World Health Organization
REGIONAL OFFICE FOR Europe

CVD ASSESS implementation manual

Preventing cardiovascular disease (CVD) in primary health care:
assessing essential interventions using routine data (CVD ASSESS)

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Development of CVD ASSESS

Purpose of CVD ASSESS

The purpose of CVD ASSESS is to provide a free, open-source, standardized data collection method for use in resource-limited settings to assess essential CVD interventions in primary health care using routine clinical data.

CVD ASSESS was initially developed to measure the impact of implementing essential cardiovascular disease interventions in primary health care. It was designed for use in settings with a range of types of medical health record infrastructure (from paper-based records to electronic health records). It has been tested in low- and middle-income countries, including in health facilities with no Internet or mobile service coverage using paper-based data extraction forms. It has been used to extract data from nearly 10 000 paper-based patient records.

Components and intended audience

This implementation manual is intended for people working at the national level (such as a health ministry), and the contents of the CVD ASSESS package are relevant to those working at the subnational level (such as programme managers) and the primary health care level (such as data collectors, clinical statisticians and clinicians).

Component	Description
Implementation guide (this document)	An overview of CVD ASSESS
Data Collection Training Module	Material to train data collectors
Data collection field guide	Important information and troubleshooting for data collectors
Data collection forms	Forms used to collect raw data from patient records: online, offline, and paper versions

Core indicators

Table 1 shows the list of core indicators and the questions they seek to address. An expanded table is available in the Annex that details the numerators and denominators in greater detail. Using CVD ASSESS will provide you with the necessary raw data to calculate the core indicators. In addition, you may wish to further analyse the raw data and develop subsequent indicators. We encourage that users at least report the core indicators so that performance can be compared with that of other countries that have also used CVD ASSESS and reported core indicators (1,2).

Table 1. Core indicators for preventing and managing CVD risk, to be adapted to the local context

Question	Indicator
Are CVD risk factors being measured?	Proportion of eligible patients who have all risk factor values recorded as required for calculating the risk score
Are CVD risk factor measurements being converted to a total risk score?	Proportion of patients aged 40 years or older who have visited in the past 12 months who have all measurements required for calculating the risk score within 12 months of the most recent date of visit and have a documented risk score
Are CVD risk scores calculated correctly?	Proportion of patients aged 40 years or older who have visited in the past 12 months who have all measurements required for calculating the risk score within 12 months of the most recent date of visit and have a documented risk score that is correct
Are patients being risk scored?	Proportion of eligible patients with a documented risk score
Are statins prescribed to the correct patients?	Proportion of eligible patients prescribed a statin

Table 1 continued

Question	Indicator
Are statins prescribed correctly based on documented risk score?	Proportion of patients eligible based on documented risk score prescribed a statin
Are patients with existing disease who do not require the calculation of a risk score to prescribe statins prescribed statins?	Proportion of patients with existing CVD prescribed a statin Proportion of people with diabetes older than 40 years prescribed statins
Is the blood pressure of high-risk patients controlled?	Proportion of high-risk patients (such as score ≥15% or diabetes and age older than (40 years) whose last two recorded blood pressure measurements were <130/80 mmHg, of which one was measured in the past 12 months
Is the blood pressure of low-risk patients controlled?	Proportion of low-risk patients (such as score <15%) whose last two recorded blood pressure measurements were <140/90 mmHg, of which one was measured in the past 12 months
Are patients with existing CVD prescribed basic medications to reduce risk?	Proportion of patients with existing CVD prescribed a statin and aspirin and blood pressure-lowering treatment
Is the blood glucose of patients with diabetes controlled?	Proportion of patients with diabetes with glycaemic control as defined by the last two HbA_{1c} measurements
Is the blood pressure of patients with hypertension controlled?	Proportion of patients with confirmed hypertension whose systolic blood pressure is <140/90 mmHg at the last two visits, of which one was measured in the past 12 months
What is the prevalence of high blood pressure?	Proportion of people whose last two systolic blood pressure measurements are 140/90 mmHg or above, of which one was measured in the past 12 months

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How to implement CVD ASSESS

Human resources

Establish a steering committee

Consider establishing a steering committee to provide project oversight and management. When possible, the steering committee should strive to include representatives from primary health care (such as family physicians and nurses) to help to inform project development, knowledge dissemination and health-care improvement. Project teams need to ensure adequate technical support from those with experience in biostatistics, data analysis and appropriate research methods. The project management aspects the steering committee may consider coordinating include:

- project oversight and ethical standards;
- project management;
- reviewing and adapting CVD ASSESS to the local context;
- recruiting, commissioning and overseeing data collection and analysis;
- coordinating knowledge sharing and dissemination; and
- using data to advocate for changing policy and improving health care.

