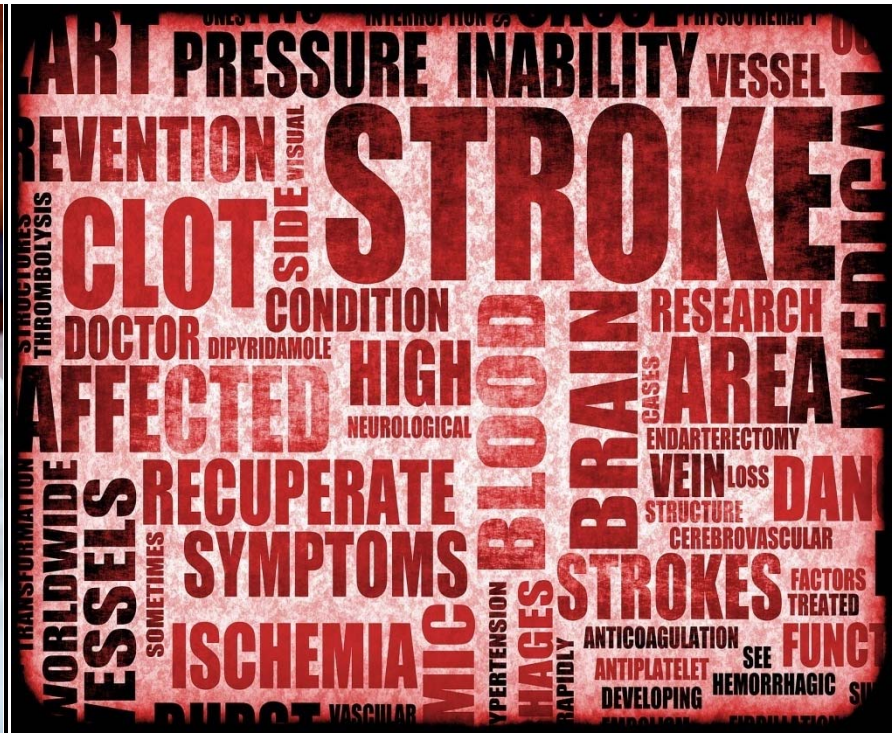
KCE REPORT 181B

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

# LES UNITÉS NEUROVASCULAIRES: EFFICACITÉ, INDICATEURS DE QUALITÉ ET ORGANISATION





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KCE REPORT 181B
HEALTH SERVICES RESEARCH

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# LES UNITÉS NEUROVASCULAIRES: EFFICACITÉ, INDICATEURS DE QUALITÉ ET ORGANISATION

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| | Bruxelles), Vincent Thijs (UZ Leuven), Yves Vandermeeren (Cliniques Universitaires UCL, Mont-Godinne), et Geert Vanhooren (AZ Sint Jan Brugge-Oostende) ont été consultés vu leurs compétences professionnelles relatives à la prise en charge de l'accident vasculaire cérébral. Pour cette raison ces experts peuvent, par définition, avoir certains conflits d'intérêt relatifs au sujet de cette étude.<br>Rémunération pour une communication, subside de formation, prise en charge de frais de voyage ou paiement à l'occasion d'une participation à un symposium: Yves Vandermeeren (support Boeringher); Geert Vanhooren (invitations régulières comme expert pour des conférences) |
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# PRÉFACE

Les données probantes relatives aux modèles de prise en charge du patient sont plutôt des denrées rares, ce qui complique souvent la prise de décision des autorités de santé lorsqu'elles planifient des modèles de soins pour une population de patients.

Pour l'accident vasculaire cérébral, de précédents rapports KCE nous ont mis la puce à l'oreille : la prise en charge dans une unité neuro-vasculaire aurait des bénéfices nets et ce, d'après plusieurs études de bonne qualité. Nous avons voulu en avoir le cœur net : ce rapport analyse de manière pointue l'impact de ces unités neuro-vasculaires sur l'état de santé du patient. Comment penser l'organisation de ces unités? Une analyse de la situation dans d'autres pays pionniers et un relevé des indicateurs de qualité donnent la direction à prendre.

Les unités neuro-vasculaires existent dans notre pays depuis quelques années : leur création et leur fonctionnement dépendaient des priorités des hôpitaux et cliniciens. Il est temps aujourd'hui d'assurer à chaque patient une prise en charge optimale : nul doute que les résultats de ce projet inspireront les parties intéressées par la qualité des soins et par la reconnaissance officielle des unités neuro-vasculaires.

Pour ce projet, nous avons pu compter sur l'expertise scientifique et clinique de deux équipes de recherche enthousiastes : nous remercions l'équipe de Deloitte et celle de la KULeuven pour la qualité de leur travail et leur collaboration tout au long de cette étude.

Jean-Pierre CLOSON
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Directeur Général

# RÉSUMÉ

## QU'EST-CE QU'UNE UNITÉ NEURO-VASCULAIRE ("STROKE UNIT")?

Les accidents vasculaires cérébraux sont fréquents, entre 200 et 230 par an pour 100 000 habitants. Pour une meilleure prise en charge de ces pathologies, des unités de soins spécifiques ont été créées depuis plusieurs années : les unités neuro-vasculaires ou "stroke units". L'objectif est de prodiguer le plus tôt possible des soins spécifiques afin de diminuer la mortalité et d'améliorer les chances de récupération.

La Société Belge pour les accidents vasculaires cérébraux (Belgian Stroke Council) définit une unité neuro-vasculaire en mentionnant les critères développés précédemment dans la littérature scientifique internationale : "une entité géographique distincte au sein de l'hôpital, spécifiquement dédiée aux patients atteints d'accident vasculaire cérébral (ou porteurs de symptômes, tant que le diagnostic neurologique n'a pas été posé), avec une équipe multidisciplinaire ayant un intérêt et une expertise pour les accidents vasculaires cérébraux : médecins, infirmiers, kinésithérapeutes avec en outre des ergothérapeutes, logopèdes, case manager, professionnel qui planifie la sortie de l'unité ou assistant social.

Ce rapport analyse de manière spécifique les unités neuro-vasculaires de type aigu, qui admettent les patients dans les 7 jours au maximum suivant l'accident. Actuellement de nombreuses unités de ce type existent en Belgique mais elles ne sont pas reconnues de manière officielle suivant des critères de qualité précis.

# OBJECTIFS DU RAPPORT

Les questions de recherche analysées dans le cadre de cette étude sont les suivantes :

1. Quelles sont les données probantes relatives à l'efficacité d'une admission au sein d'une unité neuro-vasculaire (revue systématique de littérature et méta-analyse)?
2. Quels sont les critères de qualité proposés dans la littérature pour les unités neuro-vasculaires et quelles en sont les sources de données probantes?
3. Comment les unités neuro-vasculaires sont-elles organisées dans d'autres pays et quel en est le processus d'assurance de qualité (revue de littérature et interviews d'experts)?
4. Sur base des réponses aux questions précédentes, quelles sont les suggestions pour l'organisation des unités neuro-vasculaires en Belgique et comment en évaluer la qualité des soins?

Les résultats de la recherche sont présentés en trois parties :

- La description de l'organisation des unités neuro-vasculaires dans d'autres pays avec analyse des critères de qualité utilisés;
- L'analyse de l'efficacité d'une admission du patient dans une unité neuro-vasculaire lors de la phase aiguë de l'accident vasculaire;
- Les modèles d'organisation et de mesure de la qualité proposés pour la Belgique.

# COMMENT CES UNITÉS SONT-ELLES ORGANISÉES DANS D'AUTRES PAYS?

## Procédures d'agrément

Une procédure officielle et obligatoire d'agrément des unités neuro-vasculaires, organisée et financée par les autorités, existe en Ecosse, dans la région de Londres et en France. En Allemagne, l'agrément n'est pas obligatoire : celui-ci est organisé par un organisme privé et financé par l'hôpital.

La procédure d'agrément comprend des visites sur place (entre autres par du personnel spécialisé), une revue de dossiers, parfois des interviews. Les critères considérés peuvent concerner également d'autres aspects organisationnels de l'hôpital.

## De nombreux indicateurs de qualité disponibles

### *Utilisation d'indicateurs de qualité pour l'agrément*

De nombreux critères utilisés dans le cadre de la procédure d'agrément ont été identifiés dans la revue des modèles utilisés dans d'autres pays. Ils concernent des aspects :

- de structure (e.a. formation du personnel, équipe multidisciplinaire, nombre de lits, personnel, nombre et type de professionnels de l'équipe);
- de processus (e.a. thrombolyse, délai avant une procédure diagnostique ou thérapeutique, imagerie cérébrale);
- de résultats (mortalité, réadmission, pneumonie intra-hospitalière).

