

*Congresso Nazionale*  
**AGGIORNAMENTI INFETTIVOLOGICI:**  
**HIV, EPATITI & .....**  
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**SCREENING DI HCV NELLE POPOLAZIONI SPECIALI:  
DIFFICOLTA' DI UNA PRESA IN CARICO APPROPRIATA E DIFFERENZIATA**



Anna Linda Zignego

# Background

- The health issue (including health inequality) in reference to particular population groups (i.e. homeless, underprivileged people, and migrants) is of growing interest for the public health
- Screenings for infectious diseases are essential in improving the living conditions of the vulnerable and will aid in ceasing their spread throughout the community



Sharma S et al. J Hepatol 2015

# Background

It's Time to  
Eliminate  
Hepatitis C



- The advent of DAA led to the establishment of elimination targets by 2030 (**WHO targets**: diagnosis of 90% HCV infected and treatment of 80%) [*WHO Global Health Sector Strategy Towards Ending Viral Hepatitis. 2016* and *WHO Regional Office for Europe. Action Plan for the Health Sector Response to Viral Hepatitis in the WHO European Region. 2017*]
- **In Italy** free-of-charge DAA treatment has been available since **2014** and **restricted to individuals with severe disease**
- Expanded access to DAA was achieved in **2017** [*Italian Medicine Agency. Redefinition of Treatment Criteria for Chronic HCV Therapy*]
- **In Tuscany**, a triennial action plan was launched in **2018** with the aim of increasing treatment coverage and contributing to the elimination of HCV in the region [*DGR397/2018*].
- In **2021**, a **national one-time screening** program was launched [*DGRT 1538/2022 "Launch of a free screening programme to prevent, eliminate and eradicate the hepatitis C virus, in implementation of art. 25-sexies of D.L.n. 162/2019. Approval of the project"*] targeting **people in prison, PWUD** and the **1969-1989 birth cohorts**

# Background



- Underserved populations represent the key populations according to WHO 2030 goals for HCV micro-elimination
- Previous studies assessing the seroprevalence of anti-HCV and HBsAg in underprivileged and homeless people used similar screening approaches but the results are different in terms of positivity percentage, risk factors and linkage to care strategies, since they depend on local social contexts
- Most data come from prevalence screening conducted in the USA, in different regions and cities and in different kind of shelters

# Background

|                         | Country           | Population features                                       | N°                                                               | antiHCV+ | HBsAg+                            | Main risk factors                                                                                                                        |
|-------------------------|-------------------|-----------------------------------------------------------|------------------------------------------------------------------|----------|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| Sherriff et al, 2003    | Oxford, UK        | homeless                                                  | 98                                                               | 26.5%    | -                                 | ID use; sharing tools for drug injection; age                                                                                            |
| Stein et al, 2004       | California, USA   | homeless men                                              | 198                                                              | 52.5%    | -                                 | ID use; length of homeless period                                                                                                        |
| Inciardi et al, 2006    | Florida, USA      | female sex workers                                        |                                                                  | -        | 53.3% anti HBc Ab                 | ID use; age; prostitution                                                                                                                |
| Sahajian et al, 2007    | Lyon, FR          | underprivileged people                                    | 944                                                              | 4.7%     | -                                 | -                                                                                                                                        |
| Schwarz et al, 2008     | Baltimore, USA    | homeless families living in shelter or transitional house | 336 children<br>168 caregivers                                   | -<br>19% | -                                 | ID use                                                                                                                                   |
| → Tafuri et al, 2010    | Bari, IT          | migrants                                                  | 529                                                              | 4.5%     | -                                 | -                                                                                                                                        |
| Gelbert et al, 2012     | California, USA   | homeless                                                  | 534                                                              | 26.7%    | 2.9% HBsAg+<br>30.9% anti-HBc Ab+ | ID use; length of homeless period                                                                                                        |
| Strehlow et al, 2012    | USA               | homeless                                                  | 387                                                              | 31%      | -                                 | ID use; incarceration; tattoos<br>age; lack of family life; ID use; number of sexual partners and sexually transmitted infection history |
| Pereira et al, 2013     | Central Brazil    | homeless men                                              | 481                                                              | 2.5%     | -                                 | -                                                                                                                                        |
| → Prestileo et al, 2013 | Palermo, IT       | sex workers                                               | 239                                                              | 0.4%     | -                                 | -                                                                                                                                        |
| Nyamathi et al, 2013    | California, USA   | gay and bisexual young homeless                           | 267                                                              | -        | 52% anti-HBs Ab+                  | ID use                                                                                                                                   |
|                         |                   |                                                           | <b>HCV test</b><br>242,740<br>homeless<br>5,424,685 non-homeless |          |                                   |                                                                                                                                          |
|                         |                   |                                                           | <b>HBV test</b><br>128,262<br>homeless<br>1,499,203 non-homeless |          |                                   |                                                                                                                                          |
| Noska et al, 2017       | USA               | homeless and non-homeless veterans                        |                                                                  | 15.3%    | 1.8%                              | -                                                                                                                                        |
| → Levorato et al, 2017  | Padua, IT         | homeless                                                  | 59                                                               | 13.5%    | -                                 | -                                                                                                                                        |
| Legoupil, 2017          | Paris, FR         | homeless, sex workers                                     | 341                                                              | -        | 6.51% HBV Ab and HBsAg            | -                                                                                                                                        |
| → Cuomo et al, 2019     | Modena, IT        | migrants                                                  | 304                                                              | 3.3%     | -                                 | -                                                                                                                                        |
| → Coppola et al, 2020   | Italy             | immigrants                                                | 3,839                                                            | 1.6%     | -                                 | -                                                                                                                                        |
| Fiore et al, 2020       | IT                | prisoners                                                 | 2376                                                             | 10.4%    | -                                 | -                                                                                                                                        |
| Figgatt et al, 2020     | Philadelphia, USA | drug user                                                 | 337                                                              | -        | 1.9% HBsAg<br>24.3% anti-HBc Ab   | ID use; homelessness, incarceration                                                                                                      |

