Decreasing trends in number of depot medroxyprogesterone acetate starters in Norway – a cross-sectional study

Running headline: Decreasing trends in starters of DMPA

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#### **Abstract**

*Introduction:* In this study, we examined changes in depot medroxyprogesterone acetate (DMPA) prescriptions over a time-period when new professions started prescribing, and when the method gained some negative media attention. *Material and methods*: The Norwegian Prescription Database provided data on hormonal contraception from 2006 through 2012. We estimated annual number of DMPA users by calculating doses sold per day/1000 women and calculated, for each contraceptive method on annual basis, a proportion of defined daily doses of all hormonal contraceptives in 5-year age groups at reproductive age. All analyses were done in SPSS, version 22, with chi-square test, t-test, and survival analysis with p < 0.05 as significance level. Results: There were minor differences in overall DMPA use during the study years. The take-out rate was equivalent to 11-12 per 1000 women aged 15-49 years. DMPA sales amounted to nearly 4% of all daily doses of hormonal contraceptives sold. General practitioners and physicians without a specialty were the major prescribers. The number of starters decreased by nearly 40% during the study years and was consistent across age groups. The average use duration among starters was 17.7 (95% CI: 17.5–17.9) months (range 0–90). There were minor changes in the relative proportion of long-term users beyond 24 months during the study years. Conclusions: DMPA plays a minor role in the overall use of hormonal contraception in Norway, even among teenagers. The number of starters is decreasing, indicating a more restrictive attitude toward first use, especially among general practitioners.

#### **Key words**

depot medroxyprogesterone acetate, female contraception, hormonal contraception, contraception behavior, electronic prescriptions, physician prescribing patterns, synthetic progestogens, contraceptive injections

#### **Abbreviations**

ATC code Anatomical Therapeutic Chemical classification system code

BMD bone mineral density

DMPA depot medroxyprogesterone acetate

BMI body mass index

LNG-IUD levonorgestrel releasing-intrauterine device

NorPD Norwegian Prescription Database

# **Key message**

Overall use of DMPA was relatively stable in Norway during the study period. Decreasing trends in starters of DMPA were observed. General practitioners reduced prescriptions of DMPA relative to other prescribers during years of conflicting bone mineral density results.

#### Introduction

Scandinavian (1–4), European (5–8), and American (8–10) studies have shown low user rates for depot medroxyprogesterone acetate (DMPA). In general, and for DMPA in particular, there are few direct comparative studies with other contraceptives.

DMPA use has been a controversial issue in recent years, as the metabolites reduce serum estrogen levels, which in turn reduce bone mineral density (BMD) (11). Young, long-term users in particular have shown a significant decline in BMD (12–16), which is reversible after discontinuation of DMPA (13, 15, 16). It is unclear whether changes in BMD during DMPA use influences later risk of fractures (17). In addition, research has demonstrated that DMPA has metabolic effects consistent with mild insulin resistance, weight gain, and increased fat mass, especially abdominally (18). A Brazilian study found greater increase in body mass index (BMI) over a three-year period in women, who at study start had BMI < 29.9 kg/m² and used DMPA, than women who used a levonorgestrel intrauterine device (LNG-IUD) (19). Similar results are reported from USA among young (12 to 18 years) obese (BMI > 30 kg/m²) women at baseline, who gained significantly more weight over an 18-month period than women who used oral hormonal contraception (9.5 kg compared to 0.2 kg) (20). However, the results on weight gain are controversial, as another USA study found no correlation between DMPA use and weight gain (21).

In Norway authorization of public health nurses and midwives as prescribers of oral contraceptives to women aged 16 to 19 years started in 2002 (22). From March 1, 2006, this license expanded to cover DMPA, the vaginal ring and contraceptive patch, in addition to oral contraceptives (23).

The debate on possible side effects of DMPA on BMD may influence prescription practice. The purpose of this study was to examine changes in DMPA prescriptions over a time-period when new professions started as prescribers and the drug gained some negative media attention.

#### Material and methods

The Norwegian Prescription Database (NorPD) was established on January 1, 2004, and registered drugs delivered from pharmacies to users (24). A fictitious number is created from the personal identification number given to all Norwegians at birth or immigration. These pseudonyms allow tracing of prescriptions for both users and prescribers over time. The NorPD

includes information on month and year of birth, gender, and users' home municipality. Detailed information about the drugs are also registered. Subscriber information consists of gender, year of birth and graduation, profession, and year and type of specialty.

