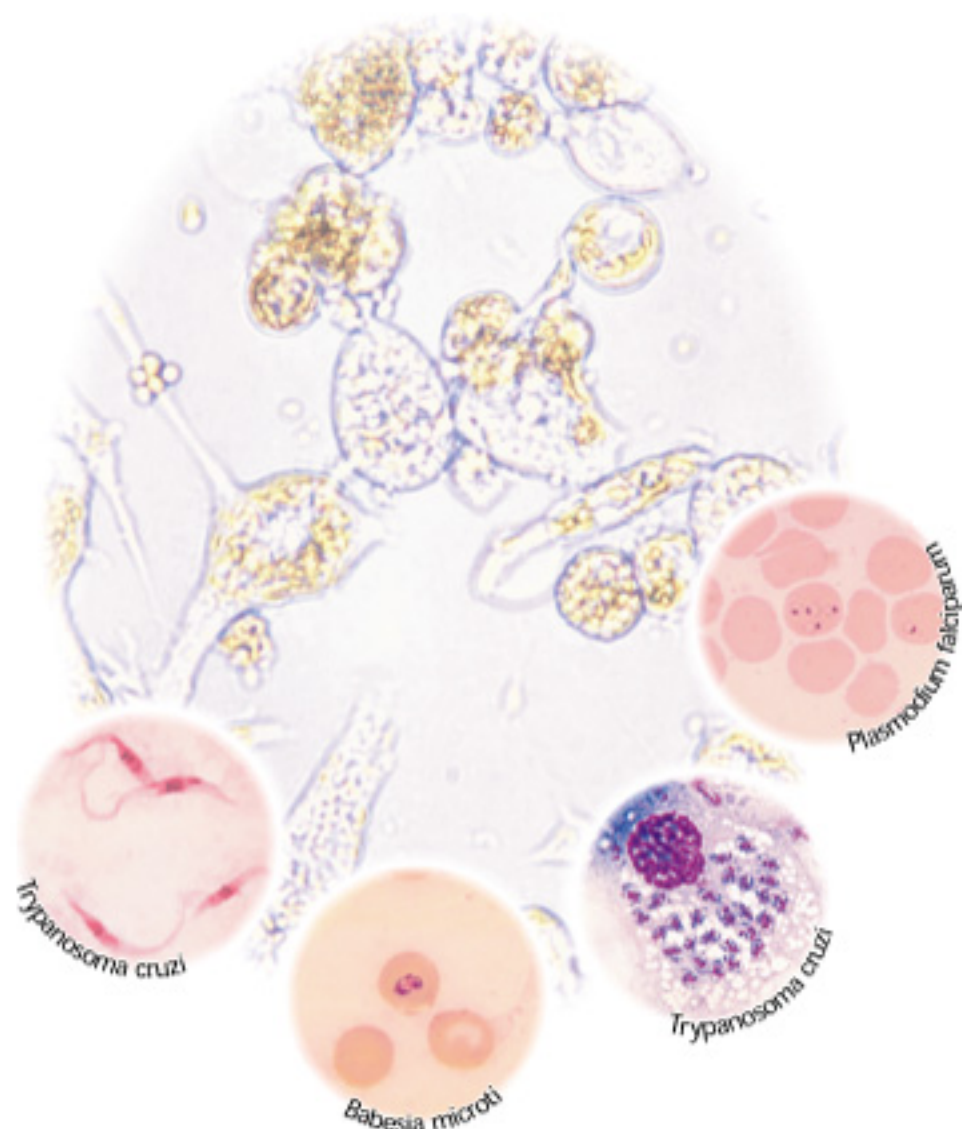


Blue Ribbon Committee on Bloodborne Parasitic Diseases



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maintain and improve their health.

Health Canada

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Blue Ribbon Committee on Bloodborne Parasitic Diseases

*Health Canada
Centre for Infectious Disease Prevention and Control
Bureau of Infectious Diseases
Blood-borne Pathogens Division**

** Now the Health Care Acquired Infections Division, Blood-borne Pathogens Section.*

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Introduction

Several parasitic diseases have emerged recently in Canada, mainly as the result of cases detected in Canadian travelers, immigrants, or refugees. Some of these diseases cause prolonged parasitemia and could pose a risk to the blood transfusion system of the country. Malaria, babesiosis, and Chagas' disease are three clear examples. However, the actual prevalence of these infections in Canadians as well as in populations living in certain high-risk areas of the world remains largely unknown.

Health Canada's Blood-borne Pathogens Division of the Bureau of Infectious Diseases, Centre for Infectious Disease Prevention and Control (CIDPC), Population and Public Health Branch, is responsible for the evaluation of risks of parasitic diseases and has successfully conducted surveillance studies on

viruses and prions. In order to improve the investigative, surveillance, and risk assessment aspects related to bloodborne pathogens, the Division hosted a meeting of the Blue Ribbon Committee on 5 and 6 March, 2001, in Ottawa. Participants included international experts currently involved in research and laboratory diagnosis of bloodborne parasites and parasitic diseases; their expertise and extensive experience provided important insights.

This report first provides background information on bloodborne parasites and the surveillance systems in place both in Canada and internationally, and then goes on to outline the processes and outcomes of the March meeting.

Background

Bloodborne Parasitic Pathogens in Canada

Interest in bloodborne pathogens has been high since the release of the Final Report of the Commission of Inquiry on the Blood System in Canada (Krever commission)⁽¹⁾. The recommendations in this report, specifically concerning the need for greater vigilance to protect the safety of the blood supply, have led to an increase in the resources available to achieve that end. Although Canada's blood supply is now as safe as it can be at this point in time, there is a clear need to examine old, new, and renewed threats to Canada's blood collection/donation system.

Parasitic diseases have always been an important consideration for blood safety, and the threat is growing, given increased travel and changing immigration patterns. The broad spectrum of new immigrants arriving in Canada together with other factors, such as global warming and the potential expansion of parasite-endemic areas, dictate a continued high degree of vigilance against the possibility of parasitic infection within the blood supply.

The role of CIDPC is clear: to identify risk, assess that risk, and advise on policy options to maintain the safety of the blood supply. However, fulfilling this role depends on well-defined scientific requirements to serve as the basis for surveillance activities. Identifying and defining these scientific requirements and recommendations were underlying goals of the conference.

Although risk among blood donors is obviously a major concern, consideration of the risks posed by parasitic diseases should not focus solely on this aspect. Discussion of the impact of bloodborne parasitic pathogens on the population at large is also important, specifically concerning the following: infections imported with population movement; infections that occur with returning travelers;

and infections that are endemic to Canada. Discussion of these issues must also take into account that in some cases the risk of transmission of secondary infection will be rather restricted or even unique.

