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Knowledge and Attitudes of Healthcare Workers toward Ethical Management of Medical Artificial Intelligence Application in Pediatrics: A Cross-Sectional Study

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Knowledge and Attitudes of Healthcare Workers toward Ethical Management of
Medical Artificial Intelligence Application in Pediatrics: A Cross-Sectional Study

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ABSTRACT

Objectives Various MAI-driven systems have been put into use, which challenged the clinical experience and sense of agency among pediatric healthcare workers in consultation, diagnosis, and treatment. We aimed to investigate knowledge and attitudes toward Ethical Management of Medical Artificial Intelligence Application in Pediatrics among healthcare workers.

Design A single-center cross-sectional study using convenience sampling.

Setting Data from a tertiary children’s hospital in July 2022 in Shanghai, China.

Participants There were 137 pediatricians, 135 nurses and 60 health information technicians. Both inclusion criteria should be met: (i) working as a pediatrician (including graduate students in pediatrics), nurse, and health information technician in the hospital, (ii) with experience in using pediatric MAI system at work. Participants were excluded if their answering time was less than 150 seconds which was based on a pilot survey, or their answers were illogical.

Primary and secondary outcome measures Healthcare workers’ knowledge and attitude level toward ethical management of MAI application in pediatrics were investigated through 21-item Likert scale questionnaire. The participants’ gender, age, educational level, occupation, and professional titles were also collected.

Results Most of the participants had low-level knowledge, and high-level awareness of ethics implementation in pediatric AI. In the knowledge dimension, 3.6%-29.5% of the participants replied to “not at all familiar”, 37.0%-53.6% replied to “slightly familiar”. In the attitude dimension, 52.4%-62.0% of them replied to “agree” and 19.9%-33.7% replied to “strongly agree”. Health information technicians accounted for the highest proportion of the participants who had high-level knowledge, and doctors accounted for the highest proportion among those who had high-level acceptance.

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Conclusions It is important to popularize the basic knowledge and conduct further research to verify approaches for ethics implementation in MAI.

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INTRODUCTION

Artificial Intelligence (AI) originated at Dartmouth Conference in 1956. The AI system in our study refers to the one with the capacity to process data and information by reasoning, learning, perceiving, predicting, planning, or controlling.^{1,2} The application of AI systems in the clinical domain is characterized by screening high-risk individuals for a certain disease, matching effective personalized treatment, facilitating clinical decisions, and improving resource allocation and personal health management.³⁻⁵

Children might not clearly provide medical history by themselves or cooperate well with physical examination, which increased the difficulties in diagnosis, treatment, and nursing care. In contrast to the heavy workload in pediatric clinical practice, there is a great shortage of pediatric healthcare workers in China. According to the 2021 China Health Statistics Yearbook, the number of pediatricians was 168,000, and the number of pediatricians per 1,000 children (0-14 years old) was 0.66 as of 2020.⁶ Recently the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the World Health Organization (WHO) both advocated the development and deployment of MAI for children and youth. Supported by algorithms, more AI-driven systems for pediatric clinical practices have consequently brought about new scenes of its application such as analyzing radiology imaging of children,^{7,8} making an accurate diagnosis for children with the common or rare disease based on electronic medical records or multimodal clinical data,⁹⁻¹² identifying the risk of early deterioration for critically ill children through medical record data and video materials,^{13,14} and using robots for pre-consultation, triage and referrer for children.¹⁵ However, while AI brings higher efficiency, accuracy, and convenience to pediatric clinic, it also leads to ethical issues such as privacy protection, prejudice, and determination of medical damage

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infringement liability, alienation of doctor-patient relationship, and assuring human rights for decision-making.^{16,17}

Research institutions both in China and other countries have put forward several principles, guidelines, and norms for ethical governance of MAI, such as the WHO guidance of *Ethics and Governance of Artificial Intelligence for Health* and the UNESCO recommendation on the ethics of artificial intelligence issued in June and November 2021 respectively,^{1,17} the *New Generation of Ethical Norms of Artificial Intelligence* by the Ministry of Science and Technology of China published in September 2021,¹⁸ and the *Guidelines of Strengthening Governance over Ethics in Science, Technology* by the General Office of the State Council of China issued in March 2022.¹⁹ They laid a theoretical foundation for ethical governance on MAI development and application, while focusing on MAI in pediatric, there were also some suggestions on the aspects of core values in pediatric medicine such as privacy, safety, fairness, and accountability. In addition, the real risk of future ethical issues is not only from AI system design, but also its deployment.²⁰ Ethical considerations for AI system often work on the hypothetical situations where the system will be built. Once AI system comes into use in the real world, the actual ethics issues may deviate from the original design control. Above and beyond building AI algorithms in medicine, deploying them for clinical use is incredibly complex. This process requires the availability of a massive amount of data, integration into complex existing clinical workflows, compliance with clinical norms, guarantee of patient safety, concerns about the financial aspect, as well as keeping healthcare workers' dominance in aspects of diagnosis, treatment, and nursing care.²¹ Ethical questions regarding AI systems in medicine pertain to all stages of AI system life cycle. For most of the pediatric clinical healthcare workers, their roles as MAI actors are end-users, not researchers,

programmers, engineers, or data scientists. It is an important role in the whole life cycle of MAI system in pediatrics. The crucial step toward ethical management in MAI is to learn the awareness and views of these participants about it.

The survey of ethical management toward MAI application in pediatric healthcare workers with end-users' role would help clarify the dilemmas of it, draw on countermeasures, and avoid risk in the future application of MAI application in pediatrics.

METHODS

Study Design and setting

This cross-sectional study was carried out following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement in July 2022 at Children's Hospital of Fudan University (a national children's medical center in Shanghai, China). Data were collected through the Questionnaire Star application (a professional questionnaire survey application in China). QR code generated by the application was provided to the director of medical service department, nursing department and medical information center of the hospital, who were responsible for informing all eligible healthcare workers (including postgraduate medical students) to fill out the questionnaire on cellphone by scanning the code. All the questions were set as compulsory questions and the questionnaire could only be submitted once by a participant.

The study was approved by the Research Ethics Board of Children's Hospital of Fudan University (No.2022-52). Informed consent was obtained from all participants involved in the study.

Patient and public involvement

No patient involved.

Participants and sampling

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We used convenience sampling to select participants. Both inclusion criteria should be met: (i) working as a pediatrician (including graduate students in pediatrics), nurse, and health information technician in the hospital, (ii) with experience in using pediatric MAI system at work. Participants were excluded if their answering time was less than 150 seconds which was based on a pilot survey, or their answers were illogical (such as same answers to all items, unreasonable answers to birthday, etc)

We estimated the sample size using the adjusted Yamane's formula,²² setting the alpha level at 0.05, population size at 1580, margin of error at 0.05, and p at 4, and a sample size of 222 individuals was required. Assuming a 20% attrition rate,²³ 265 participants were finally recruited for this study.

Measures

The basic information data collected included gender, age, educational level (Bachelor's degree, Master's degree, Doctor's degree, Others), occupation (pediatrician, nurse, or health information technician), and professional titles (ungraded, junior, intermediate, and senior).

In order to understand the healthcare workers' knowledge and attitude level toward ethical management of MAI application in pediatrics, 21-item Likert scale questionnaire was used. Regarding the knowledge on ethical management of MAI application, it was asked by 10 questions, data were collected from the answers ranging from 'not at all familiar' to 'extremely familiar'. Regarding the attitude of ethical management of MAI application, it was asked by 11 questions, data were collected from the answers ranging from 'strongly disagree' to 'strongly agree'. Prior the study, we performed factor analysis for construct validity, calculated the interrater agreement (IRR), item-level content validity index(I-CVI), scale-level CVI (S-CVI) for content validity, and

Cronbach alpha coefficient for internal consistency. The factor analysis showed good construct validity of the two components of knowledge and attitudes. The inter-rater agreement, I-CVI, and S-CVI were excellent. The Cronbach's alpha of knowledge and attitude was 0.964 and 0.933 respectively which showed good reliability. The questionnaire was pre-tested in a convenience sample of 6 healthcare workers. Based on their feedback, minor changes were made to enhance clarity and appropriateness of the questions.

Statistical analysis

Microsoft Office Excel 365 for Windows (Microsoft Corp, Redmond, USA) was used to establish a database. Data were analyzed using SPSS V.25.0 for Windows (IBM, Armonk, New York, USA). The response rate was calculated by the number of final participants divided by recruited participants to the survey. The basic characteristics and responses were described as n (%), and Chi-square test was used to test differences of proportions among pediatricians, nurses, and health information technicians. No plan for missing data was required, as participants finished the questionnaire completely.

RESULTS

Participants

Of the 411 healthcare workers who were recruited to participate, 359 completed questionnaires were returned, with a response rate of 87.3%. 27 questionnaires were excluded (5 with illogical birthday answers, 13 with short answering time, and 9 with the same answers to all the items). Finally, 332 questionnaires were included in the analysis. The age of the final participants ranged from 19 to 56 years old (Mean=32.39 , SD=7.232). As shown in Table 1, 176 (53.0%) were female, 116 (34.9%) were pediatricians, 21(6.3%) graduate students, 135(40.7%) nurses, and 60 (18.1%)

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health information technicians. Among the participants, 35.5% of them held a master's degree or above and senior professional accounted for 46.1%.

Table 1 Basic information of participants

Characteristic	Participants [n (%)]
Gender	
Male	156 (47.0)
Female	176 (53.0)
Occupation	
Pediatrician	116 (34.9)
Nurse	135 (40.7)
Graduate student	21 (6.3)
Health information technician	60 (18.1)
Education level	
Other lower	48 (14.5)
Bachelor's degree	166 (50.0)
Master's degree	103 (31.0)
Doctor's degree	15 (4.5)
Professional titles	
Ungraded	58 (17.5)
Junior	153 (46.1)
Intermediate	81 (24.2)
Senior	40 (12.0)

Knowledge and attitude level toward ethical management of MAI application in pediatrics

In the knowledge dimension, nearly none of the participants have achieved 'extremely familiar' at all questions of the relevant knowledge of ethical management of MAI application in pediatrics. Marking all the questions in this dimension with K1 to K10, and K1 was the top question which the participants chose 'moderately familiar' most, but that only accounted for 9.6%. K5 was the bottom question with 'moderately familiar' to all the participants, that accounts for 3.9%. Most of the

participants chose ‘not at all familiar’, "rarely familiar" or "uncertain" to questions in the knowledge dimension, among which "rarely familiar" answers were most common (Table 2).

Marking all the questions in the attitude dimension with A1 to A11, most of the participants agreed with the statement in A1-A3, A5, A6, A8 and A9. In A4, 41.9% of the participants held neutral attitude, while the rest of the participants have great disputes on the statement, which the same situation in A7, A10 and A11(*Table 3*).

Table 2 Participants’ knowledge to ethical management of MAI application in pediatrics (N=322)

Knowledge	Not at all familiar n (%)	Rarely familiar n (%)	Uncertain n (%)	Moderately familiar n (%)	Extremely familiar n (%)
K1 Understanding of pediatric MAI system	12(3.6)	123(37.0)	165(49.7)	32(9.6)	0(0.0)
K2 Common ethical issues of pediatric MAI system	43(13)	165(49.7)	102(30.7)	22(6.6)	0(0.0)
K3 Causes of K2	58(17.5)	154(46.4)	102(30.7)	18(5.4)	0(0.0)
K4 Coping strategies to K2	66(19.9)	179(23.8)	79(23.8)	8(2.4)	0(0.0)
K5 Principles, norms and guidelines of ethical management in MAI	71(21.4)	175(52.7)	72(21.7)	13(3.9)	1(0.3)
K6 Policies or regulations of ethical management in MAI	85(25.6)	173(52.1)	66(19.9)	8(2.4)	0(0.0)
K7 Content of ethical review of pediatric MAI	91(27.4)	178(53.6)	55(16.6)	8(2.4)	0(0.0)
K8 Ethical supervision mechanism while using Pediatric MAI system	104(31.3)	170(51.5)	53(16.0)	10(3.0)	0(0.0)
K9 Ethical risk Management while using Pediatric MAI system	98(29.5)	171(51.5)	53(16.0)	10(3.0)	0(0.0)
K10 Consequences of ethical violations while using MAI system in pediatrics	82(24.7)	163(49.1)	69(20.8)	18(5.4)	0(0.0)

Table 3 Participants’ attitude to ethical management of MAI application in pediatrics (N=322)

Attitude	Strongly disagree n (%)	Disagree n (%)	Neutral n (%)	Agree n (%)	Strongly agree n (%)
A1 AI experts should be involved in research ethics committee while reviewing MAI application study.	5(1.5)	13(3.9)	66(19.9)	182(54.8)	66(19.9)
A2 Principles, norms and guidelines of ethical management should be easy to understand and be transformed into workable process.	2(0.6)	3(0.9)	47(14.2)	179(53.9)	101(30.4)

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A3 Ethical expert should be involved in pediatric MAI application project.	0(0.0)	4(1.2)	56(16.9)	169(50.9)	103(31.0)
A4 An unified way of ethical review can be a barrier to the technical innovation of pediatric MAI.	10(3.0)	77(23.2)	139(41.9)	80(24.1)	26(7.8)
A5 The subject of ethical responsibility in pediatric MAI should be clarified.	1(0.3)	3(0.9)	59(17.8)	198(59.6)	71(21.4)
A6 Participating in ethical education and training program focusing on MAI is helpful.	0(0.0)	3(0.9)	46(13.9)	206(62.0)	77(23.2)
A7 It is necessary to take children's and guardians' opinions into account while providing direct care to children through AI system. When children's opinions are contrary to the guardians', we should adopt the guardians' ones.	3(0.9)	59(17.8)	81(24.4)	132(39.8)	57(17.2)
A8 Establishing effective supervision mechanism is helpful.	1(0.3)	3(0.9)	42(12.7)	174(52.4)	112(33.7)
A9 Content of ethical supervision can be dynamically adjusted according to the clinical context.	2(0.6)	10(3.0)	63(19.0)	176(53.0)	81(24.4)
A10 After totally understanding the ethical risk while using MAI system, the proportion of children or guardians who refuse to use it will increase.	4(1.2)	69(20.8)	139(41.9)	102(30.7)	18(5.4)
A11 Strict ethical risk management can hinder MAI system using in pediatrics.	7(2.1)	72(21.7)	139(41.9)	93(28.0)	21(6.3)

Comparison of knowledge and attitude toward ethical management of MAI application in pediatrics among different occupational groups

In order to describe the result more directly, in the knowledge dimension, 'not at all familiar' and 'rarely familiar' were merged together as 'not familiar', 'moderately familiar' and 'extremely familiar' are merged together as 'familiar'. Similarly, in the attitude dimension, 'strongly disagree' and 'disagree' were merged as 'disagree', 'agree' and 'strongly agree' were merged as 'agree'. Graduate students who had Practicing Physician Qualification Certificate belonged to pediatricians. Then, we compared the answers to the questions in knowledge and attitude dimension among different occupation groups.

