

Introduction

Medications are part of society as a possibility of relief or solution to the health problems of population. The prescription is an indivisible part of the medical process and it is necessary to know the specific indication of drugs and do it on a diagnosis as accurate as possible.

However, there are legal limits within the authorization processes for marketing by regulatory agencies, which can create barriers to these prescription premises, such as the approved indications for medicines. Off-label use (off-label use, unusual, unofficial, unauthorized, unapproved, alternative use) includes:

Use of medication in situations not covered in the approval of the product: different dose or frequency, different indications, different age groups or administration by a different route.

Doses for children use to be reference. Clinical trials usually focus in adult population, in consequence there are limited or no pediatric documentation with respect to many approved drugs. Ethical and other considerations must be considered when a drug used has not been adequately tested in a pediatric population. The use of off label drugs is a transversal problem in health systems and studies in LATAM related to the prevalence of prescription of drugs with no approved indication are incipient.

Some studies shows not conclusive results of prevalence (17%-60%) of off label use of drugs in pediatric population.

Objectives

Primary Objective:

Characterize the trend of prescription and use of off label drugs, in pediatric units at a high complexity hospital for the year 2015.

Secondary Objectives:

- Establish the trend of the prescription and use, according to the medical specialty, of off label drugs for the year 2015
- Establish the pharmacological categories of off-label drugs prescribed and used for the year 2015.
- Determine the cost of off label drugs prescribed and used for the year 2015.

Methods or Study Design

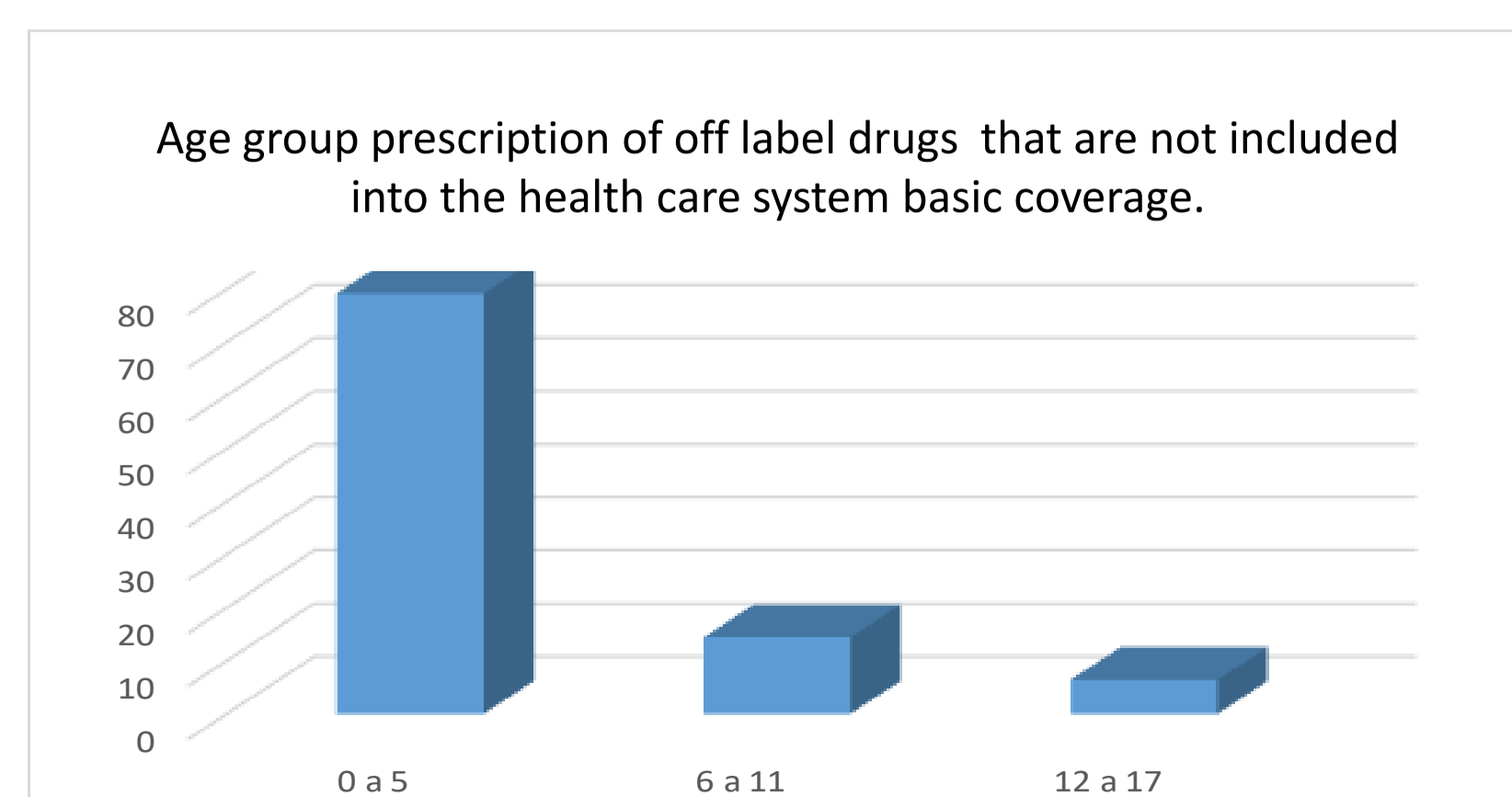
A descriptive observational study with retrospective data was developed, which characterizes the trend of prescribing and use of medications, with an off-label indication in the pediatric hospitalization service at a high complexity hospital. A sample of 299 inpatient pediatric clinical records were analyzed during 2015 and the drugs were divided into two categories according to coverage or not coverage of health care system. Study focus on those drugs with off label use that are not included into the health care system basic coverage.

