




BMJ Open Cultural adaptation of a patient decision-aid for insulin therapy

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ABSTRACT

Introduction Patient decision-aids (PDAs) support patients in selecting evidence-based treatment options. PDA is useful only if the user understands the content to make personalised decisions. Cultural adaptation is a process of adjusting health messages so that the information is accurate, relevant and understandable to users from a different population. A PDA has been developed to assist Malaysian patients with secondary drug failure to initiate insulin therapy to control their type 2 diabetes mellitus (T2DM). Likewise, patients with T2DM in neighbouring Singapore face similar barriers in commencing insulin treatment, which a PDA may facilitate decision-making in selecting personalised therapy.

Objective The study aimed to explore the views and perceptions of Singaporean primary care providers on the Malaysia PDA to initiate insulin therapy and described the cultural adaptation process used in the design and development of a new PDA, which would be trialled in a Singapore primary healthcare institution.

Method Qualitative research method was deployed to conduct one-to-one in-depth interviews of the healthcare providers at the trial site (SingHealth Polyclinics—SHP), including six primary care physicians and four nurses to gather their views and feedbacks on the Malaysian PDA. The interviews were transcribed, audited and analysed (standard content analysis) to identify themes relating to the content, layout, concerns of the original PDA and suggestions to the design of the new SHP PDA.

Results Cultural adaptation of the new PDA includes change to the overall design, graphics (including pictograms), presentation styles, additional contextualised content (personalisation, subheadings, cost and treatment option), modified phrasing of the subtitles and concerns (choice of words) relevant to the new users.

Conclusion A PDA on insulin therapy underwent cultural adaptation before its implementation in another population in a neighbouring country. Its relevance and effectiveness will be evaluated in future research.

INTRODUCTION

Patient decision-aid (PDA) is a tool to facilitate decision making by providing relevant information about their treatment options and probable outcomes to the target audience, and to allow clarification of their personal values and preferences.¹ Such tools are often used in shared decision making

Strengths and limitations of this study

- The study shows that a patient decision-aid (PDA) can be culturally adapted for a different population via review and modification of its content, design, presentation and graphics.
- Qualitative feedbacks from targeted users (primary care providers), and input from the investigators are key steps to contextualise the PDA content in this cultural adaptation process.
- Cultural adaptation of a validated PDA is usually faster compared with one which has to be developed from scratch (cultural optimisation).
- Feedbacks from the patient-users will be gathered at the next 'lab testing phase' as a continuum of the cultural adaptation of the PDA.
- The cultural adaptation across different language used in the PDA could be different and await further research.

(SDM) between the healthcare provider and patient in situations when there are multiple options for investigation and treatment.^{2–3} The PDA needs to be contextualised to the local culture, the population's health literacy, the local clinic or hospital workflow, healthcare system and associated policies for it to enhance the SDM process.

PDAs have been developed to support SDM in the selection of therapeutic options to treat a wide range of conditions, from metabolic diseases to malignancy management. The development of these PDAs conventionally involves a series of steps and background studies: qualitative research to understand the values and preferences of the patients; identifying barriers faced by their care providers; assembling of the evidence-based treatment options; design and layout of the PDA; printing or digitalising the tool before pilot testing of the prototype.^{4–5} The entire process from conceptualising to prototyping can be long and costly but it is a necessary investment of resources in clinical area where essential information to make informed decision is lacking.⁶

Nonetheless, many PDAs have been developed over the past decade due to contributions from researchers worldwide, including those from the SDM pioneers in the Ottawa Hospital Research Institute.⁷ An inventory of these PDAs can be found at its website.⁸ It includes a PDA developed by a group of researchers from the University of Malaya (UM) on insulin initiation targeted at local Malaysians with poorly controlled type 2 diabetes mellitus (T2DM) despite being on multiple oral hypoglycaemic agents. This PDA was developed over the years using the conventional method and has been implemented in selected local public primary healthcare clinics (Poliklinik Kesihatan) in the Klang Valley in Malaysia.^{9 10}

