



[原著]

## Research on information to be handled in pharmaceutical education for regenerative medicine products based on a consciousness survey involving board-certified oncology or senior oncology pharmacists

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### Summary

We reviewed the field of regenerative medicine products to be focused on in pharmaceutical education based on the results of a questionnaire survey, and made a proposal. The subjects of this questionnaire survey consisted of students belonging to the Faculty of Pharmaceutical Sciences Doctoral Course of Tokyo University of Pharmacy and Life Sciences (FPS-DC-TUPLS students) and Japanese Society of Pharmaceutical Health Care and Sciences (JSPHCS)-certified Board certified Senior Oncology Pharmacist (BCSOP) and Board certified Oncology Pharmacist (BCOP). As a concrete example, we evaluated the importance of the information described in the package insert of a regenerative medicine product, Kymriah<sup>®</sup>. Importance assessment in 5 grades was adopted. We analyzed differences in the points of view for evaluating information between the two groups, and prepared a proposal to fulfill pharmaceutical education.

We compared the median value on importance assessment between BCSOP and/or BCOP and FPS-DC-TUPLS students. For a portion of the information on adverse reactions to Kymriah<sup>®</sup>, the rate of BCSOP and/or BCOP who scored 5 was significantly higher than that of FPS-DC-TUPLS students. In addition, for a portion of the information on the adverse reactions, the rate of mid-level BCSOP and/or BCOP, with a career of 11 to 20 years, who scored 5 was significantly higher than that of FPS-DC-TUPLS students.

These results suggested that FPS-DC-TUPLS students underestimate the importance of information on adverse reactions. For pharmaceutical education on regenerative medicine products, information on adverse reactions should be sufficiently explained to pharmacy students at the opportunity of clinical training.

**Keywords:** Regenerative Medicine Product, BCSOP, BCOP, Package Insert, Pharmaceutical Education, Gap analysis

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### Introduction

With respect to the environment surrounding regenerative medicine products, advances in technological development and legislation have facilitated clinical research and treatment in many fields. Regenerative medicine products are manufactured and sold after inspection by regulatory authorities, as indicated for drugs. As a law associated with the application of regenerative medicine products for approval, the “Ordinance on Good Laboratory Practice regarding the safety of regenerative medicine products” was released in 2014, and regulations on the quality of the safety test to be attached to materials for approval application were established (1). In 2016, “technological guidance for the quality of regenerative medicine products (processed human cell products) and implementation of non-clinical and clinical studies” was issued, and quality control strategies for processed human cell products and precautions for the implementation of non-clinical and clinical studies were determined (2). According to these laws, data are collected for the application of regenerative medicine products for approval. As of December 2022, 15 regenerative medicine products are commercially available in Japan (3). In the future, new products may be further developed in this field.

Among regenerative medicine products, there are some products of which the features resemble those of drugs. Therefore, pharmacists may also handle regenerative medicine products. For example, “Kymriah<sup>®</sup> suspension for intravenous infusion (Kymriah)” is used as a single intravenous dose to treat recurrent or refractory CD19-positive B-cell acute lymphoblastic leukemia and recurrent or refractory CD19-positive

diffuse large B-cell lymphoma (4). Kymriah has an effect via systemic circulation, which resembles the action mechanism of drugs. However, the interval after regenerative medicine products became commercially available is short in comparison with drugs; therefore, the handling of these products in pharmaceutical education has not been sufficiently established. In our university, the handling of these products in pharmaceutical education is also extremely limited to lectures.

Pharmaceutical education must educate high-quality pharmacists acquiring the abilities necessary for clinical practice. It is important to learn clinical practice through opportunities, such as internship, for world-wide pharmaceutical education (5). Internship-based experience involves all pharmacists’ activity fields, promoting pharmacy students’ growth (6). However, in Japan, the necessity of enhancing clinical training before and after graduation from university has recently been reviewed belatedly in the field of pharmaceutical education (7). Thus, to achieve the social mission of pharmaceutical education, it is important to incorporate opinions from medical settings. Concerning drugs, many studies to confirm opinions from medical settings using a questionnaire survey have been conducted. Various studies, such as a questionnaire survey on the contents of information that hospital/insurance pharmacy pharmacists ask pharmaceutical companies to disclose (8) and a consciousness survey on the usability/convenience of drug information provision on the home pages of pharmaceutical companies (9), are progressing. The outcomes of these studies are reflected by pharmaceutical

education on drugs, and pharmaceutical education to develop human resources as pharmacists required by medical settings is being expanded. However, few questionnaire surveys on regenerative medicine products involving clinical settings have been conducted. A small number of questionnaire surveys on regenerative medicine products involved the general population, being social consciousness surveys regarding an impression on treatment with such products (10, 11).

