

## IQCP - Coming Soon to Your Laboratory?

IQCP has been the buzzword in clinical laboratories since the training and transition period began in January 2014; and agencies, organizations, and vendors are providing resources to help your laboratory understand the program, decide if IQCP is for you, and then provide templates for performing and documenting your IQCP.

IQCP (Individualized Quality Control Plan) is a program that allows laboratories to tailor their quality control program to see how they can best ensure quality testing, throughout all phases-pre-analytic, analytic, and post-analytic, and continue to meet CLIA requirements for non-waived tests. IQCP will cover all test systems, new and existing, in all specialties aside from pathology. Laboratories must have their programs in place by the end of the transition and training period, which is January 1, 2016.

CDC has published a free on-line instructional workbook, "Developing an IQCP; a Step-by-Step Guide" designed to assist laboratories in deciding if IQCP is right for them and to tailor their program over time. They have a webpage dedicated to IQCP, found [here](#).

Manufacturing companies, accreditation agencies, and professional organizations have also developed resources designed to educate and assist in the development of your IQCP Risk Assessment and Quality Control Plan. For example, the [College of American Pathologists](#) and the [Joint Commission](#) have published flyers outlining the changes. The [American Society for Microbiology \(ASM\)](#) features information and templates on their website, with special tools for microbiology laboratories. Bio-Rad and Thermo-Scientific have educational resources available online, and Alere has an IQCP Orientation Webinar, found on their [website](#).

### For more information on IQCP

[CMS website: Individualized Quality Control Plan \(IQCP\)](#)

### For questions, or comments, please e-mail:

[IQCP@cms.hhs.gov](mailto:IQCP@cms.hhs.gov)

To request hardcopies of the **IQCP Workbook**, please e-mail: [CLIA@cdc.gov](mailto:CLIA@cdc.gov)

## IQCP Training Resources:

### CACMLE Clinical Microbiology Webinar: "What's New with the CAP Microbiology Checklists and IQCP?"

Wednesday - July 22, 2015 at 11:00 AM

This presentation by clinical microbiologists Susan Sharp and Yvette McCarter will review new requirements from the most recent CAP microbiology checklists as well as the historically more difficult to interpret microbiology checklist requirements. Practical methods for complying with these requirements will be provided. In addition, the new Individualized Quality Control Plan (IQCP), currently under development as an alternate QC option by the Centers for Medicare and Medicaid Services (CMS), which we anticipate will be incorporated in the 2015 CAP checklists will be reviewed.

Registration form: [2015 Webinar/Teleconference Registration Form - Microbiology](#)

### CDC Archived Webinar

(available on CDC Train soon)

### [CLIA and Individualized Quality Control Plan \(IQCP\)](#)

This basic level webinar will discuss the Centers for Medicare & Medicaid Services (CMS) alternate quality control (QC) option - Individualized Quality Control Plan (IQCP) for non-waived testing, which was released in August 2013. This presentation explains the background and history of CLIA QC regulations and provides an overview of the three parts of an IQCP: Risk Assessment, Quality Control Plan and Quality Assessment. The webinar will include information about QC options available to laboratories during the IQCP Education and Transition Period.

## Additional IQCP resources from CMS:

[CLIA Individualized Quality Control Plan Introduction, CLIA IQCP](#)

[Considerations When Deciding to Develop an IQCP](#)

[CLIA IQCP, What is an IQCP?](#)

