Gesundheitsökonomie: ADHS als Beispiel

Was kann die Gesundheitsökonomie
zu einer effektiven und effizienten Versorgung
in der Kinder- und Jugendpsychiatrie beitragen?

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Jahrestagung des BKJPP

Gelsenkirchen, den 11. November 2004

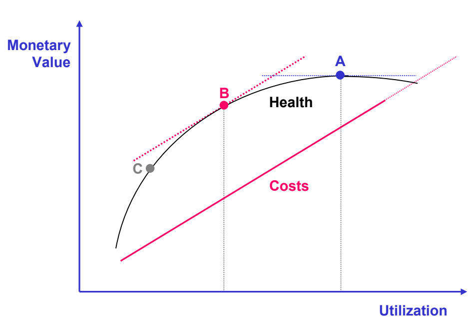
ÜBERSICHT

Themen

- **Zur Logik der Kosteneffektivität**
  Anliegen, Reichweite und Grenzen
- **Relevanz für ADHS**
  Ökonomische Dimension der ADHS
- **Evaluationen zu ADHS**
  - *Kanada*
  - *England*
  - *USA*
  - *Datenlage und Forschungsbedarf in Deutschland*

GESUNDHEITSÖKONOMIE

Determining the optimal level of health care utilization:
(A) evidence based medicine, (B) economic evaluation[1]



[1] cf. Victor R. Fuchs: "Health Care and the United States Economic System", *The Milbank Memorial Fund Quarterly*, April 1972, pp. 211-237.

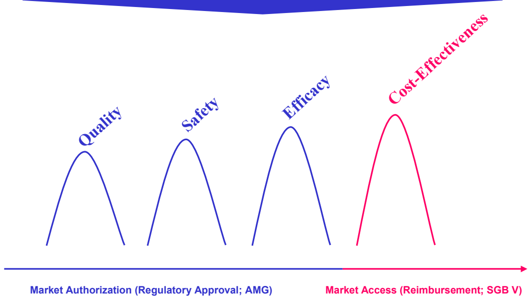
Ein zentrales Thema der Gesundheitsökonomie

Rationale Ressourcenallokation

- **Wie können begrenzte Ressourcen so eingesetzt werden, daß sie den größten gesundheitlichen „Nutzen“ produzieren?**
- Anwendung des „ökonomischen Prinzips“ auf die **Produktion von Gesundheit**:
  - Maximale **Ziel**erreichung („Effektivität“) mit definierten Mitteln
  - Definierte **Ziel**erreichung mit einem Minimum an Mitteln („Effizienz“)

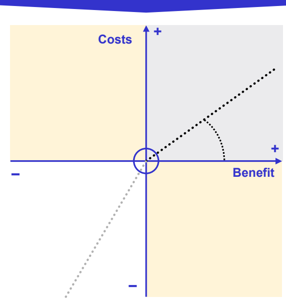
The Political Debate

The Infamous “Fourth Hurdle”



Economic evaluation of new medical technologies

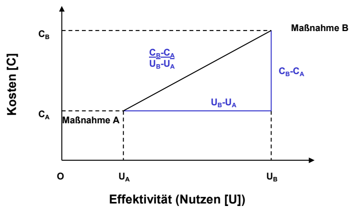
The Cost-Effectiveness Plane



Black (1990)

Grundprinzipien

Inkrementelle Analyse



Bestimmung einer „inkrementellen Kosten-Nutzen-Relation" („ICER": *Incremental Cost-Effectiveness Ratio*)

Anwendung in der Gesundheitspolitik

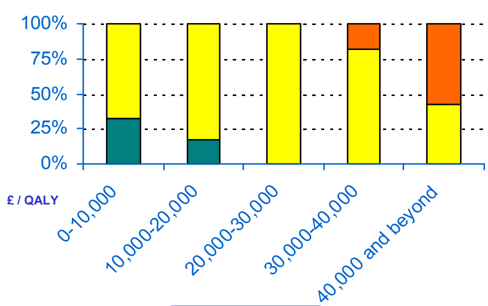
Kosten-Effektivität: Einige Grenzwerte

- **Politisch, nicht wissenschaftlich determiniert**
- **International gebräuchliche Grenzwerte:**
  - **Neuseeland** (PHARMAC): NZ-$ 20,000 / QALY[1]
  - **Australien** (PBAC): A-$ 42,000 / LYG bis A-$ 76,000 / LYG[2]
  - **England** (NICE): £ 30,000 (bis £ 40,000) / QALY
  - **Vereinigte Staaten** (USA: MCOs): US-$ 100,000 / QALY[3]

