CANVECTOR THE NETWORK NEWS

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CanVECTOR is a pan-Canadian, patient-oriented, Community Development Program centered on venous thromboembolismrelated research, training, and knowledge translation.

Greetings CanVECTOR friends,

When we last wrote, we had just closed off 2017 and entered 2018 with hope, as we waited to hear the verdict on our submitted proposals and reports. We've gotten responses and reviews since then and like most things in life, there's good news and bad news.

Let's start with the bad news: our Letter of Intent to the Networks of Centres of Excellence competition by the Government of Canada was not invited to move forward to the next application phase. Although this was disappointing, the reviews were very positive, suggesting that application pressure was the main reason we did not move onto the next stage. We look forward to the next opportunity to fund our network beyond 2020 (no doubt something is around the corner, e.g. SPOR, team grant, NCE again, etc). We can't win them all (but we will try once again)!

Thankfully, there is much more good news to focus on. Our mid-term review from the CIHR-ICRH international external advisory panel was very positive and the suggestions, helpful. The international reviewers suggested we consider leadership succession planning at all levels of CanVECTOR, grow our basic science activities and focus on sustainability of the network: all advice we are heeding. Our membership renewal exercise over the past few weeks was well-received with the vast majority of members wanting to remain members and asking to become more engaged. We've renewed important partnerships and welcomed new ones; these commitments show the value of our work to our communities on a national scale. We also ran another successful Pilot Trials competition, while the

past funded ones continue to make progress, even to full-scale clinical trials (read our first success story with the COBRRA study on page 2). Our platforms continue to launch important projects (see page 3 to learn more about the Patient Partners platform evaluation project) and proceed with important activities, like our Training, Mentoring, and Early Career Development platform that just closed the Fellowship & Studentship competition and will soon do the same with the Research Start-Up and Travel Awards competition. We've also been busy planning future events and meetings, like the next Trainee Boot Camp in June and not to mention the 3rd Annual Conference! We are pleased to announce that this year's Annual Conference will be hosted by co-Chairs Drs. Shannon Bates and Vicky Tagalakis in Montreal on October 25-27, 2018.

Writing out this long list of positives reminds us of the good that is to come, and the importance to keep on forging ahead – to stay engaged and to stay hungry!

Please remember that if you ever have any suggestions or ideas for the network, drop us a line anytime. Plus I (Marc) am on sabbatical for the next couple of months so I may have a little extra time to answer your e-mails ;)

Happy reading!

Susan R. Kahn

Susan and Marc

The COBRRA journey: from 72 patient pilot trial to 2760 patient full-scale trial

Congratulations on completing the COBRRA pilot trial and securing the funding from CIHR to conduct the full-scale trial at CanVECTOR centres!



An Interview with Dr. Lana Castellucci

1. What questions are the COBRRA pilot and COBRRA full-scale studies addressing?

COBRRA stands for Comparison of Bleeding Risk between Rivaroxaban and Apixaban in patients with acute venous thromboembolism (VTE). The rationale for the trial was based on differences in composite bleeding rates in the EINSTEIN and AMPLIFY trials evaluating rivaroxban and apixaban to warfarin, respectively. In the COBRRA trial, patients with acute VTE are randomized to rivaroxaban or apixaban; these direct oral anticoagulants (DOACs) were chosen because they are the most commonly used for VTE treatment. This is the first study to directly compare DOACs for acute VTE. The COBRRA pilot study was a feasibility study that aimed to recruit 72 patients in 4 centres. One of the unique things about it was that we included 2 established research centres (Ottawa and Hamilton) and two new research sites (Edmonton and Sherbrooke). We also looked at medication adherence in the pilot because rivaroxaban is taken once daily and apixaban is twice daily. In Ottawa we used 3 different tools to monitor this, and the other sites each used two different tools. The pilot study successfully met feasibility requirements and we have now started the full-scale trial. The COBRRA trial is a multi-centre

randomized controlled trial (RCT) and the objective is to evaluate the safety of rivaroxaban and apixaban for treatment of VTE. The primary outcome is clinically relevant bleeding (major bleeding or clinically relevant non-major bleeding). Participants with provoked and unprovoked VTE will be followed in the study for 3 months. Medication adherence will also be evaluated, although in a simpler format compared to the pilot study, using a patient questionnaire.

