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Case Report

Umbilical Cord Tissue Collection and Regenerative Medicine in a North Eastern Italy Region. Report about a Case of Inadequate Health Legislation

Abstract

We describe an exemplary case of inadequate health legislation and defensive medicine, regarding umbilical cord tissue collection for personal "private" use.

Background

In an article entitled "Reductio ad absurdum: Informed consent", Garfield highlights as informing is a form of defensive medicine and the prevention is more a matter for lawyers than for doctors, without diminishing the ethic of informed consent [1]. In Europe e.g., in regard to cord blood harvesting, many pregnant women ask that their cord blood be stored, hoping to cure, with this blood component, future pathologies of their sons and relatives: informed consent is mandatory for this collection to take place [2]. In Italy and in France private cord blood banks are forbidden (the collection may only be done for solidarity use at public bank) because this health practice subverts the concept of a solidarity purpose of the blood and its components, including stem cells [3]. Nevertheless, regarding "private" cord blood collection, if the family wishes this, solely for export to a foreign bank of countries where storage are permitted, the Friuli Venetia Giulia (FVG, a North Eastern Italy region), has approved on November 2010 this possibility and identified in the Medical Directorate of Institute for Maternal and Child Health, the department that can agree to export such products to a foreign country [3]. In 2011 the first pregnant woman sent her cord blood to Switzerland, for storage at private bank.

Case description

In 2015-16s the "private" collection highlighted an increase of requests for export to neighbouring countries, as Switzerland, St. Marino Republic, Slovenia and the countries of northern Europe (Netherlands, Germany, Belgium, England); in these countries not only cord blood, but also umbilical cord tissue storage, are allowed [4].

Actually the new therapeutic possibilities in cellular therapy and regenerative medicine with the umbilical cord tissue employ are rising, and the requests for cord tissue storage are increasing: i.e. thirty per year in 2015-16s at Children's Hospital of Trieste (The regional capital city of FVG region) [5,8]. In Europe there is a high number of cord tissue cryopreservation and storage banks, and the families have the possibility to store umbilical cord segments, but currently sending to foreign bank isn't possible in Italy, failing specific regulations for collection this placental tissue: the old Decree N° 62/CSR/2010 indeed, doesn't regulate cord tissue but only cord blood. The aim of this paper is to highlight the question about the possibility to store cord tissue for "private" personal future use, overstepping health legislation's absence.

In this report we describe a case in regard to cord specimen collection in absence of specific medico-legal legislation, as by a family requested. In this experience the Medical Directorate of Children's Hospital has set up a new procedure to authorize both cord and tissue collection. The family signs an informed consent of awareness, which makes it clear that can be no claims against the Institute, medical doctors and obstetricians, in connection with the collection, packing, storage, dispatch of this tissue. Further, the collection is not obligatory and in any circumstances be assured, especially if the request undermines the health of mother and newborn, or other health conditions. The family signed this informed consent form:

"It is not covered by the current Italian legislation the release of an authorization for the export of cord tissue; the responsibility of the Institute ends with the taking over of the cord tissue by the family for the sending; the family will provide the obstetric staff with the written relevant instructions for the collection of material that will be



delivered to the company indicated to transport as a mere biological residue; there is not today a scientific therapeutic data about effectiveness of this organic residue and the current Italian legislation prohibits its employ for human transplantation; the Institute is relieved of any responsibility in case of missing withdrawal and/or circumstances that can endanger the mother's health"[9].

Discussion

The public expenses in health system must be connected with the improvement of the cures: ethical considerations of umbilical cord tissue collection for research and clinical use should be pay more attention by the health legislation institution in all over the world, and not only in North Eastern Italy Region.

We make the point that, in contrast to the actual abundance of information and studies regarding physiological mechanisms in regenerative medicine and related diseases [10], the case of cord tissue collection in Italy, is an example where the health legislation is often too slow to provide the legal framework that deals with the evolution of health care. The lack of such legislation forces departments and medical doctors to avoid medical legal problems with self-protection forms against a confusing background with dubious proven effectiveness in case of a medico-legal dispute.

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