

1 **A systematic review and meta-analysis of the use of high-fidelity simulation in obstetric ultrasound.**

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4 Brian P Dromey, MBChB, MRCOG, Clinical Research Fellow^{1, 2};
5 Donald M Peebles, MBBS, MD¹, MRCOG, Professor of Obstetrics;
6 Danail V Stoyanov, PhD², Professor of Robot Vision.

7
8 ¹ Institute for Women's Health, University College London, London, UK.

9 ² Wellcome/EPSRC Centre for Interventional and Surgical Sciences (WEISS), University College
10 London, London, UK.

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13
14 Correspondence should be addressed to;

15
16 Dr Brian Dromey
17 Institute for Women's Health,
18 University College London,
19 2nd Floor Charles Bell House | 43-45 Foley St | London | W1W 7TS.
20 Telephone: +44 (0)7969780828
21 e-mail: b.dromey@ucl.ac.uk
22
23
24

25 **KEYWORDS**

26 Ultrasound, Pregnancy, Simulation, Novice, Expert, Training, Education.

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29 This work should be attributed to Research Department of Maternal & Fetal Medicine, UCL EGA
30 Institute for Women's Health, Faculty of Pop Health Sciences, University College London, Gower St,
31 Bloomsbury, London WC1E 6BT, United Kingdom

44 **ABSTRACT**

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There is little global consensus on how to train, assess and evaluate skill in obstetric ultrasound. The outcomes of curricula, where present, are often based on the number of clinical cases completed, rather than objective outcomes. The central question in this review is whether simulation enhances training and prepares trainees for clinical practice. A systematic review was conducted of the currently available literature in accordance with PRISMA guidelines. Studies considering the use of simulators in training or assessment of sonographers were eligible for inclusion. We conclude that simulation is best used for acquisition of technical skills and image optimisation. Best outcomes are observed when simulation augments traditional learning, with a strong focus on specific, objective and measurable skills. Integrating simulation into training curricula could allow trainees to contribute to clinical service while learning. How skills learned in a simulated environment translate to the clinic is poorly addressed by the literature.

87 INTRODUCTION

88 Ultrasound is a flexible, cost-effective investigation which can be performed at the patient bedside.
89 Despite these advantages ultrasound is known to be operator dependent and have high inter-operator
90 variability¹. Training and competence assessment are of great importance to ensure safe clinical
91 practice. In obstetrics, ultrasound can be used in acute clinical care to perform basic tasks such as
92 confirmation of the fetal heartbeat or assessment of fetal presentation. Away from the delivery suite,
93 intermediate level skills, such as monitoring fetal growth and wellbeing have a higher training demand
94 and require ongoing assessment of competency and quality assurance². Advanced applications include
95 the diagnosis of major congenital abnormality, generally performed by doctors with a specialist interest
96 in fetal medicine. A number of percutaneous, in-utero, ultrasound guided procedures are used to treat
97 Fetal Anemia, Congenital Diaphragmatic Hernia and Bladder Outflow Obstruction. A recent consensus
98 statement considered US essential to the safe, timely and effective practice of Obstetrics and
99 Gynaecology³, but acknowledged that training remains challenging. Given the wide variety of
100 applications and that some techniques are performed at low frequency by highly specialized operators,
101 a flexible, stepwise approach to skills training would seem the optimal solution. The consensus paper
102 concluded that *“Modern obstetrics and gynecology practice is virtually impossible without the use of
103 ultrasound”*⁴. The authors continued *“it is clearly desirable for all obstetricians and gynecologists to have
104 been trained robustly in basic sonographic skills so that their scanning in antenatal and gynecological
105 clinics and on the labor ward is both safe and reproducible”*. Although widespread use of ultrasound is
106 desirable, training in ultrasound is a challenge and there is little global consensus on how to train, assess
107 and evaluate skill in obstetric ultrasound. Competence is not necessarily directly related to clinical
108 experience. Tolsgaard et al⁵, remarked that some experienced clinicians did not display expert-like
109 behaviors despite daily use of obstetric ultrasound in their clinical practice. The authors hypothesized
110 that poor basic training may be a root cause of this, suggesting that the operators did not have the
111 correct foundation to benefit from later clinical training. The authors further hypothesized that the
112 expected improvement in performance was not seen because sustained, deliberate practice rarely
113 occurs in clinical practice. Attempts have been made by organizations such as The International Society
114 of Ultrasound in Obstetrics and Gynaecology (IUSOG) and others to standardize requirements across
115 Europe. The differences in delivery of clinical service may partly explain why there has been little global
116 standardization of training and performance assessment to date. Practice differs widely, in Germany
117 and Italy all obstetric ultrasound is delivered by obstetricians, or doctors training in obstetrics. In the UK
118 and Denmark⁴ over 90% of routine obstetric ultrasounds are performed by sonographers or midwives.
119 The majority of doctors performing obstetric ultrasound are sub-specialist in fetal medicine who do not,
120 generally, perform routine screening.
121 Traditional teaching of ultrasound, like surgery, has taken the form of “see one, do one, teach one”⁶,
122 initially under the supervision of a more experienced operator. The outcomes of curricula, where
123 present, are often based on the number of clinical cases completed, rather than objective outcomes of
124 competence⁷. Contemporary training curricula have evolved in response to patient safety concerns,
125 increasing medical sub-specialization and reduced training hours due to working time regulations. There
126 have been concerns that ‘the specialist of tomorrow’ will have significantly less experience in advanced
127 procedures at the completion of their training than their trainers had at an equivalent career stage⁸.
128 These concerns are not limited to obstetrics and have been raised in many specialties. Ultrasound
129 examinations, much like laparoscopic surgery require the operator to interpret a dynamic image
130 produced by the three-dimensional (3D) position and motion of the ultrasound probe by means of a two-
131 dimensional (2D) visual display. It is accepted that laparoscopic skill and performance metrics improve
132 with training and experience⁹. Similarly, it might be expected that an ultrasonographers’ performance
133 would improve with training and practice. It is hypothesized that as a novice gains experience and
134 familiarity with a technique that their performance evolves¹⁰, this is often referred to as a learning curve.