The purpose of this study was to clarify priority issues of regenerative medicine products to be handled in pharmaceutical education. We conducted a questionnaire survey on the importance of the information described in the package insert of a regenerative medicine product involving pharmacy students and hospital pharmacists, and analyzed differences between the two groups. If the results of this study reveal differences in the points of view between pharmacy students and hospital pharmacists, it may become possible to establish pharmaceutical education to fill the gap. Through such a step, we proposed pharmaceutical education necessary for pharmacists who handle regenerative medicine products. This study may contribute to patients' advantages by producing high-quality pharmacists required in clinical practice.

### Materials and Methods

On a questionnaire survey on the information described in the package insert of a regenerative medicine product, we adopted the package insert of Kymriah (12) as a concrete example. Kymriah has features resembling those of drugs, and may be handled by pharmacists. The subjects of this questionnaire survey were Japanese

Society of Pharmaceutical Health Care and Sciences (JSPHCS)-certified Board certified Senior Oncology Pharmacist (BCSOP) and Board certified Oncology Pharmacist (BCOP) who may handle Kymriah. They were requested to participate in this questionnaire survey by e-mail based on the e-mail addresses published on the Web page for JSPHCS members. On the request e-mail, the purpose and contents of this study were described, and explained to the responders. The responders were requested to input responses to the questionnaire using formrun (Basic Inc.), and the responses were collected via the Web. The survey period was from January 8, 2022, until February 22, 2022. A similar questionnaire survey was conducted involving all students belonging to the Faculty of Pharmaceutical Sciences Doctoral Course of Tokyo University of Pharmacy and Life Sciences (FPS-DC-TUPLS students). The survey period was from January 27, 2022, until March 4, 2022. Concerning the contents of the questionnaire, we adopted a response system to evaluate "the importance of information on each item described in the package insert" and "the importance of concrete information described in the package insert" in 5 grades (Table 1). Responders were instructed to grade from: 1 to 5 in accordance with the importance of information (5: the most important, 1: the least important). The median of the responses obtained was expressed as a radar chart (Figs. 1 and 2). The rate of responders evaluating the importance as 5 was expressed as a percentage (Figs. 3 and 4). The results of this questionnaire survey were compared between BCSOP and/or BCOP and FPS-DC-TUPLS students using PASW<sup>®</sup> Statistics 17.0 software (IBM Japan Service Company Ltd.). The Kruskal-

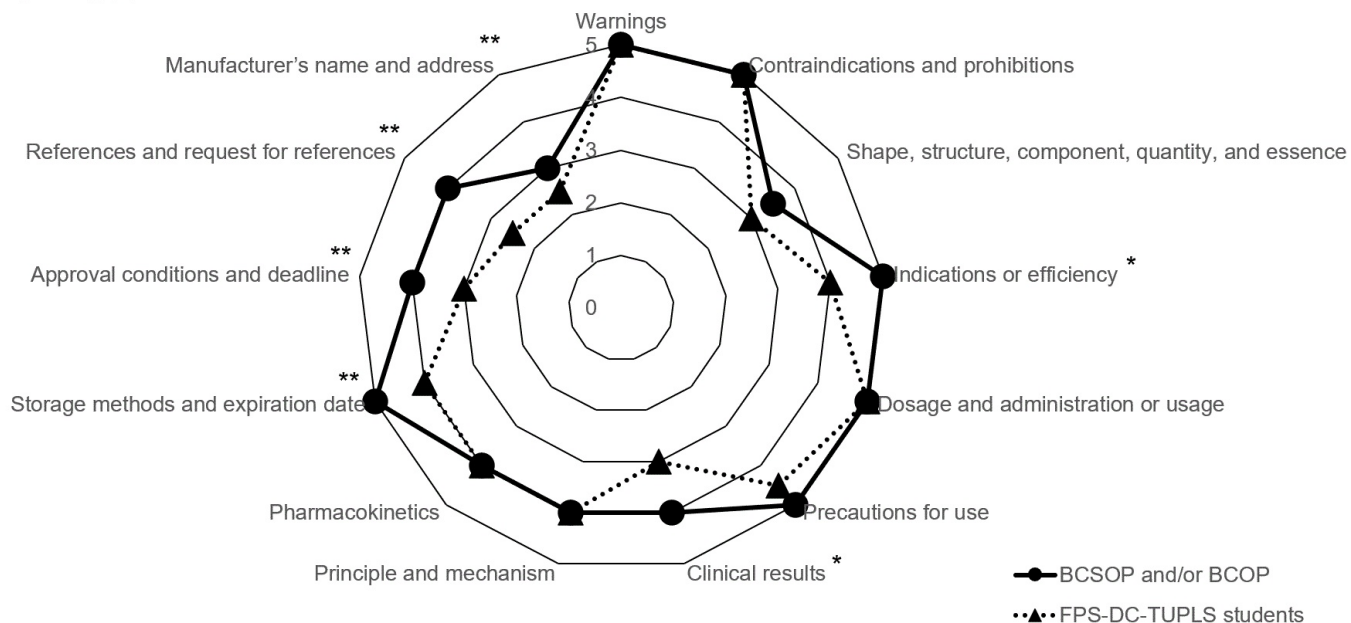
Table 1 Questionnaire associated with the package insert of a regenerative medicine product

