Clinical Audit: Legal Medicine Service and clinical risk management

R. Giannini*, G. Terranova**

In Italian National Health System Legal Medicine Service, officially assigned by Regional laws to Prevention Department, was charged with the institutional task of assessing and evaluating permanent impairment and handicap in accordance with national disabilities rights laws; that's the reason why legal medicine service counselling in a clinical setting has traditionally been considered an unusual application.

Since 1992 a sperimental project has been implemented in ASL3 (Local Health Care Organization - Pistoia Health Care Trust in Tuscany) Pescia hospital; ten years later the successful experience was carried out in Pistoia hospital.

In this enviroment our competence was focused on :

- clinical malpractice and claims analysis
- clinical records analysis and quality evaluation
- informed consent (forms and medical education)
- farmacological adverse events collecting data
- guide-lines implementation
- death causes (epidemiological indicators)

This activity is performed by medico legal specialists together with clinical staff without a structured manager's support. The challenge for 2005 is to build a risk map of the Health Care Organization to improve services' quality, patient safety and clinical risk prevention.

Since the publication of a First Class Service in UK in 1998 local health services' quality became a basic element of performance management in every public health care system, so we sorted out clinical audit[1] as the most effective tool to perform Clinical Governance[2], by monitoring health care providers' with gold standars. Clinical Audit can facilitate clinicians in learning evidence-based medicine (EBM) by means of clinical guide-lines implementation. So health care services can be improved with EBM. Clinical audit is useful in evaluating clinical outcomes and patients' perceived satisfaction. Deming's audit cycle includes the following steps :

- observing current practice
- setting standards
- comparing practice to standards and implementing change
- verifying outcomes

This is a continuous process. It has been suggested that audit is similar to research.

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[1] "Systematic and critical analysis of the quality of clinical care, including the procedures used for the diagnosis , treatment and care, the associated used of resources and the resulting outcomes and quality of life for the patients" (Quality in the NHS 'A first class service'. London , DoH, 1998)

[2] "Clinical governance is a powerful, new and comprehensive mechanism for ensuring that high standards of clinical care are mantained through the NHS and the quality of service is continuously improved" (Clinical Governance in Primary Care Oxford; Radcliffe Press, 2000) or " A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an enviroment in which excellence in clinical care will fluorich" (DoH, 1998)

Since 1992 Legal Medicine Service has been collecting claims data in a special software. Following graphs describe trends in incidence of claims, their distribution by medical specialty (with general and orthopaedic surgeons, obstetricians and emergency physicians being most frequently envolved) and causes of clinical negligence (misdiagnosis, technical failure, miscommunication between patient and doctor…). The rate of litigation increased during the period 1992-2004 but we didn't observe the uncontrolled explosion spread out by media. Unfortunately, there is very little information about claims settlements and the costs that have been incurred because of the time lag between incidents, claims and settlements and lack of communication with Insurance Companies. Nevertheless, data arising from clinical malpractice claims helped us in building a risk map and an effective risk management system. We didn't use self incident reporting because we found no evidence of its effectiveness (in literature the reported number of identified errors was always small in comparison with the number of examinations carried out and the theorical estimate of adverse events occurring in hospitals). On the contrary we performed:

- **an internal and retrospective case record analysis**, identified medical errors and organisation's failures, discussed results with physicians during internal audits and selected priorities based on the above analysis.
- **a proactive approach analysing data** from informatic data bases as SDO, clinical records, and epidemiological indicators.

Criteria to identify adverse events, discussed with participating clinicians, may be applied in the single case by a specific professional, the Facilitator. For each problem the work group agrees upon right correctives such as guide-lines implementation or new forms. These actions may be effective to plan changes in patient management.

