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Portable Ultrasound Devices in Emergency Departments

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Portable Ultrasound Devices in Emergency Departments

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Health technology assessment (HTA) agencies face the challenge of providing quality assessments of medical technologies in a timely manner to support decision making. Ideally, all important deliberations would be supported by comprehensive health technology assessment reports, but the urgency of some decisions often requires a more immediate response.

The Health Technology Inquiry Service (HTIS) provides Canadian health care decision makers with health technology assessment information, based on the best available evidence, in a quick and efficient manner. Inquiries related to the assessment of health care technologies (drugs, devices and procedures) are accepted by the service. Information provided by the HTIS is tailored to meet the needs of decision makers, taking into account the urgency, importance, and potential impact of the request.

Consultations with the requestor of this HTIS assessment indicated that a systematic review would meet their needs.

Systematic review of clinical trials

The systematic review of clinical trials was prepared by two internal HTIS reviewers in consultation with an external clinical expert(s). Research questions and selection criteria were developed jointly by the two HTIS reviewers and the external clinical expert(s). The literature search was carried out by an information specialist using a standardized search strategy.

Each HTIS reviewer independently selected studies for inclusion according to the predetermined selection criteria. All articles considered potentially relevant by at least one reviewer were acquired from library sources. Reviewers independently made the final selection of studies to be included in the review and differences were resolved through discussion. A list of included and excluded studies (along with reasons for exclusion) are provided in Appendix 8.

Data were extracted from original articles independently by two or more external reviewers.

A draft of the systematic review portion of the report was written by one HTIS reviewer with input from the second reviewer and external clinical experts as required. The draft was reviewed by the second HTIS reviewer and the external clinical experts. The draft was finalized based on the input received.

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EXECUTIVE SUMMARY

Title: Portable Ultrasound Devices in Emergency Departments
Date: September 1, 2005

Context and Policy Issues

In the emergency department (ED), prompt and accurate diagnoses made by physicians are a prerequisite for the effective and timely treatment of patients with serious illnesses and injuries. Modern diagnostic methods such as ultrasonography (U/S) and computed tomographic (CT) scanning play a role in enhancing the quality of medical care. The machines that are used are often located in imaging departments, are complicated to operate, and may be unavailable outside regular daytime working hours. A survey conducted in 2002 reported that after-hours U/S was available to Canadian emergency physicians (EPs) in 94% of hospitals, and 75% of these scans were performed by radiologists or ultrasound technicians. Although 88% of the radiologists regarded the emergency service as "good or excellent," only 48% of the EPs agreed, and 29% of them thought that the emergency radiology service was "poor."

Smaller, portable ultrasound (pU/S) devices, which can easily be brought to the bedside, have been introduced. EPs, surgeons, and other non-radiologists have started to perform emergency ultrasound examinations with the intent of improving the certainty of diagnoses and potentially reducing the use of certain invasive examinations. Because these non-radiologists may receive limited or no U/S training, and do not have the same knowledge of U/S as radiologists, the chances of misdiagnosis may increase. It is unclear if and how much training is required; and what the minimum requirements of reporting are to ensure accountability.

Portable devices need to be distinguished from hand-held machines for U/S. The latter do not have the technical capabilities of the larger devices.

Research Questions

1a. What is the evidence of effectiveness (improved technical outcomes, improved clinical decision making, improved patient-relevant outcomes, and reduced harm) when non-radiologists use pU/S devices for assessing abdominal trauma, abdominal aortic aneurysm (AAA), and ectopic pregnancy?
1b. What is the evidence regarding the effect of diagnostic accuracy on the effectiveness of these interventions?
1c. What is the evidence regarding the effect of user-dependent variables on the effectiveness of the intervention, specifically for the user (general practitioners, EPs, and other non-radiologists), the type of training, the length of training, and previous experience in emergency U/S examinations?
2a. What guidelines exist regarding the use of these devices for the indications?
2b. What is the level of evidence supporting these guidelines?
2c. Are the recommendations in the guidelines consistent with the evidence?
3. What are the ethical and legal implications of using and reporting information from pU/S and other ultrasound imaging technologies?

Methods

A protocol was developed a priori, and clinical questions were developed in consultation with methodological and clinical experts. Published literature was obtained by searching multiple databases using a defined search strategy and by searching the bibliographies of selected papers. For Research Questions 1a and 2a, two reviewers independently and systematically applied inclusion and exclusion criteria to all available literature, and performed data extraction. One reviewer rated the quality of the included studies. For Research Question 3, a qualitative-review approach was adopted. A quantitative review of the clinical effectiveness of pU/S use in EDs was conducted. Summary likelihood ratios (LRs) and post-test probabilities in clinical scenarios were calculated, based on the data from individual studies, to evaluate the clinical effectiveness of ED pU/S.

Findings

From 1,020 initial citations, 135 were identified as potentially meeting the selection criteria. After the full reports were reviewed, 49 were judged to have met the inclusion criteria. Of the 49 reports, 29 addressed Research Question 1a (clinical effectiveness of pU/S). The included studies were two comparative studies and 16 case series reports of pU/S for abdominal trauma; one case series

report for AAA; three comparative studies and four case series reports for ectopic pregnancy; and three case series reports detailing more than one use. The quality of the identified primary studies was impaired by potential selection bias, differential use of a reference standard, or failure to use a blinded reference standard. For Research Question 1c, we identified six training guidelines and nine training programs. For Research Question 2a, two clinical practice guidelines and three systematic reviews were identified.

Research Question 1a: We did not identify any studies that reported mortality rates or patient survival rates for any condition. One retrospective comparative study examined the effect of emergency U/S on time to diagnosis and on time to operative treatment. A statistically significant difference was shown in favour of pU/S in EDs. False-positive and false-negative diagnosis data were routinely reported. The most frequently reported outcome measures in the included studies were sensitivity and specificity. Among patients with abdominal trauma, most of the values of sensitivity for detecting free fluid were between 0.80 and 0.90; a similar range of sensitivity for detecting free fluid plus organ injury was observed. The values of specificity were typically 0.96 to 1.00, for the detection of intraperitoneal free fluid. For patients with AAA, the sensitivity of emergency U/S was reported to be 1.00. Emergency U/S had a sensitivity of 0.82 to 1.00, and a specificity of 0.88 to 1.00 in detecting ectopic pregnancy. The summary estimates of positive LRs were 61.76, 14.57, and 14.55 for blunt abdominal trauma, ectopic pregnancy, and AAA respectively. The summary estimates of negative LRs were 0.20, 0.08, and 0.06 for blunt abdominal trauma, ectopic pregnancy, and AAA respectively.

Results from one prospective comparative study showed that the accuracy of the diagnosis is associated with greater observer education. The U/S training courses for EPs and other non-radiologists usually consisted of a didactic session, followed by a hands-on practical session with live human models. In the primary studies identified, previous training experience of eight to 12 hours of didactic sessions and 15 to 50 supervised U/S scans were reported by most researchers. The minimum number of pU/S scans ranged from 50 to 500, while the minimum number of accurate scans recommended in the training guidelines ranged from 15 to 25.

All the identified trials were conducted in metropolitan hospitals, so we could not differentiate, based on the available evidence, between emergency pU/S in a rural location and that in an urban location.

Research Question 2a: Two clinical practice guidelines suggested that focused abdominal sonography for trauma (FAST) was useful as an initial screening tool when used by surgeons for patients with blunt abdominal trauma. The recommendations from these guidelines were inconsistent with the findings of three systematic reviews. One concluded that more trials should be conducted before ultrasound is accepted as a standard test for the evaluation of blunt trauma. Another review concluded that in terms of clinically suspected abdominal trauma, other effective assessment (i.e., CT) should be performed regardless of the initial sonographic findings. The third review concluded: "There is insufficient evidence from RCTs to justify promotion of ultrasound-based clinical pathways in diagnosing patients with suspected blunt abdominal trauma."

In six guidelines that describe training and credentialing requirements, the minimum number of pU/S scans ranged from 50 to 500, while the minimum number of accurate scans recommended ranged from 15 to 25. Recommendations about documentation suggested that pU/S reports be labelled as "limited ED ultrasound," to differentiate it from the formal U/S examinations performed by a radiologist in the imaging department. We did not find evidence of ongoing experience or continuous training on clinical effectiveness. All recommendations in the six guidelines seemed to be consensus-based with some unstructured consideration of the literature. Standards for the amount of training of non-radiologists were generally higher than reported in the included primary studies. Documentation standards were generally more elaborate than those reported in the primary studies.

Research Question 3a: The ethical responsibilities of non-radiologists with respect to ED pU/S are similar to those required of radiologists. Patients should be informed that ED pU/S is a focused,

limited examination. Greater adherence to specialty-specific guidelines for emergency U/S, such as those developed by the Canadian Emergency Ultrasound Society (CEUS), will minimize misdiagnosis and potential litigation.

Conclusions and Implications

The results of this review suggest that the demonstrated benefits of ED pU/S performed by non-radiologists are limited to improving diagnostic certainty. We did not find convincing evidence that ED pU/S administered by a non-radiologist has an impact on outcomes that is relevant to patients' health. In this report, we were unable to identify compelling evidence of improving time to diagnosis or time to operative treatment. These patient-relevant outcomes are reported so infrequently that statements for or against ED pU/S are impossible to make.

There is enough evidence from studies of blunt abdominal trauma, AAA, and ectopic pregnancy to suggest that ED pU/S performed by non-radiologists is an effective tool for improving diagnostic certainty. pU/S is likely to improve the certainty of diagnosis in an ED. These results are robust – the estimated effect remains similar even when only studies of a higher quality are considered. The non-therapeutic advantages of using this technique are that it is easier to use and repeat, it is inexpensive to perform with the available technology, and it is non-invasive.

There is evidence of misdiagnosis with pU/S, which is associated with inexperience. There is additional evidence of improved performance from non-radiologist physicians who undergo training. Training programs that use didactic and practical sessions (a minimum of 50 scans for each medical use) have shown improved effectiveness. Misdiagnoses with pU/S scans that are performed by trained non-radiologist physicians can still occur, but at rates akin to those observed in similar studies of radiologist-performed U/S scans.

We were able to identify clinical practice guidelines for emergency U/S examinations for patients with abdominal trauma. None of the guidelines are specifically intended for non-radiologist physicians. Decisions to implement ED pU/S will need to be based on tacit knowledge and local guidance.

