Global HPV Reference LabNet Autumn Meeting

Date: 9 October 2026 | Location: Virtual (Microsoft Teams)

Participants (43 atendees, 15 NRLs)

Participant	NRL
Maria Alejandra Picconi	Argentina
Dolores Fellner	Argentina
Mariel Correa	Argentina
Dave Hawkes	Australia
Hamerlinck Hannelore	Belgium
Jade Pattyn	Belgium
Sharon Dhillon	Belgium
Marc Arbyn	Belgium
Aida Sivro	Canada
Vanessa Schulz	Canada
Yang Huan	China
Meihui Gu	China
Shangying Hu	China
Fanghui Zhao	China
Xuelian Zhao	China
Jesper Hansen Bonde	Denmark
Ulrike Wieland	Germany
Timmy Donkoh	Guest/Ghana
Francois Uwinkindi	Guest/Rwanda
Francesca Carozzi	Italy
Clementina Cocuzza	Italy
Marianna Martinelli	Italy

Participant	NRL
Iwao Kukimoto	Japan
Noé Escobar	Mexico
Federica Inturrisi	MSF
MSFF lilongwe	MSF
Kristiane Søreng	Norway
Kate Cuschieri	Scotland
Mario Poljak	Slovenia
Anja Oštrbenk	Slovenia
Sara Arroyo Mühr	Sweden
Joakim Dillner	Sweden
Emel Yilmaz	Sweden
Camilla Lagheden	Sweden
Penelope Gray	Sweden
Sadaf Sakina Hassan	Sweden
Miriam Elfström	Sweden
Nannan Jiang	USA
Nguyen Trang	Vietnam
Maribel Almonte	Former WHO
Mariluz Hernandez	WHO
Prebo Barango	WHO

Agenda

- Introduction, LabNet updates and proficiency testing (Joakim Dillner)
- Introduction of new NRL members: Malawi and China
- International collaboration on standards for HPV prevalence studies – Delphi (Sara Arroyo Mühr)
- International Task Force: mentorship, twinning and support mapping (Sara Arroyo Mühr)
- International consensus on validation of new HPV assays (Joakim Dillner and discussion)
- Discussion, follow-up and closing

1. Introduction and proficiency testing (ppt attached at the end)

• Joakim highlighted LabNet's continuing focus on low-cost, internationally standardised evaluation of HPV assays, proficiency testing and knowledge exchange across the network. LabNet has 20 appointed NRLs, with discussions ongoing with six additional countries.

• The long-standing genotyping panel maintains its established composition. The 2026 screening proficiency panel has stricter sensitivity requirements informed by the LabNet collaborative analytical-threshold studies (J Med Virol, 2026); HPV68 has been excluded in line with the WHO target product profile (TPP).

• For the 2026 proficiency panels, direct subscriptions were reported from 78 laboratories for genotyping and 186 laboratories have ordered the screening panel. LMIC laboratory fees are routinely waived. NRLs can request panels in bulk for national or regional EQA programmes; Argentina, Peru, Norway and Canada are NRLs that are doing this for 2026.

• The published collaborative analytical-threshold study involved ten laboratories but used CIN2+ as endpoint. Sweden has comtinued with invasive cancer as endpoint. Registry linkages identified 187 samples taken before invasive cervical cancer diagnosis. Comparison with the results from the collaborative study using CIN2+ found very similar results regarding optimal analytical thresholds. Optimal analytical thresholds were surprisingly similar for clinician-taken samples and for self-samples. NRLs with PCR databases linkable to cancer registries were encouraged to replicate the approach.

• A staged framework for HPV assay evaluation was introduced: 1. analytical performance using international standards, 2. clinical validation and 3. inter-laboratory reproducibility.

2. Introduction of new members: Malawi and China

Malawi: The planned NRL presentation could not take place. A presentation is to be rescheduled for a future meeting.

China: Shangying Hu, representing Fanghui Zhao's team at the Cancer Hospital, Chinese Academy of Medical Sciences, described the laboratory's HPV epidemiology, screening, assay evaluation, vaccine trials and cancer prevention work. The team highlighted its experience in proficiency testing and clinical evaluation of HPV assays, and its interest in contributing to regional reference-laboratory capacity and international collaboration.

3. HPV prevalence studies – Delphi consensus initiative (ppt attached at the end)

Sara Arroyo reviewed the first Delphi round intended to improve standards for HPV prevalence research in the post-vaccination era. Seven NRLs contributed 12 individual responses across laboratory methods, study design, vaccination data, reporting/comparability and overall feasibility.

• Broad agreement: report assay analytical performance; participate in EQA; define target population and sampling strategy; report sampling calendar period, age/birth cohorts and vaccination coverage where available; use transparent denominators, genotype-specific results and harmonised reporting formats suitable for comparison or meta-analysis.

• Outstanding disagreements: whether clinically validated screening tests must be used in epidemiological surveillance; whether a minimum of eight individually detected genotypes should be mandatory; whether opportunistic samples are acceptable; availability of individual-level vaccination linkage; feasibility across all settings.

• Participants distinguished clinical screening from epidemiological surveillance. Kate Cuschieri and Dave Hawkes explained why broad genotype detection and analytically appropriate methods may be valid for surveillance despite lack of screening validation. Maribel Almonte and Jesper Hansen Bonde emphasised assay quality and between-study comparability. Joakim warned that changing assay sensitivity over time can falsely suggest genotype replacement.

• Specimen types (clinician-collected, self-collected and urine) should be reported explicitly; one universal specimen method was not prescribed. Multiple HPV infections should be reported per genotype in prevalence studies rather than collapsed according to clinical risk hierarchies.

• Potential alignment with the IARC KRONOS initiative was raised. Increasing participation in the Delphi and obtaining example country data were considered important for drafting a useful guidance paper.

Follow-up discussed: recirculate the Delphi among the LabNet members for further input (approximately one month was suggested), refine disputed statements and scope, invite example datasets/tables, consult relevant parallel initiatives including CHRONOS, and continue with writing up the manuscript.

4. International Task Force: capacity building and collaboration

• Sara Arroyo reported on a survey mapping NRL areas of expertise, support needs and interest in serving as mentors or mentees.

• A proposed skills/support directory could help countries identify expertise and arrange direct technical support or structured twinning. The France–Gabon collaboration was discussed as one example.

• Potential collaboration with the International Cancer Screening Network on focused, interactive practical webinars was mentioned.

• Next steps: complete responses, refine how the mapping is presented/shared and explore suitable mentoring partnerships and materials. Participation and resource commitments remain voluntary and to be confirmed.

