



Dutch Health Care Inspectorate (inspectie voor de gezondheidszorg, IGZ)

Inadequate quality and safety of a surgical process: an integrated audit

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Van:

Verzonden: zaterdag 10 september 2005 7:41

Aan: CAIO Anes Cardio-anesthesiologen

Onderwerp: mortaliteit hartchirurgie Nijmegen tweemaal zo hoog als in andere Nederlandse centra!
Beste allemaal,

Gistermiddag is er een beleidsmiddag ketenzorg hartchirurgie geweest.

Hier zijn NICE-data gepresenteerd en het blijkt dat Nijmegen in vergelijking met de andere Nederlandse centra geen ziekere patiënten opereert, maar wel een mortaliteit heeft die ruim tweemaal zo hoog is als de andere Nederlandse hartcentra. Ook is in Nijmegen het aantal re-sternotomiën wegens een nabloeding hoger. Dit zijn ZEER ernstige problemen. De chirurgen waren tevereden met een mortaliteit van ongeveer 3% voor de electieve coronairchirurgie



Anonymous announcements

- E-mail September 10th 2005 of Prof. D.:
 - Policy meeting about cardiac surgery care chain
 - NICE data: mortality CABG twice national average
revisions for bleeding very high
mortality valves inacceptably high
 - He would not choose cardio-surgical therapy at UMC
 - Because of the severity of the problems direct action is necessary
 - He sets a call for improvement of the quality



Actions IGZ

- A telephone notice to the director medical affairs on Monday September 26th 2005
- Confirmation of the appointments made by telephone in a letter of September 28th 2005:
 - He shall collect more information
 - He shall answer within one week



What else?

Thursday September 29th 2005

- Report in different national Dutch media (radio, papers, television) about the problems in the UMC.

Friday September 30th 2005

- Anonymous report that under-qualified personnel is working at the cardiac surgery department



Re-actions UMC I

- Letter of October 5th 2005 of the UMC to the IGZ with the answers on the questions signed by:
 - Chairman Board of Governors; Heads department Cardiac Surgery, Intensive Care and Cardiology
 - A cardiac surgeon, running the local database
- Position of the heart-lung center within the UMC
- The meaning of the policy meeting on September 9th 2005
- The context of the email of prof D.
- The assessment of the mortality rates
- The conclusions of the Cardiac Lung Center and the Board of Governors on the observed mortality rates.



Re-actions UMC II

Wij hebben onze output in de afgelopen 8 jaren nader geanalyseerd. Zowel de geaccumuleerde cijfers over 8 jaren als de toetsing van de cijfers per jaar leveren dezelfde conclusies op. De conclusies zijn:

- a. In de CABG groep (totaal 3713 patiënten in de jaren 1997 – 2004) is de overall Euroscore $2,9 \pm 2,6$ en de mortaliteit bedraagt 3,2% afgezet tegen een EMR van 2,90 – 2,94 (95% betrouwbaarheidsinterval). Voor de drie risicogroepen afzonderlijk zijn de uitkomsten als volgt:

| | OBSERVED (Hartlongcentrum UMC St Radboud) | | | | | | EXPECTED |
|---|---|-------------|---|-------------|-------------|-------------------------|----------------------|
| | N | % | Euroscore (mean \pm SD) | Mortaliteit | % | 95% CL mortaliteit UMCN | Euroscore 95%CL |
| Totaal | 3713 | | 2.98 ± 2.6 (0-18) | 120 | 3.2 | 2.6 – 3.8 | |
| Euroscore overleden patiënten (n=120) : 6.9 ± 3.3(1-18) | | | | | | | |
| Per Euroscore- risicogroep | | | | | | | |
| Laag | 1808 | 48.7 | 0.8 ± 0.8 (0-2) | 5 | 0.3 | 0.28 – 0.3 | 1.27 – 1.29 |
| Medium | 1352 | 36.4 | 3.8 ± 0.8 (3-5) | 45 | 3.3 | 2.3 – 4.2 | 2.90 – 2.94 |
| Hoog | 553 | 14.9 | 7.6 ± 2.0 (6-18) | 70 | 12.7 | 9.8 – 15.4 | 10.93 – 11.54 |

De analyse van de cijfers per jaar geven hetzelfde beeld.



