Pill scares: What causes them and how do we prevent them

Øjvind Lidegaard

First global conference in contraception, reproductive and sexual health
Copenhagen, May 25, 2013

Department of Gynaecology, Rigshospitalet
University of Copenhagen

OC generations according to oestrogen dose and progestogen type

Progestogen generation

	1 Estrans NETA	2 Levonor-gestrel	"2" Norges-timate	3 Deso-gestrel	3 Gesto-dene	4 Dros-pirenone
50 high	High dose		EVRA NuvaRing		-	-
30-40 mid	1st	+	2nd +	+	+	+ 4th
20 low	-	-	-	3rd	+	+
E2/DNG	+	-	-	-	-	
POC	+	LNG-IUS		+		
				+	Implant	

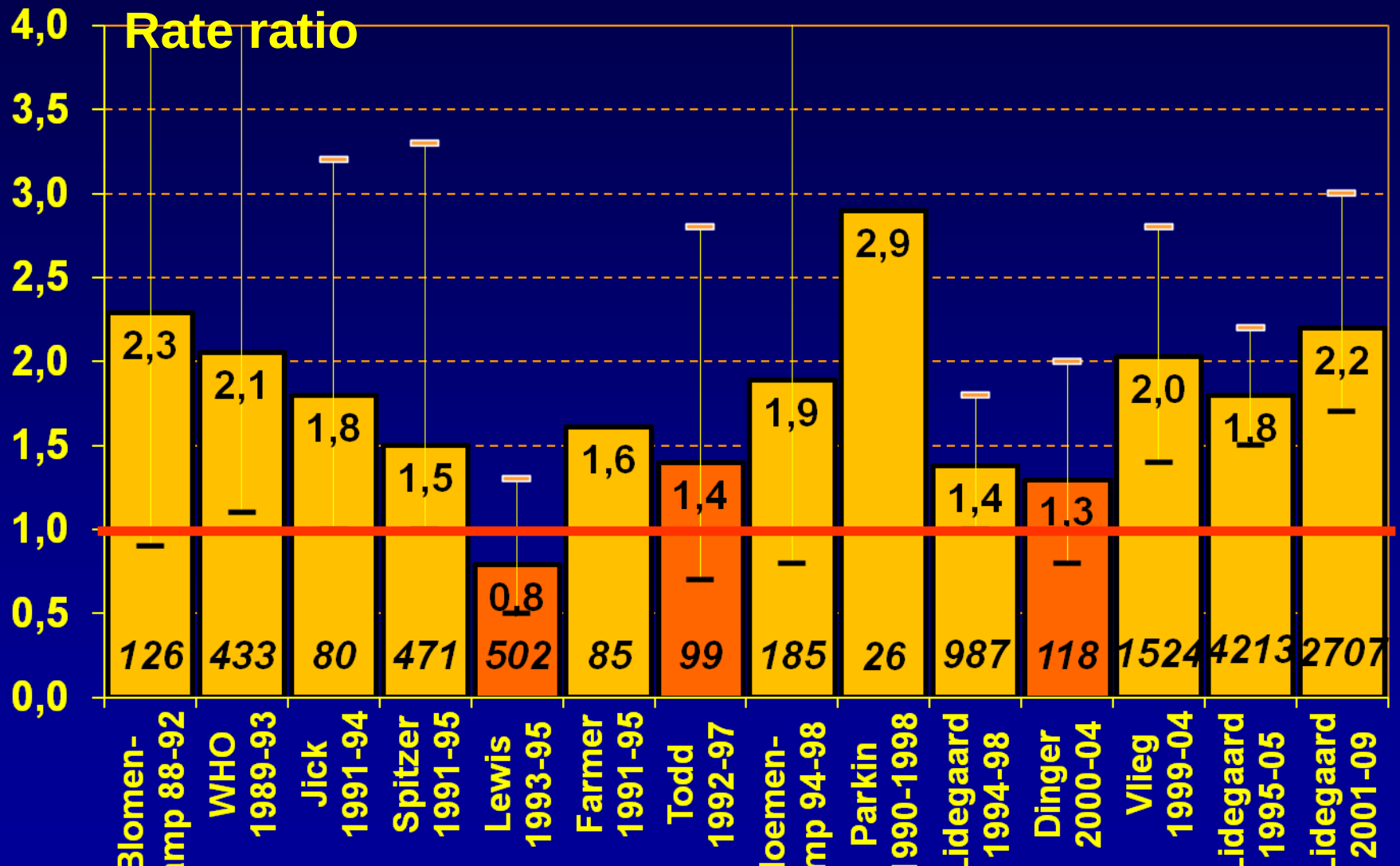
Consumer dissatisfaction

- Generally, consumers become dissatisfied, if the promises a manufacturer gives not hold true.
- Probably, users of hormonal contraception form no exception from that general rule.
- Let us consider the two most recent pill scars, the scare in mid 1990's with 3rd generation OC, and the crisis in France this year, with Diane and 4th generation OC with drospirenone.

Pill crisis in the mid 1990's

- When 3rd generation OC were launched in late 1980's, they were marketed as not only less androgenic, but also as safer than the older products with respect to venous thrombosis.
- Then successive studies were published:

3rd versus 2nd generation COC



Pill crisis in the mid 1990's

- When 3rd generation OC were launched in late 1980's, they were marketed as not only less androgenic, but also as safer than the older products with respect to venous thrombosis.
- Then successive studies were published.
- Women realised, that the promises they were told, did not hold true.
- And we got the crisis.

