

A multicentre twinning for authorizing/auditing transplant centres: approach and lessons learnt

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Accord WP6

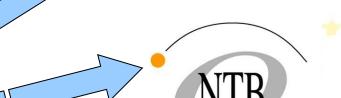




Czech Republic Koordinacni Stred

Koordinacni Stredisko Transplantaci (KST)





Lithuania

National
Transplantation
Bureau (NTB)



Italy

Centro Nazionale Trapianti (CNT)



Cyprus

Ministry of Health (NoH)

Authorisation and Audit system for Transplant Centres



Malta

Mater Dei Hospital MoH: Superintendence of Public Health :Health Care

Standards Directorate





THE CHOSEN APPROACH

Authorization needed to start activity

Authorization of teams and centres

Check on application of protocols

Periodic auditing of transplant centres

Check on activity data

Collection of activity data and evaluation of outcomes

Check on supplied outcome data





GUIDE DEVELOPMENT

An Authorization and Audit system for Transplant Centres (AATC)

•A two step procedure: analysis of each country's system through the paper work, development of guide for Authorizing and Auditing tx systems



FINAL PRODUCT: OCTOBER 2012

Guide with Essentials for developing Authorization & Audit systems



Accordination in Organ Donation

GUIDE INDEX

- 1. Introduction
- 2. Authorization / accreditation procedures
- 3. Evaluation of transplant outcomes
- 4. Vigilance system and reporting of adverse events and reactions
- 5. Auditing
- 6. References

ANNEX 1. SAMPLE LIST OF ASPECTS TO BE CONSIDERED IN AUDITING KIDNEY TRANSPLANT CENTRES

ANNEX 2. SAMPLE LIST OF ASPECTS TO BE CONSIDERED IN AUDITING LIVER TRANSPLANT CENTRES



ACCORD THE TRAINING COURSE

COURSE STRUCTURE: <u>designed Oct-Nov 2013</u>

<u>3-week e-learning plus face to face</u>

Participants: 11 staff members from National Competent Authorities from Malta (Paul Calleja, Miriam Azzopardi), Czech Republic (Pavel Brezovsky, Premysl Fryda, Eva Pokorna) and Lithuania (Audrone Buziuviene, Asta Kubiliene, Vita Gembutiene, Vytautas Zekonis). Staff from Cyprus (Michalis Voniatis, Xenia Ashikales) for e-learning only

Faculty: coordinators, kidney, liver and multiorgan surgeons, quality manament experts, quality evaluation experts



TRAINING CONTENTS

Nov 2013 - Feb 2014

The main <u>objective</u> was first getting acquainted with <u>selected</u> relevant documents available from existing national (such as Italian or French systems) or international (Council of Europe recommendations) organizations.

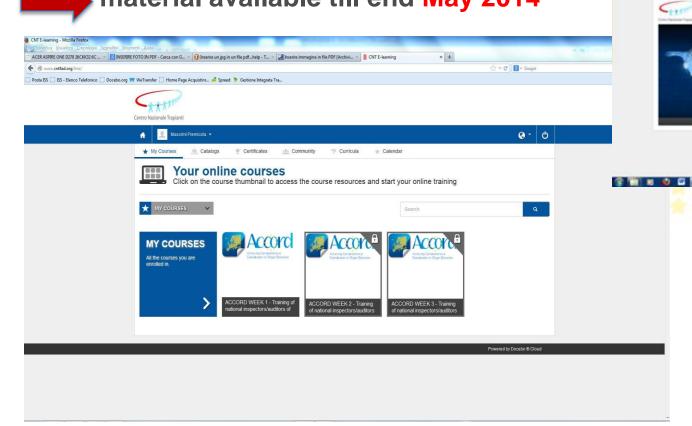
A second aim was <u>incentivate discussions</u> between participants about their experience with local situation both during **E-learning forum** as well as during **face-to-face simulations**



E-LEARNING PHASE

Nov - Dic 2013

Performed through CNT E-learning platform
 material available till end May 2014



ACCORO Achieving Comprehensive Coordination in Organ Donatio

FACE-TO-FACE

Rome, February 5-7 2014













Face-to-face contents and training methodology:

- ♦ Audit and self evaluation
- Interactive discussion on issues of single countries (final assignment from E-learning phase)
- Presentations from surgeons, tailored on outcomes of onsite visits
- ♦ Role playing at atransplant centre



Face to face Course - February 5-7 2014 - Rome

Closing
Round table: Feedback and suggestion S. Chatzixiros, V.Sparacino, C.Font Sale
Presentation of power point elaborated from each participating country (10 minutes each)
Coffee break
Question and remarks
Possibility of self evaluation Audit C. Font-Sala - H. Cresvaux, ABM, France
Audit methodology - external evalutation V. Sparacino- IT
Welcome and presentation
4.00 – 18.00 <i>- AULA ZAMPIERI Via <mark>Giano della</mark> Bella,</i> 34

