

# Diverse Preconception Cohort of Digital Health Platform Shows Promise for Addressing Fertility Care Gaps

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# Abstract

About 10 percent of women (6.1 million) in the United States ages 15-44 have difficulty getting pregnant or staying pregnant. Addressing fertility challenges requires an understanding of not only the causes of infertility, but also modifiable risk factors that can impact the likelihood of pregnancy. However, current research on factors influencing conception is often conducted among people who are already engaged in medical fertility treatments. In addition, existing databases are not representative of the U.S. population demographically. This retrospective study describes the demographics of participants of a digital fertility platform who were seeking fertility guidance prior to conception. Demographic data collected from participants who enrolled in Doveras Fertility Inc. (Doveras)'s digital health offerings in 2023 and 2024 were analyzed. Doveras offers personalized preconception lifestyle and behavioral intervention programs, delivered through an innovative digital fertility health platform, for individuals and couples to improve various endpoints along the reproductive and maternal health journey. This paper reports on the inception cohort of the first 600 enrolled participants (Doveras Preconception Cohort I), a subset of a wider pool of Doveras participants enrolled. Doveras achieved this enrollment of a notably diverse and representative population: 65.9% of female-identifying participants identify as White and 34.1% as non-white; 60.5% of male-identifying participants identify as White and 39.5% identify as non-white. The cohort also demonstrates a wide geographical spread, with participants recruited from 46 U.S. states, and represents a population that may have limited access to preconception healthcare: more than half (61%) of participants live in states with 13 OBGYNS or fewer per 100,000 population. The Doveras digital fertility platform presented herein may provide an opportunity to reach a broader and more diverse U.S. population during the preconception period than currently has access to medical fertility care.

Keywords: Preconception; Digital Health; Pre-pregnancy Lifestyle; Maternal Health; Fertility; Behavioral Health



**Abbreviations:** ACOG: American College of Obstetricians and Gynecologists; WHO: World Health Organization; EARTH: Environment and Reproductive Health; LIFE: Longitudinal Investigation of Fertility and the Environment; PRESTO: Pregnancy Study Online

#### Introduction

In the United States, 10 percent of women in their reproductive years have difficulty getting pregnant or staying pregnant [1]. Responding to this growing crisis, investment in the reproductive health industry has largely focused on clinical treatments like in vitro fertilization, which costs on average between \$40,000-\$60,000 per patient to achieve a pregnancy [2]. In the United States, as in many other countries, economic, racial, ethnic, geographic, and other disparities affect both access to fertility treatments and treatment outcomes [3]. Less attention has been paid to ways of improving financially accessible or preventative care for fertility and reproductive health, including ways to individually boost fertility treatment outcomes.

Decades of academic research have established that modifiable environmental and lifestyle factors can play an important role in not only male and female fecundity, but also maternal health outcomes and the prevalence of noncommunicable diseases such as obesity and heart disease in the next generation [4]. According to the American College of Obstetricians and Gynecologists (ACOG), addressing modifiable factors during the pre-pregnancy period can "reduce the risk of adverse health effects by optimizing health and addressing modifiable factors" [5]. Similarly, the World Health Organization (WHO) stresses the importance of adopting healthy behaviors during the pre-pregnancy window: "Preconception care promotes the health and wellbeing of women and couples, as well as improves pregnancy and child health outcomes" [6].

In the United States, there are a number of academic preconception cohorts that contribute high-quality research on the relationship between reproductive and fertility health and modifiable lifestyle factors, including but not limited to topics like diet, supplements, environmental toxin and endocrine disrupting chemical exposure, sleep, mental health, and exercise. Four of the most notable large observational cohorts and their respective study years of interest include the Environment and Reproductive Health (EARTH) Study (2004-2017) [7], the Longitudinal Investigation of Fertility and the Environment (LIFE) Study (2005-2009) [8], Pregnancy Study Online (PRESTO, 2015-2017) [9], and Time to Conceive: A Study of Fertility (2010-2016) [10]. The Nurses' Health Study also has a preconception subset (NHS III, 2010-2022) [11].

