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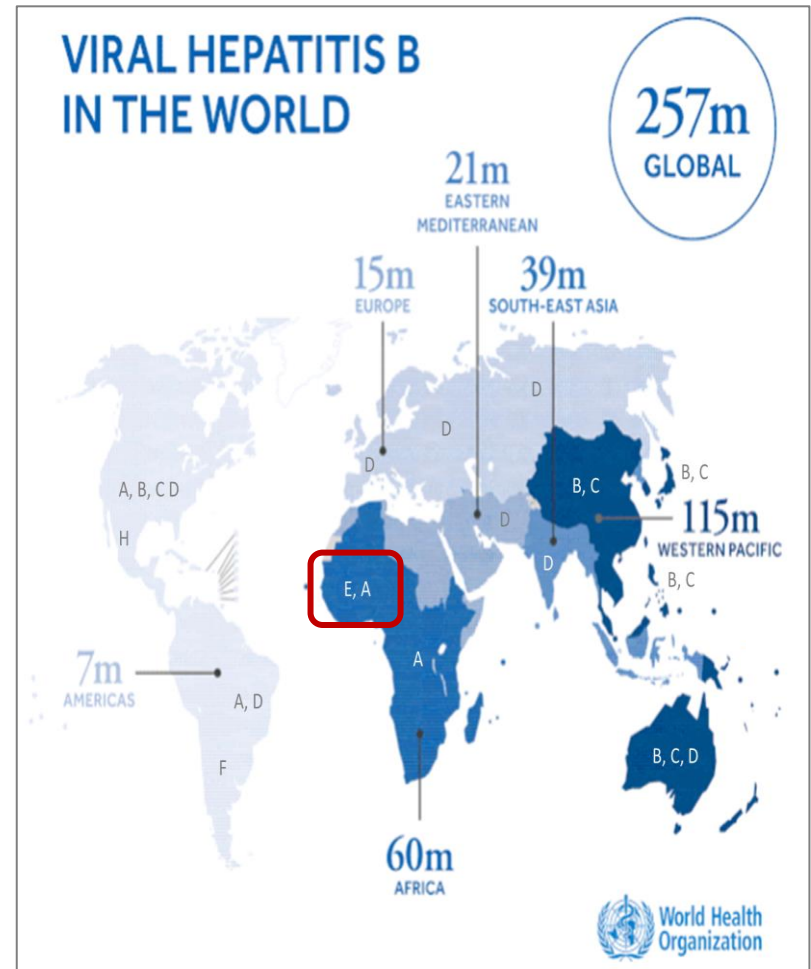


