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Response

Response to Volkow P et al. – Cross-border paid plasma donation among injection drug users in two Mexico–U.S. border cities – International Journal of Drug Policy 20 (2009) 409–412

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Volkow et al. (2009) provide an analysis of intravenous drug users (IDUs) in two Mexico–US border towns, some of whom donated plasma in centers on the US side of the border. Their findings demonstrate that most of the IDUs attempting to donate did so prior to the 1980s. This is confirmed through their specifying manual plasmapheresis as the collection technology; this procedure has been superseded by automated plasmapheresis for over 20 years. Nevertheless, their finding that two IDUs donated in the period 2003–2005 is of concern, as by this time the safety paradigm which has ensured the safety of plasma therapies was in place. Lack of veracity in answering the Donor History Questionnaire (DHQ) used to select plasma and blood donors or the Respondent-Driven Sampling (RDS) used by Volkow et al. is clearly potentially problematic when engaging with IDUs motivated by payment. This problem is not limited to paid donors; in a National Heart, Lung and Blood Institute (NHLBI) study of unpaid US blood donors, 51% of hepatitis C (HCV) positive and 1% of HCV negative donors admitted intravenous drug use (Murphy et al., 2000), despite this being an excluding factor in the DHQ. Motivating factors to donate blood and plasma are multiple and complex, and range from cash payment to volunteerism. Some forms of widely used non-cash incentives are also crucial in maintaining the motivation to donate (Lactera & Macis, 2010), and have also been associated with risk factors (Read, Herron, & Hughes, 1993).

The prospect of economically vulnerable, at risk individuals donating plasma is clearly confronting. The ethical aspect is, arguably, beyond the influence of the plasma industry (Del Pozo, 1994); at the least, it can be counter-poised with the ethical consequences of depriving patients from the products generated by the two-thirds of the global plasma supply which is provided by paid US donors. Unquestionably, the supply of these essential medicines depends on individuals who expect payment for their donation. The best efforts of the unpaid donor sector have failed to supply the necessary plasma. The demographics of the two sectors differ greatly (Ritter, Willand, Reinhard, Offergeld, & Hamouda, 2008). The issue is whether the safety of the supplied raw material and the final therapeutic products are affected by this particular demographic.

The safety depends on a set of measures implemented by the sector(s) and overseen by regulators, designed to ensure (1) the exclusion of high risk individuals through donor selection, (2) the testing of all plasma for relevant pathogens and (3) the elimination of pathogens through manufacture. The kind of measures suggested by Volkow et al., such as inspection for injection sites, have been embedded in the DHQ for many years. Lime all safety measures in place, this is overseen by the US Food and Drug Administration (FDA), which licenses centers on the basis of the "strict compliance with regulations" advocated by Volkow et al. in addition, the US paid source plasma industry qualify all donations by testing all donors twice on separate occasions before releasing the plasma into manufacture. Prior to plasma pooling, the donations are held in inventory for 60 days over which they are subject to recall if the donor develops any disqualifying features post donation. These processes result in a safety profile in qualified plasma donors which is superior to that of the general US population. The viral maker rates for donors in the US–Mexico border centers are significantly lower than those in the total plasma donor population (Table 1). This indicates that any historical deviations from good selection procedures detected by Volkow et al. are not affecting the safety of plasma collected in this region.

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Table 1
Viral marker rates for source plasma donors.

Compensated qualified[a] plasma donors[b]	Positive marker rate/10^5 donors		
	HIV	HCV	HBV
All of USA	14.12	53.56	31.5
Border centers	2.7	27	31.5

[a] See http://www.pptaglobal.org/program/Qualified_Donor_Standard_v3-0.pdf for a description of the donor qualification process.
[b] Internal data for 2005 collected by the PPTA (Data for donations was converted to donors by applying a conversion factor of 15, which is the average donation rate per year for the source plasma donor population).

Infections vehicled through plasma derivatives have occurred, historically, through products from paid and unpaid donors. Their obviation for the past 20 years has occurred primarily as a result of robust pathogen elimination techniques built into the manufacture. Volkow et al. express concern about emerging pathogens. The two agents which have emerged as major blood safety threats in the past 10 years – West Nile Virus (WNV) and variant prions – have not been associated with donor payment. They have been transmitted through unpaid donor components but not through paid donor derivatives, because of the presence of pathogen elimination in the latter, not the former. It is a sober fact that the emergence of an untested, epidemiologically uncharacterized agent will contaminate the blood supply, irrespective of whether donors are paid or not. We agree with Volkow et al. that sole reliance on pathogen elimination is inadvisable, and hence the plasma industry has implemented selection measures, through the qualification and inventory processes, which are over and above those mandated. The industry includes all donors who fail the selection process in a National Donor Deferral Registry (NDDR) which is shared between the different companies to ensure that unsuitable donors do not donate. In addition, the industry has introduced nucleic acid testing (NAT) before it was mandated for the unpaid blood sector, and performs NAT for other agents such as parvovirus B19 and hepatitis A, which are not tested in the unpaid sector. It is worth noting the presence of these pathogens is unrelated to the donors' compensation status.

In summary, Volkow et al. show that a small number of plasma donors in their area of analysis may have concealed their risk status, possibly because of the payment offered. The multi-layered scientifically based measures introduced by the plasma industry over the past two decades has ensured that no pathogen transmissions have occurred since 1994, irrespective of whether donors were paid or not. Payment is necessary to ensure the supply of vital, life-saving derivatives. More effort is needed to expand the population of individuals willing to donate plasma, as the demand for the derivatives continues to increase.

References

Del Pozo, P. R. (1994). Paying donors and the ethics of blood supply. *Journal of Medical Ethics*, *20*, 31–35.
Lactera, N., & Macis, M. (2010). *Motivating altruism—A field study. Discussion Paper No. 3770*, Institute for the Study of Labor 2008. On http://ftp.iza.org/dp3770.pdf. Accessed on 7 April 2010.
Murphy, E. L., Bryzman, S. M., Glynn, S. A., Ameti, D. I., Thomson, R. A., Williams, A. E., et al. (2000). Risk factors for hepatitis C virus infection in United States blood donors NHLBI Retrovirus Epidemiology Donor Study (REDS). *Hepatology*, *31*(March (3)), 756–762.
Read, E. J., Herron, R. M., & Hughes, D. M. (1993). Effect of nonmonetary incentives on safety of blood donations. *Transfusion*, *33*, 45S (suppl, abstr)
Ritter, S., Willand, L., Reinhard, B., Offergeld, R., & Hamouda, O. (2008). Blutspenderpopulationen in Deutschland: Demographie und Spendeaktivität. *Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz*, *51*, 915–925.
Volkow, P., Brower, K. C., Loza, O., Ramos, R., Lozada, R., Garfein, R. S., Magis-Rodriguez, C., Firestone-Cruz, M., & Strathdee, S. A. (2009). Cross-border paid plasma donation among injection drug users in two Mexico-U.S. border cities. *International Journal of Drug Policy*, *20*(5), 409–412.

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