The Evolution of Transplant Immunosuppression in B.C. - From Innovator Brands to Alternative Brands

Olwyn Johnston, MB, MRCPI, MD, MHSc

Transplant Nephrologist & Clinical Assistant Professor of Medicine
University of British Columbia (VGH), Vancouver
Olwyn.Johnston@vch.ca

BC KIDNEY DAYS
Hosted by BC Transplant and the BC Renal Agency

October 16, 2014

No conflict of interest to declare

You are seeing a patient who is 5 years post successful living donor transplantation

The patient has been on tacrolimus (Prograf) and mycophenolate mofetil (Cellcept) since transplantation and is stable.
Recently alternative brand (generic) drugs have been introduced and are much cheaper than the innovator drugs.

1. Would you switch the patient from Cellcept to alternative brand MPA?

2. Would you switch the patient from Prograf to alternative brand tacrolimus?

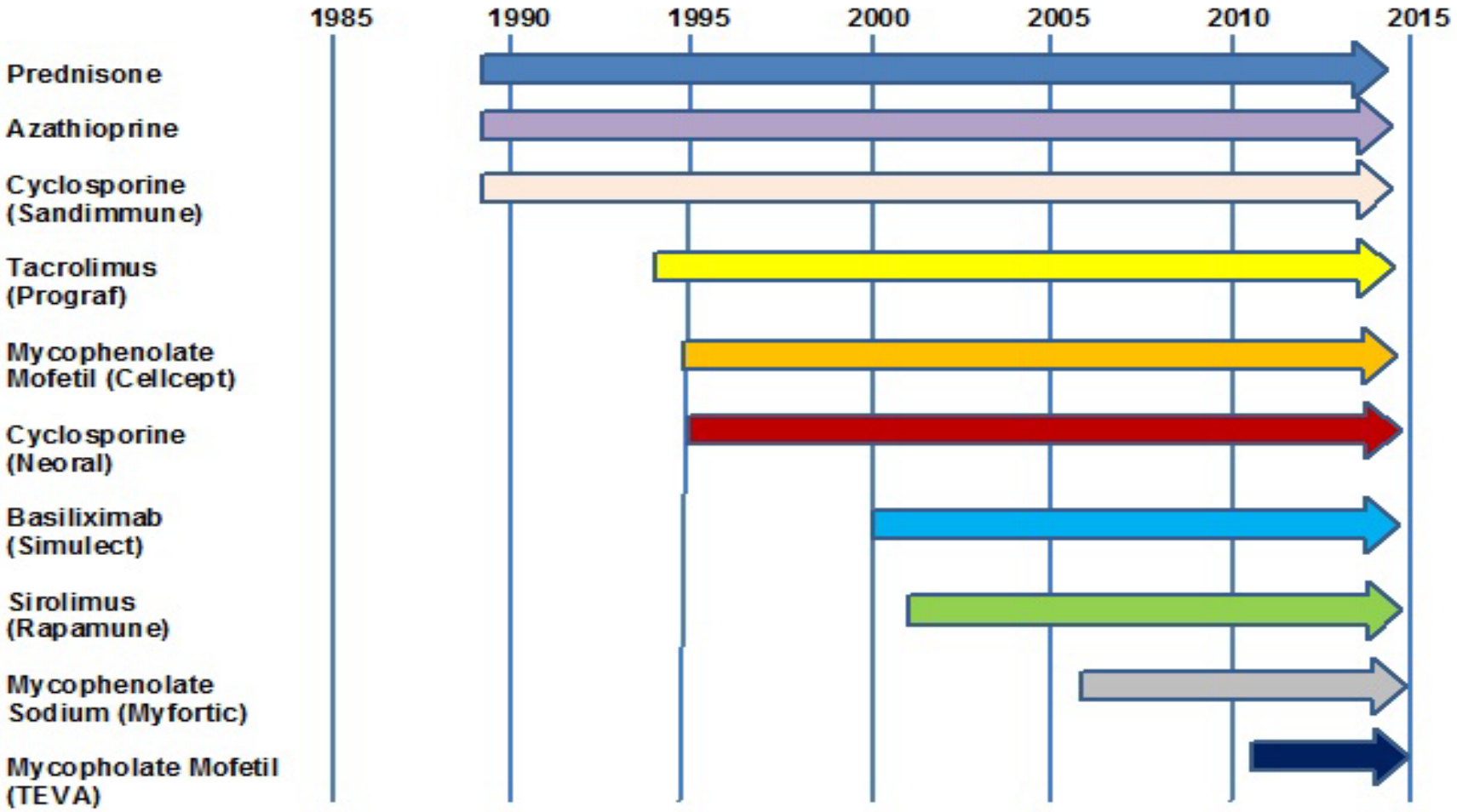
Objectives
Questions we will answer

1. **How has transplant immunosuppression use changed over time in BC?**

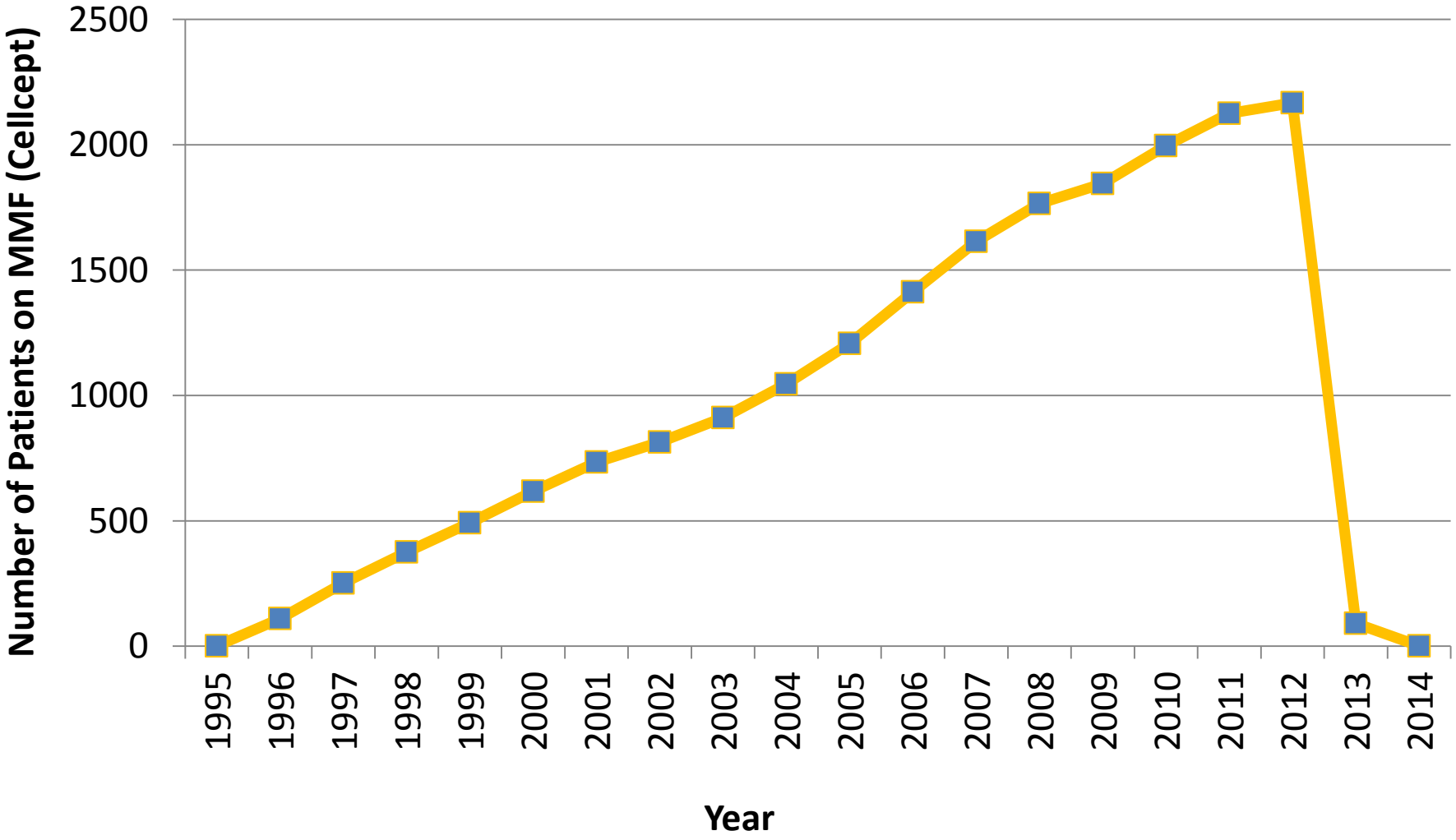
2. What is a generic or ‘alternative brand’ drug?