The current crisis

	VTE no	Risk /10,000	Rate ratio DRSP/2nd gen	
Dinger[07]	118	9.1	1.0 (0.6-1.8)	4th/2nd
Seeger[07]	57	13.0*	0.9 (0.5-1.6)	4th/???

BMJ

Hormonal contraception and risk of venous thromboembolism: national follow-up study

Øjvind Lidegaard, professor,[1] Ellen Løkkegaard, consultant,[2] Anne Louise Svendsen, statistician,[3] Carsten Agger, data manager[4]

[1]Gynaecological Clinic, Rigshospitalet, Copenhagen University, DK-2100 Copenhagen, Denmark

ABSTRACT

Objective To assess the risk of venous thrombosis in current users of different types of hormonal

BMJ

RESEARCH

The venous thrombotic risk of oral contraceptives, effects of oestrogen dose and progestogen type: results of the MEGA case-control study

A van Hylckama Vlieg, research fellow,[1] Helmerhorst, professor of clinical epidemiology of fertility,[1,2] J P Vandenbroucke, professor of clinical epidemiology,[1] C J M Doggen, research fellow,[1] F R Rosendaal, professor of clinical epidemiology, head of department[1,3,4]

risk of venous thrombosis than oral contraceptives with levonorgestrel. Progestogen only pills and hormone releasing intrauterine devices were not associated with

VTE and drospirenone

	VTE no	Risk /10,000	Rate ratio DRSP/2nd gen	
Dinger[07]	118	9.1	1.0 (0.6-1.8)	4th/2nd
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Vlieg[09]	1,524	na	1.7 (0.7-3.9)	4th/2nd
Lidegaard[09]	4.213	7.8	1.6 (1.3-2.1)	4th/2nd

Expert Meeting on the
Benefits and Risks of Oral Contraceptives

Saturday, 12 December 2009, 11am to 4 pm

Maritim Pro Arte Hotel, Friedrichstrasse 151, Berlin

Faculty:

Prof. Corinne de Vries Dept Pharmacy & Pharmacology, Bath Univ, UK

Dr. Jürgen Dinger

Dr. Diana Mansour Gynaecologist, Contraception and sexual health Newcastle,

Prof. Samuel Shapiro

Dr. Anne Szarewski Clinical Officer family planning, Margaret Pyke, UK

Dr. Carolyn L. Westhoff Director, division of Family Planning and Preventiv

Invitation sent out by Bayer in November 2009

Critique

REVIEW

Risk of venous thromboembolism among users of oral contraceptives: a review of two recently published studies

Samuel Shapiro, Jürgen Dinger

Abstract

Background Two recent studies, a cohort study from Denmark, and a case-control study from The Netherlands, have reported increased risks of venous thromboembolism (VTE) among users of oral contraceptives (OCs) containing desogestrel, gestodene, drospirenone and cyproterone, relative to the use of levonorgestrel.

Critique In the Danish study the comparisons were not valid. (1) VTE risk is highest soon after commencement of OC use, and duration of use was underestimated for levonorgestrel users, but not for drospirenone users; for the remaining compounds duration was only slightly underestimated. The underestimation for levonorgestrel resulted in systematic overestimation of the relative risks for the compared OCs. (2) Duration was also incorrectly estimated: only the duration of current use, *not duration of all episodes of use* was relevant to VTE risk. (3) Confounding was not adequately controlled.

In The Netherlands study the comparisons were not valid. (1) The relative risk for drospirenone versus levonorgestrel was not statistically significant. (2) Extensive publicity had been given to the risk of VTE among users of desogestrel, gestodene, drospirenone and cyproterone: information bias and detection bias were therefore likely. (3) Inadequate allowance was made for duration of use. (4) The combination of two different control groups, both of them likely to have been biased, into a single category was not valid.

Conclusion The best evidence continues to suggest that the increased risk of VTE in OC users is a class effect, dependent on the estrogen dose and duration of use, and independent of the progestogen used.

Keywords combined oral contraceptives, progestogen, risk assessment, venous thromboembolism

J Fam Plann Reprod Health Care 2010; **36**(1): 33–38
(Accepted 25 November 2009)

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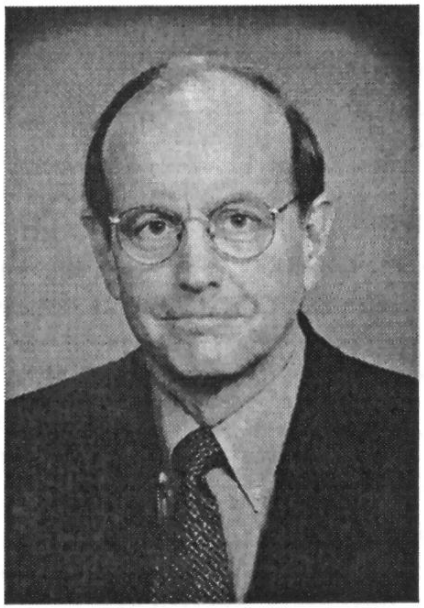
Conclusion The best evidence continues to suggest that the increased risk of VTE in OC users is a class effect, dependent on the estrogen dose and duration of use, and independent of the progestogen used.

