

## Formulating Design Recommendations for the Acceptance of the Use and Results of Point-of-Care Testing in Low- and Middle-Income Countries: A Literature Review

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## **FORMULATING DESIGN RECOMMENDATIONS FOR THE ACCEPTANCE OF THE USE AND RESULTS OF POINT-OF- CARE TESTING IN LOW- AND MIDDLE-INCOME COUNTRIES: A LITERATURE REVIEW**

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### **ABSTRACT**

In low- and middle-income countries (LMIC), diagnostics are not always available in remote areas. Hospitals and healthcare centres are often too far from the community, and waiting times are up to a few hours even for relatively simple procedures. Moreover, travelling to the healthcare centre and taking the diagnostic test is frequently unaffordable. Point of Care Tests (POCTs) can improve the availability, accessibility and affordability of the diagnostics by providing the test at the time and place of patient care. Although many POCTs have been developed already, there remain challenges to enable the healthcare workers (HCW) and the patients to use the device in practice. In this paper, we aim to provide a systemic overview of the barriers and opportunities for the adoption of use and acceptance of the results of POCTs based on the literature. The barriers and opportunities were clustered into six themes and used to draw out recommendations for the future design.

**Keywords:** User centred design, Human behaviour in design, Acceptance, Point of Care Test, Requirements

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## 1 INTRODUCTION

For the majority of people in lower- and middle-income countries (LMICs), health care is often inaccessible (Peters *et al.*, 2008). Hospitals and care centres are too distant and waiting times can be up to a few hours or days, even for relatively simple treatments.

In terms of accessibility, Point of Care Tests (POCTs) can significantly improve the quality of health care in LMICs. Nichols (2007) defines point of care testing as “laboratory diagnostic testing performed at or near the site where clinical care is delivered” (p.893). The POCT takes place outside of the hospital and can be performed by both health care workers and patients, depending on the context of a target user. Well-known examples of POCTs are pregnancy tests and rapid malaria diagnostics tests. The POCT serves as the first step of health care before taking further actions. There are two subgroups of POCTs, which are digital and non-digital POCTs. The pregnancy test is an example of a non-digital POCT. An example of a digital POCT is a blood glucose meter deploying simple microchips and screens. In this review, both digital and non-digital POCTs will be addressed.

Considering the potential benefits of POCTs, the question raises why POCTs are not yet common practice in LMICs. According to a study performed by Iwamoto *et al.* (2017), there are five barriers for care in LMICs, also known as the A’s of access to care: Accessibility, Availability, Acceptability, Affordability, and Accommodation. Compared to traditional health care, applying POCTs helps to overcome three of these barriers: accessibility, availability, and affordability. In terms of availability, the POCTs can be easily implemented in remote areas comparing to conventional diagnostic devices. Whereas traditional diagnostic devices can be used only at one location and take longer time to process results, POCTs are flexible to be used in various contexts of usage to make a quick diagnosis and as such increase the accessibility. Lastly, the POCT can significantly reduce the financial restrictions of patients including the cost of transport to the healthcare and cost of treatment resulting in increased affordability.

Still, the main challenge lies in overcoming its acceptability and accommodation in the local healthcare systems. Especially, the lack of acceptability and trust by the end-users are serious barriers but have not been studied in depth so far. Due to a proliferation of POCTs with less sensitivity than a standard diagnostic method, there is often distrust of the test results. In the case of malaria rapid diagnostic tests, the Health Care Workers (HCWs) and febrile patients usually do not accept a negative result and prescribe or take antimalarial medicine nevertheless. This not only causes resistance against antimalarial medication but also prevents the patients from receiving the proper treatment (Iwamoto *et al.*, 2017). Currently, there are not many existing studies addressing these issues for LMIC settings.

Therefore, the objective of this paper is to identify the barriers and opportunities of POCTs from previous research in LMIC settings and address a set of design recommendations for a future research. The recommendations will guide how to increase the acceptability of prospective POCTs by the end-users. As our starting place, the domain of this study is defined as publications on the POCTs for mainly tropical diseases such as malaria within Sub-Saharan Africa region.

