1ST NATIONAL BIO-THERAPEUTICS CONGRESS — PUTTING PATIENT FIRST

22 NOVEMBER 2014
The rising costs in healthcare – Can Biosimilars help?

Dr. Paul Cornes
Dr Paul Cornes
Conflict of interest

- Salary received:
  - United Kingdom National Health Service
- Honoraria received:
  - Roche
  - Janssen
  - Sandoz
  - Lilly
  - European Generics Association
  - Teva
  - Hospira
The rising costs in healthcare - can Biosimilars help?

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Consultant Oncologist,
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Comparative Outcomes Group

ESO Task Force Advisory Board on Access to Innovative Treatment in Europe

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6500 Bellinzona - Switzerland

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Question

- Is there sufficient money in the health system to afford innovation in medicine?

- Please choose your best response:

1. No – we do not have the budget to introduce innovation
2. Unsure
3. Yes – we have the chance to increase spending on innovative treatments
There is a cost to cancer care

“Think about health spending as not consumption but investment”

David E. Bloom, professor of economics and demography at Harvard

File:David E. Bloom at the World Economic Forum Summit on the Global Agenda 2008.jpg
Good news for medicine

- Basic cancer science is paying back on its investment
- One medical paper a minute is added to the PubMed US National Library of Medicine

Good news for cancer treatment: Cancer survival is improving

OECD data on the G7 countries

Aaron Carroll. How do we rate the quality of the US health care system – Disease Care. The Incidental Economist. October 21, 2010 at 4:00 am. Accessed April 29, 2014
Good news for cancer treatment: Cancer survival is improving

Median Survival with Cancer in the UK has risen 10-fold since 1971

1971, 50% 1 year survival

2010, 50% 10 year survival

Good news for cancer treatment

- This investment in innovation means that novel targeted biologic approaches now dominate drug development.
- It is predicted that 2012 was probably the year where biologic therapy use outnumbered cytotoxic treatments.

Good news for cancer treatment: Innovation in cancer drugs

At this rate our decade will add 67 new cancer drugs by 2020!

Cornes P. Pictogram created from data in - Savage P. Development and economic trends in cancer therapeutic drugs: Analysis of modern and historical treatment costs compared to the contemporary GDP per capita. J ClinOncol 32, 2014 (suppl; abstr e17535)
Good news for cancer treatment: Survival impact of some targeted therapies

<table>
<thead>
<tr>
<th>Cancer Disease</th>
<th>Old Model</th>
<th>Old Survival</th>
<th>Personalized Model</th>
<th>Personalized Survival</th>
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<tr>
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<td>Chronic myeloid leukemia</td>
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<td>Imatinib</td>
<td>&gt;22 years</td>
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<td>Imatinib</td>
<td>Close to 5 years</td>
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<td>Relapsed Hodgkin lymphoma</td>
<td>Chemotherapy</td>
<td>1.2 years</td>
<td>Brentuximab vedotin</td>
<td>22.4 months</td>
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Good news for cancer treatment

Drugs in development, 2010

900 drugs in development are for cancer

Source: Medco, R&D Directions

*Top ten therapeutic areas for the world’s big pharmaceutical firms, includes drugs in Phase I, II, III or awaiting FDA approval

Bad news for cancer

Delivering affordable cancer care in high-income countries


Elkin EB, Bach PB. Cancer’s next frontier: addressing high and increasing costs. JAMA 2010;303:1086-1087.
Bad news for cancer treatment

- There will be more cancer to treat as the population ages

- Expected rise in 20 years
Bad news for cancer treatment

- Innovative drug development is slow and expensive

- From 5000 - 10000 compounds in pre-clinical trials:
  - only 0.1% reach clinical trial stage
  - of these, only 10-20% are finally approved

- It takes 15 years from the target discovery to the market at 1.4 Billion Euro / drug
BROOKLYN DAILY EAGLE
And Complete Long Island News

WALL ST. IN PANIC AS STOCKS CRASH

Attempt Made to Kill Italy's Crown Prince

Hollywood Fire Destroys Films Worth Millions

Fear 52 Perished in Lake Michigan Ferry is Missing

Piece of Plane Like Diteman's is Found at Sea

High Duty Group Gave $700,000 to Coolidge Drive

Carnegie Charge of Paid Athletes Houses Colleges

Hoover's Train Halted by Auto Placed on Rails

Warner Sought to Keep Sea Trip Secret, Aids Say

Some Named as Head of New Exchange Bank
ASCO 2009 Meeting emphasis: individualised care and cost-effectiveness

USA Medical insurance costs are rising faster than earnings and general inflation

Ward E. CA Cancer J, 2008;58:9-31
Cost of USA cancer care 1963 to 2004

Cancer treatment spending, in billions

US$

$72.1

$27.5

$13.1

$1.3
In 2003, Medicaid spent $33.7 billion on drugs (19% of national spending for drugs and more than 10% of the Medicaid budget).
Planning for the future: what will happen to costs?