From January 1, 2004 to June 30, 2013, 9 237 169 prescriptions of hormonal contraceptives (from Anatomical Therapeutic Chemical classification system codes (ATC codes) G02B and G03A) were registered in NorPD. We excluded contraceptive prescriptions to men (n=1 723), research-related contraceptive prescriptions (n=643), prescriptions to non-Norwegian citizens/persons with incomplete identity (n=11 890), and obvious errors in birth year (n=4 523). We also excluded prescriptions undertaken by dentists (n=1 065), dental assistants (n=369), veterinarians (n=74), opticians (N=19), and prescriptions with errors in number of packages delivered over the counter at pharmacies (n=959). In total, 9 215 904 valid prescriptions for hormonal contraceptives were identified, among which we identified 33 134 first-time DMPA users from January1, 2006 to December 31, 2012 as study participants. After excluding 115 women who lacked information on year of birth and/or gender of prescriber, the study population comprised 33 019 first-time DMPA users.

We estimated duration of use in months, from date of first collected DMPA prescription until the date of last continuous DMPA prescription, or date of prescription collection for other hormonal contraceptives. The study includes women who collected other hormonal contraceptive prescriptions at the same take out or within the first 20 days after a DMPA prescription, since this demonstrated an intention to start using DMPA. Use duration for this group was set to zero months.

"Switchers" began using DMPA within 28 days from expiration of last collected contraceptive, if last contraceptive was oral, vaginal ring, or a patch. We did not define a time limit in instances where last hormonal contraceptive was a LNG-IUD or an implant, since we do not know the exact time of removal before DMPA initiation. At study end, women who collected another hormonal contraceptive within 28 days after expiration of last DMPA prescription comprised the "switchers." At study start, "pause" in use of hormonal contraception was restricted to women who submitted a DMPA prescription 29 days or later after expiration of the most recently collected contraceptive prescription. At study end, pause denoted women who collected another hormonal contraceptive 29 days or later after expiration of last dispensed DMPA prescription. Continuous DMPA users were women who collected another DMPA within 29 days after expiration of the most recent delivery.

In the overall assessment of hormonal contraceptive consumption, we set the duration of implant use to 2 years (Implanon/Nexplanon) and 4 years (Jadelle), and the LNG-IUD

(LevoNova/Mirena) to 4 years. For other hormonal contraceptives, we estimated annual number of users by calculating the daily doses sold per day/1000 women in 5-year age groups at reproductive age (15–49 years), depending on the number of packages and package size (as indicated in the ATC code) dispensed at each visit. Statistics Norway online service provided denominator data (age by calendar year) (25).

User age was categorized as 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, and 45–49 years, whereas prescriber age was categorized as 23–34, 35–44, 45–54, and 55–79 years. The 208 starters aged 11 to 14 years were included in the 15–19 age group, while the 382 starters aged 50 to 54 years were included in the 45–49 age group. Prescriber profession was categorized as general practitioner, gynecologist, other specialty, public health nurse, or midwife. Physicians without status as specialist in the NPD were categorized as doctors with no specialty. This category comprised postgraduate medical students who were doing their internship, physicians in a residency-training program, or medical students who had a contemporary license issued in the fifth year of medical school. Physicians with more than one specialty were denoted with the most recent specialty.

Within the entire database, we created the variable "volume of prescriptions per provider," categorized as < 10, 10 thru 23, 24 thru 47, and 48 or more prescriptions a year.

All analyses were done in Statistical Package for Social Sciences (SPSS) version 22.0, with chi-square tests for categorical variables, t-tests for continuous variables, and cumulative duration of use estimated by survival analysis with a significance level of p < 0.05.

### Ethical approval

The NorPD board reviewed the protocol and gave permission for use of data (PDB 1459, saksnr. 16/12041). Studies using anonymous data from nationwide registers are by Norwegian legislation exempted from institutional regulatory board approvals and written informed consent from patients.

#### **Results**

On a population level, the number of DMPA collections from pharmacies in Norway was relatively stable, across age and in total, during the study period (Table 1). The lowest and highest take-outs were consistent by year, lowest among women < 24 years and highest among 40–44 years. The take-out number was equivalent to user rates of 11–12 per 1000 women of reproductive age 15–49 years (Table 1) and amounted to nearly 4% of all hormonal methods used

across the study years (Table 2). DMPA use relative to all other hormonal contraceptives increased significantly by age, with minor year-to-year differences (Table 2).

