

Modifying behaviour on STI including HIV and oncogenic HPV: a draft protocol for a registry open to the registered subject, generating the concept of a 'STI passport'

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Summary

Background Sexually transmissible infections (STI) include both HIV and oncogenic HPV with the risk of cervical and oral cancer. Sexual behaviour is the key to the problem but appears very difficult to influence. The STI tend to have different channels of management and don't seem to be managed in a manner that is sufficiently comprehensive.

Methods Analytical consideration of the factors involved. Induction of a solution approach.

Findings Design of a protocol of a STI registry that also covers HIV and oncogenic HPV. The registry would provide a natural environment for education, discussion of doctor and client, and exchange of information between consenting clients. The registry would be open to the registered subject. Registration can be seen as not just useful for the internal system of public health itself but also as a service to the external public. While the registry would protect privacy, people are free to disclose their status to potential partners. People can also ask their potential partner to disclose that status, when it becomes common knowledge that such registration can exist. This facility adds to the sense of control, which is an important psychological factor for behaviour. Provision of this natural environment of information and control fosters the habit of safe sexual conduct. The registered status of infection then can function as a passport that guards the flows between the infected and the non-infected. Capacities, barriers, sticks and carrots determine the effectiveness and efficiency of the scheme.

Interpretation The protocol offers promising avenues for both research by the academia and advance experimentation in communities.

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Introduction

In public health there are three tectonic plates - so to speak - that are slowly moving towards a collision that will cause some tremors. The first plate concerns cervical cancer screening, the second plate concerns STI in general, and the third plate concerns the behavioural sciences. The first plate of cervical cancer screening is adapting to the finding that the cancer is basically caused by oncogenic HPV that can be transmitted sexually. A frequently heard reasoning in cervical cancer screening circles about the virus is “(...) without the availability of effective therapies, it is premature to recommend widespread screening (...)”¹ while from the viewpoint of STI the reasoning would be rather different, for example that a person at least might want to know about an infection in order to protect others. The second tectonic plate concerns the sexually transmissible infections in general, where the T in STI reads ‘transmissible’ rather than ‘transmitted’ since for example HIV infections can also be caused by needles and blood transfusions. Similarly, it is STI and not STD since one can be a carrier without signs of true disease.² The 1996 Global Burden of Disease study³ already assigned cervical cancer to the category of ‘unsafe sex’. The burden of unsafe sex in 1990 in the developed and developing regions is 2.1% resp. 3.7% of disability adjusted lifeyears (DALYs). This inclusion of oncogenic HPV into STI however is not often copied in the national statistics, and researchers and managers are hesitant to do so. The third tectonic plate concerns economics and psychology, or the science and art of the modification of behaviour as opposed to a reliance on techniques such as the Papanicolaou smear or vaccinations. Medicine may have a bias in favour of matter, material objects and tools since these are relatively easy to patent, test, manufacture and sell on the market, so that there arise commercial companies that make profits and that invest in more matter, objects and tools. Conversely, economic and psychological approaches are less easy to patent, test, manufacture and sell on the market, with little commercial activity. Perhaps subsidized research at the academia creates a balance, but one rather suspects an imbalance.

These three plates move slowly not only because of the complexities and the different historical origins of the fields but also because researchers and managers are conscientious with respect to the privacy and intimacy of sexual behaviour. That the plates will collide at some moment in time however is obvious from the very logic of the subject and the economic need to pool resources. If infections with HPV can be prevented all along with the prevention of infections with other STI including HIV, then there would be a reduced burden on screening for cervical cancer, and there would be less need for vaccines for either type of virus. Similarly, modification of human behaviour is key, as principally has been shown by the social psychologist Aronson in his masterly “The Social Animal”.⁴ If we could influence behaviour then this would win the greatest benefit. When sex education by parents and schools would include the discussion about the natural history of cervical cancer, then the whole issue of safe sexual conduct could become more of a ‘package deal’ and the advantages of a healthy sexual life could become so much more convincing. Thus, a comprehensive and coordinated approach towards sexual behaviour would include all aspects.

The need for a comprehensive approach has been recognized long before. At the 1996 EUROGIN conference, for example, Meheus already presented a general framework for the prevention of STI that covers the whole range of exposure of the non-infected, transmission by the infected, treatment, behaviour of the health care system itself, health education, counselling and the use of the law.⁵ Yet the road to implementation is difficult. A recent review on strategies for HPV prevention concludes “there is little evidence that infection can be avoided by behavioral change” and the focus shifts to vaccination.⁶ Thus, the conclusion that ‘behaviour is key’ might be obvious and generally accepted, but the real problem are the limits here, real or perceived. In addition, as well, two economists state recently that “the economic approach to infectious diseases is in its infancy, somewhat oddly (...) Policy toward infections is of great importance. Yet only recently have economists begun to look at these questions in a formal way.”⁷ Thus it is safe to conclude that uncertainties and

bottlenecks abound, both at the level of individual behaviour and at the level of overall management and policy making.