## 2 METHODS

In order to execute the literature review, three steps were undertaken. First, the relevant literature on the topic of POCTs was selected and relevant insights were collected. Second, we identified the possible clusters of the problems associated with acceptance and grouped them into the barriers and opportunities. Third, the collected insights were analysed further to extract themes and restructure them. Based on the result, design recommendations were derived by the principal authors.

### 2.1 Definition of terms

Two main subjects were used to find suitable literature: “point of care” and “acceptance of technology”. Each article that provided information about the acceptance and use of a point of care system (within the Sub-Saharan Africa) was reviewed, as well as articles that discussed how technology was accepted in a broader sense.

## 2.2 Eligibility criteria

Due to the comparative novelty and fast developments in the domain of POCTs, only articles published after 1998 are selected. The literature should be relevant for developing the design criteria including in-depth description of the context and system around the POCT and interactions with the users (either the HCW or the patient). Studies describing merely the principle of technology were excluded. We included literature reviews and the studies conducted in the LMIC settings.

## 2.3 Information sources and search strategy

As the main source for literature, Google Scholar was used to broadening our scope of the search. We investigated not only the scholarly literature but also work in progress, thesis and unpublished work. The following combinations of keywords were used: POC AND acceptance, POCT AND acceptance, Point of care AND acceptance, POC AND acceptance AND Africa, POCT AND acceptance AND Africa, Point of care AND acceptance AND Africa, Technology acceptance. The references for each paper were also cross-checked to find other relevant literature. From the initial search, more than 1330 studies were identified. The title and abstract were read by the principal authors to determine the relevance. The relevant papers were examined in more detail in order to check if it meets selection criteria. Finally, 19 studies were determined as eligible for our scope of research and thematically reviewed.

## 2.4 Data abstraction and synthesis

With the reviewed studies, a manual thematic analysis was performed. At first, the literature was read and parts that were related to barriers and opportunities were highlighted by two researchers. The highlighted insights were collected into one document and printed with their sources. The printed insights were first grouped into barriers and opportunities and by the type of user group; healthcare worker, the patient, or both. Next each group (for example barriers for CHWs) was manually further clustered to identify general themes. Eleven major themes for the barriers and five themes for the opportunities were identified. The tables in the next chapter show the barriers and opportunities structured by these themes. Lastly, all clustered insights were put on a wall and re-evaluated by all authors to see if the insights were in the proper category.

## 3 BARRIERS

In this review, a barrier is defined as an obstacle that prevents an HCW or patient adoption or acceptance of using a POCT. The overview of the barriers is shown as Table 1. In addition, it was possible to distinguish the external and internal barriers within the results. For instance, a regulation and financial restriction play a role as an external barrier which are difficult for the individuals to cope with by themselves. The emotions and habits of the user describe more internal barriers, which may have more opportunities for future intervention.

Table 1: Barriers to implementing POCTs in LMICs.

HCW	Patient
<b>Regulation related barriers [A]</b>	
<p><b>Lack of regulations on data security</b> Lack of regulations on the data security makes it difficult to operate (Mourad, 2012; Steinhubl, Muse, &amp; Topol, 2015; Wallis, Blessing, Dalwai, &amp; Shin, 2017).</p> <p><b>Lack of regulatory standards on quality</b> Low quality POCTs may result in mistrust of POCTs (Pai, Vadnais, Denkinger, Engel, &amp; Pai, 2012; Peeling &amp; Mabey, 2010; Yager, Domingo, &amp; Gerdes, 2008).</p>	<p><b>Insecurity on the data privacy</b> Patients are reluctant to share their data to protect their data privacy (Mourad, 2012; Steinhubl <i>et al.</i>, 2015).</p> <p><b>Lack of regulations on the patient privacy</b> The regulations for patient privacy and confidentiality are outdated (Wallis <i>et al.</i>, 2017).</p> <p><b>Lack of regulatory standards on quality</b> Low quality POCTs may result in mistrust of POCTs (Hutchinson, Corbie-Smith, Thomas, Mohanan, &amp; Del Rio, 2004; Pai <i>et al.</i>, 2012; Peeling &amp; Mabey, 2010; Yager <i>et al.</i>, 2008).</p>