An editor

Epidemiologic Research Using Administrative Databases

Garbage In, Garbage Out



David A. Grimes, MD

Administrative databases stem from claims made for services by health care providers and institutions.[1] Simply put, they are billing systems. These databases were created for reasons other than epidemiologic research—a key limitation. Data fields commonly include only basic demographic information, drug dispensing, provider visits, and hospitalization. Examples of administrative databases often used by researchers include Medicare, Medicaid, and those of health maintenance organizations such as Kaiser Permanente.

Vital records, such as birth certificates, represent another administrative database commonly used for epidemiologic research.[2,3] Again, these data are collected for civil and legal purposes, not for research.

Research using administrative databases has important strengths and weaknesses. Sample sizes are often large, which provide power to find differences. Those enrolled may be representative of the community of interest. Recording of drug prescriptions occurs contemporaneously, which

Grimes, Obstet Gynecol Nov 2010, 116: 1018-19

Research using vital records should be limited to simple descriptive reports with caveats about data accuracy. Using birth certificate information for epidemiologic analyses is inappropriate because of well documented deficiencies in information quality[3]. Similarly, epidemiologic research using adminstrative databases, such as the Danish National Patient Registry, must at a minimum validate each reported outcome by chart review[9] or by patient interview.

In recent decades, the computer science concept of "GIGO" ("garbage in, garbage out") has somehow come to mean "garbage in, gospel out[10]." When computer software tackles a large database, many accept the "computerized" output as trustworthy, regardless of the quality of the input. Sadly, no fancy statistical machinations can compensate for poor-quality data. Publications relying on unconfirmed database reports of venous thromboembolism should be ignord.

Grimes. Obstet Gynecol 2010; 116: 1018-19

An editor

Epidemiologic Research Using Administrative Databases

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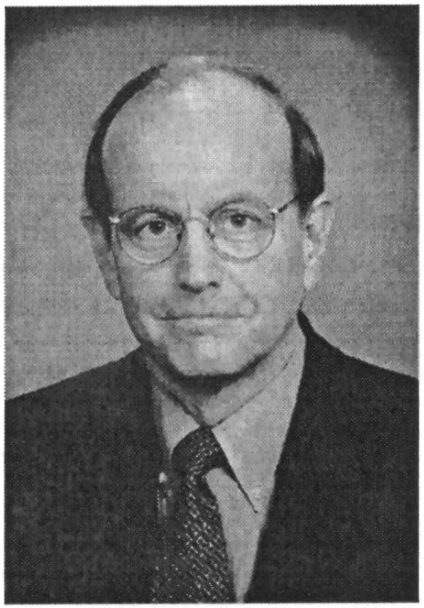

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Financial Disclosure

Dr. Grimes serves as a consultant (DSMB member) for Bayer.

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OC and VT: Methods

National Health Registry (>1977)

VT diagnoses,

Previous CaVD/canc.

Pregnancies, surgery

Registry of Medicinal products (>1995):

OC use (>1995)

Anticoagulation therapy

BP↑, DM, Hyperchol.

1995 → 2001 → 2005 → 2009

1.3 million women

Cause of Deaths Registry (>1977)

Lethal VT

Statistics Denmark

PIN-codes, education

vital status, emigration

Lidegaard et al. BMJ 2011

BMJ

BMJ 2011;343:d6423 doi: 10.1136/bmj.d6423

RESEARCH

Risk of venous thromboembolism from use of oral contraceptives containing different progestogens and oestrogen doses: Danish cohort study, 2001-9

Øjvind Lidegaard *professor of obstetrics and gynaecology*[1], Lars Hougaard Nielsen *statistician*[1], Charlotte Wessel Skovlund *data manager and scientific assistant*[1], Finn Egil Skjeldestad *professor of clinical medicine*[2], Ellen Løkkegaard *senior registrar in obstetrics and gynaecology*[3]

[1]Gynaecological Clinic 4232, Rigshospitalet, University of Copenhagen, Denmark; [2]Department of Obstetrics and Gynaecology, Institute of Clinical Medicine, University of Tromsø, Norway; [3]Department of Obstetrics and Gynaecology, Hillerød Hospital, University of Copenhagen, Denmark

Abstract

Objective To assess the risk of venous thromboembolism from use of

thromboembolism was not increased with use of progestogen only pills or hormone releasing intrauterine devices. If oral contraceptives with

OC and VT: Progestogen type Confirmed versus non-use

ug EE	NETA	LNG	NGM	DSG	GSD	Drsp	CPA
50	6.2 (3.0-13.2)	4.5 (2.9-6.9)	Patch	na	na	na	na
30-40	2.2 (1.1-4.5)	3.0 (2.4-4.0)	3.5 (2.9-4.3)	6.6 (5.6-7.8)	6.2 (5.6-7.0)	**6.4** (5.4-7.5)	6.4 (5.4-7.5)
20	na	na	na	4.8 (4.1-5.6)	5.1 (4.4-5.9)	6.9 (4.2-11.5)	na
				Vg. Ring			
POP	0.7 (0.3-1.5)			0.6 (0.2-1.9)			
Mirena		0.7 (0.5-1.1)					

