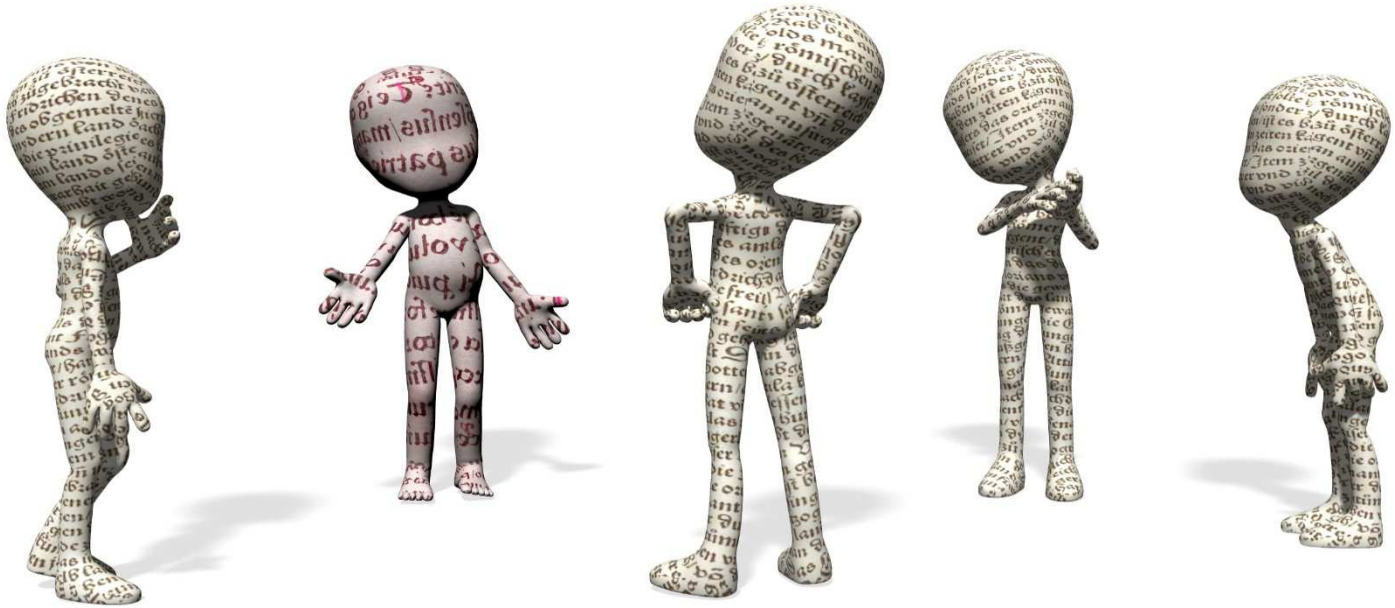


The Safetots Initiative

Conflict of Interests

- None



Background

DEVELOPMENT/PLASTICITY/REPAIR

Early Exposure to Common Anesthetic Agents Causes Widespread Neurodegeneration in the Developing Rat Brain and Persistent Learning Deficits

Vesna Jevtovic-Todorovic[1], Richard E. Hartman[2], Yukitoshi Izumi[3], Nicholas D. Benshoff[3], Krikor Dikranian[3], Charles F. Zorumski[3], John W. Olney[3], and David F. Wozniak[3]

+ Show Affiliations

The Journal of Neuroscience, 1 February 2003, 23(3): 876-882;

Background

Defining Safe Use of Anesthesia in Children

Bob Rappaport, M.D., R. Daniel Mellon, Ph.D., Arthur Simone, M.D., Ph.D., and Janet Woodcock, M.D.

Rappaport B et al – NEJM 2011

Safe Anaesthesia in Children

- What is **safe** in paediatric anaesthesia?

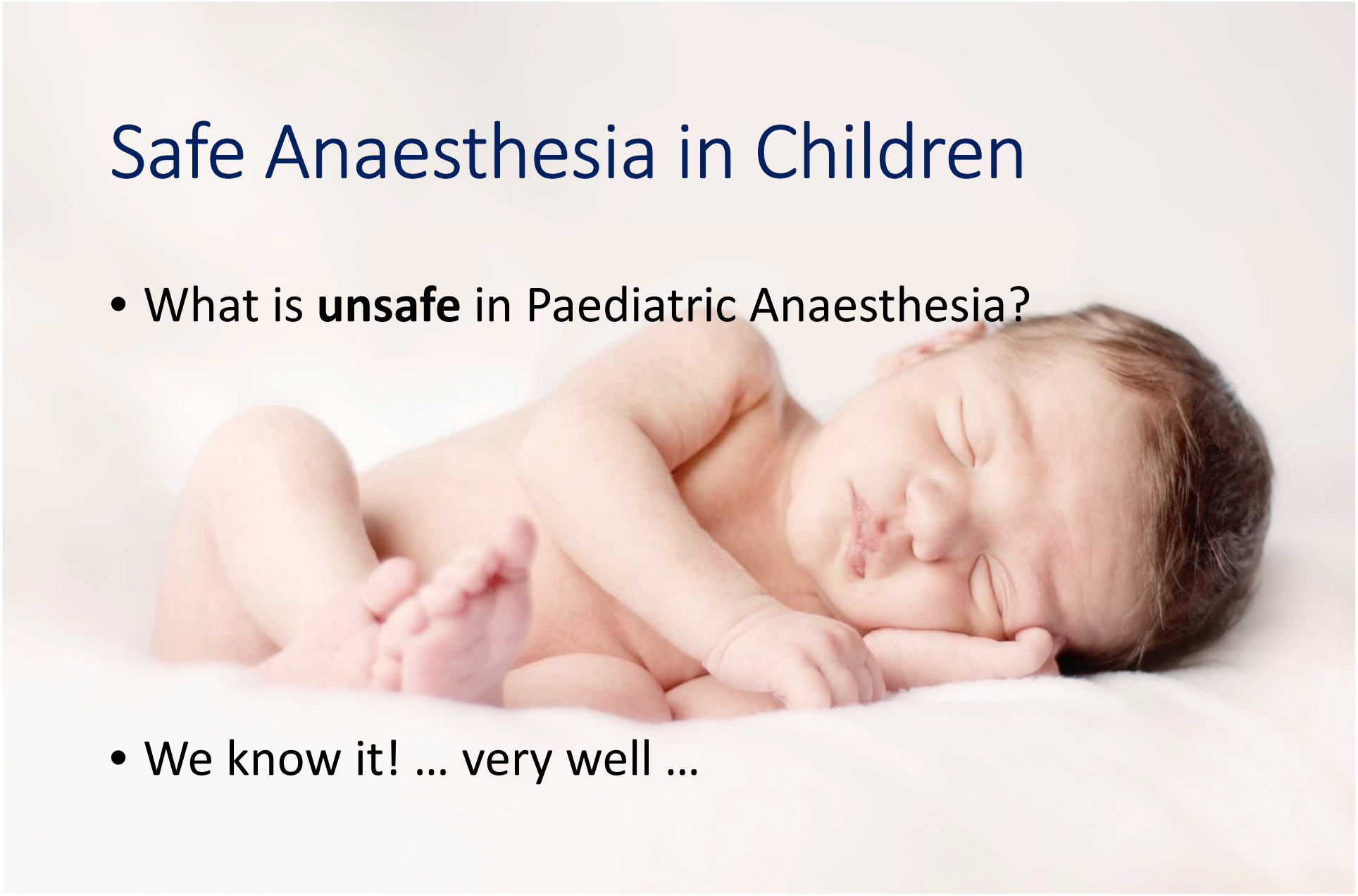


- We don't know it!

Rappaport B et al – NEJM 2011

Safe Anaesthesia in Children

- What is **unsafe** in Paediatric Anaesthesia?



- We know it! … very well …

The Risk in Paediatric Anaesthesia



ESPA

Bordeaux 1 April 2016

What is the Risk in Paed Anaesth?

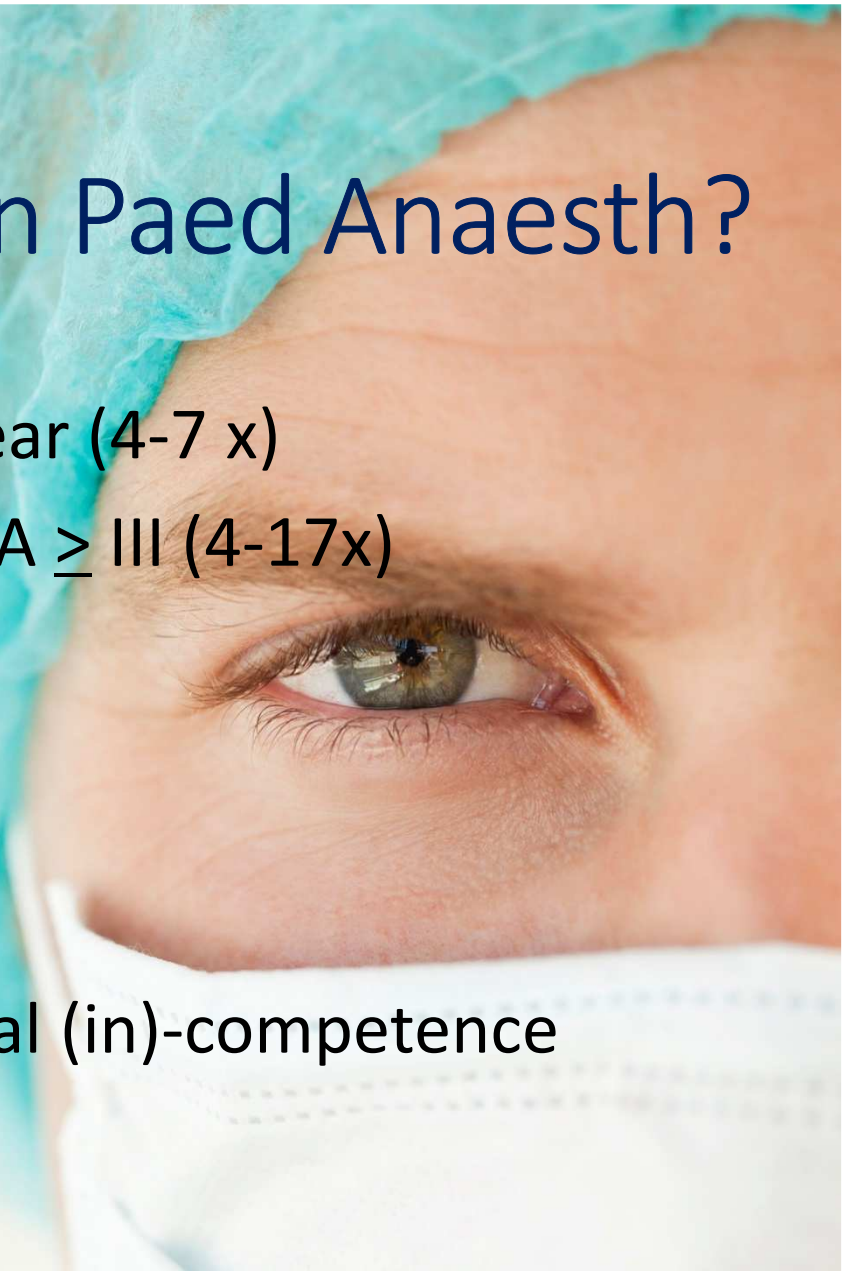


- Children undergoing anaesthesia have an increased perioperative risk as compared to the adults

- Up to 9 % suffer intraoperative complications
  - Mainly respiratory events (53-77 %)

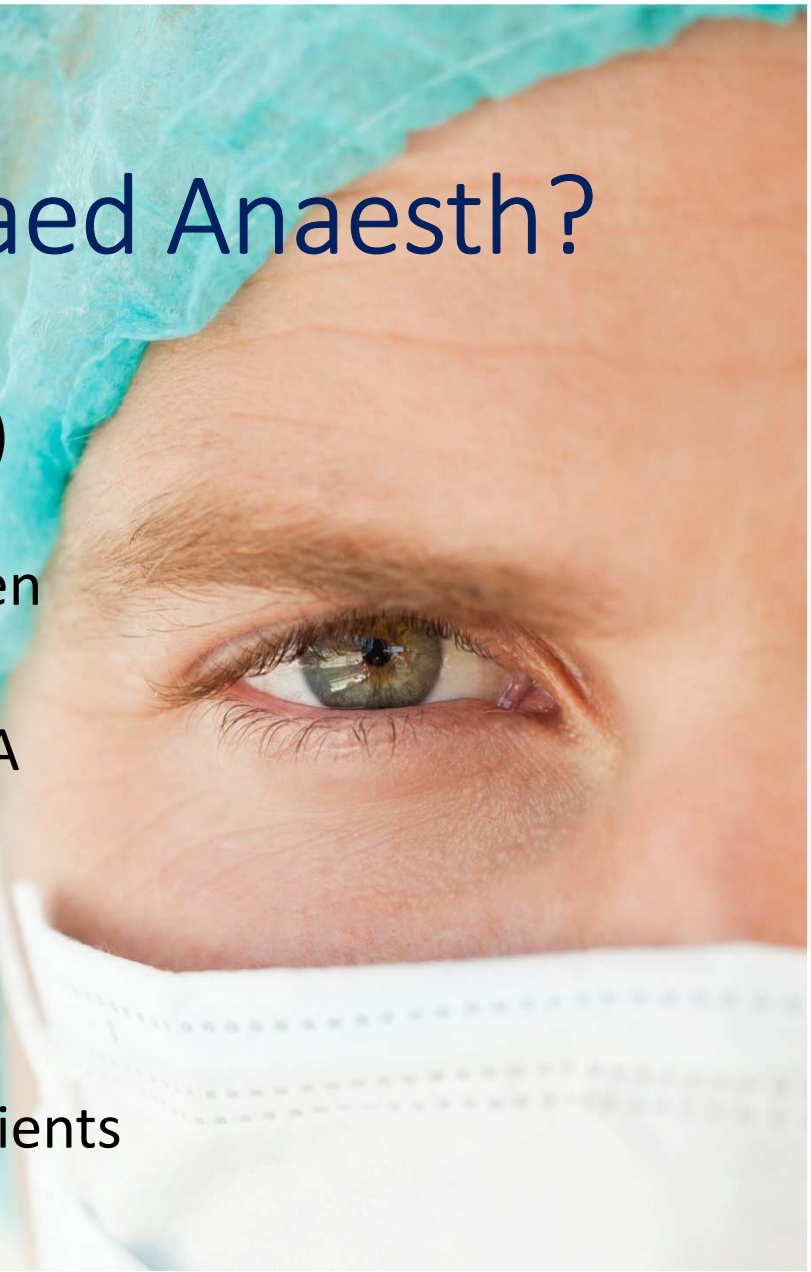
Paterson and Waterhouse – Pediatr Anesth 2011

What are the Risks in Paed Anaesth?



