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Improving Childbirth and Maternal Care - How to Foster the Use of Good Practices for Patient Safety

Barbara Labella, Roberta De Blasi, Vanda Raho,
Giulia De Matteis, Quinto Tozzi and
Giovanni Caracci

Additional information is available at the end of the chapter

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Abstract

Despite the global effort toward improving childbirth and maternity care, there are still complications (hemorrhage, infections, and high blood pressure) that may arise unexpectedly. To end preventable mortality, every woman needs skilled care at birth. The aim of this chapter is to present some solutions implemented by Frontline professionals and healthcare organizations made available through the Italian Observatory on Good Practices for Patient Safety, a national program to improve patient safety by promoting diffusion and active dissemination of evidence-based practices.

Keywords: childbirth, maternal care, patient safety, best practices

1. Vignette

A healthy 30-year-old woman after a straightforward delivery gave birth to a healthy girl. She was discharged from hospital the following day, but within the first week, she felt unwell and had fever. She saw her general practitioner (GP) twice during that week, but he did not notice anything wrong. Later that week, she was admitted to hospital with abdominal pain and septic shock. Her condition worsened rapidly and, despite the excellent inpatient care, she died shortly afterward.

2. Introduction

Despite the fact that maternal mortality rate in Italy is one of the lowest in Europe [1], sepsis remains one of the leading causes of preventable maternal death [2]. The body is vulnerable after pregnancy. Resources are depleted, and whether the birth was natural or surgical, large areas of the body are exposed and vulnerable to infection. To end preventable mortality, every pregnant woman needs skilled care at birth. Furthermore, it is crucial for a safe childbirth that continuity of care is ensured.

To prevent the occurrence of adverse events such as the one described above, the Local Health Authority of Treviso (Italy) has set up a multidisciplinary working group (gynecologists, obstetricians, nurses, anesthesiologists, and neonatologists) that has been mapping the whole path toward childbirth, from pregnancy to delivery, with the aim of ensuring (1) continuity of care before, during, and after childbirth, (2) uniform services are delivered, and (3) appropriate care based on the assessment of pregnancy-related risks regarding the case at hand. Besides the above, an analysis of adverse events and near misses has been carried out and situations that may influence the decision-making of professionals—such as confidence in own skills and lack of or excessive consideration of the patient's perspective—identified. Therefore, the following actions have been carried out:

- Identification of a suitable space for handover, possibly in front of a board so as to ensure that the professionals have all relevant information at the moment of taking charge.
- Definition and adoption of strategies aimed at promoting dialog between professionals in specific situations that are potentially at risk due to human or environment factors.
- Drafting an updated list of procedures already in place within the organization.

Participation of all the professionals involved in childbirth is a key strength of the practice outlined, as it led to the definition of shared procedures and improved the information flow from one step to another.

The importance of safe practices to improve quality not only in maternal care but also in patient care, in general, has been put in the spotlight by the publication of the report by the Institute of Medicine, “To err is human” [3]. The need “to promote safe practices to prevent the most commonly occurring adverse events such as medication-related events, healthcare-associated infections, and complications during or after surgery” has been highlighted by the Council Recommendation on patient safety [4] and, more recently, by the European Parliament Resolution on a safer healthcare in Europe [5].

In Italy, some actions, within a specific national program, have been launched to improve quality and safety in childbirth and maternal care. They are also inspired by what the OECD highlighted in the *Review of Health Care Quality: Italy 2014. Raising Standards* [6]: “a range of quality-related activities have been developed in Italy, with varying depth and scope, and with little co-ordination across these approaches by central agencies.” This situation was a result of the organization of the Italian Healthcare System, which is a regional-based system that provides universal coverage free of charge at the point of use. The wide autonomy

granted to the Regions and Autonomous Provinces (R&APs) has led to a huge heterogeneity in the quality and safety of the services provided [6–8]. The need for a nationwide initiative to improve patient safety, coordinated at central level, was translated into an agreement between the Italian government and the R&APs, which entrusted the National Agency for Regional Healthcare Services (Agenas) with the task of monitoring, promoting, and supporting regional and local initiatives on clinical risk and patient safety, with a focus on monitoring and promoting dissemination of good practices for patient safety. Based on this mandate, the National Observatory on Good Practices for Patient Safety was established as a national program to improve patient safety by promoting diffusion and active dissemination of evidence-based practices.

3. The Observatory on good practices for patient safety—aim and implementation

The general aim of the Observatory is to ensure that the care every patient receives is as safe as the state-of-the-art of knowledge allows by stimulating local governments, healthcare organizations, and professionals to implement evidence-based safe practices. Its activities are based on the belief that top-down and bottom-up actions are complementary in order to achieve continuous quality and safety improvement in healthcare [7–10]. Drawing on this belief, multiple stakeholders have been involved in the Observatory's scope definition, design, and implementation (Ministry of Health, R&APs, Agenas, healthcare organizations, and professionals).

The Observatory's scope was defined on the basis of a restricted survey among the leading experts in quality and safety at international level in order to define what a good practice is. The result of the survey was the following definition of good practices for patient safety: evidence-based interventions, sustainable over time and potentially transferable, that have been implemented at regional/local level and proved to be effective in improving patient safety.

The Observatory's activities are implemented through a cyclic model shaped on the PDSA cycle, whose main steps are [7] (**Figure 1**):

The Observatory model of intervention is based on five main phases that are sequential from a logical and temporal point of view: after defining/updating and sharing models and tools, good practices are identified and collected in a web database; they are evaluated, classified, and subjected to dissemination actions while priorities are set for the next cycle. These phases are annually covered in a spiral process tending to continuous improvement.

1. Defining and sharing the models and tools among all stakeholders

As mentioned, the Observatory has been designed and implemented based on the input of multiple stakeholders. Furthermore, stakeholders are periodically asked to provide feedback on the tools used to collect and share patient safety practices so as to revise them accordingly.