It was found that pediatricians, nurses, and health information technicians showed significant differences in the proportions to the answers at 'unfamiliar', 'uncertain' and 'familiar' in K1-K3 and K5, where health information technicians accounted for the highest proportion at 'familiar',

followed by pediatricians then nurses (*Table 4*). In the attitude dimension, participants from different occupation groups showed significant differences in the proportions to the answers at ‘disagree’, ‘neutral’ and ‘agree’ in A1-A3, A5, A6, A8 and A9, where pediatricians or nurses accounted for the highest proportion at ‘agree’, followed by health information technicians. However, in A4, A7, A10 and A11, pediatricians, nurses and health information technicians held relative balanced proportions at ‘disagree’, ‘neutral’ and ‘agree’, indicating that there were debates in the views towards the statements of the four questions (*Table 5*).

Table 4 Comparison of knowledge toward ethical management of MAI application in pediatrics among different occupational groups [N of pediatricians=137, N of nurses=135, N of health information technicians (HIT)=60]

Knowledge	Pediatricians n (%)	Nurses n (%)	HIT n (%)	Chi-Square, χ^2	Sig, P
K1 Understanding of pediatrics MAI system					
Unfamiliar 135(40.7)	54(39.4)	67(49.6)	14(23.3)	20.064	<0.001
Uncertain 165(49.7)	71(51.8)	61(45.2)	33(55.0)		
Familiar 32(9.6)	12(8.8)	7(5.2)	13(21.7)		
K2 Common ethical issues of pediatric MAI system					
Unfamiliar 208(62.7)	83(60.6)	95(70.4)	30(50.0)	11.311	0.023
Uncertain 102(30.7)	44(32.1)	36(26.7)	22(36.7)		
Familiar 22(6.6)	10(7.3)	4(3)	8(13.3)		
K3 Causes of K2					
Unfamiliar 212(63.9)	81(59.1)	99(73.3)	32(53.3)	10.969	0.027
Uncertain 102(30.7)	49(35.8)	31(23.0)	22(36.7)		
Familiar 18(5.4)	7(5.1)	5(3.7)	6(10.0)		
K4 Coping strategies to K2					
Unfamiliar 45(73.8)	99(72.3)	106(78.5)	40(66.7)	7.753	0.101
Uncertain 79(23.8)	36(26.3)	27(20.0)	16(26.7)		
Familiar 8(2.4)	2(1.5)	2(1.5)	4(6.7)		
K5 Principles, norms and guidelines of ethical management in MAI					
Unfamiliar 246(74.1)	96(70.1)	110(81.5)	40(66.7)	16.128	0.003
Uncertain 72(21.7)	38(27.7)	21(15.6)	13(21.7)		
Familiar 14(4.2)	3(2.2)	4(3.0)	7(11.7)		

K6 Policies or regulations of ethical management in MAI					
Unfamiliar 258(77.7)	107(78.1)	108(80.0)	43(71.7)	3.045	0.550
Uncertain 66(19.9)	27(19.7)	25(18.5)	14(23.3)		
Familiar 8(2.4)	3(2.2)	2(1.5)	3(5)		
K7 Content of ethical review of pediatric MAI					
Unfamiliar 269(81.0)	111(81.0)	113(83.7)	45(75.0)	6.334	0.176
Uncertain 55(16.6)	24(17.5)	20(14.8)	11(18.3)		
Familiar 8(2.4)	2(1.5)	2(1.5)	4(6.7)		
K8 Ethical supervision mechanism while using Pediatric MAI system					
Unfamiliar 274(82.5)	115(83.9)	112(83.0)	47(78.3)	2.495	0.646
Uncertain 50(15.1)	20(14.6)	20(14.8)	10(16.7)		
Familiar 8(2.4)	2(1.5)	3(2.2)	3(5.0)		
K9 Ethical risk Management while using Pediatric MAI system					
Unfamiliar 269(81.0)	112(81.8)	111(82.2)	46(76.7)	4.120	0.390
Uncertain 53(16.0)	23(16.8)	20(14.8)	10(16.7)		
Familiar 10(3.0)	2(1.5)	4(3.0)	4(7.7)		
K10 Consequences of ethical violations while using MAI system in pediatrics					
Unfamiliar 245(73.8)	100(73.0)	105(77.8)	40(66.7)	9.260	0.055
Uncertain 69(20.8)	28(20.4)	28(20.7)	13(21.7)		
Familiar 18(5.4)	9(6.6)	2(1.5)	7(11.7)		

Table 5 Comparison of attitude toward ethical management of MAI application in pediatrics among different occupational groups [N of pediatricians=137, N of nurses=135, N of health information technicians (HIT)=60]

Attitude	Pediatricians n (%)	Nurses n (%)	HIT n (%)	Chi-Square, χ^2	Sig, P
A1 AI experts should be involved in research ethics committee while reviewing MAI application study.					
Disagree 18(5.4)	8(5.8)	5(3.7)	5(8.3)	16.315	0.003
Neutral 66(19.9)	14(10.2)	34(25.2)	18(30.0)		
Agree 248(74.7)	115(83.9)	96(71.1)	37(61.7)		
A2 Principles, norms and guidelines of ethical management should be easy to understand and be transformed into workable process.					
Disagree 5(1.5)	3(2.2)	1(0.7)	1(1.7)	10.320	0.035
Neutral 47(14.2)	10(7.3)	24(17.8)	13(21.7)		
	124(90.5)	110(81.5)	46(76.7)		

Agree 280(84.3)					
A3 Ethical expert should be involved in pediatric MAI application project.	1(0.7)	1(0.7)	2(3.3)	17.971	0.001
Disagree 4(1.2)	11(8.0)	28(20.7)	17(28.3)		
Neutral 56(16.9)	125(91.2)	106(78.5)	41(68.3)		
Agree 272(81.9)					
A4 An unified way of ethical review can be a barrier to the technical innovation of pediatric MAI.					
Disagree 87(26.2)	33(24.1)	33(24.4)	21(35.0)	3.442	0.487
Neutral 139(41.9)	60(43.8)	59(43.7)	20(33.3)		
Agree 106(31.9)	44(32.1)	43(31.9)	19(31.7)		
A5 The subject of ethical responsibility in pediatric MAI should be clarified.	0(0.0)	2(1.5)	2(3.3)	11.958	0.018
Disagree 4(1.2)	17(12.4)	25(18.5)	17(28.3)		
Neutral 59(17.8)	120(87.6)	108(80.0)	41(68.3)		
Agree 269(81.0)					
A6 Participating in ethical education and training program focusing on MAI is helpful.					
Disagree 3(0.9)	0(0.0)	2(1.5)	1(1.7)	10.858	0.028
Neutral 46(13.9)	13(9.5)	18(13.3)	15(25.0)		
Agree 283(85.2)	124(90.5)	115(85.2)	44(73.3)		
A7 It is necessary to take children's and guardians' opinions into account while providing direct care to children through AI system. When children's opinions are contrary to the guardians', we should adopt the guardians'.	32(23.4)	20(14.8)	10(16.7)	3.667	0.453
	30(21.9)	35(25.9)	16(26.7)		
Disagree 62(18.7)	75(54.7)	80(59.3)	34(56.7)		
Neutral 81(24.4)					
Agree 189(56.9)					
A8 Establishing effective supervision mechanism is helpful.	0(0.0)	2(1.5)	2(3.3)	13.088	0.011
Disagree 4(1.2)	9(6.6)	21(15.6)	12(28.3)		
Neutral 42(12.7)	128(93.4)	112(83.0)	46(66.7)		
Agree 286(86.1)					
A9 Content of ethical supervision can be dynamically adjusted according to the clinical context.					
Disagree 12(3.6)	3(2.2)	6(4.4)	11(18.3)	9.893	0.042
Neutral 63(19.0)	17(12.4)	29(43.0)	29(48.3)		
Agree 257(77.4)	117(85.4)	100(35.6)	20(33.3)		
A10 After totally understanding the ethical risk while using MAI system, the proportion of children or guardians who refuse to use it will increase.	33(24.1)	29(21.5)	40(66.7)	2.062	0.724
Disagree 73(22.0)	52(38.0)	58(20.7)	13(21.7)		

Neutral	139(41.9)	52(38.0)	48(1.5)	7(11.7)		
Agree	120(36.1)					
A11 Strict ethical risk management can hinder MAI system using in pediatrics.		36(26.3)	29(21.5)	14(23.3)	1.223	0.874
Disagree	79(23.8)	54(39.4)	58(43.0)	27(45.0)		
Neutral	139(41.9)	47(34.4)	48(35.6)	19(31.7)		
Agree	114(34.3)					

DISCUSSION

The applications for AI systems in health care provided expected results including identification of individuals at high risk for a disease, improving diagnosis, matching effective personalized treatment, and optimizing cost-effectiveness.^{16, 24} In pediatrics, projected benefits associated with MAI are reflected in using decision support system to make accurate and personalized diagnosis and nursing intervention, big data sources (including patient electronic medical records, exam and laboratory information, dynamic video images of patients) to help identify risks and prognosis of some diseases, or robots to better allocate pediatric nurses' time and efforts so that they could pay more attention to direct patients' care.²⁵⁻³⁰ However, MAI system also has the potential to threaten values of autonomous decision-making of doctors or nurses, privacy, and safety of pediatric patients or their caregivers, which were core values in medicine.^{31, 32} Previous studies on ethical management in AI paid more attention to regulating researchers, programmers, engineers, data scientists in the stages of research, design, and development, but failed to notice that ethical questions regarding AI pertain to all stages of its life cycle, and those at the end-of-use stage is equally important. Therefore, in order for the MAI system to promote quality of care and minimize potentially disruptive effects, its deployment and use must take ethics into account.³³ Obtaining the information about the end-users' awareness and views toward ethical management while using pediatric MAI system may help policymakers make more meaningful and implementable ethical norms or policies, which are the premises to promote the implementation of

MAI ethical governance.

In the survey, we investigated pediatricians, nurses and health information technicians who never participated in the research of development or application of MAI systems but were in the use of or used to use pediatric MAI system at work. The proportion of pediatricians was roughly equal to that of nurses, the proportion of health information technicians was relatively small here. In the knowledge dimension, 3.6%-29.5% of the participants chose 'not at all familiar' to the questions, 37.0%-53.6% chose 'rarely familiar', 2.4%-9.2% chose 'moderately familiar', only one respondent chose 'extremely familiar' to K5. It showed that the overall knowledge -level of all participants was low, which was consistent with the results of Zheng.³⁴ While analyzing the answers to each question, we found that when the question referring to the detailed approaches of ethical management, the level of awareness was extremely low, such as ethical principles, guidelines, or norms (2.4% of the participants chose 'moderately familiar'), coping strategies to ethics issues (2.4% of the participants chose 'moderately familiar'), supervision mechanism and risk management (3% of the participants chose 'moderately familiar'). Comparison of knowledge among different occupational groups, it could be seen that health information technicians accounted for the highest proportion at 'familiar', followed by pediatricians then nurses, which suggested that it is necessary for the hospital administrators to provide a training program for pediatricians and nurses at ethical management in the use stage of MAI system life cycle.