### *Autres indicateurs de qualité*

Par ailleurs l'étude a réalisé un relevé des indicateurs de qualité :

- Utilisés au niveau national (e.a. en Suède) ou régional pour évaluer la qualité des soins prodigués aux patients souffrant d'accident vasculaire cérébral,
- Publiés dans les bases de données relatives aux indicateurs de qualité et dans la littérature scientifique : des dizaines d'indicateurs de structure, de processus et de résultats ont été répertoriés. Pour chacun d'entre eux les sources, l'utilisation, d'éventuelles données probantes sont détaillés dans le rapport scientifique et ses suppléments.

### Conséquences de la non obtention d'un agrément

Si l'unité neuro-vasculaire ne remplit pas les critères de la procédure d'agrément, les conséquences varient suivant les pays :

- Non-renouvellement de l'agrément;
- Développement d'un plan d'amélioration;
- Conséquences en termes de réputation lorsque les résultats sont publiés sur un site public;
- Conséquences financières telles qu'une diminution ou suppression de financement par les caisses d'assurances ou le gouvernement.

## QUELLE EST L'EFFICACITÉ DES UNITÉS NEURO-VASCULAIRES?

Une méta-analyse basée sur une dizaine d'études conclut que l'admission en phase aiguë dans une unité neuro-vasculaire produit des résultats positifs sur les paramètres suivants :

- Le risque d'institutionnalisation à la sortie de l'hôpital;
- Un indicateur qui combine les risques d'institutionnalisation et de décès;
- Un indicateur qui combine les risques de dépendance et de décès : cependant les résultats ne sont pas significatifs pour chacune des conséquences étudiées séparément;
- Une très légère diminution de la durée du séjour hospitalier.

D'autres interventions réalisées au sein des unités neuro-vasculaires ont été étudiées :

- Les études sont insuffisantes pour se prononcer au sujet des bénéfices de la mobilisation très précoce;
- Une large étude a démontré les bénéfices de l'existence d'un protocole pour prendre en charge la fièvre, l'hyperglycémie et les problèmes de dysphagie ;
- Le monitoring continu en phase aiguë a aussi des effets positifs sur les résultats des soins.

Par contre, les données ne permettent pas de démontrer l'efficacité :

- D'un retour précoce à domicile avec une équipe de soignants qui assure le suivi à domicile;
- D'une revalidation motrice intensive après sortie de l'hôpital.

# QUELLES PROPOSITIONS POUR LA BELGIQUE?

## Quatre scenarios possibles pour l'organisation des unités neuro-vasculaires

Au vu des résultats de cette étude, quatre scenarios sont envisagés pour la reconnaissance des unités neuro-vasculaires en Belgique :

- Existence d'une unité dans chaque hôpital : cette solution présente un avantage d'accessibilité mais les coûts risquent d'être élevés et la qualité difficile à assurer de manière uniforme;
- Des unités très spécialisées dans un nombre restreint d'hôpitaux : cette solution offre a contrario des soins de très haute qualité mais pose d'autres problèmes : accessibilité dans certaines régions, nécessité de "bypass" par les ambulances, réticences d'hôpitaux de proximité qui craindront de perdre des patients, capacité trop limitée des centres spécialisés;
- Une combinaison des deux solutions précédentes, à savoir des soins de très haute qualité dans des centres spécialisés suivis par des soins subaigus dans des centres situés dans des hôpitaux périphériques. Cette solution nécessite des accords de collaboration clairs entre institutions hospitalières et des incitants spécifiques afin que le renvoi des patients près de leur domicile soit effectif;
- Une thrombolyse dans chaque hôpital et des unités neuro-vasculaires dans certains centres spécialisés : cette dernière possibilité pose la question de volumes suffisants dans certains hôpitaux pour garantir une thrombolyse rapide et effectuée suivant des standards de qualité avant transfert. Par ailleurs les accords de collaboration stipulés au point précédent sont d'application.

## L' enregistrement de la qualité des soins est nécessaire

### *Déterminer l'objectif, les procédures et les conséquences*

Un premier point d'attention concerne la définition par les parties concernées des objectifs d'une collecte de données relative aux unités neuro-vasculaires : information relative à l'épidémiologie et à la qualité des soins au niveau national ou régional? Agrément des unités? Benchmarking entre hôpitaux? Processus d'amélioration de la qualité au sein d'un hôpital?

Un second point est la définition d'une procédure de collection de données et en particulier par quelle organisation (gouvernementale ou non), anonymisation et propriété des données (cf. rapport KCE 41 relatif aux indicateurs de qualité cliniques).

Enfin, les conséquences devront être définies a priori avec les parties concernées : acquisition ou perte d'agrément, conséquences financières, réputation, dynamique d'amélioration de la qualité (via des feedbacks ou via des contacts avec les hôpitaux performants).

### *Sélectionner les indicateurs*

Il est nécessaire de sélectionner un set limité d'indicateurs de qualité parmi les indicateurs proposés dans ce rapport. Cliniciens, gestionnaires de données et autres parties concernées (patients, autorités) doivent participer à cette sélection. Les sets retenus dépendront de l'utilisation (un benchmarking demanderait une définition standard très stricte des indicateurs avec prise en compte du profil des patients). Ces indicateurs doivent être par ailleurs précisés pour standardiser la collecte des données. Des valeurs-seuil seront définies sur base des données collectées et des standards publiés dans la littérature.

Il est important que cette sélection soit complétée par la sélection de données médicales et sociodémographiques potentiellement utiles pour l'interprétation des résultats et l'organisation des soins.

### *Tester la faisabilité*

La collecte de données requiert un test pilote pour vérifier la disponibilité des données administratives et la faisabilité d'une collecte additionnelle.

# RECOMMANDATIONS[a]

***A l'attention du Ministre après avis des organes compétents (Conseil national des établissements hospitaliers) :***

**Vu l'incidence de l'accident vasculaire cérébral (2 pour 1000 habitants par an) et l'importance d'une prise en charge optimale en phase aigüe, le KCE formule les recommandations suivantes.**

- **Il est recommandé de distinguer deux types d'unités neuro-vasculaires :**
  - **Des unités de type hyper aigu, capables d'effectuer dans les premières minutes de l'admission la mise au point diagnostique nécessaire avant une thrombolyse éventuelle. Cette prise en charge aiguë doit se faire en suivant des procédures qui en garantissent la sécurité et idéalement, doit être terminée dans les deux heures qui suivent l'accident vasculaire ;**
  - **Des unités neuro-vasculaires qui prennent le patient en charge après les trois premiers jours, en particulier dans des hôpitaux de proximité.**
- **Le nombre d'unités de type hyper aigu agréées doit se baser :**
  - **sur les données socio-démographiques, sur l'accessibilité géographique et sur les incidences attendues dans chaque région;**
  - **en particulier sur la possibilité d'atteindre le centre dans les 30 minutes suivant la prise en charge du patient par des professionnels.**
- **Le succès de ce système échelonné adapté à l'état clinique du patient requiert :**
  - **une sensibilisation de la population et des médecins généralistes afin d'orienter dès les premières minutes les patients vers le centre hyper aigu le plus proche;**
  - **des accords avec les services d'ambulance pour conduire rapidement le patient au centre hyper aigu le plus proche ;**
  - **des accords formels entre institutions de soins possédant des unités de type hyper aigu et les hôpitaux de proximité agréés pour la suite du traitement ;**
  - **des incitants financiers et un cadre légal relatifs au transfert des patients après la phase aiguë.**

[a] Le KCE reste seul responsable des recommandations adressées aux autorités publiques

- **Pour garantir la qualité de la prise en charge de l'accident vasculaire cérébral en milieu hospitalier, il convient de disposer d'indicateurs de qualité adaptés aux deux types d'unités neuro-vasculaires, en vue de leur octroyer un agrément. Plusieurs étapes préalables sont nécessaires :**
  - **Définition de l'objectif, des modalités et des conséquences de la mesure de ces indicateurs, en partenariat avec les parties concernées ;**
  - **Sélection de sets limités d'indicateurs adaptés à chacun des deux types d'unités. Ces indicateurs seront identifiés à partir des indicateurs proposés dans ce rapport (et éventuellement ceux à paraître au niveau européen pour les unités de type hyper aigu). Les patients plus âgés présentant des pathologies complexes devront bénéficier d'une attention particulière et d'éventuels indicateurs complémentaires.**
- **Ce rapport se limite à la prise en charge du patient en phase aiguë; une attention aussi importante doit être accordée lors de la sortie de l'hôpital pour assurer une continuité des soins optimale avec la première ligne et l'environnement quotidien du patient (domicile ou institution). Cette continuité devrait être assurée grâce à la définition d'un programme de soins assorti d'une collecte de données en vue**
  - **d'analyser l'épidémiologie des accidents cérébrovasculaires ;**
  - **de mesurer la qualité des soins prodigués ;**
  - **de planifier les structures de prise en charge (en phase aiguë et à long terme).**

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# LIST OF ABBREVIATIONS

| 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 |

# SYNTHÈSE

# 1 INTRODUCTION

## 1.1 L'accident vasculaire cérébral

L'accident vasculaire cérébral (AVC) est un problème majeur de santé publique dans les pays occidentaux. Il constitue la troisième cause de mortalité, après l'infarctus du myocarde et le cancer, et la principale cause d'invalidité à long terme. Soixante pourcents de ceux qui en sont frappés décèdent ou développent des séquelles qui les mènent à des degrés importants de dépendance, ce qui représente un fardeau pour leur entourage et leur communauté.

