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Canadian Society of Hospital Pharmacists
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Liability and Risk Management: Guidelines for Hospital Pharmacists

PREFACE

This is the 2001 edition of the Canadian Society of Hospital Pharmacists Liability and Risk Management: Guidelines for Hospital Pharmacists.

These guidelines were approved under the title of Guidelines for Liability and Risk Management; the title was fine-tuned in 2009.

1. INTRODUCTION

Malpractice cases are increasing at a rate of approximately 10% per year. Although the number of cases which are brought forward to Canadian courts are a small fraction of those in the US courts, the awards can be substantial. The purpose of this paper is to raise awareness among hospital pharmacists of the issues and risks of negligence litigation. The assessment tools included are intended to assist hospital pharmacists in determining their personal risk, while identifying opportunities for risk management and reduction. However, as it is impossible to eliminate risk, it is prudent to investigate the consequences of negligence litigation before such an incident occurs.

Pharmacists should understand some basic principles of law. In order for the plaintiff's lawyer to prove negligence, four key points need to be demonstrated:

a) It must be proven that the hospital pharmacist owed a duty to the plaintiff. It is clear that, as long as a pharmacist is acting as an employee of the hospital and performing tasks that are normally expected of hospital pharmacists, the pharmacist does owe a duty to the patient.
b) It must be proven that there has been a breach in the standard of care which would be expected under the circumstances. This is often a difficult issue in that standards are constantly changing. There are criteria by which the standard of care will be identified by the court. These are:

i) that the hospital pharmacist must perform to the standard of care which could "reasonably be expected of a prudent practitioner of the same experience and standing";[1] and,
ii) that if the hospital pharmacist "holds him/herself out as a specialist, a higher degree of skill is required".[1]

One important point that should be considered in looking at what is required to prove negligence is the issue of negligence versus an error in judgement. If a number of alternative approaches would have met the standard of care, but the one taken resulted in a loss or injury, then negligence cannot be established since the outcome is the result of a bona fide exercise of judgement. However, if there is no documentation to establish that the course of action taken was based on a conscious decision, the court may assume that an absence of action was an omission due to negligence.
Two factors which should be noted are that when peer standards are sought, they are primarily from institutions of similar size and status rather than from published standards, and that they deal with the knowledge, skills and standards current to the event in question rather than at the time of the trial.
c) It must be proven that loss or injury occurred. Without loss or injury, there can be no damages awarded to the plaintiff. Therefore, there is no point in pursuing a costly and time consuming legal battle. The measure of the loss or injury will determine the amount of the damages assessed.
d) It must be established that the breach of the standard of care was directly responsible for the loss or injury and that the loss was foreseeable and avoidable.

It is not possible to protect all patients from injury all of the time. Therefore, some incidents may result in legal action being taken if the patient and their lawyer feel that the injury was a result of negligence. It is the responsibility of hospital pharmacists and their managers to ensure that standards of care are being met, and that documentation exists to

demonstrate that those standards are being met. There are two common scenarios from which litigation may result:

a) “oops” scenario - in this case the harm to the patient is immediate and obvious and the incident or mistake which led to the injury is apparent. Immediately documenting the events from each individual’s perspective will add credibility to the testimony at a much later date.
b) “silent” scenario - occurs when an injury results from routine care but is perceived by the patient to be due to negligence. These cases are often not known until legal documents are served on the hospital. This may not happen for years after the actual event. For these types of situations, only prophylactic documentation will do. This means documenting all actions and the decisions behind them as well as documenting the decisions made which result in no action being taken. It means keeping copies of policies and procedure manuals, not just of the current vintage but in archives appropriately dated for retrieval so that the particular policy or procedure in effect at some time in the past would be known.

Finally, it requires care on the part of policy makers and staff to ensure that what is documented is what is meant. A policy which requires a specific action under certain circumstances may be entirely appropriate; however, it should allow flexibility for professional judgement or for unusual circumstances in terms of workload and staffing. Routine documentation is essential in order for the material to be available should it be required.