135 The reasons for this are complex, related to familiarity with the task at hand, the surgical equipment, its
136 limitations and an appreciation of normal anatomy.

137 Simulation has been proposed as a strategy to shorten skill acquisition time and to allow clinicians
138 learn in a safe, blame-free environment. Ultrasound seems an ideal candidate, but uptake has been
139 disappointing. This might be because little attention has been focused on how to effectively integrate
140 simulation into modern training curricula. A recent survey of UK trainees in Obstetrics & Gynaecology
141 reported that 79% considered simulation essential for training in ultrasound and that 90% would
142 participate in a formal simulation-based training program. When provided, 76% of trainees found the
143 simulator useful for improving clinical skills. 54% never, or rarely, used the ultrasound simulation
144 facilities available to them, citing a lack of formal guidance; unawareness of facilities; inconvenient
145 access times, clinical workload and time pressures as barriers to participation¹¹.

146 The aim of this review is to investigate the use of high-fidelity simulation in obstetric ultrasound, to
147 identify its usability for learners and to establish if the skills obtained in a simulated environment can be
148 translated to improved clinical performance.

149 The central question in this review is: ***Do training tools enhance training and prepare trainees for
150 clinical practice?***

151 The secondary questions are if skills can be transferred to the clinical setting and if transferred skills are
152 robust and sustained in the medium and long term?

153

154 **METHODS**

155 *Protocol & Registration*

156 A systematic review was conducted of the currently available literature. The review was completed in
157 accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses
158 (PRISMA) standards for quality of reporting systematic reviews¹². The protocol was registered on the
159 International prospective register of systematic reviews (PROSPERO)¹³ database in February 2019
160 as, "High-fidelity ultrasound simulation in obstetric ultrasound. Serious training tools or gaming toys? A
161 review of the current literature", reference number CRD42019122974. The registered protocol is
162 available on the Prospero database at <https://www.crd.york.ac.uk/prospero/>.

163 *Eligibility Criteria*

164 Studies considering the use of simulators in the training or assessment of ultrasound operators were
165 eligible for inclusion. The PICO (Population, Interventions, Comparisons and Outcomes) model was
166 considered when designing the search strategy¹⁴. The Population was considered to be any trainee in
167 ultrasound, these may be doctors or allied health professionals. Interventions considered suitable were
168 any use of a simulator, either before commencing clinical training or concurrent with clinical training.
169 Suitable comparators included cohorts not trained on simulators, either in a parallel or crossover design.
170 Outcomes showing a positive, negative or no correlation on performance after the use of ultrasound
171 simulators were considered suitable for inclusion.

