Pharmacist-Driven Risk Mitigation with Intravenous and Subcutaneous Immunoglobulin: Patient 360 Survey Outcomes Insights

Amy E. Clarke, DNP, RN, IgCN®[1] · Luba Sobolevsky, PharmD, IgCP®[1] · Benjamin Pratt, PhD, LCSW[2]

1 Immunoglobulin National Society, Calabasas, CA, U.S. 2 University of Central Oklahoma, Edmond, OK, U.S

Abstract

Background
Immunoglobulin (Ig) therapy is a complex, high-risk treatment requiring specialized expertise in medication management and patient education. Adverse drug reactions (ADRs) with intravenous (IVIG), subcutaneous (SCIG), and facilitated SCIG (fSCIG) are common and impact safety and tolerability. Although premedication is widely used, patient-reported data suggest that infusion practices, monitoring, and education may have a stronger influence on outcomes. Pharmacists play a key role in these domains.

Objectives
To evaluate the association between infusion practices, premedication use, clinician competence, and patient-reported adverse events in IVIG and SCIG/fSCIG therapy, and to identify pharmacist-driven opportunities for risk mitigation.

Methods
A confidential, deidentified longitudinal survey (IgNS Patient360) was distributed to IgNS patient subscribers via a HIPAA-compliant platform (March–December 2025). Interim analysis included 309 respondents receiving IVIG or SCIG/fSCIG. Patient-reported ADRs, premedication use, infusion practices, monitoring, education, and follow-up were analyzed using descriptive and exploratory methods.

Results
Among IVIG patients (n≈133), 95% reported routine premedication; however, 84% reported ADRs (46% mild, 38% moderate). Premedication was not associated with a reduced frequency or severity of ADRs. Unnecessary escalation of infusion rates was associated with increased ADR risk. Higher perceived clinician competence was associated with a reduced rate of escalation ($p<0.001$), fewer pump errors (32%), a lower likelihood of blood pressure changes (65%), and a reduced incidence of headache (trend).

Among SCIG/fSCIG patients (n≈176), 97% reported local reactions (66% mild, 30% moderate, 1% severe). Common issues included insertion pain (69%), leakage (56%), infusion pain (39%), needle dislodgement (17%), pump errors (16%), and prolonged duration (15%). Premedication was not associated with reduced reaction severity. Higher satisfaction with training was associated with fewer pump errors, less pain, and greater confidence.

Conclusion
ADRs in Ig therapy are more strongly associated with infusion practices, clinician competence, and education than with routine premedication. Pharmacist-driven strategies focused on protocol optimization, education, and follow-up may reduce preventable ADRs and improve patient outcomes.

Introduction

Immunoglobulin (Ig) therapy is a complex, often lifelong treatment used across more than 70 immunologic, neuromuscular, and inflammatory diagnoses. Adverse drug reactions, systemic with IVIg and local with SCIg/fSCIg, remain common and directly affect tolerability, adherence, and quality of life.

Premedication is widely used to prevent these reactions, yet patient-reported data increasingly suggest that infusion practice, monitoring, education, and follow-up exert a stronger influence on outcomes. Pharmacists, central to medication management, protocol design, and the interdisciplinary team, are uniquely positioned to lead risk-mitigation strategies.

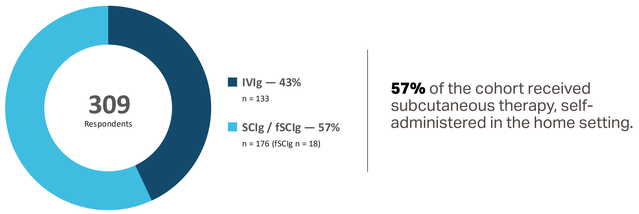
Methods

A confidential, deidentified longitudinal survey (IgNS Patient 360) was distributed to IgNS patient-subscribers via a HIPAA-compliant platform (March–December 2025). This interim analysis includes 309 respondents receiving IVIg or SCIg/fSCIg in home and infusion-center settings.

Patient-reported ADRs, premedication use, infusion practices, monitoring, education, and follow-up were analyzed using descriptive and exploratory regression methods. A validated nursing-competence index (Cronbach's $\alpha = .85–.91$), derived via principal component analysis, related perceived clinician competence to safety practices and outcomes.

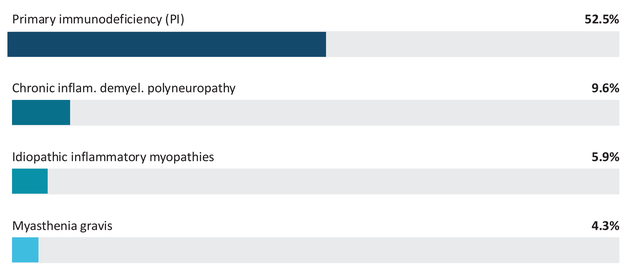
N = 309 respondents | **HIPAA-compliant platform** | **Home & infusion-center**

Figure 1. Study cohort by route of administration



57% of the cohort received subcutaneous therapy, self-administered in the home setting.

