



Proper Medical Prescriptions and Cord Blood Harvesting Improvement at a Children's Hospital of North Eastern Italy

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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ABSTRACT

A systematic harvesting of hematopoietic progenitor cells for transplant purpose in oncology begun in Friuli Venetia Giulia (FVG), a region of north east Italy, at the end of 2000. The actual economic crisis in Italy and in all Europe slows down number births and the cord blood related collection, because tests' ticket during pregnancy and medical visits are many expensive; nevertheless some specific medical prescriptions and test during pregnancy are exempt from tickets in public health, but not all doctors and patients know rules and modalities of exemption in obstetric-gynecology. Moreover there are formal errors due to the bad quality of external quality control (EQC) of some tests useful to the validation of the cord blood collection. The aim of this work is to study the impact of formal errors in prescriptions and tests validation at a Children's Hospital of Trieste (main town of FVG region). To this aim had been performed a monitoring, during 2013-14s, to improve appropriateness of prescriptions related to stem cells collection and to make more suitable and safe transplants and related medical cares. 3300 medical prescriptions were monitored for 24 months (from 2013 January to 2015 December), and studied with a χ^2 test before and after analysis not in compliance with activities and was introduced a management protocol of improvement: the

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external quality assessment (EQA) of the tests was performed by Biodev (Milan, Italy). Results. The comparison of prescriptions and external tests during 2014-15s has highlighted a significant decreasing of not appropriate requests, mistakes of prescriptions about obstetric exemptions ($p < 0.05$), with a improvement of cord blood harvesting and a re-entry of EQA in the first or second SD. These data stress the continuous use of the sanitary activities monitoring, with updated protocols and severe controls, as key points to improve cares and to avoid improper costs in public health.

Keywords: Pregnancy; exemptions; appropriateness; cord blood harvesting.

1. INTRODUCTION

In Italy families that wish to have a child and pregnant women can have, in public sanitary system, some specialistic services without ticket payment: blood tests and obstetric visits with medical ultrasonography imaging of the foetus. This is possible in case of: prenatal diagnosis, pregnancy monthly monitoring, miscarriage or threats of abortion. If there are situations of clinical or genetic risk for the foetus, the couple can do specific additional tests to check and monitor the pregnancy. Every medical prescription must have family name and surname of the patient, exemption code, date, no more than eight tests of the same specialist branch, diagnostic question and the indication of low or high priority [1-3].

A systematic harvesting of hematopoietic progenitor cells for transplant purpose in oncology has been begun in Friuli Venetia Giulia (FVG), a region of north east Italy, at the end of 2000. The actual economic crisis in Italy and in all Europe slows down the cord blood collection for transplanting purpose, because tests' tickets during pregnancy and medical visits are very expensive; nevertheless some specific medical prescriptions and tests, for cord blood harvesting and cryopreservation enclosed, during pregnancy, are exempt from tickets in public health. But not all doctors and patients know rules and modalities. This causes a high numbers of formal errors, about the exemptions in obstetric-gynaecologic prescriptions and hindrances in collection and in validation of the tests [4-9].

All errors and omissions during prescription phase have repercussions on hospital organization of visits and controls, on the patients waiting time and their health status, cares and diagnostic treatment. The lack of clinical information about diagnostic problem and the indication of levels of urgency-priority (routine, less urgent, urgent, emergency) of

these requests, as the correct indication of the clinic investigation on the prescription-paper, are essential and compulsory, but not always described by the specialist. Many couples know that stem cells could be life saving in many pathologies and ask to their general medicine doctor the harvesting of cord blood cells, for cryopreservation at Padua Cord Blood Bank (public system), or at foreign Cord Blood Bank (Switzerland, England, Germany, Spain or other EU countries) because the establishment of private cord blood banks in Italy is forbidden. The tests for umbilical stem cells harvesting and cryopreservation are part of these controls, with some differences about tests requested by public or private blood stem cells banks (Table 1) [10-16].

