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Article

What are the features of non-expert opinions on regenerative medicine? Opinion analysis of workshop participants

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ABSTRACT: Regenerative medicine (RM) has the potential to strongly impact on society. To determine non-experts' impressions of RM, we analyzed opinions obtained from workshops in which participants freely discussed RM. Three major features were apparent. First, non-experts were most concerned with the possible effects of RM after it has been fully realized in society. Second, non-experts expressed concerns not only about RM itself, but also about the governance and operation of the technology. Third, non-experts were not only concerned about direct influences of RM, but also about its potential indirect influences. These identified features are likely to be controversial issues when RM is introduced into society. It is important to promote early discussion of these issues by society as a whole.

1. Introduction

In this study, we focused on regenerative medicine (RM) as an example of science and technology in the early stages of introduction into society. The main objective of this study was to identify the features of RM that are of interest to non-experts. In identifying these features, we hope to determine what type of communication framework is needed to facilitate productive dialogue between experts and non-experts.

The term 'regenerative medicine' has multiple meanings.[1] In the current study, we take RM to refer to the medical technique of transplanting human cells, tissues and organs grown artificially from stem cells. The recent development of embryonic stem (ES) cells and induced pluripotent stem (iPS) cells displaying differentiation competence for several types of tissues and organs makes RM an increasingly viable future treatment. RM could resolve the problem of organ shortages and provide a cure for spinal cord injury and diabetes, neither of which can currently be cured entirely.[2] RM has the potential to solve some current medical problems and to change the use of medicine and medical prostheses, and thus constitutes an important new technology.[1]

Current research on RM aims to establish this as a viable medical technology and to introduce it into society. But RM involves stem cell research, an area of study with widely publicized ethical issues.[3,4] It is also likely that RM will have wide-ranging impacts on society. As such, it is particularly important to determine how non-experts perceive the relationship between society and RM.

Genetic engineering provides an example of a similar technology that has had a large impact on society. Genetically modified products and food have been developed for widespread use. However, public acceptance of genetically modified food in Europe has been particularly problematic[5]. The introduction of genetically modified food into the market caused controversy among stakeholders, agriculture groups, policy makers, environmental groups, citizens and industry, not only in Europe, but also in Japan and elsewhere.[6,7] This controversy is now international in scope, and continues unabated.

Since the controversy began, dialogues about genetically modified food have been held in a number of regions.[8] The experience with genetic engineering suggests that communication with the public is important in building a relationship between society and a new technology. To restore public confidence in experts, dialogues were actively conducted in England.[9,10] However, the experience from the dialogues regarding genetically modified food revealed that contention was already prevalent, suggesting that it may be too late to resolve this issue. This situation highlights the importance of discussing such problems from a variety of viewpoints before they become overly controversial and reach a stalemate.[8] In the case of genetically

modified food, it has been found that the present controversies were already identified in discussions with citizens before the conflict.[8] Listening to public opinion is important not only for building a relationship between society and new technology, but also to identify potential problems before they arise.

In the current study, we first analyzed newspaper articles on RM to determine which points of interest have already been identified. We then set up a workshop in which non-experts freely discussed RM, and analyzed the points of interest they mentioned. The objective of this study was to identify the features of non-expert opinions by comparison of these two analyses.

2. Methods

2.1 Data Collection

(1) The discourse of newspapers

The issues reported on by newspapers can be considered as already identified in society. Newspapers have an agenda-setting function.[11] Therefore, we considered the issues published in newspapers to indicate the potential agenda already identified in society. Newspapers constitute a form of media in which the opinion from an expert group, including scientists, policy makers and so on, are described. Thus, articles in newspapers tend to reflect the perspectives of an expert group. In this study, the articles about RM in newspapers were analyzed and used as the basis for evaluation of non-experts' points of interest. Because each article in a newspaper has a coherent meaning that can be identified, we treated each newspaper article as an analytic unit.

We selected Asahi-Shimbun, Mainichi-Shimbun and Yomiuri-Shimbun, as three leading newspapers in Japan, analyzing articles published in the last 3 years (2006.01.01~2009.06.10). The development of human iPS cells was reported on November 20, 2007, so there were many articles about RM between 2007 and 2008.[12,13,14,15] Using each newspaper's database we searched for articles that included the term 'saisei iryo' ('regenerative medicine') during the selected period. We found 252 articles in Asahi-Shimbun, 244 articles in Mainichi-Shimbun and 323 articles in Yomiuri-Shimbun. We eliminated articles that were not news reports, for example event announcements, book reviews and reader's columns. The final number of analyzed articles was 173 in Asahi-Shimbun, 183 in Mainichi-Shimbun and 236 in Yomiuri-Shimbun.