Prevention of HEpatitis B related
Liver CANcer

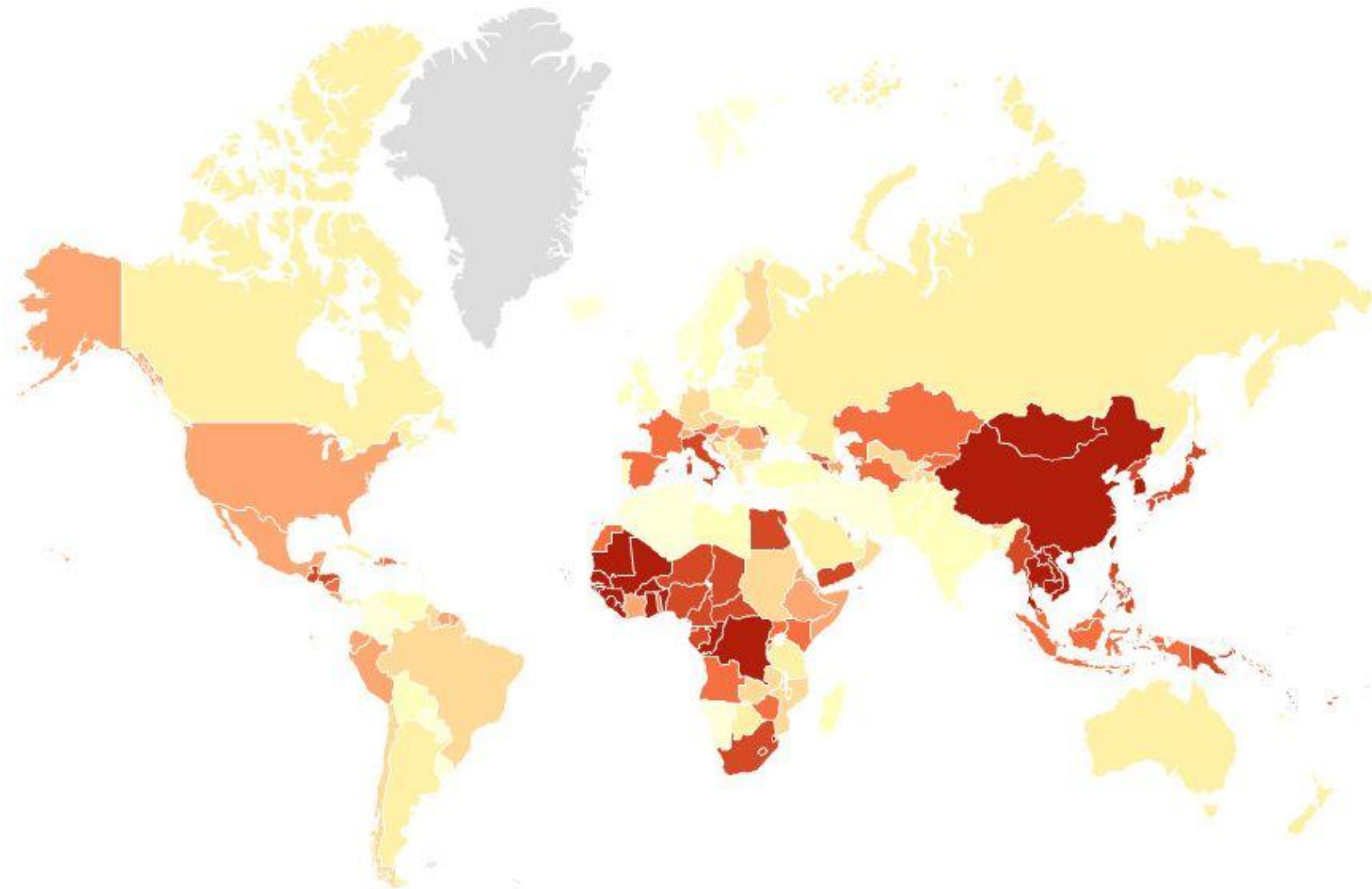
Epidemiology of Viral Hepatitis B

Viral Hepatitis B | In brief

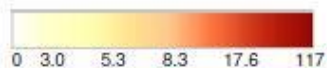
- ❑ 257 million people (3.5% of the population) with chronic HBV infection
- ❑ Chronic HBV infection results in > 1 million deaths/year from cirrhosis and liver cancer
- ❑ Prophylactic vaccine but no universal cover
- ❑ Antiviral therapies to slow down progression but no cure and not available for the majority of Chronic carriers
- ❑ 10 genotypes (A to J) based on genome sequence divergence (>8%) which determine disease progression



Hepatocellularcarcinoma-More than 50% due to HBV



HCC incidence in men per 100 000, 2008 (*GLOBOCAN 2008, CIRC*)

