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How informatics shakes the very foundations of medicine – Rightly so?

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Proposition

Regarding the pervasiveness of informatics throughout society it is more likely that informatics affects medicine than that it does not.

Are the effects marginal or central?

Here I will address central effects only.

What I will not talk about (although it matters)

- Encryption and other data integrity technology
- Health care as an industry and its business IT

What I will talk about – and challenge

- The paradigm that planned scientific experimentation is the only source of clinical insight
- The legislation that only physicians can treat patients
- The utilities of protecting privacy vs saving lives

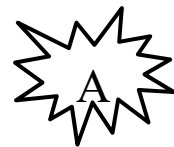
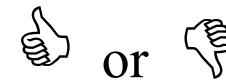
Sources of clinical insight – 1920 - 2020

- Pre clinical-trials: Judgment
- Nature of insight from clinical trials: Evidence
- Nature of findings in ad hoc data collections: ?

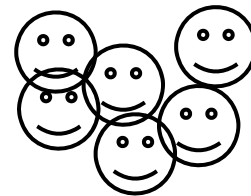
Core clinical question

- Does a treatment **A** work?

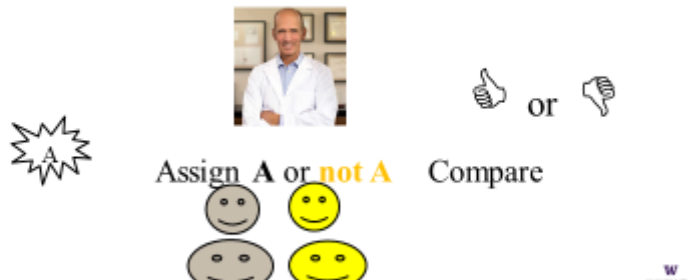
History reflected, 1920ies



Assign A Observe



History reflected: Hand-matched pairs of presumably equal responders, 1930ies



Position and critique

- Full trust in physicians' capacity to
 - Identify patients where effect can be expected
 - Build pairs of equal prognosis
 - Compare outcomes
 - Replicates physiological research idea where equal units can be treated differently
- Risk of
 - Selection bias
 - Inappropriate criteria for equalness



reflected

Enter R.A. Fisher 1)

- Plant geneticist
- Experimenter
- Statistician



1) Ronald Aylmer Fisher and Jerzy Neyman and Egon S Pearson and A. Bradford Hill and ...



History reflected: Seed/fertilizer related yield, since 1925



0	0	1	1	1	0
0	0	0	1	1	0
1	1	0	0	0	1
1	0	1	0	1	1
1	1	0	0	0	0
0	1	0	0	0	0
0	1	1	1	1	1
0	0	1	1	1	0

t-test

Position and limitation

- Controls for unknown factors
 - Presumably equal lots foster repeated evaluation of same proposition
 - Maximizes the likelihood to detect a difference if it is there
- However, humans
 - cannot be cut into ever smaller
 - are not equal

imbi

1) Let the experimenter who is driven to use statistical methods not forget this, that the very fact that he is compelled to use statistical methods is a reflection on his experimental work. It shows that he has the very object of experiment as his cause. 2)

