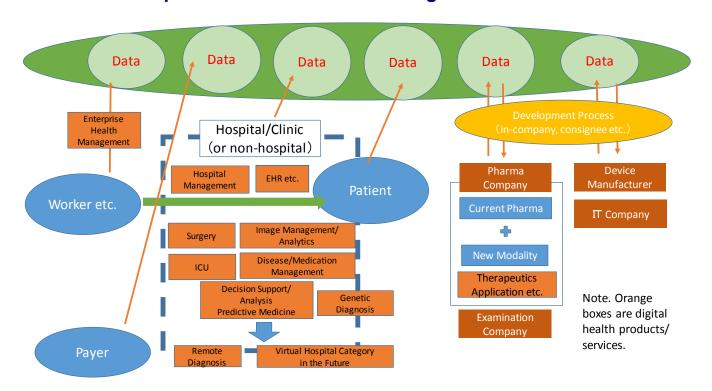


Possibility of pushing forward digitalization of Japanese medical sites (Short version)

1-1. Theme of this report

- Thematically this report considers the possibility of pushing forward digitalization of hospitals and other medical sites based primarily on input from medical doctors, product providers, and specialists.
- In the US, products and services in this area are developed rapidly and, from the global viewpoint, utilization of electronic health records (EHR) also advances. On the other hand, in Japan, it is difficult to say that general healthcare is changing in a digital-based way. Of course, there are some early adopters among both medical institutions and companies.
- Therefore, I probed the opinions of medical institution and medical company personnel as well as a wellinformed resident in the US and endeavored to discern what is meant by 'digital health' of medical sites. For that reason, interviews constitute the main part of this report and I omit published papers in this English short version.

1-2. Relationship between medical site and digital health



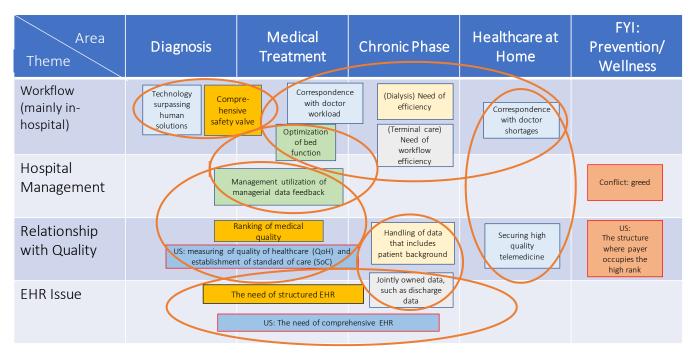
 The term 'digital health' can be defined in different ways. In the diagram above, I describe the product type assumed in this report. As a matter of course, many products and services exist in the prevention area, and there is also another landscape in genetic screening. However, the scope of this report is on the domain directly in hospitals and clinics.

1-3. Method

- The method is simple, I posed a common set of questions to 1) companies, 2) a well-informed person in the US, and 3) medical institutions (2018/4-7).
- The common questions are listed below.
 - ✓ What are the issues regarding current Japanese medical sites (respective areas)? Is it possible to improve quality and reduce costs by making the areas data-driven?
 - Are connections between areas possible? What are the obstacles? What are the core technologies?
 - ✓ For which diseases would adoption of digitalization be especially effective?
 - ✓ What de facto environment should be created?
 - ✓ What kind of usage is possible (necessary) in Japan's medical system in 2025?

2-1. Problems identified in interview set #1

[Input from medical doctors/management and experts]

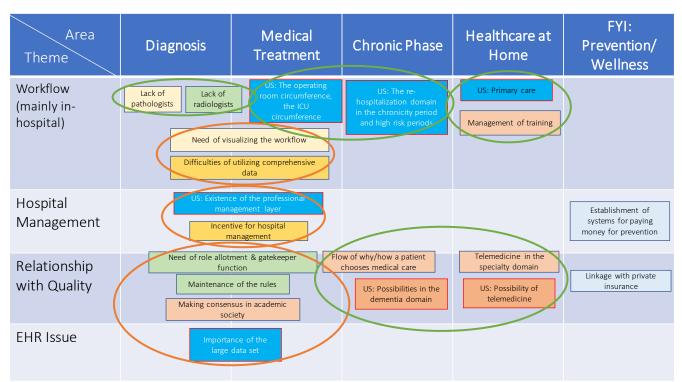


Based on the interviews, the diagram above plots various comments, with common issues circled. The common issues are as follows.

- Problems of the choice between technological and human solutions
- 2. Desire for on-site (hospitals, clinics etc.) efficiencies
- How the need for telemedicine corresponds with the overall medical environment
- 4. The problem of hospital managers not being able to compare management data relatively
- 5. The problem of doctors not being able to compare medical quality relatively
- 6. The way of extracting the data that doctors need
- 7. Appropriate EHR procedures

2-2. Problems identified in interview set #2

[Hearing from companies and Experts]



On the other hand, what is the company side's opinion of such a movement? The diagram above plots various issues, including the same types of groupings as in the previous diagram. As follows, I took out common things and divided them into 'Theme to be solved' and 'Current essential problems'.

