USAID Report

MiracleFeet Brace: January – June 2016

Sample

The primary study sample included 152 clubfoot patients from five countries – Argentina, Liberia, Nicaragua, the Philippines, and Tanzania. Of the sample, 140 patients had idiopathic clubfoot and 16 had undergone previous surgery, other than a tenotomy. The average pre-cast Pirani score of the sample was 4.03. Patients' ages ranged from less than one month to 12 years. Of the sample, 5 were from Argentina, 20 from Liberia, 35 from Nicaragua, 79 from the Philippines, and 30 from Tanzania. A subset comparison group was used in the Philippines, where 17 of the 79 participants used a non-MiracleFeet brace. All other study participants used the MiracleFeet brace. A non-probability, convenience sampling was used for the selection of this sample (Fig. 1).

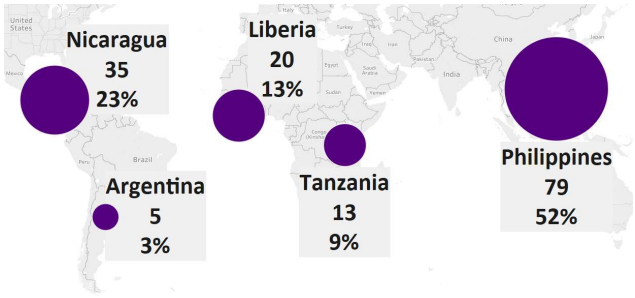


Fig. 1 In this figure, size represents the total number of records per location. Location, total number of participants, and percent of total sample is provided.

A secondary study sample was comprised of 16 healthcare providers treating clubfoot in five low-income countries – Argentina, Botswana, the Philippines, and South Africa. All provider data were based on treatment with MiracleFeet brace (Fig. 2)

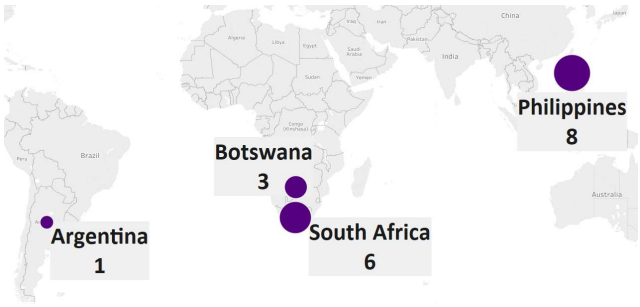


Fig 2 Size represents the total number of records per location. Location and total number of records are provided.

Methods

Over the course of six months – January 1, 2016 to June 30, 2016 – patient and provider data were collected from seven low-income countries. Commcare, a free, open-source mobile survey application specifically designed for use in low-resource settings was the primary tool used in data collection. In addition to mobile data, paper surveys were used in Botswana and South Africa. Two primary surveys were employed – a parent feedback survey and a provider feedback survey.

The parent feedback survey was composed of two separate questionnaires – one administered at registration and another used at each follow-up visit. Variations between these two questionnaires included general demographic questions and indication of clubfoot type and previous surgery (asked only at registration) and questions concerning sores, brace removal and general brace problems (used exclusively at follow-up visits). Both questionnaires included identical questions aimed at measuring ease of use and perceived comfort of the brace.

Questions concerning brace ease of use employed a Likert-type scale to measure responses and included the following questions:

1) How easy is it to put the shoe on?
2) How easy is it to lace the shoe?
3) How easy is it to place the heel at the bottom of the shoe so that the foot is flat?
4) How easy is it to clip the shoe onto the bar?

Possible responses to these questions were, "easy", "fair", and "difficult" and were assigned a value of 25, 12.5, and 0, for a total possible combined score of 100. Responses were scaled, scored, and aggregated for use in data analysis.

Parental feedback data were collected on-site by in-country coordinators. Caretakers of 152 clubfoot patients and 16 healthcare providers using the MiracleFeet brace in their clinic participated in the parent feedback survey. Coordinators used the Commcare mobile survey application to record

participant responses at registration and each subsequent follow-up visit. Completed surveys were then uploaded to the Commcare online database in preparation for analysis.

Secondary data from the International Clubfoot Registry (ICR), allocated by The Center for Bioinformatics and Computational Biology at the University of Iowa, provided patient Pirani scores. These data allowed for comparison of ease-of-use and comfort scores to clinical outcomes, an important aspect of our overall analysis.

