Raising the profile of register studies for epidemiological and health care purposes - the example of stroke

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Learning objectives

- Getting familiar with the definitions of different types of stroke registers
- Identifying the potential of different types of stroke registers for different research questions
- Clarifying the outputs provided and the requirements for data collection according to different research questions

Register studies

- No real research - only counting numbers?

OR

- A neglected type of research studies?

Content

- Definition of stroke register
- Potential of register studies for
  - Epidemiology
  - Outcomes research
  - Health services research
  - Intervention evaluation
- Summary

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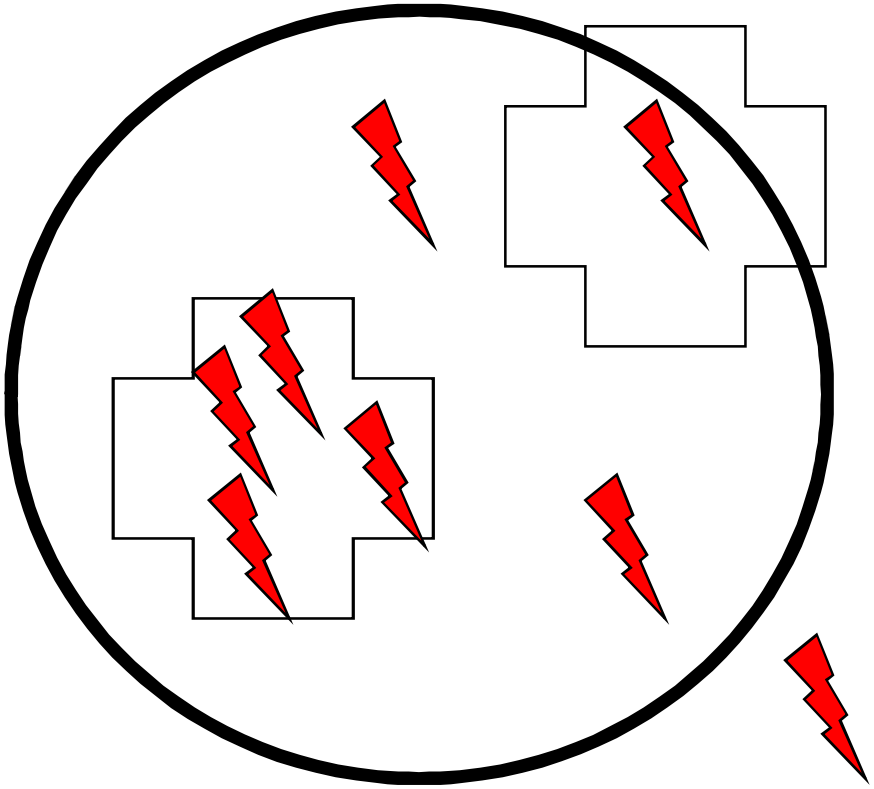
Definition register

- The systematic collection and recording of data related to patients

Principal type of register
Case series

Population at risk
(city/ district/ country)



Hospital-based stroke registers

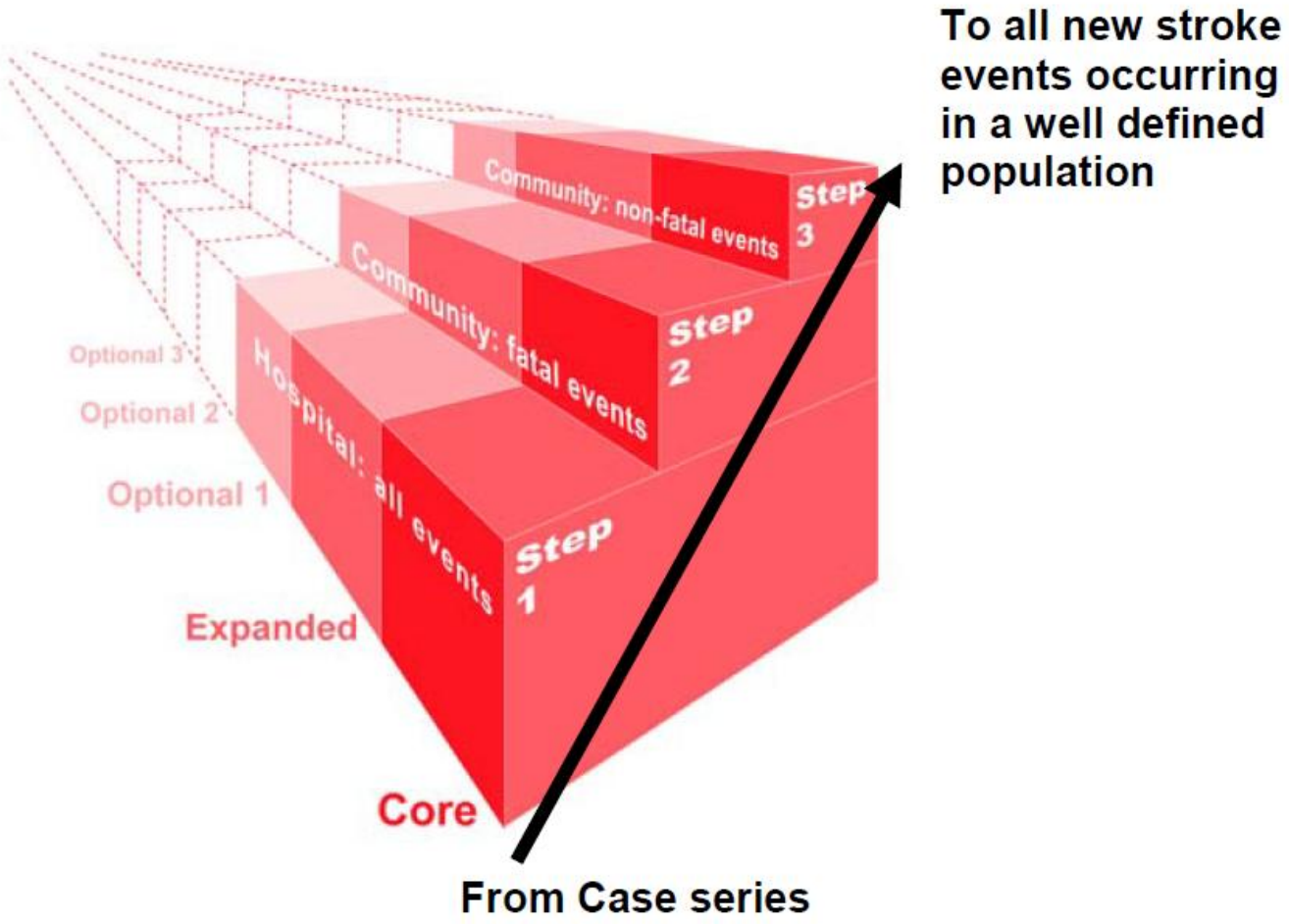
>Source population unknown
=> case series

>Source population known
=> rates for hospital-based stroke patients provided

Population-based stroke registers

=> Information on whole stroke population

Type of stroke registers



http://www.who.int/chp/steps/Manual.pdf

Study types

Descriptive studies	- Correlation studies	
	- Case reports/ case series	**Registers**
	- Cross sectional surveys	**Registers**
Observational studies	- Case-control studies	**Registers**
	- Cohort studies	**Registers**
Intervention studies	- Clinical trials	**Registers**

=> Disease registers?

