Optical Confederation response to the Royal College of Ophthalmologists consultation on draft standards and guidance on refractive surgery

The Optical Confederation welcomes the opportunity to respond to this consultation. The Optical Confederation represents the 12,000 optometrists, 6,000 dispensing opticians, 7,000 optical businesses and 45,000 ancillary staff in the UK, who provide high quality and accessible eye care services to the whole population, including providers of community refractive surgery. We work with other organisations to improve eye health for the public good and are partners with the College of Ophthalmologists on the Clinical Council for Eye Health Commissioning.

It is unfortunate that we were excluded from the Working Group which developed these drafts as we have a lot of expertise, data and evidence to share which the Working Group may have found helpful. We note that the Working Group which sat behind the 2011 standards for laser refractive surgery was substantially more representative of the industry as a whole, and we consider that the College's failure to strike a similar balance in the present Working Group represents a missed opportunity which has substantially undermined the draft guidance.

That said there is a lot that is good and which we welcome in this guidance (particularly the patient information on procedures), the majority of which our members would happily use.

We do, however, think the College has got it fundamentally wrong in a number of crucial respects:

- a failure of process with inadequate representation of providers, optometrists and patients and not applying its NICE accredited methodology to these drafts which would have made for a more robust process. The evidence base for the proposed changes is flimsy, and there has been a clear failure to reflect the fact that refractive surgery is clinical in nature and that there is a lesser impetus for change than there was to the 'bucket shop' surgery addressed by the GMC's guidance on cosmetic surgery;
- misunderstanding the practicalities of community refractive surgery – a point we made many times during the guidance development phase;
- inappropriate attempts to fetter the clinical decisions of individual surgeons and other regulated professionals, including in relation to delegation. It imposes

requirements beyond those in the GMC's cosmetic surgery guidance (and in relation to delegation in general) and goes far beyond what is appropriate and necessary in the circumstances;

- misunderstanding, misreading or belittling of the roles and skills of registered optometrists (and potentially ophthalmic nurses) in the patient information and consent process, all but ignoring the inherent safeguards arising from their registration with the GOC. The proposed guidance will result in reduced access to care for patients who would benefit clinically from such surgery. Access to refractive surgery should not be restricted only to wealthy patients;
- failure to understand how elements of advertising (e.g. offers) enable community businesses to even out workload between peaks and troughs, thus making best use of the workforce and facilities available. This allows providers to increase patients' access to services, making them available at reasonable prices. In addition, it goes far beyond the Advertising Standards Authority's own guidance and is another example of the College exceeding its proper remit;
- lack of understanding of the needs and wishes of patients – evidence on which would willingly have been supplied by the Optical Confederation and its members to the working group – which has led to a theoretical rather than a practical (or evidence based) approach to these issues;
- the guidance will have the effect of improperly and unnecessarily restricting competition in the market so that only a small number of surgeons at the higher-end of the market will be able to provide services which fully comply.

We find it difficult to reconcile the College's aim, stated at the Industry Day on 11 May, to enable more patients to benefit from refractive surgery with this draft guidance which, we suggest, will put unnecessary obstacles in the way, reducing patients' access to safe, high-quality care. The barriers in the current draft guidance will further restrict levels of access to care, which are felt by the Working Group, and others, to be significantly lower than where they should be.

It will be the practical application of the guidance rather than theoretical ideals which will of course most benefit patients and the public. It is in the best interests of patients for registered clinicians, working in teams, to use their combined skills to maximum effect to provide patients with safe, high-quality care in a way which adequately addresses the needs of patients.

We strongly urge the College to amend the draft guidance to address these concerns so that it avoids imposing an unnecessary straitjacket on practitioners and patients. In the absence of such changes it may be that further multidisciplinary guidance is required for community refractive surgery to complement, or even amend, the current RCOphth draft standards.

This would be to support practices and practitioners – surgeons, optometrists and other staff – to comply with the spirit of this guidance in more accessible community settings.

We deal with each of the above points in turn below. In addition, we attach, at Annex A, suggested textual amendments which would make the guidance acceptable to the Optical Confederation, and at Annex B, excerpts from relevant GMC guidance on consent with which we believe the guidance should comply but not embroider.

NICE Process

Although we understand the cost arguments outlined at the Industry Day on 11 May, it is a matter of regret to us that the College decided for whatever reason to undertake the development of this guidance outside its NICE approved process.

The Optical Confederation through the Clinical Council on Eye Health Commissioning was happy to support the College's cataract guidance issues in 2015 which was properly developed with full stakeholder and expert input. There have been some minor glitches around the College's recent glaucoma guidance developed under the same system but at least the system has provided space for mature discussion between groups of professionals about evidence, safety and outcomes and an agreed way forward.

