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A Pilot Study to Determine the Effectiveness of Probiotic Use in Elderly Patients with Antibiotic-Associated Diarrhea

By

Jenna Peate

A THESIS

Presented to the Faculty of

The Graduate College at the University of Nebraska

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Under the Supervision of Professors Kaye Stanek-Krogstrand and Julie A. Albrecht

Lincoln, Nebraska

July, 2010

A Pilot Study to Determine the Effectiveness of Probiotic Use in Elderly Patients with Antibiotic-Associated Diarrhea Jenna Peate University of Nebraska, 2010

Advisors: Kaye Stanek Krogstrand and Julie Albrecht

Long-term care settings have the majority of their patients on multiple antibiotics, and outbreaks of antibiotic-associated diarrhea and Clostridium difficile are common. Probiotics have been used with these patients to reduce these side effects. Probiotics can re-establish the composition of intestinal microflora, enhance immune response, and clear pathogens from the host which may reduce the symptoms of antibiotic-associated diarrhea. Therefore, the goal of this study was to conduct a retrospective study of the effectiveness of using probiotic in elderly patients in a long-term care facility in a Midwestern city who suffered from antibiotic-associated diarrhea. The probiotic, CulturelleTM had been administered once a day to eight males and twelve female patients who were taking antibiotics and stool consistency and number were recorded. Out of the original group, seven of the patients receiving the probiotic appeared to have positive effects while two patients had negative effects on stools. Thirteen patients showed no change in stool consistency and number. It was difficult to determine the effects of the probiotic due to the use by the facility of a bowel movement protocol for preventing constipation and impaction, and the lack of dietary records.

Published studies in patients in long-term facilities vary greatly in terms of trial design, type and dose of probiotic and duration of treatment, which may explain why probiotics work for some patients and not for others. Probiotic use is becoming more

accepted with antibiotic-associated diarrhea but due to the lack of definitive evidence about efficacy and the safety of probiotic use, more studies need to be conducted.

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Chapter I. Introduction

Long-term care settings have the majority of their patients on multiple antibiotics and outbreaks of antibiotic-associated diarrhea and *Clostidium difficile* are common. Probiotics have been used with antibiotic use to reduce or possibly prevent these side effects (Hamilton-Miller, 2004; Isolauri, 2001; McFarland, 2006). Published studies for patients in long-term care facilities vary greatly in terms of trial design, type and dose of probiotic and duration of treatment which may explain why probiotics appear to work for some patients and not for others.

The most susceptible group for antibiotic-associated diarrhea in the hospital appears to be the elderly (Hamilton-Miller, 2004). Elderly people may be regarded as immunocompromised due to their decrease in their ability to fight infections as they age. That is one reason why researchers develop strategies that can boost immunity in the elderly (Hamilton-Miller, 2004). Gill et al. (2001) reported the beneficial effects of the administration of *L rhamnosus* for three weeks in elderly subjects. These beneficial effects were: decrease in irregular stools and decrease in irregular consistency. Improvements in symptoms were shown in subjects over 70 years old and who had immunity issues prior to treatment with the probiotic.

It is known that probiotics can re-establish the composition of the intestinal microflora, enhance immune response, and clear pathogens from the host; all of which may reduce the symptoms of antibiotic-associated diarrhea. The use of probiotics is expanding to treat antibiotic-associated diarrhea and becoming more accepted. However, there is a lack of strong evidence about the efficacy and safety of probiotic use. Because of this situation, more studies need to be conducted (McFarland, 2006).

1

The goal of the present study was to retrospectively examine the effectiveness of using a probiotic in institutionalized elderly patients in a long-term care facility in a Midwestern city who had received antibiotics and had antibiotic-associated diarrhea and/or *Clostidium difficile*.

Chapter II. Literature Review

The word, probiotic, is associated with the Greek term that means "for life". Reid (2003) defined probiotic as live microorganisms administered in adequate amounts, which has beneficial physiological effects on the host. Many credit the Russian researcher, Dr. Elie Metchnikoff, for the development of probiotics (Reid, 2005). Brown (2004) states that a probiotic is a nonpathogenic organism, such as yeast or bacteria, in foods that can exert a positive influence on the host's health. The theory behind probiotics is that live microorganisms in food or supplements improve microbial balance of the intestinal tract.

The use of probiotics has been reported to be effective in the elderly population suffering from antibiotic-associated diarrhea and some who have *Clostridium difficile* (Hamilton-Miller, 2004; Isolauri, 2001). Probiotics are strains of bacteria that are naturally occurring in our intestinal tract. Different probiotic strains have been studied in the clinical setting and have been used to treat and/or prevent certain diseases (Hamilton-Miller, 2004; Isolauri 2001). The concept of probiotic use has advanced rapidly over the last several years. A bacterium or product containing bacteria is not considered a probiotic unless the bacteria are viable at the time of use in sufficient quantity to confer a physiologic health benefit. The intentional modification of the intestinal microbiota with probiotics leads to select clinical beneficial effects, such as reduction of diarrhea. Such specific effects with ingestion of particular strains have been demonstrated (BioDrugs,

1999). Table 1 provides an example of the probiotic bacterial strains and when they are

used (Douglas and Sanders, 2008).

Indication	Genus, species, strain (commercial strain designation)	Products (format)
Infant diarrhea	L. rhamnous GG (LGG)	Culturelle TM (capsule) Danimals TM (drinkable yogurt)
	<i>L. Casei DN114001</i> (Immunitas)	DanActive TM (fermented milk)
Inflammatory bowel conditions (primary evidence in pouchitis)	8 strain combination of 3 Bifidobacterium strains, 4 Lactobacillus strains and S. thermophilus	VSL#3 TM (powder)
Antibiotic associated diarrhea; C. difficile	S. cerevisiae (S. boulardii)	Florastor TM (powder) Lalflor TM (capsule)
	L. rhamnosus GG	Culturelle TM (capsule) Danimals TM (drinkable yogurt)
	L. casei DN114001 L. acidophilus CL 1285 plus L. casei	DanActive TM (fermented milk)
		BioK+CL1285 TM (fermented milk, capsule)
Gut transit time	B. animalis DN137 010 (Bifidus regularis)	Activia TM (yogurt)
Keeping healthy	L. reuteri ATCC 55730	BioGala Chewable Gut Health Tablets TM , BioGala Gut Health Probiotic Straws TM
	L. casei DN114001	DanActive TM (fermented milk)
Atopic dermatitis (primary evidence is prevention when fed to newborn infants)	L. rhamnosus GG	Culturelle TM (capsule) Danimals TM (drinkable yogurt)

Table 1. List of Bacterial and Yeast Strains Used as Probiotics

Lactose intolerance	Most strains L. bulgaricus	All yogurts with live, active
	and/or S. thermophilus	cultures
Colic in Infants	L. reuteri ATCC 55730	Reuteri drops
	(Protectis)	
Immune support	B lactis HN019 (HOWARU	Strain sold as an ingredient
	or DR10)	for dairy and supplement products
	B lactis Bb-12	Good Start Natural Cultures TM (infant formula)
	L casei DN 14001	DanActive TM (fermented milk)
Vaginal applications	L rhamnosus GR-1 plus L reuteri RC-14	Fern-Dophilus TM (capsules)
Irritable bowel syndrome	B infantis 35264 (Bifantis)	Align TM (capsules)
symptoms		
Douglas 2008		

Douglas, 2008.

Lactobacillus bacterial strains are typically used for non-pathogenic infections and some opportunistic infections. Lactobacillus strains are normally found in the small intestine. Of more than 100 Lactobacillus bacterial species, the following are commonly used probiotics: L. acidophilus, L. casei, L. rhamnosus, and L. fermentum. Most of the time, *Streptococcus* bacterial strains are not used as a health benefit. However, there is one strain that has been shown to be helpful: Streptococcus thermophilus. Enterococcus bacterial strains are typically used for infections due to opportunistic pathogens. Bifidobactrium bacterial strains are typically used for non-pathogenic infections and some isolated cases of human infection. They are strictly anaerobic and normally found in the large intestine. There are over 30 Bifidobactrium bacterial strains; some common strains are: B. bifidum, B. adolescentis, B. animalis, and B. therophilum. Spores of a number of *Bacillus* bacterial strains are used as probiotics and are often classified as soilbased probiotics. Some examples of the Bacillus species are: Bacillus cereus, B. subtilis, and B. coagulans. Saccharomyces yeast strains are typically used for non-pathogenic

infections and some isolated cases of human infection. Of the *Saccharomyces* yeast species the *S. boulardii* is the only one used as a probiotic. This yeast strain seems to be unaffected by gastric acid and bile. It has been used alone and in combination with other bacterial strains to be effective with *Clostridium difficile* and diarrhea (Olmstead et al., 2008).

Dependence of the intestinal microbes in the food makes it possible to take measures to modify intestinal microflora and to replace the harmful microbes with good microbes (Culligan et al., 2009). Companies develop and market probiotics as a functional food. When a person ingests billions of "good" bacteria, which are normally found in a healthy gut, they may improve the immune system (Marteau et al., 2001). Probiotics can help stabilize the gut microbial environment and the intestinal barrier, enhance systemic responses, and mucosal IgA (antibody responsible for mucosal immunity) responses, thus promoting the formation of the immunologic barrier in the gut mucosa. It has been shown that probiotic consumption increases specific intestinal microflora, but does not usually increase the total bacteria in the intestinal tract (Brown, 2004). Probiotics were reported to reduce pathogens found in the gut due to nonspecific host resistance (Salminen et al, 1998). Marteau and associates (2001) believes that through modulation of the endogenous ecosystem or the immune system, the probiotics can influence the intestinal physiology. Brown (2004) suggested that studies have shown that to see a positive effect, large quantities of probiotics must be consumed. Probiotic benefits are based on survival of the bacteria or yeast strains in the gastrointestinal tract, as well as overall health. Some variables that affect the benefits of probiotics are: the strain, storage conditions, chemical additives, and other interactions (Brown, 2004).

It has been suggested that disruption of the balance in the gastrointestinal tract can contribute to diarrhea and other gastrointestinal side effects (Brown, 2004). When patients are placed on antibiotics, a common side effect is diarrhea. This is thought to be caused either by increasing gastrointestinal motility or by disturbing the normal flora of the colon (Kyne, Farrell and Kelly, 2001). Another hypothesis is that antibioticassociated diarrhea may be the result of overgrowth of toxigenic *Clostridium difficile* in the intestinal tract. Clostridium difficile is a spore-forming, gram-positive anaerobic bacteria that produces two toxins. *Clostridium difficile* is commonly associated with patients in hospitals as well as long-term care facilities. Diseases that result from *Clostridium difficile* infections include: sepsis, perforations of the colon, toxic megacolon, pseudomembranous colitis, and sometimes death (CDC, 2004). Symptoms of *Clostridium difficile* usually include: watery diarrhea, fever, loss of appetite, nausea, and abdominal pain (CDC, 2004). Patients that are at an increased risk for Clostridium *difficile* include those who have antibiotic exposure, gastrointestinal surgery, immunocompromised conditions, and long term stays in healthcare settings (CDC, 2004). *Clostridium difficile* is transmitted through the feces, which can be passed to patients by healthcare workers who do not follow safety and sanitation rules. In 23% of patients, Clostridium difficile associated disease will resolve within two to three days of discontinuing the antibiotic to which the patient was previously exposed. The infection is usually treated with ten days of antibiotic use, such as metronidazole or vancomycin (CDC, 2004).

Diarrhea

Diarrhea is defined as an increase in frequency of bowel movements and/or an increase in water content of stools that affects either the consistency or the volume of fecal output. Other definitions describe diarrhea as the abnormality in stool production as greater than 200 g/day for adults, and greater than 20 g/kg for children (Donowitz et al.; Kokke and Saidi, 1995). The etiology of the diarrhea can also serve as a framework for discussion and understanding of diarrheal conditions. Diarrhea can be classified in different ways. First, diarrhea can be either acute or chronic. Acute diarrhea is considered short-term, whereas chronic diarrhea can last several weeks. Chronic diarrhea is usually associated with electrolyte imbalances, malabsorption, dehydration, and malnutrition (McFarland, 2006). Second, diarrhea can also be classified as either secretory diarrhea or osmotic diarrhea. Secretory diarrhea is when there is an increased amount of active secretion, therefore, an inhibition of absorption occurs. Usually there is not structural damage to the intestinal tract. Osmotic diarrhea occurs when too much water is drawn to the bowels, which can be the result of malabsorption. Antibioticassociated diarrhea (AAD) and *Clostridium difficile* disease (CDD) are common conditions linked to the use of antibiotics (Culligan et al., 2009). In antibiotic-associated diarrhea, diarrhea occurs in less than or equal to 20% of patients who receive antibiotics (McFarland, 2006). Antibiotic-associated diarrhea results from a microbial imbalance that leads to a decrease in gut microflora, which, in turn, is responsible for colonization resistance and to a decrease in the fermentation capacity of the colon. Studies evaluating the efficacy of probiotics for the treatment of these two conditions (AAD and CDD) have had mixed results (McFarland 2006). McFarland (2006), defined diarrhea as ≥ 3 loose

stools within 24 hours for ≥ 2 days or ≥ 5 loose stools within 48 hours. Antibioticassociated diarrhea was defined as diarrhea within 2 months of exposure to antibiotics. *Clostridium difficile* disease was defined as diarrhea associated with a positive *Clostridium difficile* culture or toxin within a month of exposure to antibiotics (McFarland, 2006).

The Elderly Population

The most susceptible group for antibiotic-associated diarrhea in the hospital appears to be the elderly (Hamilton-Miller, 2004). Elderly people may be regarded as immunocompromised due to their decrease in their ability to fight infections as they age. That is one reason why researchers develop strategies that can boost immunity in the elderly (Hamilton-Miller, 2004). Gill et al. (2001) reported the beneficial effects of the administration of *L* rhamnosus for three weeks in elderly subjects. These beneficial effects are decrease in irregular stools and decrease in irregular consistency. Improvements in symptoms were shown in subjects over 70 years old and who had immunity issues prior to treatment with the probiotic. Van de Water et al. (1999) found that yogurt consumption for one year decreased the incidence of allergies and inflammatory markers in a group of healthy elderly subjects. There are three common problems in the elderly population: malnutrition, constipation, and a decreased ability to fight infections. Probiotics may have a beneficial effect on all of these problems. Further research is necessary to determine long term outcomes and the most suitable probiotic strains to administer to the elderly (Hamilton-Miller, 2004).

Only one trial has been conducted specifically in elderly subjects, and no benefit from taking *S. boulardii* was reported. This study had a major limitation; the dose of 226

mg *S. boulardii* daily was low (D'Souza, 2002). Other studies have reported positive effects with a daily dose of 1 g *S. boulardii*. A meta-analysis of nine trials concluded that probiotics may be useful in treating antibiotic induced diarrhea but further trials are needed with the elderly population (D'Souza et al., 2002).

McFarland 2006 conducted a meta-analysis of 31 randomized controlled trials. The meta-analysis revealed that probiotics had a significant protective effect against the development of antibiotic-associated diarrhea. This study also revealed that the probiotic strains that were found effective with antibiotic-associated diarrhea were *S. boulardii, L. rhamnosus GG*, and a mixture of two strains of *Lactobacilli*. No adverse events were reported for a majority of the trials and those that did reported minor adverse events including thirst and constipation (McFarland, 2006). The clinical and economic costs of antibiotic-associated diarrhea are significant and better treatments are needed. Probiotics may offer potential effective therapy for antibiotic-associated diarrhea by restoring intestinal microbial balance.

The Gastrointestinal Tract

The gastrointestinal tract provides a protective barrier between the internal environment and microorganisms in the external environment. The first line of host defense is directed toward the elimination of foreign antigens that have penetrated the mucosa, and the regulation of immune responses (Isolauri, 2001). As a result, the gastrointestinal barrier controls antigen transport and the generation of immunologic properties in the gut (Ducroc et al., 1983). The mucosal surface of the gut prevents a large amount of pathogens, toxins, and allergens from entering through this barrier. However, the mucosal surface also has to allow nutrients to enter. The intestinal flora

actively interacts with this mucosal surface. The gut is considered the largest lymphoid organ in the body. The gut associated lymphoid tissue (GALT) evolves and responds to the presence of and changes in the intestinal flora. Lack of this "microbial experience" leads to significant pathophysiological consequences. One example would be an underdeveloped GALT in animals without effective intestinal flora results in persistent enteritis, severe infections, and poor survival. An effective and metabolically active intestinal flora is critical for the maintenance of a healthy gut epithelium, vitamin production, and bile acid metabolism. Additionally changes in the human microflora have been correlated with modulated local and systemic immune responses of the GALT (BioDrugs, 1999). Adult intestinal microflora contains approximately 500 different bacterial strains. The strains with health-promoting properties principally include bifidobacteria and lactobacilli. When inflammation or infection occurs, the microfloral balance of the gut is altered in such a way that the numbers of potentially pathogenic bacteria grow, and the healthy interaction between the host and microbe is disturbed so that an immune response may be induced by resident bacteria (Salminen et al., 1998).

