Patients reporting in Croatia

Patients association's experiences

Jurica **ESTER**, dipl. ing.

Croatian association of renal patients on peritoneal dialysis

Croatian Transplant Association

Croatian association of renal patients on PD exists for nine years and brings together people on PD, their family members and medical staff. The active membership currently counts 286 members. **Croatian Transplant Association** exists six years and brings together people with transplanted solid organs, and we have over 1000 members in Croatia. We are very active in international cooperation, and we were hosts and organizers of the **EUROPEAN TRANSPLANT AND DIALYSIS GAMES, Zagreb 18.-25.08.2012** which were attended by **28 countries and over 400 participants**, and **HALMED** was a proud sponsor of Games and Symposium on pharmaco vigilance which was held during the Games.

In our work and activities, we closely collaborate with the **Ministery of Health** in the implementation of activities to raise awareness about the importance of organ donation. We also work together with the **medical institutions and medical personnel** on improving the conditions of treatment for dialyzed and transplant patients.
Together with **HALMED,** on two occasions we have jointly organized patients education - 28/29.04.2012. in Daruvar Spa and during ETDG 2012 Zagreb.
With **Industry** we have a partnership through supporting of our many activities, both in Croatia and abroad, and our stationary for patitents in Zagreb (**House of Life**) We are proud that we are recognized as a reliable partner in the implementation of notable projects withCroatian Society for Nephrology, Dialysis and Transplantation of Croatian Medical Association

Patient with CKD on chronical HD - informal way of reporting possible adverse drug reaction (before on-line reporting for ADRs exists in CRO)

When patient thinks that medicinal product or device causes side effects

gladly discuss it with other patients

maybe discuss it on association meetings

hardly never discuss it with doctor

association gets informed about incident

association discretly discuss matter with medical staff

"It's normal to feel these health problems due to all diagnosis you have"

- most common answer a patient with CKD can expect

Practical example 1:

PROBLEM WITH SOLUTION FOR HAEMODIALYSIS IN HOSPITAL HD UNIT

- Patients have noticed an **increased number** of cases of blood pressure drop during and after haemodialysis treatments
- After expressing their concern to nurses, there is no improvement
- Patients are complaining to doctors and seek explanation
- Patients learned from technicians on dialysis that due to the transition to a central delivery solution, a new solution with altered ratios of electrolytes is in use
- Patients unsuccessfully demanded a return to the previous solution where there were not so many adverse reactions
- Association went to the holder of license to talk and to draw their attention to the rumors and the possibility of notification the Agency by the patients. Distributor benevolently accepts the fact.
- On organized two-day patient education **in collaboration with Agency** about the possibility of reporting adverse reactions – this above case was officialy reported
- Agency's investigation confirmed the medical correctness of the solutions, but patients who reacted badly to the new solution were returned to the old solution

The Agency contended medical correctness of solutions, but could not claim association with adverse events. It remains to be seen whether the monitoring of adverse reactions can be better regulated on the hospital HD wards without jeopardizing patients anonymity, because ADRs mostly occur during dialysis sessions.

Practical example 2:

ENDOTOXINS IN PERITONEAL DIALYSIS SOLUTIONS PRODUCED AT THE PLANT

- Due to the lack of sufficient alternative sources for endotoxin-free dialysis solutions, the CHMP could not recall all affected products
- Patients in one hospital in Zagreb were **mostly redirected to another** manufacturer solution, while in other hospitals doctors had options to decide the appropriateness of possible errors commited by patients themselves when connecting to other manufacterer connection systems that they've been trained 'overnight' for, and **options to remain** on questionable solutions

After approx. a year, Association tried to collect data on the total number of peritonitis in all hospitals with PD patients. But we could only concluded the following:

- there was **no systematic monitoring** of the incidence and causes of peritonitis
- there was **only** enhanced and detailed monitoring of patients which were on solutions from manufacturer who had a case with endotoxin in their solutions
- Although doctors were legally obligated to report to the Agency any case of peritonitis as a **side effect of PD solution** - in practice it did not work, there were no reports
- **We officially addressed to HALMED** asking for an explanation, which resulted in alerting its staff and emergency actions

Aftermath of our addressing to Agency on this particular case

- We realized that the system is set up in a way that there is a big pressure on distributors and license holders themselves to investigating rumors, visit the hospital wards and at the end, report ADRs of their own medicinal products which they themselves are puting on the market
- We realized a fact, stated on the Agency's official website, that in 2009 there were only four (4) reports of ADRs by **nephrologists,** and in the 2010, the year when the mentioned case happened – there was **NONE (Ø)**
- cca 3000 patients on dialysis in Croatia treated solely by nephrologists and **no reports** of adverse reactions? Even of expected ones?

We questioned the possibility of high-quality implementation of the rules based on the obligation of the distributors to visit the hospital and ask doctors about ADRs;

- We know that visiting doctors is legally limited for covert marketing
- Do distributors have sufficient staff members who can spend their days touring the hospitals all over Croatia, running around doctors who are already overburdened with work, and ask them for ADRs?
- Distributors are under no circumstances allowed to approach patients and possibly ask for side effects. Doctors, on the other hand, are obligated to do exactly that!

We manage to agree with **Agency for Quality and Accreditation in Health Care and Social Welfare** that in the regular reports of hospital coordinators under paragraph unwanted occurrences, peritonitis comes as independent paragraph.

What we propose not only as medical laymen, but as patients for whom this whole system of pharmaco vigilance exists;

- From our long experience in the promotion of organ donation, when Croatia was penultimate in Europe 6years ago, and now, already second year in a row, **first in World** in realized donors per million inhabitants - the most important thing is to implement **synchronized educational campaign** that should involve the **media, the general population, patients, associations and medical staff** - all in order to raise awareness to the **possibility** and also the **obligation to report adverse reactions**.
- It is important to **emphasize the fact** that reporting of adverse reactions is for the **common good**, and that with it we can **improve the beneficial effects** ofmedicines and medical devices. Only then can we expect more than **only 45 reports** of ADRs by patients, like there were in 2012 in Croatia

We are more than excited to finally have Croatian representatives in Patients' and Consumers Working Party (PCWP) as HALMED went into full membership of EMA!

Billboard for European Transplant&Dialysis Games organized by our association in collaboration with **HALMED**. A **great example of good practice in joint patients' education.**

THANK YOU FOR YOUR ATTENTION !!!