1	Title: Medical Curriculum: How do we Manage Incidental Findings in Educational Settings?	
2	Short Title. Management of Incidental Findings	
л Л	Short The. Management of meldental Thomgs	
5	Authors: Ourania Varsou. ^{1,}	^{2*} Alun Hughes. ² Robert Humphreys ^{2,} Anita Laidlaw ²
6		
7	Affiliations	
8	1. Anatomy Facility, School of Life Sciences, University of Glasgow, Scotland UK	
9	2. School of Medicine, University of St Andrews, Scotland UK	
10		
11	*Corresponding Details:	Ourania Varsou
12		School of Life Sciences
13		Anatomy Facility
14		Thomson Building
15		University Avenue
16		Glasgow G12 8QQ
17		Scotland UK
18		Tel: +44 (0)141 330 7726
19		E-mail: <u>o.varsou@googlemail.com</u>
20		ORCID: 0000-0002-7789-1185
21		
22		
23	Notes on Contributors	
24	Ourania Varsou, BSc, MBChB, PgCert, PhD, AfHEA, RET Fellow, is a Lecturer in Anatomy	
25	at the School of Life Sciences, University of Glasgow, Scotland UK. Her interests include the	
26	integration of imaging in anatomy teaching and scholarship of teaching and learning.	
27	Robert Humphreys, is a Lecturer at the School of Medicine, University of St Andrews	
28	Scotland UK.	
29	Alun Hughes, is a Senior Lecturer and Director of Teaching at the School of Medicine	
30	University of St Andrews, Scotland UK.	
31	Anita Laidlaw, PhD is a Senior Lecturer and Head of the Division of Education in the Schoo	
32	of Medicine, University of St Andrews, Scotland UK. Her interests include student and health	
33	professional wellbeing.	
34		

35 Abstract

36 Medical curricula encompass two practical-based teaching categories with likelihood of 37 identifying incidental findings (unexpected and previously undiagnosed findings with potential health implications) in live models for demonstration purposes. One relates to clinical skills 38 39 involving peers and simulated or volunteer patients. The other involves laboratory sessions, with live models, for the purposes of demonstrating scientific principles. As educationalists, it 40 41 is our professional and ethical duty to have guidance on how to manage incidental findings. In this commentary, we have outlined our best practice guidelines formalised as a written policy 42 exploring consent, debriefing, and the teachers' role. Our aim was to develop an 'easy-to-43 follow' standardised mechanism. 44 45 Keywords: Incidental findings; teaching; education; clinical skills; medicine. 46

- 47
- 48

49 Background

Regulatory bodies, including the General Medical Council (GMC), ensure medical curricula 50 are standardised with the aim of having graduates who are competent doctors. As such, there 51 are certain clinical skills medical students must learn, practise, and demonstrate while 52 undertaking their studies. These include physical examinations and core practical procedures. 53 Initially, students practise within a 'safe' simulated teaching environment that may entail peer 54 physical examinations and/or examinations of simulated patients (individuals emulating 55 medical conditions or participating as anatomical live models). Once students have developed 56 57 a solid scientific and clinical foundation, they practise with volunteer patients (individuals with pathologies that typically are related, or may be rarely unrelated, to the physical 58 examination/practical procedure undertaken within educational settings). Depending on the 59 curriculum, medical students may also participate as volunteers in practical sessions that are 60 not clinical in nature (pre- and post-exercise heart rate measurement in science labs). Despite 61 not being clinical skills per se, some of these practicals examine analogous responses that, 62 whilst educational in utility, may be fundamentally or conceptually linked to diagnostic 63 procedures and hence uncover a potential incidental finding. 64

65

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

77

Current literature on the identification and management of incidental findings in educational 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.

87

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.

95

96 Planning Phase

Our planning stage included identification of existing publications, advice from internal and 97 external teaching stakeholders, discussion with the University risk advisor to ensure 98 compatibility with insurance/liability policies, and ultimately submitting all written 99 100 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 101 102 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 103 104 ultimate goal.