Question A: Please select the importance of information on each item described in the package insert of Kymriah (5-grade assessment).	
1. Warnings	8. Principle and mechanism
2. Contraindications and prohibitions	9. Pharmacokinetics
3. Shape, structure, component, quantity, and essence	10. Storage methods and expiration date
4. Indications or efficiency	11. Approval conditions and deadline
5. Dosage and administration or usage	12. References and request for references
6. Precautions for use	13. Manufacturer's name and address
7. Clinical results	
Question B: Please select the importance of the following information described in the package insert of Kymriah (5-grade assessment).	
1. It is necessary to confirm a CD19-positive reaction by flow cytometry.	8. Incidence of neuropathy in clinical trials
2. Dose for lymphocyte depleting chemotherapy before Kymriah administration	9. Breakdown of neuropathy events in clinical trials
3. Information on stability (Intravenous administration must be completed within 30 minutes after thawing.)	10. Incidence of infectious diseases in clinical trials
4. If hypo- $\gamma$ -globulinemia appears, management, such as immunoglobulin supplementation, should be performed.	11. Incidence of hypo- $\gamma$ -globulinemia in clinical trials
5. As bone marrow suppression may occur, a blood test must be regularly conducted.	12. Incidence of bone marrow suppression in clinical trials
6. Information on adverse reactions in Japanese patients in clinical trials	13. Incidence of tumor lysis syndrome in clinical trials
7. Concrete symptoms of cytokine release syndrome	14. Incidence of infusion reactions in clinical trials
	15. In CR-/CRi-achieving patients, the CAR gene is detected for a long period ( $\geq 548$ days).
Question C*: Please let us know about your attribute information.	
1. Please select your career as a hospital pharmacist. (years).	Option: 0-100 years
2. Please select your position.	Option: Managerial position, non-managerial position
*Question C was established only for the questionnaire survey involving BCSOP and/or BCOP.	

Kruskal Wallis

\*  $P < 0.05$

\*\*  $P < 0.01$



**Figure. 1** Assessment of the importance of each item in the package insert of a regenerative medicine product

On this questionnaire survey, responses were obtained using a 5-grade assessment: 5 (importance: high) to 1 (importance: low). Responses from BCSOP and/or BCOP and FPS-DC-TUPLS students were collected, and the median on importance assessment for each item in the package insert is expressed as a radar chart.

Wallis or Pearson's chi-square tests were performed. A p-value of 0.05 or 0.01 was regarded as significant. When test multiplicity-related p-value correction is necessary, Bonferroni's method was used.

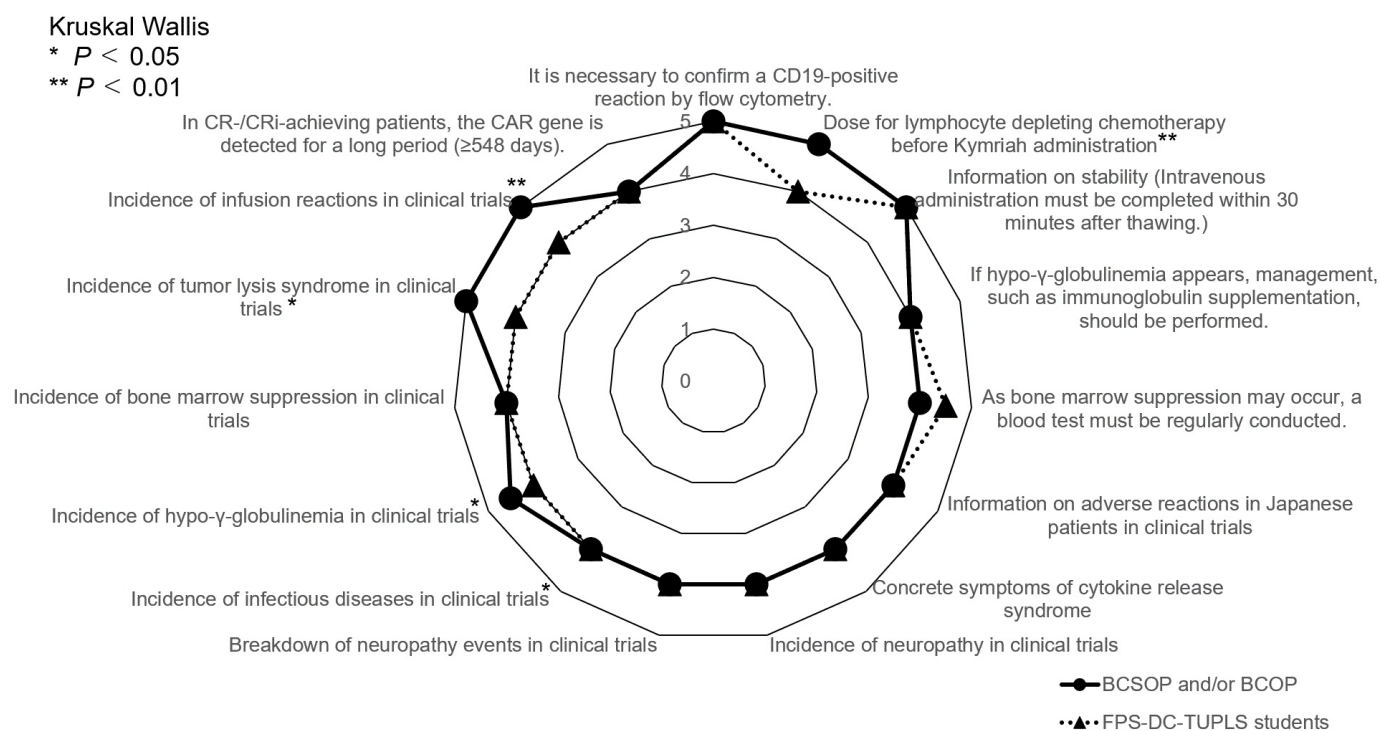
Prior to this study, its protocol was approved by the Human Subjects Research Ethics Review Committee, Tokyo University of Pharmacy and Life Sciences (Receipt No.: JINI-2021-014). Furthermore, we inquired of the Japanese Society of Pharmaceutical Health Care and Sciences whether the e-mail addresses published on the Web page for the JSPHCS members may be used for the purpose of research. In addition, the e-mail addresses were used based on judgment by the Ethics Review Committee of our university.

