CAPABILITY

First Workshop
May 7-9, 2007
Trolleholm Castle

Jörg Schmidtke, Hannover, Germany

Translating genetic tests from research into practice in Germany:
Cascade screening for hereditary nonpolyposis colorectal cancer – a model approach

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Fitting new model approaches into a changing healthcare system – Why and how?

Tab. 2: Different models/types of health care systems

	Financing	**Service provision**	**Regulation**	**Country examples**
National Health Service	Public: taxes according to income (direct taxes) and consumption	Public providers	Dominating regulation mechanism: hierarchical, planning and tight control by the state	Finland, Italy, Portugal, Spain, Sweden, UK, Serbia/Montenegro
Social Insurance System	Public: contributions according to income	Private and public providers	Dominating regulation mechanism: collective bargaining, legal framework and some control by the state	Czech Republic, France, Germany, Lithuania

source: Grimmeisen and Rothgang

Germany:

- genetic testing is delivered almost exclusively in out-patient healthcare

- outpatient healthcare is dominated by private practice, contracted (long-term) by the social insurance system

- small contribution by policlinics in University and other hospitals

- some hospital departments or doctors have short-term contracts with the social insurance system.

Germany

- compulsory health insurance (CHI)
- insurance premia fixed percentage of income
- income threshold → opt-out → private insurance (10%)
- components of CHI in out-patient care:

• Physicians: *providers*
• Krankenkassen (sickness funds, “health insurance”): *payers*
• Kassenärztliche Vereinigungen (associations of CHI physicians): *distributors*

Note: Both: statutory bodies with self administration, as such part of the public authority, i.e. both regulated by law, and by virtue of their statutes, law-makers

Within the German framework of healthcare

- decision making processes up to the individual physician

- decisions based on state of the art (everybody entitled to such treatment)

- not clear if (all) predictive tests are covered in a legal sense

- no definition of prior risk levels (two notable exceptions)

- on paper: no priorisation, no rationing

- measures must be medically necessary = "indicated" = "sufficient, appropriate and economic" (SGB V)

Priorisation – level of prior risk

Two formal "legally binding" guidelines:

- exclusion of CF in offspring of men with CBAVD (~ 2%)

- eligibility for BRCA predictive testing if risk $\geq$ 20%

    note: no maternal age cut-off for prenatal karyotyping

- financing of out-patient healthcare based on a fee schedule

- in the case of genetic testing services: method-orientated (comparable to the US Medicare/Medicaid system).

-fee schedule based on a floating point value system (a few exceptions in EURO).

-e.g. PCR 625 points, DNA-Sequencing 2810 points

- point value oscillates (three-monthly) depending on regional gross turnover of all healthcare services; currently about 0.03 EUR

Example: FBN1-Sequencing (625+2810)x66x0.03= EUR 6801.30
(USA: 3200; int. commercial: EUR 1300)