2. From your experience with the COBRRA pilot trial, was there any aspect that surprised you?

The great thing about the pilot study was that everyone was very excited to help get it off the ground, both locally and at the other participating sites.

3. Was there anything that you learned about the logistics or practical aspects of conducting the COBRRA pilot trial that led to changes to the procedures for the full-scale COBRRA trial?

Yes, the pilot study was designed based on our practices in the Ottawa Thrombosis Unit and we learned that other centres have a different structure, requiring changes to be made.

For example, other sites don't see their patients in person as frequently as we do in Ottawa. To accommodate that, we included a telephone follow-up visit so that coordinators could contact patients by phone to capture the necessary information. We also included this option in the design of the full-scale study.

4. How do you think the pilot trial contributed to your success in the CIHR Project Grant competition?

I think the pilot data was very helpful! Based on reviewer feedback from previous CIHR applications, it was indicated that pilot data would be helpful to inform on the success of a full-scale trial. This was especially important since the full-scale trial has a very large sample size of nearly 2800 patients. At the time that the project grant was awarded, we had nearly completed recruitment for the pilot study, demonstrating feasibility.

5. Can you describe how the start-up for the COBRRA trial was shorter or easier due to the groundwork that was done for the pilot trial.

In Ottawa, the pilot study definitely made the transition to the full-scale study easier. The research team was already familiar with eligibility criteria and screening processes, making it a relatively simple transition. This also worked well for 2 of our pilot sites, Edmonton and McMaster, which are already up and running for the full-scale study. McMaster has recruited 2 patients since opening a week ago!

6. At what stage is the COBRRA trial at now?

We're in our first 6 months. We opened in Ottawa in December and have recruited approximately 75 patients. Several CanVECTOR centres will be participating in the trial and are currently under review for ethics and contracts.

7. How many sites are you expecting to participate in the study?

We anticipate that 12-15 sites are needed to participate in the COBRRA trial.

8. How can members learn more about the COBRRA trial and possibly join the study as a participating centre?

We would be very happy to hear from anybody who is interested in participating or in hearing more about the study! You can <u>contact me</u>, or the multi-centre coordinator, <u>Yan He</u>. There is also information on <u>CanVECTOR</u>'s website and <u>ClinicalTrials.gov (NCT03266783)</u>.



WE CAN NOW ANNOUNCE THE WINNERS OF THE PILOT TRIAL COMPETITION! Congratulations to: Dr. Kerstin de Wit and Dr. Aurelien Delluc! Dr. de Wit will be leading the PEITHO-III pilot study in Canada and Dr. Delluc will lead the splanchnic vein thrombosis pilot.

The Patient Perspective: The Patient Partners Platform Kicks-Off its Evaluation Plan

With patient engagement being such a recent and novel approach in health research, the Patient Partners platform is keen to undertake an evaluation of its patient engagement program. This will allow the gathering of precious feedback to help shape how we move forward, as well as contribute to the science of patient engagement and hopefully, establishing best practices in the field. We are partnering with the Centre of Excellence on Partnership with Patients and the Public (<u>https://ceppp.ca/en/</u>), based at the University of Montreal for this endeavor. For those who were in attendance at CanVECTOR's annual conference last November, Dr. Agustina Gancia presented an overview of our evaluation plan.

OUR PROGRAM EVALUATION HAS THREE MAIN OBJECTIVES:



Monitor and understand patient engagement practices through the "life-course" of funded research projects and the network;



Assess the **experience of patients and researchers** collaborating as partners;



Understand factors that influence perceived partnership success, including characteristics of research context and partnership support.

