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High coverage and adherence to dose intervals of the national school-based HPV vaccination program in Sweden during 2012–2019

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ABSTRACT

Background: Close monitoring of vaccination coverage is important for cervical cancer prevention efforts. The study aims to describe the HPV vaccination coverage by dose in girls eligible for HPV vaccination within Sweden's childhood immunization program and provide an estimate on dose timing compliance.
Methods: Vaccination records between 2012 and March 2019 were obtained for girls born in 2000–2006 from the vaccination registers in Sweden. The mid-time population counts for the respective birth cohorts were taken as the denominator. Full-dose coverage and coverage with at least one dose of the vaccine were calculated within the two-dose and three-dose regimen, by region. Dose compliance was calculated within the two-dose regimen.
Results: Vaccination coverage with at least one dose of the vaccine was >80% within birth cohorts 2001–2006. Full-dose coverage within a two-dose and three-dose regimen were 73.4% in birth cohorts 2004–2005, and 56.3% in birth cohorts 2000–2001, respectively. Little variation was observed in vaccination coverage between regions. Dose completion was 91.8%, and 72.8% in girls that initiated a two-dose and three-dose regimen, respectively. Among girls receiving a two-dose regimen, 93.0% received the second dose 6–12 months after dose one.
Discussion: In conclusion, high levels of HPV vaccination coverage were observed with little variation between regions. Dose timing compliance was particularly high in the two-dose regimen. To fully benefit from the impact of HPV vaccination, it will be important to further push the vaccination coverage and reach the girls that do not or partially engage with HPV vaccination.

1. Introduction

Cervical cancer is the fourth most common cancer in women worldwide (Sung et al., 2021). The role of HPV in the carcinogenesis of cervical cancer has been well established (Bosch et al., 2002; Dürst et al., 1983), and as a result, the first HPV vaccines became available in 2006. There are currently three HPV vaccines available worldwide: a bivalent vaccine (Cervarix™; GlaxoSmithKline) targeting HPV types 16 and 18, a quadrivalent vaccine (Gardasil™; Merck & Co., Inc., Rahway, NJ, USA) targeting HPV types 6, 11, 16 and 18, and a nonavalent vaccine (Gardasil-9TM; Merck & Co., Inc., Rahway, NJ, USA) targeting HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. HPV types 16 and 18 have been found in 70% of the cervical cancer cases, and HPV types 31, 33, 45, 52, and 58 are associated with an additional 20% of cervical cancer cases (Guan et al., 2012). Other licensed vaccines include one quadrivalent HPV (types 6, 11, 16, and 18) vaccine that was licensed in India in 2022 (Cervical cancer vaccine CERVAVAC: India's 1st indigenously developed vaccine - Top things [Internet]. Zee Business., 2022), and two bivalent HPV (types 16 and 18) vaccines that were licensed in China in 2019 (Cecolin® [Internet]. WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)., 2021), and 2022 (Walvax's Cervical Cancer Vaccine Gets Greenlight to

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Go to Market in China [Internet], 2022).

