



Risk compensation and biomedical prevention: **Give PrEP a chance!**

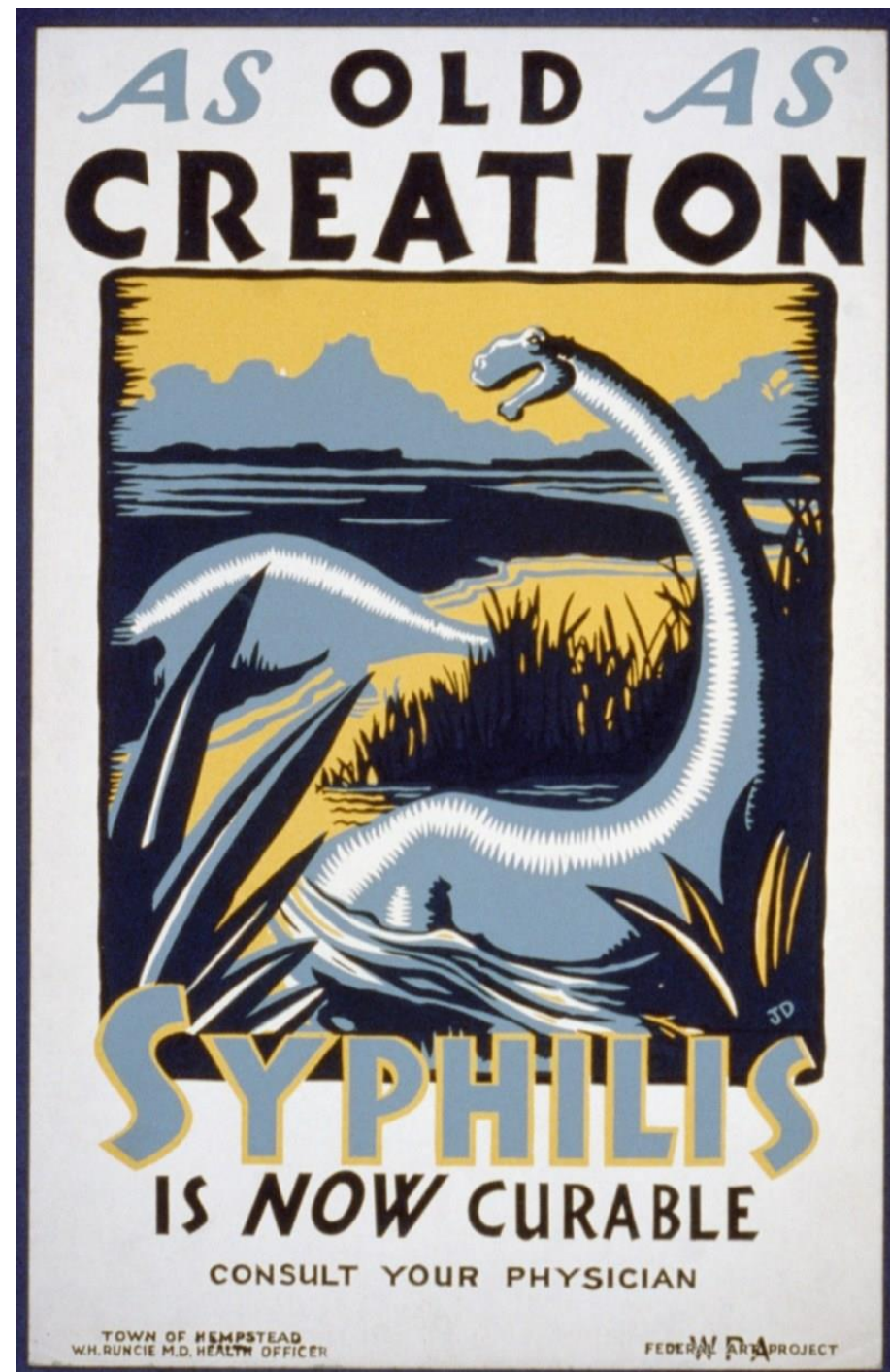
Daniela Rojas Castro