The number of DMPA starters decreased from nearly 6 200 in 2006 to 3 800 in 2012 (Table 3). There was a year-by-year reduction in first DMPA prescriptions among all age groups. Despite the declining number of starters, the relative age distribution remained consistent across study years, indicating an evenly distributed decrease in number of DMPA starters across age (Table 3).

Most women who started using DMPA did so after a pause in hormonal contraception usage (Table 4, upper panel). The proportion of women without a previous registration in NorPD or a pause increased by age above 20 years. More young women switched from oral contraceptives to DMPA, whereas older women may have switched from LNG-IUDs to DMPA. There were minor differences in the proportion of women switching from progestin-only pills to DMPA across age. Only a small proportion of women switched from patch, vaginal ring, or implant to DMPA (Table 4, upper panel).

Within 29 days after the expiration of the last DMPA prescription, nearly 63% of starters did not collect any other hormonal contraceptive from pharmacies, indicating a pause in hormonal contraceptive use. Sixteen percent continued with DMPA at study end, as indicated by prescriptions with duration beyond study end. A significantly greater number of young users switched to oral contraceptives, while few DMPA users switched to vaginal ring, patch, progestin-only pills, implant, or LNG-IUD (Table 4, lower panel).

Except for women less than 20 years of age, male providers, versus female providers, prescribed more DMPA to starters (Table 5). Among providers below 45 years, females dominated in all professional groups listed in Table 5, whereas males dominated among providers 45 years of age or above (data not shown).

Medical doctors without a specialty and general practitioners were the main DMPA providers. Gynecologists prescribed nearly 12% of all DMPA prescriptions to starters, relatively more DMPA to women 35 years or older than younger women. Other specialist provided 4% of the total volume of prescriptions to starters, evenly distributed across age (Table 5). Public health nurses/midwives prescribed nearly 20% of DMPA prescriptions to women 19 years or younger, which comprised 5% of the total volume of DMPA prescriptions across study years.

In Norway, contraceptive prescriptions are valid for four years. At each pharmacy visit, 96% of the starters took out only one injection. As one injection gives contraceptive protection for three months, the continuation rate will vary with the number of consecutive prescriptions refilled within the duration window. The average use duration among DMPA starters was 17.7

(95% CI: 17.5–17.9) months (range 0–90 months). We analyzed the cumulative proportion of starters that continued at 3, 6, 9, 12, 18, 24, 36, 48, and 60 months, including the 299 (0.9 %) women who collected another contraceptive prescription within 20 days of the DMPA prescription, under the assumption that these women did not start using DMPA but had an intention to start (intention-to-treat analysis). The cumulative proportion of users at 3 months was 73% (95% CI: 72.6–73.6), at 6 months 59%, 9 months 50%, and 12 months 43%. The continuation rate declined further to 28%, 21%, 16%, and 13% at 24, 36, 48, and 60 months, respectively. After 12 months of use, the cumulative proportion of users was significantly higher for women 30 years or older compared to younger women. The estimates for cumulative proportions of starters that continued changed minimally after excluding the 299 women who collected a contraceptive other than DMPA within 20 days of start.

#### Discussion

DMPA plays a minor role in the overall use of hormonal contraception in Norway (Table 1 and 2) and in the other Nordic countries (4). However, the overall DMPA use was lower in Denmark but higher in Sweden, especially among women above 35 years of age, compared to the Norwegian user pattern (4). According to WHO's most updated data on contraceptive prevalence, the prevalence of DMPA use in 2013 was less than 2% in Austria, UK, and Finland, and 1% or lower in France, Germany, and Switzerland (8). Across continents, prevalence was highest in the Caribbean, Central- and South-America (5–7%), while being much lower in Europe (0.7%) and North-America (0.1%) (8). Data from the 2011–2013 National Survey of Family Growth in the US did not report separate data on DMPA but summarized the use of vaginal ring, patch, and DMPA to 4.4% (10), similar to DMPA use data reported from the most recent contraceptive survey in France (8). Among first contacts within the Sexual and Reproductive Health surveys in England over the years 2013–2014, a 9% prevalence was reported (6). However, it is difficult to compare results across studies, since the definition of the denominators differed that much between studies.

We found a steady decline in starters in all age groups. Among providers, general practitioners were the significant group in reducing DMPA prescriptions (data not shown). Prescriptions from gynecologists and MDs without a specialty declined slightly, whereas midwifes/public health nurses prescribed the same magnitude of DMPA across the study years. Judged by first prescriptions, we may speculate that public debates about the health risks of

DMPA could have prompted general practitioners to reduce DMPA prescriptions over the years, whereas the other professions showed little change in first prescriptions.

