

Screening of Hepatitis B and C amongst  
underprivileged people :  
a prevention initiative for guests  
accommodated at SONACOTRA residences  
in the Lyon area



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# Introduction

This initiative is part of an ongoing programme of prevention of hepatitis B and C amongst underprivileged people in the Lyon area undertaken since 1999 by ADHEC and its partners :

- LESP,
- Lyon CPAM and CES,
- HCV Reference Pole and City/Hospital Network,
- Associations

# Background

- The counter Exclusion Law (1998)
- LESP 1999, Lyon area, lack of awareness of HV B C
- Increased prevalence of hepatitis virus :
  - ADHEC 2003, Lyon area, Health centres  
Ac anti-HCV = 4,7%
  - INVS 2004 CES, CMU beneficiaries  
Ag Hbs = 2,1%      Ac anti-HCV = 2,65%
- Necessity to develop awareness, screening and healthcare to limit transmission.

# The Problem

- Organisation of hepatitis virus screening in France
- Little is offered within the structures of healthcare
- Offered in CES, but the most unfavoured are hardly reached, or not at all
- To enable access to screening of those at risk, intervening upstream of healthcare structures in recipient residences
- No evaluation of the operation of hepatitis virus prevention initiatives in residences accommodating these groups of people
- Awareness and encouragement for screening could increase the identification of those at risk, accessibility, acceptability, coverage and likewise optimise care of screened patients.

# Objectives of our initiative

- To compare and evaluate the effectiveness of two intervention strategies aimed at improving the screening of hepatitis virus B and C amongst guests accommodated at SONACOTRA residences in the Lyon area.
- To carry out a comparative operational and economic evaluation of screening and care of those screened according to each strategy adopted.

# Methods (1)

- « Here-and-elsewhere » prospective intervention with a pragmatic aim
- Screening integrated into a global healthcare approach : Periodical health examination proposed by CES and CPAM of Lyon
- Operational evaluation and comparison of the two strategies (S1 and S2) with reference to 'no intervention' (S0)

# Methods (2)

- Strategy 1 (minimalist intervention) :
  - information given collectively,
  - individual prevention consultation
  - **orientation** towards a CES for EPS and screening
  - Individual consultation for notification of results and medical care organised by CES doctors, in connection with their GP, or by default, the hepatitis virus Reference Pole in Lyon.
- Strategy 2 (maximalist intervention) :
  - information given collectively,
  - individual prevention consultation
  - **EPS and screening carried out in place** (« delocalised screening »)
  - Individual consultation for notification of results and « delocalised » medical care by the mobile team doctor, in connection with their GP or by default, the hepatitis virus Reference Pole in Lyon.

# Methods (3)

- **Success (S)** being defined by EPS and screening tests effectively being carried out, and by the medical care of those screened positive, the following could be estimated :
  - the **probability of success (S)** in the case of intervention (S1 or S2) and in the case of 'no intervention' (S0) and compared :
  - the **probability of success (S) of strategies S1 and S2**
- Multi centre study
  - 'No intervention' (S0) in 6 residences,
  - S1 strategy applied in 3 residences,
  - S2 strategy applied in 3 other residences.
- Cost evaluation by each screened case and by each case screened positive in each strategy, S1 and S2.

# Hypotheses to be tested

- Do strategies S1 and S2 encourage the achievement of EPS and screening of hepatitis virus as well as the care of those screened positive ?
- Is one of the strategies S1 or S2 more cost/efficient than the other ?

# Study Population

## ■ Target Population

Persons in vulnerable situations accommodated in SONACOTRA residences.

## ■ Study Population

Persons in vulnerable situations accommodated in SONACOTRA residences in the Lyon area.

## ■ Sample

Persons in vulnerable situations accommodated in 12 SONACOTRA residences in the Lyon agglomeration.

# Composition of the Sample Group

- Sampling : 2 stage survey
- **First stage** : stratification of the 37 residences in the Lyon area by distance from CES.
  - 10 situated more than 11 kms
  - 18 situated between 6 and 10 kms
  - 19 situated between 1 and 5 kms
- **Second stage** : stratification of the residences according to their capacity (<160 and >160 residents)
- **Randomisation** : random sampling by drawing lots in an establishment in each of the 6 strata and the application of S0 by drawing lots and of one of S1/S2 for those chosen.