(2) The discourse of non-expert groups

How can we know what concerns non-experts have about RM? Recent surveys on public attitudes toward RM have been conducted as part of surveys of attitudes toward stem cell research.[16,17] Although these surveys show general trends in public attitudes toward RM, they tend to lack sufficient detail. Because these previous surveys did not cover aspects of peoples' hopes or concerns regarding RM, or the reasons underlying them, they do not enable a full understanding of the nature of current controversies or provide clues for resolving them. In addition, the questions in previous surveys tended to be based on the interests of researchers (often experts), and were thus unlikely to address the particular concerns of non-experts. To accurately identify public concerns and ensure that a sufficiently wide range of issues is covered, it is important to conduct extensive surveys regarding non-expert's opinions, expressed in their own words.

In the current study, we conducted 'opinion eliciting workshops' (WS), in which people with no expertise in RM discussed the topic freely.[18] The opinions obtained were treated as the object of analysis. Although there is diversity in the population constituting the category 'non-experts', in this study we examined a sample of mothers who were currently engaged in raising children. A sample of mothers was chosen for two reasons. First, mothers tend to have connections to various groups throughout the age range, including children and elderly people. Second, mothers have interests in the everyday aspects of science and technology, such as medical care, food and energy, through maintaining a household. The WS took the following format:

1) The required time for each WS was 2 hours.
2) The WS included five people per group with 2 groups in each WS.
3) Participants were given a 5-minute presentation.
4) Participants discussed among themselves, with discussion supported by facilitators.

The process followed at each WS was as follows:

(1) Self-introduction (5 min)
(2) Information provision (5 min)
(3) Indication of each participants opinion (written on a sticky note) (5 min)
(4) Sharing of opinions with the group and the grouping of opinions by participants.
(5) Arranging the groups of opinions by each group of participants (30 min)
(6) During steps (4) and (5), further opinions were added to the discussion by participants

In our paradigm, a single opinion written on a sticky note was treated as an individual point of interest. We collected 434 points of interest from 69 participants, obtained over seven WSs on dates from 2008.07~2009.03. The participants were aged in their 20s and 30s, and all had children under 6 years of age. According to a questionnaire survey of 30 participants, 20 (66.7%) had some knowledge of RM before the WSs.

2.2 Data Analysis

2.2.1 Creating categories by analyzing newspaper articles

Initial categories of issues were created by analyzing newspaper articles. Figure 1 shows the procedure.

Key sentences were extracted from the 127 articles in Asahi-Shimbun (2007.11.21~2009.06.10) gathered in the analysis. These sentences were arranged and grouped using the KJ method,[19] and used to create a basic framework of eight categories. All newspaper articles collected were placed into at least one of these eight categories. In general, each article was sorted into a single category, but, depending on the content, multiple selections of up to three categories could be made for an article. These eight categories were collectively termed 'categories version 1'.

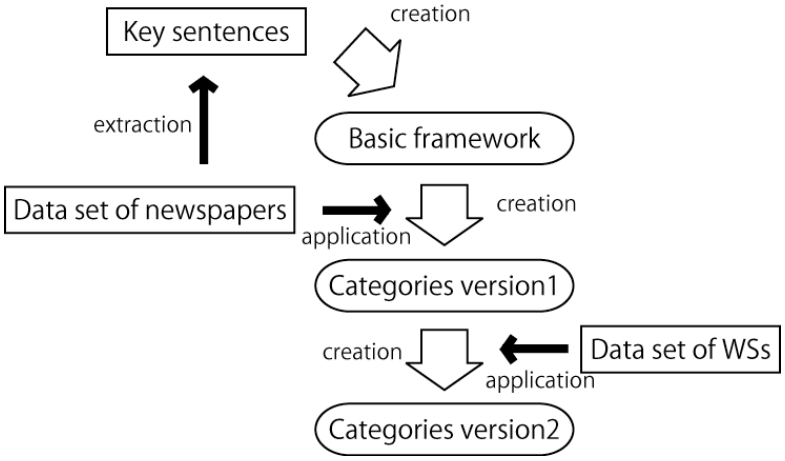

Figure 1. Procedure for creating categories.

