



WHO Collaborating Centre  
in Human Factors and Communication  
for the Delivery of Safe and Quality care

# Centre for Clinical Risk Management and Patient Safety (GRC)

Department for Health of the Tuscany Region

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and Communication for the Delivery of Safe and Quality care

THINK, FEEL, ACT Patient Safety



# Background

The Clinical Risk Management and Patient Safety Centre (GRC) is a clinical governance structure instituted in 2003 by the Tuscan regional council. GRC builds on the expertise and vision of the former Ergonomics and Human Factors Research Centre in Healthcare (CRE), founded in 2000 as a joint endeavor of the Florence Healthcare Trust, the University of Florence and Siena.

The GRC now enrolls professionals of different disciplines (public health, clinical risk management, industrial design, human factors, organization studies, communication science, law, psychology, international relations). The GRC since the beginning of the activity is connected to a scientific committee.

GRC promotes the safety culture through the active and cross disciplinary learning from adverse events and errors. The GRC aims to construct a shared vision for safety through the sharing of experiences and the development of collaborative projects for patient safety. The centre proposes standards for the operational contexts and supports the effective measurement of critical process and measures.

Since 2011, GRC coordinates the Regional Committee for Compensation since the innovative choice of the Regional Government of bringing in-house the management of claims and litigation.

GRC since 2006 coordinates the National Technical Committee of Regions for patient safety (State-Regions agreement -2006).

The GRC Centre, in collaboration with Sant'Anna University in Pisa, holds annually an advanced course for clinical risk managers. The participation to course is a requirement to be formally appointed with the role of clinical risk manager in Tuscany hospitals. The scientific director and the executive officers hold positions as lecturers in patient safety, ergonomics and human factors at the University of Florence, Pisa and Siena.

GRC organized in Florence in 2005 the first International Conference "Healthcare Ergonomics and Patient Safety", that soon after became a triennial conference and a scientific programme of the International Ergonomics Association (IEA). GRC actively contribute to the steering Committee of the Conference in Strasburg (2008), Oviedo (2011) and Taipei (2014) and edited conference proceedings for the Florence, Strasburg and Oviedo conference.

Since its founding the Centre GRC has carried out important R&D projects for Italian and European Institutions:

- National Research Project "Promotion of Innovation and Risk Management" funded by the Ministry of Health and the Agency for Regional Health Services 2004-2007. This project laid the foundation for the clinical risk management in our country, developing a database for the management of claims, analyzing systems reporting<sup>1</sup>, introducing the practice of clinical audit and M&M;
- National Project of the Ministry of Health to Tuscany GRC Centre on Patient Centred Medical Record 2008-2011. The research allowed to define the standard of integrated medical record;
- Project of the Ministry of Health "Epidemiology study of adverse events in Italian Hospitals 2008-2010. This study allowed to obtain the first data on adverse events in Italy;
- National project SiGRT for the development of an integrated system for risk management in organ donation and transplantation, 2010-2013. This project contributed to the development of the Notify library for the surveillance of adverse events and reactions inn transplant and the subsequent appointment of the National Transplant Centre as WHO-CC;
- European Project HANDOVER (2011-2013) for the design and the implementation of the handover safety practice at the transition of care;
- European Project REMINE (2009-2011) for the proactive risk assessment of critical care process and the use of electronic health records to alert the clinicians and anticipate adverse events.

GRC also collaborated at other international cooperation programs with the Balkan countries, Middle East and South America.

# MIM Project

## Minimal Information Model for patient safety

GRC has joined the WHO-EU MIM project in 2014 - *Minimal Information Model for patient safety* - It has taken part in all phases of the project. Experts from GRC actively participated at all the on-line meeting and at the discussion by email related to the development of the project.

### Step 1

Survey of understanding whether the minimal eight data elements in each report provide sufficient information about the event:

- July 2014, GRC sent the 50 requested reports of adverse events, randomly selected from the regional RLS database of around 9000 reports collected in 2013.
- July 2014, GRC sent the English translations of the adverse event record and the user guide on the RLS.

### Step 2

Survey of building a basic taxonomy for the INCIDENT TYPE category:

- September 2014, GRC experts filled in the two requested questionnaire on the basic taxonomy for the incident type.

### Step 3

General survey of PS-R & LS for assessment of feasibility of using MIM and best practices:

- January 2015, GRC involved a dozen of power users (risk managers and patient safety officers) of the RLS to respond to the general survey on the feasibility of MIM.

In 12th-13th May 2015, GRC has been involved in the International Expert Consultation in Warsaw to validate the model at the European level.

