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2014 Italian Presidency of the Council of the European Union

Best practice for reporting adverse events

CONFERENCE QUALITY SAFETY AND COST-EFFECTIVENESS

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D.ssa Lucia Guidotti
Ministero della Salute
l.guidotti@sanita.it

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Introduction

- Comparing different systems: a constructive approach
- The Italian system for quality in PS
- Conclusions

Comparing different systems: a constructive approach

Most part of the EU MS have a system to gather information on adverse events-

key points:

- Web based
- Anonimous
- A clear definition of what event is important to signal

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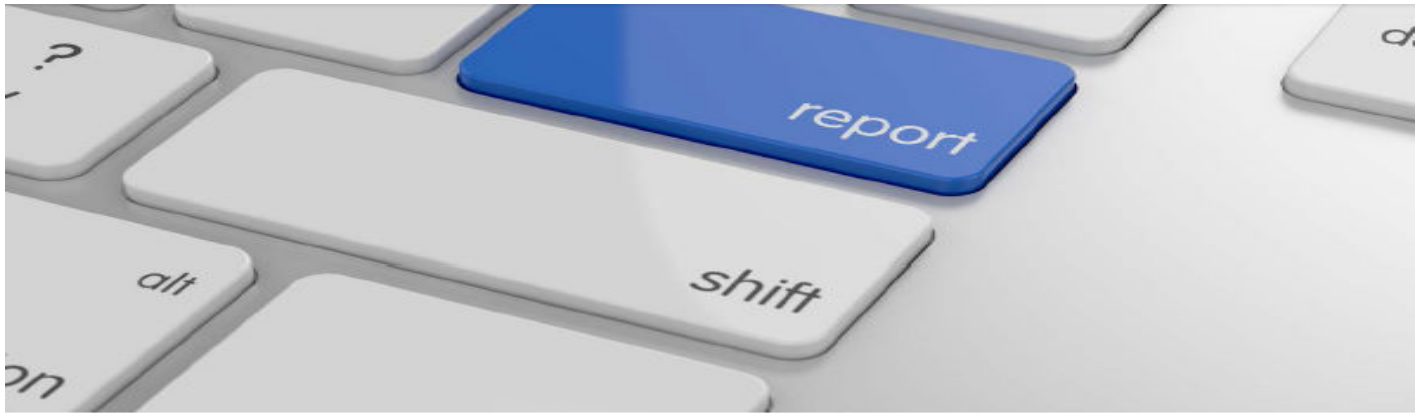
Comparing different systems: a constructive approach



Key findings and recommendations on

Reporting and learning systems for patient safety incidents across Europe

Report of the
Reporting and learning subgroup of the European Commission PSQCWG

May 2014

EU Menber State	Name of the reporting system for incidents	Level
AUSTRIA	1. CIRSmedical.at. 2. Regional CIRS Network. 3. Local RLS	Regional (stand-alone) Local (stand-alone)
BELGIUM	Reporting and learning system for incidents and near-incidents.	Local (stand-alone)
CYPRUS	Reporting systems for adverse events and near incidents in public hospitals	Local (stand-alone)
CZECH REPUBLIC	Nationwide incident reporting system.	National
DENMARK	Danish patient safety database.	National
ESTONIA	Different names in regional hospitals — local stand-alone systems.	National Local (stand-alone)
FRANCE*	Reporting and Learning systems at regional and local level have different names.	Regional (stand alone) Local (stand alone)
GERMANY**	1. CIRSmedical.de. 2. Hospital CIRS Network. 3. Error reporting and learning system for primary care in Germany. 4. Network CIRS Berlin.	Nationwide (1, 2, 3) Regional (4)
HUNGARY	National reporting and learning system (NEVES).	National
IRELAND	National adverse event management system (NAEMS).	National
ITALY	Sentinel events monitoring system.	National Regional Local (connection to a central system)
LATVIA	Some hospitals have established their own reporting and learning systems.	Local (stand-alone)
LUXEMBOURG	Hospitals have established their own reporting and learning systems at local level.	Local (stand-alone)