The provider feedback survey aimed to assess the ease of use and perceived comfort of the brace from the provider's point of view, as well as the provider's overall satisfaction with the MiracleFeet brace. This survey used questions similar to those in the parent feedback survey as well as a direct question regarding satisfaction. As with the parent feedback survey, responses were scored and aggregated for use in analysis.

Results

Parent Feedback Survey Results

In total, 152 parents of children with clubfoot participated in the parent feedback survey. During the six-month interval, a total of 335 surveys were collected. Of the 152 participants, 17 were assigned to a comparison group in the Philippines. This group used a non-MiracleFeet brace for treatment and provided 56 of the 335 completed surveys. The Philippines provided the greatest amount of data at 67% of completed surveys, with Nicaragua contributing 12%, Liberia 9%, Tanzania 9%, and Argentina 3% (Fig. 3).

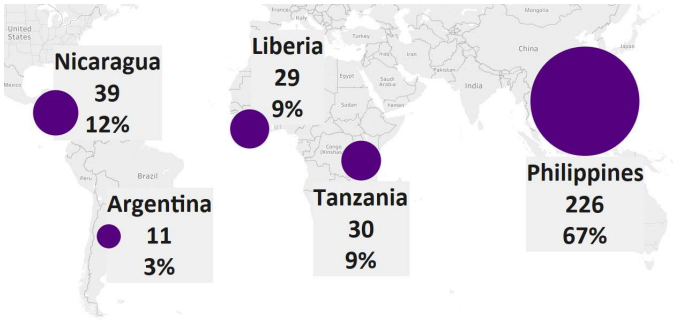


Fig. 3 Size represents the total number of completed surveys. Country, number of completed surveys, and percent of total completed surveys is provided.

Of the 135 participants using the MiracleFeet brace, five discontinued use of the brace during treatment. Two stopped use due to the child being able to remove the shoes from the brace, two were switched to a non-MiracleFeet brace by the provider due to non-compliance issues – parents were not clipping the shoes to the bar, and one patient moved out of range of the clinic offering the MiracleFeet brace. No participants of the study experienced a relapse over the six month duration of the study.

Measuring ease of use as described previously, we found an average ease-of-use score of 85.66, with Liberia reporting the lowest overall score (64.66) and Argentina reporting the highest (100.00) (Fig. 4).

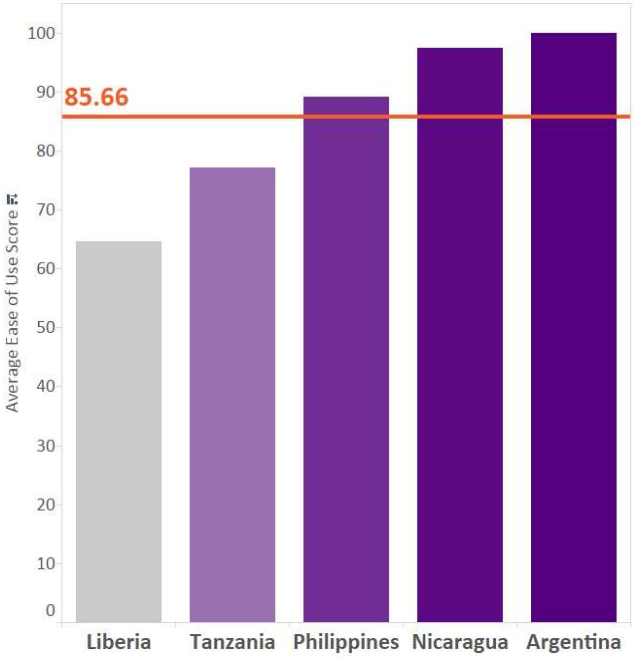


Fig. 4 This figure shows the average of ease-of-use score across all locations for MiracleFeet brace only. Color gradient represents individual average ease-of-use score.

Analysis of individual components of the ease-of-use score revealed that the highest scores were attributed to the ease of lacing the shoe, followed by ease of clipping the shoe and ease of putting the shoe on, with ease of placing the heel at the bottom of the shoe receiving the lowest scores (Fig. 5).

Notable differences in individual ease-of-use scores were found between countries, with Argentina having the highest average scores for each individual measure (Nicaragua also scoring a 25 for lace score) and Liberia having the lowest scores for each individual measure (Fig. 6).