- Age below < 1 month / < 1 year (4-7 x)
- Patients with comorbidity ASA ≥ III (4-17x)
  - Cardiac
  - Respiratory
- Emergency surgery (3x)
- ENT-Surgery
- Anaesthetists and institutional (in)-competence

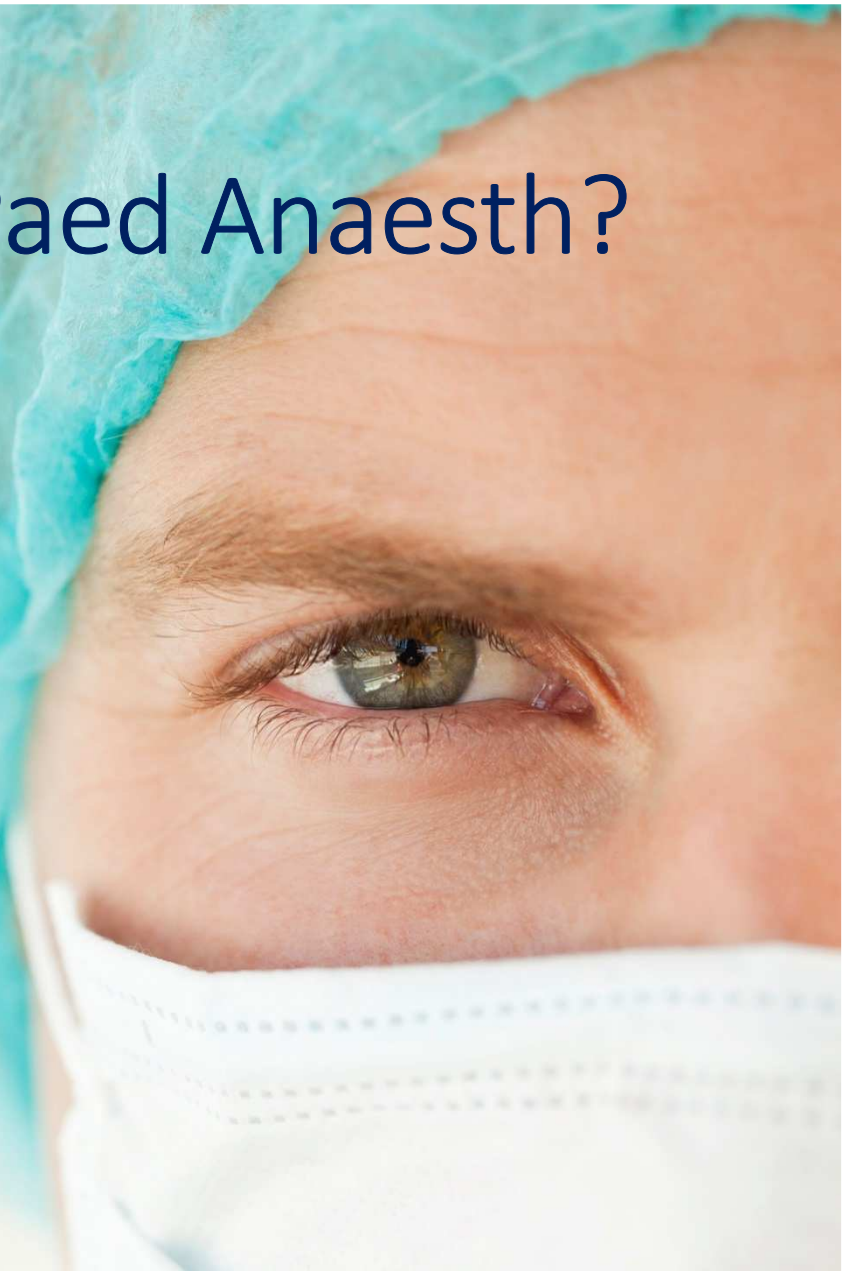
What is the Risk in Paed Anaesth?



- Cardiac Arrest (POCA-Registry)
  - > 1 Mio Anaesthetics in children
  - 150 Anaesthesia related CA (1.4 : 10’000)
  - 55% Infants and newborns
  - 72% Mortality in newborns
  - > 30% Previously healthy patients

Morray JP – Anesthesiology 2000

What is the Risk in Paed Anaesth?



- Cardiac Arrest
  - Infants: 19-24/10’000
  - All 1-7/10’000

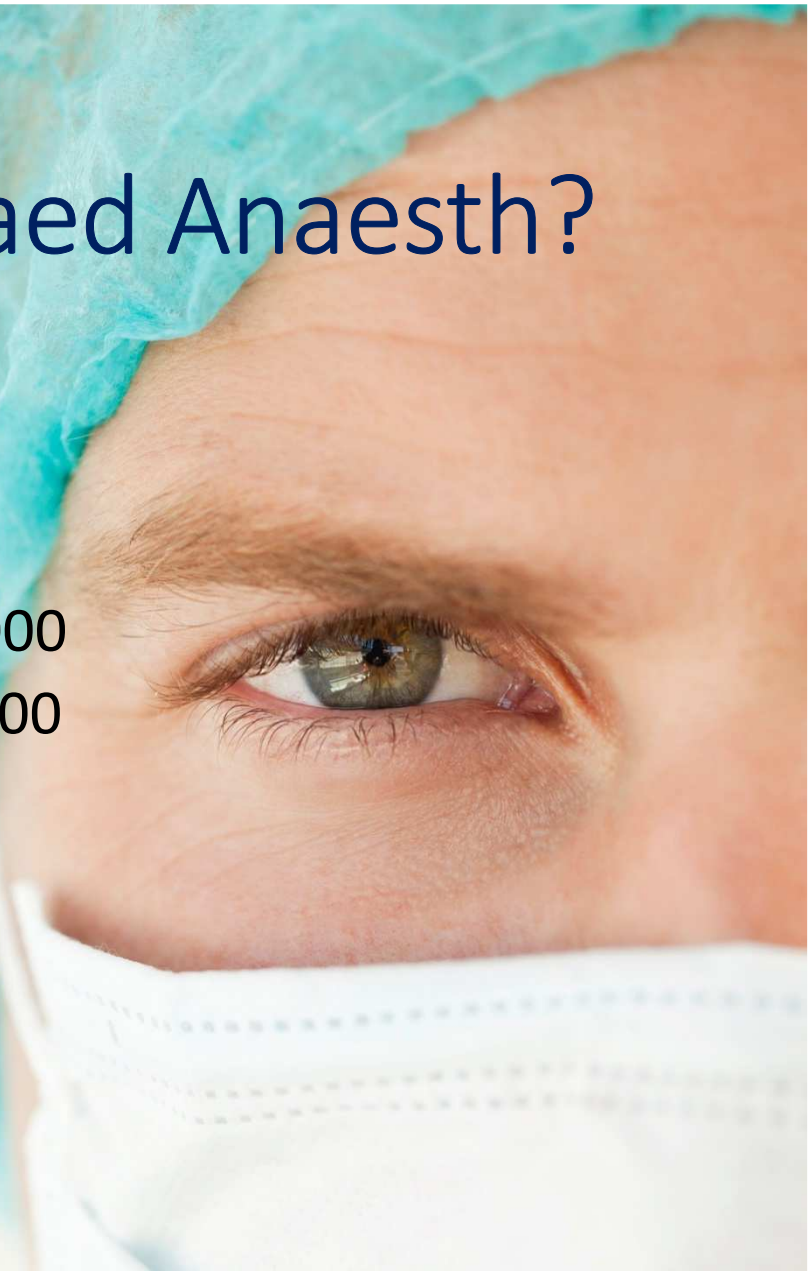
Paterson and Waterhouse – Pediatr Anesth 2011

What is the Risk in Paed Anaesth?

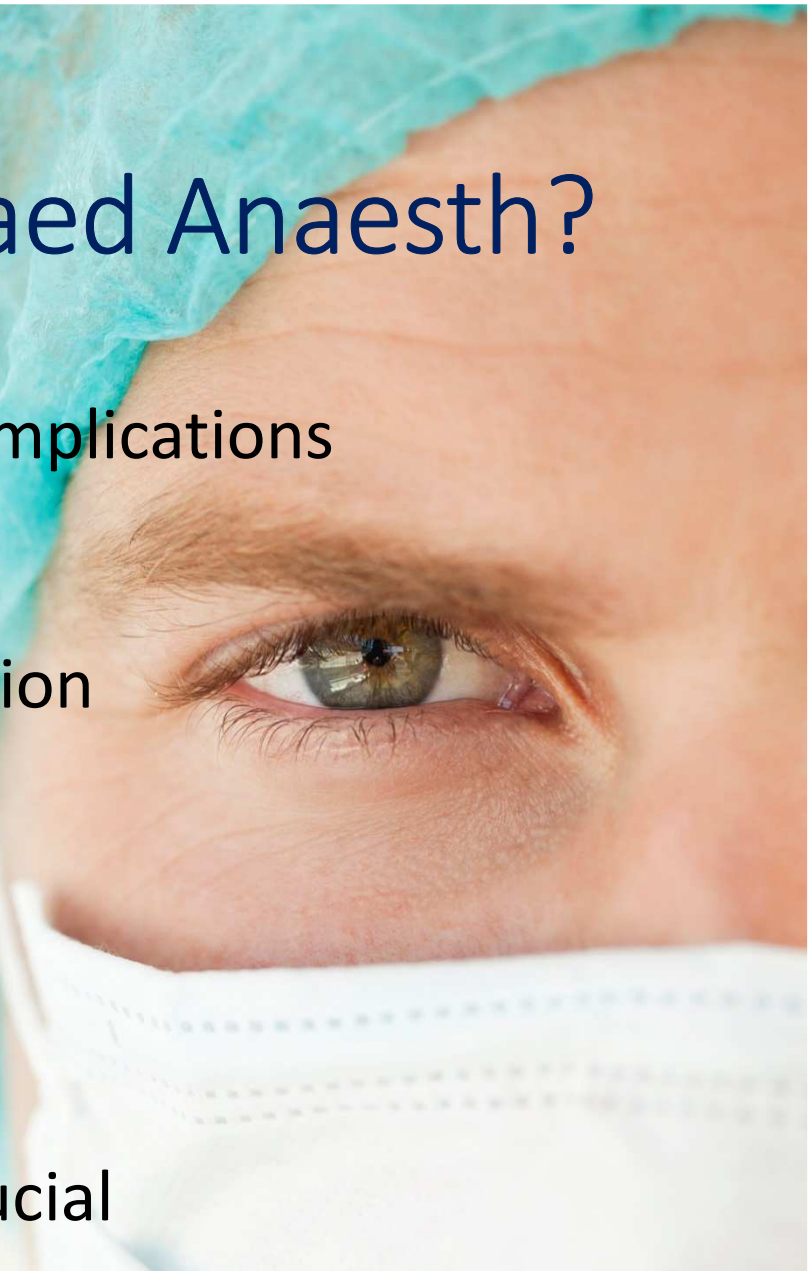
- Anaesthesia related Mortality

  - Children 0.2 – 2.9 / 10’000
  - Adults 0.07 / 10’000

  - Children 2-29 / 100’000
  - Adults 1 / 300’000



What is the Risk in Paed Anaesth?



- Reasons for Higher Rate of Complications
  - Low respiratory reserves
  - Functional airway obstruction
  - High closing capacity
  - Bradycardia (Hypoxaemia)
  - Low circulatory reserves
  - Difficult vascular access
  - → … time and skills are crucial

Dangers in Paed Anaesth



ESPA

Bordeaux 1 April 2016

What is dangerous in Paed Anaesth?

- Inexperience in Paediatric Anaesthesia
  - Non-paediatric anaesthesiologists have higher rates of bradycardia when compared with paediatric anaesthetists

    2.12 % versus 0.82 % ($p < 0.001$)

Keenan RL – Anesthesiology 1994

What is dangerous in Paed Anaesth?

- Inexperience in Paediatric Anaesthesia
  - Non-paediatric anaesthesiologists
    have higher rates of cardiac arrests
    in children compared with paediatric anaesthesiologists

    4:2033 versus 0:2310 ($p < 0.048$)

    4:2033 ≈ 19.7:10'000 (1-7:10'000)

Keenan RL – J Clin Anesth 1991

What is dangerous in Paed Anaesth?

