

STRATEGIC PLANNING AND GOVERNANCE

Mission and/or Core Values: how the Healthcare Provider participates in a national or regional assessment program

Federico II University Hospital is a 22 building hospital including almost overall pathway of adults and children care, due to the teaching and research mission .

Safety relates to the application and promotion of structures and processes in the hospital, for which evidence demonstrates prevention or reduction of risks. Hence, safety is not restricted to patient safety, but also relates to staff and environmental safety. Quality and safety of all buildings is constantly monitored. Quality of care is guaranteed from continuous improvement quality program and change control policies. Clinical audit together with professionals are periodic. Clinical Engineering Service is responsible for technology improvements and HTA together with Hospital Medical Direction.

Handling of accident and near miss incident reporting is defined according to national laws.

Rare diseases are characterized by a low prevalence and they are often life threatening.

As recent studies have reported that obtaining a correct diagnosis for these conditions take almost 5 years in Europe and 7.3-7.6 y in US., due to the low prevalence of each disorder, it is difficult to develop a public health policy specific to each subgroup of disease. It is possible, however, to have a global approach. This is a challenge particularly in the areas of drug and research. Our hospital favours networking activity, and synergies with professionals in order to design specific pathways of care for rare conditions and rare tumours and to cope with the need of gaining efficiency and efficacy.

By 2001 (DM 279) we are in the national network and into a consortium of 8 regions for rare disease, covering almost all pathologies; more over we have a consortium representing a series of rare tumours including hematologic ones.

Globally our hospital is focused on a multidimensional approach to performance assessment in order to favour and to disseminate values within the hospital and initiate or support quality improvement strategies.

Educational material, including general presentation of quality improvement principles and detailed description of indicators, is available for patients and physicians.

Hospital direction collects two times for year report of results to individual ECs and support voluntary participation in an (inter)-national benchmarking network to compare results and interpret them.

Staff orientation is tested, intended as to the extent to which staff is appropriately qualified to carry out their tasks (job description), has all the facilities for continuous learning, and work in a supportive environment, providing specific expertise.

Organization chart

strategies that are in place to ensure care is patient centered and patients are empowered

Patient centeredness puts the patient in the centre of service provision and evaluates the services provided challenging against the needs and expectations of patients, family and caregiver . This includes client orientation (prompt attention, access to supportive networks, communication processes) and respect (patient autonomy, confidentiality, dignity). Our hospital favours networking activity, and synergies with professionals. Network policies are designed to connect health care providers and centers of expertise of highly specialized healthcare, for the purpose of

improving access to appropriate pathways of diagnosis, treatment high-quality healthcare. Physicians and experts who network widely already, are encouraged to share knowledge and experience in order to define tailored pathway of care with the HP.

Each path of care is aimed to design the overall steps of diagnostics tools required to identify the peculiar clinical conditions. This is particularly followed in rare diseases milieu.

The path includes the core network of consultants required to handle therapies and complications. Finally it details a summary of therapies provided.

In parallel Ec's are involved in defining as well as possible the natural history of an orphan disease and the variability of that history. Balanced screening programs allow first to increase the number of cases correctly diagnosed (**diagnostic enrichment**), then, for some conditions, to test therapies in patients with a high likelihood of having an endpoint (**prognostic enrichment**) or of having a high likelihood to reach a response (**predictive enrichment**).

Support to networking activities has been guaranteed in order to cope with the lack of available patients to be enrolled in clinical trials which incorporate clinical endpoints, negatively impacting a study's ability to reach a reasonable level of power to detect a statistically significant change. Support to networking activities is also established in order to enroll a significant fraction of the total available population of patients in clinical path of care, including tailored follow-up 's schedules

Business continuity plan of the organization, management and business continuity plan of the Healthcare Provider

Business continuity (BC) refers to maintaining business functions or quickly resuming them in the event of a major disruption, whether caused by a fire, flood, epidemic illness or a malicious attack across the Internet. We have planned outlines procedures and instructions for emergencies, including informatics attacks with written roles and schedules that everyone must follow in the face of such disasters. BC covers business processes, assets, human resources, business partners and more.

