Standard Operating Procedure

Croatian Society for Liver Disease "Hepatos", Croatia

EU4health Civil Society Alliance

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Version	Date	Author	Main changes
v1.0	30/04/2026	Antonio Martin	Initial Draft
v2.0	21/09/2026	Hepatos	Creation of Croatian version
v3.0	12/10/2026	Hepatos	Hepatos-specific service model, safeguarding, consent, data protection and clinical-role clarifications
v3.0	26/10/2026	Steering Committee	Approval

List of Abbreviations

GDPR	General Data Protection Regulation
HBV / HCV / HIV	Hepatitis B / C Virus / Human Immunodeficiency Virus
ICH-GCP	International Council for Harmonisation – Good Clinical Practice
MASLD	Metabolic Dysfunction-Associated Steatotic Liver Disease
MIHC	Mobile InfoHep Centre – mobile clinic (Croatia)
PoC	Point of Care
PWUD	People Who Use Drugs
RDT	Rapid Diagnostic Test
SOP	Standard Operating Procedure
WP	Work Package

1. Purpose and Scope

This Standard Operating Procedure (SOP) establishes the procedures for planning, implementing, documenting and following up mobile outreach activities delivered by the Croatian Society for Liver Disease “Hepatos” through its Mobile InfoHep Centre (MIHC), within the MOBHOPE project. The MIHC brings preventive liver-health and viral-hepatitis services closer to people who may face barriers to accessing conventional healthcare. In cooperation with public-health institutes, hospital centres and local partners, the service model may include confidential counselling, rapid testing for HCV and HIV, non-invasive liver assessment by transient elastography (FibroScan®), health education, specialist advice and referral/linkage to care, according to the services approved and available at each activity.

The SOP covers the full process for planning, conducting, documenting and following up Society Hepatos field visits, primarily through the MIHC, under the MOBHOPE project (EU4Health 2024, Grant Agreement No. 101233203). It aims to ensure:

- Consistent, safe, person-centred service delivery in line with consortium requirements.
- Clear traceability between field activities and MOBHOPE work packages (WP1–WP5), deliverables and key performance indicators (KPIs).
- Integration of MOBHOPE screening, referral and operational research activities into routine mobile outreach without creating unnecessary barriers to access.
- Compliance with the GDPR, applicable Croatian legislation, relevant ethical requirements and approved MOBHOPE procedures.
- Preservation of low-threshold, person-centred access for people who may face barriers to conventional healthcare, including in rural community, therapeutic-community, prison and probation settings.
- Clear separation of clinical consent and research consent, protection of confidentiality, and role-appropriate involvement of healthcare professionals, Hepatos staff and volunteers.

This SOP applies to Hepatos staff, MIHC team members, collaborating health professionals, volunteers and other persons involved in preparation or delivery of mobile outreach activities, according to their assigned role.

To facilitate implementation, a shortened Croatian-language operational version may be used. It should focus primarily on the practical procedures in Sections 3, 4 and 7 and the relevant annexes. This user-friendly reference is intended for field personnel and should contain only the procedures needed for day-to-day work. This SOP remains the master document governing operational procedures, ethics and data management.

2. Normative and Documentary References

This SOP should be read in conjunction with the following documents:

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 ethics, institutional and operational procedures applicable to Croatian activities.
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. Relevant guidance from ECDC, WHO, EASL and the World Hepatitis Alliance, where applicable.
10. European Toolkit for the Elimination of Viral Hepatitis in Prisons (EuroHePP), ECDC/EUDA: https://eurohepp.ecdc.europa.eu/

Use by Hepatos: EuroHePP will be used as a practical reference tool when planning and improving hepatitis B and C prevention and screening activities in prison settings, preparing cooperation with prison healthcare services, and developing referral and linkage-to-care pathways. Where relevant, the team will consult the toolkit's sections on needs assessment and service planning; implementation across the care cascade (prevention, testing, diagnosis, treatment, monitoring, and linkage to care after release); monitoring and evaluation tools; and examples of good practice and available resources. Selected recommendations and tools may help identify gaps in existing procedures and inform improvement proposals within MOBHOPE. EuroHePP is a supporting technical resource and must be adapted to Croatian legislation, local institutional rules, approved MOBHOPE protocols, available services, and healthcare professionals' authorised scope of practice. It does not replace mandatory national procedures or clinical judgement.

