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# The "Telefono Rosso": a service for the prevention of birth defects and for the evaluation of teratogenic risk

Pierpaolo MASTROIACOVO *(a)*, Mariangela SERAFINI *(a, b)*, Massimo PAGANO *(b)*, Marco DE SANTIS *(b, c)*, Ida VERCILLO *(b, c)* and Eleonora CELESTINI *(a, b)*

*(a) Servizio di Epidemiologia e Clinica dei Difetti Congeniti, Istituto di Pediatria, Policlinico Universitario A. Gemelli, Rome, Italy*
*(b) Centro Internazionale sugli Esiti Sfavorevoli della Riproduzione ICARO-ASM, Rome, Italy*
*(c) Istituto di Clinica Ostetrica e Ginecologica, Policlinico Universitario A. Gemelli, Rome, Italy*

**Summary.** - The "Telefono Rosso" ("Red telephone") is a specialized service for preconceptional counselling and teratogenic risk evaluation. In both cases the choice of telephone communication allows to reach a wide basin of users with personalized information. The service finds one of its main reasons in the marked disinformation which exists in this field and in the wrong risk perception shown by a high proportion of users. In addition to serving the community to prevent birth defects and to prevent some induced abortions, the "Telefono Rosso" represents a unique opportunity to add to the current body of knowledge by documenting the outcomes of pregnancies exposed to a variety of agents. In this respect the "Telefono Rosso" may be considered an additional source of post-marketing surveillance.

*Key words:* teratogen information service, teratogens, drugs in pregnancy, preconceptional counselling, prevention of induced abortions.

**Riassunto** *(Il "Telefono Rosso": un servizio per la prevenzione dei difetti congeniti e per la valutazione del rischio teratogeno).* - Il "Telefono Rosso" è un servizio specializzato per la consulenza preconcezionale e la valutazione del rischio teratogeno. In entrambi i casi il vantaggio di utilizzare il telefono è di poter raggiungere una vasta utenza con informazioni personalizzate. Il servizio trova una sua giustificazione nella disinformazione esistente in questo settore e nella errata percezione del rischio riproduttivo mostrata dall'utenza. Oltre a servire la comunità nella prevenzione dei difetti congeniti e di alcune interruzioni volontarie di gravidanza, il "Telefono Rosso" rappresenta un'opportunità unica di ricerca scientifica documentando gli esiti di gravidanze esposte ad un'ampia gamma di fattori. In quest'ottica il "Telefono Rosso" può essere considerato una fonte aggiuntiva di dati per la farmacovigilanza.

*Parole chiave:* teratogeni, farmaci in gravidanza, consulenza preconcezionale, prevenzione aborti indotti.

## Introduction

The aim of this paper is to describe the main features of the "Telefono Rosso", a service for the prevention of birth defects and for the evaluation of teratogenic risk. The goals, the current operative structure and work load will be presented first, followed by an outline of the main features of the service; finally, the results of the service will be discussed, both in terms of prevention of induced abortions (IA) and the study of reproductive outcomes exposed to some specific environmental agents.

## The "Telefono Rosso"

### *Aims of the "Telefono Rosso"*

The aims of the "Telefono Rosso" are:

a) inform women in reproductive age, before conception or during the first months of pregnancy, on which are the genetic, constitutional and environmental factors that increase the risk of birth defects in the offspring and how to control and eliminate them;

b) evaluate whether a given genetic, constitutional or environmental factor, perceived as dangerous by the woman, is really harmful or not; if it is, offer accurate indications on the type of defect which can be foreseen (qualitative risk assessment), on the expected frequency of that outcome (quantitative assessment of the individual risk which can be attributed to the exposure) and on current methods which allow prenatal or early postnatal diagnosis;

c) aid the physicians to choose the drug therapy of choice for their patients who are planning a pregnancy or during pregnancy;

d) evaluate the possible cause of birth defects in case of couples who have had a fetus, newborn or child with a birth defect.

