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Brief Communication

Continuously Evaluating Performance in Deceased Donation: The Spanish Quality Assurance Program

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The Spanish Quality Assurance Program applied to the process of donation after brain death entails an internal stage consisting of a continuous clinical chart review of deaths in critical care units (CCUs) performed by transplant coordinators and periodical external audits to selected centers. This paper describes the methodology and provides the most relevant results of this program, with information analyzed from 206,345 CCU deaths. According to the internal audit, 2.3% of hospital deaths and 12.4% of CCU deaths in Spain yield potential donors (clinical criteria consistent with brain death). Out of the potential donors, 54.6% become actual donors, 26% are lost due to medical unsuitability, 13.3% due to refusals to donation, 3.1% due to maintenance problems and 3% due to other reasons. Although the national pool of potential donors after brain death has progressively decreased from 65.2 per million population (pmp) in 2001 to 49 pmp in 2010, the number of actual donors after brain death has remained at about 30 pmp. External audits reveal that the number of actual donors could be 21.6% higher if all potential donors were identified and preventable losses avoided. We encourage other countries to develop similar comprehensive approaches to deceased donation performance.

Key words: donation after brain death, quality, tissue and organ donation and procurement, transplantation

Abbreviations: AD, Actual Donor; CCU, Critical Care Unit; DBD, Donors after Brain Death; ONT, Organización Nacional de Trasplantes; PD, Potential Donor; pmp, per million population; QAPDD, Quality Assurance Programme in the Deceased Donation Process; TC, Transplant Coordinator.

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Introduction

Transplantation is a consolidated therapy that benefits around 100,000 patients worldwide annually (1). In contrast, it has been estimated that around one million people need a transplant nowadays (2). This organ shortage is one of the main obstacles for the full expansion of transplantation therapies.

The significant development of transplant programs in Spain has been the result of an optimized performance in deceased donation, leading the country to an activity of 32–35 donors per million population (pmp). This has been possible through the coordinated efforts of numerous professionals and the key role of in-hospital transplant coordinators (TCs), with a specific profile (3–5). However, deceased donation is a complex process, which requires continuous evaluation to identify areas for improvement where efforts should be directed. This is the main objective of the Spanish Quality Assurance Program in the Deceased Donation process (QAPDD), another key element of the so-called Spanish Model (6).

Notwithstanding international recommendations on the development of QAPDD, the existence of these programs is still limited to a few countries, at least in Europe (7–11).

The creation of the Spanish QAPDD was promoted by the Spanish National Transplant Organization (ONT) in 1998.

Specifically focused on the process of donation after brain death (DBD), it was developed with three objectives: (1) to estimate the potential of deceased donation; (2) to evaluate performance in the process, analyzing the reasons for losing potential donors, as a tool to identify areas for improvement; and (3) to describe hospital factors with impact on the aforementioned areas.

This paper intends to describe the methodology of the Spanish QAPDD and to summarize the main results with the aim of promoting the development of similar approaches.

Materials and Methods

The evaluation of the process of DBD in the Spanish QAPDD takes place in two complementary phases: an *internal evaluation* and an *external evaluation*.

Definitions

Potential donor (PD): Person with a clinical condition consistent with brain death.

Actual donor (AD): Person from whom at least one organ has been recovered for the purpose of transplantation.

Critical Care Unit (CCU): Hospital unit with the capability of mechanical ventilation.

Internal evaluation

The internal evaluation consists of a retrospective analysis of the medical records of deaths occurred in CCUs of procurement hospitals performed by TCs to identify PDs. Each case is analyzed to verify whether the PD was referred to the TC and, if not, the reasons. The causes why identified PDs were not converted into ADs are assessed: brain death diagnosis not completed, medical unsuitability, maintenance problems, refusal of permission for organ donation, judicial refusal, lack of appropriate recipients or organizational problems.

For every PD, demographic and clinical information is collected as well as data relating to consent and judicial authorization, when required. Information is also collected on number of hospital and CCU beds, hospital and CCU deaths and neurosurgical activity.

Information is managed by ONT. Indicators are built on the potential of DBD, the overall performance in the process and the areas for improvement. The program offers global results, but indicators are also provided for hospitals classified based on the availability of neurosurgery.