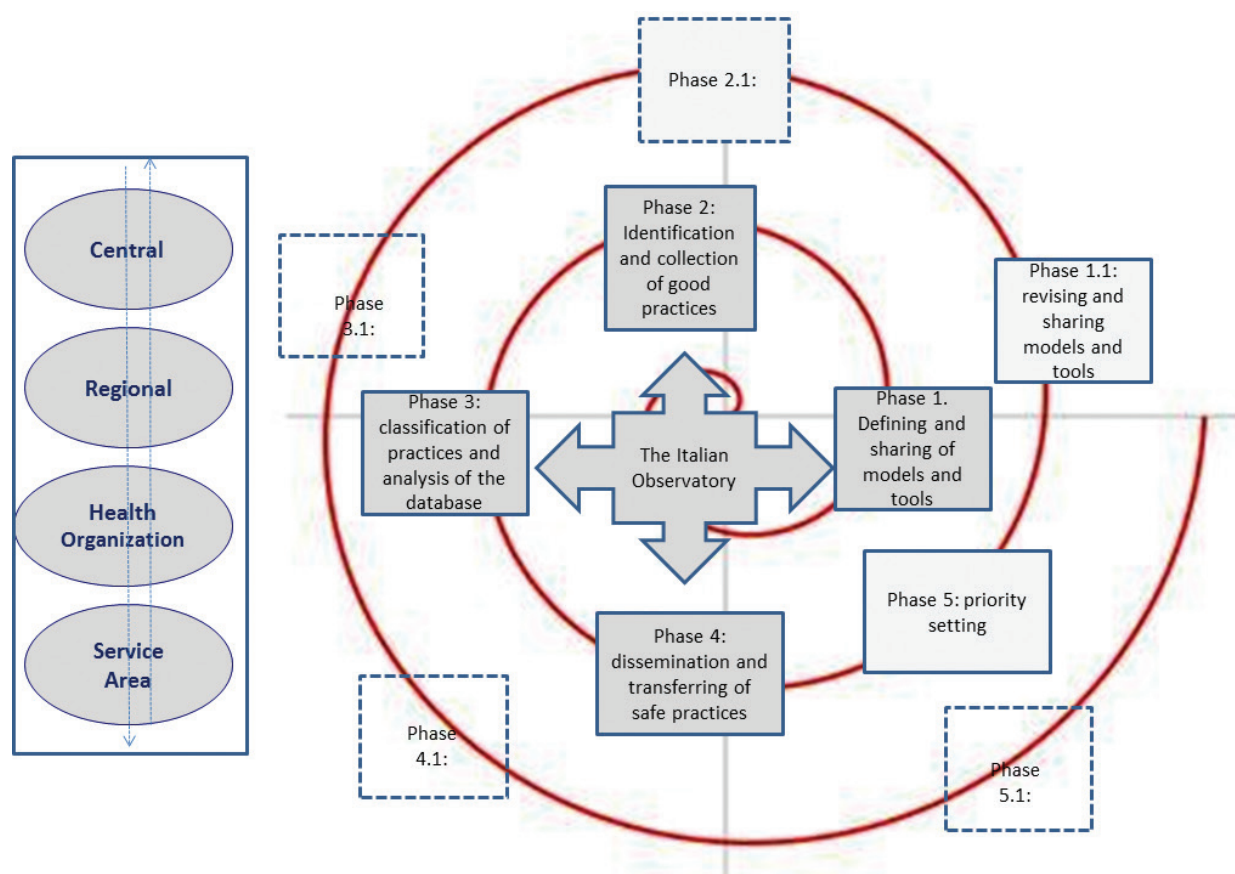


Figure 1. The Observatory model of intervention.

2. Identification and collection of patient safety practices

The tool used to collect patient safety practices is the Call for Good Practices, issued annually to invite regional health authorities to coordinate the collection of patient safety activities carried out at regional/local level.

Every year a focus on a specific safety-related problem is defined, so as to align the patient safety activities carried out at national level with the international ones. Therefore, over the years, the Call has been paying special attention to practices related to the following topics: surgical site infections, medication reconciliation, and hand hygiene. The focus of the 2016 edition of the Call has been defined based on the proposals made by the regional representatives who have been participating in the periodic survey aimed at collecting their feedback on the usability of the tools of the Observatory and on possible improvements to be implemented. As a result, child-birth and maternal care have been identified as an area where more needs to be done to ensure good quality care is delivered throughout childbirth and major complications are prevented.

Participation in the Call is fully web based and articulated in a three-level system: healthcare organizations/professionals (reporting); regional representatives—experts in patient safety appointed by the Regional Health Authorities (approval/validation); Agenas (collection/classification).

The Observatory developed and shared with the R&APs a standard form for reporting the practices consistent with Standard for Quality Improvement Reporting Excellence (SQUIRE—www.squire-statement.org) guidelines [11] and supported by a computer-based tool to help professionals calculate the implementation costs. In 2014, a revision was made to the reporting form to allow transfer of the practices at European level. Agenas, in fact, has been participating in and supporting the activities of the PaSQ Joint Action (co-funded and supported by the European Commission under the Public Health Programme, Agreement Number 20112101), whose main objective was to improve patient safety and quality of care through sharing information and experiences and implementing good practices. To do so, a form to collect patient safety practices (PSPs) has been developed and tested at European level [7]. It has then been translated into Italian and made available to healthcare organizations and professionals to report their PSPs to the Observatory.

The Call takes about 5 months, from mid-May to mid-October. The practices submitted, once validated by the regional representatives, feed an Internet archive (<http://buonepratiche.agenas.it/practices.aspx>) publicly available and searchable by some—simple—search criteria (e.g., year, classification, and adverse event the practice aims to reduce).

3. *Classification of practices*

The practices submitted to the Observatory have been classified into three main categories until 2014:

- **Good practices:** Experiences fully implemented which include a detailed evaluation of results (either by quantitative or qualitative analyses).
- **Potential good practices:** Ongoing/not fully implemented experiences, with incomplete report of results.
- **Initiatives:** Interventions not yet implemented or with very limited documentation about efficacy.
- From 2014 onwards, the Observatory applies the classification model developed at European level (PaSQ Joint Action) [7]:
 - **Safe practice:** A practice that was implemented and the before and after measurement has documented that it enhanced one or more aspects of patient safety. The before and after evaluation could be qualitative as well as quantitative.
 - **Potentially safe practice:** A practice that was implemented and a before measure was established. However, no after measure is reported.
 - **Not proven effective practice:** A practice that was implemented, but the before and after measure did not show improvements.
 - **Not implemented practice:** A practice that was not implemented yet. This could be the case, e.g., if the practice is under development or it is just an idea.
 - **Not evaluated practice:** A practice that was implemented, but before measure was not established.

4. *Exploitation, dissemination, and promotion of transfer of safe practices—priority settings of next call*

The Observatory approach was aimed at setting up actions for gradual transition from passive spread of safe practices to active and planned adoption in a sustainable way [6, 7, 9, 12, 13]. Therefore, further to web diffusion and traditional dissemination tools (presentations in national and international conferences, brochures, and scientific papers), some specific tools have been tested to disseminate and promote the transfer of safe practices. As a part of an increasingly widespread dissemination of good practices, a model for inter-regional transfer of safe practices has been tested. The model is based on the exchange of experiences and knowledge between three groups of Regions (Northern, Central, and Southern) that are contiguous from the geographical and cultural point of view and their models for clinical risk management have similar organizational features [7]. The tool consists of a standard workshop format that is reproducible and adaptable to different contexts. The strengths of this tool, as declared by professionals, health organizations, and regions involved, lie in the fact that it enables an open and direct discussion between organizations sharing similar problems and allows a more widespread dissemination of the safe practices.

A peer review program for promoting transfer of safe practices at inter-regional level has been developed and tested. For the first test, the peer review program has been focused on good practice for safe surgery (to answer to specific needs expressed by professionals and to keep the Observatory aligned with the international indications). In collaboration with the Association of Italian Hospital Surgeons (ACOI), the Italian Society of Anesthesia Analgesia and Intensive Care (SIAARTI), and the Association of Operating Room Nurses (AICO), the specific model of intervention and procedures have been developed and tested at the Day Surgery Unit of the Niguarda Ca' Granda Hospital in Milan. The program is still ongoing in the Lombardy Region.

