SF36  
SF12  
(KCCQ)  
Kansas City Cardiomyopathy Questionnaire  
EQ-5D  
Owestry disability index  
Charlson score  
Euroscore  
PCI  
IIEF  
Continence Score  
IPSS Questionnaire  
UFS QOL  
(Uterine Fibroid Symptom and Quality of Life questionnaire)  

Inova / Charité  
Enteryx / Revive  
Revive  
Charite  
Revive  
Sicilian Registry / Taxus  
Sicilian Registry  
Endocare  
Endocare  
Endocare  
UFE
Score and e-CRF

Score implementation in e-registry a big challenge for KIKA
Introduction

 Nowadays more and more clinicians think that it is not possible to separate disease from individual personal and social context.

 In addition risk models are used in order to support surgical/medical decision

 As a consequence health related life quality score implementation in e-CRF going to increase
Score data in medical registry

Score characteristic

- Assesment/Decision Tool
  - Scores are designed for assesment
  - Assesment is performed to make decision

- Demanding data collection
  - The user needs immediately the results
  - The data collection has to be performed at once
  - The patient becomes the person we are speaking to
Expertise and data score management

We need to develop an expertise in implementation of score on line

➢ To capitalize on our experience and knowledge
➢ Centralized information on the score
  ➢ That’s why we are implementing Eventa library

Eventa Library is being implemented in order to set up

➢ score standard
➢ SOPs for score implementation in project

You are welcome to send your comments at:

pc@kikamedical.com
subject: Eventa Library

The different types of score

Risk model

Purpose: this type of score going to provide predictive value based on risk factor (for Euroscore European System for Cardiac Operative Risk Evaluation a mortality predictive value is calculated in adult cardiac surgery).

Method

1995-1999: 19000 patients undergoing open heart surgery has been observed. Risk factors have been defined by statistic analysis method. From this cohorte observation the risk model Euroscore has been created for an European population.
Scientific Validation

- Euroscore has been validated in several countries by trial comparing predictive value of Euroscore with local models or previous systems.
- Euroscore translation has been validated by taking into account cultural differences and/or differences in population.

- This score is now widely used in Europe and elsewhere. It has been well validated and is becoming a reference tool for surgical decision making. Some think Euroscore could be an international standard which can be used as a benchmark for risk assessment in inter-hospital and international studies.
Quality of life assessment

Purpose: A state of complete physical, mental, and social well-being and not merely the absence of disease. It is also agreed that HRQL is multi-dimensional, subjective and, ideally self-administrated.

The scale can be a generic one or aimed at a specific disease.

Method

The height health concept the most used was selected in order to build the SF36. Those concepts have been also chosen because there the most affected by diseases and treatments.

A first selection of 149 items has been performed. And the SF36 form is based on this selection.
Scientific Validation

- The validity of the content of SF36 has been compared with that of other widely used generic health survey.
- The score has to be validated in the specific disease, in the population, in the language.
- SF36 is not aimed to measure sleep adequacy, cognitive functioning, sexual functioning, health distress, family functioning, self esteem, eating, recreation and hobbies, communication, and symptoms and problems that are specific to a particular condition.
Score already set up in Eventa

- Euroscore:
  - Item presentation
  - Type of information collected

- Algorithm:
  - Missing data Management
  - Score calculation
  - Algorithm reference

