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Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation

National Report Baseline Evaluation: Spain
(2nd Draft Version)

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List of contents

| | |
|---|----|
| Resumen en castellano de la Evaluación del Punto de Partida | 1 |
| 1. Analysis of newspapers and magazines | 6 |
| 2. Analysis of literature | 36 |
| 3. Secondary analysis of data - opinion polls | 39 |
| 4. Expert interviews | 41 |
| 5. Conclusions | 52 |
| 6. References | 60 |

Resumen de la Evaluación del Punto de Partida

Objetivos y metodología

El primer bloque de trabajo del proyecto está dedicado a la investigación empírica sobre el estado actual del debate sobre xenotrasplantes en Alemania, Austria y España. Sus objetivos son:

1. Analizar el discurso actual en los tres países.
2. Identificar los factores que pueden influir en el debate.
3. Identificar posibles participantes para el diálogo Neo-Socrático y sus posiciones hacia los xenotrasplantes.
4. Identificar posibles argumentos para el diálogo Neo-Socrático.

La metodología propuesta para alcanzar estos objetivos es la siguiente:

- Análisis de contenido de las noticias publicadas en diarios y revistas de gran difusión.
- Análisis de la literatura y legislación existentes sobre los xenotrasplantes.
- Análisis de estudios de opinión pública relacionados.
- Entrevistas a expertos que estén vinculados de alguna forma con el tema de los xenotrasplantes (médicos, investigadores, representantes de asociaciones de pacientes, representantes de administraciones públicas, defensores de los derechos de los animales, etc.).

Forma del debate nacional sobre los xenotrasplantes

La información obtenida con las dos principales fuentes del trabajo -análisis de prensa y las entrevistas a los expertos- pone de manifiesto que el debate sobre los xenotrasplantes en España no ha comenzado, aunque esta afirmación requiere algunos matices.

El análisis de contenido de la prensa ha revelado una cierta preocupación por los riesgos potenciales que los xenotrasplantes pueden representar para la salud pública. Sin embargo, esta preocupación no se refleja en un verdadero debate social, sino que la prensa lo ha introducido como uno de los principales obstáculos para conseguir implantar órganos de animales. Por otra parte, el escaso número de artículos de opinión es un indicador del pobre interés que este tema ha suscitado.

Las entrevistas con expertos arrojan el mismo resultado. Con la excepción de aquellos representantes de la defensa de los derechos del animal, todos los demás expresan serias dudas sobre la posibilidad de debates éticos sobre xenotrasplantes. Se presta más atención a los problemas técnicos en lugar de los éticos, en el caso de la puesta en práctica de esta técnica. Los expertos relacionados con la defensa de los animales reconocen que el debate sobre estos derechos en España es nulo, pero expresan su deseo de provocarlo.

Las encuestas de opinión -estudios del Centro de Investigaciones Sociológicas (CIS) y Eurobarómetro 46.1- muestran un apoyo mayoritario de la sociedad española al uso de órganos animales para solucionar el problema de las listas de espera en trasplantes. La ausencia de

posiciones enfrentadas en las encuestas es otro indicador de la ausencia de polémicas acerca de los xenotrasplantes.

La única iniciativa existente en España para abordar el tema de los xenotrasplantes desde una perspectiva social fue llevada a cabo por la Subcomisión de Xenotrasplantes de la Comisión Permanente de Trasplantes del Consejo Interterritorial del Sistema Nacional de Salud. Su objetivo fue establecer unas pautas para la investigación y ensayos clínicos desde el punto de vista técnico, pero sin poner énfasis en los aspectos éticos.

El único comité sobre ética en la investigación científica en España fue creado en abril de 2002, y se conoce como Comité Nacional de Ética para la Ciencia y la Tecnología. Este comité está compuesto por doce miembros, y su tarea más urgente debía ser pronunciarse sobre la investigación con células madre embrionarias. Es de suponer que si los trasplantes de órganos animales fueran a ser una realidad, este Comité tendrá que pronunciarse. Muchos de los entrevistados por nosotros han criticado duramente la composición del Comité, considerando que hay sesgos religiosos que pueden influir negativamente en el avance de las investigaciones, por ejemplo en el caso de las células madre.

Los expertos consideran que el debate ético sobre los xenotrasplantes, así como sobre otros desarrollos biotecnológicos, se debe presentar más frecuentemente en la opinión pública a través de los medios de comunicación. Normalmente son las noticias sobre los aspectos técnicos las que prevalecen, salvo en el caso de las células madre, donde siempre son noticia las reservas éticas. Hay que evitar las noticias sensacionalistas, dejando bien claro cuales son los posibles beneficios de cada desarrollo, pero también sus riesgos e inconvenientes.

Otra forma de potenciar los debates éticos sería a través de la formación de foros multidisciplinarios. Para el caso de los xenotrasplantes, estos foros podrían formarse por expertos en trasplantes, inmunólogos, virólogos, expertos en salud pública, representantes de los pacientes, defensores de los derechos del animal, etc. Las opiniones obtenidas en estos grupos deben ser tenidas en cuenta por los Gobiernos antes de aprobar líneas de investigación o legislación.

Contenido del debate

El análisis de contenido de la prensa muestra los siguientes contextos donde aparecen los xenotrasplantes: "Viabilidad científico-técnica", "Beneficio-Riesgo", "Escasez de órganos", "Uso de animales" y "Regulación". Estos contextos reúnen el 90% de las noticias.

Las entrevistas a los expertos han arrojado un resultado similar, aunque el uso de animales tiene una representación muy baja, ya que sólo tres entrevistados de un total de 19, lo consideraron relevante. Para el resto, los xenotrasplantes son vistos como una solución a la escasez de órganos, cuyo obstáculos principales son el rechazo y el riesgo no evaluado para la salud pública a consecuencia de las infecciones.

La prensa, el medio más influyente junto con la televisión, no parece tener una postura tomada respecto a los xenotrasplantes. De la lectura de los artículos no se desprende una estrategia

clara. Sin embargo, la mayoría de noticias sí desprenden cierto optimismo y una actitud positiva hacia el uso de órganos animales, ya que representan la solución a la temida escasez de órganos.

Los expertos relacionados con la investigación biomédica muestran interés en promover las investigaciones, aunque algunos de ellos creen que sería recomendable profundizar en otras opciones, como las células madre o el incremento de donaciones. Sus opiniones versan sobre los obstáculos técnicos, no tanto en las cuestiones éticas.

Aquellos activistas involucrados en la defensa de los derechos de los animales se oponen a los xenotrasplantes por varios motivos. Primero, porque consideran que los animales deben tener los mismos derechos que el ser humano. En segundo lugar, las condiciones de vida de los animales dedicados a la investigación son inaceptables, ya que no tienen nada que ver con sus hábitats naturales.

Los pacientes que esperan un trasplante ven en los xenotrasplantes una esperanza para la solución de sus problemas. Pero también confiesan un interés creciente por otras alternativas como el desarrollo de órganos artificiales o la investigación con células madre.

En resumen, el caso español permite la identificación de tres colectivos: científicos, ecologistas y pacientes. Cada uno de ellos adopta diferentes posiciones dependiendo de sus intereses, que son difíciles de reconciliar.

Como se ha señalado, el debate ético en la prensa es mínimo. Una cuarta parte de los artículos no presenta ningún aspecto ético, aunque sea de forma velada. De los restantes, los aspectos más tratados son el riesgo que suponen los xenotrasplantes para la salud pública y, a mucha distancia, los valores éticos.

Las entrevistas de nuevo confirman este resultado. Todos los expertos coinciden en señalar que los riesgos de infecciones y pandemias deben ser estrictamente valorados antes de poner en práctica los xenotrasplantes. El uso de animales ha sido propuesto como problema ético sólo por aquellos entrevistados relacionados con la defensa de los derechos del animal.

Como algunas entrevistas han sido semi-estructuradas, han aparecido ideas que dan lugar a debates éticos de gran calado, como las propuestas de "socializar" los cadáveres como fuente de órganos o la de incrementar las donaciones mediante incentivos pecuniarios pagados por el sistema público de salud.

En cuanto a las regulaciones de los xenotrasplantes, se recogen en el informe de la citada Subcomisión de Xenotrasplantes que se publicó en 1999. Para reducir a mínimos el riesgo de pandemias, este informe propone una exhaustiva monitorización del paciente trasplantado para controlar la posibilidad de infecciones. Cabe preguntarse si es factible un seguimiento tan estrecho del individuo y si ese seguimiento es legítimo debido a la intromisión que supone de la vida privada.

Actores del debate

En un debate ético en España sobre los xenotrasplantes, estos son los actores que deberían participar:

- Medios de comunicación: imprescindibles para promover el debate en la opinión pública.
- Representantes de la Administración: Ministerios de Sanidad y Consumo, Ciencia y Tecnología, Administraciones Regionales, Organización Nacional de Trasplantes.
- Científicos y médicos con experiencia en trasplantes.
- Activistas de asociaciones de defensa de los derechos del animal.
- Asociaciones de pacientes.

Algunos grupos propuestos en la guía del proyecto no han sido considerado en las entrevistas por su escasa relevancia en España.

Los grupos políticos no tienen ninguna opinión formada sobre el tema de los xenotrasplantes o, al menos, eso es lo que nos han transmitido. La situación de las células madre es un caso opuesto, donde las implicaciones morales han desatado la guerra entre los políticos, más interesados en el cruce de acusaciones que en la investigación.

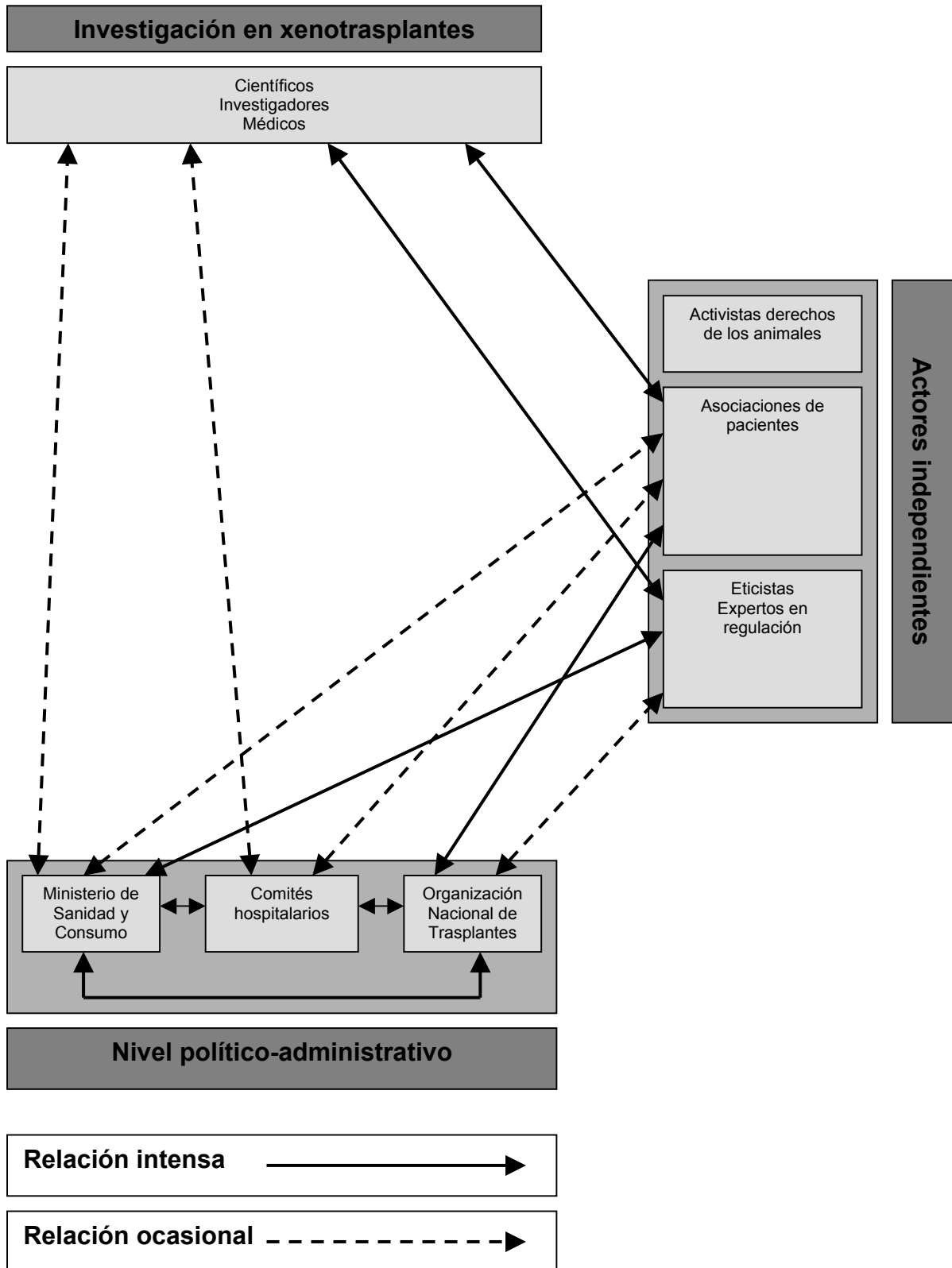
Tampoco se ha incluido a la industria farmacéutica porque no existe en España ninguna empresa que esté desarrollando investigaciones sobre xenotrasplantes. Las compañías privadas de servicios médicos han sido excluidas porque los trasplantes sólo pueden realizarse dentro del sistema público de salud.

Los escasos investigadores españoles mantienen contactos con la comunidad internacional. Ellos conocen la evolución de las investigaciones en el contexto internacional pero son conscientes de la dificultad que tienen para provocar el debate en España. Una actitud de discreción es aún más evidente en aquellos investigadores que trabajan bajo contratos de empresas privadas.

Otra conexión internacional viene impuesta por los aspectos normativos, en particular dentro del contexto europeo. El anterior responsable de la Organización Nacional de Trasplantes, Rafael Matesanz, fue también presidente de la Comisión de Trasplantes del Consejo de Europa. Esta Comisión asume, entre otros objetivos, la tarea de diseñar una política común de xenotrasplantes en Europa. En 1999 se publicó una moratoria que recomendaba el abandono de las investigaciones por el riesgo que suponen para la salud pública. Las autoridades españolas, encabezadas precisamente por Matesanz, no la aceptaron.

Todos los expertos entrevistados son susceptibles de participar en la siguiente fase del proyecto, que es el diálogo Neo-Socrático, aunque otras personas no entrevistadas también pueden involucrarse. Casi todas las personas contactadas hasta el momento han expresado su conformidad con la realización del diálogo, considerándolo un buen método para poder establecer un nuevo mecanismo de discusión y decisión en debates sobre temas científicos.

Actores del debate de xenotrasplantes en España



1. Analysis of newspapers and magazines

1.1. Goals

The three goals addressed in the first workpackage are:

- To analyse the current XTP discourse in Spain.
- To identify factors which might influence the debate of current XTP discourse in Spain.
- To identify Spanish actors and to analyse their position towards XTP. These actors may further participate in the Neo Socratic Dialogue.