- Occasional Paediatric Anaesthesia
  - Severe complications
    (1:500; n= 351/173'000)

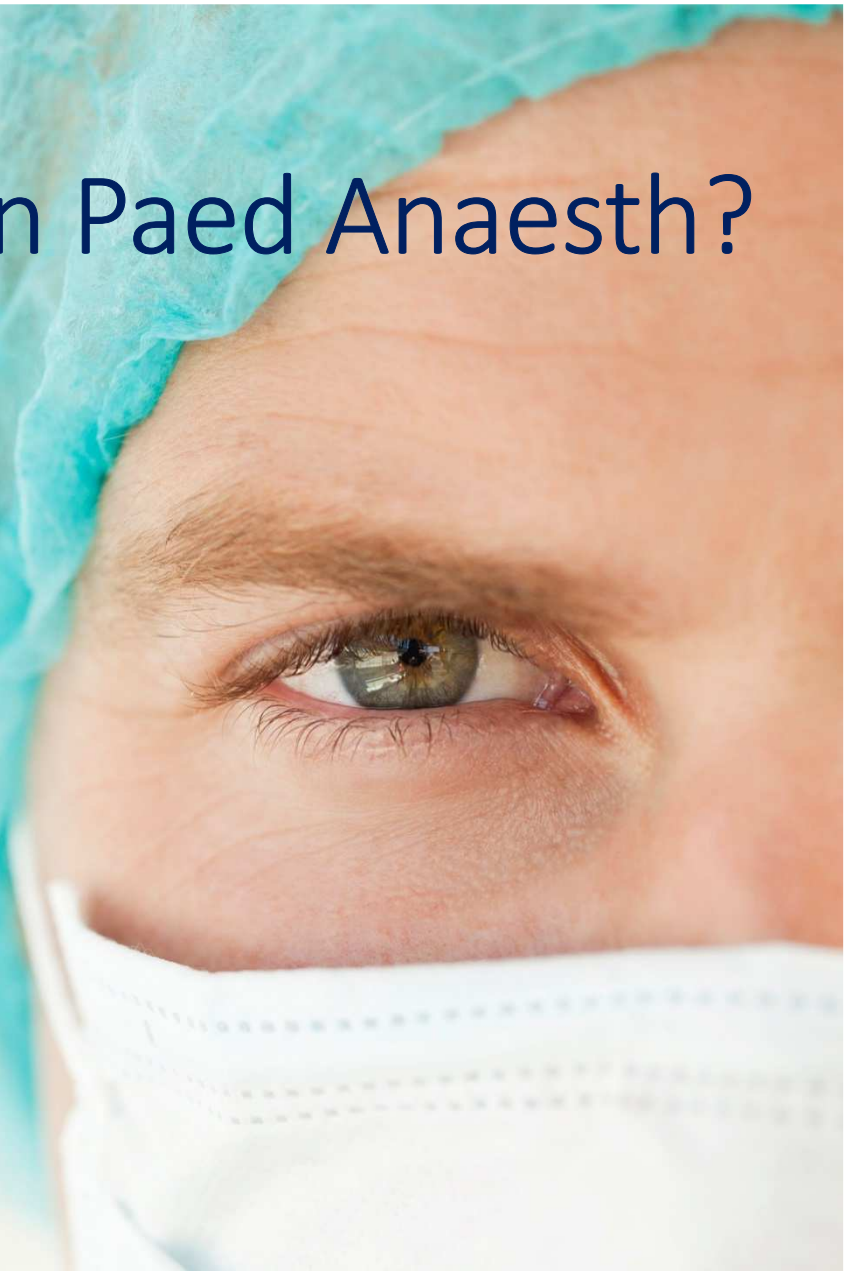
- < 100 Anaesthetics / year 7.0 +/- 24.8 per 1000 *
- 100-200 Anaesthetics / year 2.8 +/- 10.1 per 1000 *
- > 200 Anaesthetics / year 1.3 +/- 4.3 per 1000

* p<0.05 compared to > 200 anaesthetics / year

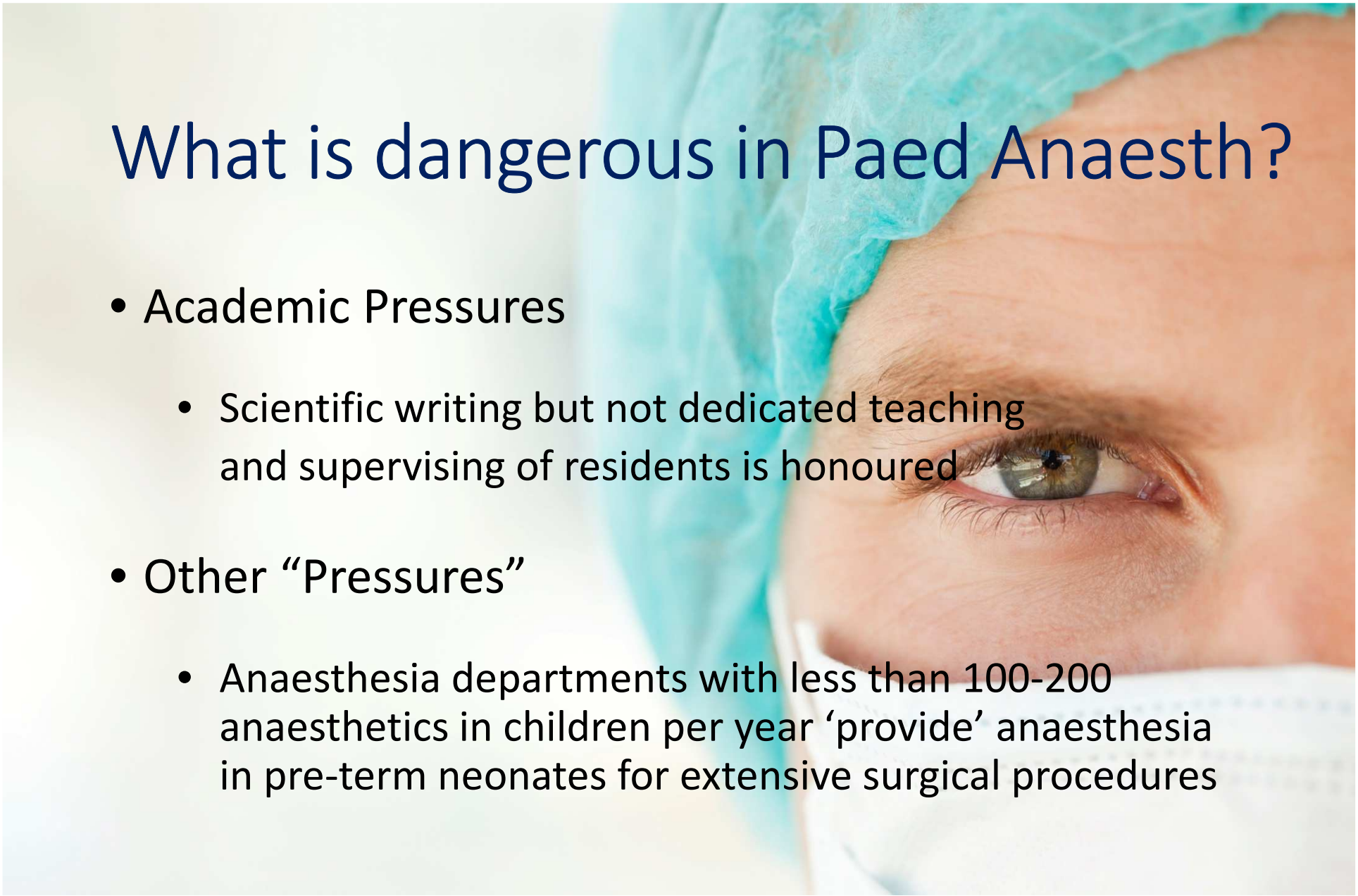
Auroy Y – Anesth Analg 1997

What is dangerous in Paed Anaesth?

- Economic Pressure
  - Lack of even basic staffing
  - Lack of logistic resources for paediatric anaesthesia



What is dangerous in Paed Anaesth?



- Academic Pressures
  - Scientific writing but not dedicated teaching and supervising of residents is honoured
- Other “Pressures”
  - Anaesthesia departments with less than 100-200 anaesthetics in children per year ‘provide’ anaesthesia in pre-term neonates for extensive surgical procedures

What is unsafe in Paed Anaesth?

- Trespassing safety limits
- Leaving normal



What is unsafe in Paed Anaesth?

- Hypotension



What is unsafe in Paed Anaesth?

- Hypotension – Definition (Reduction of SBP)
  - Survey SPA and APA

	% of responders		
	SPA	APA	*p*
10-20%	12.3	10.3	ns
20-30%	70.3	89.7	***
30-40%	10.9	0	***
>40%	6.5	0	***



Nafiu OO – Pediatr Anesth 2009

What is unsafe in Paed Anaesth?

- Hypotension – Systolic Threshold Values for Therapy
  - Survey SPA versus APA

	Thresholds (mean±SD)		
	SPA	APA	*p*
Neonate	45.5±8.5	49.6±8.4	***
Infant-2y	54.8±8.3	59.6±9.1	***
2-12 y	66.9±8.9	70.1±6.8	***
>12 y	78.4±10	84.5±5.3	***



Nafiu OO – Pediatr Anesth 2009

What is unsafe in Paed Anaesth?

- Hypotension – Definitions
  - **Pediatric Advanced Life Support**
    - systolic < 60 mm Hg in neonates
  - Brain Trauma Foundation Guidelines
    - systolic < 70 mm Hg + 2 (age in yrs)
  - British Association of Perinatal Medicine
    - MAP < infant's gestation age in weeks

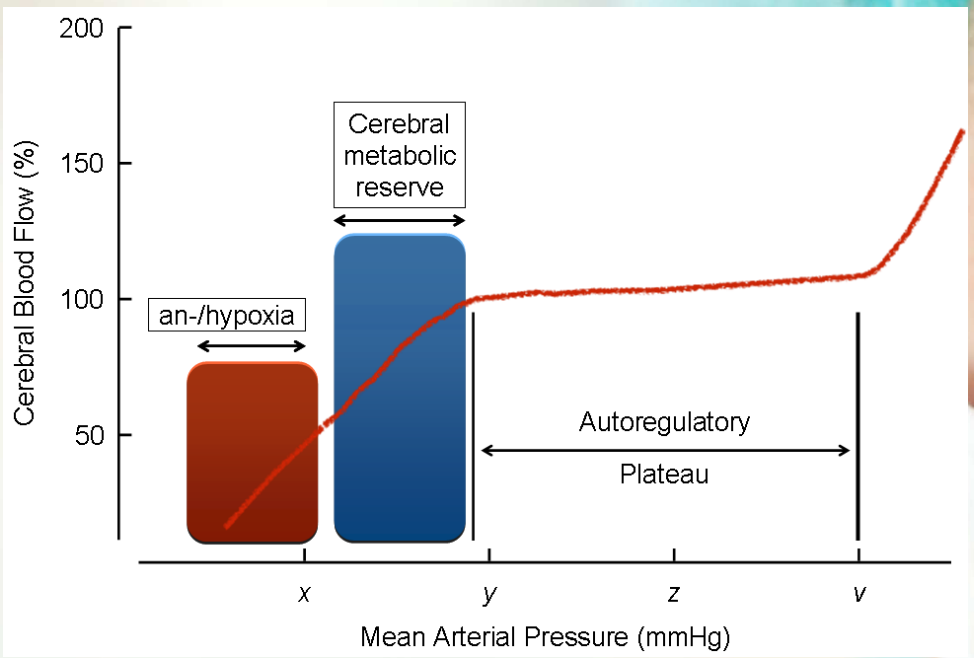
AHA – Circulation 2000

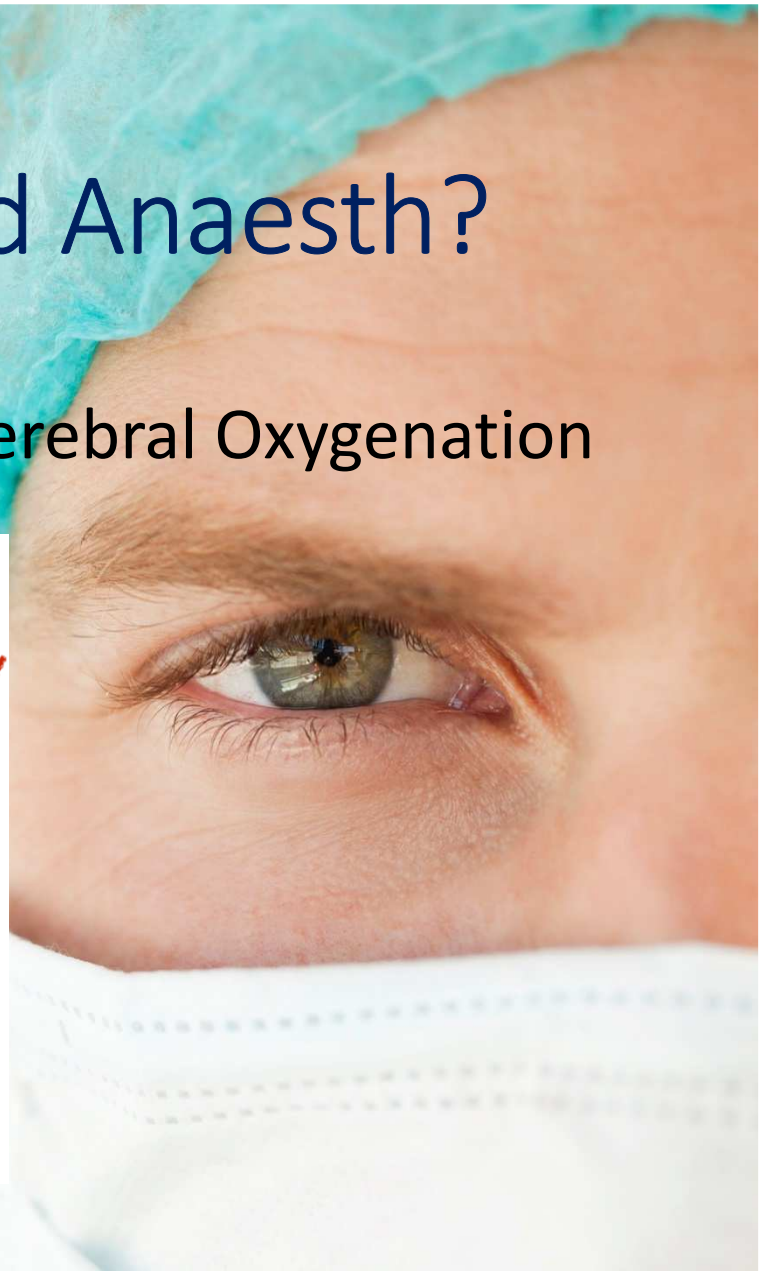
What is unsafe in Paed Anaesth?

- Hypotension – Lower Limit of Cerebral Perfusion
  - Small Children (Sevoflurane 1 Mac)
  - MAP > 45 mm Hg → CBF adequate/ sufficient oxygenation ✔
  - MAP 35-45 mm Hg → CBF altered / sufficient oxygenation Δ
  - MAP < 35 mmHg → CBF inadequate / insufficient oxygenation ✖

What is unsafe in Paed Anaesth?

- Hypotension – Lower Limit of Cerebral Oxygenation





Rhondali O et al – Pediatr Anesth 2015

What is unsafe in Paed Anaesth?

- Hypotension – Clinical Consequences



Infantile Postoperative Encephalopathy: Perioperative Factors as a Cause for Concern

Mary Ellen McCann, A.N.J. Schouten, Nicole Dobija, Carlos Munoz, Lianne Stephenson, Tina Y. Poussaint, C.J. Kalkman, Paul R. Hickey, Linda S. de Vries and Robert C. Tasker

Pediatrics; originally published online February 10, 2014;

McCann ME – Pediatrics 2014

What is unsafe in Paed Anaesth?