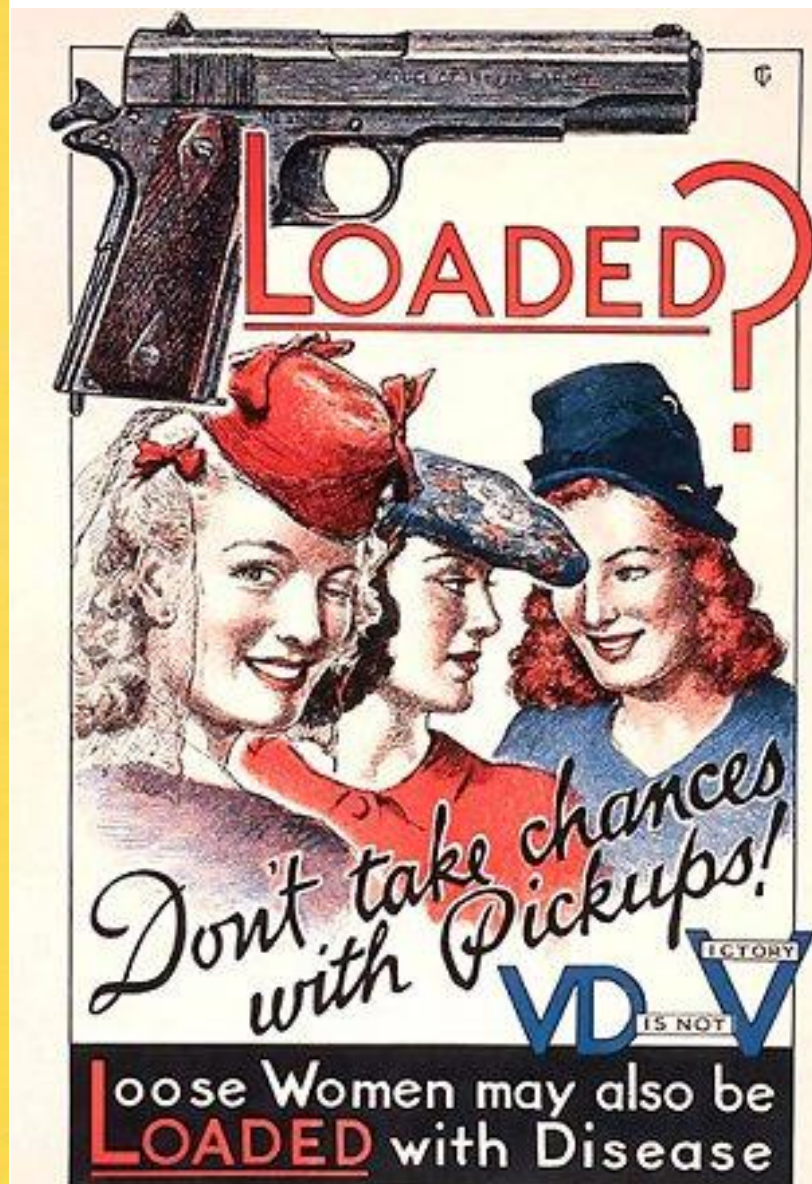
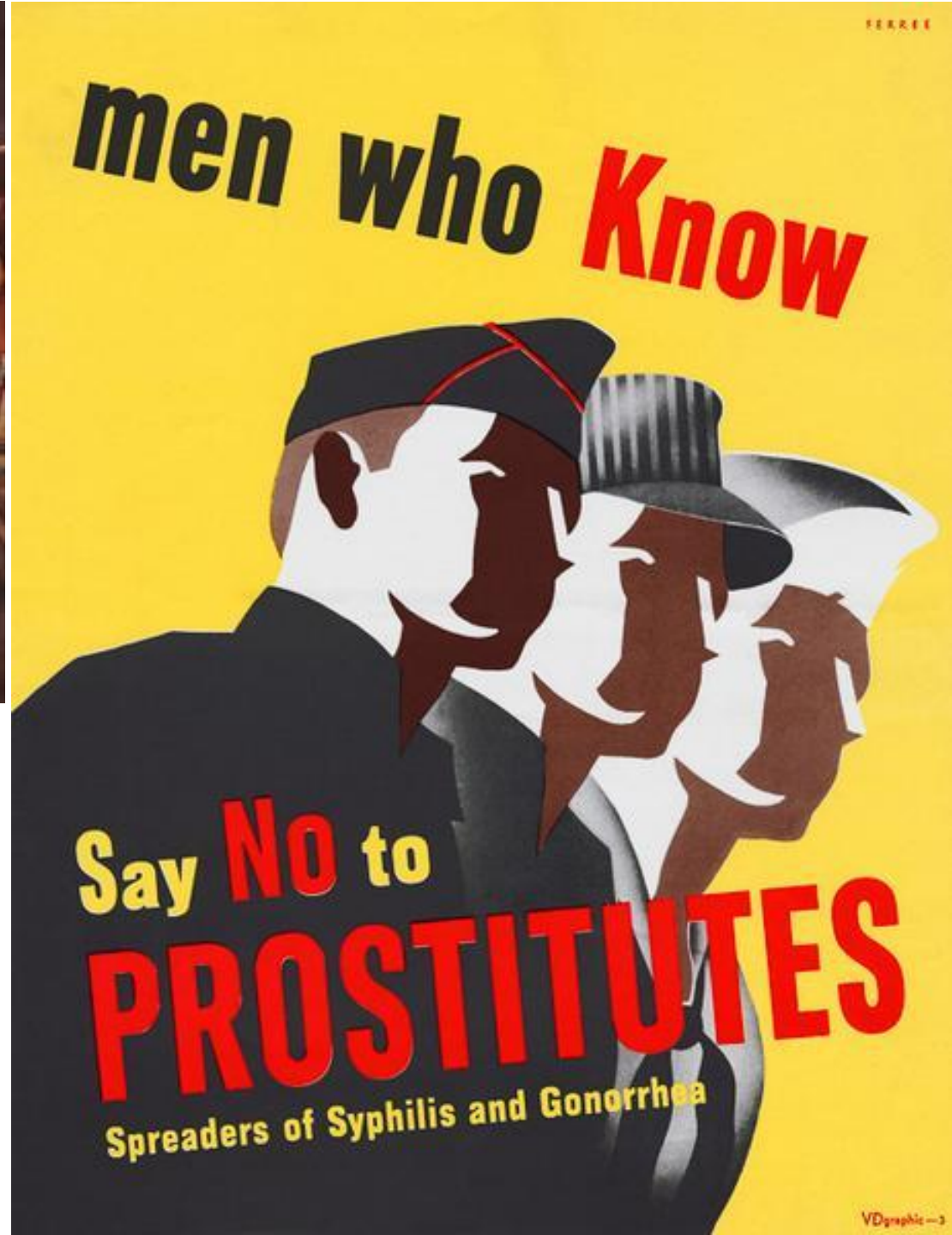
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Venereal Diseases (VD)

