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Hospital-based Pharmacy and Therapeutics Committees: Evolving Responsibilities and Membership

Environmental Scan

Context

In this report, the term Pharmacy and Therapeutics Committee (P&TC) refers to a committee responsible for managing drug-related issues for the hospital(s) represented by the committee. Synonymous terms, such as Drugs and Therapeutics Committee (D&TC), may be used in some Canadian jurisdictions, as indicated in the findings tables. In Canada, these hospital-based committees may function at an individual hospital level, regional or district health authority level, or provincial level.

Traditionally, P&TCs have focused on establishing and maintaining a limited drug list, or formulary "that meets the needs of physicians and their patients as well as those of the health care organization."[1] However, these simple drug list–based formularies have evolved into "comprehensive systems of medication use policies intended to ensure safe, appropriate, and cost-effective use of pharmaceuticals in patient care."[2]

Accordingly, the responsibilities and membership of P&TCs have evolved as well. Today's P&TC responsibilities may include broader medication use–related activities such as adverse drug event monitoring and reporting, development of clinical care plans and guidelines, drug-use evaluation, establishment of therapeutic interchange policies, evaluation of medication-related patient safety issues, and more recently, management of drug product shortage issues.[2,3] Furthermore, the contemporary committee's function of providing a sound program to maximize rational drug use is influenced by multiple factors, such as the increasing numbers and costs of new drugs, the complexities associated with their safe and effective use, rising prevalence of patients with numerous comorbidities, and an increasingly aging population.[4]

Along with P&TCs' evolving responsibilities, the traditional hospital P&TC membership of physicians, pharmacists, and nurses has expanded to be more multidisciplinary. Today's committees may include representatives from administration and quality assurance, other health care practitioners, and also the public.[3]

The importance of objective evaluation of drug efficacy, safety, toxicity, and costs performed by P&TCs managing hospital formularies cannot be underestimated, as almost all patients admitted to hospital receive some type of drug therapy.[5]

Objectives

The objective of this Environmental Scan is to gather information regarding one hospital-based P&TC from each Canadian province.

The following questions will be addressed:

1. What are the terms of reference for hospital-based P&TCs, particularly with respect to the committee's membership, as well as roles and responsibilities?
2. Do these committees involve economic discussions for formulary inclusions, or does someone else make these decisions? If these decisions are made by someone else, who are they made by?

Findings

It is not intended that the findings of this Environmental Scan provide a comprehensive review of the topic. Results are based on communication with key informants, and/or review of P&TC terms of reference documents gathered as of June 15, 2011.

Of the 10 Canadian provinces surveyed, responses were received from eight. Respondents represented provincial-level P&TCs from three jurisdictions (British Columbia, Alberta, New Brunswick), health region–level committees from three jurisdictions (Saskatchewan, Manitoba, Newfoundland and Labrador), and tertiary-care hospital-level P&TCs from two jurisdictions (Ontario, Prince Edward Island).

Membership

Beyond the traditional P&TC membership, consisting of physicians, pharmacists, and nurses, the three responding provincial-level P&TCs indicated expanded membership, with members representing the following areas:

- pharmaceutical services division of the provincial ministry of health
- faculty of medicine from a university
- faculty of pharmaceutical sciences from a university
- risk management or patient safety
- chief financial officer
- the public
- laboratory services (ad hoc basis)
- diagnostic imaging services (ad hoc basis)
- clinical nutrition (ad hoc basis).

Regional health authority (RHA) administration representation was present on all three responding health region-level P&TCs through:

- an RHA-level General Manager
- the Vice-President of Pharmacy
- the Vice-President Professional Standards
- the Vice-President Medical Services, and/or
- the Regional Director of Acute Care Services.

In addition, other non-traditional members of one of the RHA-level P&TCs included a clinical dietician and the Regional Risk Management and Client/Staff Safety Advisor.

The two responding hospital-level P&TCs included the following non-traditional members:

- administration representatives: Vice-President of Professional Services, Director of Hospital Services
- an ethicist
- a medical microbiologist.

In addition, at least one P&TC from each of the provincial-, health authority–, and hospital-level committees indicated that they had the capability to consult other clinical specialists or health care staff on an advisory basis, and include them in issue-specific discussions when necessary.

