CLAIMS

1. A method for eliciting an immune response against *C. difficile* toxin A and toxin B in an adult human subject at risk for a primary symptomatic *C. difficile* infection, the method comprising administering to the subject a composition comprising C. difficile toxoid A and toxoid B at least three times, each administration being about seven days apart.
2. The method of claim 1 wherein the immune response elicited is sufficient to prevent and / or reduce a primary symptomatic *C. difficile* infection in the adult human subject.
3. The method of claim 1 wherein the immune response elicited is sufficient to prevent the onset of a symptomatic *C. difficile* infection in the adult human subject.
4. The method of any one of claims 1-3 wherein the second administration is about 7 days after the first administration and the third administration is about 30 days after the first or second administration.
5. The method of claim 4 wherein the third administration is about 30 days after the first administration.
6. The method of any one of claims 1-3 wherein the second administration is about 7 days after the first administration and the third administration is about 180 days after the first or second administration.
7. The method of claim 6 wherein the third administration is about 180 days after the first administration.
8. The method of any one of claims 1-7 wherein the composition comprises each of C. difficile toxoid A and toxoid B, having a purity of at least about 90% or greater, in a ratio of about 3:1 to about 1:1.
9. The method of claim 8 wherein the ratio of C. difficile toxoid A and toxoid B is about 3:2.
10. The method of any one of claims 1-9 wherein the composition comprises a combined total of C. difficile toxoid A and toxoid B of about 40 to 500 μg.
11. The method of claims 1-10 wherein the composition comprises an adjuvant.
12. The method of claim 11 wherein the composition comprises an aluminum adjuvant.

13. The method of any one of claims 1-12 wherein the subject at risk is at least 40 years of age and:

(i) has had, in the 12 month period before the first administration, at least 2 hospital stays, each lasting at least about 24 or 72 hours, and has received systemic (not topical) antibiotics, or

(ii) is anticipated to have an in-patient hospitalization for a planned surgical procedure within 60 days of the first administration.

14. The method of claim 13, wherein the anticipated hospitalization is planned to be for at least about 24 or 72 hours and is for a surgery involving at least one of the following systems:

(i) kidney/bladder/urinary system;

(ii) musculoskeletal system;

(iii) respiratory system;

(iv) circulatory system; and

(v) central nervous system.

15. The method of any one of claims 1-14 wherein the adult human subject is at least about 65 years or older.

16. The method of any one of claims 1-15 wherein an immune response against *C. difficile* toxin A and / or toxin B is sustained for at least about 60 days.

17. The method of claim 16 wherein an immune response against *C. difficile* toxin A and / or toxin B is sustained for at least about 210 days.

18. The method of claim 17 wherein an immune response against *C. difficile* toxin A and / or toxin B is sustained for at least about 1000 days.

19. Using a composition comprising C. difficile toxoid A and toxoid B in producing a medicament for eliciting an immune response against *C. difficile* toxin A and toxin B in an adult human subject at risk for a primary symptomatic *C. difficile* infection by administering the composition to the subject at least three times, each administration being about seven days apart.

20. The use of claim 19 wherein the immune response elicited is sufficient to prevent and / or reduce the risk of a primary symptomatic *C. difficile* infection in the adult human subject.

21. The use of claim 19 wherein the immune response elicited is sufficient to prevent the onset of a symptomatic *C. difficile* infection in the adult human subject.

22. The use of any one of claims 19-21 wherein the second administration is about 7 days after the first administration and the third administration is about 30 days after the first or second administration.

23. The use of claim 22 wherein the third administration is about 30 days after the first administration.

24. The use of any one of claims 19-21 wherein the second administration is about 7 days after the first administration and the third administration is about 180 days after the first or second administration.

25. The use of claim 24 wherein the third administration is about 180 days after the first administration.

26. The use of any one of claims 19-25 wherein the composition comprises each of C. difficile toxoid A and toxoid B, having a purity of at least about 90% or greater, in a ratio of about 3:1 to about 1:1.

27. The use of claim 26 wherein the ratio of C. difficile toxoid A and toxoid B is about 3:2.

28. The use of any one of claims 19-27 wherein the composition comprises a combined total of C. difficile toxoid A and toxoid B of about 40 to 500 μg.

