

대한의학회 임상진료지침 교육 워크숍

AGREE 평가 실습자료



대한의학회
Korean Academy of Medical Sciences

2017년 임상진료지침 교육 워크숍 (고도화 과정) - AGREE 2 평가

실습 방법 안내

자료 구성

(1) 2017-AGREE-실습-guide

- AGREE 2 문항과 문항별 scoring guide를 제시하였다.
- 각 문항에는 평가 시 참고할 수 있도록 실습자료의 관련 페이지 혹은 부록을 제시하였다.
실습자료는 '2017-AGREE2-심화실습-예습용_편집본-NICE Stroke 2008'이다.

(2) 2017-AGREE-실습-예습용_편집본-NICE Stroke 2008

실습 방법

1. AGREE 2 평가 교육과 실습은 교육 워크숍 2일차 일정으로 진행한다.
2. 과정 참가자는 AGREE 2 평가 교육에 참여하기 전, 배포한 상기 자료를 활용하여 스스로 평가를 진행한다.
3. 실습조 토의 준비 및 진행
 - ✓ (교육 1일차) 실습조의 참가자 개인에게 AGREE 2 문항 2~3 문항씩 배정한다.
 - ✓ (교육 2일차) AGREE 평가 실습 (조별실습) 각 조의 facilitator 주도로 구성원 개별 의견을 발표하고 토의한다. (50분)
4. 전체 토의
 - ✓ (교육 2일차) 각 조의 발표자와 토의자 2인을 선정한다.
() 조 발표 () 토의 1 () 토의 2 ()

✓ 각 조의 대표자는 '발표'로 배정된 문항에 대한 평가 결과를 발표한다. '토의'로 배정된 조는 '발표'조의 의견에 대한 동의/반대/추가 등의 의견을 제시하여야 한다.

AGREE 2 문항번호	발표 담당	토의 담당 1	토의 담당 2
1, 2, 3, 22, 23	1조	3조	4조
4, 5, 6, 7, 8	2조	4조	5조
9, 10, 11, 12	3조	5조	1조
13, 14, 15, 16, 17	4조	1조	2조
18, 19, 20, 21	5조	2조	3조

Korean Scoring Guides for the AGREE II - Domain 1. Scope & purpose -

사용설명:

Modified Delphi Consensus process 를 통해 도출된 배점기준임: 배점기준은 1, 3, 5, 7 점에 해당하는 기준점에 대하여 정의하였음. 각 배점기준의 기준을 일부 충족하지 못할 경우 평가자(peer reviewer)의 판단에 따라 2, 4, 6 점을 배점하도록 함.

AGREE item	점수	Scoring guide
1. 진료지침의 전반적인 목적이 구체적으로 서술되어 있다.	7	진료지침의 목적에 들어가야 할 모든 요소들(대상, 보건상의 목적, 예상되는 편익 또는 결과)이 서술된 경우
	5	진료지침의 목적에 보건상의 목적(예방, 선별검사, 진단, 치료, 등)과 대상만 서술된 경우
	3	진료지침의 목적에 보건상의 목적(예방, 선별검사, 진단, 치료, 등)만 서술된 경우
	1	진료지침의 목적이 서술되어 있지 않은 경우
2. 진료지침에서 다루고자 하는 건강관련 질문들이 구체적으로 서술되어 있다	7	진료지침에서 다루는 질문이 PICO 요소를 포함하고 있고, 별도의 리스트로 되어 있어 찾기 쉽고 내용이 명확하게 서술된 경우
	5	질문이 일목요연한 문장이지만, 별도의 리스트로 되어 있지 않거나, PICO 의 요소가 없거나 부족한 경우
Appendix A	3	질문이 단어로만 이루어진 소제목과 같이 최소의 정보로 제시되어 있는 경우
	1	진료지침에서 다루는 질문임을 유추할 수 없는 경우
3. 진료지침을 적용할 인구집단 (환자, 일반인 등)이 구체적으로 서술되어 있다.	7	진료지침 적용대상을 특징짓는 기본요소(대상집단, 성별, 나이) 및 지침의 주제에 합당한 관련 요소(임상적 상태, 병의 중증도/진행단계, 동반질환, 제외되는 대상)들이 서술되어 있는 경우
	5	진료지침 적용대상을 특징짓는 요소들이 독립된 소단원으로 정리되어 있으나, 필요한 모든 요소를 포함하지 못한 경우
Appendix B (p6)	3	진료지침 적용대상을 특징짓는 요소들이 일부 산발적으로 서술되어 있는 경우
	1	진료지침 적용대상을 질환명만으로 표현한 경우

Korean Scoring Guides for the AGREE II - 2. Stakeholder involvement -

AGREE item	점수	Scoring guide
4. 진료지침 개발 그룹은 모든 관련 전문가 집단을 포함하고 있다.	7	구성원은 주제와 영역에 적합한 전문가들이 모두 포함되어 있으며, 지침개발그룹의 개개인에 대하여 이름, 전문 학문분야, 소속기관, 지역, 지침개발그룹 내에서의 역할이 명시되어 있고, 적어도 한 명의 지침개발 방법론 전문가(예, 체계적 문헌고찰 전문가, 역학자, 통계학자, 문헌정보학자)를 포함하고 있는 경우
	5	지침개발방법론 전문가를 포함하고 있지 않으면서, 구성원 개개인의 지침개발그룹 내에서의 역할이 명시되어 있고 주제와 영역에 적합한 전문가들을 포함하는 경우
v~vi	3	지침개발방법론 전문가를 포함하고 있지 않으면서, 구성원 개개인의 지침개발그룹 내에서의 역할이 명시되어 있거나 또는 주제와 영역에 적합한 전문가들이 포함되어야 하는 요건의 일부만을 충족하는 경우
	1	지침개발그룹의 개개인에 대한 정보가 없는 경우
5. 진료지침을 적용할 인구집단 (환자, 일반인 등)의 관점과 선호도를 고려했고, 그 내용을 포함하고 있다.	7	지침적용 대상 집단의 관점(경험과 기대), 선호도를 조사하여 이를 반영하였으며, 조사방법이 체계적이고, 경험과 기대가 어떻게 반영되었는지에 대한 내용이 명확히 서술된 경우
	5	지침적용 대상 집단의 관점(경험과 기대), 선호도를 조사하여 이를 반영하였으나, 조사방법이 체계적이지 않거나 명확히 서술되어 있지 않은 경우
p5 (section 2.4) p95 (10.1.5)	3	지침적용 대상 집단의 관점(경험과 기대), 선호도가 서술되어 있으나, 조사방법이 서술되지 않은 경우
	1	지침적용 대상 집단의 관점(경험과 기대), 선호도가 서술되어 있지 않은 경우
6. 진료지침을 주로 활용할 사용자 집단이 분명하게 규정되어 있다.	7	진료지침을 실제 사용할 사람이 누구(예를 들면 류마티스 내과 전문의, 가정의, 요통환자 등)인지 사용자가 어떤 분야에서 어떻게 사용할 수 있는가에 대한 정보가 명시된 경우
	5	진료지침의 실제 사용자의 범위는 명시되어 있으나 사용자가 어떤 분야에서 어떻게 사용할 수 있는가에 대한 정보가 없는 경우
p5	3	진료지침의 실제 사용자의 범위와 분야에 대해 서술되어 있지 않으나 유추 가능한 경우
	1	진료지침의 실제 사용자에 대한 서술이 없는 경우

Korean Scoring Guides for the AGREE II - Domain 3. Rigour of development -

AGREE item	점수	Scoring guide
7. 근거의 검색에 체계적인 방법이 사용되었다.	7	검색의 요소(검색 데이터베이스, 검색기간, 검색어, 검색전략) 등이 모두 서술되어 있고, 내용은 목적범위에 적합하며, 재검색이 가능할 정도로 상세한 경우
	5	검색의 요소들이 서술되어 있으나, 목적범위에 적합하지 않고. 재검색이 가능할 정도로 상세하지 않은 경우
p8 Appendix A	3	검색의 요소들 중 일부만 서술되어 있는 경우
	1	검색의 요소들이 서술되어 있지 않은 경우
8. 근거 선택의 기준이 분명하게 서술되어 있다.	7	포함/배제의 기준이 잘 제시되어 있고, 이론적 근거가 명확하게 제시되어 있으면서 진료지침의 목적범위에 부합하는 경우
	5	포함/배제의 기준이 잘 제시되어 있으나 근거가 불명확하거나 진료지침의 목적범위에 부적합한 경우
p8 Appendix A	3	포함/배제의 기준이 제시되어 있지 않지만 유추가 가능한 경우
	1	포함/배제의 기준이 제시되어 있지 않은 경우
9. 근거 자료의 강도와 한계가 분명하게 서술되어 있다.	7	사용한 근거의 질 평가 도구(예, Jadad 척도, GRADE 법)에 대한 명시가 있으며, 근거자료의 강도 및 한계와 관련 있는 모든 요소(연구설계, 제한점, 결과의 일관성, 편익/위해의 규모, 적용가능성)가 서술된 경우
	5	사용한 근거의 질 평가 도구에 대한 명시는 있으나 근거자료의 강도 및 한계와 관련 있는 요소 중 일부만 서술된 경우
p9 p56~57 (7.2.2 & 7.2.5) p92~95 (10.1.2&10.1.5)	3	근거의 질 평가 도구의 사용에 대한 명시가 없으며, 근거자료의 강도 및 한계와 관련 있는 요소 중 일부만 서술된 경우
	1	근거의 질 평가 도구의 사용에 대한 명시가 없으며, 근거자료의 강도 및 한계와 관련 있는 요소에 대한 서술이 없는 경우
10. 권고안 도출 방법이 분명하게 서술되어 있다.	7	권고안의 도출 방법(Delphi 기법, 불일치해결방법)과 결과가 서술되어 있고, 공식적 합의과정이 최종 권고안 도출에 어떻게 반영되었는지가 기술된 경우
	5	권고안의 도출 방법과 결과가 서술되어 있으나, 공식적 합의과정이 최종 권고안 도출에 어떻게 반영되었는지가 기술되지 않은 경우
p9~10 p57(7.2.5) p95(10.1.5)	3	권고안의 도출 방법 또는 결과에 대한 간략한 서술이 있는 경우
	1	권고안의 도출방법과 결과에 대한 서술이 없는 경우

11. 건강상의 편익, 부작용, 위험 요인이 권고안 도출시 고려되었다.	7	건강상의 편익, 부작용, 위험 요인 모두에 대한 근거문헌 및 데이터가 제시되어 있고, 권고안에 그 내용이 반영되어 있는 경우
	5	건강상의 편익, 부작용, 위험 요인에 대한 근거문헌 및 데이터가 제시되어 있지 않으나, 권고안에 그 내용이 반영되어 있는 경우
p56~58 p92~95	3	건강상의 편익, 부작용, 위험 요인에 대한 근거문헌 및 데이터도 제시되어 있지 않고, 권고안에 일부만 반영된 경우
	1	건강상의 편익, 부작용, 위험 요인이 권고안에 반영되지 않은 경우
12. 권고안과 이를 뒷받침하는 근거를 명확하게 연결 지을 수 있다.	7	권고안이 근거와 연결되어 있으며, 권고안이 지침의 근거요약과 근거표에 연계되어 있는 경우
	5	권고안이 근거와 연결되어 있고, 핵심 근거의 요약이나 참고문헌 목록이 있으면서, 근거표가 제시되지 않은 경우
p56~58 p92~95	3	권고안의 일부만이 근거와 연결된 경우
	1	권고안이 지침의 근거요약과 근거표에 연계되어 있지 않은 경우
13. 진료지침은 출판 전에 외부 전문가들에 의한 검토 과정이 있었다.	7	외부검토자(인원수, 검토자의 유형, 소속), 검토목적, 시행방법(평가척도, 개방형질문), 수집 정보와 결과(핵심소견의 요약)가 모두 서술되어 있고, 수집 정보가 개발과정과 권고안에 어떻게 반영되었는지를 서술한 경우
	5	외부검토자, 검토목적, 시행방법, 수집 정보와 결과가 일부 서술되어 있으면서, 수집 정보가 개발과정과 권고안에 어떻게 반영되었는지를 서술한 경우
p11(9)	3	외부검토자, 검토목적, 시행방법, 수집정보와 결과가 일부 서술되어 있으나, 수집정보가 개발 과정과 권고안에 어떻게 반영되었는지를 서술하지 않은 경우
	1	외부검토자, 검토 목적, 시행방법, 수집 정보와 결과에 대한 서술이 없으면서, 수집 정보가 개발과정과 권고안에 어떻게 반영되었는지도 서술하지 않은 경우
14. 진료지침의 갱신 절차가 제시되어 있다.	7	지침개정 일정과 방법론이 제시되어 있고, 개정을 결정하는 판단기준이 명시되어 있는 경우
	5	지침의 일정과 개정을 결정하는 판단기준에 대한 서술이 간략히 또는 일부만 서술되어 있는 경우
p11	3	지침의 향후 개정에 대한 계획이 있으나 일정과 방법이 구체적으로 제시되어 있지 않은 경우
	1	지침개정 계획에 관한 언급이 없는 경우

