KCE REPORT 181A

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

STROKE UNITS: DOELTREFFENDHEID EN KWALITEITSINDICATOREN

Het Federaal Kenniscentrum voor de Gezondheidszorg

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KCE REPORT 181A
HEALTH SERVICES RESEARCH

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	Bruxelles), Vincent Thijs (UZ Leuven), Yves Vandermeeren (Cliniques Universitaires UCL, Mont-Godinne), en Geert Vanhooren (AZ Sint Jan Brugge-Oostende) werden geraadpleegd omwille van hun professionele competenties op het gebied van stroke. Daarom kunnen al deze experts per definitie een zekere mate van belangenconflict hebben ten opzichte van het onderwerp van deze studie. Betalingen om te spreken, opleidingsvergoedingen, reisondersteuning of betaling voor deelname aan een symposium: Yves Vandermeeren (support Boeringher); Geert Vanhooren (regelmatig uitgenodigd als expert voor conferenties)
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VOORWOORD

Wanneer we adviezen moeten verlenen over organisatiemodellen voor de zorg, stuiten we meestal op hetzelfde probleem: goede studies zijn erg zeldzaam of onbestaand. Dit maakt het voor de overheid stellig niet gemakkelijker wanneer zij de zorg voor een bepaalde groep patiënten moet uittekenen.

De zorg voor patiënten met een CVA werd al in een vroeger KCE rapport onder de loep genomen. Een opname in een neuro-vasculaire eenheid *(de zogenaamde Stroke Units)*, zo bleek uit een aantal degelijke studies, zou een duidelijk voordeel bieden. Wij wilden dit verder uitklaren, en scherp krijgen wat nu precies het gunstig effect op de gezondheidstoestand van de patiënt was van een opname in een dergelijke eenheid. En hoe moet je dan de organisatie van deze eenheden binnen het gezondheidsbestel zien? Hiervoor kunnen we kijken naar het voorbeeld van een aantal landen die hierin een pioniersrol speelden. Verder zijn er ook kwaliteitsindicatoren te vinden die richtinggevend kunnen zijn.

Sinds enkele jaren beschikt ook ons land over neuro-vasculaire eenheden, maar hun oprichting en werking berustten enkel op de visie en het initiatief van individuele clinici en ziekenhuizen. Vandaag wordt het tijd om voor elk CVA-patiënt een optimale zorg te garanderen. Dit werk zal ongetwijfeld ter inspiratie kunnen dienen van de actoren die begaan zijn met de kwaliteitsborging en officiële erkenning van deze eenheden.

Voor dit project konden we een beroep doen op de wetenschappelijke en klinische deskundigheid van twee enthousiaste onderzoeksequipes: onze dank gaat dan ook uit naar de medewerkers van Deloitte en van de KULeuven voor hun kwaliteitsvol werk en de fijne medewerking doorheen heel dit project.

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SAMENVATTING

WAT IS EEN NEURO-VASCULAIRE EENHEID ("STROKE UNIT")?

Het cerebrovasculair accident (CVA) is een veel voorkomende aandoening; per jaar krijgen tussen 200 en 230 personen op 100 000 er mee te maken. Om deze aandoening beter te kunnen behandelen werden enkele jaren geleden specifieke verzorgingseenheden opgericht: de neuro-vasculaire eenheden of 'stroke units'. Het doel van deze stroke units is om zo snel mogelijk specifieke zorgen toe te kunnen dienen en zo het aantal sterfgevallen te verminderen en de kansen op herstel te vergroten.

De Belgian Stroke Council (BSC) definieert een stroke unit als volgt: "een afzonderlijke geografische eenheid in het ziekenhuis die specifiek gewijd is aan patiënten die een cerebrovasculair accident doormaken (of, zolang de neurologische diagnose nog niet werd gesteld, die de symptomen ervan vertonen), met een multidisciplinair team dat geïnteresseerd is in en deskundig is op het gebied van CVA's: artsen, verpleegkundigen, kinesitherapeuten en daarnaast ook ergotherapeuten, logopedisten, een case manager, een zorgverlener die het verlaten van de unit plant, of een maatschappelijk assistent.

Dit rapport bestudeert specifiek stroke units van het acute type, die patiënten opnemen tot maximaal 7 dagen na het vasculair accident.

Momenteel bestaan er talrijke units van dit type in België, maar ze zijn niet allemaal officieel erkend volgens duidelijke kwaliteitscriteria.

DOELSTELLING VAN HET RAPPORT

De onderzoeksvragen die bestudeerd werden in het kader van deze studie zijn de volgende:

- Wat zijn de wetenschappelijke bewijzen aangaande de doeltreffendheid van opname in een stroke unit (systematische literatuurreview en meta-analyse)?
- Welke kwaliteitscriteria voor stroke units worden aangetroffen in de wetenschappelijke literatuur en welke wetenschappelijke bewijzen bestaan er voor deze criteria?
- Hoe zijn stroke units in andere landen georganiseerd en waaruit bestaat het proces van kwaliteitsbewaking (literatuurreview en interviews van experten)?
- Op basis van de antwoorden op voorgaande vragen, wat zijn de suggesties voor de organisatie en de kwaliteitsevaluatie van stroke units in België?

De resultaten van het onderzoek worden in drie delen voorgesteld:

- De beschrijving van de stroke units in andere landen met analyse van de gebruikte kwaliteitscriteria;
- Analyse van de doeltreffendheid van opname van een patiënt in een stroke unit tijdens de acute fase van het vasculair accident;
- De organisatiemodellen en modellen om de kwaliteit te meten die voorgesteld worden voor België.

HOE ZIJN DEZE UNITS GEORGANISEERD IN ANDERE LANDEN?

Erkenningsprocedures

In Schotland, Londen en Frankrijk bestaat een officiële en verplichte erkenningsprocedure voor de stroke units die wordt georganiseerd en gefinancierd door de overheid. In Duitsland is erkenning niet verplicht: deze wordt georganiseerd door een privé-organisatie en gefinancierd door het ziekenhuis.

De erkenningsprocedure omvat bezoeken ter plaatse (o.a. door personeel dat gespecialiseerd is in CVA), een review van het dossier, soms ook interviews. De erkenningscriteria kunnen ook betrekking hebben op andere organisatorische aspecten van het ziekenhuis.

Talrijke kwaliteitsindicatoren zijn beschikbaar

Gebruik van kwaliteitsindicatoren voor erkenning

In het overzicht van de organisatiemodellen in andere landen zijn talrijke kwaliteitsindicatoren vermeld die worden gebruikt in het kader van de erkenningsprocedure. Het betreft hier aspecten van:

- de structuur (o.a. opleiding van personeel, multidisciplinair team, aantal bedden, personeel- aantal en type van zorgverleners in de equipe);
- het proces (o.a. thrombolyse, duurtijd van een specifieke diagnostische of therapeutische procedure, medische beeldvorming van de hersenen);
- de resultaten (mortaliteit, heropname, pneumonie die opgelopen werd in het ziekenhuis).

Andere kwaliteitsindicatoren

Bovendien wordt in de studie een overzicht gemaakt van de kwaliteitsindicatoren:

- gebruikt op nationaal (bijv. in Zweden) of regionaal niveau om de kwaliteit van zorg verstrekt aan patiënten met CVA te evalueren;
- gepubliceerd in de wetenschappelijke literatuur: tientallen indicatoren voor structuur, proces en resultaten zijn geïnventariseerd. Voor elk daarvan worden de bronnen, het gebruik en eventueel de wetenschappelijke bewijzen gedetailleerd weergegeven in het wetenschappelijke rapport en de appendices.

Niet toekennen van de erkenning: gevolgen

Indien een stroke unit niet voldoet aan de criteria van de erkenningsprocedure, verschillen de gevolgen van land tot land:

- niet hernieuwen van de erkenning;
- ontwikkeling van een plan tot verbetering;
- gevolgen in termen van reputatie wanneer de resultaten op een openbare website worden gepubliceerd;
- financiële gevolgen zoals een vermindering of afschaffing van de financiering door de verzekeringsinstellingen of door de overheid.

WAT IS DE DOELTREFFENDHEID VAN STROKE UNITS?

Uit een meta-analyse gebaseerd op een tiental studies bleek dat opname in een stroke unit tijdens de acute fase van een CVA tot positieve resultaten leidt voor volgende parameters:

- het risico om in een verzorgingsinstelling opgenomen te worden bij het verlaten van het ziekenhuis;
- een indicator die de risico's van opname in een verzorgingsinstelling en overlijden combineert;
- een indicator die de risico's van zorgafhankelijkheid en overlijden combineert: nochtans zijn de resultaten niet significant voor elk van de gevolgen als ze afzonderlijk worden onderzocht;
- een zeer lichte daling van de verblijfsduur in het ziekenhuis.
- Andere interventies, die uitgevoerd worden op stroke units, zijn eveneens onderzocht:
- om uitspraken toe te laten over de voordelen van vroegtijdige mobilisatie zijn de studies ontoereikend;
- uit een grote studie bleek dat het bestaan van een protocol om koorts, hyperglycemie en problemen van dysfagie aan te pakken, voordelen biedt.
- continue monitoring in de acute fase heeft ook positieve gevolgen op de resultaten van de zorg.
- De gegevens laten daarentegen niet toe om de doeltreffendheid aan te tonen van:
- een vroegtijdige terugkeer naar huis met een team van zorgverleners die de nazorg thuis garanderen;
- een intensieve motorische revalidatie na het verlaten van het ziekenhuis.

WELKE OPLOSSINGEN VOOR BELGIË?

Vier mogelijke scenario's voor de organisatie van stroke units

Op basis van het resultaat van deze studie werden vier scenario's in overweging genomen voor de erkenning van stroke units in België:

- Het bestaan van een "basis" eenheid in elk ziekenhuis: deze oplossing biedt het voordeel van de toegankelijkheid, maar de kosten zullen waarschijnlijk erg hoog zijn en het zal moeilijk zijn om een uniforme kwaliteit te garanderen;
- Erg gespecialiseerde eenheden in een beperkt aantal ziekenhuizen: deze oplossing biedt daarentegen zorgverlening van een zeer hoge kwaliteit, maar hierbij stellen zich dan weer andere problemen: de toegankelijkheid in sommige regio's, de noodzaak van "bypass" door ziekenwagens, terughoudendheid van de nabijgelegen ziekenhuizen die vrezen patiënten te verliezen, een te beperkte capaciteit in gespecialiseerde centra;
- Een combinatie van beide voorgaande oplossingen, namelijk zorgverlening van zeer hoge kwaliteit in gespecialiseerde centra gevolgd door subacute zorg in de centra die zich in nabijgelegen ziekenhuizen bevinden. Voor deze oplossing zijn duidelijke samenwerkingsovereenkomsten tussen de ziekenhuisinstellingen nodig, evenals specifieke stimuli om ervoor te zorgen dat de patiënten daadwerkelijk naar een ziekenhuis in de buurt van hun woning worden gezonden;
- Thrombolyse in elk ziekenhuis en stroke units in bepaalde gespecialiseerde centra: bij deze laatste mogelijkheid stelt zich de vraag of bepaalde ziekenhuizen wel voldoende volumes zullen realiseren om een snelle thrombolyse volgens de kwaliteitsnormen te kunnen garanderen vóórdat de patiënt overgebracht wordt. Daarnaast zijn ook de samenwerkingsovereenkomsten die vermeld werden in het vorige punt, van toepassing.

Registratie van de zorgkwaliteit is noodzakelijk

- Een eerste aandachtspunt betreft het definiëren door de stakeholders van het doel van het verzamelen van gegevens inzake stroke units: informatie met betrekking tot de epidemiologie en de zorgkwaliteit op nationaal of regionaal niveau? Erkenning van de units? Benchmarking tussen ziekenhuizen? Procedures voor kwaliteitsverbetering in een ziekenhuis?
- Een tweede punt is het definiëren van een procedure voor dataverzameling en meer in het bijzonder door welke instantie dit dient te gebeuren (overheid of niet), anonymisatie, en databeheer (cfr. KCE rapport 41 over klinische kwaliteitsindicatoren).
- Tenslotte zullen van tevoren samen met de stakeholders de gevolgen gedefinieerd dienen te worden: verkrijgen of verliezen van erkenning, financiële consekwenties, reputatie, dynamiek van kwaliteitsverbetering (door middel van feedback of door contacten met ziekenhuizen die goed presteren).

Selectie van indicatoren

- Het is noodzakelijk een beperkte set van kwaliteitsindicatoren te selecteren uit de indicatoren die voorgesteld werden in dit rapport. Clinici, gegevensbeheerders en andere stakeholders (patiënten, overheden) moeten aan deze selectie deelnemen. Welke set weerhouden wordt hangt af van het gebruik (benchmarking zou een zeer strikte standaarddefinitie van de indicatoren vragen waarbij rekening wordt gehouden met het patiëntenprofiel). Deze indicatoren dienen bovendien ook gepreciseerd te worden om de dataverzameling te standaardiseren. Drempelwaarden kunnen gedefinieerd worden op basis van de verzamelde gegevens en standaarden die gepubliceerd werden in de literatuur.

Testen van de haalbaarheid

- Het verzamelen van gegevens vereist een piloot test, om de beschikbaarheid van administratieve gegevens en de haalbaarheid van bijkomende gegevensverzameling te verifiëren.

AANBEVELINGEN[a]

Ter attentie van de Minister na advies van de bevoegde organen (Nationale raad voor ziekenhuisvoorzieningen):

Rekening houdend met de hoge incidentiecijfers van cerebrovasculair accident (jaarlijks 2 per 1000 inwoners) en het belang van een optimale aanpak in de acute fase, formuleert het KCE volgende aanbevelingen.

- **Het is aanbevolen twee types stroke units te onderscheiden:**
  - **Hyperacute units, die in staat zijn om in de eerste minuten na opname de noodzakelijke diagnostische oppuntstelling uit te voeren met het oog op een eventuele thrombolyse. Deze acute zorgverlening dient te verlopen volgens procedures die de veiligheid ervan garanderen, en dient, in ideale omstandigheden, uitgevoerd te zijn binnen de twee uren die volgen op het vasculair accident;**
  - **Stroke units die zorg verlenen aan de patiënt na de eerste drie dagen, meer specifiek in nabijgelegen ziekenhuizen.**
- **Het aantal hyperacute units dat erkend wordt dient gebaseerd te zijn:**
  - **op socio-demografische gegevens, op geografische toegankelijkheid en te verwachten incidenties in elke regio;**
  - **meer bepaald op de mogelijkheid om het centrum te bereiken binnen de 30 minuten volgend op het eerste professionele contact met de patiënt.**
- **Het succes van dit getrapte systeem, dat aangepast is aan de klinische toestand van de patiënt, vereist:**
  - **een sensibilisatie van de bevolking en de huisartsen om patiënten vanaf de eerste minuten te door te sturen naar de meest nabije hyperacute unit;**
  - **overeenkomsten met de ambulancediensten om de patiënt snel te vervoeren naar de meest nabije hyperacute unit;**
  - **formele overeenkomsten tussen instellingen met een hyperacute unit en de nabijgelegen ziekenhuizen die erkend zijn voor het verder zetten van de behandeling;**
  - **financiële incentives en een wettelijk kader in verband met de transfer van patiënten na de acute fase.**

[a] Het KCE blijft als enige verantwoordelijk voor de aanbevelingen die aan de overheid worden geformuleerd.

- **Om de kwaliteit van de ziekenhuiszorg voor cerebrovasculaire accidenten te kunnen garanderen, dient men te beschikken over kwaliteitsindicatoren aangepast aan de twee types van stroke units, met het oog op het toekennen van een erkenning. Meerdere voorafgaandelijke stappen zijn noodzakelijk:**
  - **Definitie van de doelstelling, de modaliteiten en de gevolgen van het meten van deze indicatoren, in samenspraak met de betrokken partijen;**
  - **Selectie van beperkte sets van indicatoren, aangepast aan elk van de twee types van units. Deze indicatoren zullen bepaald worden vertrekkende van de indicatoren die voorgesteld zijn in dit rapport (en eventueel deze die op Europees niveau zullen verschijnen voor de hyperacute units). Er moet extra aandacht besteed worden aan oudere patiënten met een complex ziektebeeld, eventueel door middel van bijkomende indicatoren.**
- **Dit rapport beperkt zich tot de zorg voor de patiënt in de acute fase; er dient evenveel aandacht te gaan naar een optimale continuïteit van zorg met de eerste lijn en de dagelijkse omgeving van de patiënt (thuis of in een instelling) op het ogenblik dat hij ontslagen wordt uit het ziekenhuis. Deze continuïteit dient verzekerd te worden door een zorgprogramma te definiëren, in combinatie met het verzamelen van gegevens die als doel hebben:**
  - **het analyseren van de epidemiologie van cerebrovasculaire accidenten;**
  - **het meten van de zorgkwaliteit van de verstrekte zorgen;**
  - **het plannen van de zorgstructuren (in de acute en chronische fase).**

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ABBREVIATION	DEFINITION
ADL	Activities of daily living
AF	Atrial fibrillation
AM	Automated monitoring
AVERT	A Very Early Rehabilitation Trial for Stroke
BP	Blood pressure
CCT	Controlled clinical trials
CI	Confidence interval
CT	Computed tomography
DET	Data extraction template
DRG	Diagnosis-related group
DVT	Deep vein thrombosis
ECG	Electrocardiogram
ER	Emergency room
ESD	Early supported discharge
ESO	European Stroke Organization
ESUS	Extended stroke unit service
FAST	Face, arm, speech, and time
GRADE	Grading of Recommendations
GMW	General medical ward
HASU	Hyper Acute Stroke Unit
HTA	Health technology assessment
IMT	Intensive motor training
ISO	International Organization of Standardization
IV	Intravenous
LDL	Low-density lipoprotein
MeSH	Medical subject heading
MRI	Magnetic resonance imaging

mRS	Modified Rankin Scale
NICE	National Institute for Health and Clinical Excellence
NIHSS	National Institutes of Health Stroke Scale
OR	Odds ratio
OSUS	Ordinary stroke unit service
OT	Occupational therapist
PT	Physiotherapist
QASC	Quality in Acute Stroke Care
QI	Quality indicator
QoL	Quality of life
RCT	Randomized controlled trial
SD	Standard deviation
SIGN	Scottish Intercollegiate Guidelines Network
SoF	Summary of Findings
SSS	Scandinavian stroke scale
ST	Speech therapist
SU	Stroke unit
TIA	Transient ischemic attack
t-PA	Tissue plasminogen activator
VEM	Very early mobilization
VTE	Venous thromboembolism

SYNTHESE

1 INLEIDING

1.1 Cerebrovasculair accident

Het cerebrovasculair accident (CVA) vormt een belangrijk probleem voor de volksgezondheid in Westerse landen. Het is de derde belangrijkste oorzaak van sterfte na hartinfarct en kanker, en de voornaamste oorzaak van langdurige invaliditeit. Zestig procent van de mensen die erdoor getroffen worden sterft of ontwikkelt restletsels die leiden tot een belangrijke mate van afhankelijkheid, wat een last betekent voor hun entourage en de gemeenschap.

De incidentie van CVA (eerste episode en recidieven tezamen) wordt in België geraamd op 200 tot 230 per 100.000 inwoners per jaar, ofwel 19.000 gevallen per jaar, of 52 gevallen per dag. De hospitalisatiekosten die ze met zich meebrengen, worden geschat op ongeveer € 191,6 miljoen (cijfers van 2007).

We onderscheiden twee categorieën CVA's:

- ischemisch CVA of herseninfarct (80%) als gevolg van de occlusie van een bloedvat in de hersenen door een bloedklonter;
- hemorragisch CVA of hersenbloeding (20%). In dit geval ontstaat er een scheur in de wand van een bloedvat in de hersenen, soms op de plaats van een bloedvatverwijding (aneurysma). Arteriële hypertensie is dan de belangrijkste risicofactor.

De symptomen van een CVA zijn variabel en ontstaan snel: verlamming, onduidelijke spraak, verlies van gezichtsvermogen, verwarring... De ernst van een CVA hangt af van de omvang van de beschadiging aan het hersenweefsel. Het is daarom van essentieel belang dat de patiënt zeer snel wordt behandeld. Bij een trombose staat het nu vast dat een behandeling om de bloedklonter op te lossen (trombolyse) die binnen 4,5 uur wordt opgestart (of minder indien mogelijk) de ernst van de restletsels kan verminderen, maar deze behandeling vereist een zeer streng toezicht vanwege de inherente risico's (oncontroleerbare bloedingen). Het is ook noodzakelijk om met zekerheid de diagnose van trombose te kunnen stellen voordat een dergelijke behandeling wordt opgestart, want deze mag absoluut niet uitgevoerd worden bij een hersenbloeding.

Deze differentiële diagnose is vooral gebaseerd op beeldvorming van de hersenen.

Soms verdwijnt de occlusie van het cerebrale bloedvat snel genoeg vanzelf om geen restletsels te veroorzaken: dan gaat het om een transiënt ischemisch accident (TIA). De verschijnselen ervan zijn dezelfde als voor CVA, maar duren slechts enkele seconden tot enkele minuten voordat alles weer normaal wordt. Een TIA kan dus onopgemerkt voorbijgaan, maar is een belangrijk alarmsignaal dat een voorbode kan zijn van een ernstiger CVA, en daarom moet de patiënt dan dringend worden onderzocht.

1.2 Stroke units ("Neurovasculaire Eenheden ")

Traditioneel worden CVA's behandeld op de afdeling inwendige geneeskunde (neurologie) in de ziekenhuizen. Maar vooral sinds de komst van de trombolyse is het noodzakelijk geworden om 24 uur per dag zeer snel te kunnen ingrijpen met een hoge mate van technische competentie. Om aan deze noodzaak te voldoen zijn de "Neurovasculaire Eenheden" (Stroke units, van het Engelse woord stroke, dat CVA betekent) ontstaan, die het mogelijk maken om onmiddellijk technische diagnostische onderzoeken en een behandeling met trombolyse uit te voeren, en die ook andere specifieke verbeteringen mogelijk maken wat betreft zorg, om zo de mortaliteit te doen dalen en de kans op herstel te vergroten.

De definitie van stroke unit die wordt voorgesteld door de Belgian Stroke Council luidt als volgt: "een afzonderlijke geografische eenheid in het ziekenhuis die specifiek gewijd is aan patiënten die een cerebrovasculair accident doormaken (of waar een CVA vermoed wordt- zolang de neurologische diagnose nog niet werd gesteld of nog niet duidelijk is), met een multidisciplinair team dat geïnteresseerd is in en deskundig is op het gebied van CVA's (artsen, verpleegkundigen, kinesitherapeuten en daarnaast ook ergotherapeuten, logopedisten, case managers, zorgverleners of andere professionals die het vertrek uit de unit moeten plannen)."

Deze stroke units bestaan onder verschillende werkingsmodaliteiten. Dit rapport onderzoekt meer in het bijzonder:

- units van het acute type die patiënten opnemen tijdens de acute fase, maar hen snel overdragen (binnen de zeven dagen) aan minder gespecialiseerde diensten.
- geïntegreerde units die acute zorgen en revalidatie combineren, die patiënten opnemen tijdens de acute fase, maar ook de revalidatie kunnen opstarten en uitvoeren gedurende ten minste een week.

Drie andere vormen van behandeling worden niet onderzocht in dit rapport:

- Gemengde revalidatiediensten: diensten met een multidisciplinair team die niet-specifieke revalidatiediensten aanbieden;
- Mobiele stroke units: multidisciplinaire teams (zonder gespecialiseerde verpleegkundigen) die CVA-patiënten verzorgen in verschillende afdelingen;
- De neurovasculaire revalidatie-eenheden die patiënten opnemen na de acute fase (7 dagen vanaf het begin van het CVA).

1.3 Zorgkwaliteit: dringend nood aan evaluatie

De Belgian Stroke Council publiceerde in 2009 erkenningscriteria voor stroke units. Na het verschijnen van deze publicatie volgde echter geen officieel erkenningssysteem voor stroke units, en evenmin de oprichting van een registratiesysteem voor de zorgkwaliteit. Daardoor zijn er vandaag grote verschillen wat betreft bestaande structuren en toegepaste procedures, en waarschijnlijk ook wat betreft aangeboden zorgkwaliteit in de verschillende stroke units in het land.

Na raadpleging van experts besloot het KCE om een studie te wijden aan het evalueren van de efficiëntie van stroke units, de kwaliteitsindicatoren die erop toegepast kunnen worden, en de optimale manier om dergelijke units te organiseren in België. Tegelijkertijd startte een andere werkgroep binnen de Nationale Raad voor Ziekenhuisvoorzieningen een studie naar kwaliteitscriteria voor stroke units, om advies te kunnen geven aan de Minister van Volksgezondheid. Leden van deze werkgroep werden gevraagd als expert voor het project van het KCE en er vonden in de loop van het project uitwisselingen plaats om ervoor te zorgen dat deze studie van het KCE en de aanbevelingen van de Nationale Raad voor de Minister zouden steunen op gemeenschappelijke wetenschappelijke grondslagen.

2 DOELSTELLINGEN VAN DEZE STUDIE

Deze studie heeft als doel om de kwaliteit van de zorg voor patiënten in de acute fase van CVA te verbeteren. Hiervoor hebben we een analyse gemaakt van de organisatie van acute stroke units in andere Europese landen, en hebben we in de wetenschappelijke literatuur de efficiëntie van en kwaliteitsindicatoren voor stroke units onderzocht.

De onderzoeksvragen die in dit kader geanalyseerd werden zijn:

1. Hoe zijn stroke units in andere landen georganiseerd en waaruit bestaan de processen van kwaliteitsbewaking en de kwaliteitscriteria? (literatuurreview en bevraging van experts)
2. Wat zijn de wetenschappelijke bewijzen aangaande de doeltreffendheid van een opname in een stroke unit? (systematische literatuurreview en meta-analyse)
3. Welke kwaliteitscriteria voor stroke units worden aangetroffen in de wetenschappelijke literatuur en welke wetenschappelijke bewijzen bestaan er voor deze criteria? (literatuurreview)
4. Op basis van de antwoorden op voorgaande vragen: wat zijn de suggesties voor de organisatie en de kwaliteitsevaluatie van stroke units in België?

De antwoorden op deze vier vragen worden systematisch samengevat in de volgende hoofdstukken van deze synthese.

3 HOE ZIJN DEZE UNITS GEORGANISEERD IN ANDERE LANDEN?

Het eerste deel van deze studie is gewijd aan het analyseren van de organisatie van stroke units in zes Europese landen/regio's: Duitsland, Zweden, Nederland, Frankrijk, Schotland en de "London Stroke Services" in Groot-Brittannië.

De informatie werd verzameld door een gedetailleerde vragenlijst te sturen naar experts in elk land. Het onderzoeksteam heeft vervolgens het geheel van de verkregen antwoorden geanalyseerd en besproken, en daarna een aantal punten verduidelijkt aan de hand van interviews.

In de volgende paragrafen geven we achtereenvolgens een samenvatting van de erkenningsprocedures in deze verschillende landen, de procedures voor evaluatie van de kwaliteit, en de manier waarop de toegang tot stroke units wordt gepland en georganiseerd.

3.1 Erkenning van stroke units

Er bestaan erkenningsprocedures in 4 van de 6 onderzochte landen/regio's. In Schotland, Londen (London Stroke Services) en Frankrijk zijn deze procedures verplicht; ze worden georganiseerd en gefinancierd door de overheid. Er bestaat ook een erkenningsprocedure in Duitsland, maar ze is er niet verplicht en wordt uitgevoerd door privéorganisaties en gefinancierd door de ziekenhuizen. Nederland en Zweden hebben geen erkenningsprocedure.

De erkenningsprocedures omvatten bezoeken ter plaatse en een evaluatie van patiëntdossiers, en eventueel ook bepaalde extra procedures. Een deel van het personeel dat verantwoordelijk is voor deze erkenningsprocedures is zelf specifiek opgeleid voor de behandeling van CVA. De erkenning omvat soms naast de stroke unit zelf een aantal andere aspecten van de zorg, zoals de begeleiding van de patiënt die een CVA doorgemaakt heeft wanneer hij overgebracht wordt van thuis naar het ziekenhuis. De erkenning kan om de 1, 3 of 5 jaar verlengd worden.

Verschillende types stroke units kunnen een erkenning krijgen. Zo onderscheidt men in de London Stroke Services enkele zeer specifieke eenheden, de "hyperacute" eenheden (hyper acute stroke units - HASU). Sommige landen maken ook een onderscheid tussen regionale en supraregionale eenheden, of tussen zogenaamde "primaire" eenheden en "geïntegreerde" eenheden die alle nodige interventies voor de behandeling kunnen doen, zoals interventionele radiologie of carotischirurgie.

De erkenningscriteria in de vier onderzochte landen/regio's kunnen worden ingedeeld volgens de structuur van de unit, de procedures die er worden toegepast en de impact op de outcome van de patiënten.

3.1.1 Structuurcriteria

- Er is een minimum aantal bedden vereist in Frankrijk (4 bedden) en Duitsland (6 bedden). In de London Stroke Services bedraagt het minimum aantal bedden 8, maar dit aantal kan aangepast worden in functie van de planning van de opvangcapaciteit voor de hele regio (zie 3.3);
- Er is een minimaal jaarlijks volume aan activiteiten vereist in Frankrijk (300 patiënten) en Duitsland (250 patiënten voor de primaire eenheden en 500 patiënten voor de geïntegreerde eenheden). Bovendien moet er in Duitsland ook een minimum aantal trombolyses uitgevoerd worden;
- Het opleidingsniveau van het personeel en de aanwezigheid van een multidisciplinair team (met variabele samenstelling) worden steeds vermeld.

Andere structurele indicatoren worden ook genoemd, zoals hart/oxygenatiebewakingsapparatuur of gedocumenteerde behandelingsprotocollen.

3.1.2 Procedurecriteria

Er werd een twintigtal procedure-indicatoren gevonden; de volgende indicatoren worden gebruikt in het erkenningssysteem van de 4 onderzochte landen:

- Indicatoren in verband met de snelheid van de behandeling (tijd tussen thuis en ziekenhuis, tijd voor de medische beeldvorming van de hersenen, duur van het verblijf op de spoeddienst);
- Indicatoren in verband met de hyperacute procedures (vooral de trombolyse en het opsporen van slikproblemen);
- Indicatoren in verband met diagnostische procedures (bijvoorbeeld percentage patiënten dat een medische beeldvorming van de hersenen ondergaat).

3.1.3 Criteria in verband met de impact op de outcome van de patiënten

De mortaliteit in het ziekenhuis of binnen de stroke unit is het enige criterium in verband met de uiteindelijke toestand van de patiënten wanneer de behandeling ten einde loopt, dat gebruikt wordt in elk van de 3 landen/regio's die outcome criteria in hun erkenningsprocedure opnemen. Andere indicatoren zijn complicaties (pneumonie, trombose) of het aantal heropnames.