- Validation:
  - Eventa library
  - Score implementation in Registry

www.euroscore.org
SF-36® Measurement Model

<table>
<thead>
<tr>
<th>Items</th>
<th>Scales</th>
<th>Summary Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>3a. Vigorous Activities</td>
<td>Physical Functioning (PF)</td>
<td>Physical Health</td>
</tr>
<tr>
<td>3b. Moderate Activities</td>
<td>Role-Physical (RP)</td>
<td></td>
</tr>
<tr>
<td>3c. Lift, Carry Groceries</td>
<td>Bodily Pain (BP)</td>
<td></td>
</tr>
<tr>
<td>3d. Climb Several Flights</td>
<td>General Health (GH)*</td>
<td></td>
</tr>
<tr>
<td>3e. Climb One Flight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3f. Bend, Kneel</td>
<td></td>
<td></td>
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<tr>
<td>3g. Walk Mile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3h. Walk Several Blocks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3i. Walk One Block</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3j. Bathe, Dress</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4a. Cut Down Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4b. Accomplished Less</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4c. Limited in Kind</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4d. Had Difficulty</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Pain-Magnitude</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Pain-Interferes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. EVGFIP Rating</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11a. Sick Easier</td>
<td>General Health (GH)*</td>
<td></td>
</tr>
<tr>
<td>11b. As Healthy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11c. Health To Get Worse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11d. Health Excellent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9a. Pep/Life</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9b. Energy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9c. Worn Out</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9d. Tired</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Social Extent</td>
<td>Vitality (VT)*</td>
<td></td>
</tr>
<tr>
<td>10. Social Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5a. Cut Down Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5b. Accomplished Less</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5c. Not Careful</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9b. Nervous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9c. Down in Dumps</td>
<td>Social Functioning (SF)*</td>
<td></td>
</tr>
<tr>
<td>9d. Peaceful</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9f. Blue/Sad</td>
<td></td>
<td></td>
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<tr>
<td>9h. Happy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Significant correlation with other summary measure.
SF36

- Item presentation
- Type of information collected

Algorithm

- Subscale
- Missing data Management
- Total score calculation
- Algorithm reference

Validation

- Eventa library
- Score implementation in Registry

www.sf36.org
Score Management on line

Design and Data Collection for e-Score Form

- Adaptation to web tool of a validated form
  - Guideline for the e-crf conception
  - Standard form
  - Scientific references

- Clear process for the data collection
  - Data Entry
  - Signature
  - SDV
  - Data validation
  - Data correction
Score data analysis

- Descriptive statistics on line
- Type of statistics
- Objective of online statistics
Data score validation

- Internal consistency
- Missing data
- Warning set up according the logistic rules
- Consistency with other e-CRF data
- Consistency between the data of the score
Statistics for e-score

Plan the statistics on line

- Number of score completed by visit
- Means of the score by visit
- Means of difference between baseline and follow up visit

Final statistic report

- Clear Statistic Plan analysis objective
- Programmed by SAS at the end of the study but can be put on line in PDF format
HRQL and Guidance

Administrative Guidance
- Guidance EAMEA
- Draft for HRQL

Guidance FDA
- Secondary end point
- Link to specific diseases (oncology)
- The phase III cannot be based only on HRQL

(PRO) Patient report outcome
- To collect the patient feedback on the treatment
- Collect data from the patient
- Because the trials are now taking into account the patient point of view
Conclusion

We need:
- Some tools should be implemented to have the most accurate data for the score
- Check list to propose efficient full process since data collection to data analysis
- Plan statistics on line
- Include statistic analysis in the final statistic plan
- Internal rules to adapt the paper score to the web technology
- Standardized score the one way to improve scoring on line
- We need to follow regulation evolution guidance to be compliant (best will be participate to elaboration to the guidance)
References for additional information

Regulatory documents

- EMEA (European Medicines Agency)
  - European guidance document for assessment of Health-Related Quality of life in clinical trials
  - Refection paper on the regulatory guidance for the use of health-related quality of life measures in the evaluation of medicinal product

- Websites:
  - www.SF36.org
  - www.euroSCORE.org
Meeting
- comity
  
  http://www.fda.gov/ohrms/dockets/ac/00/backgrd/3591b1a.pdf

Articles
- Measuring quality of life Using quality of life measure in the clinical setting
  
  http://bmj.bmjournals.com/cgi/content/full/322/7297/1297?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&andorexactfulltext=and&searchid=1131025515573_7333&stored_search=&FIRSTINDEX=0&sortspec=relevance&volume=322&firstpage=1297&resourcetype=1

- The logistic EuroScore
  
  http://www.euroscore.org/logistic.pdf

- Validation of European System for Cardiac Operative Risk Evaluation (EuroScore) in North American cardiac surgery
  
  www.euroscore.org/ejctsjun2002.PDF
Any Question?