Many countries have introduced HPV vaccination since, mostly concentrated in high income countries (Bruni et al., 2021). Despite the HPV vaccination efforts, a global coverage of HPV vaccination of an estimated 15% has been achieved (Bruni et al., 2021). In Sweden, HPV vaccination became first available in 2006. From 2007 to 2011 Sweden offered opportunistic HPV vaccination to girls aged 13–17 years old at reduced costs, and about 25% of these girls were vaccinated (Tegnell et al., 2009; Leval et al., 2013). In 2012, a school-based free-of-charge HPV vaccination program was initiated where girls in grade 5–6 (starting with girls born in 1999) were offered vaccination as part of the national childhood immunization program. Vaccination coverage with at least one dose of the vaccine reached 80% from the start and has since gradually increased (coverage for the two-dose HPV vaccination regimen in girls born in 2008: 81%) (statistik-for-hpv-vaccinationer-andel-vaccinerade-flickor-tom-2015-12-31.pdf [Internet], 2022; Statistik för HPV-vaccinationer — Folkhälsomyndigheten [Internet], 2022). In addition to school-based HPV vaccination, a catch-up vaccination campaign was implemented, where girls born between 1993 and 1998 could get HPV-vaccinated free of charge. Around 50% of the eligible girls received the HPV vaccine within this organized catch-up program (statistik-for-hpv-vaccinationer-andel-vaccinerade-flickor-tom-2015-12-31.pdf [Internet], 2022). Following updated evidence (Human papillomavirus vaccines: WHO position paper, 2015), a 2-dose regimen given 6 months apart was adopted in the fall of 2015. The quadrivalent HPV vaccine was exclusively used in the programs until fall 2019, after which it was replaced by the nonavalent HPV vaccine (Statistik för HPV-vaccinationer — Folkhälsomyndigheten [Internet], 2022).

In 2020, the World Health Organization adopted a new Global Strategy for eliminating cervical cancer as a global health problem (Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: World Health Organization;, 2020). To achieve this goal; the cervical cancer incidence needs to drop below 4 cases per 100,000 women-years by 2030. The strategy itself captures a comprehensive triple-intervention approach where high HPV vaccination and cervical screening coverage needs to be achieved, as well as early diagnosis and effective management of the disease. Close surveillance of vaccine effectiveness on the population level will be crucial in the elimination project, both in terms of studying feasibility and coverage of differing dose regimens, as well as compliance to dose timing regimens in large-scale programs. In countries with excellent data gathering possibilities, high coverage and good compliance, the best type of extensive infrastructure for vaccine follow-up is generated. Such surveillance is particularly possible in a country such as Sweden which already has a strong data infrastructure in place since several decades. We therefore aim to describe the HPV vaccination coverage by dose in girls eligible for HPV vaccination within Sweden's childhood immunization program and provide an estimate on dose timing compliance, by using the nationwide registries.

2. Methods

2.1. Data resources and study population

We used the Swedish Total Population Register to retrieve the number of girls born in 2000–2006, i.e. those who were eligible to receive school-based HPV vaccination between the Fall of 2012 and March 2019. The mid-time population size over the studied period, i.e. at the end of 2015, was used to represent the size of the underlying population. We further used the Swedish Vaccination Register (SVEVAC) (Vaccination i Sverige mot HPV - RCC Kunskapsbanken [Internet], 2022)and the Swedish National Vaccination Register (NVR) (Nationella vaccinationsregistret — Folkhälsomyndigheten [Internet], 2021) to retrieve information on HPV vaccination by using the personal identification number and date of vaccination during 2012-March 2019 (number of doses of vaccine administered = 678,031). During 2012 and up to January 2013, HPV vaccinations were reported to SVEVAC, which required individuals' informed consent to be registered with identification. Vaccination records of individuals that did not provide informed consent were reported to SVEVAC, but as anonymous vaccinations. The proportion of anonymous registrations was 25% in SVEVAC in 2012 (Vaccination i Sverige mot HPV - RCC Kunskapsbanken [Internet], 2022). This affected only one of our targeted birth cohorts, 1999, which was mostly vaccinated in 2012 and recorded in SVEVAC with significant number of anonymous vaccinations. It hindered the ascertainment of dose identification which makes the assessment of vaccine coverage potentially inaccurate. Therefore, birth cohort 1999, although eligible for school-based vaccination, was excluded from the analysis. From January 2013, HPV vaccinations within the school-based program are fully reported to the Swedish National Vaccination Register, which is a mandatory reporting system with personal identification number. All identified HPV vaccinations in SVEVAC and National Vaccination Registers up to March 2019 were thus included in this study. Vaccinations given outside of the school-based HPV vaccination program continued to be registered in either SVEVAC and/or NVR and were included in this study as such. An overview of the mode of HPV vaccine delivery and registries recording HPV vaccination is shown in Fig. 1.

