SCIENTIFICBRIEF Florajen3 Prevents Antibiotic-Associated Diarrhea in Hospitalized Patients

A common side effect of antibiotic therapy is diarrhea. Antibiotic-associated diarrhea is estimated to affect 11-40% of people taking antibiotics. Nearly all antibiotics can cause diarrhea. Antibiotic-associated diarrhea may occur while an individual is taking antibiotics or up to 2 months after a course of antibiotics has concluded. Most of the time, a specific microbial cause for AAD is not found. However, in severe cases, the bacterium, *Clostridium difficile* may be the underlying cause. During antibiotic treatment, disruptions of gastrointestinal flora occur in which many populations of normal organisms believed to keep *Clostridium difficile* growth and activities in check, are dramatically reduced. Unfortunately, few antibiotics are capable of eradicating *Clostridium difficile*, especially the spore form of the bacteria. Thus, as an opportunistic microorganism, *Clostridium difficile* may overgrow in the intestinal tract as a consequence of exposure to antibiotic medications if there is inadequate healthy normal flora to suppress its actions.

Hospitalized patients receiving antibiotic therapy are especially prone to developing *Clostridium difficile* diarrhea. Recently, this bacterium caused diarrheal outbreaks in several Canadian hospitals and was responsible for over 100 deaths. *Clostridium difficile* associated-diarrhea frequently extends hospital stays for affected patients (by 3-7 days) resulting in higher hospital costs (up to \$1 billion per year). In addition, the microorganism has been associated with a 4-fold increase in mortality rates compared to unaffected individuals.

Currently, placing affected patients in isolation and utilizing good hand hygiene (ie. hand-washing between patients) are measures utilized by most hospitals to curb infections caused by *Clostridium difficile*. However, the strategy of a Mesa, Arizona, hospital also relies upon probiotics.

Probiotics are live microorganisms—often the same types of bacteria normally found in healthy gastrointestinal tracts. Probiotics may restore the balance of "good" bacteria in the digestive system and keep *Clostridium difficile* from over-growing.

In 2001, Valley Lutheran Hospital (now called Banner Baywood Medical Center) decided to investigate just how effective Florajen3 (*Lactobacillus acidophilus, Bifidobacteria bifidum*, and *Bifidobacteria longum*) might be for preventing *Clostridium difficile* diarrhea.

A protocol was developed such that all hospitalized patients at Valley Lutheran Hospital who were prescribed antibiotics also received Florajen3. A dose of one Florajen3 capsule was administered three times daily to patients receiving antibiotics. Medical records were retrospectively reviewed on a monthly basis to determine the incidence of *Clostridium difficile* diarrhea diagnosis, as well as the impact that this diagnosis had on length of hospitalization. Data were collected over a 3 month time period (February through April) during three consecutive years (1999, 2000, and 2001).

In 2001, once Florajen3 was included as part of patients' therapeutic regimens, the overall incidence of *Clostridium difficile* diarrhea decreased by 66% (p=0.0027)¹ at this hospital.

Furthermore, it is estimated that the probiotic intervention reduced the incidence of *C. difficile* by 11 % (p=0.0016) in those taking antibiotics. Based upon this data, administration of Florajen3 prevented one patient from acquiring *C. difficile* diarrhea for every 9 patients treated. In addition, the length of hospitalization for those affected by *C. difficile* was reduced by 2 days in patients getting the probiotic. This suggests that the severity of diarrhea was also reduced in those affected by *C. difficile* 3.

To our knowledge, this study --conducted in 2001- was the first to examine outcomes of Florajen3 in hospitalized patients prescribed antibiotics. These results highlight the dramatic reductions in incidence of *Clostridium difficile*-associated diarrhea that are possible when Florajen3 is added to therapy of hospitalized patients receiving antibiotics.