Surrey West Sussex and Hampshire Cancer Network

Integrated Regulatory and Commercial Planning: Internal Approaches and Value to Payers

UK perspective

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Integrated Regulatory and Commercial Planning

- Payers – who are they?
- Decision Makers- what influences them?
- Value – how is this perceived?

What about the patient perspective?

Current situation for Cancer drugs in England

- **Payer**
  - Hospital → PCTS → Cancer Drugs Fund
  - Drug — Drug + Attendance — Drug
- **Decision Makers:**
  - Commissioners → Cancer Networks
  - Prescribers
- **Value**:
  - Commissioners → Cost effectiveness
  - Prescribers → Clinical effectiveness

What about the patient perspective?

Cancer Drugs Fund- assessment and evaluation of drugs – scoring criteria

- NICE, SMC, AWMSG
- Evidence - Phase 3 RCTs preferred
- Sliding scale for PFS/DFS/TTP or OS (only one used) use HR, p-value and NNT
- Quality of life

Criteria	Score
Good published evidence of a major improvement of QoL, using validated tool	2
Good published evidence of a minor improvement in QoL, using a validated tool	1
Little or no evidence of improvement of QoL, or no QoL data collected in the trial	0
Published evidence of a minor deterioration in QoL, using a validated tool	Minus 1
Published evidence of a Major deterioration in QoL, using a validated tool	Minus 2

Cancer Drugs Fund- assessment and evaluation of drugs – scoring criteria

Compared to existing treatment

- Toxicities, side effects
- Dose and route, number of cycles, associated medication
- Frequency of administration, inpatient stays, outpatient consultations, location of treatment
- Impact on service support; pharmacy, biochemistry, haematology, histology, radiology, radio-isotopes, CT scanning, MRI unit

- Degree of unmet need

Cancer Drugs Fund- assessment and evaluation of drugs – scoring criteria

QALY Value	Score for independent	Score for pharmaceutical company
< £10,000	8	4
< £20,000	6	3
< £30,000	4	2
< £40,000	2	1
> £40,000	0	0
None available	0	0

Going forward what additional information is required – for decision making

- Unmet need - Information on drug vs radiotherapy vs surgery
- Identification of specific patients for treatment - cytogenetic testing
- Cost of toxicities and side effects
- Impact on support services
- QoL – often missing - PROMs
- Adherence/ persistence information
- Value based pricing – definition of value and innovation!

So what needs to happen?

- Relevant information needs to be generated alongside clinical trials
- Maybe trials need to be redesigned to take account of what is happening in the real world?
- Involvement of commercial at an earlier stage in product development
- Involvement of payers at an earlier stage in product development!

Questions?

Surrey West Sussex and Hampshire Cancer Network

The ongoing healthcare reform and its impact on DAK's contracting strategy

ISPOR 14th European Congress

Dr. Cornelius Erbe

Madrid, November 7, 2011

DAK: Germany's longest-standing and third-largest statutory health insurance company is a quality leader

- Germany's third largest nationwide health insurance company
- Health experts since 1774
- Approx. 5.6 million insured, approx. 8.0% market share
- 835 offices nationwide
- Approx. 14,500 capable and friendly employees
- Annual expenditures [2009]: EUR 16.1 billion in health insurance EUR 1.7 billion in nursing care
- Test winner – many awards for quality performance and services

Agenda

A. Introduction: the "fair price"

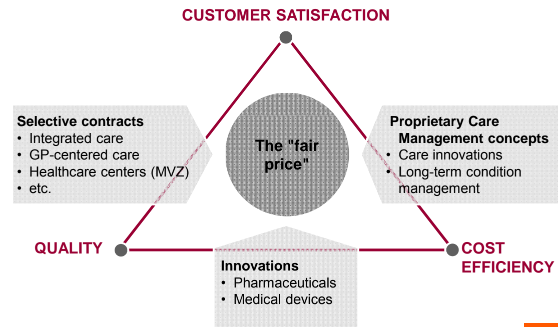
B. Measuring the effects in healthcare reality

C. Evaluating an "innovative" product relative to standard care

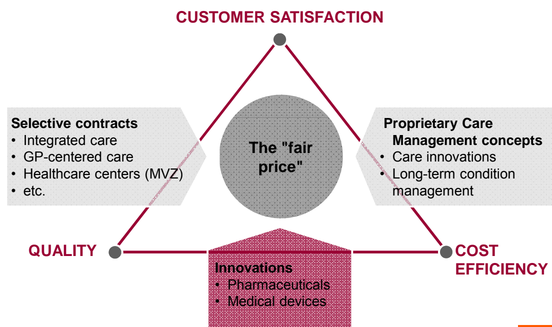
D. Deriving DAK's strategy based on the findings

A. Introduction: the "fair price"

How can we determine the "fair price" of DAK-specific care concepts?