Concerning the attitudes of healthcare workers towards ethical management in the use of pediatric MAI system, we found that their views on the statement of A1-A3, A5, A6, A8 and A9 were mostly positive, especially pediatricians and nurses have more proportions of positive attitudes, and we could deduce that they had the motivation to implement ethics in the use of MAI system and

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were willing to promote it, where the premise is that they could get the appropriate knowledge. We also found that there were debates among pedestrians, nurses and health information technicians at the statement of A4, A7, A10 and A11. Among them, the debates about A4, A10 and A11 have verified some research results, such as when we emphasized on the threatening aspects from AI, ethical regulation in MAI was the only solution to ensure safety, autonomy, and privacy, however when we commenced to practice regulation, the embarrassing was that supervision always lagged the development of artificial intelligence technology.^{35, 36} On the other hand, the technology based on artificial intelligence is widely dependent on big data, which is easily influenced by misjudgment and prejudice, and these could result in inequality in healthcare.^{16,37} The debate at A4 originated from the different cultural backgrounds of the east and the west. In ancient Chinese culture, the under-age needs to absolutely follow their parents' instructions, while in western culture, the wishes of children of school age and above who have cognitive ability should be respected. How to balance the children's willing and their parents' decision against Chinese cultural background is still a challenge deserving further consideration and discussion.

Strengths and limitations of this study

This study presented convenience samples from only one children's hospital in Shanghai, although it is a national medical center in China, which still potentially limited the possibility of generalizing the results. Selection bias related to narrow inclusion and exclusion criteria may also have occurred. Thus, new studies in different and larger populations can help to validate our findings.

CONCLUSION

The survey results revealed that pediatric healthcare workers had low-level knowledge, and high-level awareness. It is important to popularize the necessary knowledge of ethical management

of MAI among them, and it is necessary to conduct further research to verify approaches for ethical management in MAI.

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Comparative survey among pediatricians, nurses, and health information technicians in ethics implementation knowledge and attitude of social experiments based on medical artificial intelligence at children's hospitals in Shanghai: a cross-sectional study

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1 Comparative survey among pediatricians, nurses, and health information technicians in
2 ethics implementation knowledge and attitude of social experiments based on medical
3 artificial intelligence at children's hospitals in Shanghai: a cross-sectional study
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ABSTRACT

Objectives Implementing ethics is crucial to prevent harm and promote widespread benefits in social experiments based on medical artificial intelligence (MAI). However, insufficient information is available concerning this within the pediatric healthcare sector. We aimed to conduct a comparative survey among pediatricians, nurses, and health information technicians regarding ethics implementation knowledge and attitude of MAI social experiments at children's hospitals in Shanghai.

Design and setting A cross-sectional electronic questionnaire was administered from July 1, 2022, to July 31, 2022, at tertiary children's hospitals in Shanghai.

Participants All the eligible individuals were recruited. The inclusion criteria were: (i) being a pediatrician, nurse, and health information technician at the hospital, (ii) having been engaged in or currently participating in social experiments based on MAI, and (iii) being voluntary participation in the survey.

Primary outcome Ethics implementation knowledge and attitude of MAI social experiments among pediatricians, nurses, and health information technicians.

Results There were 137 pediatricians, 135 nurses, and 60 health information technicians who responded to the questionnaire at tertiary children's hospitals. 2.4%-9.6% of participants were familiar with ethics implementation knowledge of MAI social experiments. 34.3%-86.1% of participants held an 'agree' ethics implementation attitude. Health information technicians accounted for the highest proportion of the participants who were familiar with the knowledge of implementing ethics, and pediatricians accounted for the highest proportion among those who held 'agree' attitudes.

Conclusions There is a significant knowledge gap and variations in attitudes among pediatricians,

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45 nurses, and health information technicians, which underscore the urgent need for individualized
46 education and training programs to enhance MAI ethics implementation in pediatric healthcare.

47 **Strengths and limitations of this study**

- 48 ⇒ In this cross-sectional study, less than one-tenth of participants were familiar with ethics
49 implementation knowledge of MAI social experiments. More than three-fourths of participants
50 held an 'agree' ethics implementation attitude.
- 51 ⇒ Health information technicians accounted for the highest proportion of familiar those with the
52 knowledge of implementing ethics, and pediatricians accounted for the highest proportion
53 among those holding 'agree' attitudes.
- 54 ⇒ The findings indicated a significant knowledge gap and variations in attitudes among
55 pediatricians, nurses, and health information technicians, which underscore the urgent need for
56 individualized education and training programs on MAI ethics implementation within different
57 occupations.
- 58 ⇒ The limitations included specific conducted context, online surveys, and self-reporting, self-
59 designed questionnaires.

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INTRODUCTION

Medical artificial intelligence (MAI) is rapidly advancing and has the potential to revolutionize healthcare. China has a large population base, and there is an insufficient distribution of medical resources, particularly in the field of pediatrics. According to the 2021 China Health Statistics Yearbook, the total number of pediatricians in China was reported to be 168,000. This data corresponds to a ratio of approximately 0.66 pediatricians per 1,000 children aged 0-14 years old, as of the year 2020.¹ The utilization of algorithms can facilitate the emergence of various AI-driven systems for pediatric clinical practices, including the analysis of radiology imaging in children,^{2,3} enable accurate diagnoses for children with common or rare diseases based on electronic medical records or multimodal clinical data,⁴⁻⁷ identify the risk of early deterioration in critically ill children by leveraging medical record data and video materials.^{8,9} Robots can also be employed for pre-consultation, triage, and referral services for children, further expanding the scope of AI implementation in pediatric healthcare.¹⁰ Therefore, implementing artificial intelligence in pediatric healthcare in China is indeed a pressing need.

An MAI social experiment refers to a research study or intervention that utilizes artificial intelligence (AI) technology in the context of social interactions and healthcare. Conducting MAI social experiment is crucial for exploring the application of MAI and analyzing its potential impacts, which helps properly handle the relationship between medical artificial intelligence, humans, and society.¹¹⁻¹³ Due to the high level of uncertainty and significant ethical risks associated with medical artificial intelligence, implementing ethics in these social experiments is of utmost importance.^{14,15} Research institutions in China and other countries have made significant efforts to establish principles, guidelines, and norms for the ethical governance of MAI. Prominent examples include

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89 the WHO Guidance of *Ethics and Governance of Artificial Intelligence for Health*, the UNESCO
90 recommendation on the ethics of artificial intelligence issued in June and November 2021
91 respectively,^{15,16} Health Insurance Portability and Accountability Act (HIPAA)the *New Generation*
92 *of Ethical Norms of Artificial Intelligence* by the Ministry of Science and Technology of China
93 published in September 2021,¹⁷ and the *Guidelines of Strengthening Governance over Ethics in*
94 *Science, Technology* by the General Office of the State Council of China issued in March 2022.¹⁸
95 There are also helpful regulatory frameworks. In the United States, MAI must be approved by the
96 Food and Drug Administration (FDA, that classifies them as "software as a medical device"), while
97 the collection, storage, and disclosure of personal health information is regulated mainly by the 1996
98 Health Insurance Portability and Accountability Act (HIPAA). In the European Union, privacy
99 protection is guaranteed by the General Data Protection Regulation (GDPR), which applies when a
100 processor or controller processes personal data in the context of the activities of its establishment.¹⁹
101 Their contributions have laid a theoretical foundation for ethical governance in MAI social
102 experiments. While their focus was on pediatric patients, they also provided valuable suggestions,
103 including privacy, safety, fairness, and accountability.

104 Pediatricians, nurses, and health information technicians have more opportunities to be potential
105 researchers in MAI social experiments. Their ethics implementation knowledge and attitudes are
106 vital in mitigating ethical risks and then may influence decision-making processes and pediatric
107 patient care. However, studies explicitly focusing on pediatricians, nurses, and health information
108 technicians, investigating their ethics implementation knowledge and attitude of MAI social
109 experiments, are limited.

110 This cross-sectional study aims to fill this research gap by investigating and then comparing

ethics implementation knowledge and attitude of MAI social experiments among pediatricians, nurses, and health information technicians. This study will provide valuable insights into ethics implementation in MAI social experiments in pediatrics. The findings will contribute to developing tailored education and training programs and inform the formulation of guidelines and policies that promote AI's responsible and ethical use in children's hospitals.

METHODS

Study Design and setting

This cross-sectional study was conducted at two tertiary children's hospitals in Shanghai from July 1, 2022, to July 31, 2022, following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement. The study was approved by the Research Ethics Board of the Children's Hospital of Fudan University (No.2022-52). Informed consent was obtained from all participants involved in the study.

Patient and public involvement

No patient was involved in this study.

Participants and sampling

Participants in the study were voluntary, and the information collected was anonymous. All the eligible individuals were recruited. The inclusion criteria were: (1) being a pediatrician, nurse, or health information technician at the two hospitals, (2) having been engaged in or currently participating in social experiments based on medical AI, and (3) being voluntary participation in the survey. According to the pilot test results, data from the participants were excluded from the final analysis if the recorded answering time for the entire questionnaires was less than 150 seconds. Additionally, participants who submitted the same response to all items were also excluded from

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the analysis.

The sample size was estimated using the adjusted Yamane's formula,²⁰ setting the population size at 1580 based on information obtained from the hospital's human resources department, alpha level at 0.05, margin of error at 0.05, ρ at 4. Assuming a 20% attrition rate,²¹ 266 participants were finally recruited for this study.

Measures

A web-based survey was conducted to gather information and collect data through wenjuanxing (<https://www.wjx.cn>), a professional and widely used website for conducting surveys in China. The content of the survey could be categorized as follows: (1) basic sociodemographic information, including gender, age, educational level (Bachelor's degree, Master's degree, Doctor's degree, Others), types of occupation (pediatrician, nurse, or health information technician), levels of professional titles (ungraded, junior, intermediate, and senior), (2) 21-item questionnaire. The questionnaire was written in Chinese, and the knowledge-Attitude-Practice model was used as the conceptual framework to define its construct.^{19,20} The questionnaire was pilot tested on 52 individuals for face validity and reliability. The items were found to be reliable, with a Cronbach's alpha coefficient of 0.727, which is considered acceptable.²² Item-content validity index(I-CVI) and scale-content validity index(S-CVI) were 0.791 and 0.877, respectively.²³ Detailed information on the questionnaire development and content can be found in Supplementary Material.

Participants could scan the QR code using their cellphones or login in on their computers to access and complete the questionnaire. The purpose of the survey and answering instructions were described on the first page of the online questionnaire. The participants were suggested to complete the questionnaire within 5 to 10 minutes. There is a limit on participants' IP addresses to avoid

multiple enrolments. A reminder for checking blank answers was set to block the submission of unfinished questionnaires. The QR code and website address of the questionnaire was provided to the two hospitals' medical service department, nursing department, and medical information center. The directors of the three departments took responsibility for recruiting all eligible healthcare workers, including eligible medical students, to participate in the study.

Statistical analysis

Microsoft Office Excel 365 for Windows (Microsoft Corp, Redmond, USA) was used to establish a database. Data were analyzed using SPSS V.25.0 for Windows (IBM, Armonk, New York, USA). The response rate was calculated by the number of final participants divided by recruited participants to the survey. The basic characteristics and responses were described as n (%), and Chi-square test was used to test differences of proportions among pediatricians, nurses, and health information technicians. No plan for missing data was required since participants could not submit the questionnaire unless they completed it.

RESULTS

Participants characteristics

Of the 411 individuals recruited to participate, 359 completed questionnaires were returned, with a response rate of 87.3%. 27 questionnaires were excluded (5 with unclear demographic information, 13 with short answering time, and 9 with the same answers to all the items). Finally, 332 questionnaires were included in the analysis. The age of the final participants ranged from 19 to 56 years old (Mean=32.4, SD=7.2). As shown in Table 1, 176 (53.0%) were female, 137 (41.2%) were pediatricians, 135(40.7%) were nurses, and 60 (18.1%) were health information technicians. Among the participants, 35.5% held a master's degree or above; senior-level

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177 professional titles accounted for 46.1%.

178 Table 1 Basic information of participants

Characteristic	Participants [n (%)]
Gender	
Male	156 (47.0)
Female	176 (53.0)
Type of occupation	
Pediatrician	137 (41.2)
Nurse	135 (40.7)
Health information technician	60 (18.1)
Education level	
Other lower	48 (14.5)
Bachelor's degree	166 (50.0)
Master's degree	103 (31.0)
Doctor's degree	15 (4.5)
Level of professional titles*	
Ungraded level	58 (17.5)
Junior level	153 (46.1)
Intermediate level	81 (24.4)
Senior level	40 (12.0)

179 * Professional titles symbolize the professionalism of healthcare workers. The evaluation process for these titles is guided by the
180 National Health Commission of the People's Republic of China. Typically, there are four levels that represent the proficiency
181 levels of knowledge and skills within a specific area of specialization, and individuals holding these titles are often entrusted with
182 leadership responsibilities.,

183 Ethics implementation knowledge and attitude of MAI social experiment among physicians,
184 nurses, and health information technicians in pediatrics

185 The items within the knowledge dimension were marked as K1 to K10. K1 referred to the present
186 status of conducting social experiments based on MAI, K2 to K4 pertained to ethical issues
187 associated with conducting such experiments, and K5 to K10 addressed the requirements for ethics
188 governance in MAI social experiments according to norms and principles. There were critical

knowledge gaps. K1 received the highest rate of participants selecting 'familiar', but this only accounted for 9.6% of the participants. K4, K6-K8 received the lowest rate of participants selecting 'familiar', accounting for 2.4% of the participants. The rate range of participants selecting 'familiar' was from 2.4% to 5.4%. K5-K10 received the lowest rate range of participants selecting 'familiar', with 2.4% to 5.4% of participants choosing this option. Most participants responded with 'unfamiliar' and 'uncertain' to the items in the knowledge dimension (Table 2).

