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Managing incidental findings reported by medical, sonography and other students performing educational ultrasound examinations

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ABSTRACT

The evolution of ultrasound imaging into a key technology for diagnostic practice has resulted in its incorporation into medical student education worldwide. While the introduction of ultrasound into medical schools' curricula is relatively recent, training of sonographers and other ultrasound users is mature. Ultrasound is being used in a variety of learning environments and clinical settings, from courses in anatomy and physiology to clinical rotations where medical and other students may scan healthy volunteers or patients, sometimes with little to no supervision. Educators may be apprehensive about a perceived high likelihood that students will encounter unexpected findings during these sessions, which could distress the patient or ultrasound model as well as the student, and result in problems that would be more pronounced if incidental findings are complex. Policies are needed to address how to manage incidental ultrasound findings that are identified during educational activities. This document summarizes the background and provides a framework for establishing and implementing a well-designed and thoughtful approach for dealing with incidental findings observed in volunteer subjects by medical students during training courses in ultrasound diagnostic scanning. The subject's confidentiality should be respected, and review of incidental findings should be transparent without provoking unnecessary anxiety. It is the responsibility of the instructor or supervisor to ensure adequate clinical follow-up if indicated.

52 # 1 INTRODUCTION

53 The ultimate goal of introducing ultrasound imaging into the education of medical students is
54 to improve the medical care received by patients around the world, but instructing hundreds of
55 thousands of medical students even in basic scanning techniques creates many challenges. These
56 include securing adequate funding and equipment, integrating courses into existing curricula,
57 and training sufficient faculty members.

58 One specific challenge is that medical students may detect unexpected or incidental findings
59 (IF) during a certain percentage of their examinations. This issue is not new to medical education
60 since students may detect unexpected findings during any physical examination. In comparison,
61 however, encountering potential evidence of a previously unknown abnormality by imaging has
62 special implications because the diagnosis may be much more definitive. IF are often considered
63 not to be a major concern, but if improperly handled in specific circumstances they could put an
64 entire educational program at risk. Without proper planning, unwise choices regarding their
65 handling can create stressful situations not only for the subject scanned and for the student, but
66 also for the medical school.

67 Educational programs that incorporate training in using ultrasound as a bedside diagnostic
68 imaging tool need to anticipate the possibility of IF. Each academic institution should have a
69 standard approach in place. We review the prevalence of IF, discuss relevant ethical and legal
70 factors, and suggest practical approaches for how they can be managed. The thrust of this article
71 concerns medical students but many principles can be adapted for students from other
72 disciplines or derived from existing protocols used in sonography training programs.

2 DEFINITIONS

An incidental finding made by a medical student during an ultrasound imaging examination is the unintended and unexpected discovery of an abnormality that may be clinically significant. It may be made on a patient, a healthy volunteer, or a peer. The term “educational ultrasound examination” encompasses all ultrasound examinations performed by medical students as well as other ultrasound students. It covers situations in which medical students scan while supervised directly by an educator, and those in which the responsible teacher is absent but available for a later consultation.

3 PREVALENCE OF INCIDENTAL FINDINGS

To our knowledge, no large or formal analyses of IF detected by medical or other healthcare professional students have yet been performed. Case series have been reported (Fox, et al. 2011) (Siegel-Richman and Kendall 2017), and examples for sonographer students are given in an excellent report from the Society of Diagnostic Medical Sonography (SDMS) in the USA (Michael, et al. 2019). Until more systematic information has been collected and reported, any conclusions about the expected prevalence of IF during educational ultrasound examinations must be provisional. Nonetheless it is predictable that some IF will be identified – either because they are potentially serious (which will be rare) or because they are lesions of unknown significance (which may be quite common). In each case more detailed assessment and appropriate management or reassurance will be needed. Both false positive and false negative interpretations will occur (Wilkinson, et al. 2016, Woodward and Toms 2009) so it is essential that an educational examination is never used as a substitute for a formal clinical investigation.