*Operative structure*

Doctors specialized in obstetrics and gynecology or in pediatrics with a special training in teratology and genetics are in charge for replying to users. The users are both women and doctors.

Every counselling of the "Telefono Rosso" is considered as a proper medical act, just as any other, direct intervention. The ideal, privileged user is the woman, before conception or during the first months of pregnancy. Phone calls by other family members or friends are discouraged. This attitude is aimed to emphasize the importance of the direct contact between patients and the physicians of the "Telefono Rosso". In particular situations anonymous requests are accepted.

*Preconceptional counselling*

For every woman that calls, a medical record is filled. If the counselling is requested before conception, questions are asked in order to recognize possible, previously undetected genetic, constitutional or environmental risk factors (Table 1) and information aimed at health promotion of the offspring is given (Table 2).

If the counselling is requested during pregnancy, all information relevant to the assessment of the teratogenic risk is asked (Table 3) then the medical record is filled and finally all data relevant to health promotion of the child is given.

*Risk assessment*

The assessment of teratogenic risk is performed according to the guidelines, summarized by Jelovsek *et al.* [1], which are the product of a consensus of recognized experts in this field.

If the requested exposure is relatively common and well known, the physician on duty answers within a few minutes, on the basis of knowledge and information acquired during the preparation course which includes the study of selected books [2-6] and the ongoing update which makes use also of systematic reviews of relevant literature, e.g., Medline and Toxline. To evaluate rare or unusual factors the three data banks available in the computer are consulted (TERIS, REPROTOX, RCD-ASM). This involves a minimum waiting time for the patient. Rarely the answer is postponed for a few hours or days to allow consultations with experts in specific fields, for example, toxicologists, or with other similar services which are part of two international organizations (ENTIS-OTIS). RCD-ASM is the data bank of the "Telefono Rosso" on drugs (Appendix 1). When deemed necessary the woman is invited to go at a second or third level center for direct assistance (Table 4).

**Table 1.** - Personal and family information requested for all women, to detect fetal risk factors

- Maternal age
- Data on previous pregnancies
- Genetic diseases in the family
- Consanguinity with the partner
- Susceptibility to rubella, toxoplasmosis, chickenpox
- Maternal chronic diseases (e.g.: diabetes, hypertension, epilepsy)
- Lifestyle habits (eg: diet, alcohol, smoke, narcotics)
- Working activity
- Laboratory exams (e.g.: test for thalassemic trait, blood group)

**Table 2.** - Information on health promotion of the fetus given to all women

1 - Do not use narcotics (e.g., cocaine, marijuana, heroin)
2 - Do not smoke
3 - Do not drink high proof alcoholic drinks and limit to a minimum the use of wine
4 - Do not perform tiresome working activities
5 - Do not follow strict hypocaloric or vegetarian diets, but a balanced diet with frequent meals during the day
6 - Do not eat raw or undercooked meat; wash vegetables very well
7 - Avoid the use of drugs if not absolutely necessary and contact the "Telefono Rosso" to choose the drug of choice during pregnancy (may change according to the gestational period)
8 - Avoid the use of aspirin or other NSAID in the last period of pregnancy
9 - Avoid the daily use of vitamin preparations containing more than 8,000 IU of vitamin A
10 - Take folic acid in the periconceptual period (from at least three months before conception to at least three months after)
11 - Perform tests for toxoplasmosis, rubella, cytomegalovirus, chickenpox (beginning in the preconceptual period and if during pregnancy once a month if negative).
12 - Undergo regular visits at the obstetrician from the first month of gestation and with the recommended periodicity

**Table 3.** - Information requested for the evaluation of teratogenic risk and the preparation of a personalized counselling

- Gestational age at the time of exposure (if confirmed by ultrasound examination or not)
- Type of exposure, period, dosages, reasons
- Other exposures
- Information already given by other physicians
- Planning and acceptance of the pregnancy

