

Quality of vision: A consensus building initiative for a new ophthalmologic concept

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PURPOSE. *Many studies have addressed the quantification of visual acuity, and the conventional method of measuring it has so far demonstrated serious limitations. Vision testing requires new methods that can more precisely express the quality of vision as perceived by the patient.*

METHODS. *This study employed the Delphi method of consensus building. Concepts associated with quality of vision (QoV) were identified by a board of experts and proposed to participating specialists in two subsequent questionnaires. Upon receipt of the completed questionnaires, the replies were classified to determine the building blocks of a consensus.*

RESULTS. *By analyzing the replies to the two questionnaires, the authors determined the key elements of QoV on which a consensus was found among the respondents.*

CONCLUSIONS. *A consensus was reached on the opinion that the quantification of visual acuity by traditional means is inadequate for investigating QoV. Although visual acuity is still a basic element for testing, the experts believe that contrast sensitivity, reading speed, and microperimetry are additional parameters necessary for quantifying QoV. The use of a psychometric questionnaire on visual function could allow a better interpretation of visual impairment. (Eur J Ophthalmol 2006; 16: 851-60)*

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INTRODUCTION

The quantification of visual capacity has been frequently studied in recent years. The conventional means of measurement, using the Snellen chart, has shown serious limitations that have been highlighted recently by new treatment strategies for visual impairments

(1-4). One of the more striking examples involves photodynamic therapy (PDT): numerous published trials have demonstrated that the change in visual acuity is not proportional to the outcome measured with other techniques, such as contrast sensitivity testing or microperimetry (5-10).

It has also been found that the patient's subjective

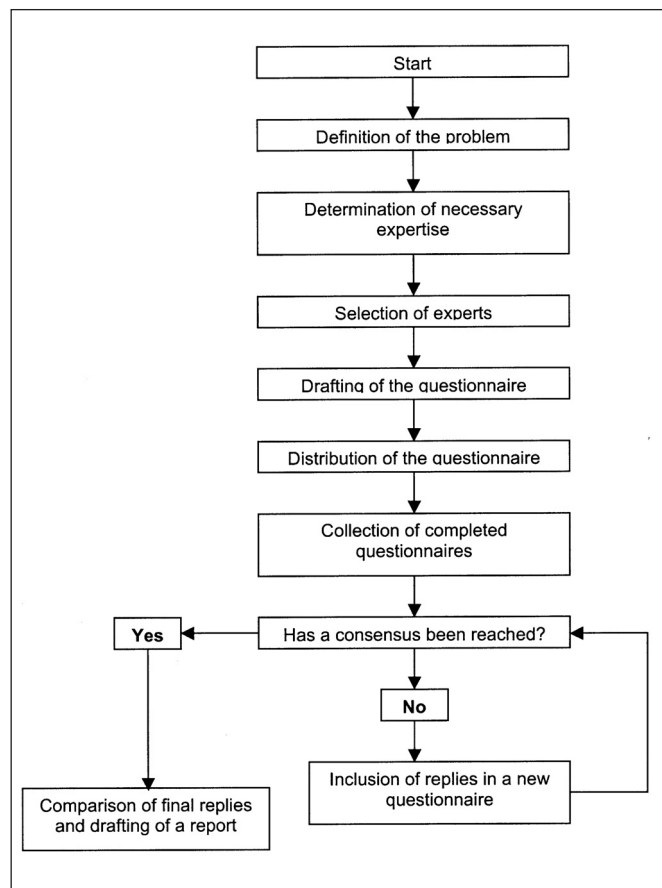


Fig. 1 - Phases of the Delphi method.

experience does not always correspond to the conventional objective measurement of vision. The most classical tests, like the Snellen chart, explore the sensitivity of just a tiny fraction of central vision. Most experts agree that vision measurement requires new methods that more precisely express the quality of vision as perceived by the patient (11-13).

More recently developed techniques have tried to gather more information on the functional capacities of the sense of sight. They have achieved this by using tests that measure retinal function as well as foveal sensitivity, and by quantifying the impact of vision loss on quality of life (11, 14-16).

The purpose of this study was twofold: to measure the degree of consensus on the need to use new instruments for determination of quality of vision among patients with age-related macular degeneration (ARMD), and to determine which instruments are best suited to this purpose.