2. RISK ASSESSMENT

Appendix A is a self-assessment tool which may assist pharmacists in efforts to determine their relative risks.

There are different risk profiles for pharmacists who are employees of a health care facility depending on whether they have management responsibilities. In addition, pharmacists must be cognizant of non-job related activities which may place them at risk for litigation.

Negative responses imply a greater risk while positive responses may imply a lesser risk of litigation. Negative responses may indicate a need for increased risk management activities.

3. LITIGATION AWARENESS

Pharmacists must educate themselves regarding the litigation process. It should be noted that regulations and procedures vary provincially. The following section identifies examples of information and procedures pharmacists should be familiar with prior to and during the provision of their professional expertise.

3.1 Preparation

3.1.1

Know the insurance coverage provided by your employer or institution retaining your service.

3.1.2

Is defence provided and paid for under the coverage agreement?

3.1.3

Determine the insurance company’s position with respect to suing individual staff members if damages are awarded. Is there the expectation for overlap with personal malpractice insurance?

3.1.4

Is the policy restricted to events related only to patients or would it assume responsibility for consultation given to staff which led to personal injury arising from malpractice?

3.1.5

Know what assistance, e.g., Risk Management Department, is available in your institution.

3.2 Investigation of an incident or formal claim

3.2.1

Documentation and evaluation functions should be conducted upon notification of either an incident or formal claim.

3.2.1.1
Determine the extent of the patient's injury and identify the persons who would be potentially liable.

3.2.1.2
Investigation should address the following:

a) Have statements been taken or fully noted conversations held with all parties involved, e.g., witnesses, nurses, medical staff, pharmacy staff;
b) Has conflicting information been resolved;
c) What is the nature of the injury;
d) Has the hospital counsel rendered an opinion (written);
e) Have the insurance representatives been notified; and,
f) Has the provincial licensing body been notified, if this is a provincial requirement?

3.3 Response to a claim

3.3.1

After complete evaluation of the claim or potential claim the hospital will establish a claim file. A number of activities should occur so as to improve the defence position of the hospital:

a) Place original medical record under lock and key;
b) Ensure all portions of medical record are present; and,
c) Collect policies and procedures concerning the incident.

3.4 Litigation process

The litigation process in Canada includes:

a) Statement of Claim;
b) Statute of Limitations;
c) Statement of Defence;
d) Affidavit of Documents;
e) Examination of Discovery:
    i) discovery of documents;
    ii) independent medical examination of plaintiff;
f) Pre trial motions;
g) Preparation for trial;
h) Pre-trial conference;
i) The trial:
    i) Provincial Superior Court;
    ii) Court of Appeal; and,
    iii) Supreme Court of Canada.

4. SUMMARY

Pharmaceutical care demands "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patients quality of life."[2] Inherent in assuming the additional responsibility is an associated increase in accountability. The provision of pharmaceutical care and the resulting documentation in the patient's health record will increase the perception of duty owed by the pharmacist to the patient by other health care workers and the public. This will increase the risk of negligence litigation to the pharmacist.

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APPENDIX A: RISK ASSESSMENT TOOL

Topic/Question	Yes	No
Practising Health Care Facility Pharmacist:		
1. Do you always comply with the following standards, to a level consistent with your peers (If not, is your reason documented?): a) CSHP Standards of Practice; b) Provincial pharmacy acts; c) Narcotic and Controlled Drug Act; d) health care facility policies and procedures; e) pharmacy department policies and procedures; and/or, f) other applicable standards?		
2. Do you routinely participate in continuing education events?		
3. Do you routinely review pertinent literature to maintain your competence?		
4. Do you document your patient care activities in a way which could be retrieved as evidence?		
5. Are you licensed to practice pharmacy in your province?		
6. Do you practice at a level commensurate with your level of training and experience, i.e., how would your practice compare with others of similar training and experience?		
7. Do you use available and appropriate resources in preparing relevant responses to drug information requests?		
8. Do you communicate patient care activities to relevant members of your department and other caregivers to ensure continuity of care?		
9. Are your actions in the best interests of the patient?		
10. Do you maintain confidentiality of information?		
Pharmacist with Management Responsibilities **Note:** *If hands on practice is a part of your responsibility, section for a practising pharmacist also applies.*		
Policy Development:		
1. Are pharmacy department policies and procedures established to ensure compliance with: a) provincial pharmacy legislation; b) Narcotic and Controlled Drug Act; and, c) health care facility policies and procedures?		