Proposed Measurements

- An external group of (internationally oriented) advisers is created by the Board of Governors (klankbordgroep).
- An internal audit committee performs a focused analysis of all complications and all deaths from January 1st 2004
- Deeper analysis in the cardio-surgical chain
- Creation of specialised groups internally concentrating knowledge by discipline.
- Optimization of regular complication and mortality meetings
- Stricter surgical indications in high risk patients.



Letter of the IGZ to the Board of Governors of Oktober 10th 2005

- Confirmation of the appointments of October 7th 2005
- The IGZ proposed a professor in cardiology as a member of the external group of advisers
- An internal group reports to the Board of Governors
- An external group reports to the Board of Governors and the IGZ
- High risk patients with an additive EuroSCORE > 10 will not be operated for the time of the investigations



Anonymous letter of October 20th 2005

- Board of Governors trivializes the problems
- Problems described by Prof D. are the top of the iceberg
- Investigation of two retired professors had no results
- Dubious surgical indication settings
- The own data of the department are “somewhat different from the reality”
- Peri-operative morbidity asks for a further investigation
- A call to IGZ to assess the patient data on their own.



Discussion Board of Governors – IGZ

October 25th 2005

- External advisory group becomes an independent external audit committee of the UMC and the IGZ.
- IGZ has the chair.
- The IGZ starts investigations.
- No formal order, for the time being, to stop cardiac surgery
- Board of Governors must take action if necessary



Assignment External Investigations

Committee cardio-surgical chain of care

UMC of December 9th 2005

- a senior health inspector, chair
- a professor in cardiology, vice-chair
- a nursing scientist
- a professor in thoracic anaesthesia
- a professor in cardiac surgery
- an internal medicine/ intensive care specialist



Assignment

- Systematic analysis of complete cardio-surgical care chain, mortality and morbidity included.
- Personal orientation of the members of the External Investigation Committee on the mode of working within the UMC, each in their own medical domain
- Focused additional investigation of the IGZ on parts of the quality system



Audit methodology

- Interviews under strict confidentiality
- Assessment of procedures
- Assessment of medical files (also in relation to the assessment of the internal committee) of died patients
- Assessment of reported data

- No assessment of operative indication
- No assessment of patients refused for therapy
- No assessment of other medical files



Interviews

- Board of Governors
- Cardiac Surgeons
- Anesthetists
- Intensivists
- Cardiologists (also of referral hospitals)
- Nurses



What is quality of care?

- A therapy that has the best risk-benefit balance in relation to the patient-specific morbidity and co-morbidity and to the socio-economic situation.