From [Middle English](#) [venereal](#), [venerealle](#) (“of or relating to sexual intercourse”), from [Latin](#) [venereus](#), [venerius](#) (“of or relating to sexual love”),^[1] from [Venus](#) (“Roman goddess of love”)^[2] (from [Proto-Indo-European](#) [*wenh₁-](#) (“to love”)) + [-eus](#), [-ius](#) (suffix forming [adjectives](#) from [nouns](#)).





Moral judgements on **sex** and prevention: a tale as old as time

“We might virtually stamp out this disease were we not hampered by the widespread belief that **nice people don’t talk about syphilis, nice people don’t have syphilis, and nice people shouldn’t do anything about those who do have syphilis.**”

Dr Thomas Parran, US Surgeon General (1936-1948)

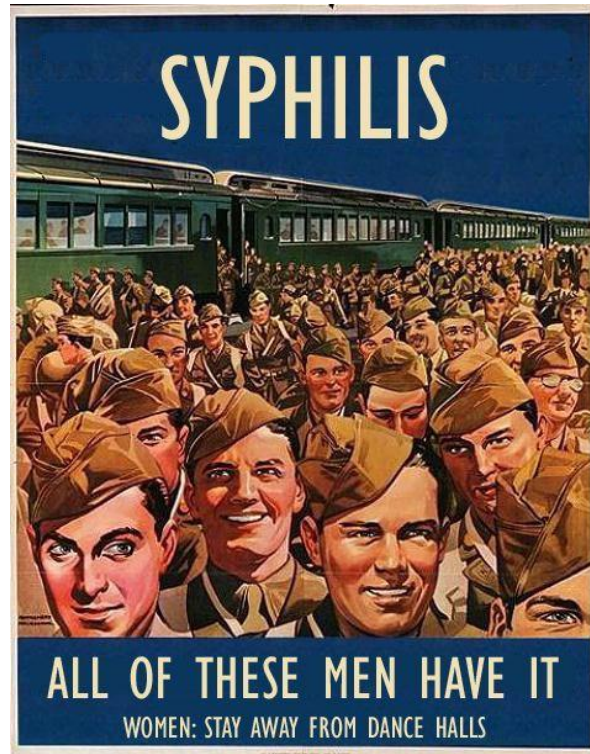
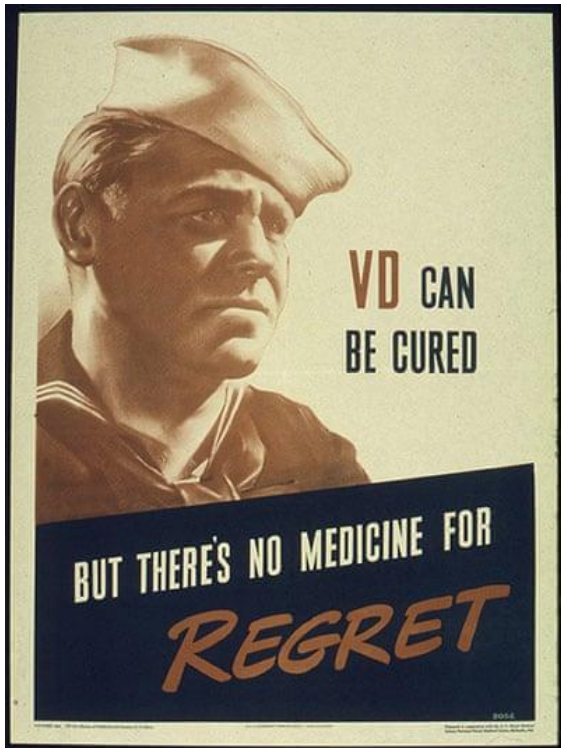
Why don’t we stamp out syphilis?