In the meanwhile, GRC has redesigned the RLS with a new web-application including the full ICPS taxonomy, which has been reviewed and adapted to the national Italian context.

#### Step 4

Extension of the MIM-PS in low and middle-income countries (LMIC):

- September-December 2015, GRC collaborated with WHO HQ at the design and development of MIM-PS for low and middle income countries;
- January-March 2016, GRC received and analyzed reports, protocols and procedure from 5 LMIC;
- March 2016, GRC participated at the WHO meeting in Sri Lanka to present the report of the systems analysis conducted on the data provided from LMIC and to collaborate at the preliminary review of the updated WHO guidelines on reporting and learning systems.

As a result of the pilot application of MIM in LMIC, GRC is collaborating with the WHO HQ to support the establishment and development of RLS in LMIC, as well as to design a global knowledge sharing platform for patient safety that is part of the term of references as collaborating centre.

# Safe childbirth checklist

In 2015 WHO released the final version of the WHO Safe Childbirth Checklist (WHO SCC) after several years of field-testing, refinement and numerous collaborative projects activated around the world.

The WHO Safe Childbirth Checklist was designed as a tool to improve the quality of care provided to women giving birth. The tool was developed and designed in 2008 for low and middle-income countries and the program and the related pilot checklist were initially tested in Africa and Asia.

In order to gain a better understanding of how to effectively implement the Checklist in different settings around the world, WHO established the Safe Childbirth Checklist Collaboration, a collaborative field-testing exercise to explore implementation and usability of the Checklist in diverse settings around the world. Participants were invited to use the Checklist with the aim of exploring facilitating factors and barriers to effective implementation and use of the Checklist.

In 2015, GRC took part in the Safe Childbirth Checklist Collaboration Program after the launch of a pilot project on the use of an adapted prototype of the Safe Childbirth Checklist in several Hospitals of Tuscany Region. The pilot study involved 2 Teaching Hospitals and 2 Healthcare Trusts.

The pilot project can be defined as a implementation research whose aim was to re-design the WHO Safebirth Checklist according to the context of application and to introduce the tool for supporting sharp-end healthcare workers coping with critical activities during delivery.

The study was based on quantitative analysis aimed at evaluating: the checklist impact on clinical practice through a prospective pre and post-intervention study based on clinical records review, the usability and feasibility of the tool and the user's compliance by different healthcare operators.

# African Partnership for Patient Safety

African Partnerships for Patient Safety (APPS) is a WHO Patient Safety Program building sustainable patient safety partnerships between hospitals in countries of the WHO African Region and hospitals in other regions.

APPS is concerned with advocating for patient safety as a precondition of health care in the African Region and catalysing a range of actions that will strengthen health systems, assist in building local capacity and help reduce medical error and patient harm. The program acts as a channel for patient safety improvements that can spread across countries, uniting patient safety efforts.

The approach promoted by APPS emphasizes bidirectional and intercontinental transfer of knowledge, experience and solutions between front line health-care operators and it stimulates structural and behavioral changes at the hospital. Within APPS framework, the Tuscany Region in 2015 promoted a partnership with focus on patient safety and quality improvement with two hospitals in Kenya.

The regional Centre for Clinical Risk Management and Patient Safety and the Centre for Global Health, thanks to several years of experience respectively in patient safety and global health, supported the University Hospital of Siena (Italy), the Ruaraka Uhai Neema Hospital and North Kinangop Catholic Hospital to build a partnership for improvement following the APPS approach and focusing on critical areas of intervention for increasing the quality and safety of services delivered both in Kenya and in Italy.

The program for improvement jointly developed by Italy and Kenya focuses on critical areas in the global arena like infection and prevention control, safety in maternal and neonatal care and safety in surgery with the aims of facing the magnitude of harms and death in Kenya and in Italy as a direct result of unsafe healthcare.



Since the beginning of the partnership in 2015, three field missions have been done by the Italian partners including clinical staff and patient safety experts. In both hospitals in Kenya has been constituted a group of facilitators that represents the Patients Safety Team (PST). PST has been trained on basic principles of patient safety and clinical risk management: they will provide cascade training and act as leaders and champions for improvement. Italian and Kenyan PST have been defined strategies for implementing safety and quality programs in the four main areas of improvement (surgery, childbirth and Infection Prevention Control) and patient safety tools (e.g. Surgical Safety Checklist, Safe Childbirth Checklist, Hand Hygiene Campaign) have been customized according to local workflow, clinical procedures and cultural peculiarities.