In this part of the report, we aim to reach these goals by analysing the documents related to XTP that were published in Spanish newspapers and magazines. So this first part has its own goal. We attempt to discover the characteristics of the information published in Spain about XTP. We have analysed daily quality newspapers and scientific magazines, from January 1995 to March 2002.

We raise some questions that should be answered by the analysis of the press. These questions were suggested in the adopted baseline evaluation guidebook:

- When were the reports published? Are there any peaks of reporting?
- In which section of the newspapers are the reports mainly published: eg. health, science, politics, miscellaneous.
- Does the reporting raise any ethical questions or is it only technical?
- How polarised is XTP presented in the media? Does reporting emphasize the advantages, the risks or is it balanced?
- Does reporting deal with the question on how to solve the conflict?
- Which actors are involved in the debate? In which form are they involved?
- Which potential relevant actors are excluded/do not participate? Why?
- Which positions do relevant actors take? How do they argue for these positions?
- Which ethical questions are raised?
- Which solutions/regulations are being debated?
- In which context is XTP primarily being debated (e.g. transplantation, animal rights). How is XTP framed as problem?
- How do international actor-networks (e.g. researchers, surgeons, policy-makers) influence the discussion on ethical aspects of XTP? In what way do national documents refer to those from other countries respectively international organisations?)
- Which actors could participate in the Neo Socratic Dialogue?

1.2. Methods

1.2.1. Press in Spain

When proceeding with the guidebook agreed by the partners, we have found some problems. It was recommended to search the information in three daily quality newspapers, those with the highest print run; one tabloid and two popularising scientific magazines. In Spain, there are limits to this application.

First of all, it is impossible to find any tabloid in Spain. A tabloid is defined as a short daily newspaper, with many photographs and information published in a short and simple way. This kind of newspaper is generally found in Central European countries and United Kingdom. So we decided to analyse four daily quality papers, instead of one tabloid.

Second, there are few popularising scientific magazines and usually they are not dealing with specific focused topics. We chose two of the most popular, though we were expecting poor results on the xenotransplantation issue. The results confirmed such expectations.

Before entering into the analysis of the information retrieved from the newspapers, we consider of interest to give some details of the reading habits in Spain. There is high quality daily press but it is also true that Spaniards read less than other European citizens. Press is valued as the most prestigious and influential mass media but the level of reading is low as compared to other mass media, i.e., television.

A public institution, the "Centro de Investigaciones Sociológicas" (Sociological Research Centre), adscribed to the Ministerio de la Presidencia (Ministry of Presidency) carries out national qualified public opinion surveys. One of these surveys¹ addressed the issue of leisure habits and, among them, it is possible to find information about the habits of reading. A summary of these results is given below.

¹ "Consumo cultural", Boletín 22, October-december 1999. www.cis.es

| Leisure activity | % Every day or in most days |
|-----------------------|-----------------------------|
| I watch tv | 87 |
| I listen to the radio | 49 |
| I listen to music | 42 |
| I read newspapers | 32 |
| I read books | 17 |
| I read magazines | 4 |

As we can see above, only about 32% of Spaniards read newspapers every day or in most days. However, almost all Spaniards (87%) watch tv. Only 4% read magazines some days in a week. We can say that magazines are an excluded mass media.

In the same poll, we can see the differences between men and women. Men read newspapers in 41% of the cases, more than women (24%). And speaking about age, 38% of people between 35 and 54 years old read newspapers every day. Differences between cultural level are very wide. People with University degrees read newspapers (55%) much more than people without elementary studies (25%). Employed people read much more than unemployed people, 41% and 31% respectively. Upper and medium-upper class people read more than working class people, 56% and 20% respectively.

Now, we can explain some information about magazines reading habits. Women read more magazines than men. Though this difference is less significant than in the case of newspapers, 27% and 21%. If we speak about age, young people (18-24 years old) read much more magazines than medium aged people (45-54 years old), 37% and 22% respectively. Magazines reading habit raises if we consider the educational level. University graduates read much more magazines than people without elementary studies, 39% and 8%. Students like magazines much more than pensioner, 37% against 15%. And finally, there are big differences between different social classes. 35% of upper and medium-upper class people read magazines and 17% in the case of working class people.

1.2.2. Sample

As we said before, we decided to include four daily quality papers instead of three. They are: *"El País"*, *"El Mundo"*, *"ABC"*, *"La Vanguardia"*. We think it is interesting to spend some lines to describe, in short, these newspapers. Then, we justify our choice giving information about circulation and readers of each newspaper.

"El País"

PRISA, the mass media holding founded in 1973, is the publisher of this newspaper and José Ortega y Gasset Spottorno, the son of the very well known Spanish philosopher, was the founder. Jesús Cebeiro is the present director. The first issue appeared in 1976, after the dictatorship of Franco finished and this is because this journal has been named as *"the democracy newspaper"*.

"*El País*" is one of the daily opinion-leader in Spain. It is a paper of reference and a successful publication since 1976. It is read by nearly every person in a decision-making position. Politically, it is centre-left.

Its sections are: International, Opinion, National, Society, Culture, Agenda, Sports, Economy and Radio/TV. As it can be seen in the sections order, this newspaper is very interested in the international news, especially those related to Europe. Speaking about formal aspects, it can be said that this is a sober and concise journal.

"*El Mundo*"

Unidad Editorial, S.A., is the publisher of this paper, established in 1989. It was founded when a group of journalists from another Spanish newspaper, *Diario 16*, left that paper due to internal disputes. Pedro José Ramírez is the actual director.

It is a successful paper from its beginnings. It is said that this success is due to relevant enquiries published in the nineties, that uncovered several corruption cases in Politics. Occasionally this paper has been considered, because of that, as a sensationalistic journal.

The first rubrique is Opinion, followed by National, Europe, International, Society, Economy, Sports, Radio/TV. This journal is also very interested in European news. The design of this paper is very well considered, because it has won several international prizes. Politically, it is centre-right, although this is not very defined because different trends can emerge in its opinion articles.

"*ABC*"

It is one of the oldest journal in Spain. It was founded in 1903 by Torcuato Luca de Tena, as a weekly magazine, and turned into a daily paper in 1909. José Antonio Zarzalejos is the present director and *Prensa Española, S.A.* is the publisher company.

Speaking about formal aspects, it is very conservative. The first section is called "Faces of the news", where the reader can find photographs of people related to the facts occurred. Other sections are Opinion, National, International, Society, Economy, Obituaries, Leisure, People, Radio/TV. It is a conservative and monarchist journal since its origin. The design can be considered old-fashioned, in comparison to the rest of the Spanish newspapers.

"*La Vanguardia*"

This newspaper was founded by Carlos and Bartolomé Godó in 1881 and is published by Javier Godó. It can be said that this journal belongs to a familiar company, since more than 100 years ago. The actual director is José Antich.

It is sold mainly in Catalunya, but it is easy to find it through all Spain. It is read by decision-making people from Catalunya, which is a very relevant region of Spain in all those aspects related to Politics and Economy. The sections are International, Politics, Opinion, Society, Culture, Sports, Economy. Politically, it is centre.

Three out of the four newspapers were chosen on the basis of circulation criteria. Circulation is defined as the total amount of copies sold in a day. The audit of circulation data of printed media is carried out by a private organization, OJD².

| Daily newspaper | Circulation per day |
|----------------------|---------------------|
| <i>El País</i> | 433617 |
| <i>El Mundo</i> | 312366 |
| <i>ABC</i> | 279050 |
| <i>La Vanguardia</i> | 191673 |

Source: OJD, January 2001-December 2001

Another indicator concern the concept of readers, corresponding to the number of persons who actually read a newspaper in a day. This figure is always higher than the one referred to circulation and provides a more accurate information on the quantity of persons that may have access to a given piece of information.

Readers figures are given by AIMC³, obtained by EGM⁴, a wide survey about population habits in relation to mass media. Objectives of AIMC are: research, measurement, control and diffusion of audience of mass media, using periodical surveys.

| Daily newspaper | Readers per day |
|----------------------|-----------------|
| <i>El País</i> | 1526000 |
| <i>El Mundo</i> | 916000 |
| <i>ABC</i> | 791000 |
| <i>La Vanguardia</i> | 594000 |

Source: AIMC, EGM, April 2001-March 2002.

² It is a non-profit organization whose objective is to provide useful and timely information about the circulation of printed media for advertisers, advertising agencies, publishers and general use. The OJD was set up on October 20th 1964 and from that date circulation audits have been issued uninterruptedly. In December 2001 the circulation of 850 publications was audited. That meant approximately: 97% of daily newspapers; 93% of consumer magazines; 62% of business magazines; 100% of telephone directories.

The OJD's general principles:

- a. Privacy and independence
- b. Voluntary membership
- c. Audit procedures to provide reliable circulation figures
- d. Compulsory audits for publisher statements and publisher cooperation during the verification process.
- e. Personal participation of the publisher in case of doubts.
- f. Privacy of the information provided to the OJD for audit purposes.
- g. Use of standard formats and the absence of comments in audit reports.
- h. Professional collaboration with other companies that carry out activities related to the OJD's main objective.

www.ojd.es

³ "Asociación para la investigación de los medios comunicación", (Association for research of mass media). www.aimc.es

⁴ "Estudio general de medios", (General analysis of mass media). www.aimc.es

Similar criteria have been applied to the selection of magazines. Two popular science magazines have been selected. They are: "*Muy Interesante*" and "*Quo*", which addresses scientific topics to the general public, not specialists, by writing with a pleasant, attractive style and using simple terms. The target of these magazines are people with medium educational level.

| Magazines | Circulation per month (Jun00-Jun01) |
|-----------------|-------------------------------------|
| Muy Interesante | 283690 |
| Quo | 160503 |

Source: OJD, June2000-May2001

| Magazines | Readers per month (Apr01-Mar02) |
|-----------------|---------------------------------|
| Muy Interesante | 1700000 |
| Quo | 916000 |

Source: AIMC, EGM, April2001-March2002

1.2.3. Information gathered

All the articles were published between January 1995 and March 2002. We have found 185 information units in total; 178 from newspapers and only 7 from magazines.

The following keywords were used: "*xenotransplantation*", "*animal+transplantation*", "*animal+organs*", "*pig+cells*", "*pig+organs*", "*transgenic+pigs*", "*pig+transplantation*", "*dolly*". The most part of the information units were found under the keyword "*xenotransplantation*".

We decided to make recourse to the keyword "dolly" because after the birth of the famous sheep, a lot of articles on cloning appeared. We have assumed that some of these articles could have some links with xenotransplantation. The results were not significant, though the use of this keyword afforded some additional information. Articles found under "dolly" dealt with cloning, and this scientific development could be used in xenotransplantation, in order to obtain cloned genetic modified pigs to avoid rejection.

Now, we are going to explain the method used for searching the units of information in our newspapers and magazines.

The search for the information provided involved several steps and methodologies: Internet, personal contacts with the responsables of the publications. The assistance provided by the persons from the media was in general very satisfactory: broad and generous (in very few cases it was necessary to pay an stipend for the articles).

1.2.4. Information processing and data warehouse

It is essential to use a data warehouse to keep all the information. Firstly, we recorded all the analysis of the articles in Access 97, provided by Microsoft. This software is used all around the world. This software tool allows us to use the information recorded in Word 97, Excel 97 and Power Point 97. Access 97 can create high quality report.

We used SPSS 10.0 as software for the analysis of the data. This well famous software provides great flexibility and versatility in the analysis and exploitation of data.

1.2.5. Information analysis: variables and categories

Each document identified has been recorded as one item in both data warehouses, Access 97 and SPSS 10.0. We have analysed each document using 31 variables. Some of them have fixed options or categories. The variables are:

"Publication"

| Id | Publication |
|-----------|--------------------|
| 1 | El País |
| 2 | El Mundo |
| 3 | La Vanguardia |
| 4 | ABC |
| 5 | Muy Interesante |
| 6 | Quo |

This variable with prefixed categories allow us to classify each document taking into account the name of the publication.

"Year", "Month", "Day", "Day of the week"

"Type of publication"

| Id | Type of publication |
|-----------|----------------------------|
| 1 | Daily Paper |
| 2 | Magazine |

"Section"

| Id | Section |
|-----------|----------------|
| 1 | Opinion |
| 2 | Society |
| 3 | Health |
| 4 | Others |

This variable with prefixed categories allows us to classify each document taking into account the section where the information was published.

"Type of information"

| Id | Type of information |
|-----------|----------------------------|
| 1 | News or report |
| 2 | Editorial |
| 3 | Opinion article |
| 4 | Interview |
| 5 | Others |

"Headline"

This variable contains the headline of the document⁵.

"Keyword"

This variable contains the exact word which we can use to search the document.

"Summary"

It sums up the information of the documents, including the most important facts or issues stated in the articles or reports⁶.

"Subject identified"

| Id | Subject presented |
|-----------|---|
| 1 | Benefit XTP-Solving donor shortage |
| 2 | Benefit XTP-Patient's quality of life |
| 3 | Benefit XTP-Others |
| 4 | Hurdles-Present state of the art of XTP |
| 5 | Hurdles-Hyperacute rejection |
| 6 | Hurdles-Acute rejection |
| 7 | Hurdles-Chronic rejection |
| 8 | Hurdles-Genetic engineering against HAR |
| 9 | Hurdles-Rejection-Others |
| 10 | Hurdles-Infection risks |
| 11 | Hurdles-Infection known or unknown pathogens |
| 12 | Hurdles-Infection to population or pandemy |
| 13 | Hurdles-Infection related to PERV's |
| 14 | Hurdles-Infection risk management |
| 15 | Manipulation of animals-Genetic engineering |
| 16 | Manipulation of animals-Cloning source animals |
| 17 | Manipulation of animals-Animal welfare |
| 18 | Alternatives to XTP-Increase of donation, prevention, optimization of allotransplantation, etc. |
| 19 | Alternatives to XTP-New scientific researchs (gene therapy, artificial organs, etc.) |
| 20 | Societal questions-Research financing |
| 21 | Societal questions-Present regulations |
| 22 | Societal questions-Regulatory initiatives |
| 23 | Societal questions-International competitiveness |
| 24 | Societal questions-Acceptance of animal use |
| 25 | Societal questions-Religious beliefs |

⁵ This variable has not been translated into english, because is used in our research as an internal tool.

⁶ Idem.

| | |
|----|---------------------------------------|
| 26 | Societal questions-Public acceptance |
| 27 | Societal questions-Economical affairs |
| 28 | Societal questions-Others |
| 29 | None |

This variable with predefined categories tell us the main subjects appearing in each document and related to the first column of the table of the methodological guidebook. We experienced great difficulties when using the very sophisticated categories scheme of the methodological guidebook and leading us to ask about their usefulness, because we have not found so much different subjects in the documents read. Besides, the categories of the guidebook are divided into three levels of analysis. This division adds more unnecessary complexity.

It was found more useful to reduce to 29 categories. There are five main issues: Benefit XTP; Hurdles; Manipulation of animals; Alternatives to XTP; Societal questions. Each one is divided into secondary issues. The most part of documents deal with several subjects, though we have identified the main subject within each article.

"Presentment of facts"

This variable expresses the facts present in the document. They concern the news related to recent research, developments, regulations, etc. This variable relates to the one of the second column of the methodological guidebook⁷.

