

5th HEPATITIS C
TECHNICAL ADVISORY
GROUP
TAG Meeting

HCV TREATMENT INTEGRATION IN HARM REDUCTION SETTINGS

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Background

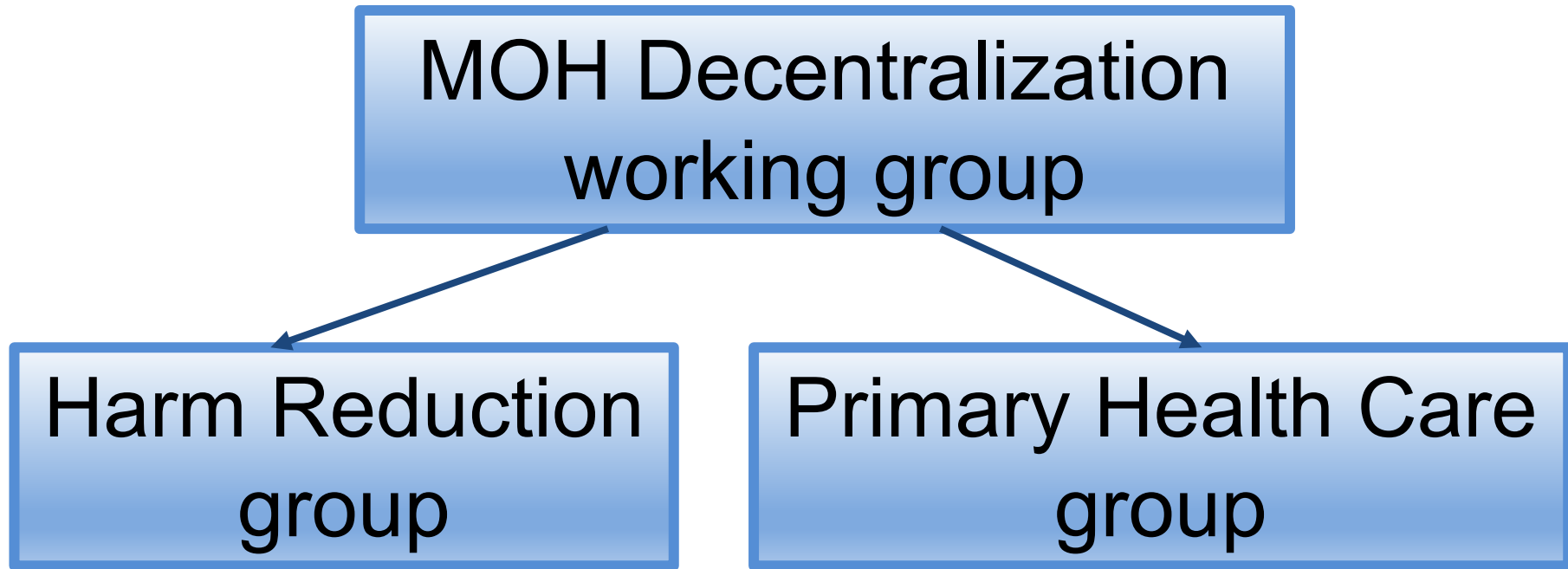
- People who inject drugs (PWID) represent a major share of hepatitis C burden in Georgia
- Ensuring access to treatment for HCV+ PWID is needed to reduce transmission and reach elimination goals
- Integration of treatment services into Harm Reduction (HR) settings could facilitate access for HCV infected PWID.