Korean Scoring Guides for the AGREE II - Domain 4. Clarity of presentation -

AGREE item	점수	Scoring guide
15. 권고안은 구체적이며 모호하지 않다.	7	권고안의 목적, 적용할 환자나 상황 모두에 대해 명확히 서술되어 있고, 근거의 해석이 불확실할 때 그 불확실성까지 구체적으로 서술된 경우
	5	권고안의 목적, 적용할 환자나 상황, 권고사항에 대한 설명이 명시되어 있으나 구체적이지 않은 경우
p58(7.2.6) p95(10.1.6)	3	권고안이 명시되어 있으나 권고안의 목적, 적용할 환자나 상황이 모호한 경우
	1	권고안이 명시되어 있지 않은 경우
16. 임상 상태나 건강 이슈를 관리하기 위한 다양한 대안이 분명하게 표현되어 있다.	7	권고안에서 주 치료와 그 대안을 명확하게 구분할 수 있도록 지침에 서술되어 있고 이의 적용 대상과 임상상황이 모두 서술되어 있는 경우
	5	권고안에 다양한 선택방안이 제시되어 있으면서, 적용 대상이나 임상상황이 서술되어 있는 경우
p58(7.2.6) p95(10.1.6)	3	권고안에 다양한 선택방안이 제시되어 있으나, 적용 대상이나 임상상황에 대한 서술이 없는 경우
	1	권고안에 선택방안, 적용 대상, 임상상황에 대한 서술이 없는 경우
17. 주요 권고안은 쉽게 확인할 수 있다.	7	구체적 권고 사항들이 하나의 소단원에 모여 있고, 권고 사항의 주요 내용을 쉽게 알아 볼 수 있도록 특별한 서식(권고 사항을 요약한 글상자, 굵은 글씨나 밑줄표시, 흐름도나 알고리즘)으로 표현된 경우
	5	구체적 권고 사항들이 하나의 소단원에 모여 있으나, 특별한 서식으로 표현되지 않은 경우
p14~15 p58(7.2.6) p95(10.1.6)	3	구체적 권고사항들이 지침 내 여러 부분에 산재해 있으면서, 특별한 서식으로 표현된 경우
	1	구체적 권고 사항들이 지침 내 여러 부분에 산재해 있는 경우

Korean Scoring Guides for the AGREE II - Domain 5. Applicability -

AGREE item	점수	Scoring guide
18. 진료지침은 이를 실행하는데 있어 장애요인과 촉진요인을 서술하고 있다.	7	권고안 적용 시 촉진요인과 장애요인 모두에 대해 그 유형, 정보수집과정, 요소를 반영한 과정 등이 구체적으로 서술되어 있고, 장애요인 극복 전략이 제시되어 있는 경우
	5	권고안 적용 시 촉진요인과 장애요인 일부에 대해 그 유형, 정보수집과정, 요소를 반영한 과정 등이 구체적으로 서술되어 있으나, 장애요인 극복 전략이 제시되어 있지 않은 경우
7.2.1 / 7.2.5 / 7.2.6 10.2.1 / 10.2.5 / 10.2.6	3	권고안 적용 시 촉진요인과 장애요인에 대해 고려했다는 서술만 있는 경우
	1	권고안 적용 시 촉진요인과 장애요인에 대한 서술이 없는 경우
19. 진료지침은 권고안이 의료현장에서 실제 사용될 수 있도록 도와주는 조언과 도구를 제시하고 있다.	7	진료지침 보급과 실행을 위한 보조자료(예, 요약문서, 체크리스트, 알고리즘, 실행매뉴얼, 장애요인 분석과 해결방안, 진료지침 실행을 촉진하는 요소들을 정착시키는 도구, 예비조사 결과와 교훈 등)가 있고, 그 활용방법도 제시하고 있는 경우
	5	진료지침 보급과 실행을 위한 보조 자료는 있지만, 그 활용방법이 제시되어 있지 않고 그 내용을 진료지침 내에서 찾을 수 없는 경우
p11 Table 2.3 p14~15	3	진료지침 보급과 실행을 위한 보조 자료는 없으나, 그 내용을 진료지침 내에서 찾을 수 있는 경우
	1	진료 지침 보급과 실행을 위한 보조 자료가 없고, 그 내용도 진료 지침 내에서 찾을 수 없는 경우
20. 권고안 적용 시 필요로 할 수 있는 잠재적인 자원의 영향과 의미가 고려되어야 한다.	7	권고안 적용 시 비용 정보(예, 유형, 정보수집과정, 비용편익분석/비용효과분석, 구입비용, 예산관련문제 등)가 모두 제시되어 있고, 적합한 전문가가 비용 정보 분석에 참여한 경우
	5	권고안 적용 시 비용 정보의 일부가 제시되어 있고, 적합한 전문가가 비용정보 분석에 참여한 경우
p57 (7.2.4)	3	권고안 적용 시 비용 정보로써 구입비용이나 예산 관련 문제가 서술되어 있는 경우
	1	자원과 관련된 문제에 대한 내용을 진료지침 내에서 찾을 수 없는 경우

21. 진료지침은 수행 정도에 대한 감독 및 평가 기준을 제시하고 있다.	7	권고 사항을 모니터링하고 평가할 수 있는 주요 기준(지침의 활용도, 권고사항 순응도 및 영향평가)들이 모두 제시되어 있으며, 측정 방법이 명확히 서술되어 있는 경우
	5	권고 사항을 모니터링하고 평가할 수 있는 주요 기준들이 일부 제시되어 있으면서, 측정 방법이 서술되어 있는 경우
p10*	3	권고 사항을 모니터링하고 평가할 수 있는 주요 기준들이 일부 제시되어 있으나, 측정 방법이 서술되어 있지 않은 경우
	1	권고 사항을 모니터링하고 평가할 수 있는 주요 기준들에 대한 내용을 지침 내에서 찾을 수 없는 경우

* NICE homepage : <https://www.nice.org.uk/Guidance/CG131>

Korean Scoring Guides for the AGREE II - Domain 6. Editorial independence -

AGREE item	점수	Scoring guide
22. 재정후원단체의 의견이 진료지침의 내용에 영향을 주지 않았다.	7	재정지원자 이름(또는 재정 후원이 없다는 분명한 언급)이 있고, 재정지원자가 진료지침 내용에 영향을 주지 않았다는 내용이 포함되어 있으며, 재정지원자로부터 받을 수 있는 잠재적 영향에 대한 서술이 있는 경우
	5	재정지원자 이름(또는 재정후원이 없다는 분명한 언급)이 있고, 재정지원자가 진료지침 내용에 영향을 주지 않았다는 내용이 포함되어 있으나, 재정지원자로부터 받을 수 있는 잠재적 영향에 대한 서술이 없는 경우
p11 (2.10)	3	재정지원자 이름(또는 재정 후원이 없다는 분명한 언급)이 있으나, 재정 지원자가 진료지침 내용에 영향을 주지 않았다는 내용이 없으며, 재정 지원자로부터 받을 수 있는 잠재적 영향에 대한 서술이 없는 경우
	1	재정지원자 이름(또는 재정후원이 없다는 분명한 언급)이 없고, 재정지원자가 진료지침 내용에 영향을 주지 않았다는 내용이나 재정지원자로부터 받을 수 있는 잠재적 영향에 대한 서술이 없는 경우
23. 진료지침 개발에 참여한 구성원들의 이해관계가 기록되어 있고 그 내용이 언급되어 있다.	7	지침개발그룹 구성원들의 상충되는 이해관계나 잠재적인 이해관계(예: 구성원이 지침관련주제로 제약회사 후원을 받은 경우 이를 명시) 유무에 대한 언급이 있고, 잠재적인 이해상충관계 확인 방법이 서술되어 있고, 이해상충 관계가 진료지침이나 권고안에 미치는 영향을 최소화하는 방법도 제시되어 있는 경우
	5	지침개발그룹 구성원들의 이해상충관계 유무에 대한 언급이 있고, 확인 방법이 서술되어 있으나, 잠재적인 영향에 대한 서술이 없는 경우
Appendix D	3	지침개발그룹 구성원들의 이해상충관계 유무에 대한 언급은 있으나, 확인 방법이나 잠재적인 영향에 대한 서술이 없는 경우
	1	지침개발그룹 구성원들의 이해상충관계에 대한 언급이 없는 경우

STROKE

National clinical guideline for diagnosis
and initial management of acute stroke and
transient ischaemic attack (TIA)

Published by



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National Collaborating Centre for Chronic Conditions

The National Collaborating Centre for Chronic Conditions (NCC-CC) is a collaborative, multiprofessional centre undertaking commissions to develop clinical guidance for the National Health Service (NHS) in England and Wales. The NCC-CC was established in 2001. It is an independent body, housed within the Clinical Standards Department at the Royal College of Physicians of London. The NCC-CC is funded by the National Institute for Health and Clinical Excellence (NICE) to undertake commissions for national clinical guidelines on an annual rolling programme.

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Contents

	Guideline Development Group Members	v
	Preface	vii
	DEVELOPMENT OF THE GUIDELINE	
1	Introduction	
1.1	Background	3
1.2	Incidence and prevalence	4
1.3	Health and resource burden	4
1.4	Definition	4
2	Methodology	
2.1	Aim	5
2.2	Scope	5
2.3	Audience	5
2.4	Involvement of people with stroke and TIA	5
2.5	Guideline limitations	6
2.6	Other work relevant to the guideline	6
2.7	Methodological background	7
2.8	The process of guideline development	8
2.9	Disclaimer	11
2.10	Funding	11
3	Key messages of the guideline	
3.1	Key priorities for implementation	13
3.2	Algorithms	14
4	Glossary and definitions	17
	THE GUIDELINE	
5	The rapid recognition of symptoms and diagnosis	
5.1	Pre-hospital prompt recognition of symptoms of TIA and stroke symptoms	25
5.2	Early versus late assessment of people with TIA, and identifying those at high risk of stroke	29
6	Imaging in TIA and non-disabling stroke	
6.1	Suspected TIA – referral for urgent brain imaging	41
6.2	Type of brain imaging for people with suspected TIA	43
6.3	Early carotid imaging in people with acute non-disabling stroke or TIA	44
6.4	Urgent carotid endarterectomy and carotid stenting in people with carotid stenosis	47
7	Specialist care in acute stroke	
7.1	Specialist stroke units	51
7.2	Brain imaging for the early assessment of people with acute stroke	56

8	Pharmacological treatments for people with acute stroke	
8.1	Thrombolysis in people with acute ischaemic stroke	59
8.2	Aspirin and anticoagulant treatment in people with acute ischaemic stroke	60
8.3	Antiplatelet and anticoagulant treatment in people with acute venous stroke	68
8.4	Antiplatelet and anticoagulant treatment in people with stroke due to arterial dissection	69
8.5	Antiplatelet and anticoagulant treatment in people with acute stroke due to antiphospholipid syndrome	71
8.6	Reversal of anticoagulation treatment in people with haemorrhagic stroke	72
8.7	Anticoagulation treatment for other comorbidities in people with acute stroke	74
8.8	Statin treatment in people with acute stroke	80
9	Maintenance or restoration of homeostasis	
9.1	Supplemental oxygen therapy	83
9.2	Blood sugar control	84
9.3	Blood pressure control	86
10	Nutrition and hydration	
10.1	Assessment of swallowing function	91
10.2	Timing of enteral feeding	96
10.3	Oral nutritional supplementation	98
11	Early mobilisation and optimum positioning of people with acute stroke	101
12	Avoidance of aspiration pneumonia	105
13	Surgery for people with acute stroke	
13.1	Surgical referral for acute intracerebral haemorrhage	107
13.2	Surgical referral for decompressive hemicraniectomy	110
14	Research recommendations	113
	REFERENCES	114
	Appendices and evidence tables:	
	available online at www.rcplondon.ac.uk/pubs/brochure.aspx?e=250	

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DEVELOPMENT OF THE GUIDELINE

1 Introduction

1.1 Background

Stroke is a preventable and treatable disease. It can present with the sudden onset of any neurological disturbance, including limb weakness or numbness, speech disturbance, visual loss or disturbance of balance. Over the last two decades, a growing body of evidence has overturned the traditional perception that stroke is simply a consequence of aging which inevitably results in death or severe disability. Evidence is accumulating for more effective primary and secondary prevention strategies, better recognition of people at highest risk and thus most in need of active intervention, interventions that are effective soon after the onset of symptoms, and an understanding of the processes of care that contribute to a better outcome. In addition, there is now good evidence to support interventions and care processes in stroke rehabilitation. In the UK, the National Sentinel Stroke Audits^{2,3} have documented changes in secondary care provision over the last 10 years, with increasing numbers of patients being treated in stroke units, more evidence-based practice, and reductions in mortality and length of stay. In order for evidence from research studies to improve outcomes for patients, it needs to be put into practice. National guidelines provide clinicians, managers and service users with summaries of evidence and recommendations for clinical practice. Implementation of guidelines in practice, supported by regular audit, improves the processes of care and clinical outcome.