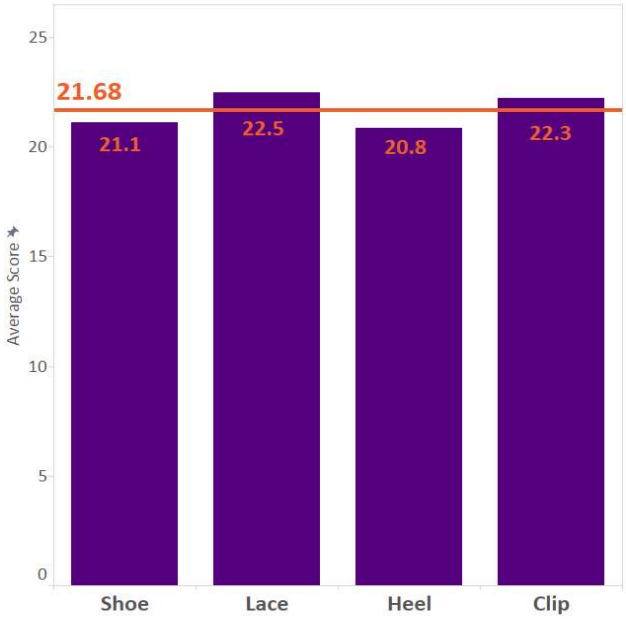
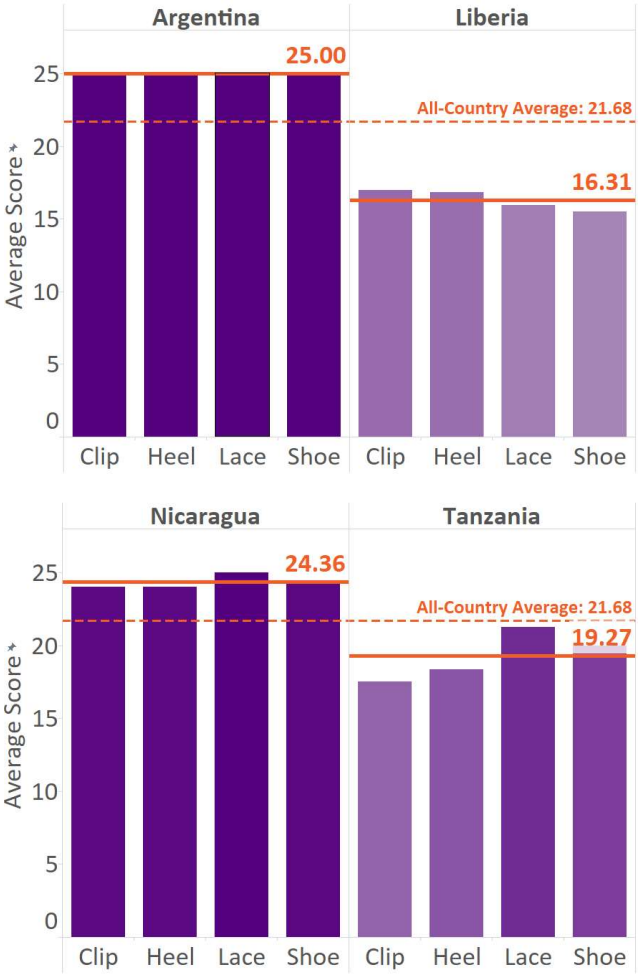


Fig. 5 This figure shows average MiracleFeet brace shoe score, lace score, heel score and clip score for all countries.



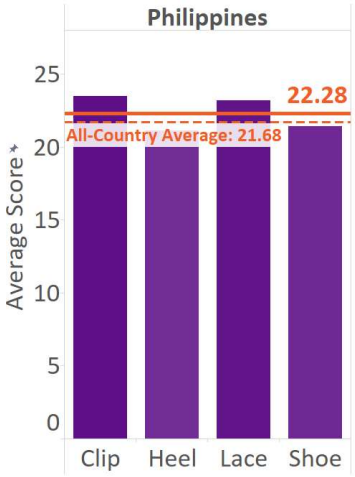


Fig. 6 This figure shows **average** MiracleFeet brace clip score, heel score, lace score and shoe score for each location. Color gradient represents overall clip score, heel score, lace score and shoe score.

Other variations found between MiracleFeet brace data and Other brace data include differences in reports of brace removal by the child and the brace causing red spots or blisters.

