Done	82 (90.1)	9 (9.9)	18.380, 1, <0.001
	Not done	48 (62.3)	29 (37.7)	
Seen IEC of PEP-SDR	Yes	42 (73.7)	15 (26.3)	0.674, 1, 0.412
	No	88 (79.3)	23 (20.7)	
Trust in health workers	Yes	98 (90.7)	10 (9.3)	30.837, 1, <0.001
	No	32 (53.3)	28 (46.7)	
Taking other medicines for comorbidity	Yes	55 (68.8)	25 (31.2)	6.5, 1, 0.011
	No	75 (85.2)	13 (14.8)	
Fear of adverse drug reactions	Yes	33 (62.3)	20 (37.7)	10.109, 1, 0.001
	No	97 (84.3)	18 (15.7)	

SDR: Single-dose rifampicin, Bold values indicate p value <0.05 (statistically significant)

associated with SDR uptake.

LR was performed to ascertain the effects of the predictor variables with $P < 0.2$ in bivariate analysis on the likelihood of uptake of SDR. All the assumptions of LR were met. The LR model was statistically significant, $\chi^2(8)=125.52$, $P < 0.001$ and correctly classified 91.7% of cases. The model explained 80.1% (Nagelkerke R^2) of the variance in SDR uptake. Hosmer–Lemeshow test showed that the model had a good fit ($P=0.806$). Household contacts, increasing knowledge score of contacts, counseling for PEP-SDR by health workers, trust in health workers, and not taking other medicines for comorbidity were associated with increased uptake of SDR (Table 3).

To further understand, the barriers and facilitators of SDR uptake, FGDs, and IDIs were conducted among contacts of leprosy patients, ANMs, and ASHAs. Tables 4 and 5 reflect

the codes and categories derived from the transcripts. Both barriers and facilitators of SDR uptake were attributed to factors related to “contacts,” “drug administrators/health workers” and “program.” Following are some of the quotes.

Barriers to SDR uptake

Contact-related factors

Non-acceptance of being healthy

“If the drug is given to people, everyone might not take it. They will say, I am not suffering from any disease; I will not take it. Why should I take it?” (ASHA, 30 years, and block T).

Fear of side-effects

“There could be allergy, palpitations, etc., I get sick with the slightest smell of medicine” (Contact, 45 years, and block A).

Table 3: Factors affecting SDR uptake among the contacts of leprosy patients using multivariable binary logistic regression (n=168)

Variables	β	Significance	Crude OR (95% CI)	aOR (95%CI)
Gender (females)	1.32	0.92	1.66 (0.80–3.44)	3.75 (0.81–17.38)
Type of contact (household)	2.62	0.006	3.27 (1.47–7.27)	13.72 (2.09–90.19)
Knowledge score of contacts	1.16	<0.001	2.04 (1.60–2.62)	3.18 (1.88–5.38)
Counseling for PEP-SDR (done)	2.48	0.004	6.66 (2.99–14.84)	11.98 (2.20–65.15)
Counseling for side effects of PEP-SDR (done)	2.23	0.074	5.51 (2.40–12.60)	9.25 (0.81–105.95)
Trust in health workers (yes)	5.03	<0.001	8.58 (3.76–19.57)	152.96 (13.17–1776.09)
Taking other medicines for comorbidity (No)	3.58	0.005	2.62 (1.23–5.58)	35.82 (2.94–436.02)
Fear of adverse drug reactions (No)	0.70	0.440	3.27 (1.54–6.91)	2.01 (0.343–11.76)
Constant	-10.81	<0.001		0.00

SDR: Single-dose rifampicin, Bold values indicate p value <0.05 (statistically significant)

Table 4: Transcripts derived codes and categories reflecting the barriers of SDR uptake

Codes	Categories	Theme
Lack of knowledge of disease, transmission, and prevention	Contact-related factors	Barriers of SDR uptake
Pill burden		
Fear of disease occurrence because of consumption		
Fear of side-effects of drug		
Non-acceptance of being healthy		
Stigma of disease and status disclosure		
Discouragement from family		
Work-related absence	Drug administrator (DA)/health worker-related factors	
Increased work load		
Lack of knowledge or wrong knowledge of transmission and prevention		
Improper counseling before drug distribution		
Wrong knowledge of contraindications of drug	Program-related factors	
Patient dissatisfaction with ongoing other programs		

SDR: Single-dose rifampicin

Table 5: Transcripts derived codes and categories reflecting the facilitators of SDR uptake

Codes	Categories	Theme
Awareness of possible side effects (very few side effects)	Contact-related factors	Facilitators of SDR uptake
Health-seeking behavior		
Fear of discrimination from society	Drug administrator (DA)/health worker-related factors	
Faith in health worker		
Effective counseling before drug distribution		
Counseling regarding PEP-SDR side-effects		
A good relationship, helpful attitude, and prompt support		
Follow-up of contacts		
Supervised drug administration		
Belief in National programs	Program-related factors	
IEC-Miking, signboards		
Accompaniment of multipurpose workers for solving queries		

SDR: Single-dose rifampicin

Health worker-related factors**Wrong or no knowledge of disease transmission**

“Patient should stay in one room, should urinate or defecate in designated place but not outside, should not share food.” (ASHA, 28 years, and block T).

“I do not know how it spreads. Please tell.” (ASHA, 35 years, and block T).

Improper counseling before drug distribution

“We have not consumed, it because we do not know what the drug is for? What is the utility? Health workers

just handed it over to us” (Contact, 45 years, female, and block A).

Wrong knowledge of contraindications of the drug

“ASHA did not give me drugs because of high pressure. She said I cannot be provided drugs because of pressure.” (Contact, 50 years, male, and block A).