METHOD

The Delphi method

The study employed the Delphi technique, conceived and developed in the mid-1950s by researchers at the Rand Corporation as a way to predict the impact of technologies or interventions on complex systems, which has often been used in the social and health care context (17-19).

The Delphi method (Fig. 1) is traditionally based on three fundamental concepts. The first is anonymity. The participants never meet each other during the process. Each submits his or her opinions independently, by completing a specially designed questionnaire. The replies are then disclosed to all participants, without identifying the particular respondent. The second concept is controlled feedback. The process consists of several rounds, during each of them the respondents are asked to judge all the opinions expressed in the previous rounds, often presented in the form of statistics. The last concept is statistical group response. The Delphi method reaches a collective opinion or a collective decision and expresses it in terms of a statistical score.

In addition to these basic characteristics, the Delphi method can be described as follows:

- It requires individual effort for the expression of an opinion.
- It requires written answers to questionnaires.
- The individual opinions (questionnaire responses) are collected and assembled by the project coordinator.
- The respondents have enough time to come up with and evaluate opinions (unlike task force meetings, in which, quite often, not enough time is allowed to assess other people's opinions).

The positive results from previous studies, aimed at assessing the Delphi method's ability to make an accurate synthesis of several individuals' opinions, have encouraged the use of this technique in various sectors. It has been shown that the Delphi technique can overcome many of the limitations intrinsic to traditional group decision-making processes.

Usually, the presence of one or more of the following aspects in a process using the Delphi method ensures the success of the procedure:

- The problem being addressed does not lend itself

to evaluation by way of highly precise analytical techniques, but may benefit from the subjective opinions of a group of experts.

- The experts who are asked to evaluate the issue at hand represent different currents of thought, in terms of their personal experience and/or expertise.
- The method requires a higher number of experts than could effectively interact at a meeting.
- Problems of time, cost, and geographical distance would make it difficult and impractical to hold frequent meetings.

Another advantage of the Delphi method is its flexibility. Depending on the nature of the problem, the method can be adjusted for improved overall efficacy. For example, since the use of strict statistical methods for setting guidelines is rather problematic, due to the qualitative nature of the expected result, the use of modified classification procedures makes it possible to monitor and express the process by which a consensus is developed.

The Delphi method and the consensus on quality of vision

To judge the level of expert consensus regarding the concept of quality of vision, the Delphi method was used according to the standard sequence of events. A small group of specialists, the board of experts (comprised of nine retina specialists selected from Italian universities, university clinics, and private ophthalmologic institutions), examined the scientific literature (1-16, 20-33) and developed a 16-item, multiple-choice questionnaire (Q1; Tab. I). The questionnaire was designed for an expert panel consisting of 70 ophthalmologists, including retinologists and non-retinologists, randomly selected from within the country. As a psychometric tool the board of experts chose the 25-item National Eye Institute Visual Function Questionnaire (VFQ-25), derived from direct interviews with patients with a variety of eye disorders.

The Q1 questionnaire was designed on the basis of the following criteria:

1. The most commonly used tests for measuring vision (Snellen and ETDRS charts).
2. New tests developed in recent years (reading speed, contrast sensitivity, and microperimetry).
3. The effects of visual impairment on quality of life, measured by new psychometric tests (VFQ-25).

4. Exclusion of all aspects not relating to ARMD.

Q1 was written in order to avoid possible bias caused by inadvertently influencing replies, so the sequence of questions follows no apparent logic. The rule of thumb in deciding on three hypothetical replies was to include one highly unlikely choice, one highly likely choice, and one of average probability. For each question, space was provided for comments. As usual, two apparently off-topic questions (11 and 14) were included to decondition the respondent.

Q1 was then sent to the expert panel of 70 ophthalmologists.

After the replies to Q1 were processed, a second questionnaire (Q2) was developed, in which the replies to the Q1 questions that were chosen in the majority of cases were presented once again for classification on a scale of 0 (total disagreement) to 9 (complete agreement) (Tab. II). Q2 was presented to the same expert panel and replies were collected and processed in the same way as for Q1.

