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848279

AUG 20 2010

Mr. Michael Marchbank
Chief Operating Officer
Provincial Health Services Authority
700 – 1380 Burrard St
Vancouver BC V6Z 2H3

Dear Mr. Marchbank:

Further to our discussion on July 28, 2010, I am writing to you to request that the Provincial Health Services Authority (PHSA) present the Ministry of Health Services (the Ministry) with options for establishing a virtual clinic for patients with complex symptomatology possibly related to underlying infectious disease. Options would include enablers such as telehealth/telemedicine and involve collaboration with the College of Physicians and Surgeons of British Columbia.

The virtual clinic, involving both family physicians and specialists, would take a multidisciplinary approach to chronic diseases of unknown aetiology to assess and develop treatment plans for this patient population. Ideally, it would also introduce new diagnostic modalities particularly in immunology and virology.

As we discussed, it is important for PHSA to collaborate with other jurisdictions, including the Federal Government, and to build upon existing knowledge and approaches for treating Lyme Disease. I know it is a priority for both PHSA and the Ministry to ensure that patients' concerns are addressed and to make certain that they receive the best possible diagnosis and consistent treatment advice for the management of *Borrelia burgdorferi* and other related infectious diseases.

I look forward to receiving your response by November 15, 2010, and an opportunity to engage with you in a discussion on the best way to move forward on this project. If you have any questions concerning this request, please do not hesitate to contact Ms. Leigh Ann Seller by telephone at: 250 952-1274.

Sincerely,

Heather Davidson
Assistant Deputy Minister

pc: Ms. Leigh Ann Seller

Ministry of Health Services
Assistant Deputy Minister
Health Authorities Division
6-2, 1515 Blanshard Street
Victoria BC V8W 3C8

EMAIL RESPONSE

876446

s. 22

Dear s. 22

Thank you for your email of March 31, 2011, expressing your concern regarding diagnosis and treatment for Lyme disease. I have been asked to respond to you on behalf of the Honourable Michael de Jong, Minister

I am sorry to read of your experiences around your diagnosis and treatment of Lyme disease. The Ministry of Health (the Ministry) takes your concerns seriously. The Ministry asked the Provincial Health Services Authority (PHSA) to present options for a clinic for patients presenting with complex symptomatology possibly related to underlying infectious diseases. As a result of the proposal, the Ministry in partnership with PHSA, is developing a provincial clinic and research study that will help patients with complex chronic diseases, such as Lyme disease, fibromyalgia, and chronic fatigue syndrome. Additionally, PHSA will be meeting with representatives from CanLyme as development of the clinic and research study move forward.

In regard to your concerns about the funding available for the clinic and research study, the provincial government, through the Ministry, provides annual capital funding to the health authorities. The health authority prioritizes the needs of the health facility within its jurisdiction of responsibility and allocates capital funding accordingly. I encourage you to share your concerns with PHSA, as your input is valuable to the effective delivery of health care services.

The clinic and research study are in development and should be operating by Fall 2011. The clinic will take referrals from family physicians or other health care providers for patients with symptoms of these chronic illnesses. The goal is to help patients by accurately diagnosing their conditions, providing treatment and helping with ongoing symptom management.

Additional information about the clinic will be available from your family physician after the development of the program is complete. I believe that the final comment in your letter referring to additional training for physicians in May, is speaking to the annual Lyme awareness note. BC Centre for Disease Control sends out Lyme awareness notes in May. An example of one can be found at: http://www.bccdc.ca/NR/rdonlyres/9F45908D-959A-442D-BB50-39897C53EF51/0/EPI_education_lymebrochure2007_20090508.pdf

Again, thank you for writing. I appreciate the opportunity to respond.

Sincerely,

Effie Henry
Executive Director

Rinta, Darcy HLTH:EX

From: Scheiber, Alex HLTH:EX
Sent: Tuesday, January 11, 2011 9:10 PM
To: Rinta, Darcy HLTH:EX
Subject: Fw: Lyme Disease proposal

Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

----- Original Message -----
From: Seller, Leigh Ann HLTH:EX
Sent: Tuesday, January 11, 2011 07:33 PM
To: Scheiber, Alex HLTH:EX
Subject: Fw: Lyme Disease proposal

Re: BN - can we target end of day Thursday for BN?

Leigh Ann Seller - sent from wireless handheld

----- Original Message -----
From: Davidson, Heather (ADM) HLTH:EX
Sent: Tuesday, January 11, 2011 06:52 PM
To: Seller, Leigh Ann HLTH:EX
Subject: RE: Lyme Disease proposal

Thanks. Yes I just found out about the meeting from Michael and I see it is on my calendar now too. Whatever you can put together in time frame will be good. I would like to get something to DM by Friday so he can review in advance of Monday's meeting. I mentioned to DM today that we had report from PHSA and staff were reviewing and preparing response.

-----Original Message-----
From: Seller, Leigh Ann HLTH:EX
Sent: Tuesday, January 11, 2011 6:32 PM
To: Davidson, Heather (ADM) HLTH:EX
Subject: Lyme Disease proposal

Heather, we are still reviewing the proposal from PHSA and getting feedback from other divisions. Michael Marchbank called me today to say that the DM has set a meeting with him on Monday on this subject. I understand that he also advised you of this meeting.

We will do a BN for you to forward with the report outlining any issues that require follow up work. Let me know if you have further direction on this.

Thx, LAS
Leigh Ann Seller - sent from wireless handheld

Rinta, Darcy HLTH:EX

From: Scheiber, Alex HLTH:EX
Sent: Friday, January 7, 2011 9:53 AM
To: Rinta, Darcy HLTH:EX; Shorter, Richele HLTH:EX
Subject: FW: Chronic Disease Program

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

From: Brady, Bruce K HLTH:EX
Sent: Friday, January 7, 2011 9:35 AM
To: Scheiber, Alex HLTH:EX
Subject: RE: Chronic Disease Program

Will do. Thanks

From: Scheiber, Alex HLTH:EX
Sent: Friday, January 7, 2011 9:30 AM
To: Brady, Bruce K HLTH:EX
Cc: Rinta, Darcy HLTH:EX
Subject: FW: Chronic Disease Program

Bruce, could you please review the attached proposal for a Clinical Program for Chronic Complex Disease (mostly in response to Lyme disease issues) and send me any feedback you have. Would like to target end of next week if possible. Thx

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

From: Seller, Leigh Ann HLTH:EX
Sent: Wednesday, December 22, 2010 7:21 AM
To: Scheiber, Alex HLTH:EX; Rinta, Darcy HLTH:EX; Shorter, Richele HLTH:EX
Subject: FW: Chronic Disease Program

From: Miller, Erin (EA to Michael Marchbank) [mailto:EMiller4@phsa.ca]
Sent: Thursday, December 16, 2010 11:12 AM
To: Davidson, Heather (ADM) HLTH:EX
Cc: Paton, Susan HLTH:EX; Walker, Andrea; Seller, Leigh Ann HLTH:EX; Peatt, Lenora HLTH:EX
Subject: Chronic Disease Program

Hi Heather,
Please see the attached letter and proposal from Michael.
Erin

Erin Miller
Executive Assistant to Michael Marchbank
Chief Operating Officer
Provincial Health Services Authority

700 - 1380 Burrard Street
Vancouver, BC
V6X 2H3 Canada
604-675-7427 Phone
604-708-2727 Fax
Erin.Miller@phsa.ca
http://www.phsa.ca

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Rinta, Darcy HLTH:EX

From: Boland, Blair HLTH:EX
Sent: Thursday, January 13, 2011 1:47 PM
To: Scheiber, Alex HLTH:EX; Brady, Bruce K HLTH:EX
Cc: Rinta, Darcy HLTH:EX
Subject: RE: Draft BN Chronic Disease Clinical Program
Attachments: bb+BBcomments_867032 Clinical Program for Chronic Complex Disease .doc

One addition added.

s. 13

Blair Boland
Director, Health Authority Funding
Ministry of Health Services
(250) 952-2250
blair.boland@gov.bc.ca

From: Scheiber, Alex HLTH:EX
Sent: Thursday, January 13, 2011 1:17 PM
To: Brady, Bruce K HLTH:EX; Boland, Blair HLTH:EX
Cc: Rinta, Darcy HLTH:EX
Subject: FW: Draft BN Chronic Disease Clinical Program

Thanks Bruce. Good suggestions. Blair, can we have an eta for your comments?

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

From: Brady, Bruce K HLTH:EX
Sent: Thursday, January 13, 2011 12:25 PM
To: Rinta, Darcy HLTH:EX
Cc: Scheiber, Alex HLTH:EX
Subject: RE: Draft BN Chronic Disease Clinical Program

Hi Darcy

My comments are attached.

Bruce

From: Rinta, Darcy HLTH:EX
Sent: Thursday, January 13, 2011 10:01 AM
To: Boland, Blair HLTH:EX; Brady, Bruce K HLTH:EX; Power, Stephanie A HLTH:EX
Cc: Scheiber, Alex HLTH:EX
Subject: Draft BN Chronic Disease Clinical Program
Importance: High

Please review and provide any changes/additions as soon as possible. It must go to Heather Davidson today. Thanks!

Darcy Rinta
Manager, Performance Accountability (PHSA)
Health Authorities Division
Ministry of Health Services
Phone: 250-952-2423
Darcy.Rinta@gov.bc.ca

From: Scheiber, Alex HLTH:EX
Sent: Tuesday, January 11, 2011 9:24 PM
To: Boland, Blair HLTH:EX; Brady, Bruce K HLTH:EX
Cc: Rinta, Darcy HLTH:EX
Subject: Re: Chronic Disease Program

Blair and Bruce, just learned today that the DM is meeting with Michael Marchbank and Heather Davidson on Monday to discuss this proposal so I have been asked to write a BN by Thursday describing outstanding issues. Would appreciate by Thursday morning at the latest any feedback you can provide Darcy and I by Thursday so that we can incorporate in the BN.

Thanks.
Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

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From: Scheiber, Alex HLTH:EX
Sent: Thursday, January 06, 2011 09:38 AM
To: Boland, Blair HLTH:EX
Cc: Rinta, Darcy HLTH:EX
Subject: RE: Chronic Disease Program

Assuming you saw this.

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

From: Boland, Blair HLTH:EX
Sent: Thursday, January 6, 2011 8:58 AM
To: Scheiber, Alex HLTH:EX
Subject: RE: Chronic Disease Program

Hi Alex,

I could be wrong but I don't recall seeing the BN. Could you please send me a copy? Thanks.

Blair Boland
Director, Health Authority Funding
Ministry of Health Services
(250) 952-2250
blair.boland@gov.bc.ca

From: Scheiber, Alex HLTH:EX
Sent: Wednesday, January 5, 2011 5:21 PM
To: Boland, Blair HLTH:EX
Subject: Fw: Chronic Disease Program

Fyi
Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

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From: Scheiber, Alex HLTH:EX
Sent: Wednesday, January 05, 2011 05:19 PM
To: Power, Stephanie A HLTH:EX; Tregillus, Valerie HLTH:EX
Subject: Fw: Chronic Disease Program

Stephanie and Val, could you kindly review the attached draft proposal from PHSA and send me your feedback? If you need background info on the subject (focusing on Lyme disease) I can send you a BN. Thx.
Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

---

From: Seller, Leigh Ann HLTH:EX
Sent: Wednesday, December 22, 2010 07:20 AM
To: Scheiber, Alex HLTH:EX; Rinta, Darcy HLTH:EX; Shorter, Richele HLTH:EX
Subject: FW: Chronic Disease Program

From: Miller, Erin (EA to Michael Marchbank) [mailto:EMiller4@phsa.ca]
Sent: Thursday, December 16, 2010 11:12 AM
To: Davidson, Heather (ADM) HLTH:EX
Cc: Paton, Susan HLTH:EX; Walker, Andrea; Seller, Leigh Ann HLTH:EX; Peatt, Lenora HLTH:EX
Subject: Chronic Disease Program

Hi Heather,
Please see the attached letter and proposal from Michael.
Erin

Erin Miller
Executive Assistant to Michael Marchbank
Chief Operating Officer
Provincial Health Services Authority

700 - 1380 Burrard Street
Vancouver, BC
V6X 2H3 Canada
604-675-7427 Phone
604-708-2727 Fax
Erin.Miller@phsa.ca
http://www.phsa.ca

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Kelln, Brenna HLTH:EX

From: Seller, Leigh Ann HLTH:EX
Sent: Monday, January 17, 2011 3:35 PM
To: Scheiber, Alex HLTH:EX
Subject: RE: fyi

Did not get that from MM

From: Scheiber, Alex HLTH:EX
Sent: Monday, January 17, 2011 3:16 PM
To: Seller, Leigh Ann HLTH:EX
Subject: Re: fyi

s. 13

Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

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From: Seller, Leigh Ann HLTH:EX
Sent: Monday, January 17, 2011 03:01 PM
To: Scheiber, Alex HLTH:EX
Subject: RE: fyi

s. 13

From: Scheiber, Alex HLTH:EX
Sent: Monday, January 17, 2011 3:00 PM
To: Seller, Leigh Ann HLTH:EX
Subject: Re: fyi

s. 13

Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

---

From: Seller, Leigh Ann HLTH:EX
Sent: Monday, January 17, 2011 02:42 PM
To: Scheiber, Alex HLTH:EX
Subject: fyi

s. 13

Leigh Ann Seller
Executive Director, Provincial Co-Lead
Integrated Primary and Community Care
and Performance Accountability (PHSA, NHA)

Ministry of Health Services
6-2, 1515 Blanshard Street, Victoria BC V8W 3C8
Phone: (250) 952-1274 Cell: (250) 217-9909
Fax: (250) 952-1282
Email: LeighAnn.Seller@gov.bc.ca

TEAMWORK CURIOSITY PASSION SERVICE COURAGE ACCOUNTABILITY
I N T E G R I T Y

Please consider the environment before printing this e-mail

Rinta, Darcy HLTH:EX

From: Scheiber, Alex HLTH:EX
Sent: Thursday, January 6, 2011 11:22 AM
To: Power, Stephanie A HLTH:EX; Tregillus, Valerie HLTH:EX
Cc: Rinta, Darcy HLTH:EX
Subject: RE: Chronic Disease Program

s. 13

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

From: Power, Stephanie A HLTH:EX
Sent: Thursday, January 6, 2011 10:14 AM
To: Scheiber, Alex HLTH:EX; Tregillus, Valerie HLTH:EX
Cc: Rinta, Darcy HLTH:EX
Subject: RE: Chronic Disease Program

Hi Alex...

s. 13

Thanks

stephanie

From: Scheiber, Alex HLTH:EX
Sent: Thursday, January 6, 2011 9:55 AM
To: Tregillus, Valerie HLTH:EX
Cc: Rinta, Darcy HLTH:EX; Power, Stephanie A HLTH:EX
Subject: RE: Chronic Disease Program

s. 13

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

From: Tregillus, Valerie HLTH:EX
Sent: Thursday, January 6, 2011 8:37 AM
To: Scheiber, Alex HLTH:EX; Power, Stephanie A HLTH:EX
Cc: Bar, Sherry C HLTH:EX
Subject: RE: Chronic Disease Program

s. 13

Valerie Tregillus
Executive Director , Provincial Co-Lead
Integrated Primary and Community Care
BC Ministry of Health Services
phone: 250-952-2961
fax: 250 952-1417
PLS NOTE NEW EMAIL ADDRESS mailto:valerie.tregillus@gov.bc.ca

From: Scheiber, Alex HLTH:EX
Sent: Wednesday, January 5, 2011 5:20 PM
To: Power, Stephanie A HLTH:EX; Tregillus, Valerie HLTH:EX
Subject: Fw: Chronic Disease Program

Stephanie and Val, could you kindly review the attached draft proposal from PHSA and send me your feedback? If you need background info on the subject (focusing on Lyme disease) I can send you a BN. Thx.
Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

From: Seiler, Leigh Ann HLTH:EX
Sent: Wednesday, December 22, 2010 07:20 AM
To: Scheiber, Alex HLTH:EX; Rinta, Darcy HLTH:EX; Shorter, Richele HLTH:EX
Subject: FW: Chronic Disease Program

From: Miller, Erin (EA to Michael Marchbank) [mailto:EMiller4@phsa.ca]
Sent: Thursday, December 16, 2010 11:12 AM
To: Davidson, Heather (ADM) HLTH:EX
Cc: Paton, Susan HLTH:EX; Walker, Andrea; Seiler, Leigh Ann HLTH:EX; Peatt, Lenora HLTH:EX
Subject: Chronic Disease Program

Hi Heather,
Please see the attached letter and proposal from Michael.
Erin

Erin Miller
Executive Assistant to Michael Marchbank
Chief Operating Officer
Provincial Health Services Authority

700 - 1380 Burrard Street
Vancouver, BC
V6X 2H3 Canada
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604-708-2727 Fax
Erin.Miller@phsa.ca
http://www.phsa.ca

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Rinta, Darcy HLTH:EX

From: Rinta, Darcy HLTH:EX
Sent: Thursday, February 17, 2011 1:35 PM
To: Rinta, Darcy HLTH:EX
Subject: RE: Lyme disease and not responsive

s. 13

-----Original Message-----
From: Scheiber, Alex HLTH:EX
Sent: Thursday, February 17, 2011 1:29 PM
To: Rinta, Darcy HLTH:EX
Subject: Fw: Lyme disease and not responsive

Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

----- Original Message -----
From: Scheiber, Alex HLTH:EX
Sent: Tuesday, February 15, 2011 05:12 PM
To: XT:HLTH Marchbank, Michael
Cc: Seller, Leigh Ann HLTH:EX
Subject: Lyme disease and not responsive

not responsive

not responsive s. 13

s. 13

not responsive

Thanks.
Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

Rinta, Darcy HLTH:EX

From: Scheiber, Alex HLTH:EX
Sent: Thursday, January 27, 2011 2:55 PM
To: Rinta, Darcy HLTH:EX
Subject: FW: Chronic Disease Program
Attachments: 867032 Clinical Program for Chronic Complex Disease Approved by Heather Davidson January 14 2011.docx

Why did she comment on the BN- that's already gone?

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

From: Barnard, Kelly HLS:EX
Sent: Thursday, January 27, 2011 2:47 PM
To: Scheiber, Alex HLTH:EX
Cc: Seller, Leigh Ann HLTH:EX; Rinta, Darcy HLTH:EX
Subject: RE: Chronic Disease Program

Hi Alex,

I spoke to Leigh Ann about this and given that this is going ahead I will keep the additional feedback short:

s. 13

Hope this helps,
Kelly

From: Scheiber, Alex HLTH:EX
Sent: Thursday, January 27, 2011 1:55 PM
To: Barnard, Kelly HLS:EX
Cc: Rinta, Darcy HLTH:EX
Subject: Re: Chronic Disease Program

Kelly, when do you expect to finish your detailed review? We are aiming to have Mohs feedback to phsa by the end of the week but if that's too soon let me know. Thx
Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

From: Barnard, Kelly HLS:EX
Sent: Tuesday, January 25, 2011 05:02 PM
To: Scheiber, Alex HLTH:EX
Subject: RE: Chronic Disease Program

I will have a detailed look at it. On first glance ...

s. 13

s. 13 s. 17

s. 13

Hope this helps.
KB

From: Scheiber, Alex HLTH:EX
Sent: Tuesday, January 25, 2011 3:52 PM
To: Barnard, Kelly HLS:EX
Cc: Rinta, Darcy HLTH:EX
Subject: FW: Chronic Disease Program

Kelly, please review the email string below and let me know if you can review this proposal from PHSA. Thanks.

From: Kolodziejczyk, Dean HLTH:EX
Sent: Friday, January 21, 2011 9:38 AM
To: Scheiber, Alex HLTH:EX; Moen, Shelley HLTH:EX
Cc: Rinta, Darcy HLTH:EX
Subject: RE: Chronic Disease Program

Hi Alex,

Right now I have too much on my plate to pick this up as well. Perhaps run this by Kelly Barnard. I understand that she works for the HA division now and this is more related to public health than to my background.

s. 13

Dean Kolodziejczyk
Medical Consultant
Medical Services Branch, Medical Services Division
3-1 1515 Blanshard St
Victoria BC V8W 3C8
(250) 952-1541

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

From: Scheiber, Alex HLTH:EX
Sent: Thursday, January 20, 2011 3:02 PM
To: Kolodziejczyk, Dean HLTH:EX; Moen, Shelley HLTH:EX
Cc: Rinta, Darcy HLTH:EX
Subject: FW: Chronic Disease Program

s. 13

Thanks.

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

Rinta, Darcy HLTH:EX

From: Scheiber, Alex HLTH:EX
Sent: Friday, April 15, 2011 8:44 AM
To: Rinta, Darcy HLTH:EX
Subject: FW: Lyme Disease

Alex Scheiber
Director, Performance Accountability, PHSA Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

-----Original Message-----
From: Seller, Leigh Ann HLTH:EX
Sent: Friday, April 15, 2011 7:55 AM
To: Scheiber, Alex HLTH:EX; Henry, Effie HLTH:EX
Subject: Fw: Lyme Disease

Fyi

----- Original Message -----
From: Seller, Leigh Ann HLTH:EX
Sent: Friday, April 15, 2011 07:54 AM
To: 'Michael.Marchbank@phsa.ca' <Michael.Marchbank@phsa.ca>
Subject: Lyme Disease

I forgot to ask you who is lead for Lyme as Effie and Alex need to discuss how to respond to stakeholders. As discussed yesterday, it would be good to confirm that St. Pauls is being considered as a site for the clinic, I think it will be seen as very positive by stakeholders.

Pages 19 through 23 redacted for the following reasons:
- -
S13

Harrison, Shannon HLTH:EX

From: Whitmarsh, Graham HLTH:EX
Sent: Tuesday, March 29, 2011 8:47 AM
To: Davidson, Heather (ADM) HLTH:EX
Cc: Fagan Taylor, Kate HLTH:EX; Seller, Leigh Ann HLTH:EX
Subject: Re: 867032 Clinical Program for Chronic Complex Disease Approved by Heather Davidson January 14, 2011

s. 13

On 2011-03-29, at 8:43 AM, "Davidson, Heather (ADM) HLTH:EX" <Heather.Davidson@gov.bc.ca> wrote:

s. 13

Heather Davidson

Assistant Deputy Minister

Health Authorities Division

Ministry of Health

250 952-1049

From: Porter, Rodney PAB:EX
Sent: Tuesday, March 29, 2011 8:34 AM
To: Seller, Leigh Ann HLTH:EX; Scheiber, Alex HLTH:EX; Davidson, Heather (ADM) HLTH:EX; Kendall, Perry HLS:EX
Cc: Jabs, Ryan PAB:EX; Neufeld, Laura R PAB:EX; Stewart, Michelle PAB:EX
Subject: FW: 867032 Clinical Program for Chronic Complex Disease Approved by Heather Davidson January 14, 2011
Importance: High

s. 13

Thanks.

.C. doctors lack ability to diagnose Lyme disease
Vancouver Sun
Tuesday, March 29, 2011
Page A03
By Pamela Fayerman

B.C. doctors are failing to comply with a requirement to report all cases of Lyme disease to public health authorities and are confused about diagnosing it, according to a report published in the current B.C. Medical Journal.

Humans can get Lyme disease if they are bitten by an infected tick. The blacklegged, sesame-seed-sized tick is found throughout southern B.C.

Two weeks of early treatment with antibiotics is essential to prevent potentially serious long-term disabilities such as arthritis, persistent pain, fatigue, neurological symptoms or even death.

Two-thirds of doctors said they know Lyme disease is a reportable one. And yet, only 10 cases were officially reported to the BC Centre for Disease Control last year, a number similar to previous years.

But a survey done in 2008 -and only now released -shows that 148 doctors recalled diagnosing 221 cases in 2007. In that year, only 13 cases were officially reported.

The B.C. Medical Journal report also raised serious questions about the diagnosis and treatment of Lyme disease.

Sixty-three per cent of doctors said they were unaware that a bulls-eye rash is the only symptom they need to see in order to make a clinical diagnosis of Lyme disease.

Such a rash means a prescription for antibiotics can be given without the need for laboratory testing.

But studies have shown that up to 65 per cent of those with Lyme disease may not develop a rash. In such cases, treatment might not be started unless there is a positive lab confirmation. And such testing -to detect antibodies -can't be used until weeks after the initial infection.

Another report also says doctors lack knowledge about Lyme disease and that better testing is urgently needed.

HOW TO PROTECT YOURSELF AGAINST LYME DISEASE:

. Put insect repellent containing DEET on all uncovered skin while walking in woods or tall grass.

. Stay on cleared trails while hiking.

. Check skin (including folds), clothing and scalp when leaving an area where ticks may live.

. Check pets for ticks as well.

. Remove ticks immediately and completely. Remember, there may be more than one tick present.

See a doctor promptly if you suspect you have been bitten by a tick.

Pamela Fayerman/Vancouver Sun Source: BC Centre for Disease Control and Vancouver Sun

Written by Provincial Health Services Authority official Brian Schmidt and presented to the provincial government in May 2010, it notes that many doctors are skeptical about chronic Lyme disease, partly because the symptoms are similar to other ailments like chronic fatigue syndrome and fibromyalgia.

Schmidt said the current state of diagnostic testing methods for Lyme disease is inadequate and recommends that B.C. "lead the nation" in developing new tests based on genetic sequencing. He also urged more education for doctors and for those who work outdoors.

Provincial health officer Dr. Perry Kendall said an awareness campaign for doctors and the public will be launched in May.

As well, the government has approved funding to address the need for research and also to open a new clinic, probably at the University of B.C., for chronic disease patients like those with Lyme disease.

At the clinic, infectious disease experts would work beside immunologists and other specialists on difficult patient cases that may be caused by bacterial, viral or fungal infections.

"Even if we can't cure them, maybe their symptoms can be better managed," Kendall said.

Meanwhile, Dr. Bonnie Henry, a BC Centre for Disease Control expert who co-authored the B.C. Medical Journal article on physician awareness of Lyme disease, conceded there is a disconnect between the numbers doctors say they are diagnosing and the number they are reporting to provincial authorities.

