

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

Misuse of Principle of Caution

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

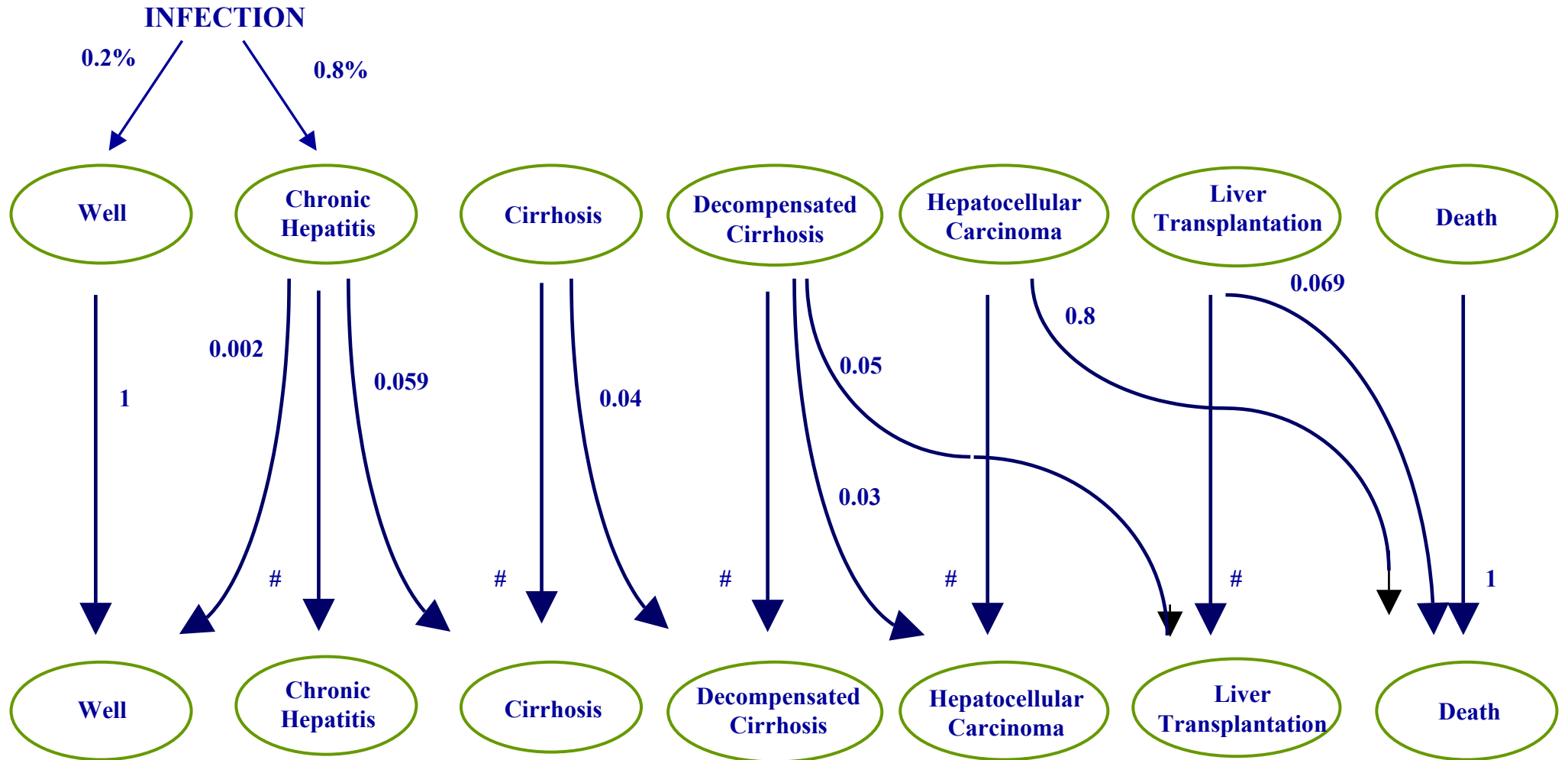
HYPOTHESIS (2) : Markov model



