

Subcutaneous Injectable MPA Contraceptive in India

Introduction

Family Planning (FP) is one of the most cost-effective solutions for achieving gender equity. It empowers women with the knowledge and agency to control their bodies and reproductive choices (1). As a young country with a third of its population aged 15-34 years (2), India has achieved the replacement level of Total Fertility Rate (TFR). The percentage of people using modern contraceptives for family planning (FP) increased to 56.4% in 2019-21 from 47.8% in 2015-16. There was a notable preference for limiting methods, particularly female sterilisation. More recently, India's commitment to the FP2030 goals includes ensuring access to an expanded range of contraceptives with the addition of new contraceptive choices. India's commitment to the FP2030 goals includes ensuring access to an expanded range of contraceptives by introducing new contraceptive options. Providing a diverse range of contraceptive options, encompassing both spacing and limiting methods, is essential for addressing the evolving needs and preferences of women and couples. Besides, India is also committed to SDG Goal 4, Target 3.7, which emphasises explicitly universal access to sexual and reproductive healthcare services, information and education, and the integration of reproductive health into national strategies and programmes.

In July 2023, the Government of India announced the introduction of two new contraceptives to the public health system - *Subcutaneous depot medroxyprogesterone acetate or DMPA-SC and Subdermal implants*. The incorporation of Injection Depot Medroxyprogesterone Acetate - Subcutaneous (DMPA-SC) as a self-care contraceptive option into India's national Family Planning Programme represents a promising and timely opportunity¹, that can play a crucial role in our collective commitment to achieving universal access to sexual and reproductive healthcare services.

Introduction to DMPA-SC

Globally recognised for its remarkable cost-effectiveness²³⁴, DMPA-SC emerged as a transformative innovation, enhancing contraceptive access, particularly within low-income communities.

¹ UNFPA, `Enhancing women's reproductive autonomy - a case for self administration of DMPA-SC in India, 2023. https://india.unfpa.org/sites/default/files/pub-pdf/dmpa-sc unfpa brief on self administration.pdf
² PATH's multi-country study evaluated DMPA-SC delivery costs, across 'facility', 'community'', and "self-injection' approaches. Community-based costs were lowest in Uganda (\$7.69), followed by self-injection in

<u>Uganda (\$7.83) and Senegal (\$8.38), while self injection incurred minimal direct non-medical costs.</u>

3 The cost-effectiveness per averted pregnancy and Disability Adjusted Life Years in Uganda favored self-injection of DMPA SC and projected an annual societal savings of \$84,000.

⁴ Sherpa, et al. *A prospective cohort study to assess the acceptability of Sayana Press among 18–49-year-old women in Nepal,* 15 July 2021, Elsevier, https://doi.org/10.1016/j.contraception.2021.07.009



In 2011, DMPA-SC emerged as a promising innovation that offered enhanced contraceptive access, particularly in low-income communities. This subcutaneous form of the well-known DMPA-IM contraceptive is presented in the convenient drug delivery mechanism known as the "Uniject injection system". In this system, the hormone (Medroxyprogesterone acetate) is kept in a liquid form in a silastic pouch with a self-locking, very thin injection needle, preventing drug leakage until the system is activated. This method holds the potential to bolster contraceptive utilisation on a global scale significantly. Other than the advantages of efficacy, reversibility, discretion, and suitability during breastfeeding, the user-friendly nature of DMPA-SC extends to its compatibility with task-shifting to lower-level healthcare personnel and even self-injection. This adaptability has yielded favourable outcomes in seven countries where DMPA-SC pilots increased user satisfaction and continuation rates, underscoring its potential to positively impact FP efforts (4).