In a situation like this it is generally fruitful to consider the role of information, at both the individual and management level of use. If change is slow, what is the role of information? Important is not just information itself but also whether and how it will be used. Some countries already have national registries that store results of cervical cancer screening. The advantages of having a registry are obvious, for both research and management. The same logic points to the potential usefulness of a registry of STI.

When we target sexual behaviour (and try to overcome the aforementioned limits) then we must consider the whole fabric of society, and an STI registry can function as a fixture in that whole. The idea is to create an environment that fosters responsible conduct, where it becomes internalised in each person that sexual behaviour must be safe and where that is not something that people have to think about. The environment would have different fixtures, but the registry would play a central role (and the present discussion concentrates on that). In sex education or in the discussion of client and doctor, or between consenting adults, the registry would pop up as a topic to consider. A key angle to consider then is the following. It is not unreasonable to allow people access to the information that is stored about themselves in that registry. Since information about STI status can affect behaviour, and since people, and notably new lovers, might show their own information to each other, it is proper to consider ways of access to the registry that causes that the information is used and that modifies behaviour towards an improved public health. The registry then would change from a medical tool only into a service provider for the general public too.

This line of reasoning results into the enclosed draft protocol on a STI registry that is open to the public. Appendix A lists the protocol and appendix B gives a small example of its use. Some readers may wish to first consider that example before continuing with this paper. Appendix C lists some selected research areas.

The basic idea of the registry is that sticks and carrots can motivate people to make the best use of the information generated by medical science. The non-infected and the infected are like different 'countries', such that the flow of people between these may be controlled and so that the non-infected can be protected by having a testimony to the effect. Access to the registry might be seen as having a STI passport. In the middle ages, lepers had their rattles, but in modern times we can be more humane by using systems that respect privacy and that rather target the non-infected.

Interestingly, I came across the work of dr. Andrew Pipe, of the University of Ottawa, and of the Canadian Centre for Ethics in Sport. One of his problems is the abuse of drugs in sports, and one can imagine that there are huge negative incentives here. He also believes that continuous control has its limits and that behaviour modification is key, and that for example a sports medicine code of ethics is of fundamental value to help induce that modification.⁸ His philosophy appears to overlap with the one outlined above, of creating an environment where the positive incentives are enhanced and the negative ones contained.

Below, we will shortly consider the three different tectonic plates and the forces that move them. Since readers may originate from one area only, they will benefit from considering the two other areas. This paper will not summarize those areas though, we will only focus on our topic. The advantages and disadvantages of the protocol are indicated including the directions for possible research. The paper concludes that communities could already start working and experimenting with the protocol so that practical experience will help discover the better local implementations.

Oncogenic HPV

This paper actually found its original inspiration in an article by professors Helmerhorst and Meijer.⁹ These renowned researchers who have done so much good for mankind express their

concern about the possible stigma if cervical cancer were branded or labelled as a sexually transmitted disease. Their position is well summarized by the title of their article: "*Cervical cancer should be considered as a rare complication of oncogenic HPV infection rather than a STD*". Indeed, in the current perception of the natural history of cervical cancer, the oncogenic HPV that can be sexually transmitted is just the causal agent.¹⁰ In the whole chain of causality, the immune system is as much a factor since most infections clear and the immune system fails only once in about 1% of the subject lives. Oncogenic HPV has a high prevalence, for example 6.8% (95% CI 6.2-7.5) in Swedish women aged 32-38¹¹ or even higher in younger age groups.¹² A trial in the UK, using the age distribution of women screened in England, found an age-standardised oncogenic HPV-positive rate of 8.8%.¹³ Yet, the risk to get the virus over a whole life time is in the range 50-100%. HPV thus is very much like the common cold, though with a zing to it. If cervical cancer were to get the stigma of a STI then this would cause worries for large sections of the population and the threat of cancer would put a burden on normal and healthy sexual behaviour. As Helmerhorst and Meijer originate from the liberal country of The Netherlands their concern deserves special notice, since the stigma of a STI could even be stronger for less liberal cultures, rather causing more worries and not necessarily causing safer sexual conduct.