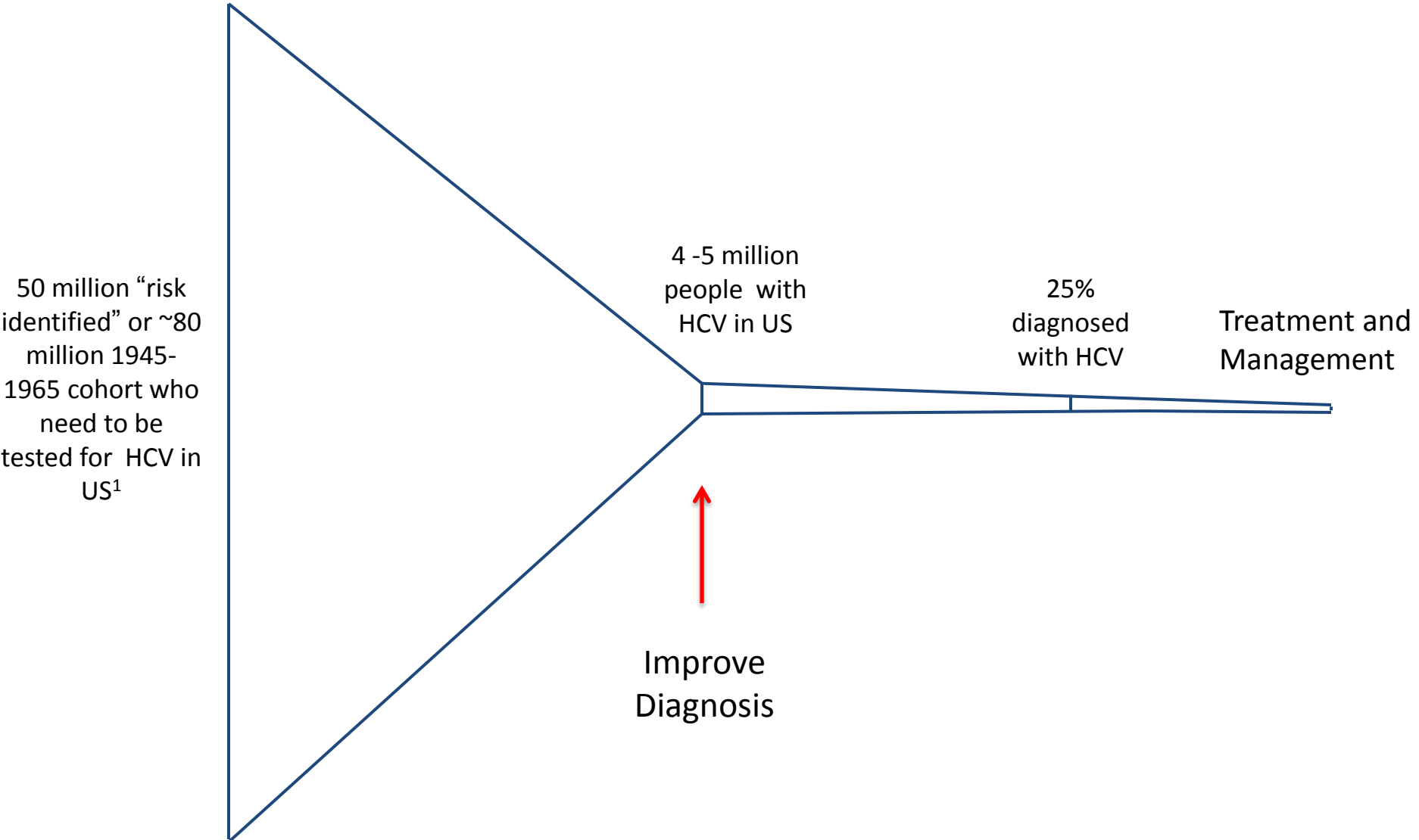


PHELICAN Partners



- Lyon 2 University – Lead? M Préau
- INSERM U1052, Lyon, France
- International Agency for Research on Cancer (?)
Prevention section
- MRC Laboratories, Fajara, Gambia (?)
- Ministry of Health, Banjul, Gambia
- Le Dantec Hospital, Dakar, Senegal
- Pasteur Institute Morocco?
- European countries eligible as LMC?
- CHU Lyon, Limoges, France?

Efficient Identification of Patients with HCV



¹Tomaszewski Am J Public Health 2012; 102 (11):e101⁵

Research Agenda



- Two research Cohorts
 - Hepatocellular Carcinoma Case Control study (HC₃)
 - HEP B patient Cohort (HEPBC)
- SHS Approaches
 - Lyon 2, CRCL
 - Prevention service? – IARC
 - Virology - Inserm

HEPBC: Hepatitis B Chronic Carriers and clinical setting



- Primary Objective

Determine/Compare who and where are
Chronic HBV carriers in Several countries
And Compare the clinical setting to promote
improvements



HEPBC STUDY:



- Sample SIZE ? Different countries???
- To be evaluated



Hepatocellular Carcinoma Case- Control Study – HC₃



- Objectives
 - To develop a research platform for scientific studies of hepatitis B virus (HBV) viral genetics of HCC and promote treatment (Curative or Paliative)

HC₃ - Design



- **Study design**

- Hospital-based case-control study of incident HCC patients and two sets of control participants matched on age and sex. One set of controls will be HBV infected without HCC and one set will be uninfected healthy controls.

- **Study duration**

- Recruitment of study subjects will take place over a period of 2 years.