172 *Information Sources*

173 **The search strategy developed was intended to provide results of relevance to training in obstetric
174 ultrasound was agreed between the named authors.** The search was completed on 30th of October
175 2018. The search strategy used four database search tools, PubMed, EMBASE, Scopus and Web of
176 Science. Publications for inclusion were identified using the search terms "Simulat*" & "Training" &
177 "Obstetric*", either as keywords or contained within the manuscript title. The "obstetric*" wildcard was
178 used to capture variations including "obstetrician", "obstetrics" and "obstetric". "Simulat*" wildcard was
179 used to capture variations such as simulated, simulation and simulator. The search terms were

180 combined using the Boolean operator "OR". The search was limited to articles in English and duplicates
181 were removed by the author (BD) as part of the screening procedure to assess full-text articles for
182 inclusion. No further papers were identified by examining the bibliography of the papers read in full.

183 *Search*

184 The process is represented in *Figure 1*. 2,581 records were identified. 2,470 were excluded by screening
185 the titles of the abstract. The reasons for exclusions were Non-English, Different Topic, Non-Obstetric
186 Ultrasound, Conference/Congress Abstract (full text not available) and Communication to Editor. From
187 a pool of 2,581 results 111 results were retrieved from the search engine results for screening. Once
188 duplicates were excluded and abstracts were examined for relevance 39 papers were deemed suitable
189 for inclusion. Three full-text articles were excluded as the content was not relevant to simulation in
190 ultrasound.

191 *Study Selection*

192 The remaining 36 articles were read in full. The motivation for this review was, as stated earlier, to
193 determine if the literature has reported behaviors which could be used to establish the utility of
194 simulators in obstetric ultrasound training. Studies which considered the use of high-fidelity simulators
195 in ultrasound were considered for inclusion. The concept of 'fidelity' refers to the realism of a particular
196 simulator, how closely the simulator replicates the task being learned. All simulators replicate one, or
197 more, parts of a clinical task for the purposes of education. High fidelity simulators generally have
198 some degree of computer control, interactivity or trainee feedback. High fidelity simulators are thought
199 to increase realism and to have greater educational value because of this. Although there is wide
200 variation in the design of ultrasound simulators all are, by their nature, high fidelity simulators. No
201 studies were excluded based on the type of simulator used.

202 Studies examining the use of simulators in obstetric ultrasound or systematic reviews on the topic were
203 eligible for inclusion. All of the included studies included novice operators. Study design was varied.
204 Authors chose to compare novice and expert performance when using a simulator, while others chose
205 to observe novice behavior before and after using a simulator. Studies were not excluded based on the
206 type of medical professional selected to form the novice/inexperienced group as we recognize that
207 obstetric ultrasound is performed by clinicians from a variety of backgrounds, including radiology,
208 obstetrics, midwifery and by sonographers.

209 No were studies excluded based on their date of publication, as commercially-available, high fidelity
210 ultrasound simulators are relatively new to the market. All studies were published between 2002 and
211 2018.

212 Studies were excluded if their primary outcomes were not in obstetric ultrasound. Studies were also
213 excluded if the study did not include an educational intervention using a simulator. Although ultrasound
214 validation studies were included in the qualitative analysis, these were excluded from the quantitative
215 analysis as the primary outcome measured simulator performance rather than the learners change of
216 performance.

217 *Data Collection Process*

218 Two researchers independently reviewed the 36 full-text articles. Discrepancies were resolved by
219 discussion the validity of the methods and quality of the content within the manuscript. After
220 discussion, eight studies were included in the qualitative analysis (Burden¹⁵, Todsén¹⁶, Chalouhi¹⁷
221 Pittini¹⁸, Jensen¹⁹, Madsen²⁰, Monsky²¹, Maul²²), four studies were included in the quantitative analysis
222 as four studies did not report findings in a format suitable for inclusion in the meta-analysis.

223 *Data Items*

224 A database of the 36 included papers was created using Microsoft Excel. For each full-text article
225 read, the following data were recorded; Title, Author, Article Title, Journal Title, Keywords, Problem

226 Statement, Research Method, Statistical Methods Used, Number of included participants, Author
227 Conclusions, Findings in relation to past research, reviewer summary and reviewer notes.