We produced the following forms on the basis of Failure Mode and Effect Analysis (FMEA) and Root Causes Analysis (RCA):

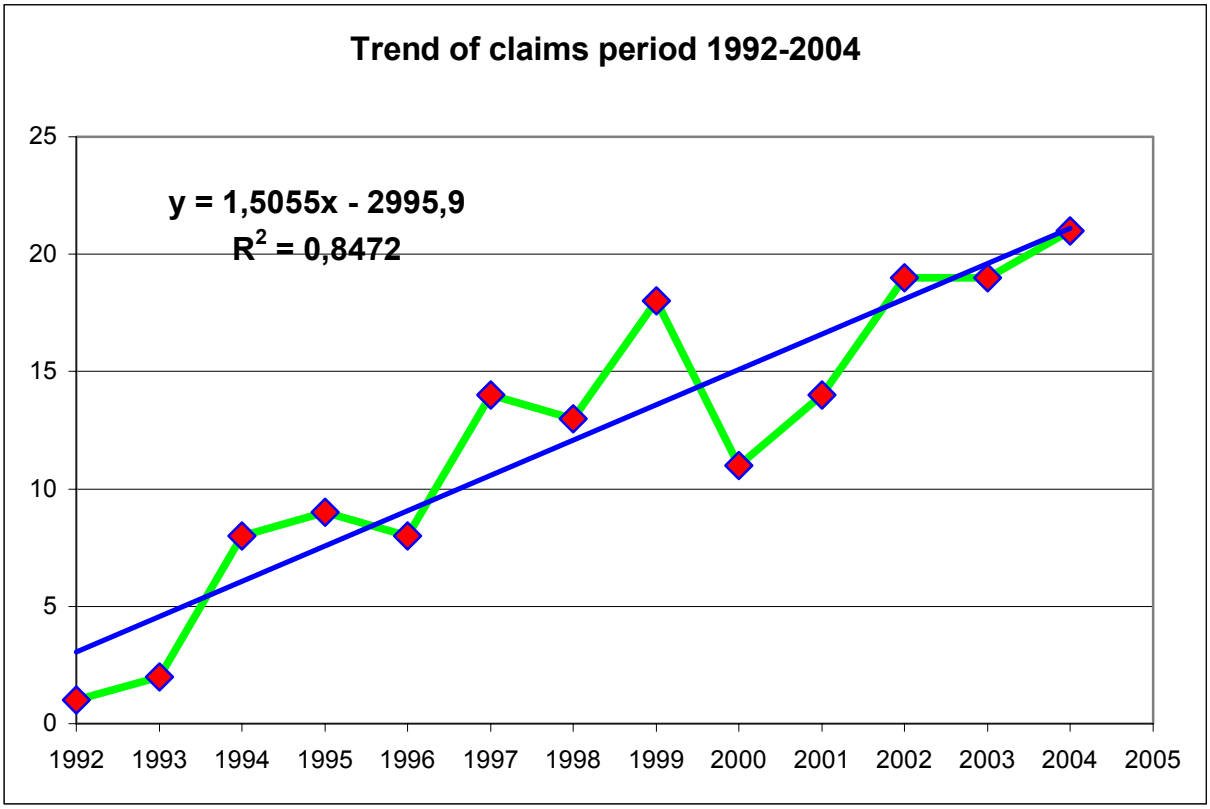
- **THE FACT** (a syntetic description of the adverse event, selecting key words for literature research)
- **ANALYSIS SHEET** (a form where clinicians and other professionals make judgments, explain their point of view, discuss any sort of failing and suggest appropriate corrective actions)
- **ASSESSMENTS FORM** (containing agreements achieved for managing risk, subjects identified , each responsibility, and the timing of actions)
- **ANAGRAPHIC FORM** (a final synthesis of audit process with every information needed for a proper classification)

