Pharmacogenomics

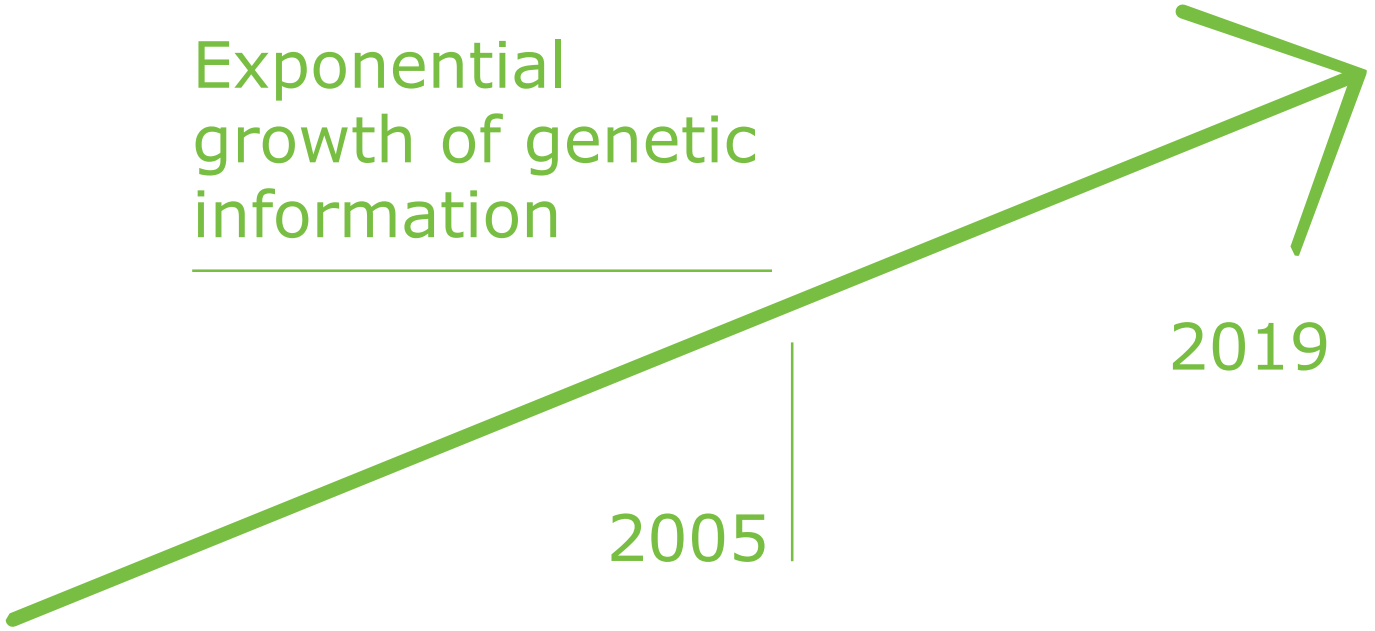
Christopher Trevors
National Director, Genetic Health Solutions

Dynacare

Disclosures

- I am a full-time employee of Dynacare which sells pharmacogenomics services

The Evolution of Genetics and Medicine



Classical Genetics

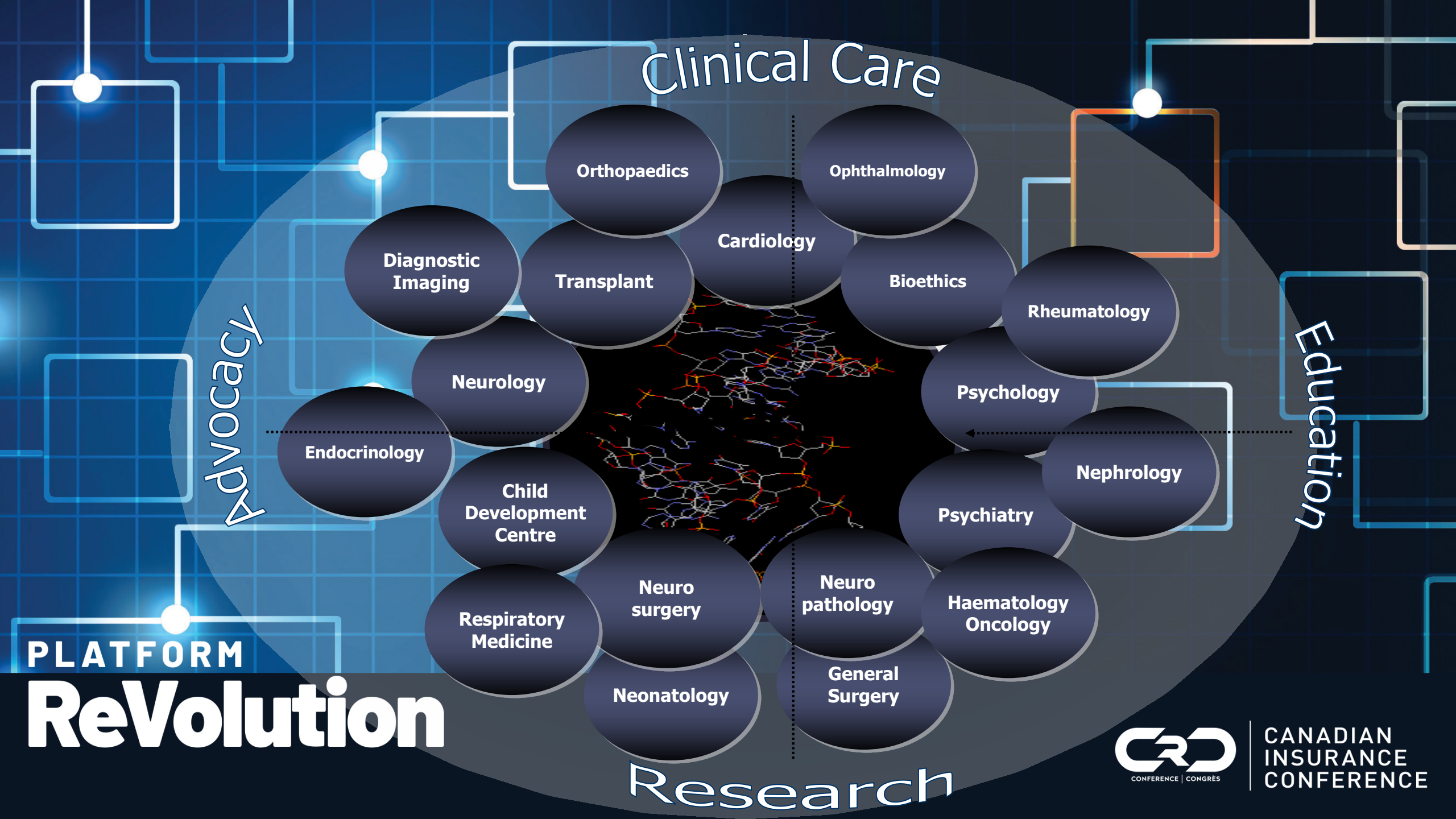
- Defining genetic disorders
- Developing genetic diagnostic tools
- Genetic counselling

Genomic Medicine

- Improving diagnostic capabilities
- Treatment of genetic disorders
- Genomic Counselling

The Future

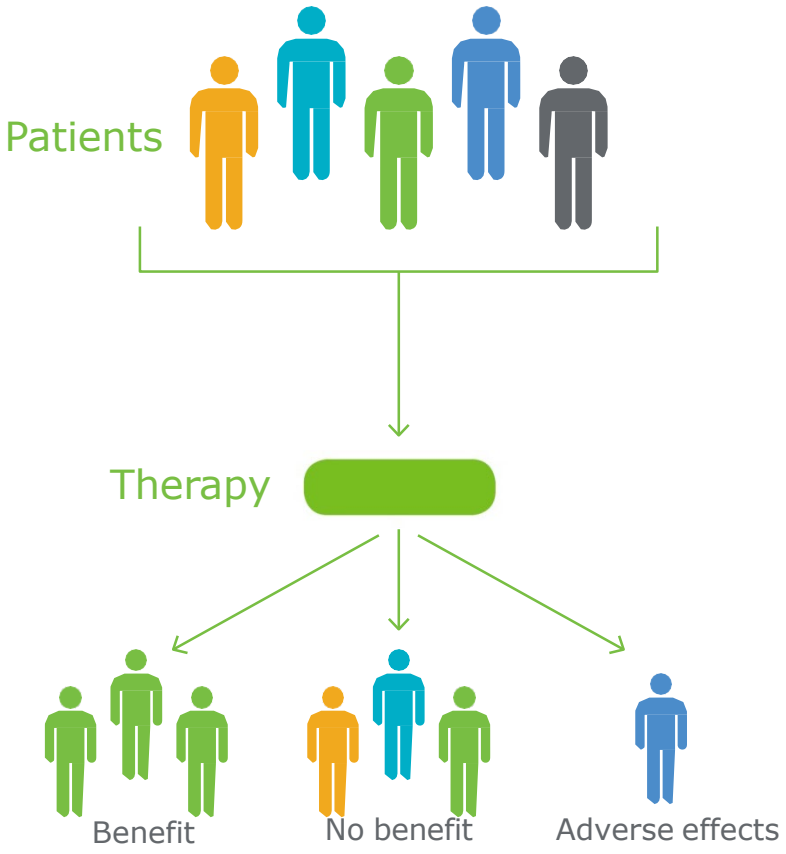
- Predicting & managing risk
- Disease prevention
- Personalized Medicine