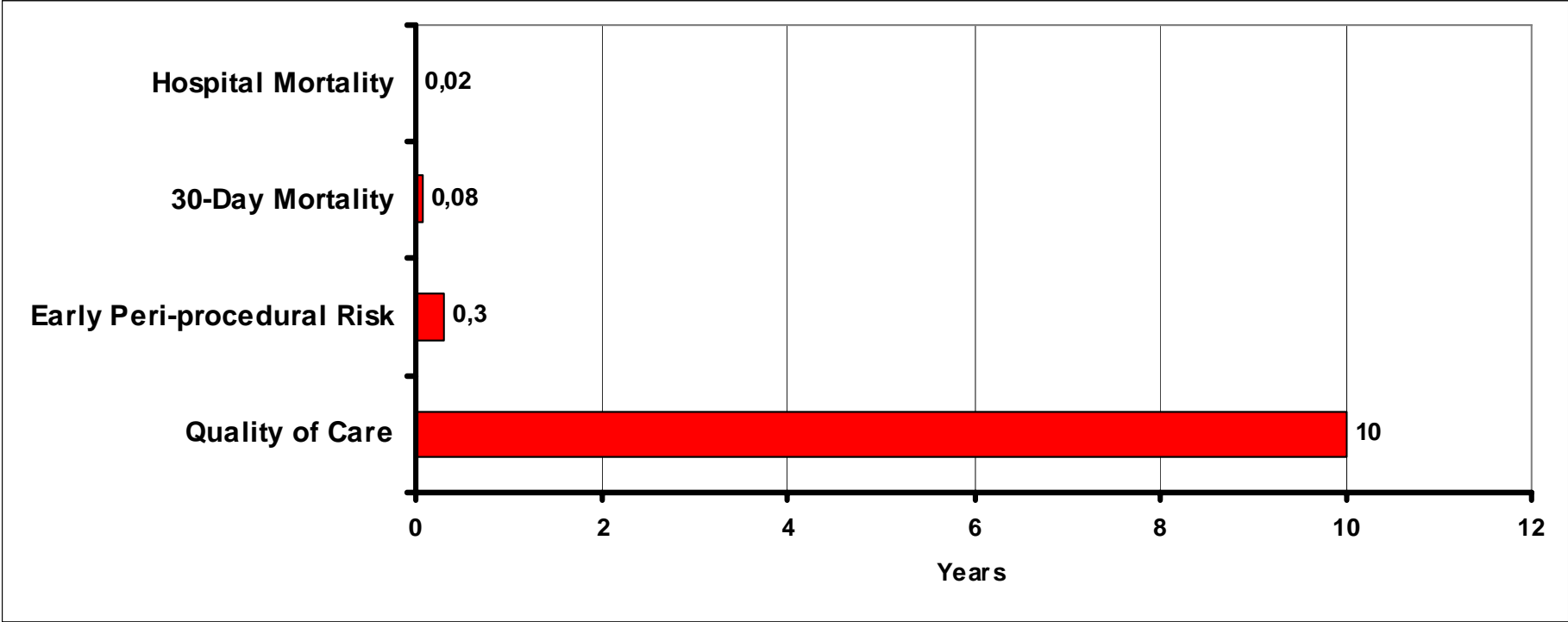


Should surgeons allow insight in the quality of their surgical performance?

- Yes. Society and Patient can only allow the aggression of the physical integrity of the patient under a positive proof of cost-benefit.
- Yes, Society and Patient have the right and the duty of control of the quality of the delivered care. There is a need for a standard of care.