# Studies Reporting HCV Data Among Migrants

| Authors          | Year | Type of Study                                   | Sample | Population                             | HCV Prevalence (%) | HCV-RNA Positive (%) | Treatment        | Genotypes (%)                                               | SVR   |
|------------------|------|-------------------------------------------------|--------|----------------------------------------|--------------------|----------------------|------------------|-------------------------------------------------------------|-------|
| Zermiani et al.  | 2012 | Retrospective                                   | 345    | Migrant sex workers                    | 0.9                | NA                   | NA               | NA                                                          |       |
| Prestileo et al. | 2013 | Prospective                                     | 239    | Migrant sex workers                    | 0.8                | NA                   | NA               | NA                                                          |       |
| Laganà et al.    | 2015 | Prospective, observational, single-center study | 320    | Pregnant migrant women                 | 0.9                | NA                   | NA               | NA                                                          | NA    |
| Coppola et al.   | 2015 | Cross-sectional                                 | 882    | Undocumented, asylum seekers           | 4.0                | 83                   | NA               | NA                                                          | NA    |
| Scotto et al.    | 2016 | Retrospective, multicenter                      | 3421   | Migrants (not specified)               | 6.2                | 63                   | IFN + ribavirine | 1 (48.7%)<br>2 (10.9%)<br>3 (19.4%)<br>4 (21%)              | 48.8% |
| Prestileo et al. | 2017 | Model of management                             | 133    | Migrant inmates                        | 40.6               | 63                   | 37%              | 1a (20.5%)<br>1b (8.8%)<br>2 (5.9%)<br>3 (50%)<br>4 (14.7%) | NA    |
| Buonfrate et al. | 2018 | Cross-sectional                                 | 118    | Asylum seekers                         | 0.85               | NA                   | NA               | NA                                                          | NA    |
| Cuomo et al.     | 2018 | Retrospective                                   | 304    | Undocumented, asylum seekers, refugees | 3.3                | NA                   | NA               | NA                                                          | NA    |
| Donisi et al.    | 2020 | Retrospective                                   | 315    | Asylum seekers                         | 1.9                | NA                   | NA               | NA                                                          | NA    |
| Marrone et al.   | 2020 | Retrospective                                   | 836    | Unaccompanied minors                   | 1.1                | 67                   | NA               | NP                                                          | NA    |
| Prestileo et al. | 2021 | Cross-sectional                                 | 2639   | Newly arrived undocumented migrants    | 0.9                | 75                   | DAAAs            | 1a (22.3%)<br>1b (5.6%)<br>3 (44.4%)<br>4 (27.7%)           | 5.6%  |
|                  |      |                                                 |        |                                        |                    |                      |                  | 1a (6.6%)                                                   |       |

The undeserved populations still represent the most important targets in HCV micro-elimination  
More studies are needed, particularly to assess the actual scenario of HCV among these subpopulations

*Babudieri et al. Healthcare2023*

|                 |      |                 |    |                                 |     |     |    |    |    |
|-----------------|------|-----------------|----|---------------------------------|-----|-----|----|----|----|
| et al.          | 2021 | Retrospective   | 62 | Refugees                        | 1.0 | 100 | -  | NP | 0  |
| Fiore et al.    | 2021 | Retrospective   | 49 | Undocumented                    | 2.2 | NA  | NA | NP | NA |
| Lapadula et al. | 2022 | Cross-sectional | 66 | Migrant transgender sex workers | 0   | 0   | NA | NA |    |

