A Human Factor Event-Based Learning Assessment Tool for Assessment of Errors and Diagnostic Accuracy in Histopathology and Cytopathology

[1]David N. Poller MD FRCPath MIAC, [2]Massimo Bongiovanni MD MIAC, [3]Beatrix Cochand-Priollet MD, MIAC , PhD, [4]Sarah J. Johnson MB BS PhD FRCPath and [5]Miguel Perez-Machado MD, FRCPath

1. Department of Pathology Queen Alexandra Hospital, Cosham, Portsmouth, PO6 3LY, UK,

2. Synlab Suisse SA, Pathology, Lausanne, Switzerland

3. Department of Pathology, Cochin Hospital, University of Paris, 27 rue du faubourg St Jacques, 75679 Paris cedex 14, France

4. Department of Cellular Pathology, Royal Victoria Infirmary, Newcastle upon Tyne, NE1 4LP, UK

5. Department of Pathology, Royal Free Hospital, Pond Street, London, NW3 2QG, UK

Correspondence to

Dr DN Poller MD FRCPath

Consultant Pathologist

Department of Pathology

Queen Alexandra Hospital

Cosham

Portsmouth

PO6 3LY, UK

david.poller@porthosp.nhs.uk

Licence for Publication

The corresponding author has the right to grant on behalf of all authors and does grant on behalf of all authors, an exclusive licence (or non-exclusive for government employees) on a worldwide basis to the BMJ Publishing Group Ltd to permit this article (if accepted) to be published in JCP and any other BMJPGL products and sublicences such use and exploit all subsidiary rights, as set out in our licence (http://group.bmj.com/products/journals/instructions-for-authors/licence-forms)

Please note that the exclusive licence above for publication only applies to the text of the main article and it does not apply to the two pages of Table 1, the text of the survey questionnaire, as previously used in the online version of the survey on the website www.PathLab.org[tm]. The worldwide copyright and the exclusive rights for use of the two pages in table 1, the text of the survey questionnaire, are retained in full by the corresponding author, Dr D Poller. This has been previously agreed with the BMJ Publishing Group Ltd.

Competing interests.

Non-declared for any of the authors

Abstract

This review article summarises systems for categorisation of diagnostic errors in pathology and cytology with regard to diagnostic accuracy and the published information on human factors in pathology to date. A 12 point event-based checklist for error in diagnostic accuracy in histopathology and cytopathology is proposed derived from Dupont's 'Dirty Dozen' human factor checklist, as utilised in the aerospace industry for aircraft maintenance. This human factor checklist comprises 12 human factors implicated in defects in aircraft maintenance; (i) failure of communication, (ii) complacency, (iii) lack of knowledge, (iv) distractions, (v) lack of teamwork, (vi) fatigue, (vii) lack of resources, (viii) pressure, (ix) lack of assertiveness, (x) stress, (xi) norms, and (xii) lack of awareness. The accompanying article explains practical examples of how each of these 12 human factors may cause errors in diagnostic accuracy in pathology. This checklist could be used as a template for analysis of accuracy and risks of diagnostic error in pathology either retrospectively 'after the event' or prospectively at the time of diagnosis. There is a need for further evaluation and validation of this proposed 12 point human factor checklist and similar systems for categorisation of diagnostic errors and diagnostic accuracy in pathology based on human factor principles.

The role of human factors (HF) in clinical medicine is undisputed. A definition of HF that is widely accepted is as follows '.. *environmental, organisational and job factors in human and individual characteristics which influence behaviour at work in a way which can affect health and safety*' [1]. Human factor analysis has been widely applied in aviation and aerospace industries but has been increasingly seen as important in medicine, particularly in critical care and acute medical settings to explain and reduce rates of clinical error and improve decision making in areas that are of high clinical risk[2-4]. There has been little discussion of the role of human factors in diagnostic specialties such as pathology, cytology, or radiology. Published HF studies in diagnostic specialties have primarily addressed the HF aspects of care involving either handovers from clinical teams to pathology[5] or aspects of HF involved in multidisciplinary case discussion which are common to other clinical specialties and not just pathology and radiology[6] or fatigue[7] . One of the authors (DNP) initially sought to devise a more in-depth tool utilising HF principles for assessment of accuracy of individual pathologists' diagnoses, applicable to the study of diagnostic errors. The definition of a diagnostic error in the literature varies. In 2015 The United States Institute of Medicine re-defined diagnostic error in a wide ranging way as '*the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient*', encompassing three aspects- accuracy, timeliness and communication [8]. This HF tool assesses accuracy of diagnosis alone. It does not address issues of timeliness of explanation of the patient's health problem or of communication to the patient. It is also important to define what constitutes accuracy. Variation in diagnostic interpretation and reporting practice is not uncommon, and in many cases