2.2. Statistical analysis

We calculated the quadrivalent HPV vaccine coverage with the full number of doses, as well as at least one dose (1+), within the three- and two-dose regimens, by birth cohort and region of Sweden (North, Middle, Stockholm Gotland, West, Southeast, and South of Sweden). This was calculated as the number of girls vaccinated with >=1 dose, 2-doses given as part of the two-dose regimen, or three-doses given as part of the three-dose regimen, divided by mid-time population size over the studied period. Number of doses of each individual was ascertained by identifying the valid number of times receipt of the vaccine was recorded in the registers, i.e. an independent dose needed to be at least two weeks apart from another dose, to avoid double counting of the same dose (Herweijer et al., 2014). Dose completion was calculated as percentage of girls completing 2- and 3-dose schedule with 2 and 3 doses respectively. Among girls who received two doses in the two-dose regimen, we evaluated the adherence to the recommended time interval between doses thereby differentiating between time periods: <6 months, >=6 months and < 12 months, and >=12 months. Adherence to time interval >=5 months and < 12 months, was also evaluated. This as a third dose of the vaccine should be given if the interval between dose one and two is less than five months (World Health Organization, 2017). We used SAS 9.4 for data management and analysis.

3. Funding and ethical permit

Ethical approval for this study was granted by the Swedish ethics review authority Etikprövningsmyndigheten and is on file with Karolinska Institutet. Informed consent from the study participants was not required, due to the population-based nature of the study. The corresponding author further warrants that the study met the institution's or the data curator's guidelines for protection of human subjects concerning safety and privacy. The study was funded by MSD.

4. Results

The underlying cohort consisted of 387,981 girls who were born during 2000–2006 and residing in Sweden at the end of 2015 (Appendix Table A).

The coverage of quadrivalent HPV vaccination with at least one dose stabilized at or above 80% from birth cohort 2001 to 2006 (range: 82.1% to 83.1%) (Table 1, Supplemental Fig. 1). Overall, there was little variation in coverage across the six regions in Sweden (Appendix Tables B – D).

