A Survey of Practical Policies to Promote Rational Drug Use (RDU) of Pharmacy and Therapeutics Committee (PTC) in Thailand

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Background and Objective: Pharmacy and Therapeutics Committee (PTC) was defined by World Health Organization (WHO) as a group of multidisciplinary professionals in a hospital to manage an effective drug inventory control and improve rational drug use (RDU). Even though a PTC was established in all hospitals under the jurisdiction of Ministry Of Public Health (MoPH) there was limited data describing practical policies to promote RDU of PTCs in Thailand. This study was aimed to obtain existing information on their current performances and practical policies that have been utilized in the PTCs. This information will assist in guiding the directions of PTC performances and policies to improve RDU in Thailand.

Method: This qualitative study was conducted in 5 purposive sampling of pharmacists who had works related to in a PTC of each hospital under the jurisdiction of MoPH in lower northern part of Thailand. The documentary analysis and data triangulation were performed using official regulatory data from each hospital and information gathered from the questionnaires.

Results: PTC structures and functions of all hospitals were adhered to WHO and Thai MoPH guidelines. Their practical policies to promote RDU were related to planning on cost-effective hospital formulary and inventory controls, developing drug system policies and clinical guidelines,
Introduction

A Pharmacy and Therapeutics Committees (PTC) was firstly established in the US in the 18th century as a group of multidisciplinary professionals in hospitals who had functions to evaluate clinical uses of medications and develop policies to manage effective formulary control\(^1\)-\(^3\). PTC was recognized and established in all hospitals in the US during the 1960s and expanded their responsibilities to promote cost-effectiveness and rational drug use (RDU)\(^2\), \(^4\). Since 1987, “Thai drug management manual” stated that all hospitals under the jurisdiction of Ministry Of Public Health (MoPH) must set up a PTC\(^5\)

The PTC should promote RDU through establishing restricted drug-use policies, selecting cost-effective therapeutic alternatives as determined by clinical practice guideline (CPG), as well as managing the hospital formulary in accordant with the National Essential Drug List (NEDL). However, these PTCs have focused mostly on managing the hospital formulary lists\(^6\). The recent studies in Thailand reported that the barriers in PTC functions were lacking of clearly defining job description of PTC and assessing outcomes after utilizing policies were crucial.

Conclusions: Though PTCs’ practical policies were established for improving RDU they had been struggling to establish the effective formulary systems and implemented RDU policies. To improve performances of the PTCs, clarifying job descriptions of PTC committee, providing effective human resources, developing leadership skill, increasing frequency of official meetings, and promoting efficient communication and distribution of in-house policies may be warranted.

Keywords: Pharmacy and Therapeutics Committee, practical policy, rational drug use
Methods

The study was approved by the Ethics Committee of Naresuan University (No.5302040028). This study was a questionnaire-survey and documented study. The purposive sampling was utilized to identify 5 pharmacists from 5 hospitals under the jurisdiction of MoPH in lower northern part of Thailand. The respondents had to have ability to give the rich and profound information on PTC and were related to their PTCs as either a PTC member or a member of sub-committee working under supervision of the PTC.

A self-administered questionnaire was developed and validated by researchers and literature reviews. Baseline characteristics of the hospitals and respondents and the PTC functions and strategies for RDU policies were collected. The interview was performed for more details if needed in each question. The structure of the questionnaire was divided into 2 parts. The first part composed of baseline characteristics of the respondent and the hospital, the open-ended questions on PTCs’ structure, functions, and practical policies to promote RDU in the hospital, the overall satisfaction of participants to the PTC, and strengths and weaknesses of the PTC in the hospital. Furthermore, there were open-ended questions on how to resolve the problems or improve weaknesses in any activities of the PTC. The second part was the questions related to DUE activities. These questions asked about the top ten maximum expenditure of all medications in a year, the top ten maximum expenditure of antibiotic drugs in a year, medication lists which had been conducted DUE, type of DUE (retrospective, concurrent, or prospective methods) conducted in the hospital, and details on DUE activities.

