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"Risk-structure compensation"

Third-party payers

Collector of resources

Health fund

Ca. 135 sickness funds

Ca. 45 private insurers

Uniform wage-related contribution

+ possibly additional premium (set by sickness fund),

Risk-related premium

Choice of fund/ insurer

Strong delegation

(Federal Joint Committee)

& limited governmental control

Choice

Contracts, mostly collective No contracts

Population Universal coverage:

Statutory Health

Insurance 86%,

Private HI 10%

Providers

Public-private mix, organised in associations ambulatory care/ hospitals



Key characteristics:

- a) Sharing of decision-making powers between the sixteen *Länder* (states), the federal government and statutory civil society organizations
 - i.e. important competencies are legally delegated to membership-based, self-regulated organisations of payers and providers
- b) German health care [almost] = Statutory health insurance (SHI)

 SHI Cornerstone of health service provision is the Fifth Book of the German

 Social Law (SGB V)
 - i.e. it organizes and defines the self-regulated "corporatist" structures and give them the duty and power to develop benefits, prices and standards
- c) Existence of substitutive private health insurance alongside SHI



Key characteristics:

d) Sectoral borders

Provision of ambulatory and inpatient services.

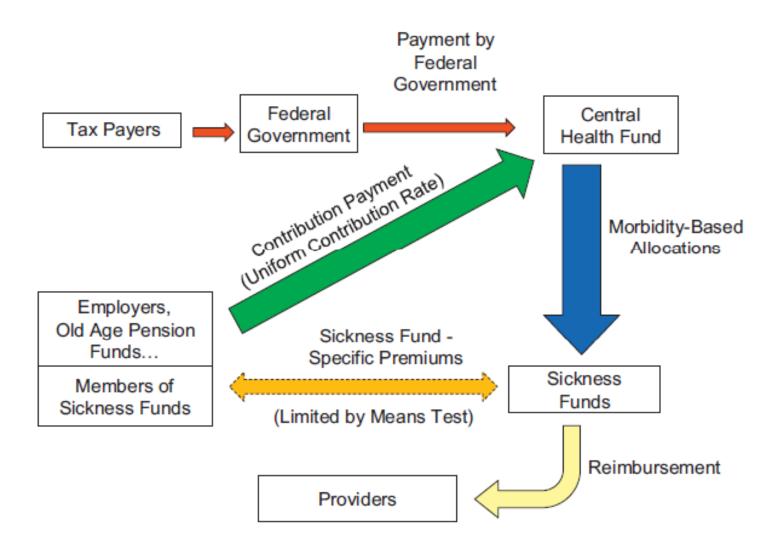
Planning, resource allocation, provision and financing are separate for ambulatory (office-based physicians) and inpatient (hospitals) sector.

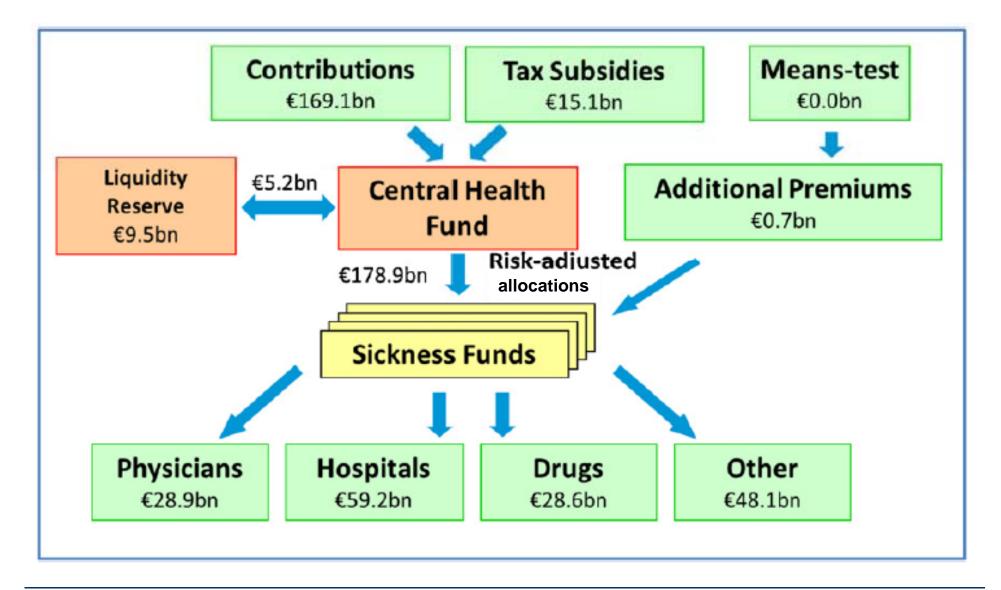
- →Complicates the provision of health care delivery (problematic especially for chronically ill → answers: Disease Management Programmes and selective "integrated care" contracts)
- →Increases the amount of specialists
- →Increases the health care expenditure
- → Various reforms have tried to lessen sectoral borders (last in 2012 by creating a new in-between sector for highly specialized ambulatory care)

	in the old times	Conslib.	Conslib.		Grand c	oalition	Conslib.
		1994/95	1996/97	2004	2007	2009	2011
Compulsory	Mandatory only for e	Univer	sal covera	age in SHI			
insurance	up to certain income	2			(or PHI)	
Choice	For employed above certain income within 1 year					years	within
between SHI							1 year
and PHI							
Choice of	For certain profession	nal groups	For most in	sured	For all insured except		
SHI fund	only		(97%)		farmers		
							1
							