"Information context"

| Id | Information context |
|-----------|----------------------------------|
| 1 | Donor organ shortage |
| 2 | Scientific-technical feasibility |
| 3 | Benefit-Risk in XT |
| 4 | Regulation |
| 5 | Economic problem |
| 6 | Societal values impacts |
| 7 | Individual impacts |
| 8 | Unclassified |
| 9 | Use of animals |

This variable with predefined categories contains information about the context in which facts happen and corresponds to the third column of the methodological guidebook.

"Ethical questions"

| Id | Ethical questions |
|-----------|--------------------------|
| 1 | Cultural values |

⁷ This variable has not been translated into english, because is used in our research as an internal tool.

| | |
|---|----------------------------|
| 2 | Risk |
| 3 | Equal access to XT |
| 4 | Patient and society rights |
| 5 | Animal Welfare |
| 6 | Economics |
| 7 | Regulation |
| 8 | Others |
| 9 | None |

The table above lists different ethical questions that can be raised in each publication.

"Solutions offered"

Some articles deal with problems related to xenotransplantation, and sometimes the solutions are found in the same articles⁸.

"Sources"

This refers the exact sources which are cited in the document. If a document does not cite any source, it is assumed that the content has been created by the author⁹.

"Main sources"

| Id | Main sources |
|-----------|---------------------|
| 1 | Press agency |
| 2 | Scientific magazine |
| 3 | Interviews |
| 4 | Press conference |
| 5 | Author |
| 6 | Others |
| 7 | Unknown |

This variable has predefined categories. It shows the main source used in the information. Sometimes, the source is explained in the article, but in other cases the sources are unknown.

This variable is a good indicator for the quality of the information. If a piece of information has been written by using different sources, this is an indicator of the self-interest of the publication in the topic dealt with in the document.

"Actors of the information"

It is relevant for us to consider the main actors and institutions which appear in a document. Most of the documents, cite several actors, like doctors, researchers, institutions, hospitals, Universities, etc¹⁰.

⁸ This variable has not been translated into english, because is used in our research as an internal tool.

⁹ Idem.

¹⁰ Idem.

"Main actor" "Secondary actor"

| Id | Type of actors |
|-----------|-----------------------|
| 1 | Individual scientists |
| 2 | Politicians |
| 3 | Industrial scientists |
| 4 | NGO |
| 5 | Religious |
| 6 | Others |
| 7 | Mixed |

We have chosen these categories to classify the different actors, which appear in a document. In most of the articles, there is more than one actor. So we have decided to include two variables, one for main actor and another one for secondary actor. It is important to say that in many cases, as we will see later, main and secondary actors belong to the same group.

"Author"

Which indicates the exact name of the author, if known.

"Author opinion"

This variable collects the opinion of the author. Authors express their opinion in very few documents¹¹.

"Science %" "Political-societal %" "Ethics %" "Economics %"

This variable indicates the extension of each document that is dedicated to these different issues: science, politics or society, ethics, economy as a reflection of the aspects of xenotransplantation have been more important for Spanish press.

"Location"

| Id | Place |
|-----------|-----------------|
| 8 | USA |
| 9 | Europe |
| 10 | Spain |
| 11 | Other countries |
| 12 | International |
| 13 | United Kingdom |
| 14 | Unclassified |

This variable shows the place where the information have occurred, i. e., the origin. Sometimes, the information has not a specific origin, like in the case of opinion articles. Then we have considered that documents are international. Otherwise, if several countries are cited, we consider also that the piece of news is international.

¹¹ This variable has not been translated into english, because is used in our research as an internal tool.

"Use of technical terms"

| Id | Technical terms |
|-----------|------------------------|
| 1 | Very few |
| 2 | A few |
| 3 | Some |
| 4 | A lot |

We have measured the level of comprehension of the news by this variable. It can be said that a complex vocabulary reveals a high quality document. But this way of writing may be dangerous in printed mass media. People will lose interest if they cannot understand the information because of the vocabulary. News must be written in a simple way, in order to attract the interest of readers, while writers must consider also that simple words are not the same as simple ideas.

"Attitude"

| Id | Attitude |
|-----------|-----------------|
| 4 | Positive |
| 5 | Neutral |
| 6 | Negative |

It is possible to notice the attitude of mass media towards xenotransplantation by reading the documents. If a document shows advantages mainly, we can consider that the attitude is positive. But if disadvantages or risks are more frequent, the attitude will be the opposite.

"Figures"

This variable indicates if the newspapers or magazines have used photographs, tables, graphics, schemes, to illustrate the document. Figures are used in printed media to attract attention. Use of figures shows also the importance or relevance given to documents or issues.

1.3. Content analysis

1.3.1. Quantity of documents

"El Mundo" published the highest number of documents and "La Vanguardia" the lowest. The magazines only published seven documents in total, a figure that confirms the lack of interest about xenotransplantation in the general magazines as we were foreseeing.

Publication * Year

| Recuento | Year | | | | | | | | Total |
|-----------------|------|------|------|------|------|------|------|------|-------|
| | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | |
| ABC | 10 | 4 | 4 | 6 | 7 | 8 | 3 | 2 | 44 |
| El Mundo | 7 | 4 | 9 | 14 | 15 | 8 | 2 | 4 | 63 |
| El País | 2 | 7 | 1 | 8 | 9 | 5 | 3 | 7 | 42 |
| La Vanguardia | | 5 | 7 | 4 | 5 | 3 | 4 | 1 | 29 |
| Muy Interesante | 1 | | 1 | 1 | | | | | 3 |
| Quo | 1 | | 1 | | 1 | 1 | | | 4 |
| Total | 21 | 20 | 23 | 33 | 37 | 25 | 12 | 14 | 185 |

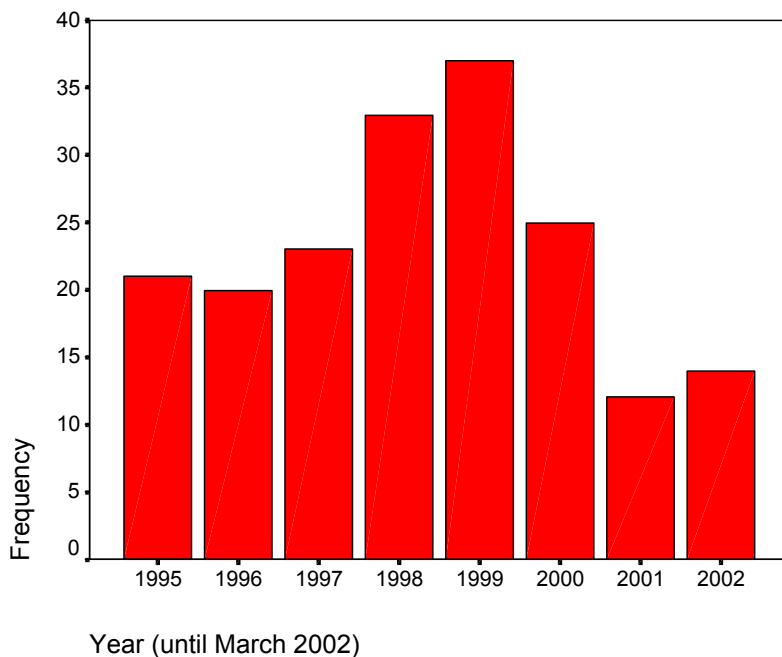
The content analysis was until March 2002, so there are less documents in this year in comparison with others.

1.3.2. Publication dates

Studying the peaks of reporting is one of the objectives of this report. As we can see in the table below, there are peaks of reporting corresponding to years in 1998 and 1999, with 33 and 37 documents respectively.

Year

| | Freq | % |
|-------|------|-------|
| 1995 | 21 | 11,4 |
| 1996 | 20 | 10,8 |
| 1997 | 23 | 12,4 |
| 1998 | 33 | 17,8 |
| 1999 | 37 | 20,0 |
| 2000 | 25 | 13,5 |
| 2001 | 12 | 6,5 |
| 2002 | 14 | 7,6 |
| Total | 185 | 100,0 |



A possible explanation of this fact relates to the decision, in 1998, of the Roslin Institute, that created Dolly in 1997, to research about transgenic pigs to reduce the problems related to rejection.

Several news about the infection risk were published during 1998. Infection risk may cause pandemics, and this fact caused fear in population. These are some of the reasons which may explain the high number of documents in 1998.

A second argument relates to the fact that Council of Europe recommended a moratorium to stop xenotransplantation research in 1999. One month later, Spanish authorities decided to continue xenotransplantation research. Mr. Matesanz, Chairman of the Permanent National Transplant Commission, said that if Europe stopped research, the United States would be ahead of Europe. Mr. Matesanz also stated that the moratorium had been based on political issues, not on scientific ones. Printed media followed this controversy in several documents during 1999.

Thirdly, one research related to infection risk was published in scientific magazines during summer. This research, in which 160 patients all over the world had taken part, confirmed the very low probability of infection by porcine viruses. This sort of news increased the reliability in xenotransplantation. All newspapers published documents related to this research, as a new hope raised on the use of animal organs as source for transplants.

However, the strong crisis produced by the "mad cows" case reduced the interest for the research on xenotransplantation. On the other side, the use of stem cells to repair damaged organs or to develop organs in the laboratory emerged as an alternative to reduce organ shortage. News about stem cells became to outweigh those on xenotransplantation.

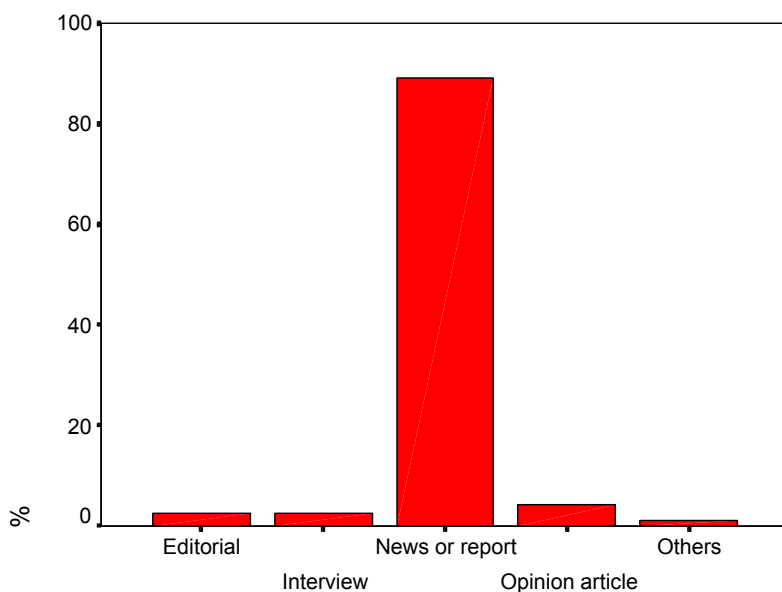
1.3.3. Types of documents

In Spanish newspapers, news or reports, 89.2%, are the most frequent. The difference with the rest of documents is very wide, as it can be seen in the table and graphics below.

Editorials represent only the 2.7% of the total. This figure suggests that the printed media do not lend great interest to xenotransplantation, because they have not published articles to express their own opinion.

Type of information

| | Freq | % |
|-----------------|------|-------|
| Editorial | 5 | 2,7 |
| Interview | 5 | 2,7 |
| News or report | 165 | 89,2 |
| Opinion article | 8 | 4,3 |
| Others | 2 | 1,1 |
| Total | 185 | 100,0 |



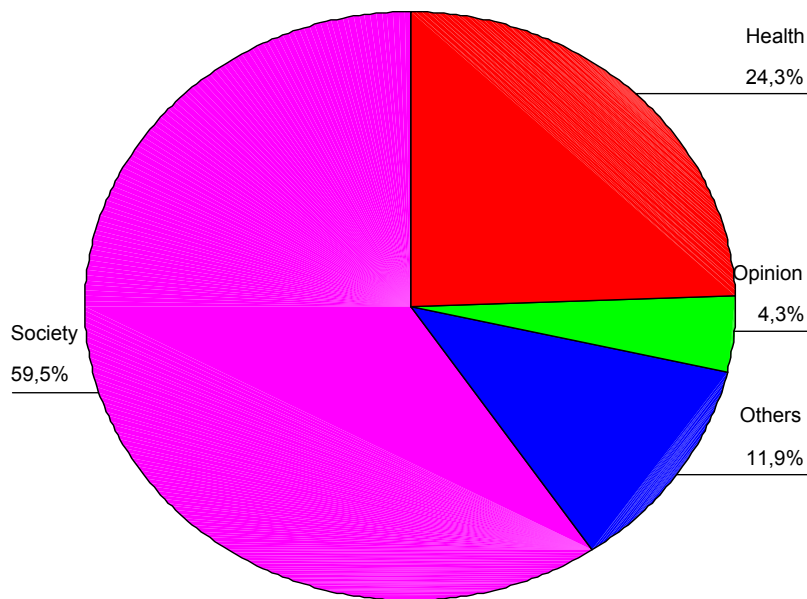
Type of information

Opinion articles amount to 4.3% of the total. This figure is also very low, what confirms our previous hypothesis about the lack of opinion and debate in mass media about the use of animal organs. It is true that it can be found positive, neutral and negative attitude towards xenotransplantation in the opinion articles, but the low number limits any conclusion.

Interviews are the 2.7% of total. Most part of people interviewed were scientists. There appear interesting opinions of Ian Wilmut, the "father" of Dolly; Rafael Matesanz, the Chairman of the Spanish Permanent Transplant Commission; Thomas Starzl, the doctor who made the first human transplant more than 30 years ago. There is a variety of opinions towards xenotransplantation in the interviews.