4. Results

The main result of the activities described in this chapter is a publicly available database of patient safety improvement interventions including 2628 experiences (Figure 2).

Year	Number of practices reported to the Observatory
2008	361
2009	356
2010	282
2011	300
2012	310
2013	230
2014	299
2015	233
2016	257

Figure 2. Number of practices reported to the Observatory per year.

An average of 300 practices per year has been submitted to the Observatory. The number ranged from a maximum of 358 in 2008 to a minimum of 230 in 2013. Since 2014, the trend is in the direction of a recovery.

This year's focus is on experiences aimed at improving quality of maternal care that resulted in submission of the 43 practices some of which are briefly outlined in the box (titles are provided for all of them); they represent evidence-based, implemented real solutions to the problem presented in the beginning of this chapter.

The application of the National Recommendations for the healthcare safety: a questionnaire for the internal monitoring in the Clinical Units of the University Hospital of Parma [14]

Parma Hospital—Emilia Romagna Region

Aiming to improve: (1) Analyze the applicability, relevance, and effective implementation of each National Recommendation within all the clinical units of the University Hospital of Parma. (2) Assess whether the training events for the dissemination of all National Recommendations have had repercussions in the clinical care practice. (3) Check whether the tools provided for the spreading of the specific contents of the National Recommendations are actually considered useful by the chiefs of clinical units. (4) Identify suggestions for improvement in order to increase the safety culture in the University Hospital.

Description of PSP: (1) The Clinical Governance Structure of the University Hospital of Parma has promoted an internal survey, in all clinical units, for monitoring the application of National Recommendations for the Clinical Risk Management. The monitoring has included: (1) The creation of the questionnaire, developed by the professionals of the Clinical Governance Structure in collaboration with the Nursing Directorate (time required 3 months). The questionnaire, prepared in a pdf mode, had "forms" fillable directly online by the managers of all clinical units. The compilation of "filter" questions has allowed managers to bypass entire sections of the questionnaire if they have evaluated one or more Recommendations as "not applicable" in their clinical units. The questionnaire has allowed to automate the insertion phase of data. (2) Sending the online questionnaire by email to all clinical units' chiefs/coordinators evaluated as eligible to the survey. The questionnaire has been accompanied by an introductory note that has explained the survey's objectives and the methodology used. All clinical units have been represented by one or more questionnaires compiled by their representatives (chief of clinical unit or coordinator). (3) Results' processing (time required 3 months). (4) Dissemination of the final report to the chiefs/coordinators through the Intranet site and use of the results for the 3-year program of safety management (time required 3 months).

Methods used for evaluating results: Process indicators—Coordinators participated in 75% of cases, whereas chiefs of clinical unit doctors responded in the remaining 25% of cases. About 81% of clinical units that were eligible for detection has joined the survey (N = 59). The departments that have joined more to the survey were the General and Specialist Surgery Department and the Geriatric Department. Outcome indicators: The National Recommendations that have been highlighted as more applicable in the clinical units are (1) the 9th, regarding the malfunctioning of electromedical devices: 100 of clinical units, (2) the 13th about the falls prevention: 89.8% of clinical units, (3) the 8th for the prevention of violence against healthcare workers: 88.1% of clinical units, and (4) the 17th, regarding the drugs reconciliation 86.4% of clinical units. The more a recommendation has contents that concern all clinical units, much less was found to be homogeneous in its effective dissemination/application in the teaching hospital. In fact, the recommendations, whose contents are general and applicable for 60–100% of clinical units of the teaching hospital, were found to have a non homogeneous application: in fact, except for the two recommendations on the safety of drugs use (the 7th and the 12th), applied in 100% of the clinical units, all the other remaining recommendations have achieved the levels of application inferior to 8.5%. Instead, the National Recommendations whose content was "specific" or limited to specific clinical areas (e.g., the prevention of maternal or neonatal death) have obtained 100% of application in the few clinical units concerned.—An average of 8% of clinical units has evaluated "scarce" the utility of the training events and of the tools made available by the Clinical Governance Structure, in particular for the 9th and 4th Recommendations (regarding "the malfunctioning of electromedical devices" and "the prevention of patient's suicide," respectively), also by considering them highly relevant.—37.5% of the structures in which the Recommendation n.10 is considered has highly relevant, has evaluated the specific tools made available by the Clinical Governance structure as not useful in which the Recommendation 10 (focused on "Prevention of bisphosphonates-induced osteonecrosis") is considered highly relevant, also has evaluated as not useful the specific tools and training events made available by the Clinical Governance Structure to improving safety. These recommendations will, therefore, be the subject of specific projects within the three-year planning (Plan on the Safety of Care Program 2016–2018) in the Parma Teaching Hospital. An average of 8.7 suggestions/proposals for the improvement of the local application of each among the 17 National Recommendations has been obtained.

Newborn Emergency Transport Service (NETS): the experience in the Province of Reggio Emilia [15]

Local Health Authority of Reggio Emilia—Emilia Romagna Region

Nursing skills video-tutorial (infant/child 0–3) [16]

University Hospital of Trieste—Friuli Venezia Giulia Region

Aiming to improve: *Keywords:* maternal and child nursing skills, simulations, safe care, and effective communication. The training of nursing staff in maternal and childcare must take place in the safest possible manner. The simulation provides a solution for safe learning, offering to those who practice two major advantages: on the one hand, the “permission to make mistakes” and, on the other, the opportunity to learn through clinical experience. Building on the experience of the laboratory, 2nd year CDL Nursing 2012–2013 AA will be implementing further simulations for learning in a safe environment with the aim of improving the clinical learning of nursing students within maternal and childcare. To test the possible improvement of the practice, it will compare the performance of students of 2012–2013 AA with those of 2016–2017 AA (CDL Nursing—Department of Medical, Surgical and Health Sciences-University of Trieste).

Description of PSP: Simulation Design Scale (Student Version)

Methods used for evaluating results: Simulation Design Scale (Student Version) and compare the performance of students of 2012–2013 AA with those of 2016–2017 AA (CDL Nursing—Department of Medical, Surgical and Health Sciences, University of Trieste)

“Dry cord care” in the treatment of the neonatal cord stump [17–19]

University Hospital of Udine—Friuli Venezia Giulia Region

HFMEA applied to >24 weeks pregnant patients’ pathway [20]

University Hospital of Udine—Friuli Venezia Giulia Region

Aiming to improve: To ensure safer care, we decided to apply HFMEA to our 24th week pregnant patients’ pathway. Our analysis started from patient acceptance and ended in temporary observation (before hospitalization).

Description of PSP: First of all, the multiprofessional team was assembled. The team analyzed the entire pathway, describing 6 main phases, 28 activities, and 45 potential failure modes (PFM). For each PFM, the professionals assigned a numerical value, risk priority number (RPN) to identify activities at risk, in accordance with literature. To establish the priority of interventions, we decided to put in place corrective actions for PFM with RPN numerical values > the third quartile.

