

# Home Infusion Immunoglobulin Patterns and Dynamics in Patients Diagnosed with Primary Immunodeficiency in the United States

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## Abstract

**Background:** Immunoglobulin (IG) therapies remain important treatments for primary immunodeficiency (PI). As PI diagnoses have risen, evolving IG options and care have broad implications on patient health. Treatment settings, in particular IG infusions within the home, have received increasing attention regarding benefits and potential patient impact. Opportunities remain to understand IG home infusion patterns, as data to date has been limited and prior studies have had relatively smaller sample sizes (<2k) and/or methodologies that could have potential subjective bias (e.g. surveys).

**Objective:** This study aimed to understand IG use dynamics among patients with PI in the home infusion setting in a broad US population based cohort, including potential differences within selected subgroups (i.e., IG type [intravenous (IV)/subcutaneous (SC)], gender [male (M)/female (F)], and age [0-16/17-44/45-64/65+]).

**Methods:** This retrospective analysis included closed medical and pharmacy claims from US patients of all ages between 01 January 2019 and 31 December 2019. Patients had to have a PI diagnosis (i.e., International Classification of Disease-10th Revision codes indicating PI conditions), ≥1 IG claims within the study time period, and IG home infusion claims codes. Patients were compared on demographics by IG type, gender, and age using chi-square tests of independence; two-sided p-values <0.05 were considered statistically significant.

**Results:** Overall, N=27,491 patients with PI infused with IG in the home setting were included in the sample, with 13,368 patients on IVIG and 14,123 patients on SCIG. In IV/SC comparisons, greater proportion of patients with PI were female (F) in both IV and SC, with SC cohort (F, 68.0%) having higher proportion of females compared to proportion of females within IV (F, 64.5%) [p<0.001]. Age distribution of IV patients had greater concentration in older working age (45-64, 41.5%) compared to SC (45-64, 34.0%); SC showed greater concentration in older adults (65+, 30.5%) compared to IV at the same age range (65+, 25.1%) [p<0.001]. In gender comparisons, greater proportion of males were at younger ages (0-16, 18.6%) compared to females (5.3%); whereas greater proportion of females (45-64) were at older working ages (41.7%) than males (29.7%) [p<0.001]. Deeper review based on age subgroup analyses echoed that the 17+ age cohorts had greater proportion females than males [p<0.001].

**Discussion:** This study provides key insights into dynamic differences that can exist among patients with PI receiving IG infusion in the home setting, based on IG type, gender, and age subgroups. While prior studies have reflected similar aggregate patterns, the current analysis and large sample suggests important differences in IG home infusion trends that can be specific to each patient subpopulation. These perspectives can help facilitate awareness of current trends in IG adoption and inform care discussions between patients and health care providers about IG therapy for PI in the home infusion setting.

**Conclusion:** These insights suggest important implications for IG adoption in each subgroup and strengthens potential opportunity for developing tailorable solutions for each community. Future research should further review longitudinal trends and continue to explore contemporary updates in IG home infusion for patients with PI.

**Keywords:** Primary Immunodeficiency, Immunoglobulin, Home Infusion

## Introduction

- Immunoglobulin (IG) therapies remain important treatments for primary immunodeficiency (PI) [1]
- As PI diagnoses have risen, evolving IG options and care have broad implications on patient health [1,2]
- Treatment settings, in particular IG infusions within the home, have received increasing attention regarding benefits and potential patient impact [3]
- Opportunities remain to understand IG home infusion patterns, as data to date has been limited [4,5]
- Prior studies have had relatively smaller sample sizes and/or methodologies that could have potential subjective bias (e.g. surveys) [4,5]

## Objective

This study aimed to understand IG use dynamics among patients with PI in the home infusion setting in a broad US population based cohort, including potential differences within selected subgroups (i.e., IG type [intravenous (IV)/subcutaneous (SC)], gender [male (M)/female (F)], and age [0-16/17-44/45-64/65+]).

## Methods

This was a retrospective observational study that used closed medical and prescription claims data from US patients diagnosed with PI. Claims data were sourced via Komodo Healthcare deidentified claims databases, that contain clinical/ prescription encounters in the US, including hospital networks, physician networks, claims clearinghouses, pharmacies, and health insurers.