Reports of child removal varied widely between braces. Among parents of MiracleFeet brace users, 11 reported that their child could remove the brace, while 130 reported that their child could not remove the brace. Although there were fewer parents of Other brace users in the study, a much higher proportion reported brace removal, with 18 reporting that their child could remove the brace and 21 reporting that their child could not remove the brace. Thus, only 8% of parents of MiracleFeet brace users reported child removal compared to 46% of parents of Other Brace users (Fig 10).

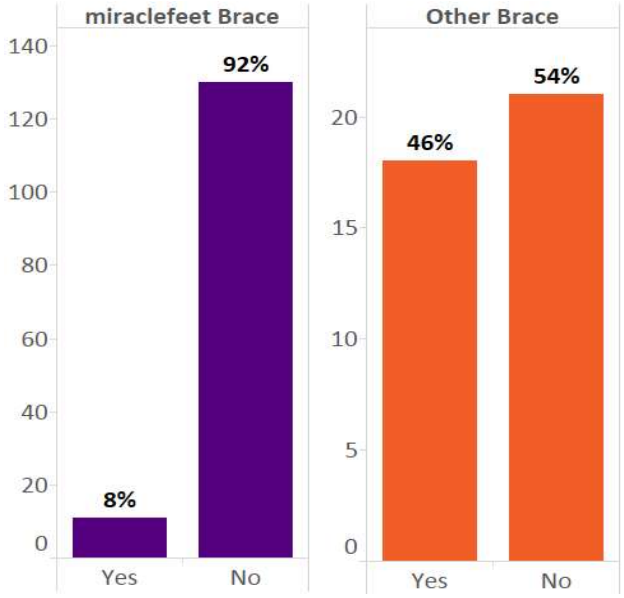


Fig. 10 This figure shows number of parents in the Philippines reporting that their child can or cannot remove the brace. Color difference represents the different braces. Percentages shown represent the percent of total within each group.

Parents of brace patients were also asked if the brace had caused any red spots or blisters. Results showed that no users of Other Brace reported the appearance of red spots or blisters, while 13% (18 of 141) of MiracleFeet Brace users in the Philippines reported red spots or blisters (Fig. 11).

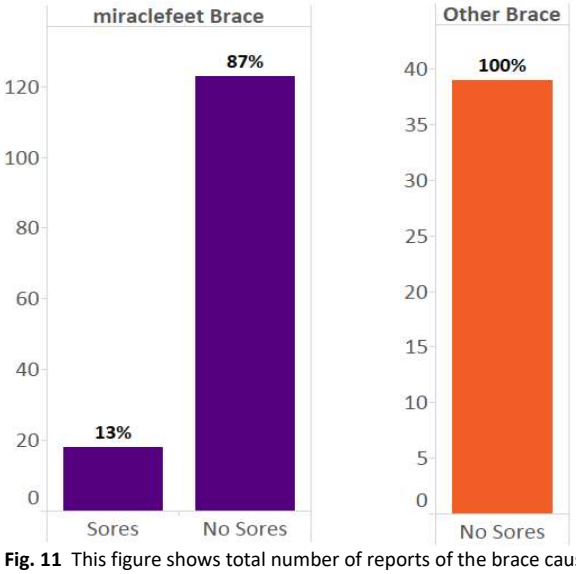


Fig. 11 This figure shows total number of reports of the brace causing red spots or blisters. Color difference represents the different braces. Percentages shown represent the percent of total within each group.

Provider Feedback Survey Results

Provider feedback surveys were used to gather data from healthcare professionals using the MiracleFeet brace to treat clubfoot in low-income countries. A total of 16 providers participated and 18 completed surveys were submitted for analysis. Data were gathered solely from MiracleFeet brace users.

Providers were asked directly what their overall satisfaction with the brace was. No providers reported Poor Satisfaction, one reported Average Satisfaction, ten reported Good Satisfaction, and seven reported Excellent Satisfaction (Fig. 12).

Fig. 12 This figure shows total number of records for each response to the overall satisfaction question.

Providers were also asked the following questions pertaining to ease of use, functionality, and comfort of the MiracleFeet brace:

- How easy is it to adjust the angles of the brace?
- How easy is it to clip the shoe to the bar?
- How comfortable does the brace appear?
- Does the foot remain flat in the shoe?
- How well does the shoe maintain its original shape?
- Doe the shoe rub or cause blisters or sores?

