ROAD TO HCV ELIMINATION IN HIV/HCV COINFECTED PATIENTS BY SCREENING AND UNIVERSAL ACCESS TO DAA: BASELINE DATA FROM THE FIRST SCREENING OF NOCO (NO COINFECTION) STUDY

PE 37/30

A. d'Arminio Monforte[1], A. Tavelli[2], A. Cozzi-Lepri[3], S. Cicalini[4], A. Calcagno[5], R. Rossotti[6], E. Grilli[4], F. Bai[1], E. Quiros-Roldan[7], E. Girardi[8], A. Antinori[4], M. Puoti[6]
for the NoCo Study of the Icona cohort

1 ASST Santi Paolo e Carlo, University of Milan, Clinic of Infectious and Tropical Diseases, Dept of Health Sciences, Milan, Italy, 2 Icona Foundation, Milan, Italy, 3 Institute for Global Health, University College of London, London, UK, 4 Clinical Division of HIV/AIDS, INMI "L. Spallanzani" IRCCS, Rome, Italy, 5 Unit of Infectious Diseases, Department of Medical Siences, Amedeo di Savoia Hospital, University of Torino, Torino, Italy, 6 ASST Grande Ospedale Metropolitano Niguarda Division of Infectious Diseases, Milan Italy, 7 Department of Infectious and Tropical Diseases, University of Brescia, ASST Spedali Civili Hospital, Brescia, Italy, 8 Clinical Epidemiology Unit, INMI "L. Spallanzani" IRCCS, Rome, Italy

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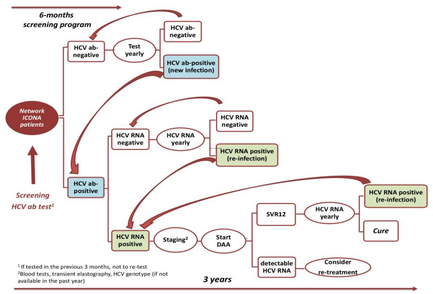
Contact Information
Antonella d'Arminio Monforte
antonella.darminio@unimi.it

BACKGROUND & NoCo STUDY

- Major barriers to HCV elimination in HIV population: (i) proportion of individuals unaware of their HCV infection, (ii) costs of DAA treatments, (iii) high reinfection rates among high risk population like men sex with (MSM) and persons who inject drugs (PWID) and (iv) lack of targeting for vulnerable groups (migrants, homeless, prisoners)
- The NoCo study collects data on HCV screening and anti-HCV treatment, involving 40 Italian clinical sites, of the ICONA Network, aiming to cover 65.000 patients (≈50% of PLWH in Italy)

Figure 1: Flowchart of 3-year HCV screening and DAA treatment program of NoCo Study



¹ If tested in the previous 3 months, not to re-test
²Blood tests, transient elastography; HCV genotype (if not available in the past year)

- The general aim of NoCo Study, is to obtain HCV elimination in the HIV/HCV co-infected population in Italy over a 3-year period of increased HCV testing, and extensive DAA treatment.
- Each center enrols all HIV-positive patients accessing care in a 6-months time window,

starting on a different date according to site activation date. Enrolled patients are tested for HCV Ab and eventually for HCV RNA. Those resulted to be HCV RNA positive are treated with available DAA until exhaustion. Yearly HCV Ab and HCV RNA tests, are guaranteed for HCV Ab negative and HCV Ab positive patients respectively, in order to promptly detect new/re-infections.

AIMS

The aims of this analysis of the NoCo study are:

- To estimate, the overall prevalence of HCV co-infection at study entry (first NoCo screening).
- To identify prevalence and predictors of HCV seroconversions at first NoCo screening .
- To estimate the prevalence of chronic active HCV infection (ie. HCV RNA positive): at study entry, at second NoCo screening, overall at last available HCV-RNA screening, and according to calendar year.

DESIGN AND METHODS

STUDY POPULATION

- Subjects included are those screened for HCV from September 2017 to September 2019 and belonging to the centers of the Icona network, participating to NoCo study. Patients have been included regardless of their previous HCV status or other characteristics.

STATISTICAL ANALYSIS

- Observational cohort study
- Outcomes:
  -Prevalence of HCV Ab-positive at enrolment in NoCo
  -HCV seroconversions at study entry (transition from HCV Ab negative, at last HCV Ab test done before study entry, to HCV Ab positive at first NoCo screening) and predictors using unadjusted and adjusted logistic regression model.
  -Prevalence of chronic HCV infection (i) at first NoCo screening, at second screening using an (ii) on-treatment (OT) approach and (iii) an intention-to-treat analysis (ITT) [details in Table 3]. Prevalence of chronic HCV infection has been also evaluated (iv) according to calendar year: from the year of first NoCo screening to the year of last available follow-up (FU). Last observation carried forward (LOCF) method is used for imputing missing HCV RNA/year of FU or for missing HCV RNA at second screening as shown in Table 3.

