

# Are the Voices of Women and Men Equally Represented in Ethics Committees? An Italian Survey

Paola Mosconi<sup>1\*</sup>, Lucio Lionello<sup>2,3</sup>, Lorenzo Di Spazio<sup>4</sup> and Lucia Alberghini<sup>2</sup>

<sup>1</sup>Mario Negri Institute for Pharmacological Research, Milano, Italy and AUSL Ethics committee, Bologna, Italy

<sup>2</sup>AUSL Ethics committee, Bologna, Italy

<sup>3</sup>University of Bologna, Department of Pharmaceutical Sciences, Bologna, Italy

<sup>4</sup>University of Milano, Department of Pharmaceutical Sciences, Milano, Italy

## Abstract

**Introduction:** Ethics committees are considered very important in the discussion of ethical questions and clinical research, but little information is available in its representation with respect to the society. World Health Organization stated that the composition of an ethics committee should be representative and balanced.

**Objective:** To describe the proportions of males and females in a sample of 170 Italian ethics committees.

**Materials and methods:** We examined gender distribution in ethics committees by analysis of the data-base available on the institutional free access website of the National Monitoring Centre for Clinical Trials. The findings were compared to a similar sample collected in 2008, and with the percentages of females and males who graduated between 1959-1968 and between 1979-1990, obtained from the National Statistics Institute.

**Results:** In 2010 ethics committees had 69% male and 31% female members. This imbalance only in part reflects the male/female ratio among graduates in the two ranges of years considered. The greatest differences are among medical doctors, with 83% males and 17% females. It contrasts with predominance of women among nurses and volunteers (males 34%, females 66%).

**Conclusions:** We found two kinds of gender imbalance: one among medicine graduates where males predominate and one among nurses and volunteers, with mostly females. This situation is discussed in relation to the representativeness and roles in ethics committees decision making. Progress is needed towards a more equal representation.

**Keywords:** Ethics committees; Gender; Equity

## Introduction

Clinical practice and research raises many ethical issues to which the community is required to respond. In industrialized countries ethics committees (ECs) are called to give general support on ethical questions and to examine clinical research protocols before they are offered to patients [1,2].

As recognized by the World Health Organization (WHO) the composition of an EC should be representative and balanced: "... ECs should be multidisciplinary and multi-sectorial in composition, including relevant scientific expertise, balanced age and gender distribution, and laypersons representing the interests and the concerns of the community..." [3]. However, Moerman and colleagues described the variability of gender equality in the composition of ECs, and the generally limited attention to gender balance [4]. Even high-profile EC, such as United Nations Educational, Science and Cultural Organization (UNESCO) and WHO, suffer an uneven gender representation [5].

Gender representativeness is discussed in the social sciences and medicine, stressing the importance of an equitable distribution of men and women to ensure impartial discussion of different points of views. Several issues must be considered from the representation of women in science and medicine to the impact of the different voices (do males and females really differ in their opinions on ethical issues?). This topic is rarely discussed [6], even at the level of individual committees.

In Italy a ministerial decree in 1992, adopting the European guidelines for good clinical practice entrusted local ECs with the evaluation of research protocols in order to ensure the respect of rights and safety of subjects involved in clinical research. Currently in

Italy there are 254 ECs, their distribution varying widely in relation to the population covered - on average one EC for each 237,560 inhabitants with a range from 127,866 to 900,790 inhabitants, and at regional level the mean is 12,7 ECs/region, ranging from 61 ECs in Lombardy to one in Valle d'Aosta and Umbria [7,8]. Each EC is an independent organization, especially in its relations with investigators. The composition of the ECs is established by law - a clinician, pharmacologist, pharmacist, statistician, voluntary worker, nurse, ethicist and general practitioner are all required; the number of members varies, and each is independently selected and directly nominated by the management of the structure in which the EC operates. A total of 3270 people are involved in the activities of Italian ECs.

This study describes the composition of a representative sample of Italian ECs as regards to the gender distribution among members, and discuss how this might influence decision making.