3. Responsibilities

Role*	Responsibilities
MIHC / Outreach Coordinator / Team Lead for Hepatos	Plans logistics, coordinates host organisations and partners, leads the on-site team, ensures SOP compliance and escalates incidents.
Participating Specialist / authorised healthcare professional	Performs or supervises approved screening and FibroScan®exams, provides counselling, communicates results, initiates referral and oversees clinical safety.
Hepatos Staff / Outreach Worker	Participant engagement, health education, support with participant flow, documentation and follow-up within the assigned role.
Data Officer	Manages approved project data collection, data quality, pseudonymisation and GDPR-compliant handling.
Volunteer / Peer Support	Supports outreach, information and participant flow within the assigned role and supervision.
Driver / Logistics Officer	Vehicle operation, route planning, equipment loading/unloading, stock traceability and safe transport.
MOBHOPE Lead	Supervises MOBHOPE integration, reporting and coordination with consortium structures.

*One person can take on multiple roles.

4. Process Overview

Each outreach visit is organised into five consecutive phases (Phases 0–4).

PHASE 0 –PREPARATION (prior to the visit)

#	ACTIVITY / STEP	RESPONSIBLE
0.1	Identify the location and target population (e.g. community/public setting, street outreach, shelter, therapeutic community, prison, probation office or harm-reduction service)	Outreach Coordinator
0.2	Obtain municipal / prison permits and coordinate with local partners	Outreach Coordinator / Hepatos Staff
0.3	**Stock check and traceability:** Verify quantities and expiry dates of the rapid diagnostic tests (RDTs) and other consumables actually approved and planned for the visit, personal protective equipment, and cleaning/waste supplies. Record stock before and after the activity. Include PCR/point-of-care molecular testing supplies only where that testing is approved for the activity and the equipment is available.	Hepatos Staff / Logistics Officer
0.4	**Equipment check:** Check the FibroScan® device and accessories in accordance with the manufacturer's instructions and the local equipment log. Check REDCap access and device battery. Prepare current approved questionnaires and consent materials in Croatian and other relevant languages. Prepare PCR/point-of-care equipment only when this testing is included in the approved activity plan.	Hepatos Staff / Logistics Officer
0.5	**Confirm questionnaire availability:** Verify current version, and sufficient copies REDCap or paper version (if no network available at target site). This includes: a) List of beneficiaries b) Informed consent for FibroScan®exam and/or testing c) Stigma Survey	Data Manager
0.6	**Verify availability of communication and educational materials:** Leaflets, brochures, posters, digital content. Ensure MOBHOPE/EU4Health branding is visible.	Hepatos Staff / Logistics Officer
0.7	**Review activity with medical/ prison staff and local experts before departure:** Check for site-specific staff, number of beneficiaries who have signed up for the activity, local experts, treating physicians and public health experts, or protocol amendments.	Outreach Coordinator /Hepatos Staff
0.8	**Loading the vehicle:** Follow Loading protocols (heavy items low and secured; containers in designated areas and secured). Ensure MOBHOPE branding and EU flag are visibly displayed on the vehicle exterior.	Driver / Full team
0.9	**Team briefing and set-up (approximately 10 minutes):** Review roles, participant flow, safety procedures, the target population and anticipated needs. Review pending referrals with the local hospital and on site. Confirm that all team members have signed the confidentiality agreement.	Outreach Coordinator