Training and credentialing guidelines are important with respect to the ethical and legal requirements for emergency pU/S examinations that are performed by EPs, because guidelines for other specialties include topics that are not pertinent to emergency medicine. Training programs exist for the performance of U/S examinations. A training standard for physicians who use pU/S in the ED is important to ensure patient safety. Recommendations regarding the amount of continuing experience needed to maintain competence are essential.

Additional prospective, comparative, high quality studies, designed to measure the impact of ED pU/S on efficiency, while monitoring clinical efficacy, would be helpful for making evidence-based decisions. The body of evidence describing diagnostic performance needs to be supplemented with results that demonstrate the effect of this intervention on diagnostic reasoning and time to definitive care.

ABBREVIATIONS

AAA	abdominal aortic aneurysm
ac	accuracy
CI	confidence interval
CPG	clinical practice guideline
CT	computed tomography
DPL	diagnostic peritoneal lavage
ED	emergency department
EP	emergency physician
FAST	focused abdominal sonography for trauma
IUP	intrauterine pregnancy
LR	likelihood ratio
NPV	negative predictive value
PPV	positive predictive value
pU/S	portable ultrasound
U/S	ultrasonography

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1 INTRODUCTION

Prompt and accurate diagnoses made by physicians are a prerequisite for effective and timely treatment of patients with serious illnesses and injuries. Modern diagnostic methods such as ultrasonography (U/S) and computed tomography (CT) scanning provide clear images for displaying anatomic structures, and are more readily accepted than invasive techniques by patients and physicians. These machines are inaccessible to patients at their bedside in a hospital emergency department (ED) because of their size and heavy weight. They are usually located in a hospital's imaging department, and require trained staff to operate.

Smaller U/S devices have been developed. They are compact (similar to a laptop computer or even smaller), light (about 9 kg for a laptop-sized scanner), and mobile.[1] These portable U/S (pU/S) machines can easily be brought to the point of patient care. These devices are used to obtain quick diagnoses, potentially reduce the use of certain invasive examinations, and reduce delays to definitive care. For example, a woman may undergo a culdocentesis if it is suspected that she has a ruptured ectopic pregnancy; yet this approach can be avoided by using a non-invasive U/S examination in the emergency room. The compact machines may have fewer features compared with conventional full-sized machines and may provide lower quality images; thereby possibly making judgement more difficult.[1] These scanners are sufficient to detect free fluid in the abdominal cavity, cardiac movements, pericardial fluid, the location of the gestational sac, or a dilated aortic artery. In contrast to the conventional U/S scans, the emergency pU/S examinations are performed for the purpose of answering a limited number of questions.

- Is there evidence of free peritoneal fluid?
- Is there evidence of a pregnancy outside the uterus?
- Is there evidence of an abdominal aortic aneurysm?
- Is there a pericardial effusion?

Table 1: Portable ultrasound (pU/S) units licensed for sale in Canada

Manufacturer	Make and Model
Aloka Co.	ProSound SSD-3500
B-K Medical	Hawk 2102 EXL, Falcon 2101 EXL, Merlin 1101, Mini Focus
Esaote	Aquila, Caris, Caris Plus, Falco, Megas CVX, Megas GPX, MyLab30CV, Picus, Picus Plus
GE Healthcare	LOGIQ Book XP, LOGIQ 3
Hitachi Medical Systems	EUB-2000, EUB-525, EUB-405 Plus
Medison	MySono 201, SonoAce 8000, SonoAce Pico
Philips Ultrasound	iU22, EnVisor, HD3, HD11, HDI-5000
Shimadzu	SDU-450XL, SDU-350XL
Siemens Medical Solutions	SONOLINE G20, SONOLINE G40, SONOLINE Adara, SONOLINE Omnia
SonoSite	TITAN, Micromaxx
Teratech	Terason 2000
Toshiba	JustVision 200, JustVision 400, Nemio 10, Nemio 20, Xario

This information, which is current to August 2005, was compiled from various sources, including manufacturers' web sites, and *Health Devices International Sourcebase* [database online]. Plymouth Meeting (PA): ECRI; 2005. Available: http://www.ecri.org/ (accessed 2005 Aug). *Medical Devices Active Licence Listing (MDALL)* [database online]. Ottawa: Health Canada; 2005. Available: http://www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic_e.html (accessed 2005 Aug).

2 RESEARCH QUESTIONS

1a. What is the evidence of effectiveness (improved technical outcomes, improved clinical decision making, improved patient-relevant outcomes, reduced harm) when non-radiologists use pU/S devices for assessing abdominal trauma, abdominal aortic aneurysm (AAA), and ectopic pregnancy?
1b. What is the evidence regarding the effect of diagnostic accuracy on the effectiveness of these interventions?
1c. What is the evidence regarding the effect of user-dependent variables on the effectiveness of the intervention, specifically for the user [general practitioners, emergency physicians (EPs), and other non-radiologists], the type of training, the length of training, and previous experience in emergency U/S examinations?
2a. What are the guidelines for the use of these devices for the above indications?
2b. What is the level of evidence underlying these guidelines?
2c. Are the recommendations consistent with the evidence?
3. What are the ethical and legal implications of using and reporting information from pU/S and other U/S imaging technologies?

The analytic frameworks for Question 1a are shown in Figures 1, 2 and 3. The purpose of analytic frameworks (formerly called causal pathways) is to present the questions that need to be answered using the literature review.[2] The specific questions are depicted by linkages that relate interventions and outcomes. These linkages serve the dual purpose of identifying questions to help structure the literature review, and of providing an "evidence map" after the review for identifying gaps and weaknesses in the evidence.

The research questions should be free of value (i.e., focusing on the effects rather than judgments). The relative impact of any intervention should be judged based on convincing evidence of its demonstrated effect versus that of appropriate comparators on the beneficial and harmful outcome measures that are identified.

3 REVIEW METHODS

3.1 Selection Criteria

3.1.1 Types of publications.

Full reports, or abstract and conference proceedings that provide enough details about the study designs and outcome measures of interest, were included.

3.1.2 Types of trials.

Case series and comparative studies (prospective and retrospective cohort studies, case-control studies, and randomized controlled trials) were included. Case reports were excluded.

3.1.3 Types of interventions.

The report focuses on the pU/S devices used in EDs by EPs, trauma surgeons, or other specialists (other than radiologists or radiology technologists). Studies that did not describe who performed the U/S were excluded. Studies that involved a full-sized or palm-sized U/S system were excluded. The U/S units that were examined in our report included older portable models (still bulky, but compact compared with the full-sized machine) and newer models (laptop-sized).

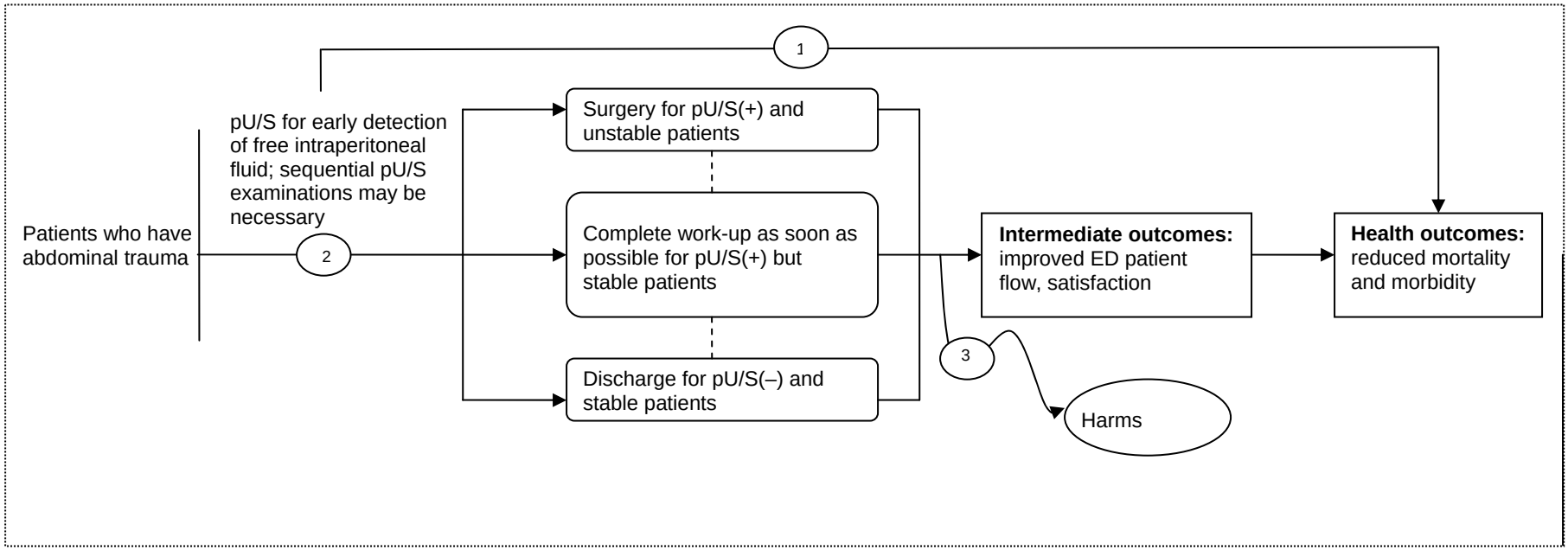
3.1.4 Appropriate comparators.

CT scans, diagnostic peritoneal lavage (DPL), or formal U/S scans by radiologists were comparators.

3.1.5 Types of patients.

This review focused on patients who were seen in an ED, with suspected abdominal trauma (proportions of penetrating injuries <20% of the sample), AAA, or ectopic pregnancy.