The two hospitals started the piloting of customized patient safety tools and practices. PST is monitoring the pilots from the ground and is providing coaching and training on the job. Italian partners are supporting the local team at distance and through regular visit on the ground. A first usability and feasibility evaluation and an evaluation of impact on clinical practices are expected by the end of 2016.

Project inspired by WHO initiatives

# The Citizens' Academy

Starting from a collaboration with the Patients for Patient Safety of the WHO, the GRC has organized since 2008 a series of initiatives to involve citizens in policy and practices for patient safety, some specifically focused on patients activation.

Silvana Simi from Italy, Jolanta Bilinska from Poland and Margaret Murphy from Ireland are the three WHO champions who were more involved in these activities.

The Citizen Academy is a course organized by the Centre in collaboration with the Laboratory *PartecipaSalute* of the Research Institute Mario Negri of Milan and it is an education event tailored on patients' representatives needs and point of views.

The Academy trained representatives of 30 patient's associations for a total of 100 participants coming from differentiated pathologies and from different Italian regions. The course consists in one year course performing an education program on the topics of patient safety, the evaluation and improvement of healthcare assistance, the identification of shared solutions on main issue of patient safety, including the communication of adverse events.

Each patient champion enters a certification process and eventually gains the rights of membership to the permanent group of fellows of the Citizens Academy. These fellows are then involved into the institutional activities of GRC, such as the Safety Walkarounds (since 2014), Root Cause Analysis limited to specific cases (since 2009), the design and redesign of safety practices (since 2008).

# Education and Training for Patient Safety

Since 2006, GRC designed and developed an original certificate program for Clinical Risk Manager, it is an annual 100 hours course, including classroom activities mixed with case studies and role plays, organized and delivered in collaboration with the Sant'Anna University in Pisa. International scholars like Charles Vincent (Oxford University, UK), John Ovretveit (Karolinska University, Sweden) and Julius Pham (Johns Hopkins, USA) gave lectures at the program in recent years.

GRC has also a patient safety certificate of 40 hours for facilitators, intended for front-line clinicians involved in RLS and implementation of safety practices.

GRC produced and distributed in 2014 a multimedia package for the training of healthcare professionals, on the basis of the WHO patient safety curriculum. The product is currently available in Italian, the learning packages are delivered by means of interactive short movies, presentations and references. The topics includes: the application of surgical safety checklist, incident reporting and learning, adverse events disclosure, medication error, hospital acquired infections and patient falls.

Also some cartoons have been produced in 2015 for the education of citizens about patient safety. They are distributed through the online tube channel of GRC and soon also in the public and waiting areas of the healthcare trusts of the Tuscany Region.

GRC has also a collaboration with the three simulation centres of the Tuscany Region and has developed an original approach for the simulation in situ, transferable also to low-income countries.

*Previous projects in collaboration with WHO*

## Clean Hands Campaign

The Centre GRC started the Clean Hands Campaign in 2006, following the experience of the Geneva Academic hospital and then the WHO guidelines. The recommended indicators are a mandatory part of the in-hospital surveillance since 2011. Also, we have a safety practice for the correct use of the antibiotics and the surveillance of antimicrobial resistance surveillance since 2009.

## Safer Surgery Save Life

**Surgical Safety Checklist:** the Centre has promoted the implementation of the WHO surgical safety checklist since its launch in 2011, a member of our team also joined the presentation with Atul Gawande that took place in London. Now it is part of the accreditation requirement and we have further developed a more comprehensive checklist covering the entire surgical pathway.

*Project with the Global Sepsis Alliance*

## Sepsis clinical pathway

Since 2012 the Centre GRC actively support the actions of the Global Sepsis Alliance (GSA) for the reduction of the sepsis burden by promoting the World Sepsis Day, regional and national activities for the development of a multidisciplinary sepsis clinical pathway aiming to the World Sepsis Declaration. In 2016 the GRC was honored with the Global Sepsis Award as a Government and Health Care Authority.

## Global Knowledge Sharing Platform (GKSP)

Healthcare systems are still missing a timely and systematic way to share the lessons learnt on patient safety incidents. The GKSP will fill this gap providing an on-line application to report and discuss sentinel events, near misses and errors as well as harmless events with outstanding learning potential.

The Centre GRC will design and pilot a global knowledge sharing platform for risk management in real time on sentinel events and for producing and sharing knowledge on the effective actions to prevent or reduce patient safety incidents.

