5th Asia Cancer Forum

What Should We do to Raise Awareness on the Issue of Cancer in the Global Health Agenda?

Organized in Collaboration with 20th APCC Medical Platform Asia NPO Health Medicalcare Promotion Date: November 12 (Thu.), 2009,12:00-15:00 Location: Tsukuba International Congress Center

Contextual Intelligence Collective Intelligence Continuous Intelligence

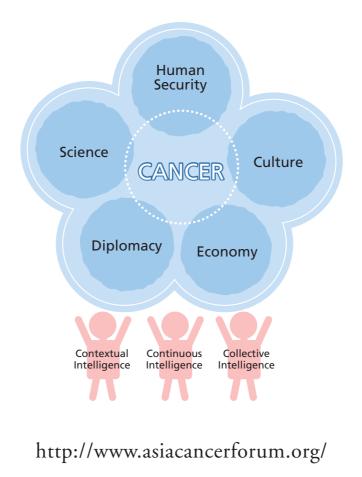


What Should We do to Raise Awareness on the Issue of Cancer in the Global Health Agenda?

The Asia Cancer Forum has been engaging with the global health community to share information about the current challenges for cancer in developing countries and to discuss future trends. Discussions also focus on how we can enhance communication and cooperate in improving the global health status.

It is our intention to position our agenda as an item to be included within the next Millennium Development Goals (MDGs) of the United Nations.

The starting point of the debates within the Asia Cancer Forum is the concept of human security. Based on the concept of human security, we are discussing the following questions: What should we do to achieve this goal? And, further, what items should be added to the revised MDGs?



Preface

Asia Cancer Forum Norie Kawahara

Progress in science bestows upon people the promise of limitless possibilities and the means to live longer. Humankind has devoted much time and effort in the fight against disease.

Of all diseases cancer causes the longest suffering and impediment to people's lives, and the final brave fight against the disease, or the shock of being confronted with it creates a negative image among patients and their families.

Cancer is not merely a biological phenomenon, it also has anthropological aspects.

It is strongly colored by the cultural impact of various interlinked lives. The cultural diversity in Asia may be an obstacle to overcoming cancer, but this cultural diversity is also a tremendously powerful force for seeking to live longer. It is our responsibility to carefully bring together the various societies in Asia and seek to address the various different views and perceptions regarding cancer in the region.

Cancer is a disease that is still thought of as a scourge of industrialized nations, but its incidence is in fact increasing most rapidly in the developing world, including India and China, which makes it all the more urgent for Asia to decide how to face and overcome cancer.

In the near future the international community is likely to face an unjust situation in which some people with the same disease will be cured while others will suffer and die. It is this grave reality that we must address.

As we address this issue we must recognize that this is more than a humanitarian movement. The issue is inextricably linked with the evolution of life science itself. Science is utilizing humankind as a research resource and must bear the responsibility for such treachery. Life science must transcend national boundaries and become part of the "intelligence" bestowed equally upon all human beings.

Asia Cancer Forum in preparation for the APCC, has been convened 4 times since June 2008. Through our deliberations on the agenda item "What can we do to raise awareness about the issue of cancer in the global health agenda?" we arrived at the "Concept Notes" for this meeting, with the help of comments from Dr. Akaza of Japan, Dr. X. S. Hao of China, Dr. Harold Varmus of the United States and Dr. Alwan of WHO. The Asia Cancer Information Network, part of the Asia High-Tech Network initiated in 2004, is the precursor of the Asia Cancer Forum. The starting point was a proposal I made in an article for "Nature" in 2002*.

Progress in large-scale human genome research has dramatically increased the amount and content of personal data used in many areas of biomedical research. Life science exists within a collaborative environment involving medicine, research and industry. Personal data, data derived from human sources, are collected with the guiding principle of sharing the "collective assets of humankind", and the realization that these resources are the joint property of the world community constitutes the very essence of science.

*Tsuboi, E., Kawahara, N., Mitsuishi, T., Oshima, A., Yonemoto, S. NATURE 417, 2002; 689

Mission

The Universal Declaration of Human Rights states that everyone has the right to share in scientific advancement and its benefits equally. Based on that spirit enshrined in the Declaration, with the aim of overcoming the common challenge of cancer that is faced by humanity as a whole, and linking it to human life in the Asian region, we have attempted to bring together several types of "intelligence", which we have subsumed as the "3Cs."

- Collective Intelligence
- Contextual Intelligence
- Continuous Intelligence

The relationship between these three forms of modern intelligence and the activities of this forum are described below.

Contextual intelligence is an intuitive skill that helps a leader align tactics with objectives to create smart strategies in new situations. Contextual intelligence consists partly of analytic capabilities and partly of tacit knowledge built up from experience, which tends to be expressed in rules of thumb.

This is a concept expounded by Joseph Nye in his book *The Powers to Lead*, and this kind of intelligence requires a top-down approach. In terms of policy challenges it leads to questions about what kind of agenda-setting should be employed.

Collective intelligence is a shared or group intelligence that emerges from the collaboration and competition of many individuals.

George Pór, defined the collective intelligence phenomenon as "the capacity of human communities to evolve towards higher order complexity and harmony, through such innovation mechanisms as differentiation and integration, competition and collaboration."

This is a type of intelligence that supports a bottom-up approach. In the context of the Asia Cancer Forum our attempt to create a common base for information collection by providing information on such topics as cancer prevention educational activities for children and women's self-respect issues and cancer, is a part of such a bottom-up approach.

Continuous Intelligence is a new approach that derives immediate insights from fast changing, "live" data, and determines the immediate actions front-line personnel can take to proactively solve problems, or reduce risk. This is an expression taken from IT terminology and it denotes a type of intelligence that seeks to create driving force to link the two prior noted intelligences (contextual and collective) towards the future, without losing or disconnecting the main aspects of these two kinds of intelligence. The Asia Cancer Forum has used these scientific metaphors to create a concept note on this issue, as seen below.

