

WP5 - Outcome of counselling:

i) National expert contact in Valencia (Spain):

Counselling started at national level, making contact with the maximum experts of legal medicine at University of Valencia (Spain) and at the Medical College. Firstly, we interviewed Dr. Marina Gisbert Grifo from the Legal Department at University of Valencia. She stressed the fact that they have never had any notice of a particular claim to a multidisciplinary team. This might be related to the fact that a decision is made by a wide number of physicians and not a unique person makes the decision more credible and robust.

Then, we contacted with the Legal Department of the Medical College in Valencia. As Dr. Gisbert announced, they haven't managed until the date any particular claim that has been performed to a multidisciplinary board. They don't know about previous cases.

Both experts, at University and at the Medical College suggested that in order to preserve medical responsibility it is essential that a formal informed consent is prepared with the complete information of how the information of the patient is going to be discussed by different experts and always warning of the possible side-effects that can occur if the decisions of the multidisciplinary team are followed (surgery, chemotherapy, radiotherapy or other particular treatments). If an informed consent is signed by the patient or relatives explaining the whole process of the multidisciplinary discussion, there should be no legal problems related to the tumour board. In this case, any possible errors or associated medical negligence are to be treated as any other normal medical activity and has nothing to do with the entire tumour board. All of these matters should be specified in the informed consent so the tumour board is exempt of liability.

ii) International expert contact:

According to an agreement at the ExPO-r-Net meeting in Brussels (21.05.2015) contact was made with Nikolaus Forgo as medico legal international expert that has already been in cooperation with The European Network for Cancer Research in Children and Adolescents (ENCCA) project.

The opinion expressed was that the issue is indeed rather complex and the main point we will have to be mindful of is who is liable for the decisions of the board. On the one hand, there is the physician of the patient, on the other the treating advisory TB itself. This is a specific medical law issue and it will heavily depend on the national legislation in each country. Therefore, if a virtual tumour board is held within members of different countries - which will be the case in the ExPO-r-Net network - the responsibility of a possible claim will be different according to the countries involved.

The second main concern about patient confidentiality was also discussed. The use of videoconference systems with the scope of discussing a particular patient will always mean processing of patient data and hence needs a legal ground for the processing. Furthermore, the data will be shared across many hospitals. Usually the processing of patient data in care is based on the so-called care exemption, which allows the care provider to process patient data. Sharing data with a virtual tumour board may be seen as reaching beyond what is considered normal care practice, hence, we should also consider whether asking the patient for specific consent should be an option. We should also always remember that the persons with whom the information is being shared should remain under the obligation of medical secrecy. (CDAs between centres / MDs involved in the VTB.)

A specific conference system fulfilling the requirements of security and confidentiality is needed for this purpose. This is a requirement from the view of medical law or right

(confidentiality), as well as from the data protection law.

iii) Summary and practical issues

- Legal experts aren't aware of previous claims to a multidisciplinary tumour board.
- Liability of a medical issue is currently determined in each country by national legislation.
- A standard informed consent is needed to exempt the tumour board of any legal responsibility.
- Sharing data with a virtual tumour board is beyond normal care practice so the patient must be asked for consent.
- A legal ground for processing data is needed and individuals sharing virtual information must remain under the obligation of medical secrecy.

D. REQUEST / ANSWER FORMS

Specific request and answer forms for virtual tumour boards have been designed for this purpose. The request form gathers all the main information that needs to be considered in order to address a patient's need in a tumour board. It must be completed by the patients' physician prior to the meeting. After the discussion takes place, an answer form collecting all the conclusions and final recommendations made by the tumour board must be available. This form will be completed by the tumour board coordinator and sent to the individual physician that made the initial request. (For the original documents see ExPO-r-Net intranet).

E. INFORMED CONSENT

A specific informed consent for virtual tumour board discussion has been created. The document underwent an internal and external review and the fourth version was finally accepted on the 19th October 2015. The following questions are explained in the document:

i) Introduction

This is an invitation for your child's diagnosis and treatment to be discussed in a virtual tumour board of the ERN-PaedCan. This can only happen if you give your informed consent.

