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Title: Medical Curriculum: How do we Manage Incidental Findings in Educational Settings?

Short Title: Management of Incidental Findings

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36 **Abstract**

37 Medical curricula encompass two practical-based teaching categories with likelihood of
38 identifying incidental findings (unexpected and previously undiagnosed findings with
39 potential health implications) in live models for demonstration purposes. One relates to
40 clinical skills involving peers and simulated or volunteer patients. The other involves
41 laboratory sessions, with live models, for the purposes of demonstrating scientific principles.
42 As educationalists, it is our professional and ethical duty to have guidance on how to manage
43 incidental findings. In this commentary, we have outlined our best practice guidelines
44 formalised as a written policy exploring consent, debriefing, and the teachers' role. Our aim
45 was to develop an 'easy-to-follow' standardised mechanism.

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47 **Keywords:** Incidental findings; teaching; education; clinical skills; medicine.

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50 **Background**

51 Regulatory bodies, including the General Medical Council (GMC), ensure medical curricula
52 are standardised with the aim of having graduates who are competent doctors. As such, there
53 are certain clinical skills medical students must learn, practise, and demonstrate while
54 undertaking their studies. These include physical examinations and core practical procedures.
55 Initially, students practise within a ‘safe’ simulated teaching environment that may entail peer
56 physical examinations and/or examinations of simulated patients (individuals emulating
57 medical conditions or participating as anatomical live models). Once students have developed
58 a solid scientific and clinical foundation, they practise with volunteer patients (individuals
59 with pathologies that typically are related, or may be rarely unrelated, to the physical
60 examination/practical procedure undertaken within educational settings). Depending on the
61 curriculum, medical students may also participate as volunteers in practical sessions that are
62 not clinical in nature (pre- and post-exercise heart rate measurement in science labs). Despite
63 not being clinical skills per se, some of these practicals examine analogous responses that,
64 whilst educational in utility, may be fundamentally or conceptually linked to diagnostic
65 procedures and hence uncover a potential incidental finding.

66

67 During practical-based teaching, the serendipitous discovery of a potential incidental finding
68 in individuals, who participate in such sessions as live models for demonstration purposes, is
69 possible. Extrapolating from the existing literature on incidental findings in research
70 involving human subjects, these are defined as “a finding concerning an individual research
71 participant that has potential health or reproductive importance and is discovered in the
72 course of conducting research but is beyond the aims of the study” [1:219]. In the broader
73 sense, incidental findings also encompass clinically insignificant and false positive findings
74 especially as the artefactual nature of the latter is only revealed following further assessment
75 [2]. In educational settings, an incidental finding can then be defined as an unexpected and
76 previously undiagnosed finding with potential health implications [3] identified in an
77 individual student or simulated/volunteer patient while participating in a practical-based
78 session.

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80 Current literature on the identification and management of incidental findings in educational
81 settings, especially those involving medical curricula, is scarce. A retrospective survey

revealed an estimated incidence of 1.5% per year in medical students, for all teaching sessions not restricted to clinical skills, with the majority of such incidents unsurprisingly occurring during practicals and clinical sessions [4]. A prospective study noted a more reflective incidence range of 0.23% to 1.05% per year during early clinical skills teaching [5]. Even though these figures may seem reasonably low, they should be critically interpreted and not let us – educationalists – be falsely reassured as they still highlight the fact that incidental findings do get discovered during practical-based teaching.

As educationalists, it is our professional and ethical duty to have mechanisms in place for the management of incidental findings allowing for standardisation and preventing any undue distress to implicated individuals by potential variability in practice. With the above information in mind and the emerging advice from published literature on the implementation of relevant processes [4-6], we have produced best practice guidelines as a written policy [7] discussing consent processes and face-to-face debriefing sessions that are described below along with our planning and thinking process.

Planning Phase

Our planning stage included identification of existing publications, advice from internal and external teaching stakeholders, discussion with the University risk advisor to ensure compatibility with insurance/liability policies, and ultimately submitting all written documentation for independent review to the School of Medicine Ethics committee (approval code: MD13175). This process flushed out important logistical and ethical concerns that we addressed within the guidelines that show what our and other institutions have adopted as best practise but may have not necessarily been formalised as a written policy, which was our ultimate goal.

We aimed to answer the following three questions relating to ethical considerations in the context of managing incidental findings in educational settings of medical curricula:

Question 1. What constitutes informed consent?