- Study time period: 01 Jan 2019 to 31 Dec 2019
- Inclusion Criteria
  - Diagnosed with PI (ICD-10 codes: D80.1, D80.2, D80.3, D80.4, D80.5, D80.6, D80.7, D81.0, D81.1, D81.2, D81.5, D81.6, D81.7, D81.8, D81.9, D82.1, D82.4, D83.0, D83.1, D83.2, D83.8, D83.9, G11.3) –AND–
  - Had ≥1 IG claims in study period (J code, NDC code) –AND–
  - Had associative code for IG home infusion
- Exclusion Criteria
  - Not meeting all inclusion criteria
- Index date was defined as the first home infusion IG claim within the study period
- IG therapy type (IV/SC) was determined based on the claim at index IG home infusion treatment

Variables
IG Route of Administration
Age
Gender
U.S. Region

## Data Analysis

- Bivariate comparisons were conducted by IG type, gender, and age via Chi-square tests (as all were categorical variables)
- 2-sided p-values <0.05 were considered statistically significant

## Reflection: Database Limitations

- Claims databases includes data from insured populations, and results may not generalize to uninsured patients who receive IG infusion in the home infusion setting
- Original purpose of the data was collected for claims purposes; data respectively can be variable depending on institution, insurer, etc. Coding and population of fields can vary
- Certain variables recorded could not be appropriately classified; all variables presented and reviewed here though had <5% of claims per subpopulation group that had this challenge
- Details as to the rationale of specific selection is not present in claims data; the data reflects ultimately the outcome of IG selection

## References

- Prez E, Orange J, Bonilla F, et al. Update on the use of immunoglobulin in human disease: A review of evidence. *J Allergy Clin Immunol* 2017; 139: S1-46.
- Kobrynski L, Powell R, Bowen S. Prevalence and Morbidity of Primary Immunodeficiency Diseases, United States 2001–2007. *J Clin Immunol*. 2014 Nov; 34: 954–961.
- Rider N, Kutac C, Hajjar J, et al. Health-related quality of life in adult patients with Common Variable Immunodeficiency Disorders and Impact of Treatment. *J Clin Immunol*. 2017; 37: 461-475.
- Jones G, Vogt K, Chambers C, et al. What is the burden of immunoglobulin replacement therapy in adult patients with primary immunodeficiencies? A systematic review. *Front Immunol*. 2018;9:Paper 1308.
- Huang F, Feuille E, Cunningham-Rundles C. Home care use of intravenous and subcutaneous immunoglobulin for Primary Immunodeficiency in the United States. *J Clin Immunol*. 2013; 33: 49-54.