3. What are the ‘myths’ and concerns with alternative brand formulations?

1. How has transplant immunosuppression use changed over time in BC?



Frequency of MMF (Cellcept) use over time in BC



How are Transplant Medications Funded and Dispensed By Province?

Province	Dispensing of IS	Funding of IS
AB	Select Hospital Pharmacies	AHS
BC	**12 select pharmacies -hospital & community**	**BCT**
MB	Community pharmacies	Mixed
NB	Community pharmacies	Rx drug program for transplant
NFLD	Select hospital pharmacies	MOH high cost drug budget
NS	Select hospital pharmacies	MOH high cost drug budget
ON	Community pharmacies	Mixed
QUE	Community pharmacies	RAMQ
SK	Select hospital pharmacies	Mixed

Objectives
Questions we will answer

1. How has transplant immunosuppression use changed over time in BC?

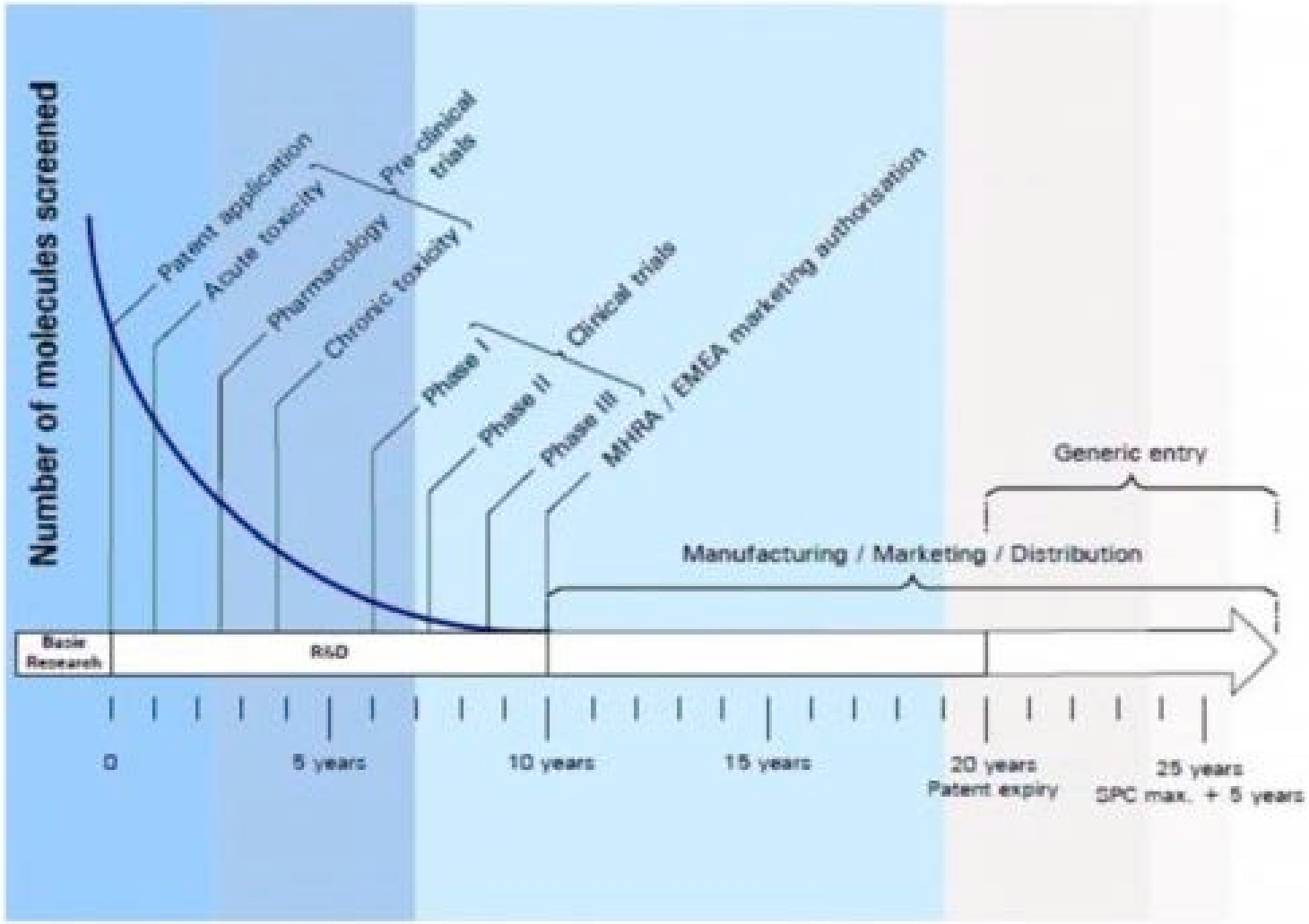
2. **What is a generic or 'alternative brand' drug?**

3. What are the 'myths' and concerns with alternative brand formulations?

2. What is a generic or ‘alternative brand’ drug?

…a drug that is comparable to brand/reference/innovator drug in dosage form, strength, route of administration and quality.

After patent expiration → Alternative brand drug



Patent expiry dates on Innovator drugs in Canada

TABLE 1. Patent expiry on oral immunosuppressive drug formulations in Canada[a]

Branded product	Medicinal ingredient	Dosage form(s)	Projected patent expiry date[b]	Therapeutic drug monitoring
Cellcept	Mycophenolate mofetil	Capsules, tablets	29 November 2011[c]	Not routine
Prograf	Tacrolimus	Immediate release capsules	30 July 2013[c]	Yes
Cellcept	Mycophenolate mofetil	Oral suspension	27 September 2014[d]	Not routine
Rapamune	Sirolimus	Oral solution	28 September 2014[c]	Yes
Myfortic	Mycophenolate sodium	Enteric-coated tablets	10 April 2017[c]	Not routine
Rapamune	Sirolimus	Tablets	02 March 2018[d]	Yes
Advagraf	Tacrolimus	Extended release capsules	25 March 2019[d]	Yes

[a] Cyclosporine no longer has patent protection in Canada. Although generic formulations with bioequivalence to Neoral are available on the Canadian market, Neoral continues to be the product of choice and is covered under most publicly funded drug plans for SOTR.

[b] As per Health Canada Patent Register (4).

[c] Patented composition of matter.

[d] Patented formulation.

SOTR, solid organ transplant recipients.