Lidegaard et al. BMJ 2011; 343: d6423

VTE and drospirenone

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Seeger[07]	57	13.0*	0.9 (0.5-1.6) 4th/???
Vlieg[09]	1,524	na	1.7 (0.7-3.9) 4th/2nd
Lidegaard[09]	4.213	7.8	1.6 (1.3-2.1) 4th/2nd
Dinger[10]	680	na	1.0 (0.5-1.8) 4th/2nd
Lidegaard[11]	4,246	9.3	2.1 (1.6-2.8) 4th/2nd

Combined oral contraceptives, venous thromboembolism, and the problem of interpreting large but incomplete datasets

Jürgen Dinger,[1] Samuel Shapiro[2]

[1]Director, ZEG - Berlin Center for Epidemiology and Health Research, Berlin, Germany
[2]Visting Professor of Epidemiology, Department of Epidemiology, University of Cape Town, Cape Town, South Africa

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Received 11 November 2011
Accepted 14 November 2011

Background

In 2009, Lidegaard *et al.*[1] published findings in the *British Medical Journal*, derived from a Danish retrospective cohort study of the risk of venous thromboembolism (VTE) associated with the use of combined oral contraceptives (COCs). Their analysis was based on data derived from national health registries, and they concluded that "oral contraceptives with desogestrel, gestodene, or drospirenone were associated with a significantly higher risk of VTE than oral contraceptives with levonorgestrel". That report has previously in the publication differ from those mentioned in the re-analysis submitted to EMA (one example is given below).

Since the mid-1990s there has been heated debate regarding the risk of VTE associated with the use of different progestogens, and those who have followed the discussion can only note with concern its confrontational and increasingly sharp tone, which, unfortunately, is also reflected in the published responses to the re-analysis,[5–7] and more particularly in the authors' replies.[8 9]

The heat of the debate may have some-

Dinger & Shapiro, on the road again

We conclude that the best evidence continues to suggest that the increased risk of VTE among COC users is a class effect. In the Danish data an analysis confined to women who used COCs for the first time from 2001 onward did not support any differential effects of progestogens. Surprisingly, this information was neither presented nor discussed in the published re-analysis.[4] Any potential differences, if they exist at all, are probably beyond the resolving power of the 'epidemiological microscope'.

Dinger & Shapiro. J Fam Plan Repr Health Care 2011: Nov. 14.

OC and VT: Progestogen type Confirmed versus non-use

ug EE	NETA	LNG	NGM	DGS	GSD	Drsp	CPA
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30-40	2.2 1.1-4.5	3.0 2.4-4.0	3.5 2.9-4.3	6.6 5.6-7.8	6.2 5.6-7.0	**6.4** 5.4-7.5	6.4 5.4-7.5
20	na	na	na	4.8 4.1-5.6	5.1 4.4-5.9	6.9 4.2-11.5	na

		Vg. Ring	
POP	0.7 0.3-1.5		0.6 0.2-1.9
Mirena		0.7 0.5-1.1	

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Parkin[11]	61	2.3	2.7 (1.5-4-7) 4th/2nd
Jick[11]	186	3.1	2.8 (2.1-3.8) 4th/2nd
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BMJ

BMJ 2012;344:e2990 doi: 10.1136/bmj.e2990

RESEARCH

Venous thrombosis in users of non-oral hormonal contraception: follow-up study, Denmark 2001-10

Øjvind Lidegaard *professor*[1], Lars Hougaard Nielsen *statistician*[1], Charlotte Wessel Skovlund *data manager*[1], Ellen Løkkegaard *senior registrar*[2]

[1]Gynaecological Clinic 4232, Blegdamsvej 9, DK-2100 Copehagen Ø, Juliane Marie Centre, Rigshospitalet, University of Copenhagen, Denmark; [2]Department of Obstetrics and Gynaecology, Hillerød Hospital, University of Copenhagen, Denmark

Abstract

Objective To assess the risk of venous thrombosis in current users of

Conclusion Women who use transdermal patches or vaginal rings for contraception have a 7.9 and 6.5 times increased risk of confirmed

HC and VTE according to oestrogen dose and progestogen type

ug EE	NETA	LNG	NGM	DSG	GSD	Drsp	CPA
50	6.2 3.0-13.2	4.5 2.9-6.9	**7.9*** 3.5-17.7	**6.5'** 4.7-8.9	na	na	na
30-40	2.2 1.1-4.5	3.0 2.4-3.8	3.5 2.9-4.3	6.6 5.6-7.8	6.2 5.6-7.0	6.4 **5.4-7.5**	6.4 5.1-7.9
20	na	na	na	4.8 4.1-5.6	5.1 4.4-5.9	6.9 4.2-11.5	na
POP	0.7 0.3-1.5			0.6 0.2-1.9			
Mirena		0.6 0.4-0.8					

*EVRA 'Vg ring

Lidegaard, BMJ 2012; 344: e2990

…….on the road again

Publication in BMJ on May 10, 2012

- Anne Szarewski (14.5.2012)
  “…biologically nonsensical results”

…….on the road again

Publication in BMJ on May 10, 2012

- Anne Szarewski (14.5.2012)
- Samuel Shapiro (16.5.2012)
  "..the Danish registry is an unsuitable resource for the evaluation of VTE risk"

…….on the road again

Publication in BMJ on May 10, 2012

- Anne Szarewski (14.5.2012)
- Samuel Shapiro (16.5.2012)
- Mary E. Gaffield (16.5.2012)
  "These new data .. may lead to a new (unfounded) scare…."