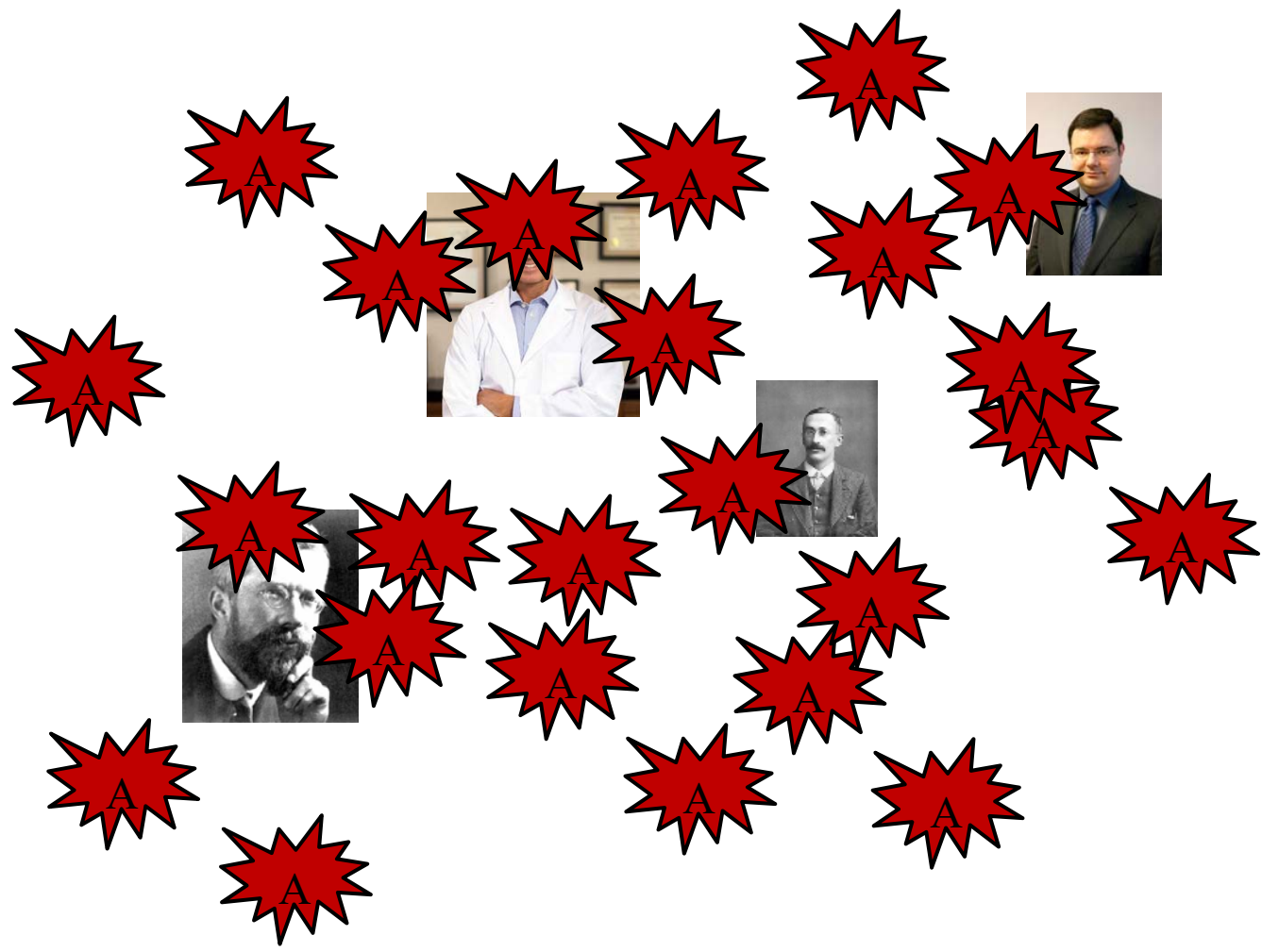
2) G Udny Yule 1924

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Two trends converge, starting late 1940ies

- Number of new substances grows much faster than number of inspired physicians
- Scepticism about „inspired“ mounts
- „... transfer of authority from institutions to methods“ 1)
- „... clinical researchers ... under the ,benevolent tyranny of statisticians“ 2)

imbi



Randomized Controlled Trial RCT

- Specify: experimental and control condition
- Filter a priori: exclusion/inclusion criteria
- Randomize