To better analyze the replies to Q2, three categories of agreement were defined:

- Score of 0–3: Disagreement
- Score of 4–5: Partial agreement
- Score of 6–9: Agreement

All data were analyzed using SPSS Statistical Software (SPSS Inc., Chicago, IL, USA). After every round, the level of agreement was evaluated based on the percentage of similar answers to each question. To reach consensus, a cut-off level of 75% of agreement was required for the first round (Q1) and 60% for the second round (Q2). These consensus levels were established in consideration of the literature (34) and agreed on by all members of the board before the study began.

On the basis of the replies to Q1 and Q2, a draft consensus was drawn up and discussed by the board of experts in order to determine the elements of quality of vision on which a definitive consensus had been reached.

RESULTS

The percentage of respondents choosing each reply is presented in Tables I and II. By analyzing and evaluating the replies to both questionnaires, the board identified the following statements about quality of

TABLE I - QUESTIONNAIRE 1 FOR THE EVALUATION OF THE DEGREE OF CONSENSUS ON KEY ELEMENTS OF QUALITY OF VISION

1.	Do you think that the concept of quality of vision (QoV) is relevant in clinical practice?	
	No	3.7%
	Somewhat	22.2%
	Very much	74.1%
2.	Assuming that the three problems that most affect quality of life in the elderly are hearing loss, vision loss, and motor impairment, which of the three do you think is most disabling?	
	Hearing loss	1.9%
	Vision loss	87.0%
	Motor impairment	11.1%
3.	Regardless of the clinical type of vision loss, do you think that conventional Snellen charts are sufficient for measuring QoV, or would QoV be better investigated in another manner?	
	Conventional Snellen charts are thorough and sufficient	1.9%
	Snellen charts provide a partial but sufficient assessment of QoV	5.6%
	Snellen charts should be supplemented with other examinations for the evaluation of QoV	92.5%
4.	Various vision problems make nighttime and daytime driving more difficult and therefore cause dependence on other people. In your opinion, what is the most important function to investigate to account for this difficulty?	
	Retinal sensitivity in the macular area	17.2%
	Contrast sensitivity	70.7%
	Visual acuity measured with Snellen charts	12.1%
5.	Most patients with maculopathy complain that it is difficult to read. What is the most important function to investigate to quantify that limitation?	
	Visual acuity (ETDRS)	10.5%
	Reading speed	80.7%
	Fixation stability	8.8%
6.	Many ophthalmologic problems lead to enough vision loss to affect the patient's psychological state, by aggravating anxiety or causing depression. What test should be administered to best correlate vision loss with the psychological dimension?	
	Measurement of visual acuity (ETDRS)	3.6%
	Measurement of visual distortion (Amsler Grid)	3.6%
	National Eye Institute Visual Function Questionnaire (NEI VFQ-25)	92.8%
7.	In patients with visual impairments, the limited ability to perform everyday activities or common manual tasks is conditioned by their reduced independent mobility. What is the best way to investigate this aspect?	
	Measuring visual acuity (Snellen charts)	13.8%
	Measuring contrast sensitivity	19.0%
	Testing for absolute or relative scotoma (perimetry/microperimetry)	67.2%
8.	Although most vision problems emerge late in life, it is not uncommon to see clinically relevant vision impairments in younger patients. Do you think QoV should be investigated with different tools depending on the patient's age?	
	QoV is independent of age	59.3%
	Yes, with different tools for patients older or younger than 60	25.9%
	Yes, with different tools for patients older or younger than 40	14.8%
9.	The sudden onset of central vision impairment has significant consequences for the performance of many sight-related tasks. In this early phase, what is the most important aspect to investigate in terms of the consequences on QoV?	
	Reading speed	27.4%
	Visual acuity (ETDRS)	35.5%
	Visual distortion (Amsler Grid)	37.1%
10.	Patients with visual impairments have more frequent household accidents that are often associated with bone and joint injuries. What is the best tool for testing the function most closely related to the higher rate of accidents?	
	National Eye Institute Visual Function Questionnaire (NEI VFQ-25)	56.9%
	Measurement of contrast sensitivity	29.4%
	Measurement of fixation stability	13.7%