*Babudieri et al. 2023*

# Background

## Recruitment strategies

- A successful strategy employed a voucher system of **reimbursement** for agreeing to undergo testing or completing a survey  
Stein JA et al. Drug Alcohol Depend 2004; Sherriff LC et al. J Public Health Med 2003; Page K et al. BMC Public Health 2017
- This strategy is especially effective since a major problem for underprivileged people is the lack of money  
Gelberg L et al. Public Health Rep 2012; Van Laere IR et al. BMC Public Health 2009; Baggett TP et al. Am J Public Health 2010
- One of the key points to assure the success of the testing campaign is the **site of recruitment**
- The **onsite strategy** seems to be advantageous in terms of compliance

# Key-points and strategies...

## ...for the screening campaign

- The *on site* strategy;
  - Choose sites attended by many people at the same time;
  - Choose sites frequently attended by the same people;
- [e.g. meal centers distributing free meals are a strategic option]

- Overcoming the mistrust of the target population;
- The collaboration with the shelter's director and volunteers;

## ... for the post-screening

- The collaboration with the shelter's director and volunteers
- The strong and effective collaboration with the social care service, in order to assure adequate conditions (transportation services, housing etc.) for increase linkage to care and treatment compliance.

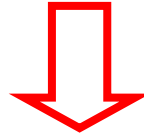
Importance of a careful work of disseminating information to the target population and to the staff of the chosen sites

# Aims

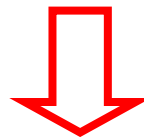
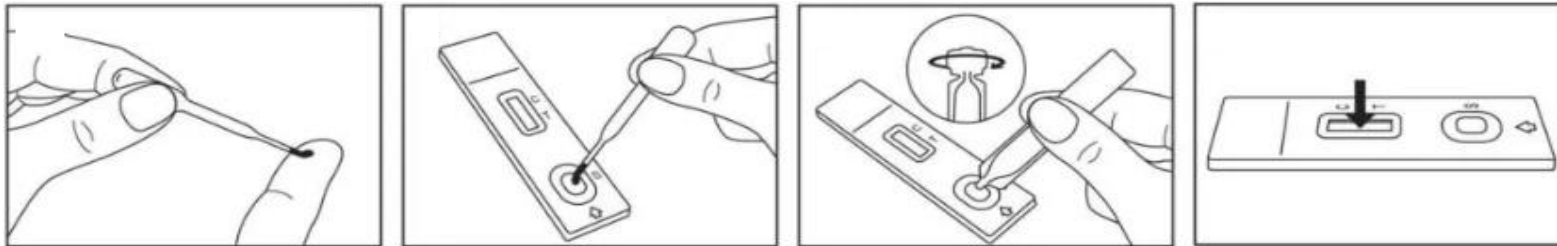
- To promote health protection and facilitate access to social health systems in vulnerable groups of the population, with a general goal of not denying the equality of rights to specific groups or subjects
- To help a global elimination plan for the two major hepatic viruses in the populations, more generally, including people in economic hardship
- To perform an epidemiological analysis with the aim of acquiring knowledge and awareness with regard to the spread of viral hepatitis in a small group of subjects who avoid official health care channels
- To inform and put subjects at ease relative to the prevention strategy of infectious diseases (viral hepatitis) and the possibilities concerning clinical care and therapies

# Methods

All subjects received an informed consent, available in multiple language



Patients were tested for HBsAg positivity and anti-HCV positivity via capillary blood sampling.



**HBsAg and anti-HCV antibody positive** patients underwent second level screenings and were treated or monitored.

# Methods

## The study involved three phases:



### First phase: from January 2019 to December 2019

HBV and HCV onsite screenings at different charities and shelters: three meal centers in the cities of Florence (*Caritas center*), Prato (*La Pira center*) and Sesto Fiorentino (*Misericordia center*); the *S. Vincenzo school of Italian for foreigners*, located in Prato.

Pre-pandemic  
phase

### Second phase: from January 2022 to December 2023

following the start of the COVID-19 pandemic, there was an expansion of screening which also included the new virus and fell within the scope of the "*SECONDI*" project, financed by the Tuscany Region (*Bando Ricerca COVID 19 Toscana. Partners: AUSL Toscana Centro, MASVE center University of Florence and ARS Toscana*) with the involvement of a network of 8 voluntary associations with consolidated healthcare experience with this type of population (*Anelli Mancanti, Croce Rossa Italiana, Medici per i Diritti Umani-MEDU, CAT Cooperativa sociale, CARITAS-Stenone, Medici Senza Frontiere, Corpo Italiano di Soccorso Ordine di Malta-CISOM, Fondazione Bartolomei Corsi*)