# Randomisation

The totality of persons in vulnerable situations accommodated in these 12 residences will constitute the study sample

	> 11 km		6-10 km		1-5 km	
	< 160	> 160	< 160	> 160	< 160	> 160
<b>S0</b>	Residence 1	Residence 2	Residence 3	Residence 4	Residence 5	Residence 6
<b>S1</b>	Residence 7			Residence 8	Residence 9	
<b>S2</b>		Residence 10	Residence 11			Residence 12

# Sample Size (1)

- Results of the study « Parcours santé » at the ARES SONACOTRA Residence in Colombes (2002)
  - 42% of the guests accommodated at the residence participated in an information session held collectively
  - 38% of the guests asked for an individual medical consultation
  - 35% of the guests accepted EPS + screening (HV, HIV)
- Delocalised EPS at CES CPAM de Lyon (30% coverage)
- Average capacity of the 37 SONACOTRA residences in the Lyon agglomeration of 250 guests/residence. The number of study target subjects is therefore about 1,500. If it is assumed that 40% of the guests accept participation in the prevention initiative, the number of potential subjects able to be included in the study could therefore be about 600.

# Sample Size (2) : No of cases required

Intervention being defined as the proposition of carrying out EPS + screening, and success of the intervention being defined as effectively carrying out the tests and/or EPS :

- $p_0$ , being the expected probability of success in the case of strategy 2 (EPS and tests carried out in place),  $P [S/S_2] = 35\%$
- $p_1$ , being the expected probability of success in the case of strategy 1 (orientation for carrying out EPS and tests),  $P [S/S_2] = 20\%$
- $d$ , being the expected minimum difference between the 2 strategies ( $d=15\%$ )
- $\alpha = \beta = 0,05$  is applied identically in the 2 groups (S1 and S2)

The minimum number of subjects necessary by group, in an intervention which would allow the difference  $d$  to be demonstrated with the risk of the first type  $\alpha$  and the strength  $(1-\beta)$  which had been fixed beforehand, we are given by the following formula :—

$$\frac{2}{n} = 4 \frac{(\arcsin \sqrt{p_1} - \arcsin \sqrt{p_0})^2}{(\epsilon \alpha + \epsilon 2\beta)^2}, \text{ being } n = 230 \text{ subjects in each group}$$

# Study Organisation

## 3 partners

- **ADHEC** (preparation, organisation, coordination, data analysis)
- **CES** (EPS, screening, medical care, data analysis)
- **Hepatitis Reference Pole** (specialised care and treatment of those screened positive)

# Practical Execution of the Study (1)

- **Preparatory phase** of the initiative (3 months) in the 6 residence S1,S2
- **Intervention** announced by poster + personal invitation by mail.
- Overall duration of the programme : **18 months**

# Practical Execution of the Study(2)

## Information phase

Once per month in each of the residence (S1 and S2), CES team (doctor + nurse) :

- **Collective information** session (1H) followed by
- Proposal of **individual appointment**

# Practical Execution of the Study(3)

## EPS and Screening phase

### ■ S1 Strategy

- On issue of **information** (Day 1), **orientation** towards CES and made of appointment (Day 7 after info)
- Usual procedure for **carrying out** EPS + screening (Day 7)
- **Announcement consultation** +/- proposition of serology confirmation and test PCR (Day 14)
- **Consultation to announce confirmed results + PCR** and proposition of care at CES (Day 21)

### ■ S2 Strategy

- **Delocalised** EPS session + screening (Day 7 after info) at residence
- **Announcement consultation** +/- proposition of serology confirmation + test PCR (Day 14)
- **Consultation to announce confirmed results + PCR** and proposition of care (Day 21) at residence

# Practical Execution of the Study(4)

## Care of positive cases

If PCR positive, after informed consent of the patient, telephone contact with their GP for medical care (complementary check up). In absence of GP, patient directed to the hepatologist of the Reference Pole.