5. Validation of new HPV assays – toward international harmonization (ppt attached at the end)

• Joakim outlined a three-step model: (1) analytical validation using international standards and relevant genotype-specific thresholds; (2) evaluation using clinical samples; and (3) inter-laboratory reproducibility and described how it had been used to select a high-performance, low cost 8 HPV type-test for use in an LIC country.

• The discussion focused on how the LabNet recommendations would align with VALGENT, work described by Marc Arbyn on a tiered validation framework. WHO reported that facilitation of an international consensus process is underway.

• Jesper Hansen Bonde, Maribel Almonte, María Alejandra Picconi and others raised the importance of avoiding conflicting frameworks that could confuse laboratories, manufacturers and programmes. The need for international coordination and clearly defined scope was broadly supported.

• Maribel emphasised that reproducibility and transferability depend on more than testing in a second high-resource laboratory. Joakim suggested that interlaboratory reproducibility testing should encompass at least one NRL from a low-income country; Rwanda will be used for the first demonstration project.

• Clinical sample selection may show high variability between countries with different geographic variations in genotype distribution, previous screening and vaccination histories. The LabNet has so far used the global metaanalysis of HPV types in cervical cancer by the IARC/WHO as a global standard.

• Francois Uwinkindi emphasised the urgent demand for affordable, quality-assured and sufficiently specific tests for screening implementation in Rwanda and other resource-constrained settings, including reducing unnecessary follow-up and costs.

• Discussions around IPVS Athens and possible WHO meetings were welcomed as venues for coordination.

6. Closing

Joakim thanked participants for their engagement and encouraged continued discussion through IPVS Athens, WHO and LabNet collaborations.

7. Follow-up activities

Activity	Lead / involved	Status / suggested next step
Proficiency panels	IHRC / LabNet	Complete QC and planned late-October distribution
Delphi prevalence guidance	Sara / interested NRLs	Further consultation, revise statements and seek example datasets. Chronos involvement consultation.
Mentorship skills mapping	Sara / LabNet NRLs	Complete survey and review directory approach
International assay-validation guidance	Joakim, WHO and partners	Align frameworks and continue discussions around IPVS

INTRODUCTION

Joakim Dillner

Center for Cervical Cancer Elimination, Karolinska University Hospital & Karolinska Institutet, Stockholm, Sweden

International HPV Reference Center, Karolinska University Hospital, Stockholm, Sweden







Karolinska Institutet

KAROLINSKA UNIVERSITY HOSPITAL

Agenda 20261009

13:00–13:10 Introduction – Joakim Dillner

13:10–13:20 Introduction of new members – Malawi and China

13:20–13:50 International collaboration on reporting of HPV prevalences – Delphi study results (Sara Arroyo)

13:50–14:15 International Twinning activities (Sara Arroyo)

14:15–14:50 Global HPV Laboratory Network Guidelines on Validation of New HPV Screening Tests (Joakim Dillner)

14:50–15:00 Other questions

- Current funding is focussed on development of a guideline for an inexpensive and internationally standardised evaluation of new HPV assays.
- The genotyping and screening proficiency panels remain a core activity.
- Networking for mutually beneficial exchange of experiences continue to be a major part of our activities.

Global HPV Labnet Proficiency panels

- Traceable to international standard preparation of DNA with defined amount (International Unit) to allow reproducibility of panels over time - necessary to compare quality over time.
- Tests detection of multiple infections
- High capacity to detect typing error
- Possible to use with all known HPV DNA tests
- **Genotyping (vaccinology & research) panel: No change in composition.**
- HPV types: 9 HPV vaccine types and the additional 5 types that are classified as oncogenic.
- 40 samples with plasmids, one negative control
- **Screening panel: Important changes in 2026: Increased sensitivity demanded. HPV68 deleted.**
- HPV types: The 7 most oncogenic HPV types and the additional 5 types that are classified as oncogenic
- 12 samples with plasmids, one negative control

Participation

- Announced on the internet (www.hpvcenter.se) + Newsletter mailings.
- Subscription fee. Waiving of fee for LMIC labs possible.
- 2026 years panel will be distributed in the end of October 2026

- NRLs offered the proficiency screening panels in bulk if they want to arrange national QC programs: Launched in Norway, Canada, Peru and Argentina

- The **genotyping panel: 78** laboratories worldwide
- The **screening panel: 186** laboratories worldwide

- Argentina
- Australia
- Belgium
- Brazil
- Canada
- France
- Gabon
- Germany
- Italy
- Japan
- Malawi
- Mexico
- Norway
- Perú
- Rwanda
- Scotland, UK
- Slovenia
- Sweden
- USA
- Vietnam