EU Menber State	Name of the reporting system for incidents	Level
NETHERLANDS	Nationwide reporting and learning system for medication incidents: Centrale Medicatie-incidenten Registratie (CMR) is now extended to a system for all healthcare incidents. Local reporting systems in hospitals and primary care	National Local (connection to the central system)
NORWAY	Incident reporting system.	National
SLOVAKIA	Mandatory reporting of incidents and voluntary reporting of errors in the provision of hospital healthcare.	National
SLOVENIA	Nationwide incident reporting system.	National
SPAIN	Sistema de Notificación y Aprendizaje para la Seguridad del Paciente (SINASP)	National Regional Local (connection to a central system)
UNITED KINGDOM	National reporting and learning system.	National Local (connection to a central system)

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Comparing different systems: a constructive approach

Developments:

- An European network to share information among member states

SEaL-Share Exchange and Learn:

a voluntary mechanism for sharing and exchanging information on PS

Barriers:

Language, differences among health systems, common definitions, blame-free, accountability

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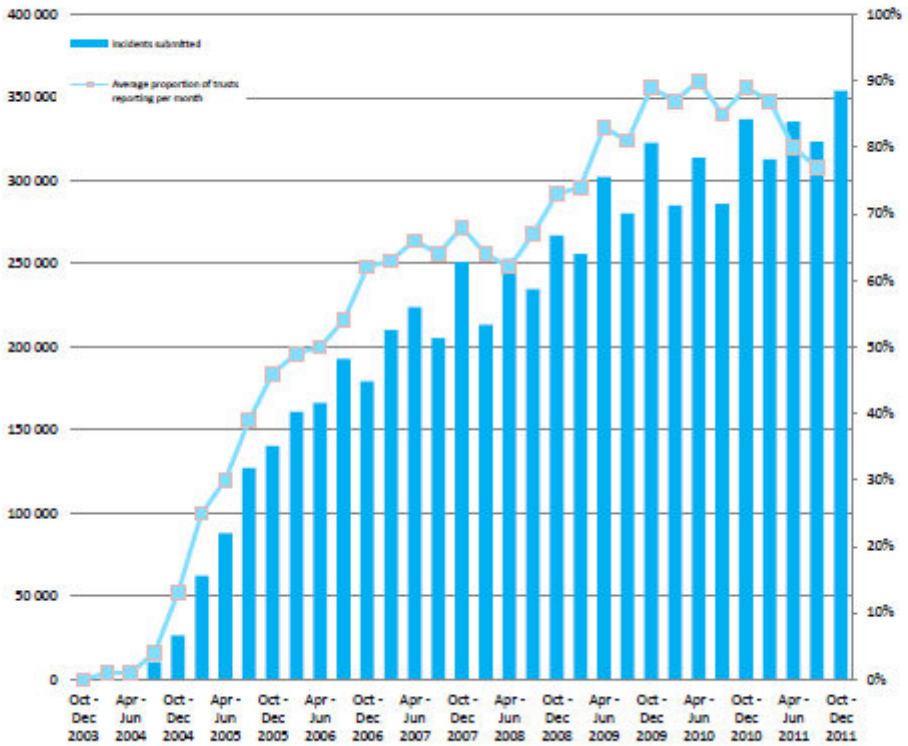
How -Approach of SeAL for the response to reported cases at MS level

- Notification of the case (or cases) in a Member State
- Validation of the notification at the level of the Member State;
- determination of the seriousness of the accident that has occurred and whether it is possible to respond;
- response within the Member State



Around **12,000,000** incidents have been reported.

