

British Columbia Association of Laboratory Physicians

Frances Rosenberg MD PhD FRCP(C) President

Department of Laboratories
St. Paul's Hospital
Vancouver BC V6Z 1Y6
Phone (604) 806-8190
Fax (604) 806-8158
email rosenbrg@stpaulshosp.bc.ca

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Dr. Dan McCarthy
Director of Professional Relations
British Columbia Medical Association
115-1665 West Broadway
Vancouver BC V6J 5A4
Fax#736-4566

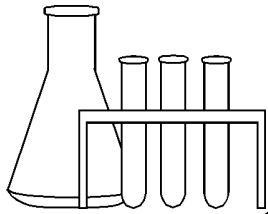
Dear Dr. McCarthy,

The British Columbia Association of Laboratory Physicians has learned of the College of Pharmacy's proposed expansion of their scope of practice into the area of laboratory testing. We have discussed this proposal within our Section and would like the attached remarks forwarded to the Health Professions Council as an addendum to the British Columbia Medical Association's submission.

Like other British Columbia physicians, we have encountered specific situations where we have collaborated with pharmacists to improve the quality of health care. We respect their knowledge of drug therapy and the important role they play in ensuring safe and effective drug therapy. We hope that they can appreciate our desire to ensure the safety and effectiveness of laboratory testing.

Sincerely yours,

Frances Rosenberg, MD PhD FRCP(C)



from the British Columbia
Association
of

Laboratory Physicians

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Concerns about the College of Pharmacy's proposed extension of their scope of practice to include: "Performing screening and monitoring procedures using pharmacy-based laboratory tests, including the associated quality control functions, and interpreting and communicating the results."

The British Columbia Association of Laboratory Physicians (BCALP) is a Section of the British Columbia Medical Association. Our members are medical doctors with specialty certificates in Laboratory Medicine. Our special expertise includes all aspects of laboratory testing and its application to patient care. As practitioners of laboratory medicine, we believe our comments on this matter will interest the Council.

Risk of harm

The activities included under this heading involve the practice of medical laboratory technology and the practice of medicine. The delivery of these services involves the performance of two reserved acts¹:

- 1) Making a diagnosis, identifying a disease, disorder or condition as the cause of signs or symptoms of the individual
- 2) Performing the following physically invasive or physically manipulative acts:
 - a) procedures on tissue below the dermis, below the surface of a mucous membrane, in or below the surface of the cornea, in or below the surfaces of the teeth, including the scaling of the teeth

The designation of these services as reserved acts by the Health Professions Council indicates that there exists significant risk of public harm from the provision of these services.

Although the applicant's summary statement might suggest that the pharmacists only propose to perform test procedures, the explanatory text shows that they do not intend to limit themselves to test performance. Phrases like "to offer a diagnosis", "determine if they have iron deficiency anemia", "offer definitive advice (about iron deficiency anemia) to the patient" indicate they intend to diagnose and treat health conditions.

BCALP members expressed concern that the pharmacists were not qualified to perform the services they were proposing to offer the public. The application provides some specific instances where public harm might result. The section on hemoglobin assessment was particularly worrisome. There are many causes of low hemoglobin, of which iron deficiency is but one. The approach outlined by the pharmacists is dangerous as it could delay appropriate investigation and treatment of the cause of the anemia (e.g. occult malignancy, bleeding ulcer). Serious treatable conditions may well be masked by supplemental iron therapy precluding early diagnosis and cure of potentially life threatening lesions. Iron deficiency in males of any age and postmenopausal females warrants investigation for blood loss, which usually arises from the gastrointestinal tract and may be the first sign of a malignant tumor or ulcer. In addition, the comment about hemoglobin assessment shows little insight into the nature of iron deficiency. Body depletion of iron

stores occurs before anemia develops. Many Canadian women or children may have symptomatic iron deficiency without anemia. The pharmacist who uses the hemoglobin level to determine the need for iron supplementation could very well cause harm. Another concerning example is that of cholesterol testing. As cholesterol is but one risk factor for atherosclerosis, a high-risk patient who receives a good cholesterol reading at a pharmacy may falsely conclude that their atherosclerosis risk is low.

Technology

The reasonableness of this proposal hinges on the ability of modern technology to provide accurate and precise analyses for some laboratory tests in non laboratory settings. The applicant identifies some of the issues that providing testing within this context raises without attempting to address them. On page 4, they provide examples of procedures that properly trained pharmacists might perform and on page 5, they recognize that the performance of some types of diagnostic procedures requires more qualifications than the tests they anticipate performing in pharmacies. How will they know which tests are appropriate for pharmacists to perform? At present some of the tests they mention are clearly out of scope technically, i.e., PSA and osteoporosis marker testing. The simpler tests for H pylori cannot distinguish between active and inactive infections. Misinterpretation of these tests can result in unnecessary concern and promote unnecessary antibiotic use. PSA testing in subjects with prostatitis could give the mistaken impression of prostate cancer.

Environment

In the United States, there is a class of medical laboratory tests called “waived tests”² that non-medical technologists may perform. To obtain this classification, tests must meet certain specific criteria³ and receive Food and Drug Administration (FDA) approval⁴. The designation is specific for the method used to perform the test. Any facility providing these services will qualify for reimbursement under insurance plans if it receives a certificate of waiver under the Clinical Laboratory Improvement Amendments (CLIA) regulations. To obtain this certificate, the facility must meet certain basic laboratory standards that address staff qualifications and operational requirements. These standards differ from pharmacy standards.