4 PRINCIPLES FOR MANAGING INCIDENTAL FINDINGS

95 When a medical student is scanning in the presence of an supervisor, whether a physician or
96 another designated ultrasound educator, managing any IF will become the immediate
97 responsibility of the supervisor. Similar processes should be followed if the medical student is
98 scanning alone and the supervisor is available for consultation afterwards. Whenever IF are
99 suspected or observed, the student and the supervisor have an ethical responsibility to arrange
100 for appropriate further evaluation. The only exception would be if the subject has specified that
101 they do not wish to be informed about any IF (Siegel-Richman and Kendall 2017), although that
102 would be unusual. In one study the proportion of volunteers who requested that no action should
103 be taken in case of IF being found, was 3% (Illes, et al. 2006). If the designated supervisor is not
104 a clinician, then a named clinical colleague should be available to advise on further investigation
105 and management or to propose suitable referral.

106 Educators should neither discount IF inappropriately nor cause unwarranted alarm. They
107 should adhere to established ethical principles of transparency, confidentiality, and consent.
108 Patients or subjects in whom IF are discovered by medical students should be protected by local
109 policies that reflect the availability of diagnostic services and that minimize any personal financial
110 burden arising as a consequence of their participation.

111 ***4.1 Transparency***

112 The default policy should be that all subjects – whether volunteer, patient, or peer – should
113 be kept fully informed about the proposed educational examination. The more students,
114 instructors, and scanning subjects are informed of what to expect if an IF is found, the less likely
115 it will be that such a finding will evoke a strong emotional response or negative reaction.
116 Informing participants about IF should always include planning and organising the next steps and
117 follow-up.

118 Transparency of processes could also be important if any legal issues arise as a consequence
119 of an IF that has not been diagnosed or managed appropriately. It is advisable for educators to
120 comply with standards regarding documentation, thereby confirming in case of enquiry that
121 established procedures have been followed.

122 Ultrasound examinations are considered to be harmless but inappropriate discussion may
123 cause psychological harm and overdiagnosis can also have adverse consequences (Tarique, et al.
124 2018). An unresolved question is whether or not all IF – including even trivial or minor findings
125 that have no clinical consequences – need to be discussed with the subject.

126 ***4.2 Confidentiality***

127 Ideally, the same rules with regards to confidentiality of data about personal health should be
128 followed in an educational setting as in any clinical setting, but that can be difficult to achieve in
129 practice when an IF is found during a course.

130 If further assessment of the IF is indicated, then it will be necessary to inform other healthcare
131 professionals. In routine clinical practice consent to refer a patient can be assumed, but in the
132 context of an educational examination it should be explicit. In the European Union permission to
133 share personal data and images should be documented in order to confirm compliance with the
134 provisions of the General Data Protection Regulation. Similar rules exist in the USA Health
135 Insurance Portability and Accountability Act [HIPAA regulations]. Otherwise, the principle should
136 be that personal information is shared only if it is essential for the wellbeing of the subject, or if
137 consent has been given for some information to be shared with the students participating in the
138 course.

139 Some authors have recommended that an IF should be ignored initially, for example by
140 switching to image another organ, and then discussed later in a more private setting (Siegel-
141 Richman and Kendall 2017). If an IF may be serious, then it would be wise for the instructor to

142 refrain from emphasizing the abnormality to a group of students. Otherwise, the detection of an
143 IF may provide a useful opportunity for learning, which would be appropriate as long as during
144 preparation for the course the subject has been informed that the images will be discussed and
145 the students have been asked to use language that will not cause anxiety.

146 ***4.3 Informed consent***

147 The subject's autonomy should always be respected. Of course, participation as a model in an
148 educational ultrasound course is voluntary and the subject can quit at any moment without giving
149 a reason (Tarique, et al. 2018). No pressure should be exerted on a student as some will prefer
150 not to volunteer (Rees, et al. 2009). Fewer medical students agree to act as subjects for peer
151 scanning than report that they will be willing to perform the examinations (Chen, et al. 2011). It
152 may be useful (for the volunteer as well as the student) to briefly explain bioeffects of ultrasound
153 and the prudent use of ultrasound, as well as the ALARA (As Low As Reasonably Achievable)
154 principle.