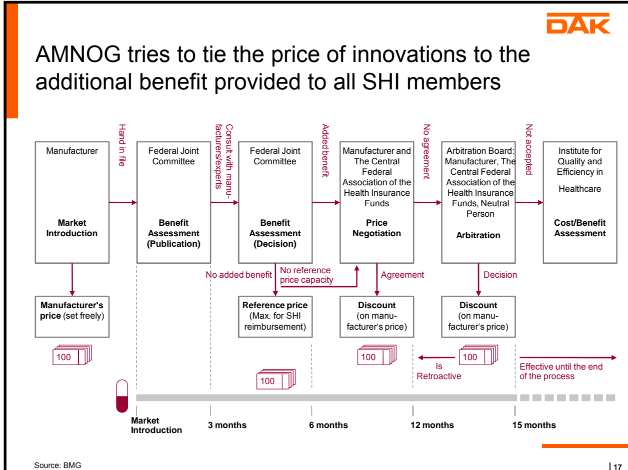


Finding a fair price for DAK customers is a challenge – especially for pharmaceuticals



Consistent pricing in the pre-AMNOG world is increasingly being replaced by individualized prices

	Pre-AMNOG world	Post-AMNOG world
Quality	Generally high	High for individual health insurance companies
Target group	All SHI members	Only DAK members
Service providers involved	All accredited service providers	Approved certified service providers
Access to service	All	Clearly defined target group
Benefits	Same for all SHI members	Specific to DAK members
Price	**Same for all health insurance companies**	**DAK-specific**