Hennekens C et al. Lippincott Williams & Wilkins 1987

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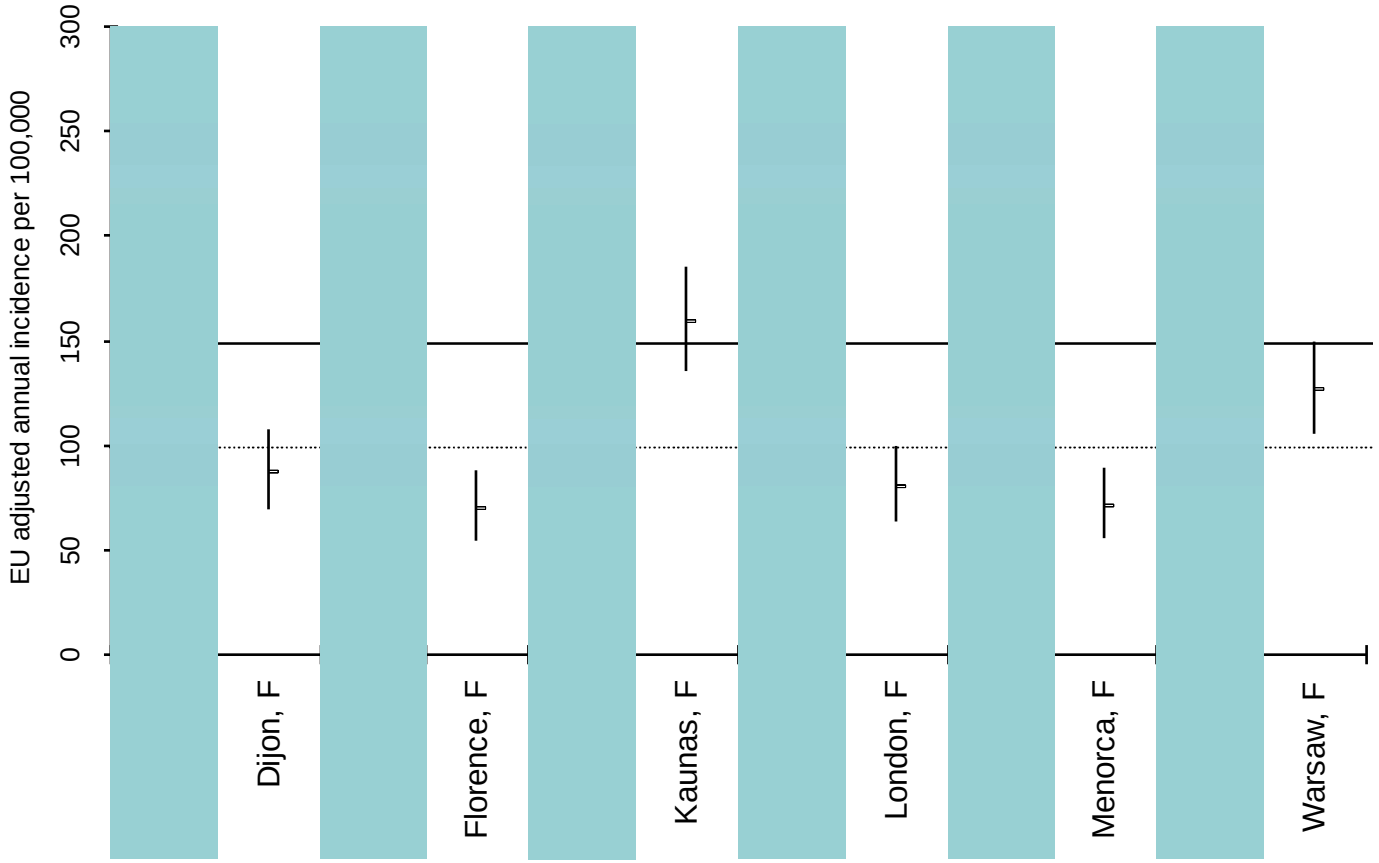
Potentials of stroke registers: Epidemiology

Data provided	- Incidence (FELS)
	- Time trends
Requirements	- Population-based register (for incidence)
	- Stable case ascertainment (for time trends)

European Registries of Stroke Collaboration
Incidence differences in Europe, 2004-2006



Annual stroke incidence rate and 95% CI per 100000 population adjusted to the European population for males (M) and females (F); the line represents the mean annual incidence rate adjusted to the European population for all centers

