

REPORT

UICC-ARO Symposium at the UICC 2016 World Cancer Congress

How Can We Mobilize Action to Realize UHC in Asia?

Hideyuki Akaza¹, Norie Kawahara^{1*}, Takashi Fukuda², Shigeo Horie³, Hasbullah Thabrany⁴, Shinjiro Nozaki⁵

Abstract

The 2016 World Cancer Congress, organised by UICC, was held in Paris in November 2016, under the theme “Mobilizing action – Inspiring Change.” As part of Track 4 presentations on the theme of “Strengthening cancer control: optimizing outcomes of health systems,” UICC-Asian Regional Office (UICC-ARO) held a symposium to discuss the issue of mobilizing action to realize UHC in Asia. Introducing the symposium, Hideyuki Akaza noted that universal health coverage (UHC) is included in the Sustainable Development Goals and one of the key issues for achieving UHC will be how to balance patient needs with the economic burden of cancer. Speakers from Japan and Indonesia addressed various issues, including the current status and challenges for medical economic evaluation in Asia, the importance of resource stratification, prospects for precision medicine, and the outlook for cancer control and UHC in developing and emerging countries in Asia. Key issues raised included how to respond to the rising costs of treating cancer as new and increasingly expensive drugs come to the market. Speakers and participants noted that health technology assessment programs are being developed around Asia in order to evaluate the cost-effectiveness of drugs in the face of budgetary constraints within increasingly pressurized national health systems. The importance of screening and early detection was also noted as effective means that have the potential to reduce reliance on expensive drugs for advanced cancers. The symposium was chaired jointly by Hideyuki Akaza and Shinjiro Nozaki (WHO Kobe Centre).

Keywords: UHC- cost-effectiveness- health technology assessment- primary prevention- early detection

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1. Introduction

For the UICC Asia Regional Office (UICC-ARO) one of the significant outcomes of the previous UICC World Cancer Congress (WCC) in Melbourne in 2014 was the launch of a program at the WHO Kobe Centre (WKC) aimed at realizing universal health coverage (UHC) for cancer in Asia. In the 2016 WCC in Paris, the UICC-ARO symposium sought to engage in further discussion on the important theme of UHC and deepen shared recognition of the issues surrounding UHC in the cancer community. UHC is a concept that is defined as ensuring all people have access to quality health and medical services at a price that does not create economic hardship for the persons using such services. The realisation of UHC is one of the most urgent and pressing issues for Asia, where incidence of cancer is increasing rapidly. The symposium was held as part of ongoing efforts by both UICC-ARO and WKC to develop a body of research and data that will

help to guide initiatives for cancer control in the region.

2. Opening

Hideyuki Akaza (UICC-ARO) noted that the aim of the symposium would be to discuss measures to mobilize action on Universal Health Coverage (UHC) in Asia. UHC is cited in the “Good Health and Wellbeing” goal of the Sustainable Development Goals of the United Nations, which states that “ensuring health lives and promoting the well-being for all at all ages is essential to sustainable development...more efforts are needed to fully eradicate a wide range of diseases and address many different persistent and emerging health issues.” (<http://www.un.org/sustainabledevelopment/health/>).

As part of its current activities, UICC-ARO is addressing the question of the “Economic burden of cancer in Asian countries: How should we face the current situation?” from a variety of angles and seeking to bring

¹Department of Strategic Investigation on Comprehensive Cancer Network, Research Center for Advanced Science and Technology (RCAST), the University of Tokyo, UICC-Asia Regional Office (UICC-ARO), ²National Institute of Public Health, ³Juntendo University Graduate School of Medicine, ³WHO Kobe Center, Japan, ⁴Universita Indonesia, Indonesia. *For Correspondence: norie.kawahara@med.rcast.u-tokyo.ac.jp

together a wealth of multidisciplinary knowledge about cancer in Asia and its related socioeconomic factors.

Japan is now the country with the largest aged population. Already in 2016 25% of the population in Japan is aged 65 year or over and it is expected that other countries will be following Japan in the years to come.

