

9

YORK REGION EMERGENCY MEDICAL SERVICES PARTNERSHIP WITH SOUTHLAKE REGIONAL HEALTH CENTRE IN THE ATLANTIC CARDIAC CARE STUDY

The Community and Health Services Committee recommends the adoption of the recommendations contained in the following report dated April 25, 2012, from the Commissioner of Community and Health Services.

1. RECOMMENDATIONS

It is recommended that:

1. Council approve York Region's partnership with Southlake Regional Health Centre and York Primary Percutaneous Coronary Intervention Group for the participation of York Region Emergency Medical Services in the Administration of Ticagrelor in the Catheterization Lab or in the Ambulance for New sT elevation myocardial Infarction to open the Coronary artery (ATLANTIC Cardiac Care Study).
2. The Commissioner of Community and Health Services be authorized to execute the necessary contracts on behalf of York Region for this project.
3. Staff report back to Council on the outcomes of the study.

2. PURPOSE

This report seeks Council's approval for York Region Emergency Medical Services (EMS) to participate in the ATLANTIC clinical study (Administration of Ticagrelor in the Cardiac Catheterization laboratory or in the Ambulance for New sT elevation myocardial Infarction to open the Coronary artery - abbreviated to ATLANTIC). ATLANTIC is an international multicentre clinical study that will evaluate the administration by paramedics of a medication called Ticagrelor, for its effectiveness and its benefit in treating a specific type of heart attack prior to hospital admission.

Ticagrelor is currently administered as part of standard in-hospital care to heart attack patients.

3. BACKGROUND

Surviving a heart attack requires prompt attention and specific treatment interventions

When the blood supply to the heart muscle is slowed or stopped because of a blockage, a heart attack occurs. Atherosclerosis, the narrowing of coronary arteries due to plaque build-up, causes more than 90% of heart attacks. The length of time the blood supply is cut off determines the severity of damage to the heart muscle.

Currently, York Region EMS paramedics transport patients suffering from heart attacks, which meet specific clinical and time criteria, directly to the cardiac catheterization laboratory at Southlake Regional Health Centre.

Interventional cardiologist at Southlake Regional Health Centre developed a research proposal to study the early administration of Ticagrelor

The interventional cardiologists providing care at Southlake Regional Health Centre work collectively as the York Primary Percutaneous Coronary Intervention (PPCI) Group, providing outpatient care and participation in clinical research. The York PPCI Group developed a research grant proposal to evaluate the early administration of Ticagrelor. The funding grant proposal was submitted to Astra Zeneca, the pharmaceutical manufacturer that produces Ticagrelor.

Astra Zeneca had provided funding to establish an existing international clinical trial assessing the administration of Ticagrelor by paramedics

An existing international clinical trial evaluating the early administration of Ticagrelor was already established by Astra Zeneca. Results will not be published until the trial is complete. The trial is deemed completed when 2,000 patients have been enrolled worldwide. To date, 309 patients have been enrolled. The York PPCI Group was granted approval to join the Canadian arm of the ATLANTIC trial. The ATLANTIC clinical study will evaluate if Ticagrelor is beneficial and more effective than the current treatment for heart attacks when it is administered early in the pre-hospital environment by paramedics and is then followed by care in the cardiac centre. Industry involvement is common in clinical research. Furthermore, trials must meet stringent research ethics and privacy integrity approvals to ensure ethical conduct.

ATLANTIC is a multi-national study

It is anticipated that other Canadian EMS agencies will be involved with ATLANTIC including Edmonton, Winnipeg, St. John, Halifax, and St. John's. The Canadian arm of the study is coordinated through the University of Alberta, with Dr. Robert Welsh as the study coordinator. Locally, the ATLANTIC clinical study will be overseen by Dr. Warren Cantor, interventional cardiologist, Southlake Regional Health Centre. The lead

coordinating investigator for the study is Professor Gilles Montalescot, Institut de Cardiologie, Unité de Soins Intensifs de Cardiologie, Hôpital Pitié-Salpêtrière, Paris, France. Internal reviews will be conducted every three to four months until the completion of the study, by a third party appointed by the Data Safety Board of Astra Zeneca.

York Region EMS has participated in previous research studies with pending results

York Region EMS has successfully participated in a number of past studies. Most recently, York Region EMS was only one of two sites in Canada that participated in a cardiac care study called Strategic Reperfusion Early After Myocardial Infarction (STREAM). The trial evaluated the impact of patients diagnosed with a specific type of heart attack receiving clot dissolving drugs and direct admission to the Southlake Regional Health Centre cardiac catheterization laboratory versus direct admission to the Southlake Regional Health Centre cardiac catheterization laboratory. York Region EMS has been informed that the official results are pending.

York Region EMS paramedics successfully enrolled 25 patients into the study. STREAM was an opportunity that demonstrated that York Region EMS administrative and front line staff are capable of participating in high profile, complex, international clinical trials with a high degree of reliability and clinical competence.

In August 2008 York Region EMS began participating in clinical research in partnership with Research Outcomes Consortium, an international research effort evaluating a number of interventions provided by paramedics for critical patients and staff is awaiting the study results.

4. ANALYSIS AND OPTIONS

The Central East Pre-Hospital Care Program will provide medical delegation and clinical oversight

The Central East Pre-Hospital Care Program provides York Region EMS with medical delegation, continuing medical education and clinical care review. The required medical delegation and oversight to participate in the ATLANTIC study will be provided by the Central East Pre-Hospital Care Program.

Paramedics will administer Ticagrelor under the authority of a cardiologist to consenting study participants

Currently, York Region EMS paramedics transport patients suffering from heart attacks with specific indications, including electrocardiogram findings and time from symptom onset, directly to the cardiac centre at Southlake Regional Health Centre. Patients who do

not meet these indications are transported to the closest hospital. This practice will remain unchanged with ATLANTIC.

Under the study protocol, paramedics will complete a standardized informed consent document and will administer Ticagrelor under the authority of an interventional cardiologist while in transit to the cardiac centre at Southlake Regional Health Centre.

Personal health information is protected

The ATLANTIC study utilizes an electronic case record, which is housed with an independent company and at arms length of the sponsor. Data will be de-identified and patient confidentiality will be assured.

ATLANTIC adheres to Canada's federal privacy law, *Personal Information Protection and Electronic Documents Act*, and the Ontario health information privacy legislation, *Personal Health Information Protection Act 2004*, in preserving patient confidentiality. We have consulted with Risk Management and Legal Services staff to protect the Region's interests.

Link to key Council-approved plans

This report directly contributes to supporting the 2011-2015 Strategic Plan objective to *optimize the health of the community for all ages and stages through health care delivery, protection, prevention and promotion*.

5. FINANCIAL IMPLICATIONS

Southlake Regional Health Centre will supply the medication to be used in the study at no cost to York Region. No additional costs will be incurred by York Region to participate in the ATLANTIC clinical trial and existing staff resources will support the initiative.

6. LOCAL MUNICIPAL IMPACT

All lower tier municipalities will have access to evidence-based pre-hospital care protocols during transport to Southlake Regional Health Centre. After receiving their initial care, patients will be repatriated back to their local hospitals to recover and be closer to home and family.

7. CONCLUSION

Participation in the ATLANTIC study project is an opportunity for York Region EMS paramedics to provide the most appropriate treatment strategy to heart attack patients.

It is recommended that York Region EMS participate in the ATLANTIC clinical study.

For more information on this report, please contact Norm Barrette, Chief and General Manager, Emergency Medical Services, at Ext. 4709.

The Senior Management Group has reviewed this report.