CASE REPORT : SINGLE-USE CRANIAL DRILLS, HIGH-RISK DEVICES !

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SCAN ME !

BACKGROUND & IMPORTANCE

Single-use cranial drills

- Used in neurosurgery to perforate cranial bones
- Connectors : Hudson chuck + motor
- Automatic disengagement

ACCUMULATION OF ADVERSE EVENTS (AEs)

From june 2018 to October 2020

- 18 AEs recorded in our hospital :
- ✓ 7 of which resulted in a material safety declaration to the *Agence Nationale de Sécurité du Médicament et des produits de santé* for risk of cerebral damage

AIM & OBJECTIVES

- **Analyse the causes** of these AEs in order to propose corrective and preventive measures

MATERIALS & METHODS

- **Chronological analysis** of Material Safety (MS) data
- Contact and discussions with **the various people involved in the circuit :** the operating room, the biomedical ingineering, the sterilisation department
- **Other healthcare establishments were questionned** to obtain feedback on the management of this type of AE
- Search of MS data *via* **the American MAUDE database was carried out for the period**, targeting the devices used in our centre
- **Causal analysis** using the 5M method : Ishikawa diagram

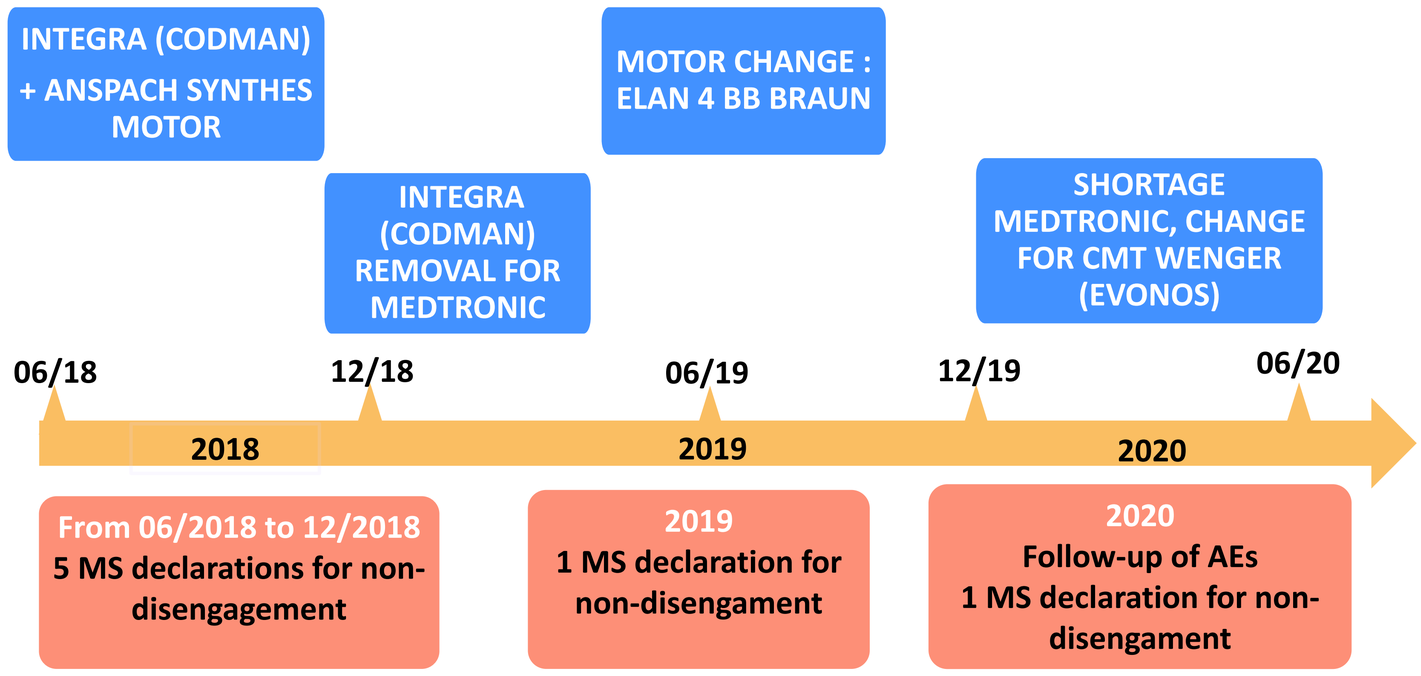

Figure 1 : Timeline showing AEs and equipment for cranial drills and engines at Rennes University Hospital

