Training Manual on Quality Criteria and Quality Indicators
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1. INTRODUCTION

The ODEQUS indicators are measuring tools that indicate the presence and intensity of an organ donation event and which are based on a system in quantitative measures again and again, to which is referred to as 'monitoring'. The indicator is a quality criterion that assesses the level of quality achieved by an organ donation unit.

Individually each ODEQUS indicator provides information timely and referred to a unique aspect of the donation process (Living or deceased), but to have enough information that allows identifying the level of quality of the unit is necessary to monitor a selected set of indicators. Indicators monitoring systems are conceived as an overall assessment of a service, which evaluates a set of practice in organ donation on a regular basis and allows professionals to have an overall view of the quality of the Organ Donation Unit.

The ODEQUS Training Manual was developed by experts from Avedis Donabedian Institute (Spain) and by ODEQUS Project experts in the framework of the Organ Donation European Quality System (ODEQUS Project), co-financed by the Executive Agency for Health and Consumers, contract PHP 2009110. During the project the experts have reached a consensus on the best practices in organ donation and were trained on how to develop and apply Quality Indicators based on the selected criteria. The present Training Manual is a compilation of the training performed during the project, through this Manual the further professionals trained will have the capacity to apply the ODEQUS Quality Criteria and Quality Indicators at hospital level.

Additionally it should be recalled that the adoption of a system of indicators monitoring implies commitment from the Organ Donation Unit of acting in the moments in which evaluated practice gives information of results according to the standards established, discuss results achieved, identify causes and develop improvement actions when need it. Otherwise, the measurement becomes a routine and does not have any utility in the management of the Unit; this last one is another reason of the importance to train the professional before applying the ODEQUS Quality Criteria & Indicators.
TRAINING OBJECTIVE

To introduce and put into practice the use of ODEQUS Quality Indicators and evaluation/auditing procedures, both for organizational structures and clinical procedures of organ donation services, defined and based on the ODEQUS Quality Criteria list.

PROFESSIONALS COMPETENCES

Professionals will be able to:

1. Identify different aspects of the Quality Improvement Process specifically applied in the donation and transplantation area.
2. Differentiate Quality Criteria and Quality Indicators used/applied/developed in the daily hospital practice.
3. Know how to apply methods of statistical analysis and transformation of results to process/develop/obtain relevant information in the field of donation.
4. Develop leadership skills to manage the organization of the donation process in order to improve quality control systems.
5. Use different type of information and communication technologies (ICT) as tools for data collecting and analysis.
6. Identify the main reasons of escapes in the Deceased Organ Donation Process at hospital level.
7. Participate actively in improvement actions for the living/deceased organ donation process within the hospital.

PROFILE OF THE TRAINED PROFESSIONALS

The training program in Quality Criteria and Quality Indicators is address to:

- Donor/Transplant coordinators
- Healthcare professionals involved in the donation field
- Professionals from the hospital Quality Department
- Regional authorities in organ donation and transplantation
- National authorities in organ donation and transplantation
TRAINING PROGRAM

Proposal of contents for a three full-day program in Quality Criteria and Quality Indicators in Living and Deceased Organ Donation are specified below:

Day 1

- Introduction to Quality Programs in Organ Donation
- Terminology
- Mapping best practices in organ donation considering structure and processes.

**Main goals of work day 1:**
- Reach a consensus about the best practices in organ donation.
- Agreement concerning the general mapping (methodology and contents).
- Quality Criteria details and the way it’s stated.
- Understand the terminology and explanation of terms.

Day 2

- Quality Criteria
- Quality Indicators

**Main goals of work day 2:**
- Realize the importance of selecting good QC in order to create effective Indicators.
- Decide what to measure (quality criteria).
- Develop the measurement tool (indicator).
- Set the expected result.
- Validate the indicator (relevance, feasibility, reliability).

