The Tuscany quality improvement programme in organ donation: the first year experience

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KEYWORDS

SUMMARY – There is evidence that the worldwide shortage of donor organs may be due to failure to turn many potential into actual donors. Following the success of the national network of physicians in charge of organ donation, a quality improvement programme in organ donation was set up a year ago in Tuscany. This paper describes the implementation process and initial outcome of the quality improvement programme.

INTRODUCTION

The shortage of cadaveric organ donors imposes a severe limit on the number of patients who can benefit from transplantation, while there is an ever-increasing demand for cadaveric solid organs all over the world. Partial strategies in many countries have resulted in small or transient increases in organ donation or even no improvement at all1-3. There are data, however, that show that this shortage is not wholly due to a lack of potential donors, but mainly to failure to turn many potential into actual donors. The establishment since the early nineties in Spain of a national network of specifically trained part-time dedicated and strongly motivated hospital physicians in charge of the whole process of organ donation has resulted in a sustained increase in cadaveric organ donors4-5 with a progressive decrease of the renal waiting lists for transplantation1,4.
Organ donation and transplantation is like a chain of events that can always be broken by the weakest link. Any increase in organ donation rates mainly results from efforts to overcome obstacles in every step of this process. The main principles of this philosophy have been implemented in Italy, resulting in marked increases in organ donation rates. However, to consolidate these organ donor rates over the years, it is important to establish an ongoing evaluation programme of every step of the process to detect and solve any problems.

We describe in this paper the process of implementation and the results obtained during the first year of a quality improvement programme in organ donation in the hospitals of the Tuscany region.

Objectives:

Like any other programme for evaluating the donation process, the objectives of the Tuscany Programme are the following:

- Definition of the theoretical capacity of organ procurement depending on the characteristics of the hospital
- Detection of the obstacles in the process of organ donation and procurement and analysis of the causes of potential donor losses, as a tool to identify improvement areas
- Description of hospital factors which can influence the donation and transplantation process.

METHODS

We adopted the basic principles of the Spanish programme for evaluation of the process of organ donation which has been widely described in the literature. This programme was developed and implemented in Spain during the nineties after being tested and verified in some regions. For its implementation in Tuscany it was necessary to modify some of the steps of the process because of the differences between Spanish and Italian legislation, especially with respect to brain death diagnosis. Besides this point and the idiomatic translation, special care was taken to keep the general structure of the programme unmodified to make the results obtained comparable with international standards.

The whole original programme is divided into two phases:

- Internal audit or self evaluation
- External evaluation.

During the first year of implementation, the Tuscany Programme was restricted to the Internal Evaluation phase, as a previous experience of internal audit is strictly necessary for the external evaluation.

Methodology of the Internal Audit

The programme is based on the systematic review of all medical records of patients dying in intensive care units (ICU) at least every three months. For the purpose of this programme, we define an intensive care bed as a hospital bed with mechanical ventilation and intensive care facilities where a patient can be admitted for more than 12 hours.

Three kinds of data shifts should be fulfilled periodically. An individual data shift should be fulfilled for every patient with the clinical diagnosis of brain death, and a compilation of all these diagnoses should be sent to the central office of Pisa at least every three months. Then an ICU data shift with the number of deaths, number of brain deaths and organ donors should be fulfilled for every ICU of the hospital and sent to the central office every three months. Finally, every year general data of every hospital should be collected on the total number of deaths, number of available beds, neurosurgery procedures and patients admitted to the ICU and emergency rooms.

Individual, ICU and hospital data are introduced in the database kindly provided by the Spanish National Transplant Organization (ONT) and modified according to Italian characteristics and legislation. The database incorporates an application which automatically calculates the different indexes accepted internationally.

The shift shows the donation process as a flux reduced to three steps identified with three linked questions. The computer programme does not allow the brain death outcome process to be interrupted in more than a single point, and after identification, the main cause of this breakdown should be selected among the different possibilities offered by the programme. The shift also includes questions related to family consent and demographic questions about the donor.

The ICU data shift collects the number of deaths, brain deaths and organ donors of every ICU of the hospital. One shift must be sent every three months. Additionally, on a yearly basis some up-to-date general information of the hospital (number of beds, neurosurgical procedures, total in-hospital deaths, etc.) should also be collected and sent to the central office in Pisa. General and specific reports are drawn up in this office and distributed periodically.
Classification of the Hospitals

At the start of the programme, the public Tuscany hospital network comprised four University Hospitals (Aziende Ospedaliere A.O.) -three general and one specifically paediatric-, and 12 local health units (USL) mostly formed by several small hospitals.

According to the criteria accepted internationally\textsuperscript{10,11}, hospitals were classified in the following categories depending on the existence of certain facilities:

- Type I: Hospitals with a solid organ transplant programme and neurosurgery
- Type II: Hospitals with neurosurgery but without solid organ transplant programmes
- Type III: Hospitals without transplant programmes or neurosurgery.

