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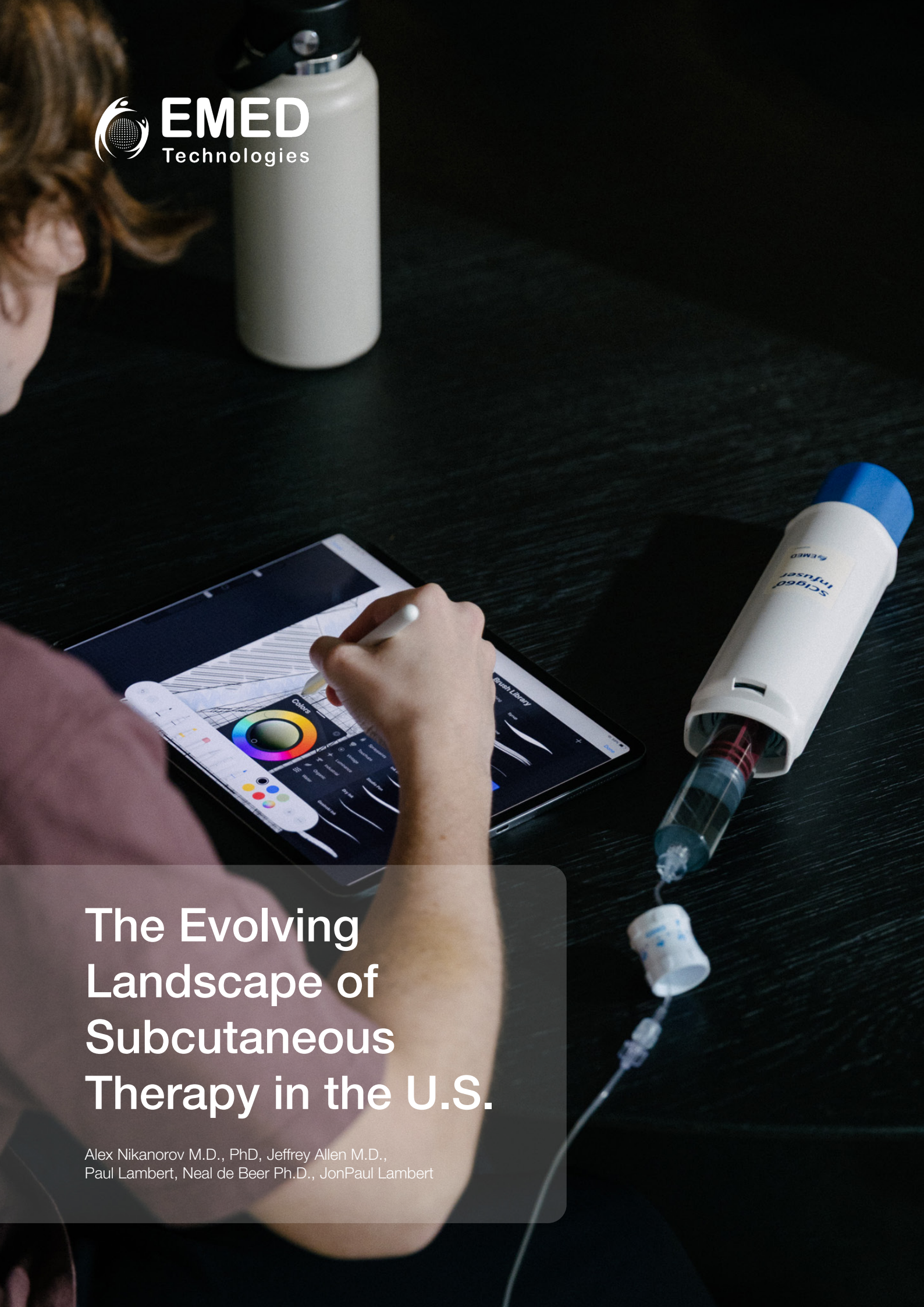
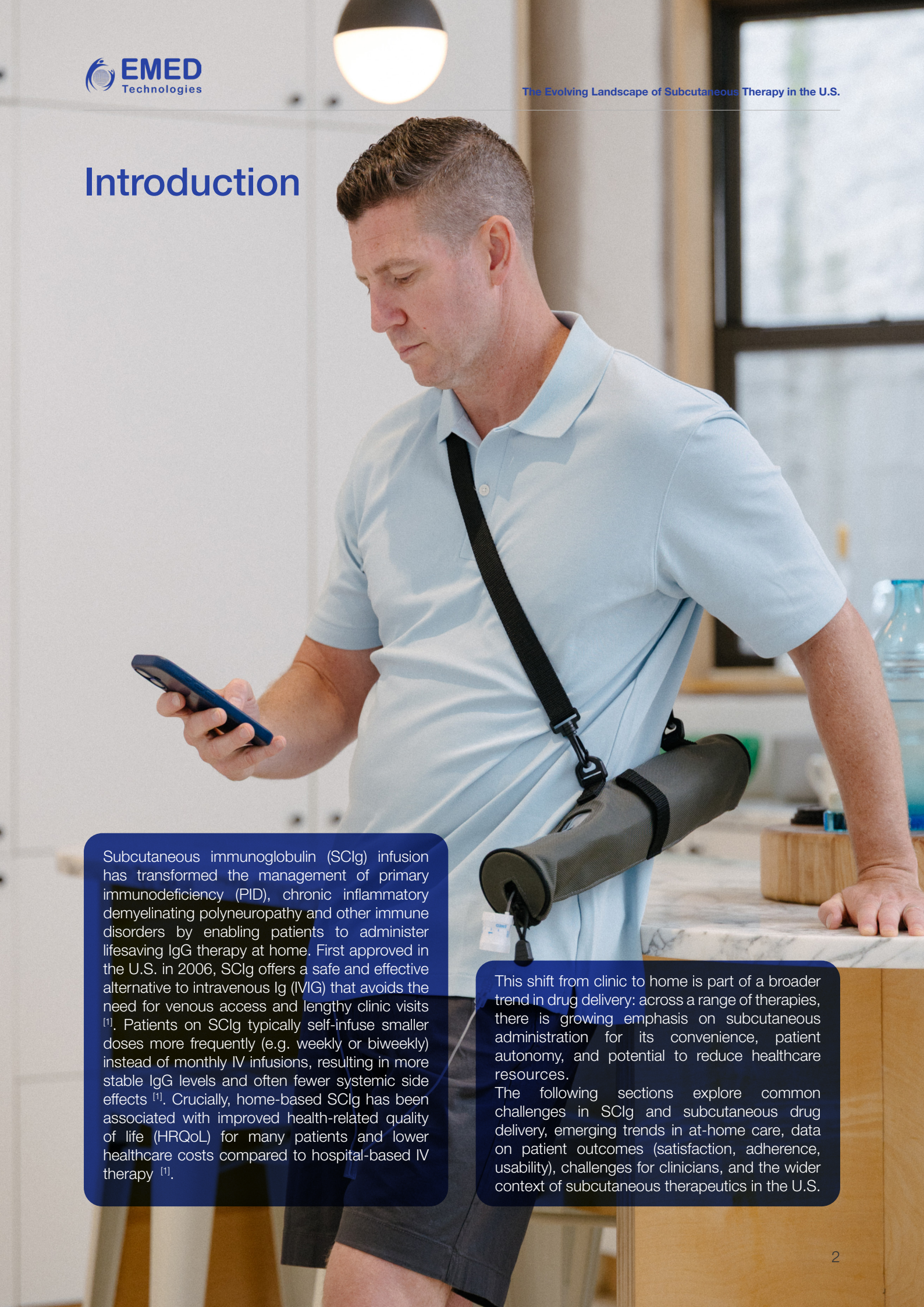