Day 3

- How to apply the Quality Indicators in a hospital
- The hospital evaluation process
- Internal and External Audits
- Clinical Cases

**Main goals of work day 3:**
- Understand the internal and external hospital evaluation process (Audits)
- Test the applicability and feasibility of indicators (clinical cases)
QUALITY CRITERIA AND QUALITY INDICATORS TRAINING

(Lisbon, April 4-5, 2011)
## Development of Quality criteria and quality indicators

### Quality criteria
- Conditions that should be met by the healthcare practice in order to be considered a quality practice.
- Measurable aspects regarding a problem, program or service with which it will monitored

<table>
<thead>
<tr>
<th>Problem / Program</th>
<th>Criteria</th>
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</table>

### Characteristics of quality criteria
- Valid
- Relevant
- Realistic
- Acceptable
- Measurable
- Reliable
- Few

### Sources for quality criteria
- Legal normative
- Ethical and deontological codes
- Care protocols / Clinical practice guidelines
- Scientific literature
- Expert opinion
- Common practice / leading institutions

### Mapping the quality criteria
- Activities - what?
- Working settings/ areas - where?
- Pathologies, types of patients - to who?
- Circuits - when?

### Mapping the quality criteria: Example for ICU

#### Activities
- Diagnostic
- Therapeutic
- Preventive
- Information
- Transfers
- Documental
- Teaching
- Research
- Others...

#### Working settings / areas
- Boxes
- Service areas (storage, pharmacy ...)
- Others...

#### Pathologies
- Cardiologists and CPR
- Metabolism and Nutrition
- Toxicology
- Sedation y Analgesia
- Transplants
- Infections
- Bioethics
- Neurology and trauma
- Nursing
- Other...

#### Circuit
- Admission
- Assessment
- Care
- Transfer to unit
- ....
### Examples of quality criteria

- All patients are informed about their rights and responsibilities in a manner and language they can understand.
- Informed consent is obtained before a patient participates in clinical research, clinical investigation and clinical trials.
- The organization has implemented an approach to ensuring correct-site, correct-procedure and correct-patient surgery.
- Each patient’s initial assessment(s) includes an evaluation of physical, psychological, social, and economic factors, including a physical examination and health history.

### Priorization of quality criteria

- Prevalence (Burden of the disease)
- Risk (mortality, morbidity)
- Cost of lack of quality
- Variability in performance
- Evidence available of the effectiveness of performance

### Quality Indicators

*In God we trust...... all others must bring data.*

_Edward Deming_

### Benefits of assessment using indicators

- Specific aspects of care are assessed
- Quantitative results
- Valid, reliable and objective information
- Early “alarm sign” (identify improvement areas)
- Identification of areas of excellence
- Availability of standards
- Comparison (Benchmarking)
INDICATORS

Expression of the measurement for an event
- Measurable
- Objective
- Acceptable
- Relevant
- Evident-based

MONITORING

Measures and assess in a periodic and planned basis the relevant aspects of care

Indicator: a thing that indicates the state or level of something
(Oxford dictionary)

Indicator: a measure used to determine, over time, an organization’s performance of functions, processes and outcomes.
(Joint Commission International)

Indicators are not:
- A practice guideline manual
- A goal by itself (System to collect data)
- Punitive system for control
- Permanent

Type of indicators
- Structure: Resources and organization of care.
  Ex. Protocol, circuit
- Process: The way care is provided
  Ex. Adherence to protocol
- Results: Achievement of goals
  Ex. Mortality, adverse events, length of stay, nosocomial infections, readmissions, etc.

DEVELOPMENT OF INDICATORS

1 - Decide what to measure
2 - Develop the measurement tool (indicator)
3 - Set the expected result
4 - Validate the indicator

The way things happens in real life:

Main principle: we need to be realistic
2- Develop the indicator

<table>
<thead>
<tr>
<th>Name</th>
<th>Justification</th>
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<tbody>
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</table>

**Dimension**

Characteristics of the healthcare in order to be considered a quality care:
- Effectiveness and appropriateness
- Efficiency
- Safety
- Patient-centered care
  - satisfaction
  - timeliness
  - continuity of care
- Accessibility and equity

**Formula for rate-based indicators**

Portion of the denominator population that satisfies the condition of the performance measure to be an indicator event

\[ \frac{\text{Overall population of interest that the measure is interested in evaluating}}{\text{denominator}} \times 100 \]

- Proportion: The numerator is expressed as a subset of the denominator
- Ratio: The numerator is not necessarily a subset of the denominator (number of patients on fewer than three medications, number of patient days)

**Clarification of terms**

Explanation or definitions for terms included on the formula that are ambiguous or could have several interpretations.