Singapore is an island state in close geographical proximity to peninsula Malaysia. Its population comprising multiethnic Asians (Chinese, Malays and Indians) is similar to those in Malaysia. Singaporeans, aged 18–69 years, also face increasing prevalence of T2DM from 4.3% in 1990 to an estimated 15.9% in 2050.¹¹ In addition, the overall Singapore population is ageing rapidly due to declining birth rates and longer average lifespan of the individual. With the expectant increase in the number of years a patient has to live with diabetes, many will develop secondary drug failure over time and will require insulin to maintain normoglycaemia.¹² Yet local studies have shown that patients with T2DM are reluctant to initiate insulin due to multiple factors.^{13 14} The barriers include misperception and poor understanding of the T2DM and its treatment by patients; failure to recognise the values and preferences by their healthcare providers; and/or lack of opportunities and practices in SDM by both stakeholders during their consultation in primary care setting.¹⁵ These barriers are identical to those faced by Malaysian patients with T2DM.¹⁶ There is a need to address these barriers towards insulin therapy to optimise glycaemic control in these patients.

Using a PDA to facilitate SDM between patients and their healthcare providers can potentially reduce the barrier towards insulin initiation. In view of the similarity between the populations in Singapore and Malaysia, we postulated that PDA developed by UM could be adapted and implemented in similar publicly funded primary care clinics (polyclinics) in Singapore. Nevertheless, literature suggests that culturally adapted health messages tend to be more effective when they are used in healthcare interventions.^{17 18} Bailey *et al* had also shown that a PDA, which they developed to intensify treatment of T2DM, resulted in significant improvement in the knowledge, decisional self-efficacy, and decisional conflict among the users in their pragmatic randomised controlled trial.¹⁹

Furthermore, the training and practices of primary healthcare providers, and the public primary healthcare infrastructure, financing policy and system delivery differ to various extents between the two nations. We postulated that differences in the views and expectations exist between the two groups of healthcare providers on the content and layout of the PDA, which could impact on their future PDA utility. Hence, this study aimed to

explore the views and perceptions of Singapore primary care providers on the Malaysian PDA developed by UM and to report the cultural adaptation process used in the design and development of a new PDA to be used in a Singapore public primary healthcare institution.

METHOD

Qualitative research method was used to gather the views and perceptions of primary care providers at a polyclinic in the eastern region of Singapore.

Study site

This polyclinic is approximately 1760 m² in size with open access to its 53 800 multiethnic Asian residents.²⁰ Its polyclinic 14 physicians and 28 nurses serve approximately 500 walk-ins and scheduled ambulatory patients daily during office hours. The polyclinic provides a wide range of primary healthcare services based on a subsidised copayment scheme by the patients. The T2DM Registry shows the primary care professionals manage 5471 patients with T2DM at this study site, of which 3.56% have HbA1c of 9.5% or higher based on its monthly quality indicators for T2DM.²¹ All the polyclinic healthcare team members manage patients with T2DM during their clinical work but SDM is not explicitly incorporated into the local clinical guidelines and practices.²²

Subjects

AK is a member of the study team working at the study site. She provided her colleagues with the institution review board approved study information leaflets (which also contained the interview topic guide) and invited them to participate in the study voluntarily during the polyclinic staff meeting. A total of six polyclinic physicians and four nurse counsellors volunteered to be interviewed. They were then provided with a print copy of the original PDA (UM), which is available in four languages. All of them opted for the English version, as it is the common language of communication in Singapore. They were given at least 3 days to review the content and layout of the PDA (UM) before their scheduled interviews.

Topic guide development

The topic guide was aligned to the broader aims of the study to explore the views and perspectives of the participants (healthcare providers) on shared decision-making in initiating insulin as part of the intensification of the T2DM treatment of their patients and their comments on the use of the proposed PDA (online supplementary appendix 1). In the latter, the questions in the topic guide specifically seek their views on the depth and breadth of information and the language used in the UM PDA (figure 1).

