CLIA Regulations Assessment Workgroup Interim Report

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CLIA Regulatory Assessment Workgroup

Co-Chairs

Dr. Kimberle Chapin
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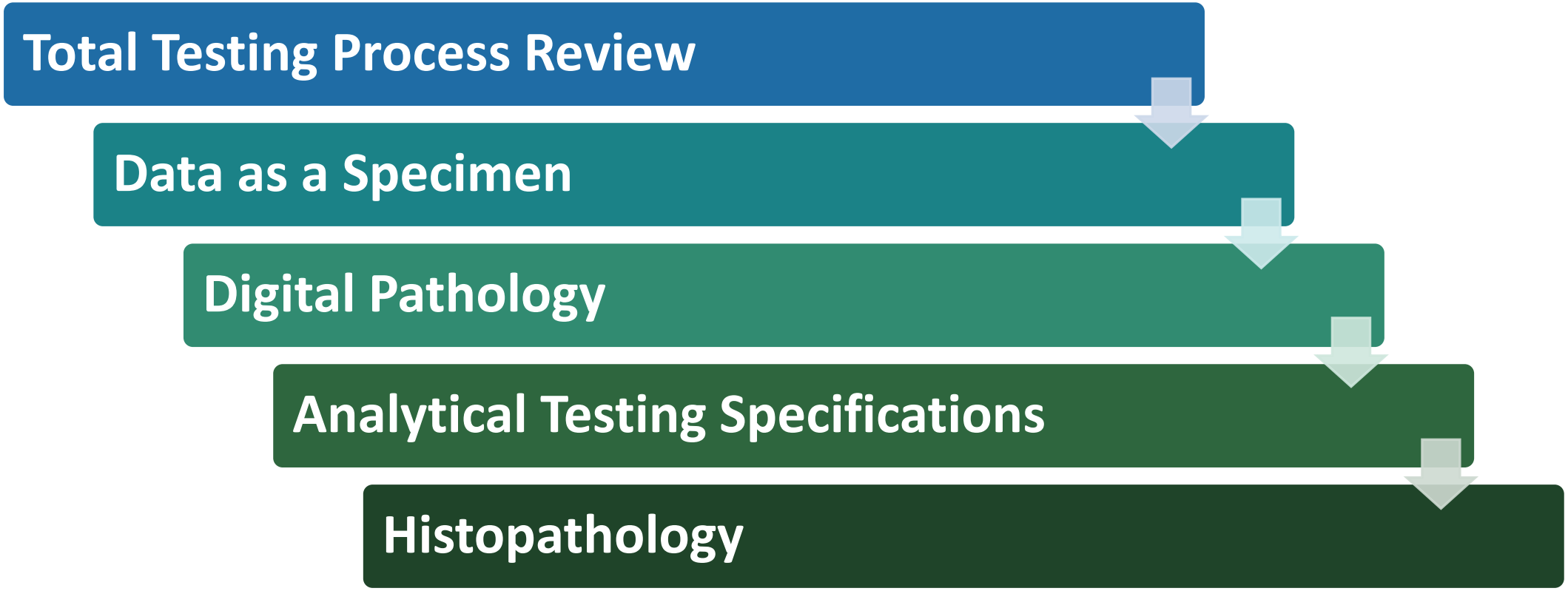
Workgroup Charge

- **Established to provide** input to CLIAC for deliberation on how CLIA might specifically be updated, considering the April 2019 reports by the Personnel Regulations, Non-Traditional Workflow Models, and Next Generation Sequencing workgroups.
- **Charged with providing advice** to CLIAC for consideration in making recommendations to the Department of Health and Human Services on revising the CLIA regulations.

Discussion Topics



Workgroup Members

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- Víctor R. De Jesús, PhD – CDC Ex Officio
- Tamara Pinkney, MT(ASCP) – FDA Ex Officio
- Heather L. Stang, MS, MT(AMT) – Workgroup DFO

Workgroup Agreements

- Total Testing Process
- Data as a Specimen
- New CLIA Certificate Type
- Remote Testing
- At-Home Specimen Collection
- Personnel
- Other Areas

Total Testing Process

1. A laboratory's requirements under CLIA should start when a specimen arrives in the laboratory for testing.

2. A laboratory's requirements under CLIA should continue through the total testing process, including data interpretation, and reporting even when performed remotely.

