Shifting the Paradigm in Health Care

“A patient centric strategy for community-based management of chronic disease”
“Healthcare providers are coming to recognize their role in shaping behavior and the importance of having an ongoing relationship using sophisticated customer relationship software tools which enables them to coach patients. Innovative groups will have a “patient centric” focus through the integration of behavior shaping tools with systems that inform and facilitate patient compliance to “evidence based” treatment plans”

(Institute for Alternative Futures)
Global Forces of Change

Evidence-based medicine

Proliferation of clinical guidelines (diabetes, heart disease, kidney disease, hypertension)

Information (Internet) is shifting the base of power from the physician to the patient (patient centric medicine)
Global Forces of Change

Chronic disease is a growing problem that consumes a significant proportion of health care expenditures.

Diabetes – annual costs in Canada - $9 billion USD – direct costs $2.6 billion (8% of total Canadian health care expenditures in 1998) *

Technology is moving testing to the “point-of-care” – mobile clinics, community based wellness programs – results given to the patient together with medical information

The Drivers of Change within the Canadian Healthcare System
Chronic Disease - Today’s Aging Reality

CVD, diabetes, renal disease - costly problems and the incidence is increasing. Lifestyle issues impact all of these diseases.

Poorly managed by clinicians
*CMAJ 2004;171:1189-1192
*Can J Cardiology 2008; 24:363-368*

Evidence based treatment – proven to reduce morbidity and mortality

Patient compliance to treatment is poor
*Circulation 1997;95:1085-1090*

Successful treatment requires ongoing patient education, commitment and reinforcement
What are the Challenges?

Reduce morbidity

Reduce hospitalizations

Reduce physician workload

Reduce management costs

Reduce patient wait times

Improve accessibility
The Current System

Patient calls to make appointment with their physician

Attends (days later) and waits to see physician (travel ($10), parking ($5), two hours of patient’s time ($50), physician’s office visit ($26.53)

Blood work ordered
The Current System

Patient travels to blood collection center – HbA1c, lipids, creatinine, glucose, eGFR – travel ($10), parking ($2.50), one hour of patient’s time ($25), tests ($51.64)

Follow-up visit to physician - (travel ($10), parking ($5), two hours of patient’s time ($50), physician office visit ($26.53)

Total: $262.69
Is there an alternative approach?
The incidence of chronic disease in the population is growing and chronic disease is a driver of future costs.

The adherence to evidence based treatment guidelines is required for the cost-effective management of chronic disease.

The rate of patient compliance to treatment is a key predictor of future disease burden and costs.

Future healthcare costs can be reduced by increasing the rate of patient compliance to the treatment of chronic disease.
Chronic disease is a driver of future cost

Adherence to evidence-based Rx is integral to managing chronic conditions

The rate of patient compliance to treatment is a key predictor of future disease burden and cost

Future healthcare costs can be reduced by increasing the rate of patient compliance to the treatment of chronic disease

Therefore:

Implement a community-based “patient centric” system that will provide direct access to blood tests and health care information delivered through a telecommunications system specifically designed for improving patient compliance
The “patient centric” Strategy

Empower the individual – move selected tests to the community for direct access by the patient, capitalize upon resources in the community to assist in chronic disease management and to increase compliance

Broaden the scope of practice for pharmacists and other healthcare providers to include blood tests at “point of care” (HbA1c, lipids, creatinine, glucose, eGFR, INR)

Provide test results to the patient together with information on what the tests mean and what they may do to improve their health.

Provide supportive messaging for enhancing lifestyle modifications and compliance to treatment. Copy of results to physician
The Benefits

Reduced morbidity – better patient compliance

Reduced hospitalizations – better patient compliance

Reduced physician workload – fewer patient visits

Reduced management costs – fewer office visits, fewer repeat blood tests, standardized testing, standardized messaging, aggregated outcome data, centralized purchasing
The Benefits

Reduced wait time – one hour vs 5 hours of patient’s time

Improved accessibility – available locally – closer to home

Savings to MSP ($51.64)

Savings to the patient ($137.50)

Total savings (short term): $189.14 (72% decrease)

Additional savings longer term (enhanced compliance with reduced morbidity)

Reduced patient load burden in the physician’s office
Questions?