1.3.4. Sections

| Section | | |
|---------|-----|-------|
| | | % |
| Health | 45 | 24,3 |
| Opinion | 8 | 4,3 |
| Others | 22 | 11,9 |
| Society | 110 | 59,5 |
| Total | 185 | 100,0 |



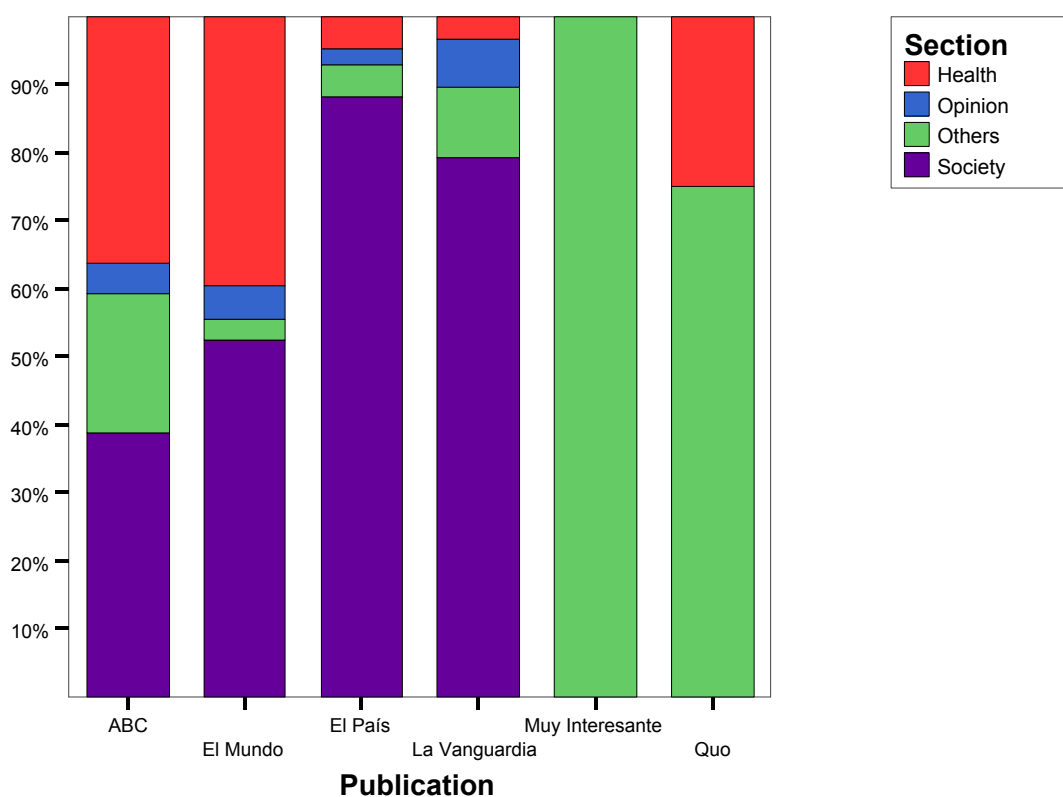
Most of the documents, 59.5%, have been published under the society heading, while those published in the health section amount to 24.3%. Only 4.3% of documents were published in the opinion section as stated before. This last figure argues in support of the idea that there have been very few debates in Spain on the issue of xenotransplantation.

It is however worth to mention that there are differences about this breakdown between sections among the newspapers studied as it is shown in the table and graphics below.

Table on distribution of xenotransplantation news in sections

% de Publication

| | Section | | | | Total |
|-----------------|---------|---------|--------|---------|--------|
| | Health | Opinion | Others | Society | |
| ABC | 36,4% | 4,5% | 20,5% | 38,6% | 100,0% |
| El Mundo | 39,7% | 4,8% | 3,2% | 52,4% | 100,0% |
| El País | 4,8% | 2,4% | 4,8% | 88,1% | 100,0% |
| La Vanguardia | 3,4% | 6,9% | 10,3% | 79,3% | 100,0% |
| Muy Interesante | | | 100,0% | | 100,0% |
| Quo | 25,0% | | 75,0% | | 100,0% |
| Total | 24,3% | 4,3% | 11,9% | 59,5% | 100,0% |



The policy of *ABC* and *El Mundo* to publish most of the documents on xenotransplantation in the health section must relate to the fact that both journals have a separate health supplement. The other two newspapers, *El País* and *La Vanguardia* have followed a different trajectory with most of the documents appearing under the society rubric.

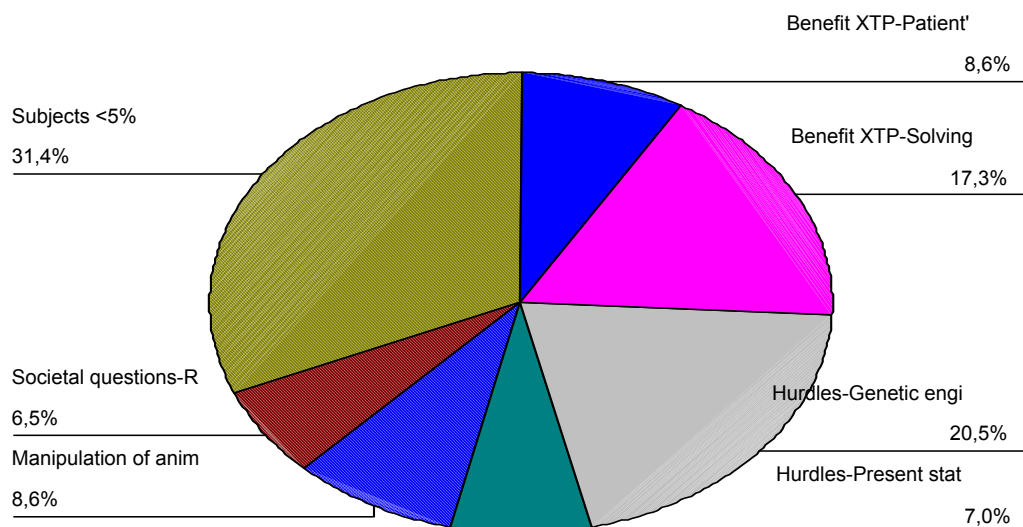
1.3.5. Subjects in the media

This is the most relevant part of content analysis allowing us to answer some of the questions proposed in the baseline guidebook. The identification of the subjects in the printed media allows to

discover which issues are most relevant in public debate, and whether it does exist. This may also provide insights on how to correct the deficits on information.

Subjects presented

| | Freq | % |
|--|------|-------|
| Alternatives to XTP-New scientific researchs (gene therapy, artificial organs, etc.) | 3 | 1,6 |
| Benefit XTP-Others | 1 | ,5 |
| Benefit XTP-Patient's quality of life | 16 | 8,6 |
| Benefit XTP-Solving donor shortage | 32 | 17,3 |
| Hurdles-Acute rejection | 1 | ,5 |
| Hurdles-Chronic rejection | 1 | ,5 |
| Hurdles-Genetic engineering against HAR | 38 | 20,5 |
| Hurdles-Hyperacute rejection | 2 | 1,1 |
| Hurdles-Infection known or unknown pathogens | 3 | 1,6 |
| Hurdles-Infection related to PERV's | 7 | 3,8 |
| Hurdles-Infection risk management | 2 | 1,1 |
| Hurdles-Infection risks | 8 | 4,3 |
| Hurdles-Infection to population or pandemy | 8 | 4,3 |
| Hurdles-Present state of the art of XTP | 13 | 7,0 |
| Manipulation of animals-Animal welfare | 2 | 1,1 |
| Manipulation of animals-Cloning source animals | 9 | 4,9 |
| Manipulation of animals-Genetic engineering | 16 | 8,6 |
| Societal questions-Acceptance of animal use | 1 | ,5 |
| Societal questions-Economical affairs | 1 | ,5 |
| Societal questions-International competitiveness | 1 | ,5 |
| Societal questions-Present regulations | 3 | 1,6 |
| Societal questions-Public acceptance | 3 | 1,6 |
| Societal questions-Regulatory initiatives | 12 | 6,5 |
| Societal questions-Religious believes | 2 | 1,1 |
| Total | 185 | 100,0 |



Six subjects emerge as the most relevant in printed media. From the 29 subjects proposed initially, we have drawn back some because their lack of significance.

Main subjects are: benefit XTP-patient's quality of life (8.6%); benefit XTP-solving donor shortage (17.3%); hurdles-genetic engineering against HAR (20.5%); hurdles-present state of the art of XTP (7%); manipulation of animals-genetic engineering (8.6%); societal questions-regulatory initiatives (6.5%).

The most common subject refers to the use of genetic engineering against hiper-acute rejection, this is, those news related to transgenic pigs. The pigs were created by several companies, like Imutran, Novartis or Roslin Institute.

News related to "*humanized*" pigs are very interesting for newspapers for two causes. Firstly, transgenic pigs increased the successful feelings in xenotransplantation. Using genetic modified pigs lead to reduce the risk of hyper-acute rejection. This is a very positive development in research, and a very optimistic fact for public opinion. Mass media like hyperbole in the news to underline both positive and negative aspects.

Second, research in genetic modified animals raises always sensationalistic sentiments. Scientists have achieved "*humanized*" pigs to avoid rejection. The crossing natural barriers, by means of genetic engineering, is a very controversial issue, which always attracts interest of the mass media. Moreover, this subject always raises ethical discussions.

Benefit of xenotransplantation, seen from solving donor shortage problem, is the second issue in order of importance. Documents which deal with this issue, usually state the worrying deficit of human organs. It is common to find documents which show figures about donation rates or waiting lists in different countries. Articles that reveal organ traffic from third world countries are also found.

Manipulation of animals using genetic engineering is the third subject. This issue is similar to the first one, related to hiper-acute rejection. But the difference is that, in this case, animals are the centre of attention.

The fourth subject looks to the benefit of xenotransplantation, as seen from the patient's point of view. These documents state the several advantages which patients will obtain with respect to their quality of life.

The fifth issue is a societal question, the regulatory initiatives. This subject is very often linked to infection and pandemics risks. Infection is a serious threat to public health. Many governments have notice of that people are scared by that possibility and health authorities have attempted to reduce fear by regulating research. Strict regulation have been also applied to clinical trials.

The European moratorium for xenotransplantation research adopted in 1999 was based on risk infection. Some days later, many news against this moratorium were published. The Spanish authorities did not accept the advice of the European Council, since Spain has a very strict regulation about xenotransplantation to manage risk infection. On the other hand, the moratorium could produce a very wide gap between United States and Europe.

British regulatory initiatives also attracted attention of mass media. This country is very permissive about stem cells research, but on the other hand, British authorities have regulated strictly xenotransplantation research. Many documents have been published dealing with this issue.

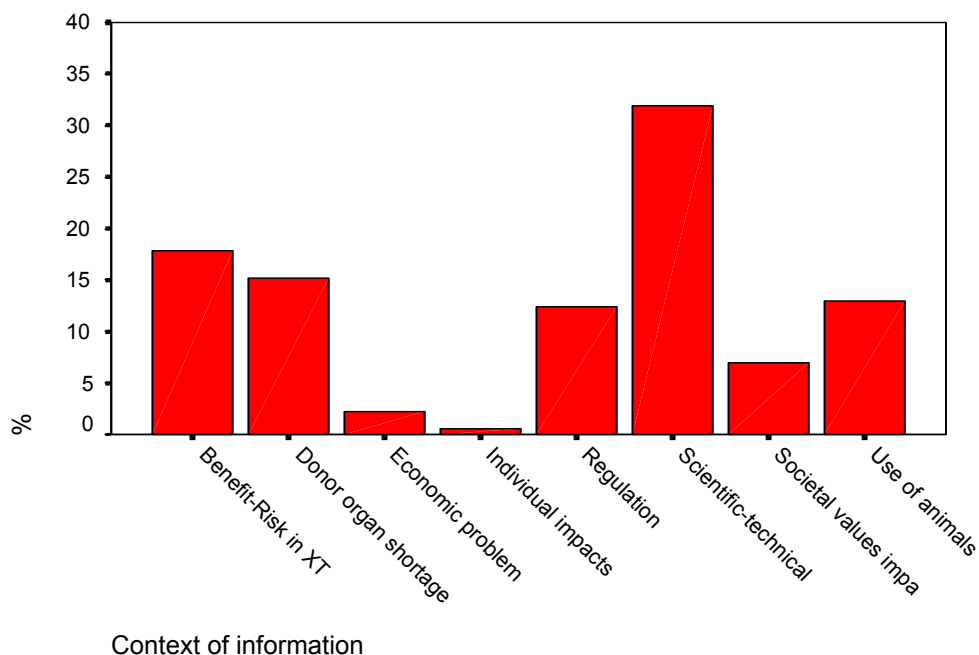
1.3.6. Information context

The guidebook indicated several categories to classify the variable called "Framing the problem", which means the context in which the information is framed. We have noted that the categories proposed are too complex for the Spanish case.

Four contexts, which are: "Scientific-technical feasibility", "Benefit-Risk", "Donor organ shortage", "Use of animals" and "Regulation" represent the 90% of documents. For further details, see the table and graphic below.

Context of information

| | Freq | % |
|----------------------------------|------|-------|
| Benefit-Risk in XT | 33 | 17,8 |
| Donor organ shortage | 28 | 15,1 |
| Economic problem | 4 | 2,2 |
| Individual impacts | 1 | ,5 |
| Regulation | 23 | 12,4 |
| Scientific-technical feasibility | 59 | 31,9 |
| Societal values impacts | 13 | 7,0 |
| Use of animals | 24 | 13,0 |
| Total | 185 | 100,0 |



Scientific and technical aspects of xenotransplantation overpasses largely the other contexts. Within this context, the genetically modified animals and the present state of xenotransplantation are the two most relevant subjects presented.

Benefit *versus* risk comes in second position with 17.8% of total. In this case, the most relevant subjects are infection risk caused by PERV and risk of pandemics.

Xenotransplantation as a solution to organ shortage is dealt with in 15.1% of the documents. These articles expound coments about this worrying situation in different countries. Alternative options to solve lack of organs, apart from xenotransplantation, like artificial organs or the use of stem cells to make organs in laboratories, are presented.

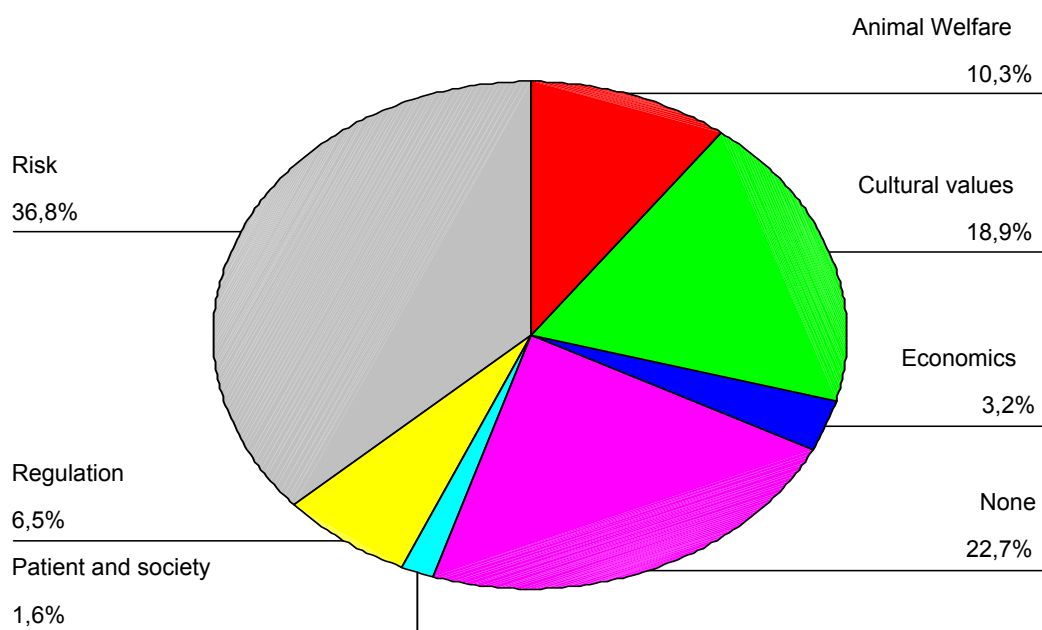
Regulation context is the fourth issue,12.4%. Regulatory initiatives are the most common subject presented with reference to the European moratorium and British legislation.