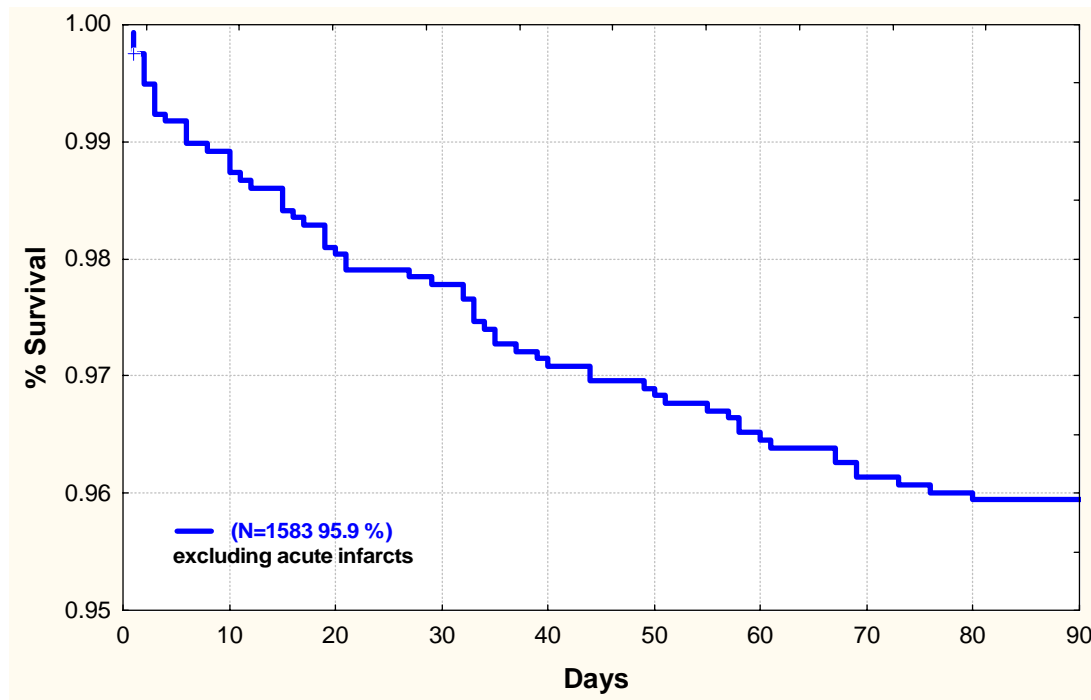


What is quality of care? the interval





What is quality of care? the interval



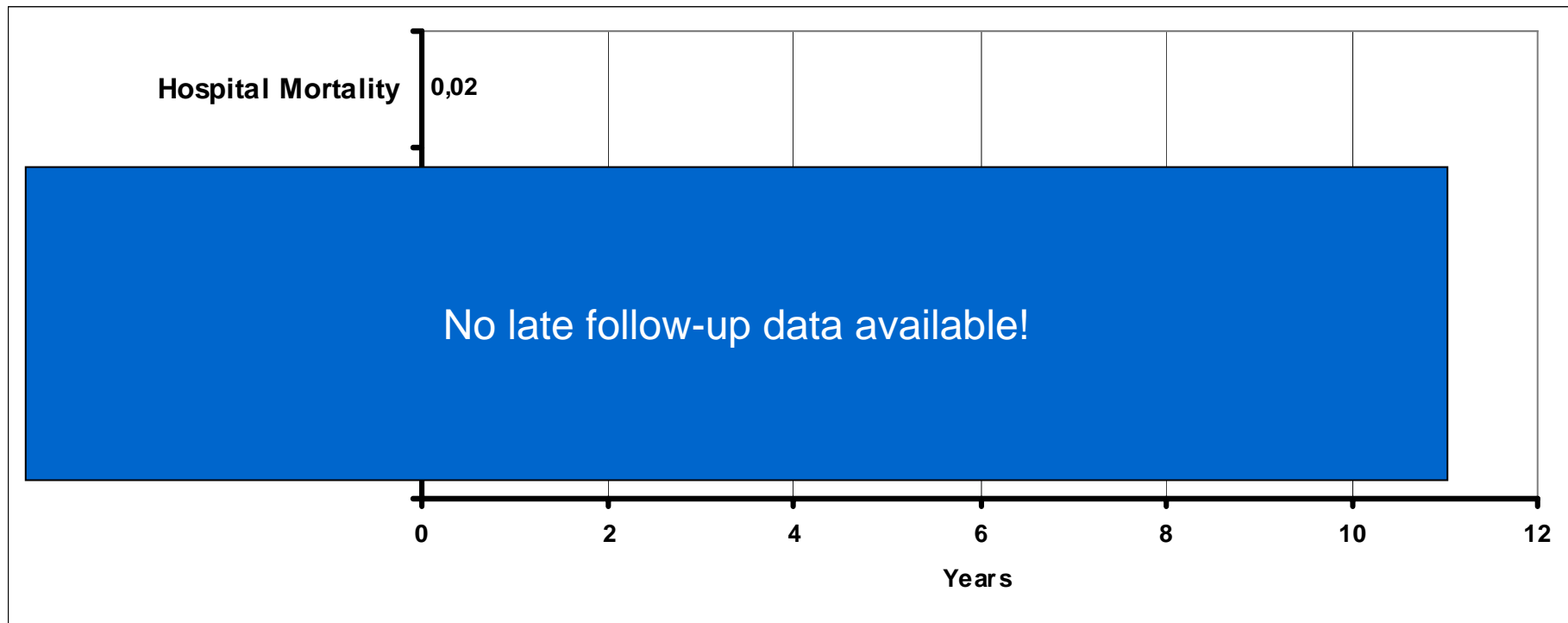


Complexity!

- Variability in patients
- Variability in procedure
- Variability in medical practitioners
- Variability in resources
- Absence or limitations of scoring systems