3.1.4 Wat als een ziekenhuis faalt?

Als een ziekenhuis niet voldoet aan de vereiste criteria voor de erkenning van de stroke unit, lopen de gevolgen sterk uiteen:

- In Schotland wordt aan ziekenhuizen die niet slagen voor de erkenningsprocedure gevraagd om een verbeteringsplan in te dienen, maar er zijn geen andere gevolgen, meer bepaald op financieel vlak. Maar aangezien deze resultaten openbaar worden gemaakt aan professionals en het grote publiek, lopen ze wel het risico dat ze hun reputatie verliezen…
- In Londen worden ziekenhuizen die niet slagen voor de eerste beoordeling niet meer erkend voor CVA-behandelingen. Als ze na een gunstige eerste beoordeling niet meer aan de vereiste criteria voldoen, blijft een intrekking van de erkenning in theorie mogelijk, maar de gevolgen zijn vooral voelbaar op het vlak van reputatie of financieel verlies, want ook hier worden de resultaten openbaar gemaakt. De instellingen kunnen ook een deel van de supplementaire premie verliezen die ze krijgen als ze erkend worden.
- In Frankrijk heeft het niet krijgen van de erkenning financiële gevolgen voor het ziekenhuis. Toch worden de resultaten enkel bekendgemaakt aan de autoriteiten van de betrokken instelling.
- In Duitsland werkt het systeem met positieve incentives. Ziekenhuizen die de erkenning krijgen, worden gepubliceerd op een officiële lijst, die ook terug te vinden is op de site van de German Stroke Society. De financiering van het ziekenhuis staat los van het erkenningsproces, hoewel de terugbetalingscriteria ook kwaliteitscriteria kunnen bevatten, die verschillen in functie van de verzekeringsinstellingen.

Soms worden financiële incentives gekoppeld aan de preferentiële opname van patiënten in de stroke unit in plaats van in niet-gespecialiseerde diensten (Zweden, Frankrijk, Londen, Duitsland)

3.2 Evaluatie van de zorgkwaliteit

In de 6 onderzochte landen/regio's werden er systemen voor het meten van de CVA-zorgkwaliteit uitgewerkt op nationaal of regionaal vlak, ongeacht of er al dan niet erkenningsprocedures bestaan.

Onder de aangegeven kwaliteitsindicatoren maakt men veel gebruik van het percentage van de CVA patiënten die worden opgenomen in stroke units, het uitvoeren van een trombolyse, de tijd die verloopt eer de trombolyse wordt uitgevoerd, en het opsporen van slikproblemen. Veel voorkomende outcome indicatoren zijn mortaliteit, het percentage patiënten dat in een verzorgingstehuis opgenomen wordt, en de bestemming van de patiënt na de ziekenhuisopname.

Deze resultaten worden soms gepubliceerd op officiële websites (bijvoorbeeld in Zweden), en kunnen gebruikt worden voor benchmarking tussen regio's of tussen ziekenhuizen (met vermelding van de naam van het ziekenhuis)

Tot slot is het interessant om te benadrukken dat in de 6 onderzochte landen/regio's de beroepsorganisaties richtlijnen hebben uitgewerkt voor het organiseren van stroke units; ook in België is dit het geval.

3.3 Toegang tot stroke units

We zien enkele opvallende kenmerken wat betreft het plannen van de opvangcapaciteit en de toegangsvoorwaarden voor stroke units in de verschillende onderzochte landen:

- Planning van de opvangcapaciteit: Londen is de enige onderzochte regio waar de gezondheidsinstanties gebruik maken van een formele methode om het aantal eenheden dat nodig is voor de behandeling van CVA op zijn grondgebied te plannen. Deze berekening is gebaseerd op een vrij breed scala van parameters, zoals de verwachte demografische veranderingen, de vermoedelijke gemiddelde verblijfsduur, of de impact van preventieve strategieën.
- "Bypass" door ambulances: in 3 van de 4 landen/regio's die werken met een erkenningssysteem mogen de ambulances de ziekenhuizen voorbijrijden die niet over een stroke unit beschikken.
- Profiel van de patiënten: in de 6 onderzochte landen/regio's worden alle patiënten met symptomen van een CVA of hersenbloeding opgenomen in de stroke units. Er bestaan echter wel verschillen tussen de landen/regio's wat betreft de opname van de patiënten met een transiënt ischemisch accident (TIA) of een subarachnoïdale bloeding.

3.4 Samengevat: vijf modellen

Samengevat kunnen we vijf organisatiemodellen onderscheiden:

- In Duitsland worden de kwaliteitsnormen bepaald door beroepsorganisaties, en de erkenning wordt afgeleverd door een professioneel certificatiebureau. Alleen stroke units die deze erkenning gekregen hebben, worden gepubliceerd op een officiële site. Als een ziekenhuis deze erkenning niet krijgt, kan haar reputatie dus achteruitgaan en afhankelijk van de verzekeringsmaatschappijen eventueel financieel verlies lijden.
- Het Franse model voorziet in een verplichte erkenning die georganiseerd en gefinancierd wordt door de overheid, met financiële verliezen als de erkenningsprocedure fout loopt. Alleen de ziekenhuisdirectie krijgt de resultaten van de procedure te zien.
- De London Stroke Services hebben een erkenningsprocedure die de eigenschappen van de twee voorgaande modellen combineert: organisatie en financiering door de overheid, financiële gevolgen en gevolgen op vlak van reputatie als het ziekenhuis niet aan de criteria voldoet.
- Schotland heeft een verplichte erkenningsprocedure en maakt gebruik van feedback om het verwachte kwaliteitsniveau te bereiken: ziekenhuizen die niet voldoen aan de criteria krijgen speciale aandacht en steun van de overheid om hun indicatoren te verbeteren.
- In het Zweedse model is er geen formele erkenningsprocedure. Het meten van kwaliteitsindicatoren vormt de motor van de zorgkwaliteit op vlak van CVA.

4 WAT IS DE DOELTREFFENDHEID VAN STROKE UNITS?

Zijn stroke units werkelijk doeltreffender voor de behandeling van CVA-patiënten dan klassieke neurologische diensten? Zijn er meer patiënten die een CVA overleven, houden ze er minder restletsels aan over, zijn ze beter in staat om opnieuw zelfstandig thuis te wonen?

Al deze vragen werden reeds onderzocht in 2009 (op basis van cijfers van 2006) in een Cochrane-review die de doeltreffendheid van stroke units analyseerde. Aan deze eerste bron van informatie voegden we een selectie van 7 andere studies toe die sindsdien over hetzelfde onderwerp gepubliceerd werden, wat het totaal van ons onderzoek brengt op 20 (gerandomiseerde en niet-gerandomiseerde) studies.

De algemene kwaliteit van deze studies kan matig worden genoemd: de registratie van de resultaten en de omschrijving van de betrokken populaties waren over het algemeen correct, maar de randomisering of het feit of het onderzoek dubbelblind uitgevoerd was, waren in veel studies weinig of helemaal niet gedocumenteerd.

De onderstaande tabel vat de studies samen die in aanmerking werden genomen in onze literatuurreview.

Tabel 1: Samenvatting van de in aanmerking genomen studies

Eerste vergelijkingscategorie		Tweede vergelijkingscategorie
I.	Stroke units versus andere zorgmodellen (12 studies)	Acute stroke unit versus algemene ziekenhuisdienst (4 studies)
		Geïntegreerde stroke unit versus algemene ziekenhuisdienst (7 studies)
		Geïntegreerde stroke unit versus mobiel team (1 studie)
II.	Stroke units met specifieke zorgen versus conventionele stroke units (5 studies)	Stroke units met zeer vroege revalidatie (2 studies)
		Acute stroke unit met protocol (opvolging van koorts, hyperglycemie en slikproblemen) (1 studie)
		Stroke unit met continue monitoring (3 studies[1])
III.	Stroke units gevolgd door een specifieke interventie, versus opvolging met conventionele zorgen (3 studies)	Stroke unit gevolgd door vroege terugkeer naar huis met opvolging (2 studies)
		Stroke unit gevolgd door intensieve motorische revalidatie (1 studie)

[1] Eén studie onderzocht zowel de continue monitoring als de zeer vroege revalidatie.

De gepoolde analyse van deze verschillende studies toont aan dat een ziekenhuisopname georganiseerd in stroke units de resultaten van de patiënt aanzienlijk verbetert op vier indicatoren (waarvan twee samengestelde):

- Risico op institutionalisering (het risico om na ontslag uit het ziekenhuis te worden overgebracht naar een verzorgingsinstelling voor chronische zorg);
- Overlijden of institutionalisering;
- Overlijden of afhankelijkheid (gemeten door een score op basis van specifieke beoordelingsschalen, zoals de Modified Rankin Scale of de Barthel Index);
- Duur van de hospitalisatie (gemiddeld verschil van - 0,27 dagen).

Het effect op de andere parameters is minder overtuigend:

- Het voordeel van de stroke units afzonderlijk gemeten voor het risico op afhankelijkheid is niet significant.
- Het voordeel op vlak van mortaliteit bereikt nipt het significantieniveau van 5% op basis van de analyse van alle gepubliceerde studies. Bovendien verdwijnt deze significantie wanneer de analyse zich beperkt tot gerandomiseerde studies.
- Drie studies analyseren de impact van de stroke units op de levenskwaliteit na een CVA: twee ervan melden geen significante verbetering.

Twee studies leveren gegevens over de effecten op lange termijn: de impact van stroke units op het overlijden is positief op 5 jaar, maar voor langere opvolgingsperiodes verschillen de gegevens tussen de twee studies.

Sommige studies suggereren dat bepaalde aanvullende maatregelen efficiënt zijn:

- Zeer vroege mobilisatie: patiënten binnen de 24 uur na begin van het CVA uit bed laten komen lijkt hun evolutie positief te beïnvloeden, maar er zijn studies op grotere schaal nodig om de doeltreffendheid van een dergelijke maatregel te bevestigen.
- Protocollen voor behandeling van koorts, hyperglycemie en slikproblemen zijn maatregelen waarvan de voordelen op vlak van mortaliteit en afhankelijkheid werden aangetoond in een brede studie.
- Continue monitoring van de vitale parameters in de acute fase heeft een bewezen positieve invloed op de hospitalisatieduur en op samengestelde indicatoren zoals het aantal overlijdens of opnames in een instelling, en het aantal overlijdens of afhankelijkheid.

Er is geen enkel bewijs voor de doeltreffendheid van interventies na de hospitalisatie, zoals het vroegtijdig terugkeren naar huis met een zorgteam dat instaat voor de opvolging thuis (2 studies) of de intensieve motorische revalidatie na vertrek uit het ziekenhuis (1 studie), maar deze interventies waren niet relevant voor de doelstelling van onze studie en we hebben geen bijkomend literatuuronderzoek gedaan over deze onderwerpen.

5 KWALITEITSINDICATOREN

Naast de erkenningsprocedures is het ook belangrijk om een systeem in te voeren voor het registreren van de zorgkwaliteit op basis van zorgvuldig gekozen kwaliteitsindicatoren. Deze kwaliteitsindicatoren kunnen dezelfde zijn als de indicatoren die de basis vormen van de erkenningscriteria, maar ze kunnen ook gebruikt worden voor andere doeleinden, zoals bijvoorbeeld in Zweden, waar er geen erkenningsprocedure voor de stroke units bestaat, maar waar de zorgkwaliteit wordt gecontroleerd door een groot aantal kwaliteitsindicatoren.

Aan de hand van een onderzoek naar de kwaliteitsindicatoren in de wetenschappelijke literatuur konden we een eerste reeks van 98 kwaliteitsindicatoren (QI's) identificeren. Een tweede selectieproces liet ons toe om de indicatoren uit te sluiten die niet overeenstemden met de context van de zorg voor CVA in de acute fase (meer bepaald de langdurige zorg) en om bepaalde indicatoren die dezelfde parameters meten te combineren.

De uiteindelijke reeks indicatoren die we verkregen na deze literatuurreview bestaat uit 48 items, waarvan de meeste betrekking hebben op de procedures. Ze werden voorgelegd aan een panel van 7 artsen (6 clinici en een data manager), die de opdracht kregen om deze indicatoren te beoordelen op basis van 6 criteria: relevantie, validiteit, haalbaarheid, betrouwbaarheid, specificiteit, en mogelijkheden voor verbetering. Enkele bijkomende indicatoren die naar voren gekomen waren uit de evaluatie van de bestaande praktijk in andere landen, werden ook voorgelegd aan het panel van experts.

De paragraaf hieronder geeft voorbeelden van indicatoren, in het bijzonder van indicatoren die ondersteund worden door wetenschappelijke bewijzen. Hun definities, de onderliggende wetenschappelijke bewijzen en de resultaten van de classificatie door de experts zijn gedetailleerd terug te vinden in de appendix van dit rapport.

5.1 Structuurindicatoren

Er werden vijftien structuurindicatoren geïdentificeerd in de literatuur. Slechts twee ervan werden ondersteund door kwalitatief hoogstaande studies die het bewijs leveren van een verband tussen de indicator en een verbetering van parameters: de aanwezigheid van een gespecialiseerd multidisciplinair team en het beschikbaar zijn gedurende 24 uur per dag van medische beeldvorming van de hersenen (met specifieke radiologische expertise).

Andere minder sterke indicatoren zijn bijvoorbeeld:

- Gegevens over het aantal opnames op de spoeddienst/in het ziekenhuis;
- Deelname van het personeel aan opleidingen voor de acute behandeling van CVA;
- Beschikbaarheid van vasculaire beeldvorming en (cardiologische) diagnosetechnieken in het ziekenhuis;
- Documentatie en evaluatie van het risico in het medische dossier.

5.2 Procedure-indicatoren

De procedure-indicatoren werden ingedeeld volgens de verschillende fasen van de behandeling waarop zij betrekking hebben:

- Zeven indicatoren hebben betrekking op de hyperacute fase (de eerste 24 uur na het begin van het CVA): onder andere de mogelijkheid tot beeldvorming van de hersenen, trombolyse en screening van slikproblemen genieten de hoogste evidentieniveaus;
- Vijf indicatoren hebben betrekking op de acute fase (24-48 uur na het begin van het CVA): opname in een stroke unit, vroege behandeling met trombocytenremmers, vroege revalidatie en/of evaluatie van de mobiliteit worden ondersteund door hoge evidentieniveaus. Er werden lagere niveaus gevonden voor profylaxe van veneuze trombo-embolie en voor het evalueren van de voedingstoestand;

- Zes kwaliteitsindicatoren hebben betrekking op de postacute hospitalisatiefase (vanaf 48 uur na het begin van het CVA): onder andere het elektrocardiogram (ECG) en het monitoren van de parameters van de patiënt (gewicht, bloedsuiker, bloeddruk, koorts, enz.) worden ondersteund door een systematische review. Er is ook een gerandomiseerde gecontroleerde trial over vasculaire beeldvorming;
- Tien indicatoren hebben betrekking op het ontslag uit het ziekenhuis: het coördineren van de thuiszorg en het verschaffen van informatie aan de patiënt/het gezin worden ondersteund door hoge evidentieniveaus afkomstig van systematische reviews. Er werden ook enkele gerandomiseerde trials geïdentificeerd over het vooropstellen van revalidatiedoelstellingen en het voorschrijven van bepaalde medicijnen (anticoagulantia bij atriumfibrillatie, bloeddrukverlagende en cholesterolverlagende middelen).

5.3 Outcome indicatoren

Mortaliteit is de meest genoemde outcome indicator in de literatuur. Andere indicatoren zijn de verbetering van de spraak, de mate van afhankelijkheid, de levenskwaliteit, nosocomiale pneumonie en het aantal heropnames in het ziekenhuis.

6 BESLUIT: WELKE VOORSTELLEN VOOR BELGIË?

6.1 Vier mogelijke scenario's voor de organisatie van stroke units

Net als in andere landen zou de erkenning van stroke units in België onder de verantwoordelijkheid kunnen vallen van een organisatie die afhangt van de federale of gewestelijke overheid of van een privéorganisatie. De betrokkenheid van de beroepsorganisaties blijft nodig om de criteria vast te stellen, bij voorkeur in overeenstemming met de Europese normen.

Wat zijn dan de mogelijk pistes om stroke units te organiseren en te erkennen? Aan de hand van de voorbeelden die we in andere landen zien, kunnen er vier scenario's worden overwogen.

- **Een stroke unit in elk ziekenhuis**

Volgens dit eerste scenario zou aan alle ziekenhuizen gevraagd worden om te voorzien in een stroke unit die voldoet aan bepaalde normen. Een dergelijke organisatie zou ervoor zorgen dat alle patiënten snel toegang hebben tot specifieke zorgen (in tegenstelling tot wat er zou gebeuren in een systeem waar sommige ziekenhuizen worden voorbijgereden - zie hieronder).

Het nadeel van dit scenario is dat het invoeren van een stroke unit aanzienlijke financiële middelen vergt. Het zou ook moeilijk zijn om overal de nodige expertise te verzekeren, evenals de mogelijkheid om 24 uur per dag trombolyse uit te voeren.

- **Zeer gespecialiseerde zorg (hyperacute units) in een beperkt aantal ziekenhuizen**

Een tweede scenario is dat hyperacute units zouden worden erkend in een beperkt aantal ziekenhuizen, die gekozen worden op basis van hun aantal opnames en hun geografische spreiding. Dankzij deze optie zou er heel snel een diagnose gesteld kunnen worden en een trombolyse uitgevoerd kunnen worden, gevolgd door een optimale monitoring, zonder de infrastructuur te moeten vermeervoudigen. Enkele geselecteerde centra zouden kunnen zorgen voor uiterst gespecialiseerde behandelingen, zoals interventionele radiologie of neurovasculaire chirurgie.

De voordelen van deze formule zijn de concentratie van de middelen, een groter behandelingsvolume en dus meer ervaring bij de professionele teams.

De nadelen zijn dat de ziekenhuizen die geen trombolyse kunnen uitvoeren, moeten worden voorbijgereden door de ambulances, waardoor ze hun gedragscode zouden moeten wijzigen, naast de noodzakelijke opleiding van het ambulancepersoneel. Actieve samenwerking met de eerstelijnszorg - en in het bijzonder de huisartsen - zou een ander onmisbaar element zijn in de haalbaarheid van een dergelijk systeem. Bovendien zouden sommige ziekenhuizen zonder hyperacute units de neiging kunnen hebben om patiënten die in hun invloedszone wonen, te behouden. De lange afstanden zouden ook een probleem kunnen vormen voor de families van patiënten die worden overgebracht naar een verafgelegen ziekenhuis. Indien dergelijke units zouden worden toegewezen aan specifieke ziekenhuizen, zou het tot slot kunnen dat de opvangcapaciteit van deze ziekenhuizen van tijd tot tijd overschreden wordt.

- **Hyperacute units, gevolgd door een transfer naar lokale stroke units**

Na enkele dagen behandeling onder monitoring in een hyperacute unit, zouden de patiënten kunnen worden overgebracht naar een stroke unit in de buurt van hun woning (zie organisatie van de London Stroke Services). Deze oplossing zou ook een aanpassing van de ambulancediensten vergen, maar de problemen van de opvangcapaciteit, het verlies van patiënten en de lange afstanden voor de familieleden zouden kleiner zijn.

- **Trombolyse in alle ziekenhuizen, stroke units in enkele ziekenhuizen**

Een laatste optie zou zijn om de trombolyse los te koppelen van de diensten van een stroke unit. In een dergelijk ‘drip and ship’-model zouden alle ziekenhuizen in staat zijn om trombolyses uit te voeren, maar als ze niet over een stroke unit beschikken, zouden ze nadien al hun patiënten met CVA moeten doorverwijzen naar een ziekenhuis dat wel is uitgerust met een stroke unit. Er zou extra op gelet moeten worden dat de trombolyseprocedure werkelijk op elk moment toegankelijk is in alle ziekenhuizen, en dat ze overal veilig verloopt. Een ander nadeel zou zijn dat sommige ziekenhuizen niet het vereiste minimum aantal patiënten zou halen, wat ertoe zou kunnen leiden dat trombolyses worden uitgevoerd in diensten waar het personeel niet over de nodige ervaring beschikt. Ten slotte zou de verplichting om een patiënt door te verwijzen naar een ziekenhuis met een stroke unit direct na de trombolyse - en dus in kritieke toestand - de patiënt kunnen blootstellen aan grote risico's en kunnen leiden tot hoge transportkosten.

Welke optie er ook wordt gekozen, ze moet de nodige incentives bevatten om het principe van opname van alle patiënten in stroke units in te voeren. Het samenwerken tussen ziekenhuizen die verschillende diensten aanbieden is een oplossing om ervoor te zorgen dat alle patiënten toegang krijgen tot hoogwaardige zorg bij CVA en dit in het bestaande netwerk van ziekenhuisvoorzieningen.

6.2 Het is noodzakelijk om de kwaliteit van zorg te registreren

6.2.1 Doelstellingen bepalen

In het kader van deze studie maakten we een uitgebreide inventarisatie op van kwaliteitsindicatoren, met een eerste selectie door experts. Op basis van dit werk wordt voorgesteld om het onderzoek verder te zetten en de belangrijkste kwaliteitsindicatoren voor acute zorgen bij CVA te selecteren. Er moeten bijkomende stakeholders betrokken worden bij het selectieproces, meer bepaald de vertegenwoordigers van de ziekenhuizen en patiëntenorganisaties.

Maar de uiteindelijke keuze van de indicatoren zal in de eerste plaats afhangen van de doelstellingen die voor het kwaliteitssysteem worden vooropgesteld:

- Als men een monitoring op nationale schaal beoogt van de doeltreffendheid van de zorg die verleend wordt aan patiënten met CVA (zoals dit gebeurt in andere landen), dan moeten bepaalde patiëntengegevens gemakkelijk verkregen kunnen worden via administratieve databanken. Deze monitoring vereist een betrouwbaar, permanent en gecentraliseerd registratiesysteem (zie Zweden).
- Als er een erkenningsprocedure moet worden ingevoerd, moeten er ook andere kwaliteitsindicatoren in worden opgenomen, zoals het gebruik van zorgprotocollen, strategieën voor opleiding van het personeel ter plaatse en oplijsting van het personeelskader.
- Als benchmarking tussen ziekenhuizen moet worden gestimuleerd, moet er een reeks zeer gestandaardiseerde kwaliteitsindicatoren worden ontwikkeld met een duidelijke omschrijving van de tellers en noemers (waaronder bijvoorbeeld het meten van de tevredenheid van de patiënten met een gestandaardiseerd instrument). In zo'n situatie is het ook belangrijk om rekening te houden met de heterogeniteit van de patiëntprofielen (case-mix correctie).
- Ten slotte kunnen andere reeksen indicatoren nuttig zijn voor het ziekenhuis om zijn eigen prestatieniveau te monitoren op lange termijn en interne feedback te kunnen geven.

In dezelfde logica vormt de keuze van de cut-offwaarden ook een belangrijk punt. Er werden immers weinig cut-offwaarden gevonden in de literatuur en de keuze ervan steunt niet altijd op wetenschappelijke bewijzen (bv. aantal bedden, aantal complicaties).

Een kwaliteitsregistratiesysteem zal bovendien duidelijk maken welke informatie nodig is om rekening te kunnen houden met de patiëntprofielen, de termijnen voor procedures, het gebruik van de middelen binnen het ziekenhuis, maar ook de gegevens over behandeling met geneesmiddelen.

Het harmoniseren van de kwaliteitsindicatoren voor stroke units staat ook op de agenda van de European Stroke Organisation (ESO).

6.2.2 De gevolgen bepalen

Voordat de gegevensinzameling wordt geïmplementeerd, moeten de belangrijkste stakeholders het eens worden over het mogelijke gebruik van deze gegevens:

- Erkenning van stroke units;
- Feedbacksysteem om de zorgkwaliteit te verbeteren (met eventuele steun van de academische wereld, wetenschappelijke organisaties en privébedrijven);
- Officiële publicatie, zoals dat ook gebeurt in andere landen, met de onvermijdelijke risico's wat betreft interpretatie van de resultaten (bv.: vertekende resultaten als gevolg van het patiëntenprofiel); deze interpretatie moet ondubbelzinnig zijn;
- Financiële incentives of negatieve gevolgen (financieel verlies, verlies van erkenning);
- Hulp aan minder goed presterende ziekenhuizen, via verbeteringsplannen;
- Rolmodellen: goed presterende ziekenhuizen kunnen hun ervaring delen met ziekenhuizen die minder goed presteren.

6.2.3 Nog enkele voorwaarden voor de implementatie van de procedures om de kwaliteit te meten

Tot slot vereist het invoeren van een systeem dat de kwaliteit meet, dat er een piloottest wordt uitgevoerd om de haalbaarheid van de gegevensinzameling te beoordelen. Ook over het anoniem maken en centraliseren van de gegevens dienen er beslissingen te worden genomen.

Belangrijke outcome indicatoren, zoals invaliditeit, institutionalisering en sterftecijfers na de hospitalisatie vereisen de mogelijkheid om verschillende databases te koppelen bij gebrek aan een systeem van gecentraliseerde gegevensverzameling tijdens het opvolgen van de patiënt.

SCIENTIFIC REPORT

1 BACKGROUND AND RESEARCH QUESTIONS

1.1 Stroke: a public health problem

Stroke is a major problem in Belgium. The estimated crude incidence ranges from 200 to 230 (first ever and recurrent) per 100 000 inhabitants per year[1] and hospitalization cost of stroke related disorders was estimated around 191.6 million euro in 2007[2].

Stroke carries remarkable risk of mortality and long-term disability. In 2002, 5.5 million people died of stroke, which accounted as 10% of total deaths worldwide[3]. Sixty percent of those who suffer a stroke die or become dependent even where advanced technology and facilities are available, placing a burden on family and community. In the UK (2000), more than 4% of the National Health Service spending was devoted to stroke services[3].

1.2 Development of stroke units

Traditionally, the care of stroke patients was provided within departments of general medicine, neurology or geriatrics. For a few years “stroke units” have been created. This term refers to organized inpatient care for stroke patients, provided by a multidisciplinary team specialized in stroke management[4].

1.3 Context and scope of this study

1.3.1 Interest of stakeholders for an accreditation procedure

Stroke units exist in Belgium but there is no accreditation procedure to assess their compliance with a set of official standards (e.g. from the guidelines published in the international literature). As a consequence, there is a large variability in the structure, process and probably the quality of care provided to stroke patients. A set of clearly defined quality criteria is therefore required for the accreditation of stroke units to guarantee the quality of care for all stroke patients in Belgium.

The topic of quality of care/rehabilitation for stroke patients has been proposed by a scientific team to the KCE. The disease itself has been selected given its incidence and important sequels. However, the first overview of the literature and contacts with stroke experts highlighted the redundancy of evidence-based guidelines on this topic together with the lack of standardization for the stroke units in Belgium. Therefore the KCE decided to focus on the efficacy and quality indicators for the Belgian stroke units.

A working group from the National Council for hospitals (Conseil National des Etablissements hospitaliers – Nationale Raad voor Ziekenhuisvoorzieningen) began at the same time a work on quality criteria for stroke units to formulate advice to the Government. Members from this group were also involved as experts in this project to share a common scientific knowledge.

1.3.2 Limitation to the acute phase (to 7 days)

The restriction of the scope to the acute care of the patient with stroke relied on different arguments:

- The interest of the stakeholders (clinicians and authorities) consulted at the beginning of the project (see previous paragraph);
- there is less evidence on the organisation of care after the initial phase of the disease;
- the KCE already published many reports on rehabilitation e.g. for stroke patients (see KCE reports 40[5] and 87[6]).

The choice of a 7 days period is based on the criterion used in other researches [7-11].

1.4 Research objective and questions

This study aims to investigate the clinical benefits of stroke units, the quality indicators proposed in the international literature and the organization of stroke units in other European countries.

1. What is the evidence about the impact of admission to acute stroke units on patient outcomes (systematic review and meta-analysis)?
2. Which quality criteria for stroke units are proposed in the literature and what is their underlying scientific evidence (literature review)?
3. How are stroke units organized in other countries? What is the quality assurance process, including the quality criteria (literature review and interviews of experts)?
4. In view of the previous questions, what are the suggestions for the organization of stroke units in Belgium and for the assessment of quality of stroke care?

2 EFFICACY OF STROKE UNITS: SYSTEMATIC LITERATURE REVIEW AND META-ANALYSIS

2.1 Methods

This systematic literature review followed the methodology proposed by the process notes of the KCE "Search for Evidence & Critical Appraisal: Good Clinical Practice". The researchers additionally performed a meta-analysis based on the data from the selected studies.

Prior to commencement of this study, a preliminary literature search identified a Cochrane review on organized inpatient (stroke unit) care by the Stroke Unit Trialists' Collaboration (SUTC)[12], published in 2009. An assessment of this review indicated that it was a good source to identify the randomized controlled trials (RCTs) and controlled clinical trials (CCTs) on the efficacy of stroke unit care (i.e. Research Question 1). The literature search of the Cochrane review was conducted in April 2006: it included all published and unpublished RCTs and prospective CCTs comparing organized inpatient stroke care with alternative care.

The scope of the Cochrane review was somehow broader than that of this study. The Cochrane review included all types of stroke units irrespectively of their pattern of organization (i.e. mobile stroke team or mixed rehabilitation ward) or the type of stroke patients who received care in these units (i.e. acute stroke patients or post-acute stroke patients). Therefore the researchers of this study used this review to identify stroke unit trials published before 2006 and they only selected the trials with a clear focus on acute stroke patients who were treated in an environment which fits the strict definition of acute stroke unit (see before).

A complementary search in the index literature identified the trials published after 2006.

2.1.1 Inclusion and exclusion criteria

2.1.1.1 Population

The patient population group under investigation are acute stroke or stroke-like patients who had their first symptoms during the past 7 days prior to hospital admission i.e.:

- Patients admitted to hospital for suspected or confirmed recent stroke. The clinical definition of stroke is in line with SUTC: focal neurological deficit due to cerebrovascular diseases, excluding subarachnoid haemorrhage and subdural haematoma.
- Patients with recent onset of transient ischemic attack (TIA) or other cerebrovascular diseases, as the diagnosis of stroke may be not certain at the admission to the hospital.

The word "acute" allows distinguishing acute stroke unit from other modalities of care, after the acute phase of stroke. In this study, the investigation of the pathway of stroke care is continued until patients are discharged from stroke unit, which varies between 7 days to more than one month.

