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definition
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case report

Clinical Risk Management

Keywords
Dinamic and predictive approach, Health Service complexity, Clinical Risk assessment

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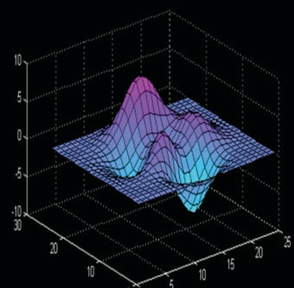
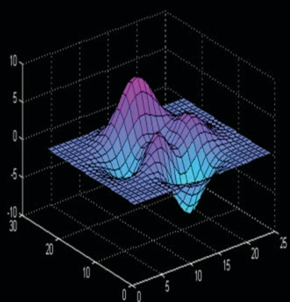
ASL Roma B



Iatromics project

By Maurizio Musolino



NOTES ON HOSPITALS:

BEING

TWO PAPERS READ BEFORE THE NATIONAL ASSOCIA
FOR THE PROMOTION OF SOCIAL SCIENCE,
AT LIVERPOOL, IN OCTOBER, 1858.

WITH

EVIDENCE GIVEN TO THE ROYAL COMMISS
ON THE STATE OF THE ARMY IN 185

BY

FLORENCE NIGHTINGALE.

LONDON:
JOHN W. PARKER AND SON, WEST STRAND.
1859.

PREFACE.

IT may seem a strange principle to enunciate as the very first requirement in a Hospital that it should do the sick no harm. It is quite necessary, nevertheless, to lay down such a principle, because the actual mortality *in* hospitals, especially in those of large crowded cities, is very much higher than any calculation founded on the mortality of the same class of diseases among patients treated *out of* hospital would lead us to expect.

1859.

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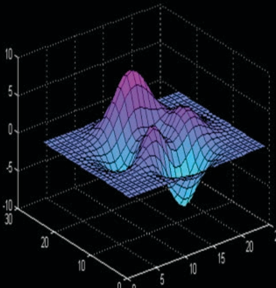

The numbers of Health Service complexity

➢ Population (Italy) (age: 0-14 = 14%; >65 years = 20%)	60×10^6
➢ Asl Companies	180
➢ Population (mean value per Asl)	331.218
➢ Hospitals managed by Asl	470
➢ Hospital Company	97
➢ IRCCS	55
➢ University Hospitals	10
➢ Private Hospitals	629
➢ Hospital occupancy	270.000
➢ Hospital admissions	8.200.636
➢ % PIL	≈ 10 %

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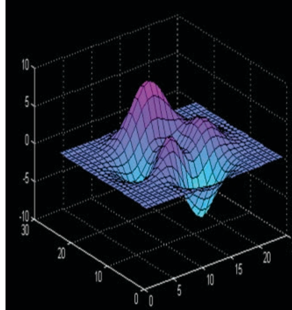
What is Clinical Risk Management?

A **system** designed to **protect the organization**, its employees patients and visitors from injury and loss of tangible and intangible assets

Risk is a natural part of all healthcare. There is always the potential that an unwanted or unexpected outcome will occur whenever any action is taken.

Clinical risk management is therefore essential for improving patient safety, and all practices are expected to undertake it as part of their clinical governance procedures.



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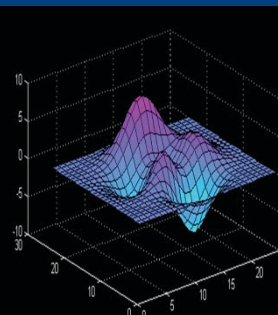
What is a Near Miss?

A **near miss** is an **unplanned event that did not result in injury**, illness, or damage – but had the potential to do so. Only a fortunate break in the chain of events prevented an injury, fatality or damage



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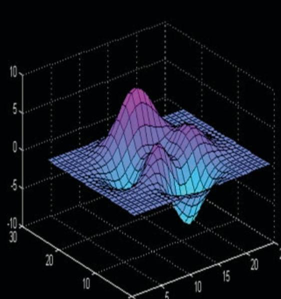

What is an Adverse event?

An **Adverse event** is any adverse change in health or **side effect** that occurs in a person who participates in a clinical trial, while the patient is receiving the treatment (study medication, application of the study device, etc.).

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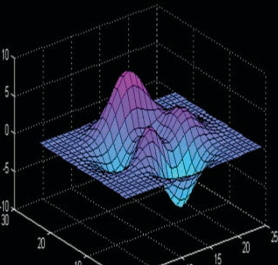

What is a Sentinel Event?

A **Sentinel Event** is defined by The Joint Commission as any unanticipated event in a healthcare setting resulting in **death or serious physical or psychological injury** to a patient or patients, not related to the natural course of the patient's illness.

- Procedures involving the wrong patient or body part resulting in death or major permanent loss of function
- Suicide in an inpatient unit
- Retained instruments or other material after surgery requiring re-operation or further surgical procedure
- Intravascular gas embolism resulting in death or neurological damage
- Haemolytic blood transfusion reaction resulting from ABO incompatibility
- Medication error leading to the death of patient reasonably believed to be due to incorrect administration of drugs
- Maternal death or serious morbidity associated with labour or delivery
- Infant discharged to wrong family
- **Other catastrophic event**

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Causes of adverse events

Adverse Event

Patient, cure and care, work environment

Direct (or immediate) causes

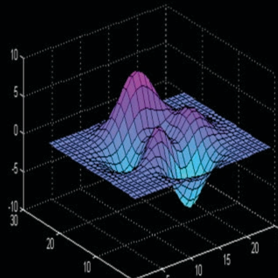
Complexity of health organizations

Indirect (or deep) causes

Organization and management

Root causes

Learning, culture organization



Starting conditions of the process

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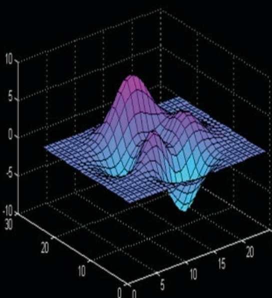

Correct Outcome

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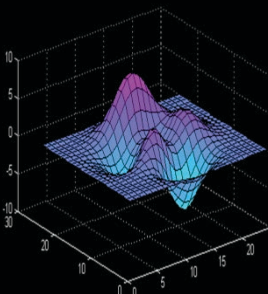

Starting conditions of the process

(small differences in starting time)

Adverse Event

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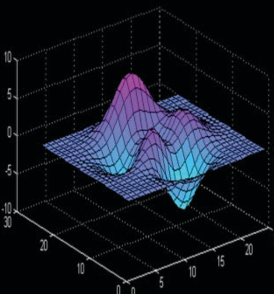

A case report:
Surgery preoperative check list

CHECK-LIST CHIRURGICA PREOPERATORIA (SEZ.1)

☐ **ELEZIONE** ☐ **URGENZA**

Cognome:	**Nome:**	**Data di nascita:**

Modalità di ricovero: **L.S.** ☐ **W.S.** ☐ **D.S.** ☐ **Altro** ....

