

UK and Japan Symposium on Medical Imaging and Artificial Intelligence

(Professor George E Griffin & Professor Nobuo Ueno)

Tuesday 23 January, 2018

Academy of Medical Sciences, 41 Portland Place, W1B 1QH, UK

Chair: Professor David Hawkes

Perspectives on Regulatory and Ethical Considerations of Medical Images and AI

Makoto Hashizume, MD, PhD, FACS

Distinguished Professor

Kyushu University





My Profile

- 1979; start as a general surgeon
- 1991; Laparoscopic surgery
- 1999; PI of national projects on development of surgical robotic system
- 2000; Robotic surgery at Kyushu University Hospital
- 2004; director at Training Center for MIS
- 2006; director (Em Med and Critical Care Center)
- 2011; director (Center for Advanced Med Innovation)
- 2014; PI of the national project on MCA
- 2017; Chief of WG on evaluation index of Medical Image & AI at the Ministry of Health, Labour and Welfare

Location of Kyushu University

FASCINATING COUNTRY
JAPAN



⑤ Himeji Castle (Hyogo)



① Nikko Toshogu Shrine (Tochigi)



④ Kinkakuji (Kyoto)



Fukuoka

Tokyo



③ Mt. Fuji (Shizuoka)



② Sensoji Temple (Tokyo)

**Kyushu University Hospital,
Fukuoka, Japan**

Kyushu University Hospital



Information-guided surgery

AI is related to all of the following step in surgery

Computer-aided detection (CADe): No, size, meta earlier diag., borderline of malignant tissue

Computer-aided diagnosis (CADx)

accurate diag., resection line based on pathology

Indication, planning, or evaluation of skill

Image-guided navigation during surgery

Orientation: anatomy (organ, vessels, tumor)

Difficult case: show the appropriate access

Prognosis of patients depend on these decision



Notice for Medical Image and AI

(WG on evaluation index of CAD with AI at the Ministry of Health, Labour and Welfare)

Current problems and management focused on computer-aided detection and diagnosis (CADE and CADx)

- Basic concept
- Algorithm and function
- Assessment for safety, quality and function at premarketing and after the market
- Risk management



The current problems on AI for Medical Devices

Black box of the processing

Continued change of function

(pros & cons)

Reliability of database



Black box of the processing

The algorithm or judgement rationale via neural network is black box in AI.

- Whatever the diagnosis suggested by CAD was correct or not, it is hard to explain the reason or to show the evidence why or how the results were induced. It is also hard to prospect the processing when the non-labelled data was used in deep network.
- Clinical problem is that nobody knows when some trouble had occurred and where to be improved. The outcome is closely related to the treatment strategy and prognosis.



Continued change of function pros & cons

- The function of the device might continuously be improved or lowered by self-learning algorithm, while nobody noticed the change of function. The latter case leads to tragedy for the patients.
- The characteristics of self-learning or self-data collection might have an adverse effect on the function after the market (after CAD with AI had obtained certification or approval as a medical device by PMDA; Japanese Pharmaceutical and Medical Device Agency).



Reliability of database

The origin, quality and volume of the data are key factors to the outcome of AI-related CAD.

- Transfer learning is known to improve the network function, but non-medical images, or non-labelled or non-reliable data might be used in the learning processes, especially in deep learning.
- It is also the same as in the data set for validation or test. This might miss-lead to an incorrect or wrong direction.
- The problems is that there is no way to know that it is wrong or incorrect at the on-site.

What should we do to those problems?



- The Ministry for Health, Labour and Welfare is now working on to make an evaluation index for the CADe or CADx with AI which would be applied for certification or approval as a medical device.
- Government would not like to suppress or control the development of AI- related medical devices, but rather actively support it under consideration of advantages and disadvantages of AI.