differences in diagnosis may have little or no clinical impact or consequences. Diagnostic errors may be classified or graded according to various different systems, three differing systems are described below[9] [10] [11]. The UK Royal College of Pathologists (UK RCPath) categorises diagnostic discrepancies in five categories[9].

Category A. Inadequate dissection, sampling or macroscopic description. The RCPath states that where relevant this should be assessed against guidance such as RCPath datasets and tissue pathways. The UK RCPath also comments that it should be remembered that the pathologist issuing the final report may not have dissected, described and sampled the specimen. This category also includes failure to request further work (e.g. histological levels, immunostains) where these are clearly required to make a diagnosis.

Category B. Discrepancy in microscopy

1. A diagnosis that one is surprised to see from any pathologist (e.g. an obvious cancer reported as benign).

2. A diagnosis that is fairly clearly incorrect, but which one is not surprised to see a small percentage of pathologists suggesting (e.g. a moderately difficult diagnosis, or missing a small clump of malignant cells in an otherwise benign biopsy)

3. A diagnosis where interobserver variation is known to be large (e.g. disagreements between two adjacent tumour grades, or any very difficult diagnosis)

Category C. Discrepancy in clinical correlation. This would represent a failure to answer the clinical question (if clearly expressed on the request form) despite the answer being evident from the material available; or a failure to indicate that a specimen is clearly inadequate to answer the clinical question

Category D. Failure to seek a second opinion in an obviously difficult case. This could imply overconfidence or may be indicative of dysfunctional relationships with a department. It is important that any second opinion is clearly evidenced within the report.

Category E. Discrepancy in Report. This would imply include typographical errors and internal inconsistencies or ambiguities in the report should have been corrected before authorisation. It would also include cases where there is suspicion that reports may have been allocated the wrong patient, case mix-ups etc.

The Royal College of Pathologists of Australasia Quality Assurance programme (RCPAQAP) classifies diagnostic discrepancies as follows [10]

Concordance. The preferred diagnosis is essentially/substantially identical with the target diagnosis, that is, accurate diagnosis

Minor discordance. The preferred diagnosis has one or more minor differences from the target diagnosis, that is, minor diagnostic inaccuracy.

Major discordance. The preferred diagnosis is substantially different from the target diagnosis, that is, inaccurate diagnosis

The French Quality Assurance Association in Pathology, Association Francaise d'Assurance Qualite en Anatomie et Cytologie Pathologique, (AFAQAP), in 2016 established an online national register of second opinions, e.g. for when a pathologist sends a case to a colleague for a second opinion which defines levels of discrepancy as follows[11].

(i)Impact of the diagnostic discrepancy on patient management (from the pathologist's perspective): none, minimal, major, or not known

(ii)Impact of the diagnostic discrepancy on patient management (after clinical case review with name of clinician, speciality and date of discussion): none, minimal, major or not known

(iii) The AFAQAP also categorises the discrepancy based on the stain(s) or laboratory technique(s) and asks the respondent to specify which stain(s), antibody(ies) or probe(s) were associated with the discrepancy

____YES____NO	Standard stain
____YES____NO	Special stain(s)
____YES____NO	Immunocytochemistry (cytology)
____YES___ NO	Immunohistochemistry (histology)
___ YES___ NO	In-situ hybridisation
____YES____NO	Molecular technique