The continuation rate at 12 and 24 months (43% and 28%) of follow-up were lower than reported for DMPA users from the US-based CHOICE study (58% and 38%) (26). CHOICE, covering the 2007–2011 period, recruited women 14–45 years of age who had no desire to conceive within 12 months, and provided contraception at no cost for the participants (26). Similarly, case series assessing BMD by duration of use report higher continuation rates at two years than the present study (78% (12), 52% (13)). Women in clinical trials on contraceptive methods may be more motivated for long-term use than women provided the method on general terms. In addition, participation in clinical trial includes regular but shorter follow-up windows, better overall care, and investigators that may have an interest in keeping the women in the studies. All these factors, in addition to free contraception during trials, may explain lower continuation rates in the present register study relative to clinical trials like the CHOICE study (26).

In Norway, all citizens have a right to choose a general practitioner from a list of authorized physicians (27). Over the study years, 99% of the target population of women at reproductive age had a regular doctor (27). Contraceptive counselling is considered a task for general practice, thus explaining why general practitioners were the main providers of DMPA at any age. Gynecologists contribute to contraceptive counselling, especially among older women of reproductive age, but far less than general practitioners and doctors with no specialty. The prescriber pattern for first prescriptions of DMPA in Norway is very similar to what has been reported for vaginal ring (28) and implants (29).

To ease access to hormonal contraception in Norway, women 16–19 years of age receive a reimbursement of 100 NOK (~ 14 USD) for 3 months of use when the prescription is dispensed at the pharmacy (23). In practice, DMPA has been free of charge for this subset of younger women over the study years. Despite this fact, DMPA use decreased among younger women over time (Table 1 and 2), as did the number of DMPA starters across all age groups (Table 3). Barriers toward DMPA use across the study years may be users' and providers' increased "beliefs" in weight gain, in addition to the possible providers' concerns of DMPA's effect on BMD in younger women.

### Conclusion

The use of DMPA plays a minor role in the overall use of hormonal contraception in Norway.

The number of DMPA starters is declining. In particular, general practitioners are prescribing less DMPA to first-time users, whereas other professions show little or no change in prescription pattern over years with conflicting BMD data.

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## **Legends tables:**

Table 1. Estimated number of contraceptive depot medroxyprogesterone acetate (DMPA) users per 1000 women by age and calendar year. Norway 2006 through 2012 (‰).

Table 2. Estimated proportion of depot medroxyprogesterone acetate (DMPA) users out of all women using hormonal contraception by age and calendar year. Norway 2006 through 2012 (%).

Table 3: Depot medroxyprogesterone acetate (DMPA) starters by age and calendar year. Norway 2006 through 2012 (%).

Table 4: Percentage of depot medroxyprogesterone acetate (DMPA) starters switching method at study start (upper panel) and at study end (lower panel) by age and total. Norway 2006 through 2012 (%).

Table 5: Sex and profession of provider by age user of depot medroxyprogesterone acetate (DMPA). Norway 2006 through 2012 (%).

Table 1: Estimated number of contraceptive DMPA users per 1000 women by age and calendar year. Norway 2006 through 2012 (%)

Year/	2006	2007	2008	2009	2010	2011	2012
Age	‰	‰	‰	‰	‰	‰	‰
15-19	8.7	8.7	8.7	8.3	8.0	7.9	7.6
20-24	12.8	12.8	12.8	12.3	11.9	11.4	11.0
25-29	11.2	11.2	11.2	11.0	10.8	10.6	10.4
30-34	10.8	10.8	10.8	10.9	10.9	10.9	10.7
35-39	13.8	13.8	13.8	13.8	13.9	14.1	14.3
40-44	16.1	16.1	16.1	15.7	15.4	15.3	15.1
45-49	11.8	11.8	11.8	11.7	11.5	11.3	11.0
Total	12.3	12.3	12.3	12.1	11.9	11.7	11.6

Table 2: Estimated proportion of DMPA users out of all women using hormonal contraception by age and calendar year. Norway 2006 through 2012 (%).