2 - To take into account long term consequences

• Model of natural HCV history = Markov

NATURAL HISTORY OF HCV DISEASE



HYPOTHESIS (2bis) : treatment option



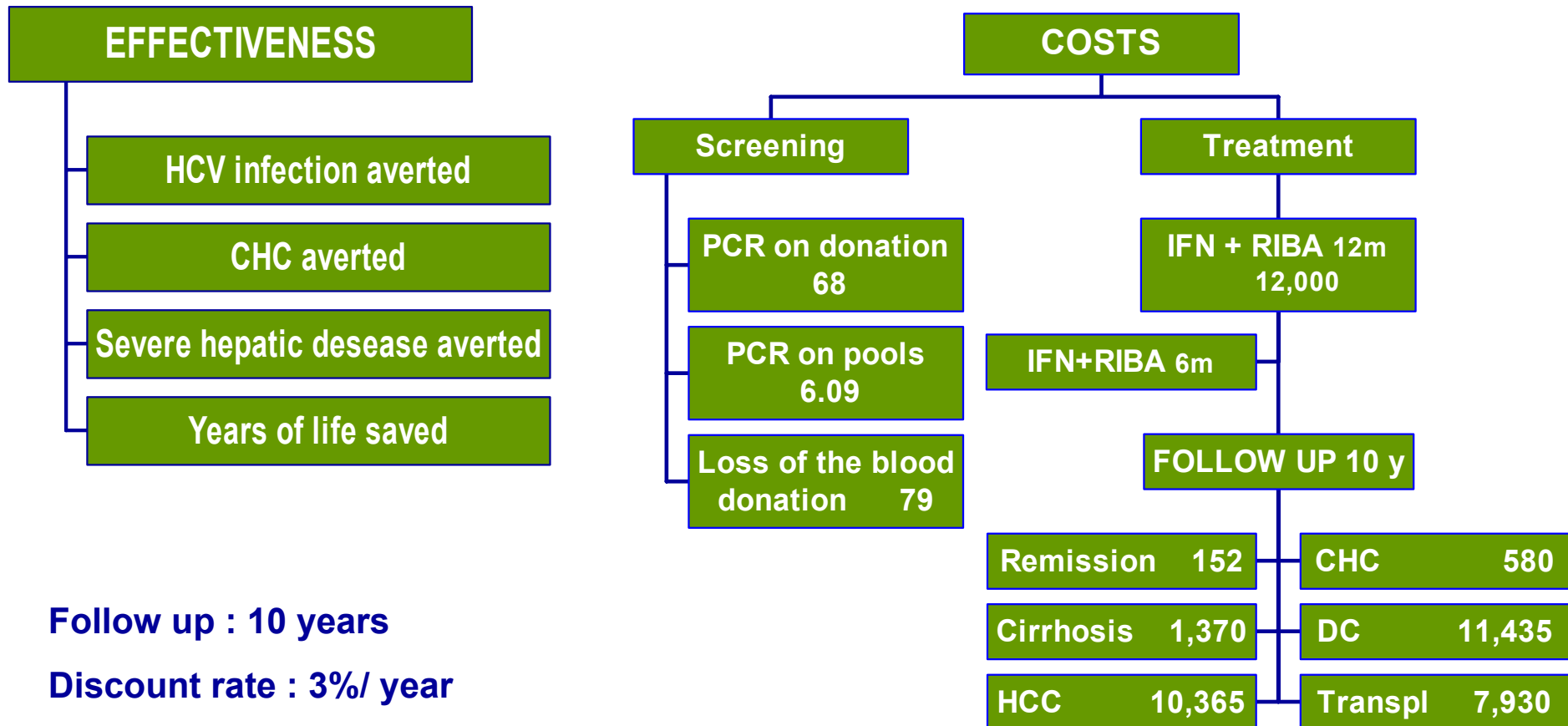
2 - To take into account long term consequences

