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Review Article

Validated simulation models in pediatric surgery: A review

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ABSTRACT

Introduction: This review evaluates the validation and availability of simulation models in the field of pediatric surgery that can be used for training purposes.
Methods: MEDLINE and EMBASE were searched for studies describing a simulation models in pediatric surgery. Articles were included if face, content and/or construct validity was described. Additionally, the costs and availability were assessed. Validation scores for each model were depicted as percentage (0–100), based on the reported data, to compare the outcomes. A score of >70% was considered adequate.
Results: Forty-three studies were identified, describing the validation process of 38 simulation models. Face validity was evaluated in 33 articles, content in 36 and construct in 19. Twenty-two models received adequate validation scores (>70%). The majority (27/38, 70%) was strictly inanimate. Five models were available for purchase and eleven models were replicable based on the article.
Conclusion: The number of validated inanimate simulation models for pediatric surgery procedures is growing, however, few are replicable or available for widespread training purposes.
Level of evidence: Level II.

1. Introduction

Until present, training for specific pediatric surgery procedures remains challenging. This is firstly owing to the high technical complexity of procedures with a small working space [1] and secondly to limited case exposure as a result of the rarity of some of the pediatric surgical conditions [2]. The latter leads to little exposure in clinical setting, which is exaggerated by the increasing emphasis on efficiency and maximizing productivity in the operating theater [3]. During training, operative time is increased, especially in the early stages of a trainee's learning curve [4]. Trainees subsequently decrease the number of patients that can be operated in one day and hence increase costs. Pressure to increase theater throughput can result in compromising the training opportunities of surgical trainees [3]. Moreover, there is the ethical debate regarding less experienced surgeons operating on live patients less than supervision [4]. Traditionally, training is mostly based on the apprenticeship model and mentoring. This model assumes that trainees gain knowledge and skills simply by exposing them to procedures and they learn to perform surgical procedures by operating on patients less than strict supervision, which in time becomes less strict until the surgeon is fully capable of performing the procedure without supervision [2]. However, if supervision is not strictly monitored, it may result in an increased risk of treatment failure exposing the patient to a higher risk of complications. Particularly in this current era where maintaining competency, patient outcome, and safety is being increasingly scrutinized, it is worthwhile to critically look at other ways of training besides the traditional apprenticeship model of surgical training [5].

An alternative is simulation based training, using inanimate or animate simulation models. Simulation models have demonstrated their merit for skill acquisition [6]. However, with the increasing number of simulation models in pediatric surgery it is important to evaluate their validity. This review assesses the validation of these simulation models and describes the current availability and costs.

2. Methods

2.1. Information sources and search

Eligible studies were identified through an online search of MEDLINE and EMBASE. The search including the following index terms: "pediatric or pediatric" combined with "surg" and "simulation". Additional terms were "model" and "simulation training". The search strategy was designed in cooperation with librarians to minimize sampling bias. The full search strategy is described in Supplementary Fig. 1. No restrictions regarding language, year or publication type were imposed.

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2.2. Study eligibility criteria

Titles and abstracts were screened according to the preferred reporting items for systematic reviews and meta-analysis (PRISMA) guidelines. All retrieved studies were independently assessed by two reviewers (MJ and SB) through Rayyan QCRI according to the eligibility criteria [7]. Articles were first screened on title and abstracts. Remaining results were examined on full text. Conflicts were resolved by discussion. Studies were eligible for inclusion if the authors described any form of validation of a simulation model for general pediatric surgery (as defined by the European training requirements [8] including pediatric urology, pediatric traumatology but excluding pediatric neurosurgery [9]). Exclusion criteria were: studies only describing simulation models, simulation models for other specialties, simulation models for nonsurgical procedures, conference abstracts, letters to the editor, nonenglish articles and studies not published in full text. In case of duplicate publications from one institute, the most recent and complete dataset was considered for inclusion. Models were classified based on the procedure to be practiced.

2.3. Data extraction

The following variables were extracted: first author, country, year of publication, number of participants, type of validation of the simulation model, score for the validation, costs of construction and/or use of the model, replicability of the simulation model, and availability of the model. In order to be considered a replicable model, written or video instructions, detailed enough to produce the simulation model at-home, needed to be provided in the article. Furthermore, only materials that were easily available to the researchers (e.g. common materials that could be found in a hospital or bought at a dime store) were to be used, without the need for expensive equipment.

Scores for validation were calculated based on the reported data and depicted as percentage (0–100) of the scale used in the article. A score of >70% on the used scale used was considered adequate for validation and >90% was considered excellent. Regarding the number of participants, eight experts and eight novices or trainees was regarded the minimum requirement for adequate participant numbers [10].

Types of validation were based on the definitions by McDougall and Van Nortwick et al. [11,12]. Assessment of the realism of the simulation models (by experts and nonexperts) was regarded face validity. The judgement of the appropriateness of the simulator as a teaching modality (assessed by experts) was regarded content validity. Construct validity was defined as the ability of the simulation model to distinguish between the experienced and inexperienced pediatric surgeon, which meant that the simulation model had the capability of an objective assessment tool [11–13].

