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厚生労働科学研究費補助金（障害者対策総合研究事業）
研究分担報告書

統合失調症初回入院患者における
意思決定共有モデルの治療満足度への有効性
－無作為化比較試験－

研究分担者　奥村泰之　国立精神・神経医療研究センター 精神保健研究所
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研究要旨

研究目的：治療早期からの関係性がアドヒアランス維持の方略として注目されている。本研究では、統合失調症の初回入院患者における意思決定共有モデルの治療満足度への有効性を検討する。

研究方法：

無作為化比較試験、オープン試験、中央登録による割り付けの隠匿化。

セッティング：１施設の精神科病院の急性期病棟。

調査対象：入院時の診断が統合失調症、統合失調症での精神科入院が初回である患者。

介入法：通常診療に加えて入院中の１週間ごとに、①患者に治療に対する認識を聴取する質問票への回答を求め、②患者と医療スタッフの合同ミーティングを開催して、③患者と医療スタッフの情報共有のための治療計画書を作成することを繰り返す介入プログラム、あるいは通常診療のみ。

評価項目：退院時の治療満足度、退院時の薬物療法に対する態度、退院１年後の治療脱落率。

結論：意思決定共有モデルは、治療満足度の向上に寄与し、その結果として、治療アドヒアランスの向上や再入院率の低下に寄与することが期待できる。

研究協力者氏名・所属施設名及び職名

石井　美緒　横浜市立大学医学部大学院医学研究科
精神医学教室　博士課程

A. 研究目的

抗精神病薬の服薬アドヒアランスと臨床的予後との関連は多くの先行研究により明らかになっている[1]が、抗精神病薬のアドヒアランスは身体科薬など他の薬と比べて不良である[2]とも言われる。統合失調症の予後改善に向けて、服薬アドヒアランスの維持・向上に向けての模索が続いている。

近年、初回入院時の患者-治療者関係がその後の服薬アドヒアランスを予測する[3]、患者の治療満足度が高いと治療継続率が高い[4]など、統合失調症の治療において、治療早期からの取り組みとして、患者の視点を取り入れることへの関心が広まりつつある。さらに、治療上の意思決定

においても、患者の意向を重視する試みが始められつつある。意思決定共有モデル（Shared Decision Making）は、治療上の意思決定モデルの一つであり、Charles[5]によると、従来型のパターナリスティックモデルとインフォームドコンセントとの中間に位置し、患者と治療者が治療に関する情報・意向を共有するものである。

国際的には、意思決定共有モデルの適用は、統合失調症の治療ガイドラインに明記される[6][7][8]など、一定のコンセンサスが得られている。その一方で、意思決定共有モデルの有効性に関する先行研究は限られている[9]。2010年にコクラン共同計画に報告された、Duncanら[10]の系統的展望によると、精神科領域における意思決定共有モデルに関する無作為化比較試験はHamann[11]とLoh[12]の2つに限られていた。Hamann[11]は統合失調症入院患者を対象に、意思決定共有モデルに基づく心理教育プログラムを施行したところ、患者の治療参画への意向が増すという結果を得ている。また、Loh[12]はうつ病の入院治療において、医師・患者双方に対する意思決定共有モデルトレーニングを行うことにより患者の治療満足度が高まることを示している。

これまでの研究は、治療早期の患者層に着目していないため、過去の治療経験等の影響を除外できないことなどの限界が残されている。そこで、本研究では、統合失調症初回入院患者における、意思決定共有モデルの治療満足度への有効性を検討することを目的とする。

B. 研究方法

研究法は、無作為化比較試験とする。無作為化は中央登録、最小化法により実施する。症例登録期間は、2013年5月から2014年5月とする。本研究は、静岡県沼津市にある、沼津中央病院の精神科救急入院料病棟で実施する。倫理審査は、横浜市立大学にて承認を得る。また、臨床試験登録はClinicalTrials.govにて行う。

