Standard Operating Procedure

UMC, Spain

Field	Details
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Project Title:	Mobile Hepatitis Outreach and Prevention Effort
Project Acronym:	MOBHOPE
Project Website:	https://mobhope.eu/
Call:	EU4H-2024-PJ-03
Topic:	EU4H-2024-PJ-03-2-c
Beneficiaries:	Ares do Pinhal – Associacão de Recuperacão de Toxicodependentes (Portugal); Hrvatsko društvo za bolesti jetre – Hepatos (Croatia), Fundación para la Investigación Biomédica del Hospital Gregorio Marañón (Spain); Unidad Móvil de Cribados – Madrid Positivo (Spain)
Starting Date:	November 1st, 2025
Project Duration:	36 months
Work Package:	WP1 – Communication and Health Promotion for Viral Hepatitis Prevention
Task:	T1.7 – Implement Screening Protocols
Deliverable:	D1.3 – Screening & Referral Protocols
Due Date:	October 31st, 2026
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Version	Date	Author	Main changes
v1.0	30/04/2026	Antonio Martin	Initial Draft
v1.5	09/07/2026	Antonio Martin	Refinement for Mobile Unit Check
v2.0	25/10/2026	Pablo Ryan Murúa	Operational revisions based on Madrid UMC field practice; consent, diagnostics, TAS, REDCap and EU4Health alignment (review draft).
v2.0	26/10/2026	Steering Committee	Refinement for Mobile Unit Check

List of Abbreviations

AdP	Ares do Pinhal (Portugal)
TAS	Patient accompaniment and navigation service (UMC)
UMC	Unidad Móvil de Cribado, operated by Madrid Positivo (Spain)
HBV / HCV	Hepatitis B / C Virus
HCC	Hepatocellular Carcinoma
HIV	Human Immunodeficiency Virus
MASLD	Metabolic Dysfunction-Associated Steatotic Liver Disease
PCR	Polymerase chain reaction
HCV RNA	Hepatitis C virus RNA
IFU	Manufacturer instructions for use
CEIm	Research Ethics Committee for medicinal products
PoC	Point-of-care
REDCap	Research Electronic Data Capture (identifiable local dataset)
SOP	Standard Operating Procedure
TAS navigator	UMC peer/navigator providing accompaniment and follow-up
WP	Work Package
GDPR	General Data Protection Regulation

1. Purpose and Scope

This SOP specifies how the Unidad Móvil de Cribado (UMC), operated by Asociación Madrid Positivo, plans, performs and documents its community outreach, integrated screening, liver assessment, hospital referral and TAS patient navigation activities in the MOBHOPE project (EU4Health, Grant Agreement 101233203). It applies to outreach personnel and hospital-based medical advisers and complements the approved participant information and consent form.

- Uniform, safe, and consortium-compliant service delivery.
- Clear traceability between field activities and MOBHOPE Work Packages (WP1–WP5), Deliverables, and Key Performance Indicators (KPIs).
- Integration of operational research activities within routine clinical care without disrupting low-threshold access for vulnerable populations.
- Compliance with GDPR, ICH-GCP, the Declaration of Helsinki, and national ethical regulations.

The routine field team comprises one nurse, one health educator and one patient navigator/peer. Dr Jorge Valencia and Dr Pablo Ryan, hospital-based specialists in infectious diseases/internal medicine, provide clinical advice, interpretative support and escalation of clinical and diagnostic incidents. The educator and navigator proactively recruit participants; the nurse performs healthcare procedures within professional competence.

The UMC normally operates 09:00–15:00, with flexible afternoon or evening deployment when indicated, and typically attends about 15–20 people per outreach day. Visits cover streets, squares, areas where people use drugs, shelters, migrant centres, addiction services and other community settings; The short Spanish SOP is a companion field guide; this English document remains the full procedure.

2. Normative and Documentary References

This UMC SOP is read with the following applicable legal, ethical, technical and consortium documents:

1. MOBHOPE Grant Agreement 101233203 and its legally effective Description of the Action (DoA); DoA V12 (October 2026) remains a proposed amendment unless formally approved.
2. World Medical Association Declaration of Helsinki (2024 revision), insofar as the approved research component is concerned; favourable CEIm HGUGM opinion for MOBHOPE-RESEARCH (9 September 2026).
3. Regulation (EU) 2016/679 (GDPR), Spanish Organic Law 3/2018 (LOPDGDD), Law 41/2002 on patient information and autonomy, Law 14/2007 on biomedical research and relevant public-health reporting requirements.
4. Regulation (EU) 2017/746 on in vitro diagnostic medical devices and Spanish Royal Decree 942/2025 on in vitro diagnostic devices, including appropriate qualifications and use in line with manufacturer instructions.
5. UMC Madrid Participant Information and Informed Consent v2, dated 25 August 2026, as accepted in the favourable CEIm opinion, and any formally approved subsequent amendments.

6. MOBHOPE Data Management Plan v2.0 (22 October 2026); distinguish identifiable UMC clinical records from data authorised for optional project sharing.
7. MOBHOPE Dissemination, Exploitation and Communication Plan (DECP), version 2.0; use the approved EU4Health communication materials and funding acknowledgement.
8. MOBHOPE Research Methodology Framework and Screening & Referral Protocols (D1.3), as approved and applicable to the mobile-service setting.
9. Current instructions for use (IFU) of each rapid test, Cepheid Xpert HCV assay and Echosens FibroScan system; apply the precise specimen, operating, quality-control and maintenance requirements for the devices in service.

