What Patients Want

Consumer Involvement in the Design of a Randomized Controlled Trial of Routine Oxygen Supplementation After Acute Stroke

Khalid Ali, MBBS, MRCP; Christine Roffe, MRCP, MD, FRCP; Peter Crome, MD, PhD, FRCP, FFPM

Background and Purpose—To involve stroke patients and carers in the design of a study of oxygen supplementation in acute stroke and to obtain their views on the importance of the study, consent issues, relevance, and acceptability of the outcome measures, and the preferred method of follow-up.

Methods—This study involved qualitative and quantitative research. Three focus group meetings were held with individuals who have had personal experience of stroke, mostly stroke patients and their partners or carers (an association of young stroke sufferers and 2 dysphasia support groups each from a different town in the West Midlands, UK). The researchers explained the planned oxygen supplementation study and encouraged participants to comment and make suggestions in a semistructured interview. The audience was then asked to complete a questionnaire relating to the study.

Results—Seventy-three people (67% stroke patients and 33% carers; mean age 64; range 31 to 86 years; and 47% males) attended the 3 meetings. The overall response rate to the questionnaires was 70%. Most of the respondents considered the study worthwhile (97%) and the planned outcome measures relevant. In addition, assessment of speech, memory, sleep, and cognitive function was raised by >20% of respondents as important outcomes. Seventy-five percent would agree with assent from a family member on behalf of incompetent patients, and 92% would agree to a doctor recruiting incompetent patients to the study and seeking consent/assent later. The majority of respondents (80%) preferred personal contact with the researcher or a representative to a questionnaire for follow-up.

Conclusions—Involvement of stroke patients and carers helped us identify outcome measures that are important to the stroke population but not routinely addressed in stroke assessment scales. A high proportion of respondents asked for waiver of consent and agreed to family’s assent on behalf of incompetent patients. Although consumer involvement has helped us to make the study more relevant to the public, it has also led to difficult scientific and ethical conflicts in protocol design. (Stroke. 2006;37:000-000.)

Key Words: caregivers ■ ethics, medical ■ informed consent ■ outcome ■ stroke

Consumer involvement in the early stages of planning research has become a medical as well as a political priority.1–4 It is encouraged by research ethics committees in the United Kingdom but is not a compulsory requirement for obtaining ethical approval. A survey by Chambers et al showed that only a small percentage of researchers actively involve the public in consultation before undertaking their research.5 Consultation is especially relevant because the available evidence suggests that clinicians’ and patients’ agendas and priorities can be quite different.6

Involvement of patients and carers empowered by information is likely to result in an overall better standard of clinical service delivery and care. Thus, consumer involvement has become an integral part of the development of clinical stroke management guidelines in the United Kingdom.7,8

Potential benefits of consumer involvement in the planning and design of research include better recruitment, a more reliable and acceptable research protocol, and dissemination of the results through consumers, leading to improved standards of care after evidence-based clinical practice. A study of consumer involvement in solving the ethical problems related to thrombolysis for acute stroke showed that 89% of respondents were prepared to accept the treatment with its inherent risk of fatal intracranial hemorrhage in the context of a clinical trial. Consumer involvement helped in addressing complicated ethical dilemmas in consent issues, improved consent procedures, and resulted in a trial design which was ethically sound and acceptable to the research ethics committee.9

The objectives of the consultation presented here were to identify the opinions and views of stroke patients and carers on: (1) the relevance and importance of a planned study of the effect of routine oxygen supplementation after an acute stroke on the functional outcome; (2) ethical and consent issues; (3) the relevance of the planned outcome measures to individuals who...
have had personal experience of stroke; and (4) methods for follow-up.

The aim of involving the stroke population in the design of the study (see supplemental Appendix 1 for a flow chart of the proposed Stroke Oxygen Study, available at http://stroke.ahajournals.org) was to identify their priorities and produce research that is realistic based on real-life patients and carers and responsive to their needs and expectations.