The network of coordinators covers all the hospitals or group of hospitals, with the exception of the paediatric one. The three University hospitals (A.O. of Florence, Pisa and Siena) were classified as Type I. There is only one hospital categorized as Type II (the USL of Livorno) and the remainder were categorized as type III. However, as the potential for organ donation and the characteristics of brain deaths are mainly dependent on the availability of neurosurgery (10, 11), unless specified, the indexes were calculated considering together the three Type I and the one Type II hospitals, all with neurosurgery.

Implementation of the Program

Before starting the implementation of the program, a twelve month retrospective analysis was performed in all the Tuscany hospitals in order to make an initial approach to the potential for organ donation. The results of this study are summarized in Figure 1. After this initial study, a specific training course was held in Pisa for all the coordinators and at least one anaesthetist for every hospital (Figure 2). This course was shared by a group of experts of the Spanish ONT.

After this training course, we started a four month pilot study in four of the largest hospitals to check the possible problems of the programme and the possibility to adapt the methodology to the Italian reality. Then, the programme was started on October 1\textsuperscript{st} 2002 in all the Tuscany hospitals (Figure 2). A further training course specifically directed to the nurse coordinators and anaesthetists was celebrated in May 2003 in order to consolidate the implementation of the programme.

Results

The results of the first 12 month period in the 16 hospitals are summarized in Tables 1 and 2 and Figure 3. We establish a clear distinction between hospitals with and without neurosurgery. Table 1 shows the number of brain deaths and the different indexes relating hospital parameters and some characteristics of this population.

Hospitals with neurosurgery showed a percentage of brain deaths / deaths in ICU of 14.7\%, while in those without neurosurgery this percentage was just 8.6\%. This difference can be extended to the other estimated indexes (referred to
Table 1

Brain deaths in Intensive Care Units (ICU). Characteristics and annual rates depending on the availability of neurosurgery

<table>
<thead>
<tr>
<th></th>
<th>All hospitals</th>
<th>With neurosurgery</th>
<th>Without neurosurgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of brain deaths in ica</td>
<td>214</td>
<td>120</td>
<td>94</td>
</tr>
<tr>
<td>Mean age of brain deaths (years)</td>
<td>59.2</td>
<td>55.5</td>
<td>63.9</td>
</tr>
<tr>
<td>Brain deaths/ all icu deaths</td>
<td>11.2%</td>
<td>14.7%</td>
<td>8.6%</td>
</tr>
<tr>
<td>Brain deaths/ all hospital deaths</td>
<td>1.9%</td>
<td>2.9%</td>
<td>1.33%</td>
</tr>
<tr>
<td>Brain deaths/ icu beds</td>
<td>57.3%</td>
<td>64.9%</td>
<td>50.3%</td>
</tr>
<tr>
<td>Brain deaths/ hospital beds</td>
<td>1.66%</td>
<td>1.84%</td>
<td>1.19%</td>
</tr>
<tr>
<td>Brain deaths/ icu patients</td>
<td>2.39%</td>
<td>2.52%</td>
<td>2.21%</td>
</tr>
</tbody>
</table>

Table 2

Actual donors in Intensive Care Units (ICU) and annual rates depending on the availability of neurosurgery

<table>
<thead>
<tr>
<th></th>
<th>All hospitals</th>
<th>With neurosurgery</th>
<th>Without neurosurgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual donors</td>
<td>95</td>
<td>51</td>
<td>44</td>
</tr>
<tr>
<td>Mean age actual donors</td>
<td>59.5</td>
<td>55.5</td>
<td>64.5</td>
</tr>
<tr>
<td>Actual donors/ deaths in icu</td>
<td>5.0%</td>
<td>6.3%</td>
<td>4.0%</td>
</tr>
<tr>
<td>Actual donors/ all hospital deaths</td>
<td>0.58%</td>
<td>1.02%</td>
<td>0.39%</td>
</tr>
<tr>
<td>Actual donors/ icu beds</td>
<td>27.03%</td>
<td>32.09%</td>
<td>22.45%</td>
</tr>
<tr>
<td>Actual donors/ hospital beds</td>
<td>0.69%</td>
<td>0.91%</td>
<td>0.53%</td>
</tr>
<tr>
<td>Actual donors/ all icu patients</td>
<td>1.13%</td>
<td>1.27%</td>
<td>0.99%</td>
</tr>
</tbody>
</table>

Table 3

Outcome of the brain death audit during the pilot period

<table>
<thead>
<tr>
<th></th>
<th>All the hospitals</th>
<th>With neurosurgery</th>
<th>Without neurosurgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not referred</td>
<td>0.9</td>
<td>1.7</td>
<td>0</td>
</tr>
<tr>
<td>Maintenance problems</td>
<td>10.7</td>
<td>11.2</td>
<td>9.6</td>
</tr>
<tr>
<td>Medical contraindication</td>
<td>15.9</td>
<td>15</td>
<td>17</td>
</tr>
<tr>
<td>Family refusal</td>
<td>23.8</td>
<td>25.8</td>
<td>21.3</td>
</tr>
<tr>
<td>Other</td>
<td>4.2</td>
<td>3.3</td>
<td>5.3</td>
</tr>
<tr>
<td>Actual donors</td>
<td>44.5%</td>
<td>42.9%</td>
<td>46.8%</td>
</tr>
</tbody>
</table>

Figure 3 - Outcome of the brain death audit during the first year period of implementation of the programme.

