

Title:

The importance of subcutaneous formulations from a cancer patient's perspective

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

Key objective is to identify and address the barriers in adopting subcutaneous oncology therapies. SC therapy have the benefit of reduced in-hospital time, but they have lower bioavailability, high absorption variability, local injection site reactions - also a common problem with patient discomfort. Also, another barrier to implement it is, the use of concurrent IV regimens along with SC drugs, thereby effectively neutralising the advantages of SC formulation - because patient still needs to spend time in hospital, needs IV access.

Hospital administration may view it as less profitable, due to higher costs of therapy and reduced in-hospital time leading to lesser bed revenues, which may make it lesser attractive for private hospitals. Rare psychological factor exists, in which there is less face time with oncology team, potentially diminishing the emotional support patient receive during treatment. Also, the methodology of manual pressure and syringe visibility can exacerbate patient anxiety and needle phobia.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

- To address the challenges in SC formulation, already recombinant Hyaluronidase is used and protein engineering done - to reduce pain, avoid local site reactions and to deliver better efficacy.
- To eliminate the burden of IV access, chemoport can be used or wherever possible, oral chemo drugs can be given.
- To bridge the emotional support, home nurses can be appointed, who can give psychological support and provide maintenance therapies effectively.
- To help the hospitals economically, they can be helped by approving full amount of insurance claimed and incentivising for setup of fast-track SC clinics.
- These steps can help in improving patient convenience and safeguard the well-being of the patient.

Full Name:

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

To develop a patient centered subcutaneous oncology treatment framework that minimizes hospital dependency, reduces treatment related physical and psychological burden, improves patient convenience and adherence, addresses lack of care givers and optimizes healthcare resource utilization without compromising clinical efficacy or safety.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Problem statement: A 48-year-old woman Daily wage worker with Breast Cancer receiving adjuvant intravenous Trastuzumab and pertuzumab at a government cancer center spends nearly an entire day in hospital for registration, cannulation, infusion, observation, pharmacy delay, and travel, need for care giver /attender bedside. She loses daily wages, experiences repeated venous access pain, anxiety related to IV procedures, and treatment fatigue despite responding well clinically. Similar challenges are faced by elderly patients, rural populations, working individuals, and overcrowded oncology centers.

Although effective therapies exist, conventional intravenous administration increases patient burden, infusion bed occupancy, nursing workload, hospital congestion, and indirect financial toxicity. Many patients perceive cancer treatment as physically and emotionally exhausting because therapy delivery itself becomes a prolonged hospital centered experience.

Solution:-

“SMART-SC Oncology Program-Safe, Minimal-Hospital, Accessible, Rapid Therapy through Subcutaneous Care.

Step-wise Implementation

CANCER PATIENT REQUIRING TARGETED THERAPY

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Evaluate Eligibility for SC Formulation

- HER2-positive cancer (SC Trastuzumab/Pertuzumab)
- Hematologic malignancy (SC Rituximab/Daratumumab)
- Other approved SC therapies

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Clinical Suitability Assessment

- Stable patient
- No severe prior infusion reaction
- Appropriate indication

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Enrollment into SMART-SC Clinic

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Dedicated Fast-Track SC Administration Unit

- Appointment-based visits
- Nurse-led injection delivery
- Minimal waiting time
- Short post-treatment observation

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Patient-Centered Benefits

- Reduced hospital stay and waiting time
- Avoids repeated IV cannulation and venous access pain
- Greater comfort and convenience
- Reduced psychological stress associated with infusion therapy
- Improved treatment adherence and patient satisfaction
- Faster return to normal daily activities and work
- Reduced caregiver burden and travel expenses

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Clinical Advantages

- Comparable efficacy and safety to intravenous formulations in approved settings
- Lower infusion-related chair/bed occupancy
- Shorter administration time
- Simplified treatment delivery
- Useful in elderly and poor venous access patients



Healthcare System Benefits

- Reduced overcrowding in oncology daycare units
- Better utilization of infusion chairs for chemotherapy patients
- Reduced nursing workload and infusion monitoring time
- Increased patient throughput in busy cancer centers
- Cost savings related to infrastructure and resource utilization



Challenges

- Higher upfront cost
- Limited awareness
- Rural access barriers
- Staff training needs



Practical Solutions

- Biosimilar adoption
- National nurse training
- Satellite SC clinics
- Tele-follow-up systems
- Standard safety protocols



Humanized Oncology Care in Both High- and Low-Resource Settings



HUMANIZED, EFFICIENT, AND ACCESSIBLE CANCER CARE

Esteemed pharmaceuticals like Roche can support the SMART-SC model in government oncology settings by improving access to approved subcutaneous formulations, supporting biosimilar affordability programs, and helping establish nurse led fast-track injection clinics. They can contribute through training of healthcare staff, development of standardized administration protocols, digital appointment systems, patient education materials, and pharmacovigilance support. Pharma backed public private partnerships can also help create satellite subcutaneous therapy centres in high-volume hospitals, reducing infusion burden and improving patient convenience. There will be added advantages which includes improved treatment adherence, increased patient reach, better real-world utilization of therapies, stronger physician confidence, optimized healthcare integration, and generation of real-world outcome data. Faster and more convenient treatment delivery can also improve long term continuation of therapy, patient satisfaction, and overall uptake of approved oncology products in an ethical and sustainable manner.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