The Evolving Landscape of Subcutaneous Therapy in the U.S.

Alex Nikanorov M.D., PhD, Jeffrey Allen M.D.,
Paul Lambert, Neal de Beer Ph.D., JonPaul Lambert

Introduction



Subcutaneous immunoglobulin (SCIg) infusion has transformed the management of primary immunodeficiency (PID), chronic inflammatory demyelinating polyneuropathy and other immune disorders by enabling patients to administer lifesaving IgG therapy at home. First approved in the U.S. in 2006, SCIg offers a safe and effective alternative to intravenous Ig (IVIG) that avoids the need for venous access and lengthy clinic visits [1]. Patients on SCIg typically self-infuse smaller doses more frequently (e.g. weekly or biweekly) instead of monthly IV infusions, resulting in more stable IgG levels and often fewer systemic side effects [1]. Crucially, home-based SCIg has been associated with improved health-related quality of life (HRQoL) for many patients and lower healthcare costs compared to hospital-based IV therapy [1].

This shift from clinic to home is part of a broader trend in drug delivery: across a range of therapies, there is growing emphasis on subcutaneous administration for its convenience, patient autonomy, and potential to reduce healthcare resources.

The following sections explore common challenges in SCIg and subcutaneous drug delivery, emerging trends in at-home care, data on patient outcomes (satisfaction, adherence, usability), challenges for clinicians, and the wider context of subcutaneous therapeutics in the U.S.

Patient and Caregiver Challenges in SCIg Therapy

While patients overwhelmingly prefer at-home SC infusions to at home or in-clinic IV infusions, the self-administration process is not without challenges. A recent qualitative study of U.S. patients on SCIg identified several salient barriers that impact treatment adherence, satisfaction, and daily life [2]:

Logistics of Supplies

Patients are often responsible for managing medication refills and infusion supplies, which can be burdensome. Ordering from specialty pharmacies, coordinating shipments, and dealing with dispensing errors or missing items were common frustrations. Many patients reported having to make extra calls and keep backup stock due to incorrect or late shipments [2]. Storing bulky supplies at home (and disposing of associated waste like needles and packaging) adds another layer of inconvenience. These logistical hurdles can cause stress and risk delays in therapy if not carefully managed.

Device Handling and Procedure Complexity

Administering SCIg involves multi-step procedures that can be daunting, especially for new patients. Key challenges include preparing the medication (drawing up doses from vials, warming and pooling Ig if needed), priming tubing sets manually, and programming infusion pumps or devices [2]. Patients must also learn to insert and secure multiple subcutaneous needles (often steel needle sets) at infusion sites. Troubleshooting pump alarms or occlusions can be difficult without on-site help, and device issues may arise due to insufficient training in these technical steps. Each seemingly small task (e.g. loading a syringe driver reservoir correctly) can become a barrier if the user is unsure, illustrating how device design and training critically impact the patient experience.

Physical Discomfort and Local Reactions

Although SCIg tends to be associated with fewer systemic side effects (e.g., headache, fatigue) compared with the large infusions used for IVIG, local SCIG reactions can be troublesome for some patients. Needle insertion pain and a burning or stinging sensation during the SC infusion are commonly reported. In surveys, about one-third of patients experience pain during the SCIg infusion and a similar proportion report injection-site pain on needle insertion [3]. Swelling at infusion sites is also frequent – moderate swelling and redness at the SC needle sites can affect ~40–50% of infusions, though these reactions are typically transient [3]. While local reactions are expected and usually mild, they nonetheless can negatively impact comfort and perceived ease of use. Some patients adjust by rotating sites or using shorter needles (e.g. 6mm) to minimize discomfort [3].