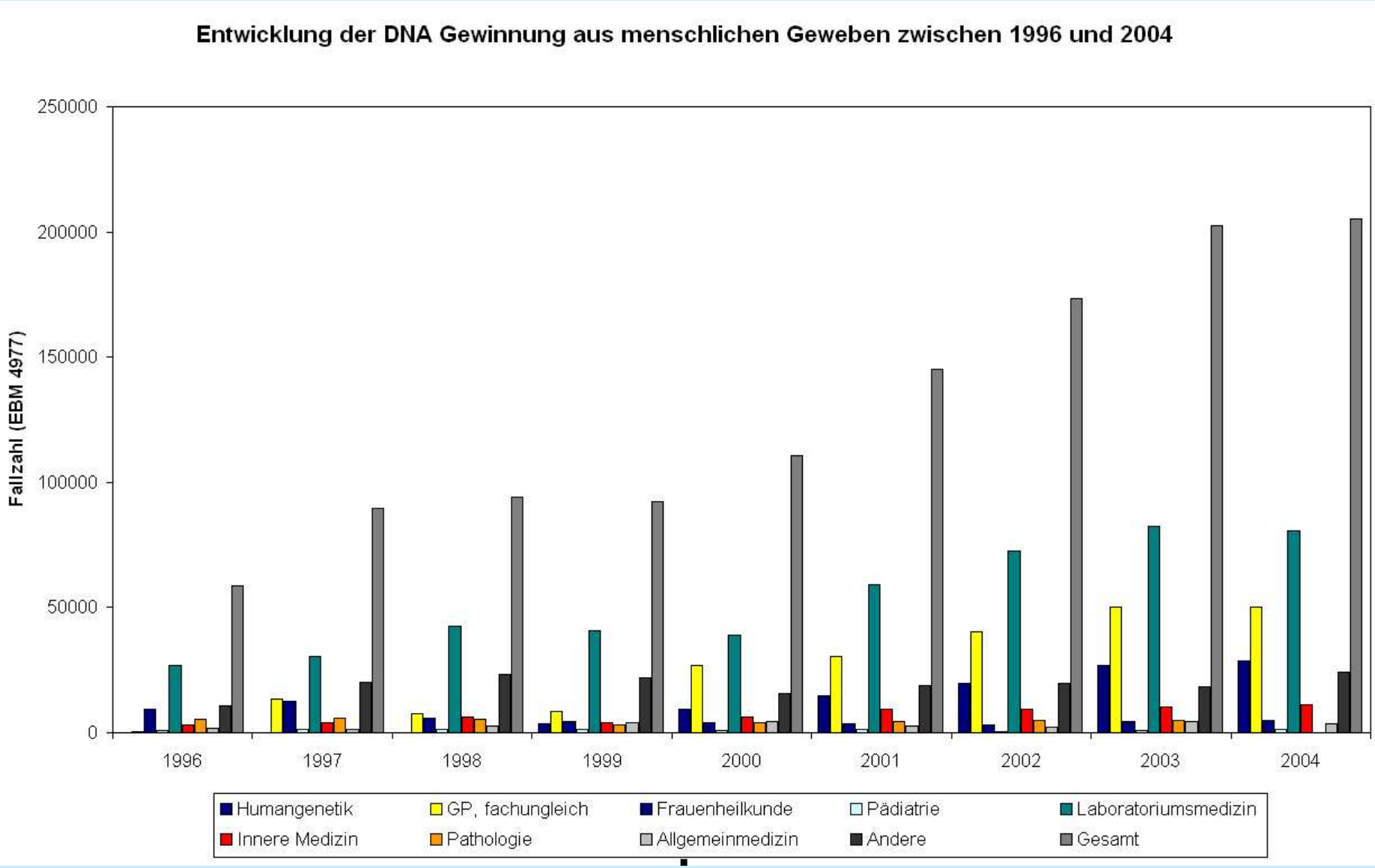
- floating point value: optimal system to facilitate introduction of new services due to scientific progress