One of most enduring myths and misconception in community is that cancer therapy is painful and utmost reason of patients refusing definitive treatment. Many times we do encounter patients who tell us, Doctor please write some me some tablet I don't want any intravenous medication and most of times we are helpless. Here lies the importance of novel modalities and newer innovative and formulations which make drug administration patient friendly and ensure compliance which is utmost requirement of cancer care.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Subcutaneous formulations have brought a major positive change in cancer care. This method of drug administration provides advantages to multiple groups including pharmacists, oncologists, patients, and healthcare economists.

From an oncologist's perspective, subcutaneous formulations are almost revolutionary because they allow flexible appointment scheduling, easier patient triaging, and smooth switching from intravenous therapy while maintaining similar efficacy and minimal adverse reactions. This has simplified patient management significantly.

From a patient's perspective, subcutaneous administration reduces fear related to intravenous medications, saves time, and improves overall quality of life. Patients experience less anxiety, shorter hospital visits, and a more comfortable treatment experience.

From a pharmacist's perspective, subcutaneous formulations reduce compounding costs, decrease medication wastage, and simplify drug preparation procedures. From the viewpoint of healthcare economists, these formulations are both patient-friendly and healthcare-system friendly, while also being cost-saving. The list of advantages continues to grow. Therefore, there is a strong need for more such formulations that make drug administration easier and more convenient.

In resource-limited countries, the shortage of healthcare manpower is severe and directly affects the quality of cancer care. In many Regional Cancer Centers and medical oncology day-care units, patients frequently present with recent or previous extravasation injuries. At the same time, access to central venous catheters, PICC lines, and chemo ports is often limited in resource-constrained settings. In such situations, subcutaneous administration becomes highly advantageous.

Time-saving and easy administration techniques with minimal pain are a major benefit in oncology care. Their impact on quality of life is very significant. Today, oncology practice includes subcutaneous formulations of immunotherapy agents, antibody-drug conjugates, bispecific antibodies, and even some chemotherapy drugs. These formulations have significantly reduced the risk of infusion reactions and promoted a more patient-friendly treatment approach, with many patients willingly preferring subcutaneous therapy over intravenous treatment.

We must also understand that some patients strongly believe in the placebo effect of intravenous medications and may feel that intravenous therapy is more powerful or effective. Therefore, oncologists must remain respectful of patient preferences while providing proper counselling regarding the possibility of switching to subcutaneous therapy. Patients should be reassured regarding similar efficacy before making a treatment switch.

At times, patients completely rely on the oncologist's recommendation, which highlights the importance of strong clinical evidence, trial data, and proper counselling to support shared decision-making.

Another important advantage of subcutaneous administration is the ease of delivery in community healthcare settings where shortages of trained professionals and healthcare manpower are greatest. Subcutaneous administration can help bring cancer care closer to patients' homes, thereby improving quality of life in multiple aspects.

It is also important to ensure that these subcutaneous formulations remain cost-effective and financially comparable to available intravenous preparations so that treatment preferences are not influenced by financial toxicity. However, there should be a very low threshold for referring patients who develop adverse reactions to bispecific antibodies or other complex molecules to appropriate higher centers whenever required.

In certain healthcare delivery models, financial and logistical systems may favor intravenous therapies because they require infusion infrastructure and longer patient stays. As oncologists, we must remain careful and unbiased in our decision-making. The primary focus should always remain the quality of life and overall well-being of our patients.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

To evaluate the importance of subcutaneous formulations from a cancer patient's perspective by explaining how they transform cancer therapy administration, improve comfort, convenience, adherence, and quality of life, while being supported by clinical evidence. The objective is also to identify key challenges such as safety concerns, injection-site reactions, cost, logistics, clinician acceptance, rural access, and severe obesity, and to propose practical mechanisms to improve the uptake of these formulations in oncology care.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Subcutaneous Oncology: Pathway Returning Time to Cancer Patients

Cancer treatment should not only extend survival. It should also protect dignity, comfort, and daily life. From a cancer patient perspective, subcutaneous formulations are important because selected cancer medicines can be given as short injections instead of long intravenous infusions, while maintaining comparable efficacy, safety, and therapeutic drug exposure.

Clinical evidence supports this shift. Studies such as HannaH, FeDeriCa, PHranceSCa, COLUMBA, IMscin001, and CheckMate 67T support subcutaneous formulations of therapies such as trastuzumab, pertuzumab, rituximab, daratumumab, atezolizumab, and nivolumab. These studies show comparable pharmacokinetics, clinical outcomes, and safety when compared with intravenous therapy.

