Published in final edited form as:

Vaccine. 2009 November 27; 27(51): 7167–7172. doi:10.1016/j.vaccine.2009.09.027.

Evaluating the cost-effectiveness of rabies post-exposure prophylaxis: A case study in Tanzania

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Abstract

Although fatal if untreated, human rabies can be prevented through post-exposure prophylaxis (PEP), which involves a course of vaccination and immunoglobulin administered immediately after exposure. However, high costs and frequent lack of rabies vaccine and immunoglobulin lead to about 55,000 deaths per year worldwide. Using data from a detailed study of rabies in Tanzania, we calculate a cost-effectiveness ratio for PEP when the WHO-recommended Essen regimen, a 5-dose intramuscular vaccination schedule, is adopted. Our analyses indicate a cost-effectiveness ratio for PEP of \$27/quality-adjusted life year (QALY) from a health care perspective and \$32/QALY from a societal perspective in Tanzania. From both perspectives, it is “very cost-effective” to administer PEP to patients bitten by an animal suspected to be rabid. Moreover, PEP remains “very cost-effective” provided that at least 1% of doses are administered to people who were actually exposed to rabies.

Keywords

Cost-effectiveness; Rabies; Post-exposure prophylaxis

1. Introduction

Despite the existence of post-exposure vaccines for victims of rabid-animal bites since 1885, an estimated 30,000–70,000 people die worldwide of rabies each year [1]. Most of these deaths occur in developing countries because of inadequate control of rabies in domestic dog populations. Although the death rate can be lowered substantially through the use of effective rabies post-exposure prophylaxis (PEP) [2], the economic impact of rabies is significant in many developing nations where rabies carries a considerable public health

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burden. Costs are incurred directly for wound treatment, from PEP, and indirectly from transportation, accommodation and income loss while obtaining PEP.

In the case of a bite by a rabid animal, effective PEP comprises immediate washing of the wound(s) followed by prompt administration of a cell-culture vaccine (CCV) and purified rabies immunoglobulin (RIG) according to World Health Organization (WHO) recommendations [3]. As RIG is extremely expensive and rarely available in developing countries, the rabies vaccine is often the only means of protection. Although safe and effective, CCVs are also expensive and often in short supply. Reducing their cost and preventing delays in administration are particularly important in resource-limited settings. Indeed, the incidence of rabies in developing countries might be directly affected by the inability of rabies-exposed victims to afford PEP.

We describe an approach to estimating the cost-effectiveness of PEP against human rabies using intramuscular administration of rabies vaccine based on the WHO-recommended Essen regimen in the United Republic of Tanzania. We use epidemiological parameters estimated from a detailed study in Tanzania on the accuracy of rabies recognition, the distribution of bite injuries by suspect rabid animals, the age profile of bite victims, the proportion of bite victims that develop clinical disease, and the costs associated with bites from suspected rabid animals. In our analysis, we evaluated the cost-effectiveness of PEP in Tanzania from both health care and societal perspectives. We conclude that PEP is a very cost-effective intervention that substantially reduces the health burden associated with rabies infections. In addition, we find that PEP is still very cost-effective even when 99% of bite victims to whom PEP is administered have not been exposed to rabies.

2. Methods

2.1. Data collection and parameter estimation

We collected data on victims bitten by suspected rabid animals from two administrative districts in Northwest Tanzania: Serengeti, which is inhabited by multi-ethnic, agro-pastoralist communities and has a high-density dog population, and Ngorongoro, which is inhabited by low-density pastoralist communities and has a lower density dog population [4,5]. We used records from hospitals and medical dispensaries that provided details of patients with animal-bite injuries ($n = 1322$) as well as case reports from livestock offices and community-based surveillance activities as primary records to initiate contact tracing of potential rabies-exposures. We traced 1080 of the incidents that occurred between January 2002 and December 2006 to investigate whether potentially suspect rabid animals were involved. We conducted interviews to assess the case history of the exposed individual, to identify the source of exposure and other contacts if known as well as the actions taken to administer first aid and seek further medical attention. The same procedure was followed for all associated exposures/cases to give a total of 648 exposures. We diagnosed cases in animals using the 'six-step' method [6] based on epidemiological and clinical criteria [4,5,7] through retrospective interviews with witnesses. Wherever possible, we collected brain samples from animals that caused bite injuries, which were then tested for case confirmation, and laboratory results were used to calculate the rabies recognition probability [7].