The documentary analysis and data triangulation were performed using information gathered from the questionnaires and official regulatory data from each hospital in order to describe the structure and functions of the PTC. The results were obtained through quantitative and qualitative methods. Descriptive statistics were utilized to describe numerical data. Content analysis was conducted to analyze functions and policies of the PTC.

Results

Baseline characteristics of the hospitals and the respondents

We conducted this study in a regional hospital and 4 general hospitals under the jurisdiction of MoPH. Of all hospitals, the average numbers per a hospital of the physicians, pharmacists, nurses and dentists were 64, 21, 376, and 9, respectively. The number of daily out-patients and the percentage of bed occupancy per a hospital ranged from 700 to 1,058 patients and 75.12 to 105.23%, respectively (Table 1). There were 5 pharmacists participating in the study and the majority was males (80%) and the mean age of all respondents was 48±4.18 years old. There was variability of the respondents’ experiences which were less than 1 year, 8, 10, greater than 10, and 21 years related to their PTCs.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Regional hospital</th>
<th>General hospitals 1</th>
<th>General hospital 2</th>
<th>General hospital 3</th>
<th>General hospital 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of PTC members</td>
<td>16</td>
<td>21</td>
<td>18</td>
<td>15</td>
<td>17</td>
</tr>
<tr>
<td>Number of physicians</td>
<td>138</td>
<td>38</td>
<td>75</td>
<td>30</td>
<td>38</td>
</tr>
<tr>
<td>Number of pharmacists</td>
<td>38</td>
<td>15</td>
<td>20</td>
<td>14</td>
<td>18</td>
</tr>
<tr>
<td>Number of nurses</td>
<td>604</td>
<td>335</td>
<td>337</td>
<td>290</td>
<td>313</td>
</tr>
<tr>
<td>Number of dentists</td>
<td>13</td>
<td>6</td>
<td>9</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Number of daily outpatients</td>
<td>800-1000</td>
<td>1058</td>
<td>700</td>
<td>700</td>
<td>1300</td>
</tr>
<tr>
<td>Bed Occupancy Rate (%)</td>
<td>105.2</td>
<td>75.12</td>
<td>81.57</td>
<td>70.00</td>
<td>128.88</td>
</tr>
</tbody>
</table>
Baseline characteristics of PTCs

All hospitals operated similar PTC structures which consisted of a director of the hospital as a chairperson, a head of pharmacy department as a secretary, and all other multidisciplinary professionals were committee members. The majority of the committee incorporated mostly physicians and pharmacists. Besides, the committee was mainly associated with 12 to 14 members whom were heads of each medical department. To function efficiently, they also co-operated with other sub-committees to facilitate their jobs. They performed all PTC functions stated by Thai MoPH. However, a job description for each position in the committee was not determined in any hospital. Moreover, all PTCs were aimed to manage efficient and effective medicine inventory controls according to limited budgets. The PTCs worked up to support patient safety and RDU policy through the process of drug use evaluation (DUE), reporting medication error (ME), and monitoring of adverse drug reaction (ADR). PTCs had the formal meetings 1 to 4 times per year which were the meetings on drug selection of 1-2 times per year (Table 2). The respondents stated that the directors of the PTCs and the members had work overload so attending the PTC’s meeting usually was postponed and irregularly conducted. Some of directors were not interested in the PTC activities since their hospitals could run and resolve the drug use problems by other committees in the hospitals.

The objectives of the PTC in each hospital were different in order to accomplish missions of the hospital. All PTC appointment orders from 5 hospitals declared a similar PTC objective which was to succeed in management of pharmaceutical inventory control. The other objectives of the PTC in each hospital followed each hospital’s guideline for hospital accreditation. Only one respondent declared that patient safety was a main objective of the RDU policies in the hospital.

PTC operations and strategies for RDU policies

1. Managing the hospital formulary lists and drug supplies

All PTCs from 5 hospitals primarily attempted to manage their hospital formulary lists and drug supplies according to National Essential Drug List (NEDL). Which were about 542 to 650 drug items in each hospital formulary list. The proportion of essential drugs (ED): non-essential drug (Non-ED) ranged from 70:30 to 85:15 items or 52.7:33.6 to 238:117 million baht (Table 2). Their duty currently included promoting cost-control policies and reducing over prescribing medicines using several strategies including utilizing policies of generic substitutions and restriction use of medicine, limiting budget to a purchase order and requiring authorization for specific drug-use.

