

Current status of utilization of Risk Management Plan in medical practice in Japan and PMDA's approach to further utilization

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About J-RMP

- J-RMP is a document that compiles information on risks or lack of information identified in the review process of the application for marketing authorization of a drug, as well as activities for mitigation and avoidance of such risks.
- J-RMP is required for new drugs and biosimilars/follow-on biologics for which approval applications are submitted on or after April 1, 2013 and application of the J-RMP to generic drugs started on August 26, 2014.
- Preparation and implementation of a J-RMP are conditions for granting marketing authorization of drugs (since October 1, 2014).
- As of December 31, 2018, 384 of J-RMPs have been published on PMDA website.

Objective

PMDA conducted a surveillance to understand the status of utilization of J-RMP at clinical settings and to consider our approach for promoting further utilization.

Efforts to promote utilization of J-RMP by pharmacists

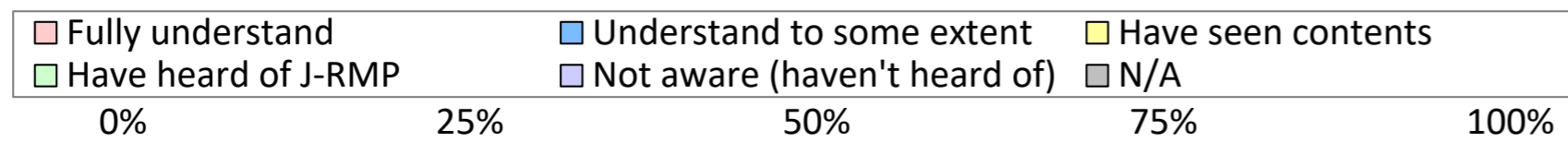
Aug. 2013	Start of publishing J-RMP on the PMDA website
Dec. 2014	A guideline for pharmacists working at hospitals to utilize J-RMP was published by Japanese Society of Hospital Pharmacists (JSHP)
May. 2016	Start of attaching 'Outline Sheets' to J-RMP when publishing J-RMP on the PMDA website
Jun. 2017	Start of putting 'RMP Marking' *on relevant materials based on J-RMP *RMP Marking 

Method

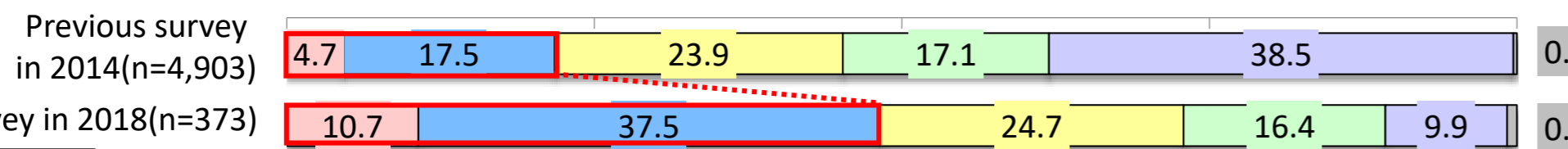
	Hospital survey	Pharmacy survey
Survey period	January 9 to February 16, 2018	
Survey subjects	10% of hospitals across the country (844 facilities)	5% of health insurance pharmacies across the country (2,934 facilities)
Survey procedure	Facilities responded by completing the web survey form or returning the completed survey form by post.	
Respondents	Pharmaceutical safety management supervisors	Supervising pharmacists or pharmacists responsible for drug information (DI) management
Number of responses	373 facilities (44.2%)	1,647 facilities (56.3%)

Result

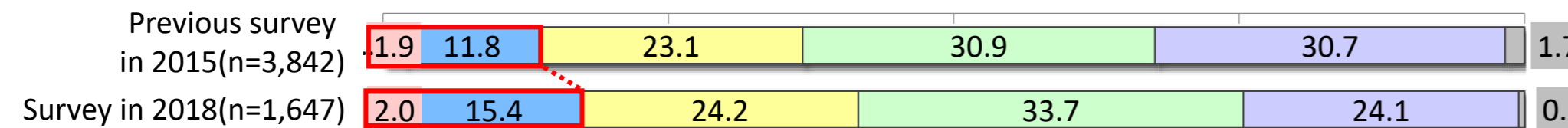
Awareness of J-RMP



Hospital



Pharmacy



The percentage of facilities that understood J-RMP was increased from the previous survey among hospital respondents, whereas, however, the percentage in pharmacies was not a significant increase from the previous survey.

Reasons for having not used J-RMP

(facilities that responded as "Fully understand" or "Understand to some extent", AND "Have not used" J-RMP)

Reasons (Top3)	Hospital (%)	Pharmacy (%)
Did not have an opportunity to utilize J-RMP	58.4	60.7
Did not know how to utilize J-RMP	38.2	24.9
Thought that other information such as package insert and interview form* is enough	32.6	36.4

*interview form: academic documents provided by pharmaceutical companies that complement the package insert