The same concern about stigmatization is also expressed by Giles¹⁴ with respect to HPV itself rather than the cancer. Similarly, Cuzick et al.¹⁵ express their concern about testing on HPV as part of screening for cancer: "The use of HPV testing reinforces the fact that cervical cancer is caused by a sexually transmitted virus, and it will be essential for the test result and its implications to be communicated sensitively. However, the patient or her partner could have been infected many years previously."

With HPV there is the same distinction as with HIV with respect to 'transmitted' and 'transmissible'. The virus may be transmitted in other ways than sex but then becomes transmissible by sex: "The conclusion seems inescapable that some but not all cervical HPV infection is acquired by means other than sexual intercourse."¹⁵ The latter also shows from evidence on children^{16 17 18} and virgins¹⁹ and the degree of sexual or skin contact²⁰ including oral contact and oral cancer.²¹ The status of condom use is subject to discussion²² but helps cytological regression and HPV clearance in women^{23 24} and similarly for men²⁵ so that the conclusion remains that sexual behaviour is the 'predominant' risk factor.²⁶ An important issue is latency, i.e. that infections may occur early in life, remain undetectable for a long period and only surface when the immune system is off-balance later in life.²⁷ Though latency has not been proven, its possibility has consequences when one considers influencing sexual behaviour since one would need to target youngsters before they become sexually active.

Given the ubiquity of HPV, some research focusses on the rare instances in life that the immunity system breaks down. Yet, the 1% of possible cancer cases that currently can only be prevented by programme screening still amount to such large numbers that possibly too many factors are involved.

The research on a HPV vaccine is promising. For example, Kulasingam and Myers²⁸ consider the possibility of a \$200 human papillomavirus vaccine and they discuss the potential health and economic impact of adding it to screening programs. Their summary findings are: "Vaccination only or adding vaccination to screening conducted every 3 and 5 years was not cost-effective. However, at more frequent screening intervals, strategies combining vaccination and screening were preferred. Vaccination plus biennial screening delayed until age 24 years had the most attractive cost-effectiveness ratio (44 889 dollars) compared with screening only beginning at age 18 years and conducted every 3 years. However, the strategy of vaccination with annual screening beginning at age 18 years had the largest overall reduction in cancer incidence and mortality at a cost of 236 250 dollars per life-year gained compared with vaccination and annual screening beginning at age 22 years. The cost-effectiveness of vaccination plus delayed screening was highly sensitive to age of vaccination, duration of vaccine efficacy, and cost of vaccination. (...) Vaccination for HPV in

combination with screening can be a cost-effective health intervention, but it depends on maintaining effectiveness during the ages of peak oncogenic HPV incidence. Identifying the optimal age for vaccination should be a top research priority.” It may be added that they used a higher incidence of oncogenic HPV, and if that would be much lower due to safer sexual conduct, then the vaccine would no longer be cost-effective in its application in a screening programme. Hence the obvious scope for coordination.

A reaction to the above view on the danger of stigma and labelling would be to share the concern but to turn the argument around, i.e. to explicitly combine HPV with STI and thus to join all budgets to promote that sexual behaviour is healthy. Others follow this approach as well,²⁹ so it is useful to better understand why it has not been convincing till now. One factor can be that screening for cancer is specialist field with a reliance on technique and notably the Pap smear. Fortunately there is a growing awareness in the world of cervical cancer screening on the importance of behaviour. For example, an important issue for screening is attendance, and psychologists Sheeran and Orbell found ways to increase it from 69% to 92% in their trial.³⁰ Facts like these make you think about the importance of behaviour.

STI and the rising need to pool resources

In rich nations like the UK and the Netherlands, HPV kills more people than HIV. Yet, the lower number of HIV deaths in these rich nations may only come from a delay due to improved treatment.

The UK Health Protection Agency published the “first annual combined report on HIV and Sexually Transmitted infections (STIs) in the United Kingdom” in November 2003.³¹ The website mentions: “There were just over 1.5 million attendances at genitourinary medicine clinics in England, Wales and Northern Ireland in 2002, a 15% increase on 2001.” and “The estimated prevalence of diagnosed HIV infections in adults increased between 2001 and 2002 by 20% to 34300, and undiagnosed HIV infections increased by 17% to 15200.” Clearly, STI are in the rise. In The Netherlands the prevalence of HIV is stable but other STI rise^{32 33} though it always is difficult to distinguish true incidence from easier registration. Some points may be noted. Genital warts are included in the HPA report (as they are caused by HPV too) but cervical cancer is not explicitly mentioned though it has been mentioned in the 2001 report. The ONS mortality statistics for England and Wales report 1001 deaths for cervical cancer in 2002 and 439 ‘unspecified’ cases (that are cervical cancer when they are not corpus uteri). The “infections with a predominantly sexual mode of transmission” curiously cause only 3 male and 2 female deaths. HIV is listed separately though, and 2002 showed 160 male deaths and 38 female deaths, indicating that HPV is more lethal.³⁴ The Netherlands show the same, cervical cancer caused 258 deaths in 2000 and HIV 132 (of which 106 men and 26 women). Dutch motorcycle deaths are about 80 per year.

