Abstract

Aims. – There is a need for evaluation of screening and grading services for diabetic retinopathy (DR) in compliance with quality-assurance (QA) standards. We describe the screening/grading QA programme set up for OPHDIAT© over the 2005–2006 period.

Methods. – Screening and grading objectives, evaluation criteria and minimum acceptable QA standards were set. To ensure the quality of DR photos, the proportion of nongradable photos in at least one eye had to be less than 10%. To ensure grading accuracy, intergrading agreement had to be greater than 90%. Grader-generated reports had to be available in less than 48 h for more than 80% photos. Readers had to grade 500 to 3000 photos per year.

Results. – Sixteen screening centres were opened between June 2004 and December 2006, and 14,769 patients were screened. Percentages of nongradable photos were consistently below the QA requirement (less than 10%). Overall, 800 photos were graded a second time by a reader blinded to original grading; agreement between graders ranged from 92 to 99%. More than 90% of grader-generated reports were produced within 48 h. The number of readings by each grader nearly achieved the QA standard.

Conclusion. – QA for DR telescreening should be a continuous process to provide performance feedback, thus guaranteeing a high standard for delivered results. Almost all of the predetermined QA standards in OPHDIAT© for screening and grading were met. Besides the quality/sensitivity of the screening/grading modalities, it is important to evaluate at-risk patients so that they can be treated efficiently; this should be addressed in a global QA programme.

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Résumé

Procédures d’assurance qualité et d’évaluation de la performance du réseau OPHDIAT©.

But. – Le but de ce travail est d’exposer les procédures d’assurance qualité mises en place sur le réseau de dépistage de la rétinopathie diabétique (RD) OPHDIAT© et leurs résultats sur la période 2005–2006.

Méthodes. – Des objectifs de qualité pour le dépistage de la RD et la lecture de photographies ont été définis. Afin de s’assurer d’une bonne qualité des photographies et de leur interprétabilité, il a été défini que le pourcentage de patients ayant des photographies du fond d’œil non interprétables dans au moins un œil doit rester inférieur à 10 %. Afin de s’assurer de la qualité de la lecture des photographies du fond d’œil, la concordance entre lecteurs doit être supérieure à 90 %. Les comptes rendus du fond d’œil doivent être à disposition des sites de dépistage dans les 48 heures pour au moins 80 % des patients. Les lecteurs doivent lire les photographies de 500 à 3000 patients par an.

Résultats. – Seize centres de dépistage ont été ouverts entre juin 2004 et décembre 2006 et 14 769 patients ont été dépistés. Le pourcentage de patients ayant des photographies du fond d’œil non interprétables dans au moins un œil est resté stable au cours de la période et toujours inférieur à 10 %. Les photographies du fond d’œil de 800 patients ont été lues une seconde fois par un lecteur ne connaissant pas les résultats de la première lecture ; la concordance entre lecteurs était comprise entre 92 et 99 %. Plus de 90 % des comptes rendus de lecture des photographies ont été réalisés dans les 48 heures après la prise de photographies. Le nombre de lectures réalisées par chaque lecteur est proche du critère préétabli.

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1. Introduction

Diabetic retinopathy (DR) is the leading cause of visual impairment and blindness in the working population today [1]. Laser photoagulation therapy is effective in reducing DR progression [2], and vitrectomy can prevent severe vision loss in subjects with advanced-stage DR in many cases [3]. However, these interventions are often initiated when DR has progressed to a measurably severe stage in which some visual acuity (VA) may already be lost. Identifying and treating subjects before the development of vision-threatening complications is therefore important and achievable only by regular eye examination.

In France, the Association de Langue Française pour l’Étude du Diabète et des Maladies Métaboliques (Alfrediam) and Agence Nationale d’Accréditation et d’Évaluation en Santé (Anaes) recommend annual eye screening after the diagnosis of diabetes [4,5].

Since the usefulness of digital photography in detecting DR has now been established [6], appropriate screening strategies involving digital image capture and transmission to digital reading centres for evaluation have been developed in several countries, such as Scotland [7] and the UK [8]. In France, a telemedical network for DR screening, ophtalmologie-diabète-télémédecine (OPHDIAT©), was successfully set up in Île-de-France and has now been operational for three years [9].

