

Caregiver Training Results in Accurate Reporting of Stool Frequency

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Abstract : Background: Accuracy of caregiver reported outcomes is essential for infant growth and tolerability study success. Crying/fussiness, stool consistencies, and other gastrointestinal characteristics are important parameters regarding tolerability, and inter-caregiver reporting can see a significant amount of subjectivity and vary greatly within a study, compromising data. This study sought to elucidate how caregiver reported questions related to stool frequency are answered before and after a short amount of training and how training impacts caregivers' understanding, and how they would answer the question. Methods: A digital survey was issued for 90 days in the US (n=121) and 30 days in Mexico (n=88), targeting respondents with children ≤ 4 years of age. Respondents were asked a question in two formats, first without a line of training text and second with a line of training text. The question set was as follows, "If your baby had stool in his/her diaper and you changed the diaper and 10 min later there was more stool in the diaper, how many stools would you report this as?" followed by the same question beginning with "If you were given the instruction that IF there are at least 5 minutes in between stools, then it counts as two (2) stools...". Four response items were provided for both questions, 1) 2 stools, 2) 1stool, 3) it depends on how much stool was in the first versus the second diaper, 4) There is not enough information to be able to answer the question. Response frequencies between questions were compared. Results: Responses to the question without training saw some variability in the US, with 69% selecting "2 stools", 11% selecting "1 stool", 14% selecting "it depends on how much stool was in the first versus the second diaper", and 7% selecting "There is not enough information to be able to answer the question" and in Mexico respondents selected 9%, 78%, 13%, and 0% respectively. However, responses to the question after training saw more consolidation in the US, with 85% of respondents selecting "2 stools," representing an increase in those selecting the correct answer. Additionally in Mexico, with 84% of respondents selecting "1 episode" representing an increase in the those selecting the correct response. Conclusions: Caregiver reported outcomes are critical for infant growth and tolerability studies, however, they can be highly subjective and see a high variability of responses without guidance. Training is critical to standardize all caregivers' perspective regarding how to answer questions accurately in order to provide an accurate dataset.

Keywords : infant nutrition, clinical trial optimization, stool reporting, decentralized clinical trials

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