Are evidence-based guidelines being followed for the monitoring of ocular toxicity of hydroxychloroquine? A nationwide survey of practice amongst consultant rheumatologists and implications for clinical governance

A. Samanta, L. Goh¹ and A. Bawendi

Objective. To determine whether consultant rheumatologists monitor the ocular toxicity of hydroxychloroquine according to standards set by national guidelines.

Method. An observational cross-sectional questionnaire study of all consultant rheumatologists in the UK was undertaken. The main outcome measure was the proportion of rheumatologists who practise in compliance with nationally set standards.

Results. A wide variation in practice was found. Nearly half the respondents did not assess either baseline visual symptoms or visual acuity, and 3% undertook infrequent visual monitoring at intervals of longer than 1 yr. At least a quarter of rheumatologists within the survey routinely referred patients to ophthalmology, either for baseline visual screening or for regular visual monitoring. Such use of ophthalmology services was outside the recommendations of the guidelines and would suggest that these referrals were unnecessary. No differences in monitoring practices were ascertained between respondents from district general and teaching hospitals.

Conclusion. The present study shows that nationally set guidelines for the monitoring of ocular toxicity of hydroxychloroquine are not consistently followed by rheumatologists with regard to baseline assessment, referral to ophthalmology and frequency of monitoring. Clinical guidelines aim to reduce variations in practice and to promote uniform and consistent best practice. The present study demonstrates a lack of conformity to national guidelines in respect of the monitoring of ocular toxicity of hydroxychloroquine. Clinical governance provides a framework for assuring quality in health care. The implications of this study for clinical governance would include understanding why barriers to the use of guidelines might occur and how they might be overcome, risk management, accounting for the reasonableness of a decision for positive divergence and audit.

KEY WORDS: Hydroxychloroquine, Ocular toxicity, National guidelines, Clinical governance.

Clinical guidelines are systematically developed statements aimed to assist practitioners in optimising decisions about appropriate health care for specific clinical conditions [1]. They serve to help clinicians provide best practice based on evidence. Nationally developed guidelines aim to reduce variations in clinical practice and ‘postcode lottery’ health-care provision, and have the long-term objective of leading to uniform and consistent health care throughout the country. Clinical governance is the framework through which quality in health-care provision is assured, and is driven by the government’s agenda for the quest for excellence in the National Health Service (NHS) [2].

Hydroxychloroquine has long been used to treat a wide range of rheumatological conditions and its most serious side-effect is that of ocular toxicity [3]. In order to minimise this risk for those on long-term treatment, the Royal College of Ophthalmology (RCO) published guidelines for the monitoring of such patients [4]. These guidelines state that a baseline assessment prior to starting treatment should include asking about visual impairment and recording the best corrected visual acuity. Patients should then be monitored on a yearly basis by enquiring about visual symptoms and rechecking acuity. Referral to ophthalmologists is appropriate only if patients have visual symptoms or signs detected at baseline, or if they develop changes in visual acuity or blurred vision whilst on treatment.

The RCO guidelines are nationally endorsed and evidence based. In addition, they have the approval of two respected learned medical bodies—the Royal College of Ophthalmology and the British Society for Rheumatology (BSR). It would therefore seem a reasonable expectation that rheumatologists should monitor patients on hydroxychloroquine according to the standards set by these guidelines.

The aim of the study was to assess whether consultant rheumatologists monitored for ocular toxicity of hydroxychloroquine according to the standards set by RCO guidelines.

Methods

A questionnaire was designed on the basis of the standards for monitoring set by the RCO guidelines. The questionnaire was initially piloted locally, and refined.
A total of 465 consultant rheumatologists in the UK, identified through the BSR, were sent the questionnaire along with a letter of explanation. The questionnaire covered baseline assessment, referral to ophthalmology and long-term monitoring. Non-responders received a second distribution.

Results
Of a total of 465 rheumatologists who were sent questionnaires, 396 replies were received (85%). Of these, 40% were from teaching hospitals, 57% from district general hospitals and the remaining 3% did not specify the type of hospital in which they worked.

A total of 47 and 49% of respondents, respectively, did not assess either baseline visual symptoms or baseline acuity, and 3% undertook visual monitoring less frequently than at least once a year. Furthermore, 28 and 27% of respondents, respectively, routinely referred to ophthalmology either for baseline visual screening or for routine visual monitoring of patients on treatment with hydroxychloroquine. There was no correlation between respondents who routinely referred for visual screening and those who referred for visual monitoring. No differences were ascertained between respondents from district general or teaching hospitals in respect of their reported monitoring practices. The results are shown in Table 1.

