

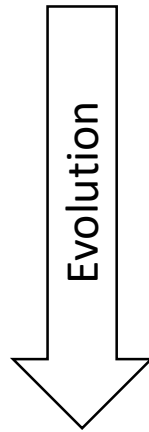
Recommandations : comment faire ?

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Méthodes pour établir des recommandations

Preuves par l'EBM

- RCT
- Méta-analyses (Cochrane)



Etablissement de recommandations

- Comité d'experts (UHMS)
- Conférences de consensus (SRLF, ECHM)
- Evaluation institutionnelle par les établissements de santé publique (HAS, NICE)
 - Groupe littérature
 - Groupe lecteurs (professionnels, patients)



European Committee for Hyperbaric Medicine (ECHM)

Fondé en 1990

2 objectifs :

- Développer la connaissance de la Médecine Hyperbare parmi la communauté médicale et sa reconnaissance par les institutions européennes et nationales
- Encourager les bonnes pratiques clinique et la qualité des soins délivré en Médecine hyperbare



ECHM : fonctionnement

ECHM Board of Representatives

- Bureau des représentants
- Composé de tous les présidents actuels des sociétés scientifiques européennes de plongée et de médecine hyperbare
- Organe directeur de l'ECHM

ECHM Executive Board

- Formé de 9 à 12 membres en plus des membres fondateurs
- Pas plus de 2 membres d'un même pays, au moins 50% des pays européens représentés
- Elu par le Board of Representatives
- Chargé des affaires courantes

ECHM : fonctionnement

L'ECHM fonctionne par le biais de sous-comités permanentes et ponctuelles

Les sous-commissions permanentes sont:

- ***Workshop and Consensus Conference Bureau***

Propose :

Sujets

Sélection du comité scientifique et des membres du jury

Lieu et date

Organisateur local

Publication

Ces propositions sont ensuite votées par le **BR**
Membres actuels: A. Marroni, D. Mathieu et J. Kot

- ***Finance Bureau***

- ***Research Sub Committee***

- ***Education and Training sub Committee***



Une méthodologie qui s'est enrichie

- En 1994, un jury a défini les recommandations à partir des rapports d'experts et des discussions avec l'auditoire de la conférence.
- En 2004, la présentation des recommandations a été enrichie par le classement des recommandations tant par le niveau de preuve appuyant la recommandation que par son importance pour la pratique.
- En 2016, il a été proposé des recommandations non seulement en fonction de leur importance et du niveau de preuve appuyant ces recommandations, mais aussi en fonction de la confiance du public dans ces recommandations.

La nouvelle méthodologie

L'ECHM a demandé à un panel d'experts reconnus dans chaque domaine

- de fournir des rapports basés sur une étude exhaustive de la littérature disponible
- et de présenter une synthèse des preuves et une proposition de recommandations

TOPICS AND EXPERTS

Mechanisms of action of HBO2

C Muth / P Radermacher – (Germany)

Indications :

- | | |
|---|--------------------------------|
| • Dysbaric illness | A Marroni (Italy) |
| • Gas embolism | R Van Hulst (the Netherlands) |
| • Carbon monoxide poisoning | D Mathieu (France) |
| • Anaerobic soft tissue infections | D Mathieu (France) |
| • Crush injury/open fracture | I Millar (Australia) |
| • Delayed wound healing | P Longobardi (Italy) |
| • Diabetic foot lesion | M Londahl (Sweden) |
| • Radionecrosis | V Souday (France) |
| • Sudden deafness | M Cimsit (Turkey) |
| • Compromised skin graft and flap | J Kot (Poland) |
| • Persistent osteomyelitis | K Hasmler (Germany) |
| • Burns | P Germonpré (Belgium) |
| • Anoxic encephalopathy | E Parmentier (France) |
| • Stroke and other neurologic conditions | S Efrati (Israel) |
| • Femoral head necrosis | G Vezzani (Italy) |
| • Acute ophthalmological disorders | J Desola (Spain) |
| • Other presently non accepted conditions | R Pignel (Switzerland) |