PHASE 1 – ARRIVAL AND PARTICIPANT RECRUITMENT

#	Activity / Step	Responsible
1.1	**Site assessment and safety check:** Visual assessment in case of outdoor activities (terrain, power outlets, safety, private area for conversation/ counselling for anti-HCV reactive patients, waiting area for other beneficiaries with chairs or small table for forms/survey intake) inside prisons (lighting, power outlets, exam bed, table for testing, private area	Outreach Coordinator/ Hepatos Staff / Logistics Officer

	for conversation/ counselling for anti-HCV reactive patients, waiting area for other beneficiaries with chairs or small table for forms/survey intake, check for presence of conflict or hazards). If unsafe, relocate to alternative location or room.	
1.2	**Set up and signpost the mobile unit:** In case of outdoor activities: Park in agreed location, set up signage and external tent/shaded area. Open service side, set up clinical area, informational/educational point, and waiting/intake area. For inside prison activities: meet with safety/prison/medical staff and go over the list of signed up patients. Check patient charts	Full team
1.3	**Activate equipment and prepare the service area** Prepare the FibroScan® device, approved testing workstation and data-collection tools. Clinical tests and examinations must be performed only by appropriately qualified and authorised healthcare professionals. Prepare molecular/PCR equipment only where the activity protocol approves it and the equipment is available.	Hepatos Staff / Outreach Worker Data Manager
1.4	**Active outreach to participants:** Outreach staff and volunteers engage with the community and distribute leaflets, using word-of-mouth communication where appropriate. Communication should be low-threshold, non-judgemental and person-centred.	Outreach staff/ volunteers
1.5	**Distribute educational materials:** Leaflets, videos, infographics in local language.	Outreach staff/ volunteers
1.6	**Introduce the service** Explain the services available for that visit, that participation is voluntary and free of charge, and how confidentiality is protected. Do not promise anonymity where coded research data are collected.	Any team member
1.7	**Explain Informed Consent (IC):** Provide the approved information materials in a language the participant understands. Explain planned clinical procedures, voluntary participation, confidentiality and its limits, data use, and the right to decline any service without pressure. Answer questions and check understanding.	Outreach staff/ volunteers
1.8	**Explain the MOBHOPE research component** Explain the research purpose, including care-cascade and stigma-related data collection, and that research participation is voluntary and separate from clinical care. Obtain separate approved research consent before research questionnaires or research-specific data collection.	Outreach staff/ volunteers/ Outreach Coordinator
1.9	**Obtain the applicable consent** Authorised healthcare professional (clinical consent) / trained and designated research staff (research consent)	Outreach staff/ volunteers
1.10	**Assign a project participant code** Generate the unique code specified by the approved protocol. Do not enter names or direct identifiers in REDCap unless explicitly authorised by the approved data plan. Record the relevant consent status.	Data Officer