Table 1 summarizes the membership of the P&TCs surveyed.

Table 1: Membership of Surveyed Pharmacy and Therapeutics Committees

Level of P&TC	Committee Membership
British Columbia	
Provincial-level P&TC *The terms of reference for this committee are still in draft phase and are subject to change.	Membership consists of the following: <u>A. 21 voting members:</u> • at least 3 representatives, from both pharmacy and medicine, representing each of 6 RHAs (VCH-PHC count as 1 RHA) • 2 of the above representatives (1 pharmacy and 1 medical lead), appointed by the BC Health Authorities Leadership Council to the Co-Chair positions • 1 representative from each of Pharmaceutical Services Division, Ministry of Health Services; Faculty of Medicine at UBC; Faculty of Pharmaceutical Sciences at UBC. <u>B. 2 non-voting members:</u> • Drug Review Subcommittee Chair and Vice-Chair. Additional non-voting members may be appointed by the voting members.
Alberta	
Provincial-level D&TC	The provincial hospital services D&TC terms of reference document is currently being developed and information is therefore not available; previously existing P&TCs have been dissolved.
Saskatchewan	
Health region-level P&TC	Membership consists of: • medical staff representatives from each of the departments of medicine, surgery, anesthesia, emergency medicine, pediatrics, infectious disease, and family medicine; will include 1 medical department head • 1 representative from the Care Group of the Divisions of Continuing Care and Family Health • Director and Manager, Clinical Pharmacy Services • nursing representatives from each of 3 tertiary-care hospitals • 1 health region-level General Manager and the Vice-President responsible for Pharmacy, representing administration. The Chair is appointed from among physician representatives. The position of Secretary is assigned to the Manager, Clinical Pharmacy Services.

Level of P&TC	Committee Membership
Manitoba	
Health region-level P&TC	Members are to come from a variety of backgrounds and sites in the region. Membership currently consists of: • Regional Director of Pharmacy as the committee Chair • 1 pharmacist representative from each of the regional hospitals and 1 pharmacist from a community hospital • 1 nurse representative from each of a regional hospital, a community hospital, and a personal care home • Chief of Staff from each of the regional hospitals, 1 physician from a community hospital, and 1 general practitioner anesthetist from one of the regional hospitals • the Regional Director of Acute Care Services. Other clinical specialists can be included on an issue-specific basis, as needed.
Ontario	
Hospital-level P&TC	Membership consists of: • Vice-President, Professional Services; Director, Pharmacy; Manager, Pharmacy Operations; Chief Clinical Pharmacist; 2 Drug Information Pharmacists; an ethicist • 1 representative from each of the following areas: Clinical Directors, Clinical Managers, and Integrated Cancer Program; 1 representative from the departments of anesthesia, obstetrics and gynecology, surgery, psychiatry, and critical care • 2 representatives from the department of medicine (as 1 representative from the cardiovascular-specific health centre co-located with part of the hospital and 1 from laboratory medicine).
Quebec	
Hospital-level P&TC	No response received.
New Brunswick	
Provincial-level D&TC	The Chair and members of the provincial-level committee are selected by the Regional Professional Advisory Committees or RMACs of both of the province's RHAs. Membership consists of: • physicians — Medical Chiefs of Staff from each of the 2 RHAs (i.e., Chairs of each RMAC); Chairs of Zone MACs • nursing — from each of the two RHAs: 1 registered nurse in clinical practice; 1 administrative registered nurse involved in nursing policy development; Vice-President of Nursing