3. Results

3.1. Study selection

The combined search resulted in 4917 articles, consisting of 4499 unique citations and 418 duplicates. After screening 43 articles were found eligible for inclusion and data extraction. The PRISMA flowchart for study selection is shown in Fig. 1.

3.2. Study characteristics

An overview of included studies can be seen in Supplementary Table 1. A total of 38 simulation models were described. The majority of the studies (91%) were published after 2013, with most publications in 2014, 2015, and 2016 (six each year). The majority of articles described a process for face (33 articles), content (36 articles) or construct (19 articles) validation. A total of 22 (58%) simulation models received adequate validation scores for at least one form of validation (20 face validation and 21 content validation).

The majority (27, 70%) of simulation models were strictly inanimate, five were living animal models, one simulation model used a chicken cadaver and five consisted of an inanimate casing with fetal bovine tissue for organs. No articles regarding augmented or virtual reality were identified.

Of all studies, fourteen calculated or estimated the costs of construction of the simulation model, ranging from €0.20 to €1800. A detailed description or video material for replication was provided for eleven models [14–24] and only five models were available for purchase [16,25–28].

3.3. Pediatric surgical simulation models

3.3.1. ECMO cannulation

Overall, two validation studies describing two different simulation models were identified, both describing an inanimate simulation model [25,14]. The model described by Botden et al. is a low budget model which can be used for ECMO cannulation. It consisted of a 3D printed reusable base with small water-balloons to simulate the vessels. It was evaluated by a target group and experts and showed face and content validity with scores of 76% and 78% respectively [25]. The article by Thompson et al. described a simulation model for initiating ECMO treatment, including the cannulation. It consisted of a high-fidelity mannequin model with latex tubing for vessels to simulate veno-arterial cannulation of an unstable neonate. Face and content validity statements were scored on a 5-point Likert scale, however, outcome scores of this process were not provided. Videos for replication are provided and costs of construction are estimated at $25 [14]. The model described by Botden et al. is commercially available for €75 [29] (Table 1).

3.3.2. Congenital diaphragmatic hernia

A total of seven articles described six simulation models for MIS repair of congenital diaphragmatic hernia (CDH) [15–17,30,31–33]. No simulation models for open repair of a congenital diaphragmatic hernia were found. Of the six models, five were inanimate models [15–17,30,31] and one was a rabbit model (New Zealand white rabbit, 3.0–3.5 kg) [32,33]. For the rabbit model, described by Perez-Merino et al. and Uson-Casaus et al., an incision was made in the Bochdalek triangle of the rabbits to introduce an experimental diaphragmatic hernia, which was thoracoscopically repaired after 72 h. For this model face validity was established (scores 78% and 86% respectively) as well as content validity (80% and 92% respectively) [32,22]. Uson-Casaus et al. also describe a process of construct validity based on total time, VAS performance scores and quality of the sutures, however, the latter two are subjective scores which are not suitable for demonstrating construct [32].

Barsness et al. established face (82%) and content (86%) validity of an inanimate neonatal ribcage model, which can be used without an additional box trainer [31]. The model consists of the left side of a neonatal thoracic cavity, which is printed in acrylonitrile-butadiene-styrene plastic and covered with a synthetic silicon rubber skin. Bökkerink et al. have developed an inanimate CDH model that can be used in any conventional box trainer. This model consists of a round plastic cup covered with a nonlatex surgical glove with the fingers cut off. It showed both face (70%) and content (72%) validity [16]. Ljuhar et al. describe a validation process for an inanimate simulator which can be used for both CDH repair and inguinal hernia repair [17]. The model consists of three pieces of ply wood with an opening on the side. A piece of neoprene