L'incidence de l'AVC (premier épisode et récidives confondus) est estimée, en Belgique, entre 200 et 230 pour 100 000 habitants chaque année, ce qui représente 19.000 cas par an, ou 52 cas chaque jour. Les coûts d'hospitalisation qu'ils entraînent ont quant à eux été estimés aux alentours de €191.6 million (chiffres de 2007).

On distingue deux catégories d'AVC :

- les AVC ischémiques ou infarctus cérébraux (80%), qui résultent de l'occlusion d'une artère du cerveau par un caillot de sang ;
- les AVC hémorragiques ou hémorragies cérébrales (20%). Dans ce cas, il se produit une déchirure de la paroi d'une artère du cerveau, parfois à l'endroit d'une dilatation (anévrisme). L'hypertension artérielle est alors le principal facteur de risque.

Les symptômes d'un AVC sont variables et s'installent rapidement : une paralysie, des troubles de l'élocution, une perte de vision, de la confusion... La gravité d'un AVC dépend de l'étendue des lésions du tissu cérébral. Il est donc essentiel que le patient soit pris en charge très rapidement. Dans le cas d'une thrombose, il est désormais établi qu'un traitement visant à dissoudre le caillot (thrombolyse) instauré endéans les 4 ½ heures (ou moins si possible) permet de diminuer la gravité des séquelles : ce traitement nécessite cependant une surveillance très stricte à cause de ses risques inhérents (saignements incontrôlables). Il est également impératif de pouvoir poser un diagnostic certain de la thrombose avant d'instaurer un tel traitement, car il est totalement contre-indiqué en cas d'hémorragie cérébrale. Ce diagnostic différentiel repose essentiellement sur l'imagerie cérébrale.

Il arrive que l'occlusion de l'artère cérébrale se résorbe spontanément, assez rapidement pour ne pas laisser de séquelle : il s'agit alors d'un accident ischémique transitoire (AIT). Ses symptômes sont les mêmes que l'AVC, mais ils ne durent que quelques secondes à quelques minutes avant le retour à la normale. L'AIT peut donc passer inaperçu mais il est un signal d'alarme important qui peut annoncer un AVC plus grave, et doit de ce fait être exploré en urgence.

## 1.2 Les "unités neuro-vasculaires" (Stroke Units)

De façon traditionnelle, les AVC étaient pris en charge dans les services de médecine interne (neurologie) des hôpitaux. Mais, notamment depuis l'avènement des traitements thrombolytiques, il est devenu nécessaire de pouvoir agir extrêmement rapidement, 24h/24, et avec un haut degré de technicité. C'est pour répondre à cette nécessité que sont apparues les "unités neuro-vasculaires" (Stroke Units, du mot anglais stroke qui désigne l'AVC) qui permettent notamment de mettre en œuvre immédiatement les techniques de diagnostic et les traitements de thrombolyse, ainsi que d'autres améliorations spécifiques des soins, de façon à diminuer la mortalité et à améliorer les chances de récupération.

La définition de l'unité neuro-vasculaire proposée par le Belgian Stroke Council est la suivante : « une entité géographique distincte au sein d'un hôpital, spécifiquement dédiée aux patients atteints d'AVC (ou suspects d'AVC – tant que le diagnostic neurologique n'a pas encore été posé ou n'est pas clair), avec une équipe multidisciplinaire ayant un intérêt et une expertise pour la prise en charge des AVC (médecins, infirmiers, kinésithérapeutes, mais également ergothérapeutes, logopèdes et case managers, travailleurs sociaux ou autres professionnels chargés de planifier la sortie de l'unité). »

Ces unités neuro-vasculaires existent sous différentes modalités de fonctionnement. Ce rapport examine en particulier :

- Les unités aiguës qui admettent des patients pendant la phase aiguë mais les transfèrent rapidement (endéans les sept jours) vers des services moins spécialisés.
- Les unités intégrées, combinant soins aigus et revalidation, qui admettent des patients en phase aiguë mais peuvent aussi entamer la revalidation pendant au moins une semaine.

Trois autres types de prise en charge ne sont pas examinés dans ce rapport :

- Les services de revalidation mixtes : services avec une équipe multidisciplinaire proposant des prestations de revalidation non spécifiques ;
- Les unités neuro-vasculaires mobiles : équipes multidisciplinaires (sans personnel infirmier spécialisé) délivrant les soins aux patients souffrant d'AVC dans différents départements ;
- Les unités de revalidation neuro-vasculaire qui admettent les patients après la phase aiguë (7 jours à partir du début de l'AVC).

### 1.3 Qualité des soins : un besoin urgent d'évaluation

Le Belgian Stroke Council a publié en 2009 des critères d'agrément pour les unités neuro-vasculaires. Toutefois, cette publication n'a pas été suivie de la mise en place d'un système d'agrément officiel de ces unités neuro-vasculaires, ni de la création d'un système d'enregistrement de la qualité des soins. En conséquence, il existe aujourd'hui une grande hétérogénéité dans les structures existantes, dans les procédures mises en œuvre et probablement dans la qualité des soins offerts dans les différentes unités neuro-vasculaires du pays.

Après consultation des experts, le KCE a décidé de consacrer une étude à l'évaluation de l'efficacité des unités neuro-vasculaires, aux indicateurs de qualité pouvant s'y appliquer, et à la manière optimale d'organiser de telles Unités en Belgique. Au même moment, un autre groupe de travail, au sein du Conseil National des Etablissements hospitaliers, a entamé une étude sur les critères de qualité des unités neuro-vasculaires de manière à pouvoir conseiller la Ministre de la Santé. Des membres de ce groupe de travail ont été sollicités comme experts pour le projet du KCE, et des échanges en cours de projet ont visé à s'assurer que cette étude du KCE et les recommandations du Conseil National à l'attention de la Ministre reposent sur des bases scientifiques communes.

# 2 OBJECTIFS DE CETTE ÉTUDE

Cette étude a pour objectif d'améliorer la qualité des soins pour les patients en phase aiguë d'AVC. Pour ce faire, nous avons analysé l'organisation des unités neuro-vasculaires aiguës dans d'autres pays européens, et nous avons étudié leur efficacité et leurs indicateurs de qualité dans la littérature scientifique.

Les questions de recherche analysées dans ce cadre sont les suivantes :

1. Comment les unités neuro-vasculaires sont-elles organisées dans d'autres pays et quels en sont les processus d'assurance de qualité et les critères de qualité ? (revue de littérature et interviews d'experts)
2. Quelles sont les données probantes démontrant l'efficacité d'une admission au sein d'une unité neuro-vasculaire ? (revue systématique de littérature et méta-analyse)
3. Quels sont les critères de qualité proposés dans la littérature pour les Unités Neuro-Vasculaires et quelles en sont les sources de données probantes ? (revue de littérature)
4. Sur base des réponses aux questions précédentes, quelles sont les suggestions pour l'organisation des Unités Neuro-Vasculaires en Belgique et comment en évaluer la qualité des soins ?

Les réponses apportées à ces quatre questions sont résumées systématiquement dans les chapitres suivants de cette synthèse.

# 3 COMMENT CES UNITES SONT-ELLES ORGANISEES DANS D'AUTRES PAYS ?

Une première partie de cette étude est consacrée à l'analyse de l'organisation des Unités Neuro-Vasculaires dans six pays/régions européens : l'Allemagne, la Suède, les Pays-Bas, la France, l'Ecosse et les "London Stroke Services" en Grande Bretagne.

Les informations ont été récoltées via l'envoi d'un questionnaire détaillé à des experts dans chaque pays. L'équipe de recherche a ensuite analysé et discuté le corpus de réponses obtenu, puis clarifié certains points par des interviews.

Dans les paragraphes qui suivent, nous résumerons successivement les procédures d'agrément de ces différents pays, les procédures d'évaluation de la qualité et les manières de planifier et d'organiser l'accès aux Unités Neuro-Vasculaires.