Updates from the MT

Laboratory Services

Bureau

800-821-7284

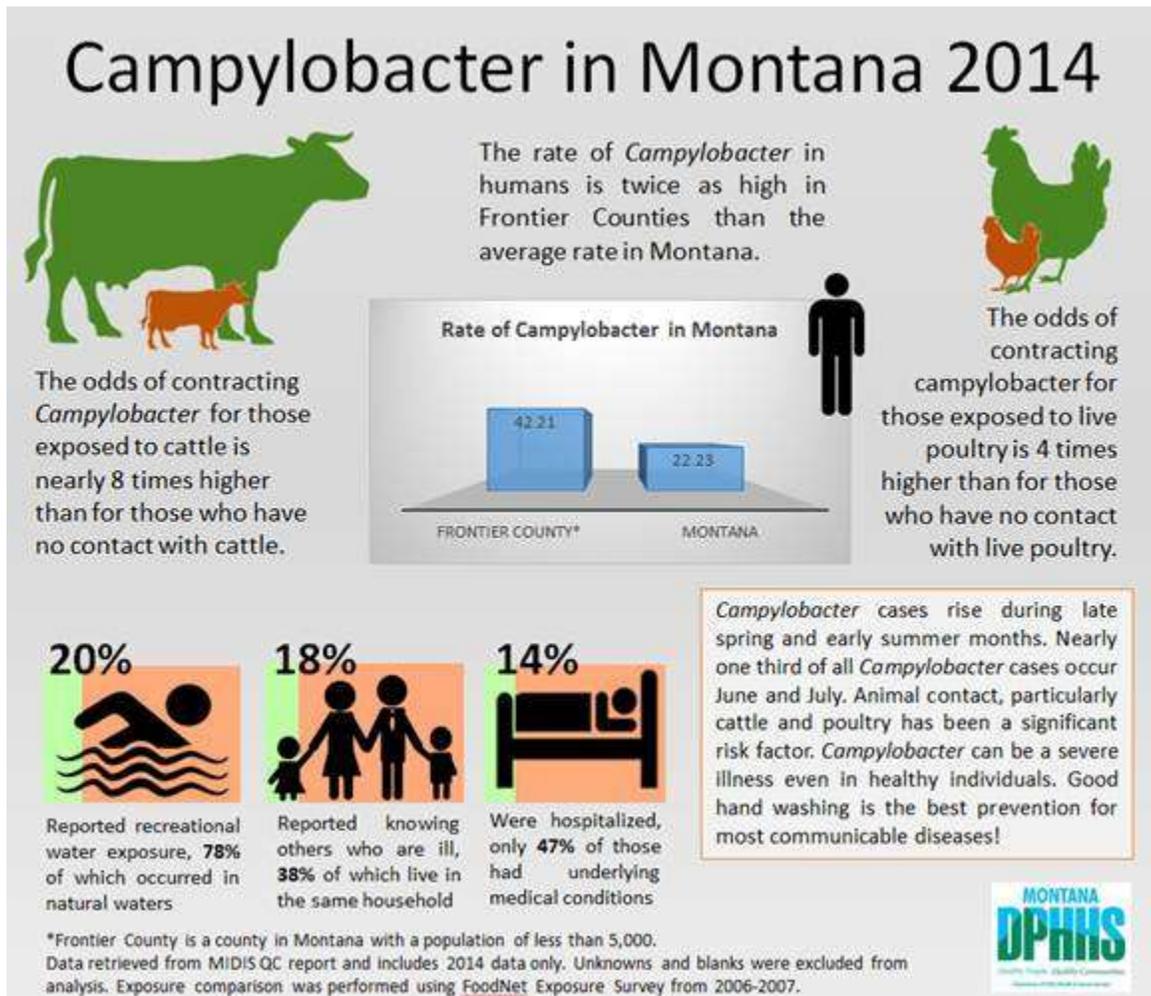
[www.lab.hhs.mt.gov](http://www.lab.hhs.mt.gov)



## Montana Communicable Disease Weekly Update

Release date: 6/5/2015

### Infographic of the Week:



## DISEASE INFORMATION

**Summary – MMWR Week 21 - Ending 5/30/15** Preliminary disease reports received at DPHHS for the reporting period May 24–30, 2015 included the following:

- **Vaccine Preventable Diseases:** Pertussis (3), Varicella (1)
- **Invasive Diseases:** *Streptococcus pneumoniae* (3)
- **Enteric Diseases:** Campylobacteriosis (13), Cryptosporidiosis (4), Giardiasis (5), Salmonellosis (1), Shiga-toxin producing *E. coli* [STEC] (5)
- **STD/HIV:** Chlamydia (48), Gonorrhea (15), Syphilis (0), HIV\* (0)
- **Hepatitis:** Hepatitis B, chronic (1), Hepatitis C, chronic (8)
- **Vector-borne Diseases:** Colorado Tick Fever (1)
- **Travel Related Conditions:** Legionellosis (1)
- **Animal Rabies:** (0)
- **Elevated blood lead:** (0)

\* A case is included if a new confirmatory test or report was received by DPHHS. Cases include both persons who were newly diagnosed and persons newly reported in Montana who may have been diagnosed in another state or country.