Several key components are essential to succeed in setting up a telemedical network: administration; screening; grading; referrals; treatment and follow-up; information-system management; and quality assurance (QA). The purpose of QA is to measure performance with the intention to foresee and prevent any possible problems, and to guarantee adequate confidence in the entire system and its results. It also aims to increase efficiency and effectiveness through the use of planned and systematic quality-control activities, including documentation and appropriate training. Among the key components listed above, screening and grading need to be followed closely to ensure that medically significant data are accurately assessed and referred and, where necessary, without delay. This report describes QA in relation to screening and grading activities within the OPHDIAT© network, and presents its first quality-control results.

2. Methods

OPHDIAT© is a telemedical network covering the Île-de-France area [4]. Its organization has been described elsewhere [9]. Briefly, the network comprises 16 local screening centres, opened between 2004 and the end of 2006, linked through a central server to the OPHDIAT© Reading Centre (Fig. 1). Each local screening centre is equipped with a nonmydriatic camera (model CR-DGI, Canon, Tokyo, Japan, or model TRC-NW6, Topcon, Rotterdam, The Netherlands), with the retinal photographs taken by trained orthoptists or nurses. After appropriate JPEG compression, the photos are sent, together with administrative and clinical data, to the central server, where they are stored. Six certified ophthalmologists in the OPHDIAT© Reading Centre grade the photos after downloading them from the central server. The grader-generated reports, including diagnosis of DR level, diagnosis of nondiabetic ocular disorders and recommendations for follow-up, are sent to and stored in the central server. Reports are printed at the local screening centres after uploading them from the central server, and sent by mail to general practitioners (GPs) and patients. All the transactions between the local screening centres, the central server and the OPHDIAT© Reading Centre take place through the Internet.

Screening and grading objectives, evaluation criteria, and the minimum acceptable QA standards associated with these objectives and derived from the French recommendations for DR screening, were recently approved by the French Society of Ophthalmology (http://www.sfo.asso.fr) and are presented in Table 1.

To meet these objectives, all of the operators responsible for screening and grading received intensive theoretical and practical training. At the local screening centres, all camera operators/retinal screeners received a half-day of theoretical training, and a three-day practical course on camera operation and retinal photo acquisition. The theoretical training was given by two ophthalmologists (AE and PM) and one qualified orthoptist (NR). General information on diabetes and its complications, on DR (rationale and objectives of screening) and on OPHDIAT© were given in the theoretical session. The orthoptist was responsible for the practical sessions. The use and maintenance of digital cameras, the acquisition, transfer and archiving of the retinal photos, appraisal of the quality and interpretability of the photos, as well as the recognition of artifacts requiring further photography, were studied during the three-day course. The screeners were also trained on the software used and on the security of the network. The objective was to maintain the proportion of nongradable photos to below 10% (Table 1).

Before they began to grade the retinal photos, all screeners also underwent an intensive training programme provided by the senior ophthalmologist (AE) responsible for the OPHDIAT© Reading Centre. The monitors to be used for displaying the retinal photographs had to be a minimum of 19 in, with a minimum resolution of 1280 × 1024, and able to show more than 60% of
the image at any time on the screen, as per the official French recommendations [10].

Over the course of this programme, DR was discussed, and retinal photos read to practice how to detect and accurately grade DR. Image quality was assessed, again according to the French recommendations [10]. A photograph was considered to be of acceptable quality if the centre of the fovea and the retinal vessels were clearly visible, and if more than two thirds of the image could be assessed. DR was graded according to the simplified French DR classification system for DR screening [11]. After reading and grading at least 100 retinal photos, each trainee performed a self-evaluation with test photos representing different DR grades to check the accuracy of interpretations; the objective was to achieve a rate of at least 90% accuracy. Furthermore, after receiving an accreditation to grade, each grader was supervised by an experienced reader during the first two or three assessments.

Interpretive accuracy of the retinal photos was verified quarterly. At this time, retinal photos of 50 subjects (200 photos) randomly selected from the central server database were regraded by the senior ophthalmologist (AE), who was blinded to the previous grading. The percentage of concordant gradings was recorded. The objective was to obtain at least 90% agreement between both assessments (Table 1).

The time lag between receiving the retinal photos on the central server and their interpretation (the grader-generated report) was assessed every six months. The objective was to read and interpret at least 80% of the photos within 48 h of their arrival at the central server (Table 1).