## 3.1 Agrément des Unités Neuro-Vasculaires

Il existe des procédures d'agrément dans 4 des six pays/régions étudiés. Ces procédures sont obligatoires en Ecosse, à Londres (London Stroke Services) et en France ; elles sont organisées et financées par les pouvoirs publics. Il existe également une procédure d'agrément en Allemagne, mais elle n'est pas obligatoire et est menée par des organismes privés, financés par les hôpitaux. Les Pays-Bas et la Suède n'ont pas de procédure d'agrément.

Les procédures d'agrément comprennent des visites sur place et un examen de dossiers de patients, et éventuellement certaines procédures supplémentaires. Une partie du personnel responsable de ces procédures d'agrément est lui-même formé spécifiquement à la prise en charge des AVC. L'agrément englobe parfois, en plus de l'unité neuro-vasculaire elle-même, certains autres aspects de la prise en charge, comme par exemple la gestion du patient victime d'AVC pendant son trajet du domicile à l'hôpital. L'agrément est renouvelable tous les 1, 3, ou 5 ans.

Différents types d'Unités Neuro-Vasculaires peuvent faire l'objet d'un agrément ; par exemple, au sein des London Stroke Services, on distingue quelques unités très particulières, les unités « hyper-aiguës » (hyper acute stroke units – HASU). Certains pays font également une distinction entre des unités régionales et supra-régionales, ou encore entre des unités dites « primaires » et des unités « intégrées » capables de délivrer l'entièreté des interventions nécessaires au traitement, comme la radiologie interventionnelle ou la chirurgie de la carotide.

Les critères d'agrément dans les quatre pays/régions étudiés peuvent être classifiés selon la structure de l'Unité, les procédures qui y sont mise en œuvre, et l'impact au niveau du devenir des patients.

### *3.1.1 Critères de structure*

- Un nombre minimal de lits est exigé en France (4 lits) et en Allemagne (6 lits). Dans les London Stroke Services, le nombre minimum de lits est de 8 mais il peut être adapté en fonction de la planification de la capacité d'accueil pour l'ensemble de la région (voir 3.3) ;
- Un volume annuel minimal d'activité est requis en France (300 cas) et en Allemagne (250 cas pour les unités primaires et 500 cas pour les unités intégrées). En outre, en Allemagne, il faut également réaliser un nombre minimal de thrombolyses ;
- Le niveau de formation du personnel et la présence d'une équipe multidisciplinaire (de composition variable) sont toujours mentionnés.

D'autres indicateurs structurels sont également mentionnés, comme l'équipement de monitoring cardiaque/d'oxygénation ou des protocoles de traitement documentés.

### 3.1.2 Critères de procédures

Une vingtaine d'indicateurs de procédures ont été identifiés ; ceux qui sont utilisés dans les systèmes d'agrément des 4 pays étudiés sont les suivants :

- Les indicateurs relatifs à la rapidité des prises en charge (délai domicile-hôpital, délai avant l'imagerie cérébrale, temps de séjour en service d'urgences) ;
- Les indicateurs relatifs aux procédures hyper-aiguës (en particulier la thrombolyse et la détection des troubles de la déglutition) ;
- Les indicateurs relatifs aux procédures de diagnostic (par ex. pourcentage de patients bénéficiant d'une imagerie cérébrale).

### 3.1.3 Critères relatifs à l'impact sur le devenir des patients

Le seul critère relatif au devenir des patients qui soit utilisé dans les 3 pays/régions qui incluent de tels critères dans leur procédure d'agrément est la mortalité à l'hôpital ou au sein de l'unité neuro-vasculaire. D'autres indicateurs sont les complications (pneumonie, thrombose) ou le taux de récidives.

### 3.1.4 Et en cas d'échec ?

Si un hôpital ne remplit pas les critères exigés pour l'agrément de son unité neuro-vasculaire, les conséquences sont très variables :

- En Ecosse, les hôpitaux qui échouent à la procédure d'agrément sont priés de proposer un plan d'amélioration, mais il n'y a pas d'autres conséquences, financières notamment. Toutefois, comme ces résultats sont rendus publics auprès des professionnels et du grand public, ils risquent d'y perdre en notoriété…
- A Londres, les hôpitaux qui échouent à l'évaluation initiale ne sont plus reconnus pour les prises en charge d'AVC. Si, après une évaluation initiale favorable, ils ne remplissent plus les critères exigés, un retrait de l'agrément reste théoriquement possible mais les conséquences se font surtout sentir en termes de notoriété ou de pertes financières, étant donné que, là aussi, les résultats sont publics. L'établissement peut aussi perdre une partie de la tarification majorée prévue en cas d'agrément.
- En France, un échec d'agrément porte à conséquences sur le plan financier pour l'hôpital. Les résultats ne sont toutefois communiqués qu'aux autorités de l'établissement concerné.
- En Allemagne, le système fonctionne avec des incitants positifs. Les hôpitaux qui obtiennent l'agrément sont publiés sur une liste officielle, visible notamment sur le site de la German Stroke Society. Le financement de l'hôpital est indépendant du processus d'agrément bien que les critères de remboursement puissent également inclure des critères de qualité, variables en fonction des organismes assureurs.

Des incitants financiers sont parfois aussi liés à l'admission préférentielle des patients dans l'unité neuro-vasculaire plutôt que dans des services non spécialisés (Suède, France, Londres, Allemagne).

## 3.2 Evaluation de la qualité des soins

Dans les 6 pays/régions étudiés, des systèmes de mesure de la qualité des soins d'AVC ont été développés, aux niveaux national ou régional selon les cas, et ceci indépendamment de l'existence ou non de procédures d'agrément.

Parmi les indicateurs de qualité identifiés, le pourcentage de patients victimes d'AVC qui sont admis dans les unités neuro-vasculaires est très largement utilisé de même que la réalisation d'une thrombolyse, le délai avant l'instauration de celle-ci, et la détection des troubles de la déglutition. Des indicateurs de résultats fréquents sont la mortalité, le taux d'institutionnalisation, la destination du patient après l'hospitalisation.

Ces résultats sont parfois publiés sur les sites officiels (par ex en Suède), et peuvent servir au benchmarking entre régions ou entre hôpitaux (avec mention du nom de l'hôpital).

Enfin, il est intéressant de souligner que, dans les 6 pays/régions étudiés, les organisations professionnelles ont développé des guidelines pour l'organisation des unités neuro-vasculaires, comme c'est également le cas en Belgique.

## 3.3 Accès aux Unités Neuro-Vasculaires

Quelques caractéristiques notables se détachent du tableau en ce qui concerne la planification de la capacité d'accueil et les modalités d'accès aux unités neuro-vasculaires dans les différents pays étudiés :

- Planification de la capacité d'accueil : Londres est la seule région étudiée où les autorités de santé utilisent une méthode formelle pour planifier le nombre d'unités nécessaires à la prise en charge des AVC sur son territoire. Ce calcul est basé sur une série de paramètres assez larges, comme les changements démographiques attendus, la durée moyenne probable du séjour, ou encore l'impact des stratégies de prévention.
- « Bypass » par les ambulances : dans 3 des 4 pays/régions qui fonctionnent avec un système d'agrément, les ambulances sont autorisées à court-circuiter les hôpitaux qui ne disposent pas d'une unité neuro-vasculaire.
- Profil des patients : dans les 6 pays/régions étudiés, tous les patients présentant des signes d'AVC ou d'hémorragie cérébrale sont admis dans les unités neuro-vasculaires. Par contre, il existe des différences entre pays/régions au sujet de l'admission des patients qui font un accident ischémique transitoire (AIT) ou une hémorragie sub-arachnoïdienne.

## 3.4 En résumé : cinq modèles

En résumé, on peut distinguer cinq modèles d'organisation :

- En Allemagne, les standards de qualité sont déterminés par des sociétés professionnelles et l'agrément est délivré par une autorité certifiante professionnelle. Seules les unités neuro-vasculaires qui obtiennent cet agrément sont publiées sur un site officiel. En cas d'échec, l'hôpital peut donc voir baisser sa notoriété et éventuellement, en fonction des compagnies d'assurances, subir des pertes financières.
- Le modèle français prévoit un agrément obligatoire, organisé et financé par les autorités gouvernementales, avec pertes financières à la clé en cas d'échec de la procédure d'agrément. Seule la direction de l'hôpital est avisée des résultats de la procédure.
- Les London Stroke Services ont une procédure d'agrément qui combine des caractéristiques des deux modèles précédents : organisation et financement par les autorités publiques, conséquences financières et en termes de notoriété en cas de non-compliance avec les critères.
- L'Ecosse a une procédure d'agrément obligatoire et fait appel au feedback pour obtenir le niveau de qualité attendu : les hôpitaux qui ne remplissent pas les critères bénéficient d'une attention spéciale et d'aides de la part du gouvernement pour améliorer leurs indicateurs.
- Dans le modèle suédois, il n'y a pas de procédure formelle d'agrément. C'est la mesure des indicateurs de qualité qui est le moteur de la qualité des soins en matière d'AVC.