It is regrettable that we have to say that we fear this has not been the case in the development of these refractive surgery guidelines. Evidence which could have been asked for and which we would willingly have submitted under the NICE framework was not called for or requested. Nor, despite our repeated representations, including via the College of Optometrists, did the Working Group allow for appropriate input from community providers and particularly not from any optometrists actually engaged in the day-to-day delivery of community refractive surgery. We have senior individuals within our membership who have significant experience in community refractive surgery. As noted above, theory is great but no substitute for experience. We believe this was a serious omission as we said in correspondence at the time and, sadly, the resultant draft guidance has done nothing to assuage our fears in this regard.

We also have concerns about the patient input. We would have expected the College to set up a group of patients who had undergone community refractive surgery (proportionately balanced in relation to outcomes) and scientifically taken their views on board. There is no indication in the draft guidance that this happened or what alternative arrangements were put in place to obtain a representative sample of patients' views.

At the industry day on 11 May, the Working Group's patient representative made a virtue of the fact that she has not had refractive surgery and has not considered it. This is hardly

ideal. Furthermore, we consider that the Patients' Day on 18 May was unfit for purpose with only a small number of patients attending, mostly from a small pre-known lobby group with a very specific 'anti' agenda.

It is unacceptable, unscientific and unevidence-based for the patient input to this guidance to be guided by an individual who has never had and will never have a refractive surgery procedure, plus a small group of patients that are dissatisfied with their outcomes. We would welcome clarification of the analysis that was carried out on patient experience and patient views and how these were obtained during the development of the draft guidelines. We would be interested to know what steps the College took to review that evidence and obtain a more balanced sample of the views of patients who have undergone community refractive surgery in 'high street' as well as 'Harley Street' facilities. It would have been good if the Working Group had considered, for example, consumer group meetings inviting patients who are contemplating laser eye surgery and who are more typical of refractive surgery patients today. We are keen to know how the Working Group has satisfied itself that it has taken into account a satisfactorily representative spectrum of patient views and experience. It seems clear to us that none of this essential underpinning research has taken place and that this is a major shortcoming both in the process and in the resultant guidance.

We have further substantial concerns that the College's guidance does not take into account the reality of safe, effective community refractive surgery which enjoys an enviably high level of patient satisfaction. In our view, the College is in serious danger of introducing overly prescriptive guidance to address a largely illusory problem on the basis of an extremely flimsy evidence base. In spite of concerns sent by our members to the Chair of the working group throughout the process, there is still a distinct and disturbing lack of clarity over why the College considers that there is a 'problem' with refractive surgery which can only be addressed through guidance which goes beyond the GMC's own cosmetic surgery guidance, particularly in circumstances where cosmetic surgery is a far less suitable comparator to refractive surgery than cataract surgery (which itself is – rightly taking a risk-based view - subject to less restrictive guidance than cosmetic surgery).

In short, we do not believe, on what we have seen so far, that the College has met its own professed standards in this area. The lack of adequate representation from providers, optometrists or patients to has been a major failing in the process and would not have occurred if the College had followed its NICE approved protocols.

The practicalities of community refractive surgery

The majority of community refractive surgery in the UK is provided by three major companies whose records in terms of safety, outcomes, access, service quality and patient satisfaction are exemplary. We can provide solid evidence of all of these parameters and

would have happily provided it if the College had wished. It is of paramount importance that we all respect the high satisfaction rates that community refractive surgery currently displays. We must not allow the thoughts of a small and partial minority to overshadow the experience of the majority, whether this be by public consultation or the perception created by a fraction of patients who have an unbalanced perception of the services provided.

Community refractive surgery provides a safe and cost-effective route for many to benefit from refractive surgery which might otherwise be beyond their means. As the draft guidance recognises, community refractive surgery is unlikely to ever be funded by the NHS and has by definition therefore to be offered as a private service at the patient's own expense. Community refractive surgery offers patients a safe, high-quality service with excellent outcomes which provides much wider access to care than other service models.

As noted above, the quality and outcomes of community refractive surgery are as good as, and in many cases better, than other service models. The added social value that community refractive surgery companies have brought is to reduce health inequalities and to increase access to refractive surgery for individuals who would otherwise have been excluded from receiving care.