			T				
					1		

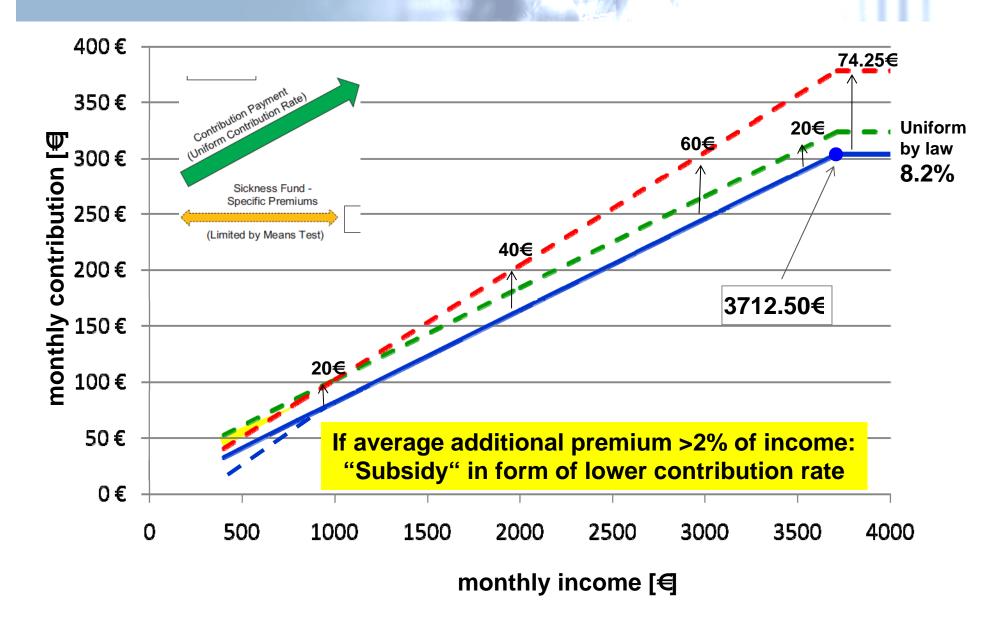
	in the old times	Conslib.		Red-green	Grand	coalition	Conslib.
		1994/95	1996/97	2004	2007	2009	2011
							T
Financial contribution	Contribution rate of	differing am	ong sicknes.	s funds		possibly premium sickness Actual amount	fund Tax subsidy if
						at 1%	add'l premium >2%
							•
							T

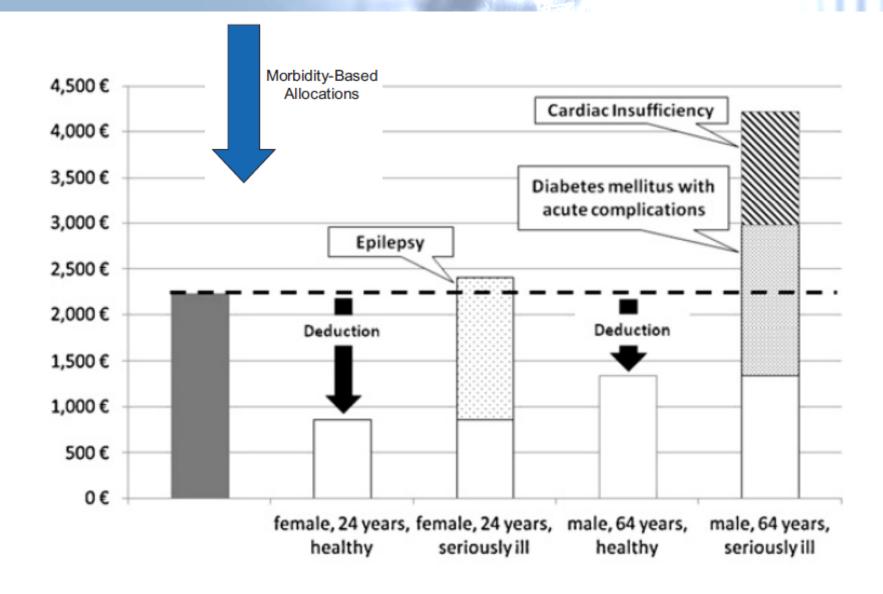
	in the old times	Conslib.	Conslib.		Grand	coalition	Conslib.
		1994/95	1996/97	2004	2007	2009	2011
Risk-struc-	None; pooled	Risk struc	cture	+ DMPs as		+ morbi	dity from
ture com-	expenditure for	compens	ation based	criterion &	high-	80 disea	ases
pensation	pensioners	on age ar	nd sex	cost pool			
<u>-</u>							
					<u> </u>		



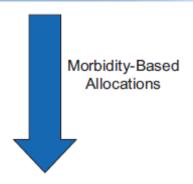














Accuracy of prediction for revenue and expenditure, in 2009-2011.

