Standard Operating Procedure

Ares do Pinhal, Portugal

Field	Details
Project Number:	101233203
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
Dissemination Level:	Public
Document Version:	2.0 – 26/10/2026

Disclaimer
Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency. Neither the European Union nor the granting authority can be held responsible for them.

MOBHOPE Project Coordination Team
info@mobhope.eu
mobhope.eu

Co-funded by the European Union

PARTNERS

Table of Contents

List of Abbreviations 3

1. Purpose and Scope 4

2. Normative and Documentary References 4

3. Responsibilities 4

4. Process Overview 5

PHASE 0 – PREPARATION AND DAILY PLANNING 5

PHASE 3 – INTEGRATED HEALTH, SCREENING AND PSYCHOSOCIAL INTERVENTION 8

5. Activity Map by Work Package 10

6. Ethical Considerations and Data Protection 10

6.1 General Principles 10

6.2 Informed Consent 10

6.3 Data Management 10

7. Incident Management and Emergency Situations 11

8. Monitoring Indicators Linked to the SOP 11

ADDENDUM: Standard Mobile Unit Practice and MOBHOPE Activities 12

Annex A: Session Stock Checklist (template) 13

Annex B: Vehicle Loading Map (guidelines) 14

Annex C: Stock Traceability Log (template) 15

Annex D: Informed Consent Form (internal) 16

Annex E: Users' Information Materials 17

Annex F: Incident and Deviation Log (template) 18

Annex G: Session Debriefing Form (template) 20

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	26/10/2026	Hugo Faria	Final Version
v2.0	26/10/2026	Steering Committee	Approval

List of Abbreviations

AdP	Ares do Pinhal (Portugal)
DOT	Directly Observed Therapy
FIBHGM-UMC	Mobile Screening Unit, Fundación para la Investigación Biomédica del Hospital Gregorio Marañón (Spain)
HBV / HCV	Hepatitis B / C Virus
HCC	Hepatocellular Carcinoma
HIV	Human Immunodeficiency Virus
MASLD	Metabolic Dysfunction-Associated Steatotic Liver Disease
MIHC	Mobile InfoHep Centre – Hepatos (Croatia)
PREM / PROM	Patient-Reported Experience / Outcome Measures
OAT	Opioid Agonist Therapy
DOT	Directly Observed Therapy
PWID / PWUD	People Who Inject Drugs/ People Who Use Drugs
REDCap	Research Electronic Data Capture
SOP	Standard Operating Procedure
SW	Sex Workers
WP	Work Package
GDPR	General Data Protection Regulation

1. Purpose and Scope

This SOP describes the complete process for planning, executing, and documenting field outreach visits of the **Portuguese Mobile Integrative health and social care unit from *Ares do Pinhal* (ADP)** within the MOBHOPE project (EU4Health 2024, Grant Agreement No. 101233203). Its purpose is to ensure:

- 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.

This SOP applies to all staff involved in mobile outreach visits, including: Clinical staff (physicians, nurses); Social workers; Peer educators and peer workers; Data managers and researchers; Drivers and logistics officers; Outreach coordinators.

To facilitate the operational implementation of this SOP, an abbreviated version may be implemented in the local language (i.e. Portuguese). This operational version will primarily include the practical procedures described in Sections 3, 4, and 7, together with the relevant annexes from the present document. It is intended as a user-friendly reference for field personnel and will contain only the procedures required for day-to-day implementation, while the present SOP will remain the master document governing all operational, ethical, and data management requirements.

2. Normative and Documentary References

This SOP must be read in conjunction with:

1. MOBHOPE Project 101233203 Grant Agreement, Annex 1 Description of the Action, 14/10/2025.
2. Declaration of Helsinki (latest version in force).
3. Regulation (EU) 2016/679 – GDPR.
4. Directive 2005/28/EC and Regulation (EU) 536/2014 (where applicable).
5. Local IRB/REC protocols of each participating country.
6. Data Management Plan (DMP) – Deliverable D5.1 (M6).
7. Dissemination, Exploitation and Communication Plan (DECP) – Deliverable D4.6 (M6).
8. Research Methodology & Tools – Deliverable D2.1 (M6).
9. ECDC and World Hepatitis Alliance guidelines on screening and stigma.

