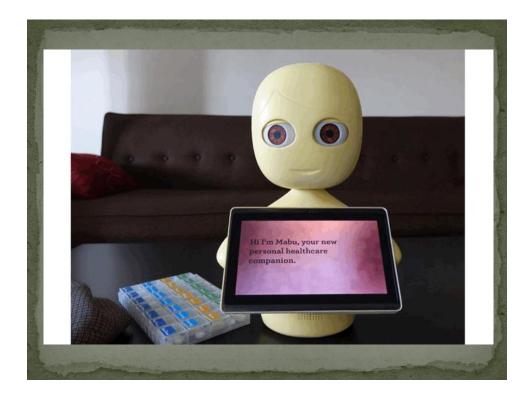# Panelists and COI disclosure

Moderators:

Natalie Afshari MD none

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Panelists:

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Ophthalmic Digital Health Panel 1

- Panel Questions
- 1. What are the safety and effectiveness concerns when a digital health device provides a diagnosis (e.g., a computer-assisted diagnosis for screening diabetic retinopathy by adding on software to fundus camera images)

  In comparison to when a digital health device provides information as an aid for diagnosis to the eye care provider

- 4. What are the assets, threats, and vulnerabilities that should be considered and identified as a threat to the privacy of a patient by ophthalmic digital health device developers?
- a. Transmission of information to electronic medical records or other databases
- b. Storage of information on the personal device or cloud devices
- c. Monitoring patient behavior and location

Question 1

- What are the safety and effectiveness concerns when:

  A digital health device provides a diagnosis (e.g., a computer-assisted diagnosis for screening diabetic retinopathy by adding on software to fundus camera images)

  In comparison to the digital device that provides information as an aid for diagnosis to the health care provider

Question 4

- 4. What are the assets, threats, and vulnerabilities that should be considered and identified as a threat to the privacy of a patient by ophthalmic digital health device developers?
- a. Transmission of information to electronic medical records or other databases
- b. Storage of information on the personal device or cloud devices
- c. Monitoring patient behavior and location

Other Questions

- Ocular imaging is it superior to hand drawings?
- Use of imaging for ER exams
- Is the I phone camera a medical device if so any constrains on it for ocular imaging?
- What is the major obstacle to acceptance of telemedicine in Ophthalmology

Panel 1 Moderator Summary

Question 1 and 4
Safety and effectiveness and concerns when a digital health device provides information as an aid for diagnosis and the assets, threats, and vulnerabilities to be considered and identified

-The tempo of the disease may reflect on how important the device contribution is to the diagnosis.
-A physician end user maybe able to override any machine inconsistencies.
-Some of the safety factors depend on the end user.
-There should be some assurance that the doctor is up to date in the management of that disease.
(Some of the Diabetic retinopathy disease patients may read the images better than some doctors!)
-We have come a long way in privacy but have some ways to go in digital health.
-There is evidence that local storage and cloud based storage have similar security profiles.
-Industries are being created to assess the level of cyber security (SOC document).