ESPRAS
European Society of Plastic, Reconstructive & Aesthetic Surgery

Research proposal:
Scientifically developed and evidence-based quality indicators in breast reconstruction
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Introduction

The World Health Organisation (WHO) defines quality in healthcare as 'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with evidence-based professional knowledge' (https://www.who.int/news-room/fact-sheets/detail/quality-health-services). During the past decades, the usage of quality indicators (also called performance indicators and quality measures) has become increasingly popular to make performance data publicly available and are often reported annually by hospitals/governmental bodies. Quality indicators concern structure, process, and outcome

measures [1]; that is, technical aspects of health care such as attributes of the healthcare provider, steps taken in providing the healthcare and the impact of the healthcare on the patient or population [1].How the quality indicators are developed is a key factor to whether they will truly increase quality in healthcare and detect suboptimal structures, processes, or outcomes [2]. Ideally quality indicators are based on clinical studies, but such evidence is rarely sufficient and therefore the experience of experts often needs to be incorporated. In such a process, the transparency of the methodological process and the composition of the expert group are key to the validity of the quality indicators [3].

Currently, the only available quality indicator for breast reconstruction is the *proportion of patients receiving immediate reconstruction at the same time as mastectomy*. The indicator level/standard of care has been set at a minimum of 40 per cent [4]. The development process of the indicator as well as the scientific rationale and evaluation of it is unclear. It is not detailed and transparent how the working group, developing the quality indicator, was established and no board-certified plastic surgeons, the only speciality with knowledge about and experience of all types of breast reconstructions, were included in the core group [4]. Nor were any representatives, with active roles in any of the professional societies for plastic and reconstructive surgeons involved. This makes the credibility of the quality indicator low [2]. Another key element in guideline development is the establishment of an analytical framework on which to base the gathering and evaluation of scientific evidence and the rationale for the resulting guidelines and quality indicators [5]. In case of the quality indicator for breast reconstruction no such framework is stipulated and the evidence for the indicator is not graded. Nor has the evidence, scientific soundness, and transparency of development for the standard of

care been presented. The group motivates this by ‘cosmetic satisfaction’ and ‘quality of life’. Nonetheless, it is unclear whether a 40 percent frequency of immediate breast reconstruction affects the probability of achieving these outcomes and will produce credible and reliable improvements of care [2]. Moreover, the indicator has not been risk adjusted [2], that is it is not adjusted for patient related factors that can influence the frequency of immediate breast reconstructions, such as comorbidities making a breast reconstruction medically unsound. For example, in the group of patients having a mastectomy there will be women having it to avoid radiotherapy postoperatively due to comorbidities or because breast preserving surgery might be afflicted with a higher rate of complications. In such patients it is likely that breast reconstruction is not a viable option. The frequency of such patients might vary between different types of hospitals and different types of geographical areas. In addition, the quality indicator does not take into consideration that breast reconstruction is a preference sensitive adjunct in breast cancer treatment and not all women might want a breast reconstruction, which makes frequency of women having it a less valid quality indicator and might even encourage *gaming* [6], that is to improve the result of the indicator directly rather than the underlying system which is whether women who want breast reconstruction have access to it or not. It may also promote *measurement fixation* [6], where meeting the target becomes more important than the spirit of the measurement and other important aspects in the health care delivery, for example encouraging women who have a large risk for complications to have breast reconstruction as only the frequency of women having reconstruction is measured, not the frequency of complications. [6]. Risk of *Tunnel vision* occurs when a quality indicator displaces other important factors that are not measured [6], in the case of breast reconstruction for example the frequency of reconstructive

failure and long-term revision rates. Such effects are of little benefit to the patients and do not increase quality. This underlines that professionals working with breast reconstruction on a daily basis and those who see the entire spectrum of potential benefits and drawbacks with breast reconstruction should be involved in the development of quality indicators [6].

In brief, there are no scientifically established quality indicators for breast reconstruction with a sufficient level of credibility that meet criteria of validity, reliability, sensitivity, specificity, and feasibility (applicability) [1, 7], to be implicated in clinical practice.

Aim

The aim of this study will be to develop evidence-based quality indicators for breast reconstruction using scientific methods.