Year/	2006	2007	2008	2009	2010	2011	2012
Age							
15-19	2.4	2.4	2.4	2.2	2.1	2.1	2.1
20-24	2.4	2.5	2.4	2.3	2.2	2.1	2.0
25-29	2.6	2.8	2.8	2.8	2.8	2.8	2.6
30-34	3.2	3.3	3.3	3.4	3.5	3.5	3.3
35-39	4.8	4.8	4.8	5.0	5.1	5.3	5.3
40-44	7.6	7.4	7.3	7.0	6.9	6.9	6.5
45-49	11.1	10.5	10.4	9.5	9.0	8.5	7.9
Total	3.8	3.9	3.9	3.8	3.8	3.8	3.6

Table 3: DMPA starters by age and calendar year. Norway 2006 through 2012 (%).

Year/	2006	2007	2008	2009	2010	2011	2012
Age	Age N=6 186 N		N=5 914	N=4 227	N=4 212	N=4 021	N=3 799
15-19	24.3	23.8	25.5	27.4	26.8	26.3	27.3
20-24	19.7	19.0	18.3	17.9	19.5	21.2	20.6
25-29	14.0	14.0	14.2	13.1	12.4	12.9	12.0
30-34	13.5	14.9	13.1	12.4	12.0	12.0	11.5
35-39	14.0	14.1	13.6	13.3	13.3	11.5	11.5
40-44	9.3	9.1	9.7	10.5	10.0	10.0	9.4
45-49	5.0	5.1	5.6	5.5	5.9	6.2	7.7
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0

Table 4: Percentage of DMPA starters switching method at study start (upper panel) and at study end (lower panel) by age and total. Norway 2006 through 2012 (%).

Age/	15-19	20-24	25-29	30-34	35-39	40-44	45-49	Total
	N=8 485	N=6 411	N=4 407	N=4 273	N=4 357	N=3 192	N=1 894	N=33 019
At study start								
1st registr. in NPD	24.3	16.3	28.0	33.6	44.6	55.4	66.9	32.6
Pause	32.3	47.0	42.9	37.6	29.0	21.5	14.1	34.8
OCs	33.4	23.9	14.0	12.2	10.5	8.0	4.5	19.1
Vaginal Ring	1.3	2.0	1.8	1.4	1.1	0.5	0.4	1.3
Patch	2.1	2.2	1.9	1.4	1.1	0.7	0.2	1.6
POPs	5.6	6.1	7.1	7.4	6.3	5.2	3.9	6.1
Implant	0.7	1.1	1.0	1.0	1.1	0.7	0.6	0.9
LNG-IUD	0.2	1.4	3.2	5.5	6.4	8.1	9.4	3.6
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
At study end								
Pause	54.0	62.3	67.1	64.8	64.3	66.1	78.1	62.7
OCs	21.2	14.4	11.1	8.1	5.3	3.7	1.6	11.9
Vaginal Ring	2.0	1.7	1.2	1.3	0.6	0.5	0.2	1.3
Patch	2.2	1.7	1.2	1.1	0.7	0.3	0.1	1.3
POPs	4.0	4.3	4.1	3.7	3.1	2.1	2.0	3.6
Continues with DMPA	14.0	13.3	13.0	17.8	22.3	23.9	15.5	16.4
Implant	2.3	1.4	0.7	0.9	0.8	0.4	0.1	1.2
LNG-IUD	0.4	0.7	1.8	2.3	2.8	3.0	2.5	1.6
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

 $<sup>1^{</sup>st}$  registr.  $-1^{st}$  registration in the Norwegian Prescription Database. OCs = oral contraceptives. POPs= progestin only pills. LNG-IUD=levonorgestrel intrauterine device.

Table 5: Sex and profession of provider by age user of DMPA. Norway 2006 through 2012 (%)

Age user/	15-19	20-24	25-29	30-34	35-39	40-44	45-49	Total
Provider	N=8 485	N=6 411	N=4 407	N=4 273	N=4 357	N=3 192	N=1 894	N=33 019
characteristics								
Sex								
Male	40.7	53.0	56.1	58.0	57.8	55.7	52.5	51.8
Female	59.3	47.0	43.9	42.0	42.2	44.3	47.5	48.2
Medical specialty								
No specialty	33.7	38.4	37.4	33.8	29.9	26.6	23.3	33.4
Gen. practitioners	38.9	47.6	49.1	50.0	51.9	46.8	37.2	45.8
Other specialists	3.5	4.8	4.7	4.9	3.4	3.0	2.4	4.0
Gynecologists	4.7	7.5	8.7	11.3	14.8	23.6	37.0	11.6
Public health nurse	19.2	1.6						5.3