

INTRODUCTION

Childhood constipation one of the most common reasons for pediatric outpatient visits and is often difficult to manage.¹ The most common type of constipation is functional constipation which is defined as persistent infrequent and/or difficult bowel movements that is often difficult or painful to pass and is not caused by any underlying systemic cause or anatomical defect that does not have a physical (anatomical) or physiological cause (Rome IV criteria for diagnosis of constipation).^{1,2} Diagnosis of pediatric functional constipation consists of a comprehensive assessment of patient history and physical examination. If patient is refractory to initial treatment, laboratory investigation including blood tests and thyroid function tests might be carried out.² In addition, further testing is carried out if treatment fails, laboratory tests is negative, and organic cause is suspected.² This could result in costly unnecessary and more invasive tests.

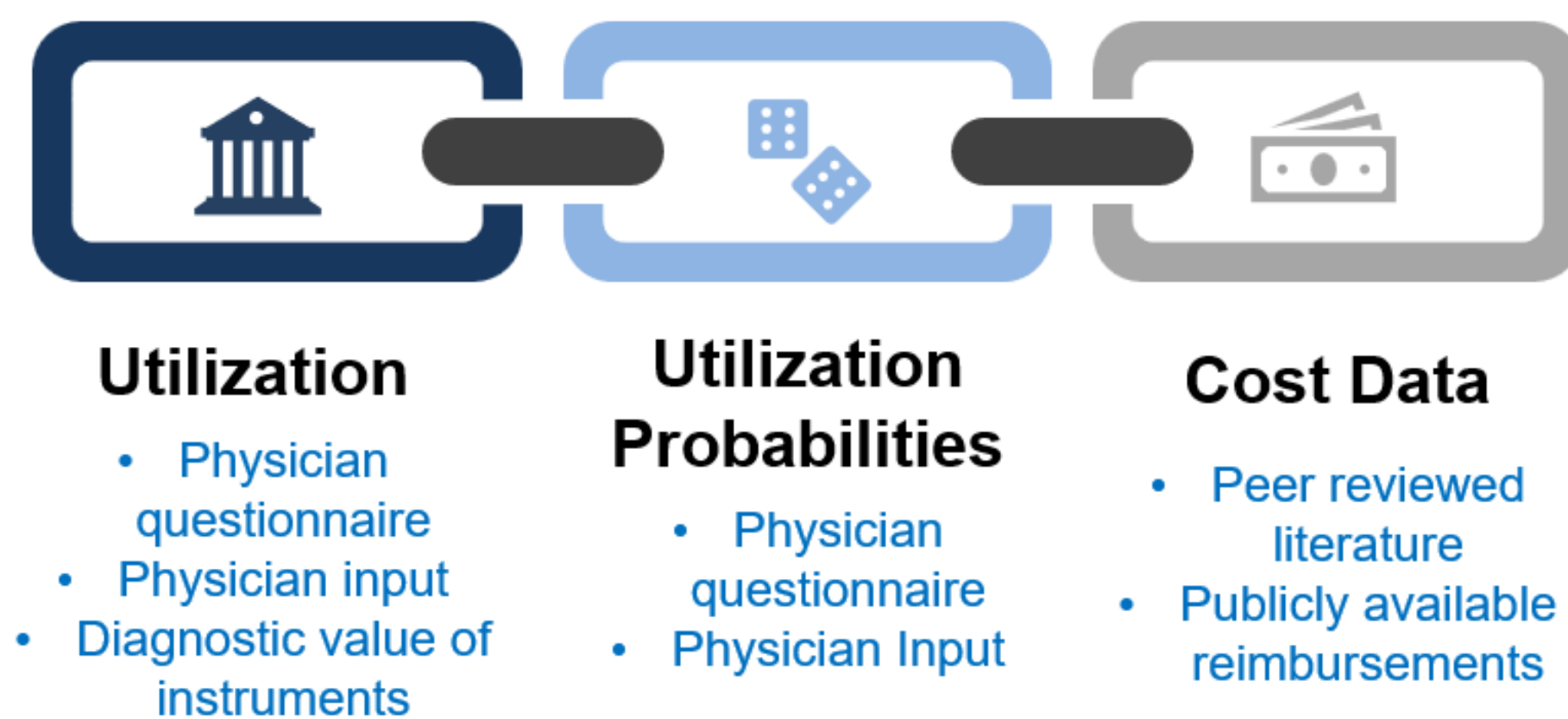
OBJECTIVE

The aim of this decision analytic model was to evaluate the incremental costs or costs savings associated with the use a medical device technology to reduce unnecessary tests in pediatric patients with constipation.

METHODS

- SITZMARKS® capsule is a safe, non-invasive tool used to detect blockage or colonic inertia in pediatric or adult patients with constipation³. Sitzmark®'s cost impact compared to current standard of care (SOC) was evaluated using TreeAge 2021 software in a hypothetical population of pediatric patients who presented with inadequate colonic motility in an outpatient setting in the US.
- A two-stage approach was employed to build the model. First stage consisted of concept elicitation of answers from pediatric physician/ provider response to questionnaire regarding diagnosis of pediatric functional constipation. Furthermore, the second stage consisted of development of a patient simulation model using the findings from the physician/ provider survey and peer reviewed literature.