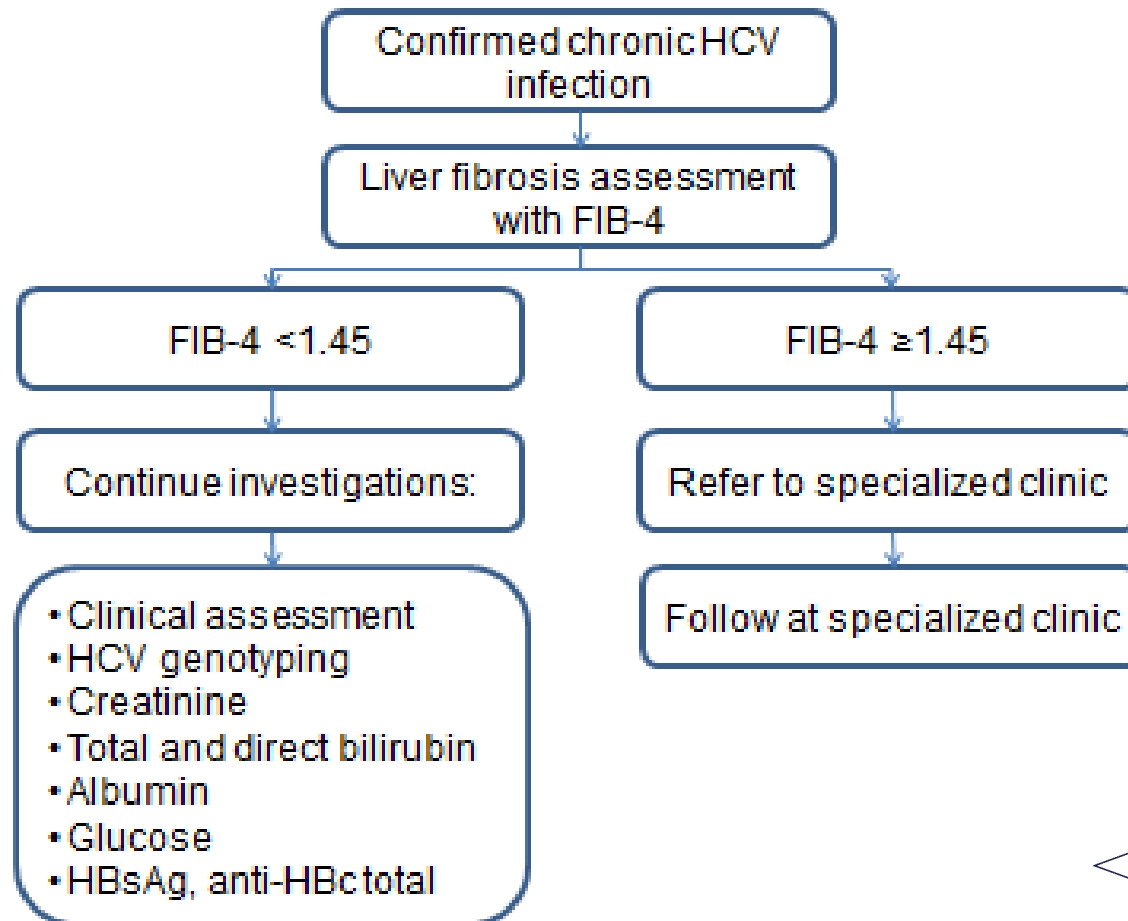
Hepatitis C treatment outcome among people with history of drug use

- Initial concerns among medical personnel and policy makers that PWID would have poor treatment compliance that would lead to poorer outcomes.
- Studies estimating SVR rates among PWID compared to those without a history of injection drug use.
- Treatment outcomes among PWID were similar to non-PWID, suggesting that treatment adherence may be sufficiently similar to achieve reasonably comparable clinical outcomes.

HCV treatment decentralization



Simplified algorithm of pre-treatment diagnostics



Simplified treatment monitoring algorithm at HR centers

Simplified treatment monitoring procedures				
Measurements	Treatment Duration (weeks)			After treatment completion (weeks)
	4	8	12	12 or 24
Clinical assessment	X	X	X	X
HCV RNA quantitative				X
Complete blood count	X*	X*	X*	
ALT	X	X	X	

* only for patients receiving Ribavirin containing regimens



Pilot project of HCV treatment integration with HR services

- Integration of HCV treatment with HR services in 4 centers (*Funded by CDC*)
- From Jan 2018, FIND project assessing effectiveness of models of HCV viremia testing for confirmation and cure among people who inject drugs
- In arm one of this study, several HR centers perform on-site HCV RNA testing using GeneXpert platform to improve linkage to care among PWID