PHASE 2 – CLINICAL CARE AND RESEARCH ACTIVITIES

#	Activity / Step	Responsible
2.1	Brief medical and risk history: Collect only information required by the approved clinical procedure or research protocol. Sensitive questions must be asked privately, respectfully and only when relevant. Volunteers may support communication and participant flow but must not independently take clinical histories, interpret results or perform clinical procedures unless appropriately qualified and authorised.	Outreach staff/ volonteers/
2.2	Perform rapid diagnostic tests (RDTs) for HIV and HCV: Test for anti HCV and/or HIV as per request and recommendation. Record times of each test used. Read results within manufacturer's stated time window. Finger-prick blood for PCR testing when needed.	Authorised healthcare professional
2.3	**Administer questionnaires:** Research questionnaires, including the approved stigma questionnaire, are voluntary and may be administered only after the relevant research consent has been documented. Use the current approved version. Enter responses into REDCap within the period specified by the DMP/protocol; if a 72-hour target is used, keep paper forms secure until entry and verification.	Data Officer
2.4	**Perform liver elastography (FibroScan®):** Assess liver stiffness non-invasively and, where applicable, assess steatosis associated with MASLD. Record and explain the results, and provide lifestyle advice (alcohol reduction, nutrition and physical activity).	Trained and authorised FibroScan® operator / participating specialist
2.5	**Communicate test results to participant confidentially:** Private counselling. Negative: reinforce prevention, recommend vaccination (HBV) if needed, advise re-testing if ongoing risk. Positive/Reactive: activate referral pathway (Phase 3), provide immediate emotional support, advise and perform confirmatory testing if beneficiary agrees.	Participating Specialist / authorised healthcare professional
2.6	**Post-test counselling:** Harm reduction, safer practices, alcohol, tobacco, mental health resources.	Outreach staff/ Participating Specialist (Expert/Physician)
2.7	**Distribute approved health-information materials** Offer leaflets, videos or infographics in available languages, including information on liver health, viral hepatitis, prevention and access to care	Outreach staff/ volunteers
2.8	**Individual health education and counselling (where available):** Cover viral hepatitis prevention, treatment advantages, linkage-to-care pathways	Participating Specialist (Expert/Physician)
2.9	**Apply approved anti-stigma interventions (if available):** Use respectful, person-first and non-stigmatising language; protect privacy; challenge misinformation without blaming the individual; and distribute approved dignity-promoting materials. Deliver any structured intervention only as specified in the approved MOBHOPE protocol.	Peer / Outreach staff/ volunteers
2.10	**Refer participant to mental health, addiction, or social services as needed:** Issue referral, offer counselling if accepted.	Participating Specialist / authorised healthcare professional / designated staff member

2.11	**If participant agrees to follow-up:** Use the project-approved code for research records. Do not record personal contact details in REDCap unless explicitly required and authorised by the approved data plan. Any contact details needed for clinical follow-up must be stored separately in the authorised clinical system.	Data Officer

PHASE 3 – REFERRAL AND LINKAGE TO CARE

#	Activity / Step	Responsible
3.1	**Reactive screening result or clinically significant finding**	Participating Specialist / authorised healthcare professional; Hepatos staff support referral and navigation within their role
3.2	**Record referral in the Cascade-of-Care system in REDCap:** Record only the data fields authorised by the protocol/DMP, using the project code. Do not enter direct identifiers into REDCap unless explicitly authorised.	Data Manager
3.3	**Offer support before the first healthcare appointment, where needed and agreed** With the user's agreement, explain the referral pathway, help identify practical barriers and offer navigation or accompaniment where available.	Outreach staff/ volunteers/ Outreach Coordinator
3.4	**Support continuity of care** With the user's agreement, help them understand the referral or treatment plan and contact the responsible healthcare provider if needed. Diagnosis, treatment decisions, treatment administration and clinical monitoring remain the responsibility of authorised healthcare providers.	Outreach staff/ volunteers/ Outreach Coordinator
3.5	**Record cure outcome / undetectable viral load when available:** Update REDCap with treatment initiation, follow-up status.	Data Manager
3.6	**Provide information on additional social resources**	Outreach staff

PHASE 4 – VISIT CLOSURE AND DOCUMENTATION

#	Activity / Step	Responsible
4.1	**Count of participants seen, tests performed, and active referrals:** Reconcile with entries.	Outreach Coordinator / Data Manager
4.2	Complete and synchronise all pending records: Ensure that all registered service users have received the planned tests/examinations and that their results have been explained to them.	Outreach Coordinator / Data Manager
4.3	**Record attendance and materials used for activity reporting:** Training sessions, educational materials distributed	MOBHOPE Lead
4.4	**Document qualitative observations:** Barriers, incidents, improvement opportunities, user feedback. Use internal template (if available).	Any team member

