

Comparison of new expanded functions of pharmacists among Japan, the US, and the UK

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Abstract

Introduction: Pharmacists' role had been changed to be focused more as an expert on medication therapy such as collaborative drug therapy management in the US and supplemental prescriber and independent prescriber in the UK. The Ministry of Health, Labor and Welfare (MHLW) in Japan published a notice, "Enhancing the team approach in health care system by the cooperation of health care provider," that stated outlines about pharmacists' role as an expert on medication therapy. In this manuscript, we compare the regulations among the US, the UK, and Japan and discuss how Japanese pharmacists should conduct their expected role. **Materials and Methods:** Databases used to identify laws and regulations on the new pharmacists' role in the three countries are as follows; WestLaw[®] for the US, the legislation.gov.uk for the UK, and "Database services of acts and regulations on health, labor and welfare" at the MHLW website for Japan. **Results:** Comparison on the laws and regulations shows each regulatory authority established each way to regulate the new pharmacists' role even though the role in each country is quite similar. In Japan, pharmacists have limited prescription rights by sharing the rights with the physician under the protocol within the Japanese team approach model, but the regulations are minimum. **Discussion and Conclusions:** The laws and regulations for the new pharmacists' role are broken away from sameness or identify among the three countries. In Japan, an individual pharmacist must build up strong credibility with the team members and the patient and must show his/her capability to them when playing the new pharmacists' role.

Key words: Expanded Pharmacist's Functions, Japanese team approach model, Requirements

INTRODUCTION

The role of pharmacists had been focused on dispensing with accuracy so far, however, their role recently has been changed to be focused more as expert on medication therapy. Pharmacists are expected to play a pivotal role on medication therapy management through the collaboration with prescriber and other health-care providers.^[1,2]

In the US, pharmacist acquired authority from the 1990s to conduct collaborative drug therapy management (CDTM) that allowed the pharmacist to select, prescribe, monitor, adjust, and discontinue drug therapy under the agreement between the prescriber and the pharmacist to provide high-quality, low-cost care using his/her knowledge and skills in managing drug therapy and his/her ability to identify and resolve complex drug-related problems.^[3] In the UK, pharmacist who had

completed the accredited educational program became able to prescribe medication first as a supplemental prescriber (SP) that needed to make an agreement with the prescriber to provide services under scope of the agreement for the purpose of enhancing patient access to treatment, improving patient care, and using resources more effectively^[4] and then became able to prescribe it as an independent prescriber (IP) who could provide the service independently.^[5]

In Japan, though regulations of pharmacist and a health-care environment are different from these countries, the

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expectation and desire for pharmacist has been changed to same direction that pharmacist should play a pivotal role in medication therapy management.^[6,7] The Ministry of Health, Labor and Welfare (MHLW) has introduced a new framework to optimize and ensure safety and efficacy of medication therapy by utilizing pharmacist abilities in the team care approach that consists of multiple health-care providers.^[8] In this manuscript, we introduce the team approach to optimize the ability of pharmacist in Japan, compare to other pioneering countries and discuss how Japanese pharmacists should conduct their expected role.

MATERIALS AND METHODS

In the US, because state government keeps the authority to regulate pharmacist and pharmacy, the regulations depend on the state.^[9] Hence, when comparing the regulations, we focus on the states which are the first and last two states from the top of the list of state population in each the US Census region and the state (Wisconsin) with a unique history which CDTM was introduced first at 2000 that was allowed by the state law provision of WIS. STAT. Ann. §§448.03 (2) (e) about a physician's general delegation with no specific provision on a pharmacist drug therapy management which the CDTM law provision as WIS. STAT. Ann. §§450.033 about the physician's specific delegation to pharmacist was added by 2013 WISCONSIN ACT 294.^[10] A database that is used to identify state laws and regulations on the new role of pharmacists in the 17 states is WestLaw® and databases at an official law and regulation archive website of each state government.

In the UK, a database that is used to identify them is the legislation.gov.uk that is the official archive website.