[Theme to be solved]

- 1. Lack of doctors in diagnosis areas
- 2. Absence of new services in treatment similar to what is already available in the US
- 3 .Support for management training by doctors
- 4. Quality-related aspects of telemedicine

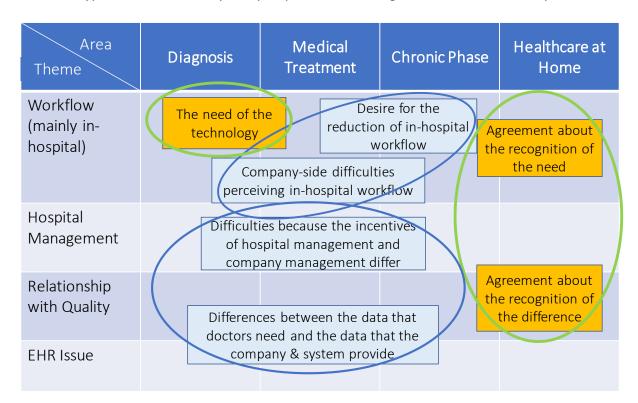
[Current basic problems]

- 5. Can't see in-hospital workflow / Difficulties utilizing integrated data inside hospitals
- 6. Management incentive from the medical side
- 7. Setting up the rules and reaching consensus among academics

2-3. Point of view from both sides

In many areas the medical institution / doctor side's point of view varies from that of the company side. In the diagram below, the green rings indicate where recognition is common and the blue rings indicate where gaps exist.

- 1. Common desires: Making rules and deepening technologies
- 2. Common recognition: Need for digitalization in medical care for elderly persons and healthcare at home
- 3 .Difference: Mutual thinking about the in-hospital workflow
- 4. Difference: Type of data necessary and perspective of management incentive in hospitals



3-1. US situation

Based on the interviews of well-informed persons in the US, actions promoting digital health proceed in flows:

- 1) Promotion of digitalization
- 2) Support for regulation of new technology and solutions to digitization issues
- 3) Efficient support for software examination

- The HITECH Act (2009) played an important role in "promotion of the digitization" and promoted the spread of EHR.
- The 21st Century Cures Act enforced in 2016 had an aim to help accelerate medical advances by accelerating the FDA's approval process and increasing federal government funding, and it helps clarify how the FDA should regulate new technology and solutions.
- And, recently, the efficiency of the FDA's examination of Pre-cert medical software advances has been improved.
- Also in the US, there seems to be no opposition axis like in Japan. Due to the high costs of the healthcare system and private insurance system, there are no disincentives for improvement of in-hospital workflow.
- However, even in the US, despite EHR being widespread, it does not cover all data comprehensively.
 Various data are being integrated in the wellness areas served by entrants such as Google and Apple, and development is ongoing in the diagnosis & medical treatment areas.

Note: Comprehensive data use may be understood in terms of its compatibility and its potential to be integrated.

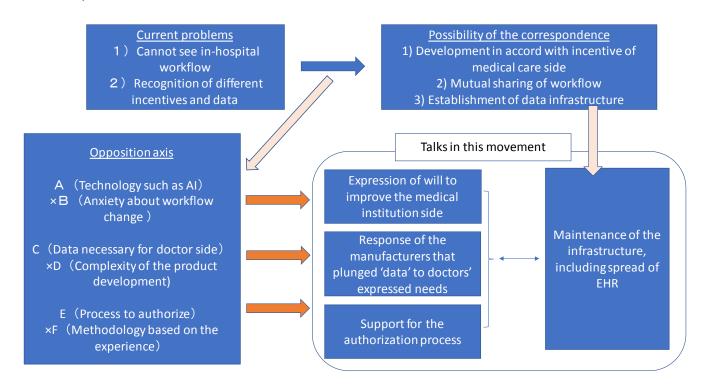
3-2. The opposition axis that disturbs progress

- In Japan, the elements mentioned above seem to be ongoing at the same time from the policy-side aspect. The progress on site in medical institutions is gradual in most cases due to the existence of an opposition axis centered on the following.
 - -Anxiety about workflow change associated with technology such as AI
 - -Complexity of product development that meets the needs of doctors
 - -Methodology of authorization in line with the experience in the existing clinical department
- In addition, to get past such an opposition axis, we need to examine the whole workflow and cooperative framework among the different types of companies involved in addressing the issues.

4. Necessary directionality

- Based on rearrangements up to this point, below is an approximation of the directionality needed in order for 'digital health' to advance in medical sites.
- ① The medical side expressing unambiguous will regarding improvement of the medical institution side, in order to get company-side support for workflow improvement
- The company side showing a framework promoting data-use, in order to fully address the medical side's needs to avoid the development of products of the product-out type
- ③ Showing benefit of appropriate digitization, and maturing product and service authorization process (product approval, recognition among academic society, arrangement of guidelines)
- In addition, the next generation medical infrastructure act (enforcement in 2018) and so on will
 progress the infrastructure maintenance. Also, at the global point of view, examples like Estonia's
 collection of all the data of all patients and integrating it in one computer system serving the various
 parties simultaneously.
 - However, even if there are some advances in Japan by early adopters in leading areas, the overall situation might not significantly change on either the medical or the company side.

Based on the potential of Japanese medical institutions, doctors, companies and different types of industry, we need to create opportunities for discussion and delineate an appropriate sharing of the both the workflow arrangement and its actual performance. There appear to be extremely high opportunities for compromise and agreement. Creation of institutional incentives for the purpose will also be necessary.



[Healthcare Industry Office / Tatsufumi Aoyama]

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