For patients, the benefits are direct and meaningful. Subcutaneous formulations reduce painful venous cannulations, hospital waiting time, infusion chair anxiety, travel burden, and caregiver dependence. They can improve adherence, satisfaction, and continuity of care, while giving patients more time for family, work, recovery, and normal life.

My proposed pathway includes five steps.

1. Use only approved, evidence-backed subcutaneous cancer therapies.
2. Screen patients for indication, allergy history, comorbidities, body habitus, injection-site suitability, and monitoring needs.
3. Train oncology nurses in technique, counselling, adverse-event recognition, and documentation.
4. Create fast-track injection clinics to reduce infusion-unit overcrowding.
5. Collect patient-reported outcomes: pain, anxiety, satisfaction, time saved, and preference.

Challenges include clinician hesitation, injection site reactions, cost, reimbursement barriers, cold chain logistics, rural access, and severe obesity. These can be addressed through clinical guidelines, nurse training, monitoring systems, total value assessment, better storage systems, hub and spoke cancer care models, and individualized assessment. In severe obesity, appropriate needle selection, suitable injection sites, observation, and pharmacovigilance are essential, with intravenous therapy retained when absorption or safety is uncertain.

Subcutaneous formulations are not merely faster injections. They are an evidence-based redesign of cancer care that returns time, control, and dignity to patients.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

What are mechanisms to address the challenges faced in transitioning into subcutaneous formulations and how to enhance the usage of these formulations in oncology?

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

"Chair-time saved" by using the subcutaneous formulations is a relevant to the hospital and administration in terms of bed turnover, however the real focus should on reiterating the "life-hours re-gained for the patients and their caregivers. For a normal working-class individual, treatment duration is accounted as lost workdays, lost wages, and lost family time.

Subcutaneous therapies should focus on taking over complete maintenance phase initially. During chemoimmunotherapy, chemo dictates chair time and SC offers marginal gain. PHESGO's adjuvant year, atezolizumab maintenance in ES-SCLC/NSCLC, nivolumab post-ipilimumab in RCC etc these are the main areas where SC formulations can work currently in India. Many trials have already established non inferior outcomes with subcutaneous formulations. The attractive in and out of hospital time less than 30mins, can enable a working person to get his treatment during his break period and resume back to work.

The challenges and possible solutions

1. Cost parity- If IV plus admission costs are lesser than SC without admission, patients choose IV. Pricing should ensure total out-of-pocket is marginally lower or atleast same. Patients in Indian scenarios will prefer cost over convenience.

2. Insurance issues-. Indian insurance often mandates admission for coverage; and most subcutaneous formulations are not even covered without chemotherapy component. At times, paperwork consumes the time the subcutaneous administration saves -Manufacturers must engage insurers and regulators to enable outpatient coverage for this formulation, reiterating the fact these are essential components of cancer care.
4. Physician-led education showcasing SC as advanced delivery system, supported by PHESGO patient outcome data will mitigate patient hesitancy.
5. Anti-drug antibodies- Higher ADA rates with SC raise theoretical concerns like neutralization, altered pharmacokinetics, hypersensitivity, late-onset adverse events. However, no trials have shown a significant impact on efficacy. More awareness among oncologists regarding these topics can be initiated by manufactures with evidence-based data and this will in turn enable physicians to explain better
6. Extension of the same concept of antidrug antibodies- to explore if SC route antigen via skin dendritic cells produces non-neutralizing antibodies, and if this very feature can augment its response similar to the vaccine-like priming response-more studies can answer these questions.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

- Enable patient-centered, time-efficient cancer treatment through safe and effective subcutaneous (SC) drug delivery
- Reduce hospital dependency, travel burden, and caregiver strain by minimizing infusion time and visits
- Maintain clinical efficacy and safety equivalence with intravenous therapies for biologic agents
- Improve health system efficiency by freeing infusion chairs, reducing nursing workload, and decentralizing care
- Promote broader access to oncology care, including potential home-based treatment models for suitable patients.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.)

Imagine receiving cancer treatment in the time it takes to drink a cup of tea—not spending hours in a hospital chair. That is the promise of subcutaneous (SC) therapy. For many patients—especially the elderly, frail, working individuals, or those living far from cancer centers—this means fewer hospital visits, less disruption to daily life, and freedom from repeated painful venous access. Importantly, it also benefits caregivers, who no longer need frequent leave from work, repeated travel, or added financial burden. Treatment becomes part of life, not life on hold.

Clinical evidence supports this shift. SC formulations of drugs like Trastuzumab and Rituximab have shown efficacy and safety comparable to intravenous (IV) therapy, while being administered in minutes rather than hours. Fixed dosing reduces preparation complexity and errors, and studies consistently demonstrate strong patient preference.