**Corresponding author:** Paola Mosconi, Laboratorio di ricerca sul coinvolgimento dei cittadini in sanità, Istituto di Ricerche Farmacologiche Mario Negri, Via La Masa, 19 - 20156 Milano, Italy, Tel: 0039 02 39014503; Fax: 0039 02 33200231; E-mail: [paola.mosconi@marionegri.it](mailto:paola.mosconi@marionegri.it)

**Received** January 09, 2012; **Accepted** March 26, 2012; **Published** March 30, 2012

**Citation:** Mosconi P, Lionello L, Spazio LD, Alberghini L (2012) Are the Voices of Women and Men Equally Represented in Ethics Committees? An Italian Survey. J Clin Res Bioeth 3:129. doi:10.4172/2155-9627.1000129

**Copyright:** © 2012 Mosconi P, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

## Materials and Methods

We examined gender distribution in ECs on the basis of the data-base available on the Italian institutional free access website of the National Monitoring Centre for Clinical Trials (OsSC) coordinated by Ministry of Health and AIFA, the Italian Medicines Agency. A section of this website is dedicated to local ECs, with their composition and addresses. Ten Italian regions, across the north, center and south of the country, and covering 71% of Italian population, were sampled. The data-base was analyzed between June and September 2010, after a new law decree that refined the structure and function of Italian ECs. We collected the number of members, and each category represented in the EC - physician, pharmacist, pharmacologist, statistician, etc. was recorded as male or female. We had already collected the same data (unpublished data) in 2008 for a meeting on gender and research [10], and this served as historical control.

We examined the percentages of women and men who had graduated between 1959-1968, and between 1979-1990. These two periods were considered representative of people of average age 60-70 years and 45-55 years, the usual age ranges of the members of ECs in Italy (empirical data collected in ECs in the Emilia Romagna Region). These data were only available for four categories - physicians,

pharmacists, law and statistics graduates - and was extrapolated from the National Institute of Statistics database [11]. Analysis were done using excel, with descriptive statistics such as proportion.

## Results

Table 1 shows the distribution of males and females in 2010 and 2008. In 2010, the 170 ECs had 31% of female members and 69% males; the difference in representation of women reached 38% in Liguria against 23% in Sicily. Here Table 1 Compared to 2008, the presence of women increased by 2% and in general there was an increase in the percentage of women in ECs, except in Sicily, where the proportion dropped. The gender distribution for chairpersons was also unbalanced: out of the 170 ECs, only 17% had a woman in charge. The figures varied widely between regions: from 0% to 44% in Emilia Romagna.

In 2010 there were 75% male and 25% female graduates in the ECs (Table 2).

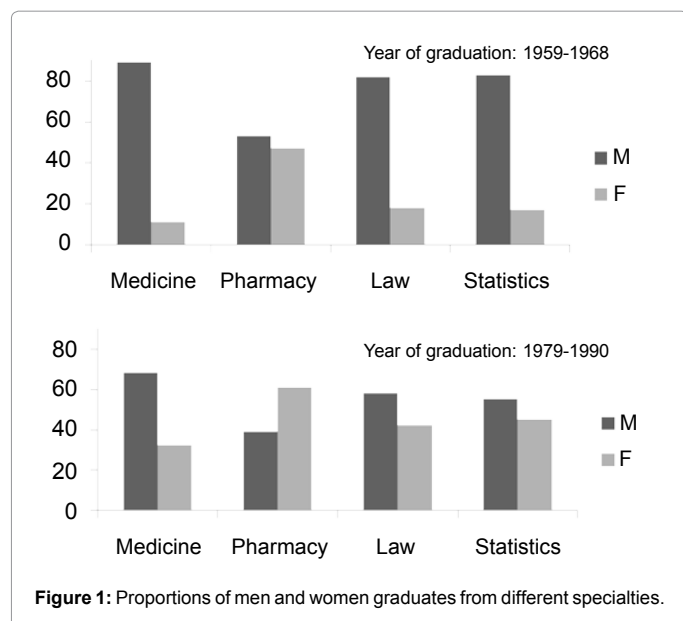
Figure 1 shows the figures for men and women graduates in medicine, pharmacy, law and statistics during the 1960s and 1980s. Here (Figure 1) Among medicine graduates in the 1960s there were 89% men and 11% women, in the 1980s there were 68% and 32%. In 2010 there were 83% male medicine graduates and 17% women in