Methods and statistical analysis plan (SAP)

Quality indicators will be developed using the Delphi technique, which has been used for quality-indicator selection since the 1970s [3, 8, 9]. The Delphi technique is a group consensus method in which a consensus is achieved by members of an expert panel participating in a series of anonymous questionnaire rounds. Individual and group feedback is collected between several rounds and the level of agreement between panel members is measured. The strength of the method lies in the anonymity of panel members, whilst still enabling the possibility of the panel to react to each other's statements. This effectively limits the dominance of any strong and outspoken individuals. In a classical Delphi method, participants never meet or directly interact. This makes the inclusion of panel members from a large geographical area possible. The specific

guidelines on how to use the Delphi technique to develop quality indicators that have been suggested by Boulkedid et al [3] will be followed.

Creation of the expert panel (criteria to choose potential participants, size, and composition): Potential experts will be asked about participation. The following data will be recorded for the experts: country where the expert is living/working, specialty (plastic surgeon, patient, reconstructive nurse), and years of experience as breast reconstructive plastic surgeon or breast reconstruction nurse. Among health care workers, only surgeons/nurses subspecialists in breast reconstruction will be asked to participate; hence, the choice will be based on expertise in the field. Patient representatives will be asked from the formal patient organisations and recruited by the experts in every country. Experts will be recruited through the elected national delegates of ESPRAS. However, as not all national delegates are subspecialized in breast reconstruction, they are able to delegate the recruitment to the national plastic surgical society or other formal channel in the country in question.

Experts have to fulfil predetermined criteria and be able to communicate in English.

Study definition of plastic surgeon:

- Board certified plastic surgeon in the country where they work > 5 years
- Subspecialist in breast reconstruction >5 years
- Work in a department of plastic surgery in a university hospital

Study definition of reconstructive nurse:

- Registered nurse in the country where they work

- Work regularly with breast reconstruction patients >3 years
- Work in a department of plastic surgery in a university hospital

Study definition of patient representative:

- A representative chosen by the elected board of a national or local patient organisation for breast cancer patients

Included countries: Countries recognised by the United Nation (UN) as European countries, as well as geographical boundaries, were used to define European countries. Transcontinental countries classified as European States by the UN were included (Azerbaijan, Georgia, and Turkey). Russia was excluded as the European Commission has suspended Russian research cooperation, the European Union does not launch any new research projects with Russian Universities and researchers. In addition, some European universities have put a ban on collaborations and the European University Association has advised that only co-operations with Russian organisations committed to 'shared European values' are initiated (https://efmc.eu/scientific-collaboration-with-russian-partners-in-the-current-situation/). In addition, countries with less than 100 000 inhabitants were excluded: San Marino, Andorra, Monaco, Vatican City, and Liechtenstein.

Number of experts of the different countries:

One expert will be included from all participating countries (Figure 1).