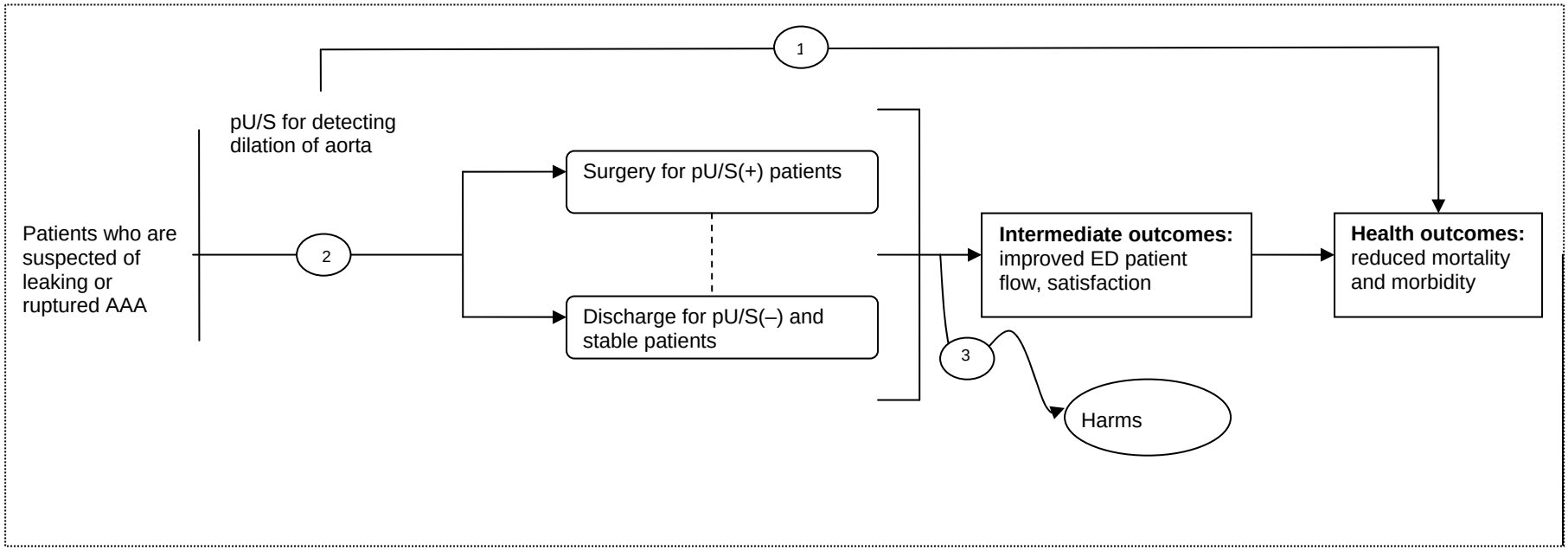
Figure 1: Analytic frameworks for abdominal trauma



Key Questions

1. What are the health outcomes (reduced mortality or morbidity, reduced ED or hospital stay, increased patient and provider satisfaction) of pU/S in EDs for abdominal trauma?
2. What is the yield of pU/S use in EDs for abdominal trauma (i.e., sensitivity, specificity, likelihood ratios)?
3. What harm is associated with pU/S use in EDs for abdominal trauma (misdiagnosis, unnecessary surgery, testing, or delays from testing)?

Figure 2: Analytic frameworks for abdominal aortic aneurysm (AAA)



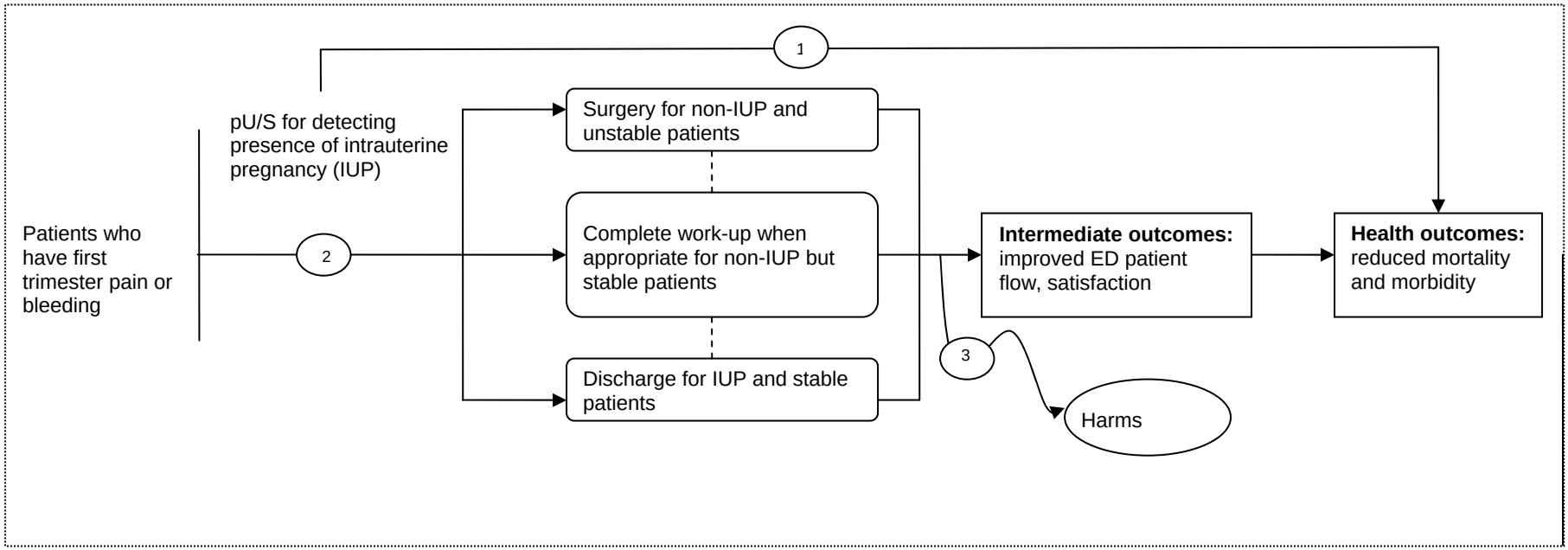
Key Questions

1 What are the health outcomes (reduced mortality or morbidity, reduced hospital stay, increased patient and provider satisfaction) of pU/S use in EDs for AAA?

2 What is the yield of pU/S use in EDs for AAA (i.e., sensitivity, specificity, likelihood ratios)? If the entire aorta is visualized, and no dilation of the aorta is detected, we can rule out this condition safely. A false negative result is very unlikely for this indication.

3 What harm is associated with pU/S use in EDs for AAA (misdiagnosis, unnecessary surgery, testing or delays from testing)?

Figure 3: Analytic Frameworks for Ectopic Pregnancy



Key Questions

1 What are the health outcomes (reduced mortality or morbidity, reduced ED or hospital stay, increased patient and provider satisfaction) of pU/S use in EDs for ectopic pregnancy?

2 What is the yield of pU/S use in EDs for ectopic pregnancy (i.e., sensitivity, specificity, likelihood ratios)? If an IUP is detected, we can rule out this condition safely, except when fertility treatments have been used. It is rare to have a false-positive result for this indication.

3 What harm is associated with pU/S use in EDs for ectopic pregnancy (misdiagnosis, unnecessary surgery, testing or delays from testing)?

3.2 Literature Search

Published literature was obtained by cross-searching BIOSIS Previews®, EMBASE®, MEDLINE®, and PASCAL databases on the DIALOG® search system. Two searches were performed. The first search was done to identify the clinical articles that were related to the use of pU/S devices in the ED for AAA, abdominal trauma, and ectopic pregnancy. Retrieval for this search was limited to the publication years 1990 to 2005 (May). The second search was performed using the same databases to identify articles related to the training and credentialing of non-radiologist physicians in the use of pU/S devices. Retrieval was limited to the publication years 1995 to 2005 (May). Regular alerts were established on all databases, and the information received from alerts is current to August 19, 2005. Parallel searches were performed on PubMed and the Cochrane Library databases. All results were limited to English-language articles.

Web sites of regulatory agencies, and health technology assessment and related agencies were searched, as were specialized databases such as those of the University of York Centre for Reviews and Dissemination, and the Radiological Society of North America RSNA Index (discontinued). The Google™ search engine was used to search for information on the Internet. These searches were supplemented by hand searching the bibliographies of selected papers, the Canadian Emergency Ultrasound Society (CEUS) Literature Review, and abstracts from conferences, including the Society for Academic Emergency Medicine (SAEM) annual meetings, from 1999 to 2004 (Appendix 1).

3.3 Data Analysis

Two reviewers (SC, KT) independently screened the titles and/or the abstracts, and systematically applied selection criteria to retrieve potentially relevant articles. The full text of every potentially relevant article was reviewed by two reviewers (SC, KT), and articles not meeting all inclusion criteria were excluded. Relevant data were extracted from each article independently by two reviewers (SC, RB). Articles related to ethical implications were reviewed by SC and HN.

Studies were classified by one reviewer (SC) according to a hierarchy for the assessment of the efficacy of diagnostic imaging.[3] This instrument is used to classify studies based on the level of their assessment of the contribution to patient management made by the diagnostic imaging modality being examined. The hierarchy consists of six levels:

- level 1, technical quality of the images
- level 2, diagnostic accuracy, sensitivity, and specificity associated with the interpretation of the images
- level 3, degree to which results influence physicians' diagnostic thinking
- level 4, degree to which imaging results affect patient management
- level 5, efficacy studies that measure the degree of effect on patient management
- level 6, analyses of societal costs and benefits of a diagnostic imaging technology.

3.3.1 Quality assessment

After classifying the selected articles, the quality of the identified studies was evaluated using a tool published by the Centre for Reviews and Dissemination (University of York, UK).[4] The tool is used to examine the quality of evidence in diagnostic studies, by taking into account the study population and the appropriate use of reference standards (Appendix 2).

3.3.2 Statistical analysis

Because the studies involved clinically similar populations, used comparable diagnostic U/S technology and reference standards, and had similar outcome measures, a quantitative review of the clinical effectiveness of pU/S use in EDs was conducted. Statistical pooling was performed only with studies that had a prospective study design, and reported the actual number of true-positive, true-negative, false-positive, and false-negative results. For true-positives, pU/S detected the free fluid, intrauterine pregnancy (IUP), or dilated aorta, and this was confirmed by reference standards. For a true-negative, pU/S did not detect the free fluid, IUP, or dilated aorta, and this was confirmed by reference standards. For a false-positive, pU/S detected the free fluid, IUP, or dilated aorta, but this was refuted by reference standards. For a false-negative, pU/S did not detect the free fluid, IUP, or dilated aorta, but this was refuted by reference standards. Positive and negative likelihood ratios (LRs), and negative predictive values (NPVs) were calculated from the collected sensitivity and specificity values using

standard formulas.[5] Positive predictive values (PPVs) were also obtained by using the LR method.[6] The individual outcome measures for each study were pooled by using the weighted mean for each indication, using Review Manager 4.2 and Confidence Interval Analysis software.[7] Means with the corresponding 95% confidence intervals (CIs) were presented. This provides a summary of the effect of pU/S technology in EDs. Positive LRs >10 or negative LRs <0.1 were proposed as thresholds that suggested convincing evidence of diagnostic effectiveness.[5] The post-test probability, based on various clinical scenarios, was generated using a nomogram proposed by Fagan.[8]

A variety of test statistics can be derived from a 2×2 table containing the true negatives, true positives, false positives, and false negatives for a diagnostic test compared to a reference standard. Test statistics include PPV and NPV; sensitivity and specificity; and positive and negative LRs. The interpretation of diagnostic test statistics is complicated by changes in the prevalence of disease. For example, PPVs and NPVs may vary between low and high incidence settings. Sensitivity and specificity, while more stable, cannot be translated easily for the clinician. Consequently, we report pooled LRs for each pU/S indication. The pre-test probability of disease can then be translated into a post-test probability after test results using are obtained using the LRs and a Fagan nomogram.[8] The true pre-test probabilities of disease are often difficult to derive. From the studies in question, we used a range of values from the incidence calculation. Low (15%) and moderate (50%) pre-test probability measures were used to derive standard post-test probabilities for each test indication.