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

HYPOTHESIS (3) : outcomes



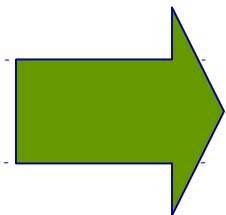
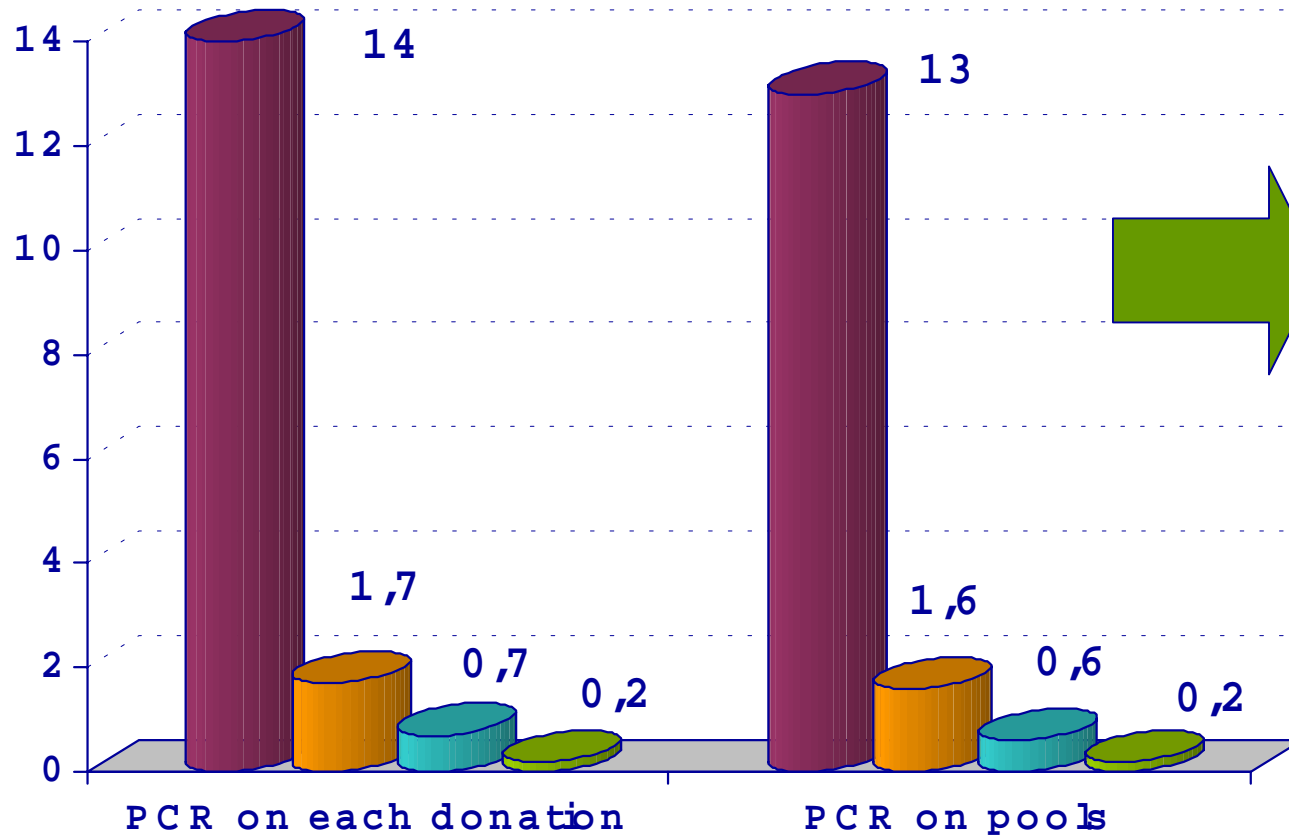
3 - Effectiveness and cost outcomes :