Methods used for evaluating results: We assigned new RPN scores for PFM > the cut-off and analyzed the improvements through Wilcoxon test: we obtained a statistically significant decrease of the RPN values ($p = 0.0009$).

Continuing education on prevention and treatment of postpartum hemorrhage [21]

IRCCS S. Raffaele—Milano—Lombardy Region

Aiming to improve: The first official Italian guidelines on postpartum hemorrhage (PPH) prevention and treatment were published in November 2016. Our clinical practice has, therefore, been updated, and its compliance to these national guidelines verified. The department’s internal guidelines, albeit updated earlier this year, have also been integrated with the newest indications regarding the use and dosage of uterotonic medications. We aim to keep training our obstetric staff and younger physicians, in particular, to face PPH with effectiveness and celerity. We recently introduced the ROTEM analysis for patients undergoing severe blood loss, as this proved to be fundamental in order to guide the utilization of blood product transfusion.

Description of PSP: Thanks to the experience gained during a practical course using a mannequin (Noelle®), we decided to focus on patients who most rapidly reach 1500 ml of blood loss. We trained on positioning intrauterine hemostatic balloons and most specifically on uterine sparing compressive surgical techniques, as our primary objective is the conservation of young patients’ subsequent fertility. To improve our further education, we organized audits in order to discuss clinical scenarios that included PPH complications.

Methods used for evaluating results: We have always divulged monthly statistical analyses of PPH cases to our clinical staff in order to raise awareness and stimulate the individual’s revision of the adverse event. We also re-examined each single severe PPH case with the obstetric staff, on call at the time, to identify and discuss inconsistencies in different clinicians’ approach to the matter. Great effort is implied in supporting the patient and her relatives after PPH. In fact, some patients risk PTSD after such a complication, and we offer an appropriate psychological—behavioral aid to prevent this disorder. Among our PPH patients, none presented this problematic.

Intensive management of pregnant women with HELLP syndrome [22]

ASREM—Molise Region

Good practices in obstetrics: the value of Audit in healthcare [23]

Local Health Authority of Asti—Piedmont Region

Aiming to improve: *Postpartum hemorrhage is a major cause of mortality and maternal morbidity: it occurs at a rate varying between 5 and 22% of total deliveries and implies a mortality rate of 1:1000 in developing countries and of 3–5:100,000 in industrialized countries. A total of 60–70% of deaths by postpartum hemorrhage is due to nonoptimal treatment. Hence, the need to apply the strategy of an “Active Management” of the third stage able to reduce the incidence of 40–50% hemorrhage. We worked according to the principles of clinical risk management, analyzing and activating adequate proceedings to restrict adverse events.*

Description of PSP: The verification on the data collected allowed to confirm the goodness of our practice of active management of the third stage by oxytocin prophylactic administration to all patients. The frequency of postpartum hemorrhage in our ward seems to be comparable to that of other Centres of Excellence in Italy. In all cases of more serious hemorrhage (>1000 ml), the treatment was rapid and an integrated multiprofessional and multidisciplinary approach that allowed us to quickly identify the cause and provide suitable therapeutic measures.

Methods used for evaluating results: examination of medical records

Prevention and management of postpartum hemorrhage in Obstetrics and Gynecology [24]

Local Health Authority of Prato—Tuscany Region

Aiming to improve: Postpartum hemorrhage is one of the most frequent causes of maternal death. More than half of the cases occur within 24 hours of delivery. Good practice calls for actions and tools for better prevention and management of this event. Practice realized in collaboration with Italian Association of Hospital Gynecologists.

Description of PSP: As a part of the project for patient safety, the Regional Center for Clinical Risk Management of Tuscany has launched a campaign on the prevention and management of postpartum hemorrhage. In order to provide a guide to individual health structures for the implementation of interventions that might lead to better prevention and management of this event, it has developed a guidance document “Best Practices for prevention and management of postpartum hemorrhage” (Chapter 2.2 Best Practices for patient Safety in Obstetrics and Gynecology, published in No. 1 of Notebooks of laboratories for patient safety). Based on the indications suggested by the Regional Good Practice LHA 4 of Prato has (1) implemented the dissemination of the document to address GRC Regional Centre to all relevant staff; (2) provided a procedure for the adoption of formalized good practice; and (3) applied the regional indications for the prevention and management of postpartum, according to the responsibilities identified, and in particular: the prevention of post-partum hemorrhage through the active management of postpartum; the timely diagnosis of postpartum hemorrhage (procedure for the estimation of blood loss), the search for the cause of bleeding, and the immediate availability of tools and materials (Kit hemorrhage); coordinated multidisciplinary management of cases of postpartum hemorrhage through the implementation of an operating instruction for the management of hemorrhagic shock; sharing with anesthetists and the blood centers operation instruction for the management of hemorrhagic shock; the planning and execution of training events on laparotomy techniques in postpartum hemorrhage; the implementation of the default grid for the documentation of cases of postpartum hemorrhage; programming an audit of any postpartum hemorrhage.

Methods used for evaluating results: The implementation is evaluated through clinical Audit and periodical internal checks on the correct application of the good practice. INDICATORS—Presence of a procedure for the formal adoption of good practice; certificates on periodic training of the surgical team; presence of a board/grid for the documentation of cases of postpartum hemorrhage; presence of alert reports about systemic analysis of cases reported with postpartum hemorrhage; availability of postpartum hemorrhage kit in the delivery room; and presence of the poster “postpartum hemorrhage” in the delivery room.

Pregnancy and delivery of a cardiopathic fetus [25]

Gabriele Monasterio Foundation Hospital—Tuscany Region

Aiming to improve: The finding of a heart defect in the fetus has significant implications for pregnancy management, delivery planning, and diagnosis of abnormalities in other organs. Fetal echocardiography can help detect fetal heart abnormalities before birth, allowing for faster medical or surgical intervention once the baby is born if needed. This improves the chance of survival after delivery for babies with serious heart defects. Some heart defects will not require immediate intervention, and the baby can be followed at the delivery hospital and as an outpatient after discharge. Other defects are more serious and require pediatric cardiac surgical services immediately after delivery. In some cases, the condition may be severe enough for the pediatric cardiologist to recommend delivery at a pediatric heart center so that an intervention can be performed within minutes of life. In all cases, these issues should be discussed and planned for during the fetal echocardiography visits. Keyword: baby childbirth birth path cardiopathy.

Knowing about a potential heart problem prior to delivery also gives a family a chance to learn more about the problem which can help themselves prepare psychologically for dealing with the extra challenges they may face following birth, such as surgery or other interventions the child may require. A coordinated fetal team that includes pediatric cardiologists, genetics counselors, obstetricians, perinatologists, neonatologists, nurses, and other subspecialists should work closely.