		No. EC		No. MEMBERS		No. MALES (%)		No. FEMALES (%)	
		2008	2010	2008	2010	2008	2010	2008	2010
North	Emilia Romagna	9	9	167	190	113 (68)	121 (64)	54 (32)	69 (36)
	Liguria	9	8	111	101	69 (62)	63 (62)	42 (38)	38 (38)
	Lombardy	62	59	938	870	692 (74)	623 (72)	246 (26)	247 (28)
Center	Veneto	11	7	168	118	121 (72)	78 (66)	47 (28)	40 (34)
	Lazio	33	31	505	495	351 (70)	330 (67)	154 (30)	165 (33)
	Marches	9	6	126	90	90 (71)	61 (68)	36 (29)	29 (32)
	Toscana	13	12	211	194	139 (66)	122 (63)	72 (34)	72 (37)
South	Calabria	13	7	168	95	118 (70)	63 (66)	50 (30)	32 (34)
	Puglia	13	10	171	140	118 (69)	96 (69)	53 (31)	44 (31)
	Sicily	32	21	428	307	320 (75)	235 (77)	108 (25)	72 (23)
<b>TOTAL</b>		<b>204</b>	<b>170</b>	<b>2993</b>	<b>2600</b>	<b>2131 (71)</b>	<b>1792 (69)</b>	<b>862 (29)</b>	<b>808 (31)</b>

**Table 1:** Distribution of men and women in ECs: 2008 and 2010.

	No. MALES (%)	No. FEMALES (%)	TOTAL
<b>Degree in medicine</b>			
Clinician	511 (90)	56 (10)	567
Coroner	68 (75)	23 (25)	91
General practitioner	199 (82)	43 (18)	242
Pharmacologist	139 (74)	49 (26)	188
Physician in chief	174 (77)	53 (23)	227
<b>Master's degree</b>			
Pharmacist	72 (36)	128 (64)	200
Law	124 (72)	48 (28)	172
Statistician	118 (64)	65 (36)	183
Bioethicist	145 (74)	50 (26)	195
Other (psychologist, theologist)	110 (74)	39 (26)	149
<b>Non-graduates</b>			
Nurse	51 (28)	128 (72)	179
Volunteer	81 (39)	126 (61)	207
<b>TOTAL COMPONENTS</b>	<b>1792 (69)</b>	<b>808 (31)</b>	<b>2600</b>
Total graduates in medicine	1091 (83)	224 (17)	1315
Total non medical graduates	569 (63)	330 (37)	899
Total graduate	1660 (75)	554 (25)	2214
Total non-graduates	132 (34)	254 (66)	386

**Table 2:** Distribution of men and women graduates in ECs in 2010.



**Figure 1:** Proportions of men and women graduates from different specialties.

ECs (Table 2). During the 1960s the percentages of male and female pharmacy graduates were 53% to 47%, during the 1980s 39% and 61%; in 2010 in ECs the figures were 36% to 64%. During the 1960s the percentages of male and female law graduates were 82% and 18%, during the 1980s 58% and 42%; the percentages in ECs in 2010 were 72% and 28%. Among statistics graduates during the 1960s counted 83% of men and 17% women were counted, this shifted to 55% and 45% in the 1980s, and, in 2010, there were 64% males and 36% females in ECs. Finally among nurses and volunteers, that not necessarily have a degree, there were 34% males and 66% females (Table 2).

## Discussion

In 2010 a third of the members in a large sample of Italian ECs were women. This is the result of a weighted average between 25% of women in positions where a degree is required, and 66% covering positions which do not require a degree. Thus there are two kinds of gender unbalance: one among medical graduates, where males predominate (first cluster), and the other among nurses and volunteers (second cluster), with mainly women. The predominance of women among nurses and volunteers is mainly due to cultural factors, women playing a major role in care services.