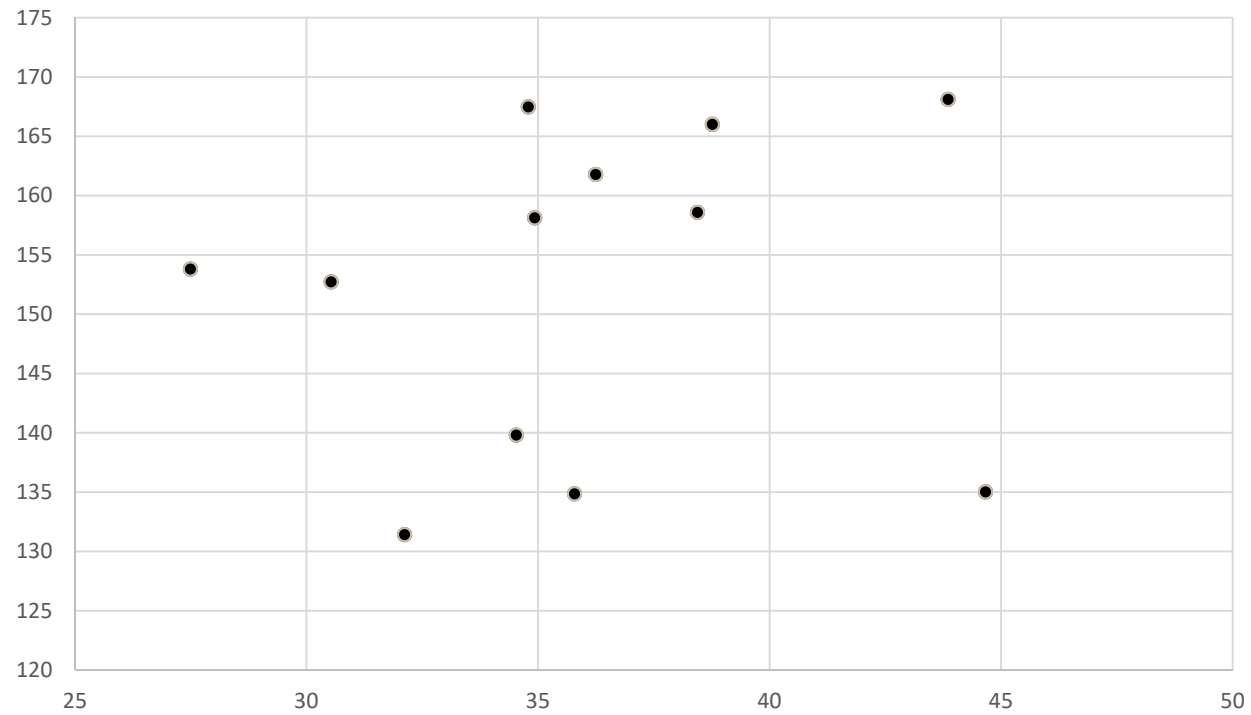
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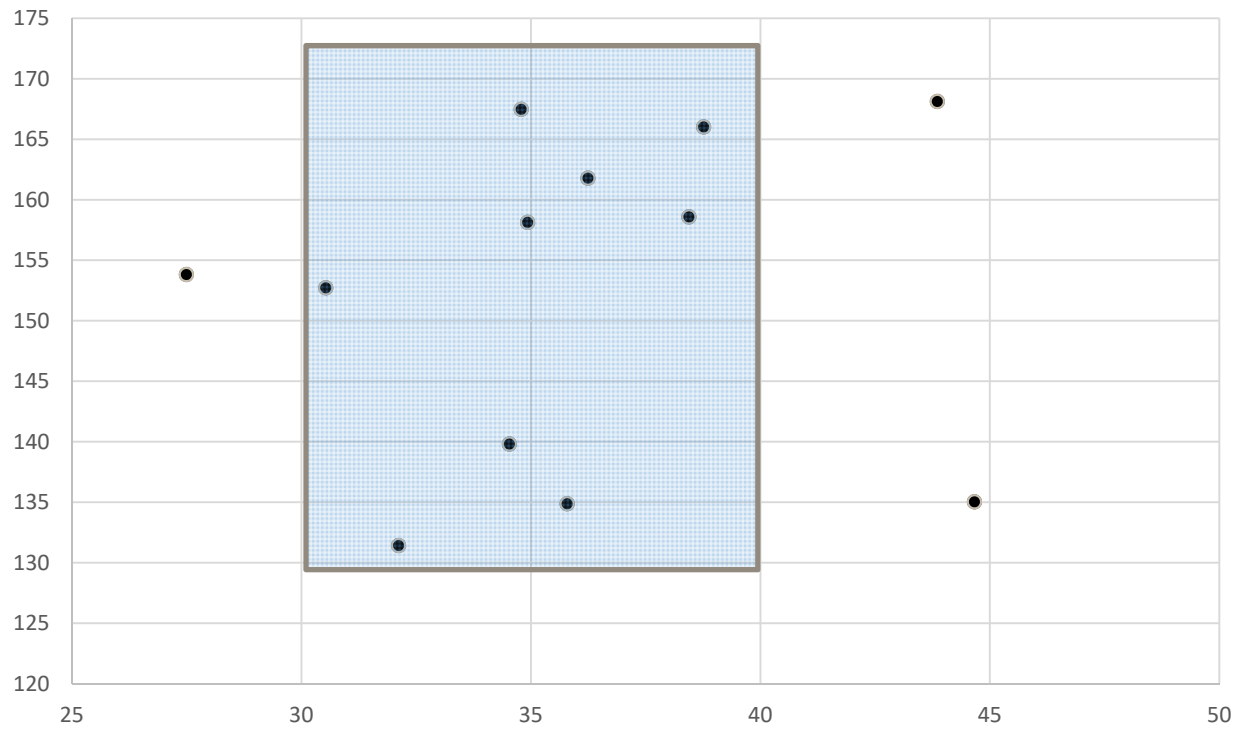
1	1	1	0	0	1
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0	0	0	0	0	1
1	0	0	0	1	1
1	1	1	0	0	0
0	0	1	0	1	1
0	1	1	0	1	1