…….on the road again

Publication in BMJ on May 10, 2012

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- Julie M Chandler (17.5.2012)

  “Higher abortion rate in areas where ….prescribing restrictions are in place”

…….on the road again

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- Anne L Connolly (18.5.2012)

  "…poor studies such as this one…"

…….on the road again

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- Mary E. Gaffield (16.5.2012)
- Julie M Chandler (17.5.2012)
- Anne L Connolly (18.5.2012)
- Jørgen Jespersen (19.5.2012)

  "We find no reason to repeat the clear and concise arguments by Anne Szarewski"

VT and drospirenone

	VT	IR	Rate ratio	
Dinger[07]	118	9.1	1.0 (0.6-1.8)	4th/2nd
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Lidegaard[11]	4,246	9.3	2.1 (1.6-2.8)	4th/2nd
FDA Kaiser[11]	625	7.6	1.5 (1.2-1.9)	4th/2nd
Gronich[11]	518	8.6	1.7 (1.0-2.7)	4th/2nd

IR = incidence per 10,000 women years

VT and drospirenone

	VT	IR	Rate ratio
Dinger[07]	118	9.1	1.0 (0.6-1.8) 4th/2nd
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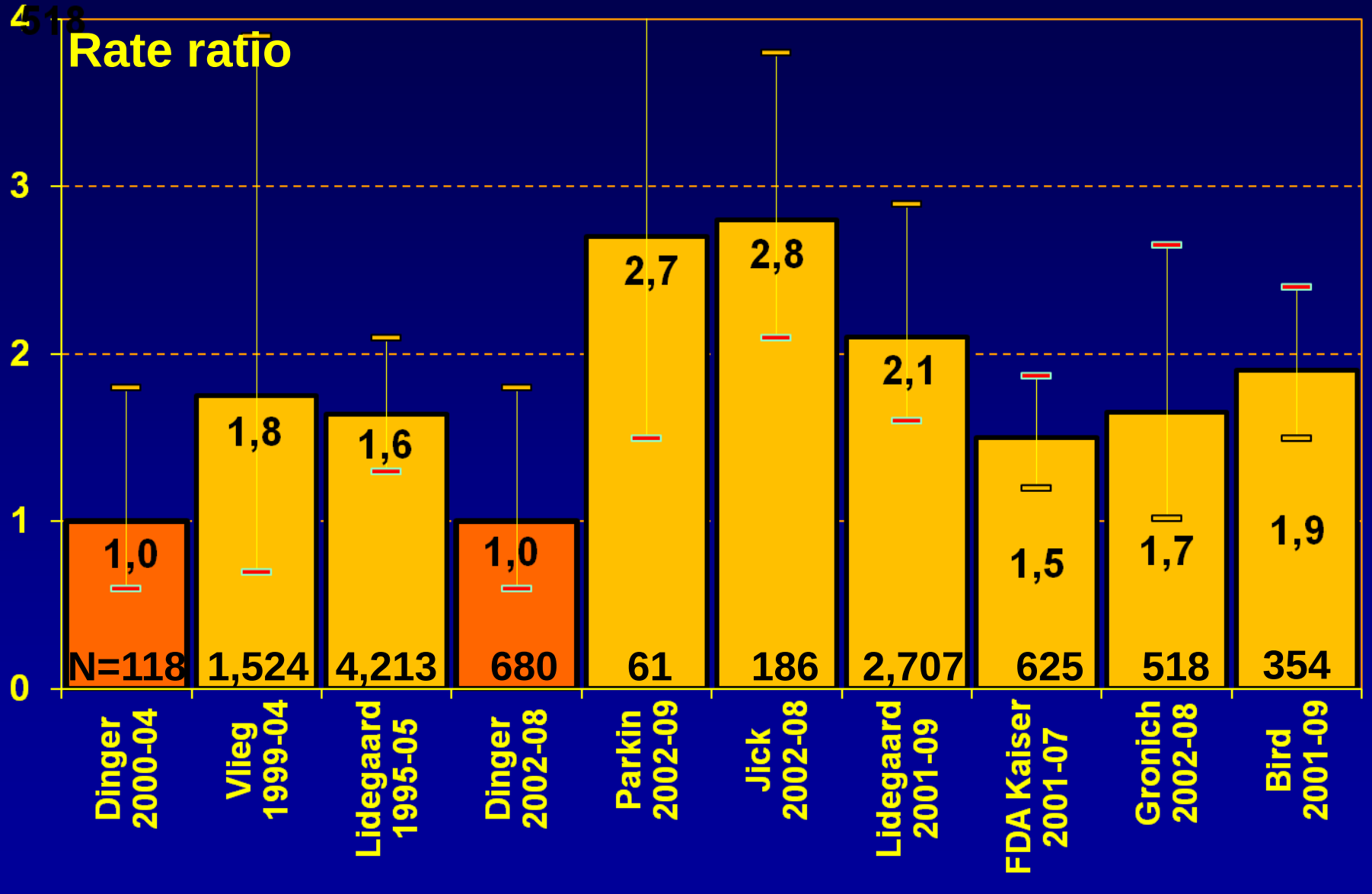
COC with DRSP vs LNG