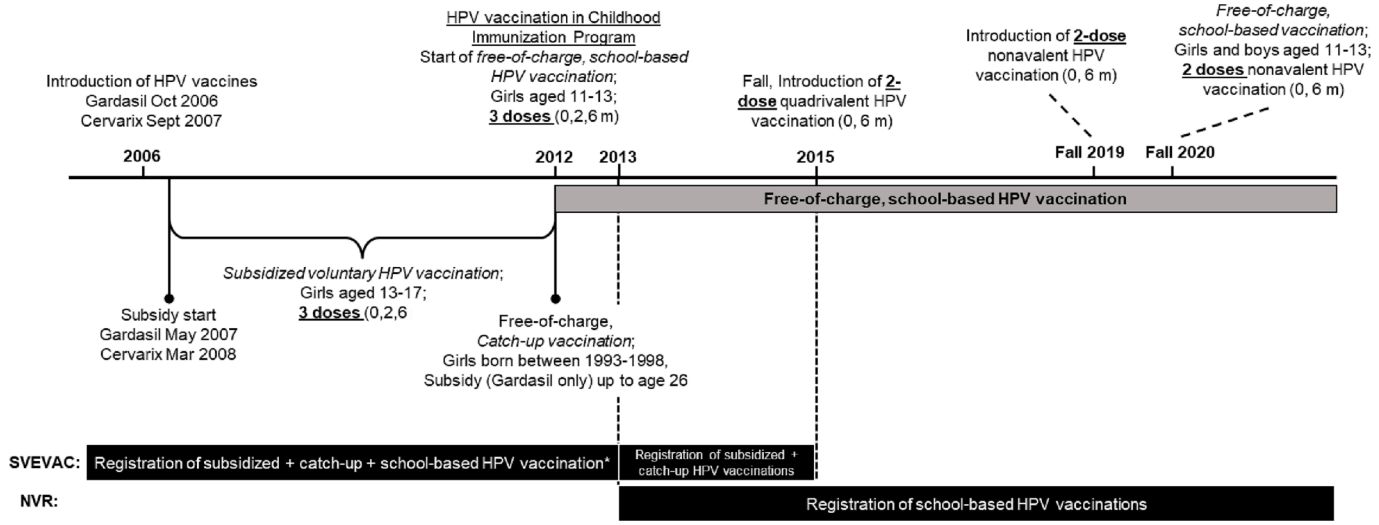

Fig. 1. HPV vaccination in Sweden. * Recording of school-based HPV vaccination was done to SVEVAC until Dec 31, 2012 after which the recording of school-based HPV vaccination was moved to the NVR. Recording of subsidized and catch-up HPV vaccinations was done to SVEVAC until Dec 31, 2015 after which SVEVAC was no longer in use to record HPV vaccinations. SVEVAC = Swedish vaccination register, NVR = Swedish national vaccination register.

Table 1
Gardasil coverage by number of doses (administered between 2012 and 08-March-2019), as part of the school-based vaccination program, by region, for female birth cohorts 2000–2006.

Birth cohort	Population denominator, N	>=1-dose coverage, n (%)	2-dose coverage, n (%)*	3-dose coverage, n (%)	Recommended policy
2000[a]	52,403	38,034 (72.6%)	4827 (9.2%)	28,157 (53.7%)	3-dose
2001[a]	52,446	43,071 (82.1%)	4542 (8.7%)	30,888 (58.9%)	3-dose
2002[b]	54,745	44,759 (81.8%)	12,036 (22%)	30,666 (56%)	3-dose until fall 2015
2003[b]	55,956	45,668 (81.6%)	39,961 (71.4%)	2477 (4.4%)	2-dose
2004[c]	56,671	44,731 (78.9%)	41,196 (72.7%)	350 (0.6%)	2-dose
2005[c]	57,101	46,332 (81.1%)	42,355 (74.1%)	151 (0.3%)	2-dose
2006[c]	58,659	48,736 (83.1%)	34,221 (58.3%)	54 (0.1%)	2-dose

N = population data in 2015 (mid-time between 2012 and 08-March-2019), n = number of vaccinated, %=vaccination coverage (n/N).
* note that this category is mutually exclusive with the category 3-dose coverage, i.e. an individual can only appear in one of these two columns.
[a] birth cohorts targeted by the school-based 3-dose vaccination program with Gardasil.
[b] birth cohorts at the transition from the school-based 3-dose to the 2-dose vaccination program with Gardasil.
[c] birth cohorts targeted by the school-based 2-dose vaccination program with Gardasil.

The percentage of girls receiving exactly three doses and exactly two doses suggested that the birth cohorts 2000 and 2001 were under the three-dose regimen, birth cohorts 2002–2003 were at transition period from three- to two-dose regimen, and birth cohorts 2004 and onwards were under almost exclusively two-dose regimen (Table 1). Full-dose coverage within the three-dose regimen was 56.3% in birth cohorts 2000–2001, and full-dose coverage within the two-dose regimen was 73.4% in birth cohorts 2004–2005 (Table 1, Fig. 2). When comparing the dose-completion between three- and two-dose regimens in girls who received the first dose, birth cohorts 2000–2001 had a three-dose completion of 72.8%, and birth cohorts 2004–2005 had a two-dose completion of 91.8% (Fig. 2). As of the end of study follow-up, birth cohort 2006 had not finished the second dose administration; this birth cohort was not included in the dose completion analysis.