We are now preparing to solicit the participation of many key stakeholders within the network, including member researchers, research coordinators, patient partners, and members of the Scientific Steering Committee and the External Advisory Board. Consent forms will be sent out by email, followed by two questionnaires which will be sent via the REDCap online platform in this first phase.



Now that you have a better understanding of our evaluation project, we may be calling upon you to participate! Just like every recruited patient is valuable and necessary to a clinical trial's success, every questionnaire IF YOU ARE SENT AN INVITATION AND CONSENT TO PARTICIPATING, YOU WILL RECEIVE THE FOLLOWING QUESTIONNAIRES:



The Readiness and Partnership Initiation Questionnaire (also known as the Inception Questionnaire), which aims to identify if the governance and management, vision, priorities, roles and responsibilities, and communication and dissemination plans were established before launching the strategy or program

CEPRM – Community Engagement and Participation in Research Measure Questionnaire, which aims to measure current patient engagement in research by quantitatively scoring 11 dimensions of engagement. Survey respondents will be asked to rate each item on a qualitative scale (how v the organization applies the dimension) and quantitative sc

the organization applies the dimension) and quantitative scale (how often patient engagement actions are taken).

completed will be invaluable to the completion and success of this evaluation and the progress of the Patient Partners platform. Keep your eyes on your inbox for this potential opportunity!

Focus on our Acknowledgement Policy

With ISTH and other conferences coming up, it's essential to know how to acknowledge CanVECTOR in your work!

Any study that is supported by CanVECTOR funds or resources (e.g. shared platforms or tools, meeting space at our Annual Conference, collaboration through the Clinical Investigators Group [CIG] meetings or teleconferences) is to be identified as a *CanVECTOR Study* and must be attributed as such in all communications (e.g. abstracts, oral presentations, publications). Even if not directly supported by Network funds or resources, if a multicenter study is conducted by one or more CanVECTOR investigators and has benefited from discussion at CIG meetings, they are encouraged to note CanVECTOR in the acknowledgement section of articles, as described to the left.

In written communications, attribution consists of adding to the Acknowledgements: "this study was supported by (or was funded by) the CanVECTOR Network; the Network receives grant funding from the Canadian Institutes of Health Research (Funding Reference: CDT-142654)"

CanVECTOR Fellows or Students must note support by the CanVECTOR Network in all presentations, publications, grant applications (related to their funded project) and in their CVs.

In CanVECTOR study-related oral presentations and research posters, the CanVECTOR logo should be used on all oral presentation slides and posters.





To read the complete Acknowledgement Policy, find it on the Member Portal under **Documents > CanVECTOR Documents** folder.

News & Updates



Marc Carrier; co-PI:

Phil Wells) recently

of 574 patients!

Congratulations to

the entire study team

– we look forward to

reading the results!





full/10.1056/ NEJMoa1712746

practice-changing work. You can read the abstract and access the article at this link: www.nejm.org/doi/

Trainees and early career investigators, mark your calendars! We will be hosting a Trainee Boot Camp in Ottawa, ON on June 22, 2018. The topic will be: "Scientific Writing for Publication". More details forthcoming.

We are pleased to announce the winners of the CAEP-CanVECTOR Research Abstract awards. These will be presented at the CAEP 2018 Conference in Calgary, AB. Congratulations to:

- Dr. Venkatesh Thiruganasambandamoorthy for his abstract entitled: "Prevalence of pulmonary embolism among emergency department patients with syncope: a multicenter prospective cohort study"
- Dr. James Andruchow for his abstract entitled: "A randomized controlled trial of electronic clinical decision support to reduce unnecessary CT imaging for patients with suspected pulmonary embolism"

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WHAT IS IT? The chance to win an international

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The Call for Proposals is here. The deadline to apply is June 8, 2018.



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Canadian Venous Thromboembolism Clinical Trials and Outcomes Research Network

The Network News is published three times a year.