Abstract: Inter-Probe

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Background: Beliefs of substitute decision makers (SDMs) of critically ill patients related to probiotics have not been well studied. We aimed to understand perspectives held by SDMs of critically ill patients invited to participate in a peer-reviewed multicenter trial: PROSPECT pilot trial.

Methods: Using rigorous development and testing methods, we generated a 2 page, feasible instrument, administered to SDMs approached for enrolment of their loved one into PROSPECT during the consent encounter. For SDMs enrolled in Inter-Prob, we collected age, sex, ethnicity, and urban or rural residence. We documented self-reported probiotics familiarity, probiotic consumption, and rationale for consent decision.

Results: Between June2014 and February2015, 104 SDMs of patients eligible for PROSPECT were approached for Inter-Prob participation in 8 centers. The Inter-Prob consent rate was 103/104 (99%), and the PROSPECT consent rate was 89/103 (86%) in this cohort. SDMs were 53 (±16) years old, 60 (59%) were female, 77 (76%) were white, and 82 (85%) lived in an urban area. 57% of SDMs reported familiarity with probiotics; 60% of SDMs reported past use, and 44% reported current use. There were no differences between SDMs who consented (N=89) or declined (N=14) PROSPECT regarding familiarity with probiotics (p=0.14), prior probiotic use (p=0.21) or likelihood of urban living (p=0.69). The most common reasons for PROSPECT consent were potential patient benefit (37%), desire to contribute to medical research (20%), and potential benefit to other patients (17%). Reasons for declining PROSPECT were belief that the patient would not have agreed (25%), not wanting to alter the treatment plan (21%), belief that the patient was too sick to receive other treatment (18%) and other reasons including uncertainty about the patient's wishes (18%).

Conclusions: We found no difference in characteristics of SDMs who consented or declined the PROSPECT Trial for their critically ill loved one. SDM consent decision rationale was related to personal beliefs regarding benefits to the patient, as well as predictions of patient's wishes.

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