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Topic/Question	Yes	No
2. Are you confident your medication-related policies and procedures are safe for all the patients in the health care facility?		
3. Do you keep copies of past policies and procedures with their effective dates?		
4. Is all of the information contained in departmental publications checked for accuracy?		
5. Are all medication-related policies and procedures reviewed and approved by the pharmacy department and by other committees as required by health care facility policy or bylaws?		
6. Are policies and procedures in place for all therapeutic interchange policies?		
7. Do your policies and procedures allow for exceptions or unusual circumstances?		
8. Do you have a mechanism to monitor compliance with policies?		
Practice Standards:		
1. Do your pharmacy services meet the standards of pharmacy practice as practised by health care facilities of similar size and type? **Note:** *Refer to CSHP and NAPRA Standards of Practice, CCHFA Standards and peer group comparisons.*		
Quality Assurance:		
1. Do you ensure that pharmacy staff provide appropriate documentation?		
2. Do you have a medication incident follow-up program?		
3. Do you document all available information when a drug misadventure occurs?		
4. Do you perform quality assurance audits on all services?		
5. Have you addressed deficiencies identified by licensing body inspection reports, accreditation surveys (CHPRB or CCHFA), or external or internal reviews?		
6. Do you ensure that confidentiality of information is maintained?		
Staffing:		
1. Do you monitor, discuss, and document non-compliance of policies and procedures with relevant staff?		
2. Do you have up-to-date job descriptions?		
3. Do you have appropriate qualifications specified in all job descriptions?		

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Topic/Question	Yes	No
4. Do you always hire according to your specific job requirements?		
5. Do you have an orientation program?		
6. Do you conduct performance appraisals at least annually or as required by the institution?		
7. Do you document discussions with staff regarding quality of performance?		
Resources:		
1. Do you ensure that appropriate drug information resources are available? **Note:** *Refer to CSHP Recommended Drug Information References for Hospital Pharmacists*		
2. Are the resources, e.g., equipment and staffing, available in your department appropriate for the services provided?		
Other Liability Risks: **Note:** *The activities of a health care facility pharmacist on behalf of a health care facility are normally covered by the health care facility's insurance policy. However, pharmacists must be cognizant of non-job related activities which may place them at increased risk for litigation. The following questions, if answered in the affirmative, identify activities which may indicate a need for private malpractice insurance.*		
1. Do you provide services as a consultant, e.g., to nursing homes, pharmaceutical industry, government agencies or other health care facilities?		
2. Do you work as a pharmacist at another pharmacy, e.g., in a part-time job at another retail or health care facility pharmacy?		
3. Do you provide drug information outside of the institution that employs you? This may include other pharmacy outlets, pharmacists, physicians, patients, friends, family, administrators, lawyers, the media, manufacturers, or other health professionals. For example, a physician calls and requests drug information to be used in care of a non-hospitalized patient or a friend asks for drug information at a social event.		
4. Do you make presentations to other health professionals, students or the public regarding drug therapy, e.g., continuing education, professional conferences, patient information seminars?		
5. Do you document the suggestions and information that you provide to members of the public? Do you recommend that the patient discuss these suggestions with their physician or pharmacist before taking action?		
6. Do you conduct any independent activities where your knowledge of drugs is used in a decision making process?		
7. Do you use physical assessment as a tool to evaluate drug efficacy or toxicity in non-health		

Topic/Question	Yes	No
care facility patients, e.g., abnormal movement rating systems, balance testing, range of motion?		
8. Do you publish in the professional literature or other publications?		
9. Do you prepare and distribute patient medication information?		