EU DRUGS AGENCY PUBLICATION ON HEPATITIS C AND INJECTING DRUG USE LOOKS AT IMPACT, COSTS AND POLICY OPTIONS

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The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the EU drugs agency, has recently Published its latest scientific monograph, Hepatitis C and injecting drug use: impact, costs and policy options [1]. This publication brings together research by international experts from the hepatitis C, drug use and public health fields. It combines analyses on the impact and costs of hepatitis C virus (HCV) infection among injecting drug users (IDUs) so as to inform future policy making in the European Union.

Since screening for HCV became available in the early 1990s, drug injecting has been the most common route of infection in the EU, largely due to risk behaviours such as sharing of needles, syringes, and other injecting equipment. While HCV may affect over 1% of the population of the EU, prevalence is substantially higher among those who have injected drugs.

The monograph points to data indicating that up to 90% of newly notified cases of HCV infection in EU countries are now occurring in IDUs [1,2]. The EMCDDA 2004 Annual Report, Published last month, cites HCV prevalence rates of between 17% and 95% in IDUs, depending on the country and study setting, underlining the need for prevention and treatment in this the main at risk population [2].

Current IDUs often encounter difficulties in accessing treatment due to concerns about their poor compliance to programmes, side effects and risk of re-infection. Recent research studies, however, have shown that treating IDUs is feasible and effective, and new guidelines recommend case-by-case decisions on treatment.

Some other key findings:

- New HCV infections occurring in 1999 in six of the most affected countries – France, Germany, Italy, Portugal, Spain and the United Kingdom – are likely to result in healthcare costs of up to 1.43 billion over the next two decades. Data presented estimate lifetime healthcare costs ranging between 13 100 and 26 200 per infected person in these six countries.
- New cost effectiveness analyses presented suggest that screening IDUs for infection and offering combination antiviral therapy to those with moderate liver disease can enhance quality of life, extend life expectancy and be cost effective. It is estimated that through avoiding the costs of liver disease related complications, over two thirds of the average treatment costs can be compensated for.
- Needle and syringe programmes (NSPs) are a key public health intervention for IDUs in general. They are cost effective in reducing the general transmission bloodborne viruses although they seem less (cost-)effective for HCV than for HIV prevention.
- Methadone maintenance treatment (MMT), though highly effective and cost effective for HIV prevention, is less so in the case of HCV. As the benefits of MMT increase with the proportion of the IDU population covered it can become a cost effective method of HCV prevention once high levels of coverage are attained.

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CONSIDERABLE PROGRESS IN EUROPEAN PREPARATIONS FOR A POTENTIAL INFLUENZA PANDEMIC

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The threat of an influenza pandemic has been heightened in the past two years by outbreaks of avian influenza concentrated in South East Asia which have resulted in human deaths. So far, the avian influenza virus seems difficult to transmit from human to human, but changes in the virus genome may well increase transmissibility. Possibly worse, a person or animal (such as a pig) could become co-infected with human and avian influenza. These viruses could then combine, creating a very novel influenza virus that is both highly pathogenic and easily transmitted to humans.

The World Health Organization has warned of an influenza pandemic threat and is urging member states to devise a national influenza preparedness plan for this eventuality [1]. It has also devised warning levels and has linked actions to each level.

The European Commission and European Union (EU) member states have responded to the influenza pandemic threat and much progress has been achieved in recent years.

Preparation by the European Commission and European networks

In response to the outbreak of avian influenza in South East Asia, the European Commission banned imports of live birds and poultry products from many countries in February 2004 [2,3]. This ban has been extended to 31 March 2005.

In March 2004, the European Commission Published a Working Paper on Community Influenza Pandemic Preparedness and Response Planning (http://europa.eu.int/comm/health/ph_threats/com/Influenza/com_2004_01_en.pdf) which called on all EU member states to complete their influenza pandemic preparedness plans, designate national reference laboratories for human influenza, achieve high vaccine coverage (especially in high risk groups), and prepare media briefing materials on influenza. The paper also stated the tasks of the European Commission in planning for a pandemic.

Surveillance of influenza in Europe (European Influenza Surveillance Scheme, http://www.eiss.org) has been considerably enhanced in recent years with funding from the Commission. Since October 2000, clinical, epidemiological and virological data have been presented on a weekly basis from October to May each year on the EISS website. In 2003 the Community Network of National Reference Laboratories for Human Influenza was created within EISS and this network is now operational (http://www.eiss.org/documents/eiss_poster_cnrl.pdf). Its primary goal is to provide high quality reference services for human influenza surveillance, guaranteeing highly qualified virological data reported to EISS as well as clinical data.

The European Commission's DG Research has also funded projects related to influenza pandemic preparedness (e.g. the FLUPAN project) and it recently started funding a multicentre network called VIRGIL (http://www.virgil-net.org/), which will address current and emerging antiviral drug resistance concerning influenza.