Methodology

General Design

Focus Group Discussions have been shown to be a valuable tool in identifying the personal experiences of a group relating to a subject\textsuperscript{10–12} but may be dominated by the views of a few outspoken individuals. Questionnaires can be completed confidentially and may encourage participation of a wider group of individuals, but the information gained is dependent on the questions asked. For this consultation, consumers’ views on the proposed research protocol were assessed by qualitative and quantitative methods using focus group interviews and anonymous questionnaires. The focus group meetings were conducted using a structured interview technique described as “a conversation with a purpose” by Holoway and Wheeler\textsuperscript{10} in which the speakers strive to give equal opportunities for all attendants to express their opinions freely to avoid 1 vocal participant dominating the discussion.

Identification of the Relevant Focus Groups

Individuals with personal experience of stroke were identified by contact with local and regional stroke groups. The first focus group meeting was held with group A (a group of younger stroke patients and their partners who meet socially on a monthly basis). To avoid bias, 2 additional groups (groups B and C: the dysphasia support groups) were chosen from outside the catchment area of the local hospital, hence they would not have had any past or potential future contact with any of the researchers or the services they provide.

The Focus Group Meetings

**Meeting 1 (Stroke-on-Trent)**

The first meeting started with a verbal presentation from 1 of the authors (C.R.) describing the planned oxygen supplementation study supported by a 1-page handout (see supplemental Figure 1). The second author (K.A.) took handwritten notes from the responses of the participants. The presentation was followed by free discussion of the project details. All participants were then asked to complete a questionnaire (see supplemental appendix 2) and post it back to the authors in a prepaid stamped addressed envelope. After the first meeting, the print size was increased and the wording of the questionnaire was modified slightly to improve reading ease and comprehension.

**Meeting 2 (Stafford)**

Meeting 2 was conducted by K.A. and a member of the dysphasia support group in a similar format to the first meeting using the modified questionnaire.

**Meeting 3 (Cannock)**

Meeting 3 was conducted by K.A. in a similar way to the above, but in addition, the meeting was also recorded with a tape recorder after taking consent from the audience. Rather than asking the participants to send the questionnaires by mail, they were asked to complete the questionnaires at the end of the meeting to improve response rate. All the questionnaires were anonymous. Each meeting lasted ~90 minutes and was held in a meeting room local pub (meeting 1) or a community hall (meetings 2 and 3).

Results

**Demographic Characteristics of Participants at the Focus Group Meetings**

A total of 73 people attended the 3 meetings: 34 in the first meeting, 19 in the second, and 20 in the third. There were 39 females (53%) and 34 males (47%). The age range of the respondents was 31 to 86 years, with an average of 64 years. There were 49 stroke patients (67%) and 24 carers (33%). The stroke patients had had their strokes 6 months to 5.5 years ago.

The demographic characteristics of attendants at each of the 3 focus group meetings were: mean age 60, 64, and 68 years; the male female ratio was 18/16, 10/9, and 10/10; 9, 6, and 9 were carers or partners of stroke sufferers; and for stroke sufferers, the time since the stroke was 2.4, 3.0, and 3.6 years, respectively.

**The Focus Group Discussion**

**Relevance of the Research Topic to the Group**

After explaining the rationale and the research question to the audience, the group was asked whether they considered the study topic relevant. This did not generate a lot of discussion in any of the 3 meetings, but there appeared to be general approval judging by the lack of disagreement and the general impression of the researchers.

**Outcome Measures Considered Relevant**

Focus group members were then asked to suggest outcome measures that they considered important. This generated a lively discussion in the first but less comments in the second and third meetings. Outcomes suggested by group members mainly focused on communication, swallowing, mood, and cognition. The most important were: ability to speak (mentioned 5 times), mood (depression mentioned twice and mood mentioned twice), mental function (a measure of intelligence, ability to concentrate), swallowing (mentioned twice), tiredness, sleep, and a 1 to 10 score of how much the patient is “back to his old self.” Purely physical functions were only mentioned twice (ability to use a fork, ability to button up a shirt).