1.1 PREPARAZIONE ALL'INTERVENTO CHIRURGICO

MEDICO CHIRURGO *firma leggibile* ____________________
(chirurgo che effettua la prima visita al paziente)

Classe di rischio tromboembolia venosa profonda
☐ **Basso** *chirurgia minore in paz.<40 anni senza fattori di rischio addizionali*
☐ **Moderato** *chirurgia minore in paz. con fattori aggiuntivi di rischio, chirurgia maggiore in paz fra 40 e 60 anni senza rischi addizionali*
☐ **Alto** *chirurgia in pazienti >60 anni o età 40<anni< 60 con fattori di rischio addizionale (malattia trombo embolica, neoplasia e ipercoagulabilità, precedenti episodi trombo embolica)*
☐ **Altissimo** *chirurgia in paz. con fattori di rischio multipli (età>40 anni, neoplasia, pregressa malattia trombo embolica, traumi maggiori, fratture vertebrali)*

MEDICO CHIRURGO *firma leggibile* ____________________
(chirurgo che visita il paziente prima dell'invio in sala operatoria)

Data di rilascio del consenso informato all'intervento chirurgico : .... / .... / ....

Data di rilascio del consenso informato alla emotrasfusione: .... / .... / ....
☐ non necessita di emotrasfusione ☐ non acconsente

Richiesto sangue per emotrasfusione : ☐ SI ☐ NO

Lato marcato con matita dermografica : ☐ Dx ☐ Sx ☐ Mediano

Antibiotico profilassi prescritta .... ☐ non prescritta

MEDICO ANESTESISTA *firma leggibile* ____________________
(medico anestesista che visita il paziente in U.O. di degenza o preospedalizzazione)

Data di rilascio del consenso informato all'anestesia: .... / .... / ....

☐ il paz. non riferisce allergie ☐ riferisce allergie a ....

INFERMIERE OSTETRICA AREA CHIRURGICA *firma leggibile* ____________________
(infermiere della U.O. di degenza)

Inizio digiuno preoperatorio: Ora ..../......... Data .... / .... / ....

Conferma della disponibilità di sangue e/o emocomponenti richiesti: ☐ SI ☐ NO ☐ non richiesti

Tricotomia: Ora .... / .... Data .... / .... / .... ☐ non necessita ☐ riferita

Verifica della assenza di protesi mobili, monili, piercing, smalto: ☐ SI ☐ NO

Verifica stato igienico della cute e delle mucose: ☐SI ☐NO | Ora invio pz. .... / ....

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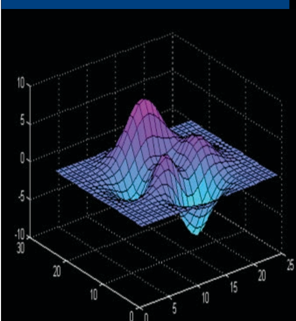

Different approaches to clinical risk management

- **Protective approach:** Good medical/ nursing practices, guidelines, scientific raccomandations
- **Reactive approach:** Ishikawa graph, London Protocol, Root Cause Analysis
- **Proactive approach:** Process analysis HFMEA
- **Predictive approach:** Modeling System, Artificial Neural Network, Fuzzy logic, Genetic Algorytm

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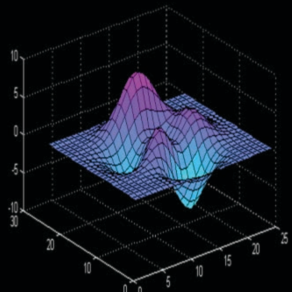
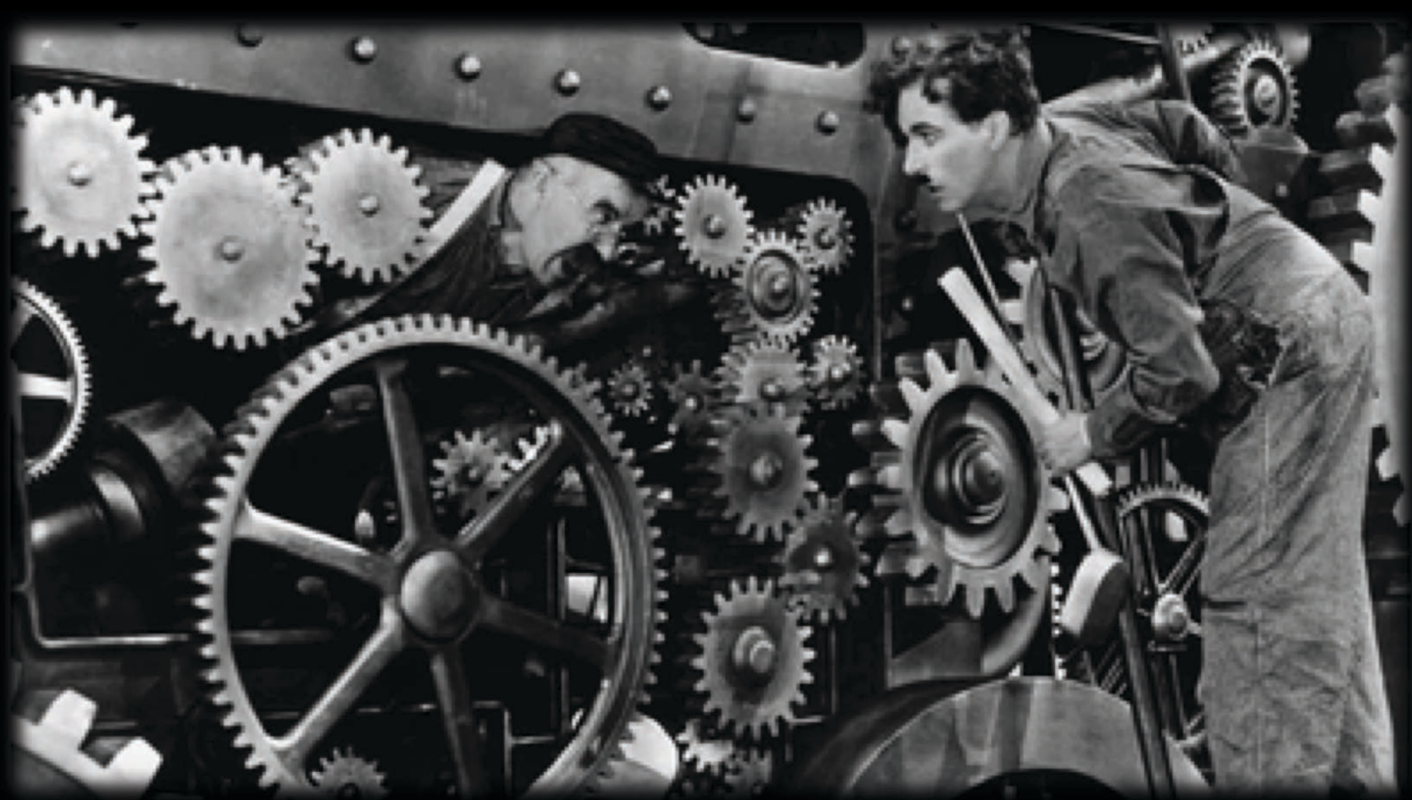