<b>Technological barriers [B]</b>	
<p><b>Adoption time</b> The time to adopt a new technology may take too long (Wallis <i>et al.</i>, 2017).</p> <p><b>Perception of technical aesthetics</b> When something looks technically difficult, HCWs expect it will be hard to use (Mourad, 2012).</p> <p><b>Anxiety of loss of the device and its data</b> HCWs are anxious to lose the device or the information stored on it (Mourad, 2012).</p> <p><b>Physical constraints</b> Some HCWs are not satisfied because they feel that digital devices have physical constraints (Wallis <i>et al.</i>, 2017).</p> <p><b>Integration of new technology</b> It is hard for HCWs to integrate a new device into their current practice due to complex nature of the system (Mourad, 2012; Wallis <i>et al.</i>, 2017).</p>	<p><b>Lack of support systems</b> If there are no support systems for reporting results of the POCTs and follow up care, POCTs will not work well (Pai <i>et al.</i>, 2012).</p> <p><b>Perception of low sensitivity</b> Patients often have prior experience with low sensitivity POCTs (Hutchinson <i>et al.</i>, 2004).</p>
<b>Economical barriers [C]</b>	
	<p><b>Lack of financial resources</b> Most people with high risk of infection cannot afford a test (Hutchinson <i>et al.</i>, 2004).</p>
<b>Socio-economic barriers [D]</b>	
	<p><b>Low socioeconomic status</b> Patients with less health literacy and competency at using mobile-based technologies are difficult to target (Wallis <i>et al.</i>, 2017).</p>
<b>HCW-Patient relation barriers [E]</b>	
<p><b>Dehumanizing the work</b> Feeling of losing human aspect of their job, turning them into ‘data collection robots’ (Wallis <i>et al.</i>, 2017).</p> <p><b>No alternative for negative result</b> Conducting only one POCT will provide an indication of that specific disease. When the result is negative, the HCW does not know which other illness the patient may have (Ruizendaal <i>et al.</i>, 2014).</p> <p><b>Language barrier</b> Conducting tests and interpreting the results in different languages can a barrier (Yager <i>et al.</i>, 2008).</p>	<p><b>Distrust in the HCW</b> The patient does not always trust the HCW. This might be the result of lack of trust in the skills of the HCW or in the mobile technology he/she is using (Mourad, 2012; Ruizendaal <i>et al.</i>, 2014).</p> <p><b>Feel impersonal</b> Because POC is focused on efficiency, the patient can perceive it as more impersonal (Hutchinson <i>et al.</i>, 2004).</p> <p><b>Language barrier</b> Conducting tests and interpreting the results in different languages can a barrier (Yager <i>et al.</i>, 2008).</p>
<b>Social environment barriers [F]</b>	

<p><b>Social influence</b> Social influence among HCWs may affect the less acceptance of using POCTs in the community (Mourad, 2012).</p>	<p><b>Fear of social exclusion</b> When people are diagnosed with a stigmatised disease, such as HIV, they are afraid of social exclusion (Hutchinson <i>et al.</i>, 2004). <b>Lack of confidentiality</b> Perceived lack of confidentiality in stigmatised diseases may reduce acceptance of POC testing in the community (Pai <i>et al.</i>, 2012). <b>Social pressure toward a health care programme</b> Social pressure from the community sometimes prohibits people from joining a health care programme (Wallis <i>et al.</i>, 2017).</p>
<p><b>Cultural barriers [G]</b></p>	
<p><b>Awareness of the false negatives</b> The HCW might treat for malaria even though the result is negative if the patients have little or no malaria protection. The HCWs are over-aware of the false negatives (Ruizendaal <i>et al.</i>, 2014).</p>	<p><b>Preference on the alternative medicine</b> Some patients choose to first try alternative medicines and seek help from the health care worker if it does not work (Iwamoto <i>et al.</i>, 2017).</p>
<p><b>Personal/emotional barriers [H]</b></p>	
<p><b>Generation gap</b> Older nurses are more resistant to mobile devices (Mourad, 2012). <b>Lack of confidence</b> Sometimes HCWs do not feel confident enough to do a test themselves and to interpret the results (Pai <i>et al.</i>, 2012). <b>Shift in focus</b> With a POCT, there could be too much focus on the device and not the patient (Mourad, 2012). <b>High work pressure</b> Many HCWs are already overburdened with current workload. Additional tasks can be difficult to adopt (Wallis <i>et al.</i>, 2017).</p>	<p><b>Fear of cross infection</b> There is a fear of cross infection when people do a test that involves bodily fluids (Ruizendaal <i>et al.</i>, 2014). <b>Lack of confidence</b> Sometimes patients do not feel confident to perform a test themselves and to interpret results (Pai <i>et al.</i>, 2012). <b>Generation gap</b> Elderly have a fear of new technology and they also do not have any experience with it, which makes it even more scary (Wallis <i>et al.</i>, 2017). <b>Emotional fear</b> The fear of dying, psychological consequences or emotional consequences might prohibit them from taking a test (Hutchinson <i>et al.</i>, 2004). <b>Perception of the time equals quality</b> People trust tests more when it takes time to get the results (Hutchinson <i>et al.</i>, 2004).</p>
<p><b>Habitual barriers [I]</b></p>	
<p><b>Reluctance in change of procedure</b> HCWs will not accept the change in procedure once it is introduced. Especially when there is recommended to not take medicine anymore. (Yager <i>et al.</i>, 2008; Mourad, 2012). <b>Habit of mistrust in tests</b> Presumptive treatment has been a behavioural tradition that makes it difficult to change perception toward a POCT (Yager <i>et al.</i>, 2008).</p>	<p><b>Habit of mistrust in tests</b> Presumptive treatment has been a behavioural tradition that makes it difficult to change perception toward a POCT (Yager <i>et al.</i>, 2008).</p>