As a confirmatory sensitivity analysis, the results of all pooled data were compared to that from prospective studies rated as having higher methodological quality (studies with a quality score ≤3). The directions and magnitudes of the effect size were examined. Similar findings suggested robust results, while statistically different findings suggested caution. The pooled results from prospective studies, which were exclusively designed and executed by non-radiologists, were compared with those that involved radiologists to explore the possibility that experimental provenance affects the clinical effectiveness of pU/S.

4 FINDINGS

The results of each study are presented in Appendix 3.

4.1 Literature

From 1,020 identified citations, 135 were selected as potentially relevant. After retrieving and reviewing the full reports, 49 were judged to have met the inclusion criteria; 29 reports addressed Research Question 1 (clinical effectiveness of pU/S). For abdominal trauma, these included two comparative studies (one prospective and one retrospective), and 16 case series reports (13 prospective and three retrospective). For AAA, one prospective case series report was identified. For ectopic pregnancy, three comparative studies (two prospective and one retrospective) and four case series reports (three prospective and one retrospective) were identified. Three prospective case series reports described pU/S being used for more than one medical condition. To look for additional evidence to answer Research Question 1c, we also identified six training guidelines and nine training programs. For Research Question 2a, two clinical practice guidelines and three systematic reviews were identified. The included and excluded studies are listed in Appendix 8.

Among the included studies, 82% only evaluated the diagnostic accuracy of the intervention, while 8% examined the impact of the use of ED U/S on physicians' diagnostic thinking and patient management.[9-14] Three of these studies used an experimental (prospective and comparative) design.[11,13,14] None of the primary studies were judged to be of the highest quality (i.e., a blind comparison with a reference standard among an appropriate, broadly defined sample of consecutive patients). A majority (97%) of the included studies had two or more attributes that are associated with potential selection bias and detection bias.

4.2 Clinical Trial Data

The characteristics of ED pU/S studies for blunt abdominal trauma, AAA, and ectopic pregnancy, and mixed indications are presented in Tables 2 to 5. Published guidelines and additional studies that examined the effect of training on pU/S use are shown in Tables 6 and 7.

Figure 1: QUOROM flowchart detailing flow of studies

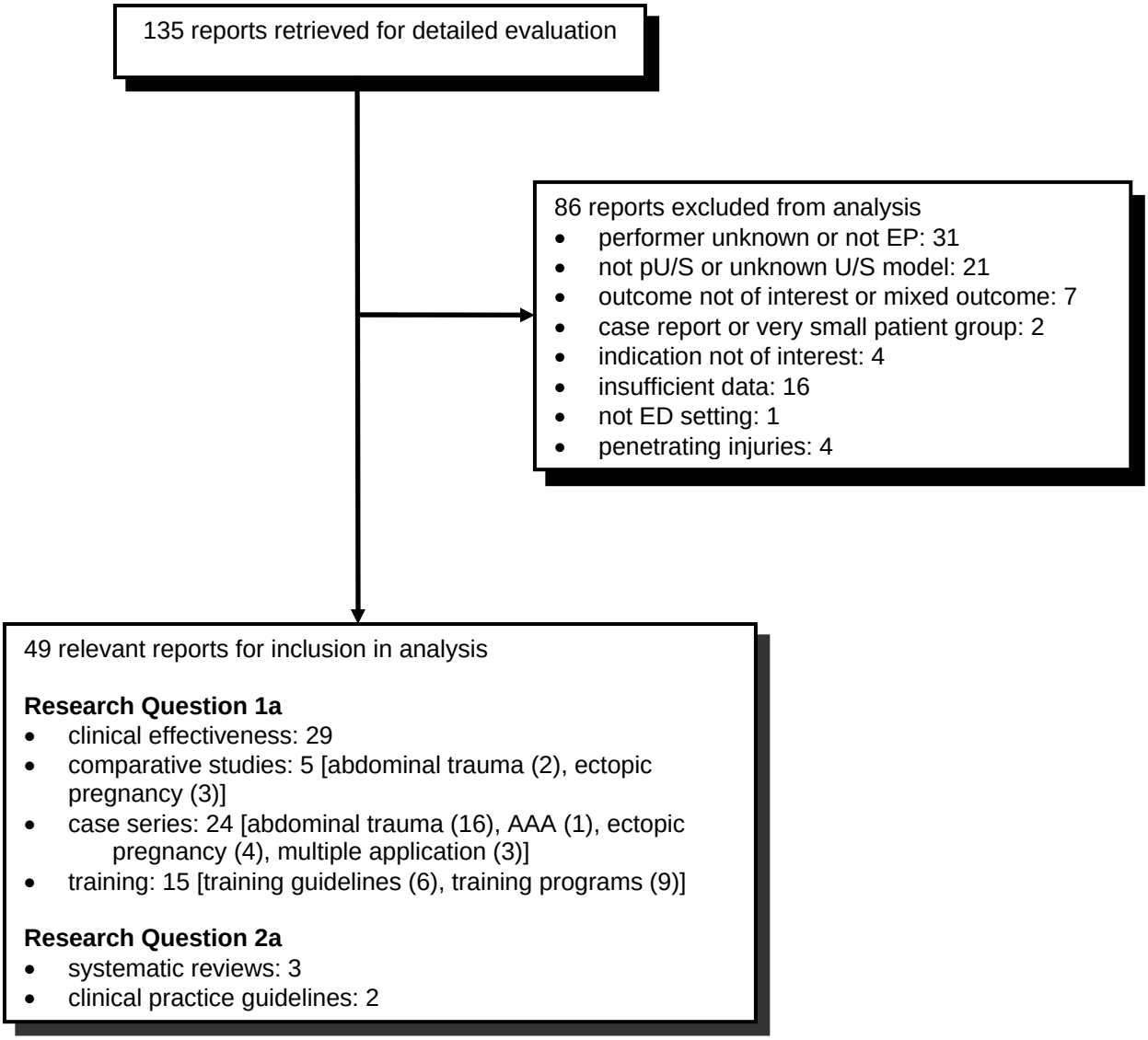


Table 2: Primary studies of pU/S used in blunt abdominal trauma						
Study	**Type**	**Design**	**Patients (n)**	**Comparators or Reference Standards**	**Out-comes**	**Quality**
Kimura[15]	case series	P, SD, SC, A	72	rU/S, lap	2	4
Jehle[16]	case series	R, SD, SC, A	44	DPL, lap	2	3
Liu[17]	comp	P, MD, MC, C, A	55	CT, DPL, surgery	2	3
Goletti[18]	case series	P, SD, SC, C	250	CT, DPL	2	3
Ingeman[19]	case series	P, SD, SC, C	97	CT, DPL, lap	2	3
Chiu[20]	case series	P, MD, SC, A	722	CT, DPL, lap, mon	2	4
McElveen[21]	case series	P, SD, SC, C	82	CT, serial exams, DPL, lap	2	2
Thomas[22]	case series	P, SD, SC, A	832	CT, DPL, lap, mon	2	4
Rozycki[23]	case series	P, SD, SC, C	1,227	–U/S: rU/S +U/S: CT or lap Inconclusive U/S: CT or DPL	2	4
Shih[24]	case series	P, SD, SC, A	170	CT, surgery	2	4
Miletic[25]	case series	R, MD, MC, C, A	242	surgery, CT, mon	2	4
Shackford[26]	case series	P, SD, SC, A	234	DPL, CT, lap, serial PE	2	4
Corbett[27]	case series	P, MD, SC, A	47	CT, lap	2	3
Stassen[28]	case series	R, SD, SC, A	23	CT	2	3
Vassiliadis[29]	case series	P, MD, SC, C	140	CT, lap, autopsy	2	3
Blackbourne[9]	case series	P, SD, SC, A	547	surgery, CT, mon	4	4
Jang[30]	comp	R, SD, SC, C	698	fU/S, CT, surgery	2	4
Suthers[31]	case series	P, SD, SC, C	120	CT, lap	2	4

Outcomes=level of outcome measures rated with Fryback and Thornbury hierarchy; P=prospective; R=retrospective; MD=multi-discipline; SD=single discipline; MC=multi-centre; SC=single centre; C=community hospital; A=academic hospital; lap=laparotomy; comp=comparative study; mon=clinical monitor; fU/S=formal U/S; PE=physical examination; rU/S=repeat U/S; DPL=diagnostic peritoneal lavage; CT=computerized tomography.

Table 3: Primary study of pU/S used in AAA						
Study	**Type**	**Design**	**Patients (n)**	**Comparators or Reference Standards**	**Out-comes**	**Quality**
Tayal[10]	case series	P, SD, SC, C	125	fU/S, CT, MRI	4	3

Outcomes=level of outcome measures rated with Fryback and Thornbury hierarchy; P=prospective; SD=single-discipline; SC=single centre; C=community hospital; MRI=magnetic resonance imaging; fU/S=formal U/S; CT=computerized tomography; MRI=magnetic resonance imaging.