At first glance, there did not appear to be any clear unbalance in gender representation among the graduates considered. The lower representation of women only in part reflects the male/female ratio among graduates in the two ranges of years considered as reported in Figure 1. Now there is a slow increase in female presence in ECs in line with historical/cultural changes that have seen a growing number of women studying and working. This is confirmed by the current female membership in ECs, which stands between their graduation. However, medical graduates seem less in line, with 83% of men to only 17% women in ECs. This imbalance reflects the impact of medical graduates in ECs: not only are medical members more than half the total, i.e. 1315 out of 2600, but they are also considered among the most influential components of an EC.

Unfortunately, little data is available in the literature on gender equality in the composition of ECs. A non representative sample of ten ECs - two each for Austria, Germany, Ireland, Netherlands and Sweden

- showed women ranging from 25% to 37%, in line with what we found in Italy [4]. The representation of women looks like a common problem, even in nations with a more deeply rooted culture of gender equality.

There were also only a few female chairpersons of ECs. According to Dickenson [6], in a work setting women are generally equally represented at lower levels but there is segregation at the top of the pyramid where they are vastly under-represented. Another kind of segregation was reported by Osborn et al. [12] who found women clustered in certain “softer” areas and males over-represented in “hard” areas. For example the main predominant “hard” and “soft” division in life sciences and medical ECs is between medicine as the “hard” area heavily weighted towards men, and ethics, nursing and lay membership as the “soft” realm to which women are drawn. This is well documented by results of our survey.

Although any EC member has the same importance and specificity, there is an important gender imbalance. The predominance of male medical graduates affects decisions because any discussion leading to the final decision is conducted by the largest group inside the EC. A gender imbalance in this group - more than in any other - risks in not allowing different perspectives and sensibilities to emerge. We believe that the gender distribution in this first cluster is only partly counterbalanced by the second, leaving unanswered questions on women’s real contribution decision makers.

Although gender is only one of the variables to be considered for the representativeness of ECs, our results suggest that cultural progress is needed in order to achieve more equality. Of course, it is impossible to have a perfect number of members in ECs or a perfect mix of members’ characteristics [13,14] but under the umbrella term “multidisciplinary” all the characteristics should be borne in mind to ensure discussions and decisions to encompass different perspectives and experiences, gender included.

## Acknowledgements

The authors thanks Gianna Costa of the Mario Negri Institute for assistance in data collection.

## References

- Larcher V (1999) Role of ethics committees. *Arch Dis Child* 81: 104-106.
- Slowther A, Johnston C, Gooddall J, Hope T (2004) Development of clinical ethics committees. *BMJ* 328: 950-952.
- World Health Organization (WHO), Operational Guidelines for Ethics Committees That Review Biomedical Research, TDR/PRD/ETHICS/2000.1 Geneva 2000 Accessed 2011 September 6.
- Moerman CJ, Haafkens JA, Söderström M, Rásky E, Maguire P, et al. (2007) Gender equality in the work of local research ethics committees in Europe: a study of practice in five countries. *J Med Ethics* 33: 107-112.
- Hinsch K (2010) Unesco develops universal norms in bioethics, woman underrepresented. *Women’s Bioethics Project*.
- Dickenson D (2006) Gender and ethics committees: where’s the “different voice”? *Bioethics* 20: 115-124.
- AIFA (2010) 9th National Report by Italian Medicines Agency Accessed 2011 Aug 29.
- Mosconi P, Colombo C, Labianca R, Apolone G (2006) Oncologists’ opinions about research ethics committees in Italy: an update, 2004. *Eur J Cancer Prev* 15: 91-94.
- National Monitoring Centre for Clinical Trials (OsSC) of the Italian Medicines Agency Accessed 2011 August 29.
- Clinical Trial Day Accessed 2011 September 28.
- National Institute of Statistics Accessed 2011 September 12.

12. Osborn M, Rees T, Bosch M, Hermann C, Hilden J, et al. (2000) Science policies in the European Union: promoting excellence through mainstreaming gender equality. A report from the ETAN network on women and science, Luxembourg: Office for Official Publications of the European Communities, 156.
13. Larcher V, Slowther AM, Watson AR (2010) Core competencies for clinical ethics committees. *Clinics* 10: 30-33.
14. Gillon R (2010) What attributes should clinical ethics committee have? *BMJ* 340: c2946.