ENHANCING THE PATIENT AND NURSE EXPERIENCE IN LARGE-VOLUME SUBCUTANEOUS DRUG DELIVERY

In this article, Omar Rahman, PharmD, Medical Director, Medical Affairs at Enable Injections, Beth Faiman, PhD, Nurse Practitioner, Department of Hematology and Medical Oncology at Cleveland Clinic Taussig Cancer Institute, and Lisa Gorski, Clinical Education Specialist/Clinical Nurse Specialist at Ascension at Home, highlight the importance of a comfortable experience for both patients and healthcare providers when it comes to large-volume subcutaneous drug delivery.

Biologic drugs, such as monoclonal antibodies (mAbs), are a class of medications that represent a rapidly expanding category of therapies, used to treat serious diseases, including cancer, metabolic disorders, cardiovascular conditions, genetic disorders and immunological diseases. These drugs were initially designed for intravenous (IV) administration due to their large, complex molecular structures, which are poorly absorbed when taken orally. However, because IV administration can sometimes be painful, less tolerated by patients and resource intensive, there has been significant growth in subcutaneous (SC) delivery options.

With the rising popularity of biologic drugs in the past decade, their administration has gradually shifted from IV to SC delivery. The SC delivery method has since been adopted in oncology as an alternative to traditional IV infusions. For example, Roche (Basel, Switzerland) launched SC formulations for rituximab, pertuzumab and trastuzumab, which were initially approved for IV administration. Clinical studies have demonstrated the long-term efficacy and safety of these SC formulations, confirming them as valid therapeutic alternatives.

The shift from IV to SC administration of biologic drugs has been facilitated by advances in high-concentration formulation development, devices for injecting large-volume doses (e.g. on-body delivery devices) and permeation enhancers. While not essential for large-volume SC delivery, permeation enhancers, such as hyaluronidase, have been at the forefront of this transition.

> "One of the major challenges with administering large-volume SC drugs combined with permeation enhancers is the administration experience for nurses."

MAJOR CHALLENGES

One of the major challenges with administering large-volume SC drugs combined with permeation enhancers (e.g. daratumumab/hyaluronidase, rituximab/hyaluronidase or pertuzumab/trastuzumab/hyaluronidase) is the administration experience for nurses. Currently, these drugs are given through a labour-intensive manual injection process using a needle and syringe. This method requires the nurse

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to exert pressure, sometimes taking several minutes to complete. During this time, the nurse must conduct and closely monitor the procedure to ensure that the medication is delivered safely and accurately. Despite the considerable time and effort required to administer these drugs, the preferences and challenges faced by nurses are often overlooked and underappreciated.

While the syringe format enables faster drug administration compared with IV infusions, it comes with several drawbacks. These include repetitive strain and needlestick injuries for nurses, who must apply consistent pressure for extended periods when administering large-volume formulations to multiple patients each day, as well as an increase in patient discomfort due to the use of larger gauge needles. Such injuries often require extended recovery periods, especially for older nurses. Additionally, repetitive strain may hinder the ability of nurses to provide continuous infusions, potentially resulting in drug misuse and escalating both direct and indirect costs.[1]

A recent meta-analysis involving 42 studies and over 36,000 nurses found that the annual prevalence of work-related repetitive strain injuries among nurses is 77.2%. The most common areas affected are the lower back (59.5%), neck (53.0%) and shoulders (46.8%).[2] These injuries might significantly impact their mental health and overall quality of life, as well as contribute to chronic conditions. They could also lead to substantial treatment costs, work restrictions, absenteeism and high turnover rates among nurses, ultimately affecting patient safety and care quality.[3–5] Nurses experiencing chronic repetitive strain injuries might require long-term medication and frequent use of pain relievers – and seek various medical consultations and alternative treatments. The financial burden of these injuries is considerable, with costs for diagnostic tests, healthcare and worker compensation estimated at between US$50,000 (£39,000) and $100,000 per nurse.[5,6]

> "While larger gauge needles can improve delivery speed, they also compromise the patient experience."