# 4 QUELLE EST L'EFFICACITE DES UNITES NEURO-VASCULAIRES ?

Les Unités Neuro-Vasculaires sont-elle réellement plus efficaces en termes de prise en charge des victimes d'AVC que les services de neurologie classiques ? Les patients sont-ils plus nombreux à survivre, gardent-ils moins de séquelles, sont-ils davantage capables de reprendre une vie indépendante à leur domicile?

Toutes ces questions ont déjà été examinées en 2009 (sur des chiffres de 2006) dans une revue Cochrane qui analysait l'efficacité des Unités Neuro-Vasculaires. Nous avons ajouté à cette première source d'informations une sélection de 7 autres études publiées depuis lors sur le même sujet, ce qui porte notre corpus de recherche à 20 études (randomisées et non-randomisées).

La qualité globale de ces études peut être qualifiée de modérée : l'enregistrement des résultats et la caractérisation des populations concernées étaient généralement corrects mais la randomisation ou le double aveugle étaient peu documentés, ou pas du tout, dans beaucoup d'études.

Le tableau ci-dessous résume les études prises en considération dans notre revue de littérature.

**Tableau 1 : Résumé des études prises en considération**

| Première catégorie de comparaison | Seconde catégorie de comparaison |
|---|---|
| I. Unités Neuro-Vasculaires versus autres modèles de soins (12 études) | Unité neuro-vasculaire aiguë versus service hospitalier général (4 études) |
| | Unité neuro-vasculaire intégrée versus service hospitalier général (7 études) |
| | Unité neuro-vasculaire intégrée versus équipe mobile (1 étude) |
| II. Unités Neuro-Vasculaires avec soins spécifiques versus Unités Neuro-Vasculaires conventionnelles (5 études) | Unité neuro-vasculaire avec revalidation très précoce (2 études) |
| | Unité neuro-vasculaire aiguë avec protocole (suivi de la fièvre, de l'hyperglycémie et des troubles de la déglutition) (1 étude) |
| | Unité neuro-vasculaire avec monitoring continu (3 études[1]) |
| III. Unités Neuro-Vasculaires suivies d'une intervention (3 études) | Unité neuro-vasculaire suivie de retour à domicile précoce avec suivi (2 études) |
| | Unité neuro-vasculaire suivie de revalidation motrice intensive (1 étude) |

[1] Une étude a investigué à la fois le monitoring en continu et la réhabilitation très précoce.

L'analyse poolée de ces différentes études montre que l'hospitalisation organisée en Unités Neuro-Vasculaires améliore significativement le devenir du patient sur quatre indicateurs (dont deux composites) :

- Risque d'institutionnalisation (risque d'être transféré dans une institution de prise en charge à long terme après son départ de l'hôpital) ;
- Décès ou institutionnalisation ;
- Décès ou dépendance (mesurée par un score basé sur des échelles d'évaluation spécifiques, comme la Modified Rankin Scale ou le Barthel index) ;
- Durée de l'hospitalisation (différence moyenne de **- 0.27 jours).**

L'effet sur les autres paramètres est moins convaincant :

- Le bénéfice des Unités Neuro-Vasculaires par rapport au risque de dépendance seule n'est pas significatif.
- Le bénéfice en termes de mortalité atteint tout juste le niveau de significativité de 5% sur base de l'analyse de toutes les études publiées. De plus, cette significativité disparaît quand l'analyse se limite aux études randomisées.
- Trois études analysent l'impact des Unités Neuro-Vasculaires sur la qualité de vie post-AVC : deux d'entre elles ne rapportent aucune amélioration significative.

Deux études apportent des données probantes sur les effets à long terme : l'impact des Unités Neuro-Vasculaires sur le décès est positif à 5 ans mais les données divergent entre les deux études pour les durées de suivi plus longues.

Quelques études suggèrent une efficacité de certaines mesures complémentaires :

- La mobilisation très précoce : sortir les patients du lit endéans les 24 heures après le début de l'AVC semble influencer favorablement leur évolution, mais des études à plus large échelle sont nécessaires pour confirmer l'efficacité d'une telle mesure.
- Les protocoles de prise en charge de la fièvre, de l'hyperglycémie et des problèmes de déglutition sont des mesures dont les bénéfices sur la mortalité et la dépendance ont été démontrés par une large étude.
- **Le monitoring continu** des paramètres vitaux **en phase aiguë a un impact positif démontré sur la durée d'hospitalisation et sur des indicateurs composites comme le nombre de décès ou d'institutionnalisations, et le nombre de décès ou la dépendance.**

Aucune donnée probante ne démontre l'efficacité d'interventions post-hospitalisation telles que le retour précoce à domicile avec une équipe de soignants qui assure le suivi à domicile (2 études) ou de la revalidation motrice intensive après sortie de l'hôpital (1 étude), mais ces interventions étaient hors sujet par rapport à l'objectif de notre étude et nous n'avons pas approfondi la recherche de littérature sur ces thèmes.

# 5 LES INDICATEURS DE QUALITÉ

En parallèle aux procédures d'agrément, il est également important d'établir un système d'enregistrement de la qualité des soins, sur base d'indicateurs de qualité soigneusement sélectionnés. Ces indicateurs de qualité peuvent être les mêmes que ceux qui sous-tendent les critères d'agrément, mais ils peuvent également être utilisés à d'autres fins, comme par exemple en Suède, où il n'y a pas de procédure d'agrément pour les Unités Neuro-Vasculaires mais où la qualité des soins est monitorée par un grand nombre d'indicateurs de qualité.

Une recherche sur les indicateurs de qualité dans la littérature scientifique nous a permis d'identifier une première série de 98 indicateurs de qualité (QI's). Un second processus de sélection nous a permis d'exclure les indicateurs qui ne correspondaient pas au contexte des soins d'AVC en phase aiguë (notamment les soins à long terme) et de combiner certains indicateurs mesurant les mêmes paramètres.

Le set final d'indicateurs obtenu au terme de cette recherche de littérature comprend 48 items, dont la plupart sont relatifs aux procédures. Ils ont été soumis à un panel de 7 médecins (6 cliniciens et un data manager) qui ont été chargés de coter ces indicateurs en fonction de 6 critères : la pertinence, la validité, la faisabilité, la fiabilité, la spécificité et les possibilités d'amélioration. Quelques indicateurs additionnels identifiés lors de la revue des pratiques dans les autres pays ont également été soumis au panel d'experts.

Le paragraphe ci-dessous donne des exemples d'indicateurs, et en particulier de ceux pour qui les données sont probantes. Leurs définitions, les données probantes sous-jacentes et les résultats de la classification effectuée par les experts se trouvent détaillés dans le supplément de ce rapport.

## 5.1 Indicateurs de structure

Quinze indicateurs de structure ont été identifiés dans la littérature. Seuls deux d'entre eux étaient soutenus par des études de haute qualité prouvant l'existence d'un lien entre l'indicateur et une amélioration de paramètres : la présence d'une équipe multidisciplinaire spécialisée et la disponibilité de l'imagerie cérébrale 24h/24 (avec expertise radiologique spécifique).

D'autres indicateurs moins robustes sont par exemple :

- Des données sur les volumes d'admission aux urgences / à l'hôpital ;
- La participation du personnel à des formations à la prise en charge aiguë des AVC ;
- La disponibilité de l'imagerie vasculaire et de techniques de diagnostic (cardiologique) dans l'hôpital ;
- La documentation et l'évaluation du risque dans le dossier médical.