Proactive approach
Health Failure Mode and Effects Analisys



Reductionistic and deterministic process analisys

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A case report: HFMEA of Central Venous Catheter

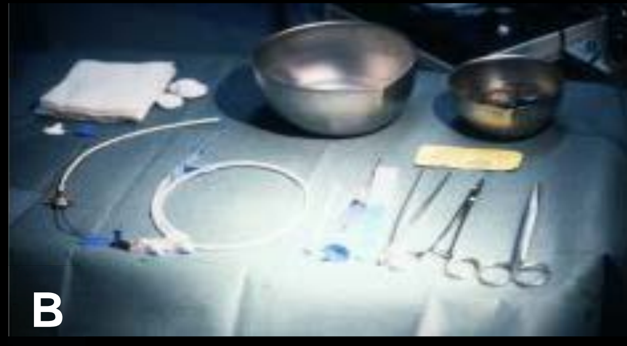
A. Grading of patient according to selected criteria.

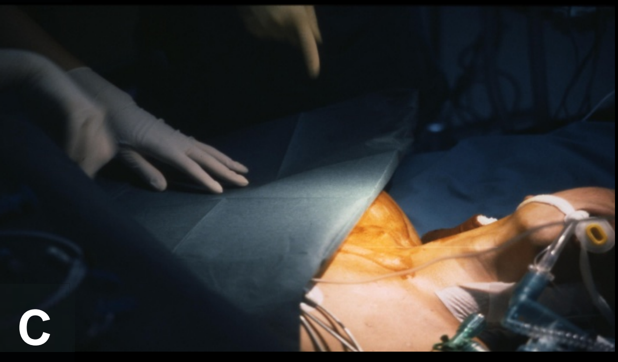
B. Preparation of materials and devices.

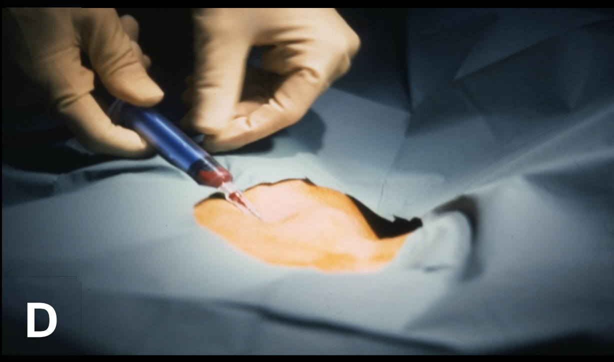
C. Preparation of the patient.

D. Catheter insertion.

E. X-ray control.







E

Priority of Risk Index (score range: 1 - 1000)

Severity of damage X Probability of occurrence X Detectability during the occurrence

Severity of damage	Probability of occurrence	Detectability during the occurrence
score: 1 - 10	score: 1 - 10	score: 10 - 1

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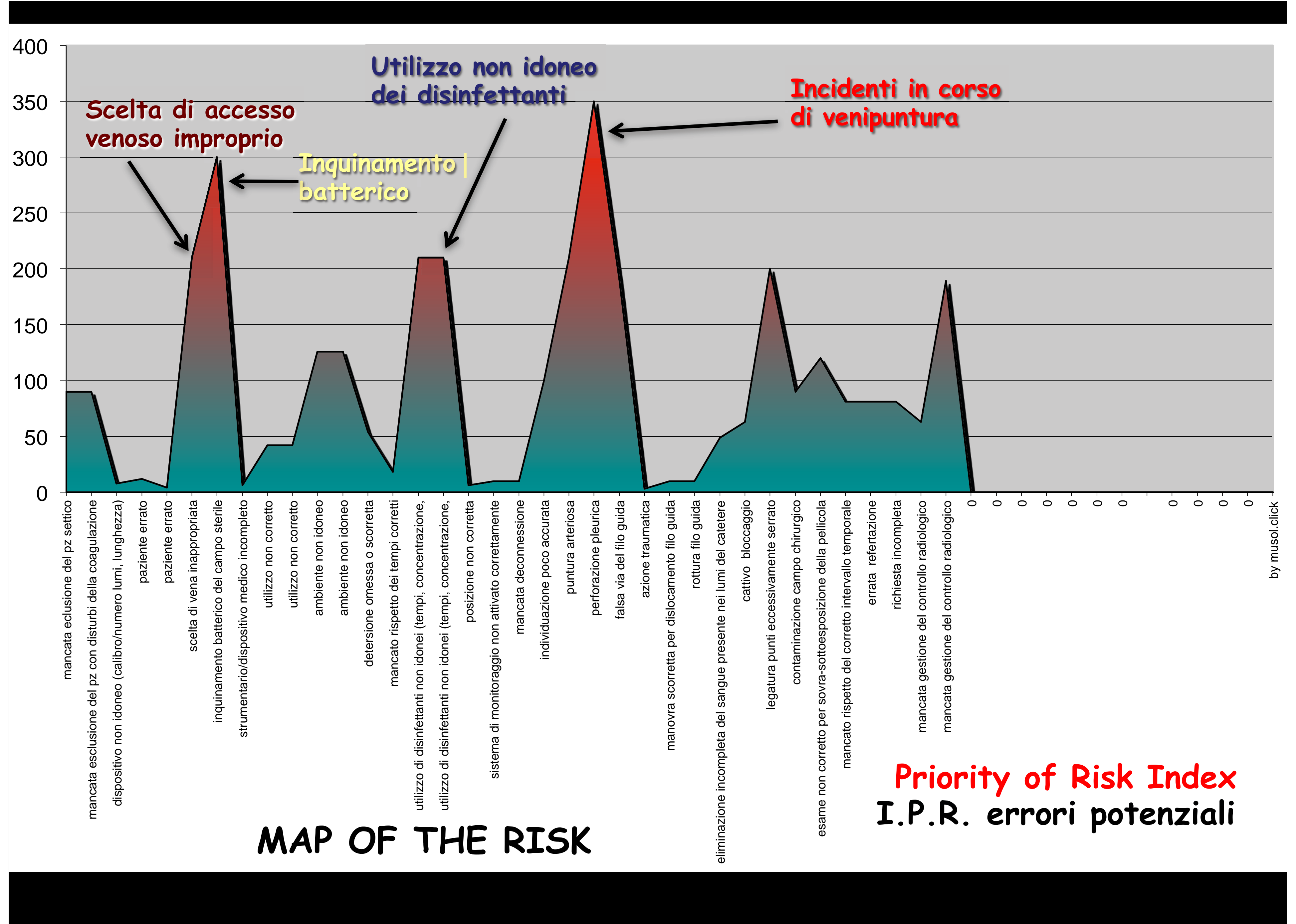