Arthropod-borne parasitic diseases

Several arthropod-borne diseases either already exist or are likely to appear in Canada. As with organisms such as the dengue virus, which is contracted by about 40 travelers who return to Canada every year, there are probably more cases than those identified through laboratory testing⁽²⁾.

With regard to arthropod-transmitted diseases endemic to Canada, several species of ticks, mosquitoes, and other insects thrive in Canada and can easily pass on various bacterial, viral, or parasitic infections. The agent that causes human granulocytic ehrlichiosis (HGE) has been found in *Ixodes scapularis* ticks endemic at Long Point on Lake Erie⁽³⁾. *I. scapularis* ticks have also been found without documented endemicity in other provinces of Canada, from Newfoundland to Saskatchewan, and the HGE agent has been documented in ticks from several of these provinces⁽³⁾. The HGE agent can survive for 18 days at 4° C, thus presenting a possible risk of transmission through blood transfusion.

Canadian laboratory examination for *Babesia* – an example of an arthropod-transmitted parasite – is not yet under way, although it is expected to start soon. A case of transfusion-transmitted babesiosis has been documented in Canada⁽⁴⁾. Developing a Canadian base of knowledge concerning the full range of potential parasitic infections and testing individuals suspected of infection for all parasitic agents are important for two reasons: (1) dual infections are commonly seen in laboratory-confirmed cases and (2) two species of ticks (*I. scapularis* and *I. pacificus*) are found either endemically or non-

endemically in many provinces of Canada and are capable of transmitting *Babesia microti*, the pathogen that causes human babesiosis⁽⁵⁾, as well as other etiologic agents such as *Borrelia burgdorferi*, the etiologic agent of Lyme disease, and the HGE agent.

Malaria

Malaria represents another emerging threat to Canada's blood system, albeit one that was endemic to Canada at the turn of the 20th century. Current research in Canada is examining *Plasmodium falciparum* malaria to determine whether it has changed in recent years as a result of climatic or other factors, such as increased travel. The number of cases seen in Canada indicates that incidence is increasing, but it is unclear whether we are learning as much as we should from the large number of cases currently cropping up. *P. falciparum*, with its potential to contaminate the blood system, is a very real threat given that both travel to, and immigration from, malaria-endemic countries is increasing. In 1997 and 1998 there were > 1,000 cases of malaria in Canada (estimates indicate that 30% of cases are not reported). The number of reported malaria cases decreased following public health information campaigns in 1998, but is increasing once again, and *P. falciparum* malaria has been detected in Toronto in travelers returning from endemic areas.

Rates of transmission are increasing, as are the risks of infection, and there is concern that strains are becoming drug resistant, particularly in endemic areas. Good evidence exists that some drugs, such as chloroquine, are failing in several malaria-endemic areas, and therefore we may see an increased number of drug-resistant cases in Canada. A recent study⁽⁶⁾ examining non-immune travelers and their risk of contracting malaria found cases in which chloroquine was not effective. Further study revealed that those who failed treatment with the drug had *falciparum* malaria isolates with gene mutations that confer drug resistance to chloroquine. Of the standard drugs, mefloquine is still deemed to be highly effective, and < 10% of people who adhere to prophylactic drug regimens get

malaria. Pre-travel advice is still considered an important tool in reducing the risk of contracting traveler's malaria; however, very little data exist on what information travelers are receiving before traveling to endemic areas.

A study at Pearson International Airport⁽⁷⁾ found that 54% of those departing for malaria-endemic countries had sought pre-travel advice, 70% of which was from family physicians, but that this interaction did not translate into the use of chemoprophylaxis. Although the public health concerns regarding traveler's malaria may not be particularly worrisome to Canadians, it certainly should be for the two to three million who visit the developing world each year. Because of inconsistent and incomplete passive systems of surveillance in Canada and the rest of the world, the burden of traveler's malaria is difficult to determine. Without knowing the number of cases seen in Canada and the rate of drug resistance, it is difficult to design contingency plans to address the issue.

McGill University currently houses the National Centre for Parasitology Services (NCPS), which, even within tight budgetary constraints, carries out a significant amount of parasitologic contract work and provides high-quality reagents in Canada and the United States (U.S.). Based on the recent experiences of the NCPS, the reappearance of a malaria epidemic in Canada (and Quebec specifically) is not unthinkable. Approximately 2,000 refugees arrived in Quebec in 2000, and in August of that year, 228 arrived on a single plane. Shortly after the arrival of that group, the NCPS witnessed a huge increase in the number of reference slides being received from outlying hospitals. Although the large number of slides presented a major increase in workload for the NCPS, the fact that these hospitals sent them in is still very positive, given that they are under no obligation to do so. Immigration practices often disperse immigrants to outlying regions upon arrival, ensuring that the majority of cases will be seen in hospitals in smaller outlying communities. This presents a major barrier to the containment of any suspected outbreak, even though most of the community hospitals

do send in samples from suspected malaria cases for screening.

Although refugees and immigrants rarely arrive in large groups, Health Canada, Citizenship and Immigration Canada, the Ministère des Relations avec les citoyens et de l'Immigration, Québec, and the McGill Tropical Diseases Centre did seize the opportunity to study how much the decision not to screen the large contingent of refugees who arrived in August cost the health care system in Canada. As well as following the August arrivals retrospectively, the study had a prospective element, in that representatives met another group of refugees upon their arrival in Quebec in December. Although the results of these studies have not yet been finalized, preliminary findings indicate that a significant number of refugees are bringing malaria with them into Canada. This has likely always been the case but has never presented a large threat since most groups of refugees and immigrants arrive in much smaller groups. The study has also already encountered some important lessons concerning testing of malarious individuals: the data seem to indicate the importance of confirmatory or second-method testing of the results.

The sobering reality of malaria among immigrants and refugees is that thousands of people come to Quebec from malaria-endemic areas every year. If a few of these individuals infected with malaria decided, for example, to hold a picnic on the banks of the St. Lawrence River in May or June, a local amplification cycle of malaria could be initiated. The chances that the parasite could survive over winter and result in the re-emergence of malaria on a long term-basis remains to be determined. Although it is difficult logistically to greet every new arrival in Canada from a malaria-endemic country, a systematic surveillance strategy, particularly of large groups of refugees, is necessary to avoid outbreaks. Canada's climate might also provide assistance, in that new arrivals could be scheduled to land in Canada in October or later to avoid subsequent infection transmitted by the mosquito population. The increase in refugees, immigrants, and travelers to malaria-endemic

regions of the world will continue to add to the burden of already overtaxed academic research units and reference diagnostic services for parasitic diseases.