## Results

### 1) Assessment of the importance of each

item described in the package insert of a regenerative medicine product

We requested 422 BCSOP and/or BCOP to participate in a Web questionnaire survey by e-mail. Responses were obtained from 50. When confirming their career as a hospital pharmacist, they consisted of 11 with a  $\leq 10$ -year career (young BCSOP and/or BCOP), 28 with an 11- to 20-year career (midcareer BCSOP and/or BCOP), and 11 with a  $\geq 21$ -year career (veteran BCSOP and/or BCOP). Fifty-three FPS-DC-TUPLS students were requested to participate in a Web questionnaire survey by e-mail. Responses were obtained from 30. We conducted a survey to evaluate the importance of the information described in each item of the package insert of Kymriah as an example (Fig. 1). We compared the median on importance assessment between the



**Figure. 2** Assessment of the importance of concrete information described in the package insert of a regenerative medicine product

On this questionnaire survey, responses were obtained using a 5-grade assessment: 5 (importance: high) to 1 (importance: low). Responses from BCSOP and/or BCOP and FPS-DC-TUPLS students were collected, and the median on importance assessment for concrete information described in the package insert is expressed as a radar chart.

BCSOP and/or BCOP and FPS-DC-TUPLS students. In 6 of 13 items in the package insert, the values in the BCSOP and/or BCOP were significantly higher than in the FPS-DC-TUPLS students. There were no items in which the value in the FPS-DC-TUPLS students was significantly higher than in the BCSOP and/or BCOP. In the item “References and request for references”, there was the most marked difference in the median on importance assessment between the BCSOP and/or BCOP and FPS-DC-TUPLS students (difference: 1.5 points), followed by the items “Indications or efficiency”, “Clinical results”, “Storage methods and expiration date”, and “Approval conditions and deadline” (difference: 1 point).

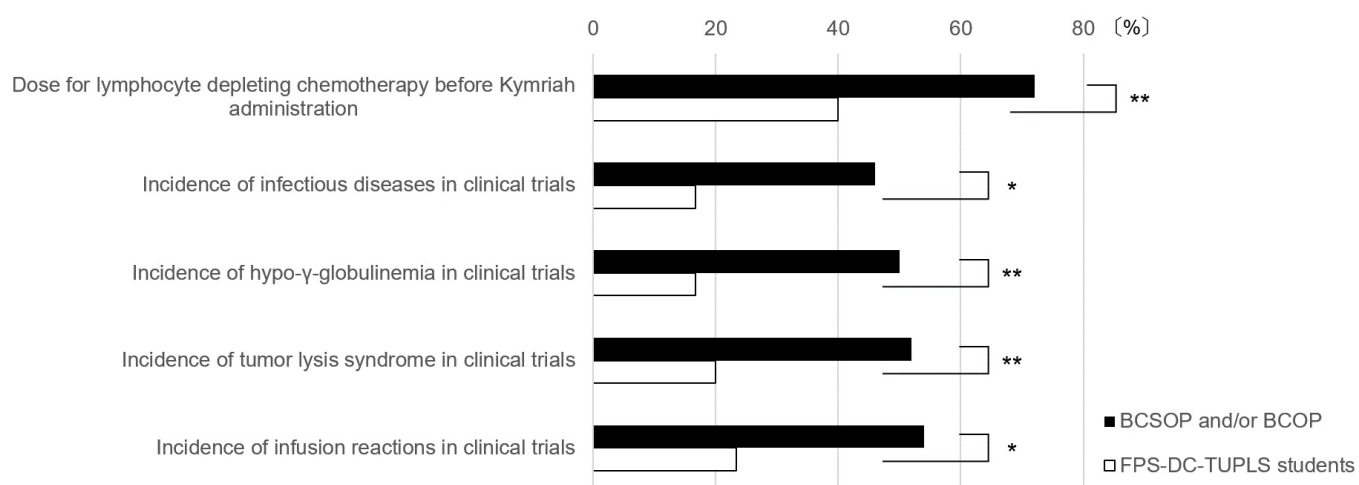
## 2) Assessment of the importance of concrete information described in the package insert of a regenerative medicine product