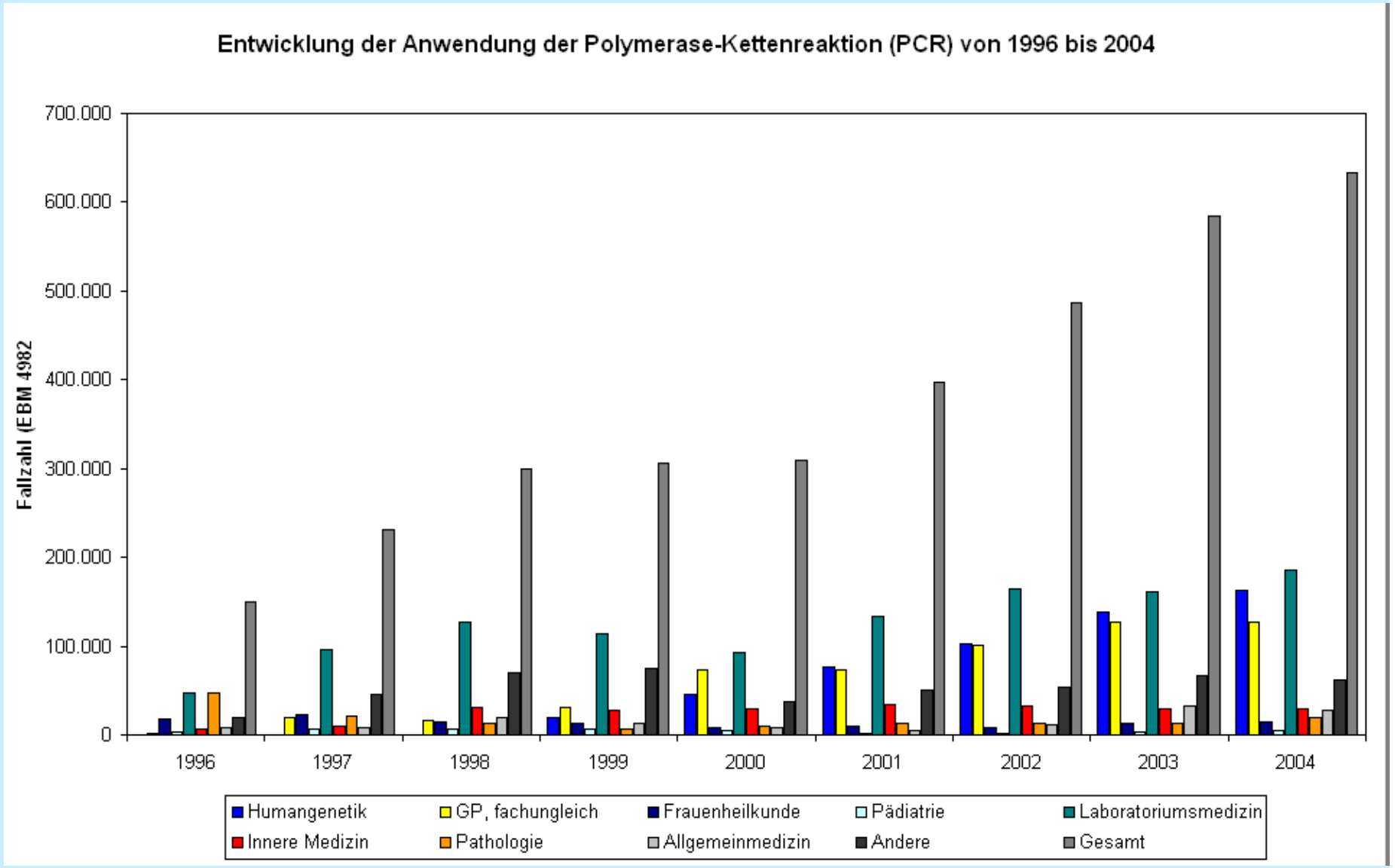
- translating research into practice: a process dominated by professional self-regulation

Example:

- in Germany, genetic testing absorbs 0.07% of total healthcare expenditure

- assumption: 10fold increase -> point value from 0.03 EUR to 0.029811 EUR (hardly felt by other specialties)


Entwicklung der DNA Gewinnung aus menschlichen Geweben zwischen 1996 und 2004
Fallzahl (EBM 4977)
250000
200000
150000
100000
50000
0
1996
1997
1998
1999
2000
2001
2002
2003
2004
Humangenetik
GP, fachungleich
Frauenheilkunde
Pädiatrie
Laboratoriumsmedizin
Innere Medizin
Pathologie
Allgemeinmedizin
Andere
Gesamt