POCT cost/benefit analysis – is it worth it?

Is community based POC testing occurring in Canada?

If so, are the test results any good?

What would a community based program look like?
CADTH

The Canadian Agency for Drugs and Technologies in Health (CADTH)

“A national body that provides Canada’s federal, provincial and territorial healthcare decision makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies”
CADTH

Point–of–Care Anticoagulation Monitoring Devices: A Better Alternative?

This document highlights key findings from a Canadian Agency for Drugs and Technologies in Health (CADTH) health technology assessment report on the clinical and cost effectiveness of point-of-care monitoring devices for long-term anticoagulation therapy (www.cadth.ca)
Oral Anticoagulation Therapy (OAT)

Prevents thromboembolic events in those patients that have an increased risk of forming blood clots

The international normalized ratio (INR) is used to monitor the effectiveness of anticoagulation ("blood thinning") therapy

Frequent monitoring of INR is crucial to ensuring an appropriate level of anticoagulation therapy - too high can lead to bleeding; too low may lead to clots

Traditionally, monitoring is achieved through regular visits to a laboratory or hospital where blood is taken and INR tested
Alternatives to usual care for the monitoring of anticoagulation therapy exist in the form of portable point-of-care (POC) testing devices.

But how well do POC anticoagulation monitoring devices work?

Do they offer value-for-money or cost savings to the health care system?

Are there factors, such as convenience, enhanced compliance that should be considered?
OAT management with traditional laboratory testing:

Patients are usually sent to a lab for testing

Once results are available, they are sent to see their doctor

Any necessary changes in therapy are then ordered by their doctor
OAT Management Options with POC

Location
The device may be used in an anticoagulation clinic, a nursing home, a doctor’s office, or a patient’s home (self-testing)

Self-testing
Patients can self-test and then inform healthcare provider of the results; necessary changes in therapy initiated

Self-management
Patients could self-manage their OAT by testing and then self-adjusting their dose as necessary
Key Findings
POC monitoring devices can improve health outcomes

- Fewer deaths
- Fewer thromboembolic events
- Better INR control
- POC monitoring devices can reduce costs:
  - Cost savings for health care payers when used in a clinical setting

Additional resources would be required to implement the use of POC devices in anticoagulation clinics or for patients eligible for self-testing at home.
Patient self-testing has not been shown to be cost effective for Canada’s publicly funded system (*dws: assumes traditional delivery model*) – but it is for society if patient and caregiver time and travel costs are considered.

Evidence suggests that in anticoagulation clinics, patients prefer POC testing to usual care.

Patients who continue self-testing and self-management with POC devices prefer it to usual care.
INR Testing in the Community

There are over 200 pharmacies in Canada today that are providing INR testing to their customers.

This testing is being monitored through the use of a common external proficiency testing program.

Assessment criteria – PGM +/- 2 SD

Participants (n=200) – as of the last challenge – there were 5 failures.
Canadian First Nations

Age-adjusted prevalence rate for Type 2 Diabetes for on-reserve First Nations people – 17.2%

Age-adjusted prevalence rate for Type 2 Diabetes in non-aboriginal population – 5%

Diabetes screening in First Nations communities remains sub-optimal

Can POCT testing for HbA1c replace the need for a fasting glucose and a glucose challenge test for the diagnosis of Type 2 diabetes on First Nations Reserves?
Diabetes screening programs are operating on First Nations reserves in British Columbia, Alberta and Manitoba

Cholestech LDX analyzers: TC, TG, HDL, Glucose, calculated LDL

DCA 2000: HbA₁c, urinary albumin/creatinine ratios
S.L.I.C.K
Screening for Limbs, Eyes, Cardiovascular and Kidney Program
Meeting the Challenge

“How best to ensure that testing at the “point of care” is comparable in quality to the testing that is carried out in centralized medical laboratories”
What are the Requirements?