We conducted a survey to evaluate the importance of concrete information described in the package insert of Kymriah (Fig. 2). We compared the median on importance assessment between the BCSOP and/or BCOP and FPS-DC-TUPLS students. Concerning 5 items, the values in the BCSOP and/or BCOP were significantly higher than in the FPS-DC-TUPLS students. Of these, 4 involved data from clinical trials. Next, with respect to the 5 items, we analyzed the rate of responders who scored 5 (importance: high) (Fig. 3). As a result, concerning all items, the rate of BCSOP and/or BCOP who scored 5 (importance:

Pearson's chi-square test

\*  $P < 0.05$

\*\*  $P < 0.01$



**Figure. 3** Rate of responders who scored 5 for concrete information described in the package insert of a regenerative medicine product

The importance of clinical trial information described in the package insert was evaluated. On this questionnaire survey, responses were obtained using a 5-grade assessment: 5 (importance: high) to 1 (importance: low). The rate of those who scored 5 is expressed as a percentage of BCSOP and/or BCOP or FPS-DC-TUPLS students.

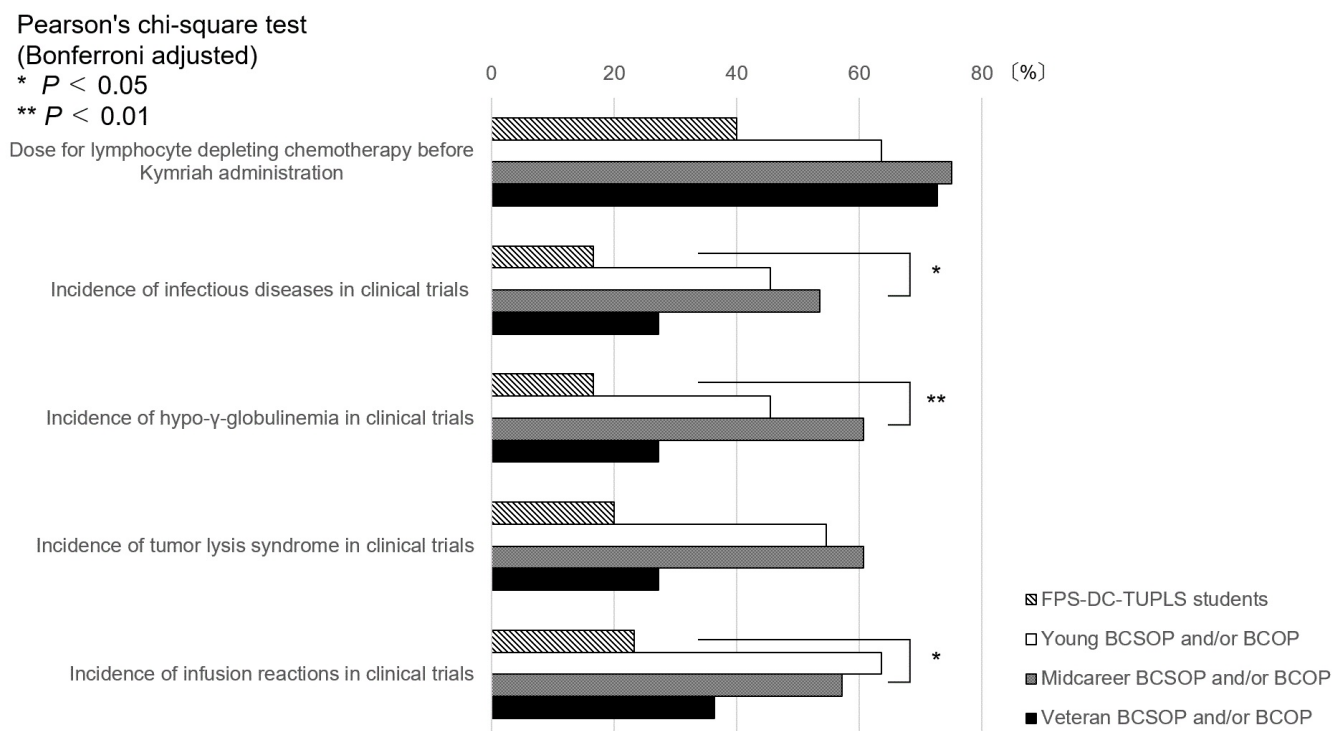
high) was significantly higher than that of FPS-DC-TUPLS students. There was the most marked difference in the rate of those who scored 5 for the information “Incidence of hypo- $\gamma$ -globulinemia in clinical trials”. According to this information, the rate of FPS-DC-TUPLS students who scored 5 was 17%, whereas that of BCSOP and/or BCOP was 50%; the latter was about 3 times higher.