Beyond individuals, healthcare systems benefit. SC therapy frees infusion chairs, reduces nursing workload, and improves day-care efficiency. Most importantly, it enables decentralised and even home-based oncology care—similar to how insulin transformed diabetes management.

However, challenges remain. Injection-site discomfort, needle anxiety, large drug volumes, and resistance to changing established IV practices can limit adoption. Initial doses may still require monitoring, and upfront costs may appear higher.

Solutions are evolving. Recombinant hyaluronidase allows larger-volume delivery, while auto-injectors and wearable devices simplify administration. Patient counselling, nurse training, and clear switching protocols build confidence. Insurance coverage is improving as overall system savings become evident.

SC formulations are transforming cancer care—shifting from hospital-centered infusion models to patient-centered, time-efficient, and potentially home-based delivery. They are likely to become standard for many biologics.

Ultimately, they do not just save time—they give patients and families back precious hours of life.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

To discuss the benefits and challenges associated with use of subcutaneous formulation of oncological drugs.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Subcutaneous (SC) formulations are now available for a wide range of oncology drugs including but not limited to trastuzumab, rituximab, pertuzumab and immunotherapy. For many cancer patients, treatment is not merely a medical journey but also an emotional and physical challenge marked by repeated hospital visits, needle fatigue, anxiety, and disruption of daily life along with significant financial toxicity stemming from logistic issues like hospital stay. SC administration addresses these concerns by enabling medicines to be within minutes rather than hours, avoiding intravenous needles or chemoports and prolonged hospital stays.

Clinical evidence has demonstrated that SC formulations of monoclonal antibodies such as trastuzumab and rituximab provide efficacy and safety comparable to IV therapy while dramatically reducing chair time, healthcare resource utilization, and patient and caregiver burden. Patients consistently report higher satisfaction because SC injections reduce waiting periods, minimize venous access complications, and allow greater flexibility in scheduling treatment. In some settings, SC therapies also support home-based administration, promoting independence and improving quality of life.

Despite these advantages, several challenges limit widespread adoption. High formulation complexity, injection-site reactions, volume limitations, cold-chain requirements, cost, availability and resistance to changes in clinical workflows remain significant barriers. Additionally, concerns regarding reimbursement policies, training of healthcare professionals, and patient awareness can slow implementation.

To overcome these hurdles, healthcare systems must invest in patient education, clinician training, and supportive reimbursement frameworks. Advances in drug-delivery technologies, including hyaluronidase-enabled large-volume injections and wearable on-body devices, are further improving tolerability and administration efficiency. Digital monitoring platforms and nurse-led community care can also enhance confidence in home administration. Indigenous production of these formulations and tiered pricing systems can increase availability and decrease cost. Ultimately, SC formulations represent more than a pharmaceutical innovation—they symbolize a transition toward compassionate and patient-driven oncology care.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

To make the evidence-based case for subcutaneous oncology formulations as a patient centered and system level efficiency intervention, and to identify the specific institutional and regulatory barriers preventing their adoption in India, with concrete solutions that address both the patient experience and the structural obstacles simultaneously.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Let me narrate like a story, She has been sitting in the chemotherapy chair for four hours. The IV daratumumab drip started at nine in the morning. It is now 1pm in the afternoon and she has another hour to go, minimum, if there are no reactions. Her husband has taken unpaid leave to bring her. Her veins are running out. She is feeling nauseous despite, pre-medications usage, she is scared about infusion reactions that, in clinical practice, rarely occur after the first two cycles but for which the same four-hour administration protocol continues cycle after cycle regardless. This patient has an alternative that most Indian oncology centres do not offer her. Subcutaneous daratumumab with recombinant hyaluronidase, studied in the COLUMBA trial, delivers the same plasma exposure and equivalent clinical outcomes in three to five minutes. The COLUMBA trial demonstrated non-inferior maximum trough concentrations, equivalent overall response rates in relapsed/refractory myeloma, and a substantially better injection site reaction profile than anticipated. The patient reported outcome (PRO) data from COLUMBA showed that patients strongly preferred SC administration for the time savings and reduction in healthcare visits. The evidence base for SC oncology formulations is now substantial across multiple drugs and tumour types. Subcutaneous trastuzumab was established as non-inferior to IV in the HannaH trial with equivalent pathological complete response rates and maintained pharmacokinetic targets. The fixed-dose SC pertuzumab-trastuzumab combination in FEDERICA confirmed the same. SC rituximab in the SABRINA trial showed equivalent response rates in follicular lymphoma and DLBCL. SC pembrolizumab, approved by the FDA in 2024, reduces administration from a thirty minute infusion to a two-to-three-minute injection delivered in any clinic room without infusion infrastructure. S/c Amivantamab in PALOMA 3 trial showed equal efficacy and reduced Infusion Related Reactions(IRR) when compared to I.V Amivantamab formulation.