Utilization of materials based on J-RMP

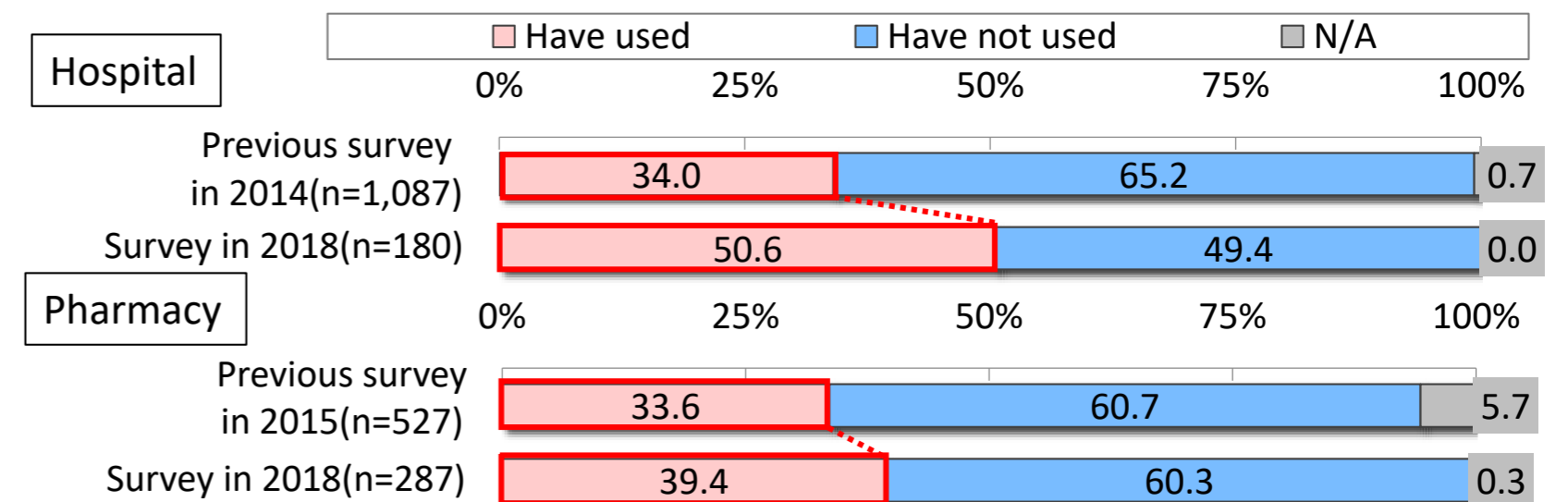
(facilities that responded as "Fully understand" or "Understand to some extent", AND "Have used" J-RMP)

How to use the materials based on J-RMP	Hospital (%)	Pharmacy (%)
Used materials for patients based on the additional risk minimization activities for medication guidance to patients	16.5	13.3
Used materials for medical professionals based on the additional risk minimization activities to share information within pharmacies or with other professions	14.3	5.3

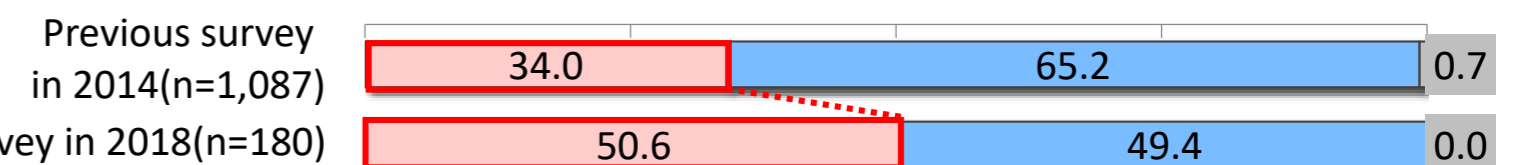
Under 20% of the hospitals and pharmacies respectively, had utilized materials based on J-RMP as part of additional risk minimization.

Utilization of J-RMP

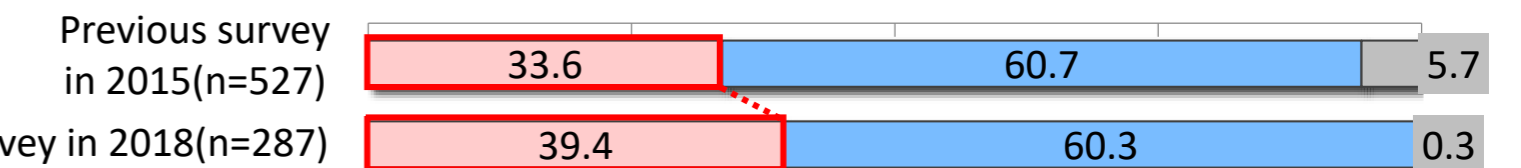
(facilities that responded as "Fully understand" or "Understand to some extent" J-RMP)



Hospital



Pharmacy



In both hospitals and pharmacies, the percentage of facilities responding as having utilized J-RMP was increased from the previous survey.

Conclusion

- Comparing with the previous survey, awareness and utilization of J-RMP made progress, however, J-RMP and relevant materials based on J-RMP are still not well utilized at clinical settings.
- One of the major factor is that the contents and the importance of J-RMP is not well understood by medical professionals in addition to the way of utilization.



To promote the utilization of J-RMP and relevant materials, it is important to 'Present the way of utilization' to medical professionals.

- It is necessary to show not only the importance of J-RMP but also how it can be utilized at clinical settings.
- PMDA will present how to utilize J-RMP in cooperation with related professional organizations of pharmacies such as through organizing symposium in academic conferences and posting articles on journals of professional organizations.
- Materials based on J-RMP will be posted on the PMDA website from April 1, 2019, both J-RMP and the materials will be downloadable from the PMDA website.