3. Responsibilities

Role*	Responsibilities
Project Coordinator (Site Lead)	Plans logistics, coordinates municipal permits, leads the on-site team, ensures SOP compliance, escalates incidents
Clinical Lead (Physician / Nurse)	Performs clinical tests, RDTs, FibroScan®, counselling, specialist referral, biosafety oversight, and all that apply
Social Worker/psychologist	Addresses social determinants, facilitates access to complementary services (housing, employment, migration support)

Data Coordinator	Manages REDCap data entry, ensures data quality and GDPR compliance
Peer Educators / Peer Workers	Participant outreach, trust-building, health education, support with informed consent, harm reduction distribution
Educator// Logistics Officer	Vehicle operation, fuel, route planning, equipment loading/unloading, stock traceability
MOBHOPE Lead	Supervises MOBHOPE integration, reports to Steering Committee (e.g. Country-Specific WP Leader)
FIBHGM Coordinator (COO)	Project Management, approves protocols, ensures GDPR compliance

*One person can take on multiple roles.

4. Process Overview

The ADP mobile intervention is structured in six interconnected phases. The model accommodates both regular mobile service delivery at established locations and targeted outreach interventions conducted in other municipalities or community settings in response to identified needs among vulnerable populations.

PHASE 0 – PREPARATION AND DAILY PLANNING

#	ACTIVITY / STEP	RESPONSIBLE
0.1	**Confirm intervention setting and schedule:** Confirm the regular mobile stop or planned outreach location, operating hours, expected target population and any relevant changes to the daily route or intervention.	Operational Coordinator
0.2	**Review participants requiring follow-up:** Identify service users due for clinical review, screening, blood tests, vaccination, medical consultation, treatment monitoring or follow-up of previous referrals. Review pending psychosocial and social-care needs when relevant.	Clinical / Psychosocial Team
0.3	**Prepare prescribed medication:** Prepare methadone and other prescribed medication according to the daily treatment list and applicable medication-management procedures. Verify prescriptions, doses and required documentation before departure.	Nurse / Clinical Staff
0.4	**Screening and clinical stock check:** Verify availability and expiry dates of HIV, HBV, HCV and syphilis rapid tests, blood collection materials, wound-care supplies, PPE and biosafety materials. Include other diagnostic materials required for planned activities.	Clinical Staff
0.5	**Harm reduction stock check:** Verify availability of sterile injecting equipment, safer smoking materials, condoms and other harm reduction materials routinely provided by the programme as well as leaflets, brochures, posters, digital content	Harm Reduction / Psychosocial Team
0.6	**Verify availability of communication and educational materials:** Leaflets, brochures, posters, digital content. Ensure MOBHOPE/EU4Health branding is visible.	MOBHOPE Lead
0.7	**Equipment check:** Verify that clinical and diagnostic equipment required for the intervention is functional and ready for use, including FibroScan®, point-of-care diagnostic equipment and digital devices where applicable.	Clinical Staff
0.8	**Data and documentation check:** Confirm availability of the required clinical records, screening documentation, referral information and MOBHOPE data collection tools/REDCap and stigma survey when MOBHOPE participants are expected.	Designated Staff / Data Staff

0.9	**Review referral pathways and scheduled consultations:** Confirm appointments, planned decentralised consultations and relevant contacts with primary care, hospital or specialist services. Identify participants requiring transport or accompaniment.	Clinical / Psychosocial Team
0.10	**Daily team briefing:** Review team roles, relevant clinical or psychosocial situations, expected interventions, follow-up priorities and any operational or safety issues.	Operational Coordinator
0.11	**Vehicle readiness and loading:** Confirm vehicle readiness and securely load medication, clinical equipment, screening materials, harm reduction supplies and documentation required for the intervention.	Driver / Full Team