Possible solution to black box

- Instead of showing the algorithm, it might be required to show the guarantee by prescribing the range of effectiveness or the limit of adverse effect on the function of the device in order to secure the safety, quality and function of the product.
- For example, the detection rate, false positive or false negative rate of diagnosis, the time to detect or functional value.

Solution for change of function

The company might be required the following condition

- Schedule an inspection period, verification method, specially in unsupervised learning
- Quality of the training, validation or test data set
- Training, or qualify the users as well as makers
- Notification system in case of abnormal operation
- Expedite the PMDA screening; different versioned products which are over the range might be recognized as a new product.
- Which is responsible, maker or medical doctor?



Risk management (1)

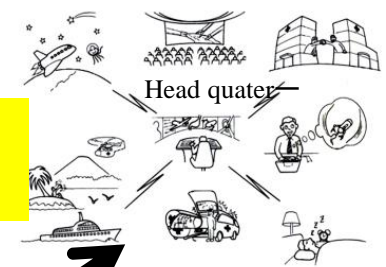
- Calibration or self test every time before operation
- Reset or recover to the level of function at the starting point before over the range or limit
- Notification system in case of fault or failure
- Emergency shut down in case of fault
- Educate the users to avoid improper use or qualify the users
- Medical doctor is responsible for the final diagnosis or decision



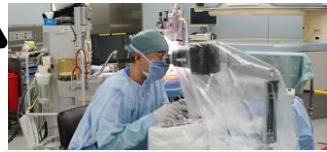
Risk management (2)

- Pathology is absolute final diagnosis so that any change in function of the product after the market would produce a significant high risk of unexpected adverse events to the patient.
- It should not give approval to such CADx as functional change occurs without control of the maker.
- Prescribe the dataset condition of movies such as endoscopy or US

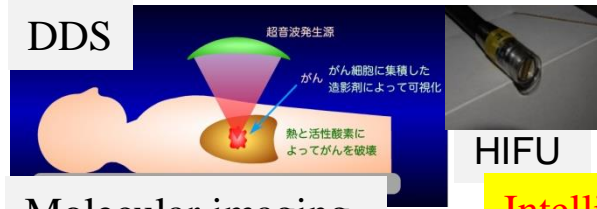
Future Medicine: **MCA based Medicine**



Robotic technology



Micro-surg. robot



Molecular imaging

Automated surgery



Single port surgery



Neuro-surg. robot

sensor

Intelligent Surgical Robotic System

Human simulation



Flexible endoscopic robot

ESD/NOTES



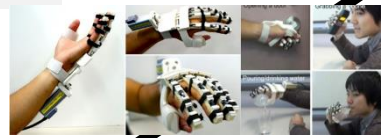
Prehospital care robot



Automated diagnosis



MRI-guided surg. robot



Rehabilitation robot



Vehicle robot



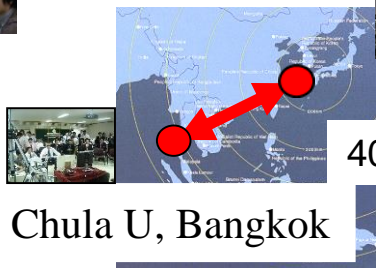
MCA: Multidisciplinary Computational Anatomy



Endoscope -holding



Muscle trainer



Chula U, Bangkok

KU, Fukuoka

4000Km

Super computing



Remote controlled Robot-surgery

AI

Information & Communication Technology CAMIT at KU



Conclusion

- The important notices were presented for safe and appropriate use of CAD with AI.
- AI is a promising tool to give a high probability of detection. However there are some problems for clinical use.
- a MCA-based medicine is one of the solution model in future medicine.
- All consideration on AI should be based on contribution to improvement in healthcare and welfare for the patients, but not for technology.

FUKUOKA
JAPAN

福岡

Thank you for your attention!

<http://www.camit.org/>
<http://www.cmeit.org/>

*Center for advanced Medical Innovation
Kyushu University Fukuoka, Japan*