- Concept Note -

What should we do to raise awareness on the issue of cancer in the global health agenda?

Key words: Health equity/MDGs/Human security/Collective intelligence

Cancer is Pandemic!

Japan, 2009

1. Background and overview

Although infectious diseases remain a significant issue, changes in population demographics brought about by successes in tackling infectious diseases are creating other issues. Developing countries, including China and India, account for more than half of the global population, and as longevity increases in the developing world, so too do incidences and deaths from cancer, causing a new and serious situation.

Cancer, however, has not acquired an appropriate position in global health agendas.

International health, which differentiates domestic and international issues, has become a global agenda, placing domestic health issues in the global context. The era of global health has brought further complexity to disease treatments, incorporating new elements into the field of health, including socio-economic concerns and political conflicts among others. This complexity means that the "fight against cancer" may not yet be a suitable issue for worldwide collaboration.

Cancer is not yet on the agenda in global health. There is still no suitable mechanism for collecting information and analyzing it in order to gain a global picture about cancer.

Many questions exist that require our attention. How have we finalized global heath agendas in the past? What have been the supporting mechanisms and philosophies that form the basis for decision-making processes? What will be the future agenda? How can cancer be developed as a global agenda item and what can we do to ensure this happens?

The Asia Cancer Forum has been engaging with the global health community to share information about the current challenges for cancer in developing countries and discuss future trends. Discussions also focus on how we can improve communication and cooperate in improving the global health status.

We are resolved to propose our agenda as an item in the next Millennium Development Goals (MDGs) of the United Nations. What should we do to achieve this goal? What should be the agendas to be added to the revised MDGs? These questions need to be discussed in the forum.

2. Objectives

Cancer has become a challenge not only for industrialized countries but also for developing countries. However, the perception of cancer as an "individual's" disease has inhibited discussion on cancer due to perceived issues relating to fairness and justice.

"Our goal changes from treatment at whatever cost to care and respect for the integrity and dignity of the person." To achieve this goal we seek to combine basic ideas and political agendas as a means of strengthening the next step towards the construction of a proposal.

3. Expected outcomes

- Currently what position do cancer issues hold in the global health community? From the outset we believe that experts should share a basic understanding about this issue, focus on top down mechanisms, and aim the outcome of our discussions towards achievement of the stated objectives.
- 2) How can we cooperate to prevent developing countries following the trend of increasing cancer incidence that has been the case in industrialized countries? We should ensure that economic development is not sacrificed and that the knowledge and experiences of industrialized countries are transferred and shared effectively. To achieve this goal, we should construct mechanisms to collect medical information over a long period and a wide range of issues. Databases should be shared to strengthen the health care system for the next generation. Another question is how can we tie a bottom up approach, including transforming the awareness of citizens on cancer incidence and cancer information sharing, into a top down policy at the state and global level?
- 3) We will seek the opinions of various experts and widen the scope of our discussion to incorporate the following:

Information Technology Pharmaceutical Industries International Organizations 4) The outputs of this meeting are also intended for presentation:

ECOSOC WHO WORLD BANK UICC World Medical Association The Seattle Science Foundation

4. Organization of the agenda

The forum will start with a video presentation by Dr. Alwan of the WHO and the program consists of three sections covering a total of three hours. In each section there will be two invited presenters, followed by question and answer sessions.

Various issues will be address, including those mentioned above: top down and bottom up issues, specific action plan, and what should be incorporated in future agendas.

AGENDA

What should we do to raise awareness on the issue of cancer in the global health agenda?

3C Intelligence

Contextual Intelligence Collective Intelligence Continuous Intelligence

12:00 Opening remarks

Tetuichiro Muto	President, NPO Health and Medical care Promotion
Hideyuki Akaza	President, APCC
Norie Kawahara	Organizer, Asia Cancer Forum

12:10 Global Challenges in Cancer Control. Video Letter Ala Alwan

WHO Assistant Director-General - Noncommunicable Diseases and Mental Health"

Session 1: What will shape the global health agenda?

Contextual Intelligence From the view point of top down

12:25 The Challenges in The Global Health.

Keizo Takemi, Senior Fellow Japan Center for International Exchange Professor, Tokai University Special Advisor, Sasakawa Health Memorial Foundation

12:40 Cancer as a Global Health Agenda.

Hajime Inoue, Executive Advisor, Department of Health and Welfare, Chiba Prefecture,

12:50 How could the issue of cancer be justified as a global health agenda?

Hiroyoshi Endo, Professor Department of International Affairs and Tropical Medicine, Tokyo Women's Medical University

Discussion

13:15 Research platform to formulate cancer prevention strategies in Asian-region. Manami Inoue, Section Head

Epidemiology and Prevention Division, Research Center for Cancer Prevention and Screening, National Cancer Center

Session 2: Where are we really?

What activity can we do against Health Equity? -Collective Intelligence – From the view point of bottom up

13:30 On dispatch as expert adviser in Thailand

Eitaka Thuboi, Former President of World Medical Association

Asian Network of Childhood Cancers Tumor Banks: Aiming for Better Cure of the Sick Children Akira Nakagawara, Director Chiba Cancer Center,

Role of Traditional Medicine for Cancer Patients.

Kenji Watanabe, Associate Professor, Center for Kampo Medicine, Keio University School of Medicine

Discussion

Session 3: What should be incorporated in future agendas? -Continuous Intelligence-

14:05 Health information in my hand.

Mamoru Iwabuchi, Associate Professor, RCAST, the University of Tokyo

14:10 Cancer: from Personal to Societal.

Tohru Masui, Chief, Division of Bioresources Research, National Institute of Biomedical Innovation

Special Comments

David HillAustralia President, UICC/Cancer Council VictoriaTomoyuki KitagawaChiarn, UICC JapanJae Kyung RohYonsei University,Korea

The Challenges of Cancer Prevention in China.