155 It has been suggested that that volunteers at ultrasound courses should be asked for written
156 informed consent (Woodward and Toms 2009). Above all, the responsible educator should be
157 actively communicating the necessary information for models (volunteers or students) to
158 consent. This information may slightly vary depending on the course setting. After reading
159 through the complete information, models can then consent rather passively via a verbal or
160 actively via a written statement. Written information should cover the following common
161 themes:

162 • the type of examination that will be performed
163 • the possibility of incidental findings, although uncommon
164 • the process that will be followed in the case of an incidental finding
165 • permission to save images (either identifiable or anonymized) if a further opinion will be

requested

Volunteers must be informed that an ultrasound scan performed during an educational class cannot replace a standard diagnostic scan. This point should be emphasized and the volunteers should understand that false identification of rare or critical findings is not unusual when students are learning how to scan, and that typical follow-up of a suspected IF may include repetition of the scan by an experienced investigator and/or a consultation with the responsible physician. They may want to decide if they would like to be informed about any IF that are detected, or else define particular situations in which they would or would not want to know (Siegel-Richman and Kendall 2017). The information that is given before obtaining consent should refer to the fact that if IF are identified, there is no legal ramification, nor is there cause for legal action if a pathological finding is demonstrated during a clinical examination at a later date and some images exist from the educational session where the pathology was already present on those images.

Suggestions for key statements to be included in the information for volunteer subjects are given in the supplement.

5 RECOMMENDATIONS FOR MANAGING INCIDENTAL FINDINGS

Previous reports all concur that each medical school needs to establish and publish a policy to ensure that educational scans are conducted safely. A framework should be implemented to ensure that IF are managed efficiently (Figure 1). Policies should be available for review and distributed to students and faculty, and on request also to scanning subjects. This will enable educators to handle all IF in a systematic manner. An analogous policy may already have been created for IF found on physical examination; if not, then this exercise may be an opportunity to establish a broader policy within the medical school. Legal advice may be helpful.

189 Optimally, a well-structured policy will remove the subjective component of decisions made
190 by the instructor regarding how to treat any potential IF, which is a major risk. Established policies
191 that comply with locally and regionally accepted rules and laws are protective to individuals and
192 institutions. Similarly, in situations where educators may be reluctant to burden primary care
193 physicians or others who might be responsible for following up or further investigating any IF,
194 established policies will likely remove some of that reluctance and further protect the individual
195 educator from criticism. The most important objective of the policy, however, should be to
196 ensure that volunteers receive appropriate and timely care.

197 We recommend in particular the SDMS report (Michael, et al. 2019) and the suggestions made
198 by Siegel-Richman et al. (Siegel-Richman and Kendall 2017) and by Fox et al. (Fox, et al. 2011).
199 Other authors have also addressed how to manage IF detected during ultrasound scans
200 performed for educational purposes (Ahn, et al. 2014, Blickendorf, et al. 2014, Griksaitis, et al.
201 2014). Although the comments in this paper refer mostly to medical students, they are relevant
202 also for educational ultrasound examinations performed by other healthcare students. Key
203 components of our recommendations are listed at the end of the manuscript.

204 ***5.1 Settings***

205 Medical students may perform educational ultrasound scans within the confines of a
206 university or medical school, in its associated hospital(s), or in other settings such as community
207 clinics or physicians' offices. The most important consideration is whether the medical student is
208 scanning independently and without immediate access to a supervisor (unsupervised), or with a
209 supervisor who is present and/or available to review images in real time (supervised) (Table 1).
210 The following scenarios can be envisaged:

211 • Students scanning students, with an instructor (supervisor) present
212 • Students scanning students, unsupervised

213 • Students scanning patients, with an instructor present

214 • Students scanning patients, unsupervised

215 • Students scanning volunteers (presumed to be healthy), with an instructor present

216 • Students scanning volunteers, unsupervised.

217

218 Students might also scan themselves or their friends or family members, unsupervised, if they
219 have unlimited access to a personal handheld device.

220 Policies for dealing with IF should be developed that cover each of these situations. Ideally,
221 the instructor should have the skills to review any potential IF in real time, so that questions can
222 be resolved with the subject still present. Rescans will be necessary whenever supervised scans
223 have been performed without saving images. When images have been saved from an
224 unsupervised scan, then the type of IF will determine what follow-up should be arranged.