External evaluation

The external evaluation addresses three objectives: (1) to verify that the internal evaluation has been performed properly; (2) to evaluate performance in the donation process through the identification of nonreferred PDs and the analysis of other causes for PD losses; and (3) to identify areas for improvement, making recommendations to TCs and hospital administrators.

The external audit is carried out by 2–3 physicians, depending on complexity of the evaluated hospital. The profile of the auditor is that of a critical care specialist, with at least 5 years' experience as hospital TC, who has worked previously in an audited hospital and with specific training in the Spanish QAPDD methodology. External auditors work with the support of the local TC team, so the audit becomes an opportunity for sharing practices and experiences identifying actions for improvement.

Regional transplant coordinators nominate annually the hospitals to be subjected to external audits. To be audited, hospitals are required to be involved in the internal audit and to have all the epicrisis reports of CCU deaths available. ONT organizes and supports the development of the external audits.

The methodology of the external evaluation entails two phases. Before the audit visit, auditors review discharge reports corresponding to CCU deaths not identified as PDs during the internal evaluation stage. They request the complete medical records of those patients whose death is related to neurological damage and for whom sufficient information is not available to identify undetected PD cases. During the visit, auditors review these medical records to determine whether they can be considered PDs. Based on data availability, auditors classify these cases as confirmed, highly probable, possible, not assessable or not PD cases (Table 1).

Auditors also review discharge reports of PDs notified during the internal evaluation, who did not become ADs. The objective is to verify whether these were really PD cases and the reasons why they did not become ADs. The auditors review the causes of loss of PDs working with the hospital TC team, discussing which losses were inadequate (medical contraindications), could have been avoided (organizational problems, family refusals) and/or were correctable (maintenance problems). They also collect information about hospital activity and facilities, hospital archives and quality of medical records.

As a result of the external audit, the number of PDs is recalculated taking into account the confirmed and highly probable PD cases (Table 1). The number of ADs the center would have reached should the process have been conducted ideally (number of possible donors) is calculated by subtracting out of the recalculated number of PD cases, the unavoidable losses: adequate medical contraindications, noncorrectable maintenance problems, family/judicial refusals not able to be reverted, unavoidable organizational problems or lack of an adequate recipient.

A final audit report is sent to the ONT, the hospital TC team, the regional TC and the hospital director, with the objective of communicating the findings and the proposed solutions. Some weeks after the audit visit, an opinion survey is sent to the hospital TC team asking for their opinion about the auditors, the report and the audit visit.

Results

Internal evaluation

Global results: At present, 140 hospitals participate in the QAPDD, where around 95% of national ADs are registered. This percentage has remained over 90% since 2006.

Between 1999 and 2010, more than 206,000 medical records of all deaths registered in the CCUs of participating hospitals were reviewed (Table 2). This has enabled the identification of 25 653 PDs, representing 2.3% of hospital deaths and 12.4% of CCU deaths, percentages significantly higher in hospitals with neurosurgery, compared to those without. It is recognized that about 1% of PDs has not been referred to the hospital TC team.

From all identified PD cases, 14 011 (54.6%) were converted into ADs. This conversion rate is higher in hospitals with neurosurgery, compared to those without (55.5% vs. 49.9%; $p < 0.05$). The main reason why PDs are not converted into ADs is medical unsuitability for organ

Table 1: Criteria applied for the identification of potential donor cases in the retrospective review of clinical charts during the external evaluation phase of the Spanish Quality Assurance Program in the Deceased Donation process, based on data availability

1. Confirmed potential donor: Any of the following circumstances must be present
- All legal requirements are properly reflected in the chart
- A neurologist or a neurosurgeon has explored the deceased and recorded the fact that brain death has occurred and there is no evidence against this diagnosis
- CCU physician has recorded the fact that brain death has occurred and there is no evidence against this diagnosis