**Consent Issues**

It was explained that the treatment (oxygen) would have to be given within 24 hours of the stroke and that many patients are unable to give fully informed consent to a research study because of the effects of the stroke. The group was asked to comment on whether these patients should be included in the study or not and who should give consent if the patient was unable to do so. In the first and second meetings, consent/assent issues hardly generated any discussion or comments. The audience drifted into issues of how a stroke was diagnosed, other treatments, and thrombolysis. However, there appeared to be general agreement that many stroke patients will be unable to give fully informed consent, and assent from relatives or a friend is acceptable. The issue of waiver of consent did not generate any discussion in this meeting, but there appeared to be general agreement. One relative asked whether nonresearch doctors from the accident and emergency unit could recruit patients to the study. In the third meeting there was a lively discussion of the topic. Responses given by group members are shown in Figure 1.
Follow-Up Arrangements

Further group discussions focused on the timing and method of follow-up. There was general agreement in all 3 groups that follow-up at 6 months was appropriate, and that it was acceptable to contact the general practitioner (GP) to obtain information on the health status of the patient. The suggested methods of follow-up by postal questionnaire, telephone, and contact with the GP were accepted and did not generate much discussion in the first group meeting. Some of the members suggested alternative means of contact such as fax and email. In the other 2 focus groups (dysphasia support groups Stafford and Cannock), this topic was more controversial (see Figure 2 for comments). Most respondents preferred personal contact (via the researcher at home, in an outpatient clinic, or via a personal visit from a volunteer from the dysphasia support group) to a postal questionnaire. Assessment of outcome via the telephone was not considered appropriate. Several individuals suggested that 1 visit at 6 months was not enough and that further appointments at 3, 12, and 24 months should be added. It was also suggested that not only the patients but also the carers should complete a questionnaire because they may have different views on patients’ progress.

Other Issues

Other comments raised in the discussion, but not directly related to the topics above, are shown in Figure 3.

"Some patients do continue to improve up to one year or more, so the follow up period should be extended up to a year or more."

"Contact by phone is not a good idea, better by personal appointment."

"Why not more assessments at 3, 6, 9 and 12 months?"

"Volunteers from the Dysphasia Support Group should visit patients and carers at home to help them complete filling in the study questionnaires."

"I think it would be a good idea for the doctor to see the patient with his or her family to explain exactly what brain damage has occurred, and what to expect. When my wife had her stroke, the consultant explained where the stroke was and it was a relief to know what you can and can’t do."

"I think most people would agree that it would be far more beneficial if they were actually met on a one-to-one basis in their own homes. I know this would be more time consuming, but they would be in a more relaxed environment and their relative or carer could be there as well."
Responses to the Questionnaires
Fifty-one (70%) of the focus group participants responded to the questionnaires, 36 (70%) have had a stroke themselves, and 15 (30%) were partners/carers of stroke patients. Questions and responses are shown in the Table. The majority of respondents thought the oxygen supplementation project was a worthwhile study and that the suggested outcome measures (a neurological score to assess the level of brain damage, a more general measure to assess the level of disability, a measure of quality of life, a measure of the ability to perform basic activities of daily living, and a measure of the ability to perform extended activities of daily living such as diving and shopping) were relevant, and all agreed that it was acceptable to contact the GP for further information and that follow-up at 6 months was appropriate. In addition to the scores mentioned in the questionnaire, respondents suggested adding other outcomes such as movement scores (n=9; 18%), mental acuity (n=9; 18%), concentration (n=8; 16%), a measure of intelligence (n=6; 12%), handwriting skills (n=6; 12%), sleep (n=5; 10%), tiredness and fatigue (n=5; 10%), speech (n=6; 12%), vision (n=5; 10%) and enjoying hobbies such as music (n=3; 5%) to the protocol. Some of these (movement, handwriting skills, social activities) are covered in the outcome assessment tools that were planned for the study (Barthel Index to assess activities of daily living, the modified Rankin Scale to assess the level of disability, the EuroQuol to assess quality of life, and the Nottingham Extended Activities of Daily Living Scale to assess wider aspects of participation activities of daily life), but memory, attention, sleep, and tiredness are not part of the standard assessment scores for outcome after stroke. Thirty-eight (75%) respondents thought it would be appropriate for the family or carers to give assent on behalf of an incompetent patient to be included in the study. Forty-seven respondents (92%) would allow a doctor to recruit an incompetent patient to the study and seek consent or assent later on (waiver of consent).