2.1.1.2 Intervention: eligibility criteria for stroke units

The definition of stroke unit care in this study is the one proposed by the Belgian Stroke Council, inspired[13]: "a geographic location within the hospital designated for stroke and stroke-like (i.e. with whom the neurological diagnosis has been be clearly established yet) patients, staffed by a multidisciplinary team (medical, nursing, physiotherapy plus occupational and speech or language therapists, case manager or discharge planner or social worker) with a special interest and expertise in stroke care". This definition was adapted from the definition used in the 2000 Cochrane review on stroke units[14].

The following ways of organizing inpatient care for stroke fit into this definition:

- Acute stroke units: they admit patients in the acute phase but discharge early (usually within seven days). They fall into three broad subcategories:
  - intensive stroke units (a model of care with continuous monitoring, high nurse staffing levels and potential for life support),
  - semi-intensive stroke units (a model of care with continuous monitoring, high nurse staffing but no life support facilities),
  - 'non-intensive' units (a model of stroke care without continuous monitoring or life support).
- Comprehensive stroke unit: they admit patients in the acute phase but also provide rehabilitation for at least one week if necessary.

This definition excludes three types of inpatient services (the 2 first ones might be comparators if the patient is transferred within 7 days):

- Mixed rehabilitation ward: a multidisciplinary team including specialist nursing staff in a ward providing general rehabilitation, for stroke and non stroke patients;
- Mobile stroke team: a multidisciplinary team (excluding specialist nursing staff) providing care in a variety of settings (for example internal medicine wards, geriatric wards).
- Rehabilitation stroke units: they usually accept patients after the acute phase.

2.1.1.3 Comparators

Comparators of stroke unit care consist of inpatient care starting from the acute phase as for example internal medicine, neurology, cardiology, geriatric wards or other patterns of organization of care (like a mobile stroke team).

Mixed rehabilitation wards (for stroke and non stroke patients) and rehabilitation stroke units do not fit as comparators because they admit patients in the post-acute phase.

The initial research question was whether stroke unit can improve outcomes compared with the contemporary conventional care. However, the most recent trials have addressed comparisons between a usual stroke unit and a stroke unit with additional services (for example with a specific protocol). The research question and analysis have been expanded to include these new study designs.

2.1.1.4 Outcomes

Primary and secondary outcomes are in line with those listed in the 2009 Cochrane review: no specific restriction has been given on the duration of the intervention or the observation period, as long as patients have been admitted to stroke unit within seven days of stroke symptoms onset.

- Primary outcomes are those reported at the end of scheduled follow up of the trial:
  - Death by the end of scheduled follow up;
  - Composite outcome: death or institutional care (care in a residential home, nursing home, or hospital) by the end of scheduled follow up;
  - Institutional care by the end of scheduled follow up;
  - Composite outcome: death or dependency by the end of scheduled follow up;
  - Dependency by the end of scheduled follow up.

However, for long-term studies (follow up longer than two years), the primary analysis incorporates the outcomes reported after one year, for the sake of comparability. In this case the long-term outcomes will be presented separately.

"Independency" was defined as the absence of need for physical assistance for daily activities (transfers, mobility, dressing, feeding or toileting). The criteria for independency were approximately equivalent to a modified Rankin score of 0 to 2, or a Barthel Index sum score of more than or equal to 90 out of 100[15, 16] (see Table 1 and 2)[17].

The scales mentioned here are illustrations of the tools used in some studies. The use of Barthel Index to measure the clinical improvement of stroke patients remains controversial. Some “ceiling effect” has been noted with Barthel Index: the maximum score can be achieved in many disabled patients[15]. Those discussions fall outside the scope of this study that reports the numbers of dependent patients as reported by the trials, irrespective of the scales used.

Table 1: Modified Rankin Scale

Score	Description
0	No symptoms
1	No significant disability, despite symptoms; able to perform all usual duties and activities
2	Slight disability; unable to perform all previous activities but able to look after own affairs without assistance
3	Moderate disability; requires some help, but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent, and requires constant nursing care and attention

Sulter G, Steen C and De Keyser J. Use of the Barthel Index and Modified Rankin Scale in Acute Stroke Trials. Stroke 1990; 30: 1538-1541.

Table 2: Barthel Index

Item	Description	Score	
		With Help	Independent
1	Feeding (if food needs to be cut up = help)	5	10
2	Moving from wheelchair to bed and return (includes sitting up in bed)	5-10	15
3	Personal toilet (wash face, comb chair, shave, clean teeth)	0	5
4	Getting on and off toilet (handling clothes, wipe, flush)	5	10
5	Bathing self	0	5
6	Walking on level surface (or if unable to walk, propel wheelchair) *score only if unable to walk	10 0*	15 5*
7	Ascend and descend stairs	5	10
8	Dressing (includes typing shoes, fastening fasteners)	5	10
9	Controlling bowels	5	10
10	Controlling bladder	5	10
Sum score			100

For further explanation on each item, please refer to Mahoney F and Barthel DW. "Functional Evaluation: the Barthel Index". M aryland State Medical Journal 1965; 14: 56-61.

- Secondary outcome measures include:
  - Patient quality of life using validated scales,
  - Length of stay in hospital or institution or both.

Studies only reporting laboratory or other outcomes without direct clinical relevance were excluded.

2.1.1.5 Language

Databases were searched for publications in English, French, Dutch or German.

2.1.1.6 Study design

The review included randomized and prospective controlled trials identified in the Cochrane review[12] or published after 2006 in the indexed literature.

2.1.2 Literature search strategy

Indexed database search was carried out in the following databases:

- Cochrane Central Register of Controlled Trials (CENTRAL)
- OVID Medline
- OVID EMBASE
- PEDRO

Clinical Trials.gov and the WHO International Clinical Trials Registry Platform were additionally used to identify ongoing trials. All searches were restricted to studies published after 2006.

The search strategies are in the supplement (chapter 1).The list of ongoing trials is in the chapter 4 of the supplement.

2.1.3 Selection of studies

The selection of studies involved two levels of screenings both performed by two independent reviewers (YS and JM):

- Level I screening on titles and abstracts
- Level II on full text of all papers passed Level I screening.

All disagreement and arbitration was resolved by a third reviewer (OS). A flow diagram (see 2.2.1) summarizes the number of articles identified at each stage of the search process with the main reasons for exclusion.

2.1.4 Assessing methodological quality and risk of bias

The SIGN (Scottish Intercollegiate Guidelines Network) criteria (e.g. randomization, concealment, blinding) ware used to assess the risk of bias in each study. The results of the quality appraisal are in the supplement, chapter 2.

The GRADE system was further used to assess the risk of bias for a group of studies that referred to the same outcome (in the part on quality indicators see 3.2).

The quality appraisal was performed independently by two reviewers. A third reviewer has been involved for arbitration in case of disagreement.

2.1.5 Data extraction

A specifically designed data extraction template (DET) has been developed to summarize key design features and results.

The assessment of risk of bias and data extraction was performed from eligible publications by a reviewer into a pre-prepared Excel® spreadsheet. A second reviewer reviewed the publication in full in order to check the extracted information and to check for any available information that had not been extracted by the first reviewer. Any discrepancies were resolved through discussion with an independent third party.

The DET (see supplement, chapter 3) captured the following information:

- Study reference
- Study type/methods
- No of participants
- Characteristics of participants
- Intervention (definition of “stroke unit”)
- Follow-up period
- Outcomes reported

Key information from DET was synthesized into a "Summary of Findings" table with the following items reported per outcome parameter:

- Outcome
- Number of participants (number of trials)
- Control group risk (range)
- Intervention group risk (range)
- Relative effect (95% confidence interval)
- Quality of the evidence (GRADE)

For identified ongoing trials, only brief information was extracted.

2.1.6 Evidence synthesis

Meta-analysis was performed in line with the latest Cochrane review on stroke unit care. Meta-analysis is a statistical procedure that pools the results of several independent studies considered to be "combinable". Well conducted meta-analyses allow a more objective appraisal of the evidence than traditional narrative reviews, provide a more precise estimate of a treatment effect, and may explain heterogeneity between the results of individual studies.

Two models which are frequently applied in meta-analysis: the fixed effect model and random effect model. In both models, the weight of a study is calculated based on the inverse of the variance of the study estimate ("the within-trial variance"). But in the random effect model, weight of each individual study will be decreased with the increasing level of variability of the effect size of the underlying studies ("the between-trial variance"). The decision on the model is dependent on the level of heterogeneity among included trials.

In this study, dichotomous outcomes were analyzed as the odds ratio (OR) with 95% confidence interval of an adverse outcome. Continuous outcomes such as length of stay in hospital or institution were analyzed as standardized mean difference with random effects. Fixed-effect model was applied unless there was statistically significant heterogeneity, in which case results were confirmed using a random-effect model. Only pair-wise (i.e. head-to-head) comparison was applied on selected outcomes.

2.2 Results

2.2.1 Overview of the search results

2.2.1.1 Number of included studies

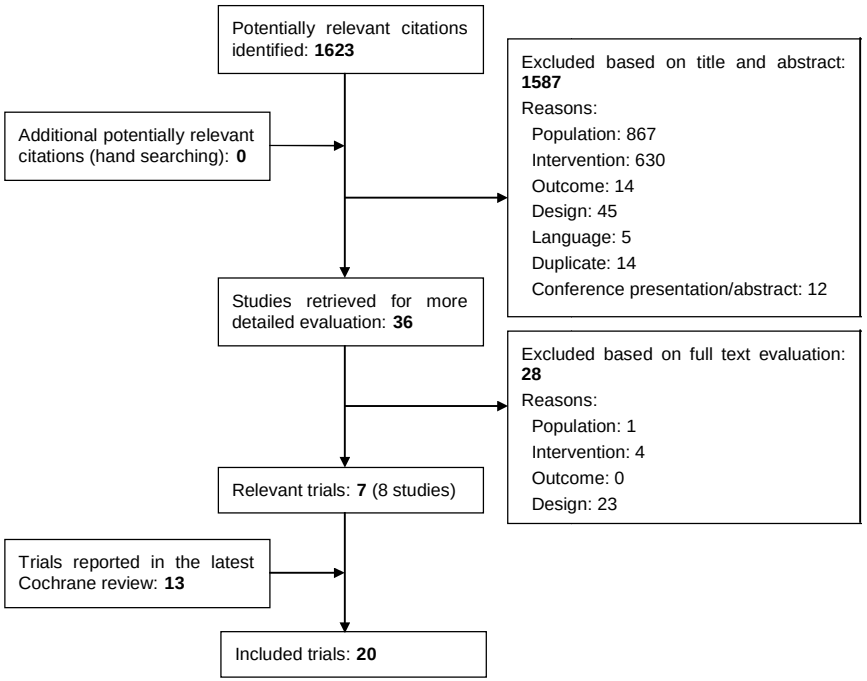
The systematic literature search performed in November 2011 identified 1623 citations on the topic of stroke unit care. Supplementary search on reference list of international guidelines on stroke care (NICE clinical guideline 68 2008; Canadian Stroke Strategy 2010) yielded no new reference. Most citations have been excluded after the first screening based on title and abstract. The full texts of 36 citations have been retrieved and assessed, resulting in eight relevant studies (seven trials) at the end.

Trials published before 2006 were identified from the latest Cochrane review on stroke unit care[12]. Seventeen trials were identified as relevant based on the criteria on population (acute stroke or stroke-like patients) and intervention (stroke unit as defined in 0). Out of those trials, four had to be excluded due to irretrievable unpublished data or publication presented in a language other than English, Dutch, French or German, resulting in 13 trials being included in the analysis. Therefore in total 20 trials were included in this study to analyze clinical efficacy of stroke unit (see Figure 1):

- 13 published before 2006 from the Cochrane review,
- 7 published after 2006 from further search in electronic databases.

All evidence tables and results of quality appraisal can be found in the supplement (chapters 2 and 3).

Figure 1: Flow chart of systematic review on clinical efficiency of stroke unit care



2.2.1.2 Characteristics of included studies

Most of the trials included in the study are randomized controlled trials (N=14). Of the 20 included trials (see Table 3 below):

- 12 compared stroke unit with alternatives (general medical ward or mobile stroke team),
- 5 trials compared stroke unit with specific protocol on certain procedure versus conventional stroke unit,
- 3 trials investigated stroke unit followed by specific intervention versus stroke unit followed by conventional care. Trials with different intervention groups are summarized.

Table 3: Summary of included trials

First category of comparison	Second category of comparison	Included trials (study type, quality of study)
I. Stroke unit versus alternatives (12 trials)	Acute stroke unit versus general medical wards (4 trials)	• Goteborg-Sahlgren[8] (RCT, high) • Stavem and Rønning 2007[18] (CCT, low) • Akershus[19] (CCT, low) • Athens[20, 21] (RCT, low)
	Comprehensive stroke unit versus general medical wards (7 trials)	• Beijing[22] (RCT, low) • Perth[23] (RCT, moderate) • Trondheim [10, 24, 25] (RCT, moderate) • Joinville[26] (RCT, low) • Edinburgh [27, 28] (RCT, low) • Umea[29] (CCT, low) • Stockholm[30] (CCT, low)
	Comprehensive stroke unit versus mobile stroke team (1 trial)	• Orpington 2000 [31] (RCT, high)
II. Stroke unit with specific protocol versus conventional stroke unit (5 trials)	Stroke unit with very early rehabilitation (2 trials)	• Langhorne 2010[11] (RCT, high[2]) • AVERT [32, 33] (RCT, moderate)
	Acute stroke unit with fever, hyperglycaemia and swallowing management (1 trial)	• Middleton 2011[34](RCT, high)
	Stroke unit with continuous monitoring (3 trials)	• Langhorne 2010[11] (RCT, high) • Groningen[35] (RCT, moderate) • Pavia[36] (CCT, low)
III. Stroke unit followed by specific intervention versus followed by conventional care (3 trials)	Stroke unit followed by early supported discharge (ESD) (2 trials)	• Fjærtoft 2011[9] (RCT, moderate) • Aksim 2006[7] (RCT, moderate)
	Stroke unit followed by intensive motor training (IMT)	• Aksim 2010[37] (RCT, moderate)

[2] Caution: the quality appraisal did not mention the very small sample size (N=32), not powered to test efficacy

- Population

The sample size of included trials varies from 32[11, 30] to 1126[34]. For the studies which specified their patient population, four trials investigated stroke unit care on elderly patients[8, 18, 19, 28, 29] and three[20, 21, 23, 36] only included first-ever stroke patients. In addition, one trial[35] had the specific patient population of ischemic hemiparetic stroke patients, one trial[31] with moderately severe stroke patients and one[30] with suspected acute cerebrovascular disease (TIA and stroke). The AVERT trial[32, 33] only included patients with pre-morbid modified Rankin Scale score less than 3. Remaining trails had no clear mentioning of the patient population as inclusion criterion.

- Disease

The definition of stroke varied between the trials. Earlier trials (published before 2006) had as most commonly cited definition 'an acute focal neurological deficits of no apparent cause other than that of vascular origin'[24]. In more recent trials, the most popularly cited definition is the WHO (World Health Organization) definition of stroke ('A stroke is caused by the interruption of the blood supply to the brain, usually because a blood vessel bursts or is blocked by a clot').

- Outcomes

Most trials used mortality, dependency and need for institutional care as primary outcomes. Four studies focused on other outcomes: improvement on balance[3] [7,37], walking[7,33] and quality of life[18]. Outcomes had been assessed at different time points after admission in a stroke unit: the shortest follow-up was the discharge point[22], the longest one ten years after discharge[10].

For detailed information on the individual trials, please refer to supplement, chapter 3.

[3] Balance was measured by the Berg Balance Scale (BBS) with a maximum score of 56. Balance was dichotomized into good balance (BBS ≥ 45) versus poor balance and increased risk of falling (BBS < 45).

2.2.1.3 *Efficacy of stroke unit: main analysis*

The main analysis is conducted on the basis of categories of stroke units summarized in 2.1.1.2. The researchers cross-checked the data presented in the latest Cochrane review with the data reported in the original trials. In case of discrepancy, they used the data published in the original publication. Additional data mentioned in the Cochrane review but not reported in the original publication were also included.

Pooled analysis has been performed on the following levels:

- stroke unit versus general medical ward with two additional analyses by subgroups:
  - o acute stroke unit versus general medical ward,
  - o comprehensive stroke unit versus general medical ward,
- stroke unit combined with automated monitoring versus standard stroke unit.

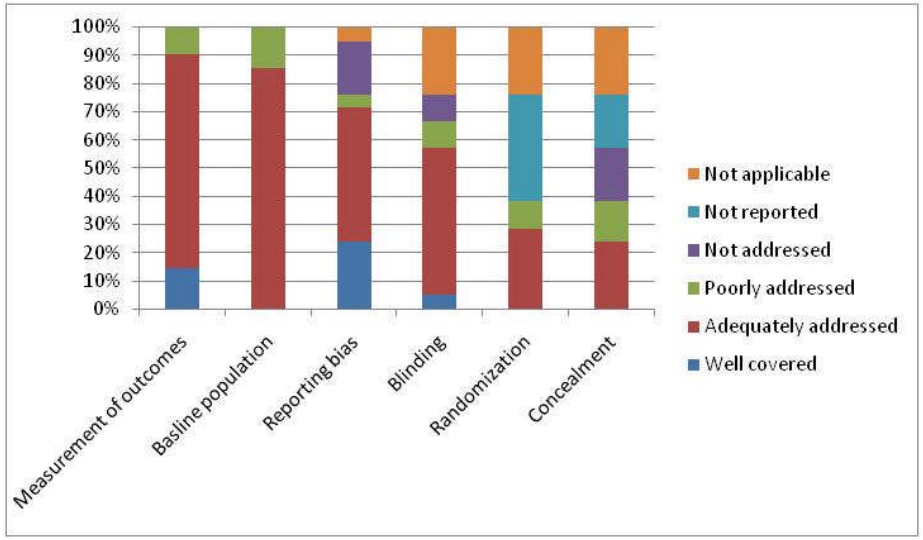
2.2.1.4 *Study quality*

Overall study quality is moderate among 20 included trials (high: 4, moderate: 7, low: 9).

- In general, outcome assessment and baseline population characteristics were well addressed in the included trials.
- Randomization or concealment is found poorly addressed or not reported in a substantial proportion of trials (see Figure 2). Block randomization was used frequently in the studies, but only very few studies reported the method to generate random series. In most cases, concealment was carried out by using sealed opaque envelopes (serially numbered or not).

For detailed description of quality assessment, please refer to the supplement, chapter 2.

Figure 2: Overall quality of included trials



2.2.2 *Efficacy of stroke units: stroke unit versus alternatives*

This section presents the findings concerning the efficacy of stroke units versus general medical ward. The efficacy of stroke unit versus mobile team is addressed separately at the end of this section 2.2.2.5.

Pooled analysis is performed on nine trials, excluding 3 trials:

- Orpington 2000[31] was the only one which compared stroke unit versus mobile stroke team, therefore cannot be pooled together with other trials that compared stroke unit and general medical ward.
- Beijing[22] and Stockholm[30] trials were excluded due to their short observation period (till end of discharge from stroke unit or general medical ward).

Forests plot of meta-analysis can be found in the section 5.1.of the supplement. For the details of the trials, please refer to the supplement, chapter 3.

2.2.2.1 *Stroke unit versus general medical ward: impact on six outcomes*

All endpoints included in the analysis have been reported between six months and 13 months after patients' enrolment.

Outcome 1: death by the end of scheduled follow up

Case fatality recorded at the end of scheduled follow up period (ranging between three weeks to 13 months) was lower in the stroke unit intervention group in nine out of the nine included trials.

Pooled benefit of stroke units is placed just on the bottom line of being significant, with estimated odds ratio of 0.84 (95% CI 0.71 to 1.00, P=0.05). Heterogeneity is not significant among pooled studies (I^2=0%, P=0.95).

The result is not significant within subgroups (smaller populations) but the effect is similar between acute and comprehensive stroke units:

- odds ratio of acute stroke unit versus general medical ward: 0.86 [95% CI 0.69 to 1.08, P=0.20];
- odds ratio of comprehensive stroke unit versus general medical ward: 0.81 [95% CI 0.61 to 1.06; P=0.12].

The benefit of stroke unit in reducing mortality just reaches significant level but such significance does not remain when analyzing the benefit of acute stroke unit and comprehensive stroke unit individually.

Outcome 2: death or institutional care by the end of scheduled follow up

By the end of scheduled follow up, more death or institutional care were recorded in general medical wards than in stroke units in ten out of the nine trials included in the analysis. Overall odds ratio is 0.70 (95% CI 0.60 to 0.83; P<0.0001) for stroke unit versus general medical ward with low indication of heterogeneity (I2= 0%, P=0.45).

In the subgroups treatment benefit of stroke unit remains significant:

- acute stroke unit: OR 0.77 [95% CI 0.62 to 0.96; P=0.02];
- comprehensive stroke unit: OR 0.61 [95% CI 0.47 to 0.79; P=0.0002].

Pooled analysis indicates that there is a clear benefit of both acute and comprehensive stroke units on reducing the chance of death or institutional care compared to general medical wards.

Outcome 3: institutional care by the end of scheduled follow up

Stroke unit care is related to significant reduction on institutionalization compared to general medical ward care, with a pooled odds ratio of 0.61 (95%CI 0.47 to 0.79; P=0.0002). This significant improvement remains when breaking down into subgroups:

- acute stroke unit: OR 0.69 (95% CI 0.48 to 0.98; P=0.04);
- comprehensive stroke unit: OR 0.53 (95% CI 0.36 to 0.77; P=0.001).

Outcome 4: death or dependency by the end of scheduled follow up

The effect of stroke unit on death or dependency appears to be significantly favourable when including all types of stroke units and in the subgroup "comprehensive stroke unit care". For all types of stroke units, the overall treatment effect is estimated at an odds ratio of 0.81 (95% CI 0.69 to 0.96; P=0.01; (I2= 36%, p=0.13).

In sub-group analyses:

- acute stroke unit: OR 0.93 (95% CI 0.75 to 1.16; P=0.52);
- comprehensive stroke unit: OR 0.67 (95% CI 0.51 to 0.86; P=0.002).

Outcome 5: dependency by the end of scheduled follow up

In terms of impact on dependency only, the benefit of stroke unit is not significant.

Patients treated in comprehensive stroke unit are more likely to be independent than patients treated in acute stroke units but both groups failed to achieve the significance threshold (P=0.05). The pooled odds ratio for acute stroke unit and comprehensive stroke unit is 1.11 (95% CI 0.83 to 1.50; P=0.47) and 0.75 (95% CI 0.55 to 1.01; P=0.06). The overall pooled odds ratio for all types of stroke unit is 0.92 (95% CI 0.74 to 1.13; P=0.42).

Outcome 6: length of stay (days) in a hospital or institution or both

Stroke unit is found to be significantly related to reduced hospital or institutional stay. Mean length of stay was respectively 28.8 days (median: 21 days) in stroke units and 40 days (median: 31 days) in general medical wards. Pooled analysis indicates an estimated standardized mean difference of -0.27 day (95% CI -0.36 to -0.19; P<0.00001) for stroke unit compared to general medical ward. There is no clear indication on heterogeneity among pooled trials (I2=0%, P=0.43). The difference between mean reduction (11.2 days) and standardized mean reduction (0.27 day) on length of stay can be explained by the weight of studies included in the analysis. For instance, the trial with the highest weight (26.5%) is Athens. In this trial, the mean reduction on hospital with stroke unit was only 0.87 day. And also by applying standardized mean difference, the difference on treatment effect has already been diminished to certain extent, compared to mean difference.

The significant difference remains stable when analysis is restricted to sub-groups:

- acute stroke unit: -0.23 [95% CI -0.34 to -0.13; P<0.0001];
- comprehensive stroke unit: -0.33 [95% CI -0.46 to -0.20; P<0.00001].

Outcome 7: quality of life

No pooled analysis could be performed on quality of life scores because the studies deployed different scales.

- Stavem and Rønning 2007[18] reported no significant improvement on quality of life with acute stroke unit on SF-36 scale on patients over 60 years.
- Goteborg-Sahlgren[8] found similar results by using Nottingham Health Profile.

Positive effect of stroke unit on quality of life has been observed by Trondheim[17-19] trial on Visual analogue scale (VAS) and Nottingham Health Profile score (Table 7).

Based on evidence from published literature, the improvement on quality of life with stroke unit remains uncertain. It seems that comparative treatment benefit of stroke unit is somehow dependent on the scale which has been used to elicit quality of life scores. For instance, by using VAS measurement, the incremental improvement on quality of life with stroke unit appears to be much more significant than that on SF-36 scales.

Table 4: Summary of findings – Stroke (acute and comprehensive) unit versus general medical ward

Outcome	# of patients (# of trials)	Intervention group risk (range)	Control group risk (range)	Odds ratio [95% CI]	P value	GRADE rating	Comments
Death by the end of scheduled follow up	2685 (9)	26.4% (8 - 39%)	30.4% (10 - 41%)	0.84 (0.71 - 1.00)	0.05	Low	Generally high risk of bias; likely publication bias
Death or institutional care by the end of scheduled follow up	2360 (8)	37.8% (21 - 46%)	47.0% (31 - 57%)	0.70 (0.60 – 0.83)	<0.0001	Moderate	Generally high risk of bias; likely publication bias; large effect
Institutional care by the end of scheduled follow up	2286 (7)	9.2% (1 – 15%)	14.1% (6 – 27%)	0.61 (0.47 – 0.79)	0.0002	Moderate	Generally high risk of bias; likely publication bias; large effect
Death or dependency by the end of scheduled follow up	2356 (8)	49.0% (34 - 66%)	52.9% (39 - 74%)	0.81 (0.69 – 0.96)	0.01	Low	Generally high risk of bias; likely publication bias
Dependency by the end of scheduled follow up	2360 (8)	20.0% (8 – 38%)	19.5% (8 – 42%)	0.92 (0.74 – 1.13)	0.42	Low	Generally high risk of bias; likely publication bias
Length of stay in a hospital or institution or both (in days)	2667 (9)	Mean: 28.9 (7.7 - 75)	Mean: 40.0 (8 - 123)	Standardized mean difference: -0.27 (-0.36 to -0.19)	<0.00001	Moderate	Generally high risk of bias; large effect

Table 5: Summary of findings – Acute stroke unit versus general medical ward

Outcome	# of patients (# of trials)	Intervention group risk (range)	Control group risk (range)	Odds ratio [95% CI]	P value	GRADE rating	Comments
Death by the end of scheduled follow up	1728 (4)	24.7% (8 - 34%)	27.2% (10 - 40%)	0.86 (0.69 - 1.08)	0.20	Moderate	Generally high risk of bias
Death or institutional care by the end of scheduled follow up	1403 (3)	36.8% (35 – 39%)	42.9% (41 – 46%)	0.77 (0.62 - 0.96)	0.02	Moderate	Generally high risk of bias
Institutional care by the end of scheduled follow up	1403 (3)	8.5% (1 - 15%)	11.3% (6 -18%)	0.69 (0.48 – 0.98)	0.04	Moderate	Generally high risk of bias
Death or dependency by the end of scheduled follow up	1399 (3)	47.4% (38 – 66%)	46.7% (39 – 67%)	0.93 (0.75 - 1.16)	0.52	Moderate	Generally high risk of bias
Dependency by the end of scheduled follow up	1403 (3)	18.9% (12 – 38%)	14.9% (8 – 42%)	1.11 (0.83 – 1.50)	0.47	Moderate	Generally high risk of bias
Length of stay in a hospital or institution or both (in days)	1728 (4)	Mean: 14.3 (7.7 - 28.3)	Mean: 16.4 (8 - 35.8)	Standardized mean difference: -0.23 (-0.34 to -0.13)	<0.0001	High	Generally high risk of bias; large effect

Table 6: Summary of findings – Comprehensive stroke unit versus general medical ward

Outcome	# of patients (# of trials)	Intervention group risk (range)	Control group risk (range)	Odds ratio [95% CI]	P value	GRADE rating	Comments
Death by the end of scheduled follow up	957 (5)	29.8% (14 - 39%)	35.5% (20 - 41%)	0.81 (0.61 - 1.06)	0.12	Moderate	Likely publication bias
Death or institutional care by the end of scheduled follow up	957 (5)	39.4% (21 – 46%)	52.1% (31 – 57%)	0.61 (0.47 - 0.79)	0.0002	High	Likely publication bias; large effect
Institutional care by the end of scheduled follow up	883 (4)	10.4% (7 – 13%)	18.0% (16 – 27%)	0.53 (0.36 – 0.77)	0.001	Moderate	Likely publication bias
Death or dependency by the end of scheduled follow up	957 (5)	51.7% (34 – 60%)	60.8% (50 – 74%)	0.67 (0.51 - 0.86)	0.002	Moderate	Likely publication bias

Outcome	# of patients (# of trials)	Intervention group risk (range)	Control group risk (range)	Odds ratio [95% CI]	P value	GRADE rating	Comments
Dependency by the end of scheduled follow up	957 (5)	21.9% (8 – 29%)	25.3% (15 – 41%)	0.75 (0.55 – 1.01)	0.06	Moderate	Likely publication bias
Length of stay in a hospital or institution or both (in days)	939 (5)	Mean: 40.4 (11 – 75)	Mean: 58.9 (12.6 – 123)	Standardized mean difference: -0.33 (-0.46 to -0.20)	<0.00001	High	Large effect

Table 7: Summary of change on quality of life (QoL) score from baseline to end of follow up

Trial	QoL scale	Stroke unit (mean ± SD)	General medical ward (mean ± SD)	P
Stavem and Rønning 2007[18] (N=325)	SF-36 physical summary (0-100, a higher score indicates a better level of health)	39.7 ± 11.9	39.7 ± 11.4	0.99
	SF-36 mental summary (0-100, a higher score indicates a better level of health)	53.3 ± 8.7	52.5 ± 8.1	0.53
Goteborg-Sahlgren[8] (N=249)	Nottingham Health Profile (0-100, a higher score indicates a poorer level of health)	23.2	26.0	Not significant
Trondheim[17-19] (N=148)	Nottingham Health Profile	77.7	63.1	0.0086
	Visual analogue scale (VAS) (0-100, a higher score indicates a better level of health)	72.8	50.7	0.0002

2.2.2.2 *Stroke unit versus general medical ward: impact on death based on RCTs only*

The treatment effect is no longer favourable on stroke unit once the analysis is limited to RCTs only (see supplement, section 5.1.7). When controlled clinical trials are given the weight 0%, pooled odds ratio reduced from 0.84 to 0.82 while 95% confidence interval is enlarged from 0.71-1.00 to 0.66-1.02. P value also dropped from 0.05 to 0.07, showing that the estimation of the treatment benefit of stroke unit on mortality can be easily altered with the change on the scope of included studies.