Data collection

You will need a team of people to collect data from patient records. Data collectors require training using the CVD ASSESS Data Collection Training Module but otherwise can comprise people with a range of skills and medical experience. It is recommended that data collectors have some knowledge of clinical medicine such that they can interpret information in patient records and make informed judgements about the data to extract. Examples of people suitable range from clinicians, including doctors and nurses, to medical students, medical residents or skilled research assistants. If data collectors have limited clinical medical experience (such as non-medical research assistants), the training should be adapted to provide additional topics such as common medical abbreviations, variation in units of measurement (such as mmol/L, mmol/mol and mg/dL) and common medications used for hypertension, diabetes and CVD.

Data analysis

You will need access to people trained in data analysis, which includes cleaning, coding, statistically analysing and communicating the data. WHO can assist in identifying this capacity if needed. Novices could be trained to do these tasks, but oversight from an experienced data scientist, statistician or epidemiologist is important. Any statistical analysis software can be used (such as SPSS or Stata), but we recommend using R *(3)* because it is free, open-source and has many freely available training courses (such as Swirl *(4)*).

Identify the public health goal

CVD ASSESS can be used for multiple purposes. For example, it can be used at the health facility level to audit records and provide feedback to frontline clinicians for improving quality. It can also be used to determine nationally or regionally representative samples of clinical performance for monitoring and evaluation. Clearly defining the public health goal will help you to plan the use of CVD ASSESS and to determine key parameters such as the population to sample, the geographies to work with, the sample size, how data will be analysed and how the findings will be shared.

Simplified question	Type
How common is the problem?	Prevalence
To what degree is early detection worthwhile?	Screening
Is the diagnostic test accurate?	Diagnosis
What will happen if we do nothing?	Prognosis
Does the intervention help?	Treatment

Establish a practice standard

To adapt the core indicators to your context, you need to identify the practice standard against which you compare current practice. In many instances, this will be your established clinical guidelines that, for example, clearly define the diagnostic criteria for hypertension and hypertension control. You can use these standards to adapt the numerator and denominator of the core indicator set described above.

Further, you can calculate the core indicator set using multiple practice standards to compare. For example, you may choose to calculate the core indicators using information from your national clinical guidance and from the sample hypertension treatment protocols in the WHO HEARTS technical package *(5)*.

Study design

The study design you choose will depend on your public health goal and/or the question your project seeks to answer.

Example goals	Example study designs
To determine the prevalence of hypertension control and diabetes control	Cross-sectional descriptive study
To determine the impact of primary health care training on essential CVD interventions	Before and after evaluation study or cluster randomized controlled trial
To provide a tool to help clinicians assess their own work and conduct quality improvement initiatives	Clinical audit

Fig. 1 and 2 show examples of two cluster randomized controlled trial study designs that used CVD ASSESS. These are simplified examples but illustrate where CVD ASSESS can be used -- in these examples for baseline and follow-up quantitative data collection.

