

Symposium: Databases for clinical research – the next quantum leap



the danish  
clinical registers

a national quality improvement programme

# Clinical registries – general definition

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- Structured collection of patient-level clinical data
- Defined by professionals (providers and patients) for non-administrative purposes:
  - epidemiological surveillance
  - quality improvement
  - clinical governance
  - research



# Danish Clinical Registries – History

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- Old Scandinavian tradition: Leprosy Registry 1856 (N), cancer registry 1942 (DK)
- Diagnosis-specific registries emerged in mid seventies as professionally owned registers – mainly used for clinical research (e.g. independent trial databases for cancer) financed by funding or participants
- 1993 The first national strategy for QI introduced the concept of publicly financed quality/**clinical research** registries – selected and owned by the medical societies, financed by health authorities and hospital owners.



# Legal definition from 2003

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- Registries which contain information about individual patients – exempt from patient consent to data collection
- Information is used for surveillance and improvement of quality  
(not research!!)
- National coverage
- Fulfilment of national criteria for functionality, data safety, data quality and methodology
- Yearly publication of all results on clinical unit level
- Pass appraisal in the National Health Board every 3 years



# DK registries: Organisation –

## *The Danish clinical quality registries® - RKKP*

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- Each registry has a professional board
- Registries supported by 3 epidemiological units and 2 units providing IT and QI support
- Governed by a secretariat referring to the 'Political Board' representing the regions, health authorities, professional and patient organisations
- Financed by the regions: Total budget around 6.5 million Euros



# DK Quality Registries Status

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## Total number 60-70

- 25 cancer registries including quality of palliative care and national screening programmes
- 12 non-neoplastic elective surgery/orthopaedic surgery, gynaecology
- 6 major chronic disease
- 5 cardiovascular disease
- 3 psychiatry
- 3 obstetrics
- 1 primary care
- 10 misc.

Variable improvement impact, research activity – and access, support function, budgets, data quality, output, governance



# DK Clinical Quality Registries – (RKKP<sub>made in GDR</sub>) mission

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- Improving prevention, diagnostics, treatment and rehabilitation **Improvement**
- Documentation for clinical governance and organisational priority setting **Management/Accountability**
- Information for citizens and patients **Transparency**
- *Research infrastructure* **Innovation**
- **In other words: Create law and order**



# Challenge: QI and Clinical research make incompatible demands to registry priorities

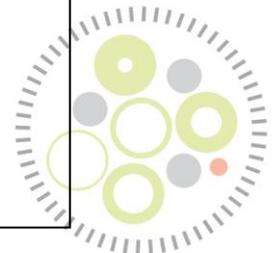
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## QI

- Closing the knowing-doing gap
- Changed behaviour in clinical teams (how to do what you have to do)
- Standardised formats
- Variation of focus, topics and variables over time
- Real-time output valued
- Reports = short briefs + ...
- Influenced by teams and organisations
- Foundation: Clinical epidemiology, social sciences, management science

## CR

- Innovation
- Expanded knowledge-base (what to do if somebody wants to do it)
- Customised formats
- Constancy over time
- Better be right than in time
- Peer-reviewed publication
- Researcher (medical?) autonomy
- Foundation: Clinical epidemiology, biomedical science



# Challenge: QI and Clinical research make incompatible demands to registry priorities

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- Strategic and operational decisions – what do we try to do?

## UTRUMQUE



# Strategic and operational decisions RKKP

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Priorities 2011-14

Standardisation of methods, outputs and efficiency

- Data collection burden balanced with quality/validity – **smart use of available data sources**
- Predictable standardised outputs to clinicians and organisation - Real-Time feed-back
- QI activities at regional/hospital/clinical level
- Coordination Health Authorities – local governments



# Strategic and operational decisions RKKP

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## Priorities 2011-14 research

- Facilitating researcher access to registries – similar to other public registries
- Try to include Health Service- and Comparative effectiveness research in QI- registry mission
- Accepting and defining research infrastructure I registries
- Standardisation of variable and algorithm specifications in registries



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# Problems and promises of innovation: why healthcare needs to rethink its love/hate relationship with the new

- Mary Dixon-Woods, Rene Amalberti, Steve Goodman, Bo Bergman,
- Paul Glasziou
- BMJ Qual Saf 2011;20(Suppl 1):i47-i51.



# Where 'Research' and Quality Registries Merge

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**Recognise the risks and costs of innovation, including the disruptive effects even of beneficial innovation.**

- **Have more effective systems for controlling the diffusion of innovation, including better systems for accrediting use of technologies (not simply approval of the product/device).**

**Study innovation at the same time as it is occurring, and collect data to link new interventions to outcomes (both intended and unintended).**

- **Run adoption and implementation studies using high quality social science methods and theory alongside trials; do not wait until the trial is complete before working out what is needed to adopt and implement the intervention in real life.**



# Technicalities - ongoing projects and ideas

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- New IT-strategy – including 'the platform' and what to do with EPR
- Redefining the concept of 'Registry' from a physical to a virtual identity (group of patients, variables and algorithms usable for improvement and clinical science selected and defined by clinicians and scientists – from available data collections covering broad clinical areas.  
e.g.: Cardiology, Emergency medicine, Cancer.....



# Technicalities - ongoing projects

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## Re-examining quality measures:

- Composite indicators
- Structural indicators
- Patient reported outcome measures
- Patient safety indicators
- Lead indicators
- Comorbidity and risk adjustment

## And derived formats plus clinical activities:

- SPC, Audit, campaigns, clinical management involvement, combine with external pressure, patient mobilisation



# How to select appropriate topics for registries (and close those who are not appropriate)

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Disease severity, incidence/prevalence, quality problems..... Improvement possibility?

- Resources – and appropriateness?
- Coupling to implementation of national clinical guidelines/  
cancer plan/cardiovascular plan/chronic care model?
- Political and patient preferences?

**Creation of a common transparent evidence-based  
framework of stratification???**



# Success?

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- Will to harsh priority setting

Or

- Increase of resources

We have the will – but hope for the last alternative