## 5.2 Indicateurs de procédures

Les indicateurs de procédures ont été classifiés selon les différentes phases de la prise en charge auxquelles ils se rapportent :

- Sept indicateurs sont relatifs à la phase hyper-aiguë (les premières 24 heures après le début de l'AVC) : parmi eux, la possibilité d'imagerie cérébrale, la thrombolyse et le screening des troubles de la déglutition bénéficient des plus hauts niveaux d'évidence ;
- Cinq indicateurs sont relatifs à la phase aiguë (24-48 heures après le début de l'AVC) : admission dans une unité neuro-vasculaire, traitement antiagrégant plaquettaire précoce, revalidation précoce et/ou évaluation de la mobilité sont soutenus par des niveaux d'évidence élevés. Des niveaux plus faibles ont été trouvés pour la prophylaxie de la thrombo-embolie veineuse et l'évaluation de l'état nutritionnel ;

- Six indicateurs de qualité sont relatifs à la phase d'hospitalisation post-aiguë (à partir de 48 heures après le début de l'AVC) : parmi ceux-ci, l'électrocardiogramme (ECG) et la surveillance des paramètres du patient (poids, glycémie, pression artérielle, fièvre, etc.) sont démontrés par une revue systématique. Il y a également un essai contrôlé randomisé sur l'imagerie vasculaire ;
- Dix indicateurs sont relatifs à la sortie de l'hôpital : la coordination des soins à domicile et l'éducation du patient/de la famille sont soutenus par des niveaux d'évidence élevés provenant de revues systématiques. Quelques essais randomisés portant sur l'établissement d'objectifs de revalidation et la prescription de certains traitements médicamenteux (anticoagulants en cas de fibrillation auriculaire, anti-hypertenseurs, hypocholesterolémiants) ont également été identifiés.

## 5.3 Indicateurs de résultats

La mortalité est l'indicateur de résultat le plus souvent cité dans la littérature. D'autres indicateurs sont l'amélioration de l'élocution, le niveau de dépendance, la qualité de vie, les pneumonies nosocomiales et le taux de réadmission.

# 6 CONCLUSION : QUELLES PROPOSITIONS POUR LA BELGIQUE ?

## 6.1 Quatre scenarios possibles pour l'organisation des Unités Neuro-Vasculaires

En Belgique comme dans d'autres pays, l'agrément des unités neuro-vasculaires pourrait être du ressort d'un organisme dépendant du gouvernement fédéral ou régional, ou d'une organisation privée. L'implication des organisations professionnelles reste requise pour en établir les critères, idéalement en concordance avec les normes européennes.

A partir de là, quelles sont les pistes possibles pour organiser et accréditer les unités neuro-vasculaires ? D'après l'analyse des exemples observés dans d'autres pays, quatre scénarios peuvent être envisagés.

- **Une unité neuro-vasculaire dans chaque hôpital**

Selon ce premier scenario, tous les hôpitaux seraient priés de se doter d'une unité neuro-vasculaire correspondant à certaines normes. Une telle organisation garantirait que tous les patients puissent bénéficier rapidement de soins spécifiques (contrairement à ce qui se passerait dans un système où certains hôpitaux seraient court-circuités – voir plus loin).

L'inconvénient de ce scénario est que la mise en place d'une unité neuro-vasculaire mobilise d'importantes ressources financières. Il serait également difficile d'assurer l'expertise nécessaire partout, ainsi que la possibilité de thrombolyse 24h/24.

- **Soins hautement spécialisés (unités hyper-aiguës) dans un nombre limité d'hôpitaux**

Un deuxième scenario est celui où des unités hyper-aiguës seraient agréées dans un nombre limité d'hôpitaux, choisis sur base de leurs volumes d'admission et de leur répartition géographique. Cette option permettrait d'assurer très rapidement la mise au point diagnostique et la thrombolyse, suivie d'un monitoring optimal, sans devoir multiplier les infrastructures. Quelques centres sélectionnés pourraient assurer les traitements hautement spécialisés comme la radiologie interventionnelle ou la chirurgie neuro-vasculaire.

Les avantages de cette formule sont la concentration des ressources, un volume à traiter plus important et donc une plus grande expérience des équipes professionnelles.

Les désavantages sont que les hôpitaux dénués de thrombolyse devraient être court-circuités par les services d'ambulances, ce qui nécessiterait des modifications de leur code de conduite, en plus de la nécessaire formation du personnel d'ambulance. La collaboration active de la première ligne – et en particulier des médecins généralistes – serait un autre point indispensable à la viabilité d'un tel système. Par ailleurs, certains hôpitaux dénués d'unités hyper-aiguës pourraient avoir tendance à garder des patients habitant dans leur zone d'influence. Les longues distances pourraient également poser problème aux familles des patients transférés dans un hôpital éloigné de leur domicile. Enfin, si de telles unités devaient être assignées dans quelques hôpitaux spécifiques, il se pourrait que la capacité d'accueil de ces hôpitaux soit débordée de temps à autre.

- **Unités hyper-aiguës suivies de transfert dans des Unités Neuro-Vasculaires locales**

Après quelques jours de prise en charge sous monitoring dans une unité hyper-aiguë, les patients pourraient être transférés vers une unité neuro-vasculaire proche de leur domicile (cf organisation des London Stroke Services). Cette solution nécessiterait également une adaptation des services d'ambulances mais les problèmes de capacité d'accueil, de pertes de patients et de longues distances pour les proches seraient moins importants.

- **Thrombolyse dans tous les hôpitaux, Unités Neuro-Vasculaires dans quelques-uns**

Une dernière option serait de découpler la thrombolyse des services d'une unité neuro-vasculaire. Dans un tel modèle 'drip and ship', tous les hôpitaux seraient habilités à pratiquer des thrombolyses, mais, s'ils ne possèdent pas d'unité neuro-vasculaire, ils devraient ensuite référer tous leurs patients victimes d'AVC vers un hôpital doté d'une telle unité. Une attention particulière devrait être portée à vérifier que la procédure de thrombolyse soit réellement accessible à tout moment et en toute sécurité dans tous les hôpitaux. Un autre inconvénient serait que certains hôpitaux n'atteindraient pas le nombre minimum de patients requis, ce qui pourrait mener à pratiquer des thrombolyses dans des services où le personnel manque de la nécessaire expérience. Enfin, l'obligation de référer un patient vers un hôpital doté d'une unité neuro-vasculaire juste après une thrombolyse – et donc en état critique – pourrait l'exposer à des risques importants, et entraîner des coûts élevés relatifs au transport.

En conclusion, quelle que soit l'option choisie, elle devra inclure les incitants nécessaires à initier le principe de l'admission de tous les patients dans des unités neuro-vasculaires. La collaboration entre hôpitaux offrant des services différents est une solution pour assurer que tous les patients aient accès à des soins de haute qualité en cas d'AVC et cela dans le réseau existant de ressources hospitalières.

## 6.2 L' enregistrement de la qualité des soins est nécessaire

### 6.2.1 *Déterminer les objectifs*

Dans le cadre de cette étude, nous avons réalisé un large inventaire des indicateurs de qualité, avec une première sélection par des experts. Sur base de ce travail, il est suggéré de pousser la recherche plus loin pour sélectionner les indicateurs-clés de la qualité des soins aigus de l'AVC. Des stakeholders supplémentaires devront être impliqués dans le processus de sélection, notamment les représentants des hôpitaux et des organisations de patients.

Mais le choix final des indicateurs dépendra avant tout des objectifs que l'on fixera au système de qualité :

- S'il s'agit de viser un monitoring à l'échelle nationale de l'efficacité des soins apportés aux patients victimes d'AVC (comme cela se fait dans d'autres pays), il est nécessaire que certaines données relatives aux patients puissent être obtenues facilement, via les bases de données administratives. Un tel monitoring requiert un système d'enregistrement fiable, permanent et centralisé (cfr Suède).
- S'il s'agit d'asseoir une procédure d'agrément, il faut inclure d'autres indicateurs de qualité comme par exemple l'utilisation de protocoles de soins, des stratégies de formation du personnel sur site et des staffing lists.
- S'il s'agit de favoriser le benchmarking entre hôpitaux, il faut mettre au point un set d'indicateurs de qualité hautement standardisés avec une définition claire des numérateurs et dénominateurs (incluant par exemple la mesure de la satisfaction des patients avec un instrument standardisé). Dans une telle situation, il est également important de tenir compte de l'hétérogénéité des profils des patients (case-mix correction).
- Enfin, d'autres sets d'indicateurs peuvent être utiles au niveau de l'hôpital dans le but de monitorer son propre niveau de performance sur le long terme et pour pouvor proposer un feedback interne.

Dans la même logique, le choix des valeurs de cut-off est également un point important. En effet, peu de valeurs de cut-off ont été trouvées dans la littérature et leur choix ne repose pas toujours sur des données probantes (ex : nombre de lits, taux de complications).

Un système d'enregistrement de qualité établira en outre quelles sont les informations nécessaires pour la prise en compte des profils des patients, des délais avant procédures, de l'utilisation des ressources au sein de l'hôpital, ainsi que des données sur les traitements médicamenteux.

L'harmonisation des indicateurs de qualité relatifs aux unités neuro-vasculaires figure également à l'agenda de l'European Stroke Organization (ESO).