Fig. 1. A summarized version of the study methods for a cluster randomized controlled trial in Tajikistan
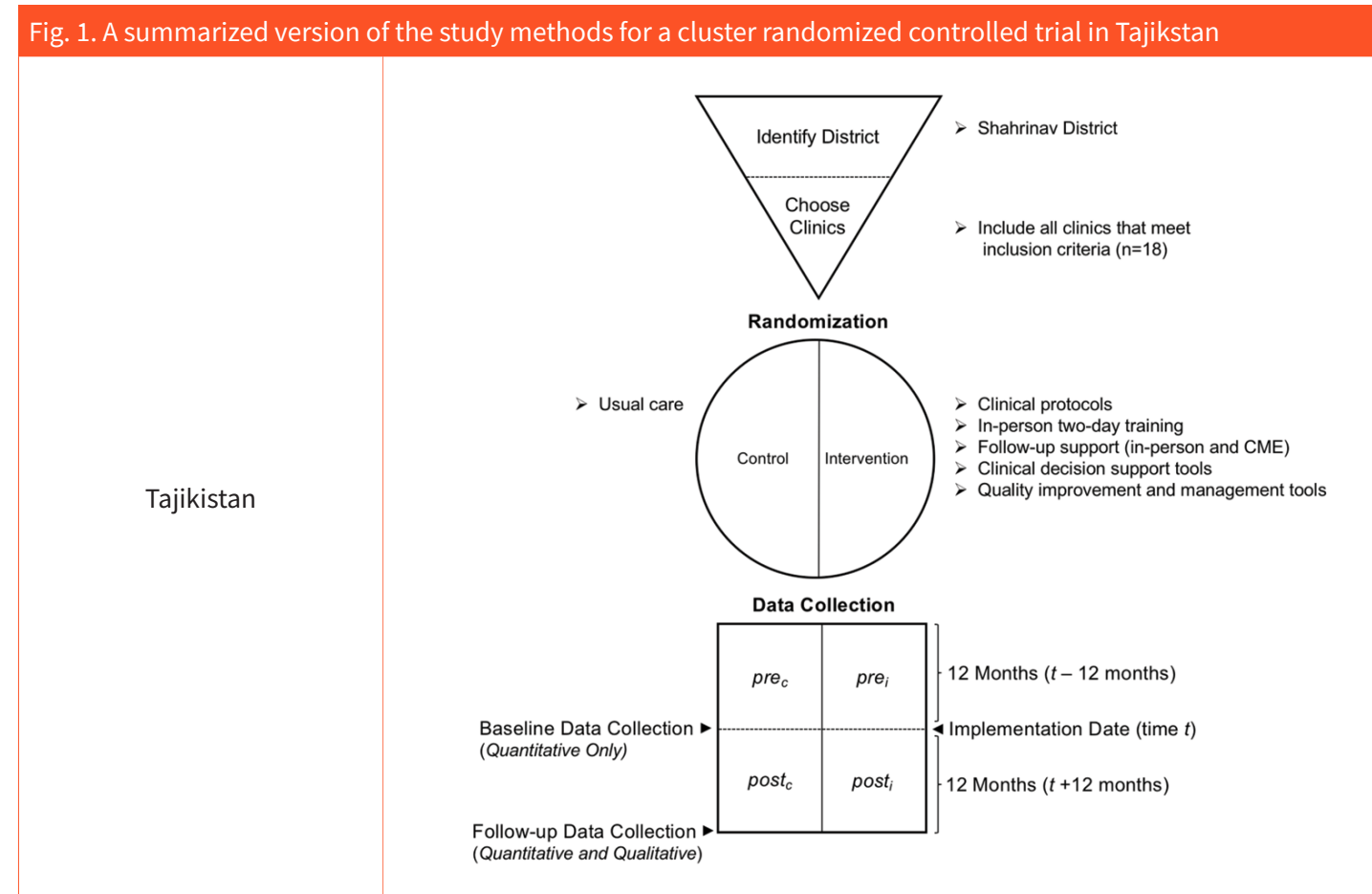
Source: Collins et al. *(1)*