The barriers to adoption in India are not primarily clinical. They are institutional inertia, absence of trained nurses comfortable with SC administration of biologics in community settings, cold chain logistics for SC formulations in satellite centres, and a cost structure where SC formulations are sometimes priced higher than IV generics or biosimilars. The solutions are correspondingly specific. Nursing training programmes for SC biologic administration should be standardised and accredited nationally through the Indian Nursing Council. SC formulations should be included in the Ayushman Bharat and other State based Government schemes formulary alongside or in preference to IV equivalents where the evidence of non-inferiority is established. Cold chain logistics support from manufacturers should be a contractual requirement of institutional procurement agreements for SC formulations.

The chair time released by SC adoption in a busy cancer centre is not a trivial benefit. A centre giving IV daratumumab to 50 myeloma patients monthly, each occupying a chair for four to six hours per cycle, is consuming 200 to 300 chair hours per month on a single drug that could be administered in 25 minutes total for the same 50 patients in SC form. That released capacity can treat additional patients without additional infrastructure investment. This is not a convenience argument instead, it is a capacity and access argument that makes our system much more better.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

To make cancer treatment more patient-friendly by reducing hospital time, procedural burden and treatment fatigue without compromising efficacy or safety.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Subcutaneous oncology formulations are changing cancer care from the patient's perspective. For many patients, the most exhausting part of treatment is not only toxicity—it is repeated hospital visits, venous access difficulty, long infusion hours, lost wages, caregiver dependence and emotional fatigue.

Subcutaneous therapy can significantly reduce this burden.

Clinical evidence in several cancers has shown that appropriately developed subcutaneous formulations can provide comparable efficacy and safety to intravenous administration while dramatically shortening administration time. This improves patient convenience, chair turnover, nursing efficiency and overall treatment experience. In busy Indian oncology centres, this can also reduce overcrowding and improve day-care workflow.

The benefits are especially meaningful for elderly patients, working individuals, women travelling long distances and patients requiring prolonged maintenance therapy. In Tamil Nadu, shorter hospital stays can reduce travel expense and treatment abandonment.

However, challenges remain: higher upfront cost perception, concerns regarding reactions, limited familiarity among clinicians, reimbursement gaps, regulatory adaptation and lack of infrastructure for decentralized administration. Some centres are also culturally accustomed to equating “long infusion with “strong treatment.

Solutions include clinician and nurse training, patient education, pharmacoeconomic studies, guideline integration, day-care workflow redesign and inclusion under government insurance pathways. Carefully selected patients may eventually receive portions of treatment closer to home under structured safety protocols.

Roche can responsibly support training, access initiatives, nursing education and real-world evidence generation.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

Challenges/ problem statement:

A day won't pass in a medical oncologist life without hearing about iv access difficulty in the clinics. Solution of central lines comes with its own bunch of problems like cost, maintenance, discomfort etc. With medical research heading towards more innovation of subcutaneous preparation, no doubt this will change the lives of our patients, giving them more comfort and convenience. This solution is an attempt to look into the challenges and improve accessibility of subcutaneous anticancer drugs.

Subcutaneous formulations of anticancer drugs now take a high seat at the "oncology care table". Some preparations of subcutaneous have more cost adding to the burden. However, in many malignancies' S/C preparations are cheaper, rapidly changing the practice of oncology. When compared to IV daratumumab, S/C preparation has significantly lesser reactions making it a go to option. Many studies have shown S/C are more convenient and comfortable and have similar efficacy. However, what remains unanswered is why majority of S/C anticancer drugs are still administered in hospital, resulting in a huge burden on healthcare.

Major reasons

1. Gap in the guidelines: There are no guidelines/SOP/regulations for the use of S/C anticancer therapy in out of hospital setting in India.
2. Fear of anaphylaxis: This is a practical issue for doctors. In reality when we compare the grade 3 anaphylaxis incidence across common drugs used in oncology, they are not much different. For example, Supportive care drugs which are more commonly used as home injections like Filgrastim, Peg Filgrastim, Romiplostim and insulin have 0.1-1%, <1%, <0.1%, <1% of reported anaphylaxis respectively. Similarly, Plesgo <1%, reported as extremely rare in many studies, trastuzumab 0.2% of reactions.
3. Administration challenges: Injections like S/C plesgo/ trastuzumab are administered over several minutes. Needs a trained Nurse to administer in the correct way. Lack of skilled staff make it challenging to implement.
4. Responsibility and liability: No clarity of responsibility / liability for ensuring the quality of care.
5. Medicolegal issues: Since there is no clarity on regulations, medical legal issues and also consumer forum litigations considering the high cost involved in some of the injections.
6. Infrastructure and training remain challenge in our country.

