

From AFSSaPS to ANSM

Coordination of vigilances

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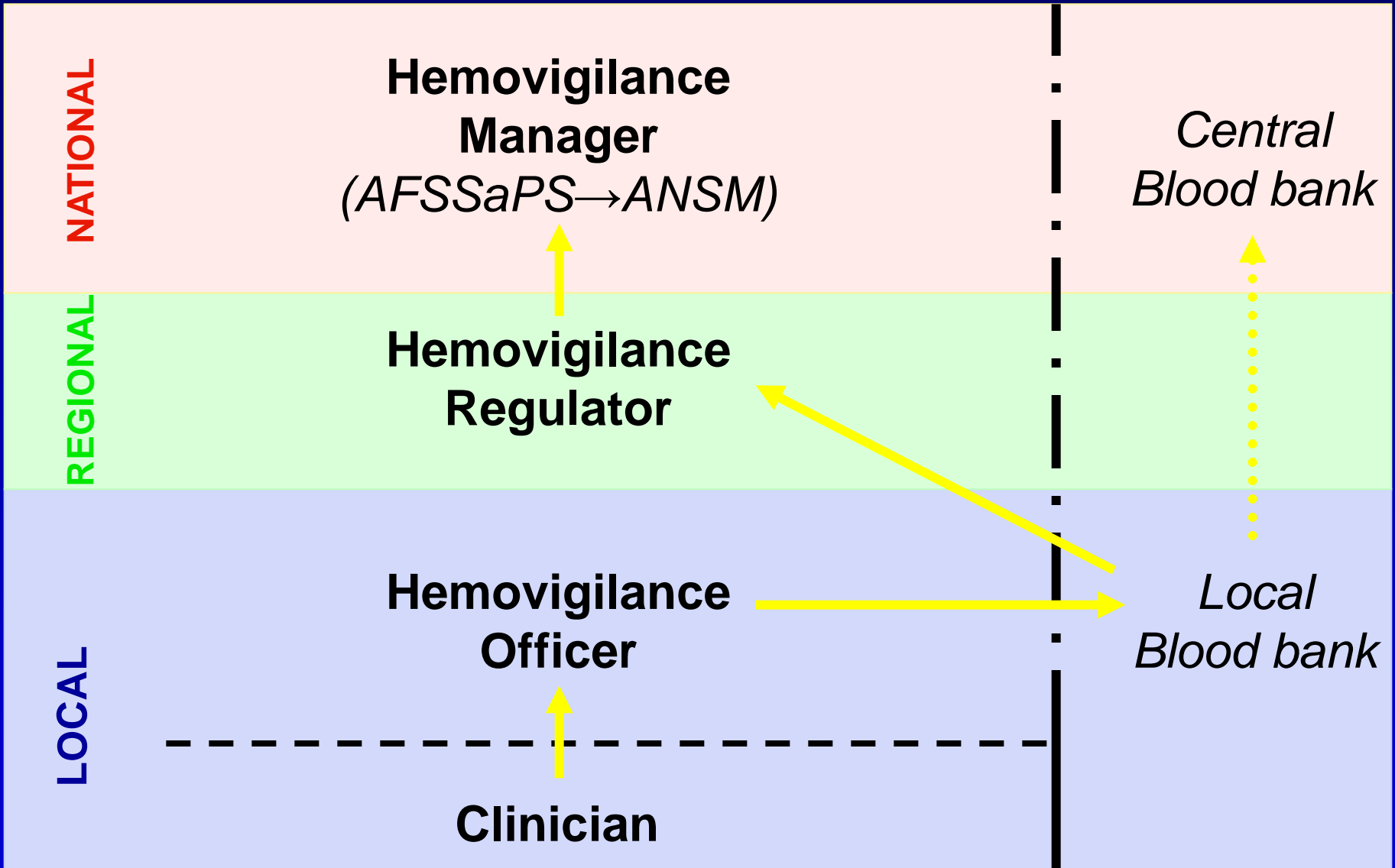
Nancy, France

On behalf of the SFVTT

SFVTT



The French Hemovigilance Network



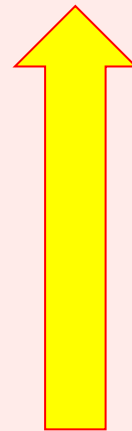
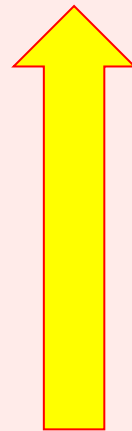
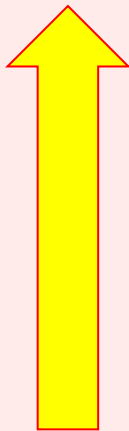
From AFSSaPS...