Kendall said officials know there is "clinical under-reporting,' of the disease. "Clearly, doctors are not reporting it."

Under the Public Health Act, there are fines or other penalties for not reporting diseases, but it is not believed the sanctions have ever been taken against a doctor.

Lyme disease activists have long accused Canadian medical authorities of being too passive about monitoring tick populations and for poor medical management of the disease. There have been concerns about the accuracy of screening testing used by Canadian laboratories, prompting many to submit samples to private American labs.

Because of the controversy, the Centre for Disease Control collaborated with the B.C. College of Physicians and Surgeons to determine gaps in awareness.

The 2008 survey, which stems from that, was mailed to all doctors who would potentially see patients about Lyme disease, including family doctors, pediatricians and internists.

Of about 5,400 doctors who received the survey, 1,869 (35 per cent) responded.

Gwen Barlee, a chronic Lyme disease patient, said she was shocked at the contents of the Schmidt report, which she recently received through a freedom of information request to the Ministry of Health.

She made the request after she heard the B.C. government had "quietly commissioned a review of LD [Lyme disease]."

Barlee said the 55-page report confirms what the Canadian Lyme Disease Foundation and support groups have been saying for years about doctors' lack knowledge and the need for better testing.

"Needless to say, as a LD sufferer, I was amazed at the contents of the report and the recommendations. For years, the B.C. government has repeatedly said that doctors are well educated about the disease, that the tests are the gold standard and that LD is a rare, easily diagnosed and easily treated disease. However, the B.C. government's own internal report shows that this is not the case," said Barlee.

She believes there are thousands of people with Lyme disease in B.C. who were not diagnosed in the early stages when antibiotics would have been effective at clearing the infection.

pfayerman@vancouversun.com

From: Seller, Leigh Ann HLTH:EX
Sent: Friday, February 04, 2011 04:13 PM
To: Stewart, Michelle PAB:EX
Cc: Davidson, Heather (ADM) HLTH:EX
Subject: 867032 Clinical Program for Chronic Complex Disease Approved by Heather Davidson January 14, 2011

Michele, Heather asked I forward to you.

<867032 Clinical Program for Chronic Complex Disease Approved by Heather Davidson January 14, 2011.docx>

557

Davidson, Julie SSBC:EX

From: Dyble, John C PREM:EX
Sent: Wednesday, September 29, 2010 2:19 PM
To: Cranston, Lynda EHSC:IN
Cc: XT:HLTH Schmidt, Brian; Kendall, Perry HLTH:EX; Boomer, Joanne HLTH:EX
Subject: Chronic Lyme Disease

Lynda,

As mentioned at the beginning of the summer, I was impressed with the thoroughness of Brian's report. It is comprehensive and provides recommendations for next steps.

I think we should get together and have a further discussion about how to move forward. I think this should include you, me, Brian, Perry, BCCDC and possibly Heather.

Could your office arrange?

Thanks,

John

Davidson, Julie SSBC:EX

From: Kendall, Perry HLTH:EX
Sent: Monday, January 17, 2011 2:20 PM
To: Young, Eric R HLTH:EX
Cc: Kendall, Perry HLTH:EX
Subject: FW: AS REQUESTED: IBN - Clinical Program for Chronic Complex Disease (Lyme) Approved January 14, 2011
Attachments: 867032 Clinical Program for Chronic Complex Disease Approved by Heather Davidson January 14, 2011.docx

This was approved in principle this afternoon. Michael Marchbank and BCCDC will be working the more detailed proposal up over the next 2-3 weeks.
Perry

P. R. W. Kendall
OBC, MBBS, MSc, FRCPC
Provincial Health Officer
Ministry of Health
4th Floor, 1515 Blanshard Street
Victoria BC V8W 3C8
Phone: 250 952-1330
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perry.kendall@gov.bc.ca
http://www.healthservices.gov.bc.ca/pho

-----Original Message-----
From: Pooler, Shelley F HLTH:EX
Sent: Monday, January 17, 2011 2:17 PM
To: Davidson, Heather (ADM) HLTH:EX; Kendall, Perry HLS:EX
Subject: AS REQUESTED: IBN - Clinical Program for Chronic Complex Disease (Lyme) Approved January 14, 2011
Importance: High

Hello, Heather and Kendall.....

Please find attached Information Briefing Document on Chronic Complex Disease (Lyme) as requested.

Best regards,

Shelley Pooler
Executive Coordinator
Office of the Assistant Deputy Minister Health Authorities Division, Ministry of Health Services
Phone: (250) 952-1125, Blackberry (250)217-9648, Fax: (250) 952-1052
Email: Shelley.Pooler@gov.bc.ca

MINISTRY OF HEALTH SERVICES
INFORMATION BRIEFING DOCUMENT

Cliff #867032 xref 829707

PREPARED FOR: John Dyble, Deputy Minister of Health Services
– FOR INFORMATION

TITLE: Proposal for a Clinical Program for Chronic Complex Disease (Lyme Disease)

PURPOSE: To summarize the Provincial Health Service Authority proposal for a clinical program for chronic complex disease.

BACKGROUND:

- There are a variety of chronic complex diseases leading to disability where the cause is unknown but it is strongly suspected that an infectious pathogen may play a role. Some of the most prevalent recognized conditions include Lyme Disease, Myalgic Encepahlomyelitis (Chronic Fatigue Syndrome), and Fibromyalgia Syndrome.
- In September 2010, the Ministry of Health Services (MoHS) asked the Provincial Health Services Authority (PHSA) to present options for establishing a virtual clinic for patients with complex symptomatology possibly related to underlying infectious disease.
- PHSA consulted with various stakeholders in developing the proposal including specialists, health care providers and affected community representatives. They submitted the draft proposal in mid December 2010.

DISCUSSION:

- The proposal outlines the rationale and design of a clinical program that will provide a model of assessment for people with a group of complex chronic diseases.
- A virtual clinic was explored by PHSA; however, the recommendation is for a physical dedicated clinic because proper assessment and testing can only be achieved in person.
- Use of nurse practitioners or similar case workers within the clinic is recommended and provides patients with a model similar to diabetic clinics and other chronic diseases.
- The proposal assumes that 5-6 patients per day would be seen at the clinic.
- An advisory structure to the program is recommended, likely comprised of two/three representative members of the affected community, and a similar number of medical/research experts chaired by the medical director.
- An early goal of the clinic, once it has established a pattern of consistent patient assessment, will be to contribute to knowledge in this area through a modest case-control study.
- The proposal is undergoing a comprehensive internal MoHS review and PHSA is incorporating the feedback including providing clarity in the following areas:
    - Estimating the unmet need (e.g., prevalence, incidence) including the number of potential candidates for this clinic;
    - Further information on the expected clinical and system-wide benefits from the proposal, and the supporting evidence, including a proposed evaluation approach;

- Estimating the current and anticipated per capita costs of managing these patients through improved care;
- Estimating of the number of lab tests conducted by the clinic and the associated costs to the Medical Services Plan; and,
- Options for implementation (e.g., strategy vs. clinic, study only, study first then re-evaluate need for clinic).

The Proposal requires further direction from senior leadership regarding the source of funding and proposed implementation plan.

FINANCIAL IMPLICATIONS:

- The proposed budget for the clinic includes one time costs of $65,000 and annual costs of $1,074,150.
- The proposed cost for the case control study is $668,010.
- Costs of screening lab tests for patients are indicated as the responsibility of MSP but estimates have not been included. The (potentially large) costs of treating or managing the patients have also not been included.

RECOMMENDED NEXT STEPS:

- PHSA to conduct further consultation with stakeholders and the General Practitioners Services Committee regarding the areas in the proposal that require clarity.
- Seek direction from Health Operations Committee and Leadership Council in March 2011 on the funding sources and implementation plan.

Program ADM/Division:	Heather Davidson, Health Authorities Division
Telephone:	250 952-1049
Program Contact:	Leigh Ann Seller, Executive Director
Drafter:	Alex Scheiber
Date:	January 13, 2011

File Name with Path: Z:\HAD General\Briefing Notes\2011\Health Authorities\PHSA\867032 Clinical Program for Chronic Complex Disease Approved by Heather Davidson January 14, 2011.docx

Davidson, Julie SSBC:EX

From: Young, Eric R HLTH:EX
Sent: Thursday, January 20, 2011 1:43 PM
To: Kendall, Perry HLTH:EX
Subject: Fw: Chronic Disease Program
Attachments: Chronic Disease Program - Dec 10 2010.pdf

Fyi
Eric R. Young, MD, BSc, MHSc, CCFP, FRCP(C)
Deputy Provincial Health Officer,
Office of the PHO
Ministry of Healthy Living and Sport
1515 Blanshard St,
Victoria, British Columbia, Canada
250-952-1330

From: Scheiber, Alex HLTH:EX
Sent: Thursday, January 20, 2011 01:37 PM
To: Young, Eric R HLS:EX
Subject: FW: Chronic Disease Program

Eric, I have received feedback from various MoHS divisions on this, but I haven't heard from you yet. PHSA is awaiting final feedback from us so that they can complete the report for HOC.

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

From: Scheiber, Alex HLTH:EX
Sent: Wednesday, January 12, 2011 8:34 AM
To: Young, Eric R HLS:EX
Cc: Seller, Leigh Ann HLTH:EX; Rinta, Darcy HLTH:EX
Subject: FW: Chronic Disease Program

Eric, I don't know if you have received or reviewed the most recent version of the Chronic Complex Disease Program proposal from PHSA (attached).

I learned yesterday that the DM is meeting with Michael Marchbank and Heather Davidson on Monday to discuss this proposal so I have been asked to write a BN by Thursday describing outstanding issues. Would appreciate by Thursday (tomorrow) morning at the latest any feedback you can provide me so that we can incorporate in the BN. Apologies for the tight turnaround time.

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

ADVICE TO MINISTER

CONFIDENTIAL ISSUES NOTE Ministry: Health Date: Feb. 10, 2011 Update: March 28, 2011 Minister Responsible: Mike de Jong	Lyme Disease Report

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BACKGROUND REGARDING THE ISSUE:

Chronic Lyme Disease Report

- On May 31st, 2010, PHSA's Brian Schmidt produced a report at the request of the DM regarding chronic Lyme disease.
- The report concludes that "the current state of diagnostic methods for chronic lyme and other related infections is inadequate," and that the incidence of lyme disease is likely to increase; it recommends that B.C. lead the country in developing and adopting new diagnostic tools including genetic testing.
- The Ministry of Health will be undertaking a study of Lyme disease sufferers that will include some who believe they have "chronic Lyme".
- Pamela Fayerman, health reporter for the Vancouver Sun, has questioned PHSA, BCCDC and Dr. Kendall about this report, and Dr. Kendall confirmed that the study had been approved and that funding had been allocated.
- The Ministry of Health has set aside $2 million for the research component of this study, to be used over three years.
- The clinical portion of the project will be funded by PHSA, from within their overall funding.
- PHSA is currently developing a detailed business case for the project, with the goal to be able to screen, diagnose, treat and research Lyme disease.

Lyme Disease

- Less than 1% of ticks in B.C. that can carry Lyme are infected with the Lyme-causing bacteria.
- Early symptoms may include a "bulls-eye" rash which spreads outward on the skin as well as fever, headache, and muscle and joint pain.
- The proportion of ticks sent in by patients, physicians, veterinarians and health care workers (about 600 - 700 Ixodes species per year) that is positive has not increased over the past 10 years. Though no systematic screening in the field has taken place for a number of years.
- The disease is endemic in low levels in southern B.C., however lab-confirmed cases are rare. The number of people who receive a clinical diagnosis is larger, but is also hard to accurately quantify as these cases are not necessarily reported to public health.
- About half of the cases of Lyme disease reported in BC residents are acquired while they are travelling to areas of North America and Europe with much higher endemic rates.
- Of the 400-600 reports of people being bitten by ticks in BC each year, only about five to 10 patients have a laboratory confirmed diagnosis of Lyme disease.
- Diagnosis of Lyme can be made by physicians based on clinical signs and symptoms (including history of tick bites) and may be further supported by lab testing by

s. 13

Davidson, Julie SSBC:EX

From: Kendall, Perry HLTH:EX
Sent: Friday, January 7, 2011 11:28 AM
To: Kendall, Perry HLTH:EX; XT:HLTH Henry, Bonnie
Subject: FYI Lyme and mortality in the USA

Lyme disease a rare cause of death: study

While controversy still brews over the long-term effects of Lyme disease, a new government study concludes that the tick-borne illness is rarely a cause of death in the U.S. Using death records collected from 45 U.S. states, researchers at the Centers for Disease Control and Prevention (CDC) found that between 1999 and 2003, there were 114 records listing Lyme disease as a cause of death. But in most cases, Lyme disease was listed as one of multiple health problems contributing to a person's death, and only 23 records showed the disease as the underlying cause. Of those, the investigators say, just one was consistent with known "clinical manifestations" of Lyme disease. In that case, the person died of respiratory failure that the death record tied to long-term effects on the central nervous system. The findings, the CDC researchers say, indicate that Lyme disease "is rare as a cause of death in the U.S." But that conclusion is unlikely to settle the broader controversy surrounding the long-term effects of Lyme disease in some people -- which, some doctors and patient groups say, do include serious and sometimes fatal health problems. Lyme disease is a bacterial infection transmitted by certain ticks. The initial symptom is most often a gradually spreading "bull's eye" rash at the site of the tick bite. Other early symptoms include fever, fatigue, headache and muscle and joint aches. Without early treatment, the infection can sometimes spread within days to weeks to different parts of the body -- causing symptoms like neck stiffness, shooting pains from nerve damage, heartbeat irregularities and a loss of muscle tone in the face called Bell's palsy.

http://www.reuters.com/article/idUSTRE70553O20110106

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perry.kendall@gov.bc.ca
http://www.healthservices.gov.bc.ca/pho

Davidson, Julie SSBC:EX

From: Kendall, Perry HLTH:EX
Sent: Monday, February 14, 2011 11:31 AM
To: Neufeld, Laura R GCPE:EX
Cc: Kendall, Perry HLTH:EX
Subject: RE: in_Lyme Disease Tests_draft_Feb10

s. 13

Hope this helps
Perry

P. R. W. Kendall
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http://www.healthservices.gov.bc.ca/pho

From: Neufeld, Laura R PAB:EX
Sent: Monday, February 14, 2011 11:09 AM
To: Kendall, Perry HLS:EX
Subject: RE: in_Lyme Disease Tests_draft_Feb10

Thanks Perry.

s. 13

Thanks!
Laura

From: Kendall, Perry HLS:EX
Sent: Friday, February 11, 2011 8:27 AM
To: Neufeld, Laura R PAB:EX
Subject: in_Lyme Disease Tests_draft_Feb10

<< File: in_Lyme Disease Tests_draft_Feb10.docx >> see my comments on Eric's comments. I would however run the final past BCCDC
PK

Davidson, Julie SSBC:EX

From: XT:Kennedy, Theresa HLTH:IN
Sent: Thursday, August 4, 2011 11:00 AM
To: s. 22
Cc: Kendall, Perry HLTH:EX; Jim Wilson; David Cubberley; Dix.MLA, Adrian LASS:EX; deJong.MLA, Mike LASS:EX
Subject: RE: Time-line for new clinic - Chronic illness

Hello s. 22

I do not have this information at the moment but will be looking into this for you and get back to you as soon as I have the information.

Regards,
Theresa

Theresa Kennedy
Provincial Health Services Authority
604-675-7401(Office)

From: s. 22
Sent: Thursday, August 04, 2011 10:06 AM
To: Kennedy, Theresa
Cc: perry.kendall@gov.bc.ca; Jim Wilson; David Cubberley; Adrian Dix; Hon. De Jong
Subject: Time-line for new clinic - Chronic illness

Ms. Kennedy,
Could you please tell me who will be heading-up the new BC clinic that will be dealing with complex chronic diseases such as Fibromyalgia, Chronic Fatigue and Chronic Lyme? When will this new clinic be accepting patients?
Thank you for your time.
s.22

Davidson, Julie SSBC:EX

From: Young, Eric R HLTH:EX
Sent: Thursday, July 14, 2011 12:09 PM
To: Patrick, David CDC:IP
Cc: Kendall, Perry HLTH:EX
Subject: Lyme disease research / clinic

Hi David,
There is a new publication from the Institute of Medicine(2011) called Critical Needs and Gaps in Understanding – Prevention, Amelioration and Resolution of Lyme and other Tick-Borne Diseases that is really jam packed with information. The Closing Panel Chapter (9) speaks about the critical needs and gaps in understanding tick-borne diseases. There are major sections on diagnosis and treatment as well as research issues. Our library has just got it in. Perhaps it might be useful as you plan the clinic/research strategy.
Eric

Eric R. Young, MD, BSc, MHSc, CCFP, FRCPC
Deputy Provincial Health Officer
B.C. Ministry of Health
and
Clinical Assistant Professor,
School of Population and Public Health
Faculty of Medicine
University of British Columbia

Rinta, Darcy HLTH:EX

From: French, Angela HLTH:EX
Sent: Tuesday, May 17, 2011 11:37 AM
To: Rinta, Darcy HLTH:EX
Subject: RE: Help for Patients with Complex Chronic Diseases

Thanks Darcy

Angela French

Health Liaison Analyst
Health and Seniors Quality Service Centre
Ministry of Health
5-3, 1515 Blanshard St.
Victoria BC V8W 3C8
Phone: 952-1890
Fax: 952-2225

From: Rinta, Darcy HLTH:EX
Sent: Tuesday, May 17, 2011 11:25 AM
To: French, Angela HLTH:EX
Cc: Scheiber, Alex HLTH:EX
Subject: RE: Help for Patients with Complex Chronic Diseases

Hi Angela,

The clinic and research study are in development and should be operating by Fall 2011. Alex is the MoH contact but there is no additional information at this time.

There is also a lot of written correspondence and people are being advised "Additional information about the clinic will be available from your family physician after the development of the program is complete."

Hope that helps, give me a call if you have any further questions.

Darcy Rinta
Manager, Performance Accountability (PHSA)

Health Authorities Division
Ministry of Health
Phone: 250-952-2423
Darcy.Rinta@gov.bc.ca

From: French, Angela HLTH:EX
Sent: Monday, May 16, 2011 11:44 AM
To: Scheiber, Alex HLTH:EX
Subject: Help for Patients with Complex Chronic Diseases

Hi Alex

We are receiving several calls, including calls redirected from the Minister's Office, with regard to the News Release – March 30, 2011 on the Complex Chronic Diseases clinic and study. We have been advising people to work with their family physician or health care provider with regard to this clinic and study as referrals will be needed to participate.

Do you have any information on the process that we can provide to the public with regard to the program? Will the physicians and health care providers receive applications or would it be done over the phone... who will the program contacts be etc.

I was given your name as the "Contact" for Lyme Disease and I am not sure if you are the correct person to provide us with the information on this specific program – are you able to put me in touch with the appropriate contact? I understand this is a collaboration between PHSA and MoH.

There has been some confusion recently with this program and people connecting with "Primary Health" here in the Ministry.

I look forward to hearing from you, thanks Alex.

Cheers,

Angela French

Health Liaison Analyst
Health and Seniors Quality Service Centre
Ministry of Health
5-3, 1515 Blanshard St.
Victoria BC V8W 3C8
Phone: 952-1890
Fax: 952-2225

Rinta, Darcy HLTH:EX

From: Hamilton, Sherry [shamilton@phsa.ca]
Sent: Monday, June 27, 2011 11:55 AM
To: Rinta, Darcy HLTH:EX
Subject: Re: chronic complex disease clinic

Hi Darcy
No update as yet
Thx
Sherry

From: Rinta, Darcy HLTH:EX <Darcy.Rinta@gov.bc.ca>
To: Hamilton, Sherry
Sent: Mon Jun 27 09:56:13 2011
Subject: chronic complex disease clinic

Hi Sherry,

At the PHSA meeting on Jun 16, you said "PHC reviewing the proposal for hosting the clinic and should hear next week". Is there any update on this?

Thanks,

Darcy Rinta
Manager, Performance Accountability (PHSA)
Health Authorities Division
Ministry of Health
Phone: 250-952-2423
Darcy.Rinta@gov.bc.ca

Rinta, Darcy HLTH:EX

From: Scheiber, Alex HLTH:EX
Sent: Thursday, June 9, 2011 5:05 PM
To: Wolsey, Ashley HLTH:EX
Cc: Rinta, Darcy HLTH:EX
Subject: Re: Lyme Disease letters

Yes please. Please copy Darcy and me. Thx
Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

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From: Wolsey, Ashley HLTH:EX
Sent: Thursday, June 09, 2011 05:02 PM
To: Scheiber, Alex HLTH:EX; Rinta, Darcy HLTH:EX
Subject: RE: Lyme Disease letters

Sure. I can send him a list – or send you a list which you can forward on if you prefer. Do you want him to just have the numbers? And a few select examples of incoming and outgoing?

From: Scheiber, Alex HLTH:EX
Sent: Thursday, June 9, 2011 5:00 PM
To: Rinta, Darcy HLTH:EX; Wolsey, Ashley HLTH:EX
Subject: Fw: Lyme Disease letters

Ok, cancel the blind copy. Can you send David the list on, say, a quarterly basis?
Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

---

From: Henry, Effie HLTH:EX
Sent: Thursday, June 09, 2011 04:49 PM
To: Scheiber, Alex HLTH:EX
Subject: Re: Lyme Disease letters

That's fine - but I want them to see the volume and interest level. I think we've done 90 this year so far I- shannon sent me the list today.

From: Scheiber, Alex HLTH:EX
Sent: Thursday, June 09, 2011 04:35 PM
To: Henry, Effie HLTH:EX
Subject: Lyme Disease letters

Ashley tells me you asked her to blind copy David Patrick on all Lyme correspondence. David said he would prefer not to get letters on this until he has hired a team to be able to cope with them. Also, they all contain the same standard messaging about Lyme so would not really be useful to him. I would prefer to copy him on only select letters (e.g. Lyme Foundation) until he has hired sufficient staff to manage correspondence. Are you ok with this?

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health
6- 1515 Blanshard St., Victoria

From: Scheiber, Alex HLTH:EX <Alex.1.Scheiber@gov.bc.ca>
To: Patrick, David
Cc: Rinta, Darcy HLTH:EX <Darcy.Rinta@gov.bc.ca>
Sent: Thu May 12 16:32:47 2011
Subject: Chronic Complex Disease Clinic- correspondence

David, the Ministry continues to receive correspondence from people asking for information and/or access to the CCDC. Some state they are suffering from various ailments, others are contacting the Minister on behalf of other patients. The correspondence branch has asked about copying you on some of the replies (so that the writer sees your name) and/or suggesting the writer contacts you for more information.

I'm mindful of the fact that this clinic is only 30% of your time and that you don't have support staff in place. Do you want us to hold off mentioning your name in correspondence?

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

Davidson, Julie SSBC:EX

From: Porter, Rodney GCPE:EX
Sent: Tuesday, March 29, 2011 8:34 AM
To: Seller, Leigh Ann HLTH:EX; Scheiber, Alex HLTH:EX; Davidson, Heather (ADM) HLTH:EX; Kendall, Perry HLTH:EX
Cc: Jabs, Ryan GCPE:EX; Neufeld, Laura R GCPE:EX; Stewart, Michelle GCPE:EX
Subject: FW: 867032 Clinical Program for Chronic Complex Disease Approved by Heather Davidson January 14, 2011
Attachments: 867032 Clinical Program for Chronic Complex Disease Approved by Heather Davidson January 14, 2011.docx

Importance: High

Could you please help.

Given the Sun and CBC coverage today on the virtual lyme disease clinic that the Ministry is working towards, can we announce the details, and is a public awareness campaign part of the clinic in May as per Perry's quote below?

Thanks.

.C. doctors lack ability to diagnose Lyme disease
Vancouver Sun
Tuesday, March 29, 2011
Page A03
By Pamela Fayerman

B.C. doctors are failing to comply with a requirement to report all cases of Lyme disease to public health authorities and are confused about diagnosing it, according to a report published in the current B.C. Medical Journal.

Humans can get Lyme disease if they are bitten by an infected tick. The blacklegged, sesame-seed-sized tick is found throughout southern B.C.

Two weeks of early treatment with antibiotics is essential to prevent potentially serious long-term disabilities such as arthritis, persistent pain, fatigue, neurological symptoms or even death.

Two-thirds of doctors said they know Lyme disease is a reportable one. And yet, only 10 cases were officially reported to the BC Centre for Disease Control last year, a number similar to previous years.

But a survey done in 2008 -and only now released -shows that 148 doctors recalled diagnosing 221 cases in 2007. In that year, only 13 cases were officially reported.

The B.C. Medical Journal report also raised serious questions about the diagnosis and treatment of Lyme disease.

Sixty-three per cent of doctors said they were unaware that a bulls-eye rash is the only symptom they need to see in order to make a clinical diagnosis of Lyme disease.

Such a rash means a prescription for antibiotics can be given without the need for laboratory testing.

But studies have shown that up to 65 per cent of those with Lyme disease may not develop a rash. In such cases, treatment might not be started unless there is a positive lab confirmation. And such testing -to detect antibodies -can't be used until weeks after the initial infection.

Another report also says doctors lack knowledge about Lyme disease and that better testing is urgently needed.

HOW TO PROTECT YOURSELF AGAINST LYME DISEASE:

. Put insect repellent containing DEET on all uncovered skin while walking in woods or tall grass.

. Stay on cleared trails while hiking.

. Check skin (including folds), clothing and scalp when leaving an area where ticks may live.

. Check pets for ticks as well.

. Remove ticks immediately and completely. Remember, there may be more than one tick present.

See a doctor promptly if you suspect you have been bitten by a tick.

Pamela Fayerman/Vancouver Sun Source: BC Centre for Disease Control and Vancouver Sun

Written by Provincial Health Services Authority official Brian Schmidt and presented to the provincial government in May 2010, it notes that many doctors are skeptical about chronic Lyme disease, partly because the symptoms are similar to other ailments like chronic fatigue syndrome and fibromyalgia.