Clinical Care
Orthopaedics
Ophthalmology
Diagnostic Imaging
Cardiology
Transplant
Bioethics
Rheumatology
Neurology
Psychology
Endocrinology
Nephrology
Child Development Centre
Psychiatry
Neuro surgery
Neuro pathology
Haematology Oncology
Respiratory Medicine
Neonatology
General Surgery
Advocacy
Education
Research
PLATFORM
ReVolution
CANADIAN INSURANCE CONFERENCE
CONFERENCE | CONGRÈS

Promise of Pharmacogenomics

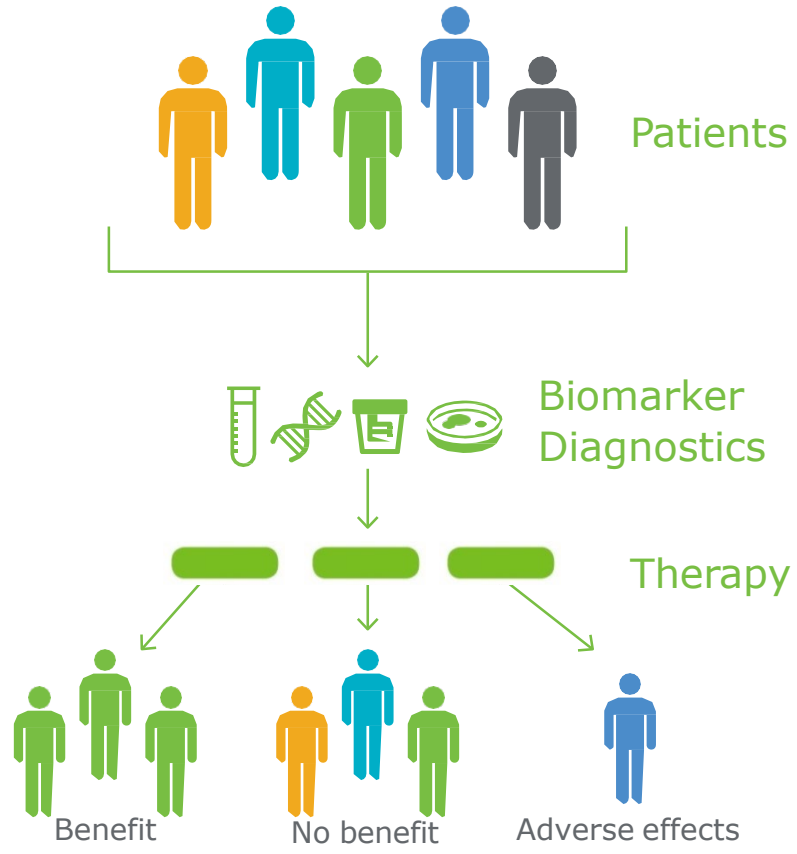
Without Personalized Medicine:

Some Benefit, Some Do Not



With Personalized Medicine:

Each Patient Receives the Right Medicine For Them



Clinical Goals

- Avoid adverse drug reactions
- Maximize drug efficacy
- Select responsive patients

The Real Cost of Medication Failures

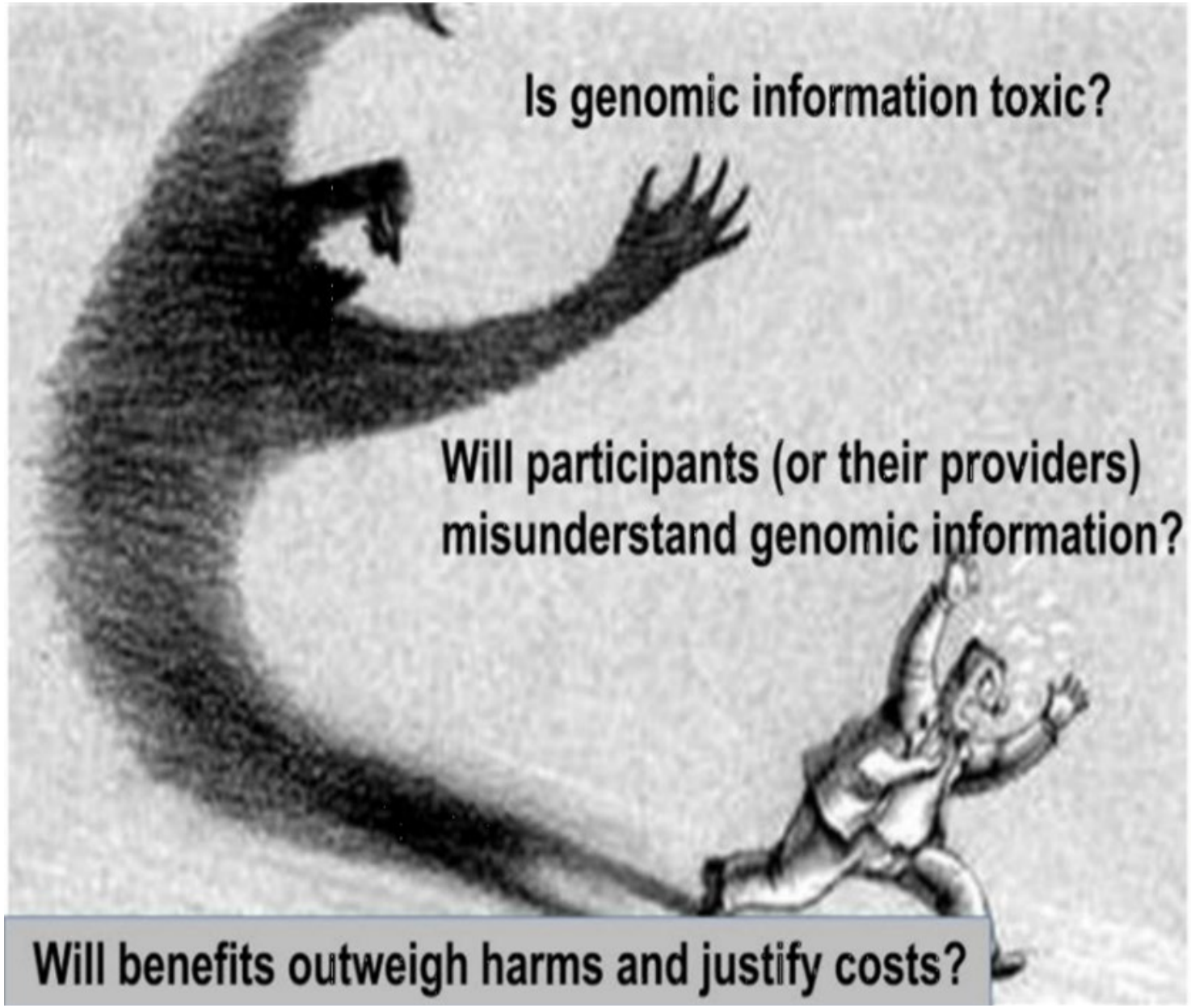
- Annual estimated cost of adverse drug reactions (ADR) in Canada is between $13-17 billion
  - Likely under estimate because 95% of ADR's not reported

- Looking at only the most severe ADR's in Canada:
  - >200,000 hospital admissions annually
  - 10,000 – 22,000 deaths annually – over 5,000 of which are children

Canadian Pharmacogenomics Network for Drug Safety

- 7.5% of people admitted to hospital in Canada experience an ADR, 36.9% of which were preventable

Baker et al. 2004


Is genomic information toxic?
Will participants (or their providers) misunderstand genomic information?
Will benefits outweigh harms and justify costs?