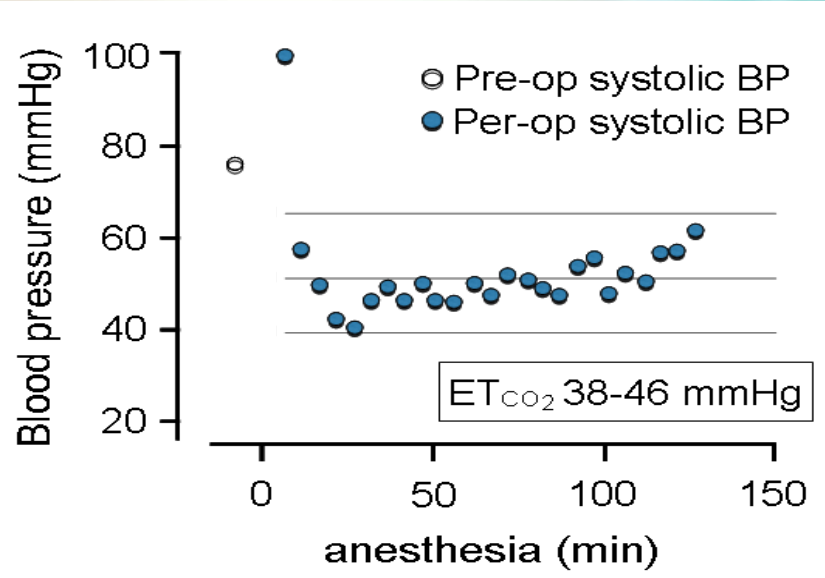
- Hypotension – Clinical Consequences
  - 6 infants
  - Age 2.7 – 16 weeks / Weight 2.5 to 4.8 kg
  - Duration of anaesthesia 120 – 185 min
  - Sevoflurane, Propofol, Remifentanil
  - Median MAP: 31.6 to 38.3 mmHg (4-26 hits below 30 mmHg MAP)

  - → Onset of cerebral seizures within 25 h in all 6 infants

McCann ME – Pediatrics 2014

What is unsafe in Paed Anaesth?

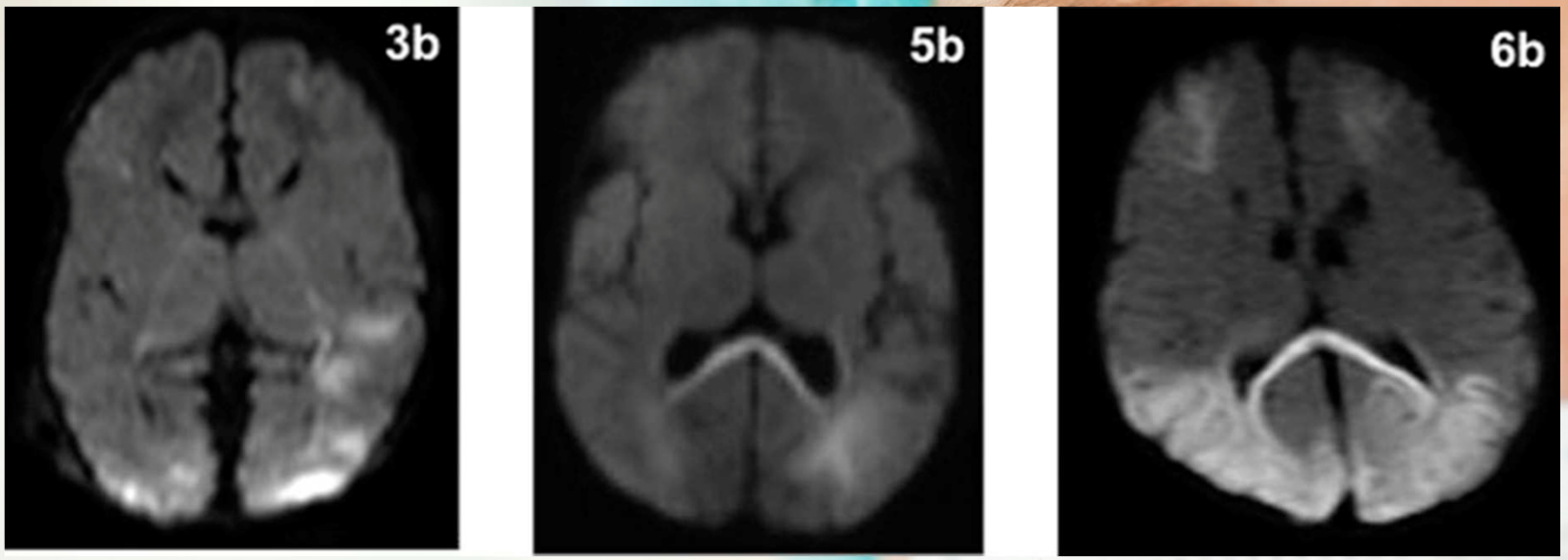
- Hypotension – Clinical Consequences



McCann ME – Pediatrics 2014

What is unsafe in Paed Anaesth?

- Hypotension – Clinical Consequences



- MRI days later showed ischaemic alterations in the watershed areas

McCann ME – Pediatrics 2014

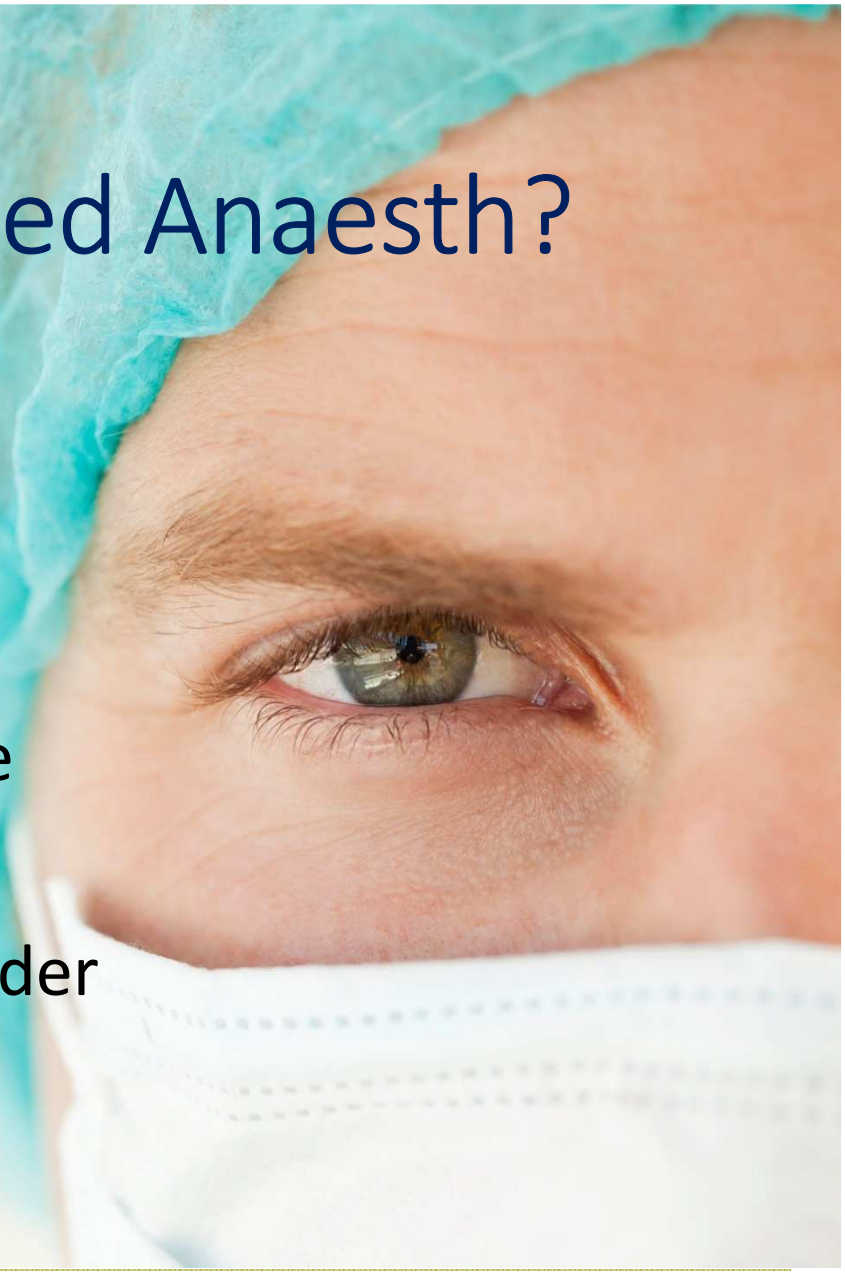
What is unsafe in Paed Anaesth?

- Hypocapnia



Zhou W – Worlds J Pediatr 2008

What is unsafe in Paed Anaesth?

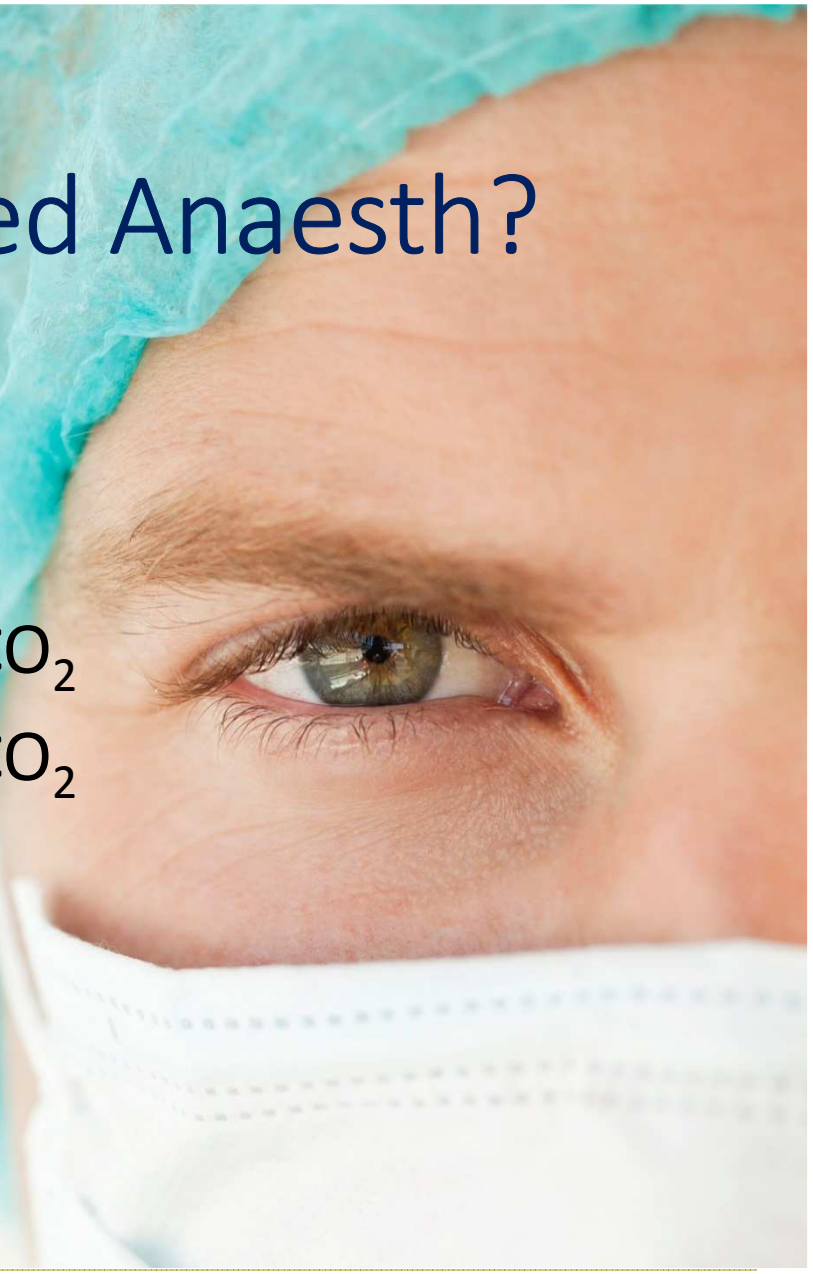


- Hypocapnia in Newborns

- Periventricular leukomalacia
- Intraventricular haemorrhage
- Cerebral palsy
- Cognition development disorder
- Auditory deficit

Zhou W – Worlds J Pediatr 2008

What is unsafe in Paed Anaesth?

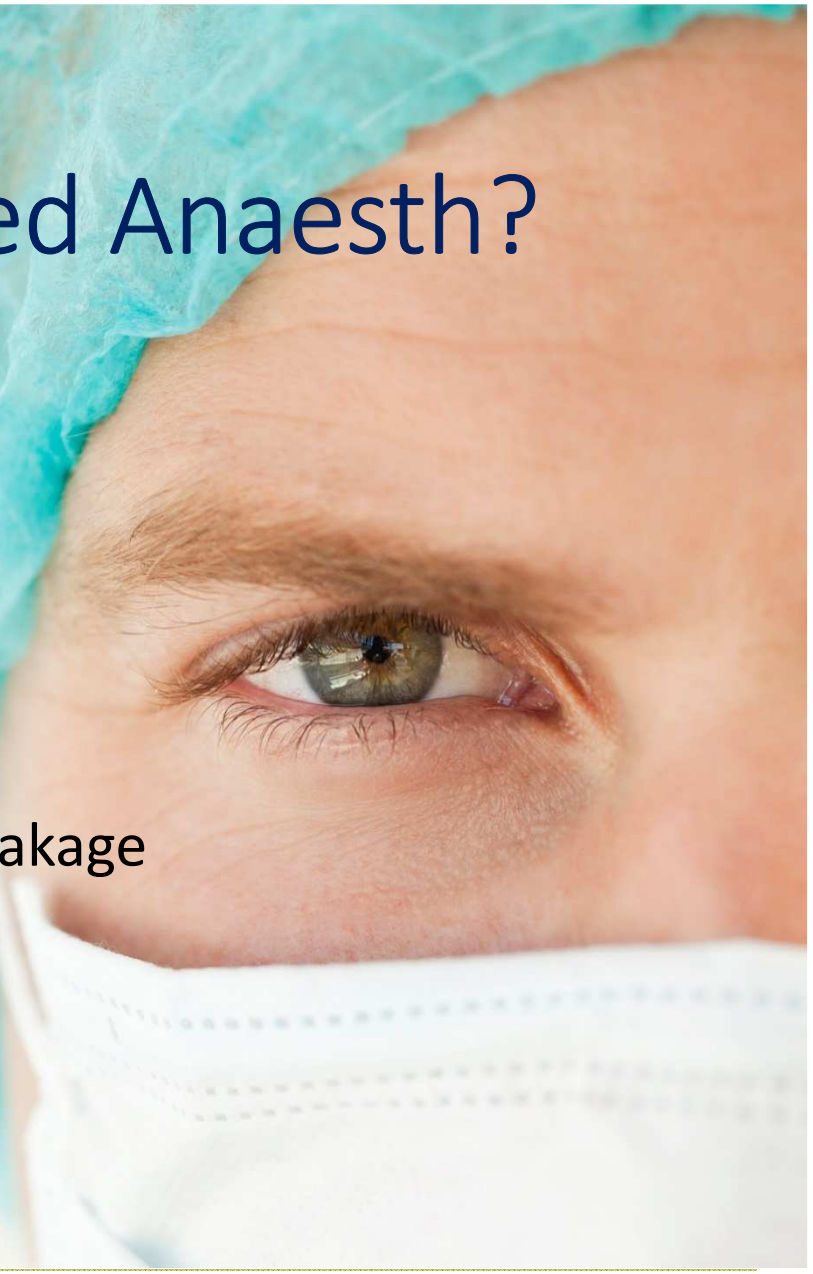


- Hypocapnia in Anaesthesia

- Mild: 4.0 – 4.7 kPa $ETCO_2$
- Moderate: 3.3 – 4.0 kPa $ETCO_2$
- Severe: < 3.3 kPa $ETCO_2$

Pappas A – J Pediatr 2011

What is unsafe in Paed Anaesth?