As society ages, so too does the incidence of cancer increase, and trends in the age-specific incidence rate have increased dramatically between 1980 and 2011 (Foundation for Promotion of Cancer Research, Cancer Statistics in Japan 2015).

In terms of the challenges in the aging society for achieving healthy life expectancy and well-being, challenges include fragility, dementia, cancer and other aspects. It is critical to accomplish UHC for cancer as cancer is a disease that is curable if it is detected early and treated adequately. If treated appropriately patients can return to their normal lives. However, the cost of treatment threatens the economic situation of the patient in some countries.

A study in Southeast Asia examined the competing outcomes of death, financial catastrophe, and alive with no financial catastrophe at 12 months after diagnosis of cancer (Nirmala, 2015). The results showed that catastrophic costs are an extremely grave issue for patients in Southeast Asian countries and in many cases people die from cancer due to lack of funds for treatment. Similar challenges also face developed countries, and financial insolvency as a risk factor for early mortality among patients with cancer is a global issue.

Cancer is a top target of UHC not only for younger populations but elderly populations. In addition, cost-effectively designed cancer treatment will contribute to ensure the wellbeing of elderly patients. Given that there are wide inequities in Asia in cancer treatment, UHC for cancer is an urgent and pressing issue.

3. Current status and challenges for medical economic evaluation of cancer care in Asia

Takashi Fukuda (National Institute of Public Health of Japan (Japan)) noted that medical expenditure is increasing even in Asian countries, due not only to population ageing but also the innovation of new technologies, with new advanced diagnostic and treatment technologies having been introduced. If insurance premiums or tax funding are limited, it will be necessary to consider the efficient use of health care budgets in order to sustain UHC.

Under such conditions, some Asian countries have started Health Technology Assessment Programs, especially use of economic evaluation for new drugs and procedures, in order to consider cost effectiveness of new treatments.

For example the Health Intervention and Technology Assessment Program (HITAP) (<http://www.hitap.net/en/>) was established in 2007 under the Ministry of Public Health in Thailand, which evaluates pharmaceuticals, medical devices, interventions, individual and community health promotion, and disease prevention. In Taiwan, a HTA program started in the Center for Drug Evaluation (CDE) in 2008 to assist the National Health Insurance

Administration of the Ministry of Health and Welfare in performing effectiveness and economic assessments on new drugs and new medical devices (<http://nihta.cde.org.tw/>). In South Korea mandatory economic evaluation data for new drugs has been required since 2008 and the Health Insurance Review and Assessment Service (HIRA) (<https://www.hira.or.kr/eng/>) makes decisions on reimbursement. For example, in Korea, Cetuximab and Fulvestrant have been rejected for reimbursement under the national health scheme, whereas Nilotinib and Lapatinib ditsylate have been approved (Cho et al., 2013). All of these drugs are reimbursable in Japan, which does not have a system to assess the cost-effectiveness of drugs.

However, in April 2012, a new committee on cost-effectiveness evaluation was established under the Central Social Insurance Medical Council in Japan, where the reimbursement and pricing decision are made. In 2015 the Japanese government issued a policy statement, in which it is stated that: "...it will consider the cost-effectiveness of insurance coverage of medicine and medical devices as a way to cope with the sophistication of healthcare. The government will introduce such cost-effectiveness analysis on a trial basis for the FY2016 revision of remunerations for medical treatment. Subsequently, it will seek to promptly introduce cost-effectiveness analysis on a full-fledged scale." (Government of Japan, "Basic Policy on Economic and Fiscal Management and Reform, 2015)

Based on this policy statement the Pilot Program of Cost Effectiveness Evaluation of Pharmaceuticals and Medical Devices in Japan started in April 2016. Target products are already marketed pharmaceuticals and devices and the evaluation results are used for reimbursement price decisions rather than an insurance coverage decision.

In Japan almost all prescription drugs are covered by health insurance schemes. All the drugs have their reimbursement prices determined at the Central Social Insurance Medical Council (Chu-I-Kyo). There are also pricing rules for new drugs and a coverage/pricing decision should be made within 60 days (90 days maximum). These prices are revised every two years based on the repricing rules.

The pricing rules for drugs and medical devices follow one of two methods: comparison to similar existing drugs, and the costing method.

