

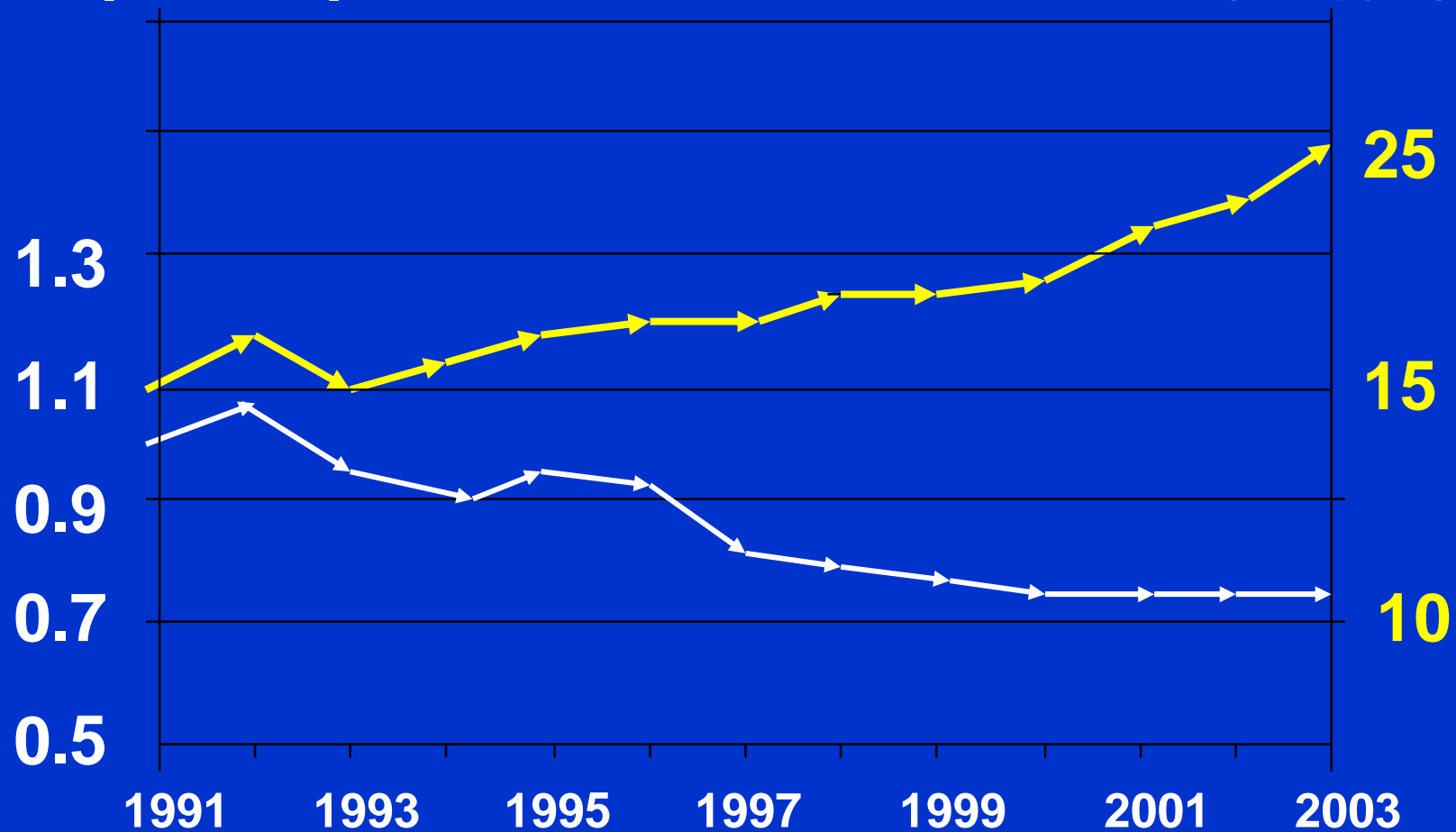


**Evidence based
health policy-making
in Germany**

Drug costs and prescriptions in Germany

No. of prescriptions, billion

Expenses,
Billion €



Self Administration of Health Care in Germany

Ministry of Health

Legal supervision

Federal Joint
Committee

Patients, Physicians, Sickness
Insurance Funds

Decision making

Institute for Quality
and Efficiency in
Health Care

Production of evidence
based information

<http://www.g-ba.de>

Tasks of the Institute for Quality in Health Care

- **Evaluation of the benefit of diagnostic and therapeutic medical procedures**
- **Evaluation of evidence based guidelines**
- **Recommendations for Disease Management Programs**
- **Evidence based information for patients and physicians**

Grades of Evidence

Pathophysiologic studies

Description of cases

Cross-sectional studies

Case control studies

Cohort studies

Randomized controlled trials



Evidence based decision making

Pathophysiologic studies

Description of cases

Cross-sectional studies

Case control studies

Cohort studies

Randomized controlled trials



Available Evidence



Sufficient Evidence

Evidence based decision making

The sufficient evidence to show a benefit of a pharmaceutical agent usually requires good quality data from randomized controlled trials (RCTs).

