

Estimate of Number of U.S. Women Harmed in 2013
Comparing VTE Risk at Scale across 1st - 4th Generation CHC's in the U.S.

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

Risk Fundamentals	
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
Unit of measure - per 10,000 woman years	10,000
2/3 of VTE cases are Deep Vein Thrombosis (DVT's) ²	0.6667
1/3 of VTE cases are Pulmonary Embolism's (PE's) ²	0.3333
DVT Mortality Rate - 6% ²	6%
PE Mortality Rate - 12% ²	12%

Calculations of Number of U.S. Women Harmed in 2013

Exposure Category by Generation of CHC ¹	Estimated incidence per 10,000 women-yr ¹	EMA Range		Number of Women	(VTE) Cases Avg. ¹	DVT 2/3 of VTE cases ²	DVT Deaths 6% Mortality Rate ²	Embolism's 1/3 of VTE Cases ³	12% Mortality Rate ²
		Low	High			Avg. ²	Avg. ²	Avg. ³	Avg. ³
1st & 2nd Gen CHC - Progestin Levonorgestrel, Norethisterone, Norgestrel or Norgestimate	5-7 out of 10,000	5	7	7,800,000	4,680	3,120	187	1,560	187
3rd Gen. CHC - Progestin Etonogestrel (Ring) or Norelgestromin (Patch)	6 - 12 out of 10,000	6	12	1,000,000	900	800	36	300	36
4th Gen. CHC - Progestin Drospirenone (i.e. Yasmin, Yaz) or Desogestrel	9 - 12 out of 10,000	9	12	2,000,000	2,100	1,400	84	700	84
ONLY CHC USERS: Total Gen1, 2, 3 & 4 CHC's (Pills, Patch & Ring)					7,680	5,320	307	2,560	307

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/2013/11/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.
- NCHS Data Brief, Number 173, December, 2014 Retrieved from <http://www.cdc.gov/nchs/data/databriefs/db173.pdf>. CDC Survey NCHS Data Brief, No. 173, December 2014
- 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, Form1 and Strength

NOTE: DVT deaths (MI's, Strokes, that don't include a PE are not included as we do not yet have a source for this data. VTE related deaths will likely increase the numbers currently stated in PE deaths.