The number of deaths in hospital, in ICU, the number of beds and patients admitted in ICU. Mean age of brain deaths was greater in hospitals without neurosurgery (63.9 vs 55.5 years).

Table 2 shows a similar analysis but referred to actual donors. Here the differences between both types of hospitals are much fewer than those found in the analysis of brain deaths (6.3% vs 4% of all deaths in ICU). The reasons are shown in Figure 3 and Table 3: a much greater efficacy in the organ donation process in the Tuscany hospitals without neurosurgery, where actual donors are 46.8% of potential donors vs 42.5% in the largest hospitals with neurosurgery. Mean age of actual donors was consistently higher in hospitals without neurosurgery (64.5 vs 55.2 years).

Discussion

The great increase in organ donor rates recorded in Spain during the nineties can be explained by the implementation of the so-called “Spanish Model”[6,15]. This strategy results from the efforts to overcome obstacles such as untrained or under trained staff, unidentified donors and reluctance to approach grieving families[6]. For the consolidation of this model in all Spanish regions, the implementation of quality improvement programmes was a useful tool during the second half of the nineties. Death audits in hospitals were applied progressively in most of
the regions to ensure that resources were used effectively and that the maximum number of organs were retrieved and transplanted\(^{10,11}\).

The translation of this model to other countries or regions is perfectly feasible\(^{16}\). Italy has probably been the country which has adopted most elements of the Spanish Model and which has worked more seriously in this direction. Not unexpectedly, Italy has been together with Spain, the country with the greatest increase in organ donation during the last ten years and the only one which at present shows significant increases\(^{17}\). After the approval of the Italian law in 1999\(^{13}\), an organization based on a coordinating system at three levels: national, regional and hospital, similar to the Spanish one has been adopted. Training courses for Italian transplant coordinators have been shared by Spanish specialists\(^{18}\). These include specific courses on mass media\(^{19}\), brain death or the different steps of the process of organ donation\(^{19}\).

During the last year we adapted the Spanish programme to the Italian situation and started its implementation in Tuscany hospitals. The first results achieved with this programme can be compared to previously published findings and it will be helpful to identify both areas for improvement in the donation and transplantation process and hospital characteristics which can influence the organ donor rates. After making a diagnosis of the situation, specific teaching programmes or adequate structural or management measures should be implemented to solve the problem.

Brain death data do not seem to be very different from those found in Spain with the same methodology, which can be considered a gold standard at international level. In the hospitals with neurosurgery, 14.7% of deaths in ICU are brain deaths in Tuscany while this percentage in Spain was 15.1%\(^{11}\). In those without neurosurgery the percentages were 8.6% in Tuscany vs 7.5% in Spain. These results show a good level of detection of brain deaths in intensive care units. Small differences can be explained by the different number of hospital beds and ICU facilities\(^{16}\).

When the number of actual donors and the whole process of organ donation is analyzed, a slightly greater efficiency was found in smaller hospitals without neurosurgery, where 46.8% of brain deaths became actual donors, than in the largest ones where this percentage was only 42.5%. The corresponding figures in Spain were 37.8% and 49% respectively, showing an inverse relation to that found in Tuscany (i.e.: higher rates of conversion of brain deaths into actual donors in Spanish hospitals with neurosurgery compared with those without).

The percentage of the Tuscany population over 60 years (28.7%) is one of the highest in Europe (Italy: 24.3, Spain: 22, mean E.U.: 20)\(^{16}\). As a consequence of this distribution of the population, the epidemiology of brain deaths in Tuscany and therefore the mean age of effective donors is one of the highest ever reported: 64.5 years in hospitals without neurosurgery and 55.2 in those with. Corresponding published figures in Spain were 55.6 and 44.9 years\(^{11}\). This fact emphasizes the need to address the quality of the organs procured for transplantation.

The data reported in this article are just preliminary and of course should be confirmed during the coming months. There are however some important data with practical consequences. The first is the great potential for growth in the Tuscany hospitals, especially in those with neurosurgery. The second is the identification of the weaker points of the process of organ donation, and as a consequence the best way to find a solution.

The development of a quality improvement programme in cadaveric organ donation is an adequate and scientific method to detect where the problems in the process of organ donation lie in every hospital. Ideally, the comparison of these data with those of other Italian or European regions should be useful to plan adequate strategies to improve cadaveric organ donation.

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13 Real Decreto 2070/1999, de 30 de diciembre, por el que se regulan las actividades de obtención y utilización clínica de órganos humanos y la coordinación territorial en materia de donación y trasplante de órganos y tejidos.