Currently, provincial public health laboratories send samples from suspected cases of infection to the NCPS or to the Centers for Disease Control and Prevention (CDC) in Atlanta. With the reorganization of the NCPS, the number of tests carried out has jumped from 1,887 in 1990 to 2,964 in 2000. If all Canadian samples were sent to the NCPS, that number would likely exceed 4,000. The NCPS has initiated significant quality assurance measures in order to maintain the highest standard of testing. It currently struggles to carry out, on a budget of \$70,000, its weighty mandate of providing reference diagnostic services in serology for parasitic diseases, research and development, surveillance of parasitologic infection, and consultation with CIDPC, provincial laboratories, and clinical parasitologists. The service could not survive without the support of McGill University and the transfer of grant money secured by researchers working in the NCPS. The scarcity of resources faced by the NCPS is a significant hurdle to be overcome as the number of tests to be processed in Canada grows.

***Trypanosoma cruzi* infection**

American trypanosomiasis (Chagas' disease) is a protozoan infection caused by the flagellate *Trypanosoma (Schizotrypanum) cruzi* and is endemic in parts of Mexico, Central America, and South America. *T. cruzi* infection is transmitted by several species of reduviid insects (commonly known as kissing bugs or flying bed bugs); of the estimated 16 to 18 million people infected each year⁽⁸⁾, up to 45,000 per year are likely to die. Since 1950 > 50 serologic surveys in Central and South American countries have been reported, with 2% to 20% positive *T. cruzi* tests. The main risk factors for human infection are place of birth or residence, low socioeconomic status, and number of blood transfusions. In the environment *T. cruzi* can survive 250 days, but it can survive for 10 to 18 days under blood bank conditions when there are some preservatives put in the blood. Other

mechanisms of transmission have included a case of oral transmission through sugar cane juice in Brazil and ingestion of the infected vector (for animals); *T. cruzi* can also be found in urine, and possibly feces and sperm.

Many of the squirrel monkeys favoured by pharmaceutical companies for biomedical research are captured in the wild and are known to have a high rate of *T. cruzi* infection. In monitoring this issue in Canada, the NCPS set up a polymerase chain reaction (PCR) detection kit, dual evaluation, and comparison of the blood under microscopic examination and enzyme linked immunosorbent assay (ELISA). The different tests returned various responses as to positivity, but PCR had a clear advantage over microscopy and commercial ELISA tests. All 19 employees who worked with the tested monkeys were negative on all tests. These findings are important because of the chronic nature of infection and the intrinsic variability of different tests, particularly when performed in different laboratories and countries. They strongly suggest that laboratories working with monkeys should consider screening animals for chronic infection. There was a very good example in Winnipeg of how easy it can be for infected blood to enter Canada's blood supply. In this case a refugee from the Congo, who arrived in Canada in 1998, eventually received a diagnosis of African sleeping sickness (*T. brucei*) in 2000. This case serves as an important warning of the need for improved serologic screening techniques, more sensitive and specific tests, a more directed pre-donation questionnaire, and pre-donation screening of blood.

Considerable debate persists over just which tests should be done and when. Officials working in the blood system still have not determined what the "gold standard" test for parasitic pathogens should be. In fact, research shows that there really is no standard, and that a combination of tests is likely required to confirm either positive or negative serostatus⁽⁹⁾.

Laboratory infections: Various measures have been undertaken to control Chagas' disease, including control of the transmission vector through the use of pyrethroid insecticides, adding Gentian violet to stored blood in areas of high endemicity, and testing blood samples in areas of low endemicity. To counter the risk of infection from organ transplantation, in urgent cases it is better to treat the infected donor 10 days before surgery and treat the recipient 10 days before and after surgery. There have been approximately 65 cases reported of accidental transmission of Chagas' disease in laboratories, in which accidental puncture, a splash with contaminated material, or surgical injuries have been the main causes⁽¹⁰⁾. Primary prevention techniques include wearing gloves, eyeglasses, and closed-toe shoes, and ensuring easy access to silver nitrate eye washes.

Community-based infections: Currently, researchers in Toronto are undertaking a community-based seroprevalence study for *T. cruzi* to help provide more data on the prevalence of this infection in Canada. There are approximately 273,820 immigrants from South and Central America living in Canada. Fewer than half of all Latin American immigrants settle in the Greater Toronto area, Kitchener-Waterloo, and the north end of Hamilton⁽¹¹⁾. Study participants are being recruited from community organizations and agencies. Blood samples from participants are being tested using Chagas' antibody enzyme-linked immunoassay. Samples that are reactive on an initial and repeat test are being sent to the CDC in Atlanta for confirmatory testing⁽¹⁰⁾. The high level of suspicion within the community is a major barrier to enrolling participants, and convincing people to join, particularly older people, has been difficult.

The study has focused primarily on immigrants, with some refugees. For community reasons the older age group, which would likely have a larger intensity of exposure, is not well represented in the study (about 65% of the group are < 45), and the majority (52%) of all

participants are from Central America. Of the total, 3% had donated blood in Canada. Researchers are aware of the risk of seropositivity in Canada and of the potential progression to disease once an individual is seropositive. Given the number of Latin American immigrants in Canada, a burden of disease is expected to materialize, but may not be recognized because of the lack of systematic surveillance. A key consideration, and one that may be overlooked in examining Chagas' disease, is that individuals infected with *T. cruzi* could present to cardiologists and may be missed. This first community-based epidemiologic study could lead to others, and more resources and funding will result in more samples being available and a greater ability to determine the prevalence and potential burden to the health care system of *T. cruzi* infection among Latin American immigrants.

Surveillance for Bloodborne Parasitic Pathogens in the U.S.

There are several complementary systems of surveillance for bloodborne pathogens in the U.S., including various emerging infectious disease networks, traditional disease or pathogen-based systems of surveillance, and surveillance systems monitoring blood donors and recipients of blood and blood products. Large-scale repositories of specimens from blood donors and recipients can also be used to study infectious complications of transfusions. While the traditional disease or pathogen-based surveillance system is useful for counting cases, other components of surveillance, such as serologic surveys, can be used to examine the incidence and prevalence of particular pathogens of interest and help monitor divergent strains.

Systems of surveillance for emerging infectious diseases

The CDC has established three complementary surveillance approaches to strengthen detection and response capabilities for emerging infectious diseases: the Epidemiology and Laboratory Capacity (ELC) Program; Emerging Infections Programs

(EIPs); and several provider-based sentinel networks⁽¹²⁾. The ELC Program operates in 43 sites across the U.S. and helps ensure that state and local health departments have in place the core epidemiologic and laboratory capacity required to address the challenge of emerging infections.

