

Development and implementation of an hepatitis D detection and linkage to care program in Catalonia. Preliminary results.

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Introduction and Aim

- Hepatitis D virus (HDV) infection still remains underdiagnosed, although most international guidelines recommend anti-HDV testing in all HBsAg-positive individuals.
- In Spain, HBsAg estimated prevalence is 0.22%, with 7.7% of anti-HDV+.¹
- This project aims to develop and implement an hepatitis D detection program for all HBsAg-positive samples that are collected in public healthcare centers of Catalonia (>95% population coverage).

Study Design

- Prospective study conducted in 2024 including 7 laboratories of the Catalan Health Institute. Anti-HDV reflex testing was performed in every non-duplicated HBsAg+ sample collected at the public health center's laboratories.
- Anti-HDV positive results were **highlighted** creating an alert system in medical records, and a sample was sent to Vall d'Hebron University Hospital for reflex HDV-RNA quantification (Fig 1).
- HDV-RNA was quantified using an in-house qRT-PCR with an automated standardized test.
- Medical records of anti-HDV positive patients were reviewed and **registered** in a digital platform (demographics, epidemiology, clinical data, lab data, and linkage to care status).
- **Linkage to care** was ensured for all HDV-RNA positive individuals.

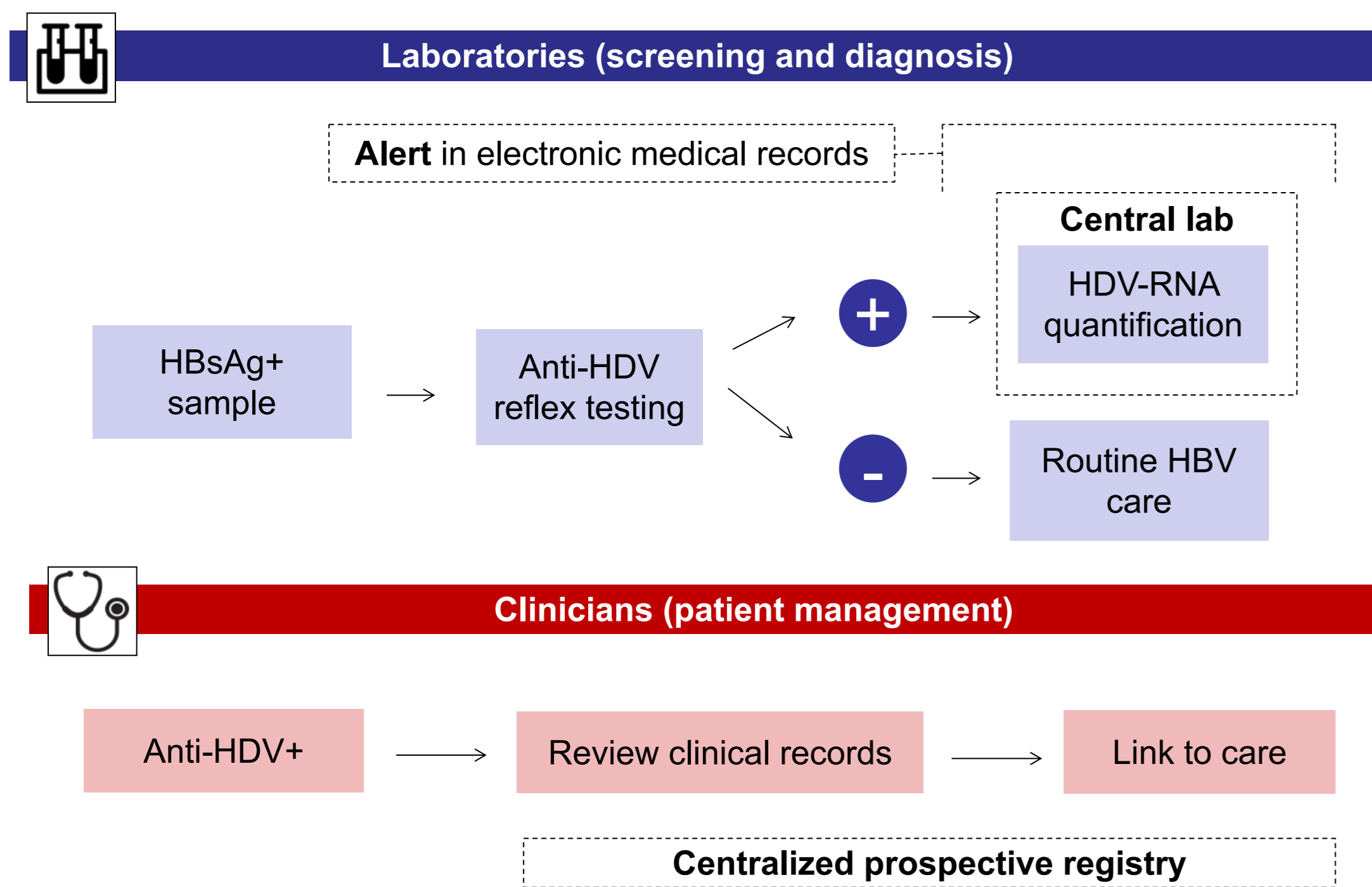


Fig 1. Laboratories and clinicians circuit from HBsAg+ sample receipt to linkage to care.

Conclusions

- The development and implementation of a regional hepatitis D program has proven to be feasible and has a wide acceptance amongst all healthcare providers, and is still ongoing.
- As a result of the program, 89% of HBsAg+ samples collected at the Catalan Health Institute laboratories were tested for anti-HDV, almost half of them being performed for the first time.
- Our preliminary results show that hepatitis D detection programs linked to the general healthcare system are crucial for optimal diagnosis and linkage to care of these patients.

Results

- From January to August of 2024, HBsAg was tested in 180,451 samples and 4,337 (2.4%) were HBsAg+.
- Anti-HDV was tested in 3,858 (89%), a total of 164 (4.3%) were anti-HDV positive, and 108 (65%) were HDV-RNA positive (Fig 2).
- As a result of the program, 1,840 (42%) anti-HDV determinations were tested for the first time.