The larger the gap between the sufficient and the available evidence the stronger the need for an extensive explanation of a positive decision.

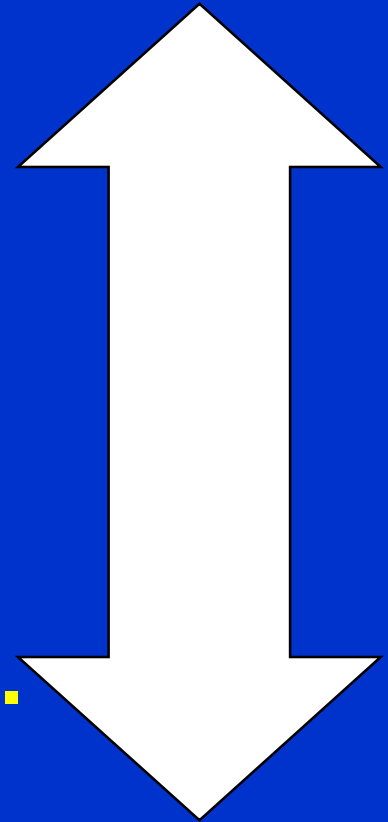
Evidence based decision making

The gap between available and sufficient evidence must be put into relation to...

Nature and severity of the disease.

Magnitude of the therapeutic effect.

Availability of alternatives.



Effects and benefits

Prove of benefit in influencing patient-relevant outcomes.

- **Mortality**
- **Morbidity**
- **Disease-related life quality**

Evaluation of benefit

**The prove of effectiveness
is not a prove of patient-
relevant benefit.**

Surrogates and Fallacies

- **Cholesterol and Clofibrate**
- **Arrhythmia and Encainid**
- **Vitamin A and lung cancer**
- **Bone density and sodium-fluoride**
- **Heart attack and hormone replacement**

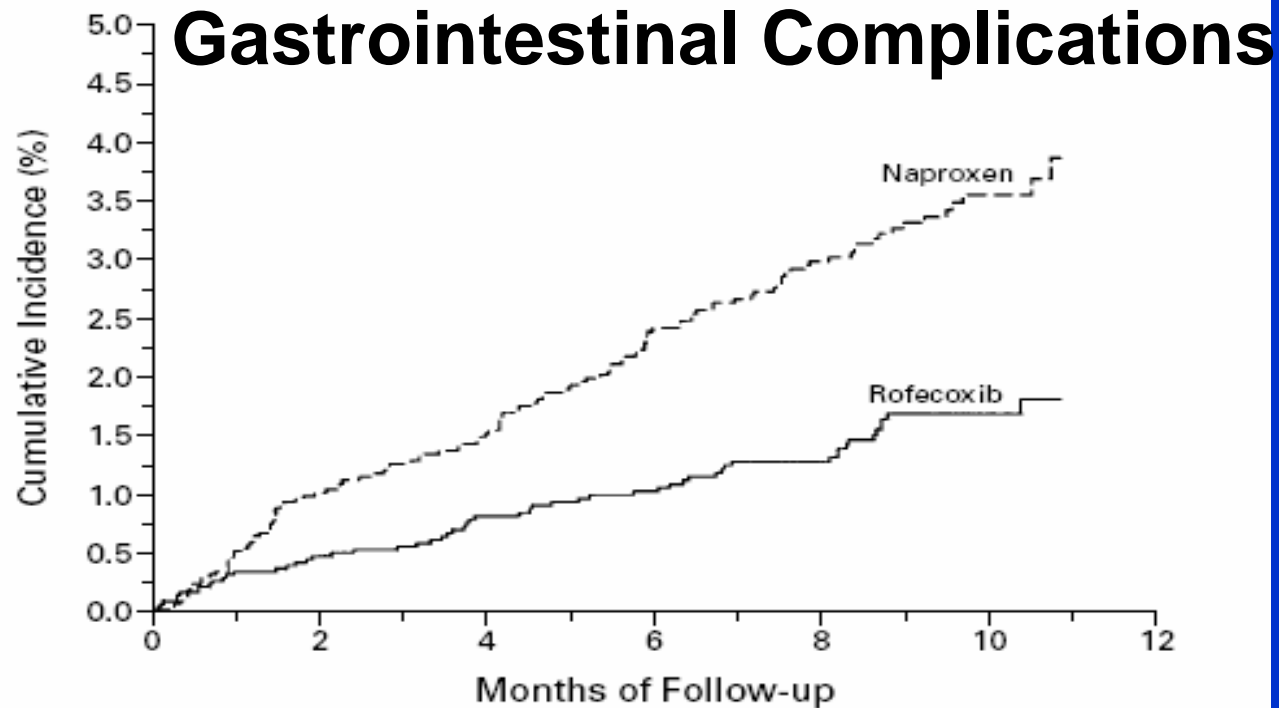
Quality in Medicine

The prove of benefit in scientific trials does not necessary mean benefit for the population.