400
350
300
250
200
150
100
50
0
Scelta di accesso venoso improprio
Inquinamento batterico
Utilizzo non idoneo dei disinfettanti
Incidenti in corso di venipuntura
mancata eclusione del pz settico
mancata esclusione del pz con disturbi della coagulazione
dispositivo non idoneo (calibro/numero lumi, lunghezza)
paziente errato
paziente errato
scelta di vena inappropriata
inquinamento batterico del campo sterile
strumentario/dispositivo medico incompleto
utilizzo non corretto
utilizzo non corretto
ambiente non idoneo
ambiente non idoneo
detersione omessa o scorretta
mancato rispetto dei tempi corretti
utilizzo di disinfettanti non idonei (tempi, concentrazione,
utilizzo di disinfettanti non idonei (tempi, concentrazione,
posizione non corretta
sistema di monitoraggio non attivato correttamente
mancata deconnessione
individuazione poco accurata
puntura arteriosa
perforazione pleurica
falsa via del filo guida
azione traumatica
manovra scorretta per dislocamento filo guida
rottura filo guida
eliminazione incompleta del sangue presente nei lumi del catetere
cattivo bloccaggio
legatura punti eccessivamente serrato
contaminazione campo chirurgico
esame non corretto per sovra-sottoesposizione della pellicola
mancato rispetto del corretto intervallo temporale
errata refertazione
richiesta incompleta
mancata gestione del controllo radiologico
mancata gestione del controllo radiologico
0
0
0
0
0
0
0
0
0
0
0
by musol.click
MAP OF THE RISK
Priority of Risk Index
I.P.R. errori potenziali

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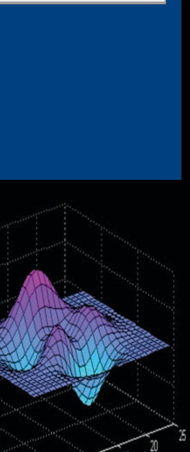
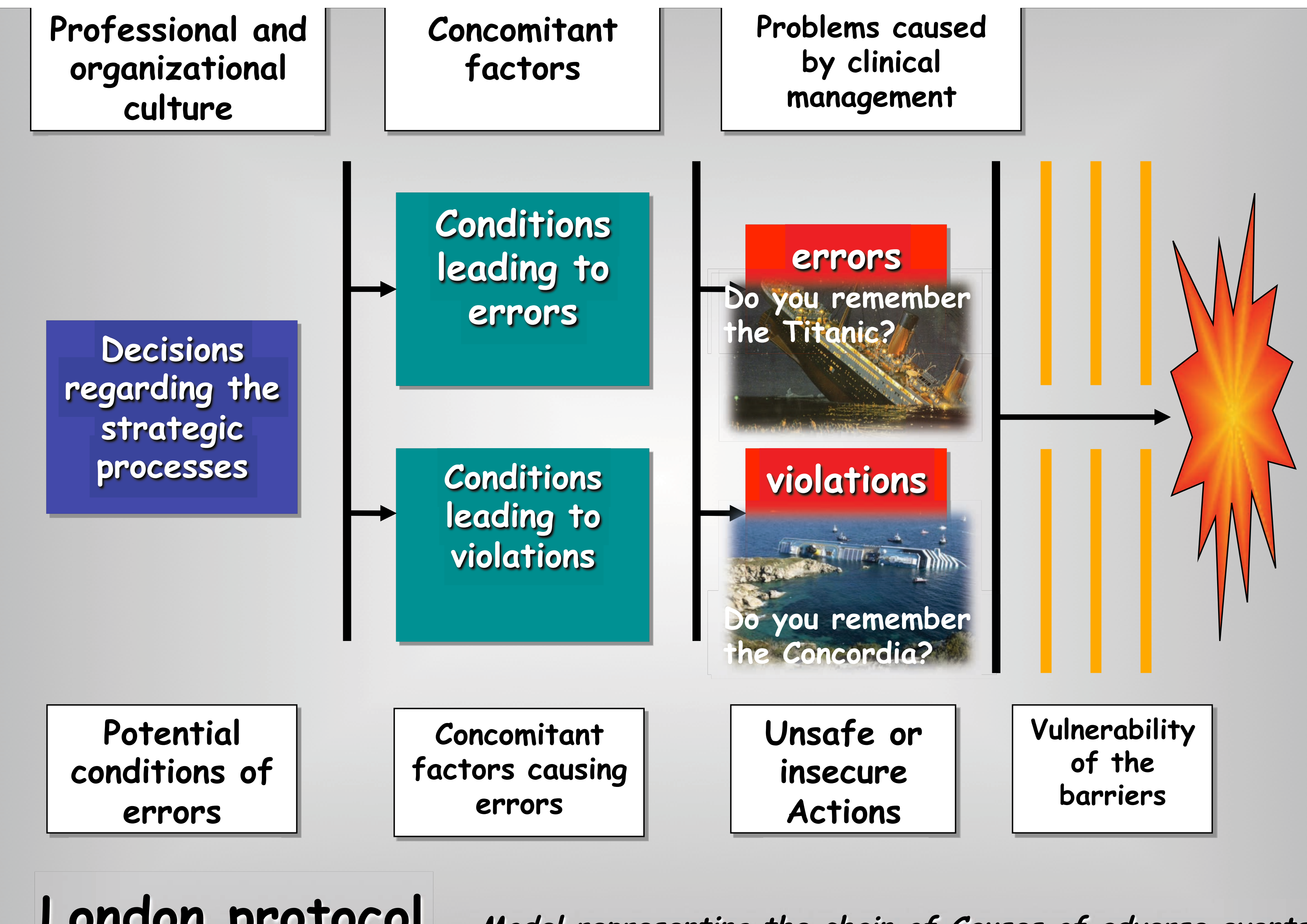