1.3.7. Ethical aspects

The guidebook proposed nine groups of ethical aspects, with several categories in each group, but we decided to simplify this complex scheme. On the basis of the initial assumption that ethical aspects in xenotransplantation are not relevant in Spain. So we have chosen only seven categories. One of them is "None", because there are many documents which do not raise any ethical aspect.

Ethical aspects

| | Freq | % |
|----------------------------|------|-------|
| Animal Welfare | 19 | 10,3 |
| Cultural values | 35 | 18,9 |
| Economics | 6 | 3,2 |
| None | 42 | 22,7 |
| Patient and society rights | 3 | 1,6 |
| Regulation | 12 | 6,5 |
| Risk | 68 | 36,8 |
| Total | 185 | 100,0 |



As illustrated, 22.7% of the documents do not raise any ethical aspect, making sense to our assumption. It is also true that most documents, 77.3%, unfold ethical discussions, but as it will be seen later, the extension of each document addressed to the discussion of ethical aspects is very low.

Most relevant ethical aspect concerns to infection risk, 36.8%. This risk may affect public health and cause pandemics and has led to a stop in xenotransplantation research, because these types of risks are not yet known.

Societal values, 18.9%, are at stake as the second most relevant ethical aspect. Mainly, the documents falling within this context deal with the natural barriers between species which could be broken. The great part of the ethical aspects addressed in the guidebook do not appear in the Spanish documents.

A 10.3% of the documents raise ethical issues concerning animal welfare. The main questions are: should animals be used for any kind of research? Should we sacrifice lots of animals to get doubtful findings? The documents state mostly several opinions against the use of primates as organ

source, because of the genetic proximity to human beings. In any case, it appears that the debate related to animal welfare presents a low profile in Spain.

1.3.8. Sources

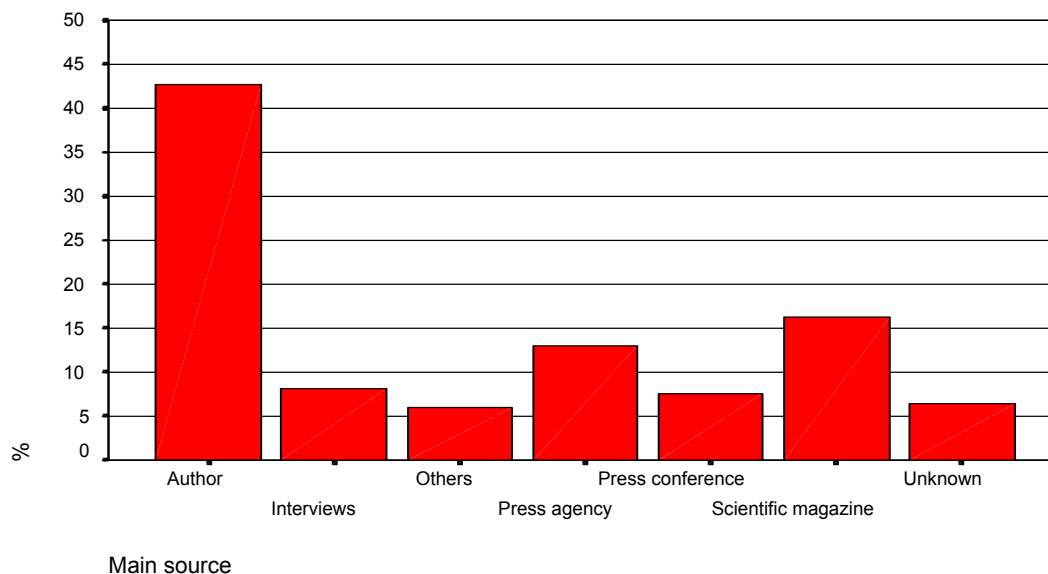
A method to assess the quality of the news published looks to the sources of the articles. The recourse to press agencies is an indicator of a limited interest and capabilities for producing news in a given field whereas the publication of articles by specialized journalists provides an indicator of the relevance of the topic for the publication. Insomuch, xenotransplantation is a highly specialized subject, in the realm of biotechnology and biomedical applications, one would not expect to find many specialists in the newspapers.

Nevertheless, an important part of the documents (42.7%) are authors documents, i.e., those documents which are signed and that do not refer to any other author. These documents should originate in the newspaper office, though it is very likely that the information is not self-produced but has its origin in scientific journals. As a matter of fact, almost one fifth of the documents (16.2%) refer to a scientific publication, though the relationship between the newspaper and the scientific journal is not clear.

Amazingly, only 13% of the documents had their origins in notices of the press agencies. This leads to a puzzling situation: a subject apparently lacking interest for the media, is being dealt with a specialized information and professionals.

Main source

| | Freq | % |
|---------------------|------|-------|
| Author | 79 | 42,7 |
| Interviews | 15 | 8,1 |
| Others | 11 | 5,9 |
| Press agency | 24 | 13,0 |
| Press conference | 14 | 7,6 |
| Scientific magazine | 30 | 16,2 |
| Unknown | 12 | 6,5 |
| Total | 185 | 100,0 |



1.3.9. Main and secondary actors

Scientists are classified in two groups. One refers to the scientists who work in public institutions ("individual scientists"). The second group ("industrial scientists") concerns those who are working for companies or private institutions (foundations).

We used two variables: "main actor" and "secondary actor", though 66.5% of total documents only quote one author.

"Individual scientists" emerge as the most frequent actors (44.3%) followed by "industrial scientists" (26.5%). Some of the scientists are referring to the work carried out by different institutions and organizations by citing work from PPL Therapeutics, Imutran, University of Cambridge, Roslin Institute, Spanish Transplant Commission, Hospital Juan Canalejo from A Coruña (Northwest of Spain, region of Galicia).

To explore the relationship between actors and place of origin, we have crossed two variables, "main actor" and "location of document". When the information arises in USA or the United Kingdom, an important part of scientists involved, around a half, are "industrial scientists". In the case of Spain, "individual scientists" are more frequently involved than those working in private companies or institutions. This result is an indicator of the small involvement of industry or private research on xenotransplantation in Spain.

Politicians are the third group involved as "main actors" (15.1% of the cases). They often appear in the documents related to regulatory initiatives, such as in the case of the European moratorium or in the frequent references to the British legislation.

The worrying absence of non governmental organizations, NGO, in the documents is worth noting. These institutions appear always as "Secondary actor", and only in 3 documents. NGOs cited are animal welfare defender, taking positions against the use of animals in research and as organ

sources. But the problem is that, in Spain, these organizations are considered of limited relevance for the public debate.

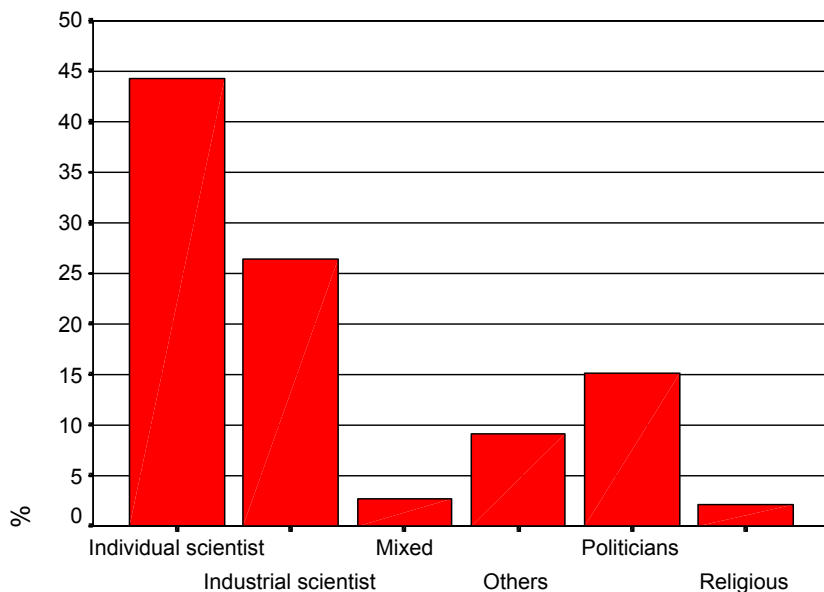
Xenotransplantation research demands the sacrifice of animals, pigs and primates. It could be thought that animal welfare defenders must take part seriously in public debate. But in the analysis content shows that animal rights are not mentioned or considered in any case. Nevertheless, we think that it is relevant and essential to include animal rights defenders in this project.

Main actor

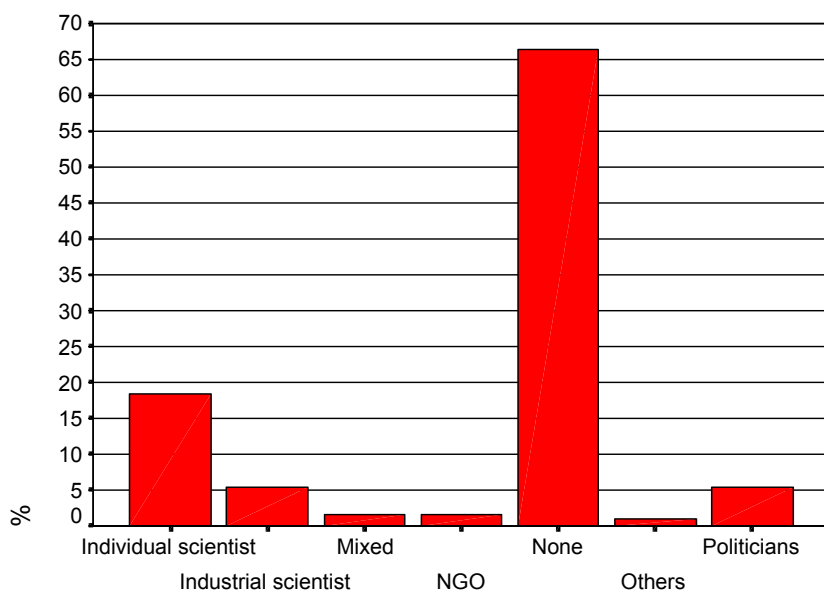
| | Freq | % |
|-----------------------|------|-------|
| Individual scientists | 82 | 44,3 |
| Industrial scientists | 49 | 26,5 |
| Mixed | 5 | 2,7 |
| Others | 17 | 9,2 |
| Politicians | 28 | 15,1 |
| Religious | 4 | 2,2 |
| Total | 185 | 100,0 |

Secondary actor

| | Freq | % |
|-----------------------|------|-------|
| Individual scientists | 34 | 18,4 |
| Industrial scientists | 10 | 5,4 |
| Mixed | 3 | 1,6 |
| NGO | 3 | 1,6 |
| None | 123 | 66,5 |
| Others | 2 | 1,1 |
| Politicians | 10 | 5,4 |
| Total | 185 | 100,0 |



Main actor



Secondary actor

1.3.10. Place of information origin

Three countries, USA, Spain and the United Kingdom, are monopolizing the information on xenotransplantation published in Spain. USA and Spain both share a low third of it with 31.4% and 30.8% of the documents, respectively. On the other hand, the United Kingdom was at the origin of one fifth (20%) of documents.

In the case of the United States, most of the information shows relation to the scientific research carried on there. This is, for instance, the case of Jeff Getty, an AIDS patient who was transplanted bone marrow from a mandrill. This experiment received great attention from the media. Another experiment that was profusely disseminated referred to the implant of cells from a pig brain to

persons affected by Parkinson disease. Another aspect that deserved great attention in the documents from USA concerned the mergers and economic alliances between firms to achieve the obtention of transgenic pigs.

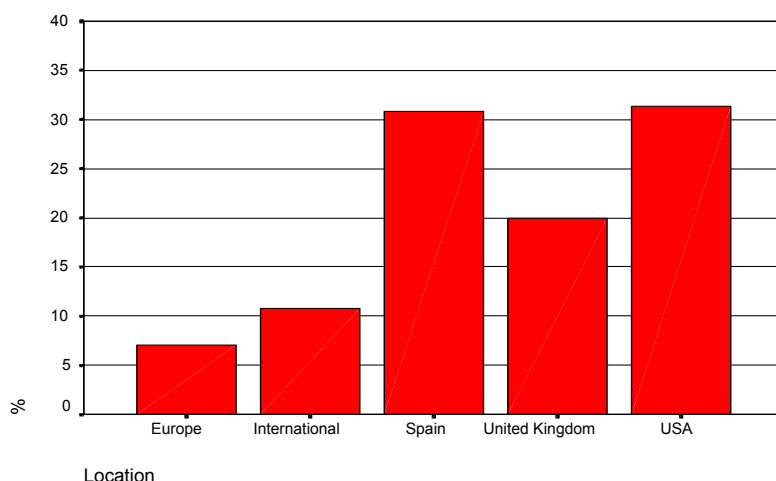
In Spain, the references to scientific achievements were lower, except for the developments attained by the team of Rafael Mañez (Hospital Juan Canalejo, referred above) who has been able to transplant hearts from transgenic pigs to primates. Another issue to which was paid attention by several articles concerns the opposition of Spain to accept the moratorium proposed by the Council of Europe.

The documents coming from the United Kingdom expanded the notice of the cloning of Dolly, the sheep, to its possible application to xenotransplantation. Animal cloning affords the obtention of animals with good potentiality for xenotransplants. As a matter of fact, the firm Imutran in collaboration with Cambridge University had been leading research aiming to obtain transgenic pigs for avoiding the hyperacute rejection.

The remaining documents, a scarce 20%, show a scattered geographic distribution in their places of origin.

Location

| | Freq | % |
|----------------|------|-------|
| Europe | 13 | 7,0 |
| International | 20 | 10,8 |
| Spain | 57 | 30,8 |
| United Kingdom | 37 | 20,0 |
| USA | 58 | 31,4 |
| Total | 185 | 100,0 |



1.3.11. Scientific, socio-political, ethical and economic contents of the documents

The approach to the qualitative measurement of the extension devoted to each one of these topics in the documents analysed relied in the subjective appraisal of such extension after careful reading each document. A given document may contain, for instance, 50% of scientific issues and

50% of economic aspects. The value 100 represents the whole of the scale and 0 accounts for the absence of reference to any topic.

As the data in the table below show, there is a great representation of the scientific aspects (40% of the 100 value). However, only very few documents pay special attention to the socio-political (2%), ethical (2%) and economic (1%) issues. These results are confirmed by looking to the lowest attention value (58% of documents with 0 scale concerning socio-political aspects, 82% for ethical aspects, 81% for economic aspects).

This qualitative approach leads to a clear-cut conclusion. The debate on the xenotransplantation issue in the Spanish press has concentrated on scientific issues or on a blend of all the issues, paying however very low attention to an in-depth discussion of the socio-political, ethical or economic aspects.