DMPA-SC, under the brand name 'Sayana Press', is readily accessible through a pre-filled, disposable injection device. Though DMPA-SC shares several similarities with intramuscular DMPA (DMPA-IM), such as its quarterly dosing regimen, high effectiveness, and similar side effect profile, it also brings some noteworthy differences to the table as follows:

CHARACTERISTICS	DMPA IM	DMPA SC
DOSAGE	150 mg MPA in 1.0 ml	104 mg MPA in 0.65 ml
INJECTION TYPE	INTRAMUSCULAR	SUBCUTANEOUS
DELIVERY METHOD	GLASS VIAL WITH SYRINGE	PREFILLED IN A SILASTIC POUCH
		WITH A NEEDLE KNOWN AS UNIJECT
		SYSTEM
NEEDLE SIZE	1 INCH (2.5 CM)	3/8 INCH (0.9 CM)
ADMINISTRATION SITE	DEEP TISSUE MUSCLE	SUBCUTANEOUS FAT

Benefits and Side Effects

Unlike DMPA IM, DMPA-SC self-injection offers numerous benefits, such as overcoming barriers to accessing clinical services, maintaining privacy and autonomy, and ease of use for women, especially unmarried, sexually active women. One of the key advantages of DMPA-SC as a self-administered method is its ability to promote consistent continued contraceptive use, even in challenging situations such as pandemics or the inability of women to contact health workers. When women proactively opt for self-injection and receive training in administering DMPA-SC, there is a significant reduction in discontinuation rates. Moreover, enabling self-injection of DMPA-SC provides women with a self-care method that potentially increases their privacy and autonomy in making decisions about if, when, and how many children to have⁵. The acceptors can switch DMPA-IM to DPMA-SC, but they are to be administered only at their specific administration site; DMPA-IM cannot be given by the SC route and vice versa.

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⁵ Murray M, Brady M, Drake JK. 2017. "Women's self-care: Products and practices." Outlook on Reproductive Health. Seattle, Washington: PATH



The side effects of DMPA-SC are similar to those of DMPA-IM, which include headaches, bleeding irregularities—including amenorrhea, irregular spotting or bleeding, prolonged spotting or bleeding, sometimes heavy bleeding, as well as some weight gain and injection-site reactions. Most recent evidence shows abdominal pain, nausea, or vomiting (47%), irregular or heavy bleeding (40%), headaches (38%), injection-site pain or irritation and amenorrhea (32%), backache (30%) and body ache (23%) among women who used Sayana Press⁶. However, these side effects declined over a nine-month follow-up period and are reversible after its use is ceased.

DMPA-SC Usage: Global Experience

More than 40 million women worldwide use injectable contraceptives, and in many low- and middle-income countries (LMIC), injectables account for at least half of modern contraceptive method use⁷. This is reemphasised by the pilot study conducted in Nepal, where it was revealed that over two-thirds of women selected DMPA-SC or Sayana Press rather than DMPA-IM when the option to select the preferred method was made available to them (5). DMPA-SC was introduced in Burkina Faso, Niger, Senegal, and Uganda in 2014 through diverse channels, such as clinics and health providers within the community. Over two years, from 2014 to 2016, healthcare providers administered more than 490,000 doses of DMPA-SC to 135,000 women who were first-time contraceptive users (6). Learnings from the study reveal that the proportion of clients choosing self-injection nearly doubled from 35 percent at the first injection to 65 percent at three months and remained constant at six months. This study design showed that more clients may be willing to choose self-injection after experiencing the first injection with a provider (6).

A randomised trial of self-administered versus health worker-administered DMPA-SC conducted in New York City, USA, showed that 63 percent of women approached for the study were interested in self-administration, and nearly all eligible women successfully self-injected⁸.