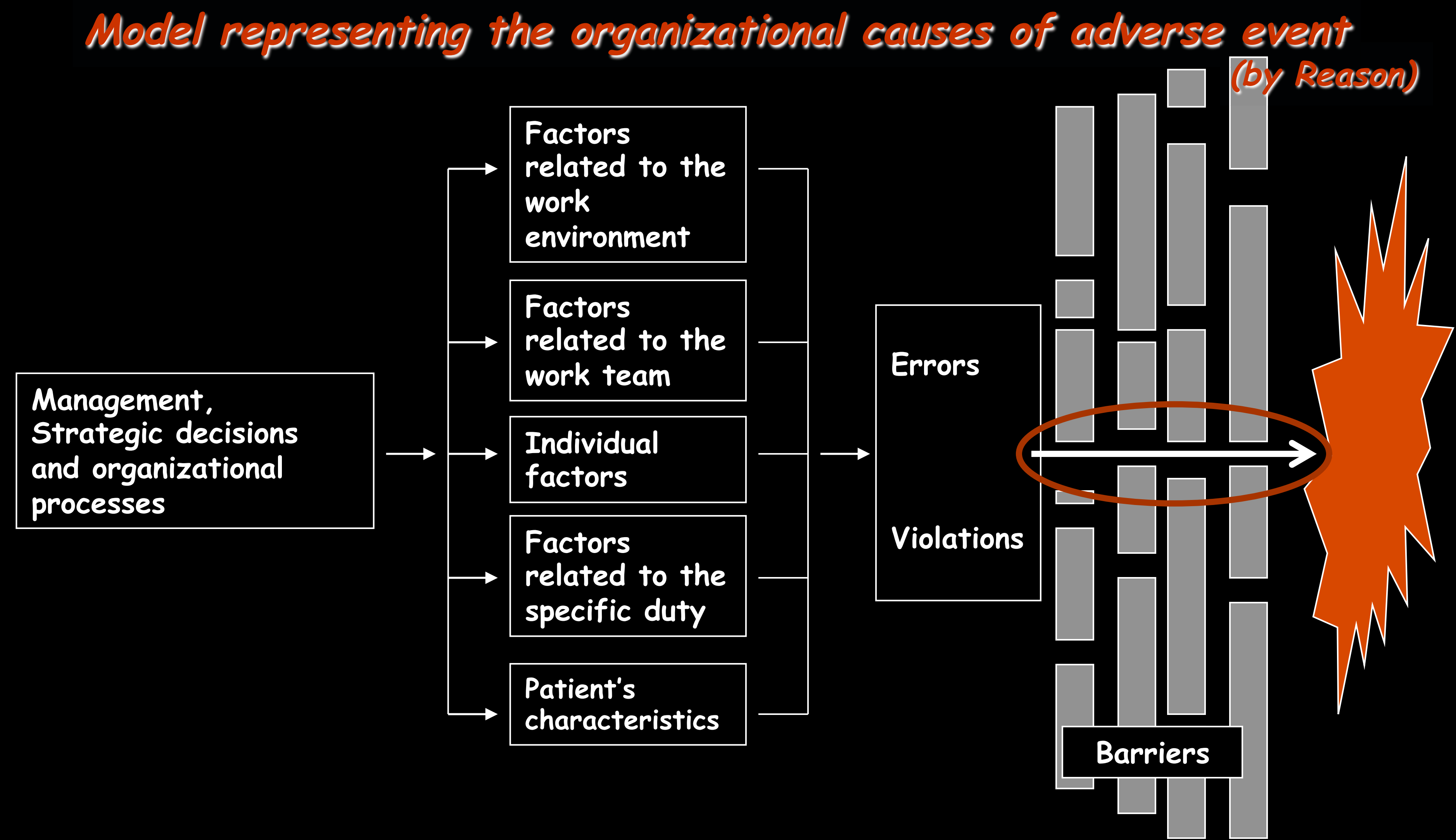
Reactive approach
Root Cause Analisys

Ishikawa's diagram

Clinical Risk Management *"Sushi style!!!"*
1953

Pareto's rule:
20% causes → 80% effect


Professional and organizational culture
Concomitant factors
Problems caused by clinical management
Decisions regarding the strategic processes
Conditions leading to errors
Conditions leading to violations
errors
Do you remember the Titanic?
violations
Do you remember the Concordia?
Potential conditions of errors
Concomitant factors causing errors
Unsafe or insecure Actions
Vulnerability of the barriers
London protocol
Model representing the chain of Causes of adverse events
(by Reason & Vincent – Dpt. Psycology of London College University)



Startegic and managerial choices, supported by favouring factors, can be causes of errors and violations. These latter could potentially turn into Care Delivery Problems if not neutralized by defensive, protective or organizational mechanisms. Delivery Problems might make the cures unsafe, and provoke the adverse event.

Rating Hospital

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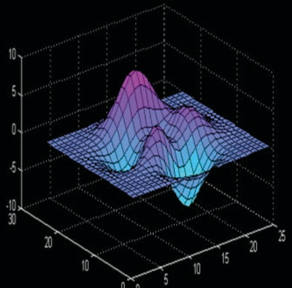

Sentinel event only

Healthcare Ministry (SIMES)

Monitor sentinel event
3° feed back
(Nation)

LAiT Informatics (data base)

Health Agency

Hospital

Root Cause Analysis
1° feed back
(Local)

Risk manager

Near miss

Adverse event

Sentinel event

Benchmarking
2° feed back
(Region)

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Rating Hospital

(P.RE.VAL.E)

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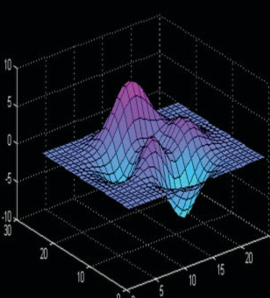

