Increasing Relevance of Health Economic Evaluations

Budgetary Impact of Treatments
for Attention-Deficit/Hyperactivity Disorder (ADHD) in Germany

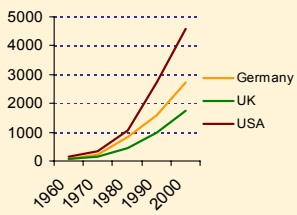
Michael Schlander
Ludwigshafen & Witten/Herdecke, Germany

IACAPAP – 16th World Congress
Berlin, Germany, August 25, 2004
International Association
for Child and Adolescent Psychiatry and Allied Professions

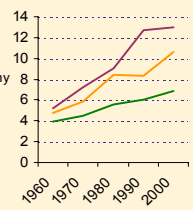
AN ECONOMIC PERSPECTIVE

Historical growth of health care spending

Health Care Spending Per Capita [US-$[1]]



Health Care Spending in Relation to GDP [%]



[1]expressed as Purchasing Power Parities (PPP's);
data source: OECD Health Data 2002

© Prof. Dr. Michael Schlander (literature and Lehrgebiete 2004

AN ECONOMIC PERSPECTIVE

Historical growth of health care spending

"Affordability" of Health Care Spending
rising faster than GDP has become a major concern

- **Signals to "providers" of health care have changed**
  - Cost sometimes seems to be more important than effectiveness, quality of care, and innovation.
  - Increasingly "value for money" (and "efficiency") is sought after.
- **Affordability**
  - An ill-defined concept !
  - Frequently, from the perspective of a third-party payer: "budgetary impact"
  - **However: health care spending rising faster than GDP will remain affordable for the next several decades**
    – providing real per-capita GDP growth rates >1% can be sustained[1]; yet:
- **Trade-offs between alternative uses of scarce resources**
  - will be necessary, such as between health care versus education.
  - Value for money will have to be shown convincingly

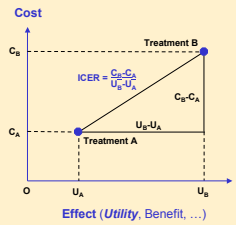
[1]M. Schlander et al. (2004)

© Prof. Dr. Michael Schlander (literature and Lehrgebiete 2004

AN ECONOMIC PERSPECTIVE

The conventional way of showing "value for money" in health economics

The Logic of Cost-Effectiveness



A medical intervention is never cost-effective in itself, but only ...

- in relation to a defined alternative
- in a defined indication
- for a specific patient group
- from a specific perspective

As a ratio, the ICER does **not** provide any information about the dimension of a program.

ICER: *Incremental Cost-Effectiveness Ratio*

© Prof. Dr. Michael Stillwell, Diversa and Lachapelle 2004

AN ECONOMIC PERSPECTIVE

Does health economics really matter in ADHD?

Opportunity Cost Associated with ADHD

- **Present and anticipated future costs?**
- **Societal or health care payer perspective?**
- **Budgetary impact analysis[1] as an established tool:**
  - Epidemiology, burden of disease
  - Transparency: perspective, data sources
  - Rates of adoption of new therapies
  - Impacts of intervention by population subgroups
  - Relationship between intermediate and final endpoints
  - Time horizon
- **The example of future ADHD medication cost in Germany**
  - Used to illustrate the future relevance of economic analyses

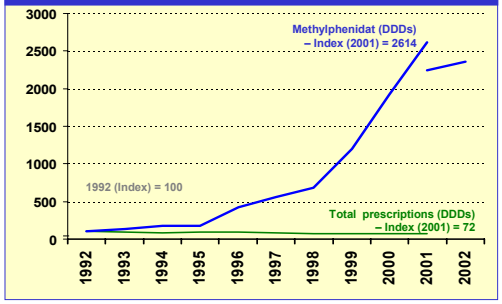
[1]cf. P. Trueman et al. (2001)

© Prof. Dr. Michael Stillwell, Diversa and Lachapelle 2004

AN ECONOMIC PERSPECTIVE

During the last decade, Methylphenidate (IR) prescriptions have grown by a factor of 26.

