Two articles (editorial)

U.S. committee gives cautious approval to embryonic gene editing

February 16, 2017 (Mainichi Japan)

An international committee convened by the U.S. National Academy of Sciences (NAS) and National Academy of Medicine released a report on Feb. 14 concluding that clinical trials of heritable germline genome editing "could be initiated," but "only within a robust and effective regulatory framework" and "if limited to only the most compelling circumstances."

- 【Related】Editorial: It's time to take a hard look at regulating human genome editing

Germline genome editing means making changes to human DNA that can then be passed down to later generations.

The report is seen by some as a shift away from the academies' previous position against genome editing of human embryos that would be implanted in a woman's womb and carried to term.

The report states that heritable genetic editing trials "must be approached with caution, but caution does not mean they must be prohibited." However, such trials should only be carried out "if limited to only the most compelling circumstances, subject to a comprehensive oversight framework that would protect the research subjects and their descendants; and have sufficient safeguards to protect against inappropriate expansion to uses that are less compelling or less well understood."

This latter category would include edits to improve physical and intellectual ability. The authors also point out that, while there are as yet no concrete research plans to carry out this kind of genetic alteration, gene editing technology is advancing quickly, and the time to consider implementing regulations is at hand.

Meanwhile, many observers are also calling for extreme caution regarding germline genome editing, pointing out that many serious technical and safety hurdles remain. For example, the chances of altering the wrong gene remain high with present technology. After editing embryonic DNA, there is also a danger that,

as the embryo grows, some of the cells will carry the edit and some will not. It is also unknown what effects edits will have on later generations.

In Japan, the Cabinet Office's expert committee on bioethics released an interim report in April last year approving basic genetic editing research on fertilized human eggs on condition that they would not then be implanted in a woman's womb. However, the government has not yet moved to draw up legislation or guidelines on germline editing.

Meanwhile, the Japan Society of Gene and Cell Therapy (JSGCT) and three other related academic organizations are currently drawing up a screening regime for genetic editing research plans.

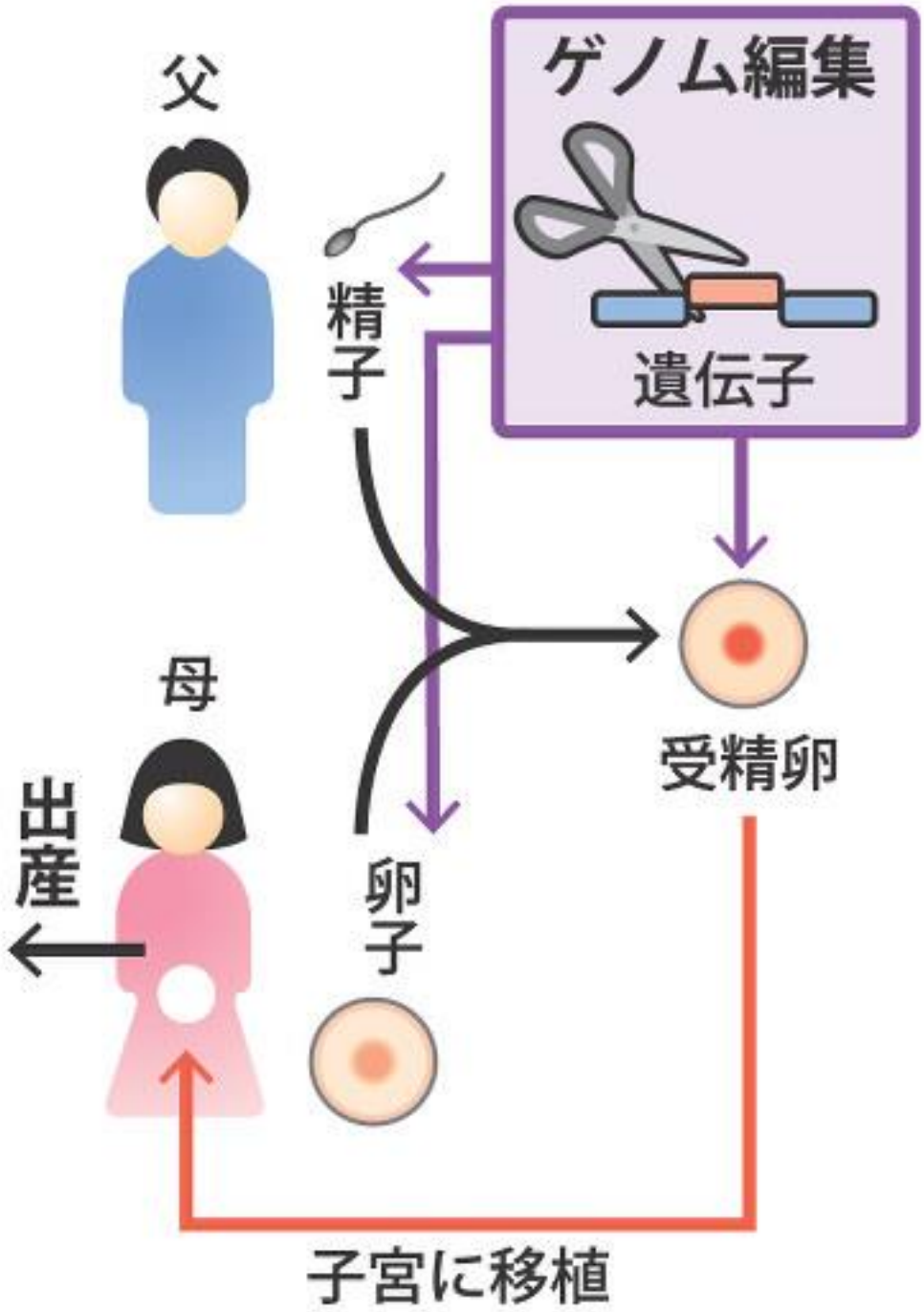
"This isn't something that should be left up to academic organizations alone," commented Hokkaido University bioethics professor Tetsuya Ishii. Furthermore, "Japanese researchers should not be aiming to create easy clinical applications for this technology, and should not use this report to support a sudden acceleration" in embryonic gene editing work, he said.