**Table 4.** - Settings where referral to a specialized center is contemplated

- Genetic diseases or malformations in the family
- Maternal chronic diseases which require treatment
- Exposure to risk factors for which prenatal diagnosis gives major information (e.g. valproic acid)

*Counselling details*

The counselling takes place according to the cultural and anamnestic characteristics of the woman. The general principles which guide the communication process have been outlined elsewhere [7]. Careful consideration is given to what information the woman already has, how and from whom she got them. Usually the counselling is longer the more conflicting the information the woman already has, compared to that given by the physicians of the "Telefono Rosso". When the conflicting information has been given to the woman by her physician, every effort is made to avoid disrupting the relationship of trust previously built. The woman is invited to promote a direct contact between the "Telefono Rosso" and her physician and it is explained that the fast pace of knowledge has imposed specific specializations and the use of adequate instruments, such as computerized data banks.

In all cases the woman is reminded that there exist a background risk of birth defects of about 3-5%, independent of the specific factor under examination and equal for all couples.

*Quality controls*

As all relevant data for each counselling are noted in the medical record, before beginning the counselling session each physician evaluates the internal consistency and completeness of the records compiled by the colleagues. Discrepancies and differences in interpretation are discussed in regular meetings. Periodically all phone calls of one complete week are taped and reviewed by all physicians of the service and the discussion that follows is aimed at blending the characteristics and increase the quality of the counselling.

*Number of counselling performed*

The "Telefono Rosso" begun its activity in June 1988 and up to June 1992 has given over 8.500 consultations. The requests have been 783 in 1988; 931 in 1989; 1,494 in 1990; 2,879 in 1991; 2,475 in the first six months of 1992 (with an expected yearly number of calls of over 5,000). This yearly increase has been noted also by other analogous services [8] and has paralleled the activation of new lines: one was present until 1989, a second was activated in 1990 and a third at the end of 1991. Every counselling takes a mean of 25 minutes.

*The type of requests*

The type of requests received in 1991 is outlined in Table 5.

**Table 5.** - Type of requests in 1991

| | Women (2,318) (%) | Physicians (561) (%) |
|---|---|---|
| **Prospective counselling** | **40.3** | **14.5** |
| Preconceptional | 11.5 | 2.7 |
| Drugs of choice | 10.0 | 6.8 |
| General information | 5.3 | 0 |
| Maternal age | 2.8 | 0.6 |
| Chronic diseases | 1.3 | 1.0 |
| Other | 9.4 | 3.4 |
| **Evaluation risk from drugs** | **40.8** | **63.5** |
| Benzodiazepines | 5.6 | 7.8 |
| Antidepressants | 1.5 | 2.1 |
| Antiepileptic drugs | 1.0 | 3.3 |
| Other | 32.7 | 50.3 |
| **Evaluation other risks** | **18.9** | **22.0** |
| Infectious diseases | 5.9 | 5.5 |
| Diagnostic radiations | 4.7 | 7.0 |
| Chronic maternal diseases | 1.0 | 0 |
| Other | 7.3 | 9.5 |

*Main characteristics of the users*

To evaluate the features of the users of the service during 1991 a sample of 245 women was selected taking the first counselling of the day. As a group of comparison a sample of women was selected from the women with a healthy newborn baby registered as normal controls in the Italian Multicentric Birth Defects Registry (IPIMC) and matched by region of residence. The two groups are compared in Table 6. Women who call the "Telefono Rosso" are slightly older, with a much higher education and have more often a working activity outside home. They are more often at their first pregnancy but women with parity above 1 have a higher rate of previous abortions.

At the time of counselling in pregnancy, at a mean of 11.5 weeks, 40.9% of women had already some information regarding the factors for which they requested the counselling, but in only 30% of cases the women were unconcerned and phoned only for confirmation. 48.9% had planned the pregnancy, while in 4.9% the pregnancy was unwanted and at the time of counselling had not been yet accepted.