TABLE I - CONTINUED

11. By law, driver's licenses are subject to minimum standards of vision that basically concern visual acuity as measured with Snellen charts. In addition to the above, what other test would you most highly recommend to judge the ability to drive safely?	
Reading speed	1.8%
Retinal sensitivity in the macular area	17.9%
Contrast sensitivity	80.3%
12. In your opinion, when studying the costs/benefits of a new treatment, is visual acuity as measured by Snellen charts a sufficient variable on its own or should other aspects be considered?	
Snellen charts are sufficient	1.8%
The testing of visual acuity (Snellen charts or ETDRS) should be supplemented with the NEI VFQ-25	67.3%
The testing of visual acuity (Snellen charts or ETDRS) should be supplemented with the measurement of contrast sensitivity	30.9%
13. Most QoV tests require a specific amount of time to be set aside during the patient examination. In your opinion, what is the ideal length of time for such testing?	
10 min	16.7%
25 min	70.3%
40 min	13.0%
14. Do you think the effect of vision loss on QoV should be investigated in all ophthalmologic patients?	
Yes, all patients	25.9%
No, only patients with visual acuity in the better eye of $\leq 5/10$	70.4%
No, only patients with visual acuity in the better eye of $\leq 1/10$	3.7%
15. If a patient complains to you of the sudden onset of visual distortion and vision loss, what is the best examination for the purpose?	
Fundus examination	71.7%
Fluorescein angiography	21.7%
Optical coherence tomography	6.6%
16. In a patient with normal visual acuity (as measured by Snellen charts) who complains of vision problems while driving, what is the most important function to test?	
Reading speed	3.6%
Contrast sensitivity	63.6%
Macular retinal sensitivity and fixation (microperimetry)	32.8%
Answers are expressed as percentage of all responses.	

vision that attained expert agreement of 75% or more (34):

01. The concept of quality of vision is relevant in clinical practice.
02. *In the elderly, among the impairments that most affect quality of life, vision loss is the most disabling.*
03. Regardless of the clinical type of vision problem, Snellen tables must be supplemented with other tests to evaluate quality of vision.
04. The variable that expresses nighttime and daytime driving difficulties and the resulting dependence on other people is contrast sensitivity.
05. The variable that should be tested to quantify reading problems in patients with maculopathy is reading speed.
06. The tool that should be used to best correlate vi-

sion loss with the psychological dimension is the National Eye Institute Visual Function Questionnaire (NEI-VFQ 25).

07. In patients with visual impairments, the limited ability to perform everyday activities or common manual tasks is conditioned by their reduced independent mobility. The best way to investigate this aspect is by searching for absolute or relative scotoma (perimetry/microperimetry).
08. Although most vision problems become significant at an advanced age, it is not uncommon to see clinically relevant visual impairments in younger patients, confirming that quality of vision is not dependent on age.
09. The sudden onset of central vision impairment has significant consequences for the performance of many sight-related tasks. In this early phase, the