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⁶ Holly M Burke, Mario Chen, Mercy Buluzi, Rachael Fuchs, Silver Wevill, Lalitha Venkatasubramanian, Leila Dal Santo, Bagrey Ngwira, 2018, "Effect of self-administration versus provider-administered injection of subcutaneous depot medroxyprogesterone acetate on continuation rates in Malawi: a randomized controlled trial", Lancet Global Health, Published online March 8, 2018 http://dx.doi.org/10.1016/S2214-109X(18)30061-51

⁷ Kim CR, Fonhas MS, Ganatra B. *Self Administration of Injectible Contraceptives: A Systematic Review*. BJOG: 2017124:200-8. https://pubmed.ncbi.nlm.nih.gov/27550792/

⁸ Beasley A, White KO, et al. *Ramdomized clinical trial of self versus clinical administration of subcutaneous depot medroxyprogestrone acetate*. Contraception 2014; 89:352-6.



Navigating Challenges for Seamless DMPA-SC Adoption: Insights from Pilot Studies

Key hurdles that demand strategic attention to ensure the seamless adoption of DMPA-SC, based on pilot studies in neighbouring countries such as Nepal⁹ & Pakistan¹⁰:

- **Fear of Self-Administration:** One significant challenge is potential users' initial fear of self-injection. Live demonstrations and targeted training programs emerge as essential strategies to dispel fears and build confidence in the self-administration process.
- Information Dissemination Gap: A notable obstacle is the insufficient awareness surrounding DMPA-SC and its self-injection features.
- **Pricing Challenges:** While public sector health facilities offer free services, economically compromised clients face obstacles in accessing DMPA-SC through private providers.
- **Understanding Client Decisions**: Exploring why clients opt for alternative methods, including partner influence, pain perceptions, and facility accessibility issues, provides valuable insights.

In India, limited pilot studies showcase the rollout and acceptance of DMPA-SC. However, a market research study conducted by Ipsos and Ipas Development Foundation investigated the factors influencing the acceptance of the concept of DMPA-SC and its self-administration among various stakeholders. It was performed in 19 major states¹¹ of India. The study found a positive perception of DMPA-SC, with 55% of participants being comfortable with self-administration with some support. It also mentioned benefits in terms of a long protection period and user convenience. Additionally, women reported that confidence would be built in the product with training for self-administration and more information on side effects and their management¹².

Though the market research reflects a positive perception of DMPA-SC, maintaining robust supply chain management is essential to a successful rollout. A global study highlights that though DMPA-SC availability has increased since its introduction, significant gaps in stock exist¹³.

⁹ Sherpa, et al. *A prospective cohort study to assess the acceptability of Sayana Press among 18–49-year-old women in Nepal,* 15 July 2021, Elsevier, https://doi.org/10.1016/j.contraception.2021.07.009

Veesar GY, Lashari T, Fida R and Veesar MA. Benefits, anxieties, acceptance, and barriers to the new injectable contraceptive DMPA-SC (Sayana Press): Clients' perceptions in Sindh, Pakistan [version 1; peer review: awaiting peer review]. Gates Open Res 2023, 7:66 (https://doi.org/10.12688/gatesopenres.14326.1)
 Assam, Andhra Pradesh, Bihar, Delhi, Gujarat, Haryana, Jharkhand, Karnataka, Madhya Pradesh, Maharashtra, Manipur, Mizoram, Nagaland, Punjab, Rajasthan, Tamil Nadu, Telangana, Uttar Pradesh, and West Bengal; both urban (73%) and rural (27%) areas covered.

¹² IDF. Insights and Recommendations for Facilitating DMPA-SC Self-Administration in India, Policy Brief. New Delhi: Ipas Development Foundation; 2023

¹³ Magalona S, Wood SN, Makumbi F, OlaOlorun FM, Omoluabi E, Pierre AZ, Guiella G, Cover J, Anglewicz P. DMPA-SC stock: Cross-site trends by facility type. Contracept X. 2022 Apr 8;4:100075. doi: 10.1016/j.conx.2022.100075. PMID: 35493973; PMCID: PMC9046645.



Rollout of DMPA-SC in India

DMPA-SC in the public health system in India has been initiated since July 2023, according to the Ministry of Health & Family Welfare (MoHFW). This rollout is part of the Phase 1 implementation, scheduled to span the next three years and encompass ten states. The geographical scope of this initiative extends to 22 districts¹⁴ across the country.