CulturelleTM

A published study demonstrated that the co-administration of antibiotics and CulturelleTM (*Lactobacillus GG*) in children significantly reduced the incidence of antibiotic-associated diarrhea. A placebo or CulturelleTM (*Lactobacillus GG*) was given to 200 children at the same time antibiotic therapy was started (Vanderhoof, 1999). The parents were questioned by telephone, every three days, about the number and consistency of stools and about numerous other gastrointestinal symptoms. Only patients assigned to a 10 day course of antibiotic therapy were considered for this study.

Probiotics were given throughout the course of antibiotic therapy. Older children were given 2 capsules per day of CulturelleTM (*Lactobacillus GG*) and children who weighed less than 12 kg were given only 1 capsule per day. The incidence of diarrheal stools was 24% in the placebo group compared with 7% in the probiotic treatment group. Usually diarrhea is one reason why children must stop antibiotic treatment. The diarrhea can also lead to inability to be in a daycare setting which means parents must miss work.

CulturelleTM (*Lactobacillus GG*) was discovered in 1985 at Tufts University in Boston, Massachusetts by Dr. Sherwood H. Gorbach and Dr. Barry R. Goldin (Amerifit Brand, 2010). CutlurelleTM is promoted as the premiere probiotic in the world. CulturelleTM consists of *Lactobacillus GG*TM (10 billion cells), microcrystalline cellulose, gelatin, and milk proteins. The producers of CulturelleTM attempted to make their product at the highest purity and potency for consumers at the time of use. They achieve this by guaranteeing that CulturelleTM contains at least 10 billion live cells per capsule at the time of use. To maintain freshness, each of the capsules are individually double-foil-protected and packed in such a way to keep light, moisture, heat and air out to assure stability and maximum potency (Amerifit Brand, 2010). Keeping CulturelleTM in a refrigerator or freezer will increase its shelf life but is not required. The CulturelleTM company promotes their probiotic as an all-natural dietary supplement that improves digestion and creates a stronger immune system. They recommend taking one capsule per day to strengthen the immune system while promoting digestive health (Amerifit Brand, 2010). Along with a balanced diet rich in fiber, vitamins and minerals, a probiotic supplement like CulturelleTM can strengthen the immune system and boost your immune response (Amerifit Brand, 2010).

Probiotic use is becoming more accepted with antibiotic-associated diarrhea but due to the lack of definitive evidence about efficacy and the safety of probiotic use in the elderly population. More controlled studies are needed in the area of elderly patients suffering from antibiotic-associated diarrhea and the effectiveness of probiotics. Thus, a retrospective case study in a long-term care facility using the probiotic, CulturelleTM, in the elderly population who are suffering from antibiotic-associated diarrhea in a long term care setting is needed.

Objectives

The objectives of this study were:

To determine changes in bowel patterns in patients who suffer from antibiotic induced diarrhea (at least 14 days of data prior to implementation of probiotic) and during the probiotic use; and

To qualitatively compare bowel records (consistency and frequency) before and after the probiotic use.

Chapter III. Materials and Methods

The present study was conducted as a retrospective case study to examine the stool scores and the use of probiotics with patients suffering from antibiotic-associated diarrhea. After approval by the University of Nebraska-Lincoln Institutional Review Board, the review of patient records at a long-term care facility in a Midwestern city began. This long-term care facility includes home health care, hospice, home delivered meals, adult day services, and elder living options. Originally, the researcher reviewed patients who were inpatient residents at the care facility. Specifically, the criterion was narrowed to those patients who had suffered from infections between March 2007 and

March 2009 and who were given an antibiotic and the probiotic, CulturelleTM (Lactobacillus GG). Using Vista KeeneTM, a program that this care facility uses to keep their medical records, the census, registration, physician orders, and care plans were examined. The census indicated when the patient had been admitted and discharged from the long-term care facility and where they went when discharged. The registration included the personal history, allergies, age, sex, and race of the patients. The physician orders were a key area to narrow the search for appropriate patients to include in the case study. It was the location for all medication orders, lab tests, appointments, diet orders, antibiotic orders, and probiotic orders. The last area examined was the care plan section of Vista KeeneTM. It provided information on the disease states and the care plan that was set forth by the dietitians and doctors.

The long-term care facility uses a program called Live Care Tracker[™] to document bowel records and stool scores for patients. Each patient record was examined individually, and the search was narrowed based on the census, antibiotic implementation, and probiotic use. After narrowing the search of patients to those who met our criteria, a list of each bowel movement per day was listed. If the patient did not have a bowel movement, it just said "No". However, if they had a bowel movement, it was scored as to size, consistency, and whether they were continent. Each time a patient had a bowel movement, it was scored in this manner.

The purpose of the bowel movement plan or protocol is to ensure regularity and prevention of impaction. At the facility, each patient is assessed to determine if he/she has regular bowel movements. If not, a plan for bowel care was initiated in a timely manner ensuring that the client remains free of constipation and impaction. The

procedure starts with resident assistants documenting patients' bowel movements each shift for their assigned client and recording it in Care TrackerTM. Next, the staff observes cognitively impaired patients for behaviors that could indicate the need to evacuate bowels, such as restlessness, digging in the rectum, and agitation. These behaviors were reported to the charge nurse for follow up. Next, the evening shift nurse or medication aide runs a "bowel movement protocol cross tab" report in Care TrackerTM to identify the total number of days each patient has not had a bowel movement. Also, if the patient does not have bowel care orders or a problem has been identified, the charge nurse will notify the physician of the patients' bowel status and request an order for use of facility bowel care protocol or other orders to manage patients' bowels as per physician order. The bowel care protocol starts at 4 pm on day three of no bowel movement at which time, 30 ml Milk of MagnesiaTM is given. At 4 pm on day four of no bowel movement, 10 mg Suppository R Bisacodyl (DulcolaxTM) is given. If no stool occurs within 4 hours of having DulcolaxTM, the patient is re-evaluated to rule out impaction and administered one of the following: Enema R of Sodium Phosphate (fleets) or 4oz Magnesium Citrate. If no results, the physician is updated on the patients' bowel status, at which time a request for routine bowel medication may be made. The nurse will update the care plan and inform the staff of the problem/need regarding the patients' bowel movement and the interventions for those patients who require bowel care programs. The nurse will follow up to ensure that the patients' bowel care plan was effective. The patients' nutrition and hydration status is assessed on admission and on an ongoing basis by the Food and Nutrition Department of the facility.

After data were collected from Live Care TrackerTM, the researcher created a graph for each selected patient to compare the number of stools per day. It was color coded to show the consistency, which was the most important part of the stool score. If the stool was soft, then orange was the designated color. If the stool was formed, green was designated. If the stool was hard, then a dark blue was designated. Lastly, if the stool was loose or diarrhea in consistency, then red was the designated color. The antibiotics, probiotics, bowel plan, and dates were placed on the graph. Graphing the stool scores helped identify the number of stools a patient had and then in combination with the color scale, the consistency. This graphing system helped identify days where symptoms were exacerbated or days that patients' stools were more normalized. The antibiotics, probiotics, and bowel plan were placed on the graph in an attempt to determine the effectiveness of the probiotic.

From the established criteria, approximately 500 medical records could be used and it was determined this was too large of a patient group to examine for this qualitative study. Too many variables were not controlled to conduct a quantitative study. The study focus was then narrowed to 20 patient records to be used as case studies. The selection criteria was to have the bowel movement data from patients who were on an antibiotic at least 14 days of data prior to implementation of probiotic, on an antibiotic while on the probiotic, and then data after the antibiotic was stopped.

Chapter IV. Results & Discussion

Both males and females were included, race did not play a part in selection, however, all 20 patient recorded were those of Caucasian race. There were eight males and twelve females in our study.

Case Study One

A white male, born on March 9, 1920, was admitted to the long-term care facility on November 23, 2004 and discharged December 22, 2004. He was readmitted on May 16, 2007 and discharged on July 18, 2007. He was readmitted on July 27, 2007 until March 20, 2008.

Bowel Movement Protocol

Case Study One was placed on the bowel movement protocol on November 24, 2004 to December 22, 2004. The movement bowel protocol was restarted on May 29, 2007 to July 17, 2007. Again the bowel movement protocol was started on July 31, 2007 to March 20, 2008.

Probiotic Plan

Case Study One was administered one capsule per day of the probiotic, CulturelleTM on August 31, 2007 with no stop date set. He was then re-administered one capsule of the probiotic, CulturelleTM, per day starting on December 27, 2007 with no stop date.

Antibiotic Plan

Case Study One was started on 500 mg LevaquinTM once a day for an unknown infection on November 23, 2004 until November 28, 2004. He was also started on 250 mg FlagylTM once a day for an unknown infection on November 23, 2004 until

November 28, 2004. He was started on 500 mg LevaquinTM once a day for a fever on August 16, 2007 until August 27, 2007. He was started on 750 mg LevaquinTM once a day for upper respiratory infection on October 22, 2007 until October 27, 2007. He was started on 750 mg LevaquinTM once a day for pneumonia on December 3, 2007 until December 8, 2007. He was started on 500 mg AzithromycinTM once a day for upper respiratory infection on December 12, 2007 until December 13, 2007. He was started on 250 mg AzithromycinTM once a day for an upper respiratory infection on December 13, 2007 until December 17, 2007. He was started on 800 mg-160 mg Bactrim DSTM once a day for urinary tract infection on January 11, 2008 until January 22, 2008. He was started on 250 mg LevaguinTM once a day for urinary tract infection on January 22, 2008 until January 30, 2008. He was started on 100 mg MacrobidTM twice a day for urinary tract infection on February 7, 2008 until February 23, 2008. He was started on 800 mg-160 mg Bactrim DSTM once a day for urinary tract infection on February 29, 2008 until March 8, 2008. He started on 800 mg-160 mg Bactrim DSTM once a day for urinary tract infection on March 10, 2008 until March 21, 2008.

Nutrition Care Plan

On December 4, 2007, Case Study One was at nutrition risk due to the following: weight loss, history of cancer, acute renal insufficiency, depression, infection, diagnosis of dehydration, and provided intravenous fluids, was on a mechanically altered soft diet, and had an alteration in nutritional laboratory values. On May 5, 2007, Case Study One was at nutrition risk due to the following: weakness, poor appetite, decreased food intakes, congestive heart failure, renal insufficiency, patient reports history of 36 pound weight loss since November 2006, patient has history of prostate cancer, patient complains of problems chewing and requests diet consistency be changed to soft consistency. Patient is edentulous and only wears an upper denture. On July 30, 2007, Case Study One was at nutritional risk due to the following: recent surgery, congestive heart failure, post ileus operation, and altered nutritional laboratory values. Patient was edentulous with upper dentures, does not wear lower dentures due to poor fit, and declined a dental referral at this time.

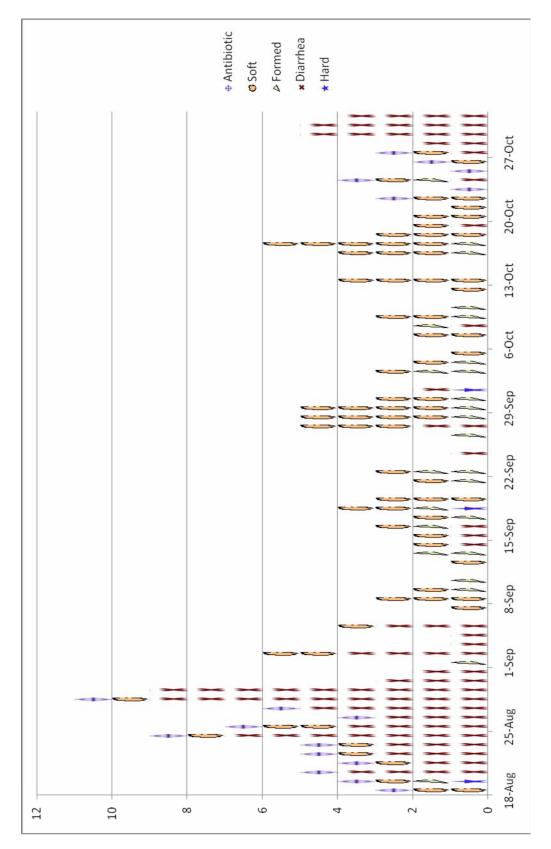


 Table 2. Case Study One Bowel Movement Chart

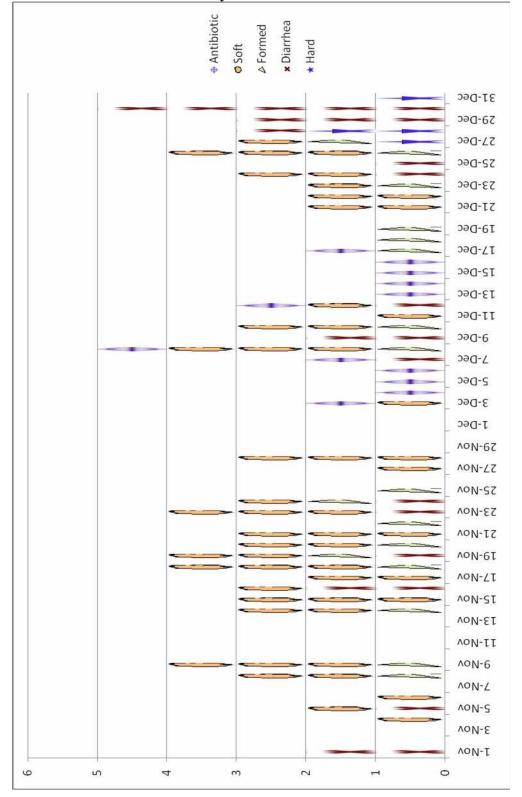


Table 2 Continued. Case Study One Bowel Movement Chart

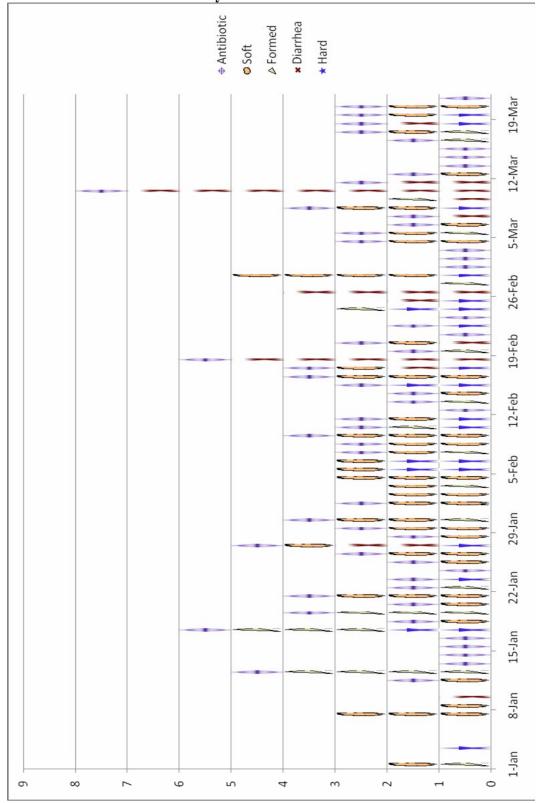


 Table 2 Continued.
 Case Study One Bowel Movement Chart

Interpretation of Bowel Movement Chart for Case Study One

Case Study One started the first antibiotic which led to an influx of diarrhea while still on the antibiotic and continued for four days. However, when the probiotic was started after those four days, Case Study One started having a more normalized bowel pattern. The probiotic was continued and the second antibiotic was started, and this time instead of an increase in diarrhea, it was minimized. The probiotic was continued when the next five antibiotics were started, and this time, there was not a notable change in stool consistency. The only change while on the probiotic was with the eighth antibiotic and it was only for one day. Case Study One was on the bowel movement protocol during the course of antibiotics and analysis of the probiotic effectiveness.

Case Study Two

A white female, born on September 12, 1923, was admitted to the long-term care facility on September 20, 2006 and discharged on October 11, 2006. She was readmitted on November 26, 2008 until December 22, 2008.

Bowel Movement Protocol

Case Study Two was placed on the bowel movement protocol on September 21, 2006 until October 11, 2006. The bowel movement protocol was restarted on December 8, 2008 until December 22, 2008.

Probiotic Plan

Case Study Two was administered one capsule per day of the probiotic, CulturelleTM, on December 8, 2008 until December 24, 2008.

Antibiotic Plan

Case Study Two was placed on 500 mg KeflexTM twice a day for an unknown reason on September 20, 2006 until September 26, 2006. She was started on 100 mg MacrobidTM twice a day for an unknown reason on September 20, 2006 until September 26, 2006. She was then started on 250 mg CiproTM twice a day for an unknown reason on December 6, 2008 until December 16, 2008. She was also given 800 mg-160 mg Bactrim DSTM twice a day for an unknown reason on December 6, 2008 until December 14, 2008.