Xi Shan Hao President, Chinese Anti-Cancer Association

Expanding Need of Cancer Medicine in Asia.

Hideyuki Akaza President, APCC

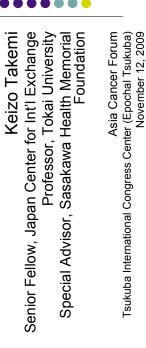
14:55 Closing Remark

Masanori Nishiyama Norie Kawahara

President, Medical Platform Asia Organizer, Asia Cancer Forum



Challenges in Global Health





Contents

An Health as foreign policy agenda

Japan's health diplomacy: Toyako G8 process as an example

Example : Challenges for Japan



Health as foreign policy agenda





Expansion of **domain** of health issues: Globalization has expanded domain of health issues to include social determinants such as social, cultural, environmental, political, and economic factors within which health and disease occur →multi-sectoral responses are required

Expansion of **scope** of impacts of health issues: Globalization has increased the speed and threats of transmission of pandemics → global responses are required (shift of the concept of 'international health' to 'global health')

Health has become global agenda: 'global health'

Global Health as Foreign Policy

Global health has become a diplomatic issue

- Realist approach: emerging pandemics and conflicts between property rights and public health
- Theoretical approach: emerging new theories such as social determinants of health, cross-sectoral approach
 - Legalistic approach: health as a human right
- Moral approach: human dignity and human security
- Japan's approach to health diplomacy: human security
- Role of human security in decision making for diplomacy
 - Okinawa Infectious Disease Initiative (2000)
- Toyako Framework for Action on Global Health (2008)

Other initiatives:

- UK (IHP+), USA (PEPFAR), Canada (The Catalytic Initiative to Save a Million Lives) •
- Foreign Policy and Global Heatth Initiative: Brazil, France, Indonesia, Norway, Senegal, South Africa, and Thailand
- High-Level Taskforce on Innovative International Financing for Health Systems Strengthening: UK

the Toyako G8 Summit and beyond Innovative decision making at

- Multi-sectoral approach is inevitable: "Participatory Diplomacy" •
 - WG on "Challenges in global health and Japan's contributions" at the track 2 level
- Collaboration among relevant ministries (foreign affairs, health, finance, and education)
- Public-private partnership
- International Advisory Board and Task Force on Global Action for Health System
- New dimensions of foreign policy
- Bilateral diplomacy
- Multilateral diplomacy
- Civil society networking

Foyako G8 process as an example 2. Japan's health diplomacy

"Challenges in Global Health & Japan's Contributions" Working group on

NG Chair: Prof. Keizo TAKEM

WG members

NGO representatives

- Japan Center for International Exchange (JCIE) → Director and WG secretariat
- Japanese Organization for International Cooperation in Family Planning (JOICFP)
 - Health Policy Institute, Japan
 - The Nippon Foundation

Experts

- Universities: Tokyo Univ., Osaka Univ., Waseda Univ., Jichi Medical Univ. International Medical Center of Japan

 - National Institute of Public Health

Governmental agency

Japan International Cooperation Agency (JICA)

Ministries

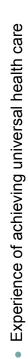
- Ministry of Foreign Affairs
- Ministry of Health, Labour and Welfare
 - Ministry of Finance
- Ministry of Education, Culture, Sports, Science, and Technology
- * UN agencies are invited as observers





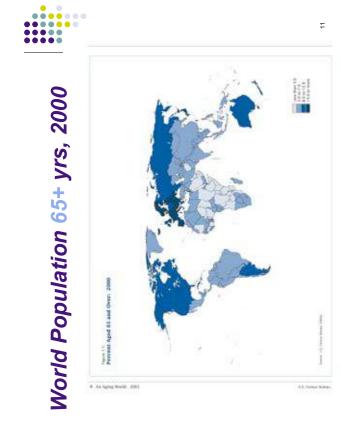
3. Challenges for Japan

Japan's Advantages

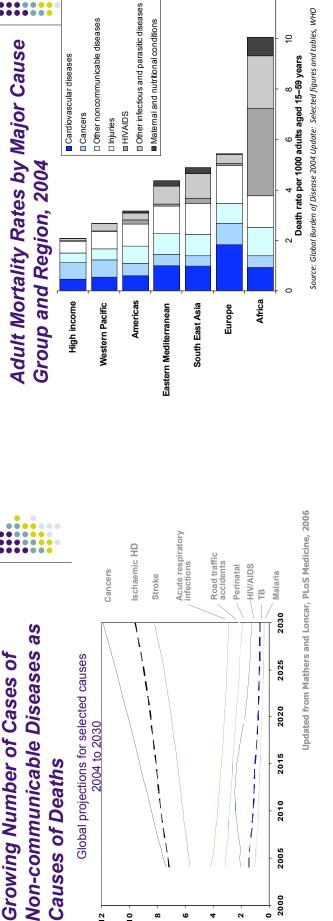


- Achieving longevity: average life expectancies → men (79.29 years), women (86.05 years)
 - Advanced aging society
- Expertise on chronic diseases

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(aths (millions)



2000

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- Maintain momentum for putting global health at the forefront of foreign policy agendas •
- Keep and enhance participatory approach to health at the domestic and global levels •
- Collaboration among relevant ministries (foreign affairs, health, finance, and education)
- Public-private partnership
- Partnership with health-related international organizations and key local organizations around the world
- contributing to global health encourage cooperation in tackling global and regional health challenges Identify Japan's comparative advantages in

Health and Human Security (within the Launching of Program on Global Japan Center for International Exchange)



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- Promote evidence-based global health policy-The Lancet Japan Series
- interdisciplinary centers of health innovation in Sub-Enhance bilateral and multilateral cooperation for global health-e.g. establishing a consortium of Saharan Africa
- approaches to global health-workshop series Promote implementation of human security



I look forward to discussing these ideas with you. 17

Cancer as a Global Health Agenda

Hajime Inoue Executive Advisor, Department of Health and Welfare, Chiba Prefecture

In view of rapid population aging, cancer incidence has increased rapidly among developed countries in the past several decades. During this period, increased cancer mortality and morbidity have received public attention, which has facilitated research into cancer prevention and treatment, and has strengthened social support in these industrialized societies.

