Assessment of Probiotics (BioK+®) in the Primary Prevention of *Clostridium Difficile* Infections at Burnaby Hospital

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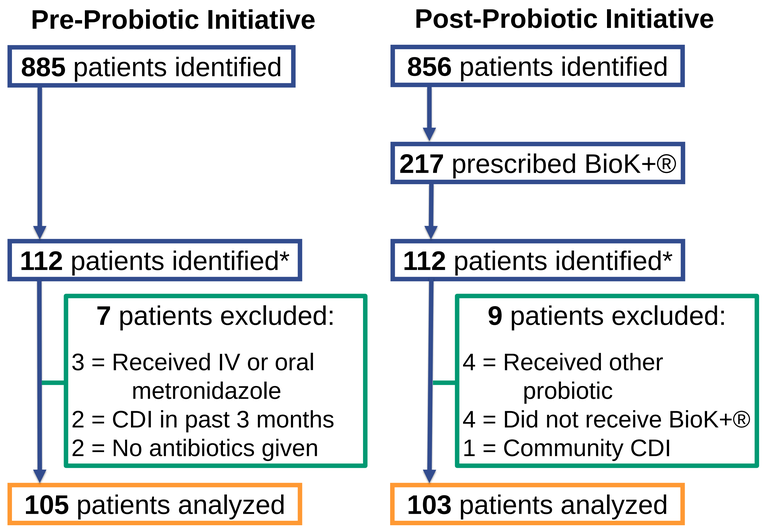
Background

- *Clostridium difficile* infection (CDI) leads to increased mortality, decreased quality of life, and is a financial burden on the Canadian health care system
  - Each case of CDI in hospital is estimated to cost a minimum of $11,930
- Target incidence of CDI in Fraser Health is less than 6 cases per 10,000 patient days
  - Incidence at Burnaby Hospital (BH) was 8.7 cases per 10,000 patient days during the fiscal period of 2015/2016
  - Despite infection control and other non-drug measures, CDI rates at BH remained above target
- One randomized control trial suggests that BioK+® (100 billion CFU of *Lactobacillus acidophilus* CL1285 + *Lactobacillus casei* LBC80R) reduces the incidence of CDI
- In December 2015, BH introduced a probiotic initiative on two medical units in an attempt to reduce CDI rates

Methods

- **Design**: Single-center, retrospective cohort study
- **Inclusion criteria**: Adult inpatient who received IV or PO antimicrobial therapy in two medical units at BH from Dec. 1, 2014 to Nov. 31, 2016
- **Exclusion Criteria**: Any patient who received metronidazole IV/PO or vancomycin PO for any reasons other than CDI, did not receive BioK+®, received any probiotic other than BioK+®
- **Sample size**: 100 patients per cohort to achieve 80% power
  - Expected rate of CDI in control 25%, intervention 10%
- **Objectives**
  - **Primary**: Incidence of primary CDI in the two medical units
  - **Secondary**: Compliance and cost of the probiotic initiative
- **Statistical Analysis:** Fisher's exact test for the primary outcome, descriptive statistics for secondary outcomes
- **Definition**
  - **Primary CDI:** Acute onset diarrhea (>3 unformed/watery stools in 24 hours) and positive *C.difficile* toxin stool test or pseudomembranous colitis on endoscopy or high clinical suspicion plus absence of CDI within last 3 months

Figure 1 –Study Participants Selection



**Based on number needed for sample size of 100 per cohort with an estimated 1 exclusion per month*

Table 1 – Baseline Characteristics

	Pre-Probiotic Initiative (n = 105)	Post-Probiotic Initiative (n = 103)
Age – years (mean ± SD)	68.8 ±17.7	74.9 ±16.9
Male – n (%)	68 (65)	65 (63)
Comorbidities – n (%)		
Cardiovascular Disease	33 (31.4)	41 (39.8)
Diabetes	23 (21.9)	28 (27.2)
Gastrointestinal Disease	8 (7.6)	13 (12.6)
Lung disease	27 (25.7)	20 (19.4)
Gastric Acid Suppression – n (%)		
H_2 Receptor Antagonists	7 (6.7)	2 (1.9)
Proton Pump Inhibitors	34 (32.4)	45 (43.7)
Antibiotics* - n		
Frequently associated with CDI†	182	187
Carbapenems	27	16
Cephalosporins	109	111
Fluoroquinolones	34	31
Lincosamides	5	8
Penicillins	70	64
Other	74	66

** Patients may receive multiple antibiotics of same class during admission*
† 3rd/4th generation cephalosporins, clindamycin, fluoroquinolones, penicillins

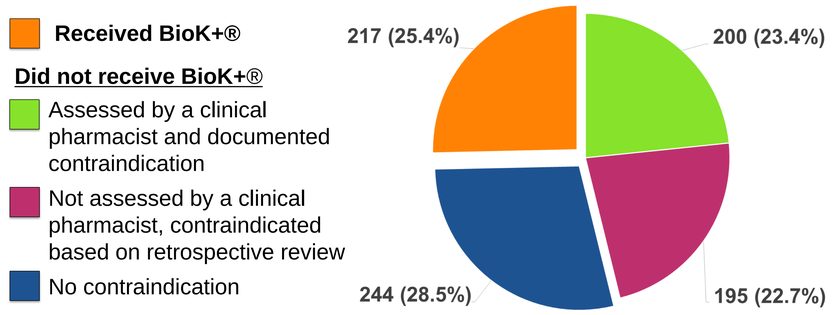
Table 2 – Incidence of CDI

	Pre-Probiotic Initiative (n = 105)	Post-Probiotic Initiative (n = 103)	*P*-value
Incidence of CDI (n(%)/year)	3 (2.9%)	2 (1.9%)	NSS

Table 3 – Cost Analysis

	Pre-Probiotic Initiative (n = 105)	Post-Probiotic Initiative (n = 103)
Estimated cost for all CDI	$35,790	$23,860
Cost of BioK+®	N/A	$1088.96
Total cost	$35,790	$24,948.96

Figure 2 – Probiotic Initiative Compliance



Discussion

- No statistical difference in the incidence of primary CDI
  - Difficult to make conclusion due to low incidence in both groups
- 51.2% of patients were not assessed for the appropriateness of the probiotic initiative
  - Of these patients, 55.6% had no contraindications and should have been prescribed BioK+®
- The drug cost of BioK+® therapy was $10.68 per patient

Limitations

- Retrospective, single-center study
- Sequential time period (possible changes in standard of practice)
- Power calculations based on published randomized control trial where rate of CDI was 25%; significantly higher than incidence seen at BH
- No access to data from CareConnect or other health authorities
  - Cannot identify CDI treated in the community or at a Non-Fraser Health hospital

Conclusion

- Insufficient data from this study to conclude whether or not BioK+® reduces primary CDI in the two medical units at Burnaby Hospital

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