Schmidt said the current state of diagnostic testing methods for Lyme disease is inadequate and recommends that B.C. "lead the nation" in developing new tests based on genetic sequencing. He also urged more education for doctors and for those who work outdoors.

Provincial health officer Dr. Perry Kendall said an awareness campaign for doctors and the public will be launched in May.

As well, the government has approved funding to address the need for research and also to open a new clinic, probably at the University of B.C., for chronic disease patients like those with Lyme disease.

At the clinic, infectious disease experts would work beside immunologists and other specialists on difficult patient cases that may be caused by bacterial, viral or fungal infections.

"Even if we can't cure them, maybe their symptoms can be better managed," Kendall said.

Meanwhile, Dr. Bonnie Henry, a BC Centre for Disease Control expert who co-authored the B.C. Medical Journal article on physician awareness of Lyme disease, conceded there is a disconnect between the numbers doctors say they are diagnosing and the number they are reporting to provincial authorities.

Kendall said officials know there is "clinical under-reporting,' of the disease. "Clearly, doctors are not reporting it."

Under the Public Health Act, there are fines or other penalties for not reporting diseases, but it is not believed the sanctions have ever been taken against a doctor.

Lyme disease activists have long accused Canadian medical authorities of being too passive about monitoring tick populations and for poor medical management of the disease. There have been concerns about the accuracy of screening testing used by Canadian laboratories, prompting many to submit samples to private American labs.

Because of the controversy, the Centre for Disease Control collaborated with the B.C. College of Physicians and Surgeons to determine gaps in awareness.

The 2008 survey, which stems from that, was mailed to all doctors who would potentially see patients about Lyme disease, including family doctors, pediatricians and internists.

Of about 5,400 doctors who received the survey, 1,869 (35 per cent) responded.

Gwen Barlee, a chronic Lyme disease patient, said she was shocked at the contents of the Schmidt report, which she recently received through a freedom of information request to the Ministry of Health.

She made the request after she heard the B.C. government had "quietly commissioned a review of LD [Lyme disease]."

Barlee said the 55-page report confirms what the Canadian Lyme Disease Foundation and support groups have been saying for years about doctors' lack knowledge and the need for better testing.

"Needless to say, as a LD sufferer, I was amazed at the contents of the report and the recommendations. For years, the B.C. government has repeatedly said that doctors are well educated about the disease, that the tests are the gold standard and that LD is a rare, easily diagnosed and easily treated disease. However, the B.C. government's own internal report shows that this is not the case," said Barlee.

She believes there are thousands of people with Lyme disease in B.C. who were not diagnosed in the early stages when antibiotics would have been effective at clearing the infection.

pfayerman@vancouversun.com

From: Seller, Leigh Ann HLTH:EX
Sent: Friday, February 04, 2011 04:13 PM
To: Stewart, Michelle PAB:EX
Cc: Davidson, Heather (ADM) HLTH:EX
Subject: 867032 Clinical Program for Chronic Complex Disease Approved by Heather Davidson January 14, 2011

Michele, Heather asked I forward to you.

From: Kendall, Perry HLS:EX
Sent: Monday, March 28, 2011 2:34 PM
To: Jabs, Ryan PAB:EX
Cc: Porter, Rodney PAB:EX; Stewart, Michelle PAB:EX; XT:HLTH Henry, Bonnie; Neufeld, Laura R PAB:EX
Subject: RE: Fayerman - BCCDC - Reportable Diseases
Importance: High

s. 13

Perry

P. R. W. Kendall
OBC, MBBS, MSc, FRCPC
Provincial Health Officer
Ministry of Health
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Victoria BC V8W 3C8
Phone: 250 952-1330
Fax: 250 952-1362
perry.kendall@gov.bc.ca
http://www.healthservices.gov.bc.ca/pho

From: Jabs, Ryan PAB:EX
Sent: Monday, March 28, 2011 2:10 PM
To: Kendall, Perry HLS:EX
Cc: Porter, Rodney PAB:EX; Stewart, Michelle PAB:EX; XT:HLTH Henry, Bonnie; Neufeld, Laura R PAB:EX
Subject: RE: Fayerman - BCCDC - Reportable Diseases

s. 22

s. 13

Ryan Jabs
Manager, Media Relations and Issues Management
Ministry of Health Communications
Public Affairs Bureau, B.C.
(250) 952-3387
Cell: (250) 413-7121
Ryan.Jabs@gov.bc.ca

From: Kendall, Perry HLS:EX
Sent: Monday, March 28, 2011 1:56 PM
To: Jabs, Ryan PAB:EX
Cc: Porter, Rodney PAB:EX; Stewart, Michelle PAB:EX; XT:HLTH Henry, Bonnie; Neufeld, Laura R PAB:EX
Subject: RE: Fayerman - BCCDC - Reportable Diseases

Yes it's accurate s. 13

s. 13

Perry

P. R. W. Kendall
OBC, MBBS, MSc, FRCPC
Provincial Health Officer
Ministry of Health
4th Floor, 1515 Blanshard Street
Victoria BC V8W 3C8
Phone: 250 952-1330
Fax: 250 952-1362
perry.kendall@gov.bc.ca
http://www.healthservices.gov.bc.ca/pho

From: Jabs, Ryan PAB:EX
Sent: Monday, March 28, 2011 1:45 PM
To: Kendall, Perry HLS:EX
Cc: Porter, Rodney PAB:EX; Stewart, Michelle PAB:EX; XT:HLTH Henry, Bonnie; Neufeld, Laura R PAB:EX
Subject: FW: Fayerman - BCCDC - Reportable Diseases

Hi Perry,

Is the info below from Dr. Daly accurate? s. 13

s. 13

Thanks,

Ryan Jabs
Manager, Media Relations and Issues Management
Ministry of Health Communications
Public Affairs Bureau, B.C.
(250) 952-3387
Cell: (250) 413-7121
Ryan.Jabs@gov.bc.ca

From: Adams, Clay [CORP] [mailto:Clay.Adams@vch.ca]
Sent: Monday, March 28, 2011 1:37 PM
To: [PHSA] Harry, Ritinder; XT:Ekramoddoullah, Lubna HLTH:IN
Cc: [PHSA] Dawkins, Laurie; [PHSA] Rehncy, Papinder; [PHSA] Tang, Tracy; May, Stephen PAB:EX; Jabs, Ryan PAB:EX; Stewart, Michelle PAB:EX
Subject: RE: Fayerman - BCCDC - Reportable Diseases

Just received this from Dr. Patty Daly...

Firstly the reportable diseases referred to must be reported to the MHO, not BCCDC – and the requirement for reporting is for not only physicians but other healthcare providers including infection control practitioners, nurses, laboratories etc. for most diseases on the list – some diseases are only reported by labs.

Under the Public Health Act, there are administrative penalties for those who fail to comply, which would cover those who fail to comply with reporting. First step would be to issue an Order from the MHO, and working through an escalating series of steps that at the extreme could include fines and imprisonment.

I am not aware of an MHO in this province who has ever had to issue an Order to any physician who deliberately refused to report a communicable disease. If such a situation were to arise, I would discuss it first with Perry Kendall to determine further action and whether this would also require a report to the College and the employer, if it were a Health Authority.

This does not mean that every time a physician sees a patient with a reportable communicable disease, they are calling to report it to us. There are significant redundancies in the system – the lab automatically sends positive reports to us, and we receive them at the same time (or some times even before) the physician. There is no need for doctors to also call and report these cases to us, and they know this. This accounts for the vast majority of reportable diseases in the province.

Does this help? She also copied Dr. Perry Kendall for comment.

Clay Adams, ABC
Vice-President
Lower Mainland Communications & Public Affairs
Fraser Health, Providence Health Care, Provincial Health Services Authority & Vancouver Coastal Health
Tel: 604-708-5280
Fax: 604-874-9182
Cell: 604-202-8789
E-mail: clay.adams@vch.ca

From: Harry, Ritinder [mailto:Ritinder.Harry@bccdc.ca]
Sent: Monday, March 28, 2011 12:23 PM
To: [PHSA] Ekramoddoullah, Lubna; May, Stephen PAB:EX; ryan.jabs@gov.bc.ca; michelle.stewart@gov.bc.ca
Cc: Adams, Clay [CORP]; [PHSA] Dawkins, Laurie; [PHSA] Rehncy, Papinder; [PHSA] Tang, Tracy
Subject: RE: Fayerman - BCCDC - Reportable Diseases

not responsive

There are no penalties for not reporting reportable diseases (even though physicians are required to report).

From: Ekramoddoullah, Lubna
Sent: Monday, March 28, 2011 11:52 AM
To: May, Stephen PAB:EX; ryan.jabs@gov.bc.ca; michelle.stewart@gov.bc.ca
Cc: Harry, Ritinder; [VCH] Adams, Clay [CORP]; Dawkins, Laurie; Rehncy, Papinder; Tang, Tracy
Subject: Fayerman - BCCDC - Reportable Diseases
Importance: High

FYI - Does anybody know the answer to this?

Lubna Ekramoddoullah
Senior Public Affairs Officer, PHSA
Lower Mainland Communications and Public Affairs
Fraser Health | Providence Health Care | Provincial Health Services Authority | Vancouver Coastal Health

Office: 604-675-7459
Blackberry: 604-313-8443
Email: lekramod@phsa.ca

From: Fayerman, Pamela (Vancouver Sun) [mailto:PFayerman@vancouversun.com]
Sent: Monday, March 28, 2011 11:50 AM
To: Ekramoddoullah, Lubna
Subject: reportable diseases
Importance: High

Lubna,
can you quickly tell me if there is any sanction for doctors who fail to report a reportable disease to BCCDC?

PAMELA FAYERMAN

Vancouver Sun Medical/Health Issues Reporter
#1 - 200 Granville Street, Vancouver, British Columbia V6C 3N3
Phone 604-605-2173

Read my Blog, **Medicine Matters,** here: **http://tinyurl.com/sunmedicine**
Follow me on **Twitter** here: **http://twitter.com/MedicineMatters**

Read my Patient Navigation series here:
http://www.vancouversun.com/news/patient-navigation-series/index.html

Davidson, Julie SSBC:EX

From: Patrick, David CDC:IP
Sent: Thursday, June 2, 2011 9:48 AM
To: Brunham, Robert CDC:IP; Kendall, Perry HLTH:EX
Subject: FW: Your report

So still don't have a full copy of the report but will ask for it directly from Brian. For starters, anyone holding a faculty position at a post-secondary institution should be prepared to stand behind their work.

David Patrick, MD, FRCPC, MHSc
Director and Professor
UBC School of Population and Public Health and
Medical Epidemiology Lead, Antimicrobial Resistance,
British Columbia Centre for Disease Control
At BCCDC:
655 West 12 Ave Vancouver BC V5Z 3L5
604-707-2541

From: Patrick, David
Sent: Thursday, June 02, 2011 9:44 AM
To: Schmidt, Brian
Subject: Your report

Hi Brian:

s. 13

David Patrick, MD, FRCPC, MHSc
Director and Professor
UBC School of Population and Public Health and
Medical Epidemiology Lead, Antimicrobial Resistance,
British Columbia Centre for Disease Control
At BCCDC:
655 West 12 Ave Vancouver BC V5Z 3L5

Davidson, Julie SSBC:EX

From: Patrick, David CDC:IP
Sent: Thursday, June 30, 2011 11:27 AM
To: Scheiber, Alex HLTH:EX; Bresler, Leon; Brunham, Robert CDC:IP; XT:HLTH Byres, David; XT:HLTH Hamilton, Sherry; Kendall, Perry HLTH:EX; pphillips@cfenet.ubc.ca; [VCH] Lefebvre, Yvonne [PH]
Cc: david.patrick@ubc.ca; Patrick, David CDC:IP
Subject: Idiopathic Chronic Disease

Hi:

I'm establishing a few listserves around this activity and want to take this opportunity to touch bases with the group focused on establishing the clinic. Here are the most important developments:

- David B is still working on confirming if Providence can take on the clinic hosting
- If so, we would likely need to move incrementally by moving fast on identification of a medical director or interim medical director to finalize design of final model and contract
- While identification of such a person could be tricky, I have a couple of excellent leads on scientifically minded specialists with an interest. Since the strongest of these is out of province, I would like to know if we have the leeway to move that recruitment along soon.
- On the research front, we have received a funding letter which will allow us to get moving with the core initial clin/epi/metagenomic study
- I will meet with leadership at CHEOS Monday. Should it be confirmed that the clinic will be sited at Providence, it would make sense to work with elements of that group as collaborators in the study and to use CHEOS clinical research infrastructure. It will help to know this soon because the easiest site to work at should Providence not come on line will be the Arthritis Research Centre and this involves a different group of clinical research support people
- I would like to take initial steps to bring together the community advisory board. To that end, I will finalize Terms of Reference and look to plan a gathering by mid-summer. It would help to know if there is some small budget to draw on for this.
- I have met separately with the CanLyme group and the National ME/FM action network.

Please let me know what I can do to further inform decisions about the siting of the clinic.

Best.

David Patrick, MD, FRCPC, MHSc
Director and Professor
UBC School of Population and Public Health and
Medical Epidemiology Lead, Antimicrobial Resistance,
British Columbia Centre for Disease Control
At BCCDC:
655 West 12 Ave Vancouver BC V5Z 3L5
604-707-2541

"Not to be absolutely certain is, I think, one of the essential things in rationality."
- Bertrand Russell

Davidson, Julie SSBC:EX

From: Brunham, Robert CDC:IP
Sent: Wednesday, June 1, 2011 7:48 AM
To: Patrick, David CDC:IP
Cc: Kendall, Perry HLTH:EX
Subject: RE: Brian Schmidt Report

Could be a role for the University as a neutral third partner to take on?

Robert C. Brunham, MD, FRCPC, OBC
Provincial Executive Director and Scientific Director,
BC Centre for Disease Control; &
Professor, Department of Medicine,
University of British Columbia

655 West 12th Avenue
Vancouver BC V5Z 4R4
Tel: 604 707 2405
Fax: 604 707 2401
Email: robert.brunham@bccdc.ca
Website: bccdc.ca

An Agency of the Provincial Health Services Authority

From: Patrick, David
Sent: Tuesday, May 31, 2011 4:48 PM
To: perry.kendall@gov.bc.ca; Brunham, Robert
Subject: Brian Schmidt Report

Now that this has been FOI'd, is it available to us?

s. 13

David Patrick, MD, FRCPC, MHSc
Director and Professor
UBC School of Population and Public Health and
Medical Epidemiology Lead, Antimicrobial Resistance,
British Columbia Centre for Disease Control
At BCCDC:
655 West 12 Ave Vancouver BC V5Z 3L5
604-707-2541

Davidson, Julie SSBC:EX

From: Patrick, David CDC:IP
Sent: Thursday, August 26, 2010 9:28 AM
To: Kendall, Perry HLTH:EX; Young, Eric R HLTH:EX
Subject: FW: Chronic Fatigue

Hi Perry:

not responsive

Was hoping to discuss this issue of CFS / potentially chronic Lyme / and murine retroviruses.

I think we now have the tools to take the inquiry to a different level.

David Patrick, MD, FRCPC, MHSc
Director, Epidemiology Services
BC Centre for Disease Control and
Professor, School of Population and Public Health
University of British Columbia
655 West 12 Ave
Vancouver, BC V5Z 4R4 Canada
PH: 604-707-2541
FX: 604-707-2516
david.patrick@bccdc.ca
www.bccdc.ca

Please note my new telephone number

From: Patrick, David
Sent: Wednesday, August 25, 2010 5:58 PM
To: Eric.Young@gov.bc.ca
Subject: Chronic Fatigue

Hi Eric:

I understand that you have received correspondence separately from Pat and Morshed.

We're all working together on this issue of murine retrovirus and CFS and like syndromes.

Please feel free to call if you want to discuss.

There is a window of opportunity to get some great inquiry going AND Patrick and Jennifer have a scientific approach to samples which is much less likely to miss important things than past methodology.

The political benefit is the opportunity to clinically engage some of these vocal groups and get some momentum on solving some of these issues.

David Patrick, MD, FRCPC, MHSc
Director, Epidemiology Services

BC Centre for Disease Control and
Professor, School of Population and Public Health
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Vancouver, BC V5Z 4R4 Canada
PH: 604-707-2541
FX: 604-707-2516
david.patrick@bccdc.ca
www.bccdc.ca

Please note my new telephone number

Davidson, Julie SSBC:EX

From: XT:HLTH Henry, Bonnie
Sent: Tuesday, October 19, 2010 11:19 AM
Subject: Lyme survey
Attachments: CPHA_Lyme_Poster_Final.pdf; LD_PhysicianSurvey_Oct18 (2).doc

This e-mail is being sent to the MHO list and BCCDC epidclin

Hi All,
You may have seen or heard reports in the media today about a research study we led looking at physician awareness and knowledge around Lyme disease in BC. This was undertaken partly as a response to criticism from some Lyme advocacy groups that doctors in BC did not know about LD and were not diagnosing and treating people in BC. We have been working on the analysis and have discussed the preliminary results of this study in a number of Lyme information sessions with physicians and recently presented a poster with some of the preliminary results at the CPHA conference. I have attached the poster here for your information. We released this poster to a Lyme advocate who had submitted an FOI request for all Lyme related material at BCCDC and they have recently released a press statement accusing the BCCDC of hiding this data so you may have local questions.

The bottom line is that doctors in BC are aware of LD and 148 reported they had seen one or more cases of LD in their practice in 2007 for a total of 221 potential cases. The knowledge scores were high and comparable to areas of high LD risk and most physicians were using recommended guidelines for assessing and treating people with LD. What we do not know is if the cases seen were acute cases, repeat cases, people who were exposed to a tick versus people with symptoms, people who saw multiple physicians or people who were exposed outside of BC etc so the number recalled by physicians is more an indicator of awareness rather than actual cases. In the same time period we did not see an increase in numbers of samples from patients submitted for testing or in rates of infection in ticks so we do not feel this is an indication of increasing risk in the province. We also see that too many docs did not know the disease was reportable and that many did not know that erythema migrans on its own could be diagnostic. We continue to provide advice to doctors about the importance of early diagnosis and treatment and to the public about prevention of LD.

This study has been submitted to a peer review journal and we are expecting the peer review process will ensure the validity of the research. I have attached as well an issues note we have prepared on this. Please feel free to refer any queries to me if you prefer.

Cheers,
Bonnie

Bonnie Henry MD MPH FRCP(C)

Director, Public Health Emergency Services

BC Centre for Disease Control

and

Assistant Professor, School of Population and Public Health,

University of British Columbia

655 West 12th Avenue

Vancouver, BC

V5Z 4R4

bonnie.henry@bccdc.ca
phone: 604-707-2497
fax: 604 707-2420

Lyme Disease Knowledge, Beliefs and Practices of Physicians in British Columbia

A.Crabtree, MPH[1], B.Henry, MD MPH FRCPC[1,2], D.Roth, MSc[1], M.Morshed, PhD SCCM[1,2], D.Blackman, MD CCFP[3]

[1]University of British Columbia, [2]BC Centre for Disease Control, [3]College of Physicians and Surgeons of BC

BC Centre for Disease Control

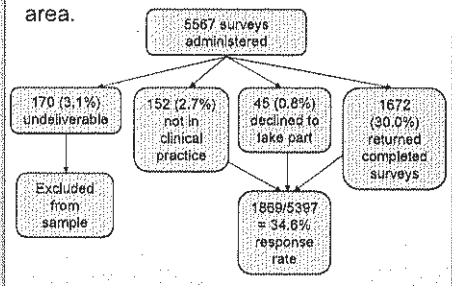
Background

•Lyme disease (LD) is a tickborne zoonosis caused by the spirochete *Borrelia burgdorferi* and transmitted to humans in North America by the bite of infected Ixodes ticks.

•Studies in high endemic areas found that, while treatment of confirmed Lyme disease generally followed accepted guidelines, testing and treatment of asymptomatic patients was common and was often tied to patient pressure[1-4]. It is unclear if these observations apply to areas of low Lyme disease activity such as BC.

Methods

•We conducted a survey of primary care and specialist (pediatrics, internal medicine) physicians in BC to assess clinician knowledge, beliefs and practices with respect to LD in this low endemic area.



•81% of respondents were family doctors

•Family physicians had practiced for an average of 21 years, while specialists had practiced for 19 years; they saw an average of 122 and 74 patients per week, respectively

Results

•148 respondents indicated that they recalled diagnosing a total of 221 cases of LD in 2007 (range 0-5 cases per physician); 13 cases were reported to the BCCDC during the same year.

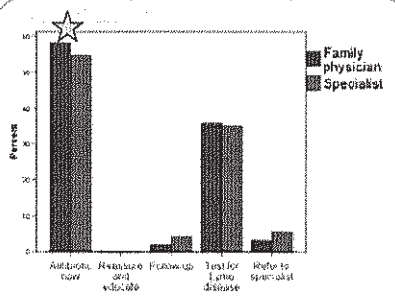
Table 1. Respondents' knowledge of basic LD facts.

Question	Response	%
EM rash is diagnosed in < 60% of patients	True	60%
	False	26%
	Don't know	14%
The physical-exam finding of EM alone is enough to diagnose Lyme disease	True	27%
	False	63%
	Don't know	10%
What is the name of the infectious agent that causes Lyme disease?	I. pacificus	2%
	B. burgdorferi	88%
	T. pallidum	0%
	B. microti	0%
What is the incubation period from tick bite to EM rash?	1-12 days	18%
	3-30 days	64%
	10-65 days	19%

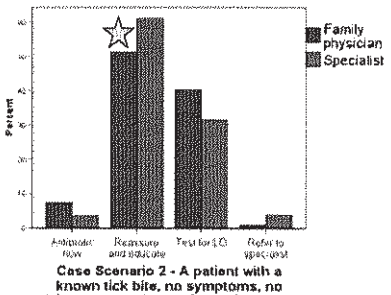
•Family practitioners and specialists scored similarly on questions about knowledge of Lyme disease, including its signs and symptoms. There were no differences between regions .

Table 2. Knowledge scores by specialty and region.

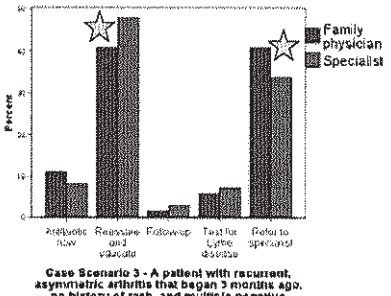
Health Authority	Average Knowledge Score (/12)	
	Family Physician	Specialist
Fraser	8.8	9.0
Interior	9.0	8.9
Northern	9.1	9.9
Vancouver Coastal	8.9	9.2
Vancouver Island	8.9	9.2



Case Scenario 1 - A patient with erythema migrans and no laboratory testing performed to date



Case Scenario 2 - A patient with a known tick bite, no symptoms, no laboratory testing performed to date, and a normal exam



Case Scenario 3 - A patient with recurrent, asymmetric arthritis that began 3 months ago, no history of rash, and multiple negative Western blot tests for Lyme disease

☆ Correct answers marked with gold stars

•In response to an item asking respondents to rate their region as high/medium/low/no risk for LD, most selected an answer that correlated well with the risk predicted by ecological niche modelling[5].

•55% of respondents indicated that, when they evaluated a patient for potential LD, it was the patient that raised the possibility first.

•27% of respondents indicated that they had treated a patient for LD in response to patient concerns even when they thought the patient did not have LD.

Conclusions

•Physicians in BC are knowledgeable about LD and are diagnosing and treating it in accordance with accepted guidelines despite the low endemicity of the disease. .

•Only 60% of respondents knew that LD is a reportable illness in BC, perhaps explaining some of the discrepancy between recalled and reported cases.

•The survey itself was well received and the answer key sent as follow-up provided an opportunity for physicians to learn more.

References

1. A. D. Fix, G. T. Strickland, and J. Grant, "Tick Bites and Lyme Disease in an Endemic Setting: Problematic Use of Serologic Testing and Prophylactic Antibiotic Therapy," JAMA.279(3):208-10, (1998).
2. M. H. Zieka, S. T. Donta, and F. C. Demarest, "Physician Preferences in the Diagnosis and Treatment of Lyme Disease in the United States," Infection.24(2):192-6, (1996).
3. A. H. Ramsey et al., "Appropriateness of Lyme Disease Serologic Testing," Annals of Family Medicine.3(4):341-4, (2004).
4. J. M. Magri et al., "Lyme Disease Knowledge, Beliefs, and Practices of New Hampshire Primary Care Physicians," Journal of the American Board of Family Practice.15(4):277-84, (2002).
5. S. Mak, M Morshed, and B Henry, "Ecological Niche Modeling of Lyme Disease in British Columbia, Canada," Journal of Medical Entomology, 47(1):69-105, (2009).

Provincial Health Services Authority
Province-wide solutions. Better health.

October 18, 2010

ISSUES NOTE: Physician Awareness of Lyme disease in BC

Background:

- In 2008, BCCDC partnered with the College of Physicians and Surgeons of BC to conduct a research study survey of the knowledge, beliefs and practices of physicians in British Columbia with respect to Lyme disease.
- The study was approved by the research institutional review board at the University of BC with BCCDC being principle investigator.
- The survey addressed respondent demographics (medical specialty, years in practice, average patients seen per week, location of practice), general knowledge about LD, laboratory testing for LD and three clinical scenarios where respondents were asked about the course of action they would take. Questions were also added to explore the geographic risk perception for LD and assess whether physicians were aware that LD is reportable to public health in BC.
- Surveys were sent to all practicing physicians in BC who were pediatricians, internists, or family practitioners and who gave a BC address as their primary practice address.
- The response rate to the survey was 35% (1869/5397); a rate that is in keeping with other similar surveys including the Canadian Physicians Survey.
- One hundred and forty-eight respondents indicated that they recalled diagnosing a total of 221 cases of LD in 2007 (range 0-5 cases per physician); while 1459 indicated they did not diagnose a case of Lyme disease in 2007. Only 58% of family physicians and 66% of specialists responded that they knew LD was reportable to public health in BC.
- This survey provides valuable insight into clinician knowledge, beliefs and practice in BC. Physicians are knowledgeable about LD and are aware of the risk of the disease in BC despite it being a low endemic area. It is also apparent physicians in BC are comfortable treating patients empirically for LD, in many cases based on patient concern and many more cases were diagnosed and treated for LD than were reported to public health.