These sources generate another example that people working in the field of STI may have difficulty coping with the concept of cancer from oncogenic HPV. In The Netherlands, the official STI public information website recognises genital warts as the second most frequent STI, with annually some 20 thousand infections. Genital warts however tend to be caused by non-oncogenic HPV. It appears that oncogenic HPV is not listed as an STI at all. It is neither mentioned that more women die from HPV than people (mostly men) from HIV. The “fact sheet on genital warts” (not a PDF but a Microsoft Word document that can only be downloaded with Microsoft Explorer and not with Netscape) focusses on warts and not HPV. It mentions the possibility of cervical cancer from HPV but this is wrapped in this statement: “Genital warts are caused by HPV. There are more types of HPV. Only some cause genital warts, mostly types 6 and 11. For some HPV types, such as 16 and 18, it has been established that they can cause cervical cancer. No association has been established between genital warts and cervical cancer.” The statement seems somewhat adequate from the viewpoint from genital warts only, but it is inadequate from the point of view that oncogenic HPV should also be listed as a STI. There is also a difference between “no association has been established” (i.e. “we did not sufficiently look for it”) and “it has been established that there is no

association". It has been established that people can have infections of more types at the same time, both non-oncogenic and oncogenic. People with non-oncogenic HPV are more likely to have oncogenic HPV than people without any HPV. Note that the literature concludes: "The association between (oncogenic/TC) HPV infection and cervical cancer is stronger than that between cigarette smoking and lung cancer and comparable in magnitude with that between hepatitis B infection and liver cancer."³⁵

The data suggest that there is a rising need to do something about sexual behaviour. If preventive activities, such as health education and contact tracing, are going to be coordinated, then inclusion of HPV would allow to join the budget of STI and HIV with that of cervical cancer screening. This conclusion is in line with the important paper by Pisani et al.³⁶ who argue to go 'back to basics': "Every year, the United Nations releases new estimates of the number of people living with HIV infection. Despite 20 years of experience with prevention programmes, this number continues to rise. To date, around 60 million people have been infected with this preventable, fatal viral infection — a sad indictment of the world's prevention efforts so far. (...) A clearer focus on the behaviours that are responsible for most exposure to HIV in a country should lead to more effective prevention efforts. (...) To say that countries cannot begin a sensible assessment of their prevention efforts without a proper analysis of who is becoming infected with HIV and how they were exposed seems almost too obvious, and yet we so rarely undertake this analysis. With five million new HIV infections to shame us over the past year, it is time to stop stating the obvious and to start doing it."

Scope for influencing sexual behaviour

The question then clearly is whether we can adequately influence sexual behaviour, and if so, how. Oakeshott et al.³⁷ are sceptical: "However, out of nearly 300 reports of sexual health interventions (ref) only three have reliably shown an increase in condom use. These were very intensive, costly and time-consuming interventions in highly selected American populations — runaway teenagers, 18-year-old female psychology students, and high risk genitourinary clinic attenders. (ref) In the most recent trial, (ref) a seven-session HIV risk reduction intervention resulted in more consistent condom use (42% versus 30%) over a 12-month follow-up period. However, there was no significant difference between the groups in STI re-infection rates." They propose a scheme themselves that appears more promising. This scheme however has a limited scope, and it is useful to consider alternatives too.

Behavioural control runs up against perverse mechanisms in the human mind. One such phenomenon is the psychological reversal of cause and effect. Take for example the case that steady couples will have learned to trust each other and then skip the use of condoms. It then appears that many people equate 'trust' with 'no condoms' and think that if they don't use condoms then this is evidence of trustworthiness. Similarly, in sex education, an insistence on abstinence before marriage may derive from blame-shifting rather than really help out. Any intervention will have to deal with such human weaknesses.