Current Guidelines:

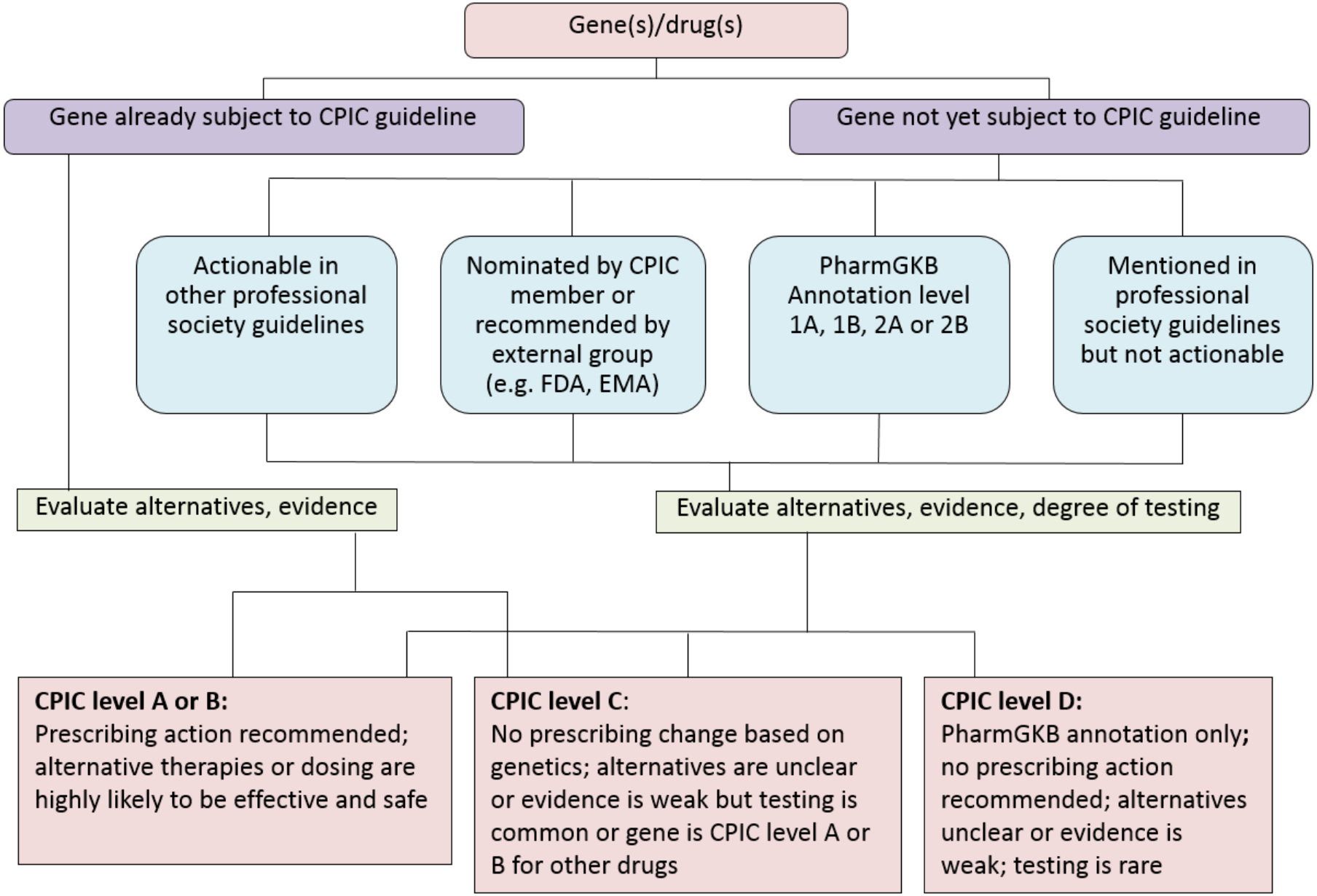
CPIC®
Clinical Pharmacogenetics Implementation Consortium

- **Partnership:**
  - PharmGKB & PGx Research Network
- **Endorsed by:**
  - **ASHP** – American Society of Hospital Pharmacists
  - **ASCPT** – American Society for Clinical Pharmacology & Therapeutics

- **Website:**
  - https://cpicpgx.org/

CPIC™
Clinical Pharmacogenetics Implementation Consortium

- CPIC guidelines help clinicians understand HOW available genetic test results should be used to optimize drug therapy.
  - Not WHETHER tests should be ordered.
- 17 guidelines produced in a standard format
  - Published in *Clinical Pharmacology and Therapeutics*
  - Freely available on PharmGKB
- Publication on CPIC guideline process
- New CPIC resources now available to support the adoption of pharmacogenetics into the EHR with CDS


Gene(s)/drug(s)
Gene already subject to CPIC guideline
Gene not yet subject to CPIC guideline
Actionable in other professional society guidelines
Nominated by CPIC member or recommended by external group (e.g. FDA, EMA)
PharmGKB Annotation level 1A, 1B, 2A or 2B
Mentioned in professional society guidelines but not actionable
Evaluate alternatives, evidence
Evaluate alternatives, evidence, degree of testing
CPIC level A or B:
Prescribing action recommended; alternative therapies or dosing are highly likely to be effective and safe
CPIC level C:
No prescribing change based on genetics; alternatives are unclear or evidence is weak but testing is common or gene is CPIC level A or B for other drugs
CPIC level D:
PharmGKB annotation only; no prescribing action recommended; alternatives unclear or evidence is weak; testing is rare

CPIC Levels:

Level	# Genes	# Drugs	Clinical Impact
A	18	29	Prescribing changes recommended
A/B	2	26	
B	20	84	
B/C	7	13	
C	25	72	No prescribing change recommended
C/D	10	34	
D	77	99	

Project Title: Integrating Pediatric Pharmacogenomic Testing into the Canadian Health Care System

- Partnership with Canadian Pharmacogenomics Network for Drug Safety (CPNDS) at UBC
- $3 Million Genome Canada Grant
- Objectives:
  - Ensure the validity, utility, accuracy and clinical relevance
  - Focused on the three most frequently prescribed therapeutic classes of drugs in children:
    1) antibiotics
    2) analgesics
    3) mental health medications

UBC partnership funded to set up pharmacogenomics in 10 hospitals across Canada

Contents lists available at ScienceDirect

Journal of Psychiatric Research

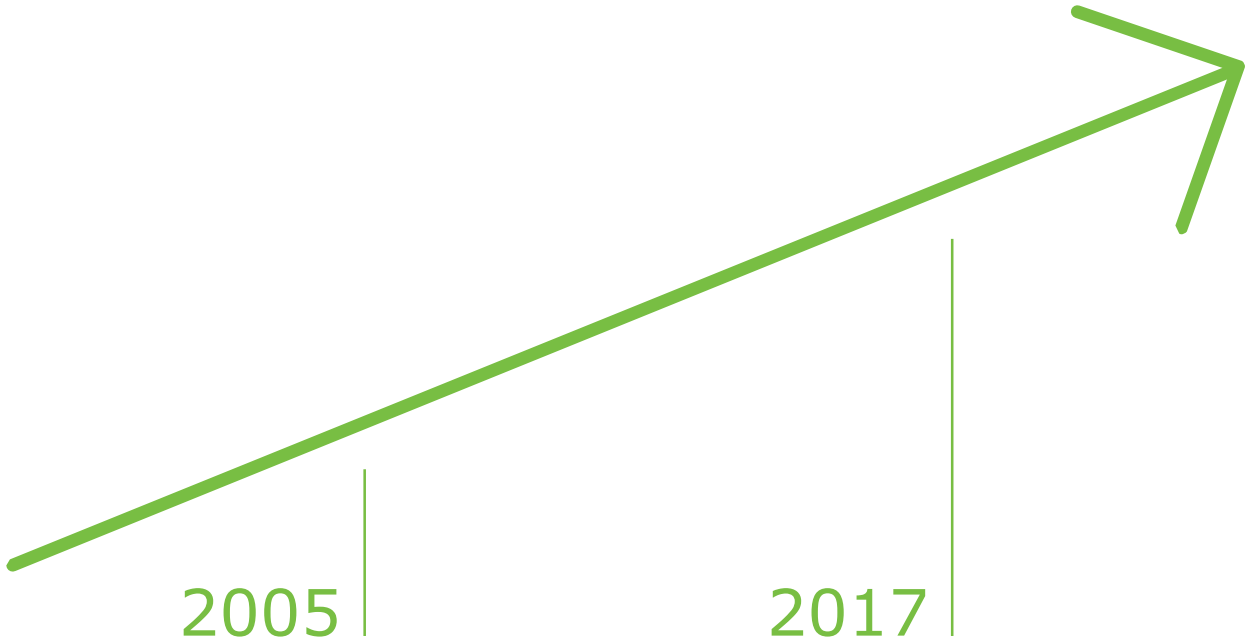
journal homepage: www.elsevier.com/locate/psychires