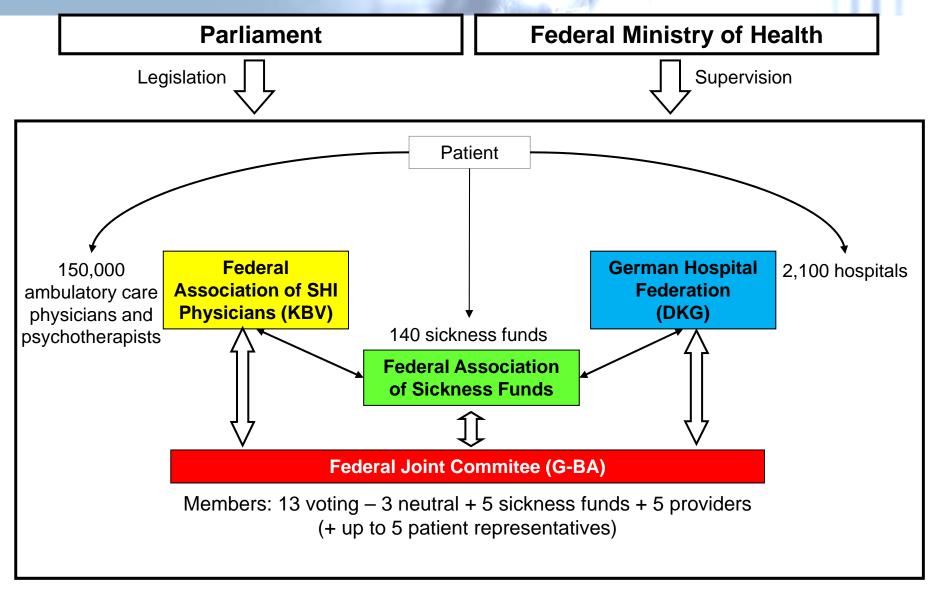
Year	Revenue of Central Health Fund			CHF payments	Expenditure of sickness funds			
	Predicted	Actual	Error		Predicted	Actual	Error	
2009	€166.8bn	€164.4bn	–€2.4bn	€166.8bn	€166.8bn	€166.2bn	–€0.7bn	
2010	€170.3bn	€174.5bn	€4.2bn	€170.3bn	€174.2bn	€171.3bn	–€2.9bn	
2011	€181.1bn	€184.2bn	€2.9bn	€178.9bn	€178.9bn	€175.2bn	–€3.8bn	
2012 ^a	€185.7bn	€188.7bn	€3.0bn	€185.4bn	€185.4bn	€181.6bn	–€3.9bn	

a Prediction of 10.11.2012.

Both the Health fund as well as the sickness funds can have higher or lower revenue and expenditure than ex-ante calculated: e.g. in 2009, the Health Fund's revenue fell short due to the fincial crisis while in the following years it was higher than predicted due to the booming economy in Germany.

	in the old times	Conslib.		Red-green	Grand	coalition	Conslib.
		1994/95	1996/97	2004	2007	2009	2011
			_				
		1		1			
Contents of benefit package	Relatively uniform be freedom for additional sickness funds			Palliative care incl.; OTC drugs excl.	Almost uniform (only 0.7 of exp. for additions by sickness funds)		•
Decisions on	Sectoral decisions		,	G-BA respo	nsible a	across sect	tors
benefits	Not evidence-based		HTA for	Drug	+ Cost	-benefit	+ early
			ambu-	benefit	assess	ment of	benefit
			latory	eval.;	drugs		eval. of
			services	IQWiG			all new
				founded			drugs

	in the old tir	d times Con		Conslib.		Red-green	Grand c	oalition	Conslib.
			1994	1/95	1996/97	2004	2007	2009	2011
Compulsory insurance	Mandatory onl certain income		oloy	Me	ergers bet	ween	Universa PHI, from	al coverage m 2009)	in SHI (or
Choice between SHI and PHI Choice of SHI fund Financial contribution	For employed a For certain pro only Contribution re	fessional	gro	allow assoc Ass mong si N ded b	erent fund ed; sickned sickness funds decided with the control of	Federal 2008) onus, dditional in SHI	for 3 y	years nsured exce	te plus Id'I premium
Risk-structure compensation	None; pooled expenditure fo	r		structu pensati	re on based on	+ DMPs as cr & high-cost p		+ morbidit diseases - DMP/ hig	y from 80 gh-cost pool
Contents of benefit package Decisions on benefits	Relatively additions t	Selection Integrate Inancia Inancia Inancia Integrated	ted of ally i	care (incent it only	2000); :ivized ~0.3%	Palliative care incl.; OTC drugs excl. G-BA respon Drug benefit eval.; IQWiG	exp. for funds)	uniform (on additions boss sectors	ly 0.7% of
					services	founded	drugs		eval. of all new drugs



Statutory Health Insurance



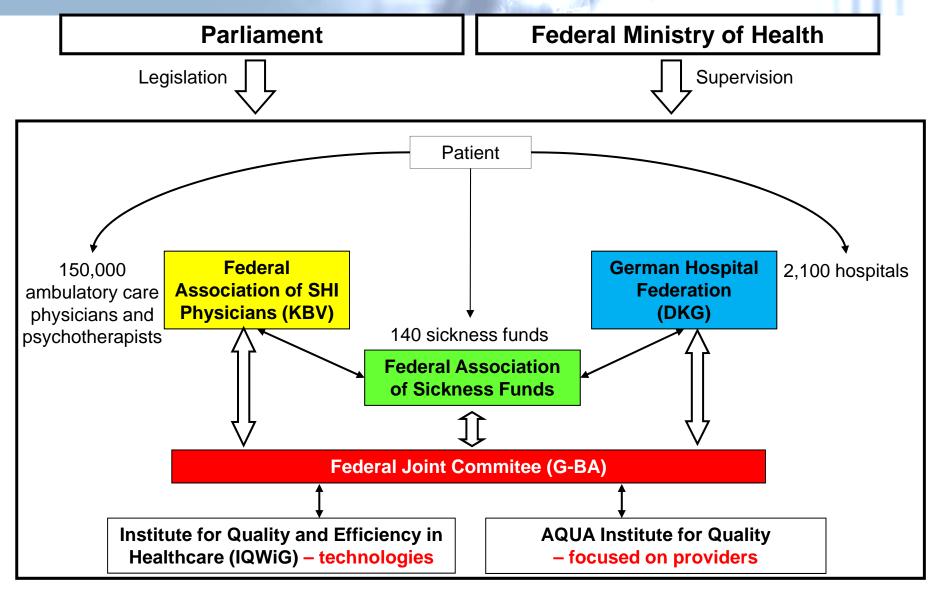
- Main functions: to regulate SHI-wide issues of access, benefits and quality (and not primarily of costs or expenditure).
- Normative function of the G-BA by legally binding directives ("sub-law") to guarantee equal excess to necessary and appropriate services for all SHI insured.
- Benefit-package decisions must be justified by an evidencebased process to determine whether services, pharmaceuticals or technologies are medically effective in terms of morbidity, mortality and quality of life.
- By law, evidence based assessments can only be used to select the most appropriate (efficient) service etc. from others – not to prioritize among service areas: if a costly innovation has a significant additional benefit, the sickness funds must pay for it.