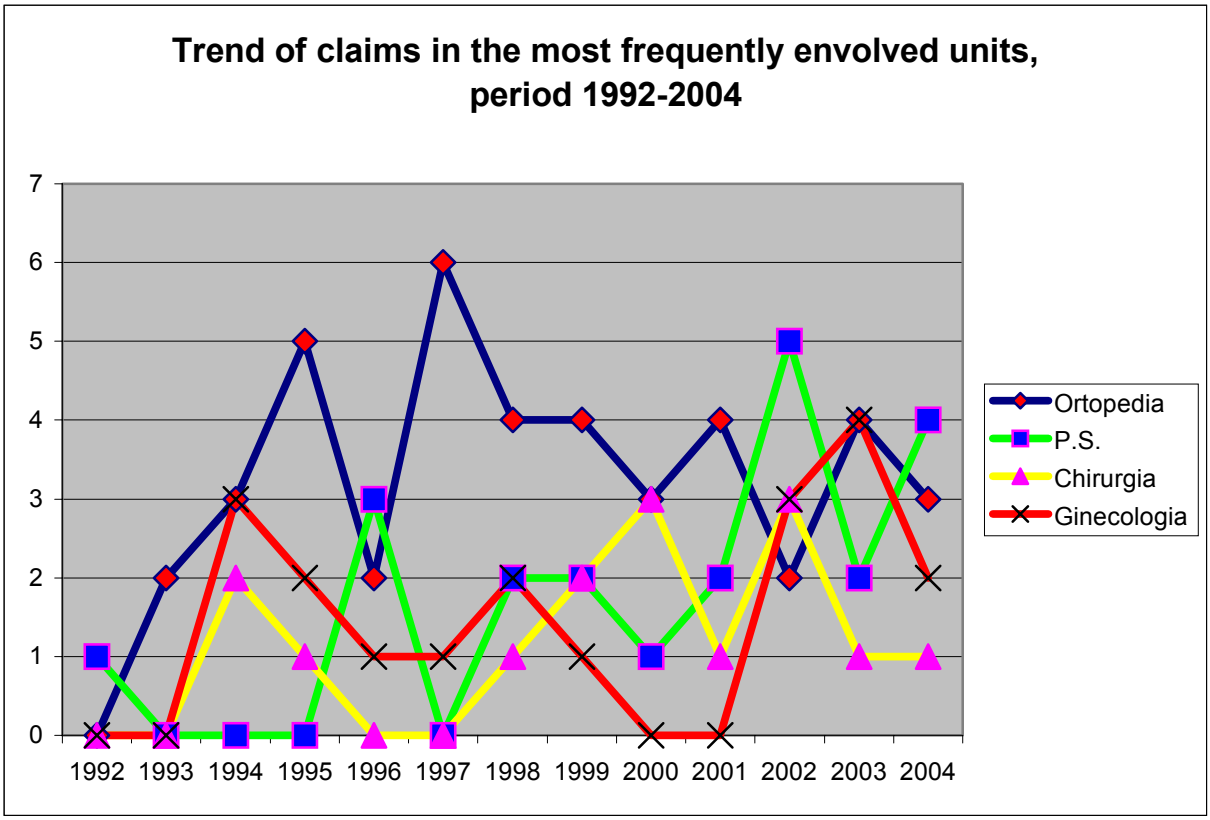
The next step of the risk management process in Pistoia Health Care Trust will focuse on building a special risk management software, based on the international best evidence, including a risk grading matrix (likelihood of occurrence per potential consequences). We are going to define categories of risk in order to provide a preventive priorisation for management action.