An argument that is key to this discussion can be found in the following paper that by itself only aims to review the literature. The point is that the design of an intervention should be based in psychological theory: "It is important to note that the scale of investment in educational initiatives to promote safer sexual behaviour (initiatives which also have important 'knock-on' effects for preventing other sexually transmitted diseases, such as gonorrhoea, as well as unwanted pregnancies) continues to fall a long way short of investment in biomedical interventions despite scientific and economic arguments about the virtues of a two-pronged approach (...). The case for funding behavioural interventions was damaged by theoretical and methodological inadequacies characterizing early HIV/AIDS education programmes."³⁸ Having recovered from these inadequacies, they conclude: "Social cognitive models, including the theory of reasoned action, the theory of planned behaviour and sociale cognitive theory, have been found to successfully predict a range of health behaviours including HIV-preventive behaviours. (...) For example, an effective cognition-change

intervention based on the TPB (theory of planned behaviour) could potentially change condom use rates from around 20-30 per cent in a control group to around 70-80 per cent in an intervention group.”

That psychology can work, does not mean that all psychology works. This is also the experience in The Netherlands.³⁹ What theory will work is quite difficult to determine, but one idea with intuitive and common sense appeal is that a person’s sense of control is important. In a study on the use of condoms it was noted: “Evidence suggested that perceived behavioral control from the theory of planned behavior was a reliable predictor of behavioral intentions”.⁴⁰ Additionally, it appears that cognitive dissonance is relevant. This appears to be an area where psychology and economics join forces on a unified paradigm. The human brain can be understood as a machine that processes information but that has scarce resources to do so. Some beliefs can be so ingrained that it costs much energy to change them, and the brain may rather neglect new contrary information. For example, we may inform teenagers about the benefits of condom use, but when they feel themselves invulnerable, then the new information will easily be neglected. Similarly, good conduct needs to be internalized and become part of the automatic reflexes, so that the brain does not need to think through again the whole issue when a case arises. To arrive at such internalization, only a comprehensive system works.

If we are to design a system that works then we should consider the interaction of behaviour with the natural history of an infection. A point of departure can be the thought experiment that all children are born without infection. If we would mark the line at the year 2000, and induce all born after 2000 not to have sex with anyone born earlier, and induce all born earlier not to have sex with anyone born after 2000, then the newly borns would be free of STIs. As a rule of thumb, that approach is interesting in itself. The point of course is that people will not be induced so easily, while some children will be infected, and while we should also be concerned about those born after 2000. Hence it is more fruitful to distinguish the different sections of the population that exist, namely the pools of the never-infected, the cured and the carriers. These statuses are true states, however, and may only be known by means of tests that can fail. By consequence we could create a registry and a protocol for dealing with entry, status change and verification. If that registry can influence the contacts and flows between these pools, without creating a false sense of security, then the benefits can be substantial.

Important aspects in sexual behaviour appear to be the perceptions on ‘steady’ and ‘casual’ partners, and one’s perceived ‘self-efficacy’ or ability to control behaviour. The key idea then is that the information in the registry allows the individual more control over the situation, so that he or she may be less likely to throw caution to the winds. The use of condoms would be an integral part of using the registry, and cognitively linked to it, so that there is no psychological barrier to bring it up for discussion and so that there can be no misunderstanding that a condom is a health tool and not some measure of the relationship. Whether this will truly be the case of course needs to be established empirically, but the idea is that this would at least be considered for the design.

Possible implementations and trials

Given all the complexities both in human behaviour and the natural histories of the STIs, there is an abundance of research opportunities on the question how such a protocol might be implemented in a cost-effective way. Yet, at the same time, the idea arises that it could be an immoral waste of time if we were to wait with experimentation till all research is in. As with Pasteur: when a vaccine shows that it works, you don’t continue testing but you administer it.

First of all, it already seems unduly conservative if we were not to publish the protocol until a version of it has been subjected to a clinical trial at only one single and particular location. It seems much better that the general idea of the protocol is published so that researchers and policy makers can consider their own versions. The application of the protocol in the context of teenagers is different from the application in the context of mature consenting adults and

this is again different from the application in the context of sex workers with commercial motives. The protocol only gives the logical calculus of the infection status and the directions of the sticks and carrots, and is of necessity empty on implementation. Social conventions, financial arrangements, available resources such as the internet or not, the existence of a NHS or not, privacy laws and so on differ per continent, country and culture, and every community has to find its way.

Secondly, the protocol seems to have more advantages than disadvantages anyway, and one should not block such easy opportunity for improvement. The protocol does not encourage unsafe sexual conduct and it does not seem to provide a false sense of security by itself. It only improves the quality of information. Whereas new lovers nowadays have to trust each other's personal testimony or have to go to a clinic just to be on the safe side, the risk of the first is reduced and the stigma and costs of the second are minimised since the information is stored and subject to quality control. The most negative aspect seems to lie with privacy. Yet, privacy is fully maintained, except for illegal events. There is a large section of the population that is comfortable with such issues, witness also the various internet sites of our modern teenagers, and at least for them that disadvantage does not exist. Admittedly, in a non-permissive society the system might evolve to something like a Big Brother, where a person for example doesn't get insurance if the infection status is not disclosed, or where the STI register becomes a sex licence just like one needs a driver's licence. Such a possible evolution however is another discussion, perhaps related to the proposal to stop tax collection since that might be abused as well.

