MSMS Tele-Town Hall
COVID-19: Testing, Tracing and Tracking

JUNE 11, 2020
12:00 PM
Contact Tracing in Michigan

June 11, 2020
Governor Whitmer’s MI Safe Start Plan

1. Uncontrolled Growth
   - What's happening with the disease?
     - Increasing number of new cases every day, likely to overwhelm the health system
   - What do we need to do to stay safe?
     - Stay Home, Stay Safe: Strict social distancing, travel restrictions, face coverings, hygiene best practices, remote work
   - What work can we do?
     - Critical infrastructure
     - First responders
     - Health care workers
     - Critical manufacturing
     - Food and agriculture
     - Essential retail (e.g., grocery)
     - Transportation
   - What factors determine progression to next phase?
     - Analysis shows epidemic growth rates slowing
     - Hospital and treatment capacity built, alternative care facilities established
     - Infrastructure for crisis response and data systems to monitor progression are in place

2. Persistent Spread
   - What's happening with the disease?
     - Case growth is gradually declining
   - What do we need to do to stay safe?
     - Safer at Home: Continued distancing, face coverings, no gatherings
   - What work can we do?
     - Critical infrastructure
     - Additional types of recreation allowed
   - What factors determine progression to next phase?
     - Cases, deaths decline for extended period
     - Monitor impact on vulnerable populations
     - Sufficiency health system capacity in place
     - Improved testing, contact tracing and containment capacity

3. Flattening
   - What's happening with the disease?
     - Cases, hospitalizations and deaths are clearly declining
   - What do we need to do to stay safe?
     - Safer at Home: Continued distancing, face coverings, safe workplace practices, no gatherings
   - What work can we do?
     - Specified lower-risk businesses with strict workplace safety measures
     - Construction
     - Manufacturing
     - Real estate
     - Outdoor work
   - What factors determine progression to next phase?
     - Cases and deaths decline more sharply, percent positivity decreasing
     - Healthcare system capacity continues to strengthen
     - Robust testing, contact tracing and containment protocols in place

4. Improving
   - What's happening with the disease?
     - Cases, hospitalizations and deaths are clearly declining
   - What do we need to do to stay safe?
     - Safer at Home: Continued distancing, face coverings, safe workplace practices, no gatherings
   - What work can we do?
     - Additional lower-risk businesses with strict safety measures
     - Other retail, with capacity limits
     - Offices, but telework required if possible
   - What factors determine progression to next phase?
     - Cases and deaths at low absolute rates per capita
     - Health system capacity is very strong
     - Robust testing, contact tracing and containment protocols in place

5. Containing
   - What's happening with the disease?
     - Continued case and death rate improvements and outbreaks can be quickly contained
   - What do we need to do to stay safe?
     - Stay Safe: Adherence to new guidelines, continued distancing, coverings, mitigated workplaces
   - What work can we do?
     - Increased size gatherings
     - Most businesses, with strict mitigation measures
     - Restaurants / bars
     - K-12 and higher ed. (live instruction)
     - Travel
   - What factors determine progression to next phase?
     - Community spread not expected to return
     - Sufficient community immunity and availability of treatment

6. Post-pandemic
   - What's happening with the disease?
     - All businesses
   - What do we need to do to stay safe?
     - Events and gatherings of all sizes with new safety guidance and procedures
   - What work can we do?
     - Social distancing rules are relaxed and large events are permitted
   - What factors determine progression to next phase?
     - High uptake of an effective therapy or vaccine

Note: This framing is being updated and refined as additional guidance from CDC and public health experts becomes available.

It is also possible to move backwards if risk increases and if we stop adhering to safe practices.
Guiding principles of our approach

- **Protect public health** by identifying and disrupting chains of transmission
- **Draw on best practices from federal guidelines** and other state experience
- **Listen to the needs of local communities, leverage local health department infrastructure**, and supplement with state resources where needed
- **Create a seamless experience for patients** who need support in testing, tracing, and isolation/self-quarantine
- **Ensure all solutions are attentive to racial and socio-economic disparities** across the state
Returning to normal

▪ Swift testing, tracing of contacts, isolation of ill, and quarantining of contacts

▪ Cases no longer spreading widely

▪ Reduced strain on health care system

▪ Partial safe reopening

Test broadly, including anyone with symptoms or exposure, to identify positive cases