Practice of Hyperbaric Oxygen Therapy:

- | | |
|---|--|
| • Organisation, operation and safety : the European Code of Good Practice | J Kot (Poland) |
| • Medical education and training | I Cali-Corleo (Malta) |
| | J Kot (Poland) |
| | J Desola (Spain) |
| | J Wendling (Switzerland) |
| • Non medical education and training | EBAss (European Baromedical Association) |
| • Contra indications to HBO | B Ratzenhoffer (Austria) |

Research

P Germonpré/C Balestra (Belgium)



La nouvelle méthodologie

L'ECHM a demandé à un panel d'experts reconnus dans chaque domaine de fournir des rapports basés sur une étude exhaustive de la littérature disponible et de présenter une synthèse des preuves et une proposition de recommandations

2 nouvelles étapes :

- Tous les rapports ont été distribués aux experts et chacun a été invité à évaluer l'importance clinique et le niveau de preuve de chaque recommandation proposée (méthode Delphi)
- Pendant la conférence, des rapports et les avis d'experts ont été présentés et discutés. Le public a voté sur la recommandation proposée et l'accord de l'auditoire a été mesuré et rapporté.



Méthode Delphi

- Rapport de chaque expert
- Attendu fin octobre 2015

Structure of a Report (Indications)

- Title
Author(s)
Institution
- Background :
 - incidence
 - clinical presentation (summary)
 - standard management (summary) and outcome (HBO excluded)
- Rationale for HBO use
 - pathophysiology
 - animal study (if any)
- Evidence – Based review of HBO use
 - Low level evidence :
Non controlled clinical studies (case studies, ...)
Non randomized controlled studies (historical control, matched control, ...)
 - Moderate or high level evidence :
Randomized Controlled trial (A et B)
- Patients selection for HBO
- Current protocol
- Cost impact
- References
- Conclusion : Recommendation
 - "we recommend" ...
 - "we suggest" ...
 - "it could be reasonable" ...

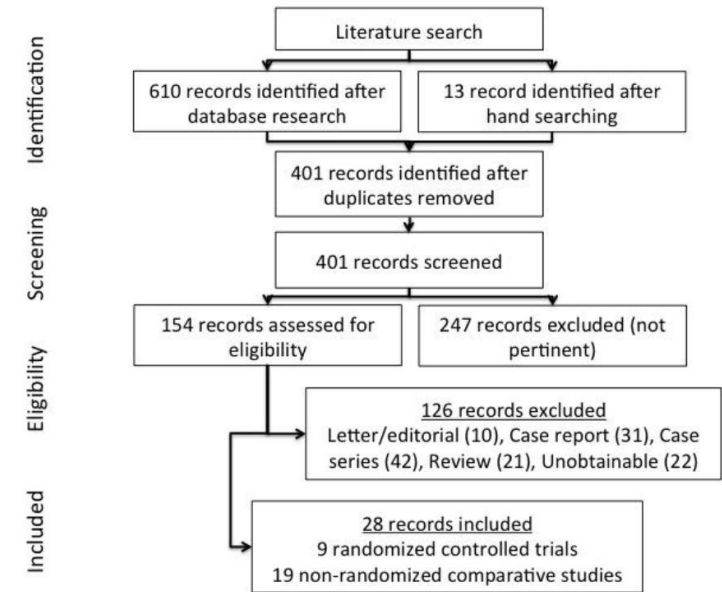


Figure 1. Flow diagram for literature search

Table for literature analysis report
(example for diabetic foot lesion and HBO use)