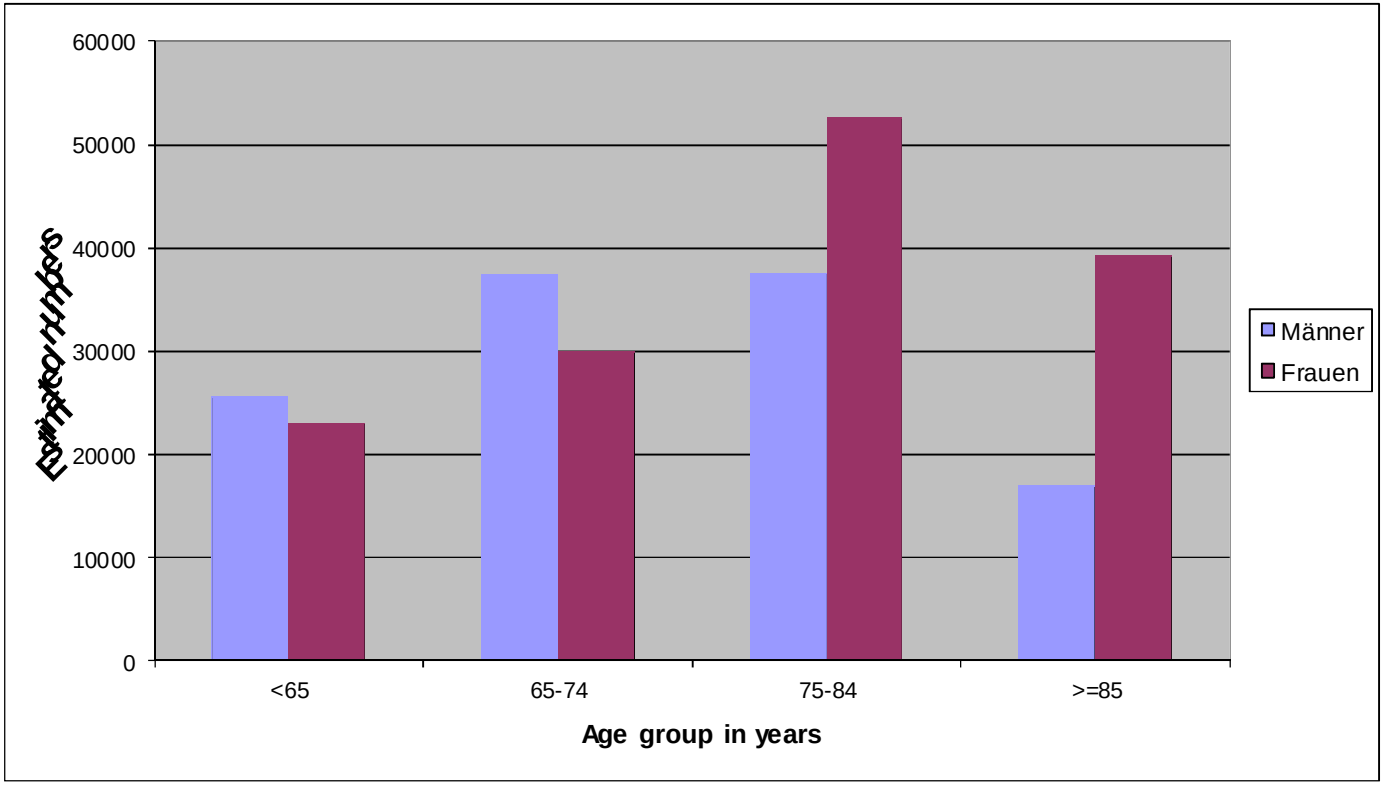
——— for men

····· for women

Heuschmann PU et al. Stroke 2009

Epidemiology of stroke in Germany (2008)

Estimated absolute numbers (first-ever & recurrent)



*based on estimates of the German population 2008
Heuschmann PU et al. Akt Neurologie 2010

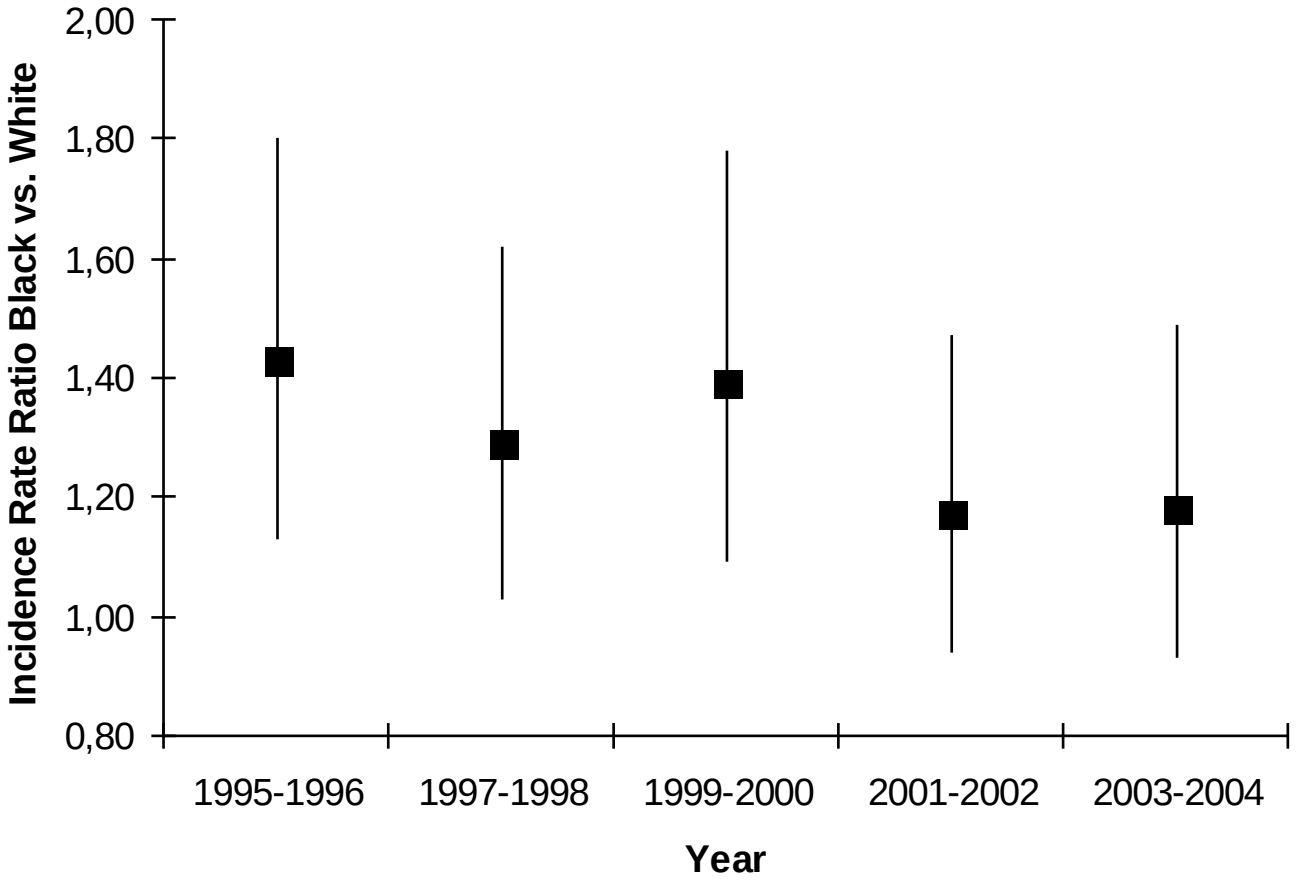
Trends in stroke incidence, 1995-2004 South London Stroke Register

	Men IRR*	Women IRR*
Total	0.82 (0.69-0.97)	0.76 (0.64-0.90)
Ischemic stroke	0.89 (0.73-1.08)	0.89 (0.73-1.09)
Intracranial haemorrhage	0.74 (0.46-1.20)	0.60 (0.35-1.02)
Subarachnoid haemorrhage	0.66 (0.30-1.44)	0.65 (0.34-1.25)
Undefined	0.46 (0.23-0.93)	0.20 (0.09-0.46)