In Canada where laboratory testing has operated within the public health care system, we have not developed as extensive a regulatory framework for addressing performance and reimbursement. Recently the Health Protection Branch has introduced new regulations for product licensing that incorporate a four tier risk based classification⁵. With few exceptions, the classification of near patient testing devices is Class III. The manufacturer must specify where the product is intended for use at home, an alternate care site or a clinical laboratory. The manufacturer may specify the qualifications that the personnel performing the test require or this may fall to the relevant regulatory bodies. Within British Columbia the College of Physicians and Surgeons has a well established system for assuring the quality of laboratory testing. The introduction of the near patient technologies has occurred within the provincial regulatory framework. The Diagnostic Accreditation Program (DAP), which operates under the College of Physicians and Surgeons of British Columbia, has the mandate for accrediting laboratory-testing facilities. The DAP has established guidelines for the use of near patient technologies within organizations that operate accredited laboratories. As simple as the technologies may appear, the provision of an environment that assures quality testing is not an easy task.

Provincial guidelines exist for the appropriate use of some of the tests listed⁶. Regular self-glucose monitoring supplemented by periodic laboratory measurement of hemoglobin A_{1c} is the Canadian and BC testing standard for diabetic care. For diabetes screening, the guidelines⁷ set out specific conditions for patient preparation. Under these conditions, testing for diabetes would not prove more accessible at a pharmacy than it is at the laboratory now. If the pharmacists screen for diabetes without following the

guidelines, they could drive up the downstream costs through improper testing. Provincial guidelines govern lipid⁸ (cholesterol) and H pylori testing⁹.

Need

The applicant submits without presenting any supporting evidence that the greater accessibility of pharmacy-based tests offers long term benefits to the patients and the health care system. Presently British Columbians enjoy easy access to quality medical laboratory testing through the existing publicly funded system. While the addition of pharmacy-based testing could expand access to tests it might lead to increased health care costs and reduced quality of health care. The community and hospital based laboratories that make up the existing delivery system focus on medical laboratory testing. The staff who operate these facilities are specialists in laboratory medicine and medical laboratory technology. The Diagnostic Accreditation Program monitors their testing proficiency at frequent intervals and inspects their facilities periodically. These clinical laboratories provide testing according to a model that incorporates testing into the diagnostic process of qualified health care professionals. The use of laboratory tests, as a tool for health care product marketing, is a very different business model.

On Page 5, the proposal mentions use of a team approach to pharmacy based procedures without offering a specific example of how this would improve health care in British Columbia. The concept is worth mentioning because the few reports of health care benefits from pharmacist testing have come from situations where the pharmacist was a member of a formal multidisciplinary team operating within a managed care system¹⁰. This submission does not attempt to demonstrate that the British Columbia community pharmacists have the capability or interest to move in this direction.

The citation from the World Health Organization obviously refers to underdeveloped countries that lack a widespread system of medical laboratories. If there are British Columbia communities large enough to support a pharmacy that lack collection facilities this should be brought to the attention of the Regional Health Boards and the Medical Services Commission.

Training and expertise

The present educational programs for pharmacists do not provide the education and training required to deliver the medical and technical services they describe. On page 4, the applicants mention acquiring the knowledge of standardized patient preparation and blood collection procedures, if necessary. How will they determine if it is necessary? How do they propose to acquire the necessary knowledge? Where will they learn blood collection? From where will they absorb the culture of laboratory practice? How many pharmacists have actually spent any time in a clinical laboratory testing area? The applicants state that their discipline has shifted from technology to problem solving and communications, where will the core competencies needed to operate a system that ensures the delivery of quality test results come from?

Conflict of interest

BCALP members expressed concern that community pharmacists who provide diagnostic laboratory tests have a potential conflict of interest. As employees or owners of businesses that profit from the sale of health care products, their testing services could lead to the inappropriate purchase of merchandise. Hemoglobin assessment is a specific example of a situation where this could apply. In Britain, the question of conflict of interest has arisen in relation to the pharmacists advisory role for over the counter drugs¹¹. Certainly, both the College of Physicians and Surgeons and the College of Pharmacy would think it highly inappropriate if laboratories wanted to sell cholesterol lowering medications to patients with abnormal test results.

Limitations

Only where they are free from conflict of interest and in an environment covered by the Diagnostic Accreditation Program should pharmacists perform “simple” laboratory tests. Pharmacists who do perform laboratory tests should have certificates of competency for blood collection.

¹ Health Professions Council. “Shared Scope of Practice Model Working Paper” <http://www.hlth.gov.bc.ca/hpc/shacope.html>

² <http://www.oshd.org/phl/ll/waivppm.htm>

³ <http://www.phppo.cdc.gov/DLS/clia/docs/hsq225p.htm>

⁴ <http://www.phppo.cdc.gov/dls/clia/chronol.asp>

⁵ <http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html>

⁶ <http://www.hlth.gov.bc.ca/msp/protoguides/index.html>

⁷ <http://www.hlth.gov.bc.ca/msp/protoguides/gps/diab/diab.html>

⁸ <http://www.hlth.gov.bc.ca/msp/protoguides/gps/cholesterol/choleful.html>

⁹ <http://www.hlth.gov.bc.ca/msp/protoguides/gps/index.html#Title>

¹⁰ Spalek, V.H. and Gong, W.C. Pharmaceutical care in an integrated health system. *Journal of the American Pharmaceutical Association*. 39(4):553-557, 1999

¹¹ Bond C.M., Bradley C. Over the Counter Drugs: The interface between the community pharmacist and patients. *British Medical Journal* 312(7033): 758-760, 1996

For additional information contact:

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email rosenbrg@stpaulshosp.bc.ca

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The British Columbia Association of Laboratory Physicians (BCALP) promotes quality within Laboratory Medicine practice and recognition for Laboratory Medicine specialists. The BCALP represents the business and economic interests of the Section of Laboratory Medicine within the British Columbia Medical Association.