2.2.2 Creating categories based on WSs

Next, the points of interest obtained from WSs were sorted into the eight categories to determine the differences between the types and frequency of issues reported in the WSs and newspapers. Reviewing the points of interest in the category *Others* revealed a prominent new issue regarding population. Concerns about this issue included factors related to the increasingly aging society in Japan, and population growth. This point was not identified in the newspaper articles and was not included in version 1 of the categories. As such, a new category, *Population issues,* was added. Additionally, other categories were modified and a

second version of the categories (version 2) was produced (table 1). Two researchers then classified each of the points obtained from the WSs. Inter-coder reliability (Cohen's kappa coefficient) was 0.74.

Categories	Content
Progress	Points related to RM research progress
Research environment	Points related to improvement of the research environment for RM
Ethical issues	Points related to reseach ethics, bioethics, and chaging views of the body, life and death
Economical issues	Points related to economic activity
Safety & risk	Points related to techniques of RM and the safety and risk of the techniques
Explanations	Explanations of RM
Anticipations	Points related to anticipations for RM
Population issues	Points related to population change
Others	Points of no application above

Table 1. Categories version2. The final categories and their contents.

3. Results

3.1 Quantitative analysis

(1) Comparison of distribution of points of interest

The distribution of points of interest into categories is shown in Table 2. The categories *Progress*, *Research environment*, *Safety & risk* and *Explanation* accounted for approximately 70% of all points of interest identified in newspaper articles. This shows that the newspaper articles focused on the research side of RM. All three newspapers showed this tendency.

Importantly, the points of interest identified in the WSs revealed markedly different trends to those identified in the newspaper articles (Table 2). The participants in the WSs were more concerned about *Anticipation*, *Ethical issues*, and *Safety & risk*, while few points of interest in the WSs were classified into the categories *Research environment*, *Progress* and *Explanation*.

Analysis of newspapers	Category	Analysis of opinions from WSs
231 (33.7%)	Progress	1 (0.2%)
225 (32.8%)	Research environment	5 (1.2%)
52 (7.6%)	Ethical issues	64 (14.8%)
52 (7.6%)	Economical issues	46 (10.6%)
33 (4.8%)	Safety & risk	62 (13.9%)
15 (2.2%)	Explanation	0 (0.0%)
4 (0.6%)	Anticipations	187 (43.1%)
0 (0.0%)	Population issues	15 (3.5%)
74 (10.8%)	Others	54 (12.4%)
686 (100%)	Total	434 (100%)

Table 2. Points distribution of newspaper artiche and opinions from WSs. This table shows number of points and (percentage) in each categories. Number of points of newspaper is total of Asahi-shimbun, Mainichi-shimbun and Yomiuri-shimbun.

3.2 Qualitative analysis

(1) Comparisons within categories

To indicate the features of concern to the WS participants we compared newspaper articles with the points of interest obtained from WSs within the same categories. The categories *Safety & risk*, *Ethical issues*, *Economic issues*, *Anticipations*, *Population issues* and *Others* were analyzed. However, the categories *Progress*, *Research environment* and *Explanation* were not analyzed, since an insufficient number of points of interest obtained in the WSs.

Safety & risk

The major topics covered in newspaper articles classified in the *Safety and Risk* category included canceration and improvements in the methods for producing iPS cells. The articles focused on problems arising from the research and development phase, for example the production of iPS cells.

Topics covered in the points of interest obtained from the WSs were almost all concerns about technical aspects of RM and questions about RM (Table 3). Two major features were identified in the WS participant's concerns.

The first feature was a tendency for WS participants to take a perspective that assumed that they, or their acquaintances, would undergo or had already undergone RM treatment, while newspaper articles were written from the perspective of research and development of RM. For example, the comments "I worry whether I can recover to my original and natural state" and "Will the new tissues connect well to my original body, and not affect my appearance?" (Table 3) are based on this standpoint taken by WS participants.

The second feature related to quality of life (for example, the comment "Even if rejection doesn't occur, will the appearance, for example coloration and texture, be okay?"; Table 3) and to identity (for example, the comment "I would be afraid to have my brain treated [with RM] because it could change my personality"; Table 3). While *Safety & risk* assessments in newspapers assumed that human lives might be threatened by RM, the points classified *Safety & risk* identified in WSs assumed that not only was life threatened, but also appearance and identity.