IRR = Incidence Rate Ratio 2003-04 versus 1995-96;
2.874 stroke patients; source population 271.817; age adjusted to the EU population

Heuschmann PU et al. Stroke 2008

Differences bw Black & White, 1995-2004 South London Stroke Register



Heuschmann PU et al. Stroke 2008

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Potentials of stroke registers: Outcomes research

Data provided	- Outcome data (e.g. disability, recurrence)
	- Prognostic modelling
Requirements	- Standardized follow-up of patients
	- Defined time points for follow-up

Outcome three month after first ever stroke European Registers of Stroke Collaboration

22% dead at 3 month

41% with poor outcome at 3 month

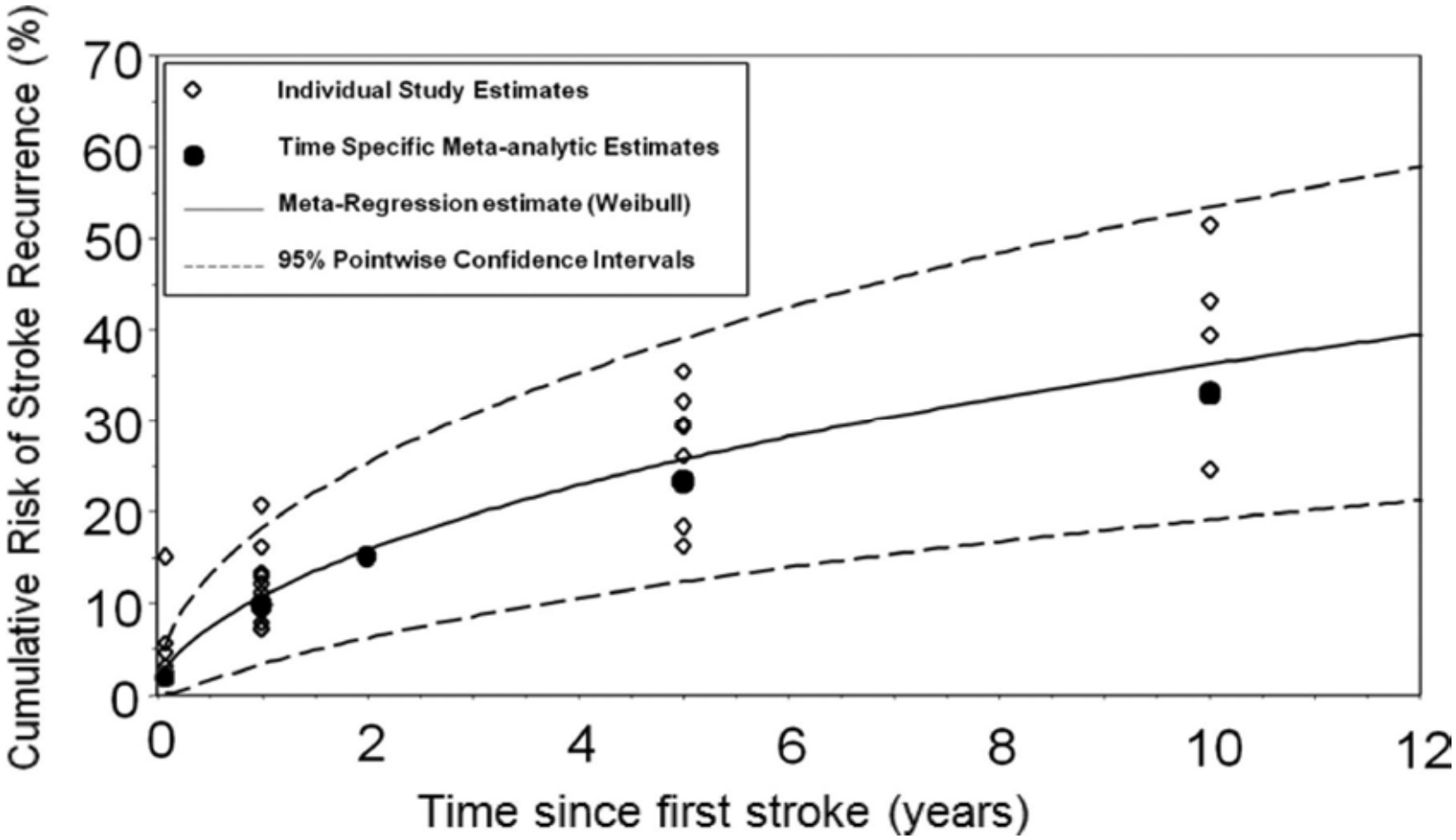
	Total	Dijon	Sesto Fiorentino	Kaunas	London	Menorca	Warsaw	*p* Value
Cumulative risk of death, % (95% CI)[a]	21.8 (20.0-23.7)	12.6 (8.9-16.3)	29.4 (22.3-36.4)	27.8 (24.7-30.9)	19.0 (15.4-22.5)	35.9 (25.1-46.8)	22.3 (15.3-29.4)	<0.001[b]
Poor outcome, % (95% CI)[c]	41.3 (39.0-43.7)	32.4 (26.8-38.0)	41.9 (34.2-49.6)	45.9 (42.3 49.5)	40.4 (35.0-45.8)	49.2 (36.8-61.7)	34.2 (25.5-42.9)	0.001

Abbreviation: CI = confidence interval.
[a] Derived from Kaplan-Meier estimates, total risk estimate weighted for center.
[b] Log-rank test across centers.
[c] Defined as death or dependent (Barthel Index < 12) or institutionalized due to stroke, total risk estimate weighted for center; all analyses were restrictec to patients without missing values.