NOTE: The attached reports have multiple pages reflecting the following information: (1) cases for the past reporting week; (2) communicable diseases YTD; (3) clusters and outbreaks; and (4) a quarterly HIV/STD summary.

## HOT TOPICS

**Rabies:** A press release went out on June 2<sup>nd</sup> (<http://dphhs.mt.gov/AboutUs/News/6-2-15rabiessafety>) urging caution regarding rabies exposures. Skunks are the most common four legged animals infected with rabies in Montana, however, the majority of reported human exposures result from bats. In 2014, there were hundreds of reports of animal bites in Montana, including over 42 reported encounters between bats and people. During the same period, 11 of the 105 bats and 5 of 11 skunks submitted to the Department of Livestock's Veterinary Diagnostic Laboratory tested positive for rabies. Rabies is also not limited to wild animals; in 2014, two dogs and one cat also tested positive.

Of interest, are the two CDC MMWR write ups regarding Montana's last two cases from 1996 and 1997. Of interest is how the cases identified as bat rabies indicated no reported bites by bats.

1996: <http://www.cdc.gov/mmwr/preview/mmwrhtml/00047605.htm>

"The patient and his family lived in a rural area and reported occasionally seeing bats outside their home but denied having had physical contact with bats. In addition, the patient was employed as a custodian for a wood and paper mill and denied contact with bats at his workplace."

1997: <http://www.cdc.gov/mmwr/preview/mmwrhtml/00049057.htm>

"A definite history of animal bite could not be documented in either case in this report and has been documented for only one of the 19 bat-related cases of human rabies since 1980. Of the remaining 18 such cases, physical contact with a bat without an evident bite or other potential exposing event was reported for eight. A history of bat contact could not be established or excluded for the remaining 10 bat-related cases, including both cases in this report."

**West Nile Virus (WNV):** The season is right around the corner. Mosquito pools are collected between May and September. The Culex mosquito is our greatest concern and those appear generally in mid-July. Reported cases usually come in at the same time to a little later. We usually first see Equine infections and then human infections. Providers should begin consideration of WNV in their differential diagnoses here soon. Prevention messaging has begun. The latest "Surveillance Snapshot" "West Nile Fever in Montana 2002-2014 is attached and is posted online. For more information see the DPHHS West Nile Virus Website <http://dphhs.mt.gov/publichealth/cdepi/diseases/westnilevirus.aspx>

**Highly Pathogenic Avian Influenza (HPAI):** The Montana/CDC Health Alert Network Messages on HPAI can be located at <http://dphhs.mt.gov/Portals/85/publichealth/documents/HAN/2015/HANAD2015-6.pdf> .

From the HAN:

"CDC considers the risk to the general public from these newly-identified US HPAI H5 viruses to be low; however, people with close or prolonged unprotected contact with infected birds or contaminated environments may be at greater risk of infection. This is something to be aware of and reinforces the need for year round influenza surveillance. For any out of season influenza cases reported, HPAI should be considered if relevant exposure history is identified.

Providers

- Clinicians should consider HPAI H5 virus infections in persons showing signs or symptoms of respiratory illness who have relevant exposure history. This includes persons who have had contact with potentially-infected birds (e.g., handling, slaughtering, defeathering, butchering, culling, preparation for consumption); direct contact with surfaces contaminated with feces or parts (carcasses, internal organs, etc.) of potentially-infected birds; and persons who have had prolonged exposure to potentially-infected birds in a confined space.
- *Clinicians and laboratories should report suspected HPAI cases in humans immediately to local health jurisdictions.* Rapid detection and characterization of novel influenza A viruses in humans continue to be critical components of national efforts to prevent further cases, evaluate clinical illness associated with them, and assess any ability for these viruses to spread among humans.
- The Montana Public Health Laboratory (MTPHL) has the ability to test for HPAI H5 viruses and a specimen should be submitted for all suspected cases. MTPHL can be contacted regarding testing at 1-800-821-7284.

