## Science and Technology Policy Workshop on a Research and Development Perspective toward Type 2 Diabetes Control

#### Hiromi Takahashi-Omoe

Science and Technology Foresight Center National Institute of Science and Technology Policy Japan

### Atsushi Ogasawara

Biomedical Innovation Center Shiga University of Medical Science Japan

#### Yutaka Seino

Kansai Electric Power Hospital Japan

#### **Abstract**

In Japan, there is an increasing prevalence of type 2 diabetes and a subsequent economic burden associated with disease care and a consequent urgent need to combat the disease. However Japan does not have a detailed research and development plan at the national level, focusing on type 2 diabetes control, such as the US strategic planning and the EU roadmap. Because the natural course of type 2 diabetes onset is considered to depend on ethnicity and lifestyle, a detailed research and development plan focusing on the Japanese should be discussed. Under the situation, the National Institute of Science and Technology Policy held a professional workshop on type 2 diabetes control on October 22, 2013. As the resuplt of workshop, 5 challenges for disease control in Japan were proposed from the aspect of research infrastructure, fundamental integration research, and applied research for implementing health and medical care.

**Keywords:** research and development for type 2 diabetes control, professional workshop, technology mapping, five challenges faced by Japan

### 1.Introduction

The prevalence of type 2 diabetes in Japan is growing. Between 1997 and 2007, the number of people with probable type 2 diabetes increased from 6.9 million cases to 8.9 million and those with impaired glucose tolerance increased from 6.8 to 13.2 million (Ministry of Health, Labour and Welfare, 2009a). This is equivalent to 17.4% of the population in 2007 having either impaired glucose tolerance or type 2 diabetes. Such high prevalence of type 2 diabetes is associated with a significant economic burden, with funds allocated to diabetes accounting for 4%-6% of the total healthcare budget (Neville, Boye, Montgomery, Iwamoto, Okamura, & Hayes, 2009). In the present situation, there is an urgent need to control type 2 diabetes in Japan, and research and development (R&D) needs to focus on contributing to healthcare and medical practice. In July 2014, the Japanese government determined the "Healthcare Policy" (Cabinet, 2014). This policy covers the five years from FY 2014, foreseeing the next 10 years. One of the focused challenges of this policy is to contribute to the top level of medical care in the world. To enable the aims of this challenge, the government has tried to create innovative methods to prevent, diagnose, and treat high priority diseases including type 2 diabetes. However, thus far, a detailed national R&D plan, such as those of the US strategic planning (National Institute of Diabetes and Digestive and Kidney Diseases, 2011) and the EU roadmap (DIAMAP, 2010), has not been developed, although a few R&D strategies and plans have already been proposed by professionals (Japan Diabetes Society, 2004) (Japan Diabetes Society, 2010) (Noda, 2007).

Because the natural course of type 2 diabetes onsets known to differ among ethnic groups (Kodama, 2013), a detailed R&D plan focusing on the Japanese should be discussed. Considering lifestyle modifications are the most effective means of delaying or preventing the development of type 2 diabetes (Cardona-Morrell, 2010), Japanspecific social environment and behavioral characteristics to influence the onset and progression of disease are needed to be studied. In this paper, we address the direction for R&D for type 2 diabetes with a view to contribute to Japan's future plan based on technology mapping and the discussions during the professional workshop hosted by the National Institute of Science and Technology Policy. Although discussion from the medical practice view point is also extremely important, it is not covered within this paper. Our proposal provides a future direction for R&D required to tackle type 2 diabetes not only for implementation in Japan but also for use in other countries.