Burden and the unmet need:

Take example of a patient with Her 2 Neu positive breast cancer received Neoadjuvant treatment with Plesgo and attained pCR, now on adjuvant Plesgo for the total duration of 1 year. She continues to visit hospital for every injection, causing significant interruption to her occupation, many a times hospitals mandate an accompanying care giver, travel cost, loss times adds to the burden. If the Plesgo can be administered in her home, all these problems could be solved.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Development of a dedicated home visit team for the administration of the subcutaneous anticancer drug, For example Phesgo.

Who sets up the team: Innovators/ pharma company like Roche can take the initiative of setting up the platform.

What constitutes a home visit team: A dedicated nurse, trained in oncology care, special training in Phesgo administration, identifying reactions/ anaphylaxis and first aid, bedside manners. Nurse is accompanied by the home visit vehicle, driver. Vehicle has basic emergency facilities and drugs.

- Patient should have a valid prescription by the treating oncologist clearly mentioning the injection dates, dose, route, patient ID, dates of next follow-up to hospital.
- Patient needs to prior book the injection schedule in the app.
- Drug is transported through appropriate storage (cold storage).
- Nurse is given a SOP to systematically follow all the steps for safe administration of the injection and digital documentation of the process, after obtaining the consent.
- Online helpline should be made available with a doctor on line, in case of assistance for the on field team.

Addressing the issue of guidelines: An effort like this needs cooperation from the Govt, manufacturers, doctor bodies, MNC like Roche can appeal to regulators for development of guidelines. Similar appeal and advocacy can be done by oncology bodies like ISO, ISMPO, ICON etc, for the benefits of the patients, this will reduce the fear of litigation.

Similar efforts are attempted in pilot projects like Flexicare care project in Poland where a study showed 57% patient satisfaction. In UK NHS had done similar institution directed pilot projects.

This can be tried as pilot projects in metro cities in India.

Already we have many palliative care initiatives happening through homecare in metros.

Benefits:

- Direct contact and follow up with the patients/ customer, helps to ensure compliance.
- Unique opportunity to enrich consumer experiences and assistance of Roche.
- Bypasses the cost of hospitals/ distributors, will benefit the patient with cheaper drugs and manufacturers to deliver the drugs directly to patients.
- Since handled by the manufacturers avoids any misuse of medication or authenticity of the drug maintained.
- Benefits patients, saves the time, cost, provides comfort and convenience of taking injections at home.
- Reduces the burden/load on hospitals where resources can be utilized for more needy patients.

Conclusion:

Newer innovation of S/C fixed dose anticancer drug's fullest potential is harnessed only if it translates to better convenience and comfort by more homecare administration. As health care professionals our motto is to cure sometimes, relieve often and comfort always, an opportunity to enhance the comfort of the patient is to an opportunity to serve humanity.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge)

As a medical oncology resident in a high-volume center, I frequently see HER2-positive breast cancer patients who have already completed surgery and chemotherapy spend many hours in the day-care receiving intravenous trastuzumab and pertuzumab, particularly during the maintenance phase, continue to occupy infusion chairs for 2–3 hours every three weeks creating congestion in already overburdened day-care, delaying treatment for others. Prolonged hospital visits result in lost wages, travel expenses, caregiver burden, and reduced quality of life.

Despite the availability of a subcutaneous fixed-dose combination of pertuzumab and trastuzumab that can be administered within minutes, its integration into routine use is still less.

But recently, evidence from the PHrancisCa Trial and FeDeriCa Trial showed patient preference for SC administration (1) due to shorter time and comfort. The COLUMBA study confirmed that subcutaneous Daratumumab, IMscin001 and IMscin002 trials revealed that subcutaneous Atezolizumab matches the efficacy and safety of intravenous formulations.

There is a need for a structured transition to enable eligible patients to receive subcutaneous therapy efficiently. The expected outcomes extend far beyond saving time. There will be reduced hospital visit, decreased day care occupancy, reduce pressure on nursing staff, improved patient satisfaction, better treatment adherence, lower caregiver burden, and reduced indirect financial costs, such as travel expenses, accommodation, and wage loss.

There is a need to build a decentralised, patient-centred, and digitally supported oncology care model in India where effective, standard treatment can be given closer to patients' homes with convenience.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

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Challenges to use S.C:

1. Financial and Reimbursement Barriers

SC has a higher retail price than its IV formulation. Insurance Coverage: can be difficult, as upfront cost of the drug itself is more than hospital stay and nursing labor with iv.

2. Clinical and Ergonomic Strain on Healthcare Staff: SC injections require nurses to stay with the patient throughout the injection process and manually push a concentrated drug for several minutes, causing hand and wrist fatigue, unlike IV infusions.

3. Biological and Formulation Constraints

Delivering these large molecules is difficult due to the less subcutaneous matrix space, needing highly concentrated (viscous) formulations or the integration of dispersion enhancers like recombinant human hyaluronidase.

Not an option for the vast majority of cancer regimens.

Injection Site Reactions (ISRs) making some patients to prefer a standard IV infusion.