Pandemic/  
post pandemic  
phases

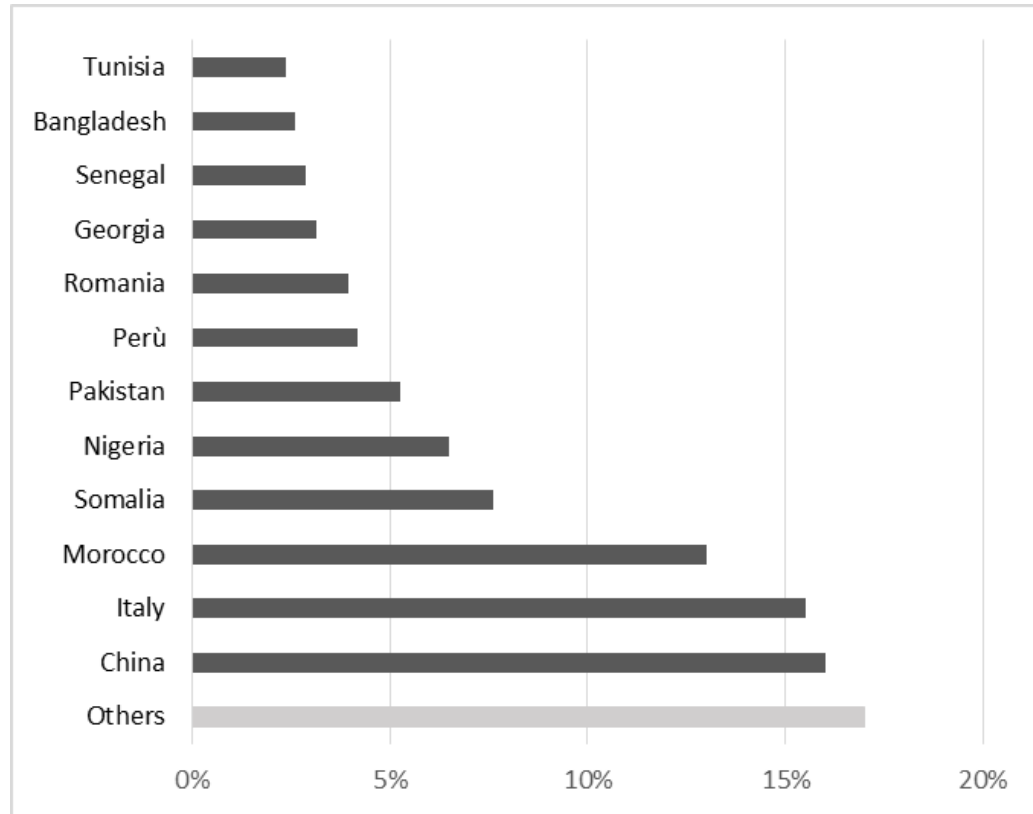
### Third phase: from May 2022, ongoing

screening has been further expanded to also include anti-TB, anti-HIV, HIV p24 antigen, and anti-TP antibodies. The project called «*MARINS*» was granted by the Pistoia and Pescia CR (PI: Gragnani L) and is being carried out in this area. The screened patients are then clinically evaluated by the Infectious Diseases units of San Jacopo and Santo Stefano Hospitals

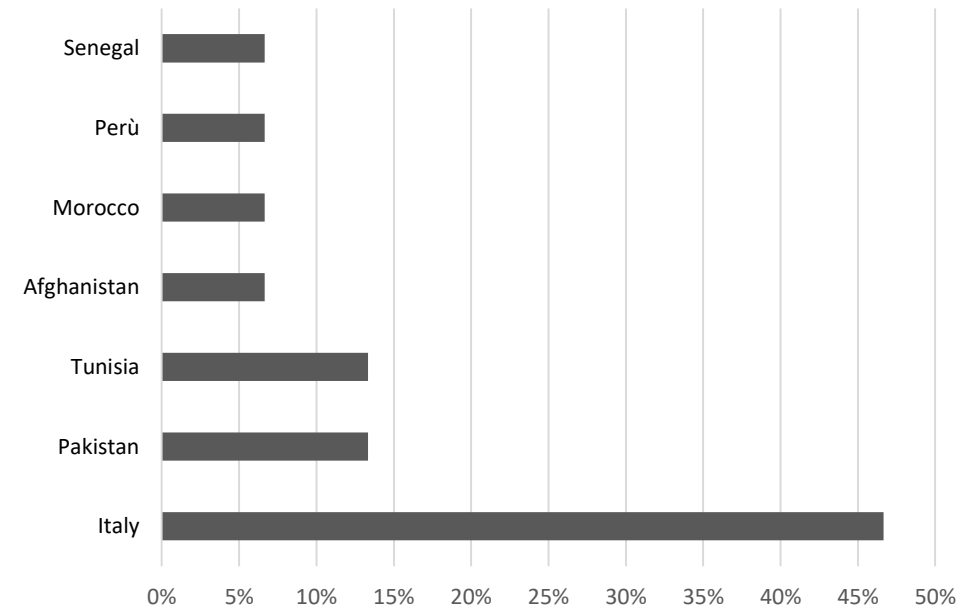
# Results of the first phase (2019)