LabNet composition expanding

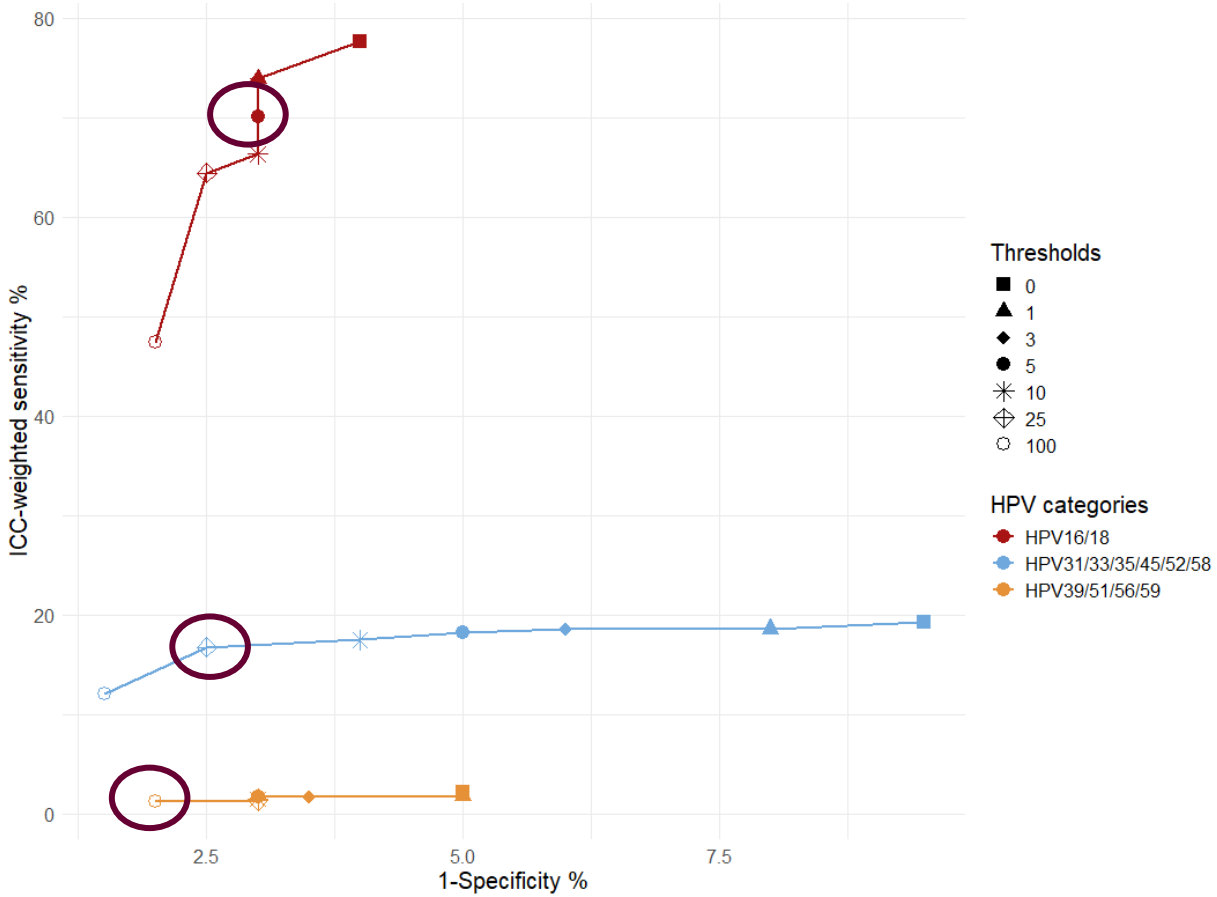
20 appointed NRLs are now members

Ongoing discussions:
China
Ghana
Ukraine
Denmark
Ethiopia
The Netherlands

Regional Reference Labs affiliated:
Lombardy and Tuscany (Italy)

Analytical threshold study

- International Collaborative Study on Human Papillomavirus Analytical Thresholds for Sensitivity and Specificity in Cervical Screening (J Med Virol. 2026 May;98(5):e70936.)
- Participating laboratories from **AUSTRALIA, BELGIUM, FRANCE, GERMANY, ITALY, SCOTLAND, SLOVENIA, SWEDEN, TÜRKİYE, and USA**
- **100 cases** (histopathologically confirmed CIN2+) and **200 population-based matched controls** (women without CIN2+ in histopathology) by age (± 5 years)
- ICC-weighted sensitivity using IARC attributable fractions for invasive cervical cancer** and 1-specificity of CIN2+ by HPV types
  - **3 IU/µl** for HPV16 and 18
  - **25 IU/µl** for HPV31, 33, 45, 52 and 58 and **25 GE/µl** for HPV35
  - **100 GE/µl** for HPV39, 51, 56 and 59.



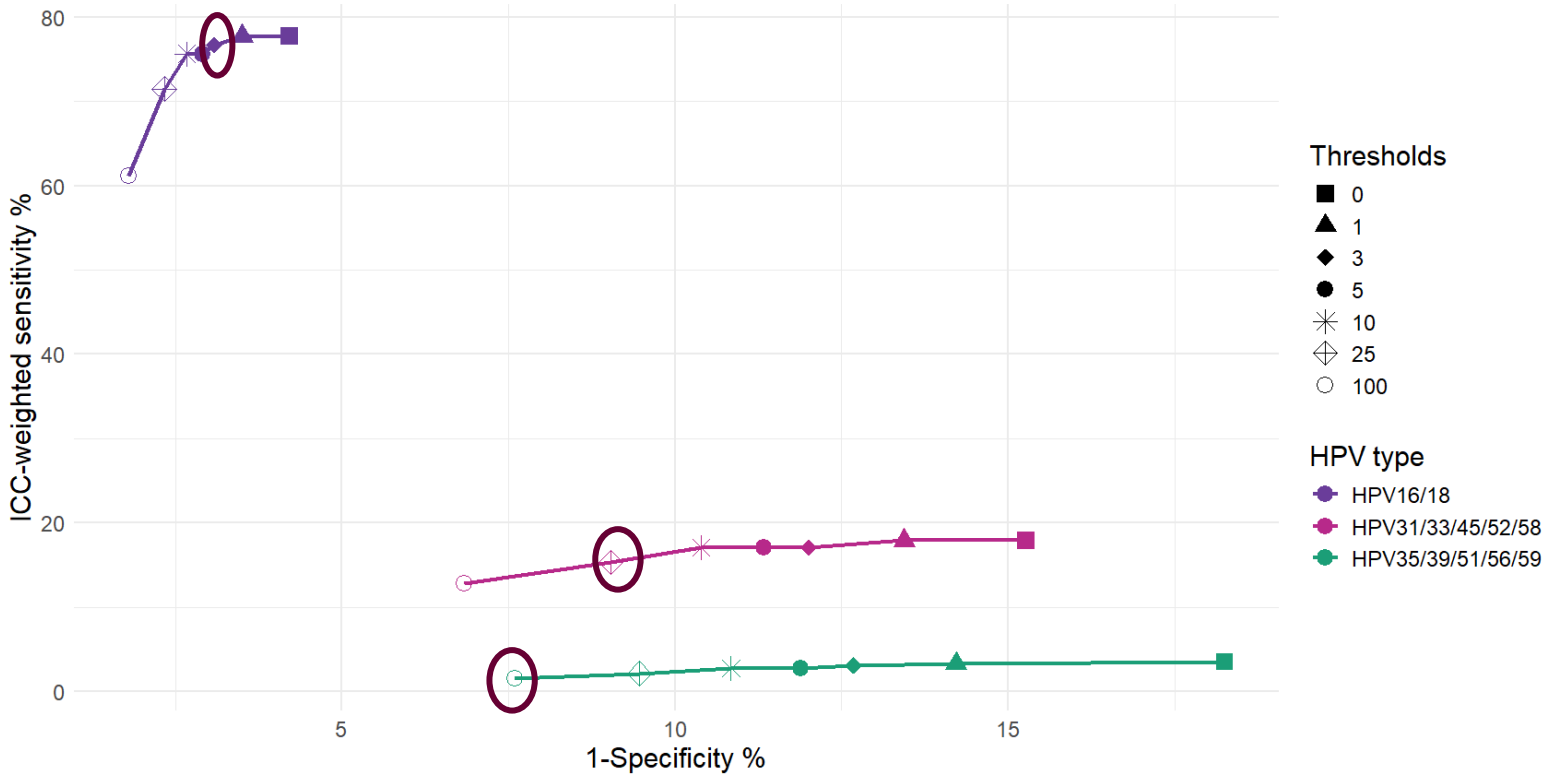
**IARC (2022). Cervical cancer screening. IARC Handb Cancer Prev. 18:1–456. Available from: https://publications.iarc.fr/604

Sweden: 120,000 HPV tests. Linked to cancer registry

CLINICIAN TAKEN SAMPLES

- Sensitivity for invasive cervical cancer** and 1-specificity of invasive cervical cancer by HPV types
- *Analytical thresholds from Study I*

- 3 IU/µl for HPV16 and 18
- 25 IU/µl for HPV31, 33, 45, 52 and 58 and
- 100 GE/µl for HPV35, 39, 51, 56 and 59.