Nutrition Care Plan

On September 25, 2006, Case Study Two was at nutritional risk due to the following: advanced age, recent compression fractures, osteoporosis, history of dysphagia, and patient is edentulous. On December 1, 2008, Case Study Two was at nutritional risk due to the following: advanced age, dementia, weakness, and altered nutrition related laboratory values. Patient has loose fitting dentures but declines a referral to the dentist.

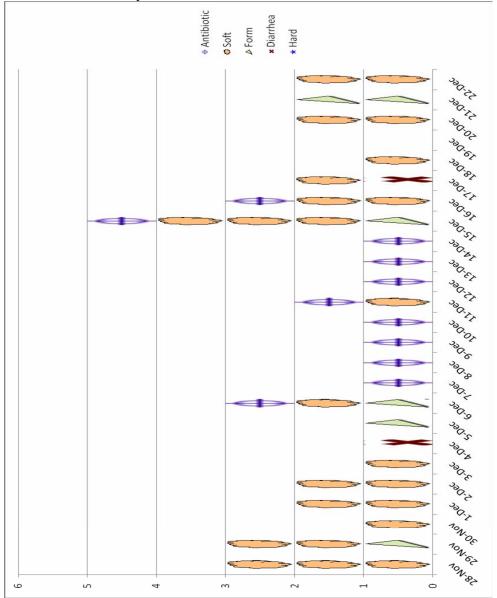


Table 3. Case Study Two Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Two

Case Study Two did not show an obvious change in stool consistency when placed on the two antibiotics and probiotic. She did have an increase in number of stools for one day after the first antibiotic was started. Case Study Two was placed on the bowel movement protocol on the same day as the probiotic.

Case Study Three

A white female, born on June 19, 1925, was admitted to the long-term care facility on March 25, 2003 and discharged April 10, 2003. She was readmitted January 9, 2007 and discharged February 1, 2007. She was readmitted on February 9, 2008 until February 16, 2008.

Bowel Movement Protocol

Case Study Three was placed on the bowel movement protocol on January 9, 2008 until February 1, 2008. The bowel movement protocol was restarted on February 8, 2008 with no stop date.

Probiotic Plan

Case Study Three was administered one capsule per day of the probiotic, CulturelleTM, on February 10, 2008 with no stop date.

Antibiotic Plan

Case Study Three was placed on 500 mg LevaquinTM once a day for an unknown reason on March 26, 2003 until March 31 2003. She was started on 500 mg DuncefTM twice a day for urinary tract infection on April 2, 2003 until April 3, 2003. She was started on 800 mg-160 mg Bactrim DSTM twice a day for an unknown reason on April 3, 2003 until April 10, 2003. She was started on 500 mg FlagylTM three times a day for an unknown reason on January 9, 2008 until January 10, 2008. She was started on 500 mg 2008.

Nutrition Care Plan

On April 4, 2003, Case Study Three was at nutritional risk due to the following: leaving more than 25 percent at most meals, urinary tract infection, constipation, and abnormal nutrition laboratory values. On January 11, 2008, Case Study Three was at nutritional risk due to the following: stroke, advanced age, history of gastrointestinal bleed, dementia, and needs total assistance with meals. On February 6, 2008, Case Study Three was at nutritional risk due to the following: stroke, gastrointestinal bleeding, food intakes of less than 50 percent, insufficient fluid intake, advanced age, altered nutritional laboratory values, needs total assistance with meals, leucocytosis, hypernatremia, stage one wound on buttock, dementia, and hypertension.

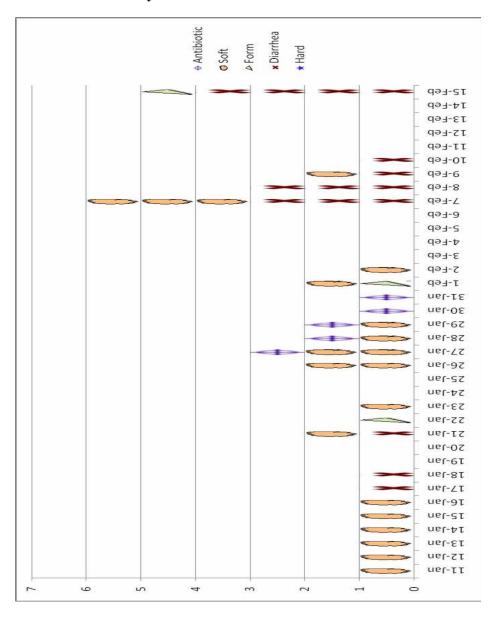


 Table 4. Case Study Three Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Three

Case Study Three did not have a noticeable change in stool consistency when placed on two antibiotics. However, Case Study Three had a bout of diarrhea at the end of taking both antibiotics that did not clear up until being administered the probiotic for three days. Case Study Three was on the bowel movement protocol while on the probiotic.

Case Study Four

A white male, born on September 12, 1925, was admitted to the long-term care facility on November 15, 2003 and discharged November 26, 2003. He was readmitted on October 22, 2007 and discharged November 13, 2007. He was readmitted on January 26, 2007 until December 11, 2007.

Bowel Movement Protocol

Case Study Four was placed on the bowel movement protocol on November 18, 2003 until November 26, 2003. The bowel movement protocol was restarted on October 23, 2007 until November 13, 2007.

Probiotic Plan

Case Study Four was administered one capsule per day of the probiotic,

CulturelleTM, on November 28, 2007 until December 7, 2007.

Antibiotic Plan

Case Study Four was placed on 250 mg LevaquinTM once a day for an unknown reason on November 15, 2003 and stopped on the same day. He was then started on 100 mg MacrobidTM twice a day for an unknown reason on November 15, 2003 until November 26, 2003. Next, he was started on 800 mg-160 mg Bactrim DSTM once a day for Methicillin-resistant *Staphylococcus aureus* (MRSA) in the urine on November 15, 2003 until November 26, 2003. He was started on 800 mg-160 mg Bactrim DSTM twice a day for an unknown reason on November 26, 2007 until December 12, 2007.

Nutrition Care Plan

On October 24, 2007, Case Study Four was at nutrition risk due to the following: advance age, recent compression fracture, diabetes, hypertension, and altered nutritional laboratory values. On November 28, 2007, Case Study Four was at nutritional risk due to the following: advance age, undesirable underweight status, 87 percent ideal body weight, fair food intakes, compression fracture, urinary tract infection, diabetes, and altered skin integrity.

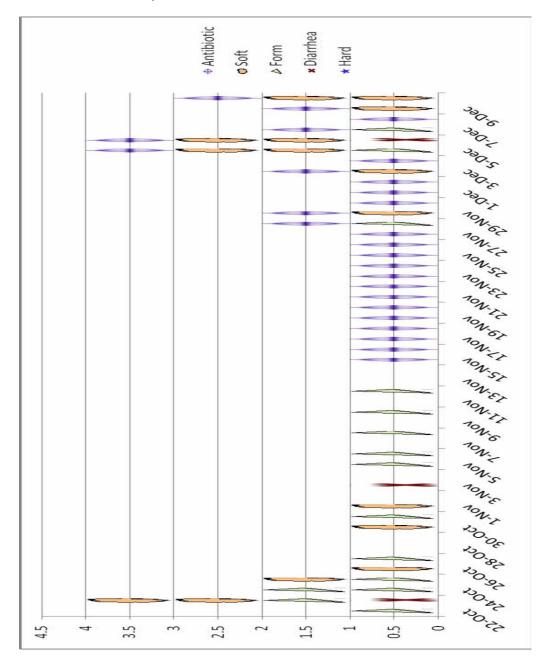


Table 5. Case Study Four Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Four

Case Study Four did not have a noticeable change in stool consistency or number of stools per day when placed on three antibiotics and the probiotic. Case Study Four was placed on and stopped the bowel movement protocol before starting the antibiotics and probiotic.

Case Study Five

A white male, born on November 21, 1949, was admitted to a long-term care facility on May 23, 2002 and discharged February 3, 2008. He was readmitted on February 8, 2008 until March 5, 2008.

Bowel Movement Protocol

Case Study Five was placed on the bowel movement protocol on February 21, 2008 with no stop date.

Probiotic Plan

Case Study Five was administered one capsule per day of the probiotic,

CulturelleTM, on February 13, 2008 until February 24, 2008.

Antibiotic Plan

Case Study Five was placed on 500 mg LevaquinTM once a day for an unknown infection on February 8, 2008 until February 17, 2008.

Nutrition Care Plan

On February 13, 2008, Case Study Five was at nutritional risk due to the following: dysphagia, urinary tract infection, dementia, and altered nutritional laboratory values.

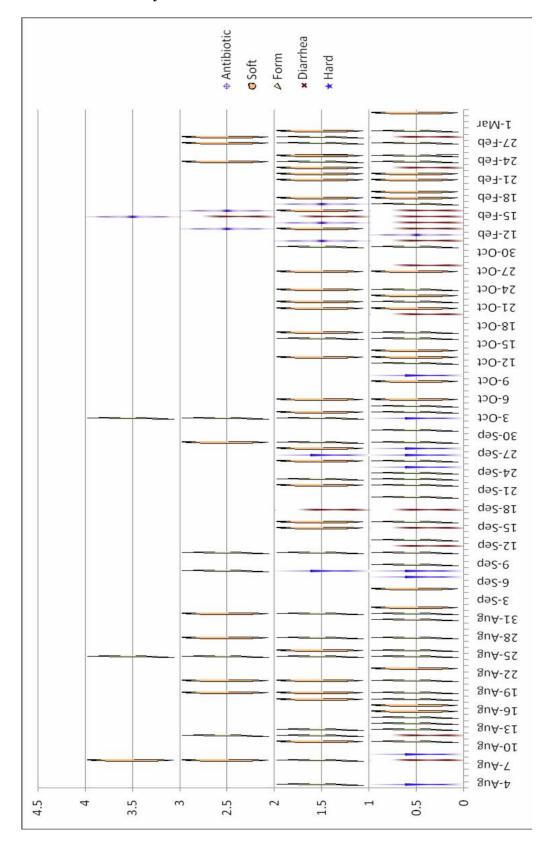


Table 6. Case Study Five Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Five

Case Study Five did not have a noticeable change in stool consistency or number of stools per day when placed on the antibiotic and the probiotic. Case Study Five was placed on the bowel movement protocol while still on the probiotic. It was continued after the probiotic was stopped, with no noticeable change in stools.

Case Study Six

A white female, born on March 25, 1914, was admitted to a long-term care facility on September 22, 2006 and discharged on October 4, 2006. She was readmitted on September 4, 2008 and discharged September 26, 2008. She was readmitted on November 3, 2008 and discharged November 24, 2008. She was readmitted on November 28, 2008 until December 6, 2008.

Bowel Movement Protocol

Case Study Six was placed on the bowel movement protocol on September 25, 2006 to October 4, 2006. The bowel movement protocol was restarted on September 5, 2008 to September 26, 2008. Again the bowel movement protocol was started on November 4, 2008 until November 25, 2008.

Probiotic Plan

Case Study Six was administered one capsule per day of the probiotic, CulturelleTM, on September 6, 2008 to September 12, 2008. She was re-administered the probiotic, CulturelleTM, once per day, November 17, 2008 to November 20, 2008. She was re-administered the probiotic, CulturelleTM, once per day, December 4, 2008 to January 7, 2009.

Antibiotic Plan

Case Study Six was placed on 250 mg FlagylTM four times a day for *Clostridium difficile* on September 4, 2008 until September 11, 2008. She was started on 250 mg CiproTM twice a day for an unknown reason on November 16, 2008 until November 23, 2008. She was started on 500 mg FlagylTM three times a day for *Clostridium difficile* on November 23, 2008 until December 3, 2008. She was started again on 250 mg FlagylTM once a day for an unknown reason, November 28, 2008 until December 16, 2008. Lastly she was started on 250 mg LevaquinTM once a day for an unknown reason on November 28, 2008 until December 1, 2008.

Nutrition Care Plan

On September 26, 2006, Case Study Six was at nutritional risk due to the following: advanced age, congestive heart failure, diabetes, hypothyroidism, altered nutritional laboratory values, and recent endarterectomy. On September 5, 2008, Case Study Six was at nutritional risk due to the following: advanced age, *Clostridium difficile*, recent pneumonia, diabetes, congestive heart failure, hypertension, dehydration, history thyroidectomy, cholycystectomy, and pressure area to right heel. On November 6, 2008, Case Study Six was at nutritional risk due to the following: a history of stroke and *Clostridium difficile*, diabetes, peripheral neuropathy, congestive heart failure, hypertension, hypothyroidism, arthritis, urinary tract infection, renal insufficiency, advanced age, dentures, deep tissue wound, noted as a "picky eater" per nursing, recent weight loss, and requires assistance with meals.

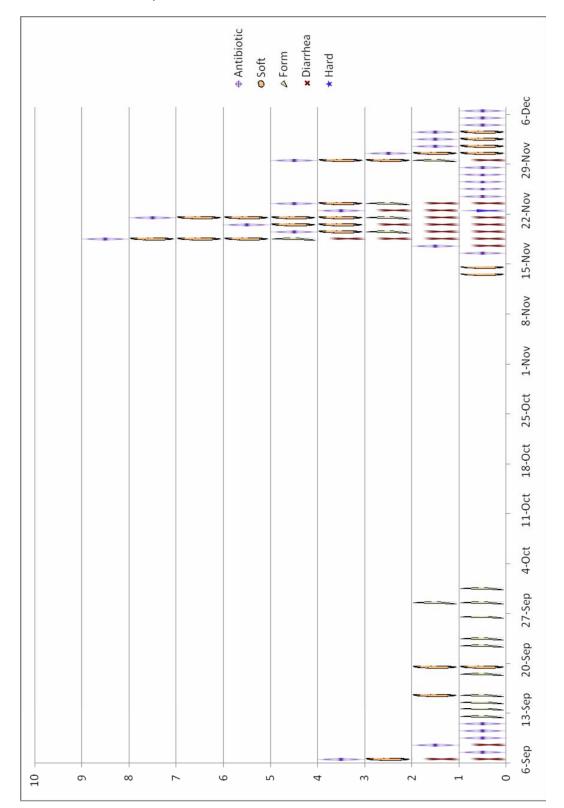


 Table 7. Case Study Six Bowel Movement Chart

Interpretation of Bowel Movement Chart for Case Study Six

Case Study Six had increase change in the number of stools after starting the first antibiotic, which was decreased when the probiotic was started. The bowel movement protocol was stopped for a period of time and when it was restarted, the consistency changed and number of stools increased. After two days, the stool became more regulated. When the next antibiotic was started, there was a noticeable increase in consistency and number of stools. The probiotic did not seem to moderate the stools. However, when another antibiotic was started, the probiotic had a noticeable increase in the number of stools. Case Study Six was started on one antibiotic and probiotic that did not work. She was also started on another antibiotic while on a probiotic that did work in normalizing the stools.

Case Study Seven

A white female, born on June 12, 1915, was admitted to the long-term care facility on November 4, 2005 and discharged November 18, 2005. She was readmitted on February 19, 2007 and discharged on February 24, 2007. She was readmitted on August 19, 2008 and discharged September 22, 2008. She was readmitted in January 13, 2009 with no discharge date.

Bowel Movement Protocol

Case Study Seven was place on the bowel movement protocol on November 4, 2005 until November 18, 2005. The bowel movement protocol was restarted on February 19, 2007 until February 24, 2007. The bowel movement protocol was restarted on August 20, 2008 until September 22, 2008.

Probiotic Plan

Case Study Seven was administered one capsule per day of the probiotic, CulturelleTM, on August 2, 2008 until September 2, 2008. She was re-administered one capsule per day of the probiotic, CulturelleTM, January 15, 2009 until January 30, 2009. She was re-administered one capsule per day of the probiotic, CulturelleTM, on February 3, 2009 with no stop date. She was re-administered one capsule per day of the probiotic, CulturelleTM, March 18, 2009 with no stop date.

Antibiotic Plan

Case Study Seven was placed on 250 mg LevaquinTM once a day for an unknown reason on November 4, 2005 until November 11, 2005. She was started on 250 mg LevaquinTM once a day for urinary tract infection on February 19, 2007 until March 1, 2007. She was started on 500 mg KeflexTM three times a day for an unknown reason on August 19, 2008 until August 27, 2008. She was started on 50 mg/1 ml solution VancomycinTM four times a day for an unknown reason on January 13, 2009 until January 23, 2009. She was started on 500 mg FlagylTM every six hours a day for an unknown reason January 13, 2009 until January 23, 2009. She was started on 50 mg/1 ml solution VancomycinTM four times a day for an unknown reason February 1, 2009 and stopped on the same day. She was started on 125 mg VancomycinTM every six hours a day for an unknown reason on February 1, 2009 until February 10, 2009. She was started on 500 mg FlagylTM every six hours a day for an unknown reason on February 1, 2009 until February 10, 2009. She was started on 250 mg FlagylTM four a day for *Clostridium* difficile on February 19, 2009 until February 20, 2009. She was started on 250 mg FlagylTM once a day for *Clostridium difficile* on March 13, 2009 until March 30, 2009.