DAK
AMNOG tries to tie the price of innovations to the additional benefit provided to all SHI members
Manufacturer
Market Introduction
Hand in file
Federal Joint Committee
Benefit Assessment (Publication)
Consult with manufacturers/experts
Federal Joint Committee
Benefit Assessment (Decision)
Added benefit
Manufacturer and The Central Federal Association of the Health Insurance Funds
Price Negotiation
No agreement
Arbitration Board: Manufacturer, The Central Federal Association of the Health Insurance Funds, Neutral Person
Arbitration
Not accepted
Institute for Quality and Efficiency in Healthcare
Cost/Benefit Assessment
No added benefit
No reference price capacity
Agreement
Decision
Manufacturer's price (set freely)
Reference price (Max. for SHI reimbursement)
Discount (on manufacturer's price)
Discount (on manufacturer's price)
100
100
100
100
Is Retroactive
Effective until the end of the process
Market Introduction
3 months
6 months
12 months
15 months
Source: BMG
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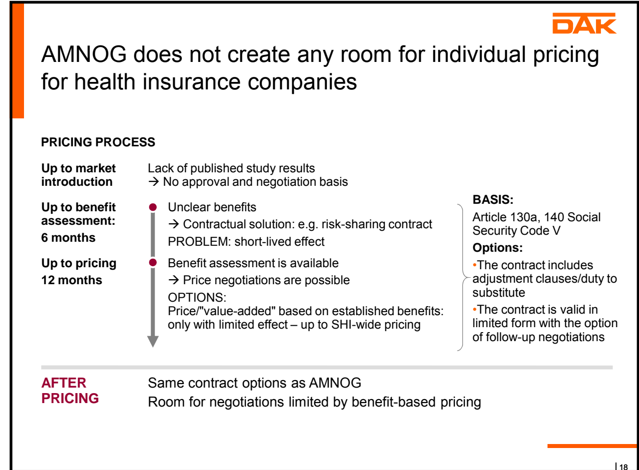
DAK
AMNOG does not create any room for individual pricing for health insurance companies
PRICING PROCESS
Up to market introduction
Lack of published study results
→ No approval and negotiation basis
Up to benefit assessment: 6 months
Unclear benefits
→ Contractual solution: e.g. risk-sharing contract
PROBLEM: short-lived effect
Up to pricing 12 months
Benefit assessment is available
→ Price negotiations are possible
OPTIONS:
Price/"value-added" based on established benefits: only with limited effect – up to SHI-wide pricing
BASIS:
Article 130a, 140 Social Security Code V
Options:
•The contract includes adjustment clauses/duty to substitute
•The contract is valid in limited form with the option of follow-up negotiations
AFTER PRICING
Same contract options as AMNOG
Room for negotiations limited by benefit-based pricing
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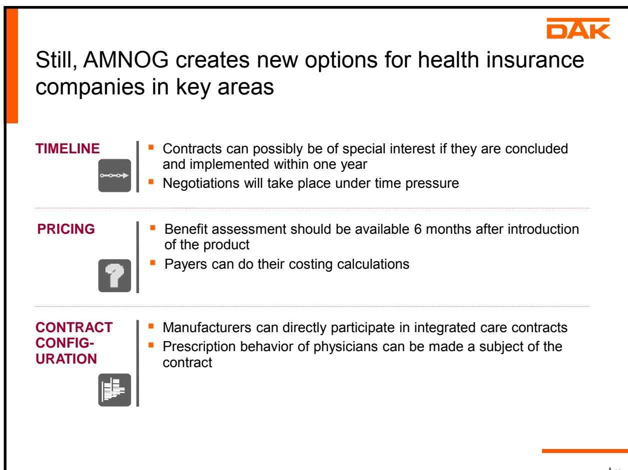
DAK
Still, AMNOG creates new options for health insurance companies in key areas
TIMELINE
Contracts can possibly be of special interest if they are concluded and implemented within one year
Negotiations will take place under time pressure
PRICING
Benefit assessment should be available 6 months after introduction of the product
Payers can do their costing calculations
CONTRACT CONFIGURATION
Manufacturers can directly participate in integrated care contracts
Prescription behavior of physicians can be made a subject of the contract
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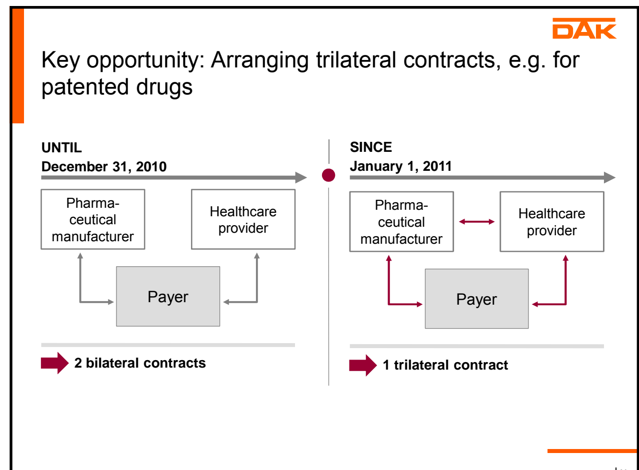
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Key opportunity: Arranging trilateral contracts, e.g. for patented drugs
UNTIL December 31, 2010
Pharmaceutical manufacturer
Healthcare provider
Payer
2 bilateral contracts
SINCE January 1, 2011
Pharmaceutical manufacturer
Healthcare provider
Payer
1 trilateral contract
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To identify the "fair" DAK-specific price, the effects must be measured correctly

Challenge in price identification

- How can the **effects of new methods** be assessed **in a holistic manner** and **across all service sectors**?
- What **change** does the **innovation** produce **compared to standard care**?
- How can we **produce significant results**?
- How can the **effects be mapped in real time** so that steering can take place as fast as possible?
- How can the **results** in different persons **be reproduced** at different points in time?

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B. Measuring the effects in healthcare reality

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DAK has developed a systematic procedure for measuring the success of care activities

Background and requirements

All insured must be considered
- Description of benefit payouts for each insured in all sectors
- All cost shifts between sectors must be mapped

The background of the insured population must be considered
- Age and gender
- Basic illnesses
- Service history
- ...