3. Responsibilities

Role*	Responsibilities
Outreach coordination / site planning	Map municipalities and hotspots from institutional, NGO and community sources; contact local providers, obtain required permissions and agree the visit itinerary and hospital referral pathway before deployment.
Nurse (on-site healthcare lead)	Perform HIV/HBV/HCV/syphilis rapid tests, indicated GeneXpert HCV RNA confirmation and FibroScan assessments if trained; explain results; provide clinical counselling; ensure biosafety and report diagnostic/clinical incidents to the medical advisers.
Health educator	Approach users proactively, build trust, explain tests and prevention, distribute condoms and MOBHOPE educational infographics and help with consent and practical access barriers.
Patient navigator / peer (TAS)	Recruit proactively; contact the receiving hospital; offer transport in the satellite car; accompany the person through appointment and pharmacy where required; identify administrative/social barriers and verify subsequent visits and adherence.
Hospital medical advisers	Dr Jorge Valencia and Dr Pablo Ryan (infectious diseases/internal medicine): advise on infectious diseases, test interpretation, complex referrals and clinical/diagnostic incidents; liaise with hospital services as required.
Driver / satellite-car support	Arrange safe travel and vehicle operation; where assigned, support the navigator’s transport, transfer and accompaniment duties.
UMC REDCap authorised staff	Capture the local UMC visit record and results at the point of care; use authorised individual access; ensure accurate identifiable-data handling and data quality.
Project coordination / MOBHOPE	Coordinate agreed project reporting, training and deliverables without replacing the UMC clinical chain of responsibility or the local controller of identifiable records.

Role allocation may vary between visits, but only authorised and appropriately trained healthcare personnel perform clinical procedures. On-site staffing and hospital clinical advice must remain clearly distinguished.

4. Process Overview

The UMC operates through five phases (0–4). Site selection is data-driven: the team maps underserved areas using institutional, NGO and community intelligence, and uses observed vulnerability and test positivity to prioritise repeat outreach.

PHASE 0 – PREPARATION (prior to the visit)

#	Activity / Step	Responsible
0.1	Map target locations: Map the Madrid region and municipalities using information from NGOs, public bodies and communities to identify vulnerable populations and high-priority hotspots.	Outreach coordination / educator / navigator
0.2	Coordinate permissions and referrals: Plan visits with local NGOs and institutions, obtain permits for streets and centres, and contact the nearest reference hospital in advance for possible referral.	Outreach coordination / TAS navigator
0.3	**Check clinical and prevention supplies: Verify expiry, conditions and stock for four rapid tests (HIV, HBV, HCV, syphilis), GeneXpert cartridges, consent forms, condoms, educational leaflets, PPE and sharps/waste supplies; record lots.**	Nurse / educator
0.4	**Check equipment and availability: Verify GeneXpert, FibroScan, appropriate probe, sample supplies, secure REDCap access, battery/power and the satellite referral car. Perform the checks required by the current manufacturer IFUs.**	Nurse / TAS navigator
0.5	**Prepare documents and forms: Use the current approved UMC information sheet and written consent, REDCap local record and optional stigma survey under its separate protocol; prepare paper contingencies only if authorised.**	Educator / nurse / authorised REDCap users
0.6	**Prepare health-promotion materials: Pack MOBHOPE leaflets/infographics and condoms with compliant EU visibility information.**	Educator / navigator
0.7	**Assess site-specific safety: Review planned location, local hazards, permissions, access and privacy arrangements.**	Outreach coordination / team
0.8	**Brief the team and receiving services: Agree staff roles, likely barriers, referral destinations, ongoing follow-up and availability of Fast Track at HUIL if the person has no accessible reference hospital.**	Nurse / educator / navigator; hospital advisers if needed
0.9	**Deploy both vehicles: Deploy UMC and satellite car, normally 09:00–15:00; alternative afternoon/night sessions are possible according to access needs and agreements.**	Team / designated driver

PHASE 1 – ARRIVAL AND PARTICIPANT RECRUITMENT

#	Activity / Step	Responsible
1.1	**Site safety and permission check:** Confirm the agreed permitted site, privacy and suitability; adjust the position or contact local partners if unsafe.	Team

