

Unlicensed and off-label drug prescription at discharge from a Swiss children's hospital

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INTRODUCTION

For children, many drugs are used without marketing authorization ("unlicensed", e.g. imported drugs, drugs prepared by a pharmacy) or outside the terms of marketing authorization ("off-label"). In Switzerland, around half of all prescriptions for pediatric inpatients were either off-label or unlicensed¹. The aim of this study was to determine the proportion of unlicensed and off-label prescriptions at discharge, which has not been investigated previously in Switzerland, and the proportion of parents informed about such a prescription.

METHODS

Prospective study including all discharge prescriptions of inpatients over a two-month period at the Children's Hospital of Aarau. Exclusion criteria: hospitalization for chemotherapy only, age over 18, re-entry during study period, no informed consent of parents. At discharge parents were asked to fill in a questionnaire about the information they got on discharge medication as well as about their satisfaction with this information. This questionnaire was available in german, french, croatian, turkish, albanian, spanish and english.

QUESTIONNAIRE

Study: Discharge medication children's hospital: Analysis of the prescriptions „off-label“ and „unlicensed“ as well as problems during the accomplishment.
Questionnaire about discharge medication

Dear parents, thank you for participating in the study mentioned above. We would like to ask you to take your time to answer this questionnaire. Please hand it filled out questionnaire to a nurse, the reception desk or mail it to us using the enclosed envelope.

Name and date of birth of your child: _____
Name of one guardian: _____
Phone number: _____ Date: _____

First language of the guardian:
☐ German ☐ French ☐ Spanish
☐ English ☐ Albanian ☐ Turkish
☐ Serbian ☐ Other: _____

Language of the discharge conversation:
☐ German ☐ French ☐ Spanish
☐ English ☐ Albanian ☐ Turkish
☐ Serbian ☐ Other: _____

How well did you understand the discharge conversation?
☐ 10 = no understanding, 10 = full understanding

When did you get your discharge prescription?
☐ before the discharge conversation
☐ during the discharge conversation
☐ after the discharge conversation

Did you get any drugs to take home? ☐ yes ☐ no
- If so, what drugs? _____

Did you get any adjuncts for application of drugs to take home? ☐ yes ☐ no
- If so, what adjuncts? _____

Who gave you information about the drugs? ☐ doctor ☐ nurses

Did someone explain the aim of the medication? ☐ yes ☐ no

If so, how satisfied are you with the explanation?
☐ 10 = dissatisfied, 10 = entirely satisfied

Did someone explain to you at what time(s) you have to give the drug(s) to your child?
☐ yes ☐ no

If so: Were you given any further information on the application of the drug(s)? (e.g. with / without food)? ☐ yes ☐ no

Did someone explain how long the medication should be taken?
☐ yes ☐ no

How satisfied are you with all the information on the medication of your child given to you?
☐ 10 = dissatisfied, 10 = entirely satisfied

Did someone mention:
- that one drug is unlicensed for children? ☐ yes ☐ no
- that one drug needs to be ordered abroad? ☐ yes ☐ no
- that one drug needs to be produced by a pharmacy? ☐ yes ☐ no

Did someone explain potential side effects? ☐ yes ☐ no

Notice: It is possible, that in your case one or all of these points were not mentioned. It could be that these points did not apply to the medication of your child.

Is there anything else you want to tell us in correlation to the prescription, the medication or the discharge conversation?