To do this, they make efficient and appropriate use of the clinical teams that work in their practices under the supervision of the operating surgeon. This means that registered and specially-trained optometrists and ophthalmic nurses often interview patients, inform them of risks and benefits and make recommendations about surgery to patients (which are then confirmed and consented with the patient by the operating surgeon). Trained optometrists are ideally placed to undertake many aspects of the pre and post-operative care of a refractive surgery patient in the same way as for cataract surgery.

We appreciate the working group being supportive of this – at the Industry Day on 11 May it was confirmed by the group that it is in agreement that optometrists are well placed to make a determination on a patient's suitability and, further to this, to make a preliminary recommendation that will be confirmed by the treating surgeon. It is somewhat incongruous that the draft guidance does little more than pay lip service to the involvement of optometrists, making the process unnecessarily cumbersome and consultant-led.

One of our community refractive surgery provider members, following the process described above, offers patients the opportunity to meet with the surgeon carrying out the procedure in advance of the day of surgery. In the event, only a very small number (fewer than 10%) of laser eye surgery patients opt to take this up, most choosing not to on the grounds that they are already very satisfied and have been well informed. Providers find that there is extremely low take up of this service regardless of whether it is inclusive or charged for separately. Providers who have promoted the option of seeing the surgeon

without additional charge have experienced minimal patient take-up, with patients happy to meet their surgeon on the day of surgery. This clearly indicates that cost is not the inhibitor

To require patients – regardless of their personal wishes – to have to see their surgeon in the days before surgery would not benefit patients and would reduce access to care. Such a requirement would increase costs and reduce the availability of the service to the people who want it and potentially put community providers out of business. The margins in community practice – because of the public value and patient benefits – are significantly lower than in other models of refractive surgery provision. This in fact is one of the benefits this service brings to the community and the public at large.

We do however understand the College's position – that, in any category of elective surgery, informed patient consent is of paramount importance and must be safeguarded - and would find acceptable a recommendation which required patients to be offered the opportunity of a discussion with their surgeon (which may be face to face or by telephone for example) to confirm the clinical recommendations and check that the patient has all the information they require, including about risk, in advance of the day of surgery. This recommendation would improve patients' ability to choose and raise standards while enabling our members to continue to provide a safe and high-quality patient-centred service without imposing restrictive and unnecessary costs that would reduce accessibility for the majority of patients.

We recognise that commercial factors are often not issues that Colleges wish to take into consideration, and are rightly secondary to patient safety. But we suggest that, in this case, and where patient safety, outcomes and service quality are not in doubt, the College should consider these issues and produce guidance that reflects the safe, daily realities of community clinical practice, and should not impose unnecessary and disproportionate burdens on those operating a model which works safely and cost-effectively.

If the College has evidence that this is not the case, we would be very pleased to see and examine it as patient safety and outcomes are our members' highest priority.

Professional Decision-making

We do not believe that it is the role of the College to fetter a surgeon's clinical or delegation decisions as this guidance attempts to do. Nor is it the College's role, we suggest, to second guess the teams within which surgeons operate or their professional decisions. If a surgeon has confidence in his or her team and is happy to delegate information giving, work up and consent procedures to members of their team, then that should be their choice as autonomous clinicians. It is the College's role to support those decisions with guidance where appropriate. The current draft is overly prescriptive in this regard and gives rise to a

sense of 'mission creep'. Not only is the draft guidance unnecessary in this regard – it is inappropriate.

Indeed, there is nothing in the draft guidance which indicates that the College has taken into account GMC or Department of Health guidance on consent and delegation[1]. In addition, there is nothing which reflects the fact that the GMC's own guidance on cosmetic surgery (on which, according to the Working Group's terms of reference, the College's draft guidance is modelled) is less prescriptive than the College's proposals in a number of regards.

As providers of high-quality, safe, community refractive surgery, Optical Confederation members would never put any surgeon in a position where they felt they had to compromise their professional or ethical standards. Indeed it would be a breach of our members' duty towards those surgeons to do so. Again, if the College has any evidence of that this has happened, we would be very glad to see and respond to it.

The same argument applies to trained optometrists who work in community refractive practice as part of the refractive surgery team. They are under a similar duty imposed by the General Optical Council (GOC) to make the care of patients their first and continuing concern, only to practise within their scope of practice and not to do anything about which they have doubts or which is outside their competence, training and skills.

Moreover, companies registered with the General Optical Council to provide community eye health services are under a similar duty (backed by heavy penalties in the form of fines or disqualification from provision) similarly not to apply pressure to optometrists or dispensing opticians to operate in any way outside GOC standards.