Emerging Infections Program (EIP)

The EIP is a population-based network of nine state health departments which, along with partners such as infection control practitioners and other federal agencies, conduct active surveillance projects and other epidemiologic, laboratory, or intervention projects that cannot be done on a routine basis. For example, these sites systematically carry out surveillance for unexplained deaths and severe illness in previously healthy people, looking for possible infectious causes that were either not recognized or may be the result of an emerging pathogen. Investigations of unexplained deaths use information about the receipt of blood transfusion – a possible mode of infection acquisition.

Provider-based networks

To supplement health department-based surveillance, three provider-based sentinel surveillance networks have been established to study conditions likely to be seen by specific kinds of health care providers. The Emergency Department Sentinel Network for Emerging Infections (or EMERGENCY ID NET) is a network of academically affiliated emergency departments at 11 university medical centres in large U.S. cities. The network monitors a number of syndromes, including bloody diarrhea, illness following exposure to animals, illness in immigrants and travelers, and first-time seizures that are not associated with head trauma or cancer.

An important provider-based tool is the Infectious Diseases Society of America Emerging Infections Network (IDSA EIN). Formed 6 years ago, this group currently comprises over 800 infectious disease consultants who practise in 49 states and 24 other countries. The network serves as a source

of information for unusual clinical events or provides assistance in case finding during outbreak investigations. It allows for research collaboration for a subset of volunteers who choose to participate in an enhanced surveillance project for a time-limited period; other projects might require submission of clinical and laboratory data. Communication and education through member surveys is done regularly on topical issues in clinical infectious diseases.

The Sentinel Network of Travel Medicine Clinics (GeoSentinel) is another key tool, which is composed of travel medicine clinics in the U.S. and foreign countries. The network monitors temporal and geographic trends of infectious diseases among the travelers, immigrants, and refugees seen in these clinics. The data are analyzed and used to develop travel advisories and recommendations for health care providers. In the future, GeoSentinel may help track the spread of disease from place to place when outbreaks occur.

Surveillance systems should be able to provide a “ready-made” infrastructure or network that can be quickly deployed to investigate unusual new problems. For example, a program of short-term active surveillance was initiated in the EIPs to assess whether variant Creutzfeldt-Jakob disease (CJD) was occurring, albeit unrecognized, in the U.S. This intensive surveillance did not detect any cases of CJD in persons < 30 years of age. It was noted during this study that review of death certificates identified 86% of CJD cases, suggesting that this is a reasonably effective tool to monitor CJD⁽¹³⁾.

Surveillance and the blood supply

Donors

Surveillance programs that focus on blood donors and recipients should provide the most direct information relative to the safety of the blood supply. One approach that has been in place for several years in the U.S. is a collaborative program with the American Red Cross and other major blood collection agencies to monitor human immunodeficiency virus (HIV) seroprevalence and incidence in

blood donors⁽¹⁴⁾. An important offshoot of this program has been the follow-up interviews of seropositive donors, used to develop epidemiologic and behavioural profiles of such donors. These provide insight into their reasons and motivation for donation, and help blood centres improve strategies for encouraging appropriate self-deferral.

The premier research program for studies of blood donors, which includes some surveillance activities, is the Retrovirus Epidemiology Donor Study (REDS)⁽¹⁵⁾. REDS, funded by the National Institutes of Health (NIH), began in the late 1980s as a large, prospective multi-centre program of research and surveillance focusing on blood safety. REDS currently operates through five geographically dispersed blood centres in the U.S. The program includes collaborating hospitals, a coordinating centre that handles protocol development, data transfer and analysis, and supporting laboratories. REDS serves as an umbrella mechanism for coordinating major blood safety research projects and collects demographic and epidemiologic data, as well as blood specimens, from its donor participants. This allows investigators to monitor donor incidence, prevalence, temporal trends, and transmission risk of various pathogens. Using large-scale anonymous mail surveys, REDS has been able to refine estimates for, and correlates of, risk behaviours among donors; determine the relationship of donor incentives and risk behaviour; and document the social and psychological impact of notification and deferral of donors due to true- and false-positive test results. REDS has also been used to evaluate new diagnostic assays, such as those for HIV p24 antigen and human herpesvirus 8 (HHV-8).

Recipients: persons with hemophilia

Historically, recipients of blood and blood products have been at increased risk of exposure to bloodborne pathogens. Programs of surveillance focusing on recipients are important mechanisms to detect, monitor, and provide a warning about known and emerging infectious threats. The Hemophilia Surveillance

System is a population-based surveillance system designed to identify all persons with hemophilia in six states⁽¹⁶⁾. Cases are identified from a variety of sources, including hemophilia treatment centres, hematologists, and others. Approximately 4,000 patients (or 25% of the U.S. hemophilia population) have been enrolled. Data are collected through retrospective chart abstraction and include available serologic testing data for the hepatitis viruses A, B, and C and HIV, and information about any infectious diseases diagnosed during hospitalization.

The second program, the Universal Data Collection System, is an active, prospective surveillance program. The target population is the estimated 17,000 to 20,000 persons in the U.S. with hemophilia and related congenital blood clotting disorders who are treated in about 140 hemophilia treatment centres. Data about the nature and extent of joint and infectious disease complications are collected. As well, a serum specimen is sent to CDC for serologic testing for hepatitis and HIV infection, and for storage in a national serum bank for use in future investigations related to blood safety issues. The system also has an acute-illness reporting component that facilitates identification and investigation of potential infection sources and outbreaks, and the development of intervention strategies to prevent further disease occurrence.

Repositories

The NIH has supported the establishment and maintenance of seven large-scale repositories of donor and recipient specimens since the mid-1970s⁽¹⁷⁾. These repositories have been extraordinarily helpful in evaluating the transmissibility of a number of bloodborne pathogens, such as non-A non-B hepatitis, HIV, and human T-cell lymphotropic virus. Recognizing the need for a more contemporary collection of high quality specimens, REDS investigators are establishing a new, large-scale repository of linked donor and pre- and post-transfusion recipient specimens. Both the CDC and the NIH Clinical Center are collaborating with the REDS investigators to increase geographic diversity and the overall

size of the repository. The repository, which has been under way since mid-2000, will retain frozen whole blood and plasma samples from donors whose units are transfused into enrolled recipients, mainly cardiac surgery patients. These recipients will be followed and tested 6 months after transfusion. As new agents are discovered, donors will be tested initially and recipients of the blood of seropositive donors will be tested subsequently for evidence of seroconversion. Control recipients who were seronegative for the pathogen of interest will also be tested for seroconversion.

T. cruzi

The prevalence of *T. cruzi* infection is believed to be higher in the U.S. than in Canada because of immigration patterns. This infection is endemic among the human population in Mexico, and Central and South America. The three main transmission methods of infection are vector-borne, congenital, and, of particular interest, blood transfusion. There have been eight reported cases of *T. cruzi* infection associated with blood transfusion in North America, two being from the same Mennonite community in Manitoba.

