Opportunistic treatment of HCV infection (OPPORTUNI-C): Study protocol for a pragmatic cluster randomized trial of immediate versus outpatient treatment initiation among hospitalized people who inject drugs

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Disclosures

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SELIHEP | Norwegian center for elimination of hepatitis C

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Background and aim

- New models of HCV care are needed to reach people who inject drugs (PWID)
- PWID are often hospitalized for inpatient treatment of various conditions
  - drug-dependency disorders, intoxications, psychosis, soft tissue infections, deep venous thrombosis, endocarditis, liver disease, etc
- Hospitalizations are not sufficiently utilized for HCV testing and treatment
- Standard of care referral to outpatient treatment often results lack of retention in the cascade of care
- **Hypothesis**: Hospitalizations represent opportunities to efficiently engage PWID in HCV treatment
- **Primary aim:** Evaluate the efficacy of opportunistic and immediate treatment of HCV infection among PWID admitted for inpatient care in departments of internal medicine, addiction medicine, and psychiatry

Pragmatic clinical trial: Mimics usual practice

Representative - generalizable - affordable

- **Recruitment from ordinary clinical practice**
- **Wide inclusion criteria, few excluded**
- **Clinical infrastructure, few research specific assessments**
- **Flexible intervention delivery**
- **Clinically relevant endpoints**
- **Collection of readily available data from the patient files**
- **Analysis according to the principles of intention to treat**

Study design: Stepped wedge cluster randomized trial

		STEPS								TOTAL
		#1	#2	#3	#4	#5	#6	#7	#8	
CLUSTERS	#1	4	4	4	4	4	4	4	4	32
	#2	4	4	4	4	4	4	4	4	32
	#3	4	4	4	4	4	4	4	4	32
	#4	4	4	4	4	4	4	4	4	32
	#5	4	4	4	4	4	4	4	4	32
	#6	4	4	4	4	4	4	4	4	32
	#7	4	4	4	4	4	4	4	4	32
TOTAL		28	28	28	28	28	28	28	28	224

Primary outcome

- Treatment completion (dispension of final DAA pack)

Inclusion criteria

- HCV RNA positive
- Age > 18 years
- Admitted for inpatient care
- Signed informed consent