Figure 2. Primary reason for Ig treatment



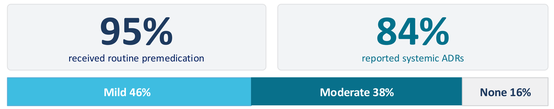
Results

IVIg: Systemic reactions persist despite premedication

Among IVIg respondents (n = 133), 95% received routine premedication, yet 84% reported systemic ADRs (46% mild, 38% moderate). Premedication was not associated with reduced ADR frequency or severity, and unnecessary infusion-rate escalation increased ADR risk.

Higher perceived clinician competence was associated with fewer unnecessary rate escalations, fewer pump errors, a lower likelihood of blood-pressure changes, and greater facilitation of pre-infusion hydration, monitoring, and follow-up.

Figure 3. IVIg systemic ADRs despite premedication (n = 133)



Premedication did not reduce ADR frequency or severity. Severity distribution among IVIg respondents.

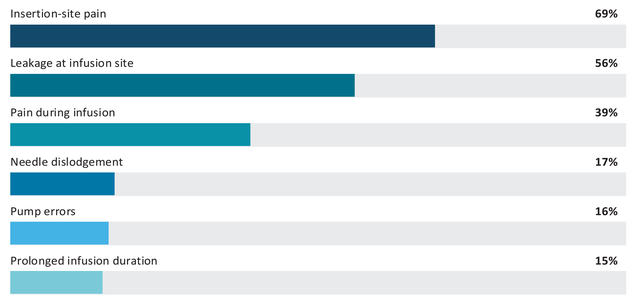
Figure 4. The competence dividend — higher perceived clinician competence and IVIg risk

Outcome	Effect with higher competence	Sig.
Unnecessary infusion-rate escalation	Reduced	p < .001
Infusion pump errors	↓ 32%	p < .05
Unanticipated blood-pressure changes	↓ 65%	p < .05
Facilitation of pre-infusion hydration	↑ 166%	p < .001
Vital-sign monitoring during infusion	More consistent	p < .001
Post-infusion follow-up	More consistent	p < .001

SCIg / fSCIg — local reactions dominate

Among SCIg/fSCIg respondents (n = 176), 97% reported local reactions (66% mild, 30% moderate, 1% severe). Premedication did not reduce reaction severity. Over 75% were satisfied with SCIg education; higher training satisfaction and clinician competence were associated with fewer pump errors and less pain.

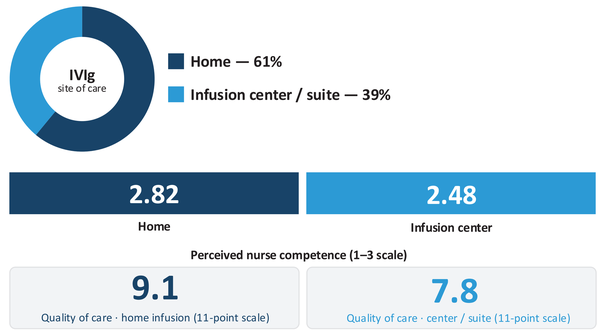
Figure 5. SCIg/fSCIg local reaction profile (n = 176)



Site of care — a measurable competence gap

Among the IVIG-treated patients, the site of care included home infusion (61%) and infusion center/suite (31%). Patients rated home nurses as more competent (2.82 vs 2.48 on a 3-point scale, $p < .001$) and reported higher quality of care. Home infusion nurses were reported to perform vital sign assessments more consistently vs. infusion center/suite nurses.

Figure 6. IVIg site of care & perceived competence



Perceived nurse competence (1 = not competent, 3 = highly competent), $p < .001$; quality of care drops 1.3 points at infusion centers ($p < .001$). Differences reflect training and access to IgNS standards, not the setting itself. Administration-related issues such as leakage at the infusion site, pain during infusion, needle dislodgement, and prolonged infusion time were reported by a significant proportion of patients.

Figure 7. Satisfaction with SCIg self-administration training

Discussion

ADRs in Ig therapy are more strongly associated with infusion practice, clinician competence, and patient education than with routine premedication. Across both routes, reactions persisted despite near-universal premedication, while higher competence consistently tracked with safer practice.

Site-of-care differences reflect specialized training and access to IgNS standards rather than the setting. Pharmacists can operationalize these findings, optimizing premedication and rate protocols, embedding competency-based education and validation, and standardizing monitoring, hydration, and follow-up across settings.

Conclusion

Pharmacist-driven strategies, protocol optimization, competency-based education, and structured follow-up, offer a higher-yield path to preventing ADRs than premedication alone. As the Ig population grows and patients move between products, routes, and sites of care, embedding pharmacist leadership in risk mitigation can reduce preventable adverse events and improve patient safety, satisfaction, and infusion quality.

Disclosures

The 2025 Patient 360 Longitudinal Survey data analysis is supported by an educational grant from GC Biopharma.