*2034 patients from 6 population-based stroke registers in Europe, 2004-2006

Heuschmann PU et al. Neurology 2011

Cumulative risk of stroke recurrence after first-ever stroke



Mohan K et al. Stroke 2011

Berlin Stroke Register

Identification of priorities of stroke care:
Attributable risk of death or poor outcome at discharge

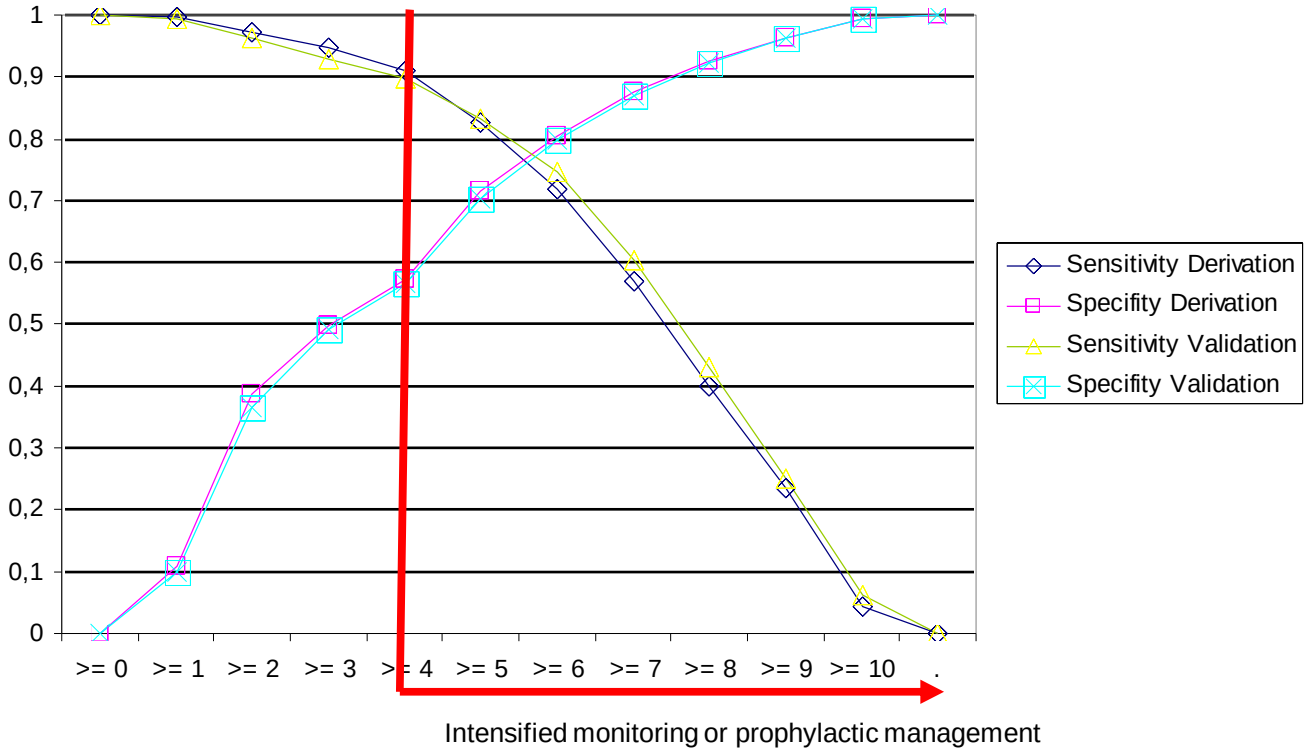
	In-hospital death		Poor outcome at discharge	
	Length of stay ?Æ days	Length of stay >7 days	Length of stay ?Æ days	Length of stay >7 days
Age ?Ø5y	14.1	22.6	13.2	3.5
Male sex	n.s.	6.2	n.s.	n.s.
Pre stroke disabled	9.0	n.s.	17.0	11.1
ICH	2.6	n.s.	2.4	1.9
Diabetes	n.s.	n.s.	2.1	2.7
Atrial fibrillation	n.s.	7.1	4.7	n.s.
Recurrent stroke	n.s.	n.s.	2.7	n.s.
Hypertension	n.s.	n.s.	10.3	n.s.
NIHSS ?16	37.5	21.5	16.6	12.3
Pneumonia	n.s.	12.2	5.1	6.4
ICP	14.3	8.3	3.9	0.6
Other complications	14.6	12.6	6.1	6.4
Total explained	92.1	90.5	84.1	44.9

* 16,518 stroke patients, 2007-2009; n.s. not statistically significant; poor outcome defined as mRS >=3
attributable risks were estimated by average sequential attributable fractions

Koennecke HC et al. Neurology 2011

Prognostic modelling
Prediction of post stroke pneumonia

Cutpoint specific sensitivity and specificty of the A^2DS^2 Score



- Potential interventions to prevent and manage targeted early complications

Hofmann S et al. Stroke 2012

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Potentials of stroke registers
Health services research

Data provided	- Monitoring patterns of stroke care
	- Detecting options for improvement
	- Regional stroke surveillance
Requirements	- Sufficient number of patients and institutions
	- Completeness of case ascertainment
	- Standardised data collection (validity/ reliability)
	- Core dataset (minimizing effort!)

German Stroke Registers Study Group

Participants (as at 2013)

- 9 regional stroke registers for monitoring quality of care
- About 220,000 patients documented each year
- About 650 hospitals participating

Heuschmann PU et al. Akt Neurologie 2010

German Stroke Registers Study Group

Data collection

- Participation voluntary in some regions but compulsory for certified Stroke Units
- Documentation of individual data during hospitalization, including e.g. diagnostics, treatment, co morbidities, complications, early outcome

German Stroke Registers Study Group

Methodological issues

Arbeitsgemeinschaft Deutscher Schlaganfall Register (ADSR)

Koordinierungsstelle: Institut f. Epidemiologie u. Sozialmedizin Universität Münster

Zentrum	lfd. Patientennr.:	Aufnahmetag und - monat	Aufn.jahr	Geburtsjahr: 19 hundert
99	99	10 20 30 / 1 2 3 4 5 6 7 8 9 / Jan Feb Mär Apr Ma Jun Jul Aug Sep Okt Nov Dez	2006 / 2007 / 2008	0 1 2 3 4 5 6 7 8 9 / 1 2 3 4 5 6 7 8 9 0

Geschlecht: Frau ○ Mann ○

Zeit Ereignis-Aufnahme: <=2h / >2-3h / >3-6h / >6-24h / >24-48h / >48h / unbekannt

Symptome bei Aufn. (nein / ja)
- Motor. Ausfälle (Arm/Hand u/o Bein/Fuss)
- Sprachstörung
- Sprechstörung
- Schluckstörung

Bewusstsein: wach / somnolent-stuporös / komatös

Dauer der Symptome: <1h / 1-24h / >24h

Rankin Skala (<=24h n. Aufnahme / Bei Entlassung)
- keine Symptome
- keine wesentl. FE
- geringe FE
- mässige FE
- mittelschwere FE
- schwere FE
- Tod

Barthel-Index (<=24h n. Aufnahme / Bei Entlassung)
- Blasenkontrolle: kontinent / gelegentl.Verlust / inkontinent
- Lagewechsel Bett-Stuhl: vollständ. selbständ. / geringe Unterstütz. / grosse Unterstütz. / vollständ. abhängig
- Fortbewegung: vollständ. selbständ. / geringe Unterstütz. / grosse Unterstütz. / vollständ. abhängig