Discussion:

- A manuscript has been submitted to a peer reviewed medical journal about this survey.
- Preliminary results from the survey were shared publicly through an FOI request.

Advice and Recommended Responses*:

*(*It is recommended that the following responses or key messages be used in communicating about this issue.)*

- This survey provides valuable insight into clinician knowledge, beliefs and practice in BC.
- Physicians are knowledgeable about LD and are aware of the risk of the disease in BC despite it being a low endemic area.
- It is also apparent physicians in BC are comfortable treating patients empirically for LD, in many cases based on patient concern and many more cases were diagnosed and treated for LD than were reported to public health.
- Lyme disease is a reportable disease; however this survey revealed that physicians are not always reporting cases to the BCCDC.
- BCCDC reports all Lyme disease cases that are reported to the Centre on www.bccdc.ca
- Diagnosis of Lyme can be made by physicians based on clinical signs and symptoms

(including history of tick bites) and be further supported by lab testing by PHSA/BCCDC.

Davidson, Julie SSBC:EX

From: Patrick, David CDC:IP
Sent: Sunday, October 17, 2010 12:12 PM
To: Patrick, David CDC:IP; s. 22 s. 22 bowie@interchange.ubc.ca; 'ted steiner'; pphillips@cfenet.ubc.ca; XT:HLTH Henry, Bonnie; Morshed, Muhammad G CDC:IP; Isaac-Renton, Judy L CDC:IP; Tang, Patrick; Gardy, Jennifer; Brunham, Robert CDC:IP; XT:Foster, Nick HLTH:IN; s. 22 Kendall, Perry HLTH:EX; Young, Eric R HLTH:EX; XT:Ogilvie, Gina HLTH:IN; tperryjr@interchange.ubc.ca; s. 22
Subject: RE: Your Comment on ME/CFS Proposal
Attachments: Proposal Document October 15.doc

Dear All:

I've spent the last few days trying to do justice to all of the useful feedback you have provided to our first draft. I'll try to deal with these thematically:

How Can This Clinic Grow to Scale to Meet Demand?

We are stressing a centre for excellence model in which best practices piloted at a clinic can be disseminated much more broadly by commitment to continuing education for health care workers, web posting of guidance for work-up and management and other methods. As such, I am going to see about estimating some support for these processes in budget development.

There is Risk of Oversimplifying Care or Ignoring Complexity

We've included a section that underscores these issues and the importance of individual assessment, the "whole person" and learning from the patient.

Issues with Respect to Testing

Can we incorporate an array of new investigative methods (eg. new form of echocardiography or new biomarkers)?

Part of the function of the clinic will be to review and stay up to date with new developments in diagnosis, prognosis and monitoring. Some of the modalities of present interest are in early stages of clinical evaluation. There is every reason to consider that a clinic could participate in such evaluation.

Experience with testing indicates that it is important to take a deliberate, logical approach to what tests are used for the following reasons:

- Interesting associations between illness and some markers are not always reproducibe or consistent after the first reports
- Some associations are real but this does not necessarily mean that a test is useful in predicting diagnosis or outcome. A test needs to have such "predictive value" to be of use to a patient. It has to help a patient manage her/his condition.

Standard testing should be well validated. Newer tests should be considered investigational until properly evaluated. If validated tests of clear value to patients are found to exist but are not yet funded in BC, the clinic will provide information to patients about them. It will also seek to identify how useful new tests could be funded.

Variations in Thought on Routine Patient Work-up

- Some but not all clinicians were suggesting Serum Protein Electrophoresis in the screening tests. We will seek to cost this but should have a more deliberate discussion about its yield.
- We have explicitly included routine Lyme serology as part of initial work-up for patients under evaluation
- What is the value of a.m. serum cortisol n this population? Does it have any role in routine work-up or only in selected patients with pertinent problems on physical examination or screening tests.

Issues of Education and Other Management

- There was a question as to whether a workshop or education module is best positioned during intake or after initial assessment. This can be worked out by clinic staff is funding is arranged.

- There were also some questions about the roles of various consultants. Would the inclusion of a Rehab specialist lead to unrealistic expectations of recovery? We use the term only to indicate a professional with knowledge of how to help people adapt to disability. Such people have to know the condition and the hazards of inducing a "crash" if people work too hard.

- Should Psychology / Psychiatry be included among funded clinic staff or available as are other speciaists for consultation as needed? Many people with ME/CFS have been furnished with a default assumption of psychological disorder as cause rather than effect of symptoms. While further discussion is required, we think this fits on the list of available consultants rather than as a resource that all patients should utilize.

- What about alternative practitioners? We think the clinic should provide unconditional support of patients. The clinic itself should focus on clearly evidence-based approaches, but patients who also seek alternative approaches would not lose eligibility for any aspect of care

Could There Be a Roll for Fee for Service in Funding?

- Dr. Venter indicated that this may be possible in the context of full support from nurse practitioners, some adjustment to billing codes as seen in Ontario and the acceptability of some group counselling/education sessions.
- I am suggesting that our first bid should be to get funding for physician sessions for the clinic to eliminate the conflict of time pressure vs. quality of care. However, a fee for service model may be a workable "Plan B".
- I'd appreciate further opinion on this synthesis

Daily Living Support
- This is an area in great need of advocacy and further work
- We think it will be more successfully addressed as a separate initiative with links to the clinic
- Proposals for better home care support are likely to have higher success if a clinic is in place to add to documentation of need

Changes to Study Protocol

- We will add some Lyme positive controls to help assure test validity.
- We have a suggestion for study work up to include some basic immunologic analyses on the blood–immunoglobulin levels/subsets, T-cell proliferative responses to common antigens, etc. I need to follow this through a bit more with the suggestor and consider some costing

Ancillary Funding from The Federal Government or Foundations

- Should be an early consideration for pursuit by the medical director and communications resource
- Philisophically, it would be best to avoid too much in the way of direct contribution from industry to avoid conflict of interest

Next Steps

- We will shortly have to respect deadlines and get our preliminary proposal submitted to PHSA for initial review.
- The Health Authority is to discuss progress on this initiative with government later this fall.
- There is a need to broaden communication about this effort to groups that have not yet been contacted during its early phases.

Please accept my thanks for your committed input to date. There should be ample opportunity for further input as the process moves ahead and we can arrange our advisory group.

My best.

David Patrick

David Patrick, MD, FRCPC, MHSc
Director, Epidemiology Services
BC Centre for Disease Control and
Professor, School of Population and Public Health University of British Columbia
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"Science flows not merely from the nature of the mind, but also from the nature of things."
Sir Francis Bacon

•

Davidson, Julie SSBC:EX

From: Morshed, Muhammad G CDC:IP
Sent: Friday, April 29, 2011 6:01 PM
To: Kendall, Perry HLTH:EX; XT:HLTH Henry, Bonnie
Cc: Young, Eric R HLTH:EX
Subject: Re: Lyme disease - meeting request with BC MOH or representative

I agree. If we get funding from that pot would help a lot.

Regards

Morshed

From: perry.kendall@gov.bc.ca
To: Henry, Bonnie; Morshed, Muhammad
Cc: Eric.Young@gov.bc.ca
Sent: Fri Apr 29 15:14:38 2011
Subject: Re: Lyme disease - meeting request with BC MOH or representative

I support that. Could it be from the researrch $ for the clinic?
P. R. W. Kendall
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From: Henry, Bonnie [mailto:bonnie.henry@bccdc.ca]
Sent: Friday, April 29, 2011 02:42 PM
To: Morshed, Muhammad G CDC:IP; Kendall, Perry HLTH:EX
Cc: Young, Eric R HLTH:EX
Subject: RE: Lyme disease - meeting request with BC MOH or representative

Would there be an opportunity to run both tests as a validation study for a year perhaps as part of a study? It may be useful to see if we pick up more cases with the C6 test. We would have to look for funding I would guess?
Bonnie

Bonnie Henry MD MPH FRCP(C)

Director, Public Health Emergency Services

BC Centre for Disease Control

and

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From: Morshed, Muhammad
Sent: Friday, April 29, 2011 1:27 PM
To: perry.kendall@gov.bc.ca; Henry, Bonnie
Cc: Eric.Young@gov.bc.ca
Subject: RE: Lyme disease - meeting request with BC MOH or representative

No, we are using whole cell antigen based EIA followed by Western blot. I have spoken to CDC folks couple of times. The main problem for us to a good validation study because we do not have any culture positive or PCR positive serum and is very difficult to get them. I tried few times and failed. Second issue, this test is not superior for late stage disease as I mentioned earlier.

Regards,

Morshed

PLEASE NOTE NEW PHONE NUMBER

Muhammad Morshed, PhD, SCCM
Program Head, Zoonotic Diseases & Emerging Pathogens
BCCDC Public Health Microbiology and Reference Laboratory
Provincial Health Services Authority
Clinical Professor
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Better health.

From: Kendall, Perry HLTH:EX [mailto:Perry.Kendall@gov.bc.ca]
Sent: Friday, April 29, 2011 12:31 PM
To: Morshed, Muhammad; Henry, Bonnie
Cc: Eric.Young@gov.bc.ca
Subject: Re: Lyme disease - meeting request with BC MOH or representative

Does bccdc employ it?
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From: Morshed, Muhammad [mailto:Muhammad.Morshed@bccdc.ca]
Sent: Friday, April 29, 2011 11:52 AM
To: Kendall, Perry HLTH:EX; XT:HLTH Henry, Bonnie
Cc: Young, Eric R HLTH:EX
Subject: RE: Lyme disease - meeting request with BC MOH or representative

Dear Dr. Kendall:

C6 is ELISA based on an immunodominant Peptide which substantially conserved among the Borrelia species that are pathogenic for humans. The assay has been evaluated by CDC and they recommended it as well as one of the screening test. The overall sensitivities for detecting IgG antibody to C6 in samples from patients with diverse manifestations of Lyme disease were equivalent to that of 2-tired testing. This test works better at early stages and 2-tired testing works better at later stages.

Regards,

Morshed

PLEASE NOTE NEW PHONE NUMBER

Muhammad Morshed, PhD, SCCM
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From: Kendall, Perry HLTH:EX [mailto:Perry.Kendall@gov.bc.ca]
Sent: Wednesday, April 27, 2011 12:41 PM
To: Morshed, Muhammad; Henry, Bonnie
Cc: Eric.Young@gov.bc.ca
Subject: FW: Lyme disease - meeting request with BC MOH or representative

FYI. Any comment on C6 ELISA??

perry

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From: s. 22
Sent: Wednesday, April 27, 2011 11:36 AM
To: deJong.MLA, Mike LASS:EX
Cc: OfficeofthePremier, Office PREM:EX; Kendall, Perry HLTH:EX; Elizabeth Wood
Subject: Lyme disease - meeting request with BC MOH or representative

Dear Honourable Mike de Jong,

Further to my email letter of April 13, 2011 and my conversation last week with Alex Schreiber, I again request a meeting with yourself or your representatives in your constituency office in Abbotsford or in Victoria to discuss
the inadequacies surrounding testing, diagnosis, treatment and physician education for Lyme disease particularly
as recommended in the Schmidt report of May 2010.

I have just returned from a Manitoba MOH meeting about Lyme disease held in Winnipeg yesterday, April 26, 2011 and know I can be helpful as a stakeholder in saving significant provincial healthcare money to help BC to
the same point as Manitoba or beyond. Elizabeth Wood, president of the Lyme Disease Support Group of Manitoba
invited me as her guest to attend this meeting to learn with the intention of sharing with BC MOH. The minutes
of yesterday's meeting are not yet available but I can say that MB MOH will be using the C6 ELISA test as of June 2011.

Please call me to discuss further and to set an appointment for a preliminary meeting. My approach will be non-confrontational with only the best interests of anyone suspecting Lyme disease and the best use of healthcare funding.

Your kind attention is appreciated and I look forward to your call.

Sincerely,

s. 22

Davidson, Julie SSBC:EX

From: Patrick, David CDC:IP
Sent: Tuesday, April 5, 2011 10:08 AM
To: Kendall, Perry HLTH:EX
Cc: Brunham, Robert CDC:IP
Subject: fyi

I caught up with Margaret Parlor, President of the national ME/CFS group this morning. She wants to write a supportive letter about the commitments to the chronic diseases clinic for the Sun.

s. 22

Not sure when though. She's a free agent.

David Patrick, MD, FRCPC, MHSc
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UBC School of Population and Public Health and
Medical Epidemiology Lead, Antimicrobial Resistance,
British Columbia Centre for Disease Control
At BCCDC:
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604-707-2541

Davidson, Julie SSBC:EX

From: XT:HLTH Henry, Bonnie
Sent: Monday, May 30, 2011 11:03 AM
To: Young, Eric R HLTH:EX; Kendall, Perry HLTH:EX; Brunham, Robert CDC:IP; Harry, Ritinder; MacKillop, Mary
Subject: FW: Today's CDC Atlanta Grand Rounds - Lyme's Disease

I don't know if you have had the chance to see this but it is an excellent overview of the Lyme disease situation in the US and one of the speakers is the person who 'discovered' the disease Dr Allen Steere.

Mary it might be helpful in dealing with these issues to know that we are not alone in our concerns and approach here at BCCDC.
Cheers,
Bonnie

Bonnie Henry MD MPH FRCP(C)

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and

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phone: 604-707-2497
fax: 604 707-2420

From: Bradley, Donna
Sent: Wednesday, May 25, 2011 1:01 PM
To: _All_BCCDC_Mail_Users
Subject: Today's CDC Atlanta Grand Rounds - Lyme's Disease

Hello everyone,

We apologize for the AV problems that kept you from watching the CDC Atlanta Grand Rounds in the Tom Cox boardroom today. We eventually got things to work, but alas, did nothing differently to finally get a positive result…so we don't know why the problems were occurring.

CDC Atlanta has a very comprehensive website that archives all of their presentations. Please click on the link below to view the **Lyme Disease: Challenges and Innovations** presentation. http://www.cdc.gov/about/grand-rounds/archives/2011/May2011.htm

Also, please note that you can look through the archives index by month & year and view any of their previously aired presentations http://www.cdc.gov/about/grand-rounds/archives/index.htm

Again, our apologies for any inconvenience. Please enjoy watching the CDC Atlanta Grand Rounds at your convenience.

Best regards,

Donna Bradley
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tel: 604 707-2570 | fax: 604 707-2401| www.bccdc.ca/ubccdc

Davidson, Julie SSBC:EX

From: Laverdiere, Charmaine HLTH:EX
Sent: Monday, May 30, 2011 8:49 AM
To: Kendall, Perry HLTH:EX
Subject: June issue BCMJ
Attachments: BCMJ_53_Vol5_lyme.pdf

Article is attached.

Charmaine Laverdiere | Library Technician | **Health and Human Services Library** | Ministry of Health | 1-1, 1515 Blanshard St. | Victoria, BC V8W 3C8 | Charmaine.Laverdiere@gov.bc.ca; Ph: 250 952-2170; Fax: 250 952-2180 | **Intranet:** http://admin.moh.hnet.bc.ca/libinfo/ | **Serving**: *Ministry of Health* | *Ministry of Children and Family Development*

From: Kendall, Perry HLTH:EX
Sent: Monday, May 30, 2011 8:37 AM
To: Laverdiere, Charmaine HLTH:EX
Subject: RE: May issue BCMJ

Authored by Bonnie Henry on Lyme disease and whether there is an epidemic in BC.
Thanks
Perry

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From: Laverdiere, Charmaine HLTH:EX
Sent: Monday, May 30, 2011 8:36 AM
To: Kendall, Perry HLTH:EX
Subject: May issue BCMJ

Hello Dr. Kendall,

We do have the May 2011 issue here in the library. Is there a particular article that I can send to you?

Charmaine Laverdiere | Library Technician | **Health and Human Services Library** | Ministry of Health | 1-1, 1515 Blanshard St. | Victoria, BC V8W 3C8 | Charmaine.Laverdiere@gov.bc.ca; Ph: 250 952-2170; Fax: 250 952-2180 | **Intranet:** http://admin.moh.hnet.bc.ca/libinfo/ | **Serving**: *Ministry of Health* | *Ministry of Children and Family Development*

Davidson, Julie SSBC:EX

From: XT:HLTH Henry, Bonnie
Sent: Thursday, May 5, 2011 9:18 AM
To: Kendall, Perry HLTH:EX
Subject: RE: bull's eye in Kaleden
Attachments: BCMJ_53_Vol2_cdc.pdf; BCMJ Lyme review revisions.pdf

Hi Perry,
the first came out in the BCCDC page in March. The second is confidential as it will come out in the June issue but is the revised version of the longer paper we had prepared last summer summarizing the work we have done looking at Lyme in BC. It was just accepted by the BCMJ last week after I submitted it in late December.
Cheers,
Bonnie

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From: Kendall, Perry HLTH:EX [mailto:Perry.Kendall@gov.bc.ca]
Sent: Wednesday, May 04, 2011 7:06 PM
To: Henry, Bonnie
Subject: Re: bull's eye in Kaleden

Can you send me copies of the 2 papers?
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From: Henry, Bonnie [mailto:bonnie.henry@bccdc.ca]
Sent: Wednesday, May 04, 2011 06:50 PM
To: Kendall, Perry HLTH:EX; Morshed, Muhammad G CDC:IP
Cc: [IHA] Parker, Dr. Rob <Dr.Rob.Parker@interiorhealth.ca>
Subject: Re: bull's eye in Kaleden

It is hard to comment on heresay from s. 22 but we have clearly said many times that there is a low but real risk and physicians should treat early based on clinical suspicion. This wa reiterated again in the BCMAJ article in March. Our study tells us that this happens and if anything docs are overly cautious.
Btw the longer Lyme in BC summary has finally been approved by BCMAJ and will come out in June.
The reality is tho that the risk is very low in the OK.
B
Dr Bonnie Henry
BC Centre for Disease Control

From: Kendall, Perry HLTH:EX <Perry.Kendall@gov.bc.ca>
To: Henry, Bonnie; Morshed, Muhammad
Cc: [IHA] Parker, Dr. Rob
Sent: Wed May 04 18:41:24 2011
Subject: Fw: bull's eye in Kaleden

Any suggestions or comment?
P. R. W. Kendall
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http://www.healthservices.gov.bc.ca/pho

From: s. 22
Sent: Wednesday, May 04, 2011 06:26 PM
To: Kendall, Perry HLTH:EX; Dr. Rob Parker <Dr.Rob.Parker@interiorhealth.ca>
Subject: Re: bull's eye in Kaleden

Dr. Parker and Dr. Kendall,

Here is a quote taken, today, from an article in an Okanagan paper:
"She was devastated to receive a call from her doctor Friday, with a message from the BCCDC – "the infectious disease specialist says they do not have any deer in Salmon Arm or the Okanagan with those ticks so stop taking the antibiotics and we will pursue neurology.""
http://www.bclocalnews.com/community/121290788.html

What are you, Dr. Parker and Dr. Kendall going to do about this mis-information being given? This patient was pulled off treatment only because of the dangerous idea that lyme does not exist in the Okanagan. What will you do to correct this mis-information?

This is what is causing chronic cases.

s. 22

On Fri, Apr 29, 2011 at 3:52 PM s. 22 wrote:
Thank you, Dr. Kendall. I know that we hear about the cases of West Nile, I hope the same will be true for lyme disease. The only reason my neighbour knew it was lyme was because she knew my story (I had a bull's eye as well.)
It would be beneficial if the public were informed as many would not even think to go to the doctor for a minor rash (like myself - and so, this is why I developed the chronic form of the disease.)
s. 22

On Fri, Apr 29, 2011 at 3:45 PM, Kendall, Perry HLTH:EX <Perry.Kendall@gov.bc.ca> wrote:

Thank you s. 22 I will ask Dr Parker to ensure that his alerts to community physicians reflect both the presence of Lyme, its diagnistic features and the fact that it is reportable by physicians to the local MOH.

Best wishes

Perry Kendall

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perry.kendall@gov.bc.ca
http://www.healthservices.gov.bc.ca/pho

From: s. 22
Sent: Friday, April 29, 2011 3:36 PM
To: Kendall, Perry HLTH:EX
Cc: Dr. Rob Parker

Subject: bull's eye in Kaleden

Dr. Kendall,

How do we make sure that a case of lyme disease is reported? My neighbour pulled out an attached tick and developed a bull's eye rash. She picked up the tick in her own yard. Luckily, her doctor consulted another doctor and decided that this was lyme disease.

Doctors here, have told me several times that there is no lyme disease here and Dr. Parker's comments lead people to believe the same thing. It is so important that doctors are aware that it is here so they can look for it.

Is there some way of making sure her case is reported? Is there some way of alerting doctors here of her case so they know that lyme is here?

s. 22

Physician awareness of lyme disease in British Columbia

Bonnie Henry, MD, MPH, FRCPC, Alexis Crabtree, MPH, Muhammad Morshed, PhD, SCCM

Lyme disease (LD) is a tick-borne zoonosis caused in North America by infection with the spirochete *Borrelia burgdorferi* sensu stricto. Humans acquire LD through the bite of an infected tick. The principal vector in British Columbia is the Pacific black-legged tick *Ixodes pacificus*. This tick is found throughout the highly populated areas of southern BC but reported LD cases remain rare. In 2008 the BCCDC partnered with the College of Physicians and Surgeons of BC to assess physician knowledge, beliefs, and practices with respect to LD in BC. We developed and mailed a survey to all practising physicians in BC who were pediatricians, internists, or family practitioners and who gave a BC address as their primary practice address. Here we present preliminary findings from the survey.

The response rate was 35% (1869/5397). One hundred forty-eight (8%) respondents recalled diagnosing a total of 221 cases of LD in the previous year, 2007 (range 0 to 5 cases per physician); 1,459 (92%) indicated they did not diagnose a case of LD in 2007. Despite 58% of family physicians and 66% of specialists responding that they knew LD was reportable to public health authorities in BC, only 13 cases were reported in 2007. Physicians scored highly on certain knowledge questions with over 90% correctly identifying the signs and symptoms of LD, the causative agent, and incubation period. Fewer were aware that erythema migrans (EM) on its own was diagnostic for LD. An overall knowledge score based on 12 questions was developed with family physicians scoring a mean of 73% (8.8/12) and specialists 75% (9.0/12). This is similar to physicians' scores on the same instrument in an area of the US where LD is much more commonly encountered.

Early treatment with a course of antibiotics based on clinical judgment is warranted if the clinical signs and symptoms are compatible with LD.

Three clinical scenarios were presented in the survey in order to evaluate physician behaviors related to LD. Scenario 1 presented a patient with EM and no laboratory testing; 58% of family physicians and 55% of specialists answered correctly that they would "give antibiotics at this time," while 36% of family physicians and 35% of specialists opted first to test for LD. Scenario 2 focused on the presentation of an asymptomatic patient with history of a tick bite; 51% of family physicians and 61% of specialists indicated correctly they would educate and reassure the patient but not prescribe antibiotics or test the patient for LD. Scenario 3 presented a patient with arthritis, no history of EM, and multiple negative tests for LD; 82% of family physicians and 81% of specialists correctly reported they would investigate causes other than LD or refer the patient to a specialist.

These results provide valuable insight into clinician knowledge, beliefs, and practices in BC. Physicians in general are knowledgeable about LD and are aware of the risk of the disease in BC despite it being a low endemic area. One issue identified in the survey was 60% of respondents were not aware that EM is considered diagnostic for LD; therefore, if the patient presents with EM, no laboratory testing is necessary. The antibody test may be negative early in LD, as it may take several weeks for the patient to develop antibodies to *B. burgdorferi*. If the diagnosis is unclear, particularly if EM is atypical or absent, and acute serology is negative, a convalescent test 2 to 4 weeks later may aid in diagnosis. However, early treatment with a course of antibiotics based on clinical judgment is warranted if the clinical signs and symptoms are compatible with LD. A person with EM if treated early with antibiotics may not develop antibodies against *B. burgdorferi*. Antibodies (IgG) may also persist in the blood for years even after curative treatment; therefore a positive antibody test posttreatment is not indicative of treatment failure. While there is no consensus on cause of persistent symptoms in some people after appropriate treatment for LD, it is clear these patients might benefit from a more coordinated model of diagnosis and care.

Physicians are reminded that LD is a reportable disease in BC and both acute clinical cases and laboratory confirmed cases should be reported to local public health.

This article is the opinion of the BCCDC and has not been peer reviewed by the BCMJ Editorial Board.

Dr Henry is medical director of the Vector-borne Disease Program at the BC Centre for Disease Control. Ms Crabtree is a research assistant at the BC Centre for Disease Control. Dr Morshed is program head of Zoonotic Diseases and Emerging Pathogens at PHSA Laboratories.

B. Henry, MD, MPH, FRCPC, M. Morshed, PhD, SCCM

Lyme disease in British Columbia: Are we really missing an epidemic?

Results from surveillance and research on Lyme disease suggest there is a real but low risk of contracting this tick-borne illness in BC.

ABSTRACT: The risk of Lyme disease depends on climate, geography, the abundance of specific insect vectors, and human interaction with these. In BC, *Ixodes pacificus*, the primary tick vector for the causeative spirochete, *Borrelia burgdorferi*, has consistently been found in low numbers in populous areas and rates of infection in this tick remain at less than 1%. Correspondingly, rates of human cases of Lyme disease in BC are less than 0.5 per 100 000 per year; this is similar to rates reported in US states with environmental epidemiology like BC's and considerably less than in high endemic areas of the eastern United States (29 per 100 000).There is no evidence to support an epidemic of Lyme disease in BC. Responses to a recent survey indicate that physicians generally are aware of the low but real risk of Lyme disease, know to treat patients with clinical symptoms, and understand that Lyme disease is preventable and treatable. Public health authorities will continue to remind residents and visitors to BC of the simple measures they can take to prevent tick bites and exposure, as well as which early signs and symptoms should lead them to seek appropriate medical treatment.

