

Relationship between NICE on TLOC and ESC on syncope

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In homage to **Richard Sutton**

Pioneer in:

- Physiological pacing
- Carotid sinus syncope
- Vasovagal syncope, tilt table testing
- Vasovagal syncope, pacemaker therapy



English leadership in these fields for more than 20 years

The Lancet and Richard Sutton (part I)

Sutton R, Chatterjee K. Heart-block in myocardial infarction. **Lancet**. 1968 Jan 13;1(7533):94.

Chatterjee K, Sutton R, Davies JG. Low intracardiac potentials in myocardial infarction as a cause of failure of inhibition of demand pacemakers. **Lancet**. 1968 Mar 9;1(7541):511.

Chatterjee K, Sutton R, Davies JG Inhibition of demand pacemakers. **Lancet**. 1968 Apr 13;1(7546):818. **Lancet**. 1968 Sep 21;2(7569):645-8.

Sutton R, Chatterjee K, Leatham A. Heart-block following acute myocardial infarction. Treatment with demand and fixed-rate pacemakers. **Lancet**. 1968 Sep 21;2(7569):645-8

Carotid sinus syncope treated by pacing

Analysis of persistent symptoms and role of atrioventricular sequential pacing

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SUMMARY Seventy patients have been paced for carotid sinus syndrome over four years. Twelve patients had persistent symptoms despite adequate ventricular pacing. Patients with persistent symptoms were found to have a significant vasodepressor response, a significant hypotensive response to ventricular pacing (pacemaker effect), and a severe hypotensive response to carotid sinus massage with introduction of ventricular pacing, which reproduced symptoms in all patients.

A group of 14 asymptomatic paced carotid sinus patients was found to have a significantly lower vasodepressor response, pacemaker effect, and combined vasodepressor response plus pacemaker effect than the group with persistent symptoms.

Atrioventricular sequential pacing was shown to eliminate the hypotensive effect of ventricular pacing and is considered to be the treatment of choice for patients with carotid sinus syndrome who have both cardioinhibitory and significant vasodepressor responses.

Pacemaker syndrome

Permanent cardiac pacing is the treatment for symptomatic bradycardia due to ventricular conduction defects, sinoatrial disease, and the carotid sinus syndrome. About 114 new pacemakers for every million people are implanted each year in Britain, and the rate is increasing. A stable rate of 300-400 per million may be reached nationally over the next five years and has already been approached by a few British centres and reached in several European countries.¹ It is increasingly important, therefore, that doctors appreciate that apparently satisfactory function of an implanted ventricular pacemaker may be associated with a whole range of cardiac symptoms,

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Editorial Review

Carotid sinus syncope

Christopher A. Morley¹ and Richard Sutton

Westminster Hospital, London, England

(Key words: carotid sinus syncope; pathophysiology of carotid sinus syncope; vasodepressor response)

The Lancet and Richard Sutton (part II)

Kenny RA, Ingram A, Bayliss J, Sutton R. Head-up tilt: a useful test for investigating unexplained syncope. **Lancet.** 1986 Jun 14;1(8494):1352-5.

Head-up tilt, a recognised stimulus to vasovagal syncope, was used to investigate syncope that remained unexplained despite full clinical and electrophysiological assessment in fifteen patients, **mean age 65 +/- 10 years**, who had had 15 +/- 19 episodes of unexplained syncope over periods of a week to 26 years. After overnight fast systolic blood pressure and heart rate were continuously monitored during 40 degrees head-up tilt for 60 min. Ten control subjects with no history of syncope were studied similarly. In ten patients (67%) and one control vasovagal syncope developed after 29 +/- 19 min (p less than 0.001). In symptomatic patients systolic blood pressure fell from 150 +/- 32 to 56 +/- 9 mm Hg (p less than 0.001) and heart rate from 62 +/- 9 to 38 +/- 12 beats per min (p less than 0.01). In each case symptoms during the test reproduced those previously experienced. **No clinical findings predicted development of syncope during tilt.** Baseline systolic blood pressure and heart rate did not differ significantly between patients and controls. **Pacemakers were implanted in seven patients** who have remained symptom-free since implant (follow-up 10 +/- 3 mo).