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Criteria</th>
<th>Minimum QA standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>To ensure photographs are of adequate quality</td>
<td>Percentage of nongradable patients for at least one eye</td>
<td>&lt; 10%</td>
</tr>
<tr>
<td>To ensure grading is accurate</td>
<td>Intergrader consistency</td>
<td>&gt; 90%</td>
</tr>
<tr>
<td>To ensure timely reporting of abnormal screening results</td>
<td>Time lag between screening and grading of the photographs</td>
<td>80% &lt; 48 h</td>
</tr>
<tr>
<td>To maintain high standard of the graders and avoid errors due to fatigue</td>
<td>Number of patients assessed by each grader per year</td>
<td>Minimum 500</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maximum 3000</td>
</tr>
</tbody>
</table>
Table 2
Date of initiation, type and activity (2005–2006) of local screening centres

<table>
<thead>
<tr>
<th>Local screening centres</th>
<th>Date of initiation</th>
<th>Type</th>
<th>Activity 2005</th>
<th>Activity 2006</th>
<th>Activity 2005 + 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lariboisière</td>
<td>20-Jun-2004</td>
<td>H</td>
<td>906</td>
<td>934</td>
<td>1847</td>
</tr>
<tr>
<td>Bichat</td>
<td>03-Sep-2004</td>
<td>H</td>
<td>666</td>
<td>891</td>
<td>1574</td>
</tr>
<tr>
<td>Avicenne</td>
<td>15-Sep-2004</td>
<td>H</td>
<td>724</td>
<td>640</td>
<td>1376</td>
</tr>
<tr>
<td>ALIS 73</td>
<td>15-Sep-2004</td>
<td>V</td>
<td>418</td>
<td>261</td>
<td>673</td>
</tr>
<tr>
<td>UCSA Fresnes</td>
<td>01-Dec-2004</td>
<td>P</td>
<td>75</td>
<td>67</td>
<td>142</td>
</tr>
<tr>
<td>Hôpital-Dieu</td>
<td>20-Dec-2004</td>
<td>H</td>
<td>1330</td>
<td>1565</td>
<td>2905</td>
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<tr>
<td>Kremlin-Bicêtre</td>
<td>01-Jan-2005</td>
<td>H</td>
<td>404</td>
<td>411</td>
<td>816</td>
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<tr>
<td>St-Louis</td>
<td>20-Apr-2005</td>
<td>H</td>
<td>523</td>
<td>1064</td>
<td>1614</td>
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<tr>
<td>Diabore</td>
<td>01-Jun-2005</td>
<td>V</td>
<td>45</td>
<td>187</td>
<td>260</td>
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<tr>
<td>Cochin</td>
<td>01-Jul-2005</td>
<td>H</td>
<td>126</td>
<td>716</td>
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<td>01-Jul-2005</td>
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<td>97</td>
<td>762</td>
<td>873</td>
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<td>Jean-Verdier</td>
<td>01-Jul-2005</td>
<td>H</td>
<td>154</td>
<td>684</td>
<td>841</td>
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<tr>
<td>CES 93</td>
<td>01-Mar-2006</td>
<td>V</td>
<td>–</td>
<td>98</td>
<td>98</td>
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<tr>
<td>Corbeil-Essonne</td>
<td>01-Apr-2006</td>
<td>H</td>
<td>–</td>
<td>541</td>
<td>589</td>
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<tr>
<td>CH Dreux</td>
<td>01-May-2006</td>
<td>H</td>
<td>–</td>
<td>175</td>
<td>175</td>
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<tr>
<td>CMS Gennevilliers</td>
<td>01-Jun-2006</td>
<td>V</td>
<td>–</td>
<td>57</td>
<td>71</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>5468</td>
<td>9053</td>
<td>14,521</td>
</tr>
</tbody>
</table>

H: hospital; V: (ville), primary-care setting; P: prison.

Finally, to maintain a high standard and avoid errors due to fatigue, each grader ideally assessed only 500 (minimum) to 3000 (maximum) patients per year (Table 1).

Any deviation from the minimum acceptable QA standards set for screening and grading activities was to be analyzed and dealt with immediately by appropriate corrective actions (such as further personal training, material replacement or environmental modifications).

As all the transactions between the various servers were via the Internet, access to the OPHDIAT© network was username- and password-protected, and all transactions were 128-bit encrypted. An audit trail monitored the activities of the OPHDIAT© network: date and time, user identification, and the programmes or commands used to initiate a transaction were recorded for each and every transaction. Access to the audit logs was strictly controlled to prevent unauthorized access, including any modifications to their integrity. The collection, storage and use of the subjects’ data were in compliance with the directives of the Commission nationale de l’informatique et des libertés (CNIL).