Komorbidität (nein / ja)
- Diabetes Mellitus
- VH-Flimmern
- Früh. Schlaganfall

ICD-10 Klassifikation akutes Ereignis:

Therapie/Sek.-Prophylaxe (nein / ja)
- Antikoagulation (Marcumar/Heparin) einschl. Empfehlung im Entlassungsbrief
- Thrombose-Prophylaxe
- Thromb.agg.hemmer <=48h nach Ereignis
- Thromb.agg.hemmer bei Entlassung
- Blutdruck

Komplikationen
- Keine Komplikationen
- Pneumonie
- Erhöhter Hirndruck
- Andere Komplikationen

Diagnostik nach Ereignis (nein / ja)
- Bildgebung - CCT
- Bildgebung - MRT
- Frische Läsion in Bildgebung
- Schluckstatus durchgeführt

Hirngefäßdiagnostik
- extrakranielle Gefäßdiagnostik
- intrakranielle Gefäßdiagnostik

Rehabilitation (nein / <= Tag 2 n. Aufnahme / >Tag 2 n. Aufnahme)
- Physiotherapie/ Ergotherapie
- Logopädie
- Mobilisierung

Information Pat. u/o Angehörige vor Entlassung (nein / ja)
- durch Arzt zu Krankheit/Prävention
- durch Sozialdienst/Pflegedienst zu Unterstützungsangeboten

Entlassungstag und - monat: 10 20 30 / 1 2 3 4 5 6 7 8 9 / Jan Feb Mär Apr Mai Jun Jul Aug Sep Okt Nov Dez

Entlassungsjahr: 2006 / 2007 / 2008

Entlassungsart: nach Hause / andere Abteilung / Reha-Klinik / externe (Akut)Klinik / verstorben / Pflegeeinrichtg./Heim

Für Kliniken mit struktureller Voraussetzung für Durchführung Thrombolyse

Thrombolyse (nein / ja)
- Lyse i.v.
- Lyse i.a.

NIH Stroke Scale bei Aufnahme

Zeit Aufnahme-1. Bildgebung: <=0.5h / >0.5-1h / >1-6h / >6h / 1. Bildgebung vor Aufnahme

Zeit Aufnahme-Beginn Lyse: <=0.5h / >0.5-1h / >1-2h / >2-3h / >3-6h / >6h

Für Kliniken die eine Nachbefragung der Patienten durchführen

Komorbidität (nein / ja)
- Hypertonie
- Hypercholesterinämie

Sekundärprophylaxe (nein / ja)
- Antihypertensiva
- Antidiabetika
- Statine

Versorgungssituation vor Akutereignis
- unabhängig zu Hause
- Pflege zu Hause
- Pflege in Institution

electronic documentation system implemented with automated checks for completeness (in some regions); core dataset with additional variables in regions

German Stroke Registers Study Group

Data collection

- Participation voluntary in some regions but compulsory for certified Stroke Units
- Documentation of individual data during hospitalization, including e.g. diagnostics, treatment, co morbidities, complications, early outcome
- Evidence-based indicators for quality of stroke care were developed and regularly updated in a multidisciplinary process

German Stroke Registers Study Group

Patient related indicators for quality of care

	Reference
• Antithrombotic therapy – antiplatelet medication <=48 h after stroke onset	95%
• Antithrombotic therapy – antiplatelet medication at discharge	95%
• Antithrombotic therapy – anticoagulation at discharge in patients with AF	80%
• Brain imaging in stroke suspicious patients	95%
• Vascular imaging in patients with ischemic stroke or TIA	90%
• Screening of patients for swallowing disorders	90%
• Early rehabilitation – physiotherapy/ occupational therapy	90%
• Early rehabilitation – speech therapy	80%
• Early mobilisation	90%
• Stroke education of patients and relatives	90%
• Seven day in-hospital case fatality for ischemic stroke patients	
• Hospital-acquired pneumonia rate for ischemic stroke patients	
• Early brain imaging <=1h of admission in patients admitted <=2h after onset	90%
• Percentage of eligible patients receiving intravenous thrombolytic therapy	60%

Heuschmann PU et al. Stroke 2006; Heuschmann PU et al. Akt Neurologie 2010

German Stroke Registers Study Group

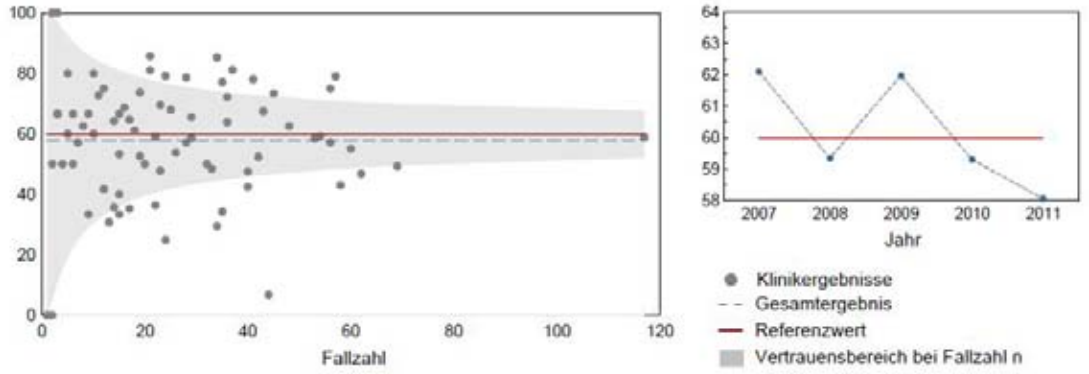
Data collection

- Participation voluntary in some regions but compulsory for certified Stroke Units
- Documentation of individual data during hospitalization, including e.g. diagnostics, treatment, co morbidities, complications, early outcome
- Evidence-based indicators for quality of stroke care were developed and regularly updated in a multidisciplinary process
- Continuous monitoring of quality of care at regional level by regular feedback and benchmarking between participating hospitals

