



# Results of a collaboration between a CRPV and an infectious disease care service

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## Introduction

**Antibiotics are one of the major therapeutic class that cause adverse drug reaction** especially when used in combination over long period of time and in patients in poor general condition. The management of osteitis is based on prolonged and multi antibiotic therapy. With the creation of a regional labeled center dedicated to the management of complex bone and joint infections (BJI) in Lyon, a systematic reporting of adverse events (AE) occurring in patients treated for infection was introduced.

**Our aim was to make an assessment of this collaboration and its benefit.**

## Material and Methods:

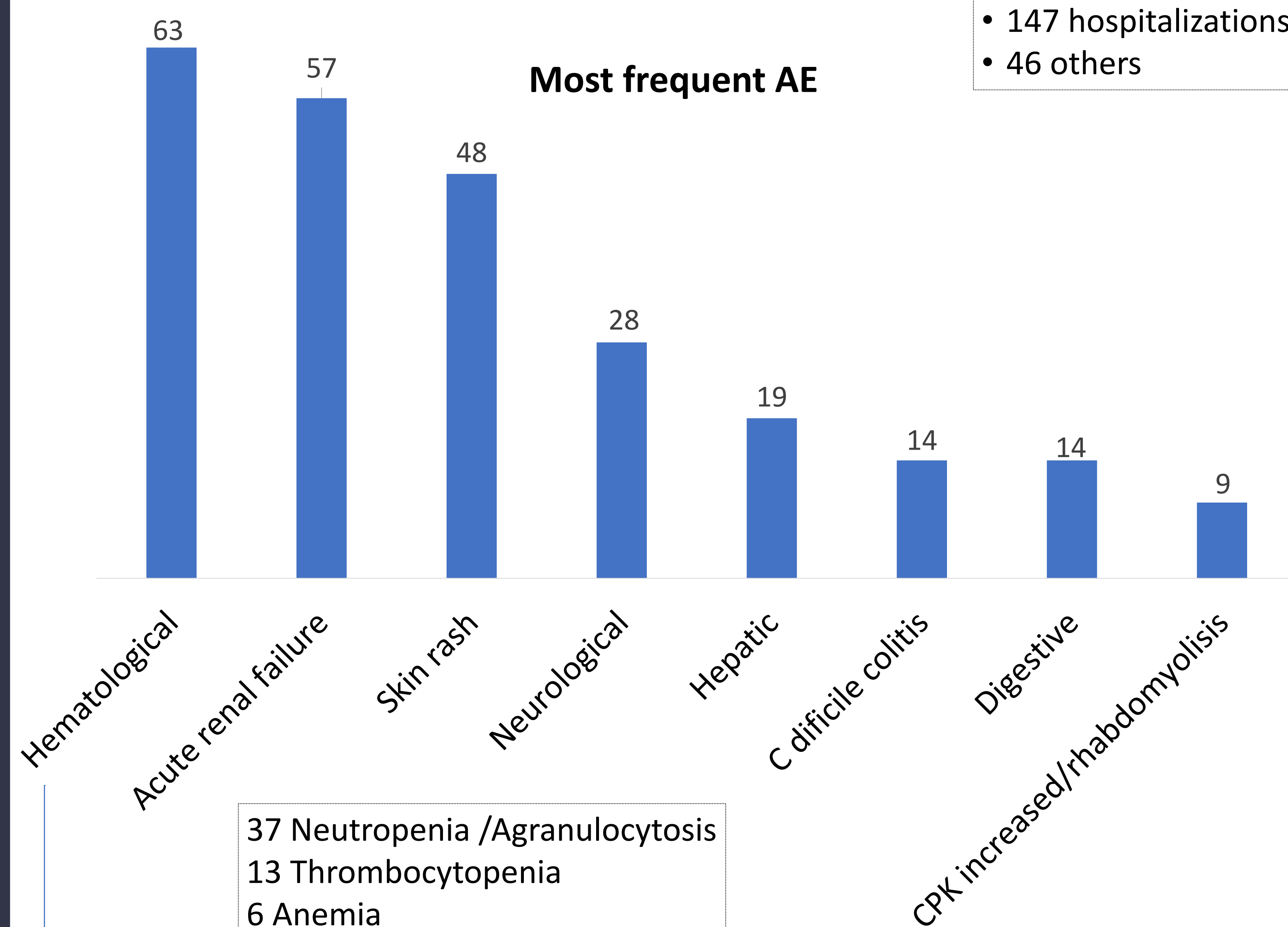
Since May 2015, all cases of AE are collected by a biomedical engineer, reviewed by a pharmacist and then systematically addressed to the regional pharmacovigilance center for evaluation. We performed a descriptive study of all these cases between May 2015 and November 2019.