2.2.2.3 *Stroke unit versus general medical ward: long-term effect*

Two studies provide evidence on long-term effect (after five years of discharge from hospital or longer) of stroke unit in comparison with general medical ward (see supplement, section 5.1.8). Some results are significant but the interpretation should be cautious, since the long term effect of the second trial had not been found in the first one.

- Athens trial[20, 21]

The mortality was reported to be 54.0% and 57.9% for patients who were enrolled to stroke unit and general medical ward at five-year follow up (n=608). After 6.5 years of stroke, mortality has increased to 60.9% for stroke unit patients and 62.9% for general medical ward patients. Benefit of stroke unit was significant at five years' follow up (P=0.015) but turned out to be not significant after six and a half years' of stroke onset (P=0.148).

- Trondheim trial[10]

The differences on mortality between stroke unit patients and general medical ward patients were more significant at the long term (n=220).

- Mortality at five years after stroke was 59.1% and 70.9% among intervention and control arm (P=0.041).
- After 10 years follow up, benefit on mortality of stroke unit increased to 75.5% versus 87.3% (P=0.0082).

2.2.2.4 *Stroke unit versus general medical ward: impact of observation period*

In order to explore the impact of observation period on treatment efficacy of stroke unit care, secondary subgroup analysis has been conducted on four non-composite primary endpoints (death, institutional care, dependency and length of hospital stay) stratified by duration of follow up period, with and without the two short-term trials (Beijing and Stockholm) mentioned previously (see supplement, section 5.1.9).

In general, the efficacy of stroke unit care does not significantly vary among subgroups with different follow up periods. The analysis indicates significant differences among subgroups on two endpoints: institutional care (P=0.005 for test on subgroup difference) and length of hospital stay (P=0.006 for test on subgroup difference). For both endpoints, test on subgroup differences only exist when the two short-term trials (Beijing and Stockholm) are included. When these two trials are excluded from the analysis, subgroup difference on treatment effect no longer exists.

2.2.2.5 *Comprehensive stroke unit versus mobile stroke team*

The Orpington 2000 trial[31] compared the efficacy of stroke unit with mobile stroke team and home care[4] on 457 patients with moderately severe stroke (who could be supported at home with nursing, therapy, and social services). This randomized controlled trial has blinded outcome assessment at three time points: three months, six months and twelve months.

Stroke unit was found to be more effective than a specialist mobile stroke team in reducing mortality, institutionalization, and dependency.

Odds ratio of stroke unit versus mobile stroke team were estimated to be:

- 0.37 (95% CI 0.21 to 0.66; P=0.001) on mortality,
- 0.46 (95% CI 0.30 to 0.72; P=0.001) on mortality or institutionalization,
- 0.71 (95% CI 0.29 to 1.72; P=0.45) on institutionalization at 12 months.

[4] Outside the scope of this review thus not addressed

2.2.3 Efficacy of stroke unit: stroke unit with specific protocols versus conventional stroke unit

2.2.3.1 Stroke unit with very early mobilization (VEM)

Very early mobilization (VEM) is defined as getting patients out of bed within 24 hours of stroke[32, 33]**:** *"Mobilization commences as soon as practical after recruitment, with the goal of first mobilization within 24 hours of stroke symptom onset. VEM continues daily for the first 14 days after stroke or until discharge (whichever is sooner) and is delivered by a nurse/physiotherapist team as set out in a detailed intervention protocol. The emphasis of VEM was to assist the patient to be upright and out of bed (sitting or standing as able) at least twice per day; in addition to their usual care, 6 days per week (to double the standard care dose)."*

Two trials were identified evaluated the efficacy of stroke units with VEM versus standard stroke unit care:

- AVERT[32, 33] (A Very Early Rehabilitation Trial for Stroke) trial: a randomized controlled trial with blinded outcome assessment on 71 stroke patients with a pre-morbid modified Rankin Scale score <3.
- Langhorne et al trial[11]: an observer-blinded, factorial (2×2) randomized controlled trial on 16 stroke patients.

In the AVERT trial, VEM reduced the time (hours) to the first mobilization after symptom onset (P for absolute risk difference < 0.001), although more patients died in the VEM group (21% versus 9%; P=0.20). In the second (very small) trial, VEM was found to be related to no significant improvement on all outcomes under investigation.

Caution should be taken when interpreting the results as both trials were Phase II trials (safety and feasibility trial with small sample size): therefore the efficacy of VEM remains to be verified by large-scale RCTs. Information on trial design and results can be found in section 3 in the supplement.

2.2.3.2 Acute stroke unit with protocol for the management of fever, hyperglycaemia and swallowing dysfunction

One recently published trial[34] addressed the issue of implementing a protocol to manage fever, hyperglycaemia and swallowing dysfunction in a stroke unit. The QASC trial is a single-blind cluster randomized controlled trial involving 19 acute stroke units in New South Wales, Australia. Randomization and allocation of interventions has been completed on stroke unit level, resulting in 626 patients allocated to intervention group and 500 to control group. Intervention stroke units received an evidence-based treatment protocol for the multidisciplinary management of fever, hyperglycaemia, and swallowing dysfunction for the first 72 hours after admission. It targeted all stroke unit clinicians, focusing on barrier identification, reinforcement of multidisciplinary teamwork, local adaptation, and use of site champions.

Three-month results provided compelling outcomes with the intervention on death and dependency (236 [42%] of 558 patients in the intervention group versus 259 [58%] of 449 in the control group, P=0.002) and quality of life scores (P=0.002 for physical health and P=0.69 for mental health) in favour of the intervention group.

However, randomization on cluster level may have introduced biases - for example, confounding factors related to patient characteristics - although the purpose was to minimize contamination of team building effects of the intervention. Furthermore, patients enrolled to the intervention were found to have higher quality of life (QoL) scores on SF-36 physician health scale (P=0.002).

2.2.3.3 *Stroke unit with versus without continuous monitoring/automated monitoring*

Automated monitoring (AM), or continuous monitoring, has been defined as following:

"The intervention is standard care in a stroke unit and a protocol-driven approach to continuous monitoring. An established commercial system (Welch Allyn Inc.) was used which included ambulatory monitoring. The protocol comprised advice in responding to abnormalities of heart rate or rhythm, blood pressure, temperature, oxygen saturation or blood glucose. Routine monitoring continued for the first three days and could be extended to 7 days if physiological variables were unstable. The patients were afterwards reverted to standard care, where monitoring involved 4-hourly checking of pulse, temperature, oxygen saturation and blood pressure." [11]

- The Langhorne et al trial[11]

This Phase II trial with a very limited sample size (N=16) was not powered to test statistical significance: the results were not included in the analysis.

- The Groningen trial[35]

AM has been provided to patients (N = 272) for at least 48 hours (or longer if required) for cardiac rhythm, blood pressure, body temperature, and oxygen saturation, therefore allowing immediate interventions. After the first 48 hours, monitoring was stopped if the condition of the patient was stable over the last 24 hours.

Results of this trial at three months showed that AM may reduce mortality (3.7% versus 25.9%, OR 0.11, 95% CI 0.02 to 0.96, P=0.05). Caution should be taken when interpreting the results from these two trials as both were pilot trials with very small sample size.

- the Pavia trial

72-hour bedside continuous monitoring was also investigated by the Pavia trial[36] (N=268). In the control arm, blood pressure and heart rate were recorded automatically every four hours during the first three days of hospitalization and four times a day thereafter, while body temperature was measured three times a day. Oxygen saturation, respiratory frequency and ECG were performed on admission to the control arm.

Results showed more "good outcomes" (modified Rankin Scale score of 0-3) at short term (discharge) in the interventional arm, with an estimated odds ratio of 2.63 (95% CI 1.4 to 4.8; P<0.02).

Overall, pooled results of these two last trials suggest positive impact of continuous monitoring in stroke units for all but one outcome:

- Improvement with AM was not significant (OR: 0.53, 95%CI 0.21 to 1.34, P=0.18) on case mortality;
- Estimated odds ratio was 0.50 (95% CI 0.36 to 0.69, P<0.0001) for death or institutional care;
- Estimated odds ratio was 0.40 (95% CI 0.27 to 0.59, P<0.00001) for death or dependency;
- AM was also related to shortened hospital stay (standardized mean difference -1.31 days, 95% CI -2.13 to -0.49, P=0.002).

Detailed information on trial design and results can be found in chapter 3 of the supplement. Forest plot of meta-analysis can be found in section 5.2. in the supplement.

Table 8: Summary of findings – Stroke unit with AM (automated monitoring) versus standard stroke unit

Outcome	# of patients (# of trials)	Intervention group risk (range)	Control group risk (range)	Odds ratio [95% CI]	P value	Quality	Comments
Death by the end of scheduled follow up	354 (2)	4.3% (3.7 – 4.5%)	9.3% (6 – 26%)	0.53 (0.21 – 1.34)	0.18	Moderate	High risk of bias
Death or institutional care by the end of scheduled follow up	322 (2)	20.5% (15 – 48%)	46.0% (42 – 67%)	0.50 (0.36 – 0.69)	<0.0001	High	High risk of bias, large effect
Death or dependency by the end of scheduled follow up	354 (2)	16.8% (15 – 26%)	42.9% (42 – 48%)	0.40 (0.27 – 0.59)	<0.00001	High	High risk of bias, large effect
Length of stay in a hospital or institution or both (in days)	322 (2)	Mean: 12.6 (9.2 – 16)	Mean: 22.5 (17.1 – 27)	Standardized mean difference: -1.31 (-2.13 to -0.49)	0.002	Moderate	High risk of bias

2.2.4 *Efficacy of stroke unit: stroke unit followed by specific intervention versus stroke unit followed by conventional care*

Interventions discussed in this section are applied after discharge from the stroke unit, with a focus on rehabilitation. These trials were initially beyond the scope of this study.

Caution should be exercised in the interpretation of the results of this section as it only describes the trials published from 2006 onwards: the trials on this topic included in the Cochrane review were not considered. The readers specifically interested in the topic of early supported discharge (ESD) will consult the results of the Cochrane review on this topic[38] (see section 2.3.4 for more information).

2.2.4.1 *Stroke unit followed by early supported discharge (ESD) /extended stroke unit service (ESUS)*

Early supported discharge (ESD), or extended stroke unit service (ESUS) is a service provided at home by a mobile team to patient during the first four weeks after discharge from a stroke unit. The mobile team consists of a physiotherapist, an occupational therapist, a nurse and a part-time physician. One of the therapists acts as a case manager for the patient[9]. The intervention places emphasis on early and intensive task-specific exercise therapy in the patients' home[7]. Patients in the control group received ordinary follow-up organized by the primary care system or further inpatient rehabilitation when more long-term rehabilitation was necessary.

Two trials investigated the clinical benefit of ESD/ESUS.

- Askim et al 2006[7] concluded that ESD has no clear effect on balance after one year.
- Fjærtoft et al.[9] conclude that ESD after stroke unit care seem to reduce death (45.8% versus 51.0%, P=0.364), institutional care (7.7% versus 14.6%, P=0.057) and the chances of living at home (46.5% versus 34.4%, P=0.032) five years after stroke (although the effect for the two first outcomes is not statistically significant).

No pooled analysis has been performed on the effect of ESD as the search strategy of this review was not designed to identify the trials on this specific topic.

2.2.4.2 *Stroke unit followed by intensive motor training*

Intensive motor training is a second topic out of scope of this report: the results of one trial retrieved on this topic are for information only. Askim et al.[37] evaluated the effect of intensive motor training after discharge from a comprehensive stroke unit. The patients from the intervention arm received additional weekly sessions of motor training during a period of 8 weeks. The study did not record any improvement in balance or functional outcomes.

2.3 Comparison of the results with other publications

2.3.1 *The Norwegian HTA on stroke unit*

In 2010, the Norwegian Knowledge Centre for the Health Services published Health Technology Assessment report named "Treatment of patients with acute stroke in stroke units (with or without early supported discharge)" (report in Norwegian with key messages and executive summary in English)[39]. This report comprises a systematic review of the literature and meta-analysis on clinical efficacy as well as a health economic analysis of stroke unit care compared with stroke unit care followed by early supported discharge or general medical ward.

2.3.1.1 *Comparison between results*

Three primary endpoints have been analyzed in the meta-analysis comparing acute stroke unit and general medical ward: death, dependency and institutionalization. Therefore it was possible to cross-compare the results of this study with the Norwegian study based on the endpoint death, as dependency and institutionalization were analyzed in combination with death in our study (cf. Cochrane methodology).

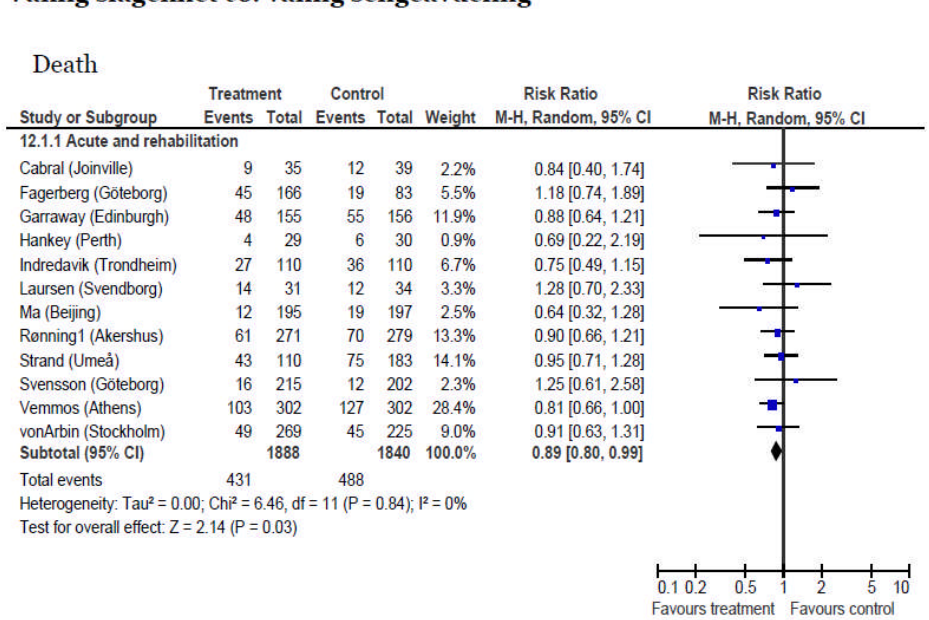
The Norwegian Stroke Unit HTA included 12 trials that have already been captured by the latest Cochrane review.

- Of those 12 trials, two were not included in our analysis due to their unpublished status: Svendborg and Goteborg-Ostra.
- One trial included in our analysis has neither been reported by the latest Cochrane review nor by the Norwegian HTA report: Stavem and Ronning 2007[18].

The Norwegian report results showed that care in stroke unit resulted in significantly lower mortality than care in general medical ward (risk ratio 0.89, 95% CI 0.80 to 0.99, P=0.03).

In this study pooled benefit of stroke units on mortality rate appears to be almost significant, with estimated odds ratio of 0.86 (95% CI 0.73 to 1.01, P=0.06).

Figure 3: Meta-analysis result in the Norwegian HTA report on stroke unit (2010)



2.3.1.2 Further analysis on discrepancy between the Norwegian HTA and the present study

As reported previously, our primary analysis showed no significant improvement at the endpoint “death by the scheduled follow up” if the patients were treated in stroke units.

- New analysis without the additional trial (Stavern and Ronning, 2007)

In order to find out the key parameter having an impact on the statistical significance of the treatment effect, we performed the following analysis (see section 5.3. in the supplement). The Stavem and Ronning trial has been deliberately removed from the analysis (weight equals 0%) for the purpose of cross-comparing. Out of the same intention we applied the same statistical analysis method as that has been reported in the Norwegian report.

The figure in the supplement indicates that pooled result do not present a significant (risk ratio 0.92, 95% CI 0.82 to 1.02) improvement with the two additional unpublished trials included in the analysis. In fact, the result is even less in favour of the interventional arm because both of the two added trials have a relative treatment effect in favour of the comparison arm. They seem not likely to be the reason explaining why the Norwegian analysis could end up with such positive result. Hence another factor should explain the difference.

- Further analysis of the data from the individual trials: discrepancy between reported percentages and estimated corresponding figures

In a last step, the actual data points were cross-checked between the primary studies: two data reporting mismatches in the Cochrane review have been noted.

First, in the Stockholm trial, mortality has been reported as 16% in general medical ward, which should correspond to 36 patients in the general medical ward arm (n=225)[30]. The Cochrane review reported more cases of deaths in the control arm (n=45). The author of the Cochrane review on stroke unit (Peter Langhorne) has been contacted on this matter. He referred to the number of deaths reported in the section “diagnostic investigations” in the Stockholm trial (“autopsies were performed in 45 of the 49 deceased in the SU and in 33 of 45 in the GMW”). However, it was not clearly reported in the trial when these 45 deceased cases were identified. The contact author of this trial is deceased therefore there is no further information available to explain this discrepancy on the number of deaths.

Second, in the Athens trial, number of deaths was 121 in the control arm[21], while in the Cochrane review this number was reported as 127.Peter Langhorne responded that the number of death of 127 was obtained from unpublished data based on intention-to-treat analysis (SU: n=309, GMW: n=308). They will revise the on-treatment population (SU: n=302, GMW: n=302) cited in the current review to intention-to-treat population in the update of their review.

These two data mismatches explain why the pooled results were not corresponding between the Norwegian HTA and the calculations presented in this report. The Stockholm trial has already been excluded from our primary analysis due to the very short follow up. It is difficult to incorporate the number of deaths of 45 into the analysis as the follow up period of this figure is unclear. The use of unpublished data is not well recognized; therefore the authors of this meta-analysis decided to keep the data and conclusions unchanged.

2.3.2 Canadian national stroke strategy

The update of the Canadian Stroke Strategy[40] in 2010, advises that patients with an acute stroke or transient ischemic attack should be treated in an interprofessional stroke unit [Evidence Level A].

This recommendation was mainly based on the evidence from the 2009 Cochrane review on stroke unit discussed above, that reported pooled odds ratio of 0.83 [95% CI 0.71 to 0.96] for stroke unit versus general medical ward, with a significant P value of 0.01.

2.3.3 NICE guideline for diagnosis and initial management of acute stroke and transient ischemic attack

The NICE guidance CG68 on stroke ("Stroke: National clinical guideline for diagnosis and initial management of acute stroke and transient ischemic attack [TIA]", 2008)[41] concluded that *"the relatively low overall mortality rate … may be due to selective entry of patients into trials" and "it was agreed that observational studies may be more representative of the stroke population as a whole"*.

It also stated that "evidence demonstrated that patients admitted to a stroke unit received therapeutic interventions and investigations more appropriately and quickly compared to those in the general medical ward" and "while better process of care are linked to better outcomes there is currently no definitive trial support that these results in a reduction in mortality and morbidity".

Their final conclusion is "there is a need for a randomized trial comparing direct admission to an acute stroke unit versus admission to a medical ward at least while the latter remains standard clinical practice."

2.3.4 Cochrane review on early supported discharge

A Cochrane review on early supported discharge (ESD) has been published in 2009 on the effect of ESD (named as "Service for reducing duration of hospital care for acute stroke patients") [38]. The authors searched the Cochrane Stroke Group's trials register in August 2004 and obtained information from individual trialists, ending up with 11 included trials (1597 patients).

The ESD group showed significant reductions (P<0.0001) in the length of hospital stay equivalent to approximately eight days. Overall, the odds ratios and 95% confidence intervals for death, death or institutionalization, and death or dependency at the end of scheduled follow up were OR 0.90 [95% CI 0.64 to 1.27, P=0.56], OR 0.74 [95% CI 0.56 to 0.96, P=0.02] and OR 0.79 [95% CI 0.64 to 0.97, P=0.02], respectively. The greatest benefits were seen in the trials evaluating a coordinated ESD team and in stroke patients with mild-moderate disability.

Improvements were also seen in patients' extended activities of daily living scores (standardized mean difference 0.12, 95% CI 0.00 to 0.25, P=0.05) and satisfaction with services (OR 1.60, 95% CI 1.08 to 2.38, P=0.02), but no statistically significant differences were seen in carers' subjective health status, mood or satisfaction with services.

The authors therefore conclude that for a selected group of stroke patients, appropriately resourced ESD services can reduce the length of hospital stay, the risk of long term dependency and the risk of admission in institution.

No adverse effect was observed on the mood or subjective health status of patients or their carers.

2.3.5 Individual patient data meta-analysis on very early mobilization after stroke

Craig et al 2010[42] conducted an individual patient data meta-analysis, a solution offers adjustment for variations at a trial level to deal with heterogeneity, based on the data from the two available trials mentioned above (AVERT and Langhorne et al 2010, see 2.2.3.1).

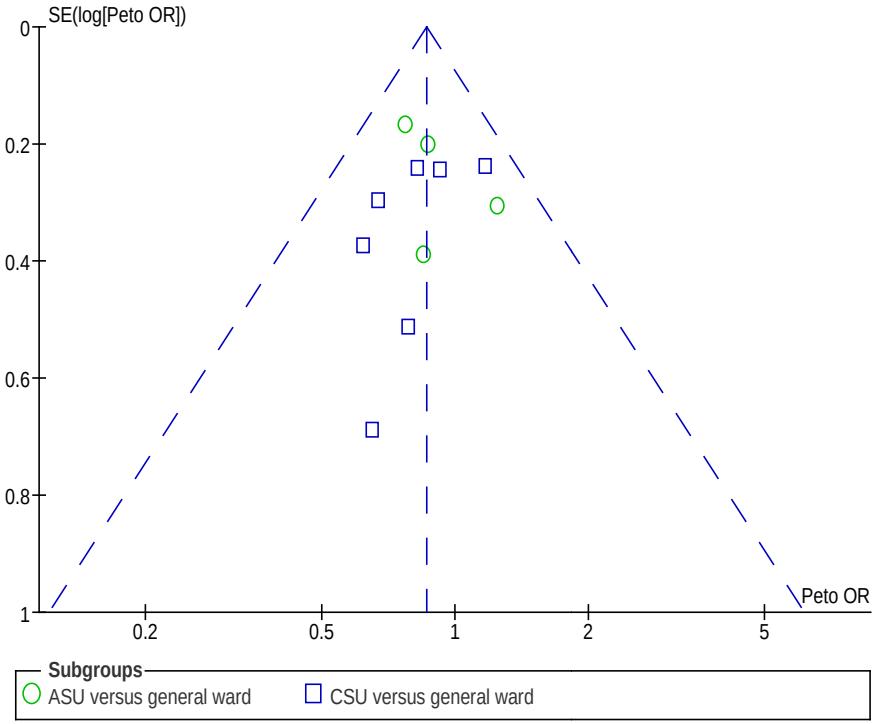
The authors conclude that time to first mobilization from symptom onset was significantly shorter among very early mobilized patients (median: 21 hours, interquartile range: 23.0 to 41.2 hours). Patients in the intervention group had significantly greater odds of independency compared with standard care patients (adjusted odds ratio: 3.11, 95% CI 1.03 to 9.33).

2.4 Possible publication bias

The primary results of this meta-analysis show a favourable treatment effect of stroke unit in comparison with general care on three out of the four primary outcomes. However, funnel plot on outcomes compared implies that this conclusion may be subject to publication bias (the tendency of researchers, editors, and pharmaceutical companies to publish positive findings rather than the negative or inconclusive ones).

Figure 4 shows an example of possible publication bias (on the comparison of stroke unit versus general medical ward, on the outcome 'death by the end of scheduled follow up'). Most of the published trials which have been included in the analysis are located on the left-hand side of the vertical axis (i.e. the side which favours stroke unit on Peto OR): in theory there should be around the same amount of trials spreading equally alongside the central vertical line. Such bias is particularly clear with trials comparing comprehensive stroke unit and general medical wards (blue squares on the funnel plot).

Figure 4: Funnel plot of comparison: stroke unit versus general medical ward (Outcome: death by the end of scheduled follow up)



2.5 Summary: efficacy of stroke units on some outcomes

- **Organized inpatient (stroke unit) care significantly improves patient outcomes in terms of:**
  - **Institutional care,**
  - **death or institutional care,**
  - **death or dependency,**
  - **length of hospital stay.**
- **Benefit of stroke unit on mortality can be easily altered with change on scope of included trials (e.g. RCTs only).**
- **Benefit of stroke unit on dependency is not significant in this meta-analysis.**
- **The meta-analysis did not pool the results on quality of life because the studies used different scales. Two of the three reported no significant improvement on quality of life.**
- **Two small studies only analyzed the effect of very early mobilization (VEM) in stroke units: further large scale RCTs are required to measure the outcomes.**
- **First experience showed very promising results on primary endpoints of stroke unit with continuous monitoring (2 trials) and stroke unit with fever, hyperglycaemia and swallowing management protocols (one RCT).**
- **Comparisons with results from other studies show that the conclusions in favour of stroke units are usually based on the Cochrane results: however, the Cochrane review was based on large amount of unpublished data whose validity cannot be further verified.**
- **Other limitations in the conclusions include:**
  - **Possible publication bias in trials comparing stroke unit and general ward;**
  - **As noticed by NICE, a lack of standardization of the control in trials and patient selection may further bias the results.**

3 QUALITY INDICATORS FOR STROKE UNITS AND ACUTE STROKE CARE

This section describes the methodology for the systematic literature review on quality indicators for stroke units.

3.1.1 Inclusion/exclusion criteria

Inclusion/exclusion criteria on population, phase of the intervention and language were similar to the criteria used for the efficacy of stroke units.

"Quality indicators of stroke unit care" refers to each single element which can apply to both stroke unit care and stroke care. Further inclusion criteria for the quality indicators were:

- acute stroke care (exclusion of quality indicators concerning the long-term care of stroke);
- quality indicators with a clear definition.

No specific criteria are imposed on type of stroke or year of publication as this search mainly relied on online databases. The latest version was used in case of different versions of the same document.

3.1.2 Literature search strategy

Publications on quality indicators from the screening phases of the first review (on the efficacy of stroke units) directly were included in the screening process of this review.

The following databases were added to benefit from the previous scientific reviews on quality indicators (generic and disease specific databases):

- Generic quality indicator databases: search (by using the keyword "stroke" when a search function available).
  - National Quality Measures Clearinghouse: http://qualitymeasures.ahrq.gov/
  - Joint Commission: http://www.jointcommission.org/
  - Clinical Indicators Support Team: http://www.indicators.scot.nhs.uk/
  - National Health Services: http://www.nhs.uk/
  - Haute Autorité de Santé http://www.has-sante.fr/portail/jcms/j_5/accueil
  - The Danish National Indicator Project: http://www.nip.dk/
- Specific databases for stroke quality indicators:
  - http://www.queri.research.va.gov/tools/stroke-quality/
  - http://www.strokebestpractices.ca/index.php/methods/performance-measures-development/
  - http://www.cdc.gov/dhdsp/docs/PCNASR_performance_measures.pdf
  - Program "Get with guidelines-Stroke":
    - http://www.heart.org/HEARTORG/HealthcareResearch/GetWithTheGuidelinesHFStroke/GetWithTheGuidelinesStrokeHomePage/Get-With-Guidelines-Stroke-Overview_UCM_308021_Article.jsp

In contrast to a systematic search strategy, an iterative 'snowballing' search approach was adopted: the result of one search could direct to another source. Several publications were also added as supplementary sources based on the recommendations of experts in this field.

A full list of articles as the origin of the quality indicators identified in this study can be found in chapter 6 of the supplement,

3.1.3 Selection of quality indicators

Indicators related to quality of stroke care measured in hospitals fell into three categories [43, 46]:

- structure indicators (care facility and organizational factors),
- process indicators (clinical and inter-personal care),
- outcome indicators (that depend on the process of care but also on other factors as e.g. the disease severity).

Some indicators also measured the quality and other parameters (incidence, institutionalization rate) at the regional or national level.

All indicators were grouped according to their shared intrinsic characteristics within the care process (see an example on 'thrombolytic therapy' in Table 9) and ordered by their occurrence in the flow of care. This process was carried out under the supervision of a medical doctor with experience on stroke care (OS).

Quality indicators concerning the long-term care of stroke were excluded at a later stage.

3.1.4 Sources of evidence

Table 9: Example of the description of a quality indicator with 4 variants

Quality indicator	Definition	Origin	Evidence base
thrombolytic therapy	Proportion of all thrombolysed ischemic stroke patients who receive acute thrombolytic therapy within one hour of hospital arrival	Canadian Stroke Strategy Core Performance Indicator Update 2010	• 1 Cochrane review (1++) • 1 meta-analysis (1+) • 8 clinical guidelines (4) • 5 national/regional audits
	percent of acute ischemic stroke patients for whom IV thrombolytic therapy was initiated at the hospital within 3 hours (less than or equal to 180 minutes) of time last known well	Centers for Medicare & Medicaid Services (CMS), USA	
	Percent of patients with acute ischemic stroke who arrive at the hospital within 120 minutes (2 hours) of symptom onset for whom IV t-PA was initiated at this hospital within 180 minutes (3 hours) of symptom onset	United States Department of Veterans Affairs, 2009	
	Acute ischemic stroke patients who arrive at the hospital within 120 minutes (2 hours) of time last known well and for whom IV t-PA was initiated at this hospital within 180 minutes (3 hours) of time last known well.	Centers for Disease Control and Prevention (CDC), USA	

The level of evidence was finally summarized by the grade of recommendation using the methodology from the Scottish Intercollegiate Guidelines Network[44] (see supplement, chapter 2). The choice of this tool was based on two criteria:

- Use of this tool for the level of evidence in the literature review on the efficacy of stroke units (see 2.1);
- Use of this tool in Catalonia in a similar work on selection of quality indicators[45].

3.1.5 Data extraction

The following information was extracted for each quality indicator:

- Name of the quality indicator
- Type of stroke patients
- Phase of care
- Definition of the quality indicator as specified in the original source
- Denominator (if applicable)
- Numerator (if applicable)
- Perfomance goal, if specified in the original source
- Origin
- Country
- Source of evidence
- Grade of recommendation
- Database
- Use of the indicator

3.1.6 Criteria to select quality indicators

3.1.6.1 Inventory of quality indicators

All available QI were first listed in an Excel file and grouped into different categories by two investigators of the team individually. The QI found in the description of the countries (see Chapter 4.2) have been added to have the most comprehensive overview of all quality indicators.

Quality indicators with a similar content but with different definitions were considered as a single QI. For example, the process indicator "*thrombolytic therapy*" answers to different definitions e.g. *"proportion of all ischemic stroke patients who receive acute thrombolytic therapy*", "*acute ischemic stroke patients who arrive at the hospital within 120 minutes (2 hours) of time last known well and for whom IV t-PA was initiated at this hospital within 180 minutes (3 hours) of time last known well*".