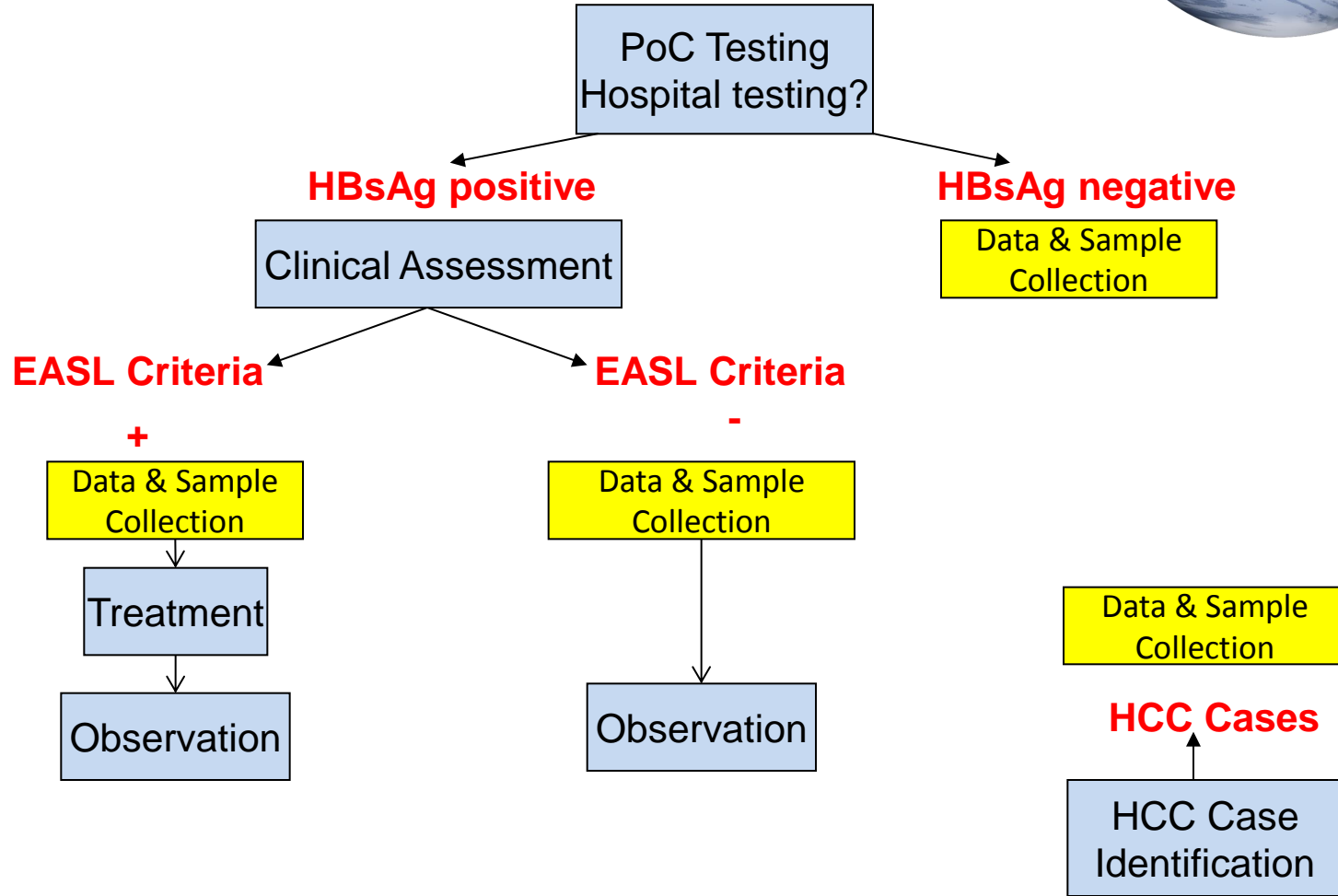
HC₃ Investigations



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- Standardized structured interview to assess socio-demographic, lifestyle and dietary exposures
- Clinical examination & Nutritional assessment (skinfold thickness)
- HBV serology & HBV DNA
- HCV serology
- Voluntary counselling and testing (VCT) followed by HIV serology*
- Liver function tests (LFTs)
- Complete blood count (CBC)
- Clotting studies
- Alfa-fetoprotein (AFP)
- HbA1c
- Liver ultrasound (US)
- Serum / plasma sample for viral sequence and genotype analysis
- Serum / plasma and urine samples for biomarkers of cancer development (annually)
- Serum for aflatoxin adducts
- EDTA blood sample for human genetic analysis

HEPBC



Political / Public Health Agenda



- Programmatic development for HBV in Several countries
 - Feasibility analysis
 - Identification of patients
 - Modelling impact of treatment on burden of disease
- Integration of HBV with HIV services ?
- Lobbying global fund / GAVI for reductions in drug costs

Training Agenda



- Research training of doctors in France
- Research training of French doctors in XXX?
- Clinical training of doctors in France

Is it good to include?

HEPBC STUDY - Endpoints



- **Primary:** Identify HBV patients in several countries/
- Hospitals to identify/improve clinical setting caveats
- **Secondary:**
 - Proportion of adult population with chronic HBV infection and the “targeted populations”
 - Incidence of Hepatocellular Carcinoma over the period of study in a treated cohort of patients with chronic HBV
 - Number of patients with chronic HBV infection who meet EASL treatment criteria and the proportion really treated
 - Proportion of patients with undetectable HBV DNA < 400 copies/ml at 1, 2, 3, 4 and 5 years of treatment.
 - Incidence of hepatocellular Carcinoma in patients who do not meet EASL treatment criteria.
 - Treatment adherence rate.
 - Average change in Fibroscan score after 3 years