

# Adjunction of Polymerase Chain Reaction in Screening for Hepatitis C virus RNA in Blood Donations :

## *Misuse of Principle of Caution*

**Sandrine LOUBIÈRE**

**INSERM Research Unit 379**

*"behavioral epidemiology in prevention and care for HIV infection",* Marseilles, France.

**Regional Center for Disease Control of South-Eastern,** Marseilles, France.

E-mail : [loubiere@marseille.inserm.fr](mailto:loubiere@marseille.inserm.fr)

**Inserm**



Institut national  
de la santé et de la recherche médicale



# OBJECTIVES



***Introduce*** Polymerase Chain Reaction (**PCR**)  
in the HCV screening of Blood donation is it  
***cost effective ?***

Does it mean something to do all that is  
"***technically possible***" independently of ***any***  
***economic consideration ?***

# HYPOTHESIS (1) : residual risk



## 1 - 3 screening strategies to compare

<i>Strategies</i>	<b>EIA</b>	<b>EIA + PCR on each donation</b>	<b>EIA + PCR on pools</b>
<i>Residual Risk</i>	<b>4.9</b> <b>(1.9 - 10.3)</b>	<b>0.7</b> <b>(0.3 - 1.5)</b>	<b>0.9</b> <b>(0.4 – 1.9)</b>
<i>Nb of false negatives avoided</i>	<b>-</b>	<b>12</b> <b>(4 - 24)</b>	<b>11</b> <b>(4 – 22)</b>