4. Safety and Regulatory Limits on Decentralization

safety concerns, hazardous drug handling protocols, and the potential risk of under- or over-dosing.

Lack of Specialized Home-Care Infrastructure

5. Operational Inconsistencies and Clinical Inertia

Real-world studies show significant variation in how clinics handle subcutaneous oncology drugs, preferring IV administration simply because of routine familiarity.

Solution:

1: EMR-Integrated Patient Screening & Triage

Automated EMR identifies HER2-positive breast cancer patients who have completed chemotherapy and are due to start maintenance (ideal time for transition), prompts doctors to assess switching to SC pertuzumab/trastuzumab.

EASE-SC study(2) demonstrated that early integration of SC dual-HER2 blockade is active and well-tolerated.

2: Establish the Outpatient "Rapid-PHESGO Kiosk" (Daycare Bypass)

Dedicate a two-chair nursing kiosk within the outpatient department (OPD) specifically for subcutaneous administration, completely bypassing the main daycare

3: Implement Standardized SC Administration Protocols

Train nurses on subcutaneous injection techniques (based on NCODA standards): Needle & Angle, Injection Site Rotation: slow subcutaneous manual injections into the thigh, alternating thighs between cycles, to minimize the risk of localized injection site reactions (ISRs). Safety Monitoring: 15 to 30-minute post-injection observation window for the first cycle.

4: Mitigate Financial Obstacles via Access Schemes

Integrate a dedicated "Financial Counselor" directly into the Rapid-PHESGO pathway to link patients to Roche India's Blue Tree Program or corporate co-pay models at the triage phase.

5: Transition to a "Shared-Care" Decentralized Model

Once patients complete their first 3 to 4 loading cycles in the tertiary hospital under supervision, they can be transitioned to regional or community clinics closer to homes for their remaining cycles.

References:

1. Patient Preference for Subcutaneous vs Intravenous Pertuzumab/Trastuzumab for HER2-Positive Early Breast Cancer - The ASCO Post. Available from: <https://ascopost.com/news/may-2020/patient-preference-for-subcutaneous-vs-intravenous-pertuzumabtrastuzumab-for-her2-positive-early-breast-cancer/>
2. Zietse M, Hu J, van Staveren ER, Spierings LEAMM, Jager A, Koch BCP, et al. Capacity and cost benefits of subcutaneous versus intravenous pertuzumab/trastuzumab: The EASE-SC study. The Breast. 2025 Dec 1;84:104573. doi:10.1016/j.breast.2025.104573.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

If we can push these SC injections out of our jammed tertiary centers and down to local community clinics, the adoption rate will massively surge. It spares the family from burning daily wages on travel.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Being chained to an IV pole for hours is honestly just demoralizing for our patients. We see this harsh reality play out every single day. A family will take a crowded bus from a remote district into Chennai or Madurai just to get a standard monoclonal antibody infusion.

But these newer subcutaneous formulations are totally flipping that clinical script. You are basically taking a gruelling two-hour IV setup and shrinking it down into a quick five-minute jab in the abdomen. And the major trial data backs this up flawlessly. We know the SC route hits the exact same survival curves as traditional IV protocols without compromising efficacy. For the patient, getting their time back is an absolute game-changer. They don't have to battle for a scarce daycare bed or sit in our crammed corridors all afternoon.

But rolling this out into routine practice has its own weird bottlenecks. There is a surprisingly stubborn psychological barrier we have to fight. A lot of folks honestly feel like a fast five-minute shot simply isn't "strong enough" to kill the tumor. They are deeply conditioned to associate sitting in a hospital bed all day with receiving serious medical care. Plus, localized injection site reactions can really panic them if they aren't warned beforehand.

And fixing this requires heavy upfront counseling. We have to sit across from them and translate the pharmacokinetics into plain terms they trust. If we can push these SC injections out of our jammed tertiary centers and down to local community clinics, the adoption rate will massively surge. It spares the family from burning daily wages on travel. We just need to break the mindset that suffering through a long IV session is the only way the medicine actually works.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

The main point is to decentralise cancer care by improving the utilisation of subcutaneous formulations rather than merely just an alternative method of administration. This can scale up the access to treatment, also ensure adherence, and finally improve patient overall experiences.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Existing Gaps

Across various centres, the efficacy and safety of Subcutaneous formulations have been on par with intravenous treatments. Despite achieving this milestone, these subcutaneous formulations usage is mostly confined to major medical centres where they are used merely as a convenience.

Patients continued to travel long distances for repeated treatments, leading to financial strain, lost wages, caregiver exhaustion, and treatment discontinuation. Current discussions mainly highlight reduced administration time and labelling Subcutaneous formulations as a care-delivery innovation, not just a drug-delivery innovation.

Solution Offered

I propose an Accredited Community Oncology Administration Model.