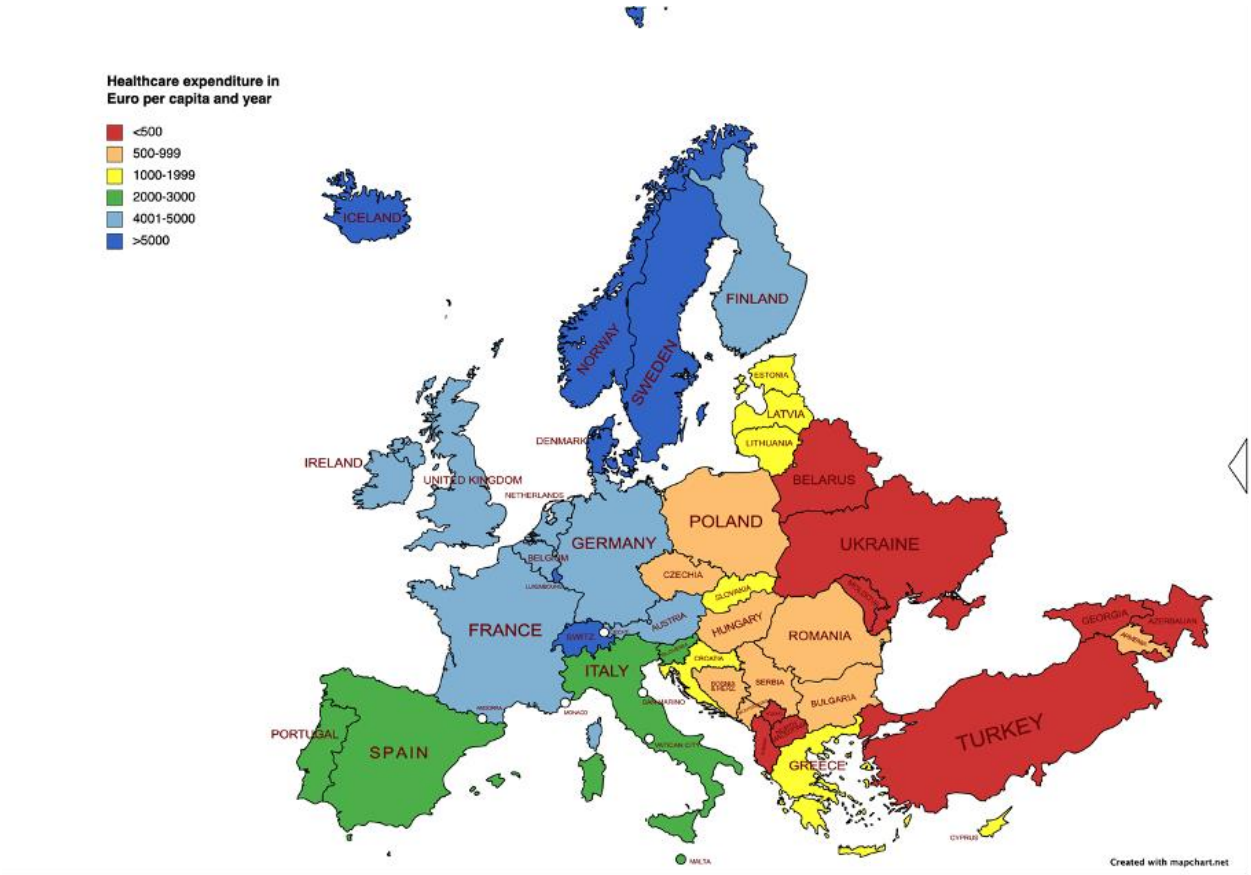

Figure 1. Healthcare expenditure in Euro per capita and year. Blue countries spend more than 4000 euro and will be given two extra experts. Green countries spend more than 2000 euros and will be given one extra expert.

In addition, all EU countries with < 35 million inhabitants will be given an extra expert and all EU countries with >35 million inhabitants two extra experts (Figure 2).