Frequency and Lifestyle Impact

SCIg usually requires more frequent dosing (often weekly) than IVIG, which is typically administered every 3 or 4 weeks[1]. Patients must integrate regular subcutaneous infusions into their routine, which can be time-consuming (a typical SCIg session may last 1–2 hours for an average dose, including setup and teardown). The need to infuse so often can be seen as a burden, especially for those with busy work schedules or for parents administering to children. On the other hand, many patients find ways to multitask (e.g. infusing in the evening while watching TV) and report that the flexibility to choose when to infuse is actually a net positive for their lifestyle [2]. Notably, patients in one study felt empowered by being able to control the timing of their treatment at home, and some said they could not imagine keeping up with life's demands if they still had to go to a clinic for infusions [2]. Thus, while frequent self-treatment is a challenge, the autonomy and time saved (no travel to infusion centers) often outweigh the inconvenience.

Caregiver Burden

For patients who are children, elderly, or have limited dexterity, caregivers play a vital role in home SCIG therapy. Caregivers (often parents or spouses) must learn the infusion technique and assume responsibility for administering the Ig or assisting the patient. This can be stressful, especially initially. Training must extend to caregivers, and the emotional burden of performing medical tasks for a loved one can be high. If a patient's vision, hand strength, or cognition is impaired, identifying a willing caregiver is essential before home therapy can even be approved [4]. In cases where no suitable caregiver is available to help a patient who cannot self-infuse, clinicians may have to provide treatment for the patient in a clinical setting (SCIg or IVIG) [4]. Caregivers also share the logistical burdens noted above (managing supplies, remembering schedules) and may experience anxiety about "doing it right" without direct professional supervision.

Support resources and clear instruction from healthcare providers are therefore crucial to alleviate caregiver stress and ensure successful home treatment. Overall, patients and families strongly favor the convenience and independence of SCIg at home despite these challenges. Avoiding day-long clinic visits and having flexibility far outweigh the challenges for most. As one qualitative study concluded, "Patients unequivocally prefer SC infusions at home to in-clinic infusions," even though the current processes "present a variety of challenges" that can be improved [2]. These insights underscore several unmet needs – from streamlining supply management to simplifying device operation – that, if addressed, could further enhance adherence, satisfaction, and quality of life for SCIg users.

Clinician Challenges in Training and Support

Shifting immunoglobulin therapy from hospital to home doesn't only affect patients; it significantly changes the role of clinicians (nurses, immunologists, and pharmacists) who support these patients. Training and education are at the heart of successful home SCIg programs. Before a patient ever infuses at home, providers must ensure they can handle the procedure safely. This means assessing the patient's (or caregiver's) cognitive and physical ability to self-administer and evaluating the home environment for basic cleanliness and safety [1]. Clinicians report that identifying appropriate candidates early and working closely with patients and home nursing teams is necessary to prevent problems down the road [16].

Hands-on training is typically provided by immunoglobulin therapy nurses. Initial training sessions often involve teaching the patient how to prepare the drug, insert the SC needles, operate the pump, recognize adverse reactions, and troubleshoot common issues. Nurses often spend several sessions supervising the patient's technique. During these trainings, practical tips are shared – for instance, how to warm the Ig solution to room temperature to lessen discomfort and variations in flow rate, how to rotate sites, and how to secure needles to avoid dislodgment. Patients are encouraged to ask questions and even practice problem-solving (e.g. what to do if the pump experiences a malfunction) under nurse guidance [1].

This up-front investment of time pays off: studies indicate that better training is linked to higher patient confidence and can improve long-term treatment satisfaction [5]. Notably, one analysis found that patients who felt adequately educated and supported during the transition to SCIg had improved perceptions of their health over 12 months, including reductions in pain and fatigue and fewer missed work or school days [5]. These findings highlight that training quality directly influences outcomes – a well-trained patient is more likely to adhere and have a positive experience.

After training, clinicians face the challenge of providing ongoing support and monitoring without the benefit of seeing the patient in person for each infusion. Severe adverse events like infusion-site infections are very rare with SCIG, but minor issues (site rashes, questions about dosing when ill, etc.) do arise. Providers often establish regular check-ins (by phone or telehealth) especially in the first few months of home therapy.

Nursing professionals play a key role in coaching patients through any difficulties and reinforcing best practices. For example, if a patient starts experiencing more site pain, a nurse might troubleshoot needle length or recommend an alternative infusion site. Frequent monitoring early on can catch adherence slippage or technique errors before they snowball [1]. However, clinicians note that such follow-up is time-intensive, and not all practices have formal protocols for it. In a survey of nurses in immunodeficiency care, a lack of standardized procedures for patient training and follow-up was identified as a challenge – each center or nurse may handle it differently, potentially leading to inconsistent patient experiences [3].