309 AE reports transmitted / 456 suspected drugs  
 211 patients – 63.4 ± 39.6 years – Sex ratio (M/F) :1.4  
 Median number of suspected drugs per case :2 (min 1-max 5),

### 198 (79%) serious AE concerning 370 drugs

- 2 deaths
- 2 threatening life
- 3 incapacities
- 147 hospitalizations
- 46 others

### Most frequent AE



- 37 Neutropenia /Agranulocytosis
- 13 Thrombocytopenia
- 6 Anemia
- 3 Pancytopenia
- 3 Hypereosinophilia
- 1 Bicytopenia

## Results:

### Most implicated class

**Anti-infectious : 95%**

Mostly **Betalactams** (30.4%) :

- Cephalosporin (48.2%),
- Penicillin (29.5%),
- Carbapenem (22.3%)

### Most frequent drugs

**Vancomycin** (n=61),  
**Cefepim** (n=32)  
**Rifampicin** (n=32).

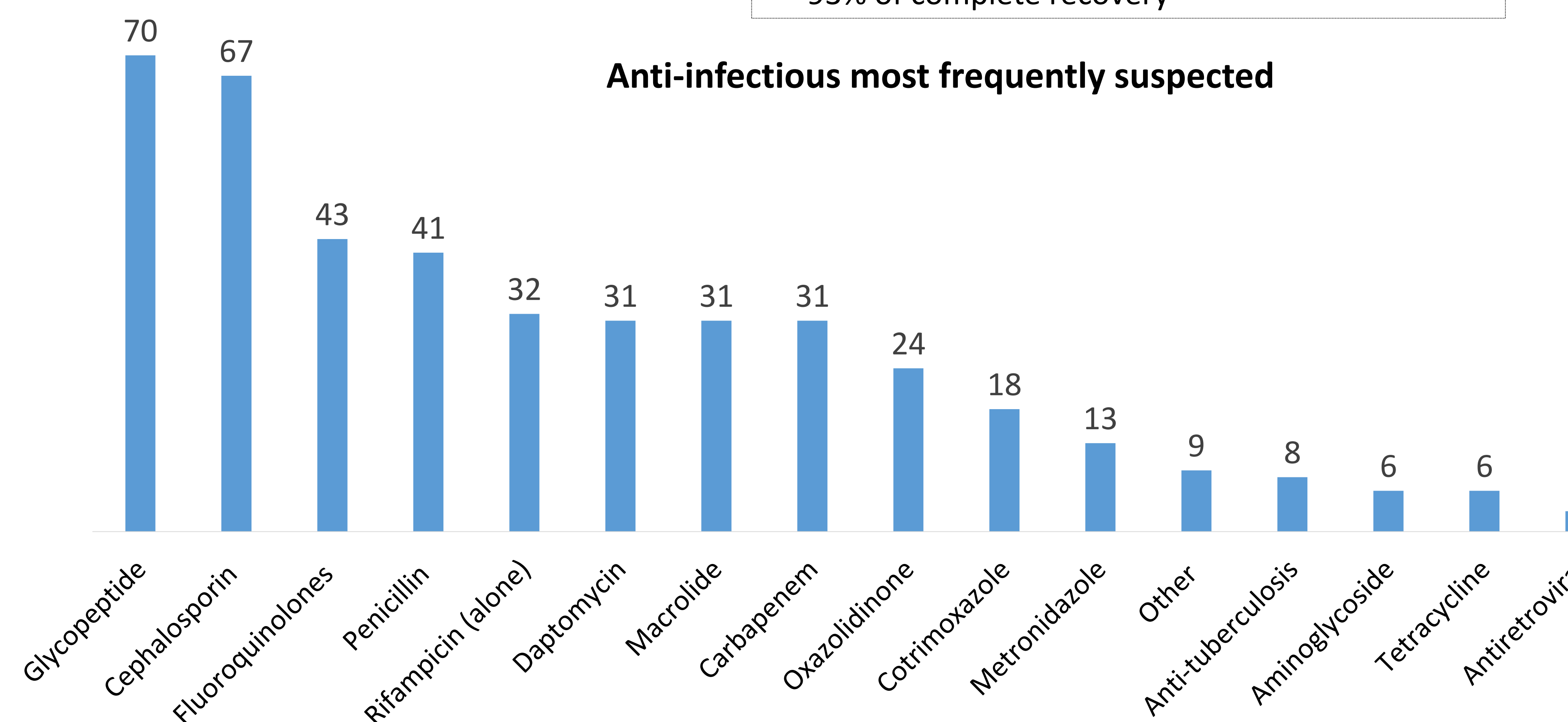
- Drug discontinuation in 398 (= 91.7%) cases
- Rechallenge was not test in 88% of cases
- 93% of complete recovery

### Table of antibiotics duration from the most frequent to less frequent

Drug	Mean treatment time
Vancomycin	24 days
Cefepim	20 days
Rifampicin	30 days
Daptomycin	27 days
Clindamycin	25 days
Linézolide	31 days
Ofloxacin	30 days
Cotrimoxazole	37 days
Amoxicilline	31 days
Pipéracillin tazobactam	21 days
Imipenem	21 days
Levofloxacin	65 days
Metronidazole	24 days
Ertapenem	35 days

Treatment duration over 20 days for most implicated drugs

### Anti-infectious most frequently suspected



### Two news safety signals have been identified :

- Risk of **acute kidney failure when using the vancomycin/piperacillin combination** (7 cases on the 309 reported)
- Risk of **DRESS associated with piperacillin** (5 cases on the 309 reported)

they led to change in professional practice in the labeled center and in our hospital, to an update of the labelling and to scientific publications (1).

## Conclusion

The implementation of this systematic collection **facilitates the emergence of new signals** concerning antibiotics used in hospital. This collaboration **benefits to public health** by improving knowledge of drug safety.

### Reference

(1) J Cottin, E Ollier, A Page, T Ferry, MN Osmont, F Kheloufi, A Gouraud .Combination of Piperacillin-Tazobactam and Vancomycin with a risk of Acute Kidney Injury: a French pharmacovigilance survey. Fundam Clin Pharmacol. 2018 ; 3