

HIV, STI, and HCV, Oh My!

Marty Soehnlén, PhD, MPH, PHLD(ABB)
Michigan Dept. of Health and Human Services
Bureau of Laboratories
Co-Chair, 2019 HIV Diagnostics Conference

2019
HIV
DIAGNOSTICS
CONFERENCE



**Optimizing Testing for HIV, STIs and HCV
in Laboratories, Public Health Programs and
Clinical Practice**

ENDING THE HIV EPIDEMIC: A PLAN FOR AMERICA



Diagnose HIV as early as possible



Treat HIV quickly and effectively



Protect people at risk



Respond quickly to clusters of new cases

HIV TRANSMISSIONS IN 2016

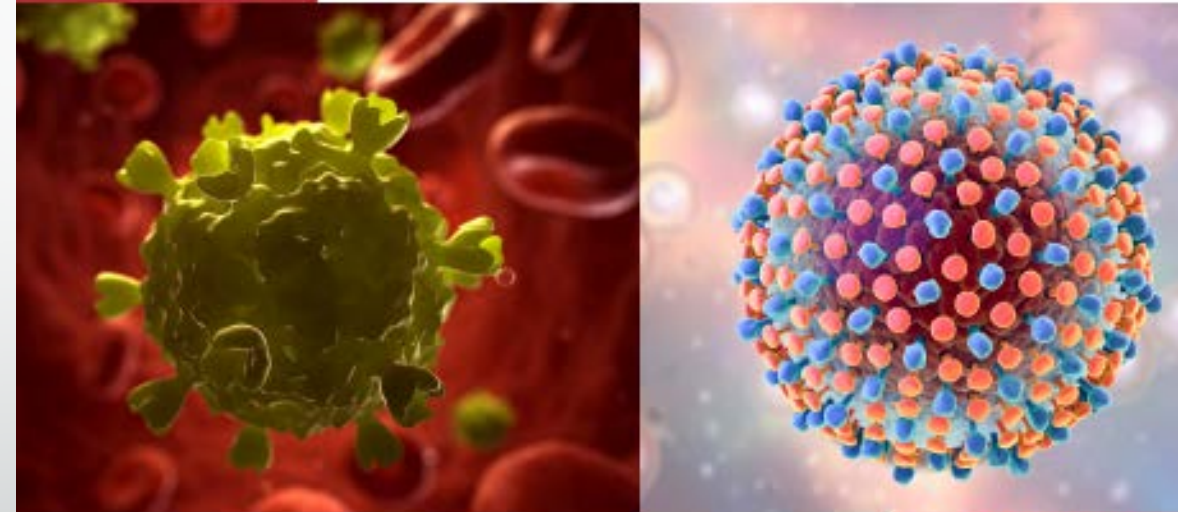
% OF PEOPLE WITH HIV	STATUS OF CARE	ACCOUNTED FOR X% OF NEW TRANSMISSIONS*
15%	didn't know they had HIV	38%
23%	knew they had HIV but weren't in care	43%
11%	in care but not virally suppressed	20%
51%	taking HIV medicine and virally suppressed	0%

*Values do not equal 100% because of rounding

Major categories:

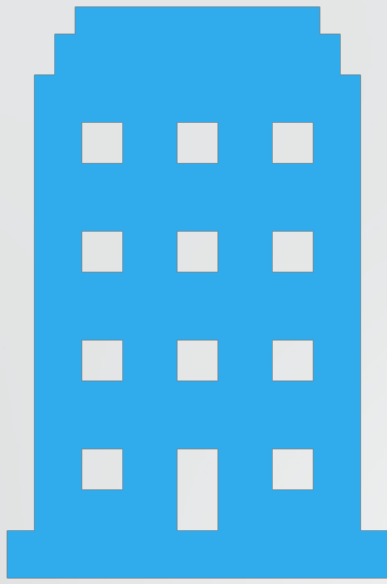
- Workforce
- HIV Assay Utilization
- Turnaround Times
- Testing Volumes & Specimen Types
- Testing Volume Trends
- HIV Infections Detected
- Planned Changes to HIV Testing
- Outreach and Training
- New Technology
- Testing for HCV
- Etc.

