

## OPINION OF SENIOR COUNSEL

for

The Association of Optometrists

(“The AOP”)

---

### *Introduction*

1. The National Institute for Health and Clinical Excellence (“NICE”) is an independent organisation, responsible for providing guidance on the promotion of good health and the prevention and treatment of ill health in England and Wales. It does so by publishing “clinical guidelines”, which are “recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.”
2. On 22 April 2009, NICE issued a clinical guideline on the diagnosis and management of chronic open angle glaucoma (“COAG”) and ocular hypertension (“OHT”). It is worthy of note that the guideline defines OHT as “(c)onsistently or recurrently elevated IOP [intraocular pressure] (greater than 21 mmHg) in the absence of clinical evidence of optic nerve damage or visual field defect.” (Page 6) The terms “consistently” and “recurrent” are not defined.

3. A number of passages which explain the context and purpose of the guidance are particularly relevant to my advice. These are as follows:-

*“NICE commissioned the National Collaborating Centre for Acute Care to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations. An independent Guideline Review Panel oversaw the development of the guideline (see appendix B).”*(Notes on the scope of the guidance, page 29)

*“Because uncertainty and variation exist in clinical practice this guideline seeks to give clear recommendations on testing for and diagnosing COAG and OHT, and on effective monitoring and treatment to prevent these conditions progressing. By implementing this guideline more people will be prevented from going blind.”* (Introduction, page 4)

*“This guideline offers best practice advice on the diagnosis and management of COAG and OHT. (Person-centred care, page 5)*

*“Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.”* (Preface)

*“Once diagnosed, people with COAG need lifelong monitoring so that any progression of visual damage can be detected. Once lost, sight cannot be restored, and controlling the condition, together with prevention, or at least minimisation of ongoing damage, is crucial to maintaining a sighted lifetime.*

4. Under the heading “Key priorities for implementation”, the guidance on diagnosis prescribes a number of tests which are to be offered to those “who are suspected of having COAG or who have OHT”. I am instructed that, currently, with the exception of a very few, the only clinicians with the skills and competencies to provide these tests are to be found in hospital eye departments. Before this guidance was issued, patients would not have been referred to hospital without significant other indicators of glaucoma, or their intraocular pressure was at a level somewhat above 21mmHg. Optometrists would simply have monitored patients with slightly raised intraocular pressures as part of the regular eye test. In the view of the AOP, in England at least the lowering of the pressure threshold means that a very large number of very low risk patients must now be referred for the formal battery of tests to be performed.
  
5. As is noted above, NICE guidelines are not intended for use in Scotland. Here, clinical guidance is devised and issued by the Scottish Intercollegiate Guidelines Network (“SIGN”). In July 2009, Optometry Scotland posted advice on its website in respect of the NICE guideline on glaucoma. Having consulted all lead clinicians for ophthalmology in Scotland, it advised that the NICE guidelines are “only advisory”, that they “do not apply in Scotland”, and that they “are at odds with the accepted Scottish guidelines”. The advice makes the assertion that guidelines developed using SIGN methodology “takes precedence over NICE in Scotland”.
  
6. It is relevant to note at this point, however, that in its publication “Clinical Guidelines: Notes for Users”, SIGN offers the following caveat about the application of its guidance:-

*“SIGN guidelines are not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual case and are*

*subject to change as scientific knowledge and technology advance and patterns of care evolve. These parameters of practice must therefore be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor in light of the clinical data presented by the patient and the diagnostic and treatment options available.”*

7. On 14<sup>th</sup> July 2009, the Scottish Government circulated a letter “reminding” practitioners of the terms of the Scottish “pathway for patients presenting with suspected glaucoma”. At or about the same time, the Scottish Government Optometric Adviser announced publically that “NICE clinical guidelines do not apply in Scotland”. The announcement continued in these terms:-

*“The relevant patient pathway in Scotland is that developed for NHS Scotland by the Centre for Change and Innovation ... ..”*

8. According to my instructions, the principal difference between the Scottish guideline and the NICE guidance is that, where OHT is present, the former mandates referral for further investigation when IOP is equal to or greater than 30mmHg, whilst the latter provides for further tests in cases where IOP is “consistently or recurrently” greater than 21 mmHg.
9. Against that background, the AOP have asked for my views on how they may best advise and protect their members in Scotland for defence, regulatory and best practice purposes.