The items within the attitude dimension were marked as A1 to A11. They were all for behaviors towards ensuring ethics implementation in MAI. A1 to A3, A5, A6, A8, and A9 received 74.4% to 86.1% of participants selecting 'agree'. For A4, A10, and A11, 41.9% of the participants held a neutral attitude (Table 3).

Table 2 Overall ethics implementation knowledge of MAI social experiment among physicians, nurses, and health information technicians in pediatrics (N=322)

Knowledge	Unfamiliar n (%)	Uncertain n (%)	Familiar n (%)
K1 The present status of conducting MAI social experiments in pediatrics	135(40.7)	165(49.7)	32(9.6)
K2 Common ethical issues in MAI social experiments in pediatrics	208(62.7)	102(30.7)	22(6.6)
K3 Reasons for ethical issues in MAI social experiments in pediatrics	212(63.9)	102(30.7)	18(5.4)
K4 Coping strategies for ethical issues in MAI social experiments in pediatrics	245(73.8)	79(23.8)	8(2.4)
K5 Principles, norms and guidelines for implementing ethics in MAI social experiments in pediatrics	246(74.1)	72(21.7)	14(4.2)
K6 Policies or regulations for implementing ethics MAI social experiments in pediatrics	258(77.7)	66(19.9)	8(2.4)
K7 Ethical review for MAI social experiments in pediatrics	269(81.0)	55(16.6)	8(2.4)
K8 Ethical supervision mechanism while conducting MAI social experiments in pediatrics	274(82.5)	50(15.1)	8(2.4)
K9 Ethical risk management approaches while while conducting MAI social experiments in pediatrics	269(81.0)	53(16.0)	10(3.0)

K10 Consequences of ethical violations while conducting MAI social experiments in pediatrics	245(73.8)	69(20.8)	18(5.4)
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Table 3 Overall ethics implementation attitude of MAI social experiment among physicians, nurses, and health information technicians in pediatrics (N=322)

Attitude	Disagree n (%)	Neutral n (%)	Agree n (%)
A1 AI experts should be involved in the research ethics committee while reviewing MAI social experiments.	18(5.4)	66(19.9)	248(74.7)
A2 Principles, norms, and guidelines for implementing ethics should be easy to understand and be transformed into a workable process.	5(1.5)	47(14.2)	280(84.3)
A3 Ethical researchers should be involved in MAI social experiments in pediatrics.	4(1.2)	56(16.9)	272(81.9)
A4 An unified way of ethical review can be a barrier to conducting MAI social experiments in pediatrics.	87(26.2)	139(41.9)	106(31.9)
A5 The subjects of ethical responsibility in pediatric MAI social experiments should be clarified.	4(1.2)	59(17.8)	269(81.0)
A6 Participating in ethical education and training programs focusing on MAI social experiments is helpful.	3(0.9)	46(13.9)	283(85.2)
A7 It is necessary to take children's and guardians' opinions into account while conducting MAI social experiments in pediatrics. When children's views are contrary to the guardians', we should adopt the guardians' ones.	62(18.7)	81(24.4)	189(56.9)
A8 Establishing an effective supervision mechanism is helpful.	4(1.2)	42(12.7)	286(86.1)
A9 Content of ethical supervision can be dynamically adjusted according to the clinical context.	12(3.6)	63(19.0)	257(77.4)
A10 After totally understanding the ethical risk while conducting MAI social experiments in pediatrics, the proportion of children or guardians who refuse to use it will increase.	73(22.0)	139(41.9)	120(36.1)
A11 Strict ethical risk management can hinder conducting MAI social experiments in pediatrics.	79(23.8)	139(41.9)	114(34.3)

Comparison among physicians, nurses, and health information technicians in ethics implementation knowledge and attitude of MAI social experiment in pediatrics

Table 4 and 5 illustrate the comparison among physicians, nurses, and health information technicians in ethics implementation knowledge and attitude of MAI social experiment in pediatrics.

It was found that pediatricians, nurses, and health information technicians showed significant differences in the proportions to choose the option of 'unfamiliar', 'uncertain', and 'familiar' in K1-K3 and K5, where health information technicians accounted for the highest proportion at 'familiar', followed by pediatricians then nurses (*Table 4*). Also, significant differences were observed in the proportions of respondents choosing the 'agree', 'neutral', and 'disagree' options in A1-A3, A5, A6, A8, and A9. Among these, pediatricians or nurses accounted for the highest proportion at 'agree', followed by health information technicians. However, in A4, A7, A10, and A11, pediatricians, nurses, and health information technicians held relatively balanced proportions at 'disagree', 'neutral' and 'agree', indicating that there were debates in the views towards the statements of the four items (*Table 5*).

Table 4 Comparing the knowledge of implementing ethics in social experiments based on MAI among healthcare workers at children's hospitals [N of pediatricians=137, N of nurses=135, N of health information technicians (HIT)=60]

Knowledge	Pediatricians n (%)	Nurses n (%)	HIT n (%)	Chi-Square, χ^2	Sig, P
K1					
Unfamiliar 135(40.7)	54(39.4)	67(49.6)	14(23.3)	20.064	<0.001
Uncertain 165(49.7)	71(51.8)	61(45.2)	33(55.0)		
Familiar 32(9.6)	12(8.8)	7(5.2)	13(21.7)		
K2					
Unfamiliar 208(62.7)	83(60.6)	95(70.4)	30(50.0)	11.311	0.023
Uncertain 102(30.7)	44(32.1)	36(26.7)	22(36.7)		
Familiar 22(6.6)	10(7.3)	4(3)	8(13.3)		
K3					
Unfamiliar 212(63.9)	81(59.1)	99(73.3)	32(53.3)	10.969	0.027
Uncertain 102(30.7)	49(35.8)	31(23.0)	22(36.7)		
Familiar 18(5.4)	7(5.1)	5(3.7)	6(10.0)		
K4					
Unfamiliar 245(73.8)	99(72.3)	106(78.5)	40(66.7)	7.753	0.101
Uncertain 79(23.8)	36(26.3)	27(20.0)	16(26.7)		

Familiar	8(2.4)	2(1.5)	2(1.5)	4(6.7)		
K5						
Unfamiliar	246(74.1)	96(70.1)	110(81.5)	40(66.7)	16.128	0.003
Uncertain	72(21.7)	38(27.7)	21(15.6)	13(21.7)		
Familiar	14(4.2)	3(2.2)	4(3.0)	7(11.7)		
K6						
Unfamiliar	258(77.7)	107(78.1)	108(80.0)	43(71.7)	3.045	0.550
Uncertain	66(19.9)	27(19.7)	25(18.5)	14(23.3)		
Familiar	8(2.4)	3(2.2)	2(1.5)	3(5)		
K7						
Unfamiliar	269(81.0)	111(81.0)	113(83.7)	45(75.0)	6.334	0.176
Uncertain	55(16.6)	24(17.5)	20(14.8)	11(18.3)		
Familiar	8(2.4)	2(1.5)	2(1.5)	4(6.7)		
K8						
Unfamiliar	274(82.5)	115(83.9)	112(83.0)	47(78.3)	2.495	0.646
Uncertain	50(15.1)	20(14.6)	20(14.8)	10(16.7)		
Familiar	8(2.4)	2(1.5)	3(2.2)	3(5.0)		
K9						
Unfamiliar	269(81.0)	112(81.8)	111(82.2)	46(76.7)	4.120	0.390
Uncertain	53(16.0)	23(16.8)	20(14.8)	10(16.7)		
Familiar	10(3.0)	2(1.5)	4(3.0)	4(7.7)		
K10						
Unfamiliar	245(73.8)					
Uncertain	69(20.8)	100(73.0)	105(77.8)	40(66.7)	9.260	0.055
Familiar	18(5.4)	28(20.4)	28(20.7)	13(21.7)		
		9(6.6)	2(1.5)	7(11.7)		

Table 5 Comparing the attitude towards implementing ethics in social experiments based on MAI among healthcare workers at children's hospitals [N of pediatricians=137, N of nurses=135, N of health information technicians (HIT)=60]

Attitude	Pediatricians n (%)	Nurses n (%)	HIT n (%)	Chi-Square, χ ²	Sig, P
A1					
Disagree 18(5.4)	8(5.8)	5(3.7)	5(8.3)	16.315	0.003
Neutral 66(19.9)	14(10.2)	34(25.2)	18(30.0)		
Agree 248(74.7)	115(83.9)	96(71.1)	37(61.7)		
A2					
Disagree 5(1.5)	3(2.2)	1(0.7)	1(1.7)	10.320	0.035
Neutral 47(14.2)	10(7.3)	24(17.8)	13(21.7)		

Agree	280(84.3)	124(90.5)	110(81.5)	46(76.7)		
A3						
Disagree	4(1.2)	1(0.7)	1(0.7)	2(3.3)	17.971	0.001
Neutral	56(16.9)	11(8.0)	28(20.7)	17(28.3)		
Agree	272(81.9)	125(91.2)	106(78.5)	41(68.3)		
A4						
Disagree	87(26.2)	33(24.1)	33(24.4)	21(35.0)	3.442	0.487
Neutral	139(41.9)	60(43.8)	59(43.7)	20(33.3)		
Agree	106(31.9)	44(32.1)	43(31.9)	19(31.7)		
A5						
Disagree	4(1.2)	0(0.0)	2(1.5)	2(3.3)	11.958	0.018
Neutral	59(17.8)	17(12.4)	25(18.5)	17(28.3)		
Agree	269(81.0)	120(87.6)	108(80.0)	41(68.3)		
A6						
Disagree	3(0.9)	0(0.0)	2(1.5)	1(1.7)	10.858	0.028
Neutral	46(13.9)	13(9.5)	18(13.3)	15(25.0)		
Agree	283(85.2)	124(90.5)	115(85.2)	44(73.3)		
A7						
Disagree	62(18.7)	32(23.4)	20(14.8)	10(16.7)	3.667	0.453
Neutral	81(24.4)	30(21.9)	35(25.9)	16(26.7)		
Agree	189(56.9)	75(54.7)	80(59.3)	34(56.7)		
A8						
Disagree	4(1.2)	0(0.0)	2(1.5)	2(3.3)	13.088	0.011
Neutral	42(12.7)	9(6.6)	21(15.6)	12(28.3)		
Agree	286(86.1)	128(93.4)	112(83.0)	46(66.7)		
A9						
Disagree	12(3.6)	3(2.2)	6(4.4)	11(18.3)	9.893	0.042
Neutral	63(19.0)	17(12.4)	29(43.0)	29(48.3)		
Agree	257(77.4)	117(85.4)	100(35.6)	20(33.3)		
A10						
Disagree	73(22.0)	33(24.1)	29(21.5)	40(66.7)	2.062	0.724
Neutral	139(41.9)	52(38.0)	58(20.7)	13(21.7)		
Agree	120(36.1)	52(38.0)	48(1.5)	7(11.7)		
A11						
Disagree	79(23.8)	36(26.3)	29(21.5)	14(23.3)	1.223	0.874
Neutral	139(41.9)	54(39.4)	58(43.0)	27(45.0)		
Agree	114(34.3)	47(34.4)	48(35.6)	19(31.7)		

DISCUSSION

This study provided analysis of pediatricians, nurses, and health information technicians' knowledge and attitude towards ethics implementation in MAI social experiments at children's

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228 hospitals in Shanghai. Similar findings were reported regarding medical staff and other professional
229 technicians' familiarity with, attitudes toward, and concerns about AI in ophthalmology.²⁴ However,
230 medical staff encompasses a wide range of professionals within healthcare sectors, and pediatric
231 medical staff is more specific. The current findings devote little to enhance MAI ethics
232 implementation in pediatric healthcare. Our study focused on pediatricians, nurses, and health
233 information technicians working at children's hospitals, and revealed that only 2.4% to 9.6% of
234 participants reported being familiar with ethics implementation knowledge of MAI social
235 experiments at children's hospitals. Regarding attitudes, the results demonstrated a relatively higher
236 percentage of participants who held 'agree' attitudes, ranging from 34.3% to 86.1%. The findings
237 indicated a significant gap in the understanding, and variations in attitudes of ethics implementation
238 among healthcare professionals in the context of MAI social experiments in pediatrics.

239 When comparing pediatricians, nurses, and health information technicians, it is noteworthy that
240 health information technicians accounted for the highest proportion of participants who reported
241 being familiar with implementing ethics, which suggested that individuals in this role may have
242 received specialized training or have greater exposure to the ethical considerations related to MAI
243 social experiments. On the other hand, pediatricians accounted for the highest proportion of those
244 with positive attitudes towards ethics implementation in MAI social experiments, which implied
245 that physicians might have a stronger sense of responsibility and awareness of the ethical
246 implications associated with MAI social experiments in the context of pediatric care. It could also
247 suggest that pediatricians, as primary decision-makers, have a more significant influence on
248 implementing ethics within the hospital setting than other medical staff.