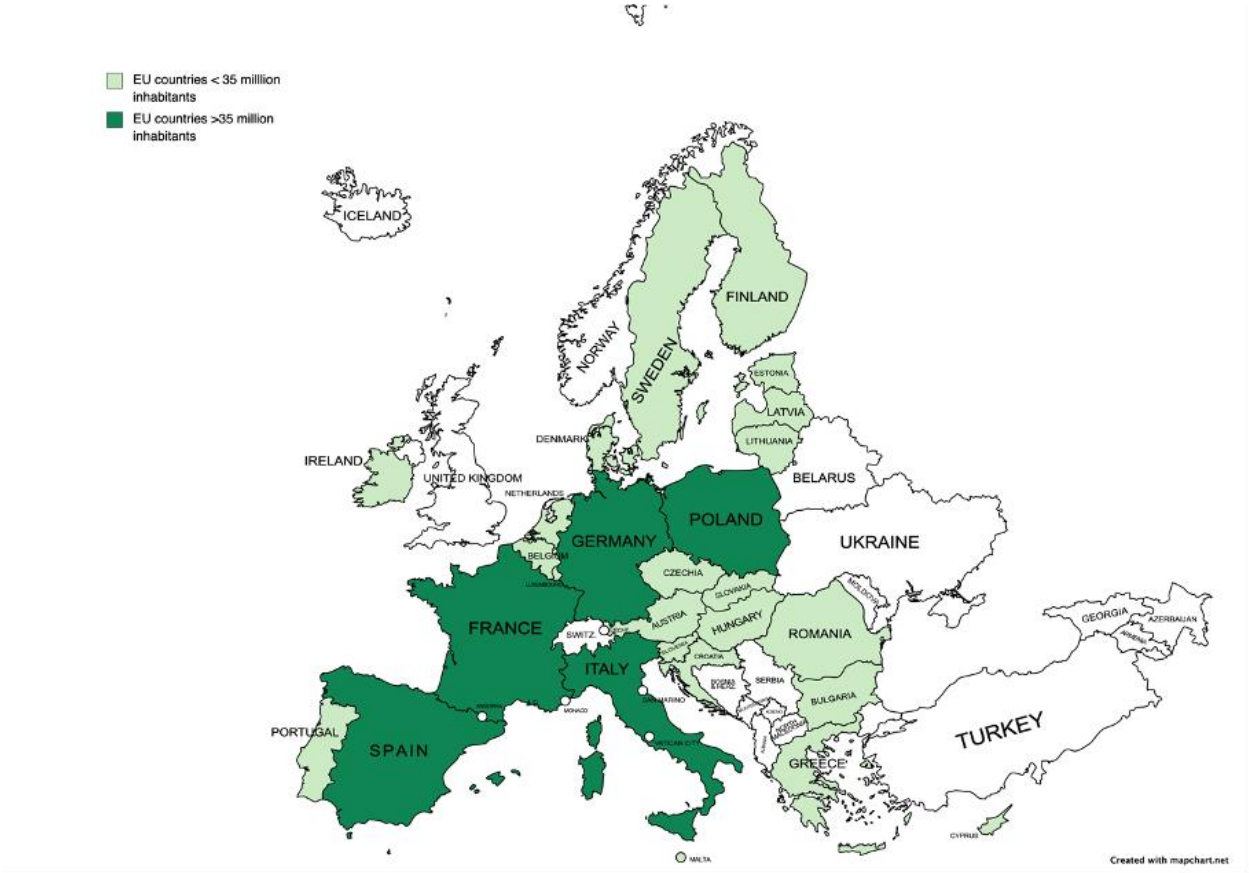

Figure 2. EU countries are marked with green. They will be given one extra expert if they have less than 35 million inhabitants (light green) and two extra experts if they have more than 35 million inhabitants (dark green).

All countries that spend >4000 euro on healthcare per capita and year (blue countries in Figure 1) will be given two extra experts. The sum of 4000 euro was chosen as there was a clear gap there, with no countries spending 3000-4000 euro on healthcare (Figure 1). Countries spending >2000 euro were given one extra expert (Figure 1). The total number of experts per country are given in Table 2 and in Figure 3.

	Plastic surgeon	**Recon nurse**	**Patient rep**	**Total**
ESPRAS North (1 delegate)				
Denmark*€€	2	1	1	**4**
Finland*€€	2	1	1	**4**
Iceland€€	2	1		**3**
Sweden*€€	2	1	1	**4**
ESPRAS west (3 delegates)				
Germany**€€	2	2	1	**5**
Ireland*€€	2	1	1	**4**
Luxemburg*€€	2	1	1	**4**
Netherlands*€€	2	1	1	**4**
Switzerland€€	2	1		**3**

United Kingdom€€	2	1		**3**
ESPRAS South-west (2 delegates**)**				
Italy**€	2	1	1	**4**
Portugal*€	2	1		**3**
Malta*	2	1		**3**
Spain**€	2	1	1	**4**
France**€€	2	2	1	**5**
ESPRAS Central and East (2 delegates**)**				
Austria*€€	2	1	1	**4**
Belarus	1			**1**
Czechia*	2			**2**
Estonia*	2			**2**

Georgia	1			**1**
Hungary*	2			**2**
Latvia*	2			**2**
Lithuania*	2			**2**
Poland**	2	1		**3**
Slovakia*	2			**2**
ESPRAS South-east (2 delegates)				
Armenia	1			**1**
Albania	1			**1**
Azerbaijan	1			**1**
Bulgaria*	2			**2**
Bosnia and Herzegovina	1			**1**
Croatia*	2			**2**

Cyprus*	2			**2**
Greece*	2			**2**
North Macedonia	1			**1**
Moldova	1			**1**
Romania*	2			**2**
Serbia	1			**1**
Slovenia*	2			**2**
Turkey	1			**1**
Ukraine	1			**1**
Non-ESPRAS countries				
Belgium*€€	2	1	1	**4**
Norway€€	2	1		**3**
Kosovo	1			**1**