PHASE 1 – TARGETED OUTREACH PLANNING AND LOCAL COORDINATION (Applicable when MOBHOPE activities are implemented outside regular ADP mobile service locations)

#	Activity / Step	Responsible
1.1	**Identify territory and target population:** Define the municipality, intervention setting and vulnerable population to be reached based on identified needs and local information.	Project / Operational Coordinator
1.2	**Establish local partnership:** Contact the municipality, local healthcare services, NGOs, community organisations, harm reduction services or other relevant stakeholders.	Project Coordinator
1.3	**Estimate expected population and needs:** Together with local partners, estimate the number and characteristics of people likely to participate and identify relevant health, social and accessibility needs.	ADP Team / Local Partner
1.4	**Active outreach to participants:** Outreach staff engage with the community, distribute flyers, Leaflets, videos, infographics in local language., use word of mouth. Low-threshold, non-judgmental, person-centred communication.	Outreach staff
1.5	**Define location and operating schedule:** Select an accessible and appropriate location and define the intervention schedule. Local partners familiar with the territory should advise on the times and locations most likely to facilitate access by the target population.	ADP Coordinator / Local Partner
1.6	**Define the intervention package:** Determine which services will be available, including screening, liver assessment, clinical consultation, psychosocial support, harm reduction and health education, according to local needs and available resources.	Clinical Lead / Project Coordinator
1.7	**Establish local referral pathways before deployment:** Identify primary care, hospital and specialist services responsible for confirmatory testing, clinical assessment and treatment. Agree, whenever possible, on direct contact points and procedures for referral.	Clinical Lead / Local Healthcare Partner
1.8	**Promote direct clinical linkage:** Whenever feasible, arrange for a clinician from the local healthcare service to participate in the mobile intervention to facilitate immediate assessment and reduce the number of steps between screening, diagnosis and treatment.	Project Coordinator / Local Healthcare Partner

1.9	**Define follow-up responsibilities:** Agree before the intervention how participants requiring subsequent care will be followed and clarify the respective responsibilities of ADP and the local partner.	ADP Coordinator / Local Partner
1.10	**Community mobilisation:** Local partners and outreach professionals inform and mobilise the target population using established community networks and trusted professionals.	Local Partner / Outreach Team
1.11	**Final deployment briefing:** Confirm team composition, equipment, diagnostic capacity, documentation, transport, referral contacts and follow-up arrangements before departure.	Project Coordinator / Full Team

PHASE 2 – MOBILE STOP / OUTREACH RECEPTION AND ENGAGEMENT

#	Activity / Step	Responsible
2.1	**Arrival and site assessment:** Confirm that the mobile stop or outreach location is accessible, safe and suitable for confidential health intervention.	Operational Coordinator
2.2	**Set up the mobile service:** Prepare the medication administration, clinical/screening and psychosocial areas according to the activities planned for that location.	Full Team
2.3	**Reception and engagement:** Welcome service users using low-threshold, non-judgemental and person-centred communication. Generate unique ID for new clients. At targeted outreach interventions, explain the services available and their voluntary nature.	Psychosocial / Outreach Team
2.4	**Routine medication administration:** At regular ADP mobile programme stops, administer methadone and other prescribed medication according to the individual treatment plan and applicable procedures.	Nurse / Clinical Staff
2.5	**Brief health observation:** Use routine contact to identify changes in general condition, treatment-related issues, symptoms, wounds or other health needs requiring assessment.	Clinical Staff
2.6	**Identify psychosocial and social needs:** Identify relevant psychological, housing, documentation, social protection, healthcare access or other difficulties requiring intervention or follow-up.	Psychologist / Social or Psychosocial Staff
2.7	**Identify screening and prevention opportunities:** Verify whether the person is due for or would benefit from HIV, HBV, HCV, syphilis or other relevant screening, vaccination, liver assessment or health and mental health education.	Clinical Staff
2.8	**Harm reduction contact:** Assess current harm reduction needs and provide appropriate materials, information and counselling.	Harm Reduction / Psychosocial Team
2.9	**MOBHOPE information and consent, when applicable:** Explain the project activities and, where operational research data are collected, apply the approved MOBHOPE information and informed-consent procedures. Distribute dignity-promotion materials, use non-stigmatising language, ensure privacy and respect.	Designated MOBHOPE Staff
2.10	**Define individual pathway:** Direct the person to medication administration, clinical assessment, screening, psychosocial intervention, harm reduction or another appropriate referral according to identified needs.	Multidisciplinary Team
2.11	**Inventory and restock consumables:** Count remaining RDT kits, harm reduction materials, food/water. Record used vs. remaining stock in Stock Traceability Log. Flag discrepancies, damaged items, or near-expiry stock for replacement. Prepare replenishment request for next session.	Mobile Unit team/clinical staff