Description of PSP: A clinical pathway was designed in Fondazione Toscana “G. Monasterio” together with Nassau Hospital for precocious diagnosis of fetal congenital heart disease and for the rest of pregnancy and delivery management. Fetal heart abnormalities are detected before birth, allowing for faster medical or surgical intervention once the baby is born in order to improve chance of survival. After in-womb diagnosis, several meetings before delivery with parents, midwife, psychologist, pediatric cardiologist, and neonatologist are planned. Delivery is planned and performed in a special, dedicated area of Pediatric Cardiology/Cardiac Surgery Department, where the presence of specifically trained obstetricians, neonatologists, midwives, and anesthesiologists together with highly trained nurses is guaranteed all over 24 hours. After birth, the baby is transferred to a dedicated Newborn Intensive Care Unit for the first interventions, where she is evaluated also by a pediatric cardiologist and a pediatric cardiac surgeon.

Methods used for evaluating results: Nonquantitative methods are now in use

Prevention and management of shoulder dystocia in Obstetrics and Gynecology [26]

Local Health Authority of Prato—Tuscany Region

Aiming to improve: Shoulder dystocia is a complication associated with childbirth for which the shoulders of the fetus do not come out spontaneously after the escape of the head and require additional obstetric maneuvers. The good practice developed at regional level provides a series of actions and instruments, consistent with international guidelines, aimed at better prevention and management of this event. Made in collaboration with Italian Association of Hospital Gynecologists.

Description of PSP: As a part of the campaign for patient safety, the Regional Center for Clinical Risk Management (RCCRM) of Tuscany has launched a campaign on the prevention and management of shoulder dystocia. In order to provide a guide to individual health agencies for the implementation of interventions that might lead to better prevention and management of this event, the RCCRM has developed a guidance document “Best Practices for the prevention and management of shoulder dystocia” (Chapter 2.1 of the best practices for patient safety in Obstetrics and Gynecology, published in No. 1 of the Notebooks of laboratories for patient safety). Based on the indications suggested by the Regional Good Practice, the Trust of Prato: implemented the dissemination of the document to address GRC Regional Centre to all relevant staff; set up a general procedure for the adoption of formalized good practice; ensured the prevention, when possible, through proper identification of risk factors for antepartum and intrapartum both at the time of taking over of the woman in labor (shared procedures and protocols for the management of all phases of childbirth); ensured adequate treatment of cases by carrying out the maneuvers required by good practice and coordinate the multidisciplinary management of cases; ensured the competence of healthcare professionals (knowledge, skills, and interpersonal skills) through training and simulation; made available the presence of a poster in all venues of labor and of childbirth aid to remember the maneuvers to be carried out; implemented a default grid for the documentation of cases of shoulder dystocia; and ensured the conduct of an audit on all cases of dystocia.

Methods used for evaluating results: The actual implementation of the provisions of good practice is periodically checked: presence of a company procedure for the formal adoption of good practice; presence of the partogram in the medical record; presence of the poster in all rooms of labor and childbirth; presence of analysis of detected cases of shoulder dystocia, with relative alert report; and presence of certificates of training with simulation.

Activation of labor analgesia in first-level structure within 24 hours [27]

Local Health Authority of Mirano—Veneto Region

Aiming to improve: Modern anesthesiology allows women to control pain during labor and delivery through epidural analgesia, a safe and effective technique that ensures the possibility of a spontaneous delivery and at the same time the complete participation of the woman during the birth of her baby. In Italy, this kind of analgesia is not yet a widespread technique, even if it is provided by the most recent Essential Levels of Care. The reasons for this lack in popularity are many: (1) cultural barriers among both professionals and patients, who are often not well informed on the procedure; (2) organizational problems such as the lack of well-trained professionals and the lack of an on-call anesthetist during the 24 hours; and (3) an increasing request of analgesia during labor as a result of safer anesthesiological and pharmacological techniques used. For all these reasons, professionals working in obstetrics and gynecology and resuscitation units of Dolo and Mirano hospitals in the latest years have made a great effort to ensure analgesia during labor to all women who deliver there 24/7 (and not only 12 hours/day as provided by the current Essential Levels of Care). In this way, every woman who desires analgesia during labor can have access to it, if the clinical situation allows it, independently of the

time of the request. Specific objectives: to ensure every pregnant woman, the possibility to have analgesia during labor 24/7, by the continuous presence of an on-call anesthetist; to reduce intrapartum complications, thanks to a specialized assistance; to reduce the number of complications after the birth, thanks to a dedicated and specialist level of assistance; to reduce the number of cesarean sections; and to increase professionals' and patients' knowledge and awareness about pain in labor.

Description of PSP: (1) Information about analgesia during labor is given during childbirth classes and obstetric visits, focusing on the technique, the risks, and the benefits for the mother and the baby and on how to access to the service, giving the pregnant women the specific forms to fill. (2) The anesthesiological visit is offered after 35 weeks of pregnancy, and it is necessary for the clinical evaluation of the pregnant woman and to explain her the technique. (3) The woman is invited to fill in the specific forms for epidural analgesia and to sign the informed consent for the procedure. (4) The working shifts guarantee there is an on-call anesthetist 24/7. (5) Daily briefing and multidisciplinary meetings are fundamental to discuss about organizational problems on the analgesia service and solve them. (6) The data on the anesthesiological chart are important for a quantitative analysis of the service. (7) It is important to evaluate the pain before and after the analgesia, using visual analog scale of pain (VAS) and to collect opinions of the patients about the assistance offered. These two parameters allow doing a qualitative analysis of the service.

Methods used for evaluating results: Evaluation of the results based on the detection of pain before and after analgesia with validated method visual analog scale of pain (VAS). Bromage scale to assess the motor blockade of the lower limbs. APGAR index of newborn.

ST analysis of fetal ECG reduce cesarean section rate for fetal distress [28]

Nursing Home Abano Terme—Veneto Region

Decreasing AUR (antibiotic use rate) in infants < 35 weeks in community-based neonatal intensive care unit (NICU) [29]

Local Health Authority of Vicenza—Veneto Region

Clinical birth pathways: new uncertainties and “error traps” in the risk assessment [30]

Local Health Authority of Treviso

Early identification and treatment of sepsis in pregnancy [31]

Hospital of Feltre

Aiming to improve: Sepsis protocol describes clinical and instrumental methods to early identify the risk of sepsis in pregnant women. The aim is to prevent the onset of sepsis and its complications.

Description of PSP: Healthcare Practitioners evaluate pregnant woman on her symptoms/signs, her risk factors to develop sepsis, and on the Quick-sepsis-related organ failure assessment (SOFA). If there is only a single symptom/sign positive, and all other parameters are negative, woman is monitored for 6–12 hours with re-evaluating of all parameters at least one time every 3 hours, carrying out specific blood chemical tests indicated in the protocol. If the parameters are positive (one or more symptoms and/or one or more risk factors and/or the Quick-SOFA is positive), woman is monitored for 12–24 hours with re-evaluating of all parameters at least one time on every 2 hours, carrying out specific blood chemical tests indicated in the protocol, including a blood gas analysis viewed by anesthetist. The gynecologist explains to the patient and her family the risk of possible sepsis diagnosis. If parameters go down, healthcare practitioners activate a series of countermeasures including the pregnant woman transfer to the intensive care.