Behavioural barriers [J]	
<p><b>Interruption of traditional practices</b> The HCW does not want to change their habits (Wallis <i>et al.</i>, 2017).</p> <p><b>Lack of support</b> Most pilot POCT projects fail unless there is adequate on-site support for the HCW that has to use it (Wallis <i>et al.</i>, 2017).</p>	
Usability barriers [K]	
<p><b>Unsatisfactory ease of use</b> Ease of use is not satisfactory (Wallis <i>et al.</i>, 2017).</p> <p><b>Excessive features</b> Applications with too many features make it hard to use (Wallis <i>et al.</i>, 2017).</p>	

Even though there are some overlaps in the barriers of the HCW and the patient, there are also clear differences, especially the technical barriers. Interestingly, no barriers in literature were found for the HCW in the economic and social-economic clusters while no behavioural and usability barriers were mentioned for a patient.

#### 4 OPPORTUNITIES

In this review, an opportunity is defined as a potential intervention that enables a HCW or patient to adopt or accept a POCT. The opportunities were clustered during the analysis phase. Table 2 provides an overview of these clusters. Five types of opportunities were identified.

Table 2: Opportunities for improving POCTs in LIMCs.

HCW	Patient
Emotional opportunities [L]	
<p><b>Professional aesthetics</b> Doctors prefer standardized hospital-like tools versus devices that look too personal (Mourad, 2012).</p>	<p><b>Professional aesthetics</b> The device that looks too personal can be perceived negatively (Mourad, 2012).</p> <p><b>Less invasive method</b> When POC testing is less invasive patients tend to accept testing earlier (Hutchinson <i>et al.</i>, 2004).</p>
Regulation related opportunities [M]	
<p><b>Enable screening of multiple diseases</b> Providing relevant information to screen multiple diseases can be effective in achieving high treatment coverage (WHO, 2017).</p>	<p><b>Recognition of training HCW</b> If patients know that the HCW is trained in using POC and false positives well, they trust the results (Ruizendaal <i>et al.</i>, 2014).</p>
<p><b>Supervision of quality</b> There has to be a committee for supervising POC devices because physicians care most about technological reliability, secure data storage, and transparent policies (Wallis <i>et al.</i>, 2017).</p>	<p><b>Supervision of quality</b> Committee for supervising POC devices is needed because patients care about a level of control privacy and data preservation (Wallis <i>et al.</i>, 2017).</p>