適格基準は、(1) 精神科救急病棟に入院、(2) 入院時診断が統合失調症圏（ICD-10のF20-F29）、(3) 精神科への入院歴は初回、(4) 中等度以上の精神遅滞、器質性・症状性精神障害の併存がない、(5) 16~65歳の患者とする。また、(6) PANSSの「概念の統合失調」の項目が4点以下、(7) 患者本人の書面同意を得られる者という2つの条件は、現在検討中の適格基準である。

症例登録から評価までの流れ図を図1に示す。入院後1週間以内に調査対象者の症例登録を行う。介入群では入院中、通常の診療に加え、週1回の介入プログラムを施行する。入院時にベースライン評価、退院時に介入後評価を行う。

介入プログラムは、意思決定共有モデルの基本的な部分である、治療者と患者の情報と意向の共有に焦点を当てたものであり、(1) 患者意見調査アンケート、(2) 患者・スタッフ合同ミーティング、(3) 治療計画書の作成、という3つの要素から構成される。介入プログラムは、毎週1回、入院中に4回以上実施する（図2）。

主要評価項目は、患者の治療満足度であり、退院前1週間以内に日本語版Client Satisfaction Questionnaireにより評価する。副次評価項目として、退院時の薬物療法への態度を日本語版Drug Attitude Inventory、退院時の症状回復の程度を日本語版Positive and Negative Syndrome Scale、退院時の機能回復の程度を日本語版Global Assessment of Functioning scale、1年後の治療脱落率を測定する。

例数設計は、治療満足度を従属変数、割り付け群を独立変数とし、期待される群間の標準化

平均値差 0.60、有意水準 5%、検定力 80%、両側検定、脱落率 10%の精度で独立な 2 群の t 検定を行うときに、100 例必要であると推定された。ここで、期待される群間の標準化平均値差は、先行研究[12]を参考に設定した。統計解析は、共変量を調整するため、線形混合モデルを用いる。

C. 考察

統合失調症治療において、意思決定共有モデルに基づく介入プログラムにより、患者の治療満足度、治療参加への意向が高まり、アドヒアランスの向上が期待されることが、本研究の臨床的意義である。特に、初回入院という治療早期の介入であるため、再入院率等の予後の改善につながる可能性も期待される。本研究の限界としては、以下の点が挙げられる。第 1 に、本研究の主要評価項目は、退院時の主観的評価項目であり、長期的な治療の効果を客観的評価項目により測定していない。第 2 に、他施設へ一般化可能性は検討できない。最後に、調査参加者と治療者とを二重盲検することはできない。