Two large seroprevalence studies⁽¹⁸⁾ in Los Angeles and Miami – two cities with large Latino populations – tested approximately 78,000 blood donors from Los Angeles and 25,000 from Miami. Prevalence rates translated back to one in 7,500 in Los Angeles and one in 9,000 in Miami. Further look-back examination identified very few cases of transmission of *T. cruzi* due to transfusion. This is in contrast to published estimates from South America, where the transmission rate from an infected donor is between 12% and 49%^(19,20). One reason for the lower rates in North versus South America may be that platelets appear to be the primary vehicle implicated in Canadian and U.S. cases, and there are relatively few platelet transfusions. Risk factors, such as recent travel to a high-risk area, can be used to screen for seropositive donors. Although these donors have been found throughout the U.S., many have asymptomatic, chronic infections, making their detection difficult.

Transfusion-transmitted malaria

Transfusion-transmitted malaria (TTM), although quite rare in the U.S., carries a high case-fatality rate because patients are often compromised by other illnesses.

In order to try and reduce the risk of TTM in the U.S., blood donors who were once residents of countries free of malaria are deferred for 1 year after return from travel to a malarious area. Donors who have had malaria are deferred for 3 years, and immigrants, refugees, citizens, or residents of malarious areas are deferred for 3 years after leaving such areas. The U.S. Food and Drug Administration recently proposed that persons who used to live in endemic areas and who return to visit would be excluded from donating blood for a period of 3 years. Of the 5,737 cases of malaria for which data were available, only 119 cases in U.S. residents had their onset > 1 year after return from travel to a malarious area⁽²¹⁾. There are outliers to these findings, and one case of *P. falciparum* arose after 9 years.

The front-line strategy for eliminating high-risk donors is the pre-donor questionnaire. The American Association of Blood Banks (AABB) collects a uniform donor history that includes the questions "Have you ever had malaria?" and "Have you traveled outside of the U.S. or Canada within the last 3 years?" However, studies show limitations in questioning potential donors, particularly concerning the ability to obtain accurate travel histories. Debate continues on ways to both simplify the questionnaire and increase its ability to gather accurate information.

At times, cases feared to be the result of local mosquito-borne transmission in the U.S. turn out to be the result of a traveler providing incorrect travel information. Investigation of any suspected case of local transmission must take this into account. Any non-*P. malariae* cases (particularly those caused by *P. falciparum*) must be treated with skepticism if there is an exceptionally long period of time between travel to a malarious area and the onset of illness.

The CDC has tried to describe the epidemiology of TTM in the U.S. to determine how the 93 cases reported between 1963 and 1999 occurred, and how they might be avoided in the future⁽²¹⁾. Of the 93 cases, 63% were the result of whole blood transfusions, 31% resulted from packed red blood cell transfusion, and only 6% were from platelet transfusion; 11% of cases were fatal. Although any infection raises concern, 62% of infected donors would have been excluded from donation if guidelines had been followed. Currently, the key to success is deemed to be improved donor screening by means of questions. The use of laboratory screening tests is being considered, though there are currently no approved tests of sufficient sensitivity.

Additional factors that can help increase safety include improving the presentation of information on malaria risk areas, and developing more accurate and detailed risk-area maps. The CDC is examining how these maps could be put on the Web site to help blood banks quickly determine what areas pose risk, but the data provided by countries to the World Health Organization are uneven and simply not available for some regions.

There are inherent difficulties in detecting parasitemia in blood samples, because blood smears do not appear to be sensitive enough. France and the United Kingdom are now using antibody screening to test blood samples of high-risk donors. This move has improved blood availability, because people who would have been eliminated as donors on the basis of travel history are allowed to donate when screening is found to be negative. The key to successful antibody testing is that a supply of antigen is needed in addition to an improved automated method that is applicable to large-scale screening.

Laboratory Services Environment

The laboratory services environment right now in most countries can be described as one of consolidation, downsizing, and cross-training. This consolidation of many companies to a few has meant tremendous staff layoffs and reduced personnel. Additionally, a severe shortage of skilled workers exists, and skilled microbiologists are very difficult to find. This situation is even worse for specialties within microbiology, such as parasitology and mycology. Cross-training of specialists, one proposed "answer" to the problem, is an incomplete solution, and ultimately a decision must be made as to whether working with generalists or specialists is preferred.

In the present medical model, when a malaria patient presents to the emergency department during the evening or night shift, there are several factors that combine to make the accurate diagnosis of malaria difficult, if not impossible:

- incomplete patient history;
- poor communication between physician and laboratory;
- failure to prepare and examine both thick and thin blood smears;
- failure to recognize and/or identify parasites present, particularly when present in low numbers;
- limited awareness of STAT request, urgency of test not communicated or heeded;
- laboratory may be closed and result may not come back for 1 day;
- non-immune patients (travelers) may not present with typical symptoms, but may present with very non-specific complaints that do not suggest malaria;
- lack of understanding that one set of negative blood films does not "rule out" malaria.

Surveillance of bloodborne pathogens will ultimately hinge on the ability of laboratories to provide definitive test results. The College of American Pathologists (CAP), as well as other proficiency testing providers such as the American Association of Bioanalysts, periodically send out encoded specimens to participant laboratories to assess their ability to perform laboratory tests and organism identification correctly. CAP provides a system of proficiency testing (PT) for > 2,000 participating laboratories in the field of diagnostic medical parasitology. Participation in a PT program is a regulatory requirement, and grading requires 90% agreement with respect to either a confirmatory laboratory test or the consensual result among all participants.

Beginning in 2001, CAP has begun to offer a new blood parasite PT module to respond to concerns that the identification of blood parasites in most laboratories is difficult, at best. It was felt that the education/PT challenges for blood parasites needed to be expanded. The program is an apparent success, given that there are > 300 laboratories participating. The new module sends out three sets of five specimens (both thick and thin smears for each of the five "challenges" in each mailing) each year.

There is still some question concerning the overall approach to the education component of PT, given that the best way to learn is to sit down at the microscope with slides from actual positive patient cases. However, most laboratory personnel do not have the time to attend workshop-format courses, another outcome of the current consolidation environment. Even with the fairly rigorous system in place in the US, PT of laboratories is still a concern, and laboratory proficiency remains uneven across the country, particularly regarding some of the bloodborne parasites.

Potential Offshore Threats to Canada's Blood Supply

Parasites found in Central and South America

Within the 19 Spanish-speaking countries in the Americas, malaria and Chagas' disease are the main parasitic diseases – although, there is an emerging danger of *Leishmania* infections.