In Japan, a database that is used to identify them is "Database services of acts and regulations on health, labor and welfare" at the MHLW website.

RESULTS

Changing Role of Pharmacists in Japan

In Japan, the team approach, which utilizes and brings each health-care providers' expertise such as physicians, pharmacists, nurses, and other comedicals, is expected as an essential factor to provide the optimal care. The MHLW issued a notice, "Enhancing the team approach in healthcare system by the cooperation of health care provider," on April 2010 to realize the team approach according to the expectation for pharmacists to ensure more cost effective, efficient, and safe drug therapy.^[11] The notice summarizes the expected function for each of health-care providers in accordance with current regulation and enforced each of health-care providers to conduct the expected function in legal manner.

The notice stated nine elements that pharmacists should fulfill to play a more active role to optimize the medication therapy in the team approach. The six elements are those mainly about the proposing, reviewing, and coworking the drug therapy management as a specialist for medications in the team to keep the safety and efficacy in more difficult, complicated, and advanced pharmacotherapy as follows;

1. Suggest the physician for selecting the medication, dose, administration route, and period of medication therapy
2. Conduct the medication therapy management as monitoring the adverse events and effect of pharmacotherapy for inpatients, outpatients, and patients at home
3. Check the adverse events and the medication effects and, if necessary, propose the optimal medication therapy to the physician in accordance with the result of blood medication level and adverse event monitoring
4. Propose the ditto prescription to the physician after considering condition and progress of the medication therapy
5. Obtain the informed consent and conduct medication therapy management for the outpatient who takes chemotherapy in cooperation with physician
6. Conduct the medication therapy management on hospitalized patient with conducting the medication reconciliation and proposing the medication plan to the physician.

Moreover, two elements are that pharmacists should manage the drug therapy individually with feedbacking to the team as (7) dispense medications separately several times for one prescription to monitor the adverse events periodically, and (8) dispense the anticancer drug with sterile preparations. The last one element is that pharmacists may exercise the limited prescribing rights as (9) under the protocol established with physicians beforehand, change the medication, adjust the dose, administration route and period, and order the clinical test, in cooperation with the physician.

Comparison of Expanded Pharmacist's Functions among Japan and the US and the UK

The expanded pharmacist's functions and laws/regulations in the seventeen states in the US, the UK, and Japan are summarized in Tables 1 and 2.

Additional license or certification and/or training for a pharmacist are not required before exercising the expanded pharmacist's function in Japan, however, are required in the UK and are required depending on the state in the US. Agreement with the physician and/or agreement with the patient are not required before exercising the expanded pharmacist's functions in Japan, however, are required in the case of SP and are required depending on the state in the US.

Table 1: Comparison of the new functions of pharmacists in each country/state as of August 9, 2019

Country/State	Additional license or registration	Postgraduate/ additional education	Agreement with the physician	Agreement/ approval with/by the patient	Written protocol or procedure	Notification on protocols/ procedures to the regulatory authority	Assessment on protocols/procedures by the hospital
Japan	No	No	No	No	No	No	No
US (CDTM)	AK	Yes	Yes	No	Yes	Yes	Yes
	CA	Yes	No (agreement or protocol)	No	Yes	No	No
DE	Not introduced						
FL	No	No	No	No	Yes	No	No
IL	No	No	No (order from the physician) ^{*1}	No	No	No	No
ND ^{*2}	No	No	Yes	No	No	Yes	No
NY	No	Yes	No (agreement or protocol)	Yes	Yes	No	No
OH	Yes (in case of controlled substances)	Yes	Yes ^{*3}	No ^{*3}	Yes	Yes	No
PA	No	No	Yes	No ^{*4}	Yes	Yes	No
RI	No	Yes	Yes	No ^{*5}	Yes	No	No
SD	No	No	No	No	Yes	No	No
TX	Yes (in case of a dangerous drug)	Yes	No (medical order/ delegation order)	No	Yes	Yes (in case of a dangerous drug)	No
VT	No	No	Yes	No	Yes	No	No
WA	No	No	No	No	Yes	Yes	No
WI ^{*6}	No	No	No	No	No	No	No
WV	No	Yes	Yes	Yes	Yes	Yes	No
WY	No	No	Yes	Yes ^{*7}	Yes	Yes	No
FL	No	No	NA	No	No	No	No
US (IP)	Yes	Yes	Yes	Yes	Yes ^{*8}	No	No
UK (IP)	Yes	Yes	NA	No	No	No	No