Approximately **4,000** incidents are reported to the NRLS per day

Around **94%** of incidents cause low or no harm

National Patient Safety Alerting System (NaPSAS)

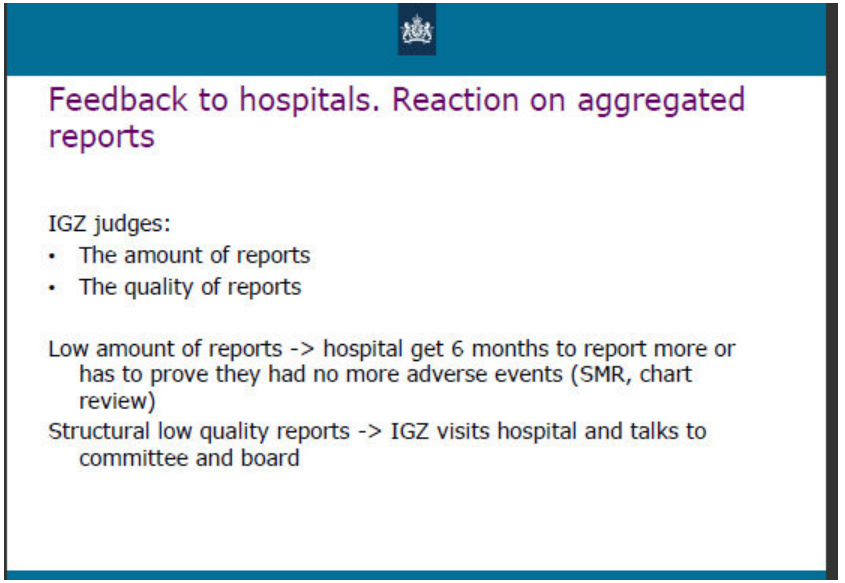
NHS

Comparing different systems: a constructive approach

- Comparing the reports

Check the quality

Check the total amount



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Comparing different systems: a constructive approach

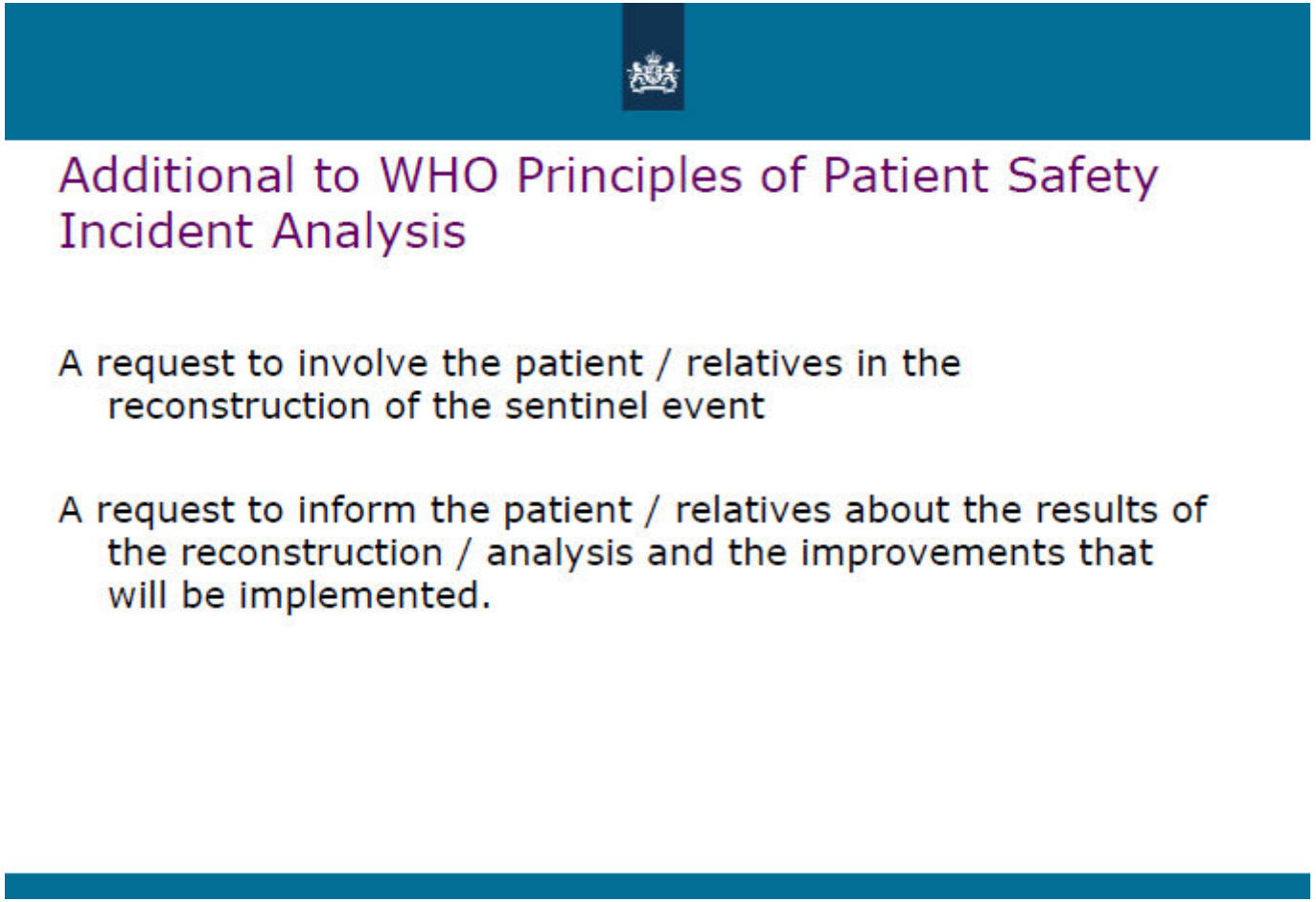
WHO Principles of Patient Safety Incident Analysis