These countries can be stratified as high-, medium-, and low-risk countries – for example, physicians in Peru, Argentina, and Uruguay will probably not encounter a patient with malaria throughout their careers. However, collection of accurate data is difficult for many countries because there is no mandatory reporting of positive malaria cases.

South America typically sees about 1 million cases of *P. falciparum* malaria per year, half of which are in Brazil. There are some 120,000 primarily from the north of Peru, about 60,000 from Bolivia and about the same for Colombia – although, it is difficult to obtain reliable numbers for Colombia. Guyana has the largest number of cases per capita.

The *Leishmania* parasite is another growing concern in the region, and 9% of donors have been found positive for the parasite in the Rio Grande do Norte region of Brazil. About 2,000 *Leishmania* cases have been documented in Brazil, but the actual number of cases is likely 10 to 20 times greater because most cases are asymptomatic. Tests show that the parasites may be there, even in healthy-looking individuals.

The three main vectors for *T. cruzi* infection are *Rhodnius prolixus*, *Triatoma dimidiata* and *T. infestans*, but dozens of secondary vectors exist. The type of vector is an important factor for eradication efforts. In the case of *R. prolixus*, the vectors can be sprayed with insecticide, but the insects enter homes from the outdoors, so elimination is virtually impossible. However, there have been examples of *R. prolixus* that live exclusively in houses, so eradication of these vectors is possible. *T. infestans* only live in houses so the vector can be eliminated with insecticides. Efforts to combat trypanosomiasis

have been undertaken in Chile and in southern Uruguay, where spraying has been a great success, albeit one at a cost of \$300 million in the previous 8 years.

Surveillance of the blood supply in Central and South America

Only Chile and Venezuela had information on number of donors, number of donors screened, and number of transfusion-acquired infections (*T. cruzi*, hepatitis B and C, HIV, and syphilis) or the risks thereof, prior to 1993.

In 1993 the number of donors being screened was highest in Peru (57.4%), and Paraguay and Bolivia were among the lowest (unknown). Only Honduras and Venezuela had begun screening all blood donors for *T. cruzi* by 1993. The prevalence in Bolivia of *T. cruzi* infection was 147.90 per 100,000, and yet a person receiving a blood transfusion in Santa Cruz in Bolivia had a 50% chance of becoming infected.

By 1997, six countries screened all donors for *T. cruzi*; for hepatitis C, the situation has improved, but there are still several countries where blood is not screened.

Of the three largest countries (Mexico, Brazil, and Argentina), Argentina did not have any information on blood donors until 1993, and hepatitis C virus was being transfused up until 1999. Brazil has a very impressive public blood bank information system and processes about 1.6 million donors per year, but has no information on private blood collections, which account for about 1 million donors. Mexico does not provide national data in this respect, but the Pan American Health Organization estimates that as many as 6,000 infected units may be transfused every year.

The increased number of countries screening for *T. cruzi* indicates improvement, but may be overly optimistic given differences in training and resources and the fact that only three countries have a system of quality assurance and proficiency testing for laboratories. Estimates put the number of recognized infections with *T. cruzi* through blood transfusion at about 260, but unpublished

cases would likely total about 400 (GA Schmunis, Pan American Health Organization, Washington DC: personal communication, 2001). It was once rare to be infected through blood transfusion in Central or South America, particularly when compared with rates of infection from insect vectors. However, successful eradication efforts mean vector transmission is very rare in southern Brazil, Uruguay, and Chile, but cases of transfusion-transmitted infection are increasing. Eliminating the risk of infection through blood transfusions has not been embraced as an important goal by all South and Central American countries. However, as accidents and incidents of violence increase, so too does the realization that anyone can become infected.

Conclusions

Given the growing number of refugees and immigrants arriving in Canada and increased travel by Canadians to areas endemic for various parasitic pathogens, the risks of these pathogens finding their way into the Canadian blood supply is genuine, and likely to escalate.

Currently, Canada relies on an informal system of surveillance for parasitic infections that developed through collaboration among the various Canadian experts working in parasitology and related fields. This system would benefit from an influx of resources to allow for a truly pan-Canadian system of serologic surveillance and testing.

A formal surveillance system could help to address issues such as the development of an easier-to-understand blood donation questionnaire, establishing consent among donors to store and test samples of donations for pathogens that may emerge in the future, and other issues. With the presence of adequate numbers of trained professionals, equipped physical plant facilities, new test formulas, and additional communication and training initiatives for the public's safety, a national surveillance system could incorporate federal and provincial government resources as well as those from the private sector. This

collaborative approach would not only improve safety through better monitoring and communication but would also provide for a more efficient use of resources.

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Meeting of the Blue Ribbon Committee: 5 and 6 March, 2001

Introduction

The Blue Ribbon Committee meeting on parasitic diseases took place on March 5 and 6, 2001, in Ottawa, and was sponsored by the Blood-borne Pathogens Division of Health Canada. Participants included international experts in bloodborne parasitic diseases and federal government representatives. The objectives of the workshop were to

- share current knowledge regarding the surveillance of bloodborne parasitic diseases and their potential transmission;
- identify key issues and concerns related to the prevention and control of bloodborne parasitic diseases in Canada; and
- make recommendations concerning the development of a Canadian surveillance strategy, to include the following: what needs to be put in place to assess the risk of bloodborne parasitic diseases; the laboratory approaches and technology that are required; and the type of research that is necessary.

This report provides an outline of the workshop and the processes used, as well as a detailed synopsis of the outputs. It is intended to be useful to workshop participants, their organizations, and any others interested in bloodborne parasitic diseases.

Welcome and Purpose of the Meeting

Dr. Antonio Giulivi, Associate Director of the Blood-borne Pathogens Division, Bureau of Infectious Diseases, Centre for Infectious Disease Prevention and Control (CIDPC), welcomed the participants and introduced the

Chairperson for the meeting, Dr. Roger Dodd, Executive Director, Biomedical Safety, of the American Red Cross. Dr. Paul Gully, Acting Director General, CIDPC, gave some welcoming remarks. Dr. José Campione-Piccardo, Science and Laboratory Advisor of the Bureau of Infectious Diseases, CIDPC, shared some organizational details and introduced the facilitator.

After review of the agenda and introductions by the participants, the rest of the first day consisted of 20-minute presentations by the experts in attendance followed by questions of clarification and a brief discussion.

During the second day, the facilitator conducted a brainstorming session related to the identification of key issues and concerns, and the development of recommendations based on the themes that emerged. The remainder of this report outlines the outputs of the second day.