225 Another, related context is when a teacher scans a student or volunteer during a lecture or
226 live demonstration of anatomy or physiology, or scans a patient during a case discussion. The
227 same responsibility for maintenance of confidentiality, and the same duty of care will apply. It
228 needs to be clarified in the informed consent document that the exam has no legal significance
229 and that the images or report have no clinical relevance.

230 ***5.2 Preparation of instructors***

231 Instructors responsible for facilitating ultrasound training sessions might be peer tutors
232 (senior medical students who have completed their training), experienced physicians,
233 radiologists, sonographers, anatomists, or professionals from other backgrounds. They should all
234 leave behind their normal clinical roles and act instead as educators (Siegel-Richman and Kendall
235 2017).

236 In order to handle IF in every situation with the same care and professionalism, a standard
237 approach should be followed. Instructors need to be aware of the local policy for handling IF. An
238 information leaflet and/or flowchart should be available to instructors during classes, giving
239 contact information for the person responsible for the course, and advice on whom to contact
240 for a further opinion or for urgent medical advice.

241 ***5.3 Preparation of students***

242 Students will participate in ultrasound imaging courses as scanners and as observers. In either
243 capacity, they should appreciate that IF although uncommon will be detected from time to time.
244 So that they do not blurt out involuntarily when they see an abnormal finding, whether real or
245 not, students should be informed how they can notify the supervisor about a possible IF without
246 giving worrying signals to the subject. A request to describe or identify an area on the screen is
247 more likely to go unnoticed than comments that leave much room for interpretation. Some
248 instructors encourage the use of phrases such as "I can't seem to define this area well, can you
249 help please?" which can serve as code to indicate to the instructor and other students that there
250 may be an IF, while continuing to project calm composure.
251 A scan may present the opportunity to discuss normal anatomical structures and variations,
252 but open speculation about an extensive differential diagnosis of an IF should be avoided in the
253 presence of the subject. Usually, it will be helpful to avoid long silences. When a student has
254 volunteered as a subject it may be appropriate to defer any discussion of an IF until after the
255 examination has been completed and it can be held privately.

256 ***5.4 Interpretation and investigation of incidental findings***

257 Each IF needs to be verified by a qualified physician or sonographer, to determine its
258 significance and decide if no action, more investigation, referral, treatment, or surveillance is

259 indicated. Categorizing findings by their level of risk to the subject or patient is important. For
260 example, the degree and urgency of the response would be markedly different for the
261 demonstration of some atheroma, the incidental discovery of a large pericardial effusion, or the
262 detection of a 3.5 cm abdominal aortic aneurysm. Decision algorithms are proposed in the Figure
263 1.

264 If an interesting incidental finding is discovered during a scanning session by an instructor it is
265 tempting to demonstrate it to the entire class, but the privacy and healthcare needs of the
266 volunteer will dictate what is appropriate. A benign finding like a cyst may be discussed during
267 the educational session, but any clinically significant IF should be discussed with the subject after
268 the session has ended, to allow proper time and confidentiality.

269 If the instructor verifies a new abnormal finding during a supervised scanning session, such as
270 a renal lesion, thyroid mass, or echocardiographic abnormality, that has been detected by the
271 student, then he or she should moderate any discussion and limit stress for the subject. How the
272 event is handled will be a learning opportunity for other students and may affect their willingness
273 to participate in similar scanning sessions in the future and/or act as a scanning model
274 themselves.

275 If an incidental finding is benign, already known, or has no immediate or short-term clinical
276 relevance, it will be reasonable to ask the subject for permission to invite other students to repeat
277 the scan. If it is potentially serious, then discussion with the subject in the presence of the
278 students should be limited. Discovery of an IF may be distressing for a patient or volunteer, and
279 clinically significant or potentially serious IF can always be discussed separately with students at
280 the end of a scanning session after the subject has been informed more privately on the
281 incidental finding and its work-up. That will allow an open discussion of the differential diagnosis,
282 which will put the IF in a proper clinical context, review the certainty of the finding, and consider

283 what actions would be appropriate as the next step.

284 It has been suggested that training medical students in ultrasound skills may lead to missing
285 diagnoses as a result of (mis)placing greater faith in “high tech” information (Feilchenfeld, et al.
286 2017). Thus, when educational scans and IF are reviewed and interpreted, it will be valuable to
287 discuss the possibility of missed diagnoses, wrong diagnoses, and overdiagnosis.