The Chu-I-Kyo has considered two major issues. The first is that the economic evaluation process may take time in addition to the approval process. As a rule, new drugs are included in the reimbursement drug list within 60 days after approval. It may be difficult to perform the economic evaluation within 60 days. This may cause the delay of coverage, which will further compound the drug lag problem that exists in Japan. A second issue is that patients basically will not want to have limited access to new technologies. If the new technologies are not covered by insurance scheme based on the economic evaluation, it may limit the access to those technologies by patients.

With regard to the selection criteria for existing drugs, those listed for fiscal years 2012 to 2015 whose price was determined by similar drug/efficacy method

were subject to the following criteria: i) The premium rate is the highest, and ii) The expected peak sales is the highest among drugs for which there is a premium of 10% or more. For drugs listed for fiscal years 2012 to 2015, whose price was determined by costing method, the following criteria were used: i) The profit premium rate is the highest, and ii) The expected peak sales is the highest among the items for which a premium of 10% or more. This process resulted in the selection of five drugs using the similar drug method and two drugs using the costing method.

With regard to the selection criteria for new drugs in the future, there are also two selection criteria. Firstly, for drug prices determined by similar drug method, the manufacturer requests a premium rate of 10% or more, and the expected sales will be over 50 billion yen for drugs 5 billion yen for medical devices. Secondly, for drug prices determined by costing method, the manufacturer requests a profit premium of 10% or more, and the expected sales will be over 10 billion yen for drugs 1 billion yen for medical devices. However, the results of evaluation for new products will not be reflected to pricing decision in the pilot program because it will not be able to be evaluated during 60 days after approval. Drugs and medical devices which will be approved after October 2016 are applicable under this new program.

In terms of the process of cost effectiveness evaluation of pharmaceutical and medical devices, the marketing authorization holder will carry out the analysis based on analysis guidelines and submit data of cost effectiveness analysis. Preliminary consultation about the framework of analysis will be held before the initiation of the analysis. Submitted data will be reviewed neutrally by a public organization, in collaboration with external specialists. At a meeting of the Special Organization for Cost-Effectiveness, results of analyses provided by the company and the review group will be appraised and a draft of the evaluation will be prepared. The marketing authorization holder who submitted the data can attend the meeting of the Special Organization for Cost-Effectiveness and directly express views at the meeting.

The Chu-I-Kyo has devised Guidelines for Cost Effectiveness Analysis, which contains 15 sections, including "Perspective of the Analysis," and "Choice of Outcomes." (Shiroiwa et al., 2015).

In terms of the process for the pilot program, the results of evaluation by the Special Organization for Cost-Effectiveness will be used for price adjustments after the application of existing pricing (re-pricing) rule of drugs and medical materials/devices. Concrete methods for price adjustments will be discussed during the process of FY 2018 revision of medical fees. The program was launched in April 2016 and now manufacturers are preparing the primary data analysis for April 2017 and it is anticipated that the results will be used in the implementation of re-pricing based on the cost-effectiveness evaluations.

Discussion

Hideyuki Akaza noted that it is imperative for pharmaceutical companies, governments and doctors

and patients to collaborate with a view to establishing UHC in Asia.

Kenji Yasukawa (Astellas Pharma Inc.) noted that the pharmaceutical industry is facing pressures with drug pricing in recent years, due to a rapid increase in the elderly population. The development costs for drugs are also increasing in recent years and only three to five percent of drug candidates that go to Phase I stage are actually launched. Due to the progress of science, governments are increasingly demanding more and more data associated with drug certification. In the near future it will become necessary to change the paradigm for drug approval in order to reduce clinical development costs, which could lead to lower drug prices. Efforts need to be made by all stakeholders, including industry, government and academia.

4. Clinical evaluation of UHC for cancer

Shigeo Horie (Juntendo University (Japan)) noted that the objectives of UHC are:

- Equity in access to health services: those who need the services should get them, not only those who can pay for them;
- Quality of health services: being good enough to improve the health of those receiving services; and
- Financial-risk protection: ensuring that the cost of using care does not put people at risk of financial hardship.