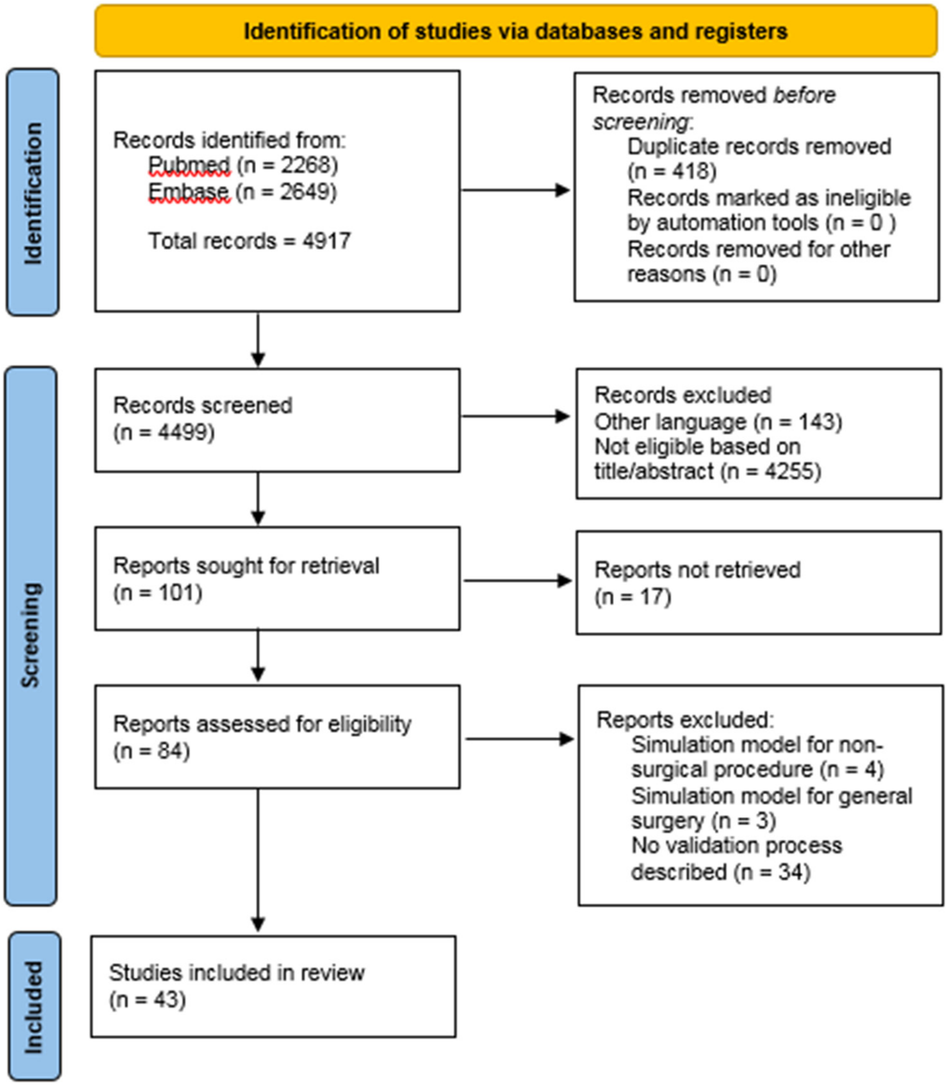

Fig. 1. Prisma flowchart.

Table 1
Simulation models for ECMO cannulation. Values are stated as numbers or percentage.

Simulation models for ECMO cannulation										
Model	Author	Type of model	Open/ MIS	Participants (experienced)	Face	Content	Validation?	Reproducable	Costs described	Available (price)
ECMO cannulation	Botden et al.	Inanimate	Open	21 (14)	76%	78%	Yes (Face, content)	No	No	Yes, (€75)
ECMO cannulation	Thompson et al.	Inanimate	Open	17 (3)	unknown	unknown	No	Yes (video)	$25	No

with a cut-out defect was places more than the opening to simulate a congenital diaphragmatic hernia. Content validation (80%) as well as construct validation (based on a combined score) was described, however, of the 107 participants none were pediatric surgeons. Therefore, content validation for pediatric surgery was not established [17] (Table 2).

Obata et al. described construct validation based on total time for their inanimate model [30]. The model consists of a left and right thoracic cavity divided by a mediastinum sheet and a detachable diaphragm unit. It is covered with a soft skin sheet. This model was established to replicate the full procedure of thoracoscopic repair of a CDH. While they also described a process for face validation, it only received a score of 68% and did not establish the validation criteria in this review. Neither did Reino-Pires et al., who reported a score of 68% for content validation for another inanimate simulation model, consisting of ordinary materials purchased in a dime store (food container, a neoprene band for the diaphragm and a body wash sponge simulating a collapsed lung) [30,15].

Uson-Casaus et al. provided a detailed description and Bökkerink et al. provided video instructions for replication of the simulation models [32,16].

Calculated or estimated costs are provided by Barsness et al. ($218), Reino-Pires et al. (€11) and Bökkerink et al. (€1.65) [15,16,31]. The inanimate simulation model by Bökkerink et al. is

Table 2
Simulation models for procedures in the thoracic cavity or chest.

Simulation models for the thoracic cavity										
Thoracic cavity/chest										
Model	Author	Type of model	Open/MIS	Participants (experienced)	Face	Content	Validation	Reproducable	Costs described	Available (price)
Chest tube placement	Al-Qadhi et al.	Inanimate	Open	24 (10)	–	60%	No	No	No	No
Pediatric chest model	Harada et al.	Inanimate MIS box trainer	MIS	30 (14)	-	–	No	No	No*	No
Pediatric chest model	Takazawa et al.	Inanimate MIS box trainer	MIS	53 (8)	-	–	No	No	No*	No
Pleural empyema	Marecos et al.	Animal (rabbit)	MIS	30 (30)	95%	-	Yes (Face)	Yes (description)	No*	No
Lobectomy (neonatal ribcage)	Barsness et al.	inanimate casing animal tissue	MIS	33 (11)	90%	88%	Yes (Face, Content)	No	No*	No
CDH simulation models										
CDH	Barsness et al.	Inanimate	MIS	40 (9)	82%	86%	Yes (Face, Content)	No	$218*	No
CDH	Obata et al.	Inanimate	MIS	29 (10)	68%	–	No	No	No*	No
CDH	Uson-Casaus et al.	Animal (Rabbit)	MIS	25 (5)	78%	80%	No	Yes (description)	No*	No
CDH	Perez-Merino et al.	Animal (Rabbit)	MIS	6 (6)	86%	92%	No	No	No*	No
CDH	Ljuhar et al.	Inanimate	MIS	107 (0)	-	80%	No	Yes	No*	No
CDH	Reino-Pires et al.	Inanimate	MIS	19 (6)	78%	68%	No	Yes	€11*	No
CDH	Bökkerink et al.	Inanimate	MIS	60 (18)	70%	72%	No	Yes (video, instructions)	€1.65*	Yes (improved version €10)
EA simulation model										
EA with TEF	Maricic et al.	Inanimate	MIS	39 (7)	86%	88%	No	No	No*	No
EA with TEF	Barsness et al.	inanimate casing animal tissue	MIS	11 (11)	90%	90%	Yes (Face, Content)	No	No*	No
EA with TEF	Barsness et al.	inanimate casing animal tissue	MIS	20 (8)	94%	92%	Yes (Face, Content)	No	$290*	No
EA with TEF	Barsness et al.	inanimate	MIS	44 (14)	82%	80%	Yes (Face, Content)	No	$202 (re-usable 20 times)*	No
EA with TEF	Deie et al.	Inanimate model	MIS	40 (6)	78%	88%	No	No	No*	No
EA	Bökkerink et al.	Inanimate	MIS	60 (18)	74%	74%	Yes (Face, Content)	Yes (video, instructions)	€0.20*	No