Among girls who were vaccinated under two-dose regimen, i.e. birth-cohort 2004–2006, and received the second dose, 93.0% received the second dose between 6 and 12 months after the first dose, which complied with the recommended 2-dose interval (Table 2, Fig. 3). Additionally, 98.6% received the second dose between 5 and 12 months after the first dose, which complied to minimum interval for two-dose vaccination.

5. Discussion

The following study showed that the full-dose HPV vaccination coverage was greater than 70% in birth cohorts of girls eligible for two-dose HPV vaccination and over 50% for birth cohorts of girls eligible for historical three-dose HPV vaccination. Coverage with at least one dose of the HPV vaccine was generally greater than 80%, with only little variations between regions, and within the birth cohorts of girls eligible for HPV vaccination within the childhood vaccination program of Sweden. The transition from a three-dose to a two-dose HPV vaccination schedule in the fall of 2015 mainly affected birth cohorts 2002–2003, after which higher dose compliance was seen. Among the more than 90% of the girls that initiated two-dose HPV vaccination completed their vaccination series, 90% did so within the recommended time interval between dose one and two.

Comparison of HPV vaccine uptake across regions is challenging as various aspects need to be considered, such as the mode of vaccine delivery, number of doses received, and the target population. Norway had reported on a vaccination coverage with at least one dose of the vaccine of 82.5% within birth cohorts 1997–2002 consisting of girls eligible for school-based HPV vaccination at the ages of 10–12 (Bjerke et al., 2021). In Denmark, the vaccination coverage with at least one dose of the vaccine has been fluctuating between 94% and 55% for cohorts of girls born between 1997 and 2006 that were eligible for HPV vaccination at age 11–12 (Hansen et al., 2020). The previous decrease in vaccination uptake has been linked to scares related to the safety of the vaccine that was spread through social media and is on the way to recovery, likely partially due to a systematic campaign performed by national health

