



Central Register of Objections for Deceased Donation in Poland 1996 to 2014: The Country With an Opting-Out System

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ABSTRACT

Background. Organ, tissue, and cell procurement from deceased donors for transplantation requires consent and authorization, documented donor's positive acceptance, or lack of objection to donation expressed while alive (consent). It also requires the fulfillment of other legal conditions required by law, such as person's legal abilities to act in this field or to obtain approval for donation (authorization). Consent to and authorization of donation from deceased donors requires regulations at the national level. Poland developed an opting-out policy with the Transplantation Act in 1996. The Central Register of Objections (CRO) was introduced on November 1, 1996. The purpose of this article is a formal analysis of all submitted objections and objection withdrawals managed by the CRO since the introduction of the registry in 1996 until the end of 2014.

Materials and Methods. All data collected by the CRO during 18 years of service was subject to analysis. The objections and withdrawals of objections are summarized in the tables, along with the age, sex, and place of residence of the registered residents.

Results. By December 31, 2014, a total of 29,288 records were registered, including 29,013 registered objections and 275 registered withdrawals of objections; this means that 0.075% of the country's population expressed objection to posthumous tissue and organ donation for transplantation. Legal representatives submitted 4208 declarations (15.6% of all declarations). The largest inflow of objections took place in 1997, the first full year of CRO activity.

Conclusion. CRO is an indispensable option in a country with opt-out system as a part of organ donation authorization protocol. Number of registered objections is extremely low, in practice, this leads to a situation where the will of the deceased most often is obtained from his family.

ORGAN, tissue, and cell procurement from deceased donors for transplantation requires consent and authorization, documented donor's positive acceptance, or lack of objection to donation expressed while alive (consent). It also requires the fulfillment of legal conditions required by law such, as a person's legally recognized ability to act in this capacity, or obtaining an approval of the prosecutor for donation (authorization). Consent to and authorization of donation from deceased donors requires regulations at the national level. Different features of the cultural, historical, religious, and legal areas in the individual countries have created different systems of expression,

documenting and determining the attitude toward organ donation after death.

There are 2 systems to express individual consent: opting-in systems, in which consent to donation has to be explicitly obtained, and opting-out systems, where donation can take place if there is no evidence of any objection to donation expressed. European countries have introduced different systems for the declaration of consent for organ donation

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after death, most of them so-called “opting-out” consent systems and others so-called “opting-in” systems. Apart from the type of consent systems, countries have tools in place to express the willingness or objection regarding donation, such as registries. In countries with an opting-out system, such as Austria, the Czech Republic, France, Hungary, Portugal, and Poland, there is an official registry of objections [1].

General regulations concerning “opting-out” policy in Poland are as follows: “If a deceased person did not express objection, when alive, it is allowed to recover cells, tissues, or organs from such person human cadaver for transplantation purposes. A legal representative of a living minor or other person, who has no full legal capacity, may state an objection for such individual. Minors above 16 years old may state an objection themselves.” “These objections shall be stated in the form of: a registration of an objection to recover cells, tissues and organs from one’s own human cadaver in the Central Objection Register; written statement with affixed one’s own signature; an oral statement made in the presence of at least two witnesses and confirmed by these witnesses in writing.” “With the purpose of registering, storing and rendering accessible an entry ... and applications for cancelling an objection, registration shall be established in a central register of objections to recover cells, tissues and organs from one’s own human cadavers, hereinafter named “Central Register of Objections.” “The information about an objection registration in the Central Register of Objections shall be imparted immediately after receipt of an inquiry from a doctor who intends to perform a recovery or a person authorized by the doctor” [2].

In Poland, the Central Register of Objections [CRO] has been operational since November 1, 1996, based on The

Cell, Tissue and Organ Recovery, Storage and Transplantation Act cited above and a Minister of Health Ordinance implementing the CRO [2,3]. According to current legal regulations, the entity responsible for CRO management is Polish Transplant Coordinating Center, Poltransplant, a national transplant organization and competent authority in donation and transplantation. Poltransplant collects the objection declarations, declarations of the objection withdrawals, and also takes care of personal data safety, prevents data loss or data destruction, and performs statistical analysis of the data at least once a year, sharing the results with the Ministry of Health and National Transplant Council. The CRO data report is published yearly in the Poltransplant Bulletin and is available on the Poltransplant Web site (www.poltransplant.org.pl) [4].

The purpose of this article is a formal analysis of all submitted objections and objections withdrawals managed by CRO since the introduction of the registry in 1996 until the end of 2014.

MATERIALS AND METHODS

All data collected by CRO during 18 years of service were subject to analysis. The objections and withdrawals of objections are shown in Tables 1–4, along with the age, sex, and place of residence of the registered residents.

RESULTS

By December 31, 2014, a total of 29,288 records were registered, including 29,013 registered objections and 275 registered withdrawals of objections; this means that

Table 1. Number of Records Registered in Central Register of Objections (CRO) in Years 1996–2014

Year	Number of Declarations Registered in CRO (3+6)	Number of Registered Objections			Number of Registered Objection Withdrawals		
		All (4+5)	Own Objection	Legal Representative's Objection	All (7+8)	Own	Legal Representative's Objection
1	2	3	4	5	6	7	8
1996	1687	1687	1439	248	0	0	0
1997	14,550	14532	12400	2132	18	15	3
1998	2404	2387	1974	413	17	15	2
1999	1688	1671	1398	273	17	16	1
2000	1107	1090	907	183	17	17	0
2001	436	430	368	62	6	6	0
2002	679	667	549	118	12	10	2
2003	380	372	323	49	8	7	1
2004	300	286	232	54	14	10	4
2005	271	260	234	26	11	11	0
2006	278	268	231	37	10	10	0
2007	1058	1032	864	168	26	22	4
2008	349	327	285	42	22	21	1
2009	333	313	271	42	20	18	2
2010	291	273	235	38	18	14	4
2011	418	395	325	70	23	21	2
2012	403	398	350	48	5	3	2
2013	892	875	709	166	17	17	0
2014	1764	1750	1376	374	14	14	0
Total	29,288	29,013	24,470	4543	275	247	28

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