This guideline covers interventions in the acute stage of a stroke ('acute stroke') or transient ischaemic attack (TIA). Most of the evidence considered relates to interventions in the first 48 hours after onset of symptoms, although some interventions of up to 2 weeks are covered as well. This guideline is a stand-alone document, but is designed to be read alongside the Intercollegiate Stroke Working Party guideline 'National clinical guideline for stroke'* which considers evidence for interventions from the acute stage into rehabilitation and life after stroke. The Intercollegiate Stroke Working Party guideline is an update of the 2004 2nd edition and includes all the recommendations contained within this guideline. This acute stroke and TIA guideline is also designed to be read alongside the Department of Health's (DH) 'National stroke strategy' (NSS).⁴ Where there are differences between the recommendations made within this acute stroke and TIA guideline and the NSS, the Guideline Development Group (GDG) members feel that their recommendations are derived from systematic methodology to identify all of the relevant literature.

Stroke has a sudden and sometimes devastating impact on the patient and their family who need continuing information and support. Clinicians dealing with acute care need to be mindful of the rehabilitation and secondary care needs of patients with stroke to ensure a seamless transition across the different phases of care. All aspects of care must be patient-centred and where possible based on full discussion with the patient and/or carer, for example some aspects of the guideline may not be appropriate for patients who are dying or who have other severe comorbidities. Healthcare professionals should also follow a code of practice accompanying the Mental Capacity Act 2005 (summary available from www.dca.gov.uk/menincap/bill-summary.htm).

* Intercollegiate Stroke Working Party. 'National clinical guideline for stroke', 3rd edition. London: RCP, 2008.

1.2 Incidence and prevalence

Stroke is a major health problem in the UK. It accounted for over 56,000 deaths in England and Wales in 1999, which represent 11% of all deaths.⁵ Most people survive a first stroke, but often have significant morbidity. Each year in England, approximately 110,000 people have a first or recurrent stroke and a further 20,000 people have a TIA. More than 900,000 people in England are living with the effects of stroke, with half of these being dependent on other people for help with everyday activities.⁶

1.3 Health and resource burden

In England, stroke is estimated to cost the economy around £7 billion per year. This comprises direct costs to the NHS of £2.8 billion, costs of informal care of £2.4 billion and costs because of lost productivity and disability of £1.8 billion.⁶

Until recently, stroke was not perceived as a high priority within the NHS. However, following the publication of the National Audit Office report in 2005, a National Stroke Strategy was developed by the DH in 2007.⁴ This outlines an ambition for the diagnosis, treatment and management of stroke, including all aspects of care from emergency response to life after stroke.

1.4 Definition

Stroke is defined by the World Health Organization⁷ as ‘a clinical syndrome consisting of rapidly developing clinical signs of focal (or global in case of coma) disturbance of cerebral function lasting more than 24 hours or leading to death with no apparent cause other than a vascular origin.’ A transient ischaemic attack (TIA) is defined as stroke symptoms and signs that resolve within 24 hours. There are limitations to these definitions. The symptoms of a TIA usually resolve within minutes or a few hours at most and anyone with continuing neurological signs when first assessed should be assumed to have had a stroke. ‘Brain Attack’ is sometimes used to describe any neurovascular event and may be a clearer and less ambiguous term to use.

2 Methodology

2.1 Aim

The aim of the National Collaborating Centre for Chronic Conditions (NCC-CC) is to provide a user-friendly, clinical, evidence-based guideline for the National Health Service (NHS) in England and Wales that:

- offers best clinical advice for the diagnosis and acute management of stroke and TIA
- is based on best published clinical and economic evidence, alongside expert consensus
- takes into account patient choice and informed decision-making
- defines the major components of NHS care provision for the management of acute stroke and TIA
- details areas of uncertainty or controversy requiring further research
- provides a choice of guideline versions for differing audiences.

2.2 Scope

The guideline was developed in accordance with a scope, which detailed the remit of the guideline originating from the DH and specified the aspects of diagnosis and the management of acute stroke and TIA care to be included and excluded.

Prior to guideline development, the scope was subjected to stakeholder consultation in accordance with processes established by National Institute for Health and Clinical Excellence (NICE).¹ The full scope is shown in Appendix B, available online at www.rcplondon.ac.uk/pubs/brochure.aspx?e=250

2.3 Audience

The guideline is intended for use by the following people or organisations:

- all healthcare professionals
- people with acute stroke or TIA and their carers
- patient support groups
- commissioning organisations
- service providers.

2.4 Involvement of people with stroke and TIA

The NCC-CC was keen to ensure the views and preferences of people with stroke and TIA and their carers were informed at all stages of the guideline. This was achieved by:

- having two people with experience of stroke and TIA as patient representatives on the guideline development group

- consulting the Patient and Public Involvement Programme (PPIP) housed within NICE during the pre-development (scoping) and final validation stages of the guideline project
- the inclusion of patient groups as registered stakeholders for the guideline.

2.5 Guideline limitations

These include:

- NICE clinical guidelines usually do not cover issues of service delivery, organisation or provision (unless specified in the remit from the DH).
- NICE is primarily concerned with health services and so recommendations are not provided for social services and the voluntary sector. However, the guideline may address important issues in how NHS clinicians interface with these other sectors.
- Generally, the guideline does not cover rare, complex, complicated or unusual conditions.
- Where a meta-analysis was available, generally the individual papers contained within were not appraised.
- It is not possible in the development of a clinical guideline to complete extensive systematic literature review of all pharmacological toxicity. NICE advises that the guidelines are read alongside the summaries of product characteristics (SPCs).
- Overall, the evidence review identified very few randomised controlled trials (RCTs) or high-quality case-control or cohort studies. Many of the studies had a small sample size and were consequently statistically under-powered. Also, some studies relied on retrospective data collection or post-hoc analysis. Furthermore, the different diagnostic tests, interventions and outcomes often precluded any meaningful comparison across studies.

2.6 Other work relevant to the guideline

Related NICE guidance:

- 'Alteplase for the treatment of acute ischaemic stroke', *NICE technology appraisal* no. TA122 (2007). Available from www.nice.org.uk/TA122
- 'Vascular disease – clopidogrel and dipyridamole', *NICE technology appraisal* no. TA90 (2005). Available from www.nice.org.uk/TA90
- 'Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition', *NICE clinical guideline* CG32 (2006). Available from www.nice.org.uk/CG32
- 'Hypertension: management of hypertension in adults in primary care', *NICE clinical guideline* CG34 (2006). Available from www.nice.org.uk/CG34
- 'Diagnosis and management of Type 1 diabetes in children, young people and adults', *NICE clinical guideline* CG15 (2004). Available from www.nice.org.uk/CG15
- 'Lipid modification guideline', *NICE clinical guideline* CG67 (2008). Available from www.nice.org.uk/CG67

2.7 Methodological background

The development of this evidence-based clinical guideline draws upon the methods described by the NICE's 'Guideline development methods manual'¹ and the methodology pack⁸ specifically developed by the NCC-CC for each chronic condition guideline. The developers' role and remit is summarised in table 2.1 below.

Table 2.1 Role and remit of the developers

National Collaborating Centre for Chronic Conditions (NCC-CC)	<p>The NCC-CC was set up in 2001 and is housed within the Royal College of Physicians (RCP). The NCC-CC undertakes commissions received from NICE.</p> <p>A multiprofessional partners' board inclusive of patient groups and NHS management governs the NCC-CC.</p>
NCC-CC technical team	<p>The technical team met approximately two weeks before each GDG meeting and comprised the following members:</p> <ul style="list-style-type: none"> GDG Chair GDG Clinical Adviser Information Scientist Research Fellow Health Economist Project Manager.
Guideline Development Group (GDG)	<p>The GDG met monthly (November 2006 to November 2007) and comprised a multidisciplinary team of professionals and people with experience of acute stroke or TIA who were supported by the technical team.</p> <p>The GDG membership details including patient representation and professional groups are detailed in the GDG membership table at the front of this guideline.</p>
Guideline Project Executive (PE)	<p>The PE was involved in overseeing all phases of the guideline. It also reviewed the quality of the guideline and compliance with the DH remit and NICE scope.</p> <p>The PE comprised of:</p> <ul style="list-style-type: none"> NCC-CC Director NCC-CC Assistant Director NCC-CC Manager NICE Commissioning Manager Technical Team.
Formal consensus	<p>At the end of the guideline development process, the GDG met to review and agree the guideline recommendations.</p>

Members of the GDG declared any interests in accordance with the NICE technical manual.¹ A register is given in Appendix D, available online at www.rcplondon.ac.uk/pubs/brochure.aspx?e=250

2.8 The process of guideline development

The basic steps in the process of producing a guideline are:

- 1 developing clinical evidence-based questions
- 2 systematically searching for the evidence
- 3 critically appraising the evidence
- 4 incorporating health economic evidence
- 5 distilling and synthesising the evidence and writing recommendations
- 6 grading the evidence statements
- 7 agreeing the recommendations
- 8 structuring and writing the guideline
- 9 updating the guideline.

▷ 1 Developing evidence-based questions

The technical team drafted a series of clinical questions that covered the guideline scope. The GDG and Project Executive refined and approved these questions, which are shown in Appendix A, available online at www.rcplondon.ac.uk/pubs/brochure.aspx?e=250

▷ 2 Searching for the evidence

The information scientist developed a search strategy for each question. Key words for the search were identified by the GDG. In addition, the health economist searched for additional papers providing economic evidence or to inform detailed health economic work (for example, modelling). Papers that were published or accepted for publication in peer-reviewed journals were considered as evidence by the GDG. Conference paper abstracts and non-English language papers were excluded from the searches.

Each clinical question dictated the appropriate study design that was prioritised in the search strategy but the strategy was not limited solely to these study types. The research fellow or health economist identified titles and abstracts from the search results that appeared to be relevant to the question. Exclusion lists, generated for each question together with the rationale for the exclusion, were presented to the GDG. Full papers were obtained where relevant. See Appendix A, available online at www.rcplondon.ac.uk/pubs/brochure.aspx?e=250 for literature search details.

▷ 3 Appraising the evidence

The research fellow or health economist, as appropriate, critically appraised the full papers. In general, no formal contact was made with authors. However, there were ad hoc occasions when this was required in order to clarify specific details. Critical appraisal checklists were compiled for each full paper. One research fellow undertook the critical appraisal and data extraction. The evidence was considered carefully by the GDG for accuracy and completeness.

All procedures are fully compliant with the:

- NICE methodology as detailed in the 'Guideline development methods – information for national collaborating centres and guideline developers' manual¹
- NCC-CC quality assurance document and systematic review chart available at www.rcplondon.ac.uk/college/NCC-CC

▷ 4 Health economic evidence

Areas for health economic modelling were agreed by the GDG after the formation of the clinical questions. The health economist reviewed the clinical questions to consider the potential application of health economic modelling, and these priorities were agreed with the GDG.

The health economist performed supplemental literature searches to obtain additional data for modelling. Assumptions and designs of the models were explained to and agreed by the GDG members during meetings, and they commented on subsequent revisions.

▷ 5 Distilling and synthesising the evidence and developing recommendations

The evidence from each full paper was distilled into an evidence table and synthesised into evidence statements before being presented to the GDG. This evidence was then reviewed by the GDG and used as a basis upon which to formulate recommendations. The criteria for grading evidence are shown in table 2.2.

Evidence tables are available online at www.rcplondon.ac.uk/pubs/brochure.aspx?e=250

▷ 6 Grading the evidence statements

Table 2.2 Grading the evidence statements NICE 2007¹

Level of evidence	Type of evidence
1++	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias.
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias.
1–	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias.*
2++	High-quality systematic reviews of case-control or cohort studies. High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal.
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal.
2–	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal.*
3	Non-analytic studies (for example case reports, case series).
4	Expert opinion, formal consensus.
*Studies with a level of evidence '–' are not used as a basis for making a recommendation. RCT, randomised controlled trial	

▷ 7 Agreeing the recommendations

The GDG employed formal consensus techniques to:

- ensure that the recommendations reflected the evidence base
- approve recommendations based on lesser evidence or extrapolations from other situations

- reach consensus recommendations where the evidence was inadequate
- debate areas of disagreement and finalise recommendations.

The GDG also reached agreement on the following:

- six recommendations as key priorities for implementation
- six key research recommendations
- algorithms.

In prioritising key recommendations for implementation, the GDG took into account the following criteria:

- high clinical impact
- high impact on reducing variation
- more efficient use of NHS resources
- allowing the patient to reach critical points in the care pathway more quickly.

Audit criteria for this guideline will be produced by NICE, following publication, in order to provide suggestions of areas for audit in line with the key recommendations for implementation.