Combined hormonal contraceptives and the risk of venous and arterial thromboembolism and cardiovascular death: misuse of automated databases

Samuel Shapiro

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Professor Samuel Shapiro, Department of Family Medicine and Public Health, University of Cape Town School of Medicine, Anzio Road, Observatory, Cape Town, South Africa;
samshap@mweb.co.za

ABSTRACT

Background In December 2011, the US Food and Drug Administration (FDA) convened a public Advisory Committee meeting to review evidence from a study commissioned by the agency. An analysis of findings derived from four databases was published on the FDA website, and presented at the meeting. Among users of combined hormonal contraceptives containing ethinylestradiol (EE) plus drospirenone (DRSP) the risks of venous (VTE) and arterial thromboembolism (ATE) were higher than

[myocardial infarction (MI) and stroke combined], in users of recently introduced combined estrogen/progestogen hormonal contraceptives (CHCs).[1] At the time of the meeting the findings had only been published on the FDA website, but not in a peer-reviewed journal.

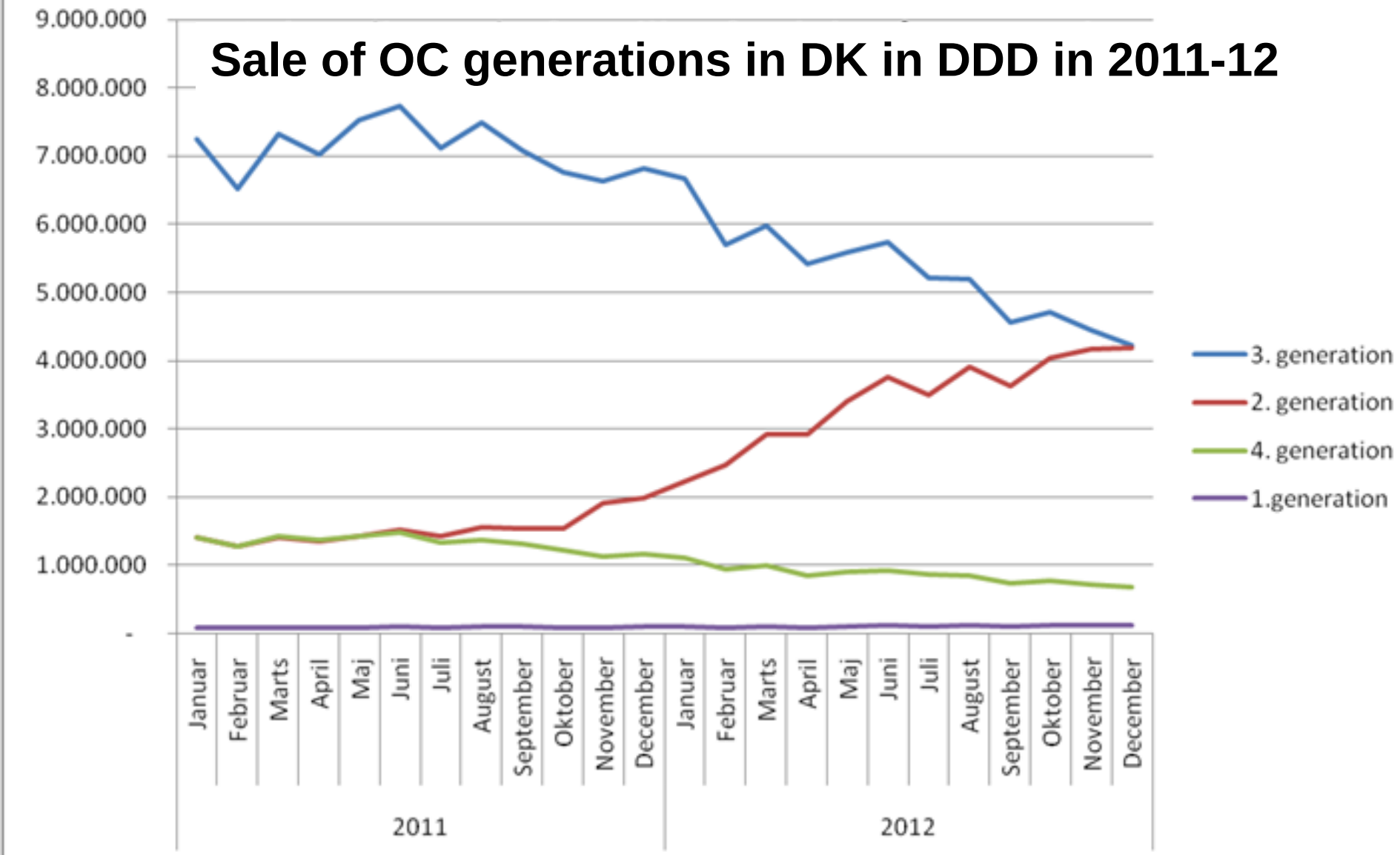
The investigators concluded that their data "[provided] another positive finding to the increasing body of evidence linking [drospirenone (DRSP)] to increased risk of VTE relative to standard low-dose

Shapiro, critique of FDA

Conclusions The best evidence continues to suggest that the increased risk of VTE in combined hormonal contraceptive users is dependent on the dose of estrogen, and independent of the progestogen used. The best evidence also suggests that DRSP does not increase the risk of ATE, and may reduce it.

