

## The Vascular Intervention Program (VIP)

*A randomized controlled trial of patient-centered education and multidisciplinary intervention to reduce risk factors for cardiovascular disease.*

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## Background and Rationale

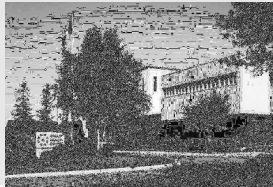
- CV disease #1 cause of mortality
- Higher incidence in Algoma
- 9 modifiable risk factors account for over 90% of the risk of myocardial infarction
- Predictable, therefore preventable
- RCT evidence for risk factor reduction as part of cardiac rehab
- Little practice based evidence for primary prevention

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## Group Health Centre

- Established 1963
- Multi-disciplinary, multi-specialty, multi-site
- > 62,000 enrolled patients
- Electronic Medical Record (EMR) since 1997



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## Goals and Objectives of VIP Demonstration Project

1. **Decrease** the modifiable **risk factors** for primary care patients at risk for vascular disease in the Algoma District.
2. **Increase** the **participation of the patient and family** in decision-making, self-care, and adherence to agreed-upon management plans.
3. **Increase collaboration** between family physicians, pharmacists, physiotherapists, dietitians and nurses in the community.
4. **Improve** patients' **access** to care, clinical outcomes and satisfaction.
5. **Provide a business case** for a practical, sustainable and generalizable model for the primary care of vascular disease in the community.

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## Primary Research Question

*What is the effectiveness of a Vascular Intervention Program after 6 and 12 months on the cardiovascular ACTION Score versus usual care (control) for a group of moderate/high risk CV patients at the Group Health Centre in Sault Ste. Marie (Algoma District)?*

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## Secondary Research Questions

- What is the effectiveness of a Vascular Intervention Program versus usual care (control) for a group of moderate/high risk CV patients at the GHC in SSM after 6 and 12 months on:
  - Individual components of the ACTION Score (e.g. BP, lipids, exercise, diet, etc.)?
  - Patient satisfaction?
  - Quality of life?
- How has the VIP increased collaboration between family physicians, pharmacists, physiotherapists, dietitians and nurses at the GHC and in the community?

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## Methods

### Design:

- Randomized Controlled Trial of medium and high risk patients

### Sample:

- Self or physician referral – Algoma District
- Informed consent
- Risk stratification into low, moderate, high
  - Framingham score of at least 12
  - Hx of diabetes or vascular disease
- Questionnaires, clinical evaluation

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## The Intervention: The Vascular Intervention Program (VIP)

Patient-centred, community-based, multi-faceted program that promotes:

- Self-management, family participation and support in health care decision-making;
- Interdisciplinary health care provider collaboration; and
- Better use of information technology to improve the management of vascular disease.

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## The Intervention (continued)

- Based on Chronic Care Model
- Patient-centered decision-making with a study nurse
- VIP workbook, Heart & Stroke
- ACTION score
- ACTION plan: patient priorities, readiness to change
- Referral to allied health team members
- Collaboration
- Cohesive approach

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## Referral to other team members

- Exercise program (VIPEX)
- Algoma Diabetes Education and Care Program – diabetes educators
- Healthy Measures lifestyle education program
- Dietitians / classes / label reading
- Smoking Cessation Counsellor
- Counselling -- stress management / depression (individual and group)
- Congestive Heart Failure Program
- Anticoagulation Program
- Pharmacist

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## Measurement

- **Using questionnaires, measurements, lab, ECG**
  - Telephone follow-up
  - Nurse contact every 6 months for evaluation purposes and in between as needed for clinical situation
- **ACTION score & components**
  - Assessment of **C**ardiovascular **T**reatable **I**ntervention **O**utcome **N**omogram
  - Evidence-based
  - 10 x 10 table
  - Maximum score: 100