I worry about side effects.
I'm afraid of side-effects arising a few years after the treatment.
I worry whether I can recover to my original and natural state.
Will the new tissues connect well to my original body, and not affect my appearance?
Even if rejection doesn't occur, will the appearance, for example coloration and texture, be okey?
I would be afraid to have my brain treated (with RM) because it could change my personality.

Table 3. Examples of the opinions obtained from the WS-Safety&risk- Original data are in Japanese. Authors translated into English.

Ethical issues

In newspaper articles, ethics were usually referred to in the context of the ethics of data fabrication and bioethics related to the use of fertilized eggs. Mention of data fabrication was generally in reference to the actions of Professor Hwang in Korea. Most articles related to bioethics took the tone that ethical issues related to the use of fertilized eggs were avoided by the improvement in methods with iPS cells. These articles also illustrated a new ethical issue related to the creation of gamete cells from iPS cells.

The dominant tone of the newspaper articles was that ethical issues had largely been avoided. In contrast, participants of the WSs discussed ethical issues related to changing lifespan, changing values, cloning, and excessive dependence on technology resulting from changes in the conception of life (Table 4). These topics are less related to the ethical issues involved in research procedures, and more closely tied to the ethical issues that will be faced by society if RM comes into general use. These points (Table 4) also suggest that participants in the WSs felt some kind of confusion and repulsion toward new technology and changes in the conception of life.

Changing lifespan
Will people become immortal?
Can people change their lifespan with the operation?
Cloning
When human clones can be produced, people will be priced and ranked.
What about human rights and dignity of artificial human?
Changing values
We will treat the value of life as unimportant.
I'm afraid all people as well as healthcare workers will lose respect for life.
Excessive dependence on technology as a result of changes in the sense of life
People may not take good care of their bodies, if anything can be regenerated.
I think people will have a diminished awareness of healthcare if their body can be regenerated.

Table 4. Examples of the opinions obtained from the WS –Ethical issues – Topics are written in bold and examples are given below them. Original data are in Japanese. Authors translated them into English.

Economic issues

In general, newspaper articles focused on the commercialization of RM. For example, newspapers included reports about a private company that obtained approval to sell tissue-engineered skin, and points of interest mainly related to patent issues (2007.08.24 in Asahi-Shimbun and Yomiuri-Shimbun). In contrast, the points of interest raised in the WSs concerned the potential influence of RM on daily life after it was commercialized. For example, participants identified medical costs, health disparity, and the commercialization of the human body as points of concern (Table 5). Concerns about medical costs and health disparity suggest that participants regarded themselves as potential users of RM. In addition, participants' comments revealed that they were concerned that RM technology may be available only to wealthy people. The topic of the commercialization of the human body included worries about the misuse of new technology increasing the organ trade. These points of interest appear to largely constitute concerns about management and regulation rather than the safety of RM technology itself.

Many points of interest identified in WSs related to the potential impact of RM on daily life after it is put into practical use and commercialized, especially the possible effects on the daily lives of participants themselves. However, some points raised in the WSs referred to the shakeout of jobs due to the creation of a new industry. This revealed that participants were concerned about the wider implications for society as well as the direct impacts on themselves.

Medical costs
Is it too expensive?
It's likely that medical cost is too high.
I worry about health disparity.
Health disparity
Because of the high cost, will only rich people have access to it?
It might be abused by those who have power and a lot of money.
Commercialization of human body
Fear of organ trade.
Risk of cell commercialization, such as cell trade.
Others
If organs can be regenerated, organ trafficking may stop.
Increasing the transplantation business.
Are some workers made redundant by it, for example dental mechanics?

Table 5. Examples of the opinions obtained fromt he WS-Economical issues - Topics are written in bold and examples are given below them. Original data are in Japanese. Authors translated them into English.

Anticipations

Although only a small number of points of interest in the newspaper articles fell into this category, it was the most common category for points of interest raised in the WSs. In the points of interest identified in the WSs, participants specifically described how they would like to use RM technology, for example, comments included "I want to erase my spots", "I hope we can grow limbs back, if people lose them in an accident," and "regeneration of organs lost because of cancer." (Table 6).

Regeneration of teeth.
I want to erase my spots.
I want a better cure for my father's baldness.
Regeneration of aging parts.
I want to rejuvenate by regenerating my skin.
I hope we can grow limbs back, if people lose them in an accident.
To cure congenital handicaps.
Regeneration of organs lost because of cancer.

Table 6. Examples of the opinions obtained from the WS-Anticipations – Original data are in Japanese. Authors translated them into English.