The impact of administering large-volume SC drugs co-formulated with permeation enhancer via syringes extends beyond the difficulties encountered by nurses. Although often overlooked, these drugs generally require larger gauge needles to enhance flow rates and manage the higher viscosity of the co-formulations. It is important to note that, while larger gauge needles can improve delivery speed, they also compromise the patient experience because larger gauge needles have larger diameters and are sometimes associated with increased pain and bleeding.[7–9] Larger gauge needles can also be more intimidating, potentially increasing patient anxiety, which may require nurses to spend more time counselling patients and can result in missed or delayed injection appointments.[10–12]

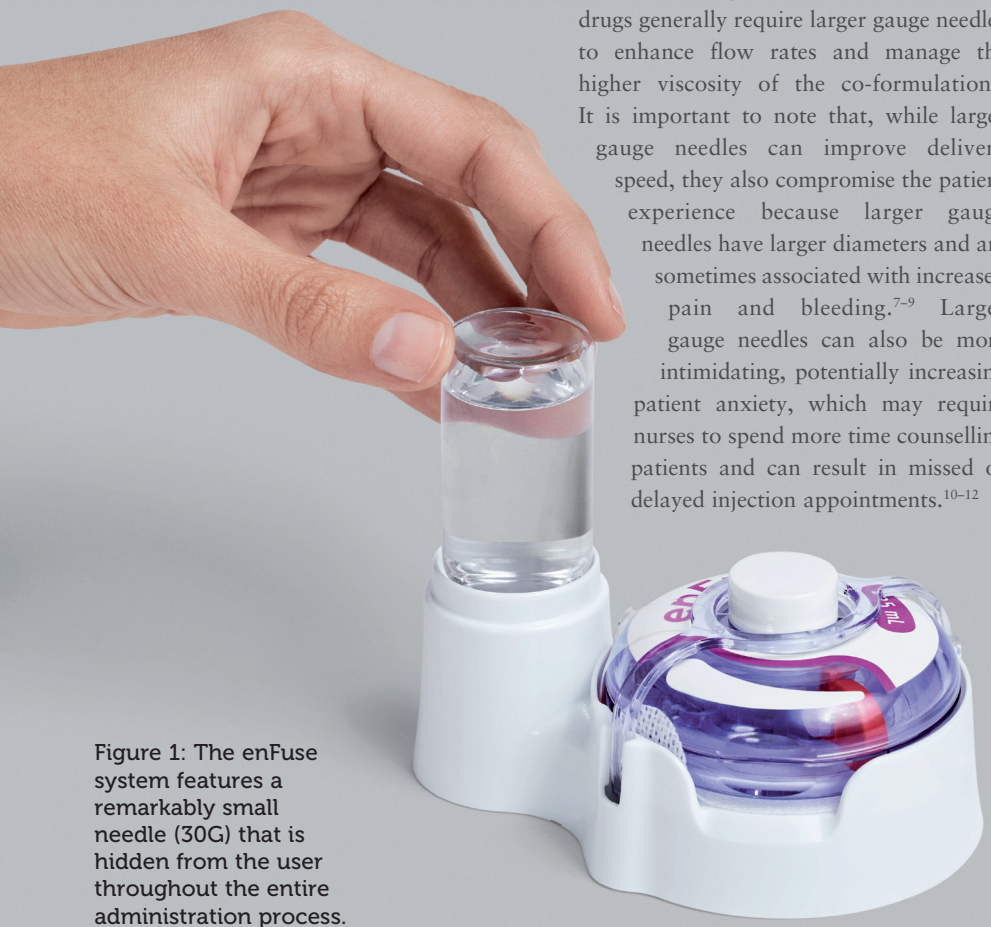

Figure 1: The enFuse system features a remarkably small needle (30G) that is hidden from the user throughout the entire administration process.

In some healthcare centres, there have been attempts to alleviate the manual administration process by using syringe pumps. However, this approach comes with its own set of challenges: it significantly increases costs, adds complexity to infusion suite arrangement, requires a time-consuming set-up and often results in crowding and logistical difficulties, further underscoring the need for more efficient and cost-effective alternatives.[1]

ON-BODY DELIVERY SYSTEM ADVANTAGES

Unlike the syringe format and the syringe pumps currently used for administering large-volume SC formulations, on-body delivery systems (OBDSs) offer several advantages. OBDSs use thinner needles, do not require co-formulation with permeation enhancers, feature a concealed needle mechanism and, most importantly, deliver the drug via the push of a button. These features address many challenges associated with large-volume SC delivery via manual syringes and syringe pumps. The hidden needle design may help alleviate patient needle phobia, while the smaller needles can enhance adherence and minimise pain.[12] Given the hands-free delivery feature of OBDSs, they have the potential to reduce the physical strain on nurses, thereby decreasing the risk of repetitive strain injuries. By using an OBDS, nurses would not have to spend several minutes directly administering a drug, allowing them to tend to other patients or responsibilities – potentially improving clinical efficiency by increasing throughput.