Survey Graphic and Reader’s Digest (1936)

“People’s own responsibility to use a condom, the relevance of being free of fear of HIV infection when having sex, and the relative importance of prevention HIV versus a possible rise in other sexually transmitted diseases because of reduced condom use.”

Jansen, Tromp and Baltussen (2016)

Moral judgements on sex and **prevention**: a tale as old as time



“People’s own responsibility to use a condom, the relevance of being free of fear of HIV infection when having sex, and the relative importance of prevention HIV versus a possible rise in other sexually transmitted diseases because of reduced condom use”

Jansen, Tromp and Baltussen (2016)

“Risk Compensation” and PrEP



for the divergent study results, despite intensive motivational counselling to use the product as intended.

Rather than considering these trials as “disastrous, because their results now cast inappropriate doubt on the preventive effects of tenofovir”, I believe we have learnt a great deal. Even if tenofovir gel does reduce the risk of HIV infection when used as intended (which is not yet established), either the effect is too small to overcome departures from the prescribed schedule, or the product is too difficult or impractical to use by the very women it is intended to protect. There are grave dangers in using a product of uncertain efficacy

efficacy of a treatment. His inference that these trials cast doubt on the efficacy of the product is flawed. True, as he notes, some useful information on adherence can be gleaned from the two so-called replication trials of the tenofovir gel, but no useful information can be gleaned about efficacy.

Although Farley may claim to share our impatience, we do not share his pessimism that the product is too difficult or impractical to use. We agree that adherence is a challenge and that additional formulations and approaches are needed. However, blinded randomised trials are not the most sensible study design to learn

PrEP: why we are waiting

Scientific research has proven that pre-exposure prophylaxis (PrEP) is highly effective in preventing HIV transmission in men who have sex with men. Therefore, the people are now asking decision makers why we are waiting.¹ So far, research on PrEP has primarily focused on apparently objective aspects of PrEP, such as biomedical effectiveness and costs. Normative aspects have received little attention, such as people’s own responsibility to use a condom, the relevance of being free of fear for HIV infection when having sex, and the

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relative importance of preventing HIV versus a possible rise in other sexually transmitted diseases because of reduced condom use. We argue that this lack of attention explains why we are waiting. Decision makers do not only base their decisions on the objective aspects, they are also responsive to normative arguments put forward by various stakeholders.

Such normative arguments are common in the popular media and

involving decision makers, citizens, advocacy groups, and potential PrEP users. Our survey confirmed that the introduction of PrEP currently hinges on normative issues.⁴

To facilitate decision making for the introduction of PrEP at the national level clarification of both objective and normative considerations is crucial. The research community can play an important part in doing ethical analyses, as a basis for a broader social

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1 The Lancet HIV. PrEP: why are we waiting? *Lancet HIV* 2015; 2: e401.

2 Ali H. Hiv-preventiepill biedt homo's seks zonder angst. <http://www.volkskrant.nl/wetenschap/hiv-preventiepill-biedt-homo-s-seks-zonder-angst-a4159995/> (accessed Oct 10, 2015).

3 Sevil M. Hiv-remmer PrEP in Amsterdam preventief verstrekt. <http://www.parool.nl/parool/nl/4/AMSTERDAM/article/detail/4085973/2015/06/22/Hiv-remmer-PrEP-in-Amsterdam-preventief-verstrekt.dhtml> (accessed Oct 11, 2015).

4 Jansen MPM, Tromo N, Baltussen R.

“Risk Compensation” and PrEP, and PEP

AIDS Behav (2010) 14:1182–1189
DOI 10.1007/s10461-010-9712-1

Use of Non-Occupational Post-Exposure Prophylaxis does not Lead to an Increase in High Risk Sex Behaviors in Men Who have Sex with Men Participating in the EXPLORE Trial

Deborah Donnell · Matthew J. Mimiaga ·
Kenneth Mayer · Margaret Chesney ·
Beryl Koblin · Thomas Coates

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Abstract Non-occupational post-exposure prophylaxis (nPEP) use is an HIV prevention strategy that has been recommended by the CDC to prevent HIV infection after a high risk sexual exposure since 1997. In a behavioral

courses were reported, with no effect of nPEP on risk of HIV acquisition in this cohort (hazard ratio = 0.91, 95% confidence interval [0.29, 2.86]). NPEP users were a riskier group: increased odds of nPEP use were observed in



“Risk Compensation” and PrEP, and PEP, and HPV vaccine



Risk Compensation and Vaccination: Can Getting Vaccinated Cause People to Engage in Risky Behaviors?