Lyme disease is a tick-borne zoonosis caused in North America by infection with the spirochete *Borrelia burgdorferi*. Humans acquire Lyme disease through the bite of an infected tick.[1] The principal tick vector in BC is the Pacific black-legged tick, *Ixodes pacificus*,[2] which is found throughout the highly populated areas of southern BC. This situation is in contrast to eastern Canada and the US, where the tick *Ixodes scapularis* is the most common vector. The low incidence of Lyme disease in BC may be explained by the fact that *I. pacificus* is a less competent vector than *I. scapularis*, is less abundant, and is less likely to feed on deer mice.[3-5] Studies have shown that infectivity rates are lower in areas where *I. pacificus* predominates than in areas where *I. scapularis* predominates. Lyme disease advocacy groups in BC have expressed concern that an

Dr Henry is ~~director of Public Health Emergency Services~~ medical director, Vectorborne disease program at the BC Centre for Disease Control. She is also an assistant professor in the School of Population and Public Health at the University of British Columbia. Dr Morshed is program head of Zoonotic Diseases and Emerging Pathogens, Provincial Health Services Authority, Public Health Reference Laboratories.

This article has been peer reviewed.

epidemic is being ignored. Surveillance and research on Lyme disease in BC indicate this is not the case.

Tick and mouse surveillance

The BC Centre for Disease Control has actively screened ticks in over 125 areas of the province. From 1993 to 1996, 10 056 ticks were tested and 40 were found positive for *B. burgdorferi* (0.40%). From 1997 to 2007, 8602 ticks were tested and 30 ticks were found positive (0.35%), demonstrating a stable, low prevalence of infection. *I. pacificus* ticks were found most commonly in the Lower Mainland and Vancouver Island; *Dermacentor andersoni*, which is not a competent vector for Lyme disease, was the tick identified most commonly throughout BC.

On Vancouver Island, active dragging for ticks at 17 sites yielded only 41 ticks, mostly *I. pacificus*, all of which were found negative for *B. burgdorferi*. Active solicitation of ticks from veterinarians on Vancouver Island and the Gulf Islands led to 115 tick submissions, all of which were found negative for *B. burgdorferi*. In the Okanagan over 2 years, 5557 *D. andersoni* ticks were collected (no *I. pacificus* ticks were found). Of 110 ticks randomly tested for *B. burgdorferi* by culture and PCR, all were found negative. A total of 219 deer mice were trapped from the same areas and tested for antibodies to *B. burgdorferi* by the National Microbiology Laboratory in Winnipeg, and all were found to be negative.

We receive 800 to 1000 ticks from physicians, veterinarians, and the public every year. Approximately half are *I. pacificus*, of which one to two per year are found to be positive for *B. burgdorferi*.

The major mammalian reservoir for *B. burgdorferi* in BC is the deer mouse. To assess prevalence in this population we tested 3500 deer mice by culture and found 30 (0.83%) positive. We also tested 164 mice for antibodies to *B. burgdorferi* and found 6 (3.66%) positive, demonstrating a low prevalence in this reservoir.

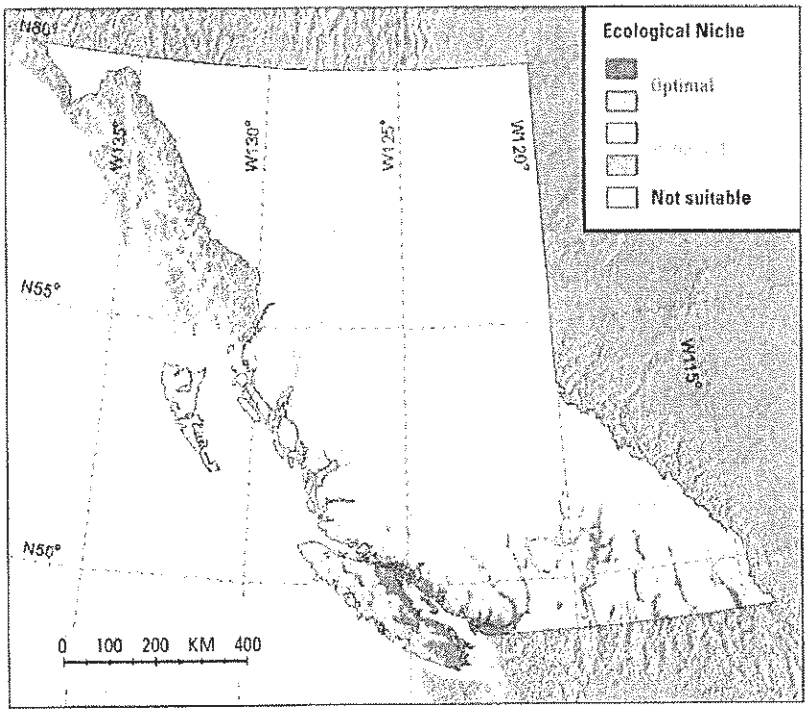

Figure 1. Forecasted ecological niche of Borrelia burgdorferi in British Columbia.

Ecological niche modeling

In order to identify areas with risk of Lyme disease transmission in BC, we undertook ecological niche modeling for both ticks and *B. burgdorferi* infection and assessed the potential impact of climate change. Modeling identified optimal environmental conditions in south coastal BC (i.e., Vancouver Island, Lower Mainland, and Sunshine Coast) and interior BC valley regions.[6] The habitat in these areas is characterized by low-lying vegetation such as high grass and brush, with abundant leaf litter and a nearby water source. Niche modeling demonstrates that *B. burgdorferi* is generally absent north of N51° latitude (Figure 1).

There is concern that global warming could lead to expansion of the ecological niche for the vector, resulting in the potential for increased exposure to infected ticks in BC.[7] Our models indicate a modest geographic range expansion for *Ixodes* ticks and *B. burgdorferi* based on 2050 climate warming projections; however, the areas where expansion might occur are sparsely populated and the densely populated centres of southern and interior BC are already within the existing ecological niche of *B. burgdorferi*. There are also variable local habitats within regions, so exact risks within a region may vary greatly.

Lyme disease may also, though rarely, be acquired from "adventitious" ticks that drop off migrating birds. These ticks pose a theoretical risk of infection during the summer months throughout the province.[8]

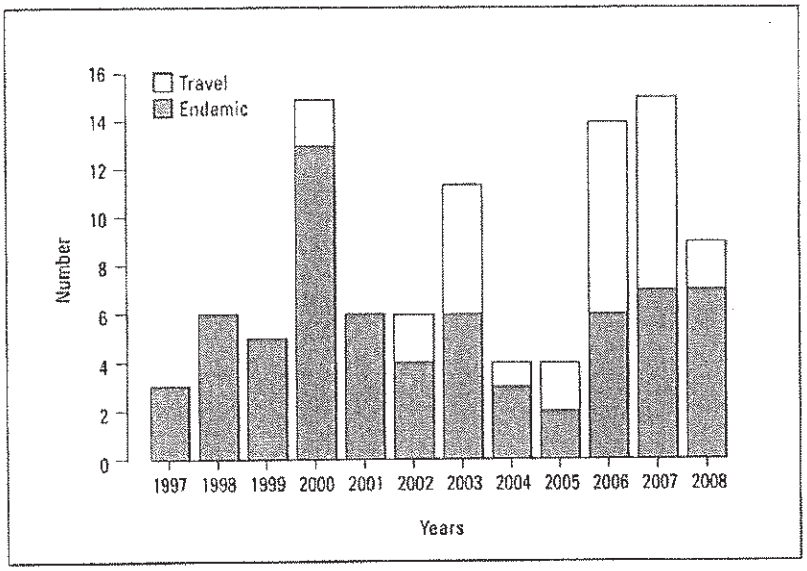

Figure 2. Number of endemic and travel-related cases of Lyme disease in BC between 1997 and 2008. Travel-related cases include patients with exposure histories in countries with endemic Lyme disease.

Human surveillance

We used capture-recapture methodology and a review of BC's three sources of passive surveillance (laboratory data, enhanced surveillance forms, and cases reported on the public health information system) to estimate the annual number of Lyme disease cases in BC between 1997 and 2008, to develop a more accurate estimate of the burden of disease, and to compare BC with Washington, California, and high endemic areas in the eastern US.

Ninety-three cases of Lyme disease were identified over the 12-year period (Figure 2); 45 patients (48.4%) were male and between 41 and 70 years of age (mean age 43.7 years, range 3.5–80.6). One-third of patients acquired their illness outside of BC. The mean age of patients with travel-related disease was 40.4 years, younger than those who acquired Lyme disease in BC (mean age 44.8 years).

The annual incidence rate of Lyme disease in BC ranged from 0.1 to 0.3 per 100 000 population, a rate similar to that of Washington and California, with yearly incidence rates of less than 0.5 per 100 000 population (including travel-related cases). These rates have remained stable over the past 10 years. In contrast, the incidence of Lyme disease in the 10 highly endemic states in US is 29.2 per 100 000 people,[9] indicating important differences in both disease risk and burden of illness.

Capture-recapture methods show underreporting of Lyme disease does occur in BC. The best model places the corrected number of cases in BC between 1997 and 2008 at 142 (95% CI:111-224), for a maximum incidence of 0.5 per 100 000 population. Underreporting is common for rare diseases when surveillance is passive.[10] Whether underreporting results from clinical cases being treated without testing and not reported or whether cases are truly not diagnosed is not known. To help gain insight into this question we looked at physician awareness of Lyme disease in BC.

Physician awareness

In 2008 we conducted a survey of physicians in BC. We modified a previously validated questionnaire[11] to collect data on respondent demographics and general knowledge of Lyme disease. The survey included questions about geographic risk perception, laboratory testing, and three clinical scenarios. Physicians were also asked whether they were aware that Lyme disease is reportable.

We sent questionnaires to all pediatricians, internists, and family practitioners who gave a BC address as their practice address. The response rate was 32% (1673/5199). Of these respondents, 148 (8%) recalled diagnosing 221 cases of Lyme disease in 2007, while 58% of family physicians and 66% of specialists indicated they knew Lyme disease is reportable.

Physicians scored high on the knowledge questions, with over 90% correctly identifying the signs and symptoms of Lyme disease as well as the causative agent and incubation period. Fewer were aware that erythema migrans (Figure 3) on its own is diagnostic. The mean overall knowledge score was 74% (8.9/12).

Three clinical scenarios were presented: Scenario 1 involved a patient with erythema migrans and no laboratory testing; more than half (57%) of all respondents answered correctly ("give antibiotics at this time"), while one-third opted to first test for Lyme disease. Scenario 2 involved an asymptomatic patient with history of a tick bite; 56% indicated correctly they would educate and reassure the patient. Scenario 3 involved a patient with arthritis, no history of erythema migrans, and multiple negative tests for Lyme disease; 82% correctly reported they would investigate causes other than Lyme disease, or refer the patient to a specialist.

Several questions addressed phy-

sicians' perceptions of risk in their community of practice. When asked about their patients' risk of developing Lyme disease after a tick bite, 94% of respondents indicated they believed their patients faced some risk. Logistic regression modeling showed that physicians have a good understanding of the spatial distribution of risk within the province, with greater risk perceived in areas where ecological conditions are most suitable for disease transmission.

The final questions of the survey addressed physician perceptions of patients requesting evaluation for Lyme disease because of nonspecific symptoms such as fatigue and musculoskeletal pains. While a majority (79% of family physicians and 72% of specialists) indicated they believed that their patients' symptoms were caused by something other than Lyme disease, 31% of family physicians and 12% of specialists reported they had treated such patients for Lyme disease because of patient concern.

This survey shows physicians are knowledgeable about and aware of the risk of Lyme disease in BC, despite the province being a low endemic area. It is also apparent physicians in BC are comfortable with treating patients empirically, in many cases based on patient concern. More cases are clinically diagnosed and treated than are reported to public health.

Clinical picture

Ticks are most likely to transmit infection after being attached for more than 24 hours of feeding, making prompt detection and removal of ticks a key way to prevent Lyme disease. A tick attached for less than 24 hours is unlikely to transmit infection, even if it is infected with *B. burgdorferi*.[12]

Erythema migrans diagnosed on physical examination, even in the absence of other Lyme-specific signs or symptoms and positive laboratory tests, establishes the diagnosis of Lyme disease.[13] Erythema migrans is an annular, slowly expanding erythematous lesion, usually 5 cm or greater in diameter, that may exhibit partial central clearing or central necrosis, giving a bull's-eye appearance. Erythema migrans typically occurs 7 to 14 days after infection (range 3 to 30 days), and in some cases secondary lesions may occur.[14] In contrast, a localized tick-bite reaction occurs within hours of the bite, expands over hours, and resolves within 48 hours. In studies, erythema migrans rash occurs in at least 80% of all patients with Lyme disease and 90% of children.[15] Patients can also experience symptoms of fatigue, chills, fever, headache, and migratory arthralgias, and lymphadenopathy, which may last several weeks if untreated.

Untreated infection can spread over several weeks or months and lead to three main syndromes:

- Neurological. Neurological abnormalities can include aseptic meningitis, cranial neuritis, Bell palsy, and radiculoneuritis. Such abnormalities affect about 5% of untreated patients.
- Musculoskeletal. Musculoskeletal manifestations can include migratory joint and muscle pains without objective signs of swelling.
- Cardiac. Rarely occurring cardiac manifestations can include atrioventricular block and acute myopericarditis.

Weeks to years after onset of infection (mean 6 months) episodes of swelling and pain in large joints (especially the knees) can occur in up to 60% of untreated patients, leading to chronic arthritis. Some patients develop chronic axonal polyneuropathy or encephalopathy. Lyme disease is rarely fatal, although patients with late disseminated disease can have severe, chronic, and disabling symptoms.[16]

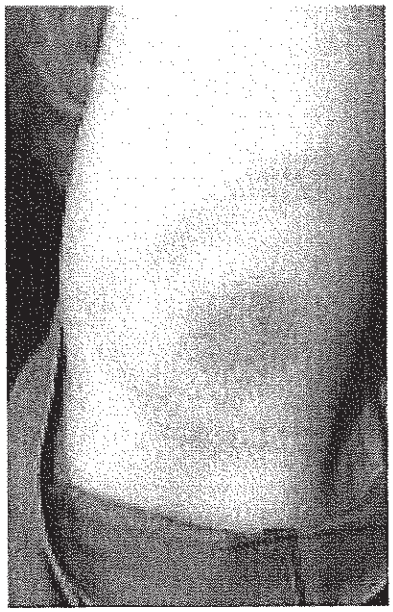

Figure 3. Erythema migrans.

Source: CDC/James Gathany

Most cases of Lyme disease are successfully treated with antibiotics. Treatment is most effective if begun early in the course of illness. However, a small percentage of patients have lingering symptoms that last months to years even after appropriate treatment. Symptoms include muscle and joint pain, arthritis, cognitive defects, sleep disturbance, and fatigue. The cause of these symptoms is not known, although there is some evidence that they result from an autoimmune response. Long-term antibiotic treatment has been found to be of no benefit in patients with long-term symptoms, and has been associated with sometimes severe adverse effects, including death.[17,18]

In addition, a group of patients with nonspecific symptoms such as fatigue, memory changes, and musculoskeletal pain have been identified by some physicians as suffering from "chronic Lyme disease" despite multiple negative laboratory tests and no

history of acute disease. This syndrome is the subject of ongoing scientific research, with a number of possible infectious and noninfectious causes being investigated. One recently discovered virus, Xenotropic murine leukemia virus, has been associated with a similar syndrome in some studies[19] but not in others.[20] There is a need for further research into the cause of this syndrome and therapeutic options for people who are suffering from its debilitating symptoms.

Diagnostic testing in BC

With the exception of direct detection of *B. burgdorferi* from biopsy specimens of erythema migrans rash, there is no validated direct test for the *B. burgdorferi* bacterium in blood or other samples and the organism cannot be easily cultured. Laboratory testing for Lyme disease relies on detection of antibodies in blood. Because antibodies to *B. burgdorferi* proteins can be induced by infection with microbes other than *B. burgdorferi*,[13] antibody tests can yield false-positive results unless properly interpreted.

A two-step process to test for evidence of Lyme disease is used by the Public Health Laboratories of the BC Provincial Health Service Authority (PHSA), following recommendations by the US Centers for Disease Control and Association of State and Territorial Public Health Laboratory Directors.

- **Step 1: Enzyme immunoassay (EIA).** This is a very sensitive test, meaning it will detect almost all true cases of Lyme disease but will also react if a patient has certain other diseases, including mononucleosis, lupus, and various microbial infections.
- **Step 2: Western blot (WB).** This test is conducted on a specimen that yields positive or equivocal/indeterminate EIA results. It is a very specific test that can distinguish between true-positive and false-positive results from the EIA. Western blot IgM is considered reactive when two markers (out of three required markers) are identified and Western blot IgG is considered reactive when five markers (out of ten required markers) are identified.

These tests, taken together, show whether a patient has ever been exposed to *B. burgdorferi*. Positive results do not demonstrate active infection and must be interpreted in light of patient history and symptoms.

Some commercial laboratories use either discredited tests (such as urine antigen tests) or interpret tests in non-standard and unproven ways. As a result, these laboratories can return a positive result that is not reproducible by public health laboratories following the internationally recognized protocols. For example, some private US labs only use one marker for IgM and three markers for IgG Western blot tests, which can result in a false-positive result and a high rate of cross-reactivity with other infections.[21] This can lead not only to unnecessary treatment for Lyme disease, but can also prevent patients from receiving treatment for the condition that is actually causing their symptoms.

Antibody tests may be negative early after infection by *B. burgdorferi*, as it may take several weeks to develop antibodies. If the diagnosis is unclear and acute serology is negative, a convalescent test 2 to 4 weeks later may aid in diagnosis. Because erythema migrans is considered diagnostic for Lyme disease, a patient presenting with this distinctive rash requires no further testing. However, a patient with erythema migrans treated early with antibiotics may not develop antibodies. If the patient presents with other symptoms of Lyme disease and erythema migrans is atypical or absent, serologic testing should be done at initial presentation and repeated after 2 weeks. Early treatment prevents late complications and should be initiated based on clinical suspicion pending laboratory results.

Even after curative antibiotic treatment, antibodies may persist in the blood for years, meaning that a positive antibody test after treatment does not indicate treatment failure. Because of long-term persistence of antibodies, asymptomatic patients should not be retested, as a positive test result can be misleading.

In BC for the past 10 years, PHSA laboratories have consistently received about 3000 patient samples for

serological testing for Lyme disease yearly. Of these specimens, about 90 have had positive or indeterminate results on EIA and 7 to 12 cases of Lyme disease have subsequently been confirmed by WB.

Conclusions

There is no evidence to support an epidemic of Lyme disease in BC. The primary vector, *I. pacificus*, is found in populous areas in consistently low numbers, and rates of infection in the tick population remain less than 1%. Human case rates in BC are less than 0.5 per 100 000.

A recent survey of clinicians confirms doctors have good knowledge of Lyme disease, are comfortable making a diagnosis given clinical signs and symptoms, and appropriately use laboratory testing to assist in diagnosis for those patients suffering nonspecific signs and symptoms.

Further research is needed to develop diagnostic tests and treatment protocols for patients suffering from nonspecific, debilitating symptoms that some physicians attribute to "chronic Lyme disease." Otherwise, Lyme disease is a preventable and treatable illness, and public health authorities will continue to remind residents and visitors to the province of the simple measures they can take to prevent tick bites and exposure as well as the signs and symptoms of acute illness so they can seek appropriate medical treatment.

Competing interests

None declared.

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Queries
BCMJ June 2011

LYME DISEASE IN BRITISH COLUMBIA: ARE WE REALLY MISSING AN EPIDEMIC? (Henry and Morshed)

1. key words
Please provide three key words or short phrases to assist with indexing.
- Lyme disease, *Borrelia burgdorferi*, surveillance

2. p. 233, first sentence under "Tick and mouse surveillance"
We have replaced "We" with "The BC Centre of Disease Control"; is this acceptable? If not, please clarify which group or authority should be credited with screening.
-this is fine.

Davidson, Julie SSBC:EX

From: XT:HLTH Henry, Bonnie
Sent: Wednesday, May 4, 2011 9:02 AM
To: Morshed, Muhammad G CDC:IP; Harry, Ritinder
Cc: XT:Taylor, Marsha HLTH:IN; [IHA] Parker, Dr. Rob; Kendall, Perry HLTH:EX; Brunham, Robert CDC:IP
Subject: RE: Positive Lab results for lyme disease - 2010

Just to note we had 7 cases 'reported' in 2010

Bonnie Henry MD MPH FRCP(C)

Director, Public Health Emergency Services

BC Centre for Disease Control

and

Assistant Professor, School of Population and Public Health,

University of British Columbia

655 West 12th Avenue

Vancouver, BC

V5Z 4R4

bonnie.henry@bccdc.ca
phone: 604-707-2497
fax: 604 707-2420

From: Morshed, Muhammad
Sent: Wednesday, May 04, 2011 8:40 AM
To: Harry, Ritinder
Cc: Taylor, Marsha; Henry, Bonnie; [IHA] Parker, Dr. Rob; perry.kendall@gov.bc.ca; Brunham, Robert
Subject: RE: Positive Lab results for lyme disease - 2010

Hi Ritinder:

Please see the email below from s. 22 I would appreciate if you please response to her email.

We have total 7 cases in 2010. 4 travel related; 3 from BC (no travel); 3 Lab confirmed and 4 clinical based on surveillance and clinical information. Out of 3 lab confirmed cases one from BC and 2 travel/residing out of BC.

Thank you.

Regards,

Morshed

PLEASE NOTE NEW PHONE NUMBER

Muhammad Morshed, PhD, SCCM

Program Head, Zoonotic Diseases & Emerging Pathogens
BCCDC Public Health Microbiology and Reference Laboratory
Provincial Health Services Authority
Clinical Professor
Department of Pathology & Laboratory Medicine
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Muhammad.Morshed@bccdc.ca

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From: s. 22
Sent: Sunday, May 01, 2011 10:01 AM
To: Morshed, Muhammad
Cc: [IHA] Parker, Dr. Rob; perry.kendall@gov.bc.ca; Jim Wilson; David Cubberley; Brunham, Robert
Subject: Positive Lab results for lyme disease - 2010

Dr. Morshed,
Could you please tell me how many lab-confirmed cases of "lyme" disease there were in 2010? (I just want to know the number of positive serological tests for 2010.)
Thank you in advance.
s. 22

Davidson, Julie SSBC:EX

From: Patrick, David CDC:IP
Sent: Monday, July 11, 2011 9:41 AM
To: Scheiber, Alex HLTH:EX; Bonnie Henry; Bresler, Leon; Brunham, Robert CDC:IP; XT:HLTH Byres, David; XT:HLTH Hamilton, Sherry; XT:HLTH Henry, Bonnie; Kendall, Perry HLTH:EX; pphillips@cfenet.ubc.ca; XT:HLTH Chan, Thomas; [VCH] Lefebvre, Yvonne [PH]
Subject: Idiopathic Chronic Disease Initiative

Hi David, Thomas, Sherry:

Could you kindly let us know if there are any updates on contract discussions?

I'm getting a fair amount of correspondence from interested parties.

Best.

David Patrick, MD, FRCPC, MHSc
Director and Professor
UBC School of Population and Public Health and
Medical Epidemiology Lead, Antimicrobial Resistance,
British Columbia Centre for Disease Control
At BCCDC:
655 West 12 Ave Vancouver BC V5Z 3L5
604-707-2541

"Not to be absolutely certain is, I think, one of the essential things in rationality."
- Bertrand Russell

Davidson, Julie SSBC:EX

From: XT:HLTH Byres, David
Sent: Tuesday, July 12, 2011 7:40 AM
To: Patrick, David CDC:IP; Scheiber, Alex HLTH:EX; Bonnie Henry; [PHSA] Bresler, Leon; Brunham, Robert CDC:IP; XT:HLTH Hamilton, Sherry; XT:HLTH Henry, Bonnie; Kendall, Perry HLTH:EX; pphillips@cfenet.ubc.ca; XT:HLTH Chan, Thomas; Lefebvre, Yvonne [PH]
Subject: RE: Idiopathic Chronic Disease Initiative

Hi David

All the information compiled from various internal groups (finance, facilities, programs, etc) is coming back to our senior team tomorrow and I can respond thereafter.

David.

From: Patrick, David [mailto:David.Patrick@bccdc.ca]
Sent: Monday, July 11, 2011 9:41 AM
To: Alex Scheiber; Bonnie Henry; [PHSA] Bresler, Leon; [PHSA] Brunham, Robert; Byres, David [PH]; [PHSA] Hamilton, Sherry; [PHSA] Henry, Bonnie; perry.kendall@gov.bc.ca; pphillips@cfenet.ubc.ca; [PHSA] Chan, Thomas (CFO); Lefebvre, Yvonne [PH]
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604-707-2541

"Not to be absolutely certain is, I think, one of the essential things in rationality."
- Bertrand Russell

Davidson, Julie SSBC:EX

From: XT:Kennedy, Theresa HLTH:IN
Sent: Wednesday, July 27, 2011 3:57 PM
To: Tang, Tracy
Cc: Kendall, Perry HLTH:EX
Subject: RE: Physician inquiry re $2-million chronic disease clinic

We will need to ask some questions and get the answers on timing we will get back to him with something more definitive.

Thanks

Theresa Kennedy
Provincial Health Services Authority
604-675-7401(Office)
604-790-0034 (Mobile)

From: Tang, Tracy
Sent: Wednesday, July 27, 2011 3:55 PM
To: Kennedy, Theresa
Cc: perry.kendall@gov.bc.ca
Subject: RE: Physician inquiry re $2-million chronic disease clinic

With respect to what we have received from the doctor, do we acknowledge receipt of his referral and say his patient will be considered for testing?

