Introduction of a parenteral nutrition protocol in neonatal and pediatric age at the NPH Saint Damien pediatric hospital in Port-Au-Prince (Haiti): results from an international multidisciplinary working team

INTRODUCTION OF A PARENTERAL NUTRITION PROTOCOL IN NEONATAL AND PEDIATRIC AGE AT THE NPH SAINT DAMIEN PEDIATRIC HOSPITAL IN PORT-AU-PRINCE (HAITI): RESULTS FROM AN INTERNATIONAL MULTIDISCIPLINARY WORKING TEAM

F. Baratta[1]; E. Ambreck[2]; V. Tomaselli[2], R. Cajuste[3]; P.H. Saint-Jean[3]; Lindsay Dorcelus[3]; J. Alix[3]; O. Louisma[3]; P. Roggero[4,5]; V. Puricelli[5]; O. Amato[5], R. Dall'Amico[6], P. Brusa[1]

[1] Department of Drug Science and Technology, University of Turin, Turin, Italy
[2] Francesca Rava Foundation - NPH Italia onlus, Milan, Italy
[3] NPH Saint Damien Pediatric Hospital, Port-au-Prince, Haiti
[4] Department of Clinical Sciences and Community Health, University of Milan, Milan, Italy
[5] Neonatal Intensive Care Unit, Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Milan, Italy.
[6] Santa Maria degli Angeli Hospital, Pordenone, Italy

A.P.P.A.® PROJECT

The *A.P.P.A.*® Project is the main activity of Aid Progress Pharmacist Agreement non-profit association. The Project, started in 2005, is the result of the cooperation between the University of Turin (Italy) and Italian Community Pharmacists. The Project focuses **on galenic laboratories (GLs) established in hospitals located in developing Countries (DCs)** in agreement with the principles of International Health Cooperation.

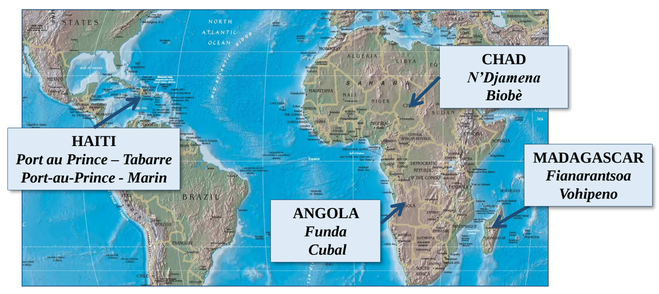
The aims of the Project are as follows:

- to set up GLs in DCs with the aim of preparing medicinal products which comply with adequate **quality** requirements. First and foremost to fight the widespread falsifing of medicines in DCs;
- to tailor dosages and pharmaceutical forms according to the **actual patient needs**;
- to **employ local staff**, teach them a "new job" and open a suitable training centers;
- to **minimize the financial commitment** necessary to prepare these medicines.

The Project is structured in different steps following which an effective and functional lab can be set up. These six steps are always preceded by a feasibility study (called step 0) that is essential to evaluate the needs of the new lab. Only if a real need for the GL is demonstrated, can the subsequent steps be carried out.

Due to the different socio-economic conditions each lab is a reality different from the others, always without forgetting the goal of opening labs that produce **quality** medicinal products. For each lab a **specific handbook** has been studied: each of them reflects the different local needs. The pharmaceutical forms proposed are **liquid preparations, capsules and ointments**. Also **sterile formulas** can be prepared. For each preparation specific tests were performed to verify the **stability** under different environmental conditions, in accordance with the European Medicines Agency (EMA) guidelines.
A.P.P.A.® labs production concerned mainly medicinal products but **preparations** suitable for food supplementation **against the malnutrition** can be set up

***A.P.P.A.*® LABS IN THE WORLD**



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THE *A.P.P.A.*® PROJECT AT THE NPH-SAINT DAMIEN PEDIATRIC HOSPITAL

- ✓ In 2011, the collaboration request of the Francesca Rava Foundation - NPH Italia onlus, leaded the execution of a feasibility study on site to assess whether the application of the *A.P.P.A.*® Project was appropriate at **the NPH Saint Damien Pediatric Hospital in Port-au-Prince (Haiti)**.
- ✓ In 2012, in agreement with the hospital management, the GL was opened. The work began with the production of a minimum number of **preparations specific for pediatric use** and **stable in tropical conditions**.
- ✓ In 10 years of work, numerous preparations have been added and significant production volumes have been obtained, such as, for example, 2500 liters of liquid preparations per year. In addition, the hospital pharmacy has been equipped with two laboratories for the production of **sterile preparations**, including oncologicals, 24 hours a day.