As for lifestyle, 15.0% of women smoked daily a mean of 12 cigarettes; 2.5% drank a mean of 2.2 glasses of wine or beer daily; 9.8% took vitamins regularly. As for immune status to Rubella, 73.9% of women were immune (9.7% following vaccination, 64.2% for natural immunity); 9.7% were still susceptible while 16.4% were not aware of their immune status.

**Table 6.** - Main features of a sample of women (245) who called the "Telefono Rosso" compared to a sample (563) of the general Italian population

| | Telefono Rosso | Population |
|---|---|---|
| **Mean age** | **30.6** | **28.6** |
| *Educational level* | | |
| Elementary | 4.3% | 11.3% |
| Junior high | 17.4% | 41.2% |
| High | 54.2% | 40.1% |
| University degree | 24.1% | 7.4% |
| *Working activity* | | |
| Home | 29.3% | 42.2% |
| Office | 22.8% | 17.8% |
| Teacher | 17.1% | 7.7% |
| Other | 30.8 % | 32.3% |
| First pregnancy | 32.9% | 42.7% |
| Spontaneous abortions *(*)* | 24.9% | 17.5% |

*(*)* Number of previous abortions over the total number of previous pregnancies.

### Prevention of induced abortions

From the beginning of the activity of the "Telefono Rosso" it was surprising to verify that many women exposed to environmental factors surely not dangerous (e.g., diagnostic radiations, non teratogenic drugs or infectious diseases) had such a high perception of risk regarding possible adverse effects on their child that they were seriously considering the option of pregnancy termination [9]. This has been experienced and analyzed also in other similar services [10, 11].

The mechanism by which the woman tends to overestimate the teratogenic risk is complex. In our opinion the most important factor is the distorted understanding that comes about when a caution note, prepared as a preventive and prospective measure, is perceived as a statement of danger which is always present. The classic example is the information note which comes with every drug. These notes include sentences such as "do not administer in the first trimester of pregnancy" or "though no teratogenic effect has been detected in animal studies, the drug should not be used during pregnancy or breastfeeding".

The aim of these sentences is not only to protect the pharmaceutical company from possible lawsuits but mainly to discourage self-administration and misuse of drugs. They are therefore general warnings and precautions and prospective in nature. The logic behind them is simple: why run even smallest risk, even if extremely unlikely, if not strictly necessary? However, when a woman discovers that the child she is expecting has been exposed to a drug, a short-circuit, irrational and unjustified, may occur: the prospective warning, the logic of not running risks if not necessary is converted in the statement "the drug is dangerous for the fetus".

There are certainly other factors that concur to the overestimation of the risk. For the woman, but also for some physicians, the information that thalidomide, valproic acid and isotretinoin are teratogenic becomes, unreasonably, "all drugs are dangerous for the fetus". Moreover, for some physicians a paper that simply suggests that a certain drug may cause a birth defect becomes in the daily practice and recollection: that certain drug is teratogenic. The distinction between hypotheses and scientific proof simply disappears.

If a woman perceives a risk as being very high, it is enough that a single physician confirms it to make this possibility appear as an unescapable reality. And in the round of consultations that a worried woman does there is always, sooner or later, a physician that confirms these worries: and it is not even necessary to state that a certain drug or exposure is teratogenic; it is enough to give an evasive or unclear answer. Based on our experience, the best policy for a physician or for a gynecologist or obstetrician who hasn't got a convincing answer to the woman's queries is to advise the woman to contact the "Telefono Rosso" or similar services.

In our modern society, where prevention has become a myth but never really applied, a reproductive risk perceived as high by the woman is often managed either through prenatal diagnosis or pregnancy termination. If prenatal diagnosis is not 100% reliable, which is the case when the risk is low, pregnancy termination becomes an option which women may consider; an option which is often accepted or sometimes even suggested by some physicians who "do not take the responsibility to continue the pregnancy".