Initial assessments and early cycles of treatment will be done at major hub centre as normal in the cancer patients

Once treatment tolerance and safety are established, these eligible patients would then be transitioned to district oncology spoke units or any community centres which are accredited to the main program for further deliverance of subcutaneous treatments.

Patient safety will be ensured by incorporating standardized protocols, trained nursing staff, cold-chain monitoring, tele-oncology support, and toxicity management by predefined pathways

The clinical vigilance is maintained by the main center while treatment is delivered closer to the patient.

This model not only reduces travel demands, treatment costing for contemporary modalities, caregiver burden but also narrows the bridge of treatment discontinuation and at same time increases the bed availability at major national centers.

Future evaluations can focus upon patient-centered outcomes like travel time saved, treatment completion rates, caregiver burden, and reduction in lost workdays.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

1. The main objective is to achieve a comprehensive paradigm shift in oncology care by transitioning from resource-intensive intravenous infusions to patient-centric, high-efficiency subcutaneous injections.
2. Optimising clinical efficacy and maximising health system throughput.
3. Eradicating "time toxicity" to restore treatment-free time and quality of life to the patient.
4. For resource optimisation and Economic benefits.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Pharmacological Advantages:

1. Proven Bioequivalence: SC formulations have demonstrated non-inferior pharmacokinetics compared to intravenous.
2. Phase 3 trials, show equivocal objective response rates and efficacy
3. Comparable Safety Profile with less infusion related reactions
4. Reduces Catheter-Related Complications like infections and thrombosis
5. Facilitation of fixed-dose combinations (e.g., pertuzumab and trastuzumab),

Resource Optimization

1. Reduction in Preparation and administration time
2. Optimized Healthcare Professional Time: from reducing time from line setup and to monitoring prolonged infusions.
3. Increases Day care Unit Capacity
4. Simplified Logistics: The "ready-to-use" nature of many SC injections simplifies the supply chain.

Economic Benefits

1. Decreases Preparation and administration Cost
2. Minimized Drug Wastage
3. Reduced Productivity Loss: Because treatments are faster, patients experience less toxicity, leading to fewer lost workdays and less disruption to their professional lives.
4. Lesser Travel and Caregiver Expenses
5. Optimized Quality of Care
6. Decreases patient anxiety and improves comfort.

Challenges and mechanisms to address these

1. More protein concentration: leads to higher viscosity, Viscosity Reducers like arginine, caffeine, or proline suppresses protein-protein interactions.
2. More Protein Aggregation: Formulating mAbs as crystalline suspensions provides superior physical-chemical stability and retains full biological activity.
3. Decreased solubility: By modulating pH and ionic strength alters the electric charge of amino acid residues, mitigating attraction between antibodies.
4. Transitioning from IV to SC is more complex and costlier than maintaining the original concentration. Using On-Body Delivery Systems allows for low-concentration, large-volume formulations.
5. Extracellular Matrix Resistance: dense, negatively charged hyaluronic acid network in the hypodermis acts as a barrier to drug transport. Can be reduced by using recombinant human hyaluronidase temporarily degrades hyaluronic acid.
6. Injection Site Pain can be reduced by Thermosensitive Hydrogels.
7. Lower Bioavailability: By using higher total doses to ensure equivalent systemic exposure.
8. Target-Specific Toxicity: mAbs like Cetuximab are unsuitable for SC due to high EGFR expression in the skin, leading to severe toxicity. Can be avoided by selecting candidates based on molecular target distribution.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

To promote the adoption of subcutaneous formulations in cancer care by improving treatment convenience, reducing healthcare burden, enhancing patient experience, and maintaining clinical effectiveness through evidence-based and patient-centered delivery models.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Subcutaneous (SC) formulations are transforming cancer therapy administration by providing faster, more convenient, and patient-friendly alternatives to traditional intravenous (IV) infusions. Several biologic therapies and targeted agents have demonstrated comparable efficacy and safety between SC and IV routes, while reducing administration time, hospital visits, and resource utilization. These benefits improve patient comfort, treatment adherence, and overall quality of life.

From a patient perspective, SC formulations reduce prolonged hospital stays, decrease dependence on infusion facilities, minimize disruption to daily activities, and improve psychological comfort by making treatment less burdensome. Healthcare systems benefit through optimized chair time, reduced workload, and improved treatment capacity.

Challenges to wider adoption include limited awareness among healthcare professionals and patients, concerns regarding efficacy and safety, training requirements for administration, reimbursement issues, availability of suitable infrastructure, and management of local injection-site reactions.

Solutions include developing standardized administration protocols, educating healthcare teams and patients, incorporating SC options into clinical guidelines where evidence supports their use, ensuring reimbursement support, and establishing monitoring systems for safety and outcomes. Home-based or community-based administration models may further improve accessibility for selected patients.

Integrating patient preferences into shared decision-making and generating real-world evidence will support wider acceptance. SC formulations represent an important step toward more convenient, efficient, and patient-centered cancer care delivery.