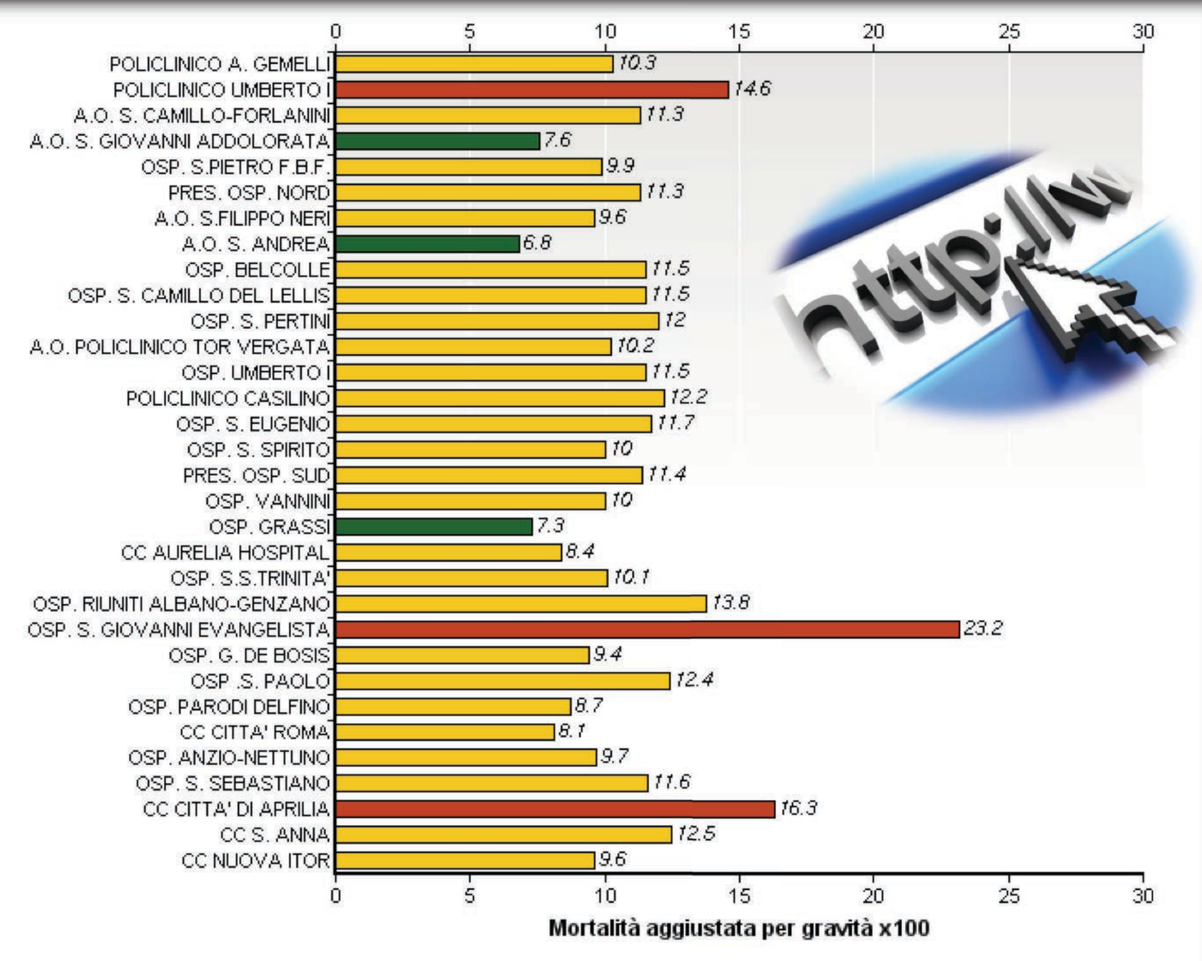

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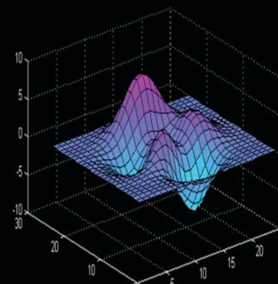

Rating Hospital

(P.RE.VAL.E)

- Esiti più favorevoli rispetto la media regionale / BENCHMARK regionale (verde)
- Esiti non diversi dalla media o dal BENCHMARK regionale (giallo)
- Esiti meno favorevoli rispetto la media o il BENCHMARK regionale (rosso)

Indicatore — Hospital X	N	Rischio grezzo	Rischio adj	RR adj		RR vs Bench	
Infarto Miocardico Acuto: mortalità a 30 giorni dal ricovero	799	11.51	12.01	1.11	giallo	1.50	rosso
Infarto Miocardico Acuto: mortalità a 30 giorni dal primo accesso	892	11.10	11.03	1.02	giallo	1.44	rosso
Infarto Miocardico Acuto senza esecuzione di PTCA: mortalità a 30 giorni dal primo accesso	378	18.78	18.81	1.01	giallo	1.20	giallo

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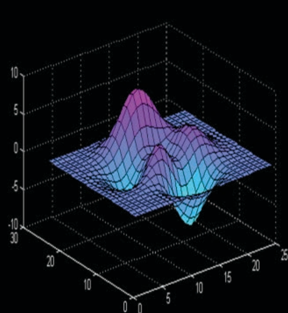

CLINICAL RISK ASSESSMENT

NON LINEAR NON DETERMINISTIC APPROACH

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Ralph Stacey's matrix

Ripetitive patterns
Procedures and guidelines
Intuition
Learning from data
Model A.I. as
Rules from data
Statistics

From models of mathematical functions to simulations with agents
Linear Flow charts
Data from rules

simplex

agreement / disagreement

certainty / uncertainty

caos

cum-plicum

cum-plexum

$$y=f[(\sum_{C=1}^{4} \overline{x}_c * n_c)+kn]$$

c = codice colore (1 - rosso; 2 - giallo; 3 - verde; 4 - bianco)
n = numero pazienti
x = tempo medio permanenza in area DEA
y = fabbisogno di letti tecnici
k = tempo di rifacimento e riordino letto tecnico (costante)

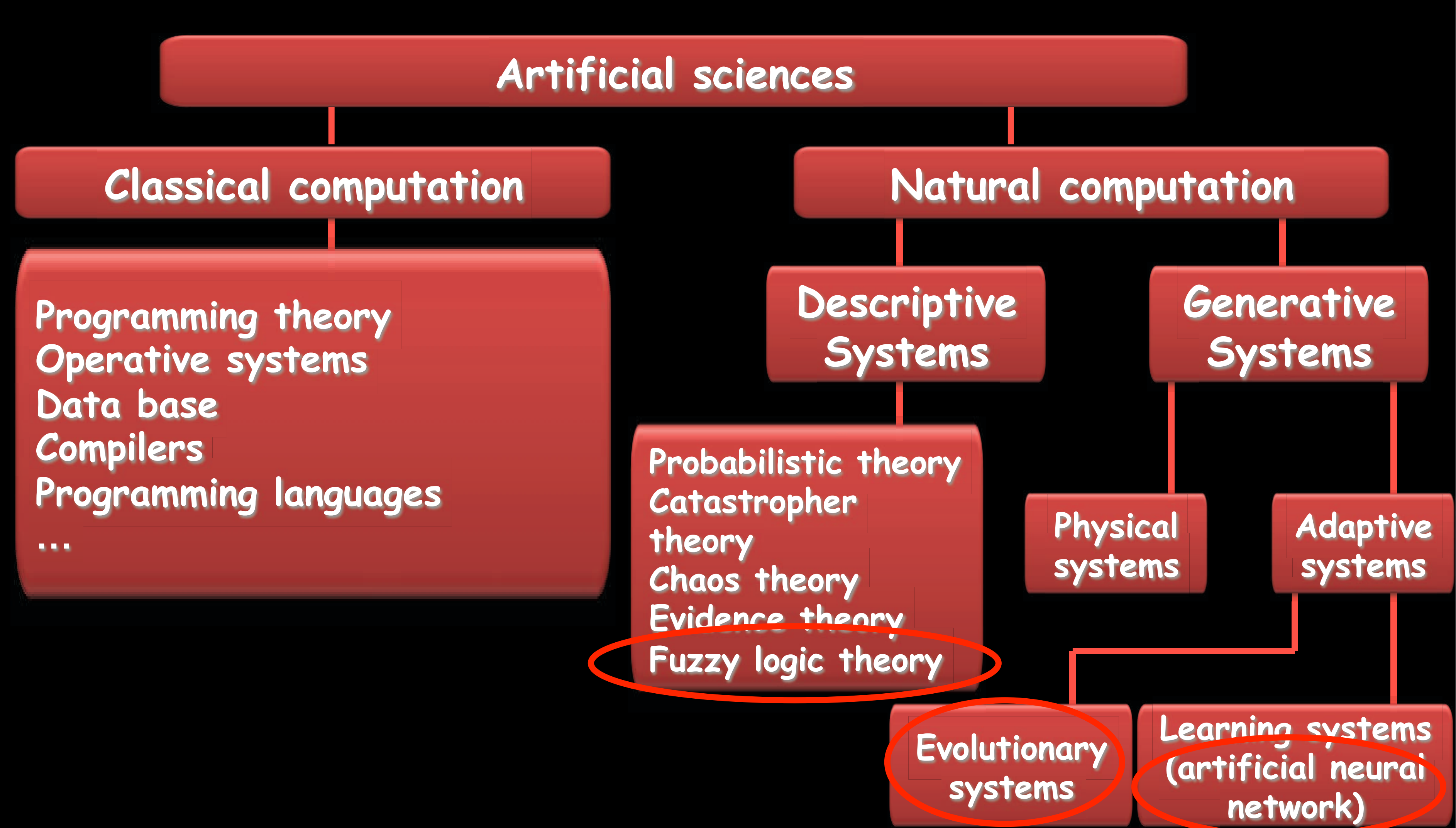
Musolino 2005

Uncer...