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ABSTRACT

Background: Some believe that vaccinating young women against human papillomavirus (HPV) will increase their risky behavior. In more formal terms, vaccination lowers risk perception, and people compensate for their lower perceived risk by reducing other preventive behaviors. **Purpose:** We test several predictions from the risk compensation hypothesis in the context of vaccination behavior. **Methods:** We obtained a random sample of adults ($N = 705$), interviewing them by phone just as the Lyme disease vaccine first became available to the public and again 18 months later. Analyses controlled for age, sex, education, and race. **Results:** Vaccinated respondents were less likely to continue engaging in two of five protective behaviors after vaccination. The frequency of these protective behaviors did not dip below that among the unvaccinated respondents. **Conclusions:** We found some evidence of regression (protective behaviors dropping, after vaccination, to levels reported by the unvaccinated cohort). However, we did not find disinhibition (exceeding the risk taking of the unvaccinated cohort), the greater threat to public health. Although we will not know for several years what effect HPV vaccination has on other behaviors, if any, data on other vaccinations can offer critically important information in the interim.

(Ann Behav Med 2007, 34(1):95–99)

that causes cervical cancer (3). The news was enthusiastically received by public health and medical professionals responsible for reducing cervical cancer deaths. At the same time, a vocal group of opponents to the vaccine renewed their opposition to its use, claiming that young women who are vaccinated would be more likely to engage in premarital sex (4). Formalizing their claim conceptually, young women may experience “sexual disinhibition”: Getting vaccinated may cause them to believe they are less at risk for cervical cancer and, for this specific reason, be more likely to engage in sexual behavior than their peers, thus increasing their risk for cervical cancer and sexually transmitted infections.

Sexual disinhibition is consistent with theories of *risk compensation* (also called *risk homeostasis*) (5). These theories propose that people have stable preferences for a certain amount of risk and that the feeling of safety created by the initial preventive activity creates a surplus of risk that will be expended elsewhere by reducing other protective actions. The findings on the effects of seat belt use that were initially offered in support of risk compensation are controversial (6). By some measures, seat belt use and air bag provision appear to cause a minority of drivers to compensate by driving less safely (7), but their use yields a net overall benefit in terms of lower mortality, and some evidence even suggests that seat belt laws reduce driving speeds (8). Numerous studies in the field of HIV prevention

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COMMENTARY

No evidence that HPV vaccination leads to sexual risk compensation

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ABSTRACT

Uptake of the HPV vaccine has been lower than the uptake of most other childhood vaccines offered in public programs. Since the HPV vaccine protects against a sexually transmitted virus, one barrier to uptake specific to the HPV vaccine may be the concern that vaccination may encourage risky sexual behaviour. Unanimous findings from recent studies show that HPV vaccination does not lead to sexual risk compensation, which is an important message to parents, clinicians and other decision-makers regarding HPV vaccination. Some issues remain to be investigated, like HPV vaccination and sexual risk compensation among boys.

ARTICLE HISTORY

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KEYWORDS

behavioral adaptation;
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papillomavirus; risk
compensation; sexual
disinhibition; sexual health;
STI

“Risk Compensation” and PrEP, and PEP, and HPV vaccine, and the morning-after pill



Contraception 77 (2008) 333–336

Contraception

Original research article

Effect of an emergency contraceptive pill intervention on pregnancy risk behavior[☆]

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Received 8 January 2008; revised 15 January 2008; accepted 15 January 2008

Abstract

Objective: Previous trials of emergency contraceptive pills (ECPs) found that in menstrual cycles ending in pregnancy, ECP use was more common among women exposed to interventions that enhanced access to the medication than among women with standard access. We examined data from one such trial to explore whether this finding has implications regarding the effect of the intervention on pregnancy risk behavior.

Methods: In our recent randomized trial, the intervention group received unlimited free ECPs in advance of need, whereas control participants obtained the medication when needed at usual cost. Participants were followed up for 1 year. In this secondary analysis, we examined ECP and contraceptive use in the cycles ending in pregnancy in that trial.

Results: Pregnancies in the intervention group appeared to have been more likely than those in the control group to be classified as “probably” or “possibly” ECP failures (12/74 in the intervention group vs. 1/74 in the control group; $p=.012$) and more likely to have occurred in the context of use of less efficacious contraceptives.

Conclusion: Unrestricted access to ECPs in this trial may have increased the frequency of coital acts with the potential to lead to pregnancy. © 2008 Elsevier Inc. All rights reserved.