Discussion
The use of an oral presentation to a focus group of individuals with personal experience of stroke followed by open discussion and a later questionnaire survey allowed the collection of qualitative and quantitative information on consumers' views of the proposed research project. The active participation of the audience who asked a wide range of questions on different aspects of strokes and stroke trials showed that the public does want to share its experiences and is willing to participate in the planning stages of new research. There was general agreement and little discussion about the relevance of the research topic. The topics that generated most discussion were consent issues, outcome measures, and the method and timing of follow-up.

Consent Issues
Stroke patients and their carers were aware of cognitive problems and the resulting inability to give fully informed consent. Most felt that inability to consent should not exclude patients from participation in a research study. The responses to this question may have been affected by the projected low risk of the suggested treatment (oxygen). However, even a higher risk treatment (thrombolysis) has been shown to be acceptable to consumers in a previous consultation, as long as there is a possibility of benefit. Waiver of consent has been suggested as an option by Lindley, Doyal, and the

Figure 3. Verbal comments not directly related to the topic of discussion.
National Institute of Neurological Disorders and Stroke workshop participants. In the United States, the Food and Drug Administration will consider waiver of consent if the following conditions are fulfilled: (1) the research involves no more than minimal risk to the subjects; (2) the waiver or modification will not adversely affect the rights and welfare of the subjects; (3) the research could not be practically performed without waiver or modification of consent; and (4) whenever appropriate, the subjects should be provided with additional pertinent information after participation. Among the scientific and ethics communities, there is general agreement that waiver of consent should only be used as a last resort when no other option is feasible. In the consultation presented here, more respondents agreed with waiver of consent than with assent from the next of kin. Reasons given for this were that relatives are emotionally involved, that they may not fully understand the risks and benefits, and that patients would not want their relatives to be exposed to the stress of the decision making in addition to the stress of the stroke. Waiver of consent was suggested by several group members but should be decided by a doctor not involved in the study rather than by the researcher. Solomon et al. showed that severe strokes may be viewed by patients as tantamount to or worse than death. This may explain the willingness of the stroke population to agree to being included in any stroke trial that may bring a beneficial outcome to the participants.

Outcome Measures

The most commonly used outcome measures in stroke research (Rankin Score, Barthel Score, National Institutes of Health Stroke Scale and similar neurological scales, and quality of life measures) focus mainly on physical health and physical recovery. There is increasing evidence that in the long term, quality of life after stroke is determined more by cognitive and emotional problems than by the level of disability. Most of the outcomes mentioned in this consultation were related to communication, mood, cognitive function, tiredness, and sleep. These are not well represented in the standard assessment tools. Most are subjective and cannot be assessed reliably in patients with dysphasia, thus excluding a significant number of patients from outcome assessment. A previous survey has shown that there are discrepancies between what medical professionals or researchers and members of the general public might consider reasonable recovery after a stroke. After the consultation, we added the outcomes suggested to the protocol. To our knowledge, there are no validated aphasia, sleep, and memory assessment tools for stroke patients suitable for questionnaire surveys. We therefore designed our own questions to address these points (Figure 4). Although this is likely to lead to results more relevant to the public, it might affect the scientific rigor of the study. Ideally, all outcomes should be assessed by validated and well-established assessment tools to allow comparison with other studies. It is also important to limit the number of different outcomes to reduce the risk of random variation producing spurious “significant” results, and the additional measures increase the number of outcomes. Also, most outcomes suggested by focus group members are subjective, and cannot be reliably assessed in patients with dysphasia, thus excluding a significant number of patients and leading to results that may not be representative of the whole sample. The potential conflict between scientific in-

<table>
<thead>
<tr>
<th>Responses to the Questionnaire Survey</th>
<th>Yes (n,%)</th>
<th>No (n,%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you think the study is a worthwhile research project?</td>
<td>50 (98%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Do you think the stroke related deficits we are measuring at the end of the study reflect your priorities as a stroke patient or carer?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A neurological score to assess brain damage</td>
<td>51 (100%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>A more general measure to assess disability level</td>
<td>49 (96%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>A measure of quality of life</td>
<td>51 (100%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>A measure to perform basic activities of daily living</td>
<td>50 (98%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>A measure to perform extended activities of daily living like driving</td>
<td>49 (96%)</td>
<td>2 (4%)</td>
</tr>
</tbody>
</table>

If oxygen is going to work, it is best given as soon as possible after the stroke. Most patients will not be able to give fully informed consent at this point in time.