Entwicklung der Anwendung der Polymerase-Kettenreaktion (PCR) von 1996 bis 2004
Fallzahl (EBM 4982
700.000
600.000
500.000
400.000
300.000
200.000
100.000
0
1996
1997
1998
1999
2000
2001
2002
2003
2004
Humangenetik
GP, fachungleich
Frauenheilkunde
Pädiatrie
Laboratoriumsmedizin
Innere Medizin
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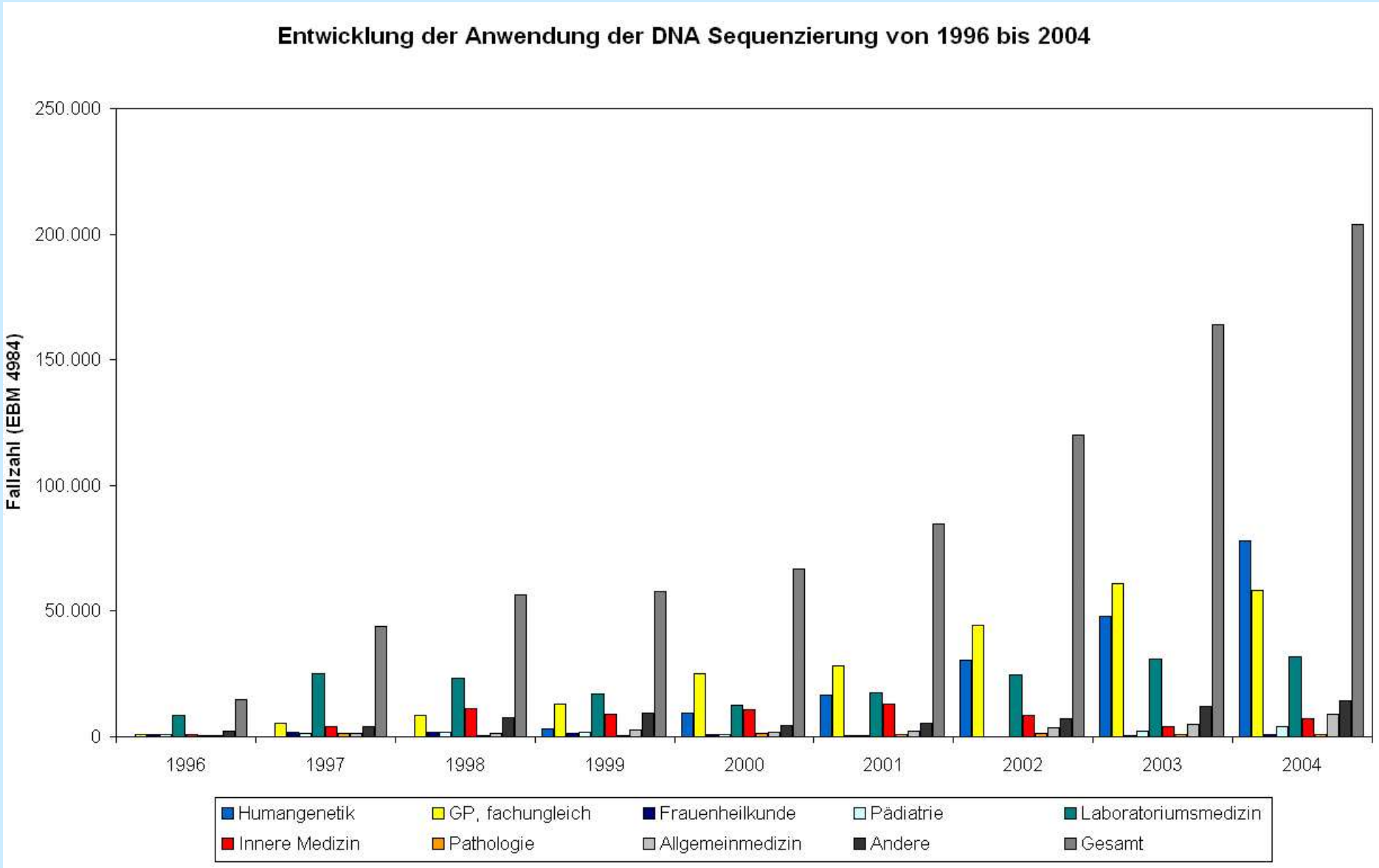
Entwicklung der Anwendung der DNA Sequenzierung von 1996 bis 2004
Fallzahl (EBM 4984)