Alternatively, despite the fact that more than 70% of cancer mortality currently occurs among middle and low-income countries, neither the appropriate attention nor the adequate allocation of resources has been made in these countries. While demographic and epidemiological transition rapidly transforms the major disease burden from infectious diseases to non-communicable disorders, global health communities have failed to adjust their focus, which was set by Millennium Development Goals (MDG) in 2000.

Adequate attention and resource reallocation relative to the emerging health challenges within developing countries - cancer and other non-communicable disorders - requires the recognition of cancer as a global health agenda. As we approach the MDG goal year of 2015, discussion will transpire regarding the establishment of a renewed global health agenda in the next five years. To prepare for this discussion as a cancer society, there is a need to gather and analyze epidemiological evidence so that cancer in developing countries receives due attention among wider health community in its future global health agenda setting.

How could the issue of cancer be justified as a global health agenda?

Hiroyoshi Endo Professor, Department of International Affairs and Tropical Medicine, Tokyo Women's Medical University

Chronic diseases that are the major cause of mortality in the world have been increasing in recent years, and according to World Health Organization (WHO) statistics for 2007, cancer now accounts for 13% of the total deaths caused by such diseases. In addition, chronic diseases, including cancer, are increasing in the developing world, creating what has been termed a "double burden." There is no refuting the fact, therefore, that whether it be the industrialized or developing worlds, chronic diseases and cancer are becoming a grave issue for human health in the 21st century.

However, faced with only epidemiological facts and figures detailing high mortality and high morbidity, the question arises as to whether cancer will be included as part of global-scale measures, including in the developing world, that must be implemented as part of a global health agenda. It is not just the scale of the issue as part of the global health agenda, but also a question of availability, including means of resolution, the human, physical and financial resources to implement these means, as well as methods of evaluation and commitment by those involved. What is required now is serious consideration of what justification exists for raising the issue of cancer alongside and in comparison with mother and child health and infectious diseases, which have formed the global health agenda to date.

Based on our long experience in dealing with measures against infectious diseases, we now seek to elucidate the differences in measures to tackle cancer and those to deal with infectious diseases, and consider what justification is required for the inclusion of measures to tackle cancer in the Millennium Development Goals (MDGs), in a similar manner to infectious diseases.

While it is true that there are differences between individual infectious diseases and various types of cancer, in general a number of commonalities also exist: (1) They strike indiscriminately (although the genetic influence on cancer incidence is larger), (2) there are means of diagnosis and treatment available (although cancer requires specialist technology, which comes at a high price), (3) they have a significant social and economic impact in addition to medical concerns (although the personal impact of cancer is larger), and (4) they are preventable through individual actions (although the degree to which cancer can be prevented is limited and behavior modification is not easy).

On the other hand the differences between infectious diseases and cancer can be listed thus: (1) time frame for treatment (infectious diseases can be dealt with in the short term, whereas cancer treatment is long term, counted usually in units of years), (2) target for

treatment (collective treatment for infectious diseases and individual treatment for cancer), (3) resources for diagnosis and treatment (overwhelming lack of resources for cancer treatment in the developing world), and (4) potential for full recovery (cancer has a high rate of reoccurrence, etc.).

Although it is not necessary to resolve all these issues, is it not now necessary to create even to a certain extent a forward-looking vision that would serve as a justification for the inclusion of cancer in the global health agenda?

Research platform to formulate cancer prevention strategies in Asian-region

Manami Inoue

Epidemiology and Prevention Division, Research Center for Cancer Prevention and Screening, National Cancer Center 5-1-1 Tsukiji Chuo-ku Tokyo 104-0045 Japan

To obtain concrete estimation of the impact of cancer as a nation, it is inevitable to conduct monitoring of disease statistics and systematic review of the epidemiologic studies and meta-analysis and estimation of population attributable fraction of major risk factors in the target population. In Asia, however, this kind of work has been limited. Insufficient evidence has prevented the most Asian populations from conducting such evaluation on a national basis. Likewise, Asian populations share similar ethnic and environmental background, and evaluation by pooled or meta-analysis among Asian populations also contributes to the estimation of impact of major risk factors and cancers in Asian region.

In Asian region, disease monitoring systems such as population-based cancer registries have been improved and increased number of epidemiological evidence from individual studies has become available in the past decade. However, current research funding usually available for cancer research in Asia is oriented to topic-specific research (i.e. association between smoking and lung cancer, etc.) and is usually domestic, not for creation and maintenance of cross-country network platform, namely, a cornerstone for formulating cancer prevention strategies in Asia. This type of platform is inevitable for cross-country communication and collaborative research, and eventually the estimation of the impact of major risk factors and cancers in Asia, and international organization and international fund are expected to play a role.

Asian Network of Childhood Cancers Tumor Banks: Aiming for Better Cure of the Sick Children

Akira Nakagawara, MD, PhD Chiba Cancer Center, Chiba 260-8717, Japan

During the last 40 years, the cure rate of childhood cancers has dramatically increased from 20% to more than 70% in the developed countries. However, it seems to be still very poor in many developing countries including those in Asia and Africa. In children, the mortality of cancer is the second following that of the accidents in developed countries, while we do not know what the status is in developing countries. Though the incidence of childhood cancers is less than 1% that of adult cancers, we estimate that more than 200,000 children a year newly suffer from cancer in Asian countries. Thus, the childhood cancer is not rare but one of the most important diseases to be cured. Therefore, it is urgent to establish the international network of childhood cancers to save the patients from cancer especially in developing countries including Asia.