Tracy Tang
Public Affairs Officer
Provincial Health Services Authority

700 - 1380 Burrard
Vancouver, BC V6Z 2H3
Canada
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604-708-2716 Fax
TTang3@phsa.ca
http://www.phsa.ca

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From: Kennedy, Theresa
Sent: Wednesday, July 27, 2011 3:38 PM
To: perry.kendall@gov.bc.ca
Cc: Tang, Tracy
Subject: RE: Physician inquiry re $2-million chronic disease clinic

Thank you Perry.

Theresa Kennedy
Provincial Health Services Authority
604-675-7401(Office)
604-790-0034 (Mobile)

From: Kendall, Perry HLTH:EX [mailto:Perry.Kendall@gov.bc.ca]
Sent: Wednesday, July 27, 2011 11:45 AM
To: Kennedy, Theresa
Subject: RE: Physician inquiry re $2-million chronic disease clinic

Heather Davidson is the lead ADM. The clinic is not yet open.
Perry

P. R. W. Kendall
OBC, MBBS, MSc, FRCPC
Provincial Health Officer
Ministry of Health
4th Floor, 1515 Blanshard Street
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Fax: 250 952-1362
perry.kendall@gov.bc.ca
http://www.healthservices.gov.bc.ca/pho

From: Kennedy, Theresa [mailto:Theresa.Kennedy@phsa.ca]
Sent: Wednesday, July 27, 2011 10:35 AM
To: Kendall, Perry HLTH:EX
Subject: Physician inquiry re $2-million chronic disease clinic
Importance: High

Hi Perry,

I am not sure who to turn to on this so I am hoping that you can point me in the right direction.

On March 30, 2011 there was an announcement about PHSA managing a clinic which will help physicians manage the clinical signs of chronic diseases such as Lyme Disease.

We have received a fax from a physician in Kamloops who would like to make a referral to this clinic.

Do you know who is looking after this project?

I appreciate your assistance.

Regards,
Theresa

Theresa Kennedy
Interim Director, Public Affairs
Provincial Health Services Authority

604-675-7401(Office)
604-790-0034 (Mobile)

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Davidson, Julie SSBC:EX

From: Tang, Tracy [TTang3@phsa.ca]
Sent: Thursday, August 4, 2011 10:19 AM
To: Kendall, Perry HLTH:EX; XT:Kennedy, Theresa HLTH:IN
Cc: XT:Ekramoddoullah, Lubna HLTH:IN
Subject: RE: Physician inquiry re $2-million chronic disease clinic

Further to this, today I got a voice from a woman in Victoria who wants to be a part of the study that is referenced in the March press release. I left her a return voice mail indicating that I could take her information and note her interest in participating but that's about all the information I had. PHSA Reception fielded the call initially.

Tracy

From: perry.kendall@gov.bc.ca
Sent: Wednesday, July 27, 2011 4:00 PM
To: Tang, Tracy; Kennedy, Theresa
Subject: RE: Physician inquiry re $2-million chronic disease clinic

No. I would recommend acknowledging receipt and offer to keep his name on file until a system for accepting referrals hase been developed.

P. R. W. Kendall
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Provincial Health Officer
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4th Floor, 1515 Blanshard Street
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From: Tang, Tracy [mailto:TTang3@phsa.ca]
Sent: Wednesday, July 27, 2011 3:55 PM
To: XT:Kennedy, Theresa HLTH:IN
Cc: Kendall, Perry HLTH:EX
Subject: RE: Physician inquiry re $2-million chronic disease clinic

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From: Kennedy, Theresa
Sent: Wednesday, July 27, 2011 3:38 PM
To: perry.kendall@gov.bc.ca
Cc: Tang, Tracy
Subject: RE: Physician inquiry re $2-million chronic disease clinic

Thank you Perry.

Theresa Kennedy
Provincial Health Services Authority
604-675-7401(Office)
604-790-0034 (Mobile)

From: Kendall, Perry HLTH:EX [mailto:Perry.Kendall@gov.bc.ca]
Sent: Wednesday, July 27, 2011 11:45 AM
To: Kennedy, Theresa
Subject: RE: Physician inquiry re $2-million chronic disease clinic

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Perry

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Theresa

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Interim Director, Public Affairs
Provincial Health Services Authority

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Rinta, Darcy HLTH:EX

From: Scheiber, Alex HLTH:EX
Sent: Friday, June 17, 2011 11:29 AM
To: Rinta, Darcy HLTH:EX
Subject: FW: Thank you for meeting
Attachments: Summary.docx

Interesting.

Alex Scheiber
Director, Performance Accountability, PHSA Ministry of Health
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

-----Original Message-----
From: Patrick, David [mailto:David.Patrick@bccdc.ca]
Sent: Friday, June 17, 2011 11:11 AM
To: XT:HLTH Hamilton, Sherry; Scheiber, Alex HLTH:EX
Cc: Tang, Patrick; Gardy, Jennifer; Morshed, Muhammad G CDC:IP; Brunham, Robert CDC:IP; pphillips@cfenet.ubc.ca
Subject: FW: Thank you for meeting

Hi gang:

Just to let you know that I've met with the CanLyme group and they seem OK with current philosophy and direction. (See my summary note copied to CFS people)

It seems that if minds are open to uncertainty - they're happy to work with us.

The next challenge will be to make sure a community advisory group really works.

Sherry - you and I should discuss the timing of its assembly but I sense that sooner will work better than later.

My best.

From: Patrick, David [david.patrick@ubc.ca]
Sent: June-17-11 10:58 AM
To: Patrick, David
Subject: FW: Thank you for meeting

David Patrick
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School of Population and Public Health
University of British Columbia
2206 East Mall, Vancouver BC V6T 1Z3
Tel: 604-822-3910
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"Not to be absolutely certain is, I think, one of the essential things in rationality." - Bertrand Russell

From: David Patrick <david.patrick@ubc.ca<mailto:david.patrick@ubc.ca>>
Date: Fri, 17 Jun 2011 10:57:13 -0700
To: "canlymec@gmail.com<mailto:canlymec@gmail.com>"
<canlymec@gmail.com<mailto:canlymec@gmail.com>>,

s. 22

s. 22 David Patrick
<david.patrick@ubc.ca<mailto:david.patrick@ubc.ca>>
Subject: Thank you for meeting

Dear Jim, s. 22 and David:

Thank you for making your way to UBC yesterday to talk about the clinic and research initiatives in BC.

I'm copying s. 22 as should keep them in the loop too.

Here's what I best remember from our conversation:

* It was good to get to know you in person and to learn of the journeys that have brought you to your roles
* We discussed the clinic concept and the importance of a model that focuses on the needs of the patients as individuals. This implies that the care people receive should not be a function of certainty of diagnosis and that the clinic needs to live a philosophy with wide open doors.
* I mentioned that we are still trying to make sure that Providence Health Care will be the final administrative home for the clinic
* We discussed the vision for a community advisory group to advise both on clinic set up and to provide input into research priorities. Even though the contract isn't signed, I'd like to get this rolling this summer
* I was very encouraged by our shared philosophy of accepting uncertainty and using it as an impetus to learn more so as to help the group that will be coming to the clinic for care. I understand how the hardest experiences of the past have resulted when care givers shut the door because a patient did not fit into an easily defined category. Patient focused care should deal with that.
* We agreed on the need for having mechanisms to jointly discuss evidence so as to better understand conclusions drawn by community and various practitioners. The "community journal club" idea
* We agreed that there were a number of relevant questions around diagnostics that should be studied.
* We had some interesting discussion about tick ecology and the desirability of more completely characterizing the tick microbiome. New sequencing technologies should help with this.
* I mentioned some initial thoughts on causal research in ME and Chronic Lyme and have included a summary of some approaches under consideration.

As mentioned, I'd be very grateful if you could help in a few ways:

* With respect to the research, can you please take the time to give me your thinking on the best way to "define" - for research purposes - the group with Chronic Lyme? (Remember that such a definition would not be used to limit access to the clinic, only to assure that others could use the same definition to confirm or refute our findings - reproducibility) I

think the group of most interest is your constituency with quite notable symptoms who may not fit the CDC diagnostic guidelines but who have some objective markers from other laboratories.

* Can we think of any other tissue (apart from blood) that could be safely and ethically requested of people that might be a more optimal place to look for Borrelia or coinfections? You had mentioned opportunistic study of surgical specimens when surgery is indicated for another reason.

* I understand the concerns of physicians currently offering treatment about being identified - given current governance approaches to treatment. Please let them know that I am happy to talk to them anonymously or to read their ideas on "research case definition" if it is passed through you. In the end, it would be optimal if the clinic could be informed by people experienced with caring for the patient group. It doesn't mean everyone has to agree - but the reality of what it takes to provide long term support / care should be described.

Most of all, I would really like your advice on a model of community interface that will make it attractive for us to recruit some of the very best young medical and scientific minds to this area. In the past, the controversy has scared many away. But I think we can create our own reality with the right kind of mutually supportive environment.

My best.

David Patrick
Professor and Director
School of Population and Public Health
University of British Columbia
2206 East Mall, Vancouver BC V6T 1Z3
Tel: 604-822-3910
Fax: 604-822-4994
www.spph.ubc.ca

"Not to be absolutely certain is, I think, one of the essential things in rationality." - Bertrand Russell

Rinta, Darcy HLTH:EX

From: Patrick, David [David.Patrick@bccdc.ca]
Sent: Thursday, June 9, 2011 6:58 PM
To: Scheiber, Alex HLTH:EX
Cc: Wolsey, Ashley HLTH:EX; Rinta, Darcy HLTH:EX
Subject: RE: letters re. lyme disease/fibr, other , etc or about PHSA chronic disease clinic

Thanks, Alex. We are going all out and appreciate the quality of response coming from our comms colleagues.

I have offered to meet in person with Jim and David but it doesn't look like we have a time or date yet.

From: Scheiber, Alex HLTH:EX [Alex.1.Scheiber@gov.bc.ca]
Sent: June 9, 2011 5:59 PM
To: Patrick, David
Cc: Wolsey, Ashley HLTH:EX; Rinta, Darcy HLTH:EX
Subject: Fw: letters re. lyme disease/fibr, other , etc or about PHSA chronic disease clinic

David, fyi attached is a summary of the correspondence received on the CCD clinic. Clearly a hot topic for the public.
Alex Scheiber, Director, Performance Accountability, PHSA, Ministry of Health Services

From: Henry, Effie HLTH:EX
Sent: Thursday, June 09, 2011 05:06 PM
To: Scheiber, Alex HLTH:EX
Subject: Fw: letters re. lyme disease/fibr, other , etc or about PHSA chronic disease clinic

This is the summary - can you send to david p?

From: Holms, Shannon HLTH:EX
Sent: Thursday, June 09, 2011 02:28 PM
To: Henry, Effie HLTH:EX
Subject: FW: letters re. lyme disease/fibr, other , etc or about PHSA chronic disease clinic

Good afternoon Effie, here is the cliff report on Lyme disease, fibromyalgia and other chronic diseases and the announcement regarding the new clinic. We have close to 90 pieces of correspondence since the beginning of the year.

We haven't done the search with the new parameters that you sent late yesterday. However, this will give you a starting point.

Shannon Holms, BASc, ABC
Director, Patient and Client Relations
Health Authority Relations and Corporate Services Branch | Health Authorities Division | Ministry of Health 6-2, 1515 Blanshard Street | Victoria B.C. | V8W 3C8 250 952 1891 or BB 250 217 8348 | email: shannon.holms@gov.bc.ca

From: Henry, Effie HLTH:EX
Sent: Wednesday, June 8, 2011 4:40 PM
To: Holms, Shannon HLTH:EX
Cc: Duesterwald, Meghan HLTH:EX; Scheiber, Alex HLTH:EX; Stevens, Valerie HLTH:EX; Hardy, Doreen M HLTH:EX
Subject: Re: letters re. lyme disease/fibr, other , etc or about PHSA chronic disease clinic

Can you also list the various diseases as environmental and others may be there - in addition to chronic fat, fiber and lymes. Thx.

From: Holms, Shannon HLTH:EX
Sent: Wednesday, June 08, 2011 02:31 PM
To: Henry, Effie HLTH:EX
Cc: Duesterwald, Meghan HLTH:EX; Scheiber, Alex HLTH:EX; Stevens, Valerie HLTH:EX; Hardy, Doreen M HLTH:EX
Subject: RE: letters re. lyme disease/fibr, other , etc or about PHSA chronic disease clinic

Effie, I can help you out with your correspondence request for numbers for Lyme disease, fibromyalgia and other PHSA chronic disease clinic queries. We can run the total number:

- for this calendar year,

- since the announcement was made for the chronic disease clinic, and

- for the last six months

If there are other parameters, please let me know.
Doreen, can you please run a cliff report using the variables mentioned above? Thanks.

Cheers,

Shannon Holms, BASc, ABC
Director, Patient and Client Relations
Health Authority Relations and Corporate Services Branch | Health Authorities Division | Ministry of Health 6-2, 1515 Blanshard Street | Victoria B.C. | V8W 3C8 250 952 1891 or BB 250 217 8348 | email: shannon.holms@gov.bc.ca

From: Stevens, Valerie HLTH:EX
Sent: Wednesday, June 8, 2011 2:26 PM
To: Holms, Shannon HLTH:EX
Cc: Duesterwald, Meghan HLTH:EX; Scheiber, Alex HLTH:EX
Subject: FW: letters re. lyme disease/fibr, other , etc or about PHSA chronic disease clinic

Hi Shannon.
Can you please run this data for Effie?

Thanks very much.

From: Henry, Effie HLTH:EX
Sent: Wednesday, June 8, 2011 2:25 PM
To: Duesterwald, Meghan HLTH:EX

Cc: Stevens, Valerie HLTH:EX; Scheiber, Alex HLTH:EX
Subject: letters re. lyme disease/fibr, other , etc or about PHSA chronic disease clinic

Can you send us a summary of the # letters - so we can let PHSA know the interest level.
Thanks.

Rinta, Darcy HLTH:EX

From: Scheiber, Alex HLTH:EX
Sent: Friday, May 13, 2011 8:00 AM
To: Wolsey, Ashley HLTH:EX; Rinta, Darcy HLTH:EX
Subject: FW: Chronic Complex Disease Clinic- correspondence

I don't want to include Dr. Patrick as a contact in correspondence at this point unless it's correspondence from organizations such as CanLyme. Once he hires some staff for the clinic we'll be able to provide a contact. For now we can say that the clinic is being developed over the next several months during which time further information will be available to the public including contact information for citizens seeking information.

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

From: Scheiber, Alex HLTH:EX
Sent: Friday, May 13, 2011 7:34 AM
To: Patrick, David CDC:IP
Cc: Rinta, Darcy HLTH:EX
Subject: RE: Chronic Complex Disease Clinic- correspondence

No problem David. We do have standard messaging for correspondence. I'm not sure Qs and As would be useful given the breadth of issues and "diseases" in some of these letters. If we do decide to write a FAQ we'll contact you with some questions and ask your help with the answers.

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

From: Patrick, David [mailto:David.Patrick@bccdc.ca]
Sent: Thursday, May 12, 2011 4:38 PM
To: Scheiber, Alex HLTH:EX
Subject: Re: Chronic Complex Disease Clinic- correspondence

Thanks for asking. Please do hold off on tying me into all that correspondence. That's essential to being able to focus on getting things done. Perhaps we need to identify a Comms contact at MoH and PHSA and provide them with some q and a and standard replies.
David Patrick

From: Scheiber, Alex HLTH:EX <Alex.1.Scheiber@gov.bc.ca>
To: Patrick, David
Cc: Rinta, Darcy HLTH:EX <Darcy.Rinta@gov.bc.ca>
Sent: Thu May 12 16:32:47 2011
Subject: Chronic Complex Disease Clinic- correspondence

David, the Ministry continues to receive correspondence from people asking for information and/or access to the CCDC. Some state they are suffering from various ailments, others are contacting the Minister on behalf of other patients. The correspondence branch has asked about copying you on some of the replies (so that the writer sees your name) and/or suggesting the writer contacts you for more information.

I'm mindful of the fact that this clinic is only 30% of your time and that you don't have support staff in place. Do you want us to hold off mentioning your name in correspondence?

Alex Scheiber
Director, Performance Accountability, PHSA
Ministry of Health
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

Rinta, Darcy HLTH:EX

From: Scheiber, Alex HLTH:EX
Sent: Tuesday, May 3, 2011 11:55 AM
To: Rinta, Darcy HLTH:EX
Subject: FW: Chronic Disease Program Update

Alex Scheiber
Director, Performance Accountability, PHSA Ministry of Health Services
6- 1515 Blanshard St., Victoria
(250) 952-3595 cell: (250) 415-6701
Fax: 952-1282

-----Original Message-----
From: Marchbank, Michael [mailto:mmarchbank@phsa.cal
Sent: Tuesday, May 3, 2011 11:08 AM
To: Patrick, David CDC:IP; Scheiber, Alex HLTH:EX; Brunham, Robert CDC:IP
Cc: XT:HLTH Hamilton, Sherry
Subject: RE: Chronic Disease Program Update

Thanks for the comprehensive update. The PHSA admin rep will be Sherry Hamilton. David she will be in touch with you very soon.

Michael
-----Original Message-----
From: Patrick, David
Sent: Monday, May 02, 2011 4:09 PM
To: Alex.1.Scheiber@gov.bc.ca; Marchbank, Michael; Brunham, Robert; Patrick, David
Subject: Chronic Disease Program Update

Good afternoon, Alex.

As discussed by phone and pursuant to your note to Michael today, I am providing you with an update on issues with respect to the Chronic Disease Clinic.

1) With respect to the body of the proposal - there were modifications to the body and the budget made back in December following Ministry feedback. Those are reflected in the attached Chronic Disease Program document. There were some specific questions likely reflecting Ministry and PHSA Board input dealt with at that time and our replies with respect to these are also attached for further context. We're not clear if you were expecting a further iteration of the program description, but as discussed, the priority right now should be trying to put this in motion.

2) As Michael has likely reported, he has been speaking with Dianne Doyle at Providence Health. Providence is interested in seeing if they can host this clinic and are suggesting Mt. St. Joseph's as a possible site. Once Michael and Dianne identify key contracting people from each organization - Peter Phillips (Clinical Lead at Providence and Head of ID) and I can sit down with those people and begin to draft a working contract.

3) I am working on Terms of Reference for an advisory group. We believe that it is critical to engage the community and experienced practitioners at the early stage of clinic design. The ad group needs to include a rep from the Canadian Lyme Foundation but also reps from other patient groups who represent large populations of people with Chronic Fatigue Syndrome and related issues.

4) Peter Phillips and I convened a meeting of potentially interested clinicians and scientists who we should involve in brainstorming around research and clinic formation. Internal Medicine at UBC has provided some value add in this in that people who have initiated similar efforts for mitochondrial disorders are willing to share experience.

5) There are some real challenges to overcome. We think it may difficult to attract a medical director but will get rolling as soon as it looks like a contract is in place.

6) One issue is to make sure that all community members are fully supportive of incoming people and where differences of opinion arise, will argue the point rather than the quality of the person. In the end, we cannot run a clinic where there is any expectation that clinicians provide treatment not supported by evidence or where harms may outweigh potential benefits. A corollary is that we will also not exclude patients who seek alternative approaches elsewhere. In my discussions with Mr. Wilson of CLF, I have consistently tried to emphasize points upon which we agree - that there is a group of patients currently not well served by the health care system and for whom it is important that we work toward a better understanding of the cause of their symptoms.

Finally, a reminder of my own challenges in this. 70% of my time is dedicated to running and growing UBC's new school of Population and Public Health. This chronic disease effort is my top priority for the day and half a week I give to BCCDC and I trust we will be able to move more quickly as contracts fall into place and we get some momentum toward finding an interim or permanent medical director.

My best.

David Patrick, MD, FRCPC, MHSc
Director and Professor
UBC School of Population and Public Health and Medical Epidemiology Lead, Antimicrobial Resistance, British Columbia Centre for Disease Control At BCCDC:
655 West 12 Ave Vancouver BC V5Z 3L5
604-707-2541

From: Patrick, David
Sent: Monday, May 02, 2011 3:34 PM
To: Patrick, David
Subject: Chronic Disease Program May 2 2011.docx

Provincial Health Services Authority
Province-wide solutions. Better health.

December 16, 2010

Heather Davidson
Assistant Deputy Minister
Health Authorities Division
Ministry of Health Services
6-2, 1515 Blanshard Street
Victoria BC V8W 3C8

Dear Heather,

Enclosed please find the proposal for the Chronic Disease Program at BCCDC. We have had conversations with the MoHS to help shape the proposal throughout its development.

I would be happy to discuss it further should you have any questions or feedback.

Sincerely,

Michael Marchbank
Chief Operating Officer

cc: Leigh Ann Seller, Executive Director
Home & Community Care and Performance Accountability
Health Authorities Division

700 - 1380 Burrard Street, Vancouver, British Columbia V6Z 2H3 Canada – TEL 604 675.7400 FAX 604 708.2700 WEB www.phsa.ca

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Provincial Health
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A Clinical Program for Chronic Complex Disease:

Raising the Standard of Assessment and Care for People Living with Chronic Fatigue Syndrome/Myalgic Encephalomyelitis, Fibromyositis Syndrome and Related Conditions

David M. Patrick

May 2, 2011

BC Centre for Disease Control
An agency of the Provincial Health Services Authority

A Clinical Program for Chronic Complex Disease

Purpose: The purpose of this paper is to outline the rationale and design of a clinical program that will provide a model of assessment for people with a group of complex chronic diseases. Such a centre will provide leadership and work in partnership with the health care community to embrace best practices in state of the art management, and to leverage scientific infrastructure in BC to optimize the probability of identifying clearer causes.

Why Now?

Community groups have long identified that people living with some debilitating chronic complex diseases are having a hard time accessing a consistent standard of care in a coordinated fashion within the health care system. In September of 2010, the British Columbia Ministry of Health Services formally asked the Provincial Health Services Authority to consider what might be done to better serve patients with complex symptoms possibly related to underlying infectious disease and further, how the province could contribute to improved understanding of etiology.

In the same time frame, (August 2010), a paper was published which provided independent validation of an association between the Chronic Fatigue Syndrome and a family of murine retroviruses. These observations require further replication and closer study with respect to both validity and cause and effect.

In the past half decade, BC scientists have adopted a number of new methods which could allow the province to make a significant contribution to understanding in this field. Rapid development in the field of metagenomics has come from breakthroughs in genome sequencing and bioinformatics. This means that scientists can search not only for *organisms* that might play a key role, such as retroviruses or *Borrelia burgdorferii* (the Lyme agent), but can also gain better insight into the role of host factors such as immune expression. This approach has yet to be applied broadly in this field.

This paper outlines a plan to address a large unmet need for clinical assessment and support, and to fund a study to learn more about the cause of these syndromes.

Background

There are a variety of chronic complex diseases leading to disability in British Columbians where a cause is unknown, but where there is a high index of suspicion that an infectious pathogen may be playing a role. This section outlines some of the most prevalent recognized conditions in this category.

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)

ME/CFS is a debilitating disease of unknown etiology responsible for a large burden of illness in British Columbia and Canada(1). Canadian Community Health Survey data indicate that an estimated 38,000 British Columbians report a diagnosis of ME/CFS(2). Among Canadians with 23 chronic conditions, those who reported ME/CFS consistently ranked as having more unmet medical and homecare need, less food security, more marginalization, more need of help with tasks, greater difficulty in social situations, less ability to work and lower personal income.

ME/CFS typically follows an acute or sub-acute onset, often following a time-limited viral infection, leading to speculation about infectious disease as trigger or ongoing cause. Only 10% of adults experience full recovery. ME/CFS affects all races and socioeconomic groups(1).

While many people will experience fatigue at different points in life, ME/CFS is distinguished by the long duration of symptoms, a clear exacerbation with exertion, sleep dysfunction, accompanying pain (in the form of myalgia or headache) and the presence of other characteristic symptoms. The Canadian Consensus definition (see appendix 1) makes use of these characteristic symptoms to arrive at a reasonably specific diagnosis. Notably, it requires that certain other conditions of known etiology which could produce similar symptoms have been excluded.

Causes of ME/CFS

The cause of ME/CFS is unknown. Over the years there have been various working hypotheses implicating roles for viruses (EBV, HHV-6 or 7, Enteroviruses, etc.), Chlamydia, Mycoplasma, Borrelia, environmental triggers, immune dysregulation (especially of RNAse L) and mitochondrial dysfunction. (1;3)

Fibromyalgia Syndrome

Primary fibromyalgia is a common yet poorly understood syndrome characterized by diffuse chronic pain accompanied by other somatic symptoms, including poor sleep, fatigue, and stiffness, in the absence of disease. (4) Fibromyalgia does not have a known distinct cause or pathology. Accruing evidence shows that patients with fibromyalgia experience pain differently from the general population because of dysfunctional pain processing in the central nervous system. Aberrant pain processing, which can result in chronic pain and associated symptoms, may be the result of several interplaying mechanisms, including central sensitization, blunting of inhibitory pain pathways, alterations in neurotransmitters, and psychiatric comorbid conditions.

Lyme Disease

Lyme disease is a tick-transmitted infection caused by *Borrelia burgdorferi* (5).
The first sign of infection is usually an erythematous circular rash called erythema migrans (EM). The EM rash typically occurs 7-14 days after infection and when diagnosed on physical examination, even in absence of other Lyme-specific signs/symptoms or positive laboratory tests, establishes the diagnosis of Lyme disease (6). In contrast to erythema migrans, a localized tick-bite reaction occurs within hours of the bite, expands over hours (not days), and resolves within 48 hours.

Early Disseminated Lyme Disease

Untreated, the infection may spread over several weeks to months leading to three main syndromes:

- **Neurologic:** in about 5% of untreated patients neurological abnormalities such as aseptic meningitis and cranial neuritis may develop including Bell's palsy and radiculoneuritis. (7)

- **Musculoskeletal**: migratory joint and muscle pains without objective signs of swelling.