PHASE 3 – INTEGRATED HEALTH, SCREENING AND PSYCHOSOCIAL INTERVENTION

#	Activity / Step	Responsible
3.1	**Brief clinical assessment:** Assess relevant symptoms, medical history, medication, previous diagnoses and current healthcare needs. Acute or potentially serious conditions take priority over routine screening.	Physician / Nurse
3.2	**Infectious disease screening:** Offer and perform HIV, HBV, HCV and syphilis screening according to applicable protocols and individual testing history/risk.	Clinical Staff
3.3	**TB pathway:** Assess the need for tuberculosis screening and activate the established screening/diagnostic pathway where indicated.	Psychossocial staff/ Clinical Staff
3.4	**Blood sampling and additional diagnostics:** Collect blood or perform other point-of-care diagnostic procedures when clinically indicated and available.	Nurses/Clinical Staff
3.5	**Liver health assessment:** Perform FibroScan® or other liver health assessment when included in the intervention and clinically appropriate.	Trained Clinical Staff (nurses/doctors)
3.6	**Communicate results:** Explain screening and assessment results confidentially, including limitations and the need for confirmatory testing or further clinical assessment where applicable, provide emotional support.	Clinical Staff
3.7	**Basic healthcare intervention:** Address needs that can appropriately be managed within the mobile setting, including OAT, basic nursing care, wound care, health monitoring and medication-related support. Refer participant to mental health, addiction or social services as needed, issue referral and offer accompaniment	Clinical Staff
3.8	**Psychological and psychosocial intervention:** Provide brief support, assess barriers to healthcare engagement and identify needs requiring additional psychological, social or addiction-related intervention.	Psychologist / Psychosocial Team
3.9	**Harm reduction intervention:** Provide safer-use materials and individualised advice regarding drug use, blood-borne infection prevention, overdose and sexual health according to need.	Harm Reduction Team
3.10	**Health promotion:** Provide brief and relevant information regarding HIV, viral hepatitis, STIs, liver health, vaccination, treatment adherence and other identified health priorities.	Multidisciplinary Team
3.11	**Record intervention:** Document relevant clinical, screening, psychosocial and MOBHOPE data in the appropriate records.	Responsible Professional

PHASE 4 – REFERRAL AND ACTIVE LINKAGE TO CARE

#	Activity / Step	Responsible
4.1	**Identify need for further care:** Count participants seen. Determine whether the participant requires confirmatory testing, primary care, specialist assessment, treatment or additional social/psychological support.	Clinical / Psychosocial Team
4.2	**Select the appropriate pathway:** Identify the healthcare or social service best suited to the person's needs. Provide information on additional social resources (housing, employment, migration support,legal aid).	Responsible Professional
4.3	**Direct clinical assessment when available:** Where a clinician from the receiving healthcare service is present during the intervention, facilitate same-site assessment and direct entry into the appropriate care pathway whenever possible.	Clinical Team
4.4	**Schedule follow-up:** When direct assessment is not possible, arrange the next consultation, examination or diagnostic procedure before the participant leaves whenever feasible.	Clinical / Psychosocial Team