* simulation model for use in a box simulator and/or needs a laparoscopic camera or instruments for use possibly resulting in additional costs.

the only model that is commercially available (€10 for an improved version) [16] (Table 2).

3.3.3. Chest/thoracic cavity

Overall, four simulation models for procedures in the thoracic cavity or chest (other than CDH) are described in five articles [34,35,36,18,37].

Marecos et al. establish excellent face validation (95%) for a living rabbit model with pleura empyema (New Zealand rabbit, weighing 3.0–4.0 kg) [18]. Furthermore, they provide a detailed description of preparation of the model in the methods. A simulation model for MIS lobectomy in an inanimate neonatal ribcage with fetal bovine tissue for organs is described by Barsness et al. [37]. They established excellent face validity (90%) as well as content validity (88%) [37].

The pediatric chest inanimate model described by Harada et al. and Takazawa et al. consisted of a pneumoperitoneum model with a detachable rubber sheet for the esophageal crura unit and styrene material for the organs (stomach, liver, spleen) which was covered with synthetic skin. The model both established construct validity for intracorporeal suturing and knot tying [34,35]. However, no face or content validity data were provided on this model.

Al-Qadhi et al. describe a model for chest tube placement consisting of a plaster shell with a multilayer silicon insert representing the thoracic cavity, filled with gauzes in a silicon layer for muscle fibers and foam for subcutaneous fat. This model receives a score of 60% for content validation [36]. No simulation models are commercially available and none of the articles provided any cost estimates (Table 2).

3.3.4. Esophageal atresia

Four models for MIS esophageal atresia (EA) repair are described in six articles [16,38–42]. All models are inanimate with the exception of the EA with TEF model described by Barsness et al., which consisted of an inanimate casing with fetal bovine tissue for the organs [38,39].

Maricic et al. describe a model consisting of domestic materials such as plastic tubes to simulate ribs and latex balloons for the esophagus which is inserted in a rubber thoracic cavity [41]. Deie et al. describe a rapid-prototyped neonatal chest model with an artificial esophagus model [42].

Face and content validity is described for all models, however, Maricic et al. and Deie et al. described the opinion of less than eight experts (seven and six respectively) [41,42]. Barsness et al. described face (90% and 94%) and content (90% and 92%) validation for the inanimate casing with fetal bovine tissue [38,39]. For the strictly inanimate simulation model developed by Barsness et al. this was 82% for face and 80% for content validation [40]. Bökkerink et al. described an inanimate simulation model consisting of two water balloons on a suturing pad, which can be used in a conventional box trainer, of which face (74%) and content (74%) validation were established.

A process for construct validation was described by Maricic et al. (based on total time, errors and incomplete anastomosis), Barsness et al. (based on OSATS) and Deie et al. (29-point checklist, error score, number of manipulations and task completion time) [39,41,42].

The EA with TEF model described by Barsness et al. was estimated to cost $290 for the construction of the inanimate casing with fetal bovine tissue for organs and $202 dollar for the inanimate model, the latter being reusable up to twenty times [38–40]. Bökkerink et al. estimate the cost of construction of the EA model at €0.20 per model and provided a detailed description and video instructions for replication of the model at home, to use in any MIS box trainer [16]. No models were commercially available (Table 2).

3.3.5. Fundoplication

One inanimate model and one animal model for fundoplication are described in a total of three articles [19,43,44]. All models are for MIS procedure, no models for open procedures were identified. Ieiri et al. describe a model consisting of a suturing pad which was modified to a suture ligature model of the crura of the diaphragm [43]. Jimbo et al. describe the development of an infant body based on computed tomography data with an esophageal crura unit made as a detachable sheet [44]. The animal model described by Esposito et al. was multifunctional with the option to practice inguinal hernia repair, varicocelectomy, nephrectomy and fundoplication [19]. However, it was only tested by ten trainees and no experts, a process of establishing content validation was conducted only by comparing it to a pig model (95% in favor of the rabbit model). Ieiri et al. and Jimbo et al. only reported construct validation for an inanimate simulation model (based on total time, force on the tissue, stitches spacing for the former and total time, suturing balance, path length and velocity for the latter). They did not describe face or content validity, therefore no rating could be given on these values [43,44]. Only Esposito et al. provided instructions for replication [19] and neither model is currently commercially available (Table 3).