▷ 8 Structuring and writing the guideline

The guideline is divided into sections for ease of reading. For each section, the layout is similar and contains:

- *Clinical introduction* sets a succinct background and describes the current clinical context.
- *Methodological introduction* describes any issues or limitations that were apparent when reading the evidence base. Point estimates (PE) and confidence intervals (CI) are provided for all outcomes in the evidence tables, available online at www.rcplondon.ac.uk/pubs/brochure.aspx?e=250. In addition, within the guideline PE and CI are cited in summary tables. In the absence of a summary table, PE and CI should be provided in the narrative text when the outcome adds something to the text and to make a particular point. These may be primary or secondary outcomes that were of particular importance to the GDG when discussing the recommendations. The rationale for not citing *all* statistical outcomes in the text is to try to provide a 'user friendly' readable guideline balanced with statistical evidence where this is thought to be of interest to the reader.
- *Evidence statements* provides a synthesis of the evidence base and usually describes what the evidence showed in relation to the outcomes of interest.
- *Health economics* presents, where appropriate, an overview of the cost effectiveness of evidence base, or any economic modelling.
- *From evidence to recommendations* this section sets out the GDG decision-making rationale, providing a clear and explicit audit trail from the evidence to the evolution of the recommendations.
- *Recommendations* provides stand alone, action-orientated recommendations.
- *Evidence tables* the evidence tables are not published as part of the full guideline but are made publicly available online at www.rcplondon.ac.uk/pubs/brochure.aspx?e=250. These describe comprehensive details of the primary evidence that was considered during the writing of each section including all statistical outcomes.

▷ 9 Writing the guideline

The first draft version of the guideline was drawn up by the technical team in accord with the decisions of the GDG, incorporating contributions from individual GDG members in their expert areas and edited for consistency of style and terminology. The guideline was then submitted for a formal public and stakeholder consultation prior to publication. The registered stakeholders for this guideline are detailed on the NICE website, www.nice.org.uk. Editorial responsibility for the full guideline rests with the GDG.

Table 2.3 Versions of this guideline

Full version	Details the recommendations, the supporting evidence base and the expert considerations of the GDG. Published by the NCC-CC. Available at www.rcplondon.ac.uk/pubs/brochure.aspx?e=250
NICE version	Documents the recommendations without any supporting evidence. Available at www.nice.org.uk/CG68
'Quick reference guide'	An abridged version. Available at www.nice.org.uk/CG68
'Understanding NICE guidance'	A lay version of the guideline recommendations. Available at www.nice.org.uk/CG68

▷ Updating the guideline

Literature searches were repeated for all of the evidence-based questions at the end of the GDG development process allowing any relevant papers published up until 31 October 2007 to be considered. Future guideline updates will consider evidence published after this cut-off date.

Two years after publication of the guideline, NICE will ask a National Collaborating Centre to determine whether the evidence base has progressed significantly to alter the guideline recommendations and warrant an early update. If not, the guideline will be considered for update approximately four years after publication.

2.9 Disclaimer

Healthcare providers need to use clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply guidelines. The recommendations cited here are a guide and may not be appropriate for use in all situations. The decision to adopt any of the recommendations cited here must be made by the practitioner in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources.

The NCC-CC disclaims any responsibility for damages arising out of the use or non-use of these guidelines and the literature used in support of these guidelines.

2.10 Funding

The NCC-CC was commissioned by the NICE to undertake the work on this guideline.

3 Key messages of the guideline

3.1 Key priorities for implementation

In people with sudden onset of neurological symptoms a validated tool, such as Face Arm Speech Test (FAST), should be used outside hospital to screen for a diagnosis of stroke or TIA.

People who have had a suspected TIA who are at high risk of stroke (that is, with an ABCD² score of 4 or above) should have:

- aspirin (300 mg daily) started immediately
- specialist assessment and investigation within 24 hours of onset of symptoms
- measures for secondary prevention introduced as soon as the diagnosis is confirmed, including discussion of individual risk factors.

People with crescendo TIA (two or more TIAs in a week) should be treated as being at high risk of stroke (as described in recommendation 5), even though they may have an ABCD² score of 3 or below.

All people with suspected stroke should be admitted directly to a specialist acute stroke unit following initial assessment either from the community or accident & emergency (A&E) department.

Brain imaging should be performed immediately* for people with acute stroke if any of the following apply:

- indications for thrombolysis or early anticoagulation treatment (see sections 8.1 and 8.2)
- on anticoagulant treatment
- a known bleeding tendency
- a depressed level of consciousness (Glasgow Coma Score (GCS) below 13)
- unexplained progressive or fluctuating symptoms
- papilloedema, neck stiffness or fever
- severe headache at onset of stroke symptoms.

On admission, people with acute stroke should have their swallowing screened by an appropriately trained healthcare professional before being given any oral food, fluid or medication.

* The GDG felt that immediately was defined as 'ideally the next slot and definitely within 1 hour, whichever is sooner' in line with the National Stroke Strategy.⁴

3.2 Algorithms

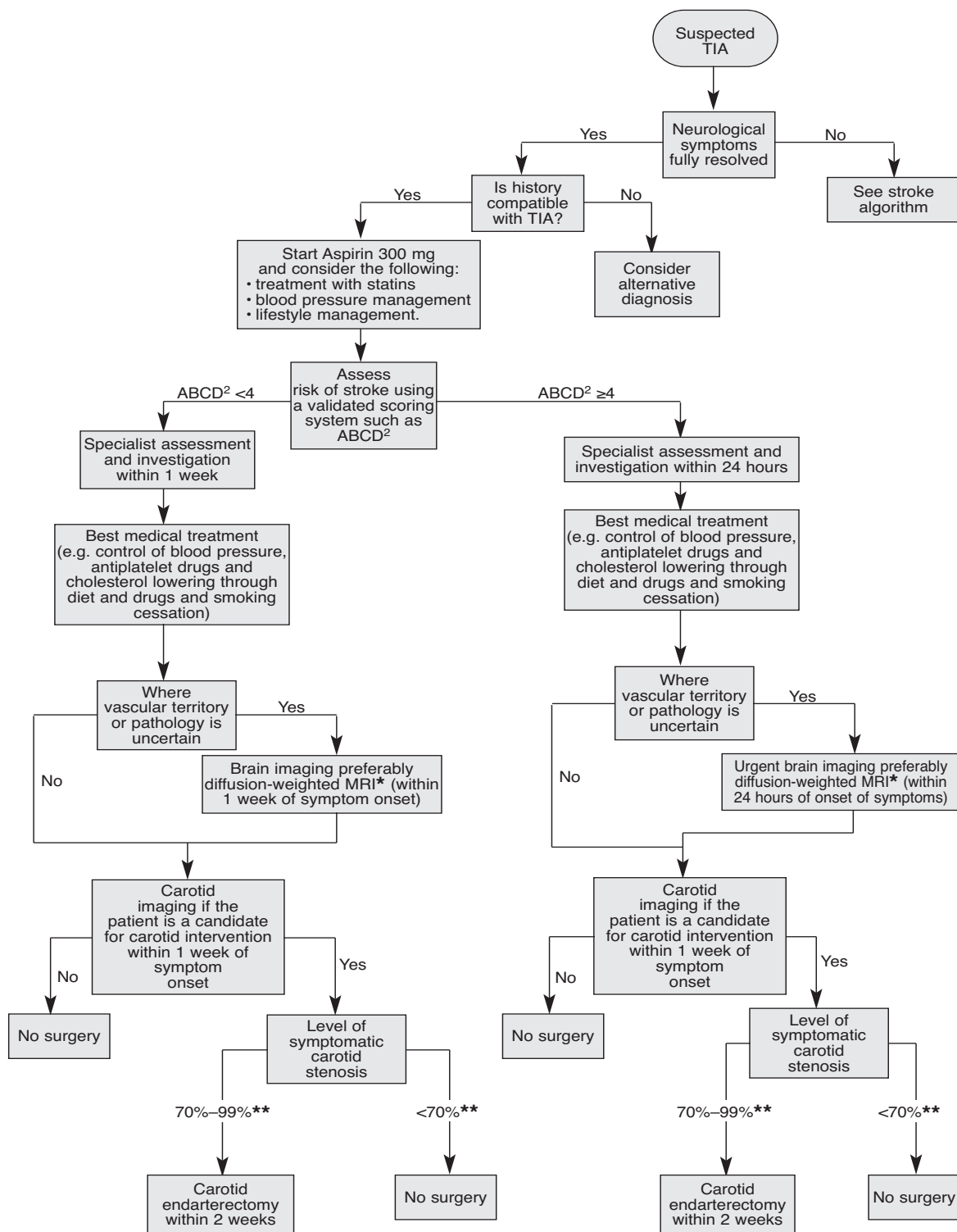


Figure 3.1 Transient ischaemic attack (TIA) algorithm

*except where contraindicated, in which case computed tomography (CT) should be used

**according to the European Carotid Surgery Trial (ECST) criteria

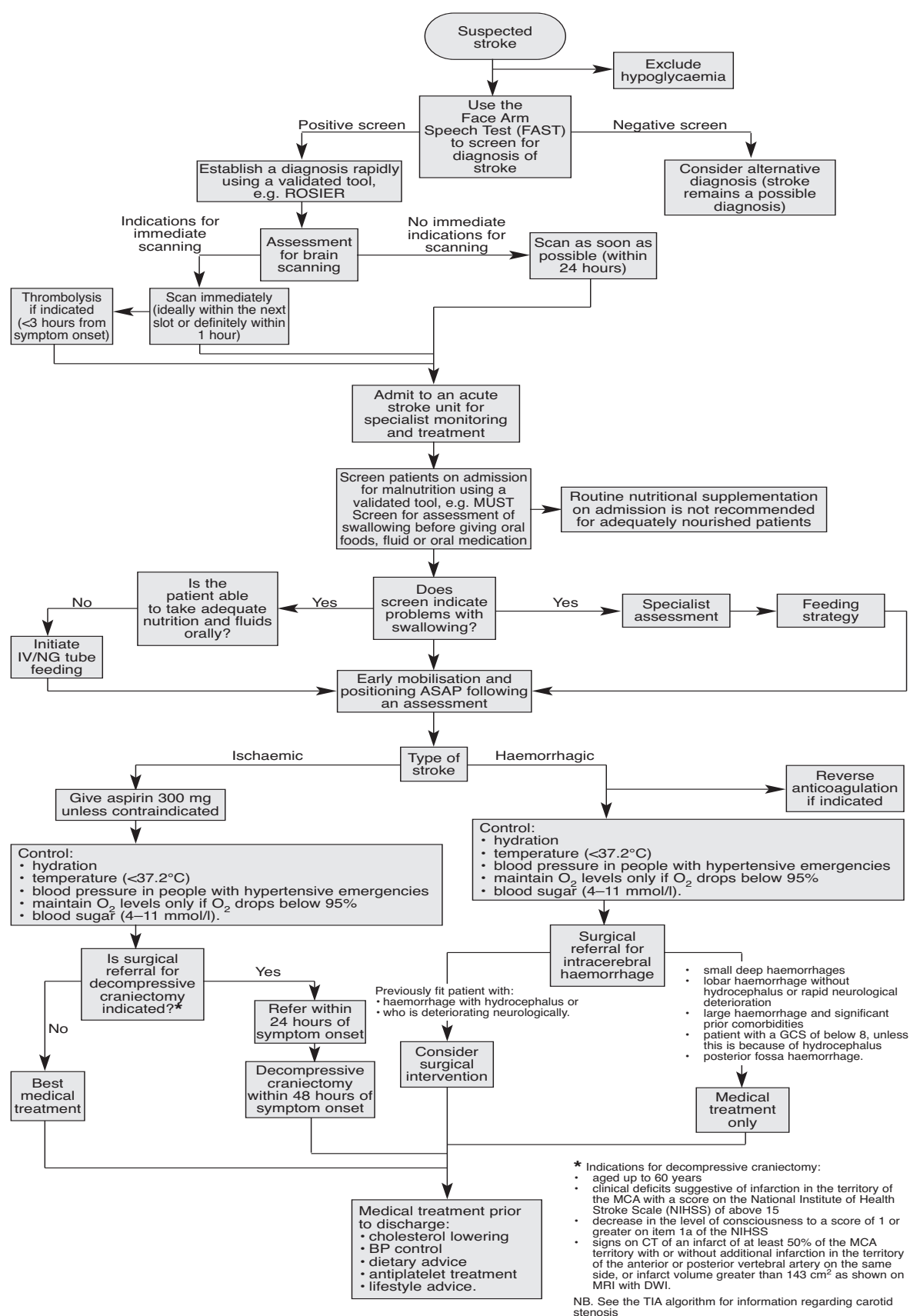


Figure 3.2 Stroke algorithm

GCS, Glasgow Coma Score; IV/NG, intravenous nasogastric; MCA, middle cerebral artery; MUST, Malnutrition Universal Screening Tool; ROSIER, Recognition of Stroke in the Emergency Room