Genetic testing as a supporting tool in prescribing psychiatric medication: Design and protocol of the IMPACT study

Deanna Herbert [a, b, 1], Maria Neves-Pereira [a, b, 1], Ruth Baidya [a, b], Sheraz Cheema [a, b], Sarah Groleau [a, b], Anashe Shahmirian [a, b], Arun K. Tiwari [a, b, c], Clement C. Zai [a, b, c, f], Nicole King [a, b], Daniel J. Müller [a, b, c, d, e], James L. Kennedy [a, b, c, d, *]

[a] Campbell Family Mental Health Research Institute, Centre for Addiction and Mental Health, Toronto, ON, Canada
[b] Molecular Brain Science Research Department, Centre for Addiction and Mental Health, Toronto, ON, Canada
[c] Department of Psychiatry, University of Toronto, Toronto, ON, Canada
[d] Institute of Medical Science, University of Toronto, Toronto, ON, Canada
[e] Department of Pharmacology and Toxicology, University of Toronto, Toronto, ON, Canada
[f] Laboratory Medicine & Pathobiology, University of Toronto, Toronto, ON, Canada

Vision



Avoid:
gentamycin
antibiotics
- increased
genetic risk
for deafness

Genomic medicine will improve
quality of life and save health care dollars.

Mental health affects us all

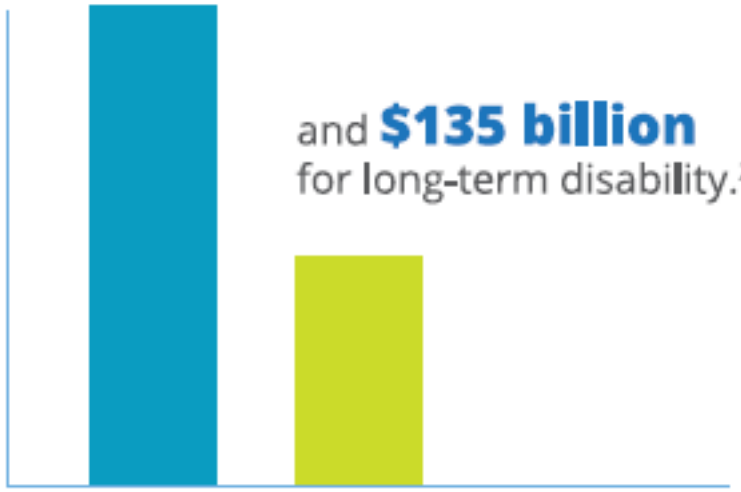
By 2020, ***depression will become the second leading cause (next to heart disease) of disability*** adjusted life years for all age groups and both sexes.[9]

500,000

Canadians, in any given week, are ***unable to work*** due to mental illness.[10]

Mental health has a cost

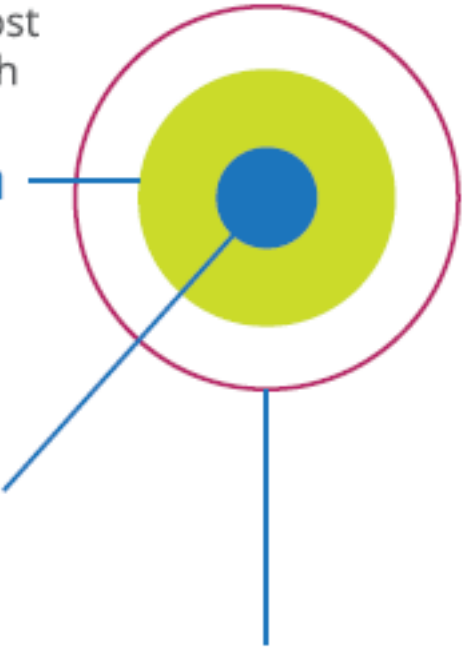
The private sector spends between **$180-$300 billion** on short-term disability for mental illness



and **$135 billion** for long-term disability.[20]

Mental health issues account for more than **$6 billion** in *lost productivity* due to absenteeism and presenteeism.[21]

The economic cost of mental health problems is **$51 billion** (2.8% of GDP [2011])...



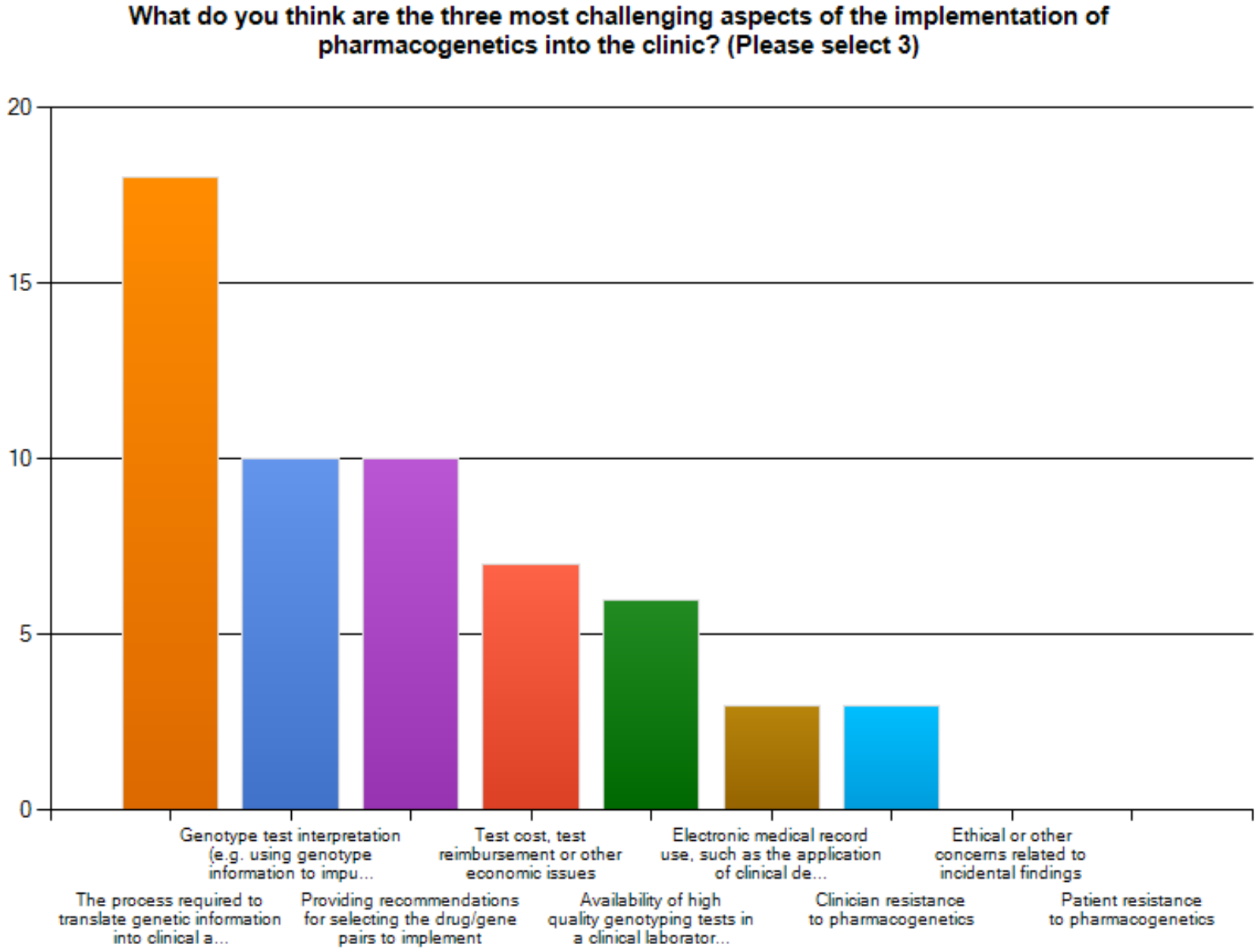
...of which **$20 billion** stems from the workplace.

In 30 years, the total cost is projected at **$2.5 trillion.**[22]

Source: Mental Health Now! Advancing Mental Health for Canadians: The Federal Role – Canadian Alliance on Mental Illness and Mental Health, 2016

Pharmacogenomic Barriers

- Lack of regulation of laboratories - testing and marketing/sales
- Over promising technology potential
- Reporting of results
  - Integration into health records
  - Interpretation
- Reimbursement
- Education:
  - Patients
  - Healthcare providers
    - Physicians
    - Nurse Practitioners
    - Pharmacists/ PharmD’s
  - Insurance providers
  - Government/ Policy Makers



Clin Pharmacol Ther. 2011 Mar;89(3):464-7.

