E-learning Objective:

To teach student to fill a spontaneous reporting form starting from this case

Clinical case n. 1

A post menopausal woman with diabetes

July 2018

In a 63-year-old woman, with diabetes mellitus since 2015, treated with an association of glibenclamide 2.5 mg and metformin 400 mg twice daily, an hypertension was diagnosed.

21 July 2018

Enalapril 20 mg/day was added to the therapy.

13 August 2018

The woman began to complain of nausea, vomiting, diarrhea, abdominal tension, hypotension. In the emergency room the patient was confused, tachycardiac (105 beats/min), with a blood pressure of 80/50 mmHg. Serum creatinine was 3.75 mg/ml, lactic acid was 12 mg/dl, potassium 5.80 mEq/l and sodium 132 mEq/l.

13 august 2018

All medications were discontinued, the woman was hydrated and given sodium carbonate; after two days the symptoms disappeared, creatinine fell to 1.90 mg/dl, lactic acid to 7.6 mg/dl and the patient resumed eating normally.

20 august 2018

The woman was discharged from hospital; only glibenclamide (2.5 mg twice daily) was added to the therapy. Blood pressure was normal, so no antihypertensive therapy was started.

At this point you have to report the case on the yellow card

Learning objectives:

- To teach student how to recognize an ADR
- To teach student how to manage an ADR

Clinical case n. 2 - A woman with intractable asthma

Interactive clinical case n. 2 – A woman with intractable asthma

A 37 years old woman, non-smoker, for years asthmatic, is hospitalized for an asthma attack, resistant to treatment with corticosteroids.

In the hospital, she is treated intravenously with aminophylline (240 mg in 500 ml of glucose solution, at a rate of 50 ml/hour).

The patient's condition, after 3 days, improves markedly, with regression of asthma attacks.

On the fourth day, the patient suffered from an irritated cough and a high fever. The patient is given 1 tablet of cefixime 400 mg; after an hour the patient complains of intense itching, with the appearance of urticaria throughout the body.

When questioned, the patient reported having had a similar episode after amoxicillin a few years earlier.

Question: What could have happened?

- 1) It's a consequence of asthma
- 2) It's an interaction between aminophylline and cefixime
- 3) It's an allergy to betalactamine
- 4) It's not possible to say on the basis of the available data, cephalosporins are different from penicillins

Comment: Before administering a drug to a patient, especially in the case of antibiotics, you should always ask if the patient have already taken that drug or similar drugs, and if he had any adverse events. Cephalosporins in 15-20% of cases have a cross-reaction with penicillins, so they should not be used in patients allergic to penicillins.

Cefixime is discontinued and, instead, a therapy with erythromycin (600 mg three times a day) is started. The patient's urticaria and itching are decreasing, and the fever disappeared. But after 4 days the patient begins to complain of vomiting and diffuse tremors. The heart rate is 120 bpm; the patient is very prostrate.

What happened?

- 1. An intolerance to erythromycin
- 2. An aminophylline overdose
- 3. An erythromycin-aminophylline interaction
- 4. She has probably eaten something that has hurt her

Comment: Vomiting, tremors and tachycardia are signs of aminophylline intoxication. The infusion dosages, however, in this case, have been corrected.

As is written in the erythromycin warning label "erythromycin, troleandomycin, propranolol, isoprenaline, cimetidine, oral contraceptives, allopurinol reduce theophylline clearance". Therefore, even in the presence of a correct dosage, the concomitant administration of aminophylline and erythromycin increased the plasmatic concentration of the drug, determining the manifestation of toxicity reactions.

The aminophylline is suspended for 24 hours, with the disappearance of the symptoms reported by the patient. It is then resumed at half the dosage for the entire period of hospitalization, even after the suspension of erythromycin (whose effects last for more 10 days after suspension). The patient is released in good condition.