To assess the risk of developing rabies following a bite by a suspect rabid animal, we calculated the proportion of bites by suspect rabid animals to different parts of the body, and the probability of subsequently developing rabies for those individuals that did not receive PEP (Table 1). We report binomial confidence intervals for all estimates of proportions. The age distribution of bite victims was estimated by fitting a gamma distribution to the ages of

individuals bitten by suspect rabid animals using Maximum Likelihood (shape parameter 1.54, 95% CI: 1.39–1.70 and rate parameter 0.088, 95% CI: 0.078–0.098) (Fig. 1).

2.2. Model

To calculate human mortality associated with rabies in Tanzania, we constructed a probability decision-tree model using the probability and outcome data (Fig. 2). This model allows us to calculate the cost-effectiveness ratio of PEP following various outcomes of bites from rabid animals using a series of probability steps, P_1 – P_3 . We assumed that individuals seek PEP with a probability P_1 when bitten by a suspect rabid animal. If the suspect animal was rabid with a probability of P_2 and PEP was not administered, then the patient will develop rabies with a probability P_3 (Table 1). Prompt administration of WHO-recommended vaccine schedules and purified rabies RIG is almost 100% effective in preventing the onset of rabies [8]. Thus, we assumed 100% efficacy of PEP when the animal was rabid. If the animal was not rabid, then normal life expectancy in Tanzania will follow, regardless of administration of PEP.

An animal that inflicts bites is classified as suspect if reported as such or if neurological signs and/or unprovoked aggression are reported [7,9]. Relatively few samples were recovered from suspected rabid animals, but previous data shows that suspected rabies cases are usually reported accurately [7]. Therefore, we assume that a suspect animal is rabid with an average probability of P_2 (0.75).

The outcome of a bite from a rabid animal is partially dependent on the location of the bite on the body. The model uses the distribution of injuries on the body together with the likelihood of the patient developing rabies, based on contact-tracing data collected on the outcome of untreated bite injuries produced by rabid animals in Tanzania (Table 1). Bites on the head, face and neck, for example, carry a much higher risk of developing rabies than bites on a foot or leg [9]. We calculate the probability of dying of rabies following a bite from a suspected rabid animal, P_{Death} , from the probability tree (Fig. 2) without PEP as $P_{\text{Death}} = P_2 \cdot P_3$.

2.3. Quality-adjusted life year score

The outcomes in our model are expressed in quality-adjusted life years (QALYs). The QALY score is a measure of overall disease burden, including both quality and quantity of life lived. It is calculated based on the number of years of life that would be added by the intervention. An individual living in full health has a weight of one and a death has a weight of zero. If the extra years would not be lived in full health, then the extra life years are given a value between zero and one to account for this. One QALY, therefore, is equal to 1 year of perfectly healthy life, where one QALY gained is analogous to one disability-adjusted life year (DALY) averted. To calculate a QALY score for rabies we considered the mortality due to the disease. For treated bites from rabid animals, we used the standard life expectancy; for untreated bites from rabid animals, we assumed that the quality-adjusted life expectancy is zero.

2.4. Costs

The economic costs associated with rabies infection include both direct (medical) costs from PEP and indirect (non-medical) costs. Cost data were based on previous literature on rabies burden and vaccination [1], and on current data from Tanzania (Tables 2 and 3). For our study, direct medical costs include the cost of PEP with rabies vaccines and RIG, as well as the cost of their administration. Indirect costs include transport to and from medical centers for each dose of PEP, accommodation costs, and loss of income while receiving PEP. We assumed that all the children under 16 years were accompanied by an adult. Therefore,

transportation costs are assumed to incur to both patients and those accompanying them. For the analysis, the costs of rabies vaccine were based on the cost to the Government of Tanzania, i.e., 11,000 Tanzanian shillings (~US \$10) per vial [1,10]. However, bite victims frequently acquire vaccine privately because government-procured vaccine is not always available and victims pay 25,000 Tanzanian shillings (~US \$20) per vial of vaccine. Therefore, we also carried out sensitivity analysis by varying the cost of PEP.