**Type**

- Structure
- Process
- Outcomes

**Data source**

- Medical records or other clinical documents
- Direct observation
- Questionnaires

**Comments**

- Scientific soundness
  - Face validity
  - Construct validity
  - Reliability
- Discussion about
  - Sensitivity
  - Specificity
- References to literature regarding scientific evidence
- Feasibility of measurement
- Data that could be related to the results
- Most common causes of non-compliance
- Recommendations for improvement

3- Establish the expected result

- Theoretical level of achievement that is expected in our environment
- Level of compliance with the criteria being measured that is acceptable based on the specific conditions of each of the centers being evaluated.
Expected results

Are set based on:

- Expert opinion
- Scientific literature
- Statistic description

4- Validate the indicator

-Relevant: The indicator measures characteristics of the healthcare system that are USEFULL for professionals, patients and managers
- Feasibility: Possibility and difficulty to monitor the indicator.
- Reliability: accuracy, repeatability of measurement, degree to which measures are free from error and therefore yield consistent results.

4- Validate the indicator

- Validity: The extent to which the method of measurement reflects the true meaning of a concept being investigated (if it really measures what it is supposed to measure)
  - Face validity: whether an indicator appears to be valid to the persons completing it. “It makes sense”
  - Content validity: whether the measuring instrument captures the true meaning of the concept
  - Construct validity: whether the indicator relates to other variables, as expected, within a given system of theoretical concepts
  - Criterion validity: how well a measure predicts another established criterion

4- Validate the indicator

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Criteria</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant</td>
<td>Impact to health status</td>
<td>Phoenlencir</td>
</tr>
<tr>
<td></td>
<td>Capability of change</td>
<td>Survey, Expert opinion, History</td>
</tr>
<tr>
<td>Scientific evidence</td>
<td>Review</td>
<td></td>
</tr>
<tr>
<td>Feasibility</td>
<td>Antecedents (are it already being measured?)</td>
<td>Survey</td>
</tr>
<tr>
<td></td>
<td>Accessibility (renovator and denominator)</td>
<td>Pilot</td>
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<tr>
<td></td>
<td>Cost of measurement (time)</td>
<td></td>
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<tr>
<td>Reliability</td>
<td>Stability</td>
<td>Test-Retest</td>
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<tr>
<td></td>
<td>Interoobser concordance</td>
<td>Kappa coefficient</td>
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4- Validate the indicator

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Criteria</th>
<th>Method</th>
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</thead>
<tbody>
<tr>
<td>Validity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Face validity</td>
<td>Survey, Number of centers</td>
<td></td>
</tr>
<tr>
<td>Context validity</td>
<td>Nivel de evidencia científica, Recomendación</td>
<td></td>
</tr>
<tr>
<td>Construct validity</td>
<td>Meta análitas</td>
<td></td>
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<tr>
<td>Criterion validity (gold standard)</td>
<td>Sensitivity, Specificity</td>
<td></td>
</tr>
<tr>
<td>Sources of bias</td>
<td>Observer, Instrument</td>
<td></td>
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"Good indicator"

- Valid: Able to identify improvement opportunities (quality problems)
- Sensible: Identifies ALL the events in which there are quality problems
- Specific: Identifies ALL the events in which there are NO quality problems.

Final remarks

1. Indicator’s don’t measure quality, people do
2. Indicators should be valid before being realiable
3. Both valid and reliability are field tested, not based only on expert opinion
4. When people are willing to know, even imperfect indicators can be useful.
Get the data first, and then distort it with your judgment

Mark Twain

WORK PLAN

Development of quality criteria

1 - Proposal of criteria
2 - Methodological review
3 - Agreement and prioritization of final criteria

Work plan

Development of quality indicators

1 - Selection & distribution of topics
2 - Indicator development
3 - Methodological review
4 - Discussion of indicators and final agreements