1.2	**Set up UMC and satellite car:** Park safely, set up a private counselling/testing area and ensure satellite car access for patient transfers to hospitals.	Team
1.3	**Start clinical and data systems:** Check safe working surfaces, RDT supplies, GeneXpert, FibroScan where indicated and HEALTH4OL-hosted UMC REDCap access.	Nurse / authorised staff
1.4	**Proactive recruitment:** Educator and navigator approach people in the surrounding community without coercion; explain screening, prevention and optional accompaniment.	Educator / navigator
1.5	**Distribute materials:** Offer MOBHOPE information on viral hepatitis, HIV and STI prevention, plus condoms.	Educator / navigator
1.6	**Explain available care:** Explain that services are voluntary, confidential and free of charge, and that referral and TAS accompaniment can be offered.	Educator / nurse / navigator
1.7	**Explain the approved information sheet:** Discuss the tests, sampling, FibroScan if indicated, identifiable REDCap data and use of clinical information; allow questions and choices.	Educator / nurse
1.8	**Explain optional MOBHOPE research:** Discuss distinct optional research questionnaires and coded-data sharing exactly as worded in the approved consent; declining these does not affect care.	Nurse / educator
1.9	**Obtain written informed consent:** Ensure the adult user signs the current approved UMC form before testing; record each consent choice; do not substitute an unapproved verbal consent process.	Nurse / educator
1.10	**Create UMC record:** Assign the UMC record code; the REDCap field nom may also contain the name under approved local procedures. Records are identifiable clinical data.	Authorised UMC staff

PHASE 2 – CLINICAL CARE AND RESEARCH ACTIVITIES

#	Activity / Step	Responsible
2.1	**Clinical/social assessment:** Collect brief clinical history, risk factors, social determinants, alcohol-use history, vulnerabilities and barriers; document contemporaneously.	Nurse with educator/navigator support
2.2	**Rapid tests: HIV, HBV, HCV, syphilis:** With signed consent, select authorised kits; check kit identity/lot/expiry and QC; collect only the specimen permitted by its IFU, add reagents as instructed and read during the prescribed window. Record reactive, non-reactive or invalid results; repeat invalid tests per IFU.	Nurse
2.3	**Record UMC encounter data:** Record sociodemographic, vulnerability, test and referral fields in the association-owned HEALTH4OL-hosted UMC REDCap during the visit. This is identifiable clinical data; optional MOBHOPE questionnaires require the relevant approval and consent.	Authorised UMC staff
2.4	**FibroScan according to Echosens:** Offer to users with reactive HBV/HCV tests or relevant alcohol-use history. Trained operator checks ≥3-hour fasting when practicable, positions participant supine with right arm raised,	Trained nurse / medical advice if needed

	uses indicated probe, obtains adequate valid measurements and records median liver stiffness in kPa and quality criteria. A value >14 kPa prompts specialist referral; it is not a standalone diagnosis of cirrhosis.	
2.5	**Confidential result communication:** Explain non-reactive, reactive and invalid tests in private, including window-period limitations. A reactive screen is not necessarily confirmed infection; offer HCV RNA PCR after reactive anti-HCV and appropriate hospital confirmation for other reactive markers.	Nurse
2.6	**Targeted prevention counselling:** Provide understandable information on HIV, viral hepatitis, syphilis, sexual health and harm reduction, using non-stigmatising language.	Nurse / educator
2.7	**Condoms and educational supplies:** Provide condoms and approved MOBHOPE infographics.	Educator / navigator
2.8	**GeneXpert HCV RNA confirmation:** Offer on-site molecular HCV confirmation following reactive anti-HCV; use only the actual validated Cepheid assay and its approved specimen, cartridge, collection volume and operating instructions. Check controls; an invalid/error/no-result result must not be reported as negative and is managed per the assay IFU.	Trained nurse
2.9	**Additional health education:** Discuss test results, prevention and access to care as appropriate; offer advice without turning the visit into a research interview.	Nurse / educator
2.10	**Dignity and stigma prevention:** Use respectful, confidential, culturally appropriate language; offer approved stigma information and optional surveys according to the separate research protocol.	Entire team
2.11	**Link to social/administrative resources:** Navigator identifies lack of documentation, health coverage, language, housing, transport or appointment barriers and contacts social workers or institutions as needed.	TAS navigator / educator
2.12	**Agree follow-up and contact arrangements:** With participant agreement and appropriate privacy safeguards, keep contact details and linked UMC identifier needed for appointments, adherence and follow-up.	Navigator / authorised UMC staff

RDT procedure: The trained nurse verifies the correct manufacturer IFU, expiry and lot, controls and permissible specimen; collects the specified sample, follows the timing/reagent steps, reads within the stated window and records valid, reactive or invalid results. A reactive screening test is not automatically a definitive diagnosis.

GeneXpert HCV: After reactive anti-HCV, offer RNA confirmation in the UMC. The trained nurse uses the exact Cepheid cartridge and its validated fingerstick/blood/plasma specimen (as applicable), follows the instrument prompts, checks on-board controls and repeats unresolved errors/invalids as specified by that product IFU; do not substitute one assay's specimen instructions for another.

Echosens FibroScan: Confirm fasting for at least 3 hours when possible; a trained operator performs a supine intercostal measurement with the right arm raised and appropriate probe, collects sufficient valid readings according to the device and reviews quality (including IQR/median where provided). Record stiffness (kPa); >14 kPa is the UMC operational referral threshold, not a definitive cirrhosis diagnosis.