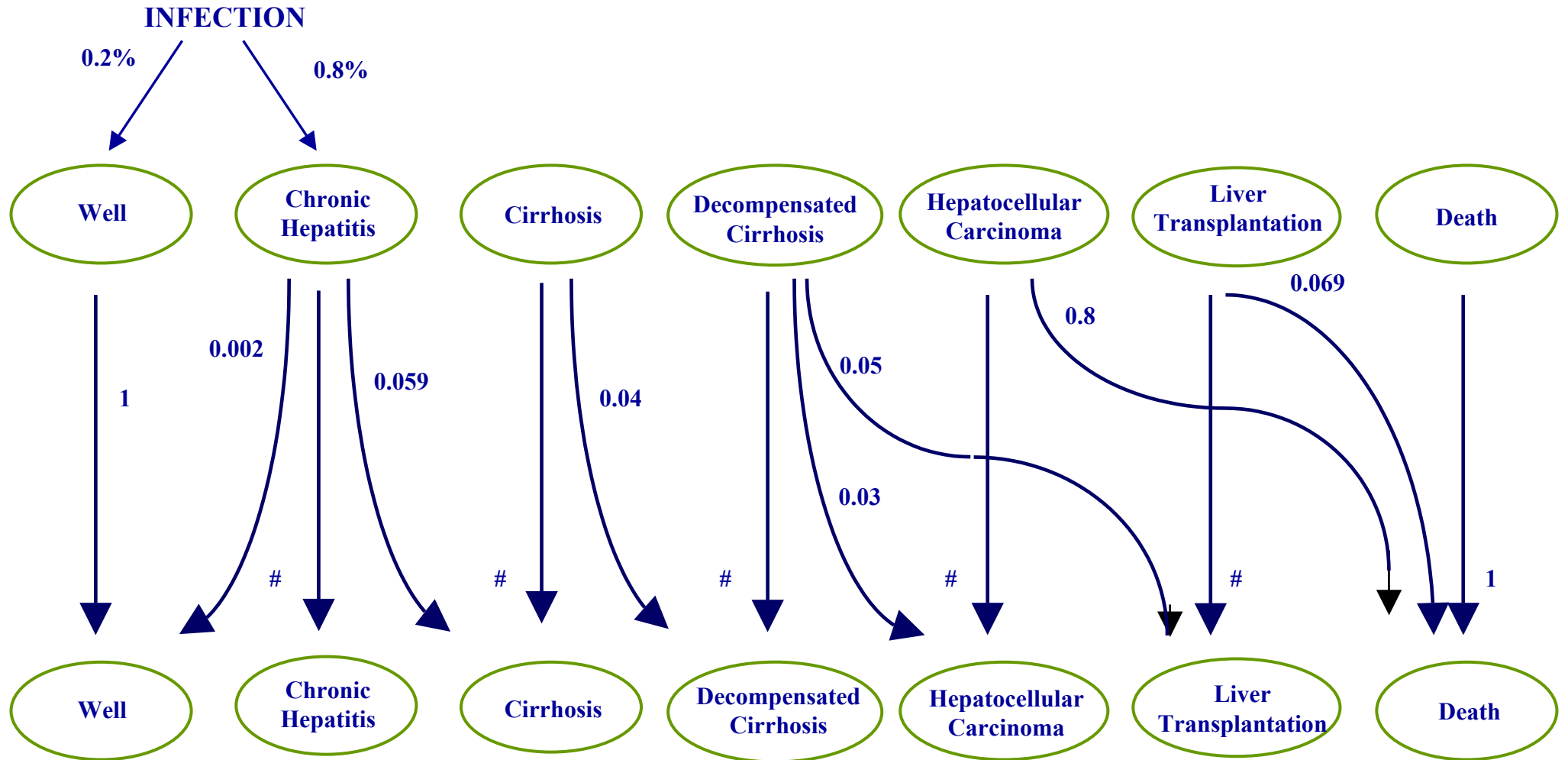
# HYPOTHESIS (2) : Markov model



2 - To take into account long term consequences

• Model of natural HCV history = Markov