2017 HIV AND HCV DIAGNOSTICS SURVEY REPORT



MARCH 2019

Measuring 2017 Data



106 Public Health
Institutions Surveyed



76% Total Completion
Rate of Survey

28

Total questions



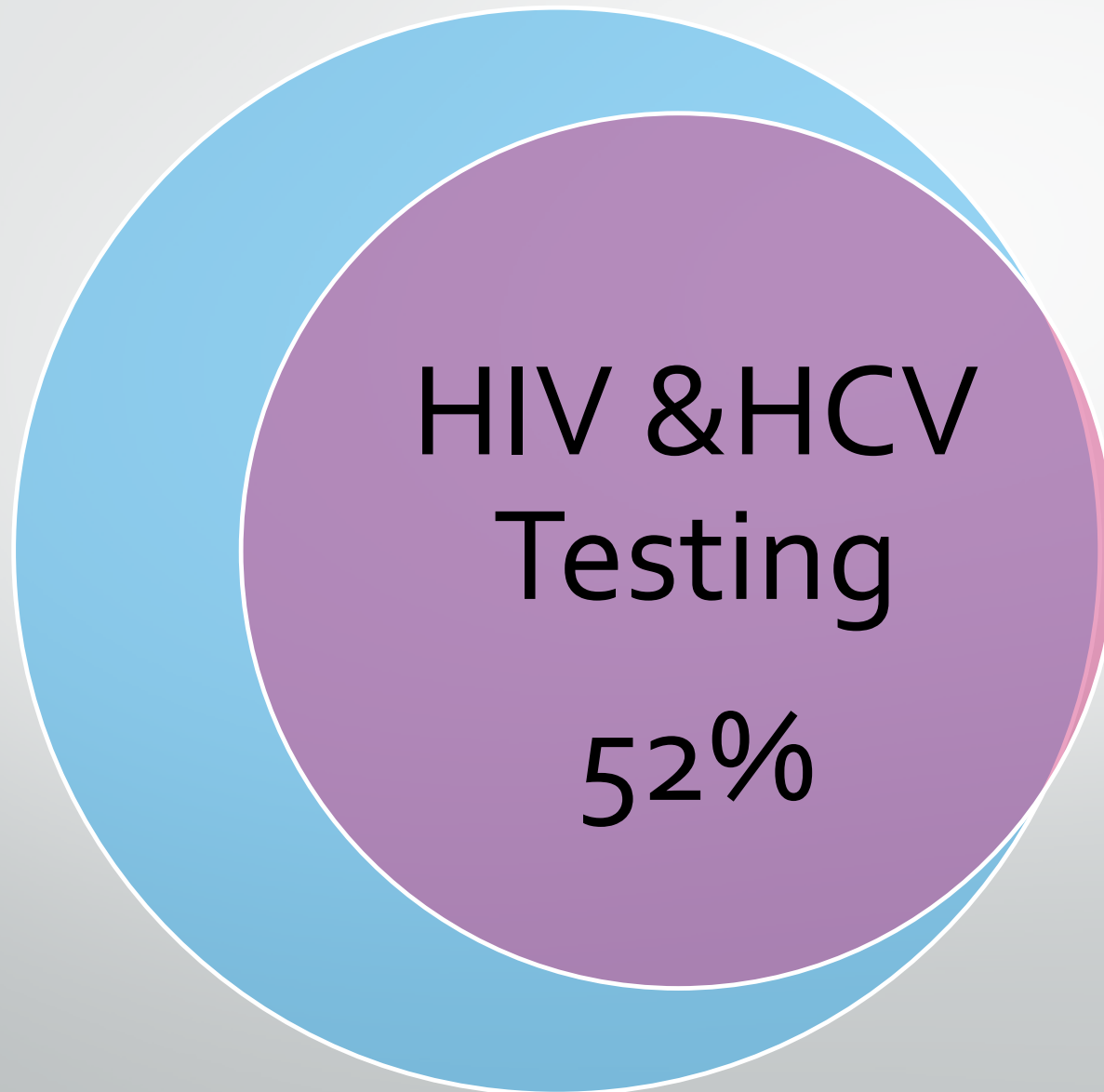
HIV and HCV Testing in PHLs



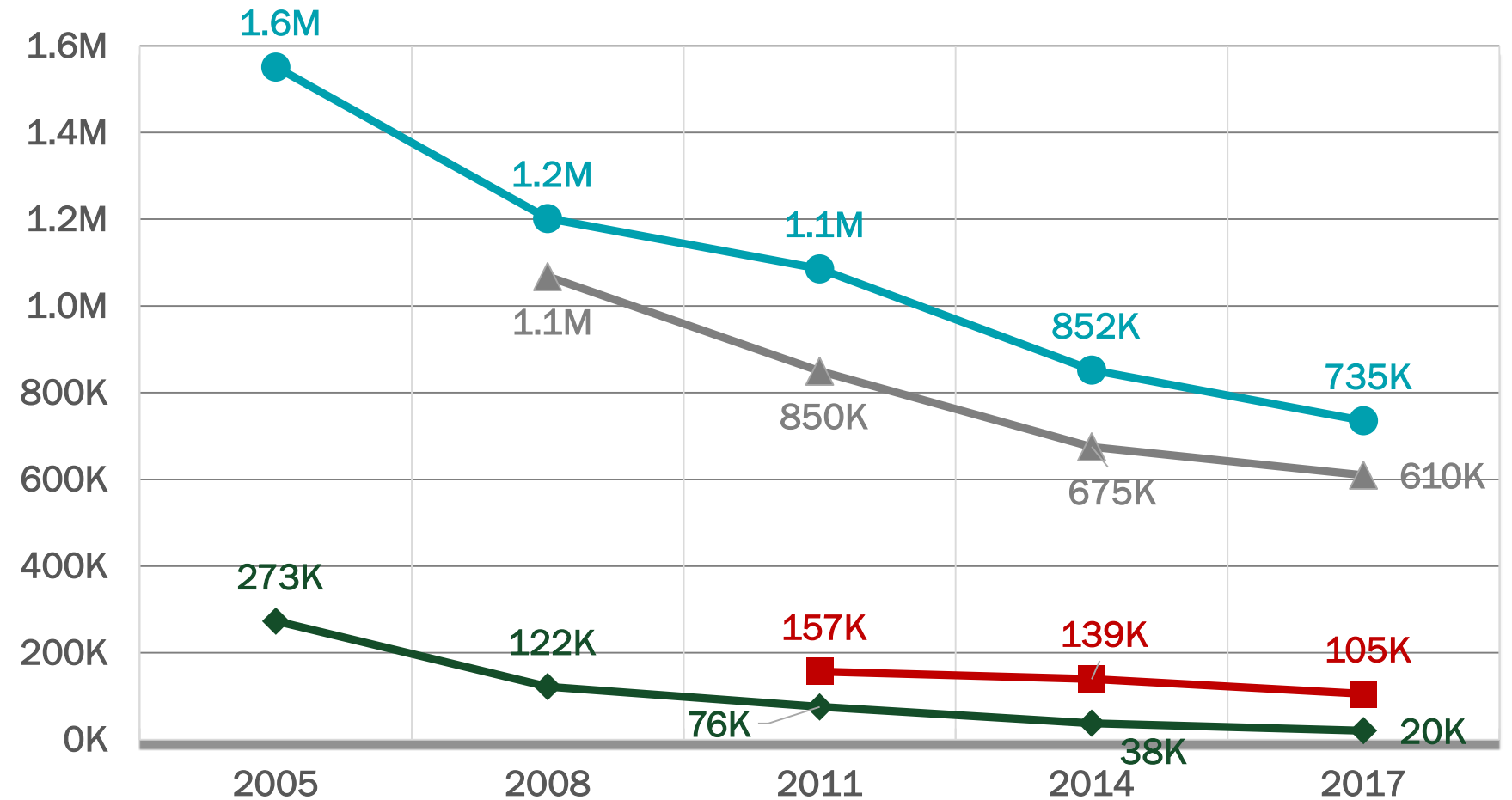
HIV
Testing 81%

HCV
Testing
54%

HIV and HCV Testing in PHLs

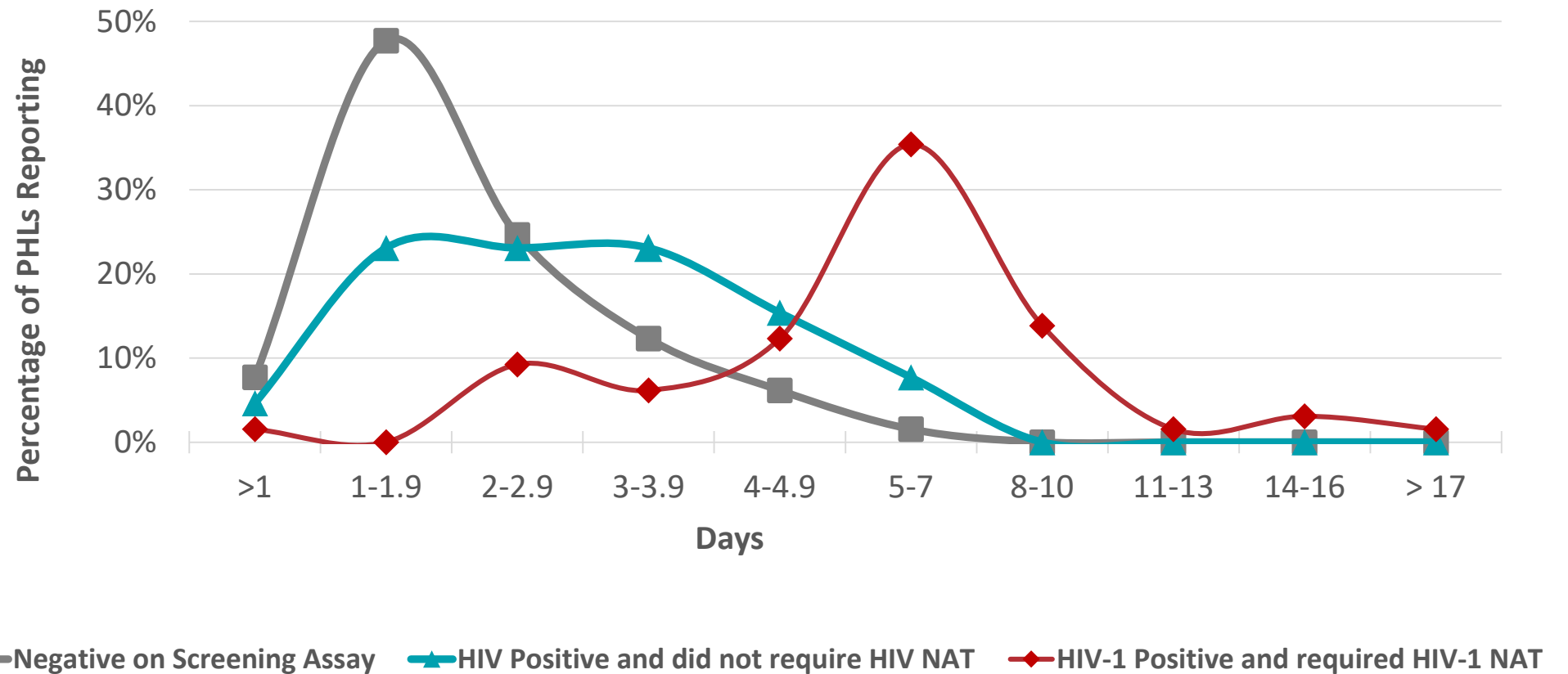


HIV Testing Volume Trends for PHL System, 2005 – 2017 (n=34)



● Total Volume ◆ Oral fluid Volume ▲ Plasma/Serum/Dried blood spot Volume ■ Whole blood Volume

Average Turnaround Time for PHLs reporting, by days (n=65)