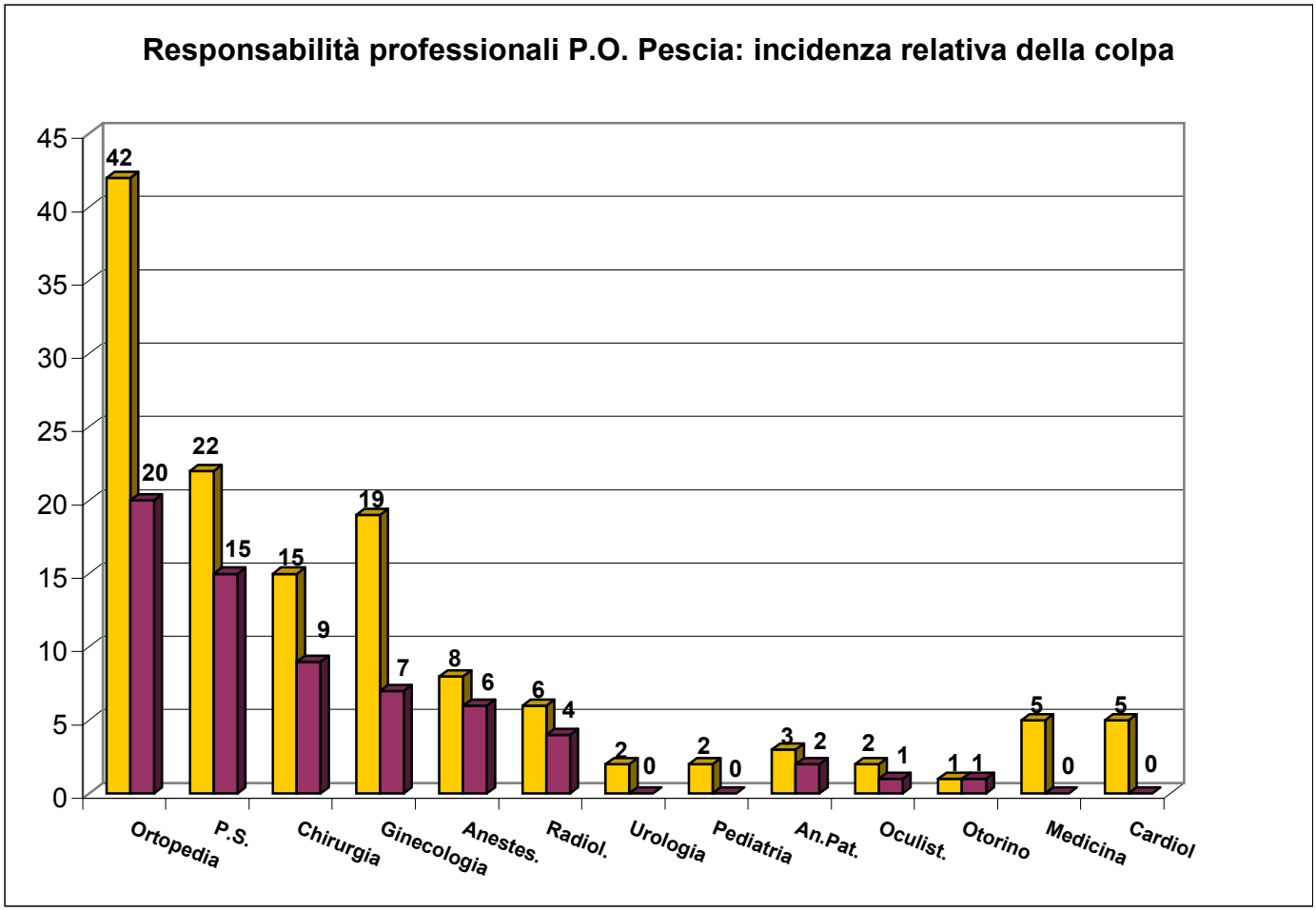
Nowadays we recognize the following barriers that could prevent from implementing clinical change:

- **lack of the official risk management trust plan** (clinical audits are most effective when part of a structured program planned and scheduled to fit with the priorities of the clinical staff)
- **inadequate top-down support** (defining personal responsibilities and specific actions reduces the likelihood of audits' failing)
- **insufficient medical education** (full partecipation in identifying and agreeing topics for audit reduces resistance to change and increases the commitments to both undertaking the audit and making changes as a result of it)

This will go a long way towards ensuring that lessons learned from incident reporting inform practice, for these lessons are best learned when the management of risk is seen not as an extra but as an integral part of care. Now we are going to implement in ASL 3 the Clinical Risk Management Regional guide line where Medico Legal Service plays a very important role in every organizational step. In fact Regional Committee of Clinical Risk Management is going to promote a medical education project to standardize local experiences and define a regional risk map; so we are involved in this new adventure.


Trend of claims period 1992-2004
y = 1,5055x - 2995,9
R2 = 0,8472
25
20
15
10
5
0
1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005


Trend of claims in the most frequently envolved units, period 1992-2004
7
6
5
4
3
2
1
0
1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004
Ortopedia
P.S.
Chirurgia
Ginecologia