Decisions are prepared by 9 sub-committees:

- Pharmaceuticals
- Quality Assurance
- Disease management programs
- Methodological Evaluation (inclusion of new ambulatory care services in benefit basket; NB: in hospitals, services can only be excluded)
- Highly specialized ambulatory care (by office-based physicians and hospitals; new sector since 2012)
- Referred Services (rehabilitation, care provided by nonphysicians, ambulance transportation etc.)
- Needs-based Planning (ambulatory care; NB: hospital capacities are planned by state governments)
- Psychotherapy
- Dental Services





Statutory Health Insurance



		Structure	Processes		Outcomes		
			Types/ numbers	Appropi- ateness	Intra- hospital	Long-term	
		Internal quality management system 2000	Nationwide external quality system based on special docu		Social in Socialii		
Federal		•	Disease Mana Programs 200	•	colon	cancer)	
Joint Committee	directives	Concentration of services (modume numbers) 2004	ninimum				
2004	2004	Assessments through Institu and Efficiency 2004					
		Public hospital quality reports 2005					
		Public hospital quality repor	ts (revised req	uirements) 2007			

| Berlin, May 22, 2013 | 18 November 2010

Important policies regarding patented drugs in Germany since 1996.

	1996-2003	2004-2006	2007-2010	Since 2011			
Evaluation of additional/		Upon application of Ministry of Health or parties in G-BA					
comparative benefit				Mandatory for all new drugs/ indications except orphan drugs $^{\rm a,b}$			
Price-setting	Free by manufacturer			Officially free by manufacturer, but de facto only for 12 months after launch			
Reimbursability (benefit basket)	All patented drugs included in benefit basket	effectiveness or with	f of effectiveness or with proven inferior th more efficient alternatives may be restricted or insulin analogues) [11]	Only drugs with proven inferior effectiveness or with more efficient alternatives may be restricted or excluded			
Reimbursement price in case of no additional benefit			and a reference price is determined per group; nce between price and reference price (example:	New drugs are grouped as well and are liable to reference price; if grouping is impossible, price may not exceed that of existing alternative			
Reimbursement in case of additional benefit	Reimbursement = price (possibly temporarily lowered by a certain %)	Reimbursement = price (possibly temporarily	Maximum reimbursement ceiling may be set following cost-effectiveness analysis (not done in a single case); in other cases reimbursement = price	Country-wide rebate on manufacturer price is negotiated between Federal Association of Statutory Health Insurance Funds and manufacturer (→ fixed reimbursement price from month 13 after launch)			
Unevaluated drugs		lowered by a certain %)	Reimbursement = price (possibly temporarily lowered by a certain %)	As before (concerns only patented drugs with market launch before 2011 and orphan drugs)			
Cost-effectiveness analysis	No	No	May be commissioned by G-BA for drugs with additional benefit (two analyses commissioned)	If negotiations fail and if one side challenges the result of the arbitration, a cost-effectiveness analysis is commissioned by the G-BA			

^a Although the additional benefit is deemed to be proven for orphan drugs, a dossier has to be submitted, and price negotiations will follow. The dossier does not have to present proof of the medical benefit and additional benefit. However, the dossier must include information on the groups of patients for whom there is significant medical additional benefit and on the extent of this additional benefit [10]. If the business volume of an orphan drug reached the amount of 50 million EUR during the last 12 months, a second (and full) dossier demonstrating additional benefits will have to be submitted within 3 months of its request by the G-BA.

^b Patented pharmaceuticals that were approved before 2011 are also assessed in the AMNOG process, if it is initiated by the G-BA.



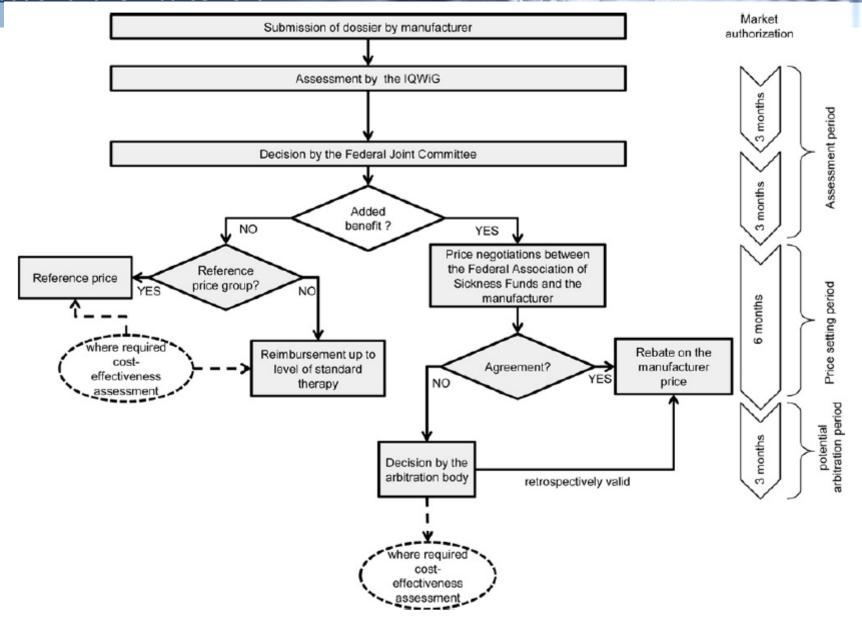


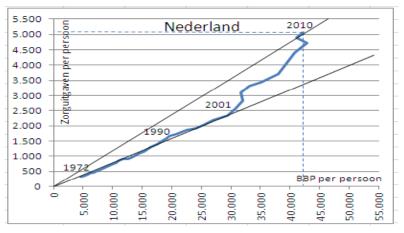
Fig. 1. Procedure for reimbursement of patented pharmaceuticals source: based on IQWiG [14].