Tested subjects: 381 (256 from the meal centers, 125 from the school)

## Geographical origin of the entire population



## Geographical origin of the anti-HCV positive subjects



# Results of the first phase (2019)

| Site                  | Tested subjects | M/F            | Mean age (yrs) | anti-HCV Ab+  | Mean age (yrs) | HBsAg+          | Mean age (yrs) |
|-----------------------|-----------------|----------------|----------------|---------------|----------------|-----------------|----------------|
| Caritas Center        | 131             | 121/10         | 44             | 8(6.1%)       | 49             | 11(8.4%)        | 42             |
| La Pira Center        | 98              | 87/11          | 45             | 5(5.1%)       | 43             | 5(5.1%)         | 39             |
| Misericordia Center   | 27              | 21/6           | 44             | 1(3.7%)       | 57             | 1(3.7%)         | 51             |
| School for foreigners | 125             | 51/74          | 37             | 1(0.8%)       | 38             | 7(5.6%)         | 35             |
| <b>Total</b>          | <b>381</b>      | <b>280/101</b> | <b>43</b>      | <b>15(4%)</b> | <b>47</b>      | <b>24(6.3%)</b> | <b>41</b>      |

Linkage to care: 5/15 (33 %) underwent second level screenings; 4/5 were HCVRNA+ and underwent DAA treatment

National prevalence: 0.68% for HCV and < 1% for HBsAg

Kondili L et al, 2021;Andriulli A et al. Eur J Intern Med 2018; Sagnelli E et al. WJG 2014, European Centre for Disease Prevention and Control. Stockholm, Sweden, 2018.

Gragnani et al, AASLD 2020

## Main Risk factors

| Meal Programs (n=256)         |      |           |                           | School for foreigners (n=125) |           |                           |                     |
|-------------------------------|------|-----------|---------------------------|-------------------------------|-----------|---------------------------|---------------------|
|                               |      |           | Anti-HCV Ab<br>prevalence | HBsAg<br>prevalence           |           | Anti-HCV Ab<br>prevalence | HBsAg<br>prevalence |
| <b>Drugs abuse</b>            |      |           |                           |                               |           |                           |                     |
| <b>ID use</b>                 |      |           |                           |                               |           |                           |                     |
|                               | yes° | 9 (2%)    | 55%* \$                   | 22%*                          | -         | -                         | -                   |
|                               | no   | 247 (98%) | 4.4%                      | 6.4%                          | 125       | 0.8%                      | 5.6%                |
| <b>Intranasal cocaine use</b> |      |           |                           |                               |           |                           |                     |
|                               | yes° | 18 (7%)   | 5.5%                      | -                             | 1 (1%)    | -                         | -                   |
|                               | no   | 238 (93%) | 5.4%                      | 7.1%                          | 124 (99%) | 0.8%                      | 5.6%                |
| <b>Smoking drugs</b>          |      |           |                           |                               |           |                           |                     |
|                               | yes° | 55 (21%)  | 11%                       | 5.4%                          | 2 (2%)    | -                         | 50%                 |
|                               | no   | 201 (79%) | 4%                        | 7%                            | 123 (98%) | 0.8%                      | 4.9%                |

\*Two IDUs had HCV and HBV coinfection; \$ p=0.0012 OR=11.16 95% CI= 3.116-39.17

# Pandemic/post pandemic phases

## SCREENING CENTERS

*Centro Attavante [Firenze]*  
*Help Center ACISjF [Firenze]*  
*Centro Il Muretto [Firenze]*  
*Centro distribuzione alimentare, Chiesa Santa Maria al Pignone [Firenze]*  
*Scuola italiana per stranieri S.Vincenzo [Prato]*  
*CAS di:*  
*Buggiano*  
*Calenzano*  
*Certaldo*  
*Fiesole*  
*Fucecchio*  
*Montecatini*  
*Montecatini Hotel Zenith*  
*Ponte Buggianese*  
*Pratolino*  
*Quintole*  
*Sesto Fiorentino*