Level of P&TC	Committee Membership
	• pharmacy — Executive Director Pharmaceutical Services from Provincial Department of Health (non-voting member); Pharmacy Director of New Brunswick Cancer Network (ad hoc, non-voting member); 1 representative from each of the two RHAs for the following positions: Pharmacy Director, Region/Zone Pharmacy Manager and, as non-voting members, Drug-Use Evaluation or Drug Information Pharmacist (• other — Chairs of any D&TC subcommittees (if not otherwise represented); Chairs of Zone Medication Management Committees (if not otherwise represented); Risk Manager/Patient Safety Representative and Chief Financial Officer from each RHA; public representative (appointed at the discretion of the committee); ad hoc Laboratory or Diagnostic Imaging or Clinical Nutritionist. The committee can also consult any member of the medical or regional health authority staff to act as advisors. Subcommittees include Provincial Formulary Review Committee and Anti-infectives Stewardship; other ad hoc committees as needed.
Nova Scotia	
District health-level D&TC	No response received.
Prince Edward Island	
Hospital-level D&TC *PEI is in the process of establishing a provincial-level D&TC, accountable to the newly formed provincial Medical Advisory Committee, for which terms of reference are being drafted. Once the committee is active, facility-based D&TC roles and responsibilities will change.	Membership consists of: • at least 3 members from representative services of active medical staff, one of whom will be the Chair of the committee • Pharmacy Manager, Pharmacy Clinical Coordinator, a clinical pharmacist, one other staff pharmacist • at least 2 representatives from nursing • Director of Hospital Services • Medical Director (ex officio member) • a medical microbiologist. The Secretary of the committee is the pharmacy department secretary. The committee has the authority to consult any member of the medical or hospital staff to act in an advisory capacity. With the upcoming transition to a provincial D&TC, it is hoped that an ethicist can become a member of the new committee, or at minimum be available on an ad hoc basis. A Medication Safety Subcommittee has been dormant but may be revitalized.

Level of P&TC	Committee Membership
Newfoundland and Labrador	
Health region-level P&TC	Committee is composed of: • 1 physician from Central Health (Chief of Service; serves as committee Chair) • 1 physician from Internal Medicine • 1 physician from Emergency Medicine • 2 physicians from any of the following services: psychiatry, surgery, anesthesiology, obstetrics and gynecology, or general practitioner • the Director of Pharmacy or designate • 2 clinical pharmacists • 1 clinical dietician • 1 representative from Community Health Division • Director of Nursing from each of 2 Regional Health Centres • VP Professional Standards and Chief Nursing Officer or designate • VP Medical Services or designate • Chief of Staff (ex officio member) • Regional Risk Management and Client/Staff Safety Advisor. Other disciplines may be invited to attend a specific meeting, without voting privileges.

D&TC = Drugs and Therapeutics Committee; MAC = Medical Advisory Committee; P&TC = Pharmacy and Therapeutics Committee; RHA = Regional Health Authority; RMAC = Regional Medical Advisory Committee; UBC = University of British Columbia; VCH-PHC = Vancouver Coastal Health and Providence Health Care.

Roles and Responsibilities

Many of the responding P&TCs' terms of reference indicated roles and responsibilities that are much broader than those related to establishing and maintaining a drug formulary listing, including but not limited to the following:

- evaluating safe, effective, ethical, and fiscally responsible drug use
- acting in an advisory capacity on all drug, as well as nutritional product use
- developing clinical guidelines and decision support tools relating to appropriate drug use
- providing educational activities for all health care professionals involved in the medication use process (i.e., prescribing, distribution, administration)
- preparing drug budget impact analyses
- developing criteria for use, treatment guidelines, and standardized orders
- reviewing adverse drug reactions and formulating recurrence prevention strategies
- establishing drug-use evaluation programs and conducting medication audits to optimize drug use
- having direct linkages to the provincial Ministry of Health for sharing information of mutual interest, and coordinating drug-related planning and/or prioritizing
- establishing subcommittees to address specialty practice areas (e.g., pediatrics, oncology, anti-infectives)
- working with other provincial organizations that may fund specific drugs in order to expedite and coordinate formulary status

Table 2 summarizes the various roles and responsibilities of the P&TCs surveyed.

