Rules and regulations in reproductive medicine: sensible requirements that should start with evidence

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Introduction

Over the last decade, reproductive medicine in Western countries has seen a vast increase in rules and regulations, promoting or mandating the responsible application of available medical technologies. These regulations are meant to improve the quality and safety of the provided services and, in the case of the European Union (EU), to bring about harmonization over national borders (Pennings, 2004; Tatarenko, 2006; Johnson and Petersen, 2008). The issues considered relate to ethical, organizational and legal issues and set technical standards. In Europe, one of the most influential recent documents concerned with artificial reproductive technology (ART) is the EU Tissues and Cells Directive from 2004 (EUTCD; 2004/23/EC), with its supplementary Technical Directives (2006/17/EC, 2006/86/EC). The EUTCD and Technical Directives cover all transplanted tissues and cells, with the exception of blood and blood products. As a result, this also encompasses gametes, zygotes and embryos when processed outside the human body, irrespective of the relations between the people involved in the treatment. The EUTCD and Technical Directives provide minimum standards that ought to be taken up in the legislation of EU member states within 2 years after the adoption of 2004/23/EC.