Methods used for evaluating results: To evaluate the results, it will use patient's clinical documents; in Italy, a specific information called “flusso SDO (Hospital Discharge Abstract)” is used to search for sepsis diagnosis in pregnant women and verify the sepsis protocol application.

Implementation of Safe Operating Rooms project by applying a surgical safety checklist tailored to the specific needs of cesarean delivery and evaluation of the impact on patient safety [32]

University Hospital of Modena—Emilia Romagna Region

Assisted Maternal Fetal Transport [33]

Local Health Authority of Piacenza—Emilia Romagna Region

Improving the management of shoulder dystocia by updating the knowledge of operators and the participation of pregnant women: health education project [34]

Local Health Authority ROMA E—Lazio Region

Protocol for assisting and surveilling newborns [35]

Local Health Authority ROMA B—Lazio Region

Presence of partner during childbirth [36]

Local Health Authority ROMA B—Lazio Region

Diagnostic-therapeutic pathways (DTPs) improve the affective-relational dimension between mother and baby through contact experiences [37]

Local Health Authority ROMA E—Lazio Region

Baby Friendly Community Initiative UNICEF Family Planners Centre EX ASL Roma B [38]

Local Health Authority ROMA B—Lazio Region

Development of integrated network for mother and child patient safety [39]

ASST Mantova—Lombardy Region

Strategies for reducing the number of cesarean sections as an indicator of quality of care in the delivery room [40]

ASST Valle Olona—Lombardy Region

Safe Delivery Room [41]

Local Health Authority of Bolzano—Autonomous Province of Bolzano

Childbirth checklist [42]

Local Health Authority CN1—Piedmont Region

Standardized procedures for the safety and appropriateness of neonatal emergency transport (STEN) and maternal-fetal assisted transport (STAM) in Piedmont Region [43]

Local Health Authority CN2

Procedure for assisting newborn with hypoxic-ischemic encephalopathy possible candidate for hypodermic treatment [44]

Local Health Authority BAT—Puglia Region

The childbirth from prenatal access to discharge from hospital [45]

Nursing Home Triolo Zanca—Sicily Region

Description of emergencies activities—gynecological-obstetric emergency [46]

Provincial Health Authority of Catania—Sicily Region

Implementation of good practices in relevant clinical obstetrics and gynecology through specific documentation integrated inside the obstetric assistance folder care [47]

Local Health Authority of Lucca—Tuscany Region

Prevention and management of shoulder dystocia [48]

University Hospital of Pisa—Tuscany Region

Prevention and management of postpartum hemorrhage [49]

University Hospital of Pisa—Tuscany Region

The checklist applied to the path medically assisted procreation [50]

Local Health Authority Versilia—Tuscany Region

Procedure for neonatal resuscitation [51]

Local Health Authority Rovigo—Veneto Region

The path leading to childbirth [52]

Local Health Authority of Thiene—Veneto Region

The autonomy of midwife in the management of labor and physiological delivery [53]

Local Health Authority of Mirano—Veneto Region

Safe childbirth [54]

Local Health Authority of Legnago—Veneto Region

Implementation of obstetrician triage at the clinic in midwifery acceptance [55]

Hospital of Padova

Assistance procedure in the postpartum hemorrhage [56]

Local Health Authority of Rovigo

Procedure for prevention of maternal death or serious illness related to labor and/or childbirth [57]

Local Health Authority of Rovigo

Guidelines for the management of sepsis in pregnancy and childbirth [58]

Local Health Authority of Rovigo

Box 1. Patient safety practices aimed at improving quality of maternal care. Titles and abstracts are taken from the Observatory on Good Practice for Patient Safety (<http://buonepratiche.agenas.it/>).

Below, we also report some of the results achieved by the Observatory by applying the logical model [59–61]. To do this, we performed a temporal analysis (2008–2014) of aggregated data collected through the annual calls for good practices. Over the years, the number of patient safety practices (PSPs) submitted to the Observatory ranged from a maximum of 361 in 2008 to a minimum of 230 in 2013 [7], while the absolute number of Health Providers who reported at least one good practice has had a fairly more stable trend. In particular, we can see an increase in the number of health providers participating in the Call from 2008 to 2010, and then a decrease from 2010 to 2014. The joint observation of this decrease and the number of good practices shows opposite patterns (an increase in the number of good practices from 2013 to 2014). This means that in 2014, a lower number of providers have been actually producing a higher number of good practices (**Figure 3**).

Even though the number of professionals reporting patient safety practices has been decreasing over time, there is an increase in the number of experiences reported from 2013 to 2014. This means that a lower number of providers have been actually producing a higher number of good practices.

Since the practices reported could be at a different stage of development, we also looked at them according to their level of implementation and evaluation of results (**Figure 4**), as derived from the classification in *good practice*, *potential good practice*, and *initiative*. At a decreasing total number of practices reported in 2013 corresponds a more balanced proportion of fully implemented good practices with respect to potential good practices (40% each). This suggests that the quality of the experiences reported has improved over time.

It is interesting to look at the distribution of the practices according to the adverse events they focus on (the experiences reported to the Observatory have to specify one or more adverse events they aim to prevent/reduce). Adverse events have been selected among the most prevalent in literature and in the Italian context [62].

Table 1 shows the list of adverse events and the total number of good practices related to them over the whole period of 2008–2014.

In general, the number of practices that related to prevention of the main surgical adverse events is very high (665). It is followed by the number of practices aimed at avoiding hospital