A joint working group of the College of American Pathologists Pathology and Laboratory Quality Centre and the Association of Directors of Anatomic and Surgical Pathology, convened an expert panel to develop an evidence-based guideline to help define the role of case review in surgical pathology and cytology[12]. While this does not provide specific definitions for interpretative diagnostic error, it is a useful consensus-based guideline. The panel assessed the published evidence for the effect of targeted case review undertaken at either the analytical or the postanalytic phase of surgical pathology or cytology cases (slides and/or reports) to either reduce or increase the rate of interpretive error detection (often measured as amended reports) compared with no review, random review, or usual review procedures. The five recommendations were as follows[12]; (i) anatomic pathologists should develop procedures for review of selected pathology cases to detect disagreements and potential interpretive errors, (ii) anatomic pathologists should perform case reviews in a timely manner to avoid having a negative impact on patient care, (iii) anatomic pathologists should have documented case review procedures that are relevant to their practice setting, (iv) anatomic pathologists should continuously monitor and

document the results of case reviews, (v) if pathology case reviews show poor agreement with a defined case type, anatomic pathologists should take steps to improve agreement.

Hence as the examples above show it can be seen that there are differences in how diagnostic accuracy is categorised and in recommendations for case reviews to address diagnostic errors. It is not the purpose of this tool to try and address these, rather to identify HF-related issues that may impact diagnostic accuracy. This event-based learning tool uses a 12 point framework widely utilised in aerospace, specifically in the process of aircraft maintenance and referred to colloquially as DuPont's '*Dirty Dozen'*[13]. The '*Dirty Dozen'* is broadly accepted as a useful tool for error management in aircraft maintenance worldwide, and is endorsed in publications from the United States Federal Aviation Authority[14] and the European Aviation Safety Agency (EASA) among others. It has also been applied in ophthalmology[15]. A 12 point questionnaire applicable to cytology and pathology was formulated by DNP with advice from the remaining authors utilising the same generic 12 factors as applied to HF errors in the '*Dirty Dozen'* process of aircraft maintenance[14]. DNP with the assistance of a writing group then devised a computer-based questionnaire template using the 12 point multi-factorial HF framework. The factors in any individual case may be single or may be multiple and may in some cases overlap. This list could be used either retrospectively as a root cause analysis tool 'after the event' and also prospectively at the time of reporting a case as self-assessment quality assurance tool.

The 12 factors applied to histopathology and cytopathology are as follows

1. Errors due to failure of communication - not receiving or seeking sufficient information (including clinical information, or laboratory information to make the diagnosis correctly). In pathology or cytology this would normally be because of lack of adequate clinical information provided to properly analyse a specimen.

2. Errors due to complacency. Diagnostic errors typically made often by senior and experienced practitioners of cytology or histopathology who fail to appreciate that a case is more complex or challenging than initially appears to be the case. These cases are often reported in reflex mode without sufficient consideration because of a failure to appreciate the complexity and nature of the diagnostic problem and the relevant differential diagnoses. This may also be a manifestation of overconfidence, in what might seem superficially to be a straightforward diagnosis.

3. Errors due to lack of knowledge. Diagnostic errors made because of lack of training, knowledge, or where personal practice is deficient or was not up to date. In diagnostic histopathology or cytology this is usually due to lack of knowledge of the relevant differential diagnoses or the relevant diagnostic pitfalls and requirements of a particular case. While these diagnostic errors tend to be made by less experienced pathologists, experienced pathologists can also fall into this trap. Another example might be a specialised pathologist/cytopathologist covering colleagues' absence or leave in a specialty with which the specialised pathologist/cytopathologist was not recently experienced.

4. Distractions. This could be for many reasons, typically interrupting emails, texts phone calls, or requirements to multi-task may cause lack of sensory attention and hence increase the risk of diagnostic error.

5. Lack of teamwork. This rather generic over-arching point that relates to any institutional or team failure. An example might be a diagnostic error made because laboratory colleagues, or a multi-disciplinary team or a departmental organisation did not support or did not assist the pathologist appropriately. Pathology samples received in the laboratory in inappropriate fixative, delayed in transit, or compromised in quality for whatever reason if this situation could have been avoided by better institutional or team working would fall into this category.