249 In the field of pediatrics, the potential advantages of MAI social experiments are evident in

various aspects. These include utilizing decision support systems for precise and personalized diagnosis and nursing interventions, leveraging extensive data sources, such as electronic medical records, examination and laboratory data, as well as dynamic video images of patients, to aid in the identification of disease risks and prognosis. Furthermore, the implementation of robots can optimize the allocation of pediatric nurses' time and efforts, resulting in improved efficiency and patient care.²⁵⁻³⁰ Nevertheless, MAI also carries the potential to pose challenges to the core values of medicine, including autonomous decision-making by doctors or nurses, and the safety and privacy of pediatric patients and their caregivers.^{31, 32} Previous studies on implementing ethics in MAI social experiments paid more attention to regulating researchers, programmers, engineers, and data scientists in the stages of research, design, and development, but failed to notice that ethical issues in MAI social experiments are equally important.^{33, 34} Obtaining information about ethics implementation knowledge and attitudes of MAI social experiments among potential researchers may help policymakers make more meaningful decisions which are the premises to promote ethics implementation in MAI experiments.

We particularly observed that 56.9% of the participants expressed 'agree' attitudes towards considering both children's and guardians' opinions, and giving priority to guardians' opinions while conducting MAI social experiments in pediatrics. Moreover, there were no significant differences among pediatricians, nurses, and health information technicians on this topic. This indicated that partial medical staff in China began to focus on the best interest of the minor when considering the trade-off between the benefits of MAI in pediatric care and the associated risks. Ethical decision-making in the context of MAI should prioritize the well-being and welfare of pediatric patients, ensuring that their best interests are upheld throughout the implementation of MAI technologies.

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This includes carefully assessing the potential risks and harms that MAI products may pose to them, such as data immortality, and developing appropriate safeguards to protect their privacy, autonomy, and overall well-being.³⁵

Strengths and limitations of this study

The strengths of this study lie in its representative population, multidimensional assessment, quantitative data collection, comparison across professions, focus on ethics implementation, practical implications, and recommendations for further research. The limitations of the study were as follows: firstly, the study was conducted in a specific context: tertiary children's hospitals in Shanghai. Therefore, the findings may not directly apply to medical staff in other regions or different types of healthcare facilities; secondly, the data collection relied on online surveys through self-reporting, utilizing self-designed questionnaires, which introduces the potential for response bias. Despite efforts to ensure anonymity and confidentiality, there is still a possibility of bias influencing the responses; thirdly, the study utilized a cross-sectional design, and it did not capture changes or developments in their knowledge and attitudes over time.

CONCLUSION

The study provides a detailed analysis of the ethics implementation knowledge and attitudes of MAI social experiments among medical staff at children's hospitals in Shanghai. The findings reveal a significant knowledge gap and variations in attitudes among pediatricians, nurses, and health information technicians, which underscore the urgent need for individualized education and training programs to enhance MAI ethics implementation in pediatric healthcare. Additionally, interdisciplinary collaboration and dialogue are crucial for developing clear ethical frameworks that guide responsible ethics implementation.

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305 **Contributor-ship statement** Y-WW, W-JF, X-BZ, and RF designed the study; Y-WW, W-JF, YG,

306 W-HF, X-LG, C-JY, L-FT, LS, J-YW performed the study; Y-WW and W-JF drafted the manuscript

307 and performed statistical analyses; Y-JZ, CJ, JY, W-BW, HX, J-WF, D-YW, X-BZ and RF

308 contributed to interpretation of the results and critically reviewed the manuscript. All authors are in

309 agreement with the content of the manuscript and have provided final approval of the version to be

310 published. X-BZ and RF are responsible for the overall content as guarantor and accepts full

311 responsibility for the finished work, have access to the data, and control the decision to publish.

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315 Social Experiment of Clinical Diagnosis Decision Support System under the Science and

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Technology Commission of Shanghai Municipality (No.21511104502), and the Application and validation of real scenarios of major pediatric respiratory diseases under the Science and Technology Commission of Shanghai Municipality (No.22511106001).

Data sharing Statement Data may be available upon reasonable request from the corresponding author.

Ethics approval The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Research Ethics Board of Children's Hospital of Fudan University (No.2022-52).

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Supplement

Questionnaire development

The questionnaire was written in Chinese. The Knowledge-Attitude-Practice model was used as the conceptual framework to define its construct. Based on the model, knowledge is comprised of scientific knowledge, local knowledge, tacit knowledge, and self-reflective knowledge.¹⁹ Attitude refers to a positive or negative option of objective evaluation.²⁰ The initial step involved systematic literature retrieval to gather guidelines, expert consensus, practice standards, and norms for implementing ethics in AI research. A librarian working in the hospital library provided valuable assistance during this process (see Appendix). Then, a focus group interview was administered, consisting of 10 experts (two medical ethics professors, one sociology professor, three artificial intelligence professors, and four medical professors proficient in medical AI implementation research). They were encouraged to express their opinions on the following questions: (1) What is your understanding of implementing ethics in medical AI research? (2) What knowledge should medical AI researchers master to help implement ethics? (3) What are your attitudes regarding implementing ethics in medical AI research? Eventually, relevant content from literature and interviews was extracted and classified, and the item pool was generated. For consultation, the item pool was sent to another ten experts, including medical ethics professors, sociology professors, artificial intelligence professors, and medical professors. Item deletion and modification were applied following the findings from three rounds of expert consultation. After that, the draft questionnaire was developed. Eight individuals, including artificial intelligence researchers and healthcare workers, were invited to complete the draft questionnaires and be interviewed with the following questions: (1) Was each item clearly expressed without ambiguity? If not, please identify

the unclear or ambiguous expressions; (2) Were any items challenging to understand? If yes, please specify the difficulties and if not, please try to explain each item in your own words; (3) What were your reasons for each of your answers? (4) What else is needed to be added? Language readability modification of each item was done according to the comments. The final questionnaire consisted of two dimensions, comprising 21 items. In terms of knowledge, respondents were asked to indicate their familiarity with the progress of conducting social experiments based on MAI, ethical issues related to conducting such experiments, and requirements for ethics governance in MAI social experiments according to norms and principles. The response options ranged from 'familiar' to 'unfamiliar'. For attitude, respondents were asked to express their agreement with behavioral statements concerning implementing ethics in MAI social experiments. The response options ranged from 'disagree' to 'agree'. The questionnaire was pilot tested on 52 individuals for face validity and reliability. The items were found to be reliable, with a Cronbach's alpha coefficient of 0.727,²² which is considered acceptable. Item-content validity index(I-CVI) and scale-content validity index(S-CVI) were 0.791 and 0.877, respectively.²³

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For peer review only

Appendix: systematic literature retrieval

1 Data Source

Databases: BYU Law, Westlaw, Web of Science, JSTOR, Springer
International Organization Website: UNESCO Library, OECD Library, EP Library, et al.

national government departments and relevant committees :Using the United States as an example: THE WHITE HOUSE(<http://www.whitehouse.gov>), Science technology council(<https://www.nstc.org.zm>), homeland security(<http://www.dhs.gov>), Information Network Sector(<http://www.nitrd.gov>), department of Defense (<https://innovation.defense.gov/>).

2 Retrieval Strategy

The title should contain: (artificial intelligence or AI or robot) and (ethic or moral or governance or risk or principle or guideline or consensus)

Time Range: January 1, 2016 to May 1, 2021

3 Primary Reference Lists

NO.	Publishing Agency	Document Title	Year
1	European Parliament	An EU framework for artificial intelligence	2020
2	European Parliament	Artificial intelligence: From ethics to policy	2020
3	European Parliament	European framework on ethical aspects of artificial intelligence, robotics and related technologies	2020
4	European Parliament	EU guidelines on ethics in artificial intelligence: Context and implementation	2019
5	European Parliament	European Civil Law Rules in Robotics	2016
6	European Commission	Ethics Guidelines for Trustworthy AI	2018
7	OECD	OECD Principles on AI	2019
8	China	网络安全标准实践指南—人工智能伦理安全风险防范指引》	2021
9	China	《新一代人工智能治理原则——发展负责任的人工智能》	2019
10	UNESCO	Recommendation on the Ethics of Artificial Intelligence	2021
11	UNESCO	Preliminary study on the Ethics of Artificial Intelligence	2019
12	UNESCO	Ethical principles for the development of Artificial	2018

			Intelligence based on the diversity of cultural expressions	
13	America		Executive Order Promoting the Use of Trustworthy AI in the Federal Government	2020
14	America		Technology Assessment: Artificial Intelligence in Health Care	2020
15	America		Artificial Intelligence Ethics Framework for the Intelligence Community	2020
16				
16	America		Four Principles of Explainable Artificial Intelligence	2020
17	America		Ethical Principles for Artificial Intelligence	2020
18	America		Principles of Artificial Intelligence Ethics for the Intelligence Community	2020
19	America		Guidance for Regulation of Artificial Intelligence Applications	2020
20	Britain		Robots and robotic devices Guide to the ethical design and application of robots and robotic systems	2016
21	The European Union		Ethics Guidelines for Trustworthy AI	2020
22	Korea		National Ethical Standards for Artificial Intelligence	2020
23	WHO		Ethics and governance of artificial intelligence for health: WHO guidance	2021
24	Australia		Australia's Artificial Intelligence Ethics Framework	2019
25	IEEE		Ethical Guidelines for the Design of Artificial Intelligence	2019
26	IEEE		Ethically Aligned Design Version 2	2017
27	Singapore		Model AI Governance Framework	2019

Appendix: the content of the questionnaire

医学人工智能社会实验伦理实施的知识 and 态度问卷

(一) 认知维度

您对下面条目所描述内容的了解程度怎样？请选出最符合自己实际情况的选项。

K1 人工智能技术在医疗领域的应用现状。

- ☐ 不了解
- ☐ 一般
- ☐ 了解

K2 医疗人工智能研发/应用中的伦理问题。

- ☐ 不了解
- ☐ 一般
- ☐ 了解

K3 医疗人工智能研发/应用相关伦理问题的成因。

- ☐ 不了解
- ☐ 一般
- ☐ 了解

K4 医疗人工智能研发/应用中伦理问题的应对策略。

- ☐ 不了解
- ☐ 一般
- ☐ 了解

K5 医疗人工智能研发/应用的伦理原则/规范。

- ☐ 不了解
- ☐ 一般
- ☐ 了解

K6 医疗人工智能研发/应用的伦理政策/法规。

- ☐ 不了解
- ☐ 一般
- ☐ 了解

K7 医疗人工智能研发/应用的伦理审查内容。

- ☐ 不了解
- ☐ 一般
- ☐ 了解

K8 医疗人工智能研发/应用的伦理监管机制。

- ☐ 不了解
- ☐ 一般

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☐了解

K9 医疗人工智能研发/应用的伦理风险管理。

☐不了解

☐一般

☐了解

K10 医疗人工智能研发/应用中出现伦理失范引发的后果。

☐不了解

☐一般

☐了解

(二) 态度维度

您对下面条目所描述内容的认同程度怎样？请选出最符合自己实际想法的选项：

A1 科研伦理（审查）委员会加入人工智能相关知识背景的专家方可对医疗人工智能项目做出全面的评估和审查。

☐不赞同

☐一般

☐赞同

A2 医疗人工智能的伦理原则/规范需转译为易于理解、可操作的工作流程才能落地执行。

☐不赞同

☐一般

☐赞同

A3 邀请伦理专家参与医疗人工智能研发/应用有助于项目的伦理管理。

☐不赞同

☐一般

☐赞同

A4 统一的伦理审查标准可能阻碍医疗人工智能的技术创新。

☐不赞同

☐一般

☐赞同

A5 明确医疗人工智能研发/应用的伦理责任主体有益于伦理管理。

☐不赞同

- ☐一般
- ☐赞同

A6 参加专门的医疗人工智能伦理教育与培训对实践项目的伦理管理有帮助。

- ☐不赞同
- ☐一般
- ☐赞同

A7 当医疗人工智能研发/应用涉及儿童时，需要充分听取儿童的意见，若儿童意见与监护人意见相悖，则采纳监护人意见。

- ☐不赞同
- ☐一般
- ☐赞同

A8 建立切实有效的监管机制有助于医疗人工智能研发/应用的伦理管理。

- ☐不赞同
- ☐一般
- ☐赞同

A9 医疗人工智能研发/应用的伦理监管内容可以动态调整。

- ☐不赞同
- ☐一般
- ☐赞同

A10 了解医疗人工智能的伦理风险后，患者或监护人拒绝使用的比例会增加。

- ☐不赞同
- ☐一般
- ☐赞同

A11 严格的伦理风险管理可能掣肘医疗人工智能的研发/应用。

- ☐不赞同
- ☐一般
- ☐赞同

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page/Line number of the manuscript
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page1/ Line 1-3 Page2-3/Line 23-46
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page4-5/Line 68-109
Objectives	3	State specific objectives, including any prespecified hypotheses	Page5-6/Line 110-115
Methods			
Study design	4	Present key elements of study design early in the paper	Page6/Line 118
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page6/Line 118-120
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	Page6-7/Line 126-133 NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page8-9/Line 175-180
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page8-9/Line 181-189
Bias	9	Describe any efforts to address potential sources of bias	NA
Study size	10	Explain how the study size was arrived at	Page6/Line 134-137

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page8-9/Line 181-189
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page8-9/Line 181-189
		(b) Describe any methods used to examine subgroups and interactions	Page9/Line 194-195
		(c) Explain how missing data were addressed	Page9/Line 196-197
		(d) Cohort study—If applicable, explain how loss to follow-up was addressed	NA
		Case-control study—If applicable, explain how matching of cases and controls was addressed	
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page10/Line 200-203
		(b) Give reasons for non-participation at each stage	Page9/Line 200-203
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page10/Table 1
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	Page10/Line 200-203
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page9/Line 203
		(b) Report category boundaries when continuous variables were categorized	Page9/Line 203-204
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page13-14/Line 236-254
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page17/Line 273-291
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page18/Line 306-313
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page17/Line 273-313
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page18/Line 304-306
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page20/Line 340-345

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Comparative survey among pediatricians, nurses, and health information technicians in ethics implementation knowledge and attitude of social experiments based on medical artificial intelligence at children's hospitals in Shanghai: a cross-sectional study

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1 Comparative survey among pediatricians, nurses, and health information technicians in
2 ethics implementation knowledge and attitude of social experiments based on medical
3 artificial intelligence at children's hospitals in Shanghai: a cross-sectional study
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ABSTRACT

Objectives Implementing ethics is crucial to prevent harm and promote widespread benefits in social experiments based on medical artificial intelligence (MAI). However, insufficient information is available concerning this within the pediatric healthcare sector. We aimed to conduct a comparative survey among pediatricians, nurses, and health information technicians regarding ethics implementation knowledge and attitude of MAI social experiments at children's hospitals in Shanghai.