Fitzpatrick A, Sutton R. Tilting towards a diagnosis in recurrent unexplained syncope. **Lancet.** 1989 Mar 25;1(8639):658-60.

71 patients with recurrent syncope which remained unexplained after standard clinical and electrophysiological investigation underwent **60 degree head-up tilt**. This procedure reproduced symptoms with vasovagal syncope in 53 (74%), 40 of whom had bradycardia, some with prolonged asystole, during syncope. The other 13 patients had predominant vasodepression with hypotension. Mean time to syncope after tilt was 25 min. Patients with conduction tissue disease and age-matched control subjects had a 15% and 7% incidence of tilt syncope, respectively. Temporary dual-chamber pacing aborted syncope in 85% of subjects, and improved cardiac index and systemic blood pressure during tilt. **Long-term results indicate that selected patients may benefit from permanent dual-chamber pacing.** Head-up tilt is useful in the investigation of unexplained syncope because symptoms are reproduced in front of a medical witness.

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"Tilt-Table Test"[Mesh]

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Toward the VASIS group



Proposed Classification for Tilt Induced Vasovagal Syncope

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Summary

A classification of vasovagal syncope is proposed on the basis of recordings of arterial pressure and heart rate during tilt-induced syncope. These include mixed, two subdivisions of cardioinhibition and vasodepression categories. There are exceptions to these fundamental groups which are chronotropic incompetence and excessive heart rate rise during tilt and positive carotid sinus massage. They are chosen to illustrate overlap between tilt positive patients who have other conditions such as sinus node disease or carotid sinus syndrome. It is hoped to provide a more pathophysiological and less arbitrary basis for future therapeutic studies and to stimulate debate.

Key words: tilt-testing, vasovagal syncope, unexplained syncope, pacemaker treatment

Dual-Chamber Pacing in the Treatment of Neurally Mediated Tilt-Positive Cardioinhibitory Syncope

Pacemaker Versus No Therapy: A Multicenter Randomized Study

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Paolo Alboni, MD; Paolo Giani, MD; Angel Moya, MD;
for the Vasovagal Syncope International Study (VASIS) Investigators

Background—This study was performed to compare implantation of a DDI pacemaker with rate hysteresis with no implant in respect to syncopal recurrences in patients with severe cardioinhibitory tilt-positive neurally mediated syncope.

Methods and Results—Forty-two patients from 18 European centers were randomized to receive a DDI pacemaker programmed to 80 bpm with hysteresis of 45 bpm (19 patients) or no pacemaker (23 patients). Inclusion criteria were ≥ 3 syncopes over the last 2 years and a positive cardioinhibitory (Vasovagal Syncope International Study types 2A and 2B) response to tilt testing. The median number of previous syncopal episodes was 6; asystolic response to tilt testing was present in 36 patients (86%) (mean asystole, 13.9 ± 10.2 seconds). All patients were followed up for a minimum of 1.0 years and a maximum of 6.7 years (mean, 3.7 ± 2.2). One patient (5%) in the pacemaker arm experienced recurrence of syncope compared with 14 patients (61%) in the no-pacemaker arm ($P=0.0006$). In the no-pacemaker arm, the median time to first syncopal recurrence was 5 months, with a rate of 0.44 per year. On repeated tilt testing performed within 15 days after enrollment, positive responses were observed in 59% of patients with pacemakers and in 61% of patients without pacemakers ($P=NS$).

Conclusions—In a limited, select group of patients with tilt-positive cardioinhibitory syncope, DDI pacing with hysteresis reduced the likelihood of syncope. The benefit of the therapy was maintained over the long term. Even in untreated patients, the syncopal recurrence burden was low. A negative result of tilt testing was not a useful means to evaluate therapy efficacy. (Circulation. 2000;102:294-299.)