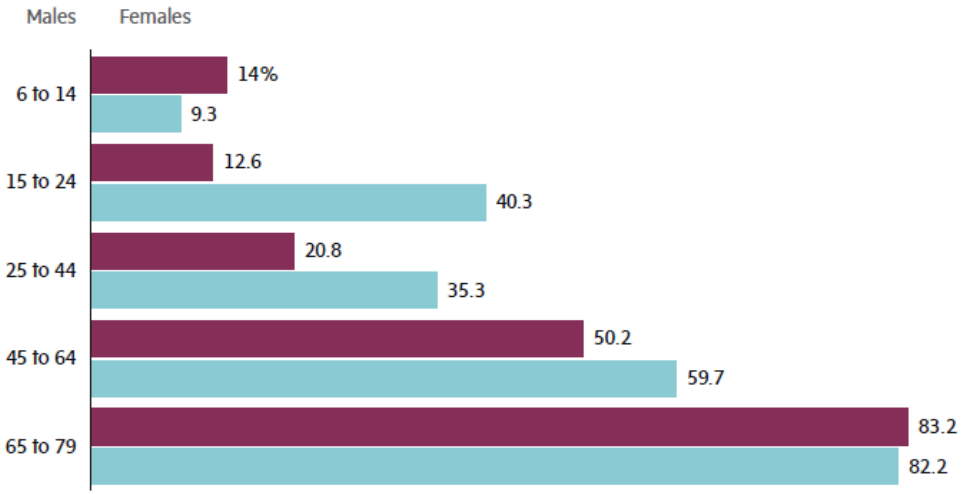
DNA on drugs: How genetic tests could make prescriptions more precise

It's well known that different people can react differently to the same drug, with some patients feeling no effect – and some experiencing unwanted, even fatal, reactions. Now that reading patients' DNA has become cheap and easy, writes **Carolyn Abraham**, pressure is mounting to make gene-guided prescriptions a regular part of publicly funded medicine

CAROLYN ABRAHAM
SPECIAL TO THE GLOBE AND MAIL
PUBLISHED MARCH 16, 2018

Drug use in Canada at a glance

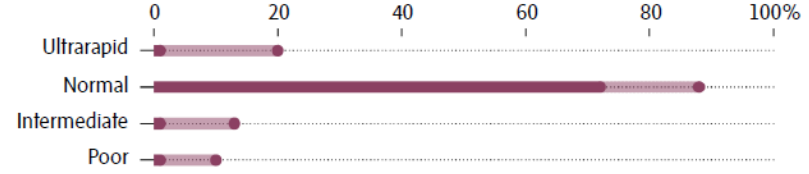
Percentage of Canadians using prescription medication, by sex and age group
2007 to 2011



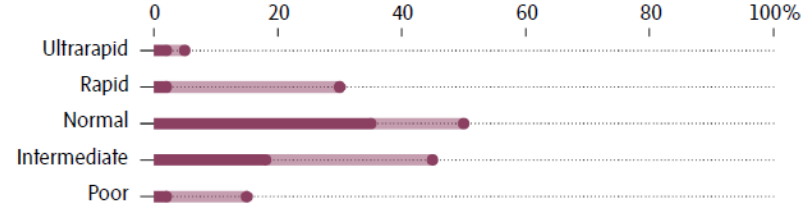
THE GLOBE AND MAIL, SOURCE: STATISTICS CANADA

HOW METABOLIZER STATUS BREAKS DOWN, WORLDWIDE, IN TWO MAJOR GENES

CYP2D6
Per-cent range of patients, by metabolizer status



CYP2C19
Per-cent range of patients, by metabolizer status



THE GLOBE AND MAIL, SOURCE: NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

PHARMACOTHERAPY

Pharmacogenomics Implementation: Considerations for Selecting a Reference Laboratory

Teresa T. Vo,[1] Gillian C. Bell,[2] Aniwaa Owusu Obeng,[3,4] J. Kevin Hicks,[5] and Henry M. Dunnenberger[6*]

Other Considerations:

- Laboratory Licensing
- Bilingual support and reporting – French & English
- Clinical and technical genetics expertise
- Understanding of ethnic differences – allele frequencies and clinical application/ limitations
- Understanding of ethical considerations
- Security of patient/ healthcare provider portals

Table 1. Four Domains for Evaluating Pharmacogenomic Laboratories

Domain	Key questions
Pharmacogene selection	1 What gene(s) is/are applicable to my clinical setting? 2 How are the genes aggregated for testing? (single gene, disease-specific panel, broad panel testing) 3 Can the laboratory provide a customized panel of genes? 4 What variants for each gene are interrogated, and are they representative of my patient population?
Logistics	1 What type of sample is required? 2 What is the turnaround time? 3 Are samples stored for future testing? 4 Are samples used for research purposes? 5 What information is included on the consent form, if required?
Reporting of results	1 How are the results returned to a provider/patient? 2 Are the results easy to interpret for a provider/patient? 3 Is the evidence for each recommendation available? 4 Does the evidence support the recommendations? 5 What educational materials are available to aid in discussion of the results?
Test cost and reimbursement	1 Does the laboratory bill patient insurance directly? 2 What patient financial assistance programs does the laboratory provide? 3 Does the laboratory provide a maximum cost for the patient?

Commercial pharmacogenetic-based decision-support tools in psychiatry

www.thelancet.com/psychiatry Vol 3 June 2016

Chad A Bousman, Malcolm Hopwood

	Manufacturer	Headquarters	Genes included	Target medications	Evidence of clinical usefulness	Regions served
Brainchip	Progenika Biopharma	Dero, Spain	*CYP2C19, CYP2D6, CYP3A4*	Antidepressants, antipsychotics	NA	Spain, Mexico, Norway, Sweden, Finland, Austria, Turkey, Middle East, Egypt
DNA4LIFE	DNA4Life	Mandeville, LA, USA	*CYP1A2, CYP2B6, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, VKORC1, OPRM1, SLC6A4, SLCO1B1*	Antidepressants, antipsychotics, anticonvulsant, anxiolytic, analgesics, antidiabetic, steroids, gastrointestinal, antivirals, anticoagulants, oncological	NA	USA
CNSDose	Baycrest Biotechnology	Albans Park, VIC, Australia	*ABCB1, ABCC1, CYP2C19, CYP2D6, UGT1A1*	Antidepressants	1 RCT[5]	Australia, USA
Genecept	Geomind	King of Prussia, PA, USA	*CYP2C19, CYP2D6, CYP3A4, ANK3, CACNA1C, COMT, DRD2, HTR2C, MTHFR, SLC6A4*	Antidepressants, antipsychotics, mood stabilisers	2 studies (1 open-label cohort, no comparator;[6] 1 cost-savings[7])	USA
GeneSight	Assurex Health	Mason, OH, USA	*CYP1A2, CYP2C19, CYP2D6, UGT1A4*, UGT2B15*, HLA-A*, HLA-B*, HTR2A, SLC6A4*	Antidepressants, antipsychotics, anxiolytics, mood stabilisers	6 studies (2 open-label, non-randomised;[8,9] 1 RCT;[10] 1 cost-effectiveness;[11] 2 cost-savings[12,13])	USA
Healthspek PGT	Healthspek	Nashville, TN, USA	*CYP1A2, CYP2B6, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, VKORC1, COMT, DRD2, OPRM1, SLCO1B1*	Antidepressants, antipsychotics, anticonvulsant, anxiolytic, analgesics, antidiabetic, steroids, gastrointestinal, antivirals, anticoagulants, oncologic	NA	USA
IGL Psychiatry	International Genetics Laboratories	Troy, MI, USA	*CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, MTHFR, SLC6A4, SULT4A1*	Antidepressants, antipsychotics, anxiolytic, analgesics, anticoagulants, urology, antimicrobials, steroids, immunosuppressants	NA	USA
Millennium PGT	Millennium Health	San Diego, CA, USA	*CYP2B6, CYP2C19, CYP2D6, CYP3A5, UGT2B15, VKORC1, COMT, MTHFR, OPRM1*	Antidepressants, antipsychotics, anticonvulsant, anxiolytic, addiction, analgesics, anticoagulants	NA	USA
MyDNA (formerly DNAdose)	MyDNA (formerly GenesFX Health)	South Yarra, VIC, Australia	*CYP2C19, CYP2C9, CYP2D6, VKORC1*	Antidepressants, antipsychotics, analgesics, wafarin, clopidogrel, tamoxifen, proton pump inhibitors	NA	Australia
Neuropharmagen	AB Biotics	Barcelona, Spain	*CYP1A2, CYP2B6, CYP2C19, CYP2C9, CYP2D6, EPHX1, BDNF, CACNG2, COMT, DRD3, GRIA3, HTR2A, LPHN3, AKT1, DDIT4, FHSD1, RPTOR*	Antidepressants, antipsychotics, anticonvulsant, mood stabilisers, addiction	NA	Spain