Within these ten states, two districts per state have been identified, and two facilities will offer the service in each district. The distribution chain for administering DMPA-SC spans from medical colleges down to sub-centers. Providers, including gynaecologists/OB-GYN specialists, need to be trained using a comprehensive Learning Resource Package (LRP) designed by the Ministry. Master trainers, certified by the Ministry, will train state-level trainers, who will, in turn, train facility-level providers. While Auxiliary Nurse Midwives (ANMs) can administer the service, the first dose requires a trained medical officer/gynaecologist's assessment. All cadres at the facility level will receive training. Supplies are dispatched to state warehouses, and the Family Planning Logistics Management Information System (FP LMIS) oversees the distribution to district officers and service providers.

A detailed assessment format for monitoring the rollout's success has been established, requiring monthly facility-level reporting to states and quarterly state-level reporting to the national level. This format tracks supply distribution, administration rates, intervals (postpartum or post-abortion), potential risks, complaints, training loads, and post-training follow-ups. Quarterly stock updates are also included.

Though the rollout is limited presently, considering the geographical span of India, the pan-India rollout requires a comprehensive strategy to be in place. Based on the discussed observations earlier, the key recommendations for pan India rollout are delineated in the following sections:

- Create an enabling environment: Supportive policy and guidelines for DMPA-SC under the FP programme, creating awareness of the benefits of self-injection through context-specific IEC materials and messages, ensuring effective client counseling, and addressing misconceptions through media engagement.
- Training of service providers: Develop training material and train doctors, nurses and
 front-line workers to properly administer and store DMPA-SC. It is crucial to train the
 frontline workers (ANMs) to provide DMPA-SC at the peripheral subhealth centres and
 community settings such as VHSNDs. This will significantly scale up access in rural remote
 areas of the country.

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¹⁴The commencement of this initiative is marked by its presence in diverse districts, including Goalpara, Nagaon, Hailakandi in Assam, Sheikhpura, Munger in Bihar, North West, South West & Central Delhi, Kutch & Bharuch in Gujarat, Yadgir & Mysore in Karnataka, Baleswar & Gajapati in Odisha, Jaisalmer & Sawaimadhopur in Rajasthan, Ramanathpuram & Erode in Tamil Nadu, Saharanpur & Chitrakoot in Uttar Pradesh, South 24 Parganas & Uttar Dinajpur in West Bengal.



- Ensure regular supply of DMPA-SC: Ensure regular and consistent supplies at healthcare facilities (Health and Wellness Centres, primary health centres, sub-centres) and front-line workers who are in close proximity to the community.
- Establish effective mechanisms for follow-up and reporting: Set up a mechanism to send SMS reminders to front-line workers (ANMs and ASHAs) for injection dates and ensure post-administration follow-ups by them to promptly report, explain, and address any side effects. Screening, counselling and follow-up support by frontline health workers are crucial to promoting the uptake of DMPA-SC among young women.
- Community Engagement and Awareness: Design and disseminate IEC (Information, Education, and Communication) & SBCC (Social and Behaviour Change Communication) materials to foster community awareness, address taboos and misconceptions, and demand generation through multiple platforms.
- Data collection & analysis: Robust data collection mechanisms for monitoring and understanding user experiences with DMPA-SC. Establishing a comprehensive system to collect and analyse data on the usage, satisfaction, and potential challenges faced by individuals receiving DMPA-SC can provide valuable insights into refining implementation strategies, addressing specific concerns, and ensuring that the delivery of DMPA-SC aligns with the needs and preferences of the population.

Conclusion

Going forward, the successful introduction of injectable contraceptives in India hinges on a comprehensive approach that addresses training, supply chain management, communication, and quality of care. Given the widespread global affirmation of client satisfaction, women's inclination toward DMPA-SC, and its cost-effectiveness, it is prudent to make this contraceptive option available for both self-administration and provider administration, with the anticipation of a heightened client adoption rate.



