

# Immunoglobulin Replacement Therapy Switching Among Patients with Primary Immunodeficiency

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## Background

Primary immunodeficiency disease (PID) is one of seven FDA approved indications for immunoglobulin (IgG) therapy and is given to patients with PID who have decreased or absent antibody production capabilities. At the time of this abstract, in the U.S., there were 12 different brands of FDA approved IgG representing 11 different formulations from five different manufacturers. Each of these formulations varies in method of manufacture and have various, individual biochemical characteristics that make each formulation unique. These different formulations are not interchangeable and patients may experience adverse events to some, but not other products.<sup>1</sup>

A review of available literature indicates that estimates of adverse events may be underestimated as most studies report intravenous reactions and do not include postinfusion reaction and adverse events.

## Abstract

**INTRODUCTION:** A majority of patients in the U.S. with an antibody deficiency have switched IgG therapy products. Switching products can have adverse effects on the patient's health.

**METHOD:** In November of 2011, a nationwide sample of almost 1,500 patient/caregivers of patients recruited from the Immune Deficiency Foundation (IDF) patient database completed an online questionnaire developed by the IDF Director of Survey Research.

**RESULTS:** Seventy-nine percent of the patients reported a switch in IgG therapy; of these 56% report a serious side effect or reaction due to the switch. Reported side effects include; fever/chills (63%), severe headache (60%), Muscle aches (54%), Aseptic Meningitis (16%) and Anaphylactic shock (15%) among others. Based on the concern of these types of side effects, patients switch products (37%), delay scheduled infusions (20%), switch off a product (20%) or refuse a particular product (19%).

**CONCLUSIONS:** Changes in the specific brand of therapy a patient uses can cause serious side effects or reactions. Patient response to these adverse events can lead to patient behavior that is contrary to the optimization of patient health outcomes.

## Objectives

- Ascertain what serious side effects, if any, occur in patients with PID who use IgG therapy
- If serious side effects occur, to document the kind of patient reported side effects, and
- Document the patient reported cause(s) of these side effects

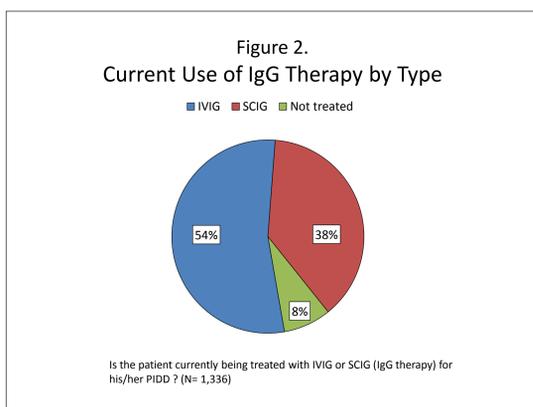
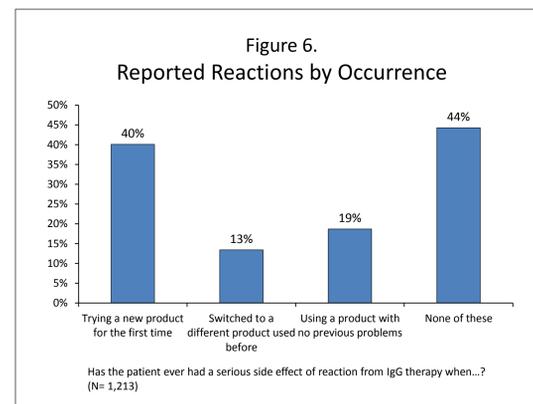
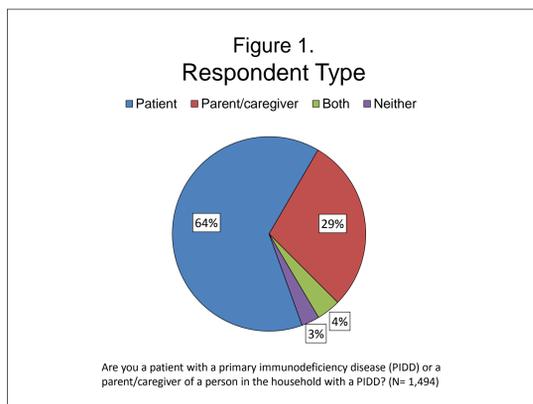
## Methodology

- Web-based survey
- Survey questionnaire developed by IDF
- IDF national patient database used as a sampling frame
- Although national in scope, results do not represent a random probability sample
- Conducted November-December 2011
- Three e-mail requests to 4,000 individuals resulted in 1,494 completions
- Analysis was conducted using PASW Statistics 18 (SPSS Inc., Chicago, IL)

