



Florida CDC HPV Typing Study

**State of Florida Department of Health
Florida Cancer Data System
University of Florida**

**Presented by:
Dr. Jill MacKinnon
Carlos Alvarez
Amy Wright**

CDC HPV Typing Study

CDC pilot study protocol HPV vaccine on HPV types Introduction

The Centers for Disease Control and Prevention (CDC) has chosen Florida to participate in a pilot project to determine the feasibility of developing a systematic approach to monitoring human papilloma virus (HPV) genotypes in several different HPV related cancers (cervix, vagina, vulva, penis, anus and selected head and neck cancers). This study will involve pathology review of randomly selected cancer diagnosed in your facility in 2004 and 2005. CDC (through their coordinating center Battelle) will cover all the costs associated with processing and shipping the specimens.

CDC HPV Typing Study

Florida Cancer Data System Project Team

Department of Health

Dr. Youjie Huang, Section Administrator

FCDS/University of Miami

Dr. Jill MacKinnon, Epidemiologist and Project Director

Gary M. Levin, CTR, Administrative Director

Megsys Herna, BA, CTR, Manager of Data Acquisition

Carlos Alvarez, BBA, Field Coordinator

CDC HPV Typing Study

Florida Central Laboratory

University of Florida

Dr. Ed Wilkinson, Pathologist

Cynthia Bevis, Business Manager

Dr. Martha Campbell Thompson, Path Lab Director

Amy Wright, Study Director

Karen Hyde, Study Coordinator

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Florida State Facility Participants (52 - Randomly Selected)

Hospital/Laboratory	Hospital/Laboratory	Hospital/Laboratory	Hospital/Laboratory	Hospital/Laboratory
SHANDS UNIVERSITY OF FLORIDA	CORAL SPRINGS MEDICAL CENTER	HOMESTEAD HOSPITAL	METROPOLITAN HOSPITAL OF MIAMI	COLUMBIA HOSPITAL
WESTSIDE REGIONAL MED CTR	CLEVELAND CLINIC HOSPITAL	BAPTIST HOSPITAL OF MIAMI	CORE PLUS LLC at KENDALL MEDICAL CENTER	DELRAY MEDICAL CENTER
MEMORIAL REGIONAL HSPITAL SOUTH	PLANTATION GENERAL HOSP	MERCY HOSPITAL	SOUTH SHORE HOSPITAL & MEDICAL CTR	BETHESDA MEMORIAL HOSPITAL
NORTH RIDGE MEDICAL CENTER	NORTHWEST MEDICAL CENTER	UNIVERSITY OF MIAMI HOSPITAL	U OF MIAMI HOSPITAL CLINICS	ST MARYS HOSPITAL
BROWARD GENERAL MEDICAL CENTER	FLORIDA MEDICAL CENTER	DOCTORS HOSPITAL	JACKSON NORTH MEDICAL CENTER	WEST BOCA MEDICAL CENTER
MEMORIAL REGIONAL CANCER CENTER/ONCOLOGY DATA CTR MEMORIAL SUPPORT SERVICES	UNIVERSITY MEDICAL CENTER	HIALEAH HOSPITAL	SOUTH MIAMI HOSPITAL	BOCA RATON COMMUNITY HOSPITAL
NORTH BROWARD MEDICAL CENTER	MEMORIAL HOSPITAL WEST	MIAMI HEART INSTITUE	CORAL GABLES HOSPITAL	GOOD SAMARITAN MEDICAL CENTER
IMPERIAL POINT MEDICAL CENTER	JACKSON SOUTH COMMUNITY CENTER	MOUNT SINAI MEDICAL CENTER	PALMETTO GENERAL HOSPITAL	JFK MEDICAL CENTER
MEMORIAL HOSPITAL PEMBROKE	AVENTURA HOSP AND COMP CANCER CTR	NORTH SHORE MEDICAL CENTER	H LEE MOFFITT CANCER CENTER	WELLINGTON REGIONAL MEDICAL CENTER
HOLY CROSS HOSPITAL	JAMES M JACKSON MEMORIAL HOSPITAL	PALM SPRINGS GENERAL HOSPITAL	LEE MEMORIAL HEALTH SYSTEM	PALMS WEST HOSPITAL

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SITES SELECTED

1 Cervical	2 Vagina	3 Vulva	4 Anus	5 Penis	6 Head/Neck	Total
176	32	44	44	50	224	570

CDC HPV Typing Study

Full Study Title:

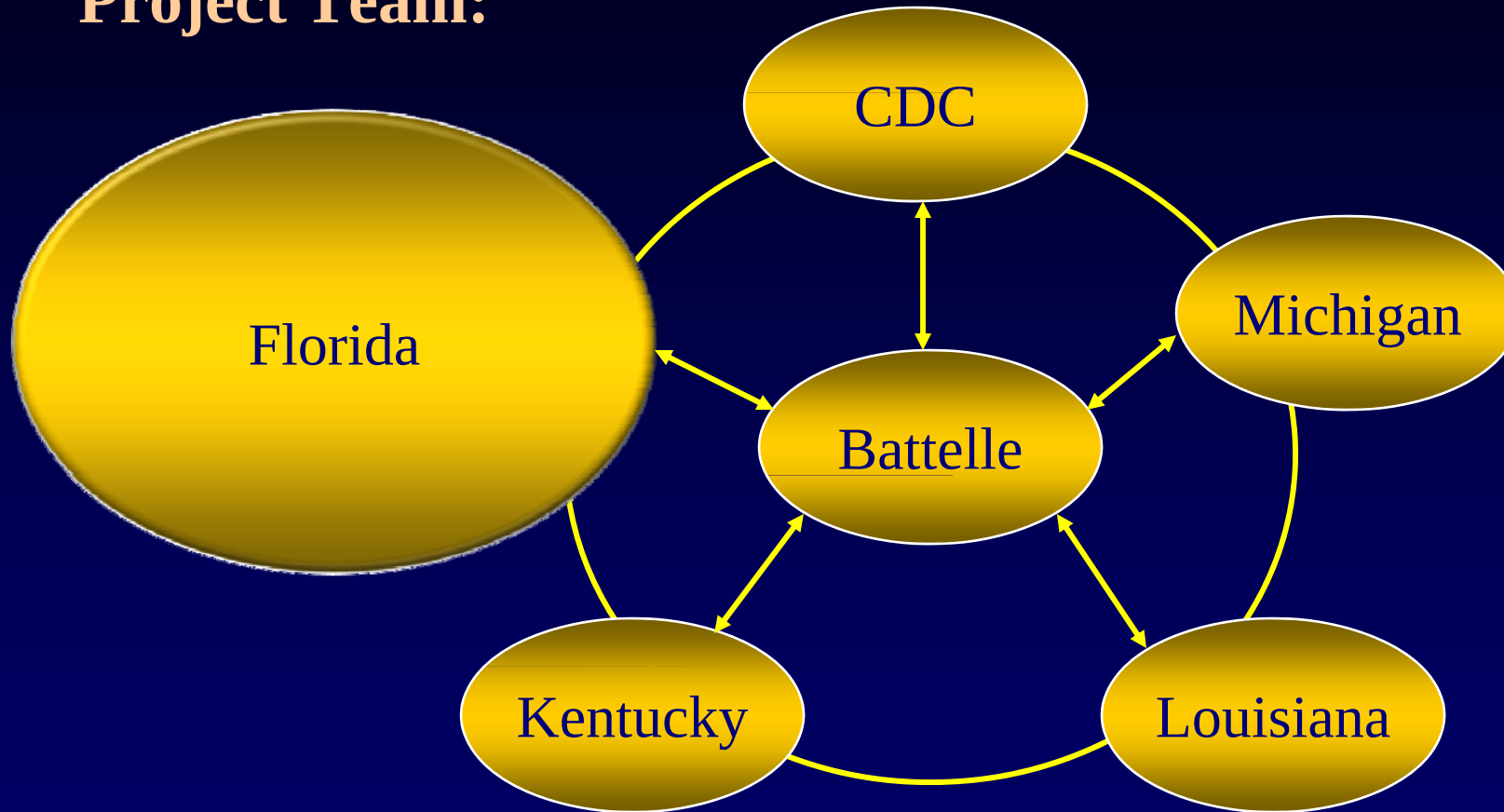
Monitoring the Impact of a Prophylactic HPV Vaccine on HPV Types in Cervical and Other HPV-associated Cancers: Using Tissues from Central Cancer Registries

Study Objective:

- **To develop an infrastructure for the systematic monitoring of HPV types in cervical cancer cases**
- **Use the infrastructure to conduct a pilot study on HPV typing on all or a sample of cervical cancer, and other HPV-associated cancer cases (penile, vulvar, vaginal, anal, and oropharyngeal) from 4 states**

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Project Team:



CDC HPV Typing Study Protocol

- State Cancer Registry (CR) search cancer records, identify eligible cases, which would be cancers with a site of cervix and other HPV-associated sites.
- Send requests to pathology labs to submit tissue samples to CDC. A randomly generated ID will be used to identify each subject

CDC HPV Typing Study Protocol

- The CR ID will serve as the link to the case data records and the pilot study Specimen ID. The list (CR ID and case identifier info) will be sent to the participating hospitals/labs for the tissue sample submission (i.e., Tissue Sample Request Form – **White Form**). CR will also send the CR IDs to Battelle for QA/QC purposes and for preparing sample collection kits and shipping materials.