4 Glossary and definitions

ABCD and ABCD²	Prognostic score to identify people at high risk of stroke after a TIA. It is calculated based on: A – age (≥ 60 years, 1 point) B – blood pressure at presentation ($\geq 140/90$ mmHg, 1 point) C – clinical features (unilateral weakness, 2 points or speech disturbance without weakness, 1 point) D – duration of symptoms (≥ 60 minutes, 2 points or 10–59 minutes, 1 point). The calculation of ABCD ² also includes the presence of diabetes (1 point). Total scores range from 0 (low risk) to 7 (high risk).
Alteplase	A drug used for thrombolysis.
Anticoagulants	A group of drugs used to reduce the risk of clots forming by thinning the blood.
Antiphospholipid syndrome	Sometimes called ‘sticky blood syndrome’ because the blood clots too quickly due to antibodies that form against the body’s phospholipids.
Antiplatelets	A group of drugs used to prevent the formation of clots by stopping platelets in the blood sticking together.
Arterial dissection	This is caused as a result of a small tear forming in the tunica intima lining of the arterial wall.
Barthel Index	Scale measuring daily functioning specifically relating to the activities of daily living or mobility. Scores range from 0 to 100.
Bedside swallowing assessment	A term covering a range of techniques.
BMI	Body mass index – an index of body weight corrected for height.
Case series	Report of a number of cases of a given disease, usually covering the course of the disease and the response to treatment. There is no comparison (control) group of patients.
Carotid artery	Main arteries in the neck supplying oxygenated blood to the brain.
Carotid endarterectomy (CEA)	A surgical procedure used to clear the inside of the carotid artery of atheroma.
Carotid stenosis	The narrowing of the carotid arteries in the neck.
Case-control study	Comparative observational study in which the investigator selects individuals who have experienced an event (for example, developed a disease) and others who have not (controls), and then collects data to determine previous exposure to a possible cause.
Cohort study	A retrospective or prospective follow-up study. Groups of individuals to be followed up are defined on the basis of presence or absence of exposure

	to a suspected risk factor or intervention. A cohort study can be comparative, in which case two or more groups are selected on the basis of differences in their exposure to the agent of interest.
Confidence interval (CI)	The probability of the observed data (or data showing a departure more extreme from the null hypothesis) when the null hypothesis is accepted.
Cochrane review	The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases including the Cochrane Database of Systematic Reviews (reviews of randomised controlled trials prepared by the Cochrane Collaboration).
CT	Computed tomography – an X-ray technique used to examine the brain.
Cost-effectiveness analysis	An economic study design in which consequences of different interventions are measured using a single outcome, usually in natural units (for example, life-years gained, deaths avoided, heart attacks avoided, cases detected). Alternative interventions are then compared in terms of cost per unit of effectiveness.
Cost-utility analysis	A form of cost-effectiveness analysis in which the units of effectiveness are quality adjusted life years (QALYs).
Decompressive craniectomy	A surgical procedure for the treatment of raised intracranial pressure. A piece of the skull is removed to allow the swelling brain to expand.
DVT	Deep vein thrombosis.
Diagnostic accuracy	The degree to which a diagnostic (or screening) tool or procedure is able to distinguish between cases and non-cases. See also 'sensitivity', 'specificity', 'negative predictive value' and 'positive predictive value'.
Dysphagia	A difficulty in swallowing.
Endarterectomy	The surgical removal of plaque from a blocked artery to restore blood flow.
FAST	Face Arm Speech Test – used to screen for the diagnosis of stroke or TIA.
FEES	Fibreoptic Endoscopic Evaluation of Swallowing. A flexible nasendoscope is inserted through the nose to the throat to observe swallowing.
FFP	Fresh frozen plasma.
GDG	Guideline Development Group.
GUSS	Gugging Swallowing Screen. A screen designed to identify patients with dysphagia and reduce the risk of aspiration.
Haemorrhage	Bleeding caused by blood escaping into the tissues.
Hydrocephalus	Raised pressure within the skull.
HTA	Health Technology Assessment, funded by the NHS Research and Development Directorate.
Incremental cost	The cost of one alternative less the cost of another.

Incremental cost effectiveness ratio (ICER)	The ratio of the difference in costs between two alternatives to the difference in effectiveness between the same two alternatives.
Independent predictor	A variable whose value predicts the occurrence of an event independent of the values of other variables.
Infarct	An area of cell death due to the result of a deprived blood supply.
INR	International normalised ratio. A measure of the clotting ability of blood, usually following use of anticoagulant drugs. It is calculated as the ratio of the length of time it takes blood to clot over the time it would take the blood of a normal subject to clot.
Intracranial haemorrhage	A bleed in the brain as a result of a ruptured or bleeding blood vessel.
MCA	Middle cerebral artery.
Meta-analysis	A statistical technique for combining (pooling) the results of a number of studies that address the same question and report on the same outcomes to produce a summary result.
Methodological limitations	Features of the design or reporting of a clinical study which are known to be associated with risk of bias or lack of validity. Where a study is reported in this guideline as having significant methodological limitations, a recommendation has not been directly derived from it.
Modified Rankin Scale (mRS)	Six-point scale with 0 for no symptoms and 6 for death measuring the degree of disability or dependence in daily activities.
MRI	Magnetic resonance imaging – a non-invasive imaging technique allowing detailed examination of the brain.
MRI with DWI	Magnetic resonance imaging with diffusion-weighted imaging.
MUST	Malnutrition Universal Screening Tool. A screening tool comprising 5 steps which help identify which adults are malnourished or at risk of malnourishment.
Northern American Symptomatic Carotid Endarterectomy Trial (NASCET)	The NASCET and ECST (see below) methods both indicate the degree of stenosis as a percentage reduction in vessel diameter. The minimum diameter of the arteries caused by stenosis (which is the maximum point of blood constriction) is compared to another diameter that represents the normal diameter of the carotid arteries when the patient is healthy. NASCET includes a measurement taken along a point of the internal carotid artery in a healthy area well beyond an area of the bulb that was caused by stenosis.
European Carotid Surgery Trial (ECST)	The ECST formula includes the estimated normal lumen diameter at the site of the lesion, based on a visual impression of where the normal artery wall was before development of the stenosis.
NCC-CC	The National Collaborating Centre for Chronic Conditions, set up in 2000 to undertake commissions from the NICE to develop clinical guidelines for the NHS.

Negative predictive value (NPV)	The proportion of individuals with a negative test result who do not have the disease.
NG feeding	Nasogastric intubation using a nasogastric tube which is inserted through the nose, past the throat and down into the stomach for the purposes of feeding.
NHS	National Health Service. This guideline is written for the NHS in England and Wales.
NICE	National Institute for Health and Clinical Excellence – a special health authority set up within the NHS to develop appropriate and consistent advice on healthcare technologies, and to commission evidence-based guidelines.
Non-significant (NS)	See ‘statistical significance’.
NSF	National Service Framework – a nationwide initiative designed to improve delivery of care for a related group of conditions.
Null hypothesis	The ‘no difference’ or ‘no association’ hypothesis that can be tested against an alternative hypothesis that postulates a difference or association that is non-zero.
Observational study	Retrospective or prospective study in which the investigator observes the natural course of events with or without control groups, for example cohort studies and case-control studies.
Odds ratio (OR)	A measure of treatment effectiveness. The odds of an event happening in the treatment group, expressed as a proportion of the odds of it happening in the control group. The ‘odds’ is the ratio of non-events to events.
Open-label study	In the context of study design, a study in which the physicians or investigators are not blinded to which patients are allocated to which treatment arm.
PE	Pulmonary embolism – a blood clot in the lungs.
PEG/PEJ	Percutaneous endoscopic gastrostomy/jejunostomy used for feeding. A gastroscope is used to insert a tube through the wall of the abdomen into the stomach.
PCC	Prothrombin complex concentrate.
Positive predictive value (PPV)	The proportion of individuals with a positive test result who actually have the disease.
p values	The probability that an observed difference could have occurred by chance. A p value of less than 0.05 is conventionally considered to be ‘statistically significant’.
Quality of life	Refers to the level of comfort, enjoyment and ability to pursue daily activities.

Quality of life-adjusted year (QALY)	A measure of health outcome which assigns to each period of time a weight, ranging from 0 to 1, corresponding to the health-related quality of life during that period, where a weight of 1 corresponds to optimal health, and a weight of 0 corresponds to a health state judged equivalent to death; these are then aggregated across time periods.
RCT	Randomised controlled trial. A trial in which people are randomly assigned to two (or more) groups: one (the experimental group) receiving the treatment that is being tested, and the other (the comparison or control group) receiving an alternative treatment, a placebo (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. Such trial designs help minimise experimental bias.
Relative risk (RR)	The number of times more likely or less likely an event is to happen in one group compared with another (calculated as the risk of the event in group A, divided by the risk of the event in group B).
ROSIER	Recognition of Stroke in the Emergency Room – used to establish the diagnosis of stroke or TIA.
Sensitivity	The proportion of individuals classified as positive by the gold or reference standard, who are correctly identified by the study test.
Sensitivity analysis	A measure of the extent to which small changes in parameters and variables affect a result calculated from them. In this guideline, sensitivity analysis is used in health economic modelling.
Side effect	An adverse event that occurs because of a therapeutic intervention.
Specialist	A clinician whose practice is limited to a particular branch of medicine or surgery, especially one who is certified by a higher medical educational organisation.
Specificity	The proportion of individuals classified as negative by the gold (or reference) standard, who are correctly identified by the study test.
Stakeholder	Any national organisation, including patient and carers' groups, healthcare professionals and commercial companies with an interest in the guideline under development.
Statistical significance	A result is deemed statistically significant if the probability of the result occurring by chance is less than 1 in 20 ($p < 0.05$).
Stenosis	Abnormal narrowing of a blood vessel.
Stenting	A metal mesh tube is placed in an artery or blood vessel to increase blood flow to an area blocked by stenosis.
Stroke	The damaging or killing of brain cells starved of oxygen as a result of the blood supply to part of the brain being cut off. Types of stroke include Ischaemic stroke caused by blood clots to the brain or haemorrhagic stroke caused by bleeding into/of the brain.

Stroke mimics	A term used to describe other clinical conditions which can mimic a stroke and confound diagnosis. Examples of these include brain tumours, epilepsy or subdural haematosis. Neurologic abnormalities similar to a stroke can also be the result of imbalances of glucose, sodium and calcium.
Systematic review	Research that summarises the evidence on a clearly formulated question according to a pre-defined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and report their findings. It may or may not use statistical meta-analysis.
Technology appraisal	Formal ascertainment and review of the evidence surrounding a health technology, restricted in the current document to appraisals undertaken by NICE.
TIA	Transient ischaemic attack – a stroke which recovers within 24 hours of onset of symptoms.
Thrombosis	A formation of a blood clot.
Thrombolysis	The use of drugs to break up a blood clot. Two examples of thrombolysis drugs are tPA and Alteplase.
tPA	Tissue plasminogen activator – a drug used for thrombolysis.
Venous stroke	The formation of a blood clot in the intracerebral veins and venous sinuses.
Videofluoroscopy	Videofluoroscopy is a test for assessing the integrity of the oral and pharyngeal stages of the swallowing process. It involves videotaping fluoroscopic images as the patient swallows a bolus of barium.
WHO	World Health Organization.

THE GUIDELINE

7 Specialist care in acute stroke

7.2 Brain imaging for the early assessment of people with acute stroke

7.2.1 Clinical introduction

Brain imaging is essential in stroke to exclude haemorrhage and stroke mimics. The 'National clinical guidelines for stroke' (2004)²⁹ recommended scanning within 24 hours of onset of symptoms to confirm diagnosis. Only 42% of patients in the 2006 Sentinel Audit³ achieved this standard. This is unacceptably low. It is recommended that by the time of the 2008 audit, 100% of patients should be scanned within a maximum of 24 hours after admission. Access to brain scanning has been difficult in the past because of a perceived lack of urgency for scanning, problems with access to scanning, or a lack of radiology or radiography support. Even though scanner availability has increased in recent years, systems are clearly not routinely in place to allow immediate or rapid access to scanning throughout the UK. Changes in clinical practice (increased availability, changes in scan request and reporting procedures) will be required to implement the new recommendation.

The clinical question to be addressed is how quickly brain imaging should be performed following an acute stroke.

7.2.2 Clinical methodological introduction

No relevant papers were identified.

7.2.3 Health economic methodological introduction

Two economic evaluations were identified that address early brain imaging following an acute stroke.

An evaluation in the US of the health economics of early scanning assessed usual US practice with practice based on National Institute of Neurological Disorders and Stroke (NINDS) recommendations on time from arrival to hospital to scanning.⁶⁸

A UK study⁶⁹ analysed the HE issues associated with the selection and timing of CT scanning after first ever stroke, including ischaemic and haemorrhagic stroke and stroke mimics, but excluding subarachnoid haemorrhage.

7.2.4 Health economic evidence statements

Both strategies in the Stahl et al.⁶⁸ analysis involved taking stroke care through the following steps:

- symptom onset
- arrival at emergency department
- thorough evaluation by an emergency medicine physician
- CT scanning and interpretation of CT findings
- administration of tPA to eligible patients.

The current practice described was an average time of 25 minutes to emergency medicine physician evaluation and approximately 1.6 hours from onset to administration of tPA.

The NINDS strategy recommended shorter times: 10 minutes to emergency medicine physician evaluation, neurologist assessment within 10 minutes, and 25 minutes to CT scan, allowing tPA administration within an hour.

The NINDS strategy was cost-saving. The results showed an increase of 0.01 QALYs and a saving of \$434 per patient, although no time horizon was stated.

Wardlaw et al. (2004)⁶⁹ compared thirteen different scanning strategies ranging from scanning immediately to scanning within 14 days; and scanning all patients to scanning no patients. Outcomes were quantified using the modified Rankin scale (mRS) as alive and independent, dependent, or dead at 6, 12, and 24 months after stroke. Life-years were estimated up to 5 years after first-ever stroke. Scanning all patients immediately was found to be the dominant strategy (less costly and more effective).