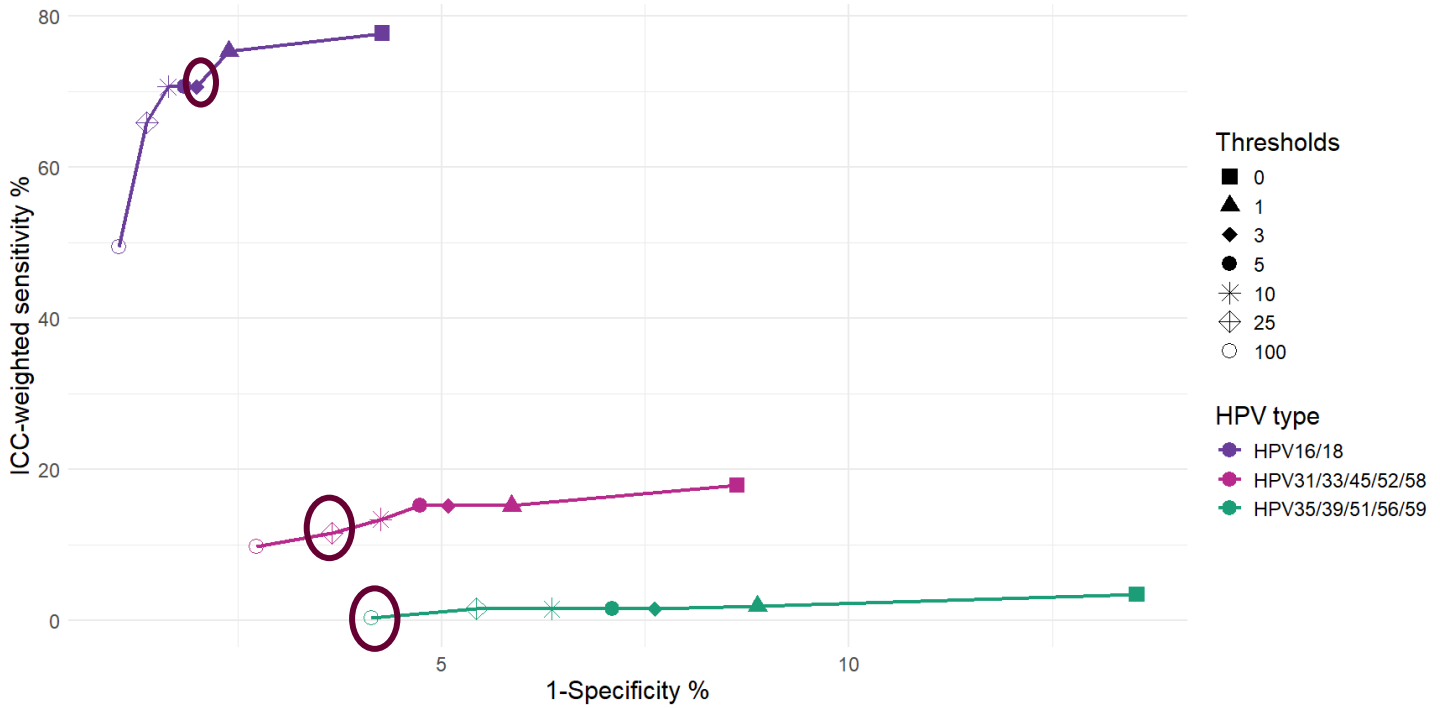
**IARC (2022). Cervical cancer screening. IARC Handb Cancer Prev. 18:1–456. Available from: https://publications.iarc.fr/604

Sweden: 175,000 selfsamples Linked to cancer registry

SELF COLLECTED SAMPLES

- Sensitivity for invasive cervical cancer** and 1-specificity of invasive cervical cancer by HPV types
- *Analytical thresholds from Study I*

- **3 IU/µl** for HPV16 and 18
- **25 IU/µl** for HPV31, 33, 45, 52 and 58 and
- **100 GE/µl** for HPV35, 39, 51, 56 and 59.



**IARC (2022). Cervical cancer screening. IARC Handb Cancer Prev. 18:1–456. Available from: https://publications.iarc.fr/604

- NRLs that have HPV PCR databases that can be linked to cancer registries are encouraged to perform similar studies.
  - We need to work towards widely reserached and well documented optimal analytical thresholds
- Discussion in the LabNet towards consensus on guidelines for assay validation can start now. Suggestion:
  - Step 1: International Standards to evaluate analytical threshold in IU/ul
  - Step 2: Clinical samples: population-based controls (specificity) and CIN2/3 (weighted according to importance of HPV type in ICC) (sensitivity) and/or clinical HPV-positive samples.
  - Step 3: Interlaboratory reproducibility
- We anticipate that NRLs will be asked by their authorities to evaluate assays in their countries.

Summary

- Current funding is focussed on development of inexpensive and internationally standardised evaluation of new HPV assays.
- The genotyping and screening proficiency panels remains a core activity
- Networking for mutually beneficial exchange of experiences continue to be a major part of our activities.

International consensus on methodological standards for HPV prevalence studies in the post-vaccination era

Delphi survey

Over 20,000 publications on HPV prevalence:

- Many lack quality-assured assays
- Study design often unclear
- Vaccination data frequently missing

Implication: Key data on vaccination effectiveness and screening design may become unpublishable.

Observations from Sweden:

- HPV16/18 prevalence declining sharply
- >83% vaccination coverage in school-based programs
- Non-vaccine HPV types remain more common
- Indirect protection observed beyond vaccinated cohorts (herd immunity)

Proposal: Guideline paper on requirements for HPV prevalence studies.