Responsabilità professionali P.O. Pescia: incidenza relativa della colpa
45
40
35
30
25
20
15
10
5
0
42
20
22
15
15
9
19
7
8
6
6
4
2
0
2
0
3
2
2
1
1
1
5
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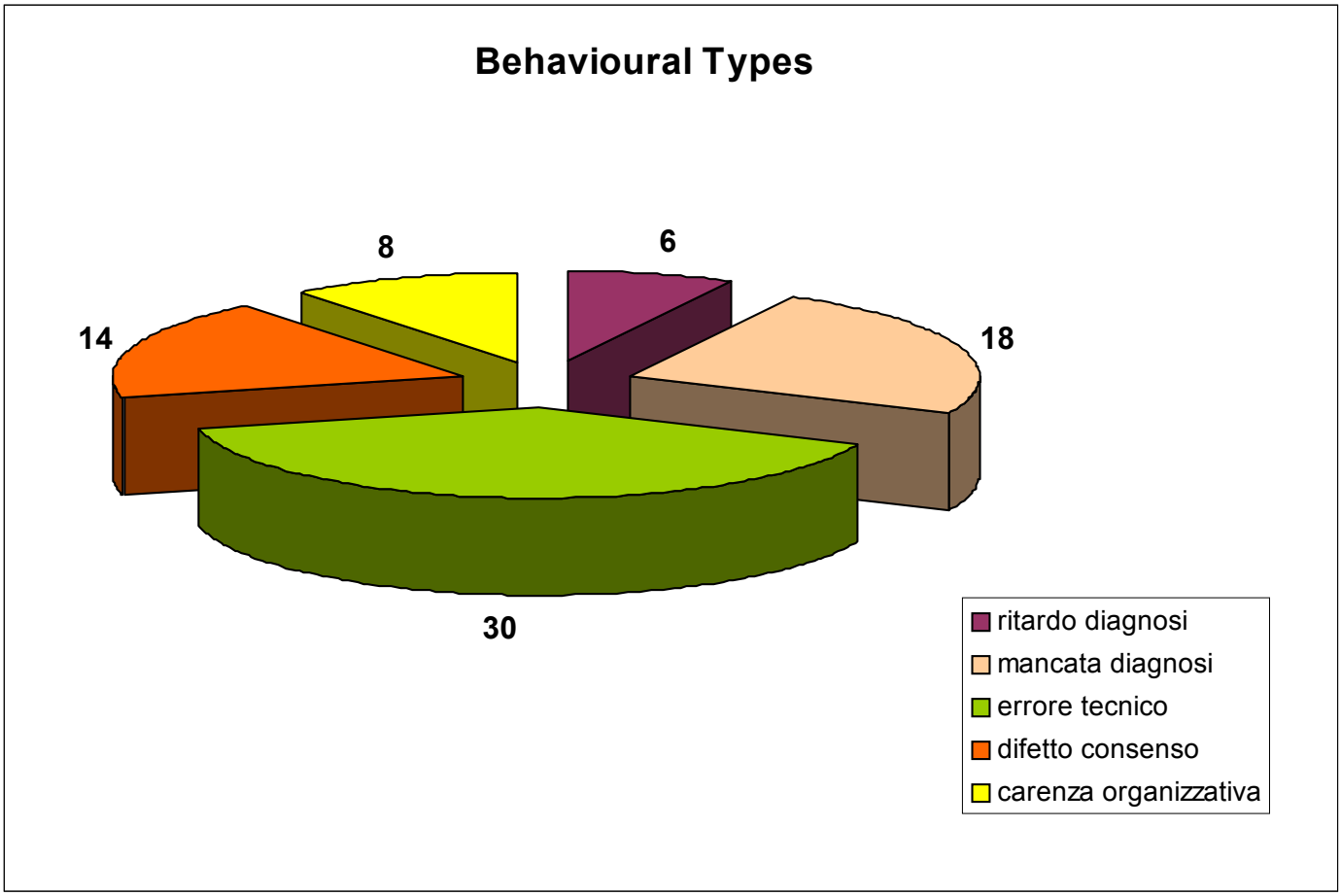
Ortopedia
P.S.
Chirurgia
Ginecologia
Anestes.
Radiol.
Urologia
Pediatria
An.Pat.
Oculist.
Otorino
Medicina
Cardiol


Behavioural Types
8
6
14
18
30
ritardo diagnosi
mancata diagnosi
errore tecnico
difetto consenso
carenza organizzativa