**Table 7.** - Information requested at follow up

| |
|---|
| Course of pregnancy, prenatal diagnosis |
| Additional exposures to drugs, other environmental exposures, maternal diseases after the previous counselling |
| Type of delivery |
| Sex, gestational age, vitality, twinning status, weight, length, head circumference of the newborn |
| Malformations or other neonatal problems |
| Number of days in hospital after delivery |
| Source of information, number of follow-ups and age of child at the last follow-up |
| Degree of satisfaction on the information received by the "Telefono Rosso" |

It has not been easy to analyze and quantify how the "Telefono Rosso" has helped some women to understand the real magnitude of the teratogenic risk and in how many cases it prevented a pregnancy termination which the woman herself did not want. The major difficulties have been: a) to understand which women were really motivated to a pregnancy termination; b) to understand if the motivation was due exclusively to the altered perception of risk; c) to understand which were the woman who purposefully overestimated the teratogenic risk to justify their wish for a pregnancy termination, due to socially less acceptable motivations. This analysis becomes even more difficult if the counselling was done through the physician caring for the woman and not to the woman herself.

In 1991 a special study was performed on 2,318 women who requested a counselling to the "Telefono Rosso", aimed to understand which were those who wanted to undergo a pregnancy termination (PT). Only those women who reported exposures which did not increase the background risk were selected. Among these, 104 were strongly willing to terminate their pregnancy. After counselling performed by the "Telefono Rosso" only 26 underwent PT. Therefore 75% of those PT presumably due to a erroneously high risk perception were prevented. This proportion could increase to 100% if the women contacted only the "Telefono Rosso" and were not misled by superficial and alarming medical consultations. Considering that in Italy around over 150,000 PT are performed every year and that, according to preliminary study performed in Campania (Scarano, personal communication), 6% of PT are due to medical reasons that do not justify the PT, it can be estimated that around 9,000 PT could be avoided only through the activity of the "Telefono Rosso".

**Table 8.** - Outcome of pregnancies in women exposed to particular agents under study

| | Tot | SA | IA | Births | |
|---|---|---|---|---|---|
| | | | | H | M |
| *Acyclovir* | 10 | 1 | 2 | 7 | 0 |
| *Antiobesity drugs* | | | | | |
| Amfepramone | 16 | 2 | 1 | 12 | 1 *(a)* |
| Fenfluramine | 22 | 3 | 3 | 15 | 1 *(b)* |
| Fendimetrazine | 11 | 0 | 2 | 9 | 0 |
| *Antiepileptics* | | | | | |
| Valproic acid | 11 | 2 | 2 | 5 | 2 *(c, d)* |
| Carbamazepine | 30 | 4 | 1 | 25 | 0 |
| Phenytoin | 5 | 1 | 0 | 4 | 0 |
| Phenobarbital | 22 | 2 | 1 | 19 | 0 |
| *Benzodiazepines (*)* | | | | | |
| Alprazolam | 12 | 2 | 7 *(e)* | 3 | 0 |
| Bromazepam | 16 | 2 | 8 | 2 | 2 *(f, g)* |
| Clorazepam | 11 | 1 | 1 | 9 | 0 |
| Diazepam | 21 | 6 | 6 | 8 | 1 *(h)* |
| Lorazepam | 31 | 2 | 8 | 21 | 0 |
| *Clomifene* | 2 | 1 | 0 | 1 | 0 |
| *Fluconazole* | 14 | 3 | 1 | 10 | 0 |
| *Lithium* | 5 | 1 | 1 | 3 | 0 |
| *Retinoids* | 3 | 0 | 3 | 0 | 0 |
| *Vitamine A >10.000 UI* | 36 | 3 | 1 *(i)* | 31 | 1 *(l)* |
| *Chickenpox* | 9 | 1 | 4 | 4 | 0 |
| *Warfarine* | 4 | 0 | 0 | 4 | 0 |

