CAN MEDICAL DEVICE REGULATIONS ENDANGER CLINICAL PRACTICE IN PEDIATRIC SURGERY?

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BACKGROUND

New European Medical Devices Regulation (MDR) came into effect in May 2021.

Regulatory complexity and stricter requirements have led to devices shortages and discontinuation of certain devices in Europe.

Orphan and pediatric devices are at a higher risk, impacting clinical practice for pediatric surgery and fetal medicine.

AIM / METHODS

We conducted a non-anonymous, network-wide survey to collect information on how the MDR is affecting clinical practice across the 52 centers within ERNICA.

RESULTS

37 responses

27 centres

16 European countries

Created with: www.mapchart.net/europe.html

33 respondents reported being affected by the MDR, with **the most mentioned devices** being:

RBI2 instrument for rectal suction biopsies to diagnose Hirschsprung's Disease
Gore-Tex mesh & **Gore Dualmesh** used in Congenital Diaphragmatic Hernia and abdominal wall defects
Gastrojejunal G-JET Tube
Bentec Medical silo for Gastroschisis

Impact on patient care:

Increased risk of complications: HCPs report having to use more invasive procedures or suboptimal alternative devices

Increased costs for hospitals and/or patients: Alternative devices are often more expensive or not reimbursed, while more invasive procedures are associated with increased hospital resources.

CONCLUSION

The findings highlight serious concerns about continuity of care in pediatric surgery and fetal medicine.

ERNICA can have a key role in mitigating the impact on patient care, safeguarding access, and fostering innovation.

FOLLOW-UP PLANS

Reaching **consensus on which alternative devices** are most suitable and disseminating recommendations → Providing input to the **regulatory amendment** via consultations and continued dialogue with the EC

Representing ERNICA HCPs in **EMA's medical device expert panels** → Connecting with **manufacturers and professional societies**, such as **EUPSA**, to explore cooperation

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