288 Comprehensive reviews of IF in different organs and systems are being published in a series
289 of position papers by the World Federation for Ultrasound in Medicine and Biology (Bialek, et al.
290 2021, Dietrich, et al. 2020, Dietrich, et al. 2020, Lewicki, et al. 2021, Trenker, et al. 2021) to give
291 recommendations on how to handle particular IF.

292 ***5.5 Documentation and review of images***

293 As for any finding during any ultrasound examination, an IF should be documented in two
294 different imaging planes, if possible, with cine loops. This may be particularly helpful for an
295 experienced reviewer to differentiate between an artifact and an incidentally found lesion
296 (Dietrich, et al. 2020, Dietrich, et al. 2020, Schmidt, et al. 2016).

297 The amount of patient identifying information that can be saved and retained by the student
298 will also vary, depending on institutional policies and government regulations. Images should be
299 stored in a secure network (Varsou 2019). Confidentiality should be maintained but it is advisable
300 with consent to store individual details with images when a significant incidental finding is
301 suspected. It is critical for IF to be reviewed, and important that a quality assurance mechanism
302 is established and used to provide educational feedback to the medical student.

303 The possibility of a student’s failure to capture images or video, or of such evidence being lost,
304 or of a lack of technical capacity, is not remote. The most challenging scenario is when no images
305 were saved, the scanning activity was unsupervised, and the student suspected an IF. Without
306 visual documentation of potential findings, the discussion becomes more theoretical and making

307 a determination may be difficult. In this case, the supervisor should be alerted by the student
308 and a concerted effort should be made to have the subject scheduled for a follow-up evaluation.

309 6 CONCLUSIONS

310 This document summarizes the background and provides a framework for establishing and
311 implementing a standard policy for dealing with IF observed in volunteer subjects by medical
312 students during training courses in ultrasound diagnostic scanning. It describes numerous factors
313 that should be considered by medical schools, which provide educational programs using
314 ultrasound, so that they can implement effective policies for responding to IF that are
315 proportionate to the risks.

316

1 RECOMMENDATIONS

Summary of Recommendations

- Educators offering a program for medical students to learn how to perform ultrasound examinations should establish a written policy concerning how to handle the discovery of incidental findings.
- An approved supervisor for each session should be named.
- The approved supervisor will be responsible for managing incidental findings.
- If the supervisor is non-clinical, then a named clinician should be available for advice.
- Processes should be similar whether students scan in a supervised context or without a supervisor immediately available.

Written information for any model participating in teaching sessions

- Should state the type of examination, the possibility of incidental findings, the process followed in case of incidental findings and the permission to save images (depending on local regulations)
- States that educational examinations do not equivale diagnostic examinations
- Should be sent in written form to models as must-read

Incidental findings in patients participating in teaching sessions

- Students should be prepared concerning the type of language that is appropriate.
- Patients should give informed consent (verbal or written) to being willingly examined in an educational setting.
- Patients should be told that incidental findings may be observed and discussed – and that the observer can clarify any discussions in private after the examination.

Incidental findings in healthy volunteers participating in teaching sessions

- All volunteers should be carefully informed and give at least verbal informed consent.
- Images should be stored only if specific consent has been given.

Incidental findings in students acting as volunteer subjects for scanning

- No pressure should be exerted on students to volunteer for peer scanning sessions.
- Normal anatomical variations may be discussed but incidental findings should not be discussed with the subject in front of his or her peers.

347 # 2 TABLE

348 **Table 1 Comparison of workflows during supervised and unsupervised scanning.**

Supervised	Unsupervised
Medical student scans subject with direct supervision available	Medical student and supervisor do not scan together
Supervisor and MS review images when subject is still present	Images are reviewed by supervisor when subject is no longer present
All identified IF are documented and discussed with the subject	Supervisor and/or MS contacts the subject to inform about IF
Subject receives instructions for follow-up and management of IF	Supervisor and/or MS contacts the subject and/or primary care doctor about arrangements for follow-up

349 MS Medical student; IF incidental findings

350

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