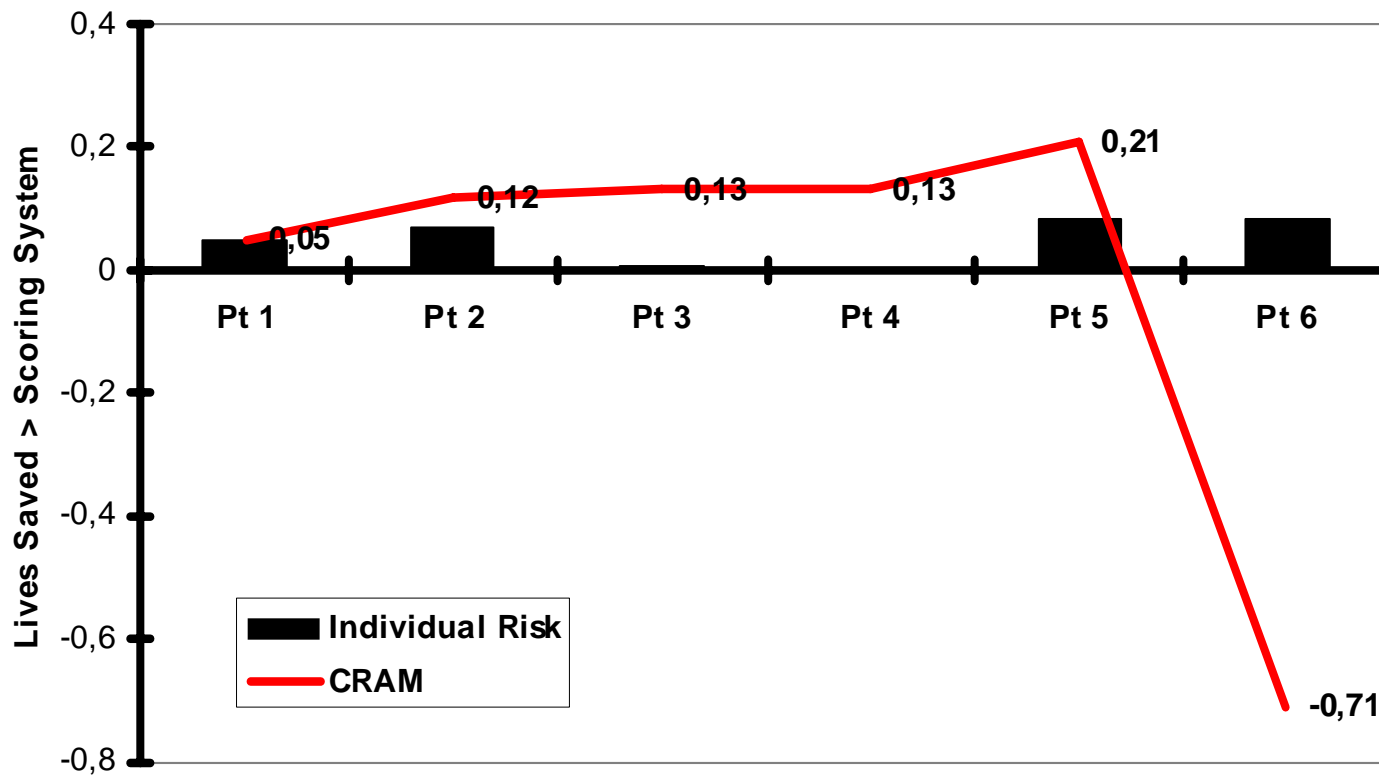


Available data reduce the observed postoperative interval to only a section of the risk interval!





Creation of a Cumulative Risk-adjusted Mortality Plot

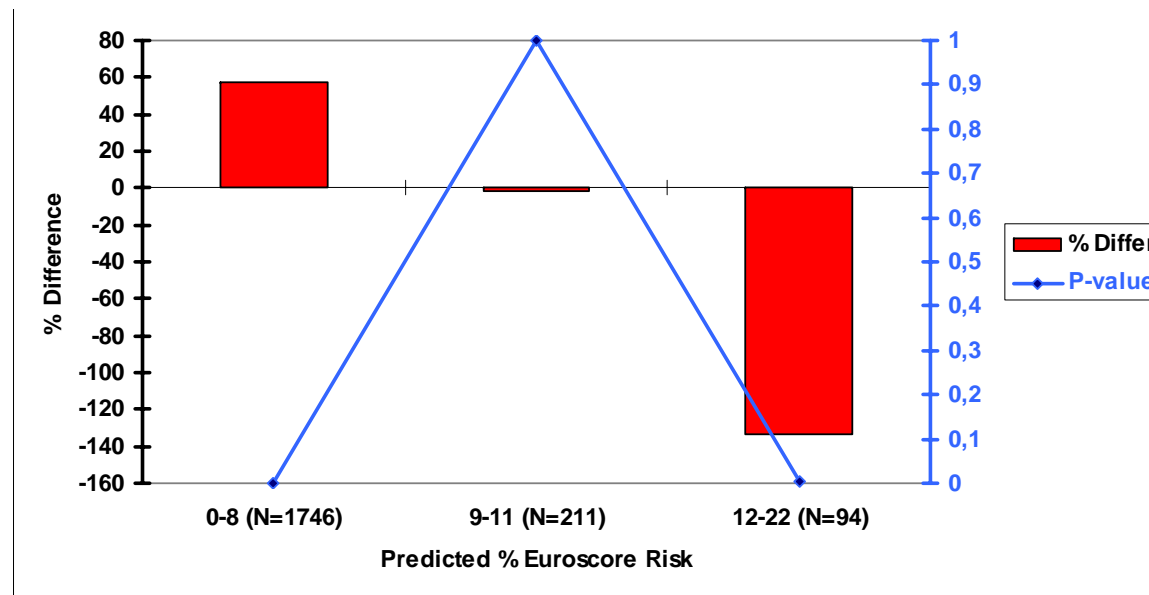




The audited dataset was restricted to the patients with an add. EUROSCORE below 11, due to instability of scoring system