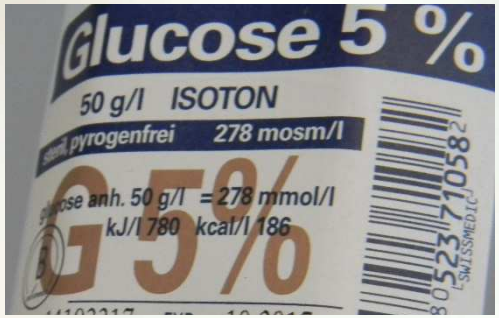


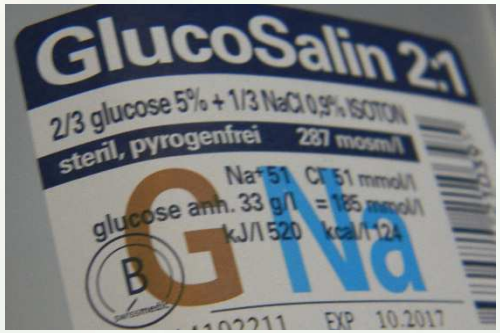
- $PaCO_2$ / $ETCO_2$ - Monitoring
- $ETCO_2$-monitoring not reliable
  - Uncuffed tracheal tubes with leakage
  - Poor correlation to $PaCO_2$

Pappas A – J Pediatr 2011

What is unsafe in Paed Anaesth?

- Perioperative Hyponatraemia





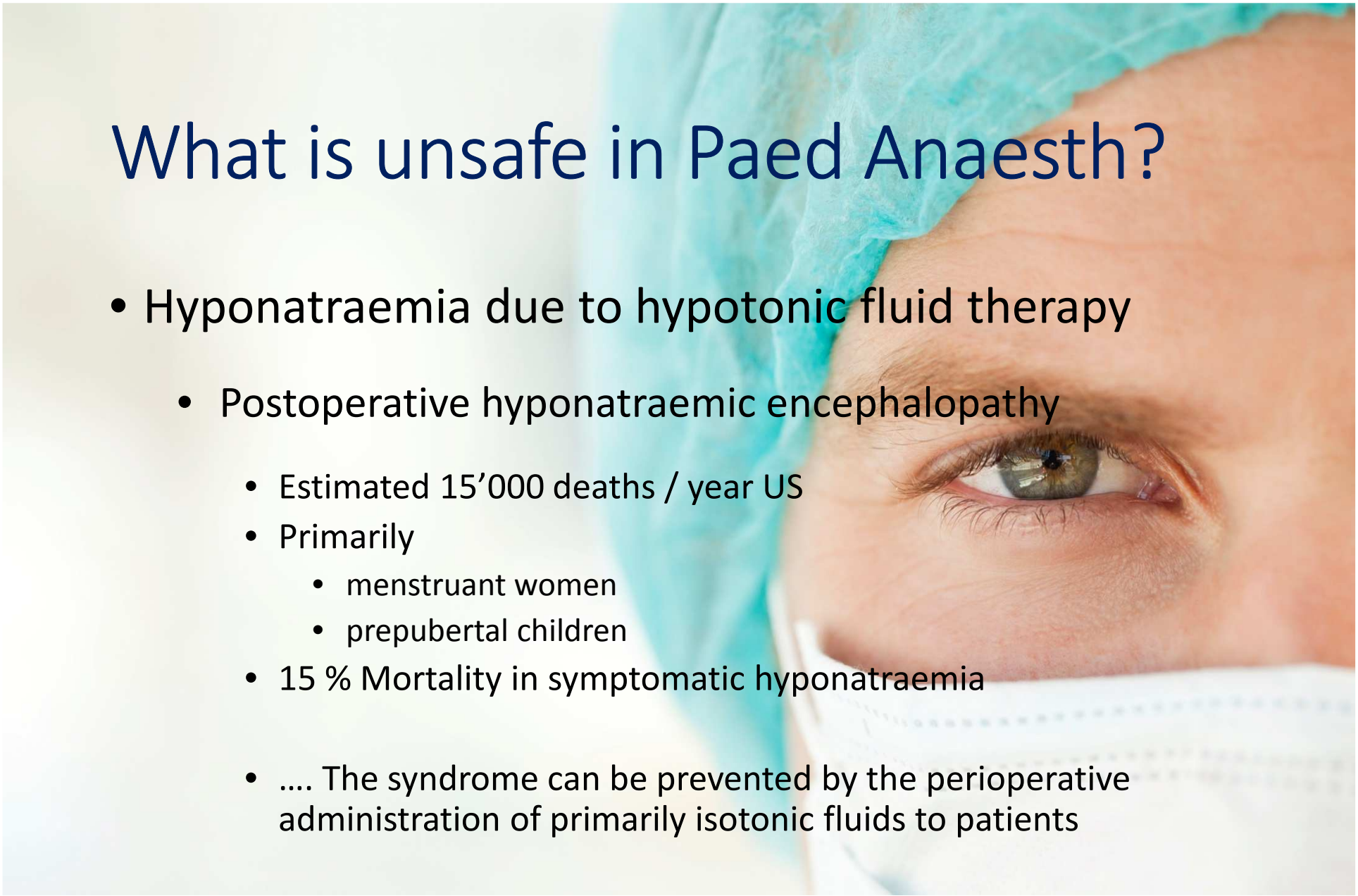
What is unsafe in Paed Anaesth?



- Hyponatraemia due to hypotonic fluid therapy
  - Hyponatraemia and death or permanent brain damage in healthy children
    - Brain swelling
    - Transtentorial herniation
    - Respiratory insufficiency / apnoea
    - Quadriplegia
    - Vegetative state
    - Brain death
    - Death

Arieff AI – BMJ 1992

What is unsafe in Paed Anaesth?



- Hyponatraemia due to hypotonic fluid therapy
  - Postoperative hyponatraemic encephalopathy
    - Estimated 15’000 deaths / year US
    - Primarily
      - menstruant women
      - prepubertal children
    - 15 % Mortality in symptomatic hyponatraemia
    - …. The syndrome can be prevented by the perioperative administration of primarily isotonic fluids to patients

Arieff AI – Pediatr Anesth 1998

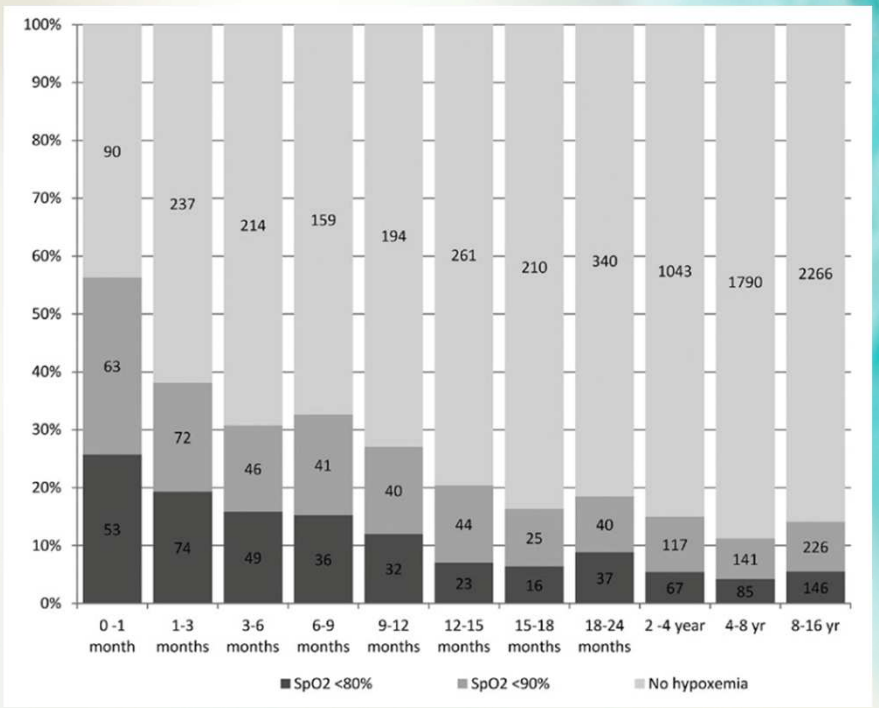
What is unsafe in Paed Anaesth?

- Hypoxaemia / Bradycardia



What is unsafe in Paed Anaesth?

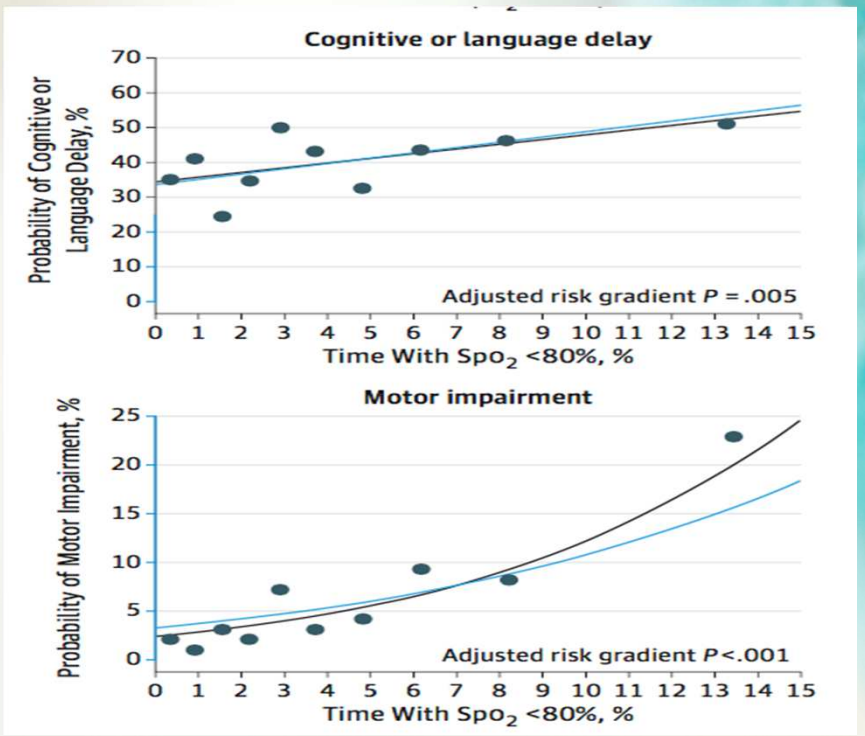
- Hypoxaemia - Incidence



deGraaff JC - Anesth Analg 2013

What is unsafe in Paed Anaesth?

