

Budget Impact Analysis of Fecal Microbiota Transplantation in Recurrent or Refractory *Clostridioides Difficile* Infection in Taiwan

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Objectives:

The incidence and financial burden associated with recurrent *Clostridioides Difficile* Infection (rCDI) are rising globally, posing significant challenges in healthcare system. Compared to antibiotic treatments, Fecal Microbiota Transplantation (FMT) is a more effective treatment for rCDI with low recurrence rate. Study has shown FMT is cost effective in Taiwan, therefore, we estimate future expenditure for FMT in treatment of refractory and rCDI through a budget impact analysis (BIA) in Taiwan should it be reimbursed.

Material and Methods:

BIA of FMT treatment was performed. It is to replace vancomycin and fidaxomicin (substitution) and/or the other FMT only (expansion) with time horizon of 1 to 5 years using population data-based model and claims data-base model. Sensitivity analysis was performed to understand the uncertainty.

Category	Assumptions and reasons
Substitution	FMT is limited to patients who are rCDI or refractory CDI after first-line treatment with metronidazole and vancomycin. <ul style="list-style-type: none"> Partially replaced vancomycin after first-line treatment (metronidazole) failure or relapse Partially replaced fidaxomicin after first-line treatment (vancomycin) failure or relapse
Expansion	FMT as a non-antibiotic treatment for rCDI or refractory CDI <ul style="list-style-type: none"> Vancomycin regimen: 125 mg qid for 10 days Fidaxomicin regimen: 200 mg bid for 10 days