Thank you for your participation in this study

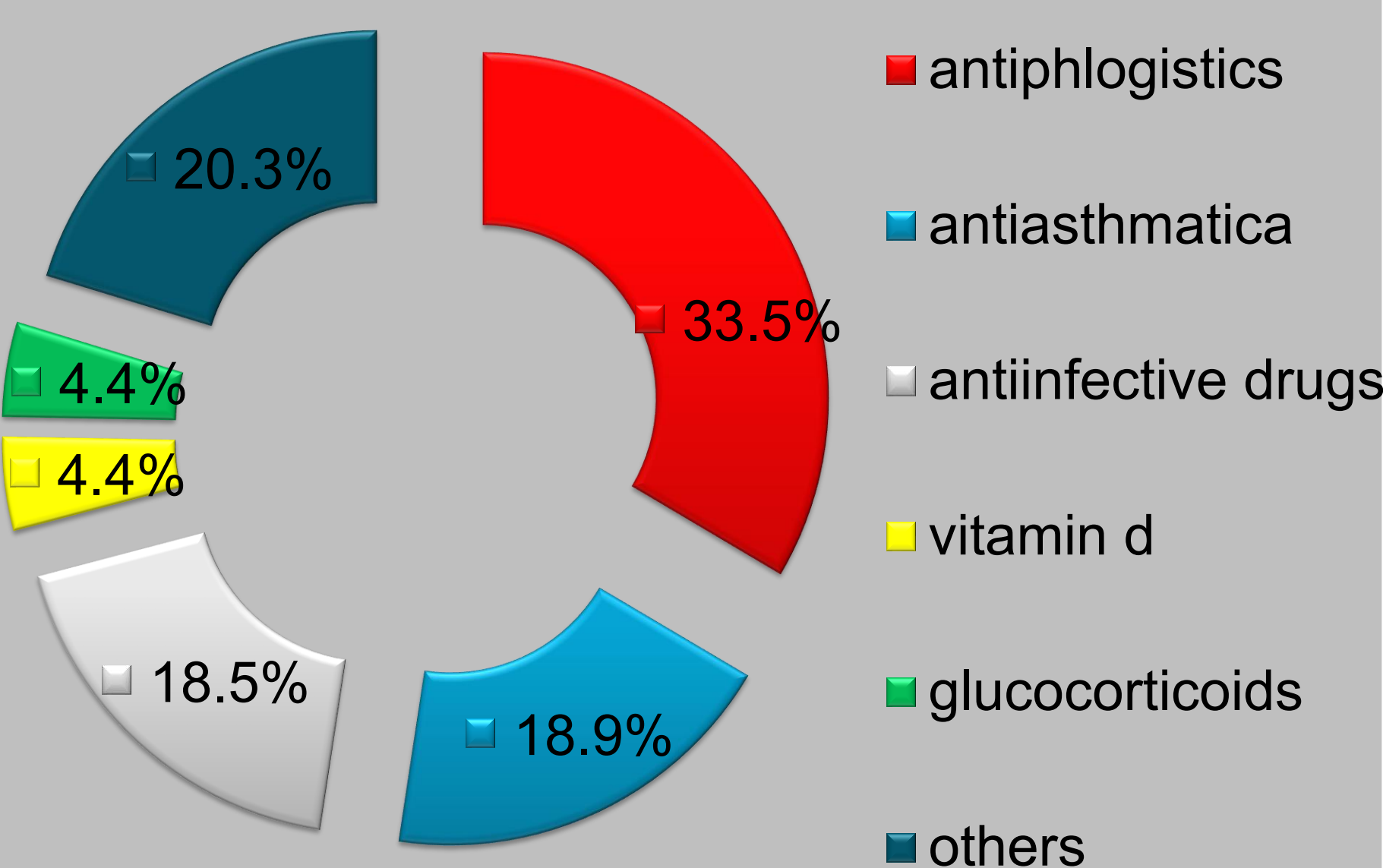
RESULTS

During the study period 503 children were discharged, 231 children could be included. For 140 children (61%) discharge prescriptions were written. Figure 1 shows the age of children getting an off-label prescription. A total of 227 drugs were prescribed, especially antiphlogistic/analgesic, antiasthmatic and antiinfective drugs (see fig.2). 38.5% of all prescriptions were off-label (see fig.3), regarding dosage in 51%, age in 40% and indication in 9% of all cases (see fig.4). Only 0.5% of drugs were unlicensed. An example of off-label prescription is shown in figure 5. Discharge questionnaires were returned of 103 of 140 children. Most parents (> 80%) were informed about purpose, dosage and use of the drugs for their child, and satisfied with obtained information, but only 9% of parents getting an off-label / unlicensed prescription for their child were informed about the off-label / unlicensed use.