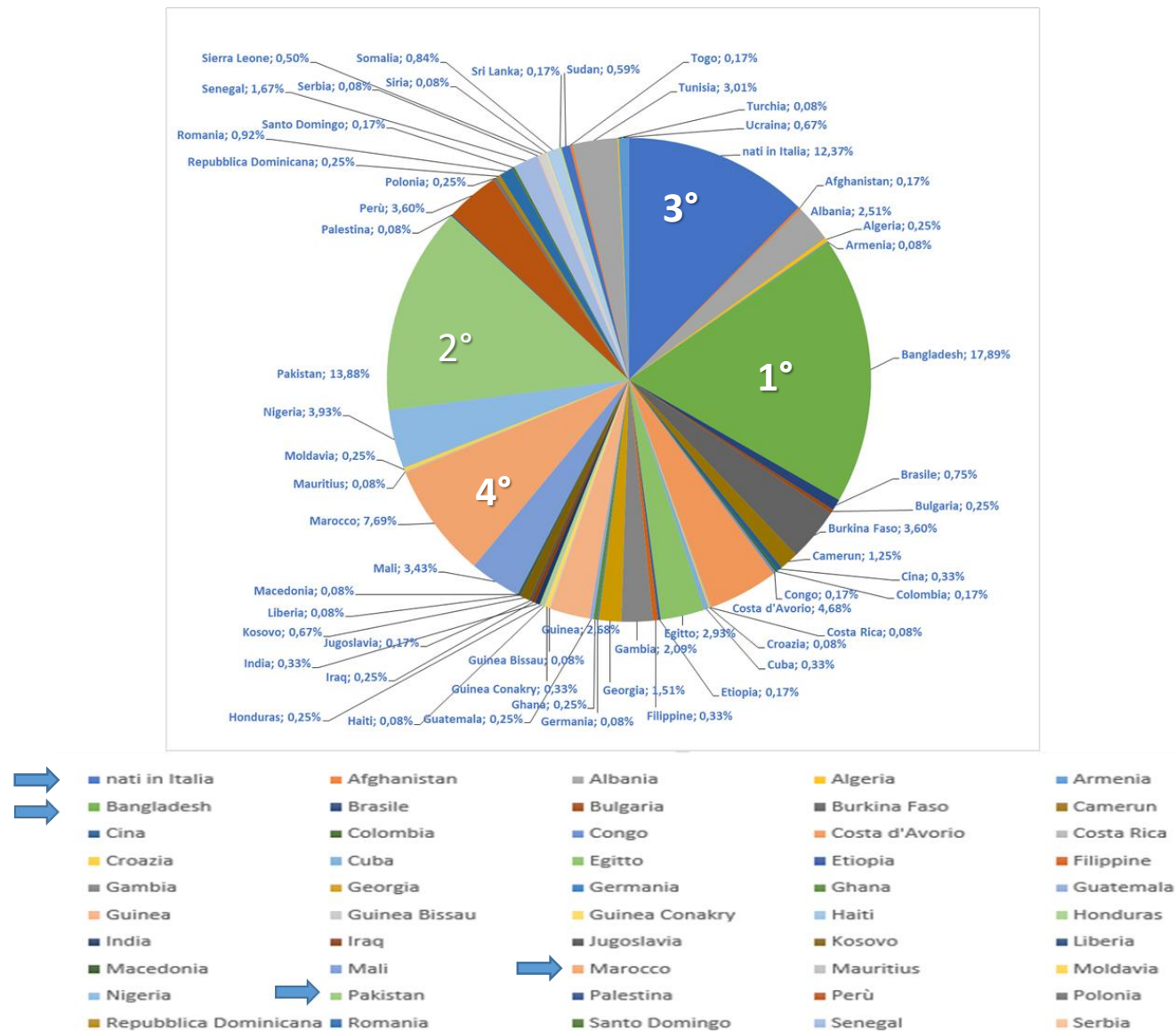


*Centro arca di Noè/Arcolaio [Firenze]*  
*Centro Emergenza Freddo c/o Misericordia [Empoli]*  
*Emporio della solidarietà [Prato]*  
*Gruppo Incontro [Pistoia]*  
*Centro il muretto [Firenze]*  
*Mensa don Siro Butelli [Pistoia]*  
*Mensa San Francesco [Firenze]*  
*Mensa Varlungo [Firenze]*  
*Misericordia [Empoli]*  
*Gruppo Incontro [Pistoia]*  
*Santa Maria Pignone [Firenze]*  
*Villa Carmen [Firenze]*  
*Caritas casa Corelli [Firenze]*  
*Caritas via Baracca [Firenze]*  
*Caritas [Prato]*  
*Centro La Pira [Prato]*  
*Misericordia [Sesto F.no]*  
*Casa Renato [Prato]*  
*Centro Islamico "Borgo Allegri" [Firenze]*