Harrison, J et al. Transplantation 2012. 83 (7):657

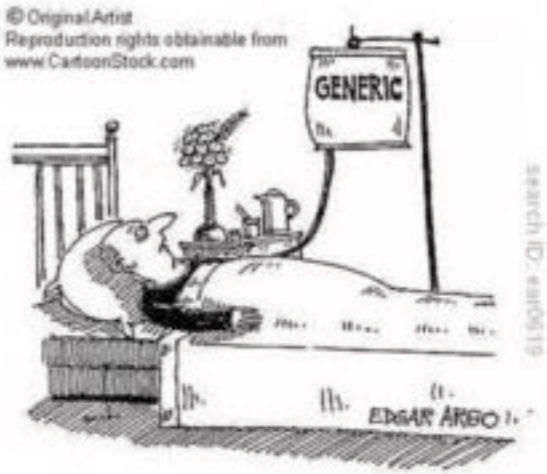
Registration of alternative brand drugs

Innovator products

– require full dossier containing pre-clinical and clinical data submitted in accordance with regulatory requirements

Generic products

– require demonstration of bioequivalence to innovator products



Objectives
Questions we will answer

1. How has transplant immunosuppression use changed over time in BC?

2. What is a generic or 'alternative brand' drug?

3. **What are the 'myths' and concerns with alternative brand formulations?**

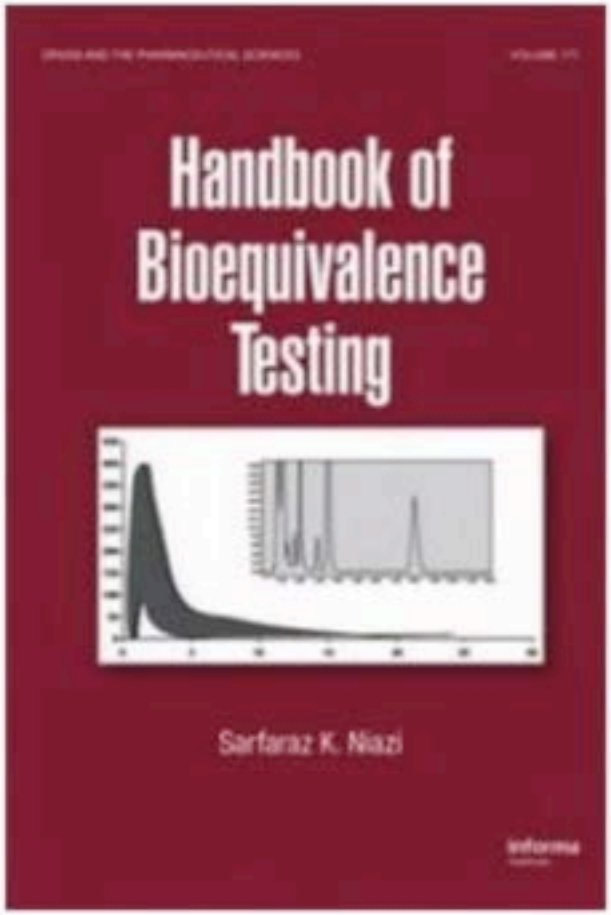
3. What are the ‘myths’ and concerns with alternative brand formulations?

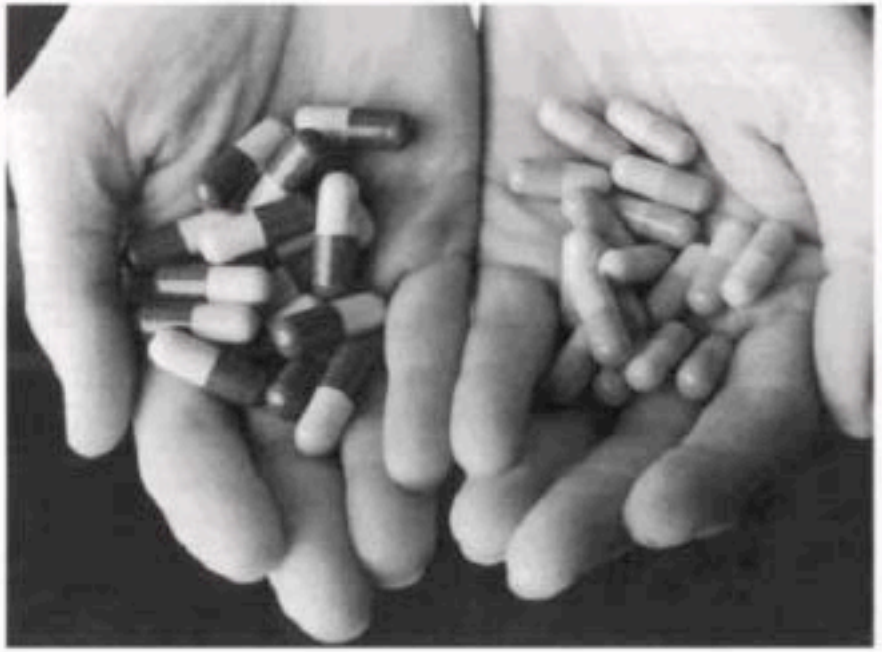
A. **Is an alternative brand drug the same as an Innovator Drug?**

A. Is an alternative brand drug the same as an Innovator Drug?

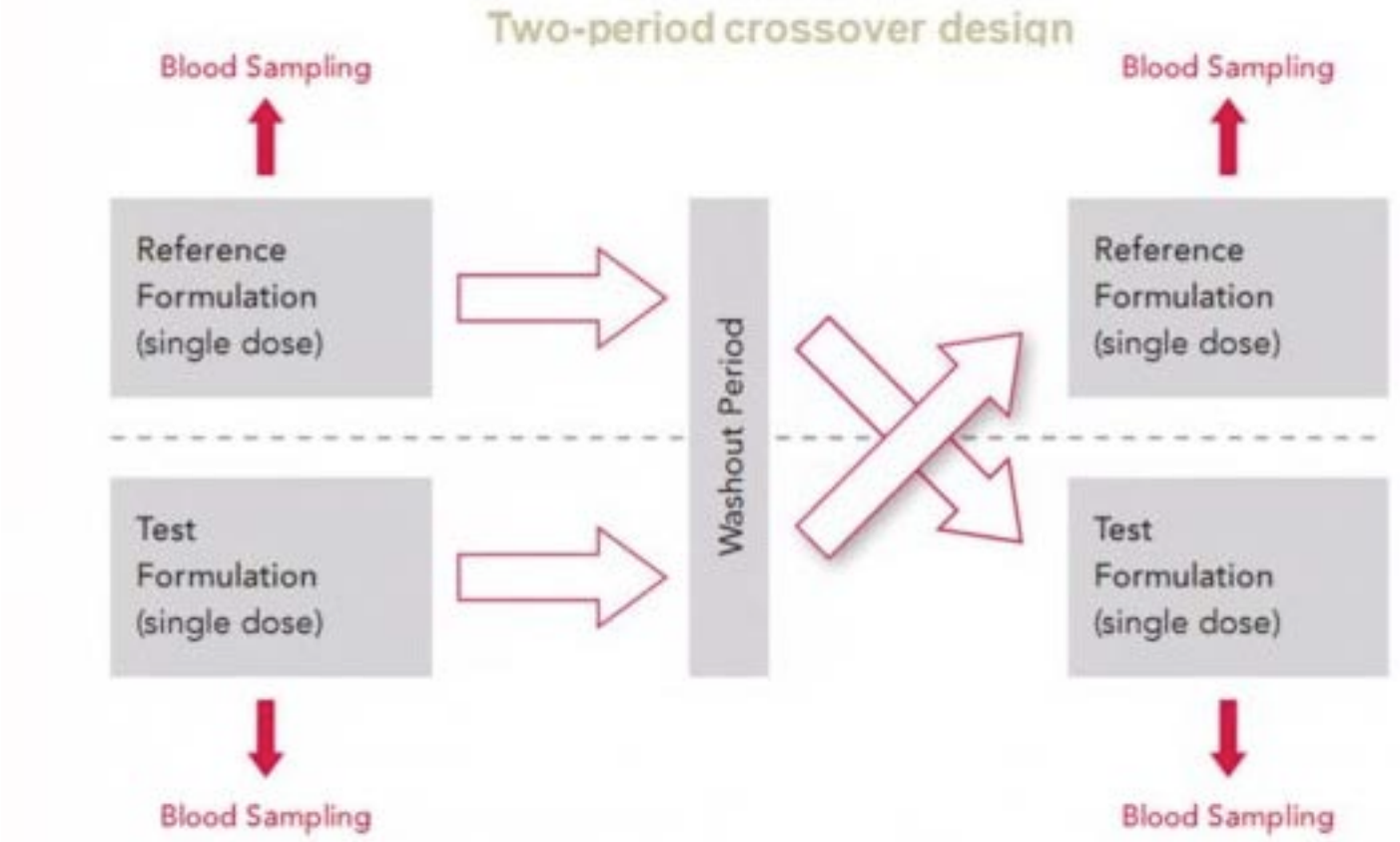
- Are they the same drug?
- Does the therapeutic window of the drug matter?
- Is substitution ok and who should decide?