Bavarian Stroke Register

Quality indicator 13: early thrombolysis*

QI 13:	**Frühzeitige Thrombolyse**		
Kennzahl:	ADSR14		
Ziel:	Möglichst hoher Anteil an Patienten, die bei entsprechenden Voraussetzungen eine frühzeitige intravenöse Thrombolysetherapie erhalten		
Ergebnis:	(Aktuell)	58,1 %	
	(Vorjahr)	59,3 %	
Referenz-bereich:	>= 60,0 %		Als Ziel-/Referenzbereich wurden Ergebnisse >= 60% definiert
Zähler:	Patienten mit intravenöser Thrombolysetherapie		
Nenner:	Patienten mit Hirninfarkt im Alter von 18-80 Jahren mit einem Zeitintervall Ereignis bis Aufnahme <= 2h und Schweregrad NIHSS 4-25 unter Ausschluss von Patienten mit intraarterieller Thrombolysetherapie		



* Nominator: tPA use;
Denominator: ischemic stroke; age 18-80;
NIHSS 4-25; admission <= 2h of onset

BAQ, 2013; www.baq-bayern.de

German Stroke Registers Study Group

Data collection

- Participation mostly voluntary but compulsory for certified Stroke Units
- Documentation of individual data during hospitalization, including e.g. diagnostics, treatment, co morbidities, complications, early outcome
- Evidence-based indicators for quality of stroke care were developed and regularly updated in a multidisciplinary process
- Continuous monitoring of quality of care at regional level by regular feedback and benchmarking between participating hospitals
- Regular combined analyses for health services research, e.g. for identifying priorities of stroke care or using data for spin-off projects

German Stroke Registers Study Group

Patient related indicators for quality of care – example Hesse

		Year	2007	2008	2009	2010
No.	Quality Indicators		%	%	%	%
1	Brain imaging	HE	96,7	97,8	98,5	99,0
		SU	99,0	99,3	99,3	99,6
2	Early brain imaging < 1h	HE	91,9	91,8	95,2	94,4
		SU	93,4	91,4	95,9	95,0
3	Vascular imaging	HE	86,2	83,8	89,0	90,6
		SU	93,9	87,9	92,4	92,9
4	Screening for swallowing disorders	HE	55,8	66,0	80,5	84,9
		SU	65,1	72,9	83,3	85,8
5	Eligible patients receiving i.v. thrombolytic therapy	HE	50,4	56,2	58,5	58,9
		SU	55,4	58,3	60,9	60,2
6	antiplatelet medication <=48 h after stroke onset	HE	89,7	90,1	92,9	93,0
		SU	91,3	91,7	94,4	93,7
7	Physiotherapy/ occupational therapy	HE	85,2	86,1	92,3	94,9
		SU	89,0	89,3	93,0	95,8
8	Speech therapy	HE	69,4	72,0	83,6	88,4
		SU	78,8	80,8	87,2	91,3
9	Antiplatelet medication at discharge	HE	85,3	91,7	92,0	93,7
		SU	87,4	92,6	93,3	94,4
10	Anticoagulation at discharge in AF patients	HE	54,5	59,2	62,2	67,2
		SU	57,4	59,4	63,8	69,1

Stroke Register Hesse; HE = Hessen total; SU = Stroke Units only
Haman G et al. Hess Aerzteblatt 2012

European Implementation Score Collaboration

Participating audits for monitoring quality of stroke care

Country or region	Audit (national or regional)	Data collection	Population coverage	Participation
Flanders- Belgium	Quality Register of Flemish Hospital Network	Continuously, 2007-2009	5 hospitals in Flanders, Belgium (2007)	Voluntary
Germany	German Stroke Register Study Group	Continuously, since 1999	562 hospitals across Germany (2009)	Voluntary/ mandatory in some regions
Catalonia- Spain	Catalan Stroke Audit	Predefined number of patients, 2005, 2007	45 acute hospitals in Catalona (2005)	Mandatory
Scotland	Scottish Stroke Care Audit	Continuously, since 2002	18 acute hospitals in Scotland (2010)	Mandatory
Sweden	RIKS Stroke	Continuously, since 1994	87 acute hospitals in Sweden (2002)	Voluntary
England/Wales/ N-Ireland	National Sentinel Audit of Stroke	Predefined number of patients, 2002, 2004, 2006, 2008, 2010	214 acute hospitals in England, Wales, N. Ireland (2008)	Voluntary

Wiedmann S et al., Stroke, 2012

European Implementation Score Collaboration

Quality indicators used in European audits (total n=123)

	Flanders-Belgium	Germany	Scotland	Catalonia-Spain	Sweden	England/ Wales/N-Ireland
Stroke Unit care	+	+	+		+	+
Brain imaging (CT and/or MRI)	+	+	+	+	+	+
Carotid/vessel imaging	+	+			+	
Swallowing test		+	+	+	+	+
Thrombolytic therapy	+	+	+		+	+
ECG during hospitalisation	+			+		
Early Aspirin or antiplatelet administration		+	+	+		+
Early mobilisation		+		+		
Assessment for rehabilitation (PT/OT)		+		+	+	+
Assessment of mood disorders				+		+
Discharge on lipid lowering therapy	+		+	+	+	+
Antiplatelet/antithrombotics therapy at discharge	+	+	+	+	+	
Discharge on blood pressure lowering therapy			+	+	+	+
Anticoagulants in patients with atrial fibrillation at discharge	+	+	+	+	+	+
Death during hospital period		+			+	

Wiedmann S et al., Stroke, 2012

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Telemedic Pilot Project for Integrative Stroke Care

(2003-2005; 5 intervention and 5 matched control community hospitals)

* Multivariable logistic regression analyses
  OR: Odds Ratio, CI: Confidence Interval