D. 健康危険情報

なし

E. 研究発表

なし

F. 知的財産権の出願・登録状況

なし

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図 1　研究の全体的な流れ

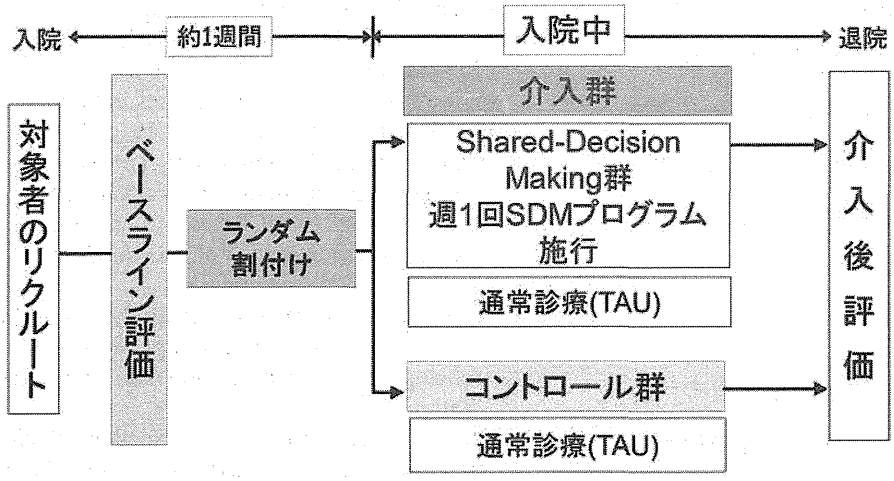
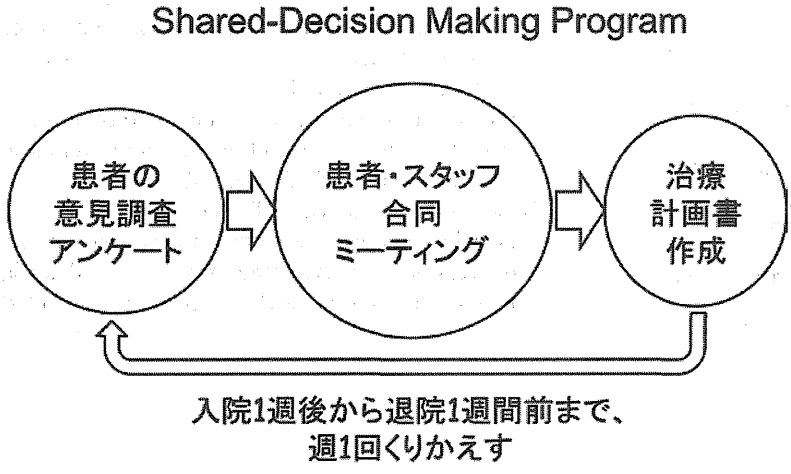


図 2 介入プログラムの流れ



Ⅲ．　研究成果の刊行に関する一覧

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書　籍

著者氏名	論文タイトル名	書籍全体の編集者名	書籍名	出版社名	出版地	出版年	ページ
Ito H	Mental health policy and services. Where we stand.	Sandra J. Lawman	Mental Health Care In Japan	Routledge	ｲｷﾞﾘｽ	2012	36-56

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厚生労働科学研究費　障害者対策総合研究事業（精神障害分野）
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平成24年度総括・分担研究報告書
研究代表者　伊藤　弘人

Ⅲ.　研究成果の刊行に関する一覧

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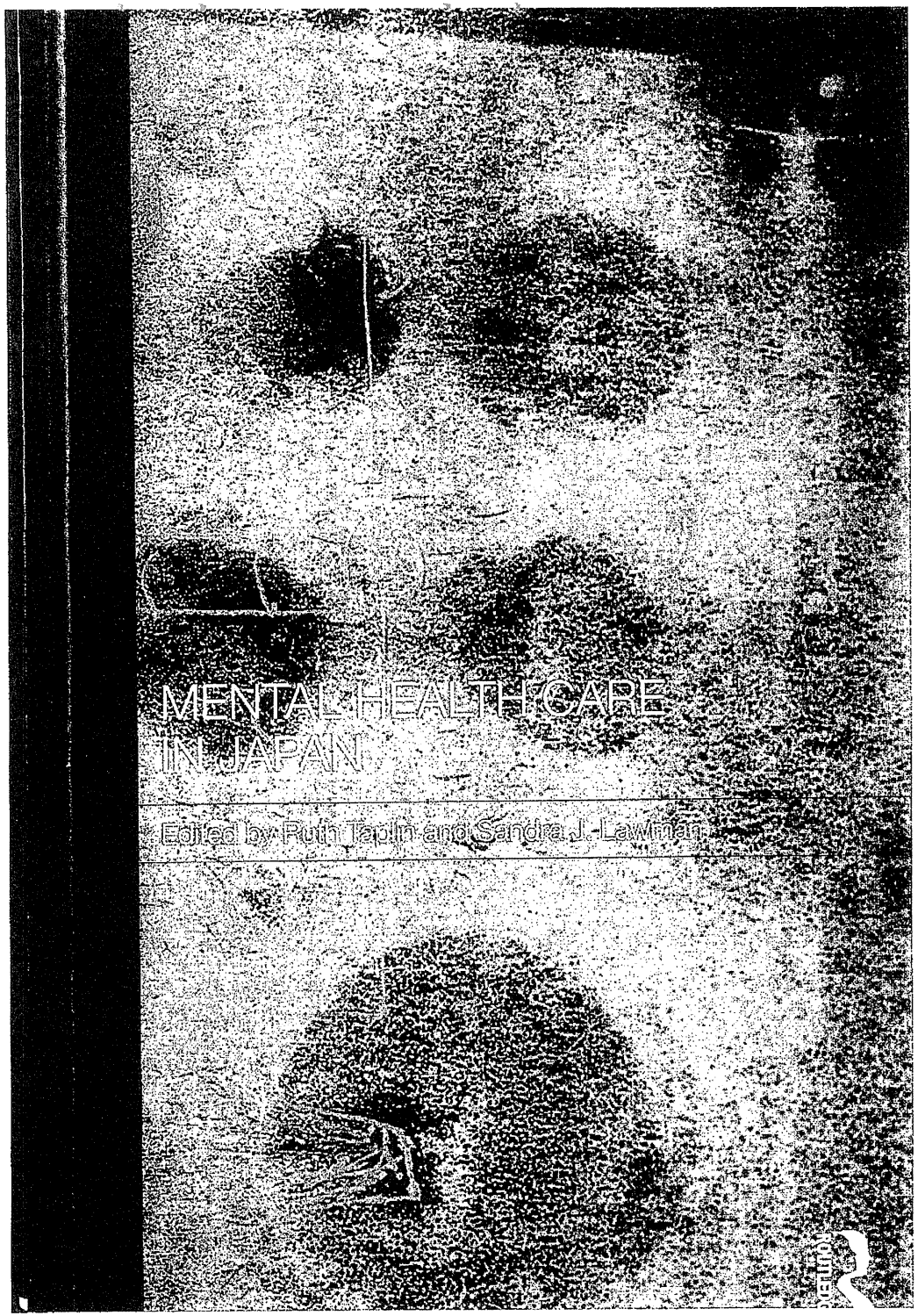