6. Fatigue. This is fairly self-explanatory but pathologists are frequently required to work long hours. There is evidence of the value of regular rest periods in enhanced diagnostic performance. Diagnostic errors made because a pathologist or cytologist was tired, either physically, or mentally exhausted would fall into this category

7. Lack of resources. Diagnostic errors made because the laboratory facilities or laboratory staffing or equipment or reagents were not adequate or appropriate for the diagnostic tasks required. This would also include consequences of lack of resources, e.g. a lack of quality in routine laboratory stains, immunohistochemistry or other ancillary techniques including molecular techniques.

8. Pressure. Errors made because of real or perceived forces including either feeling time pressured in general or in relation to a specific case to complete a diagnosis, including being pressured to make a diagnosis by a clinician or by a patient.

9. Lack of assertiveness. Errors made because of failure to speak up or document concerns about instructions, information, or other aspects of a case dealt with by somebody else.

10. Stress. Errors attributable to personal stress, or anxiety, so that the pathologists' skills in diagnostic decision making were not normal at the time of the diagnostic error

11. Norms. Errors caused by acting according to the expected yet unwritten rules of behaviour, for example by acting in a reflex fashion and intuitively rather than by fully appreciating the diagnostic issues or challenges surrounding the case

12. Lack of awareness- An error that occurred because of failure to recognise the importance or significance of a diagnosis or the differential diagnosis (even though the pathologist knew about the diagnosis and/or relevant differential diagnosis). This would overlap with (3).

The text version of this survey is shown in table 1. An online version of this survey can be viewed on the website www.pathlab.org. While a human factor approach to diagnostic error categorisation in cytology or histopathology has not as yet been validated we think it might be very useful way of analysing the complex reasons for diagnostic errors in cytology or histopathology, and that this approach could be used either prospectively at the time of reporting or retrospectively 'after the event' for confidential surveys or root cause analyses when diagnostic errors arise. We are submitting this suggestion to the journal for publication in the hope that it can the more widely disseminated and as a basis for further discussion and development.

References

1. Human factors in patient safety review of topics and tools. Report for methods and measures working group of WHO 2009.
2. Hudson P. Applying the lessons of high risk industries to health care. *Qual Saf Health Care.* 2003;12 Suppl 1:i7-12.
3. Leape LL, Berwick DM. Five years after To Err Is Human: what have we learned? *JAMA.* 2005;293(19):2384-2390.
4. Carayon P. Human factors in patient safety as an innovation. *Appl Ergon.* 2010;41(5):657-665.
5. Brennan PA, Brands MT, Caldwell L, et al. Surgical specimen handover from the operating theatre to laboratory-Can we improve patient safety by learning from aviation and other high-risk organisations? *J Oral Pathol Med.* 2018;47(2):117-120.
6. Oeppen RS, Davidson M, Scrimgeour DS, Rahimi S, Brennan PA. Human factors awareness and recognition during multidisciplinary team meetings. *J Oral Pathol Med.* 2019;48(8):656-661.
7. Poller DN, Perez-Machado M. When is it time to stop working due to fatigue? A simple human factors (HF) self-assessment test. *J Clin Pathol.* 2020.
8. Balogh EP, Miller BT, Ball JR, eds. *Improving diagnosis in health care.* Washington (DC):: The National Academies of Sciences, Engineering, and Medicine;2015.
9. *Guide to conducting an investigative audit of cellular pathology practice. .* London, UK: The Royal College of Pathologists; 2017.
10. Peck M, Moffat D, Latham B, Badrick T. Review of diagnostic error in anatomical pathology and the role and value of second opinions in error prevention. *J Clin Pathol.* 2018;71(11):995-1000.
11. Association Francaise d'Assurance Qualite en Anatomie et Cytologie Pathologique. https://www.afaqap.fr/documentation/autres-documents. Published 2016. Accessed.
12. Nakhleh RE, Nose V, Colasacco C, et al. Interpretive Diagnostic Error Reduction in Surgical Pathology and Cytology: Guideline From the College of American Pathologists Pathology and Laboratory Quality Center and the Association of Directors of Anatomic and Surgical Pathology. *Arch Pathol Lab Med.* 2016;140(1):29-40.
13. Dupont G. The Dirty Dozen errors in aviation maintenance. Issues in Aircraft Maintenance and Inspection: Human error in aviation maintenance; 1997; Washington, D.C.
14. Aviation Maintenance Handbook-general. FAA-H-8083-30 In: Oklahoma City, Oklahoma: Federal Aviation Administration; 2008: https://www.faa.gov/regulations_policies/handbooks_manuals/aircraft/media/amt_airframe_hb_vol_1.pdf. Accessed 27/2/ 2020.
15. Marquardt N, Treffenstadt, C.,Gerstmeyer,K.,Gades-Buettrich, R.,. Mental workload and cognitive performance in operating rooms. *International Journal of Psychology Research.* 2015;10:209-233.