Alternative-brand have the same active ingredients as Innovator drug but must meet Health Canada's standards for bioequivalence.



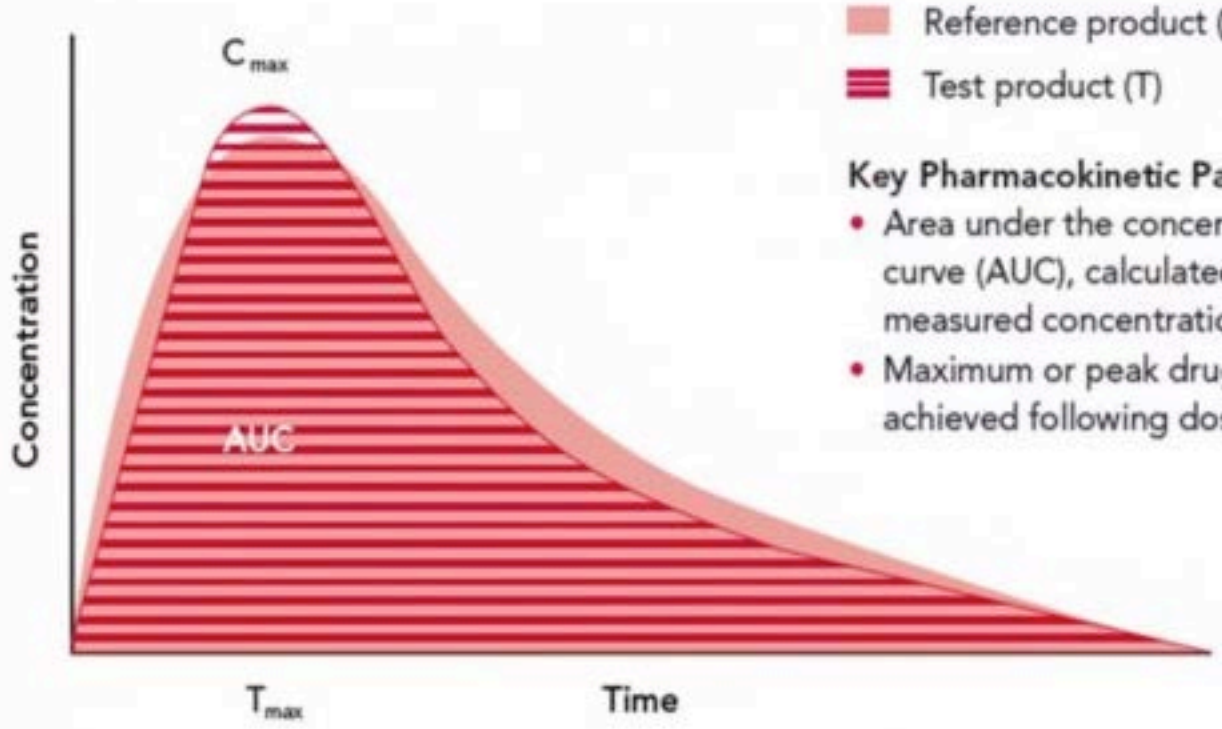


Two-period crossover design



Bioequivalence Assessment Pharmacokinetic Parameters

Comparison of the key pharmacokinetic parameters, AUC and C_{max}



Key Pharmacokinetic Parameters

- Area under the concentration-time curve (AUC), calculated to the last measured concentration (AUC_{∞})
- Maximum or peak drug concentration achieved following dosing (C_{max})

Criteria for Demonstrating Bioequivalence

Two drug products are considered bioequivalent if 90% Confidence Intervals for both AUC and Cmax mean ratios fall entirely within the acceptance limits of 80–125%

Drugs with a Narrow Therapeutic Index (NTI)

New guidelines (EMA, 2010) indicate that NTI drug products are considered bioequivalent if the Confidence Intervals for both mean AUC and Cmax ratios fall within the range 90–111%

- In Canada
  - AUC 90-112%
  - Cmax 80-125%

What is Therapeutic Equivalence?

"A medicinal product is therapeutically equivalent with another product if it contains the same active substance or therapeutic moiety and, clinically, shows the same efficacy and safety as the product whose efficacy and safety has been demonstrated"

Therapeutic equivalence of generic drugs is assumed on the basis of bioequivalence and pharmaceutical equivalence

Are drugs which are bioequivalent also interchangeable?

Perspective of health insurance companies.

Perspective of MDs.

Perspective of PharmDs.

Perspective of patients.

Concerns regarding substitution.

1. Who decides if, in whom and when substitution takes place?

Substitution: by whom and when?

If a patient is switched from innovator drug to generic drug then the treating physician may want to check drug concentrations in blood, and check if the patient is doing the right thing.

- crucial that MD takes the initiative to substitute, and not the PharmD

Health insurance companies should not force PharmDs to substitute.

Concerns regarding substitution.

1. Who decides in whom and when substition takes place?
2. Following a first substitution there will be more substitutions to other generic formulations.

Repetitive substitutions.

Driven by search for lowest price

- Health insurance companies renew contract every 6 or 12 months

Prescribers will not be informed

- PharmD will assume MD agrees, as also the first substitution was agreed upon
- MD is unaware of such follow-on substitutions, while changes in drug exposure can be more pronounced compared to substitution from brand name to first generic
- no possibility to check drug exposure or adherence

Concerns regarding substitution.

1. Who decides in whom and when substition takes place?
2. Following a first substitution there will be more substitutions to other generic formulations (price driven)
3. (Repetitive) substitutions will lead to confusion and mistakes.

Confusion and mistakes

Successively providing patients with different generic formulations will lead to confusion and errors and to reduced adherence.

For which drugs is this relevant?

Narrow therapeutic index drugs

- Calcineurin inhibitors (CsA, Tac)
- mTOR inhibitors (SRL, ERL)

- Mycophenolic acid (MMF, EC-MPS)

Concerns regarding substitution.