She was started on 125 mg VancomycinTM four times a day for *Clostridium difficile* on March 13, 2009 until March 30, 2009. She was started on 200 mg XifaxanTM three times a day for *Clostridium difficile* March 26, 2009 until April 5, 2009. She was started on 300 mg RifampinTM twice a day for an unknown reason on April 24, 2009 until May 15, 2009. She was started on 125 mg Vancomycin TM every six hours a day for an unknown reason on April 24, 2009 until May 6, 2009. She was started on 250 mg LevaquinTM once a day for urinary tract infection on June 15, 2009 and stopped the same day. She was started on 400 mg BactrimTM twice a day for an unknown reason on June 15, 2009 until June 20, 2009.

Nutrition Care Plan

On November 9, 2005, Case Study Seven was at nutrition risk due to the following: advanced age, pneumonia, congestive obstructive pulmonary disease, and anemia. On February 23, 2007, Case Study Seven was at nutritional risk due to: advanced age, decreased food intakes, congestive heart failure, and pre-renal azotemia. Case Study Seven was admitted to the hospital with a small bowel obstruction but stated that she normally does not have problems with constipation. On August 20, 2008, Case Study Seven was at nutritional risk due to the following: advanced age, hypothyroidism, hypertension, congestive obstructive pulmonary disease, urinary tract infection, and altered nutritional laboratory values. On January 15, 2009, Case Study Seven was at nutritional risk due to the following: advanced age, *clostridium difficile*, congestive heart failure, urinary tract infection, gastric esophageal reflux disease, stage two pressure areas to coccyx, and decreased food intakes.

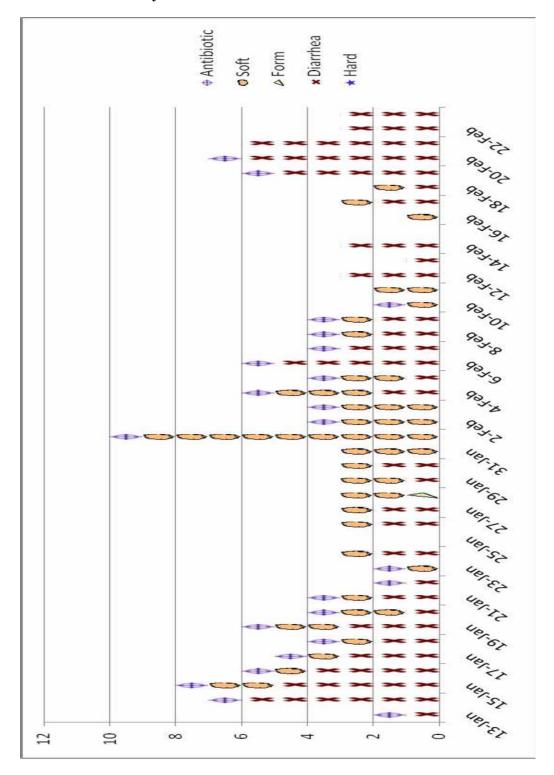


 Table 8. Case Study Seven Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Seven

The first antibiotic that was started, did not seem to have a noticeable change since the probiotic was started at the same time. However, when two other antibiotics were started, there was a huge increase in number of stools and change in consistency. Even though the probiotic was started, it did not decrease the number or the consistency of stools during the analysis period.

Case Study Eight

A white female, born on August 8, 1935, was admitted to the long-term care facility on December 20, 2006 and discharged February 27, 2007. She was readmitted on March 2, 2007 until April 2, 2007.

Bowel Movement Protocol

Case Study Eight was placed on the bowel movement protocol on December 22, 2006 until February 27, 2007. The bowel movement protocol was restarted on March 5, 2007 with no stop date.

Probiotic Plan

Case Study Eight was administered one capsule per day of the probiotic,

CulturelleTM, on March 11, 2007 with no stop date.

Antibiotic Plan

Case Study Eight was started on 500 mg Levaquin[™] once a day for an unknown reason on December 31, 2006 until January 30, 2007. She was started on 250 mg Levaquin[™] once a day for an unknown reason on January 19, 2007 until January 30, 2007. She was started on 500 mg Cipro[™] twice a day for an unknown reason on February 8, 2007 until February 14, 2007. She was started on 500 mg Levaquin[™] once a day for an unknown reason February 19, 2007 until February 27, 2007. She was started on 500 mg LevaquinTM once a day for an unknown reason February 26, 2007 until March 7, 2007. She was started on 500 mg LevaquinTM once a day for an unknown reason March 9, 2007 until March 20, 2007. She was started on 250 mg LevaquinTM once a day for an unknown reason March 22, 2007 until March 23, 2007.

Nutrition Care Plan

On December 22, 2006, Case Study Eight was at nutritional risk due to the following: dementia, left hip fracture, anemia, altered nutritional laboratory values, stage two pressure areas to left buttock and fair food intakes. On March 11, 2007, Case Study Eight was at nutritional risk due to the following: dementia, right total knee replacement, recent left hip fracture, irritable bowel syndrome, urinary tract infection, and diarrhea. *Clostridium difficile* test came back negative on March 8, 2007.

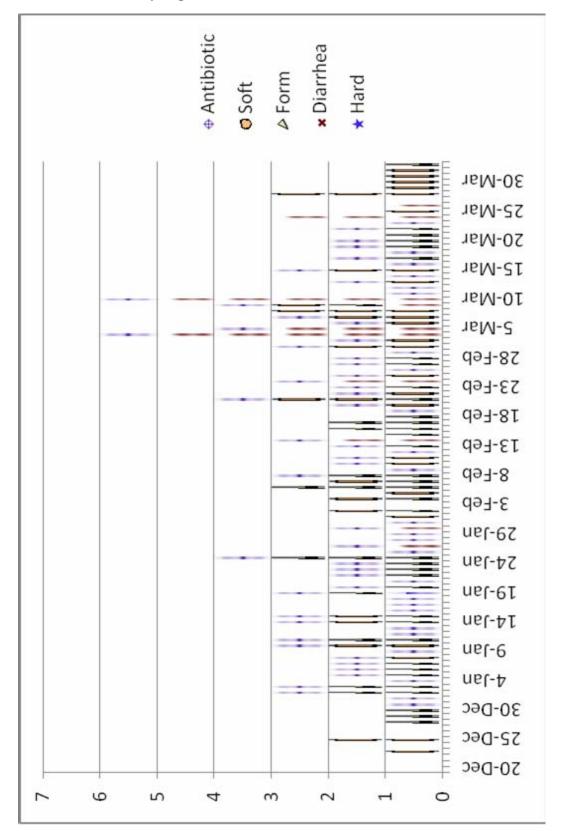


 Table 9. Case Study Eight Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Eight

Case Study Eight stool consistency and number of stools were not noticeably affected by the first three antibiotics. However, when the fourth antibiotic was started, the consistency and number increased. Once the probiotic was started, the stools became more regulated for the final analyzed period.

Case Study Nine

A white female, born on April 17, 1914, was admitted to the long-term care facility on June 12, 2007 and discharged July 9, 2007. She was readmitted on January 10, 2008 until January 27, 2008.

Bowel Movement Protocol

Case Study Nine was placed on the bowel movement protocol on June 14, 2007 until July 9, 2007. The bowel movement protocol was restarted on January 15, 2008 until January 23, 2008.

Probiotic Plan

Case Study Nine was administered one capsule per day of the probiotic, CulturelleTM, on January 11, 2008 with no stop date.

Antibiotic Plan

Case Study Nine was started on 800 mg-160 mg BactrimTM DS twice a day for pneumonia June 20, 2007 until July 9, 2007. She was started on 250 mg LevaquinTM once a day for an unknown reason July 3, 2007 until July 11, 2007. She was started on 875 mg-125 mg Amoxicillian-ClavulanteTM twice a day for pneumonia January 10, 2008 until January 17, 2008. She was started on 500 mg ZithromaxTM once a day for pneumonia January 10, 2008 until January 14, 2008.

Nutrition Care Plan

On June 14, 2007, Case Study Nine was at nutritional risk due to the following: failure to thrive diagnosis, dementia, hypertension, gastric esophageal reflux disease, and advanced age. On January 11, 2008, Case Study Nine was at nutritional risk due to the following: poor food intakes, gastric esophageal reflux disease, aspiration precautions, advanced age, altered diet consistency, nectar fluids, stage two pressure sore, and required assistance with meals.

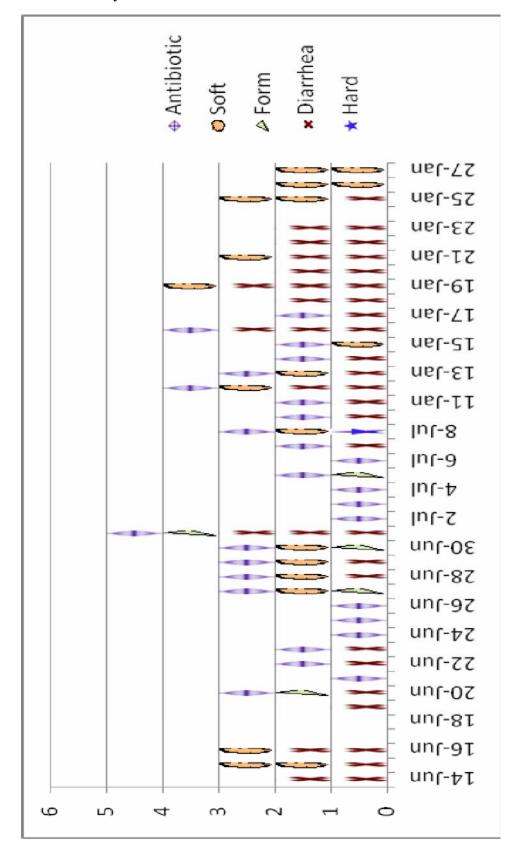


Table 10. Case Study Nine Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Nine

Case Study Nine was placed on the bowel movement protocol at the same time as being started on two antibiotics. There was not a noticeable change in stool consistency or number of stools. The bowel movement protocol was discontinued in July. In January another antibiotic and probiotic were started. The number of stools did not seem to increase, but the consistency changed and was soft even when the probiotic was administered.

Case Study Ten

A white male, born on April 16, 1930, was admitted to the long-term care facility on May 8, 2007 and discharged on May 27, 2007. He was readmitted on May 29, 2007 and discharged September 10, 2007. He was readmitted on September 12, 2007 and discharged February 3, 2008. He was readmitted on February 7, 2008 until June 19, 2008.

Bowel Movement Protocol

Case Study Ten was placed on the bowel movement protocol on May 29, 2007 until September 11, 2007. The bowel movement protocol was restarted on September 12, 2007 until January 13, 2008. The bowel movement protocol was restarted on February 28, 2008 until April 30, 2008. The bowel movement protocol was restarted May 1, 2008 until May 28, 2008.

Probiotic Plan

Case Study Ten was administered two capsules per day of the probiotic, CulturelleTM, on May 24, 2007 until August 24, 2007. He was re-administered one capsule per day of the probiotic, CulturelleTM on December 30, 2007 until February 4, 2008. He was re-administered one capsule per day of the probiotic, CulturelleTM on May 12, 2008 with no stop date.

Antibiotic Plan

Case Study Ten was started on 500 mg ZithromaxTM once a day for an unknown reason July 3, 2007 until July 6, 2007. He was started on 800 mg-160 mg Bactrim DS^{TM} twice a day for an unknown infection August 27, 2007 until August 28, 2007. He was started on 800 mg-160 mg Bactrim DSTM twice a day for an unknown infection August 27, 2008 until September 3, 2007. He was started on 500 mg LevaquinTM once a day for an unknown reason October 6, 2007 until October 13, 2007. He was started on 400 mg ZyvoxTM twice a day for an unknown reason December 13th, 2007 until December 23, 2007. He was started on 250 mg KeflexTM twice a day for unknown reason January 11, 2008 until January 21, 2008. He was started on 800 mg-160 mg Bactrim DSTM twice a day for unknown reason February 17, 2008 until February 25, 2008. He was started on 750 mg LevaquinTM every 48 hours for unknown reasons February 26, 2008 until February 29, 2008. He was started on 750 mg LevaquinTM every 48 hours for unknown reason February 26, 2008 until February 29, 2008. He was started on 80 mg/400 mg Trimethoprim with sulfaTM twice a day for unknown infection February 26, 2008 until March 3, 2008. He was started on 250 mg CiproTM twice a day for unknown infection March 3, 2008 until March 9, 2008.

Nutrition Care Plan

On May 10, 2007, Case Study Ten was at nutritional risk due to the following: stroke, aspiration pneumonia, history of hyponatremia, gastric esophageal reflux disease, esophageal dilution, and dysphagia secondary to stroke. On August 8, 2007, Case Study Ten was at nutritional risk due to the following: history of Crohn's disease, patient considered a "picky eater" by the nursing staff, and currently dependant on tube feeding. On September 17, 2007, Case Study Ten was at nutritional risk due to the following: recent bowel obstruction, history of stroke with dysphagia, aspiration pneumonia, gastric esophageal reflux disease, Crohn's disease, weight loss, and poor food intakes.

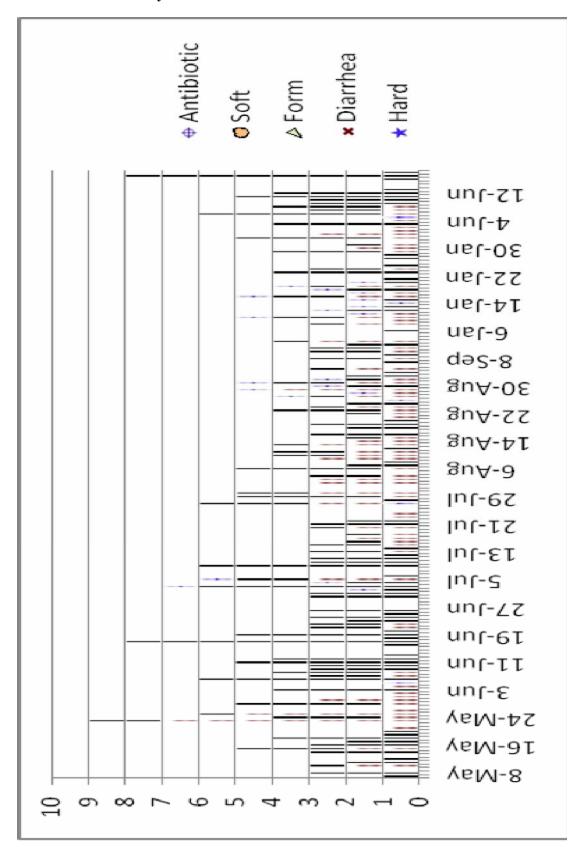


Table 11. Case Study Ten Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Ten

Case Study Ten was administered multiple antibiotics, bowel movement protocol, and probiotic. There was not a noticeable change in consistency or number of stools when Case Study Ten was placed on the probiotic during the analyzed period.

Case Study Eleven

A white male, born on April 20, 1916, was admitted to the long-term care facility on November 5, 2004 and discharged March 1, 2006. He was readmitted March 10, 2006 and discharged November 10, 2008. He was readmitted on November 10, 2008 with no discharge date.

Bowel Movement Protocol

Case Study Eleven was placed on the bowel movement protocol on November 5, 2004 until January 11, 2006. The bowel movement protocol was restarted on February 16, 2006 until March 1, 2006. The bowel movement protocol was restarted March 14, 2006 until December 30, 2007. The bowel movement protocol was restarted on January 2, 2008 until November 8, 2008. The bowel movement protocol was restarted on January 31, 2009 with no stop date.

Probiotic Plan

Case Study Eleven was administered one capsule per day of the probiotic, CulturelleTM, on March 17, 2008 with no stop date. He was re-administered one capsule per day of the probiotic, CulturelleTM on April 4, 2008 until April 12, 2008. He was readministered one capsule per day of the probiotic, CulturelleTM on June 11, 2008 with no stop date. He was re-administered one capsule per day of the probiotic, CulturelleTM on October 28, 2008 with no stop date.

Antibiotic Plan

Case Study Eleven was started on TRI-Pak[™] once a day for an unknown reason November 9, 2004 until November 12, 2004. He was started on 100 mg Macrobid twice per day for an unknown reason November 20, 2004 until November 28, 2004. He was started on 875 mg Amoxicillin[™] twice a day for an unknown reason November 29, 2004 until December 8, 2004. He was started on 400 mg Avelox[™] once a day for another unknown reason December 26, 2007 until December 30, 2007. He was started on 500 mg Levaquin[™] once a day for pneumonia December 31, 2007 until January 8, 2008. He was started on 500 mg Levaquin[™] once a day for an unknown reason March 13, 2008 until March 16, 2008. He was started on 750 mg Levaquin[™] once a day for pneumonia March 17, 2008 until March 21, 2008. He was started on 750 mg Levaquin[™] once a day for an unknown reason April 1, 2008 until April 7, 2008. He was started on 500 mg Levaquin[™] once a day for upper respiratory infection July 6, 2008 until August 13, 2008. He was started on 500 mg Levaquin[™] once a day for an unknown reason November 6, 2008 until November 8, 2008.