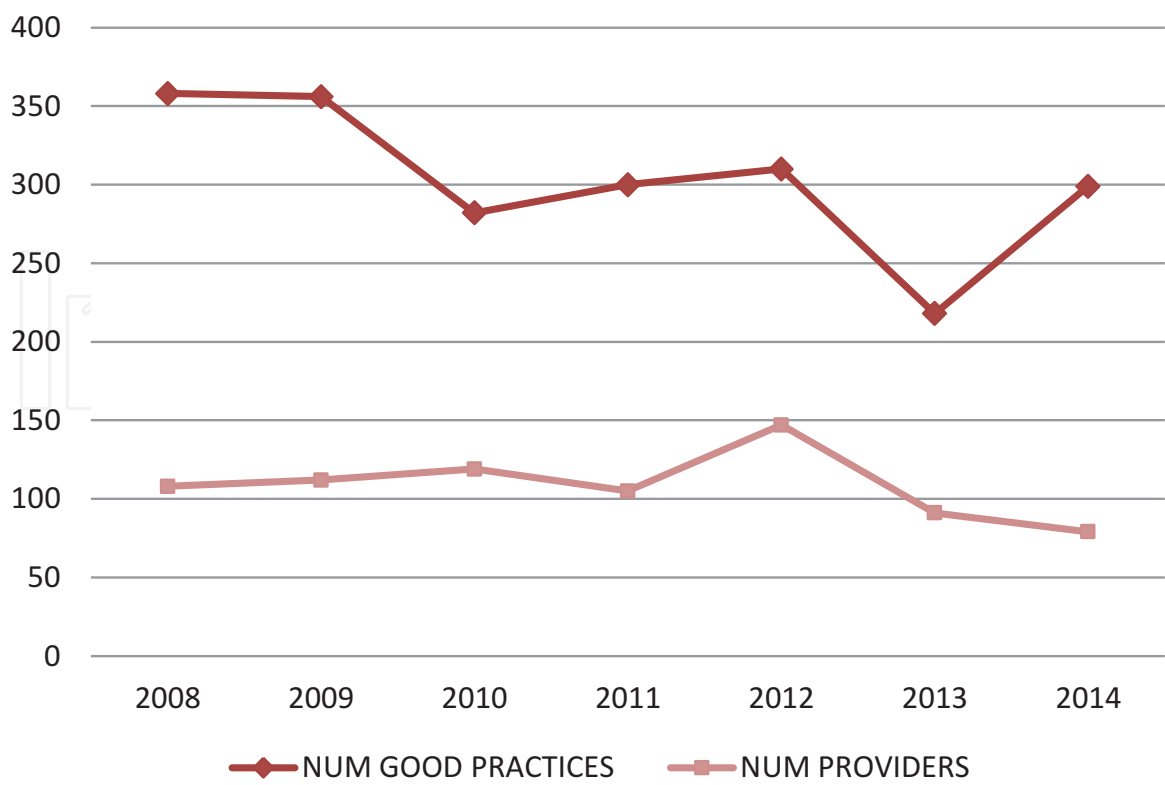


Figure 3. Number of patient safety practices and healthcare providers in the Italian Observatory 2008–2014.

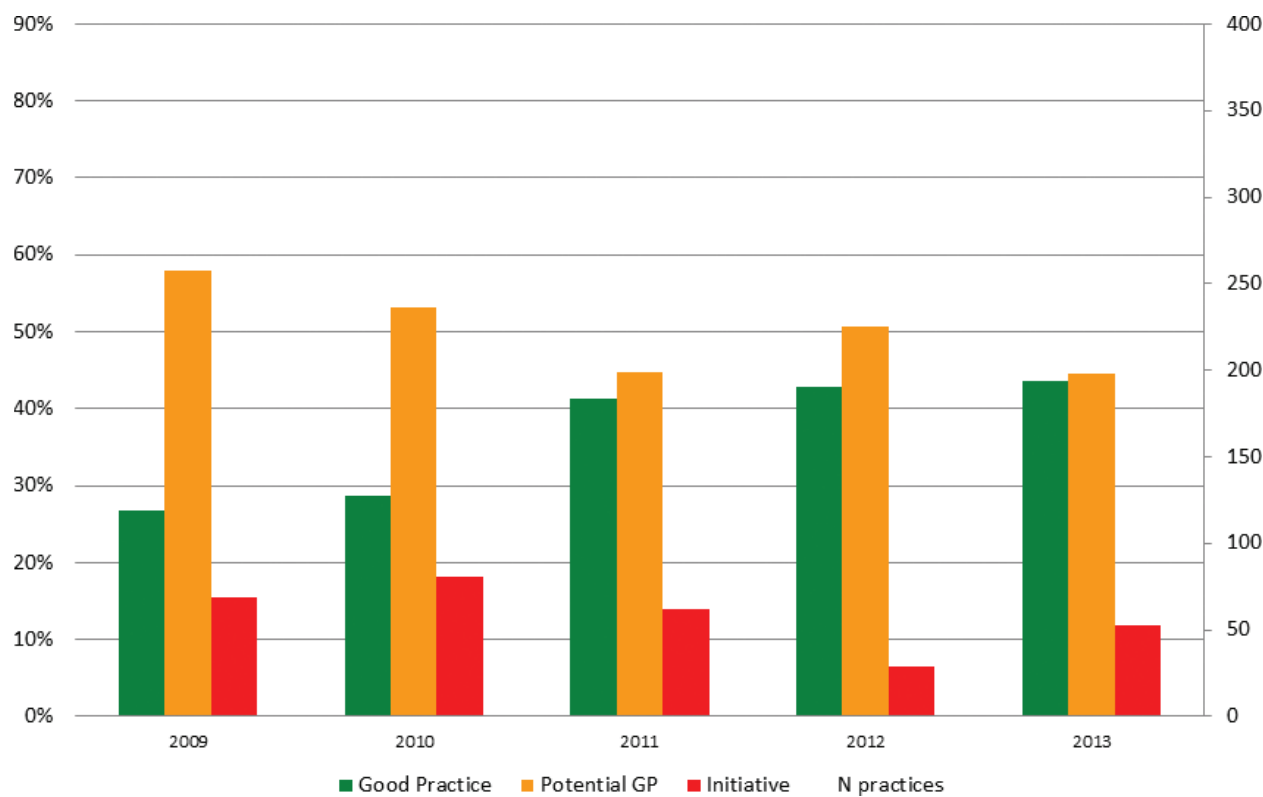


Figure 4. Absolute number of patient safety practices (right axis) and percentage of practices per level of implementation (left axis) per year 2008–2014: Analysis of temporal trend in the level of implementation of patient safety practices.

COD	Adverse events	No. of practices
1	Other clinical adverse events	430
2	Procedure on wrong patient/wrong side or body part or wrong procedure	310
3	Hospital-acquired infections	298
4	Death, coma or disability due to medication errors	296
5	Retention of material in surgical site	181
6	Death or severe adverse event unexpected after surgical intervention	174
7	Patient's fall	166
8	Adverse events related to inadequate hand hygiene	144
9	Transfusion reaction due to AB0 incompatibility	136
10	Deep venous thrombosis	128
11	Pressure ulcers	98
12	Adverse events due to malfunctioning of transportation system	90
13	Death/permanent disability in healthy newborn (weight>2.500 gr)	72
14	Violence against healthcare workers	68
15	Maternal death or severe illness associated with labor and/or delivery	65
16	Prevention of adverse events related to incorrect attribution of triage code	65
17	Suicide or attempted suicide in hospitalized patients	60
18	Violence against patients	48

Table 1. No. of practices per adverse event they are aiming to prevent/reduce.

infections (298) and those related to prevention of errors in pharmacological therapy (296). Many experiences are also aimed at avoiding patient's fall (166), reported to be the most frequent event occurring in the last 7 years in Italy [62].

The evidence of the Observatory's success in supporting and promoting regional monitoring of patient safety practices is in the participation rate in the calls: 100% (21/21) of Regions and Autonomous Provinces have been participating in the call for good practices and developed their own regional model for verification and evaluation of good practices for patient safety. However, participation rates were markedly differentiated among the regions.

Figure 5 highlights the high variability in geographical participation, with Tuscany and Lombardy regions covering together almost 50% of the overall number of practices submitted. As the practices are submitted to the Observatory using a standard form where authors are required to describe the methods they used to evaluate the results achieved using qualitative measures and quantitative indicators, the capacity of the Observatory to spread the culture of self-assessment is proved by the number of the collected practices.

By developing and testing a peer review program, the Observatory also contributed to spreading the culture of external evaluation of quality and safety, as confirmed by professionals in the feedback survey recently carried out by Agenas.