Table 2 PTC and Managing the hospital formulary lists and drug supplies

<table>
<thead>
<tr>
<th>Characteristics/Hospitals</th>
<th>Regional hospital</th>
<th>General hospitals 1</th>
<th>General hospitals 2</th>
<th>General hospital 3</th>
<th>General hospital 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Items</td>
<td>650</td>
<td>542</td>
<td>607</td>
<td>550</td>
<td>569</td>
</tr>
<tr>
<td>Proportion of items (ED:NED)</td>
<td>70:30</td>
<td>80.44:19.56</td>
<td>78.30:21.70</td>
<td>83:17</td>
<td>85:15</td>
</tr>
<tr>
<td>Proportion of drug expenditure (million baht)</td>
<td>238:117</td>
<td>52.7:33.6</td>
<td>87.8:75.2</td>
<td>70:30</td>
<td>102:29</td>
</tr>
<tr>
<td>Drug selection: adding to or deleting from the formulary (times/year)</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1-2</td>
<td>1</td>
</tr>
<tr>
<td>Formal meeting of PTC (times/year)</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>
Regarding items in the hospital formulary lists, of all hospitals, four hospitals have utilized information based on evidence based practice and the manufacturers’ drug profiles. On the other hand, another hospital only used information according to evidence based medicine. In addition, these PTCs also employed expert opinions from medical staffs and pharmacy departments. Nonetheless, PTC typically asked the pharmacy department to review the evidences and suggest the pronouncement. It is observed that the PTCs in all settings had their own criteria for selecting, evaluating, and monitoring drug-use in the formulary lists. However, there was no standard or practical criterion for selecting and evaluating the formulary lists published in any setting.

2. Developing drug system policies

All of these PTCs and their sub-committee in this study regularly developed the policies to promote RDU in order to establish the cost-effective drug systems through the supervision process of reporting of medication errors (MEs), monitoring of adverse drug reactions (ADRs), and conducting drug use evaluation (DUE) to ensure efficacy and safety of medications along with proper cost.

Of all hospitals, particularly in ADR management, the PTCs of two hospitals did not have direct responsibility in ADR management but this mission was assigned to the other committee in their hospitals. On the other hand, the PTCs from 3 hospitals had somehow involved in the ADR surveillance system in their hospitals. All of these hospitals had monitored and reported both spontaneous and intensive events but may be different in procedures. We did not speculate on the details of an ADR system in each hospital. For the hospitals that the PTC involved with ADR surveillance system, PTC would specify tracer agents to monitor if ADR occurred. For example, if the patient received chlorpheniramine and dexamethasone injections may imply that there could be some allergy event occurred. Slowing down of heart rate could also be an indicator for who received overdose of beta-blockers. A PTC in one hospital conducted root cause analysis of severe medication errors. Others did not state whether the analysis had been conducted. In addition, all PTCs were strictly on screening and preventing patients from occurring repeated-ADRs. Pharmacy departments of all these hospitals play important roles in ADR monitoring and writing reports. This information would be presented to the PTCs and the PTCs would brainstorm to find the solutions and prevent the similar events from occurring in the future.

Besides the ADR management activities, the PTCs of 3 hospitals also had to handle and monitor MEs in their hospitals. In one hospital, this function was conducted by the other committee in the hospital. Besides, there was no committee who was directly responsible for management of MEs in the other hospital. The committees mainly took actions and feed backed data from all stakeholders to the PTCs. In addition, the pharmacists in this committee played the important roles in collecting and writing reports. The information was reported directly to the PTCs which further reflected the policies to solve the problems e.g. improve information technology (IT) system and establish the preventing system to lessen prescribing errors, and defining the strategies to reduce MEs from look-alike or sound-alike drugs, and high alert medications.