Table 4: Primary studies of pU/S used in ectopic pregnancy						
Study	**Type**	**Design**	**Patients (n)**	**Comparators or Reference Standards**	**Out-comes**	**Quality**
Mateer[32]	case series	P, MD, SC, C	152	gynecologist, mon	2	3
Mateer[11]	comp	P, MD, SC, C	314	historical ectopic pregnancy	4	3
Durham[12]	case series	P, SD, SC, C	125	fU/S or mon	3	3
Shih[13]	comp	P, MD, SC, C	127	gynecologist, fU/S	2	4
Wong[33]	case series	P, MD, SC, C	151	gynecologist	2	4
Durston[34]	case series	R, MD, SC, C	120	surgery, rU/S, mon	2	4
Rodgerson[14]	comp	R, SD, SC, C	37	fU/S	3	4

Outcomes=level of outcome measures rated with Fryback and Thornbury hierarchy; P=prospective; R=retrospective; MD=multi-discipline; SD=single discipline; MC=multi-centre; SC=single centre; C=community hospital; comp=comparative study; mon=clinical monitor; fU/S=formal U/S; rU/S=repeat U/S.

Table 5: Primary studies of pU/S used in multiple indications						
Study	**Type**	**Design**	**Patients (n)**	**Comparators or Reference Standards**	**Out-comes**	**Quality**
Schlager[35]	Case series	P, SD, SC, C	pelvic: 42 AAA: 11	fU/S, surgery	2	4
Rowland[36]	Case series	P, MD, SC, C	trauma: 66 AAA: 33	CT, DPL, lap, fU/S, autopsy, or radiologist's review	2	3
Jones[37]	Case series	P, MD, SC, C	trauma: 111 AAA: 58	CT, DPL, lap, fU/S, or autopsy	2	4

Outcomes=level of outcome measures rated with Fryback and Thornbury hierarchy; P=prospective; SD=single-discipline; MC=multi-centre; SC=single-centre; C=community hospital; lap=laparotomy; fU/S=formal U/S; CT=computed tomography; DPL=diagnostic peritoneal lavage.

Table 6: Existing training guidelines for non-radiologists					
Information Source	**Applications**	**Suggested Course Formats**	**Recommended U/S Scans Needed for Proficiency**	**Credentialing Process**	**Documentation**
Mateer[38]	course material covered 4 primary aspects: physics, cardiovascular, abdominal, and obstetrics and gynecology	NR	40 hours of instruction in U/S and 150 total examinations	NR	NR
American College of Emergency Physicians [39]	trauma, pregnancy movement, echocardiography, AAA, biliary U/S, renal U/S, procedural U/S	For all primary applications: 2-day comprehensive course (8 hours didactic content, 6 to 8 hours hands-on training). For one, or limited number of applications: one-day course covering introduction, physics, operation of U/S controls, and application protocol (3 to 4 hours didactic content, 2 to 4 hours hands-on training)	Trauma: 25 to 50 scans IUP: 25 to 50 scans Emergency cardiac: 25 to 50 scans AAA: 25 scans Biliary: 25 to 50 scans Renal: 25 scans	Identify eligible providers, specify training or experience requirements, and specify emergency ultrasound privileges. All U/S studies during credentialing period should be compared with gold standard studies. Optional: outline training curriculum, specify documentation requirements for emergency U/S, define levels of credentialing, define ED U/S continuous quality improvement process	Should be documented as "emergency ultrasound," only include information specific to intended goal of examination. Should document course of action regarding U/S findings. Hand-written notes of the examination may need to be supplemented by written or computer-generated report
Australasian College for Emergency Medicine[40]	trauma, AAA	Include instructions relevant to performance and interpretation of focused U/S examinations. Course content: review of principles, operation of modern U/S machines, and U/S images depicting relevant normal and abnormal anatomy	Minimum of 25 accurate trauma examinations must be performed for FAST (>5 must be positive for intraperitoneal, pleural, or pericardial fluid). Minimum of 15 accurate scans of aorta must be performed for AAA (>5 should demonstrate an aneurysm)	Requires candidate to attend instructional workshop, perform and record requisite number of accurate proctored ED U/S, and pass exit examination. To maintain credentials, operator must undertake ≥3 hours of U/S training annually; and perform 25 trauma examinations for FAST, and 15 aorta scans annually for AAA	Should use title of "FAST" or "limited ED ultrasound for aortic aneurysm." Should describe views obtained, adequacy of those views, and indicate if findings were normal, abnormal, or indeterminate

Table 6: Existing training guidelines for non-radiologists					
Information Source	**Applications**	**Suggested Course Formats**	**Recommended U/S Scans Needed for Proficiency**	**Credentialing Process**	**Documentation**
American Institute of Ultrasound In Medicine[41]	Unspecified	NR	≥3 months of diagnostic U/S training in area(s) that physicians practise under supervision; should be involved in ≥300 sonograms to gain experience and proficiency with U/S. For multiple applications, number of required cases will be ≥500	NR	NR
The Royal College of Radiologists[42]	Focused emergency U/S: FAST, AAA. Pulseless electrical activity, tamponade, effusion. Vascular access. Pleural and pericardial fluid detection.	NR	Practical training: approximately five examinations under supervision per week 50 examinations for first practical module	For level 1 training requirement: should perform common examinations safely and accurately; recognize and differentiate normal anatomy and pathology, to diagnose common abnormalities in certain organ systems	A logbook with lists of types of examinations undertaken; additional record containing illustrated description of 10 cases in which trainee has been involved, may be collected
Canadian Emergency Ultrasound Society[43,44]	Cardiac arrest, pericardial effusion, thoracoabdominal trauma, ectopic pregnancy, AAA, undifferentiated shock, guidance for venous access	introductory ED U/S course, and hands-on training	Must complete 50 scans of each of following applications: heart for pericardial effusion, abdominal for free fluid, uterus for intrauterine pregnancy, aorta. Highly recommended that trainees be directly supervised for first 15 to 20 scans and for last 5, in each area of interest	NR	To acknowledge that study done is limited form of U/S examination, and to highlight binary nature of results obtained with ED U/S. Use of hard copy for negative image capture is strongly discouraged; while hard copy for image capture is useful for positive studies

NR=not reported; AAA=abdominal aortic aneurysm; U/S=ultrasonography; IUP=intrauterine pregnancy; FAST=focused abdominal sonography for trauma; ED=emergency department.

Table 7: Additional studies of effectiveness of training			
Information Source	**Applications**	**Course Formats**	**Effectiveness of Training Programs**
Ali[45]	to detect intraperitoneal and pericardial fluid	Workshop consisted of presentation of didactic material, demonstration and discussion of instrumentation, literature review, and hands-on training with pU/S unit. Ability to detect intraperitoneal or pericardial fluid assessed through 12 sonograms.	Workshop group increased number of correct responses, decreased number of wrong responses and indeterminate responses, as compared with control group
Lanoix[46] Lanoix[47]	cardiac, gallbladder disease, free peritoneal fluid, kidney, AAA, ectopic pregnancy	4-hour U/S training program (1 hour didactic and 3 hours hands-on training), all U/S examinations reviewed by trained specialist or radiologist. Patient's name, physician performing U/S examination, type of examination recorded on videotape; U/S examination was recorded; physician's interpretation of examination was recorded	Detecting free fluid: ss=0.94; sp=0.93; PPV=0.88; NPV=0.96. AAA: ss=1.00; sp=1.00; PPV=1.00; NPV=1.00. Pelvic: ss=1.00; sp=0.90; PPV=0.96; NPV=1.00.
Sisley[48]	abdominal trauma	U/S course consisting of didactic session and hands-on session, followed by objective structured clinical examination for assessment of physician performance in U/S evaluation of trauma, from factual knowledge of U/S and U/S interpretation skills	Results showed that factual knowledge and U/S interpretation skills improved significantly after participating in course
Kuhn[49]	AAA	3-day U/S course for EP and emergency medicine trainees, including 2 hours of aortic scans	ss=1.00; sp=1.00; PPV=1.00; NPV=1.00
Mandavia[50]	abdominal trauma, echocardiography, pelvic U/S, renal U/S, aortic U/S, biliary U/S, obstetric U/S	Phase I: 16-hour course (8 hours didactic program plus 8 hours practical laboratory teaching), followed by quiz. Phase II: further 10-month period after initial instruction, followed by repeat quiz. In phase II, all U/S printed or stored on VHS tapes, and results entered on special U/S log forms	Phase I: pre-test score versus post-test score=15.6 versus 20.2 Phase II: pre-test score, post-test score, and 10-non score were 17.1, 20.2, and 20.7 respectively
Price[51]	gynecology, cardiac abdominal scanning	8 lecture hours during first year of three-year resident program, and 8 hours annually in U/S lab. Total of 32 hours of didactic and direct experience in sonograph	No information
Bailey[52]	AAA	20-minute videotape of U/S images of abdominal aorta, 1-hour didactic seminar, and 1-hour hands-on training session	ss=1.00; sp=1.00; 1 of 79 scans unable to complete; 3 of 79 scans required verbal and manual assistance; 40 of 79 scans required verbal assistance; 35 scans able to complete independently.
Salen[53]	trauma	1-hour didactic presentation followed by 3-hour hands-on training session using human models and mannequin simulator models	Trainee satisfaction score was 82% for human models, and 78% for mannequin simulator models

Table 7: Additional studies of effectiveness of training			
Information Source	**Applications**	**Course Formats**	**Effectiveness of Training Programs**
ED Echo Instructor Staff (Ray Wiss, The EDE Course, Sudbury, ON: personal communication, 2005 July 27)	cardiac, aortic, abdominal, obstetrical	10-hour, 1-day course, with >6 hours hands-on training. Extremely high instructor-student ratios (>1:3) and machine-student ratios (>1:2)	>2,000 Canadian physicians in nearly 100 hospitals took course; >90% of graduates able to integrate U/S into practices after course

ss=sensitivity; sp=specificity; mon=clinical monitor; AAA=abdominal aortic aneurysm; U/S=ultrasonography; pU/S=portable ultrasound; PPV=positive predictive value; NPV=negative predictive value.

4.3 Analysis of Outcomes

4.3.1 Clinical effectiveness from primary studies

a) What is the evidence of effectiveness for the use of ED pU/S in blunt abdominal trauma, AAA, and ectopic pregnancy?

Patient relevant outcomes
We did not identify any studies that reported mortality rates or patient survival rates for any condition. There were few reports that evaluated the effect of pU/S on decision making and definitive care (usually surgery). One study reported that ED pU/S was associated with lower condition-related complication rates.[11] The introduction of bedside transvaginal ultrasound administered by a non-radiologist for patients with suspected ectopic pregnancy was associated with reduced rates of rupture, compared with historical controls.