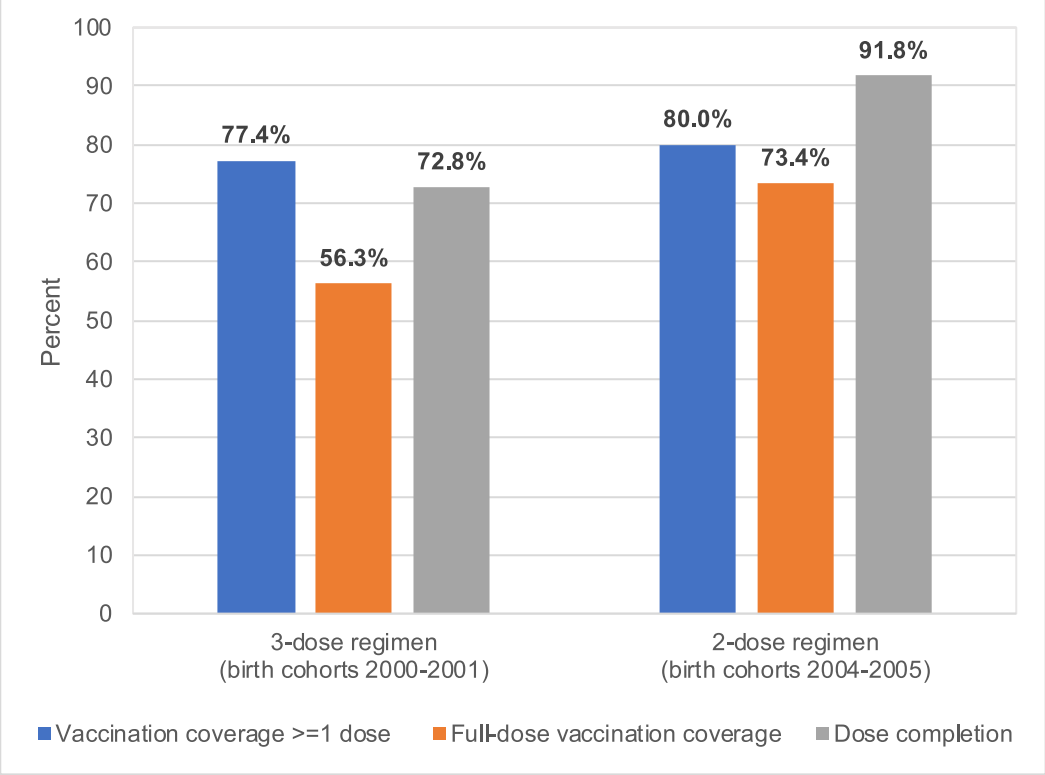

Fig. 2. Full-dose vaccination coverage, coverage with at least one dose of the vaccine, and percentage of full-dose completion among girls who received the first dose, by birth cohorts in 3-dose (2000 and 2001) and 2-dose (2004 and 2005) regimen. The denominators for vaccine coverage >=1 dose and full-dose coverage was the number of all girls in eligible birth cohorts; The denominator for dose completion was the number of girls vaccinated with at least one dose.

Table 2
Compliance with 6-month dose interval, among girls vaccinated with exactly 2-doses.

Birth cohort	Received 2 doses (n/N) %	Time (months) between dose 1 and dose 2		
		<6 months (<180 days) (n, %)	≥ 6 months and < 12 (n, %)	≥12 months (n, %)
2003	39961/55956 = 71.4%	3709 (9.3%)	36,083 (90.3%)	169 (0.4%)
2004	41196/56671 = 72.7%	2983 (7.2%)	38,020 (92.3%)	193 (0.5%)
2005	42355/57101 = 74.1%	2121 (5.0%)	40,067 (94.6%)	167 (0.4%)
2006	34221/58659 = 58.3%	1595 (4.7%)	32,551 (95.1%)	75 (0.2%)
2003–2006	Not reported[a]	10,408 (6.6%)	146,721 (93.0%)	604 (0.4%)

N = population data in 2015 (mid-time between 2012 and 08-March-2019), n = number of vaccinated.

[a] The combined statistic for 2003–2006 was not reported as not all girls in birth cohort 2006 have had the opportunity to receive the second dose.

services (Hansen et al., 2020). Australia's national statistics reported a full-dose and vaccination with at least one dose vaccination coverage of 80.2% and 88.9% in girls that had turned 15 years in 2017 (Hull et al., 2022). A regional study done in Australia at the secondary school-level showed a median completion rate of 94.0% in girls that initiated vaccination at secondary schools (Sisnowski et al., 2021). These vaccination rates with at least one dose of the vaccine observed in school-based vaccination programs in high-income countries such as Norway, Denmark, and Australia, are in the same range as the vaccination rates with at least one dose found in the current study based on a cohort of girls born between 2000 and 2006 that were eligible for school-based HPV vaccination. The recently published numbers from the WHO/UNICEF on national HPV immunization coverage, showed a full-dose coverage and coverage with at least one dose of 53%, and 67%, respectively, in high-income countries and shows that Sweden belongs to one of the countries with highest HPV vaccination coverage in the target group of girls age 9–14 years old (Bruni et al., 2021).

As expected, the national vaccination coverages reported by the Swedish Public Health Agency (Statistik för HPV-vaccinationer — Folkhälsomyndigheten [Internet], 2022) were generally comparable to what was shown in the current study in girls born in 2004–2006, despite a trend of slightly higher (around 5% higher) vaccination coverage reported by the national statistics. The reasons for this discrepancy include both different choices of denominators and the amount of follow-up time included. Over the time that girls born in each year being eligible for the vaccination, the size of the birth cohort constantly changed due to migration and death. There is therefore no precise objective choice of the denominator when calculating the vaccine coverage; rather it will vary according to study exact timing and period. Also, the gross national statistics are currently updated to the end of 2021 as compared to March 2019 in this study. Therefore, the former statistics included more vaccinations which increases the overall coverage by end of 2021, but the information is less detailed than the more in-depth analyses presented here. Also, to our knowledge, this is the first report of very good adherence to timing of doses in an entire national population, which proves how well HPV vaccination can be organized when delivered through a comprehensive school-based program.