Question 2. What constitutes a debrief session?

Question 3. What is our role as teachers?

Local Approach

Our medical students sign a School Agreement annually confirming their participation, as examiners conducting physical examinations and as live peer models, in clinical skills sessions. At a high level, this form can be viewed as written consent. However, due to the uniqueness of each session, for the above to be truly reflective of informed consent, the purpose and description of any teaching that may uncover potential incidental findings is provided to students in advance so that they can raise specific concerns (personal, cultural, health-related) that would prevent them from partaking in clinical examination training as live models. This empowers students to forewarn their tutors allowing for adjustments without compromising their clinical training. The same process applies to laboratory sessions with the caveat that students can also opt-out on the grounds of pre-existing health conditions and/or being self-conscious. In all cases, verbal informed consent is obtained by the lead teacher prior to acting as live peer models (*Question 1*).

Simulated and volunteer patients participate in teaching sessions with verbal informed consent. In our institution, volunteer patients do not partake in physical examinations whereas simulated patients act as live models for the practice of clinical skills and physical examinations. Simulated patients are informed verbally of the possibility of incidental findings before they first sign their University casual/bankworker contract and annually when these are renewed (*Question 1*). Tutors examine patients in advance of the sessions to minimise the risk of a potential incidental finding being uncovered during a class/assessment (*Question 3*).

For all relevant practical and laboratory sessions, it is emphasised to all participants (students and simulated patients) that these carry no diagnostic value and, instead, they are used purely for educational purposes in terms of consolidating scientific knowledge and linking this to related clinical applications (*Question 3*). It is also stated that there may be a possibility of identifying an incidental finding and in such cases appropriate guidance will be offered to individual students/patients.

If an incidental finding is identified, the following process is followed. The individual is invited to attend a face-to-face discussion, within 24 hours, conducted by the respective teaching tutor. This allows for effective communication of the next steps and mitigates any immediate fears relating to the potential incidental finding without providing a false sense of security. Within this discussion, the individual is advised to arrange an appointment with

their general practitioner and a template-specific letter is provided for the individual to hand to their general practitioner. This letter standardises the written information, while also concluding the debrief (*Question 2*). In terms of record keeping, the student's name and matriculation or the patients' name along with the date of the face-to-face discussion are kept in a secure file for audit purposes. This file does not contain any medical information or any details regarding to the potential incidental finding. It is of paramount importance that confidentiality and privacy is maintained at all times during the above discussions and, of course, afterwards. As "the goal of research is to seek generalisable knowledge, not to provide health information to individuals" [1:236], our capacity within a pedagogical framework is also not to diagnose. For this reason, the policy is explicit in highlighting that no staff, either clinical or non-clinical, should make a diagnosis in their capacity as educators. It is vital that an appropriately qualified and suitably trained healthcare professional, out-with the higher education institution, decides whether a finding is of significance to an individual's health or not (*Question 3*). If a student is examining another student or volunteer and notices a potential incidental finding, the same process is followed with the information communicated to the teaching tutor by the individual noting the potential incidental finding.

Summary of Ethical Considerations

A summary of the main ethical considerations from our local approach is outlined below:

- Ensure students/patients are given sufficient information, including details on the practical-based procedure/examination and risks, prior to a teaching/assessment session so that they can make an informed decision about taking part or not;
- Obtain verbal informed consent prior to relevant practical or laboratory sessions (we have opted for verbal informed consent, as the students sign the School Agreement and simulated patients hold a University casual/bankworker contract, both of which can be viewed as written consent at a high level);
- Have a standardised mechanism in place for the management of potential incidental findings;
- Maintain confidentiality at all points regarding the potential incidental finding by acting on a need-to-know basis;
- Provide no diagnosis at any point as this is out-with our remit as higher education practitioners.

Concluding Remarks

Having a standardised mechanism for the management of potential incidental findings is of paramount importance. In our case, this has been formalised as a written policy [7] since October 2017. Annual review of the incidence data, in the form of quality assurance audits, has allowed us to identify and implement sensible changes to relevant teaching sessions. On-going training for any tutor, who is involved in sessions in which a potential incidental finding may arise, is also essential. Going forward, it would be valuable to collect multicentre prospective data on the incidence of incidental findings in higher education settings to get a more representative reflection of their occurrence that will then better guide us in terms of what consensus recommendations are needed in this area.

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Compliance with Ethical Standards

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Informed Consent: NA.

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