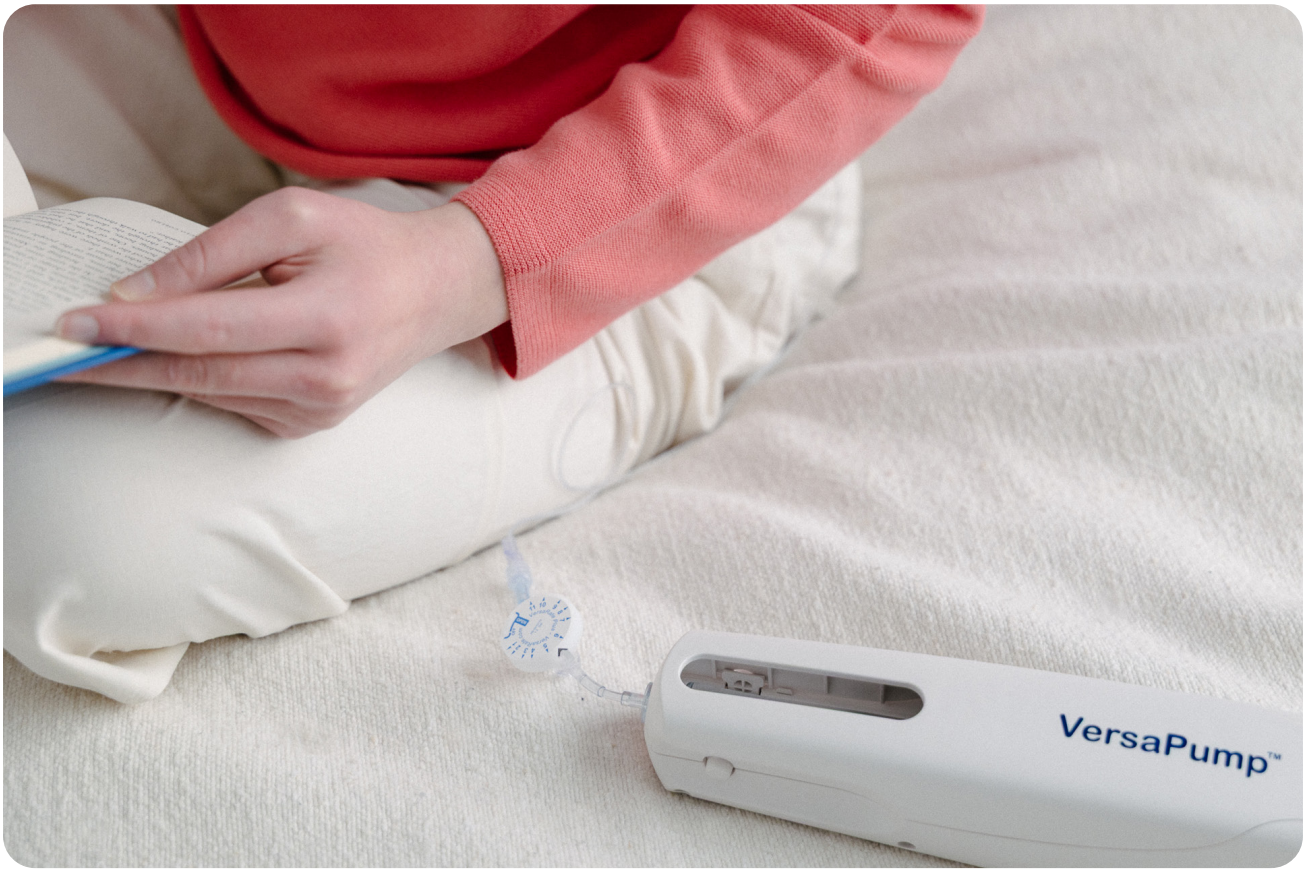
There is growing recognition that developing standardized training checklists and providing nurses with adequate time and resources for patient education are essential to support at-home therapies [1, 3].

Another challenge is ensuring adherence and proper technique over the long term. Patients may do well under supervision but later cut corners (for instance, not warming the drug, or infusing on an irregular schedule due to "therapy fatigue"). As one infusion nurse observed, patients on home therapy "are compliant initially, but over time, they sometimes become complacent," requiring periodic re-engagement and coaching [4].

Clinicians thus often take on a coaching role – reminding patients about hydration, pre-medication, and staying on schedule, and intervening if the patient starts to skip doses. If a patient consistently struggles or outcomes deteriorate (e.g. recurring infections suggesting they aren't getting their doses), the care team must investigate and may even consider a return to in-clinic infusions. Fortunately, such cases are not the norm: with careful patient selection and education, most individuals handle SCIg responsibly, and studies show that giving patients autonomy does not compromise compliance [6].

For instance, in one program where patients were allowed to choose IVIG or SCIG freely, over 90% of those who chose SCIG remained on it long-term, and even among those who initially chose IVIG, 73% eventually switched to SCIg for greater convenience [6]. Importantly, that program reported no safety issues and only a handful of patients (10 out of 143) had any compliance problems. These results reinforce that, with proper support, patient empowerment can go hand-in-hand with excellent adherence. Clinicians' challenge, then, is to continue evolving support systems to maintain high adherence without needing constant oversight.

In summary, the clinician's role in SCIg therapy extends beyond prescribing the drug – it involves being an educator, coach, and partner in the patient's self-care. Time spent on thorough training, creating individualized care plans, and maintaining communication yields dividends in patient satisfaction and outcomes [1]. By engaging patients and families in the process and setting them up for success, healthcare providers can harness the benefits of SCIg (improved quality of life (QoL) and potentially better clinical outcomes) while mitigating risks. As home infusion continues to expand, healthcare teams are actively seeking ways to standardize training, share best practices (e.g. via organizations like the Immunoglobulin National Society, which certifies Ig nurses [1]), and utilize technology to lighten the load on both patients and providers. These steps are critical to ensure that the transition of care from clinic to home is as smooth and safe as possible for all involved.



Adherence & Satisfaction: Data & Trends

Both clinical research and real-world experience indicate that patient satisfaction with SCIg therapy is high, often matching or exceeding satisfaction with traditional IVIG. Key reasons include the convenience of home treatment, greater independence, and for many, a sense of normalcy regained by not being tethered to monthly hospital visits. In surveys and studies:

Quality of Life and Preference:
An Immune Deficiency Foundation survey in 2018 found that about 61% of U.S. patients on Ig replacement were using SCIg (versus 39% on IVIG), reflecting the popularity of home-based therapy [7]. When asked about their experiences, a large majority of patients and providers agree that SCIg improves QoL. In one multi-stakeholder survey, 84% of patients reported better QoL on SCIg compared to IVIG, a sentiment strongly echoed by immunologists and nurses [8]. Patients frequently cite the flexibility to schedule infusions at their convenience and the avoidance of travel and missed work days as major advantages [2, 5]. Indeed, in a prospective study where patients switched from clinic IVIG to home SCIg, over 80% reported that their quality of life improved after the switch, with specific improvements noted in vitality and the ability to attend work/school [5]. Notably, independence and control over therapy emerge as decisive factors – one study found patients "strongly preferred" whichever route (SC or IV) gave them more autonomy and convenience, which in practice meant most favored self-administered SCIG at home over provider-administered IVIG in a clinic [6, 9].