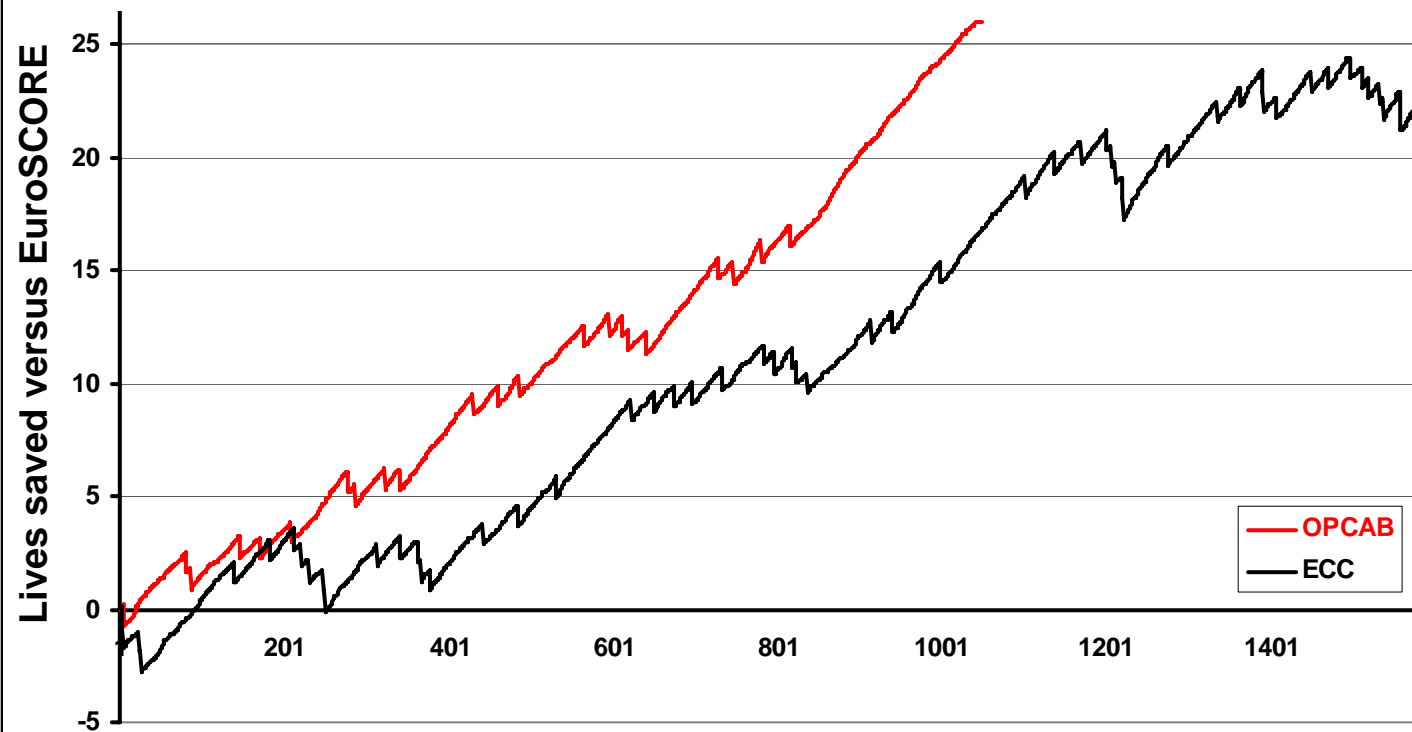
**Overall prediction of Add EUROSCORE is reasonable
But R^2 is only 0.2**

Prediction has a sensitivity of 64 % and a specificity of 87 %)