Often general medicine doctors and obstetrics do not know the difference among compulsory or not compulsory tests for cord blood cells cryopreservation and the modalities requested by private cord blood bank for stem cells sending to foreign bank. The tests for the stem cells' validation and to cure children with oncology diseases are sent to outside laboratories because the Children's Hospital has only a emergency laboratory: the test-answers return to Hemato-oncology Department by express-courier.

Actually appropriateness and quality are the answer to the clinical request: converting technologies, miniaturization and information technology are the strategic planning for a modern health care system, determining a new context between patient and clinical request [17-21].

To improve the appropriateness of the medical prescriptions and tests' quality, the Medical Directorate of the Institute for Maternal and Child Health of Trieste (main town of the FVG region) has monitored during two years, the modalities of the requests and the quality of the tests of the Hospital, and has studied the criticalities.

1.1 Medical Prescriptions

All medical prescriptions must have signed:

- Surname, Family name and address of the patient
- Sanitary Unit of residence
- A request of no more of 8 tests and exemption codex
- Short description of pathology and grade of priority (routine, less urgent, urgent or emergency)

The personnel of the Hospital Booking Centre (HBC), if the prescription presents errors or omissions, informs the patient about non conforming error, photocopies the paper and calls a doctor of the Medical Directorate who rewrites the prescriptions together with patient. Monthly a report with a check in of the errors is sent to doctors indicating the type of non conforming. All prescriptions and errors are recorded in a specific data base.

1.2 Tests' External Assessment

The tests for cord blood stem cells validation and to take care of transplanted children are sent in other centralized laboratory, outside the hospital. The reports return by express courier to the Children's Hospital: the external quality assessment (EQA) had to verified monthly by physician equip of the hospital and had been discussed and recorded in a specific data base.

1.3 Aim

This retrospective study concerns the medical doctors involved in prescriptions during pregnancy, especially in the obstetric-gynaecologists tests prescribing, and the physicians which receive tests' medical reports analyzed in other centralized laboratory, without EQA.

Tests and medical prescriptions have been monitored for 24 months (from 2013 January to 2015 February), before and after an analysis of non conforming activities and the introduction of a management protocol about exemptions and control data quality.

The first purpose of this work is to study the impact of the formal errors, especially related to cord bloods collection, during the medical prescriptions at a Children's Hospital of Trieste.

The second aim is the monitoring of tests carried out during 2014-15s, to improve stem cells collection and to make more suitable transplants and medical cares with safe data and a better EQC.

2. MATERIALS AND METHODS

3300 prescriptions (1680 in 2013 - 1720 in 2014) and 10 external tests of laboratory have been monitored and controlled, from January 2013 to December 2015. The 30% of the prescriptions (total number 990 in 2013) and the 20% (total number 660 in 2014) of the tests regarded the cord blood validation.

Medical doctors' prescriptions, errors, omissions in the papers and the data of EQA of the tests, have been listed monthly, step by step. In 2014 January has been done a meeting with general medicine doctors, obstetrics, physicians and oncologists, to check the first reports and to explain the exemption protocols.

At the same time they controlled the standard deviation (DS) of the quality of the viral tests performed out hospital. The reports concerned 10 tests; of these, 2 were out the second SD (Syphilis western blot and HTLV I-II tests). The physicians of the laboratory of Children's Hospital asked to their colleagues of centralized laboratory an improvement of the quality of these tests: at the end of 2015 a new report of EQA, had be sent to health involved personnel.

About the prescriptions the data of the study were related to:

- Incorrect prescription of the tests
- Test's numbers (more than eight)
- Illegible writing
- Absence priority codex
- Incomplete or incomprehensible data

About viral controls the tests out the second SD the data were related to:

- Syphilis western blot IgG-IgM (MarDx, Carlsbad, USA)
- HTLV I-II (Avioq, North Carolina, USA, T-cell lymphotropic test)

In December 2014 has been done a final report. The frequency distribution of errors was studied using χ^2 test. The EQA of the tests returned to general medical doctors and oncologists was performed by Biodev (Milan, Italy).