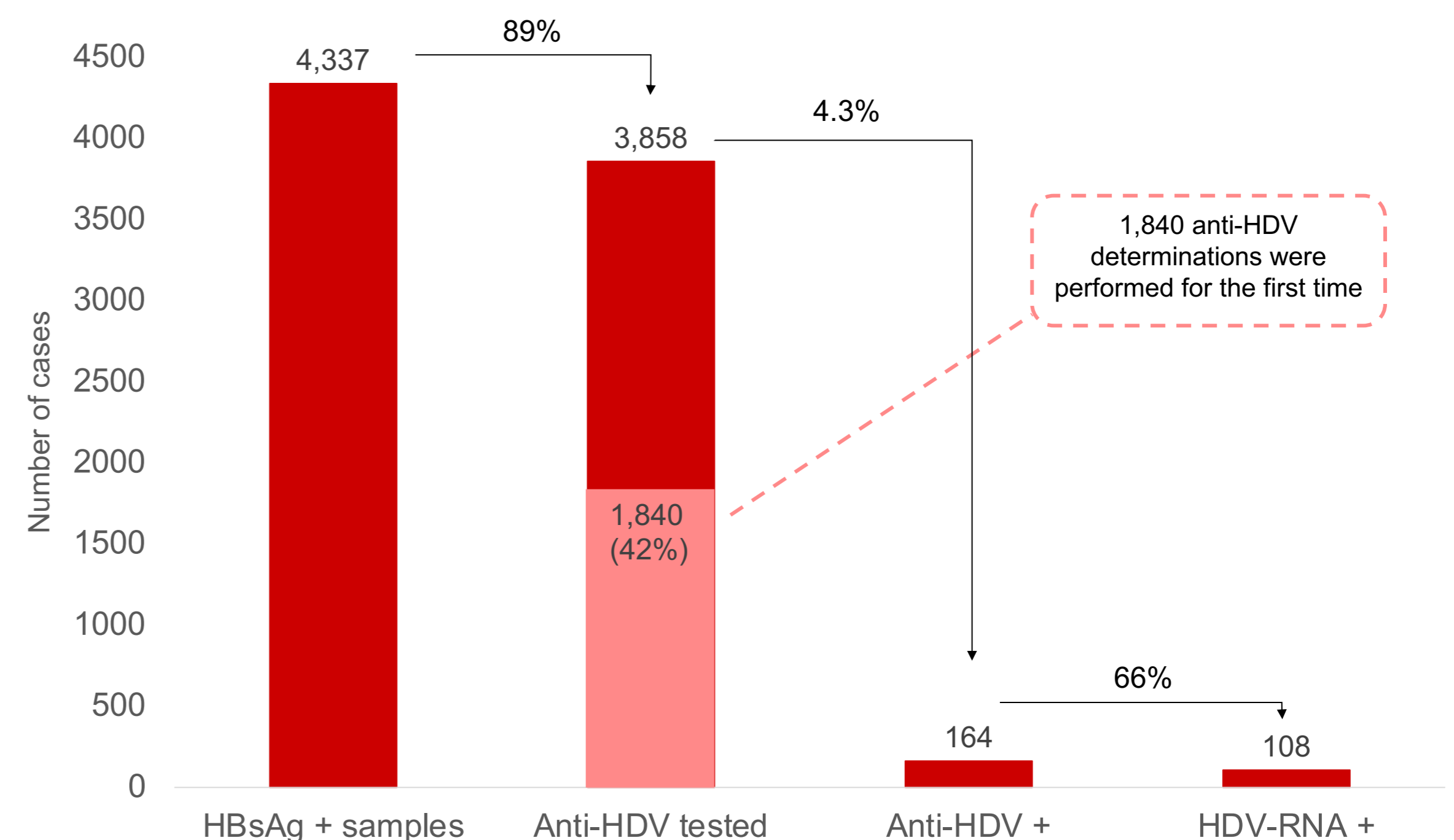


Fig 2. Cascade of samples tested on the program.

- Clinical data -available today- was collected in 113 anti-HDV+ subjects.

	Total anti-HDV+ (N=113)	Previous anti-HDV+ (N=91)	New anti-HDV+ (N=22)	p-value
Age, md (IQR)	52 (42-58)	53 (43-58)	46 (36-59)	0.119
Male, n (%)	76 (67%)	62 (68%)	14 (64%)	0.800
Ethnicity, n (%)				
Caucasian	78 (69%)	66 (73%)	12 (55%)	0.125
African	24 (21%)	17 (19%)	7 (32%)	0.243
Risk factors, n (%)				
Parenteral	44 (39%)	41 (45%)	3 (14%)	0.007
PWID	21 (19%)	19 (21%)	2 (9%)	0.358
Sexual	15 (13%)	13 (14%)	2 (9%)	0.731
Transfusion <1975	7 (6%)	6 (7%)	1 (5%)	0.999
4 (4%)	4 (4%)	0 (0%)	0.999	
HCV co-infected, n(%)	23 (20%)	20 (22%)	3 (14%)	0.557
HIV co-infected, n(%)	18 (16%)	12 (13%)	6 (27%)	0.115
ALT, md (IQR)	38 (21-68)	38 (21-69)	37 (22-72)	0.506
Detectable HDV-RNA, n(%)	50 (44%)	42 (46%)	8 (36%)	0.478
Liver cirrhosis, n(%)*	37 (33%)	31 (34%)	6 (27%)	0.620
Liver decompensation, n(%)**	8 (7%)	7 (8%)	1 (5%)	0.999
HCC, n(%)	4 (4%)	3 (3%)	1 (5%)	0.999

*assessed by transient elastography or ultrasound; **ascites, variceal bleeding or hepatic encephalopathy

- All patients who tested positive for HDV-RNA were contacted and scheduled with a referral hepatologist.