1. Who decides in whom and when substition takes place?
2. Following a first substitution there will be more substitutions to other generic formulations (price driven)
3. (Repetitive) substitutions will lead to confusion and mistakes.
4. What does the patient want?

Transplant International © 2011 European Society for Organ Transplantation **24** (2011) 770–779

A survey to determine the views of renal transplant patients on generic substitution in the UK

Mubarak N. Al Ameri,[1] Clare Whittaker,[2] Arthur Tucker,[1] Magdi Yaqoob[1,2] and Atholl Johnston[1]

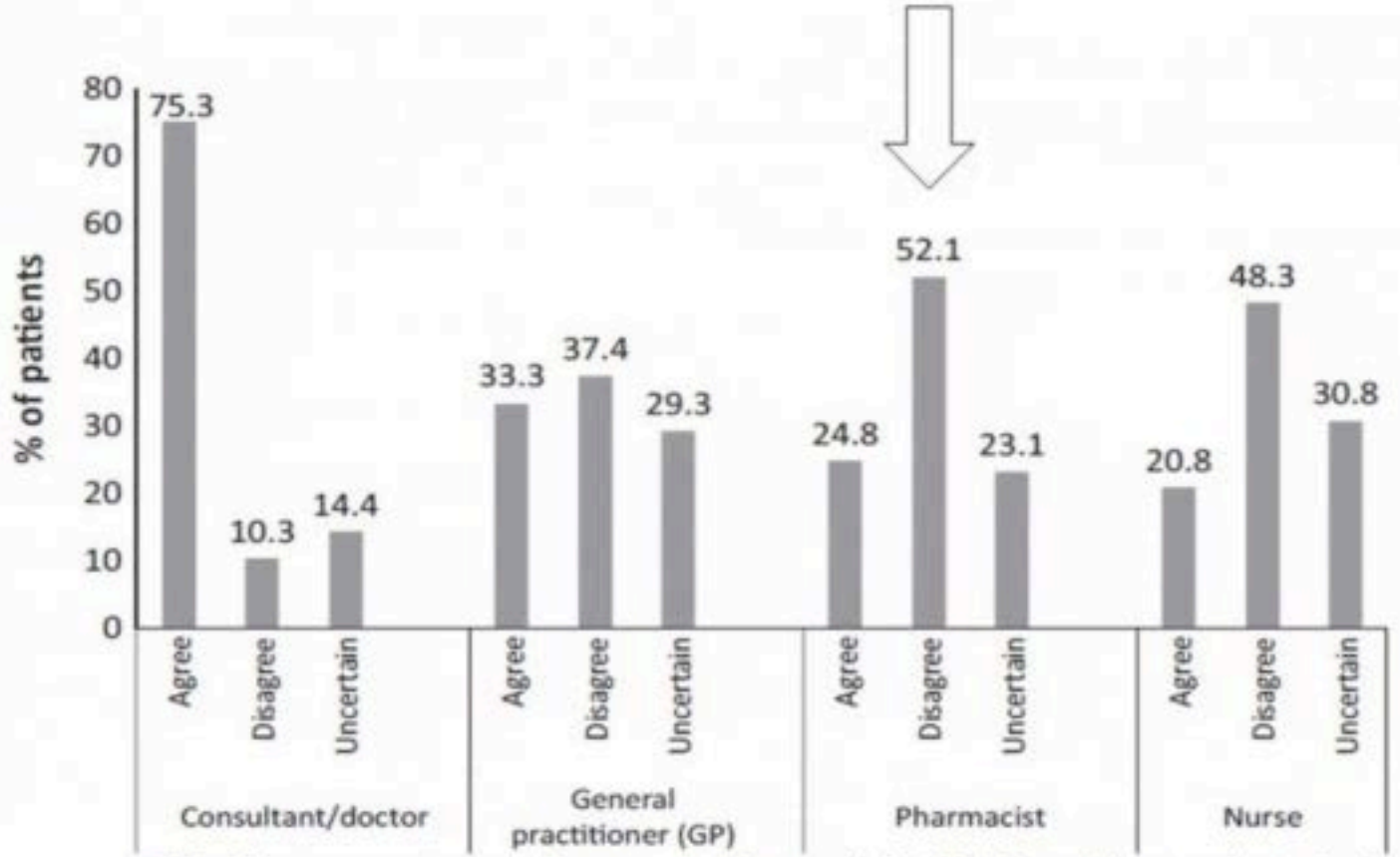
1 Clinical Pharmacology, William Harvey Research Institute, Barts and The London, School of Medicine and Dentistry, Queen Mary University of London, UK

2 Barts and The London, Royal London Hospital, Renal Transplant Clinic, Whitechapel, London, UK

Table 2. Questions and responses evaluating renal patients' general knowledge of generic medicines and substitution.

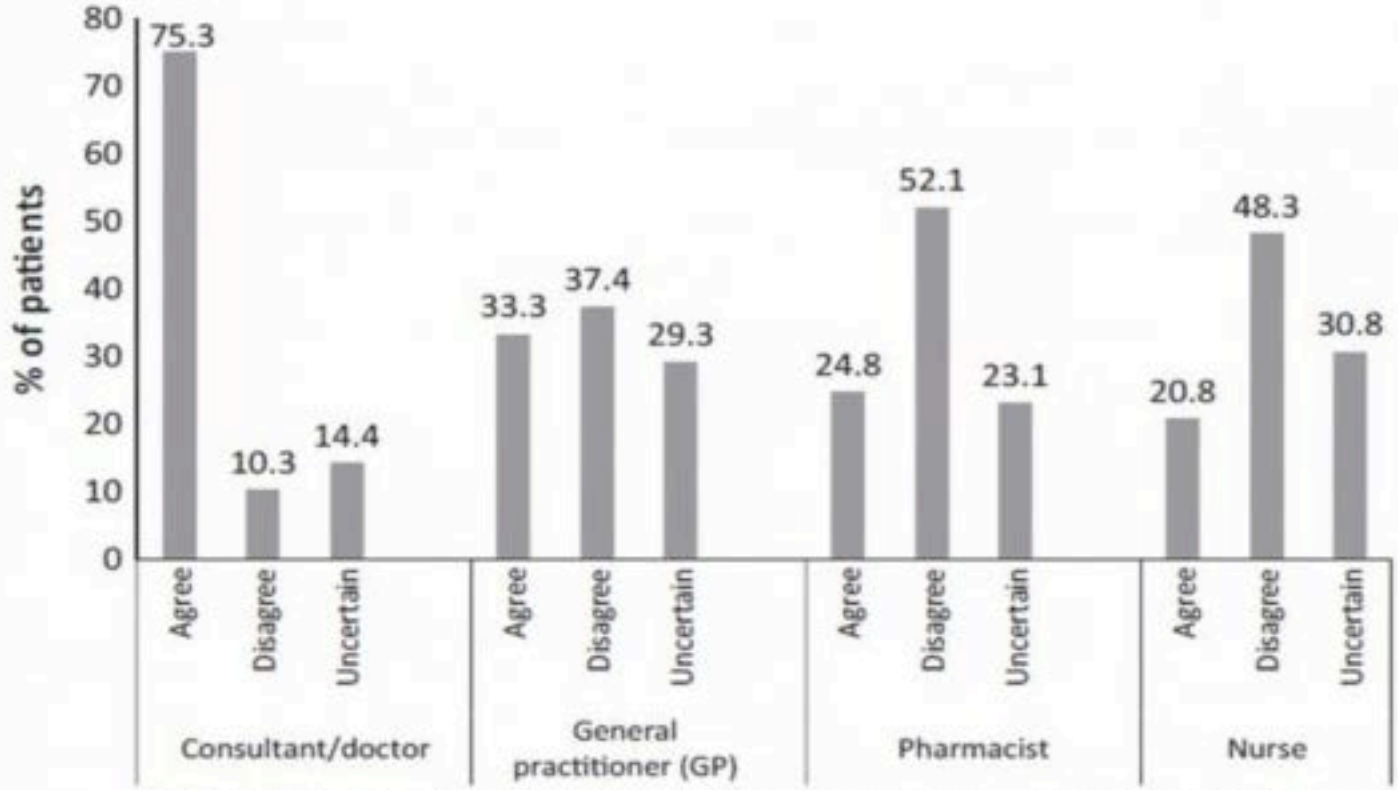
Questions	Answers	Number of responders	Percentages of responders
Would you agree to switch your current branded ciclosporin to a generic form to save the NHS money? (*n** = 135)	Agree	31	23
	Disagree	50	37
	Uncertain	54	40
Do you think that generic medicines are equivalent and have the same quality as the branded medicines? (*n** = 146)	Agree-always	24	16
	Disagree-always	10	7
	Yes-sometimes	50	34
	Uncertain	62	43