- Do you think it would be appropriate to ask a member of the patient’s family or a close friend to assent to the study on behalf of the patient? | 38 (75%) | 13 (25%) |
- Would you be happy for another doctor not involved in the study to decide on behalf of the patient? | 47 (92%) | 4 (8%) |
- Would you be happy for the researchers to contact the patients and find out how they are doing after 6 months? | 51 (100%) | 0 (0%) |

What would be the most appropriate method of contact?

- By telephone | 2 (4%) | ... |
- By a postal questionnaire | 10 (20%) | ... |
- In an outpatient clinic | 39 (76%) | ... |
- Would you be happy for your GP to be asked about your condition 6 months after being included in the study? | 51 (100%) | 0 (0%) |

Should patients be given the option to be included in more than one study?* | 25 (49%) | 26 (51%) |

*This question was only included in the questionnaires for groups 2 and 3.
The findings in this consultation relate to the study discussed and may not all be generalizable to other studies. This would apply particularly to issues of consent and the general value of the research but less to the groups’ comments on outcome measures and follow-up.

Participants in the focus groups were not a random selection representative of all strokes but younger, socially active, and living at home. Most participants who had had a stroke had had their strokes several years before. Frailer individuals and those without access to private transport would not have been able to attend the meetings. Such selection bias is inevitable for focus group discussions but does not invalidate the findings. We cannot exclude that we have missed issues important to frail and very elderly patients. The fact that 2 of the 3 meetings were held with dysphasia support groups may have introduced bias with greater emphasis on communication problems. However, communication was also raised as 1 of the most important outcomes in the focus group meeting held with younger strokes (Stoke). In the discussions about follow-up, only members of the dysphasia groups considered telephone follow-up unacceptable. This is clearly related to their personal experience of dysphasia and the fact that telephone communication in this condition is difficult, if not impossible. We do not consider this a bias but an important aspect to consider in study design.

Conclusions

The involvement of stroke patients and carers helped us identify important outcome measures very important to the stroke population but not routinely addressed in the stroke assessment scales. They also helped in clarifying their preferred method of follow-up after a stroke. Although assent by the next of kin is the most commonly used method of involving incompetent patients in research studies, this consultation suggests that consumers may prefer waiver of consent. Although consumer involvement has helped us to make the study more relevant to the public, it has also led to difficult scientific and ethical conflicts in protocol design.

Follow-Up

Although most multicenter studies opt for follow-up by questionnaire, patients and carers in this consultation preferred personal contact. This may not be possible for large studies because of the costs involved but should be made an option for patients who feel uncomfortable with completing questionnaires and for patients with dysphasia. Most ongoing multicenter studies will allow telephone contact as a main or supplementary method of outcome assessment. A large number of respondents in the consultation reported here rejected this method of contact as inappropriate. This question raised no comments in the first consultation with the young strokes group members but was considered very important in the 2 meetings with the dysphasia groups. However, personal contact may lead to potential bias in an open trial if performed by the local investigator and is very expensive. We therefore suggest that alternative methods of follow-up should be done by an independent assessor and offered to dysphasic patients but not as a routine for all follow-ups.

Limitations of This Study

The population included in this consultation all had personal experience of stroke and may be more willing to be involved in research because of this. Some of the participants of the first focus group meeting may have been cared for by 1 of the researchers in the past, and this may have biased responses. It can also be argued that the researchers knew some of the members in the focus group in the first meeting from the stroke clinic. The second and third meetings were conducted with a group of stroke patients and carers who were not involved with the researchers in any clinical context. The questionnaires were anonymous, and there were no major differences between the outcomes of the discussions and the questionnaire.