Provide test results that are accurate and traceable to a defined base of accuracy.

Make sure that the test results are reported in a uniform and consistent manner.

Reporting system should promote the uniform interpretation and application of evidence-based guidelines. Use common reference intervals, critical limits, reporting comments.
What are the Requirements?

Provide consistent test results over time for uniform monitoring and treatment decisions

Have systems that confirm the accuracy and quality of the test results produced

Standardize instrumentation, reagent supplies and calibration. Allows testing data from different sites to be merged for trending, assessing outcomes and formulating health care policy
Understanding the Challenge

Health care workers, patients, the lay public

“looks simple – can’t be that complicated”
“blind faith in the test results”
“surely the instrument couldn’t be sold if it wasn’t giving the correct answer”

Minimal to no experience or formal training in laboratory procedures
Understanding the Challenge

Lack of appreciation for the operating procedures that are required to ensure a quality test result

Poor understanding of the need for quality control
(“too time consuming”, “too expensive”, “don’t see why we need to do it”, “its always in control so why continue to do it”)

Unfamiliar with the potential sources of error (pre, analytical and post)
Cholestech
Baseline performance assessment data for a Cholestech analyzer prior to its release for use in a mobile diabetes screening program that was to operate on First Nations Reserve in Alberta
Cholesterol

$y = 0.9954x + 0.0802$

$R^2 = 0.903$
HDL

$y = 0.9103x + 0.1116$

$R^2 = 0.9874$
$y = 0.9578x + 0.342$

$R^2 = 0.8982$
Glucose

$y = 0.9078x + 0.4936$

$R^2 = 0.9967$
The reagent lot specific performance for this analyzer was assessed at CEQAL and considered to be acceptable.

The analyzer was approved and released for use in the field together with a human serum accuracy based Internal Quality Control program (IQC).
Internal Quality Control Program

Fresh human serum pools, two levels, no additives or stabilizers. Target values assigned by CRMLN credentialed reference methods as operated at CEQAL

IQC performance limits established – blue line correct answer, values between the green lines are “ok”, values outside of the red lines indicate problem – don’t report patient results
Marked shift occurred in the IQC results between run 25 and 26.

Why?
Comments from the Field

I think I tested the same sample twice

Forgot to write down the result

Using up reagents – been out of fridge for more than one month

Reagents not warmed up

End of clinic – didn’t bother to repeat

Used outdated reagents – will try again
Comments from the Field

I think there were bubbles in the pipette

Controls went missing – don’t know why

Possible air in the pipette – will rerun tomorrow

Guess I must have used the wrong sheets

Someone else ran the test
What were the Findings?

Discovered that two types of cassettes were being used; TC + glucose and lipid panel + glucose

Performance of the TC + glucose cassette had not been evaluated

There had been a change in reagent lot number and the change had not been recorded

A number of out of range IQC values had not been recorded
What were the Findings?

A number of different reagent lot numbers from Cholestech were then used to measure total cholesterol in the same human serum IQC sample (orange)

Duplicate values graphed. First data point (original lot used in pre-launch baseline studies)

Blue line is the correct answer, between red lines is acceptable. Note significant between lot variation in results produced
# Cholestech Uncorrected Lipid/Glucose IQC Data

Alberta SLICK

This spreadsheet is to be used ONLY for the following:

- **Lipid /Glucose IQC Lot#**: 200702
- **Cholestech Reagent Lot #**: C107111
- **Cholestech Instruments**: ALL
- **expiry**

1. Enter information into each column from left to right. The lot # of IQC is on each vial, enter lot # from vial you are using.
2. If your Lot # entries are green, you may proceed with IQC testing. If lot # is red, you are using the wrong spreadsheet.
3. Enter IQC results from the Cholestech print-out into the appropriate columns.