Renal transplant patients' views on generic substitution in the UK



Would you agree to switch to a generic medicine if initiated by your hospital consultant/doctor, GP, pharmacist or nurse?

Renal transplant patients' views on generic substitution in the UK



Would you agree to switch to a generic medicine if initiated by your hospital consultant/doctor, GP, pharmacist or nurse?

My opinion…

Conditions that need to be fulfilled to substitute:

1. Initiative is by MD
2. Only one substitution (branded generic)
3. Under controlled conditions
4. Patient must be informed and must agree
5. High quality producer able to guarantee stock

3. What are the ‘myths’ and concerns with alternative brand formulations?

A. Is an alternative brand drug the same as an Innovator Drug?

B. Why is testing different for alternative brand vs Innovator

B. Why is testing different for an alternative brand vs Innovator

- Alternative brand is not a new chemical entity
- Need to prove pharmaceutically equivalent and bioequivalent to Innovator
- Testing performed in **healthy volunteers**

Innovator products

– require full dossier containing pre-clinical and clinical data submitted in accordance with regulatory requirements

Generic products

– require demonstration of bioequivalence to innovator products

Factors influencing pharmacokinetics of immunosuppressive medications in solid organ transplant

Factor	Description	Relevance for approval of generic formulations
Disease state	Absorption and metabolism of medications in SOTR may differ from healthy volunteers due to the presence of co-morbid disease states (*9–12*). Pharmacokinetic profiles of immunosuppressive drugs are known to change with time post-transplant (*9, 13*).	Bioequivalence studies conducted in healthy volunteers receiving a single dose of the medication do not capture the potential impact of co-morbidities nor the longitudinal variability that may occur with chronic use.
Drug-drug interactions	SOTR are required to take multiple medications. Co-administration of other drugs, including other immunosuppressants, may influence the pharmacokinetic profile of immunosuppressive medications. These effects may be different from one formulation to another (*9, 13, 14*).	Bioequivalence studies are not conducted in the presence of commonly co-administered medications, which may have clinically relevant implications for SOTR.
Drug-food interactions	Rate and extent of absorption is known to be affected by food for some immunosuppressants, including cyclosporine, tacrolimus and mycophenolate, and may differ according to product formulation (*9, 13, 15, 16*).	Bioequivalence testing in both the fed and fasted state is required for critical dose drugs. Unique formulation-specific dietary interactions with branded or generic products are not likely to be captured with current regulatory approval processes.
High risk populations	Differences in immunosuppressant pharmacokinetics in the pediatric population have been well-described (10,17). Differences in bioavailability of immunosuppressants have been demonstrated in certain ethnic subgroups as a result of P-glycoprotein and cytochrome P450 enzyme polymorphisms (*10, 18, 19*).	Bioequivalence studies are not conducted in pediatrics. Populations with potentially altered immunosuppression absorption patterns or polymorphisms are under-represented in bioequivalence studies.

Harrison, J et al. Transplantation 2012. 83 (7):657

3. What are the 'myths' and concerns with alternative brand formulations?

A. Is an alternative brand drug the same as an Innovator Drug?
B. Why is testing different for alternative brand vs Innovator
C. **What is different about critical dosing drugs?**

GUIDANCE DOCUMENT

Conduct and Analysis of Comparative Bioavailability Studies

Published by authority of the
Minister of Health

Adopted Date	2012/02/08
Effective Date	2012/05/22

Health Products and Food Branch

Critical dose drugs: Definition

"Drugs where comparatively small differences in dose or concentration lead to dose- and concentration-dependent, serious therapeutic failures and/or serious adverse drug reactions which may be persistent, irreversible, slowly reversible, or life threatening, which could result in inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, or death" HC

Criteria for demonstrating bioequivalence in Critical Dose Drugs

- The 90% CI of the relative mean AUC of the test to reference formulation should be within 90% to 112% inclusive.

- The 90% CI of the relative mean Cmax of the test to reference formulation should be between 80% and 125% inclusive.

These standards apply to (but not limited to) the following formulations:

- **cyclosporine**;
- digoxin;
- flecainide;
- lithium;
- phenytoin;
- **sirolimus**;
- **tacrolimus**;
- theophylline; and
- warfarin

3. What are the 'myths' and concerns with alternative brand formulations?

A. Is an alternative brand drug the same as an Innovator Drug?
B. Why is testing different for alternative brand vs Innovator
C. What is different about critical dosing drugs?
D. Are there differences between 'brands' of alternative brands?

Expedients (inactive ingredients) may differ

Mycophenolate Mofetil	Inactive Ingredients
Cellcept	• croscarmellose sodium, magnesium stearate, povidone (K-90) and pregelatinized starch. • Capsule shells : black iron oxide, indigotine (FD&C blue#2), gelatin, potassium hydroxide, red iron oxide, shellac, titanium dioxide, and yellow iron oxide
TEVA	• croscarmellose sodium, magnesium stearate, microcrystalline cellulose, povidone (K-90) and pregelatinized starch. • Opadry coating: hypromellose, polyethylene glycol, talc, titanium dioxide, FD & C Red #40 Allura Red AC Aluminum Lake, FD & C Blue #2 Indigo Carmine Aluminum Lake • Capsule: Gelatin, FD & C Blue 1, FD & C Red 40, D&C Red 28, D&C Yellow 10 • Ink: black iron oxide, polyethylene glycol and shellac
APO	cellulose - microcrystalline , croscarmellose sodium, silica - colloidal anhydrous, magnesium stearate, Opadry Film-Coating System 20B50135 Purple

Cost

Mycophenolate Mofetil	Cost per 500mg tablet
Cellcept	$4.12
TEVA	$0.30
Other alternative brand	<$0.50