Figure 4. Outcomes added to the protocol after the focus group discussion.
14. Doyal L. Informed consent in medical research: Journals should not publish research to which patients have not given fully informed consent—three exceptions. BMJ. 1997;314:1107.
Appendix 1

Stroke Oxygen Study (SOS)

Flow chart

Patient eligible for the study
Acute stroke
Less than 24 hours after hospital admission
No definite indications for oxygen treatment
No definite contraindications for oxygen treatment
No other serious medical condition limiting life expectancy to a few months or less

Explain study
Obtain informed consent or informed assent

Document baseline oxygen saturation
Complete randomisation form

Phone xxxx to randomise the patient

Prescribe
Either or

No routine oxygen
Oxygen is not given routinely, but may be prescribed if definite clinical indications develop

Humidified oxygen per nasal cannula for 3 nights
3 l/min if oxygen saturation at baseline is ≤ 93%
2 l/min od oxygen saturation at baseline in > 93%

Continuous humidified oxygen per nasal cannula for 72 h
3 l/min if oxygen saturation at baseline is ≤ 93%
2 l/min od oxygen saturation at baseline in > 93%

1 week post recruitment
Complete Assessment Form 1
Compliance, highest/lowest BP/HR/T/O2, antibiotics, sedatives, NIHSS, CT/MR diagnosis

6 months post recruitment
SOS team to send assessment form 2 to the patient
(home/institution, Rankin, Barthel ADL, EuroQuol, Nottingham EADL)

Please contact Dr C. Roffe, Springfield Unit, City General Hospital, Stoke-on-Trent for any queries regarding the study. SOS team contact numbers: Daytime 01782/552313. Nights and Weekends 01260 28 11 59. Mobile 07740 372852.
Appendix 2
The Questionnaire

We would be extremely grateful if you could fill in the following questionnaire:

1. Are you male or female?
2. How old are you?
3. Have you had a stroke, or are you a carer/relative?  Yes  No
4. If you have had a stroke, how long ago?
5. Do you think the study is a worthwhile research project?  Yes  No

6. Do you think the stroke-related deficits we are measuring at the end of the study reflect your priorities as a stroke patient or carer?
   - A neurological score to assess the level of brain damage  Yes  No
   - A more general measure to assess the level of disability  Yes  No
   - A measure of quality of life  Yes  No
   - A measure of abilities to perform basic activities of daily living  Yes  No
   - A measure of the ability to perform extended activities of daily living such as driving and shopping  Yes  No

7. What other relevant issues should be asked to reflect the late problems in strokes?

8. If oxygen is going to work, it is best given as soon as possible after the stroke. Many stroke patients will not be able to give fully informed consent at this point in time.
   - Do you think it would be appropriate to ask a member of the patient's family or a close friend to consent to the study on behalf of the patient?  Yes  No
   - Would you be happy for another doctor not involved in the study to decide on behalf of the patient?  Yes  No
   - Would you only allow recruitment of patients who fully understand the consent form and patient information leaflet?  Yes  No

9. Would you be happy for the researcher to contact patients to find out how they are doing after 6 months?  Yes  No

10. What would be the most appropriate method of contact?
    By phone
    By a postal questionnaire
    In an outpatient clinic

11. Would you be happy for your GP to be asked about your condition six months after being included in the study?  Yes  No

12. Would you be happy for a stroke patient to be included in more than one research study?  Yes  No
The Stroke Oxygen Study
Dr C. Roffe / Dr K. Ali

Many stroke patients have low or borderline low oxygen levels. Oxygen levels may fall after the stroke, even in patients who have normal levels on admission. Low oxygen levels may increase the brain damage caused by the stroke. Too much oxygen could also damage the brain. Oxygen treatment is safe, cheap and painless, and could be given routinely to all stroke patients, but does limit mobility of the patients. Since early mobilisation is one of the most important aspects of acute stroke care, oxygen treatment may interfere with this.

Routine oxygen treatment could prevent hypoxia and worsening brain damage. It could, however limit mobility, and delay rehabilitation.

We therefore do not know whether it is best to give oxygen to all stroke patients or whether it should only be given to patients with low blood oxygen levels.

The aim of the study is to find out:

1. Whether oxygen should be given routinely after stroke
2. Whether it is best to give it just at night when it does not interfere with rehabilitation
3. Which patients are most likely to benefit.

We may have to recruit up to 4000 patients to the study to find the answer to these questions.

We would like to discuss the study with you and get our views on whether it is worthwhile, its design, the consent process and on the method of assessing outcome.

Figure I.
What Patients Want. Consumer Involvement in the Design of a Randomized Controlled Trial of Routine Oxygen Supplementation After Acute Stroke

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