4.5	**Waste management and decontamination:** Dispose of waste in designated containers/bags. Transfer to disposal containers per national regulations. Clean workstations, FibroScan® probes, and all reusable surfaces with approved disinfectant.	Outreach Coordinator / Outreach Worker
4.6	**Inventory and restock consumables:** Count testing kits, educational/informational materials. Record used vs. remaining stock in Test Log. Flag discrepancies, damaged items, or near-expiry stock for replacement. Prepare replenishment request for next session.	Logistics Officer / Outreach Worker
4.7	**Team debriefing (~15 min):** Share findings, difficulties, improvement suggestions.	Outreach Coordinator
4.8	**Share an activity summary with the host organisation and MOBHOPE Lead as required** Report aggregate or appropriately de-identified activity information, referrals and operational issues. Do not disclose an individual's test result or health information to custodial, probation or other host staff unless legally authorised and necessary for care, with the user's consent where required.	Outreach Coordinator
4.9	**Update the risk register if a new incident is identified** Record the incident in the designated project register and notify the relevant project lead in accordance with the incident-management procedure.	Outreach Coordinator / COO
4.10	**Archive consent forms securely** Store paper consent forms in a secure, access-restricted archive. Keep any code key or link to identifying information separately, with access limited to authorised personnel.	Outreach Coordinator / Data Manager
4.11	**Maintain and store equipment** Clean and store FibroScan® equipment in accordance with the manufacturer's instructions. Secure any approved molecular-testing equipment, shut down the laptop/tablet, log out of REDCap and recharge devices as required.	Hepatos Staff / Outreach Worker Data Manager

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, 1.5, 2.7, 2.8	D1.1–1.3 / MS1.1–1.3
WP2 – Cascade of Care & Operational Research	0.4, 0.5, 2.2–2.4, 3.1–3.6, 4.1–4.3	D2.1–2.4 / MS2.1–1.4
WP3 – Stigma & Human Dignity	1.7–1.8, 2.9, 4.4	D3.1, D3.2, D3.4, D3.5 / MS3.1–3.4
WP4 – Standardisation & Quality Improvement	0.7, 4.7–4.9	D4.2–4.4 / MS4.1–MS4.6
WP5 – Coordination & Evaluation	0.2, 0.7, 0.9, 1.8, 1.10, 4.1, 4.6, 4.8, 4.9	D5.1–5.5 / MS5.1–MS5.6

6. Ethical Considerations and Data Protection

6.1 General Principles

All MIHC services are voluntary, free of charge and delivered in a person-centred, non-judgemental and non-stigmatising manner. Access to routine services must not depend on willingness to take part in MOBHOPE research. Clinical care and research participation must be explained as separate choices, and refusal or withdrawal from research must not affect access to services. Use only the minimum data necessary for each purpose. Research data entered in REDCap must use the project-approved participant code and must not include names or direct personal identifiers. Coded data may remain personal data under the GDPR and must not be described as anonymous unless irreversible anonymisation has been verified. All personnel must follow applicable ethical approvals, national requirements, the Declaration of Helsinki and ICH-GCP where applicable.

In prisons, probation offices and other institutional settings, participation must be voluntary and must not affect a person's legal status, privileges or access to other services. Where feasible, offer information, consent discussions and communication of results in a private setting. Share individual health information with institutional staff only where lawful and necessary for care, and in accordance with the participant's consent and applicable confidentiality rules.

6.2 Informed Consent

Before undergoing a FibroScan® examination and/or testing for viral hepatitis and HIV, each user must be informed of the purpose and procedure, potential benefits and risks, and data confidentiality. The user must sign an informed consent form before the examination, testing and/or survey participation/data collection, confirming that they have understood the information provided and voluntarily agree to the procedure. Consent to participate in the research/survey is incorporated into the standard forms used by the Society Hepatos and users are informed of the purpose and intended use of the collected data before signing.

Users must be given the opportunity to ask questions and withdraw from the procedure at any time. Test results are communicated to users individually, together with information on further steps and options for linkage to healthcare. Personal and health data are processed in accordance with applicable data protection regulations.

The purpose, voluntary nature, use of data, limits of confidentiality, and options for withdrawing consent must be explained in language the participant understands, allowing sufficient time for questions and confirmation of understanding.