PHASE 3 – REFERRAL AND LINKAGE TO CARE

#	Activity / Step	Responsible
3.1	**Clinical referral triggers:** Offer referral after reactive HIV/HBV/syphilis screening, detectable HCV RNA, other clinically concerning reactive/positive findings or FibroScan >14 kPa. Discuss urgency and confirmatory testing with hospital advisers as required.	Nurse / hospital medical advisers
3.2	**Choose receiving service:** Contact the user's reference hospital (infectious diseases/hepatology); if there is no accessible reference pathway, offer Hospital Universitario Infanta Leonor Fast Track. Coordinate with receiving staff before transfer.	TAS navigator / hospital advisers
3.3	**Offer TAS escorted referral:** Offer transport in the satellite car. TAS educator/navigator accompanies the user to hospital, through the consultation where permitted and requested, and onward to hospital pharmacy when needed.	TAS navigator / educator
3.4	**Record and verify care cascade:** Record date/destination, acceptance, appointment, attendance and follow-up if known; contact the user to verify tests, clinic/pharmacy appointments and treatment adherence without claiming undocumented completion.	Navigator / authorised UMC staff
3.5	**Support diagnosis and treatment:** Liaise with specialists about confirmatory laboratory tests and indicated therapy; support ongoing contact and adherence after initiation.	Navigator / nurse / hospital advisers
3.6	**Address access barriers:** Assess administrative eligibility, language, transport, housing and trust barriers; coordinate social-work support and facilitators and avoid dropping a referral solely because of such barriers.	TAS navigator / educator

PHASE 4 – VISIT CLOSURE AND DOCUMENTATION

#	Activity / Step	Responsible
4.1	**Reconcile encounters and referrals:** Check that recorded encounters, tests, GeneXpert results, FibroScan examinations and ongoing hospital pathways match the day's activity.	Nurse / authorised REDCap staff
4.2	**Finish UMC REDCap recording:** Complete locally collected demographic, vulnerability, clinical and linkage fields at the time of care or as soon as operationally possible; verify accuracy and safe access.	Authorised UMC staff
4.3	**Record information delivered:** Record service locations, educational materials, condoms offered and care referrals where relevant.	Educator / navigator
4.4	**Review barriers and positivity:** Review observed need, positivity and engagement. Prefer future visits to areas with marked vulnerability or reactive results; reduce visits to persistently low-need/low-yield areas, considering access and equity.	Team / outreach coordination
4.5	**Dispose of clinical waste safely:** Dispose of sharps and diagnostic biohazard waste in approved containers, disinfect the clinical area and clean devices according to their IFUs.	Nurse / team

4.6	**Restock and maintain devices:** Record lots and expiry of RDTs/cartridges, replenish clinical supplies, prepare FibroScan and GeneXpert and secure the vehicles.	Nurse / logistics support
4.7	**End-of-session review:** Identify referrals needing TAS follow-up, missed appointments and practical improvement points.	Nurse / navigator / educator
4.8	**Project reporting when appropriate:** Contribute de-identified or authorised coded activity indicators to project reports according to approved consent, applicable DMP and sponsor arrangements.	UMC authorised lead / project manager
4.9	**Register incidents and corrective actions:** Record important clinical/diagnostic, equipment, safety or privacy incidents; clinical cases go to nurse and Dr Valencia/Dr Ryan for advice.	Nurse / outreach coordination
4.10	**Protect consent and records:** Store signed consent and identifiable data under the approved local procedures with restricted access; separate optional research-sharing consent from care.	Authorised UMC staff
4.11	**Secure equipment and access:** Shut down/logout protected REDCap sessions; clean and store testing devices, probes and samples as their manufacturer directs.	Nurse / authorised staff

5. Activity Map by Work Package

This brief activity map identifies the SOP contribution to the project without repeating every DoA activity or treating consortium-wide targets as obligations of the Madrid unit.

Work Package	Associated SOP activities	Key Deliverables / Milestones
WP1 – Prevention & communication	Outreach education, approved infographics and condoms; UMC rapid-test screening / referral SOP.	T1.7 / D1.3 and agreed WP1 dissemination outputs
WP2 – Cascade of care	Community mapping, test results, GeneXpert, FibroScan, referrals, TAS and follow-up.	Operational findings and cascade indicators; D2.2 where relevant
WP3 – Dignity & stigma	Respectful care and optional approved stigma surveys/materials, without treating surveys as compulsory screening.	Approved WP3 research and anti-stigma implementation
WP4 – Quality improvement	Quality checks, IFU adherence, incidents and learning across mobile units.	SOP harmonisation / standard service package
WP5 – Coordination & reporting	Aggregate or appropriately authorised data, risk monitoring and project administration.	DMP and project reports, subject to lawful data sharing

6. Ethical Considerations and Data Protection

6.1 General Principles

Care is voluntary, free of charge, confidential and non-stigmatising. The approved information/consent form is explained and signed before testing. The UMC REDCap dataset is hosted on a Health4OL association-owned server and can contain names, contact data and sensitive clinical information: it is identifiable health data, not anonymous data. Access is restricted to authorised personnel and governed by applicable data-protection requirements. Written research/data-sharing options are separate from provision of clinical care.

6.2 Informed Consent

The team provides and explains the UMC Madrid Participant Information Sheet and Informed Consent, version 2 (25 August 2026), reviewed by the CEIm. All tested users sign the clinical procedure consent before testing; specific optional consent choices (including data sharing for MOBHOPE-RESEARCH) must be recorded as presented. The approved research consent applies to adults aged 18 or older; minors are outside that research protocol. Refusal of optional research or data sharing does not affect routine clinical assistance.

