An Introduction to AI-Guided Image Acquisition

Marjan Nabili, PhD
FDA/CDRH/OHT7/Division of Radiological Health (DRH)
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Outline

• Advantages of Ultrasound imaging
• Challenges associated with Ultrasound image acquisition
• How AI can assist with image acquisition
• Portable point-of-care Ultrasound systems
• Future Direction
Advantages of Ultrasound Imaging

- No ionizing radiation
- Low cost and widely accessible
- Portability
- Real-time imaging/ Real-time feedback
- Variety of clinical applications

Ultrasound could be an attractive modality for AI/ML space both for image acquisition and post processing.
Challenges linked with ultrasound image acquisition

- Operator/user dependent
- Variability across different manufacturer
- Many presets
- Noise/artifacts
AI-guided Image Acquisition

What could be the benefits:

- Reproducibility
- Standardized procedures
- Improve efficiency and reliability

Clinical AI applications may assist the acquisition of standardized images independent of the operator, guiding both sonographers and non-experts in sonography, potentially including lay users, to acquire images with equivalent diagnostic quality.
AI-guided Image Acquisition

Recently the FDA authorized marketing of software to assist medical professionals in the acquisition of cardiac ultrasound, or echocardiography, images.

Other AI-guided/less automated examples which assist with image acquisition and optimization

- auto focus, auto depth, auto EF, etc.
Challenges with AI-guided image acquisition

**Device error** - Failure to provide guidance on acquiring diagnostic-quality images or signals

**User error** - Operator failure to follow the guidance provided by the device to acquire diagnostic-quality images or signals

Errors could lead to delay, prolonged examination, or additional unnecessary procedures, due to algorithm failure.
Point-of-care Ultrasound

Evolution of mobile computing technology along with advancement of US systems into more portable devices

Future Direction

Advantages of ultrasound imaging makes it an attractive modality for in-home monitoring tool with real-time feedback

- Safety and effectiveness should match the professional use environment

Benefits
- Provide valuable information and should be used under supervision of health care professional
- Could benefit patients in rural areas with limited access to clinics/healthcare facilities

Risks
- Risks may increase with unnecessary prolonged exposure to ultrasound energy
- Incorrect interpretation of information by user
- There may be no oversight of how the device is used

https://www.fda.gov/radiation-emitting-products/medical-imaging/ultrasound-imaging
Pre-Submissions to FDA

• Requesting feedback regarding potential or planned medical device applications

• Example questions could include:
  – Appropriate regulatory pathway for a specific intended use
  – Feedback on whether a proposed set of performance testing would be sufficient to support the intended use
  – Feedback on whether a proposed set of performance testing and labeling addresses any applicable special controls

• FDA Guidance Document: Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff, dated May 7, 2019 [https://www.fda.gov/media/114034/download](https://www.fda.gov/media/114034/download)
Summary

• Through this workshop, FDA is seeking to engage with stakeholders to explore benefits and risks of evolving applications of AI in radiology.

• As the benefit-risk profile changes, it is critical to adapt the methods used to evaluate and characterize their performance.

• In this workshop, FDA is also seeking innovative and consistent ways to leverage existing methods and to develop new methods for validation of these AI-based algorithms and explore opportunities for stakeholder collaboration in these efforts.