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European Society of Regional Anaesthesia & Pain Therapy ESRA ITALIA

ESRA Italian Chapter



CLINICAL RISK

"the hazard that a patient can suffer from an involuntary damage, ascribable to healthcare, which causes an increase in the hospitalization period, a worsening in clinical conditions or death."

https://www.salute.gov.it/imgs/C_17_pubblicazioni_640_allegato.pdf



STRUCTURAL and TECHNOLOGICAL CAUSES

- 1. Safety of the spaces;
- 2. Equipment and tools (working, maintenance, renovation);
- 3. infrastructures, links, digitalisation, computerisation.

MANAGEMENT FACTORS AND WORK CONDITIONS

1. Organisation (roles, responsibilities, work distribution);

2. Policy and management of human resources: various types of leadership, merit base employement, monitoring of the activities, training and updating of the team, workload and shifts;

3. Organizational communication system;

4. Environmental aspects (such as: spaces, screens, alarms, noises, lights);

5. Healthcare promotion campaign: guidelines, diagnostic and therapeutic pathways, mistakes reporting systems.

HUMAN FACTORS (individual and team)

Individual carachteristics: (feeling, focus, memory, the ability of making decisions, being aware of their own responsibilities, physical and mental conditions, psychomotor abilities) e professional knowledge;

Interpersonal and team dynamics, capacity of cooperation.

USERS CARACHTERISTICS

epidemiology and socio-cultural aspects (such as demographic aspects, race, growth environment, education level, ability to manag situations, complexity and comorbidities of acute and chronic pathologies;
Social network.

EXTERNAL FACTORS

- laws;
- Financial requirement;
- Social, economic and cultural background;
- Influences by other people, media opinions, or trade association;
- insurances.

CLINICAL AUDIT

5. Implementing change

1. Identify problem or issue

4. Compare performance with criteria & standards

3. Observe practice / data collection

2. Set criteria & standards

it's a mean to:

1. Guarantee that patients receive the best therapies

- Improve the multidisciplinary work;
- Promote the optimization of the available resources;
- Be an opportunity of training and improving.

2. In the specific field of safety of patient the audit allows to:
- identify the risks linked to clinical activities and organizations
- identify mistakes

- identify causes and factors that contributes to adverse event learn how to improve.

AUDIT CONTENTS

- 1. Clinical and welfare activities outcome;
- 2. Healthcare services;
- 3. Resources and their use;
- 4. All kinds of formal and informal aidnformali;
- 5. Organisation processes.

1. *How to choose the topics*: they can involve the evaluation of tratments, services, policies and organisations. The criteria that can help to define the priorities are: how many times the same mistake or problem can arise, how much serious the consequences can be, how easy it can be to find the best solution or to prevent the bad event.

2. Definition of the aims: They must be specific and detailed.

3. *Identification of targets:* The clinical audit is an activity based on comparisions with specific targets about services and cares.



CLINICAL CASE

- 60 YEARS OLD MALE PATIENT SUFFERING FROM LUMBAR RADICAL PAIN NOT RESPONDING TO PHARMACOLOGICAL THERAPY BECAUSE OF THE PRESENCE OF MULTIPLE HERNIATIONS IN LUMBAR REGION
- THE DOCTOR GIVES INDICATION TO START WITH A CYCLE OF EPIDURAL BLOCK

• INFORMED CONSENT FORM ABOUT THE PROCEDURE



COUNTERPART'S CENSORSHIP 1

2. ABSENCE OF HOSPITAL PROTOCOL

1. NOT WELL WRITTEN INFORMED CONSENT

- Transitory slight improvement of the symptoms after the first epidural nerve, but exacerbation of back pain after the third procedure, for this reason the patient hab been sent to a neurosurgical center that gives indication to intervention '.
- After 40 days from the thir and last epidural block, he has been admitted to hospital in neurosurgery ward, and the same day 38 degrees fever occurs.
- A blood culture has been taken and the patient received a neurosurgical intervention of lumbar stabilization with laminectomy arthrodesis, and fixation devices.
- Antibiotic prophilaxis (cafazolin 2gr iv)
- During surgical operation flogisitic and purulent material has been isolated from subcutaneous up to bone and sent to coltural (only histological) exam.

COUNTERPART'S CENSORSHIP 2

<u>The patient should have been better studied for his septic condition, as he had</u> <u>fever when he was admitted to hospital, and they should have waited at least for</u> the results of his blood colture before admitting him to the operatory theatre.