250.000
200.000
150.000
100.000
50.000
0
1996
1997
1998
1999
2000
2001
2002
2003
2004
Humangenetik
GP, fachungleich
Frauenheilkunde
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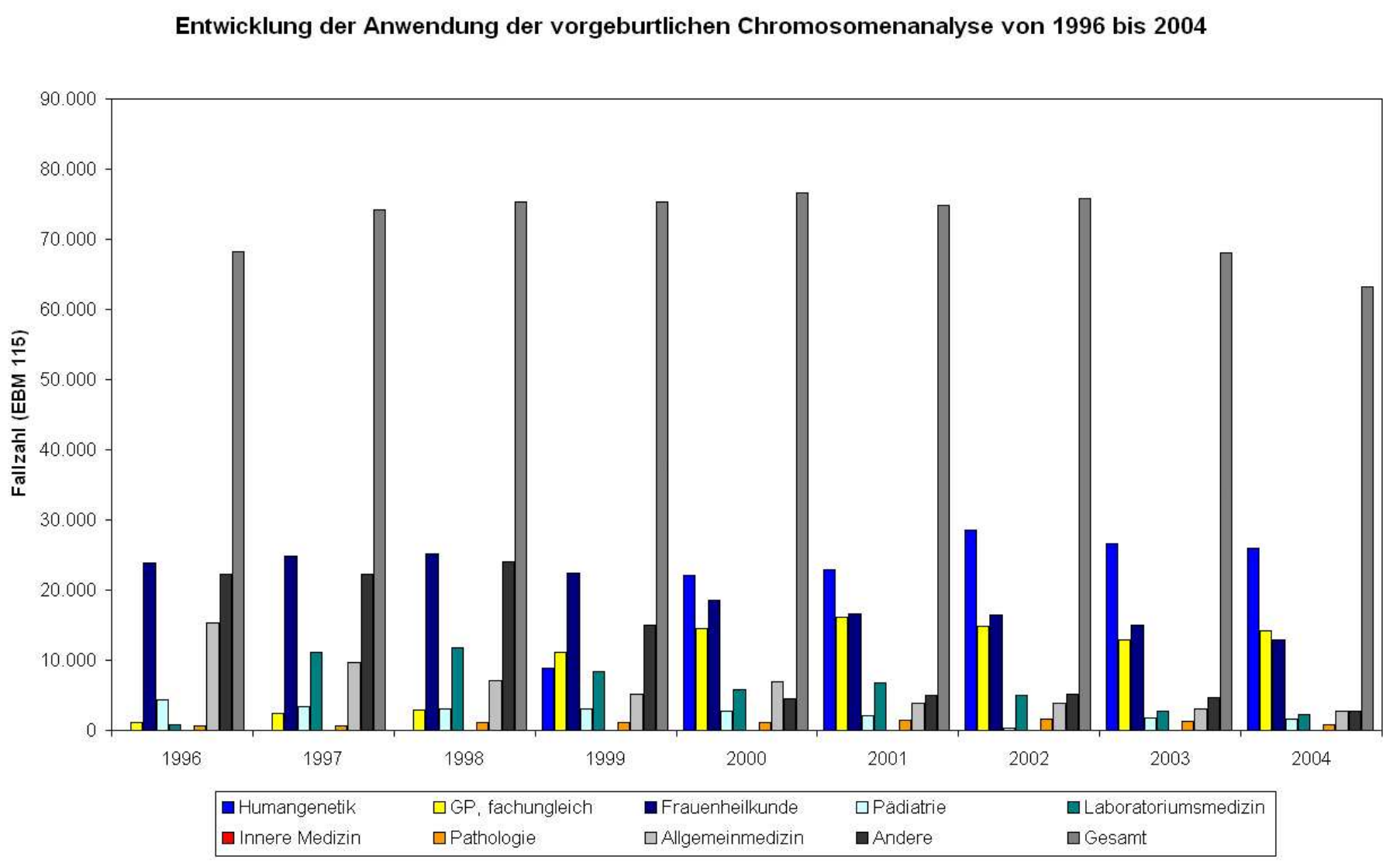
Entwicklung der Anwendung der vorgeburtlichen Chromosomenanalyse von 1996 bis 2004
Fallzahl (EBM 115)
90.000
80.000
70.000
60.000
50.000
40.000
30.000
20.000
10.000
0
1996
1997
1998
1999
2000
2001
2002
2003
2004
Humangenetik
GP, fachungleich