Methylphenidate (IR only) Prescription Trend[1]



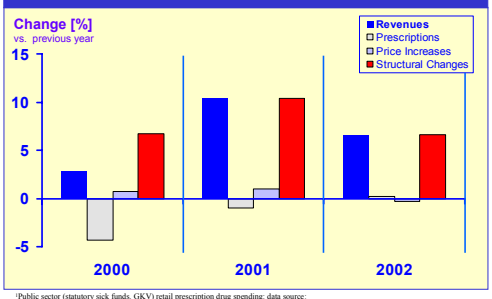
[1]Source: U. Schwabe, D. Paffrath 1993 – 2003; note change of database for year 2001/2002; all data on "public" spending refer to statutory sick funds (GKV); without parallel imports

© Prof. Dr. Michael Stillwell, Diversa and Lachapelle 2004

AN ECONOMIC PERSPECTIVE

In line with the dynamics of other European pharmaceutical markets, new products have been the dominant growth driver in Germany.

Prescription Drug Spending[1]: Cost Drivers



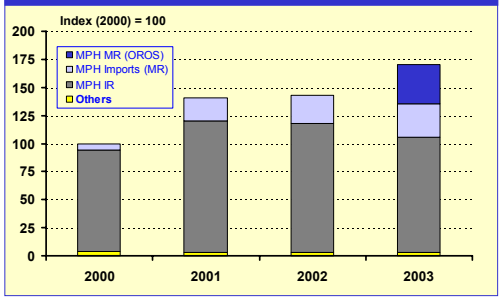
[1]Public sector (statutory sick funds, GKV) retail prescription drug spending; data source: U. Schwabe and D. Paffrath 2001-2003

© Prof. Dr. Michael Schlander, Hirzenrod Ludwigsfelde 2004

AN ECONOMIC PERSPECTIVE

Since the year 2000, Methylphenidate (MR) prescriptions have continued to grow rapidly

Recent (2000-2003) Stimulant Prescriptions Trend[1]



[1]according to preliminary data from one German sickness fund: GEK (2004), DDD shares; "others": pemoline, fenetylline

© Prof. Dr. Michael Schlander, Hirzenrod Ludwigsfelde 2004

AN ECONOMIC PERSPECTIVE

Estimating the future impact of ADHD on pharmaceutical spending (perspective of the Statutory Health Insurance, SHI [GKV])

Budgetary Impact Analysis (1): Current Situation

- **Aggregate prescription data for 2002 are consistent with:**
  - > 60,000 patients treated[1]
  - **Pharmacotherapy prevalence (6-18y) >0.5 percent** (MPH IR only)
  - Assuming 95% of total prescriptions are written for ADHD in this age group
  - Approximately 60% Ritalin; the remainder MPH IR, branded generics
  - Assuming no false positive diagnoses:
    - Case 1: true prevalence according to ICD-10:
      Actually diagnosed: ≥ 20% (est. <35%)
      Stimulant treatment in ≥ 20% (est. <60%) of diagnosed ADHD cases
    - Case 2: true prevalence according to DSM-IV:
      Actually diagnosed: ≥ 9% (est. <20%)
      Stimulant treatment in ≥ 9% (est. <50%) of diagnosed ADHD cases

[1]Assuming that the majority of patients will receive appropriate long-term treatment. This, of course, is a simplification. Note that this does not, however, change the projections presented since increased duration of pharmacotherapy is part of the anticipated trend.

© Prof. Dr. Michael Schlander, Hirzenrod Ludwigsfelde 2004

Estimating the future impact of ADHD on pharmaceutical spending (perspective of the Statutory Health Insurance, SHI [GKV])

Budgetary Impact Analysis (2): Assumptions

- **Utilization:**
  - for medication, on average 250 DDDs / treated patient year
- **Acquisition costs:**
  - Methylphenidate, Immediate Release (IR): €1.41 / 30mg [DDD] (Equasym[R] 10)[1]
  - Methylphenidate, Modified Release (MR): €2.72 / 36mg [DDD] (Concerta[R])[1]
  - Atomoxetine: market price unknown; assumed to correspond to Concerta[R]
- **Epidemiology:**
  - True prevalence: **Scenario 1 2.4%** (corresponding to ICD-10 criteria)[2]
  - True prevalence: **Scenario 2 6.0%** (corresponding to DSM-IV criteria)[2]
    - by 2009, 50% of ADHD patients will be actually diagnosed
    - by 2009, 80% of those diagnosed will receive pharmacotherapy[5]
    - of those, 25% Methylphenidate IR[3], 50% Methylphenidate MR[3], 25% Atomoxetine[4]

[1]based upon German ex-pharmacy prices, January 2004 (data source: ifap Index, Q1 2004); [2]B. Brühl et al. (2000); [3]Methylphenidate or "stimulants"; [4]reasoning will be discussed – please note, however, that these estimates shall not be construed / interpreted as sales forecasts; cf. -> Datamonitor (2002) and recent U.S. post-launch data [5]USA: 90% according to Safer (2000)