Hemo

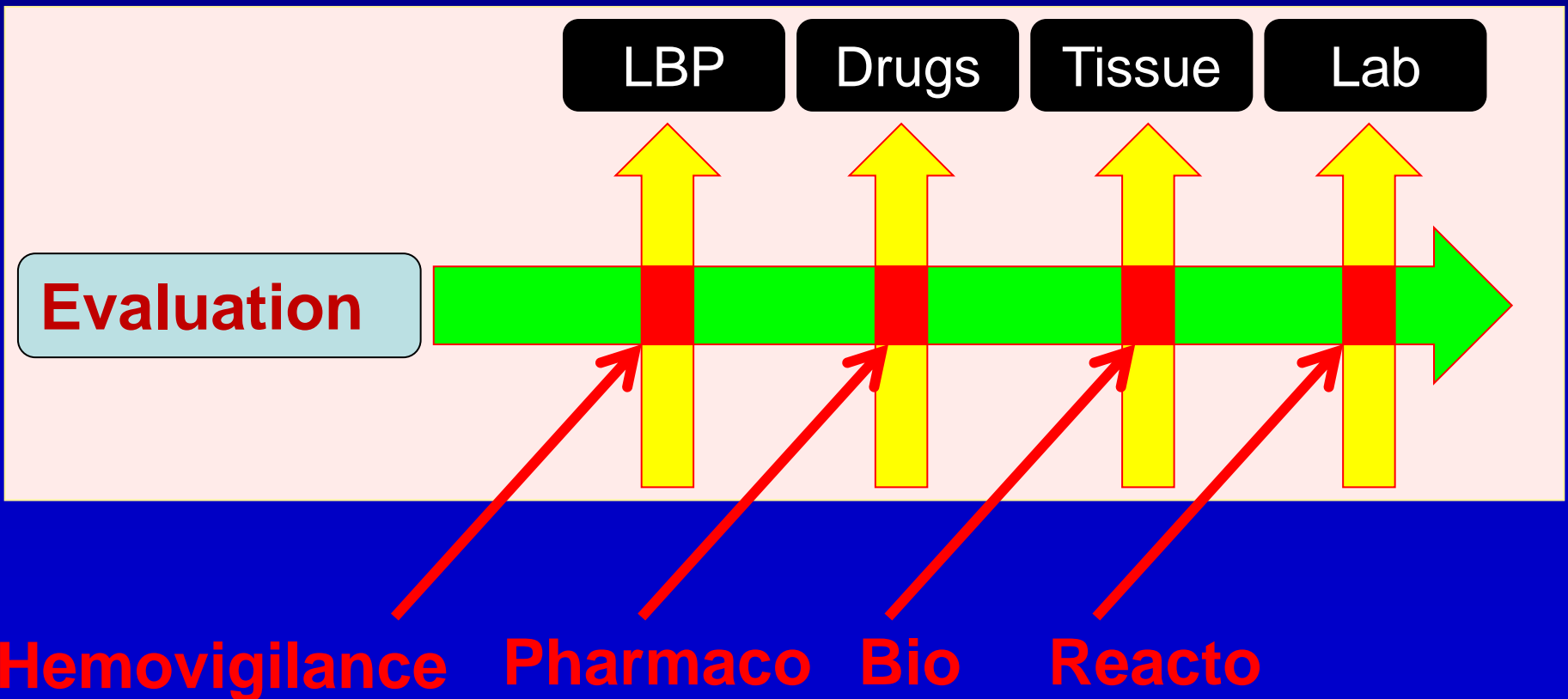
Pharm

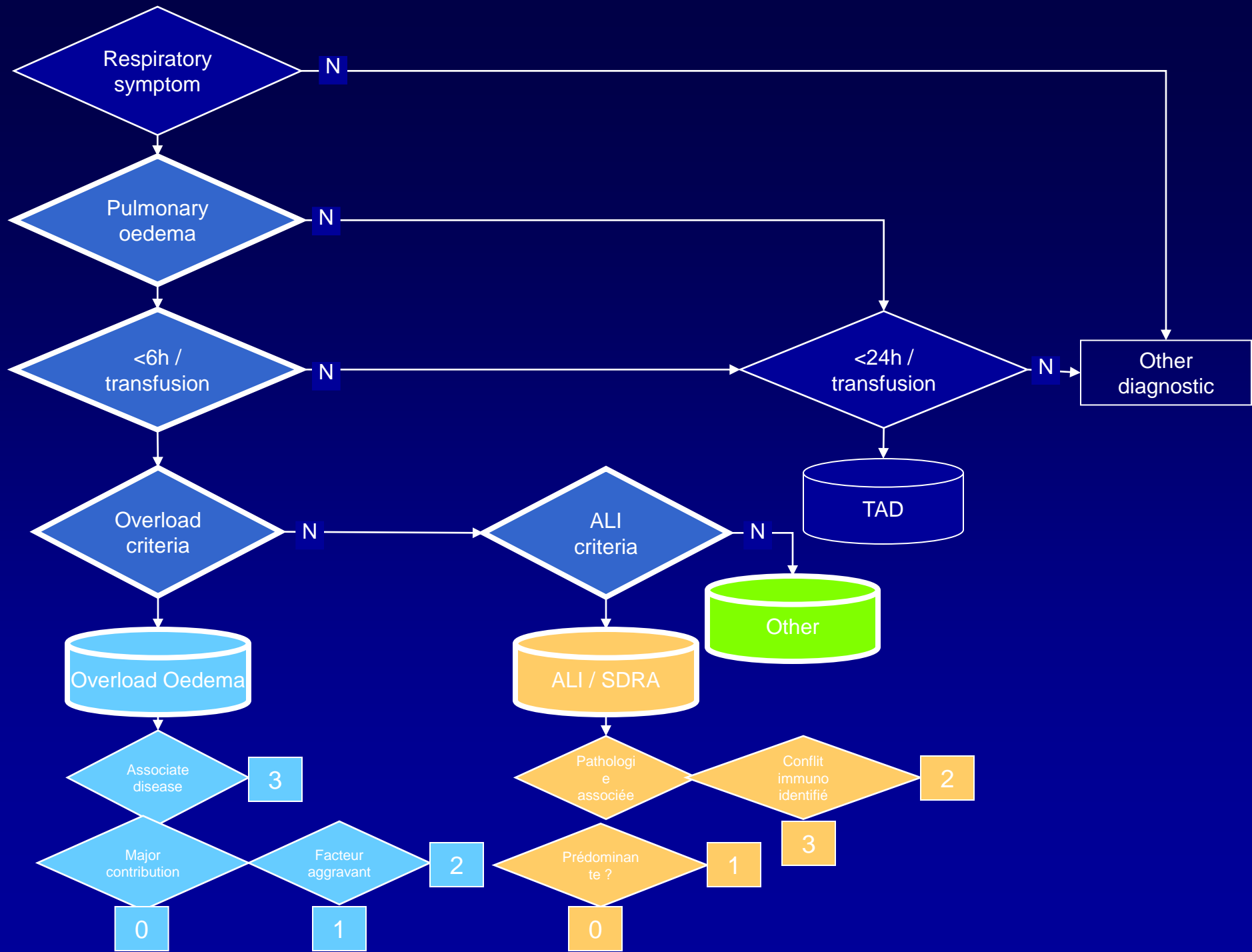
Bio

Reacto



... to ANSM





A case report (blood center)

- Mrs X, 42, death 10 hrs after a plasma donation
- Blood donor since 2009, 6WB & 2 plasma
- No adverse event, no CV risk factors
(H=1.73m/W=75Kg-67Kg 4mths before),
BP=120/80
- Donation : th=825 ml, sc=680 ml
- Vp=9:50am. 10:23am (5th cycle)=alarm (return line). Decision : stop donation (424 ml)
- Acute pain + feel faint / needle withdrawal
- Decision : keep lying ; BP idem
- Snack, discharged and returned home

A case report (home)

- 4:30pm, Mrs X called her GP for anxiety, paresthesia (feet and hands).
- 5:30pm, Dr Y came : lying on her sofa, anxious, “cold and hot”, cramps (feet & hands), heaviness/left arm, pain at veinipunction site.
- BP=120/80, exam = OK
- Hypothesis = Mg or Ca disorder
- Hydroxyzine + Mg. Husband → chemist
- 7:15pm = death

Imputability (1)

- “The use of causality assessment of spontaneously reported postmarketing adverse reactions by drug regulators has varied considerably. Most countries’ drug regulators have some method of approaching causality, but this method has been most well-defined in France, Australia and United States.”

Imputability (2)

- “In France—owing in part to the considerable original work and interest in adverse reaction causality by a regulator, J. Dangoumeau, and his colleagues—all reports of suspected reactions must be evaluated by the “French Method”. This method combines symptomatologic and chronologic criteria to give a “Global Intrinsic Score”, and then adds bibliographic data from standardized sources to give an “Extrinsic Score”.