Study (authors, year)	Type	Nb patients	Aim(s) / Evaluation criteria	Inclusion / Exclusion criteria	HBO protocol (pressure, time, nb of session)	Results	Conclusion / comment
Davis 1987	Retrospective Case series	168 patients	Limb amputation	All types	?	70% healed with walking capability (with or without minor amputation) 30% required major amputation (BKA or AKA) Healing failure if no possibility of bypass in case of PAD	Case series. No evidence for HBO efficacy
Zamboni 1997	Controlled Study	10 patients (5 HBO, 5 control)	Wound size reduction	Consecutive insulin-dependent diabetic patients with chronic low extremity wound	2 ata/2 hours 30 sessions/7weeks	HBO plus standard care reduced wound size compared to standard care alone (p < 0.05) At 4-6 months, HBO group had higher complete healing than control (4/5 vs 1/5)	Favors HBO Small series No randomization Low level of evidence
Kessler 2003	RCT Not double blinded	28 patients	Wound size reduction	Wagner 1-3	2.5 ata/90 min 20 sessions /2 weeks	Wound size smaller at 2 weeks (end of HBO treatment) in HBO group (p = 0.037) but significant difference lost at 4 weeks. More wound healed at 2 months in HBO group	Favors HBO Moderate level of evidence
Londahl 2010	RCT Double blinded	94 patients (49 HBO, 45 sham)	Complete healing	Wagner 2 – 4	2.5 ata/85 min 40 sessions /8 weeks	Complete healing rate at 1 year higher in HBO group vs sham (p=0.03) Larger difference if	Favors HBO Number of HBO sessions need over 35

Les niveaux de preuve des études cliniques

Niveau de preuve	
A	≥ 2 études concordantes, de grande échelle, en double aveugle, randomisées et contrôlées, avec peu ou pas de biais méthodologique
B	études randomisées en double aveugle, mais avec quelques défauts méthodologiques, études de petits échantillons ou une seule étude
C	opinion commune d'experts
D	études non contrôlées sans consensus d'experts
E	absence de preuve, biais méthodologique ou d'interprétation empêchant toute conclusion
F	procédure non indiquée car aucune preuve existante

ECHM type of recommendations

Type 1: Très recommandé

Type 2 : Recommandé

Type 3 : Optionnel

Non recommandé

Strength of Recommendation (Consensus-Based)	Level of Evidence (Based on Grading of Recommendations Assessment, Development and Evaluation System)
Level 1 = Strong recommendation = "We recommend..." The course of action is considered appropriate by the large majority of experts with no major dissension. The panel is confident that the desirable effects of adherence to the recommendation outweigh the undesirable effects	Grade A = High level of evidence The true effect lies close to our estimate of the effect
Level 2 = Weak recommendation = "We suggest..." The course of action is considered appropriate by the majority of experts but some degree of dissension exists amongst the panel. The desirable effects of adherence to the recommendation probably outweigh the undesirable effects	Grade B = Moderate level of evidence The true effect is likely to be close to our estimate of the effect, but there is a possibility that it is substantially different
Level 3 = Neutral recommendation = "It would be reasonable..." The course of action could be considered appropriate in the right context	Grade C = Low level of evidence The true effect may be substantially different from our estimate of the effect
No recommendation No agreement was reached by the group of experts	Grade D = Very low level of evidence Our estimate of the effect is just a guess, and it is very likely that the true effect is substantially different from our estimate of the effect

Méthode Delphi

Fin octobre
2015

- Réception de tous les rapports
- Distribution à l'ensemble des experts

Décembre
2015

- 1^{ère} série de commentaires
- Modification des rapports

Février
2016

- 2^{ème} série de commentaires sur les textes modifiés

Mars 2016

- Réception des rapports modifiés

15 avril
2016

- Les rapports présentés et vote de l'assemblée d'évaluer le degré d'agrément





Dysbaric Illness : We recommend HBOT/recompression therapy tables (USN TT5&6 or HeO Cx30) for initial treatment of DI