Nutrition Care Plan

On November 28, 2005, Case Study Eleven was at nutritional risk due to the following: partial dependence on tube feeding for macronutrient and hydration needs, history of weight loss, history of pressure ulcers, edentulous, history of constipation, altered nutritional laboratory values, advanced age, nausea, and vomiting.

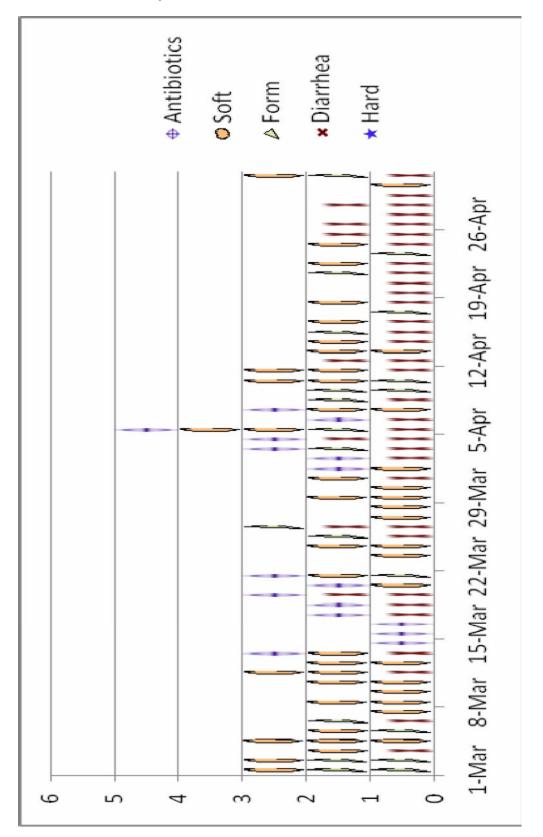


 Table 12. Case Study Eleven Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Eleven

Case Study Eleven was placed on the bowel movement protocol before being placed on antibiotics and probiotic. Once the antibiotics and probiotic were started, there was no noticeably change in consistency and number of stools.

Case Study Twelve

A white male, born on August 30, 1918, was admitted to the long-term care facility on October 10, 2008 and discharged October 22, 2008. He was readmitted on November 19, 2008 and discharged November 20, 2008. He was readmitted on December 1, 2008 and discharged December 24, 2008. He was readmitted December 27, 2008 and discharged January 14, 2009. He was readmitted January 27, 2009 until February 21, 2009.

Bowel Movement Protocol

Case Study Twelve was placed on the bowel movement protocol on December 20, 2007 until February 1, 2008. The bowel movement protocol was restarted on October 10, 2008 until October 31, 2008. The bowel movement protocol was restarted on December 9, 2008 until December 26, 2008. The bowel movement protocol was restarted on January 7, 2009 until January 14, 2009. The bowel movement protocol was restarted on February 2, 2009 with no stop date.

Probiotic Plan

Case Study Twelve was administered two capsules per day of the probiotic, CulturelleTM, on October 16, 2008 until October 26, 2008. He was administered two capsules per day of the probiotic, CulturelleTM, December 1, 2008 until December 26, 2008.

Antibiotic Plan

Case Study Twelve was started on 750 mg LevaquinTM once a day for pneumonia October 10, 2008 until October 13, 2008. He was started on 1000 mg/10 ml intravenous fluid VancomycinTM once a day for an unknown infection December 1, 2008 until December 11, 2008.

Nutrition Care Plan

On December 27, 2007, Case Study Twelve was at nutritional risk due to the following: advanced age, a recent right hip fracture, chronic constipation, hypertension, and altered nutritional laboratory values. On October 16, 2008, Case Study Twelve was at nutritional risk due to the following: advanced age, pressure sores, fractured scapula, pneumonia, loose stools, and altered nutritional laboratory values. On December 6, 2008, Case Study Twelve was at nutritional risk due to the following: advanced age, pressure sores, fractured scapula, pneumonia, loose stools, and altered nutritional laboratory values. On December 6, 2008, Case Study Twelve was at nutritional risk due to the following: advanced age, altered diet consistency thickened due to aspiration, pneumonia, Methicillin-resistant *Staphylococcus aureus* (MRSA) plus sputum, and history of bladder cancer. On January 3, 2009, Case Study Twelve was at nutritional risk due to the following: advanced age, weakness, Methicillin-resistant *Staphylococcus aureus* (MRSA), sepsis, and altered nutrition laboratory values.

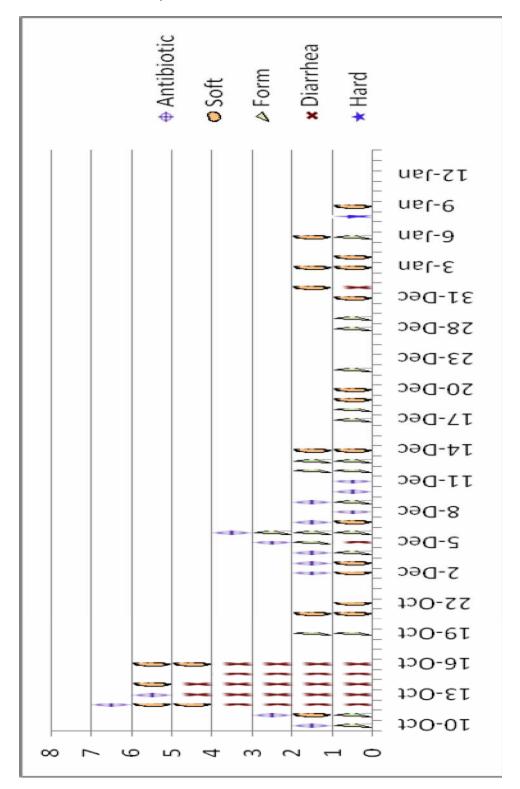


Table 13. Case Study Twelve Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Twelve

Case Study Twelve was started on an antibiotic which changed the consistency and number of stools until the probiotic was started. Once the probiotic was started, the consistency and number of stools was noticeably regulated.

Case Study Thirteen

A white female, born on May 12, 1919, was admitted to the long-term care facility on October 14, 2006 and discharged May 16, 2007. She was readmitted on May 21, 2007 and discharged April 20, 2008. She was readmitted on April 21, 2008 and discharged May 9, 2008. She was readmitted on May 13, 2008 and discharged May 31, 2008. She was readmitted on June 9, 2008 with no discharge date.

Bowel Movement Protocol

Case Study Thirteen was placed on the bowel movement protocol on October 16, 2006 until October 19, 2006. The bowel movement protocol was restarted on April 20, 2007 until April 25, 2007. The bowel movement protocol was restarted on May 20, 2007 until May 22, 2007. The bowel movement protocol was restarted on August 6, 2007 until August 9, 2007. The bowel movement protocol was restarted on November 24, 2007 until April 10, 2008. The bowel movement protocol was restarted on April 20, 2008 until April 22, 2008. The bowel movement protocol was restarted on May 9, 2008 until May 13, 2008. The bowel movement protocol was restarted on May 9, 2008 until May

Probiotic Plan

Case Study Thirteen was administered one capsule per day of the probiotic, CulturelleTM on July 21, 2007 until August 2, 2007. She was administered one capsule per day of the probiotic, CulturelleTM on December 28, 2007 until January 10, 2008. She was administered one capsule per day of the probiotic, CulturelleTM on June 10, 2008 until July 1, 2008. She was administered one capsule per day of the probiotic,

CulturelleTM on September 9, 2008 until September 17, 2008. She was administered one capsule per day of the probiotic, CulturelleTM on November 25, 2008 until December 3, 2008. She was administered one capsule per day of the probiotic, CulturelleTM on December 21, 2008 until December 29, 2008. She was administered one capsule per day of the probiotic, CulturelleTM on July 1, 2009 until July 13, 2009. She was administered one capsule per day of the probiotic, CulturelleTM on July 1, 2009 until July 13, 2009 until August 16, 2009.

Antibiotic Plan

Case Study Thirteen was started on 300 mg ClindamycinTM once a day for an unknown infection October 14, 2006 until October 19, 2006. She was started on 300 mg CleocinTM three a day for an unknown infection November 3, 2006 until November 25, 2006. She was started on 300 mg ClindamycinTM once a day for an unknown infection March 13, 2007 until April 20, 2007. She was started on 200 mg MacrobidTM twice a day for urinary tract infection April 23, 2007 until May 1, 2007. She was started on 250 mg LevaquinTM once a day for pneumonia September 6, 2007 until September 7, 2007. She was started on 500 mg Biaxin filmtabTM twice a day for pneumonia September 7, 2007 and was stopped the same day. She was started on 750 mg LevaquinTM once a day for an unknown reason September 7, 2007 until September 12, 2007. She was started on 300 mg ClindamycinTM four times a day for pneumonia November 24, 2007 until December 5, 2007. She was started on 500 mg LevaquinTM once a day for pneumonia November 24, 2007 until December 5, 2007. She was started on 500 mg LevaquinTM once a day for pneumonia November 24, 2007 until December 5, 2007. She was started on 500 mg LevaquinTM once a day for lower respiratory infection February 2, 2008 until February 26, 2008. She was started on 500 mg LevaquinTM once a day for an unknown reason April 21, 2008 until April 26, 2008. She

was started on 100 mg MacrobidTM twice a day for urinary tract infection April 23, 2008 until May 1, 2008. She was started on 500 mg LevaquinTM once a day for pneumonia May 14, 2008 until May 21, 2008. She was started on 500 mg LevaquinTM once a day for an unknown reason June 9, 2008 until June 12, 2008. She was started on 800 mg-160 mg Bactrim DSTM once a day for an unknown infection September 4, 2008 and stopped the same day. She was started on 750 mg LevaquinTM once a day for an unknown reason September 4, 2008 until September 15, 2008. She was started on 750 mg LevaquinTM once a day for an unknown reason December 17, 2008 until December 23, 2008. She was started on 750 mg LevaquinTM once a day for an unknown reason June 30, 2009 until July 5, 2009. She was started on 750 mg LevaquinTM once a day for an unknown reason August 2, 2009 until August 9, 2009.

Nutrition Care Plan

On January 11, 2008, Case Study Thirteen was at nutritional risk due to the following: advanced age, undesirable overweight status, diabetes, congestive heart failure, osteoporosis with history of vertebral fracture, anemia, hypertension, constipation, gastric esophageal reflux disease, hypothyroidism, and altered nutritional laboratory values. On April 22, 2008, Case Study Thirteen was at nutritional risk due to the following: humoral fracture, frequent urinary tract infections, congestive heart failure, hypothyroidism, asthma, osteoporosis, hypertension, history of peptic ulcer, advanced age, altered nutritional laboratory values, dentures with mouth pain, altered diet consistency, and aspiration risk. On May 16, 2008, Case Study Thirteen was at nutritional risk due to the following: high aspiration risk, peptic ulcer, chronic anemia, diabetes, hypothyroidism, humoral fracture, advanced age, altered nutritional laboratory

values, altered diet consistency, and loose upper denture. On June 10, 2008, Case Study Thirteen was at nutritional risk due to the following: advanced age, congestive obstructive pulmonary disease, left humoral fracture, diabetes, osteoporosis, hypothyroidism, anemia, high aspiration risk, and upper dentures not fitting properly.

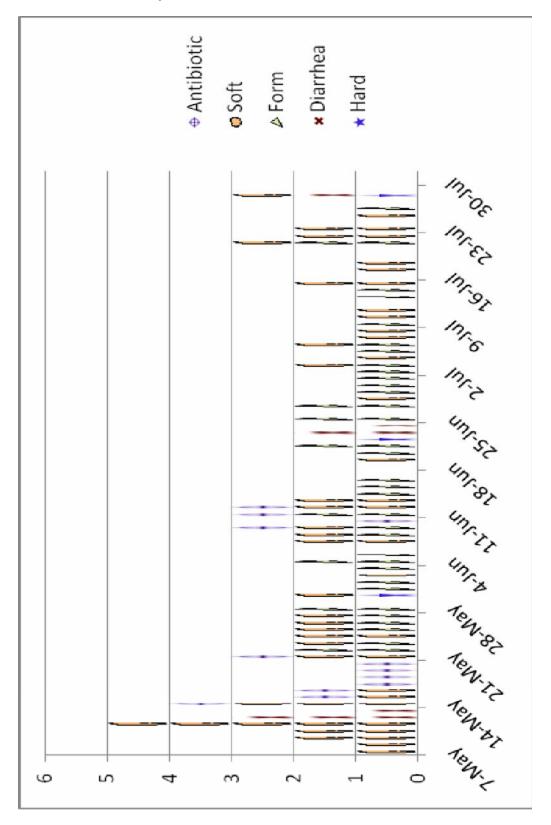


Table 14. Case Study Thirteen Bowel Movement Chart.

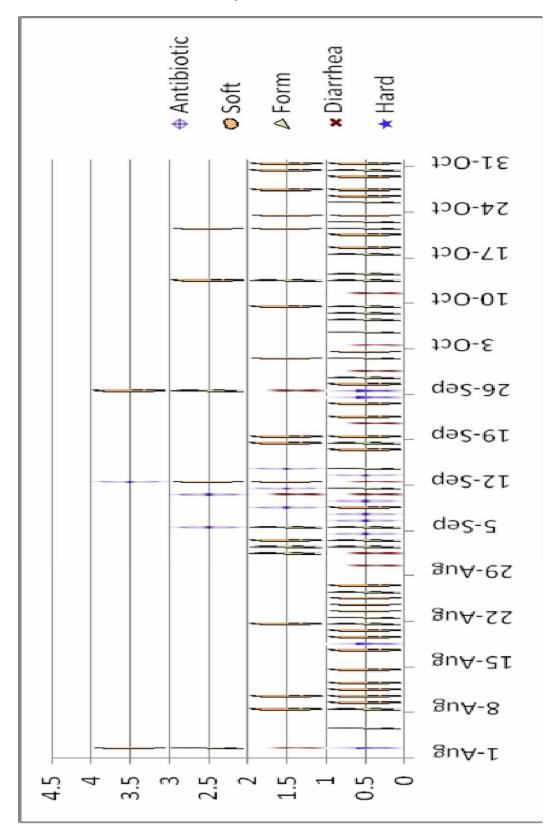


 Table 14 Continued.
 Case StudyThirteen Bowel Movement Chart.

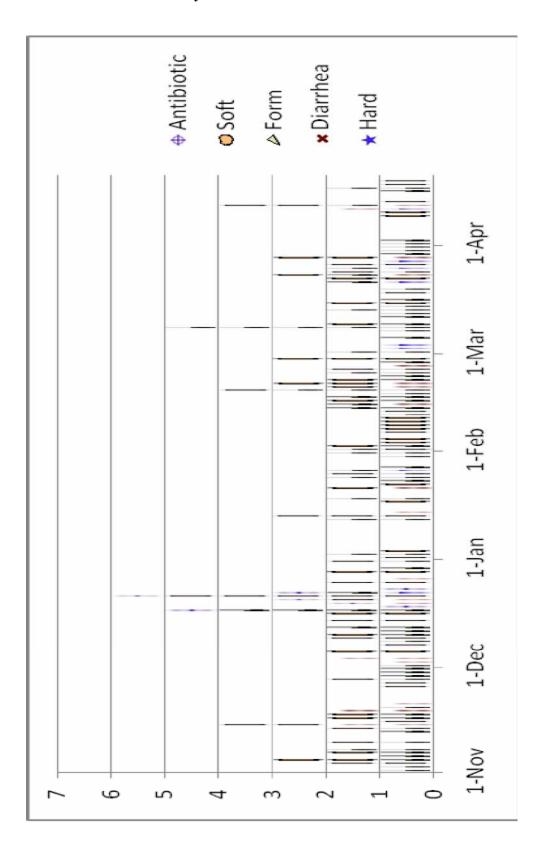


 Table 14 Continued.
 Case StudyThirteen Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Thirteen

Case Study Thirteen was first started on a number of antibiotics followed by the bowel movement protocol and then the probiotics. When the probiotic was administered, the antibiotic and bowel movement protocol were continued. There was no noticeable change in stool consistency or number when the probiotic was started.

Case Study Fourteen

A white female, born on June 12, 1915, was admitted to the long-term care facility on May 3, 2007 and discharged December 22, 2007.

Bowel Movement Protocol

Case Study Fourteen was placed on the bowel movement protocol on May 4, 2007 until October 31, 2007. The bowel movement protocol was restarted on November 13, 2007 until December 19, 2007.

Probiotic Plan

Case Study Fourteen was administered one capsule per day of the probiotic, CulturelleTM, from July 10, 2007 until July 25, 2007. She was administered one capsule per day of the probiotic, CulturelleTM, as it was restarted on November 14, 2007 with no stop date.