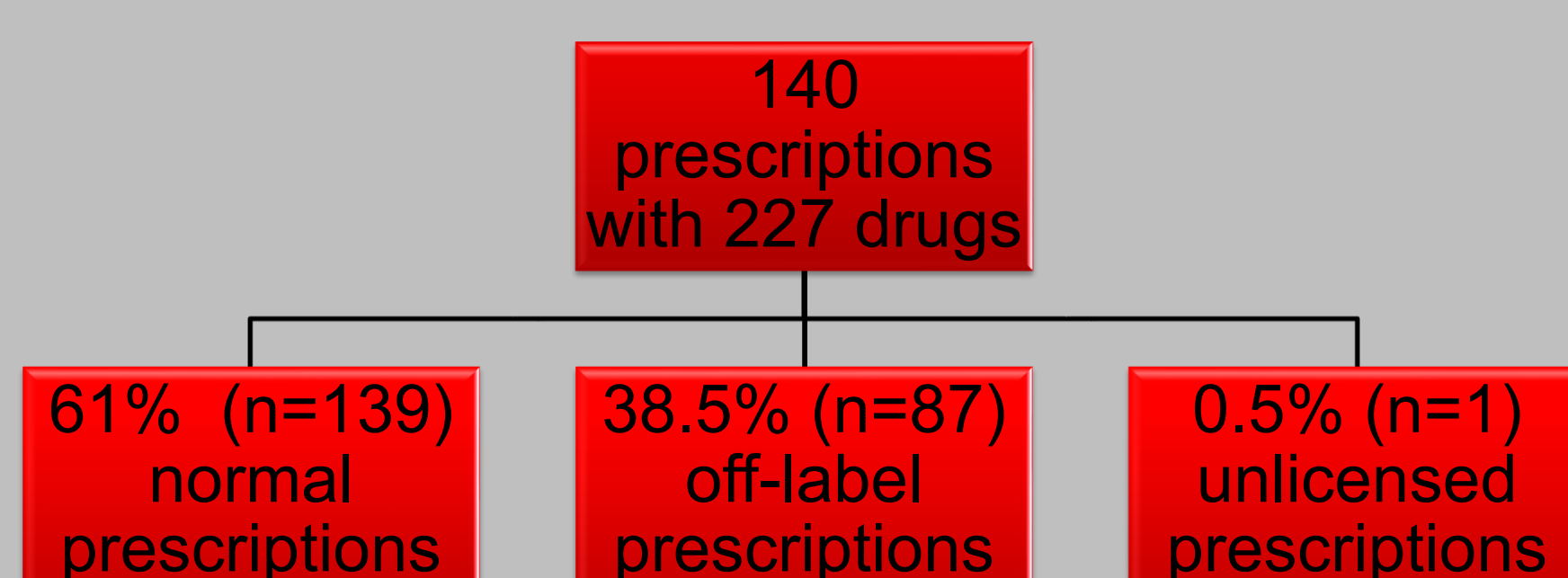
CONCLUSION

There is a high percentage of drugs prescribed off-label at hospital discharge. Most drugs are well known substances and regularly prescribed for children. This emphasizes the need for an update of marketing information of older substances, or the need of a national database for drug use and dosage in children.