#### 2.Methods

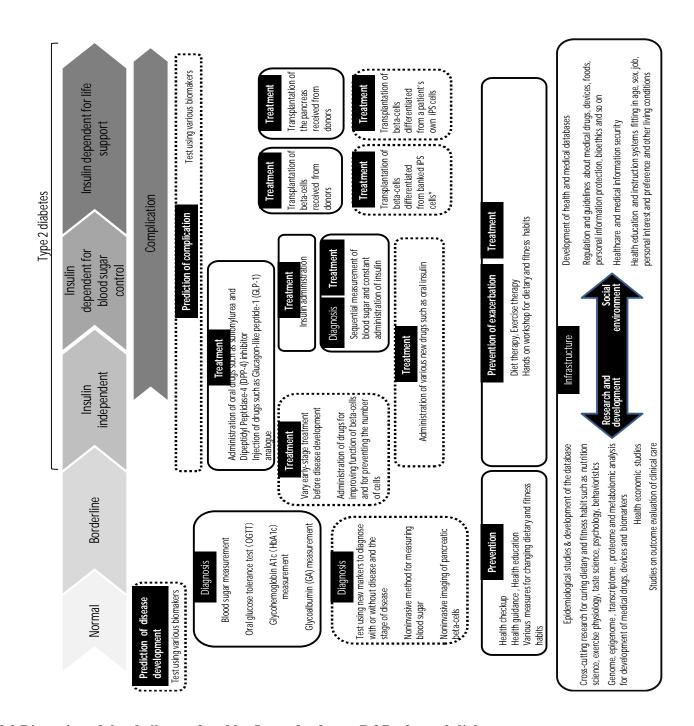
A professional workshop on type 2 diabetes control was held by the National Institute of Science and Technology Policy on October 22, 2013. After current and future possible technologies for control of the disease were mapped, the R&D for future challenges faced by Japan were discussed with regard to science and technology policy. Considering an interdisciplinary R&D plan is required for type 2 diabetes control, the participants in the workshop were chosen from various fields such as biomedical research, public health, science and technology policy, economics. Specifically they were as follows (areas of expertise, their affiliations and positions were as of October, 2013): Dr. Mitsuhiko Noda (diabetes research-general, National Center for Global Health and Medicine), Prof. Nobuya Inagaki (medical equipment and diabetes research, Kyoto University), Dr. Kohjiro Ueki (medical drug and diabetes research, University of Tokyo), Prof. Yoshiya Kawaguchi (regenerative medicine, Kyoto University), Dr. Kazuyo Tsushita (diet and exercise therapy, Comprehensive Health Science Center, Aichi Health Promotion Foundation), Dr. Yasuhiro Kanetani (medical information and public health, National Institute of Public Health), Dr. Shinji Takemura (medical information and public health, National Institute of Public Health), Dr. Atsushi Goto (diabetes research-general, National Center for Global Health and Medicine), Mr. Takafumi Kakudo (medical equipment industry policy, Ministry of Economy, Trade and Industry), and Prof. Masahiro Kuroda (macroeconomics, Promotion Committee for Science of Science and Innovation Policy). The chairman of the workshop was Prof. Yutaka Seino who is the president of Japan Association for Diabetes Education and Care and the Asian Association of the Study of Diabetes.

#### 3.Results and discussion

## 3.1 Technology mapping for type 2 diabetes control

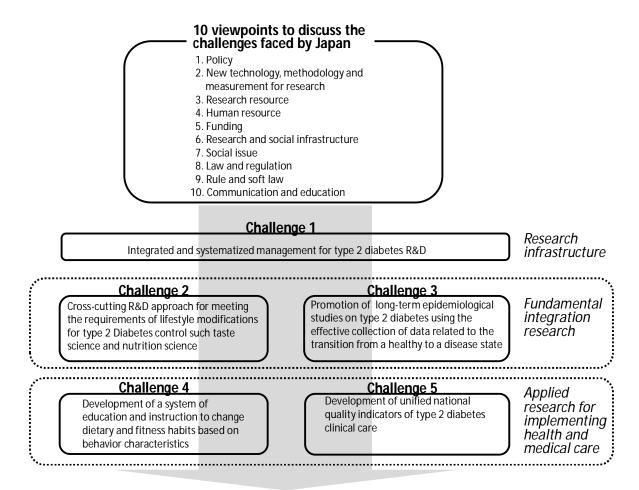
The current and possible future technologies for type 2 diabetes control were mapped by combining the countermeasures that can be used against the disease (disease prediction, prevention, diagnosis, and treatment) with the disease stages (normal, borderline, insulin independence and dependence) (Figure 1). The disease stages were based on the classification and diagnosis criteria determined by the Japan Diabetes Society in response to international standardization (Japan Diabetes Society, 2012). Of the technologies shown in Figure 1, the following were chosen for particular discussion as emergent key technologies considered capable of leading to future disease control: (1) prediction, biomarkers to determine the risk of developing the disease and the complications involved; (2) prevention, a health education system that effectively uses information and communication technology; (3) diagnosis, noninvasive techniques such as pancreatic beta-cell imaging and blood sugar measurements using near-infrared spectroscopy; and (4) treatment, drugs to restore and preserve beta-cell function, and transplantation of beta-cells differentiated from banked-induced pluripotent stem cells (banked-iPS cells). Additionally it was discussed that these mapped technologies required infrastructure development in viewpoint of R&D and social environment (the bottom part of Figure 1).

Figure 1: Technology map for type 2 diabetes control
Dashed lines show prospective technologies. \*Induced pluripotent stem cells



## 3.2 Discussion of the challenges faced by Japan for future R&D of type 2 diabetes

Subsequently the challenges faced by Japan in relation to type 2 diabetes control were discussed and proposed from the policy's 10 standpoints as shown below and in Figure 2. The standpoints were determined by referring to the US strategic planning (National Institute of Diabetes and Digestive and Kidney Diseases, 2011) and the EU roadmap (DIAMAP, 2010).