In a recent double-blinded online survey conducted by a third-party vendor, nurses with experience administering large-volume SC drugs co-formulated with permeation enhancers using SC syringes were asked about their experiences and preferences compared with the enFuse (Figure 1) – an OBDS featuring the first-ever hands-free wearable technology designed to deliver large volumes (5–25 mL) of drugs subcutaneously.[13]

In a detailed scenario that assessed factors beyond just delivery time – including administration method, nurse effort, needle

size, time, patient mobility, preparation and additional direct costs – while assuming the same efficacy, safety and cost, 44 out of 45 nurses (97.78%) preferred the enFuse over the syringe typically used for administering daratumumab/hyaluronidase. The main reasons for this preference were:

1. Reduced nurse effort due to hands-free delivery
2. Less patient pain from a smaller needle
3. Elimination of needlestick injuries with a hidden needle mechanism
4. Improved clinic efficiency from hands-free operation.[13]

Regarding their views on the current needles used for large-volume SC drugs administered via syringes, a total of 94.44% (17/18) of haematology and oncology nurses and 90.91% (20/22) of nurses with experience administering daratumumab/hyaluronidase believed that smaller gauge needles would reduce needle phobia for oncology patients. Additionally, 93.33% of the nurses in the full sample believed that a hidden needle mechanism would eliminate the risk of needlestick injuries.[13]

When comparing preferences between traditional syringe pumps and the enFuse, an overwhelming 97.78% of nurses in the full sample expressed a clear preference for enFuse for preparation and administration of 5–25 mL of drug product. This finding is particularly noteworthy because, although some centres are investing in syringe pumps to alleviate the physical strain on nurses administering daratumumab/hyaluronidase, the results indicate that nurses would favour an OBDS over a syringe pump.[13]

PRIORITISING OVERALL EXPERIENCE

These results and clinical practice trends reveal that speed of delivery is not the foremost consideration for nurses when it comes to large-volume SC administration. Instead, factors such as effort, preparation, patient mobility, needle size and risk of needlestick injuries play a more significant role in their preferences. While the traditional focus on rapid delivery of large-volume SC drugs has often led to compromises in patient comfort and increased physical strain on nurses, the preference for hands-free OBDSs suggests that a shift towards prioritising overall experience is warranted. Hands-free administration with OBDSs not only reduces the burden on healthcare providers but also enhances their ability to engage in other clinical activities, potentially offering greater economic value despite a longer injection time.

> "It is essential to re-evaluate the impact of current large-volume SC administration practices to ensure a more patient- and provider-friendly approach."

The focus on speed has led to a reliance on larger gauge needles and uncomfortable SC administration practices, inadvertently compromising the overall patient and healthcare provider experience. The overemphasis on quick administration, without considering the discomfort it brings, highlights the necessity for a paradigm shift towards prioritising patient and healthcare provider experience in large-volume SC drug delivery. Looking ahead to the future of SC drug development, it is essential to re-evaluate the impact of current large-volume SC administration practices to ensure a more patient- and provider-friendly approach.

ABOUT THE COMPANY

Enable Injections is a global healthcare innovation company developing and manufacturing drug delivery systems designed to improve the patient experience. Enable's body-worn enFuse delivers high-volume pharmaceutical and biologic therapeutics via SC administration, with the aim of improving convenience, supporting superior outcomes and advancing healthcare system economics.

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ABOUT THE AUTHORS

Omar Rahman, PharmD serves as Medical Director of Medical Affairs at Enable Injections. His experience in the biopharmaceutical industry spans multiple functional areas, including externally sponsored research, expanded access and field medical. Dr Rahman's tenure at argenx and Alexion provided him with specialised training in rare diseases, with a specific focus on neurology and haematology. He earned his Doctorate of Pharmacy from St. John's University (NY, US) followed by a Masters of Public Health from the University of Pittsburgh (PA, US).

Beth Faiman, PhD, is an adult nurse practitioner in the Department of Hematology/Oncology at the Cleveland Clinic Taussig Cancer Institute and a member of the Case Comprehensive Cancer Center under the Cancer Prevention, Control and Population Research Program. She is the editor of several books and author of numerous chapters and papers, including editor of the 3rd Edition of the Multiple Myeloma Textbook for Nurses (2021) and both editions of the Blood and Marrow Certification Manual for Nurses (2017, 2023). Dr Faiman has also served on the American Board of Internal Medicine and American Society of Hematology, further solidifying her influence in the field.