Frauenheilkunde
Pädiatrie
Laboratoriumsmedizin
Innere Medizin
Pathologie
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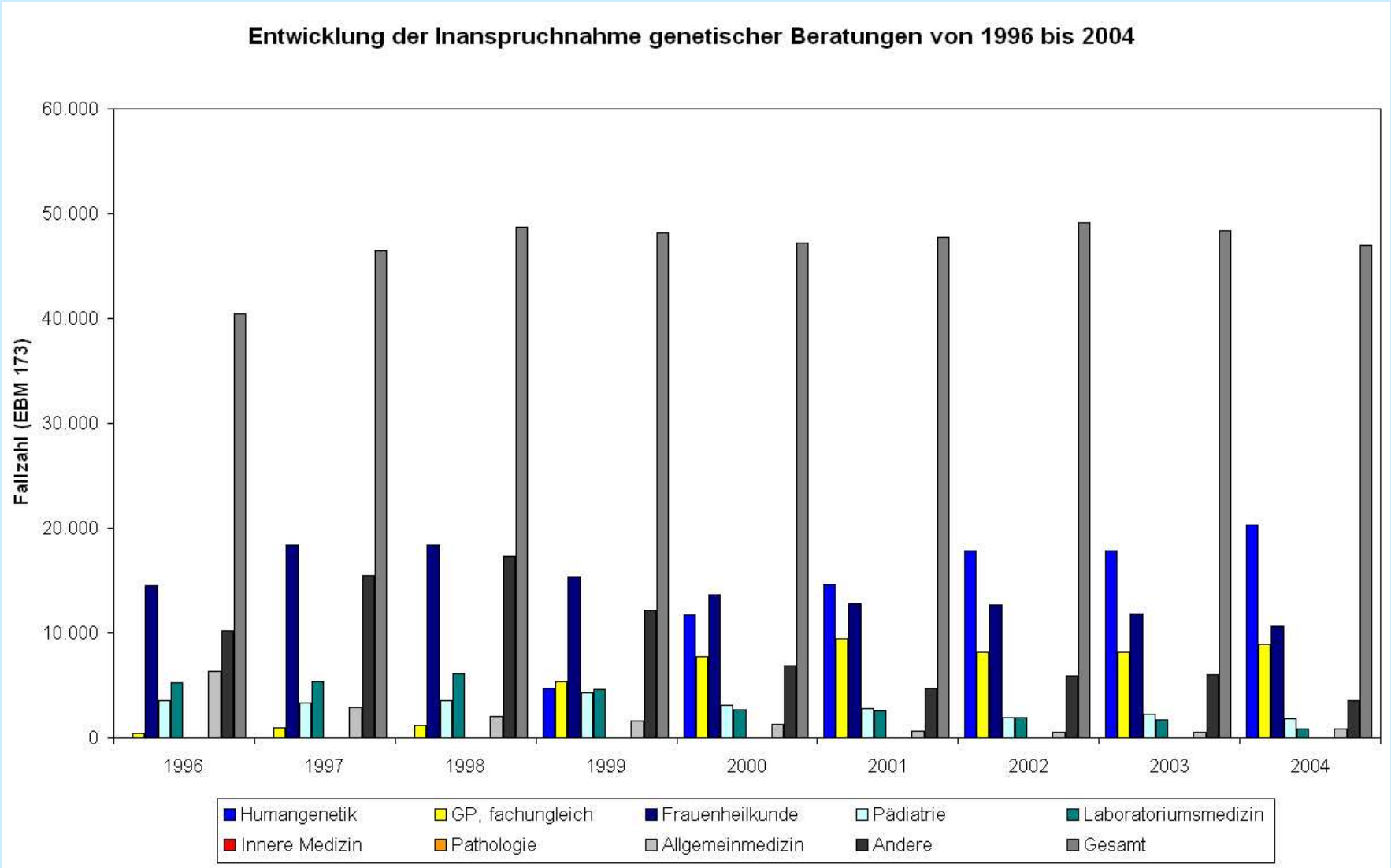
Entwicklung der Inanspruchnahme genetischer Beratungen von 1996 bis 2004
Fallzahl (EBM 173)
60.000
50.000
40.000
30.000
20.000
10.000
0
1996
1997
1998
1999
2000
2001
2002
2003
2004
Humangenetik
GP, fachungleich
Frauenheilkunde
Pädiatrie
Laboratoriumsmedizin
Innere Medizin
Pathologie
Allgemeinmedizin
Andere
Gesamt