# NATURAL HISTORY OF HCV DISEASE



# **HYPOTHESIS (2bis) : treatment option**



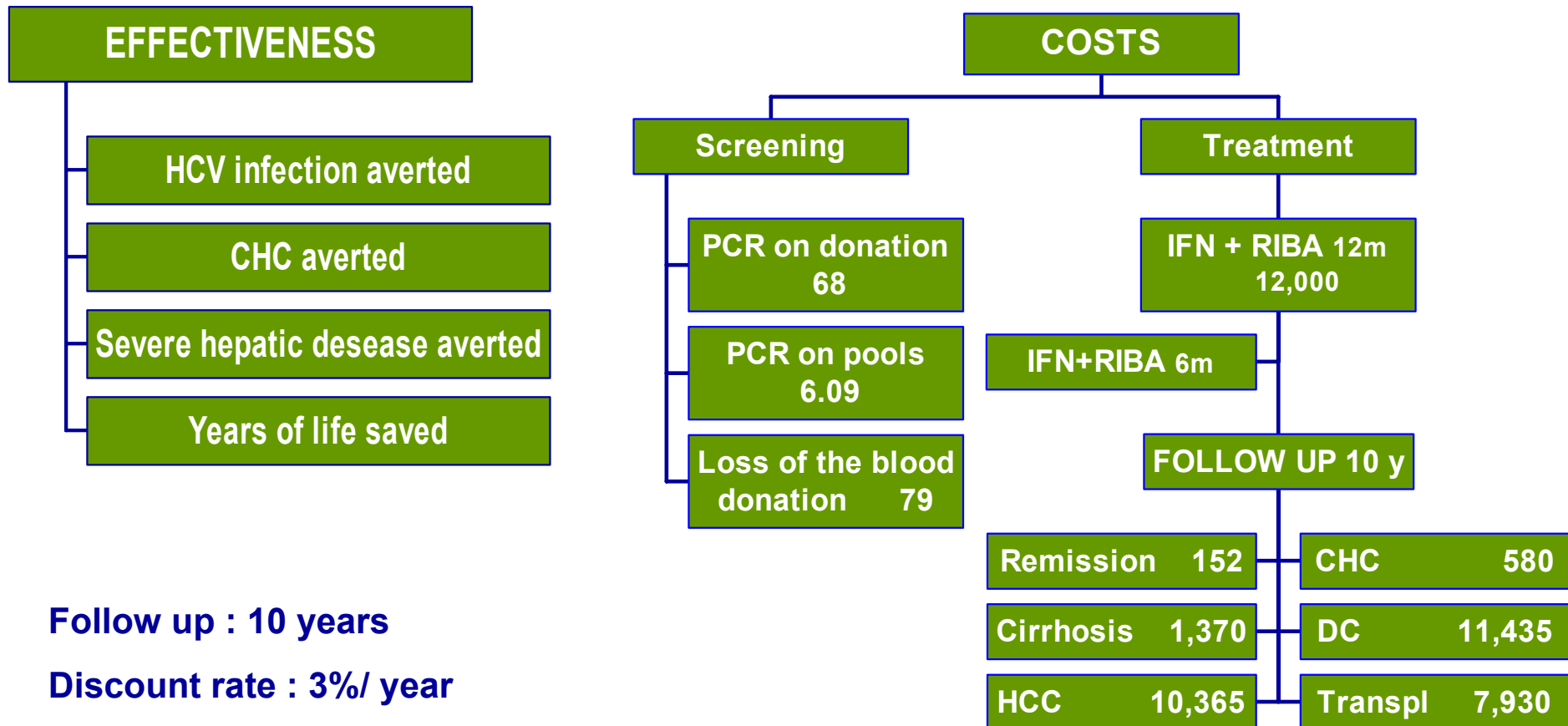
## **2 - To take into account long term consequences**