Table 2: Roles and Responsibilities of Surveyed Pharmacy and Therapeutics Committees

Level of P&TC	Committee Roles and Responsibilities
British Columbia	
Provincial-level P&TC *The terms of reference for this committee are still in draft phase and are subject to change.	The committee is responsible for developing and maintaining a single drug formulary that applies to the entire province's hospital-based drug use, including policies, structures, and procedures that support the formulary. Subcommittees, reporting directly to the P&TC, can be formed to advise the P&TC. 1. Drug Review Subcommittee: • completes all drug reviews • work teams created under this subcommittee help complete drug reviews and lead development of clinical guidelines and decision support tools related to appropriate pharmaceutical utilization • supplements the review with a budget impact analysis, which is sent to local or regional health authority P&TCs for consultation • has direct linkage to Ministry of Health Secretariat for planning or prioritizing files of mutual interest • presents recommendations to provincial P&TC for decision. 2. Appeals Subcommittee: reviews all submitted appeals. 3. Pediatrics Subcommittee: BC Children's and Women's Pharmacy, Therapeutics and Nutrition Committee reviews all pediatric medications and makes recommendations to the provincial P&TC. Partner committees are standing committees of the provincial P&TC that review drug use and formulary status in specialty areas where funding is provided by the organization for its decisions. Organizations include the BC Cancer Agency Priorities and Evaluation Committee; BC Transplant Society Renal, Lung, Heart, and Liver Transplant Guideline Committees; BC Renal Agency P&TC; BC Centre for Excellence in HIV/AIDS Advisory Committee on Drug Evaluation and Therapy; and the BC Centre for Disease Control Communicable Disease Policy Committee. The provincial P&TC expedites review of the partner committees' formulary decisions for consideration of formulary status on the provincial health authorities' formulary.
Alberta	
Provincial-level D&TC	The Alberta Hospital Services D&TC terms of reference is currently being developed and information is therefore not available; previously existing P&TCs have been dissolved.

Level of P&TC	Committee Roles and Responsibilities
Saskatchewan	
Health region-level P&TC	The committee is responsible for: • providing evaluative, educational, and advisory capacity to medical staff and health region administration on all drug and nutritional product use matters • serving as an organizational line of communication between medical, pharmacy, and nursing staff • developing and maintaining a formulary of drugs and parenteral nutrition products for the region • establishing policies, guidelines, procedures, and health care professionals' education programs to ensure safe, appropriate, and cost-effective drug and nutritional therapy • reviewing adverse drug reactions and formulating recommendations to prevent recurrence • developing and reviewing drug-use evaluation programs to optimize drug use • participating in quality assurance activities as they relate to distribution, administration, and utilization of drugs • establishing guidelines and policies regarding safe use of medications available from Health Canada's Special Access Program. The committee may also: • invite to meetings individuals who can contribute specialized or unique knowledge, skill, and judgments, when deemed necessary • establish necessary subcommittees to address specialty practice areas.
Manitoba	
Health region-level P&TC	The committee is responsible for: • advising administration, medical, and patient care staff of the RHA on all matters relating to the use of medication • acting as a resource for local hospital P&TCs • creating and maintaining a regional formulary as an evidence-based drug-use guide for the region • receiving and providing an evidence-based evaluation of all formulary addition requests • working cooperatively with other RHAs in assessing drug therapy • making recommendations for stocking specialty medications in order to ensure access to them and encouraging appropriate sharing of resources • working with local P&TCs, when possible and appropriate, to review and standardize regional policies and procedures relating to the prescribing, distribution, and administration of medications • helping to coordinate medication-related continuing education presentations for the region's health care professionals • working with facility staff to conduct medication audits and evaluate drug use reviews • helping to ensure that patients of the RHA receive safe, effective, and appropriate pharmacotherapy • assisting in the evaluation and review of adverse drug reporting activities to Health Canada's Adverse Drug Reaction Reporting Program • advising the regional MAC on any drug research projects occurring in the RHA's facilities.