4.5	**Assess barriers to attendance:** Identify transport, documentation, language, financial, psychological or other barriers that may prevent successful access to the receiving service.	Psychosocial Team
4.6	**Provide care navigation:** Explain where, when and how to attend; facilitate communication with the receiving service and resolve practical barriers where possible.	Case Manager / Psychosocial Team
4.7	**Arrange transport or accompaniment when required:** Provide or organise transport and/or professional accompaniment for participants who are unlikely to access care autonomously.	Psychosocial Team
4.8	**Document referral and responsible follow-up:** Record the referral, training, educational mateials distributed, harm reduction kits issued, scheduled appointment and professional/service responsible for monitoring the outcome.	Responsible Professional

PHASE 5 – FOLLOW-UP AND CONTINUITY OF CARE

#	Activity / Step	Responsible
5.1	**Monitor referral outcome:** Verify whether scheduled consultations, diagnostic procedures or examinations were attended and completed.	Case Manager / Psychosocial Team
5.2	**Follow up clinical results:** Review confirmatory results and ensure that clinically relevant findings are communicated and acted upon.	Clinical Staff
5.3	**Monitor treatment initiation and continuity:** Where applicable, verify whether treatment has been initiated and identify barriers to adherence or continuation.	Clinical / Psychosocial Team
5.4	**Support treatment through the mobile programme:** Where prescribed and operationally applicable, support medication administration and directly observed treatment through the regular mobile service.	Nurse / Clinical Staff
5.5	**Manage missed appointments:** Re-establish contact where possible, identify reasons for non-attendance, address modifiable barriers and arrange a new appointment when appropriate.	Case Manager / Psychosocial Team
5.6	**Maintain psychosocial follow-up:** Address ongoing social or psychological barriers that may affect healthcare access, treatment or stability.	Psychologist / Psychosocial Team
5.7	**Reassess health needs:** Use subsequent mobile contacts to identify new symptoms, screening needs, treatment issues or other healthcare needs.	Multidisciplinary Team
5.8	**Multidisciplinary case review:** Discuss complex situations requiring coordinated clinical, psychological and social intervention.	Multidisciplinary Team
5.9	**Coordinate continuity after targeted outreach:** For interventions in other municipalities, confirm transfer/follow-up with the designated local service and maintain communication until continuity of care is reasonably established.	ADP Coordinator / Local Partner
5.10	**Record cascade-of-care outcome:** Document the relevant outcome according to MOBHOPE WP2 definitions (e.g. referral, attendance, confirmation, treatment initiation and follow-up status).	MOBHOPE / Data Staff
5.11	**Send visits summary to MOBHOPE Lead:** Include number of users attended, tests performed, referrals issued, operational issues, safety concerns, deviations. On a regular basis.	Clinical staff/MOBHOPE team

5. Activity Map by Work Package

The table below shows which SOP activities contribute directly to each MOBHOPE WP, facilitating tracking of milestones and deliverables.

Work Package	Associated SOP activities	Key Deliverables / Milestones
WP1 – Communication & Health Promotion	0.6, 1.4, 2.7, 2.10	D1.1–1.3 / MS1.1–1.3
WP2 – Cascade of Care & Operational Research	0.7, 0.8, 2.7, 2.9, 3.2, 4.1, 4,2, 4.8, 5.6, 5.10	D2.1–2.4 / MS2.1–1.4
WP3 – Stigma & Human Dignity	3.6, 3.7, 4,6, 4,7	D3.1, D3.2, D3.4, D3.5 / MS3.1–3.4
WP4 – Standardisation & Quality Improvement	0.1, 0.8, 2.1, 1.11	D4.2–4.4 / MS4.1–MS4.6
WP5 – Coordination & Evaluation	0.1, 0.10, 1.1,1.2, 2.3, 2.9, 2.1, 3.11, 4.1, 5.11	D5.1–5.5 / MS5.1–MS5.6

