InsSciDE
Inventing a shared Science Diplomacy for Europe

InsSciDE Work Package 5: **Health Diplomacy as a Tool for a Strengthened and Innovative Europe**	
Case Study n°5.3	**EU Health policy at different levels: Infectious Diseases, Blood Safety, and Science Diplomacy**
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Abstract

Blood safety is a crucial public health issue. In the last thirty years, advancing blood safety became a central goal in response to the HIV/AIDS[1] epidemic and other pandemics and crises. The related efforts to enhance blood safety involved intense collaboration among European Union (EU) Member States and at an international level. This InsSciDE case study explores the past and future importance of science diplomacy at various levels of the policy: cooperation among EU member states and other European countries; cooperation among the EU and other developed countries; the global leadership role of the EU in addressing blood safety.

Responding to the transmission of infectious disease through blood products, the European Medicines Agency (EMEA, now EMA) developed and promoted new policies to ensure the safety of patients. EMA, in cooperation with the United States Food and Drug Administration (US FDA) and the World Health Organisation (WHO), promoted the use of new diagnostic practices to handle the possibility of the transmission of infectious diseases. Similar policies were adopted to improve the safety of blood transfusions. The organization of the national blood transfusion services, following recent EU directives, was set under common standards to ensure a minimal degree of blood safety throughout the EU area.

At the same time, knowledge and resource sharing permitted East European and Balkan countries to develop and modernize their infrastructure. At a global level, following calls by WHO, the EU and diplomacy for science have both played a crucial and continuing role in assisting developing countries to achieve the targets of blood availability and safety. The case study will focus on the use of diagnostic technologies for blood screening as a means of enhancing blood safety, in relation to the overall blood safety initiatives at European and global scale. Through this case study, we will attempt to understand the role of European health diplomacy in promoting blood safety both in the European area and in response to global challenges.

Introduction

In the post-HIV era, enhancing blood safety became a principal goal in high-income countries and worldwide. The governance of the blood systems reached this goal through their transformation of risk management institutions. Intense collaboration among EU Member States and at international level resulted in the adoption of a series of measures targeting the reduction of the risk of transfusion-transmitted infections for patients. The EU policy efforts led to setting standards to ensure a minimal common degree of blood safety throughout the EU area. Knowledge and resource sharing permitted East European and Balkan countries to develop and

[1] Human immunodeficiency virus/Acquired immune deficiency syndrome

modernize their blood collection, storage and transfusion infrastructure. At the same time numerous efforts at global level assisted middle- and low-income countries to achieve the targets of blood availability and safety.

Our case study directs attention to policies and practices adopted to improve blood safety. It explores the technology-driven policies that since the late 1990s seek to reduce the risk of transfusion-transmitted infections through the use of molecular diagnostic technologies for blood screening. Our study furthermore reveals responses to such policies: for instance transfusion medicine professionals have shown concern that the adoption of molecular diagnostics widens the gap between high-income and middle/low-income countries with regard to access to safe blood, and they also have reconsidered the approaches implemented in some programs assisting low-income countries to improve blood transfusion services. The study aims to locate notions of health diplomacy in the efforts to secure widespread blood availability and blood safety.

The case study will contribute to the InsSciDE objective of a broader understanding of science-based health diplomacy. Studying a wide range of actors and practices, we will locate and highlight European and global joint actions in health policy and health diplomacy processes.

Actors

The case study will produce a detailed mapping of the relevant actors. These include (but are not limited to) transfusion medicine professionals; EU national blood transfusion services and the European Blood Alliance (EBA); the Directorate-General for Health and Food Safety of the EU; the European Directorate for the Quality of Medicines and Health Care (EDQM) of the Council of Europe; EMA and US FDA; the WHO Blood Transfusion Safety unit; the companies that produce medical diagnostic technologies.

Disciplinary/methodological approach

We will study primary documentary sources, such as: scientific literature on the topic of blood safety; policy documents related to major shifts in blood systems governance and blood safety initiatives; gray literature. Following the analysis of documentary sources and through cross-referencing we shall identify crucial actors to be interviewed. They will include transfusion medicine specialists with long experience of policies for the improvement of blood safety; officials, policymakers and consultants from the Directorate-General for Health and Food Safety of the EU; officials from the WHO Blood Transfusion Safety unit.

Essential bibliography

Farrell, A.-M. (2012). *The Politics of Blood: Ethics, Innovation and the Regulation of Risk.* Cambridge: Cambridge University Press.

Irwin, R., & Pearcey, M. (2013). Editors' Introduction. *Journal of Health Diplomacy*, 1 (1), 1-2.

WHO Global Database on Blood Safety (GDBS), available at http://www.who.int/bloodsafety/global_database/en/.