To define a person as being a *highly probable* or a *possible potential donor case*, the following issues are considered
- **Etiology of the process causing death:** It must be one of the known etiologies that cause brain death and must be severe enough to cause it
- **Conditions:** Absence or no evidence of spontaneous breathing and movements
- **Findings in clinical exploration**
  - Progressing nonreactive mydriasis (*de novo* nonreactive mydriasis in a patient with severe neurological condition, in the context of a severe clinical deterioration and which is not explained by drug interference)
  - Absence of at least one of the following brain stem reflexes: corneal, oculocephalic, oculovestibular, coughing and gag
  - Negative atropine test
- **Clinical signs**
  - Abrupt arterial hypotension, causes other than enconing having been disregarded
  - Abrupt polyuria, causes other than enconing having been disregarded
  - Refractory and progressive intracranial hypertension (intracranial hypertension which progresses in the minutes or hours before death, toward limits that provoke a cerebral perfusion pressure of 0 or close to 0 mmHg, with no response to therapy)

2. Highly probable potential donor
Etiology + Conditions + 1 finding (at least) in clinical exploration + 1 clinical sign (at least)
Etiology + Conditions + 2 findings (at least) in clinical exploration

3. Possible potential donor
Etiology + Conditions + 1 finding (at least) in clinical exploration
Etiology + Conditions + 1 clinical sign (at least)

4. A case *is not assessable as a potential donor* in any of the following circumstances
- Etiology of the process is known, severe and consistent with brain death, but there is no additional information in the clinical chart or the clinical chart is not available
- Etiology of the process is known, severe and can lead to brain death, but the diagnosis could not be confirmed because of the withdrawal of life-sustaining therapies
- Etiology of the process is known, severe and can lead to brain death, but exposure to barbiturates or muscle relaxant drugs is present at the moment of cardiac arrest
- Infratentorial processes with no legal diagnosis of brain death

Any other situation will be considered as *not potential donor*

Table 2: Cumulative results of the internal evaluation stage. Years 1999–2010

	All hospitals (n = 140)	Hospitals with neurosurgical unit (n = 71)	Hospitals without neurosurgical unit (n = 69)	p*
Deaths in CCUs	206 345	158 167	48 178	
Potential donors	25 653	21 653	4 000	
Actual donors	14 011	12 013	1 998	
Potential of donation				
% PDs/deaths in CCUs	12.4	13.7	8.3	0.00
% PDs/deaths in hospitals	2.3	2.8	1.1	0.00
Conversion rate				
% Actual donors/PDs	54.6	55.5	49.9	0.00
Causes of loss of potential donors				
% PDs not referred/PDS	1.1	1	1.6	0.001
% Medical contraindications/PDs	26	25.5	28.6	0.00
% Maintenance problems/PDs	3.1	2.8	4.3	0.00
% Family refusals/PDs	13.3	13.3	13.4	0.96
% Judicial refusals/PDs	0.3	0.3	0.1	0.03**
% Brain death diagnosis not completed/PDs	0.1	0.1	0.2	0.16**
% Lack of recipient/PDs	0.7	0.6	0.9	0.59**
% Organizational problems/PDs	0.5	0.5	0.5	0.17**

PD = potential donor; CCU = critical care unit.
*χ^2 test. **Yates correction

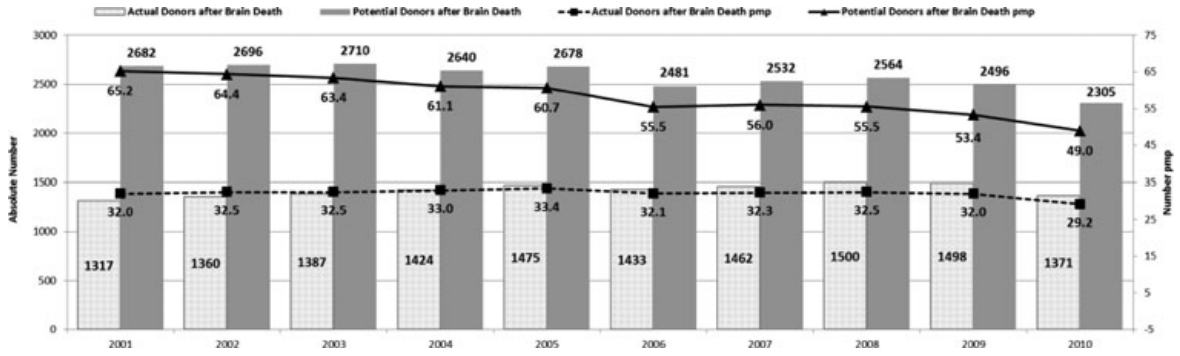

Figure 1: National estimated potential for donation after brain death (absolute number of potential donors and rate per million population) and actual donation after brain death (absolute number of ADs after brain death and rate per million population) in Spain for the years 2001–2010. A potential donor is defined as a person with a clinical condition consistent with brain death.

donation (26%), followed by refusals to donation (13.3%) and problems in donor maintenance (3.1%) (Table 2). These percentages differ depending on the type of hospital, medical contraindications and problems in donor maintenance being more frequent causes for PD losses in hospitals without neurosurgery.