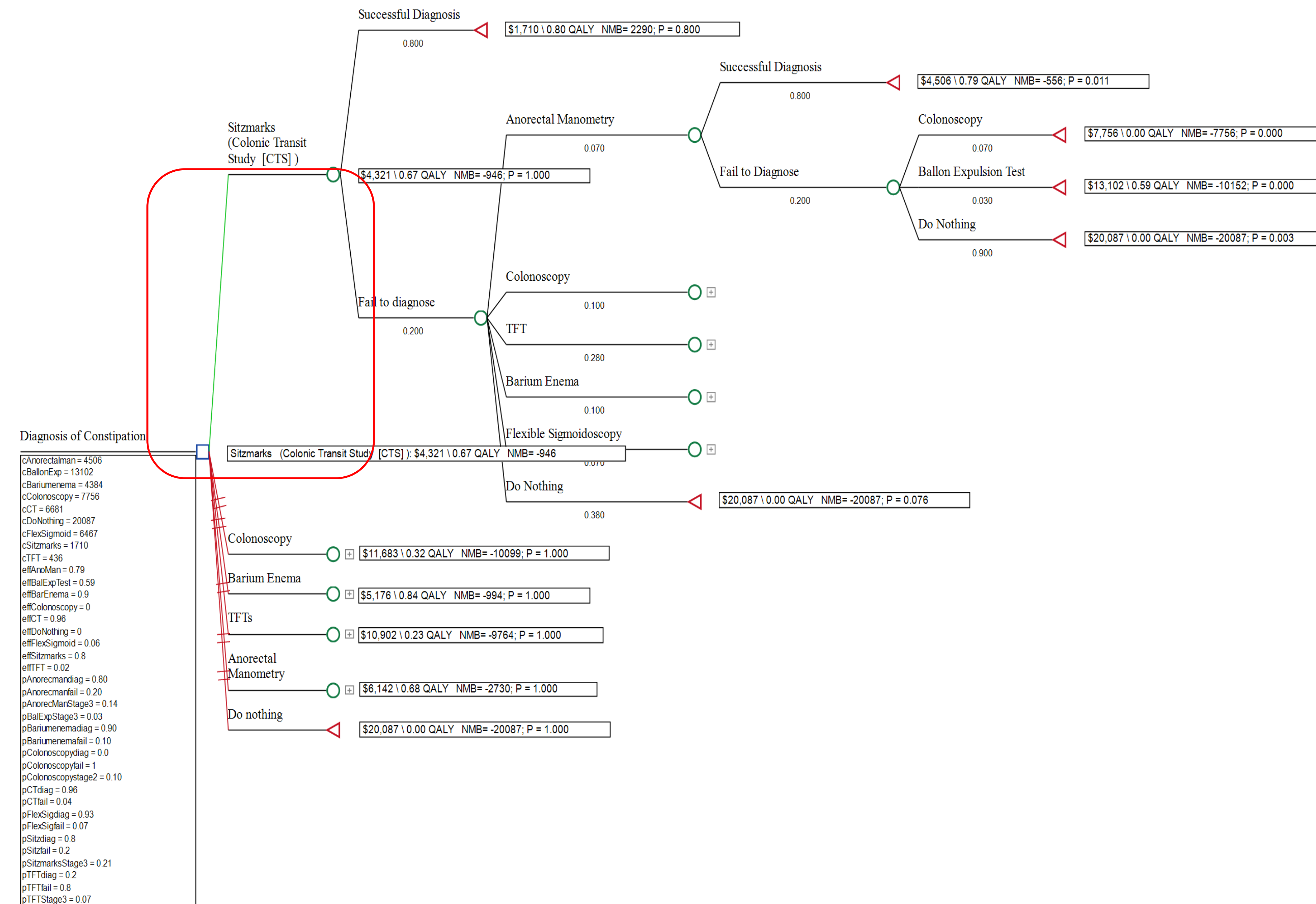
Figure 1. Three Main Inputs Utilized For the Model



- Model inputs were from a United States (US) payer perspective over a 1-year time horizon. Costs for procedures were derived from estimated private payer reimbursements and adjusted to 2021 dollars. Base case costs, sensitivity analysis and incremental cost effectiveness (ICE) were evaluated. The cost of 10 capsules of Sitzmarks® is \$849.