DAK approach to measuring success

DAK success measuring looks at the total of all service events for the insured in question (= participants)

A suitable mathematical procedure helps create a risk-adjusted control population
- Risk adjusted using up to 35 routine parameters

Comparing the development of the participants against the control population **based on up to 1,200 parameters shows the success** of the action

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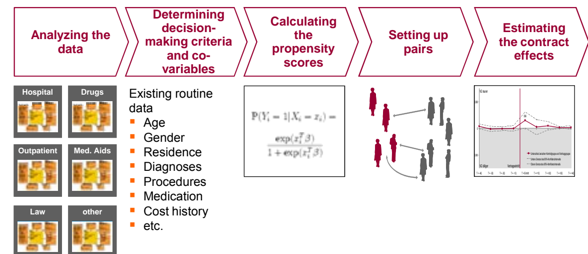
The procedure is based on all routine service data, and the results can be reproduced

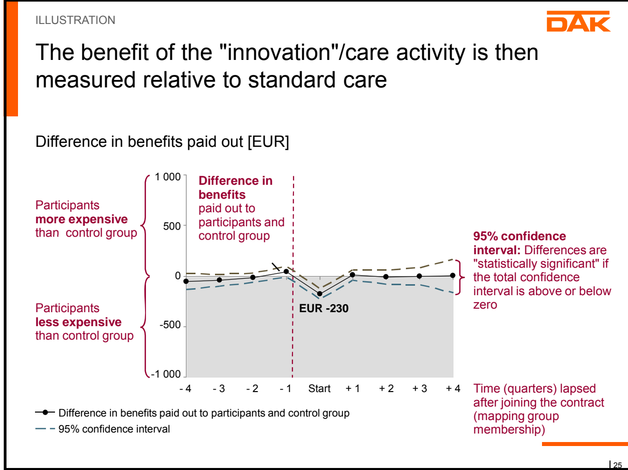
Analyzing the data → Determining decision-making criteria and co-variables → Calculating the propensity scores → Setting up pairs → Estimating the contract effects



Existing routine data
- Age
- Gender
- Residence
- Diagnoses
- Procedures
- Medication
- Cost history
- etc.

$$P(Y_i = 1 | X_i = x_i) = \frac{\exp(x_i^T \beta)}{1 + \exp(x_i^T \beta)}$$

According to Rubin, Waterman: Estimating the Causal Effects of Marketing Interventions Using Propensity Score Methodology



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C. Evaluating an "innovative" product relative to standard care

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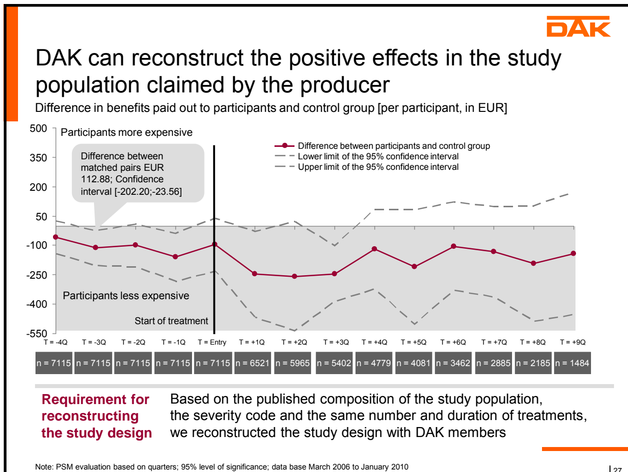

