

Comparing Annual VTE Impact (estimated) across 2nd - 4th Generation Combination Hormonal Contraceptives in the U.S. 2013 - All Users

Analysis calculates the risk for each generation of CHC based on prescription data from IMS Health & CHC Contraception Use Report 2013 - Women (aged 15-44)

Data Points - Risk Fundamentals

Total Women in US aged 15-44 ³	61,000,000
Total Women in US aged 15-44 using contraception ³	37,500,000
Women (aged 15 - 44) in US using either Pill / Patch / Ring during 2013 per CDC - All CHC users ^{3,4}	10,800,000
1st & 2nd Generation CHC users in 2013 ^{3,4}	7,800,000
3rd Generation CHC users in 2013 ^{3,4}	1,000,000
4th Generation CHC users in 2013 ^{3,4}	2,000,000
DVT Mortality Rate - 6% ²	6%
PE Mortality Rate - 12% ²	12%

Annual Estimated Impact of Blood Clots related to the use of Combination Hormonal Contraceptives - Pills, Patch & Ring

Exposure Category by Generation of CHC ¹	Estimated Blood Clot incidence (per 10,000 women per year of use) ¹	Number of Women ^{3,4}	VTE "Blood Clot" Cases Average	DVT Events (2/3 of VTE cases are DVT) ² Average	DVT Deaths 6% Mortality Rate ² Average	DVT Deaths per 100,000 Users Average	Pulmonary Embolism (PE) Events (1/3 of VTE Cases are PE) ² Average	PE Deaths 12% Mortality Rate ² Average	PE Deaths per 100,000 Users Average	DVT & PE Deaths Combined per 100,000 Users Average	Increased Risk of Death over non CHC users & not pregnant
Women not using a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000	23,500,000	3,525	2,350	141	0.6	1,175	141	0.6	1.2	same
1st & 2nd Gen CHC - Progestin Levonorgestrel, Norethisterone, Norgestrel or Norgestimate	About 5-7 out of 10,000	7,800,000	4,680	3,120	187	2.4	1,560	187	2.4	4.8	400%
3rd Gen. CHC - Progestin Etonogestrel (NuvaRing) or Norelgestromin (Patch)	About 6 - 12 out of 10,000	1,000,000	900	600	36	3.6	300	36	3.6	7.2	600%
4th Gen. CHC - Progestin Drospirenone (i.e. Yasmin, Yaz) or Desogestrel	About 9 - 12 out of 10,000	2,000,000	2,100	1,400	84	4.2	700	84	4.2	8.4	700%
Total Generation 1, 2, 3 & 4 CHCs (Pills, Patch & Ring)			7,680	5,120	307	10.8	2,560	307	10.8	21.6	

Calculations used to establish risk of VTE, DVT & PE

Venous Thromboembolism (VTE) Impact:

Calculation used to estimate the number of women that will develop a VTE due to the increased estrogenic effects of a particular generation of Combined Hormonal Contraceptive (CHC).

$$\text{VTEs from a particular generation of CHC} = \text{Number of Users of that CHC} * (\text{EMA Estimated VTE Incidence Rate}^1 \text{ for that CHC Generation}) / 10,000$$

Deep Vein Thrombosis (DVT) Impact:

Calculation used to estimate the number of women that will develop DVT due to the increased estrogenic effects of a particular generation of Combined Hormonal Contraceptive (CHC).

2/3 of VTEs are DVT.² So (using the previously calculated "VTE's from a particular CHC")

$$\text{DVT from a particular CHC} = (2/3) * \text{VTEs from a particular CHC}$$

Calculation used to estimate the number of women who will DIE annually due to a DVT caused by the increased estrogenic effects of a particular generation of CHC.

The Mortality rate of DVT is 6%.² So for each CHC (using previously calculated "DVTs from a particular CHC")

$$\text{Deaths from DVTs for a particular CHC} = \text{DVTs from a particular CHC} * 0.06$$

Pulmonary Embolism (PE) Impact:

Calculation used to estimate the number of women that will develop PE due to the increased estrogenic effects of a particular generation of Combined Hormonal Contraceptive (CHC).

1/3 of VTEs are PEs.² So (again, using the previously calculated "VTEs from a particular CHC")

$$\text{PEs from a particular CHC} = 1/3 * \text{VTE's from a particular CHC}$$

Calculation used to estimate the number of women who will die annually due to a PE caused by the increased estrogenic effects of a particular generation of CHC.

Mortality rate from PEs is 12%.² So for each CHC (using previously calculated "PEs from a particular CHC"),

$$\text{Deaths from PEs for a particular CHC} = \text{PEs from a particular CHC} * 0.12$$

References

- European Medicines Agency. 2013. Benefits of combined hormonal contraceptives (CHCs) continue to outweigh risks – CHMP endorses PRAC recommendation., Press Release dated 11/22/2013. Retrieved from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/20/13/11/news_detail_001969.jsp&mid=WC0b01ac058004d5c1
- A. L. Nelson, MD & C. Cwiak, MD, MPH, (2011). Combined Oral Contraceptives (COCs). In Hatcher, R. D., MD, Trussell, J., PhD., Nelson, A. L., M.D., Cates Jr., W., M.D., MPH, Kowal D., M.A., P.A., Policar, & M. S., MD, MPH. Contraception Technology (20th Edition). Chapter 11, (pp.249-275). Bridging the Gap Communications.
- CDC Survey NCHS Data Brief, Number 173, December, 2014 Retrieved from <http://www.cdc.gov/nchs/data/databriefs/db173.pdf>.
- Individual pill, patch and ring data was sourced from IMS Health's National Prescription Audit, Hormonal Birth Control Products, May 2001 - Dec 2014, Measures include NRx, TRx, Layout: USC5, Mol, Brand/Generic, Product, Form and Strength

NOTE: DVT death outcome other than a PE are not included in final totals for discussion as a reliable source for this data has not been found. The final total of VTE related deaths will likely increase from what is currently shown for PE deaths.

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