Requirements:

- Use LabNet-proficient laboratories and validated assays
- Clearly defined sampling strategy (population-based, calendar year)
- Include vaccination coverage data

International consensus on methodological standards for HPV prevalence studies in the post-vaccination era

Delphi survey

7

NRLs participating

12

individual answers

5

response domains

COUNTRIES REPRESENTED

Argentina · Brazil · France · Italy · Norway · Peru · Slovenia

Aim:
review the first responses, agree what we can already call consensus,
and decide whether to run another Delphi round or move toward a manuscript.

SECTIONS

LABORATORY METHODS

STUDY DESIGN

VACCINATION DATA

DATA REPORTING AND COMPARABILITY

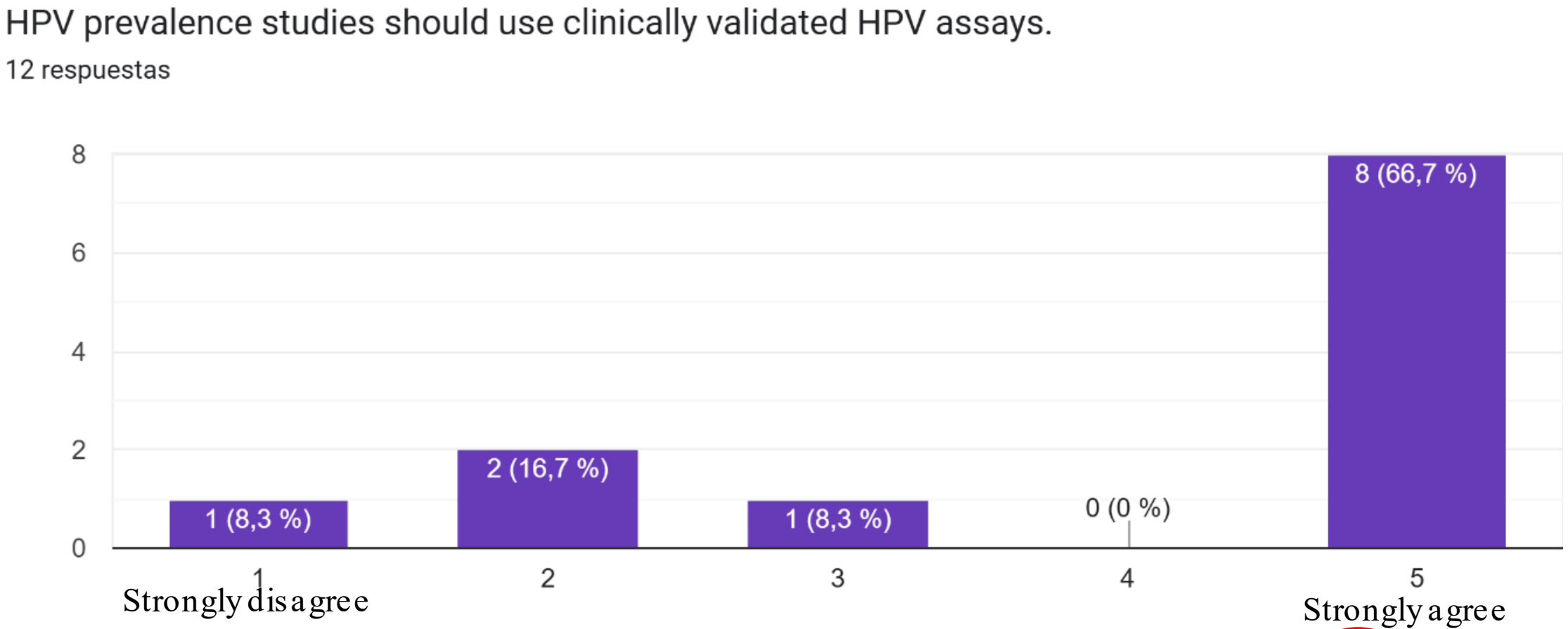
FINAL SECTION

SECTIONS

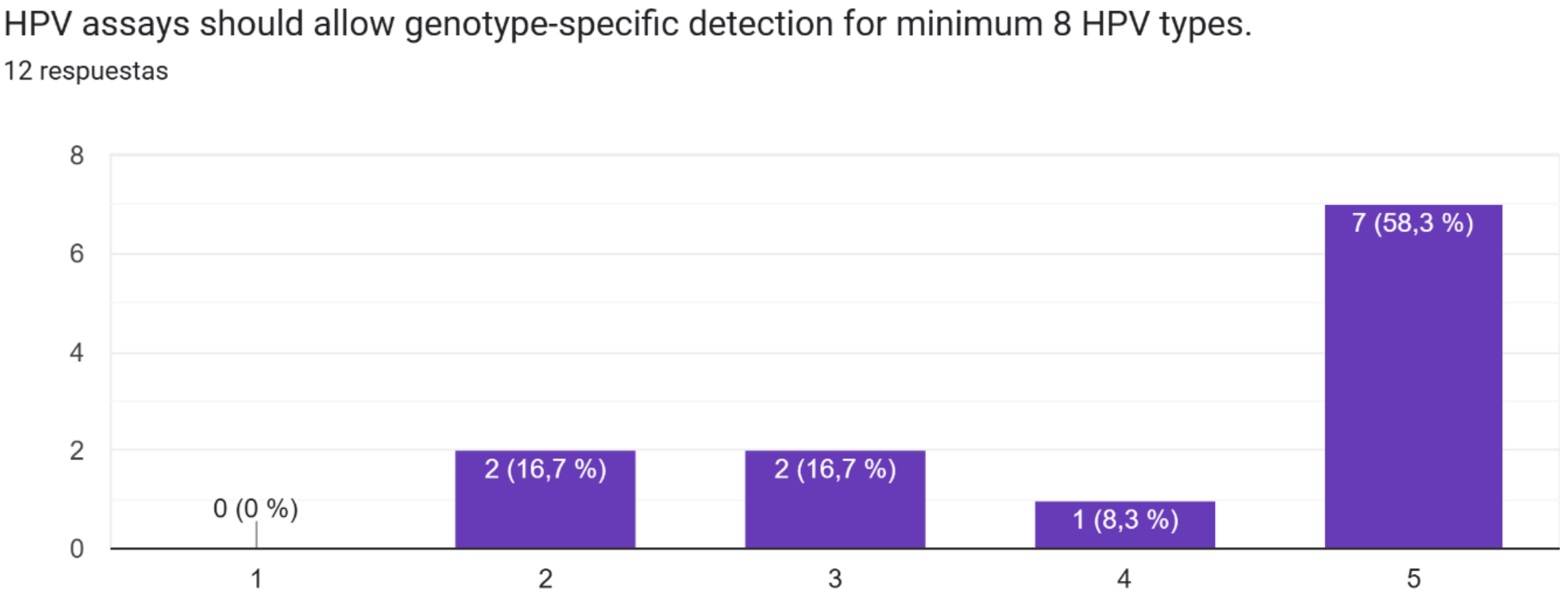
LABORATORY METHODS

- The analytical performance characteristics of the HPV assay should be clearly reported.
- Laboratories performing HPV testing should participate in external quality assurance (QA) programmes.
- Participation in international QA programmes (e.g., HPV LabNet) is recommended.
- Use of assays with broad genotype coverage is recommended for epidemiological studies.