CR Central Registry White Form

CDC Cancer/HPV Surveillance System Tissue Sample Request Form/List

CDC Cancer/HPV Surveillance System Tissue Sample Request Form/List					
Facility Contact Information:					
No.	Patient's Full Name	Patient's DOB	Patient ID	Cancer Site	CR ID (CR generated unique ID)
1					<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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13					<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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15					<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Requested By (Cancer Registry):					Requested Date:

CDC HPV Typing Study Protocol

Tissue sample submission

- **The local hospital/path lab will ship the tissue block to the Central Path Lab at the University of Florida and the CPL will prepare and ship the requested tissue sample to CDC. The remaining tissue block will be returned to the local hospital/path lab.**

CDC HPV Typing Study Protocol

- Pathology labs prepare tissue sections and H&E stained slides using standardized protocol to minimize contamination. Samples are de-identified by using CR ID and Specimen ID. The lab submits these samples to CDC HPV Lab. The linkage documents are maintained by the local hospital/path lab. The shipping reports (i.e., **Yellow Form** of SOP 102) only contain anonymous CR ID and/or specimen IDs. The CPL, Battelle, and CDC will not have any identifier information.

SOP 102

Tissue Samples Collection, Preparation, Shipping, and Reporting For Hospitals/Labs Submitting Tissue Blocks to a Central Path Lab

CDC Cancer/HPV Surveillance System Tissue Block Submission Form

Facility Contact Information:		Facility ID: Request ID:	
CR ID Please Print/Write Clearly	Diagnosis Remarks (by hospital/path lab)	Submission Remarks (by hospital/path lab)	Returning Remarks (by central path lab)
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<div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> </div> <p>Is Tissue Available? ☐ YES ☐ NO</p> <p>✓ Tissue Site: ☐ Cervix ☐ In situ-Cervix ☐ Anal ☐ Penile ☐ Vaginal ☐ Vulvar ☐ H&N HPV *Please specify actual site in Remarks.</p>	*If submitting H&N, please specify site:		
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Relinquished by Facility: (Print Name)		Date:	
Signature:		Time:	
Relinquished by Central State Study Path Lab: (Print Name)		Date:	
Signature:		Time:	

CDC HPV Typing Study Protocol

- Battelle will provide sample collection supplies, monitor the de-identified tissue samples' shipment status (e.g., cross check shipping reports from hospitals and CDC HPV lab), ensure sample safe delivery and receipt, and provide technical assistance to CRs and participating hospitals/path labs as needed.

CDC HPV Typing Study Protocol

- FCDS will prepare the de-identified data file per study protocol (e.g., CR ID, demographic data, etc.) and send the de-identified data file to Battelle via secure file transfer protocol.

CDC HPV Typing Study Protocol

- CDC HPV Lab confirms receipt of samples, conducts sample analyses (e.g., PCR genotyping, HPV variant and viral load status, etc.), and send the results to Battelle via secure file transfer protocol. The lab results will not alter any treatment of the cancer cases as it is a retrospective analysis and the cancer cases already have undergone treatment. The file submission method will require data to be received in a consistent and clean format.

CDC HPV Typing Study Protocol

- Battelle collates and merges databases (from all CRs). Battelle will run additional quality assurance programs to ensure that cancer cases data from CR's and genotyping results from CDC are consistent and clean.

CDC HPV Typing Study

Procedures for the Path Lab: 3-Step Approach

1. Locate & Retrieve subject's tissue sample per CR request.
2. Prepare tissue sample per SOP.
3. Ship & Report tissue sample per SOP.

All supplies (except a few small items), shipping cost and materials will be provided by Battelle. All sample containers (tubes and slides) will also be pre-labeled by Battelle.