3.3.6. Pyloromyotomy

For practicing pyloromyotomy four inanimate MIS simulation models were identified [20,45,46,47]. Ballouhey et al. described a low cost replicable model using basic materials such as a balloon filled with silicone paste. The model was placed in a pediatric laparoscopic surgery simulator for use [20]. They established face validity (78%) and content validity (78%). They described construct validity as well, however, this was based on subjective scores by expert observers and not the simulation model itself (OSATS, pyloromyotomy OSATS, mucosal perforation and incomplete pyloromyotomy) [20]. A detailed description of the model was provided in the supplementary data of the article for replication of the model. Williams et al. established face validity (83%), content validity (83%) for their 3D printed model for use in a box trainer. They attempted construct validity based on mean procedural time, however, the latter was not discriminative [45]. Plymale et al. described face (80%) and content validation (85%) for a middle fidelity MIS simulation model [46]. Skertich et al. described the development of a model for gastroschisis, perforated NEC and pyloromyotomy. For pyloric stenosis silicone a raw sausage with a core of an inflated balloon was used, which was placed in a box trainer. They describe excellent face (96%) and content validity (82%), however, only trainees and no expert pediatric surgeons were included [47]. They do provide cost estimates for construction of the model, which are €290 per simulation model [47] (Table 3).

3.3.7. Duodenal atresia

For duodenal atresia two (partly) animate simulation models were identified [48,49]. Ordorica-Flores et al. describe the validation process of a rabbit model (weighing 3.0–4.5 kg) with excellent face validity (96% score) and content validity (84% score) [48]. The costs are estimated at $32 per rabbit. Barsness et al. describe a model consisting of an inanimate casing with fetal bovine tissue for the organs [49]. They describe face validity (88%) as well as excellent content validity (95%), however, this is based on the opinion of only six experts. Simulation models are not commercially available (Table 3).

3.3.8. Bile ducts

Two simulation models are described in three articles [22,50,51]. Schwab et al. and Santos et al. described an inanimate simulation model for common bile duct surgery consisting of a liver, gallbladder, extrahepatic biliary system and duodenum, all

Table 3
Simulation models for procedures in the upper abdomen.

Model	Author	Type of model	Open/ MIS	Participants (experienced)	Face	Content	Validation	Reproducable	Costs described	Available (price)
Simulation models for procedures in the upper abdomen										
Fundoplication simulation models										
Fundoplication	Ieiri et al.	Inanimate	MIS	20 (10)	-	-	No	No	No*	No
Fundoplication	Jimbo et al.	Inanimate	MIS	49 (15)	-	-	No	No	No*	No
Fundoplication	Esposito et al.	Animal (Rabbit, Pig)	MIS	10 trainees	-	95%	No	Yes (instructions)	No*	No
Pyloromyotomy										
Pyloromyotomy	Ballouhey et al.	Inanimate	MIS	80 (15)	78%	78%	Yes (Face, content)	Yes (instruction)	No*	No
Pyloromyotomy	Williams et al.	Inanimate	MIS	27 (9)	83%	83%	Yes (Face, content)	No	$30*	No
Pyloromyotomy	Skertich et al.	Inanimate	MIS	28 (0)	96%	82%	No	No	€290*	No
Pyloromyotomy	Plymale et al.	Inanimate,	MIS	55 (29)	80%	85%	Yes (Face, Content)	No	No*	No
Duodenal atresia simulation models										
Duodenal atresia	Ordorica-Flores et al.	Animal (rabbit)	MIS (use in simulator)	13 (13)	96%	84%	Yes (Face, Content)	No	$32*	No
Duodenal atresia	Barness et al.	inanimate casing with animal tissue	MIS	18 (6)	88%	95%	No	No	No*	No

* simulation model for use in a box simulator and/or needs a laparoscopic camera or instruments for use possibly resulting in additional costs.

created out of synthetic materials [22,50]. Schwab et al. described face (80%) and content validity (90%), however this was only based on the opinion of trainees. Santos et al. described construct validity, however this was based on OSATS scores given by expert observers and not the model itself.

Burdall et al. described the validation process of an inanimate model for laparoscopic choledochal surgery [51]. However, the model only scored 56% on their scale for face and 68% for content validity, additionally, no experts were included [51]. Santos et al. provided a detailed description of the model and estimated the costs of construction at $465 [22]. No description for replication or cost estimates were provided of the model by Burdall et al. [51] (Table 4).

3.3.9. Gastroschisis

Two simulation models for silo placement in gastroschisis were identified [47,52]. Skertich et al. describe a simulation model for silo placement for gastroschisis, which can also be used for percutaneous drain placement for perforated NEC and laparoscopic pyloromyotomy [47]. This simulation model scored excellent for face (98%) and content validity (82%), however, no experts were included in this validation process and therefore validation was not established. Bacarese-Hamilton et al. described the validation process of another inanimate model for silo placement, using an umbilical cannulation simulation mannequin, which demonstrated face (78%) and content validity (82%) [52]. Skertich et al. estimated the costs of their model at €450 [47]. Both models were not commercially available (Table 4).