Antibiotic Plan

Case Study Fourteen was started on 250 mg LevaquinTM once a day for an unknown reason July 5, 2007 until July 11, 2007. She was started on 100 mg MacrobidTM once a day for an unknown infection July 7, 2007 until July 16, 2007. She was started on 300 mg OmnicefTM twice a day for urinary tract infection November 12,

2007 until November 20, 2007. She was started on 875 mg-125 mg AugmentinTM twice a day for urinary tract infection December 6, 2007 until December 13, 2007.

Nutrition Care Plan

On May 4, 2007, Case Study Fourteen was at nutritional risk due to the following: osteoporosis, hypothyroidism, dementia, urinary tract infection, pneumonia, depression, mild dehydration, hypercholesterolemia, altered nutritional laboratory values, poor food intakes, advanced age, and dentures. On November 14, 2007, Case Study Fourteen was at nutritional risk due to the following: osteoporosis, recent fracture, hypothyroidism, dementia, urinary tract infection, depression, altered nutritional laboratory values, history of poor food intakes, advanced age, and dentures.

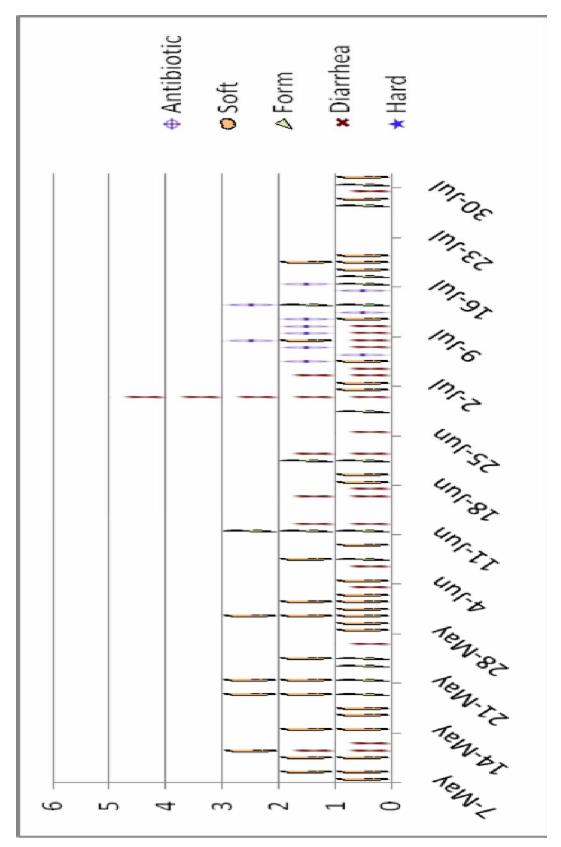


 Table 15. Case Study Fourteen Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Fourteen

Case Study Fourteen was started on the bowel movement protocol prior to starting antibiotics and probiotic. There was not a noticeable change in the consistency and number of stools when the first two antibiotics were started since the probiotic was started at the same time. When the next round of antibiotics and probiotic were started, the only noticeable change was a decrease in number of stools. For the rest of the analyzed period, there was not a noticeable change in consistency.

Case Study Fifteen

A white male, July 12, 1919 on, was admitted to the long-term care facility on April 18, 2007 and discharged on May 3, 2007. He was readmitted on February 18, 2008 until March 5, 2008. He was readmitted on June 24, 2008 until June 28, 2008.

Bowel Movement Protocol

Case Study Fifteen was placed on the bowel movement protocol on April 18, 2007 until January 28, 2008. He was restarted on the bowel movement protocol on June 25, 2008 with no stop date.

Probiotic Plan

Case Study Fifteen was administered one capsule per day of the probiotic, CulturelleTM on February 22, 2008 until March 31, 2008. He was administered one capsule per day of the probiotic, CulturelleTM on June 26, 2008 until July 3, 2008.

Antibiotic Plan

Case Study Fifteen was started on 500 mg LevaquinTM once a day for pneumonia February 18, 2008 with no stop date.

Nutrition Care Plan

On May 2, 2007, Case Study Fifteen was at nutritional risk due to the following: history of recurrent pneumonia, congestive obstructive pulmonary disease, anemia, altered nutritional laboratory values, edema, and 76 percent of ideal body weight on admission to facility. On February 22, 2008, Case Study Fifteen was at nutritional risk due to the following: chronic constipation, congestive obstructive pulmonary disease, dementia, chronic anemia, gastric esophageal reflux disease, stage two wound to coccyx, and infection. On June 26, 2008, Case Study Fifteen was at nutritional risk due to the following: 81 percent ideal body weight, congestive obstructive pulmonary disease, pneumonia, dementia, altered nutritional laboratory values, thrush, decreased appetite and decreased food intakes.

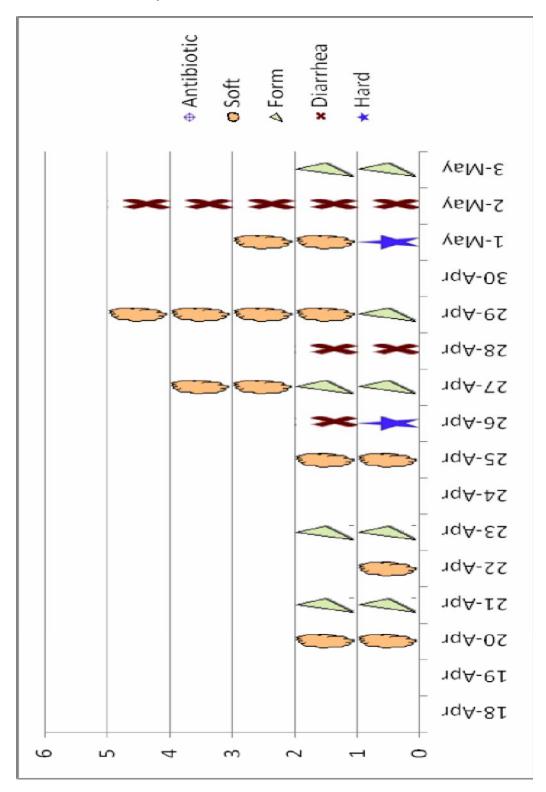


Table 16. Case Study Fifteen Bowel Movement Chart.

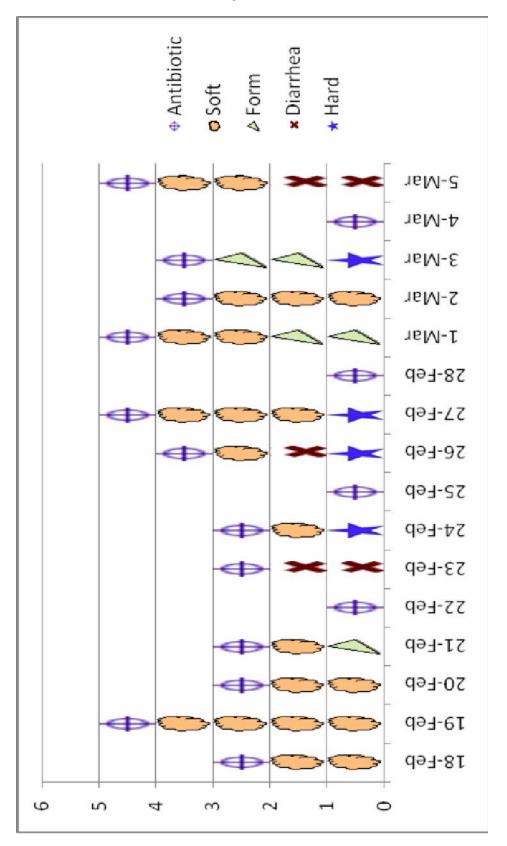


Table 16 Continued. Case Study Fifteen Bowel Movement Chart.

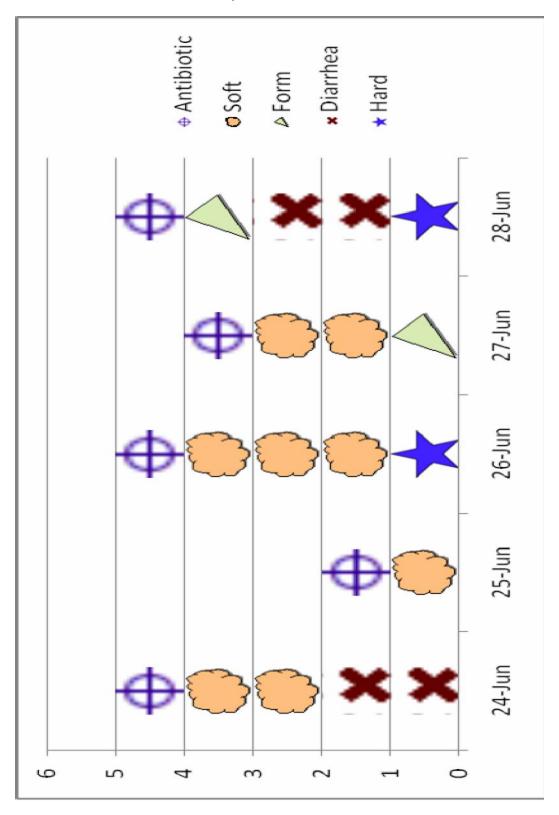


 Table 16 Continued.
 Case Study Fifteen Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Fifteen

Case Study Fifteen was started on an antibiotic which did not noticeably change the consistency and number of stools before and while the probiotic was administered.

Case Study Sixteen

A white male, born on August 3, 1933, was admitted to the long-term care facility on October 16, 2007 and discharged October 30, 2007. He was readmitted November 5, 2007 until December 7, 2007. He was readmitted December 13, 2007 until January 12, 2008. He was readmitted May 15, 2008 until May 23, 2008.

Bowel Movement Protocol

Case Study Sixteen was placed on the bowel movement protocol on October, 17, 2007 until October 30, 2007. He was restarted on the bowel movement protocol on December 15, 2007 until January 12, 2008. He was restarted on the bowel movement protocol on May 15, 2008 with no stop date.

Probiotic Plan

Case Study Sixteen was administered one capsule per day of the probiotic, CulturelleTM on November 5, 2007 until December 8, 2007. He was administered one capsule per day of the probiotic, CulturelleTM on December 28, 2007 until January 10, 2008. He was administered one capsule per day of the probiotic, CulturelleTM on May 16, 2008 until June 2, 2008.

Antibiotic Plan

Case Study Sixteen was started on 250 mg LevaquinTM once a day for urinary tract infection October 16, 2007 until October 24, 2007. He was started on 875 mg AugmentinTM once a day for an infection November 5, 2007 until November 13, 2007. He was started on 100 mg MacrobidTM once a day for urinary tract infection November

13, 2007 until November 15, 2007. He was started on 875 mg AmoxicillinTM twice a day for an unknown reason November 23, 2007 until December 1, 2007. He was started on 500 mg LevaquinTM once a day for an unknown reason December 4, 2007 until December 8, 2007. He was started on 875 mg AugmentinTM twice a day for urinary tract infection December 11, 2007 until December 13, 2007. He was started on 800 mg BactriumTM twice a day for an unknown reason December 31, 2007 until January 10, 2008.

Nutrition Care Plan

On May 16, 2008, Case Study Sixteen was at nutritional risk due to the following: urinary tract infection, anemia, history of prostate cancer, history of colon cancer, and altered nutritional laboratory values.

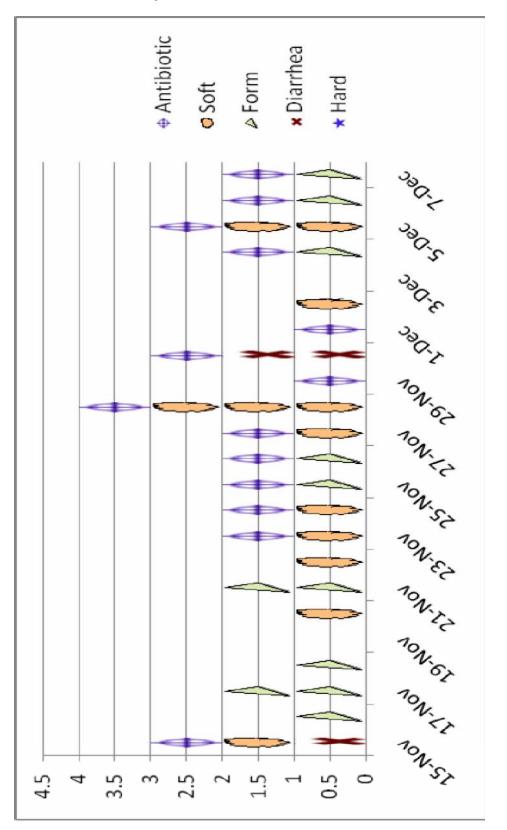


 Table 17. Case Study Sixteen Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Sixteen

Case Study Sixteen was started on an antibiotic which did not noticeably change the consistency and number of stools before and while the probiotic was administered.

Case Study Seventeen

A white female, born on April 20, 1933, was admitted to the long-term care facility on January 11, 2008 and discharged on February 5, 2008. She was readmitted on February 13, 2008 and discharged on March 3, 2008. She was readmitted on July 26, 2008 until on October 3, 2008.

Bowel Movement Protocol

Case Study Seventeen was placed on the bowel movement protocol on July 29, 2008 with no stop date.

Probiotic Plan

Case Study Seventeen was administered one capsule per day of the probiotic, CulturelleTM, on February 22, 2008 with no stop date. She was re-administered one capsule per day made into paste of the probiotic, CulturelleTM on August 18, 2008 with no stop date.

Antibiotic Plan

Case Study Seventeen was started on 100 mg DiflucanTM once a day for an unknown infection February 24, 2008 until March 2, 2008.

Nutrition Care Plan

On January 15, 2008, Case Study Seventeen was at nutritional risk due to the following: recent stroke, hypertension, diabetes, hyperlipidemia, and recent sacral fracture. On February 22, 2008, Case Study Seventeen was at nutritional risk due to the following: Cushing's Syndrome, urinary tract infection with fever, diabetes,

hyperlipidemia, obesity, history of stroke times two, sacral fracture, gastric esophageal reflux disease, altered nutritional laboratory values, very picky eater, and food intakes less than 75 percent. On July 29, 2008, Case Study Seventeen was at nutritional risk due to the following: fracture to the right humerous bone, diabetes, and obesity.

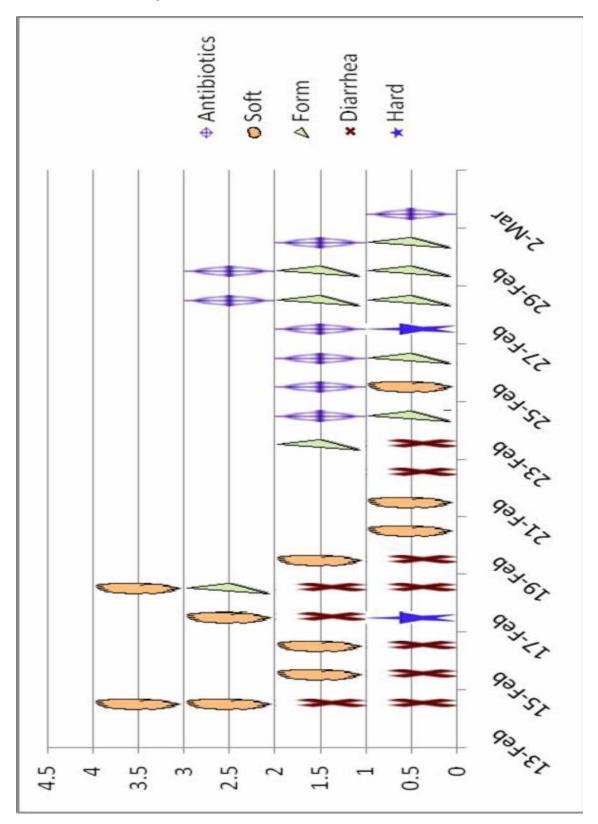


 Table 18. Case Study Seventeen Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Seventeen

Case Study Seventeen was started on an antibiotic which changed the consistency and number of stools until the probiotic was started. Once the probiotic was started, the consistency and number of stools was noticeably regulated. The bowel movement protocol was started before the antibiotic and probiotic were started with no stop date.

Case Study Eighteen

A white female, born on July 18, 1918, was admitted to the long-term care facility on February 22, 2008 and discharged on March 10, 2008.

Bowel Movement Protocol

Case Study Eighteen was placed on the bowel movement protocol on February 25, 2008 with no stop date.

Probiotic Plan

Case Study Eighteen was administered per day one capsule of the probiotic,

CulturelleTM, on February 28, 2008 until March 4, 2008.

Antibiotic Plan

Case Study Eighteen was started on 500 mg Levaquin[™] once a day for urinary tract infection February 22, 2008 until February 25, 2008.

Nutrition Care Plan

On February 28, 2008, Case Study Eighteen was at nutritional risk due to the

following: advanced age, pneumonia, and altered nutritional laboratory values.