Design and setting A cross-sectional electronic questionnaire was administered from July 1, 2022, to July 31, 2022, at tertiary children's hospitals in Shanghai.

Participants All the eligible individuals were recruited. The inclusion criteria were: (i) being a pediatrician, nurse, and health information technician at the hospital, (ii) having been engaged in or currently participating in social experiments based on MAI, and (iii) being voluntary participation in the survey.

Primary outcome Ethics implementation knowledge and attitude of MAI social experiments among pediatricians, nurses, and health information technicians.

Results There were 137 pediatricians, 135 nurses, and 60 health information technicians who responded to the questionnaire at tertiary children's hospitals. 2.4%-9.6% of participants were familiar with ethics implementation knowledge of MAI social experiments. 34.3%-86.1% of participants held an 'agree' ethics implementation attitude. Health information technicians accounted for the highest proportion of the participants who were familiar with the knowledge of implementing ethics, and pediatricians accounted for the highest proportion among those who held 'agree' attitudes.

Conclusions There is a significant knowledge gap and variations in attitudes among pediatricians,

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45 nurses, and health information technicians, which underscore the urgent need for individualized
46 education and training programs to enhance MAI ethics implementation in pediatric healthcare.
47 **Strengths and limitations of this study**
48 ⇒ In this cross-sectional study, less than one-tenth of participants were familiar with ethics
49 implementation knowledge of MAI social experiments. More than three-fourths of participants
50 held an 'agree' ethics implementation attitude.
51 ⇒ Health information technicians accounted for the highest proportion of those familiar with the
52 knowledge of implementing ethics, and pediatricians accounted for the highest proportion
53 among those holding 'agree' attitudes.
54 ⇒ The findings indicated a significant knowledge gap and variations in attitudes among
55 pediatricians, nurses, and health information technicians, which underscore the urgent need for
56 individualized education and training programs on MAI ethics implementation within different
57 occupations.
58 ⇒ The limitations included specific conducted context, online surveys, and self-reporting, self-
59 designed questionnaires.
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INTRODUCTION

Medical artificial intelligence (MAI) is rapidly advancing and has the potential to revolutionize healthcare. China has a large population base, and there is an insufficient distribution of medical resources, particularly in the field of pediatrics. According to the *2021 China Health Statistics Yearbook*, the total number of pediatricians in China was reported to be 168,000. This data corresponds to a ratio of approximately 0.66 pediatricians per 1,000 children aged 0-14 years old, as of the year 2020[1]. The utilization of algorithms can facilitate the emergence of various AI-driven systems for pediatric clinical practices, including the analysis of radiology imaging in children[2,3], enable accurate diagnosis for children with common or rare diseases based on electronic medical records or multimodal clinical data[4-7], identify the risk of early deterioration in critically ill children by leveraging medical record data and video materials[8,9]. Robots can also be employed for pre-consultation, triage, and referral services for children, further expanding the scope of AI implementation in pediatric healthcare[10]. Therefore, implementing artificial intelligence in pediatric healthcare in China is indeed a pressing need.

An MAI social experiment refers to a research study or intervention that utilizes artificial intelligence (AI) technology in the context of social interactions and healthcare. Conducting MAI social experiment is crucial for exploring the application of MAI and analyzing its potential impacts, which helps properly handle the relationship between medical artificial intelligence, humans, and society[11-13]. Due to the high level of uncertainty and significant ethical risks associated with medical artificial intelligence, implementing ethics in these social experiments is of utmost importance[14,15]. Research institutions in China and other countries have made significant efforts to establish principles, guidelines, and norms for the ethical governance of MAI. Prominent

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89 examples include the World Health Organization(WHO) Guidance of *Ethics and Governance of*
90 *Artificial Intelligence for Health*, the United Nations Educational, Scientific and Cultural
91 Organization (UNESCO) recommendation on the ethics of artificial intelligence issued in June and
92 November 2021 respectively[15,16], Health Insurance Portability and Accountability Act (HIPAA),
93 the *New Generation of Ethical Norms of Artificial Intelligence* by the Ministry of Science and
94 Technology of China published in September 2021[17], and the *Guidelines of Strengthening*
95 *Governance over Ethics in Science, Technology* by the General Office of the State Council of China
96 issued in March 2022[18]. There are also helpful regulatory frameworks. In the United States, MAI
97 must be approved by the Food and Drug Administration (FDA), which classifies MAI as "software
98 as a medical device", while the collection, storage, and disclosure of personal health information is
99 regulated mainly by the HIPAA issued in 1996. In the European Union, privacy protection is
100 guaranteed by the General Data Protection Regulation (GDPR), which applies when a processor or
101 controller processes personal data in the context of the activities of its establishment[19]. Their
102 contributions have laid a theoretical foundation for ethical governance in MAI social experiments.
103 Though their focus was on pediatric patients, they also provided valuable suggestions in privacy,
104 safety, fairness, and accountability.

105 Pediatricians, nurses, and health information technicians have more opportunities to be potential
106 researchers in MAI social experiments. Their ethics implementation knowledge and attitudes are
107 vital in mitigating ethical risks and may influence decision-making processes and pediatric patient
108 care. However, studies explicitly focusing on pediatricians, nurses, and health information
109 technicians, investigating their ethics implementation knowledge and attitude of MAI social
110 experiments, are limited.

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Enseignement Supérieur (ABES).

This cross-sectional study aims to fill this research gap by investigating and comparing ethics implementation knowledge and attitude of MAI social experiments among pediatricians, nurses, and health information technicians. This study will provide valuable insights into ethics implementation in MAI social experiments in pediatrics. The findings will contribute to developing tailored education and training programs and inform the formulation of guidelines and policies that promote the responsible and ethical use of AI in children's hospitals.

METHODS

Study Design and setting

This cross-sectional study was conducted at two tertiary children's hospitals in Shanghai from July 1, 2022, to July 31, 2022, following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement. The study was approved by the Research Ethics Board of the Children's Hospital of Fudan University (No.2022-52). Informed consent was obtained from all participants involved in the study.

Patient and public involvement

No patient was involved in this study.

Participants and sampling,

Participants in the study were voluntary, and the information was collected anonymously. The inclusion criteria were: (1) being a pediatrician, nurse, or health information technician at the two hospitals, (2) having been engaged in or currently participating in MAI social experiments, and (3) being voluntary participation in the survey. According to the pilot test results, data from the participants were excluded from the final analysis if the recorded answering time for the entire questionnaire was less than 150 seconds. Additionally, participants who submitted the same

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response to all items were also excluded from the analysis.

The sample size was estimated using the adjusted Yamane's formula[20], setting the population size at 1580 based on information obtained from the hospital's human resources department, alpha level at 0.05, margin of error at 0.05, and ρ at 4. We arrived at a sample size of 226. Assuming a 20% attrition rate[21], 272 participants were finally planned to be recruited for this study.

Measures

A web-based survey was conducted to gather information and collect data through wenjuanxing (<https://www.wjx.cn>), a professional and widely used website for conducting surveys in China. The survey consisted of two sections. One is about basic sociodemographic information, including gender, age, educational level (Bachelor's diploma, Master's diploma, Doctor's diploma, Others), types of occupation (pediatrician, nurse, or health information technician), levels of professional titles (ungraded, junior, intermediate, and senior) and the other is a 21-item questionnaire. They were all written in Chinese, and the knowledge-Attitude-Practice model was used as the conceptual framework to build the structure of the 21-item questionnaire. Detailed information on the questionnaire development and its English version can be found in Supplemental Appendix A, B and C. In the Response options for the knowledge dimension in the questionnaire were 'familiar', 'uncertain', and 'unfamiliar'. For attitude, response options were 'disagree', 'neutral', and 'agree'. The questionnaire was first pilot-tested through convenience sampling. A sample of 52 individuals was surveyed for reliability and face validity. The items were found to be reliable, with an acceptable Cronbach's alpha coefficient of 0.727[22]. Item-content validity index(I-CVI) and scale-content validity index(S-CVI) were 0.791 and 0.877, respectively[23].

Participants could scan the QR code using their cellphones or log in on their computers to

access the questionnaire. The purpose of the survey and answering instructions were described on the first page of the online questionnaire. The participants were suggested to complete the questionnaire within 5 to 10 minutes. There is a limit on participants' IP addresses to avoid multiple enrolments. A reminder for checking blank answers was set to block the submission of unfinished questionnaires. The QR code and website address of the questionnaire were provided to the medical service departments, nursing departments, and medical information centers. The directors of the three departments took responsibility for recruiting all eligible healthcare workers, including eligible medical students, to participate in the study.

Statistical analysis

Microsoft Office Excel 365 for Windows (Microsoft Corp, Redmond, USA) was used to establish a database. Data were analyzed using SPSS V.25.0 for Windows (IBM, Armonk, New York, USA). The response rate was calculated by the number of final participants divided by recruited participants to the survey. The basic characteristics and responses were described as n (%), and Chi-square test was used to test differences of proportions among pediatricians, nurses, and health information technicians. No plan for missing data was required since participants could not submit the questionnaire unless they completed it.

RESULTS

Participants characteristics

Of the 411 recruited individuals, 359 completed questionnaires were returned, with a response rate of 87.3%. In total, 27 questionnaires were excluded (5 with unclear demographic information, 13 with short answering time, and 9 with the same answers to all the items). Finally, 332 questionnaires were included in the analysis. The participants' baseline information is shown in

Table 1. The age of the final participants ranged from 19 to 56 years old (Mean=32.4, SD=7.2). Among them, 176 (53.0%) participants were female, 137 (41.2%) were pediatricians, 135(40.7%) were nurses, and 60 (18.1%) were health information technicians. 35.5% held a master's diploma or above, and senior-level professional titles accounted for 46.1%

Table 1 Basic information of participants

Characteristic	Participants [n (%)]
Gender	
Male	156 (47.0)
Female	176 (53.0)
Type of occupation	
Pediatrician	137 (41.2)
Nurse	135 (40.7)
Health information technician	60 (18.1)
Education level	
Other lower	48 (14.5)
Bachelor's diploma	166 (50.0)
Master's diploma	103 (31.0)
Doctor's diploma	15 (4.5)
Level of professional titles*	
Ungraded level	58 (17.5)
Junior level	153 (46.1)
Intermediate level	81 (24.4)
Senior level	40 (12.0)

* Professional titles symbolize the professionalism of healthcare workers. The evaluation process for these titles is guided by the National Health Commission of the People's Republic of China. Typically, there are four levels that represent the proficiency levels of knowledge and skills within a specific area of specialization, and individuals holding these titles are often entrusted with leadership responsibilities.

Ethics implementation knowledge and attitude of MAI social experiment among physicians, nurses, and health information technicians in pediatrics

The items within the knowledge dimension were marked as K1 to K10. K1 referred to the present

status of performing MAI social experiments, K2 to K4 pertained to related ethical issues, and K5 to K10 addressed the requirements for ethics governance in MAI social experiments. There were critical knowledge gaps. K1 received the highest rate of participants selecting 'familiar', but this only accounted for 9.6% of the participants. The number of the response option as familiar was the lowest in K4, K6-K8, with the same proportion of 2.4%. Most participants responded with 'unfamiliar' and 'uncertain' to the items in the knowledge dimension (**Table 2**).

The items within the attitude dimension were marked as A1 to A11. They were all for behaviors towards ensuring ethics implementation in MAI. A1 to A3, A5, A6, A8, and A9 received 74.4% to 86.1% of participants selecting 'agree'. For A4, A10, and A11, 41.9% of the participants held a neutral attitude, respectively. (**Table 3**).