Mental Health Care in Japan

Mental health, including widespread depression, a high suicide rate and institutionalisation, is a major problem in Japan. At the same time, the mental health care system in Japan has historically been more restrictive than elsewhere in the world. This book looks at the challenges of mental health care in Japan, including problems such as the institutionalisation of long-term patients in mental hospitals. The book discusses the latest legislation to deal with mental health care, and explores the various ideas and practices concerning rehabilitation into the workforce, the community and service user groups that empower the mentally ill. It goes on to look at the social stigma attached to the mentally ill in Japan and Britain, which touches upon the issue of counselling those with post traumatic stress after the recent earthquake.

Ruth Taplin is Director of the Centre for Japanese and East Asian Studies, London, and is Editor of the *Interdisciplinary Journal of Economics and Business Law* (www.ijebl.co.uk).

Sandra J. Lawman is an Associate for the Shaftesbury Partnership.

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Edited by Ruth Taplin and Sandra J. Lawman

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Satoru Hashimoto is Associate Professor of Kansai University Faculty of Law. He specialises in the theory of the structure of the firm and non-profit organisations, and teaches 'theory of industrial systems', 'theory of the corporate system' and related subjects at his university. His recent interest is in change in corporate structure within the context of change occurring in the welfare state and he is currently engaged in theoretical and substantive research in this area. Recent research has also focused on third-sector organisations and social enterprise. Commissioned by the Ministry of Health, Labour and Welfare in Japan, he is now conducting research on disabled people within the Japanese

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Yayoi Imamura (MD) graduated from Sapporo Medical University in April 2002. She has since worked in a number of neuropsychiatry divisions in different hospitals in Japan, with the most recent being a post from April 2010 until present in the Division of Social Reintegration Support Services, Department of Psychiatry, Tokyo Metropolitan Matsuzawa Hospital, which is currently regarded as the best and most modern in Japan. She lectures at various venues including Sapporo Medical University, and is a regular speaker at study meetings and seminars related to alternative approaches towards mental illness. Some of her interviews are available over the Internet. She is currently writing a book on an advanced method that could be applied to people with mental illness. Her major publications include the following co-authored articles: 'Possibility of regional mental treatment – perspective from Tohoku and Hokkaido regions', *Psychiatria et neurologia Japonica* 108: 957 (2006); 'Attempted suicide at an emergency centre', *Psychiatria et neurologia Japonica* 105: 804 (2003).