6.3 Data Management

UMC uses its own REDCap database hosted on an association-owned HEALTH4OL server within the REDCap consortium. The nurse/team records sociodemographic factors, social determinants, vulnerability indicators, test results and care-cascade activities at the visit, including the name field nom where appropriate under the approved consent and GDPR. Identifiable information stays within the authorised local care workflow. Coded records are not automatically anonymous; any optional transmission to FIBHGM must comply with the separate informed-consent choice, the applicable research protocol and the approved DMP. Do not describe the UMC database as an anonymous MOBHOPE-wide registry. Apply role-based access, secure storage of signed forms and procedures for lawful retention, data-subject rights and security incidents.

7. Incident Management and Emergency Situations

	Response Protocol
Urgent clinical/diagnostic finding	The nurse assesses the person and consults Dr Valencia/Dr Ryan when needed; organise appropriate urgent healthcare/hospital care based on clinical risk. FibroScan >14 kPa requires assessment but does not by itself imply an emergency.
Acute distress or patient safety risk	Prioritise immediate safety and appropriate medical/emergency assessment; offer support without coercion or compulsory research questions.
Test refusal / withdrawal of optional consent	Respect the decision; explain support options. Handle existing clinical records and any withdrawal or erasure request according to lawful obligations and consent scope; do not promise automatic deletion.

Personal data / device security incident	Secure affected data/equipment; inform the authorised privacy responsible person promptly and follow GDPR, local incident reporting and the applicable DMP.
Rapid-test, GeneXpert or FibroScan failure	Stop the affected procedure; document error/lot and repeat or redirect only as authorised by the relevant IFU. Inform nurse and medical advisers for diagnostic safety.
Physical security incident	Protect participants and staff, stop or relocate activity if required and record/escalate through the UMC coordination pathway.
Needlestick / occupational exposure	Initiate immediate first aid and occupational exposure evaluation per established local clinical procedures; escalate to nurse and hospital advisers without delay.

8. Monitoring Indicators Linked to the SOP

Monitoring is part of the routine UMC workflow and is summarised for MOBHOPE only when appropriate authorisation exists. No cumulative numbers or site-specific test positivity results are embedded in this SOP; operational counts belong in reports such as D2.2 and D5.2.

UMC domain	What is documented	Data source / reporting
Planning	Site, date, permit, partner, territorial need and repeat-visit rationale.	Field planning / local review
Service contacts	Visitors assisted; consent status and limitations of counts of unique people.	UMC visit register
Population reached	Age, sex/gender, relevant vulnerability factors and settings.	UMC REDCap
Rapid screening	HIV/HBV/HCV/syphilis tests and reactive/non-reactive/invalid results.	UMC REDCap / test logs
HCV confirmation	GeneXpert HCV RNA tests performed and qualitative/quantitative results, as appropriate to assay.	UMC REDCap / GeneXpert
Liver assessment	FibroScan examinations, liver stiffness (kPa), quality and referral >14 kPa.	UMC examination log
Referral offer	Referral indicated, accepted, destination and TAS accompaniment offered.	UMC clinical / TAS record
Care linkage	Appointment, attendance, pharmacy, treatment initiation and subsequent adherence when documented.	TAS follow-up / approved record
Barriers	Administrative, language, transport, housing, stigma and follow-up difficulties.	TAS observations
Stigma surveys	Optional participation and survey completion only with separately approved consent.	Approved stigma survey database
Quality and safety	Lot traceability, device checks, invalid tests, incidents and corrective actions.	UMC logs / IFUs
Project reporting	Only aggregate or consent-authorised coded outputs; no fixed target claims in this SOP.	DMP / D2.2 and other reports

ADDENDUM:
Standard Mobile Unit Practice and MOBHOPE Activities

The table distinguishes the UMC operational workflow from the additional MOBHOPE documentation and quality tasks. It does not authorise services not actually delivered by Madrid Positivo.

Area	Standard Practice	Added by MOBHOPE (WP)
Outreach and education	Proactive street/centre recruitment by educator and navigator; preventive counselling and condoms.	Approved multilingual MOBHOPE infographics and dissemination documentation.
Consent	Written clinical procedure consent for each tested adult.	Distinct optional research and data-sharing choices under CEIm-approved forms.
Screening	HIV, HBV, HCV and syphilis rapid tests.	IFU-led test quality and project harmonisation.
Liver and HCV RNA	Reactive anti-HCV triggers GeneXpert HCV RNA; FibroScan for HBV/HCV reactivity or alcohol history.	Structured screening/referral algorithm; FibroScan >14 kPa for assessment.
Care linkage	Reference hospital or HUIL Fast Track with satellite-car transport when accepted.	TAS navigation, adherence support and care-cascade follow-up.
Data	Association-owned local HEALTH4OL REDCap, possibly including nom and clinical data.	Only lawful aggregate/optionally consented coded sharing; no automatic anonymisation.
Quality	Nurse leads clinical controls and consults hospital medical advisers about incidents.	Project learning, audit and agreed SOP reviews.
Coordination	UMC links with NGOs/institutions and reference hospitals before field visits.	Joint MOBHOPE implementation and deliverable contributions.

