

THE HIGH COURT

[2023] IEHC 708

[Record No. 2021/3192P]

BETWEEN

T.M.

PLAINTIFF

AND

HEALTH SERVICE EXECUTIVE

DEFENDANT

AND

MEDLAB PATHOLOGY LIMITED

THIRD PARTY

RULING of Ms Justice Reynolds delivered on the 1st day of November, 2023

Preamble

- 1.** This ruling concerns the revisiting of the Protocol for Release Of CervicalCheck Cytology Slides (“the **Protocol**”).
- 2.** The first version of the Protocol was issued in June 2018, following engagement between the National Screening Service (“**NSS**”) and a number of stakeholders.
- 3.** The primary purpose of the Protocol was to facilitate the timely and secure transmission of slides from the repositories in which they were stored on behalf of the **NSS**, to independent experts nominated by or on behalf of individual patients.
- 4.** Given that the slides play a pivotal role in the litigation process, it was considered essential that a defined set of rules would be in place to ensure the security

and integrity of the slides, particularly in circumstances where many of the independent experts to whom slides were being sent were based outside of this jurisdiction.

5. Subsequent to the implementation of the Protocol issues arose. In particular, objection was made in relation to two specific elements:

- (i) The requirement that a plaintiff seeking access to their slides identify their expert to the HSE and the laboratory holding custody of their slides, even though those parties were (or were likely to be) defendants to the plaintiff's clinical negligence action; and
- (ii) Issues relating to the specification to be applied to digital images taken of the slides prior to their release, and a related question as to whether such images should be released to the patient or their expert at the time the physical slides were being released.

6. Mr. Justice Cross, having heard submissions on the issues from the relevant parties in the context of four specific sets of proceedings then ongoing, delivered a ruling of 20 December, 2018.

7. On foot of that ruling, a revised version of the Protocol was prepared by the NSS in January, 2019. This is the version of the Protocol presently in operation.

Concerns in relation to adherence to the Protocol

8. During the hearing of the T.M. proceedings, concerns arose in relation to the defendant's contracted laboratory's lack of adherence to the Protocol, notably as follows:

- “(i) A marking on one of the plaintiff's samples was removed from the slide without leave of court.*

- (ii) *The marking was removed by a person unqualified to so do, a legal assistant.*
- (iii) *The legal assistant had been engaged in handling cytology samples, including the plaintiff's, for the purpose of selecting and preparing sets of slides for "blind reviews" intended to be carried out in the defence of the proceedings and, was also engaged in taking the imaging required by the Protocol.*
- (iv) *Compliance with para. 8 of the Protocol and the magnification of digital imaging."*

9. The proceedings were subsequently compromised by the parties.

10. However, given the very serious issues that had arisen surrounding the handling of slides and in circumstances where the Protocol had not been revised or updated since early 2019, the court considered it prudent to revisit the terms of same with a view to putting in place a more robust set of rules. The court's paramount consideration at all times was to ensure the security and integrity of patient slides and their availability to all relevant parties at all stages of the litigation process.

11. Thereafter, a period of constructive engagement ensued with (and between) all relevant stakeholders who wished to engage in the process, culminating in a final draft of the revised Protocol which substantially amends and embellishes the existing Protocol. This is the draft to which the remaining issues presently before the court fall to be considered.

Issues for determination

12. The outstanding issues to be resolved by the court are:-

- “1. Whether the NSS and/or its Contracted Laboratories should organise (and pay for) the return-leg courier once slides have been independently reviewed by the plaintiffs’ experts, or alternatively, whether the current practice (whereby the return courier is typically organised and paid for by or on behalf of the plaintiff) should be retained.*
- 2. Whether, notwithstanding the revised Chain of Custody arrangements now proposed by the NSS through the revised protocol, existing systems by which the release of slides to experts (and the return of same) is recorded by or on behalf of the NSS should also be revised:*
- a. so as to make such information available to all relevant parties by means of “a shared Google document”, or equivalent, with all relevant parties having live/direct access to same; and,*
 - b. all relevant parties being required to update the “shared Google document” on an ongoing basis.*
- 3.*
- (a) Whether the imaging requirements should be amended to ensure that whole slide imaging is the default , rather than macroscopic and microscopic imaging, the details and quality of which were at issue in the TM case.*
 - (b) Further, whether the digital images taken by the NSS’ Contracted Laboratory before each physical slide is dispatched to a plaintiff’s independent expert should be released to the plaintiff in all cases, and without condition, at the same point as the physical slide is released or, alternatively, whether the current practice, endorsed by Mr. Justice Cross in a ruling delivered on 20 December 2018 should be*

retained, being a practice in which the digital images are retained by the Contracted Laboratory, as a failsafe, and released to a plaintiff solely in the event that a slide is lost or damaged in transit.