Results

- ❖ The proportion of prescription and use of off label drugs, that are not included into the health care system basic coverage, for the selected sample was **20.9%**. 125 cases of treatments with off label drugs that are not included into the health care system basic coverage were identified,
- ❖ Pediatric intensivists (47.2%) and pediatricians (41.6%) were the major prescribers of off label drugs that are not included into the health care system basic coverage.

Medical speciality	Off label prescription cases	%
Pediatric Intensivist	59	47,2
Pediatrician	52	41,6
Pediatric cardiologist	9	7,2
Neonatologist	4	3,2
Liver transplantation	1	0,8
Total	125	100

- ❖ The group of 0-5 years represents 79.2% of the prescriptions off label drugs that are not included into the health care system basic coverage.



- ❖ Defect of the ventricular septum, defect of the atrial septum and coarctation of the aorta (20%, 12.8% and 8%) were the pathologies which have more prescriptions of off label drugs that are not included into the health care system basic coverage. Cardiovascular diseases in general accounted for 74% of cases
- ❖ 11 different medications prescribed with off label indication were found. Intravenous cefuroxime and Dexmedetomidine were the most prescribed with 90.4% of the cases.

Medication	Number of off label treatments
Cefuroxime 750mg iv	92
Dexmedetomidine 100mcg ml/ 2ml iv	21
Valganciclovir 50mg/ ml oral suspension x 100ml	3
Risperidone 1 mg/ml oral suspension x 20 mL	2
Anidulafungine x 100 mg iv	1
Baclofen 10 mg Tablet	1
Basiliximab 20 mg iv	1
Cefuroxime axetil 250mg/5ml oral suspension	1
Inmunoglobulin G 5 gr iv	1
Olanzapine 5mg Tablet	1
Polietilenglicol 160 gr. 3350ml Powder	1
Total	125

- ❖ The value of off label drugs that are not included into the health care system basic coverage in the analyzed sample was \$ 74,721,766 COP. (21,976 Eur)

off label drugs that are not included into the health care system basic coverage	Total Value (COP)
Dexmedetomidine 100mcg ml 2ml iv	\$ 31.796.631
Cefuroxime 750mg iv	\$ 23.923.230
Basiliximab 20 mg iv	\$ 8.241.856
Anidulafungine x 100 mg iv	\$ 7.362.868
Valganciclovir 50mg/ ml x 100ml oral suspension	\$ 2.272.635
Inmunoglobulin G 5 gr iv	\$ 717.192
Risperidone 1 mg/ml oral suspension x 20 mL	\$ 147.656
Cefuroxime axetil 250mg/5ml oral suspension	\$ 116.820
Olanzapine 5mg Tablet	\$ 88.112
Polietilenglicol 160 gr. 3350ml Powder	\$ 46.676
Baclofen 10 mg Tablet	\$ 8.090

Conclusions

The variables defined for the study allowed a characterization of the trend of the prescription and use of off label drugs in pediatric units at a high complexity hospital for the year 2015. The causes of off label use in the defined sample were all observed.

The pharmacological categories off label drugs that are not included into the health care system basic coverage were directly related to the main pathologies responsible for their formulation. The two most off label prescribed drugs are included in the institutional clinical practice guidelines, despite their non-indicated use. As an university hospital, the residents that rotate are learning and executing this type of uses that will surely be replicated when they go out to practice in other institutions.

The use off-label drugs generates economic risks for the institution, which are related to the non-payment by health insurance companies. This situation generates a conflict between the economic and the clinically needs for the patient.

It is possible to conclude that the off-label use of drugs depends on many factors, and even on individual cases of patients, which implies that each point of view has its part of reason. At the institutional level, knowledge of these situations is important, as a team to define a management policy for this type of use of these medications.

In one way or another at the institutional level it is necessary to define informative and control strategies for the management of the off label use of medicines in general and mainly for those that are not included into the health care system basic coverage.

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