Montenegro	1			**1**
TOTAL	**75**	**21**	**12**	**108**

Table 2. Experts per country

*One extra expert – EU country <35 million inhabitants
**Two extra experts – EU country >35 million inhabitants
€ One extra expert – spends >2000 euro per capita and year on healthcare
€€Two extra experts – spends >4000 euro per capita and year on healthcare

Grey marking: The countries can choose if they want to include a breast recon nurse or a patient rep depending on the organisation of the country

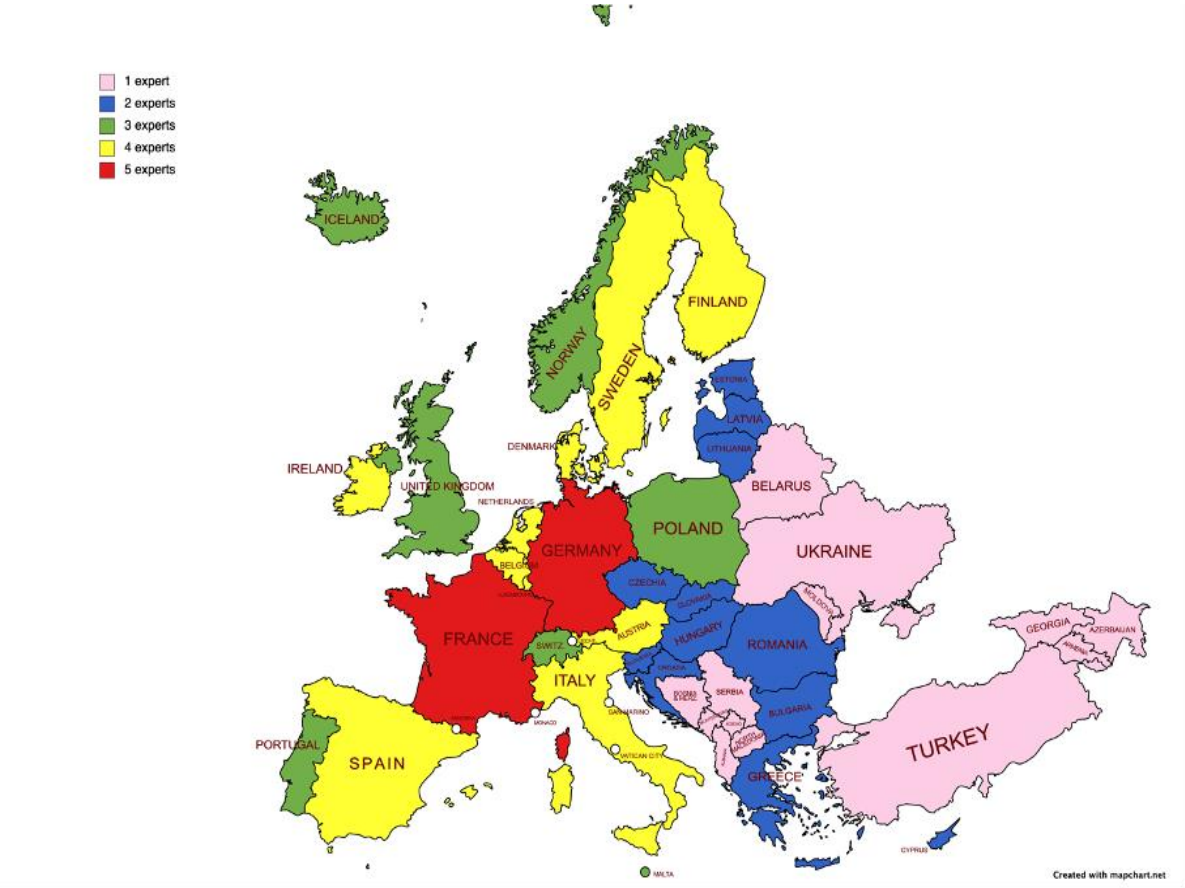

Figure 3. Number of experts per country.

Delphi methodology: All questionnaires will be sent, and answers collected, via Google Forms. All experts will be anonymous to each other throughout the study. The identity of the experts will be known by the people collecting the data to enable remainders. Two reminders will be sent to each expert. No financial compensation will be given to the experts. Response rate will be recorded for each Delphi round. All experts who participate will be offered an inclusion in the acknowledgment section if they wish to. Experts who participate actively in the grading of evidence work will be offered co-authorship.