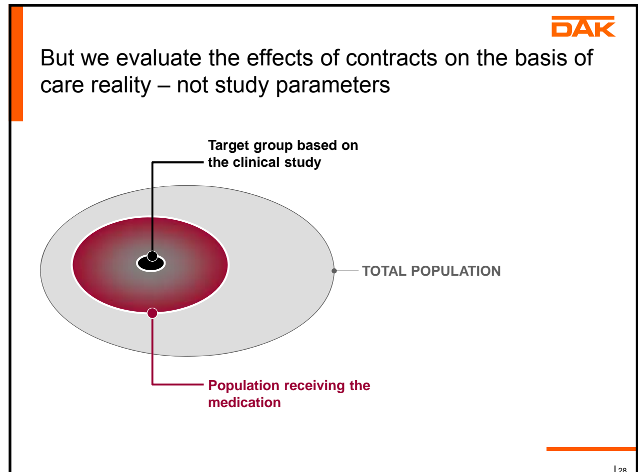

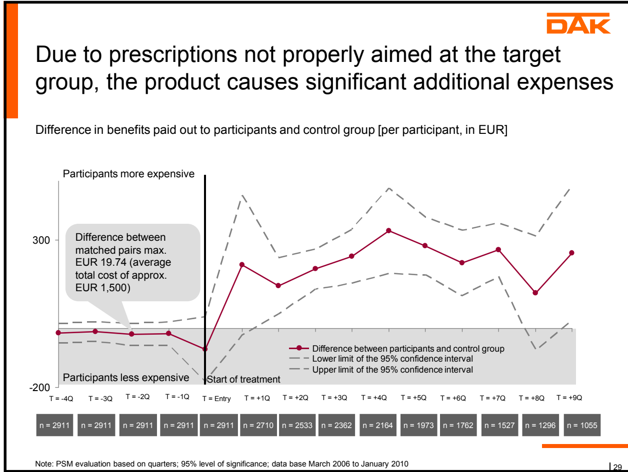
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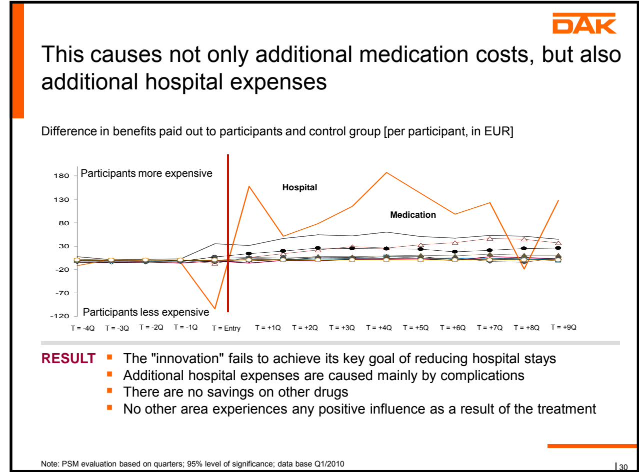
Due to prescriptions not properly aimed at the target group, the product causes significant additional expenses
Difference in benefits paid out to participants and control group [per participant, in EUR]
Participants more expensive
300
Difference between matched pairs max. EUR 19.74 (average total cost of approx. EUR 1,500)
Participants less expensive
-200
Start of treatment
Difference between participants and control group
Lower limit of the 95% confidence interval
Upper limit of the 95% confidence interval
T = -4Q
T = -3Q
T = -2Q
T = -1Q
T = Entry
T = +1Q
T = +2Q
T = +3Q
T = +4Q
T = +5Q
T = +6Q
T = +7Q
T = +8Q
T = +9Q
n = 2911
n = 2911
n = 2911
n = 2911
n = 2911
n = 2710
n = 2533
n = 2362
n = 2164
n = 1973
n = 1762
n = 1527
n = 1296
n = 1055
Note: PSM evaluation based on quarters; 95% level of significance; data base March 2006 to January 2010
| 29