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It has historically been difficult to personalize, simplify, and scale the key datasets and synthesized learnings from academic research into practical lifestyle and dietary interventions that can support people trying to conceive at home or at the fertility clinic. One-size-fits-all dietary and lifestyle recommendations are not optimal, and intervention plans must be tailored to the biological, lifestyle, and clinical characteristics of not only individual patients, but also to the unique reproductive scenario of the couple for continuous engagement and adoption. Furthermore, it has been difficult to make evidence-based preconception guidance and information accessible, while misinformation relating to medical care, including fertility care, has become more widespread online. A potential solution is the combination of a digital platform that leverages existing established clinical science with behavioral and data science, along with machine learning, to build a personalized intervention for each individual and couple based on the measurement and/ or prediction of individual responses to interventions to achieve their unique reproductive journey goals.

#### **Methods**

This retrospective study included participants enrolled in the Doveras digital fertility platform. Doveras has designed and developed personalized preconception lifestyle and behavioral intervention programs, delivered through its innovative digital fertility health platform, for individuals and couples to improve various endpoints along the reproductive health journey. Based on a comprehensive baseline assessment and continued self-reporting through the platform, users receive continuous tailored guidance based on synthesized clinical trial data from Doveras' review of over 100,000 published clinical studies. This guidance is designed to translate the high-quality, relevant published clinical research for users in a personalized and digestible manner to support their outcomes across various endpoints, including but not limited to: improved egg and sperm parameters, improved chances of clinical pregnancy, improved chances of live birth, and ultimately, decreased risk of adverse maternal and child health outcomes.

This study evaluated anonymised participants in the Doveras digital fertility platform after completion of an online baseline assessment encompassing self-reported personal demographics, past medical history, and various lifestyle and behavioral characteristics. Data collection occurred from November 2022 to June 2024. The Doveras Preconception Cohort I detailed in this paper represents the inception cohort of 600 participants enrolled within the larger eligible population of Doveras users. The study was approved by Salus IRB (IRB: 24072). Demographic data from these participants was analyzed including age, race, sex, and geography. In addition, data related to the phase of participants' fertility

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journey as well as their methods of attempting to achieve conception was reviewed. These participants purchased access to a Doveras preconception lifestyle and behavioral intervention tool after discovering Doveras through online marketing, organic discovery via digital search tools, physician referrals, and/or word of mouth referrals.

#### **Results**

The Doveras digital fertility platform's baseline assessment captures granularity around the phase of the participants' fertility journey as well as their type of fertility journey (conception via sex or fertility treatment). The Doveras Preconception Cohort I represent a population with a "high-intent to conceive". The majority of participants have never had a previous birth (84.2%). The cohort largely comprises people who are trying to conceive via sexual intercourse (63.9%), or planning to conceive via intercourse within the next 3-6 months. The majority of participants (60.5%) did not report previous history of a fertility-related medical condition. However, 52.2% report that they have not yet seen a healthcare provider regarding their fertility.

The baseline assessment also captures demographic and biological data on both individual and couple characteristics. The Doveras Preconception Cohort I am, on average, in their mid-30s (mean age: 34 years). It is also racially diverse, with female-identifying participants reporting 65.9% as White, 14.5% as Asian, 8.5% as Hispanic, 7.3% as Mixed/Other race; and 3.8% as Black, and male-identifying participants reporting 60.5% as White, 17.8% as Asian, 10.4% as Hispanic, 5.1% as Mixed/Other race, and 6.2% as Black. Overall, the non-white female-identifying population is 34.1% and the non-white male-identifying population is 39.5% (Table 1 in the discussion section below compares the racial/ethnicity composition of major American preconception cohorts).