7.2.5 From evidence to recommendations

No clinical trial was identified to answer this question. However, it is clear that there are some patients in whom urgent scanning will result in immediate changes in clinical management. In the absence of reviewing the evidence on which patients should receive urgent scanning, a consensus was reached by the group. It was agreed that patients who are on anticoagulant therapy, have a known bleeding tendency, a depressed level of consciousness, unexplained progressive or fluctuating symptoms, papilloedema, neck stiffness or fever, severe headache at onset and/or indications for thrombolysis or early anticoagulation should receive immediate (next available slot or within 1 hour; within 1 hour out of hours) brain imaging. This consensus was based on both clinical experience and a recommendation made in the Intercollegiate Stroke Working Party guideline (2004 edition).²⁹ The GDG felt that immediate imaging of this patient population would result in changes in clinical management. For the remaining acute stroke patients, the clinical consensus of the group was that scanning should be performed as soon as possible (certainly within 24 hours). The health economic evidence supports the cost effectiveness of immediate scanning, although there may be limitations to the UK study because of changes in radiology staff costings. Immediate scanning, whilst cost effective, maybe difficult to implement because of scanning availability.

7.2.6 RECOMMENDATIONS

- R18 Brain imaging should be performed immediately* for people with acute stroke if any of the following apply:
- indications for thrombolysis or early anticoagulation treatment (see sections 8.1 and 8.2)
 - on anticoagulant treatment
 - a known bleeding tendency
 - a depressed level of consciousness (Glasgow Coma Score (GCS) below 13)
 - unexplained progressive or fluctuating symptoms
 - papilloedema, neck stiffness or fever
 - severe headache at onset of stroke symptoms.
- R19 For all people with acute stroke without indications for immediate brain imaging, scanning should be performed as soon as possible.**

* The GDG felt that 'immediately' was defined as 'ideally the next slot and definitely within 1 hour, whichever is sooner' in line with the National Stroke Strategy.⁴

** The GDG felt that 'as soon as possible' was defined as 'within a maximum of 24 hours after onset of symptoms'.

10 Nutrition and hydration

10.1 Assessment of swallowing function

10.1.1 Clinical introduction

Dysphagia (swallowing difficulty) is common after acute stroke with reported incidence varying in different studies depending on definition but commonly quoted at around 40%.¹⁶¹ Patients who have dysphagia are likely to have poorer outcomes, specifically a higher incidence of death, disability, chest infection and longer length of stay. The majority of patients will recover, however, a proportion will have persistent abnormal swallowing physiology and aspiration at 6 months despite resuming oral intake.¹⁶² Food and fluids may be withdrawn if the patient is felt to be at risk of aspiration of oropharyngeal contents into the trachea. Withdrawal of food or fluid necessitates immediate replacement of fluids to avoid dehydration which can be given intravenously or subcutaneously. However, the concurrent need for oral medications and nutrition often necessitates early placement of a nasogastric (NG) feeding tube for patients with abnormal swallow. Tube feeding may be supplemented or replaced by modified fluids (thickened) or diet (puree or soft diet) as swallowing recovers. Non-oral feeding is not entirely without hazard and it does not prevent the aspiration of saliva. Being placed nil by mouth also has psychological impact. Screening for swallowing difficulty after stroke is a key part of the clinical assessment of an acute stroke patient, and is one of the important process indicators for stroke.³ Swallow safety can be evaluated using an agreed swallow screening tool which can be administered as soon as possible after admission by an appropriately trained healthcare professional. Usually, small volumes of water are administered and a judgment is made about whether the patient coughs, has a change in voice quality, respiratory patterns, pooling of fluid within the oral cavity or leakage from the mouth. This technique does not pick up 'silent' aspiration. Careful clinical observation and monitoring are essential even after a patient has 'passed' a swallow screen. A more detailed swallow assessment will usually include a detailed assessment of behaviour, function and cognition as it relates to swallowing and assessment with a broader range of food and fluids of varying texture and consistency. It may also include instrumental assessment such as fiberoptic endoscopic evaluation of swallowing (FEES). Videofluoroscopy (VF) is the 'gold' standard assessment for the detection of aspiration and its underlying pathophysiology. It is the only technique that can evaluate the efficacy of therapeutic interventions such as postural techniques and dietary modifications. However, it has some limitations for stroke in that patients need to be able to sit up and follow detailed instructions and that specially-trained staff are required. This may not be practical particularly early after stroke. FEES is more accessible in that it can be performed at the bedside, however, it too requires the patient to be compliant and able to follow instructions. It has limitations in its ability to detect aspiration during the swallow and aspiration has to be assumed from post-swallow residue patterns in the pharynx and larynx. It is difficult to determine the efficacy of therapeutic interventions with FEES alone. However it is not associated with radiation exposure and can be repeated whenever necessary.

The clinical question to be addressed is how best to assess the presence and severity of swallowing difficulties after stroke.

10.1.2 Clinical methodological introduction

- ▷ Accuracy of bedside swallowing assessment vs videofluoroscopy vs fibreoptic endoscopic evaluation of swallowing

Five studies were identified that reported the diagnostic accuracy of bedside swallowing assessment (BSA), videofluoroscopy (VF) and fibreoptic endoscopic evaluation of swallowing (FEES).^{163–167} One additional study was on a newly developed screening tool, the Gugging Swallowing Screen (GUSS).¹⁶⁸ Only studies which compared two or more of these investigations were included. However, two of these studies reported on the accuracy of clinical signs and historical information elicited from BSA and medical assessment, rather than comparing the accuracy of BSA directly with VF.^{165,166} Three studies investigated the reliability of BSA.^{164–166} One study was excluded due to methodological limitations.¹⁶⁹ The GUSS was compared with FEES.¹⁶⁸

One study (N=60) looked at the sensitivity and specificity of BSA for predicting aspiration on VF of swallowing.¹⁶⁵ A follow-up of this study reported on a larger sample (N=165) to determine whether individual or a combination of measures on a BSA are associated with aspiration on VF.¹⁶⁶ **Level 1b++**

One study (N=128) looked at the diagnostic accuracy of BSA compared with VF, and interobserver agreement for the clinical and videofluoroscopic diagnosis of swallowing disorders and aspiration admitted to an acute stroke unit.¹⁶³ **Level 1b++**

A small study (N=49) compared BSA with FEES¹⁶⁷ and a further study (N=20) reported the inter- and intra-judge reliability of a BSA.¹⁶⁴
Level 1b++

The GUSS (N=19 and N=30) is a simple stepwise bedside screen that assesses non-fluid and fluid nutrition with the aim of reducing the risk of aspiration during the test to a minimum. The GUSS yielded four categories of severity (0 to 9 severe, 10 to 14 moderate, 15 to 19 mild, and 20 points as no dysphagia). The validity of the GUSS was established by FEES.¹⁶⁸ **Level 1b++**

All of the studies were prospective. The patient populations were broadly comparable, except one study reported on stroke patients who were younger in comparison to the other studies (mean 60 years).¹⁶³ **Level 2+**

One study included patients within 24 hours of stroke onset¹⁶⁷ and one 7 days or less.¹⁶³ The remaining three studies included patients up to 6 weeks post stroke, but the significant majority were examined within 2 weeks.^{164–166} **Level 1b++**

- ▷ Effect on clinical outcomes

Overall, five studies were identified.^{170,171,162,172,173}

Three studies compared patients with and without swallowing impairment using a BSA,^{173,172,170} and two BSA and VF.^{174,162} Follow-up periods ranged from discharge to 5 years. **Level 3+**

10.1.3 Health economic methodological introduction

No papers were identified.

10.1.4 Clinical evidence statements

Accuracy of bedside swallowing assessment vs videofluoroscopy vs fiberoptic endoscopic evaluation of swallowing

▷ Bedside swallowing assessment (BSA) and videofluoroscopy (VF)

One study on patients with acute stroke reported that BSA underestimated the frequency of dysphagia and overestimated the frequency of aspiration when compared with VF. The table below reports the data for any clinical evidence of dysphagia or aspiration.¹⁶³ **Level 1b++**

Two studies reported on the accuracy of a BSA at predicting aspiration on VF;^{165,166} one of these was a follow-up study.¹⁶⁶ Only the results of a global judgement of aspiration from the 3-oz swallow test are reported here (see table 10.1 below), but a regression analysis revealed that the most important predictors of aspiration in addition to this measure were the presence of dysphonia and jaw weakness.¹⁶⁶ **Level 1b++**

Table 10.1 The results of a global judgement of aspiration from the 3-oz swallow test

	Incidence on VF	Sensitivity (95%CI)	Specificity (95%CI)	PPV (95%CI)	NPV (95%CI)
Mann et al. Dysphagia	82/128 (64%)	73% (62 to 82%)	89% (76 to 96%)	92% (83 to 97%)	65% (52 to 77%)
Mann et al. Aspiration	28/128 (22%)	93% (76 to 99%)	63% (53 to 72%)	41% (29 to 54%)	97% (89 to 100%)
McCullough et al. (2001) Aspiration	22/60 (37%)	68%* 77%**	82% 63%	NR NR	NR NR
McCullough et al. (2005) Aspiration	43/165 (26%)	54%***	89%	62%	86%

NR, not reported; *Spontaneous cough on trial swallow; **Overall estimate of aspiration. No other signs of measures met the criteria for sensitivity or specificity (60% or more);¹⁶⁵ ***Global measure of aspiration¹⁶⁶

▷ BSA compared with FEES

A study reported on whether BSA could predict aspiration compared with FEES.

The accuracy of BSA was sensitivity 86%, specificity 30%, PPV 73% and NPV 73%. These results indicate that BSA underestimated aspiration risk when compared with FEES and overestimated aspiration risk in patients who did not exhibit aspiration risk.¹⁶⁷ **Level 1b++**

▷ GUSS compared with FEES

Table 10.2 below shows the sensitivity, specificity, PPVs and NPVs for the GUSS; these were compared with the FEES results in the first sample. The content validity of GUSS indicated that there was a significantly higher aspiration risk with liquids compared with semisolid textures, supporting the subtest sequence used for the test. **Level 1b++**

Table 10.2 The sensitivity, specificity, PPVs and NPVs for the GUSS, these were compared with the FEES results in the first sample

FEES, highest score			
GUSS	Aspiration risk, PAS (5 to 8)	No Aspiration Risk, PAS (1 to 4)	Accuracy
First sample (N=19)			
Aspiration risk (0 to 14)	13		3 PPV 81%
No aspiration risk (15 to 20)	0	3	NPV 100%
	Sensitivity 100%	Specificity 50%	Prevalence 68%
Second sample (N=30)			
Aspiration risk (0 to 14)	14	5	PPV 74%
No aspiration risk (15 to 20)	0	11	NPV 100%
	Sensitivity 100%	Specificity 69%	Prevalence 10%
PAS, Penetration-Aspiration Scale; PPV, positive predictive value; NPV, negative predictive value			

PAS, Penetration-Aspiration Scale; PPV, positive predictive value; NPV, negative predictive value

▷ Inter- and intra-judge reliability

Four studies study reported on the reliability of a BSA.^{163–166} **Level 1b++**

The interobserver agreement in the clinical diagnosis of any evidence of a swallowing disorder and aspiration between two speech pathologists on initial clinical assessment was good. Similar results were reported on VF for any evidence of a swallowing disorder aspiration.¹⁶³ **Level 1b++**

The inter- and intra-judge reliability for a 3-oz swallow test and an overall measure of the presence or absence of aspiration was good.^{165,166} Inter- and intra-judge reliability for relating the presence or absence of aspiration from VF was good.¹⁶⁵ An additional study reported relatively low intra-judge reliability between two speech–language pathologists on the 3-oz swallow and an overall rating of dysphagia but good inter-judge reliability.¹⁶⁴ **Level 1b++**

The interrater reliability of the GUSS performed by two ‘therapists’ with a maximum of 2 hours between the two assessments (first sample N=19) was excellent.¹⁶⁸ **Level 1b++**

▷ Effect on clinical outcomes

Overall, swallowing impairments were associated with increased mortality.^{171,173,170} Two studies reported a significantly higher proportion of patients with aspiration compared to those without an episode of pneumonia or a chest infection.^{171,174} One study reported that risk of developing pneumonia was almost four times higher for young aspirating patients compared with young non-aspirating patients. This reduced to 1.75 times for old aspirating patients compared with old non-aspirating patients. Three studies reported an association with measures of disability and dysphagia.^{171,173,170} **Level 2+**

One study reported that dysphagia was statistically associated with a longer stay in hospital.¹⁷¹ Two studies reported that patients with dysphagia were statistically more likely to be discharged to institutional care¹⁷¹ or were living in a nursing home at a follow-up.¹⁷³ **Level 2++**

In four studies, multivariate analysis reported that dysphagia or swallowing impairment at baseline was an independent predictor of outcome, namely mortality,^{172,170,171} disability,¹⁷⁰ chest infection.¹⁶² **Level 2++**

10.1.5 From evidence to recommendations

Swallow screening is useful in determining early management of feeding after stroke, however, it is not very accurate in isolation. The sensitivity and specificity of screening is such that some patients will be judged unsafe to swallow when there is no evidence on instrumental assessment that they are aspirating, and a smaller number will be assessed as safe to swallow when in fact they are not. The GUSS bedside screen appears to be a better predictor than other clinical assessments of aspiration as detected by FEES, but the numbers in this study are small.