## Development of the countermeasures against type 2 diabetes in Japan

Figure 2:Conceptual diagram of the challenges faced by Japan for future type 2 diabetes R&D

## 3.2.1 Challenge 1: Integrated and systematized management for type 2 diabetes R&D

In Japan, R&D for type 2 diabetes control were not managed in an integrated manner. One of the reasons for this is the enormous scope that R&D needs to cover (as is clear from Figure 1) and the other is a complex structure for R&D funding among related ministries, depending on the individual technological fields involved, such as drugs, devices, or tissue engineering. In 2017, the latter problem has been partially solved by the Japan Agency for Medical Research and Development (AMED) which has been launched since April 2015(Japan Agency for Medical Research and Development, 2017). AMED has unified the management of practical research projects directly related to type 2 diabetes control. However basic biomedical research (e.g. genetic and metabolism research) and social science research (e.g. research on social environment and behavioral characteristics) have been supported mainly by other funding system such as the Grants-in-Aid for Scientific Research, KAKENHI (Japan Society for the Promotion of Science, 2017). To systematize R&D for type 2 diabetes control, an effort to make the connection among fundamental and practical biomedical research and social science research is needed.

#### 3.2.2 Challenge 2: Cross-cutting R&D approach for meeting the requirements of lifestyle modifications

Because lifestyle modifications are considered the most effective means of delaying or preventing the development of type 2 diabetes (Cardona-Morrell, 2010), cross-cutting studies on altering dietary and fitness habits should be further promoted. Japan is currently promoting disease R&D based on ideas for technologies such as drugs, devices, and tissue engineering. However, it is considered that Japan should concentrate on R&D for meeting the needs of modified lifestyles, integrating varied research fields such as nutritional science, exercise physiology, taste science, psychology, behavioristics, and other new academic disciplines. In the professional workshop, taste science was discussed particularly as a possible field for expansion because the science can be used to analyze taste disorders linked to childhood and adult obesity and can contribute to a cure for such disorders.

# 3.2.3 Challenge 3: Promotion of long-term epidemiological studies using the effective collection of data related to the transition from a healthy to a disease state

Because the natural course of type 2diabetes onset can differ among ethnic groups (Kodama, 2013), epidemiological studies focusing on the Japanese should be used to compare data from other Asian and Caucasian groups. To promote studies in Japan, countermeasures for effectively collecting data on the transition from a healthy to a disease state should be conducted. Of the several possible countermeasures, the use of integrated data provided from the national health checkup program and medical organizations is important. Data from health checkups collected under the "Standard Health Checkup and Counseling Guidance Program" since FY 2008 are able to provide information directly related to type 2 diabetes (Ministry of Health, Labour and Welfare, 2014). Medical chart, receipt data and the Japanese diagnosis procedure combination (DPC) data, representing approximately 45% of all acute care inpatients in Japan (Yasunaga, 2017), are considered as valuable data provided by medical organizations. In the workshop, the attendees concluded that the data from health checkups, medical charts, receipt data, and DPC of each individual should be integrated for analysis of the natural course of disease onset and transition according to medical intervention.

## 3.2.4 Challenge 4: Development of a system of education and instruction to change dietary and fitness habits based on behavioral characteristics

Japan promotes health care through national programs and related ministry activities (Ministry of Health, Labour and Welfare, 2017a)(Ministry of Health, Labour and Welfare, 2017b)(Yamamoto, 2008); however, the messages from these approaches have not been effectively communicated to the public. It has been reported that there is a low rate of health checkup attendance in Japan, and subsequent medical examinations attended after such checkups are low (Ministry of Health, Labour and Welfare, 2009b). In addition, it is not uncommon for individuals to wait until the disease is advanced before attending a medical examination, and it is also noted that individuals withdraw from disease therapy (Ministry of Health, Labour and Welfare, 2009b). It is considered, therefore, that the development of systems to efficiently and effectively educate and lead people according to national programs and ministry activities is required and that such systems should target people of all ages and genders who have a wide-range of lifestyles, such as differing types of employment, differing personal interests and preferences. These programs should be developed in synchronization with the Japan Association for Diabetes Education and Care (JADEC)(International Diabetes Federation, 2017) and the Japan Diabetes Society.

#### 3.2.5 Challenge 5: Development of unified national quality indicators for type 2 diabetes clinical care

An evaluation of quality indicators used in clinical care of type 2 diabetes is essential not only for securing patients 'quality of life and ensuring quality of medical care but also for measuring and evaluating the performance of health professionals. However, the view of the attendees of the workshop is that outcomes for type 2 diabetes clinical care have not been adequately evaluated in Japan because of a lack of unified and well-established indicators. Since major programs for the development of quality indicators for disease care have been conducted in the OECD, the EU, and the US (Fleming, 2001) (Nicolucci, 2006) (Pajunen, 2010), the Japanese government should consider developing unified indicators and subsequent evaluation methods using these indicators.

#### 4.Conclusion

We have proposed 5 challenges based on technology mapping and discussion within the professional workshop, however, these challenges depend on the successful collaboration between related ministries, institutions, researchers in various fields and industrial circles, in common with the US and EU. Given that Japan does not have a detailed R&D plan focusing on type 2 diabetes at the national level, it is considered that the government needs to create this in agreement with the relevant stakeholders.

## 5. Competing interests

Yutaka Seino is the president of Japan Association for Diabetes Education and Care. Hiromi Takahashi-Omoe and Atsushi Ogasawara have nothing to declare.

### 6. Acknowledgements

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