228 *Statistical Analysis - Risk of Bias*

229 As part of the data collection and meta-analysis analysis process included studies were scored using
230 the Medical Education Research Study Quality Instrument (MERSQI) tool²³. MERSQI is an instrument
231 developed for measuring the quality of education research studies. The maximum score is 18, made up
232 from the following domains, Study design (3), Number of institutions sampled (1.5), Follow-up (1.5),
233 Outcome assessment (3), Validity evidence (3), Data analysis (3) and Outcome type (3). A score of ≥ 12
234 is considered an indication of high study quality. The MERSQI authors describe their assessment of 210
235 medical education research studies published in 13 peer-reviewed journals. Over a fifteen-month period
236 the mean MERSQI score was 9.95 (SD, 2.34; range, 5-16). We calculated the mean MERSQI score for
237 included manuscripts of 11.88 (SD, 1.81; range, 9.5-15). In this context the articles included are, at least,
238 reflective of study quality seen in broader medical education.

239 *Statistical Analysis - Summary Measures & Synthesis of Results*

240 Review Manager 5.3²⁴(The Cochrane Collaboration, 2014.) was used to produce forest plots of the
241 included studies. Meta-Essentials ²⁵ running on Excel (Microsoft Excel for Mac Version 16.32) was
242 used to perform the meta-analysis and to calculate the sensitivity and specificity of each included
243 study. The results are shown in *Figure 2*, finding favorable effect for improved accuracy of biometry in
244 obstetric ultrasound following simulation training.

245 All the included studies had similar methodology and all included novice participants. In all studies a
246 group of novice operators was asked to complete a specified training package. Their performance was
247 compared before and after completion of the training package. No study compared novice with expert
248 performance, either before or after the training. No study compared objective clinical performance
249 before and after training. All studies were completed in a training center, or simulation suite, none were
250 undertaken in a clinical area. Measures of heterogeneity indicated moderate heterogeneity.
251 Cochrane's Q value was calculated at 6.73.

252 Eight studies were included in the qualitative analysis, all eight studies recruited doctors. None of the
253 included studies recruited nurses, sonographers, midwives or students. Five studies recruited doctors
254 from Obstetrics & Gynaecology^{15,16,17,20,22} the remaining studies recruited trainees in Emergency
255 Medicine¹⁶, and Radiology²¹. One study recruited any post graduate year 0-5 doctor¹⁸. The calculated
256 I² value of 40% indicates moderate heterogeneity between the studies, despite difference in design,
257 methodology and reporting. In total six models of simulator were used, UltraSim, VimedixTM US
258 simulator, Canadian Amnio Model, Scantrainer, UltraSim and SonoTrainer. A summary of the findings
259 of the qualitative analysis is presented in *Table 1*.

260

261 **RESULTS**

262 The results of the meta-analysis find that superior performance has been achieved after training using
263 high-fidelity ultrasound simulation. All the evaluated results considered performance before and after a
264 training event using an ultrasound simulator.

265 As detailed in the methodology, eight studies Burden¹⁵, Todsén¹⁶, Chalouhi¹⁷, Pittini¹⁸, Jensen¹⁹,
266 Madsen²⁰, Monsky²¹ and Maul²² were included in the qualitative analysis. Five outcome measures from
267 four studies were included in the quantitative analysis^{15,16,21,22}. In total 214 participants were recruited
268 to the four studies, 129 were novice participants (56%). All four studies reported positive effect on
269 operator performance. Specifically the performance improvements were noted in the measurement of
270 Crown Rump Length (reported in three studies) and in Femur Length (reported in two studies). These

271 improvements were seen, regardless of the model of simulator used. Across the eight studies six
272 models of simulator were used.
273 All studies had similar aims, but the subsequent training or instruction differed. All studies established
274 baseline performance for each user and all studies did this using a simulator. All studies used a single
275 model of simulator. The participants undertook assessment and training on the same model of simulator.
276 Studies by Burden¹⁵ et al, Lous²⁶ et al, Todsén et al¹⁶, Chalouhi et al¹⁷, Pittini et al¹⁸ and Jensen et al¹⁹
277 required participants to attend a single simulator session, these studies did not compare simulator-
278 based training to other training methods.

279 Madsen et al²⁰ repeatedly assessed participants over two months while Monsky et al²¹ required
280 participants to compete ten hours of self-directed learning using the simulator and compared final
281 performance to doctors of similar grade who had not participated.