Hiroto Ito was appointed by the government of Japan in December 2011 as one of the members to prepare to include mental illness as one of the five major diseases in Japan (along with acute myocardial infarction, cancer, diabetes and stroke). He is also starting a nationwide collaborative project on screening and treatment of co-morbidities of persons with mental disorders and physical illness. From 2006 to present he is also Director, Department of Social Psychiatry at the National Institute of Mental Health, National Center of Neurology and Psychiatry, Tokyo, Japan. His recent publications include: Ito, H., Setoya, Y. and Suzuki, Y. 'Lessons learned in developing community mental health care in East and South East Asia', *World Psychiatry* (in press); Miyamoto, Y., Tachimori, H. and Ito, H. 'Formal caregiver burden in dementia: impact of behavioral and psychological symptoms of dementia and activities of daily living', *Geriatric Nursing* (in press); Kobayashi, M., Ito, H., Okumura, Y., Mayahara, K., Matsumoto, Y. and Hirakawa, J. 'Hospital readmission in first-time admitted patients with schizophrenia: smoking patients had higher hospital readmission rate than non-smoking patients', *International Journal of Psychiatry in Medicine* 40: 247–57 (2010).

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Ruth Taplin is Director of the Centre for Japanese and East Asian Studies, which won Exporter of the Year in Partnership in Trading/Pathfinder for the UK in the year 2000. She received her doctorate from the London School of Economics and is the author/editor of 15 books and over 200 articles. She wrote freelance for *The Times* newspaper for nine years on Japan, Taiwan and Korea. Taplin studied Japanese at Durham University over 20 years ago as part of a special course for future leaders in the Japanese field in the UK. Her most recent books include: *Decision-making and Japan: A Study of Japanese Decision-making and its Relevance to Western Companies* (reprinted by Routledge in 2003, first published by The Japan Library in 1995); *Exploiting Patent Rights and a New Climate for Innovation in Japan* (Intellectual Property Institute, 2003); *Valuing Intellectual Property in Japan, Britain and the United States* (Routledge, 2004); *Risk Management and Innovation in Japan Britain and the United States* and (with Masako Wakui) *Japanese Telecommunications Market and Policy in Transition* (both published by Routledge, 2005); *Innovation and Business Partnering in Japan, Britain and the United States* (Routledge, 2006); *Outsourcing and Human Resource Management: An International Survey* (Routledge, 2008); *Intellectual Property and the New Global Japanese Economy* (Routledge, 2009); and (co-edited with Alojzy Z. Nowak) *Intellectual Property, Innovation and Management in Emerging Economies* (Routledge, 2010). Professor Taplin is a featured author of Routledge. She is editor of the *Interdisciplinary Journal of Economics and Business Law* (www.ijebl.co.uk).

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severe mental illness', *Contemporary Clinical Trials* 30(1): 40–6 (January 2009); Thornicroft, G., Brohan, E., Rose, D., Sartorius, N. and Leese, M. 'Global pattern of experienced and anticipated discrimination against people with schizophrenia: a cross-sectional survey', *Lancet* 20(373): 408–15 (January 2009); Tansella, M. and Thornicroft, G. 'Implementation science: understanding the translation of evidence into practice', *British Journal of Psychiatry* 195(4): 283–5 (October 2009).

2 Mental health policy and services

Where we stand

Hiroto Ito

Introduction

A fundamental challenge in mental health policy is to establish a system that provides better mental health care. To accomplish this goal, it is necessary to improve access to mental health care and to provide quality services, while at the same time controlling costs. It is difficult, however, to establish a system that maintains a balance between access, costs and quality care. In addition, there are increasing calls for community care, rather than inpatient care, for persons with mental illness.