Shapiro S. J Fam Plan Reproduc Health Care 2013: 39: 89-96

Sale of OC generations in DK in DDD in 2011-12



http://laegemiddelstyrelsen.dk/da/topics/bivirkninger-og-forsoeg/bivirkninger/nyheder/laeger-foelger-anbefalinger-for-brugen-af-p-piller

Basic question.

Is there a differential risk of VT with use of hormonal contraceptives with different progestogens?

If no: You should expect no change in the occurrence of VT when women shift from 3rd/4th generation pills to 2nd generation.

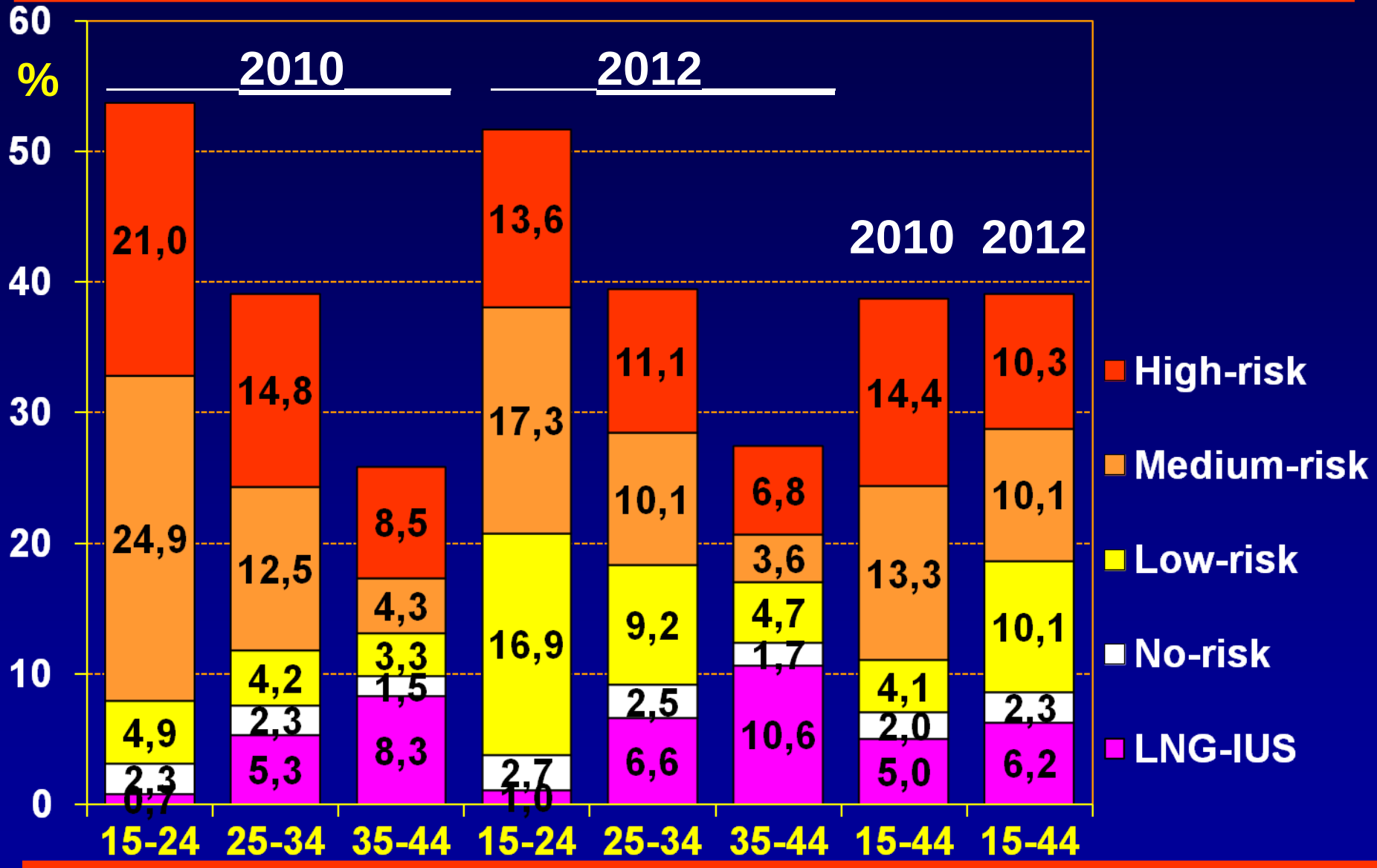
If yes: You should expect a 50% fall in VT in non-pregnant women shifting from the newer products to 2nd gen. pills

HC and VTE according to oestrogen dose and progestogen type

	NETA	LNG	NGM	DGS	GSD	DRSP	CPA
High Dose	Na	Na	**6** Patch	**6** Vg. Ring	Na	Na	Na
Middle Dose	**3**	**3**	**3**	**6**	**6**	**6**	**6**
Low Dose	Na	Na	Na	**5**	**5**	**6**	Na
POC	**1**	**1** LNG-IUS	Na	**1**	Na	Na	Na

Lidegaard et al. 2013. Submitted.

