Patient savior,
cost killer,
both, or
neither?
What is the problem?

- “During the past three generations the diseases afflicting Western societies have undergone dramatic changes. Polio, diphtheria, and tuberculosis are vanishing; one shot of antibiotic often cures pneumonia or syphilis; and so many mass killers have come under control that two-thirds of all deaths are now associated with the diseases of old age. These changes in health status are generally equated with decrease in suffering and attributed to more or to better medical care.”

Ivan Illich, 1976
Population health

- 1913 Russian Empire
  - 159.2 mil. citizens
  - 23 143 physician
  - 11 medical schools

- 2000 Russian Federation
  - 146 mil. citizens
  - 700 000 physicians (more than 23 000 in St.Petersburg alone)
  - about 80 medical schools

- «Almost everyone believes that at least one of his friends would not be alive and well except for the skill of a doctor, there is in fact no evidence of any direct relationship between this mutation of sickness and the so-called progress of medicine”
Продолжительность жизни

Годы


в возрасте 30 лет, мужчины
And it is not all...

- «The medical establishment has become a major threat to health. The disabling impact of professional control over medicine has reached the proportions of an epidemic»
  
  Ivan Illich, 1976
Tuberculosis
Thalidomide

- Synthesized in 1954
- Marketed in 1957
- Neuropathies
Thalidomide and congenital abnormalities

Graph showing the relation between malformations of the thalidomide type and the sales of thalidomide (figures for Germany excluding Hamburg).

- Thalidomide sales (January 1961 = 100)
- 845 abnormalities of the thalidomide type (October 1961 = 100)
Diethylstilbestrol
Diethylstilbestrol

Vaginal adenocarcinoma
Flecainid

- Synthesized in research labs of 3M company (3M Pharmaceuticals)
- US Market approval in mid-80
- In 1989 NIH started clinical trial to assess effectiveness of flecainid and encainid
Flecainide

- After one year study prematurely terminated
  - Controls - mortality 5%
  - Treatment group - mortality 10%
- At that time flecainide market share was 20% of all antiarrythmics
Fen-Phen

- "Obesity Inc."
- Obesity treatment
  - Pondimin (drowsiness)
  - Phentermin (palpitations)
- Combination
- M. Weintraub (121 человек) -
- combination treatment
FDA estimates that 363,000 to 725,000 patients in the US could suffer from valvulopathy associated with Pondimin and Redux.
Is it SO bad?
### Wilson’s model of costs and benefits

<table>
<thead>
<tr>
<th></th>
<th>Concentrated benefits</th>
<th>Diffuse benefits</th>
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</thead>
<tbody>
<tr>
<td><strong>Concentrated costs</strong></td>
<td>Alternating victories. Equally matched opponents. Battles between organized interest groups</td>
<td>A losing policy. Organized opposition with little organized support. Need to reframe policy effects to get out of this box</td>
</tr>
<tr>
<td><strong>Diffuse costs</strong></td>
<td>A winning policy. Organized support with little organized opposition</td>
<td>Incremental policy development, without strong, organized support or opposition</td>
</tr>
</tbody>
</table>
What to do - alternatives

- Governmental control - licensing, approval, HTA

- Professional control - EBM
Governmental control

- 1906 - Pure Food and Drug Act - Upton Sinclair novel *The Jungle*
- 1938 - Food, Drug and Cosmetic Act, FDC - tragedy of Elixir Sulfanilamide
- 1962 - Kefauver-Harris Bill= Amendments to FDC - tragedy of thalidomide
- 1976 - Medical Device Amendments - after Dalkon-Shield IUD scandal
- 1990 - Safe Medical Devices Act - after Bjork-Shiley heart valve scandal
Drug regulation

- Before 1938 - adulteration of food/drugs
- 1938 - inform FDA and market
- 1962 - FDA approval
  - IND
  - Clinical trials, phases I, II and III
  - NDA
  - Approval/Marketing
  - Advertising regulation (on/off label, brief summary)
Medical devices regulations

• Before 1976 - only misbranding and adulteration

• 1976 Law
  – Class I - only general controls
  – Class II - only general controls and performance standards
  – Class III - pre-market approval (PMA)
    • Frequently form 510(k) was used for putting devices to market - for devices that are analogs of already existing

• 1990 Law
  – Tracking system is created
  – Status of 510(k) changed to more like PMA
But what about cost?
Without regulation

Supply

Demand

Price

Volume

Without regulation

Equilibrium

Supply

Demand

Equilibrium

Volume
Regulation, additional costs

1. Supply is lower...

2. Prices are higher...

3. ...and volume is lower
Results

- Longer time to market
- Higher price
- Less R&D and production (why nobody is advertising aspirin for MI prevention?)
- Once again patient is at loss?
  - Lower probability of harm
  - Lower probability of benefit
Professional control

- Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise and patient values.

- Selection is done by expert - physician in collaboration with patient
Five steps of EBM

- Translate information needs into answerable clinical questions
- Find best answers (evidences)
- Critically appraise evidences
- Integrate literature data with clinical experience, patient prognosis and patient preferences
- Evaluate own effectiveness
What we are losing?
Literature problems
Sample from what?
EBM demands

- Relevant research integrated with clinical practice
- Trained medical personnel that can and want to work with medical literature
- Partnership with patient
- Sufficient self-esteem of the patient and appropriate educational level
But what about money?

- Best treatment is not always the cheapest
- If patient himself is paying then he selects option with best cost-benefit ratio he can pay for
- But we need to remember who is paying:
Cost inflation

Price w/o insurance

Price with insurance

Volume

Price w/o insurance

Price with insurance

Volume
And if financed from taxes...
Correspondingly...

- If there is no regulation but treatment is paid for by public funds, EBM has a potential to cost inflation.
- From the other side if government is not intervening, then regulatory costs are lower and their negative economic effect also. This lowers the costs.
Summary results of EBM

- Treatment is more adequate for a particular patient
- Prestige and responsibility for physician is higher
- Balance of harm and benefits is better
- But economic effect is not clear, especially if….
- Health care corrupted
Conclusion

- State is regulating drug/devices market not because it is just wants to, but because of political atmosphere around this market
- EBM, if widely used could play a buffer role both against greedy pharmaceutical companies and bureaucratized governmental control
- Best variant - EBM + soft governmental control
Correspondingly, EBM:

- Patient savior? May be.
- Cost killer? May be.

- But there is a long way to go… And we should start with medical training.
- *Medicine should realize that self-critique like EBM is not very pleasant thing, but alternatives are worse*