# Pandemic/post pandemic phases

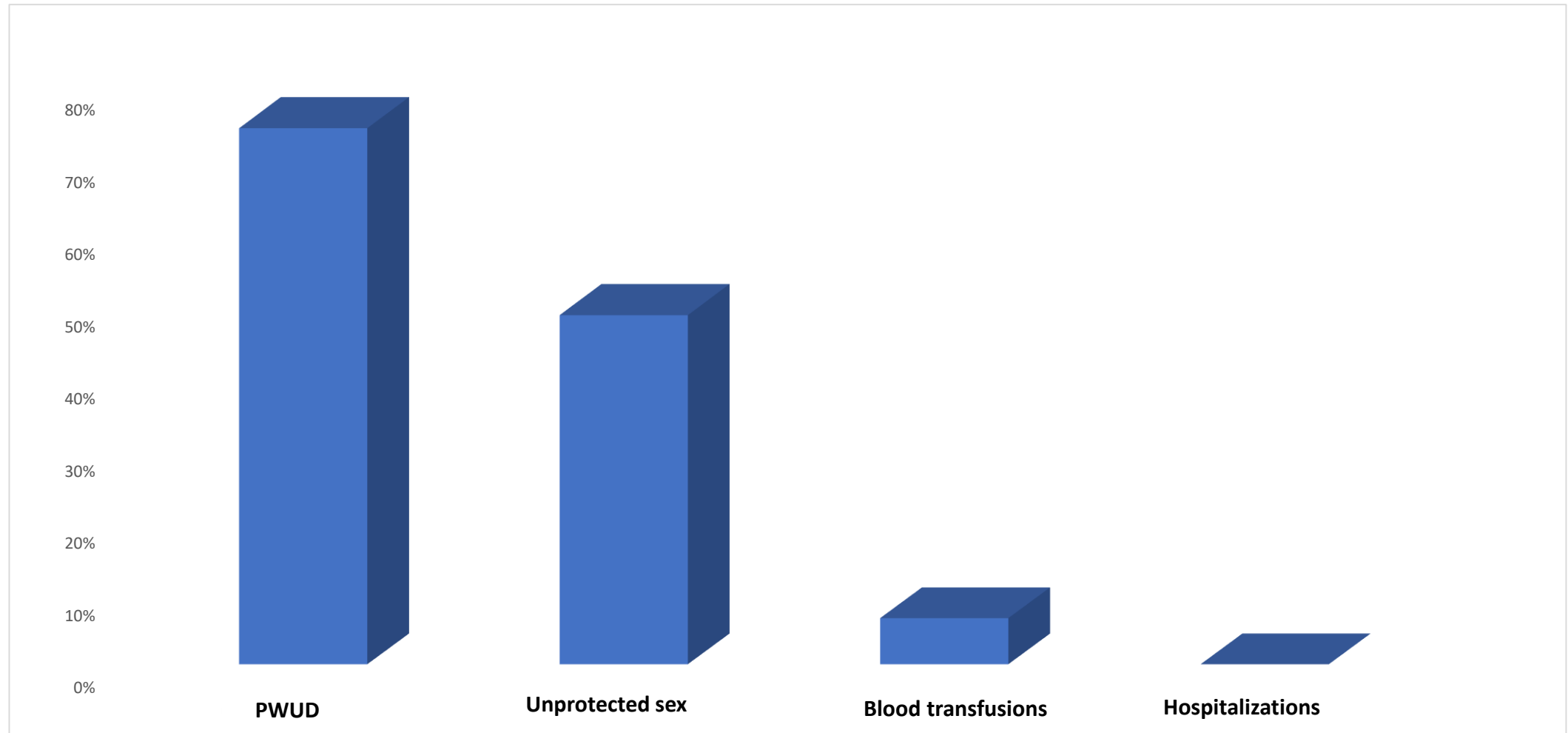
Tested subjects: 1.195, 946 (79%) M, Mean age: 36 yrs. [390 (33%) born 1969-1989]