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EUROPEAN
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CARDIOLOGY®

STUDY DESIGN

International study on syncope of uncertain aetiology 3 (ISSUE 3): pacemaker therapy for patients with asystolic neurally-mediated syncope: rationale and study design

The Steering Committee of the ISSUE 3 Study

Received 24 August 2006; accepted after revision 30 September 2006



Guidelines for the diagnosis and management of syncope (version 2009)

10 The Task Force for the Diagnosis and Management of Syncope of the European Society of Cardiology (ESC)

Authors/Task Force Members, Angel Moya (Chairperson) (Spain)*, Richard Sutton (Co-Chairperson) (UK)*, Fabrizio Ammirati (Italy), Jean-Jacques Blanc (France), Michele Brignole¹ (Italy), Johannes B. Dahm (Germany), Jean-Claude Deharo (France), Jacek Gajek (Poland), Knut Gjesdal² (Norway), Andrew Krahn³ (Canada), Martial Massin (Belgium), Mauro Pepi (Italy), Thomas Pezawas (Austria), Ricardo Ruiz Granell (Spain), Francois Sarasin⁴ (Switzerland), Andrea Ungar⁷ (Italy), J. Gert van Dijk⁹ (The Netherlands), Edmond P. Walma (The Netherlands), Wouter Wieling^{6,12} (The Netherlands)

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Available on www.escardio.org/guidelines



*National Institute for
Health and Clinical Excellence*

Issue date: August 2010

**Transient loss of
consciousness
(‘blackouts’) management
in adults and young people**



*National Institute for
Health and Clinical Excellence*

Issue date: August 2010

Transient loss of consciousness (‘blackouts’) management in adults and young people



*National Institute for
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Quick reference guide

Issue date: August 2010

Transient loss of consciousness

Transient loss of consciousness (‘blackouts’) management
in adults and young people



*National Institute for
Health and Clinical Excellence*

Understanding NICE guidance

Information for people who use NHS services

Transient loss of consciousness (‘blackouts’) management in adults and young people