3.3.10. Perforated NEC

As mentioned previously, the simulation model by Skertich et al. could be used for drain placement for perforated necrotizing enterocolitis (NEC) as well. Although they reported excellent scores for face (100%) and content (82%) validity, no experts were included in this process, therefore validation was not established. Costs for construction were estimated at €1000 and the model was not commercially available [47].

3.3.11. Urology

Millán et al. described the validation of an inanimate simulation model for uretral reimplantation [23]. The model consisted of a water balloon and nasogastric tube covered with a silicone box, for use with MIS instruments. They established face (88%) and content validation (90%).

Two inanimate models for pyeloplasty were identified [21,53]. Cheung et al. described a process of face validation for a 3D printed silicone MIS model which can be used in a box trainer, however, the model scored only 68% on their used scale and was only evaluated by three experts [53]. The simulation model for open pyeloplasty described by Rod et al., consisting of two water balloons, achieved a score of 82% for face validity as well, however, for content validation it only achieved 70% [21]. Cheung et al. and Rod et al. described the costs for construction of the simulation model ($100 and less than $1 respectively), the latter also provided a detailed description for replication [21,52]. Construction costs of the model by Millán et al. were estimated at $25 per model and written instructions for replication of the model were provided [23]. None of these simulation models were commercially available (Table 5).

3.3.12. Anorectal malformations

Van Ling et al. described the development and validation process of a simulation model of an anorectal malformation with perineal fistula [26]. This model consisted of a sponge for the perineal body and a double layered balloon for the rectal fistula. It showed face (80%) and content (84%) validity, the construction costs were

Table 4
Abdominal simulation models.

Abdominal simulation models Bile ducts simulation models Model	Author	Type of model	Open/MIS	Participants (experienced)	Face	Content	Validation	Reproducable	Costs described	Available (price)
Common Bile duct	Schwab et al.	Inanimate	MIS	30 (0)	80%	90%	No	No	No*	No
Common Bile duct	Santos et al.	Inanimate	MIS	21 (5)	-	–	No	Yes, instructions	$465*	No
laparoscopic choledochal surgery	Burdall et al.	Inanimate	MIS	10 (0)	56%	68%	No	No	No*	No
Gastroschisis (silo placement)										
gastroschisis	Skertich et al.	Inanimate	Open	28 (0)	98%	82%	No	No	€450	No
Gastroschisis	Bacarese-Hamilton et al.	Inanimate	Open	18 (14)	78%	82%	Yes (Face, Content)	No	No	No
NEC (drain placement)										
Perforated NEC	Skertich et al.	Inanimate	Open	28 (0)	100%	82%	No	No	€1000	No

* simulation model for use in a box simulator and/or needs a laparoscopic camera or instruments for use possibly resulting in additional costs.

Table 5
Urogenital, anorectal and inguinal hernia simulation models.

Urogenital, anorectal and inguinal hernia simulation models Uretral reimplantation Model	Author	Type of model	Open/MIS	Participants (experienced)	Face	Content	Validation	Reproducable	Costs described	Available (price)
Uretral reimplantation	Millán et al.	Inanimate	MIS	34 (12)	88%	90%	Yes (Face, Content)	Yes	$25*	No
Pyeloplasty simulation models										
Pyeloplasty model	Cheung et al.	Inanimate	MIS	25 (3)	68%	–	No	No	$100 *	No
Pyeloplasty model	Rod et al.	Inanimate	Open	118 (44)	82%	70%	Yes (Face, Content)	Yes	$1	No
Anorectal malformation										
Anorectal malformation with perineal fistula	Van Ling et al.	Inanimate	Open	44 (24)	80%	84%	Yes (Face, Content)	No	€70 -€100	Yes (€75)
Inguinal hernia										
Inguinal hernia	Ljuhar et al.	Inanimate	MIS	107 (0)	-	80%	No	Yes	No*	No

* simulation model for use in a box simulator and/or needs a laparoscopic camera or instruments for use possibly resulting in additional costs.

provided (€70-€100) and it is commercially available online for €75,- [26] (Table 5).

3.3.13. Inguinal hernia

Ljuhar et al. describe a simulation model for the MIS repair of an inguinal hernia [17]. This model can be placed in a box trainer for training. They describe a process of content validity (80%) but did not include pediatric surgeons in the process, therefore content validation for use in training for pediatric surgery was not established. For construct validation they used a novel scoring system which did discriminate between novices and experts, but was based on subjective measures. A detailed description of the construction is provided in the article [17]. The model is not available for purchase (Table 5).

3.3.14. MIS simulators

Overall, four MIS box trainers and one animal model for MIS training are described in seven articles [24,27,28,54–57]. The Pediatric Laparoscopic Simulator (PLS) is the most frequently described (four articles) MIS box trainer. Content validity was only established by Retrosi et al. (86%) [27]. Construct validity was established by Azzie et al. (peg transfer, extracorporeal suturing and intracorporeal suturing), by Nasr et al. (intracorporeal suturing), Trudeau et al. (advanced suturing) and Retrosi et al. (object transfer, precision cutting and intracorporeal suturing) [27,54–56]. The latter compare the PLS to the EoSim, establishing excellent content (90%) and construct validity for the EoSim as well.