Thirdly, a basic objection to the protocol might be that it would simply not be used, or only used by those who practice safe sex already, so that clinical trials to determine its properties and cost-effectiveness would be useless anyway. The answer to this objection is that there are sticks and carrots here. First of all, there are clear advantages to participation, especially for those currently at risk. Sex education can be more inclusive with respect to all consequences of unsafe sexual behaviour, not only unwanted pregnancy, future fertility and AIDS but also cancer. A current attitude can be "if I cannot do anything about it, if I cannot control the situation, then I don't want to know", possibly associated with abuse of drugs and alcohol to suppress anxiety, but the protocol provides a degree of control that counters that sense of impotency so that sex education will get more attention. The protocol limits the role of the condom to the unsafe stage of a relationship, and participants can sooner enjoy the benefits of a safe relationship once they have learned to trust each other. The set-up induces partners to concentrate on the real factors for trust rather than the 'cargo cult' imagery. There is the advantage of quality control, with an added bonus similar to a lottery. On the other hand, there is the risk of losing the clean STI status. This is an advantage for the group as well. Compare this with the law against stealing. People generally don't steal and that is not because there is a law against it, yet the law is useful for a minority that needs it, and the existence of the law and its enforcement generates security for all so that people generally flock to the state of law.

There is an obvious point of caution. Youngsters might be tempted to oppose the scheme just for the fun of it, 'being the irresponsibles that they are'. In some subcultures, it might increase group standing if one says that one is infected with some dangerous germ. People can be irresponsible, witness current unsafe behaviour anyway. Poor resource countries have people walking freely who would be hospitalized elsewhere. In practice however, once the resources are there, all depends upon framing. Responsibility comes with a degree of control. Once the issue is presented as something basically dull and practical, which it rather is, there is little fashionable about it. Perhaps a dramatist would write a play of the modern Romeo and Juliet where the one has code blue and the other red, so that love seems impossible, causing their suicide, but, at heart, that does not seem like an appealing improvement over the true Shakespeare.

Finally, central registration is a sensitive issue by itself, witness the quite different example of organ donation, and this now combines with the sensitive issue of sexual behaviour, creating

sensitivity to some higher power. In anonymous questionnaires, women tend to mention a numbers of partners that is rather low. Will those women participate when the registry claims a similar anonymous status but requires the true number of partners ? Only experimentation will tell, and the true test comes from model designs that rely on psychological theory. Partner notification of diagnosed STI is the direct sensitive issue to deal with. It is obviously advisable to ask the partner to instruct the registry to this effect before consuming the relationship, yet a person should also send a notification that the relationship has been ended, otherwise one would send and get messages on former partners of years ago. Will people duly obey this menu ? Risky behaviour often continues even with the acquired cognition of the risk, so the scope of success would be lower than potentially thought. Here the point of the whole exercise is that the registry provides a service to the risk-averse and risk-neutral, and should help them to keep their distance from the risk-prone. Whether the protocol can survive these severe practical conditions can only be shown in practice or by simulations that sufficiently mimic reality. Researchers and managers in the field of STI including cervical cancer screening will have to deal with these issues and questions.

Conclusion

The acronym STI should rather stand for “sexually transmissible infection” rather than “sexually transmitted infection” and it should then include HIV and HPV and subsequent risks of cancer. The common denominator of sexual transmission causes the link with human behaviour in areas of privacy and intimacy. Here we should not just use technical means but also facilitate safe behaviour. The traditional method of having only one partner in life, possibly enforced by strict family surveillance, is unduly restrictive for the pursuit of happiness, at least for large sections of the population. The draft protocol presented here outlines the skeleton of a workable scheme that would combine safety and freedom. The current freedom as it exists today also means lack of information and security, and many would gladly accept a few restrictions in exchange for those. Communities such as local health departments or medical schools or even commercial insurance networks could already start experimenting with the protocol, such that experience is generated and health already improves, while researchers can design their trials to pinpoint true cost-effectiveness.

Appendix D adds some comments on the state of the discussion since this draft of April 25.

Conflict of interest statement

The author might eventually benefit commercially from the ideas presented here.