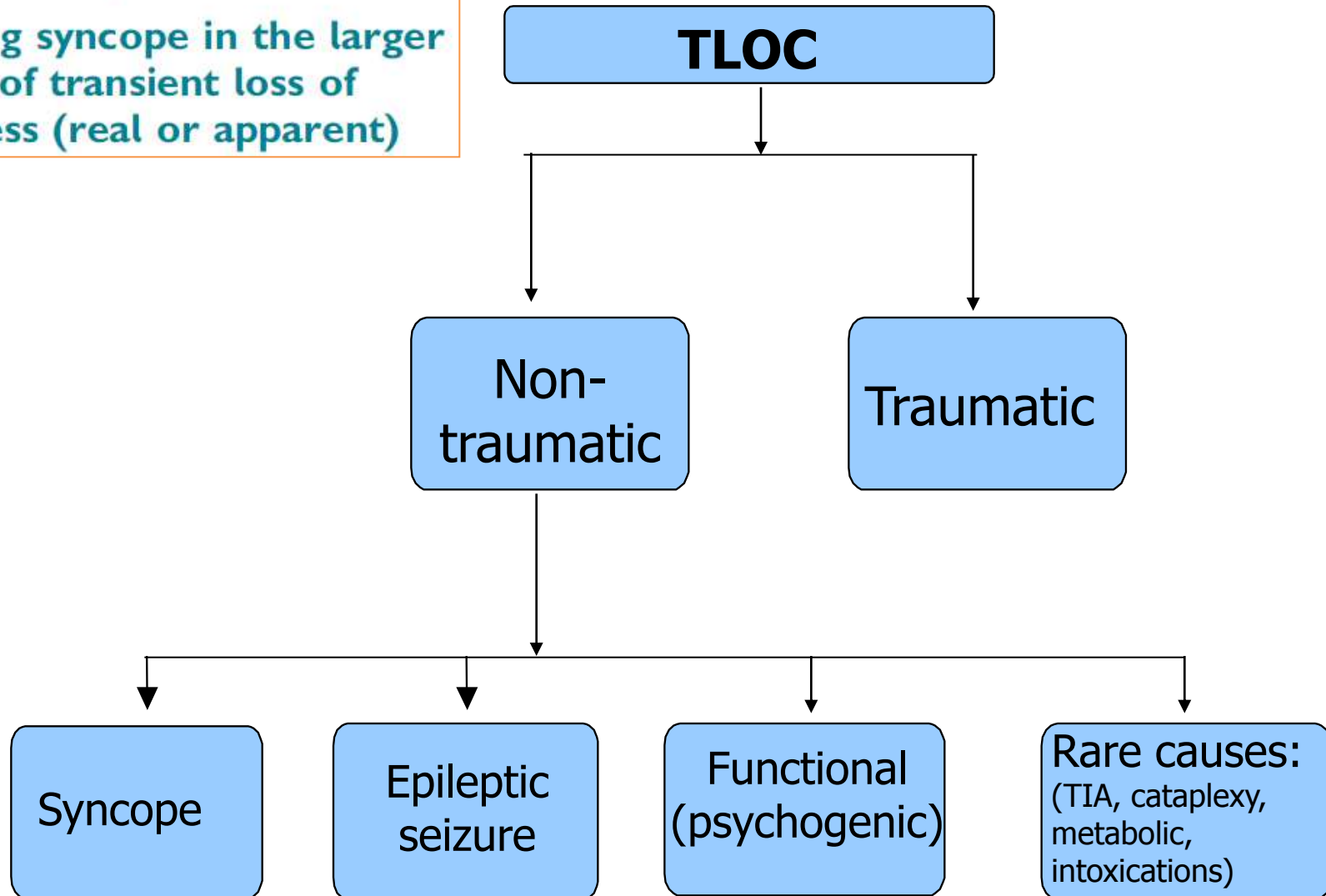
Full Guideline

ESC versus NICE

ESC guidelines	NICE guidelines
Guidelines for the diagnosis and management of syncope (version 2009)	Transient loss of consciousness ('blackouts') management in adults and young people
T-LOC of suspected syncopal nature	Assessment, diagnosis and specialist referral of adults and young who have experienced a blackout (TLoC)

1.2 Classification and pathophysiology

1.2.1 Placing syncope in the larger framework of transient loss of consciousness (real or apparent)



Conditions incorrectly diagnosed as syncope

Disorders with partial or complete LOC but without global cerebral hypoperfusion

- Epilepsy
- Metabolic disorders including hypoglycaemia, hypoxia, hyperventilation with hypocapnia
- Intoxication
- Vertebro-basilar TIA

Disorders without impairment of consciousness

- Cataplexy
- Drop attacks
- Falls
- Functional (psychogenic pseudo-syncope)
- TIA of carotid origin

3.5.3 Decision rules for a diagnosis of psychogenic pseudosyncope versus other forms of syncope

There was low-quality evidence from one study of the ESC guidelines for the diagnosis of psychogenic pseudosyncope. The paper was unclear on the definition of psychogenic pseudosyncope and it was assumed that the guidance in the ESC guidelines should be used^{33,145}.

Factors contributing to a diagnosis of psychogenic pseudosyncope included a high frequency of attacks (many in a day); lack of a recognisable trigger; eyes usually closed; long period of lying on the floor, young age.

The sensitivity was 86% with much uncertainty around the estimate and the specificity was 100% with very little uncertainty.

