A needed Convention against trafficking in human organs

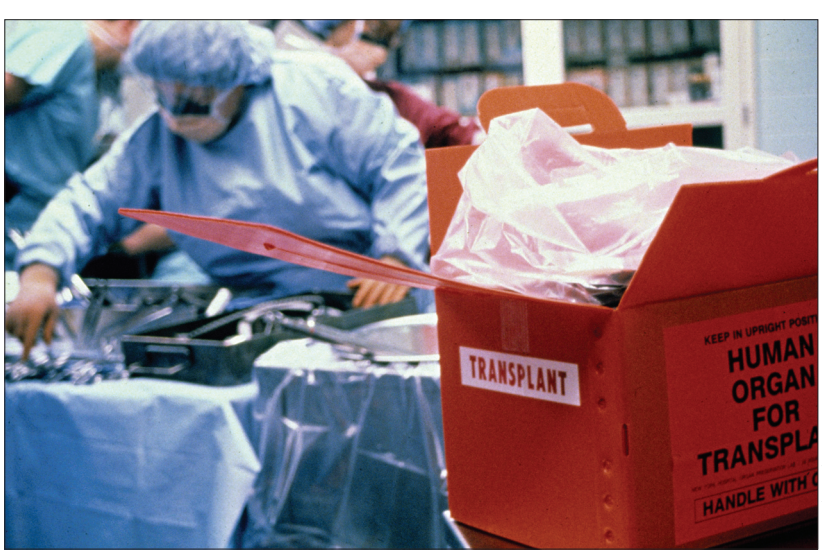
More than 114 000 organ transplants are done annually in over 100 countries.[1] Estimating that 5–10% of kidney transplants result from commercial transactions,[2,3] WHO has warned against the worldwide "trade for profit in human organs",[4] which tarnishes this life-saving therapy.[5] Although legislation forbidding organ sales exists in most countries,[6] progress has been impeded by weak enforcement and the absence of comprehensive binding international instruments to harmonise regulations and improve cross-national cooperation.

The Convention against Trafficking in Human Organs,[7,8] soon to be adopted by the Council of Europe, provides a solution to these problems by identifying distinct activities that constitute "trafficking in human organs", which ratifying states are obligated to criminalise. The central concept is "the illicit removal of organs", which consists of removal without the free, informed, and specific consent of a living donor; removal from a deceased donor other than as authorised under domestic law; removal when a living donor (or a third party) has been offered or received a financial gain or comparable advantage; or removal from a deceased donor when a third party has been offered or received a financial gain or comparable advantage.

Additionally, the Convention criminalises the use, preparation, preservation, storage, transportation, transfer, receipt, import, and export of illicitly removed organs and the solicitation or recruitment of organ donors or recipients, where carried out for financial gain or comparable advantage. The promising, offering or giving of any undue advantage to or the request or receipt of any undue advantage by health-care professionals, public officials, or people who direct or work for private institutions for the illicit removal of organs or for the use of organs that have been illicitly removed are also criminalised. The Convention calls for states to employ preventive measures, cooperate internationally in investigation and prosecution (including extraditing accused people), and protect witnesses and especially victims (including through civil damages). Implementation will be monitored and facilitated by a Committee of the Parties. Importantly, the Convention has international scope, because it is open to any nation and not restricted to the 47 Council of Europe member states.

The Convention is intended to complement the provisions included in other international instruments criminalising human trafficking for organ removal. The UN Protocol to Prevent, Suppress and Punish Trafficking in Persons[9] defines human trafficking as an action ("the recruitment, transportation, transfer, harboring or receipt of persons") that occurs by means of "threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person". Among the purposes identified by the Protocol is "removal of organs". In Europe, human trafficking for organ removal is also included in the Council of Europe Convention on Action against Trafficking in Human Beings[10] and the European Union Directive 2011/36/EU on Preventing and Combating Trafficking in Human Beings and Protecting its Victims.[11] These instruments are important in countering the use of the human body to "give rise to financial gain", as prohibited under the Convention on Human Rights and Biomedicine.[12]

Yet the legal instruments intended to combat human trafficking for organ removal leave gaps because sometimes the three components of this problem (action, means, and purpose) are difficult to prove.[13] Establishing an illegal means can be problematic, since force or fraud are not always used and the "abuse of



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a position of vulnerability" is somewhat ill defined. Likewise, when sellers take the initiative, by contacting potential recipients or intermediaries, prosecutors can struggle to show that the person has been trafficked, even if the seller was driven to act by poverty or other desperate needs. Moreover, human trafficking for organ removal does not encompass commercial transactions involving organs from deceased persons, nor the diversion of properly obtained organs for illicit use by physicians providing transplant services to patients who do not qualify to receive them within national programmes or at facilities that serve so-called transplant tourists.