[1]C. Pritchard (2002); QALY: "quality-adjusted life year"; [2]George et al. (2001); LYG: "life year gained"
[3]D.M. Cutler, M. McClellan (2001)

NICE and cost-effectiveness thresholds

Cost-Effectiveness and NICE Recommendations



NICE aims to find sub-groups in which interventions are more cost-effective

Recommendation: "Selected Use"

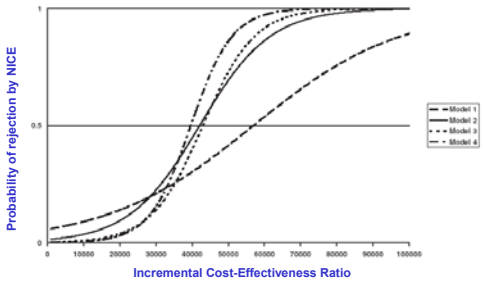
Typical Examples[1]:

- 'only for second-line use'
- 'only where other drugs are contra-indicated'
- 'in Type 1 but not Type 2 diabetes'
- 'only if other drugs have been tried and failed'
- 'only for those with severe disease'
- 'in cases with specific co-morbidities'

[1]adopted from Martin Buxton (2004)

NICE and cost-effectiveness thresholds: a probabilistic interpretation[1]

Cost-Effectiveness and NICE Recommendations



[1]Source: N. Devlin & D. Parkin, *Health Economics* 2004, 13: 437-452

Ein „fünftes Kriterium" für die Evaluation neuer medizinischer Interventionen

Budgetäre Auswirkungen

- **Rationale:** Ohne Kenntnis der budgetären Auswirkungen („*budgetary impact*") einer Maßnahme können ihre **Opportunitätskosten** nicht bestimmt werden.
- **In der Praxis: Kann eine neue Maßnahme innerhalb des Rahmens vorgegebener Budgets finanziert werden („*affordability*")?**[1]
  - Perspektive der Kostenträger
  - „Budgetary Impact Analysis":
    - Teil der Bewertungen medizinischer Technologien in England (NICE)
    - Obligatorisch für neue Medikamente in Australien und Finnland

[1]In Deutschland spielten die erwarteten budgetären Auswirkungen implizit eine wichtige Rolle bei der Entscheidung, sog. "*Life-Style*"-Medikamente wie Viagra® von der Kostenerstattung auszunehmen.

RELEVANZ FÜR ADHS

Wesentliche gesundheitsökonomische Aspekte

Ökonomische Evaluation von ADHS

- **„Burden of Disease"**
  - Epidemiologie (und diagnostische Kriterien)
  - Kurz- und langfristige Krankheitsfolgen; volkswirtschaftliche Kosten
- **Therapeutische Interventionen**
  - Nutzen-Risiko-Profil („Wirkung") unter experimentellen Bedingungen (Ergebnisse klinischer Studien)
  - **Effektivität** („Wirksamkeit") unter Praxisbedingungen
  - „Indirekte" und „intangible" Behandlungsfolgen
  - Behandlungskosten und **Kosten-Effektivität** („ICER")
- **Relevanz für Kostenträger**
  - Budgetäre Auswirkungen
  - Kosten-Nutzen-Relation aus volkswirtschaftlicher Perspektive

AN ECONOMIC PERSPECTIVE

A societal perspective

ADHD: Burden of Disease (Overview)[1]

- **Health care system**
  - 50% increase in bike accidents; 2-4x more motor vehicle accidents
  - 33% increase in emergency room visits
- **School and occupation**
  - 46% expelled; 35% drop out; lower occupational status
- **Family**
  - 3-5x parental divorce (or separation); 2-4x sibling fights
- **Employer**
  - parental absenteeism and productivity
- **Society**
  - 2x risk of substance abuse disorders (and earlier onset and lower probability to quit in adulthood)
  - Criminal behavior; justice and legal system costs

[1]multiple references, cf. S. Williams (2004)