Bökkerink et al. compared the EoSim to the LaparoscopyBoxx and establish face (77% and 84% respectively) and content validity (79% and 90% respectively) for both simulators, with a favor for the LaparoscopyBoxx [28]. Torres et al. described a neonatal box trainer and established face (82%) and construct validity for nine basic exercises and an intracorporeal suturing task (based on total time needed for the exercise) [57]. For content validity, however, the simulator scored a mere 64%.

Zimmerman et al. described the use of chicken cadavers for neonatal laparoscopic surgery training. Adhesiolysis, cholecystectomy, intestinal resection and intestinal anastomosis were performed on the model and face (77%) and content (84%) validity were established [24]. Cost estimates are provided for the EoSim (€1800) and Laparoscopyboxx (€315), including 3 mm instruments. Both box trainers can be used either with MIS camera or with a tablet resulting in less additional costs (Table 6).

4. Discussion

This review provides an overview of the simulation models that are currently validated for use in the training for pediatric surgical procedures. By applying criteria for adequate validation of the pediatric simulation models, an indication can be given about areas where simulation models in pediatric surgery may be improved. Of all identified simulation models with a validation process ($n = 38$), only twenty-two received adequate validation scores, leaving ample room for improvement.

4.1. Validation of simulation models

Establishing the validity of simulation models is critical before examining the effectiveness of simulation-based training [58]. However, before validity can be assessed, consistent terminology should be used. In the included studies there was a lack of this consistency in the terminology, and terms were used in a different context to that described by McDougall and Van Nortwick et al. [11,12]. Furthermore, some studies failed to label the assessed validity, even though it had been demonstrated in the study. Other

Table 6
MIS trainer simulation models.

MIS trainer										
Model	Author	Type of model	Open/MIS	Participants (experienced)	Face	Content	Validation	Reproducible	Costs described	Available (price)
Neonatal laparoscopic surgery	Zimmerman et al.	Chicken cadavers	MIS	27 (9)	77%	84%	Yes (Face, Content)	Yes	No*	No
Neonatal Box trainer	Torres et al.	Inanimate	MIS	49 (unknown)	82%	64%	No	No	No*	No
PLS	Azzie et al.	Inanimate	MIS	84 (45)	-	-	No	No	No*	No
PLS	Nasr et al.	Inanimate	MIS	75 (37)	-	-	No	No	No*	No
PLS	Retrosi et al.	Inanimate	MIS	28 (8)	-	86%	Yes (Content)	No	No*	No
PLS	Trudeau et al.	Inanimate	MIS	60 (39)	-	-	No	No	No*	No
EoSim	Retrosi et al.	Inanimate	MIS	28 (8)	-	90%	Yes (Content)	No	No	Yes (€1800)
EoSim	Bökkerink et al.	Inanimate	MIS	32 (17)	77%	79%	Yes (Face, Content)	No	No	Yes (€1800)
LaparoscopyBoxx	Bökkerink et al.	Inanimate	MIS	44 (24)	84%	90%	Yes (Face, Content)	No	No	Yes (€315)

* simulation model needs a MIS camera or MIS instruments for use possibly resulting in additional costs.

studies used different criteria, such as the Standards for Educational and Psychological Testing [59]. Although a broad range of different scales was used, most studies reported the use of Likert-scale but failed to present data in the intended way [60,61]. In order to compare simulation models and gain insight in whether a simulation model achieved adequate validation, we expressed face and content validation as a percentage on the scale used by the authors.

In addition to receiving adequate scores, adequate numbers of participants (including experts) are needed for proper validation [10,62]. Some studies failed to include experts all together, others stated that experts were asked for their opinion, however, these experts were not pediatric surgeons. Content validity is by definition not possible without experts, resulting in a lack of knowledge of the appropriateness of the model. Moreover, there was a noticeable lack of power analysis to determine the number of required subjects, which suggest that studies relied on convenience samples of subjects rather than predetermined required numbers.

Simulation models that received adequate validation scores with the correct number of participants and experts were the ECMO cannulation model by Botden et al. [25], pleura empyema model by Marecos et al. (only face validity) [18], the lobectomy model and the CDH model by Barsness et al. [31,37] and two EA with TEF models by Barsness et al. [38–40], three pyloromyotomy models (by Ballouhey et al. [20], Williams et al. [45] and Plymale et al. [46]), an animal model for duodenal atresia by Ordorica-Flores et al. [48], a gastroschisis model by Bacarese-Hamilton et al. [52], a model for ureteral reimplantation by Millán et al. [23], a pyeloplasty model by Rod et al. [21], a simulation model for ARM by Van Ling et al. [26], the neonatal laparoscopic surgery model by Zimmerman et al. [24], the PLS and the EoSim evaluated by Retrosi et al. (both only content validity) [27], the EoSim and the LaparoscopyBoxx evaluated by Bökkerink et al. [28].

4.2. Evaluation and limitations of simulation models

The majority of the evaluated simulation models were inanimate. Models entirely made out of animal specimens were described for only four procedures: pleural empyema [18], CDH [32,33], MIS procedures [19] and duodenal atresia [47]. For all but one of these procedures (pleural empyema) an inanimate alternative was identified [15–17,27,28,30,31,48,54–57].