In 2008, at the meeting of the Advances in Neruoblatoma Research (ANR2008) held in Chiba, Japan, the Steering Committee and the Advisory Board members of the ANR Association decided to take an action to start to establish the international tumor bank of neuroblastoma, one of the most common but still very poor prognostic pediatric solid tumors. The goal of this project is to make the tumor banks of pediatric solid tumors in the main cities in each Asian country to provide the internationally standardized pathological and molecular diagnoses to the doctors and hospitals treating the patients in local area. So far, we are successful to make the Asian network linking the key stations in Taiwan, China (5 cities), Korea, India (3 cities), Bangladesh, Thailand, Vietnam and Japan. This project will be expanded to other Asian countries as well as Africa in the near future and further connected to the similar systems in United States and Europe.

We are currently trying to link this project with the International Society of Pediatric Oncology (SIOP) and hopefully the UICC to collaborate together to fight against childhood cancers in the whole world.

Role of traditional medicine for cancer patients

Kenji Watanabe, MD, PhD, FACP Center for Kampo Medicine, Keio University School of Medicine

For a long period of human history, traditional medicine has taken care of all kinds of diseases of mankind, including cancer, even though, the main target of traditional medical treatment has been infectious diseases.

The main reason why cancer is featured in modern days, is the prolongation of the longevity. This is true not only in developed countries but also developing countries.

In Asian countries, cancer is a big problem. For the wealthy people, all kinds of the treatment are available. On the other hand, for almost all the people, access to the modern treatment is limited.

Traditional medicine in East Asia, originated from ancient China includes traditional Chinese medicine in China, traditional Korean medicine in Korea and Kampo medicine in Japan.

In Japan, more than 70% of physicians use Kampo medicine in daily clinic with high-tech medicine. Most of the diseases are good indications of Kampo medicine including cancer.

Of course, herbal drugs or acupuncture is not comparable to chemotherapy or irradiation to diminish cancer. However, these chemotherapy or irradiation is sometimes too strong for elder people and more natural course is comfortable. For those patients, traditional medicine is useful to relieve pain or agony.

In 1997, NIH approved that acupuncture is useful to control a pain of cancer patients. This effect appears via endorphin in the brain. Also acupuncture stimulates the immune system. Herbal medicine is also used for the variety purposes of cancer treatment, i.e., prevention of the cancer recurrence or metastasis, or pain control in the palliative care.

In conclusion, for the people modern therapy can be chosen, that is the best and traditional medicine may be supplemental therapy. Also traditional medicine is useful as a primary care for the people to whom modern medicine is not available.

Health information in my hand

Mamoru Iwabuchi, Associate Professor, RCAST, the University of Tokyo

Today's information technology (IT), particularly mainstreaming technology, such as mobile phones and the Internet, can be used as a basic infrastructure to disseminate information. This could be true even in developing coutries or their rural areas, where a mobile phone can be shared among people. The objectives of our project is to provide important and useful information about the prevention of canser. The prototype using mobile phones will be discussed in the presentation.

Cancer: from Personal to Societal

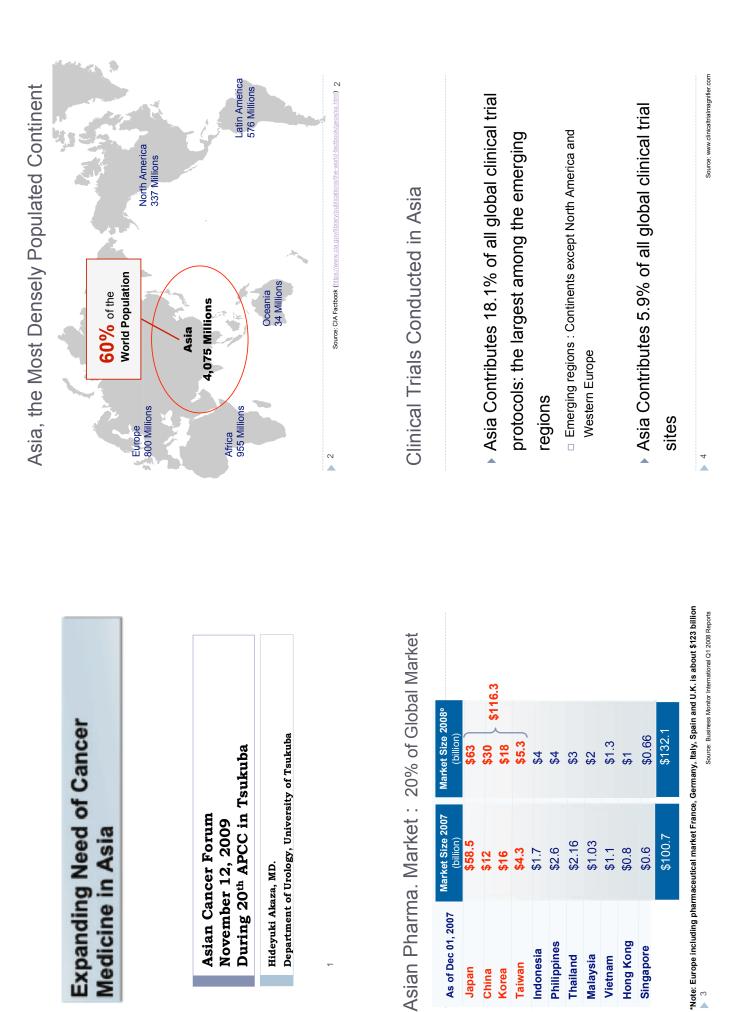
Tohru Masui National Institute of Biomedical Innovation 7-6-8 Saito-Asagai, Ibaraki-shi, Osaka 567-0085, Japan

Though communicable diseases are still the major concern in global health, longevity of life and significant but not full wellbeing of population in the world have framed cancer up a global health agenda. Society should be responsible for the life of a person and population, though it never happened consistently or satisfactory. Now cost of treatments and care of cancer patients limits our imagination and dream on quality of life of the global population. The cost could widen feeling of inequality and strengthen envy on economic status. This could deeply spoil self respect and integrity of people and countries.