To be credible, an Analysis must:

- Include participation of leadership and those closely involved
- Address conclusions with recommendations for reducing risk
- Include consideration of relevant literature and other sources of information
- Include an evaluation plan to determine if recommendations are implemented and if so, what impact was achieved (if any)

Comparing different systems: a constructive approach

- Another issue: the patient involvement in SE



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The Italian system for quality in PS

- How can we use the reports to improve patient safety?

- How can we promote learning from reported events?


Sentinel Events
Data collection and analysis
The Italian System
Monitoring and Evaluation
Recommendations

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The Italian system for quality in PS

- collection of information on sentinel events
- analysis of causes and contributing factors
- elaboration and implementation of specific recommendations
- Verification of the implementation at local level

The Italian system for quality in PS

Analysis of Sentinel Events

- The MoH has a National Observatory about sentinel events

- The adverse events, processed in a completely anonymous and confidential way, are forwarded to the National Health Information System throught a specific flow called Information System Monitoring Errors (SIMES).

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National System reporting principles and features

Non-punitive	**Operators, health organizations and regions are free to report without fear of penalty or punishment**
Confidential	**The identities of the patient, reporter, and institution are kept confidential**
Independent	**The monitoring system is independent of any other authority with punitive power against those who report**
Expert analysis	**The data are analyzed by experts who understand the clinical circumstances, causes and contributing factors**
Timely	**The data is analyzed in a timely manner and recommendations are quickly disseminated to regions, organizations and operators**
Systems-oriented	**The recommendations are aimed at system changes and processes**
Responsive	**Disseminate reports, recommendations, and evaluate the implementation**

