Institut de recherche
Centre universitaire de santé McGill
Research Institute
McGill University Health Centre

McGill

L'experience de l'unité d'évaluation des technologies (TAU) de CUSM - Regarder dans le rétroviseur pour mieux voir l'avenir

James (Jay) Brophy MD PhD
Professor
Departments of Medicine and of Epidemiology, Biostatistics, and Occupational Health
McGill University

SYMPOSIUM SUR L'ÉVALUATION DES TECHNOLOGIES ET DES MODES D'INTERVENTION EN SANTÉ : aujourd'hui et demain

CHUM

Conflicts of Interest

None

Learning Objectives

1. Understand TAU's historical perspective
2. Appreciate the successes & failures
3. Future applications

Maurice McGregor - An inspirational sentinel

- Founder & 1st president of Le Conseil d'évaluation des technologies de la santé du Québec (1988-94), precursor of AETMIS and INESSS
- Founder MUHC TAU 2001
- Chevalier l'Ordre National du Québec

Montreal Climate March, September 27, 2019

MUHC TAU Founding Principles

- To advise the hospital in difficult resource allocation decisions based on sound, scientific technology assessments, and a transparent, fair decision-making process that considers effectiveness and costs

- To develop policy recommendations based not only on the data but are also consistent with values of the community and consider relevant social, legal, or ethical issues

- Final responsibility for decision making is not TAU's

TAU successes

End-user involvement in health technology assessment (HTA) development: A way to increase impact

Maurice McGregor, James M. Brophy
McGill University and *McGill University Health Centre*

Results: To date, 16 reports have been completed, each within 2–4 months. Five recommended unrestricted use, seven recommended rejection, and four recommended very limited use of the technology in question. All have been incorporated into hospital policy. Budget impact is estimated at approximately $3 million of savings per year.

Friends of the process

- Evidence based medicine
- Other HTA agencies
- Professional guidelines
- Knowledgeable clinicians
- Published cost-effectiveness studies

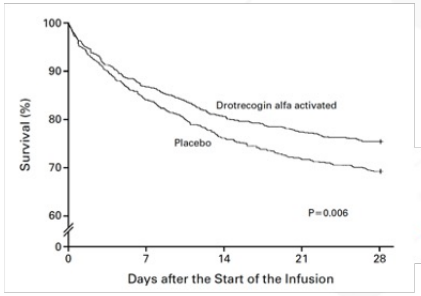
EBM / CEA / Guidelines

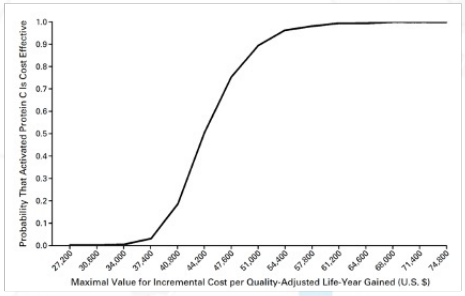
The NEW ENGLAND JOURNAL of MEDICINE

EFFICACY AND SAFETY OF RECOMBINANT HUMAN ACTIVATED PROTEIN C FOR SEVERE SEPSIS

Special Article

AN ECONOMIC EVALUATION OF ACTIVATED PROTEIN C TREATMENT FOR SEVERE SEPSIS





NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

Final Appraisal Determination

Drotrecogin alfa (activated) for severe sepsis

1 Guidance

1.1 Drotrecogin alfa (activated) is recommended for use in adult patients who have severe sepsis that has resulted in multiple organ failure (that is, two or more major organs have failed) and who are being provided with optimum intensive care support.

CUSM expert clinicians
Should be standard of care
70 cases / yr
Request a budget of $800K /yr

SYMPOSIUM SUR L
DES TECHNOLOGI
D'INTERVENTION
aujourd'hui et dema

CHUM

APC – TAU opinion

- Concerns about the RCT, missing data, consistency, need for replication study -> not recommended
- Cost effective studies useless if effecticvness has not been first established

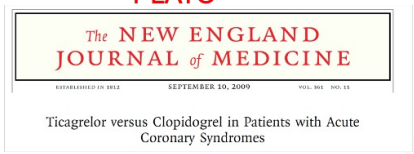
Drotrecogin alfa (activated) for severe sepsis (TA84)

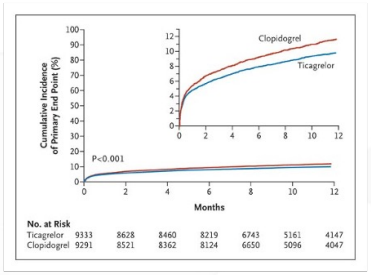
November 2011 On 25 October 2011, Eli Lilly and Company announced the withdrawal of its Xigris (drotrecogin alfa [activated]) product in all markets following results of the PROWESS–SHOCK study, which showed the study did not meet the primary endpoint of a statistically significant reduction in 28-day all-cause mortality in patients with septic shock. The company is working with regulatory agencies on this withdrawal, and is in the process of notifying healthcare professionals and clinical trial investigators. As a result of this, NICE has withdrawn its guidance on the use of drotrecogin alfa (activated) for severe sepsis.