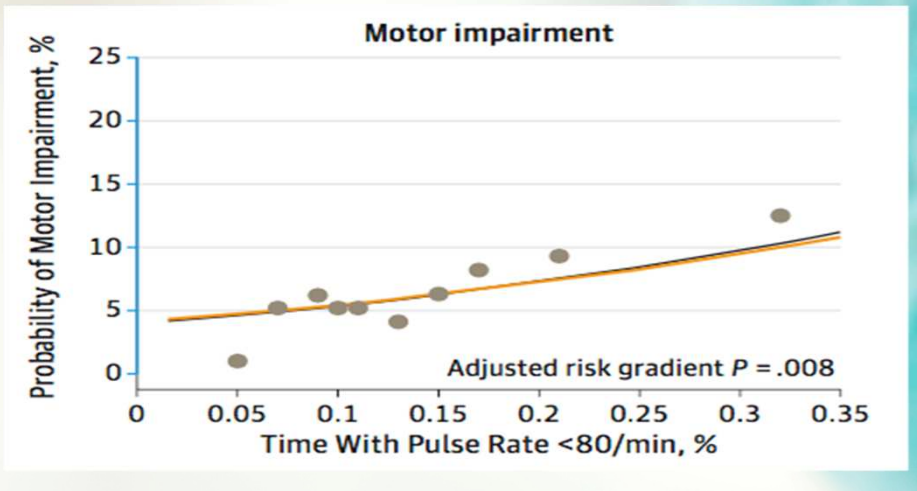
- Hypoxaemia / Bradycardia



Poets CF - JAMA 2015

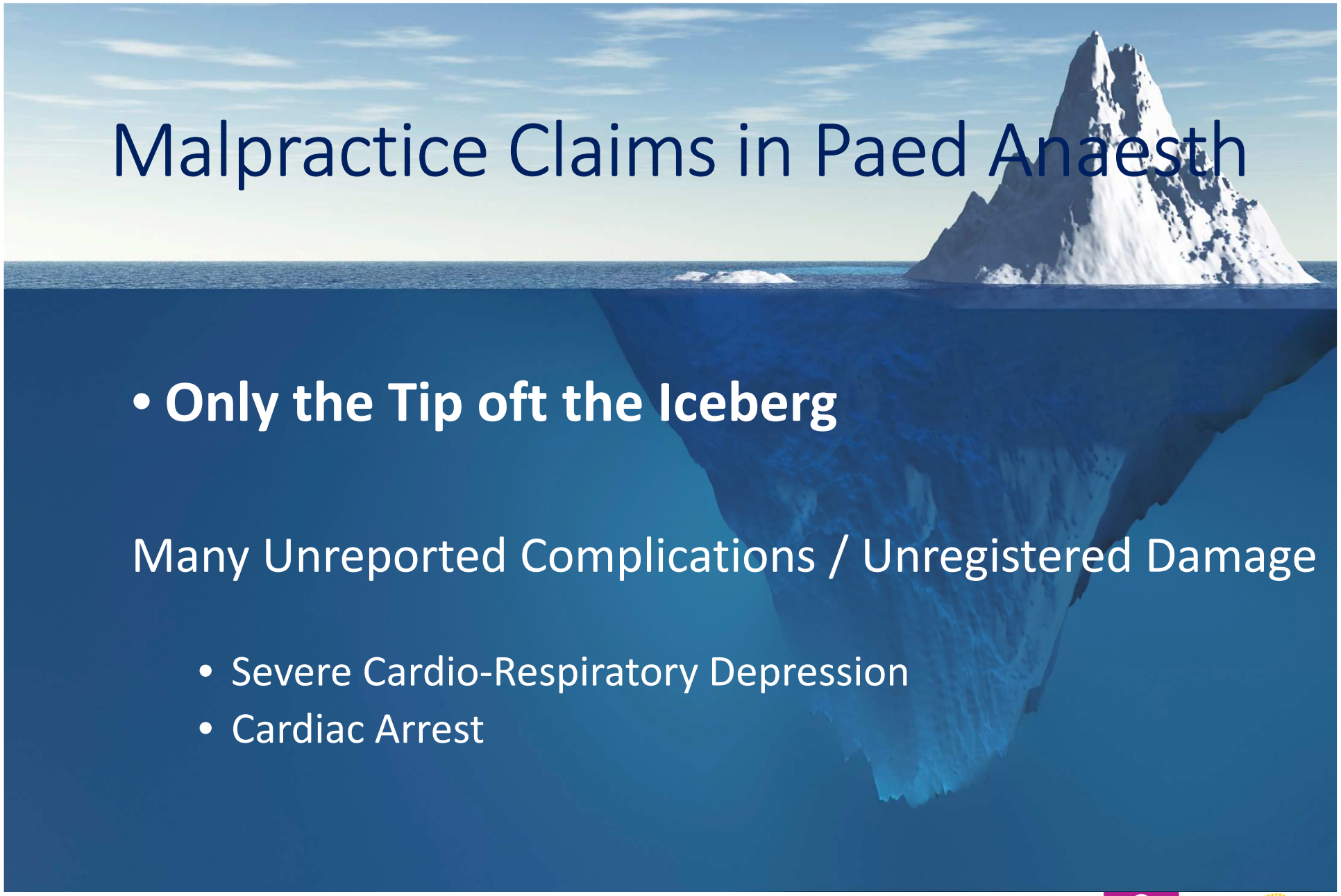
What is unsafe in Paed Anaesth?

- Hypoxaemia / Bradycardia



Poets CF - JAMA 2015

Malpractice Claims in Paed Anaesth

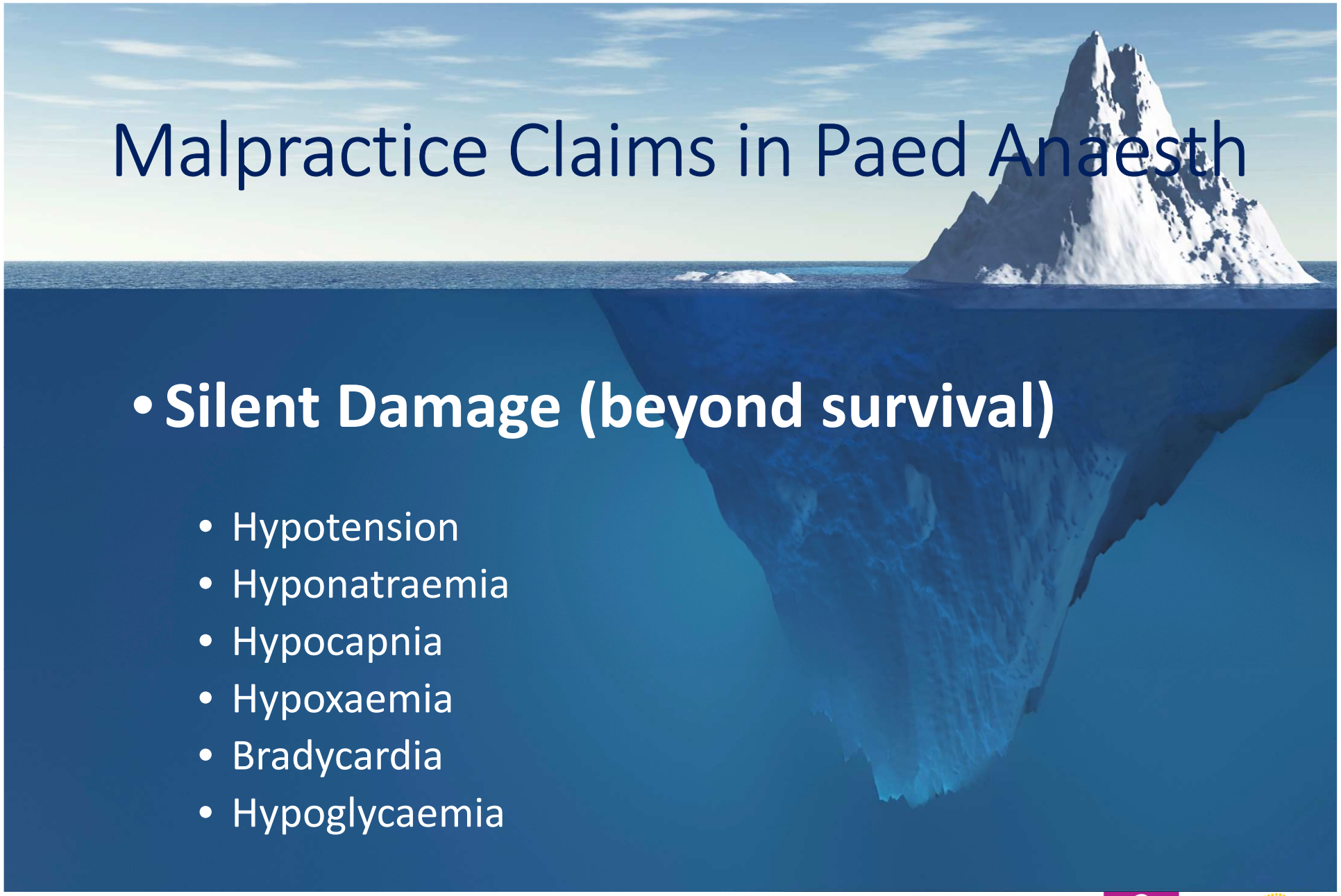


- **Only the Tip oft the Iceberg**

Many Unreported Complications / Unregistered Damage

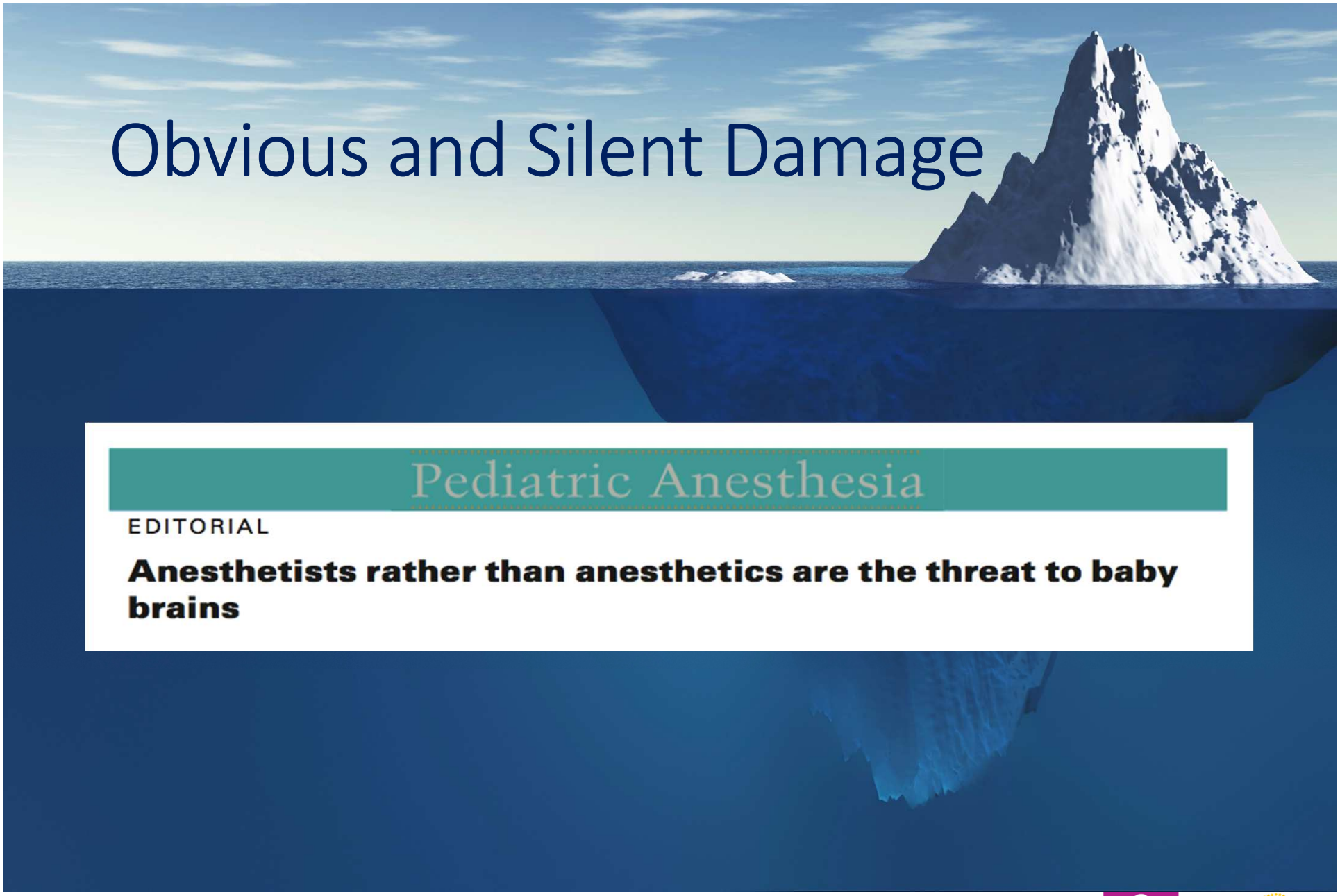
- Severe Cardio-Respiratory Depression
- Cardiac Arrest

Malpractice Claims in Paed Anaesth



- **Silent Damage (beyond survival)**
  - Hypotension
  - Hyponatraemia
  - Hypocapnia
  - Hypoxaemia
  - Bradycardia
  - Hypoglycaemia

Obvious and Silent Damage



Pediatric Anesthesia

EDITORIAL

Anesthetists rather than anesthetics are the threat to baby brains

Weiss M et al – Pediatr Anesth 2013

Anaesthesia Morbidity ignored …

Anesthetic Neurotoxicity — Clinical Implications of Animal Models

Bob A. Rappaport, M.D., Santhanam Suresh, M.D., Sharon Hertz, M.D., Alex S. Evers, M.D., and Beverley A. Orser, M.D., Ph.D.



Rappaport BA - NEJM 2015

Anaesthesia Morbidity ignored …

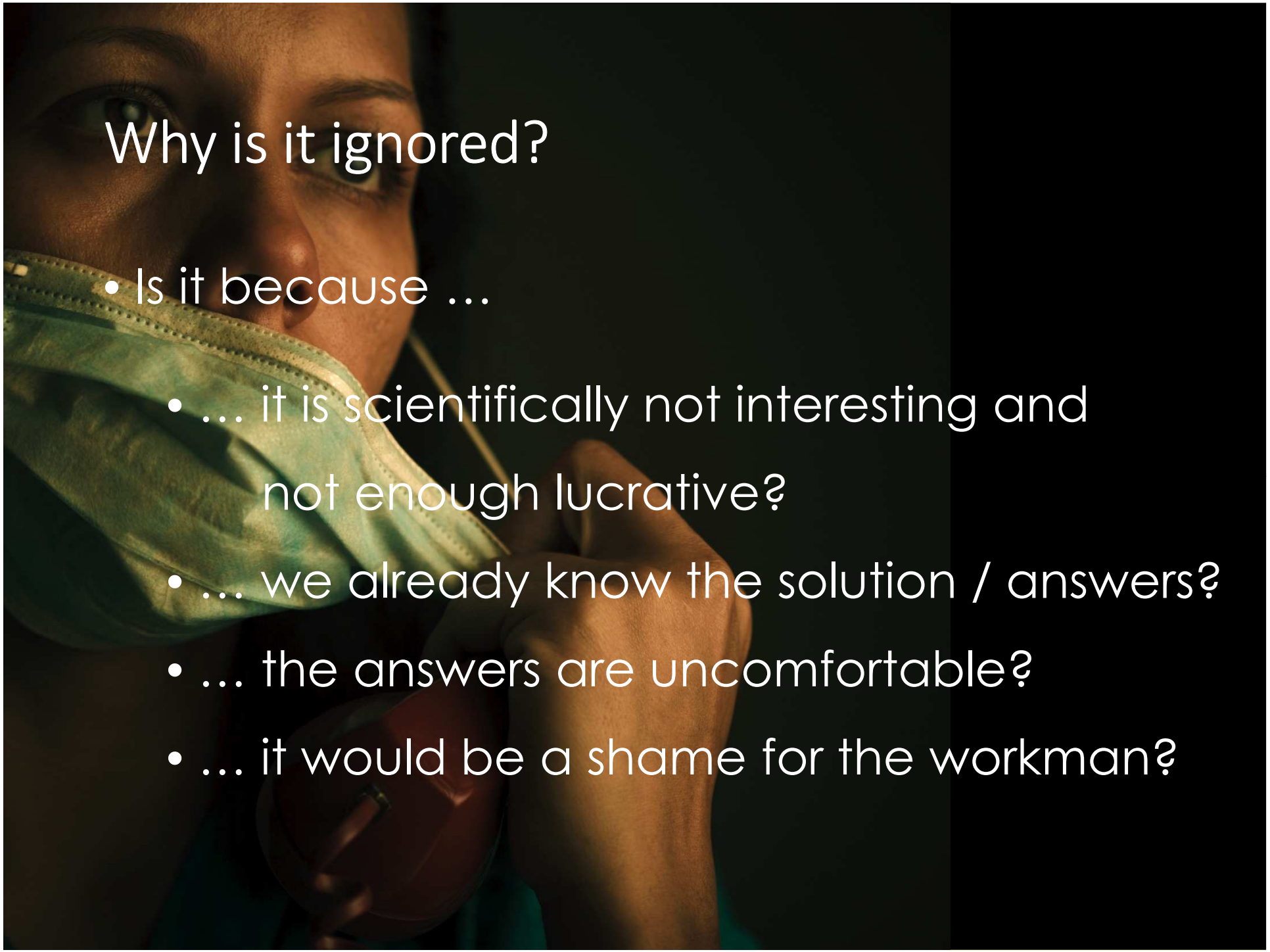
Neurotoxicity of Generic Anesthesia Agents in Infants and Children