3. RESULTS

The comparison of prescriptions from 2013 January to 2014 December has highlighted the a statistically significant decrease in the number of incorrect exemptions between 2013 vs 2014 ($p < 0.05$, χ^2 test); (Table 1). Also the all other incorrect modalities of prescription showed a decrease (Table 2).

About the external quality assessment of the Syphilis test and HTLV I II test, there was an

improvement of EQA: The tests' data, compared with the data of Reference Laboratories that using the same methodology, showed a decreasing of indeterminate tests and a re-entry of the values in the first or second standard deviation (Figs. 1, 2, 3, 4).

The cord blood harvesting improved from 31 collected bugs in public system and 28 in private system of the 2013 years, to 40 and 32 respectively of the 2014 year.

Table 1. Tests and exemptions in public and private system

Harvesting tests requested	Time of collection of samples of pregnant women for public system	Time of collection of samples of pregnant women for private system	Exemption in private system	*No exemption public system	Compulsory tests in public system
HCV	Third trimester	No more 30 days from delivery	No	Yes	Yes
Hepatitis B pattern	—	No more 30 days from delivery	No	Yes	No
HBs Ag only	Third trimester	—	—	—	Yes
HIV 1/2	Third trimester	No more 30 days from delivery	No	Yes	Yes
SYPHILIS TEST	Third trimester	No more 30 days from delivery	No	Yes	Yes
HTLV I-II (if endemic area)	Not requested	No more 30 days from delivery	No	Yes	No

Note: * Supplementary ticket in private system (€300)

Table 2. Total number and percentage of 3300 not conforming prescriptions (1680 in the year 2013, 1720 in the year 2014)

Prescription	Total number 2013	Percentage 2013	Total number 2014	Percentage 2014
*Incorrect exemption	450	26.78	20	1.16
Tests' number more than eight	110	6.54	61	3.54
Illegible writing	80	4.76	32	1.86
Absence priority codex	71	4.28	22	1.27
Incomplete or incomprehensible data	62	3.69	21	1.22

Note: * $p < 0.05$, χ^2 test

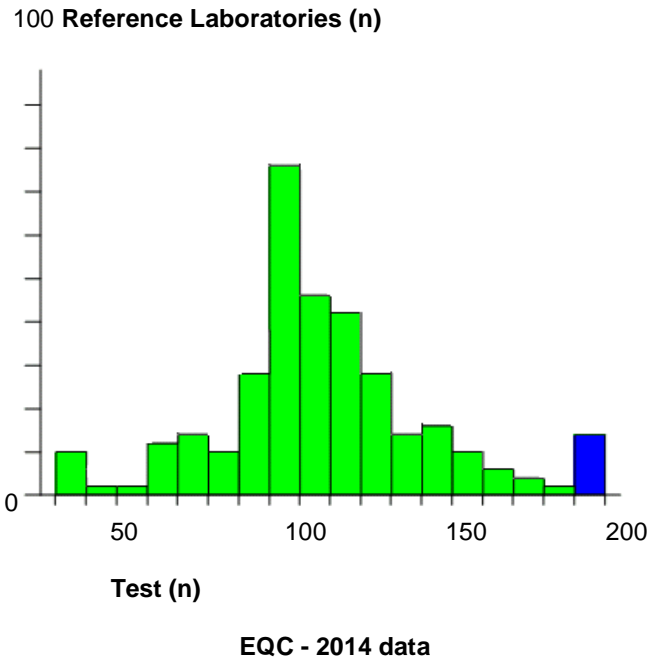


Fig. 1. Syphilis western blot IgG-IgM. 2014 year, EQC test data control. In black our indeterminate tests compared with references laboratories (middle column)
Abbreviation: EQC: external quality control