Responses to each question were scored and, after combining scores, an average was calculated. Results showed that the individual averages of the rub score, angle score, and comfort score all fell below the overall average, with rub score receiving the lowest score. Individual averages of the flat score, clip score, and shape score were all above the overall average, with shape score scoring the highest (Fig. 13).

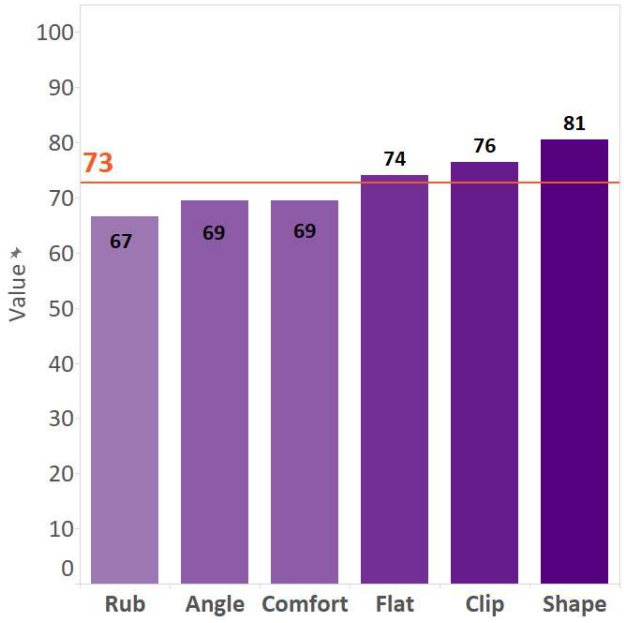
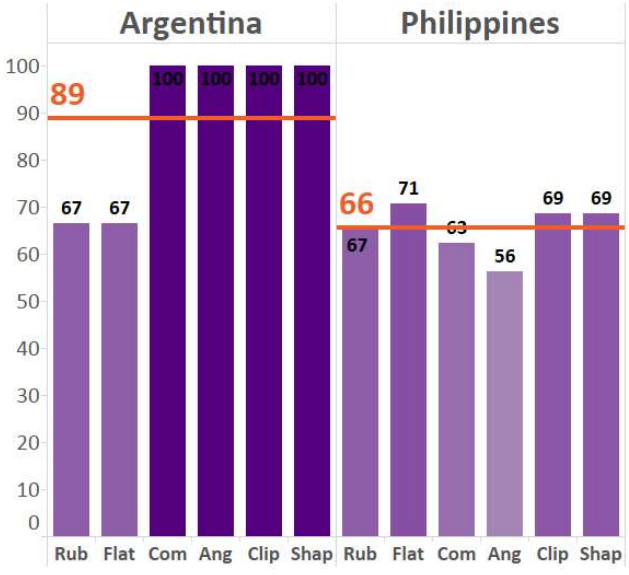


Fig. 13 This figure shows combined survey scores for individual provider feedback questions concerning ease of use, functionality, and comfort. An overall average score is also provided.

Analysis of the various scores between countries showed consistency in that shape and clip scores were regularly ranked higher than other scores. However, scores varied widely between countries, with the overall average ranging from 66 in the Philippines to 89 in Argentina (Fig. 14).



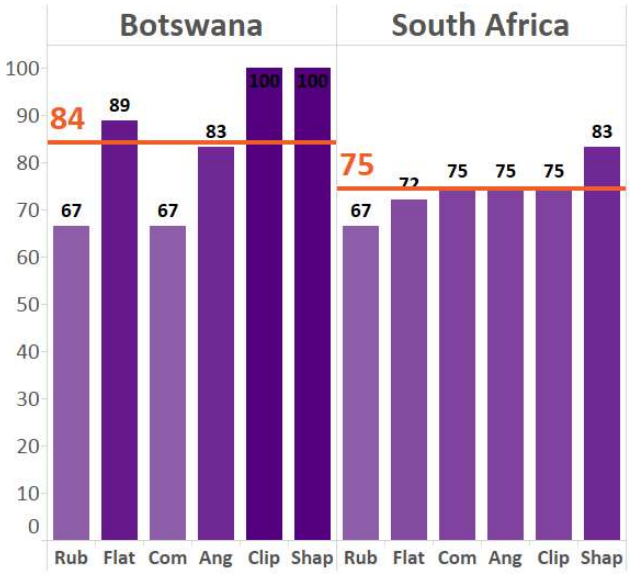


Fig. 14 This figure shows individual scores by country for providers using the MiracleFeet brace. Overall average scores per country are also shown.