What is the driver for increased spending: ageing populations or medical treatment?

Medical treatment
The world spends more each year for cancer treatment

- Global spend on oncology drugs: projected for 2010-12

Spend doubled in 4 years 2004-2008

Data: IMS
Innovation is expensive

12 drugs were approved by the US Food and Drug Administration (FDA) for various cancer indications in 2012

11 were priced above $100,000 per year

Timeline of novel cancer drug approval

Association of novel drugs and cancer mortality

Association of novel drugs and cancer mortality

Estimated - new medicines have accounted for 50-60% of the increase in cancer survival rates since 1975

Cost of cancer drugs by year of approval

Cancer drug costs rise 5x faster than other classes of medicine

Limits on Medicare's ability to control rising spending on cancer drugs

What are policy-makers trying to do?

Medical Cost Inflation puts health services at jeopardy

There is no evidence that spending more will consistently improve health.
There is also no evidence that simple budget cuts will consistently improve health.
Focus care to where it helps us live longer and live better

“Estimates suggest that as much as $700 billion a year in health care costs do not improve health outcomes. They occur because we pay for more care rather than better care.”

- Peter Orszag, director of the White House Office of Management and Budget, May 2009 interview with NPR
Education to promote cost-effective care

“billions of euros are wasted, say researchers, because doctors prescribe branded drugs when a generic equivalent is just as good”

DrugWatch

No-name heroes can save Europe billions

Anna Wagstaff

Wagstaff A. Cancer World 2007 March/April p24-28
USA – annual savings from generics in billions USD

http://americannewsreport.com/generic-drugs-saved-consumers-1-trillion-8815263
Wyatt E: Justices to take up generic drug case. New York Times, December 8, 2012:B1
1 trillion dollars in 100 dollar notes looks like

http://americandigest.org/mt-archives/5minute_arguments/the_awesome_awfulness_of.php. Cited 1 July 2013
Speed of uptake of generics differs by country within the EU

Share loss after LoE by country
(average of 6 retail products each with lifecycle products)

- Spain
- Italy
- France
- Germany
- UK

Source: IMS MIDAS retail panels, each analogue weighted equally

Sheppard A. Generic Medicines: Essential contributors to the long-term health of society. IMS HEALTH, London, UK
Access to innovative drugs differs by country within the EU.

Controlling costs with generics and biosimilars permits access to innovation.

Biosimilar medicines

Time to consider biosimilar use is now – the number and value of biologic drugs set to lose patent protection per year to 2015 suggests rapid savings may be gained to reinvest in better care.

Generics bring treatments into reimbursement that might otherwise be unaffordable

- Shrank WH, The use of generic drugs in prevention of chronic disease is far more cost-effective than thought, and may save money. Health Aff (Millwood). 2011 Jul;30(7):1351-7
Cost and access:
A survey of Oncologists - USA

- Even in the wealthiest countries there are barriers to accessing the best treatment

- A third of US Oncologists would offer more trastuzumab to breast cancer patients if a lower cost biosimilar was available!

Half of Oncologists in Brazil & Mexico

Four out of 5 of Oncologists in Russia

Savings from biosimilars - Sweden

- Skane University Hospital in Sweden
- Annual saving of €650,000 (6 million SEK)
- From Switching to biosimilar Human Growth Hormone Omnitrope from the original biologic, Somatropin

With no loss of efficacy

With no serious or unexpected adverse drug reactions

Savings from biosimilars - UK

- University College London Hospitals NHS Trust also indicate the substantial cost savings possible when switching all patients in a single center from originator rhGH to biosimilar rhGH, with annual savings estimated as in excess of £200,000 / Euro 240,000
Savings from biosimilars - London

- Savings from biosimilar G-CSF switch in London
- G-CSF purchasing cost £3.3 million per year in 2010

£2 million saving from biosimilar switch predicted by 2012

Data from UK indicates biosimilars expand access to G-CSF

UK G-CSF volume growth
Percent change vs. previous year

Sept 2008 Biosimilar G-CSF approved

2007 2008 2009 2010

Data from UK indicates biosimilars expand access to G-CSF

UK G-CSF volume growth
Percent change vs. previous year

Physicians were able to rewrite treatment algorithms increasing primary prophylaxis due to affordability

Biosimilar G-CSF filgrastim use has surpassed Neupogen in UK

Suggests biosimilar drug will deliver real life improvements in the quality of care

Nearly twice as many patients treated after biosimilars introduced.
Biosimilars bring treatments into reimbursement that might otherwise be unaffordable

- Trends in use of white cell growth factors - G-CSF before and after biosimilar introduction in the EU
Biosimilars improve the standard of care

- % of G-CSF as biosimilars vs Neupogen in Europe, Feb 2013

But not all European Countries access the benefits equally.