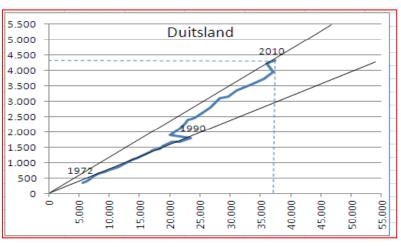


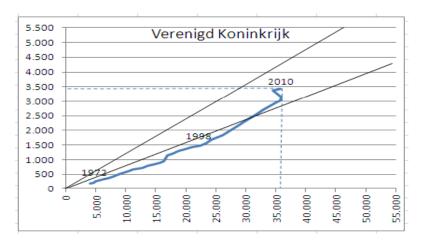
- No overall expenditure limit or cap but since 1970s legal requirement for "income-oriented" expenditure growth.
- In 1990s main legally required instruments: sectoral budgets (ambulatory, dental, hospitals) and caps (pharmaceuticals), growing in line with contributory income of insured.
- Since 2001 (pharmaceuticals), 2005 (hospitals) and 2009 (ambulatory care) more flexible arrangements trying to balance need and expenditure control
 - → greater role for contract partners to negotiate volumes;

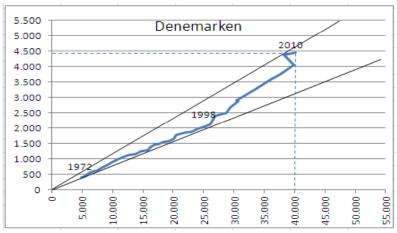
but legislator is intervening time after time, especially in times of financial deficit.

Expenditure as % of GDP has been stable over long periods (unlike e.g. in NL or DK) but reunification and recession in 2009 were major forces for increases