Disclosure of role of funding source

The author learned about the situation by involvement in a study at Erasmus MC on the cost-effectiveness of screening for cervical cancer. He put in a number of his own and yet unpaid hours to write the paper.

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Appendix A: A draft protocol

The following is a draft protocol, more oriented on the participants rather than on the registry itself. This is only an outline, and quite some rules and logistics are required to have the system really work.

- (1) A registry is managed by an independent organisation. Records on participants are changed only by the organisation and changes are based upon official information and medical tests only. Records contain proper identification, such as a recent photograph.
- (2) Entry in a registry by a participant requires a signed consent to the protocol and a fee of at least 50 euro. This holds even for entry at puberty. Entry in the registry requires passing an exam on sex education, the meaning of tests and the application of the protocol.
- (3) The penalty or fine for not fulfilling the duties of the protocol is that a participant loses the entry fee, has to do the entry procedure again for continued service, and may be subjected to legal consequences. The reward of fulfilling the duties of the protocol is that one is not fined while one can benefit from the services of the registry.
- (4) A participant in a registry has access only to the own account, always at the registry's office and preferably by a password protected internet link. A participant can order the release of status information to a designated person at the same or another registry. This status information concerns only what one needs to know for safe sexual contact and does not need to contain the full life history.
- (5) There are the following registration categories (with a traffic light colour code for easier recognition):
 - (a) Status unknown (white). People not registered. People who are waiting for a (non-random) test result. People who lost an earlier better status but have not been tested to determine their new status.
 - (b) Never-tested never-infected (green). Entered at early puberty at 12 years without a test since, but also without contra-indication that a test might be needed.
 - (c) Tested never-infected (blue). Was green before but was randomly tested under the protocol for quality control with now a verified negative status.
 - (d) Tested non-infected with unknown history or with some earlier negative tests (yellow). Entered at any time other than puberty and was tested negative but it is not truly known what happened before since earlier negative tests contain only limited information.
 - (e) Tested non-infected with known history of cure (orange). Had a known positive episode, but is fully cured with tests to prove it.
 - (f) Test positive carriers (red). There is at least one recognised infection that is not cured, either HPV, HIV or other STI. The status on each infection is recorded.
 - (g) The rank order of high to low safety is blue-green-yellow-orange-white-red. This would be registered per infection and for the 'total' that gives the worst status.
- (6) A registry has a quality control programme. By sampling methods, people are called for testing. Who does not attend the test, gets the new status 'unknown' (white) and is fined. Who was registered as negative and is tested negative again, receives a reward of 20 euro. Who was registered as negative and is tested positive (new status red) either did not stick to the protocol or was a victim of a false-negative contact, and thus can be fined unless one participates in contact tracing with the result of finding such a false-negative.
- (7) A registered person may always leave the registry and then receives the entry fee back. The register keeps the records (a red remains red, otherwise the new status becomes white).
- (8) An application for entry in a registry also implies a consent for a search in known registries for earlier records. Participation similarly implies consent for the inclusion of pap smear results. Medical tests may also be taken for archival purposes only, such that for example the cost of analysis of those samples is delayed till contact tracing. Consent is also given for the use of all records for research purposes.

- (9) Participants apply these rules with respect to new contacts:
- (a) A sexual contact with a partner of different rank must be reported. The person with the higher rank files the report and receives the lower rank of the partner.
 - (b) When someone within a registry contacts someone without a registry (white), one asks this person to join the registry, with either a negative (yellow) or positive (red) result.
 - (c) For new contacts it is encouraged to have the three months use of condoms because of the HIV incubation period, and then to take the HIV test in case of doubt.
 - (d) Also depending upon the results of the quality control program, the registry may impose stricter rules on registration of new contacts, for proper contact tracing.
- (10) The costs for the registry and the various tests are carried by the participants, and the whole enterprise could well be exploited commercially, but can be subsidised on public health grounds.

Appendix B: A guiding example

Suppose that Romeo and Juliet meet at a party, fall in love, and after a string of dates with serious holding hands they desire to consume their love. As a rule, they check with friends whether their partner is reliable, and for the first three months they would use condoms anyway because of the incubation period of HIV. But the STI registry will provide them with more certainty about their decisions. In a country with limited resources, the registry might use paper only, otherwise the registry can use the internet. Romeo logs into his registry, enters his password, and allows Juliet to read the relevant data from the monitor. Similarly for Juliet. Possibly there are different registries with different standards, possibly in commercial competition, and then Romeo and Juliet can order a translation, so that, after some automated email exchanges between the registries, they can read their partner's status at their own registry. The new lovers thus have more control over their situation. Having this control, it may be easier for them to stick to the three months use of condoms before they decide whether those are still needed.