## *Standard of Care*

10. I begin by considering whether a failure to follow published guidelines might be held to constitute negligence in a case where, following such a failure, a patient develops a disease which might otherwise have been prevented. The test which would be applied in determining whether or not the clinician fell below the standard of care expected of him or her is that laid down in the Scottish case of *Hunter v Hanley* 1955 SC 200. To establish negligence the claimant would have to prove that the course adopted by the clinician was one “which no professional man of ordinary skill would have taken if he had been acting with ordinary care”. That test has subsequently been adopted and developed in England.
11. In the January 2008 revised edition of its publication, “SIGN 50: A Guideline Developers Handbook”, SIGN gave consideration to the legal implications of guidelines. Its analysis is helpful, and I set it out in full:-

*“The potential medico-legal implications of clinical guidelines have been of ongoing concern to medical practitioners since the establishment of a Scottish national guideline development programme was first proposed. Dr Pamela Abernethy of Simpson and Marwick WS, one of the leading Scottish experts on medical negligence, provided an initial paper on the legal implications of guidelines to SIGN and NHS Scotland in December 1995. In this paper she concluded that clinical guidelines do not rob clinicians of their freedom, nor relieve them of their responsibility to make appropriate decisions based on their own experience and according to the particular circumstances of each patient. It is stressed that the standard of care required by law derives from customary and accepted practice rather than from the imposition of practices through clinical guidelines.*

*“Dr Abernethy refers to the 1955 case of *Hunter v Hanley* as establishing the standard of care required under Scottish Law and describes the three-step test used to establish the liability of a healthcare professional where it*

*is alleged that (s)he has deviated from normal practice. The Central Legal Office (CLO) advised SIGN in 2006 that the Hunter v Hanley test is still the appropriate test in Scotland for liability for clinical negligence, i.e. it must be established that the course the healthcare professional has adopted “is one which no professional man of ordinary skill would have taken if he had been acting with ordinary care”. This test was developed further by the Bolam<sup>1</sup> test, i.e. a healthcare professional is not guilty of negligence if “he has acted in accordance with a practice accepted as proper by a responsible body of men skilled in that particular art”. A healthcare professional may therefore defend a charge of negligence with evidence that (s)he acted in conformity with the practice accepted by another body of opinion. The test applied by the Court is therefore based on what is actually done in practice rather than on a prescription of what should be done as proposed by guidelines.*

*“Dr Abernethy states also that customary and accepted practice will be established in court by introduction of expert testimony. Although clinical guidelines will not be introduced as a substitute for expert testimony, they may be referred to by an expert witness as evidence of such customary and accepted practice. The CLO has advised SIGN that this is still the case. The Hunter v Hanley test has been developed since 1995 by the 1997 case of Bolitho v City and Hackney Health Authority<sup>2</sup>. This case introduced a more critical approach to the evidence supplied by expert witnesses and provided that where it can be demonstrated that professional opinion is not capable of withstanding logical analysis, the judge would be entitled to determine that the opinion was not reasonable or responsible.*

*“The CLO advice to SIGN following this case is that the opinions of medical experts may not be regarded as final and authoritative. Although*

---

<sup>1</sup> *Bolam v. Friern Hospital Management Committee* [1957] 1 W.L.R. 582.

<sup>2</sup> [1998] A.C. 232.

*a defendant may present expert opinion that his practice was sound, the judge may look at additional evidence to determine whether the practice was in fact logical. **It may be that evidence based guidelines will be referred to as part of that additional evidence and the court may require to know why such guidelines were not followed and the reasoning behind the decision not to follow them. There is consequently greater potential for clinical guidelines to have a greater role in identifying the standard of care.*** (My emphasis)

*“In addition to this legal development in the determination of the duty of care, the origins of some guidelines which have been produced since 1995 may be relevant in the future in determining their legal status. **There is an argument that some guidelines produced by organisations such as SIGN and NICE could come to be regarded as authoritative guidance in view of the robust methods used in their production and also in view of the national status of these organisations.*** (My emphasis)

*“Some established national guidelines may be referred to by the court at present as a starting point from which to consider a healthcare professional's conduct. The *Hunter v Hanley* test does of course still apply in determining the standard of care and at present such guidelines do not set the standard of care. (This is stated in each SIGN guideline).*

*“If the law were to develop in the future to accredit a more authoritative status to guidelines of this nature, the burden of proof, in the opinion of some commentators, may move to the healthcare professional where such a guideline is not adhered to. Instead of the plaintiff being required to prove that the healthcare professional failed to provide a minimum standard of care in accordance with the *Hunter v Hanley* Test, the healthcare professional may be required to prove that the care met the required standard of the *Hunter v Hanley* test although the guideline has*