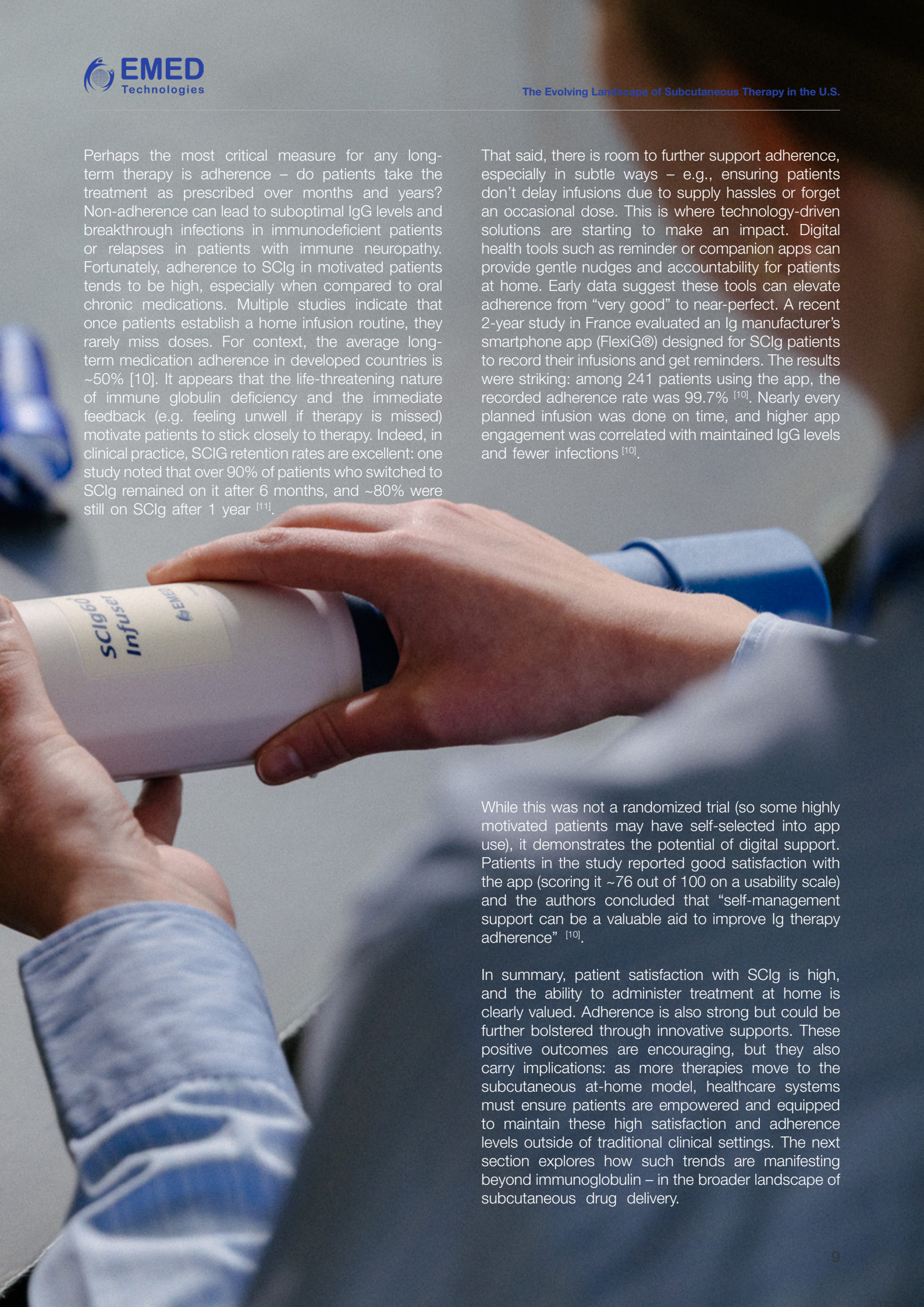
Treatment Satisfaction:
Formal satisfaction scores mirror these qualitative preferences. A National Home Infusion Foundation analysis of 326 Ig therapy patients found no significant difference in overall satisfaction between those on IVIG and those on SCIG – both routes achieved very high satisfaction ratings (~98% of patients were satisfied with the quality of their home infusion services) [5]. This suggests that when therapy is tailored to patient preference, people tend to be satisfied whether they chose IV or SC routes of administration. However, when drilling down to specific aspects, SCIg often rates better on convenience, while IVIG might rate higher on nurse support (since a nurse is present for IV infusions) – yet both groups in this study had access to home nursing or pharmacy support as needed, which likely equalized general satisfaction [5]. Another insight was that patient choice drives satisfaction: those who have the option to select the modality that fits their life are happier with treatment, underscoring the value of accommodating patient preferences [5, 6]. The sense of normal life that home therapy enables is a recurring theme in patient satisfaction. Even children and adolescents on SCIg have reported feeling less "sick" because they can do their infusions at home rather than being reminded of their illness in a clinic setting [9].

Efficacy and Tolerability Perceptions

From a clinical standpoint, IVIG and SCIG are equally effective in maintaining IgG levels and preventing infections in PID, but patient perceptions can differ [18]. In a large clinical trial of patients with CIDP treated with IVIG, transition to SCIg was shown to be an effective therapy for maintenance of disease control" [17]. Interestingly, surveys have found that about 60% of patients consider SCIg more effective than IVIG for them, even though the therapies are clinically equivalent [8]. This patient perception may stem from fewer systemic side effects and the feeling of fewer "peaks and troughs" in Ig levels with frequent SC dosing. Clinicians generally consider them equally efficacious (as do roughly half of nurses surveyed), but the fact that many patients feel better on SCIg is an important satisfaction driver [8]. On tolerability, because IV infusions deliver a large dose at once, they carry higher risk of transient systemic reactions (headache, fever, etc.), whereas SCIG's smaller, frequent doses cause mostly local site reactions. Many patients prefer mild local reactions over the flu-like systemic reactions that are more common with IVIG. In the same survey, ~64% of patients and ~65–69% of providers felt SCIG is better tolerated than IVIG [8]. Only a small minority of patients (<10%) found SCIG less tolerable than IVIG [8]. These data reinforce that SCIG is at least as satisfying as IVIG for most, and often more so, due to a combination of efficacy, tolerability, and lifestyle factors.