some test

Assumptions and implications

- Question warrants human subjects experiments
- Subjects represent a meaningful population
- Subjects by and large are equal
- Their being not equal is mapped into variance
- Variance blurs the result, may even spoil it
- Outcome of test determines conclusion

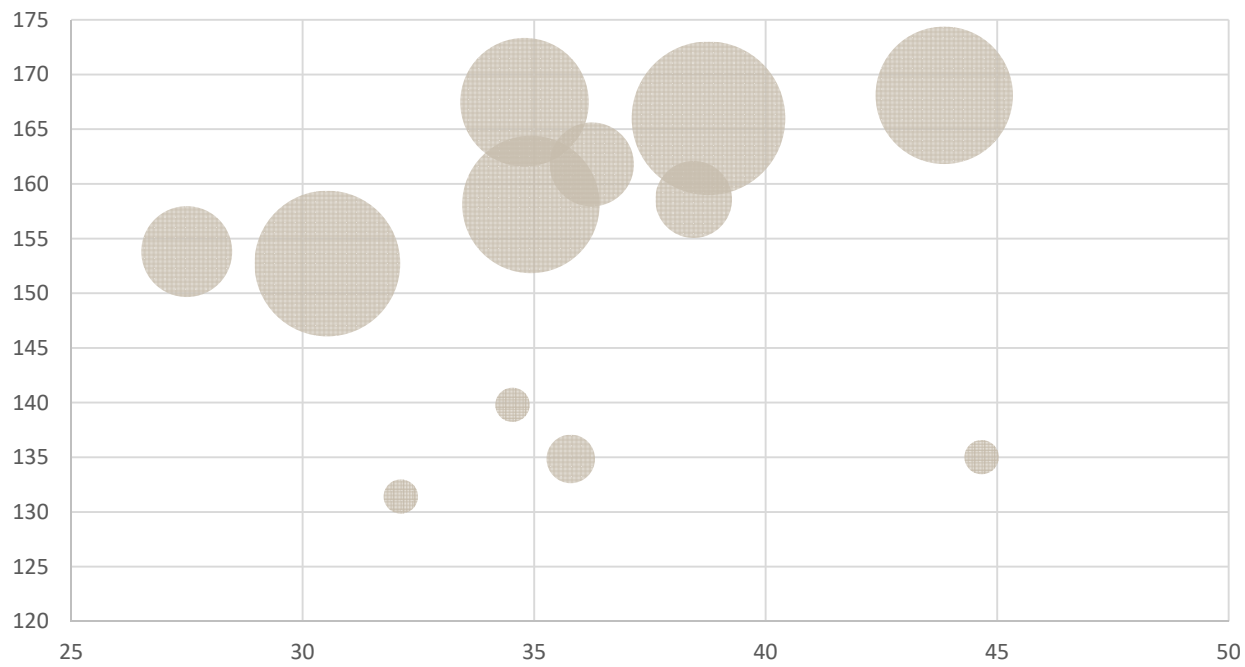


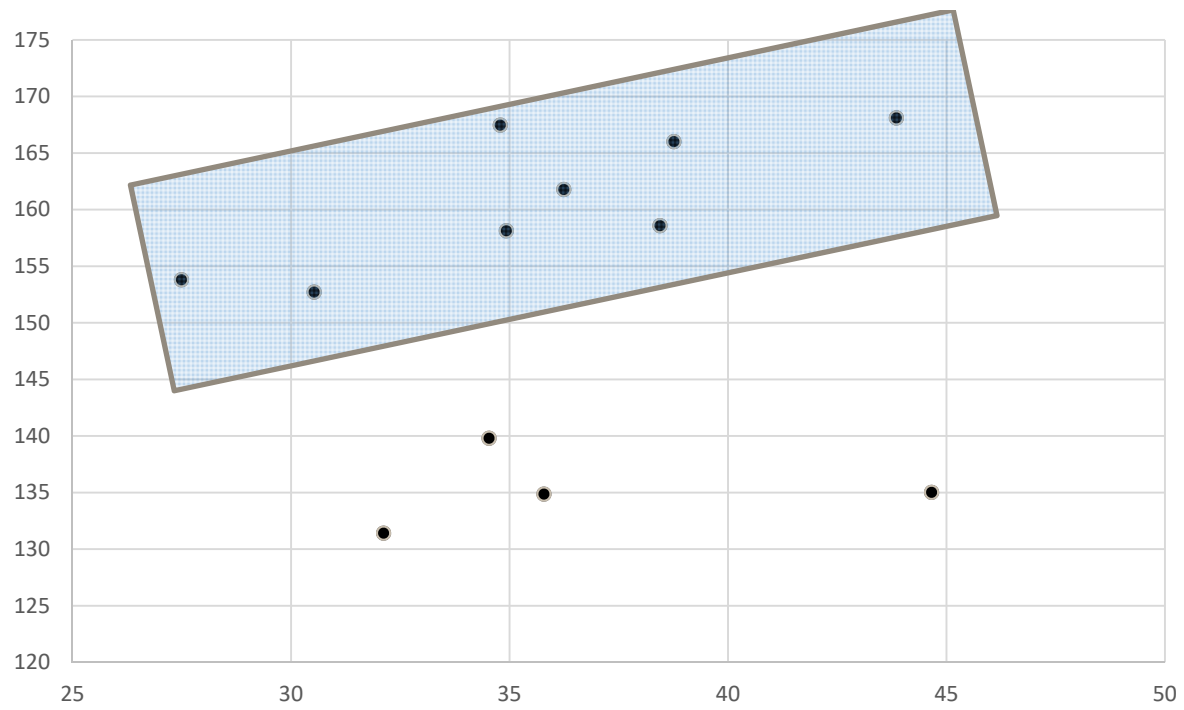


RCT failure vs Data analytics opportunity

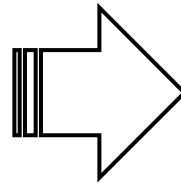
- RCT
 - Expects large effects within rectangle
 - Has no data outside rectangle
- Data analytics
 - Expects nothing
 - Has data for all subjects

Surprise





H



What do real life big data analytics change?

They are realistic

- Real humans living their lives
- Real physicians who combine „evidence“ and judgment

Data collections are huge

- IBM, Microsoft, Google have millions

Gaining the right insight right

- Collect data as they come
- Explore for apparent effects
- Filter a posteriori for data quality
- Characterize responding cohorts

Giving the right insight the right name

What is officially called „off-label use“

- and by that wording has a negative connotation –
- bears the potential of new insights emerging from wisdom of the crowds and algorithmics.

If data analytics „shows“ something, can we use it?

- RCT maximizes the likelihood to find an effect when the right question was asked
- Maximum likelihood is the

negotiated social order 1)

Maximum likelihood is a utility

It is not truth

If data analytics „shows“ something, can we use it?

- RCT achieves nothing when the wrong question was asked
 - Treatment not effective in cohort altogether
 - Subgroups not paid attention to

In such cases humans have been subject to an experiment without utility

Doesn't this call for *a new social order* ?

- What is the utility of data analytics findings?

- Speed
- Coherence
- Absence of human subjects experiment

*Benevolence
No Maleficience*

- An what are its risks, its negative utilities?