Use technology and tracing teams to rapidly identify close contacts of positive cases

Safely isolate positive cases and facilitate self-quarantine of contacts to prevent spread
Overall approach

Goals:
- Reach 90% of confirmed cases and contacts within 24 hours of referral
- 75% of cases see completed investigation within 1 day
- 50% of cases should elicit at least one contact within 1 day

Local Heath Departments
- Primary responsibility for case investigations
- Lead contact tracing unless “opt-in” to state centralized efforts
- Lead on referring individuals to community resources

MDHHS
- Provides additional support for LHDs on case investigations
- Conducts contact tracing for LHDs that opt-in
Tracing: Goals and Approach

Goal
Investigate 90% of all COVID positive cases within 24 hours of referral, identify all COVID positive contacts and reach 90% of all contacts within 24 hours of referral, and ensure that the State of Michigan has 2,000-3,000 contact tracers available.

Approach
- **Support Local Health Departments** with case investigation and contact tracing
- **Develop a state-run contact tracing platform** to be leveraged by Local Health Departments using improved technology
- Communicate the importance of contact tracing to the public
Tracing: Key Initiatives

Support for Local Health Departments (LHDs)

Create volunteer database and deploy volunteers to LHDs that request additional support

Establish clear case investigation and contact tracing metrics and partner with LHDs in the implementation of these metrics

Provide LHDs with access to modernized contact tracing technology platform

Identify availability of additional federal funds to support LHD case investigation and contact tracing

Centralized Contact Tracing

Recruit and train an appropriately-sized cohort of contact tracing volunteers and/or paid staff that is flexible/scalable to meet statewide needs

Build and deploy new technology platform to conduct automated contact tracing

Address “upstream challenges” with contact tracing, including access to accurate phone numbers and other contact information

Effectively refer affected individuals to appropriate community support through Local Health Departments

Communications

Use mass communications, social media, and community engagement to help members of the public understand the importance of “answering the call” when called by a Local Health Department or the State of Michigan
The role of technology

- Symptom Tracking (MI Symptom)
- Test finder (Castlight)
- Accessing benefits (MiBridges)
- Contact Tracing
- Testing sign-up
Contact Information

Jonathan Warsh
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A Testing Primer: SARS-CoV-2 (COVID-19)

Marty K. Soehnlen, PhD, MPH, PHLD(ABB)
MDHHS, Bureau of Laboratories
Director of Infectious Disease
Types of tests available currently

**Diagnostic**

- Real-time reverse transcription PCR (i.e. FDA EUA approved molecular testing)
- Rapid direct viral detection (i.e. Abbott ID Now systems)
- Antigen Rapid Detection (Quidel)

**Surveillance and Research Uses**

- Serology testing
  - IgM
  - IgG
  - IgA
  - Total Ig
Molecular Biology Basics

- For SARS-CoV-2 Virus
  - Extract total nucleic acid for use in reverse transcription real-time PCR
  - Many platforms look for specific regions of the nucleocapsid protein while a few also look for envelop proteins
  - Limits of Detection (LOD) values vary between platforms and can range from a few hundred to few thousand copies/mL
  - Common Results may be:
    - Detected (Positive)
    - Not Detected (Negative)
    - Presumptive Positive (not all markers are positive)
    - Indeterminate (often too borderline for the instrument to call successfully – may need a recollection/retests)
    - Invalid (interfering substance present and needs a recollection/repeat test)
Molecular Assays

**Basic steps:** sample collection, RNA extraction, RNA transcribed to cDNA, general PCR steps

**Pros**
- Directly detects presence of the pathogen
- Sensitivity is widely regarded as highest using molecular assays
- Do not need “living material” to detect presence of the pathogen

**Cons**
- Unknown length of time that genetic material remains in the host
- Sensitivity/specificity varies by assay
- More expensive
- Turn around times vary by instrument and method
- Many of the transport media utilized require cold chain
- POC molecular based tests tend to have lower sensitivity
Immune System Basics

• The role of the immune system is to protect the body against pathogens and other foreign particles

• Two primary branches of the immune system
  • **Innate** - the first line of defense against pathogens; includes some cells, a variety of proteins, and physical/chemical barriers (i.e. skin and pH)
  • **Adaptive** - B Lymphocytes (**antibody production**) and T Lymphocytes

• The adaptive immune system is responsible for creating memory cells that can provide long-term immunity to a pathogen
Timeline of an Immune Response
Antibodies

• 5 main classes of antibodies: IgA, IgD, IgE, IgM, and IgG
  • Ig is short for immunoglobulin, which is another name for antibody. The letter at the end, (A,D,E,M,G) describes the type of antibody.