Population issues

This category was seen only at WSs. The main topics were acceleration of demographic aging and population growth (Table 8).

Others

In the newspapers, topics such as the development of RM abroad and the work of Dr. Yamanaka were included in the category *Others.* Topics obtained from the WSs included vague anxiety, the extent to which RM should be used, arguments against the use of RM for cosmetic purposes, and the concern that people could become almost entirely dependent on RM (Table 7).

Vague anxiety
Where are we going from here?
The extent to which RM should be used
I don't think that beauty treatments should be given as well as care for disease.
How should we draw a line between cure and operations to enhance lifespan?
Arguments against the use of RM for cosmetic purposes
Why are you hung up on youthful looks?
I think eternal youth is unnatural.
Concerns about depending almost entirely on RM
Could people come to use RM needlessly?
I'm concerned that people would replace anything using RM.

Table 7. Examples of the opinions obtained from the WS-Other – Topics are written in bold and examples are given below them. Original data are in Japanese. Authors translated them into English.

The aging population is rapidly increasing.
If regeneration of organs allows elderly people to live a long time, increasing numbers of elderly people will cause other social issues.

Table 8. Examples of the opinions obtained from the WS-Population issues – Original data are in Japanese. Authors translated the minto English.

Research environment
Development of laws regarding RM.
How will personal information about individuals cells be managed?
Progress
It will take more time for RM to be useful than I hope.

Table 9. Examples of the opinions obtained from the WS-Research environment and Progress- Categories are written in bold and examples are given below them. Original data of examples are in Japanese. Authors translated the minto English.

4. Discussion

The present results indicated clear differences between the points of interest raised by newspaper articles and those identified the WSs in each category. In this section, we discuss the features of non-expert opinions, especially the features that were apparent across several categories.

4.1 Time frame: before or after introduction to wider society

The results of the quantitative and qualitative analyses suggest that non-experts were concerned about how their society, their families and themselves, would be affected if the practical use of RM became widespread. This differs markedly from the points raised in newspaper articles, which focused mainly on the current progress of RM studies toward the practical use of RM.

We propose that, because the non-experts imagine themselves as potential 'users' of RM, they are interested in issues concerning fully realized RM technology. In contrast, newspaper articles discuss RM from the standpoint of development and promotion, or, in other words, issues concerning RM before it is fully realized. RM as thought of by non-experts and RM as portrayed in newspaper articles thus have different 'time frames'.[20]

4.2 The object of anxiety: technology or governance and operation

The points of interest reported in newspaper articles tended to be mainly points of fact, whereas in the WSs many of the points of interest expressed anxieties or asked questions. This is mainly because non-experts do not have sufficient knowledge about RM to express facts. But the anxieties and questions they have may not necessarily be resolved if they are given detailed factual knowledge about RM. Many of the non-experts' anxieties and questions cannot be given clear scientific answers, such as issues related to long-term influences and values such as a changing conception of life.

The results also revealed that participants were worried not only about technical safety problems but also about the governance and operation of RM after it is introduced into society (tables 3 and 9). The points "How will personal information about individuals' cells be managed?" in the category of *Research environment* and "RM technology won't be used wrongfully, will it?" in the category of *Economic issues* demonstrate that non-experts are worried about the governance and operation of RM technology, not just the safety of RM technology itself. A tendency for concern not only about technology, but also about governance and operation is also seen in non-expert opinions of GM technology and nuclear power as well.[21,22,23]

4.3 The extent of influence of RM: direct and indirect

Non-expert points of interest with RM are closely related to values such as changes in the conception of life (Table 4.) and the encouragement of the perspective of eugenics (for example, cures for congenital disorders (Table 6.) and the production of clones of brilliant people (Table 4.)). While experts tend to emphasize technical aspects of RM, for example safety, efficiency and efficacy, non-experts were concerned not only about the direct influence (risk and efficacy) of introducing RM into society, but also the indirect influence on society and its values. Non-experts were also more interested in the changes in society RM may produce if it is widely applied. Furthermore, this interest emerges from a more basic concern about the changes RM may have on the individuals' own lives. This notion is further supported by the finding that points in the category of *Population issues* arose only in WS, and not in newspaper articles. To summarize, non-expert participants were concerned most with the vision for the future. This concern is succinctly expressed by the comment "Where are we going from here?" (Table 7).