ゲノム編集

影響未知数　出産容認、技術・安全面に課題

毎日新聞 2017 年 2 月 16 日　東京朝刊

ゲノム編集技術を使った出産のイメージ



米科学アカデミーが１４日、狙った遺伝子を改変する「ゲノム編集」技術で受精卵や生殖細胞の異常を修正して子どもをもうけることを容認するとの報告書を公表した。重い遺伝性疾患に限るなどの条件付きだが、これまでは子宮に戻さない基礎研究に限るとしてきた姿勢を転換した。

報告書によると、ゲノム編集が容認されうるのは、重い遺伝性疾患で他に治療法がない場合で、数世代にわたる影響の追跡調査を行うなどの条件を付けた。身体能力や知能の向上などを目的とするのは禁止した。現時点で具体的な計画はないが、技術の進歩が速いことから、考慮する時期に来ていると判断した。

一方、現状では、技術面や安全面で克服すべき課題が山積しており、慎重な意見も多い。現在の技術では狙ったものとは違う遺伝子を改変してしまう確率がまだ高い。分裂して成長していく受精卵の場合、改変された細胞と改変されていない細胞が混ざる危険性もある。子孫に与える影響も未知数だ。

日本では昨年４月、政府の生命倫理専門調査会が、子宮に戻さないことを条件に、受精卵の基礎研究を容認するとの中間報告書をまとめた。

法規制や指針作成は見送られ、日本遺伝子細胞治療学会などの関連４学会が研究計画を審査する仕組み作りを進めている。

石井哲也・北海道大教授（生命倫理）は「本来は学会に任せておくべきことではない。安易に臨床応用を目指すべきではなく、今回の報告書を支えに日本で急加速するようなことがあってはならない」と指摘する。【藤野基文】

http://mainichi.jp/articles/20170216/ddm/002/040/132000c

Editorial: It's time to take a hard look at regulating human genome editing

January 19, 2016 (Mainichi Japan)

Interest is rising in genome editing as the next generation of the technology begins to make a serious impact. Scientists have been able to edit DNA strands for a while now, replacing sections of code. The newest techniques, however, are far more accurate, far more efficient and far cheaper than anything that has come before.

This has implications not just for the genetic engineering of laboratory animals and the alteration of agricultural plants and livestock. It has also made it quite likely that we will see the pace of development of human applications speed up. Which means we need to start asking some important questions, such as, "Can we allow genetic edits to fertilized eggs or reproductive cells that will then be passed down to a person's descendants, whatever the purpose may be?"

Genetic manipulation of fertilized eggs is prohibited in Japan and the West. However, the newest gene editing technology has much greater potential than its predecessors. The international community needs to reconsider world-wide regulation of human genetic engineering, and Japan cannot be late to the table.

Intense debate on the ethics of human genome editing was reignited in spring last year after the release of one particular research paper by a team in China. The team attempted to replace genes that coded for a blood disease with a normal section of DNA, and they performed the experiment using fertilized eggs. The team had no intention of creating a baby, but the experiment set off shockwaves nonetheless.