DUE was one of practical restricted drug use policies that all hospitals in this study have operated in order to promote RDU. The objectives of performing DUE were to control and monitor the medicine prescribing of these exceptional items to ensure the proper use regarding efficacy and safety for individual patient. Of all 5 hospitals, different committees ran this function. In two hospitals, other committees in their hospitals were responsible for performing this function. Conversely, the PTCs of 3 hospitals were responsible for conducting DUE. The PTCs delegated the DUE activities and implement the policies through sub-committees’ reports. After the sub-committees determined cost-effective drug items regarding to the hospital formulary lists, the secretary of the PTC, the head of the pharmacy department, distributed the general drug policies to other medical practitioners trough the hospital intranet system, notification letters, the formal meeting minutes, regulatory documents
and official announcements, as well as face to face communications. The pharmacists from these three hospitals carried out DUE using a retrospective method rather than a concurrent method due to limiting of human resources in data collection process. In some special cases, some high-cost items were allowed to use by specialist physicians. These PTCs conducted DUE on several drugs. The most frequent antibiotic items which were conducted DUE show in Table 3. In addition, the other items that more than one hospital conducted DUE was celecoxib. The medications that need to perform DUE were defined by several criteria including the drugs which were in the index of the essential national list, high cost, or risky to cause ADRs or MEs, or irrational drug use. There were 3 PTCs had interventions after DUE activities, for example, developing the form to restrict the use and defining the criteria for prescribing some medications.

In terms of developing or adapting standard treatment guidelines (STGs) there were two hospitals whose PTCs were responsible for this function. One hospital gave the example showed that they had developed a protocol guiding rational drug prescribing for patients who needed chemotherapy. Another hospital had developed a STG for antibiotic use. The success of the STG implementations was not investigated in this study. Moreover, the PTC role as an advisory committee to medical staffs, the hospital administration department or the pharmacy department was almost none existent in any of the enrolled hospitals.

According to the overall satisfaction to the PTCs, three of five participants were satisfied on their PTC operations. On the other hand, the other two participants were not satisfied with their PTCs because they thought that their PTCs did not perform activities as they should and the policies were not completely implemented. Some practitioners might not update and/or adhere to the policies. As a result, the policies may not be successfully adhered. To resolve these issues, the respondents suggested that the PTC should contribute the various routes of communications and provide availability of materials for education on rational clinical practice and evidence-based medicine information.

In terms of strengths, the respondents stated that their PTCs had ability to manage budget for medication expenditure. The chairperson of the PTC used a compromising method to reduce conflicts among the committee members. In addition, the committee members usually shared ideas, opinions, and suggestions during the PTC meetings. On the other hand, the respondents were also mentioned to the weaknesses of their PTCs. The important issue was that the policies were not completely implemented. The compromising method in meeting might cause leniency in process of policy implementation. Moreover, the meeting were often postponed because of the conflicts of the PTC member works’ schedules. Particularly, the chairperson was the main key person who led the directions of the committee. But the chairperson usually had a lot of works, so they could not delegate the time to direct the PTC policies.

<table>
<thead>
<tr>
<th>Number</th>
<th>Drug</th>
<th>Regional hospital</th>
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<th>General hospital 2</th>
<th>General hospital 3</th>
<th>General hospital 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Piperacillin+tazobactam</td>
<td>X</td>
<td>√</td>
<td>x</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>2</td>
<td>Imipenem+cilastatin</td>
<td>x</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>3</td>
<td>Cefoperazone+salbactam</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>x</td>
</tr>
<tr>
<td>4</td>
<td>Amoxicillin+clavulunic acid</td>
<td>√</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>4.1</td>
<td>1.2 g injection</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Ciprofloxacin injection</td>
<td>√</td>
<td>x</td>
<td>√</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>6</td>
<td>Fosfomycin injection</td>
<td>√</td>
<td>x</td>
<td>√</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>7</td>
<td>Meropenem injection</td>
<td>√</td>
<td>x</td>
<td>x</td>
<td>√</td>
<td>√</td>
</tr>
</tbody>
</table>

Table 3 The example of antibiotic drugs conducted DUE in the hospitals
Discussion

This study surveyed the current activities and practical policies of the PTCs in the hospitals under the jurisdiction of MoPH in lower northern part of Thailand. Several RDU policies had been utilized. To promote RDU policies, PTC is believed to be a key in order to balance between the cost and quality of care. Over two decades ago, Thai MoPH regulated and accomplished setting up a PTC in all levels of hospitals under the jurisdiction of MoPH to manage effective inventory control, improve rational drug use and warrant patient safety.