- Lack of transparency
- Framing effects

Risk of maleficience



Consumer Health Informatics – a definition

- IT related methods, services, and equipment to enable the individual to safely play a more active role in preventive and medical care.
- Suggested abbreviation!
 - **Consumer Health Informatics – ConsHI**

ConsHI Examples

- Taipei, Taiwan
 - Patients with online dosage advice control asthma better ¹⁾
- Leiden, The Netherlands
 - Depression is equally well controlled in Internet and group CBT, but effort reduced ²⁾
- iPhone app MySugr junior
 - Parent assists diabetic child with insulin dosage ³⁾

1) Liu et al 2011, doi: 10.1183/09031936.00000810

2) Spek et al 2007, doi: 10.1017/S0033291707000542

3) iStore

Health care workforce 2025-30

... or dramatic shortage

Table 2.1 Summary of figures from growth and dilution scenarios

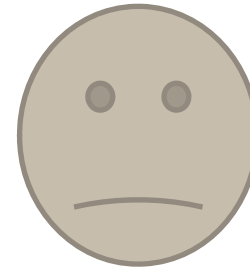
	Physicians (1000)	Nurses	I ...	Physician per ... Old agers	Nurse
USA					
Baseline ~2010	678.3	2578.8		58.4	15.4
Growth scen.	1226.4	3785.0			
Dilution scen.				97.5	25.6
Germany					
Baseline ~2010	325.9	877.4		51.9	19.3
Growth scen.	430.0	1158.3			
Dilution scen				78.0	29.0

Strong increase...

State of the art

- ConsHI service are galore
- (Some) mobile apps and internet services demonstrate equal or superior effectiveness

In RCTs



The Level determines the legal character

- Level 0: Publishing and searching
- Level 1: Existing provider – patient relation enhanced by ICT
 - Contrast to telemedicine: Patient active partner in ConsHI
- Level 2: Virtual service
- Level 3: Clients as providers

State of the art

- Under Ethikkommission surveillance some services operate virtual only – legally
- When scientifically approved they cannot go into routine use – Fernbehandlungsverbot
- (Baden-Württemberg has announced an experiment of limited Fernbehandlung)

Level 2

Illegal, if practicing medicine



AMA H 478,997



Level 3 – Legal or illegal? It depends ...

Table 17.1 Legal status of level 3 posting in social media

Qualification	Disclosure of professional role	Service type	Relation to client	Legal state	Comment, keyword
Lay person	(N/a)			Legal	Free speech
Physician ^a	No			Illegal	Confidence ^b
	Yes	Information		Legal	Conduct ^c
		Well-being			
		Prevention		Varies	cf. Sect. 17.5.2
		Practice of medicine	In-person initiated	Legal	Level 1 ^d
	Virtual only	Illegal	Explicitly excluded in professional codes		

Mining: ADEs from big patient self support sites

- Scan message boards of
 - breastcancer.com
 - komen.org
 - ..
 - oprah.com
- Map to standardized vocabularies
- Identify associations ADE – medication
 - ~ 20 so far unknown

Sect, 6.3.3 Adrian Benton, Lyle Ungar, Shawndra Hill, Sean Hennessy, et al: Identifying potential adverse effects using the web: A new approach to medical hypothesis generation. J.Biom.Inf. 2011

Laws and Ethical Dilemmas

- Professional codes request in-person encounter before technology enters
- Professionals are running low in supply
- Telemedicine **dilutes** existing expertise
- Level 2 services **multiply** existing expertise
- Stage 3 services **add** new knowledge

Laws and Dilemmas

Those services that hold the strongest promise to make health services available although human professionals are getting scarce are prohibited by law.

Are ethical arguments strong enough to necessitate advancement of law?





Function vs protection

- So far we have proceeded as if data analytics and ConsHI could happen without any threat to confidentiality.
- These threats are there, however.
- In Data analytics they are part of the business model of the analysts.

What would we wish ...

- That we have all insights from data analytics
- And all individual guidance of ConsHI
- To us, personally
- Without making known who we are.
- But in case of a lethal risk we want to be found and taken care of.

„One thing is more important than privacy protection: patient protection“

(Carl-Theo Ehlers, German pioneer of Medical Informatics)

An analogy

- Suppose you suffer a medical emergency in the street
- A potential helper comes by
- He may know you
- Thereby exposing the relation between your personality and your medical condition
- Should he rather go his way?

A final plea

- We should not be fatalistic about privacy
- But it may end fatal if we encourage privacy protection to dominate function



Vielen Dank

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