## Capacity building on Reporting and Learning practices for LMICs

In order to expand the use of reporting and learning systems for patient safety in Low Middle Income Countries (LMICs), capacity building for learning component in reporting and learning systems would be critical. A pilot on GKSP would give LMICs the training to input data based on MIM and to analyze data by using the data submitted by each country.

The Centre GRC will define and design the training materials for reporting and learning using MIM for Low Middle Income Countries

## Global Resource for Best Practices in Patient Safety and Quality of Care (GRBP)

Many safety practices have been effectively implemented in health systems worldwide, yet it still takes a lot of time to transfer evidencebased solution from the pioneering sites to other providers. The GRBP will be built to connect outreach centres involved in implementation of safety practices, so to share methods, tools and experiences of the local users to speed up the effective dissemination of patient safety and quality of care strategies.

The Centre GRC will contribute to the design and setting up of a Web based platform for identifying and sharing scalable solutions and systems leverages for improving patient safety and quality of care, to support the implementation of safety and quality practices in healthcare systems, from high, middle and low income countries.

# Dissemination and implementation of safety practices

Besides the quality of the safety practices, the capabilities of local facilitators, the methods used to implement change and the characteristics of the context are key determinants of success. The Centre GRC will therefore organize international collaboratives between low, middle and high income countries to improve the effective dissemination of the WHO campaigns for patient safety: clean care is safe care, surgical safety, safe childbirth and medication safety.

## Patient Safety Academy

The WHO patient safety academy is an educational initiative dedicated to policy makers, with ongoing initiatives to promote active learning, political initiatives and knowledge sharing between national, regional and local governments involved in health delivery, promotion and protection. The Centre GRC will organize study tours, seminars and prepare case studies on the integration and evaluation of patient safety in health policies. This activity will initially focus on the WHO Region of Europe, followed by inter-regional activities involving other WHO regions.

A repository of learning materials for policy makers and patient safety advocates on existing norms and recommendations, the evaluation of the impact of a selection of policies and a guide on different strategies to integrate safe and quality care in the systems governance will be set up by the Centre.

## Human factors and ergonomics (HFE) checkpoints in healthcare

Practical and easy-to-implement solutions for improving safety, health and working conditions in healthcare systems, with a specific focus on human-machines physical and cognitive interactions.

Inspired by the International Labour Office (ILO) ergonomics checkpoint, this guide will encompass high-risk situations in the healthcare contexts, showing with graphic representation the unsafe and safe behaviours in the use of medical devices, tools and medications.

Also, the book will include a user guide for the application of evidence-based HFE methods to assess and redesign usable tools and interfaces, with a specific focus on point of care technologies.

# Collaborations with the IEA

The Centre GRC will organize special sessions on human factors in healthcare within the next conferences of the International Ergonomics Association (IEA), especially for the IEA World Congress (Florence, 2018) in collaboration with WHO.

## Patient empowerment toolkit

On the basis of currently available tools and experiences, the patient empowerment toolkit will be designed and developed to support active learning of the individuals and the communities on the safe and appropriate use of healthcare services and treatments. *The Learning to question* approach will be devised through graphic materials available both on-line and off-line, so to enable individual learning as well as the use of the materials in social events within patients associations, schools and local communities.

## WHO Patient Safety curriculum

WHO patient safety curriculum is a milestone of the world alliance, yet to be fully appreciated and integrated in the academic programs and continuous professional development of the healthcare workers. The Centre GRC will support and collaborate with WHO and with some of the best global universities and integrate the WHO patient safety curriculum in the academic programs and the professional courses. The Centre GRC will also design and deliver an international patient safety certificate for healthcare workers.





# The public healthcare service of the Tuscany Region by numbers

3.6 millions citizens

50000 employees

36 hospitals, more than

100 primary care districts

2498 facilitators on the front line, distributed in each ward

38 risk managers and patient safety managers

53 expert patients trained in quality and safety at the citizens academy

48992 participants in patient safety CPD courses in 2015

2004 > 443 incident reports

2015 > 10447 systems analysis of incident reports

2006 > 2 safety practices

2015 > 32 evidence based safety practices

DVT complications from *Per one thousand surgical procedures* 1.87 in 2012 to 1.49 in 2015

Sepsis from 2.7 in 2014 to 2.5 in 2015

Among the lowest in the world with 4 maternal deaths every

100000 deliveries

-6% of the Italian national average of mortality in ICU

15 litigations per 10000 hospital admissions, constantly decreasing since the launch of the in-house communication and compensation programme

Half the time needed for the compensation with the in-house service, with an estimated 50 millions euros saved per year





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