*not been applied. This is, however, only conjecture and at present the burden of proof remains with the plaintiff.*

*“The CLO has advised SIGN that there has to date been no reference to SIGN guidelines in any reported cases of medical negligence.*

*“It is important to emphasise that SIGN guidelines are intended as an aid to clinical judgement not to replace it. Guidelines do not provide the answers to every clinical question, nor guarantee a successful outcome in every case. The ultimate decision about a particular clinical procedure or treatment will always depend on each individual patient's condition, circumstances and wishes, and the clinical judgement of the healthcare team.*

*“Guidelines are, however, intended to address variation in practice. While there is no compulsion to implement any SIGN guideline or individual recommendations, NHS Boards, clinical teams, and individual practitioners in primary and secondary care should all be able to define the standard of care which they provide, and to justify if necessary why these do not meet nationally agreed recommendations.”*

12. I agree with legal aspects of these views. Whilst they do not address the particular problem which arises in this case, that being that the two guidelines under consideration appear to set different clinical standards, they do provide assistance.
  
13. One can envisage a case in which a patient undergoes an IOP test in Scotland. The optometrist administering the test records a pressure of 25.5 mmHg and applies the Scottish guideline. No further test is carried out and the patient subsequently manifests symptoms of glaucoma. If the patient were able to establish, on a balance of probabilities that, if he or she had been managed according to the terms of the NICE guideline, symptomatic COAG would have been avoided, the *Hunter*

*v Hanley* test would fall to be applied to determine whether or not the clinician had been negligent. It would not be a sufficient answer to a charge of negligence simply to point to the advice of Optometry Scotland or to the Scottish Government's announcement. In my view, the court would be interested to know what was the **clinical** basis for the adoption of the Scottish guideline, in preference to the NICE guidance.

14. The glaucoma patient pathway contains no explanation for the adoption of the threshold figure of 30 mmHg. There appears to be, however, a scientific basis for the selection of 21 mmHg as the threshold. For example, in a paper entitled "The clinical effectiveness and cost-effectiveness of screening for open angle glaucoma: a systematic review and economic evaluation", published in the Health Technology Assessment journal in 2007, the authors make this observation:-

*"OAG is diagnosed primarily by glaucomatous optic neuropathy (cupping) and a compatible visual field defect, in the presence of an open, normal appearing, anterior chamber angle. **Raised intraocular pressure (IOP) of at least 21 mmHg (two standard deviations above the mean) used to be considered as a part of the definition of OAG, but population studies have consistently found that many people with OAG have an IOP below this level. The risk of developing glaucoma, and for worsening of existing glaucoma, does, however, increase with increasing IOP. More advanced disease at diagnosis is also associated with a higher IOP.** (Page 4, my emphasis)*

15. It is later explained in the paper that the mean IOP in adult populations is consistently estimated at 15-16 mmHg, with a standard deviation of 2.5-2.8. The selection of 21 mmHg as the threshold is, therefore, intelligible by reference to these figures.

16. Further, in the relevant NICE Guideline Consultation Comments Table, Alcon UK, an eye care company, refers to a number of studies and offers this comment:-

*“Based upon this body of scientific research, we feel that the IOP threshold documented in the guidance of less than 21mmHg is too high, and recommend that the threshold value for treatment of OHT and suspected COAG is decreased from this documented value to less than 18 mmHg in line with current research.”*

17. That suggestion is rejected for reasons which NICE gives, but it serves to suggest that a threshold pressure of 30 mmHg may be too high.

*Conclusion*

18. In my opinion, therefore, following the Scottish guideline in preference to the NICE guidance, without a supportable scientific justification for doing so, will put a clinician at risk of being held to have been negligent. If there is no such justification, it would be difficult to claim that adherence to the Scottish guideline is in accordance with best practice, or the clinician’s professional obligations.
19. The AOP may consider that it can best assist its members by pressing the relevant Scottish authorities for an explanation for the selection and retention of the 30 mmHg threshold and a reasoned assurance that it is supported on the basis of current scientific knowledge and technology and patterns of care. (See paragraph 6 above) If no sufficiently cogent explanation were forthcoming, that would militate against advising the AOP’s members in Scotland to adopt the Scottish guidance.

THE OPINION OF



Albany House,  
Albany Street,  
Edinburgh EH1 3QR  
7<sup>th</sup> September 2009

OPINION OF SENIOR COUNSEL

for

The Association of Optometrists

---

Sept 2009

Simpson & Marwick