Delphi questionnaire preparation: Before the start of the first Delphi round, the expert panel will be used to generate the indicator selection which will be included in the first questionnaire.

The experts will be sent a form, with a few examples of possible quality indicators (Table 1) and asked to add all other relevant quality indicators they can think of and motivate the scientific rationale for them.

Quality indicator	**Rationale**
Proportion of patients who have access to both implant based and autologous breast reconstruction.	Several studies have indicated that patients receiving autologous breast reconstruction have a higher patient satisfaction than patients receiving implant-based breast reconstruction (PMID: 31538071, 32332522, 31711862)
Frequency of implant loss/flap loss	Implant loss/ flap loss is the ultimate complication of a breast reconstruction, affecting the patient considerably (PMID: 34427538, 27740955) as well as creating costs for the healthcare system
Waiting time for delayed breast reconstruction	A few studies have suggested that waiting for a breast reconstruction might create psychosocial distress (PMID 27673514)

Table 1. Examples of possible quality indicators sent to the panel during the Delphi questionnaire preparation

Delphi round 1 All the suggestions given in the Delphi questionnaire preparation round, including the suggested scientific rationale will be listed and sorted into structure, process, and outcome quality indicators. The experts will be informed about the responses of the group

(quantitative feedback). During the first Delphi round the experts will be asked to grade the importance of each suggested quality indicator on a four-point Likert scale (one being ‘not important and four being ‘essential’). The response frequency will be recorded.

Delphi round 2: Quality indicators that received a mean score of 3 (cut off value) in the first round will be selected for the second round. Missing values will be given the score of 1 (‘not important’), assuming that the expert would have actively scored it if he/she had thought it was important. Competence scores with a standard deviation (SD) 1, and hence a diverse grading, implying a contradicting consensus, will be excluded [10]. The experts will be informed about the responses of the group (quantitative feedback). In round 2, the experts will beasked to grade the quality indicators ’do not agree’ or ’agree’. The percentage of agreement will be recorded for each indicator.

Evidence grading of the indicator, standard of care and risk adjustment

A modified Delphi technique will be used as a steering committee meeting will be held after the second Delphi round. During the meeting the attending experts will grade the evidence of all the potential quality indicators receiving >70 or 80 per cent of agreement in round 2 (depending on the number of quality indicators). Evidence will be graded according to the Oxford Centre for Evidence-based practice into level 1-5 (https://www.cebm.ox.ac.uk/resources/levels-of-evidence/oxford-centre-for-evidence-based-medicine-levels-of-evidence-march-2009). The steering committee will also develop suggestions for standard of care levels and define any risk-adjustments strategies needed.

Delphi round 3: The quality indicators from round 2 will be sent with the evidence grading and standard of care and be asked to indicate if they 'agree' with the standard of care or it should be 'higher' or 'lower' and if the quality indicator and standard of care is 'feasible' or 'not feasible' in their country. The percentage of agreement will be recorded for each indicator.

Time plan

1. Recruit experts
2. Send out pre-round questionnaire. First remainder after 1 week and second reminder after 2 weeks (to those who have not answered). Experts who have not answered after the second reminder will be excluded and the national society/delegate informed?
3. The quality indicators will be sorted, thematises, and duplicates removed. Steering committee approves list of potential quality indicators to be sent out in round two.
4. Four weeks after pre-round: First Delphi round questionnaire is sent out. First remainder after 1 week and second reminder after 2 weeks (to those who have not answered).
5. Scores will be calculated and indicators receiving a mean score of 3 or above will go through to the next round..
6. Four weeks after first Delphi round: Second Delhi questionnaire is sent out. First remainder after 1 week and second reminder after 2 weeks (to those who have not answered).
7. The steering committee will evidence grade, suggest standard level of care, and risk adjustment, for the quality indicators receiving >70 or 80% agreement (depending on the number of indicators) in the second Delhi round.

8. When the work of the steering committee is ready: The final Delphi round questionnaire is sent out. First remainder after 1 week and second reminder after 2 weeks (to those who have not answered).
9. Publication of quality indicators with evidence grading, suggested standard of care, and feasibility.

References

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