- See the attached CDC Health Alert Network message for additional clinical recommendations.”

**Dramatic Increases In Montana Gonorrhea Cases Continue (Quarterly Update attached):** A Health Alert Network message is being developed that will be sent out with recommendations for providers.

The number of gonorrhea cases has doubled in each of the last two years to a new high of 433 in 2014, and the first quarter of 2015 has continued to show this increased trend. The overall number of cases of gonorrhea has increased especially in counties associated with American Indian reservations.

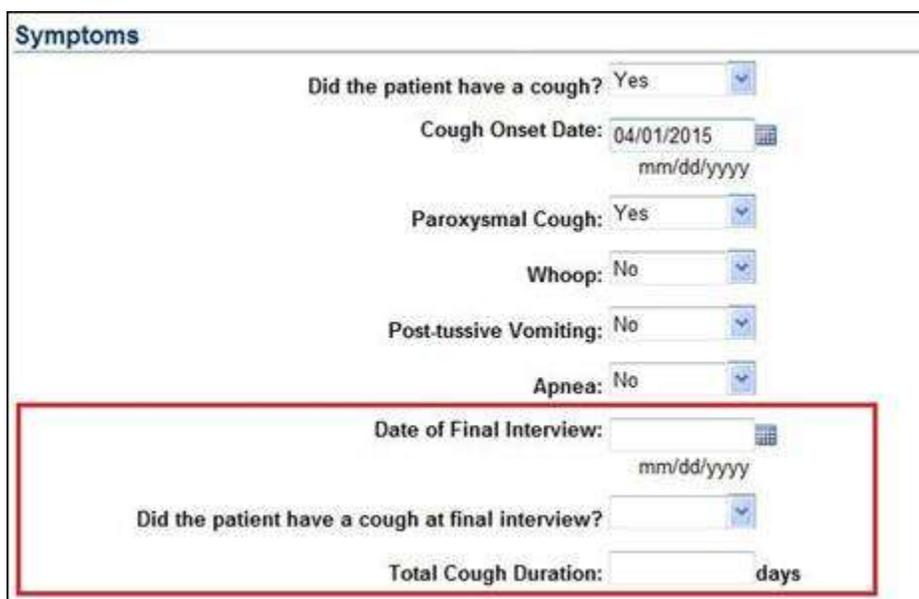
Actions needed to break the transmission cycle:

- Medical providers are urged to screen those at risk, and treat gonorrhea using the updated guidelines as set forth by the CDC in 2012. <http://www.cdc.gov/mmwr/PDF/wk/mm6131.pdf>
- Local health departments and public health nurses are reminded that urgent and immediate follow up of a gonorrhea report is required to interview index cases, to ensure proper treatment, and to identify and treat sexual contacts as appropriate.
- Reports on interviewing and proper treatment must be submitted to the state within seven business days of receiving notice of a positive gonorrhea. A subsequent report can be submitted later if partner services are not completed with seven days.
- Both medical providers and public health nurses should be aware of the CDC recommendation that persons testing positive for STD also be tested for HIV.

### INFORMATION/ANNOUNCEMENTS

**Pertussis:** As of June 1, Montana has 161 cases of pertussis reported for 2015. Looking at the data in MIDIS, we have noticed that some key information is missing from the majority of cases to date. It is very important that we have a **final interview date** and **total cough duration** completed for each pertussis case in the system in order for it to meet case definition by CDC. Along with a positive lab result, a confirmed case of pertussis needs to have documentation of >14 days of cough.

If your jurisdiction has pertussis cases reported in 2015, please take a few minutes to review them in MIDIS and update with this information. Below is a screen shot of the section of the pertussis page in MIDIS where the final interview and cough duration information should be entered. As always, thank you for your help keeping our Montana data as accurate and complete as possible!



**Symptoms**

Did the patient have a cough? Yes

Cough Onset Date: 04/01/2015  
mm/dd/yyyy

Paroxysmal Cough: Yes

Whoop: No

Post-tussive Vomiting: No

Apnea: No

Date of Final Interview: mm/dd/yyyy

Did the patient have a cough at final interview?