An Orphan Research Question in Search of a Sponsor

Bruce M. Psaty, MD, PhD[1,2]; Richard Platt, MD, MS[3,4]; Russ B. Altman, MD, PhD[5,6]

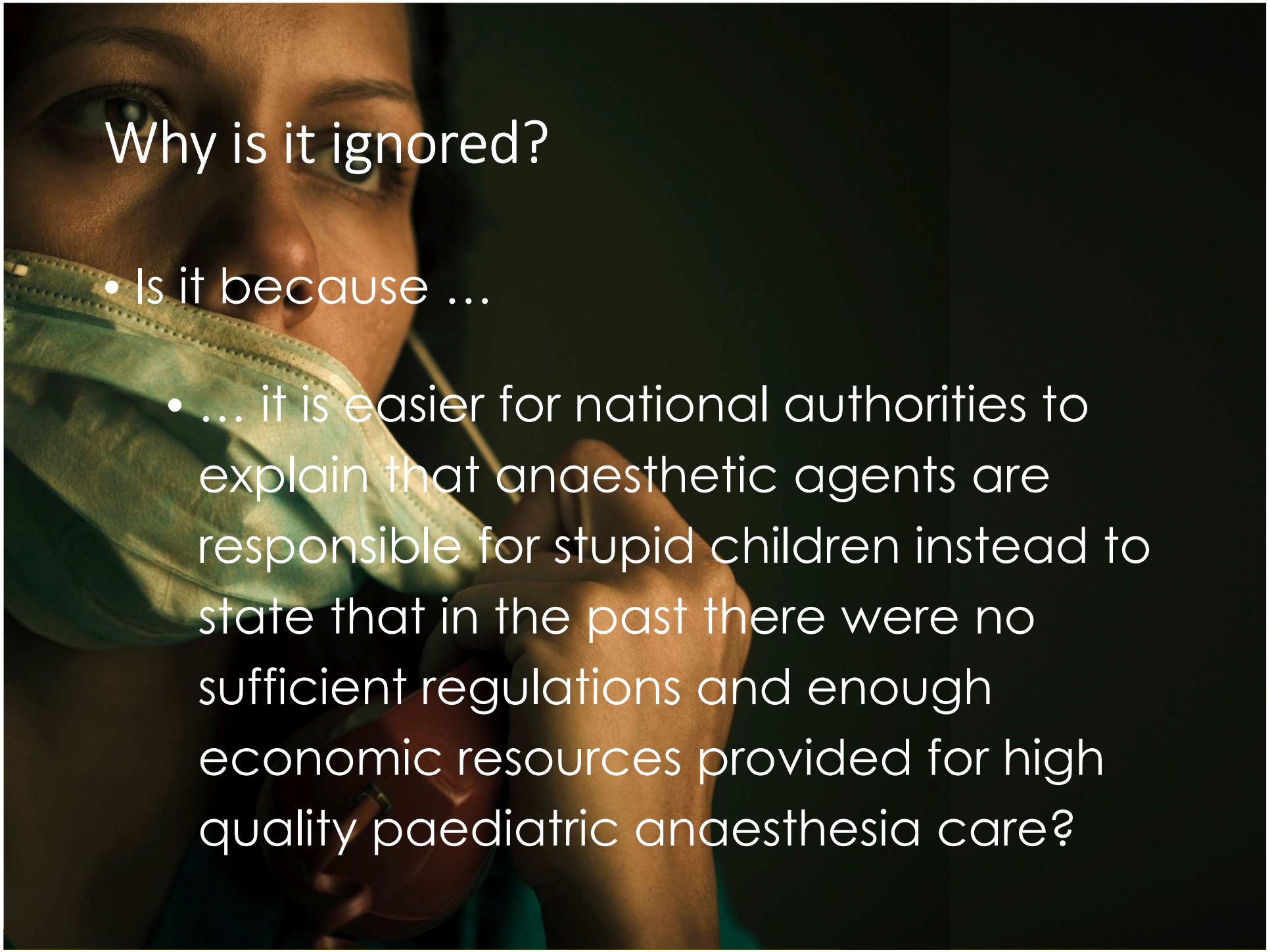


Psaty BM - JAMA 2015



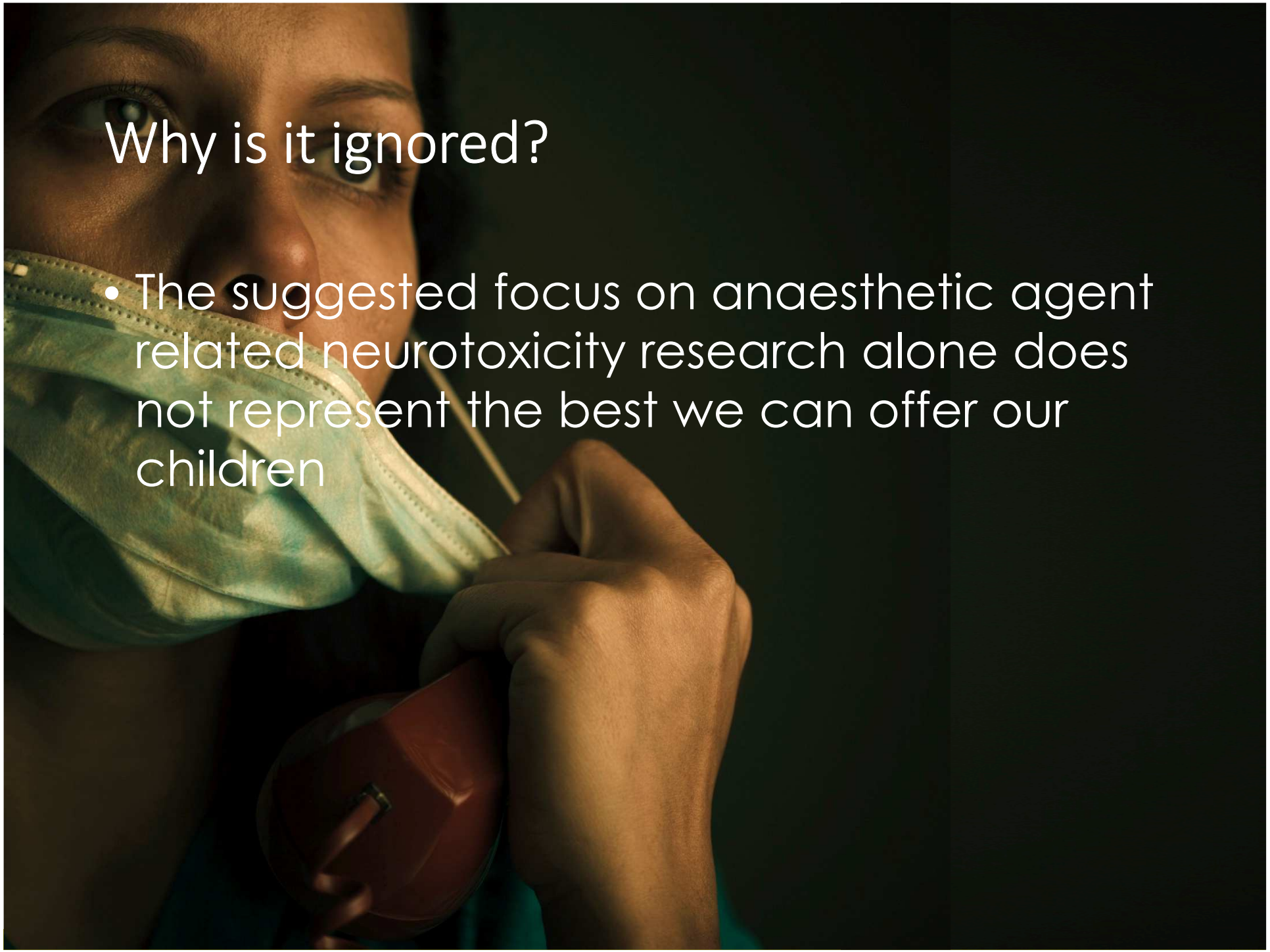
Why is it ignored?

- Is it because …
  - … it is scientifically not interesting and not enough lucrative?
  - … we already know the solution / answers?
  - … the answers are uncomfortable?
  - … it would be a shame for the workman?



Why is it ignored?

- Is it because …
  - … it is easier for national authorities to explain that anaesthetic agents are responsible for stupid children instead to state that in the past there were no sufficient regulations and enough economic resources provided for high quality paediatric anaesthesia care?



Why is it ignored?

- The suggested focus on anaesthetic agent related neurotoxicity research alone does not represent the best we can offer our children

Defining Safe Paed Anaesth



ESPA

Bordeaux 1 April 2016

Defining the …

- the WHO …
- the WHERE …
- the WHEN …
- the HOW …



The WHO

- Children undergoing anaesthesia must be anaesthetized by well trained and experienced paediatric anaesthesiologists



The WHO

- Minimum case load of a paediatric anaesthesiologist

Table 1
Frequency of current experience for a children's anaesthetist

Class	Monthly	Weekly	Daily	i.e. Annually
1 (Infants < 6 months)	√			12
2 (Children and infants < 3 years)		√		50
3 (Children < 10 years)			√	300



Lunn JN – Paediatr Anaesth 1992
Auroy Y – Anesth Analg 1997

The WHO

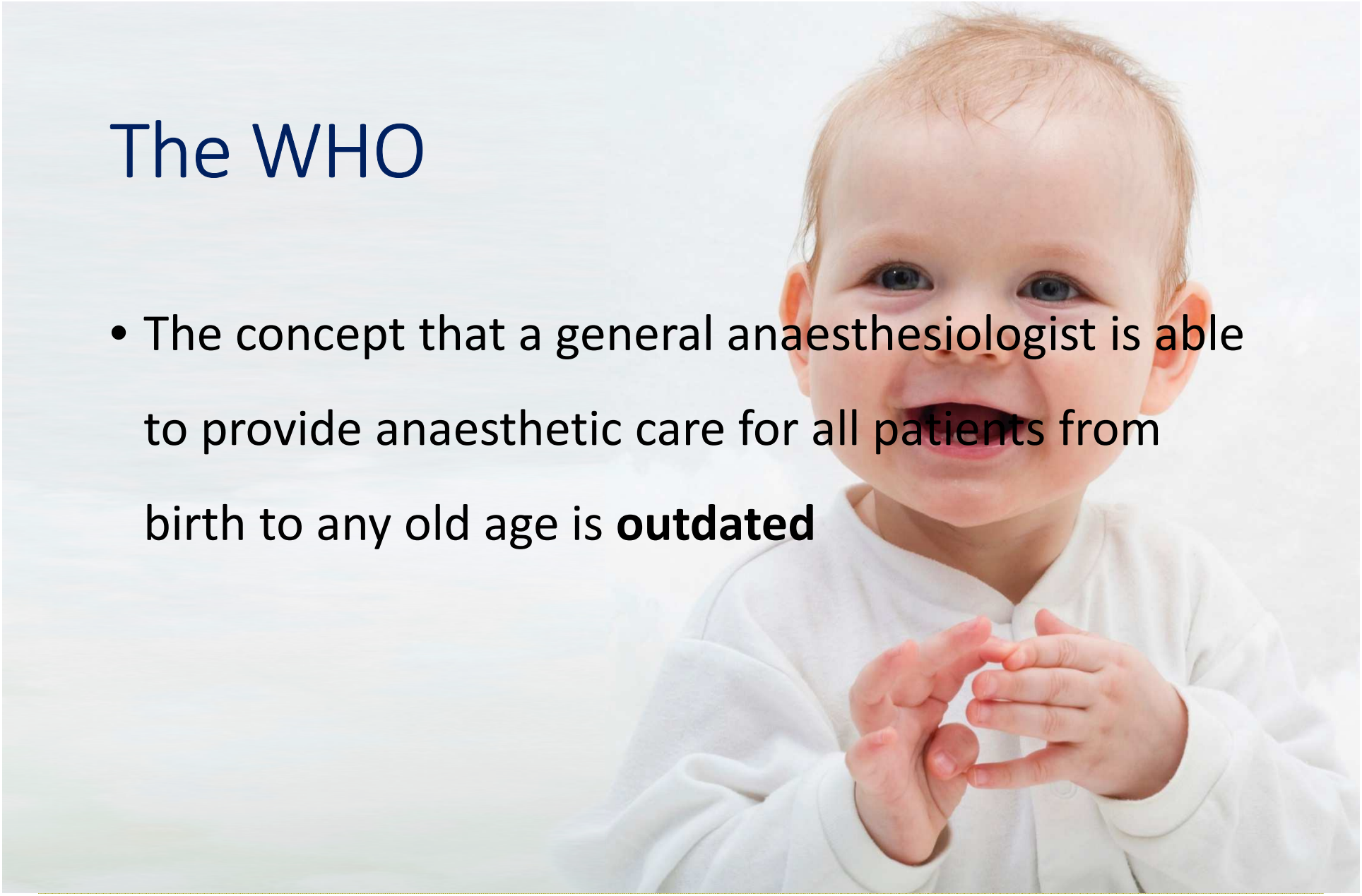


- Residents/fellows in paediatric anaesthesia must be supervised in 1:1 manner by an experienced paediatric anaesthesiologist

.