Keywords: Emergency contraception; Pregnancy; Unprotected sex; Increased access

“Risk Compensation” and PrEP, and PEP, and HPV vaccine, and the morning-after pill, and HAART

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Sex Transm Inf 2001;77:184–186

Short report

Increase in sexually transmitted infections among homosexual men in Amsterdam in relation to HAART

Ineke G Stolte, Nicole H T M Dukers, John B F de Wit, Johan S A Fennema, Roel A Coutinho

Objectives: We investigated if a rise in rectal gonorrhoea and early syphilis among men who have sex with men (MSM) in Amsterdam coincided with the introduction of highly active antiretroviral therapies (HAART) in July 1996 and determined risk factors for these sexually transmitted infections (STI).

Methods: Subjects were patients of the STI clinic of the municipal health service in Amsterdam. Surveillance data (1994–9) represented consultations (n=11 240) of MSM (n=6103). For analyses we used logistic regression.

Results: Comparing the periods before and after the introduction of HAART, the infection rate for rectal gonorrhoea increased from 4% to 5.4% ($p=.001$) and for syphilis, from 0.5% to 0.8% ($p = 0.050$). Independent risk factors for rectal gonorrhoea (younger age, western nationality, and concurrent infection with another STI) and for early syphilis (non-western nationality and concurrent infection with rectal gonorrhoea) did not change after HAART became available. For rectal gonorrhoea, however, the infection rate increased only among men who had exclusively homosexual contacts (OR 1.38, $p<0.01$), compared with bisexual men. For early syphilis, the infection rate increased only among men of western nationality (OR 3.38, $p<0.01$) compared to men of non-western nationality.

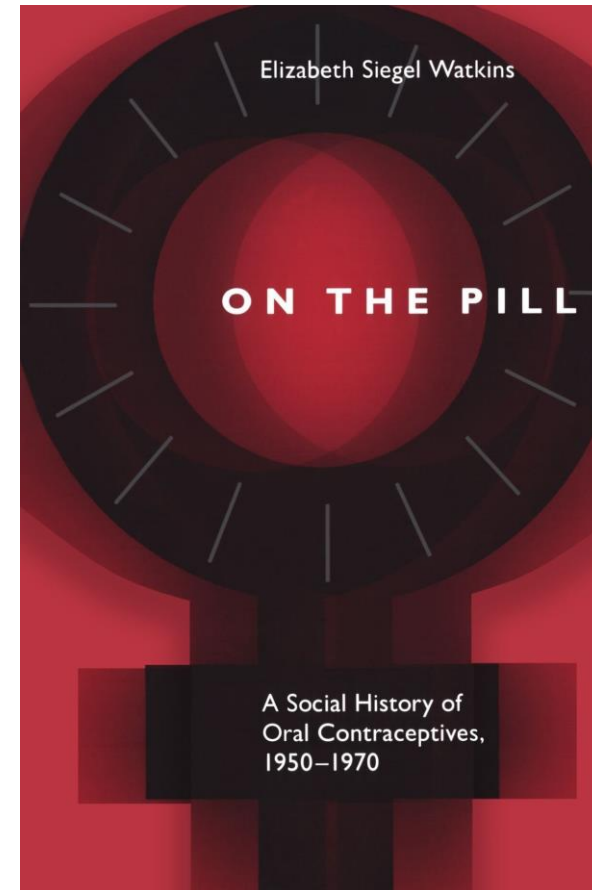
Conclusions: Infection rates of rectal gonorrhoea and early syphilis increased, indicating a change in sexual behaviour, possibly as a result of the introduction of HAART. For now, it is important to find out how sexual behaviour is changing and to keep monitoring trends in STIs (including HIV) among MSM in Amsterdam.

(*Sex Transm Inf* 2001;77:184–186)

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“Risk Compensation” and PrEP, and PEP, and HPV vaccine, and the morning-after pill, and HAART, and the “pill”



“Risk Compensation” and PrEP, and PEP, and HPV vaccine, and the morning-after pill, and HAART, and the “pill”, and even condoms and seat belts



Viewpoint

Condoms and seat belts: the parallels and the lessons

John Richens, John Imrie, Andrew Copas

Condoms and car seat belts are applied to the human body to save lives. For both, there is an abundance of evidence of benefit to individuals directly exposed to risk. When evidence of benefit is sought at population level it becomes much harder to show beneficial effects. We look at evidence that suggests that the safety benefits of seat belts are offset by behavioural adaptation, and we ask whether condom promotion could also be undermined by unintended changes in sexual risk perception and behaviour.

Seat belts—what does the evidence show?