- **Cardiac**: although rare, cardiac manifestations can include atrioventricular block and acute myopericarditis. (7)

Late Disseminated Lyme Disease

Weeks to years after onset of infection (mean 6 months) episodes of swelling and pain in large joints (especially the knees) develop in up to 60% of untreated patients, leading to chronic arthritis. Some patients develop chronic axonal polyneuropathy or encephalopathy. Lyme disease is rarely, if ever fatal although patients with late disseminated disease can have severe, chronic and disabling symptoms (7;8).

'Chronic' Lyme Disease and Current Controversy

Most cases of Lyme disease are successfully treated with antibiotics. Treatment is most effective if begun early in the course of illness. However, a percentage of patients with Lyme disease may have lingering symptoms that last months to years, even after treatment with antibiotics. These symptoms include muscle and joint pains, arthritis, cognitive defects, sleep disturbance, or fatigue. The biological basis of the syndrome is not known (9). There is some evidence that it can result from an autoimmune response, in which a person's immune system continues to respond even after the infection has been cleared. There is no consensus that chronic *Borrelia burgdorferi* infection persists among such patients after receipt of recommended antibiotic treatment regimens. Despite anecdotal reports of benefit, antibiotic therapy has not been shown to be consistently useful in randomized controlled trials so that most medical guidelines do not recommend antibiotics for patients with chronic (≥6 months) symptoms after they have already received recommended treatment regimens for Lyme disease. Nevertheless, many patients who see no other therapeutic options will continue to seek this treatment. Long term antibiotic treatment for this and other conditions has been occasionally associated with severe adverse effects, including death (10;11).

In addition, there are a group of persons with symptoms such as fatigue, memory changes and musculoskeletal pain who have never had a history of acute Lyme disease and who have been identified by some physicians as suffering from chronic or late Lyme disease. The methods or tests used by these practitioners to arrive at a diagnosis have not been sanctioned or externally validated by testing authorities in North America and Europe.
However, what is clear is that while there is controversy about cause, this is another group of patients with considerable symptomatic overlap with ME/CFS who have unmet health care needs and a requirement for state of the art investigation and care.

Lyme Disease Diagnostic Testing in BC

Laboratory testing for Lyme disease largely relies on detection of antibodies in a person's blood. One source of confusion is that antibodies that react to *Borrelia burgdorferi* proteins can also be induced by infection with microbes other than *Borrelia burgdorferi* (12). Thus antibody tests can yield false positive results unless properly interpreted (13). The PHSA Public Health Laboratories recommends a two-step process to test for antibody evidence of Lyme disease in accord with recommendations by the American Public Health Laboratory Network, US Centers for Disease Control, Canadian Public Health Network and similar international authorities. Even after curative antibiotic treatment, antibodies may persist in the blood for years; therefore a positive antibody test post treatment is not considered indicative of treatment failure. (14).

The Murine Retrovirus Hypothesis – Could a Newly Identified Virus Cause ME/CFS?

In 2009, Lombardi and colleagues identified a strong association between the presence of a murine retrovirus (XMRV) and the Chronic Fatigue Syndrome. (15) The virus was found in 67% of patients compared with 3.7% of healthy controls. The strength of association was notable, so it was disappointing when 5 subsequent papers failed to identify the virus in similar studies. (16-20)

Just as the hypothesis seemed dead, Lo and Alter reported finding a murine retrovirus in 32 of 37 (86.5%) of ME/CFS subjects compared with only 3 of 44 (6.8%) healthy volunteer blood donors. (21) This paper differed from the previous in representing a broader phylogenetic inquiry and offered a possible explanation for the negative studies – the prior investigators had been looking for one specific virus when the relevant association might be with a family of viruses.

At this point, more work is needed to understand whether the observed relationships could be laboratory artifact or whether they are real. (22) If there is an association with murine retroviruses, there also needs to be more positive evidence of cause and effect. Finally, since the role of these viruses is not yet clear, any studies of causation in this population should be cognizant of other possible microbial and host elements.

The Issue of Complexity

"In cutting up a system (into its elements), the Analytic method destroys what it seeks to understand"(23).

There is considerable danger in oversimplifying plans for evaluation and management of these disorders. When underlying causes are not yet known and clear biological markers with high predictive value remain elusive, much relies on characterizing patients according to their symptoms. Symptoms cannot be experienced or measured by the clinician and must be understood from the point of view and context of the patient. While forming diagnoses and definitions out of groups of such symptoms may prove helpful for studies, there is a real risk of missing the importance of interactions between symptoms that will vary between individuals. Therefore, while a standardized approach to assessment may be desirable for some reasons, each person needs to be assessed individually.

The implications of complexity to clinical care are that individual assessment is needed at the same time as some degree of standardization. Clinicians and patients need to learn about the condition from each other.

The implications to research and discovery are that clinicians and scientists do not yet know all of the right questions - let alone the answers. Therefore, qualitative methods are required to generate fresh hypotheses. Qualitative methods refer to an array of techniques where patients themselves identify themes and hypotheses that may be relevant to their well-being. This could involve themes of cause, care, or of interaction with health care system or society. This is in contrast to standard quantitative science where we use experimental methods to answer questions we have already thought of ourselves. We use this iterative qualitative approach to increase the chance that we will be asking the right questions. In the following proposal, we seek to add to this approach by testing not only established hypotheses, but generating new ones through clinical interaction and the science of metagenomics.

It should be noted that while such complexity seems daunting, the challenges are not dissimilar from those of individual management of other chronic diseases, such as diabetes. Regular evaluation of symptoms over time allows an ongoing assessment of trends in well being and how these are correlating with interventions.

Reasons for Perception of Unsatisfactory Care by Patients

There are several factors that have led to poor satisfaction with care which must be considered when designing a clinical service for people with ME/CFS and related conditions.

1) These syndromes have no one clear unambiguous biological marker on which to hang a diagnosis. This can only be overcome by use of meticulous clinical assessment and case definitions in the short term, and a search for specific causes and markers in the longer term.

2) The average patient needs at least a 90 to 120 minute preliminary assessment, and follow-up visits may also need to be fairly lengthy. This creates very poor economic incentive for health care workers dependent on fee for service to make room in their practices.

3) Since causal pathways are not well understood, there is a risk of confusing a psychological consequence of an illness with its cause. Unfamiliarity with diagnostic criteria may lead to mislabeling (e.g. depression), referral elsewhere and a revolving door of specialist visits with no single care provider coordinating care.

4) Information on modalities that help people is not well codified and physicians feel that they can do nothing.

5) Some patients have a firm belief in a specific cause. This can impede the search for other remedial factors or lead to pressure for specific forms of therapy which the clinician feels are not evidence-based.

The Importance of Managing Hope and Client/Patient Expectations

Thousands of people with ME/CFS and related conditions have had a challenge obtaining a consistent standard of care to date. There will be great hope that a new initiative will immediately correct this deficit. It will be important to communicate clearly that we will build a strong working model and have plans to disseminate learning and standards or practice throughout the province, but that this cannot happen overnight.

Chronic Disease Management in British Columbia

British Columbia has a strong model of chronic disease management for arthritis, asthma, cardiac disorders, diabetes and chronic pain. Similar efforts are in place for known chronic infectious diseases such as HIV and viral hepatitis. The large unmet need for patients with ME/CFS, FMS and similar syndromes represents a challenge but also an opportunity to extend the province's approach to chronic disease management and investigation.

Model for a Clinical Program

After consulting with caregivers and community, we are envisioning a clinical care program model in which staff contributes to improving the standard of practice throughout the province.

Most people consulted on clinical services for ME/CFS insisted on the need for a physical dedicated clinic. Virtual services for public and professional education could represent considerable added value, but proper assessment and testing can only be achieved in person.

Such a clinic could make use of space used for other purposes, but should be cognizant of the need for a clean, accessible, irritant-free environment and of a setting which is unlikely to lead to perceptions of stigmatization. There should be proximity to transit, accommodation and other relevant services. The optimal location for such a clinic would be in clinic space attached to a major teaching hospital.

A clinic should not be insular but needs to function as a designated focus of excellence in care of this patient group. This implies connectivity with other institutions and a capacity for continuing health education to improve the community standard of care. Evaluation and Referral Packages could be made available for download from the Web or completed online by patients / physicians. The suggested minimum workup could also be recommended per the website.

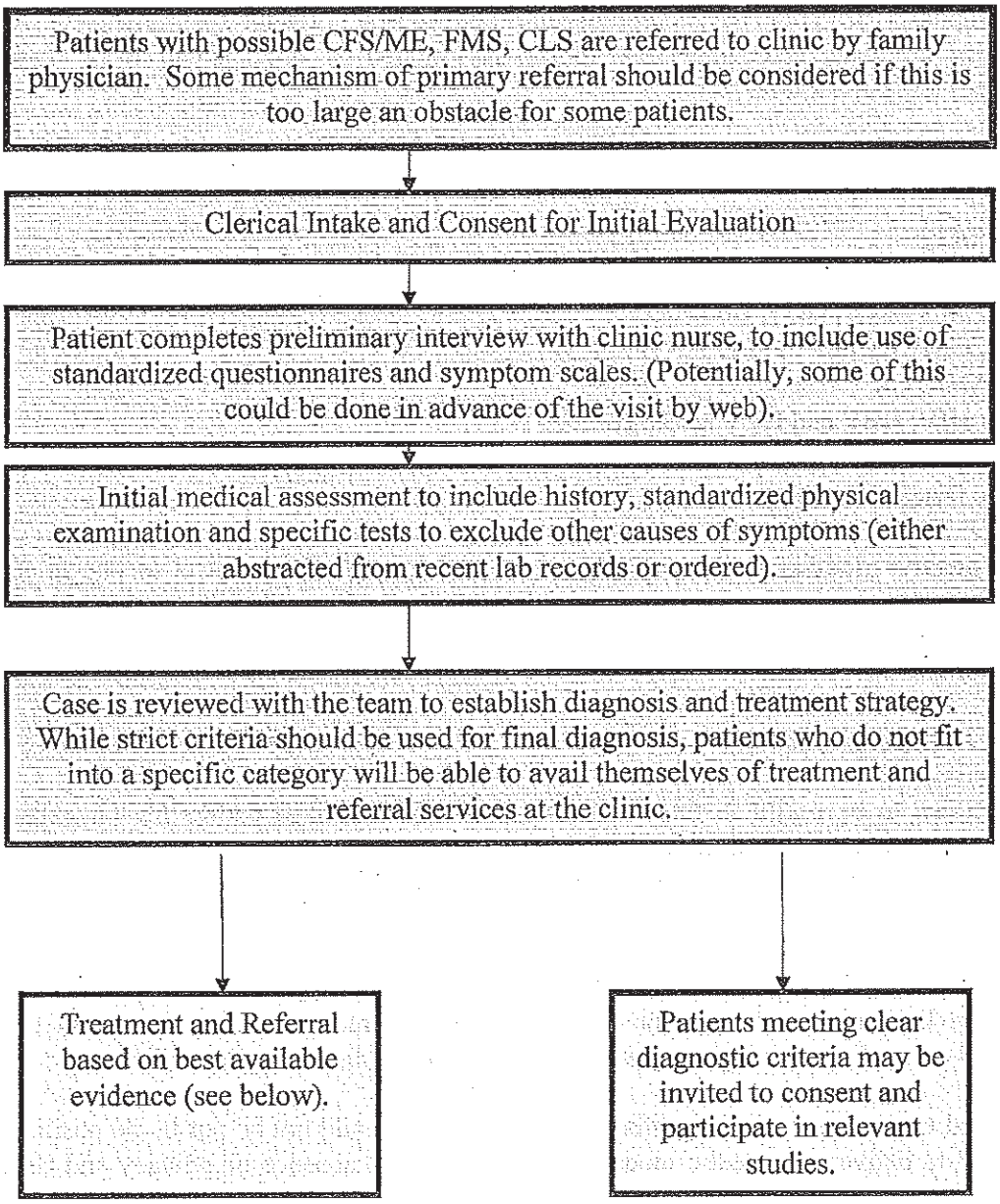
Conceptually, a clinic could be funded by BC's Provincial Health Services Authority. It is also important to consider the contribution of other health authorities, given their operation of the majority of clinic space and staff in the province. While BCCDC operates specific clinical prevention services for CD control, it is not the natural home for the ME/CFS service. This is because such a clinic needs to draw on the services of clinicians such as family practitioners, general internists and pediatricians and because the existing purpose-built clinic facilities for TB and STI management are not suitable for the patient population.

The recommended use of nurse practitioners or similar case workers within the clinic is essential. It provides ME/CFS patients with a model similar to what is seen in clinics for diabetes and other chronic diseases. It is respectful of the complex nature of ME/CFS and will assure that the clinic can provide sufficient time for all aspects of a proper assessment. Nursing functions include pre-interview, administration of various questionnaire scales, patient education, etc.

Advisory Board

We recommend that as with other services provided to a patient group that has endured some degree of marginalization in the past, an advisory structure is essential. This should most likely be comprised of two or three representative members of the affected community, and a similar number of medical/research experts chaired by the medical director.

Appendix One: Overview and Concept of Patient Flow



Appendix Two: Currently Relevant Screening Tests and Therapeutic Modalities

It is very important to identify any remediable causes of symptoms due to known causes. Much of this can be accomplished by a practiced and careful history and a physical examination with particular emphasis on complete neuromuscular and musculoskeletal examination. At a minimum, the following screening tests should be ordered or documented from recently performed tests done elsewhere:

- Complete Blood Count
- ESR
- Ca, P, Mg
- Glucose, electrolytes, Cr
- AST, ALT, ALP, GGT, Bilirubin
- TSH, CRP, ferritin
- RF, ANA, CK
- RPR, HIV, HBV and HCV serology
- Urinalysis
- Lyme Disease Serology

If there are positive findings on history, physical or laboratory tests, referral to one or more specialists for more complete assessment may be required. For example, any evidence of sensory, motor or reflex deficits may require neurological assessment to rule out other causes of neuromuscular disease.

Present-day Therapeutic Modalities

Modalities shown to be useful in this context include individualized counseling on exercise, activity and life-pacing, referral to a rehabilitation specialist with a focus of expertise in ME/CFS, stress reduction and relaxation, group discussion / education, nutritional advice and sleep maximization. (1) Pain management must also be included.

If a clinic is funded, further work will be required to review approaches with experienced clinicians from BC and elsewhere. For example, some informants mention that small group discussion and counseling on life-pacing can add value and may increase clinic efficiency.

Evidence-based treatments are to be preferred and clinicians should not be put in the position of being required to deliver therapeutic modalities where there is absence of efficacy and risk of harm to patients.

Appendix 3: Roles and Responsibilities within the Program

Medical Director

- Creates a standard of consistent, evidence-based assessment
- Monitors standard of care and stays current with evidence base for therapy
- Medical supervision of clinic staff
- Depending on skill-set – may provide research leadership or liaise with another study PI
- Time working for clinic should be supported by a salary structure or sessions
- Organizes his/her staff to provide outreach and continuing health education to other providers to assure an improving standard of care for ME/CFS patients in the broader community
- Liaises with hospitals, local public health units or community centres to extend awareness, information and support

Clinic Physicians

- Provide consistent initial assessments according to clinic guidelines
- Provide follow-up assessments as required
- Sessional or salaried compensation
- Must be skilled with pediatric as well as adult assessment
- Provide consultation services for referring physicians via Telehealth to determine if referral is appropriate

Nurse Practitioner / Case Management (Eventually 3 needed)

- Conduct much of the initial interview
- Conduct much of the standardized follow-up
- Conduct of group discussion education sessions
- To discuss relative time allocation of Nurse Practitioner vs MD
- Salaried

Clerical Support

- Patient intake
- Maintenance of charts
- Retrieval of lab tests

Web Master / Communications

- Maintaining an up to date website to support patient intake, professional education, public education and chat/blog functions
- Maintaining strong ties to affected community and coordinating meetings of advisory board
- Working with extramural funders to increase resourcing for studies or new modalities of care

- Planning formal course activities to disseminate best-practices among health care workers in British Columbia

Consultants that need to be available but need not be funded by the clinic

- Neurology
- Rheumatology
- Immunology
- Infectious Disease
- Medical Microbiology
- Psychiatry
- Psychology
- Rehabilitation Medicine
- Physiotherapy
- Nutrition
- Specialist in Sleep Disorders or referrals to Sleep Clinic
- Registered Massage Therapy
- Legal Advice
- Paediatrics

Clinic Design Phase

It is expected that the medical director and one or more nurse practitioners will need the support of a research assistant to pull together materials to create an optimal design for patient flow. Literature will require reviewing in more detail than was possible for this proposal. Approaches, forms, scales and therapeutic strategies in use in other successful clinics should be reviewed and clinic documentation designed. Ideally, this will be supported by IMIT so that there are mechanisms to convert forms into electronic records. This planning must also be cognizant *a priori* of the need to organize information in such a way as to be able to analyze data for quality control and research purposes.

Staff Training Phase

It must be recognized that there are very few physicians or nurses working with a current focus on these syndromes. Accordingly, any plan for setting up a clinic must include initial paid training and ongoing study by staff. We envision a planned one week orientation in which knowledge of the conditions is reviewed, staff may hear patient perspectives, a thorough familiarization with assessment and relevant scales is effected, and there is review of effective treatment modalities and referral patterns. Long term, staff would need to conduct a "rounds" function for educational update at least every two weeks.

Appendix Four: Study Considerations

An early goal of the clinic, once it has established a pattern of consistent patient assessment, will be to contribute to knowledge in this area.

Initially, we propose a modest case-control study in which patients with clear ME/CFS are compared with healthy controls, a chronic disease control group and, if funding allows, a group with FMS.

The objectives of this study would be to:

a) Formally test the hypothesis of an association between ME/CFS and murine retroviruses in ME/CFS patients in BC, and
b) To look for other microbial and host factors associated with ME/CFS (hypothesis generating approach)

In this study, groups of 25 ME/CFS, 25 FMS, 25 healthy controls and 25 controls with a known chronic disease (RA or MS) would be recruited. (This sample would be sufficient to test the hypothesis of a significant odds ratio exceeding 5 between CFS and control groups for murine retrovirus).

The two control groups (combined n=50) would need to be assessed using the standard clinic approach as used for patients referred to the clinic. This will generate costs for clinic personnel and laboratories. (See budget).

All subjects would have blood drawn for serum and peripheral blood mononuclear cells (PBMC).

The primary outcome variable would be detection of a NA sequence from PBMCs compatible with a murine retrovirus. This determination would take care to learn lessons from published papers: a broad inquiry of the gag gene would be used; there would be care to properly blind test and to use the same lots of reagents for testing of cases and controls.

Secondary outcome variables (or hypothesis-generating studies) would be:

a) Serology for organisms potentially associated with ME/CFS including Borrelia (C6 peptide), Anaplasma, Ehrlichia, Babesia, Ricketsia, Q fever, Bartonella, Francisella, Mycoplasma, and spiroplasma.
b) Metagenomic analysis of nucleic acid derived from the PBMC pool to search for differences between cases and controls with respect to microbial nucleic acid, as well as host nucleic acid and transcription. This technique has enormous power to identify factors associated with disease that have not been identified using other methods.
c) Consideration of use of an oligopeptide array (McGeer) to examine cross reactivity between XMRV and other murine retroviruses in order to resolve contradictory studies in the literature.

Lyme positive controls should be included to assess sensitivity of the various methods. Specimens will be sought from 2 patients with culture positive late Lyme arthritis and 2 patients with culture positive Lyme neuroborreliosis.

Analysis

The principle analysis would be assessment of the unadjusted OR for murine retroviruses.

Other differences will be evaluated as secondary analyses using crude odds ratios and an adjusted level of significance.

Role of PI

Responsibility for all aspects of conduct of the study:

- Consults with experts and community
- Finalizes protocols for study
- Assures compliance with ethical standards and full consent
- Manages budgets and assures proper use of funds
- Keeps current with relevant literature to avoid duplication of studies done elsewhere
- Supervision of study staff
- Regular meetings with clinic staff

Appendix Five: People Consulted in the Development of this Proposal

- Bruce Carruthers, Internist and Specialist in ME/CFS Care (Semi-retired)
- Jan Venter, Family Physician and Practicing Specialist in ME/CFS
- Sherri Todd, National ME/CFS Action Network (BC Chapter)
- Margaret Parlor, National ME/CFS Action Network
- s. 22
- Bill Bowie, Infectious Diseases
- Bonnie Henry, BCCDC
- Patrick Tang, PHSA Labs
- Judy Isaac-Renton, PHSA Labs
- Jennifer Gardy, BCCDC
- Bob Brunham, BCCDC
- Muhammad Morshed, BCCDC
- Tom Perry, Department of Medicine, UBC
- Andy Mason, Department of Medicine, University of Alberta
- Ted Steiner, Infectious Diseases

Appendix 6: Canadian Clinical Working Case Definition for ME/CFS

Patients must have:

1. Fatigue
2. Specifically also Post-exertional malaise or fatigue
3. Sleep dysfunction
4. Pain (usually myalgias or HA)
5. Two or more of a list of neuro-cognitive manifestations
6. At least one symptom from two of the following categories: Autonomic (e.g. bowel/bladder, tachycardia, postural hypotension); Neuroendocrine (temperature disturbance, marked weight/appetite change, etc.); Immune (LAN, sore throat, malaise, new "sensitivities" to foods, allergens, etc.)
7. Duration of illness at least 6 months

Diagnosis also requires systematic exclusion of various endocrine, rheumatologic and neurological causes of similar symptoms.

Budget Considerations

Clinic:

Assumptions: 2 physicians, 2 nurses, small start up seeing maximum 5-6 patients per day 5 day workweek, 7 hours of contact time per day
Assumes that clinic, and setup (computers, etc) are provided using existing resources and space

Item		One time cost
Initial website development, creation and hosting, using Content Management System for ease of maintenance and further development	Software, development time and webmaster, functionality development and refinements	**$65,000**

Item		Annual Cost
Medical Director	0.5 FTE	$125,000
Physician Sessions(specialist)	535 specialist sessions (at 478.66cost) 50 weeks, 5 days a week, 535 sessions per year, and assuming a 3% increase in 2011	$295,800
Alternate salaried Family physician (1 of each at quoted initial workup would be able to see only 2 per session, 4 per day).	535 FP sessions at 405.78 per session. 535 sessions and assuming 3% increase in 2011	$252,350
Nurse Case Manager or Nurse practitioner	2 position w. Nurse practitioner 92k per yr plus benefits **OR** Senior Nurse: 85k/yr including benefits	$210,000
Clerical	1 receptionist, 1 transcriptionist including benefits	$84,000
Screening Lab Tests	For patients – MSP cover *	
	For 25 controls – 15 tests at MSP rate	$12,000

Webmaster/communications resources for online presence and ongoing updating	.4 webmaster for ongoing updates 1	$26,000
Supplies-office		$5,000
Supplies- clinic		$25,000
Total assuming space and IT support provided		**$1,074,150**

* We estimate net savings to MSP over time with respect to screening tests because coordinated care at one centre and clear listing of tests of known value will lead to reduced overall billings to labs as redundant testing by various practitioners and testing of dubious value can be eliminated.

In the event that a higher volume of patients would be seen, the increase might be seen only in the sessional hours, as the nursing and clerical support would be able to support a significant increase.

Study

Item		Cost for Full Study
PI	10%	$ 24,000
Research Nurse	85,000 x 2 years	$170,000
Research Epidemiologist	50,000 half time x 2 years	$100,000
Lab testing PCR	$50 per 3 tests x 100 study samples	$5,000
Indexing of Metagenomic Samples	6,000	$6,000
Sequencing of samples	50,000	$50,000
Bioinformatic Analsyis	35,000	$35,000
Lab testing serology	15/test X 10 agents/subject x 100 subjects	$15,000
Genomics lab equipment lease	$11,000/mo x 1 yr	$132,000
Lab tech	1 FTE x 1 year	$70,000
Lab coordinator	0.25 FTE x 1 yr	$25,000
Controls and cost	100 people at 160 per participant	$16,000 honoraria if required
Research oversight committee	4 meetings (includes travel, meeting costs, etc.)	$10,000
Dissemination	Publication costs, conference fees and travel for dissemination.	$10,000
Total		**$668,010**

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Centre for Excellence in Chronic Complex Disease Assessment and Investigation

Comment [a1]: Is this an appropriate name for this centre? It seems to be focusing on ME/CFS. What other chronic complex diseases would it address?

David M. Patrick
October 18, 2010

BC Centre for Disease Control
An agency of the Provincial Health Services Authority

Chronic Complex Disease Assessment and Investigation

Purpose: The purpose of this paper is to outline the rationale and design of a centre for excellence that will provide a model of assessment for people with a group of complex chronic diseases. Such a centre needs to lead the health care community to embrace best practices in state of the art management, and to leverage scientific infrastructure in BC to optimize the probability of identifying clearer causes.

Comment [a2]: The paper goes well beyond this to include study considerations,

Comment [I3]: Think we should avoid the word Center for Excellence – Is there some other language we can use? – multidisciplinary care center?

Comment [I4]: Will provide leadership and work in partnership with the health care community?

Why Now?

Community groups have long identified that people living with some debilitating chronic complex diseases are having a hard time accessing coherent care within the health care system. In September of 2010, the British Columbia Ministry of Health Services formally asked the Provincial Health Services Authority to consider what might be done to better serve patients with complex symptoms possibly related to underlying infectious disease and further, how the province could contribute to improved understanding of etiology.

Comment [I5]: Think it is more a consistent standard of care that is equal to other chronic health care conditions

In the same time frame, (August 2010), a paper was published which provided independent validation of an association between the Chronic Fatigue Syndrome and a family of murine retroviruses. These observations require further replication and closer study with respect to both validity and cause and effect.

In the past half decade, BC scientists have adopted a number of new methods which could allow the province to make a significant contribution to understanding in this field. Rapid development in the field of metagenomics has come from breakthroughs in genome sequencing and bioinformatics. This means that scientists can search not only for *organisms* that might play a key role, such as retroviruses or *Borrelia burgdorferii* (the Lyme agent), but can also gain better insight into the role of host factors such as immune expression. This approach has yet to be applied broadly in this field.