Sadly, the draft guidance fails to recognise that optometrists and their employers have substantial regulatory responsibilities of their own in the form of their GOC registration. Their responsibilities are analogous to those of surgeons, and to suggest (as the draft guidance implicitly does) that the GOC's system of regulation is not fit for purpose or that GOC registrants as a class cannot be trusted to comply with their regulatory responsibilities is utterly wrong. The draft guidance ignores the safeguards woven into models of community refractive surgery (which differs markedly from 'bucket-shop' cosmetic surgery) and the draft guidance, which would effectively render that model redundant, risks throwing the baby out with the bathwater.

[1] At Annex B we enclose relevant extracts from the GMC consent guidance, the Department of Health reference guide to consent for examination or treatment, GMC Good Medical Practice and the GMC guidance on delegation and referral.

Roles of other Members of the Clinical Team

We feel strongly that the overwhelming emphasis in this guidance on the role of the surgeon downplays and belittles the role of trained and registered optometrists who work alongside them in community practice.

Increasingly, as we know, clinicians are encouraged to work in teams rather than isolation – indeed the GMC requires as much – and the days of the solo 'hero surgeon' who must do everything are long gone. In many areas of surgery, aspects of the process are delegated to other clinicians including trained nurses or other professionals and we feel this guidance undervalues those professionals and their roles, and fails to take into account the extent to which they are able to contribute in their own right as part of a multi-disciplinary team.

We appreciate that the role of the College is to give advice to surgeons but, in doing so, it should as a professional body take account of the realities of team working and the roles of other professionals and should reflect those roles and relationships in its guidance.

It follows therefore that we do not believe that optometrists are not qualified to take consent of patients planning to undergo community refractive surgery. This is not to say that we do not fully agree that the surgeon performing the surgery should verify (and is ultimately responsible for) consent, and for ensuring that the patient has fully understood all of the options and any risks, before the day of surgery: we do. However, we cannot see any good reason why the first part of this process should not be delegated appropriately to fully-trained professional colleagues such as optometrists or registered ophthalmic nurses, under the appropriate supervision of an ophthalmic surgeon.

Indeed, it was confirmed at the Working Group Industry Day on the 11 May that an optometrist can determine suitability of a patient and make a preliminary recommendation to a patient concerning a refractive surgery procedure. However, as we have pointed out above, this is not yet included within the draft guidance.

We agree entirely that such tasks should never be performed by receptionists, or any other clerical staff but would ask that the College recognises the significant difference between these categories of staff and professional colleagues working in clinical teams. To the extent that the draft guidance rests on the assumption that regulated professionals are no different from clerical staff (and should, for the purpose of the guidance be treated in the same way), it is wrong and should be amended to take into account the important role they play and the surgeon's ability to utilise them appropriately as part of the wider clinical team.

Advertising and marketing standards

We fully agree that advertising and marketing for refractive (or any other) surgery should be responsible and accurate. However we fear the College misunderstands the purposes of advertising. We note that the guidance goes beyond what is recommended by the GMC in this regard and would question what competence and expertise College members actually have to advise in this area. We would also welcome clarification of the scientific support the College has additionally used on these issues.

Simply relying on and repeating the views of the AAO is not sufficient or evidence-based.

The Advertising Standards Agency does already of course have competence in this area and can take steps (including punitive steps and pro-active action) to issue guidance if it wishes.

There are three clear objectives in advertising:

- to inform patients and potential patients about services available;
- to build brand reputation and value;
- to support workflow to enable services to be provided to the greatest number in the most cost-efficient and effective way.

These aims should be well understood to the College which of course uses advertising and communications for all of the above purposes including early-bird bookings to ensure sufficient volume at conferences etc. It is on the last point in particular that we feel there has been misunderstanding.

We disagree strongly with the proposals in paragraph 1.5 about deals, offers and packages, and in particular the description of them being “socially irresponsible”.

Offers are not in any way intended to attract into surgery people for whom that surgery is not appropriate. It would not be in anyone’s interest for this to happen – not least the patient or the provider’s brand reputation – and systems are in place in our sector to ensure that any such patients are advised not to proceed and cannot have the procedure with the given provider. Our members routinely decline to treat patients who have attended a consultation but for whom surgery would not be appropriate. If patients are not suitable, they are simply not treated. As we have made clear above, our members and their employees are regulated in their own right. Any breach of the requirements of their registration can and should be dealt with under the existing arrangements.

Rather, offers are intended to encourage patients who are considering or planning to have a procedure to come forward at a time when the provider has capacity to accommodate them. It is in these areas that offers can be made at marginal cost which smooth out patient

flows and enable providers to manage their capacity effectively over peaks and troughs. It allows prices to be held down for all patients whilst ensuring clinical throughput and stable remuneration for surgeons and other clinicians.