Topic extension

| | Science % | | Political-social % | | Ethical % | | Economics % | |
|-------|-----------|------|--------------------|------|-----------|------|-------------|------|
| | Freq | % | Freq | % | Freq | % | Freq | % |
| 0 | 12 | 6% | 107 | 58% | 152 | 82% | 149 | 81% |
| 25 | 22 | 12% | 43 | 23% | 21 | 11% | 31 | 17% |
| 50 | 37 | 20% | 24 | 13% | 4 | 2% | 4 | 2% |
| 75 | 40 | 22% | 7 | 4% | 4 | 2% | 0 | 0% |
| 100 | 74 | 40% | 4 | 2% | 4 | 2% | 1 | 1% |
| Total | 185 | 100% | 185 | 100% | 185 | 100% | 185 | 100% |

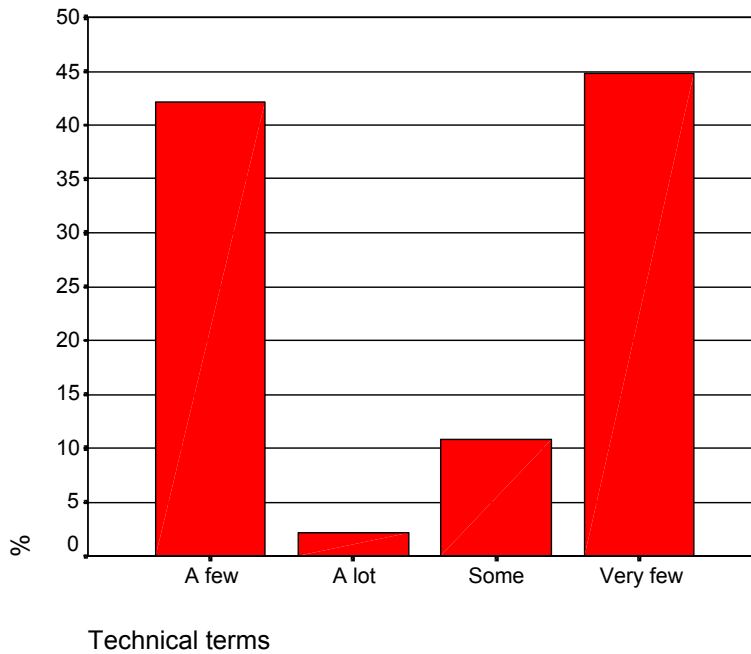
1.3.12. Use of scientific (technical) terms

Though the scientific aspects did obtain the greater representation in the documents analysed, the analysis on the use of scientific terms reveals a puzzling and interesting situation. The great majority of the documents (87.1%) are using few or very few scientific terms. This indicates that the newspapers and their journalists have achieved great results in the efforts of dissemination, thus facilitating the understanding of the readers. The use of specialized scientific terms may difficult the understanding even for persons with medium or high cultural levels.

The positive result with respect to cultural dissemination has to be matched with a proper use of the language in order to avoid the employment of too poor terminology what would run against the quality of the information.

Technical terms

| | Freq | % |
|----------|------|-------|
| A few | 78 | 42,2 |
| A lot | 4 | 2,2 |
| Some | 20 | 10,8 |
| Very few | 83 | 44,9 |
| Total | 185 | 100,0 |



1.3.13. Attitudes towards xenotransplantation

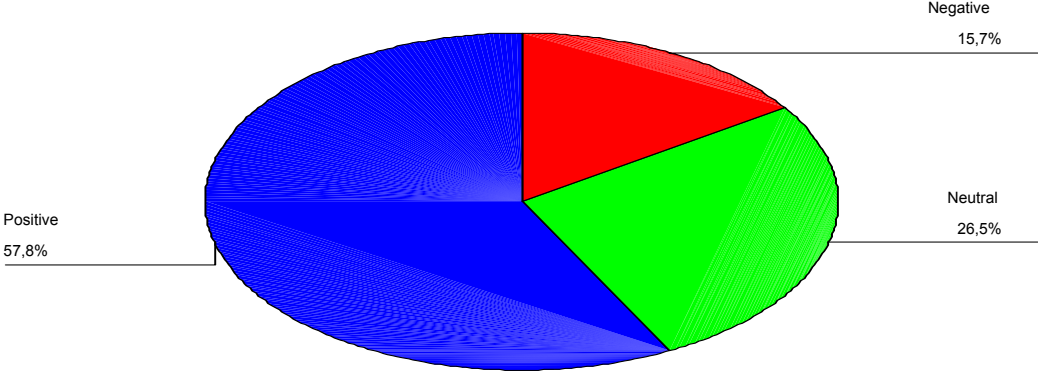
The first part of the baseline analysis has to see which are the attitudes of the Spanish printed media towards transplantation of animal organs. We have assessed these attitudes by exploring the position of the articles with regard to benefits (solution to organ shortage, improvement in quality of life) as compared to risks (high risks for public health, rejection, abuse on animals).

As the results recorded in the table and figure below show, the positive attitudes towards xenotransplantation predominate (57.8%) over the negative ones (15.7%).

This is a very important factor in order to shape the public opinion and its influence on the development of research and application of xenotransplantation in Spain.

Attitude

| | Freq | % |
|----------|------|-------|
| Negative | 29 | 15,7 |
| Neutral | 49 | 26,5 |
| Positive | 107 | 57,8 |
| Total | 185 | 100,0 |



2. Analysis of literature and regulations related to xenotransplantation

2.1. "Recommendations for the regulation of xenotransplantation activities in Spain" (Extracted from the report of the Xenotransplantation Subcommission of the National Transplant Commission)¹²

This document was published in 1999 and is the summary of the recommendations gathered in a work group composed by representatives of Public Administration and experts in: transplants, virology, immunology, public health, bioethics. This paper is considered as the most relevant document in order to understand all fields related to xenotransplantation in Spain. Its content is:

- Current problems
- Non-immunological aspects
- Viral infections
- Non-viral infections
- Legal aspects in the national and international realms
- Ethical and psychosocial aspects
- Conclusions
- Recommendations of the Subcommittee on xenotransplants for the regulation of these activities in Spain

2.2. Literature

- Alonso, A., (2000), "Experiencias de un trasplantado, memorias de trasplantes", Madrid, Ayuntamiento de Madrid y Caja Madrid.
- Arias, M., Gómez Fleitas, M., Francisco, A. L. M., (1996), "Xenotrasplante", Barcelona, Editorial Sandoz.
- Díaz Benito, V. M., (2001), Thesis "El sector de la biotecnología en España: su estudio a través del concepto de "Sistema de innovación"", Madrid, Facultad de Ciencias Políticas y Sociología, Universidad Complutense de Madrid.
- Romeo-Casabona, C., et al., (2002), "Xenotrasplante: aspectos científicos, éticos y jurídicos", Granada, Editorial Comares.
- Sociedad Española de Biotecnología, (2002), "Biotecnología y salud, preguntas y respuestas", Madrid, Edita Sociedad Española de Biotecnología.

2.3. Regulations

- Law 14/1986, 25th April, Ley General de Sanidad.
- Law 30/1979, 27th October, Organ Transplantation.
- Royal Decree 426/1980, 22th February, Organ Transplantation.
- Royal Decree 411/1996, 1st March, Human Tissues.
- Law 15/1994, 3rd June, Genetical Manipulation.
- Royal Decree 951/1997, 20th June, Genetical Manipulation.
- Law 35/1988, 22th November, Assisted Reproduction Techniques.
- Law 42/1988, 28th December, Embryo and Foetus Donation.
- Article 159 Penal Law, Genetical Manipulation.

¹² See "Xenotrasplante", Subcomisión de xenotrasplante de la Comisión Permanente de Trasplantes del Consejo Interterritorial del Sistema Nacional de Salud, Organización Nacional de Trasplantes, Ministerio de Sanidad y Consumo, 1999, Madrid.

3. Secondary analysis of data-opinion polls on attitudes towards Xenotransplantation

Only two surveys related to xenotransplantation or linked subjects have been carried out in Spain. One of them had been developed by the Centro de Investigaciones Sociológicas (Sociological Research Centre), adscribed to the Ministerio de la Presidencia (Ministry of Presidency) and it took place all over the country during 1996. The second one is an Eurobarometer (European Comission, Directorate General XII, Science, Research and Development) carried out all over the 15 state members during 1996. Comments and conclusions raised by these two opinion polls about xenotransplantation are summarized in the following paragraphs.

The CIS survey¹³ was carried out in Spain considering population between 16 and 64 years old as the universe and choosing a sample of 2730 people. The total valid answers were 2552, obtained from 20th April to 20th May 1996.

There are no specific questions refered to xenotransplantation but if it possible to find some related issues, like human transplantation and genetic modified animals.

One question deals with the improvements achieved in our quality of life due to some relevant scientific developments: computers, genetic engineering, space exploration, biotechnology, solar energy, telecommunications, *in vitro* fertilization, nuclear energy and transplantation.

The 97% of people interviewed thought that transplantation has contributed to improve life quality. This medical issue obtained the highest level of positive attitude compared to the others developments exposed above and this figure confirms the traditional positive opinion of Spaniards towards transplantation.

This high acceptance could be due to the successful work of the Spanish transplantation organization since 15 years ago, because its efficiency is well perceived in the Spanish society. Another cause could be the enormous solidarity showed in our country, which has the highest donation rate all over the world.

Another question asked people about their wishes of improvement and development in the same issues cited before, this is, in which issues people do expect for much more research and innovation. 81% of the people want more successful research in all aspects related to transplantation, though xenotransplantation was not suggested in the interview. In spite of the absence of this specific mention, it is likely to suppose that only a few people are against this technique.

Opinion towards genetic engineering to modify different types of living organisms is also asked. The organisms concerned were: plants, bacteria, animal cells, human cells, human embryos.

¹³ "La imagen social de las nuevas tecnologías biológicas en España" (Social perceptions of new biological technologies in Spain), Atienza, Julián and Luján, José Luis. Survey No. 2213, 1996, CIS, Madrid. www.cis.es.

Genetic engineering applied to animal cells could be the link with xenotransplantation. As it was commented in this report, genetic modified pigs to reduce rejection is one of the main issues.

36.5% of people expressed a positive attitude towards this technology, though there are more people who rejected it, 44.1%. It should be noted that 18% of people choose the "Do not know" option in this question. This could be a good indicator about the high lack of knowledge in this field. It is time to think about the reliability of a survey in which almost a fifth part of interviewed people do not know anything about the issue asked.

There are different attitudes if we take into account the educational level. The 50% of people with University degrees show a positive attitude towards genetic modification. On the other hand, only 30% of people with a low educational level express positively about modified animals. It can be found similar differences if we take into account social classes. People classified as high or medium-high class are more receptive towards genetic modified animals than those of the worker class.

The Eurobarometer¹⁴ was carried out from 18th October to 22th November 1996, in the 15 countries of EU. The universe was people older than 15 years old and the sample amounted to 16246 individuals.

There is a chapter called "Attitudes to different applications of biotechnology and genetic engineering" where questions about animal organs for transplantation are asked. The chapter considers various issues related to modern biotechnology: which types of research benefit society, which are morally acceptable, which should be encouraged; which types of research could involve risks for society; Europeans thoughts about regulating modern biotechnology in order to avoid risks; which authorities are best placed to regulate biotechnology.

69% of Spaniards interviewed thought that genetic modified pigs, which could be used as an organ source, was a beneficial development for human beings. The acceptance is higher than European average, 54%. It is also true that 15% of Spaniards do not know which are the benefits of this new technology, what we assume as worrying situation, because the average in European countries is lower, 10%.

The 53% of Spanish sample think that xenotransplantation involves serious risks to public health. Near a fifth part of people interviewed are unaware of that risks. Maybe this lack of information explains why Spaniards notice less risks than the rest of Europeans.

The 47% of Spaniards think that the use of animals for transplantation is morally acceptable. There is a big difference at this point with European average, 36%. The knowledge in our country is lower than the average, because near 20% of Spanish people answer "Do not know".

More than a half of Spaniards, 53%, think that research in xenotransplantation should be encouraged but Europeans seem less interested in this issue, because they support the same opinion in the 36% of cases.

¹⁴ Eurobarometer 46.1, European Commission, Directorate General XII, Science, Research and Development. www.europa.eu.int.

We are able to point out some conclusions from this Eurobarometer. Spaniards seem more receptive towards the use of animal organs for transplantation and they perceive less risks for public health. But must be said that knowledge about biotechnology, generally speaking, is much lower in Spain than the European average. The results of an opinion poll in which interviewed people do not know much about the issue concerned, must be looked with caution.

4. Summary of experts interviews

The interviews to experts aimed attainment of the following objectives as adopted by the common guidelines:

- To analyze the current discourse in Spain on XTP
- To identify factors which might influence the debate of the current discourse in Spain
- To identify actors for the Neo Socratic Dialogue and to analyze their position towards XTP

4.1. *Some hits on the methodology*

The guide adopted considered the convenience of interviewing individuals from different fields of activity, such as representatives of firms with relevant participation in research, members of organizations in favour of animal rights, patients associations, organizations responsible for transplant coordination at different levels (national, regional, local), professional associations (medical doctors in transplant specialities), representatives of religious groups, members of commission on bioethics, officials from ministries and other organs of Administration, researchers, famous people in social terms, journalists, nurses, politicians, insurances companies.

As it has been done in other parts of the work, the specific situation of Spain demanded adaptations from the common frame. As it has been shown from the press analysis, the debate on xenotransplantation issues in Spain presents a low profile. Some of the collective mentioned do not hold any position or perform any activity in relation to xenotransplants. Consequently, they have been discarded as potential interviewees.

Interviews have been carried out either in person where this has been possible or by electronic mail in some cases where it has been impossible to match the agendas of the interviewees with that of the project. It is also worth to recall that this matching was made more difficult because some of the interviewees do work and live outside Madrid.

The personal interviews have been recorded, though a complete transcription of the tapes was not seemed necessary¹⁵ as we considered our task to translate the most important messages and reflection for each one of the experts.

The e-mail interviews responded to a structured questionnaire, while the personal ones were carried out according to a semi-structured version.

There are pros and cons in both systems. The semi-structured way allows to get richer information (as new issues can arise along the interviewing process) but it makes less easy to establish comparisons.

The surveys included some questions of broad character concerning biotechnology: financial and social support, state of the dissemination on the technology and its influence of public opinion.

¹⁵ The tapes are kept as support documents

With respect to xenotransplants, the surveys pointed out the issues related to social-political impact: economic aspects, ethical issues and technical aspects linked to safety and risk.

The information gathered is organized in the following way:

- a) A section of the responses related to the general issues and with the consensus reached by all the interviewees.
- b) A second part with the more specific comment of people interviewed with special reference to the topics concerned with xenotransplantation.

4.2. Opinion about general issues on biotechnology

As a previous step to the questions specifically addressed to the experts in relation with xenotransplants, they were asked some broader questions related to the situation of research and media popularisation on biotechnology in Spain.

Almost unanimously, the interviewees consider that funding for R&D activities in general, and for biotechnology in particular, is insufficient. Some of them even argue that this situation is quite critical, leading Spain to remain in the bandwagon of the scientific and technological enterprise.

In some specific, controversial issues, like the research on stem cells, there is a stop to it on the basis of political reasons, besides the traditional economic shortage. Some of the experts qualified this situation as an important regression in view of the great potentialities offered by this type of research.

Only one of the interviewees, who is responsible of the management of funds for the research on biomedical and health problems, stated that in Spain all the project with certified quality and based on sound science receive appropriate funding. The problem for him stems in the absence of research in some fields, a failure that drives to lack of funding in some areas.