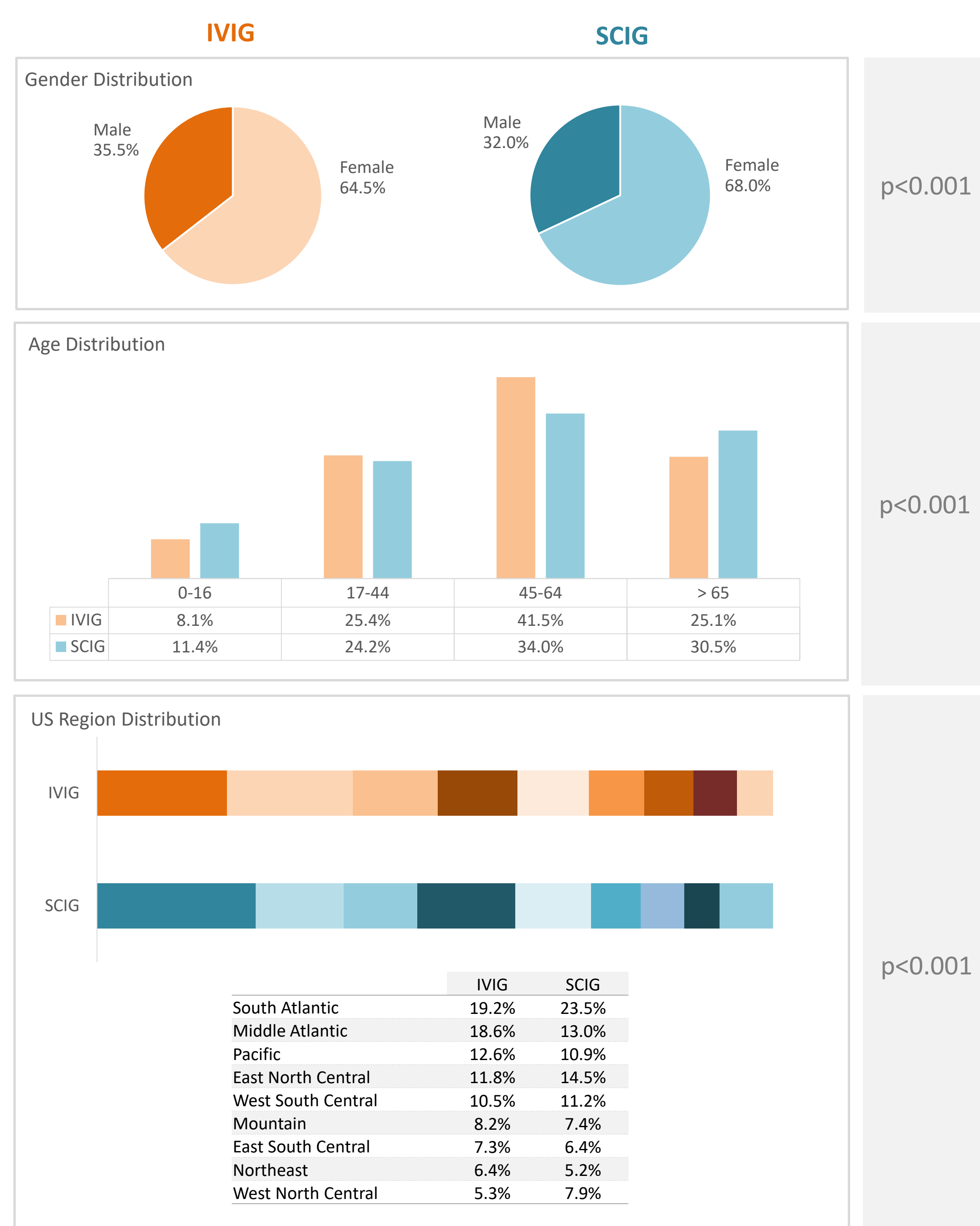
## Results

- A total of 27,491 patients with PI infused with IG in the home setting in 2019 calendar year and were included as variables reported allowed in respective sample.

### Route of Administration Subgroups

- Breakdown by IVIG vs. SCIG showed differences per administration [p<0.001; Figure 1]
- Greater proportion of patients with PI were female (F) in both IV and SC, with SC cohort (F, 68.0%) having higher proportion of females compared to proportion of females within IV (F, 64.5%) [p<0.001]
- Age distribution of IV patients had greater concentration in older working age (45-64, 41.5%) compared to SC (45-64, 34.0%); SC showed greater concentration in older adults (65+, 30.5%) compared to IV at the same age range (65+, 25.1%) [p<0.001]
- Slight regional distribution difference between IVIG and SCIG use [p<0.001]

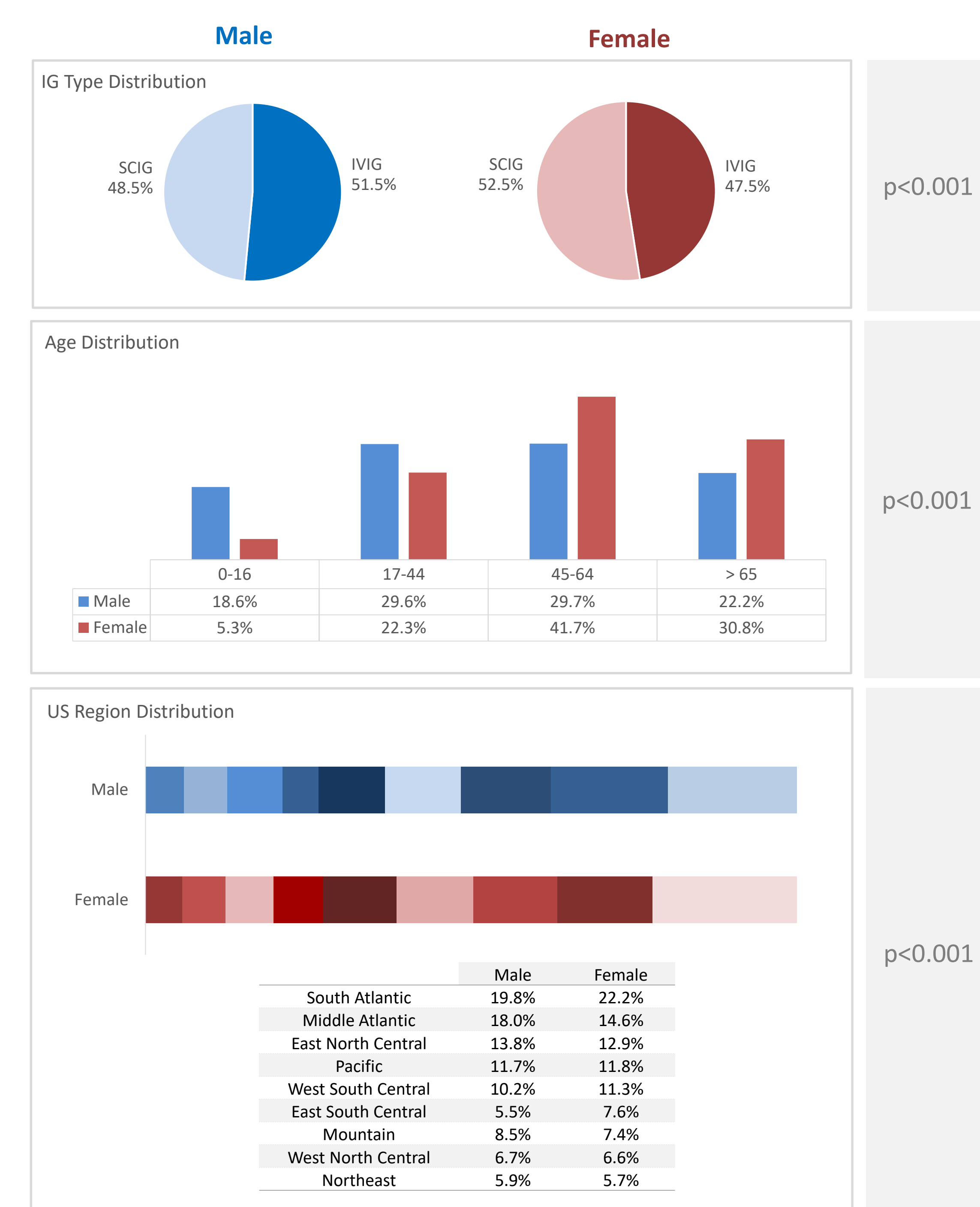
Figure 1. Subgroup Demographic Comparison by IVIG (n=13,368) and SCIG (n=14,123)<sup>a</sup>