Previous research has shown that, compared to other modes of vaccine deliveries such as opportunistic and catch-up vaccination, uptake of HPV vaccination was most effective in school-based HPV vaccination programs free-of-charge, with minimal inequities in vaccine uptake in terms of ethnic background and socioeconomic characteristics (Cervical cancer vaccine CERVAVAC: India's 1st indigenously developed vaccine - Top things [Internet], 2022; Fisher et al., 2014; Hansen

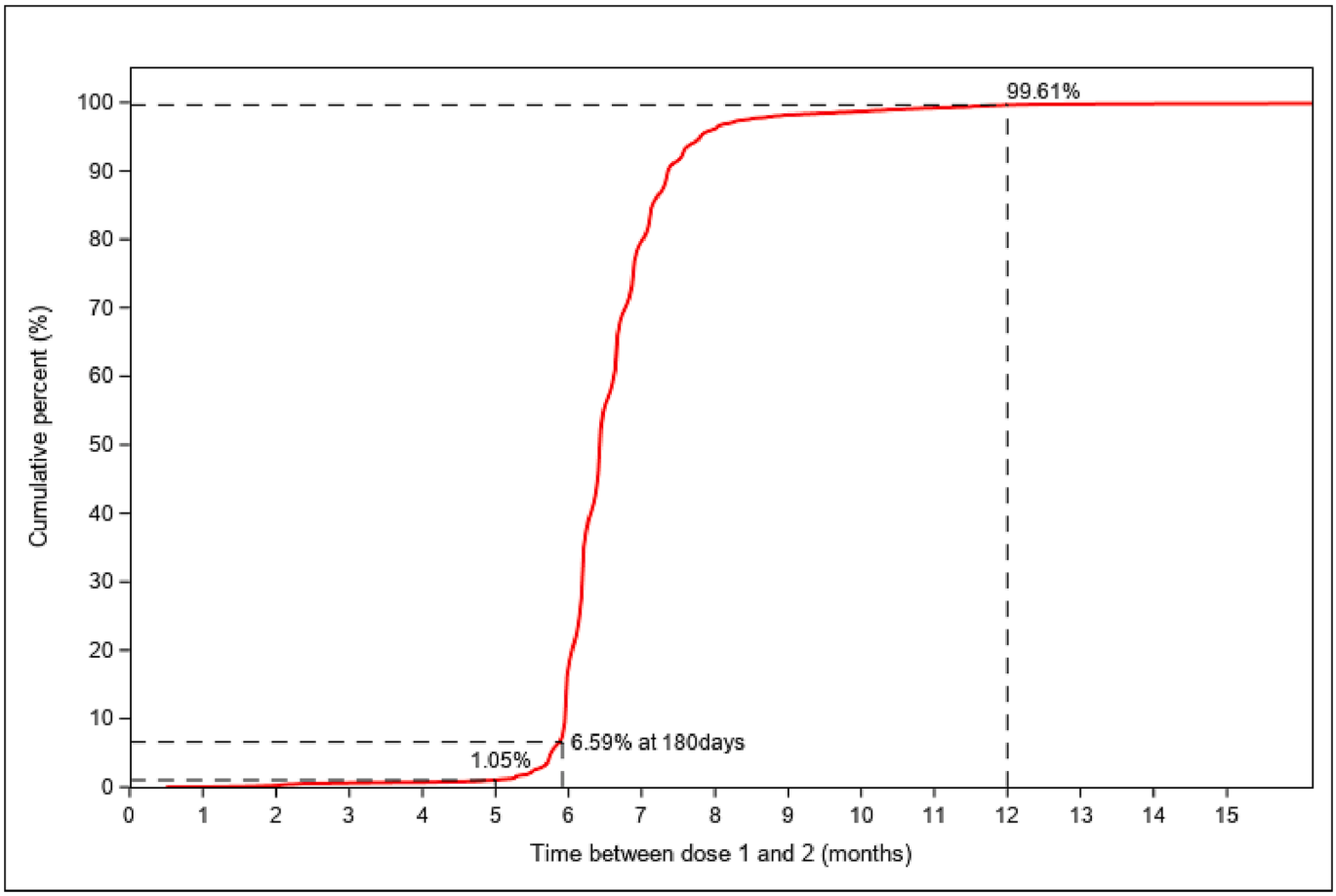

Fig. 3. Cumulative percent of time between dose one and two in those girls born 2003–2006 who received exactly two doses of the HPV vaccine.

et al., 2020; Hull et al., 2022; Wang et al., 2019). In our study, there was still a proportion of girls eligible for school-based HPV vaccination that chose not to engage or fully engage with vaccination. This highlights that, in a high-income country such as Sweden with an effective school-based HPV vaccination program in place, there is still room for improvement to increase vaccine uptake. Further research will be necessary to identify factors that affect the likelihood of getting vaccinated such as an in-depth assessment of socioeconomic factors, concerns about vaccine safety, and familial history of diseases of relevance to cervical cancer. As such, more resources can be allocated to reach this group of girls and their parents.

Strengths of this register-based study include the use of data capturing the entire country, thereby enabling an estimation of national HPV vaccination coverage. We were able to precisely define the denominator of girls eligible for HPV vaccination and further stratify the coverage by region due to individual linkages of the vaccination data to demographic and population registries. In addition, the use of individual level data ensured the complete ascertainment of HPV vaccination by dose.

Limitations include the higher percentage of anonymous registration of HPV vaccinations to SVEVAC in 2012, which mainly affected birth cohort 1999 leading to an underestimation of HPV vaccination coverage. This birth cohort was subsequently excluded from the analyses. Furthermore, both SVEVAC and the national vaccination register do not include explicit information on