4. *Whether it is necessary and appropriate to include an enforcement provision, within the protocol, pursuant to which, without prejudice to such other remedies as may be available to it, and subject to the Court, the NSS would be at liberty to refuse to release (or to direct a Contracted Laboratory to release) any further or other Programme Slides to a Nominated Laboratory or Expert in the event that:*

- (a) acting reasonably, the NSs discerns a pattern of material non-compliance on the part of a Nominated Laboratory (and/or the Receiving Laboratory Official associated with such laboratory) in returning Programme Slides to Contracted Laboratories within specified time periods; and/or,*
- (b) in any case where the NSS has reasonable cause to be concerned that a Nominated Laboratory and/or Receiving Laboratory Official and/or Expert may be in default of any of their obligations under the terms of this Protocol as they relate to one or more Programme Slides.”*

Issue 1 – Organisation of return courier

13. The current practice is that the plaintiff’s legal representatives organise and pay for the return courier.
14. The issue is addressed at para. 5 of the existing Protocol:

“The slides will be returned by the requesting patient or legal representative of the patient or deceased patient to the contracted laboratory in a secure fashion within a period of not more than 30 working days (or ten working days in the context of legal proceedings that are being fast-tracked through case management in the event proceedings are issued).”

- 15.** The revised Protocol at para. 7 addresses both the receipt of patient slides at a nominated laboratory and the return of those slides. It is common case that it provides considerably greater detail and more stringent provisions than currently provided for under the existing Protocol.
- 16.** Certain stakeholders have contended that the NSS and/or the Contracted Laboratories should be responsible for organising the return of patient slides. It was argued that this would reduce the number of third parties handling slides. The NSS disputes that there should be any change to the *status quo* and contends that the proposed change would in fact increase the number of parties dealing with the slides.
- 17.** Currently there are only two parties involved in the return of the slide: the expert and the courier. Under the proposed change in approach, another party-the NSS contracted laboratory or the NSS itself- would necessarily be involved in organising the courier, thus increasing co-ordination challenges and the risk of slides being lost.
- 18.** The purpose of revisiting the Protocol is to enhance the security arrangements surrounding the handling of patient slides and reduce the risks associated with the transporting them for one laboratory to another.
- 19.** In the circumstances, I am satisfied that the proposed change not only fails to enhance those arrangements but in fact complicates them further and can only conclude that the current practice be retained.

Issue 2 – Chain of Custody record/Google document

20. It has now been conceded by all parties that “*a shared Google document*” is wholly inappropriate, having regard to GDPR and other insurmountable issues.

21. Notably, the existing Protocol makes no provision for securing Chain of Custody records. However, there is now general agreement by all stakeholders that the extensive provisions incorporated in the revised Protocol will minimise the risk of slides going missing.

Issue 3 – Imaging requirements

22. The question arises as to whether the current imaging requirements under the existing Protocol (at para. 8) should be amended to ensure that whole slide imaging is the default rather than macroscopic and microscopic imaging. A further issue in dispute is whether the digital images taken by the NSS’ contracted laboratory before each physical slide is dispatched to a plaintiff’s independent expert should be released to the plaintiff in all cases, and without condition, at the same point as the physical slide is released or, alternatively, whether the current practice should be retained, being a practise in which the digital images are retained by the contracted laboratory, as a fail-safe, and released to a plaintiff solely in the event that a slide is lost or damaged.

23. At the outset, it was conceded by all parties that the current imaging requirements should be amended to ensure that whole slide imaging is the default going forward, where available, rather than macroscopic and microscopic imaging. It is common case that whole slide imaging is superior and where available, ought to utililised.

24. The real issue in contention is whether the digital images taken by the NSS' Contracted Laboratory before each physical slide is dispatched to a plaintiff's independent expert should be released to the plaintiff in all cases at the same point as the physical slide is released, or whether the *status quo* should be retained. Under the current practise digital images are retained by the contract laboratory, as a fail-safe, and released to a plaintiff solely in the event that a slide is lost or damaged in transit.

25. As already outlined, this matter was previously ruled upon by Mr. Justice Cross resulting in the established practice of images being retained solely as a fail-safe.

26. The main reasons now advanced for directing the release of images at the outset of litigation appear to be twofold:

- (a) It would allow experts give a preliminary view on a slide without the expense and inconvenience of transporting the original slide which would be advantageous to impecunious plaintiffs.
- (b) It would reduce the likelihood of later disputes about slide quality as every party would have seen the slide at the outset.