National potential of DBD and overall performance in the process over time

The potential of DBD in Spain over time is represented in Figure 1. Because the internal evaluation has not covered all hospitals authorized for organ procurement, the national figures on the number of PDs and the corresponding pmp rate have been estimated based on the national number of ADs. This approach is identical to the one used by Sheehy et al to estimate the national pool of PDs in the USA (12). According to this estimation, the potential of DBD has remained well over 50 PD cases pmp most of the years, but with a progressive decline over time, from 65.2 PDs pmp in 2001 to 49.0 PDs pmp in 2010.

Notably, the profile of PDs has also changed over the years. In 1999, median age (ICR) of PDs was 52 (30–65) versus 60 (47–72) years in 2010. Traffic accidents and strokes represented the cause of death in 22.2% and 49.8% of PD cases respectively in 1999. The corresponding percentages in 2010 were 5.4% and 67.5%. In spite of these changes, performance in the realization of the BDB process improved over time, increasing from 48.5% PDs converted into ADs in 1999 to 59.5% in 2010 (Figure 1).

External evaluation

Since 2001, 111 external audits have been performed all over the country (66 in hospitals with neurosurgery and 45 in centers without). Quantitative results are shown in Table 3. Data have been reviewed from 20,080 CCU deaths, identifying 2,529 PDs (confirmed and highly probable PDs as specified in Table 1).

According to the external audit, 167 (6.6%) PDs were never referred to the TC, figure far greater than the 1.8% of nonreferred PD cases described in the internal evaluation at those same hospitals.

When analyzing further causes of PD losses, according to the auditors' criteria, 11.6% of losses due to medical

Table 3: External evaluations. Global results from all the evaluated hospitals (111 centers). Years 2001–2010

	Internal evaluation		External evaluation	
	N	%	N	%
CCU deaths	19 736		20 080	
Medical records not found			198	1
Potential donors	2 480	12.6	2 529*	12.6
Not referred	45	1.8	167	6.6
Medical contraindications	665	26.8	580	22.9
Inadequate	-	-	*67*	*2.6*
Maintenance problems	77	3.1	57	2.3
Correctable	-	-	*24*	*0.9*
Family refusals	356	14.4	350	13.8
Avoidable	-	-	*5*	*0.2*
Organizational problems	10	0.4	19	0.8
Avoidable	-	-	*6*	*0.2*
Lack of adequate recipient	17	0.7	22	0.9
Coroner refusals	7	0.3	9	0.4
Impossible to evaluate	6	0.2	17	0.7
Actual donors	1 297	52.3		
Possible donors			1 577**	62.4

CCU = critical care unit.
*Confirmed and highly probable cases of potential donors. **The number of possible donors is calculated by subtracting from the identified cases of potential donors (2 529) the unavoidable losses: adequate medical contraindications (513), noncorrectable maintenance problems (33), not avoidable family refusals (345) and organizational problems (13) as well as coroner refusals (9) and lack of adequate recipients (22). Cases impossible to evaluate are also subtracted (17).

Table 4: External evaluations. Hospitals with neurosurgical facilities (66 centers). Years 2001–2010

	Internal evaluation		External evaluation	
	N	%	N	%
CCU deaths	14 981		15 231	
Medical records not found			176	1.2
Potential donors	2 035	13.6	2 088*	13.7
Not referred	31	1.5	126	6
Medical contraindications	537	26.4	483	23.1
Inadequate	-	-	*58*	*2.8*
Maintenance problems	56	2.8	46	2.2
Correctable	-	-	*20*	*1*
Family refusals	296	14.5	284	13.6
Avoidable	-	-	*3*	*0.1*
Organizational problems	7	0.3	18	0.9
Avoidable	-	-	*5*	*0.2*
Lack of adequate recipient	14	0.7	18	0.9
Coroner refusals	6	0.2	6	0.3
Impossible to evaluate	5	0.2	9	0.4
Actual donors	1083	53.2		
Possible donors			1 310**	62.7