(Table continues on next page)

	Manufacturer	Headquarters	Genes included	Target medications	Evidence of clinical usefulness	Regions served
(Continued from previous page)						
PGXL	PGXL Laboratories	Louisville, KY, USA	*CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, NAT2, VKORC1, COMT, F2, F5, HLA-B, MTHFR, OPRM1, SLC6A4, SLCO1B1*	Antidepressants, antipsychotics, anticonvulsant, anxiolytic, analgesics, antidiabetic, steroids, gastrointestinal, antivirals, anticoagulants, oncological	NA	USA
PGxPredict	Transgenomic	Omaha, NE, USA	*ABCB1, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, VKORC1, F2, F5, MTHFR*	Antidepressants, antipsychotics, anticonvulsant, anxiolytic, analgesics, anticoagulants	NA	USA
PGxOne	Admera Health	South Plainfield, NJ, USA	*CYP1A2, CYP2C19, CYP2C9, CYP2D6, DYPD, TPMT, UGT1A1, VKORC1, F5, G6PD, HLA-B, IFNL3*	Antidepressants, antipsychotics, anticonvulsant, anxiolytic, analgesics, anticoagulants, oncological	NA	USA
Pharm D	DNA Stat	Addison, TX, USA	*CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, VKORC1, F2, F5, MTHFR*	Antidepressants, antipsychotics, anticonvulsant, anxiolytic, analgesics, anticoagulants	NA	USA
PharmaQx 3-0	BiogeniQ	Montreal, QC, Canada	*CYP2C19, CYP2C9, CYP2D6, CYP3A5, NAT2, TPMT, VKORC1, SLCO1B1*	Antidepressants, antipsychotics, anticonvulsant, anxiolytic, analgesics, anticoagulants, oncological	NA	Canada
Pharmaco Gene†	GeneticHealth	London, UK	NA	NA	NA	UK
PillCheck	GeneYouIn	Toronto, ON, Canada	*CYP2C19, CYP2C9, CYP2D6, DYPD, TPMT, UGT1A1*	Antidepressants, antipsychotics, anxiolytic, analgesics, anticoagulants, antimicrobials, antivirals, gastrointestinal	NA	Canada
PsychPanel†	GeneAlign	Greenville, SC, USA	NA	Antidepressants, antipsychotics, anticonvulsant, anxiolytic	NA	USA
RenaissanceRX	RenaissanceRX	New Orleans, LA, USA	*CYP1A2, CYP2C19, CYP2C9, CYP2D6, UGT1A1, UGT2B7, VKORC1, MTHFR, OPRM1*	Antidepressants, analgesics, anticoagulants, beta blockers, antiarrhythmic	NA	USA
Script Letters	Life Letters	Sydney, NSW, Australia	*CYP2C19, CYP2D6*	Antidepressants	NA	Australia
TreatGx	GenXys	Vancouver, BC, Canada	*CYP2C19, CYP2C9, CYP2D6, VKORC1, G6PD, HLA-A, HLA-B, SLCO1B1*	Antidepressants, analgesics, anticoagulants	NA	Canada
YouScript	Genelex	Seattle, WA, USA	*CYP1A2, CYP2B6, CYP2C19, CYP2D6, CYP3A4, ADRA2A, COMT, GRIK4, HTR2A, HTR2C, MTHFR, SLC6A4*	Antidepressants, analgesics, anticoagulants, beta blockers	NA	USA

NA=not available. RCT=randomised clinical trial. *These genes were not included in clinical studies evaluating the GeneSIght panel. †Not fully assessed due to limited amount of information available.

Table: **Commercially available pharmacogenetic tools relevant to psychiatry practice**

DTC – Direct to Consumer

- Wellness vs Medical test
- Laboratory Licensing
- Healthcare provider regulation
- Clinical support – clinicians & consumers/patients

The Pharmacogenomics Journal (2017) 00, 1–8
www.nature.com/tpj

REVIEW

Cost-effectiveness of pharmacogenetic-guided treatment: are we there yet?

M Verbelen[1], ME Weale[2] and CM Lewis[1,2]

- Examined 137 PGx associations in FDA, 44 economic evaluations related to 10 drugs

- Conclusions:
  - 57% drew conclusions in favour of PGx testing (30% cost-effective; 27% cost-saving)
  - If genetic info was freely available in health record – 75% would be in support (25% cost-effective; 50% cost-saving)

RESEARCH ARTICLE

WILEY ADAA

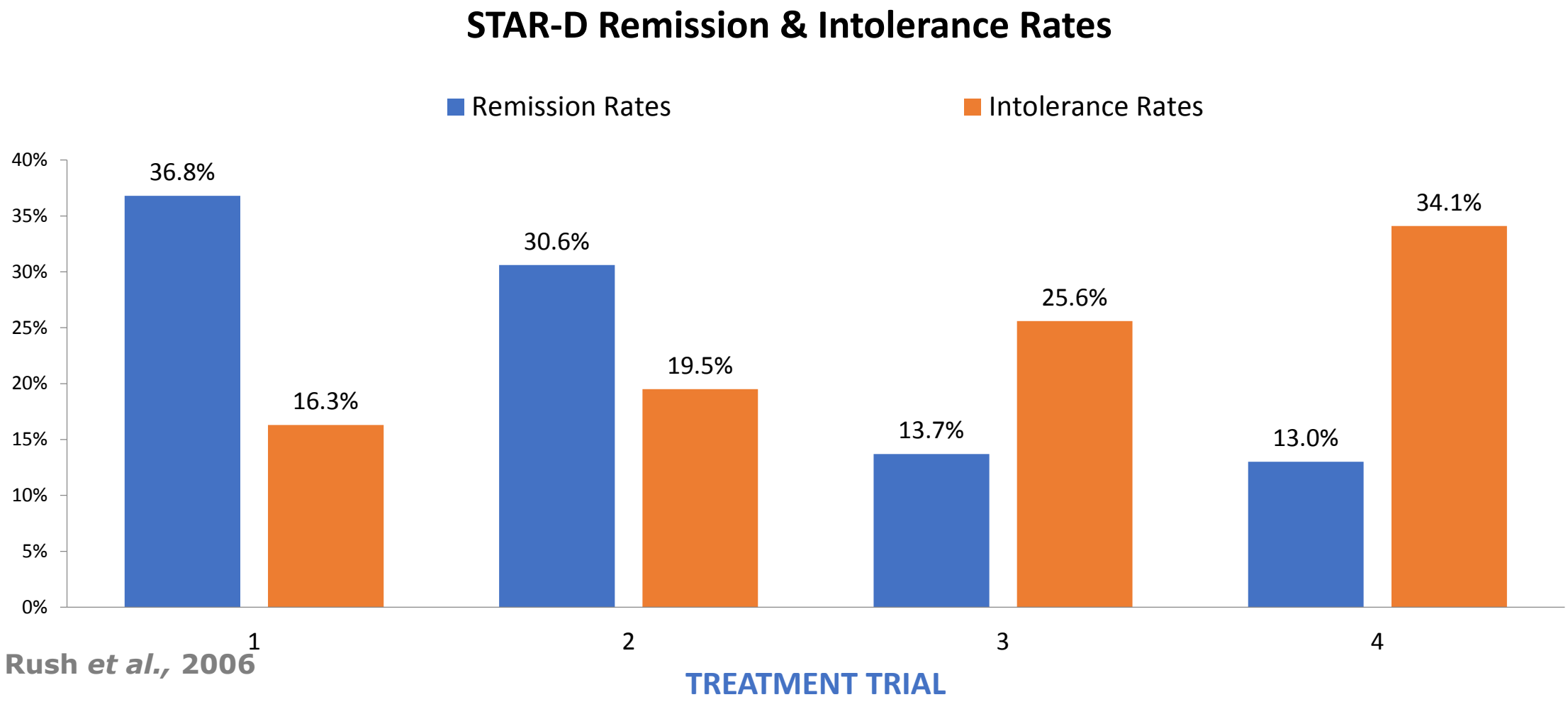
Pharmacogenetic testing among patients with mood and anxiety disorders is associated with decreased utilization and cost: A propensity-score matched study