^{*1}Pharmacist may serve patient care functions authorized by a physician for his or her identified patient or groups of patients under specified conditions or limitations in a standing order from the physician. Pharmacist may provide medication therapy management services with following protocols of a hospital pharmacy and therapeutics committee with respect to the fulfillment of medication orders in case of in a licensed hospital. ^{*2}Authority to prescribe schedule II drugs may not be delegated to a pharmacist. ^{*3}The content of a consult agreement shall be communicated to each patient. The patient or patient's agent, guardian may terminate the agreement. ^{*4}Protocol must contain the provision of providing an opportunity for the patient to refuse management of drug therapy by a pharmacist. ^{*5}Informed consent shall include provision to allow the patient to withdraw from collaborative practice at any time. ^{*6}WI does not require legally and regulatory the protocol, but the protocol and agreement are required practically because WIS. STAT. Ann. §§448.03 (2)(e) asks the pharmacist directed, supervised, and inspected by a physician when the pharmacist is delegated patient services to by the physician who has the power to direct, decide, and oversee the implementation of the patient services. ^{*7}The patient or patient's agent, parent, or guardian may cancel the collaborative practice agreement at any time by the written notice. ^{*8}Clinical management plan has to be drawn up, with the patient's agreement, following diagnosis of the patient by the independent prescriber, and following consultation and agreement between the independent and supplementary prescribers

Table 2: Related provisions in each country/state as of August 9, 2019

Country/State	Statutory citation (s)	Regulatory citation (s)
Japan	No explicitly provision*	No explicitly provision*
US (CDTM) AK	AS § 08.80.480 (30)	12 AAC 52.240
CA	CAL. Bus. And Prof. Code §§4052.1, 4052.2 and 4052.6	16 CCR § 1730, 1730.1, 1730.2 and 1731 (2018)
DE	Not introduced	
FL	FLA.STAT. Ann. §465.003 (13) and §465.0125	FLA. Admin. Code Ann. r. 64B16-27.1001 and 64B16-27.830
IL	225 ILCS 85/3 (aa)	-
ND	NDCC, 43-15-01. 24 & 43-15-31.4	NDAC 61-04-08
NY	McKinney's Education Law § 6801, § 6801-a and § 6827.2	8 NYCRR 63.10 and 63.7
OH	R.C. § 4729.01 (D) & § 4729.39	OAC 4729:1-1-01, 4729:1-6-01, 4729:1-6-02 and 4729:1-6-03
PA	63 P.S. § 390-2, § 390-9.1 and § 390-9.3	49 Pa. Code § 27.1, § 27.301, § 27.302, § 27.311 and § 27.312
RI	Gen.Laws 1956, § 5-19.2	216-RICR-40-15-1.2, 1.4, 1.13
SD	SDCL § 36-11-19.1 (6)	-
TX	TEX. OCC. Code Ann. §§157.101(b-1), 157.001 and 551.003 (33)	22 TEX. Admin. Code §§295.13, 193.6 and 193.15
VT	26 V.S.A. § 2022 (15)	Vt. Admin. Code 20-4-1400:1.10
WA	WASH. rev. Code Ann. §18.64.011 (28)	WASH. Admin. Code §§246-863-100, 246-863-110 and 246-863-095
WI	WIS. STAT. Ann. §§450.01 (16) and 450.033	-
WV	W. Va. Code, § 30-5-4, § 30-5-18 and § 30-5-19	W. Va. Code St. R. § 11-8, § 15-1-2 and § 15-3-4
WY	W.S.1977 § 33-24-101 and § 33-24-124	WY Rules and Regulations 059.0001.20 § 1-5
US (IP) FL	FLA.STAT. Ann. §465.003 (14) and §465.186	FLA. Admin. Code Ann. r. 64B16-27.200, 64B16-27.210, 64B16-27.220 & 64B16-27.230
UK (SP/IP)	Health and Social Care Act 2001 §63 Extension of prescribing right	The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006