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

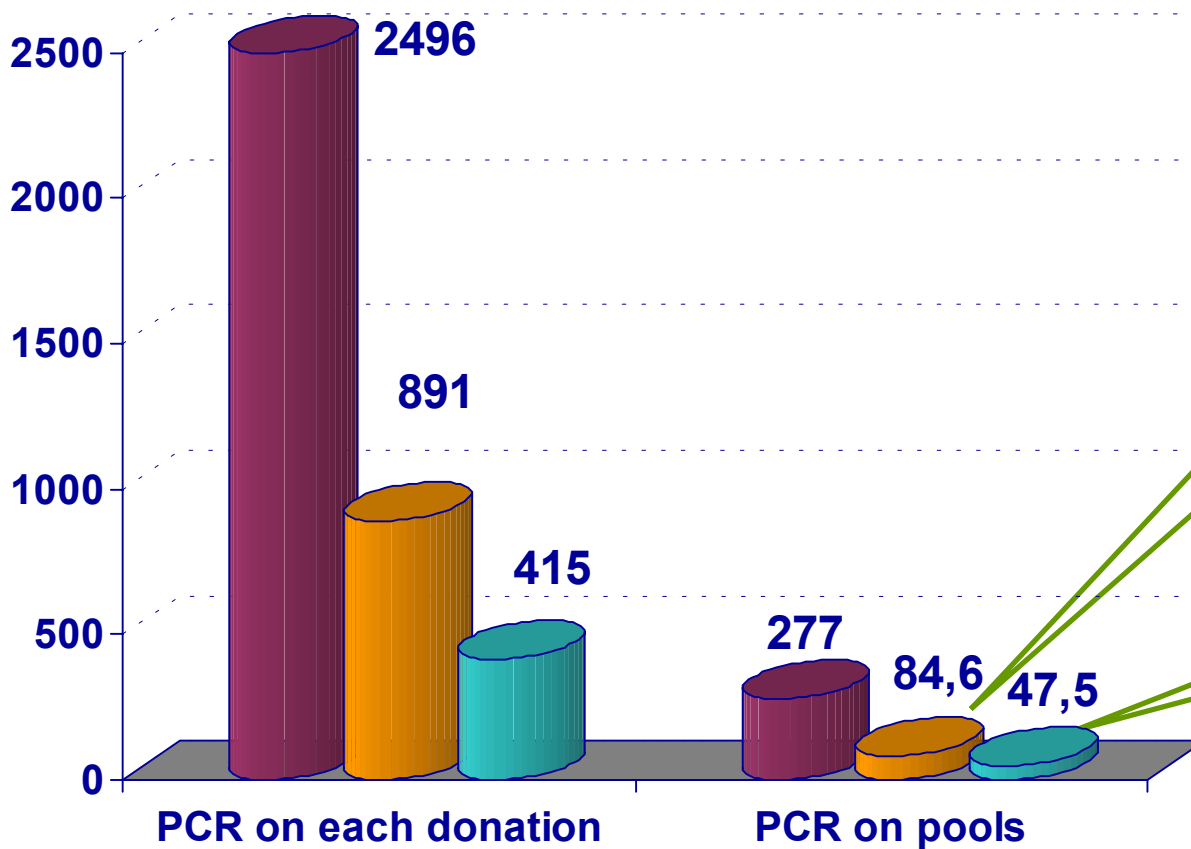


Study	Effectiveness	Total costs	Strategies	Incremental cost-effectiveness	
Loubière, Rotily, Durand- Zaleski, Costagliola	PCR on pools	< 1 life year saved	+ € 16.7 M	EIA + PCR on pools	€ 84.6 M
				High / low HCV residual risk	[€ 47.5 M – € 277 M]
Vox Sanguinis 2001 ;80 pp : 199-204	PCR on each donation	< 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
Discount rate		
Baseline (3%)		
5%	€ 891.1 M	€ 84.5 M
10%	€ 891.2 M	€ 84.6 M
Cost of treatment and follow up		
Baseline		
-50%	€ 891.3 M	€ 84.9 M
+50%	€ 890.7 M	€ 84.1 M
Cost of PCR test		
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)
Busch 1995	Blood donors	HCV (HBV)	ALT, EIA EIA, ALT	QALY	?	-\$87 900 \$ 7 931 000	
Vergnon 1996	Blood donors	HCV	ALT, HCV, HBV	True Positive	€ 5.8 M	€ 2,173	-
Sailly 1997	Blood donors	HBV HCV HIV HTLV	EIA + confirmation test	Seroconversion avoided	€ 38 M	-	€ 4,878 € 10,976 € 103,000 € 915,000
Djossou 1999	Blood donors	HIV	EIA + Ag p24	True Positive	€ 59 M	€ 1.5 M	-
Pereira 2000	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

ACKNOWLEDGEMENTS



Dr Dominique COSTAGLIOLA, INSERM SC4, Faculty of Medicine Saint-Antoine, Paris, France

Pr Isabelle DURAND-ZALESKI, Hospital Henri-Mondor, Créteil, France

Pr Jean-Paul MOATTI, INSERM U379, Marseilles, France

Dr Michel ROTILY, INSERM U379, Marseilles, France

The expert committee : Pr BRUN-VEZINET,

P Hervé, D Costagliola, F Barin,

H Agut, JP Cazenave, J Coste, C Defer, P De Micco, JC Desenclos, B Flan, JJ Lefrère, M Maniez-Montreuil, C Michon, JM Pawlotsky, C Rouzioux, M Schlotterer, P Bergeat, L Claquin, B Dazey, M Delpech, F Denis, I Durand-Zaleski, S Laperche, P Loiseau, P Marcellin, L Noel, M Rotily, R Salmi, D Vignon.

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.