27. There is almost universal agreement amongst stakeholders that physical slides present the best available evidence and that such evidence should be utilised in all cases where available.

28. The inherent danger in relying on digital images, however good the quality, is that it will necessarily give rise to an assessment by the plaintiff's experts upon a review that is conducted in a manner materially different to that performed by the original screener, and therefore distorting the value of the views expressed by the expert in due course in the context of the review exercise. This creates an environment

wherein the views of the plaintiff's expert are necessarily contaminated and distorted by what is observed on the digital images.

29. It has been widely acknowledged in prevailing international guidelines that the best possible evidence in the context of cervical cytology litigation has to be that which most clearly mirrors the context in which the physical slide was examined and reported ie. within the CervicalCheck programme by the original screener.

30. In all the circumstances, I see no basis for alteration to the existing provisions and am satisfied that the current practice whereby digital images are retained as a fail-safe should be maintained.

Issue 4 – Enforcement provision

31. The final matter for determination is whether, subject to the court and without prejudice to such other remedies as may be available to it, the NSS should be at liberty to refuse to release (or to refuse to direct a Contracted Laboratory to release) any further or other slides to a nominated laboratory or expert in the event that the NSS discerns a pattern of material non-compliance on their part in returning slides and/or has reasonable cause to be concerned that a laboratory and/or laboratory official and/or expert may be in default of any of their obligations under the terms of the Protocol.

32. The issue arises in circumstances where there have been persistent failures on the part of certain experts to return slides within the 30 day period prescribed for under the current regime and this has proved extremely problematic for the NSS. Accordingly, the NSS seeks the inclusion of an enforcement provision to provide it with a mechanism by which it can address the problem, in circumstances where the existing Protocol has no such procedure.

33. It is common case that because of the specialised nature of cervical pathology, a relatively small number of experts are engaged in cervical cancer negligence cases. Where experts are receiving and reviewing large numbers of slides and failing to return them in a timely fashion (and outside of the permitted time frame under the current regime), this leads to significant delays in the progress of litigation and poses potential risks to the integrity of the slides.

34. This has proved exceedingly problematic for the NSS which has expended significant resources in embarking on what have become known as “*Slide Retrieval Exercises*” with a view to ameliorating the situation, and with some limited degree of success.

35. There has been strong objection to the proposed enforcement provision in circumstances where it is argued that it is an attempt to fetter the patient’s right to access their cytology slides; would appear to give a unilateral power to the NSS to effectively veto a plaintiff’s chosen expert witness and amounts to an infringement of the plaintiff’s constitutional rights.

36. I accept the concerns raised by the NSS as to the extent of the problem to date. However, I am also mindful of the new provisions in the revised Protocol which specifically address the issue, in particular the provisions at para. 4 which now permit an expert to nominate a defined but limited period within which a review of the patient’s slides will be carried out and the slides thereafter returned.

37. Furthermore, there are additional provisions at para. 8 dealing with “*Compliance and Remedies*” and any aggrieved party (whether the NSS or otherwise) has liberty to:

... “*make such application to the Court as may reasonably be required in connection with the operation of the arrangements set out herein.*”

38. I am therefore satisfied on balance that the proposed enforcement provisions are disproportionate and unnecessary in circumstances where there are now provisions designed specifically to deal with this issue.

39. Whilst some consideration was given to increasing the 30 day turn around period for the review of patient slides with a view to alleviating the pressure on experts, again this would appear to be unnecessary in light of the new provisions at para. 4 referred to above.

40. Finally, all stakeholders are to be commended for their productive engagement since this process commenced. The amendments, additions and overall improvements to the draft revised Protocol have addressed very significant issues including the adoption of a defined standard (“*good laboratory practice*”) to be applied in the handling of cytology slides; the introduction of documented procedures surrounding the handling of the slides; the introduction of a further explicit requirement that the qualifications of a person involved in the handling of slides must be documented and commensurate with the task to be performed by them together with the application of a uniform standard to all laboratories, to include those contracted to the NSS, as well as those laboratories at which independent experts operate. Further, I am grateful to the legal teams for all their assistance in the matter.

Conclusions

- 1.** The practice whereby the return slides are organised and paid for by or on behalf of the plaintiff should be retained.
- 2.** The NSS should not be required to implement a live-tracking system by means of a system built around “Shared Google Documents” or equivalent.

- 3.** Whole slide imaging (as opposed to macroscopic and microscopic imaging) should be utilised as the default where available, and the said imaging should only be released in the event that slides are lost or damaged in transit or otherwise cannot be located.
- 4.** The proposed enforcement provision at para. 8 should be removed.