In this context we are asked to change our policy on our health. We, now, should seek consistent and coherent policy on our life. This issue is closely relating to rapid aging of population in the world, developed and developing countries.

"Our goal changes from treatment at whatever cost to care and respect for the integrity and dignity of the person."

This is an essential remark on our concerns. We may have to change key words from unlimited to limited. One question is how we could allocate our limited resources on our life in the world. This is a global issue and is different from the sense of importance of communicable diseases as a global health agenda. What we are facing in this global health agenda becomes a focus of our health policy. In this Asia Cancer Forum I would like to incubate our shared question.



Growing Opportunity for Clinical Trials

In Asia;

- A large patient population
- A significant emerging bio-pharmaceutical market
- potential
- Good quality of data
- Cost effective environment

with qualified medical infra-structure

Geographic Shift of Studies to Asia

2

Source: 파렉셸 분석자료

Critical Points: Regulatory Differences

- Implementation Status of ICH-GCP
 - Sample Testing/Submission
- Trial Specimen Export
- Taiwan: not for human embryonic germ cell, including cell line
- Thailand: Material Transfer Agreement signed between site and lab
- Lab Kits/Devices Importation Permit required for Taiwan, Korea, Thailand
- ICF/Commitment letter/Contract: Specific templates
- Taiwan: most sites' indemnity statement difficult to be revised
- Hong Kong: specific indemnity agreements, some sites have specific contract

templates

Korea: agreement of subject compensation should be provided

Critical Points: Language Differences

English
Vernacular

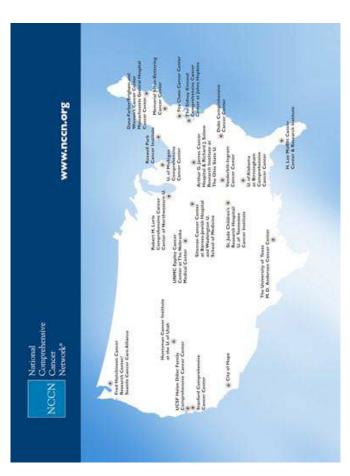
A great deal of

- translations required for
- Korea : Summary of IB, protocol, CMC, ICF, Label
 - Thailand : Part of protocol, Synopsis, ICF
- Taiwan : Synopsis, ICF
- Other Asian countries : ICF, Label (if given to patients)

Required Documents	Taiwan	Korea	China	Taiwan Korea China Singapore Malaysia Thailand	Malaysia	Thailand
Protocol Synopsis	•	•	•	•	•	•
Protocol	•	:	•	•	•	:
Investigator Brochure	•	:	•	•	•	•
Case Report Form	•	•	•	•	•	•
Informed Consent Form	•	•	•	:	:	:
Investigators' CV	•	•	•	•	•	•
COA (Certificate of Analysis)	•	•	•	•	•	•
Information of placebo/comparator	•	•	•	•	•	•
GMP certificate			•	•	•	•
Local applicant's license	•				•	
Label for investigational drugs	•	•	•	•	•	•
Indemnity letters	•	•			•	
Published full article				•	•	
Certificate of insurance	•	•	•	•	•	•

6

Source: 파렉셀 분석자료





Objective and Procedure of Asian Statement on NCCN guideline

- Objective:
- Raise the problems
- Find the way to solve

Procedure:

- 1. Specify and collect the problems
- 2. Select and provide relevant solution
- Sort out the evidences and recommendation by assigned panel members

1st NCCN Asia Scientific Symposium

Report

Since 2006, NCCN has been in close collaboration with Chinese oncology experts headed by Dr. Yan Sun in developing the China edition of the NCCN Guidelines. This project achieved huge success in China, and is under rapid expansion. In making full use of the present opportunity for summit discussion, this symposium especially incorporated panel meetings of NCCN experts and Chinese experts to update the China versions of available NCCN Guidelines as well as develop new NCCN Guidelines. Experts from China paid high attention to the development of NCCN Guidelines that are especially tailored to China's situation. Their intense research on relevant clinical evidence before the meeting and lucid presentation of their viewpoint and findings during the discussion gained wide recognition from NCCN Panel Members. The resulting updated China editions of NCCN Clinical Practice Guidelines in OncologyTM, created through the joint efforts of Chinese experts and NCCN experts, shall be instrumental in pushing forward the standardization of clinical oncology practice in China.

www.nccn.org/international/pdf/Synopsis_1st_NCCN_Asia_Symposium_Repo____ nt_KS%20_2.pdf

Summary

- Cancer health science is rapidly expanding all over the world.
- In Asia-Pacific, it is time to set our endeavor in cancer health science.
- What should we and can we do for from Japan?
 - What is the role of academic site?
- What is the role of industry (pharmacy)?
- What is the role of journalism?What is the role of the government?

Back-ups

Steady Growth of Asian Countries (Protocols)

		2005	2006	2007	2008	2009 (up to July/20)
	-	USA	USA	USA	USA	USA
Destrict builde	2	Germany	Germany	Germany		Germany
	с С	Canada	Canada	Canada	Canada	Canada
`.)	4	France	France	ΛK		France
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Protocol	6	South Africa	Brazil	Israel	Denmark	China
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	5		Argentina	Argentina	Hungary	Czech Republic
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	24	Argentina	Korea	Brazil		Hungary
		Japan	India	Switzerland		Mexico
	26	Israel	Japan	Taiwan	Argentina	Taiwan
	27]	Taiwan	Finland	China	Taiwan	Argentina
	28	Korea	China	South Africa	South Africa	Finland
	29	Greece	Romania	Finland	Switzerland	Norway
	30	India	Taiwan	Romania	China	Slovakia

Results of FDA Inspections

14

No Asian Country prompted 'Official Action Indicated',

while North America and Europe prompted action in 1.8% and 3.5%, respectively.

