第59回定例朝食会
「技術革新と医療技術評価」

2016年10月14日

HGPI Health and Global Policy Institute

今回の朝食会では、前回に引き続き「医療技術評価（ HTA : Health Technology Assessment）」をテーマとし開催しました。東京大学公共政策大学院客員教授・大西昭郎氏をお招きし、産官学でご経験をされてきた視点から、「技術革新と医療技術評価」について、その考え方や制度の国際比較、ならびに日本の今後の政策への期待や、当分野で今後の産官学が果たすべき役割などについてお話頂きました。

講演者ご紹介：大西昭郎氏　　東京大学公共政策大学院　客員教授

東京大学工学部卒、 ペンシルバニア大学ウォートンスクール修了（経営学修士）
通商産業省、マッキンゼー・アンド・カンパニー、経済協力開発機構(OECD: Organisation for Economic Co-operation and Development)を経て、IT企業の経営に携わった後、日本メドトロニック株式会社取締役副社長、内閣官房医療イノベーション推進室次長、株式会社ソラスト常務執行役員を歴任。現在日本アビオメッド株式会社副社長。2012年から東京大学公共政策大学院で教鞭もとる。

講演内容要旨

■技術革新と医療制度

1980～90年にかけて、バイオテクノロジー、エレクトロニクス、材料技術の基礎が作られ、バイオ遺伝子組み換えの技術も台頭してきた（2000年に最初のヒトゲノム解析が完了）。技術の進歩に伴い医療の制度面でもどのように新しい医療技術を取りいれていくかが検討され始めた。米国では医薬品と医療機器の技術の違いが着目され、安全性や有効性を評価する薬事制度の再検討が進み、1997年にFDA改革法が成立した。また、診療報酬の面では、1983年から、治療の方法や手段ではなく診断群ごとに治療費が評価される「診断群分類（DRG : Diagnosis Related Group）」の導入が始まった。これにより、原則として、薬、機器や手技ごとの費用ではなく、診断された疾病コードごとに病院の報酬が定まり、支払いがなされる。

■医薬品と医療機器の違い

医薬品と医療機器はその性質が大きく異なる。医薬品はそのもととなる物質を「発見」することで特許が認められるのに対し、医療機器は、「発明」がその対象であり、性能や効果等を発揮する機構やメカニズムの新規性があって初めて認められる。このため、新しい医療機器が必ずしも新しい特許になるとは限らない。治験の実施においても大きな違いがある。医薬品の場合、治験を中断しても通常の治療に戻ることが難しくない場合も多いが、植込み型の医療機器の場合などは、体内に埋め込んだ医療機器を取り出すことに伴うリスクがあることから治験の中止は容易ではない。

■日本の医療制度

日本では、2014年に「薬事法」が「薬機法」に改正されるまで、医薬品の規制の考え方を反映した薬事法のもとで医療機器、さらには再生医療製品の規制が運用されてきた。また、保険制度に関しては、診療報酬、薬価、材料価格（一部の医療機器はここに含まれる）や評価の方法を2年ごとに改訂することで運用されてきた。ここにきて高齢化と技術革新により医療費の増額は今後10年で1.5倍になるとも言われており、医療技術評価の試行が検討されているほか、制度についていろいろな議論がなされている。

■医療評価への取り組み、将来展望

医療技術評価は、個別の技術や製品の有用性をどう評価するかという観点に加えて、医療制度の枠組みの中で、それら製品や技術の使い方などがもたらす医療の質の向上を評価することを検討していくことも重要ではないだろうか。医療の目標を「医療の質」というところに置き、これらが計測できるアウトカム指標などをとりいれた評価制度の取り組みの動きも、欧米では始まっている。今後の動向に期待したい。

詳細はこちらから

http://www.hgpi.org　►「第59回定例朝食会」で検索

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59th Breakfast Meeting

Technology Innovation and HTA

October 14, 2016

HGPI Health and Global Policy Institute

At this Breakfast Meeting, HGPI will invite another expert on "Health Technology Assessment (HTA)" following the previous meeting. Prof. Akio Onishi, Visiting Professor of "the University of Tokyo Graduate School of Public Policy" (GraSPP) will talk about "Technology Innovation and HTA" based on his experiences in public, private, and academic sectors. He will expound on HTA from various perspectives such as international comparison of its systems, its future policy makings within Japan, and role of public, private and academic partnership.

Speaker : Prof. Akio Onishi

Visiting Professor, the University of Tokyo Graduate School of Public Policy

Prof. Onishi received BS in engineering from the University of Tokyo, and MBA from the Wharton School of the University of Pennsylvania. He started his career at Ministry of International Trade and Industry, and later worked at McKinsey and Company, and Organisation for Economic Co-operation and Development (OECD). After his experience in managing IT company, he served as the Executive Vice President at Medtronic Japan, Deputy Director General at Office for Medical Innovation in Cabinet Secretariat, and Managing Officer at Solasto Corporation. He is currently the Executive Vice President at Abiomed Japan. Since 2012, he is the Visiting Professor of GraSPP.

Meeting Summary

Innovation and health care systems

The period from 1980 to 1990 saw the creation of a foundation for biotechnology, electronics, and materials technology, as well as the development of biogenetic modification techniques (the first human genome analysis was completed in 2000). This was also when people began to consider ways to adopt new pharmaceuticals and medical technology into health care systems, along with progress in technology.
In the United States, people began to notice the differences between pharmaceuticals and medical technology. Progress was made on the reconsideration of the systems used to evaluate drug safety and efficacy, leading to the passage of the FDA Modernization Act in 1997.
In addition, in terms of medical payments, the Diagnosis Related Group (DRG) system was introduced in 1983 to evaluate medical fees based on the diagnoses given rather than the methods or processes of treatment used. As a general rule, this system means that payments to hospitals are decided not per medicine, device and procedure, but per diagnosis code.

The difference between pharmaceuticals and medical technology

Pharmaceuticals and health technology have greatly different properties. While pharmaceuticals are developed from "discovered" substances, and then become recognized after being patented, health technology is "developed" and recognized once it shown to have a new structure or mechanisms that allow it to demonstrate new properties and effects and so on. Therefore, new health technology does not always result in a new patent.
The execution of clinical trials is also a big difference here.
With pharmaceuticals, it is usually not difficult to return to a normal treatment even if the clinical trial is stopped, but with implanted health technology, for instance, it is not easy to stop treatment due to the risks associated with removing the health technology from the body.

The health care system in Japan

In Japan, up until the Pharmaceutical Affairs Act and the Pharmaceuticals and Medical Devices Act were amended in 2014, health technology was regulated based on the Pharmaceutical Affairs Act, which reflected thinking about the regulation of pharmaceuticals. Regulations for regenerative medicine devices were also applied.
In addition, regarding the insurance system, methods for evaluating medical payments, drug costs, and materials prices (including some health technology) have thus far been amended every two years. Some are now saying that medical costs will rise to 1.5 times what they are today over the next ten years due to the aging of society and technological innovations. A variety of discussion is underway to consider the use of HTA and other systems.

Initiatives and future prospects for health care assessments

In addition to considering how we should evaluated the usefulness of individual technologies and products via HTA, it is also crucial to consider the evaluation of improvements in the quality of medical care brought about by the different ways people use products and technology in the midst of health care frameworks.We are seeing the start of movement on initiatives for assessment systems that take into account outcomes that can measure this, having set the quality of medical care as the goal for medicine. I am excited for this trend.

For further information

http://www.hgpi.org/en/ ► Search "59th Breakfast Meeting"

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