Roy H. Perlis MD, MSc[1] | Rajesh Mehta RPh, MS[2] | Alison M. Edwards MStat[2] | Arun Tiwari MBA[2] | Guido W. Imbens PhD[3]

Depress Anxiety. 2018;1–7. wileyonlinelibrary.com/journal/da

Savings of ~ $4000 USD per patient per year

TIME: Treatment Resistance - Depression



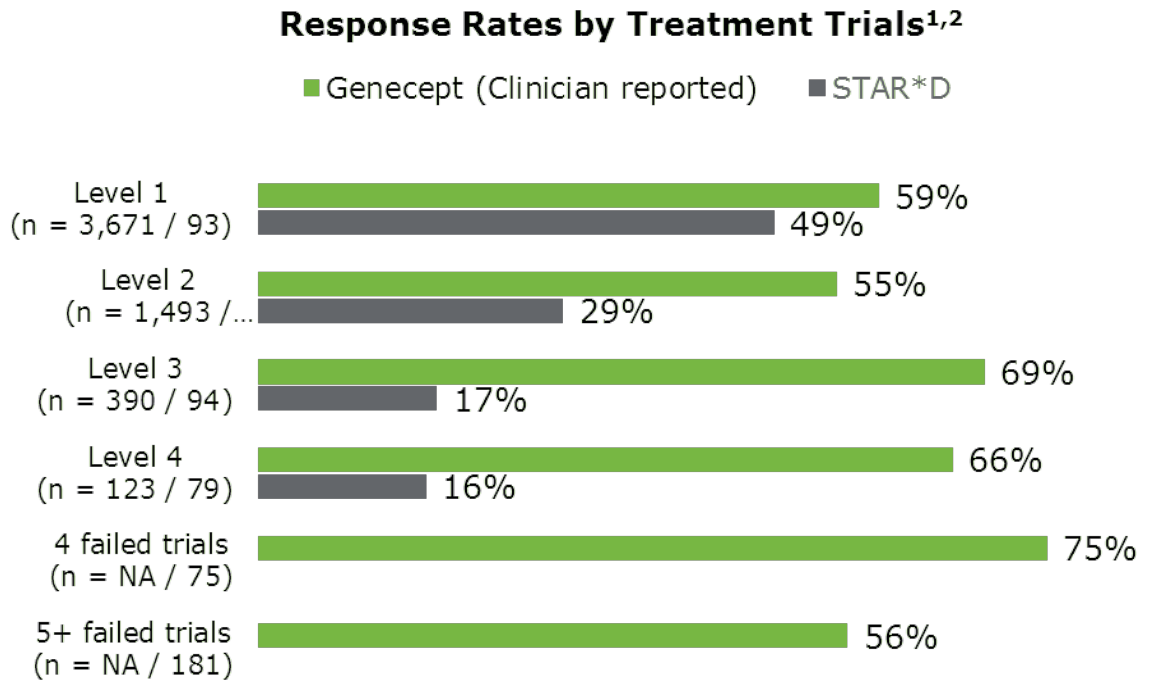
Rush *et al.*, 2006

Response rates are comparable regardless of the number of failed treatment trials

On average…

63%

of patients across all levels of treatment resistance receiving Genecept- guided treatment showed a clinically significant response



1. Levels indicate either stages of treatment in STAR*D or number of previously failed adequate treatment trials, with level 1 indicating zero previous treatment trials
2. Response measured by ≥ 50% reduction in QIDS-SR16 (STAR*D) or CGI-I of 1 or 2 (Genecept™-Clinician Reported)

Pharmacogenetic-Guided Psychiatric Intervention Associated With Increased Adherence and Cost Savings

Jesen Fagerness, JD; Eileen Fonseca, MS; Gregory P. Hess, MD, MBA, MSc; Rachel Scott, PharmD; Kathryn R. Gardner, MS; Michael Koffler, MBA; Maurizio Fava, MD; Roy H. Perlis, MD, MSc; Francis X. Brennan, PhD; and Jay Lombard, DO

Amer. Journal of Managed Care; 20(5)

Adherence:

- PGx – increase 6.3%
- Control – increase 0.3%

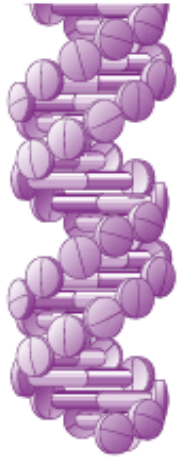
Costs:

- PGx – increase slightly in drug costs $418
- PGx – decrease in use of medical services - overall savings $562

Research Article

For reprint orders, please contact: reprints@futuremedicine.com

Pharmacogenomics



Pharmacogenetic tests and depressive symptom remission: a meta-analysis of randomized controlled trials

Chad A Bousman*,‡,1,2,3, Katarina Arandjelovic‡,4, Serafino G Mancuso5, Harris A Eyre4,5,6,7 & Boadie W Dunlop8

[1]Departments of Medical Genetics, Psychiatry, & Physiology & Pharmacology, University of Calgary, Calgary, Alberta T2N 4N1, Canada
[2]Alberta Children's Hospital Research Institute, Calgary, Alberta T2N 1N4, Canada
[3]Hotchkiss Brain Institute, University of Calgary, Calgary, Alberta T2N 4N1, Canada
[4]IMPACT SRC, School of Medicine, Deakin University, Geelong, Victoria, 3220, Australia
[5]Department of Psychiatry, University of Melbourne, Melbourne, Victoria, 3220, Australia
[6]Innovation Institute, Texas Medical Center, Houston, TX 77030, USA
[7]CNSDose LLC, Westlake Village, CA 91359, USA
[8]Department of Psychiatry & Behavioral Sciences, Emory University School of Medicine, Atlanta, GA 30322, USA
*Author for correspondence: Tel.: +1 403 210 7273; chad.bousman@ucalgary.ca
‡Authors contributed equally

- Use of PGx > standard of care
  - More severe presentation (Mod to severe depression)
  - Multiple MDx failures

Limitations:

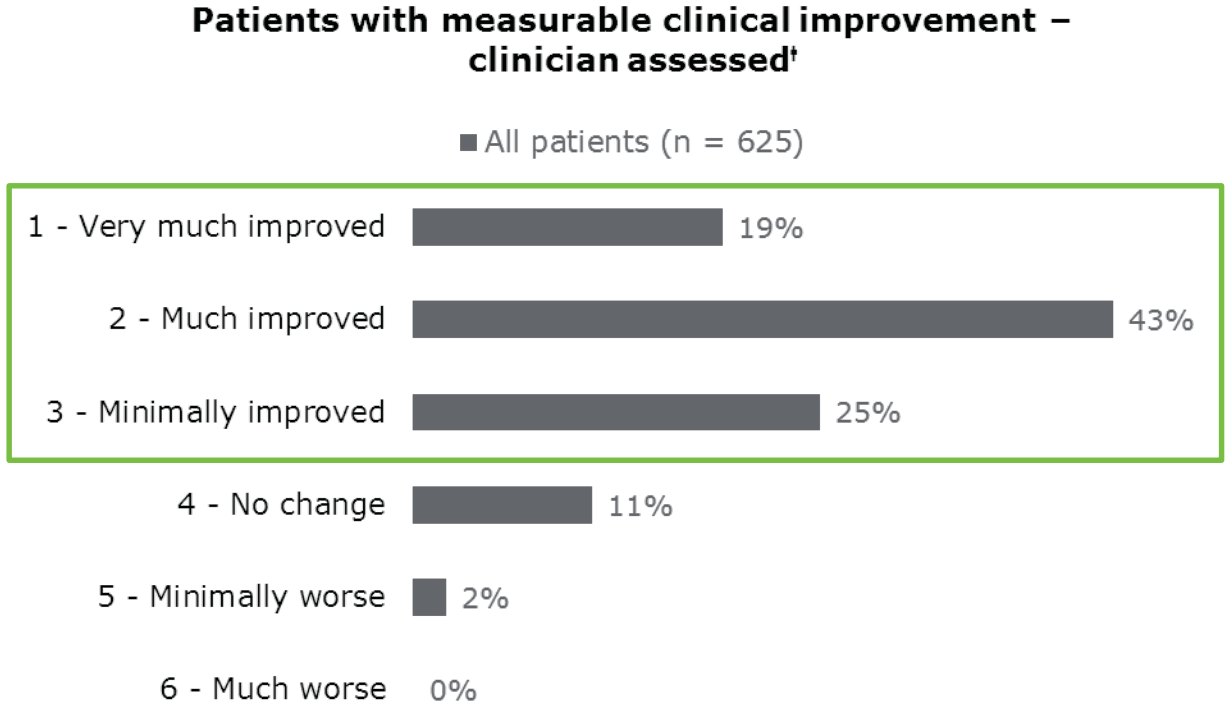
- No PGx tools available globally
- Different eval tools for Dx
- Variability in tests