1- Strongly agree

4- Disagree

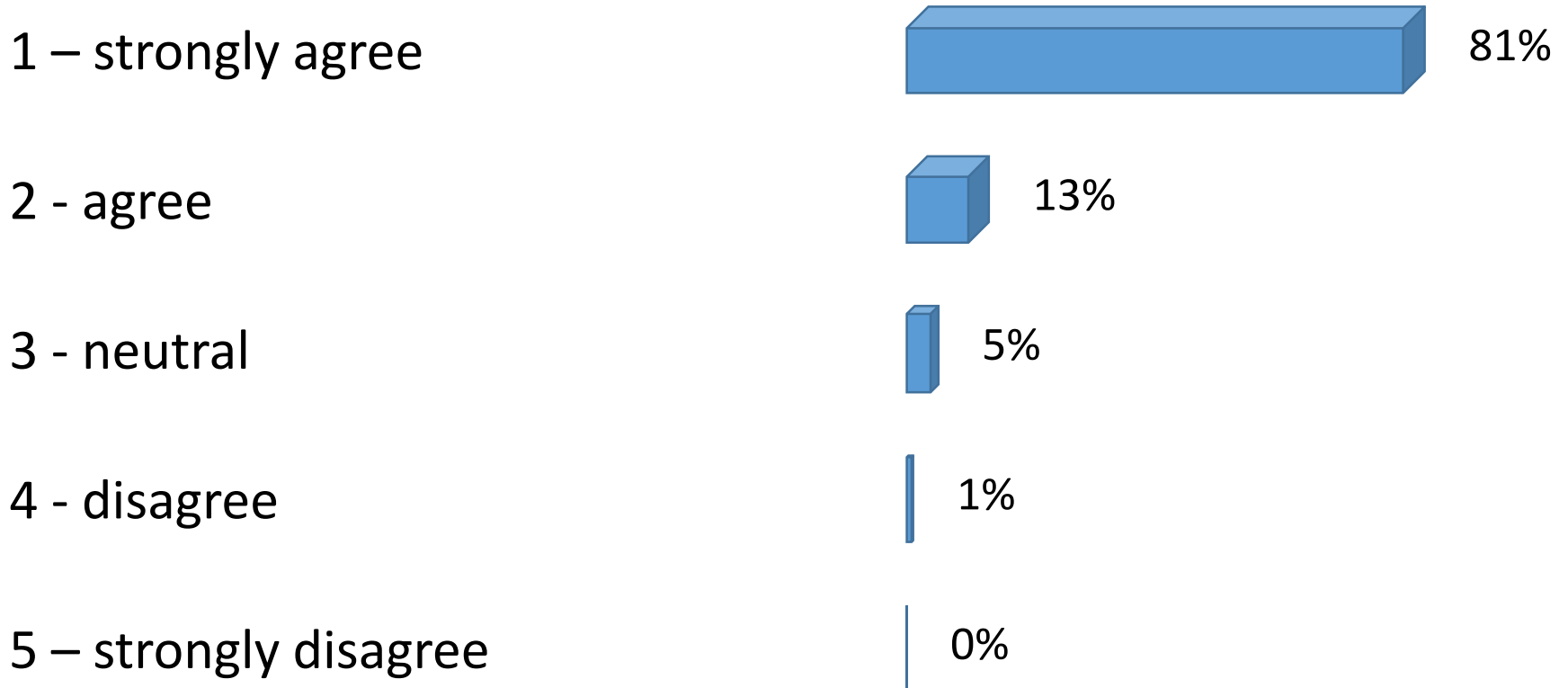
2- Agree

5- Strongly disagree

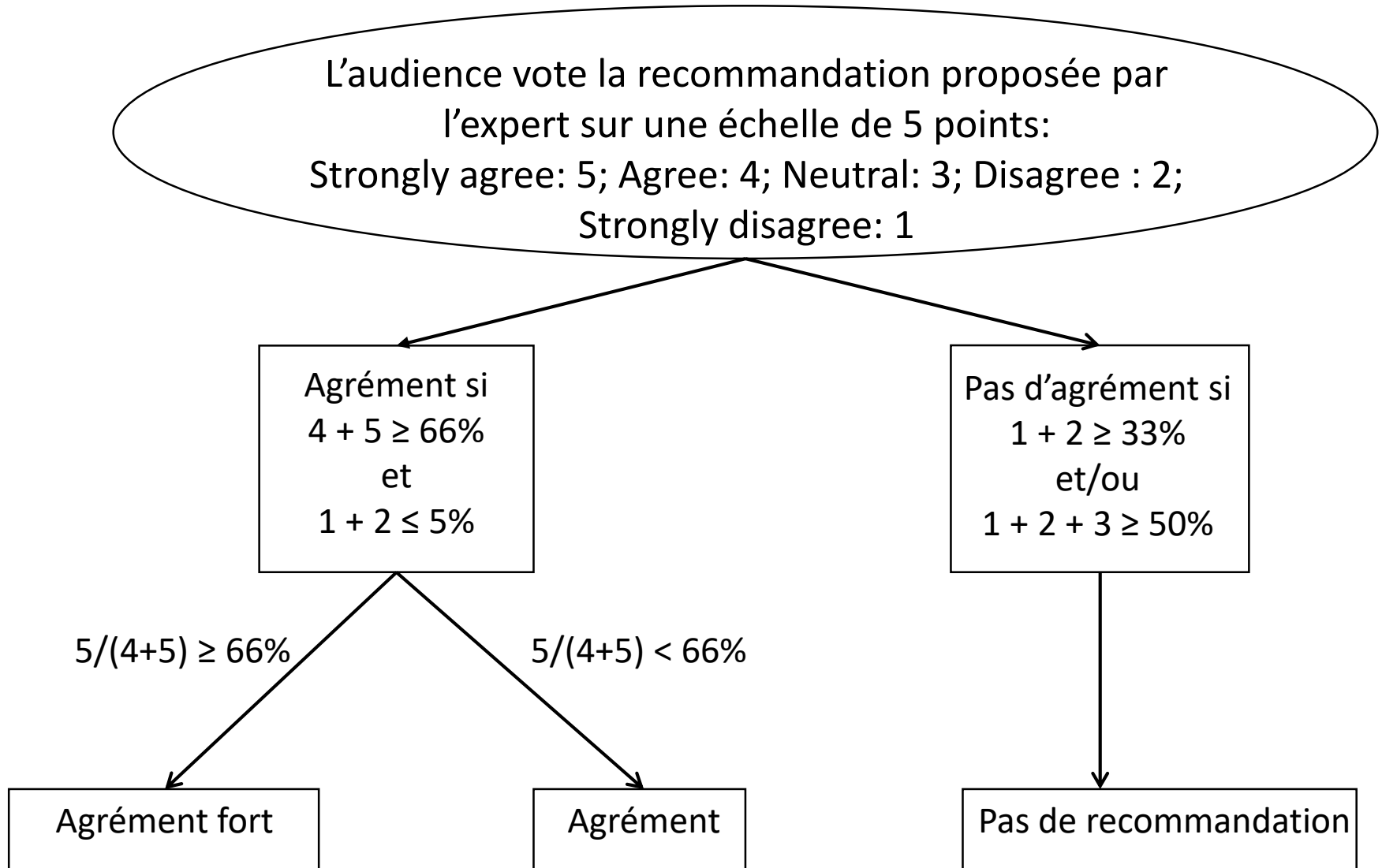
3- Neutral

Dysbaric Illness

We recommend hyperbaric oxygen therapy/recompression therapy tables (USN TT5&6 or HeO Cx30) for initial treatment of DI



Agrément





European Committee for Hyperbaric Medicine

ECHM 2016 list of indications

Type 1 : Strongly recommended - « We recommend ... »

CONDITION	ACCEPTED			NON ACCEPTED			AGREEMENT	COMMENT
	Level of Evidence			Level of Evidence				
	A	B	C	D	E	F		
Type I								
CO poisoning		X					Strong agreement	No change
Open fractures with crush injury		X					Strong agreement	No change
Prevention of osteoradionecrosis after dental extraction		X					Strong agreement	No change
Osteoradionecrosis (mandible)		X					Strong agreement	No change
Soft tissue radionecrosis (cystitis, proctitis)		X					Strong agreement	Proctitis changed from T2 to T1
Sudden deafness		X					Strong agreement	Evidence upgraded from C to B Recommendation from T2 to T1
Decompression illness			X				Strong agreement	No change
Gas embolism			X				Strong agreement	No change
Anaerobic or mixed bacterial infections			X				Strong agreement	No change