282 Three studies examined operator performance in the first trimester of pregnancy measuring the Crown
283 Rump Length (CRL). The remaining two studies examined performance in fetal biometry in the second
284 trimester. One study specifically reported Femur Length but other measures of fetal biometry were not
285 reported. Some studies used expert operators as a control group. One study compared the use of a
286 high-fidelity ultrasound simulator to a theoretical training package, one study compared 10 hours of self-
287 direct learning using the UltraSim to conventional clinical training.

288 As stated earlier, the aims of this review were to investigate the use of high-fidelity simulation in obstetric
289 ultrasound, to identify its usability for learners and to establish if the skills obtained in a simulated
290 environment can be translated to improved clinical performance, which is sustained over time. The
291 papers included in the qualitative review have been scored against these aims in *Table 2*. The study
292 design used by authors predominantly focused on the functionality and usability of ultrasound
293 simulators. The majority of studies have not focused on how skills are translated from the simulation
294 suite into the clinical environment, how the acquired skills translate to clinical practice and if the skills
295 are maintained over time.

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297 **Discussion**

298 All the included studies look to validate the concept of using simulation for training or assessment in
299 obstetric ultrasound. This finding is reassuring and supports the uptake of simulation as a training
300 methodology across many medical specialties. Our meta-analysis shows that skills can be acquired,
301 improved and assessed by means of a high-fidelity simulator. In particular, our findings suggest that
302 simulation can be best used for acquisition of technical skills¹⁵ and image optimisation²⁷. Superior
303 technical ability may accelerate a learner's time to competence²⁰. Our review of the literature finds that
304 simulation training can be used to equip novice ultrasound practitioners with sufficient skills to perform
305 basic obstetric ultrasound in a clinical environment under direct supervision.

306 Our findings suggest that consideration ought to be given to integrating simulation training into the
307 clinical curriculum. Even in research settings trainees reported clinical commitments as barriers to
308 engaging with simulation training¹¹. The highest levels of engagement, 90%, were seen when
309 participation was mandated by the faculty by Monsky et al²¹. The authors undertook simulator-based
310 assessment of Radiology Residents before taking overnight call. The authors were surprised to find that
311 their findings challenged established beliefs within the radiology department that Residents were
312 suitably and adequately trained prior to taking up semi-autonomous clinical practice. The participant
313 survey also highlighted Residents' concerns about their own preparedness for overnight calls. As a
314 result, the authors modified the Residency training program at their hospital. The redesigned curriculum
315 addressed these concerns, an additional 8 weeks of targeted, clinical training, focusing specifically on
316 transvaginal ultrasound was provided. Twelve months later, the experiment was repeated. The authors

317 found that residents performed significantly better on the simulator and reported higher confidence in
318 performing ultrasound. Senior clinicians also reported higher subjective performance scores for
319 Residents when being assessed.

320 Studies by Bernardi et al²⁷ and Maul et al²², showed that even novice operators could achieve
321 competent performance in obstetric ultrasound when being trained by means of simulation alone. The
322 authors compared their simulation-based curriculum to conventional didactic teaching of ultrasound
323 theory and practice.

324 The example of simulator use in pilot training is often used as justification for the use of simulation in
325 medical education. It is true that high fidelity simulators are universally used for training airline pilots.
326 When considering the use of simulation in medicine it is important to understand that full-motion flight
327 simulators are integrated into pilot training, assessment and licensing. Initial pilot training and recurrent
328 assessment in a simulator take place every six months for commercial pilots. Mandatory emergency
329 simulator sessions allow trainers to create an entirely immersive experience, recreating the systems
330 and motion of the aircraft and the human factors which have been recurrent contributors to accidents
331 and near-misses. None of the simulators described to date have addressed the clinical context in which
332 the trainee will eventually work. The current devices focus on technical skills proficiency, while ignoring
333 communication with patients and colleagues, distractions and clinical management which contribute to
334 overall clinical performance. Our review finds that that trainees in obstetric ultrasound can benefit from
335 the use of a high-fidelity simulator but that these tools are not formally integrated into medical education
336 curricula. It is preferable that training programs be based on objective outcomes, rather than trainer
337 reports and arbitrary numbers of cases recorded in a log book.