Planned Changes from Survey Respondents

Screening Immunoassay

Additions or Changes

- Two PHLs plan to bring on new screening assay
- Four PHLs plan to replace existing screening assay with a new screening assay
- One PHL plans to refer screening to another laboratory

Eliminate or Decrease

- Three PHLs plan to or already have discontinued HIV testing, including screening
- One PHL plans to discontinue dried blood spot testing

Supplemental Antibody Assay

Additions or Changes

- Two PHLs plan to add a supplemental assay to be performed on site
- One PHL plans to replace existing supplemental assay with a new assay
- One PHL plans to modify an existing supplemental assay (for oral fluid testing)

Eliminate or Decrease

- Three PHLs plan to or already have discontinued HIV testing, including supplemental testing

Supplemental HIV-1 Nucleic Acid Assay

Additions or Changes

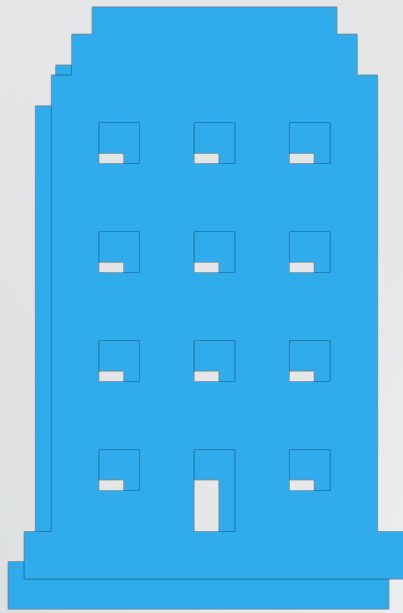
- Six PHLs plan to add an HIV-1 NAT to be performed on site
- One PHL plans to add an HIV-2 NAT
- One PHL plans to replace an existing HIV-1 NAT performed on site with a new HIV-1 NAT
- One PHL plans to modify an existing HIV-1 NAT (changing instrument for a laboratory developed test)