## GEOGRAPHICAL ORIGIN OF THE ENTIRE POPULATION



## Pandemic/post pandemic phases

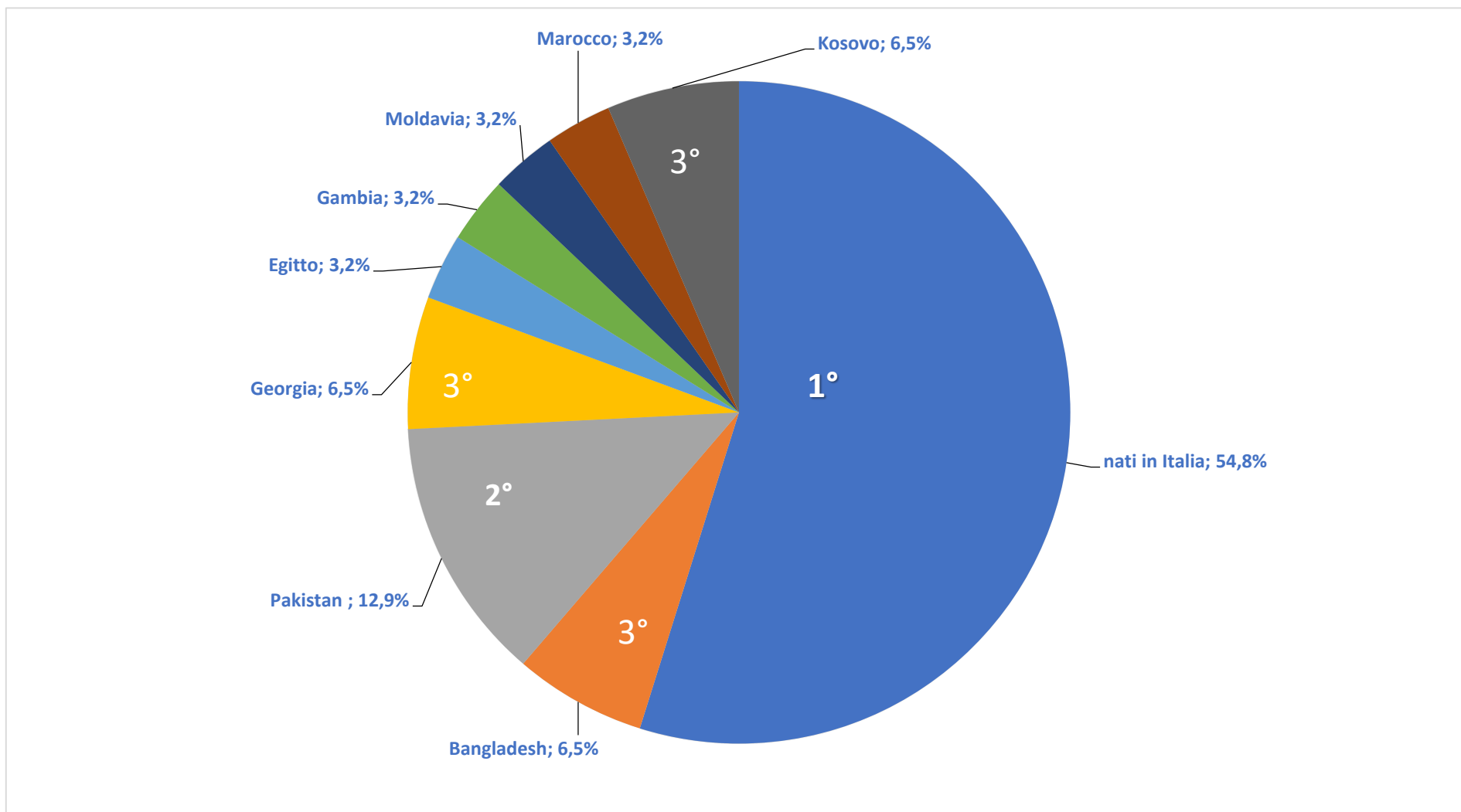
### Anti-HCV+ Risk Factors



# POST-PANDEMIC PHASES

Positive subjects: 32 (2.7%), 28 M (88%), Mean age: 50 yrs.

## GEOGRAPHICAL ORIGIN OF THE ANTI-HCV POSITIVE POPULATION





# Conclusions

- Screening strategies to reach the WHO's goals do not generally include homeless people, due to low linkage to care and low compliance
- In this prospective screening study, including counselling and linkage to care, we used free-testing strategies on sites frequented by homeless people and/or foreigners originating from endemic areas
- A higher prevalence of previously unknown positivity for anti-HCV than the reported Italian national one was shown with the highest positivity percentages detected in Italian subjects followed by subjects from Pakistan and then by those from Bangladesh, Kosovo and Georgia
- The high prevalence (33%) of people born between '69 and '89 in addition to the very high prevalence of PWUD (about 80%) is of further support to a complementary help even towards the most recent national screening strategies

Available data suggest that, maintaining the current levels of diagnosis and treatment, about 60% of high-income countries will be late (about 20 years) to eliminate HCV when aiming to meet the WHO's 2030 targets

Our results suggest the implementation of this screening strategy as it could reveal residual "pockets" of HCV infection

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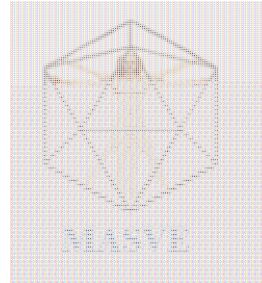
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**Ospedale**  
**San Jacopo**  
**di Pistoia**



*A very special thanks goes to all the people who agreed to be interviewed and tested for this study. By sharing the stories of their lives, they made the screening campaign one of the most enriching experience of our careers*