To date, Japan has developed many initiatives to address these issues. In 1961, when Japan was entering an era of high economic growth, the government implemented a universal health insurance system that provides free access to health care by allowing people to use health insurance at any medical facility.[1] The number of psychiatric hospital beds was concurrently increased so that persons with mental illness, who had not otherwise had access to psychiatric care, could receive appropriate treatment.

As 50 years have now passed since the universal health care system was introduced, certain institutional problems have begun to emerge. Although the need for a transition from inpatient care to community care was identified in the 1960s, no notable changes have been made, at least as far as the number of psychiatric beds is concerned. Because of the high economic growth achieved early on ahead of other Asian countries, Japan has been faced with issues relating to the universal health care system and an excess of psychiatric beds since the 1980s.

Japan's health policy has not received much international attention. Consequently, the large number of existing psychiatric beds has continued to be raised as an issue, despite the fact that Japan's mental health policy and services have changed considerably.[2,3]

In this chapter, current developments in mental health policies in Japan are reviewed for a better future.

Mental health needs

Health care for people with mental disorders

Figure 2.1 shows changes in the number of patients' visits over time according to the Patient Survey, which is conducted every three years by the Japan Ministry of Health, Labour and Welfare. The numbers of patients with cancer, acute myocardial infarction, stroke and diabetes have not changed so much, but that of mental disorders has increased since 2002, primarily due to the increase of outpatients with depression. About one million people are medically treated.

Patients with schizophrenia were used to being hospitalised, and those who admitted in 1950–70 are now long-stay elderly patients. In recent years, however, the proportion of young long-stay patients has decreased, and newly admitted patients are discharged sooner. A new facility other than a hospital is required for this patient group in the community where physical care is also available.

In Japan, patients with dementia have been treated in psychiatry. Although patients suffering from dementia are common in general hospitals and geriatric facilities in reality, the dementia unit can be established in only psychiatry under the health care system. As the society is rapidly ageing in Japan, it affects more and more people, and a national strategy is urgently needed.

Mental health in the general population

Japan has had one of the world's highest suicide rates for years, and it remains above 30,000 for the thirteenth straight year. The suicide rate rose from 18.8 suicides

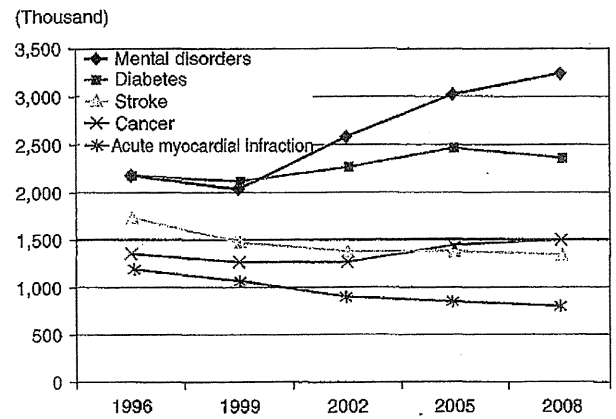

Figure 2.1 Number of patients.*

Note: * Patient Survey.

per 100,000 population in 1997 to 24.9 per 100,000 in 2010.[4] A prolonged recession seems to affect this trend. The National Police Agency suggested common reasons including health concerns, unemployment and financial difficulties. As suicide is a major issue in Japan, the Basic Act on Suicide Prevention was enacted in 2006. Multidimensional countermeasures are being implemented through both the high-risk group approach and population approach, but unfortunately the suicide rate does not appear to be declining as expected. The Japanese Medical Association developed and distributed the *Manual for Suicide Prevention for General Practitioners: Early Detection and Treatment of Depression* to educate physicians via training programmes. A nationwide suicide prevention study has accumulated data since 2005. The results will be reported soon. Further effective plans based on those results are needed.