Appearance

MMF Cellcept

MMF TEVA

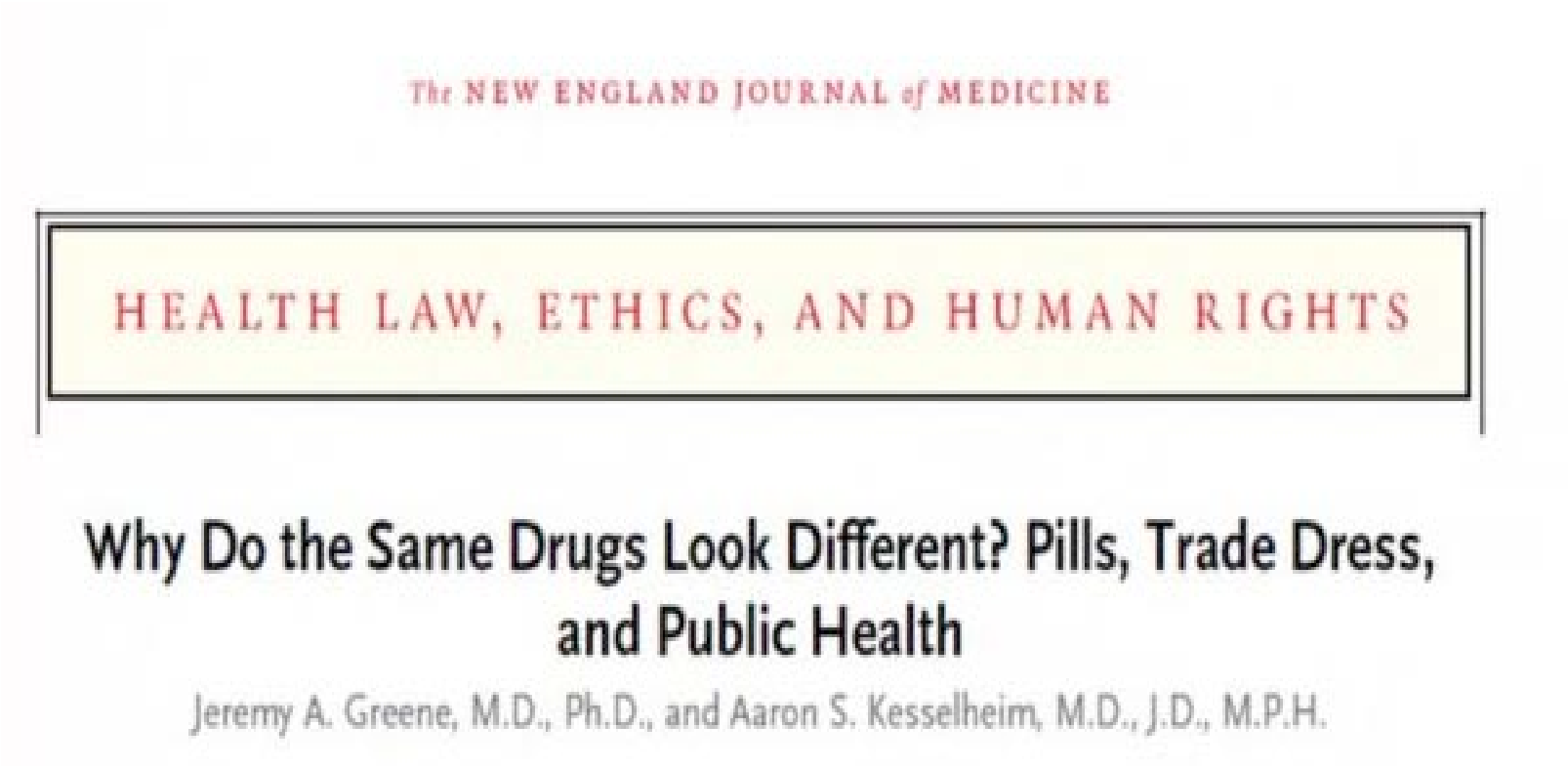
MMF APO

MMF MYLAN

3. What are the 'myths' and concerns with alternative brand formulations?

A. Is an alternative brand drug the same as an Innovator Drug?
B. Why is testing different for alternative brand vs Innovator
C. What is different about critical dosing drugs?
D. Are there differences between 'brands' of alternative brands?
E. **Does the appearance of a drug make a difference?**

Innovator drug and alternative brand drug usually differ in shape and color, resulting in confusion and mistakes



The NEW ENGLAND JOURNAL of MEDICINE

HEALTH LAW, ETHICS, AND HUMAN RIGHTS

Why Do the Same Drugs Look Different? Pills, Trade Dress, and Public Health

Jeremy A. Greene, M.D., Ph.D., and Aaron S. Kesselheim, M.D., J.D., M.P.H.

Why do Innovator and Alternative brand drug not have the same appearance?

Drug manufacturers claim exclusive ownership of the physical aspects of their products — including the size, shape and color — as private property under a subset of trademark law called "trade dress."

This limits generic-drug manufacturers to design follow-on products with the same physical appearance of the innovator brands.

JAMA Intern Med. 2013;173(3):202-208.

ORIGINAL INVESTIGATION

Variations in Pill Appearance of Antiepileptic Drugs and the Risk of Nonadherence

Aaron S. Kesselheim, MD, JD, MPH; Alexander S. Misono, MD, MBA; William H. Shrank, MD, MSHS; Jeremy A. Greene, MD, PhD; Michael Doherty; Jerry Avorn, MD; Niteesh K. Choudhry, MD, PhD

Sorting out drugs on the kitchen table.

Visual cues paramount to identification of pills.

Changes in appearance will confuse patients.

Why do patients who experience changes in pill color have an increased risk of interruptions in medication use?

A pill's physical attributes have been linked to expectations of efficacy of both placebos and pharmacologically active prescription drugs

Thus, changes in pill appearance may not only deprive patients of these expectations of efficacy, but potentially even have the opposite effect—a belief that the newly substituted pill will be less efficacious (the so-called nocebo effect).

Nonpersistence may result.

Cautions

- Drug shortages and repetitive switching

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Drug Shortages — A Critical Challenge for the Generic-Drug Market

Bruce A. Chabner, M.D.

N Engl J Med 2011; 365:2147-2149 | December 8, 2011 | DOI: 10.1056/NEJMp1112633

THE GLOBE AND MAIL

JACALYN DUFFIN

Why Canadians can expect more shortages of generic drugs

JACALYN DUFFIN

Contributed to The Globe and Mail

Published Friday, Mar. 07 2014, 7:30 AM EST

Last updated Friday, Mar. 07 2014, 7:34 AM EST

THE GLOBE AND MAIL

Hospitals scramble with backup plans in face of national drug shortage

KIM MACKRAEL, CARYS MILLS AND ANNA MEHLER PAPERNY

The Globe and Mail

Published Thursday, Mar. 08 2012, 10:11 PM EST

Last updated Thursday, Sep. 06 2012, 1:08 PM EDT

Cautions

- Drug shortages and repetitive switching
- Non-physician prescribing
- Uncertainty in some patient populations
- Critical dosing drugs

Allard and Fortin *Canadian Journal of Kidney Health and Disease* 2014, 1:23
http://www.cjkhd.org/content/1/1/23

Canadian Society of Nephrology/
Société Canadienne De Néphrologie
CSN/SCN

CANADIAN JOURNAL OF
KIDNEY HEALTH AND DISEASE
Journal Canadien de la Santé et de la Maladie Rénale

REVIEW Open Access

Is it ethical to prescribe generic immunosuppressive drugs to renal transplant patients?

Julie Allard[1] and Marie-Chantal Fortin[1,2,3*]

Ethical conflicts

- Distributive justice
- Physician duty
- Risk-benefit analysis
- Conflict of interest
- Patients informed consent
- Logistics (drug shortages)

Is it ethical to prescribe alternative brand immunosuppressive drugs?