CCU = critical care unit.
*Confirmed and highly probable cases of potential donors. **The number of possible donors is calculated by subtracting from the identified cases of potential donors (2 088) the unavoidable losses: adequate medical contraindications (425), noncorrectable maintenance problems (26), not avoidable family refusals (281) and organizational problems (13) as well as coroner refusals (6) and lack of adequate recipients (18). Cases impossible to evaluate are also subtracted (9).

Table 5: External evaluations. Hospitals without neurosurgical facilities (45 centers). Years 2001–2010

	Internal Evaluation		External Evaluation	
	N	%	N	%
CCU DEATHS	4 755		4 849	
Medical records not found			22	0.5
Potential donors	445	9.4	441*	9.1
Not referred	14	3.1	41	9.3
Medical Contraindications	128	28.8	97	22
Inadequate			*9*	*2*
Maintenance problems	21	4.7	11	2.5
Correctable			*4*	*0.9*
Family refusals	60	13.5	66	15
Avoidable			*2*	*0.5*
Organizational problems	3	0.7	1	0.2
Avoidable			*1*	*0.2*
Lack of adequate recipient	3	0.7	4	0.9
Coroner refusals	1	0.2	3	0.7
Impossible to evaluate	1	0.2	8	1.8
Actual donors	214	51.9		
Possible donors			267**	60.5

CCU = critical care unit.
*Confirmed and highly probable cases of potential donors. **The number of possible donors is calculated by subtracting from the identified cases of potential donors (441) the unavoidable losses: adequate medical contraindications (88), noncorrectable maintenance problems (7), not avoidable family refusals (64) as well as coroner refusals (3) and lack of adequate recipients (4). Cases impossible to evaluate are also subtracted (8).

unsuitability were based on inadequate medical contraindications (67 out of 580), 42.1% of the maintenance problems were correctable (24 out of 57), and 1.4% of refusals to donation and 31.6% of the organizational problems could have been avoided (5 out of 350 and 6 out of 19, respectively). Taking into account all these preventable circumstances, it could be estimated that, although 1,297 ADs were registered in the audited hospitals, if the whole donation process had taken place in ideal conditions, the number of ADs could have reached 1,577 (21.6% higher).

Tables 4 and 5 provide the results of the external audit, based on the presence of neurosurgery. The number of medical records reviewed in centers with neurosurgery was 15,231, with 2,088 patients fulfilling criteria of confirmed and highly probable PD cases (13.7% of CCU deaths). The estimated number of possible donors is 1,310, compared to the 1,083 ADs registered. In the hospitals without neurosurgical facilities, 441 cases of confirmed and highly probable PDs were identified (9.1% of CCU deaths). With 214 ADs in those hospitals, according to the external audit, such number should have reached 267 should the process have been conducted without any inadequate/avoidable loss.

Comparing data from external evaluations according to the presence of a neurosurgical unit (Tables 4 and 5), a higher proportion of PDs not referred to the TC is observed in those centers without neurosurgery.

Discussion

The main philosophy of the Spanish Model is an organizational approach to the deceased donation process, including its continuous evaluation, the essence of the QAPDD (3–5). We aim to highlight the important information offered by this program, and to provide an overview of its methodology, for other countries to examine the feasibility of developing similar approaches.

Key aspects of the QAPDD are

(1) Data collection in the internal phase is part of the routine of TCs, which does not imply a high additional workload (an estimate of 1 hour of work *per* identified PD) and ensures the *sustainability of the program*.
(2) The information provided allows the construction of *key simple quality indicators*, however, relevant for a comprehensive assessment of the process. Typically, performance in deceased donation has been evaluated

through the conversion rate. As recognized by some experts, this metric is not comprehensive since it does not asses the previous critical step of PD identification (13). This is evaluated in the Spanish program by combining data from the clinical chart review with mortality data, through the percentage of hospital and CCU deaths which fulfill brain death criteria (12.4% and 2.3%, respectively). The value of these indicators is different between hospitals with/without neurosurgery, so reference indicators are provided *per* hospital type. Hospitals with percentages below these reference values might be having problems in donor identification.