◆ References:

- ❑ SOP 102: Tissue Samples Collection, Preparation, Shipping, and Reporting for Hospitals/Labs Submitting Tissue Blocks to a Central Path Lab

CDC Green Form Cancer/HPV Surveillance System Specimen Chain Of Custody Record

CDC Cancer/HPV Surveillance System Specimen Chain of Custody Record (Green Form)

Facility Contact Information:		Facility ID: Request ID:	
CR ID Please Print/Write Clearly	Tissue Sample ID	Conditions	Remarks
<div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div> <div>Is Tissue Available?</div> <div> ☐ YES ☐ NO </div> <div> <div>✓ Tissue Site:</div> <div> ☐ Cervix ☐ In situ-Cervix </div> <div> ☐ Anal ☐ Penile </div> <div> ☐ Vaginal ☐ Vulvar </div> <div> ☐ H&N HPV *Please specify actual site in Remarks. </div> </div> </div> </div>	Barcode Specimen ID	☐ Good ☐ See Remarks	*If submitting H&N, please specify site:
	Barcode Specimen ID	☐ Good ☐ See Remarks	
	Barcode Specimen ID	☐ Good ☐ See Remarks	
	Barcode Specimen ID	☐ Good ☐ See Remarks	
Diagnosis:			
<div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div> <div>Is Tissue Available?</div> <div> ☐ YES ☐ NO </div> <div> <div>✓ Tissue Site:</div> <div> ☐ Cervix ☐ In situ-Cervix </div> <div> ☐ Anal ☐ Penile </div> <div> ☐ Vaginal ☐ Vulvar </div> <div> ☐ H&N HPV *Please specify actual site in Remarks. </div> </div> </div> </div>	Barcode Specimen ID	☐ Good ☐ See Remarks	*If submitting H&N, please specify site:
	Barcode Specimen ID	☐ Good ☐ See Remarks	
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	Barcode Specimen ID	☐ Good ☐ See Remarks	
	Barcode Specimen ID	☐ Good ☐ See Remarks	
	Barcode Specimen ID	☐ Good ☐ See Remarks	
Diagnosis:			
Relinquished by: (Print Name)			Date:
Signature:			Time:

CDC HPV Typing Study

Standard Operating Procedures for hospitals and path labs submitting **tissue blocks** to a central path lab at University of Florida for the proposed HPV Typing pilot study.

The tissue block will be shipped in the container provided by Battelle. Battelle will provide a zip-lock bag for each subject's tissue sample. There will be a CR ID label on each zip-lock bag. The cancer registry will send you a Tissue Sample Request Form with a CR ID assigned to each subject. **Please use the zip-lock bag with the correct CR ID Label for each subject.** Put the tissue block sample box/cassette in the zip-lock bag. Use one zip-lock bag for one subject's tissue sample.

CDC HPV Typing Study

Yellow Form

6.2 Tissue Block Submission and Reporting:

6.2.3 Please record the subject's CR ID (per Tissue Sample Request Form) on the Tissue Block Submission Form (Yellow Form).

6.2.4 Please check the box (Yes or No) to indicate if the subject's tissue sample is available. If not all samples are submitted (e.g., inadequate sample or cannot locate the sample), please record the CR ID and check No on the Tissue Block Submission Form.

6.2.5 Please check the box to indicate the site of the tissue sample.

☐ Cervix

☐ Anal

☐ Penile

☐ Vaginal

☐ Vulvar

☐ H&N HPV (Head and Neck – HPV associated sites)

CDC HPV Typing Study

Yellow Form

6.2.6 Please provide diagnosis remarks and submission remarks if applicable. **If you are submitting H&N sample, please specify the actual site in remarks.** Please record the date and time of shipping the samples, print, and sign the Tissue Block Submission Form.*

* Use the top (1st) signature block. The lower (2nd) signature block is for the central path lab use when they return the tissue block.

6.2.7 Make a copy of the Tissue Block Submission Form for your own file and send the original with the tissue sample(s) to the central path lab.

6.2.8 Sending Shipping Records to Battelle: Please fax a copy of the Tissue Block Submission Form to Battelle (919-544-0830, Attention: Natalie Madero).

CDC HPV Typing Study

Shipments:

6.3 Shipments should be made on Monday through Wednesday to ensure that the shipment will arrive during a regular work day. Avoid shipping samples that may arrive on a Federal holiday. If you are not sure, please contact the central path lab's coordinator : Amy Wright, ajwright@pathology.ufl.edu , phone 352-273-7755.

Please e-mail the central path lab coordinator and cc Battelle Team (Natalie Madero: MaderoN@battelle.org) on the shipping day to give them a heads up and to ensure that someone will be there to receive the samples.

6.5 Central Path Lab Returning the Tissue Blocks: Once the tissue sample is processed and submitted to CDC, the central path lab will return the tissue block to its original hospital/path lab.

CDC HPV Typing Study



CDC HPV Typing Study



CDC HPV Typing Study

Questions & Answers

Florida Project Team Contact Information

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