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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.

1 INTRODUCTION

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

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

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

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

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

4.1 Transparency

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

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

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

4.2 Confidentiality

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

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

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

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

4.3 Informed consent

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

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

- the type of examination that will be performed
- the possibility of incidental findings, although uncommon
- the process that will be followed in the case of an incidental finding
- 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.

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

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

5.1 Settings

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

- Students scanning students, with an instructor (supervisor) present
- Students scanning students, unsupervised

- Students scanning patients, with an instructor present
- Students scanning patients, unsupervised
- Students scanning volunteers (presumed to be healthy), with an instructor present
- Students scanning volunteers, unsupervised.

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

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

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

5.2 Preparation of instructors

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

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

5.3 Preparation of students

Students will participate in ultrasound imaging courses as scanners and as observers. In either capacity, they should appreciate that IF although uncommon will be detected from time to time. So that they do not blurt out involuntarily when they see an abnormal finding, whether real or not, students should be informed how they can notify the supervisor about a possible IF without giving worrying signals to the subject. A request to describe or identify an area on the screen is more likely to go unnoticed than comments that leave much room for interpretation. Some instructors encourage the use of phrases such as “I can’t seem to define this area well, can you help please?” which can serve as code to indicate to the instructor and other students that there may be an IF, while continuing to project calm composure.

A scan may present the opportunity to discuss normal anatomical structures and variations, but open speculation about an extensive differential diagnosis of an IF should be avoided in the presence of the subject. Usually, it will be helpful to avoid long silences. When a student has volunteered as a subject it may be appropriate to defer any discussion of an IF until after the examination has been completed and it can be held privately.

5.4 Interpretation and investigation of incidental findings

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

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

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

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

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

what actions would be appropriate as the next step.

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

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

5.5 Documentation and review of images

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

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

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

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

6 CONCLUSIONS

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

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.

2 TABLE

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

MS Medical student; IF incidental findings

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