infection through the administration of a bacteria, a bacteria nutrient, and an antimicrobial agent. These references, however, relate solely to adult administration and do not disclose the administration of probiotics to infants to treat respiratory tract infections or AOM.

[00020] The gut microflora in infants is known to be far less developed than that of an adult. While the microflora of an adult human consists of more than 10^{13} microorganisms and nearly 500 species, some being harmful and some being beneficial, the microflora of an infant contains only a fraction of those microorganisms, both in absolute number but also in species diversity. Because the bacterial populations and species vary so immensely between the gut of an infant and the gut of an adult, it cannot be assumed that a probiotic administration designed for an adult would necessarily be beneficial for an infant.

[00021] It would be beneficial, therefore, to provide a probiotic remedy for the treatment and or prevention of respiratory infections and AOM in infants.

SUMMARY OF THE INVENTION

[00022] Briefly, the present ~~invention~~disclosure is directed to a novel method for preventing or treating respiratory infections in infants, comprising administering to the infant a therapeutically effective amount of at least one *Bifidobacterium* species in conjunction with at least one probiotic bacterial species that promotes the growth and adherence of the selected strain of *Bifidobacteria* in the intestine. In one embodiment, the *Bifidobacterium* species can be chosen from among the *Bifidobacteria* that demonstrate immunomodulatory properties. These species may include, for example, *B. bifidum, B. adolescentis, B. animalis, B. lactis, B. infantis, B. longum,* and *B. thermophilum*. A particular species useful in the present invention is *B. lactis* Bb-12.

[00023] In one embodiment, the probiotic that promotes *Bifidobacteria* adherence is a member of the Lactobacillus species, such as, for example, *L. rhamnosus* GG (LGG), *L. delbrueckii* subsp. *bulgaricus*, or a combination of both.

In one aspect, there is provided an infant formula for use in preventing development of respiratory infection and/or acute otitis media, the infant formula comprising:

a lipid or fat;

a protein source selected from the group consisting of whey protein, casein protein, nonfat milk, and hydrolyzed protein;

one or more *Bifidobacterium* species comprising *Bifidobacterium lactis* Bb-12; and

one or more bacterial species comprising *Lactobacillus rhamnosus* GG.

In another aspect, there is provided an infant formula for use in preventing development of respiratory infection and/or acute otitis media, the infant formula comprising:

a lipid or fat;

a protein source selected from the group consisting of whey protein, casein protein, nonfat milk, and hydrolyzed protein;

one or more *Bifidobacterium* species; and

one or more adherence-promoting probiotic.

In another aspect, there is provided the use of the infant formula as defined herein in the manufacture of a medicament for preventing development of respiratory infection and/or acute otitis media.

In another aspect, there is provided the use of the infant formula as defined herein in the manufacture of a medicament for preventing development of respiratory infection and/or acute otitis media.

CLAIMS:

1. An infant formula for use in preventing development of respiratory infection and/or acute otitis media, the infant formula comprising:

a lipid or fat;

a protein source selected from the group consisting of whey protein, casein protein, nonfat milk, and hydrolyzed protein;

one or more *Bifidobacterium* species comprising *Bifidobacterium lactis* Bb-12; and

one or more bacterial species comprising *Lactobacillus rhamnosus* GG.

2. The infant formula of Claim 1, wherein the lipid or fat is present at about 3 to about 7g per 100 kcal.

3. The infant formula of Claims 1 or 2, wherein the protein source is present at about 1 to about 5g per 100 kcal.

4. The infant formula of any one of the preceding Claims, wherein the respiratory infection is selected from the group consisting of upper respiratory infection, influenza, croup, respiratory syncytial virus, bronchitis, bronchiolitis and pneumonia.

5. The infant formula of any one of the preceding Claims, wherein the amount of both the one or more bacterial species comprising *Lactobacillus rhamnosus* GG and the one or more *Bifidobacterium* species is between 10^5 and 10^{11} cfu per day.

6. The infant formula of any one of Claims 1 to 4, wherein the amount of both the bacterial species comprising ~~one or more~~a *Lactobacillus rhamnosus* GG and the one or more *Bifidobacterium* species is between 10^6 and 10^8 cfu per day.

7. The infant formula of any one of the preceding Claims, wherein the ratio of the *Bifidobacterium lactis* Bb-12 and the *Lactobacillus rhamnosus* GG is between about 5:1 and 1:5.

8. The infant formula of any one of Claims 1 to 6, wherein the ratio of the *Bifidobacterium lactis* Bb-12 and the ~~one or more~~ *Lactobacillus rhamnosus* GG is between about 10:1 and 1:10.

9. The infant formula of any one of Claims 1 to 6, wherein the ratio of the *Bifidobacterium lactis* Bb-12 and the ~~one or more~~ *Lactobacillus rhamnosus* GG is about 1:1.

10. An infant formula for use in preventing development of respiratory infection and/or acute otitis media, the infant formula comprising:

a lipid or fat;

a protein source selected from the group consisting of whey protein, casein protein, nonfat milk, and hydrolyzed protein;

one or more *Bifidobacterium* species; and

one or more adherence-promoting probiotic.

11. The infant formula of Claim 10, wherein the lipid or fat is present at a level of about 3 to about 7g per 100 kcal.

12. The infant formula of Claims 10 or 11, wherein the protein source is present at a level of about 1 to about 5g per 100 kcal.