3. Results

Sixteen local screening centres were opened between June 2004 and December 2006. Their opening dates, location/type (hospital, primary-care setting, prison) and activity (number of DR screening examinations) are presented in Table 2. Eleven of these centres were opened in hospitals and accounted for 91.5% (13,510/14,769) of the total activity of the OPHDIAT© network; four centres (comprising 7.5% of the total activity) were opened in a primary-care environment and one centre (1%) was in a prison.

The percentages of nongradable photos per quarter and per type of centre during 2005–2006 ranged from 0.0 to 46.1% (Fig. 2). In the summer of 2005, an especially high and unexpected rate (46.1%) of nongradable photos was recorded in the prison-based centre, which was traced back to an insufficiently trained technician. Otherwise, the proportion of nongradable photos per quarter was consistent and almost always below the minimum acceptable QA standard (<10%).

During 2005–2006, 800 (5.4%) retinal photos (two photos per subject; 50 subjects per quarter) were randomly selected from the central server database to be graded a second time by a reader blinded to the original grading. Agreement among graders ranged from 92 to 99% (Fig. 3). During this period, 37 inconsistencies were recorded, consisting of 36 underestimations (false negatives) and one overestimation (false positive) of the disease. Among the 36 underestimations, 34 eyes were diagnosed as ‘normal’ instead of having mild nonproliferative diabetic retinopathy (NPDR), including one undiagnosed microaneurysm. These diagnostic errors had no clinical consequences. One eye was diagnosed with mild instead of moderate NPDR (so the patient was not referred to an ophthalmologist when he should have been), and one eye was diagnosed with moderate instead of severe NPDR (no negative outcome as this patient was referred to an ophthalmologist). The overestimation concerned an eye diagnosed with mild NPDR instead of ‘normal’ (the error was due to an artifact).

During the 2005–2006 period, more than 90% of the retinal photos on the central server were interpreted within 48 h of having arrived (and more than 70% were interpreted within 24 h) (Fig. 4).

The number of readings by each grader during 2005–2006 (Fig. 5) nearly reached the predetermined QA standards (between 500 and 3000 readings per year), and one reader (AE, the senior ophthalmologist responsible for the OPHDIAT© Reading Centre) assessed more than 3000 patients in 2006 while another reader (SJ) had only joined the OPHDIAT© Reading Centre in 2006.
4. Discussion

The efficiency and effectiveness of telemedicine in the detection and management of DR have already been demonstrated in several countries, such as Scotland [7] and the UK [8], where national programmes are now in place. Telemedicine has the potential to improve DR screening [12]. Indeed, it provides several advantages over the standard ophthalmological examination. It allows for the availability of multiple screening sites that are independent of the presence of a local ophthalmologist, thus enhancing patients’ access to care. The combined lack of pupil dilation, rapidity of the evaluation procedure and easy access to screening sites are all advantages that can increase patient compliance with the recommended yearly fundal examination. Teletransmission also makes it possible to send all photographs to a centralized Fundus Photography Reading Centre. The use of skilled readers and standardized protocols makes for an improved quality of interpretation of the images.
Even when the grader is an ophthalmologist, our experience has shown that the grading process using telemedicine is more efficient. An ophthalmologist can read around 15 telemedicine cases per hour as opposed to taking half a day to conduct 15 examinations with ophthalmoscopy after pupil dilation. In addition, centralized grading makes daily grading possible even while limiting the burden of work for each grader, who may only have to grade once a week.