The structures of the PTCs in this study was comparable to the guidelines of Thai drug management manual, WHO, previous studies in Thailand, and other countries. Even though, the roles of the PTC in each hospital are mostly the same, the strengths of the PTC in each hospital mainly depends on the support of the administration. In the other words, the PTC could function effectively if the director and the administration team give full supports to the committee. However, when the new director or the new administration team has been appointed, the direction of the PTC may be changed. Therefore, the role of the leader is the most important factor to determine the success of the PTC in each hospital. The direction of the PTC should be pointed by the system not a person. How to stabilize the function and strengthen the PTC are truly needed to discuss seriously in the national level.

The previous study in Thailand by Sripairoj et al. demonstrated that, the term of PTC membership was not defined. It was noted that, this situation was the same as the international PTCs which the membership and structures had not been changed overtime. The dominate membership of drug and therapeutic committee (DTC) were medical, nursing, and pharmacy representatives. Moreover, some DTC members included consumers, general physicians, and community pharmacists. But the PTC members in this study did not include the consumers, general physicians, and community pharmacists. The results showed that mostly PTC members usually were the head of each medical department and the representatives from pharmacy department. With their overloads of daily activities, therefore, they might not have enough time to contribute in the PTC meetings and activities. This characteristic of the positions of the PTC assembly as in a study by Sripairoj et al. In Lao, most of PTC members held the position of head of departments or a hospital director and they had been recruited to the permanent PTC tasks.

In terms of numbers of frequency of the meetings, the frequency of the meeting in the PTCs was 1-4 times and duration of not more than 3 hours/time. Therefore, all issues could not be completely discussed in the limited time. The meeting of these PTCs was irregular due to the directors of the hospitals and the members had over workload which was similar to the previous study. Therefore, unsurprisingly, the committee had focused mostly on drug selection during the limited time in the meeting which related to the main budget of the hospital. If they had times, other issues would be considered. Therefore, the availability of the members is crucial in order to advocate the PTC performances. Because of over workload of PTC members in both Thailand and Lao, the PTCs could not perform PTC tasks appropriately. In Lao, poor PTC performances also were due to have irregular meeting, have many positions held by PTC members, lack of interest in PTC’s responsibility, have insufficient knowledge about PTC functions and responsibilities, and loss of training PTC members. Besides, formula list control, the ideal PTC should play roles in developing policies on the use of drugs, monitoring patients safety, establishing and developing guidelines for medical management, and planning on the overall budget framework by considering both patients safety and cost effectiveness. According to PTC functions defined in the appointment orders, in these settings, the functions of these PTCs were different in details. They had been struggling on performing the ideal functions mentioned previously and tried to develop their performances as their capacity and ability. However, some gaps were still remained. To improve PTC performance and overcome the barriers during discussion, there has been suggested
that, assigning priority to PTC decision, training PTC members in PTC activities, recruiting more dynamic PTC leaders and improving reporting system and meeting techniques were needed.

In the present study, the respondents stated that the PTC members knew their responsibilities but not realized their individual tasks. This may be one of the most important weaknesses of the PTC in order to improve their performances. Defining job descriptions may facilitate and motivate the PTC members to comprehend their co-operations. Moreover, some hospitals included only physicians and pharmacists in the committee; this might be a crucial barrier for policy distribution and implementation to all stakeholders.

Unsurprisingly, all PTCs from these hospitals mainly focused on managing inventory supply. Although most of the participants stated that their PTCs carefully considered evidence-based medicine information and drug profiles from the manufacturers, there was no standard or practical criterion for selecting and evaluating the formulary lists published in any setting. Therefore, bias data may be considerably concerned on quality of drug information and might affect the PTCs’ judgments. This showed that the development of PTCs to promote RDU in Thailand have not been moved from the past.