Table 1 Human Factors Checklist for Diagnostic Accuracy in Histopathology and Cytopathology based on Dupont's 'Dirty Dozen' copyright PathLab.org™ all rights reserved

HOW WAS THE ERROR DISCOVERED?

_____Review by departmental pathology colleague(s) (general)
_____Review of FNA cytology after histology assessment (eg after surgical resection)
_____Review after I remembered making the error
_____Review by pathology trainee(s)
_____Review of cytology or histology at a multidisciplinary meeting
_____Review by outside pathology consultation or expert
_____Review after query or a complaint by clinician
_____Review after a patient complaint or legal action
_____Other

_____I have not made any diagnostic error(s)
_____I cannot remember the details of any error(s) I have made
_____Time interval between error & date of completion of checklist

DID THE ERROR DELAY OR AFFECT A PATIENT'S CARE OR TREATMENT?
_____YES
_____NO
_____NOT SURE

DID THE ERROR CAUSE HARM TO A PATIENT?
_____YES
_____NO
_____NOT SURE

DO YOU THINK YOU WILL MAKE THE SAME OR A SIMILAR ERROR (S) IN THE FUTURE ?
_____YES
_____NO
_____NOT SURE

In relation to the THIS DIAGNOSTIC ERROR THAT I PERSONALLY MADE IN MY OWN PRACTICE
I BELIEVE THAT THE REASON(S) FOR ME PERSONALLY MAKING THE ERROR WERE AS FOLLOWS

1.FAILURE OF COMMUNICATION- I did not receive or seek sufficient or correct information (including clinical information, or laboratory information to make the diagnosis correctly)

_____YES
_____NO
_____NOT SURE

2.COMPLACENCY- I was overconfident because I had made what seemed to me at the time to be a straightforward diagnosis which I had made many times before
_____YES
_____NO
_____NOT SURE

3.LACK OF KNOWLEDGE - I made the error because my training, knowledge, or personal practice was deficient or was not up to date
_____YES
_____NO
_____NOT SURE

4.DISTRACTIONS - I made the error because I was disturbed, distracted, or interrupted or not fully concentrating on the diagnostic task
_____YES
_____NO
_____NOT SURE

5.LACK OF TEAMWORK - I made the error because my laboratory colleagues, my multi-disciplinary team or my departmental organisation let me down or did not assist me appropriately
____YES
____NO
____NOT SURE

6.FATIGUE - I made the error because I was tired, either physically or was mentally exhausted
____YES
____NO
____NOT SURE

7.LACK OF RESOURCES - I made the error because my laboratory facilities or laboratory staffing or my equipment or my reagents were not adequate or appropriate.
____YES
____NO
____NOT SURE

8.PRESSURE - I made the error because of real or perceived forces including either feeling time pressured in general or specifically in relation to a case to complete a diagnosis, including being pressured to make a diagnosis by a clinician or by a patient.
____YES
____NO
____NOT SURE

9.LACK OF ASSERTIVENESS - I made the error because of my failure to speak up or document my concerns about instructions, information, or other aspects of a case dealt with by somebody else.
____YES
____NO
____NOT SURE

10.STRESS - I made the error because of personal stress, or because I was over anxious so that my skills in diagnostic decision making were not normal at the time I made the error
____YES
____NO
____NOT SURE

11.NORMS - I made the error because I did what I would normally do according to the expected yet unwritten rules of behaviour, by acting in a reflex fashion and intuitively rather than by fully appreciating the diagnostic issues surrounding the case
____YES
____NO
____NOT SURE

12.LACK OF AWARENESS - I made the error because I failed to recognise the importance or significance of the diagnosis or the differential diagnosis (even though I knew about the diagnosis and/or relevant differential diagnosis)
____YES
____NO
____NOT SURE