Intermediate outcomes
The most frequently reported outcome measures in the included studies were diagnostic test characteristics, such as sensitivity and specificity. Among patients with abdominal trauma, most of the sensitivity values for detecting free fluid were between 0.80 and 0.90; a similar range of sensitivity for detecting free fluid plus organ injury was observed. The values of specificity for detecting intraperitoneal free fluid were between 0.96 and 1.00. For patients with AAA, the sensitivity of emergency U/S was reported to be 1.00.[10] ED pU/S was associated with a sensitivity of 0.82 to 1.00, and a specificity of 0.88 to 1.00 in detecting ectopic pregnancy.

No comparative studies examined the effect of introducing ED pU/S on the rates of surgery, the use of CT scans, or the use of DPL. False-positive and false-negative rates are derived from case series. For abdominal trauma, most false-negative rates ranged between 0.10 and 0.25, while the false positive rates were between zero and 0.04. For ectopic pregnancy, false-negative rates ranged from 0.01 to 0.18, and were usually related to a early pregnancy where the gestational sac was too small to detect with certainty. For AAA, one study reported a false-positive rate of 0.02,[10] while no false-negative findings were observed.

The average time from emergency admission to ED pU/S performance was usually within 30 minutes,[15,18,19,31] while one study reported that the time from admission to the performance of a CT scan was one hour and 19 minutes.[18] ED pU/S was usually performed within five minutes,[18,21,22,25] while 40 minutes was required for a CT scan, and 15 minutes for a DPL.[21]

Time to diagnosis and patient flow were generally unreported. One comparative study[14] examined the effect of ED pU/S on time to diagnosis, and time to operative treatment. This retrospective study compared 16 ED pU/S examinations by emergency medicine faculty or senior residents with 21 formal U/S examinations performed by radiologists for suspected ectopic pregnancy. The time to diagnosis was reduced by 139 minutes after the introduction of ED pU/S ($p<0.0001$), while the time to operative treatment was reduced by 211 minutes upon the introduction of ED pU/S ($p<0.0001$).

Harmful outcomes
Among studies, 10% reported on inadequate ultrasound examinations due to obesity or subcutaneous emphysema (0.8 to 4.5%),[18,19] or technical problems with the U/S unit (1.8% to 2.5%).[19,27] The unnecessary surgery rates in patients with false-positive ED pU/S examinations were reported in a few case series. In the studies of Thomas *et al.,* and Rozycki *et al.*, 50% of the false-positive cases underwent non-therapeutic surgery.[22,23] In the study of Goletti *et al.*, the unnecessary surgery rate was 2.44%.[18] Both false-negative cases (n=2) in the study of Jehle *et al.* required surgical intervention.[16] In the study of Rozycki *et al.*, 12 of 16 false-negative cases needed surgical repair for the abdominal trauma, and one patient with false-negative results died.[23] The details of the consequence of false-positive or false-negative diagnoses are presented in Appendices 3, 4, and 5.

The reasons for false-negative results have been attributed to the inability of the machine to detect intraperitoneal fluid (i.e., small amounts of free fluid); or to operator inexperience.[15,22,29] Other explanations have been that there was no hemoperitoneum when the pU/S examination was performed, and by the time that the CT scan and exploratory laparotomy were performed, blood had accumulated.[47] When the presence of intraperitoneal

free fluid is used as an indicator of abdominal organ injury, some injuries without large amounts of free fluid are likely to be missed. In several studies, the false-negative cases in patients with abdominal trauma were related to bowel injury.[17,19,23,25,28] The consequences of false-negative results varied. One article reported that the false-negative results were found in patients who were hemodynamically stable, but required no therapeutic laparotomy.[37] In another prospective case series, there was one case of a patient with a false-negative examination who died.[23] For patients with ectopic pregnancy, the possible reasons for misdiagnosis would be an early gestational sac that is too small to be detected. One study reported a false-positive case, in which an intrauterine device was judged to be an intrauterine pregnancy.[32] False-negative results in ectopic pregnancy can put a patient at risk of delayed treatment and increased complications, and may cause severe consequences such as unexpected death.

Two false-positive results were described in patients with AAA. The aortic diameter measured using pU/S was found to have a larger measurement than that made using CT,[10] implying that pU/S may lead to unnecessary further investigations.

b) What is the evidence regarding the effect of diagnostic accuracy on the effectiveness of these interventions?

To demonstrate the probability that a test will give the correct diagnosis, PPV, NPV, and positive and negative LRs were calculated. Data from those prospective studies reporting the actual numbers of true-positive, true-negative, false-positive, and false-negative were pooled (Tables 8 to 10).

Table 8: Estimates for blunt abdominal trauma

Study Type	Number of Studies	PPV Mean (95% CI)	NPV Mean (95% CI)	LR(+) Mean (95% CI)	LR(–) Mean (95% CI)
All prospective studies[9,15,17,19,21-24,26,27,29]	12	0.943 (0.913 to 0.963)	0.973 (0.967 to 0.979)	661.7 (33.16 to 115.04)	0.20 (0.15 to 0.29)
Studies with quality scores ≤3[17,19,21,27,29]	5	0.926 (0.861 to 0.962)	0.920 (0.885 to 0.945)	25.96 (13.01 to 51.80)	0.23 (0.15 to 0.34)
Multi-discipline[17,27,29]	3	0.944 (0.866 to 0.978)	0.900 (0.846 to 0.937)	27.64 (10.43 to 73.22)	0.21 (0.11 to 0.43)
Single discipline[9,15,19,21-24,26,31]	9	0.942 (0.908 to 0.964)	0.978 (0.972 to 0.983)	79.99 (37.68 to 169.82)	0.19 (0.13 to 0.30)

PPV=positive predictive value; NPV=negative predictive value; LR(+)=positive likelihood ratio; LR(–)=negative likelihood ratio.

Table 9: Estimates for ectopic pregnancy

Study Type	Number of Studies	PPV Mean (95% CI)	NPV Mean (95% CI)	LR(+) Mean (95% CI)	LR(–) Mean (95% CI)
All prospective studies[12,13,32,33,35]	5	0.704 (0.627 to 0.771)	0.983 (0.963 to 0.992)	14.57 (3.31 to 64.16)	0.08 (0.04 to 0.17)
Studies with quality scores ≤3[12,32]	2	0.595 (0.435 to 0.737)	0.990 (0.965 to 0.997)	24.21 (0.82 to 717.75)	0.09 (0.02 to 0.34)
Multi-discipline[13,32,33]	3	0.674 (0.574 to 0.760)	0.979 (0.952 to 0.991)	24.16 (0.29 to 1998.71)	0.09 (0.04 to 0.20)
Single-discipline[12,35]	2	0.754 (0.629 to 0.848)	0.991 [0.950 to 0.998]	8.73 (2.34 to 32.50)	0.05 (0.01 to 0.37)

PPV=positive predictive value; NPV=negative predictive value; LR(+)=positive likelihood ratio; LR(–)=negative likelihood ratio.

Table 10: Estimates for AAA					
Study Type	**Number of Studies**	**PPV Mean (95% CI)**	**NPV Mean (95% CI)**	**LR(+) Mean (95% CI)**	**LR(–) Mean (95% CI)**
All prospective studies[10,35-37]	4	0.828 (0.765 to 0.877)	0.956 (0.923 to 0.975)	14.55 (2.36 to 89.60)	0.06 (0.02 to 0.23)
Studies with quality scores ≤3[10,36]	2	0.762 (0.681 to 0.828)	0.955 (0.918 to 0.975)	13.54 (1.11 to 165.43)	0.07 (0.01 to 0.78)
Multi-discipline[36,37]	2	0.794 (0.719 to 0.854)	0.927 (0.874 to 0.959)	11.89 (0.59 to 238.71)	0.08 (0.01 to 0.47)
Single discipline[10,35]	2	0.947 (0.827 to 0.985)	1.000 (0.962 to 1.000)	21.98 (2.85 to 169.37)	0.03 (0.00 to 0.23)

PPV=positive predictive value; NPV=negative predictive value; LR(+)=positive likelihood ratio; LR(–)=negative likelihood ratio.

Table 11: Post-test probability according to various clinical scenarios			
Disease	**Pre-test Probability**	**Post-test Probability**	
		Positive Test	**Negative Test**
Trauma	15%	92%	3%
Ectopic pregnancy		73%	1%
AAA		73%	1%
Trauma	50%	98%	17%
Ectopic pregnancy		94%	7%
AAA		94%	6%
Trauma	75%	99%	38%
Ectopic pregnancy		98%	19%
AAA		98%	15%

AAA=abdominal aortic aneurysm.

The post-test probabilities of ED pU/S for diagnosing blunt abdominal trauma, ectopic pregnancy, and AAA, given different clinical scenarios, are presented in Table 11. The post-test probability after a positive test is high when the pre-test probability is >50%, while the post-test probability after a negative test is low when the pre-test probability is <15%.

c) What is the evidence of the effect of user-dependent variables on the effectiveness of the intervention?

Results from one comparative study showed that the accuracy of the diagnosis is associated with observer education.[30] Another study compared CT scan, DPL, or radiologist-performed formal U/S with emergency U/S, and showed that the latter was similar in effectiveness to the others in assessing abdominal trauma.[17]

Type of training
In the primary studies identified, training commonly consisted of a didactic session, followed by a hands-on practical session on live human models. Training sessions generally focused on experience involving a proportion of positive models. Instructional formats varied from delivering a lecture, reviewing pU/S images, demonstration, or a mix of all three.

Length of training
In the primary studies identified, previous training experience consisting of eight to 12 hours of didactic sessions, and 15 to 50 supervised pU/S scans were reported by most researchers.[10,12,21-23,26,27,31,32,34,36]

Number of scans needed for proficiency
This outcome varied from 15 to 50 for each application. One study reported that 10 examinations should not be used as the minimum standard for ultrasonographic diagnosis in abdominal trauma

patients.[30] Most studies required a certain portion of positive scans to demonstrate proficiency.

Setting
All the identified trials were conducted in metropolitan hospitals. Some (31%) studies were conducted in academic hospitals, while 62% were conducted in community hospitals. Two studies (7%) were conducted across both settings. Based on the available evidence, we were unable to examine ED pU/S in a rural location.

We did not find direct evidence from the identified studies regarding the effect of continued experience on the effectiveness of ED pU/S.