3) Influence of the length of work experience on the results of importance assessment for information in the package insert

Concerning the above 5 items with significant differences, as shown in Figure 2, we analyzed the rate of BCSOP and/or BCOP who scored 5 with respect to the length of work experience (Fig. 4). The hospital pharmacist’s career was categorized by 10 years: young BCSOP and/or BCOP with a  $\leq 10$ -year career, midcareer BCSOP and/or BCOP with an 11- to 20-year career, and veteran

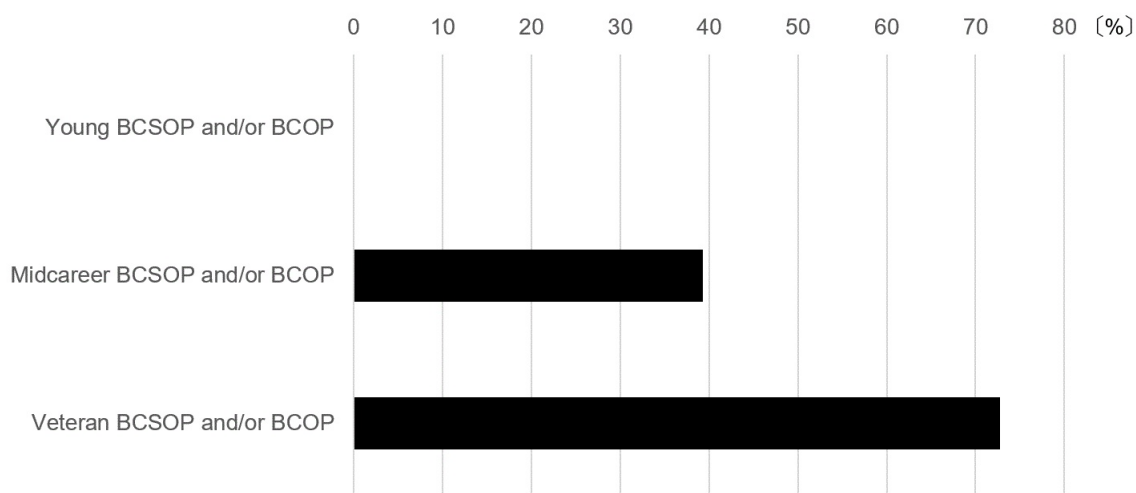
BCSOP and/or BCOP with a  $\geq 21$ -year career. The rates of midcareer BCSOP and/or BCOP who scored 5 for “Incidence of infectious diseases in clinical trials”, “Incidence of hypo- $\gamma$ -globulinemia in clinical trials”, and “Incidence of infusion reactions in clinical trials” were significantly higher than those of FPS-DC-TUPLS students. Excluding “Incidence of infusion reactions in clinical trials”, the rate of those who scored 5 was the highest in midcareer BCSOP and/or BCOP, followed in order by young BCSOP and/or BCOP and FPS-DC-TUPLS students. The rate of those who scored 5 for “Incidence of infusion reactions in clinical trials” was the highest in midcareer BCSOP and/or BCOP, followed in order by young BCSOP and/or BCOP, veteran BCSOP and/or BCOP, and FPS-DC-TUPLS students. Concerning all information, the rate of veteran BCSOP and/or BCOP who scored 5 was lower than that of





**Figure. 4** Results of importance assessment for information in the package insert and length of BCSOP and/or BCOP' work experience

The importance of clinical trial information described in the package insert was evaluated. On this questionnaire survey, responses were obtained using a 5-grade assessment: 5 (importance: high) to 1 (importance: low). The rate of those who scored 5 is expressed as a percentage of FPS-DC-TUPLS students, BCSOP and/or BCOP with a  $\leq 10$ -year career (young BCSOP and/or BCOP), those with an 11- to 20-year career (midcareer BCSOP and/or BCOP), or those with a  $\geq 21$ -year career (veteran BCSOP and/or BCOP).