The reported data refer to every individual drugs, be it in monotherapy or associated with other drugs. The data therefore cannot be summed. *(*)* Only as chronic use

Legend: Tot = total women with completed follow-up. SA = spontaneous abortions. IA = induced abortions. Births H = Healthy newborns, without malformations. Births M = newborns with a structural malformation detectable in the first weeks of life. *(a)* Clubfoot; *(b)* CDH; *(c)* hypospadias; *(d)* eyelid ptosis and blepharophimosis; *(e)* Trisomy 21; *(f)* mild hydronephrosis; *(g)* PDA; *(h)* VSD; *(i)* Trisomy 13; *(l)* Bil hydronephrosis.

## Outcome of pregnancies exposed to specific agents under study

One of the most interesting aspects of the Teratogen Information Services (TIS) and the "Telefono Rosso" is the contribution they may give to a better understanding of teratogenic factors through the systematic reporting of follow-up studies. In fact, the indications on teratogens which appear in the scientific literature are often conflicting and rarely definitive. A major problem of the literature review for those who wish to obtain practical indications to be used in teratogenic risk counselling is the bias due to the policy of publication. It is well known that a study that suggests a new side effect of a drug or another exposure, though it may be methodologically flawed in some way has a higher chance to be sent for publication and accepted compared to another study, methodologically much more robust and reliable, that failed to observe a specific effect. It is therefore important to have a cohort of women, exposed to particular agents, ascertained at the time of exposure, on which to evaluate the frequency of the most important reproductive outcomes, e.g., intrauterine growth retardation, birth defects, handicaps in infancy.

The "Telefono Rosso" chose varicella and 10 categories of drugs as exposures on which to conduct follow up studies. A woman is enrolled after she gives her consent, following a detailed explanation of the aim of the study and the importance of follow-up.

At least one other time during pregnancy and three weeks after the expected date of delivery the woman is reached by phone to collect data on the health of the child. If necessary a copy of the medical records or a visit of a specialist at one of the centers of dysmorphology linked to "Telefono Rosso" (Sindronet) is requested. In Table 7 are outlined the information which is requested at the follow-up interviews. A phone interview at the second and seventh year of life has been scheduled. In Table 8 is listed the outcome of those pregnancies exposed to the agents under study.

Appendix 1

## Reproductive Counselling Data Bank (RCD)

The Reproductive Counselling Data Bank (RCD) is produced with the financial support of the Associazione Italiana Studio Malformazioni, Italian Association Study Malformation (ASM), for the physician of the "Telefono Rosso".

The updated version of February 1992 includes 747 records on the same number of active pharmacologic principles. Every record is formed by 4 parts. In the first part, general information on the drug is given, including the international classification ATC (Anatomic and Therapeutic Classification), the usual therapeutic dosage, the year of introduction in the Italian market and/or the availability in various countries in the world. This last information may help identify those substances that having being used for a longer time and on a wider population may be expected to be safer in pregnancy, in the absence of specific studies, compared to less widespread or more recent drugs.

In the second part are reported the studies on the use of the drug in pregnancy in humans, both clinical and epidemiologic. When necessary also experimental studies are reported. The reproductive outcomes which are considered include structural malformations, functional disabilities and transient alterations which may or my not be seen in the newborn (e.g., withdrawal syndrome, hyperbilirubinemia)

In the third part are outlined the personal conclusions after a critical review of the available literature. The conclusions are particularly suited for retrospective counselling, when the drug has already been administered. In case of a possible risk to the fetus, the most appropriate precautions for the management of the pregnancy and the newborn are given, including prenatal diagnosis.

The fourth part gives two classifications of the reproductive risk, the first valid for a prospective counselling, when the drug has yet to be given, the second for a retrospective counselling, when the drug has already been administered.

Finally, the fifth part lists the literature references from which the record has been prepared.

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