(3) A key methodological aspect is the use of a *standardized methodology* for the identification of PD cases (Table 1), which helps to guarantee uniformity in the assessment of the potential of donation.

(4) Although some organizations have developed similar initiatives (11–18), an exclusive feature of the Spanish methodology is the *combination of a continuous internal monitoring with a periodic external evaluation.* Data from the internal evaluation help to select centers to be audited (a limited number yearly to reduce the cost of this phase). External evaluations allow the formulation of recommendations usually related to resources, updated protocols and collaboration with other hospital units. Such recommendations are addressed to the TCs, but also to the hospital managers, something which facilitates the implementation of specific actions. The internal evaluation results of the QAPDD allow assessing the impact of these improvement measures.

(5) *Training* in interpretation of the results and translation procedures are obviously essential

The Spanish QAPDD provides relevant data for designing local and national strategies. At a national level, the main reasons that prevent the full realization of the process are medical contraindications and refusals of consent to proceed with donation. These findings have fostered the development of policies targeted at achieving consensus on the evaluation of medical suitability of PDs and training initiatives on family approach (5).

Data derived from the program also allow international comparisons, as for the national pool of PDs. Sheehy et al estimated the number of PDs in the USA to be 13 317 in 1999, corresponding to about 40 PDs pmp (12). In the Netherlands, the estimation for what the authors defined as a realistic PD pool was 34.2 to 38.7 pmp (14). More recently, the national PD audit in the United Kingdom allowed the estimation of such potential, which strikingly did not reach 25 PDs pmp (15). In the North East donor region in Germany, the rate of PDs ranged from 38 to 45 pmp for the years 2002 to 2005 (16). Finally, according to the Spanish QAPDD, persons fulfilling clinical criteria consistent with brain death were 49 pmp in 2010. Taking into account that 26% were deemed unsuitable for organ donation, the potential of DBD in Spain would be about 36 pmp, similar to Sheehy's estimation for the USA, but much higher compared with that of some European countries (11).

Different hypotheses could justify the differences observed in the potential of DBD across countries. First, the methodologies applied for estimating the potential of donation are not identical. Until recently, there has not been a common agreement on what is universally defined as PD (19). Second, the potential for donation is usually assessed within the CCUs, understood as a rather static compartment. However, policies facilitating the identification and referral of persons with a devastating brain injury outside a CCU might provide room for further increasing the PD pool, this being an area in which Spain has been working (5). Third, countries differ in their understanding of medical contraindications to organ donation (11). Finally, end-of-life practices seem to be different across countries with regard to withdrawal of life-sustaining therapies (20). Studying the potential for donation across countries through a similar methodology is essential to better understand differences in national performance.

Notably, the potential of DBD in Spain has been decreasing over time. The progressive reduction in mortality relevant to organ donation and the more extended use of decompressive craniectomy might justify this (21,22). Moreover, practices in end-of-life care in Spain could be evolving toward those described in Northern or Central European countries years ago (20). The profile of PDs has also changed, with a progressive increase in age and in the percentage of those who die because of a stroke. In spite of this, the conversion of PDs into ADs has improved across time. The role of the QAPDD in this improvement is difficult to determine. But its importance in terms of inspiring local and national strategies and of creating the spirit of self-evaluation and continuous improvement is to be acknowledged.

Finally, important lessons can be derived from the experience with external audits. The potential for donation seems to be underestimated with a self-evaluating approach. Notably, 6.6% persons with a clinical condition consistent with brain death and medically suitable are not identified as PDs (9.3% in hospitals without neurosurgery). Moreover, further PD losses are preventable. Particularly, 11.5% of these losses are considered inadequate by auditors. According to the external evaluation, performance could improve to such an extent that the number of ADs would be 21.6% higher. Hence, the external evaluation approach is the gold standard in the assessment of the deceased donation process.

In conclusion, data derived from the Spanish QAPDD, as conceived, provide essential information to design tailored strategies to our needs. Countries should foster the development of programs of this nature. If built with a common

methodology, there would be the additional benefit of a better understanding of differences in performance across countries and room for international benchmarking.

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