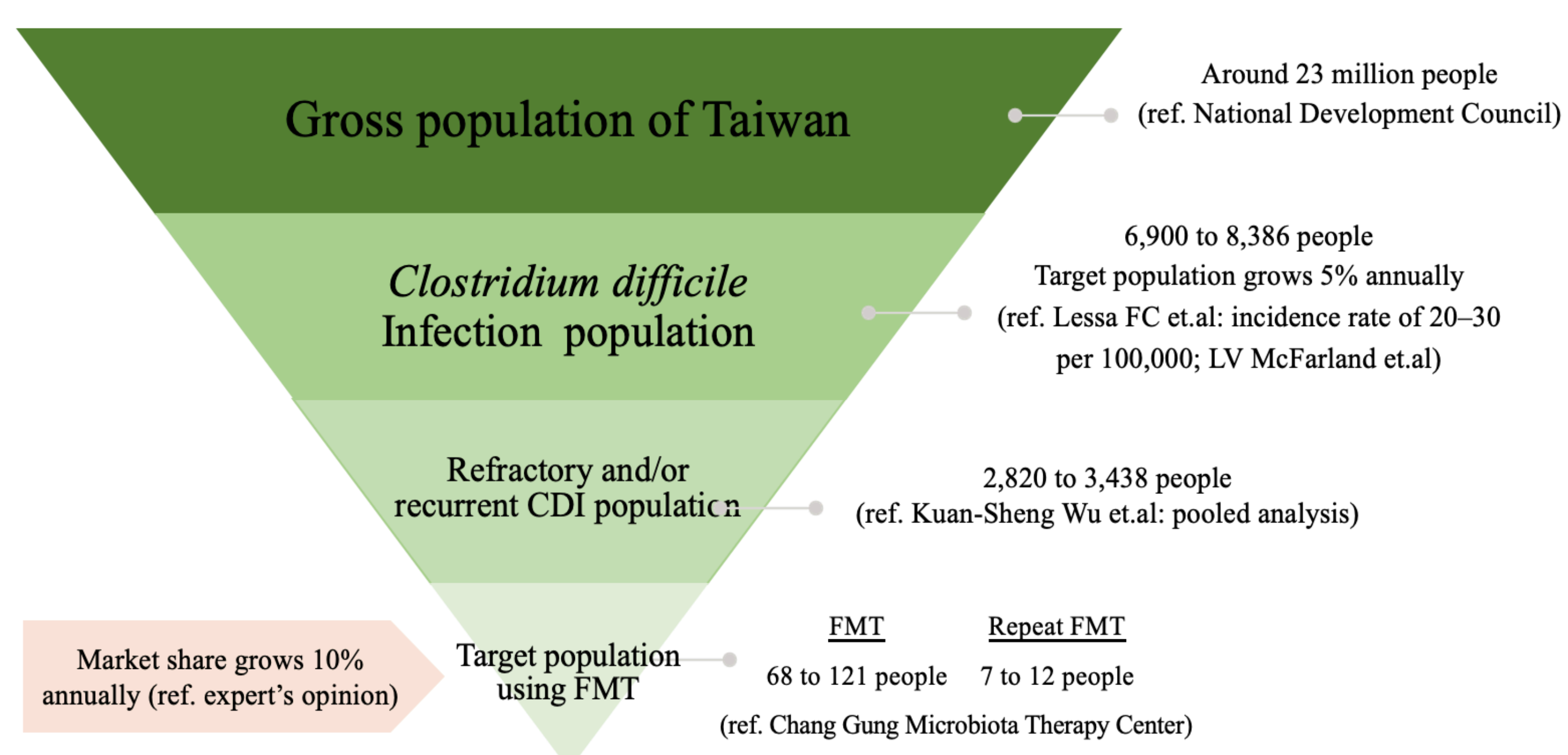


Figure 1. Population data-based model of FMT

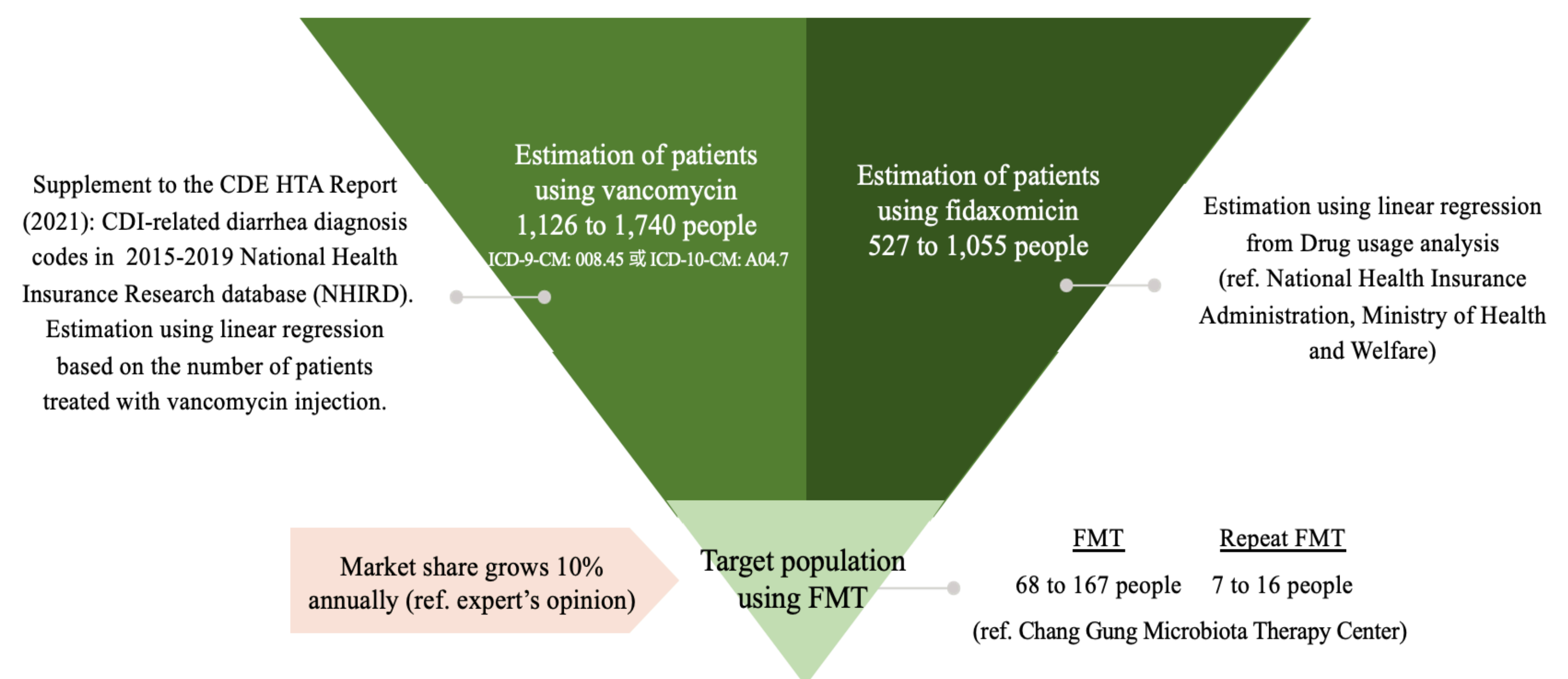


Figure 2. Claims data-base model of FMT

Results:

The refractory and rCDI population rose from 75 to 133 people from first year to fifth year in population data-based model; 75 to 183 people from first year to fifth year in population data-based model. The budget impact in expansion scenario were from USD180,230 (NT\$5,046,450, first year) to USD319,608 (NT\$8,949,038, fifth year) and USD93,601 (NT\$2,620,831, first year) to USD162,769 (NT\$4,557,538, fifth year) using population data-based model. The results in expansion scenario were from USD180,230 (NT\$5,046,450, first year) to USD439,762 (NT\$12,313,338, fifth year) and USD93,112 (NT\$2,607,138, first year) to USD216,858 (NT\$6,072,026, fifth year) in substitution scenario partially replaced vancomycin and fidaxomicin using claims data-based model in Taiwan.

Conclusions:

The results of BIA indicated that the adoption of FMT as a treatment option for refractory and rCDI would likely result in reasonable and affordable budget impact. Additionally, this information can inform the decision maker in public policies making, such as the rCDI treatment in the coverage of National Health Insurance.