TABLE II - QUESTIONNAIRE 2 FOR THE EVALUATION OF THE DEGREE OF CONSENSUS ON KEY ELEMENTS OF QUALITY OF VISION

	Score: 0–3: disagreement	Score: 4–5: partial agreement	Score: 6–9: agreement
1. The concept of quality of vision is highly relevant in clinical practice.	0.0%	0.0%	100.0%
2. In the elderly, of the impairments that most affect quality of life, vision loss is the most disabling.	2.0%	2.0%	96.0%
3. Regardless of the clinical type of vision problem, Snellen tables must be supplemented with other tests to evaluate quality of vision.	0.0%	2.0%	98.0%
4. The variable that expresses nighttime and daytime driving difficulties and the resulting dependence on other people is contrast sensitivity.	0.0%	4.1%	95.9%
5. The variable that should be tested to quantify reading problems in patients with maculopathy is reading speed.	2.0%	0.0%	98.0%
6. The tool that should be used to best correlate vision loss with the psychological dimension is the National Eye Institute Visual Function Questionnaire (NEI VFQ-25).	0.0%	0.0%	100.0%
7. In patients with vision impairments, the limited ability to perform everyday activities or common manual tasks is conditioned by their reduced independent mobility. The best way to investigate this aspect is by testing for absolute or relative scotoma (perimetry/microperimetry).	4.0%	4.0%	92.0%
8. Although most vision problems emerge late in life, it is not uncommon to see clinically relevant visual impairments in younger patients, because quality of vision is independent of age.	4.0%	6.0%	90.0%
9. The sudden onset of central vision impairment has significant consequences for the performance of many sight-related tasks. In this early phase, the aspect that best expresses the effects on quality of vision is visual distortion (measured using the Amsler Grid).	8.0%	18.0%	74.0%
10. Patients with visual impairments have more frequent household accidents that are often associated with bone and joint injuries. The most appropriate tool for evaluating the function best correlated with this increased rate of accident is the National Eye Institute Visual Function Questionnaire (NEI VFQ-25).	2.0%	8.2%	89.8%
11. By law, driver's licenses are subject to minimum standards of vision that basically concern visual acuity as measured with Snellen charts. The ability to drive safely should also be judged by measuring contrast sensitivity.	0.0%	2.0%	98.0%
12. In evaluating the cost/benefit ratio of a new treatment, the measurement of visual acuity (Snellen or ETDRS charts) should be supplemented with the National Eye Institute Visual Function Questionnaire (NEI VFQ-25).	2.0%	4.1%	93.9%
13. Quality of vision should ideally be evaluated through tests lasting a total of 25 minutes or less.	0.0%	4.0%	96.0%
14. Quality of life changes caused by visual impairments should only be analyzed in patients with visual acuity of <5/10 in the better eye.	12.0%	8.0%	80.0%
15. If a patient complains to you of the sudden onset of visual distortion and vision loss, the best examination for the purpose is fundus examination.	0.0%	0.0%	100.0%
16. In a patient with normal visual acuity (as measured by Snellen charts) who complains of vision problems while driving, the most important function to test is contrast sensitivity.	2.0%	6.0%	92.0%

Answers are expressed as percentage of all responses

aspect that best translates the effects on quality of vision is visual distortion (measured using the Amsler Grid).

10. Patients with visual impairments have more frequent accidents in the home that are often associated with bone and joint injuries. The most appropriate tool for evaluating the function best correlated with this increased rate of accident is the National Eye Institute Visual Function Questionnaire (NEI-VFQ 25).
11. By law, driver's licenses are subject to minimum standards of vision that basically concern visual acuity as measured with Snellen charts. The ability to drive safely should also be judged by measuring contrast sensitivity.
12. In evaluating the cost/benefit ratio of a new treatment, the measurement of visual acuity (Snellen or ETDRS charts) should be supplemented with the National Eye Institute Visual Function Questionnaire (NEI-VFQ 25).
13. Quality of vision should ideally be evaluated through tests lasting a total of 25 minutes or less.
14. Quality of life changes caused by visual impairments should only be analyzed in patients with visual acuity of $\leq 5/10$ in the less impaired eye.
15. If a patient reports the sudden onset of visual distortion and vision loss, the best examination for the purpose is fundus examination by means of biomicroscopy.
16. In a patient with normal visual acuity (as measured by Snellen charts) who complains of vision problems while driving, the most important function to test is contrast sensitivity.

DISCUSSION AND CONCLUSIONS

Age-related macular degeneration is the leading cause of blindness in people aged 65 or over in developed countries (3, 21). As the average life expectancy increases, a higher percentage of the population is likely to develop this serious sensory impairment. In recent years, new treatments have been developed to prevent or limit damage from this disease. The Macular Photocoagulation Study (MPS) (22) demonstrated the effectiveness of laser treatment in ARMD with extrafoveal choroidal neovascularization (CNV), and the Treatment of Age-Related Macular Degeneration

with Photodynamic Therapy (TAP) Study showed that PDT is effective for the long-term limitation of damage caused by subfoveal CNV (5, 6).

The main endpoint of these and many other well-designed trials, aimed at testing new medical treatments or surgical procedures, has been visual acuity as measured through conventional methods. Specialists agree, however, that changes in visual acuity can express only part of the subjective perception of vision. Questionnaires have thus been developed to assess the extent to which vision problems affect everyday activities and therefore quality of life (11-13). Dating to 1998, these tools are gradually joining the array of diagnostic tests included in most clinical protocols. One extensively used questionnaire is the VFQ-25 (or the 39-item version), which measures quality of life in relation to quality of vision. The VFQ-25 investigates and quantifies the full range of problems that a visually impaired patient may face. Numerous studies have confirmed its validity and its correlation with conventional tests.

