

## Development of a standardised European protocol for hepatitis C prevalence surveys in the general population

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### BACKGROUND AND AIMS

Reliable and standardised estimates of hepatitis C virus (HCV) prevalence are needed to effectively plan and monitor responses. The heterogeneous methodology used in many surveys makes obtaining comparable prevalence estimates challenging.

To address this, the European Centre for Disease Prevention and Control (ECDC) contracted the Robert Koch-Institute to carry out the SPHERE-C project aimed at developing an evidence-based protocol for undertaking HCV prevalence surveys in the general population, to support EU/EEA Member States in their efforts to generate robust estimates of HCV prevalence.

### METHODS

This protocol is being developed based on a synthesis of evidence based methodologies. After the priorities of Member States were identified through a survey, an expert meeting was held at ECDC in December 2016 to discuss these priorities and review the scientific information and evidence on these types of studies. During this meeting a consensus was reached to focus on developing protocols for studies targeting the general population. Draft survey objectives were formulated, and it was agreed that probability-based sampling methods will be used. A second draft of the protocol was then discussed at a second expert group meeting (September 2017), where the context of the protocol was discussed in more detail and the plans for the piloting of the protocol were discussed.

In 2018, the protocol will be piloted in three countries:

- Finland: nested survey collection
- Italy: residual samples
- Bulgaria: stand-alone survey

### RESULTS

Three different methods relying on probability-based sampling are proposed in the protocol (Figure 1). In each step of the protocol, minimum requirements are listed along with an ideal 'gold' standard with suggested options for possible expansion of the survey, where applicable. The three designs are:

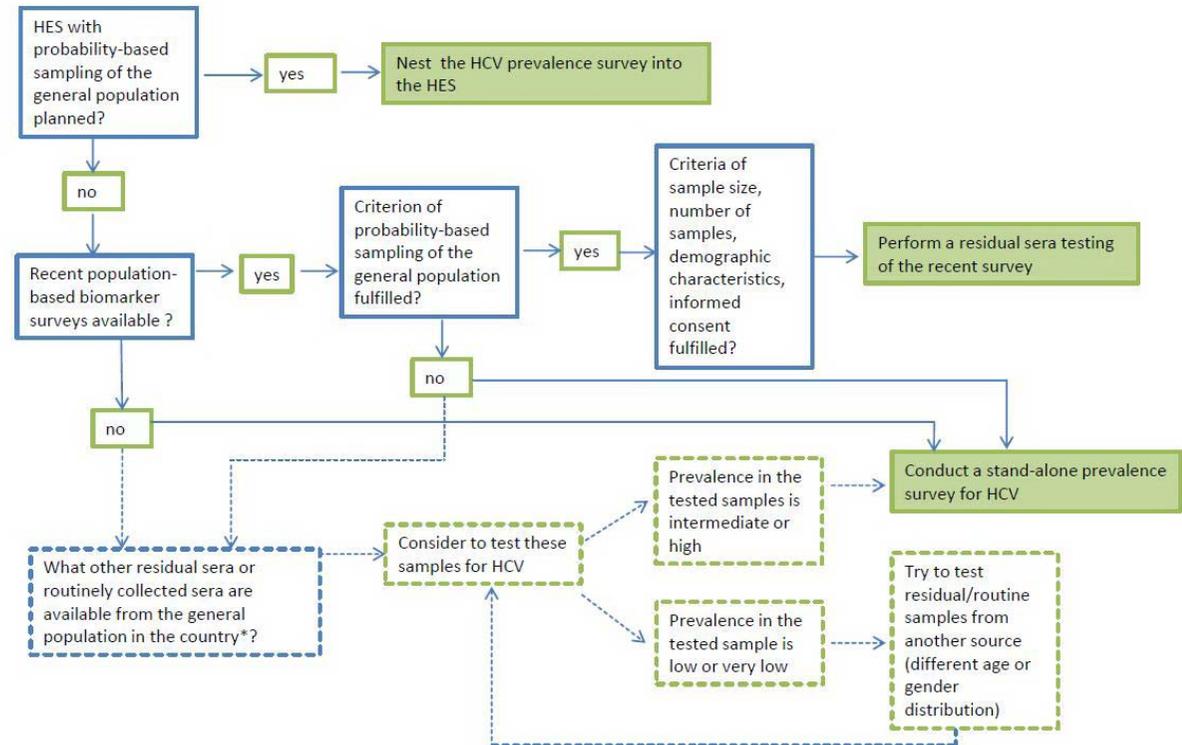
- 1) **A nested survey design**, where an HCV prevalence survey is nested in a larger health survey of the general population, e.g. a national Health Examination Survey (HES)
- 2) **A residual sera testing design**, where specimens already collected are tested retrospectively for HCV
- 3) **A stand-alone survey**, with the main aim to measure HCV prevalence.

The protocol covers all key areas that need to be considered when carrying out an HCV prevalence survey. These include:

- Objectives
- Study design
- Study population
- Sampling methods and recruitment
- Specimen collection and laboratory testing
- Additional data and analysis
- Budgetary considerations.

Some elements of the protocol differ according to design, e.g. sampling is outlined only in detail for the stand-alone survey, including possible sampling frames, sampling methods and sample size, these are already determined for the nested and residual designs.

Figure 1: Considerations when planning a prevalence survey for hepatitis C in the general population



----- : Not further elaborated on in protocol

\*If necessary to conduct a stand-alone survey, but there is lack of resources, alternative methods can be used. These include: samples from routine procedures e.g. from antenatal care screening, blood donor or pre-employment screening or residual samples collected for another purpose, (e.g. people visiting health care clinics). The final protocols will include an Annex with useful references as well as pros and cons for these alternative methods (currently under development).

### Conclusions

The SPHERE-C project aims to develop more standardised and comparable HCV prevalence surveys to produce robust estimates of prevalence in the general population.

Lessons learned from the pilots will be incorporated in the final protocol and will contribute to understanding and addressing challenges for each of the designs. This survey protocol will add to the various ECDC activities to support countries in their efforts to eliminate HCV.