- 💧 Model of natural HCV history = Markov**
- 💧 One treatment option available = IFN + Ribavirin**
  - response rate : 40%**
  - response rate in relapsers : 50%**

# HYPOTHESIS (3) : outcomes



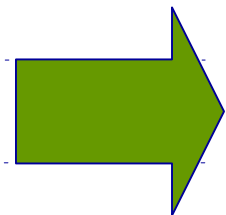
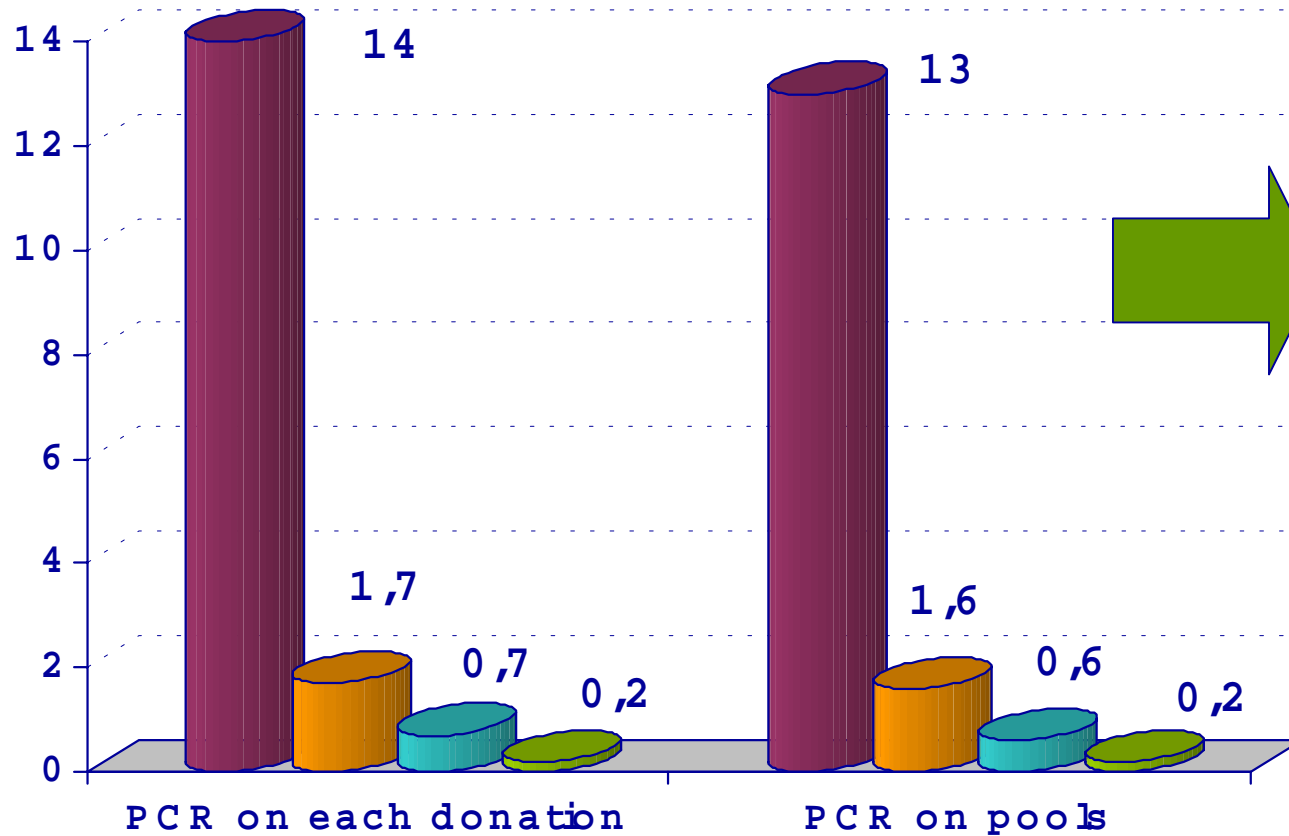
## 3 - Effectiveness and cost outcomes :