The Doveras Preconception Cohort I also exhibits significant geographic diversity, representing 46 U.S. states within the period of data collection. More than half (61%) of participants live in states with 13 OBGYNS or fewer per 100,000 population, which may suggest limited availability of or access to preconception care [12]. 28% of participants

live in states the Centers for Disease Control and Prevention identify as part of the "diabetes" belt, where risk of comorbidities that impact adverse reproductive, maternal, and child health outcomes are more prevalent [13]. This cohort represents a combination of individuals and couples both planning and actively trying to conceive. 60% of femaleidentifying participants in the sub cohort elected to invite a male-identifying partner, and over 70% of those invited partners enrolled and participated. This can be compared with the PRESTO preconception cohort's report that 57% of enrolled female participants invited their male partners to participate in the study, of which 50% enrolled [9]. Of the Doveras Preconception Cohort I's male partners, 17% report known sperm parameter issues, while 66% have not yet seen a doctor to discuss their fertility.

## **Discussion**

The Doveras digital fertility platform, through its Doveras Preconception Cohort I, shows promise in its ability to expand upon existing preconception cohorts and preconception literature by bridging gaps in the populations studied in existing preconception research. Specifically, the Doveras Preconception Cohort I is uniquely more racially and geographically diverse, speaking to its potential to capture and engage a previously difficult to reach cohort participant audience.

#### **Racial Demographics**

Approximately two-thirds of the Doveras Preconception Cohort I reports being White, while roughly one-third of the cohort reports being non-white. This can be compared to other large American preconception cohorts, which report an 80+% white participant population. The racial demographic breakdown of the Doveras Preconception Cohort I compared with that of other large preconception cohorts can be found in (Table 1). Since infertility affects many, these cohorts are all important for capturing different subsets of the population. The Doveras digital fertility platform may be a method to educate a diverse group as well as an opportunity for more inclusive reproductive health research.

	Doveras		EARTH		LIFE		PRESTO	<b>General Population</b>
Year/Source	2023		2004-2017		2005-2009		2013-2015	2022 U.S. Census Data
Race/Ethnicity (%)	Female	Male	Female	Male	Female	Male	Female	Female & Male
White	65.9%	60.5%	83%	86%	85%	87%	83%	58.7%
Black	3.8%	6.2%	4%	3%	5%	6%	3%	13.1%
Asian	14.5%	17.8%	8%	7%	3%	2%	2%	6.0%
Mixed/Other	7.3%	5.10%	4%	4%	11%	15%	4%	3.2%
Hispanic/Latino	8.5%	10.40%	Unk	Unk	Unk	Unk	6%	18.9%

Table 1: The Racial/Ethnicity Composition of American Preconception Cohorts Compared To General Population.

#### **Geographic Reach**

The Doveras Preconception Cohort I have also naturally captured participants in nearly all 50 U.S. states, and has been able to detail the urban/rural classifications of its population as well as their access to reproductive and/ or maternal healthcare services. The results shared above signal that a high proportion of Doveras participants are from geographic areas with low accessibility to reproductive healthcare services. The self-selection of this population to Doveras' center of reputable fertility and preconception care suggests the gap for this kind of digital health platform in our healthcare system is particularly large in non-urban locations.

#### **Male Partner Participation**

Identifying and recruiting couples at the trying to conceive moment is historically challenging for academic preconception cohorts. Males are the silent partner in fertility challenges: according to the American Society for Reproductive Medicine (ASRM), "When a couple has trouble having a baby, there's about a 50-50 chance that the man has a problem contributing to the pregnancy" [14]. Beyond the early diagnostic and intervention value of engaging a male population early in a couple's fertility journey, male participation in family planning can also support and improve the mental as well as physical health of the female partner during fertility challenges.

As such, the Doveras digital fertility platform is designed to encourage male participation in a couple's fertility journey. Product decisions include the default selection of the "couple's" version of the program and the ability to include a partner at no additional cost. In-product features also encourage male participation throughout the program. In combination, these product choices have allowed for comparatively strong recruitment and retention of male participation, as detailed in the results section.