More than 80 countries have laws that require motorists and passengers to wear seat belts. Most people believe that thousands of lives have been saved. Adams commented that “strength of convictions about what this legislation has achieved is remarkably independent of objective evidence”.¹ Figure 1 shows data from the 17 countries that had 80% of the world’s cars in the 1970s. Comparison of the 13 countries that passed seat-belt laws with the four countries that did not shows a large excess of deaths in those countries that passed laws. UK predictions were of 1000 lives saved and 10 000 injuries avoided each year.² A report on the European experience, commissioned by the UK government’s Department of Transport and then suppressed by that department,

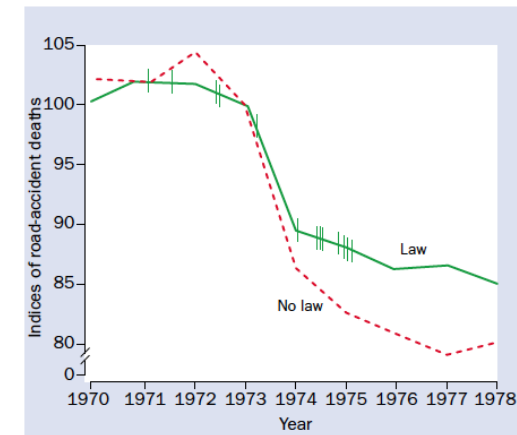


Figure 1: Indices of road-accident deaths for 13 countries with and four countries without seat-belt laws

1973 (the “energy crisis” year)=100. Bars indicate the dates at which laws came into effect in the “law” group. Reproduced from Adams¹ with permission.

Strong evidence that seat belts have saved lives is not currently available. In Sweden, increasing seat-belt use

“Risk Compensation” and PrEP, and PEP, and HPV vaccine, and the morning-after pill, and HAART, and the “pill”, and even condoms and seat belts, but also needle exchange



Needle Exchange, Pragmatism, and Moralism

Roel A. Coutinho, MD, PhD

In 1917, the United States sent an army to Europe to intervene in the Great War. The arrival of the American Expeditionary Force (AEF) in the French seaports is described by Allan Brandt in his book *No Magic Bullet* as a clash of sexual cultures.¹(pp96–121) It was a time of a strong moral crusade against prostitution, and in the United States the military authorities had joined forces with this movement. Throughout the country, red light districts had been closed and prostitutes had been arrested and forcibly checked for the presence of venereal diseases. Prostitutes found to be

How Did the Needle Exchange Program Start and Evolve?

This story came to mind when I read A.R. Moss's provocative editorial about the discussion on needle exchange in the United States.² Again, there is a clash between moralism and pragmatism, this time within the United States. The first needle exchange program in the world was established in Amsterdam in 1984 by the local Junky Union and was soon taken over by the Amsterdam Municipal Health Service.³ The policy in Amsterdam toward drugs

grams worked, and such programs had been started all over the world. HIV was spreading fast among injecting drug users, so we had decided to go ahead with this public health intervention and not wait for formal proof of the effectiveness of the program.

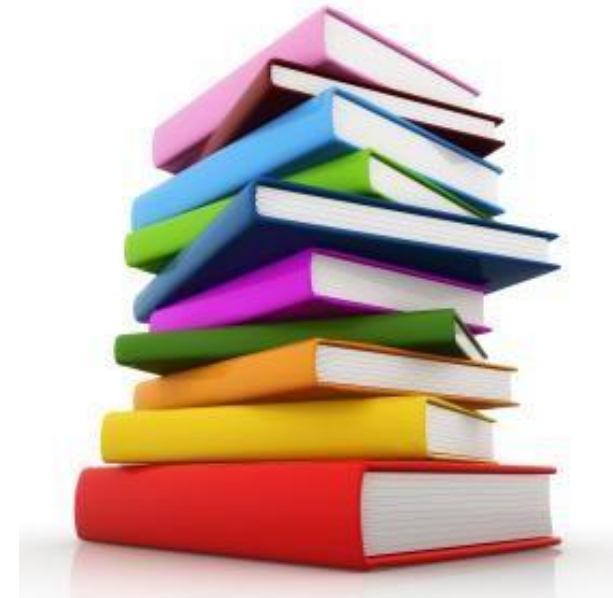
That meeting was 14 years ago, and the debate in the United States has not ended. Pragmatic supporters of needle exchange and their moralistic opponents seem to be immobilized in a trench war. Federal AIDS funding for needle exchange programs is forbidden. In the late 1980s, as Moss notes,

“Risk Compensation” and PrEP, and PEP, and HPV vaccine, and the morning-after pill, and HAART, and the “pill”, and even condoms and seat belts, but also needle exchange, and many other prevention tools...

Risk compensation and disinhibition are **not** interchangeable concepts

Disinhibition: lowering or absence of self-restraint to avoid risk (Hogben and Liddon 2008; Leeman, Toll and Volpicelli 2007)

Risk compensation: related to “risk equilibrium”, defined as “a system in which individuals accept a certain level of subjectively estimated (or perceived risk to their health in exchange for benefits they expect to receive from (an) activity” (Wilde 1994)



Risk compensation “theory” or “concept”: automobiles to HIV

The Effects of Automobile Safety Regulation

Sam Peltzman

University of Chicago



Condoms and seat belts: the parallels and the lessons

John Richens, John Imrie, Andrew Copas

A vigorous condom-promotion policy could increase rather than decrease unprotected sexual exposure, if it has the unintended effect of encouraging greater sexual activity...