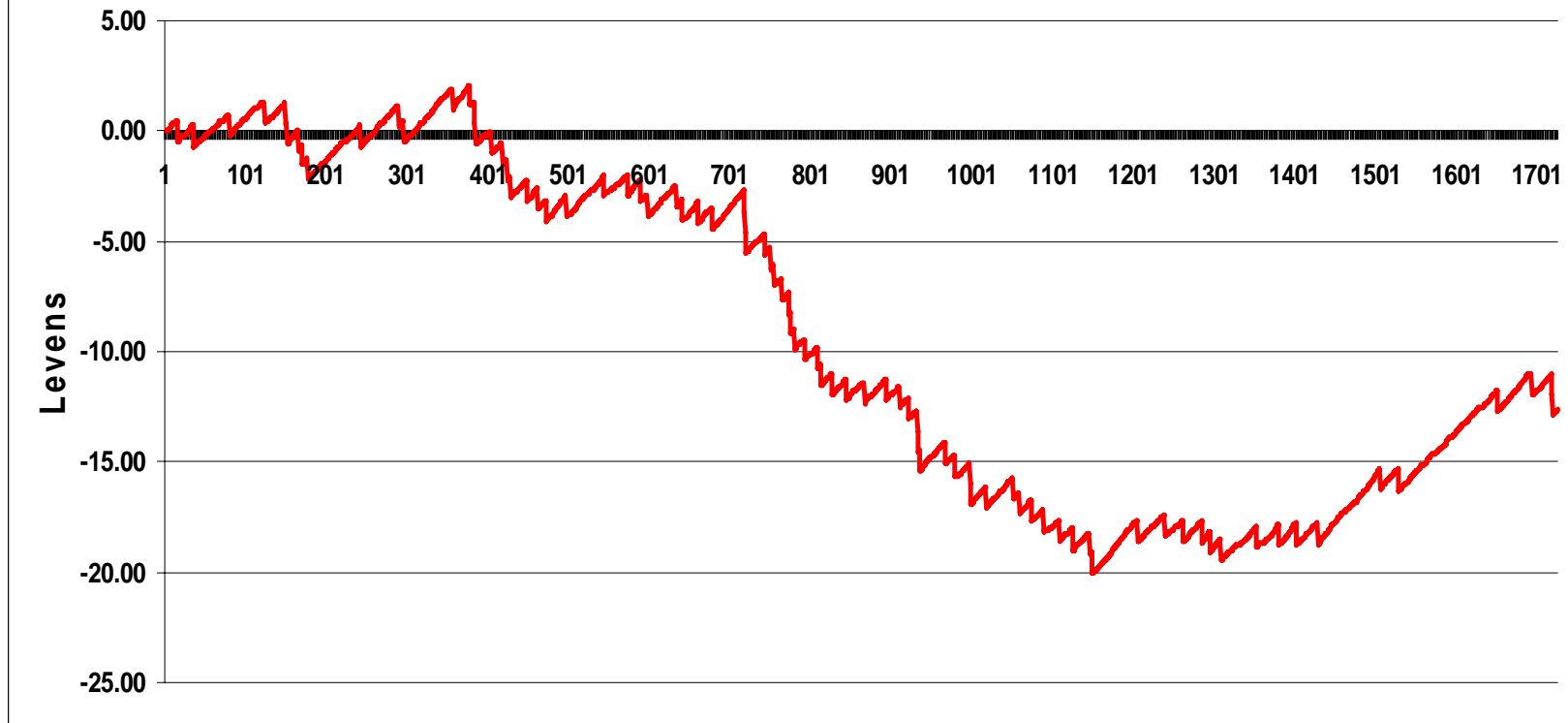


An example of how the plots should look if very high risk patients are excluded, here add Eur > 15 excl