Caos Area
... ? ...

ARTIFICIAL ADAPTIVE SYSTEM

Massimo Buscema, Marco Intraligi, DEDALO, GESTIRE I SISTEMI COMPLESSI IN SANITA' volume 1 - N.2/2003. (p. 27 - 40)

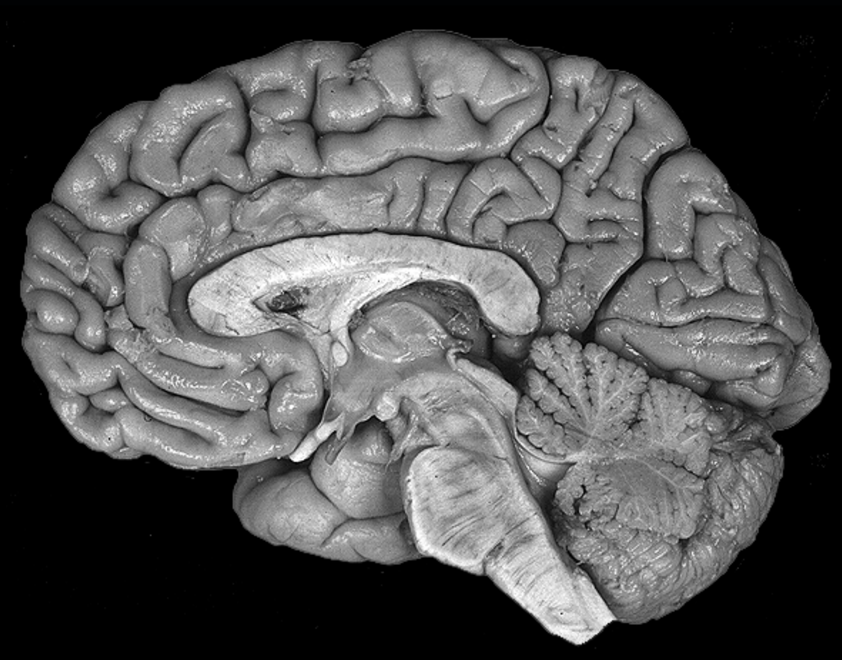


Theoretical systems in combined form artificially reproduce the human way of managing the reality.

Fuzzy Logic theory

Evolutionary systems

Learning systems (artificial neural network)



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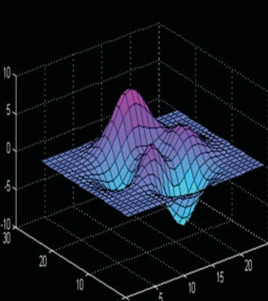
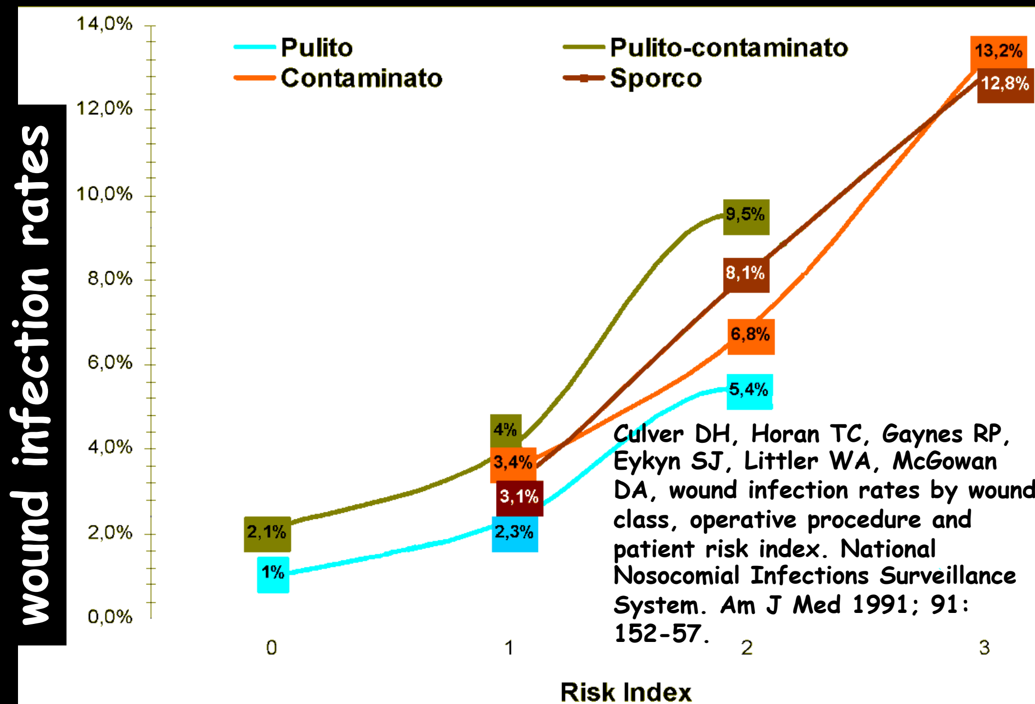