Overall ethics implementation knowledge of MAI social experiment among physicians, nurses, and health information technicians in pediatrics (N=322)

Knowledge	Unfamiliar n (%)	Uncertain n (%)	Familiar n (%)
K1 The status quo of conducting MAI social experiments in pediatrics.	135(40.7)	165(49.7)	32(9.6)
K2 Common ethical issues in MAI social experiments in pediatrics.	208(62.7)	102(30.7)	22(6.6)
K3 Underlying reasons for ethical issues in MAI social experiments in pediatrics.	212(63.9)	102(30.7)	18(5.4)
K4 Coping strategies for ethical issues in MAI social experiments in pediatrics.	245(73.8)	79(23.8)	8(2.4)
K5 Principles, norms and guidelines for implementing ethics in MAI social experiments in pediatrics.	246(74.1)	72(21.7)	14(4.2)
K6 Policies or regulations for implementing ethics in MAI social experiments in pediatrics.	258(77.7)	66(19.9)	8(2.4)
K7 Content of ethical review for MAI social experiments in pediatrics.	269(81.0)	55(16.6)	8(2.4)
K8 Ethical supervision mechanism for MAI social experiments in pediatrics.	274(82.5)	50(15.1)	8(2.4)
K9 Ethical risk management approaches for MAI social experiments in pediatrics.	269(81.0)	53(16.0)	10(3.0)

K10 Consequences of ethical violations for MAI social experiments in pediatrics.	245(73.8)	69(20.8)	18(5.4)
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Table 3 Overall ethics implementation attitude of MAI social experiment among physicians, nurses, and health information technicians in pediatrics (N=322)

Attitude	Disagree n (%)	Neutral n (%)	Agree n (%)
A1 AI experts should be involved in the research ethics committee for MAI social experiments in pediatrics	18(5.4)	66(19.9)	248(74.7)
A2 Principles, norms, and guidelines on implementing ethics in MAI social experiments in pediatrics should be easy to understand and be transformed into a workable process.	5(1.5)	47(14.2)	280(84.3)
A3 Ethical researchers should be involved in MAI social experiments in pediatrics.	4(1.2)	56(16.9)	272(81.9)
A4 A unified ethical review can be a barrier to performing MAI social experiments in pediatrics.	87(26.2)	139(41.9)	106(31.9)
A5 Clarified subjects of ethical responsibility in MAI social experiments in pediatrics can facilitate ethical supervision.	4(1.2)	59(17.8)	269(81.0)
A6 Participating in ethical education and training programs focusing on MAI social experiments is helpful for ethical supervision.	3(0.9)	46(13.9)	283(85.2)
A7 It is necessary to take children's and guardians' opinions into account while performing MAI social experiments in pediatrics. When children's views are contrary to the guardians', we should adopt the guardians' ones.	62(18.7)	81(24.4)	189(56.9)
A8 Establishing an effective supervision mechanism is helpful.	4(1.2)	42(12.7)	286(86.1)
A9 Content of ethical supervision can be dynamically adjusted according to the clinical context.	12(3.6)	63(19.0)	257(77.4)
A10 The number of children or guardians against MAI will increase after having a comprehensive understanding of the ethical risk in MAI social experiments in pediatrics.	73(22.0)	139(41.9)	120(36.1)
A11 Strict ethical risk management can hinder performing MAI social experiments in pediatrics.	79(23.8)	139(41.9)	114(34.3)

Comparison among physicians, nurses, and health information technicians in ethics implementation knowledge and attitude of MAI social experiment in pediatrics

The comparison was conducted among physicians, nurses, and health information technicians concerning their ethics implementation knowledge and attitude of MAI social experiment in

pediatrics. It was found that pediatricians, nurses, and health information technicians showed significant differences in the proportions to choose the option of 'unfamiliar', 'uncertain', and 'familiar' in K1-K3 and K5, where health information technicians accounted for the highest proportion at 'familiar', followed by pediatricians then nurses (**Supplemental Table 1**). Also, significant differences were observed in the proportions of respondents choosing the 'agree', 'neutral', and 'disagree' options in A1-A3, A5, A6, A8, and A9. Among these, pediatricians or nurses accounted for the highest proportion at 'agree', followed by health information technicians. However, in A4, A7, A10, and A11, pediatricians, nurses, and health information technicians held relatively balanced proportions at 'disagree', 'neutral' and 'agree', indicating that there were debates in the views towards the statements of the four items (**Supplemental Table 2**).

DISCUSSION

This study provided an analysis of pediatricians, nurses, and health information technicians' knowledge and attitude towards ethics implementation in MAI social experiments at children's hospitals in Shanghai. Similar findings were reported regarding medical staff and other professional technicians' familiarity with, attitudes toward, and concerns about AI in ophthalmology[24]. However, medical staff encompasses a wide range of specialties within healthcare sectors. The current findings devote little to enhancing MAI ethics implementation in pediatric healthcare. Our study focused on pediatricians, nurses, and health information technicians working at children's hospitals, and revealed that only 2.4% to 9.6% of participants at children's hospitals reported being familiar with ethics implementation knowledge of MAI social experiments. Regarding attitudes, the results demonstrated a relatively higher percentage of participants who held 'agree' attitudes, ranging from 34.3% to 86.1%. The findings indicated a significant gap in the understanding, and variations

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in attitudes towards ethics implementation among healthcare professionals in the context of MAI social experiments in pediatrics.

On the one hand, health information technicians accounted for the highest proportion of participants who reported being familiar with implementing ethics, suggesting that individuals in this role may have received specialized training or have greater exposure to the ethical considerations related to MAI social experiments. On the other hand, pediatricians accounted for the highest proportion of those with positive attitudes towards ethics implementation in MAI social experiments, which implied that physicians might have a stronger sense of responsibility and awareness of the ethical implications associated with MAI social experiments in the context of pediatric care. It could also suggest that pediatricians, as primary decision-makers, have a more significant influence on implementing ethics within the hospital setting than other medical staff.

In the field of pediatrics, the potential advantages of MAI social experiments are evident in various aspects. These include utilizing decision support systems for precise and personalized diagnosis and nursing interventions, leveraging extensive data sources, such as electronic medical records, examination and laboratory data, as well as dynamic video images of patients, to aid in the identification of disease risks and prognosis. Furthermore, the implementation of robots can optimize the allocation of pediatric nurses' time and efforts, resulting in improved efficiency and patient care[25-30]. Nevertheless, MAI also carries the potential to pose challenges to the core values of medicine, including autonomous decision-making by doctors or nurses, and the safety and privacy of pediatric patients and their caregivers[31, 32]. Previous studies on implementing ethics in MAI social experiments have always paid more attention to regulating researchers, programmers, engineers, and data scientists in the stages of research, design, and development, but failed to notice

that ethical issues in healthcare staff are equally important[33, 34]. Obtaining their information about ethics implementation knowledge and attitudes of MAI social experiments may help policymakers make more meaningful decisions which are the premises to promote ethics implementation in MAI experiments.

We particularly observed that 56.9% of the participants expressed 'agree' attitudes towards considering both children's and guardians' opinions, and giving priority to guardians' opinions while conducting MAI social experiments in pediatrics. Moreover, there were no significant differences among pediatricians, nurses, and health information technicians on this topic. This indicated that healthcare staff in China have begun to focus on the best interest of the minor when considering the trade-off between the benefits of MAI in pediatric care and the associated risks. Ethical decision-making in the context of MAI should prioritize the well-being and welfare of pediatric patients, ensuring that their best interests are upheld throughout the implementation of MAI technologies. This includes carefully assessing the potential risks and harms that MAI products may pose to them, such as data immortality, and developing appropriate safeguards to protect their privacy, autonomy, and overall well-being[35].

Strengths and limitations of this study

The strengths of this study lie in its representative population, multidimensional assessment, quantitative data collection, comparison across professions, focus on ethics implementation, practical implications, and recommendations for further research. The limitations of the study were as follows. Firstly, the study was conducted in a specific context of tertiary children's hospitals in Shanghai. Therefore, the findings may not directly apply to medical staff in other regions or different types of healthcare facilities. Secondly, the data collection relied on online surveys by self-reporting

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of self-designed questionnaires. Despite efforts to ensure anonymity and confidentiality, there is still a possibility of bias influencing the responses. Thirdly, the study utilized a cross-sectional design, and it did not capture changes or developments in their knowledge and attitudes over time. Consequently, we intend to broaden the scope of our research in future studies by incorporating patients into our study population and increasing the sample size.

CONCLUSION

The study provides a detailed analysis of the ethics implementation knowledge and attitudes of MAI social experiments among medical staff at children's hospitals in Shanghai. The findings reveal a significant knowledge gap and variations in attitudes among pediatricians, nurses, and health information technicians, which underscore the urgent need for individualized education and training programs to enhance MAI ethics implementation in pediatric healthcare. Additionally, interdisciplinary collaboration and dialogue are crucial for developing clear ethical frameworks that guide responsible ethics implementation.

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Appendix A: Questionnaire development

The questionnaire was written in Chinese. The initial step involved systematic literature retrieval to gather information on implementing ethics in social experiments based on medical artificial intelligence from guidelines, expert consensus, practice standards, and norms. A librarian working in the hospital library provided valuable assistance during this process (see Appendix B). Then, a focus group interview, consisting of 10 experts (two medical ethics professors, one sociology professor, three artificial intelligence professors, and four medical professors proficient in medical artificial intelligence social experiments), was conducted. In the interview meeting, all experts were encouraged to express their opinions on the following questions: (1) What is your understanding of implementing ethics in medical artificial intelligence (MAI) social experiments? (2) What knowledge should medical staff, involved in MAI social experiments, master to facilitate implementing ethics? (3) What are your attitudes regarding implementing ethics in MAI social experiments? Eventually, relevant contents from literature and interviews were extracted, and then they were classified according to the Knowledge-Attitude-Practice model. Based on the model, knowledge is comprised of scientific knowledge, local knowledge, tacit knowledge, and self-reflective knowledge [1]. Attitude refers to a positive or negative option of objective evaluation [2]. After item generation, item deletion and modification were made according to experts' opinions through three rounds of Delphi expert consultation. Ten experts, including medical ethics professors, sociology professors, artificial intelligence professors, and medical professors, were invited. Eventually, the draft questionnaire was developed.

Before the formal survey started, eight individuals (according to the cognitive debriefing guidelines provided by the PROMIS Translation Director from our previous study), including

artificial intelligence researchers and healthcare workers, joined the cognitive debriefing. The purpose of the cognitive debriefing is to confirm that all items are understood by the target participants as intended. First, they were invited to complete the draft questionnaires, and after that they were interviewed with the following questions: (1) Was each item clearly expressed without ambiguity? If not, please identify the unclear or ambiguous expressions; (2) Were any items challenging to understand? If yes, please specify the difficulties, and if not, please try to explain each item in your own words; (3) What were your reasons for each of your answers? (4) What else is needed to be added? All participants were able to correctly explain the meaning of the item and respond logically in their own words on 17 items. Language readability modification of the other 4 items was made according to the participants' comments. The final questionnaire consisted of two dimensions, comprising 21 items. In the context of the knowledge dimension, respondents were asked to express their familiarity with various aspects, including the progress, ethical issues related to conducting MAI social experiments, and ethics governance according to norms and principles for such experiments. The response options ranged from 'familiar', 'uncertain' to 'unfamiliar'. In the attitude dimension, respondents were asked to express their agreement with behavioral statements concerning implementing ethics in MAI social experiments. The response options ranged from 'disagree', 'neutral' to 'agree'. The questionnaire was pilot-tested through convenience sampling from June 6, 2023, to June 17, 2023. A survey was conducted with a sample of 52 individuals to assess the face validity, focusing on determining the relevance and accuracy of the 21 items, as well as examining their reliability according to the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) methodology for assessing the content validity and reliability of Patient-reported Outcome Measures (PROMs) [3,4]. The items were found to be reliable, with

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an acceptable Cronbach's alpha coefficient of 0.727[5]. Item-content validity index(I-CVI) and scale-content validity index(S-CVI) were 0.791 and 0.877, respectively [6].

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Appendix B: Systematic Literature Retrieval

1 Data Source

Databases: BYU Law, Westlaw, Web of Science, JSTOR, Springer
International Organization Website: UNESCO Library, OECD Library, EP Library, et al.

national government departments and relevant committees :Using the United States as an example: THE WHITE HOUSE(<http://www.whitehouse.gov>), Science technology council(<https://www.nstc.org.zm>), homeland security(<http://www.dhs.gov>), Information Network Sector(<http://www.nitr.gov>), department of Defense (<https://innovation.defense.gov/>).

