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Cost Effective Analysis: Updated Thai Red Cross Intradermal Regimen in Animal Bite Cases

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Abstract

Rabies is considered one of the most fatal diseases. South East Asian countries show relatively high prevalence of rabies and considerable deaths due to rabies, which is totally preventable by simple measures like wound cleaning and prompt, complete Post exposure prophylaxis. There are currently two regimes in practice to provide PEP, one is 5 doseIM Essen Regime and the other 4 dose updated Thai Red Cross regime. This study compares the two regimes based on their cost effectiveness. Cost effectiveness is an important measure which helps policy makers to utilise the ever dwindling resources in an attempt to improve population health. The study findings indicate that the Updated Thai Red Cross regime is cost effective than the Essen Regime not only with regards to the cost of the vaccine, but also for improving the compliance of the patient and ensures completion of PEP which is essential for the prevention of Rabies and its fatality. **Key words**: Rabies, Cost effectiveness, Post exposure prophylaxis.

Introduction

Every health program or intervention aspires to maximise the population health. Scarcity of resources especially in developing countries like India makes it obligatory to look for cost-effective alternatives to the existing traditional ways of diagnosis and treatment. There is a need for maximum utilisation of the resources, and therefore make funds and resources available for opportunities that may have been otherwise lost.

2015

Estimating the costs of health interventions is important to policy-makers for a number of reasons including the fact that the results can be used as a component in the assessment and improvement of their health system performance⁽¹⁾ Health interventions is any use of resources aimed at improving health outcomes be they preventive, promotive, curative. rehabilitative or palliative⁽²⁾Cost-effectiveness analysis is effective in decreasing the disease burden, by promoting interventions that comparatively less are expensive.

Rabies being invariably fatalcan be readily prevented by prompt and appropriate post exposure prophylaxis. Therefore PEP is the most criticallifesavingintervention essential for the prevention of rabies in humans after exposure. Most of the estimated 7 million people exposed to rabies live in resources poor countries, where lifesaving vaccines are not always available and easily affordable.⁽²⁾

In some countries, governments provide vaccine free-of-charge or subsidize its cost,but budgets allocated for this are often insufficient, resulting inshortages or leaving only a few centres with a reliable supply ^{(2).} Similar situation exists in Maharashtra where the Anti-rabies vaccine is available free of cost at the government hospitals, but many a times interrupted supply due to budgetary constraints lead to unavailability of the vaccine at the health facility. The unavailability of vaccines has an even greater impact as it the animal bite patients fail to promptly obtain and complete PEP resulting in rabies death. Thus the policy for prevention of rabies should aim at improving the vaccine supplies, reducing the indirect costs like (travel cost, loss of wages etc.) and enhance the compliance of the animal bite patients to PEP.

In this study we compare the cost effectiveness of the two PEP regimes currently in practice in the state of Maharashtra and discuss the effects of PEP in terms of its, availability and accessibility, thereby providing supportive evidence for policy makers and prompting further research.

Methodology

The present study was planned as a Retrospective record based study. The study wasconducted at the Anti-Rabies Clinic of Government Hospital and Medical Collegefrom rural Maharashtra.

All the animal bite cases attending the ARV clinic were categorised and treated according to the institutional protocol, which is updated regularly as per the national guidelines of DGCI.

The Updated Thai Red Cross regime was introduced in the hospital in March 2008. For the purpose of the study two years data before and after implementation of the Updated TRC regime (period of March 2006- February 2010) was obtained. The data was organised so that all animal bite cases treated with 5 dose Essen regime from March 2006 to February 2008 were taken as one group and all animal bite cases treated with Updated Thai Red Cross regime from March 2008 to February 2010 were included in the other group.

Name of the regime	Route of	Dosage	No of injections	Volume of vaccine	Total visits
	administration	schedule	required per visit	used per course	required
Essen 5 dose regimen	IM	0,3,7,14,28	1-1-1-1-1	5 ml	5
Updated Thai Red	ID	0,3,7,28	2-2-2-2	0.8 ml	4
Cross Regimen					

Table 1: The details of the two regimes that were compared for cost effectiveness.