**Jones JK. Determinating causation from case reports
Pharmacoepidemiology/2nd Ed. p.369. 1004.Willey & sons.**

Extrinsic imputability

Theory

- B4 : classical
- B3 : widely published
- B2 : 1 or 2 case-reports
- B1 : non published according to B3 or B2
- B0 : never published

Practice

- Textbooks
 - *Mollison PL et al. 10th Ed, 1997 : p 8.*
- FDA database : 2 deaths/MI (≈100 M donations)
 - *Sazama K. Transfusion 1990 ; 30 : 583-90.*
- Case-reports
 - *Rosencher J et al. Int J Cardiol 2011 ; 150 : 119-20.*
- Deaths/MI are more frequent in young patients
 - *Goldberg RJ et al. Am J Cardiol 1998 ; 82 : 1311-7;*
 - *Holmes DR et al J Am Coll Cardiol 1999 ; 33 : 412-9.*

Intrinsic imputability

Chronology

Yes

Neither yes nor no

No

Semiology

Yes

Neither yes nor no

No

Semiology

- *Additional information* : the donor experienced nausea and vomiting at 6:30pm

Intrinsic imputability

Chronology

Yes

Neither yes nor no

No

Semiology

Yes

Neither yes nor no

No

Conclusion

- The transition from AFSSaPS to ANSM gives to the hemovigilance the opportunity to benchmark from pharmacovigilance methods
- The French Imputability Method for drugs may be relevant for transfusion
 - To built guidelines
 - When a complex and rare event occurs
- But is too time-consuming in the daily practice of hemovigilance