There are people that see big things for the treatment of genetic diseases and other illnesses using this kind of genetic editing. But the danger that the technology will be used to create "designer babies" -- choosing eye or skin color, or inserting genes for athletic ability, and so on -- cannot be denied.

Moreover, altering the genes of a fertilized egg means changing the genetic code for not just the person it grows into, but for their descendants as well, and all without them being able to give their permission. It may be possible that we will alter the human genome sometime in the future. There also remains the risk that the genetic editing process will alter DNA sections other than the one targeted, which means we have very real worries over the safety of genome editing.

The final statement at the International Summit on Human Gene Editing held in December by the British Royal Society, the U.S. National Academy of Sciences, and the Chinese Academy of Sciences, stated, "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." The statement did, however, approve of basic research into human gene editing, "subject to appropriate legal and ethical rules and oversight."

In Japan, there is no legal ban against developing clinical applications for editing the genes of fertilized eggs included in the administrative guidelines governing genetic therapies. There are also no clear-cut rules on basic research into the field. If this state of affairs continues, the state of the art may quickly outpace regulation, leaving the government to play catch-up. The country needs to quickly sort out the possibilities and ethical challenges of this new technology, and consider developing rules -- including legal measures -- to govern it.

It is extremely important to coordinate discussions on human gene editing among academic societies, the Science Council of Japan, and the government's own expert committee on bioethics. Moreover, we must regularly rethink the legal framework for reproductive assistance treatments that are closely linked to human gene engineering.

Practical research into genetic editing for crops and farm animals is also ongoing but, from a safety perspective, is there any difference between the plants and animals altered with the new techniques versus those already in use? We need to consider this question carefully and repeatedly.

http://mainichi.jp/english/articles/20160119/p2a/00m/0na/020000c

社説

ゲノム編集　課題整理し歯止め急げ

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新世代の遺伝子組み換え技術、「ゲノム編集」への関心が高まっている。遺伝子の切り張りはこれまでも広く行われてきたが、従来技術に比べ、ねらい通りに、効率よく、より安価に遺伝子を改変できるのが特徴だ。

このため、実験動物の遺伝子改変や野菜・家畜の品種改良はもとより、人への応用が加速する可能性が出てきた。そこで問題となるのは、目的がなんであれ、子孫に伝わる人の受精卵や生殖細胞の遺伝子改変が許されるかどうかだ。

受精卵の遺伝子操作は日本や欧米諸国では一定のルールのもとで禁止されてきた。しかし、新技術にはこれまで以上の潜在力がある。国際的に規制の再検討が必要であり、日本も後手に回らないようにしたい。

この技術の倫理的課題がクローズアップされたきっかけは、昨春、中国のチームが論文発表した研究だ。人の受精卵で血液疾患の原因遺伝子を正常なものに置き換える基礎研究で、子どもの誕生を目的とするものではなかったが、波紋を広げた。

こうしたゲノム編集の応用については、遺伝病などの治療につながると期待する声もある。一方で、子どもの目の色や肌の色を選んだり、運動能力を高める遺伝子を導入したりと、望みの子どもをつくる「デザイナーベビー」につながる恐れも否定できない。

しかも、受精卵の遺伝子を操作すればその影響は次世代の同意を得ないまま子孫に伝わる。将来、人類の遺伝子を変化させてしまうかもしれない。狙った場所とは異なる場所に遺伝子が導入される可能性も残され、安全性への懸念も残る。

米英中の科学アカデミーは昨年１２月、国際会議を開き、人の受精卵や生殖細胞の改変について「安全性や有効性の問題の解決、社会的合意形成などが満たされない限り臨床応用は無責任」とする声明を公表した。一方で、基礎研究は容認している。

日本では遺伝子治療の行政指針などで受精卵の遺伝子改変の臨床応用を禁じているが法規制はない。基礎研究にも明確なルールがない。このままでは、現実が先行し、規制が後追いになる恐れがある。早急に技術の可能性と倫理的課題を整理し、法規制も視野にルール作りの検討を急ぐ必要がある。

その際には学会や日本学術会議、政府の生命倫理専門調査会などが連携して議論を進めることが大事だ。この技術と密接に関係する生殖補助医療分野の法規制も改めて考えるべきだろう。

農業・畜産分野でも品種改良への応用研究が進むが、従来型の遺伝子組み換え作物と安全面などで違いがあるか。改めて検討が必要だ。