DAK
This causes not only additional medication costs, but also additional hospital expenses
Difference in benefits paid out to participants and control group [per participant, in EUR]
180
130
80
30
-20
-70
-120
Participants more expensive
Participants less expensive
Hospital
Medication
T = -4Q
T = -3Q
T = -2Q
T = -1Q
T = Entry
T = +1Q
T = +2Q
T = +3Q
T = +4Q
T = +5Q
T = +6Q
T = +7Q
T = +8Q
T = +9Q
RESULT
The "innovation" fails to achieve its key goal of reducing hospital stays
Additional hospital expenses are caused mainly by complications
There are no savings on other drugs
No other area experiences any positive influence as a result of the treatment
Note: PSM evaluation based on quarters; 95% level of significance; data base Q1/2010
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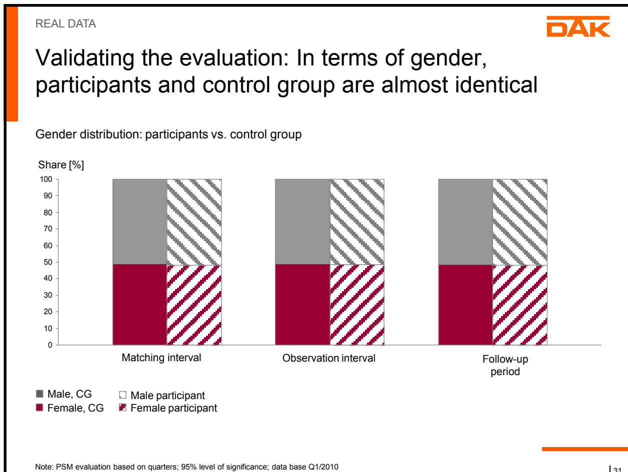
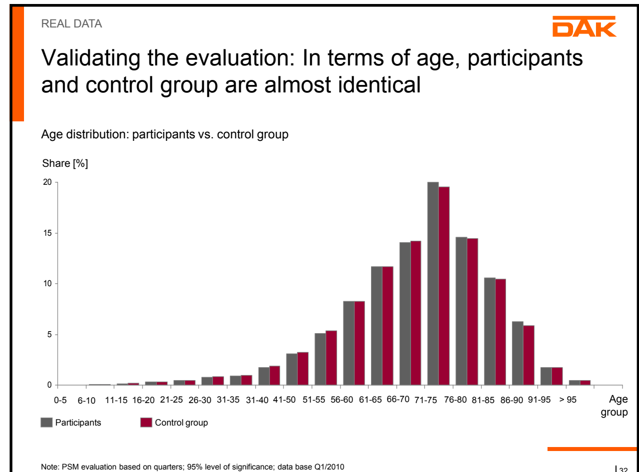
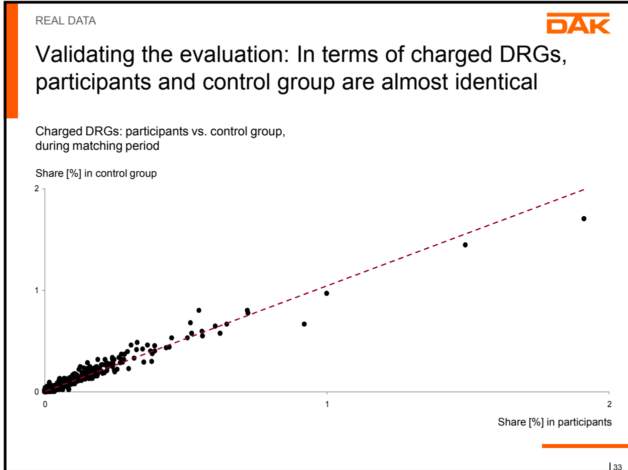
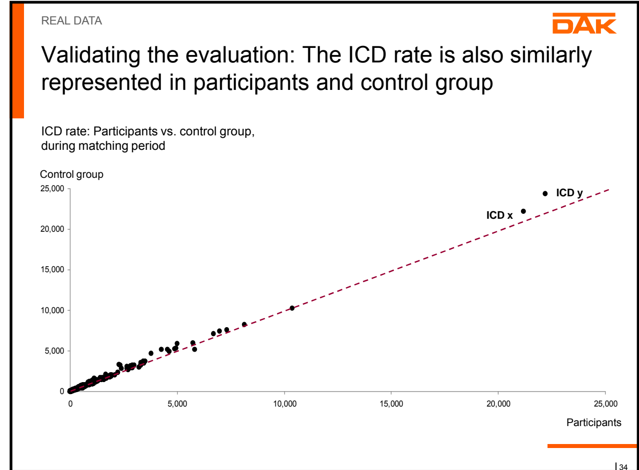

REAL DATA
DAK
Validating the evaluation: In terms of gender, participants and control group are almost identical
Gender distribution: participants vs. control group
Share [%]
100
90
80
70
60
50
40
30
20
10
0
Matching interval
Observation interval
Follow-up period
Male, CG
Female, CG
Male participant
Female participant
Note: PSM evaluation based on quarters; 95% level of significance; data base Q1/2010
| 31


REAL DATA
DAK
Validating the evaluation: In terms of age, participants and control group are almost identical
Age distribution: participants vs. control group
Share [%]
20
15
10
5
0
0-5
6-10
11-15
16-20
21-25
26-30
31-35
31-40
41-50
51-55
56-60
61-65
66-70
71-75
76-80
81-85
86-90
91-95
> 95
Age group
Participants
Control group
Note: PSM evaluation based on quarters; 95% level of significance; data base Q1/2010
| 32