This is no different in kind from traditional advertising in ophthalmology which offers, for example, opportunities to “jump NHS waiting lists”.

With respect to celebrity endorsements (paragraph 4.3), whilst we agree that there needs to be clarity in respect to any financial arrangement, such an endorsement can assist the public in understanding the benefits that refractive surgery can bring. Such an approach can bring into refractive surgery suitable patients who, the College itself regrets, are not currently coming forward for surgery. A celebrity endorsement, by increasing public awareness, can also benefit the sector as a whole and not simply the individual service provider which performed the procedure on the celebrity.

Furthermore, we would suggest that the College should properly respect the roles of agencies such as the ASA, whose policies in these areas are well founded. Going over and above the guidance of advertising and marketing regulators is not in the interests of patients and is an inappropriate step into territory which is properly the domain of the ASA and is another example of 'mission creep'.

We would ask that the College reconsider these points and amend the guidance to use less inflammatory language and also to reflect a better understanding of how community providers can provide a service at more reasonable rates to a greater number of people. To do otherwise, as the College suggests, would drive up prices without any impact on safety, quality or outcomes. Patients would not benefit, and would not experience an improvement in the care they receive. The guidance would simply put refractive surgery out of the reach of many lower income individuals who may wish to have refractive surgery for practical reasons in their own lives.

There is a public utility argument here which we fear has not been fully understood or reflected by the College in this guidance and we would ask you to re-consider.

To be clear we would have no problems if the guidance were to contain advice that the use of offers etc. should be appropriate, a reminder that they are about managing workloads and that they should not be used in any way to induce patients to have surgery for whom such surgery is inappropriate. This however would be very different from the currently proposed blanket ban which, in our view, is unnecessarily prescriptive and manifestly inappropriate.

Finally, we disagree with the proposal (paragraph 4.11) that the medical director of the provider "must take responsibility for the final content for the clinical and safety content of any advertising, including imperative clinical claims etc". Whilst this may be appropriate where surgeons are working in their own small practices, it would be unreasonable to ask them to take on this role in larger providers. It is commonplace for larger providers to have a Marketing Director who is responsible for all related matters in this field. In our view, the principles in paragraphs 4.2-4.4 should therefore apply to providers not clinicians employed by them.

Needs and Wishes of Patients

Hundreds of thousands of patients resident in the UK have safely and effectively undergone community refractive surgery in the past five years with tens of thousands planning to do so each year. That they have been able to do so at reasonable prices is a testament both to the companies that provide these services and the surgeons, optometrists and other clinicians that work so effectively within them.

We cannot therefore in all honesty and in the public interest accept proposals in the College guidance which would undermine these benefits and deny services to many patients through increased costs without evidence-based justification on the grounds of safety, patient experience or outcomes. We would ask the College seriously to think again.

Anti-competitive

Finally, we are concerned that the draft guidance will have the effect of improperly distorting competition among providers of refractive surgery. The requirement that patients must be seen by the same consultant at various stages of the process without any scope for delegation to trained, registered optometrists will ensure that only a very small number of consultants will be able to deliver refractive eye surgery in accordance with this requirement. In practice, these will be the more expensive, 'Harley Street' practitioners at the higher-end of the market.

It is of substantial concern to us that the majority of consultants on the Working Group are among this group and stand to benefit substantially from the proposed changes. In that, as we have set out at length above, the proposed changes are unsupported by evidence, are unnecessary, and will greatly restrict patient choice, we cannot see any justification for the College effectively to restrict competition in the wider market, particularly in circumstances where those who stand to benefit from the changes were among its core architects.

Conclusion

In short we feel the process and the outcomes of this guidance are flawed. To publish it in its current form would, in our view, inhibit the safe expansion of community refractive surgery, potentially bring the College and professions into disrepute and be open to challenge. If that were to happen, it is likely that some providers will have substantial difficulty following some or all of the College guidance due to its prescriptive nature. Certainly, in the Optical Confederation, we may be forced to develop our own guidance for surgeons and optometrists in liaison with relevant insurer bodies.

We would be extremely reluctant to take such a step and we remain committed to working with the College to arrive at a version of the guidance which bolsters patient safety while ensuring proper access without being unnecessarily restrictive. We would far prefer to endorse College guidance to which we could lend whole-hearted support and which would not, inadvertently, reduce access to care for many patients, thereby widening the health inequalities gap, without any evidence of improvement to patient safety, quality or outcomes.

If it would be helpful, we would be more than happy to meet with the College to discuss further along with clinicians actively engaged in this field.