Hormonal contraception 2010 & 2012



Lidegaard et al. 2013. Submitted

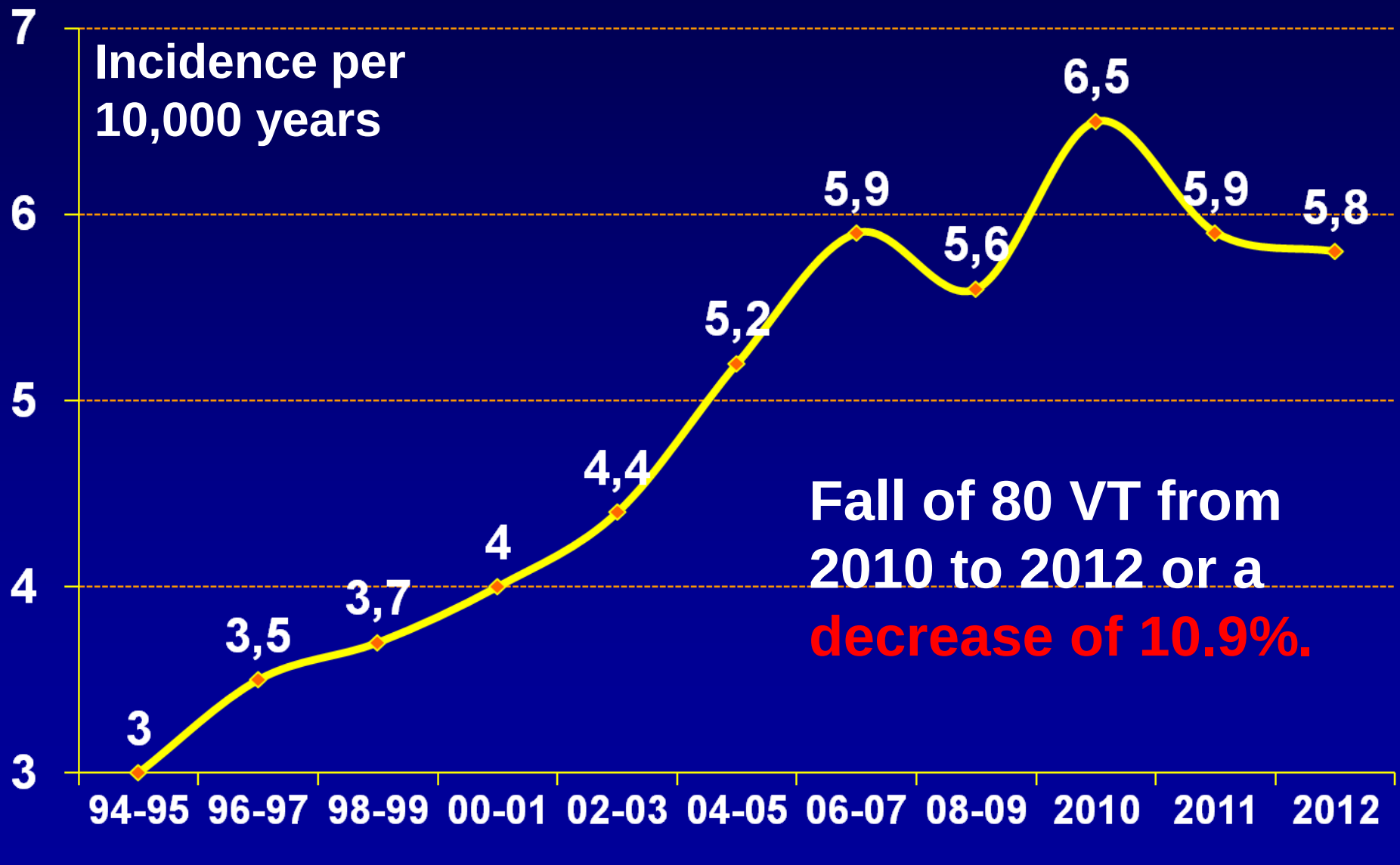
Expectation

One third of women on 3rd/4th generation pills shifted from 2010 to 2012 to 2nd gen. Which decrease in number of VT would you expect as a consequence of this shift?

$$\frac{(0.391 \times 3.9) + 0.609 \times 1}{(0.387 \times 4.4) + 0.613 \times 1} = 0.921$$

Thus, we would expect a decrease of 7.9%.

Venous thrombosis in DK 1994-2012 in non-pregnant women 15-44 years old



The current crisis

- In France women were never told about the higher risk of VT with use of 3rd, 4th generation COC and with CTA.

To avoid further pill scares

- Recognize the overwhelming scientific evidence of a differential risk of VT with different types of progestogens.
- Tell women about this differential risk.
- Invites women to switch.
- Don’t overdramatize the risk

The current crisis

- Don’t believe those colleagues who tell you that information about risk inevitably will cause a pill scare.
- Don’t downplay or deny results from large valid trustworthy studies.
- Accept, that some women prefer to take a risk of VT in order to comply better with hormonal contraception.
- But first of all: Be honest and truthful !!

  (it’s also much easier)

Hormonal contraception and pill crisis

Thanks for your attention

www.lidegaard.dk/slides

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