Key Issues and Concerns

Participants were asked to respond to the question *What are your key issues and concerns related to the prevention and control of bloodborne parasitic diseases in Canada?* They were asked to preface their responses with “how to” or “I wish”. Their brainstormed list of responses follows:

- I wish to know the Canadian risk populations (i.e., travelers, refugees, and immigrants) without being judged as racist.
- How to determine whether donor screening by history and questionnaire is effective in reducing bloodborne parasitic diseases.
- I wish to know the laboratory capacity in Canada for testing for the respective

parasites. I wish to know the entire list of bloodborne parasites related to endemic and imported risk.

- I wish appropriate tools were available to assess the risk (e.g., simple serologic assays).
- How to assess physicians' and laboratory workers' skill levels and awareness of blood parasites.
- I wish there were systems of surveillance available to monitor and track parasitic diseases in blood donors and recipients.
- I wish to know if new technologies (e.g., micro arrays) will be useful in screening for previously unknown or undetected pathogens in the blood.
- I wish to know the range of titres of antibodies in the blood.
- I wish to know the viability, stability, and infectivity of different blood products/ components.
- I wish to know the utility of doing seroprevalence studies of important bloodborne pathogens, (e.g., *Trypanosoma*).
- I wish to measure Canadian research capacity to do surveillance, detection, and confirmation and to plan appropriate interventions for personal, popular, and public health issues related to bloodborne parasites.
- I wish to know whether the emerging technology of pathogen inactivation will render moot the need for screening for parasites.
- I wish to know from good clinical studies the clinical consequences of exposure to bloodborne parasites/parasites in blood products.
- I wish to know the overall number and geographic distribution of Hispanics in Canada – from Mexico, Central and South America.
- I wish to know the availability of chemoprophylaxis – other than gentian violet – for storing blood.
- I wish to know what impact studies of the kind proposed here would have on the immigrant and refugee population (e.g., can these studies be done so as to ensure their cooperation?).
- I wish to know how to make sample size estimates for the proposed studies.
- I wish to know the mode of acquisition and transmission of bloodborne parasites.
- I wish to know the likelihood of secondary transmission in Canada.
- I wish to know the geographic distribution of *Ixodes scapularis* ticks in Canada and the proportion infected with *Babesia microti*.
- I wish to plan and provide social and medical support to high-risk populations for prevention and control using the federal/provincial/territorial policy structure.
- I wish to know if primary prevention strategies to prevent vector-borne diseases for people who live in Canada will decrease the risk of parasite bloodborne infections (e.g., malaria, *Babesia*).
- I wish to know how large the problem must be (i.e., what seroprevalence in the Canadian donor base will be tolerated) before regulators or operators feel compelled to institute donor screening.
- How to assess the potential of new technology related to the current blood screening procedures/options.
- I wish to know the prevalence of *T. cruzi* in the Canadian Latino population.
- I wish to know how often Canadians travel to babesiosis risk areas in the U.S. (e.g., Cape Cod, Long Island).
- I wish to know how such resources will be identified to assist in the development of programs for surveillance, research, and prevention of bloodborne parasitic diseases.

- How to gain access to the target populations (e.g., immigrants, refugees, travelers)
- I wish to know the blood donation practices of different ethnic and risk groups in Canada.
- I wish there were suitable policies in support of an international mandate (e.g., to do work outside of Canada, such as CDC's Global Health Program).
- I wish for an infectious disease global network (based in Health Canada).
- How to stimulate the expeditious development of laboratory assays for screening blood donors for evidence of parasitic infections.
- I wish to know if the use of the word "parasitic" is too constraining in the context of these discussions.
- I wish to know all of the quality parameters for laboratory and non-laboratory activities related to surveillance.
- I wish to know of the most efficient way to collect samples for these studies.
- I wish to know how much more data are needed before action is taken.
- I wish to know the public's view of what is acceptable infectious risk in blood products.
- How to minimize the need for blood transfusion.
- How to stimulate the use of alternative products to human blood.
- I wish that the current discussion would lead to action rather than to an action plan.
- I wish to know what currently unidentified parasites might pose problems in the future vis-à-vis bloodborne transmission.
- I wish to know if there are better ways to educate clinicians to be aware of and consider all parasitic diseases (e.g., malaria) in their diagnoses.

- I wish we had better information, (e.g., cost/benefit analyses of both existing and future screening tools) for decision-making on balancing blood safety and blood availability.
- How to communicate with the general public concerning bloodborne parasitic diseases and levels of risk.

Key Themes

Participants were asked to identify the key themes from the previous brainstormed list. Their themes were

- professional education;
- policies in place (i.e., existing legislation);
- policy development (e.g., decision analysis, risk management, and risk communication);
- epidemiology and demography (e.g., building networks);
- sociologic aspects and public education (e.g., how to manage different ethnic populations, reactions, approachability);
- technical (i.e., infrastructure, laboratories, testing, quality issues, and logistics);
- laboratory research and development (e.g., development of techniques to detect and inactivate pathogens);
- resources.

Cross-cutting Issues

The following cross-cutting issues were identified by the group:

- mandate;
- definition of what we mean by bloodborne parasites (e.g., a list/profile of the epidemiology of transmission);
- action plan that leads to action with evaluation of the expected results.

Mandate

This was noted to mean the following:

- to deal with emerging bloodborne pathogenic infections in Canada.

Initially, the Bureau of Infectious Diseases was given this mandate in 1998, and it was renewed in 2001 for 5 years (i.e., till 2006)

Definition of bloodborne parasites

It was agreed that the list of diseases from bloodborne parasites includes the following:

- malaria – includes *Plasmodium* species;
- trypanosomiasis – hemoflagellates;
- babesiosis;
- leishmaniasis;
- toxoplasmosis – *Toxoplasma* species;
- other (new or unknown agents at this time; agents of low transmission potential, e.g., tissue helminths/protozoa).

Identified Needs and Recommendations Related to Themes

This section includes each of the themes outlined above, the requirements within each theme, and related recommendations for the federal government, developed by participants. The recommendations were given priority according to the following criteria:

A1-	Essential or critical for moving forward
A -	Very important
B -	Important
C -	Nice to have, a luxury

The priority ranking is noted in bold brackets after each recommendation.

Theme – technical

We need:

- good tests;
- tests that determine risks for the individual and for the blood system;
- screening, diagnostic tests, prognostic tests;
- continuous quality assurance/quality improvement programs;
- laboratory infrastructure (sufficient staff and facilities);
- a mechanism for transfer of new technologies from research and development;
- maintenance and/or enhancement of technology exchange among reference and diagnostic laboratories.