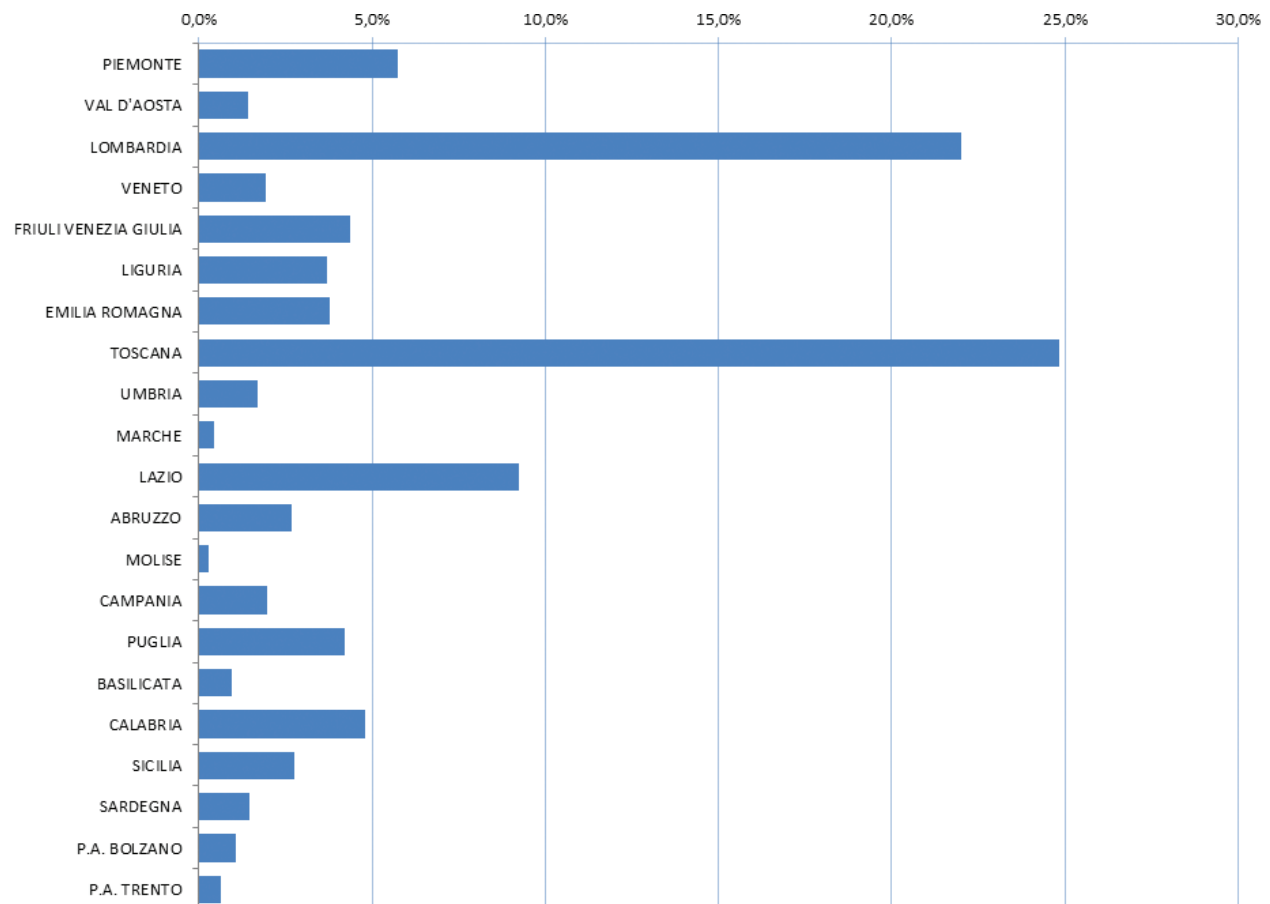


Figure 5. Percentage of patient safety practices per regions/Autonomous Province in 2008–2014: there is high variability in geographical participation, with Tuscany and Lombardy covering together almost 50% of the overall number of practices submitted.

Hundred percent of the practices submitted to the Observatory and published in the web portal includes an abstract, whose aim is to communicate to nonprofessionals in a comprehensible way the intervention informing citizens about the resources used and the results achieved in order to establish transparency and accountability.

Data collected by the Observatory clearly depict its effectiveness as a tool for promotion, dissemination, and application in the Italian context of state-of-the-art of safe practices. The Observatory has also proved to be an effective tool for reducing heterogeneity in patient safety activities among the Italian regions.

5. Conclusion

The adoption of a bottom-up approach within a national improvement program has greatly contributed in Italy to spreading knowledge and experience to improve patient safety in the healthcare system. Both the patient and the GP from the vignette would have benefited from the knowledge-sharing platform provided by the Observatory. As pregnancy is fraught with potential for worry and confusion, the patient would have benefited from the experience of the professionals dealing with quality and safety issues in their everyday life. However,

consultation of the Observatory's database would have provided the GP with the chance of exchanging views with colleagues on the best way for a rapid identification of sepsis.

The Italian experience shows that key success factors of a national patient safety improvement program are a strong government mandate, solid scientific foundation and reference theories, inclusion of stakeholders, and continuous attention to the needs of those (professionals and health organizations) who are in charge of implementing the good practices for patient safety.

In the review carried out by the OECD on the quality of healthcare in Italy [6], the Italian Observatory was described as a "key action to improve patient safety" and as an "example to emulate."

The Observatory has proved to be an effective strategy to overcome some of the main barriers to implementing evidence-based safe practices [63] at an individual level:

- Lack of understanding of the organization or the structure of electronic databases, lack of search skills, lack of library/database: the Observatory database is searchable by simple search criteria and is dedicated exclusively to evidence-based safe practices.
- Lack of knowledge about evidence-based safe practice: the Observatory is a free source of knowledge that is continuously updated by professionals themselves and at organization/institution level.
- Organizational budget for acquisition of information resources.
- Organizational budget for training in resource use: a survey recently carried out by Agenas confirmed that the Observatory free database is usable, used, and useful for professionals.

The debate about method for evaluating healthcare quality improvement and patient safety national programs is still very open [64, 65], whereas outcome evaluation is very complex (case—control studies and randomized control trials are not applicable); the process evaluation we used to assess the results of the Observatory is considered an important tool for describing the intervention and for explaining its success or lack of effect and to enable other people to replicate the intervention with the appropriate adaptations [66].

We applied the logical model that is commonly used in evaluating public health intervention as it grants transparency, accountability, and collaboration with stakeholders [67]. This model well fits for planning, managing, and evaluating quality and patient safety improvement programs [68] as it allows to evaluate, in a transparent and accountable way, whether the objectives for which the intervention had been planned have been achieved. From this perspective, the results achieved by the Observatory on Good Practices for Patient Safety—after 9 years of working—are very encouraging, allowing us to consider it an important lever with which to improve patient safety.

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Author details

Barbara Labella*, Roberta De Blasi, Vanda Raho, Giulia De Matteis, Quinto Tozzi and Giovanni Caracci

*Address all correspondence to: labella@agenas.it

National Agency for Regional Healthcare Services (Agenas), Rome, Italy

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