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Letter to Editor

Unavailability of Dedicated Dosage Vials of Anti-rabies Vaccine and Immunoglobulin for Intradermal Route Despite its Proven Advantage over Intramuscular Route

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I N F O

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Rabies represents a neglected tropical disease (NTD) which is predominantly present in Asian and African countries. Despite being a completely fatal disease, there is a lack of treatment as well as great disparities related to its prevention. World Health Organisation (WHO) had long back recognised the intradermal (ID) route of anti-rabies vaccination and immunoglobulin (RIG) to be as effective as the intramuscular (IM) one. The currently licensed rabies vaccine being globally used is prepared by inactivated purified rabies virus grown either in tissue culture or in embryonated duck or chicken eggs. The current recommended dosage includes one-site IM injection on days 0, 3, and 7 followed by the last dose between days 14 and 28. As an alternative IM regimen, the vaccine can be administered at two sites on day 0 followed by one-site injections on days 7 and 21. ID immunization should be administered at two sites on days 0, 3, and 7.[1] Therefore, the additive advantage includes a reduction in cost, dosage and frequency of the injections.[1] Keeping in mind the tremendous advantages the ID regimen offers, it is important that it is available in the market in the correct dosage along with compatible syringes. The recommended dosage and the number of injections of IM and ID vaccines are 0.5 ml & 4 and 0.1 ml & 3, respectively.[2] Therefore, the cumulative dose is reduced by more than 80% along with a reduction in the number of visits. Once a person is fully vaccinated, he does not require RIG after a second bite later in life. Hence a reduction in cost gives a long-term advantage for further infection management as well.

The RIG is an immediate intervention to provide passive immunization in severe or grade 3 bites. The dosage of RIG is 40 IU/kg and 20 IU/kg for equine and human-derived RIG, respectively.[2] The total dosage is to be infiltrated in the wound and the leftover quantity becomes useless as the IM infiltration is no longer recommended. This observation gives way to dosage reduction without compromising the efficacy.[2,3] Now conservation of the remaining volume becomes a challenge as an open vial cannot be left for a longer time and should be used within a specified time (6 hours). In order to address this need, a 'pooled strategy' was devised in India.[4] This strategy pools all the partially used eRIG vials for other patients. This is applicable for 24 hours and then it is discarded. Therefore this strategy is best suited for centers with high patient load along with patients who are ready to take it from an open vial (generally poor patients). Most of the patients from an affordable class and the private sector find it challenging to accept this strategy.

There are almost 10 companies involved in the production of rabies vaccines and immunoglobulin in India.[5] For an average person with a weight of 60 kg, the required equine RIG is 2400 IU and human RIG is 1200 IU. Each vial of human IG has 300 IU and equine IG has 300–1500 IU. Therefore, 8 and 4 vials are required, respectively. Smaller dosage vials will help save RIG where infiltration area or body weight is low. Also, intra-lesional RIG infiltration raises the possibility of bite area-based dosage rather than that based on body weight. The needle-syringe used for the ID route is similar to the insulin syringe itself.[6] There is a definite cost-cutting in comparison to the IM needle with syringes. Since these are smaller syringes and smaller vials, it will allow better storage as well as easy dispensing apart from efficient disposal. Therefore, the scope of prefilled syringes with needles, like many available vaccines, can be considered to make things simple and efficient.

We appeal to the industries involved in the production of rabies vaccine and immunoglobulin to produce smaller dosage vials and help make it affordable and available to the people of India. The vaccine and RIG wastage, thus, can be successfully checked.[7] Additionally, micro-needle patches should be made to ensure better delivery for the ID route of the vaccine. We also appeal to the Drug Controller General of India (DCGI) to direct the rabies vaccine companies to write "for ID/ IM use" on their vaccine vials and "for only wound infiltration based on the size of the wound/s" on the RIG vials[4,8,9] in compliance with WHO and Indian guidelines[10] rather than using a weight-based formula to calculate the dose. National Centre for One Health can support this initiative by taking the matter with the government of India and DCGI itself and also with the companies involved to achieve rabies-free India by 2030 as per the call of the WHO.

Conflict of Interest: None

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