© Prof. Dr. Michael Schlander, Diversa and Ludwigsburg 2004

AN ECONOMIC PERSPECTIVE

Estimating the future impact of ADHD on pharmaceutical spending (perspective of the Statutory Health Insurance, SHI [GKV])

Budgetary Impact Analysis (3): Estimates

Scenario	(1) "ICD-10"	(2) "DSM-IV"	(3) "Baltimore, Md."
Population 6-18y	10.8 mill.	10.8 mill.	10.8 mill.
Prevalence (6-18y)[1]	259,200	648,000	"4,6% Pharmacotherapy"[2]
Treatment prevalence	103,680	259,200	496,800
Assumptions on treatment – see "Epidemiology"			
Cost of therapy (2009)[3]	**€ 62.0 mill.**	**€ 155.0 mill.**	**€ 297.0 mill.**
Cost of therapy (2002)[4]	€ 22.5 mill.	€ 22.5 mill.	€ 22.5 mill.
Increase over 2002	**+ 176%**	**+ 589%**	**+ 1,220%**
	(x 2.8)	**(x 6.9)**	**(x 13.2)**

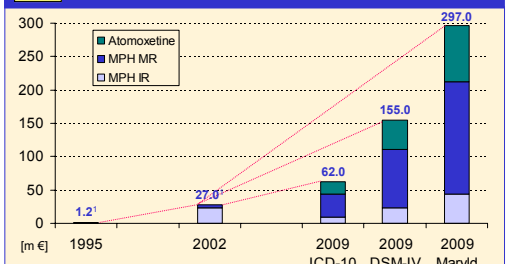
[1]Data source; Federal Statistical Bureau (Statistisches Bundesamt);
[2]D.J. Safer et al. (1996): 5-14y olds in Baltimore Public Schools, 1995;
[3]prescription drugs only; this figure compares to total spending on psychotropic drugs of € 1,333.3 mill. in 2002 (Schwabe & Paffrath 2004);
[4]attributable to ADHD (assumed: 95% of total revenues)

© Prof. Dr. Michael Schlander, Diversa and Ludwigsburg 2004

AN ECONOMIC PERSPECTIVE

Estimating the future impact of ADHD on pharmaceutical spending (perspective of the Statutory Health Insurance, SHI [GKV])

Budgetary Impact Analysis (4): Estimates



[1]Data source: Schwabe und Paffrath (1996, 2003); GEK (2004); MPH sales data adjusted by excluding 5% share of indications other than ADHD in children and adolescent; year 2002 data include an estimated revenue of 4.6m€ MPH MR reimports

© Prof. Dr. Michael Schlander, Diversa and Ludwigsburg 2004

Estimating the future impact of ADHD on pharmaceutical spending (perspective of a pediatrician in private practice, Germany)

Budgetary Impact Analysis (5): Pediatrician

Scenario	(1) "ICD-10"	(2) "DSM-IV"	(3) "Baltimore, Md."
Acquisition cost of therapy[1]	€ 62.0 mill.	€ 155.0 mill.	€ 297.0 mill.
Increase over 2002	+ 176%	+ 589%	+ 1,220%

Impact on the Prescription Drugs Budget of a German Pediatrician in Private Practice:

Assumptions:

Registered pediatricians in private practice (2002):	n = 6,790
1/3 of these physicians participate in treatment of ADHD with stimulants:	n = 2,241
these 2,241 physicians account for 44% of total prescriptions for ADHD[2]:	Rx value = 4,422 € (2002)

Results:

	(1)	(2)	(3)
Marginal budget impact	€ 7.750	€ 26.000	€ 53,900
Drug budget increase	+ 9.3 %	+ 31.3 %	+ 65.0 %

*(net increase of GKV prescription value compared to **total** in 2002)*

[1]drug acquisition costs (not accounting for special GKV discounts);
[2]cf. I. Schubert et al. (2002); average total value of prescriptions by a German pediatrician (2002): **83,000 €**; data excluding reimports

© Prof. Dr. Michael Schlander, Diversa and Ludwigsburg 2004

Explaining the profound increase in expected prescription drug spending

Reasons for Increased Spending on ADHD Treatment

1. Growing awareness (education & promotional efforts by industry)
   - **ADHD will be diagnosed more frequently (and earlier)**
2. Growing acceptance of pharmacotherapy
   - **More prescriptions per diagnosed patient**
3. Improved therapeutic options
   - Methylphenidate („Modified-Release" preparations)
   - Atomoxetine
   - **Higher cost per DDD**

- These factors combined exert a **multiplicative effect**, leading to the expectation of a pronounced increase of drug expenditures.
  - Other cost components (including, but not limited to, diagnostic procedures and cognitive-behavioral therapy) are likely to increase as well.