The following information regarding the patients was obtained from the records maintained at the ARV clinic as well as the Medical Store.

- Number of new cases attending the clinic during the study period,
- Number of follow up cases for subsequent vaccination as per schedule,
- Number of vaccine vials utilized during the specified period
- Number of total cases vaccinated during the study period
- Government rate purchase cost of vaccine per vial

Based on the above data, the no of patients provided PEP under each regime was summed up. Total cost spent on the vaccine in each regime was calculated and compared. The Cost of Rabies Immunoglobulin and indirect cost like travel cost, loss of wages etc., was not included in the study. The data was analysed with MS excel.

Results

The study results show that in all 22975 number of patients presented to the Anti- rabies Vaccine clinic during both regimens period. Of which 51% & 49% cases were vaccinated during Essen IM & Updated TRC ID regimen period respectively.

Table 2: Regimen wise distribution of animal bite cases vaccinated, actual vaccine vials utilized and its cost during the study period.

Name of the regime	New cases	Follow up	Total cases	No of vaccine	Total cost of
		cases		vials utilised	the vials
Essen 5 dose regime	7462	4264	11726	11750	25,73,250
	(61.2)	(39.5)	(51.0)	(70.0)	(70.0)
Updated Thai Red	4733	6516	11249	5049	11,05,731
Cross ID regime	(38.8)	(60.5)	(49.0)	(30.0)	(30.0)

According to the available literature, the vaccine wastage is about 0.2% and 10.8% during Essen IM regimen and Updated TRC ID regimen

respectively. The above table shows a total of Rs 14,67,519 (57%) reduction on cost spent on vaccine by changing regimen from Essen IM regimen to Updated TRC ID regimen.

2015

Table 3:Estimated total visits to ARV clinic, Vaccine vials and its cost for new cases completing the schedule of intramuscular and intradermal regimen during thestudy period.

	New cases	Required Number	Total Estimated	Estimated vaccine	Estimated total
	attended	of Visit to ARV	visits to ARV	vials including	Vaccine vial
Regimen	ARV clinic	Clinic for complete	Clinic for	wastage factor for	cost (Rs).
		schedule per new	completing	vaccination	
		case	schedule		
Essen IM	7462	5	37310	37386	81,87,534
regimen					
Updated TRC	4733	4	18932	8391	18,37,629
ID regimen					
-					

The above data shows that, when total vaccine vials as per the new cases attending the ARV clinic during the two different regimes were estimated, and the total cost of the vaccine vials was calculated, it showed 77% of cost reduction with Updated TRC ID regimen as compared to Essen IM regimen. Also when it was assumed that the same number of cases attended ARV Clinic during both period, it showed 69% of cost reduction in vaccine vial cost with Updated TRC ID regimen.

Discussion

To put it simply resources, people, time, facilities, equipment, and knowledge are scarce. Choices must and will be made concerning their deployment and methods such as 'what we did last time', educated guesses 'are rarely better than organised consideration of the factors involved in a decision to commit resources to one use instead of another⁽³⁾

One of the obstacles for inefficient utilisation of resources is lack of data on cost and effectiveness.For most countries, but particularly for low- and middle-income countrieswhere the majority of the world's poor live, there has been little progress towards the goal of providing affordable and timely information on the costs and effects of a wide array of interventions to inform policy.

Developing countries like India face a dual challenge of providing quality health services and also optimum utilisation of the scarce resources.

Severely fatal disease like rabies can be prevented by simple treatment like wound cleaning and prompt and complete Post exposure prophylaxis. Incomplete PEP vaccination is lesseffective and almost 10% of human rabies cases reported from study in India had received incomplete PEP vaccination with CCVs⁽²⁾

The key element in prevention of Rabies and untimely deaths due to the disease is complete PEP. This PEP can be ensured to all the patients seeking treatment for animal bite cases by providing uninterrupted supplies of vaccine at all levels of health delivery system. Constraints on resources and unavailability of vaccines forces the patients to travel to far off places for getting the PEP , or spend out of pocket , this affects the

2015

compliance of the patients towards completing the PEP schedule

Following WHO approval of Updated Thai Red Cross intradermal (ID) administration of PEP vaccines, there has been significant discussion of the value of ID versus intramuscular (IM) vaccine delivery for animal bite cases.^[4]