The group of experts (see colophon) was further consulted at this stage to ensure that no major quality indicator had been omitted.

In a later phase, seven experts (6 clinicians and one data manager) rated the indicators on a scale from 1 (strongly disagree) to 9 (strong agree). They were asked to take the following 6 dimensions into account[46]: relevance, validity, reliability, specificity, feasibility, potential for improvement. The results are displayed in chapter 9 of the supplement.

3.2 Results of the literature search

3.2.1 Results of database search and selection of quality indicators

The initial search identified 98 QI's: 55 process indicators, 26 outcome indicators and 17 structure indicators.

The selection process further:

- excluded indicators that did not fit into the context of acute stroke care (e.g. long-term care of stroke);
- merged indicators from the same process of care/ patient outcome/ hospital structure,
- regrouped or separated the quality indicators from their initial category upon experts' advice.

The final set had 48 indicators: 28 on process, 5 on outcomes and 15 on structure.

The details and the full list of all QI extracted from literature in this research are presented in the apart document under.

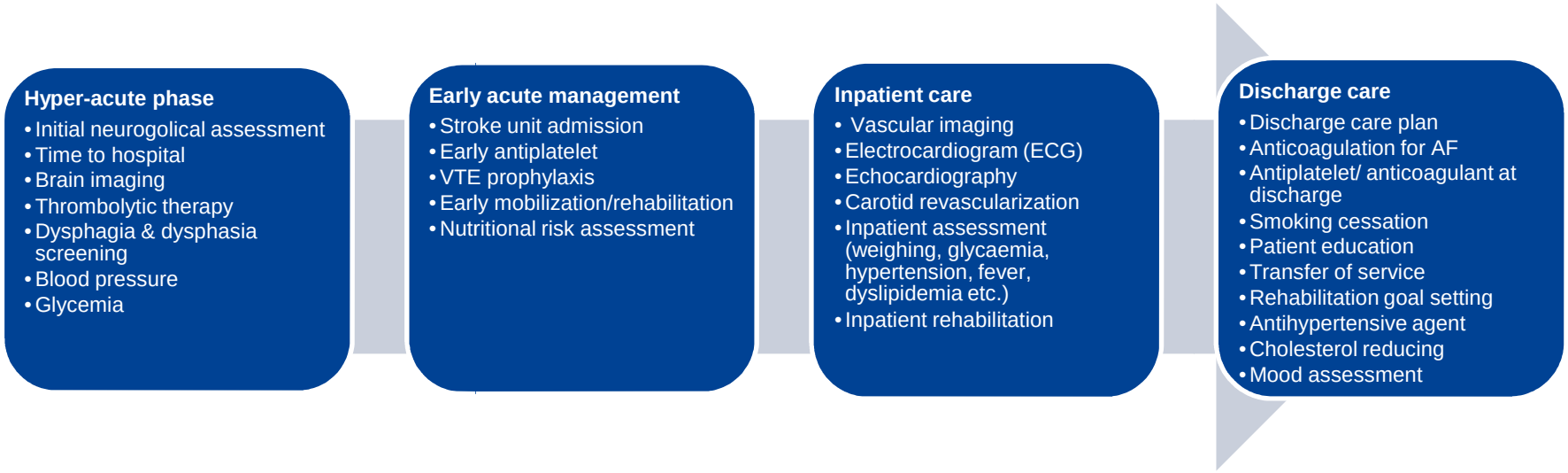
All quality indicators and their source of evidence are presented in the tables in the following sections.

3.2.2 Process quality indicators

28 process indicators have been found in the literature and/or used by national/regional institutions and/or sentinel audits. Some of them are are restricted to certain patient populations (e.g. anticoagulation for patient with atrial fibrillation) rather than all types of stroke patients. Therefore, different denominators have to be defined for process indicators with disparate target populations.

The following sections follow the flow of care: from the hyper-acute phase (24 hours after onset) to discharge from the stroke unit:

Figure 5: Process indicators following the flow of stroke care



3.2.2.1 *Process indicators - Hyper-acute phase (first 24 hours after stroke onset)*

Seven process indicators fit into the hyper-acute phase of stroke care defined as the first 24 hours after stroke onset:

- Three have been frequently cited by national/regional institutions and/or sentinel audits: brain imaging, thrombolytic therapy and dysphagia screening. They are supported by evidence of high quality (systematic reviews, meta-analyses, randomized controlled trials);
- There is some evidence on initial neurological assessment and early determination of glycaemia;
- Very limited evidence has been identified around time to hospital and early determination of blood pressure.

The table below summarizes the definition, source and evidence. The description of all studies is in chapter 7 of the supplement.

Table 10: Process indicators at the hyper-acute phase of stroke care (first 24 hours after stroke onset)

Quality indicator	Definition	Cited by	Evidence
1. Initial neurological assessment	Assessment of level of consciousness, eye movement, visual inattention, cognitive test, visual field testing, sensory testing	National sentinel audit (UK)	• 1 RCT (randomized controlled trial) (1+) • 1 retrospective case review (2+) • 3 national/regional audits
2. Time to hospital	Proportion of acute ischemic stroke patients who arrive at hospital within 3.5 hours of stroke symptom onset	Canadian Stroke Strategy (Canada)	Expert opinion (4)
3. Brain imaging	Proportion of stroke patients who receive a brain CT/MRI within 24 hours of hospital arrival, and with clear diagnosis of site/type of lesion	• Canadian Stroke Strategy (Canada) • ADSR study (Germany)[42] • National Committee for Quality Assurance (NCQA, USA)	• 1 Cochrane review and 2 other systematic reviews (1++) • 1 health technology assessment (HTA) report • 1 RCT (1+) • 2 prospective studies (2++) • 2 retrospective studies (2+) • 5 clinical guidelines • 9 national/regional audits

Quality indicator	Definition	Cited by	Evidence
4. Thrombolytic therapy	Percent of acute ischemic stroke patients for whom IV thrombolytic therapy was initiated at the hospital within 3 hours of time last known well[5]	• Canadian Stroke Strategy (Canada) • Centers for Medicare & Medicaid Services (CMS, USA) • Department of Veterans Affairs (USA) • Centers for Disease Control and Prevention (CDC, US)	• 1 Cochrane review and 1 meta-analysis (1++) • 8 clinical guidelines • 5 national/regional audits
5. Dysphagia & dysphasia screening	percentage of patients who underwent a dysphagia screening process before taking any foods, fluids or medication by mouth	• National Stroke Foundation (Australia) • Institute for Clinical Systems Improvement (ICSI, USA) • National Committee for Quality Assurance (NCQA, USA) • ADSR study (Germany) • Catalonia Stroke Audit (Spain)[45] • Canadian Stroke Strategy (Canada) • The European Implementation Score (EIS) Collaboration[43]The Danish National Indicator Project (Denmark)	• 2 systematic reviews (1++) • 1 HTA report • 2 RCTs (1+) • 1 prospective study (2++) • 1 retrospective study (2+) • 9 clinical guidelines • 8 national/regional audits
6. Blood pressure	Baseline determination of blood pressure at the emergency department	Catalonia Stroke Audit (Spain)	Unknown
7. Glycaemia	Baseline determination of glycaemia at the emergency department	Catalonia Stroke Audit (Spain)	• 1 RCT (1+) • 1 retrospective study (2+)

[5] The 3 hours here refer to 'time to needle from stroke onset', which requires a patient's arrival at hospital within 2 hours of symptom onset and IV thrombolytic therapy within 1 hour of hospital arrival.

3.2.2.2 Early acute management (24 – 48 hours after stroke onset)

Five process indicators have been identified at the phase of early acute management, defined as 24 to 48 hours after stroke onset:

- Three of them were supported by evidence (from Cochrane reviews): stroke unit admission, early antiplatelet administration, and early rehabilitation/mobilization assessment).
- Less evidence is found on the prophylaxis of venous thromboembolism;
- No evidence is found to support the use of nutritional risk assessment as a quality indicator of stroke care ;

The indicator of early assessment of rehabilitation/mobilization needs was merged the indicator early mobilization/ rehabilitation, considering that they are two sequential processes. This indicator also comprises assessment by physiotherapist, occupational therapist, and speech therapist.

Table 11.summarizes the definition, source and underlying evidence. The description of all studies is in chapter 7 of the supplement.

Table 11: Process indicators during the early acute management of stroke (first 24 – 48 hours after stroke onset)

Quality indicator	Definition	Cited by	Evidence
8. Stroke unit admission	The proportion of all acute stroke patients who are managed on a designated geographically defined integrated, acute, and/or rehabilitation stroke unit at any point during hospitalization	• National Stroke Foundation (Australia) • The Danish National Indicator Project (Denmark) • National sentinel audit (UK) • Canadian Stroke Strategy (Canada)	• 1 Cochrane review (1++) • 3 clinical guidelines • 5 national/regional audits
9. Early antiplatelet	Proportion of acute ischemic stroke and TIA patients who receive acute antiplatelet therapy within the first 48h hours of hospital arrival	• ADSR study (Germany) • Canadian Stroke Strategy (Canada) • National Stroke Foundation (Australia)	• 1 Cochrane review (1++) • 13 clinical guidelines • 6 national/regional audits
10. VTE (venous thromboembolism) prophylaxis	Percent of patients who have received VTE prophylaxis (or who have documentation why no VTE prophylaxis was given the day of or the day after hospital admission)	• Centers for Medicare & Medicaid Services (CMS, USA) • Catalonia Stroke Audit (Spain)	• 1 prospective study (2++) • 9 clinical guidelines • 3 national/regional audits
11. Early mobilization/rehabilitation (and its assessment)	Proportion of stroke patients with a rehabilitation assessment within 48 hours of hospital admission for acute ischemic stroke and within 5 days of admission for hemorrhagic stroke.	• The European Implementation Score (EIS) Collaboration • Catalonia Stroke Audit (Spain) • Canadian Stroke Strategy (Canada) • National sentinel audit (UK) • The Danish National Indicator Project (Denmark) • HAS (France) • ADSR study (Germany) • Department of Veterans Affairs (USA)	• 2 Cochrane reviews and 3 other systematic review (1++) • 1 RCT (1+) • 2 prospective studies (2++) • 13 clinical guidelines • 9 national/regional audits
12. Nutritional risk assessment	Proportion of patients who have an assessment of nutritional risk no later than the 2nd day of hospitalization	The Danish National Indicator Project (Denmark)	Unknown

3.2.2.3 *Process indicators - Inpatient care (after 48 hours of stroke onset)*

There are six process indicators at the stage of care after 48 hours of stroke onset (inpatient care).

- Two of them (Electrocardiogram and inpatient assessment on weighing, glycaemia, hypertension, fever etc.) have been rated as Grade A due to the evidence of a systematic review performed on components of effective stroke unit care[47];
- There is one randomized controlled trial around vascular imaging;
- Very limited evidence has been found around echocardiography, carotid revascularization and late-stage inpatient rehabilitation.

The table below (Table 12) summarizes the definition, source and underlying evidence. The description of the included studies is in the chapter 7 of the supplement.

Table 12: Process indicators during the inpatient care phase of stroke care (after 48 hours after stroke onset)

Quality indicator	Definition	Cited by	Evidence
13. Vascular imaging	Percentage of patients with ischemic stroke or TIA who receive vascular imaging of extra cranial arteries (Doppler or Duplex or DS-angiography or CT-angiography or MR-angiography) during hospitalization.	• ADSR study (Germany) • The Danish National Indicator Project (Denmark)	• 1 RCT (1+) • 1 retrospective study (2+) • 3 national/regional audits
14. Electrocardiogram (ECG)	ECG during hospitalization	• ADSR study (Germany)	• 1 systematic review (1++) • 1 RCT (1+) • 2 national/regional audits
15. Echocardiography	Echocardiography in ischemic stroke	Canadian National Sentinel audit	• 1 retrospective study (2+) • 1 national/regional audit
16. Carotid revascularization	Wait time from ischemic stroke or TIA symptom onset to carotid revascularization	Canadian Stroke Strategy (Canada)	Expert opinion
17. Inpatient assessment (weighing, glycaemia, hypertension, fever etc.)	Assessment and/or management of weighing, glycaemia, hypertension, fever, incontinence, pressure sores etc.	• National sentinel audit (UK) • Catalonia Stroke Audit (Spain) • Department of Veterans Affairs (USA)	• 1 systematic review (1++) • 2 RCTs (1+) • 1 prospective study • 3 clinical guidelines • 3 national/regional audits
18. Late-stage inpatient rehabilitation	Patient/carer awareness of diagnosis, prognosis, therapy goals; social work assessment	National sentinel audit (UK)	• 1 clinical guideline • 3 national/regional audits

3.2.2.4 *Process indicators - Discharge care*

10 process indicators were identified related to care at discharge phase.

- Evidence of high level was found for two of them (discharge care plan and patient/family education);
- There is some evidence on rehabilitation goal setting and on the use of the following medications: anticoagulation for atrial fibrillation, anti-hypertensive agent, cholesterol reducing medication;
- Very limited evidence was found for antiplatelet/ anticoagulant at discharge, smoking cessation, transfer of service and mood assessment before discharge.

The table below (Table 13) summarizes the definition, source and underlying evidence.

Table 13: Process indicators at discharge

Quality indicator	Definition	Cited by	Evidence
19. Discharge care plan	Percentage of stroke patients with documented care plan developed and provided to patient/family prior to hospital discharge	National Stroke Foundation (Australia)	• 1 systematic review (1++) • 1 RCT (1+) • 1 prospective study (2++) • 4 national/regional audits
20. Anticoagulation for atrial fibrillation	Percent of ischemic stroke patients with atrial fibrillation/flutter who are prescribed anticoagulation therapy at hospital discharge	• Centers for Medicare & Medicaid Services (CMS, USA) • Centers for Disease Control and Prevention (CDC, US) • Department of Veterans Affairs (USA) • The Danish National Indicator Project (Denmark) • ADSR study (Germany)	• 1 RCT (1+) • 8 clinical guidelines • 6 national/regional audits
21. Antiplatelet/ anticoagulant at discharge	Patients with an ischemic stroke prescribed antithrombotic therapy at discharge	Centers for Disease Control and Prevention (CDC, US)	• 1 prospective study (2++) • 6 clinical guidelines
22. Smoking cessation	Patients with ischemic or hemorrhagic stroke	• Centers for Disease Control and	4 clinical guidelines

Quality indicator	Definition	Cited by	Evidence
	with a history of smoking cigarettes, who are, or whose caregivers are, given smoking cessation advice or counselling during hospital stay	Prevention (CDC, US) • Department of Veterans Affairs (USA)	
23. Patient/family education	Patients or their caregivers who were given education and/or educational materials during the hospital stay addressing all of the following: personal risk factors for stroke, warning signs for stroke, activation of emergency medical system, need for follow-up after discharge, and medications prescribed at discharge	Centers for Disease Control and Prevention (CDC, US)	• 1 systematic review (1++) • 1 RCT (1+) • 3 clinical guidelines • 1 national/regional audit
24. Transfer of service	Percentage of new patients with a stroke or TIA who have been referred for further investigation	• British Medical Association • Canadian Stroke Strategy (Canada) • HAS (France)	2 clinical guidelines
25. Rehabilitation goal setting	Rehabilitation goals agreed by the multi-disciplinary team by discharge	National sentinel audit (UK)	• 1 RCT (1+) • 2 clinical guidelines
26. Antihypertensive agent	Percentage of stroke patients with documented evidence that antihypertensive agent was prescribed and administered prior to discharge from the hospital during audit period	National Stroke Foundation (Australia)	• 2 small RCTs (1+) • 1 clinical guideline • 5 national/regional audits
27. Cholesterol reducing medication	Percent of patients with ischemic stroke on arrival with LDL>100 mg/dl, or LDL not measured, or on cholesterol-reducer prior to admission, who are discharged on cholesterol reducing drugs (e.g. statin)	• Centers for Medicare & Medicaid Services (CMS, USA) • Centers for Disease Control and Prevention (CDC, US) • Department of Veterans Affairs (USA) • The European Implementation Score (EIS) Collaboration	• 1 RCT (1+) • 7 clinical guidelines
28. Mood assessment	Mood assessed by discharge	National sentinel audit (UK)	• 1 prospective study (2++) • 2 clinical guidelines • 4 national/regional audits

3.2.2.5 *Summary: process indicators*

Overall, there is consensus around process indicators at the hyper-acute and acute stage of care for stroke (first 48 hours after stroke onset). Studies of high quality are available for the following process indicators: brain imaging, thrombolytic therapy, dysphagia screening, admission to a stroke unit, early antiplatelet administration, early mobilization/rehabilitation (and its assessment), record of electrocardiogram (ECG), inpatient assessment (weight, glycaemia, hypertension, fever etc.), and discharge care plan and patient/family education.

3.2.3 *Outcome indicators*

This section presents the definition of outcome indicators used in other countries. Only five of them have been identified through database search. Mortality is the most frequently used by national/regional institutions. Other outcome indicators include improvement on speech and language, dependency, quality of life and hospital-acquired pneumonia.

Table 14: Outcome indicators used by national/regional institutions and/or audits

Quality indicator	Definition	Cited by
Mortality	Stroke death rates for 7-day in-hospital stroke fatality; 30 day all cause mortality; one year all cause mortality, for patients with ischemic stroke, intracerebral hemorrhagic stroke, subarachnoid haemorrhage, and transient ischemic attack	The European Implementation Score (EIS) Collaboration Agency for Healthcare Research and Quality (AHRQ, USA) ADSR study (Germany) ISD Scotland (UK) The Danish National Indicator Project (Denmark) Canadian Institute for Health Information (CIHI, Canada)
Improvement on speech and language	Proportion of stroke patients in each risk-adjusted group that make at least one level of progress on the each item of the Functional Communication Measure (FCM)	National Center for Evidence-Based Practice in Communication Disorders (USA)
Dependency	Percentage of patients dependent in transfer from bed to chair (Barthel Index Item “Transfer” 0–10 within first 24 hours after admission) who are mobilized within the first 2 days after admission.	Department of Veterans Affairs (USA) ADSR study (Germany)
Quality of life	Probability of patients treated in a specific hospital for good quality of life (measured with validated instrumental scales, e.g. SF-36 at three months) three months after stroke in comparison to all hospitals.	ADSR study (Germany)
Hospital-acquired pneumonia	Probability of patients to acquire new pneumonia during stay in a specific hospital in comparison to all hospitals adjusted for age, sex, stroke severity and artificial respiration.	ADSR study (Germany)

3.2.4 Structure indicators

Fifteen structure indicators have been identified (see Table 15). Most of them apply at the hospital level (e.g. 24-hour availability of brain imaging), some apply at regional/national level (e.g. new stroke events). Very limited evidence has been found except for 2 of them (training on medical staff and a multidisciplinary team in the hospital). Details on the corresponding systematic review[48] are in the supplement, chapter 7.

Table 15: Structure indicators cited by national/regional institutions and audits

Quality indicator	Definition	Cited by	Evidence base
Stroke/TIA register	The practice can produce a register of patients with stroke or TIA	British Medical Association (BMA, UK)	Unknown
Training on medical staff	Participation of hospital staff in training of emergency medical services in stroke. Training could be performed in cooperation with other hospitals. Training should be performed at least once a year.	ADSR study (Germany)	1 systematic review (1++)
Stroke education campaign	Participation of the hospital in stroke education campaigns of the population	ADSR study (Germany)	Unknown
A multidisciplinary stroke team in the hospital	Implementation of a multidisciplinary stroke team[6] in the hospital[7]	ADSR study (Germany)	1 systematic review (1++)
24 h availability of brain imaging (including radiological expertise in	24 hours availability of brain imaging including radiological expertise[8] in 'stroke imaging' in the hospital.	ADSR study (Germany)	Unknown

[7] A multidisciplinary stroke team is defined as daily presence of physician, nurse and physiotherapist, presence of speech therapist, occupational therapist and social service if required and 24 hours availability of physician with stroke expertise (at least 6 month training in certified stroke unit or at least 6-month training in hospital treating >250 stroke patients per year). Development of integrative multidisciplinary treatment concepts, regular multidisciplinary team meetings, multidisciplinary ward rounds, regular continuous education of all stroke team members required.

[8] Radiological expertise in 'stroke imaging' is defined as a physician with experience in interpretation of CT/MRI (at least 6 months training in neuroradiological department or 6 months training in certified stroke unit). If no radiological expertise is present at the hospital, telemedicine consultation for the interpretation of the images is possible.

Quality indicator	Definition	Cited by	Evidence base
'stroke imaging' in the hospital)			
An internal and external quality management system in the hospital	Existence of an internal system for quality management in the hospital, including continuous evaluation of operational procedures and workflow in the hospital, and participation of the hospital in a standardized project for external comparison of quality of care (benchmarking), including documentation of standardized stroke assessment scales.	ADSR study (Germany)	Unknown
Availability of vascular imaging and of diagnostic cardiologic methods at the hospital	Availability of vascular imaging (defined as diagnostic facilities to examine cerebral arteries including extra cranial carotid arteries using ultrasound [Doppler or Duplex] or angiographic methods [CT-, MR- or DS-angiography] and of diagnostic cardiologic methods at the hospital[9]). Diagnostic methods may not necessarily be performed in the same hospital where stroke care takes place	ADSR study (Germany)	Unknown
Availability of biological monitoring in the hospital	Availability of biological monitoring in the hospital to monitor basic vital parameters including blood pressure, heart rate, body temperature and oxygen saturation.	ADSR study (Germany)	Unknown
Documentation & risk assessment	Conformity scoring for the content of the patient's dossier treated for stroke, including documented pre-morbid function, smoking history, NIH Stroke Scale score etc.	Department of Veterans Affairs (USA) HAS (France)	1 prospective study (2++) 2 clinical guidelines
New stroke events	Age-standardized rate of new stroke events admitted to an acute care hospital, per 100,000 population age 20 and older	Canadian Stroke Strategy (Canada)	Unknown

[9] Defined as evaluation by cardiologist including availability of long-term ECG, transthoracic and transesophageal echocardiography

Quality indicator	Definition	Cited by	Evidence base
Stroke admission (ER)	The emergency department admission volumes for patients with ischemic stroke, intracerebral hemorrhagic stroke, subarachnoid haemorrhage, and transient ischemic attack.	Canadian Stroke Strategy (Canada)	Expert opinion (4)
Stroke admission (inpatient)	The hospital inpatient admission volumes for patients with ischemic stroke, intracerebral hemorrhagic stroke, subarachnoid haemorrhage, and transient ischemic attack.	Canadian Stroke Strategy (Canada)	Expert opinion (4)
Readmission rate	Proportion of acute stroke and TIA patients that are discharged alive that are then readmitted to hospital with a new stroke or TIA diagnosis within 90 days of index acute care discharge	Canadian Stroke Strategy (Canada)	Expert opinion (4)
Length of stay (stroke unit)	Median total time spent on a stroke unit for each patient during inpatient stay	Canadian Stroke Strategy (Canada)	Expert opinion (4)
Discharge destination (acute)	Distribution of discharge locations (dispositions) for acute stroke patients from acute inpatient care to: home (with and without services); inpatient rehabilitation (General or specialized); long term care; and to palliative care (each stratified by stroke type and severity).	Canadian Stroke Strategy (Canada)	Expert opinion (4)

3.2.5 Summary of findings: quality indicators

48 quality indicators have been identified on quality of stroke care through a search in disease specific and generic quality indicator databases: 28 process indicators, 5 outcome indicators and 15 structure indicators.

3.2.5.1 Evidence that support the quality indicators

The body of evidence found in the literature differed according to the type of indicator:

- A large amount of evidence has been identified for the process indicators:
  - Brain imaging
  - Thrombolytic therapy
  - Dysphagia screening
  - Admission to a stroke unit
  - Early antiplatelet administration
  - Early mobilization/rehabilitation (and its assessment)
  - Record of electrocardiogram (ECG)
  - Inpatient assessment (weighing, glycaemia, hypertension, fever etc.)
  - Discharge care plan
  - Patient/family education.
- The evidence for structure indicators was scarce and found only for 2 indicators: training on medical staff and multidisciplinary stroke team in the hospital. The link between organization and outcomes is probably difficult to show as many other factors play a role.
- The research was not designed to search for evidence to support the use of outcome indicators, as the outcomes considered (death, institutionalization) are the desired results of a process of care of high quality.

3.2.5.2 Different quality indicators describe the same aspect of care

In this study, a 'quality indicator' refers either to a single indicator or to a set of indicators which share the same feature/theme of acute stroke care.

For instance, the quality indicator 'thrombolytic therapy' encompasses definitions as 'proportion of all thrombolysed ischemic stroke patients who receive acute thrombolytic therapy within one hour of hospital arrival' and 'percent of patients with acute ischemic stroke who arrive at the hospital within 120 minutes of symptom onset for whom IV t-PA was initiated at this hospital within 180 minutes of symptom onset'. In this case, the quality indicator refers to a set of sub-indicators, which can also be individually used as quality indicators. For other indicators (e.g. 'electrocardiogram' or 'mood assessment'), there is no further subdivision of the indicator itself.

Indicators within a same category slightly differ from each other. Illustrations are:

- the differences in response time (e.g. a brain CT within 24 hours of stroke onset or one hour after admission),
- different populations as denominator (e.g. anticoagulants for ischemic stroke patients or stroke patients of all types),
- precision of description of the intervention (e.g. thrombolytic therapy or t-PA).

The differences between indicators within a category may be interesting to explore, as they reflect different purposes and settings. That is the reason why all indicators initially selected are displayed in the results.

3.3 Addition of a set of quality indicators from the analysis of the countries

31 additional indicators were added to the questionnaire to experts based on the findings from the analysis of the countries (see Chapter 4.2). The analysis yielded mostly structural quality indicators. Process and outcome parameters were already well covered by the literature search.

Table 16: Additional quality indicators identified from the analysis of the countries

Type Indicator	Description parameter
Structure	Presence of a laboratory that is available 24/7
	Presence of a team providing interventional radiology services (stenting, thrombectomy, coiling) (24/7)
	Presence of an internal quality management system in the hospital
	Presence of neurosurgery department or presence of a protocol to transfer to a facility allowing neurosurgery
	Presence of telemedicine
	Presence of vascular surgery department or presence of a protocol to transfer to a facility with vascular surgery
	Training & education of physiotherapists (e.g. training in stroke, annual course attendance,…)
	Training & education of nurses (e.g. training in stroke, annual course attendance, …)
	Training & education of occupational therapists (e.g. training in stroke, annual course attendance,…)
	Training & education of other paramedic disciplines (e.g. training in stroke, annual course attendance,…)
	Training & education of physicians(e.g. training in neurology or stroke, NIHSS certification, attendance of conferences)
	Presence of a multidisciplinary team
	Staffing level of specialized physicians (vascular neurologist, stroke medicine specialist)
	Staffing levels of nurses (e.g. nurses per bed, nurses per admissions per year)
	Staffing levels of occupational therapists
	Staffing levels of other paramedic disciplines (e.g. psychologist)
	Staffing levels of physicians
	Staffing levels of physiotherapists
	Staffing levels of specialized stroke nurses
	Presence of a minimum number of beds
	Presence of automated blood pressure monitoring within the stroke unit
	Presence of cardiac monitors within the stroke unit

Type Indicator	Description parameter
	Presence of emergency ventilatory support within the stroke unit in order to transfer patients with respiratory insufficiency to in-house intensive care unit
Process	Presence of oxygen saturation measurements within the stroke unit
	Related to education of families
	Related to the conduct or volume of carotid endarterectomy
	Early supported discharge rates
	Documentation of frequent multidisciplinary meetings
Outcome	Institutionalization rates
	Patient satisfaction with services
	Quality of life measures

4 ANALYSIS OF STROKE UNITS IN OTHER COUNTRIES

4.1 Methods

4.1.1 Research questions and definition

The purpose of this chapter is to answer to the third research question:

“How are stroke units organized in other countries? What is the quality assurance process (including the quality criteria)?”

4.1.1.1 Definitions

- Accreditation

This term refers to the compliance with a set of standards defined by an organization. The compliance is assessed by some form of external review, assessment, or audit. Self-accreditation will not be covered.

- Quality indicators

These refer to norms, criteria, standards and other direct qualitative and quantitative measures used in determining the quality of health care. Here we focus on measures used for defining performance of health care providers in stroke care.

This project focuses on both aspects:

  - Most accreditation procedures entail the assessment of quality measures or criteria,
  - On the other hand health payers/insurers may follow quality criteria or measures related to stroke care in general without formal accreditation of a center as a “stroke unit”. For instance, any hospital may have to measure a parameter like stroke mortality regardless of the presence of an accreditation procedure.

- Stroke units

This term has been defined in the first part of the study (see 2.1.1.2) i.e. a discrete ward caring exclusively for stroke patients with a multidisciplinary team including specialist nursing staff. The focus is on acute stroke units accepting patients within the first seven days of stroke. As mentioned above, they generally fall into 3 subcategories: intensive stroke units, semi-intensive stroke units and non-intensive units.

These stroke units may or may not provide rehabilitation for at least several weeks if necessary (comprehensive stroke units).

4.1.2 Selection of the countries

For feasibility reasons the researchers decided to limit the study to an in-depth analysis of five countries (or regions). The following criteria were considered in the selection (Table 17):

- Existence of a national (regional) stroke quality improvement measures like national quality plans, quality registrations,
- Presence of guidelines for setting up a stroke unit,
- Presence of an accreditation system for stroke units,
- Historical interest and participation in the development of stroke units,
- Similarity with the Belgian health care system,
- Availability of information in Dutch, English, French or German.

Table 17: overview of the countries and regions considered for the analysis

List of countries / regions considered	Stroke unit accreditation	National stroke registry or quality register	National guidelines on stroke units	Historical development of stroke units	Similarity with Belgian health care system	Language
Norway	No	Yes	Yes	Yes	Yes	No
Finland	No	Yes	Yes	Yes	Yes	No
Denmark	No	Yes	Yes	Yes	Yes	Yes
Sweden	No	Yes	Yes	Yes	Yes	Yes
England	Yes	Yes	Yes	Yes	Yes	Yes
Scotland	Yes	Yes	Yes	Yes	Yes	Yes
USA	Yes	No	No	No	No	Yes
Canada	Yes	Yes	Yes	No	No	Yes
Italy	No	No	Yes	No	Yes	No
Spain (Catalonia)	No	Yes	Yes	Yes	Yes	Yes
Germany	Yes	Yes	Yes	No	Yes	Yes
Netherlands	No	No	Yes	No	Yes	Yes
France	Yes	Yes	Yes	No	Yes	Yes
Switzerland	No	No	No	No	Yes	Yes

Ten out of the 14 countries/regions met the criteria mentioned above (see Table 17 above): five were finally selected (Scotland, Sweden, the Netherlands, France and Germany) in addition to the recently developed "London Stroke Services" (added in a further step upon advice of experts)[49].