2.5. Cost-effectiveness ratio

To assess the balance between the cost and incremental health effects of PEP, we performed a cost-effectiveness analysis. We calculated the cost-effectiveness from a health care perspective whereby only medical costs (to the health provider) are considered, and from a societal (or public health) perspective, whereby both medical and non-medical costs are included (i.e., costs to both the health provider and to the bite victim). We discounted costs and benefits at 3% per year and the future benefits of normal life expectancy of 51 years in Tanzania [11]. We further assumed that clinical cases of human rabies have only one outcome (death) and that PEP is completely effective in preventing a clinical case of rabies and resultant death, if administered as recommended [2,3,12].

We evaluated cost-effectiveness ratios as the incremental cost-effectiveness ratio (ICER) in terms of dollars per QALY gained:

$$\frac{\text{Costs}_{\text{PEP}}}{\text{Effectiveness}_{\text{PEP}} - \text{Effectiveness}_{\text{NoPEP}}},$$

where subscripts 'PEP' and 'No PEP' refer to individuals who received PEP and those who did not receive PEP, respectively. The ICER was calculated as the cost of PEP divided by QALY gained (Table 4).

We used the *World Health Report* 2002 standard of cost-effectiveness [13,14]. This standard defines cost-effectiveness depending on GDP (gross domestic product) per capita. Interventions that gain each additional QALY at a cost less than GDP are "very cost-effective", whereas interventions that gain each additional QALY at a cost less than three times the GDP per capita are "cost-effective" [14,15].

3. Results

When the standard WHO-recommended 'Essen' regimen is used, the cost-effectiveness ratio for PEP in Tanzania is US \$27/QALY from a health care perspective and US \$32/QALY from a societal perspective. The costs per QALY gained are much less than the GDP of US \$1,400 per capita in Tanzania, which demonstrates that PEP is a very cost-effective intervention that substantially reduces the health burden associated with rabies infections, based on WHO guidelines [13,14]. In addition, the cost-effectiveness ratio from a health care and societal perspective is estimated at US \$555 and US \$668 per life saved, respectively. When government vaccine is not available and animal-bite victims purchase vaccine privately at US \$20 per dose [1,10], the cost-effectiveness ratios from a health care and societal perspective become US \$910 and US \$1024 per life saved, respectively.

Children were bitten by suspect rabid animals disproportionately more often than adults (Fig. 1) [5]. The mean age of rabies victims in Tanzania is 18 years, resulting in 4.8 QALYs lost on average per bite victim who did not receive PEP (Figs. 3 and 4). Based on the age profile of bite victims and the number of annual rabies deaths thought to occur currently (~1500 [9]), we estimate that a total of 5693 QALYs could be gained each year in Tanzania

if all victims of bites from suspected rabid animals received appropriate PEP. The cost-effectiveness of PEP administration decreases (i.e., costs per QALY increase) with the age of infection, because the QALYs gained decrease as the age of infection increases (Fig. 3). In Northern Tanzania only 86% of patients who report to hospital receive PEP, as a consequence of vaccine shortages and/or inability to pay for the vaccine [5]. By preventing PEP shortages and providing PEP free-of-charge to all rabid-suspect animal-bite injury patients, at least 30% of current human rabies deaths could be prevented very cost-effectively.

If PEP were to be administered indiscriminately to patients reporting with animal-bite injuries, including to those with little or no possibility of genuine exposure to the virus, a threshold could be reached whereby PEP administration is no longer cost-effective. Our model shows that the probability of receiving PEP following an animal bite for which the intervention is no longer “very cost-effective” is 1% (Fig. 5). Consequently, the rabies recognition probability (P_2) would need to be less than 0.01, such that 99% of patients unnecessarily receive PEP following bites by non-rabid animals. Thus, we conclude that even when 99% of bite victims to whom PEP is administered have not been exposed to rabies the intervention is still “very cost-effective”. The price of PEP per dose for which the intervention no longer becomes “very cost-effective” is US \$810 from a health care perspective and US \$805 from a societal perspective (Fig. 6).

4. Discussion

We developed a decision-analysis of rabies infection to evaluate the cost-effectiveness of PEP in Tanzania. Our study demonstrates that, although the cost of human rabies vaccine and RIG are relatively expensive compared to other therapeutic agents, PEP is a highly cost-effective intervention in terms of saving human lives and averting QALYs lost when administered to people bitten by rabid-suspect animals in Tanzania. The high cost-effectiveness in terms of QALYs saved partly reflects the age distribution of animal-bite victims, with children bitten disproportionately more often than adults; averting the death of a child through PEP results in more QALYs saved than averting the death of an adult.

