資料2

総合科学技術・イノベーション会議
生命倫理専門調査会
2015年12月15日

ヒトゲノム編集・インターナショナルサミットについて

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内閣府総合科学技術・イノベーション会議　生命倫理専門調査会専門委員
Global Alliance for Genomics and Health (GA4GH), Steering Committeeメンバー

International Summit on Human Gene Editing

開催概要

主催：米国科学アカデミー、米国医学アカデミー
　　中国科学院、英国王立協会
会場：米国科学アカデミー（ワシントンDC）
日程：2015年12月1－3日

日本を含む約20か国から参加者

日本からの参加者（研究関係は5名）：
- 北海道大学・安全衛生本部　石井哲也教授　（講演者）
- 国立成育医療研究センター・生殖医療研究部　阿久津英憲部長
- 埼玉医科大学・ゲノム医学研究センター　三谷幸之介教授
  （日本遺伝子細胞治療学会・理事）
- 筑波大学・医学医療系/生命科学動物資源センター　高橋智教授
  （日本学術会議の推薦）
- 大阪大学・大学院医学系研究科　加藤和人

他に、メディア関係者が参加。

プログラム(第一日)

- Context for Summit
  (David Baltimore, Chair of the Planning Committee)
- Context Through Three Lenses: Scientific, Historical, Legal
- Scientific Background on Gene Editing Technologies
- Applications of Gene Editing Technology: Human Germline Modification
- Societal Implications of Emerging Technologies
- Limits to Our Understanding
  Eric Lander, Broad Institute of Harvard and MIT

プログラム(第二日)

- Applications of Gene Editing Technology: Basic Research
- Applications of Gene Editing Technology: Somatic Cell Therapy
- Governance at the Institutional and National Level
- International Perspectives
  Nigerian Academy of Sciences (Nigeria)
  German National Academy of Sciences (Germany)
  Department of Biotechnology, Government of India (India)
  そのほか France, Israel, South Africa, Sweden**から参加**

プログラム(第三日)

- Interrogating Equity
- Governance, Regulation, and Control
- Going Forward: Closing Thoughts
  (David Baltimore, Chair of the Planning Committee)

全体の印象

- **医学・生物学から、人文学、社会科学まで、広い範囲の専門家による講演と議論が含まれており、単なる医学・医療の課題としてではなく、社会および人類全体にとっての課題、と捉えるべきという意図が読み取れた。**
- **1975年のアシロマ会議(安全性の議論が中心)とは異なり、今回は、社会的・倫理的課題を扱う、より複雑な会議であるというコメントが、最終日にBoltimore博士よりなされた。 国際的なコンセンサスを作るのは難しい、だからこそ、継続的な検討が必要、という認識を多くの関係者が持っているという印象を受けた。**

Statement by

Ralph J. Cicerone, President, U.S. National Academy of Sciences
Victor J. Dzau, President, U.S. National Academy of Medicine
Chunli Bai, President, Chinese Academy of Sciences
Venki Ramakrishnan, President, The Royal Society

We thank the organizers of our International Summit on Human Gene Editing for their thoughtful concluding statement and welcome their call for us to continue to lead a global discussion on issues related to human gene editing. Together with academies around the world, and in coordination with other international scientific and medical institutions, we stand ready to establish a continuing forum for assessment of the many scientific, medical, and ethical questions surrounding the pursuit of human gene-editing applications. The forum will mobilize the global expertise necessary to help society develop norms for acceptable uses of human gene-editing technology. This is an important moment in human history and we have a responsibility to provide all sections of society with an informed basis for making decisions about this technology, especially for uses that would affect generations to come.

下線は報告者による。以下のスライドも同じ。

1. Basic and Preclinical Research. Intensive basic and preclinical research is clearly needed and should proceed, subject to appropriate legal and ethical rules and oversight, on (i) technologies for editing genetic sequences in human cells, (ii) the potential benefits and risks of proposed clinical uses, and (iii) understanding the biology of human embryos and germline cells. If, in the process of research, early human embryos or germline cells undergo gene editing, the modified cells should not be used to establish a pregnancy.