4.3.2 Current guidelines

a) Clinical practice guidelines

Two clinical practice guidelines (CPGs) were identified.[54,55] Both guidelines suggested that FAST was useful as an initial screening tool when used by surgeons for patients with blunt abdominal trauma. The recommendations were classified as "reasonably justifiable" or made with "moderate clinical certainty."

What is the level of evidence underlying these guidelines?
Both CPGs used a systematic review approach, regarded as the highest level of evidence, to support consensus recommendations. One guideline[55] described the five studies supporting its recommendations. The other guideline primarily relied on data from four studies, but cited other studies narratively to support its recommendation.

Are the recommendations consistent with the evidence?
The characteristics of identified systematic reviews are presented in Table 12. Details about CPGs and systematic reviews are provided in Appendix 7. The recommendations from these guidelines are inconsistent with the findings of three systematic reviews.[56-58] In one review that included 11 prospective studies, the authors conclude that more trials should be conducted before U/S is accepted as a standard test for the evaluation of blunt trauma.[58] A more recent review identifies 30 prospective trials and concludes that in terms of clinically suspected abdominal trauma, another effective assessment (i.e., CT) should be performed regardless of the initial sonographic findings.[57] A systematic review that included trials of RCT and quasi-RCT design by the same authors concludes, "There is insufficient evidence from RCTs to justify promotion of ultrasound-based clinical pathways in diagnosing patients with suspected blunt abdominal trauma."[56]

b) Training guidelines

Six guidelines that describe training and credentialing requirements are listed in Table 6.[38,39,41-44,59] One guideline, which was developed by the Canadian Emergency Ultrasound Society (CEUS),[44] also outlines requirements for documentation.

The minimum number of pU/S scans range from 50 to 500, while the minimum number of accurate scans recommended ranged from 15 to 25. Recommendations for training guideline documentation suggest that reports should be labelled as "limited ED ultrasound" to differentiate them from the formal U/S examinations performed by a radiologist in the imaging department.[39,43,59] The patient's identifying number, the goal of the U/S scan, and relevant parameters (e.g., the amount of free fluid, diameter of the aorta, presence or absence of intrauterine pregnancy) should also be documented. There should be a written report with a picture of the image. The process of U/S assessment may be videotaped.

What is the level of evidence underlying these guidelines?
All recommendations seem to be consensus-based with some unstructured consideration of the available literature.

Are the recommendations consistent with the evidence?
Standards for the amount of training are generally higher than those reported in the included primary studies. Recommended documentation standards are generally more elaborate than those observed in the primary studies.

4.3.3 Ethical and legal implications

In the ED environment, decisions must be made quickly, often with incomplete information.[60] Against this backdrop, EPs have adopted U/S to advance the timely and accurate evaluation and

Table 12: Comparison of systematic reviews						
Author	**Years Searched**	**Sources**	**Intervention and Comparators**	**Number of Primary Studies**	**Characteristics of Included Trials**	**Topics**
Pearl [58]	1980 to 1994	MEDLINE®, and references from initial search	U/S versus CT, DPL, or lap	11	11 prospective (4 full-sized machines; 1 performed by radiologists)	Blunt abdominal trauma
Stengel [57]	since the first available reference July 2000	MEDLINE, EMBASE®, Cochrane Library of Systematic Reviews	U/S versus CT, DPL, lap, clinical observation	30	30 prospective (10 full-sized machines; 9 performed by radiologists)	Blunt abdominal trauma
Stengel [56]	1966 to 2004	MEDLINE, EMBASE, CENTEAL, CCMed, publishers' databases, controlled trials registers, Internet and hand search	ED U/S versus CT, DPL, clinical monitoring	5 RCTs and quasi-RCTs	5 (1 full-sized machine; 2 performed by experts)	Blunt abdominal trauma
Chen CCOHTA (this report)	1990 to 2005	BIOSIS Previews®,P P EMBASE, MEDLINE, PASCAL, web sites of related agencies	ED U/S versus CT, DPL, lap, formal U/S, clinical monitoring	29	23 prospective, 6 retrospective (all examined compact, pU/S machines; performed by non-radiologists)	Blunt abdominal trauma, ectopic pregnancy, AAA

Lap=laparotomy; U/S=ultrasonography; CT=computerized tomography; DPL=diagnostic peritoneal lavage; ED=emergency department; RCTs=randomized controlled trials; AAA=abdominal aortic aneurysm.

treatment of acute patients. Are EPs are qualified to provide this service?[39,61] In this report, we restrict the analysis to published references, and limit the analysis to concepts and issues that are based on the results of the literature search.

The ethical responsibilities of EPs with respect to ED pU/S are similar to those required of radiologists. These responsibilities entail at least seven elements: assessing the appropriateness of the imaging examination, participating in the informed consent process, protecting patients' interests, providing excellent image interpretation, communicating effectively with other physicians and patients, seeking continued learning, and continuously improving quality.[62] In the emergency context, patients must be informed that ED pU/S is a focused, limited examination.[39]

With respect to legal implications, ED pU/S should not be considered any differently from any other emergency medicine skill.[63] To avoid possible litigation, institutions should:

- adhere to delineated training and credentialing guidelines, such as those developed by CEUS. The CEUS guidelines provide recommendations for training, scope of practice, quality assurance, and certification of ED staff.[44]
- monitor the use of ED pU/S, which must be incorporated into the quality improvement or assurance process to document the positive aspects of ED pU/S and the deficiencies for which corrective action can then be implemented.[61]

Primary applications for ED pU/S include trauma, ectopic pregnancy, AAA, and emergency echocardiography.[39] Malpractice suits related to the missed diagnosis of ectopic pregnancy is a frequent type of litigation involving formal U/S in the United States;[64] but this type of litigation is rare for ED

pU/S.[65,66] Misinterpretations of AAA with ED U/S have also been reported in the literature.[67] Greater adherence to specialty-specific guidelines for emergency U/S will minimize misdiagnosis and potential litigation.[44]

5 DISCUSSION

This systematic review examines the implications of pU/S examinations that are performed by non-radiologists in an ED. To improve the reliability of this study's findings, a protocol was written a priori, and a comprehensive search of evidence was conducted, using techniques empirically shown to reduce reviewer bias. The quality of the evidence was assessed, and an appropriate qualitative and quantitative synthesis of the evidence was conducted.

This report examines three patient groups, based on their prevalence in the ED and on interventions intended to improve diagnostic certainty (e.g., pU/S has the potential to improve patient relevant outcomes such as rates of survival).

Abdominal trauma: Portable U/S examinations are used to detect internal bleeding resulting from organ injuries, by observing the anechoic area at particular points in the abdominal cavity. However, 10% to 30% of the visceral lesions are not accompanied by free fluid,[57] so pU/S is not absolutely predictive for these injuries.

AAA: This condition may present in different ways; sometimes, the clinical manifestations are atypical, so a prompt diagnosis is difficult to make. The patients present with urologic, gastrointestinal vascular symptoms and signs that often mislead physicians to consider other common ED problems. An increase in mortality has been observed when the diagnosis is delayed or missed; a 40% decrease in death rates was observed between patients who were initially suspected with AAA (and had the condition), compared with those who were not inititally suspected with AAA.[68]

Ectopic pregnancy has been associated with decreasing mortality rates, but it remains a life-threatening condition for women of childbearing age. In clinical practice, physicians usually rule out an ectopic pregnancy when intrauterine gestation is present, because the rate of combined ectopic and intrauterine pregnancies is low (one in 30,000 pregnancies).[32]

We identified 29 clinical studies related to the effectiveness of ED pU/S when delivered by a non-radiologist. Although 79% (23 of 29) of the studies were conducted prospectively, three of these studies used a comparative design, allowing for direct inferences about the relative effectiveness of the intervention. Most of the identified studies (69%) were prospective case series and examined diagnostic performance. These were conducted using approaches that can influence the accuracy or precision of the measured study outcomes: some enrolled patients consecutively, others enrolled a convenience sample, based on the availability of staff to perform the U/S scan, or a patient's hemodynamic stability; some had a large sample size, while others had few study participants; and various modalities were used to confirm the diagnosis after the ED pU/S examination.

We used a hierarchy[4] to assess the methodological quality of the included primary studies, with lower scores representing better study quality. Among the 29 studies, 16 (55%) had a score of four, which was defined as low quality; 41% (12 of 29) obtained a score of three; and 3% (1 of 29) achieved a score of two, which indicated high quality. Our selection criteria did not allow us to choose studies that could obtain the lowest possible score. The fact that few studies achieved a high quality score often reflected convenience sampling and lack of blinding. This could highlight some technical challenges of conducting studies in the ED. For example, in many studies, it is unlikely that all EPs would have been sufficiently trained to use pU/S to allow for consecutive enrolment. Ultimately, these studies of poor methodologic quality do not provide convincing evidence that ED pU/S, that is administered by a non-radiologist, demonstrates an impact on outcomes that are relevant to the health of patients.

The ED, like other acute care settings, is a poor environment in which to perform pU/S examinations. For example, lighting is often difficult to control, time is often limited, space is cramped; and patients are not prepared as they are with elective ultrasound examinations. For example, illness and pain, lack of cooperation, and increased gas between the transducer and the organ

in question may result in a poor quality scan. In some cases, a pU/S may be technically impossible to complete. The few studies that report these outcomes, however, suggest that technical difficulties have a small impact on the performance of pU/S in the ED.

From the large number of prospective case series reports identified, we can asssess the technical validity of ED pU/S, and project its theoretical effect on diagnostic thinking. LRs are used to determine the utility of these tests in clinical practice, because of their stability, ease of use, and efficiency.[69] The pre-test probabilities, severity of disease, and post-test probabilities need to be considered in clinical decision making. Evidence from all three disease states suggest that ED pU/S is an effective tool for improving diagnostic certainty in abdominal trauma, AAA, and ectopic pregnancy. ED pU/S increases the post-test probability of disease in all three tests; while it is unable to exclude the disease with certainty in any. With a low pre-test probability of disease, however, all three pU/S tests (for the three disease states) produce a low post-test probability of disease in the ED (<3%). These results are robust – the estimated effect remains similar even when only studies of higher quality are considered. Misdiagnoses (i.e., false-positive results and false-negative results) with pU/S scans performed by EPs and other non-experts do occur; at rates similar to those observed in radiologist-performed U/S scans.[70-75] This implies that experts and non-experts contribute similarly with respect to the accuracy of a diagnosis, for the conditions that were studied.