Annex A:
Session Stock Checklist (template)

Category	Item Description	Target Quantity	Actual Quantity	Checked (✓)
1. Prevention	Condoms for users			
1. Prevention	Educational leaflets / MOBHOPE infographics			
1. Prevention	Approved information sheets / signed consent copies			
1. Prevention	Patient referral information / TAS contact forms			
2. RDTs & Clinical	HIV rapid-test kits			
2. RDTs & Clinical	HBV rapid-test kits			
2. RDTs & Clinical	HCV rapid-test kits			
2. RDTs & Clinical	Syphilis rapid-test kits			
2. RDTs & Clinical	Fingerstick lancets, approved sampling consumables, gauze			
3. Biosafety & PPE	Portable Sharps Containers (Empty)			
	Biohazard waste bags (Yellow/Red)			
	Nitrile gloves (S, M, L), masks, aprons			
	Hand sanitizer / Disinfectant wipes			
4. IT & Documentation	REDCap authorised device / charge			
4. IT & Documentation	Secure network access / power source			
4. IT & Documentation	CEIm-approved consent forms (current version)			
4. IT & Documentation	Test result handouts / local referral forms			
4. IT & Documentation	Pens / materials for documentation			
5. Liver/HCV RNA	FibroScan device / suitable probe			
5. Liver/HCV RNA	GeneXpert instrument / assay cartridges			
5. Liver/HCV RNA	Echosens gel / Cepheid approved sampling devices			
6. Logistics	Satellite TAS car: keys/fuel/safe access			
6. Logistics	Referral destination/contact list			
6. Logistics	Approved MOBHOPE prevention handouts			

Prepared by: _____ **Date:** _____

Reviewed by: _____ **Date:** _____

Annex B:
Vehicle Loading Map (guidelines)

For safe operations, separate clinical stock, patient information materials, clean supplies, sharps and clinical waste during loading and outreach; secure medical devices and the satellite vehicle in accordance with local safety rules.

[ZONE 1: CABIN (Driver & Co-pilot)]

- Allowed: Personal belongings, staff food/water (sealed), mobile phones, vehicle documentation, clean outerwear.
- Prohibited: ANY clinical material, sharps, biohazard waste, or user-facing consumables.

[ZONE 2: CLEAN STORAGE (Locked Compartments)]

- Allowed: unopened HIV/HBV/HCV/syphilis rapid tests; GeneXpert cartridges and approved sampling supplies; FibroScan probe supplies; condoms; prevention leaflets; clean PPE.
- Rule: Must be physically separated from Zone 3.

[ZONE 3: CLINICAL WORKSPACE (Main Service Area)]

- Allowed: FibroScan® (when in use), active RDT workstation, laptop/tablet (on clean desk), active PPE.
- Rule: Surfaces must be disinfected before and after every user. No food or drink allowed in this zone.

[ZONE 4: CONTAMINATED / WASTE AREA (Secure & Locked)]

- Allowed: Portable Sharps Container (sealed), Biohazard waste bags (sealed).
- Rule: Must be in a spill-proof, locked container at the floor level or dedicated secure cabinet to prevent accidental opening during transit.

Annex C:
Stock Traceability Log (template)

Record manufacturer, product/assay, lot, expiry and quantities for rapid tests and GeneXpert cartridges; keep maintenance/serial records for FibroScan and GeneXpert according to the relevant device instructions.

Date: _____

Location(s): _____

Item Name	Manufacturer	Lot / Batch Number	Expiry Date	Qty Start	Qty End
HIV Test					
HBV Test					
HCV Test					
Syphilis Test					
GeneXpert HCV Cartridge / device log		(Serial No.)	N/A	1	1

Notes / Discrepancies:

_____

Verified by (Logistics): _____

Verified by (Clinical Lead): _____

Annex D:
Informed Consent Form (internal)

Approved consent: UMC-MADRID-HIP-CI v2 dated 25 August 2026, favourable CEIm opinion dated 9 September 2026. An unaltered reproduction of the approved two-page information sheet and consent is inserted below. The signed original is retained according to the approved local record-management procedure.

MADRID POSITIVO | UNIDAD MÓVIL DE CRIBADO

FUNDACIÓN INVESTIGACIÓN BIOMÉDICA HOSPITAL GREGORIO MARAÑÓN

Co-funded by the European Union

HOJA DE INFORMACIÓN Y CONSENTIMIENTO INFORMADO

Procedimientos de la Unidad Móvil de Cribado – Madrid Positivo

UMC-MADRID-HIP-CI | Versión 2 | 25 de agosto de 2026 | Investigador principal: Dr. Pablo Ryan

Título completo del estudio: Multicenter operational study of mobile outreach, integrated screening, liver assessment, linkage to care and stigma among underserved adults in Spain, Portugal and Croatia (MOBHOPE-RESEARCH).

¿Por qué le ofrecemos esta atención?

La Unidad Móvil de Cribado (UMC) de Madrid Positivo ofrece gratuitamente información preventiva, cribado, valoración del hígado y apoyo para acceder a la atención sanitaria. Este documento es para personas adultas (18 años o más).

Su decisión. Usted decide libremente. Puede aceptar unas actuaciones y rechazar otras, no responder preguntas y cambiar de opinión antes de cada procedimiento. Su decisión no afectará al resto de la atención, a la ayuda que reciba ni a su situación administrativa. No tendrá que pagar y no recibirá compensación económica.