RESULTS

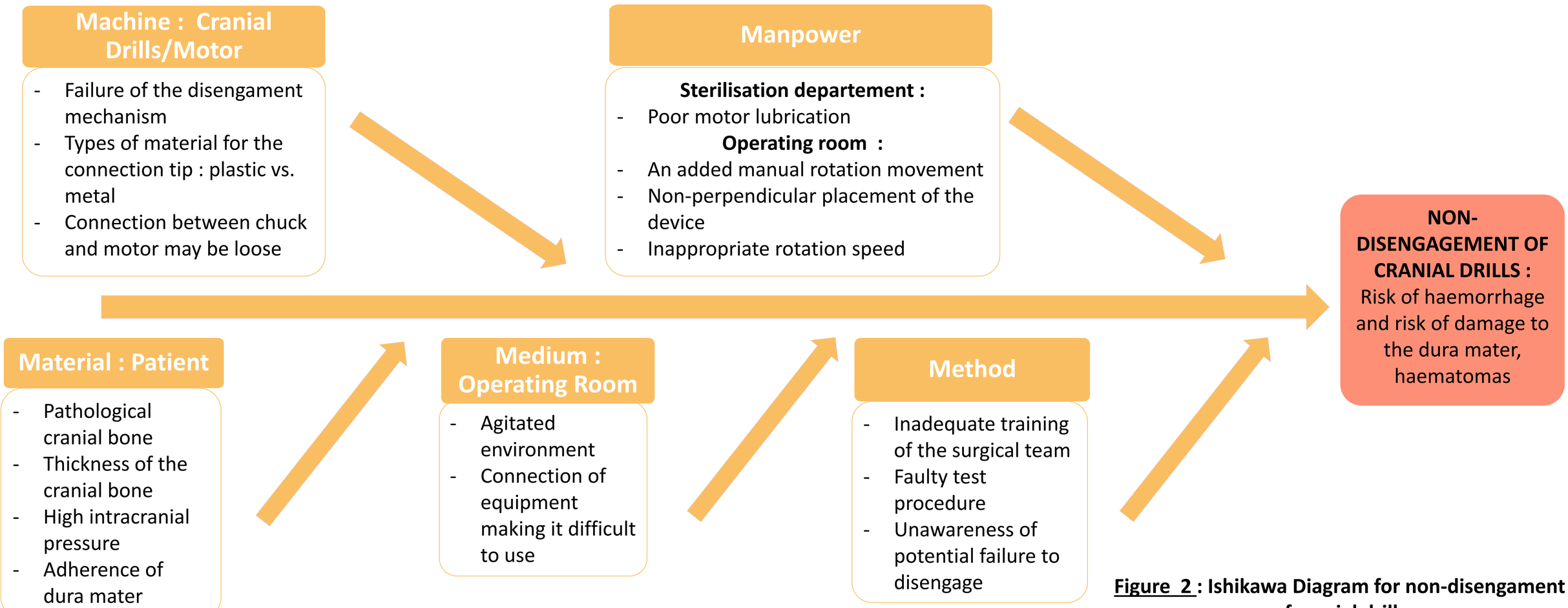

Figure 2 : Ishikawa Diagram for non-disengament of cranial drills

CORRECTIVE MEASURES

- ✓ Iterative change of supplier for cranial drills
- ✓ Training for the medical team : evidence of inappropriate motor rotation speed
- ✓ Monitoring of abnormal connection between chuck and motor nationally by the supplier
- ✓ Biomedical intervention: overhaul of motors, testing of a new Hudson chuck

PREVENTIVE MEASURES

- ✓ Integrate disengagement performance into cranial drills selection criteria

CONCLUSION & RELEVANCE

- Single-use cranial drills require **careful handling for optimum disengagement**
- The material causes have been identified, but **the human component cannot be ruled out**
- Corrective measures have been **implemented** to reduce the risk of these AEs
- Preventive measures also need to **be developed** such as revised selection criteria for the next call for tenders, or **best practices audits in the operating room**
- The impact of these corrective and preventive measures will be assessed though **AEs monitoring**

ID : NP-008
28TH EAHP CONGRESS : 20-21-22 MARCH 2024, Bordeaux
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