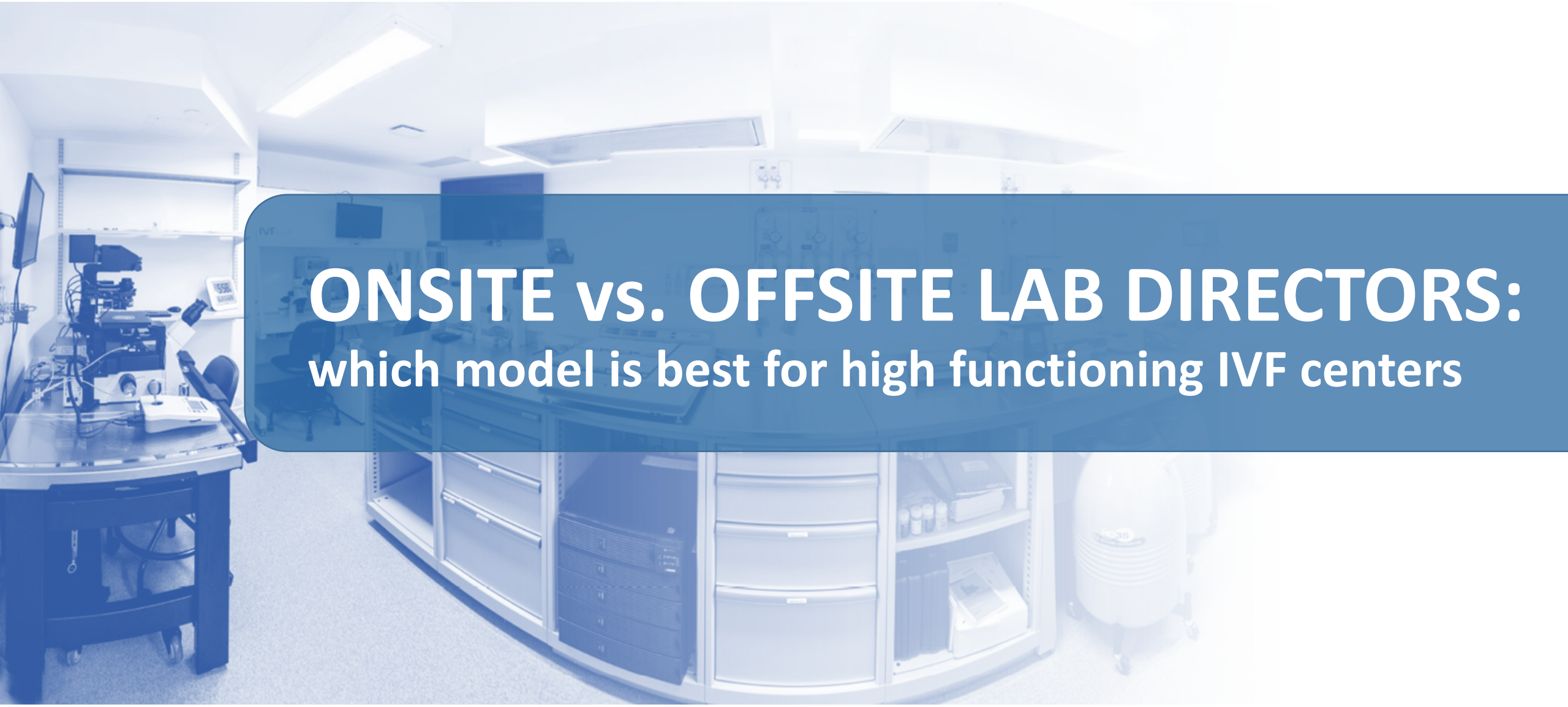


ONSITE vs. OFFSITE LAB DIRECTORS:

which model is best for high functioning IVF centers

Jason E. Swain, PhD, HCLD

DISCLOSURE

- Nothing to disclose relevant to this lecture

OBJECTIVES

1. State regulatory requirements for IVF lab directorship.

2. Differeniate key differences between directorship models.

3. Determine which directorship model is best suited for specific labs.

LABORATORY DIRECTOR

The lab director is responsible for the overall operation and administration of the lab, including the employment of competent qualified personnel. While the director can delegate some responsibilities, the director is ultimately responsible and must ensure that all the duties are properly performed and applicable regulations are met. The director must ensure that the lab develops and uses a quality system approach that provides accurate and reliable patient results and outcomes.