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## ACTION Score

Risk Factors	1	2	3	4	5	6	7	8	9	10
Patient/Family History	< 40 or known CVD, DHD, PAD	Age < 45	Age < 50	Age < 55	Age < 60 or unknown history	Age < 65	Age < 70	Age < 75	Age > 75	No History
Diabetes	Type 2 > 30yrs or Type 1	Type 2 > 20yrs	Type 2 > 10yrs	Type 2 > 5yrs	Type 2 > 10yrs	Type 2 > 5yrs	Type 2 < 5yrs	N/A	IGT or IPIG***	None
Blood Pressure	> 180 / or 110	< 180 / 110	< 160 / 100	< 150 / 95 with meds	< 150 / 90 without meds	< 140 / 90 with meds***	< 140 / 90 without meds	< 130 / 80 with meds****	< 130 / 80 without meds	< 120 / 80 without meds
Lipid (LDL)	> 4.0	< 4.0	< 3.75	< 3.5	< 3.25	< 3.0	< 2.75	< 2.5	< 2.25	< 2.0
Smoking Status (in months)	> 1 pack / day	< 1 pack / day	Second Hand Smoke or Quit < 3	Quit > 3	Quit > 6	Quit > 9	Quit > 12	Quit > 18	Quit > 24	Never Smoked
Nutrition	0-9	> 10	> 20	> 30	> 40	> 50	> 60	> 70	> 80	> 90
Abdominal Girth	M > 120cm F > 110cm	M < 120 F < 110	M < 115 F < 100	M < 110 F < 100	M < 105 F < 95	M < 100 F < 90	M < 95 F < 85	M < 90 F < 80	M < 85 F < 75	M < 80 F < 70
Activity Level	None	< 30min / week	> 30min / week	> 60min / week	> 90min / week	> 120min / week	> 150min / week	> 200min / week	> 260min / week	> 300min / week
Physiologic Age	5	n/a	4	n/a	3	n/a	2	n/a	1	0
Psychosocial	0-1	2	3	4	5	6	7	8	9	10

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## Measurement

### Multiple secondary outcomes:

- Quality of Life – EQ5D
- Patient satisfaction – CSQ-8
- Motivation questionnaire (Prochaska)
- Eating assessment
- International Physical Activity Questionnaire (IPAQ)

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## Analysis

### Patient characteristics:

- Descriptive statistics

### ACTION Score (primary outcome):

- Analysis of covariance (ANCOVA) for individual ACTION score components, as well as the overall ACTION score

Multiple imputation was conducted, however results were similar with imputed and non-imputed data; therefore results using non-imputed data are presented.

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## Qualitative Substudy

Content analysis of data from focus groups:

- Separate groups per health care provider
- Semi-structured interview guide, facilitator, taped, transcribed, cleaned
- Pre: 29 participants in 4 groups
- Post: 20 participants in 4 groups

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## Results: Patient Characteristics

660 patients screened; 420 were enrolled in the study

Characteristic	Intervention N=208	Control N=212
Sex (% male)	55.3	53.3
Age (mean, SD)	65.2 (10.2)	64.3 (9.2)
Diabetes (%)	49.5	55.2
Hypertension (%)	76.0	73.6
Hyperlipidemia (%)	68.8	74.5
MI (%)	25.0	21.7
Stroke (%)	6.7	3.3
Current smoker (%)	11.5	8.5
Current alcohol	2.9	2.9

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## Change in total ACTION Score (out of 100)

Intervention vs. Control after 6 months ( $n = 196$  I,  $192$  C)

- 3.19 (95% CI 1.48 to 4.91;  $P = 0.0006$ )

Intervention vs. Control after 12 months ( $n = 177$  I,  $168$  C)

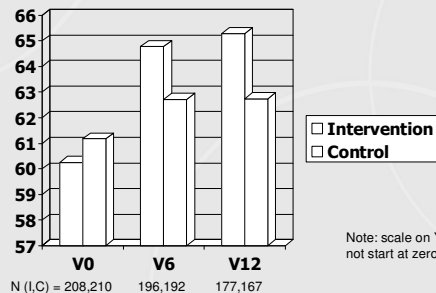
- 3.84 (95% CI 2.31 to 5.38;  $P < 0.0001$ )

- Main components contributing to change: blood pressure ( $P = 0.002$ ), nutrition ( $P = 0.0003$ ), activity level ( $P = 0.004$ ), physiological age ( $P = 0.002$ ), abdominal girth ( $P = 0.08$ )

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## Change in Total ACTION Score



N (I,C) = 208,210 196,192 177,167

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Comparison of proportion of patients (%) in each group with a change of 1 or more on the ACTION Score at 12 months