Discussion
Although a number of clinical guidelines have been developed in rheumatology [5], to the knowledge of the authors the RCO guidelines are the only available evidence-based guidelines in the UK for monitoring ocular toxicity of hydroxychloroquine and currently reflect the ‘gold standard’. The response rate in the current study was 85%. This is higher than previous postal [6] or e-mail [7] questionnaire studies aimed at rheumatologists. The replies from respondents following a reminder were no different to those who responded the first time. It is therefore unlikely that non-responder bias would alter the results. To the authors’ knowledge there is no previously published similar study in this country. The authors believe that the present high response rate would provide a reliable reflection of current practice in this area.

About half the respondents did not undertake baseline visual assessment before starting hydroxychloroquine and 3% monitored for ocular toxicity on a basis of less than 1 year. According to the guidelines, referrals to ophthalmology should be made only if there are baseline symptoms or if ocular symptoms develop whilst on treatment. However, 28% of respondents routinely referred to ophthalmology for baseline assessment, and 27% for follow-up. These results show that practice by rheumatologists diverges from the standards set by the RCO guidelines. It is acknowledged that the present study may reflect only a ‘snapshot’ picture of a single aspect of clinical practice, and may not necessarily be indicative of what happens in other areas of practice where guidelines operate. However, the published literature from the USA [8] and the UK [9] indicate that guidelines generally may only have a modest effect on actual practice. More research is required to ascertain how closely guidelines are followed in other areas of clinical practice in rheumatology.

The purpose of nationally endorsed evidence-based guidelines is to achieve a sustained shift towards best practice in a uniform and consistent manner. If this objective is to be realised then the starting point is to evaluate current practice by measuring this against established guidelines, which act as a benchmark of best practice. Clinicians need to understand the implications that the results of such an exercise may have for clinical governance, which is the framework through which their individual practice might be affected.

First, there is a need to explore why there might be only a partial uptake of guidelines. There could be a number of hurdles between good guidelines and their practical implementation [10]. There may be doubts as to the validity or relevance of the guidelines themselves. Clinicians may lack awareness of guidelines, or be hostile to challenges to established practice. There may be work environment factors that contribute to the limited use of guidelines such as inertia of the organisation to change, lack of resources or poor organisational performance. Root causes such as these need to be examined in detail. Clinicians, managers, policy makers, educators and trainers within, as well as between, trusts need to work together through clinical governance to erode such potential barriers.

Second, the non-adherence to guidelines may be relevant to the area of clinical risk management. This would be particularly important if there is medical litigation following an adverse event consequent to guidelines not being followed. What would be the legal position in such a situation? The conventional view is that if expert testimony supports the practice of the defendant doctor, then there is no breach of the standard of care in law. However, this is by no means certain [11]. It is possible that guidelines, especially those carrying the weight of national authority, may have a more indicative role in setting the legal standard [12].

Third, it would fall within the framework of clinical governance to provide justification as to why there should be positive divergence from nationally endorsed guidelines. On an individual patient basis there might be clinical justification on a case-specific need. However, at trust level there needs to be a framework to account for the reasonableness of positive divergence, should such an organisational decision be made [13].

Finally, robust mechanisms are required within clinical governance for subjecting national guidelines to the audit process. There are at least two levels for such audits. At a local level, audit would need to be repetitive and long term in order to ensure the effective implementation of guidelines. In addition, guidelines in rheumatology need to be examined within the broader issue of national clinical governance using an externally commissioned audit. The BSR would be an obvious candidate for such a project. A possible approach would be a continuous national audit based around a short minimum data set, using electronic means of data harvesting [14].

The present study was targeted at all consultant rheumatologists in the UK, and shows that monitoring for ocular toxicity of hydroxychloroquine diverges from standards set by published guidelines. The guidelines used in this study were evidence based, nationally developed and endorsed by two respected national bodies—the Royal College of Ophthalmologists and the British Society for Rheumatology. Whilst we acknowledge that the current results reflect only a single area of clinical practice, we nonetheless believe that these results may have generic implications for practice in clinical rheumatology. Modern medical practice operates within the framework of clinical governance, which provides for the accountability of quality in health care. The aim of clinical governance is to promote best practice through the use

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<th>Table 1. Results of baseline screening, frequency of monitoring and referral to ophthalmology</th>
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<td>Respondents who did not:</td>
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<td>- Assess baseline visual symptoms</td>
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<td>- Assess baseline visual acuity</td>
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of well-developed evidence-based guidelines. Disease-modifying agents are routinely used in rheumatology, and have the potential for adverse effects. Guidelines for the monitoring of these agents have been developed to reduce the risk of harm to patients. Rheumatologists should reflect on their own practice in relation to established guidelines and should be aware of the clinical governance implications if these are not followed.

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Rheumatology

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<td>Rheumatologists do not conform to national guidelines for monitoring ocular toxicity of hydroxychloroquine.</td>
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<td>Clinicians should reflect on their practice in relation to guidelines.</td>
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<td>Clinical governance implications of non-compliance include recognizing hurdles, risk management and audit.</td>
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References