Perhaps the most critical measure for any long-term therapy is adherence – do patients take the treatment as prescribed over months and years? Non-adherence can lead to suboptimal IgG levels and breakthrough infections in immunodeficient patients or relapses in patients with immune neuropathy. Fortunately, adherence to SCIg in motivated patients tends to be high, especially when compared to oral chronic medications. Multiple studies indicate that once patients establish a home infusion routine, they rarely miss doses. For context, the average long-term medication adherence in developed countries is ~50% [10]. It appears that the life-threatening nature of immune globulin deficiency and the immediate feedback (e.g. feeling unwell if therapy is missed) motivate patients to stick closely to therapy. Indeed, in clinical practice, SCIG retention rates are excellent: one study noted that over 90% of patients who switched to SCIg remained on it after 6 months, and ~80% were still on SCIg after 1 year [11].

That said, there is room to further support adherence, especially in subtle ways – e.g., ensuring patients don't delay infusions due to supply hassles or forget an occasional dose. This is where technology-driven solutions are starting to make an impact. Digital health tools such as reminder or companion apps can provide gentle nudges and accountability for patients at home. Early data suggest these tools can elevate adherence from "very good" to near-perfect. A recent 2-year study in France evaluated an Ig manufacturer's smartphone app (FlexiG®) designed for SCIg patients to record their infusions and get reminders. The results were striking: among 241 patients using the app, the recorded adherence rate was 99.7% [10]. Nearly every planned infusion was done on time, and higher app engagement was correlated with maintained IgG levels and fewer infections [10].



While this was not a randomized trial (so some highly motivated patients may have self-selected into app use), it demonstrates the potential of digital support. Patients in the study reported good satisfaction with the app (scoring it ~76 out of 100 on a usability scale) and the authors concluded that "self-management support can be a valuable aid to improve Ig therapy adherence" [10].

In summary, patient satisfaction with SCIg is high, and the ability to administer treatment at home is clearly valued. Adherence is also strong but could be further bolstered through innovative supports. These positive outcomes are encouraging, but they also carry implications: as more therapies move to the subcutaneous at-home model, healthcare systems must ensure patients are empowered and equipped to maintain these high satisfaction and adherence levels outside of traditional clinical settings. The next section explores how such trends are manifesting beyond immunoglobulin – in the broader landscape of subcutaneous drug delivery.

The Broader Landscape of Subcutaneous Drug Delivery

SCIg's success is part of a larger shift in how medications are delivered. Across the industry, we are witnessing "the rise of subcutaneous administration" for a variety of biologic drugs that were once given exclusively by IV. This trend is driven by the same factors benefiting SCIg: patient convenience, reduced healthcare utilization, and improved access to therapy. Several key developments characterize the U.S. landscape of subcutaneous drug delivery:

- **IV-to-SC Transitions**
  Pharmaceutical companies have invested heavily in reformulating injectable therapies to be given subcutaneously. Notably, in oncology and immunology, a number of monoclonal antibodies that used to require hour-long IV infusions now have SC injection formulations. Examples include trastuzumab and rituximab (cancer therapeutics that now come in SC forms combined with hyaluronidase to aid absorption) and daratumumab for multiple myeloma, among others [2]. A recent analysis identified 182 large-volume subcutaneous (LVSC) biopharmaceuticals either approved or in development – roughly 15% of all biologics in those pipelines [12]. These range from oncology drugs to treatments for chronic autoimmune and cardiovascular diseases [12]. The push for SC options reflects a broad recognition: subcutaneous delivery can reduce treatment burden and potentially improve patient uptake of therapy [13]. Patients with rheumatoid arthritis, for instance, have largely transitioned from IV infusions (like infliximab) to at-home SC injections of biologics (like etanercept or adalimumab) because it allows them to administer treatment on their own schedule and avoid frequent clinic visits. Likewise, many patients with multiple sclerosis, migraines, osteoporosis, myasthenia gravis and other chronic conditions now self-inject SC medications using autoinjector pens. This proliferation of SC therapies has normalized the concept of home self-injection well beyond the world of immunoglobulins.

- **Advances in Delivery Devices**
  A limiting factor for subcutaneous delivery has been the volume that can be administered comfortably. Traditional autoinjectors handle ~1–2 mL, but many biologics require larger doses. To overcome this, new device technologies have emerged. Handheld autoinjectors are now being designed for doses up to 5–10 mL, using innovations like stronger springs and slower injection rates to accommodate higher volumes [12].
  For volumes beyond ~10 mL, on-body injectors (OBIs), small wearable pumps, and near body infusion pumps come into play [12]. These devices adhere to the body (often on the abdomen or arm) and can infuse a medication subcutaneously over a longer period (minutes to hours) without a patient holding a syringe. They have already been used for drugs like pegfilgrastim (Neulasta® OnPro, an on-body injector that delivers a dose 27 hours after chemotherapy, enabling patients to avoid a return clinic visit) and for high-dose oncology combos (e.g. pertuzumab/trastuzumab in one device). Tethered SC infusion pumps – essentially the same concept as an insulin pump or the pumps used for SCIg – are another solution for very large volumes (>20–30 mL) [12]. In fact, the long experience with insulin pumps in diabetes care (used by hundreds of thousands of patients for continuous SC insulin infusion) has paved the way for acceptance of wearable SC devices in other diseases.
  As noted by Schneider and Lange, pumps are "already established in the market for therapies such as SC immunoglobulins, which often require high-volume administration" [12]. Together, these advances mean that more therapies than ever can be delivered via the subcutaneous route, even if they require large doses, by using the appropriate device (from simple syringes to sophisticated wearables). This device innovation is a crucial enabler of moving treatments out of IV infusion centers and into patients' homes.