The paragraphs below provide more detailed justification for the selection of these countries.

- Scotland

Scotland spurred on to the development of stroke units by performing randomized trials of different types of stroke care (and early supported discharge systems). Scotland organizes repeated nationwide audits of stroke unit care[50] The Scottish Stroke Care Audit (SSCA) was established in 2002 and now includes all hospitals managing acute stroke in Scotland. [51]Explicit quality criteria and targets have been formulated by the National Health System Quality improvement Scotland (NHS-GIS), now called Healthcare Improvement Scotland (HIS). Scotland also developed a national quality plan for stroke[52].

- Sweden

Sweden was chosen to represent the Scandinavian countries as its model for stroke unit care and quality improvement measures is similar to its neighbours but the information is available in English.

This country contributed to the development of stroke units and has a mandatory registration system for stroke patients which also assesses long term outcome and patient satisfaction[53]. Almost 84% of the Swedish stroke patients are admitted in stroke units. All Swedish hospitals that admit acute stroke patients participate to the national quality register Riks-Stroke, established in 1994. Riks-Stroke is one of the world's largest stroke registers with a total of more than a quarter of a million stroke events recorded[54].

Moreover, the Swedish National Board of Health and Welfare has created guidelines for the organization of stroke care.

- France

France has a national quality plan for stroke: the legislation regulates stroke unit organization [55]. The number of neurovascular centres dramatically increased from 33 in 2007 to 78 in 2010.

- Germany

Germany has growing number certified stroke units. An independent system of stroke unit accreditation is provided by LGA Intercert in collaboration with the Deutsche Stiftung Schlaganfall hilfe and the German Stroke society[56, 57]. There is a stepped system of stroke units with regional and supraregional stroke units. Accreditation is available for stroke units, comprehensive stroke units and stroke units providing telemedicine care. National quality criteria for stroke care been developed by an explicit process. The systematic collection and registration of stroke quality criteria is mandatory for reimbursement of hospitals in some German "Länder".

- The Netherlands

The Netherlands developed national guidelines and explicitly provided guidance for the organization of stroke units since 1997[58].

- Reasons for exclusion of other countries

The USA, Switzerland and Italy did not meet at least three or more of the postulated criteria.

European countries were selected rather than Canada.

Respondents of the region of Catalonia validated the content of the questionnaire but their responses were not included in the analysis (Catalonia does not have any stroke unit accreditation; two audits have been performed on quality parameters)[45, 59].

4.1.3 Selection of experts within selected countries

The following experts were contacted:

- Scotland

Professor Martin Dennis chairs the Scottish Stroke Care Audit.

Professor Peter Langhorne published extensively on stroke unit organization and is member of the steering committee of the Scottish Stroke Care Audit.

- Sweden

Professor Bo Norrving is president of the World Stroke Organization and member of the Riks-stroke steering committee.

Professor Kjell Asplund is register manager of the Riks-stroke database.

- France

Professor Didier Leys is president of the European Stroke Organization (ESO) and is member of the Stroke unit accreditation committee of the ESO.

Professor France Woimant was closely involved in the creation of the legal advice on the creation of neurovascular units and in the national action plan for Stroke 2010-2014.

- Germany

Professor Bernd Ringelstein wrote the Das Stroke Unit-Buch, chaired the Stroke unit accreditation committee of the ESO.

Professor Peter Heuschmann was intimately involved in the creation of quality criteria for stroke and stroke rehabilitation through the *Arbeitsgemeinschaft* Deutscher Schlaganfall Register.

- The Netherlands

Professor Martien Limburg is a member of the steering committee of the Kennisnetwerk CVA NL and headed the guideline for the CBO (Centraal Begeleidings Orgaan voor de intercollegiale toetsing) on stroke care. A second stroke expert was contacted but never gave any answer.

- London Stroke Services

Dr. Patrick Gompertz is a Royal College of Physicians Peer reviewer, a member of the Healthcare for London Clinical Advisory Group and Lead for the North East London Clinical Stroke Network.

Gill Gluckie, stroke specialist nurse, is the clinical lead for stroke at Guy's and St. Thomas' hospital, within the South East London stroke network. She is on the panel for development of London wide performance standards and is an assessor for other units within London

4.1.4 Methods

4.1.4.1 Development of the questionnaire

A questionnaire (25 pages – see supplement, chapter 10) assessed different aspects of stroke unit accreditation and quality criteria for stroke. It was first developed by a multidisciplinary team (neurologist practising in a stroke unit and nurse). The content and face validity of the questionnaire was then checked with the other members of the research team and by the members of the scientific committee of the Belgian Stroke Council. A further refinement of the questionnaire was performed by dr Sonia Abilleira and Miquel Gallofre from the Catalan Agency for Health Information, Assessment and Quality (CAHIAQ).

The issues addressed in the questionnaire are summarized in Table 18 and Table 19 below.

Table 18: Questions on stroke unit accreditation in other countries

When did stroke unit accreditation start?
What types of stroke units are certified?
Is the chain of stroke care certified or only the stroke unit?
Are other processes certified that are not directly related to stroke unit care, but are related to acute stroke diagnosis an d treatment?
Who performs the accreditation?
How is the accreditation performed?
To whom are the results provided?
What are the consequences if accreditation is not achieved?
Is a quality improvement plan provided in order to obtain accreditation?
Is a redress procedure available?
Is the accreditation procedure mandatory or voluntary?
Can any hospital apply for accreditation?
Are different types and levels of stroke unit certified?
Which structural criteria are taken into account?
Which staffing level is required?
Which staffing types are required?
Which education and training is required?
Which documentation of standard operating procedures is required?
Is a certain minimal volume of patients required?
Which quality criteria are taken into account? Structural, process and outcome indicators relevant to stroke care and hospital safety
What is the legal basis of the accreditation?

Are there national or regional guidelines addressing stroke unit organization?
Are there financial incentives or disincentives to certify stroke units?
Are there financial incentives to measure stroke quality parameters?
What are the costs of accreditation?
How often is accreditation required?
How many stroke units are certified?
How was the number of required stroke units determined/planned?

Table 19: Questions on the use of quality criteria in other countries

Which official organization collects quality measures?
Is this a continuous data or discontinuous quality measurement?
How often are data collected?
Who assesses the results of the data collection?
Which indicators are collected on a national or regional level?
How were the quality indicators developed?

4.1.4.2 *Identification of possible quality criteria*

The possible quality criteria were selected from a limited systematic literature search in MEDLINE database as the first part of the study (see Chapter 3) was not yet completed. Following MESH terms were used: 'Stroke', 'Program evaluation', 'quality indicators health care'. Date limits were from 2000 until September 2011. Only publications which discussed acute stroke settings and suggested the use of process-, outcome or structure quality indicators were selected. This evaluation was done based on title and abstract.

The possible quality criteria were tabulated and cross-checked with other sources i.e.:

- a recent paper on quality criteria in use in Europe;
- the stroke quality measures listed in the National Quality Measures Clearinghouse[60];
- the Agency for Healthcare Research and Quality[61];
- the Canadian Stroke Strategy Performance Measurement Manual[62].

Additional potential quality criteria were suggested by the members of the Scientific Board of the Belgian Stroke Council. The quality criteria list is not exhaustive but the respondents of the different countries had the opportunity to complete the list with other indicators.

4.1.4.3 *Data collection*

The questionnaire was sent out electronically to two designated experts per country. After electronic data entry, the research team performed a telephone interview or a face to face interview with the experts to discuss inconsistencies among the respondents and to clarify some answers to the questionnaire. If necessary, additional international experts were sought if the experts considered that another person was more appropriate to answer some questions. Documents and guidelines that were available online or forwarded by the experts were reviewed.

The quantitative information is presented in tables and cross tabulations. The textual and qualitative-narrative information was interpreted by the two principal researchers (DM and VT) independently. After the qualitative data extraction, the information was compared by the researchers and validated by the respondents per country.

4.2 Results

4.2.1 Survey respondents

As stated above 2 experts were invited to participate in each country. Eleven out of twelve participants responded (see Table 20).

Table 20: Validation of the descriptions of the regions/countries: names of experts

Country	Sweden	Sweden	The Netherlands	Scotland	Scotland	London	London	France	France	Germany	Germany
(sub) Region		Scania (South Sweden)	Flevoland	Lothian	Scotland	London	London	Ile de France (Parisian region)	Nord Pas de Calais	National	Münster
Name	Kjell Asplund	Bo Norrving	Martien Limburg	Martin Dennis	Peter Langhorne	Patrick Gompertz	Gill Gluckie	France Woimant	Didier Leys	Peter Heuschmann	E. Bernd Ringelstein
Date of interview	7-2-2012	26-03-2012	7-2-2012	7-2-2012	9-2-2012	23-3-2012	22-03-2012	24-02-2012	20-1-2012	9-2-2012	9-2-2012
Position(s)	Chair, Riks-stroke	Professor senior lector Steering committee member Riks stroke	Neurologist	Lead clinician for stroke in Lothian and Scotland	Professor/ consultant	Consultant Stroke Physician	Clinical lead, stroke, Guy's and St. Thomas' hospital, clinical lead, S/East London stroke network	Vascular neurologist. Neurologist referent of the "Ile de France" Regional Health Agency (governemental agency)	Professor of neurology. Head of department	Coordination of the data pooling of the German Stroke Register Study Group; development of quality indicators	Chairman German Stroke Unit Committee and Head of the Department of Neurology, University Hospital Münster

For Sweden, The Netherlands and Germany the responses reflect the situation at the country level. For France (Lothian area and Nord Pas de Calais), and Scotland the responses reflect both the national and the regional level. London-UK reflects the situation at the regional level.

4.2.2 Accreditation procedure

4.2.2.1 Accreditation of stroke units

- Countries with a formal process of accreditation are Scotland, Germany, France and UK-London.
  - Since 2010, in Scotland accreditation is organized on a "national" level by a government agency.
  - In London accreditation is implemented since 2010. It was the result of continuous conceptual work with clinicians (via the clinical expert panel), patients (via the patient panel) and commissioning management and finance colleagues (commissioning and finance working group) after the publication of 'Healthcare for London: A framework for action' (http://www.nhshistory.net/darzilondon.pdf).
  - Germany has an accreditation at the national level since 1996: a semi-private company (Public Interest Body) - in a direct cooperation with stroke experts nominated by the German Stroke Society - is responsible for accreditation. A certification is also directly co-managed and updated from time to time in cooperation with representatives of the German Stroke Foundation (SDSH)
  - In France, rules and criteria are set on a national level[55] but the accreditation process is done by the regional health agency according to these national criteria.

The accreditation procedure is mandatory in Scotland, UK-London and France, not in Germany.

In Scotland there is no explicit accreditation certificate a hospital can achieve, but there are national standards and the 'accreditation' is based on feedback on the performance towards these standards..

Sweden and The Netherlands have no formal accreditation procedure.

- Types of hospitals that can apply for the accreditation process

Only specific types of hospitals can apply for the accreditation process in Scotland, UK-London and in Germany.

In Scotland only hospitals accepting acute patients are suitable for accreditation.

In Germany the criteria are more extensive: the hospitals have to:

- accept a minimum number of acute stroke patients,
- have an emergency room and an intensive care unit,
- the presence of specific technical requirements like 24/7 laboratory and neuro imaging,
- either have neurological departments or internal medicine departments if they hire 2 fulltime neurologists for their stroke unit team (the latter is true for actually 5 of 205 certified German stroke units)

Following a London wide consultation on the proposed location of hyper acute stroke units (HASU) and TIA services, the Joined Committee of Primary Care trusts agreed to designate eight HASUs (hyper acute stroke units, see further), 24 stroke units and 24 TIA services. Many assumptions were used for capacity planning e.g. population and demographic change, further consideration of the likely length of stay in a HASU, inclusion of beds for stroke related procedures, allowance for the impact of prevention strategies. Details can be found in the Stroke acute commissioning and tariff guidance[63].

- Types of stroke units certified

In France and Germany the certifying authority recognizes a subdivision in primary stroke units and "full-spectrum comprehensive units" (centres capable of delivering the full spectrum of care to seriously ill patients with stroke and cerebrovascular disease, i.e. offering neurosurgical services, interventional radiology procedures, carotid surgery etc). The same is applicable for the recognition of subdivisions in regional or supra-regional stroke units.

In London only there is a subdivision between stroke units: hyper acute stroke units (HASU) provide the immediate response to a stroke. The patient's length of stay is up to 72 hours. Other stroke units (that provide multi-therapy rehabilitation and ongoing medical supervision follow a patient's HASU stabilization.

Table 21: Types of stroke units certified within the countries/regions.

	Number of countries/ regions	Sweden	Netherlands	Scotland	UK-London	France	Germany
Intensive Stroke units (a model of care with continuous monitoring, high nurse staffing and the potential for life support)	1	No	No	No	Yes	No	No
Semi-intensive stroke units (a model of care with continuous monitoring, high nurse staffing but no life support facilities)	4	No	No	Yes	Yes	Yes	Yes
Non-intensive stroke units (a model of stroke care without continuous monitoring or life support)	3	No	No	Yes	Yes	Yes	No
Comprehensive stroke units (providing rehabilitation in the same units for several weeks)	3	No	No	Yes	Yes	No	Yes
Rehabilitation hospitals where stroke patients are mixed with other types of neurologic or other patients	1	No	No	No	No	Yes	No

4.2.2.2 Accreditation of additional aspects of stroke care

The countries/region mentioned above also accredit other aspects of stroke care, either preceding or following stroke unit care (see Table 22 below).

For Germany “other” refers to teaching and provision of information to patient and family. For UK-London, ‘other” means TIA clinics. In France additional aspects are accredited, but there are regional differences.

Table 22: Additional aspects of care (other than stroke units) considered for the accreditation

	Number of countries/regions	Scotland	UK-London	France	Germany
Prehospital care	2	No	No	Yes	Yes
Emergency services	4	Yes	Yes	Yes	Yes
Intensive care services	2	No	No	Yes	Yes
Post-stroke unit rehabilitation (chronic rehabilitation)	2	No	No	Yes	Yes
Outpatient stroke clinic or follow up clinic	3	Yes	No	Yes	Yes
Early supported discharge teams	2	Yes	No	No	Yes
Other	2	No	Yes	No	Yes

In France only direct stroke processes, including e.g. prehospital stroke care, are taken into account for accreditation. Other indirect processes (e.g. quality of radiology reports) are not investigated.

Scotland, UK-London and Germany also certify other processes indirect related to stroke management. In London the performance standards require processes are in place for access to carotid surgery, neurosurgery, imaging, rehabilitation etc. but these are often about accessibility rather than quality per se. Carotid endarterectomy is assessed as time from high risk transient ischemic attack to surgery.

A detailed list of additional processes related to stroke are listed in the table 23 below.

Table 23: Additional aspects of care (other than stroke care) considered for the accreditation

	Number of countries/regions	Scotland	UK-London	Germany
Contact with prehospital services	1	No	No	Yes
Carotid artery procedures (endarterectomy or stenting)	3	Yes	Yes	Yes
Quality of carotid surgery	3	Yes	Yes	Yes
Quality of brain imaging investigations	2	Yes	No	Yes
Quality of cardiac investigations	1	No	No	Yes
Quality of interventional radiology (endovascular procedures)	1	No	No	Yes
Quality of neurosurgical services	1	No	No	Yes
Quality of general hospital safety measures (fall prevention)	1	No	No	Yes
Other aspects	2	Yes	No	Yes

4.2.2.3 Methods for accreditation procedure

- The accreditation teams use three different methods: site inspection, interviews with key personnel and patient data review. It is important to notice that in France regional differences in the accreditation procedure are present. Not all of the stated procedures in this paragraph are nationwide used, but in some or more regions of France they are.
- Site inspection by an accreditation team is done in all four countries: Scotland, UK-London, France and Germany. In France and Germany key personnel involved in the stroke care process, is interviewed in a structured way. In Scotland questionnaires are sent out by electronic means or by mail.
- Patient data review is carried out in all four countries as well. In Germany, a basic patient data set (approximately 50 items) must be fed into a regional stroke data bank for benchmarking. This data includes information for quality indicators. The review is retrospective in Scotland and also in Germany: post factum patient records are selected and reviewed. The collected data or averages are sent to the accreditation agency.

In all countries accreditation is done by personnel specifically trained in stroke.

In Scotland each hospital has a designated independent auditor who works for the Scottish stroke care audit. They review the care of all patients with respect to key performance indicators. The data are collected centrally each month and reviewed both centrally and local. A team working for the national audit and the national advisory committee visit each hospital yearly to review their systems, their data and to help with service improvement. A key target is early delivery of stroke unit care and so these visits aim to assess whether the stroke units fulfil the basic requirements i.e. the presence of a geographically defined area for stroke patients, documentation that the staff have all received a basic level of specialist training and that multidisciplinary meetings happen at least every week. If a unit consistently fails to meet these criteria then that hospital will fail to meet the target.

In two countries (France and Germany) a physician specialized in stroke medicine or a stroke neurologist participate in the procedure together with an independent audit specialist. In one country a specialized nurse or paramedic is part of the accreditation team instead of a medical doctor.

In Germany the stroke specialist is a medical doctor appointed as stroke specialist by the German Stroke Society that has a pool of experts. The professional auditor is from the private company. He is professionally trained in certification procedures, not only for stroke. Most of these professional auditors have previously been nurses. In UK-London there is always a clinician present, either the London stroke director or a clinical lead from a London stroke network. A member of the stroke network and a commissioner are also usually present.

4.2.2.4 Validity and renewal of accreditation

(Re-)accreditation intervals vary across the countries under scope.

- In Scotland and London UK the accreditation procedure is performed on an annual basis.
- In Germany the procedure is performed every 3 years, but the stroke unit receives a list of improvements for further recommendations. After 1,5 years, the quality management of the hospital is obliged to report on further improvements during this period.
- France has a 5 year cycle for the accreditation procedure.

4.2.3 Dissemination and implementation of accreditation findings

The publication of the results of the procedure differs between the countries.

- Scotland and UK-London have the most open policy. The reports are publically accessible (website), so government officials, specialists in the own institution, staff members of the department hosting stroke unit, members of the board of the institution/hospital and patients can read the reports.
- In Germany only staff members of the department hosting the stroke unit and members of the board of the institution/hospital can read the reports.
- In France the reports are sometimes restricted to members of the board of the institution/hospital. In some regions the staff members of the department hosting stroke unit and the specialists of the own institution can read the reports too.

4.2.4 Costs of accreditation

Except for Germany, the costs for a stroke unit accreditation process is paid by the national or regional authorities: the hospitals do not pay for the accreditation procedure. In Germany the Hospital or trust pays about € 3000 for the accreditation.

4.2.5 Consequences of the accreditation procedure

The consequences for a hospital that does not meet the stroke accreditation conditions vary from country to country.

- In Scotland hospitals are mandated to propose an improvement plan, but there are no consequences in terms of admission or financial losses. However, the hospital loses (part of) its reputation because of disclosure of the findings to medical professionals or the general public.

- In UK-London, units who failed the initial 'go live' process are no longer commissioned to provide services. Once units are commissioned, sanctions for not meeting criteria are mainly financial or reputational. No commissioned unit has been decommissioned though this is theoretically possible.
- In France, a failure to achieve accreditation has financial consequences resulting in decreased reimbursement at the hospital or at the patient level.
- Germany proposed positive incentives. Only hospitals that achieve stroke accreditation appear in the official list of certified institution visible, for instance, on the webpage of the German Stroke Society (DSG)[57]. Hospitals are mostly, but not always, encouraged to improve and to apply again.

4.2.6 *Legal framework and guidelines for stroke units*

France and one state in Germany have a legal framework for stroke units.

- France has a legal document for the implementation of stroke units [55].
- In Germany one state (Saarland) has issued a rule that emergency doctors are only allowed to transfer acute stroke patients to certified stroke units.

All countries have guidelines from professional societies on how to create and organize stroke units.

- In Sweden guidelines are issued by the National Board of Health and Welfare, a governmental agency. Professions, but also other stakeholders, are deeply involved in the guideline work[64].
- In the Netherlands many documents from 'Nederlandse Vereniging voor Neurologie' are available online[65, 66].
- In Scotland guidelines are published[67 , 68 , 69].
- In France guidelines are published[70].
- In UK-London respondents mentioned the following documentation: RCP national clinical guidelines and National Institute for Health and Clinical Excellence, National stroke strategy[71].
- Germany respondents mentioned the following publications:
  - Ringelstein, 2007[72]
  - Ringelstein, 2000[73]
  - Ringelstein, 2005[74]
  - Faiss, 2008[75]
  - Ringelstein, 2011[76]
  - Ringelstein, 2011 (2)[77]

4.2.7 *Which criteria does a formal accreditation procedure take into account to certify a stroke unit?*

This chapter makes a distinction between:

- criteria or features that a stroke unit must fulfil,

  actual measured quality indicators which are taken into account for accrediting the stroke unit.

4.2.7.1 *Structure, staff levels and training, documented processes and volumes for stroke units*

- Criteria for accreditation: structure

In Germany there is a distinction between regional stroke units and supraregional stroke units. Both regional and supraregional stroke units can ask to be accredited as a comprehensive stroke unit when additional criteria are fulfilled. A minimum number of 4 monitored beds is needed for regional stroke units, and a minimum of 6 monitored beds for the supraregional stroke units. For comprehensive stroke units, additionally an equal number of non-monitored beds is required.

In France a minimum of 4 beds is required.

In UK-London each unit size was designated based on activity, prevalence data and agreement with the provider. There are requirements for the units e.g. rehabilitation facilities, radiology service (CT, MRI etc). All of the certified stroke units (hospital name), the number of designated beds and the general structural requirements per type of stroke unit (HASU, TIA, Stroke unit) are listed[63].

Table 24: Structural features for the accreditation of stroke units in Scotland, UK London, France, and Germany

	Number of countries/regions with quality indicator	Scotland	UK-London	France	Germany
Presence of a minimum number of beds	3	No	Yes	Yes	Yes
Presence of cardiac monitors within the stroke unit	3	No	Yes	Yes	Yes
Presence of automated blood pressure monitoring within the stroke unit	3	No	Yes	Yes	Yes
Presence of oxygen saturation measurements within the stroke unit	3	No	Yes	Yes	Yes
Presence of emergency ventilatory support within the stroke unit in order to transfer patients with respiratory insufficiency to in-house intensive care unit	2	No	Yes	No	Yes

- Staff level

In table 25 personnel features are listed; 2 out of 4 countries have nursing staffing levels. The need for a multidisciplinary team is present in all 4 countries. Scotland has only one of these requirements.

In France one can only run a stroke unit when there is a physician with a special training called ‘diplôme interuniversitaire neurovasculaire’. The multidisciplinary team is defined without staffing levels: nurses and ‘aide soignant’ need to be present 24/7; a physiotherapist, speech and language therapist, psychologist, occupational therapist and social assistant need to be available on a daily basis by law. Germany has the most extensive personnel regulation for stroke units.

Table 25: Staff level for the accreditation of stroke units in Scotland, UK London, France, and Germany

	Number of countries/regions with quality indicator	Scotland	UK-London	France	Germany
Staffing levels of physicians	2	No	Yes	No	Yes
Staffing level of specialized physicians (vascular neurologist, stroke medicine specialist)	3	No	Yes	Yes	Yes
Staffing levels of nurses (e.g. nurses per bed, nurses per admissions per year)	2	No	Yes	No	Yes
Staffing levels of specialized stroke nurses	1	No	No	No	Yes
Staffing levels of physiotherapists	2	No	Yes	No	Yes
Staffing levels of occupational therapists	2	No	Yes	No	Yes
Staffing levels of other paramedic disciplines (e.g. psychologist)	2	No	Yes	No	Yes
Presence of a multidisciplinary team	4	Yes	Yes	Yes	Yes

In Germany at least a two-shift system with stroke-trained physicians working on the stroke unit is compulsory. An experienced stroke unit director, a board certified neurologist, is the supervisor. The qualification of a vascular neurologist does not exist in Germany: the specialist physicians are neurologists with experience in stroke medicine as documented by their CV. For primary stroke units, 1.5 nurses per bed are required. For stroke unit centres, 2 nurses per bed are required. Each stroke unit team must have 2 stroke specialized nurses. An adequate number of physiotherapists and occupational therapists must be available. Each patient must be treated during one physiotherapy time unit (approx 30 minutes every day, also on the weekends). The insurance companies meticulously scrutinize these aspects and refuse reimbursement, if this criterion is not fulfilled unexceptionally. If the patient suffers from a neuropsychological deficit, he must receive a neuropsychological diagnostic and therapeutic support.

In UK-London staffing levels are very precisely defined, with a distinction between HASU staffing and Stroke unit staffing (see Table 26). For nursing staff the recommended skill mix in HASU units is at least 80/20 (trained/non trained). In Stroke units the limit is lower (skill mix of 65/35 for trained/non trained).

Table 26: Staffing in stroke units – London UK

	HASU (WTE/bed)	Stroke Unit (WTE/bed)
Physiotherapist	0.15	0.17
Occupational therapist	0.14	0.16
Speech and language therapist	0.07	0.08
Nursing (24/7 provision)	2.9	1.35

In Sweden no staffing levels are defined for stroke units but the multidisciplinary team is defined: it consists of a stroke physician, stroke nurse, physiotherapist and occupational therapist as a minimum.

- Education and training of the personnel

Hospitals need to document education and training of personnel.

Table 27: Education and training of the personnel

	Number of countries/regions with quality indicator	Scotland	UK-London	France	Germany
Training & education of physicians (e.g. training in neurology or stroke, NIHSS certification, attendance of conferences)	4	Yes	Yes	Yes	Yes
Training & education of nurses (e.g. training in stroke, annual course attendance, …)	3	Yes	Yes	No	Yes
Training & education of physiotherapists (e.g. training in stroke, annual course attendance,…)	3	Yes	Yes	No	Yes
Training & education of occupational therapists (e.g. training in stroke, annual course attendance,…)	3	Yes	Yes	No	Yes
Training & education of other paramedic disciplines (e.g. training in stroke, annual course attendance,…)	3	Yes	Yes	No	Yes
Documentation of frequent multidisciplinary meetings	3	Yes	Yes	No	Yes

- France

In France this is only necessary for physicians (training in stroke, NIHSS certification, attendance of conferences). Any physician (in any speciality) needs to document his/her education and training. Stroke units in Scotland, UK-London and Germany need to document more features.

- Scotland

In Scotland physicians are expected to maintain a relevant Continuing Professional Development (CPD) level but this is not specific for stroke unit care. All stroke personnel are expected to undergo basic training in core competencies and then to proceed with more advanced training modules. Recently a system was set up to ensure that all staff are trained within the first 3 months of work in a stroke unit. On line learning[78] as well as face to face courses are used. There are 4 levels:

- the Stroke Core Competencies[79];
- the Stroke Advancing Modules[80].
- the Thrombolysis Masterclass[81].
- the newly developed Stroke4Carers website[82], primarily aimed at unpaid carers.

Staff are expected to have regular appraisals and a personal development plan. The latter may be based on the "Scot toolkit".

- Germany

Training of physicians in neurology and stroke, NIHSS certification, attendance to conferences is defined as well as attendance to in-house education. There are 1-week fulltime special courses in Germany for nurses who want to specialize in stroke (including an examination). Each stroke unit must have at least 2 nurses with this special training as discussed in the paragraph 'Staff level'. Next to this an annual course attendance is compulsory. The education and training of physiotherapists and occupational therapists is not defined. Only physiotherapists specialized on neurology can hired by stroke units.

- London

Some educational criteria/indicators are listed in the UK-London standards to accredit stroke units, TIA clinics and HASU's. Illustrations are the provision of and attendance at multidisciplinary team stroke training programmes, the provision of structured training plan for new or rotational staff, the active involvement in local stroke networks, and the completion of leadership training for key players of stroke care.

- Sweden

In Sweden many educational activities are performed on a voluntary basis. The completion of a voluntary educational programme for stroke unit staff leads to a stroke care certificate, issued by the patient organization stroke-Riksförbundet[83].

- Protocols

The presence of documented treatment protocols are also part of the accreditation systems.

- France, UK-London and Germany require the documentation of the following protocols: protocols related to acute treatment, to secondary prevention, to common stroke complications, to complication prevention (dysphagia, pressure ulcer) and finally protocols related to rehabilitation.
- In Scotland only protocols related to acute treatment, secondary prevention and complication prevention are checked.

- Volume of activity

A minimal volume of stroke patients is a requirement in France and Germany only:

- in France the minimum recommended volume is 300 stroke cases per year;
- in Germany a distinction is made between primary stroke units (absolute minimum 250 cases per year) and stroke centres (500 stroke patients per year). Moreover Germany there also determined a minimum number of thrombolyses within a time frame (4,5 hours after onset): a distinction is made between primary stroke units (minimum of 25 IV thrombolyses per year) and stroke centres (minimum of 45 IV thrombolyses per year).

- in UK-London a capacity planning exercise was done for stroke unit and HASU beds. All the key assumptions, including occupancy, are listed[63]. The occupancy rate for stroke units was set at 95% and HASU 90%. In the final result of this exercise the minimum number of beds per hospital is 8.(e.g. The Royal London Hospital has 12 HASU beds and 8 ASU beds)

4.2.7.2 Quality indicators measured for the accreditation of stroke units

Quality indicators are presented for the 4 countries with accreditation.

- Quality indicators: structure

Germany has the highest number of structural indicators, including all 12 items from the list in Table 28.

Table 28: Quality criteria measured for the accreditation of stroke units: structure

	Number of countries/regions with quality indicator	Scotland	UK-London	France	Germany
Percentage of stroke patients in hospital that are admitted to a stroke unit	4	Yes	Yes	Yes	Yes
Presence of a laboratory that is available 24/7	3	No	Yes	Yes	Yes
Presence of an intensive care unit within the hospital	3	No	Yes	Yes	Yes
Presence of neurosurgery department or presence of a protocol to transfer to a facility allowing neurosurgery	3	No	Yes	Yes	Yes
Presence of vascular surgery department or presence of a protocol to transfer to a facility with vascular	3	No	Yes	Yes	Yes

	Number of countries/regions with quality indicator	Scotland	UK-London	France	Germany
surgery					
Presence of diagnostic imaging of the carotid and/or intracranial arteries (duplex, TCD, CTA, MRA)	3	No	Yes	Yes	Yes
Presence of advanced imaging (MRI or IADSA or advanced CT) or presence of a protocol to transfer to a facility with advanced imaging (24/7)	3	No	Yes	Yes	Yes
Presence of a team providing interventional radiology services (stenting, thrombectomy, coiling) (24/7)	1	No	No	No	Yes
Presence of telemedicine	2	Yes	No	No	Yes
Presence of a stroke registry	1	No	No	No	Yes
Presence of an internal quality management system in the hospital	2	Yes	No	No	Yes
Presence of an external quality management system (benchmarking system)	3	Yes	Yes	No	Yes

- Process indicators

The list of process indicators includes 19 items; they are ranked according to the number of countries included them.