We also present the first detailed rabies contact-tracing study in Tanzania. From these results, we calculated the proportion of people bitten by rabid animals who subsequently develop rabies, in relation to age, site of wound and PEP administration. These data (shown in Table 1) are broadly consistent with results of much earlier studies, including studies that report the outcome of rabid wolf bites, and support the notion that the risk of developing rabies is much greater when bites are inflicted in the head and neck area than when inflicted on the torso or foot [16-19].

Many bite victims (~25% in Northern Tanzania) do not attend hospital and do not seek PEP, primarily due to a lack of awareness [5]. Our study shows that PEP is “very cost-effective” and thus reinforces the importance of health departments providing information about rabies prevention to those currently unaware of the critical importance of receiving prompt PEP. In almost all rabies endemic countries, these individuals comprise predominantly the rural poor, who are most at risk of rabies. Efforts to raise the awareness about the importance of seeking PEP that target these communities are therefore recommended. In other situations, bite victims do attend hospital for treatment, but vaccines are not available [20]. Although we assumed delivery of RIG to all bite victims, in many developing countries RIG is not available and therefore delivery of rabies vaccine is often the only means of protection. Our estimates of the cost of PEP are therefore greater than current expenditure, but this study indicates that investing in supplies of RIG would be “very cost-effective”, especially when delivered to those most at risk with serious injuries to the head, face and neck. Given the

cost-effectiveness of the intervention, it is clearly a judicious investment for health departments to ensure availability of PEP.

Despite the cost-effectiveness of PEP (as defined by WHO), the relatively high costs of human rabies vaccine and RIG mean that optimization of PEP remains a key issue in rabies endemic countries, particularly those with limited health budgets. Although PEP is still cost-effective even when only 1% of cases treated are actually exposed to rabies, it is ideal to ensure that PEP is not given indiscriminately to those with little or no possibility of exposure to the virus. As a result of recent shortages, more judicious use of PEP has been recommended in Western Europe and North America [21,22], but the issue is also pressing in countries with endemic canine rabies, where shortages are commonplace and unnecessary administration directly affects availability for those in genuine and urgent need of PEP [5].

Although PEP is very cost-effective in treating bite victims, the economic burden associated with PEP delivered to animal-bite victims (and the trauma associated with being bitten by a rabid animal) are expected to increase unless efforts are made to eliminate the disease from domestic dog populations [23]. We therefore recommend future studies to integrate the impacts of domestic dog vaccination campaigns on reducing the economic costs associated with PEP delivery and to evaluate the cost-effectiveness of the two strategies used in combination.

We found that PEP is a highly cost-effective health intervention in Tanzania that has the potential to avert over 5000 QALYs each year. Effective PEP administration will not only save lives but also decrease the economic burden associated with the disease. As the rabies recognition probability increases and PEP can be administered more judiciously, cost-effectiveness increases and the economic burden associated with the disease decreases. Nevertheless, PEP administration remains a very cost-effective intervention as long as the rabies recognition probability is greater than 1%. This cost-effectiveness holds true for both a societal and a healthcare perspective. Thus, health departments should ensure that PEP is available and accessible to those bitten by rabid animals while providing information and education about the necessity of obtaining prompt PEP.

Acknowledgments

We thank M. Magoto, E. Sindoya, the Serengeti Viral Transmission Dynamics team, as well as the livestock field-officers of the Ministry of Water and Livestock Development in Mara and Arusha Regions for invaluable field assistance. We are grateful to the Tanzanian Government ministries, TANAPA, TAWIRI, the NCA Authority, the Tanzania Commission for Science and Technology, and the National Institute for Medical Research for permissions. This research was funded by Notsew Orm Sands Foundation, the National Institutes of Health/ National Science Foundation Ecology of Infectious Diseases Program Grant DEB0225453, National Science Foundation Grant DEB0513994, Pew Charitable Trusts Award 2000-002558 (to Princeton University), The Heinz Foundation and the Wellcome Trust.

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Fig. 1. Age distribution of suspected rabid-animal-bite victims and data fitting using a gamma distribution.

Fig. 2.

Decision tree for determining cost-effectiveness of post-exposure prophylaxis (PEP) following the bite of a suspect rabid dog for preventing human rabies deaths. We define $P1$, $P2$ and $P3$ as the probability of receiving PEP, the probability that the suspected animal is rabid, and the probability of developing rabies based on the site of the bite, respectively (see Table 1 for parameter/probability estimates).