adapted from Lucian Leape; 2005

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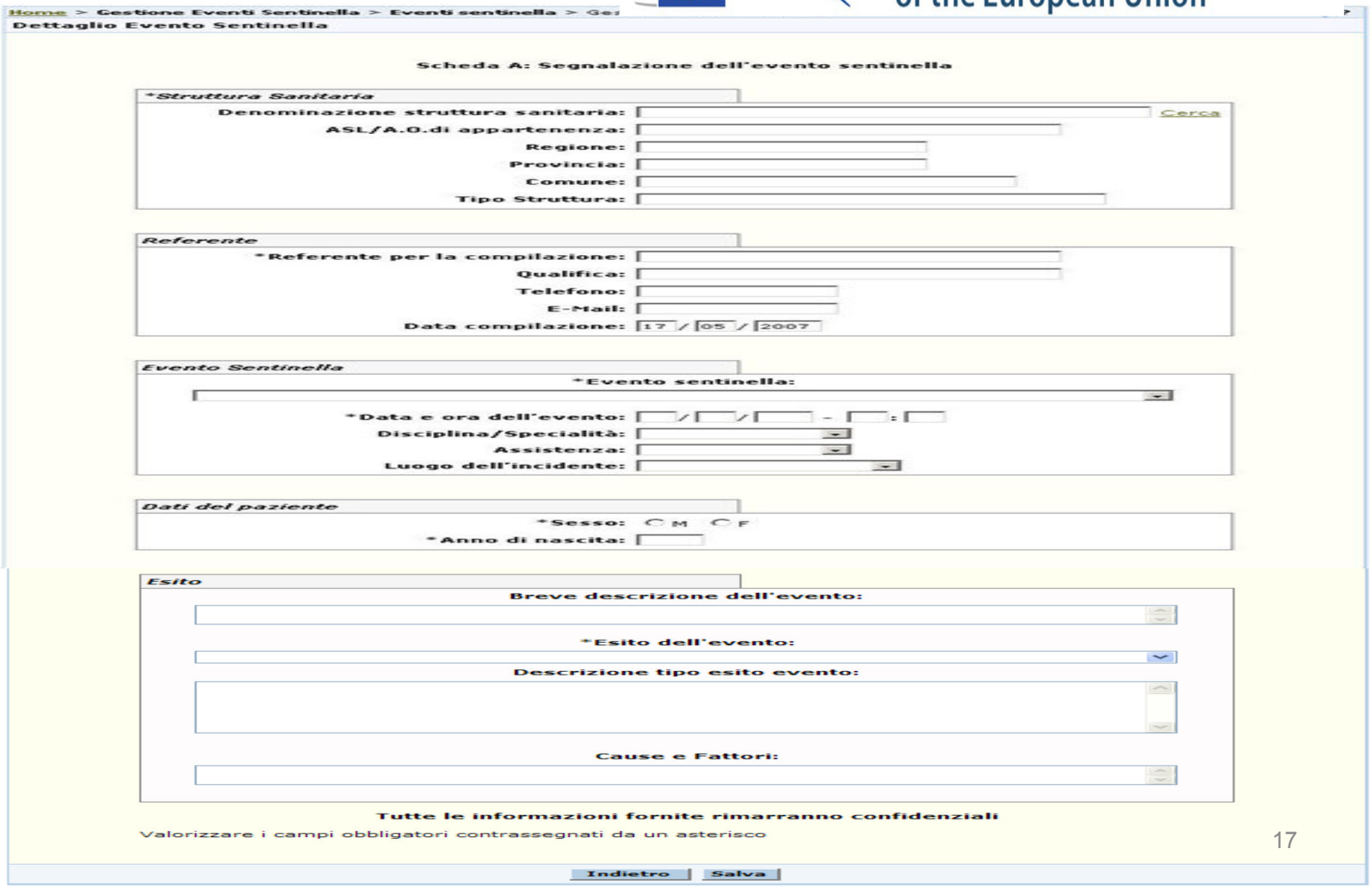