Level of P&TC	Committee Roles and Responsibilities
Ontario	
Hospital-level P&TC	The committee is responsible for: • formulating and recommending adoption of policies regarding evaluation, selection, and therapeutic use of drugs • evaluating whether drug utilization within the institution is safe, effective, ethical, and fiscally responsible • recommending development of educational programs to meet needs of all professional staff involved with distribution, prescribing, and administering drugs • advising medical and hospital administration on all matters pertaining to drug use • developing a formulary of drugs accepted for use in the hospital and providing for its timely and systematic revisions • basing formulary drug selection on objective evaluation of a drug's therapeutic value, safety, and cost • recommending drug use–related education programs for the hospital's professional staff • studying problems related to the distribution, administration, and prescribing of drugs • initiating and/or directing drug utilization reviews and analyzing the results.
Quebec	
Hospital-level P&TC	No response received.
New Brunswick	
Provincial-level D&TC	The committee advises on all pharmaceutical or parenteral product use–related matters within the province's 2 RHAs, including: 1) maintaining and approving a formulary along with conditions and/or criteria for their use, reflecting rational, evidence-informed, safe, and cost-effective therapy, and 2) developing and maintaining policies and procedures regarding safe and effective use of these products, as well as any related devices. Supporting functions include: • promoting quality drug and parenteral nutrition therapy via ongoing drug-use evaluation identifying opportunities to improve therapeutic outcomes, cost-effectiveness, and patient safety • developing and maintaining policies and procedures for additions, deletions, and criteria for use for formulary drugs, as well as procedures for requesting non-formulary drugs • identifying medication use–related patient risk issues and recommending strategies to promote safe medication use (e.g., high-risk medications) • reviewing drug advisories and warnings from Health Canada, as well as the pharmaceutical industry, and issuing directives, as appropriate • educating medical and other health care professional staff in the RHAs regarding optimal pharmaceutical and parenteral nutrition use • ensuring regular evidence-informed reviews and approval of all RHA protocols relating in any way to pharmaceutical and parenteral nutrition products (e.g., criteria for use, treatment guidelines, pre-printed orders).

Level of P&TC	Committee Roles and Responsibilities
Nova Scotia	
District health-level D&TC	No response received.
Prince Edward Island	
Hospital-level D&TC *PEI is in the process of establishing a provincial-level D&TC, accountable to the newly formed provincial MAC, for which terms of reference are being drafted. Once the committee is active, facility-based D&TC roles and responsibilities will change.	The committee is responsible for all matters relating to drug usage in the hospital, and makes recommendations in the following areas: • policies and procedures for the prescribing, distribution, and administration of drugs • evaluation of new drugs and current drug therapies • maintenance and updating of the hospital formulary • safety issues regarding drug utilization • care map content (care maps are clinical pathways and predetermined physician order sets involving drug therapy, which are reviewed by the committee).
Newfoundland and Labrador	
Health region-level P&TC	The committee's purpose is to assist in the development and surveillance of pharmacy and therapeutics policies and practices, particularly drug utilization with the regional health Board. Duties include, but are not limited to: • preparing, amending, updating, and supervising the implementation of the hospital formulary suited to the Board's needs • undertaking critical evaluation of all requests for changes to the formulary • making recommendations to administration and medical staff with respect to maintenance and improvement of policies and procedures relative to the safe, effective, and economical use of medication • monitoring drug utilization, implementing controls (when necessary), and evaluating clinical data concerning drugs, special feeding, and special diets requested for the hospitals • reporting to the MAC and providing communication and liaison between the medical staff, pharmacy, dietary, and nursing departments and other health care providers • performing other duties, within its mandate, as may be referred to it from time to time by the MAC.

D&TC = Drugs and Therapeutics Committee; MAC = Medical Advisory Committee; P&TC = Pharmacy and Therapeutics Committee; RHA = regional health authority.

Economic Discussions

Table 3 summarizes the decision-making, including economic considerations, of the P&TCs surveyed.

Table 3: Decision-making of Surveyed Pharmacy and Therapeutics Committees

Level of P&TC	Committee Decisions
British Columbia	
Provincial-level P&TC *The terms of reference for this committee are still in draft phase, and are subject to change.	Decisions are made in accordance with accepted rules of evidence, taking into consideration relevant literature, safety issues, clinical experience, and cost-effectiveness evaluation. Although costs are considered in decision-making, each individual health authority must fund the drug from its budget. A financial impact assessment is provided with each of the P&TC's recommendations.
Alberta	
Provincial-level D&TC *Terms of reference are still being developed.	Pharmacoeconomic and budget impact are discussed at the committee meetings. If a significant budget increase (specific amount to be determined) is required for a proposed formulary drug addition, the D&TC will not add the drug to the formulary until funding allocation from the Alberta Health Services finance department has been obtained. Details of the budget allocation process after D&TC has made its formulary recommendation have not yet been formalized.
Saskatchewan	
Health region-level P&TC	Recommendations of the P&TC are presented to the health district-level MAC for adoption. Formulary selection criteria are based on objective evaluation of relative therapeutic merits, safety, and cost. Through the administrative representative on the committee, the P&TC seeks approval from the health region's senior leadership (includes CEO and Vice-Presidents) for recommendations involving increased capital funds or operational budget expenditures.
Manitoba	
RHA-level P&TC	The Regional P&TC is a subcommittee of the Regional MAC. Minutes of the P&TC meetings are circulated to member facilities, and unless written responses are received within the 4- to 6-week minute review period regarding any recommendation concerns, the recorded recommendations are considered