ECHM 2016 list of indications

Type 2 : Recommended - « We suggest ... »

CONDITION	ACCEPTED			NON ACCEPTED			AGREEMENT	COMMENT
	Level of Evidence			Level of Evidence				
	A	B	C	D	E	F		
Type II								
Diabetic foot lesions		X					Strong agreement	No change
Femoral head necrosis		X					Strong agreement	Evidence upgraded from D to B Recommendation from NA to T2
Compromised skin grafts and musculocutaneous flaps			X				Strong agreement	No change
Central retinal artery occlusion (CRAO)			X				Strong agreement	Upgraded from T3 to T2
Crush Injury without fracture			X				Agreement	Added
Osteoradionecrosis (bones other than mandible)			X				Agreement	No change
Radio-induced lesions of soft tissues (other than cystitis and proctitis)			X				Agreement	No change
Surgery and implant in irradiated tissue (preventive treatment)			X				Agreement	No change
Ischemic ulcers			X				Agreement	No change
Refractory chronic osteomyelitis			X				Agreement	No change
Burns 2 nd degree more than 20% BSA			X				Agreement	Upgraded from T3 to T2
Pneumatosis cystoides intestinalis			X				Agreement	Upgraded from T3 to T2
Stage IV neuroblastoma			X				Agreement	No change



European Committee for Hyperbaric Medicine

ECHM 2016 list of indications

Type 3 : Optional - « It would be reasonable ... »

CONDITION	ACCEPTED			NON ACCEPTED			AGREEMENT	COMMENT
	Level of Evidence			Level of Evidence				
	A	B	C	D	E	F		
Type III								
Brain injury (acute and chronic TBI, chronic stroke, post anoxic encephalopathy) in highly selected patients			X				Agreement	TBI added; chronic stroke upgraded from NA to T3; post anoxic encephalopathy, no change
Radio-induced lesions of larynx			X				Agreement	No change
Radio-induced lesions of the CNS			X				Agreement	No change
Post-vascular procedure reperfusion syndrome			X				Agreement	No change
Limb replantation			X				Agreement	No change
Selected non healing wounds secondary to systemic processes			X				Agreement	No change
Sickle cell disease			X				Agreement	Upgraded from NA to T3
Interstitial cystitis			X				Agreement	Evidence upgraded from E to C Recommendation from NA to T3



European Committee
for Hyperbaric Medicine

ECHM 2016 list of indications

No recommendation

CONDITION	ACCEPTED			NON ACCEPTED			AGREEMENT	COMMENT
	Level of Evidence			Level of Evidence				
	A	B	C	D	E	F		
NO RECOMMENDATION								
Post sternotomy mediastinitis				X			Agreement	No change
Malignant otitis externa				X			Agreement	No change
Acute myocardial infarction				X			Agreement	No change
Retinitis pigmentosa				X			Agreement	No change
Facial (Bell's) palsy				X			Agreement	No change



European Committee for Hyperbaric Medicine

ECHM 2016 list of indications

Negative recommendation – « We recommend not treating ... »

CONDITION							AGREEMENT	COMMENT
	Level of Evidence			Level of Evidence				
	A	B	C	D	E	F		
NEGATIVE RECOMMENDATION (TYPE 1)								
Autism spectrum disorders		X					Agreement	Added
Multiple sclerosis		X					Agreement	No change
Cerebral palsy		X					Agreement	No change
Tinnitus		X					Agreement	No change
Acute phase of stroke			X				Agreement	Added
Placental insufficiency			X				Agreement	No change

Conclusion : Entre les conférences de consensus

- Workshop réguliers
- Réunion annuelle de l'ECHM afin de déterminer les prochaines conférences de consensus
- A prendre en compte: le temps consacré et la logistique importante
- Implication indispensable de toutes les sociétés savantes