However, the successful setting-up of a telemedical network is complex as it requires, among other things, that many systems be managed by professionals who have dedicated responsibilities. To guarantee efficiency in such a system, adequate QA procedures need to be in place, with standards that are set and validated. For this, several recommendations are already available [7,8,13]. France has also recently issued guidelines for DR screening using fundal photography [10].
OPHDIAT© is the first telemedical network to be established in France for DR screening; specific QA standards were set to ensure the quality of photos and accuracy of grading, and to reduce the time between screening and grader-generated reports. The quality of the retinal photos is of the greatest importance as they can be only assessed if the grader is assured of their quality. In addition, the lower the proportion of rejected photos, the more efficient the system performance, as any suspected DR in poor-quality photos requires a referral for further clinical assessment, which is time-consuming. The QA standard set to maintain the percentage of nongradable patients to less than 10% was less stringent than the less than 5% used in the UK [14]. In the UK, however, screening is carried out after pupil dilation to facilitate retinal imaging. This improves the quality of the photos, of course, but it is also inconvenient for the patient as it involves being unable to drive a car for at least two hours after the examination. Without mydriasis, this standard (<5%) would be difficult to achieve. In France, guidelines set the criteria for nongradable patients to less than 10% [10]. To reach this objective, all of our camera/retinal screeners received theoretical and practical training with, as the minimum requirement, the ability to recognize unsatisfactory images so that corrective actions could be taken immediately. Theoretical training is important because these operators are often the first to be in contact with patients and can, therefore, gain the patients’ confidence by discussing screening outcomes and treatment options with them. In OPHDIAT©, the overall proportion of nongradable patients was within the minimum QA standard set, although there were some localized exceptions. Because it is essential to have high-quality retinal photographs, an orthoptist was recently appointed to train and teach the camera/retinal operators at each screening centre.

Grading the photos must also be closely monitored, as this is an integral part of the guarantee of confidence in the whole system. First, reading conditions and especially the characteristics of the displays used for grading were defined and met. However, as guidelines exist and access to high-performance displays is becoming easier every day, this is no longer a problem. Also, grading accuracy needs to be continuously assessed. In OPHDIAT©, all the graders received training from a senior ophthalmologist. In addition, they performed their first two or three grading sessions under the supervision of an experienced reader. There are several ways to increase the accuracy of grading, and one is to provide graders with access to a database (DB) of selected and relevant retinal photos to help them to accurately identify and grade DR. Such a DB, located on a website, is under construction in the OPHDIAT© network.

The assessment of the quality of grading by double-readings of selected DR photos appears to be a standard technique across all the various guidelines in use. However, there are differences in the recommendations as regards the number of photos to be read twice, the procedures used for selecting such photos and how to measure agreement itself; for example, agreement between two graders may be as simple as a ‘yes’ or ‘no’, or it may be rather more sophisticated and include weighted deviations [15]. The number of photos to be read twice can also vary widely [16,17]. In OPHDIAT©, about 5% of the photos were read twice. The procedure for selecting those 5% is a heavy task as, in our system, it has to be done manually, although the procedure will soon be fully automatic, as a result of the increase in the proportion of photos to be reread. Our objective is to read about 10% of our photos a second time—which translates to 1400 photos for the 2005–2006 period and 35 half-days of work.

The agreement between the double-readings in our system was satisfactory; in most cases, any inconsistencies corresponded to underestimations with no clinical consequences. Only one eye was misdiagnosed with mild instead of moderate NPDR, and so was not referred to an ophthalmologist; however, the risk for moderate NPDR to progress to sight-threatening DR at one year is low, around 5% [18], and the subsequent examination after one year, as recommended, would probably have corrected the diagnosis. Furthermore, in general, fundal photography is more sensitive than biomicroscopy for the detection of DR [19].

Finally, the time between screening and delivery of a grader-generated report was also monitored. Our QA criterion to deliver more than 80% of the grader-generated reports within 48 h of screening was met, and was even more stringent than the UK’s requirement [8,14]. Also, even though this criterion is perhaps the most difficult to fulfil due to the growing number of screening centres and the difficulty of recruiting graders, this QA standard was nevertheless satisfied in OPHDIAT©, as more than 90% of the grader-generated reports were produced within the 48 h following screening. Nevertheless, the current lack of cost considerations of the reading task does not encourage reader recruitment. However, the French health authorities have recently reached a consensus concerning reading fundal photographs in the absence of the patient (Haute Autorité de Santé, http://www.has-sante.fr), and this may prompt the French National Health Insurance System to draw up a cost estimation. Moreover, automated reading systems are currently being developed in several countries, and are likely to prove helpful in the future [20].

Quality control for diabetic retinopathy telescreening should be a continuous process that evaluates every service and provides feedback on performance, thus guaranteeing that a high standard of results is delivered. We defined the evaluation criteria and the minimal acceptable QA standards related to screening and grading within the OPHDIAT© network, and this was the first step in the implementation of those procedures. Almost all of the QA standards set in OPHDIAT© were achieved. Nevertheless, we are aware that, in addition to the quality/sensitivity of the screening/grading modalities, it is also important to provide tools to identify those at risk so that they can be treated early and efficiently. Additional QA procedures have yet to be set up and a QA standard agreed upon.

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