## References

1. Gelfand EW. Differences between IGIV products: impact on clinical outcome. *Int Immunopharmacol* 2006; 6:592-9

## Results



**Figure 7. Reactions to Switch in IgG Therapy Products**

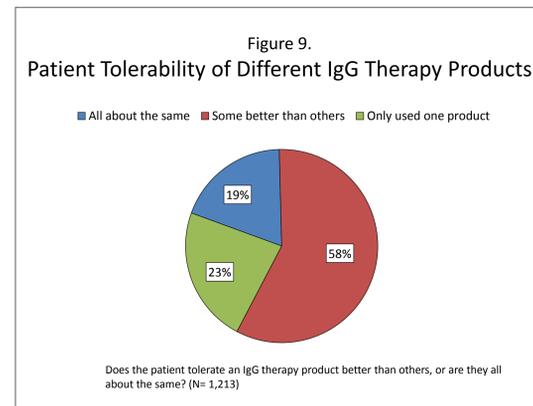
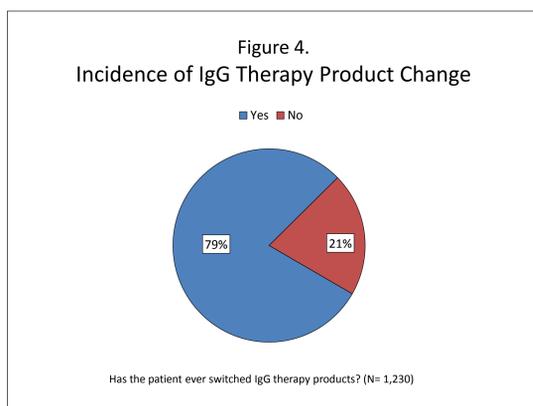
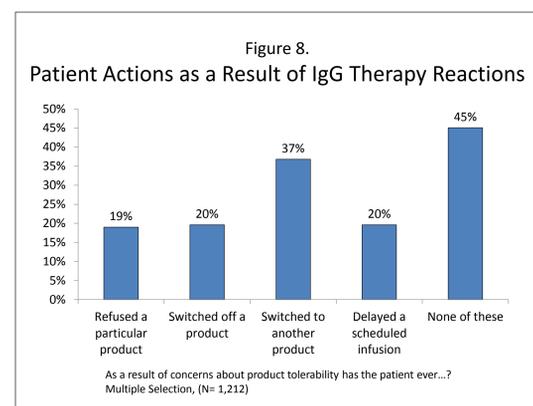
Abdominal pain	149 (23.7%)	Fainting	41 (6.5%)
Anaphylactic shock	95 (15.1%)	Muscle aches	338 (53.7%)
Anxiety	107 (17.0%)	Kidney problems	25 (4.0%)
Aseptic meningitis	99 (15.7%)	Seizure	17 (2.7%)
Fever/chills	393 (62.5%)	Stroke	1 (0.2%)
Headache	354 (56.3%)	Blood clot	6 (1.0%)
Severe headache	380 (60.4%)	Hives	140 (22.3%)
Hepatitis	7 (1.1%)	Vomiting	152 (24.2%)
Increase in blood pressure	153 (24.3%)	Wheezing	123 (19.6%)
Drop in blood pressure	129 (20.5%)	Other	97 (15.4%)

Please tell us what kind of reactions the patient has EVER had when they have switched IgG therapy products. Multiple selection, Base: those reporting a serious side-effect/reaction from therapy (N= 629)

**Figure 3. Location of Patient IgG Therapy**

Infusion Site	Distribution
At home, self infused	519 (42.1%)
At home, nurse infused	258 (21.1%)
Doctor's private office	91 (7.4%)
Hospital outpatient	132 (10.8%)
Hospital clinic	62 (5.1%)
Infusion suite	135 (11.0%)
Other	2.7 (2.2%)

Where does the patient normally receive their IgG therapy? (N= 1,223)



**Figure 5. Reasons for IgG Therapy Product Switch**

Reason for Switch	Distribution
Doctor recommended it	191 (24.5%)
Insurance company only pays for one	55 (7.0%)
Infusion place only offers one	90 (11.5%)
Infusion place out of usual product	122 (15.6%)
Patient had reactions to previous product	268 (34.3%)
Personal choice to switch	55 (7.0%)

Why did the patient have their usual IgG Therapy product switched? (N= 781)

## Conclusions

- Although a large majority of patients have experienced switches in the product they use for their IgG therapy, these changes are not without risk. Data from this survey demonstrates that changes in the specific brand of therapy a patient uses can cause serious side effects or reactions. Each time a patient switches a product there is a very real possibility that the patient will experience a serious side effect or adverse event.
- Although some of these side effects may seem relatively benign, to the patient there are very real differences in tolerability between the different IgG therapies. The differences in these products can impact patient quality of life and drive patient behavior that can result in poor health outcomes for the patient.
- Matching patients to a specific IgG therapy product that is well tolerated is important to the long-term health optimization outcomes for the patient. Switching a patient with PID off a well tolerated product on which they have been stabilized should only be taken under careful consideration when the patient and the patient's prescribing physician have been consulted.