Fig. 2. A summarized version of the study methods for a cluster randomized controlled trial in the Republic of Moldova
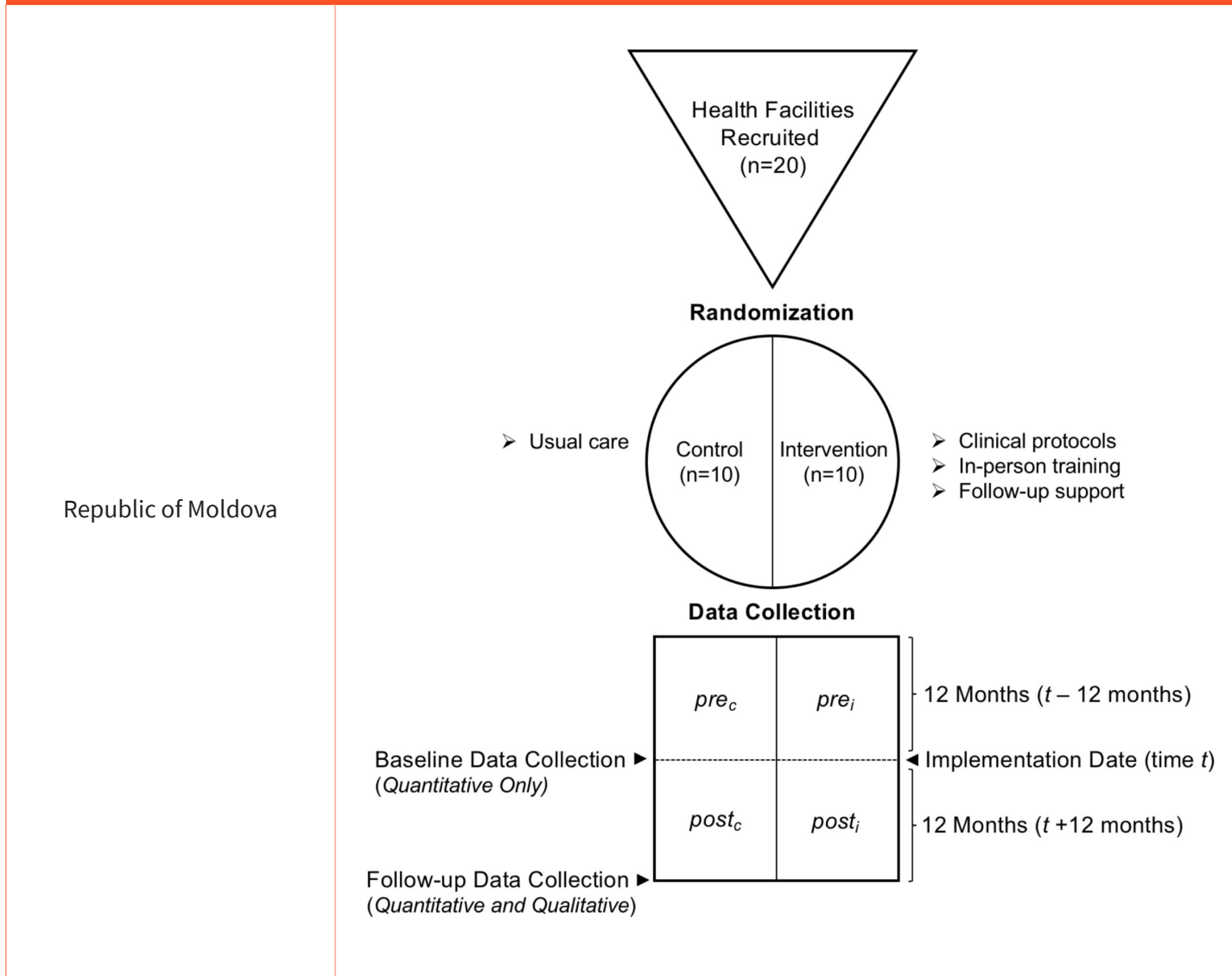
Source: Collins et al. *(2)*

Population sample

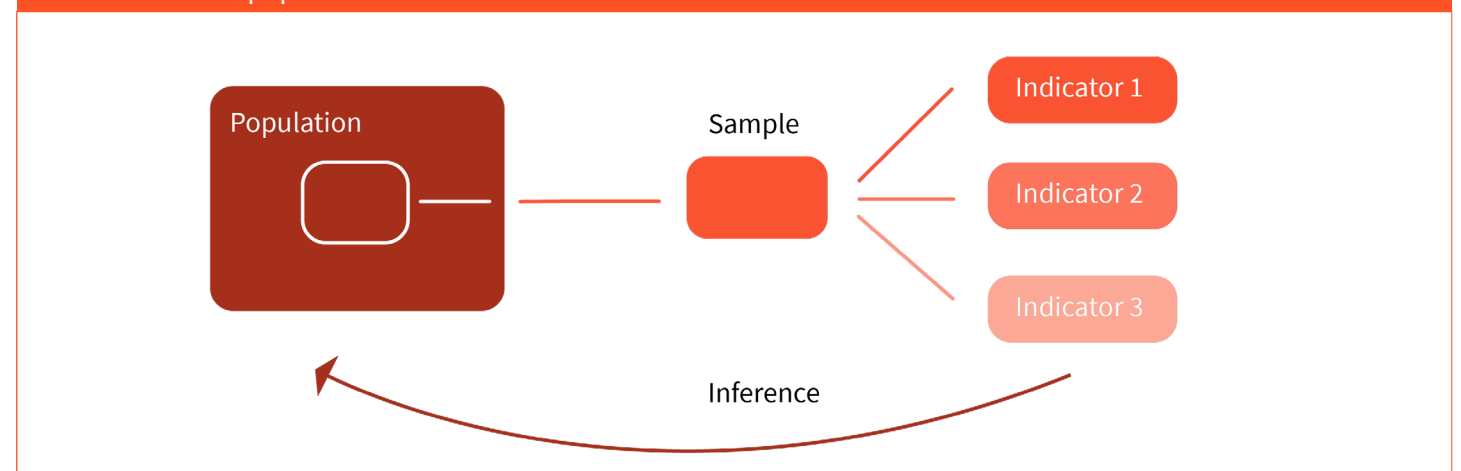Your population sample will depend on your public health goal, study design and overall research question. Including all patients of your target population in your study is typically not feasible. We therefore take samples of a given population so that we can make reasonable inferences about the population as a whole (Fig. 3). In an ideal world, we would include the entire target population, but this is simply not feasible. Random sampling is the gold standard method of sampling a predefined population in a way that increases external validity. The degree to which you can randomly sample a population depends on your context, expertise and resources.

