

**HPV Serology Standardization Meeting**  
**Virtual**  
**June 29-30, 2021**

**Agenda**

**Day 1: Tuesday June 29, 2021**

**9:00 AM - 9:10 AM**

**Welcome and Meeting Goals**

*Ligia Pinto, Frederick National Laboratory for Cancer Research (FNLCR)  
and Elizabeth Unger, Centers for Disease Control and Prevention (CDC)*

**9:10 AM - 10:50 AM**

**Session I: HPV Serology Standardization Efforts: An Update**

*Chair: Elizabeth Unger, CDC*

**Objectives:**

- Provide updates on HPV Standards for the 9 HPV types of interest
- Describe availability and implementation approaches of International Standards, as well as other key reagents for HPV serology
- Identify other key reagents in standardization

9:10 AM - 9:15 AM

Introduction to the Session

*Elizabeth Unger, CDC*

9:15 AM - 9:30 AM

HPV Serology Standardization Initiative at FNLCR: An update

*Ligia Pinto, FNLCR*

9:30 AM - 9:50 AM

WHO International Standards (IS) for HPV serology: Recent development and implementation plans

*Dianna Wilkinson, National Institute for Biological Standards and Control (NIBSC)*

9:50 AM – 9:55 AM

Q&A

9:55 AM - 10:50 AM

Facilitated Discussion #1 (*Moderator: Dianna Wilkinson, NIBSC*)

- Standards implementation
- Reporting results in International Units (IU) – methods and consensus on best practices
- Neutralization assays standardization and reporting in IU
- Calibration to International Standards procedure
- Other reagents needed for standardization

**10:50 AM - 11:10 AM**

**Break**

**HPV Serology Standardization Meeting**  
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**Day 1: Tuesday June 29, 2021 (Continued)**

|                           |  |
|---------------------------|--|
| <b>11:10 AM - 1:00 PM</b> | <b>Session II: Developments and Challenges in HPV Serology Assays</b><br><i>Chair: Ligia Pinto, FNLCR</i><br><b><u>Objectives:</u></b> <ul style="list-style-type: none"><li>• Review recent serology assay developments to evaluate immunogenicity of current and next generation vaccines</li><li>• Discuss approaches to determine assay cut-off values</li></ul> |
| 11:10 AM - 11:15 AM       | Introduction to the Session<br><i>Ligia Pinto, FNLCR</i>   |
| 11:15 AM - 11:30 AM       | HPV serology multiplex assays at FNLCR: An update on development and validation<br><i>Troy Kemp, FNLCR</i>   |
| 11:30 AM - 11:45 AM       | Serology assays for L2-based HPV vaccines<br><i>Richard Roden, Johns Hopkins University</i>  |
| 11:45 AM - 12:00 PM       | Observations on use of children's sera to establish assay cut-off<br><i>Gitika Panicker, CDC</i>   |
| 12:00 PM – 12:10 PM       | Q&A  |
| 12:10 PM - 1:00 PM        | Facilitated discussion #2 ( <i>Moderator: Elizabeth Unger, CDC</i> ) <ul style="list-style-type: none"><li>• Definition of cut-off value</li><li>• Can cut-off values be established in IU/ml and harmonized?</li><li>• Interlaboratory comparisons for establishing cut-off value</li><li>• New questions raised by new assays</li></ul>                            |
| <b>1:00 PM</b>            | <b>End of Day 1</b>  |

**HPV Serology Standardization Meeting**  
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**Day 2: Wednesday June 30, 2021**

**9:00 AM – 9:35 AM**

**Session I & II (Continuation)**

9:00 AM – 9:15 AM

Development of high-throughput assay for HPV neutralizing antibodies  
*Jianhui Nie, National Institutes for Food and Drug Control*

9:15 AM – 9:30 AM

Anti-HPV Monoclonal Antibodies: A key resource for Serology Assay QC  
*Neil Christensen, Penn State University*

9:30 AM – 9:35 AM

Q&A

**9:35 AM – 12:55 PM**

**Session III: HPV serology assessments in one dose immunobridging studies and new prophylactic vaccines in development**

*Chairs: Deborah Watson-Jones, The London School of Hygiene & Tropical Medicine (LSHTM) and Joakim Dillner, Karolinska Institutet (KI)*

**Objectives:**

- Review of assays used or planned to be used in HPV vaccine trials and immunobridging studies
- Review of progress of ongoing one dose HPV vaccine trials
- Discuss standardization and data analyses plans

9:35 AM - 9:40 AM

Introduction to the Session  
*Joakim Dillner, KI*

9:40 AM - 9:55 AM

HPV serology testing in Merck vaccine studies: Recent developments and observations  
*Alfred Saah, Merck & Co., Inc.*

9:55 AM - 10:10 AM

HPV Serology Assays: A collaborative approach for implementation  
*Aparna Kasinath, Syngene International Limited*

10:10 AM - 10:30 AM

One dose immunobridging trials: Review of study portfolio progress and plans for harmonization of analyses  
*Anne Schuind, PATH*

10:30 AM - 10:45 AM

DORIS Study: Review of immunobridging plans and preliminary data  
*Deborah Watson-Jones and Kathy Baisley, LSHTM*

10:45 AM - 11:00 AM

Immunogenicity of a prime and deferred-booster dosing schedule: Preliminary review of results  
*Vikrant Sahasrabuddhe, National Cancer Institute*

11:00 AM - 11:15 AM

KEN-SHE study: Planned Antibody Testing  
*Denise Galloway, Fred Hutchinson Cancer Research Center and Ruanne Barnabas, University of Washington*

11:15 AM – 11:30 AM

Design of an alternative-dose schedule trial evaluating the Inovax bivalent HPV vaccine  
*Niranjan Bhat, PATH*

11:30 AM – 11:40 AM

Q&A

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**Day 2: Wednesday June 30, 2021 (Continued)**

|                            |  |
|----------------------------|--|
| <b>11:40 AM – 11:55 AM</b> | <b>Break</b>   |
| 11:55 AM – 12:15 PM        | Overview of new HPV prophylactic vaccines in development<br><i>Peter Dull, The Bill &amp; Melinda Gates Foundation</i>                   |
| 12:15 PM – 12:30 PM        | Immunobridging trials for new schedules and vaccines: A regulatory perspective<br><i>Jeff Roberts, U.S. Food and Drug Administration</i> |
| 12:30 PM – 12:55 PM        | Q&A & Open Discussion  |
| <b>12:55 PM – 1:00 PM</b>  | <b>Closing Remarks</b>   |

TIMEZONES

|             |        |         |
|-------------|--------|---------|
| *US EDT     | 9AM    | 1PM     |
| Australia   | 11PM   | 3AM     |
| Belgium     | 3PM    | 7PM     |
| China       | 9PM    | 1AM     |
| England     | 2PM    | 6PM     |
| France      | 3PM    | 7PM     |
| Germany     | 3PM    | 7PM     |
| India       | 6:30PM | 10:30PM |
| Netherlands | 3PM    | 7PM     |
| Sweden      | 3PM    | 7PM     |
| Switzerland | 3PM    | 7PM     |
| Uganda      | 4PM    | 8PM     |
| US PDT      | 6AM    | 10AM    |
| US CDT      | 8AM    | 12PM    |

\*all times in agenda are listed as US EDT