AN ECONOMIC PERSPECTIVE

A third-party payer perspective

Direct (Medical) Costs Associated with ADHD

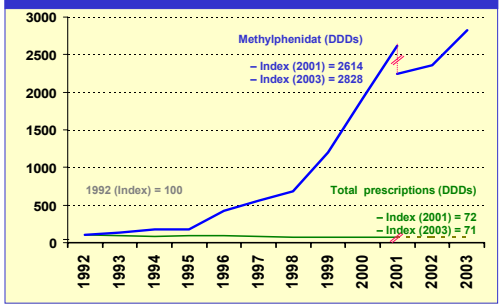
- **Birth cohort study Rochester, MN (1976/82 – 1995)**[1]
  - 7.5% of cohort (309 / 4,119) met criteria for ADHD
  - 9-year median costs more than doubled with ADHD (US-$4,306 vs. US-$1,944)
  - Study did not include outpatient drugs (not covered by Medicare)
- **Employer database study (1996-1998)**[2]
  - Annual direct cost per ADHD patient US-$ 1,574 compared to US-$541 in controls
- **Medical Expenditure Panel survey (1996)**[3]
  - Overall costs comparable with asthma (based on n=165 / 5,439 children age 5-20y)
- **North Dakota DoH Claims Database estimates (2003)**[4]
  - Mean prevalence 3.9 percent (peak at 10y of age; population n=7,745)
  - Annual cost of care US-$ 649 compared to US-$ 495 for controls
  - 1.9% of total health care expenditures for children was attributable to ADHD ->
  - The U.S. cost of care attributable to ADHD would be US-$ 2.15 bn annually

[1]C.L. Leibson et al. (2001); [2]A.R. Swensen et al. (2003); [3]E. Chan et al. (2002); [4]L. Burd et al. (2003); much of the economic impact of ADHD is related to the costs of family members of ADHD patients (cf. Swensen et al. 2003; Lesesne et al. 2003)

AN ECONOMIC PERSPECTIVE

During the last decade, Methylphenidate (IR) prescriptions have grown by a factor of >28.

Methylphenidate (IR only) Prescription Trend[1]

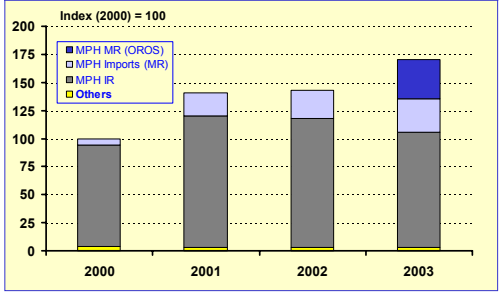


[1]Source: U. Schwabe, D. Paffrath 1993 – 2004; note change of database for year 2001/2002; all data on "public" spending refer to statutory sick funds (GKV); without parallel imports

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

AN ECONOMIC PERSPECTIVE

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

Budgetary Impact Analysis (1): 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)

AN ECONOMIC PERSPECTIVE

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

Budgetary Impact Analysis (2): Estimates

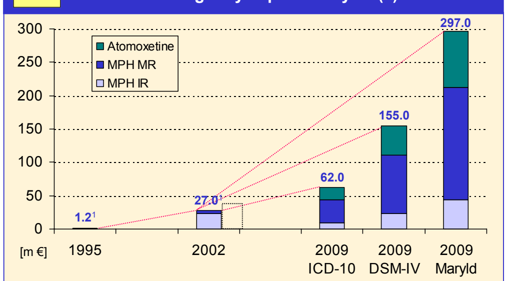
Scenario	(1) "ICD-10"	(2) "DSM-IV"	(3) "Baltimore, Md."
Population 6-18y	10.8 mill.	10.8 mill.	10.8 mill.
Prevalence (6-18y)[1]	259,200	648,000	"4,6% Pharmacotherapy"[2]
Treatment prevalence	103,680	259,200	496,800
Assumptions on treatment – see "Epidemiology"			
Cost of therapy (2009)[3]	**€ 62.0 mill.**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

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



[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; cf. 2003 (AVR 2004): 36.7m€ (excl. imports)

AN ECONOMIC PERSPECTIVE

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.