*No explicitly legal limitation on a physician delegates the physician's authorization to comedicals under the physician's supervision. Ministry notice provides a guidance on the delegation method as "Therapy management by team that consists of physicians and comedicals"

The protocol is required legally and regulatory in all country and states except CDTM in Illinois, Wisconsin, and IP in the UK. Illinois and Wisconsin do not require legally and regulatory the protocol. However, the physician's standing order is required in Illinois, and the protocol and agreement are required practically in Wisconsin because the state law asks the pharmacist directed, supervised, and inspected by the physician when the pharmacist is delegated patient services to by the physician.

DISCUSSION

The drug therapy became to being wide spread and complex because pharmaceuticals became to be developed by the new advanced technology. Moreover, since quality of care is not

different from the one of physician,^[12] the needs for using low-cost medical experts instead of physicians resulted from that higher needs for cost effective and efficient management of national health services accompanied by rising health-care services costs up due to such as the jumping up the price of innovative drugs.^[13,14] As the result, the role of pharmacists recently has been changed to be focused on as an expert on medication therapy. The role of the US, the UK, and Japanese pharmacists also has been changed similarly to the medication therapy management in addition to the traditional works. However, comparing to the regulation on the new role of pharmacists for medication therapy, management among the UK, the US, and Japan shows each regulatory authority established each way to give a pharmacist expanded function, typically Delaware has not introduced CDTM.

The IP has the independent prescribing right with no limitation. The pharmacist in Florida also has the independent prescribing right only within the formulary provided by Florida regulation of FLA. Admin. Code Ann. r. 64B16-27.220. Pharmacists at some of the states such as Texas are provided by the delegation of physician's prescribing rights. Moreover, pharmacists in Japan put the expanded function into practice by sharing the role on drug therapy management with the physician who is a manager of the team that the pharmacist belongs to. However, those in other of some of the states such as Florida pharmacists and the SP are provided by the pharmacist's legal rights as the limited prescribing rights with requiring the physician's involvement through the protocols and some other methods.

These differences would have been formed over long time under political influences, economical influences, and various influences according to social needs of each country. The MHLW allows the pharmacist to have limited prescription rights that are shared with the physician under the protocol within the Japanese team approach model with no defined regulation.

Even many states in the US and the UK have a define provision about process and methods of pharmacist prescribing and other comedicals' prescribing, it is recognized that the relationship and communication are important practically to assure the effectiveness and safety.^[15,16] Hence, when exercising the expanded pharmacist's functions in Japan, pharmacist must build up more strong credibility with an individual physician, other comedicals, and a patient and must show his/her capability to them.

This Japanese physician's self-governance approach is unique against other countries because the Japanese regulatory authorities restrain themselves from intervening the actual practice and the relationship between the physician and the pharmacist through the explicitly regulations. Some regulatory authorities intervene through requirements of pharmacist such as training requirements.

CONCLUSIONS

In addition to the traditional function of pharmacist, the expected new role of pharmacist which focuses on as an expert on medication therapy management is similar among the US, the UK, and Japan though the laws and regulations for the new pharmacists' role are broken away from sameness or identify. These differences would have been formed over long time under political influences, economical influences, and various influences according to social needs of each country. However, the most important thing for particularly Japanese pharmacists is that an individual pharmacist must build up strong credibility with the team members and the patient and must show his/her capability to them when playing the new pharmacists' role because of the minimum requirements.

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