### 6.2.2 *Déterminer les conséquences*

Avant d'implémenter la collecte des données, les principaux stakeholders devront se mettre d'accord sur les usages possibles de ces données :

- Agrément des unités neuro-vasculaires ;
- Système de feedback en vue d'améliorer la qualité des soins (avec un support possible du monde académique, d'organisations scientifiques et de sociétés privées) ;
- Publication officielle, comme cela se fait dans d'autres pays, avec les inévitables risques liés à l'interprétation des résultats (ex : biais lié au profil des patients) ; cette interprétation doit être dénuée de toute ambiguité ;
- Incitants financiers ou conséquences négatives ( pertes financières, perte d'agrément) ;
- Aides apportées aux hôpitaux moins performants, via des plans d'amélioration ;
- Rôles de modèle : des hôpitaux très performants peuvent partager leur expérience avec ceux qui sont moins performants.

### 6.2.3 *Encore quelques conditions à l'implémentation des procédures de mesure de la qualité…*

Finalement, l'implémentation d'un système de mesure de la qualité requiert la réalisation d'un test pilote pour évaluer la faisabilité de la récolte de données. La question de l'anonymisation et de la centralisation des données exige également que des décisions soient prises.

Des indicateurs de résultats importants, comme l'invalidité, l'institutionnalisation et les taux de mortalité en post-hospitalisation nécessitent de pouvoir établir des liens entre différentes bases de données, étant donné l'absence de système de récolte de données centralisé pendant le follow-up du patient.

# 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)<br>*score only if unable to walk | 10<br>0* | 15<br>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". Maryland 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

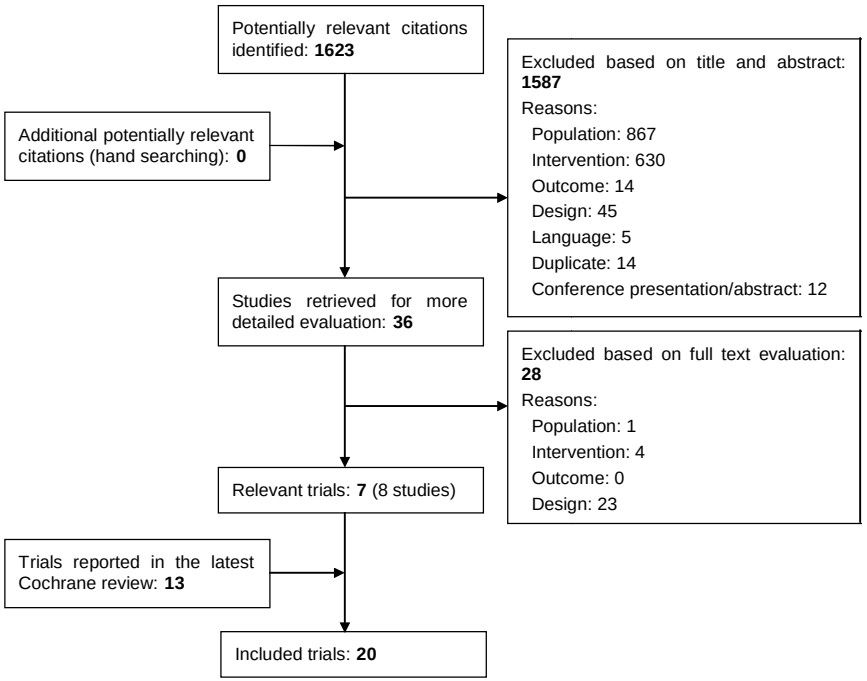
The systematic literature search performed in November 2011 identified 1623 citations on the topic of stroke unit care. Supplementary search on reference list of international guidelines on stroke care (NICE clinical guideline 68 2008; Canadian Stroke Strategy 2010) yielded no new reference. Most citations 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)<br>• Stavem and Rønning 2007[18] (CCT, low)<br>• Akershus[19] (CCT, low)<br>• Athens[20, 21] (RCT, low) |
| | Comprehensive stroke unit versus general medical wards (7 trials) | • Beijing[22] (RCT, low)<br>• Perth[23] (RCT, moderate)<br>• Trondheim [10, 24, 25] (RCT, moderate)<br>• Joinville[26] (RCT, low)<br>• Edinburgh [27, 28] (RCT, low)<br>• Umea[29] (CCT, low)<br>• 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])<br>• 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)<br>• Groningen[35] (RCT, moderate)<br>• 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)<br>• 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.

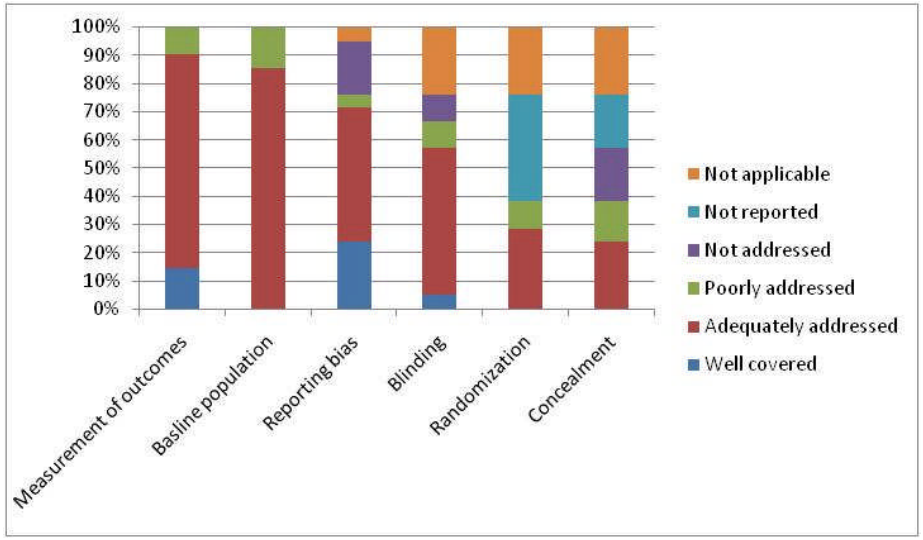
#### 2.2.1.4 *Study quality*

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).

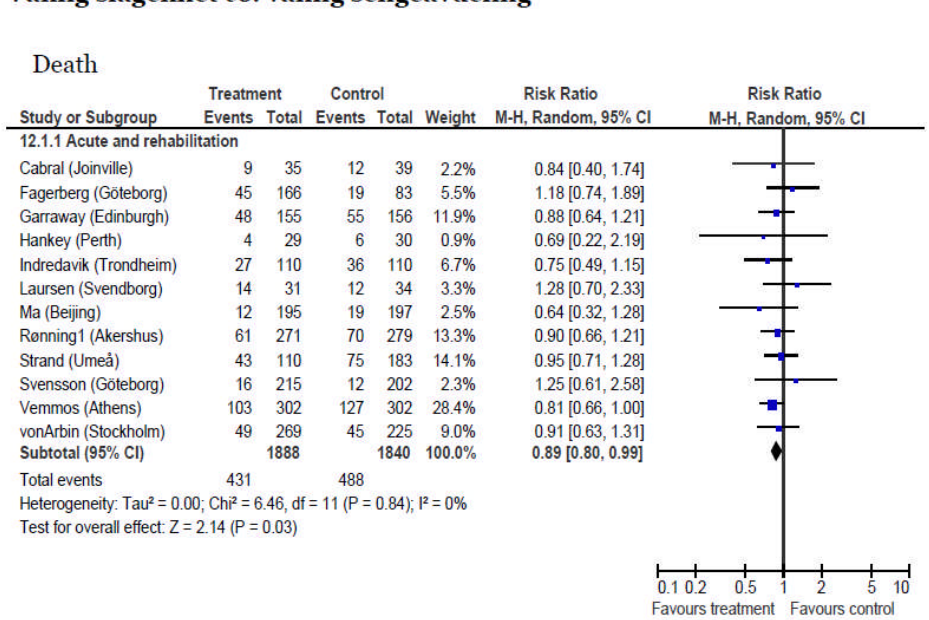
The Norwegian Stroke Unit HTA included 12 trials that have already been captured by the latest Cochrane review.

- 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).