6. Ethical Considerations and Data Protection

6.1 General Principles

All services provided within the mobile unit will be voluntary, free of charge, and delivered in a non-stigmatising manner to ensure equitable access and respect for all users. User confidentiality will be protected through the use of pseudonymised codes, with no names or personal identification numbers recorded in the database. All personnel will conduct their activities in accordance with the ethical principles of the Declaration of Helsinki and the International Council for Harmonisation Good Clinical Practice guidelines. All users will receive the same package of clinical and support services regardless of their decision about research participation. Users may allow their pseudonymised data to be used for MOBHOPE operational research; however, this decision will be entirely voluntary and will not affect their access to routine care or any other programme services.

6.2 Informed Consent

Standard informed consent for clinical care will be mandatory for any clinical test or procedure, as part of routine healthcare activities associated to the mobile unit. This consent will be provided in the participant's preferred language, and will clearly explain the use of their data for cascade-of-care analyses, stigma assessment, and other operational research activities related to MOBHOPE's aims. For participants who are minors, informed consent procedures will follow national age-of-consent regulations. Where required, consent will be obtained from both the legal guardian and the minor in accordance with applicable legal and ethical requirements.

6.3 Data Management

All data will be entered into REDCap, hosted on the HEALTH4OL (biomad servers), and managed in compliance with the General Data Protection Regulation (GDPR). Access to research data within REDCap will be role-based, with each participating entity able to access only the data collected through its own mobile unit, while MOBHOPE's Global Project Coordinator will have centralised access to pseudonymised data for cross-site monitoring and analysis. Clinical care data will remain within each participating entity's own patient record system and will be managed according to local institutional policies

and applicable regulations.Research data anonymisation, retention periods, access rights, and data-sharing procedures will be governed by MOBHOPE's Data Management Plan (D5.1). Paper informed consent forms and any documents containing identifiable information will be stored securely in locked containers and transported using secure procedures. All personnel with access to REDCap will use individual, role-based accounts and will log out after each session to maintain data security. The capture of photographs or videos of users will be strictly prohibited unless explicit written consent for image use has been obtained through a specific image consent form.

7. Incident Management and Emergency Situations

	Response Protocol
Urgent positive result (e.g. very high viral load, advanced cirrhosis)	Hospital referral within 24 h. Flag as urgent in REDCap.
Participant in crisis (mental health, self-harm risk)	Activate local safeguarding protocol. Do not collect research data at that moment. Offer accompaniment.
Refusal of test / withdrawal of consent	Respect immediately. Delete data on request. Offer support services.
Data security incident (device lost, data breach)	Notify Data Manager and COO within 2 h. Follow DMP breach protocol.
Equipment failure (Fibroscan®, GenXpert, etc.)	Document incident. Use contingency protocol (backup RDTs). Notify Outreach Coordinator.
Physical safety incident during visit	Evacuate per local protocol. Notify authorities. File incident report within 48 h. Update risk register (WP5) and/or notify COO.
Needlestick injury or exposure incident	Manage immediately per Post-Exposure Prophylaxis Protocol. Report within 1 h.

8. Monitoring Indicators Linked to the SOP

The following MOBHOPE indicators are monitored directly through the activities captured in this SOP:

Work Package	Key Indicator(s)	Target
WP1	No. of training sessions/year	≥12
	% knowledge improvement ≥30% (pre/post-test)	≥30%
	Beneficiaries reached by health education	3,000
WP2	No. of RDTs and elastographies performed (streets/shelters)	4,400
	No. of prison-based tests and/or liver exams	600
	Linkage-to-care rate for positive cases	≥80%
	Time from diagnosis to specialist evaluation	<30 days
WP3	No. of stigma questionnaires completed	≥600
	Reduction in stigma score (pre/post)	≥20%
WP4	Team feedback incorporated into draft standard service package	Qualitative
WP5	Data synced in REDCap within 48 h of each visit	100%
	Rate of missing mandatory fields	<5%

ADDENDUM:
Standard Mobile Unit Practice and MOBHOPE Activities

The table below provides a schematic comparison of what a mobile unit outreach visit typically involves (baseline) and what MOBHOPE specifically adds, indicating the relevant WP and task for each addition.