Fig. 3. Simplified illustration of how indicators from a sample of a population are used to make inferences about the state of the entire population

Determining the sample size

Similar to the population sampling strategy, your sample size will depend on the overall goal of your project and may (such as a prevalence study or randomized controlled trial) or may not (such as a clinical audit by individual clinicians) be an important aspect of your methods.

However, there are clearly defined methods of determining a sample size based on the outcomes you are measuring, the difference you wish to detect, the probability of detecting that difference and the margin of error you are comfortable accepting. You should consult with a statistician when designing this part of your project.

Example from the Republic of Moldova

A sample size of 20 primary health care centres was chosen because it was seen as a good balance of allowing for variation in clinic geography and demography while still remaining feasible for the pilot implementation. Half the centres (n = 10) will be randomly allocated to the intervention arm and half (n = 10) to the control arm. Baseline data will be collected from both intervention and control clinics, ensuring that baseline data are collected before implementation occurs.
Source: Collins et al. *(2)*.

Example from Tajikistan

A total of 400 patient records will be sampled at baseline and follow-up from each of the intervention and control arms (n = 800). The sample is based on a power calculation for the primary indicator (proportion of hypertensive patients whose blood pressure is controlled), estimated based on a WHO report that the control level in low- and middle-income countries is generally about 20–25%. A 10 percentage point difference between the intervention and control arms could be detected having 310 to 350 observations in each group using 0.05 type I error rate and 0.2 type II error rate. Sampling will be stratified by gender and selected in a 1:1 ratio of men to women (200 men and 200 women per arm). In the event that there are too few patients of a given gender, patients from the opposite gender will be substituted.
Source: Collins et al. *(1)*.

Project protocool

Writing a project (or research) protocol before beginning data collection is best practice. This is to ensure scientific quality, reduce research waste, clearly define aims and objectives and outline ethical oversight. Although there are many forms that such protocols may take shape, reviewing existing published protocols using CVD ASSESS may be helpful *(1,2)*.

Of course, your protocol may take many forms based on the aim of your project, from descriptive epidemiology to randomized controlled trials. Nevertheless, examples of some of the information you should consider including in your protocol include:

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References

1. Collins DRJ, Laatikainen T, Shoismatuloeva M, Mahmudzoha I, Rahimov Z, Sultonova D et al. Evaluation and pilot implementation of essential interventions for the management of hypertension and prevention of cardiovascular diseases in primary health care in the Republic of Tajikistan [version 1; peer review: 2 approved]. F1000Research. 2019;8:1639 (https://doi.org/10.12688/f1000research.20234.1, accessed 23 September 2020).

2. Collins D, Ciobanu A, Laatikainen T, Curocichin G, Salaru V, Zatic T et al. Protocol for the evaluation of a pilot implementation of essential interventions for the prevention of cardiovascular diseases in primary healthcare in the Republic of Moldova. BMJ Open. 2019;9:e025705. doi:10.1136/bmjopen-2018-025705.

3. The R Project for Statistical Computing [website]. Vienna: R Foundation; 2020 (https://www.rproject.org, accessed 23 September 2020).

4. Swirl [website]. Boston: Swirl; 2020 (https://swirlstats.com, accessed 23 September 2020).

5. HEARTS technical package [website]. Geneva: World Health Organization; 2020 (https://www.who.int/cardiovascular_diseases/hearts/en, accessed 23 September 2020).

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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