Data as a Specimen

1. The CLIA definition of a laboratory includes the terminology “materials derived from the human body,” and that “derived” should apply to images and data because they are a derivation of material from the human body.
2. The term “materials” should be defined in CLIA as the patient specimen, including data derived from a patient specimen such as images, genetic and protein sequence(s), –omics data, and other data that is used for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.
3. The definition of a “test system” should be modified in CLIA to all of the instructions, instrumentation, equipment, reagents, supplies, software algorithms, data analysis procedures, and other components needed to perform an assay or examination and generate test results.

New CLIA Certificate Type

1. If an entity is manipulating information, performing data analysis, etc., received from a clinical laboratory and returning it to the laboratory for inclusion in the patient report or for patient care, that entity needs to have the appropriate CLIA certificate.
   - Under that CLIA certificate, they are subject to the same patient confidentiality and requirements as the referring laboratory.
2. Entities that perform informatic analysis and interpretation of laboratory data should be certified under CLIA. This may require a new type of CLIA laboratory designation beyond Certificate of Compliance or Accreditation.

Remote Testing

1. If a laboratory employee works out of their home or at another remote location performing duties such as data analysis and interpretation associated with that laboratory, then those activities would be covered through an extension of that laboratory's CLIA certificate.
2. Under a distributive model where a laboratory performs the wet laboratory work, and another separate entity performs the data analysis and/or interpretation, those two sites should have separate and distinct CLIA certificates, and proficiency testing should be required for both locations.
3. The CLIA regulations should be revised to allow remote analysis for any CLIA specialty or subspecialty.
4. A laboratory's CLIA certificate covers the qualified laboratory personnel when using a VPN to review and report cases remotely.

At-Home Specimen Collection

The COVID-19 pandemic brought at-home specimen collection to the forefront. Laboratory testing quality begins during specimen collection, and it would be very difficult to inspect the front-end process of specimen collection, including at-home or remote, packaging, transportation, patient information validation, etc.

There should be more stringent requirements for stability studies both with the vendor and as a confirmation in the laboratory to address the specimen shipment issues.

- Vendors should perform studies (stability, transportation, etc.) on at-home collected specimens and provide that information as part of the FDA approval process. These studies should include specimen stability.
- FDA should consider requiring a human adequacy control for detection in a specimen and at-home collection and testing.
- Specimen collection devices should have internal controls to ensure sufficient specimen was collected and monitor the specimen's integrity during transportation to the testing laboratory.
- Laboratories that choose to use a home collection device that has not been cleared for use by the FDA will need to submit that device for FDA review and approval.
- Laboratories must have policies in place to accept and reject specimens collected outside of their laboratory, including home-collected specimens. If the laboratory chooses to test a specimen that falls outside of the collection device's manufacturer's instructions, then the laboratory will need to provide performance studies to validate that modification.

Personnel

1. Workgroup members agree that CLIA should broadly define new personnel roles, such as the personnel performing activities such as bioinformatic data analysis, variant classification, variant analysis for patient care, etc. (variant scientists).
2. CLIA should require training and competency assessments for staff such as pathology assistants, image technicians, cytotechnologists, and histotechnologists that are performing digital pathology and digital image analysis. This may require the establishment of a new personnel category in CLIA or additional competency requirements.
3. A new specialty is needed to accommodate the post-analytic analysis of laboratory data or results to accommodate other practice areas such as next generation sequencing (NGS), drug screen toxicology, etc.

Other Areas

1. The use of robotics should fall under CLIA because laboratory personnel are responsible for ensuring that the robotic equipment performs as expected through validation and establishment of performance characteristics.
2. For any digital data, laboratories should have a policy/procedure to ensure specimen integrity throughout the analytical process.
3. Any device that's storing data should require an identification number for the image, a patient identifier, and an institutional identifier.
4. Laboratories must implement software and devices which are compliant with the applicable components of the HIPAA Final Security Rule. In addition, laboratories must ensure that devices that are implemented do not impose a significant risk to the safety and security of the patient data that the laboratory stores, manages, creates, or analyzes. FDA must ensure that the software and systems of any test system or device are HIPAA Security Rule compliant and contain software that is currently supported by its developer for at least 5 years from the date of the approval, including operating system software and database software.