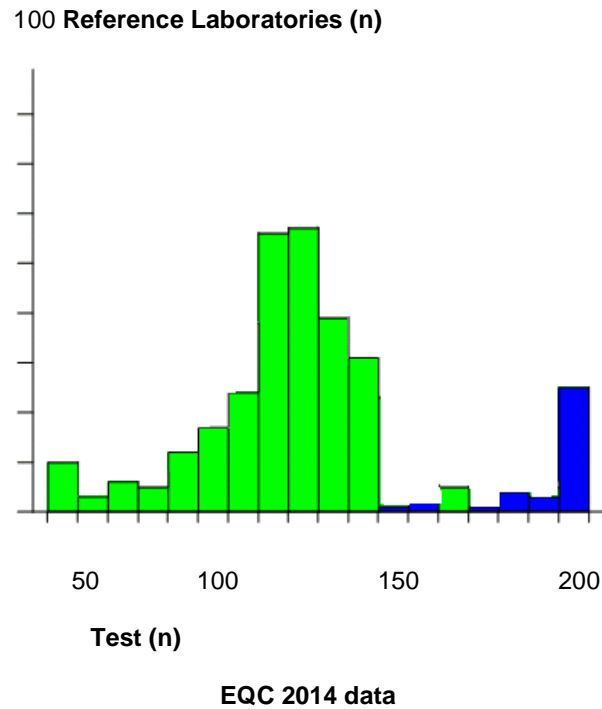


Fig. 2. HTLV I-II T-cell lymphotropic virus. 2014 year, EQC test data control. In black our indeterminate tests compared with reference laboratories (middle column)
Abbreviation: EQC: external quality control

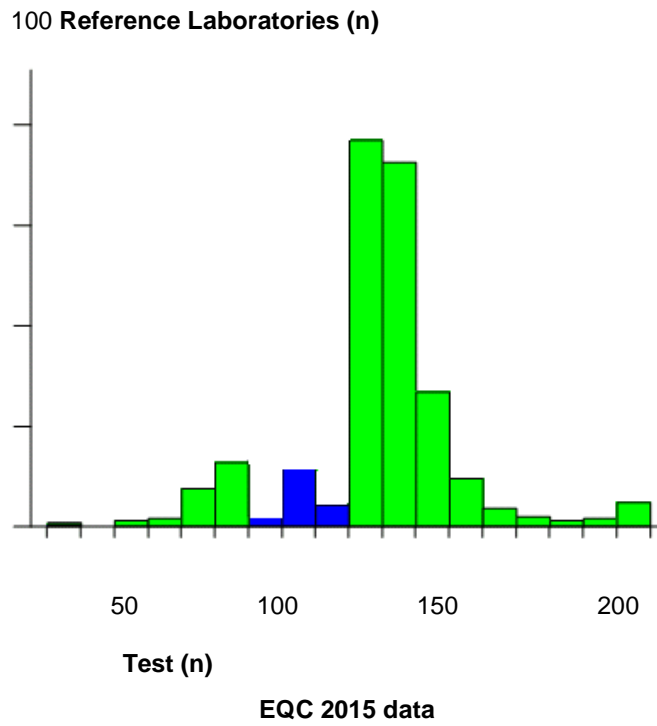


Fig. 3. Syphilis western blot IgG-IgM. 2015 year, EQC test data control. In black our indeterminate tests compared with other reference laboratories (middle column)
Abbreviation: EQC: external quality control.