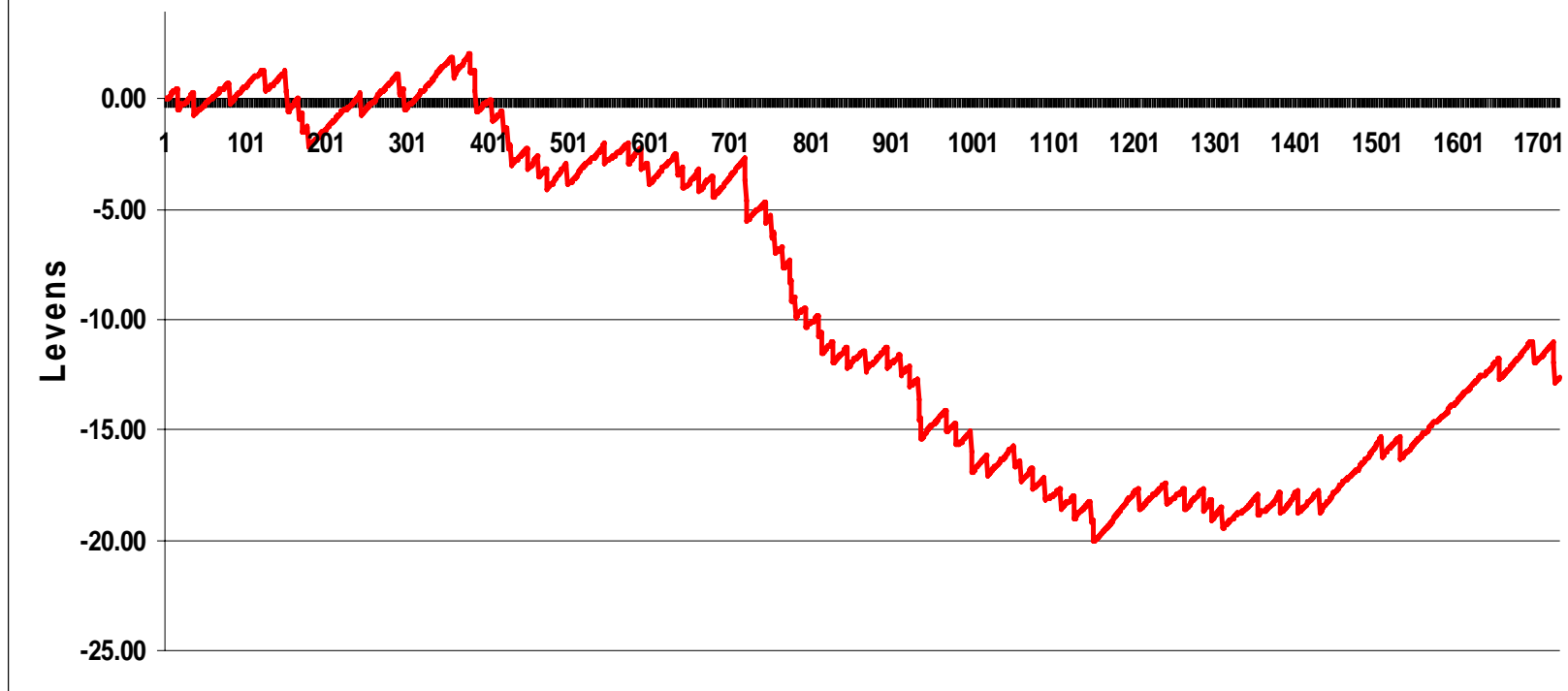


**CUSUM resultaten,
patiënten tot en met Additief EuroSCORE 10,
2003, 2004, 2005**





Ethical aspects of this observation !





Conclusions of the investigation

- Assessment of risk profile and complexity of care
- Mortality
- Morbidity
- Conclusion of the case record reviews
- Causes of the elevated mortality and morbidity
 - Process control
 - Multidisciplinary collaboration
 - Leadership
 - Internal tensions
 - Specializations and skills
 - Focus on quality
 - Motivation



Decisions of the IGZ

- The order to stop to cardiac surgery on adults immediately
- All cardio-surgical chain processes must be organized in accordance with current practice standards
- Written care protocols must be developed and implemented
- Written agreements about responsibilities
- Designation of specialists for the cardio-surgical chain
- General and medical supervision of the perfusionists must be arranged

- No personal action taken against individual specialists



Organisational changes leading to the restart of October 1st 2006

- Chair and subsequent Chair of Board of Governors replaced
- New Head of the cardio-surgical department
- Written procedures
- Specialized personnel for the cardiac surgery
- Supervision of perfusionists



Follow up UMC

- Unannounced visits to the department
- Monthly reports of the mortality data
- Presentation of the situation after a half year



Other effects

- Contacts with Netherlands Society of Thoracic Surgeons (NVT)
 - Prevention of new similar case
 - Transparency of outcome indicators
 - Signaling of bad performance within the NVT
- Role of Board of Governors in case of bad performance
 - Influenced by lack of leadership
 - Influenced by ignorance on quality control
- Effects of the report on other (also non-cardiac surgery) departments



The Council on Safety

- Investigation Council on Safety wants to be informed about the outcome of the investigations (letter of October 18th 2005 of the chair of the Council tot the chair of the Board of Governors of the UMC)
- Preparation of the Council: wants to have insight in probable structural safety problems in cardiac surgery in the Netherlands in general



Lessons learned

- Position of the investigation committee
- Composition of the investigation committee
- Commitment of the parties in the investigation
- The value of the data
- The expected explanation of the data
- Unpredictable media
- The power of IGZ
- Effects of blaming and shaming