number of doses. Subsequently, an algorithm based on date of vaccine delivery has been developed similarly to several previous comprehensive studies on HPV vaccination (Herweijer et al., 2014). The algorithm is expected to have a high validity given the high quality of reporting to the vaccination registries, and we excluded vaccination dates that were less than two weeks apart. Also, a limitation is that we included data up until end of 2019, and the coverage and dose timing compliance during the pandemic should be a next area for priority of study.

In conclusion, with its organized school-based vaccination program, Sweden has an effective infrastructure in place with high levels of HPV vaccination coverage with little variation between regions. Over 90% of girls vaccinated with a 2-dose schedule were vaccinated within the recommended time interval. To fulfil the target for HPV vaccination to eliminate cervical cancer, it will be important to further push the national HPV vaccination coverage and reach the unvaccinated group. The high-quality performance and systematic data gathering of the Swedish program generates an excellent data collection infrastructure for future large-scale, long-term follow up of vaccine effectiveness and public health outcomes related to different dose regimens.

CRediT authorship contribution statement

Jiangrong Wang: Conceptualization, Methodology, Software. **Eva Herweijer:** Writing – original draft, Software. **Sara Nordqvist Kleppe:** Data curation, Writing – original draft. **Susanne Hartwig:** Conceptualization, Methodology, Software, Supervision. **Christine Velicer:** Conceptualization, Writing – review & editing. **Carol Koro:** Supervision. **Karin Sundström:** Conceptualization, Methodology, Software, Supervision.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: The study was funded by Merck and Co., LLC. KS has received

unrestricted research grants for other studies on HPV-vaccination in Sweden. SH and CV are employees of Merck and Co., LLC. CK was previously an employee of the study Sponsor.

Data availability

The authors do not have permission to share data.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pmedr.2023.102342.

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