Interviews

In-depth interviews were conducted on each de-identified participant using the topic guide after obtaining their written consent. Each interview was audio-recorded

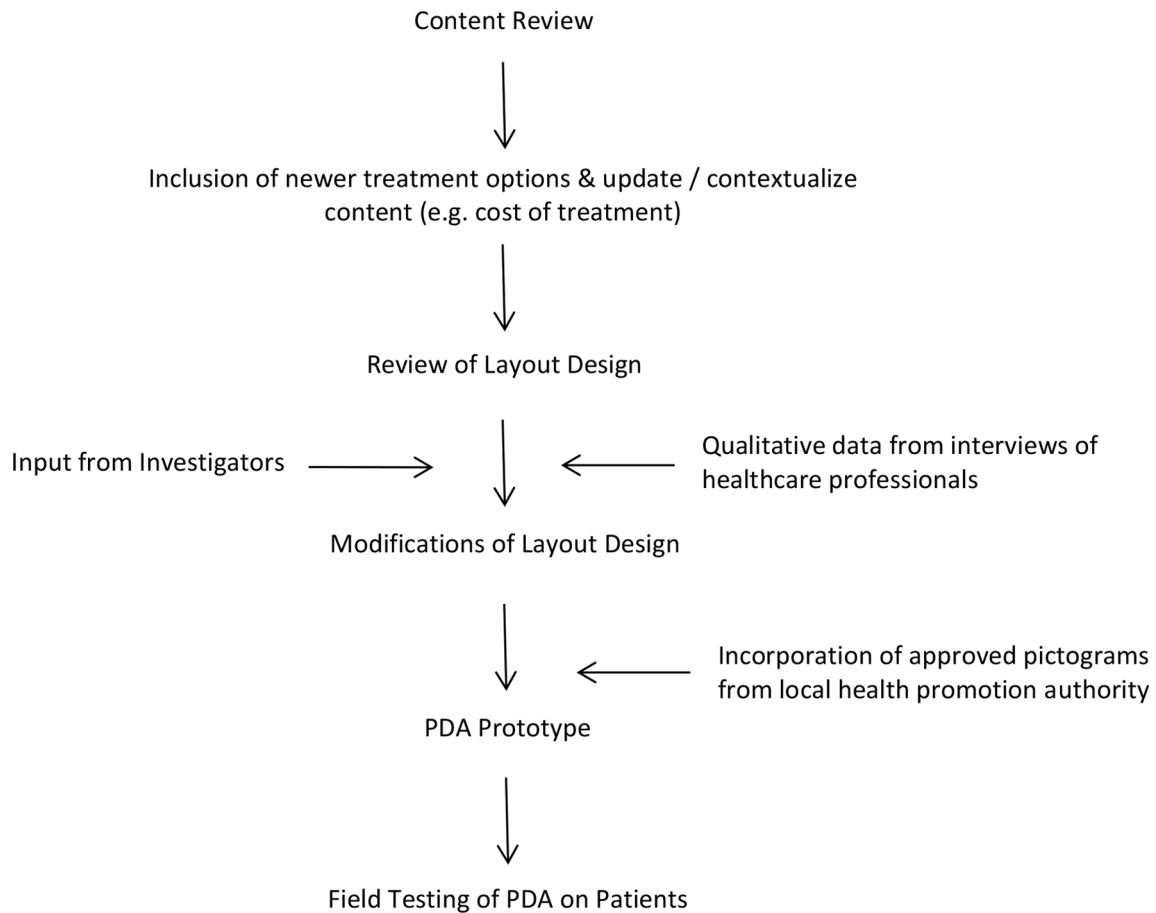


Figure 1 Cultural adaptation and development pathway of patient decision aid (PDA).

in a quiet room, which lasted 30–40 min. To avoid conflict of interest, the interviewers from the study team were not staff at the study site. The recordings were transcribed into text and then coded by two independent study team members.

Data analysis

Using standard content analysis, the codes were used to identify emergent themes on the content, layout, applications and implementation of the PDA. Those pertaining to the content and layout were collated and identified as the potential areas of change in the design of the new PDA (SingHealth Polyclinics—SHP).

Adaptation and transformation into the new PDA

Content

Investigators carried out content review to update the evidence on the effectiveness and adverse effects of the treatment options for T2DM, including new categories of oral (sodium glucose (SGLT2) inhibitors) and injectable (GLP-1 agonist) drug therapies, which are available in Singapore and would be included in the new PDA. These two treatment options were not available at the public Malaysian primary care clinics at the time of the review of the PDA (UM).

The investigators sought the assistance of the pharmacist to replace the estimated cost of the treatment options

based on Singapore currency and local healthcare finance policies, which differ from those in Malaysia.