- **3330 (+1998 suspected) clinical entities are due to the malfunction of a single gene**

- **Molecular basis identified in 2107 (63.3%) disorders**

(OMIM May 4th, 2007)

- **6-8% of the EU population are affected by one of these condition** ***(WHO Report on Priority Medicines for Europe and the World, 2004)***

- **A huge, and steadily rising potential for genetic testing – An enormous challenge for health care services**

Germany

Thus, in view of such long term developments or sudden changes in more costly areas (e.g. drug prescription, organ transplantation), limitations are being set, e.g.

- limited total point volume per practice
- limited point volume per patient,
- limited number of patients

- type of budgeting varies between regions
- some institutions are exempt from any such limitations (e.g. short-term contracts with hospital doctors or departments).

Widespread dissatisfaction with floating point volume system:

- non-predictability of income,

- varying monetary value of doctor’s work hour.

As of (probably) 2009

- fee schedule in fixed EUR
- consequently, expansions of some services on the cost of others no longer possible
- only way to expand is by increasing insurance premium, which is, however restricted by national policy
- therefore, much stricter budgeting rules are becoming inevitable.

At the level of fee schedule:

- oversight by the social insurance system over expenditure based on morbidity figures
- → reimbursement based on average cost per case or family

Two already existing alternatives to the "old" system will win the race:

-"Out-patient care in the hospital" (Ambulante Behandlung im Krankenhaus, §116b SGBV)

- based on special contracts between particular hospitals and CHI
- no restrictions as in "open system"
- already in place for three rare diseases (CF, Marfan, haemophilia)

- "Integrated Care" (Integrierte Versorgung, §140a ff SGBV)

- based on special contracts between selected health care provider and CHI
- no restrictions as in "open system"
- already in place for BRCA1/2 testing, and, very recently for HNPCA

→ Both initiatives may be understood as steps towards implementing reference centers for rare diseases (BRCA, HNPCC by definition), as recommended by the EU Rare Diseases Task Force

Plans:

- status report „Familial bowel cancer in Germany“
    - evaluate biomedical state-of-the-art
    - collect existing guidelines (e.g. BÄK-Richtlinien)
    - collect other sources of regulation
    - follow work and development of existing HNPCC-consortium (participants, structure, function)
    - evaluate state of health care in Germany as compared to international status
    - evaluate status of health care at Hannover Medical School and other regional hospitals, out-patient care, including family approach
- monitor strategic development in Germany, Hannover in particular
- monitor specialist training
- monitor CME activities
- monitor public education

Plans – in a wider perspective:

Clinical genetics community (German Society of Human Genetics) responds to developments within (priorisation needs) and outside (EUROGENTEST) the system:

Guidelines to define

- clinical validity of genetic testing
- clinical utility of genetic testing

in the following settings

- diagnostic
- predictive
- pre-reproductive
- prenatal

for top 100 of genetic diagnostic hit list