Discussion

With an overall average ease-of-use score of 85.7, Quarter 1 and 2 results show that parents of children being treated for clubfoot find the MiracleFeet brace fairly easy to work with. The scoring system used equated responses of Difficult to 0, Fair to 50, and Easy to 100. Therefore, the results show that, on average, study participants gave the brace an above-average rating in regards to ease of use.

These findings are of particular importance to the study as the MiracleFeet brace employs new technologies and functionality not previously seen in clubfoot braces, such as shoes that can be removed from the brace and an innovative window used to ensure proper wearing of the shoe.

Between-country results of the ease-of-use score reveal that Liberia has a much lower scores than the other countries. Although further investigation is needed to understand the factors contributing to the difference, an assessment of the feasibility of brace usage and of standardized survey procedures in Liberia may be useful. Moving forward, understanding this difference should be an important area of focus, as advancing Liberia from its current score to that of Argentina or Nicaragua would represent a 50% increase in the brace's ease-of-use rating.

Analysis of the individual ease-of-use scores – shoe, lace, heel, and clip – is critical to understanding

where further innovation may be employed. Results show that ease of putting the shoe on and ease of placing the heel at the base of the shoe received the lowest scores. As such, if changes are made to the brace in the future, these two measures should be considered for design improvement.

These results provide promising evidence that use of the MiracleFeet brace is resulting in a significant pattern of increasing ease of use and decreasing Pirani score with progressive visits, while Other Brace is not.

In light of these findings, it is necessary to consider that the individual visit sample sizes among the Other Brace group were much smaller than those of the MiracleFeet brace group. However, we deem the sample sizes large enough to produce statistical power, validating their use in the comparison presented.

An additional valuable insight provided by analysis is the drastic difference in the ability of the child to remove the brace between MiracleFeet brace and Other Brace. Parents of Other Brace users were nearly six times as likely to report brace removal, compared to parents of MiracleFeet brace users. Further investigation is needed to understand what is causing this variance. However, as child removal accounted for 40% of MiracleFeet brace discontinuation of use, these numbers may have serious implications relating to compliance of Other Brace use. These findings suggest that, with significantly fewer reports of removal, MiracleFeet brace may greatly increase compliance rates.

Another major difference shown in the data was the reported appearance of red spots and blisters in 13% of MiracleFeet brace users, while Other Brace users reported no red spots or blisters whatsoever. These findings suggest that any further innovations and design changes to the MiracleFeet brace should address shoe comfort. These findings may also be related to brace removal issues found among discontinued use cases; however, further analysis is needed to assess this.

Similar to overall ease-of-use score measured among parents, Total provider satisfaction scores for the MiracleFeet brace were promising. Of the 18 provider feedback surveys, 10 reported Good satisfaction, 7 reported Excellent, 1 Reported Average, and 0 reported Poor. As such, 94% of providers reported an above average rating for the MiracleFeet brace.

Among individual provider scores, rub, angle, and comfort scores all fell below average, while flat, clip and shape scores were above average. These findings once again offer direction in considering design upgrades. Furthermore, investigation of factors leading to differences in average scores between countries may offer additional direction as they are better understood.

Moving forward, variations between individual scores, both for parental feedback and provider feedback should be used as design changes and other innovations are considered for the MiracleFeet brace. Furthermore, as factors leading to score variations between countries are better understood, the information should be used to modify implementation, training, and survey practices.

Additional comparison studies should be conducted in order to better understand key utilization and clinical outcome differences between the MiracleFeet brace and other braces. As these differences are better understood, they may serve as a benchmark for all brace types in an effort to improve clubfoot treatment and outcomes.

Limitations

As shown in the results section, nearly 50% of the data were from visit one, with percentages steadily decreasing from visit two through eight. Although many first visits took place late in quarter two and therefore have not had the opportunity to register any follow-up visits, there are still a number of data that seem to have been lost to follow-up as multiple cases have reported no data for months at a time. In light of these findings, a major limitation to this study is survey non-response bias. This external validity error suggests that there may be an inherent difference between those consistently participating in follow-up surveys and those not consistently participating. As such, a lack of data from this inherently different group skews the data and does not accurately represent the true values of the study sample.

Lastly, we recognize the limitations associated to the non-probability sampling method that was used for this study. Purposive sampling was employed in selecting the specific target population and,

although this was an appropriate method for the study, using this data to generalize to other populations or settings may not be appropriate.