February 6th – 9.00 – 13.00 POLICLINICO UMBERTO I° <u>Dept Paride Stefanini, IIIrd</u> floor, Room Manlio Carboni

Onsite Visit at Multiorgan Transplant Centre at Policlinico Umberto I°, Viale del Policlinico 155, Rome

9.30 - 9.45	Simulation of audit visit. F. Nudo, V. Sparacino, F.D'Alessandro, S. Chatzixiros - IT
	Participants are divided in two groups of auditors. A filled audit form is distributed and time
	is allotted for revision of answers.

9.45 - 10.00 Transplant centre staff available for questions from auditors groups to clarify doubtful items

10.00 - 10.15 Coffee Break

10.15 - 10.45 An auditor/audited experience - P. Berloco - IT

10.45 – 13.00 Feedback from groups with critical discussion on methodology, proposed forms, which aspects should be analyzed in each country's reality

Moderators: F.Nudo, V.Sparacino, F.D'Alessandro, S.Chatzixiros

13.00 - 14.30 Lunch

 February 6th – 14.30 – 18.00 AULA ZAMPIERI, Via Giano della Bella, 34

 14.30 – 15.00
 Evaluation of transplant outcomes – M. Caprio - IT

 15.00 - 15.30
 Adjusted ys crude survivals – M. Caprio - IT

 15.30 – 16.00
 Coffee break

 16.00 – 16.30
 Question and Remarks

16.30 Closing

February 7th - 9.30 - 13.00 AULA ZAMPIERI, Via Giano della Bella, 34

Inspiration from other sectors

9.30 – 10.15 The tissue experience: EUSTITE and SOHOVS training for inspectors – **D.Fehily-IT**10.15 – 10.45 Coffee Break

Transplant centres from authorization to certification - National and international standards:

 10.45 - 11.30
 Kidney Transplant Centre - L. Furian - IT

 11.30 - 12.15
 Liver Transplant Centre - R. Romagnoli - IT

 12.15 - 12.30
 Question and remarks

12.30 – 13.00 PRACTICAL WORK (to be discussed)

13.00 Closing



ROLE PLAYING





SIMULATION OF AN AUDIT OF LIVER TRANSPLANT CENTERS

ACCORD training course on quality assurance of transplant centres

AUDIT FORM SECTIONS

- 1. Organizational chart
- 2. Technical features of the surgical facility
- 3. Waiting list management
- Activities of retrieval and transplant from deceased donors
- 5. Results and post-transplant follow-up
- 6. Review of medical records of patients on the waiting list
- 7. Review of medical records of transplanted and followed up patients

‡ +		
	Transplant Contra	DATE AUDIT
	Transplant Centre	
Facility where the transplant centre is located:		
	Address	



STUDY VISITS: eving Comprehensive rdination in Organ Donation before and after

Two sets of study visits were conducted in the twinned countries:

- ♦ To discuss the feasibility of transferring or adapting the guide to local situation JUNE-SEPT 2013
- ♦To perform joint inspections APRIL-MAY 2014

Meetings were held with local authorities and transplant centre responsible persons.

Visiting teams were typically made of experts of quality management and transplant centres inspectors. In each team a surgeon and/or clinician expert in the specific activity of the visited centre was included.

Reports were drawn up after each visit.



AFTER THE TRAINING....



CNT provided continuous support to twinners in transferring and adjusting the proposed system to their local needs.



Czech Republic and Lithuania twinners asked for a formal joint audit



Malta asked for a second expert meeting at transplant centre with all local actors with the aim of clarifying possible solutions to local needs



CONCLUSIONS

Experience and know-how were successfully transferred in three out of four countries

Two countries, Czech Republic and Lithuania, have taken huge steps forward in making the results of this transfer permanent

Malta and Cyprus have not launched a national auditing program, mainly because of their small size, but there are important ongoing activities to improve the approach to local issues, through international cooperation.



TWINNING LEGACY

The proposed Guide on Essentials for developing Authorization and Audit systems of Transplant Centres has shown to be easily adaptable to every National Health system within the EU, it has the potential to be widely distributed and adopted by other member States, and the same goes for the E-learning training programme for auditors.

On such basis, the idea of **building international team of auditors** could become a reality and this would be of enourmous **interest for countries with a limited number of transplant centres**, where conflict of interest between specialists exists, for the sake of comparison with other European realities, but with a sound attention to the specifities of each national situation.



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