Appendix C: Some selected research areas

The discussion in the main body of the text generates a number of questions. Some people may already know the answer to some of the questions and then the challenge is dissemination. Given the complexity, we should speak about research areas rather than research questions, and the following selection is only indicative.

- (1) The protocol gives only a general scheme and can be published without a previous clinical trial. The next step is to fill in the details for particular implementations, so that one can identify what is already feasible and what is unknown or questionable and in need of empirical testing. What could be the barriers to such implementation research, and how could such barriers be removed ?
- (2) Under what conditions can cervical cancer screening incorporate the STI aspects and under what conditions can the control of STI incorporate the cancer aspects ?
- (3) As Pisani et al.³⁶ claim that prevention should go back to basics, and as Abraham et al.³⁸ claim that much has been tried in the area of behaviour modification but not with the theoretical focus that is needed, then (a) either these authors are misguided, (b) or there is scope for more consensus on approaches that can work indeed, (c) or there are too many entrenched interests. How could we establish what is the case ?
- (4) Are there groups at risk that attach less value to privacy and that welcome the permanent status of surveillance ?

- (5) Can larger groups be educated, not only youngsters but whole cultures, to separate the notions of love and affection from the notions of safe behaviour and technique ?
- (6) Can the numbers with irresponsible behaviour be reduced by social inducement, psychological framing and the use of a comprehensive system, with mandatory elements and quality control ?
- (7) Disadvantages are costs, possible perceived loss of privacy, a false sense of security. Advantages are more security on partners and situations, prevention on a wider scope of diseases, healthier sex life, financial benefits. Which sticks and carrots apply to what group and to what degree, and how strong are the barriers with respect to drugs, alcohol and peer pressure ?
- (8) Social psychology identifies some general mechanisms concerning how something becomes a taboo. Almost anything can become a taboo, it is just a mechanism. In the present case, it are matters of privacy and sexual behaviour that run that risk, both at the individual and policy making level. How can these processes be countered ?
- (9) It would be possible to use of the internet as a mode of access to the registry. Is this advisable or not, under what conditions ? (a) It should always be part of a comprehensive scheme that includes education and quality control. (b) It should be reliable (with 'garbage in, garbage out'). (c) Internet applications are very sensitive to the format. It is possible that a good design only follows from experimenting a lot.
- (10) Are the present laws on privacy sufficient or would we need additional legislation (per country) ? Or is it rather the execution of those laws ?
- (11) As oncogenic HPV is much like the common cold, though with a risk, can such a scheme really reduce its prevalence ? Should it still be legal, to knowingly infect someone with a virus with that risk ?
- (12) What is the cost-effectiveness of the most effective and least costly implementation that one can start experimenting with ?

Appendix D: State of the discussion from April 25 – December 3, 2004

This draft paper of April 25 2004 had to be put aside because of developments at the Dept. of Public Health at Erasmus MC that caused my curious dismissal starting August 1 2004.

Comments on those developments are not relevant to the present topic of discussion, though, for completeness, Dutch readers are referred to my website. What remains interesting is that I used the concept of cognitive dissonance also to explain those developments and that it appeared that some people did not understand its meaning. In my experience it is a crucial concept – see also Aronson's book – and it should be known by any scientist.

The paper was drafted for The Lancet or the Journal of Medical Hypotheses or an online journal. Since the process of completion was stalled, I can usefully submit it now to the Economics Working Papers Archive at the Washington University in St. Louis. At first glance there seems to be little economics in the paper, but a moment of reflection will cause one to see that the issue of management is strongly present. I nevertheless hope that the medical community takes note too.

I am really hard pressed in time, but what prompted me to take these few minutes to compose this appendix is The Economist, November 27th 2004:

- In "The new face of AIDS", page 88-89, the issue of abstinence features strongly. What brings a smile is their discovery: "Wealthy older men can afford many sexual partners, and often prefer them young." It is amusing how good journalism apparently requires some obvious banalities such as these. However, they also state more grippingly: "And a

disease that creates the conditions that favour its spread is the most dangerous disease of all.”

- In the Books and Arts section, p93, there is a short review of Bjorn Lomborg, “Global Crises, Global Solutions”, CUP 2004. Notably: “Better, for instance, to spend resources on the immediate problem of AIDS in Africa than the more distant one of global warming.” However, in January 2005, Dutch University Press will publish the 2nd edition of my “Definition & Reality in the General Theory of Political Economy” (DRGTPE). If this economic analysis is understood, then huge resources will become available, and it remains advisable to both fight STI and do something about global warming.

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