### Gender Subgroups

- While less men are infused with IG compared to women, the distribution of IV and SC among those who receive IG is distributed in similar proportions to the two administration routes; men lean slightly more IVIG (51.5% v. 47.5%; p<0.001) [Figure 2]
- Greater proportion of men were at younger ages (0-16, 18.6%) compared to women (5.3%); whereas greater proportion of women (45-64) were at older working ages (41.7%) than men (29.7%) [p<0.001]
- Slight regional distribution differences found between gender [p<0.001]

Figure 2. Subgroup Demographic Comparison by Male (n=9,184) and Female (n=18,059)<sup>a</sup>



### Age Subgroups

- SCIG was higher compared to IVIG in age groups 0-16 and 65+ groups in particular [p<0.001; Table 1]
- Deeper review based on age subgroup analyses echoed that the 17+ age cohorts had greater proportion females than males [p<0.001]
- Regionally variations [p<0.001 between age groups], with age groups 17+ each having higher proportion in South Atlantic

Table 1. Subgroup Demographic Comparison by Age Cohort<sup>a</sup>

	0-16 N=2,660	17-44 N=6,734	45-64 N=10,241	65+ N=7,582	p value
Immunoglobulin type					< 0.001
IVIG	40.6%	50.0%	53.8%	43.9%	
SCIG	59.4%	50.0%	46.2%	56.1%	
Gender					< 0.001
Male	64.0%	40.3%	26.6%	26.8%	
Female	36.0%	59.7%	73.4%	73.2%	
US Census Division					< 0.001
Middle Atlantic	18.0%	17.6%	16.4%	12.5%	
South Atlantic	17.3%	17.6%	19.9%	28.1%	
West South Central	14.8%	11.2%	10.6%	9.6%	
East North Central	13.2%	14.5%	13.4%	11.7%	
Pacific	10.6%	12.4%	11.9%	11.4%	
West North Central	8.4%	6.9%	6.3%	6.1%	
Mountain	7.5%	7.8%	7.4%	8.4%	
Northeast	5.9%	6.4%	6.6%	4.1%	
East South Central	4.3%	5.6%	7.4%	8.1%	

<sup>a</sup> Samples provided for full range of data available. Certain variables had small number of claims (≤5%) that had unavailable field entries and were not included in bivariate quantifications.

## Discussion

- This study provides key insights into dynamic differences that can exist among patients with PI receiving IG infusion in the home infusion setting
- While prior studies reflected on patterns, the current analysis and large sample suggests important differences in IG home infusion trends that can be specific to each IG type, gender, and age subgroup population
- These perspectives can help facilitate awareness of current trends in IG adoption and inform care discussions between patients and health care providers about IG therapy for PI in the home infusion setting

## Conclusion

- These insights suggest important implications for IG adoption in each subgroup and strengthens potential opportunity for developing tailored solutions for each community. Future research should further review longitudinal trends and continue to explore contemporary updates in IG home infusion for patients with PI

## Sources of Funding

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## Disclosure Statement

- Wing Yu Tang (presenting author) and Donna Palumbo are employees and stock stakeholders of Pfizer.
- Connie Sullivan and Bill Noyes of National Health Infusion Association were Pfizer consultants on this IG home infusion study.
- Martine Maculaitis and Bridget Balkaran are employees of Kantar Health and were Pfizer consultants on this IG home infusion study.