"Risk compensation" and PrEP: STIs

Clinical Infectious Diseases

MAJOR ARTICLE



Effects of Pre-exposure Prophylaxis for the Prevention of Human Immunodeficiency Virus Infection on Sexual Risk Behavior in Men Who Have Sex With Men: A Systematic Review and Meta-analysis

Michael W. Traeger,^{1,2} Sophia E. Schroeder,^{1,3} Edwina J. Wright,^{1,4,5,6} Margaret E. Hellard,^{1,4,5} Vincent J. Cornelisse,^{5,7,8} Joseph S. Doyle,^{1,5,6} and Mark A. Stoove^{1,4,6}

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HIV and risk behaviour

Risk compensation: the Achilles' heel of innovations in HIV prevention?

Michael M Cassell, Daniel T Halperin, James D Shelton, David Stanton

The benefits of new methods of prevention of HIV could be jeopardised if they are not accompanied by efforts to change risky behaviour

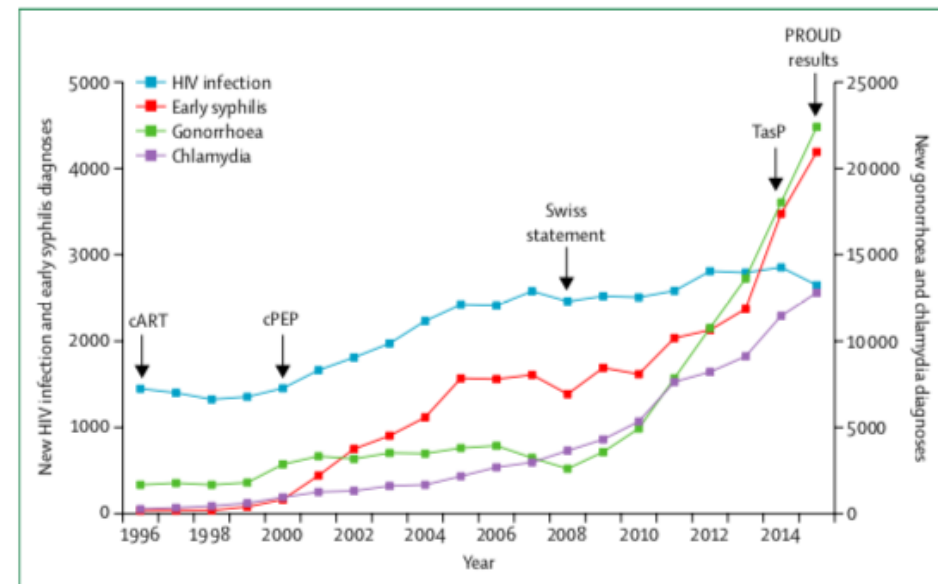


Figure 10: New diagnoses of HIV infection, early syphilis, gonorrhoea, and chlamydia

Using preexposure prophylaxis, losing condoms?
Preexposure prophylaxis promotion
may undermine safe sex

Kamair Alaei^{a,b}, Christopher A. Paynter^{a,b}, Shao-Chiu Juan^{a,b}
and Arash Alaei^{a,b}

"Risk compensation" and PrEP: STIs

- PrEP outcome: HIV prevention, no other STIs prevention
- Condomless sex may lead to HIV and STIs, but psycho-social mechanisms to prevent the former and the latter are different
- Other STIs do not necessarily represent for individuals the same health concern as HIV



"Risk compensation" - **Methodological** considerations

(Holt 2017)

- ☞ Studies mostly focused on **behavioural** measures (attitudes, risk perceptions)
- ☞ **Timing** in the change of attitudes and behaviour is important but not always clear
- ☞ Some studies **did not find** that a change in behaviour led to risk increase
- ☞ Even if changes in behaviour or risk perception are observed **they will likely not undermine** the high effectiveness of the prevention strategy
- ☞ Interventions are **not considered from a community level** (limited to individual approach)

**“Our obsession with risk compensation
directly impedes PrEP access”**

(Golub 2018 - HIVR4P Madrid)

PrEP: a concern or an **opportunity** for STI control?

- ✿ Increases the frequency of HIV and other STIs testing
- ✿ Promotes early diagnosis and treatment of HIV and other STIs
- ✿ Long-term: decline in STI incidence (routine testing - detection of asymptomatic STIs)
- ✿ Alleviates fears of HIV
- ✿ Allows a more fulfilling sex life
- ✿ Empowers people to protect themselves and others



How can we move forward (and do better)?

- Risk Compensation: STOP IT
- Work with healthcare providers!
- Multidisciplinary approach
- Expansion of PrEP delivery and offer to other populations
- Political will to test other interventions



¡Gracias!