<u>Il paziente avrebbe dovuto essere studiato meglio per lo stato infettivo, febbre presente al ricovero nel sospetto di infezione e attendere la risoluzione dell'infezione prima del trasferimento in sala operatoria, almeno attendere l'esito dell'emocoltura.</u>

- After three days from the intervention the patient had still fever and the coltural exam showed the positivity for MSSA.
- Antibiotic therapy has been started (teicoplanine 400 mg).
- After 10 days the patient has been admitted again to the operatory room to remove fixation devices.
- After 40 days of antibiotic therapy new fixation devices have been positioned (third surgical intervention).

COUNTERPART'S CENSORSHIP 1

Inadequate antibiotic therapy because of kind of antibiotic, timing and dosage



• DIMISSIONE DAL REPARTO DOPO 60 GIORNI DI DEGENZA CON PEGGIORAMENTO DELLA CONDIZIONE DELL'ARTICOLARITA' LOMBARE (BLOCCO IN ARTRODESI).

OUT OF HOSPITAL

• The patient has been released from hospital after 60 days of recovery, suffering from a deterioration in lumbar articular condition.

REQUEST FOR DAMAGES COMPENSATION TO TWO DIFFERENT HEALTHCARE STRUCTURES

WHERE THE EPIDURAL NERVE BLOCK WAS MADE.

WHERE THE SURGICAL OPERATION WERE MADE.

The anesthesiology doctor who made the epidural block in the first hospital has been involved (EX ART 13.2017)

CENSURE CONCLUSIVE DA PARTE DEL RICHIEDENTE

First hospital and Anesthesiologist

- 1. The manuevre has been conducted without a sterile procedure;
- 2. Absence of more detailed and specific informed consent form;
- 3. Diagnosis of spondylodiscitis caused by lack of sterile procedures.

Second hospital (neurosurgery department)

- 1. having carried out surgery without waiting for blood culture examination;
- 2. having positioned the fixation devices even with a suspected infection in the epidural site;
- 3. incorrect choice, dosage and timing of antibiotic therapy.

ANAESTHESIOL OGIST DEFENSE

1. The presumed infection observed during the operation has not been confirmed by the histological exam that has shown only bones cells without inflammatory cells.

2. The MSSA infection after 40 days from the last nerve block can have been caused by another infectious event (from skin or urinary tract,...).

CONCLUSIONS

The responibilities has been entirely assigned to the second hospital and the neurosurgical department for non-fulfillment of professional obligations.

The damages has been totally compensated by the second healthcare structure.

What did we learned in the anaesthesiological field by the clinical audit?

It's very important to have a detailed informed consent form specific fo every procedure;
 It is useful to give a copy of the written and signed informed consent form to the patient where the loco-regional anaesthesiological procedure are well described;

3. It's essential to clearly write the initial neurological and clinical condition of the patient;

4.It should have been written in the informed consent form that, if the patient decide to stop the treatment before completing it, the doctor must have been promptly informed.

Thanks for your attention.



Bibliografia

1) Cohen, M. R. (ed.) 1999, Medication errors (AphA publications, Washington DC)

2) Kohn, L. T., Corrigan, J.M., Donaldson, M. S. (eds.) 2000, To err is human builing a safer

health system, (National Academy press, Washington DC)

3) Pittet D, Hugonnet S, Harbarth S, Mourouga P, Sauvan V, Touveneau S, Perneger TV 2000, Effectiveness of a hospital-wide programme to improve compliance with hand hygiene. Infection Control Programme, Lancet, 356(9238):1307-12.

4) Reason, J. 1997, Managing the risks of organizational accidents, (Ashgate, London)

5) Reason J; L'errore umano; Il Mulino; Bologna; 1990

6) Reason J; Human error: model and management; British Medical Journal; 2001; 320: 768-70

7) Vincent, C. 2001, Clinical risk management, (BMJ press, London)

8) Weick, K. E. and Sutcliffe, K. M. 2001, Managing the unexpected, (Jossey-Bass, San Francisco)

9) WS Atkins Consultants Ltd; Root causes analysis: literature review; Contract research report for health and safety executive; 2001

10) Canadian root cause analysis framework -

11) Root Cause Analysis VA national center for patient safety

12) Institute for healthcare improvement : failure modes and effects analysis tool process data report

13) www.weibull.com/basics/fmea.htm

14) WHO draft guidelines for adverse event reporting and learning systems