<p><b>Integrate into the existing programs</b> In case of malaria, ICCM (Integrated Community Case Management) programs help the HCW to adhere to negative RDT results and let the patient know what disease he/she has. (Ruizendaal <i>et al.</i>, 2014; WHO, 2017).</p>	<p><b>Empowered by having ownership</b> Patients can be empowered by giving them access to ownership of their medical data (Steinhubl <i>et al.</i>, 2015).</p>
<p><b>Technological opportunities [N]</b></p>	
<p><b>Building a system around POCT</b> Ensuring the mechanisms in place for quality assurance, reporting of results, notification of cases, and initiation of action on the results of the tests. (Pai <i>et al.</i>, 2012).</p>	
<p><b>Social opportunities [O]</b></p>	
<p><b>Community sensitization</b> Community sensitization ensures comprehension of the intervention and trust (Ruizendaal <i>et al.</i>, 2014).</p>	<p><b>Community sensitization</b> Community sensitization ensures comprehension of the intervention and trust. (Ruizendaal <i>et al.</i>, 2014)</p>
<p><b>Usability opportunities [P]</b></p>	
<p><b>Consider the context of use and the user</b> The POCT has to be created according to the context of use and the user (Pai <i>et al.</i>, 2012; Wallis <i>et al.</i>, 2017). One requirement can be the product has to be robust (Chin, Linder, &amp; Sia, 2012).</p> <p><b>Optimise the ease of use</b> POC tests should be easy to use and interpret, preferably self-contained and fully automated (Chin <i>et al.</i>, 2012; Wallis <i>et al.</i>, 2017).</p> <p><b>Evaluation with the users</b> Testing with user group should be done throughout the development of the system, not only at post-implementation (Burgess &amp; Sargent, 2007; Gadd, Baskaran, &amp; Lobach, 1998; Wallis <i>et al.</i>, 2017).</p> <p><b>Tailored to the user group</b> Not all users have the same needs, so the POCT should be tailored to the user group (Steinhubl <i>et al.</i>, 2015).</p> <p><b>Provide adequate training</b> HCWs need to be trained (Peeling &amp; Mabey, 2010; Price, 2001; Ruizendaal <i>et al.</i>, 2014; Wallis <i>et al.</i>, 2017)</p>	<p><b>Consider the context of use and the user</b> The POCT has to be created according to the context of use and the user (Pai <i>et al.</i>, 2012; Wallis <i>et al.</i>, 2017). One requirement can be the product has to be robust (Chin, Linder, &amp; Sia (2012).</p> <p><b>Optimise the ease of use</b> POC tests should be easy to use and interpret, preferably self-contained and fully automated (Chin <i>et al.</i>, 2012; Wallis <i>et al.</i>, 2017).</p> <p><b>Evaluation with the users</b> Testing with user group should be done throughout the development of the system, not only at post-implementation (Burgess &amp; Sargent, 2007; Gadd, Baskaran, &amp; Lobach, 1998; Wallis <i>et al.</i>, 2017).</p> <p><b>Tailored to the user group</b> Not all users have the same needs, so the POCT should be tailored to the user group (Iwamoto <i>et al.</i>, 2017; Steinhubl <i>et al.</i>, 2015).</p>

The opportunities for the HCW and the patient in some categories do not differ greatly. However, there are compelling differences such as more regulatory opportunities for the patient and less social opportunities for the healthcare worker.



## 5 RECOMMENDATIONS

The design recommendations were formulated in order to operationalise our insights on the barriers and opportunities. We believe that the recommendations can guide other design researchers or engineers who want to develop more acceptable POCTs for LMICs. Each recommendation refers back to the source which is indicated by a letter of the category. It is also differentiated if the recommendation is addressed for the HCW or the patient.

Table 3: Recommendations for POCTs in LMICs

	HCW	Patient
<b>Emotional (The emotional impact on an HCW or patient)</b>		
Make sure that the POCT looks professional. This gives confidence to both HCWs and patients. [L]	✓	✓
Empower patients to have control over their own data. [M]		✓
Keep into account what impact a positive result of certain types of diseases can have on a patient (e.g. HIV). [H]		✓
Clarify the added value of the new POCTs to ensure adoption.	✓	✓
<b>Social (The impact on the social interaction)</b>		
When designing for the HCW, community sensitization is important. This way, patients' trust in the community HCW can be improved. [O]		✓
The POCT should not take away from the interaction with the patient. [E]	✓	
<b>Product-Environment Interaction (To fit its functions in a certain system or environment)</b>		
The POCT should become a part of the existing system. This system includes the quality assurance, reporting and case alerts, and the next steps for patients. [B]	✓	
If possible, try to incorporate your device in the iCCM method of testing to enable more than one test and improve the case management. [M]	✓	✓
Make sure you design for the conditions the POCT will have to go through: weather, storage, number of uses, etc. [P]	✓	✓
<b>Usability and Human-Product Interaction (Easy-to-use and comfort)</b>		
Try to make POCTs as less invasive as possible. This way patients are not scared away by complicated methods. [L]		✓
Include training with the device with correct procedure and familiarise the test. This improves the accuracy of tests and reliability of HCWs. [P]	✓	
Ensure the new POCT is easy to learn and it fits in HCW's routine. [B] [I] [P]	✓	
On-site support should be available for a longer period of time. For instance, only two weeks of training will not be sufficient. [J]	✓	