**GREEN = GO Proceed With Patient Testing**

**RED = STOP Do Not Proceed With Patient Testing**

4. Enter patient data from Cholestech print-out into the "Patient Lipid/Glucose Data: Regression Correction" spreadsheet.

## Cholestech Uncorrected Results in mmol/L

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POC Testing - Field Data

HbA1c as measured in BC Bio – TE = 2.9%
*(Turbidimetric Inhibition Immunoassay)*

HbA1c as measured at POC – TE = 4.8%
*(Siemens/DCA 2000)*

Recommended performance criteria for clinical laboratories in North America – TE = 7%
What are the current laboratory licensing requirements in BC?

Is a medical laboratory license required for the provision of POC testing in the community in BC?

Do community based POC testing sites in BC have to be accredited?
Laboratory licensing in BC

Medical laboratories must be licensed to be reimbursed by government for their tests

Only licensed and accredited medical laboratories can bill the healthcare system for lab tests

Drawing of blood for diagnostic purposes is deemed to be a medical act and must be done under the supervision of a licensed physician (College of Physicians and Surgeons)
Laboratory licensing in BC

What about point of care testing?

Point of care testing is currently being operated in pharmacies and community health centers.

This testing is being done and done so without licensure.

The healthcare system is not being billed for these tests and as such a licensure is not a required.
Laboratory licensing in BC

What about point of care testing?

In that the facility is not licensed there is no requirement for accreditation under the DAP

Community based testing is typically not diagnostic, rather it is for management purposes

Patients electing to stick their own finger (no physician involved)
The new funding model for healthcare

Patient will trigger re-imbursement

Separates the purchaser of the service from the provider of the service

Brings market discipline of the private sector into healthcare
A New Funding Model for Healthcare

Emphasis will be on quality of service and meeting the needs of the customer (the patient)

Hospitals and healthcare facilities will compete with each other for the customer (Singapore model)
Point of Care Testing/New Funding Model

Point of care testing sites in the community may end up being licensed if they want to be reimbursed for the tests they provide.

Licensing requirements will include training, the use of appropriate quality control systems, compliance with POCT standards with periodic inspections.

Patients electing to be tested at these sites will trigger a reimbursement from the healthcare system for the tests provided.
Confidentiality issues will be resolved by having the patient decide whether or not they want to access the community based system.

All testing sites will be linked and standardized – limited test menu for chronic disease management – group purchase, common equipment, reference intervals, critical limits.

Data aggregated for outcome assessments and tracking of drug side effects.
“The future is all around us
it just hasn’t organized itself yet”
What is happening?

Government is embracing “patient centric” care

Government is passing legislation to expand the scope of practice for pharmacists to include blood testing and drug renewals

Special practices being prototyped for managing patients with two or more chronic diseases

Some funding will shift to support the “patient centric” model – patient access to service triggers remuneration for service
Given This - What is Needed?

An online system for monitoring the quality of testing at the “point-of-care”, for training and certifying the end-user and for the automatic messaging of health care and compliance enhancing information to the public.
Community Support System

One-click management support
Messages for supporting self-management

Bi-directional communications
Patient/next-of-kin communications

Automated reminders/notifications/alerts for enhancing compliance

Test results automatically communicated with interpretative messaging
Automated Telephone Systems

Enhance compliance – function as a home monitor, educator and counsellor

Automatically asks questions to monitor patient’s health and to reinforce targeted health-related behaviours – such as medication taking, diet, exercise, anti-smoking, weight loss **

Non compliant hypertensive patients - 38% improved compliance

** Am J Hypertension (1996); 9:285-292
Am J Health Promot (2001); 15:215-224
J Med Sys (1998); 22:95-1022
CMAJ (2009);180:927-933
I’m now in charge of my health. I test my coagulation factor every two weeks – at my pharmacy. I get the results instantly – as does my doctor. If I need to change my medication, it’s done right there and then. It’s convenient, it tells me what I need to know and it works.
“In times of drastic change it is the learners who inherit the future. The learned usually find themselves equipped to live in a world that no longer exists”

(Eric Hoffer)
Thank You
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