The study revealed that during Essen IM regimen period, total estimated subsequent visits of new cases considering five visits for each case to attend ARV clinic for completing schedule was 37,310 cases, but out of this, 4264 (12%)cases attended ARV clinic while out of 18.932 estimated cases, 6516 (35%)cases attended during Updated TRC intradermal regimen. The study shows that follow up cases for completing the schedule during intradermal regimen increased from 12% to 35%. This could be because of non availability of the vaccine at the study centre during the study period, forcing the patients to go to other centres for vaccination, or less number of visits for intradermal regimen increases the compliance.Katie Hampson et al study results provide evidence to show that a simplification to universal ID delivery of PEP could have massive advantages in low-income countries, reducing the volume of vaccine use, mitigating vaccine shortages and making PEP more affordable to the most vulnerable.^{[2].}

This favours the hypothesis of the current study that less number of visits as well as less no of vials of ARV vaccine per person leads to availability of vaccine for more no of patients, thereby improving the PEP for animal bite cases and thus causing a greater impact of averting considerable deaths due to rabies. Thus Use of intradermal route of administration of anti-rabies vaccine allows wider coverage of PEP in available quantity of vaccines and hence makes it cost effective.^[5]

Also the present studyindicates that almost equal number of total cases received ARV vaccine doses during intramuscular (51%) as well as intradermal (49%) regimen and further data shows that of the total vials during the study period,30% of the vaccine vials were utilized during the intradermal regimen as compared to 70 % vaccine vials utilized during the intramuscular regimen.

Our findings are similar with the Katie Hampson et al^[2] stating that, in animal bite cases attending clinics, the updated TRC and 4-site ID regimens use just 40% of the volume of vaccine in comparison to conventional IM regimens (Essen 5-dose) when 0.5 ml vials are used and 20% of the volume when 1 ml vials are used.

Higher cost of intra-muscular administration of CCV is a limiting factor for its wider use. ^[5]The total cost spent on vaccine is directly related to the vaccine utilized during both regimens.

57 % of cost is saved during intradermal regimen as compared to intramuscular regimen though the number of total cases attended, werealmost similar. Shantavasinkul P&Wilde H stated that the intradermal PEP regimen can now reduce the vaccine cost by ~60-70%.^[6] Quiambao BP et al also stated that Purified chick embryo cell rabies vaccine (PCECV) administered as 0.1 ml intradermally, according to the Thai Red Cross (TRC) regimen could reduce the cost of PEP by up to 84% when compared to the traditional five-dose Essen regimen.^[7]

2015

Clinical trials conducted in India proved intradermal route to be safe, efficacious and feasible for use in the country. ^[5]The immune response induced by ID administration of anti-rabies vaccine is adequate and protective against rabies. ^[5] Subsequently DCGI has approved IDRV. And according to the guidelines, an ideal IDRV clinic should be any hospital (preferably public health hospitals) treating on an average four or more case of animal bites per day. Medical officers and staff nurses (or health staff) trained for ID administration. Having adequate supply of insulin syringes, 26G needles, approved ID rabies vaccines, posters and patient education materials. All reconstituted vaccine unused at the end of 6-8 h must be discarded. The two site ID route is ideal in terms of economic benefits, safety and efficacy

Despite being more economical, misperceptions about ID, the lack of strong recommendations and a profusion of complex schedules have deterred their widespread adoption. The updated TRC is the only currently WHO approved ID regimen. Giving vaccine intradermal is not a big issue as onsite training for the health care staff can be provided.

Increased use of ID regimens could therefore prevent vaccine shortages and enable wider vaccine distribution, both increasing the number of patients that can be treated and the overall accessibility of PEP.^[2]

To strengthen the Intradermal Regime, it is necessary to publicize the benefits and usefulness of the regime among the government institutes, but mainly in the private practitioner sector. Related research in the above area is desirable so as to build supportive evidence in the same. At the heart of any policy change is the belief that scarce health resources should be allocated, in a manner, so as to provide the highest level of health benefit to the population.

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2015

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