RESULTS

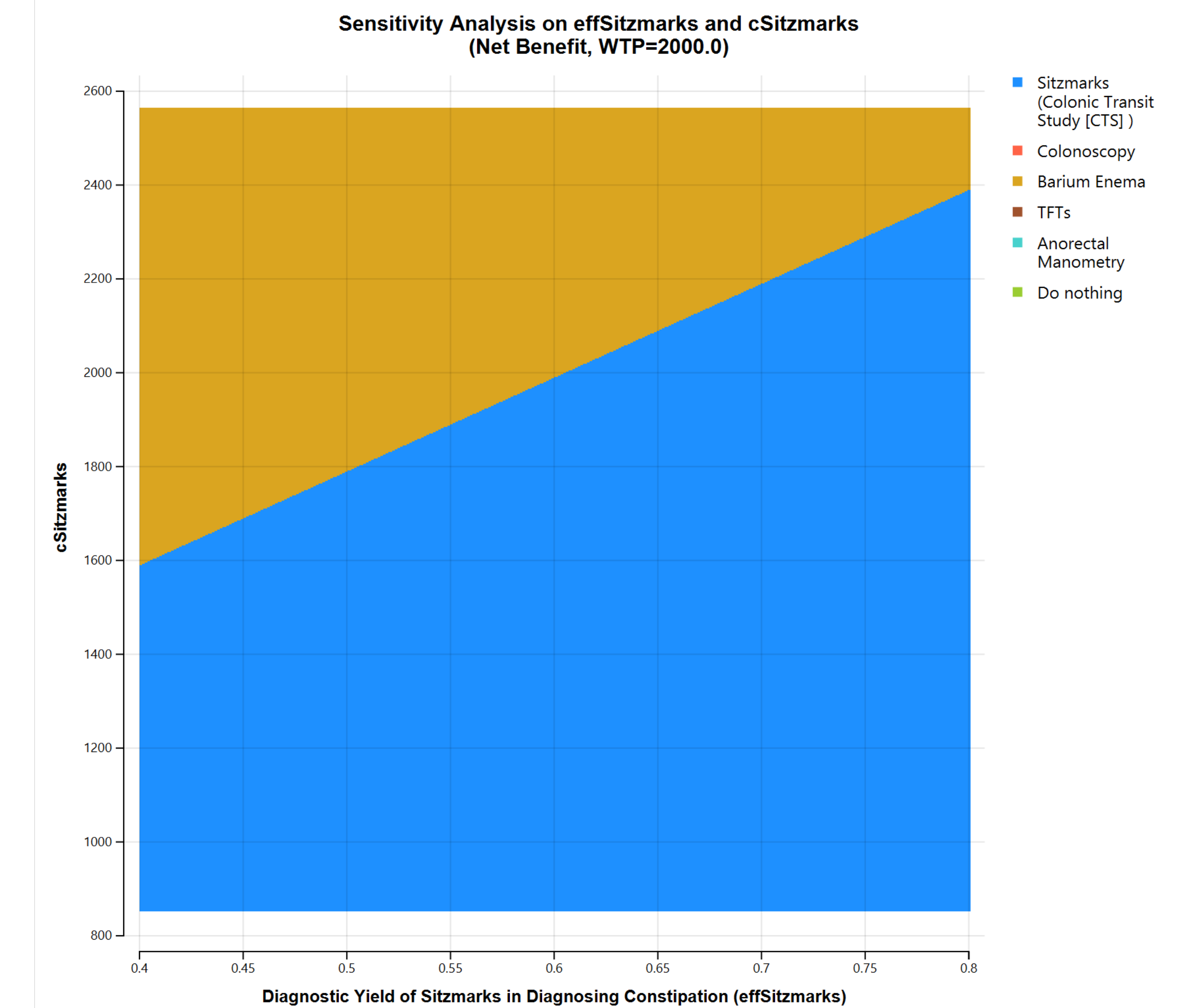
- A total of 32 pediatric physicians/ providers responded to the survey and of those, 29 responses were used in the development of the model (3 were deleted due to incomplete data).
- According to the responses, the use of Sitzmarks® ranked 11th, 6th, and 2nd for use in first, second, and third line, respectively, for the diagnosis of pediatric constipation despite 80% diagnostic yield reported.
- The use of Sitzmarks® capsule as first-line resulted in an expected value of \$4,321 per patient versus barium enema with an expected value of \$5,176 (Figure 2).
- Incremental cost effectiveness analysis, showed that Sitzmarks dominated all standard of care.
- Results of one-way sensitivity analysis showed that Sitzmarks® remained the preferred option up to a ~50% increase in total costs. At about ~50% increase in total costs of Sitzmarks®, Barium enema became the most preferred Option. Thus, the costs of Sitzmarks would need to exceed ~50% for standard of care to be less expensive than Sitzmarks®, Figure 2. The Use of Sitzmarks® as First Line Provides Cost Savings



- Results of two-way sensitivity analysis that varied the total cost of Sitzmarks® (~800 to ~2600) and the diagnostic yield (40% to 80%) of Sitzmark showed that the total costs of Sitzmarks® is sensitive to the diagnostic yield. For instance, at a higher cost and higher diagnostic yield, Sitzmarks® is the preferred option. However, as costs continues to increase, barium enema becomes the preferred option (Figure 3).

RESULTS (Continued)

Figure 3. Two Way Sensitivity Analysis



CONCLUSIONS

The use of Sitzmarks® as a first line diagnostic tool may improve diagnostic accuracy of constipation and results in significant cost savings associated with unnecessary tests with low diagnostic yield.

REFERENCES

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- Allen P, Setya A, Lawrence VN. Pediatric Functional Constipation. [Updated 2022 Aug 19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK537037/>

DISCLOSURES

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