According to the World Health Organization, UHC is conceptually appealing but its application will vary from one country to another given the diversity of country levels of economic development, health system resources and epidemiological challenges. It is important to identify ways of measuring UHC across countries that are comparable but adaptable to local contexts (WHO, 2013).

Breast cancer survival is a key indicator for UHC in cancer control. Breast cancer survival might serve as a measurement of how countries are covering prevention, care, and treatment. However, there is a need for well-trained health workers and functioning infrastructure. To measure UHC in breast cancer control, one idea is to analyze new cases of breast cancer against breast cancer mortality. This kind of analysis demonstrates that there are high mortality rates in lesser developed countries, which may have a low incidence of breast cancer, but also lack the infrastructure and medical care to treat breast cancer.

The fundamental barriers to UHC for cancer care can be identified as eligibility and accessibility to primary prevention, survivorship and palliation. It is essential to achieve good communication between all aspects of cancer care to achieve UHC, including screening, diagnosis, rehabilitation and palliation. UHC and clinical guidelines should be stratified according to the resource availability and be utilized for bench-marking. For localized prostate cancer, resource-stratified guidelines have been established in Asia, which correspond to the level of healthcare resources available.

Western cancer guidelines present tremendous choices for first-line and subsequent therapies. If patients can have greater access to drugs, they can enjoy a longer lifespan. However, even in developed countries the achievement of

sustainable UHC is increasingly becoming a challenge.

Last year President Obama of the United States proposed precision medicine in oncology, which is focused on identifying which therapies will be most beneficial for each patient based on genetic characterization of their cancer. One idea could be to do a liquid biopsy to check the status of bio-markers and determine the most effective types of treatment.

While increasing survival is important for UHC in cancer treatment, what is equally if not more important is to maintain quality of life and reduce the disease burden. It is important to share decision making with patients for this purpose.

To achieve UHC for cancer in Asia there are many issues that must still be tackled. These include diversity in the Asian region and the importance of resource stratification. In addition, it is important to give consideration to evaluation and appraisal of technologies and medicines. Precision medicine will increasingly become important for ensuring sustainable UHC in Asia, and it is essential that treatment decisions are made in a shared manner.

5. Universal health coverage in Indonesia: prospect and challenge

Hasbullah Thabrany (Universitas Indonesia (Indonesia)) noted that there is high cancer incidence in Indonesia, but the nation is extremely large with many distant islands, which presents a challenge in terms of coverage and provision of treatment.

From 2012-2014 the ASEAN Cost in Oncology (ACTION) was implemented by the George Institute, Sydney, funded by Roche Asia Pacific. A total of 10,000 new cases were examined in eight countries and each new case was observed for 12 months after diagnosis (http://partnerships.ifpma.org/uploads/documents/212_1481213678.pdf). In Indonesia ACTION involved 2,335 cases from 12 centers. Participation was voluntary and it took time to register cases and also proved difficult to follow cancer patients for 12 months who did not have insurance coverage. After one year only 29% of the initial patients could still be followed. In the ACTION study in Indonesia the most prevalent cancers were breast and cervical cancer, representing 36.19% and 17.42% of all cases, respectively. Most of the cases that were identified were already T3 and T4 cancers at diagnosis, indicating that people were coming to hospital at a late stage. In terms of the economic burden on households among patients in the ACTION study, 59.5% of all patients experienced financial hardship after diagnosis, with some patients having to resort to selling their home (4.3%), taking out a loan (10.4%) or selling assets (13.7%). Of the patients who experienced catastrophic expenditures, over 90% of patients who were treated in private hospitals experienced catastrophic expenditure, compared to approximately 45% who received treatment in public hospitals. In terms of the proportion of families complaining of financial hardship, approximately 55% of families experienced financial hardship at diagnosis, which rose to 65% after one year.

Following the ACTION study, health care reform was launched in Indonesia in 2014. The reform is moving toward UHC through a national health insurance system (INA-MEDICARE). It is aimed that the system will cover 257 million people by 2019. The system that is being used follows the Korea and Taiwan model the single payer system for health care. Premiums are 5% of wages and people on low incomes receive government subsidies. The system already covers approximately 168 million people. The system provides comprehensive benefits. All necessary but most cost-effective healthcare is covered, including all types of cancers. The benefits are provided in public and contracted private hospitals. A Commission on Health Technology Assessment has been established to decide whether new medical technologies are covered.