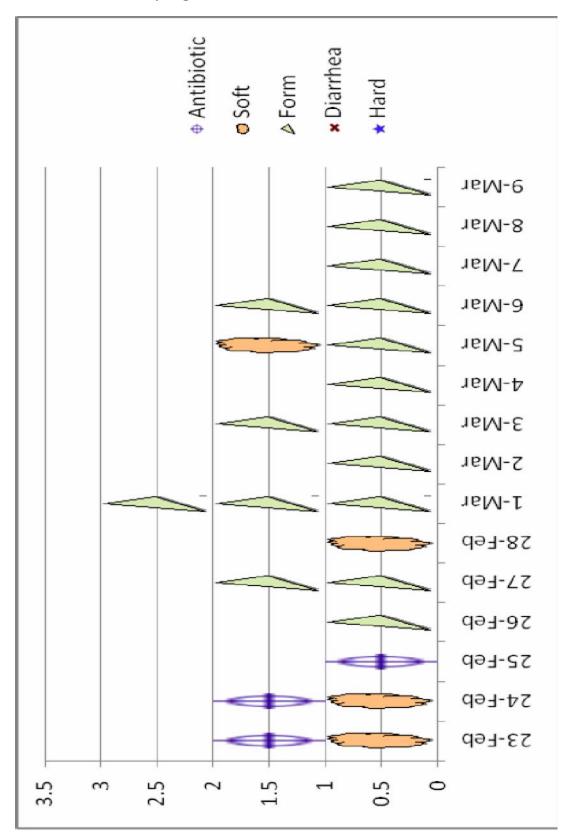


 Table 19. Case Study Eighteen Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Eighteen

Case Study Eighteen did not have any noticeable changes in consistency when she was started on the antibiotic, bowel movement protocol, and probiotic. However, the number of stools decreased when she was started on the antibiotic, bowel movement protocol, and probiotic.

Case Study Nineteen

A white female, born on November 22, 1906, was admitted to the long-term care facility on March 6, 2008 and discharged on March 17, 2008. She was readmitted on March 20, 2008 and discharged March 31, 2008. She was readmitted on April 2, 2008 and discharged April 10, 2008. She was readmitted on April 15, 2008 until May 2, 2008.

Bowel Movement Protocol

Case Study Nineteen was placed on the bowel movement protocol on March 17, 2008 with no stop date.

Probiotic Plan

Case Study Nineteen was administered one capsule per day of the probiotic, CulturelleTM on March 13, 2008 and stopped the same day. She was re-administered one capsule per day of probiotic, CulturelleTM on March 24, 2008 until April 12, 2008. She was re-administered again one capsule per day of the the probiotic, CulturelleTM on April 13, 2008 until April 15, 2008.

Antibiotic Plan

Case Study Nineteen was started on 500 mg LevaquinTM once a day for pneumonia March 17, 2008 until March 18, 2008. She was started on 250 mg LevaquinTM once a day for pneumonia March 20, 2008 until March 24, 2008. She was restarted on 250 mg LevaquinTM once a day for pneumonia March 30, 2008 until March 31, 2008. She was started on 500 mg AugmentinTM once a day for pneumonia April 2, 2008 until April 9, 2008. She was started on 250 mg LevaquinTM once a day for an unknown reason April 2, 2008 until April 9, 2008.

Nutrition Care Plan

On March 13, 2008, Case Study Nineteen was at nutritional risk due to the following: advanced age, recent decrease in appetite, infection (pneumonia), weakness, anemia, and congestive heart failure. On March 24, 2008, Case Study Nineteen was at nutritional risk due to the following: advanced age, pneumonia, congestive heart failure, anemia, hypoalbuminemia, altered nutritional laboratory values, decreased appetite, and constipation. On April 3, 2008, Case Study Nineteen was at nutritional risk due to the following: advanced nutritional risk due to the following: advanced nutritional laboratory values, decreased appetite, and constipation. On April 3, 2008, Case Study Nineteen was at nutritional risk due to the following: advanced age, unstable wound to the left lower shin, pneumonia, congestive heart failure, heart failure, renal insufficiency, and anemia.

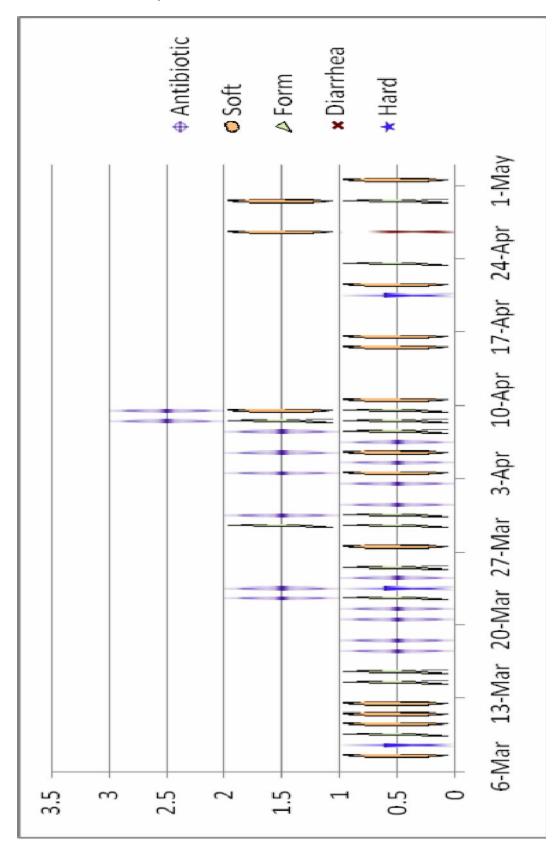


Table 20. Case Study Nineteen Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Nineteen

Case Study Nineteen did not have any noticeable changes in consistency and number of stools when she was started on the antibiotic, bowel movement protocol, and probiotic.

Case Study Twenty

A white female, born on December 4, 1923, was admitted to the long-term care facility on March 27, 2007 and discharged on May 7, 2007. She was readmitted on June 20, 2008 and discharged August 4, 2008. She was readmitted on August 8, 2008 until September 22, 2008.

Bowel Movement Protocol

Case Study Twenty was placed on the bowel movement protocol on March 28, 2007 until May 20, 2007. The bowel movement protocol was restarted on June 20, 2008 until July 31, 2008.

Probiotic Plan

Case Study Twenty was administered one capsule per day of the probiotic, CulturelleTM, on March 28, 2007 with no stop date. She was re-administered one capsule per day of the probiotic, CulturelleTM, on July 7, 2008 until July 16, 2008. She was readministered again one capsule per day of the probiotic, CulturelleTM, on July 28, 2008 until August 8, 2008. She was re-administered one capsule per day of the probiotic, CulturelleTM, on August 11, 2008 until August 18, 2008.

Antibiotic Plan

Case Study Twenty was started on 100 mg MacrobidTM twice a day for urinary tract infection July 4, 2008 and stopped the same day. She was started on 500 mg LevaquinTM once a day for an unknown infection August 8, 2008 until August 11, 2008.

She was started on 500 mg MetronidazoleTM three times a day for an unknown infection August 8, 2008 until August 11, 2008.

Nutrition Care Plan

On March 28, 2007, Case Study Twenty was at nutritional risk due to the following: advanced age, she leaves more than 25 percent at most meals, patient states about 20 pounds weight loss, recent pneumonia, bronchitis, hypertension, iron deficiency, anemia, congestive heart failure, osteoporosis, gastric esophageal reflux disease, acute renal failure, and hypothyroidism. On June 23, 2008, Case Study Twenty was at nutritional risk due to the following: advanced age, right hip fracture, congestive heart failure, altered nutritional laboratory values, diverticulosis, and a history of 108 pounds weight loss 18 months ago. Patient declines snacks and/or supplements at this time. On August 11, 2008, Case Study Twenty was at nutritional risk due to the following: advanced age, diverticulitis of sigmoid colon, congestive heart failure, and frequent diarrhea for past several months.

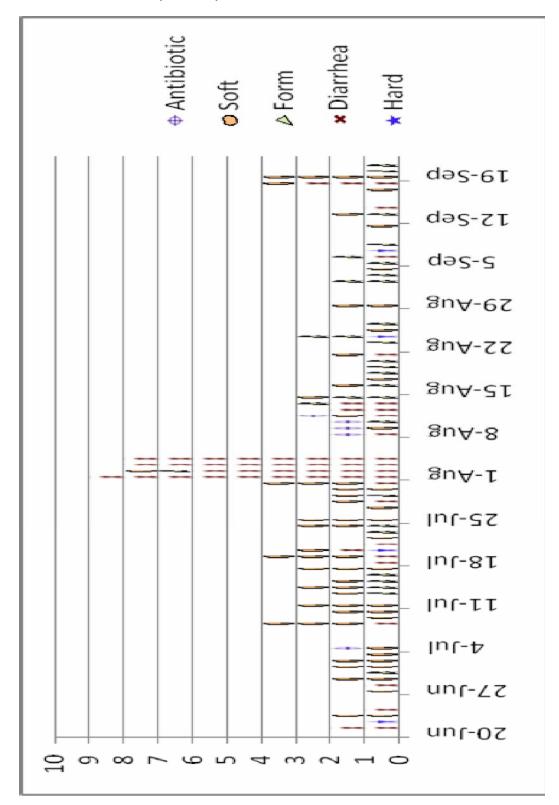


 Table 21. Case Study Twenty Bowel Movement Chart.

Interpretation of Bowel Movement Chart for Case Study Twenty

Case Study Twenty was started on the bowel movement protocol and antibiotic at the same time but did not show any noticeable change in consistency and number of stools. When both were stopped, the probiotic was started and there was an increase in number of stools and change in consistency. During the rest of the analyzed period, there was not the same increase that was shown when the antibiotic and bowel movement protocol stopped. Case Study Twenty is one of two cases that showed a negative affect when taking the probiotic.

Discussion

From these data, the researcher expected to determine a protocol for dietitians to follow when they have patients suffering from antibiotic-associated diarrhea and are considering placing them on a probiotic. Even though there were noticeable limitations to the study, the researcher was able to see a connection between the antibiotic used and the effectiveness of the probiotic. These results are summarized in Table 22. The following antibiotics were administered to one case study each: OmnicefTM, Azithromycin TM, Amoxicillian TM, Clindamycin TM, DucefTM, Metronidazole TM, Amoxicillian-Clavulante TM, Cleocin TM, Rifampin Cleocin TM, Biaxin filmtab TM, TRI-PakTM AmpicillinTM, Xifaxin TM, Zyvox TM, and Trimethoprim with sulfa TM. Keflex TM and Augmentin TM were each administered to three case studies. Cipro TM and Flagyl TM were each administed to four case studies. MacrobidTM was administered to eight of the case studies. Levaquin TM was administered to eighteen of the case studies.

Antibiotics affect patients differently, especially when they are associated with their stool consistency and number of stools. Typically, antibiotics are used for patients suffering from an infection. The data collected did not always state the reason for implementation of the antibiotics.

The results of this study appeared to illustrate that for patients in a long-term care facility, probiotic may be useful in regulating stool consistency and number of stools (Table 23). However, for eleven of the twenty patients their stools had a period where there was no noticeable effect with probiotic use. Ten of the patients who were placed on probiotics had positive effects (either stool consistency became more regulated or number of stools decreased). Case Study Seven had success with the probiotic when on only one antibiotic, however, when multiple antibiotics were started, the probiotic could not regulate the stools. Two of the patients who were placed on probiotics had negative effects on their stools (either stool consistency became less regulated or number of stools increased). It was difficult to determine the effect of the probiotic due to the use of the bowel movement protocol and lack of dietary records. Two case studies, ten percent, were diagnosed and treated for *Clostridium difficile*.

Case Study	Case Study Antibiotics	Effectiveness of Probiotic
One	 Levaquin TM 500 mg Flagyl TM 250 mg Levaquin TM 500 mg Levaquin TM 750 mg Levaquin TM 750 mg Azithromycin TM 500 mg Azithromycin TM 250 mg Bactrim DS TM 800 mg/160 mg Levaquin TM 250 mg Macrobid TM 100 mg Bactrim DS TM 800 mg/160 mg Bactrim DS TM 800 mg/160 mg 	The probiotic was started after the first antibiotic and was continued while the second, third, fourth, fifth, sixth, seventh, eighth, ninth, tenth, eleventh, and twelfth antibiotic were started. When the third antibiotic was started, it was clear that the probiotic decreased the number of bowel movements and regulated the stool consistency. During the eleventh and twelfth antibiotic, there was an increase in number of bowel movements, but it was clear that the probiotic decreased the side effects from antibiotic use.
Two	 Keflex TM 500 mg Macrobid TM 100 mg Cipro TM 250 mg Bactrim DS TM 800 mg/160 mg 	The probiotic was started after all four of the antibiotics and did not show any noticeable change of stool consistency and number of bowel movements.
Three	 Levaquin TM 500 mg Duncef TM 500 mg Bactrim DS TM 800 mg/160 mg Flagyl TM 500 mg Ampicillin TM 500 mg 	After the fourth and fifth antibiotics were stopped, there was an increase in number of bowel movements and stool consistency. Later, the probiotic was started and regulated the stools.
Four	 Levaquin TM 250 mg Macrobid TM 100 mg Bactrim DS TM 800 mg/160 mg Bactrim DS TM 800 mg/160 mg 	The probiotic was started after the first three antibiotics and continued during the fourth antibiotic. The probiotic did not show any noticeable change of stool consistency and

Table 22. Antibiotic and Effectiveness of Probiotic

		number of bowel
		movements.
Five	1. Levaquin [™] 500 mg	The probiotic was started during the antibiotic plan and did not show any noticeable change of stool consistency and number of bowel movements.
Six	 Flagyl TM 250 mg Cipro TM 250 mg Flagyl TM 500 mg Flagyl TM 250 mg Levaquin TM 250 mg 	The probiotics were started throughout the antibiotic plans. The probiotic did not show any noticeable change of stool consistency and number of bowel movements.
Seven	 Levaquin TM 250 mg Levaquin TM 250 mg Levaquin TM 250 mg Keflex TM 500 mg Vancomycin TM 50 mg/1 ml Flagyl TM 500 mg Vancomycin TM 50 mg/1 ml Vancomycin TM 125 mg Flagyl TM 500 mg Flagyl TM 250 mg Flagyl TM 250 mg Flagyl TM 250 mg Kifaxan TM 200 mg Rifampin TM 300 mg Vancomycin TM 250 mg Eactrim TM 400 mg 	When the probiotic was started with only one antibiotic, the stool remained regular. However, when the remaining antibiotics were started, the probiotic could not regulate the stool consistency or number of stools.
Eight	 Levaquin TM 500 mg Levaquin TM 250 mg Cipro TM 500 mg Levaquin TM 500 mg 	There were no issues with the first three antibiotics affecting the stools. When the fourth antibiotic was started, the stool consistency and number of stools was increased. When the probiotic was started, it regulated the stools.
Nine	 Bactrim DS TM 800 mg/160 mg Levaquin TM 250 mg Amoxicillian-Clavulante TM 875 mg/125 mg Zithromax TM 500 mg 	Antibiotic one and two were started prior to the probiotic. There was not a noticeable change in stool consistency and number of stools. When the fourth antibiotic was started, the consistency

Ten	 Zithromax TM 500 mg Bactrim DS TM 800 mg/160 mg Bactrim DS TM 800 mg/160 mg Levaquin TM 500 mg Zyvox TM 400 mg Keflex TM 250 mg Bactrim DS TM 800 mg/160 mg Levaquin TM 750 mg Levaquin TM 750 mg Trimethoprim with sulfa TM 80 mg/400 mg Cipro TM 250 mg 	of stools increased, however the number of stools remained the same.The probiotic did not show any noticeable change in stool consistency when the antibiotics were administered. However, the number of stools increased even when the probiotic was implemented.
Eleven	 TRI-Pak TM Macrobid TM 100 mg Amoxicillin TM 875 mg Avelox TM 400 mg Levaquin TM 500 mg Levaquin TM 500 mg Levaquin TM 750 mg Levaquin TM 750 mg Levaquin TM 500 mg Levaquin TM 500 mg 	The probiotic was started at the same time as the antibiotic and there was no noticeable change in stool consistency and number of stools.
Twelve	 Levaquin TM 750 mg Vancomycin TM intravenous fluid 1000 mg/10 ml 	When the first antibiotic was started, the stool consistency and number of stools increased. However, when the probiotic was started, the stool consistency and number of stools decreased. The probiotic regulated the stools even when the second antibiotic was started.
Thirteen	 Clindamycin TM 300 mg Cleocin TM 300 mg Clindamycin TM 300 mg Clindamycin TM 200 mg Macrobid TM 200 mg Levaquin TM 250 mg Biaxin filmtab TM 500 mg Levaquin TM 750 mg Clindamycin TM 300 mg Levaquin TM 500 mg Levaquin TM 500 mg Levaquin TM 500 mg 	The probiotic was started after the bowel movement protocol was implemented. There was no noticeable change in the stool consistency. However, the number of stools increased but then decreased when the probiotic was started.