¿Qué puede hacerse en la Unidad Móvil?

Según sus necesidades y después de explicárselo, el equipo puede darle información sobre VIH, hepatitis virales e infecciones de transmisión sexual, preservativos y consejos preventivos; realizar pruebas rápidas de VIH, hepatitis B, hepatitis C y sífilis; y hacer preguntas breves sobre salud, acceso a la atención y experiencia con el servicio. Puede omitir cualquier pregunta.

Una prueba rápida reactiva es preliminar y debe confirmarse cuando corresponda. Tras una prueba reactiva de anticuerpos puede realizarse una PCR de ARN/ADN en la UMC o en el laboratorio para saber si la infección está activa. Un resultado negativo puede no detectar una infección muy reciente durante el periodo ventana.

Cuando sea necesario para el diagnóstico o la atención, podrá obtenerse sangre mediante punción en el dedo, recogerse sangre seca en una tarjeta (DBS) o extraerse sangre de una vena para enviarla al laboratorio. Cualquier otra muestra deberá explicarse y registrarse específicamente. Las muestras se usarán solo para las pruebas indicadas, se eliminarán según la normativa y no se guardarán en un biobanco, no se utilizarán para otros estudios.

Si existe sospecha de enfermedad hepática o un resultado positivo de hepatitis B o C, puede ofrecerse un FibroScan (elastografía transitoria). Es una exploración rápida, sin agujas y sin radiación. El equipo comunicará los resultados de forma privada y, si necesita atención, podrá organizar una derivación, enviar al centro receptor la información clínica mínima necesaria y, si usted lo desea, ofrecer acompañamiento por un educador de la UMC.

Beneficios, molestias y salud pública

La atención puede facilitar información, diagnóstico temprano y acceso al tratamiento, aunque no se garantiza un beneficio personal. La punción o extracción puede causar dolor breve, hematoma, pequeño sangrado o mareo y, muy raramente, infección. El FibroScan suele ser indoloro y puede producir una ligera presión. Algunas preguntas o resultados pueden preocuparle. Algunas infecciones son de declaración obligatoria; cuando proceda, se comunicará a Salud Pública únicamente la información exigida por la normativa.

¿Cómo se utilizarán sus datos?

Esta actividad forma parte de MOBHOPE, proyecto europeo EU4Health coordinado por la Fundación para la Investigación Biomédica del Hospital Gregorio Marañón (FIBHGM), que busca mejorar el diagnóstico temprano y la vinculación asistencial de personas con dificultades para utilizar los servicios sanitarios habituales.

Asociación Madrid Positivo es responsable de sus datos identificativos y asistenciales y conserva localmente la clave que relaciona su identidad con un código. Solo si usted lo autoriza expresamente en la página 2, Madrid Positivo enviará de forma segura a FIBHGM los datos mínimos codificados sobre la atención, resultados, derivación y cuestionarios opcionales. FIBHGM coordina y analiza el conjunto central junto con los datos codificados de las unidades móviles a nivel europeo para evaluar MOBHOPE y mejorar los circuitos comunes. No recibirá su nombre, teléfono, correo, dirección completa, DNI/NIE, tarjeta sanitaria, clave local ni muestras biológicas. Los resultados se presentarán agrupados, sin identificarle.

Los datos asistenciales se tratan para prestar atención y cumplir obligaciones sanitarias; el uso y la cesión opcionales para MOBHOPE se basan en su consentimiento explícito. Se aplican el Reglamento (UE) 2016/679 (RGPD), la Ley Orgánica 3/2018, la Ley 41/2002, la Ley 14/2007 y la Ley 33/2011, junto con la normativa de vigilancia epidemiológica. Los registros asistenciales se conservarán durante los plazos legalmente aplicables. Los datos se conservarán durante el proyecto y el periodo aprobado necesario para las obligaciones científicas, legales y de auditoría; después se eliminarán o anonimizarán.

Puede solicitar, cuando proceda, acceso, rectificación, supresión, limitación, oposición y portabilidad, y retirar el consentimiento para usos futuros. La portabilidad se aplica a los datos que usted haya facilitado cuando el tratamiento se base en su consentimiento y se realice por medios automatizados; podrá recibirlos en un formato estructurado, de uso común y lectura mecánica o pedir su transmisión a otro responsable cuando sea técnicamente posible (artículo 20 del RGPD y artículo 17 de la Ley Orgánica 3/2018). La retirada detendrá nuevas recogidas y cesiones opcionales; no eliminará la asistencia ya prestada, los registros o notificaciones legalmente obligatorios, ni datos ya anonimizados o incluidos en un análisis finalizado. Puede reclamar ante la Agencia Española de Protección de Datos (www.aepd.es) y/o a Madrid Positivo.

Contacto

Contacto del Investigador Principal y del equipo. Madrid Positivo-UMC. Dirección: C/ Gamonal 77 bis, 4.º, local 38, 28031 Madrid. Horario: lunes a viernes, 09:00-15:00. Teléfono: 91 223 71 83. Móvil / WhatsApp: 662 959 491. Correos del equipo: madrid_positivo@madridpositivo.org y unidadmovilcribado@gmail.com. Investigador principal: Dr. Pablo Ryan (pablo.ryan@salud.madrid.org).