In terms of the four highest claim costs under the UHC system, the largest claims were for cardiovascular disorders, followed by renal failure, cancer and stroke. In 2014 there were 702,000 claims for cancer, which rose to 938,000 in 2015. Costs related to cancer care amounted to 31 billion IDR for outpatients and 786 billion IDR for inpatients in 2015. More than a quarter of a million cancer patients have benefited from UHC and mortality is on average 8.3%, although there is higher mortality among males for gastric cancer (14.0%) and lung cancer (16.7%).

In terms of prospects and challenges for UHC in cancer in Indonesia, cancer patients will continue to have better access and less household burdens in receiving cancer treatments. Health care providers and oncologists will also have better chances to enhance treatments and control of cancer patients. Pharmaceutical and medical technology companies have a better position than before in supplying cancer control and treatments. However, many cancer patients live a long way from the limited number of cancer centers/hospitals and have less access due to transportation and other non-medical costs. There are also increasing cases covered by the health insurance system, which is generating concerns about the cost of claims on the limited resources available. There is also a shortage of oncologists in Indonesia. Studies and research on how to ensure adequacy and equity of cancer control, including screening and early diagnosis, are among the top priorities for the coming years.

Discussion

Louise Abbot (Roche, Singapore) asked about the sustainability of UHC in Indonesia, given all the cost pressures that are faced. She asked whether individual contributions would be sufficient and if the government would have to look at other sources of finance, such as private insurance models in order to make the system sustainable and maximize the benefits.

Hasbullah Thabrany responded that only 3.6% of GDP is spent on healthcare in Indonesia, which is still a small proportion. One option that has already been approved by the government is to divert taxation from cigarettes to healthcare. The current law limits excise on tobacco to 50% of the price, and in order to raise revenues through increased taxation on tobacco it will be important to change this law in the future. Negotiations will also be

needed with pharmaceutical companies in order to ensure sustainability.

Takashi Fukuda asked what kind- of criteria are used to select the drugs that are approved for use under the national health system in Indonesia.

Hasbullah Thabrany responded-that a commission, chaired by pharmacologists and also comprising various specialists, meets annually to assess drugs based on literary review and clinical experience. There have been cases where drugs have been rejected, and some have been reinstated. Takashi Fukuda noted that there are increasing numbers of very expensive drugs available, which would likely put pressure on the UHC system in Indonesia. Hasbullah Thabrany responded that the premium for UHC is still too low in Indonesia and in order to deal with increasing costs it will be necessary to consider whether premiums should be raised in the future. This is a difficult issue and one that the government is continuing to tackle.

A participant from Roche, Indonesia, asked about the role of patient organization in improving UHC in various countries. Shigeo Horie responded that in the case of Japan one of the issues is drug lag, meaning that some drugs that are available in the west are not available in Japan. Patient advocacy groups have campaigned to achieve the approval of drugs. However, medical expenditure in Japan is currently equivalent to all tax revenue. Although the healthcare system in Japan appears to be highly advanced, the reality is that the system as it currently stands is eating up the resources of future generations. It will therefore be important for Japan to implement some kind of cost-effectiveness analysis system in the future to ensure that the healthcare system remains sustainable.

Hasbullah Thabrany noted that patient groups in Indonesia are still very weak, but they have the potential to provide impetus to government officials in the future.

Shinjiro Nozaki (WHO Kobe Center) noted that the WHO Kobe Center has started a new scheme for collaborative research with Asian and international academics on innovation for UHC and ageing. WHO Kobe Center is currently in discussions with UICC-ARO to start collaborative research in the field of cancer. When considering future threats for global health it is important to tackle the issue of UHC in aging societies, in which cancer and other NCDs pose significant and increasing threats. Cancer is the biggest cause of death in most Asian countries and therefore the WHO Kobe Center is looking to work with academics in Asia and identify new and innovative ways to achieve UHC in cancer in Asia.

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