LABORATORY METHODS



LABORATORY METHODS



LABORATORY METHODS

1. I believe the best approach to HPV prevalence studies is to use tests that allow for the individual identification of the greatest number of genotypes with the highest possible sensitivity; a different approach from screening tests. It is essential that laboratories performing these studies have a proven track record of adequate performance on DNA Typing Proficiency Panels.

2. Non-clinically validated methods may be useful if they are sensitive and can detect a wide range of genotypes.

4. I would recommend the use of a genotyping test with a broad genotype coverage and a high analytical sensitivity.

SECTIONS

STUDY DESIGN

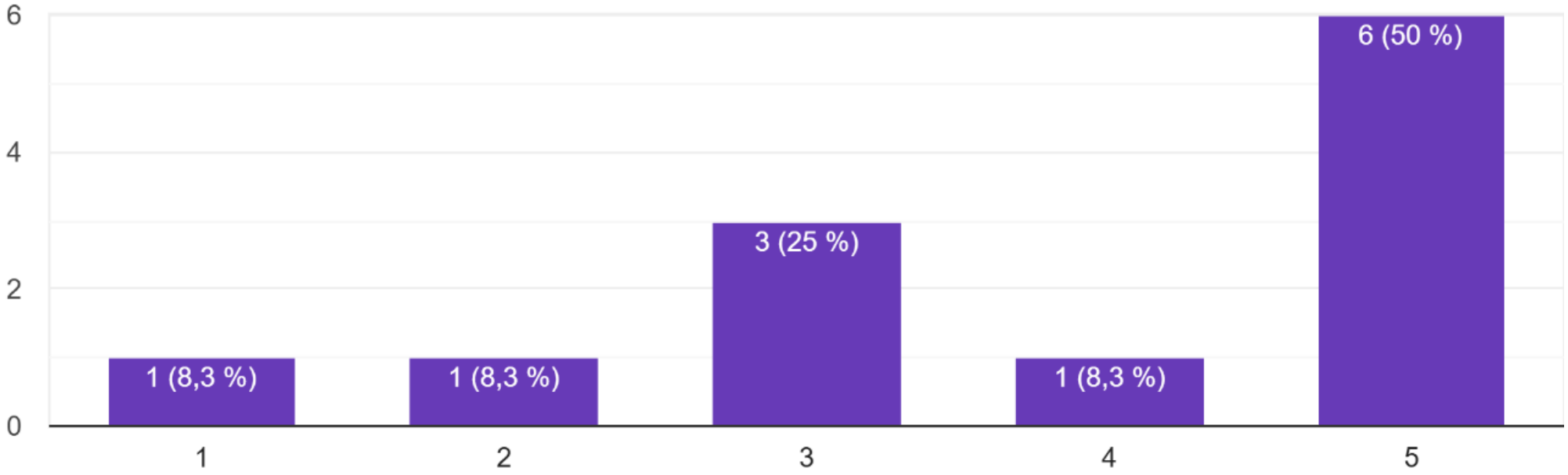
STUDY DESIGN

- The target population of HPV prevalence studies should be clearly defined.
- Sampling strategies should be explicitly described.
- Population-based sampling should be used where feasible.
- The calendar period of sampling must be clearly specified.
- Results should be stratified by age group.
- Results should be stratified by birth cohort where possible.
- Alignment of study populations with vaccination cohorts is recommended.

STUDY DESIGN

Sentinel or opportunistic sampling may be acceptable if clearly justified.

12 respuestas





STUDY DESIGN

1. While rigorous population-based studies with cohort alignment of vaccinated individuals are ideal, I suggest trying to make the most of the available data from different countries while being somewhat flexible, without compromising the quality of the work.

SECTIONS

VACCINATION DATA

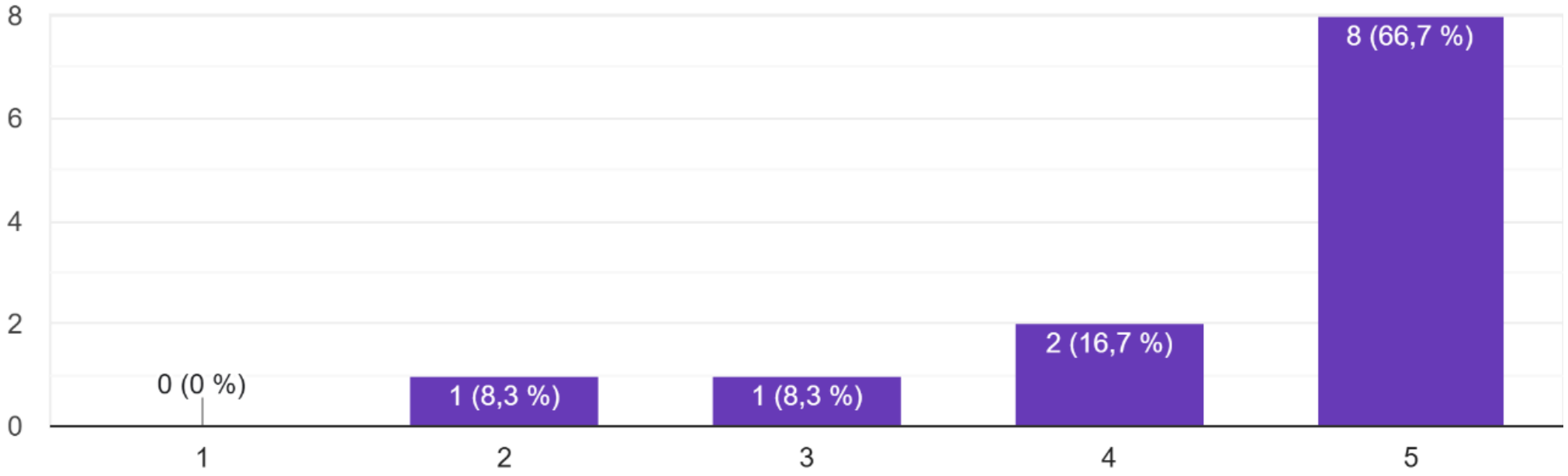
VACCINATION DATA

- HPV prevalence studies should report vaccination coverage for the relevant population.
- Vaccination coverage should be reported by birth cohort where possible
- Lack of vaccination data significantly limits interpretation of HPV prevalence results.