#### **Fertility Journey Intent**

The Doveras Preconception Cohort I is predominantly comprised of hopeful first-time-parents-to-be, as 84.2% of participants report having no prior live births. This firsttime-parent population is considerably higher than the LIFE (52%), PRESTO (70%), and Nurses Health studies (57%), and comparable to the EARTH study (87%). The distinction of the Doveras Preconception Cohort I is that it has so far collected data from first-time-parents primarily trying to conceive without medical assistance, while the EARTH population follows sub fertile couples attending a fertility clinic. The Doveras Preconception Cohort I may capture a uniquely high-intent preconception moment for couples trying to conceive for the first time, and/or before the need to escalate for medical support and intervention has been identified.

#### **Conclusions**

The demographic characteristics of this inception cohort, Doveras Preconception Cohort I, reflect a uniquely racially and geographically diverse population. The cohort captures female, male, and couple-level data for couples at the high-intent moment of planning or trying to conceive. These characteristics signal the Doveras digital fertility platform can contribute to advances in reproductive health and care, including by:

- Expanding upon existing datasets to fill gaps in the research, specifically around population diversity, among other contributions;
- Accelerating the speed and volume of research in this area given quality of data collection and high engagement of users, and
- Contributing to training risk stratification and identification models to advance preventative intervention during the preconception window. Together, these contributions may be able to help identify and reduce adverse fertility and maternal health challenges for individuals and couples. Additionally, the platform may help people escalate to medical care faster to diagnose or treat medical conditions that cannot be resolved or managed with behavioral modifications alone.

Such representative datasets, research, and models can contribute to addressing the fertility and reproductive health challenges that are unique to the United States, namely where populational diversity and disparities in access to care may shape the kinds of preconception care that can best support the health and outcomes of individuals and couples planning pregnancy.

## **Author Disclosure Statement**

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/ or publication of this article: N.L. is the founder and CEO of Doveras Fertility Inc. N.M. and M.R. are employed by Doveras Fertility Inc. Dr. M.E, Dr. L.W., A.J.G. and E.M. are advisors for Doveras Fertility Inc.

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## References

- 1. Office of Women's Health (2024) Infertility. Department of Health & Human Services.
- 2. (2024) IVF In Vitro Fertilization. Fertility IQ by inflection.
- 3. Ethics Committee of the American Society for Reproductive Medicine (2021) Disparities in Access to Effective Treatment for Infertility in the United States: an Ethics Committee Opinion 116(1): 54-63.
- 4. (2019) Pre-pregnancy Counseling. The American Society of Obstetricians and Gynecologists.
- 5. (2014) Preconception Care. World Health Organization.
- 6. Gaskins AJ, Chavarro JE (2018) Diet and fertility: a review. Am J Obstet Gynecol 218(4): 379-389.
- Messerlian C, Williams PL, Ford JB, Chavarro JE, Mínguez-Alarcón L, et al. (2018) The Environment and Reproductive Health (EARTH) Study: A Prospective Preconception Cohort. Human reproduction open 2018(2): hoy001.
- 8. Buck Louis GM, Schisterman EF, Sweeney AM, Wilcosky TC, Gore-Langton RE, et al. (2011) Designing prospective cohort studies for assessing reproductive

and developmental toxicity during sensitive windows of human reproduction and development--the LIFE Study. Paediatric and perinatal epidemiology 25(5): 413-424.

- Wise LA, Rothman KJ, Mikkelsen EM, Stanford JB, Wesselink AK, et al. (2015) Design and Conduct of an Internet-Based Preconception Cohort Study in North America: Pregnancy Study Online. Paediatric and perinatal epidemiology 29(4): 360-371.
- 10. (2017) Time to Conceive: A Study of Fertility. ClinicalTrials.gov.
- Wang S, Minguez-Alarcon L, Capotosto MP, Mitsunami M, Gaskins AJ, et al. (2023) Pregnancy Intention, Changes in Pregnancy Intention, and Pregnancy Incidence Among Female Nurses in North America. JAMA network open 6(5): e2311301.
- 12. (2024) data.HRSA.gov. Health Resources & Services Administration.
- 13. (2015) CDC Identifies Diabetes Belt. National Center for Chronic Disease Prevention and Health Promotion (U.S.), Division of Diabetes Translation.
- 14. (2008) Diagnostic Testing for Male Factor Infertility. The American Society for Reproductive Medicine.