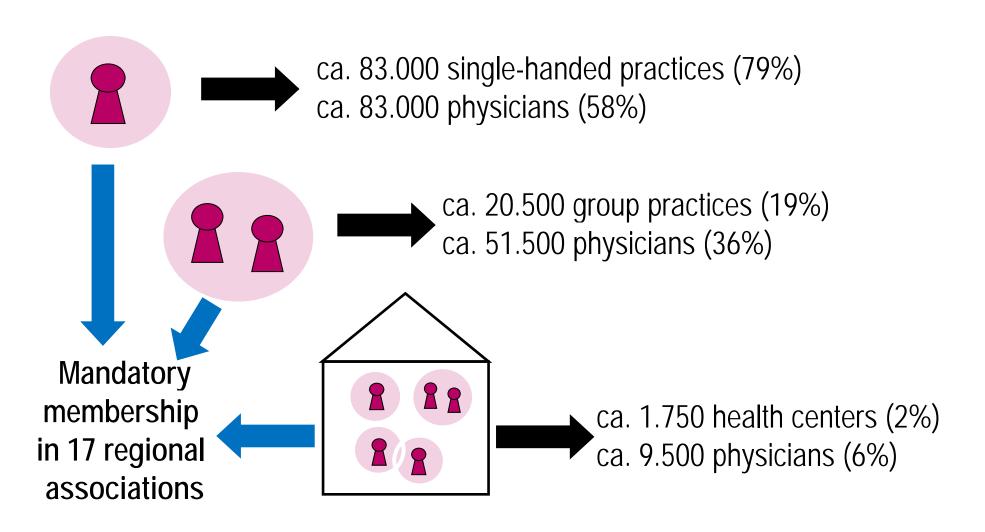


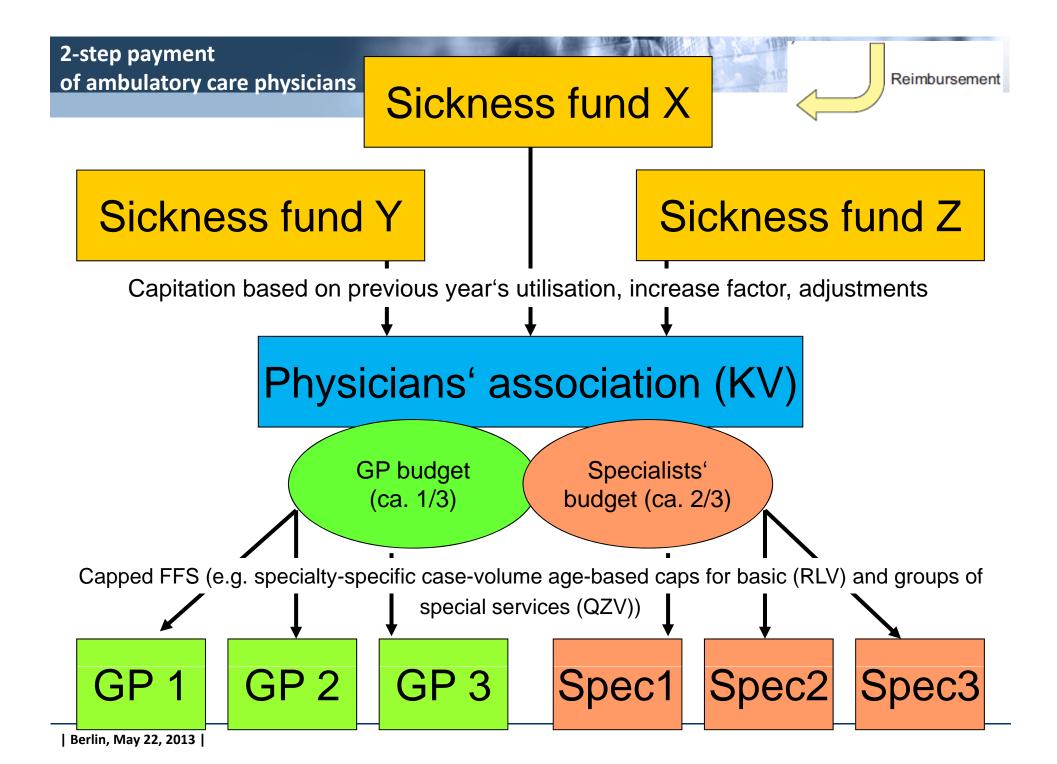




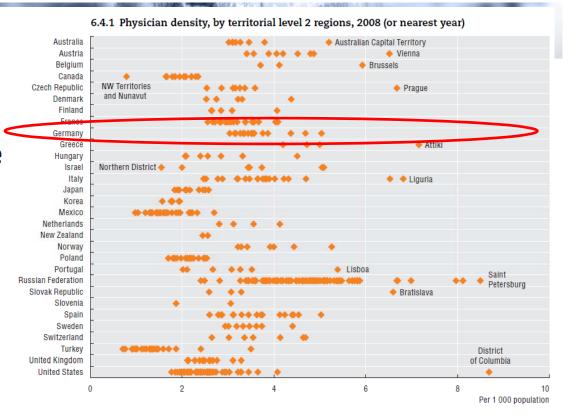


ca. 145.000 physicians, of which ca. 130.000 self-employed

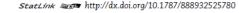


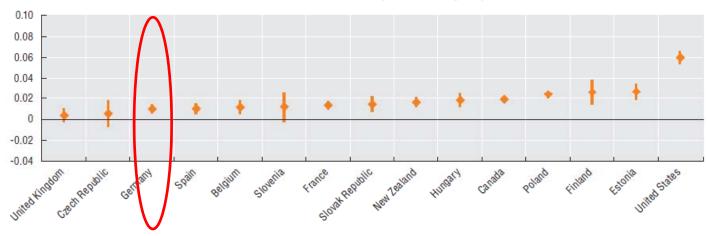


Physician density by region and patient access by income



6.5.1 Horizontal inequity indices for probability of a doctor visit (with 95% confidence interval),
15 OECD countries, 2009 (or nearest year)





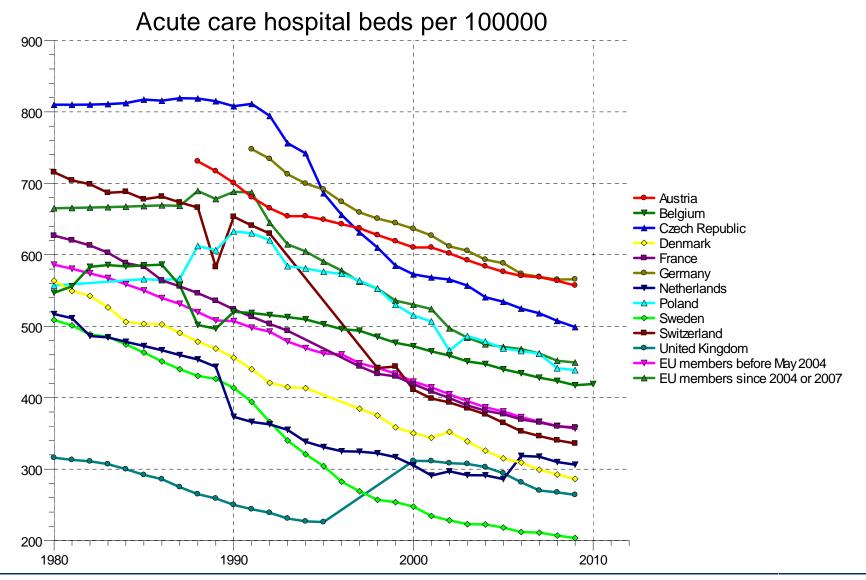
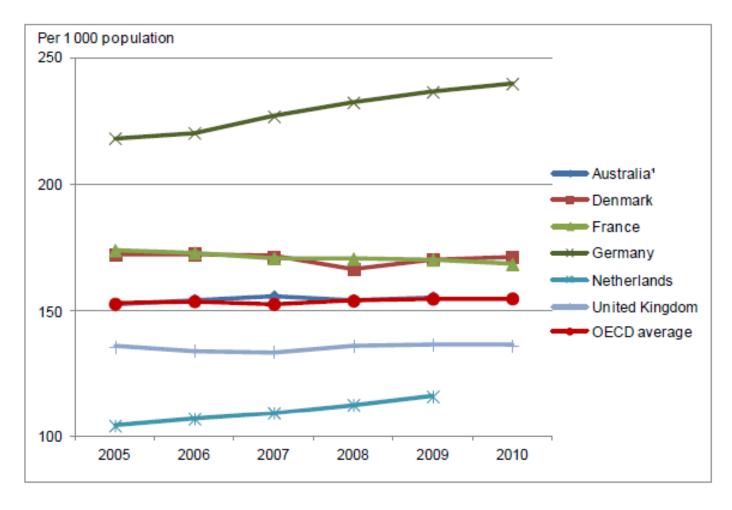




Abbildung 4: Anstieg der Krankenhausleistungen in den letzten fünf Jahren, ausgewählte OECD-Staaten