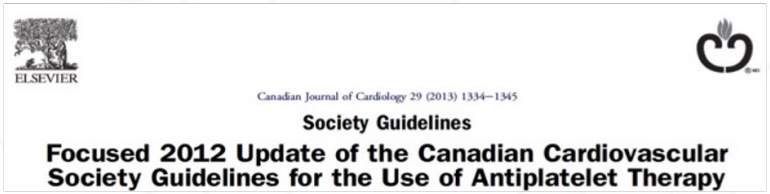
Technology appraisal guidance Published 22 September 2004

EBM & guidelines – Example # 2

PLATO







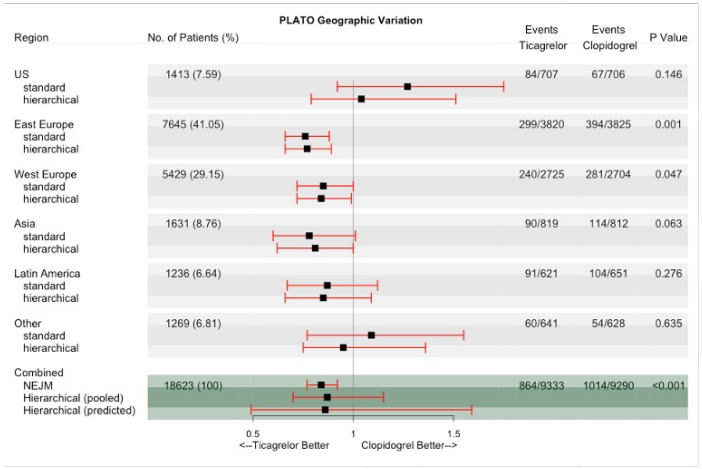
2. We recommend ticagrelor 90 mg twice daily over clopidogrel 75 mg daily for 12 months in addition to ASA 81 mg daily in patients with moderate to high risk NSTEACS (as defined in PLATO[16]: ≥2 or more of (1)

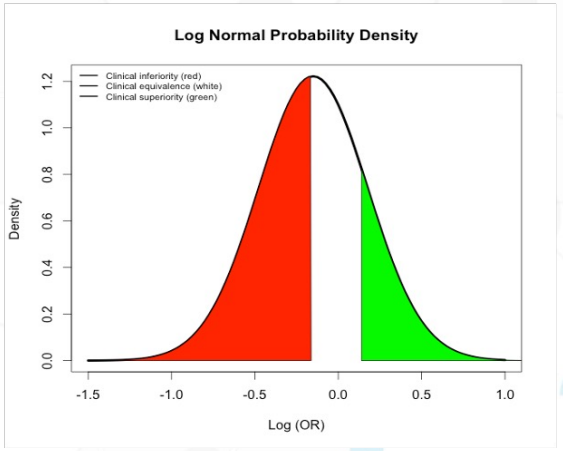
(Strong Recommendation, High-Quality Evidence)

Reanalysis

Hierarchical

Bayesian





Suggests a low probability that ticagrelor (@$1200/y) is clinically superior to clopidogrel (@$168/y)
$25MM / year additional expense

Practical Problems With Pharmacoeconomic Analyses (n=326)

Nature of Problems	Details of Problems	No. (%) of Problems
Estimate of comparative clinical efficacy (n = 154)	Availability of trials	12 (4.8)
	Poor-quality trials	31 (12.4)
	Analysis of interpretation of trial results	32 (12.9)
	Use of surrogate outcomes	15 (6.0)
	Determining therapeutic equivalence	64 (25.7)
Comparator issues (n = 15)	Uncertainty about choice of comparator or inappropriate comparator	15 (6.0)
Modeling issues (n = 71)	Technical aspects of the model	24 (9.6)
	Unsubstantiated assumptions	15 (6.0)
	Uncertainty about costs	32 (12.9)
Calculation errors (n = 9)	Errors that introduced serious inaccuracies in the estimation of the cost-effectiveness ratios	9 (3.6)
Total		**249 (100)**

76% had significant problems

JAMA. 2000;283:2116-2121

Friends and foes

Friends

- Evidence based medicine
- Other HTA agencies
- Professional guidelines
- Knowledgeable clinicians
- Published cost-effectiveness studies

Foes

- Evidence based medicine
- Other HTA agencies
- Professional guidelines
- Knowledgeable clinicians
- Published cost-effectiveness studies

Other barriers

- Cognitive biases
  - Technological imperative
  - Prestigious proponents of a technology in the absence of credible evidence (halo effect)
  - Lack of opportunities for scientific inquiry and skepticism in clinical education
- Conflicts of interest
  - Promotions by various sponsors
- Lack of resources (human and financial)

Reasons for past TAU successes

- Relevance (on-site selection & production of reports)
- Multidisciplinary members with an ability to perform critical analyses
- Awareness of scientific and cognitive biases
- Awareness of intellectual and financial COIs
- Formulation of policy reflecting community values

L'avenir d'UETMIS

Il est important de rappeler notre perspective historique car

plus les choses changent, plus elles restent pareilles