Every potential threat has been evaluated by provisionally considering:

- How likely is the event ;
- How much impact would it have on the ability to operate;
- How long would it impact your operation

In health centers some suggestions in prioritizing essential functions are to examine the functions that enable an organization to provide vital services (Icu's, Transplants, Critical Care) and maintain the safety of the general public and staff within your health center (Ec's, rare disease Ec's)

The alternative facilities for CSE storage and drugs supply are pre-determined obviously creating diagnostic back up facilities located in alternative sites into the regional or national (I.E CSE DISASTER PLAN) community. In the last 3 years our hospital performed 3 simulations concerning radiologic and biologic mayor accidents, with good results.

Conflict of Interest and Research Policy

Concerning the choose of effective topics of research the hospital favors that

1. Every proposal has to be assessed after back ground information, in order to summarize the problem be addressed
2. inherent previous research has to be discussed
3. every proposal has to describe clearly what the research address , why and how
4. objective background and significance of the proposed work has to be estimated

5. hypothesis, variables investigated and question to be answered or new questions generated have to be discussed.

In setting methodology and experimental schedule researchers have to describe

1. what and how experiments will be run
2. what, how much, how often and why equipment and material will be used; this may consent to gain enough details and to enable replication of the study;
3. procedures in protocols have to be ordered by chronologically sequence or type of procedure;
4. experimental design including hypothesis testing variables measured, how many replicates, controls, treatments;
5. why each procedure will be done has to be stated and the source of any specific type of equipment , enzyme, culture, from peculiar supplier evaluated;
6. every modification to equipment or tailored equipment constructed to the study have to be stated;
7. all measurements and either interval of estimates or errors of measurements have to be recorded and quantified;
8. overall material and method section have to be discussed.

Our hospital favors projects developing effective results of impact of care or on population or theory enhancing as well as including translational research designs.

Hospital policy requires that

1. tables and figures and the design of statistical analysis have to be discussed previously
2. **if needed, patient and ethical approval have to be assessed**
3. **eventual disclosure has to be considered concerning results**
4. second opinion of ambiguous estimates may be desirable and helpful

Hospital follows the process of publishing and promoting research and encourages that published results may be shared among colleagues by seminars, promoting draft journal club , also into the Hospital web Magazine *Area Comunicazione* (WWW.areacomunicazione.policlinico.it)

Procedure to review the ethical implications of research activities.

All research activities of faculty, staff, student, or others who are involved in human subjects research that falls under the jurisdiction of the Federico II Ethic Committee (EthC) are reviewed. SOPs adopted by Federico II HCP, simplifies the organization and documentation of clinical trials and ensures the safeguarding of the Good Clinical Practice. These procedures ensure the protection of subjects involved in clinical experimentation and the transparency of the decisions taken.

Federico II Ethics Committee expresses its opinion about:

- clinical trials evaluating pharmacological interventions
- clinical trials evaluating medical devices and diagnostics
- observational prospective cohort studies of drug
- genetics, pharmacogenetics and pharmacogenomics studies
- protocols aimed at the evaluation of new procedures in medical, nutritional, surgical and psycho-social field;
- every procedure that involves the use of human tissue for scientific purpose.

The EthC also expresses its acknowledgment on non-interventional studies

EthC has written concerning

- the activities of the EC President, of the technical-scientific secretariat, of the chief of the Health Department delegate
- the responsibilities and duties of the Ethics Committee members, of the clinical investigator and of the promoter of Profit and non-profit studies
- all the procedures relating to the request for an opinion of the EC on the trial, which also enshrines the application to the research conduction by the promoter, substantial amendments request, prospective observational studies, studies on medical devices
- meeting modalities and course, the definition of the agenda
- the revision procedure of clinical trials according the Declaration of Helsinki, the Good clinical practice, the EMA guidelines
- the revision method describing clinical trials involving children
- the reporting of modalities
- the methods of supply and storage of experimental drugs
- the clinical trial monitoring procedures, the modalities for the communication of any adverse or unexpected drugs reactions
- the information related to the closure of clinical trials
- the economic aspects and the methods of protection of personal data

List of teaching objectives

Federico II Healthcare Provider (HCP) participates in education and training activities such as continuing medical education and distance learning aimed at staff, students, and other care professionals.