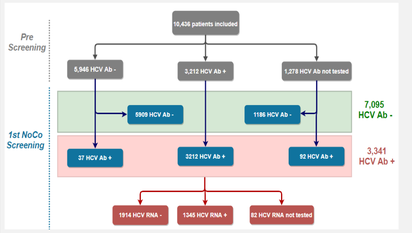
RESULTS

- 10,436 patients were screened for HCV and have been included in the NoCo Study. 9,158 subjects (87.8%) had available anamnestic data on HCV serology before enrolment with a median of 2.4 years (IQR: 1.1-5.8) from last known HCV Ab negative test to first NoCo screening and of 12.5 years (4.0-21.0) for HCV Ab positive patients.
- Before enrollment 5,946 patients were HCV Ab negative (57.0%), 3,212 were HCV Ab positive (30.8%) and 1,278 (12.2%) had an unknown HCV serostatus [Fig.1].
- At first NoCo screening 68.0% of patients (n=7,095) were HCV Ab negative and 32.0% (n=3,341) where HCV Ab positive [Fig.1]
- Demographic characteristics according to first NoCo screening are shown in Table1

Table 1: Main baseline characteristics of total population and according to the first NoCo screening result

	HCV Ab negative N=7,095 (68.0%)	HCV Ab positive N=3,341 (32.0%)	p-value	Total N=10,436
Age, Median (IQR)	46 (37-54)	54 (49-57)	<.001	50 (41-56)
Gender, Female n(%)	1541 (21.7%)	824 (24.7%)	0.001	2365 (22.7%)
Nationality, Italian, n(%)	5520 (77.8%)	3155 (94.4%)	<.001	8675 (83.1%)
Mode of HIV Transmission, n(%)			<.001	
Heterosexual	2783 (39.2%)	424 (12.7%)		3207 (30.7%)
PWID	196 (2.8%)	2308 (69.1%)		2504 (24.0%)
MSM	3084 (43.5%)	401 (12.0%)		3485 (33.4%)
Other/Unknown	1032 (14.5%)	208 (6.2%)		1240 (11.9%)
On ART, n(%)	5804 (81.8%)	3214 (96.2%)	<.001	9018 (86.4%)
Years from HIV diagnosis, median (IQR)	6.7 (2.3-13.1)	22.8 (13.5-30.5)	<.001	10.1 (3.6-20.7)
Year 1st NoCo Screening, n(%)			<.001	
2017	157 (2.2%)	113 (3.4%)		270 (2.6%)
2018	4393 (61.9%)	2572 (77.0%)		6965 (66.7%)
2019	2545 (35.9%)	656 (19.6%)		3201 (30.7%)

Figure 2: Flowchart first NoCo screening



92/1,278 (7.2%) participants with unknown HCVAb status before enrollment, resulted HCV Ab pos [Fig.2]:

-4.6% for MSM
-50.0% for PWID
-4.3% for Hetersexual
-8.3% for Other/Unknown

- 37/5,946 (0.6%) patients HCV Ab negative before NoCo screening had an HCV seroconversion [Fig.2]. Median years from last HCV Ab screening to detection of seroconversions was 3.5 years (IQR: 1.0-5.4).
- The only independent predictor of HCV seroconversion was being PWID (AOR vs. Heterosexual=7.58; 95%CI: 2.76-20.78) [Table2].

Table 2. Predictors of HCV seroconversions at first screening using a logistic regression model (Adjusted for all the factors showed in table*)**

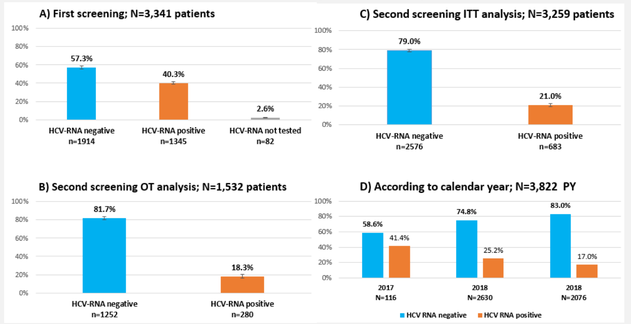
	OR (95%CI)	p-value	AOR (95%CI)	p-value
Gender Male (vs. Female)	1.45 (0.60-3.48)	0.406	1.72 (0.63-4.71)	0.280
Mode of HIV Transmission				
Heterosexual	1.00		1.00	
PWID	8.94 (3.18-21.10)	**<.001**	7.58 (2.76-20.78)	**<.001**
MSM	1.22 (0.56-2.67)	0.606	0.97 (0.40-2.37)	0.959
Other/Unknown	0.91 (0.29-2.87)	0.879	0.79 (0.25-2.55)	0.699
Age, per 10 years older	0.80 (0.61-1.07)	0.142	0.75 (0.53-1.07)	0.114
Italian (vs. Non- Italians)	1.38 (0.66-2.86)	0.381	1.52 (0.68-3.22)	0.321
Yrs. from HIV Diagnosis, per 10 yrs longer	1.10 (0.72-1.66)	0.642	1.29 (0.80-2.08)	0.289