. (www.clin	www.clinicaltrialmagnifier.com	nifier.com
	Official Action (%)	Official Action Voluntary Action (%)	No Action (%)	Number of Inspection
Asia	0	58.3	41.7	36
North America	1.8	51.8	46.4	2711
Latin America	2.5	54.3	43.2	81
Europe	3.5	56.1	40.4	287
East Europe	1.3	49.3	49.3	150
Africa	3.2	38.7	58.1	31
Oceania	0	57.1	42.9	7

Data security is crucial for Japanese science

Rules that are based solely on voluntary guidelines will not gain the trust of the public.

Sir— The Japanese parliament is currently discussing new data-protection legislation, the first to be introduced in Japan, which will provide scientists with a broad exemption from the proposed rules. This exemption has not been widely discussed, and few citizens are even aware of the issue. Although the biomedical research community and pharmaceutical industry initially indicated tacit consent, concerns are now being voiced.

We believe the bill does not constitute an adequate regulatory framework for privacy protection in biomedical research. Several ministries, agencies and scientific societies have, in the past, drafted guidelines that have increased awareness of ethical issues, such as informed-consent procedures and review by research ethics committees. Yet the scope of the existing guidelines is restricted and there is considerable confusion about how the rules would be applied. We fear that data protection based solely on voluntary guidelines is insufficient to win public trust.

Progress in large-scale human genome research has dramatically increased the amount and content of personal data used in many areas of biomedical research. Large online databases linking personal

Collaboration can work if inequality is recognized

Sir—Your News report "Science collaboration stymied by relentless Middle East conflict" (*Nature* 417, 209–210; 2002) mentioned my support for Palestinian– Israeli cooperation. I would like to expand on my views. The Palestinian–Israeli conflict is neither a scientific issue nor a personal conflict but a struggle between two peoples over the same land. Therefore neither scientific collaboration in itself nor the personal relationships developed therein can advance the cause of peace unless conflict-related issues are also addressed and resolved.

Israelis have a strong army, resources, freedom and control over the land; Palestinians have none of these. One is occupier and the other is occupied. This inequality underlies any interaction between Palestinians and Israelis, including scientific cooperation, and should be the framework for any constructive dialogue. Unfortunately, this imbalance is often replicated in the collaboration and becomes a cause of frustration and disengagement on the part of the Palestinian partner.

It requires courage and commitment to

information with genomic and clinical data are now feasible. For example, BioBank UK (see *Nature* 417, 9; 2002) is seen by many observers as an important step forward for clinical-genomics research in Britain. But its success will depend on the participation of UK citizens. Such support is unlikely without a well-conceived scientific strategy and, equally important, a convincing legal and regulatory framework for privacy protection.

Assembling large-scale cohorts for genome research remains very difficult in Japan; we believe a more widespread sharing of resources is now inevitable. Yet without a coherent, transparent approach to data security and data protection, the Japanese public is unlikely to support efforts to build large databases containing medical information and lifestyle details linked with genetic samples, because of distrust and the perception that Japan's medical and scientific community is unable to govern itself.

An inadequate data-protection regime could harm progress in clinical genetics and other biomedical sciences in Japan for many years. The result could well be that Japanese scientists and enterprises go

widen the partnership beyond the realm of science, to rise above the current polarization and high emotional pitch in our respective societies, to place universal humanitarian values above nationalism and to take a clear stand for justice and peace. Yet it is possible, as demonstrated by individual academics as well as organizations such as Médicins sans Frontières, Physicians for Human Rights and the Alliance of Middle Eastern Scientists and Physicians. An example of such a stand is a recent statement by 300 Israeli faculty members, which can be seen at www.seruv.org.il/ UniversitySupportEng.asp.

The international scientific community should become more actively engaged. Foreign collaborators and funding agencies can request a commitment to basic human rights and equality, and to the principle of equal academic freedom and access to education for Palestinians and Israelis. Israeli scientists and institutions should express solidarity with Palestinian universities under siege and use their political clout to assist them. All partners should insist on a return to negotiations based on UN resolutions and international law.

A boycott of Israeli science would be relatively easy but, in the long run, counterproductive. Much more challenging and elsewhere — already, Japanese companies are choosing Singapore and even Mongolia for new clinical-genomics research facilities. The Japan Association of Bioindustries Executives, a group representing the chief executives of Japan's major biotechnology companies, has just released a statement (www.jba.or.jp/jabex) urging the government to strengthen genetic privacy protection.

We believe that large databases containing both genetic and medical information are inevitable for the future of biomedical research. But without adequate data protection or public trust, such databases are unlikely to be set up in Japan. For biomedical research to progress in Japan we, as members of its scientific and medical community, believe it is time for Japanese scientists to engage in a constructive public debate on this issue. Eitaka Tsuboi

President, Japan Medical Association, World Medical Association, 28-16, Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8621, Japan Other signatories to this letter: Norie Kawahara (freelance journalist) Tadahiro Mitsuishi (attorney-at-law) Akira Oshima President, Japan Association of Cancer Registries Shohei Yonemoto Director, Center of Life Science and Society

important is to use scientific interactions creatively, to promote true reconciliation. Yehuda Tzfati

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Alliance of Middle Eastern Scientists and Physicians and Department of Genetics, The Hebrew University of Jerusalem, Jerusalem 91904, Israel

Scientific links support an unjust peace process

Sir—Cooperation between Israeli and Palestinian academics since the 1993 Oslo peace agreement (see Nature 417, 209–210; 2002) has been primarily donor-led that is, imposed or strongly encouraged via the carrot of money in a money-starved environment, with the underlying assumption that such cooperation would assist the peace process.