Table 29: Quality criteria measured for the accreditation of stroke units: process

	Number of countries/regions with quality indicator	Scotland	UK-London	France	Germany
Related to process timings: e.g. door to hospital time, door to CT time, length of stay in emergency department, proportion of time in stroke unit	4	Yes	Yes	Yes	Yes
Related to diagnostic procedures (e.g. percentage of CT or MRI, echocardiography, TCD….)	4	Yes	Yes	Yes	Yes
Related to acute medical treatment (aspirin, thrombolysis, interventional procedures)	4	Yes	Yes	Yes	Yes
Related to screening for dysphagia	4	Yes	Yes	Yes	Yes
Related to the measurement of impairment at baseline (e.g. NIHSS or other impairment scale)	3	No	Yes	Yes	Yes
Related to the measurement of impairment during in hospital follow up (e.g. 24 hour NIHSS or other impairment scale)	2	No	No	Yes	Yes
Related to assessment for rehabilitation (e.g. assessment by physiotherapy within a certain time frame)	2	No	Yes	No	Yes
Related to the measurement of physiological parameters at baseline (BP, glycaemia, temperature)	2	No	Yes	No	Yes
Related to the conduct or volume of carotid	2	Yes	Yes	No	No

	Number of countries/regions with quality indicator	Scotland	UK-London	France	Germany
endarterectomy					
Related to education of patients	2	No	Yes	No	Yes
Related to education of families	2	No	Yes	No	Yes
Related to the presence of a formal discharge plan	2	No	Yes	No	Yes
Related to discharge medication (antithrombotics, statins or hypertensive medication)	2	Yes	No	No	Yes
Related to early mobilization	1	No	No	No	Yes
Related to psychiatric disorder evaluation (mood)	1	No	Yes	No	No
Related to the measurement of the evolution of the functional status (e.g. ADL, mRS)	1	No	No	No	Yes
Related to the measurement of evolution of nutritional status	1	No	Yes	No	No
Related to advice about a healthy lifestyle	1	No	No	No	Yes
Related to completeness of stroke aetiology documentation	1	No	No	No	Yes

- Outcome indicators

Scotland just has in-hospital (or in stroke unit) mortality as an outcome indicator (see Table 30). Germany uses also complications, pneumonia, recurrent stroke and longer term functional outcome. The respondents of UK-London did not report any outcome indicator. France uses the same indicators as Germany except for the longer term outcome (only used in Germany) and “Deep venous thrombosis or pulmonary embolism” (only used in France).

Table 30: Quality criteria measured for the accreditation of stroke units: outcome

	Number of countries/regions with quality indicator	Scotland	France	Germany
In hospital or in stroke unit mortality	3	Yes	Yes	Yes
In hospital or in stroke unit complications	2	No	Yes	Yes
Pneumonia	2	No	Yes	Yes
Recurrent stroke	2	No	Yes	Yes
Deep venous thrombosis or pulmonary embolism	1	No	Yes	No
Longer term outcome (at least 30 days) after stroke assessed by a functional outcome score like mRS, Barthel index, Glasgow outcome scale or FIM)	1	No	No	Yes

4.2.8 Financial incentives

France is the only country with financial incentives for the accreditation of stroke units itself.

Sweden, UK-London, France and Germany have financial incentives to admit patients on a stroke unit versus other wards:

- In Sweden there is an increased reimbursement of individual patients but financial incentives vary from county to county (n=21) and some counties have no incentives.
- In France there is more funding for hospitals and departments that organize stroke unit care (only semi intensive beds provide extra money – 450 € / day).
- In Germany care of acute stroke patients is defined in the DRG-system by operation procedures (OPS) (a detailed list of measures provided by the institution for the care of acute stroke patients). This list must meticulously be filled (will be checked by insurance companies on a case-by-case basis). If one detail is missing, reimbursement will be refused or drastically reduced. The extra reimbursement strongly depends on the severity of the stroke and on the duration of the monitoring period. If the hospital does not provide stroke unit care (or an adequate infrastructure) they cannot charge the OPS-incentives.
- In UK-London an uplifted tariff is in place per bed day for accredited HASU. For Stroke units the uplifted tariff is calculated per spell (per stay). The uplifted tariff is based on scoring system of the achieved standards. A1 (staff and infrastructure) and A2 (performance) standards need to be met in the 'go live' phase of the HASU/stroke unit. B, C and D standards are maintenance standards. The A standards result in tariff uplift. The remaining standards need to be achieved, but do not generate a tariff uplift. If these standards are not achieved a loss of 5 % is imposed for each set [63].

The Netherlands and Scotland have no direct financial benefit or incentive to admit patients on a stroke unit. On the other hand in the Netherlands there is an extra incentive to participate into a stroke quality register that may or may not include care in a stroke unit. Quality requirements are in place, and hospitals who do not reach certain standards might/will be less contracted for stroke care/service by the health insurers.

4.2.9 Access, planning and admission in stroke units

- Planning of bed numbers

Except for UK-London, in none of the investigated countries, health authorities use a formal method to calculate the required number of stroke units for the country or region based on geographical or population based.

In UK-London, in order for effective planning to take place in units and networks, the required capacity expected for each HASU and stroke unit, expressed as a number of beds was set out by Healthcare for London. The key assumptions taken into consideration were:

  - population and demographic change,
  - consideration of the likely length of stay in a HASU,
  - consideration of the mimic rate and the length of stay of mimics,
  - re-working the overall length of stay saving in the stroke unit so it is based on, above average length of stays moving down to the average,
  - consideration of an increase in hospitalisation rates for those boroughs with below London average rates,
  - consideration of the impact of the FAST campaign,
  - inclusion of beds for stroke related procedures,
  - modification of the bed requirement for the new TIA pathway,
  - allowance for the impact of prevention strategies,
  - estimate of the impact of early supported discharge.

Details of the capacity planning process and the main assumptions used, are explained in the stroke acute commissioning and tariff guidance[63].

In Germany the Stroke Unit Committee of the German Stroke Society has made a rough calculation as follows :

- 80 million Germans produce approx. 250 000 strokes per year (including recurrences).
- Provided that 100 strokes can be treated per year in one monitored bed, 2500 stroke unit beds are needed.
- The average number of stroke unit beds per stroke unit in Germany is 6, which means that presently 1230 stroke unit beds are available. The coverage is diverging in the various states ranging from 40 to 100%.
- There is an encouraging to augment the size of the stroke units rather than to increase the number of stroke units for reasons of expertise and economics. In certain regions the government tries to regulate it.

- Bypass of hospitals by ambulances

In UK-London, France and Germany ambulances have the authority to bypass hospitals that do not have a formal stroke accreditation.

In the other countries this is not the case.

- Profile of patients admitted in stroke units

The types of patients generally admitted in a stroke unit do differ between countries. Patients with suspected strokes, patients with stroke mimics and patients with intracerebral haemorrhage are admitted in all countries/regions under study.

In some countries a distinction is made between admission of any TIA patient (Sweden, France and Germany) versus admission of only high risk TIA patients (The Netherlands, Scotland, UK-London).

Only in The Netherlands and some regions of UK-London (policy varies across London) patients with subarachnoid haemorrhage are admitted in a stroke unit.

4.2.10 National and regionally developed quality indicators

Quality indicators used at national and regional levels are displayed below. This listing is totally independent of their use in accreditation procedures or not.

4.2.10.1 National quality indicators

The summary table (Table 31) below includes 37 items. These measures are used for defining the performance of health care providers in stroke care on a national level. The criteria, except for category 'other', are ranked from high to low based on frequency of use in the participating countries.

- 'Stroke unit care', 'Performance of screening for swallowing dysfunction' and 'Performance of thrombolytic therapy' and 'Time to thrombolytic therapy' are used in all countries.
- Other frequently used national quality indicators include;
  - length of stay,
  - performance of brain imaging and blood vessel imaging,
  - use of aspirin for acute ischemic stroke treatment,
  - door to needle times for thrombolysis,
  - time to vascular surgery,
  - use of antithrombotic therapy at discharge.
- Four outcome indicators were commonly used: mortality, death or disability at 1-3-6 months, institutionalisation rate and discharge destination.
- Two suggested quality indicators in the questionnaire were not used in any country on a national level:
  - assessment and management of substance abuse,
  - completeness of aetiology information.
- Sweden reports the highest number of indicators. They refer also to the follow-up, even after discharge, to prevention, to patient-centred measures (quality of life, information, satisfaction). Extra case-mix variables are recorded:

- o ‘Patients' assessments of needs for rehabilitation and social services and to what extent they feel the needs are met’,
- o ‘Place of living and ADL function 3 and 12 months after stroke’,
- o ‘Out-patient follow-up visits’,
- o ‘Self-assessed general health’,
- o ‘Follow-up of next-of-kin's situation’.

- UK-London reports the second highest number of indicators, some of them differ from the Swedish ones: ‘time to endovascular therapy’, ‘assessment and follow up of nutritional status’, ‘long term death or disability’, ‘quality of life measures’, ‘prevention therapy adherence rates’, ‘readmission rates’.
- The respondent of Germany mentioned 2 extra indicators: ‘speech therapy’ and the ‘proportion of patients having imaging within one hour, if the stroke to door time is higher or equal to 2 hours’.

Table 31: Quality indicators used at national level

	Number of countries/regions with quality indicator	Sweden	Netherlands	Scotland	UK-London	France	Germany
Stroke unit care	6	Yes	Yes	Yes	Yes	Yes	Yes
Performance of screening for swallowing dysfunction	6	Yes	Yes	Yes	Yes	Yes	Yes
Performance of thrombolytic therapy	6	Yes	Yes	Yes	Yes	Yes	Yes
Stroke patients admitted to a stroke unit/total admissions for stroke	6	Yes	Yes	Yes	Yes	Yes	Yes
Time to thrombolytic therapy	6	Yes	Yes	Yes	Yes	Yes	Yes
Performance of brain imaging	5	Yes	No	Yes	Yes	Yes	Yes
Performance of imaging of the carotid artery	5	Yes	No	Yes	Yes	Yes	Yes
Use of antiplatelet therapy at discharge	5	Yes	No	Yes	Yes	Yes	Yes
Length of stay	5	Yes	Yes	Yes	Yes	Yes	No
Use of anticoagulants in patients with atrial fibrillation at discharge	5	Yes	No	Yes	Yes	Yes	Yes
Death during hospital period	5	Yes	No	Yes	Yes	Yes	Yes
Discharge destination	5	Yes	Yes	Yes	Yes	No	Yes
Proportion of time in stroke unit	4	Yes	No	Yes	Yes	Yes	No
Assessment by physiotherapist	4	Yes	No	No	Yes	Yes	Yes
Performance of endovascular therapy	4	Yes	Yes	Yes	Yes	No	No
Death or disability at 1, 3 or 6 months	4	Yes	Yes	Yes	Yes	No	No
Institutionalization rates	4	Yes	Yes	Yes	Yes	No	No
Use of antiplatelet therapy in the acute phase of stroke	4	No	No	Yes	Yes	Yes	Yes
Proportion of time in ER (before transfer to stroke unit)	4	Yes	No	Yes	Yes	Yes	No

	Number of countries/regions with quality indicator	Sweden	Netherlands	Scotland	UK-London	France	Germany
Assessment by occupational therapist	4	Yes	No	No	Yes	Yes	Yes
Complication rates	4	Yes	No	No	Yes	Yes	Yes
Provision of information to patients and relatives	3	Yes	No	No	Yes	No	Yes
Door to hospital time	3	Yes	No	No	Yes	Yes	No
Number of patients hospitalised within accepted time for thrombolysis	3	Yes	No	No	Yes	Yes	No
Time to endovascular therapy	3	Yes	Yes	Yes	No	No	No
Use of lipid lowering medication at discharge	3	Yes	No	No	Yes	Yes	No
Use of blood pressure lowering at discharge	3	Yes	No	No	Yes	Yes	No
Assessment and follow up of nutritional status	2	No	No	No	Yes	Yes	No
Patient satisfaction with services	2	Yes	No	No	Yes	No	No
Early supported discharge rates	2	Yes	No	No	Yes	No	No
Prevention therapy adherence rates	2	Yes	No	No	No	Yes	No
Long term death or disability	1	Yes	No	No	No	No	No
Quality of life measures	1	Yes	No	No	No	No	No
Readmission rates	1	No	No	No	Yes	No	No
Assessment and management of substance abuse e.g. alcohol	0	No	No	No	No	No	No
Completeness of aetiology information	0	No	No	No	No	No	No
Other	2	Yes	No	No	Yes	No	Yes

4.2.10.2 *Regional quality indicators*

Table 32 lists the quality indicators used for defining performance of health care providers in stroke care on a regional level. The 24 indicators, except for category 'other', are ranked from high to low based on frequency of use in the participating regions. Some indicators are used in one region and perhaps not in another region. This list is a sum of quality indicators of the different regions in our research sample. This table does not include Sweden, UK-London and Germany because those countries/regions use the national indicator set at all levels. In this inventory no extra indicators were pointed out by the respondents.

The health department of Scotland is divided in 14 health boards that serve a population from 30 000 to 1 000 000 persons.

- A national advisory group developed an action plan for stroke .
- A national audit is based on a data collection in the hospitals: the data mostly come from the coding by an administrative person who checks clinical data. Examples of formularies can be found via the following weblink[84]. This data set changes over the years and it measures the performance against national standards, derived from the SIGN guidelines.
- Different clinical networks organize the care operationally in the regions. Next to the data collected at national level they can organize initiatives within their local clinical network, based on regional indicators (non-exhaustive list in the table below).

According to the consulted experts, the following 12 quality indicators have not been used in any of the 3 countries/regions that use regional quality indicators: assessment and management of substance abuse e.g. alcohol; use of lipid lowering medication at discharge; use of blood pressure lowering at discharge; long term death or disability; complication rates; quality of life measures; readmission rates; prevention therapy adherence rates; patient satisfaction with services; provision of information to patients and relatives; early supported discharge rates; completeness of etiologic information.

Table 32: Quality indicators used at regional level

	Number of countries/regions with quality indicator	Netherlands	Scotland	France
Stroke unit care	3	Yes	Yes	Yes
Stroke patients admitted to a stroke unit/total admissions for stroke	3	Yes	Yes	Yes
Performance of thrombolytic therapy	3	Yes	Yes	Yes
Length of stay	3	Yes	Yes	Yes
Time to thrombolytic therapy	3	Yes	Yes	Yes
Discharge destination	3	Yes	Yes	Yes
Proportion of time in stroke unit	2	No	Yes	Yes
Performance of brain imaging	2	No	Yes	Yes
Performance of imaging of the carotid artery	2	No	Yes	Yes

	Number of countries/regions with quality indicator	Netherlands	Scotland	France
Performance of screening for swallowing dysfunction	2	Yes	Yes	No
Performance of endovascular therapy	2	Yes	Yes	No
Time to endovascular therapy	2	Yes	Yes	No
Use of antiplatelet therapy in the acute phase of stroke	2	No	Yes	Yes
Use of antiplatelet therapy at discharge	2	No	Yes	Yes
Use of anticoagulants in patients with atrial fibrillation at discharge	2	No	Yes	Yes
Death during hospital period	2	No	Yes	Yes
Death or disability at 1, 3 or 6 months	2	Yes	Yes	No
Institutionalization rates	2	No	Yes	Yes
Proportion of time in ER (before transfer to stroke unit)	2	No	Yes	Yes
Assessment and follow up of nutritional status	1	No	No	Yes
Door to hospital time	1	No	No	Yes
Number of patients hospitalised within accepted time for thrombolysis	1	No	No	Yes
Assessment by physiotherapist	1	No	No	Yes
Assessment by occupational therapist	1	No	No	Yes

4.2.10.3 Development of quality indicators

The process to develop quality indicators requires several steps (see Table 33). Common features include:

- the establishment of a board for guiding the development process,
- the involvement of several disciplines and patient organizations,
- the use of a prospective pilot study,
- the availability of documentation standards.

All but one country established a level of evidence of the proposed indicators.

Interestingly, only two countries defined target values for the quality indicators.

Table 33: Steps for the development of quality indicators

	Number of countries/regions	Sweden	Netherlands	Scotland	France	Germany
Standardized review of evidence	4	Yes	No	Yes	Yes	Yes
Establishment of a board for guiding development process	5	Yes	Yes	Yes	Yes	Yes
Presence of representatives from most or all disciplines treating stroke patients	4	Yes	Yes	Yes	No	Yes
Involvement of patient organizations	5	Yes	Yes	Yes	Yes	Yes
Use of a formal consensus process (e.g. Delphi)	2	Yes	No	No	No	Yes
A priori definitions of quality indicators	4	Yes	Yes	Yes	No	Yes
Division of quality indicators of process, structure or outcome	4	Yes	Yes	Yes	No	Yes
Developers made sure to cover several domains of stroke process	4	Yes	Yes	Yes	No	Yes
Target values were defined in the development of the criteria	2	No	No	Yes	No	Yes
Case mix variables were addressed	3	Yes	No	Yes	No	Yes
Inclusion of quality controls (validity of findings checked, completeness assessed)	3	Yes	No	Yes	No	Yes
Availability of documentation standards (e.g. a guide providing details and definitions on how to collect quality parameters)	3	Yes	No	Yes	No	Yes
Prospective pilot study before launching the quality criteria	3	Yes	No	Yes	No	Yes

4.2.10.4 *Communication strategy: results of the measurement of quality indicators.*

Sweden produces two series of annual reports:

- One covers the quality of care during the acute phase and the first 3 months after stroke,
- The second one reports the quality of medical care and community support during the first year after stroke.

The first report on the quality of TIA care has been also published. The reports are available on the website[53]. All reports include benchmarking between hospitals (with open labelling of the hospitals) and between regions. Riks-Stroke data have been extensively used in governmental reports, regional and local reports. They have been communicated and discussed at local, regional and national meetings. The Riks-Stroke team has been touring the country to discuss the Riks-Stroke data. An online website service is available for each participating hospital to compare the data they have reported with the regional and national data.

Scotland has also a publication of the results of the quality indicators[85]. Moreover, yearly national meetings aim to discuss the results of the quality indicators: high performing hospitals present their organization of stroke care so that everyone can learn from each other and share best practices. Finally, national auditors perform site visits and propose examples of best practices to suggest improvements during audits.

In France the communication of quality indicator results is only for internal use of the hospital. Benchmarking is done, but there is no public communication.

4.3 Summary: Quality of stroke services

In the previous chapter an overview has been given of stroke unit organization in six other countries or regions. It looked into detail at the quality assurance process, the accreditation procedures and/or the criteria for measurement of quality in stroke care.

Methodologically it is mainly based on expert consultation in these countries and regions, as well as on the consultation of some documents found in the grey literature and referred to by the contacted experts. Inherently to this methodology a possible incompleteness of the data, or a possible bias, cannot be excluded. However, by cross-checking the information from the different experts and sources, the risk of bias should be minimized.

- Common principles for quality measurement

This survey focused on countries with well-organised stroke units and related quality systems. The common principles for guiding stroke quality measurement were similar in the selected countries: criteria to define stroke units, a culture of quality monitoring, systems of feedback and incentives in different stages of operational maturity. The standards for stroke care were defined by health authorities, guided by professional experts (Sweden, Scotland, and France), sometimes completed by patient organizations (London) or defined by the professional organizations themselves (Germany).

- Adherence to standards: measurement

The methods to verify how the hospitals or stroke units adhere to these standards vary. A system with accreditation of stroke units is used in Scotland, France, Germany and the London area. The stroke units are recurrently accredited by an independent organization, either a government office or an independent authority. This organization performs site visits, evaluates structural criteria, reviews staffing lists, the presence of protocols and performs interviews of personnel and reviews charts. In Sweden no stroke unit accreditation is performed, but an extensive quality monitoring system is the way to measure the adherence to quality standards. A system of quality indicators measurement is in place also in the countries or regions where accreditation of stroke units exists.

- Complementary methods to improve the performance of the hospitals

Feedback of the accreditation or quality monitoring findings through meetings with stakeholders or reports are used in all countries as stimuli to indicate areas of improvement. Secondly, public reporting of the audit findings (Scotland, Sweden) or posting of an accreditation certificate (Germany) is used as an impetus. Finally, financial incentives are commonly used to encourage hospitals to admit patients to a stroke unit.

- Axes of quality monitoring

If one were to distil models from this survey, one could classify the differences in stroke quality monitoring across three axes: a liberal versus a governmental approach towards the development of standards of stroke care, accreditation of stroke units or monitoring of quality parameters, and the approach that is used towards hospitals failing to meet standards.

- Germany could be considered to represent a liberal model where standards are provided by a professional society, accreditation is done by a professional certifying authority and a stroke unit that is not awarded accreditation will not appear on a publically available website, will lose its reputation and, depending on the insurance company, will have financial losses. In most other surveyed countries governmental agencies monitor stroke units and quality indicators.
- Sweden could be considered the model where quality indicator measurement is the driver of stroke quality care measurement as here no formal accreditation is done.
- Scotland provides the model for an environment where feedback is used to generate improvement, as the hospitals that do not meet criteria receive special attention and help by the health authorities in order to improve the systems of care.

Key Points

- **Standards of care for stroke are defined in the surveyed countries by governmental or professional organizations;**
- **Accreditation of stroke units and nationwide registries are commonly used to ensure adherence to the standards of care;**
- **Incentives to encourage better quality are:**
  - **Public reporting of results of accreditation of stroke units,**
  - **Posting of quality indicator comparisons across several hospitals,**
  - **Increased fees for admission to an accredited stroke unit.**

5 DISCUSSION

The scope of this report was the care in acute stroke units as stipulated as in the Belgian Stroke Council Guidelines for Stroke Units[13, 14]: a geographic location within the hospital designated for stroke and stroke-like (i.e. with whom the neurological diagnosis has been be clearly established yet) patients, staffed by a multidisciplinary team (medical, nursing, physiotherapy plus occupational and speech or language therapists, case manager or discharge planner or social worker) with a special interest and expertise in stroke care.

The reader should bear are in mind that stroke is a disease that calls for other actions in terms of:

- Prevention and education campaigns in the population (e.g. to identify early symptoms);
- Rehabilitation and continuity of care at home after the acute phase.

5.1 Benefits of care in acute stroke units

A large body of literature provides evidence on the benefits of treating patients in acute stroke units, as described in section 2.2 The findings of the meta-analysis confirm the conclusions of the Cochrane review from Langhorne et al[12]: patients who receive dedicated care in a stroke unit are more likely to survive, to be discharged to home following hospital care and to be independent in their daily life after stroke. In addition, the most significant benefits of a stroke unit appear to be a reduction of the length of stay, of the demand for post-discharge institutional care and better results for composite measures such as death or institutional care, death or dependency.

However, only 3 out of the 11 trials included in this analysis comparing stroke unit care with care provision in general medical wards were published in the past ten years. In particular, the trials with large sample sizes (N>300) are old[30;19;27;28] the latest dates from 1998. This lack of recent clinical evidence is likely to be related to the fact that stroke unit care is now established as the gold standard since a few years. This finding limits the ability of the meta-analysis to demonstrate the superiority of stroke units using recent evidence.

5.2 What is a stroke unit?

One of the most crucial questions is to define what is an effective stroke unit. This definition evolved during the past decades but the key elements remain unchanged. In the 80's, a stroke unit was already comprised of specific elements: "personnel specially educated at weekly conferences", "a unit that stresses early active approach to mobilization and rehabilitation planning", "preplanned investigation program", "a close co-operation between all categories of personnel"[30]. Similarly nowadays, a multidisciplinary team, early mobilization/rehabilitation planning and a structured diagnosis/investigation process are still important features of inpatient stroke unit carej.

This review identified in the literature and in other countries the corresponding quality indicators e.g. early mobilization/rehabilitation assessment, presence of a multidisciplinary team (and documentation of meetings), training of staff, a discharge plan. Most of them have good sources of evidence.

5.3 What works within an acute stroke unit?

The exact nature of acute stroke units that would lead to improved patient outcomes remains unclear, mainly due to the complexity and connection of the individual components.

- Effective components of acute stroke units

This systematic review identified many studies that investigate the effect of specific components of acute stroke care. Two structure indicators are supported by the evidence e.g. training of medical staff and a multidisciplinary team. The composition of this team could be further defined: as an illustration, the presence of a geriatrician could be of high value given the age of most patients and the necessary continuity of care at discharge to another ward.

Many clinical indicators are supported by a high level of evidence (e.g. thrombolysis, swallowing screening and early mobilization). Only two selected studies specifically explored the relationship between components of stroke unit care and the desired patient outcomes.

  - The first one[86] recorded significant differences between stroke units and general medical wards; a staff more aware of the complications (and their prevention), faster and more comprehensive initial assessment of the patient, frequency of assessment procedures, acute management and early rehabilitation;
  - Langhorme et al identified 6 consistent characteristics of stroke units[47]: comprehensive assessment of medical problems, impairments and disabilities; active management of physiological abnormalities; early mobilization; skilled nursing care; early setting of rehabilitation plans involving carers; early assessment and planning of discharge needs.

- New strategies with promising results

Over the last years, comparisons of different monitoring strategies and types of treatments have been carried out to identify which aspects of stroke unit care are the most efficacious. Randomized trials with continuous monitoring and stroke units with implementation of standardized protocols show promising results on given endpoints. Other innovative care options (e.g. very early mobilization) call for further trials.

- A gap between the literature and the practice

Considerable emphasis has been placed on promoting thrombolysis as the hyper acute treatment option for patients with stroke within a very short therapy window. This aspect of care is therefore the topic of many quality indicators with a high level of evidence. However, a small percentage only of the eligible stroke patients (less than 20%) benefit from early thrombolysis in Belgium and abroad[87-89].

j Stavem and Ronning. Quality of life 6 months after acute stroke: impact of initial treatment in a stroke unit and general medical wards. Cerebrovasc Dis 2007; 23: 417-423.

Nevertheless, even in the absence of early thrombolysis, early and comprehensive medical assessment coupled with prompt undertaking of diagnostic investigations provided by a specialized multidisciplinary stroke team can improve the outcomes. In addition to these acute measures, measures to reduce complications and enhance recovery also play a significant role. Some illustrations based on evidence are found in the clinical quality indicators (rehabilitation assessment, prevention of swallowing complications).

5.4 Limitations in the interpretation of the results of the meta-analysis

The overall findings of the meta-analysis are in line with the Cochrane review and other Health Technology Assessments on the same topic. Small discrepancies were noted and explained in the discussion of the section on meta-analysis (see 2.3).

As stated above, the lack of recent large scale randomized control trials is a limitation to analyze the efficacy of the most recent organizational models of stroke units. There is also a shortage of studies that evaluate specific components of stroke units.

The meta-analysis indicates that the included trials may suffer from publication bias: the funnel plot analysis suggests that small studies with negative outcomes could not have been reported. The absence of small trials with negative results is seen in the trials comparing comprehensive stroke unit and general medical wards. However funnel plot analysis has its own limitations and a positive point is that the Cochrane Collaboration trialists made extensive efforts to find unpublished trials.

5.5 How to assess the quality of care in stroke units?

This research identified a large set of quality indicators to assess and evaluate the quality of care for patients in the acute phase of stroke, in particular in stroke units. A large set of indicators was identified in the literature and in other countries. Quality indicators are used for different purposes e.g. measure the efficacy of clinical care, accreditation for stroke units, benchmarking.

- Structure indicators

Structure indicators are easy to measure (e.g. number of beds, other technical infrastructure). Common quality indicators are the presence of a multidisciplinary team and the training of the staff.

Structure indicators might be interesting when (a part of) the measurement is based on self-reports by the institutions themselves. However it is difficult to establish a firm relationship between these measures and the patient outcomes. There is a general paucity of evidence on structure indicators.

- Process indicators

Some elements of the care process can be easily quantified (e.g. time span to thrombolysis). A definite advantage of many process indicators is that their impact on patient outcomes is direct and measurable. The relationship between process and outcomes can be quantified (e.g. by regression analysis) and this explains e.g. the substantial amount of evidence identified around process indicators.

Nevertheless some process indicators are more subjective measures (e.g. close co-operation within multidisciplinary team, seamless flow of care). The relationship between these processes of care and patient outcomes has been addressed by several randomized controlled trials and observational studies[47, 86]. These studies are hardly feasible in practice, as for example the measure of the impact of ‘close co-operation of the stroke team’. The restricted choice of evidence-based clinical quality indicators would eliminate these indicators.

- Connection between structure and process indicators

A connection between structure and process indicators is frequently noted in the inventory of the quality indicators. For example, the structure indicator “24 h availability of brain imaging” is actually reflected in the process indicator category “brain imaging”. In this sense, a process indicator could be perceived as being superior to the structure indicator because it also indicates if the intervention has been carried out rather than evaluating whether the facility has the capacity to provide it.

- Importance of outcome measures for institutions and decision -making

Some outcome indicators (stroke mortality, new stroke events per year) are of high interest. On one hand the follow-up of these indicators might be of interest for the hospitals themselves (e.g. monitoring of mortality). On the other hand outcome measures can support decisions from the authorities e.g. for the planning of beds in long term care institutions. However, the interpretation of outcome indicators requires caution:

  - the numbers of rare events (e.g. mortality) cannot be always interpreted at the unit level;
  - many of them are influenced by patient characteristic biases (e.g. age, baseline stroke severity) and do not allow making conclusions on the quality of care.

5.6 Choice of indicators according to the purpose

The final choice and further definition of indicators depend upon the purpose:

- One purpose may be the nationwide monitoring of stroke care performance by a governmental agency. Ideally, the data required to estimate these quality indicators should be easily obtained through existing databases. A national registration calls for a reliable continuous, centralized registration system as found in other countries (e.g. Sweden).
- An accreditation procedure requires other quality indicators, mostly indicators on the quality of the process of care.
- Benchmarking across hospitals requires a set of highly standardised quality indicators (for example a specific tool to measure patient satisfaction). In this situation the record of case mix variables is important.

In the absence of current decision on the exact purpose of a set of quality indicators in Belgium, the researchers left the selection open. Other factors can play a role in the selection e.g. the availability of the data in the administrative databases and the expected burden of the data collection.

In the same way, few cut-off values have been found in the literature and their choice does not always rely on evidence (e.g. number of beds, rate of complications). Defining cut-off values is a difficult exercise, as for example the choice of an “acceptable” complication or mortality rate, partly based on the available data and literature.