Cofinanciado por la Unión Europea mediante el Acuerdo de Subvención n.º 101233203. Las opiniones expresadas pertenecen exclusivamente a sus autores.

MADRID POSITIVO | UNIDAD MÓVIL DE CRIBADO

CONSENTIMIENTO INFORMADO

Procedimientos de la Unidad Móvil de Cribado – Madrid Positivo

UMC-MADRID-HIP-CI | Versión 2 | 25 de agosto de 2026

Título completo del estudio: Multicenter operational study of mobile outreach, integrated screening, liver assessment, linkage to care and stigma among underserved adults in Spain, Portugal and Croatia (MOBHOPE-RESEARCH).

Nombre y apellidos: _____

Confirmo que tengo 18 años o más; he leído esta hoja o me la han explicado de forma comprensible; he podido preguntar; entiendo que mis decisiones son voluntarias y que recibiré una copia firmada.

Actuaciones que acepto

Aceptación general. Con mi firma acepto que, según mis necesidades y tras recibir una explicación comprensible, la UMC pueda ofrecerme información preventiva, preservativos, pruebas rápidas de VIH, hepatitis B, hepatitis C y sífilis, PCR de ARN del VHC cuando esté indicada, punción en el dedo, sangre seca (DBS), extracción de sangre venosa, FibroScan, comunicación privada de resultados, derivación y acompañamiento por un educador. Cada actuación se explicará antes de realizarla y podré rechazarla en ese momento. Las muestras se usarán solo para las pruebas indicadas y no se conservarán para investigación ni se enviarán a FIBHGM.

Marque una opción: ☐ **SÍ** ☐ **NO**

Uso de datos codificados. Con mi firma al final de esta página, consiento expresamente que Madrid Positivo utilice los datos mínimos sobre mi atención y resultados, los sustituya por un código y envíe los datos codificados a FIBHGM para evaluarlos junto con los de las unidades móviles como parte del proyecto europeo MOBHOPE. No se enviarán identificadores directos ni muestras.

Marque una opción: ☐ **SÍ** ☐ **NO**

Opciones complementarias. También acepto que, si se me ofrecen, pueda responder a preguntas sobre acceso, barreras y experiencia con la Unidad Móvil; que, si tengo hepatitis C actual o pasada, pueda responder al cuestionario adaptado sobre estigma; y que Madrid Positivo pueda contactarme para el seguimiento de investigación durante un máximo de 12 meses, incluida, si procede, la repetición de un cuestionario aproximadamente a los 3–6 meses. Mis datos de contacto permanecerán en Madrid Positivo.

Marque una opción: ☐ **SÍ** ☐ **NO**

Firmas

Firma o marca: _____ Fecha: _____

Profesional que informa: nombre: _____ **Firma:** _____

Annex E:
Users' Information Materials (internal)

Annex F:
Incident and Deviation Log (template)

Record and escalate safety incidents promptly to the nurse and hospital-based medical advisers (Dr Jorge Valencia / Dr Pablo Ryan) when clinical or diagnostic. Data-protection incidents are routed through the association's authorised privacy process and the applicable DMP; do not assume fixed internal deadlines absent from an approved policy.

Date of Incident: _____ Time: _____ Location: _____

Reported by (Name & Role): _____

1. Type of Incident (Tick one):

[ ] Biosafety (e.g., needlestick injury, spill)

[ ] Security / Aggression (e.g., threat to staff, unsafe environment)

[ ] Protocol Deviation (e.g., test performed without consent, wrong test used)

[ ] Equipment Failure (e.g., FibroScan broken, REDCap offline)

[ ] Data Breach / Privacy Incident

[ ] Other: _____

2. Description of the Incident:

(What happened? Who was involved? What was the immediate context?)

3. Immediate Action Taken:

(First aid, evacuation, discard of faulty kit, reassurance to user, etc.)

4. Root Cause (If known):

5. CAPA Required? (Corrective and Preventive Action)

[ ] Yes [ ] No

Proposed CAPA: _____

Reporter Signature: _____ **Date:** _____

Coordinator Signature: _____ **Date:** _____

Date Escalated to Project Manager: _____ (If applicable)

Annex G:
Session Debriefing Form (template)

The team reviews important operational events, linkage-to-care barriers and locations where repeat visits are warranted at the end of a visit, documenting the discussion when relevant.

Date: _____ **Location:** _____

Team Members Present: _____

1. Operational Summary:

- Did we meet the target population as planned?

  [ ] Yes [ ] No (Explain: _____)

- Were there any bottlenecks in the patient flow or REDCap entry?

  [ ] Yes [ ] No

2. What went well today? (Successes / Best Practices)

3. What were the main challenges or barriers? (e.g., user mistrust, language barriers, weather, stock issues)

4. Pending Follow-ups for Next Visit:

(e.g., specific users who promised to return, referrals that need tracking, stock to reorder)

- User Follow-up: _____
- Referral Tracking: _____
- Logistics/Stock: _____

5. Suggestions for Improvement (Protocol / Tools / Teamwork):

Coordinator Signature: _____