Recommendations versus Guidance

Recommendations (ESC guidelines)	Guidance (NICE guidelines)
Do according to probability and level of evidence	Follow the algorithm
“The level of evidence and the strength of recommendation of particular treatment options are weighed and graded according to predefined scales”	“This guideline aims to define the appropriate pathways for the initial assessment, diagnosis and specialist referral of people who have had TLoC The approach of the Guideline Development Group was to produce a guideline in the form of an Algorithm ”

ESC guidelines

Table I Classes of recommendations

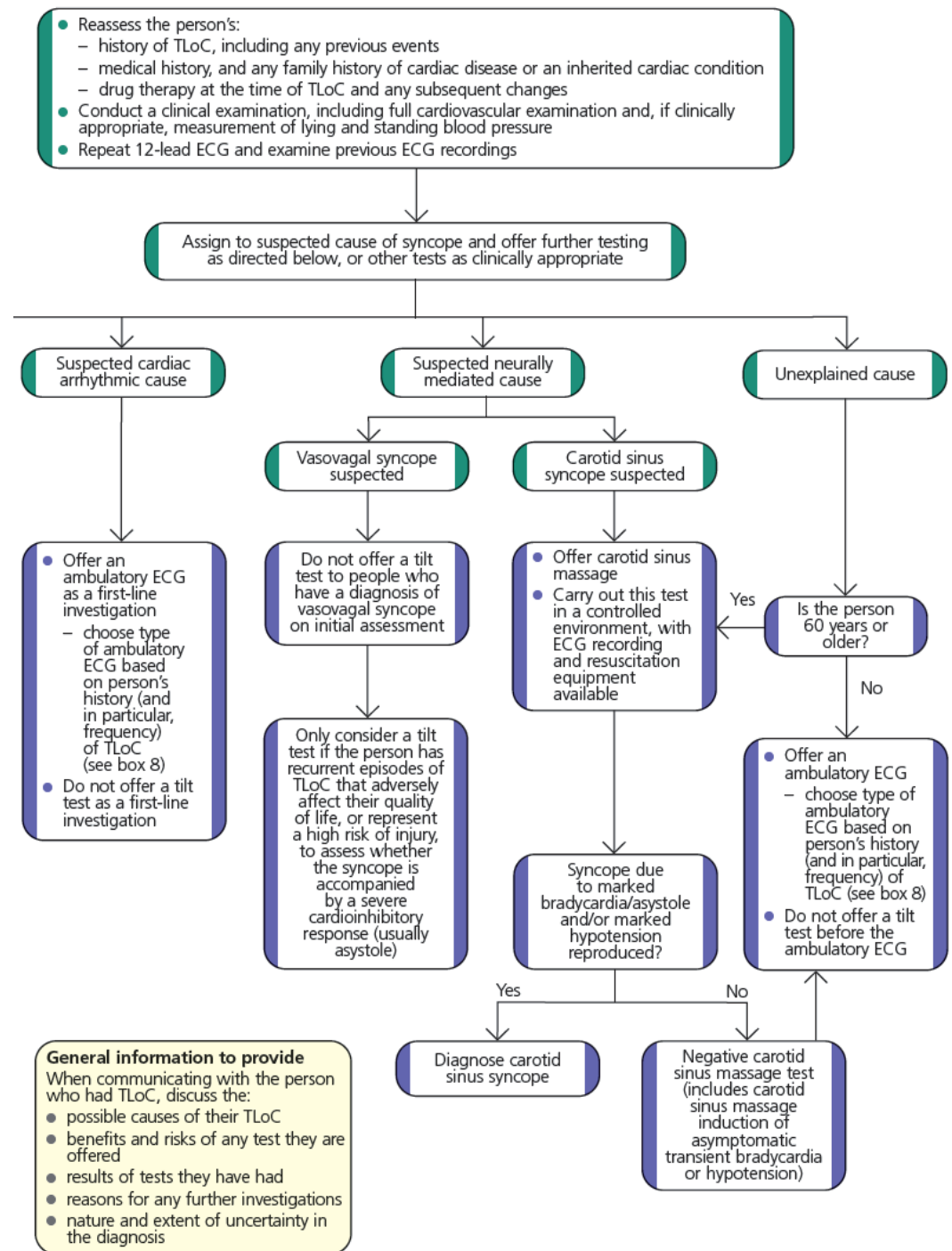
Classes of Recommendations	Definition
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.
<i>Class IIa</i>	Weight of evidence/opinion is in favour of usefulness/efficacy.
<i>Class IIb</i>	Usefulness/efficacy is less well established by evidence/opinion.
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.