References

- 1. Investing in Family Planning: Key to Achieving the Sustainable Development Goal. Starbird, Ellen, Norton, Maureen and Marcus, Rachel. 2016, Glob Health Sci Pract., Vol. 4(2), p. 193.
- 2. Youth in India Report. New Delhi: Government of India., 2017.
- 3. National Family Health Survey (NFHS- 5), 2019-21, INDIA REPORT. Mumbai: IIPS: International Institute for Population Sciences (IIPS) and ICF, 2021.
- 4. Reference manual for Injectible Contraceptives (DMPA). New Delhi: Family Planning Division. Ministry of Health and Family Welfare, Government of India, 2016.
- 5. A prospective cohort study to assess the acceptability of Sayana Press among 18–49-year-old women in Nepal. Sherpa, Yangchen Lhamo and Tonkari, Singh Bhim, et al. 6, Nepal: Elsevier, Deceber 2021, Vol. 104. https://doi.org/10.1016/j.contraception.2021.07.009.
- 6. Nai, Dela, Aboagye, Patrick and al., et. *Introduction of DMPA-SC self-injection in Ghana: A feasibility and acceptability study using Sayana® Press.* Washington, DC: Population Council, The Evidence Project, 2020.
- 7. The power to prevent pregnancy in women's hands: DMPA-SC injectable contraception. s.l.: PATH, September 12, 2018.
- 8. Youth in India Report. New Delhi: Government of India., 2017.
- 9. Contraceptive Use By Method. NYC: UN DESA, 2019. 978-92-1-148329-1.
- 10. WHO guideline on self-care interventions for health and well-being, 2022 revision . Geneva: World Health Organisation , 2022. Licence: CC BY-NC-SA 3.0 IGO.
- 11. Use of modern contraception increases when more methods become available: analysis of evidence from 1982–2009. Ross, J and Stover, J. 203-212, s.l.: Glob Health Sci Pract., 2013, Vol. 1(2). 2.
- 12. Exploring Opportunities for mCPR Growth in Bangladesh. *Track20*. [Online] December 2022. [Cited: September 26, 2023.] https://track20.org/download/pdf/Opportunity%20Briefs/english/Bangladesh%20FP%20Opportunity%20Brief.pdf.
- 13. Exploring Opportunities for mCPR Growth in Bhutan. *Track20.org*. [Online] December 2022. [Cited: September 26, 2023.] https://www.track20.org/download/pdf/Opportunity%20Briefs/english/Bhutan%20FP%20Opportunity%20Brief.pdf.
- 14. Exploring Opportunities for mCPR Growth in Indonesia. *Track20*. [Online] December 2022. [Cited: September 26, 2023.] https://track20.org/download/pdf/Opportunity%20Briefs/english/Indonesia%20FP%20Opportunity%20Brief.pdf.
- 15. India's Vision FP 2030. New Delhi: Family Planning Division Ministry of Health and Family Welfare, 2022.
- 16. Sayana® Press: can it be a "game changer" for reducing unmet need for family planning? Spieler, Jeff. 5, P 335-338, s.l.: Elsevier, 2014, Vol. 89. DOI:https://doi.org/10.1016/j.contraception.2014.02.010.
- 17. The power to prevent pregnancy in women's hands: DMPA-SC injectable contraception. s.l.: PATH, September 12, 2018.
- 18. Use of human rights to meet the unmet need for family planning. Cottingham, John, Germain, Adrienne and Hunt, Paul. 380, s.l.: The Lancet, 2012, Vol. 14. PMID: 22784536.
- 19. Cost-effectiveness of self-injected DMPA-SC compared with health-worker-injected DMPA-IM in Senegal. Mercy Mvundura, a,* Laura Di Giorgio,a Morozoff, Chloe, et al. Senegal: Elsevier, 2019. PMID: 32494776.