The issue of popularisation of science raises a similar worrying consensus. The experts express common opinions on the very poor role played by the public and private institutions (mass media) in the dissemination of research on biotechnology. This low performance is perhaps more evident for the case of public institutions.

The Spanish society is receiving high number of informations which, in many cases, are of sensationalistic nature. This strategy may be aimed to capture audiences. The news on biotechnology, by their same nature, are prone to be dealt in non-precise way either by the lack of knowledge from the transmitter or because the goal to create scaremonging and polemics.

The great majority of the experts interviewed are missing a consistent policy on dissemination of biotechnology. But it is worth to remind that education is a crucial step in order to citizens being able to assimilate information. The educational system emerges for some of the interviewees as the best means to educate people in the scientific topics.

For those being outside the educational "*milieu*" the institutional campaigns are considered as the most promising alternative to increase the degree of education and understanding on the biotechnology.

The same scientists are criticized by our experts by the lack of transparency of their research and for the difficult they have in communicating to the public their activities. It is generally believed that their prestige and trust from the public would increase if scientists were much more involved in the dissemination of biotechnology: its assets and problems, in tight collaboration with the media and the public institutions.

In summary, it can be said that the Spanish experts almost unanimously support the contention that research on biotechnology is underfunded in Spain and undergoes important problem with respect to communication to society. They mostly agree that the first issue is more serious for the healthy state of the Spanish biotechnology. The surveys confirm our starting point: the technological gaps of Spain are still on the news.

4.3. Experts interviews

4.3.1. Patients representatives

The representatives of patients associations express their complaint about the lack of public dissemination of xenotransplants and issues related to biotechnology. The society needs better knowledge of issues related to the use of animal organs before this kind of technique become a reality. If this goal is not achieved, the patient may undergo psychological problems or experience difficulties for integration into the social environment. Another goal should be to try increase the rate of donations by reducing the negative familiar reactions.

It is not seen a clear will from researchers to participate in this endeavour by making understandable thier knowledge progress to the mid-level educated society. The media do not lend too much interest to these issues, paying attention to less important topics. This lack of attention is evident for television, which should be the preferred instrument for a dissemination campaigns taking into account the high audience is able to attract.

They think that the most relevant hurdle to the extended use of xenotransplants relies on the possible infections by zootic viruses which could evolve to pandemics. Until the risks were not enough assessed, the individual benefits have to be sacrificed on behalf of the public health, though these representatives have undergone lots of problems as organ patients for two decades. The patient who having received a xenotransplant should have signed an informed consent and then he/she should accept his/her monitoring to follow the evolution of the medical process.

They express a greater optimism for the research on stem cells. The interviewees regret that research on this issue, an alternative which raises many hopes, is blocked by political and legal matters.

The strategy to foster organ donation by paying fess to the donors or their relatives is considered ethically unacceptable. One of the interviewees is personally favorable to "socialization" of dead bodies, but he knows this practice requires a profound social debate. Apart from this, xenotransplants can not be assimilated to normal treatments with drugs. One of the representatives states: "The rich people should not have more rights for living".

They do not believe that the debate on animal rights should be kept with high relevance. Animals should be used as support for human welfare since the right to health is more important than the animal rights, though is important to avoid unnecessary suffering to them and to provide good conditions for animals living.

4.3.2. Non-governmental organizations representatives

Members of non-governmental organizations, NGOs, were also interviewed. All of them are active defenders of animal rights, and they express similar opinions about xenotransplants.

All of them hold the opinion that dissemination of biotechnology in Spain is poor and biased, on which the politicians and decision makers are conveying the society with a limited number of

options. With regard to xenotransplants, the inputs to society have focused on the benefits and needs, accompanied by a strategy of intentional hiding of the potential problems, such as eventual pandemics and animal suffering.

The life conditions to which pigs or babouins are subjected seem far from normality. This is particularly shocking for the babouins which are able to foresee their future. They are living in laboratories under conditions very distinct from those they will carry on in their natural habitat. The interviewees also feel unacceptable to make distinctions between species like it occurs with pigs and primates in the case of xenotransplants.

One of the interviewees makes a strong statement: "The human beings born with strong mental deficiencies may not have a privileged moral status as compared to an animal having greater cognitive capacities". The main question is why the animals are not considered as "subjects of law".

Someone raises the possibility that mentally retarded children, those unable to experience suffering or being in a vegetative state could be donors of organs. It is interesting for him to launch this idea through public debate, though public opinion would react against it immediately.

Another idea suggested is the socialization of the organs from corpses, becoming a kind of social good, because they should aimed to help to save lives and improve the quality of life citizenship. This idea is worthy of being submitted to social debate. It should count on social opposition very likely at the onset, but it could be accepted if presented through good strategic communication plans providing solid arguments to ground it.

Another option to prevent the sacrifice of animals in relation to transplantation could be the establishment of an organ purchasing-selling system. A way to foster the donations of organs may rely in the paying to those individuals donating their organs while they are alive or to the heirs when death did occur. In order to avoid discrimination by the purchasing power, the economic incentives to donations should be taken into charge by the public health system.

All of them consider that research on stem cells to regenerate failing organs emerges as an interesting possibility, but this kind of research is blocked by extra-scientific reasons. Apart from that, the costs, the risk for public health and animal suffering derived from research on xenotransplants are clearly surpassing the benefits that may result from their use.

4.3.3. Bioethicists

The group of bioethicists is the largest one, but it has expressed very similar opinions. The main issues emerged during the interviews dealt with risk for public health, alternatives to solve organ shortage and animals rights. A summary of the main ideas expressed is given.

All of them consider that the main technical problem of xenotransplants relates to the eventual transmission of diseases, yet unknown, to humans. The great priority stems in the protection of the public health from the possible risks of infection, though the transplantation of an animal organ to a patient may represent better expectatives in his/her quality of life. The collective good must take precedence on the individual benefit. They all think that there is no enough information on the eventual

risks of diseases transmitted from the donor animals nor they have been sufficiently assessed. For them, this is an absolute prerequisite for introduction of xenotransplants into practical medicine.

The bioethicists interviewed strongly argue against the acceptability of xenotransplants by the Spanish citizens unless there were a campaign to inform properly about the solutions they may offer, the risks that may be faced and their limits. In any case, they think it is extremely difficult to foresee the reaction of society before this new technique and how much will it depend on individual positions. In the case of a patient being under very severe health conditions, it is likely that he will be highly agreeable to find the possible unique solution. One person emphasizes: "It is difficult to know how population would react on the implantation of xenotransplants, so difficult as to know which are the reactions when facing disease".

The most part of this collective do not think that the continuous monitoring of a patient would injure his/her individual freedom. The organ receptor should be averted of the conditions which, if accepted, must be fulfilled. The monitoring of the private life of the individual is one of the costs to be paid for the improvement in quality of life.

The group of bioethicists supports the use of animals for research and as source of organs, provided that all international conventions and legislation available are respected. While all of them recognize the need to avoid animals suffering and any practice of cruelty with them, they have a clear idea that animals are for helping Humanity through scientific research. They consider that the debate on the use of animals is tainted by unreconcilable positions as they are part of the intimate nature of each individual, of their convictions and values, to whom it is extremely difficult to renounce.

Everybody expresses a strong opposition to the idea of paying through the public health system to donors. An expert is more emphatic: "No part of the human body can be a commodity, subjected to commercial practices"¹⁶. The experts also gave a negative opinion on the proposal to "socialize" organs of dead bodies which will become a social good. One of them argues: "The appropriation of the human body is unacceptable. It runs against the Principle of Autonomy, whose application emerges as one of the great conquests of Humanity".

Research on xenotransplants should be fostered but without forgetting other options which may offer more promising possibilities, like research on stem cells, which is seen as the most attractive alternative. The use of embryonic stem cells should not pose an ethical problem, since this is a part of scientific progress which always represents a transgression to conventional modes of thinking. Speaking about fundings, resources distribution has to be based on sound studies aiming to establish which option holds greater probabilities to succeed.

4.3.4. Journalists

The journalists interviewed who work for the daily newspapers, consider that the main hurdle to develop xenotransplants are the risks for public health, which are not well known yet. Scientists should

¹⁶ See Bioethics Declaration, Gijón, Spain, 2000. www.sibi.org.

assess the risk as confronted to the benefits. If the risks are well evaluated and are low, priority should be given to the patients rights to improve their life expectancies and quality.

Journalists do not find any ethical problem about the use of animals as an organ source, because animals are used in several kinds of research, helping Humanity to progress.

One of them expressed very negative opinion about the feasibility of xenotransplants at short and medium term. For this reason, this person expressed worry about giving the private sector the only responsibility to fund research in this field. The firms will abandon the R&D efforts if they face difficulties to recover their investments. Public involvement is deemed essential to progress on this matter.

One interviewee suggested the view that Japan, due to the difficulties experienced by human transplantation, could be a good place to develop xenotransplantation. Due to the high donation rate and the excellent transplant organization in Spain, the use of animal organs is deemed the last option in our country.

4.3.5. Medical doctors

The group of medical doctors, some of them working in transplants departments, consider that graft rejection represents the main obstacle to the establishment of xenotransplantation into the clinical practice. They think that the hyperacute rejection problem has been overcome but they see still remaining the acute and chronic ones. They are not very optimistic about the possible solution to these two types of rejection. Moreover, the scaremonging created through the eventual transmission of infections to receptors has risen fears about the use of xenotransplants, scientists have pushed the debate and the firms have reduced or abandoned their research programs on the subject.

They hold opposed ideas about other options apart from xenotransplants to solve organ shortage. One of the interviewees is inclined to provide more support to other alternatives to organs deficit, such as to promote donor increases, split technique, artificial organs and stem cells as source for transplantation. But another medical doctor does not trust other alternatives to allotransplants, such as the eventual production of organs from stem cells. This person still considers this possibility as science-fiction. There are news appearing in the media not having yet scientific toughness and addressed to create confusion in the public opinion by raising unfounded hopes.

Some interviewees were asked about the idea of "socializing" corpses for using their organs considered as public goods to be needed for attaining social welfare. One of them is emphatic: "Any attempt to socialize a body is preposterous". This option is unacceptable in his opinion, as the dead body must be respected as if it were legacy.

They were also asked about the possibility to increase donations by making monetary incentives to the donors, if they are alive, or to relatives or heirs if dealing with dead bodies. These medical doctors do not support it, since the public health system should not to pay to get organs since organ donation has to be based on solidarity.

From a scientific point of view, the main ethical concern regards to the potential risks for public health. One of the experts is very clear in saying that the society rights must prevail over the individual ones. The implantation of the technique should be once the safety has been attained in order to achieve a clinical practice without substantial risks. If the risks are low, there is no reason to establish a strict monitoring of patients, because this practice lacks feasibility. "Xenotransplants are braked off by the risks to public health as the main and sole reason".

The Spanish society should know the progress derived and expected from biotechnology, but also the limitations underlying these technology. Public and private institutions should be actively involved in the dissemination of these issues. Nearly all of the medical doctors think that knowledge of the Spanish society about xenotransplants is rather poor, but they hold the opinion that the society would accept this technique as an alternative to correct the organ shortage.

Assuming that the transplantation with animals organs should be so successful and efficient like allotransplantation, one interviewee makes a provocative statement: "To reserve human organs for the younger patients".

The debate on animal rights in Spain is very limited and it should not be the cause of major social problems. Animals are in fact applied to other less praiseworthy human benefits like food and dressing. It is generally accepted, however, that there is a need to make distinctions between primates, leave aside the superior ones.

These doctors do not feel uncomfortable with the restrictions of individual freedom imposed to a patient that should have received a pig organ. They think that the limitation is rather soft and not so much different from that of other patients who are also subjected to restrictive practices like those suffering from AIDS. In both cases, patients suffer from certain drawbacks in their behavioural liberty but they are a tribute for the sake of public health preservation.

4.3.6. Representatives from Public Administrations

The most extended opinion within this group is that political ideologies, inside the EU, do not influence attitudes and decisions on xenotransplants. The scientific issues must overpass political and religious beliefs in order to avoid the problems risen by the case of stem cells, whose research is blocked in Spain. Social welfare and humankind progress should be at the forefront. Two of the representatives of Public Administrations can understand the precautionary position adopted by the European Council but it is against to ban research as it was underlying to 1999 moratorium, but one of them does not agree with this argument.

One of the interviewees think that funding for xenotransplantation rests essentially on support from private firms. If organs were obtained from transgenic pigs, they could be bought as other market drugs. The present system based on solidarity should decline or even disappear. There is a need to pursue the goal that the eventual new treatments with animal organs integrate into the public health system.

The same person think that the firms are searching benefits not only from the production of transgenic pigs but also from the post-intervention treatment with immunosuppressing, specific drugs. This strategy would ensure that investments can be recoverd in a continuous manner and not only by selling the transgenic animals.

In opinion of one representative, who is also a medical doctor, a good alternative to allotransplantation may result by combining xenotransplants with stem cells from the own patient. This would allow to develop organs genetically modified that should avoid rejection. Pigs should be used for these purposes as the obtention of human clones is morally unacceptable, leading to the production of specific organs for each individual. Thus, there should be a convergence among the research on xenotransplantation and stem cells.

We heard an opinion about the way to increase donation in those countries where it is still very low, like most part of EU. It is possible to increase the number of donations, a critical step to reduce the waiting lists. A country similar to Spain with the same level of development or with higher level, can achieve similar rates of organ donations. The establishment of a well structured organization is an important factor for success, but most important is that professionals keep proximity to the deceased. An appropriated and oportune action explaining to the relatives the social benefits of donation may develop positive responses. This way of doing appears to be much more effective to reduce negative familiar attitudes that any massive campaign of information to the public.

On the grounds of the experience of one person interviewed in the fields of nephrology and transplantation, we asked about the opinion on the extent of a xenotransplants: should they be a bridge or a definitive organ? Taking into account the very delicate situation of the patients, this doctor advocates for using them as a definitive solution. Patients should have difficulties to undergo two chirurgical interventions. If doctors do not think that xenotransplants are definitive solution, they should avoid to carry out the intervention.

4.3.8. Researchers

At present, the main research carried out in Spain is searching the overcoming of the graft rejection problems following the hyper-acute phase. Researchers are employing immunosupressors by implanting heart pigs in babouins, using the installations and infraestructure of the Hospital Juan Canalejo, in A Coruña (the northwest coast of Spain). The interest on xenotransplantation is declining and consequently, the economic resources are lowering. The situations appears as such in the European Union where there seems to exist reluctance to fund research projects on the topic, following the guidelines of the European 1999 moratorium.

The costs of xenotransplants must not be higher than those of allotransplants. The cost of the production of the animal organ should not be high, even it should be possible to reduce expenses related to manipulation and conservation -reduction of transfer charges-, though the follow-up of the patients once receiving the transplants should be supplied through the public health system.

Xenotransplants may offer great advantages to patients. The most important one is to eliminate the increasing percentages of patients dying before receiving the organ. Another advantage

may refer to the less deteriorating effect on the patients because the reduction in the time that elapses between need for intervention and its accomplishment.