The new Convention fills these gaps. It provides an explicit basis for prosecution of brokers, even if the means they use do not amount to human trafficking. It criminalises both corrupt officials who abuse their position within the organ donation system, and health-care professionals and others who remove, transfer, or use an organ if they know that the donor has not given valid consent or was offered payment. Physicians are likewise liable under the Convention for removing organs from deceased donors knowing that no valid authorisation was obtained or that payment was offered to obtain permission from the family. Under the new Convention, states can choose not to prosecute recipients who have purchased an organ, although recipients would be liable under instruments regarding human trafficking for organ removal if they knew that the organ came from a victim of human trafficking. People who sell an organ under circumstances of human trafficking for organ removal are entitled to protection as victims. If human trafficking is not involved, states can choose to prosecute sellers under the Convention.

In conclusion, the Convention will be a seminal international legal instrument that for the first time reaches illicit transplant practices that currently escape prosecution. By complementing each other, this Convention on trafficking of human organs and the instruments on human trafficking for organ removal provide a comprehensive legal framework to prevent and combat transplant activities that violate basic human rights. The worldwide problem of organ trafficking can only be addressed through concerted action at global level. Therefore, we urge all countries to quickly become Parties to the Convention.

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ML-F is a Scientific Officer at the Council of Europe. All other authors declare no competing interests.

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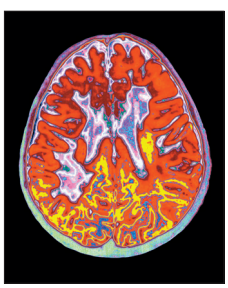
Modifying disability in progressive multiple sclerosis



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Published Online
March 19, 2014
http://dx.doi.org/10.1016/S0140-6736(13)62641-0

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Multiple sclerosis is the most common cause of chronic neurological disability in young adults in developed countries and seems to be increasing in frequency.[1,2] Disease presentation in 80–90% of patients follows an initial phase characterised by bouts of relapsing-remitting neurological dysfunction.[3] These relapses are thought to represent focal areas of inflammation in the CNS, and arise with unpredictable frequency and variable recovery.[4] However, after an inconsistent interval, most patients then develop a progressive disease course, with a gradual development of disability in the absence of relapses. The later disease phase accounts for most of the permanent disability and is thought to be mediated by neurodegenerative processes including axonal degeneration.[5] Although some controversy remains regarding the rate at which conversion to secondary progressive multiple sclerosis takes place, a figure of 2–3% per year with age-related influences is widely accepted.[6] The overall effect, in a disorder whose duration exceeds 30 years, is that most patients will, at some stage, develop secondary progressive multiple sclerosis, and at any one time most prevalent patients are in a disease phase for which there is no effective treatment.

Initial therapeutic advances targeted the early inflammatory disease phase, with several licensed immunomodulatory treatments emerging. Treatments available to clinicians for management of relapsing-remitting multiple sclerosis are now substantial. Available drugs all have an effect on relapse frequency, reduction of brain MRI lesion formation, and can reduce permanent disability when defined as worsening with no reversal in 3–6 months. However, the pattern of rising severity and frequency of serious adverse events with increasing drug efficacy needs careful patient selection, clinical management, and surveillance. Despite these limitations, early and effective intervention for relapsing-remitting multiple sclerosis is hoped to have the long-term outcome of delaying or abolishing the progressive phase. Nevertheless, evidence for the long-term outcome of early intervention has so far been elusive and, although a much debated treatment strategy, a reluctance to administer powerful immunomodulators at onset, in a disease which can have a highly variable outcome,[7] has made quantification of the effect of early aggressive immunomodulatory treatment on long-term outcome difficult. No licensed drugs have shown a convincing effect on long-term disability, or specifically on progressive disease.

Although identification of interventions that have a significant effect in modification of physical disability in progressive disease is a main aspiration of clinical trials of multiple sclerosis, an obstacle will be the large numbers of patients needed to achieve adequate power when conventional measures of disability are used. Indeed, this challenge might have contributed to negative results in trials of progressive disease to date,[8] and more accurate contemporary power calculations are needed to inform future studies that aim to report disability as the primary outcome measure. As a result, effective alternative measures to identify promising drugs in phase 2 studies are needed before large-scale investments in larger trials are considered.

In multiple sclerosis, measurement of brain atrophy has been recognised as a plausible surrogate outcome for disability,[9,10] and some studies of immunomodulatory drugs have shown an effect on reducing this outcome. Further support for the use of change in brain volume in this context has also emerged in an analysis of treatment in relapsing multiple sclerosis that showed a correlation of treatment effect on brain atrophy with the effect on disability (r^2=0·48).[11] However, the association with effect on disability was greater with use of MRI lesion activity (r^2=0·61) and greater still when both MRI outcomes were combined (r^2=0·75).[11]