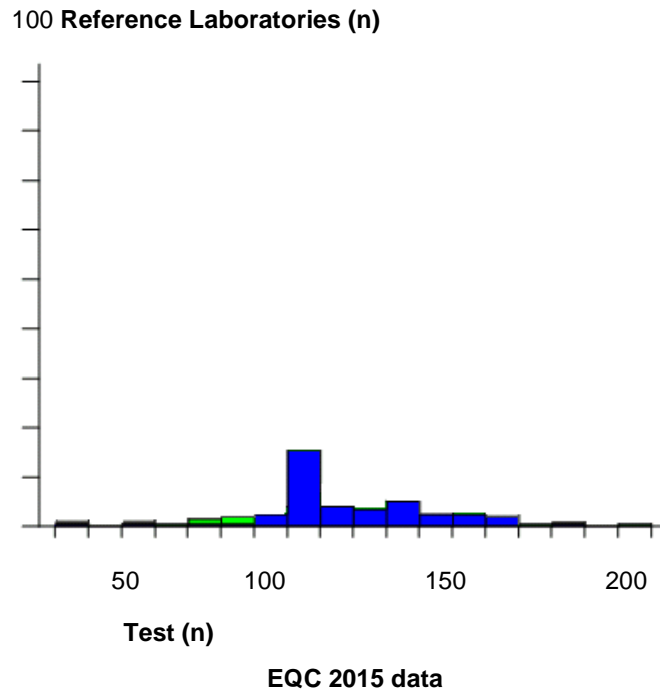


Fig. 4. HTL I-II T-cell lymphotropic virus. 2015 year, EQC test data control. In black our indeterminate tests compared with reference laboratories (middle column)
Abbreviations: EQC: external quality control

4. DISCUSSION

According to actual indications of appropriateness, the best approach to health and treatments needs specific professional competences, adherence to guidelines/consensus, affordable organization and efficient information technology assessment, in order to obtain the best outcome. The quality of the tests is an answer to the clinical request to connect experience, control and data communication to the colleague, and to overcome the barriers in which Laboratory Medicine is often confined. The improvement of cord blood harvesting without interferences by informal prescriptions, the security of the results of the tests for cryopreservation and oncology cares, the attention to avoid the costs, are the some aspects that concern medical competences of many specialities and the general medicine doctors prescriptive appropriateness.

The transformation in a new healthcare system with monitored expenses is a work in continuous progress and, in consideration of economic problems, is the only method to support public and private health system. The doctors must be protagonist of this development [22,23].

This work looks for that appropriateness of the request and the quality control of the tests are essential to avoid incorrect cures and usefulness expenses, but this approach must be compulsory for all the health workers, not only general medical doctors and specialists. The cord blood collection also and the transplants should be improved, with sustainable costs [24,25].

General medicine doctors, physicians and all care personnel are called to enormous challenge to avoid errors and formal omissions.

The public expenses in sanitary system must be connected with the improvement of the cures: The rewriting of incorrect prescriptions and exemptions and the bad quality of laboratory tests are a problem of medical appropriateness and scientific method to approach properly to this part of sanitary system. Our data stress the continuous use of the sanitary activities monitoring with updated protocols and severe controls, as key point to improves cures and to avoid improper costs in public health. There are many problems to improve, without useless costs, also the umbilical stem cells collection for transplantation purpose and to cure oncology

diseases. This experience emphasizes the importance of monitoring and controlling the many factors which are only apparently beyond the jurisdiction of the laboratory but are, on the contrary, the same problem of medical appropriateness and scientific method to the best approach to the sanitary system [26-33].

5. CONCLUSION

The evolution of the concept of "appropriateness" confirm the role of proper prescriptions in public health, as evidence-based medicine care, and as economic problem to make a sustainable medicine. Nevertheless, the large majority of reports are still dedicated to the methods of tests' execution. The ultimate challenge may be to recognize openly the national and regional political rules as measures of evidence and control, and to extend the role of proper prescriptions also to the external specialist and general medicine. The need to promote the appropriateness in all medical fields increased in these recent years in the world and in the Italy. The scientific societies, in according to the national public health system and to the reduction of health costs, promote and promulgate protocols to make possible the cures with adherence to the correct prescriptions and prevention management. The improvement, in this study with regard to cord blood harvesting and quality tests, is an approach to a care with a global involvement of gynecologists, hematologists, physicians and medical practitioners.

CONSENT

All authors declare that written informed consent was obtained from the patient (or other approved parties) for publication of this paper and accompanying images.

ETHICAL APPROVAL

The authors have obtained all necessary ethical approval from ethics committee of Institute for Maternal and Child Health of Trieste. This confirms either that this study is not against the public interest, or that the release of information is allowed by legislation.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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