ESC guidelines

Table 2 Levels of evidence

Level of Evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of Evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of Evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

Nice algorithm



ESC versus NICE guidelines

ESC guidelines

Made mostly by syncope experts (multidisciplinary but predominantly cardiologists)
(29 authors + 31 reviewers)

“Experts in the field are selected [by ESC committee for guidelines] and undertake a comprehensive review of the published evidence”

Authors listed in the front page

In absence of strong evidence, recommendations from expert opinion

NICE guidelines

Made mostly by syncope non-experts (multidisciplinary):
(11 authors + 4 reviewers)

“ a group of healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff”

Applications for GDG members were invited from the public and relevant stakeholder organisations Two patient representatives and nine healthcare professionals were invited to join the GDG.

Authors listed in appendix A

Recommendations from systematic reviews

Total 105 recommendations

Class I	50%		Evidence A	3%
Class II	37%		Evidence B	45%
Class III	12%		Evidence C	52%

ESC versus NICE guidelines

ESC guidelines	NICE guidelines
Risk-efficacy	Cost-benefit (cost-effectiveness)
“A critical evaluation of diagnostic and therapeutic procedures is performed, including assessment of the risk/benefit ratio ”	“.....receive the correct diagnosis quickly, efficiently and cost effectively , leading to a suitable management plan”

Something I don't like about NICE....

- Tilt testing down

“Do not offer a tilt test to people who have a diagnosis of vasovagal syncope on initial assessment”

“For all people with unexplained syncopeDo not offer a tilt test before the ambulatory ECG”

- Too much emphasis on syncope during exercise

- Wrong attitude to pacing for VVS

What I like more about NICE....

Key priorities for implementation

(Recommendations from the guideline that will have the maximum impact on patient care)

Initial assessment

Further assessment and referral

Specialist cardiovascular assessment and diagnosis

What I like more about NICE....

Full version

Identifying the evidence

Grading evidence

Data synthesis

Cost-effectiveness analysis

Attention to appropriateness

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What I like more about NICE....

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Patient-centred care

Questions you might like to ask your healthcare team

- Why did I have a blackout?
- Will a blackout cause any long-term problems?
- What should I do now?
- Can I drive?
- Can I continue to work?

Urgent referral

In certain circumstances you should be referred within 24 hours for a specialist cardiovascular assessment (this is an assessment of the heart and blood vessels; further information about this assessment can be found on page 11). This applies when:

- your ECG shows that something may be wrong with your heart
- you have heart failure (reduced efficiency of the heart's pumping), or have had heart failure in the past
- you have a heart murmur (an extra or unusual sound during a heartbeat)
- there is an inherited heart condition in your family, or any family members have died from heart problems at a young age (under 40)
- your blackout happened during exercise, **or**
- you have new or unexplained breathlessness.

Patient-centred care

What you can do to help if you have had a blackout

(you may be able to get checklists to help you with this from the organisations listed on page 15)

- Describe clearly what happened when you lost consciousness.
- Give as much detail as you can about your blackout, for example, how long you were unconscious for, and how you felt before and afterwards.
- If you can, provide contact details for anybody who was there when you had your blackout so that they can also describe what happened.
- Give as much information as you can about:
 - any previous blackouts
 - your medical history
 - any medicines you are taking and why
 - any family history of heart problems.
- Follow the advice you are given by healthcare professionals, for example, on what you should do if you have another blackout, how active you should be, and whether or not you can drive.
- If you haven't yet had a diagnosis, or if your healthcare professional asks you to, try to get someone to record any future blackouts that you have (for example, by getting a video recording of your blackout using a camera in a mobile phone or a detailed description of your blackout from a witness).
- If you have fainted or been diagnosed with 'situational syncope' (see pages 7 and 8), keep a record of your symptoms, when they occur and what you were doing at the time so that you can understand what causes you to faint. You may be able to avoid trigger events.

Dedicated to Richard, my mentor