European vaccine manufacturers (http://www.evm-vaccines.org/) have got together and are working on issues related to the production of an influenza vaccine in case of a pandemic, for

example how many vaccines will be needed and how can production be increased to meet these needs (http://www.evm-vaccines.org/290403%20Flu%20pandemic%20final.pdf).

The European Scientific Working Group on Influenza (http://www.eswi.org) is also active in the area of pandemic preparedness. This group organises an important scientific conference in Europe every two years where issues related to pandemic preparedness are high on the conference agenda.

Preparation by member states

The EU member states have also been active in preparing for a potential influenza pandemic. A survey carried out in November 2000 found that eight countries (50% of those surveyed) had an official pandemic plan, seven countries had a plan that was in an advanced stage or draft format and one country did not have a plan. Many of these plans have now been finalised and European countries are now starting to implement these at a national and local level. A number of countries have started to stockpile antiviral drugs (France, Belgium and the Netherlands).

Further challenges to Europe-wide pandemic planning

Consolidation of these different activities is now required and the general level of preparedness will be tested by an EC-funded simulation project (http://europa.eu.int/comm/health/ph_programme/howtoapply/call_130356_2004.htm)The simulation should help measure preparedness at a European and national level, and identify weaknesses that need strengthening or correcting.

One important challenge that has not yet been resolved is the equitable distribution of vaccines (if these are available) and stockpiled antiviral drugs. Considering EU treaties no longer hold in a situation of 'force majeure', member states could legally hoard nationally produced vaccines and/or antiviral drugs. This would be a very unfortunate development for Europe and mechanisms to ensure equitable access to vaccines and antiviral drugs within the EU should therefore be encouraged.

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Differences between new United States recommendations and existing European guidelines on the use of postexposure prophylaxis (PEP) following non-occupational exposure

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Last week the United States Department of Health and Human Services Published updated recommendations for the use of post-exposure prophylaxis (PEP) following non-occupational exposure to HIV [1]. The evidence is still unclear as to the efficacy of this intervention and this report provides a comprehensive overview of available literature, and discusses the benefits and problems with the administration of PEP in certain circumstances. It also clearly re-emphasises that the most effective way to prevent transmission of HIV is to prevent exposure, and any programme of PEP administration should not replace primary prevention.

In 2004, the Euro-NONOPEP project group Published recommendations for PEP use along with the results of their two-year Europe-wide study [2]. Although the two guidelines considered the same intervention in the same circumstances, there are marked differences in their recommendations. Both guidelines state the basic notion that PEP should be administered to people exposed to potentially infectious bodily fluids of a known HIV-infected person, when the exposure represents a substantial risk of transmission. In these cases, a 28-day regimen of highly active retroviral therapy (HAART) should be prescribed. After this point, however, they differ in three main areas.

First, the United States (US) guidelines recommend that PEP is only prescribed when the source person is known to be HIV-infected. For cases where the HIV status of the source is unknown, the guidelines state that the clinician should assess each case individually and use their judgement. The European recommendations lay out the circumstances under which PEP should or should not be considered or prescribed if the status of the source patient is unknown. If the source patient is from a group or area of high HIV prevalence (at least 15%) the European guidelines recommend that PEP be prescribed following receptive anal sex; for other exposures, anal, vaginal or oral (with ejaculation), PEP should be considered. They also state that if the source patient is not from a high-risk group, then PEP should only be considered following receptive anal sex. The US recommendations put a stronger emphasis on the potential side effects of PEP and conclude that these may well outweigh the potential benefits if the infective status of the source patient is unknown.

Second, both guidelines focus on the risk of transmission. For some transmission situations, where the partner is HIV-infected, the transmission values used by each group are similar or the same, e.g. following a blood transfusion: US, 90%; European, 90%-100%. For other exposures, the transmission risk estimates used are very different. In particular, the US document estimates the risk of transmission via receptive anal sex to be 0.5%, while the European group estimates this to be 3%. This large difference in transmission risk may have influenced the recommendations made for PEP usage. As mentioned above, the European guidelines recommend that PEP be considered in any situation where unprotected receptive anal sex has occurred. As long as there is continuing uncertainty as to the true risk of transmission via different exposures, it is difficult to reach consensus on all the situations where PEP should be prescribed.

The final significant difference concerns the advice on the regimen of antiretrovirals to use. The Euro-NONOPEP group recommends the use of triple therapy (treatment with a combination of three drugs belonging to two different classes) but states that a two-drug regimen (treatment with two nucleoside reverse transciptase inhibitors (NRTI)) is also an option. This is based on evidence that drugs acting at different stages of the virus' life cycle are superior to monotherapy and that tri-therapy has been shown to treat HIV-infected patients most effectively. However, the US recommendations state that there is no evidence to indicate that a three-drug regimen would be more effective than a two-drug regimen. They place a heavier emphasis on the possible risks of side effects and state that these should be discussed with the patients. They also consider the prescription of medication to treat side-effects of HAART.

The differences in recommendations highlight the ongoing controversy surrounding the use of PEP following a non-occupational exposure. An increasing number of countries are addressing the use of PEP and establishing recommendations [Table].