There is good evidence for a link between dysphagia and poor clinical outcome (chest infection, death, disability, discharge destination, length of stay) reinforcing the need for early detection and management.

Although aspiration is clearly associated with worse outcome, there is no evidence that the withdrawal or modification of oral intake prevents chest infection or other adverse outcomes. Research evidence is lacking and would be difficult to obtain, as it would be unethical to give oral food or most fluids to patients who are aspirating although a trial of water in this situation might be possible.

No evidence that directly compared FEES vs VF was reviewed. Each instrumental assessment has its advantages and disadvantages. VF is most widely available but is limited by practical considerations (the need to sit up and to be able to follow instructions) as well as radiation dosage. FEES is more appropriate for patients who are immobile and for whom VF might be impractical. One limitation of FEES is that the moment of swallowing is not visualised, and therefore provides less neurophysiological information than VF. Both techniques may be difficult to interpret especially by inexperienced practitioners and specialist training is necessary. All assessments only reveal the swallow at one moment in time so all patients need careful monitoring and observation and reassessment when necessary. The group were concerned that patients with persistent dysphagia were at risk of malnutrition and that those patients who remained dysphagic after 3 days should have access to detailed instrumental examination.

The patient representatives on the GDG felt that the assessment used should be that which provides the most accurate diagnosis. They also felt that it is important to distinguish whether or not tube feeding is required, and that if tube feeding is required then it is commenced as soon as possible. There was concern from the group that the recommendation was based on relatively little evidence.

10.1.6 RECOMMENDATIONS

- R43 On admission, people with acute stroke should have their swallowing screened by an appropriately trained healthcare professional before being given any oral food, fluid or medication.
- R44 If the admission screen indicates problems with swallowing, the person should have a specialist assessment of swallowing, preferably within 24 hours of admission and not more than 72 hours afterwards.
- R45 People with suspected aspiration on specialist assessment or who require tube feeding or dietary modification for 3 days should be:
 - reassessed and be considered for instrumental examination
 - referred for dietary advice.

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APPENDICES

Appendix A: Clinical question and search strategies

Question ID	Question wording	Study type filters used	Databases and years
PHAR2a	What is the safety and efficacy of aspirin versus other antiplatelet agents for the treatment of patients with acute ischaemic stroke?	Systematic reviews, RCTs	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
PHAR2b	What is the safety and efficacy of antiplatelet agents versus placebo for the treatment of patients with acute ischaemic stroke?	Systematic reviews, RCTs	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
PHAR2c	What is the safety and efficacy of anticoagulants versus placebo for the treatment of patients with acute ischaemic stroke?	Systematic reviews, RCTs	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
PHAR2d	What is the safety and efficacy of antiplatelet agents versus anticoagulants for the treatment of patients with acute ischaemic stroke?	Systematic reviews, RCTs	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
PHAR3	What is the safety and efficacy of anticoagulants versus placebo or treatment as usual for the treatment of patients with acute venous stroke?	Systematic reviews, RCTs	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
PHAR4	What is the safety and efficacy of anticoagulants versus antiplatelet agents for the treatment of patients with acute arterial dissection?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
PHAR5	For patients with acute warfarin associated haemorrhagic stroke, what is the safety and efficacy of i) vitamin K, ii) fresh frozen plasma, iii) prothrombin complex conjugate?	All study types	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
PHAR6	What is the safety and efficacy of anticoagulants versus antiplatelet agents or placebo for patients with acute stroke who may require anticoagulation for comorbidities (e.g. atrial fibrillation, prosthetic heart valve (mitral/aortic), deep vein thrombosis or pulmonary embolism)? What is the safety and efficacy of caval filters for deep vein thrombosis or pulmonary embolism?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
PHAR7	What is the safety and efficacy of anticoagulants versus antiplatelet agents for the treatment of antiphospholipid syndrome in patients with acute ischaemic stroke?	All study types	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
<i>continued</i>			

Question ID	Question wording	Study type filters used	Databases and years
STAT1	a) For patients with acute stroke (including haemorrhagic stroke), what is the safety and efficacy of i) initiating statin therapy, ii) continuing statin therapy? b) Do patients on statins, and who subsequently have a stroke, have reduced mortality and morbidity?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
ADM1	In patients with suspected stroke, what are the benefits of being admitted to specialist care versus a non-specialised unit in terms of recovery time, morbidity and mortality?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
ADM2	Does rapid admission to an acute unit reduce mortality, morbidity and length of hospital stay?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
ASM1	What is the accuracy of a pre-hospital health professional assessment tool/checklist for identifying signs and symptoms of suspected stroke/TIA?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
ASM2	How accurately do scoring systems predict which patients with suspected TIA need to be referred urgently for specialist assessment?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
ASM3	In patients with a suspected minor stroke/TIA, does early versus late expert assessment reduce mortality or morbidity?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
IMAG1	After TIA, which modality (MRI or CT) should be used?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
IMAG2	Which patients with suspected TIA should be referred for urgent brain imaging?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
IMAG3	How quickly should brain imaging be performed following an acute stroke?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
IMAG4	Which patients with suspected stroke/TIA should be referred for urgent carotid imaging?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
NUTRI1	In patients with acute stroke a) what is the accuracy of i) bedside swallowing assessment, ii) videofluoroscopy, iii) fiberoptic endoscopic evaluation of swallowing, and b) how do the results of these assessments affect clinical outcomes?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
<i>continued</i>			

Question ID	Question wording	Study type filters used	Databases and years
NUTRI2	In patients with acute stroke who can take adequate fluids orally, does oral nutritional supplementation reduce mortality and morbidity?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
NUTRI2b	In patients with acute stroke, does fluid therapy reduce mortality and morbidity?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
NUTRI3	In patients with acute stroke who are unable to take adequate fluids orally, does a) early versus late initiation of tube feeding, or b) nasogastric (NG) (including nasal bridges) versus percutaneous endoscopically guided gastrostomy (PEG) (including radiologically inserted gastrostomy tubes (RIGs)) reduce mortality and morbidity?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
PREV1	Does withdrawal or modification of oral intake prevent aspiration pneumonia after stroke?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
HYP1	What is the safety and efficacy of the interventions to control hyperglycaemia versus treatment as usual in patients with acute stroke?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
BP1	What is the safety and efficacy of measures to manipulate blood pressure versus treatment as usual in patients with acute stroke?	Systematic reviews, RCTs	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
OXY1	What is the safety and efficacy of supplemental oxygen therapy versus treatment as usual in patients with acute stroke?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
MOBIL1	Does early mobilisation versus treatment as usual reduce mortality and morbidity in patients with acute stroke?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
MOBIL2	Does placing patients with acute stroke in specific positions reduce mortality and morbidity?	Systematic reviews, RCTs, observational studies	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
REF1	Which patients with primary intracerebral haemorrhage should be referred for surgery?	Systematic reviews, RCTs	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
REF2	Which patients should be referred for decompressive hemicraniectomy?	Systematic reviews, RCTs	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007
REF3	Which patients with symptomatic carotid stenosis should be referred for urgent carotid interventional procedures (carotid endarterectomy and stenting)?	Systematic reviews, RCTs	Medline 1950–2007 Embase 1980–2007 Cinahl 1982–2007 Cochrane 1800–2007

NOTE: The final cut-off date for all searches was 31 October 2007.

Appendix B: Scope of the guideline and referral from the Department of Health

SCOPE

1 Guideline title

Stroke: national clinical guideline for diagnosis and initial management of acute stroke and transient ischaemic attack (TIA).

1.1 Short title

Stroke.

2 Background

- a) The National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Chronic Conditions (NCC-CC) to develop a clinical guideline on acute stroke and TIA for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health (DH). The guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.
- b) The Institute's clinical guidelines will support the implementation of National Service Frameworks (NSFs) in those aspects of care where a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisals published by the Institute after an NSF has been issued will have the effect of updating the Framework.
- c) In parallel to the development of the Institute's acute stroke and TIA clinical guideline, the Royal College of Physicians' Intercollegiate Stroke Working Party will also be updating their guideline to focus on longer-term management and rehabilitation. The developers will work closely with the Intercollegiate Stroke Working Party to ensure continuity and to avoid any overlapping or gaps.
- d) The DH has developed a National Stroke Strategy which was published in 2007. This addresses many of the issues regarding service models, structures and staffing. Where possible, this guideline will work closely with the Stroke Strategy Project Executive.
- e) NICE clinical guidelines support the role of healthcare professionals in providing care in partnership with patients, taking account of their individual needs and preferences, and ensuring that patients (and their carers and families, where appropriate) can make informed decisions about their care and treatment.

3 Clinical need for the guideline

- a) Stroke is the third most common cause of death in the UK, and one of the most important causes of significant adult disability. Each year in the UK, approximately 120,000 people have a first stroke, 30% of whom die within a month. In addition, about 30,000 recurrent strokes occur. The risk of having a stroke before the age of 85 years is one in four for men, and one in five for women.
- b) Stroke is a medical emergency and brain damage can be reduced if stroke is identified early enough.
- c) Stroke and transient ischaemic attack (TIA) are very similar, the only difference being that the symptoms of TIA resolve completely within 24 hours, and stroke symptoms and signs persist. With refined sensitive imaging techniques, it has been clearly shown that many people who have experienced a TIA have sustained significant permanent cerebral damage. TIA is not, therefore, a benign condition. Stroke and TIA management depends upon accurate diagnosis of the underlying pathology and aetiology.
- d) The risk of stroke within the first month after a TIA can be as high as 32% for some patient groups. With effective diagnosis, investigation and treatment, many strokes could be prevented.
- e) The recent National Audit Office report 'Reducing brain damage: faster access to better stroke care' identified major problems with the consistent delivery of high-quality stroke care to all patients in England. Evidence clearly demonstrating that stroke is both a preventable and treatable disease has accumulated rapidly over recent years, but health services have been slow to reflect this.
- f) The National Sentinel Audit in 2006 covering all hospitals in England, Wales and Northern Ireland showed that 78% of hospitals have a neurovascular clinic where only 35% of patients are seen within 7 days. Few hospitals had protocols agreed between the ambulance service and the acute Trust to ensure rapid transfer of patients with stroke to casualty, and access to brain scans remains difficult for some, particularly outside normal working hours.
- g) The cost of stroke care is high, with an estimate in the National Audit Office report of £7 billion per year. Much of this is spent on providing longer-term healthcare, social services and financial support to people with residual disability. More effective acute treatment would save lives and money.

4 The guideline

- a) The guideline development process is described in detail in two publications which are available from the NICE website (see 'Further information'). 'The guideline development process: an overview for stakeholders, the public and the NHS' describes how organisations can become involved in the development of a guideline. 'The guidelines manual' provides advice on the technical aspects of guideline development.
- b) This document is the scope. It defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the DH.
- c) The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.4.1 Groups that will be covered:

- Patients with transient ischaemic attacks (TIAs) or completed strokes, that is, an acute neurological event presumed to be vascular in origin and causing cerebral ischaemia, cerebral infarction or cerebral haemorrhage. This includes:
 - first and recurrent events
 - thrombotic and embolic events
 - primary intracerebral haemorrhage of any cause, including venous thrombosis.

4.4.2 Groups that will not be covered:

- a) Specific issues relating to the general management of underlying conditions will not be considered, but the immediate management to reduce the extent of brain damage will be included.
- b) Subarachnoid haemorrhage.
- c) Children (16 and under).

4.2 Healthcare setting

Primary and secondary NHS healthcare settings, including referral to tertiary care.

- Pre-hospital emergency care settings, including ambulance services.

4.3 Clinical management

The purpose of the guideline is to describe the initial and early management (without specifying a fixed time) aimed at reducing the ischaemic brain damage, and in the case of TIAs, preventing subsequent stroke. This includes:

- a) the rapid recognition of symptoms and diagnosis
- b) initial and early management of stroke and TIA
- c) diagnostic procedures aimed to delineate the nature and location of the pathology
- d) treatment interventions that aim to minimise the pathology
- e) management and maintenance of homeostasis (including fluids, nutrition and oxygen therapy)
- f) initial and early pharmacotherapies including thrombolysis (note that guideline recommendations will normally fall within licensed indications; exceptionally, and only where clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use the 'Summary of product characteristics' to inform their decisions for individual patients).
- g) management of complications where these are likely to affect the area of brain damage (for example, the early use of anticoagulants for venous thromboembolism in acute stroke)
- h) non-pharmacological management, including the role of early mobilisation and positioning

- i) indications for referral for specific interventions (for example, carotid angioplasty, carotid endarterectomy)
- j) identification of people who need continuing or early anticoagulation.

4.4 Status

4.4.1 Scope

This is the final version of the scope. It has been out for consultation, modified in response to comments received and signed off by one of NICE's independent Guidelines Review Panels.