NCEPOD - Report 1989

The WHO



- The concept that a general anaesthesiologist is able to provide anaesthetic care for all patients from birth to any old age is **outdated**

Aknin P – Ann Fr Anesth Reanim 2000

The WHERE

- The paediatric population undergoing anaesthesia is too small in order to maintain sufficient skills for every anaesthesiologist



The WHERE



- Children undergoing anaesthesia should be regionally concentrated in centres

- Neonates and infants must be anaesthetized in specialized paediatric centres

The WHEN



- Balance
  - general anaesthesia risk in newborn and infants

    versus
  - impact of delaying of elective procedures on the surgical/diagnostic result
  - avoiding emergency procedures which do carry a higher peri-operative risk
  - postponing surgery may risk the future well-being of the child

The HOW

- Repeated and frequent pitfalls, dangers and risks lead to guidelines and rules for behaviour in risky areas …




Swimming Pool Guidelines
1. Appropriate swimwear must be worn in the pool at all times.
2. No diving or splashing about the pool area.
3. No running about the pool area.
4. No pool usage while under the influence of alcohol or drugs.
5. Anyone under the age of 12 must be accompanied at all times by an adult.
6. No glass, drinks or food are allowed in immediate the pool area.
7. No rough playing or undue disturbances in and about the pool.
8. No pets are allowed.
9. No lifeguard is on duty. All persons using the pool swim at their own risk and sole responsibility. The hotel accepts no liability for injuries, death or loss (e.g. articles of clothing, valuables, etc.) associated with the use of the pool.
إرشادات حمام السباحة
١. يتعين ارتداء ملابس السباحة اللائقة في حمام السباحة في جميع الأوقات.
٢. غير مسموح بالغطس أو برش المياه حول حمام السباحة.
٣. غير مسموح بالركض حول حمام السباحة.
٤. غير مسموح باستخدام حمام السباحة تحت تأثير الكحول.
٥. غير مسموح للأطفال دون الثانية عشرة باستخدام حمام السباحة بدون صحبة الكبار.
٦. غير مسموح باستخدام الأكواب أو المشروبات أو الطعام في المنطقة المحيطة مباشرة بحمام السباحة.
٧. غير مسموح باللعب العنيف أو بالتسبب في أي نوع من الإزعاج داخل حمام السباحة أو حوله.
٨. غير مسموح باصطحاب الحيوانات الأليفة.
٩. لا يتوفر أي عامل إنقاذ في منطقة حمام السباحة وبالتالي فإن جميع الأشخاص سيستخدمون حمام السباحة على مسؤوليتهم الشخصية، ولا يتحمل الفندق أي مسؤولية قانونية تجاه أي حالات إصابة أو وفاة أو فقدان (مثلا: الملابس أو المقتنيات الثمينة، وما إلى ذلك) و المرتبطة باستخدام حمام السباحة.

The HOW


The 10 - N - Paediatric
Anaesthesia
Quality Checklist
1. No Fear
2. Normovolaemia
3. Normotension
4. Normocardia
5. Normoxaemia
6. Normocapnia
7. Normonatraemia
8. Normoglycaemia
9. Normothermia
10. No Pain
RL/Gluk1%
167
98
22

The HOW


The 10 - N - Paediatric
Anaesthesia
Quality Checklist
1. No Fear
2. Normovolaemia
3. Normotension
4. Normocardia
5. Normoxaemia
6. Normocapnia
7. Normonatraemia
8. Normoglycaemia
9. Normothermia
10. No Pain
RL/Gluk1%
No Fear - No Awareness

The HOW

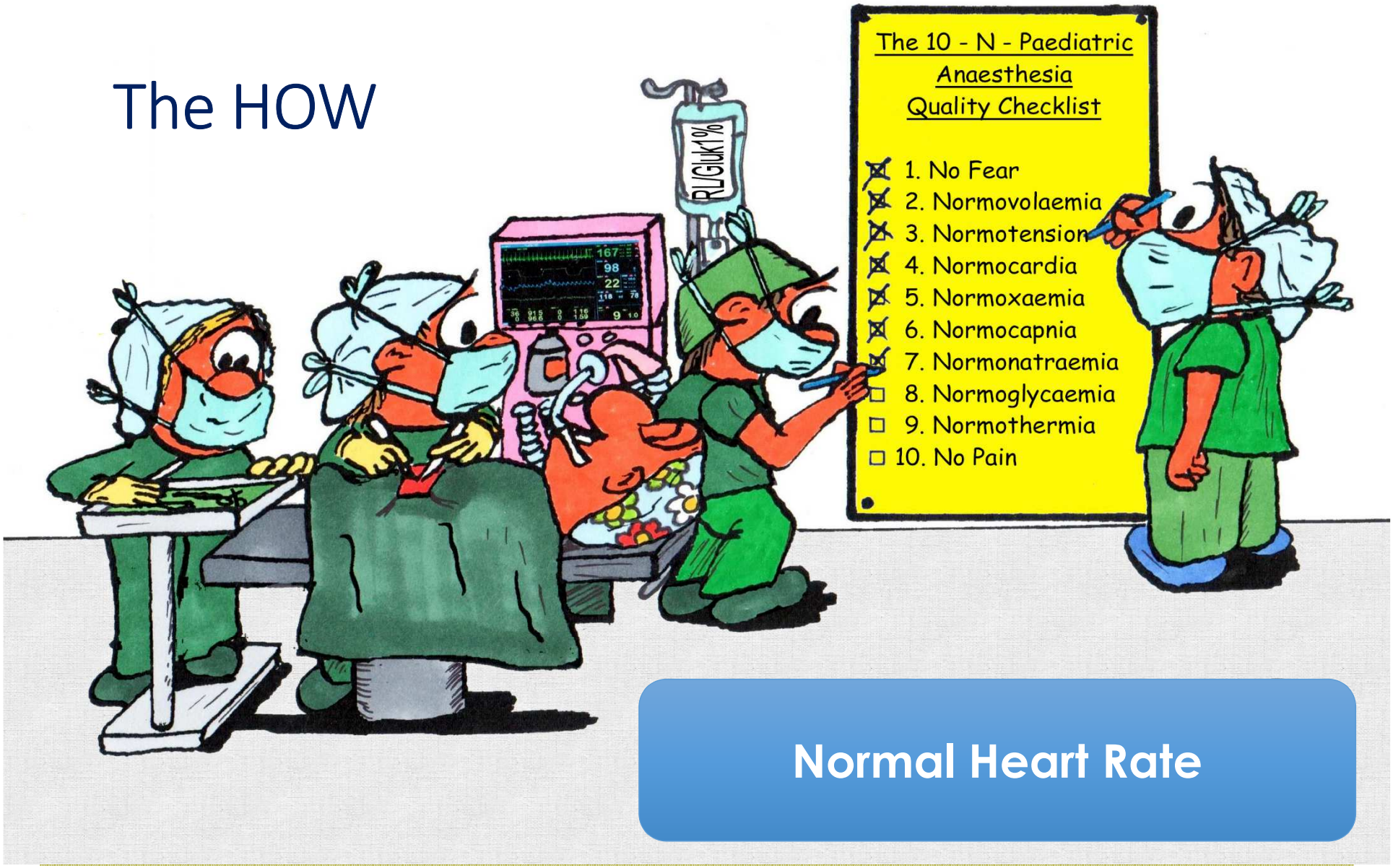


Normovolaemia

The HOW


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Anaesthesia
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8. Normoglycaemia
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98
22
Normotension

The HOW


The 10 - N - Paediatric
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RL/Gluk1%
167
98
22
Normal Heart Rate

The HOW



Normoxaemia

The HOW



Normocapnia

The HOW


The 10 - N - Paediatric
Anaesthesia
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5. Normoxaemia
6. Normocapnia
7. Normonatraemia
8. Normoglycaemia
9. Normothermia
10. No Pain
RL/Gluk1%
167
98
22
Normonaetraemia

The HOW



Normoglycaemia

The HOW


The 10 - N - Paediatric
Anaesthesia
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Normothermia

The HOW


The 10 - N - Paediatric
Anaesthesia
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7. Normonatraemia
8. Normoglycaemia
9. Normothermia
10. No Pain
RL/Gluk1%
No Pain

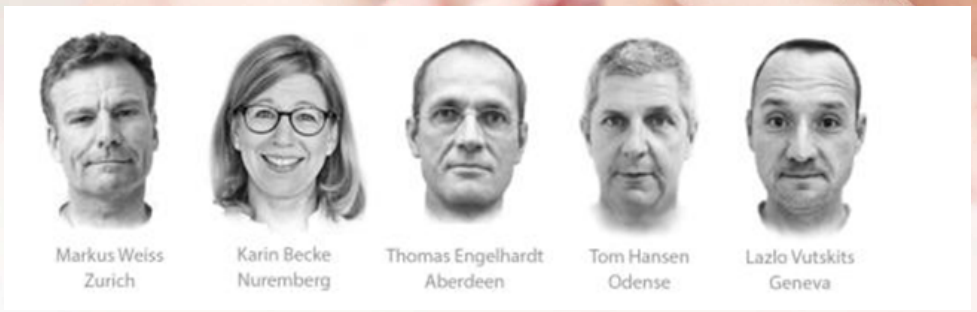
The HOW




The 10 - N - Paediatric
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8. Normoglycaemia
9. Normothermia
10. No Pain

www.safetots.org

Safe **A**naesthesia **F**or **E**very **Tot - Initiative**



SAFETOTS is a registered Trademark

Weiss M – Curr Opin Anesthesiol 2015

www.safetots.org

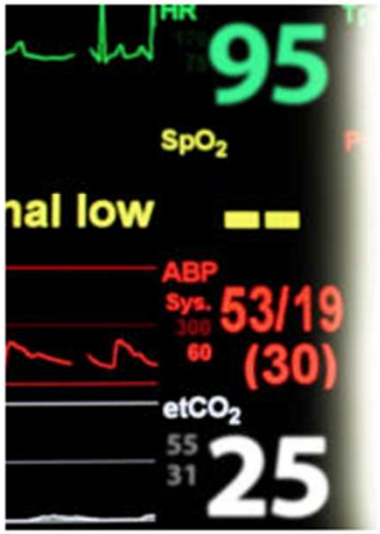
www.SAFETOTS.org



Safetots.org initiative illustrates the known perioperative causes for cerebral morbidity in young children.

www.safetots.org

www.SAFETOTS.org



"It is a poor workman who blames his tools"

Safetots.org initiative aims to focus on the safe conduct of pediatric anesthesia and to define safe use of anesthesia in young children.

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Safetots.org initiative illustrates the known perioperative causes for cerebral morbidity in young children.

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Safetots.org initiative aims to alert parents & practio-ners on the importance of education and experience of the pediatric anesthesiologist in charge.

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"Anesthesia related complications have a higher mortality in young children"



The initiative will define the 'who', 'where', 'when' and 'how' in this context which provides the framework for the safe conduct of pediatric anesthesia.

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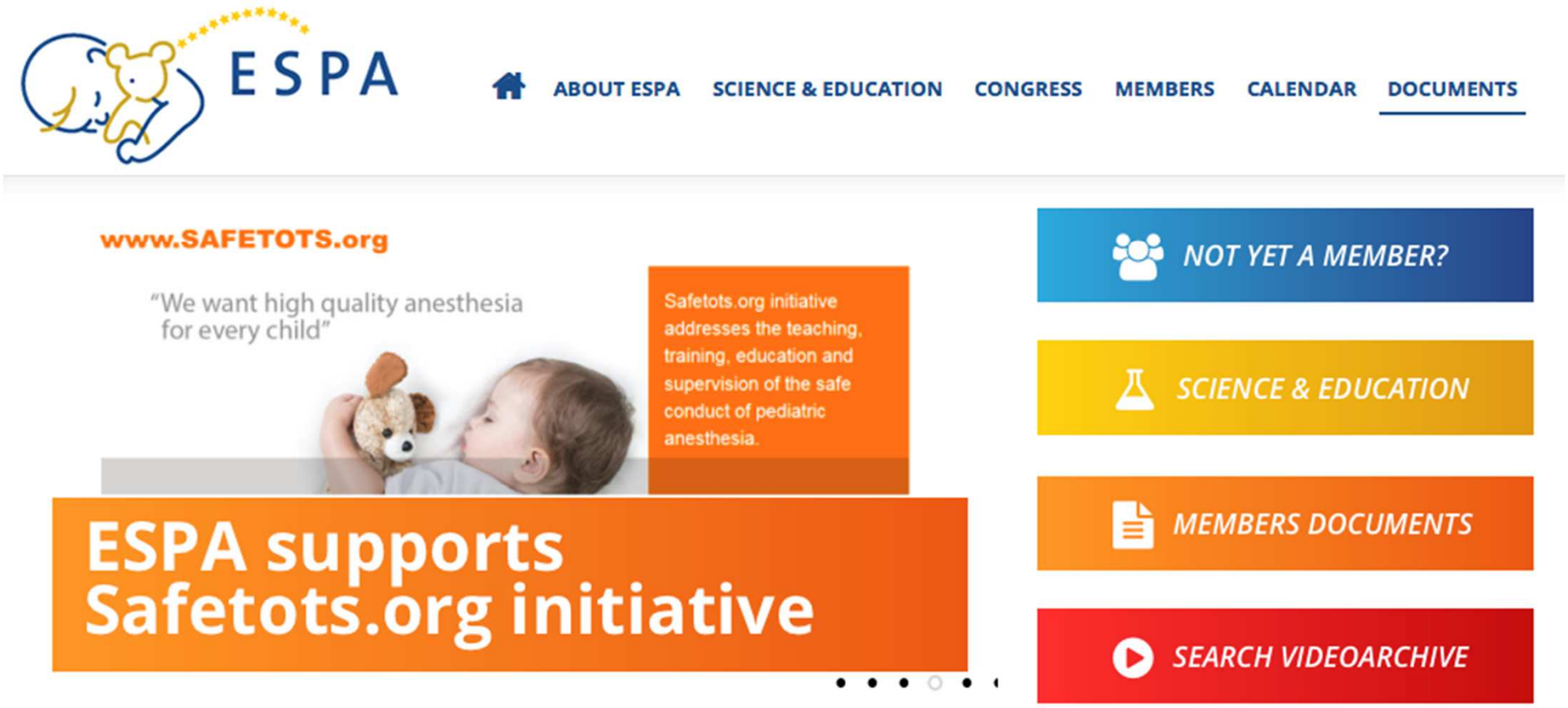
"We want high quality anesthesia for every child"



Safetots.org initiative aims to implement the rights for high quality anesthesia care for every child on an international and worldwide (WHO) level.

Weiss M – Curr Opin Anesthesiol 2015

www.safetots.org



Outlook

- **Before blaming our tools we have to ensure proper conduct of anaesthesia in all children**



Outlook

- Safetots.org
  - Website
  - Publications
  - Meetings
  - Public work



Outlook

- Research
  - Epidemiological Studies
  - Monitoring Studies
  - Outcome Studies



Outlook

European Society of Anaesthesiology ESA

ABOUT US | CONGRESSES | EDUCATION | RESEARCH | PATIENT SAFETY

APRICOT





APRICOT: Anaesthesia PRactice In Children Observational Trial:

www.esahq.org/apricot

ESPA

Bordeaux 1 April 2016

Outlook

European Society of Anaesthesiology ESA

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NECTARINE





NECTARINE: NEonate-Children audiT of Anaesthesia pRactice IN Europe.

www.esahq.org/apricot

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Thank you