Total Cough Duration: days

**Summer Institute: We urge all communicable disease epidemiology staff at local levels to sign up.**



### Registration Open

Online registration and electronic payment is now open. You will have the ability to pay the conference fee at the time of registration by either credit card or electronic check.

CDEpi:

Elton Mosher is actually planning to lead the training separating himself from his desk for this years training. We are hoping to make this years CDEpi part very interesting with 101 for new CDEp local staff of which there are a surprising amount and we will need seasoned local CDEpi warriors to help. There will also be a half day TB course with Denise Ingman where we will be working with Butte/Silverbow County to show how TB in a university setting is dealt with. Lots of good info and then Measles and Pertussis overviews with local input and interactive excercises. Be sure and catch your (stuffed) disease of choice to take home with you, no prophylaxis or treatment required...

Go to [mphti.mt.gov](http://mphti.mt.gov) to review the courses and find the link to register, or click [HERE](#) to go directly to the registration.

### \$100 Conference Fee per Person

- Courses of your choice
- Leadership Day workshops
- Wednesday luncheon

### Reserved Sessions Full

The open preregistration spots for A. Public Health Management Certificate and C. Passport to Partner Services are filled and the courses are no longer available.

### Accommodations

All participants are responsible for their own lodging, but the Holiday Inn Downtown has blocks of rooms for Summer Institute participants open from **June 1 to June 19**. Any accommodation arrangements after June 19 will be more difficult. The summer is a busy time for area hotels, so please book a room early.

Check the website occasionally for updates. When booking a room at the Holiday Inn Downtown – Missoula, be sure to mention the DPHHS Summer Institute Block.

Click [HERE](#) to book online or call 1-800-345-8082 or 1-406-721-8550.

### Q&A CORNER

**Q:** *Why do I need to conduct a final interview for pertussis cases?*

**A:** To meet the surveillance definition for pertussis, a cough of 14 days or greater needs to be documented in MIDIS. A final interview should be occur for each of your cases 2 weeks or more **after** the case is reported to you. This allows you to check in with the patient (or family) to determine the total cough duration of the illness, as well as if there are any other individuals in the household with signs and symptoms who might need to be evaluated for pertussis.

**Q:** *One of my key surveillance partners has new staff and they don't think they have to report or provide information because of HIPAA, what do I do?*

**A:** This happens occasionally although much less often than in the past. It is good to know they are concerned about confidentiality to this degree but it is a barrier to obtaining information quickly when public health needs it. The key is to know that HIPAA has a “public health exception.” As stated on the US Department of Health and Human Services webpage on this,

*“The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission... ...Accordingly, the Rule permits covered entities to disclose protected health information without authorization for specified public health purposes.”*

That information can be found at:

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/publichealth.html>

There is also an excellent FAQ on this at:

[http://www.hhs.gov/ocr/privacy/hipaa/faq/public\\_health\\_uses\\_and\\_disclosures/index.html](http://www.hhs.gov/ocr/privacy/hipaa/faq/public_health_uses_and_disclosures/index.html)

Simply sending people these links and the cover paragraph, usually suffices in solving this problem.

#### **24/7 AVAILABILITY**

*The Communicable Disease Epidemiology (CDEpi) Program is available 24 hours a day, 7 days a week, 365 days a year, to assist local health jurisdictions. Local providers should call, including after normal business hours, their local health jurisdiction. The CDEpi 24-hour line is available as a back-up to the local health jurisdiction’s 24-hour line. If you need CDEpi assistance, please call 406.444.0273. Phone calls to this number outside of normal business hours will be answered by the answering service. The answering service will immediately forward the message to CDEpi, and we will respond as quickly as possible.*

*Local health jurisdictions, please ensure that your local providers have your 24/7/365 contact information. And please inform CDEpi or the Public Health Emergency Preparedness Program of updates to your required 24/7 contact information.*

***This update is produced by the Montana Communicable Disease Epidemiology Program. Questions regarding its content should be directed to 406.444.0273 (24/7/365). For more information: <http://dphhs.mt.gov/publichealth/cdepi>***