In particular Federico II HCP has a defined set of objectives for its education and training activities. List of teaching objective of the last 3 years aimed at student, staff and other care professional are reported in Annexes 1 (2013) ,2 (2014) and 3 (2015) and available at <http://www.ecm.unina.it/> CMEcourse activated in the last 3 years:

2013: 14 Courses

2014: 69 Courses

2015 : 94 Courses

- Teaching objective for 2013: disease prevention, metabolic and genetic disorders treatment, professional responsibility, care humanization, privacy protection, pain management, learning disorders, diagnosis in clinical pathology, emergency and basic life support defibrillation.
- Teaching objective for 2014: basic life support defibrillation, pain management, health informatics, elder fragility evaluation, ear malformations, psico-neuro-endocrino-immunology, medical responsibility, radioprotection, roles and duties of the competent doctor, prevention of risks in surgery, health-monitoring, electrocardiography, spirometry, communication and reception to the patient, others.
- Teaching objective for 2015: biological risk, early diagnosis, diagnosis and management for X-Fragile syndrome, Autism spectrum disorders, tasks and skills of nursing staff, narrative medicine and evidenced based medicine, management of pediatric peripheral venous catheters, pain management, clinical risk management, prevention of hospital infection, health informatics, nutrition and lifestyle, basic life support defibrillation, emergency and evacuation plans, pre-hospitalization trauma care, pharmacovigilance, others

Furthermore, Federico II HCP promotes seminars and courses for students of Medicine and Surgery, for staff and other care professional available at the Federico II HCP website <http://www.policlinico.unina.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/1>

Federico II HCP is a highly specialized University Hospital as School of Medicine authorized to deliver medical degree, 45 different specialization courses (x courses within Network's area of

expertise). For postgraduate student, 6 different PhD courses (all within the Network's area of expertise), and 71 advanced master degrees courses are available.

2016 planning schedule will list also classes about networking policies inside the EC's for rare diseases and courses concerning the transition process from pediatrics to adults patients

Patient Experience Survey and Sample Patient Experience Reports

Federico II University Hospital conducts periodic surveys on patients' satisfaction, compared to hospitality, assistance, organization and hospital facilities.

A questionnaire is designed to systematically detect, through the use of emoticons, (emotional interfaces), an opinion on the quality of services provided. It consists of two main areas: the first is dedicated to the evaluation of the quality of reception, assistance and human relationships with health professionals, while the second aims to gather feedback on the organization and hospital facilities. A section is finally dedicated to suggestions, problems that came out and the overall judgment on admission.

Results of the survey, conducted from July 1 to October 30, 2015 in 100 patients, highlights user satisfaction with respect to the care and organizational size.

From last data, it emerges that 89% of patients provides a positive judgment on the reception received in the ward, 11% expressed a sufficient judgment, no one has indicated a negative judgment. Express as positive opinion, among 95% of respondents, 89% were satisfied with the assistance of nurses and 93% had a favorable view on the human relationship with the professionals. Patients also are satisfied with respect to the clarity of the information (89% of respondents indicating a positive judgment). Among the described strengths, we reported the constant presence of staff, speed in carrying out diagnostic tests, the kindness of the medical and nursing staff.

EC's prescribing Orphan drugs are required to cope with AIFA (Italian Agency of Drugs) requirements for either physicians or patients.

Physicians need to give complete information about the path of care, then every EC's need to evaluate, starting own patients on orphan drug, that the following steps are completed:

- inform and educate your patient and/or parents/legal guardians of children being treated about the risks
- train them to recognize signs and symptoms of serious potential infection (or Sepsis) and to seek medical advice
- provide a Patient Safety Card to patients and explain that they must carry it at all times and must show it to healthcare professionals.
- make sure your patient and/or parents/legal guardians of children being treated understand the information given
- warn them about the risk of interrupting treatment (see paragraph on treatment discontinuation)
- plan and agree with the patient and/or parents/legal guardians of children being treated on a dosing appointment schedule
- Inform them about the eventual participation in OD Registry and how to participate

Moreover patients need to have clear information about the following frequently asked questions:

- WHAT ARE THE SYMPTOMS THAT SHOULD ALERT DURING TREATMENT?
- ARE THERE STEPS THEY SHOULD TAKE BEFORE STARTING THERAPY?
- HOW IS OD ADMINISTERED?
- HOW LONG WILL THEY NEED TO TAKE OD ?

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