Fig. 3. Cost-effectiveness ratios for rabies post-exposure prophylaxis using intramuscular administration of vaccine for various ages of infections from health care and societal perspectives. QALY: quality-adjusted life year.

Fig. 4. Age distribution of a cost-effectiveness ratio for rabies post-exposure prophylaxis using intramuscular administration of vaccine (a) from a health care perspective and (b) from a societal perspective. QALY: quality-adjusted life year.

Fig. 5. Cost-effectiveness ratios for rabies post-exposure prophylaxis using intramuscular administration of vaccine from health care and societal perspectives, as P_2 (the rabies recognition probability) is varied. QALY: quality-adjusted life year.

Fig. 6. Cost-effectiveness ratios for rabies post-exposure prophylaxis using intramuscular administration of vaccine from health care and societal perspectives, at a range of costs per dose. QALY: quality-adjusted life year.

Parameter estimates used in the prediction of human deaths from rabies from injury data on bites by suspect rabid animals in Northwest Tanzania [5,7].

Table 1

Parameter description	Probability (binomial CIs)
Probability of receiving PEP if an individual that is bitten by an animal suspected to be rabid attends a medical facility (P_1)	0.86 (0.83–0.89)
Rabies recognition probability (probability of a suspected rabid animal being confirmed rabid on laboratory diagnosis) (P_2)	0.74 (0.64–0.84)
Probability of developing rabies (P_3), given a bite by a rabid animal and without prompt delivery of PEP	0.19 (0.13–0.28)
Probability of a bite to the head or neck	0.10 (0.07–0.13)
Probability of a bite to the upper extremity (arm or hand)	0.36 (0.31–0.40)
Probability of a bite injury to the trunk of the body	0.11 (0.08–0.14)
Probability of a bite to the lower extremity (leg or foot)	0.44 (0.39–0.49)
Probability of developing rabies following a bite to the head by a rabid animal	0.55 (0.28–0.79)
Probability of developing rabies following a bite to an upper extremity by a rabid animal	0.22 (0.12–0.38)
Probability of developing rabies following a bite to the trunk by a rabid animal	0.09 (0.005–0.38)
Probability of developing rabies following a bite to a lower extremity by a rabid animal	0.12 (0.06–0.23)

PEP: post-exposure prophylaxis and CIs: confidence intervals.

Table 2

Direct (medical) post-exposure prophylaxis costs and sources.

Parameter	Estimate	References
<i>Common costs</i>		
Material costs per injection (includes needles, syringes, swabs, etc.)	US \$0.10	[1]
Overhead costs per PET visit (includes anti-rabies clinic staff salaries and administration costs)	US \$0.50	[24]
<i>Tissue-culture vaccine costs</i>		
Intramuscular vaccination		
Vaccine cost per dose	11,000 TZS (equivalent to US \$10.00) (government) 25,000 TZS (private)	[1,10]
Visits per patient	5	[25]
Injections per patient	5	[1]
<i>Rabies immunoglobulin</i>		
Equine rabies immunoglobulin cost	US \$25.00	[1]
<i>Total direct cost</i>	US \$78.0	

PET: post-exposure treatment.

Table 3

Indirect (non-medical) costs of post-exposure prophylaxis and other costs associated with rabies.

Parameter	Estimate	References
Proportion of visits accompanied by an adult	0.4	[1]
No. of working days lost per person per PEP visit	0.5	[1]
Daily per capita gross national income	US \$1.87	[1]
Income loss per person per PEP visit	US \$0.94 (0.5×\$1.87)	[1]
Transport costs per person per PEP visit	US \$2.00	[25]
<i>Total indirect cost per one treatment</i>	US \$3.18 (\$0.94×0.4+\$2×1.4)	
<i>Total indirect cost for a complete regime</i>	US \$15.90	

PEP: post-exposure prophylaxis.

Table 4

DALY formula and parameters.

Parameter	Formula/estimate
DALYs	$\int_{x=a}^{x=a+L} D \cdot C \cdot x e^{-\beta x} \cdot e^{-r(x-a)} dx$ [26]
Age of onset, a	Varies
Time loss to premature mortality or duration of disability, L	51 years [11]
Disability weight, D	1 (death)
Age-weighting correction constant, C	0.1658 [26]
Age-weighting function constant, β	0.04 38 [26]
Discount rate, r	0.03

DALYs: disability-adjusted life years.