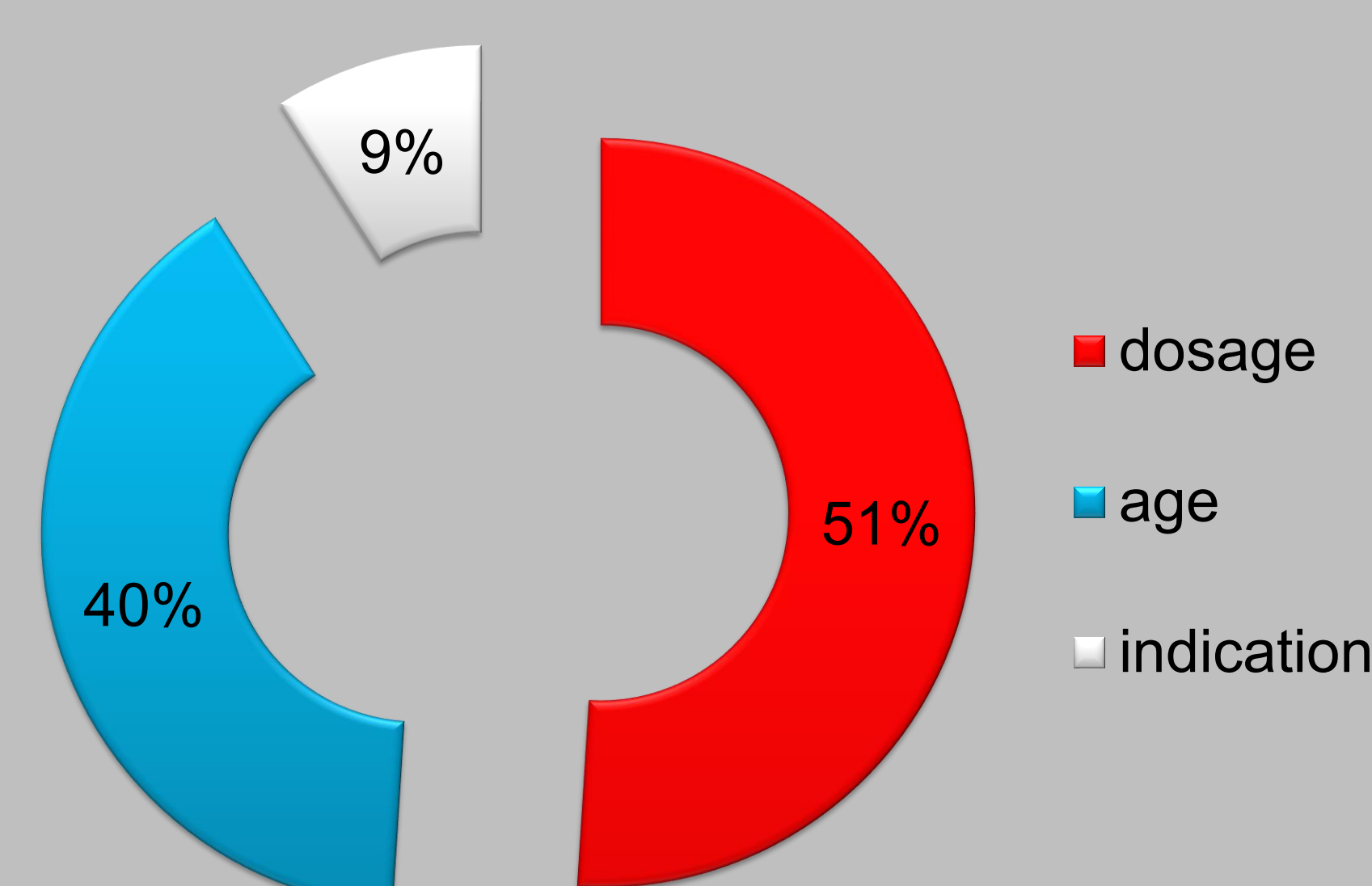
2 drug prescriptions



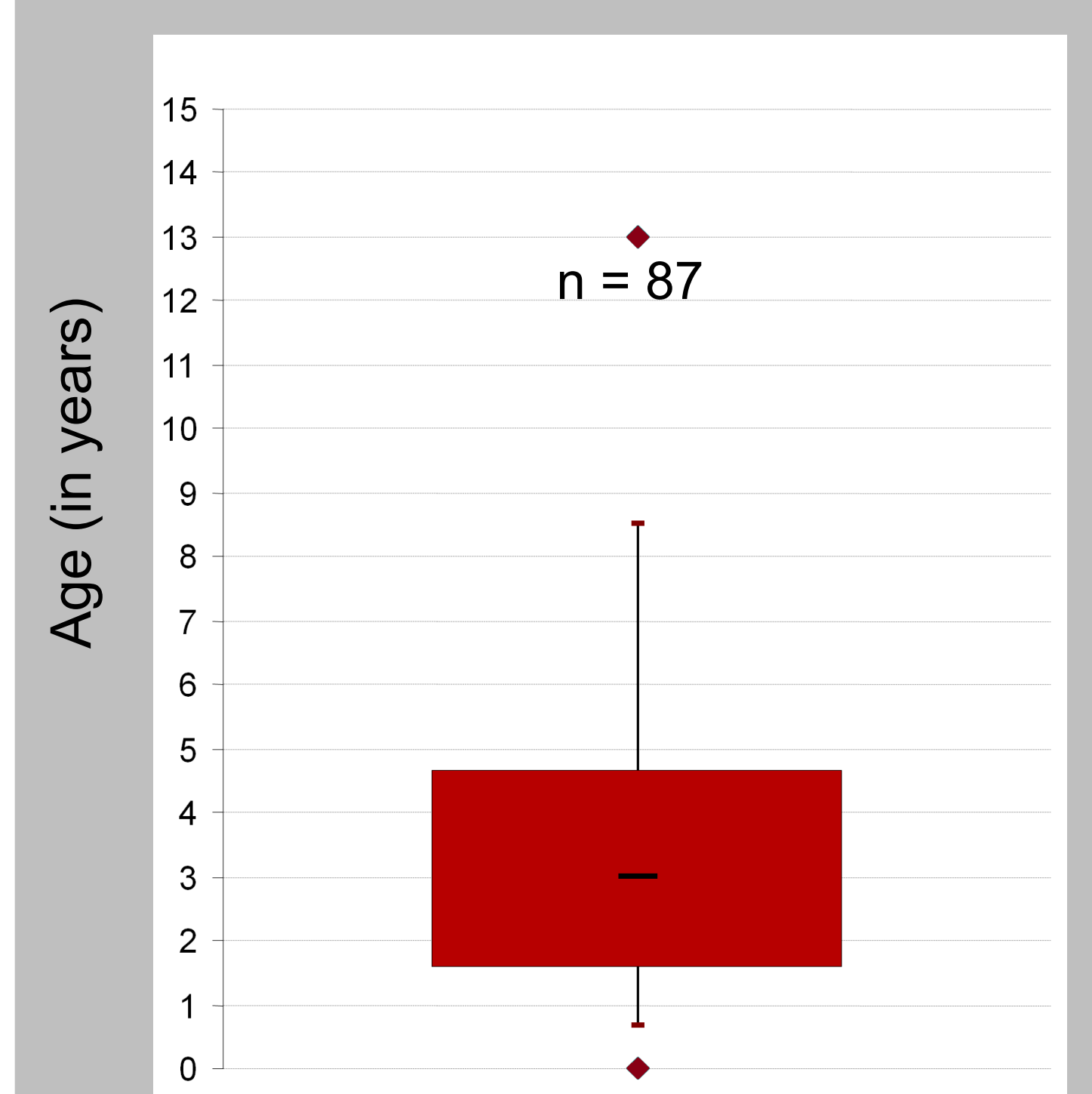
3 Classification prescriptions



4 Classification off-label prescriptions



1 Off-label prescription according to age



- 50% of the patients are between 1.5 and 4.7 years old
- 25% are younger than 1.5 years respectively older than 4.7 years

5 Antiasthmatic drugs

Ventolin® DA	Axotide® DA
• 27 x off-label in age → There is no description of dosage² under the age of 4	• 8 x off-label because of the dosage → Kompendium dosage: 2 x 100µg daily → Axotide® DA dose 125µg