2011: feasibility study

Main problem identified: preparation of capsules for children starting from high-dose industrial capsules.
Critical issues:

- Methods of preparation
- Quality of the tablets
- Stability of the preparations
- Administration of capsules for neonatal and pediatric treatment

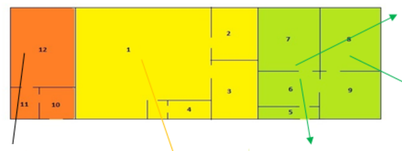
2012: development of the formulations to be prepared, opening of the galenic laboratory and of the laboratory for the preparation of sterile medicines

PREPARATIONS PEDIATRIQUES	
SIROPS	ACIDE ASCORBIQUE 10 mg/ml
	CANRENONATE DE POTASSIUM 1 mg/ml
	FER SULFATE 5 mg/ml
	IBUPROFENE 20 mg/ml
	PROPANOLOL 0,5 mg/ml
	RANITIDINE 15 mg/ml
	SALBUTAMOL 0,4 mg/ml
	VITAMINE B_6 1 mg/ ml
SOLUTIONS	CAPTOPRIL 1 mg/ml
	FUROSEMIDE 1 mg/ml
GOUTTES	NIFEDIPINE 1 mg/gtt
	RANITIDINE 4 mg/gtt
	SALBUTAMOL 0,2 mg/gtt
	VITAMINE B6 0,5 mg/gtt
SUSPENSIONS	VITAMINE B COMPLEX 5,8 mg/ml
	MAGNESIUM ET ALUMINIUM HYDROXYDE 200 mg/ml

2012-2021: annual trips to check the progress of the activities and to improve the activities of the laboratories

Annual production volumes in **2021**:
- **70.000 capsules**
- **2.500 liters of liquid preparations**
- **6.000 doses of sterile medicines**

Hospital pharmacy structure



INTRODUCTION OF A PARENTERAL NUTRITION PROTOCOL IN NEONATAL AND PEDIATRIC AGE

In the last five years, following the on-site implementation of a pediatric surgery program, there has been the **need to be able to set up bags for parenteral nutrition**. The first step in the development of the new project was to write a protocol to be applied in the different departments. In particular, thanks to the work of a multidisciplinary group, born from the collaboration between the Saint Damien Hospital, the Francesca Rava Foundation, the DSTF and the Maggiore Policlinico Hospital in Milan, a protocol called "**Protocol de Nutrition Parentérale en âge néonatal et pédiatrique"** was developed. The document contains all the useful notions relating to prescription and preparation of parenteral nutrition bags.
Parenteral nutrition, from a technological point of view, is not easy to achieve, especially in a context such as that of Haiti, also knowing the spread of nosocomial infections at the Saint Damien hospital. In this context, it was therefore necessary to develop an **easily understandable and applicable preparation procedure, that at the same time allowed to minimize the possibility of preparations contamination**. The procedures currently in use in some Italian hospitals were then analyzed and compared, the parts of interest were selected and then integrated according to the local needs. The **prescriptive flow** was organized as follow: the preparation request is sent to the Hospital Pharmacy via a specially prepared file in which only some fields can be modified in order to minimize the possibility of incorrect compilations. Pharmacists verify the feasibility of the preparation and predispose the preparation sheet and the label. Once the preparation has been completed by the technical staff, the pharmacist carries out the quality checks and, if the formulation is suitable, it is sent to the requesting Department.
The mixture for parenteral nutrition is a system in which the high number of components makes it essential to evaluate the compatibility between the elements, the stability and quality of the preparation. Given this, an important part of the work carried out during the on-site missions was the **training of the medical staff and of the pharmacists**. In addition, it was necessary to train the **technical and nursing staff** who practically had to proceed with the preparation and administration of the bags, alternating theory with practical exercises.