VACCINATION DATA

Linkage to individual-level vaccination data is recommended when feasible.

12 respuestas





VACCINATION DATA

1. Limited interoperability between screening and vaccination systems prevents systematic individual-level linkage. Without individual vaccination data, regional heterogeneity skews post-vaccination conclusions, which is a limitation for prevalence studies in Peru.

2. Agree that HPV prevalence studies should report vaccination coverage for the relevant population, however, only if this is possible.

SECTIONS

DATA REPORTING AND COMPARABILITY

DATA REPORTING AND COMPARABILITY

- HPV prevalence studies should report overall HPV prevalence.
- Genotype-specific HPV prevalence should be reported.
- Results should be stratified by key variables (e.g., age, birth cohort).
- Results should be stratified by vaccination status when available.
- Clear denominators should be reported for all analyses.
- Standardized reporting formats should be used to facilitate comparability across studies.
- Data should be reported in a way that allows pooling and meta-analysis.

DATA REPORTING AND COMPARABILITY

1. Should be clear how multiple infections are treated. Count both?

SECTIONS

FINAL SECTION

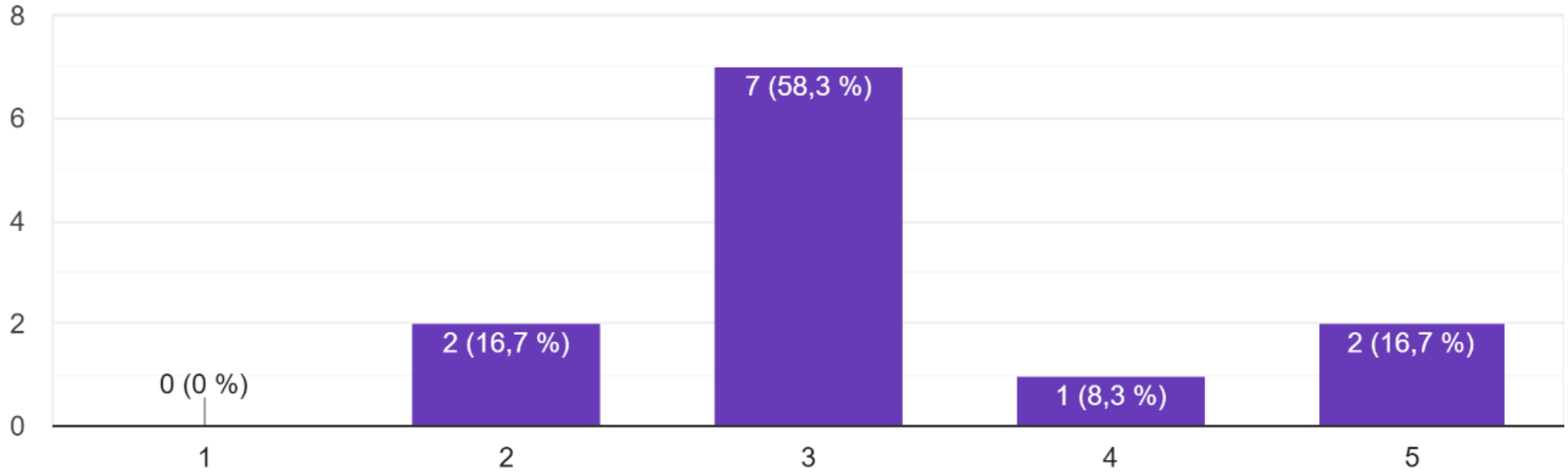
FINAL SECTION

- Overall, the proposed set of statements addresses key methodological limitations in HPV prevalence studies.
- The proposed set of statements would improve comparability of HPV prevalence data globally.

FINAL SECTION

The proposed set of statements is feasible to implement in most settings.

12 respuestas



FINAL SECTION

1. I believe there is significant heterogeneity in the possibilities of accessing and meeting the proposed requirements at the LabNet level, and even more so globally. This guide can help mitigate that heterogeneity and allow us to work more effectively together.

2. INS-Peru supports this international consensus, but it is necessary to switch to technology capable of detecting 8 genotypes, strengthen geographic access to dispersed high-Andean and Amazonian populations, improve interoperability between the vaccine database and the screening database, and apply standardized protocols with stratification by vaccine cohort (pre-2011, tetravalent, nonavalent) and clear denominators for global meta-analysis.

NEXT

Consensus decision to be reached at this meeting

Countries that would like to give example data

Manuscript

The HPV LabNet Guideline for HPV DNA test validation – suggestion and first real-life test