THE REPRODUCTIVE LABORATORIES

KEY DIFFERENCES

Embryology Lab

Procedures

Clinical Lab

Testing

Differences in regulatory & personnel requirements

ART LABORATORIES

REGULATORY AGENCIES

Federal

CDC
FDA
CMS (CLIA)

State

Tissue Bank
State DOH

Self-Regulation

CAP/TJC
SART

THE REPRODUCTIVE LABORATORIES

DIFFEERENT REGULATORY OVERSITE

Embryology Lab

Procedure Based

Tissue Bank*
FDA
CDC/SART**
CAP***/TJC***

Clinical Lab

Andrology/Endocrinology

Testing Based

State Lab Oversite*
CLIA
CAP/TJC/COLA/other
FDA
Tissue Bank*

Often perform IUI prep, sperm cryo procedures

Similarities exist – embryology lab becoming more regulated - similar to clinical lab

*Some states have additional oversite & requirements

**"Optional"- but insurance impact

***"Optional" - but required if SART member & insurance impact

Clinical Laboratory Improvement Amendments (CLIA)

Laboratory Director Responsibilities

As lab director, you must ensure that:

- testing systems in the lab provide quality services in all aspects of test performance;
- physical and environmental conditions of the lab are adequate and appropriate;
- the environment for employees is safe from physical, chemical, and biological hazards;
- a general supervisor (high complexity testing) is available to provide day-to-day supervision of all testing personnel and reporting of test results;
- employment of sufficient numbers of appropriately educated, experienced, and/or trained personnel;
- new test procedures are reviewed, included in the procedure manual and followed by personnel; and
- each employee's responsibilities and duties are specified in writing

ART LABORATORY DIRECTOR

HIGH COMPLEXITY LAB DIRECTOR (HCLD)

Be an MD or DO licensed to practice in the State in which the laboratory is located; **and**

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; **or**

Be an MD or DO or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; **and**

(i) Have at least one year of laboratory training during medical residency; **or**

(ii) Have at least 2 years of experience directing or supervising high complexity testing; **or**

Hold an earned doctoral degree (PhD) in a chemical, physical, biological, or clinical laboratory science from an accredited institution **and** -

(i) Be certified and continue to be certified by a board approved by HHS; **or**

(ii) Before February 24, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least -

Two years of laboratory training or experience, or both; **and** Two years of laboratory experience directing or supervising high complexity testing.

In addition, applicants for HCLD certification with **AAB** must:

For the specialty of Embryology, must include 60 personally performed, completed assisted reproductive procedures in humans. For the specialty of Andrology, Effective January 1, 2021, ABB applicants for Technical Supervisor and High-complexity Clinical Laboratory Director certification in the discipline of Andrology must have experience in a laboratory that has Andrology or Hematology listed on the laboratory's CLIA certificate. **AND**

Pass an **ABB** examination in General Knowledge and in at least one (1) of the following clinical laboratory disciplines or specialties: Andrology; Chemistry (including urinalysis, endocrinology and toxicology); Diagnostic Immunology; Embryology; Hematology (including flow cytometry); Microbiology (includes bacteriology, parasitology, virology, and mycology); Molecular Diagnostics; or Public Health Microbiology

Can direct andrology, endocrinology & embryology

ART LABORATORY DIRECTOR

EMBRYOLOGY LAB DIRECTOR (ELD)

Hold an earned doctoral degree* from an accredited institution with a chemical, physical, biological, or clinical laboratory science as the major subject and have successfully completed 32 semester hours (minimum) in chemistry or the biological sciences acceptable to the board.

AND

Have a minimum of two (2) years of experience within the ten (10) years immediately prior to the application date on human specimens directing or supervising embryology testing in an embryology laboratory. This experience must include 60 personally performed, completed assisted reproductive procedures in humans administered under current standards of care.