There is no doubt: even in rich nations - Savings drive increased access to treatment!

- Savings from biosimilar G-CSF switch in Southern Health Care region in Sweden (population 1.7 million)
  - Five-fold increase in daily G-CSF usage
  - But still net savings of €2 million
  - This represents a saving of 4–5% of the total drug budget

Cost saving steps with expensive drugs can compromise outcomes

- Prescription data of statutory health insurance members in Germany with G-CSF prescriptions between January 2008 and July 2010 were evaluated (originator filgrastim, n = 8726; biosimilar filgrastim, n = 4240)

- Approximately, $\frac{3}{4}$ of patients received 30 million IU dose (recommended for body weight up to 60 kg)

- Average body weight of German adult (German Federal Statistical Office) is 75.6 kg

- Suggest under-dosing was practiced to save costs
Duration of G-CSF use may affect the quality of care

Incidence of febrile neutropenia in patients receiving secondary prophylaxis

- Seven or more days of filgrastim leads to better outcomes
- 65% risk reduction
- Suggests a more affordable drug could again improve the quality of care

Scott J Managed Care Pharmacy 2003
Biosimilar use is increasing

Estimated biosimilar market potential: 2009 value of products whose patents expected to expire between 2009-2019. In absolute value

Potential EU savings from biosimilar use


**Methods:** using a sequential approach, we calculated the savings through the use of biosimilars for 8 of the 28 EU nations - France, Germany, Italy, Poland, Romania, Spain, Sweden and UK.

**Results:**
- The use of biosimilars is expected to result in overall savings between Euros 11.8 billion and Euros 33.4 billion between 2007 and 2020, with largest savings expected for France, Germany and UK.
- Biosimilar monoclonal antibodies - 1.8 to 20.4 billion Euros
- Biosimilar erythropoietins - 9.4 to 11.2 billion Euros
- Biosimilar GCSF - 0.7 to 1.8 billion Euros
Potential USA savings from biosimilar use

Predicts 378 Billion USD saved by 2029

"...generic versions of the top 12 categories of biologic treatments with patent protections that have expired or that are due to expire in the near future could save Americans $67 billion to $108 billion over 10 years and $236 billion to $378 billion over 20 years."

Dr. Robert J. Shapiro, former Under Secretary of Commerce - report released February 11, 2008

http://www.youtube.com/watch?v=gAW56_4gxS8
The predicted savings from biosimilars makes them a priority for cost-effective care


  • http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3291824/pdf/11523_2011_Article_196.pdf

"...generic versions of the top 12 categories of biologic treatments with patent protections that have expired or that are due to expire in the near future could save Americans $67 billion to $108 billion over 10 years and $236 billion to $378 billion over 20 years."
There is no consistent model for governments to promote generic & biosimilar medicines

Differing rules & incentives for use of generic medicines across EU markets leads to different market forces

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<thead>
<tr>
<th>Rules and Incentives</th>
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Contrasting generic medicines volume penetration in key countries

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There is no consistent model for governments to promote generic & biosimilar medicines

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Perhaps the physicians’ leadership is the missing driver
CAN WE AFFORD THE WAR ON CANCER?

Immunotherapy vaccines could extend survival in a handful of cancers. But personalizing treatment, payers argue, is not sustainable. Where should the line be drawn?

BY ED SILVERMAN

Two years ago, the U.S. Food and Drug Administration took a step that some thought would never occur — it approved the sipuleucel-T (Provenge) vaccine for late-stage prostate cancer. The move came after a protracted episode involving allegations of conflicts of interest among a pair of FDA advisory committee members who reviewed the tending a life by 4.1 months is worth the price of Provenge. It has also prompted larger questions about the underlying technology and the need to develop more vaccines.

Provenge is made by culturing a patient’s immune cells with a recombinant antigen. The individualized product is then infused back into the patient, activating the immune system to target and attack the cancer. This “immunotherapy” underscores the move toward personalized...
Economics – we need both innovation and value to access better cancer treatment

Gottlieb Daimler  Henry Ford
“We understand that we doctors should be and are stewards of the larger society as well as of the patient in our examination room.”

Dr. Lowell E. Schnipper,

Chief of Hematology/Oncology Beth Israel Deaconess Medical Center
Chairman of ASCO task force on value in cancer care

Strive not to be a success, but rather to be of value

Albert Einstein
Question

- Is there sufficient money in the health system to afford innovation in medicine?

- Please choose your best response:

  1. No – we do not have the budget to introduce innovation
  2. Unsure
  3. Yes – we have the chance to increase spending on innovative treatments
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