Table 6: Most common topics that PHLs provided outreach, training or education

Topics	# of PHLs	Percentage
Result Interpretation	21	65.6%
Specimen Handling/Requirements	21	65.6%
Algorithm Interpretation	19	59.4%
Result Reporting	16	50.0%
Specimen Collection	16	50.0%
Implementation of the Recommended Diagnostic Algorithm (e.g. appropriate tests, sequence)	15	46.9%
Supplemental HIV Ab differentiation tests (performance or platforms)	10	31.3%
HIV Ag/Ab or HIV Ab Immunoassays (performance or platforms for screening tests)	8	25.0%
HIV-1 NAT/RNA for Diagnosis (performance or platforms)	7	21.9%
Rapid Tests (performance and selection of test kit)	4	12.5%
Rapid Tests (i.e. implementation and quality assurance)	3	9.4%
Cost of Tests	1	3.1%
Laboratory Developed Tests	1	3.1%
Other	1	3.1%
Guidance on Validating FDA Approved tests	0	0.0%
HIV1-NAT/RNA for Viral Load/Monitoring	0	0.0%

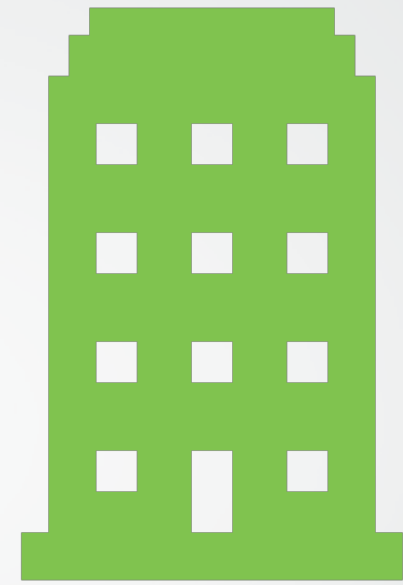
Table 7: PHL Interest in Potential New HIV Testing Technology

Proposed Laboratory Assay	All Respondents (n=81)	Currently Performing HIV Testing (n=65)	Not Currently Performing HIV Testing (n=16)
HIV-1 NAT with a dual claim (single assay that is FDA approved for diagnosis and viral load monitoring)	56%	62%	31%
Rapid HIV NAT (HIV-1 and/or HIV-2)	33%	37%	19%
Alternative supplemental HIV-1/2 antibody differentiation assay	23%	26%	13%
HIV-2 NAT	23%	23%	25%
Alternative HIV-1/2 Ag/Ab differentiating combination immunoassay	22%	23%	19%
HIV-1 p24 Ag confirmatory assay	22%	23%	19%
Rapid HIV-1/2 Ag/Ab combination immunoassay	14%	12%	19%
Other, please specify	11%	9%	19%



42 PHLs performing
anti-HCV Ab Testing

The Countdown is on as Public Health looks to eliminate Hepatitis C Virus



21 PHLs performing
HCV RNA for Diagnosis

10 PHLs performing
HCV RNA for Patient
Management /Viral load

Oh My – What a learning Experience!

- Diagnostics for HIV, STIs, and HCV
 - Sessions specific for HIV-1 and HIV-2
- Impact of algorithms
- Rapid Assays
- Point of Care Testing
- Discussion Panels
- Posters
- Opportunities to interact with laboratory, program, epidemiology, and manufacturer staff members



The Team



Conference Co-chairs

S. Michele Owen, PhD
Bobbi Van Der Pol, PhD
Marty Soehnlen, PhD

Scientific Steering Committee Co-chairs

Anne Gaynor, PhD
Laura G. Wesolowski, PhD

Conference
Manager
Lynn Barclay

Scientific Committee Members

Ana Maria Cardenas, PhD
Pollyanna Chavez, PhD
Maria Ines Garcia, PhD
Charlotte A. Gaydos, DrPH
Rachel E. Gridley, BS
Tonya Hayden, PhD

Ellen N. Kersh, PhD
Julia T. Lathrop, PhD
Carol H. Loring, MS
Eugene G. Martin, PhD
Jenny McFarlane, BA
Gillian Miles, MPH

Monica M. Parker, PhD
Liisa Randall, PhD
Arlene C. Sena, MD
Tabetha Sundin, PhD
Jeffrey A. Johnson, PhD
Eyasu H. Teshale, PhD
Joesph D.C. Yao, MD