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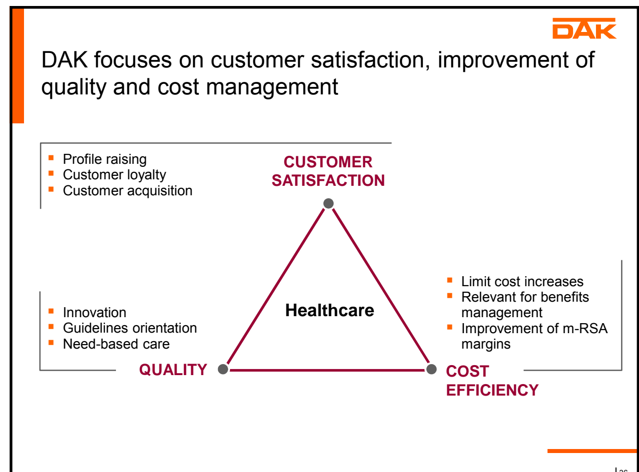
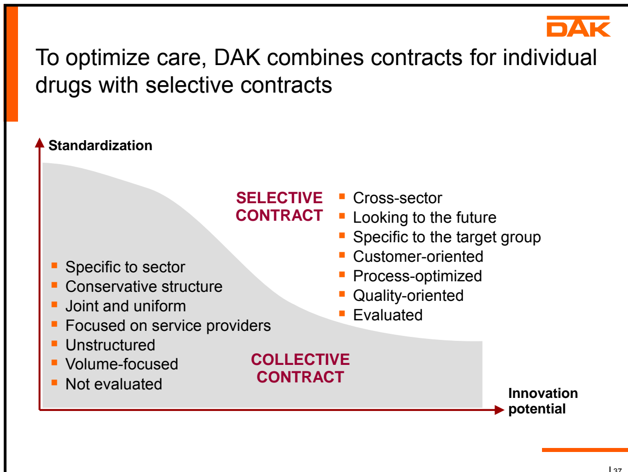
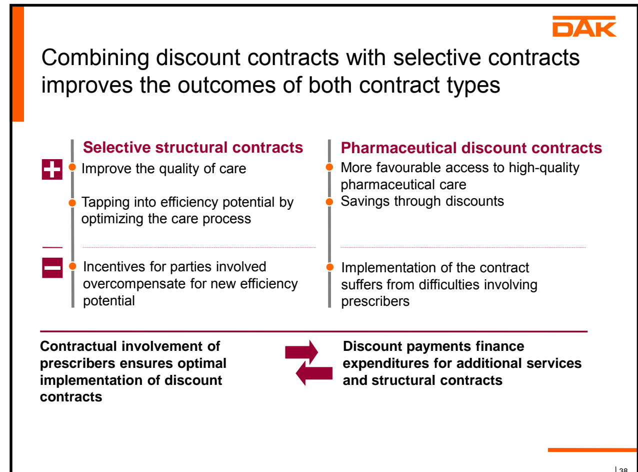
D. Deriving DAK's strategy based on the findings







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Different integrated care (IC) cooperation models are conceivable

Contractual approach	CHANCES	RISKS
Provision of pharmaceuticals	▪ Inclusion of generics ▪ Discounts for unique for special indications ▪ Discount when there is more than one relevant product available	▪ Conflicting interests in discount contracts ▪ Opening clause for price reductions necessary ▪ Tender probable
Pharmaceutical companies as service providers	▪ Boosting compliance ▪ Indication-related trainings ▪ Therapy-associated concepts (e.g. telemonitoring) ▪ Health services research	▪ Demand-based support ▪ Product marketing as a main aspect ▪ Lack of acceptance by other parties
Pharmaceutical companies as management companies	▪ Concept development and sale ▪ Acquisition and support of contract partners	▪ Selection and management of physician networks by pharmaceutical companies possible where required

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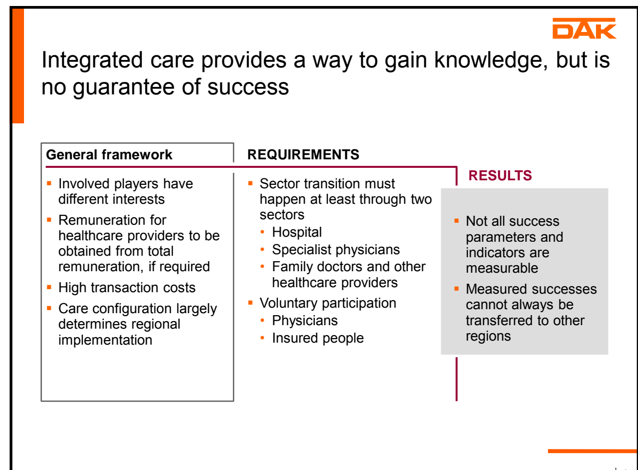

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Meaningful selective contracts with selected contract partners for defined target groups