- **Home and Outpatient Administration**
  Alongside drug and device innovation, there is a strong healthcare trend toward decentralizing care – providing treatments in lower-acuity settings when safe. Home infusion of various medications (antibiotics, chemotherapy, parenteral nutrition, etc.) is the fastest-growing segment of the U.S. health industry [4].
  In the specific context of immunoglobulin, Medicare launched a demonstration project (now a permanent benefit as of 2022) to cover home IVIG services, acknowledging that home administration improves access and adherence for many patients [5, 7].
  For other biologics, many infusion centers now offer "home infusion by referral," where a visiting nurse can come to the patient's home to administer therapies that the patient cannot self-inject (for example, IV infusions or complex SC injections). Emerging models even include hospital-at-home programs where certain cancer treatments are given at home under monitoring.
  The COVID-19 pandemic accelerated these trends by necessity – for instance, some immunodeficient patients who could not visit hospitals were rapidly trained to switch from IVIG to SCIg at home in 2020, demonstrating that with focused effort, transitions to home-based care can be accomplished safely even under duress [14, 15].
  That experience has left a lasting impression: both patients and providers have seen that home-based delivery is not only possible, but often preferable when supported appropriately. Many outpatient clinics are now actively trying to "shift to SC when possible", especially for maintenance therapies, to reduce patient exposure to healthcare facilities and to allocate clinic resources more efficiently. For example, oncology practices are evaluating which portions of a chemotherapy regimen could be given subcutaneously at home (using OBIs or pumps) versus what must be done in clinic [12].
  There are still barriers – for instance, in oncology, patients often receive combination IV drugs, so the marginal benefit of doing one drug SC at home is limited if they must come in for others [12]. However, in diseases where only a biologic injection is needed (e.g. monthly immunotherapy for autoimmune disease), at-home SC delivery can virtually eliminate clinic visits.
  The implication is a significant shift in workload from hospital infusion suites to patients and caregivers, which, again, highlights the need for supportive tools and training to maintain safety and efficacy.

- **Patient Experience and Unmet Needs**
  With this broad adoption of subcutaneous self-administration, patterns have emerged regarding patient experience. Many issues echo what we see in SCIg therapy. For instance, injection technique and anxiety are common concerns across the board. Patients starting an injectable biologic often worry about pain or whether they can self-inject correctly, leading companies to develop auto-injectors that conceal needles and simplify steps. Training materials and nurse support are typically provided when initiating therapies like interferons, TNF inhibitors, or others – yet adherence in some of these conditions remains suboptimal, partly due to patients "dropping off" when they feel better or if they struggle with injection discomfort. Usability studies have shown that simpler is better: prefilled syringes or pens improve satisfaction compared to multi-step vial preparations [16]. For example, when a 20% SCIg product was introduced in a ready-to-use prefilled syringe, patients reported higher satisfaction and convenience compared to using vials that needed manual drawing and pooling [16]. Similarly, insulin delivery has evolved from syringes to pen injectors to fully automated pumps with sensors, all aimed at reducing user burden and error. Despite these advances, gaps remain. Some therapies still rely on clunky delivery methods or frequent dosing that frustrates patients. The pain points identified in SCIg (supply management, device complexity, etc.) generalize to other home therapies too – for instance, patients on home IV antibiotics also juggle deliveries and pump setups, and those on insulin face challenges with cartridge changes and device alarms. Human factors engineering is increasingly a focus in drug delivery design to ensure that as more care moves home, the average patient (not just highly skilled ones) can manage safely. The U.S. FDA has put out guidance on patient-centered design for combination products, reflecting this priority. There is a clear opportunity for innovation in supporting patients through smartphone apps that remind and educate (as previously highlighted with the SCIg FlexiG® app success). Such technologies are still in early stages for most therapies, but their promise is significant – they tackle exactly the adherence and training challenges described above, without adding much burden on clinicians. In essence, the broader subcutaneous delivery movement is pushing medicine toward a more patient-empowered model, but to truly capitalize on this, healthcare systems must address the accompanying pain points with equal vigor.

Implications and Future Directions

The evolution of SCIg therapy and subcutaneous drug delivery at large carries important implications. Patients, caregivers, providers, and healthcare organizations are all adapting to a paradigm where "the hospital comes to the patient" instead of the patient going to the hospital. The pain points and challenges outlined in this paper are not roadblocks, but instead highlight the opportunities for future solutions. High adherence and satisfaction rates among current SCIg patients demonstrate that at-home therapy can be successful – yet they were achieved in spite of various frictions in the process (manual tasks, supply issues, etc.). Eliminating those frictions is the next step. This includes:

User-Centered Device Design

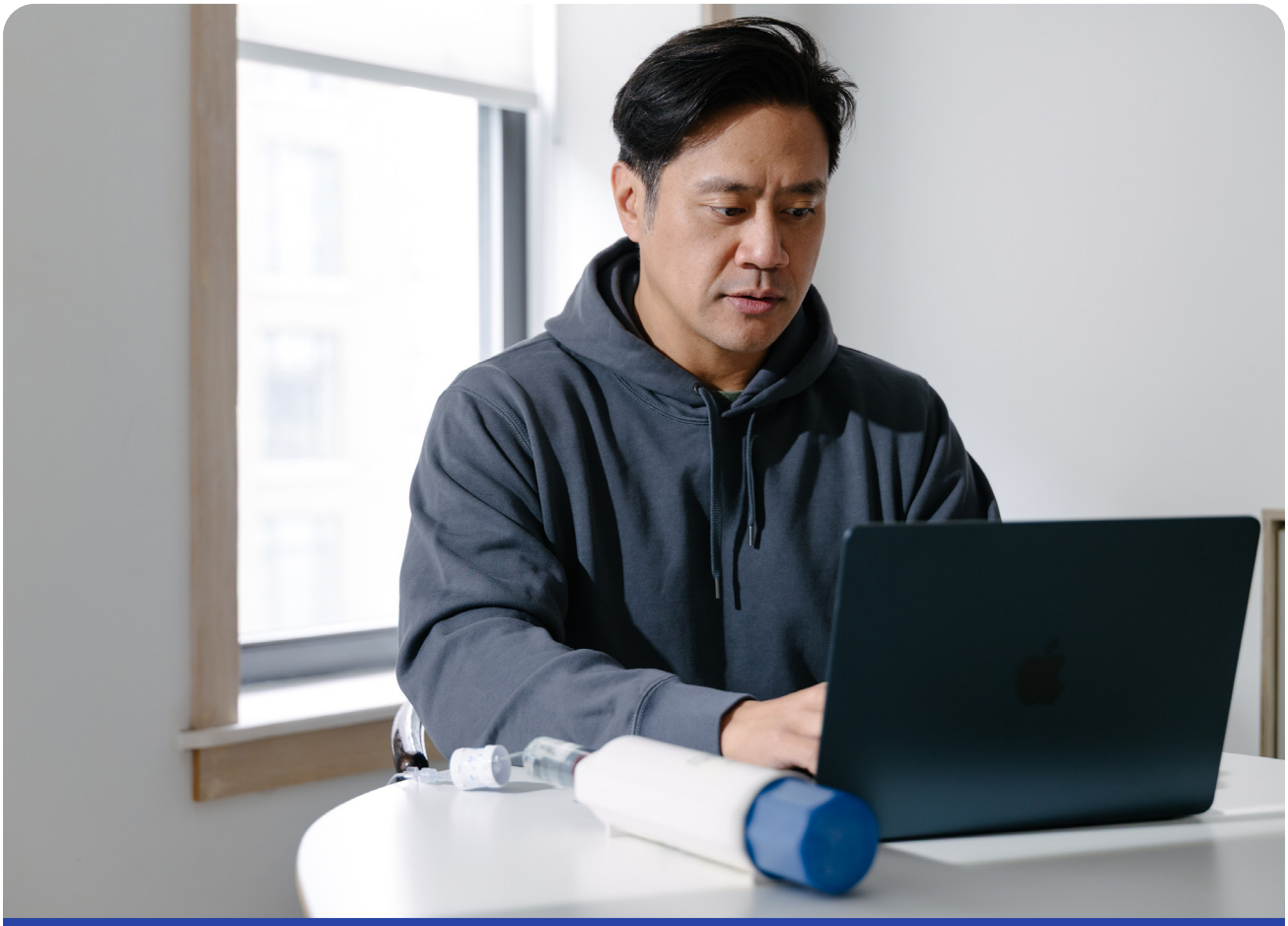
There is an unmet need for simpler, more intuitive delivery devices for large-volume SC therapies. The ideal device would minimize setup steps (for example, prefilled, pre-assembled infusion kits), reduce discomfort (e.g. optimized needles), and possibly integrate automation (assisted insertion via an inserter) to reduce user error. As one publication put it, "seemingly small design decisions have the potential to substantially impact patient experiences" [2]. Companies that focus on meeting user needs (e.g. by addressing the pain points consistently reported) will likely find receptive markets in the home therapy space.

Enhanced Training and Support

The shift to home places a premium on patient education and self-management. Ensuring every patient (or caregiver) feels fully competent is an achievable goal with standardized training protocols. Already, provider organizations are emphasizing thorough initial training and ongoing follow-up – engagement is a predictor of better SCIg satisfaction in studies [1].

Policy and Access Considerations

As subcutaneous home therapies expand, payers and policy-makers must keep pace to ensure access. The example of Medicare's IVIG home infusion benefit (finally made permanent in 2022) highlights that reimbursement structures need to align with new care models [7]. Similar efforts may be needed for other treatments. Ensuring equitable access is also crucial: patients in rural or underserved areas stand to gain greatly from at-home therapies (avoiding long travel to specialty centers), but only if they have the resources (reliable shipping of meds, internet access for support, etc.) and training. Health systems will need to identify and support patients who may struggle in a home setting and provide extra assistance or alternatives as needed so that no one is left behind by the at-home care revolution.



Conclusion

In conclusion, the U.S. experience with subcutaneous immunoglobulin infusion exemplifies both the successes and the challenges of transitioning complex care to the home. Patients, caregivers, and clinicians have navigated the learning curve and, in large part, achieved excellent outcomes – high satisfaction, good adherence, and maintained health – which speak to the viability of home-based therapy [5, 6].

At the same time, they have illuminated concrete challenges and barriers: from supply chain inconveniences to device usability issues to the need for robust training and support. The broader adoption of subcutaneous drug delivery in other fields magnifies the importance of addressing these issues. Each challenge is an opportunity for innovation: better devices and service models can significantly improve the user experience.

Moving forward, a patient-centered, innovation-forward approach will be key to unlocking the full potential of subcutaneous therapies. The goal is that patients should spend less time worrying about the mechanics of drug delivery and more time living their lives. The trends are clear: care is moving closer to the patient, and patients are ready for it – as long as we continue to support them with empathetic design and education. Subcutaneous immunoglobulin has shown what is possible: a therapy once confined to hospitals can be successfully managed at home, yielding equal outcomes and often improved quality of life [1, 6].

By learning from this experience and addressing the remaining gaps, we can extend these benefits to many more therapies and individuals, ultimately advancing a healthcare system that is more convenient, personalized, and empowering for patients.

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