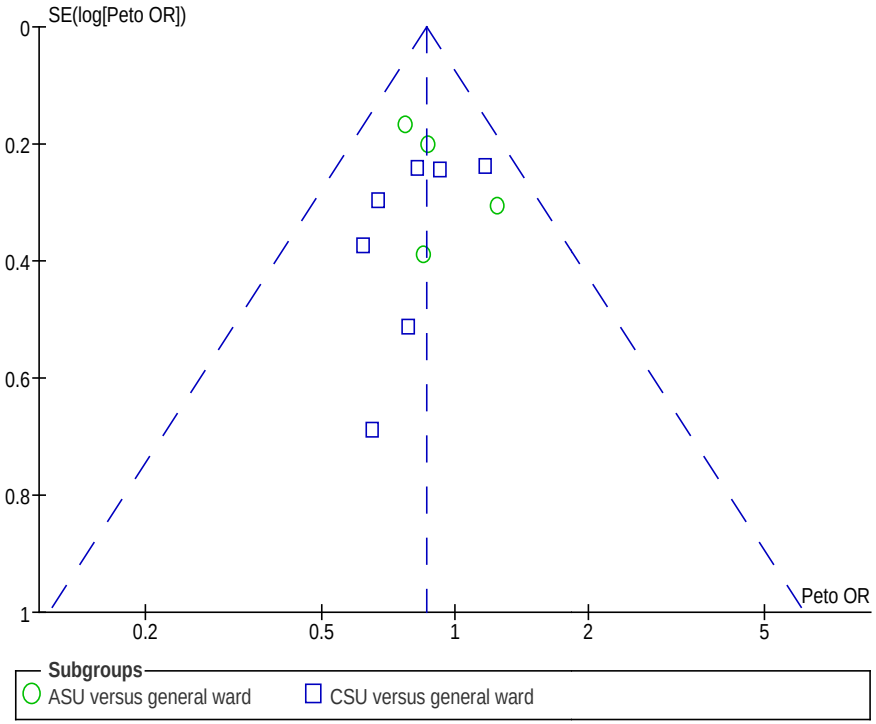
The authors conclude that time to first mobilization from symptom onset was significantly shorter among very early mobilized patients (median: 21 hours, interquartile range: 23.0 to 41.2 hours). Patients in the intervention group had significantly greater odds of independency compared with standard care 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++)<br>• 1 meta-analysis (1+)<br>• 8 clinical guidelines (4)<br>• 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.

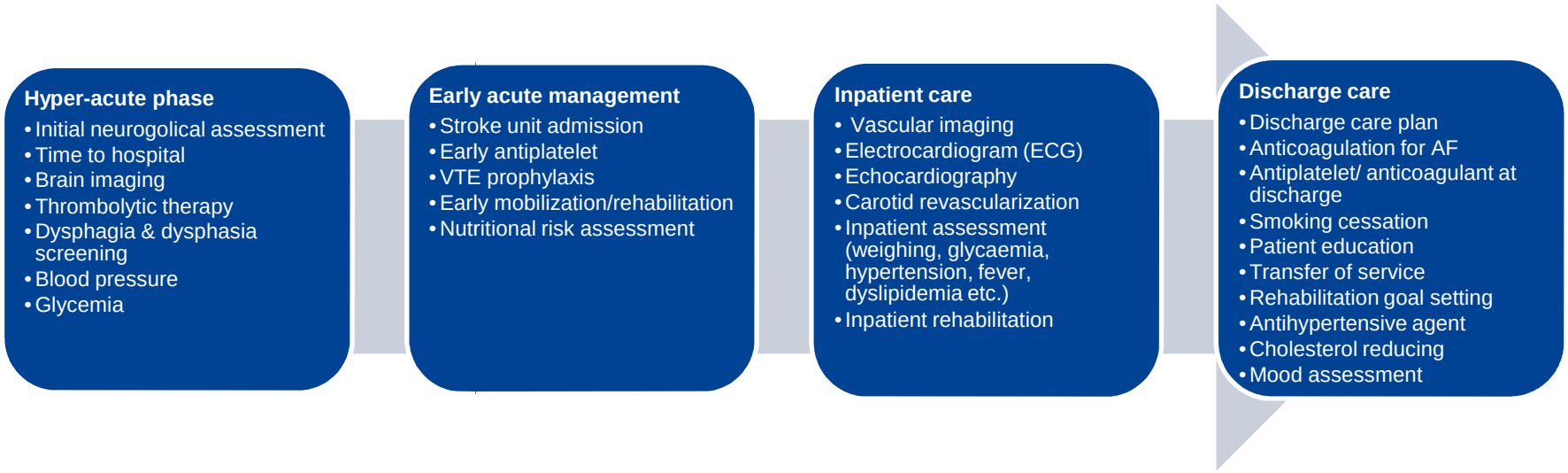
All quality indicators and their source of evidence are presented in the tables in the following sections.

### 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+)<br>• 1 retrospective case review (2+)<br>• 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)<br>• ADSR study (Germany)[42]<br>• National Committee for Quality Assurance (NCQA, USA) | • 1 Cochrane review and 2 other systematic reviews (1++)<br>• 1 health technology assessment (HTA) report<br>• 1 RCT (1+)<br>• 2 prospective studies (2++)<br>• 2 retrospective studies (2+)<br>• 5 clinical guidelines<br>• 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)<br>• Centers for Medicare & Medicaid Services (CMS, USA)<br>• Department of Veterans Affairs (USA)<br>• Centers for Disease Control and Prevention (CDC, US) | • 1 Cochrane review and 1 meta-analysis (1++)<br>• 8 clinical guidelines<br>• 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)<br>• Institute for Clinical Systems Improvement (ICSI, USA)<br>• National Committee for Quality Assurance (NCQA, USA)<br>• ADSR study (Germany)<br>• Catalonia Stroke Audit (Spain)[45]<br>• Canadian Stroke Strategy (Canada)<br>• The European Implementation Score (EIS) Collaboration[43]The Danish National Indicator Project (Denmark) | • 2 systematic reviews (1++)<br>• 1 HTA report<br>• 2 RCTs (1+)<br>• 1 prospective study (2++)<br>• 1 retrospective study (2+)<br>• 9 clinical guidelines<br>• 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+)<br>• 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)<br>• The Danish National Indicator Project (Denmark)<br>• National sentinel audit (UK)<br>• Canadian Stroke Strategy (Canada) | • 1 Cochrane review (1++)<br>• 3 clinical guidelines<br>• 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)<br>• Canadian Stroke Strategy (Canada)<br>• National Stroke Foundation (Australia) | • 1 Cochrane review (1++)<br>• 13 clinical guidelines<br>• 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)<br>• Catalonia Stroke Audit (Spain) | • 1 prospective study (2++)<br>• 9 clinical guidelines<br>• 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<br>• Catalonia Stroke Audit (Spain)<br>• Canadian Stroke Strategy (Canada)<br>• National sentinel audit (UK)<br>• The Danish National Indicator Project (Denmark)<br>• HAS (France)<br>• ADSR study (Germany)<br>• Department of Veterans Affairs (USA) | • 2 Cochrane reviews and 3 other systematic review (1++)<br>• 1 RCT (1+)<br>• 2 prospective studies (2++)<br>• 13 clinical guidelines<br>• 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)<br>• The Danish National Indicator Project (Denmark) | • 1 RCT (1+)<br>• 1 retrospective study (2+)<br>• 3 national/regional audits |
| 14. Electrocardiogram (ECG) | ECG during hospitalization | • ADSR study (Germany) | • 1 systematic review (1++)<br>• 1 RCT (1+)<br>• 2 national/regional audits |
| 15. Echocardiography | Echocardiography in ischemic stroke | Canadian National Sentinel audit | • 1 retrospective study (2+)<br>• 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)<br>• Catalonia Stroke Audit (Spain)<br>• Department of Veterans Affairs (USA) | • 1 systematic review (1++)<br>• 2 RCTs (1+)<br>• 1 prospective study<br>• 3 clinical guidelines<br>• 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<br>• 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++)<br>• 1 RCT (1+)<br>• 1 prospective study (2++)<br>• 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)<br>• Centers for Disease Control and Prevention (CDC, US)<br>• Department of Veterans Affairs (USA)<br>• The Danish National Indicator Project (Denmark)<br>• ADSR study (Germany) | • 1 RCT (1+)<br>• 8 clinical guidelines<br>• 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++)<br>• 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)<br>• 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++)<br>• 1 RCT (1+)<br>• 3 clinical guidelines<br>• 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<br>• Canadian Stroke Strategy (Canada)<br>• 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+)<br>• 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+)<br>• 1 clinical guideline<br>• 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)<br>• Centers for Disease Control and Prevention (CDC, US)<br>• Department of Veterans Affairs (USA)<br>• The European Implementation Score (EIS) Collaboration | • 1 RCT (1+)<br>• 7 clinical guidelines |
| 28. Mood assessment | Mood assessed by discharge | National sentinel audit (UK) | • 1 prospective study (2++)<br>• 2 clinical guidelines<br>• 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<br>Agency for Healthcare Research and Quality (AHRQ, USA)<br>ADSR study (Germany)<br>ISD Scotland (UK)<br>The Danish National Indicator Project (Denmark)<br>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)<br>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)<br>HAS (France) | 1 prospective study (2++)<br>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 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<br>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.<br>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).

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