In ARMD, the VFQ-25 has been widely used for research and comparison during the various phases of the illness. A recent study by Mangione et al (11) demonstrated that the VFQ-25 score correlates closely with the increasing severity of ARMD. Early stages of the disease, dry ARMD (unilateral and bilateral), and wet unilateral ARMD are associated with gradually poorer VFQ-25 scores, correlating with vision loss. If wet ARMD affects the fellow eye as well, there are serious consequences for vision-dependent activities like driving or reading. Such complaints are not paralleled by a corresponding loss of vision. For example, the score for driving remains very close to normal values until CNV appears in the other eye. At that point the score drops sharply, suggesting that patients give up driving at the onset of bilateral neovascularization. Interestingly, there is no correlation between worsening vision and the subjective perception of general health, as measured by the SF-36 Health Survey Questionnaire. There is only a weak correlation with subjective depression or anxiety, as evaluated with the Hospital Anxiety and Depression Scale (35).

These studies demonstrate that in order to prevent serious consequences on patients' quality of life, maximum effort must be addressed to limit the damage resulting from the onset of bilateral exudative ARMD. Other studies, such as those on photodynamic ther-

apy, have shown that outcomes differ according to the visual test administered. In the TAP study, for example, contrast sensitivity showed significantly better outcomes than the conventional (albeit essential) measurement of visual acuity (5). Finally, everyday experience, in light of sophisticated new treatment options, is a constant reminder that eye charts are inadequate to express a patient's subjective perception of quality of vision.

In theory, the problem could be solved with the systematic use of questionnaires like the VFQ-25, but these have obvious limitations in terms of testing time and proper comprehension of the questions, which in turn relates to the patient's mental and psychological condition. Another approach would be to use scores on specific subscales, depending on the illness in question. For example, the subscales used to test patients with ARMD would be different from those used to test patients with glaucoma, since in the former case central vision is affected while in the latter the damage is to peripheral vision.

The above considerations led to the need to identify the test or set of tests that can most accurately investigate the aspects a patient is able to quantify with the VFQ-25. The project was dubbed QoVI (Quality of Vision Index) and divided into two phases: 1) the assessment of the degree of consensus on these issues in a sample of experts with frequent clinical experience with ARMD patients; 2) the recommendation of solutions that take into account different tests or sets of tests to ensure a strong correlation with the VFQ-25.

The opinions expressed by the experts in Questionnaires 1 and 2 can be summarized as follows:

- The participants agree that QoV is a concept that deserves closer attention in clinical practice, since vision loss is known to be more severely disabling to individuals than other common impairments.
- In general, ophthalmologists agree that the conventional measurement of visual acuity is not sufficient to express QoV.
- The main indication for an investigation of QoV is best-corrected visual acuity lower than 0.5.
- Although age can cause vision problems per se that affect QoL, the same instruments can be used to evaluate QoV, regardless of age.
- A total examination time of 25 minutes is considered appropriate for measuring QoV.
- According to the respondents, contrast sensitivity is an important factor in ability for nighttime and daytime driving.

- Reading speed is the key variable for the investigation of reading difficulties in patients with maculopathy.
- The ways that visual impairments affect a patient's psychological health, social life, and employment are accurately measured by questionnaires such as the NEI VFQ-25, which is also considered useful for assessing cost/benefit issues.
- The only significant disagreement is over which test to use for front-line evaluation in the case of sudden vision loss.

In conclusion, a consensus was reached on the opinion that the measurement of visual acuity by conventional means is inadequate for investigating QoV. Although visual acuity is still a basic element for testing, the experts believe that contrast sensitivity, reading capability, and microperimetry are all parameters necessary for quantifying QoV. In addition, the use of a psychometric questionnaire on visual function could allow a better interpretation of visual impairment.

The limited literature available on this issue confirms the importance of the present study, which is the first survey conducted with robust statistical and methodologic criteria. The main finding is the existence of an expert consensus on the need for a new tool that expresses visual capability more accurately than conventional methods. This is especially important considering the extensive amount of ongoing clinical trials aimed at investigating the effectiveness of new sophisticated treatments for exudative ARMD.

A subsequent step should be to determine whether three or more tests may be combined into a QoV Index that, with sensitivity and precision, can monitor visual changes in a manner better correlated with the psycho-cognitive dimension of vision.

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