This paper outlines a plan to address a large unmet need for clinical assessment and support, and to fund a study to learn more about the cause of these syndromes.

Background

Comment [dr6]: Make clear these are examples of chronic complex diseases that could be assessed/investigated

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)

ME/CFS is a debilitating disease of unknown etiology responsible for a large burden of illness in British Columbia and Canada(1). Canadian Community Health Survey data indicate that an estimated 38,000 British Columbians report a diagnosis of ME/CFS(2). Among Canadians with 23 chronic conditions, those who reported ME/CFS consistently ranked as having more unmet medical and homecare need, less food security, more marginalization, more need of help with tasks, greater difficulty in social situations, less ability to work and lower personal income.

ME/CFS typically follows an acute or sub-acute onset, often following a time-limited viral infection, leading to speculation about infectious disease as trigger or ongoing cause. Only 10% of adults experience full recovery. ME/CFS affects all races and socioeconomic groups(1).

While many~~may~~ people will experience fatigue at different points in life, ME/CFS is distinguished by the long duration of symptoms, a clear exacerbation with exertion, sleep dysfunction, accompanying pain (in the form of myalgia or headache) and the presence of other characteristic symptoms. The Canadian Consensus definition (see appendix 1) makes use of these characteristic symptoms to arrive at a reasonably specific diagnosis. Notably, it requires that certain other conditions of known etiology which could produce similar symptoms have been excluded.

Causes of ME/CFS

The cause of ME/CFS is unknown. Over the years there have been various working hypotheses implicating roles for viruses (EBV, HHV-6 or 7, Enteroviruses, etc.), Chlamydia, Mycoplasma, Borrelia, environmental triggers, immune dysregulation (especially of RNAse L) and mitochondrial dysfunction. (1;3)

Fibromyalgia Syndrome

Primary fibromyalgia is a common yet poorly understood syndrome characterized by diffuse chronic pain accompanied by other somatic symptoms, including poor sleep, fatigue, and stiffness, in the absence of disease. (4) Fibromyalgia does not have a known distinct cause or pathology. Accruing evidence shows that patients with fibromyalgia experience pain differently from the general population because of dysfunctional pain processing in the central nervous system. Aberrant pain processing, which can result in chronic pain and associated symptoms, may be the result of several interplaying mechanisms, including central sensitization, blunting of inhibitory pain pathways, alterations in neurotransmitters, and psychiatric comorbid conditions.

Lyme Disease

Lyme disease is a tick-transmitted infection caused by *Borrelia burgdorferi* (5). The first sign of infection is usually an erythematous circular rash called erythema migrans (EM). The EM rash typically occurs 7-14 days after infection and when diagnosed on physical examination, even in absence of other Lyme-specific signs/symptoms or positive laboratory tests, establishes the diagnosis of Lyme disease (6). In contrast to erythema migrans, a localized tick-bite reaction occurs within hours of the bite, expands over hours (not days), and resolves within 48 hours.

Early Disseminated Lyme Disease

Untreated, the infection may spread over several weeks to months leading to three main syndromes:

- **Neurologic:** in about 5% of untreated patients neurological abnormalities such as aseptic meningitis and cranial neuritis may develop including Bell's palsy and radiculoneuritis. (7)
- **Musculoskeletal:** migratory joint and muscle pains without objective signs of swelling.
- **Cardiac:** although rare, cardiac manifestations can include atrioventricular block and acute myopericarditis. (7)

Late Disseminated Lyme Disease

Weeks to years after onset of infection (mean 6 months) episodes of swelling and pain in large joints (especially the knees) develop in up to 60% of untreated patients, leading to chronic arthritis. Some patients develop chronic axonal polyneuropathy or encephalopathy. Lyme disease is rarely, if ever fatal although patients with late disseminated disease can have severe, chronic and disabling symptoms (7;8).

'Chronic' Lyme Disease and Current Controversy

Most cases of Lyme disease are successfully treated with antibiotics. Treatment is most effective if begun early in the course of illness. However, a percentage of patients with Lyme disease may have lingering symptoms that last months to years, even after treatment with antibiotics. These symptoms include muscle and joint pains, arthritis, cognitive defects, sleep disturbance, or fatigue. The biological basis of the syndrome is not known (9). There is some evidence that it can result from an autoimmune response, in which a person's immune system continues to respond even after the infection has been cleared. There is no consensus that chronic *Borrelia burgdorferi* infection persists among such patients after receipt of recommended antibiotic treatment regimens. Despite anecdotal reports of benefit, antibiotic therapy has not been shown to be consistently useful in randomized controlled trials so that most medical guidelines do not recommend antibiotics for patients with chronic (≥6 months) symptoms after they have already received recommended treatment regimens for Lyme disease. Nevertheless, many patients who see no other therapeutic options will continue to seek this treatment. Long term antibiotic treatment for this and other conditions has been occasionally associated with severe adverse effects, including death (10;11).

In addition, there are a group of persons with symptoms such as fatigue, memory changes and musculoskeletal pain who have never had a history of acute Lyme disease and who have been identified by some physicians as suffering from chronic or late Lyme disease. The methods or tests used by these practitioners to arrive at a diagnosis have not been sanctioned or externally validated by testing authorities in North America and Europe.
However, what is clear is that while there is controversy about cause, this is another group of patients with considerable symptomatic overlap with ME/CFS who have unmet health care needs and a requirement for state of the art investigation and care.

Lyme Disease Diagnostic Testing in BC

Laboratory testing for Lyme disease largely relies on detection of antibodies in a person's blood. One source of confusion is that antibodies that react to *Borrelia burgdorferi* proteins can also be induced by infection with microbes other than *Borrelia burgdorferi* (12). Thus antibody tests can yield false positive results unless properly interpreted (13). The PHSA Public Health Laboratories recommends a two-step process to test for antibody evidence of Lyme disease in accord with recommendations by the American Public Health Laboratory Network, US Centers for Disease Control, Canadian Public Health Network and similar international authorities. Even after curative antibiotic treatment, antibodies may persist in the blood for years; therefore a positive antibody test post treatment is not considered indicative of treatment failure. (14).

The Murine Retrovirus Hypothesis – Could a Newly Identified Virus Cause ME/CFS?

In 2009, Lombardi and colleagues identified a strong association between the presence of a murine retrovirus (XMRV) and the Chronic Fatigue Syndrome. (15) The virus was found in 67% of patients compared with 3.7% of healthy controls. The strength of association was notable, so it was disappointing when 5 subsequent papers failed to identify the virus in similar studies. (16-20)

Just as the hypothesis seemed dead, Lo and Alter reported finding a murine retrovirus in 32 of 37 (86.5%) of ME/CFS subjects compared with only 3 of 44 (6.8%) healthy volunteer blood donors. (21) This paper differed from the previous in representing a broader phylogenetic inquiry and offered a possible explanation for the negative studies – the prior investigators had been looking for one specific virus when the relevant association might be with a family of viruses.

At this point, more work is needed to understand whether the observed relationships could be laboratory artifact or whether they are real. (22) If there is an association with murine retroviruses, there also needs to be more positive evidence of cause and effect. Finally, since the role of these viruses is not yet clear, any studies of causation in this population should be cognizant of other possible microbial and host elements.

The Issue of Complexity

"In cutting up a system (into its elements), the Analytic method destroys what it seeks to understand"(23).

There is considerable danger in oversimplifying plans for evaluation and management of these disorders. When underlying causes are not yet known and clear biological markers with high predictive value remain elusive, much relies on characterizing patients according to their symptoms. Symptoms cannot be experienced or measured by the clinician and must be understood from the point of view and context of the patient. While forming diagnoses and definitions out of groups of such symptoms may prove helpful for studies, there is a real risk of missing the importance of interactions between symptoms that will vary between individuals. Therefore, while a standardized approach to assessment may be desirable for some reasons, each person needs to be assessed individually.

The implications of complexity to clinical care are that individual assessment is needed at the same time as some degree of standardization. Clinicians and patients need to learn about the condition from each other.

Comment [I7]: Important statement.

The implications to research and discovery is that clinicians and scientists do not yet know all of the right questions, let alone the answers. Therefore, qualitative methods are required to generate fresh hypotheses. In the following proposal, we seek to add to this approach by testing not only established hypotheses, but generating new ones through clinical interaction and the science of metagenomics.

Comment [I8]: That involves the interactions between patient and health care system?

It should be noted that while such complexity seems daunting, the challenges are not dissimilar from those of individual management of other chronic diseases, such as diabetes. Regular evaluation of symptoms over time allows an ongoing assessment of trends in well being and how these are correlating with interventions.

Reasons for Perception of Unsatisfactory Care by Patients

There are several factors that have led to poor satisfaction with care which must be considered when designing a clinical service for people with ME/CFS and related conditions.

1) These syndromes have no one clear unambiguous biological marker on which to hang a diagnosis. This can only be overcome by use of meticulous clinical assessment and case definitions in the short term, and a search for specific causes and markers in the longer term.

2) The average patient needs at least a 90 to 120 minute preliminary assessment, and follow-up visits may also need to be fairly lengthy. This creates very poor economic incentive for health care workers dependent on fee for service to make room in their practices.

3) Since causal pathways are not well understood, there is a risk of confusing a psychological consequence of an illness with its cause. Unfamiliarity with diagnostic criteria may lead to mislabeling (e.g. depression), referral elsewhere and a revolving door of specialist visits with no single care provider coordinating care.

4) Information on modalities that help people is not well codified and physicians feel that they can do nothing.

5) Some patients have a firm belief in a specific cause. This can impede the search for other remedial factors or lead to pressure for specific forms of therapy which the clinician feels are not evidence-based.

The Importance of Managing Hope and Expectation

Comment [a9]: This is an implementation issue; should not be included in this proposal.

Thousands of people with ME/CFS and related conditions have had a challenge obtaining a consistent standard of care to date. There will be great hope that a new initiative will immediately correct this deficit. It will be important to communicate clearly that we will build a strong working model and have plans to disseminate learning and standards or practice throughout the province, but that this cannot happen overnight.

Chronic Disease Management in British Columbia

British Columbia has a strong model of chronic disease management for arthritis, asthma, cardiac disorders, diabetes and chronic pain. Similar efforts are in place for known chronic infectious diseases such as HIV and viral hepatitis. The large unmet need for patients with ME/CFS, FMS and similar syndromes represents a challenge but also an opportunity to extend the province's approach to chronic disease management and investigation.

Model for Clinic

Comment [dr10]: Consider having remainder of document as appendices.

After consulting with caregivers and community, we are envisioning a centre for excellence model in which staff contributes to improving the standard of practice throughout the province.

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Most people consulted on clinical services for ME/CFS insisted on the need for a physical dedicated clinic. Virtual services for public and professional education could represent considerable added value, but proper assessment and testing can only be achieved in person.

Such a clinic could make use of space used for other purposes, but should be cognizant of the need for a clean, accessible, irritant-free environment and of a setting which is unlikely to lead to perceptions of stigmatization. There should be proximity to transit, accommodation and other relevant services.

A clinic should not be insular but needs to function as a designated Centre for Excellence in care of this patient group. This implies connectivity with other institutions and a capacity for continuing health education to improve the community standard of care. Evaluation and Referral Packages could be made available for download from the Web or completed online by patients / physicians. The suggested minimum workup could also be recommended per the website.

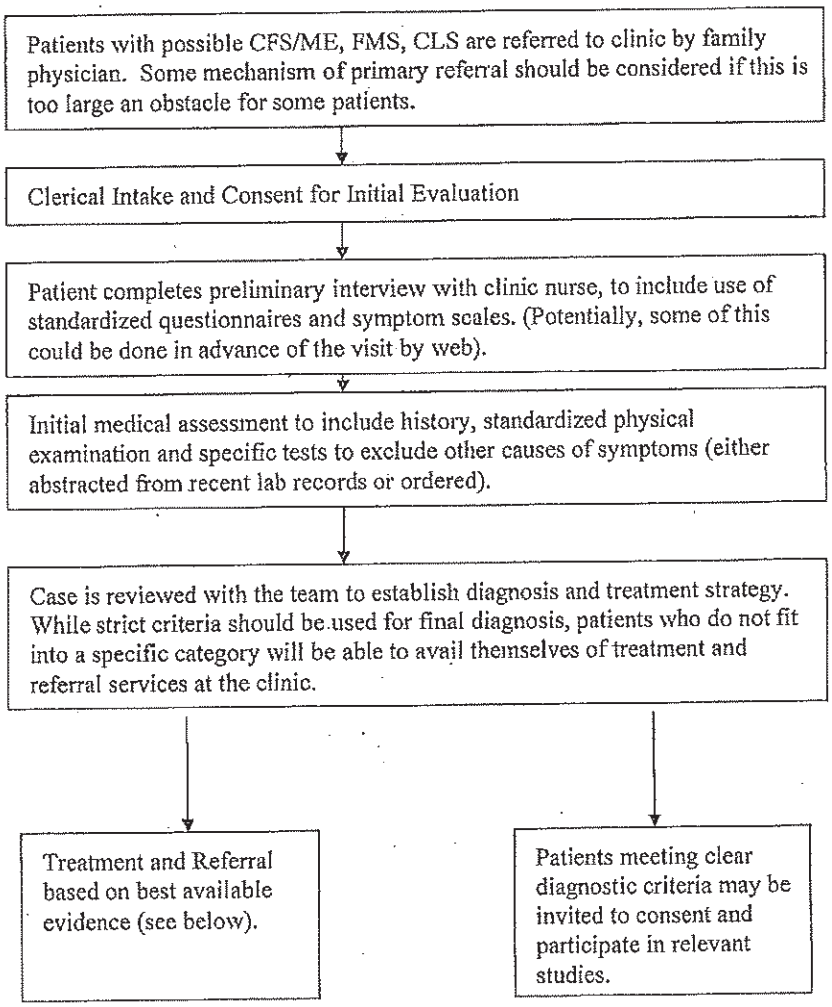
Conceptually, a clinic could be operated by BC's Provincial Health Services Authority. It is also important to consider the contribution of other health authorities, given their operation of the majority of clinic space and staff in the province. While BCCDC operates specific clinical prevention services for CD control, it is not the natural home for the ME/CFS service. This is because such a clinic needs to draw on the services of clinicians such as family practitioners, general internists and pediatricians and because the existing purpose-built clinic facilities for TB and STI management are not suitable for the patient population.

The recommended use of nurse practitioners or similar case workers within the clinic is essential. It provides ME/CFS patients with a model similar to what is seen in clinics for diabetes and other chronic diseases. It is respectful of the complex nature of ME/CFS and will assure that the clinic can provide sufficient time for all aspects of a proper assessment. Nursing functions include pre-interview, administration of various questionnaire scales, patient education, etc.

Advisory Board

We recommend that as with other services provided to a patient group that has endured some degree of marginalization in the past, an advisory structure is essential. This should most likely be comprised of two or three representative members of the affected community, and a similar number of medical/research experts chaired by the medical director.

Overview and Concept of Patient Flow



Screening Tests

It is very important to identify any remediable causes of symptoms due to known causes. Much of this can be accomplished by a practiced and careful history and a physical examination with particular emphasis on complete neuromuscular and musculoskeletal examination. At a minimum, the following screening tests should be ordered or documented from recently performed tests done elsewhere:

- Complete Blood Count
- ESR
- Ca, P, Mg
- Glucose, electrolytes, Cr
- AST, ALT, ALP, GGT, Bilirubin
- TSH, CRP, ferritin
- RF, ANA, CK
- RPR, HIV, HBV and HCV serology
- Urinalysis
- Lyme Disease Serology

If there are positive findings on history, physical or laboratory tests, referral to one or more specialists for more complete assessment may be required. For example, any evidence of sensory, motor or reflex deficits may require neurological assessment to rule out other causes of neuromuscular disease.

Present-day Therapeutic Modalities

Modalities shown to be useful in this context include individualized counseling on exercise, activity and life-pacing, referral to a rehabilitation specialist with a focus of expertise in ME/CFS, stress reduction and relaxation, group discussion / education, nutritional advice and sleep maximization. (1) Pain management must also be included.

If a clinic is funded, further work will be required to review approaches with experienced clinicians from BC and elsewhere. For example, some informants mention that small group discussion and counseling on life-pacing can add value and may increase clinic efficiency.

Evidence-based treatments are to be preferred and clinicians should not be put in the position of being required to deliver therapeutic modalities where there is absence of efficacy and risk of harm to patients.

Roles and Responsibilities

Medical Director

- Creates a standard of consistent, evidence-based assessment
- Monitors standard of care and stays current with evidence base for therapy
- Medical supervision of clinic staff
- Depending on skill-set – may provide research leadership or liaise with another study PI
- Time working for clinic should be supported by a salary structure or sessions
- Organizes his/her staff to provide outreach and continuing health education to other providers to assure an improving standard of care for ME/CFS patients in the broader community
- Liaises with hospitals, local public health units or community centres to extend awareness, information and support

Clinic Physicians

- Provide consistent initial assessments according to clinic guidelines
- Provide follow-up assessments as required
- Sessional or salaried compensation
- Must be skilled with pediatric as well as adult assessment

Comment [a11]: Would the centre of excellence provide consultation services for referring physicians via telehealth to determine if the referral is appropriate?

Nurse Practitioner / Case Management (Eventually 3 needed)

- Conduct much of the initial interview
- Conduct much of the standardized follow-up
- Conduct of group discussion education sessions
- To discuss relative time allocation of Nurse Practitioner vs MD
- Salaried

Clerical Support

- Patient intake
- Maintenance of charts
- Retrieval of lab tests

Web Master / Communications

- Maintaining an up to date website to support patient intake, professional education, public education and chat/blog functions
- Maintaining strong ties to affected community and coordinating meetings of advisory board
- Working with extramural funders to increase resourcing for studies or new modalities of care
- Planning formal course activities to disseminate best-practices among health care workers in British Columbia

Consultants that need to be available but need not be funded by the clinic

- Neurology
- Rheumatology
- Immunology
- Infectious Disease
- Medical Microbiology
- Psychiatry
- Psychology
- Rehabilitation Medicine
- Physiotherapy
- Nutrition
- Specialist in Sleep Disorders or referrals to Sleep Clinic
- Registered Massage Therapy
- Legal Advice
- Paediatrics

Clinic Design Phase

It is expected that the medical director and one or more nurse practitioners will need the support of a research assistant to pull together materials to create an optimal design for patient flow. Literature will require reviewing in more detail than was possible for this proposal. Approaches, forms, scales and therapeutic strategies in use in other successful clinics should be reviewed and clinic documentation designed. Ideally, this will be supported by IMIT so that there are mechanisms to convert forms into electronic records. This planning must also be cognizant *a priori* of the need to organize information in such a way as to be able to analyze data for quality control and research purposes.

Staff Training Phase

It must be recognized that there are very few physicians or nurses working with a current focus on these syndromes. Accordingly, any plan for setting up a clinic must include initial paid training and ongoing study by staff. We envision a planned one week orientation in which knowledge of the conditions is reviewed, staff may hear patient perspectives, a thorough familiarization with assessment and relevant scales is effected, and there is review of effective treatment modalities and referral patterns. Long term, staff would need to conduct a "rounds" function for educational update at least every two weeks.

Study Considerations

Comment [a12]: Is this section necessary given that this is a proposal for this centre? Seems like too much detail.

An early goal of the clinic, once it has established a pattern of consistent patient assessment, will be to contribute to knowledge in this area.

Initially, we propose a modest case-control study in which patients with clear ME/CFS are compared with healthy controls, a chronic disease control group and, if funding allows, a group with FMS.

The objectives of this study would be to:

a) Formally test the hypothesis of an association between ME/CFS and murine retroviruses in ME/CFS patients in BC, and
b) To look for other microbial and host factors associated with ME/CFS (hypothesis generating approach)

In this study, groups of 25 ME/CFS, 25 FMS, 25 healthy controls and 25 controls with a known chronic disease (RA or MS) would be recruited. (This sample would be sufficient to test the hypothesis of a significant odds ratio exceeding 5 between CFS and control groups for murine retrovirus).

The two control groups (combined n=50) would need to be assessed using the standard clinic approach as used for patients referred to the clinic. This will generate costs for clinic personnel and laboratories. (See budget).

All subjects would have blood drawn for serum and peripheral blood mononuclear cells (PBMC).

The primary outcome variable would be detection of a NA sequence from PBMCs compatible with a murine retrovirus. This determination would take care to learn lessons from published papers: a broad inquiry of the gag gene would be used; there would be care to properly blind test and to use the same lots of reagents for testing of cases and controls.

Secondary outcome variables (or hypothesis-generating studies) would be:

a) Serology for organisms potentially associated with ME/CFS including Borrelia (C6 peptide), Anaplasma, Ehrlichia, Babesia, Ricketsia, Q fever, Bartonella, Francisella, Mycoplasma, and spiroplasma.
b) Metagenomic analysis of nucleic acid derived from the PBMC pool to search for differences between cases and controls with respect to microbial nucleic acid, as well as host nucleic acid and transcription. This technique has enormous power to identify factors associated with disease that have not been identified using other methods.
c) Consideration of use of an oligopeptide array (McGeer) to examine cross reactivity between XMRV and other murine retroviruses in order to resolve contradictory studies in the literature.

Lyme positive controls should be included to assess sensitivity of the various methods. Specimens will be sought from 2 patients with culture positive late Lyme arthritis and 2 patients with culture positive Lyme neuroborreliosis.

Analysis

The principle analysis would be assessment of the unadjusted OR for murine retroviruses.

Other differences will be evaluated as secondary analyses using crude odds ratios and an adjusted level of significance.

Role of PI

Responsibility for all aspects of conduct of the study:

- Consults with experts and community
- Finalizes protocols for study
- Assures compliance with ethical standards and full consent
- Manages budgets and assures proper use of funds
- Keeps current with relevant literature to avoid duplication of studies done elsewhere
- Supervision of study staff
- Regular meetings with clinic staff

People Consulted in the Development of this Proposal

- Bruce Carruthers, Internist and Specialist in ME/CFS Care (Semi-retired)
- Jan Venter, Family Physician and Practicing Specialist in ME/CFS
- Sherri Todd, National ME/CFS Action Network (BC Chapter)
- Margaret Parlor, National ME/CFS Action Network
- s. 22
- Bill Bowie, Infectious Diseases
- Bonnie Henry, BCCDC
- Patrick Tang, PHSA Labs
- Judy Isaac-Renton, PHSA Labs
- Jennifer Gardy, BCCDC
- Bob Brunham, BCCDC
- Muhammad Morshed, BCCDC
- Tom Perry, Department of Medicine, UBC
- Andy Mason, Department of Medicine, University of Alberta
- Ted Steiner, Infectious Diseases

Appendix 1

Canadian Clinical Working Case Definition for ME/CFS

Patients must have:

1. Fatigue
2. Specifically also Post-exertional malaise or fatigue
3. Sleep dysfunction
4. Pain (usually myalgias or HA)
5. Two or more of a list of neuro-cognitive manifestations
6. At least one symptom from two of the following categories: Autonomic (e.g. bowel/bladder, tachycardia, postural hypotension); Neuroendocrine (temperature disturbance, marked weight/appetite change, etc.); Immune (LAN, sore throat, malaise, new "sensitivities" to foods, allergens, etc.)
7. Duration of illness at least 6 months

Diagnosis also requires systematic exclusion of various endocrine, rheumatologic and neurological causes of similar symptoms.

Budget Considerations

Clinic:
Assumptions:
2 physicians, 2 nurses, small start up seeing maximum 5-6 patients per day 5 day workweek, 7 hours of contact time per day
Assumes that clinic, and setup (computers, etc) are provided using existing resources and space

Item		Annual Cost
Medical Director	0.5 FTE	$125,000
Physician Sessions(specialist)	535 specialist sessions (at 478.66cost) 50 weeks, 5 days a week, 535 sessions per year, and assuming a 3% increase in 2011.	$295,800
Alternate salaried Family physician (1 of each at quoted initial workup would be able to see only 2 per session, 4 per day).	535 FP sessions at 405.78 per session. 535 sessions and assuming 3% increase in 2011	$252,350
Nurse Case Manager or Nurse practitioner	2 position w. Nurse practitioner 92k per yr plus benefits **OR** Senior Nurse: 85k/yr incl benefits:	$210,000
Clerical	* 1 reception, 1 transcriptionist including benefits	$84,000
Screening Lab Tests	For patients – MSP cover	
	For 25 controls – 15 tests at MSP rate	$12,000
Webmaster/communications resources for online presence and ongoing updating	(year one setup costs and website population) In subsequent years costs would likely be 1/3-1/2 less, or 43k-33k .5 staff yr. 1	$65,000
Supplies-office		$5,000
Supplies- clinic		$25,000
Total assuming space and IT support provided		**$1,074,150**

In the event that a higher volume of patients would be seen, the increase might be seen only in the sessional hours, as the nursing and clerical support would be able to support a significant increase.

Comment [a13]: What does the asterix refer to?

Comment [a14]: What is the estimated impact on MSP?

Comment [a15]: One time costs should be separated from annual operating costs.

Study

Comment [a16]: The study should not be part of this proposal.

Item		Cost for Full Study
PI	10%	$ 24,000
Research Nurse	85,000 x 2 years	$170,000
Research Epidemiologist	50,000 half time x 2 years	$100,000
Lab testing PCR	$50 per 3 tests x 100 study samples	$5,000
Indexing of Metagenomic Samples	6,000	$6,000
Sequencing and bioinformatic analysis of samples	100,000	$100,000
Single nucleotide polymorphism (SNP)chips	$325 * 96 study size	$34,944
Lab testing serology	15/test X 10 agents/subject x 100 subjects	$15,000
Genomics lab equipment lease	$11,000/mo x 1 yr	$132,000
Lab tech	1 FTE x 1 year	$70,000
Lab coordinator	0.25 FTE x 1 yr	$25,000
Controls and cost	100 people at 160 per participant	$16,000 honoraria if required
Research oversight committee	4 meetings (includes travel, meeting costs, etc.)	$10,000
Dissemination	Publication costs, conference fees and travel for dissemination.	$10,000
Total		**$717,944**

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