In order to address the technical issues related to the transmission of bloodborne parasitic diseases, we recommend that the federal government

- Build and sustain quality-based laboratory capacity to support ongoing and planned testing for diagnosis and surveillance, including reference services for our list of parasites and other emerging bloodborne parasitic infections. **(A1)**
- Maintain and/or enhance technology exchange among reference and diagnostic laboratories. **(B)**

Theme – laboratory research and development

We need:

- information on pathogenesis, test development, and vaccines;
- models to support research (e.g., strategic alliances among government, the private sector, and non-governmental groups such as academic institutions);

- research concerning the survival of pathogens during blood storage, viability, infectious dose, and pathogen inactivation;
- laboratory-based surveillance (e.g., sero surveys, field studies of vectors, molecular epidemiology, genotype analysis of pathogens).

In order to address the issues related to laboratory research and development, we recommend that the federal government

- Build and sustain research capacity for bloodborne parasitic diseases **(A)** focusing on
 - the development and evaluation of new tests
 - pathogenesis and pathogen viability in blood products
 - laboratory-based surveillance
 - molecular epidemiology
 - preventive and therapeutic interventions (e.g., vaccine development and novel therapies).
- Build and sustain networks with industry, research institutes, universities and other non-governmental organizations, international agencies (e.g., Canadian International Development Agency, International Development and Research Centre), using a full range of funding mechanisms. **(A1)**

Theme – epidemiology and demography

We need:

- to identify Canadian populations at risk
 - who they are, where they are, their donation practices, and their risk for the acquisition and transmission of bloodborne parasites;
- to identify and document Canadian travel patterns;
- to determine the prevalence and incidence among blood donors and recipients, and to assess the risk of

transmission of these parasites from infected donors;

- to assess the social and behavioural make-up of high-risk populations; to identify cultural barriers to the prevention and transmission of bloodborne parasites;
- to determine genetic susceptibility to bloodborne diseases (genetic epidemiology);
- to determine the most sensitive and specific means of identifying infected individuals.

In order to address the issues related to the epidemiology and demography of bloodborne parasitic diseases, we recommend that the federal government

- Build and sustain and/or facilitate a network for surveillance and research in the areas of the epidemiology and demographics related to our list of bloodborne parasites. **(A1)**
- Use the network to undertake surveillance and research activities related to the epidemiology of bloodborne parasitic infections. **(A1)**

Theme – sociologic aspects and public education

We need:

- to provide social marketing/public education to make the general public aware of the potential dangers of bloodborne parasitic diseases;
- to identify cultural and ethnic groups and establish a communication network with these groups (e.g., work with community leaders);
- to develop culturally appropriate and sensitive communication strategies.

In order to address the sociologic and public education issues related to the transmission of bloodborne parasites, we recommend that the federal government

- Work with the provinces, territories, and the travel industry to develop and facilitate culturally appropriate communication strategies for at-risk populations (e.g., hold town hall meetings with cultural leaders). **(A)**
- Ensure the involvement of the appropriate federal/provincial/territorial government agencies. **(A)**
- Work collaboratively with relevant at-risk populations and the general public. **(A)**

Theme – professional education

We need to

- identify the educational needs of professionals;
- evaluate existing and future innovative interventions for educating professionals;
- encourage and support technology exchange among reference and diagnostic laboratories;
- make sure healthcare providers and technicians are better trained in terms of recognition and diagnosis, and in provision of appropriate prevention strategies and therapeutic treatments.

Specifically in relation to at-risk populations, we need to

- provide updated advice and accurate information on the prevention of bloodborne parasitic diseases; and provide education on the recognition, diagnosis, and treatment of bloodborne parasitic diseases in high-risk populations.

In order to address the issues related to professional education in the area of bloodborne parasites, we recommend that the federal government

- Ensure that there is ongoing funding of the professional activities of the Canadian Association of Tropical Medicine and Travel (CATMAT) to advise on tropical medicine and travel

(e.g., matching funds from the Emergency Response and Blood-borne Pathogens divisions of Health Canada). **(A)**

- Ensure that the federal government supports national and provincial associations (e.g., Canadian College of Family Physicians, provincial medical colleges) in their efforts to promote awareness of bloodborne parasitic diseases (e.g., continuing medical education [CME] activities, workshops, national conferences). **(A)**

- Support the development of training programs for laboratory technologists in the diagnosis of bloodborne parasitic infections. **(A)**

- Contract CATMAT to develop curriculum materials for basic medical education as well as CME and the Maintenance of Competence (MoComp) for the Royal College of Physicians and Surgeons. **(A)**

Theme – policies (in place)

In order to address the issues arising from current policies related to bloodborne parasitic diseases, we recommend that the federal government

- Review current policies concerning bloodborne parasites to ensure that they are pertinent and relevant. **(A)**
- Ensure that the appropriate liaisons are formed for policy development and implementation to deal with issues of bloodborne parasites in mobile populations. **(A)**

Theme – resources

We need:

- to have human and financial resources (for both the short and the long term);
- to receive strong institutional support for the training of physicians in tropical and parasitic diseases;

- training programs and fellowships (i.e., six to eight good training positions) in the area of tropical medicine and parasitic diseases;
- to make effective use of the limited resources we have and build on existing university programs;
- to use the Millennium Chairs for Emerging Pathogens; such chairs have two tiers, one for entry level academic faculty and another for higher level academics.

In order to address the human and material resource needs in the area of bloodborne parasitic diseases, we recommend that the federal government

- Develop an appropriate human resource strategic plan including, but not limited to, funding two Millennium Chairs in Tropical Medicine and Bloodborne Parasitic Diseases. **(A)**
- Establish funding for fellowship training in tropical medicine and parasitic diseases for two individuals for 4 years. **(A)**
- Give the Blood-borne Pathogens Division the task of developing and submitting a Memorandum to Cabinet (MC) ensuring that there is appropriate funding for all of the aforementioned recommendations. **(A1)**

Theme – policy development

We need:

- to define the expected burden of disease;
- to define acceptable risk;
- to formulate a decision-making process.

In order to address the issues related to developing and implementing new policies to prevent and control the transmission of

bloodborne parasitic diseases, we recommend that the federal government

- Develop an appropriate decision-analysis framework for the management of bloodborne parasitic diseases in Canada using all the available outputs of our previous recommendations, evidence-based medicine, and evidence-based policy-making. **(A1)**
- Convene groups of experts to provide input into the development of new policies. Such policies should strive to seek a balance between risk reduction and the adequacy of the blood supply. **(A1)**

Summary

In summary, the **A1 recommendations** are related to:

- developing a network (epidemiologic and demographic aspects);
- undertaking activities within the network;
- providing support for parasite research testing;
- developing new policies, and;
- preparing a Memorandum to Cabinet for submission by September 1, 2001, for funding from April 2002 over 5 years.

The **A recommendations** deal with sustaining the network and addressing existing needs, including

- Public and professional education
- Review of current policies
- Business plan
- Development of a contribution program to meet operational needs.

The **B recommendation(s)** will be dealt with by the future Treasury Board submission. The group identified no **C recommendations**.

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