Your child has been diagnosed of a particular type of cancer. Cancer in children is a rare disease and because of the low number of cases per year, extensive experience is difficult to acquire in any one hospital treating children's cancer. Many of the cases are complex and challenging and require a detailed consideration of the different therapeutic options available. There is less experience than in other types of common diseases where a standard treatment is officially established.

Due to the specific nature of your child's cancer, the decision on the best treatment for your child may benefit from discussion at an international multidisciplinary virtual meeting to exchange opinions from established experts in this type of tumour. If you agree to this discussion, your informed consent is required to allow your treating physician to present your child's case to the VTB and share information about your child's case

ii) What is the ERN-PaedCan?

The Paediatric Oncology European Reference Network is network aiming to facilitate

“Cross-border healthcare” allowing children and young people with cancer access to expertise and specialist healthcare in a Member State other than the Member State of affiliation.

European Reference Networks (ERNs) are a feature of the EU Directive on Cross-Border Healthcare aiming to unite the best specialists from across Europe to tackle complex or rare medical conditions that require highly specialised healthcare and a concentration of knowledge and resources.

iii) What is a tumour board?

A tumour board comprises a multidisciplinary team of experts including paediatric oncologists, radiologists, surgeons, radiotherapists, pathologists, etc., discussing clinical cases where the diagnosis and treatment plan is complex. The clinical management of a patient following a discussion at a tumour board takes into account the opinion of several experts participating in the meeting.

Tumour boards are standard practice in specialist paediatric oncology centres and are part of the normal decision making process for treatment of children with cancer.

iv) What is a virtual tumour board?

A virtual tumour board is a special type of multidisciplinary meeting based on IT videoconference systems allowing the involvement of experts from different specialist centres throughout Europe. The virtual tumour board may convene rapidly to discuss urgent cases.

v) Why am I being asked for my child’s case to be discussed in a virtual tumour board?

The particular case of your child is considered “complex”. This means that the clinical features of your child’s cancer are not typical or the type of cancer does not have a standard way of treatment and there may be several treatment options that can be considered. Your doctor feels that a discussion between multiple international experts would help to determine the optimum treatment for your child. It is possible that several types of treatment may be needed and they will involve different types of specialists. Discussion with experts in the diagnosis and treatment of your child’s cancer may help your doctor to decide the best option available.

vi) Will my child’s personal data be protected?

Yes. Data will be shared across secure information technology platforms and videoconference systems that comply with the EU data protection regulations. Personal and medical details need to be provided to allow a recommendation but only physicians and data managers involved in the tumour board will have access to these data. All the members of the virtual tumour board and physicians whom the information is being shared with will remain under the obligation of medical confidentiality.

vii) What other options do I have?

Participating in an ExPO-r-Net tumour board is not obligatory and is not necessarily the only option to get advice for the treatment of your child. The ERN-PaedCan tumour board

ensures that the opinions of international experts in each type of cancer are taken into account. If you do not wish that your data is shared and evaluated by the multidisciplinary international team, you may follow the decision of your treating physician at your institution. This would be the standard way to decide the best treatment in a normal situation.

viii) Is the decision of the tumour board the final one?

No. The recommendation will be communicated by the Virtual Tumour Board co-ordinator to your treating physician by a summary of discussion and the agreed recommendations. Your treating physician will discuss these recommendations with you. You must be aware that you and your treating physician do not have to accept the recommendations made by the virtual tumour board. The final decision on the best treatment for your child will always be taken by your treating physician and yourself. The recommendations of the Virtual Tumour Board are an optional advice that may help to take this decision.

F. STANDARD OPERATIONAL PROCEDURES

A summary document designed to establish standard operational procedures (SOPs) for the creation of Virtual Tumour Boards has been created and disseminated to the community in the bi-annual meetings.

1. OPERATIONAL POLICY

i) Introduction

The purpose of this document is to create a standard operational procedures for an optimum management of the VTB.

ii) Purpose

Multidisciplinary care is the hallmark of high-quality cancer management and is demonstrated in activities such as multidisciplinary consultation and clinics, morbidity and mortality conferences and multidisciplinary cancer conferences. In the case of ERN-PaedCan, virtual tumour boards (VTB) will substitute ordinary presence meetings to give the patients in Europe the maximum quality decisions taken by experts of each paediatric malignancy.

