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Rapid Development of an Anthrax Passive Immunotherapy

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There is a clear need for efficacious vaccines and therapeutics for potential biological weapons of mass destruction. Of the Category A select agents, treatments for anthrax infections is highlighted not only by the use of Bacillus anthracis in the 2001 bioterrorist event, but also by the recent CDC decision to pull the current licensed vaccine from public use. Although antibiotic therapy is effective in the early stages of anthrax infection, it does not have any effect on the bipartite exotoxins, which are the major contributing factors to the mortality rates observed in gastrointestinal and inhalation anthrax infections. Here we present evidence that goats hyper-immunized with recombinant protective antigen (rPA83) produce anti-sera that confers protection against in vitro intoxication with anthrax lethal toxin (LeTx). Previous studies have demonstrated that goats hyperimmunized with HIV proteins produce immunoglobulins that reduce the spread of HIV (Dezube et al., 2003). In our studies, 7.5 ug of anti-PA83 immunoglobulin confers 100% protection to J774A.1 murine macrophage-like cells exposed to 50 ng LeTx. This level of immunoglobulin correlates to a dose of 50 ug/mL which is within a therapeutically achievable range for humans. These results suggest that passive immunotherapy with goat anti-sera may be a successful clinical therapeutic for the treatment of human anthrax infections. Additionally, this highly protective anti-serum was obtained over a very short period of time allowing for rapid, large-scale production of this therapeutic and its addition into the Strategic National Stockpile.