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MEMORANDUM

Date: 9/8/2022
Re: Triage algorithms for medical imaging pose a safety risk to children
From: ACR Pediatric AI Workgroup
To: Patients and their families and the medical imaging community

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TOPIC DESCRIPTION AND SIGNIFICANCE

- **In medical imaging, children are recognized as different than adults**
- Artificial Intelligence (AI) medical devices are being used to guide healthcare decisions, including AI devices that prioritize the order in which studies should be interpreted
- **To date, all FDA cleared imaging triage algorithms are cleared exclusively for use in adults**
- ***AI Triage algorithms that prioritize studies with findings for urgent interpretation pose an immediate threat to pediatric patient care in healthcare systems that care for pediatric and adult patients in a shared work environment***

CASE SCENARIO ILLUSTRATING THE PROBLEM

- A common triage device detects intracranial hemorrhage (bleeding in or around the brain) on head CT's
- Intracranial hemorrhage is an emergency; the earlier it is detected, the better the outcome
- Children and adults are both affected by intracranial hemorrhage, with hemorrhage reported in nearly a quarter of children younger than 2 years imaged with head CT
- In healthcare systems that care for both children and adults, if triage devices are used in adults but not in children, delays in care for children with intracranial hemorrhage must be anticipated
- Alternatively, if these adult devices are used on children, there are reasons to think they will not work, including differences in pediatric head circumference, brain structures, and pathophysiology. For example, in epidural hemorrhage (the type needing the most emergent surgery), there is usually an associated skull fracture in adults, but not kids
- 75% of pediatric imaging has historically been performed in mixed healthcare systems

RECOMMENDATIONS

- Immediate **warning to consumers** that **triage devices may pose risk of harm to children** when **used in mixed adult and pediatric healthcare systems for prioritization of medical imaging interpretation**
- Resource allocation to determine extent of the problem, including to mitigate potential harm to both adults and children
- Require **visible standard verbiage for all FDA labelled medical devices** to include (1) *the age of subjects the devices were tested*, and (2) *the age group in whom the devices are applicable*, and a warning when a device has not been cleared for pediatric use
- Support **legislation incentivizing AI medical device development for pediatric patients**, for example through tax incentives for vendors developing AI for children
- Support legislation that would allow FDA to **require AI device submissions** developed for use in adults **also be developed for pediatric use**, if applicable to children
- Advocate for **increased federal funding for pediatric healthcare AI research**
- Propose prioritizing AI devices designed for pediatric patients within the FDA clearance process

HEADQUARTERS
1891 Preston White Drive
Reston, VA 20191
703-648-8900

GOVERNMENT RELATIONS
505 Ninth St. N.W.
Suite 910
Washington, DC 20004
202-223-1670

CENTER FOR RESEARCH AND INNOVATION
50 South 16th St., Suite 2800
Philadelphia, PA 19102
215-574-3150

ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY
1100 Wayne Ave., Suite 1020
Silver Spring, MD 20910
703-648-8900