© Prof. Dr. Michael Schlander, Diversa and Ludwigsburg 2004

Existing economic studies of ADHD treatment

Cost-Effectiveness of ADHD Treatment (1): HTAs

- **CCOHTA (Canada, 1998)[1]**
  - Assumed daily dose MPH IR: 2 x 10mg
  - MPH IR dominated its alternatives
  - **ICER** (versus a hypothetical "Do Nothing" alternative): **CAN-$ 498 / ES** (basis CTRS, WMD)
  - Few data on on behavioral therapy.
- **NICE (England, 2000)[2]**
  - Assumed daily dose MPH IR: 3 x 10mg
  - **Cost / QALY** estimated at **£ 9,2000 – £ 14,600**

[1]J. Zupancic et al. (1998): a six-point or one standard deviation (weighted mean) difference was considered clinically relevant, CAN-$ (1997);
[2]J. Lord & S. Paisley (2000) and A. Gilmore & R. Milne (2001): NHS perspective, one-year time horizon, £ (1997)

© Prof. Dr. Michael Schlander, Diversa and Ludwigsburg 2004

Cost-Effectiveness of ADHD Treatment (2): Recent Studies

- **Cost-Effectiveness Findings from the MTA Study (USA, 2004)**[1]
  - **Medication Management** (MPH 37.7mg/d, t.i.d.) versus Community Care[2]:
    ~US-$ 360 / patient "normalized" (SNAP-IV score <1); or ~ **3,000 US-$ / QALY**
  - Combination Treatment (MPH 31.2 mg/d, t.i.d.) vs. Behavioral Treatment Only:
    ~US-$ 2,500 / patient "normalized" (SNAP-IV score <1); or ~ **21,000 US-$ / QALY**
  - Behavioral Treatment Only was dominated by Medication Management
  - Combination Treatment vs. Medication Management Only:
    ~US-$ 55,000 / patient "normalized"; or: ~475,000 US-$ / QALY (!)
- **Cost-Effectiveness MPH-OROS versus MPH-IR (England, 2004)**[3]
  - Comparable incremental cost-effectiveness of MPH-OROS as MPH-IR
  - Extended dominance of MPH-OROS over MPH-IR
    under a wide range of assumptions (regarding treatment compliance)

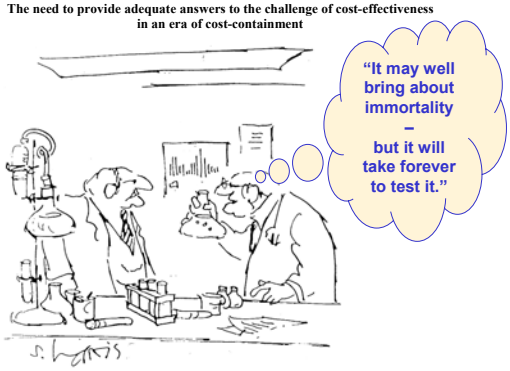
[1] P. Jensen et al. (2004): societal perspective, one-year time horizon, US-$ (2000); cost / QALY estimates are to be considered approximations;
[2] Note that most Community Care patients received MPH, mean total daily dose / day at study completion: 22.6mg, averaging 2.3 doses per day (vs. 3.0 doses per day for MTA-treated subjects) – cf. MTA (1999);
[3] M. Schlander et al. (2004)

© Prof. Dr. Michael Schlander, Heinrich-Heine-Universität Düsseldorf, Lehrgebiete 2004

Some Issues to Consider in Economic Evaluations of ADHD

- **What objectives are we pursuing?**
  - To what extent does the (utilitarian) standard health economic approach reflect our objectives?
  - How should we valuate (which) benefits?
  - How should we best incorporate process-related preferences in the consequentialist analytical framework of health economics?
- **What's the (most) appropriate time horizon?**
  - How can we best quantify long-term outcomes?
  - What are the effects of discounting future health outcomes?
- How should we best address long-term costs and outcomes?
- What should be the appropriate role of industry in these studies?

© Prof. Dr. Michael Schlander, Heinrich-Heine-Universität Düsseldorf, Lehrgebiete 2004



© Prof. Dr. Michael Schlander, Heinrich-Heine-Universität Düsseldorf, Lehrgebiete 2004