Area	Standard Practice	Added by MOBHOPE (WP)
Outreach & education	Basic outreach by educators and psychosocial team; verbal information about services.	Systematic multilingual educational materials (WP1); structured training sessions with pre/post-test.
Informed Consent	Standard clinical IC.	Additional mention for operational research and stigma assessment (WP5).
Diagnostic testing	RDTs and blood collection for HIV, HBV, HCV.	Systematic Fibroscan® liver elastography / GenXpert PoC-PCR where available (WP2).
Stigma	Non-stigmatising approach as good-practice principle	Validated WHA/ECDC questionnaire; structured anti-stigma interventions; dignity-promotion materials (WP3).
Linkage to care	Verbal or written referral to specialist for positive results.	Cascade of care recorded in REDCap; tracking time diagnosis→evaluation < 30 days; peer educator accompaniment (WP2).
Documentation	Entry in local clinical record.	REDCap entry with pseudonymised code; sync within 48 h; report to MOBHOPE Lead (WP5).
Quality & continuous improvement	Informal team debriefing.	Structured visit report within 48 h; feedback into standard package (WP4); incident logging in risk register (WP5).
Consortium coordination	Internal mobile unit coordination.	Reporting to Steering Committee; participation in consortium meetings; contribution to project deliverables (WP5).

Annex A:
Session Stock Checklist (template)

Category	Item Description	Target Quantity	Actual Quantity	Checked (✓)
1. Harm Reduction	Sterile syringes/needles (various sizes)			
	Condoms (male/female) & lubricants			
	Nasal kits / Hygiene kits			
	Sterile water ampoules / Cookers / Filters			
2. RDTs & Clinical	HIV Rapid Test Kits			
	HBV Rapid Test Kits			
	HCV Rapid Test Kits			
	HDV Rapid Test Kits			
	Lancets, alcohol swabs, gauze, band-aids			
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	Laptop / Tablet (Charged)			
	4G/5G Router / Power bank			
	Paper Consent Forms (Multi-language)			
	Participant Information Sheets			
	Clipboards & Pens			
5. Liver Assessment	FibroScan® Device (Charged)			
	FibroScan® Probes & Protective Covers			
	Ultrasound gel / Paper towels			
6. Comfort & Promo	Bottled water (For staff & users)			
	Packaged snacks / Food for users			
	Educational leaflets / Brochures (WP1)			

Prepared by: _____ **Date:** _____

Reviewed by: _____ **Date:** _____

Annex B:
Vehicle Loading Map (guidelines)

To ensure biosafety and compliance with health regulations, the mobile unit must be loaded following the "Zoning Principle".

[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 RDT kits, clean harm reduction supplies (syringes, condoms), educational leaflets, packaged food/water for users, 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)

Crucial for Quality Assurance. Must record Lot Numbers for all RDTs used to ensure traceability in case of manufacturer recalls.

Date: _____

Location(s): _____

Item Name	Manufacturer	Lot / Batch Number	Expiry Date	Qty Start	Qty End
HIV Test					
HBV Test					
HCV Test					
HDV Test					
FibroScan Probe		(Serial No.)	N/A	1	1

Notes / Discrepancies:

_____

Verified by (Logistics): _____

Verified by (Clinical Lead): _____

Annex D:
Informed Consent Form (internal)

Annex E:
Users' Information Materials

Annex F:
Incident and Deviation Log (template)

To be used for any biosafety incident, security threat, protocol deviation, or equipment failure. Must be reported to the Coordinator within 24 hours.

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)

To be completed collaboratively by the team during the 15-minute debriefing at the end of the shift (Phase 4).

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: _____