Lisa Gorski has worked for more than 40 years as a clinical nurse specialist and educator. She is the author of several books and more than 70 book chapters and journal articles. Ms Gorski is a past president of the Infusion Nursing Society (INS) and served as the chair of the INS Standards of Practice Committee from 2011 to 2024. She was inducted as a fellow into the American Academy of Nursing in 2006 and speaks nationally and internationally on standards development, infusion therapy/vascular access and home healthcare.

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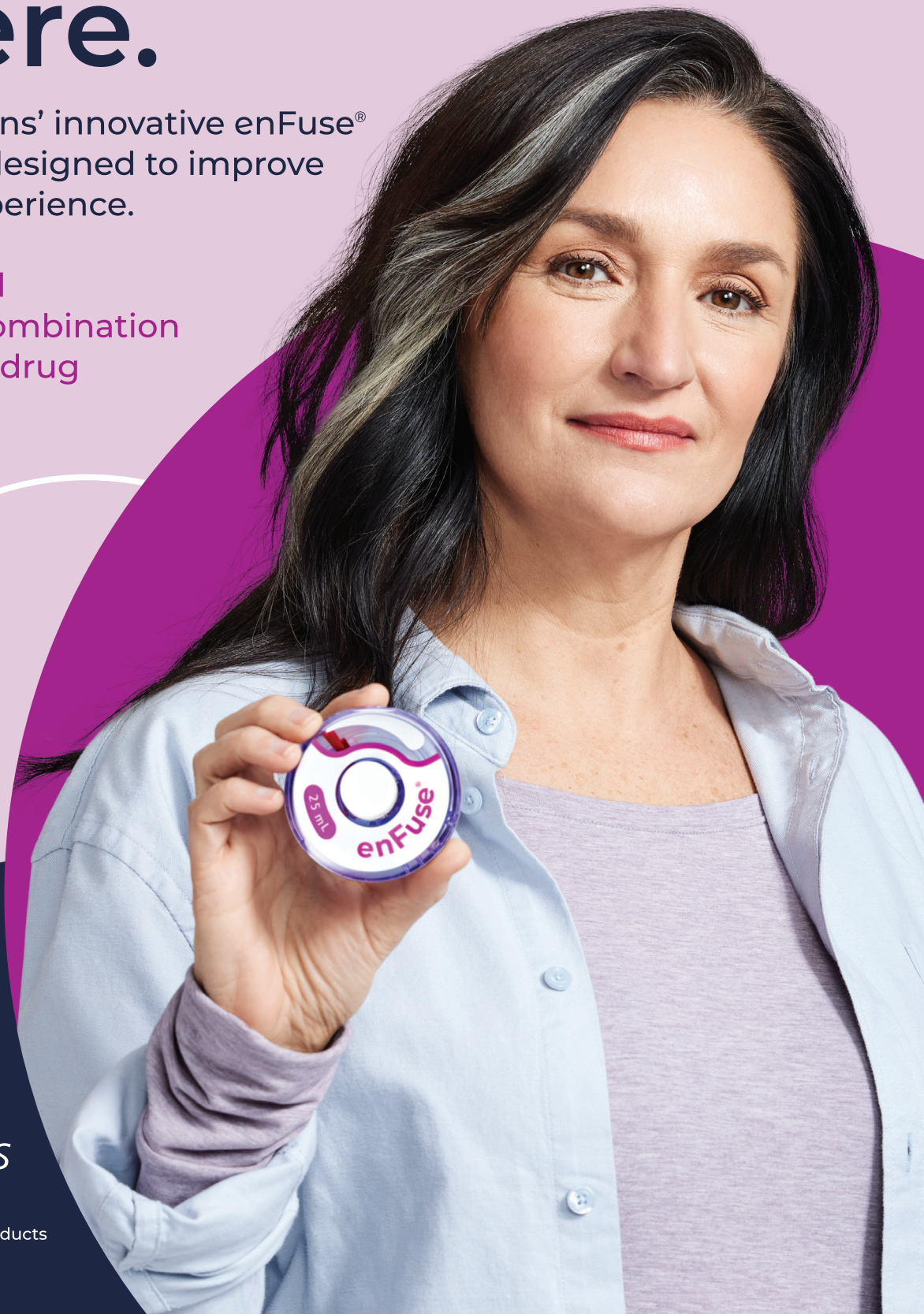

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