Carina Eklund

Center for Cervical Cancer Elimination,

Karolinska University Hospital &, Karolinska Institutet

Stockholm, Sweden









Analytical detection thresholds to detect CIN 2+ in screening

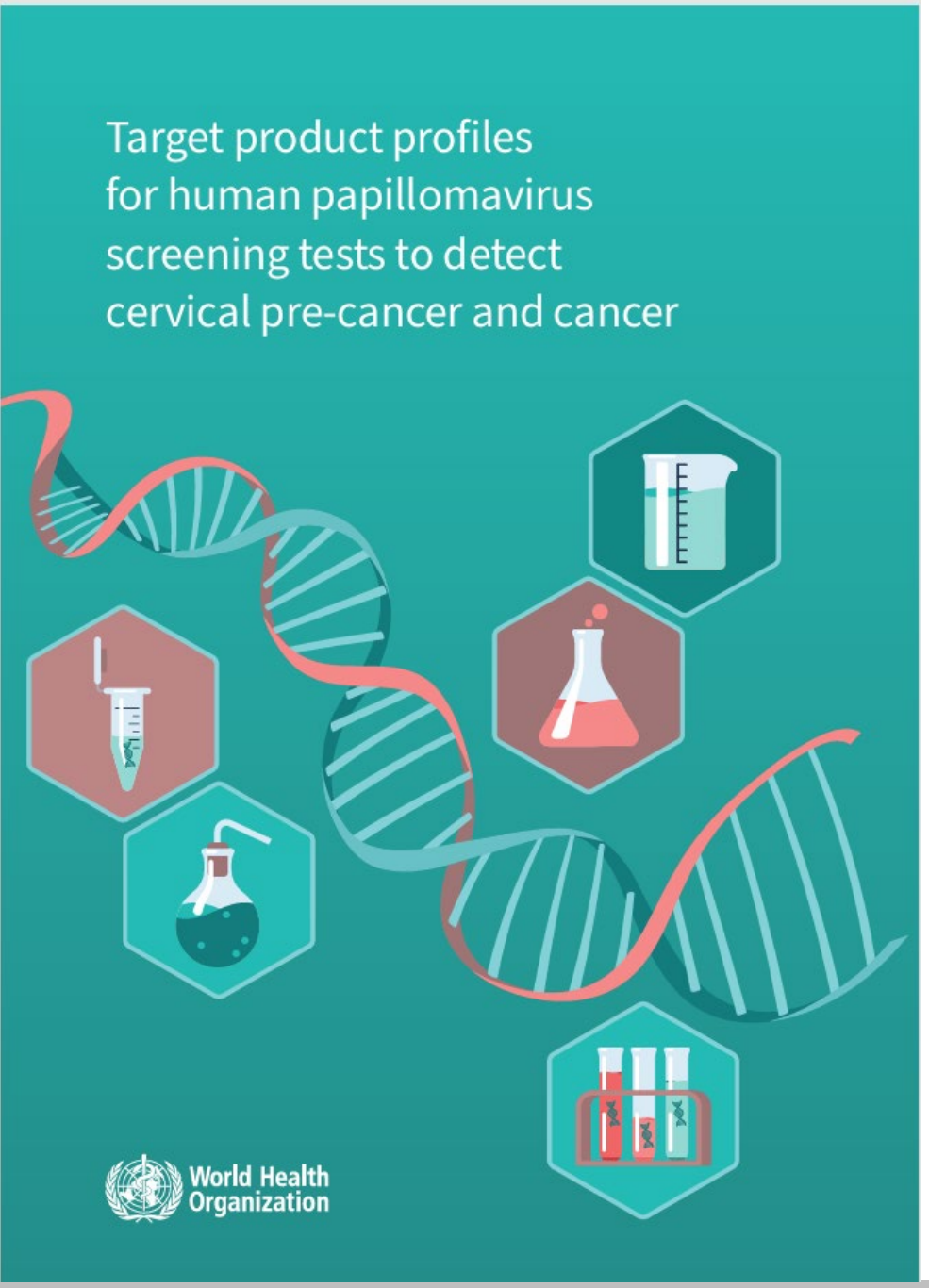
- International collaboration 10 different laboratories in 10 countries (J Med Virol. 2026 May;98(5):e70936.)
- 100 cases of CIN 2+, 200 matched controls
- Line plots of 1-specificity and ICC wighted sensitivity found optimal analytical detection thresholds:
  - HPV 16 and HPV 18; 3 IU / ul
  - HPV 31, 33, 35, 45, 52 and 58; 25 IU / ul
  - HPV 39, 51, 56, 59 and 68; 100 copies / ul

- Yilmas et al. Journal of Medical Virology, 2026; 98:e70936

Step 1: Analytical sensitivity and specificity using International Standards of HPV DNA

HPV type	Copy numbers (IU) / ul
16	10, 3, 3, 3, 1
18	10, 3, 3, 3, 1
31	100, 25, 25, 25, 5
33	100, 25, 25, 25, 5
35	100, 25, 25, 25, 5
45	100, 25, 25, 25, 5
52	100, 25, 25, 25, 5
58	100, 25, 25, 25, 5
39, 51, 56, 59, 68	1000, 100, 100, 100, 50
16 in 39, 51, 56, 59, 68	10 in 1000
None	-

The Panel contains 47 samples in total



WHO TPP 2024

Major changes:
Do NOT test for HPV68 and 66.
Testing for HPV39/51/56/59 is optional.
The tests should be able to distinguish HPV16 and 18.

Target cost <5USD or <3USD for point of care tests

Four new HPV tests fulfilling TPP were sourced

- 4 different tests validated detecting HPV 16 and 18 individually, 31, 33, 35, 45, 52, 58 in a pool as Other HR HPV

  - Test A; Lyophylised, kit contains strips with all reagents, stored at +4 degrees, 5 ul sample volume
  - Test B; Reagents stored at -20 degrees, 48 test / kit, 4 ul sample volume
  - Test C; Reagents stored at -20 degrees, 48 test / kit, 10 ul sample volume
  - Test D; Reagents stored at +4 degrees, 48 test / kit, 5 ul sample volume

  All analysed using Bio-Rad CFX96 Real-time PCR

Test validation panel results

HPV type	copies/ul/type	Test A	Test B	Test C	Test D
16	3	3 / 3	0 / 3	3 / 3	3 / 3
18	3	3 / 3	0 / 3	3 / 3	3 / 3
31	25	3 / 3	2 / 3	3 / 3	3 / 3
33	25	3 / 3	2 / 3	3 / 3	3 / 3
35	25	3 / 3	0 / 3	3 / 3	3 / 3
45	25	2 / 3	1 / 3	3 / 3	3 / 3
52	25	3 / 3	1 / 3	3 / 3	3 / 3
58	25	3 / 3	0 / 3	3 / 3	3 / 3
neg	0	0	0	0	0
39, 51, 56, 59, 68	100	0	0	0	0

Step 2: Clinical samples

- Clinical validation of test A, C and D
- 99 CIN 2+ cases and 99 matched controls (same ones as in the J Med Virol 2026 paper)
- Samples weighted by their importance in cervical cancer. Eg; HPV16 weight 1,84 ; HPV68 weight 0,2
- Proportion in invasive cervical cancers in international IARC systematic reviews/Proportion in the CIN2+ cases in this series.

Results:

	abs_sens	rel_sens	abs_spec	rel_spec
RefLab_all	99,1	100	79,8	96,4
RefLab_3_25_100	96,6	99,7	91,9	110,9
BD/Cobas	99,1	100	82,8	100
Test A	95,0	95,9	87,9	106,1
Test C	95,9	96,8	79,8	96,4
Test D	96,5	97,4	89,9	108,6

Step 3: Interlaboratory reproducibility

- No major change needed compared to the old guidelines (IJC, 2009).
- 500 samples evaluated by NRLs in 2 different countries.

Next steps

- Discussions on guideline formulation in the LabNet
- Publication (IJC target journal).

- Technology transfer so that all NRLs should be able to do this in an internationally standardised manner.