

INFECTIOUS THREATS IN “HEALTHY” DONORS: RESULTS OF A DONOR SCREENING PROGRAM FOR A NEXT-GENERATION FMT

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Background: RBX2660 (microbiota suspension), a next-generation fecal microbiota transplant (FMT) drug targeted at recurrent *Clostridium difficile* infection (CDI), is sourced from human stool. A donor program was implemented to provide reliable source material for Phase 2 studies. The results of the screening program are reported here.

Methods: Potential donors were recruited word-of-mouth; a one-time recruitment bonus and nominal payments for accepted donations were offered. Extensive screening for blood and stool pathogens was required prior to enrollment as a donor. If accepted into the program, all donors completed a basic health questionnaire just prior to each donation. All donations were made on site and stored under controlled conditions. Every donated stool was tested using the pre-enrollment pathogen screen. Donors also underwent blood testing at the end of each donation cycle (min. 14 days after last stool screen). In the case of a positive result on any of the tests, all drug product associated with that donor during a cycle was destroyed.

Results: A total of 75 potential donors were screened from July 15, 2013 through December 31, 2015. Mean age: 27 (range 19-59) years; 66% male; 94.7% white; 74.7% full or part-time students. Of these, 11 (14.7%) failed the initial screening protocol: asymptomatic *Escherichia coli* strain #0157, n=1; asymptomatic ova and parasites, n=1; rheumatoid arthritis, n=1; Grave’s disease, n=1; antibiotic use within past 90 days, n=4; travel history, n=2; hepatitis C, n=1. Eight were lost to follow-up. A total of 56 people (74.7%) passed the initial screening protocols and made at least one donation. On subsequent retesting, a further 21 donors failed rescreens: asymptomatic rotavirus, n=1; asymptomatic norovirus, n=3; asymptomatic ova and parasites, n=5, psoriasis n=1; antibiotic/medication use, n=3; asymptomatic *Yersinia*, n=1; asymptomatic methicillin-resistant *Staphylococcus aureus*, n=3; asymptomatic *Salmonella*, n=1; other, n=3.

Conclusion: Results of this donor screening program demonstrate that a substantial number of outwardly healthy volunteers may be unsuitable as stool donors due to underlying conditions including asymptomatic infections. Donors and their donations should be thoroughly tested each time their donation is to be used for treatment as their suitability as a donor may change over time.

Key words: donor screening; fecal microbiota transplantation; FMT