Program-related factors**Dissatisfaction with ongoing programs**

“Two of our leprosy patients were sent for corrective surgery. They are not satisfied. They ask us why the OT was

done? There is no improvement. Even the shoes provided do not fit and seem useless” (ANM, 32 years, and block T).

Facilitators of SDR uptake

Contact-related factors

Fear of discrimination from society

“If we do not consume the drug given by health workers, then we might face discrimination from people” (Contact, 40 years, female, and block T).

Health worker-related factors

Faith on health worker

“People believe in our words. They will consume whatever we give, believing us. We have reached that level of trust or image.” (ANM, 32 years, and block T).

Good relationship, helpful attitude, and prompt support

“Our numbers are with them. They contact us for their every problem. They always take suggestions from us. We always help and support them.” (ANM, 32 years, and block T).

Program-related factors

Belief in national programs

“The drug must be able to prevent the disease after all it must have come after rigorous testing or examination” (ANM, 35 years, and block T).

DISCUSSION

Ongoing leprosy transmission is a threat to the vision of leprosy-free India. To make the nation leprosy-free, there is a need for scaling up leprosy prevention coupled with early detection and prompt treatment. PEP-SDR has been shown to be an effective chemoprophylaxis for the prevention of leprosy.^{4,10} Despite the compelling evidence, the uptake of SDR-PEP is still low, and the WHO has emphasized its scaling up in the new Global Leprosy Strategy 2021–2030.^{11,12}

In the current study, 77.4% of contacts had consumed SDR. This acceptability rate was similar to Richardus et al.⁴ studies conducted in seven countries including India. Although the overall SDR acceptability rate in all countries was 86.9%, SDR uptake in India was reported to be 71.6%.⁴ Tiwari et al.¹³ also reported the SDR acceptability as 79%. Since the inception of PEP-SDR implementation in India, Khobragade,¹⁴ Ministry of Health and Family Welfare, reported 65.35% SDR administration to contacts till August 2020. However, Apte et al.¹⁵ reported 98.6% compliance rate among contacts in Dadra and Nagar Haveli (DNH) for which they found the reasons for the high compliance rate to trust in the health workers, health staff, and

gender-sensitive approach. The non-compliance in their study was due to some tribes, who never used to accept government services. The current study did not reveal the need for a gender-sensitive approach.

There are extremely few studies assessing the factors affecting the acceptability of SDR. The current study revealed that household contacts had higher SDR acceptability compared to neighborhood contacts. This could be because of the actual perception about the disease from leprosy cases among household members. It was also found that contacts who had higher knowledge scores regarding leprosy and PEP-SDR had higher SDR acceptability rates. Both of these factors were not probed in other studies. The study by Peters et al.¹⁶ revealed that incorrect health information that was retained posed a challenge for PEP. Research done by Mieras et al.¹⁷ showed that implementation of SDR-PEP and accompanied education led to increased knowledge of leprosy among patients, contacts, and community members.

In the current study, it was found that contacts who received counseling regarding PEP-SDR by the health workers had higher SDR acceptability. Even as per national guidelines, the health workers have important roles and responsibilities to inform about leprosy prevention and chemoprophylaxis before administering PEP,^{18,19} however, this is not properly followed. This was further reflected in qualitative study findings. One of the contacts from block A during FGD said that “We have not consumed, because we do not know what it is for? What is the utility? Health workers just came and handed over it to us and asked to consume it without talking about it.” Similar findings were obtained from a study done by Apte et al.¹⁵ where a health worker said that “It is necessary that the person understands what this medicine is for and what will happen or not happen after taking the tablet.”¹⁴ The same study¹⁵ revealed that the reason for SDR-PEP acceptability as per most of the contacts was the understanding that the drug prevents from getting the disease and spreading the disease.

The current study revealed that those contacts who had trust in health workers had higher SDR acceptability. Similar results were obtained from Apte et al.¹⁵ where it was found that a high level of trust in health workers was an important factor that contributed to the successful introduction of the SDR-PEP intervention in DNH. The same was also reflected from a qualitative study where a health worker revealed that we have reached that level of image or trust that people will consume whatever we give believing us.

It was found in the current study that those who were taking other medicines for comorbidity had lower SDR

acceptance. Inadequate knowledge of the contraindications of drugs among health workers further posed a threat to the successful implementation of SDR-PEP. Some of the health workers in the current study did not give SDR-PEP to contacts with hypertension. Similar findings were obtained from Apte *et al.*¹⁵ where it was revealed that a couple of participants refused to take the medicine provided by the health workers as they were on other medication. This further emphasized on the need to have properly trained health staff.^{15,19,20}

Limitations of the study

Though PEP-SDR is eligible for 2 years and above, yet the study was limited to adults to avoid the additional requirement of assent from grown-up children, consent from parent/guardian, and possible non-uniformity in the respondents for the study purpose. Second, the study was limited to only two blocks within the Bankura District of West Bengal.

CONCLUSION

The study revealed the acceptability of SDR among leprosy contacts in selected blocks of Bankura district, which is a highly endemic district in West Bengal for leprosy. The study provided insights into the barriers to SDR acceptance such as neighborhood contacts in comparison to household contacts, poor knowledge among contacts about leprosy and PEP-SDR, ineffective or inadequate counseling by health workers, lack of trust in health workers, and inadequate knowledge of contraindications of PEP-SDR. At the same time, awareness of possible side-effects of SDR, prompt support, resolution of queries and follow-up of contacts by health workers, belief in National programs, etc. were the facilitators of PEP-SDR implementation.

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