5. Moving forward

In this study, we analyzed the opinions obtained from WSs where mothers of young children gave their opinions on RM, as non-experts. It should be considered that this sample constitutes only one group in society, being entirely female, and may not be representative of all non-experts. Nevertheless the group represents a meaningful target of analysis, providing an important perspective among a variety of standpoints of non-experts.

This study revealed that some non-expert points of interest regarding RM were related to values that cannot be determined scientifically. The point of interest 'the extent to which RM should be used', for example, is associated with the perspective of safety, efficiency and economy, but can be considered more of a normative issue related to values. According to Klinke and Renn, in dealing with conflicts over cognitive, evaluative and normative issues, the main task is to find a balance between differing values[24,25]. This task cannot be delegated to technical risk specialists only, but requires the inclusion of scientists, policy makers, stakeholders and the general public. Thus discussion with various actors, particularly non-experts, is needed to determine the opinions of the public.

In this study, we found that the opinions obtained from WSs were different from the points presented in newspaper articles on RM. If RM is introduced into society, it is important to identify the broad range of perspectives on RM, and to present these to wider society. It is expected that the points of interest mentioned by non-experts in this study will become hot topics as society moves closer to the full realization of the practical application of RM. This is because they include the points seen in public responses to GMO and nuclear technology, which led to widespread controversy in society. For example, in the case of GMO technology, one public concern was 'the wider effects on the agricultural industry and on the countryside'.[26] This can be considered a political question about the balance of power between agribusiness, the small farmer and the consumers, not a scientific question about the effects of GMOs on human health or the environment.[26,27] However, this issue was often grouped with scientific questions about environmental or health consequences.[27] A report titled 'Science and Technology' released by the House of Lords in the United Kingdom, stated that "Some issues currently treated by decision-makers as scientific issues in fact involve many other factors besides science. Framing the problem wrongly by excluding moral, social, ethical and other concerns invites hostility."[27] As discussed in sections 4-2 and 4-3 above, non-experts showed a tendency to express concerns about not only technical safety but also issues including many other factors besides science. In the case of RM, if experts treat these issues as only scientific issues, public discourse surrounding RM may follow the same course as GMO.

To avoid this situation, discussion is needed with the public, including the perspectives of non-experts. As Wilsdon and Willis proposed based on the experience of BSE and GMO, new initiatives from the upstream stage during technological development are also needed[28]. According to their report, upstream questions, such as 'Why this technology?' 'Who is controlling it?' 'What will it mean for me and my family?' and so on, constitute public concerns. To address these concerns, it is necessary to discuss such upstream questions.[28] To make upstream engagement worthwhile, we consider it important that not only society has changed with arranging regulations, but also science and technology changes reflecting discussions with public and public concerns in some cases. Such a relationship will contribute to building a trusting relationship.

To identify and discuss these issues before problems arise, a program of dialogue is needed.[8] These programs should be begun as soon as possible to avoid the problems that plagued the acceptance of genetic engineering in Europe and Japan, since the science and technology underlying these issues is developing rapidly. An important challenge for the future is to design a system to relay the points of interest and opinions of non-experts obtained from such dialogue programs to experts, to generate productive social debate.

To gather non-experts' opinions, we designed WSs at which non-experts could freely discuss RM. These WSs have the capability not only to identify the concerns held by non-expert groups about RM, but to give non-experts a chance to learn about the potential challenges of the new technology. In these WSs, the participants themselves identified some problems related to science that did not have clear right or wrong answers. In asking questions such as "To what extent should we use RM?", non-experts showed that they recognized the ambiguity of science and the existence of 'trans-science', or questions that science alone cannot answer[29]. We believe that this discussion among non-experts can result in emergent social learning place, and that dialogue programs for the purpose of social learning are essential for building the relationship between science and society in the future.

6. Conclusion

In order to identify the features of non-expert interest in RM, we analyzed the points of interest in newspaper articles and the points of interest obtained from non-expert workshops. Our results showed differences between the points already identified by newspaper articles and the points of interest of non-experts. We identified three major features in non-experts' perspectives of RM. The first was that non-experts expressed concern about the potential effects of RM once it becomes realized and widely used. The second feature is that non-experts expressed anxieties not only about RM itself, but also about the governance and operation of the technology. The last feature is that non-experts were concerned about not only the direct influences of RM, but also the indirect influences. Some of these features were also seen in discussions about GMO and nuclear technology. To avoid repeating these conflicts, discussion about these issues framed by the public with various actors, including non-experts in wider society, are required. In addition, it will be important to build a partnership between science, technology, and society through these discussions.

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