Exclusion criteria

- Unable or unwilling to consent
- Ongoing HCV treatment

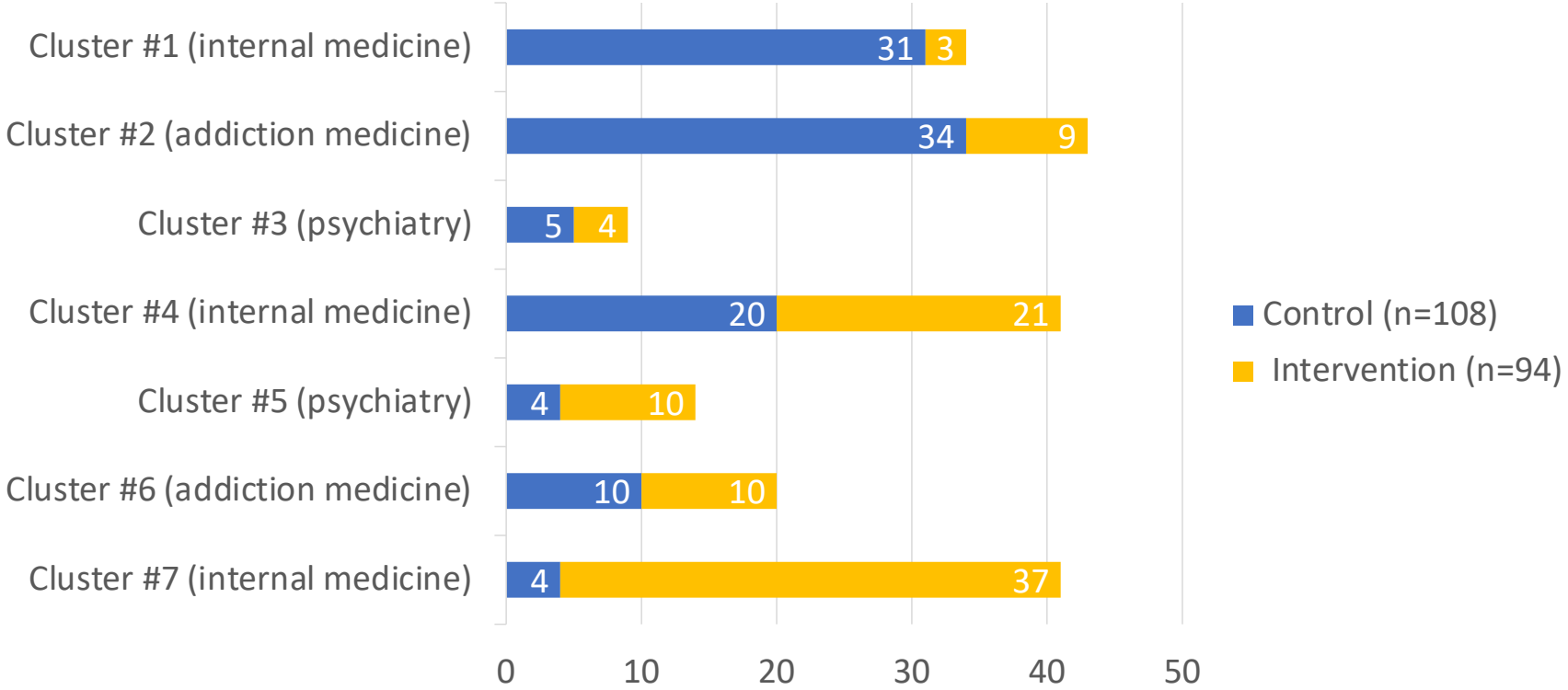
Sample size

- 224 patients

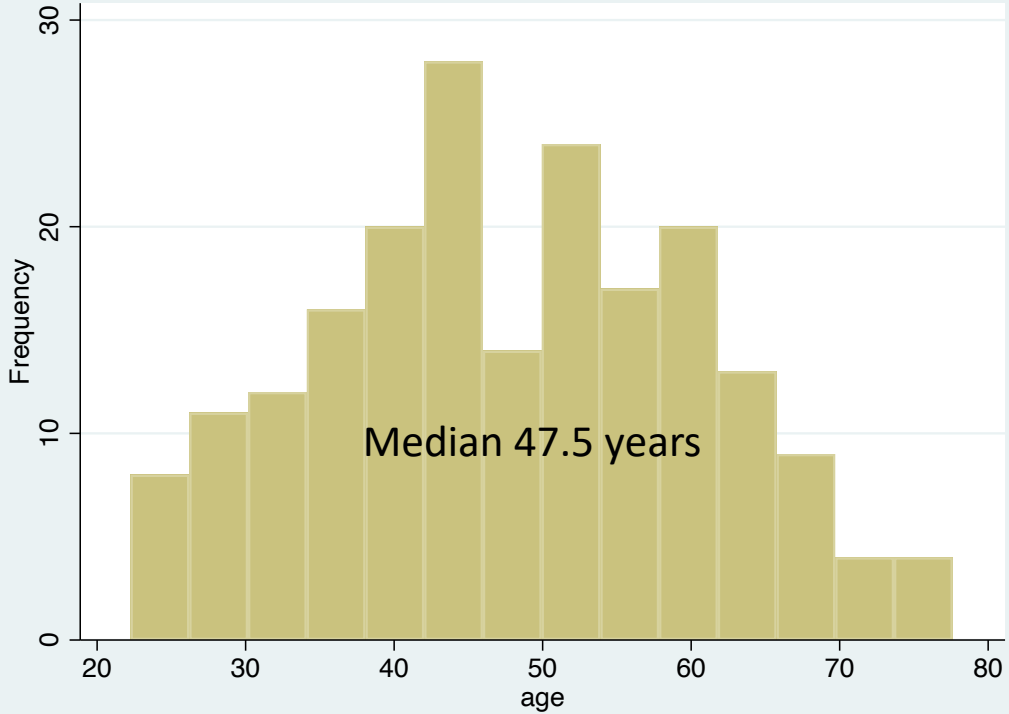
Control (=outpatient treatment)

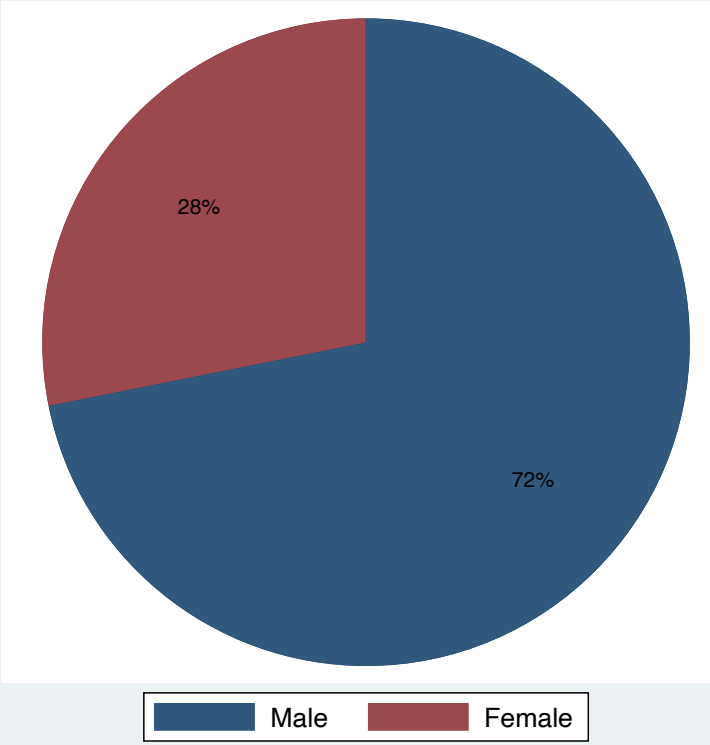
Intervention (=immediate treatment)

Status for inclusion by September 17 2021:
202 of 224 patients included



Age and gender among included participants





Conclusions

- Participant recruitment will be completed by October 2021
- The results will inform HCV elimination efforts locally and internationally
- The model of care could replace current standard of care for hospitalized individuals
- Challenges
  - Informed consent may introduce selection bias
  - Short hospital stays: HCV RNA testing not performed, results available after discharge
  - Changing epidemiology: Different treatment arenas and declining prevalence
- Strengths
  - Representative and relatively unselected population: «Real world evidence»
  - Robust study design: Logistically, politically, statistically