Layout

The format of the PDA prototype follows the guidelines from the Ottawa University Research Institute, which is open access via its website.⁷ The PDA includes the following segments: (1) knowledge; (2) values; (3) support and (4) certainty in making decision. Based on the qualitative data from the participants and iterative discussions among the investigators, features of the original PDA (UM) which were deemed relevant and essential were retained, modified or updated. The designer of both the PDA is the same person.²³

The key processes in adapting the PDA for implementation at the new target population are depicted in a flow chart in figure 1.

Patient and public involvement

No patient involved

RESULTS

The participants had comments pertaining to the dimensions of the UM PDA, its cover page, colour scheme, font size, graphics (including pictograms), presentation styles, flow of information, content (subheadings,

personalisation, cost and treatment option) and concerns (choice of words) relevant to the local population.

The translation of the themes into changes in content and layout of the new PDA are summarised in [table 1](#).

DISCUSSION

Cultural adaptation is defined as a process that looks at both language and cultural issues in the process of preparing a tool for use in another setting.²⁴ The focus is finding cultural equivalents (such as words, examples and pictures) so that the information is accurate, relevant and understandable to the different cultural population.²⁵

Cultural adaptation is prerequisite for the delivery of culturally competent interventions and positive health outcomes among multiethnic populations.²⁶ In this study, cultural adaptation of a PDA developed in one academic institution was carried out before its introduction in another healthcare organisation in a second country. In spite of similar ethnic composition in the two populations, significant changes in content and layout were carried out to develop the new PDA ([table 1](#)). They include overall design, graphics (including pictograms), presentation styles, additional contextualised content (cost and treatment option), modified phrasing of subtitles and list of concerns relevant to the local population.

The cultural adaptation in this endeavour appears to match the key strategies developed by Kreuter *et al*²⁷ to promote cultural competency in healthcare programme development.²⁷ The culturally adapted SHP PDA will be a key tool to engage patients with poorly controlled T2DM in a subsequent trial. Kreuter *et al* described five 'categories of strategies'.²⁷ As illustrated in [table 1](#), vibrant colour scheme and image of insulin injectable pens are introduced in the SHP PDA to enhance receptivity and acceptance of the material under the 'Peripheral category of strategy'. Facts and evidences are updated on the health topic in the 'Evidential category'. While English is used in both PDA, the choice of words differs slightly in certain segments (refer to results) so as to increase accessibility and understanding of the content under the 'Linguistic' category.

Removal of the concern that insulin is non-halal in the SHP PDA is an example of change under the 'Socio-cultural' category. In Malaysia, the majority ethnic group comprises Muslim Malays, who are concerned about the source of the insulin and is explicitly highlighted as a potential concern in the UM PDA. It was not in the SHP PDA as local primary care providers are aware that insulin and its analogues available in Singapore are halal-certified, besides, it is not a major or common concern among local Muslim patients. Provision of an open-ended 'other' option also allows patients to raise this concern.

The aim of 'Constituent-involving' is to enhance the understanding and 'buy-in' of the tool. Hence, the native primary healthcare providers in the institution were involved in the interviews to gather their feedback on the content and layout, focusing on the content and

layout. The objective is to understand their views of the PDA and to determine if the proposed tool addresses the main issues encountered during their prior interaction with the target patients. We postulate that the implementation of this PDA is more likely to be successful when the providers understand the objectives of SDM and PDA and are involved in the content revision as well as the design of the PDA. During the interview, their willingness to use the PDA was assessed. All the interviewees expressed that they were keen to try it. The investigators will continue to gather their input after the PDA prototype is introduced to patients in the subsequent feasibility study.

The patients or lay persons are the other main group of users. Their views and input will be sought after the PDA prototype is introduced to them in actual clinical setting in the next phase of the study. What is more critical to the latter is their understanding of the PDA content when the provider communicates the content to them according to the layout of the tool. The investigators will leverage on the feedback from both the providers and the patients to refine the PDA before the finalised version is scaled up for routine clinical use in the institution.²⁸

The proposed implementation of this PDA is aligned to the four phases recommended by Chenel *et al* in their scoping review on the cultural adaptation and validation of PDAs.²⁹ What had been accomplished constitutes the exploration and adaptation phases, the providers and the patients will next be involved in the usability testing, exploration of PDA acceptability, test-retest reliability, content, construct and criterion validation in the subsequent lab and field testing phases.²⁹