In studies of blunt abdominal trauma, the pooled positive LR for all the prospective studies is 61.76; (95% CI: 33.16; 115.04). This value lies beyond an accepted clinical threshold of 10, and indicates that a positive test result can provide convincing evidence of the presence of intraperitoneal free fluid. In studies with higher quality ratings, the positive LR [25.96 (95% CI: 13.01; 51.80)] is lower than that reported for all prospective studies. The value still demonstrates the effectiveness of ED pU/S for detecting free fluid in the abdominal cavity. The negative LR indicates that a negative pU/S cannot be interpreted with certainty to rule out the disease.

The pre-test probability of intraperitoneal free fluid ranged from 6% to 66% in the patient populations. If we assume a 50% pre-test probability of disease (blunt abdominal trauma victim, tender abdomen, with or without hypotension), a positive test would give physicians 98% certainty (based on a post-test probability) that hemoperitoneum was present. A negative test in this scenario would not exclude the diagnosis of hemoperitoneum (post-test probability=17%).

The post-test likelihood after a negative test is insufficient to rule out hemoperitoneum when pre-test probabilities are high (post-test probability=38% when prevalence is 75%). Conversely, with a lower pre-test probability (15%), a negative pU/S provides more certainty to physicians (post-test probability=3%). As a result, false negatives may occur in 38% of patients in scenarios of high prevalence of abdominal trauma; this rate decreases to 3% of patients when the prevalence is lower.

For ectopic pregnancy, the pooled positive LR for all the prospective studies is 14.57 (95% CI: 3.31; 64.16). This value lies beyond 10, indicating that a positive test result can provide convincing evidence of the presence of an ectopic pregnancy. When examining the effectiveness of studies with higher quality, the positive LR [24.21 (95% CI: 0.82; 717.75)] is higher than that reported for all prospective studies; the value demonstrates the effectiveness of pU/S for detecting an ectopic pregnancy. The negative LR is also convincing when pooled across all studies [0.08 (95% CI: 0.04; 0.17], meaning that a negative pU/S can be interpreted with near certainty to rule out the disease in low risk patients. The prevalence of ectopic pregnancy in the study population ranged from 4% to 81%. If we assume a 50% pre-test probability of ectopic pregnancy (woman of reproductive age, positive pregnancy test, relatively small uterine size, or experiencing vaginal bleeding), a positive test would provide a post-test likelihood of 94%. A negative test would provide a post-test probability of disease of 7% in the same clinical scenario. A false-negative result can occur in 19% of patients in scenarios of high prevalence of ectopic pregnancy; this rate decreases to 1% of patients when the prevalence is lower. As a result, the use of pU/S will be more efficient for ruling out ectopic pregnancy in a

setting with low disease prevalence, because of the low post-test probability.

In AAA, the pooled positive LR for all prospective studies is 14.55 (95% CI: 2.36, 89.60). This value is beyond 10, and indicates that a positive test result can provide convincing evidence of the presence of an AAA. When examining the effectiveness in studies with higher quality, the positive LR [13.54 (95% CI: 1.11; 165.43)] is similar to that reported for all prospective studies; the value demonstrates the effectiveness of pU/S for detecting an AAA. The negative LR is similarly impressive for all studies [(0.06 (95% CI: 0.02; 0.23)] and higher quality studies [0.07 (95% CI: 0.01; 0.78)]. A negative pU/S can be interpreted with confidence to rule out the disease. The prevalence of AAA in the study population ranged from 0.22 to 0.82. If we assume a 50% pre-test probability of AAA (e.g., hypertensive male or female with abdominal pain, central tenderness on examination, age >55 years, hypotension or no hypertension), a positive test would provide a post-test likelihood of 94%, and a negative result would provide a post-test likelihood of 6%. A false-negative result can occur in 15% of patients in scenarios of high prevalence of abdominal trauma; this rate decreases to 1% of patients when the prevalence is lower. As a result, the use of pU/S will be more efficient for ruling out AAA in a setting with low disease prevalence, because of the low post-test probability.

Our analysis suggests that the decision to implement ED pU/S must be based on the pU/S operator and the setting. There is evidence that the training and experience of the operator affect performance.[22,26] The ability to positively predict disease also increases with the increasing prevalence of illness; even with trained and experienced EPs, the certainty of the diagnosis varies according to the population that usually visits the ED. ED pU/S will theoretically contribute less to triaging patients in a small setting with less dedicated staff, who have less pU/S experience (e.g., one night shift weekly) and fewer individuals with disease, compared with a large setting where illness is more prevalent and there are dedicated EPs. It could be argued that there are settings (e.g., family physicians' clinics) where pU/S would be unlikely to be effective.

In this report, we were able to identify clinical practice guidelines for ED pU/S examinations in patients with abdominal trauma. These guidelines adopt a systematic review approach, which is thought to provide reliable evidence. One of these guidelines is transparent in its analysis.[55] None of the guidelines are specifically intended for non-radiologist physicians. Our findings suggest that decisions regarding the implementation of pU/S scans in patients with AAA or ectopic pregnancy will need to be made without formal guidance. Expert opinion regarding in training guidelines suggests that training should include a course in didactic and practical sessions.[45,47,48,50,53] The use of proctors and a gold standard technique for the first 50 U/S examinations is associated with a diagnostic performance that is essentially equal to that reported in the literature.[22] The relationship between diagnostic accuracy and levels of training indicates the importance of adequacy of training when deciding whether to use ED pU/S. We did not find direct evidence, from the identified studies, regarding the effect of continued experience on the effectiveness of ED pU/S. Indirect evidence from another area of diagnostic imaging suggests that a higher volume of scans is associated with improved effectiveness.[76] It is generally believed that experience and proficiency are related.

Decisions to implement ED pU/S performed by non-radiologists must be based on evidence of effectiveness of emergency U/S in general – regardless of portability and who performs the examination. The three systematic reviews identified examined the evidence from all abdominal trauma trials (30 versus 13 in our report). This larger body of evidence includes trials with full-sized U/S machines, that are used by radiologists, and suggests that emergency U/S for abdominal trauma, regardless of who performs it, is not a replacement for reference standards (e.g., CT imaging).

The results of this report and of other reviews suggest that the demonstrated benefits of ED pU/S performed by non-radiologists are limited to improving diagnostic certainty. When used in appropriate patient groups, they can assist physicians with reaching a diagnosis faster and with more certainty, and may lead to faster treatment for the individual patient. Because clinical decisions that result in real harm or benefit, such as discharge

or surgery, require a diagnostic certainty that is sufficiently convincing, it can be argued that ED p/US may never directly translate into improved health outcomes. The sole benefit that could be expected from ED pU/S may be improved ED efficiency. Our review was unable to identify enough evidence to state that pU/S reduces the time to diagnosis or time to operative treatment; these reductions were observed in one retrospective study. Additional prospective, comparative, high quality studies, designed to measure the impact of ED pU/S on patient flow while monitoring clinical efficacy, would be helpful for making evidence-based decisions.

Limitations

- Mortality, an important outcome measure for the quality of medical care, was not evaluated in most of the identified literature. All the included studies failed to report on long-term follow-up after discharge from the ED.
- The use of a convenience-based sample of patients, instead of an unselected consecutive patient group, may have led to selection bias. Given the limited availability of pU/S skills in clinical practice, this likely reflects practical considerations rather than a true selection bias. The literature review may result in an overestimation of the actual performance characteristics of the pU/S used in the emergency setting.
- For practical reasons, foreign language publications were excluded in this report. It was reported that the findings from foreign language articles are generally consistent with those in the English literature, yet some studies obtained superior results.[58]
- U/S examinations were not always verified by a reference diagnostic method; only those with negative or indeterminate results were investigated with other diagnostic techniques. This factor weakened the quality scoring of included studies, and has been shown to potentially bias research results.
- Unpublished and negative trials that are missed might result in an overestimation overestimation of the effectiveness of pU/S (publication bias). A comprehensive search of the published literature for potentially relevant studies was conducted, using a systematic strategy to avoid bias. Searching for and including studies from the grey literature, which is associated with less exaggerated estimates of benefit, was not performed because of timeline constraints.
- The authors selected some methods of data synthesis and statistical analysis after all studies had been identified and tabulated. Although the methods adopted have been widely used by others, the practice of deciding on synthesis methods a posteriori can contribute to confirmation bias.

6 CONCLUSIONS AND IMPLICATIONS

The results of this report suggest that the demonstrated benefits of ED pU/S performed by non-radiologists are limited to improving diagnostic certainty. We did not find convincing evidence to show that ED pU/S administered by a non-radiologist has an impact on outcomes relevant to the health of patients. This review also fails to identify compelling evidence of improved time to diagnosis or time to operative treatment. These outcomes are reported so infrequently that statements for or against pU/S are impossible to make.

There is enough evidence from studies of blunt abdominal trauma, AAA, and ectopic pregnancy to suggest that ED pU/S performed by non-radiologists is an effective tool for improving diagnostic certainty in these disease groups. ED pU/S is likely to improve the certainty of diagnosis. These results are robust – the estimated effect remains similar even when only studies of higher quality are considered. The non-therapeutic advantages of using this technique are that it is easier to use and repeat, inexpensive to perform with available technology, and is non-invasive.

There is evidence of misdiagnosis from using pU/S in EDs, which is associated with inexperience. There is additional evidence of improved performance from training non-radiologist physicians. Training programs that use didactic and practical sessions (a minimum of 50 scans for each medical use) have shown improved effectiveness. Misdiagnoses with pU/S scans performed by trained non-radiologist physicians can still occur, but at rates similar to those observed in similar studies of radiologist-performed U/S scans.

We were able to identify clinical practice guidelines for emergency U/S examinations in patients with abdominal trauma. None of the guidelines are specifically intended for non-radiologist physicians. Decisions to implement ED pU/S will need to be based on tacit knowledge and local guidance.

Training and credentialing guidelines are an ethical and legal requirement for ED pU/S examinations, performed by EPs,[39] because guidelines for other specialties include many topics that are not pertinent to emergency medicine. Training programs exist for U/S examinations; a training standard for physicians who use pU/S devices in ED is important to ensure patient safety.

Additional prospective, comparative, high quality studies, designed to measure the impact of ED pU/S on ED patient flow, while monitoring clinical efficacy, would be helpful for making evidence-based decisions. The body of evidence describing diagnostic performance needs to be supplemented with results that demonstrate the effect of this intervention on diagnostic reasoning and time to definitive care.

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APPENDICES

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