In Australia, the PTCs is called the Drug and Therapeutics Committee (DTC). A study determined how DTC decisions should be prioritized. They found that DTC decisions should be prioritized for implementation which may use the domains of importance as the basis for priority assignment. The survey reported that patient safety, ensuring the practice of evidence based medicine within their institution, cost, and ensure practice according to legislative requirements were the domains of importance from the most to less, respectively. However, they still had no idea how this could be done. In the settings of the present study, the cost of medicine and number of the formulary list seem to be important among other issues.

In order to promote RDU, all of these PTCs involved in management of medication errors (MEs) and adverse reactions (ADRs) as well as utilization of drug use evaluation (DUE) reports both direct and indirect ways. The pharmacists were the persons who carried these issues on hands. Supported by a qualitative study, the results suggested that the DTC decisions and policies are currently implemented by pharmacists. In addition, these activities concurred to the WHO practical guideline which stated that PTC has a role in ensuring that all medicines are prescribed, dispensed and administered to patients safely and adequately. PTC should monitor and address medication errors, monitor and ensure drug quality, as well as monitor and manage ADRs.

In Nepal, the PTC had a vital role in ensuring drug safety in the hospital. The PTC had started pharmacovigilance service by reporting The ADRs and had planned to utilize several strategies to reduce medication errors in their hospitals. In Lao, one of the PTC’s tasks was also to stimulate reporting ADRs to the PTC.

Moreover, in these enrolled settings of our study, the PTCs also had to manage MEs in their hospitals. The working groups took actions and fed back data to the PTCs to improve their hospital drug systems. Most pharmacists played the important roles in collecting and writing reports. Then the information had been reported directly to the PTCs during the meeting. However, the frequency of MEs report of these hospitals was not certain.

The PTC practical guideline defined by WHO mentioned that the pharmacists should play a dominant role in DUE process because the pharmacists are the experts in the area of medication treatment. The six steps of a DUE are establishing responsibility, developing the scope of activities and defining the objective, establish criteria for review of the medicine, collecting data (the data may be collected retrospectively, from patient charts and other records, or prospectively, at the time a medicine is prepared or dispensed). Retrospective DUE may be quicker and is the best accomplished way when considering the patient care areas and distractions, compared with other methods. The advantage of a prospective review is that the
reviewer can intervene at the time the medicine is dispensed to prevent errors in dosage, indications, interactions or other mistakes. According to our findings, all of these hospitals utilized a retrospective method rather than a concurrent method because of limitation in human resources. The process of DUE from five hospitals were different in details, but concurrence to the steps recommended by WHO\textsuperscript{11}. The secretary of the PTC, the head of the pharmacy department, usually distributed the drug policies to other medical practitioners trough many routes for helping them to disseminate the information. It is noted that, the steps of DUE in all of these hospitals were similar as stated in the guideline. However, one step that these PTCs did not performed was to follow up outcomes after they feedback DUE information to prescribers and the PTCs.

There were some limitations of the present study. Data was collected only from pharmacists. There fore some opinions on several aspects may be different if we conducted the interview with other professionals. The data from five hospitals might not be good representatives of all PTCs in Thailand because each hospital has differences in context. We did not evaluate the outcomes of the policy implementation. Further study in evaluating formulary management criteria and outcomes of these policies and PTCs’ performances are warranted.

**Conclusion**

This study found that the PTCs mainly operated on managing an effective and efficient medicine inventory supplies. The PTCs utilized several strategies to promote RDU policy in their hospitals. However, they had been struggling to establish the effective formulary systems and implemented RDU policies. With unbalances between human resources and workloads, they mostly focused on drug inventory. To improve performances of the PTCs, clarify job descriptions of PTC committee, conduct effective human resources, develop leadership skill, increase frequency of official meetings, and promote efficient communication and distribution of in-house policies may be warranted.

**Acknowledgement**

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**References**