In opinion of the researchers, public opinion in Spain does not hold enough information and arguments on the use of animal organs. Even worst, it is receiving information marked by bias and sensationalism (hyperbolic and scaremonging). Some news are very optimistic, others are criticizing the research. In summary, these news are promoted by vested interest groups, ones aiming to promote the technique, others to stop it, but both not relying on sound scientific grounds. The main problem underlying popularisation of science in Spain concerns the low educational capacities to assess the information by each individual: "In Spain, to be critical is looked unsympathetically".

Speaking about the controversial issue of using animals for research, the experts interviewed say that the pigs and babouins used in the experimental work are being treated with delicacy, much better than the treatments received by pigs in food production. Both species are living under conditions quite different from their natural habitats, but this is a requisite to prevent them from infections. Researchers are complying with all norms and conventions existing on animal uses for experimentation.

The positions of some animal rights defenders are out of proportion that do not help scientific and humankind progress. The work of researchers has been also the subject of critical views of Spanish environmentalists -see the contents frame analysis of the press-. But the research has not been put into difficulties by the pressure of environmental groups. Something quite different would have occurred if these experiments were carried out in other European countries.

Spanish society would not present strong feelings against the use of xenotransplants. The scientists trust for it on the important work accomplished by the transplantation system in this country, as a consequence of the successful trajectory of ONT (National Organization of Transplant) and the innate solidarity of Spaniards. But before arriving to a clinical implantation, there is need for a serious process of conveying well contrasted information. Research should be communicated with transparency to societies, this is the way scientific progress must reach legitimation in democratic society.

5. Conclusions

5.1. Form of the National XTP-Debate

5.1.1. In which social context is XTP being debated (eg. Government level, interest groups, public media)?

From the information gathered on the two main sources used in the Baseline Evaluation -Analysis of press and interviews to experts- we are inclined to say that the debate on xenotransplantation in Spain has not yet started, or at least it is in an embryonic state. This statement requires some nuances.

The analysis of press contents has revealed a certain concern by the eventual risks that xenotransplants can represent for the public health. However, this worry is not reflected into a true social debate, the press has simply introduced this issue along the information as to present one of the main hurdles to overcome the use of animal organs. On the other hand, the scarce number of opinion articles is an indicator of the poor interest of the media on this issue.

The interviews with the experts show a similar result. With the exception of those interviewees linked to the defence of animal rights, all the other express serious doubts about the raising of social debates on the xenotransplantation issue. They are paying attention to technical problems rather than to ethical ones in relation to the possible implantation of this technique into the clinical practice. The experts more directly involved in the protection of animal rights recognize the absence of a debate in Spain on the use of animals for experimental research but express their wishes to foster it.

The opinion surveys -study carried out by the "Centro de Investigaciones Sociológicas" and the Eurobarometer 46.1- do show a majority of the Spanish society to support the research on xenotransplants and do not offer great opposition to the possibility of using animal organs. The absence of confronted positions in the surveys is another indicator that, at this stage, there are not major controversies nor consequently a social environment to debate this issue.

5.1.2. In which form (procedure) is XTP being debated (not institutionalised/ already established institutions/ newly established institutions)?

There is no social debate on xenotransplants in Spain. Therefore, it is very difficult to think on procedures about it. The only initiative to deal with the issue if xenotransplants was taken by the Subcommittee on Xenotransplants of the Permanent Commission of Transplants of the Interegional Council of the National Health System, but this initiative aimed to approach the establishment procedures to perform research, with emphasis on the technical aspects of the issue.

5.1.3. Which competencies and methodologies did national and local committees use to evaluate the ethical impact of XTP?

There is no specific committee to deal with specific ethical problems related to xenotransplants.

On the 11th of April 2002, a National Committee on Ethics for Science and Technology, CEST, was established. It is an interdisciplinary committee composed by twelve experts whose tasks are to make recommendations on the ethical sides of the research undertaken in Spain. One of the fields where its intervention is soon expected concerns the research on stem cells. It can be assumed that this Committee should be worked in the debate on xenotransplantation if the possibility of using animal organs as donors were gaining ground. It should be mentioned that some interviewees have expressed criticisms on the composition of this Committee on the basis of certain religious biases of some of its members as they believe this might influence the opinions in some critical themes as the case of stem cells.

5.1.4. How do actors think that ethical issues of new technologies can/should be debated in public?

The recommendations on how to establish and develop mechanisms to debate the new technologies, and, in particular, the case of xenotransplants are embodied essentially in the opinion expressed by the experts. The analysis of the press contents does not throw any light on this point.

Some interviewees pointed out that the ethical aspects should be dealt in the information conveyed to the public on biotechnology as well as the technical questions on the technology are presented. News and informations on these ethical aspects of a possible technical developments in the clinical practice are missing. The situation is exactly the opposite for the case of stem cells where the ethical implications are being the most frequently discussed and, in opinion of some of the experts, responsables for stopping the research on them.

Another way to foster the ethical debates on the use of biological discoveries is to launch multidisciplinary *fora* for debate, a suggestion made by some of the experts interviewed. For the specific case of xenotransplantation, this forum would include clinical experts in transplants, researchers on aspects related to immunology, virology, public health, representatives of patients having received transplants, defenders of animal rights, etc. The opinions arising from these *fora* discussions should be conveyed to Governements who should take the into consideration before approving lines of research or legislating.

The experts also suggested that the mass media should be responsible to fostering the ethical debate on scientific research and technological developments by transmitting information not only on the technical aspects but also on the critical parts of the scientific progress: benefits and drawbacks which they may represent and their ethical implications. As has been said, the ethical debate is out from the media that have been analyzed. This seems to be a consequence of the lack of debate instead of being due to the case of stem cells, which has held strong polemics on the eventual use of embryonic stem cells, the media have reflected the controversy existing between the actors with disparities in the position with respect to that use.

5.2. Content of debate

5.2.1. In which context is XTP primarily being debated (e.g. transplantation, animal rights). How is XTP framed as problem?

The analysis of press contents showed the main contexts under which the xenotransplants are presented: "Scientific-technical feasibility", "Benefit-Risk", "Donor organ shortage", "Use of animals" and "Regulation". These contexts gather about 90% of the articles. In the previous part where the contents analysis is developed, there is wider information on these contexts.

The interviews to experts have thrown a similar result, though the "Use of animals" has had a low representativity: only three interviewees have dealt in with. For the remainders, xenotransplants are seen as an eventual solution to organ shortage, whose main problem rests on the rejection and health risks -not yet assessed- than they may represent for the public health in relation to causing possible pandemics with animal infectious agents.

5.2.2. Which positions do relevant actors take? What are their positions, interests and resources?

The press, one of the most influential media together with television, does not seem to have a defined position on xenotransplants. From the reading of articles, there is no any evident strategy emerging. Most of the documents that were subjected to scrutiny show a positive attitude towards xenotransplants. The issues at stake have been the technical problems inherent to xenotransplantation and its presentation as a possible solution to organ shortage.

The experts with links to biomedical research or clinical medicine are in favour to pursue the research on xenotransplants, though some of them also look positively to going in depth in other alternatives which may have a greater degree of feasibility in their opinion like the stem cells.

Their concerns focus on the technical-ethical aspects, as it is the risk of transmitting disease through pig viruses.

Those actively involved in the defense of animal rights are opposed to xenotransplants by various reasons. First, they consider that animals owe similar rights to their organs than human beings. On the other hand, the animals life conditions are unacceptable when they are grown for experimental research (laboratories offer dissimilar conditions with respect to natural habitats).

The patients recipient of transplants are in support of research on xenotransplants as they are seeing in this alternative technique a solution to their problems, as they are also for other alternatives, like research on stem cells or in artificial organs.

In summary, the Spanish case allows the identification of three collectives: scientists, ecologists (pro-animal rights) and patients who are attending the reception of organs. Each one of them adopts different positions depending on their interests, which are likely difficult to reconcile.

5.2.3. Which ethical questions are raised on the various levels in the XTP debate?

It is pertinent to insist on the low ethical profile on the discussion on the press. One fourth of the articles do not present any ethical aspect. More than one third are taking into account the ethical debate on the eventual risks of xenotransplants for the public health. Cultural values do come in second place but at long distance. It can be clearly stated that the press articles are divided into two positions: either they are not raising any ethical issue or they are referring to the ethical (technical) risks for public health that may result from the general use of xenotransplants.

The interviews confirm these data. Virtually all of them coincided in the concerns on the possible transmission of diseases yet unknown but whose risks, even of producing pandemics, have to be assessed. They believe the assessment has not yet been established, but, in any case, they think the application of xenotransplants should wait while risks are well known and reduced to almost zero level, within the limits of possibilities.

The ethical debate on animal rights has been raised by these interviewees who are experts on this topic. They have asked several interesting questions that may be incorporated into the debate: Why animals do not hold the same rights that of cognitive abilities? Why animals do not hold rights to their organs whereas humans do so?

Along the interviews carried out in person, semi-structured format, some new ideas and topics did emerge which can be incorporated into the ethical debates thus opening new windows for them.

The possibility to nationalize the organs from dead bodies with the goal of "saving lives" or the payment of fees to the donors or relatives from the National Health System are two ideas raised by some of the surveyed experts. These ideas, provocative as they are, may be incorporated into the debate as they may have some usefulness to solve the organ shortage problem.

5.2.4. Which solutions/regulations are being debated or have been taken?

The regulation on xenotransplants available in Spain is collected in the document issued by the Subcommittee on Xenotransplants of the Permanent Commission on Transplants of the Interregional Council of the National Health System. In this document, procedures and requirements to be followed in the research on this topic are given.

The risk for the public health, as has been explained previously, appears as the main obstacle hampering the evolution of this technique. This is not solely a technical problem but drives to a social dilemma. The risk should never be completely ruled out. Therefore, the risks would require specific evaluations (case by case?) and then, should society be ready to accept them and give free access to xenotransplants?

The solution that seems to gain points for minimizing the problem relies on the careful monitoring of the patients that have received a xenotransplant, as it was suggested in the above mentioned document.

5.2.5. If there is no debate, which position do relevant potential actors take?

The option between the risks raised by the xenotransplants to the public health being an ethical debate or a simply technical one is a personal option, at last. In any case, this issue remains at the core of the problems and has been, in the opinion of most interviewees, one of the reasons underlying the slow pace, even the stop pf, taken by research on xenotransplantation.

There is no further relevant debate in Spain on the xenotransplantation issue. It is therefore tempting to think that if the risks are well identified and assessed, they might be accepted, particularly if other options do not show better promises. This would mean an additional input for resuming research on xenotransplantation.

5.3. Actors of Debate

5.3.1. Which actors are involved in the debate? In which form are they involved?

It is important to remind that there is no substantive ethical debate in Spain on xenotransplants. If this were to occur (in the light of the two main aspects emerging from the Baseline Evaluation: risks for public health and animal rights) the actors involved should be:

- Mass media: essentials to foster the public opinion debate.
- Representatives from Administration: Ministries of Health and Consume, Science and Technology, Regional Authorities on Health, National Organization of Transplants.
- Scientists and clinicians with experience in xenotransplants research and its application.
- Activists from animal rights defenders associations.
- Patients associations.

All these groups have been involved along the Baseline Evaluation through the interviews performed.

5.3.2. Which potential relevant actors are excluded/do not participate? Why?

Some of the groups that were proposed in the Guidelines have been excluded in the case of Spain, because their absence or limited intervention in the Spanish landscape on xenotransplantation.

Politicians and political groups do not hold any defined position on xenotransplants. At least, there has not been any expression on it. This is opposite to the case of stem cells. Xenotransplants seem to be far from their application, thus becoming a remote subject of interest for politicians. Perhaps if their feasibility was settled, the politicians would manifest their positions, that may be coincident for a wide spectrum.

We have not included the pharmaceutical industry because there is no industrial involvement in Spain doing research on this subject. Neither private medical insurance companies have been taken into account as in Spain transplants can only be carried out through the National Public Health System.

The remainder collectives included in the Guidelines have been involved in the study.

5.3.3. Which particular coalitions between actors do exist?

The absence of a relevant ethical debate in the Spanish society has not favoured the development of coalitions between actors.

5.3.4. How do international actor-networks (e.g. researchers, surgeons, policy-makers) influence the discussion on ethical aspects of XTP? In what way do national documents refer to those from other countries respectively international organisations?

As in the case of other biotechnological topics, Spanish researchers (Dr. Rafael Máñez in our interviews) are in close contact with the international community. They know how the situation evolves in the international contexts but are aware at the same time of their limitations in terms both of power and interests to introduce or influence the debate in Spain. This attitude blended of realism and prudence is enhanced the researchers are working under contract or any other type of link with private firms.

Another international connection derives from the normative aspects, in particular within the European context. Rafael Matesanz (also interviewed by us) had been chairing the Transplants Commission of the European Council (Parliamentary Assembly). This Commission assumes, among other objectives, the task to design a common policy on xenotransplants in Europe. Research on xenotransplants was drawn by the 1999 moratorium, which was addressed to all members countries but that Spain did not accept.

5.4. Which actors could participate in the Neo Socratic Dialogue?

All the interviewees are potential candidates to participate in the Neo-Socratic Dialogue, though other experts non-interviewed by several reasons could be involved. We believe that the number of participants should not exceed 6 or 7 members for a good operation.

Almost all interviewees have shown interest to participate in the NSD as they believe it could be a good method to share each one uneasiness in relation to xenotransplants.

We want to state that we are disposing of a document in English (German is not common language in Spain) that provides details on the characteristics and goals of the NSD. We would like to suggest that the expert side of the XENO project on this methodology helps us in this direction in order we can convey to the participants clear messages on goals and procedures of the NSD for keeping high their interest.

6. References

6.1. Bibliography used in the Baseline Evaluation

- Alonso, A., (2000), "Memorias de trasplantes. Experiencias de un trasplantado", Madrid, Ayuntamiento de Madrid y Caja de Madrid.
- Comisión Permanente de Trasplantes del Consejo Interterritorial del Sistema Nacional de Salud
- Durant, J., Bauer, M., Gaskell, George., (1998), "Biotechnology in the public sphere", London, Science Museum.
- Muñoz, E., (2001), "Biotecnología y sociedad. Encuentros y desencuentros", Madrid, Cambridge University Press.
- Sociedad Española de Biotecnología, (2002), "Biotecnología y salud: preguntas y respuestas", Madrid, Sociedad Española de Biotecnología.

6.2. Web sites consulted:

- www.abc.es ABC Daily Newspaper
- www.aimc.es Asociación para la investigación de medios de comunicación (Association for research of mass media)
- www.cis.es Centro de investigaciones sociológicas (Sociological Research Centre)
- www.csic.es Consejo superior de investigaciones científicas (Spanish National Research Centre)
- www.diariomedico.com Diario Médico (Spanish Journal of Medicine)
- www.elmundo.es El Mundo Daily Newspaper
- www.elpais.es El País Daily Newspaper
- www.europa.eu.int/comm/dg10/epo/eb Eurobarometer
- www.google.com Google (searching web site)
- www.lavanguardia.es La Vanguardia Daily Newspaper
- www.msc.es/ont National Transplant Organization - Ministry of Health and Consume
- www.ojd.es Oficina para la justificación de la difusión (Office for research of circulation)
- www.sibi.org Sociedad internacional de bioética (International society of bioethics)