Yes, provided the following:

- Regulatory safeguards to minimize risk of substitution
- Education of patients
- Further clinical studies particularly of critical dosing IS in transplant patients
- Further health economics studies re costs related to drug substitution

Pharmacoeconomics

Choices may vary according to:

- wish of patient
- perspective of prescriber
- health care system (insurance)
- economic situation (patient, country)

Position Statements of Professional Societies on the use of alternative brand immunosuppression

Canadian Society of Transplantation (2012) [1]	• Insufficient literature regarding efficacy and safety. • Close monitoring with any change. • Not recommended in pediatric patients. • The intended drug formulation must be explicitly stated on all prescriptions to avoid substitutions. • Educate patients about formulations and substitutions. • Prescriber and patient should be involved in any decision to change formulation. Mandatory notification of the prescriber should be a legal requirement. • Licensing requirements for critical dose drugs must be re-assessed. Bioequivalence in solid organ transplant recipients (SOTR). Requirement for generic manufacturers to provide clinical outcome data in SOTR. • Transplant centres should be funded according to the increased costs associated with managing SOTR arising from the introduction of generic immunosuppression. • Repetitive substitution should be avoided. • Patients should be informed about substitution and taught how to identify different formulations of the same drug so they can alert their physician if an uncontrolled substitution is made. • The simultaneous use of different formulations in the same patients should be avoided.

You are seeing a patient who is 5 years post successful living donor transplantation

The patient has been on tacrolimus (Prograf) and mycophenolate mofetil (Cellcept) since transplantation and is stable.
Recently alternative brand (generic) drugs have been introduced and are much cheaper than the innovator drugs.

1. Would you switch the patient from Cellcept to alternative brand MPA?

2. Would you switch the patient from Prograf to alternative brand tacrolimus?

Dawn Strong BSc Phm, PharmD

BCT Pharmacist

BCT Provincial Mandate

- Responsibility for all organ donation & transplantation services across the province. As an agency governed by PHSA, BC Transplant's activities are aligned with & contribute to PHSA's three key strategic objectives of improving quality outcomes for patients, promoting healthier populations, & contributing to a sustainable health care system.

BCT Funded Immunosuppressants

- Cyclosporine
- Tacrolimus
- MPA’s
- Azathioprine
- Sirolimus
- Prednisone

CellCept Patent Expires Nov 2011

- BCT reviews literature of process, legislation, funding, interchangeability, generic issues in transplant recipients
- BCT reviews literature available on the use of alternate brands of MMF in transplant recipients
- Jan 2012 Seven new alternate brand MMF products receive Health Canada NOC
- No clinical reason not to switch to an alternate brand of MMF
- Environmental scan of other provinces

Contracting for BCT Drugs

- Drug contracts done through HSSBC/HealthPro
- HealthPro:
  - Product Evaluation Committee: physically review drugs/labelling/packaging
  - Vendor Quality Management Assessment
  - Contingency Plan with Respect to Drug Shortages
  - Manufacturing Facilities

HealthPro Awards Contract to Teva (Novo)

- BCT requests & reviews Teva data submitted to Health Canada for NOC bioavailability studies & copy of NOC
- Met with MoH Drug Optimization Committee: best method on how to introduce a change

BCT Medical Leadership Team Approval

- Presentation on alternate brand drugs, Health Canada requirements for NOC, interchangeability, use of MMF in transplant recipients, pricing, estimated cost savings
- MLT approves use of Teva MMF as phased in approach to start Sept 2012
  - De novo recipients at SPH/VGH
  - SPH/VGH patients requiring MMF at next clinic visit
  - Other clinics begin
  - Other organ groups

Process Used For Alternate Brand MMF

24/6/2012 BCT informed no CellCept 250 mg in Canada as of 16/7/2012

BCT decision to rollout Teva MMF 16/7/2012

BCT Communication Plan for MMF Roll out

MLT/ MD's/Post Transplant Clinics/ Patients/ McKesson/ BCT /Teva/ MoH

Patient Info Sheets/ Q & A for healthcare professionals

Alternate Drug Approval for Patients with ADR on Generic

Prescriber to assess, discuss, review ADR & options with patient

↓

Prescriber to send HC ADR Reporting Form & BCT Fax Form

↓

Prescriber to write Rx for patient to trial an alternate brand

↓

Patient experiences a significant ADR to 2nd alternate brand to trial one more

↓

If patient not able to tolerate alternate brands BCT Drug Strategy Review Committee to review data with prescriber & consider funding brand product

BCT Fax Form: Application for Drug Coverage for Patients Experiencing an ADR to Alternate Brand Drug

- BCT #, Patient Name, Transplant Clinic, Prescriber
- BCT alternate brand drug patient currently on
- Adverse drug reaction to alternate brand drug
- Describe patient's previous course while on brand drug
- Prescriber's evaluation and recommendation
- Attach completed Canada Vigilance Adverse Drug Reaction Reporting Form

Lessons Learned From Teva MMF Rollout

- BCT to engage physicians earlier in the process
- Need to engage each organ group transplant team to provide consistent messaging
- Education is required for transplant team and patients

BCT Drug Strategy Advisory Committee

- Created, in October 2013
- Purpose is to provide:
  - recommendations regarding an overall provincial drug strategy for BCT with a primary focus on evidence - based best practices & implementation
  - consistent evaluation of drugs & new indications for drugs to be assessed for BCT formulary
  - change management strategy when new drugs are to be prescribed in BCT patient

Drug Strategy Advisory Committee Members

- **Transplant Program Leadership** – Medical Director Renal Transplant Program/SPH Renal Transplant Program, Director VGH Transplant Program/ Renal Transplant VGH
- **BCT** – BCT Operations Director, Communications , Pharmacist, Nurse with experience in pre/post tx clinics, QA/QI Transplant Process
- **Drug Strategy Process Experts -** Clinical Director Health Pro, Medical Lead, Projects & Initiatives, BC PRA, Academic Input, Renal Transplant Program Physician, Solid Organ Transplant Pharmacist, Community Pharmacist
- **Clinical Experts -** Transplant Medical Directors Health Authorities: Island, Interior, Fraser, Northern, Cardiologist, Hepatologist, Respirologist, Pediatric Pharmacist

Generic Working Group

- Make a recommendation to forward to BCT Drug Advisory Committee as to whether or not BCT will fund alternate brands of non-critical dose drugs
- If BCT will fund alternate brands of non-critical dose drugs, determine process & monitoring required.

When Reviewing Alternate Brand Drugs What the Generic Working Group Reviews

- Review all clinical trials comparing innovator vs. alternate brand in transplant recipients (# patients, transplant type, intervention, outcome,
- Current environment in Canada
- Patient adherence
- Cost to change

Key Principles To Fund Alternate Brand Critical Dose Drugs

- BC is unique, BCT funds & identifies specific brand that will be dispensed through our 12 partner pharmacies
- Same brand of drug for in hospital & out-patients
- Assurance of drug supply for life saving medications
- All strengths of drug must be available
- Education plan for transplant patients, physicians, pharmacists & nurses
- Consistent messaging
- Must be a significant cost savings to BCT

BC Transplant

- There is now a rigorous process in place for medications to be evaluated on a provincial level
- Decisions are made that are the best for the patient
- If you have any questions please speak to BCT or the Drug Strategy Advisory Committee representative from your area

You are seeing a patient who is 5 years post successful living donor transplantation

The patient has been on tacrolimus (Prograf) and mycophenolate mofetil (Cellcept) since transplantation and is stable.
Recently alternate brand drugs have been introduced and are much cheaper than the innovator drugs.

1. Would you switch the patient from Cellcept to alternate brand MPA?
2. Would you switch the patient from Prograf to alternate brand tacrolimus?