105

106 We aimed to answer the following three questions relating to ethical considerations in the 107 context of managing incidental findings in educational settings of medical curricula:

- 108 *Question 1.* What constitutes informed consent?
 109 *Question 2.* What constitutes a debrief session?
- *Question 2.* What constitutes a debiter session
- 110 *Question 3.* What is our role as teachers?
- 111

112 Local Approach

113 Our medical students sign a School Agreement annually confirming their participation, as 114 examiners conducting physical examinations and as live peer models, in clinical skills sessions. 115 At a high level, this form can be viewed as written consent. However, due to the uniqueness of 116 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 117 students in advance so that they can raise specific concerns (personal, cultural, health-related) 118 that would prevent them from partaking in clinical examination training as live models. This 119 empowers students to forewarn their tutors allowing for adjustments without compromising 120 their clinical training. The same process applies to laboratory sessions with the caveat that 121 students can also opt-out on the grounds of pre-existing health conditions and/or being self-122 conscious. In all cases, verbal informed consent is obtained by the lead teacher prior to acting 123 as live peer models (*Question 1*). 124

125

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*).

133

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.

140

If an incidental finding is identified, the following process is followed. The individual is invited 141 to attend a face-to-face discussion, within 24 hours, conducted by the respective teaching tutor. 142 This allows for effective communication of the next steps and mitigates any immediate fears 143 relating to the potential incidental finding without providing a false sense of security. Within 144 this discussion, the individual is advised to arrange an appointment with their general 145 practitioner and a template-specific letter is provided for the individual to hand to their general 146 practitioner. This letter standardises the written information, while also concluding the debrief 147 (*Question 2*). In terms of record keeping, the student's name and matriculation or the patients' 148 name along with the date of the face-to-face discussion are kept in a secure file for audit 149 purposes. This file does not contain any medical information or any details regarding to the 150

151 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 152 of research is to seek generalisable knowledge, not to provide health information to 153 individuals" [1:236], our capacity within a pedagogical framework is also not to diagnose. For 154 this reason, the policy is explicit in highlighting that no staff, either clinical or non-clinical, 155 should make a diagnosis in their capacity as educators. It is vital that an appropriately qualified 156 and suitably trained healthcare professional, out-with the higher education institution, decides 157 whether a finding is of significance to an individual's health or not (Question 3). If a student is 158 159 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 160 noting the potential incidental finding. 161

162

163 Summary of ethical considerations

164 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.

178

179 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.

189

190 Acknowledgements

191 The authors would like to acknowledge the School of Medicine Ethics Committee for 192 reviewing the best practice guidelines.

193

194 Compliance with Ethical Standards

- 195 Funding: NA.
- 196 Conflict of Interest: The authors report no conflicts of interest. The authors alone are 197 responsible for the content and writing of this article.
- Ethical Approval: Ethical approval was granted by the University of St Andrews School of
 Medicine Ethics Committee (approval code: MD13175).
- 200 Informed Consent: NA.
- 201

202 **References**

- Wolf SM, Lawrenz FP, Nelson CA, Kahn JP, Cho MK, Clayton EW, Fletcher JG,
 Georgieff MK, Hammerschmidt D, Hudson K, et al. Managing incidental findings in
 human subjects research: analysis and recommendations. J Law Med Ethics.
 2008;36(2):219–248.
- Schmücker R. Part I: introduction. Incidental findings: definition of the concept. In:
 Weckbach S, editor. Incidental Radiological Findings. Switzerland: Springer
 International Publishing; 2017. pp. 3–7.
- 3. Varsou O. Chapter 1: The use of ultrasound in educational settings: what should weconsider when implementing this technique for visualisation of anatomical structures?.
- In: Rea, PM, Editor. Biomedical Visualisation Volume 3 (1156). Series: Advances in
 Experimental Medicine and Biology. Switzerland: Springer Nature; 2019. pp. 1–11.
- ISBN 978-3-030-19384-3. doi: 10.1007/978-3-030-19385-0_1.
- 4. Pols J, Boendermaker PM and Muntinghe H. Incidence of and sequels to medical
 problems discovered in medical students during study-related activities. Medical
 Education. 2003;37(10):889–894.

- 5. Wearn A, Nakatsuji M and Bhoopatkar H. Abnormal findings in peers during skills
 learning. The Clinical Teacher. 2017;14(1):40–44.
- 6. Boendermaker PM, Pols J and Scherpbier AJJA. Unexpected pathological findings in
 skills training and assessing skills. Medical Teacher. 1999;21(6): 586–587.
- 7. MedHandbook. Management of incidental findings in BSc (hons) medicine practical
 sessions [online guidelines]. 2020. Available from: <u>http://medhandbook.st-</u>
 andrews.ac.uk/wp-content/uploads/sites/27/2017/10/UG-teaching_management-of-
- 225 <u>teaching_incidental-findings-BSc-Hons.pdf</u> [accessed 15 Jun 2020].