The cultural adaptation process of the SHP PDA is summarised in a flow chart ([figure 1](#)). The process took 8 months to complete, from the commencement of the qualitative research involving interviews of the primary care providers to its registration for the International Standard Book Number. As alluded by Chenel *et al*,²⁹ the next step is to conduct usability, acceptability and reliability testing, and validation studies of the PDA by the patients and their providers. Success will be rated from its eventual implementation in routine clinical practice, which will require further evaluation of its reach, effectiveness, adoption and scalability using implementation science. Modifications of the PDA will be carried out iteratively to update its content and to cater to the changing demography of the population, including their literacy levels.

Another process to accelerate the PDA development is to translate the tool to local languages before its clinical application. Whether this simplified method to produce a translated PDA attains the same objective compared with one which undergoes cultural adaptation remains to be proven by robust scientific evidence.

The cultural adaptation of the SHP PDA was based on the English version of the UM PDA. The process of cultural adaptation of PDA across different language is unclear and awaits further research to gain insight. Professional certified linguists have performed forward

Table 1 Cultural adaptations of the UM PDA to develop the SHP PDA

Features (codes)	Qualitative feedbacks from primary healthcare providers (verbatim)	PDA (UM)	PDA (SHP)
Design and presentation			
Dimensions and pages	'If the PDA has more pages, information about 'insulin therapy' ... (we) can explain each symptom ... what happens when your blood sugar is high?' Doctor	20.2x20.2 cm booklet, comprising 16 pages	17.3x25.0 cm booklet, comprising 20 pages
Colour scheme	Investigators propose warm colour scheme and align to corporate branding	Blue and green background	Predominantly orange background
Key feature on cover page	'The PDA doesn't really show the pictures of the needle itself.' Doctor	Insulin Pen without revealing the needle	A pair of hands showing insulin pen with needle
Font type	The font type was recommended by designer	Helvetica Neue (regular)	Futura Std (medium)
Text font size	'The font size could be bigger' Doctor 'For old people, they might prefer a bit bigger font.' Nurse	Font size (height): 10 pt	Font size (height): 12 pt
Illustrations	'Pictures of various complications can be added ... will be (of) concern of patients' Doctor 'some pictures showing how pancreas releases sugar ... pictures will be catchy for the patients and they will understand better' Nurse	Entirely text-based content	Pictograms inserted in segments on: 'what happens when your blood sugar is high?' and 'Type 2 Diabetes and Insulin'
Summary Page of Treatment Options	'the flow (diagram) will be more clear' Doctor	Presentation in the form of six branches: each branch represents one treatment option	Presentation in the form of seven cogwheels: each cogwheel represents one treatment option.
Design on page on 'support' and 'decision'	'As in the sort of diagrams like tables if possible to put flow chart' Doctor	Design in the format of leafs with 'yes' and 'no' responses as extension of each leaf, which are consistent with the general design of the entire PDA.	Design for 'support' in the form of machinery and 'decision' in two columns
Personal notes	'(make it) personalized - there is an option to write your name, put your IC number, put your primary care provider' Doctor 'there should be column for them to write their views' Doctor	Provision for entry of personal notes at the rear of the PDA	Provision for entry of personal notes at the rear of the PDA
Content			
Languages	'With regards to the language used, we need to customize to our multi ethnic group needs.' Nurse	Available in four languages	Available in three languages
Listing and number of treatment options	'SGLT2 inhibitors are missing.' Doctor	Six treatment options: no specification of types of oral or parenteral medications	Seven treatment options. For oral and parenteral medications, specific categories of medication are presented, together with common examples. For example SGLT-2 inhibitors (Example: DapagfloZin)
Cost of treatment options	'We can state the cost range for the insulin usage. It is quite difficult because the cost fluctuates; the insulin cost and the glucose monitoring glucometer and the strip will fluctuate. You can state as estimated cost. Of course, it is in Ringgit. When reproduce make it into Sing Dollars.' Doctor	Range of costing in Malaysian currency (Ringgit) per unit (pen) or duration (per day or per month)	Range of costing in Singapore currency (Singapore dollars), which includes consumables such as needles per 4 weeks based on specific quantum of medication used (10 units of insulin per day). Context: the patient is charged each medication per week.
Glycaemic control targets	'in the local context, people may be followed up somewhere else (hospitals) than polyclinic setting ... (to indicate) blood sugar control (page 2) expressed in both millimoles per litre and milligram per litre.' Doctor	Target in ranges for fasting (4.4–6.1 mmol/L); non-fasting blood sugar (4.4–8.0 mmol/L) and single HbA1c target (<6.5%)	Pre-meal glucose range (4–7 mmol/L or 72–126 mg/dL); 2-hour post meal glucose range (<10 mmol/L or <180 mg/dL); HbA1c target options (6.5% or ≤7% or <8%)