OBJECTIVES OF THE MULTIDISCIPLINARY PROJECT

- Development of a standard operating procedure for the prescription and preparation of magisterial bags for **Parenteral Nutrition (PN)**
- Introduction of the procedure on site and **training of the local staff**

- Assessment of the **needs** of the departments of the Saint Damien hospital
- Assessment of **previous knowledge** of local staff
- Evaluation of **the on-site availability of products** for the production of bags for parenteral nutrition
- **Cost evaluation** for the purchase and shipment of materials from Italy

Development of the **"Protocol de Nutrition Parentérale en âge néonatal et pédiatrique"**

Organization of specific training courses for **medical doctors, nurses, pharmacists and laboratory technicians**


NUTRITION PARENTERALE EN ÂGE NÉONATAL ET PÉDIATRIQUE

Hôpital St Damien - Port au Prince - Haïti

26 Juillet 2018

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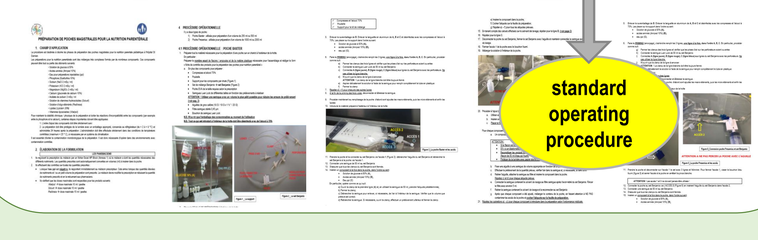
HOSPITAL PHARMACY
DEVELOPMENT AND INTRODUCTION ON SITE OF A STANDARD OPERATING PROCEDURE FOR THE PREPARATION AND QUALITY CONTROL OF PN MAGISTRAL BAGS

PHASE 1: development of the standard operating procedure

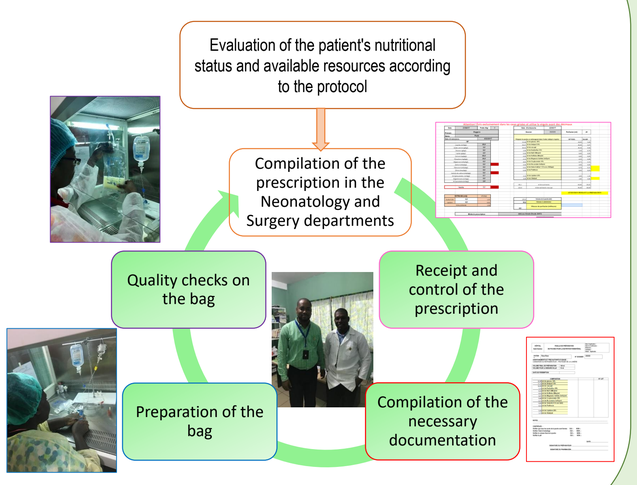
Evaluation of procedures in use at hospital pharmacies in Piedmont, Lombardy and Veneto or described in the literature

Adaptation to the needs and conditions (environmental, working and cultural) present at the Saint Damien hospital.
- ❖ Development of a detailed operating procedure but in a simple language
- ❖ Reduction in the consumption of sterile medical devices

standard operating procedure



PHASE 2: organization of the prescriptive flow



PHASE 3: introduction of the procedure on site

CRITICALITY
- ❖ Potentially unstable system
- ❖ Possible interaction between electrolytes
- ❖ Possible contamination during preparation and handling
- ❖ Prescriptive errors

THE ROLE OF THE PHARMACISTS
- ❖ Checking the prescription
- ❖ Verification of the correct application of the standard operating procedure for the preparation
- ❖ Verification of the correct execution of quality controls (pH, sterility test, visual inspection)
- ❖ General system check

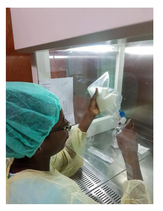
PHASE 3: training of the technical staff

1) **THEORETICAL** lessons: understanding and learning of the procedure

2) **PRACTICAL** lessons: preparation of the bags

STEP 4: quality control

Sterility tests were performed at the Department of Drug Science and Technology on bags set up at the Saint Damien hospital: all tests gave positive results



CONCLUSION

In conclusion, the procedure for the prescription and preparation of bags for parenteral nutrition was **developed and successfully introduced on site**. All personnel who participated in the training were found to be suitable. To date, the pharmacy is able to meet the demands of the departments, with the possibility of setting up magisterial bags seven days a week.
This project for the development of the parenteral nutrition procedure in Haiti started in 2017: it was an ambitious project that saw the involvement of various professionals and a great team work which, however, allowed to obtain a very important result. Currently, for reasons related to the pandemic, **the project continues in remote mode thanks to the organization of training meetings which, at least once a month, jointly involve the Haitian and Italian staff**.