# RESULTS (1) : effectiveness



## Effectiveness



< 1 severe hepatic disease avoided

< 1 year of life saved

■ Infections avoided   ■ CHC avoided   ■ Severe hepatic disease   ■ Years of life saved 8

## RESULTS (2) : Incremental CER

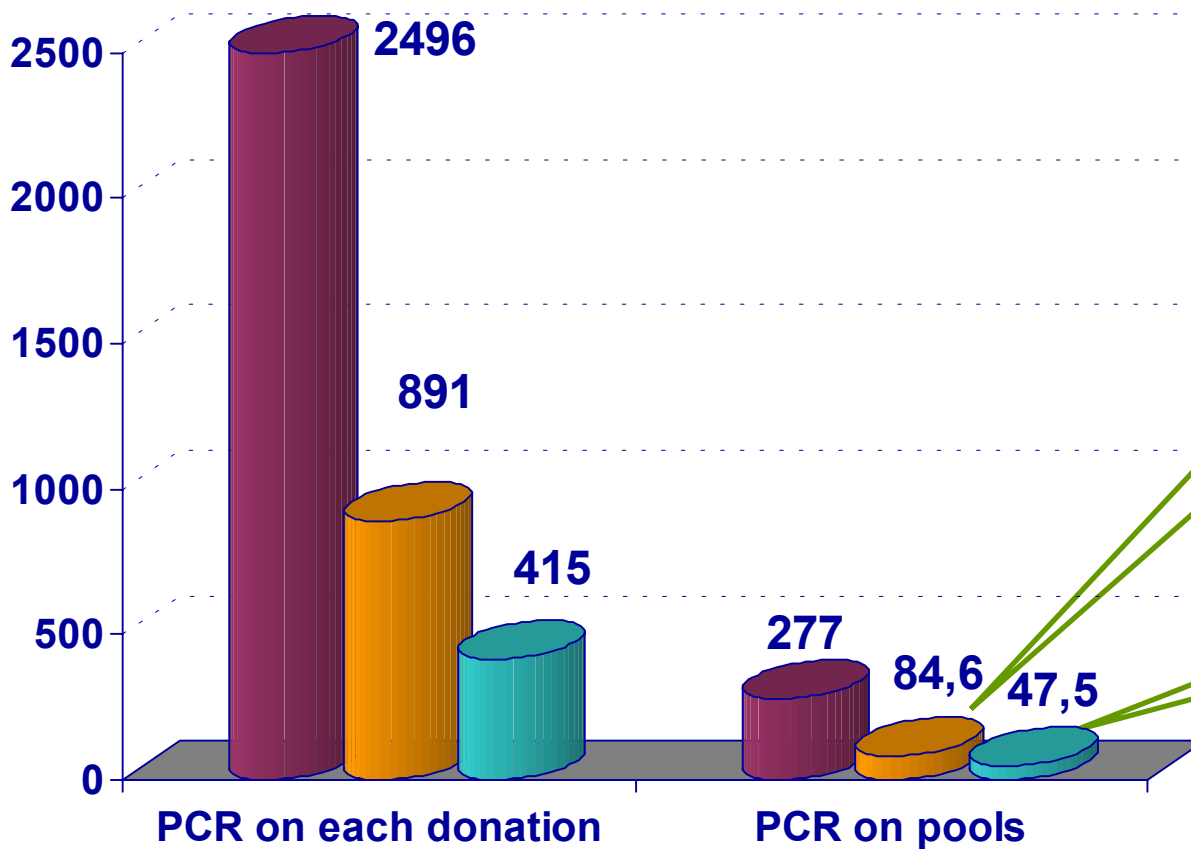


Study	Effectiveness	Total costs	Strategies	Incremental cost-effectiveness	
Loubière, Rotily, Durand- Zaleski, Costagliola	PCR on pools	< 1 life year saved	+ € 16.7 M	EIA + PCR on pools	€ 84.6 M
				High / low HCV residual risk	[€ 47.5 M – € 277 M]
Vox Sanguinis 2001 ;80 pp : 199-204	PCR on each donation	< 1 life year saved	+ € 150 M	EIA + PCR on each donation	€ 891 M
				High / low HCV residual risk	[€ 415 M – € 2496 M]

# RESULTS (2bis) : Incremental CER



CE ratio, MEuros



Baseline scenario

Optimistic scenario

Low hypothesis for residual risk

Mean hypothesis

High hypothesis

# RESULTS (3) : Sensitivity analyses

	Transfusion recipients	
	PCR on each donation	PCR on pools
<b>Discount rate</b>		
Baseline (3%)		
5%	€ 891.1 M	€ 84.5 M
10%	€ 891.2 M	€ 84.6 M
<b>Cost of treatment and follow up</b>		
Baseline		
-50%	€ 891.3 M	€ 84.9 M
+50%	€ 890.7 M	€ 84.1 M
<b>Cost of PCR test</b>		
Baseline	€ 68	€ 6.09
-50%	€ 38.8 M	€ 41.8 M
+50%	€ 1,783 M	€ 1,920 M
<i>High effectiveness (29) and extremely low cost (€ 1)</i>	€ 5.3 M	

# MAGNITUDE ORDER



**Hormonal therapy  
or Chemotherapy  
Traffic road safety**

**$\leq \$ 7,000$  / year of life saved**

*Hillner 1993*

**HCV treatment**

**$\leq \$ 20,000$  / year of life saved**

*Dusheiko 1995, Bennett 1997, Koff 2000*

**▶▶ Socially acceptable threshold**

**$\leq \$ 70,000$  / year of life saved**

*Gold 1996*

Studies	Population	Virus studied	Strategies	Effectiveness criteria	Total Cost	ICER	Average Cost (Euros)
<b>Busch 1995</b>	Blood donors	HCV (HBV)	ALT, EIA EIA, ALT	QALY	?	-\$87 900 \$ 7 931 000	
<b>Vergnon 1996</b>	Blood donors	HCV	ALT, HCV, HBV	True Positive	€ 5.8 M	€ 2,173	-
<b>Sailly 1997</b>	Blood donors	HBV HCV HIV HTLV	EIA + confirmation test	Seroconversion avoided	€ 38 M	-	€ 4,878 € 10,976 € 103,000 € 915,000
<b>Djossou 1999</b>	Blood donors	HIV	EIA + Ag p24	True Positive	€ 59 M	€ 1.5 M	-
<b>Pereira 2000</b>	Blood donors	HCV	PCR	QALY Life years saved		\$ 1 829 611 \$1 100 000	-

# QUESTIONS



1 - What is the *opportunity cost* of the introduction of PCR in HCV blood screening ?

= How many people could be detected and treated ?

2 - If Health Ministry decide PCR introduction

= Does it mean "*risk aversion*" ?

# MISUSE OF THE PRINCIPLE OF CAUTION



1 - Principle of caution = a *legal rule* for whole ?

Or = a *tool* for policy makers ?

2 - Principle of caution applied to transfusion safety

=

*Disregard the economic aspect*

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**Results in the article :**

**Loubiere S, Rotily M, Durand-Zaleski I, Costagliola D. Including polymerase chain reaction in screening for hepatitis C virus RNA in blood donation is not cost-effective. *Vox Sanguinis* 2001;80:199-204.**