Information on the POCT should be straight forward and presented clearly to be interpreted by the intended user group. E.g. consider people from rural areas with less experience of technical devices and language barriers [D] [E] [H] [P]	✓	✓
Ideally the test should be self-contained and fully automated. [P]	✓	✓
The POCT should not look challenging and cause too much effort. [B] [D]	✓	✓
User test and iteration should be done throughout the whole design process. [P]	✓	✓
Be aware of different user groups and who will be the end users of the POCT. [P]	✓	✓
The POCT should be simple and should have the features that are necessary. [K]	✓	✓
<b>Economical (Economical improvements that need to be taken into account)</b>		
The POCT should be affordable for the people that need to do the test. [C]		✓
<b>Regulation (In order to ensure the reliability before implementation)</b>		
Make sure the POCTs quality is ensured by an established organisation. [A] [M]	✓	✓

## 6 DISCUSSION

Our introduction emphasised the importance of integrating POCTs into existing health care systems. One of the main challenges is to increase the acceptability of POCTs in order to accommodate them successful in the current healthcare systems. In our literature we identified a range of barriers and opportunities on different levels. From a holistic view, new POCTs should be compatible and fit into the current practice to increase the acceptability by the end-users (HCWs as well as patients). It should be noted that, regardless of its significance, not much relevant literature was identified in this direction.

For future R&D processes, we propose taking different approaches to tackle internal and external factors. The internal factors include trust and ease of use, which are influenced by the care environment and interaction around POCTs. There were major differences between the emotions and feelings of the HCWs and the patients. For the HCWs, it was mostly directed towards the POCT and care environment. While patients mostly direct them towards their social environment including the HCW. The design approach to address the different needs of the end-users and their behaviours could contribute to improving the trust in POCTs. Moreover, it is important to take external factors into account such as regulation related to the quality of the POCTs. Even though these cannot be addressed by the product itself, considering them during the development stage will lead to a strategy for higher suitability with the current system. Acknowledging these main barriers is useful for improving the general perception of the public.

From the design engineering perspective, we believe that there are many opportunities present to improve the usability and human-product interaction. Next to the technical side of the POCTs, the end-product has to be easy to be used and implemented throughout a longer period of time with proper guidance.

This study also has certain limitations. We expect that more barriers and opportunities exist than described in our findings. However, we have attempted to get from literature the most relevant insights within our scope of research. The design recommendations derived from the insights were drawn out from the researchers' own interpretation, which could have led us into biased results. For that reason, the referral back to their original sources were incorporated to strengthen the links between them. Nevertheless, this paper presents a first step towards a future rigid set of guidelines for the development of acceptable POCTs for LIMCs.

## 7 CONCLUSION

In this research, we have identified different types of barriers and opportunities for increasing the acceptability of POCTs in LMICs. Based on these, design recommendations were generated to guide designers and other professionals working on POCTs with higher acceptability of its use and results. The main conclusion that can be drawn is that the existing health care practice around POCTs should be well understood and considered during the R&D process. On a product level, higher quality including the sensitivity and usability should be ensured in order to lower the barrier to acceptance. The interaction and environment around the POCTs are critical factors to gain more trust by both HCW and patients and to facilitate the desirable usage. Meanwhile, external factors such as more regulations on quality and training were found necessary for POCTs to be successfully adopted in the healthcare system. These initial findings shall be addressed in future studies by validating the design recommendations in real-life cases. An interesting topic could be especially the usability and human-product aspects as there is more potential improvement from the design engineering perspective.

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