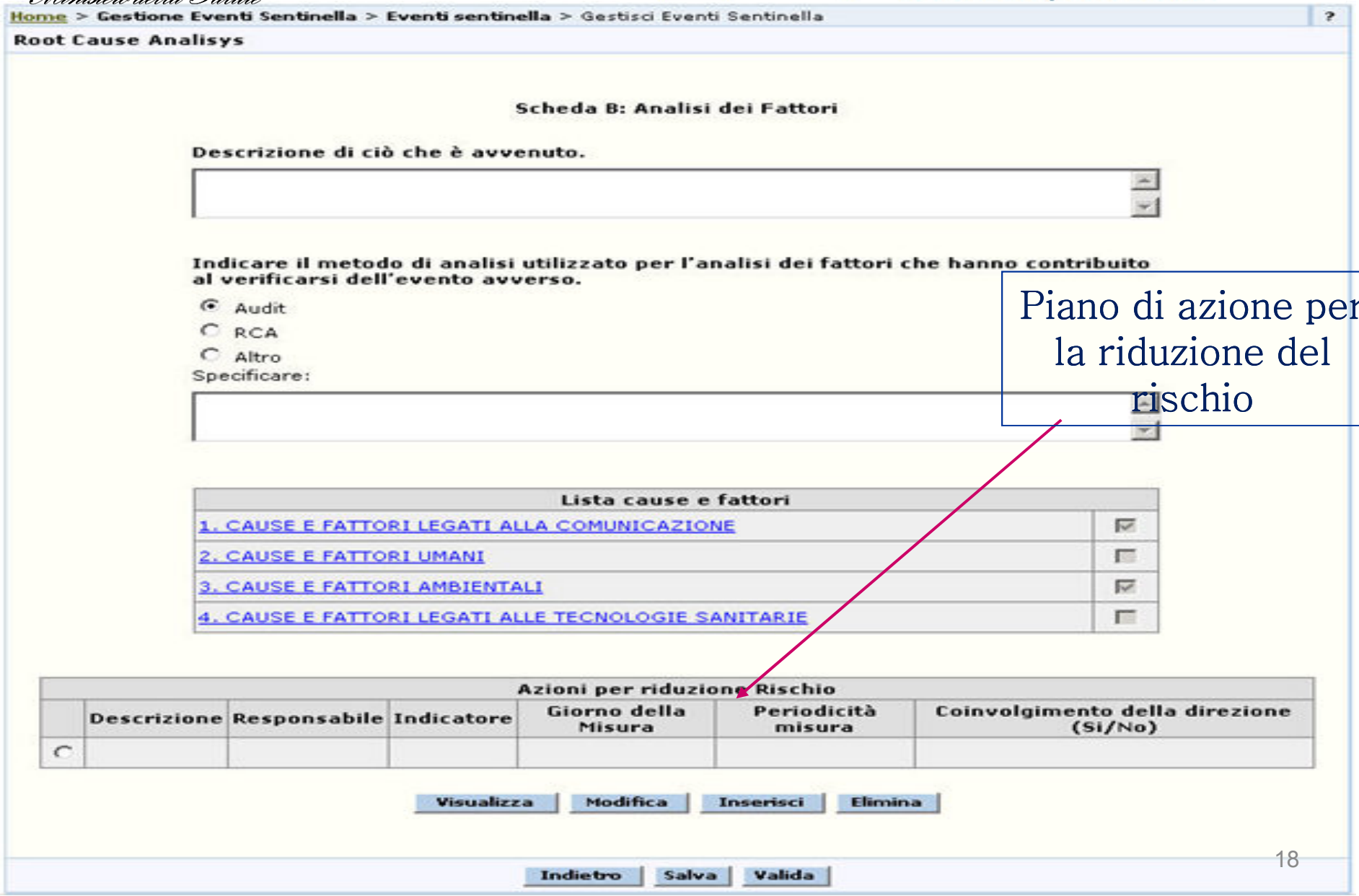

Piano di azione per la riduzione del rischio

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Italian System of sentinel Events Monitoring - Organizations involved in the process

Organizations involved in the process are:

Ministry of Health

- **Regions and Autonomous Provinces**
- **Hospitals and Health facilities**

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Italian System of sentinel Events Monitoring : Results

Information System for Monitoring Errors in Healthcare (SIMES) includes:

The Reports of sentinel events
The results of the analysis
The plans for improvement

Report
of sentinel events

TYPE OF EVENT	N°	%
Death or severe injury due to patient fall	471	24,56
Suicide	295	15,38
Every other adverse event that causes death or severe injury	275	14,34
Acts of violence sustained by healthcare workers	165	8,6
Retention of instruments or other foreign object during surgery requiring another or successive surgery or procedure performed to rectify error	159	8,29
Unexpected Death and/or Severe Harm Consequent to a Surgical Procedure	135	7,04
Death or permanent disability in healthy newborn	82	4,28
Death, coma or severe functional alterations derived from error in pharmacological therapy	79	4,12
Transfusion reaction consequent to AB0 incompatibility	72	3,75
Maternal death or illness correlated to labour and/or childbirth	55	2,87
Wrong procedure performed on correct patient	32	1,67
Death or severe injury due to an incorrect attribution of a triage code	27	1,41
Procedure performed on wrong body part (side, organ or part)	26	1,36
Procedure performed on wrong patient	16	0,83
Death or severe harm consequent to a malfunction of the transport system	15	0,78
Violent acts to hospitalized patient	14	0,73
TOTAL	**1918**	**100**