Guidelines on how to develop quality indicators have been recently proposed in the context of stroke[90]. They include a formal procedure for development and selection of quality criteria, documentation standards and a system to update the indicators on a regular basis. The use of the set of indicators should be tested in a prospective pilot study.

Harmonization of quality indicators for stroke care is on the agenda of professional organizations in Europe, by the European Stroke Organization.

5.7 Use of quality indicators in other countries

The international survey focused on countries with well-organized stroke units and related quality systems. The principles for the quality measurement of care during the acute phase of stroke were similar in the selected countries: criteria to define stroke units, culture of quality monitoring, systems of feedback and incentives in different stages of operational maturity.

The standards for stroke care are defined by health authorities, guided by professional experts (Sweden, Scotland, and France). They are sometimes completed by patient organizations (London) or defined by the professional organizations themselves (Germany).

- Adherence to standards: measurement

A system of compulsory accreditation of acute stroke units exists in Scotland, France and in the London Services; in Germany the system is not compulsory. The stroke units are recurrently accredited by an organization independent from the hospital, either a government office or a private company. This organization performs site visits, evaluates structural criteria, reviews staffing lists, the presence of protocols and performs interviews of personnel and reviews charts. There is also an extensive quality monitoring system to measure the adherence to quality standards in Sweden and in the countries or regions where accreditation of stroke units exists.

- Complementary methods to improve the performance of the hospitals

Feedback on the accreditation or quality monitoring findings through meetings with stakeholders or reports is used in all countries as stimuli to indicate areas of improvement. Moreover, public reporting of the audit findings (Scotland, Sweden) or posting of an accreditation certificate (Germany) is used as an impetus. Finally, financial incentives are commonly used to encourage hospitals to admit stroke patients to a stroke unit.

- Axes of quality monitoring

One can classify the differences in stroke quality monitoring across three axes:

  - a (non or) governmental approach towards the development of standards of stroke care,
  - accreditation of stroke units versus monitoring of quality parameters,
  - consequences for the hospitals failing to meet standards.

Germany has an accreditation process that illustrates a process not completely led by the government: the standards are provided by a professional society and accreditation is done by a professional certifying authority (similar to bodies like Joint Commission International or ISO). Medical departments have two incentives to get an accreditation: a financial incentive (they are paid more per patient if they are accredited) and a reputation incentive (publication on a website where patients can assess the provision of services within their region).

In most other surveyed countries governmental agencies monitor stroke units and quality indicators:

  - The Swedish system offers a model where quality indicator measurement is the driver of the quality care: there is no formal accreditation of stroke units;
  - Scotland follows a non-punitive approach: the hospitals are encouraged to improve their services with the help of the governmental body. The hospitals that do not meet criteria receive special attention and support from the health authorities in order to improve.

5.8 Situation in Belgium

5.8.1 Existing standards and feedback mechanisms

In Belgium, standards for stroke unit care and stroke guidelines have been published by the Belgian Stroke Council[13] and by the Société Scientifique de Médecine Générale (http://kce.docressources.info/opac/index.php?lvl=notice_display&id=1277)

However, there is neither a nationwide/ regional system for the accreditation of stroke units, nor a quality registry from the government or regional health authorities.

Two initiatives are worth mentioning. Hospital networks have developed pilot quality registries. Feedback on in-hospital stroke mortality and individual hospital costs for stroke have been provided recently to the hospitals providing acute care by the government but there is a delay of a few years between the data collection and the feedback.

5.8.2 *Consequence: heterogeneity in the implementation of (non-accredited) stroke units*

The absence of systematic quality measurement in acute stroke units probably leads to variations in the implementation of the evidence and in the quality of care for stroke patients. Moreover, in the absence of official definition of stroke units, many hospitals have set up their own stroke unit whose organization varies.

Other hospitals did not set up stroke units for diverse reasons: lack of awareness and knowledge of the benefits of stroke units by hospital directions and professionals, financial hurdles due to the additional equipment and personnel, unclear guidelines, motivational issues in clinical practice, lack of protocols, insufficient staffing (medical, paramedical or nursing level), lack of collaboration between medical departments involved in acute stroke care (e.g. emergency, neurology, radiology, cardiology departments, neurosurgery).

5.9 Towards care of high quality for stroke patients in Belgium

The evidence on the efficacy of acute stroke units and early thrombolysis suggests that all eligible patients in Belgium should have access to these treatments.

5.9.1 *Revision and dissemination of the guidelines*

The guidelines mentioned above (5.8.1) could be further updated and disseminated in collaboration with policy makers, insurance companies, sickness funds, hospitals, professional and patient organizations.

It is important that all patients would follow a definite pathway, even if they did not receive thrombolysis, as other interventions are effective.

5.9.2 *Possible scenarios for the implementation of stroke units in Belgium*

Different scenarios could be envisaged to organize and accredit acute stroke units.

5.9.2.1 *A basic stroke unit in all hospitals*

In a first scenario, all hospitals would be required to have a stroke unit that adheres to a set of norms. This organization guarantees that every admitted stroke patient has the potential to receive stroke unit care (versus a system where some hospitals are bypassed).

The drawback of that scenario is that implementation of a stroke unit requires substantial resources. The necessary experience and organization to provide 24/7 thrombolysis services might also be an issue in low volume centres. This system is adopted in Sweden, where every hospital is supposed to have a stroke unit. Surprisingly, Sweden has no accreditation of stroke units. Data on costs of stroke units in the Belgian situation are lacking but the assumption is that the costs would be high unless “basic” types of stroke units are accredited.

5.9.2.2 *Care of high quality in a restricted number of hospitals*

A second scenario is the recognition of a limited number of designated hospitals based on admission volumes and geographical catchment areas. This would ensure timely administration of thrombolysis and acute stroke services, without duplicate efforts in neighbouring hospitals. These centres (hyper acute stroke units) could additionally provide highly specialized services, like interventional endovascular services or neurovascular surgery.

The advantages are the concentration of efforts, the larger volume and experience gained by the treating hospital.

The disadvantages are that hospitals without thrombolysis would have to be bypassed by the ambulance services. This requires legal changes, training of ambulance personnel and information of general practitioners and patients. Furthermore, some hospitals can fear the loss of patients and. distances might also be a problem for the patient’s relatives. Finally, the capacity of the receiving hospitals might be overwhelmed.

5.9.2.3 *Hyper acute stroke unit followed by local stroke unit*

A mixed model similar to the London one could be organized: designated hospitals receive all stroke patients eligible for thrombolysis. After a few days of monitoring in the hyper acute stroke unit, they are referred back to the stroke unit in the vicinity of the patient's home. This solution also needs an adaptation of the ambulance service but the capacity problems, the loss of patients in the local hospitals and distances for the patient's relatives are less problematic.

After two years of service provision, the London Strategic Health Authority is evaluating the cost-effectiveness of this model. The first conclusions are that seamless transfer of care between the hyper acute stroke units and the regular stroke units avoids fragmented care.

5.9.2.4 *Thrombolysis in all hospitals, stroke units in some settings*

Another option is to disentangle thrombolysis from stroke unit care. In this so-called 'drip and ship' model, all hospitals provide thrombolysis services, but, if they do not have a stroke unit, they refer all stroke patients to a hospital with a stroke unit. A particular attention should be paid to ensure that thrombolysis services are present at all times in the hospital that initially treats the patient. The drawbacks also include the low volume of patients in some of the hospitals, the lack of experience in thrombolysis, the referral of some patients only. The safety and the cost for the transfer of recently thrombolysed patients might also be a problem, although the limited literature on this topic suggests that this is safe[91].

The option of telemedicine has been adopted in countries with rural areas (France) and/or shortage of specialists in stroke care (UK)[92]. In Belgium, the distances and the density of the population orient towards the direct reference to a specialized centre, using one of the previous scenario's.

5.9.3 *Accreditation of stroke units and/or quality monitoring system*

Accreditation of stroke units (and thrombolysis services) can be organized by an agency from the federal or regional government or through a private organization. Involvement of professional societies is required for the definition of the standards, ideally in accordance with the European ones. In Scandinavia stroke units are not accredited, but a quality registry monitors the quality using specific items for stroke unit care.

5.9.3.1 *Quality monitoring system*

As stated above, a quality monitoring system can serve several purposes (accreditation, national or international benchmarking, public accountability, research). The sets of quality indicators should match the purpose. Measurement alone cannot improve the performance of a health care system and the monitoring system should be integrated into a quality improvement cycle to enhance the overall quality of stroke care.

A previous report of the KCE on quality improvement for cancer care concluded that[93]: "In order to have a fully operational and integrative quality system, key elements are the know-how to develop clinical practice guidelines and related quality indicators, a highly effective data collection, correct data analysis and interpretation, the decision power to provide feedback to the end users, and the ability to initiate targeted and corrective actions." The same elements apply to the quality improvement system of stroke care.

5.9.3.2 *Incentives for admissions and quality of care in stroke units*

The Belgian financial system is currently partially based on the mean length of stay and does not integrate elements that reflect the quality of care. Other countries have incentives related to the care in stroke units e.g. incentives to admit patients in a stroke unit, incentives to adhere to process indicators. Moreover, the collaborations between hospitals that provide different services (e.g. acute care and rehabilitation, cf. above) is important as the set-up of stroke units in all hospitals does not seem realistic.

5.9.4 From the selection of quality indicators to the implementation of the data collection

This report provides a comprehensive list of indicators with a first selection by experts. Additional stakeholders will need to be involved in the selection process, like representatives of hospital and patient organizations.

The collecting process requires a preliminary pilot test to assess the feasibility of data collection. A high quality registration system will furthermore assess information required for case-mix correction, process times within the hospital, resource use within a hospital as well as medication data. Data managers in hospitals will need to collect data in a standardized fashion. If important outcome indicators like disability, institutionalization and mortality rates after discharge are collected, the linkage of different databases will be required in the absence of a specific data collection during the follow-up of the patient. The question of anonymisation and centralization of data also requires decisions. The example of the national cancer registry shows that this is challenging but possible.

5.9.5 Use of data and possible consequences

5.9.5.1 Feedback

A feedback system is the condition to improve the quality of care. The government has some tools that can be helpful (like portahealth[k]). Academic, scientific organizations (e.g. http://www.navigator.czv.be/) and private companies can also offer their expertise.

5.9.5.2 Public reporting

The question of public reporting is sensitive in Belgium, whilst this is currently used in other regions (e.g. Scotland). Caveats are necessary for the interpretation of the results and case mix corrections are required so that the interpretation is unambiguous. This system needs furthermore to be developed in cooperation with patient/client organizations and professionals.

5.9.5.3 Consequences for hospitals: inspiration of other countries

Finally, the Belgian health care system will have to determine the consequences of the measurement of quality indicators. Public reporting has been mentioned, financial consequences are also within the range of possibilities In some countries, underperforming hospitals propose and implement an improvement plan. Well performing hospitals set new targets. Very well performing hospitals share their experience with collaborating hospitals and become role models.

[k] Portahealth is a central secured data collection system for hospital data. Hospital send their data and receive a quality control of the information; the access is restricted to hospital administrators: http://www.health.belgium.be/eportal/Healthcare/Healthcarefacilities/Registrationsystems/index.htm).

REFERENCES

1. Kiekens C, Van Rie K, Leys M, Cleemput I, Smet M, Kesteloot K, et al. Organisation et financement de la réadaptation locomotrice et neurologique en Belgique. Brussels: Centre fédéral d'expertise des soins de santé (KCE); 2007. Health Services Research (HSR) 57B Available from: https://kce.fgov.be/sites/default/files/page_documents/d20071023019.pdf
2. Thijs V, Dewilde S, Putman K, Pince H. Cost of hospitalization for cerebrovascular disorders in Belgium. Acta Neurol.Belg. 2011;111(2):104-10.
3. Mackey J, Mensah G. The Atlas of Heart Disease and Stroke. 2004.
4. Stroke Unit Trialists' Collaboration. Collaborative systematic review of the randomised trials of organised inpatient (stroke unit) care after stroke. 1997(314):1151-9.
5. Thonnard J, Arnould C, Penta M, Nielens H, Pendeville E, Van Den Steen D, et al. Functional status of the patient: a potential tool for the reimbursement of physiotherapy in Belgium? Brussels: Belgian Health Care Knowledge Centre (KCE); 2006. Good Clinical Practice (GCP). Report 40C Available from: https://kce.fgov.be/publication/report/functional-status-of-the-patient-a-potential-tool-for-the-reimbursement-of-physio
6. Leclercq A, De Gauquier K, Ceuppens A, Boly J, Van Den Steen D, D. P. Consumption of physiotherapy and physical and rehabilitation medicine in Belgium. Brussels: Belgian Health Care Knowledge Centre (KCE); 2008. Health Services Research (HSR) KCE report 87C Available from: https://kce.fgov.be/publication/report/consumption-of-physiotherapy-and-physical-and-rehabilitation-medicine-in-belgium
7. Askim T, Morkved S, Indredavik B. Does an extended stroke unit service with early supported discharge have any effect on balance or walking speed? J.Rehabil.Med. 2006;38(6):368-74.
8. Fagerberg B, Claesson L, Gosman-Hedstrom G, Blomstrand C. Effect of acute stroke unit care integrated with care continuum versus conventional treatment: A randomized 1-year study of elderly

patients: the Goteborg 70+ Stroke Study. Stroke. 2000;31(11):2578-84.

9. Fjaertoft H, Indredavik B, Lydersen S. Stroke unit care combined with early supported discharge: long-term follow-up of a randomized controlled trial. Stroke. 2003;34(11):2687-91.
10. Indredavik B, Bakke F, Slordahl SA, Rokseth R, Haheim LL. Stroke unit treatment. 10-year follow-up. Stroke. 1999;30(8):1524-7.
11. Langhorne P, Stott D, Knight A, Bernhardt J, Barer D, Watkins C. Very early rehabilitation or intensive telemetry after stroke: a pilot randomised trial. Cerebrovasc.Dis. 2010;29(4):352-60.
12. Stroke Unit Trialists' Collaboration. Organised inpatient (stroke unit) care for stroke (Review). 2009(1).
13. Thijs V, Peeters A, Dewindt A, Hemelsoet D, De KN, Laloux P, et al. Organisation of inhospital acute stroke care and minimum criteria for stroke care units. Recommendations of the Belgian Stroke Council. Acta Neurol.Belg. 2009;109(4):247-51.
14. Stroke Unit Trialists' Collaboration. Organised inpatient (stroke unit) care for stroke. Stroke Unit Trialists' Collaboration. Cochrane Database Syst.Rev. 2000(2):CD000197.
15. Kasner SE. Clinical interpretation and use of stroke scales. Lancet Neurol. 2006;5(7):603-12.
16. Kwon S, Hartzema AG, Duncan PW, Min-Lai S. Disability measures in stroke: relationship among the Barthel Index, the Functional Independence Measure, and the Modified Rankin Scale. Stroke. 2004;35(4):918-23.
17. Uyttenboogaart M, Stewart RE, Vroomen PC, De Keyser J, Luijckx GJ. Optimizing cutoff scores for the Barthel index and the modified Rankin scale for defining outcome in acute stroke trials. Stroke. 2005;36(9):1984-7.
18. Stavem K, Ronning OM. Quality of life 6 months after acute stroke: impact of initial treatment in a stroke unit and general medical wards. Cerebrovasc.Dis. 2007;23(5-6):417-23.
19. Ronning OM, Guldvog B. Stroke unit versus general medical wards, II: neurological deficits and activities of daily living: a quasi-randomized controlled trial. Stroke. 1998;29(3):586-90.
20. Spengos K, Tsivgoulis G, Manios E, Papamichael C, Konstastinopoulou A, Vemmos K. Which patients benefit most from treatment in a stroke unit? Stroke. 2004:294.
21. Vemmos K, Takis K, Madelos D, Synetos A, Volotasiou V, Tzavellas H. Stroke unit treatment versus general medical wards: long term survival. 2001;11 Suppl:4-8.
22. Ma RH, Wang YJ, Qu H, Yang ZH. Assessment of the early effectiveness of a stroke unit in comparison to the general ward. Chin Med.J.(Engl.). 2004;117(6):852-5.
23. Hankey GJ, Deleo D, Stewart-Wynne EG. Stroke units: an Australian perspective. Aust.N.Z.J.Med. 1997;27(4):437-8.
24. Indredavik B, Bakke F, Solberg R, Rokseth R, Haaheim LL, Holme I. Benefit of a stroke unit: a randomized controlled trial. Stroke. 1991;22(8):1026-31.
25. Indredavik B, Slordahl SA, Bakke F, Rokseth R, Haheim LL. Stroke unit treatment. Long-term effects. Stroke. 1997;28(10):1861-6.
26. Cabral NL, Moro C, Silva GR, Scola RH, Werneck LC. Study comparing the stroke unit outcome and conventional ward treatment: a randomized study in Joinville, Brazil. Arq Neuropsiquiatr. 2003;61(2A):188-93.
27. Garraway WM, Akhtar AJ, Hockey L, Prescott RJ. Management of acute stroke in the elderly: follow-up of a controlled trial. Br.Med.J. 1980;281(6244):827-9.
28. Garraway WM, Akhtar AJ, Prescott RJ, Hockey L. Management of acute stroke in the elderly: preliminary results of a controlled trial. Br.Med.J. 1980;280(6220):1040-3.
29. Strand T, Asplund K, Eriksson S, Hagg E, Lithner F, Wester PO. A non-intensive stroke unit reduces functional disability and the need for long-term hospitalization. Stroke. 1985;16(1):29-34.

30. von Arbin M, Britton M, deFaire U, Helmers C, Miah K, Murray V. A study of stroke patients treated in a non-intensive stroke unit or in general medical wards. Acta Med.Scand. 1980;208(1-2):81-5.
31. Kalra L, Evans A, Perez I, Knapp M, Donaldson N, Swift CG. Alternative strategies for stroke care: a prospective randomised controlled trial. Lancet. 2000;356(9233):894-9.
32. Bernhardt J, Dewey H, Thrift A, Collier J, Donnan G. A very early rehabilitation trial for stroke (AVERT): phase II safety and feasibility. Stroke. 2008;39(2):390-6.
33. Cumming TB, Thrift AG, Collier JM, Churilov L, Dewey HM, Donnan GA, et al. Very early mobilization after stroke fast-tracks return to walking: further results from the phase II AVERT randomized controlled trial. Stroke. 2011;42(1):153-8.
34. Middleton S, McElduff P, Ward J, Grimshaw JM, Dale S, D'Este C, et al. Implementation of evidence-based treatment protocols to manage fever, hyperglycaemia, and swallowing dysfunction in acute stroke (QASC): a cluster randomised controlled trial. Lancet. 2011;378(9804):1699-706.
35. Sulter G, Elting JW, Langedijk M, Maurits NM, De KJ. Admitting acute ischemic stroke patients to a stroke care monitoring unit versus a conventional stroke unit: a randomized pilot study. Stroke. 2003;34(1):101-4.
36. Cavallini A, Micieli G, Marcheselli S, Quaglini S. Role of monitoring in management of acute ischemic stroke patients. Stroke. 2003;34(11):2599-603.
37. Askim T, Morkved S, Engen A, Roos K, Aas T, Indredavik B. Effects of a community-based intensive motor training program combined with early supported discharge after treatment in a comprehensive stroke unit: a randomized, controlled trial. Stroke. 2010;41(8):1697-703.
38. Early Supported Discharge Trialists. Services for reducing duration of hospital care for acute stroke patients Cochrane.Database.Syst.Rev. 2000(2):CD000443.
39. Hamidi V, Wisloff T, Ringerike T, Linnestad KK, Harboe I, Klemp M. Treatment of patients with acute stroke in stroke units (with or without early supported discharge). 2010.
40. Canadian Stroke Strategy. Canadian Best Practice Recommedation for Stroke Care. Update 2010. Canadian Stroke Network; 2010. Available from: http://www.strokebestpractices.ca/wp-content/uploads/2011/04/2010BPR_ENG.pdf
41. The National Collaborating Centre for Chronic Conditions. Stroke: National clinical guideline for diagnosis and initial management of acute stroke and transient ischaemic attack (TIA). 2008.
42. Craig LE, Bernhardt J, Langhorne P, Wu O. Early mobilization after stroke: an example of an individual patient data meta-analysis of a complex intervention. Stroke. 2010;41(11):2632-6.
43. Mainz J. when supervised by health professionals. Acta Psychiatr.Scand. 2008;117(5):321-2.
44. Scottish Intercollegiate Guidelines Network (SIGN). Key to evidence statements and grades of recommendations 2012.
45. Abilleira S, Gallofre M, Ribera A, Sanchez E, Tresserras R. Quality of in-hospital stroke care according to evidence-based performance measures: results from the first audit of stroke, Catalonia, Spain. Stroke. 2009;40(4):1433-8.
46. Vlayen J, van de Water G, Camberlin C, Paulus D, Leys M, Ramaekers D, et al. Indicateurs de qualit, cliniques (KCE reports vol. 41B). 2006.
47. Langhorne P, Pollock A. What are the components of effective stroke unit care? Age Ageing. 2002;31(5):365-71.
48. Langhorne P, Dey P, Woodman M, Kalra L, Wood-Dauphinee S, Patel N, et al. Is stroke unit care portable? A systematic review of the clinical trials. Age Ageing. 2005;34(4):324-30.
49. South London Cardiac and Stroke Network London Stroke Strategy [London;2011 [cited 11-04-2012]. Available from: http://www.slcsn.nhs.uk/lss/

50. Roberts MA, Allen A, Langhorne P, McEwen J, Semple DA. Organisation of services for acute stroke in Scotland--report of the Scottish stroke services audit. 2000;58(2):87-95.
51. National Health Services Scotland Scottish Stroke Care Audit website [Edinburgh;2012 [cited 12-04-2012]. Available from: http://www.strokeaudit.scot.nhs.uk/
52. Scottish Government Health Directorate Revised strategy for heart disease and stroke in Scotland [Edinburgh;2009 [cited 12-05-2012]. Available from: http://www.scotland.gov.uk/Publications/2009/06/29102453/0
53. Västerbotten County Council KA Riks Stroke Reports [Umeå, Sweden;2011 [updated 30-03-2011; cited 10/04/2012]. Available from: http://www.riks-stroke.org/index.php?content=analyser
54. National Board of Health and Welfare Stroke Guidelines [Stockholm;2005 [updated 2012/04/27/; cited 05-05-2012]. Available from: http://www.socialstyrelsen.se/nationalguidelines/nationalguidelinesforstrokecare
55. Le ministre de la santé et des solidarités France Circulaire numéro DHOS/O4/2007/108 du 22 mars 2007 relat ive à la place des unités neuro-vasculaires dans la

prise en charge des patients présentant un accident vasculaire cérébral [2007 [cited 12 June 2012]. Available from: http://circulaire.legifrance.gouv.fr/pdf/2009/04/cir_14512.pdf

56. Stiftung Deutsche Schlaganfall Hilfe Stiftung Deutsche Schlaganfall Hilfe [Gütersloh;2012 [cited 02-05-2012]. Available from: http://www.schlaganfall-hilfe.de/
57. TÜV Rheinland Group LGA Intercert. Zertifizierung von Stroke Units [Nürnberg;2012 [cited 02-05-2012]. Available from: http://www.lga-intercert.com/dienstleistungen/8-qm-systeme-in-medizinischen-einrichtungen/25-zertifizierung-von-stroke-units
58. Nederlandse Hartstichting Commissie Ontwikkeling Richtlijnen Stroke Unit. Advies opzet Stroke unit [Den Haag;2012 [cited 14-02-2012]. Available from: http://www.hartstichting.nl/professionals/toolbox/gezondheidszorg/Beroerte/
59. Abilleira S, Ribera A, Sanchez E, Tresserras R, Gallofre M. The Second Stroke Audit of Catalonia shows improvements in many, but not all quality indicators. 2012;7(1):19-24.
60. U.S. Department of Health & Human Services AfHRaQ National Quality Measures Clearinghouse [2011 [cited 14-04-2012]. Available from: http://qualitymeasures.ahrq.gov/
61. US Department of Health and Human Services Agency for Healthcare Research and Quality [2012 [cited May 2012]. Available from: http://www.ahrq.gov/
62. Canadian Stroke Network HaSFoC Canadian Stroke Strategy Performance Measurement Manual [Canada;2012 [cited 12-04-2012]. Available from: http://www.strokebestpractices.ca/index.php/methods/performance-measures-development/
63. Healthcare for London CSfL Stroke acute commissioning and tariff guidance [London;2009 [cited 14-04-2012]. Available from: http://www.londonhp.nhs.uk/wp-content/uploads/2011/03/Stroke-Commissioning-and-Tariff-Guidance.pdf
64. Socialstyrelsen National Board of Health and Welfare [Stockholm;2012 [cited 16-02-2012]. Available from: http://www.socialstyrelsen.se/nationellariktlinjerforstrokesjukvard
65. Centraal Begeleidings Orgaan voor de intercollegiale toetsing Diagnostiek, behandeling en zorg voor patiënten met een beroerte [Utrecht, The Netherlands;2012 [cited 11-06-2012]. Available from: http://www.cbo.nl/Downloads/218/rl_beroerte_09.pdf
66. Nederlandse Vereniging voor Neurologie Richtlijnen Nederlandse Vereniging voor Neurologie [Utrecht;2008 [cited 12-03-2012]. Available from: http://www.neurologie.nl/publiek/beroepsinformatie/richtlijnen/nvn-richtlijnen
67. Scottish Intercollegiate Guidelines Network (SIGN). Management of patients with stroke or TIA: Assessment, investigation, immediate management and secondary prevention. 2008. 108 (978 1 905813

40 7) Available from: http://www.sign.ac.uk/guidelines/fulltext/108/index.html

68. Scottish Intercollegiate Guidelines Network (SIGN) Management of patients with stroke: rehabilitation, prevention and management of complications, and discharge planning [Edinburgh;2011 [cited 14-04-2012]. Available from: http://www.sign.ac.uk/guidelines/fulltext/118/
69. Scottish Intercollegiate Guidelines Network (SIGN). Management of Patients with Stroke: Identification and Management of Dysphagia. 2010. 119 (978 1 905813 65 0) Available from: http://www.sign.ac.uk/guidelines/fulltext/119/
70. Woimant F, Hommel M, Adnet Bonte C, Baldauf E, Chedru F, Cohen A, et al. Recommendations for the creation of neuro-vascular units. 2001;157(11 Pt 1):1447-56.
71. Royal College of Physicians Stroke Guidelines [London;2008 [cited 14-04-2012]. Available from: http://www.rcplondon.ac.uk/resources/stroke-guidelines
72. Ringelstein EB. Recommendation for organization of special stroke departments (stroke units). 1997 implementation. 1998;69(2):180-5.
73. Ringelstein EB. Concept of interregional and regional stroke treatment in Germany. Report of the recommendation of Commission 1.06 "Stroke Units and Acute Stroke Therapy" of the German Society for Neurology. 2000;71(4):322-4.
74. Ringelstein EB. Time is brain ƒ_" Competence is brain. 2005;2006(8):1024-7.
75. Faiss JH, Busse O, Ringelstein EB. New developments in German stroke units. 2008;79(4):480-2.
76. Ringelstein EB, Busse O, Ritter MA. Current concepts of Stroke Units in Germany and Europe. 2011;162:155-60.
77. Ringelstein EB, Muller-Jensen A, Nabavi DG, Grotemeyer KH, Busse O. Comprehensive stroke unit. 2011;82(6):778-84.
78. National Health Services Scotland Stroke Training [Edinburgh;2012 [cited 26-04-2012]. Available from: http://www.stroketraining.org/
79. National Health Services Scotland Stroke Core Competencies [Edinburgh;2012 [cited 11-02-2012]. Available from: http://www.strokecorecompetencies.org/node.asp?id=home
80. National Health Services Scotland Stroke Advancing Modules [2012 [cited 10-04-2012]. Available from: http://www.strokeadvancingmodules.org/node.asp?id=advancing
81. National Health Services Scotland Thrombolysis Masterclass [2012 [cited 10-04-2012]. Available from: http://www.strokeadvancingmodules.org/labyrinth_thrombo/
82. Chest Heart & Stroke Scotland (CHSS) Stroke4Carers [Edinburgh;2012 [cited 14-04-2012]. Available from: http://www.stroke4carers.org/
83. Stroke - Riks Forbundet Stroke - Riks Forbundet [Skärholmen;2012 [cited 01-05-2012]. Available from: www.strokeforbundet.se
84. National Health Services Scotland Scottish Stroke Care Audit Forms [Scotland;2012 [updated 20-02-2012; cited 10-04-2012]. Available from: http://www.strokeaudit.scot.nhs.uk/Participants/main.html
85. Scottish Stroke Care Audit Stroke Reports Scotland [2012 [cited 14-05-2012]. Available from: http://www.strokeaudit.scot.nhs.uk/Reports.html
86. Evans A, Perez I, Harraf F, Melbourn A, Steadman J, Donaldson N, et al. Can differences in management processes explain different outcomes between stroke unit and stroke-team care? Lancet. 2001;358(9293):1586-92.
87. Boode B, Welzen V, Franke C, van OR. Estimating the number of stroke patients eligible for thrombolytic treatment if delay could be avoided. Cerebrovasc.Dis. 2007;23(4):294-8.
88. Laloux P, Thijs V, Peeters A, Desfontaines P. Obstacles to the use of intravenous tissue plasminogen activator for acute ischemic stroke. Is time the only barrier? Acta Neurol.Belg. 2007;107(4):103-7.
89. Lindsberg PJ, Happola O, Kallela M, Valanne L, Kuisma M, Kaste M. Door to thrombolysis: ER reorganization and reduced delays to acute stroke treatment. Neurology. 2006;67(2):334-6.

90. Wiedmann S, Norrving B, Nowe T, Abilleira S, Asplund K, Dennis M, et al. Variations in quality indicators of acute stroke care in 6 European countries: the European Implementation Score (EIS) Collaboration. 2012;43(2):458-63.

91. Pervez MA, Silva G, Masrur S, Betensky RA, Furie KL, Hidalgo R, et al. Remote supervision of IV-tPA for acute ischemic stroke by telemedicine or telephone before transfer to a regional stroke center is feasible and safe. Stroke. 2010;41(1):e18-e24.

92. Cerebrovascular diseases Telestroke: The Use of Telemedicine in Stroke Care [Karger;2009 [cited 12June 2012]. Available from: http://content.karger.com/ProdukteDB/produkte.asp?Aktion=Ausgabe&Ausgabe=248014&ProduktNr=224153

93. Vlayen J, Stordeur S, Vrijens F, Van Eycken E. Kwaliteitsindicatoren in oncologie: voorwaarden voor het opzetten van een kwaliteitssysteem (KCE report 152A). 2011.