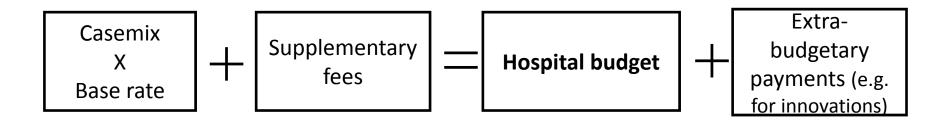


Anm. 1. Enthält keine Fallzahlen gesunder im Krankenhaus geborener Säuglinge (zwischen 3-7% aller Fallzahlen). Quelle: OECD Health Data 2012

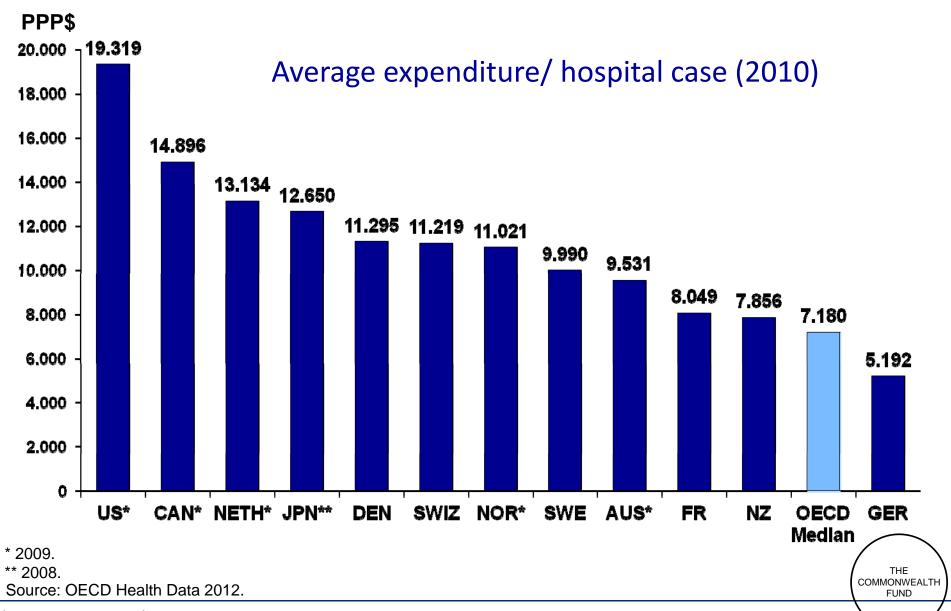


Operating costs (NB: investment costs are covered through taxes by the Länder)

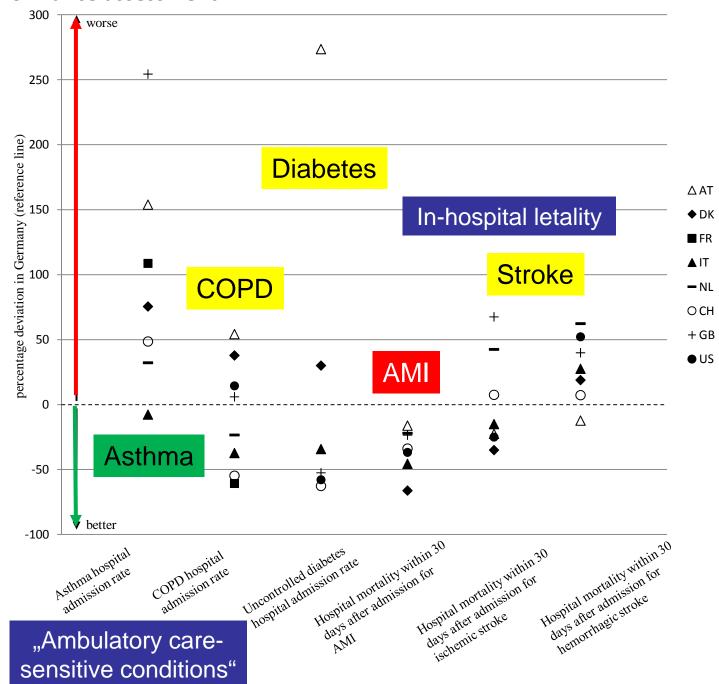
- Sickness funds negotiating activity based DRG budgets every year with every "planned" Hospital



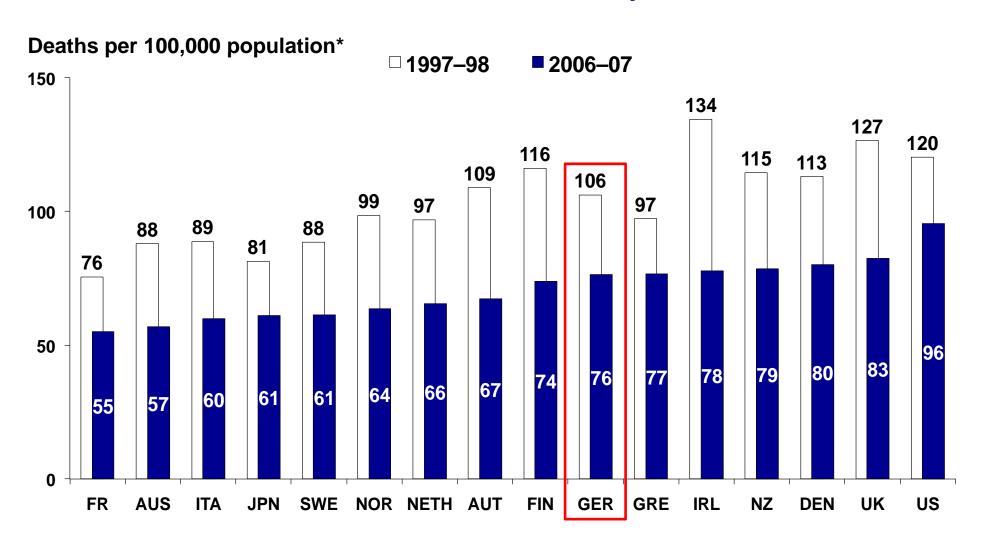
- Budget over-run adjustment (hospital pays back):
 - 65 % (standard DRGs), 25 % (drugs, medical, polytrauma and burns DRGs), Negotiation for hardly predictable DRGs
- Budget under-run adjustment (hospital receives compensation):
 - 20% (standard DRGs)