A Naturalistic study of the effectiveness of pharmacogenetic testing to guide treatment in psychiatric patients with mood and anxiety disorders

(Primary Care Companion CNS Disorders 2015; 17(2))

87%

of all patients receiving Genecept-guided treatment* showed clinically-measurable improvement



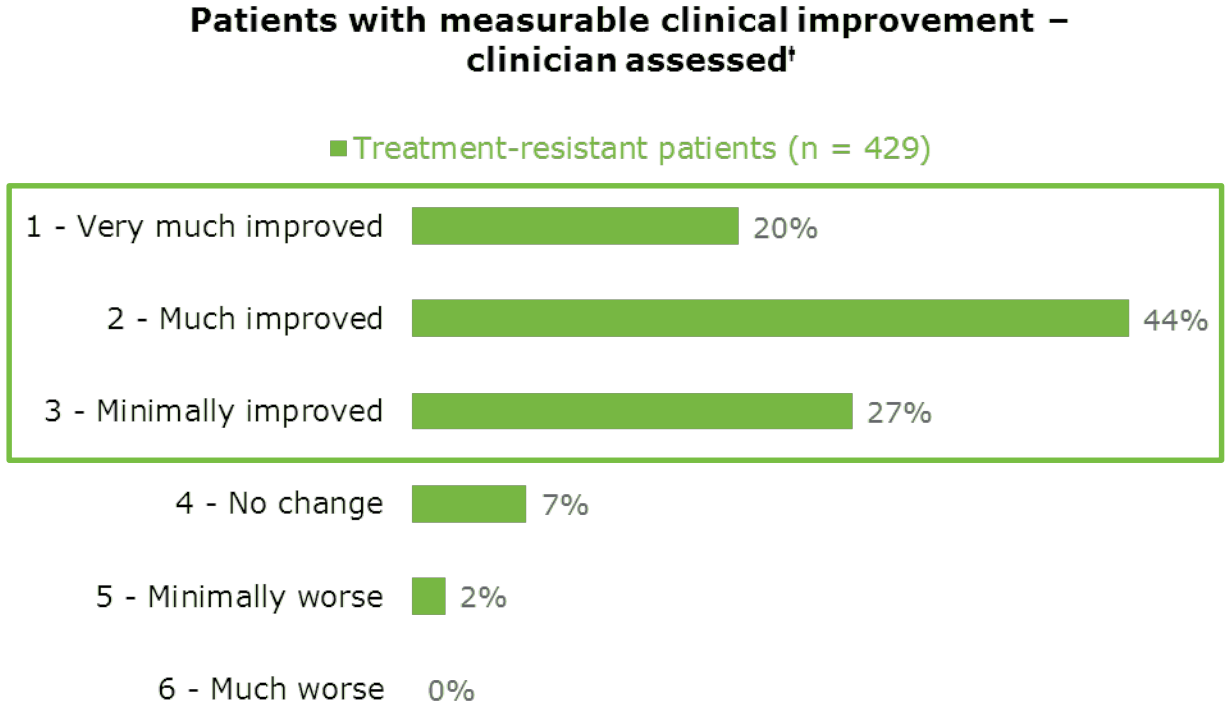
- * In an open label clinical study1 examining the effectiveness of genetic testing with the Genecept Assay
- Clinicians used the Clinical Global Impressions—Severity of Illness (CGI-S) scale for disease severity to assess improvement

A Naturalistic study of the effectiveness of pharmacogenetic testing to guide treatment in psychiatric patients with mood and anxiety disorders

(Primary Care Companion CNS Disorders 2015; 17(2))

91%

of treatment-resistant patients (i.e. those with 2 or more failed medication trials) receiving Genecept-guided treatment* showed clinically-measurable improvement



- * In an open label clinical study1 examining the effectiveness of genetic testing with the Genecept Assay
- Clinicians used the Clinical Global Impressions—Severity of Illness (CGI-S) scale for disease severity to assess improvement

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ADVANCES IN PHARMACY PRACTICE

The Innovative Canadian Pharmacogenomic Screening Initiative in Community Pharmacy (ICANPIC) study

John Papastergiou*, Peter Tolios, Wilson Li, Jane Li

Findings:

- Pharmacists cited the most common reasons for PGx testing as ineffective therapy (43.0%), to address an adverse reaction (32.6%), and to guide initiation of therapy (10.4%).
- Medications most frequently implicated in triggering PGx screening included antidepressants (33.9%), statins (22.1%), clopidogrel (12.6%), and proton pump inhibitors (12.6%).
- The types of interventions that resulted from PGx testing included change in therapy (60.3%), dose adjustment (13.2%), discontinuation of a drug (4.4%), and increased monitoring (22.1%).
- Community pharmacists have the confidence and capability to successfully implement PGx screening services into clinical practice, identify patients that are likely to benefit from such testing, and apply the results to optimize medication therapy management.

Table 2
Summary of patient demographics and rationale for pharmacogenomic testing

Number of patients	100
Lost to follow-up	4
Failed test	1
Mean age (y)	56.7
Female (%)	62
Mean number of chronic medications	4.9
Mean number of Pillcheck medications	2.0
Reason for enrollment, n (%)	
Uncontrolled condition on triggering medication	58 (43.0)
Experiencing adverse effects on triggering medication	44 (32.6)
Testing to determine optimal medication option	14 (10.4)
New medication was initiated	9 (6.7)
Concern about clopidogrel activation	6 (4.4)
Recent dose change	4 (3.0)
Medications triggering pharmacogenomic testing, n (%)	
Clopidogrel	16 (12.6)
Statin	28 (22.1)
Antidepressant	43 (33.9)
Opioid	10 (7.9)
Warfarin	9 (7.1)
Proton pump inhibitor	16 (12.6)
Other[a]	5 (3.9)

[a] Medications classified as "other" included benzodiazepines, cycloxygenase-2 selective inhibitors, beta-blockers, and nonsteroidal anti-inflammatory drugs.

PHARMACOTHERAPY

Collaborative Counseling Considerations for Pharmacogenomic Tests

Heather A. Zierhut,[1*] Colleen A. Campbell,[2,3] Allison G. Mitchell,[4] Amy A. Lemke,[5] Rachel Mills,[6] and Jeffrey R. Bishop[7,8]

Table 1. Considerations for Discussions with Patients Before and After PGx Testing

Pretest	Posttest
Current treatment and how informative for drug inefficacy, interactions, side effects	Inform patients what, if any, changes will be made to their medication regimen
Purpose of testing and role of genes in drug response and tolerability	Explain any inconsistencies with genotype and clinical outcomes
Test risks and benefits, limitations, and alternatives	Reemphasize relevance of test results for future treatments
Future benefits of PGx	Make referral if necessary
Other potential findings: disease risk, implications (if any) for relatives	Provide patient report/letter
	Consideration of ancillary findings such as disease risk associations and/or testing for family members

PGx = pharmacogenomics.

Pharmacogenomic Drivers

- Increasing evidence of clinical utility and cost savings associated with pharmacogenomic testing
- Increasing cost of drugs
- Adverse drug reactions – patient impacts and costs
- Cost of mental health in the workplace
  - Disability
  - Absenteeism & Presenteeism
- Increasing awareness of mental health issues
- Lack of other biomarkers associated with mental illness
- Broader awareness - internet, direct to consumer marketing, patient support networks
- Insurance companies innovating to control costs and attract/ retain customers

Genetic Privacy and Pharmacogenomics

CAGC - ACCG

GENETIC NON-DISCRIMINATION ACT (GNA) - formerly known as Bill S-201, May 4, 2017 passed into law in Canada.

- **Protection GNA Provides:**
  - Under GNA, providers of goods and services, including insurance providers, cannot:
    - request or require that a person undergo a genetic test
    - request or require the disclosure of previous or future genetic test results
  - Under GNA, federally regulated employers cannot use a person's genetic test results in decisions about hiring, firing, job assignments, or promotions request or require genetic test results of an employee
  - Under GNA, the Canadian Human Rights Act bans discrimination based on genetic characteristics
- **Types of Genetic Test Results Protected by GNA:**
  - genetic test result is defined as a test that analyzes DNA, RNA or chromosomes for purposes
  - such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis
  - this applies to tests done in a clinical or research setting

Thank you!!

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