

# Enrollment Trends of a Large Volume Prospective Registry Hosted by the Proton Collaborative Group

Megan Dunn, PhD <sup>1</sup>, Carl Brown MSHS, CCRC <sup>2</sup>, Ellen Hagarty, BA <sup>3</sup>, William Hartsell, MD <sup>4</sup>, Henry Tsai <sup>2</sup>, MD, George Laramore PhD, MD <sup>3</sup>, Carlos Vargas, MD <sup>5</sup>

<sup>1</sup> Proton Collaborative Group, <sup>2</sup> ProCure Proton Therapy Center- NJ, <sup>3</sup> University of Washington, <sup>4</sup> CDH Proton Center, <sup>5</sup> Mayo Clinic



## Introduction

The Proton Collaborative Group has been sponsoring a prospective registry (REG01-09) since July 2009. This registry currently holds data on over 4,300 patients that have been treated with protons across 6 different centers. Ample literature is available which describes enrollment trends and disparities for clinical trials, but participation trends for a registry have not yet been well documented or evaluated.

## Methods

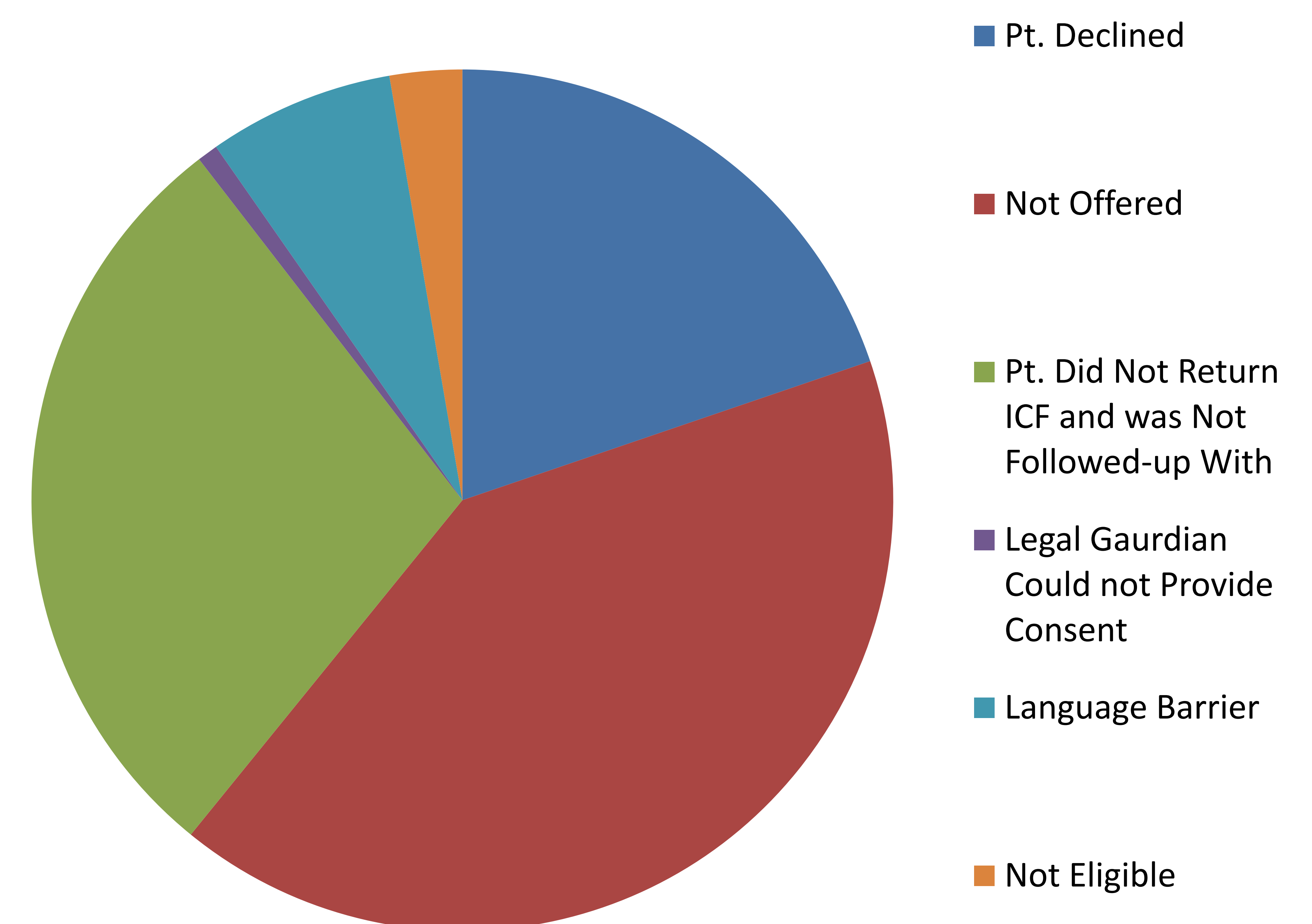
With the help of research coordinators at three of the registry's highest enrolling sites, enrollment trends were assessed. All patients who were not consented to the registry were reviewed to determine the reason for not participating. Reasons were then divided into categories for analysis, with a focus on factors potentially causing selection bias.

## Results

Out of a total of 3336 patients treated at the three highest enrolling sites, 2768 were entered onto the registry. The largest reason for non-enrollment was because patients were missed by the site staff and not offered participation. This accounted for 54% of the total non-enrolled patients. A noted bias also existed among pediatric patients: 32% of which were not enrolled based on the total number of pediatric patients treated across the three sites.

A more in depth analysis was performed at the cooperative group's highest enrolling site, which has a retrospective protocol in place allowing for detailed chart review. An enrollment bias was seen towards patients that were anesthetized for treatment, with 24% of this population not enrolled, and towards patients with a CNS diagnosis, which made up 35% of the total number of patients not enrolled. No enrollment bias was seen based on type of insurance.

## Reasons for Non Enrollment



## Conclusion

This analysis points to a need for sites to evaluate their current research staff resources, as well as how pediatric and CNS patients are approached for registry participation. Possible solutions to these issues could be to request a waiver of consent for including patients on the registry, or to educate additional site staff on the consent process and delegate this task to those who come in frequent contact with the patients.