**Figure. 5** Rate of BCSOP and/or BCOP working in a managerial position

On this questionnaire survey, responders' attributes were investigated using a selection system from managerial and non-managerial positions. The rate of those working in a managerial position in BCSOP and/or BCOP with a  $\leq 10$ -year career (young BCSOP and/or BCOP), those with an 11- to 20-year career (midcareer BCSOP and/or BCOP), and those with a  $\geq 21$ -year career (veteran BCSOP and/or BCOP) is expressed.



midcareer BCSOP and/or BCOP. Next, we confirmed the ratio of responders working in a managerial position (Fig. 5). As a result, no young BCSOP and/or BCOP was working in a managerial position. In the midcareer BCSOP and/or BCOP, the rate of those working in a managerial position was 39%. This rate was the highest (73%) in the veteran BCSOP and/or BCOP.

### Discussion

A questionnaire survey on importance assessment for the information described in the package insert of a regenerative medicine product was conducted involving BCSOP and/or BCOP and FPS-DC-TUPLS students. The importance of the information described in each item of the package insert of Kymriah as an example was evaluated. We compared the median on importance assessment between the BCSOP and/or BCOP and FPS-DC-TUPLS students. In 6 of 13 items in the package insert, the values in the BCSOP and/or BCOP were significantly higher than in the FPS-DC-TUPLS students. There was no item in which the value in the FPS-DC-TUPLS students was higher than in the BCSOP and/or BCOP. In the package insert, important information is described, but the results showed that information in the package insert was emphasized in clinical settings beyond the FPS-DC-TUPLS students' consciousness. In the item "References and request for references", there was the most marked difference in the median on importance assessment between the BCSOP and/or BCOP and FPS-DC-TUPLS students. There are various regenerative medicine products, and case-by-case management involving usage and an expiration date is required. In a survey asking pharmacists what they would do if they encountered a

clinical doubt, 79% of pharmacists chose to contact the pharmaceutical company (13). BCSOP and/or BCOP with clinical experience highly evaluated the importance of the contact information described in the "References and request for references", possibly because the necessity of asking for information is high. In the item "Indications or efficiency" among the items of the package insert, the difference in the median on importance assessment between the BCSOP and/or BCOP and FPS-DC-TUPLS students was the second most marked, followed by the items "Clinical results", "Storage methods and expiration date", and "Approval conditions and deadline". Next, we conducted a survey to evaluate the importance of concrete information described in the package insert of Kymriah. We compared the median on importance assessment between the BCSOP and/or BCOP and FPS-DC-TUPLS students. Concerning 5 items, the values in the BCSOP and/or BCOP were significantly higher than in the FPS-DC-TUPLS students. Of these, 4 involved data from clinical trials.

As shown in Figures 1 and 2, there were significant differences in the importance of clinical trial information between the BCSOP and/or BCOP and FPS-DC-TUPLS students. The BCSOP and/or BCOP may have evaluated the importance of data from clinical trials by adding their work experience in clinical settings to materials for judgment. To analyze how weighting of information is performed when BCSOP and/or BCOP or FPS-DC-TUPLS students evaluate data from clinical trials, we investigated the rate of responders who scored 5 for the information with a significant difference as shown in Figure 2. As a result, for the item "Incidence of hypo- $\gamma$ -globulinemia in

clinical trials”, the difference in the rate of responders who scored 5 was the most marked. The rate of FPS-DC-TUPLS students who scored 5 was 17%, whereas that of BCSOP and/or BCOP who scored 5 was 50%; the latter was about 3 times higher. The other information described in the package insert, with significant differences as shown in Figure 2, included clinical trial information, such as infectious disease, tumor lysis syndrome, and infusion reactions. For all information, the rate of BCSOP and/or BCOP who scored 5 was higher than that of FPS-DC-TUPLS students. Infectious diseases (14) and tumor lysis syndrome (15) may lead to serious outcomes, including death. Hypo- $\gamma$ -globulinemia may induce serious infection, resulting from a decrease in the immunoglobulin level (12). Infusion reactions include pruritus, exanthema, fever, chills, nausea, and dyspnea (12). BCSOP and/or BCOP have high-level awareness of crisis for these symptoms through their work in clinical settings, and information on symptoms that may occur, the prevention/management of symptoms, and precautions is required; therefore, this may have contributed to a high rate of BCSOP and/or BCOP who scored 5. On the other hand, a survey of pharmacy students' consciousness before and after their clinical training reported a significant increase in the number of responders who said that their clinical training experience enabled them to identify and pharmaceutically evaluate patient problems (16). Therefore, the FPS-DC-TUPLS students' insufficient experience in clinical settings may have led to generally low values on importance assessment in consideration with awareness of crisis.