2. Clinical Use*: Somatic. Many promising and valuable clinical applications of gene editing are directed at altering genetic sequences only in somatic cells – that is, cells whose genomes are not transmitted to the next generation. Examples that have been proposed include editing genes for sickle-cell anemia in blood cells or for improving the ability of immune cells to target cancer.

There is a need to understand the risks, such as inaccurate editing, and the potential benefits of each proposed genetic modification. Because proposed clinical uses are intended to affect only the individual who receives them, they can be appropriately and rigorously evaluated within existing and evolving regulatory frameworks for gene therapy, and regulators can weigh risks and potential benefits in approving clinical trials and therapies.

* “Clinical use” includes both clinical research and therapy.

3. Clinical Use: Germline. Gene editing might also be used, in principle, to make genetic alterations in gametes or embryos, which will be carried by all of the cells of a resulting child and will be passed on to subsequent generations as part of the human gene pool. Examples that have been proposed range from avoidance of severe inherited diseases to 'enhancement' of human capabilities. Such modifications of human genomes might include the introduction of naturally occurring variants or totally novel genetic changes thought to be beneficial.

Germline editing poses many important issues, including: (i) the risks of inaccurate editing (such as off-target mutations) and incomplete editing of the cells of early-stage embryos (mosaicism); (ii) the difficulty of predicting harmful effects that genetic changes may have under the wide range of circumstances experienced by the human population, including interactions with other genetic variants and with the environment; (iii) the obligation to consider implications for both the individual and the future generations who will carry the genetic alterations; (iv) the fact that, once introduced into the human population, genetic alterations would be difficult to remove and would not remain within any single community or country; (v) the possibility that permanent genetic 'enhancements' to subsets of the population could exacerbate social inequities or be used coercively; and (vi) the moral and ethical considerations in purposefully altering human evolution using this technology.

It would be irresponsible to proceed with any clinical use of germline editing unless and until (i) the relevant safety and efficacy issues have been resolved, based on appropriate understanding and balancing of risks, potential benefits, and alternatives, and (ii) there is broad societal consensus about the appropriateness of the proposed application.

Moreover, any clinical use should proceed only under appropriate regulatory oversight. At present, these criteria have not been met for any proposed clinical use: the safety issues have not yet been adequately explored; the cases of most compelling benefit are limited; and many nations have legislative or regulatory bans on germline modification. However, as scientific knowledge advances and societal views evolve, the clinical use of germline editing should be revisited on a regular basis.

4. Need for an Ongoing Forum. While each nation ultimately has the authority to regulate activities under its jurisdiction, the human genome is shared among all nations. The international community should strive to establish norms concerning acceptable uses of human germline editing and to harmonize regulations, in order to discourage unacceptable activities while advancing human health and welfare.

We therefore call upon the national academies that co-hosted the summit – the U.S. National Academy of Sciences and U.S. National Academy of Medicine; the Royal Society; and the Chinese Academy of Sciences – to take the lead in creating an ongoing international forum to discuss potential clinical uses of gene editing; help inform decisions by national policymakers and others; formulate recommendations and guidelines; and promote coordination among nations.

The forum should be inclusive among nations and engage a wide range of perspectives and expertise – including from biomedical scientists, social scientists, ethicists, health care providers, patients and their families, people with disabilities, policymakers, regulators, research funders, faith leaders, public interest advocates, industry representatives, and members of the general public.

日本の対応について

- **ゲノム編集技術は、医学医療を通して、多くの恩恵をもたらす可能性を秘めた技術であり、その適切な使い方について日本としても検討を行い、必要な研究開発を促進する必要がある。**
- **対応のレベルとして、いくつかの異なる領域での活動が並行して行われることが望ましいのではないか。**
- **それらは、1）政府としての対応（総合科学技術・イノベーション会議や、生命倫理専門調査会を含む）、2）学術コミュニティによる対応（学術会議、各種専門学会など。人文学・社会科学分野からの参加も望まれる）、3）市民や患者、企業関係者なども含む広いステークホルダーの参加による議論、などが含まれる。**
- **さらに、国際社会との協調による議論の促進、考え方のまとめなどにも参加し、必要に応じてイニシアティブを取ることが望ましい。**