A VTB is defined as a regularly scheduled multidisciplinary virtual conference to prospectively review individual cancer patients and make recommendations on best management, keeping in mind that individual physicians are responsible for making the ultimate treatment decision. The crucial element in the VTB and the difference between ordinary meetings in a single institution is that the expertise forum meet together by means of virtual IT technology, making this able to gather physicians from all European countries without needs of traveling.

Primary function

- Ensure that all suitable treatment options and the most appropriate treatment recommendations are generated for each cancer patient discussed prospectively in a multidisciplinary virtual forum.

Secondary functions

- Contribute to patient care quality improvement activities.
- Contribute to the development of standardized patient management protocols.

- Contribute to innovation, research, and participation in clinical trials.
- Create links among European countries to ensure appropriate referrals and timely consultation to optimize patient care.
- Unify criteria for the treatment and management of patients so survival rates are equally improved.
- Provide a forum for the continued education of medical staff and health professionals.

iii) Objectives of VTB

- 1) Ensure that designated specialists/experts work efficiently together.
- 2) Ensure that care is based on agreed international wide clinical guidelines, whenever possible
- 3) Ensure that mechanisms are in place to support entry of eligible patients into clinical trials.
- 4) Improve communication and enhance professional skills and knowledge between VTB members.
- 5) Identify service gaps or breakdowns in coordination so that they can be rectified.
- 6) Find optimal treatment solutions for an individual patient's cancer case based on shared expert knowledge and advice.

2. PRACTICAL FUNCTIONING - VTB STRUCTURE

2.1 ROLES AND RESPONSIBILITIES

In the participation of VTB there are 4 specific responsibilities that are carried out by different members:

- a) Individual Physicians —> Requestors
- b) National Tumour Group Coordinators
- c) VTB Coordinator —> Scheduler and Preparator
- d) Expertise - Members of VTB

i) Individual Physicians

Individual physicians are responsible of:

Making the request for the VTB via specific national tumour group coordinator.
 Provide patient case summary to VTB Coordinator (Standard Request Form available).
 Ask the patient for specific informed consent (See standard documents).
 Discussing the treatment options accepted at the VTB with the patient and making the ultimate treatment recommendations.
 Entering the VTB recommendations and the patient's final decision about their treatment into the medical record.

ii) National tumour group coordinator

The national tumour group coordinator is responsible of:

May propose VTB involving the national level only.
 Filtering national request forms from individual physicians to the VTB Coordinator.
 Resolving affordable proposals that can be worked out without the international VTB to avoid an excess of proposals.
 Ensuring patient confidentiality is always maintained.
 Establish contact between the individual physician with the VTB Coordinator if the request

is accepted.

iii) VTB Coordinator (national or international)

The Coordinator is responsible for the administrative management and individual meeting functioning. The following roles and responsibilities are carried out by the VTB Coordinator:

- Preliminary organization of the VTB.
- Creating the list of patient cases, based on the cases forwarded by individual physicians.
- Setting and starting the videoconference system.
- Schedule the meetings and ensuring availability/functioning of all the equipment.
- Notifying all core members and making a selection of expertise according to the patients to be reviewed in the board.
- Ensuring all relevant up-to-date patient information and imaging (including related electronic imaging) are entered in the system prior to the meeting.
- Recording attendance.
- Distributing annual attendance records. Make an annual report of activities
- Coordinating VTB evaluations.
- Ensuring that all forwarded cases that have been selected for presentation are discussed within the allotted time.
- Encouraging participation of all VTB members and facilitating a team environment.

iv) Expertise - Members of VTB

Responsibilities of expertise or official members of the VTB are:

- To form part of an official "Expertise VTB List" (linked to the ERN-PaedCan road map)
- Participate on the VTB when requested by the VTB Coordinator.
- Read and prepare the cases for the discussion before the meeting.
- Have an able connection and IT facilities in order to participate in the VTB from their local institutions.
- Compromise of attendance to the meetings.
- Ensuring that the patients' confidentiality is always preserved

2.2 MEETING PROTOCOL

The following section describes important details of the VTB and how it will operate to fulfil its objectives.

i) Meeting Time

The VTB will convene at a regular interval. (Frequency of meetings may vary by entity)

The meetings are scheduled to last for 1 hour approximately.

ii) Meeting Venue

The VTB will be held using the videoconferencing system proposed by the ExPO-r-Net.