338 We suggest that high-fidelity ultrasound simulation can be used to train users more quickly, however
339 our study is limited by the heterogeneity of the evidence base. The wide disparity in MFM training
340 curricula globally is reflected in the heterogeneity the studies and reported outcomes. These limit the
341 generalizability of our results, as we were able to include four studies and a total of 214 participants in
342 the meta-analysis. Even with these limited numbers we were able to show a positive effect for simulation
343 training. The positive result may reflect that by using a simulator the participants were gaining tuition
344 and experience that they would not otherwise have been exposed to. The effects seen might be
345 attributable to additional intentional practice, rather than the simulator itself. Because all studies carried
346 out baseline assessment, training and subsequent assessment on the same model of simulator, it is
347 possible that the results reflect user familiarity with the simulator, rather than a true improvement in
348 clinical skill. The limitations of the study highlight the need for future research to consider how skills
349 acquired in the simulation setting translate to a clinical setting. **Research methodology and study design
350 need careful consideration, as pre/post-test designs may over-estimate the effect of the intervention.**

351 Based on this literature review our group is developing a longitudinal study to assess trainees using
352 baseline scans on pregnant volunteers, then allowing them to undertake a training package or clinical
353 attachment. At the end of the attachment the participants will be asked to undertake fetal biometry in a
354 clinical setting. This will allow us to understand how skills obtained in a simulated environment can be
355 translated to clinical reality and how robust skills are when presented with the variability inherent in
356 obstetric scanning owing to maternal habitus, stage of pregnancy, fetal presentation and position.

357 358 **Conclusion**

359 This review finds evidence of benefit for high-fidelity ultrasound simulation. The evidence for deployment
360 in training is limited, but authors have found their own training curricula challenged by the introduction
361 of simulation-based training and assessment. In these instances, simulation has been used to augment
362 traditional learning, with a strong focus on specific, objective and measurable clinical outcomes, audit
363 and revision of the curriculum based on learner feedback.

364 Further investigation of ultrasound simulation in training should follow models closer to pilot training, where
365 training and ongoing assessment are routine, mandatory and completed by all grades. The challenges of inertia to
366 change, suspicion of simulation as a valid means of learning can be challenged by considered design of further
367 studies now that the utility and validation of this equipment is established.

368 Simulation is best considered as a waypoint to allow the learner to transition to semi-autonomous practice in a
369 supervised, clinical setting. By integrating ultrasound simulation into training curricula and promoting self-
370 directed learning trainees could contribute to the clinical service while learning a complex skill. Integrating
371 ultrasound training into clinical workflow would allow us to establish if skills acquired in the simulated
372 environment correlate with clinical performance and if skills are maintained in the longer term, which has been
373 poorly considered by the literature to date.

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483 *Figure 1 – The search strategy undertaken. PRISMA flow-chart is included as Figure 1.*

484 *Figure 2 - Forest plot diagram of Meta-Analysis. Four studies reported outcomes of fetal biometry which were suitable for inclusion in the analysis.*

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486 *Table 1 – Summary of the qualitative analysis of the included manuscripts. The table includes the stated purpose, design and findings of each study.*

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488 *Table 2 – Tabulation of the qualitative analysis of each of the included papers against the aims of the review. The use of simulators by learners and the motivations for learners to use the simulators have been considered by all authors. Some consideration has also been given to how the learner can be assessed in the simulated*

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491 *environment. Only Monsky et al considered how the skills acquired in the simulated setting compared with those*
492 *acquired by learners who had not been exposed to simulation.*

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500 Research Council (EPSRC). In collaboration with Kings College London, KU Leuven, Great Ormond Street
501 Hospital and University College Hospital (UCLH). (WT101957) ORCHID ID: orcid.org/0000-0001-9494-9724

502
503 Professor Donald Peebles, MD, is Chair and Head of the Research Department of Maternal Fetal
504 Medicine at University College London, London, UK. ORCHID ID: orcid.org/0000-0001-8562-1970

505
506 Professor Danail Stoyanov, PhD, is Professor of Robot Vision at the Department of Computer
507 Science, University College London, London, UK. He is Director of the Wellcome/EPSRC Centre for
508 Interventional and Surgical Sciences (WEISS) and a member of the Centre for Medical Image
509 Computing (CMIC). ORCHID ID: orcid.org/0000-0002-0980-3227