<table>
<thead>
<tr>
<th>Antibody Type</th>
<th>Function</th>
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<tbody>
<tr>
<td>IgA</td>
<td>Mucosal immunity</td>
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<tr>
<td>IgD</td>
<td>Lowest concentration antibody, present on early B-cells alongside IgM</td>
</tr>
<tr>
<td>IgE</td>
<td>Parasitic immunity</td>
</tr>
<tr>
<td>IgG</td>
<td>Higher affinity antibody produced as part of secondary immune response</td>
</tr>
<tr>
<td>IgM</td>
<td>Part of primary immune response, produced early in infection, less specific</td>
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If the IgM receptor matches the coronavirus antigen closely enough, the B-cell receives signals to start proliferating and mutates its receptor to try to find the best fit.

IgM receptor changes to become more specific and may switch types (IgG, IgA, etc.).

Population of memory cells created that can expand and respond quickly when exposed to the same pathogen again.

Another population of B-cells become antibody-secreting plasma cells, ready to fight the current infection.
How do Serology Tests Work?

• Serology is the term used to describe **testing of the immune responses**

• Serology tests use **serum, plasma, or whole blood** to evaluate a person’s immune response to a pathogen.
  • Looking for the presence of antibodies
  • Can be for any antibody class, but are most commonly for IgM and IgG antibodies
  • May hear Total Ig which means it measures all with specifying what is present

• Many **different methodologies** available to achieve this
  • Considerations of:
    • serum vs plasma vs whole blood
    • anticoagulant effects
    • Storage temperatures and times
Examples of Serological Assays: Enzyme Immunoassays (EIA or ELISA)

- Each well is coated with an antigen.
- Patient sample is added to the well.
- A conjugate is added to the well. It binds to the patient antibody.
- The addition of a stop solution produces a final color change measured by spectrophotometer.
- A chromogenic substrate is added. It interacts with the conjugate to produce a color change.

FIA: Fluorescent Immunoassay – similar to EIA, but utilizes fluorescence to detect either antigen or antibody.
Examples of Serological Assays: Lateral Flow

The patient sample and a diluent or buffer are added.

Indicator lines appear in the presence of the antibody in question. A control line ensures the test cartridge is functioning correctly.
Serology Assays

**Basic steps:** detection of antibodies through one of the previously described formats

- **Can assist in determining exposure history**
- Typically less expensive and often results are more rapid than PCR (not always true based on style of test which ranges from minutes to days to run)
- **Contributes to long-term knowledge of the viral responses**
- May assist with vaccine development research

- Experts do not know if IgG will be neutralizing
  - **Unknown protective effect of having recovered from infection**
  - Unknown if will be able to use a “return to work” tool or if it will indicate long-term immunity

- **High risk of cross reactivity**
  - False Positives give false hope of immune response

- **Lateral flow cards tend to have a high number of interfering substances**

- **Unclear when the IgM and IgG responses specifically start to rise for SARS-CoV-2**
When to use?

- For patient care use only the diagnostic approved tests
  - Very mixed messages nationally about the use of follow-up PCR for clearance due to very specific issues
- When using a serology test it should not be the sole basis of diagnosis, but may be helpful in determining if someone was exposed
  - Be selective of when and why you may choose a serology test or you risk causing confusion about how to proceed and what the result indicates

How do I know I’m using a good testing site?

- CLIA high or moderate complexity labs
  - CLIA certificate of waiver for Abbott ID Now
- Testing is being performed using an FDA EUA assay or product
  - Sites may verify an EUA approved test
  - Sites may submit full validation data packets to FDA to gain EUA approval for use
  - Modifications of EUA approved tests require submission to FDA too

Overall thoughts on testing
References

- http://www.fda.gov
Thank you!

For updated information on COVID-19, visit www.msms.org

If you have additional questions, email rblake@msms.org