Other IT platforms will be available to share previous information, whenever they are secure and approved to be used within the net.

iii) Notification of Meetings

The VTB Coordinator will send a bi-weekly reminder to the participants and administrative support. This reminder will include the patient case presentation agenda and details.

The notification will be sent by the VTB Coordinator in the agreed upon time intervals according to entity specific sub-networks or twinning partner.

iv) Meeting Agenda

In order to compose an agenda, the primary physician must forward patient cases to the National tumour group Coordinator (timely in advance – or at least three working days) that will filter the proposals to the VTB Coordinator.

The physician will provide the information requested in the Standard Request Form.

The VTB Coordinator will distribute the VTB patient case presentation agenda as a weekly notification to all the VTB Members (expertise). The notification of a particular case must be done at least 3 days before the meeting so individual physicians can prepare the exposure of the case.

A VTB standard virtual agenda will be used.

v) Case Review Procedure

Once the patients to be discussed have been decided, it may be necessary to implement priority categories, whereby the purpose is to ensure that the critical cases are reviewed first at the VTB.

Patients will be categorized based on the discretion of the primary physician. The categories are:

A = Urgent case to be discussed in the upcoming VTB and a treatment plan must be determined as soon as possible. These cases will be reviewed first at the VTB.

B = Important that the case is discussed at the upcoming VTB, but it is not imperative.

C = Not imperative for the patient case to be discussed in the upcoming VTB.

vi) Membership

Attendance of the required VTB members or expertise is imperative for the proper functioning of the VTB. To ensure all possible treatment recommendations are considered, representation from all required disciplines, as specified by the VTB disease site attendance criteria, is necessary.

Attendance is expected for the majority of sessions. When a required member cannot make a meeting, their designated backup will be in attendance.

Depending on the disease site VTB, representation from all or a combination of the following disciplines is required:

- 1) Paediatric oncology
- 2) Diagnostic radiology
- 3) Surgery/surgical oncology
- 4) Pathology
- 5) Radiation oncology

All required members will have a named designate who will attend on their behalf when the primary member is unable to attend the VTB.

Representation from the following disciplines is optional:

- Medical Oncology
- Teenager and young adult oncology
- Primary care physician
- Social services

- Nutrition therapy
- Pharmacy
- Nuclear medicine
- Genetics
- Pain/palliative care
- Data management
- Rehabilitation

vii) VTB Meeting Discussion Documentation

Physicians providing health care to patients are under obligation to be maintaining patient health records and to keep the information confidential. The most important aspect of documentation is that there is a clear record of relevant information about the significant aspects of the patient's healthcare. Input provided at a VTB would qualify as information that should be recorded.

Presenting physicians should complete a VTB Standard Request Form, outlining details such as the patient's diagnosis and summary, radiology and pathology findings, as well as the VTB discussion and treatment recommendation. A record of the VTB discussion, for each patient, should be kept by the VTB Coordinator and a Standard Answer Form is generated for each particular case discussed.

In addition to maintaining VTB documentation, the presenting physician should update the medical record with the final treatment plan recommended by the VTB.

2.3. URGENT CASE PROCESS

If an urgent case needs to be discussed in a VTB forum, but cannot wait for a regularly scheduled meeting, there is an alternative option. An email discussion will take place among the VTB members so that timely patient care is not compromised. This will be easily facilitated by using an email distribution list of VTB members, to be maintained and updated by the VTB Coordinator.

The primary physician will distribute the required information to the national tumour group coordinator such as the patient summary via an email and the national coordinator will direct the email to the VTB Coordinator. To easily recognize these emails the subject line should quickly identify the purpose and time sensitivity of the email response (subject line: Urgent VTB Case Review).