29. The use of any one of claims 19-28 wherein the composition comprises an adjuvant.

30. The use of claim 29 wherein the composition comprises an aluminum adjuvant.

31. The use of any one of claims 19-30 wherein the subject at risk is at least 40 years of age and:

(i) has had, in the 12 month period before the first administration, at least 2 hospital stays, each lasting at least about 24 or 72 hours, and has received systemic (not topical) antibiotics, or

(ii) is anticipated to have an in-patient hospitalization for a planned surgical procedure within 60 days of the first administration.

32. The use of claim 31, wherein the anticipated hospitalization is planned to be for at least about 24 or 72 hours and is for a surgery involving at least one of the following systems: (i) kidney/bladder/urinary system; (ii) musculoskeletal system; (iii) respiratory system; (iv) circulatory system; and (v) central nervous system.

33. The use of any one of claims 19-32 wherein the adult human subject is at least about 65 years or older.

34. The use of any one of claims 19-33 wherein an immune response against *C. difficile* toxin A and / or toxin B is sustained for at least about 60 days.

35. The use of claim 34 wherein an immune response against *C. difficile* toxin A and / or toxin B is sustained for at least about 210 days.

36. The use of claim 34 wherein an immune response against *C. difficile* toxin A and / or toxin B is sustained for at least about 1000 days.

37. A composition comprising C. difficile toxoid A and toxoid B for use in a method for eliciting an immune response against C. difficile toxin A and toxin B in a human subject, the method comprising administering the the subject the composition at least three times, each administration being about 7 days apart.

CLAIMS

1. Use of *C. difficile* toxoid A and toxoid B in the manufacture of a composition for eliciting an immune response against *C. difficile* toxin A and toxin B in an adult human subject at risk of a symptomatic *C. difficile* infection, the composition comprising toxoid A and toxoid B at a purity of about 90% or higher (w/w) and for administration at least three times to the subject, each administration being at least about seven days apart, and wherein the immune response against *C. difficile* toxin A and toxin B is sustained for at least about 210 days.
2. The use of claim 1 wherein the immune response elicited is sufficient to prevent and / or reduce the risk of a primary symptomatic *C. difficile* infection in the adult human subject.
3. The use of claim 1 wherein the immune response elicited is sufficient to prevent the onset of a symptomatic *C. difficile* infection in the adult human subject.
4. The use of any one of claims 1-3 wherein the second administration is about 7 days after the first administration and the third administration is about 30 days after the first or second administration.
5. The use of claim 4 wherein the third administration is about 30 days after the first administration.
6. The use of any one of claims 1-3 wherein the second administration is about 7 days after the first administration and the third administration is about 180 days after the first or second administration.
7. The use of claim 6 wherein the third administration is about 180 days after the first administration.
8. The use of any one of claims 1-7 wherein the composition comprises each of *C. difficile* toxoid A and toxoid B, having a purity of at least about 90% or greater, in a ratio of about 3:1 to about 1:1.
9. The use of claim 8 wherein the ratio of C. difficile toxoid A and toxoid B is about 3:2.
10. The use of any one of claims 1-9 wherein the composition comprises a combined total of *C. difficile* toxoid A and toxoid B of about 40 to 500 μg.

11. The use of any one of claims 1-10 wherein the composition comprises an adjuvant.

12. The use of claim 11 wherein the composition comprises an aluminum adjuvant.

13. The use of any one of claims 1-12 wherein the subject at risk is at least 40 years of age and:

    (i) has had, in the 12 month period before the first administration, at least 2 hospital stays, each lasting at least about 24 or 72 hours, and has received systemic (not topical) antibiotics, or

    (ii) is anticipated to have an in-patient hospitalization for a planned surgical procedure within 60 days of the first administration.

14. The use of claim 13, wherein the anticipated hospitalization is planned to be for at least about 24 or 72 hours and is for a surgery involving at least one of the following systems: (i) kidney/bladder/urinary system; (ii) musculoskeletal system; (iii) respiratory system; (iv) circulatory system; and (v) central nervous system.

15. The use of any one of claims 1-14 wherein the adult human subject is at least about 65 years or older.

16. The use of any one of claims 15 wherein an immune response against *C. difficile* toxin A and / or toxin B is sustained for at least about 1000 days.

17. Use of *C. difficile* toxoid A and toxoid B in the manufacture of composition for eliciting an immune response against C. difficile toxin A and toxin B in a human subject at risk for a primary symptomatic *C. difficile* infection, the composition comprising by toxoid A and toxoid B at a purity of about 90% or higher (w/w) and for administration at least three times to the subject, each administration being at least about 7 days apart and wherein the immune response against *C. difficile* toxin A and toxin B is sustained for at least about 210 days .