ÖKONOMISCHE EVALUATIONEN

- Kanada (CCOHTA)
- England (NICE)
- USA (MTA-Studie)
- England/Deutschland („Compliance-Modell“)

INTERNATIONALE DATEN

Übertragbarkeit („Portabilität“) gesundheitsökonomischer Daten

Interpretation internationaler Daten

- **Diagnostische Kriterien**
  - ICD-10 führt verglichen mit DSM-IV zu geringerer Prävalenz[1] und höherem Anteil hyperkinetischer Symptomatik und neurologischer Störungen[2].
  - Unterschiedliche Patientenprofile (auch bzgl. Komorbidität) müssen bei der Bewertung von internationalen Studien berücksichtigt werden.
- **Schulsystem und Betreuungskonzepte**
  - Länge des Schultages, Ganztagesbetreuung, „School Nurses“, usw.
- **Soziodemographische Aspekte und Lebensqualität**
- **Therapeutisches Vorgehen** („*resource utilization*“)
  - In USA[3] primär multimodale Therapie einschließlich Stimulanzien; in Europa[1] tendenziell (mit Unterschieden[4]) Präferenz für medikamentöse Therapie „erst wenn Verhaltenstherapie versagt“
- **Unterschiedliche Faktorkosten** („*unit costs*“)

[1]vgl. E. Taylor et al. (1998); [2]E.J. Garland (1998); [3]American Association of Pediatrics [AAP] (2001);
[4]National Institute of Clinical Excellence [NICE] (2000), im Unterschied zu British National Formulary [BNF] (2001)

AN ECONOMIC PERSPECTIVE

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); currently (2004), an appraisal update is being prepared by NICE

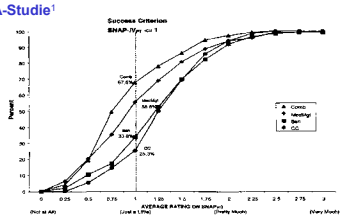
Cost-Effectiveness of ADHD Treatment (2): Recent Studies

- **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)

ADHS: Therapeutische Interventionen

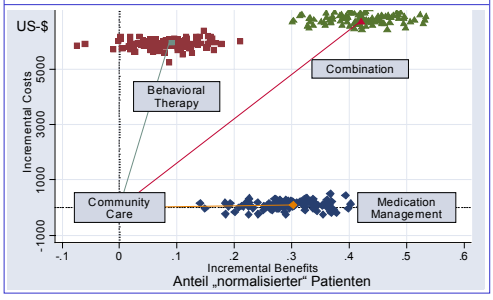
MTA-Studie[1]



Die MTA-Studie führte zu einer breiten Akzeptanz der Pharmakotherapie als 1st Line-Behandlung – mit oder ohne Verhaltenstherapie – (AAP 2001) oder als Teil einer multimodalen Behandlungsstrategie (NICE 2000).

[1]Darstellung entnommen aus J.M. Swanson (2001) [„Clinical Relevance of the Primary Findings of the MTA", J. Am. Acad. Child Adolesc. Psychiatry, Vol. 40, p.175]

MTA-Studie:
Kosten-Effektivität alternativer Therapiestrategien der ADHS



Quelle: Jensen et al. (2004); Schlander et al. (2004)

AN ECONOMIC PERSPECTIVE

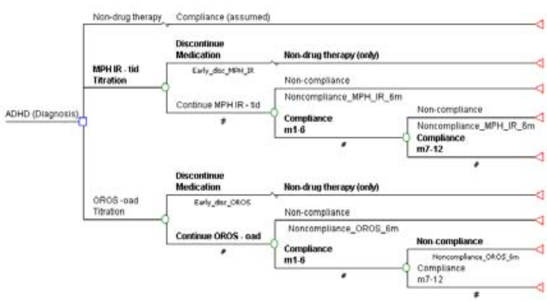
Interpreting the primary C/E analysis of the MTA

Key Economic Findings from the MTA

- From the **U.S. societal perspective**, intensive Medication Management is clearly cost-effective.
  - For **Medication Management**: estimated incremental cost per patient "normalized" ~ US-$ 360, translating into an estimated incremental cost / QALY gained of ~ US-$ 3,000 (*dimension!*).
  - Significant **impact of co-morbidity**, with more complex cases requiring more complex treatment.
  - Cost-effectiveness of **behavioral therapy** remains to be proven.
- The MTA data will be used
  - to assess the impact of ICD-10 criteria as a moderator;
  - to estimate cost-effectiveness of treatment strategies studies from the perspective of European health care systems (including NHS and GKV).