Italian System of sentinel Events Monitoring : Results

SPECIALITA	N°	%
MEDICINA GENERALE	261	13,61
NON SPECIFICATO	221	11,52
OSTETRICIA E GINECOLOGIA	207	10,79
CHIRURGIA GENERALE	205	10,69
PSICHIATRIA	152	7,92
ORTOPEDIA E TRAUMATOLOGIA	116	6,05
ASTANTERIA	115	6
CARDIOLOGIA	44	2,29
RECUPERO E RIABILITAZIONE	44	2,29
NEUROLOGIA	36	1,88
RADIOLOGIA	35	1,82
ANESTESIA E RIANIMAZIONE	33	1,72
GERIATRIA	33	1,72
UROLOGIA	31	1,62
PNEUMOLOGIA	25	1,3

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Italian System of sentinel Events Monitoring : Results

Metodo di Analisi	N.Eventi sentinella	%
RCA	581	42,66
Audit	536	39,35
Altro	219	16,08
NON SPECIFICATO	25	1,84

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Italian System of sentinel Events Monitoring : Results

FATTORI CONTRIBUENTI	N°
CAUSE E FATTORI AMBIENTALI	344
CAUSE E FATTORI UMANI	614
CAUSE E FATTORI LEGATI ALLA COMUNICAZIONE	741
CAUSE E FATTORI LEGATI ALLE TECNOLOGIE SANITARIE, FARMACI, ASSENZA DI LINEE GUIDA	1035

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Action Plans

The number of action plans submitted by health facilities compared to the total number of sentinel events is 66%

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The Italian system for quality in PS

Guidelines for the management of the relationship between patients and health care organizations at the occurrence of an **Adverse Event**

for an open and transparent communication

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Italian System of sentinel Events Monitoring : weaknesses

- Under-reporting
- Difficulty to investigate by the national level
- Difficulty in the accuracy of the information
- The quality and quantity of information are highly dependent on the organization that reports the event, its safety culture:
  - Ability to investigate (RCA)
  - Ability to respond

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Italian System of sentinel Events Monitoring : strengths

- Trend to progressive increase in reporting
- Gradual overcoming of barriers to the identification and analysis of adverse events
- Increase of the culture of safety in the health care organizations

The Italian system for quality in PS

The Recommendations System

- Recommendations arise from:

  Analysis of Sentinel Events
  Real cases, single case
  Working groups of experts

The Italian system for quality in PS

- **The Recommendations System**
- 16 Recommendations and 1 Manual

Topics:
Surgical Area: 2 Recommendations+1 Manual
Emergency Area: 2 Recommendations
Pharmaceutical Area: 5 Recommendations
Area Maternal-Infant: 2 Recommendations
Other specific Areas: 5 Recommendations

The Italian system for quality in PS

The implementation and verification

The Lea Questionnaire is a complex system for the performance evaluation of the Italian healthcare system,

It is based on an indicators system grouped by topic and annually updated.

Among these: the Clinical Risk Management and Patient Safety

Since 2011 a section on Recommendations has been introduced

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The implementation and verification

Questionnaire

- *Monitoring of the implementation of the Recommendations*
- *Centralization of the preparation of antineoplastic drugs*
- *Training for Health care workers*
- *Monitoring of adoption of Surgery Check list*

Conclusions

- maintaining attention and a commitment on safety issues
- verifications until the expected standard
- constant updating and comparison with international institutions
- participation in transnational projects, joint actions and EU iniziatives

Learing from errors….

- **Errare humanum est, perseverare autem diabolicum, et tertia non datur**

…and:

- **Well begun is half done**

THANK YOU FOR YOUR ATTENTION