OPPORTUNITIES

- Contribution to cost containment
- Improvement of patient care by combining pharmaceutical contracts with patient care programs
- Innovative approaches to cooperation between the pharmaceutical industry and health insurance companies
- Coordinated patient care with (innovative) pharmaceuticals
- Testing of regional approaches to gain knowledge
- Better compliance in pharmaceutical administration based on comprehensive approach and individual patient care

RISKS

- Higher volumes
- Bypassing efficiency audits
- IC cannot interfere with freedom of therapy
- Lack of acceptance of direct participation of the pharmaceutical industry by patients and professional associations
- Bureaucracy of tenders remains an obstacle to IC contracts
- IC remains a very detailed isolated solution

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Contract assessments so far provide important information that can help successfully implement new concepts

EXPERIENCES

- Early assignment difficult to implement
- Prescribing according to the guidelines and improved patient compliance will increase consumption of pharmaceuticals
- Optimization of drug therapy to decrease follow-up costs

Insights for new contracts

- Developing effective concepts is important for early assignment
- Involving the right patients
- Target group oriented contract concepts
- Price negotiations/discounts for relevant drug therapy are interesting
- Regular quality meetings with the contract partners to constantly refine the concepts

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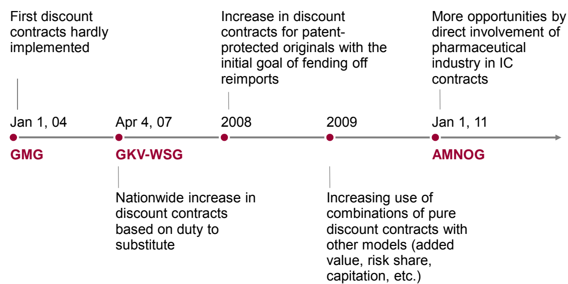
AMNOG takes into account the evolution of selective contracts



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Selective contracts with pharmaceutical companies: Why do those involved want them?

HEALTH INSURANCE COMPANY

- Access to Innovation
- Savings
- Increase in quality of care
- Improvement of compliance
- Competitive tool
- Need-based care

MANUFACTURER

- Fast market entry for new pharmaceuticals
- Fast increase/securing of market share
- Marketing tool
- Image improvement

HEALTHCARE PROVIDER

- Innovative services for patients
- Patient satisfaction
- Profit optimization
- Contract-based support

PROFESSIONAL ASSOCIATIONS

- Preserving the independence of physicians in their prescription behaviour – freedom of therapy
- Preserving the interests of all physicians

DAK

Individual health insurance companies have two options

Joining contracts for patent-protected originals is a strategic business decision for insurance companies

	PRO	CON
Individual contracts with the pharma industry	▪ Competitive advantage over other health insurance companies ▪ Taking into account the needs of your own insured	▪ High administrative workload for contract initiation and processing ▪ Nationwide contracts based on complex concepts hardly possible
Only contracts of the Federal Association of SHI funds	▪ Strengthening the power of the Federal Association of SHI funds ▪ Consistent treatment quality throughout Germany	▪ Independence from Federal Association of SHI funds ▪ No possible differentiation from competitors

DAK

DAK will continue this strategy, but make the objective effects transparent

Lever		Possible improvement area	POTENTIAL
1	Adjusting/renegotiating contracts		a EUR m
2	Rolling out successful contracts		b EUR m
3	Improving inclusion management (no. of participants/specificity		c EUR m
4	Proactively concluding new contracts		d EUR m
5	Sharing best practice/ benchmarking		e EUR m

DAK

DAK insists that all parties benefit from new contracts

The benefits of the contract for all involved …

… must be obvious

- Faster access to innovations
- Individual care for patients (personalized/stratified medicine)
- Better quality

- Better cooperation with other service providers
- Market share
- Safety of innovations

- Higher customer loyalty
- Cost cuts through better quality compared to standard care
- A strong DAK brand based on a transparent, high-quality care offer

DAK

The future belongs to individually priced selective contracts that lead to measurable improvements in care

Conclusion

- AMNOG will hardly change contract strategies in the near future, but creates opportunities for expanding/developing existing contract concepts
- The exclusive focus on price for cost containment will be pushed into the background – combined/complex concepts will prevail
- DAK can precisely measure the effects of care concepts and "innovations" compared to standard care
- We will use this skill to develop "value for money", target group specific concepts that help optimize care provision

DAK

Thank you for your attention