Audebert H et al., Lancet Neurology 2006

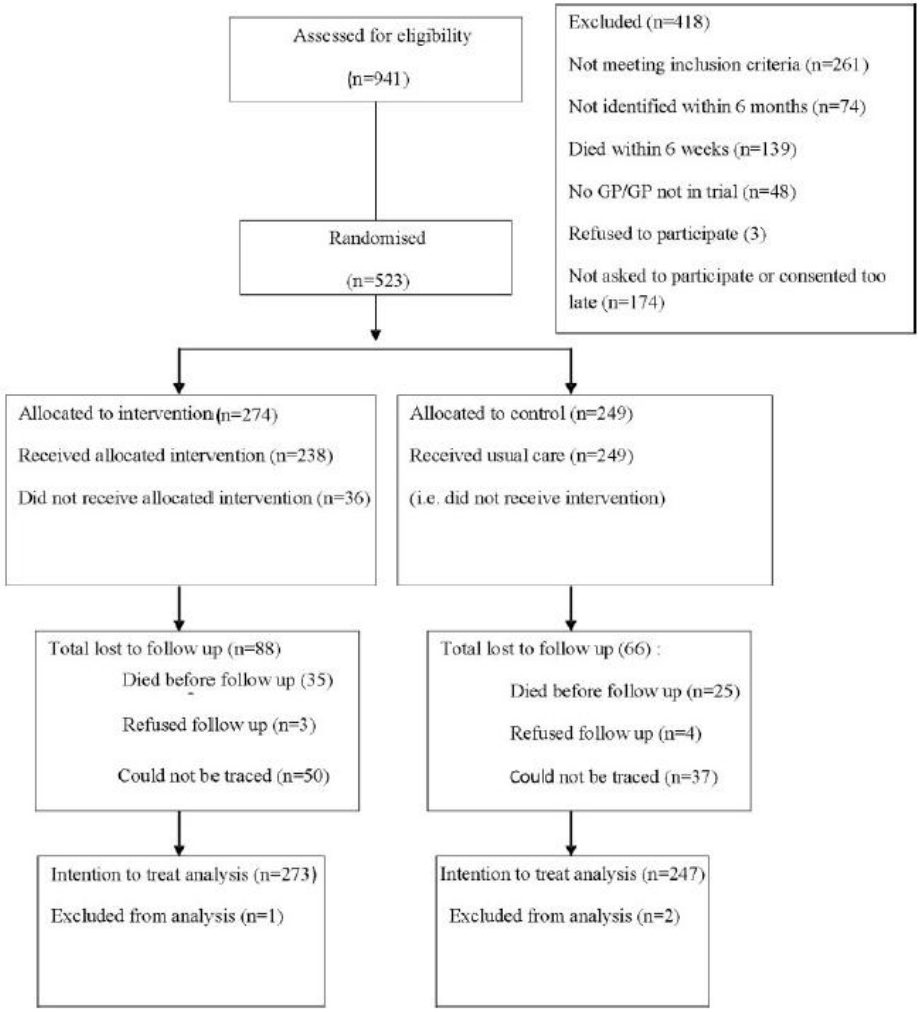
STOP STROKE Project
(cluster randomized trial embedded in the SLSR)

Intervention

- Targets patients, carers and primary care team
- Computerised system of delivering evidence based secondary prevention advice
- Uses data from the SLSR to produce a tailored secondary prevention package
  - Individualised secondary prevention care plan for patients
  - Individualised secondary prevention care plan for GPs
- Delivered at 10 weeks, 5 and 8 months post stroke
- RF management advice updated at each time point

Wolfe CDA et al. Stroke 2010

STOP STROKE Project
(cluster randomized trial embedded in the SLSR)



Wolfe CDA et al. Stroke 2010

STOP STROKE Project
(cluster randomized trial embedded in the SLSR)

	Intervention no./No.	Control no./No.	ARR (95% CI)
Treatment with antihypertensives	128/204	127/191	−3.74 (−13.03 to 5.67)
Treatment with antiplatelets	120/203	108/176	−2.25 (−11.97 to 7.59)
Smoking cessation	21/76	22/78	−0.58 (−14.52 to 13.46)
Treatment with statins	93/154	90/149	−0.01 (−10.89 to 10.89)
Treatment with hypoglycemics	42/68	42/65	−2.86 (−18.71 to 13.28)
Treatment with anticoagulants	7/41	14/40	−17.93 (−35.62 to 1.23)
Appropriate alcohol use*	171/273	167/247	−4.97 (−13.04 to 3.23)
Receipt of written information	124/273	90/247	8.98 (0.05 to 17.24)

*Appropriate alcohol use defined as no more than 14 units/week for women or 21 units/week for men.

Wolfe CDA et al. Stroke 2010

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Summary

- Different types of registers can produce various types of research evidence
- Register especially useful tool for epidemiology, outcomes research and health services research
- Each research output has specific requirements and demands
- Clarify the main purpose of your data collection when you are planning the register
- Keep documentation to a minimum!

Conclusion

- Register studies - a neglected type of research studies?
- YES - more than just counting cases
- Time to raise the research profile of registers!

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Evidence-based quality indicators for stroke rehabilitation

Board core data set rehabilitation of the Berlin Stroke Alliance

Quality Indicator	Structure	Process	Outcome	%*	Variation*
Completion of aetiological diagnostics					
Long-term cardiac monitoring in patients with possible cardioembolic stroke		X		18	0-33
Secondary prevention					
Nutrition counselling in obese patients		X		71	0-91
Control of blood pressure			X	85	76-93
Provision of smoking cessation training	X				
Cognition and affecr					
Screening of cognitive function at admission		X		74	66-95
Screening for depression		X		62	11-79
Speech and swallowing					
Screening for swallowing function at admission		X		39	26-64
Assessment by a speech therapist		X		90	87-100
Management of malnutrition	X				
Management of complications					
Record of complications	X				
Management to reduce spasticity		X		65	23-97
Sensorimotor functions and motor recovery					
Recovery of mobility			X	9	0-23
Recovery of walking function			X	30	26-50
Recovery of assistive upper limb function			X	13	0-100
Recovery of assistive upper limb function			X	18	11-13
Discharge status and after care					
Application for/ facilitation of further rehabilitation or therapy		X		81	41-98
Counselling in social law issues		X		61	36-79
Possibility of family involvement	X				

*Results of the pilot phase (3 centers; n=162 patients)

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First European Consensus Meeting on Performance Measures in Stroke Care, Lund April 11, 2011

Standardisation of quality indicators in Europe

Domains to be covered

1 Coordination of care
2 Diagnosis
3 Preservation of neural tissue
4 Prevention of complications
5 Initiation of secondary prevention
[6 Restoration of function]
7 Survival

Definitions of core baseline items

European Implementation Score Collaboration

Standards for developing quality indicators among audits

	Flanders-Belgium	Germany	Scotland	Catalonia-Spain	Sweden	England/ Wales/ Northern-Ireland
Formal procedure of development and selection of QI						
Review process of predefined methodological aspects	+	+	+		+	+
Review of evidence		+	+	+		+
Internal consensus process		+	+	+	+	
External consensus process			+			
External peer review of the developed indicators		+			+	+
Pilot study	+	+	+			+
Formal procedure of defining QI						
Standardized presentation of QI		+	+		+	+
Definition of the term QI	+	+	+		+	+
Definition of health care to be covered	+	+	+		+	+
Definition of methodological requirements	+	+	+		+	+
Formal QI board	+	+	+		+	+
Experts in	+	+	+		+	+
- Internal medicine	+	+	+	+	+	+
- Neurology	+	+	+	+	+	+
- Geriatrics	+		+		+	+
- Epidemiology		+			+	+
- QI development		+	+		+	+
- Quality assurance and management		+	+			
Quality improvement organizations		+				+
Stroke societies		+	+			+
Patient organizations		+	+		+	+

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