For minors or adults who require a legal representative, the relevant Croatian legislation and approved ethical procedures apply. Oral consent or consent obtained in the presence of a witness is permitted only where explicitly allowed by the approved protocol and applicable regulations.

6.3 Data Management

Research data must be collected and managed in the approved REDCap environment in accordance with the MOBHOPE Data Management Plan (DMP), approved study documents and the GDPR. Access must be role-based and limited to authorised users.

Clinical records remain within the responsible healthcare provider's approved record system and are managed under applicable national and institutional rules. Store paper consent forms and any documents containing identifiable information securely, separately from research data where required, and restrict access to authorised personnel. Use individual accounts, protect devices and log out after each session. Do not collect names, national identification numbers or other direct identifiers in REDCap unless the approved data-collection plan explicitly requires them. Follow the DMP for retention, deletion, data sharing and incident reporting. Do not promise that data will be deleted on request where legal, ethical or approved research requirements may require retention; refer requests to the designated data-protection contact. Photographs or recordings of service users require separate, specific consent and must comply with local rules and project requirements.

7. Incident Management and Emergency Situations

	Response Protocol
Urgent clinical finding or result requiring prompt assessment	The responsible healthcare professional assesses urgency and follows the applicable local clinical/emergency pathway. Arrange emergency care when clinically indicated; do not apply a fixed referral deadline to all positive screening results.
Participant in crisis (mental health, self-harm risk)	Activate local safeguarding protocol. Do not collect research data at that moment. Offer accompaniment.
Refusal of a test or withdrawal from research	Respect the decision without pressure and continue to offer other services the user accepts. Handle previously collected data according to the approved consent wording, GDPR, DMP and applicable retention requirements; do not promise automatic deletion where retention is required.
Data security incident (device lost, data breach)	Notify Data Manager and COO within 2 h. Follow DMP breach protocol.
Equipment failure (FibroScan®, GeneXpert, etc.)	Stop using equipment that may be unsafe or unreliable, document the incident and notify the Outreach Coordinator. Use an alternative only if approved, available and within the relevant professional's authorised scope.
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 24 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 compares the usual activities undertaken during a mobile-unit outreach visit with the additional activities introduced by MOBHOPE, identifying the relevant work package for each addition.

Area	Standard Practice	Added by MOBHOPE (WP)
Outreach & education	Basic outreach by peer workers; verbal information about services.	Systematic multilingual educational materials (WP1); structured training sessions with pre/post-test.
Informed Consent	Separate, voluntary consent for operational research and stigma assessment, in addition to the applicable consent for clinical care (WP2/WP3/WP5).	Separate, voluntary consent for operational research and stigma assessment, in addition to the applicable consent for clinical care (WP2/WP3/WP5).
Diagnostic testing	Rapid tests for HIV and HCV, with other testing only where approved and available.	MOBHOPE adds structured documentation and referral/cascade-of-care monitoring; FibroScan® liver elastography is provided as part of the MIHC service model. Molecular/PCR testing is conditional on the approved activity protocol and local availability.
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 in collaboration with local expert/treating physicians; target time diagnosis→evaluation < 30 days; peer educator accompaniment (WP2).
Documentation	Entry in local clinical record.	Structured counselling on next steps and referral support, with research data recorded under the approved project code; any clinical follow-up contact details are kept separately in the authorised clinical system (WP2/WP5).
Quality & continuous improvement	Informal team debriefing.	Structured visit report within 30 days; 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:
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 B:
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					
HCV Test					
PCR / molecular test (if approved and used)					
FibroScan Probe		(Serial No.)	N/A	1	1

Notes / Discrepancies:

_____

Verified by (Logistics): _____

Verified by (Clinical Lead): _____

Annex C:
Informed Consent Form (FibroScan® exam and testing; internal)

Annex D:
Information Materials for Service Users (internal)