- Related NICE guidance:
 - 'Clopidogrel and modified-release dipyridamole in the prevention of occlusive vascular events'. *NICE technology appraisal guidance* no. 90 (2005). Available from: www.nice.org.uk/TA090
 - 'Ischaemic stroke (acute) – alteplase'. *NICE technology appraisal guidance* no. 122 (2007). Available from: www.nice.org.uk/TA122

4.4.2 Development of guideline recommendations

The development of the guideline recommendations began in November 2006.

5 Further information

Information on the guideline development process is provided in:

- 'The guideline development process: an overview for stakeholders, the public and the NHS'
- 'The guidelines manual'.

These booklets are available as PDF files from the NICE website:

www.nice.org.uk/guidelinesmanual

5.1 Referral from the Department of Health

The Department of Health (DH) asked the Institute:

'To prepare a clinical guideline on the diagnosis and acute management of stroke and transient ischaemic attack, concentrating on initial treatment.'

Appendix C: Model to determine the cost effectiveness of immediate specialist assessment in a stroke unit compared to specialist assessment at a weekly clinic or no specialist assessment

▷ Questions:

ASM 1 What is the accuracy of a pre-hospital health professional assessment tool/checklist for identifying signs and symptoms of suspected stroke/TIA?

ASM 2 How accurately do scoring systems predict which patients with suspected TIA need to be referred urgently to a specialist assessment?

ASM 3 In patients with a suspected minor stroke/TIA, does early versus late expert assessment reduce mortality or morbidity?

ADM 2 Does rapid admission to a hyperacute stroke unit reduce mortality, morbidity and length of hospital stay?

▷ Background:

The risk of developing a stroke after hemispheric TIA can be as high as 30% within the first month, with the greatest risk being within the first 72 hours.* It is considered that effective management of patients with TIA or minor stroke requires identification of individuals at the highest risk and then appropriate early intervention.¹⁹⁵

The ABCD² score aims to identify individuals at high risk of stroke and who may require emergency intervention. The score is based on known clinical predictors of stroke:

- Age
 - <60 years=0
 - ≥60=1
- BP
 - systolic ≤140 mmHg and/or diastolic ≤90 mmHg=0
 - systolic >140 mmHg and/or diastolic >90 mmHg =1
- clinical features
 - unilateral weakness=2
 - speech disturbance without weakness=1
 - other symptom=0

* National Pre-hospital Guidelines Group. 'The recognition and emergency management of suspected stroke and TIA: guidelines supplement'. London: RCP, 2007.

- duration of symptoms
 - <10 mins=0
 - 10 to 59 mins=1
 - ≥60 mins=2
- Presence of diabetes=1

The subgroup of patients with carotid stenosis accounts for the highest proportion of early recurrent strokes. Carotid endarterectomy reduces the risk of stroke in patients with recently symptomatic stenosis. For neurologically stable patients with TIA and minor stroke, benefit from endarterectomy is greatest if performed within 2 weeks of the event and falls rapidly with increasing delay.¹⁹⁶

▷ Aim:

Population: patients with a TIA or minor stroke identified by a general practitioner (GP), in the accident and emergency (A&E) department or by an ambulance crew.

To evaluate the relative cost effectiveness of assessing TIA or minor stroke patients:

- immediately at a specialist stroke unit, or
- within 7 days at a weekly specialist stroke unit clinic, or
- by the patient's GP.

We assess cost effectiveness of each strategy not only for all minor stroke/TIA patients but also broken down by ABCD² score group.

▷ General methods:

The cost effectiveness of the different strategies was estimated using a simple decision analysis.

The NICE reference case was followed:

- Costs are measured from the perspective of the NHS and personal social services (PSS) perspective including the long-term care costs for stroke patients.
- Health outcome is measured from the perspective of the patient (not carer or family members).
- Health outcome is measured in terms of quality adjusted life years (QALYs), where one QALY is equal to one year of full health (or two years at half health etc.).
- A 3.5% discount rate was applied to both costs and effects. The discount rate reflects that people prefer to receive a benefit earlier and to incur a cost later, even in a world with zero inflation and no bank interest.¹⁹⁷

Where appropriate, we have used data and assumptions from the HTA report on the effectiveness and cost effectiveness of carotid artery assessment by Wardlaw et al.²⁷

▷ The model:

A decision tree is used to represent the model (see Figures C1, C2 and C3).

The decision model seeks to capture the following effects:

- Patients seen at a specialist clinic are more likely to be given appropriate medication and therefore will have strokes averted (in the first 90 days).

- Patients seen immediately will receive this medication sooner and therefore will have more strokes averted than those seen at weekly clinics.
- Patients seen at a specialist clinic will receive carotid artery ultrasound imaging (and subsequent carotid endarterectomy if stenosis $\geq 50\%$), which will reduce the incidence of stroke (over 5 years). Whereas patients followed up by their GP do not receive imaging or surgery.
- Patients seen at a specialist clinic immediately will be more likely to receive endarterectomy within 2 weeks, when it is more effective, compared with patients who are seen at a weekly clinic. Furthermore, more patients will have a stroke before they have surgery.
- Carotid artery imaging is not perfectly accurate.
- Endarterectomy confers a risk of death in the short term.
- Specialist clinics are more costly than GP assessment. Costs of drugs over the lifetime will be increased. But these costs will be at least partly offset by cost savings from reduced stroke treatment over the lifetime.

The effect of different treatment strategies is first modelled in terms of effect on stroke incidence. Patients are then divided into whether or not the stroke was fatal and whether or not it left them dependent. Long-term quality adjusted life expectancy is estimated for each group and for the patients who do not experience a stroke. Similarly, lifetime healthcare costs are measured for each stroke outcome.

Patients in lower ABCD² score groups have a lower baseline risk of stroke and therefore have fewer strokes averted compared with patients in higher ABCD² score groups.

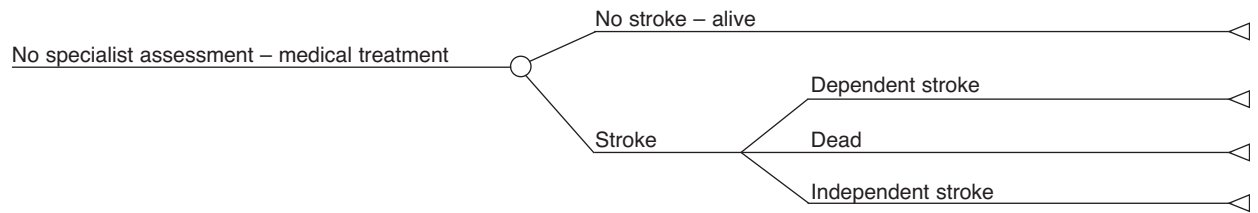


Figure C1: Decision tree arm for no specialist assessment

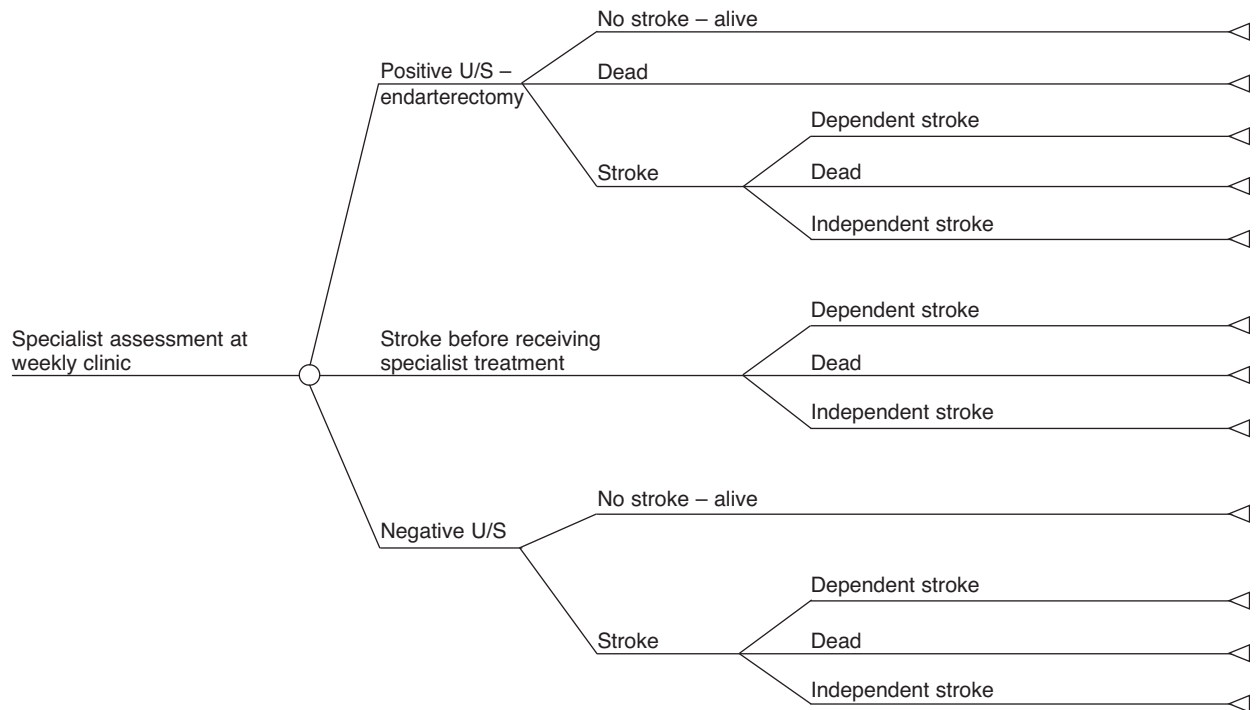


Figure C2: Decision tree arm for specialist assessment at a weekly clinic (the positive and negative scan results include true and false results)

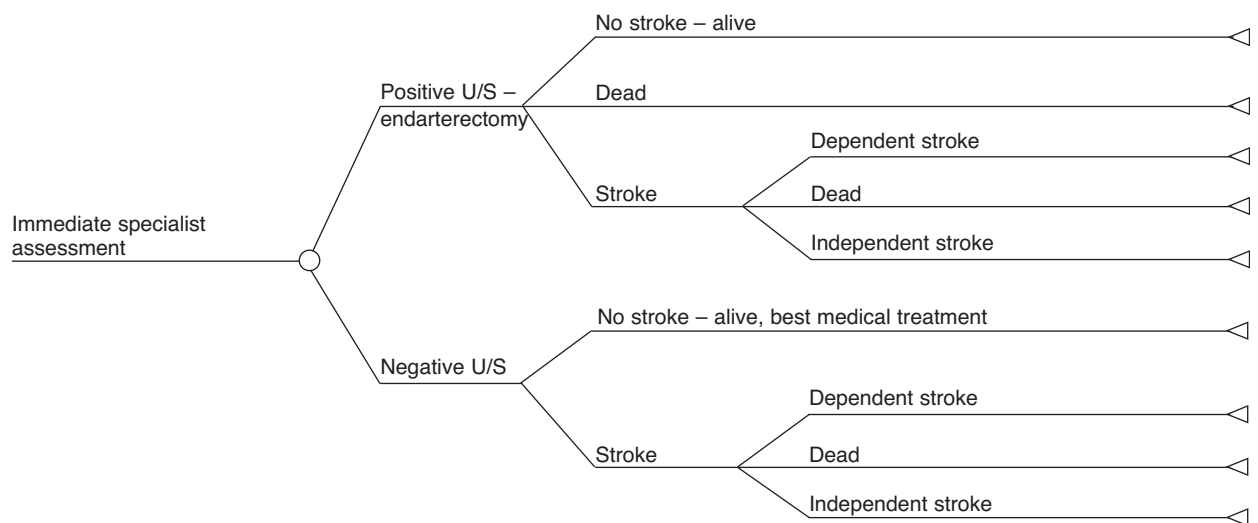


Figure C3: Decision tree arm for immediate specialist assessment (the positive and negative scan results include true and false results)

Appendix D: GDG members' declaration of interests

Name and date of signature on declaration of interests form	Personal pecuniary interest	Personal family interest	Non-personal pecuniary interest	Personal non-pecuniary interest
ALLISON Rhoda	None	None	None	None
BARKER Julie	None	Husband works for Xansa-SBS who contract out financial functions of some NHS Trusts	None	None
BOWMASTER Alan	None	None	None	None
DAY Diana	None	None	None	None
FORD Gary	Honoraria from Boehringer Ingelheim, Astra Zeneca for educational activities and advisory boards.	Family ownership of GlaxoSmithKline shares	Research grants to institution or/and unrestricted educational grants from Boehringer Ingelheim, Lundbeck, and Astra Zeneca	Director UK Stroke Research Network
HATTON Steve	None	None	Company director at BPA/College of Paramedics	None
KORNER Joseph (Form signed on 15 November 2007)	None	None	None	None
LAMONT Peter	None	None	None	None
McMANUS Richard	None	None	In the last 5 years, Dr McManus has participated in research funded by: Pfizer, Sanofi – Aventis and A. Menarini Pharma and received funding to attend a research conference from MSD.	None
MORSE Mariane	None	None	None	None
POTTER John	Received lecture and research funding from various pharma companies more directly related to this GDG	None	None	None
RUDD Anthony	None	None	None	None
TYRRELL Pippa	None	None	None	None