COST-EFFECTIVENESS OF MPH OROS

Economic Evaluation: Decision Tree Model[1]

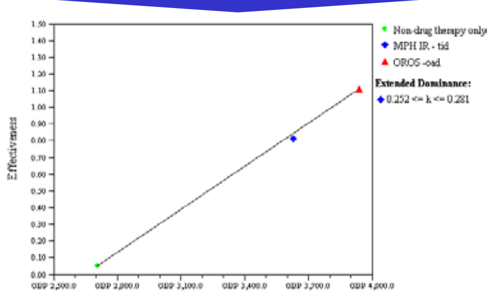

ADHD (Diagnosis)
Non-drug therapy
Compliance (assumed)
MPH IR - tid Titration
Discontinue Medication
Early_disc_MPH_IR
Non-drug therapy (only)
Continue MPH IR - tid
Non-compliance
Noncompliance_MPH_IR_6m
Compliance m1-6
Non-compliance
Noncompliance_MPH_IR_6m
Compliance m7-12
OROS -oad Titration
Discontinue Medication
Early_disc_OROS
Non-drug therapy (only)
Continue OROS - oad
Non-compliance
Noncompliance_OROS_6m
Compliance m1-6
Non compliance
Noncompliance_OROS_6m
Compliance m7-12

[1]Decision Analysis Software: TreeAge DATA Pro (2002)

COST-EFFECTIVENESS OF MPH OROS

Economic evaluation from the perspective of the UK National Health Service (NHS)

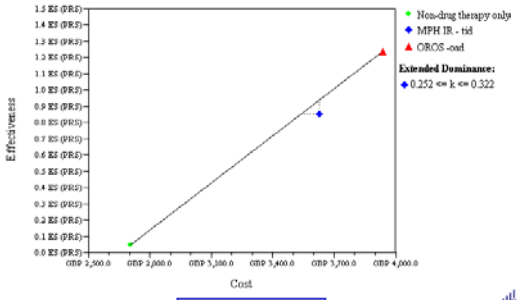
ADHD Case (1): Teacher Ratings



COST-EFFECTIVENESS OF MPH OROS

Economic evaluation from the perspective of the UK National Health Service (NHS)

ADHD Case (2): Parent Ratings



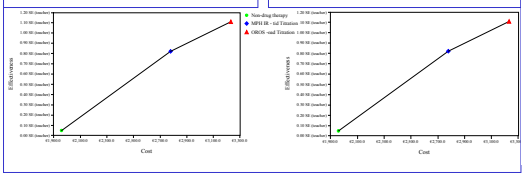
COST-EFFECTIVENESS OF MPH OROS

Case A: ADHD-adjusted compliance expectation for MPH IR

Ergebnisse: Kosten-Effektivität MPH-OROS

Lehrer-Rating
IOWA Conners I/O Scale

Eltern-Rating
IOWA Conners I/O Scale



ICER	MPH-OROS vs. MPH-IR	MPH-IR vs. CBT Only
Teacher Rating	€ 1,564 / ES CTRS (I/O) x 1y	€ 1,061 / ES CTRS (I/O) x 1y
Parent Rating	€ 1,220 / ES CPRS (I/O) x 1y	€ 1,008 / ES CPRS (I/O) x 1y

SITUATION IN DEUTSCHLAND

Wesentliche gesundheitsökonomische Aspekte

ADHS: Kosten und Kosten-Effektivität

- **Verläßliche Daten zur Versorgungssituation lückenhaft**
- **Daten zu Krankheitskosten fehlen weitestgehend**
  - gesamtgesellschaftliche / volkswirtschaftliche Perspektive
  - Perspektive der Gesetzlichen Krankenversicherung
- **Medikamentöse Therapie und Verhaltenstherapie**
  - Effektivität über 24 Monate dokumentiert (vgl. MTA-Studie)
  - Diskussion bisher fokussiert
    - auf Zunahme der MPH-Verordnungen
    - isolierte Kosten- *oder* Nutzenbewertungen (IQWiG)
  - Bisher kaum Kosten-Effektivitäts-Bewertungen
    - Methylphenidat-OROS verglichen mit Methylphenidat-IR: trotz höherer Tagestherapiekosten vermutlich vergleichbare oder zumindest akzeptable Kosteneffektivität