There are the ethical and cost considerations when using animal models for simulation-based training [63]. One article measured dyspnea and pain levels of their CDH animal models, which were significantly higher compared to control animals [33]. This underlines the notion that using animal models is a delicate ethical issue and that alternatives for animal models should always be investigated and used wherever and whenever appropriate [62,64–66]. This review shows that inanimate alternatives are available for most animal models. These inanimate simulation models have the advantage that they can be used more easily during courses in different settings, without a wet-lab facility, and at-home for continued training after a course. Most of the models are (partly) reusable [25-27,40,54–57] or lower in costs than their animal counterpart [16,53,67].

Inanimate simulation models, especially low-fidelity models, have the proclaimed disadvantage of having a lower degree of realism. However, research has shown that there is no advantage in learning success achieved by a higher degree of realism of the simulator. It is therefore questionable whether the additional costs and expenses of high-fidelity simulators are justified when comparable knowledge and skill outcomes are achieved with low-budget simulators [68].

It was noticeable that the majority of the evaluated simulation models (79%) focused on MIS surgery instead of open surgery. The development and implementation of simulation-based training was triggered by the evidence of increased complications during the early adaptation of MIS, related to the unique challenges of this surgical approach [68]. This resulted in simulation models mainly focusing on minimally invasive surgery instead of on open surgery [69]. For the latter only eight models were identified, although this is still the most common approach in pediatric surgery [70].

Only five simulation models were commercially available: a model CDH repair by Bökkerink et al. [16], the model for ECMO cannulation by Botden et al. [25], the ARM model by Van Ling et al. [26], the EoSim evaluated by Retrosi et al. [27] and the LaparoscopyBoxx by Bökkerink et al. [28]. For only eleven simulation models the authors provided written description or videos detailed enough to replicate the simulation model at-home: an ECMO cannulation model by Thompson et al., a model for CDH repair by Reino-Pires et al., a model for EA repair and a model for CDH repair by Bökkerink et al., a simulation model for inguinal and diaphragmatic defects by Ljuhar et al., an animal model for pleura empyema by Marecos et al., a fundoplication model by Esposito et al., a pyloromyotomy model by Ballouhey et al., a model for pyeloplasty by Rod et al., a model for bile duct exploration by Santos et al., a model for ureteral reimplantation by Millán et al. and the neonatal laparoscopic surgery model by Thompson et al. [14–24]. Moreover, most MIS simulation models were developed for use in a box simulator or needed a laparoscopic camera for use [15,17,18,20,22,24,30,31,34,35,37–45,48–50,52,53], possibly making it more difficult to use at-home or resulting in additional costs.

4.3. Incorporation of simulation-based training and future perspectives

In order to make optimal use of simulation based training, face, content and construct validity of the simulation models used should be established. Only when simulation models are validated in an adequate fashion the optimal effect of simulation-based training can be expected.

Preferably, simulation models are either commercially available or easily constructed and are optimized for use at-home. Inanimate simulation models that do not require expensive simulation towers or laparoscopic cameras are therefore preferred. Ideally simulation models are utilised to minimize potential risks to patients by having trainees learn part of a new procedure away from the clinical setting. Efforts should be made to implement existing and future validated procedure-specific simulation models for pediatric surgical procedures into the training curricula. By doing so, pediatric surgical trainees are given the opportunity to acquire the skill unique to pediatric surgery. Furthermore, procedures that are rare and infrequent in the clinical setting may be trained to retain the needed skills.

Future research may focus on evaluation of construct validity and assessment methods, preferably both objective and automatically generated feedback. Furthermore, future research should focus on developing more simulation models for open surgical procedures to make them widespread available for use.

5. Limitations

The quality of the included studies varied. Overall, there was a lack of this consistency in the terminology used regarding validation and almost all studies lacked a power analysis. A major flaw in several studies was the lack of including experts in the validation process [15,17,19,22,32,33,41,42,46,48,49,52,50,56], whereas experts are needed to establish validation.

Pediatric surgery is a generic term used to delineate a variety of subspecialties based on the age of the patients. This review focusses on what general pediatric surgery entails in Europe according to the European Training Requirements, however, this may vary locally. Therefore, this review may potentially omit relevant models which were not evaluated according to the for mentioned definition.

For the assessment of specific pediatric surgical skills it is important that the assessment method used has shown construct validity. However, this review focusses on the simulation models rather than on assessment methods. Therefore, it focusses on whether these simulation models resemble the clinical procedure (face validity) and have proper teaching capabilities (content validity). The next step will be to evaluate proper assessment methods and construct validity.

6. Conclusion

This review included both inanimate and animal models, which showed that there are currently adequate inanimate alternatives for animal models. The number of (inanimate) simulation models for specific pediatric surgery procedures is growing, although the validation process varied heavily between simulation models and only twenty-two met adequate face and/or content validity scores. Additionally, only five were available for purchase and eleven were replicable, using instructions from the articles, which indicates a need for more efforts to develop adequate simulation models and make these available for widespread use.

Declaration of Competing Interest

None declared.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jpedsurg.2022.06.015.

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