Level of P&TC	Committee Decisions
	approved and actionable. Any concerns received are addressed at the next committee meeting. Policy matters and any P&TC recommendations that have a major financial or staffing impact are referred to the Regional MAC, Facility Directors, Senior Administration, or the RHA Board, as appropriate.
Ontario	
Hospital-level P&TC	All P&TC recommendations are presented to the hospital's MAC. Recommendations to add a drug with an estimated annual cost impact on the hospital of <$50,000 per year are approved by the hospital's MAC. Recommendations to add a drug with an estimated annual cost impact of >$50,000 per year are forwarded to the Corporate Operations Committee, along with a summary as to whether the drug is a benefit under the provincial drug formulary. If it is a benefit, information regarding the drug's status on other provincial academic hospital drug formularies is also provided to the Corporate Operations Committee to take into consideration. The recommendation of this committee is then forwarded to Senior Management for a funding decision, which is then presented to the MAC. In the event that the funding request is not approved at all levels, the request will be submitted to the hospital CEO for a final decision. A summary of the cost impact of all P&TC decisions is sent quarterly to the hospital's Corporate Operations Committee for information.
Quebec	
Hospital-level P&TC	No response received.
New Brunswick	
Provincial-level D&TC	The provincial level D&TC makes the final decisions regarding formulary drug inclusions. The decision process includes an analysis of the financial impact of recommendations, and is binding to the hospitals once a decision is made. The Chief Financial Officers from each of the 2 RHAs are voting members of the committee, making the RHAs fully aware of the decisions and any financial impact on their budgets.
Nova Scotia	
District health-level D&TC	No response received.

Level of P&TC	Committee Decisions
Prince Edward Island	
Hospital-level D&TC *PEI is in the process of establishing a provincial-level D&TC, accountable to the newly formed provincial MAC, for which terms of reference are being drafted. Once the committee is active, facility-based D&TC roles and responsibilities will change.	The committee is a Medical Staff Standing Committee that reports and makes recommendations for approval to the hospital's MAC. Unless they are cost neutral, economic decisions may be made at the clinical service level, the facility level by reallocating funds, or if new money is needed, by the PEI Treasury Board.
Newfoundland and Labrador	
Health region-level P&TC	All recommended policies are ratified by the appropriate medical and administrative committees. The P&TC has economic discussions and makes economic decisions relating to formulary drugs. These decisions are forwarded to the MAC for final approval.

D&TC = Drugs and Therapeutics Committee; MAC = Medical Advisory Committee; P&TC = Pharmacy and Therapeutics Committee; RHA = Regional Health Authority.

Conclusion

Hospital-based Pharmacy and Therapeutics Committees (P&TCs) from the 10 Canadian provinces were surveyed regarding their terms of reference. Responses were received from eight such committees representing provincial-, health region–, or tertiary-care hospital-level P&TCs. Membership of the responding P&TCs has in most cases expanded from a basic physician-, pharmacist-, and nurse-based composition to include hospital, health region, or provincial health ministry administrative representation, as applicable, as well as ethicists, other allied health professionals, quality assurance and/or risk management personnel, academia, and the public. The roles and responsibilities of these committees have also expanded from initiating and maintaining a drug list–based formulary to activities that encompass all aspects of drug therapy on both a proactive and retrospective basis, in order to ensure safe, effective, ethical, and fiscally responsible drug use. Some jurisdictions have also established collaborative partnerships with other provincial organizations involved in managing drug formularies, to further coordinate provincial drug therapy initiatives.

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Canadian Agency for Drugs and Technologies in Health (CADTH)
600-865 Carling Avenue,
Ottawa, Ontario K1S 5S8