- 3,259 of 3,341 HCV Ab positive patients at first screening were screened for HCV RNA; 1,438/3,259 had a second HCV RNA test (44.1%) in a median follow-up of 0.6 years (IQR: 0.4-0.9).
- The remaining 1,821 patients with still not available second screening are classified using the following definitions for the ITT and OT analysis [Table 3]

Table 3. Categorization for 2nd screening ITT and OT analysis in subjects with 2nd HCV RNA test available (A), and without 2nd HCV RNA test available (B)

	N Patients	Categorization ITT	Categorization OT
(A) HCV RNA 2nd screening available	1,438	Result HCV RNA 2nd screening	Result HCV RNA 2nd screening
(B) HCV RNA 1st screening pos, DAA not yet started, on active FU	94	LOCF	LOCF
HCV RNA 1st screening pos, DAA started, still to be reached week12 post EOT	115	LOCF	Excluded
Death after HCV RNA 1st screening	10	LOCF	Excluded
Moved to other center/country or known lost to FU	5	LOCF	Excluded
Last available FU=1st NoCo screening	1,597	LOCF	Excluded

Figure 3. HCV RNA status at first screening (A), at second screening OT (B), at second screening ITT (C) and according to calendar year (D)



CONCLUSIONS

- **At study entry, PWIDs were the group at highest risk of new HCV infection in Italy. Circulation of HCV among MSM appears lower than in other European countries**
- **Overall, 79% of HCV patients have already achieved viral eradication, with an increase from 59% to 83% from 2017 to 2019.**

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Hepalcona Study Group: A Costantini (Ancona); L Monno, A Saracino, E Milano (Bari); F Maggiolo, C Suardi (Bergamo); G Verucchi, L Badia (Bologna); F Castelnuovo, C Minardi (Brescia); B Menzaghi, C Abeli (Busto Arsizio); A Pan, S Lorenzotti (Cremona); L Sighinolfi, D Segala (Ferrara); P Blanc, V Vichi (Firenze); G Cassola, C Viscoli, A Alessandrini, N Bobbio, G Mazzarello (Genova); M Lichtner, A Carraro (Latina); P Bonfanti, C Molteni (Lecco); A Chiodera, M Maracci (Macerata); A d'Arminio Monforte, M Galli, A Lazzarin, M Puoti, A Castagna, F Bai, MC Moioli, L Milazzo, C Uberti-Foppa (Milano); C Mussini, C Puzzolante (Modena); C Migliorino, G Lapadula (Monza); V Esposito, G Borgia, A Maddaloni, I Gentile (Napoli); A Cascio, M Trizzino (Palermo); D Francisci, C Pallotto (Perugia); G Parruti, F Sozio (Pescara); G Magnani, M Ursitti (Reggio Emilia); A Antinori, V Vullo, G Taliani, R Acinapura, A Vergori, A Mondi, MM Plazzi, G Siccardi, M Rivano Capparucia (Roma); G Madeddu, P Bagella (Sassari); B Rossetti, G Zanelli (Siena) P Caramello, GC Orofino (Torino).
NoCo Study Group: A Costantini, A Giacometti, O Cirioni (Ancona); G Monno, A Saracino (Bari); F Maggiolo, C Suardi (Bergamo); E Quiros Roldan C Minardi (Brescia); B Menzaghi, C Abeli (Busto Arsizio); L Chessa, F Pes (Cagliari); BM Celesia, D Scuderi (Catania) ; A Pan, P Brambilla (Cremona); M Lichtner, A Carraro (Latina); A Chiodera, P Milini (Macerata); G Nunnari, G Pellicanò (Messina); A d'Arminio Monforte, M Puoti, C Uberti Foppa, M Galli, C Moioli, G Morsica, R Curetti, A Giacomelli (Milano); V Esposito, V Rizzo (Napoli); G Magnani, R Corsini (Reggio Emilia); A Antinori, R Cauda, E Grilli, M Andreoni, E Teti, S Lamonica (Roma); A Cascio, M Trizzino (Palermo); D Francisci, E Schiaroli (Perugia); G Madeddu, A De Vito (Sassari); B Rossetti (Siena); C Di Giuli (Terni); G Starnini, A Ialungo (Viterbo).

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