AND

Pass **ABB's** examinations in Embryology Laboratory Administration and Embryology.

Can only direct embryology

LABORATORY DIRECTORSHIP

PARADIGMS

Onsite Director: present in the clinic/lab on a regulator basis, involved in daily meetings & operations. May participate in hands-on work & rotations.

Offsite Director: located remotely. Often works at or with other labs. Communicates/visits regularly & provides input as requested/required. Does not usually provide hand's-on lab support

Comprehensive guidance for human embryology, andrology, and endocrinology laboratories: management and operations: a committee opinion

Practice Committees of the American Society for Reproductive Medicine (ASRM) and the Society for Reproductive Biologists and Technologists (SRBT)

American Society for Reproductive Medicine, Birmingham, Alabama

Fertil Steril 2022; 117(6): 1182-1202

The duties of an on-site or off-site lab director are the same, and each must be available for **consultations as needed by the lab and referring clinicians**. Off-site directors must visit the lab frequently to monitor the function and quality of the lab at **minimum 4 times** a year (the CAP). For any regulatory surveys for accreditation, certification, or licensure, the lab director **must be present and on-site** to ensure immediate access by the surveyor(s). Lab directors **may direct no more than 5 labs** performing non- waived testing (5 CLIA certs*) and no more than 5 embryology labs (non-CLIA).

** May be less depending on state regulations*

LABORATORY DIRECTOR

ROLES & RESPONSIBILITIES

An active & involved lab director is best for quality & safety

Is this more likely to be accomplished thoroughly onsite or offsite?

ONSITE LAB DIRECTOR

POSSIBLE BENEFITS & CONCERNS

BENEFITS

- Real-time oversight
- Team dynamic
- Patient interaction
- Consistency

CONCERNS

- Resource allocation
  - Pay
  - Office
  - Active Involvement
  - Local dynamic

OFFSITE LAB DIRECTOR

POSSIBLE BENEFITS & CONCERNS

BENEFITS

- Improved access to directors
  - Small practices
  - Difficult locations
  - Difficult physician
  - Other
- Cost savings
  - “Corporate IVF” benefit
  - Small practices (batching)
  - More onsite staff/better pay
  - Other
- Troubleshooting/QC
  - Intra lab insight potential

CONCERNS

- Means to an end
  - saving $ as priority?
- How involved?
  - Are 5 labs feasible?
- What is incentive to advocate for lab?
- What is the incentive to push for innovation or change?
- Stability/SOPs/lab culture
- Corporate IVF - access to PI if not part of the group?

OFFSITE LAB DIRECTOR

CONSIDERATIONS

- Director must be insured
  - Either they provide their own or practice provides
- Must have a strong onsite supervisor
- Regular contact (daily, weekly)
- Communication clarity
  - lab director contacted first (i.e. Lab Director should not be hearing about incidents from the MD)
    - *You're paying a director…then use them*

LAB DIRECTORSHIP

WHICH MODEL IS APPROPRIATE

- Are you a single, stand-alone practice or part of a larger network?