On 11 March 2011, Japan experienced a devastating earthquake, the biggest one since 869, in east Japan. The subsequent tsunami with more than 30-metre waves killed nearly 16,000 people. More than 3,000 are still missing. Also, the Fukushima Nuclear Plants were seriously damaged by the tsunami. The three tragedies (earthquake, tsunami and radioactive contamination) simultaneously affected the mental health of the earthquake and tsunami survivors. Long-term care should be prepared for the affected people, especially children.

Mental health services

Acute psychiatric inpatient care

Case A: a 35-year-old man with schizophrenia. Onset occurred at the age of 20 when he was in his third year of university and he was involuntarily admitted to a psychiatric emergency unit. After 40 days, he was discharged to outpatient care and returned to university. The patient obtained a bachelor's degree, and worked part-time after repeating a year. He then started work at a small factory owned by his father. At age 28, the patient relapsed because he did not comply with his medication regimes, and he was voluntarily admitted to an acute psychiatric care unit for 20 days. Since then, the patient has been able to control his condition, and he visits the outpatient clinic twice a month and continues to hold down a job while taking medication.

The increase in the number of psychiatric beds, which started in the 1950s, came to an end in the late 1980s, when the beds were divided into acute psychiatric units and long-term care units. Then, in 1996, with a focus clearly on health insurance reimbursement, acute psychiatric care units were established under a provision that limited hospital stays to approximately three months, generating one and a half times higher reimbursement than that of general inpatient psychiatric units. Furthermore, in 2002, psychiatric emergency units were established in community hospitals with approximately three times higher reimbursement than that of general inpatient psychiatric units. In Japan, there are approximately 100 hospitals with a psychiatric emergency unit and approximately 200 hospitals with an acute

psychiatric unit. These two types of units are operated under a provision that limits the length of hospital stays and that more than 40 per cent of the patients be discharged into the community within a specified period.

Community care provided by psychiatric hospitals

Case B: a 58-year-old man with schizophrenia; he developed the condition when he was 18 years old. Highly resistant to being seen by a psychiatrist, he remained untreated. At age 25, he was, at the behest of his family, admitted to a psychiatric hospital built nearby. At the time, patients were often long-term inpatients. He was hospitalised for 15 years. When the hospital director was succeeded by his son, the treatment policies were changed, and the new hospital director recommended that he should be discharged. Several facts became apparent regarding this long-term inpatient. He had no friends and his parents were elderly so he could not live with them. He had resided at the hospital for many years and was anxious about leaving, so he was discharged to a group home near the hospital. Upon discharge, he initially had periodic outpatient visits and used day care services, but he gradually became accustomed to communal life with patients who had been similarly discharged. Until recently, he helped out at a bread factory started by the hospital while receiving job assistance. He is currently working with a meal service run by the hospital to provide meals to elderly nearby. He delivers meals to the homes of the elderly by bicycle. Elderly clients appreciate the service and he finds the work worthwhile.

More than 80 per cent of Japan's psychiatric hospitals are privately run. Taking advantage of financial support for construction of psychiatric hospitals in the 1950s and 1960s, outpatient clinics built up psychiatric beds and subsequently became psychiatric hospitals. In the 1990s, these facilities were no longer able to increase the number of beds. In addition, revenue per day for treatment in a long-term care unit was equivalent to revenue per day for community care combining outpatient care and day care. To increase the number of admissions of new inpatients and utilise beds for acute inpatient care (which offered substantial medical fee reimbursements), hospitals began gradually discharging long-term inpatients. Discharged patients transfer to group homes built by psychiatric hospitals. However, patients who cannot be provided with a discharge destination, e.g. a group home, remain as long-term inpatients. Many of these individuals have already reached age 65, they have diminished activities of daily living (ADL), and they also have physical conditions as well. As things stand, these individuals still cannot be discharged.

Community care team

Case C: a 40-year-old male with schizophrenia has received nurse's home visits from a visiting nurse station for the past five years. The nurse visits him about twice a week. In addition to making sure that he takes his medication, the nurse advises