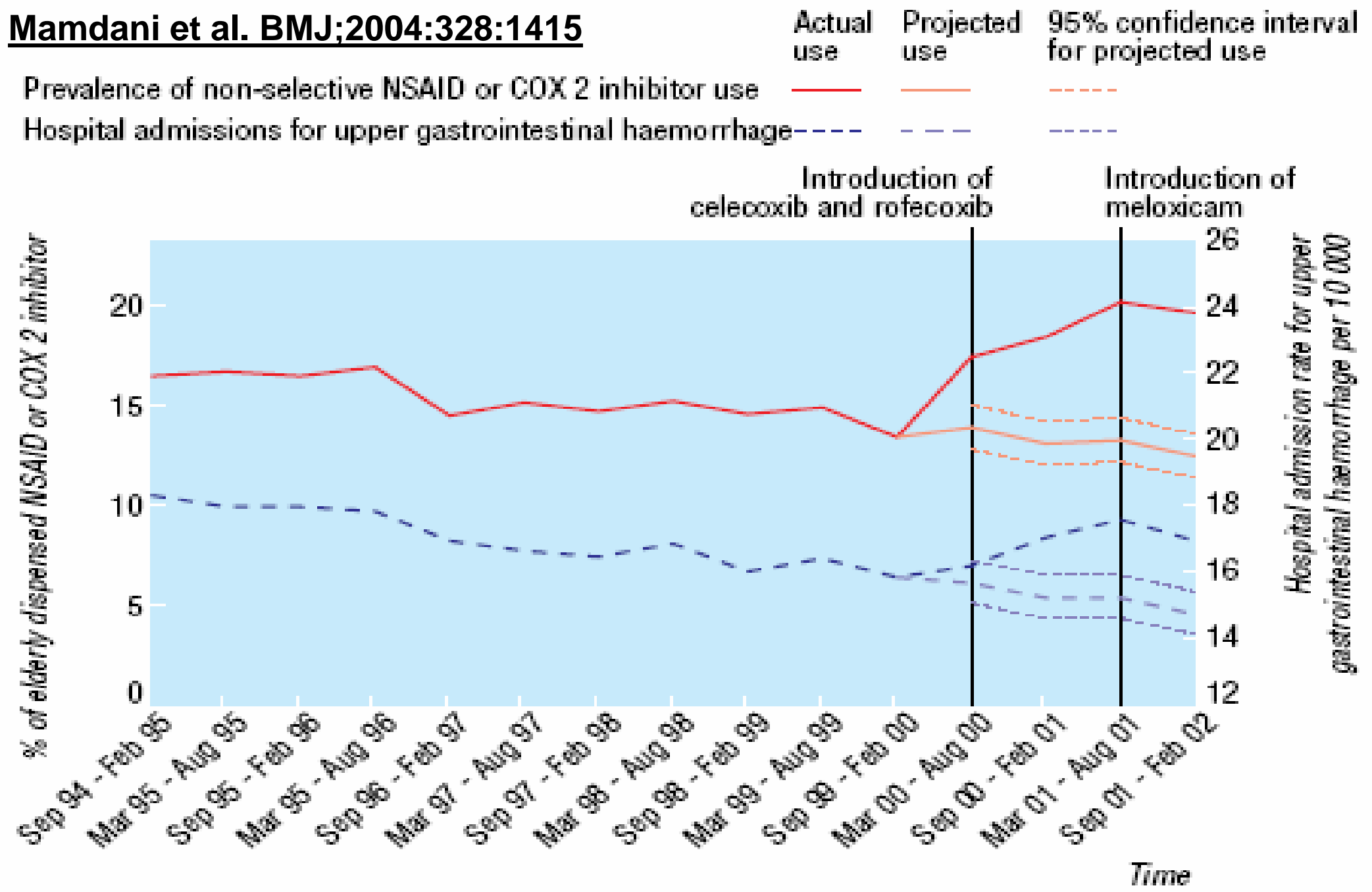
Example: VIOXX

The New England Journal of Medicine 2000

COMPARISON OF UPPER GASTROINTESTINAL TOXICITY OF ROFECOXIB AND NAPROXEN IN PATIENTS WITH RHEUMATOID ARTHRITIS



Mamdani et al. BMJ;2004:328:1415



Age and sex standardised prevalence of the use of NSAIDs and hospitalisation rates for upper gastrointestinal haemorrhage over time among elderly people in Ontario

Quality in Medicine

The prove of benefit in a population is not the benefit for the individual patient.

Quality in Medicine

Patient information:

- Probability of benefit.
- Probability of harm.
- Extent of uncertainty of this information.