This push for "Israeli–Palestinian scientific cooperation", as if science were divorced from society, was regarded by many Palestinian academics as suspect. Most Palestinians opposed a basically unjust and non-sustainable peace process, as recent events in the area clearly confirm.

Palestinian academics have been paying the very heavy price of occupation for many years, both personally and in the

Document 1

On dispatch as expert adviser in Thailand

Eitaka Tsuboi Director, Tsuboi Cancer Center Hospital Former President of World Medical Association

In 1968, at the request of the government of Thailand I traveled to Thailand as part of a Japanese expert team, for the establishment of the National Cancer Institute (NCI) of Thailand. The NCI in those days was on a small scale with only a clinical test laboratory and x-ray room being completed, among other minor facilities. Japan had provided the NCI with an x-ray television fluoroscope and a wide range of equipment for clinical testing, and in December of 1968 the King of Thailand visited the center to formally receive the equipment on behalf of the Thai government from the Japanese government. The King of Thailand attended the ceremony and the representative of Japan on this occasion was then President of the National Cancer Center (NCC) of Japan, Professor Masaru Kuru. The King of Thailand expressed his gratitude to the Japanese government for its cooperation in the establishment of the NCI. At that ceremony various displays were provided concerning new cancer examination methods being implemented at the NCC, including the peripheral tumor scrape method I have developed for the early diagnosis of lung cancer, and President Kuru provided an explanation to the King about these displays. At this point it was possible for experts dispatched from Japan to provide specific education concerning diagnosis techniques and examination methods and the NCI began to gradually grow and develop as a result. Thai doctors from various departments who had undergone study and training programs at the NCC also returned to Thailand at this time together with the Japanese expert team and with these doctors working as our counterparts we were able to implement operations smoothly at the NCI.

As the work of the NCC expert team that had been dispatched to Thailand at the time of the opening of the NCI gradually began to bring forth results, the original team returned to Japan from the National Cancer Center of Japan to be replaced by a new team.

The Ministry of Health White Paper of 1969 notes the following:

In May 1968 a survey team was dispatched from the National Cancer Center of Japan to Thailand for the establishment of the National Cancer Institute of Thailand. In November of the same year an expert team of seven persons was dispatched together with the provision of diagnosis equipment. On December 5, an opening ceremony for the NCI was held in the presence of the King of Thailand. In addition a further eight experts have been dispatched and are providing technical guidance and working to enhance the content of work at the NCI.

Document 2

Research into temporary prevention of lung cancer

With particular emphasis on the production of anti-smoking pamphlets targeting junior high school students and evaluation of their educational effect

Preventing young people taking up smoking as a primary prevention method to halt the increase in lung cancer is thought to be both realistic and effective. The "Research into Primary Prevention of Lung Cancer" implemented based on this concept is introduced in an anti-smoking pamphlet that was produced with the aim of providing anti-smoking education to junior high school students on a national scale as a form of awareness raising education.

Calling upon the wisdom of Asia and sending it to the world

Yoshiki 'Paul' Otake Founder, Executive Advisor, Aflac Japan

I am delighted that the fifth Asia Cancer Forum will be held here in Japan. I wish to express my thanks for the hard work of all those people actively involved in the front line of cancer treatment throughout Asia. I would have liked to participate in the forum and discuss the issues with everyone but unfortunately I am unable to attend. I hope that your proposals and lively discussions make for a very successful forum.

The hope and the mission of Norie Kawahara, founder of the Asia Cancer Forum, was the controlling of cancer patient numbers in the Asia region where a significant increase is expected to be seen in the coming years. It was her passion that sees us now already holding our fifth forum since the first one in June of last year.

As the first person in Japan to introduce cancer insurance, I wanted to be of some assistance to the forum and therefore I am sending this message to you.

Aflac was founded in Japan 35 years ago with the idea of saving cancer patients and their family from financial disaster. Since 1981, cancer has been the main cause of death in Japan and in 2004 accounted for a total of 320,000 out of 1,029,000 deaths. Approximately one in three people dies of cancer. It is expected that, by 2015, one in two people will die of cancer and that the 3,000,000 existing cancer patients will increase rapidly to 5,400,000, referred to as "the 2015 issues" for cancer.

Even developed countries such as Japan are currently struggling with this most serious issue of cancer. The Basic Plan to Promote Cancer Control Programs was approved by Cabinet in 2007 by way of addressing the issue, and a 20% reduction of cancer deaths by 2016 has become a national objective.

Aflac Japan will lend their support to the fight against cancer and the education program conducted by the government and local public organizations based on the plan as a community service of the highest priority. It has been my wish since I set up Aflac Japan and I am truly delighted that it has finally become a reality.

The area in which Japan can take the lead for all Asian countries is that of dissemination of accurate information about cancer, its treatment, prevention and diagnosis. Looking back over the kinds of approaches that Japan with its Basic Plan to Promote Cancer Control Programs has taken thus far, ideas to address the mismatch of policy on the one hand and the day-to-day issues for medical care workers, facilities, technology and patients on the other will connect us to better cancer treatment and better control of cancer.

I am truly delighted to give my support using the knowledge, information and worldwide network I have gained through managing a cancer insurance company and from the personal experience of being a cancer patient, in order to make the fight against cancer a global issue. I am certain this forum will prove to be a very fruitful experience and I look forward to its findings being used in future contributions to medical treatment in Japan.

I thank you for your guidance and encouragement for the development of this forum in the future.

I hope we all continue to work together to call upon the wisdom of Japan and of Asia with our proposals and information, to lead the world in the fight against cancer. My wish is to save even one person but preferably many people from the tragedy that is cancer.

Paul

Yoshiki P. Otake Founder & Executive Advisor Aflac Japan