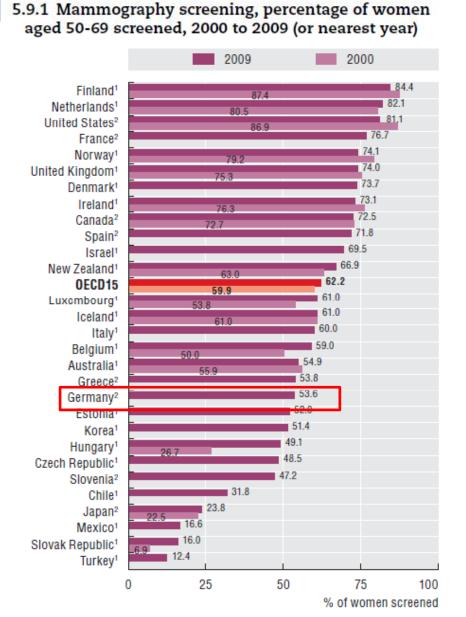
Performance assessment



Avoidable mortality



5.9.2 Breast cancer five-year relative survival rate, 1997-2002 and 2004-09 (or nearest period)



2004-09 1997-2002 89.3 United States 88.6 87.3 Japan 86.6 Canada 85.6 86.5 Norway 82.4 86.3 Finland 84.2 86.3 Iceland 86.2 Belgium 86.0 Sweden 83.1 84.5 New Zealand 77.0 84 4 Netherlands 83.5 OECD16 78.7 83.3 Germany 74.5 France 82.8 82.2 Korea 76.7 Portugal 82.0 Denmark 76.2 81.3 United Kingdom 75.0 81.2 Austria 80.3 Ireland 72.3 78.6 Czech Republic 70.8 76.9 Slovenia 67.9 20 40 60 80 100 0 Age-standardised rates (%)

—1. Programme. 2. Survey. Source: OECD Health Data 2011. Note: 95% confidence intervals are represented by I─I.

Source: OECD Health Data 2011.

5.10.1 Colorectal cancer, five-year relative survival rate, 1997-2002 and 2004-09 (or nearest period)



¬Note: 95% confidence intervals represented by I—I.

Source: OECD Health Data 2011.

5.10.2 Colorectal cancer, five-year relative survival rate by sex, 2004-09 (or nearest period)



Note: 95% confidence intervals represented by I--I.

Source: OECD Health Data 2011.

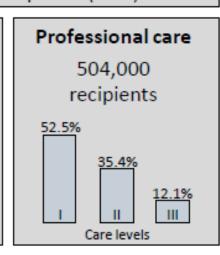


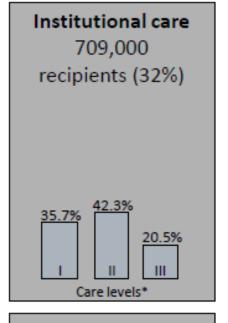
Burden of disability and dependency

2.25 million people in need of long-term care (2.5% of the population) in 2007

Home care

1.54 million recipients (68%)





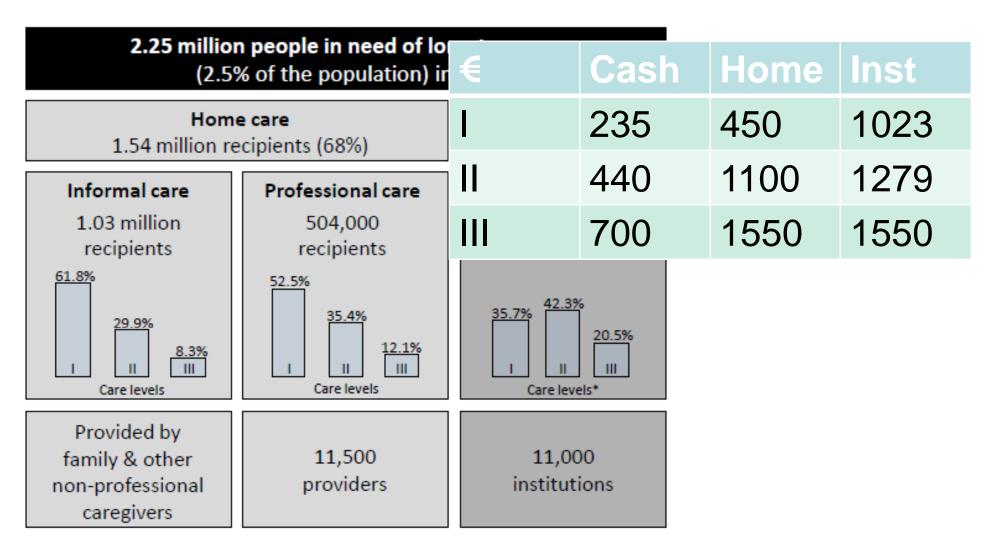
Provided by family & other non-professional caregivers

11,500 providers 11,000 institutions

^{*1.5%} not assigned



Burden of disability and dependency



^{*1.5%} not assigned