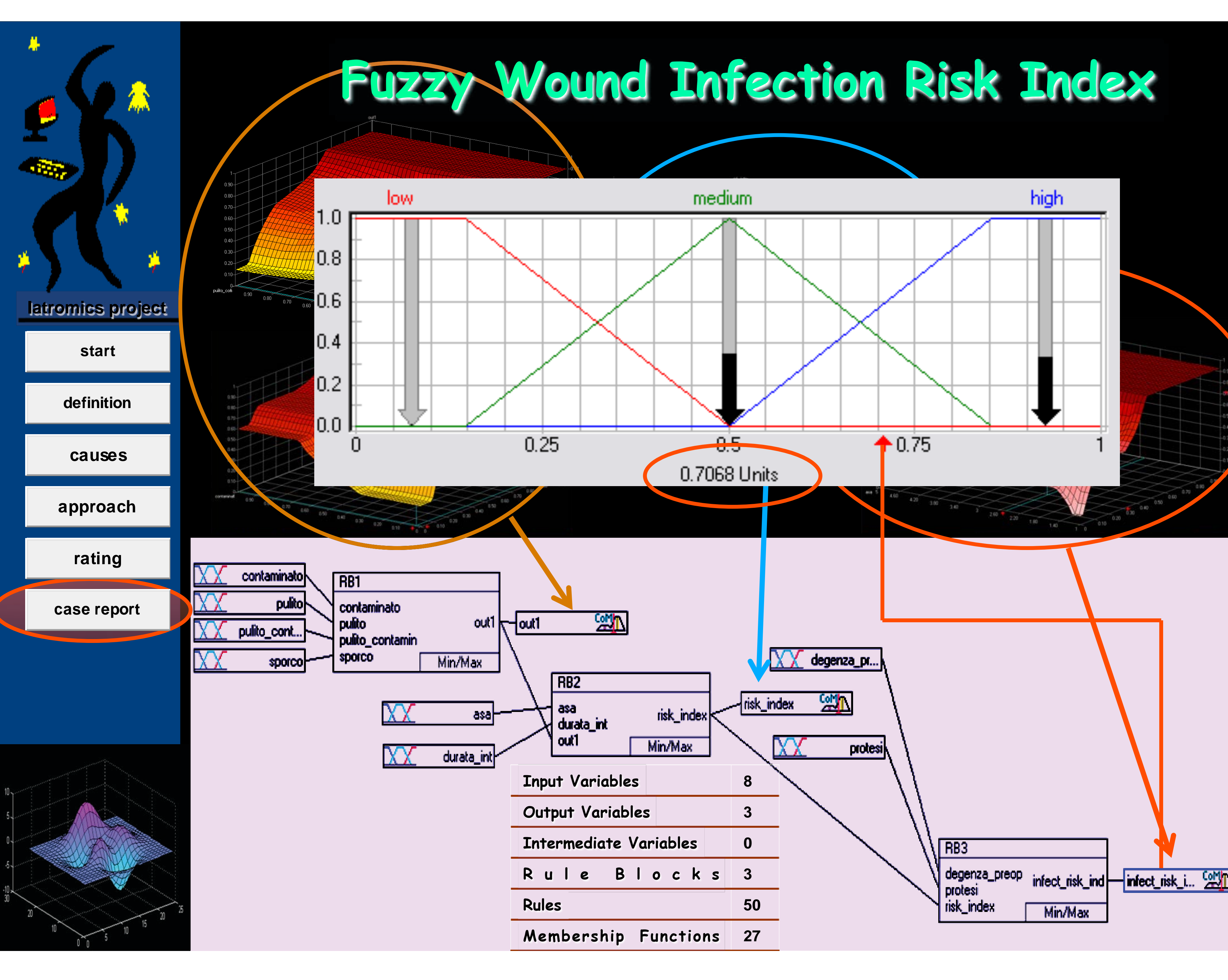
A case report:

Antibiotic resistance

Microorganisms have the ability to change their genetic heritage is through individual spontaneous mutation or through genetic exchange. This means that the bacteria are available to virtually the entire chromosome complement of all existing microorganisms are the only living things that can have an exchange of genetic material between species.

This great opportunity allows bacteria to adapt to any environment, including those dominated and determined by antibiotics.





Input Variables	8
Output Variables	3
Intermediate Variables	0
Rule Blocks	3
Rules	50
Membership Functions	27

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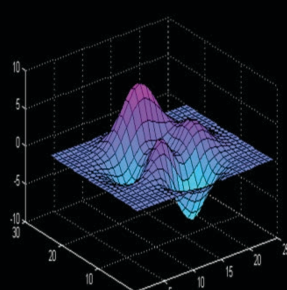

A case report:
Antibiotic resistance

NUMBER OF OPERATIONS PERFORMED IN THE OPERATING ROOM
TOTAL 5930

EXPECTED VALUE OF NUMBER OF SURGICAL OPERATIONS WITH ANTIBIOTIC PROPHILAXYS
N. Operations X Fuzzy Risk Index Infection: 5930 X 0.7 ≈ 4150

ANTIBIOTIC UNIT PROVIDED TO THE OPERATING ROOM = N ° 5148

Inappropriateness value ≈ 19%

- Start DEMING PROCESS Continuos Quality Improvement
- Hospital or Surgery Impatient Unit BENCHMARKING

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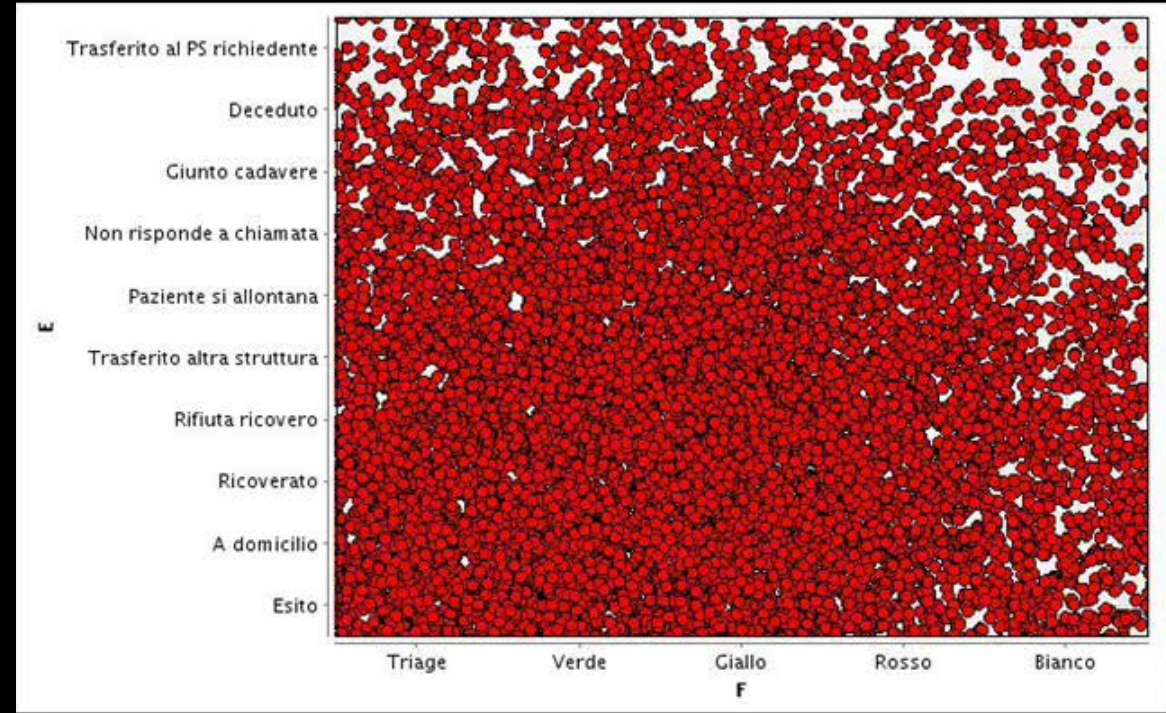
A case report:
First Aid Department



Accesso PS Triage Anamnesi Chiusura cartellino esito

maurizio.musolino@aslromab.it

Iatromics project

By Maurizio Musolino

Thanks for your attention

Maurizio Musolino

Learning from the mistakes not to repeat them
but ... to invent ever new !!!