The results suggested that work experience in clinical settings influences

the assessment of the importance of information in the package insert of regenerative medicine products. To investigate the influence of the length of clinical experience on the results of importance assessment, we analyzed the results by categorizing the BCSOP and/or BCOP based on their careers by 10 years. When analyzing the information described in the package insert, with a significant difference as shown in Figure 2, the rate of responders who scored 5 was the highest in the midcareer BCSOP and/or BCOP, followed in order by young BCSOP and/or BCOP and FPS-DC-TUPLS students, excluding the item “Incidence of infusion reactions in clinical trials”. It was shown that young and midcareer BCSOP and/or BCOP were highly interested in clinical trial information in comparison with FPS-DC-TUPLS students. Furthermore, the rate of those emphasizing clinical trial information increased with accumulated clinical experience. On the other hand, for all information, the rate of veteran BCSOP and/or BCOP who scored 5 was lower than that of midcareer BCSOP and/or BCOP. This was possibly because the rate of veteran BCSOP and/or BCOP working in a managerial position tended to be high (Fig. 5). This generation is holding managerial positions, and the scores may reflect the few opportunities to explain information on regenerative medicine products in comparison with midcareer BCSOP and/or BCOP primarily engaged in work activities on the ward.

The limitation of this study is that the survey was conducted via the Web, which resulted in a low survey collection rate. Another limitation is that the responders were limited to BCSOP and/or BCOP among hospital pharmacists and limited to FPS-DC-TUPLS students among

pharmacy students. In addition, it is difficult to conclude that the results are specific to regenerative medicine products, as this study did not have a control group with drug package inserts as a subject of survey, and it is necessary to interpret the results from these limitations. However, given the current situation where there are very few surveys on regenerative medicine products in pharmacy education, the results of this study were considered useful in considering the direction of regenerative medicine products in pharmacy education.

### **Conclusions**

This study confirmed differences in the results of importance assessment for the package insert of a regenerative medicine product between BCSOP and/or BCOP and FPS-DC-TUPLS students. There were significant differences in the importance of information on adverse reactions, such as infectious disease, hypo- $\gamma$ -globulinemia, and infusion reactions, obtained in clinical trials. We analyzed the rate of responders who scored 5 for information on these adverse reactions. There was a significant difference between midcareer BCSOP and/or BCOP with an 11- to 20-year career and FPS-DC-TUPLS students. As the reason for this, work experience in clinical settings may have influenced the results. It was suggested that pharmacy students who have not experienced clinical settings underestimate adverse reaction information. To produce high-quality pharmacists for clinical settings, it is necessary to resolve the gap in importance assessment between pharmacy students and hospital pharmacists. Recently, in Japan, the necessity of enhancing clinical training before and after graduation from

university has been reviewed belatedly in the field of pharmaceutical education (7). For pharmaceutical education on regenerative medicine products, information on adverse reactions should be sufficiently explained to pharmacy students, utilizing, such an opportunity of clinical training, and they should be educated so that they may work with awareness of crisis in clinical settings.

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### **Author Contributions**

KS contributed to the analysis of data, designed the study, and wrote the initial draft of the manuscript. CO and NY advised on the questionnaire survey. YK, NH, and SS assisted in conducting the study and critically reviewed the manuscript. All authors approved the final version of the manuscript.

### **Conflict of Interest**

The authors declare no conflicts of interest.

### **Data Availability**

All data which are available to the public are included in this published article.

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## がん指導薬剤師またはがん専門薬剤師の意識調査に基づいた再生医療等製品の薬学教育で扱うべき情報に関する研究

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### 要旨

本研究は薬学教育で注力すべき再生医療等製品の領域をアンケート調査結果から考察し、提言にまとめた。

アンケート調査の調査対象者は Faculty of Pharmaceutical Sciences Doctoral Course of Tokyo University of Pharmacy and Life Sciences に所属する学生 (FPS-DC-TUPLS students) と Japanese Society of Pharmaceutical Health Care and Sciences (JSPHCS) の認定資格を保有する日本医療薬学会がん指導薬剤師 (BCSOP) または日本医療薬学会がん専門薬剤師 (BCOP) とした。また、具体例として、再生医療等製品である Kymriah® の添付文書を用い、添付文書に記載された情報の重要度評価を実施した。重要度評価は 5 段階で回答する形式とした。両者の情報を評価する視点の違いについてギャップを分析し、薬学教育を充実させるための提言を作成した。

BCSOP and/or BCOP と FPS-DC-TUPLS students の重要度評価の中央値を比較したところ、Kymriah® の副作用情報のなかには、BCSOP and/or BCOP が score 5 と回答した割合が FPS-DC-TUPLS students より有意に高いものがあった。さらに、副作用情報のなかには、病院薬剤師歴 11 年以上～20 年以下の中堅 BCSOP and/or BCOP が score 5 と回答した割合が FPS-DC-TUPLS students より有意に高くなるものがあった。

FPS-DC-TUPLS students は副作用情報の重要性を過小評価していることが示唆された。臨床研修の機会などを活用し、副作用に関する情報を薬学生に十分に説明することが再生医療等製品の薬学教育として推奨される。

キーワード：再生医療等製品、がん指導薬剤師、がん専門薬剤師、添付文書、薬学教育、ギャップ分析