Continued

Table 1 Continued

Features (codes)	Qualitative feedbacks from primary healthcare providers (verbatim)	PDA (UM)	PDA (SHP)
Highlighting risk of treatment	'not all the common concerns were addressed in the booklet' Doctor 'Complications like physical impairment (blindness) ... patients cannot see properly to inject. Some people may have tremor, so they cannot hold the needle properly.' Doctor 'more can be added about the small side effects of the insulin therapy like atrophy, that kind of skin changes.' Doctor	Entitled 'Does insulin have side effects?' on half a page, focusing on recognising and managing hypoglycaemia and weight gain	Grouped under 'What are your concerns?' over two pages. Enlist treatment-related concerns on pain from injection; side-effects on kidney (perceived damage); weight gain; hypoglycaemia; lipodystrophy; inconvenience; expenses; discontinuity of insulin; whether insulin is halal; continuity of oral medications; addiction to insulin; necessity of use of insulin; disease progression after insulin initiation; social embarrassment; family support and open option to discuss other concerns, if any.
Understanding of treatment options	'Generally it is sufficient to provide the required information for the patient who we have given the option for the first time to choose their treatment.' Nurse	Entitled 'Do you know enough about the treatment options?' Assessment using four questions. No answer is provided.	Entitled 'Quiz Time!' Assessment using four questions. Answers are provided.
Understanding personal values and preferences in relation to treatment selection	'Page 10 (What is important to you?): I think it is quite useful. It's a kind of assurance. Patients can go through this booklet and make an effort to answer the questions. So they get to see what this option does and another option does. It clears their mind ... to make a decision.' Doctor	Page is entitled 'What is important to you?' Presented as three overlapping circles and text in two circles subtitled 'Starting Insulin' and 'Not Starting Insulin' followed by 'I want to...' and 'I want to avoid...'	Page is entitled 'What is important to you?' Presented in two columns entitled 'I want to...' and 'I want to avoid...'
Understanding concerns	'...more on the insulin side-effects; right now it just addresses two only. Actually there may be more than few; the patient may be concerned about 'Insulin may damage my kidney', which is not the case; that concern (has to be) addressed.' Doctor	Listing of known or common concerns in phrases, including 'whether insulin is halal'	Listing of known or common concerns more succinctly in single words or short phrases. 'Whether insulin is halal' is not explicitly listed as a concern

PDA, patient decision-aid; SHP, SingHealth Polyclinics; UM, University of Malaya.

and backward translation of the English version of the SHP PDA to produce the Mandarin and Malay versions to cater to the non-English speaking Chinese and Malay patients respectively. The effectiveness of these translated PDA, compared with the culturally adapted English version, will be evaluated in a separate study.

CONCLUSION

An English-based PDA on insulin therapy underwent cultural adaptation before its planned implementation in a separate nation was carried out. Gathering qualitative feedbacks from primary care providers, coupled with iterations from the investigators in the review of content and layout of the PDA, are key steps in this cultural adaptation process. The culturally adapted PDA will be implemented to support decision-making in selecting treatment options among patients with poorly controlled T2DM in the next phase of the study.

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Contributors NCT and CJN developed the substudy concept. NCT, CJN, MP and YKL conducted the interviews. MP transcribed the audio recordings. NCT and MP coded the data. NCT and YLAK analysed the qualitative data. NCT, YLAK, YKL, JF, JC, KYIP and ZSW interpreted the results. NCT, MP, KYIP and ZSW drafted the manuscript and all authors revised the manuscript and approved the final version to be published.

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Patient consent for publication Not required.

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