	11 Magrahid TM 100 mg	
	11. Macrobid $^{\text{TM}}$ 100 mg	
	12. Levaquin $^{\text{TM}}$ 500 mg	
	13. Levaquin TM 500 mg	
	14. Bactrim DS 800 mg/160 mg	
	15. Levaquin $\frac{\text{TM}}{\text{m}}$ 750 mg	
	16. Levaquin $^{\text{TM}}_{\text{TM}}$ 750 mg	
	17. Levaguin 1M 750 mg	
	18. Levaguin TM 750 mg	
	19. Levaquin TM 750mg	
Fourteen	1. Levaquin $^{\text{TM}}$ 250 mg	The first two antibiotics and
	2. Macrobid TM 100 mg	probiotic were started at the
	3. Omnicef TM 300 mg	same time. There was no
	4. Augmentin $^{\text{TM}}$ 875 mg/125 mg	change in stool consistency
	4. Augmenum 875 mg/125 mg	-
		and number of stools. When
		the third antibiotic was
		started, there was an
		increase in number of stools
		and consistency. The
		probiotic was then started
		and it decreased the number
		of stools and regulated the
		consistency. When the
		fourth antibiotic was started,
		the probiotic was already
		administered, so it
		·
		noticeably regulated the
	1 I · TM 500	stool.
Fifteen	1. Levaquin TM 500 mg	The probiotic did not show
		any noticeable change in
		stool consistency or number
		of stools.
Sixteen	1. Levaquin TM 250 mg	The probiotic was started
	2. Augmentin TM 875 mg	after the first two antibiotics
	 Macrobid TM 100 mg Amoxicillian TM 875 mg 	were administered. When
	4. Amoxicillian $^{\text{TM}}$ 875 mg	the fourth antibiotic was
	5. Levaquin $^{\text{TM}}$ 500 mg	started, there was a slight
	6. Augmentin TM 875 mg	increase in number of stools.
	7. Bactrim DS $^{\text{TM}}$ 800 mg/160 mg	However, there was not a
		noticeable change in stool
		consistency or number of
		stools with the rest of the
		antibiotics.
1 61 4	1 \mathbf{D} : flux and \mathbf{IM} 100	
Seventeen	1. Diflucan TM 100 mg	The probiotic was started
Seventeen	1. Diflucan ^{1M} 100 mg	before the antibiotic was
Seventeen	1. Diflucan ^{1M} 100 mg	-

		and number of stools.
Eighteen	1. Levaquin TM 500 mg	The probiotic was not
		administered until three
		days after the antibiotic plan
		was ended. There was an
		increase in the number of
		stools that decreased after
		the probiotic was started.
		However, the stool
		consistency never changed.
Nineteen	1. Levaquin $^{\text{TM}}$ 500 mg	The probiotic was started
	2. Levaquin $^{\text{TM}}_{\text{TM}}$ 250 mg	before the antibiotics were
	3. Levaquin $^{\text{TM}}$ 250 mg	administered. There was not
	4. Augmentin TM 500 mg	a noticeable change in stool
	5. Levaquin [™] 250 mg	consistency or number of
		stools.
Twenty	1. Macrobid $^{\text{TM}}_{\text{TM}}$ 100 mg	When the antibiotic and
	2. Levaquin TM 500 mg	bowel movement protocol
	3. Metronidazole 500 mg	were stopped, the probiotic
		was started and the number
		of stools increased.
		However, there was no
		noted increase for the rest of
		the analyzed time.

	Effect of the Probiotic Plan
	Effect of the Problotic Plan
Case Study One	The probiotic may have caused a noticeable change in stool consistency and the number of stools after being implemented. (+)
Case Study Two	The probiotic did not show any noticeable change in stool consistency. (0)
Case Study Three	After three days of taking the probiotic, the stool consistency started to normalize. (+)
Case Study Four	The probiotic did not show any noticeable change in stool consistency. (0)
Case Study Five	The probiotic did not show any noticeable change in stool consistency. (0)
<u>Case Study Six</u>	The probiotic may have caused a noticeable change in stool consistency and the number of stools after being implemented. (+)
<u>Case Study Seven</u>	When the probiotic was started with only one antibiotic, the stool was able to remain regular. However, when multiple antibiotics were started, the probiotic could not regulate the stools.(+/-)
<u>Case Study Eight</u>	There were no stool changes with the first three antibiotics. When the fourth antibiotic was started, the stool consistency and number of stools increased. When the probiotic was started, it regulated the stools. (+)
Case Study Nine	The probiotic regulated the consistency but there was not a noticeable change in number of stools. (+/0)
<u>Case Study Ten</u>	The probiotic did not show any noticeable change in stool consistency or number of stools. (0)
<u>Case Study Eleven</u>	The probiotic was started at the same time as the antibiotic and there was no noticeable change in stools. (0)
Case Study Twelve	The probiotic regulated the consistency and decreased the number of stools. (+)
<u>Case Study Thirteen</u>	The probiotic was started after the bowel movement protocol was implemented. There was no noticeable change in the stools once the probiotic was started. (0)
Case Study Fourteen	The first time antibiotics and probiotic were started at the same time. There was no

 Table 23. Summary of Effect of the Probiotic Plan

	change. When the next antibiotic and
	e
	probiotic were started, there was a decrease
	in number of stools. (0/+)
Case Study Fifteen	The probiotic did not show any noticeable
	change in stool consistency or number of
	stools. (0)
Case Study Sixteen	The probiotic did not show any noticeable
	change in stool consistency or number of
	stools. (0)
Case Study Seventeen	The probiotic regulated stool consistency
	and number of stools. (+)
Case Study Eighteen	The probiotic was not administered until
	three days after the antibiotic plan was
	ended. There was an increase in the
	number of stools that decreased after the
	probiotic was started. However, the stool
	consistency never changed. $(+/0)$
Case Study Nineteen	The probiotic did not show any noticeable
	change in stool consistency or number of
	stools. (0)
Case Study Twenty	When the antibiotic and bowel movement
	protocol were stopped, the probiotic was
	started and the number of stools increased.
	However, there was no noted increase for
	the rest of the analyzed time. (-)

Chapter V. Limitations

Since the study was retrospective and this long-term care facility did not document the patient's daily diet, there was not an accurate way to determine what the patient consumed. Aspects of the diet, such as fiber intake, could also affect the stool number, quantity and consistency. It would be important to know if the patient was eating higher fat food items that could cause gastrointestinal distress.

In addition to providing patients with a probiotic, patients were on a bowel movement protocol which provided added fiber. This protocol could mask the effect of the probiotic. It is difficult to determine the probiotic effect if the patient was given numerous stool softeners, antibiotics, as well as being on the probiotic at the same time. It is also difficult to separate the effects of each of those treatments to narrow the cause of the change in stool consistency and the increase in stool number.

Another limitation is how the stools were scored. The stools were assessed based on the judgment of the nursing staff and can be noted as inconsistent. For example, in one patient's bowel record, their stool from one bowel movement was listed as hard, diarrhea, soft, formed, and loose. Stools were scored and included time, but the nursing staff gets busy and may not always document every stool correctly.

Antibiotics affect patients differently, especially when it is associated with their stool consistency and number of stools. Typically, antibiotics are used for patients suffering from an infection. Also, antibiotics may interact differently and effect patients' stool consistency and number of stools when a probiotic is present. There may be a drugdrug interaction between the antibiotic and probiotic. With the numerous antibiotics given we were not able to determine how the antibiotic and probiotic interacted. Aslos, the data collected did not always state the reason for implementation of the antibiotics.

In most cases, patients were administered one capsule per day of the probiotic, CulturelleTM. However, some patients were administered two capsules per day of probiotic, CulturelleTM. The Culturelle manufacturer recommends that an adult take one capsule per day of the probiotic (Amerifit Brand, 2010).

Chapter VI. Future Trials and Recommendations

Probiotics may play a beneficial role in several medical conditions including antibiotic-associated diarrhea. Probiotics should be further investigated for their possible benefits to patients affected with antibiotic-associated diarrhea. At the same time, the negative effects should be researched. The combination and concentration of gastrointestinal microflora are determined and affected by a number of independent variables. Based on the results of this study, it is recommended that a protocol be set for use and research of probiotics in the elderly population.

It is recommended that a more controlled study be conducted with elderly patients suffering from antibiotic-associated diarrhea and using probiotics to regulate the consistency and decrease the number of stools. The controlled study would take into account the following recommendations. It is important to note that ethical considerations should be taken into account and quality of life should be considered when conducting the controlled study. First, the nursing staff should be taught how to correctly determine the stool consistency and be reminded of the importance of accurate documentation. If the nursing staff learns a standardized method to score the stools, it will lead to more consistent stool data. One example of how to score stool consistency is found in Table 24. This table provides pictures as well as the weight of stools. In a controlled study, the stool data would be more accurate. Fecal containment devices can allow staff to accurately measure the amount of the stool.

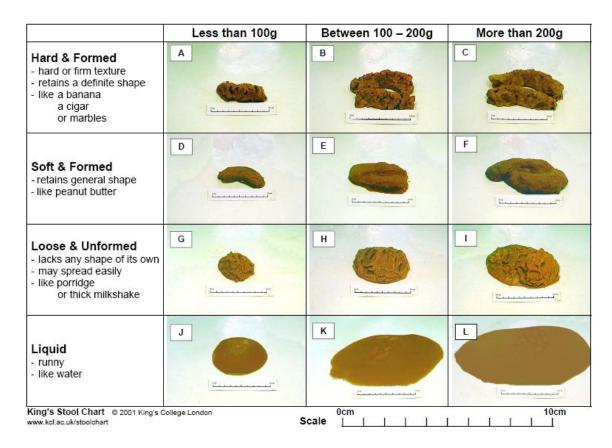


Table 24. King's Stool Chart

(King's College London, 2007)

A background of a patients' typical bowel pattern is useful when trying to determine changes when placed on the probiotic. Having a background of the patient's typical stool pattern would allow for a baseline. Not everyone has a stool everyday compared to another patient who has three or four stools per day. If the patient bowel history is collected prior to the implementation, it could potentially decrease the use of medication when not necessary. Patients' dietary intake should be recorded; a dietary intake which includes the number of grams of fiber, grams of protein, grams of carbohydrate, and grams of fat. With this record of the patient's diet, a list of any food allergies or intolerances, such as lactose intolerance, should be noted. Another aspect of diet that needs to be recorded is the amount of fluid the patient is consuming. Hydration will influence the stool consistency and number of bowel movements. When the study is conducted, the patient should be on a controlled diet, to control for the dietary affects on the stool consistency and number of bowel movements.

If a patient is on multiple regimens, such as bowel movement protocols and probiotics, then they should be excluded from the study. By excluding those patients who are on multiple regimens of the bowel movement protocol, it may be difficult to maintain a large study size especially since the patients' quality of life needs to be maintained. Or if patients on the bowel movement protocol are included in the study, it is important to control for the bowel movement protocol and have adequate information recorded (dates and times for administering the specific drug). All of the patients' medications should be documented accurately, including time and dosage of antibiotics and stool softeners.

Chapter VIII. Conclusions

Published studies for patients in long-term facilities vary greatly in terms of trial design, type and dose of probiotic and duration of treatment, which may explain why probiotics work for some patients and not for others. Probiotic use is becoming more accepted with antibiotic-associated diarrhea but due to the lack of definitive evidence about efficacy and the safety of probiotic use, more studies need to be conducted.

Overall, our research findings have shown that probiotics may have a positive effect on patients suffering from antibiotic-associated diarrhea. Due to the number of limitations, this project can be considered a pilot study for future more controlled studies to determine the effectiveness of the use of probiotics in elderly patients suffering from antibiotic-associated diarrhea.

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Appendix A. IRB Approval Letter

April 5, 2010

Jenna Peate Department of Nutrition and Health Sciences 6400 White Dove Cir Lincoln, NE 68512

Julie Albrecht Department of Nutrition and Health Sciences 119 LEV, UNL, 68583-0806

IRB Number: 2009049724 EP Project ID: 9724 Project Title: Probiotic Use in Elderly

Dear Jenna:

This is to officially notify you of the approval of your project's Continuing Review by the Institutional Review Board for the Protection of Human Subjects. It is the committee's opinion that you have provided adequate safeguards for the rights and welfare of the subjects in this study based on the information provided. Your proposal is in compliance with DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

We wish to remind you that the principal investigator is responsible for reporting to this Board any of the following events within 48 hours of the event:

* Any serious event (including on-site and off-site adverse events, injuries, side effects, deaths, or other problems) which in the opinion of the local investigator was unanticipated, involved risk to subjects or others, and was possibly related to the research procedures;

* Any serious accidental or unintentional change to the IRB-approved protocol that involves risk or has the potential to recur;

* Any publication in the literature, safety monitoring report, interim result or other finding that indicates an unexpected change to the risk/benefit ratio of the research;

* Any breach in confidentiality or compromise in data privacy related to the subject or others; or * Any complaint of a subject that indicates an unanticipated risk or that cannot be resolved by the research staff.

It is the responsibility of the principal investigator to provide the Board with a review and update of the research project each year the project is in effect. This approval is valid until 04/22/2011.

If you have any questions, please contact the IRB office at 472-6965.

Sincerely, Becky R. Freeman, CIP for the IRB

Appendix B. Bowel Movement Protocol

The purpose of the bowel movement plan or protocol is to ensure regularity and prevention of impaction. At the facility, each patient is assessed to determine if he/she has regular bowel movements. If not, a plan for bowel care was initiated in a timely manner ensuring that the client remains free of constipation and impaction. The procedure starts with resident assistants documenting patients' bowel movements each shift for their assigned client and recording it in Care TrackerTM. Next, the staff observes cognitively impaired patients for behaviors that could indicate the need to evacuate bowels, such as restlessness, digging in the rectum, and agitation. These behaviors were reported to the charge nurse for follow up. Next, the evening shift nurse or medication aide runs a "bowel movement protocol cross tab" report in Care TrackerTM to identify the total number of days each patient has not had a bowel movement. Also, if the patient does not have bowel care orders or a problem has been identified, the charge nurse will notify the physician of the patients' bowel status and request an order for use of facility bowel care protocol or other orders to manage patients' bowels as per physician order. The bowel care protocol starts at 4 pm on day three of no bowel movement at which time, 30 ml Milk of MagnesiaTM is given. At 4 pm on day four of no bowel movement, 10 mg Suppository R Bisacodyl (DulcolaxTM) is given. If no stool occurs within 4 hours of having DulcolaxTM, the patient is re-evaluated to rule out impaction and administered one of the following: Enema R of Sodium Phosphate (fleets) or 4oz Magnesium Citrate. If no results, the physician is updated on the patients' bowel status, at which time a request for routine bowel medication may be made. The nurse will update the care plan and inform the staff of the problem/need regarding the patients' bowel movement and the

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interventions for those patients who require bowel care programs. The nurse will follow up to ensure that the patients' bowel care plan was effective. The patients' nutrition and hydration status is assessed on admission and on an ongoing basis by the Food and Nutrition Department of the facility.

Appendix C. Probiotic Protocol

Purpose of the probiotic plan is to prevent/minimize diarrhea and diarrhea associated complications in immune compromised individuals. Upon admission to facility, patients receiving antibiotic therapy will receive probiotic therapy to positively influence the microflora of the colon, decreasing toxic microbial activities. The long term care facility defines immune compromised individuals as those who have a reduced resistance to illness (elderly, chronic illness). The long term care facility defines probiotics as a live mircrobial feed supplement that beneficially affects the host by improving its microbial balance. Probiotics exert their benefits through several mechanisms; they prevent colonization, cellular adhesion and invasion by pathogenic organisms, they have a direct antimicrobial activity and they modulate the host immune response. The long term care facility defines prebiotics as nourishment for probiotic bacteria to aid in faster growth of good bacteria. The probiotic is implemented when in certain situations. One situation is when a patient is admitted with recent, less than two weeks or frequent antibiotic use. Another situation is when a patient or resident is currently receiving an antibiotic. Finally, if a patient has diarrhea from an unknown etiology the probiotic will be initiated. There is a procedure that is followed for the implementation of the probiotic. The registered dietitian will initiate the probiotic after evaluation of the medical chart and patient assessment. The probiotic will be written in the medication report to be given one capsule per day, unless otherwise indicated. The dietitian will then add it to the nutrition care plan for the patient. The probiotic will be given for seven days following discontinuation of the antibiotic or until stools have been documented normal for seven consecutive days. The dietitian may recommend the

probiotic use indefinitely if the patient has chronic altered bowel movement pattern or is immunocompromised. The dietitian will be notified by the nursing staff when a probiotic is initiated. The long term care facility follows a set of instructions for the use of the probiotic. The dosage is one capsule per day of the probiotic unless the dietitian states otherwise. The long term care facility has approved using the probiotic, CulturelleTM.