PWID receiving integrated care services

Name of Center	N of patients								
	Total screened	Total anti HCV positive	Viremia tested	Total RNA/cAg positive	FIB4 Tested	Referred (N; %)	started treatm.	SVR tested	SVR rate
New Vector, Tbilisi	1058	62 (5.8%)	75	67(89.3%)	93	24 (25.8%)	66	21	95.2%
Addiction management center, Tbilisi	83	26 (31.3)	39	24(61%)	27	5(18.5%)	18	10	90.7%
Union Imedi, Batumi	332	103 (31%)	187	146 (78%)	109	43 (39.7%)	45	14	100%
Xenoni, Zugdidi	808	153 (18.9%)	390	342 (87.6%)	199	65 (32.6 %)	110	31	96.7%
Total	2281	344 (15.1%)	691	579 (83.8%)	428	137 (32%)	239	76	73 (96.1%)

Challenges during implementation of pilot project

- The treatment integration process took longer than previously expected and planned
- The MOH regulatory agency requested multiple re-arrangements at HR sites to meet regulations for treatment integration
- Because these sites were not operating as medical facilities before HCV treatment, starting treatment process was challenging
- Several steps of adjustments were needed to meet all requirements
- Cases of personnel replacement and retraining needed
- Lessons learned during this process will be very important for further enrollment of the new HR sites in HCV treatment program.



Patient satisfaction survey

- Conducted among the patients treated at participating HCV integrated care sites and comparator clinics treating HCV patients but not providing HR services
- The survey instrument was a self-administered questionnaire specifically designed for this study
- Study participants were selected by consecutive sampling at each study site
- Participation in the survey was voluntary

Four comparator clinics

- Neolab
- Infectious diseases clinic
- Hepa
- Mrcheveli



Patient satisfaction survey

- In total, 358 patients participated in the survey
- Almost half (48%) received HCV treatment at the comparator clinics not providing HR services.
- The remaining participants were treated at pilot program centers with integrated HCV treatment

Patient satisfaction survey

Characteristic	Pilot program centers		Comparator clinics		P-value
	N	%	N	%	
Facing barriers regarding enrollment in HCV elimination program					
No	162	88.0	147	84.5	0.3
Yes	22	11.9	27	15.5	
Received comprehensive information about HCV treatment and side effects					
Yes, completely	181	98.4	164	94.3	0.01
Partially/No	3	1.6	10	5.8	
Your confidentiality was protected during HCV treatment					
Yes, completely	180	97.8	166	95.4	0.2
Partially/No	4	2.2	8	4.6	

Patient satisfaction survey

Characteristic	Pilot program centers		Comparator clinics		P-value
	N	%	N	%	
Attitude from the doctor					
Satisfactory	177	96.2	170	97.7	0.3
Partially satisfactory	7	3.8	3	1.7	
Attitude from the nurses					
Satisfactory	174	94.5	172	98.9	0.6
Partially satisfactory	10	5.5	2	1.1	
Will you recommend your family member/relative/friend to be enrolled in HCV elimination program?					
Yes	184	100	174	100	
No/Not sure	-	-	-	-	

Patient satisfaction survey

Average time from registration to administration of first dose of HCV treatment medication	Pilot program centers		Comparator clinics		P-value
2 weeks	79	42.9	8	4.6	<0.0001
1 month	78	42.4	109	62.6	
2 months	20	10.9	39	22.4	
>2 months	7	3.8	18	10.3	
Average time of waiting for receiving medication at medical facility					
15 min	173	94.0	161	92.5	0.4
30 min	10	5.4	13	7.5	
60 min	1	0.5	-	-	

Major outcomes of pilot project

- Overall referral rate of patients from HR center to specialized clinics – 32%
- Integration of hepatitis C care with HR services is likely feasible
- It is highly acceptable for personnel providing HR services.
- Patient satisfaction rate is high
- Major challenge is complicated, non-standardized regulatory requirements of MOH for approval of treatment site



NSP program sites in Georgia



Next steps: Phase 2 of piloting

- 4 new sites were selected for enrollment into HCV integrated treatment in Spring, 2019
 - Tbilisi (Hepa +)
 - Akhaltsikhe HR center
 - Gori HR center (Step to the future)
 - Telavi HR center
- First introductory meeting was held with administration of newly selected centers
- Re-arrangement of sites to meet MOH regulations for HCV treatment integration was completed
- Approval from MOH to start treatment has been pending since April 20, 2019

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- TEPHINET
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- GHRN
- Participating clinics in patient satisfaction survey (NeoLab, Mrcheveli, Hepa, ID hospital)