*Note : To short cut delays in obtaining an appointment and so to optimise access to care, the Reference Pole reserves time slots for consultations for these patients.*

**Strategy S1:** the physician of CES will organize the follow-up

**Strategy S2:** the physician of mobile team will organize the follow-up and *specialised delocalised consultations could be organised in place as necessary.*

# Study Inclusion

## ■ Inclusion criteria

- residing in one of the 12 sample residences
- $18 < \text{age} < 70$
- participated (S1,S2) in a collective meeting and given informed consent during the individual prevention consultation
- residing in one of the 6 residences (S1,S2), known seropositive not benefiting from medical care

## ■ Exclusion criteria

- residing in one of the 6 residences (S1,S2), known seropositive and benefiting from medical care (GP, private or hospital hepatologist)
- screening test within the last 3 months
- urgent care administered to the patient

■ Inclusion methods : each participant at a collective meeting, will be included in the study. The individual prevention consultation will constitute the inclusion visit (consent form and information notice) under reserve of the validity of the inclusion criteria.

# Nature and conditions of data acquisition (1)

- Socio-demographic and RF HV datas
- Orientation data towards CES (S1) or towards EPS + delocalised screening (S2)
- Data completion or not (+ results) EPS + proposed screening
- Complementary assessment data and medical healthcare of those patients screened positive
- For every guest, all data collected linked by the same anonymous code identifier
- All data collected to be stored and anonymised at CES before statistical processing

# Nature and conditions of data acquisition(2)

- Those refusing questionnaire response, participation in the collective meetings, individual consultations, orientation towards CES, carrying out EPS and/or CES or delocalised tests will be anonymised (code identifier)
- Refusals of patients screened positive, of carrying out confirmation tests and/or PCR and/or medical healthcare by the GP or Reference Pole hepatologist will be anonymised (code identifier)
- Data (CES questionnaire) concerning guests of the 6 residences where no intervention will be carried out (S0) will be collected by CES (identification via residence addresses).

# Intermediate data analysis after 3 months

- Treatment and analysis of data by ADHEC + Public Health Center of CES
- Evaluation of the feasibility of strategies S1 and S2
- Evaluation of results obtained : participation, accessibility and medical care of positive cases.
- Possible adaptation to the plan

# Final analysis

- Operational evaluation : feasibility, impact, effectiveness S1 and S2
- Economic evaluation : cost of each strategy per case screened, per case screened positive, per positive case cared for
- Comparison S1/S0, S2/S0, S1/S2
- Cross analysis
  - EPS and screening results with risk factors and vulnerability indicators
  - refusals with the characteristics of those concerned

# Management of potential bias (1)

## Minimisation of inclusion bias

The selection of patients, according to inclusion criteria, will be carried out by investigating doctors proposing EPS + tests. Systematic control of compliance of inclusion criteria will be carried out by CRA during the fortnightly electronic input of data in order to correct any inclusion errors arising.

# Management of potential bias(2)

## Minimisation of selection bias

- 1 – Management and evaluation of bias in the composition of the sample
- 2 – Management and evaluation of recruitment bias of subjects having participated in collective information sessions
- 3 – Management and evaluation of non response bias
- 4 – Management and evaluation of bias due to guests lost from sight

# Management of potential bias(3)

## Minimisation of measurement bias

1 – Management and evaluation of declaration bias

2 – Management of observation bias and bias related to measurement techniques

A fortnightly monitoring of all data will be carried out by ARC in connection with the CES Public Health Pole before electronic data input, in order to optimise the accuracy of the data, to verify the link between patient questionnaire and the EPS result and screening tests, and to minimise data handling errors.

# Research Schedule

**M1 to M3 : intervention preparation**

(CNIL, CPPRB, recruitment of residences, organisation of collective meetings, individual consultations, delocalised screening, specialised CS)

**M4 to M21 : Intervention** (data collection and input)

**M7 : Intermediate analyses and corrections arising**

**M22 to M24 : Analysis, validation, editing and distributing results**

# Planning of interventions in the residences

Week Residence(F) / Strategy (S)	1 IC + E1	2 EPS+Test	3 Announcement T +/- T Confirmation + PCR	4 Announcement T Confirmation + PCR + PEC	5 EPS+TEST
F1/S2	Mo am	Mo am	Mo am	Mo am IC + EI	Mo am
F2/S2	Th am	Th am	Th am	Th am IC + EI	Th am
F3/S2	We am	We am	We am	We am IC + EI	We am
F4/S1	Mo pm			Mo pm IC + EI	
F5/S1	Th pm			Th pm IC + EI	
F6/S1	We pm			We pm IC + EI	