Risk Factor	Intervention (n=177)		Control (n=169)		P-value
	> -1 / no Δ	< 1 Δ	> -1 / no Δ	< 1 Δ	
Family history	100	0	98.2	1.8	0.20
Diabetes	99.4	0.6	99.4	0.6	0.81
Blood pressure	45.7	54.3	62.1	37.9	0.007
Lipids	68.9	31.1	66.3	33.7	0.80
Smoking	86.4	13.6	92.3	7.7	0.04
Nutrition	35.0	65.0	50.9	49.1	0.009
Abdominal girth	59.9	40.1	69.2	30.8	0.045
Activity	53.1	46.9	69.2	30.8	0.0036
Physiologic age	66.1	33.9	78.7	21.3	0.016
Psychological	49.1	50.9	56.2	43.8	0.25

## Patient Satisfaction

Client Satisfaction Questionnaire - 8 (max score = 32)

Visit	Intervention n=210	Control n=210	Difference, (95% CI); p value
V0	26.77 (SD 3.19)	26.73 SD (3.56)	
V6	27.92 (SD 4.06)	25.42 (SD 4.30)	2.50 (1.65, 3.35), p<0.0001
V12	28.55 (SD 3.89)	25.21 (SD 4.32)	3.33 (2.46, 4.21), p<0.0001

## Quality of Life

- EuroQol 5-D questionnaire, max score 100
- Both groups improved
  - Intervention (63 to 70)
  - Control (64-69)
- No significant difference between groups

## Qualitative Substudy: Collaboration

- Participants did not feel VIP improved collaboration because:
  - Well-established norms of behaviour are difficult to change
  - Some patients already had a high ACTION Score, therefore little change
  - Lack of understanding of expectations and roles
- Greater information sharing noted due to VIP

## Qualitative Substudy: Collaboration

- Patients and team identified the potential to improve with greater familiarity with VIP tools (templates, VIPNet) and changing processes of care
- Facilitators:
  - Patient focus
  - Electronic record
  - VIPNet
- Barriers:
  - Access to caregivers (location, schedules)
  - Lack of clarity of some communication
  - Limited involvement of pharmacist

## Qualitative Substudy: What is needed to improve collaboration?

- Standard documentation tools
- Feedback from program
- Meetings to share information and foster collaboration
- Flexible patient scheduling

## Discussion

- A patient-centred, nurse-led, collaborative and comprehensive program was found to produce early obvious benefits in certain areas: BP, nutrition, activity level, physiologic age
- VIP improved patient satisfaction with health care
- No change in Quality of Life detected
- Numerous barriers and facilitators to collaboration identified

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## Project Design Limitations

- Unforeseen delays in promoting the project resulted in delayed recruitment of patients
- Higher than expected improvement in ACTION scores of control patients may have been biased by:
  - Heart & Stroke information provided by study nurses
  - Learning about test results
  - Communication with intervention group members (sometimes spouses were intervention)

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## Lessons

- Study was complex and perhaps overly ambitious
- Time is required for:
  - Developing and implementing new systems
  - Allowing for fully collaborative working relationships
- Patient involvement and motivation is a key component of health care, especially management of chronic disease

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## Lessons (continued)

- Regular follow-up and assessment
- Education must be adapted to the needs and comprehension of the patient
- Clear communication and role definition
- The pace of change may be slow, and not recognized by a scoring system, yet still may be meaningful to the patient
- Generalizable to other settings

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## VIP Study Team members

Investigators: Drs. Aktar-Danesh, Catania, Ciliska, Crookston, Dolovich, Goeree, Govig, Holbrook, Hutchinson, Lee, Maloney, Nolan

Managers: Elaine Blakeborough, Sharon Cuddy

Nurses: Karen Barban, Cathy McCullough, Tracey Maitland, Susan McLean, Toni Oprici

Physiotherapy & Kinesiology: Maria Fera, Domenic Sorrenti

Information Technology: Csaba Huszka, Joshua McColeman

Pharmacy: Ron DeLuco, Carla DeLuco, Martin Engel

Assistants: Nancy Juby, Joanne Sloss, Tracey Wetzi

Statistical Analysis: Mahbulul Haq

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