2 Retrieval Strategy

The title should contain: (artificial intelligence or AI or robot) and (ethic or moral or governance or risk or principle or guideline or consensus)

Time Range: January 1, 2016 to May 1, 2021

3 Primary Reference Lists

NO.	Publishing Agency	Document Title	Year
1	European Parliament	An EU framework for artificial intelligence	2020
2	European Parliament	Artificial intelligence: From ethics to policy	2020
3	European Parliament	European framework on ethical aspects of artificial intelligence, robotics and related technologies	2020
4	European Parliament	EU guidelines on ethics in artificial intelligence: Context and implementation	2019
5	European Parliament	European Civil Law Rules in Robotics	2016
6	European Commission	Ethics Guidelines for Trustworthy AI	2018
7	OECD	OECD Principles on AI	2019
8	China	Practice Guide of Network Security - Prevention of Ethical Security Risks of Artificial Intelligence	2021
9	China	The Governance Principle of the New Generation of Artificial Intelligence-Developing Responsible Artificial Intelligence	2019
10	UNESCO	Recommendation on the Ethics of Artificial Intelligence	2021
11	UNESCO	Preliminary Study on the Ethics of Artificial Intelligence	2019

12	UNESCO	Ethical principles for the development of Artificial Intelligence based on the diversity of cultural expressions	2018
13	America	Executive Order Promoting the Use of Trustworthy AI in the Federal Government	2020
14	America	Technology Assessment: Artificial Intelligence in Health Care	2020
15	America	Artificial Intelligence Ethics Framework for the Intelligence Community	2020
16	America	Four Principles of Explainable Artificial Intelligence	2020
17	America	Ethical Principles for Artificial Intelligence	2020
18	America	Principles of Artificial Intelligence Ethics for the Intelligence Community	2020
19	America	Guidance for Regulation of Artificial Intelligence Applications	2020
20	Britain	Robots and robotic devices Guide to the ethical design and application of robots and robotic systems	2016
21	The European Union	Ethics Guidelines for Trustworthy AI	2020
22	Korea	National Ethical Standards for Artificial Intelligence	2020
23	WHO	Ethics and governance of artificial intelligence for health: WHO guidance	2021
24	Australia	Australia's Artificial Intelligence Ethics Framework	2019
25	IEEE	Ethical Guidelines for the Design of Artificial Intelligence	2019
26	IEEE	Ethically Aligned Design Version 2	2017
27	Singapore	Model AI Governance Framework	2019

Appendix C:

A questionnaire for pediatric medical staff's ethics implementation knowledge and attitude of medical artificial intelligence social experiments

I Knowledge dimension

Introduction: We would like to invite you to present how you are familiar with the statement on ethics implementation knowledge of social experiments based on medical artificial intelligence (MAI) . Please mark only one option for each item.

K1 The status quo of performing MAI social experiments in pediatrics.

- ☐Unfamiliar
- ☐Uncertain
- ☐Familiar

K2 Common ethical issues in MAI social experiments in pediatrics.

- ☐Unfamiliar
- ☐Uncertain
- ☐Familiar

K3 Underlying reasons for ethical issues in MAI social experiments in pediatrics.

- ☐Unfamiliar
- ☐Uncertain
- ☐Familiar

K4 Coping strategies for ethical issues in MAI social experiments in pediatrics.

- ☐Unfamiliar
- ☐Uncertain
- ☐Familiar

K5 Principles, norms and guidelines for implementing ethics in MAI social experiments in pediatrics.

- ☐Unfamiliar
- ☐Uncertain
- ☐Familiar

K6 Policies or regulations for implementing ethics in MAI social experiments in pediatrics.

- ☐Unfamiliar
- ☐Uncertain
- ☐Familiar

K7 Content of ethical review for MAI social experiments in pediatrics.

- ☐ Unfamiliar
☐ Uncertain
☐ Familiar

K8 Ethical supervision mechanism for MAI social experiments in pediatrics.

- ☐ Unfamiliar
☐ Uncertain
☐ Familiar

K9 Ethical risk management approaches for MAI social experiments in pediatrics.

- ☐ Unfamiliar
☐ Uncertain
☐ Familiar

K10 Consequences of ethical violations for MAI social experiments in pediatrics.

- ☐ Unfamiliar
☐ Uncertain
☐ Familiar

II Attitude Dimension

Instruction: We would like to invite you to present how you agree with the statement on ethics implementation of social experiments based on medical artificial intelligence (MAI).

Please mark only one option.

A1 AI experts should be involved in the research ethics committee for MAI social experiments review in pediatrics.

- ☐ Disagree
☐ Neutral
☐ Agree

A2 Principles, norms, and guidelines on implementing ethics in MAI social experiments in pediatrics should be easy to understand and be transformed into a workable process.

- ☐ Disagree
☐ Neutral
☐ Agree

A3 Ethical researchers should be involved in MAI social experiments in pediatrics.

- ☐ Disagree
☐ Neutral

☐ Agree

A4 A unified ethical review can be a barrier to performing MAI social experiments in pediatrics.

☐ Disagree

☐ Neutral

☐ Agree

A5 Clarified subjects of ethical responsibility in MAI social experiments in pediatrics can facilitate ethical supervision.

☐ Disagree

☐ Neutral

☐ Agree

A6 Participating in ethical education and training programs focusing on MAI social experiments is helpful for ethical supervision.

☐ Disagree

☐ Neutral

☐ Agree

A7 It is necessary to take children's and guardians' opinions into account while performing MAI social experiments in pediatrics. When children's views are contrary to the guardians', we should adopt the guardians' ones.

☐ Disagree

☐ Neutral

☐ Agree

A8 Establishing an effective supervision mechanism is helpful.

☐ Disagree

☐ Neutral

☐ Agree

A9 Content of ethical supervision can be dynamically adjusted according to the clinical context.

☐ Disagree

☐ Neutral

☐ Agree

A10 The number of children or guardians against MAI will increase after having a comprehensive understanding of the ethical risk in MAI social experiments in pediatrics.

☐ Disagree

☐Neutral

☐Agree

A11 Strict ethical risk management can hinder performing MAI social experiments in pediatrics.

☐Disagree

☐Neutral

☐Agree

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Table 1 Comparing the knowledge of implementing ethics in MAI social experiments among healthcare workers at children's hospitals [N of pediatricians=137, N of nurses=135, N of health information technicians (HIT)=60]

Knowledge	Pediatricians n (%)	Nurses n (%)	HIT n (%)	Chi-Square, χ^2	Sig, P
K1					
Unfamiliar 135(40.7)	54(39.4)	67(49.6)	14(23.3)	20.064	<0.001
Uncertain 165(49.7)	71(51.8)	61(45.2)	33(55.0)		
Familiar 32(9.6)	12(8.8)	7(5.2)	13(21.7)		
K2					
Unfamiliar 208(62.7)	83(60.6)	95(70.4)	30(50.0)	11.311	0.023
Uncertain 102(30.7)	44(32.1)	36(26.7)	22(36.7)		
Familiar 22(6.6)	10(7.3)	4(3)	8(13.3)		
K3					
Unfamiliar 212(63.9)	81(59.1)	99(73.3)	32(53.3)	10.969	0.027
Uncertain 102(30.7)	49(35.8)	31(23.0)	22(36.7)		
Familiar 18(5.4)	7(5.1)	5(3.7)	6(10.0)		
K4					
Unfamiliar 245(73.8)	99(72.3)	106(78.5)	40(66.7)	7.753	0.101
Uncertain 79(23.8)	36(26.3)	27(20.0)	16(26.7)		
Familiar 8(2.4)	2(1.5)	2(1.5)	4(6.7)		
K5					
Unfamiliar 246(74.1)	96(70.1)	110(81.5)	40(66.7)	16.128	0.003
Uncertain 72(21.7)	38(27.7)	21(15.6)	13(21.7)		
Familiar 14(4.2)	3(2.2)	4(3.0)	7(11.7)		
K6					
Unfamiliar 258(77.7)	107(78.1)	108(80.0)	43(71.7)	3.045	0.550
Uncertain 66(19.9)	27(19.7)	25(18.5)	14(23.3)		
Familiar 8(2.4)	3(2.2)	2(1.5)	3(5)		
K7					
Unfamiliar 269(81.0)	111(81.0)	113(83.7)	45(75.0)	6.334	0.176
Uncertain 55(16.6)	24(17.5)	20(14.8)	11(18.3)		
Familiar 8(2.4)	2(1.5)	2(1.5)	4(6.7)		
K8					
Unfamiliar 274(82.5)	115(83.9)	112(83.0)	47(78.3)	2.495	0.646
Uncertain 50(15.1)	20(14.6)	20(14.8)	10(16.7)		
Familiar 8(2.4)	2(1.5)	3(2.2)	3(5.0)		
K9					
Unfamiliar 269(81.0)	112(81.8)	111(82.2)	46(76.7)	4.120	0.390
Uncertain 53(16.0)	23(16.8)	20(14.8)	10(16.7)		

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Familiar	10(3.0)	2(1.5)	4(3.0)	4(7.7)		
K10						
Unfamiliar	245(73.8)					
Uncertain	69(20.8)	100(73.0)	105(77.8)	40(66.7)	9.260	0.055
Familiar	18(5.4)	28(20.4)	28(20.7)	13(21.7)		
		9(6.6)	2(1.5)	7(11.7)		

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Table 2 Comparing the attitude towards implementing ethics in social experiments based on MAI among healthcare workers at children's hospitals [N of pediatricians=137, N of nurses=135, N of health information technicians (HIT)=60]

Attitude	Pediatricians n (%)	Nurses n (%)	HIT n (%)	Chi-Square, χ^2	Sig, P
A1					
Disagree 18(5.4)	8(5.8)	5(3.7)	5(8.3)	16.315	0.003
Neutral 66(19.9)	14(10.2)	34(25.2)	18(30.0)		
Agree 248(74.7)	115(83.9)	96(71.1)	37(61.7)		
A2					
Disagree 5(1.5)	3(2.2)	1(0.7)	1(1.7)	10.320	0.035
Neutral 47(14.2)	10(7.3)	24(17.8)	13(21.7)		
Agree 280(84.3)	124(90.5)	110(81.5)	46(76.7)		
A3					
Disagree 4(1.2)	1(0.7)	1(0.7)	2(3.3)	17.971	0.001
Neutral 56(16.9)	11(8.0)	28(20.7)	17(28.3)		
Agree 272(81.9)	125(91.2)	106(78.5)	41(68.3)		
A4					
Disagree 87(26.2)	33(24.1)	33(24.4)	21(35.0)	3.442	0.487
Neutral 139(41.9)	60(43.8)	59(43.7)	20(33.3)		
Agree 106(31.9)	44(32.1)	43(31.9)	19(31.7)		
A5					
Disagree 4(1.2)	0(0.0)	2(1.5)	2(3.3)	11.958	0.018
Neutral 59(17.8)	17(12.4)	25(18.5)	17(28.3)		
Agree 269(81.0)	120(87.6)	108(80.0)	41(68.3)		
A6					
Disagree 3(0.9)	0(0.0)	2(1.5)	1(1.7)	10.858	0.028
Neutral 46(13.9)	13(9.5)	18(13.3)	15(25.0)		
Agree 283(85.2)	124(90.5)	115(85.2)	44(73.3)		
A7					
Disagree 62(18.7)	32(23.4)	20(14.8)	10(16.7)	3.667	0.453
Neutral 81(24.4)	30(21.9)	35(25.9)	16(26.7)		
Agree 189(56.9)	75(54.7)	80(59.3)	34(56.7)		
A8					
Disagree 4(1.2)	0(0.0)	2(1.5)	2(3.3)	13.088	0.011
Neutral 42(12.7)	9(6.6)	21(15.6)	12(28.3)		
Agree 286(86.1)	128(93.4)	112(83.0)	46(66.7)		
A9					
Disagree 12(3.6)	3(2.2)	6(4.4)	11(18.3)	9.893	0.042
Neutral 63(19.0)	17(12.4)	29(43.0)	29(48.3)		

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Agree	257(77.4)	117(85.4)	100(35.6)	20(33.3)		
A10						
Disagree	73(22.0)	33(24.1)	29(21.5)	40(66.7)	2.062	0.724
Neutral	139(41.9)	52(38.0)	58(20.7)	13(21.7)		
Agree	120(36.1)	52(38.0)	48(1.5)	7(11.7)		
A11						
Disagree	79(23.8)	36(26.3)	29(21.5)	14(23.3)	1.223	0.874
Neutral	139(41.9)	54(39.4)	58(43.0)	27(45.0)		
Agree	114(34.3)	47(34.4)	48(35.6)	19(31.7)		

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page/Line number of the manuscript
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	Page1/ Line 1-3
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page2-3/Line 23-46
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page4-5/Line 68-109
Objectives	3	State specific objectives, including any prespecified hypotheses	Page5-6/Line 110-115
Methods			
Study design	4	Present key elements of study design early in the paper	Page6/Line 118
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page6/Line 118-120
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page6-7/Line 126-133
		Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	
		Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	
		(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed	NA
		Case-control study—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page8-9/Line 175-180
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page8-9/Line 181-189
Bias	9	Describe any efforts to address potential sources of bias	NA
Study size	10	Explain how the study size was arrived at	Page6/Line 134-137

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page8-9/Line 181-189
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page8-9/Line 181-189
		(b) Describe any methods used to examine subgroups and interactions	Page9/Line 194-195
		(c) Explain how missing data were addressed	Page9/Line 196-197
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed	NA
		<i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	
		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page10/Line 200-203
		(b) Give reasons for non-participation at each stage	Page9/Line 200-203
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page10/Table 1
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	NA
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	NA
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	Page10/Line 200-203
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page9/Line 203
		(b) Report category boundaries when continuous variables were categorized	Page9/Line 203-204
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page13-14/Line 236-254
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page17/Line 273-291
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page18/Line 306-313
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page17/Line 273-313
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page18/Line 304-306
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page20/Line 340-345

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.