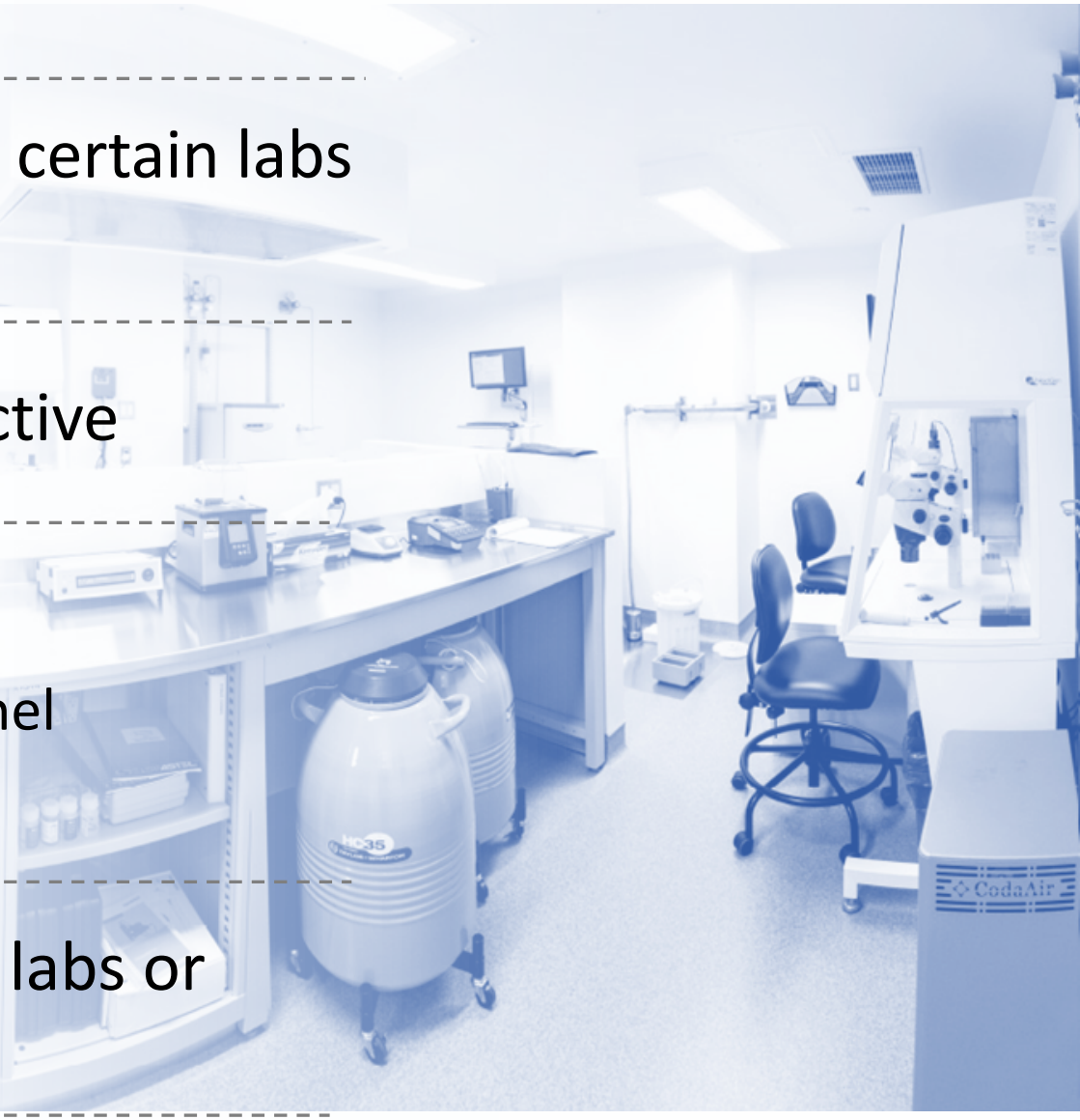
- What are you trying to accomplish?
  - Partnership, teamwork, other
  - Avoidance of ….
  - Business efficiency

- What are other responsibilities of the director
  - Other labs, obligations
  - How often onsite?
  - What are other deliverables?
    - Staffing, data, troubleshooting, SOPs, etc

- What is the pay model
  - Flat rate, fee + hourly, other

CONCLUSIONS

- Offsite directorship offers some benefits to certain labs
  - Lower cost, logistical solutions, etc
- Offsite directors must remain involved & active
- Can be a delicate balance with onsite staff
  - Requires local org chart & good onsite personnel
  - Clear duties, authority, control
- Offsite directors may not be suitable for all labs or locations



REFERENCES

- https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/revised_guidelines_for_human_embryology_and_andrology_laboratories.pdf
- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Labs
- https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtainclіacertificate.pdf
- https://www.cms.gov/regulations-and guidance/legislation/clia/clia_brochures
- https://www.aab.org/aab/HCLD.asp
- https://www.aab.org/aab/ELD.asp