

A measure of case complexity for cancer multidisciplinary tumor boards: Development and early validation of the MeDiC tool

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1. Data Analysis Procedure

Phase 1. Identification of variables: Exploratory ethnographic interviews and observations

A list of complexity factors was created by noting down quotes from the interviews with the clinicians. The items were grouped into themes.

Phase 2. Content validation of the items identified in Phase 1: Survey

To determine relevance of items identified in phase 1, we subjected them to a survey aimed at core MDT members. The responses, received on a scale of 1 to 5 (with 1 being very simple, 2 simple, 3 moderate, 4 complex and 5 very complex patient-discussion) were analysed using the *item-content validity index (I-CVI)*. This is the most widely used measure to assess content validity of individual items in tool development (Polit et al., 2006). The I-CVI was computed by dividing a number of participants giving an item a rating of 4 (complex) or 5 (very complex) by the total number of participants. The criteria for item acceptability has been recommended, and it depends on the number of participants or experts rating the items (Polit et al., 2006, 2007). While if there are less than 5 experts all have to agree for the item to be retained, if there are more than 5, such is the case in this phase, then the standards are more relaxed - i.e. the $I-CVI > 0.78$ is considered excellent, >0.71 good, and >0.67 weak (Polit et al., 2006, 2007). These criteria were applied to the data analysis, which guided the selection of items for retention, revision or deletion.

Phase 3. Content validation of the items identified in Phases 1 and 2: Team review and consensus

In this phase, the same principle in terms of the I-CVI analysis was applied to the data as in the previous phase (i.e., phase 2). The only difference is the criteria for item acceptability since the team of experts rating the items in this phase consisted of 4 clinicians. Hence, they all had to agree (i.e., $I-CVI = 1$) for an item to be retained at this stage (Polit et al., 2006, 2007).

Phase 4. Content validation and Item weighing: A national survey

To validate the items with a larger national sample and determine the level of complexity each item adds to the MDT discussion, factors that received full agreement in phase 3 were subjected to a large-scale survey. Again, the same principle of the I-CVI analysis presented in phase 2 above was applied to the data. Since the sample

was large and consisted of more than 5 experts, the same criteria for item acceptability was used as in the phase 3, i.e. the I-CVI > 0.78 is considered excellent, >0.71 good, and >0.67 weak (Polit et al., 2006, 2007). In addition, the mean rating for the qualifying items was used as the weight added to each variable when calculating the overall complexity score for individual patient-discussions. This allowed for differentiation between items based on how much complexity they add to the patient-discussion.

Phases 5. Feasibility and reliability testing

To assess feasibility and reliability, we first determined the inter-rater reliability between a clinical researcher (AM) and research psychologist (TS). Interclass correlation coefficient (ICC) was used for continuous variables, and Kappa for categorical items. Second, Cronbach's Alpha was calculated for each phase as a measure of internal consistency and tool reliability, which allowed us to determine how closely the items are related in measuring the complexity. Third, using SPSS, we also determined Cronbach's Alpha coefficient if item removed, which gave further clarity on whether the retaining the item improves scale reliability. In contrast to other reported statistics, Cronbach's Alpha coefficients and ICCs are rounded to 3 decimal places for a better precision.

Last, the items were further validated using correlation analysis between individual complexity items and the *time spent discussing a patient case*, as well as *the total complexity score* (i.e. item-total correlation). Partial correlations controlling for tumour type are reported for associations between all continuous variables (i.e., time per case, clinical complexity, logistical complexity and total complexity scores). On the other hand, for the association between continuous and dichotomous items (items 1 to 26), we report point-biserial correlation coefficients together with effect sizes (expressed as coefficient of determination or % of variability explained in the continuous variable).

Phase 6. Feasibility and reliability testing II

In this phase, we assessed feasibility and reliability on a larger sample ($N=822$) following the same process of analysis as described in phase 5 above.

Tool validation and complexity levels. To validate the instrument, we firstly determined the complexity levels within the data using percentiles and quartile values as cut-off points. We then used Kruskal-Wallis H test to test for significant differences in discussion time between different levels of complexity. If the tool measures complexity of patient-discussions, one would expect that the higher the level of complexity, the longer the discussion time.

Variability across teams. We used measures of variability in the data, such as, skew, kurtosis, means, medians, interquartile ranges, minimum and maximum values to explore differences between teams on clinical and logistic complexities. Skew relates to the asymmetry of the probability distribution, and it can be positive with a longer right tail and distribution concentrated on the left, or negative with a longer left tail and mass concentrated on the right. Kurtosis relates to the sharpness of the peak and shape of a distribution's tails in relation to the overall shape. There are three types of kurtosis, namely, a *mesokurtic distribution*, which is the one that resembles the bell curve but has fatter tails and lower peak; a *leptokurtic* is the one with thick tails and thin and tall peak; a *platykurtic* distribution is the one with a broad and short peak and slender tails.

Logistical complexity. We used frequency counts and percentages to capture logistical complexities in the meetings. We used bootstrapping with stratified sampling and tumour type as a stratification variable throughout the analyses (Wright et al., 2011).

Between Phases: Iterative Methodological Reviews

Throughout the phases described above, five further reviews of MeDiC development took place – with a focus on methodology. These were carried out by experts in patient safety and tool development (NS, TS) and cancer specialists (BWL, JG, TG and KH). This further methodological review process was time-consuming; but it enabled in depth methodological evaluation of the deliverables of each one of the clinical review/validation phases described above. It facilitated detailed examination and iterations allowing continuous appraisal of items within MeDiC, thus achieving a convergence of opinion from subject matter clinical and methodology experts¹⁰ on a rather intricate question of what constitutes a complex case for cancer MDT.

2. Item-Content Validity Indices for the Factors Identified through Interviews (Phase 1), Survey (Phase 2) and Expert Agreement (Phase 3)

#	Items identified in Phase 1 (with the exception of items marked with *)	Survey/ Phase 2	Expert agreement/ Phase 3	
		I-CVI†	I-CVI‡	Outcome
1	Unusual or rare tumour type	.82	1	Retained
2	Patient does not fit into recommended guideline & treatment pathway	.67	1	Retained
3	Conflict of opinions about treatment options	.60	1	Retained
4	Poor performance status	.46	1	Retained
5	Socio-economic issues	.46	1	Retained
6	Lifestyle risks	.12	1	Retained
7	Significant past surgical history	.56	1	Retained
8	Treatment failure	.59	1	Retained& merged with item 9
9	Treatment toxicity and contraindications to standard treatment*	.*	1	Retained & merged with item 8
10	Mental health comorbidity	.75	1	Retained& merged with item 11
11	Cognitive comorbidity	.63	1	Retained& merged with item 10
12	Immunocompromised (e.g. immunosuppressed)	.59	1	Retained& merged with item 13
13	Significant physical comorbidity	.51	1	Retained& merged with item 12
14	Missing patient information	.67	1	Retained as logistical issues
15	Lack of clarity from clinical symptoms, signs, or diagnostic tests	.65	1	Retained as logistical issues
16	Pathology not ready*	.*	1	Retained as logistical issues
17	Insufficient details on request form accompanying post-op resections*	.*	1	Retained as logistical issues
18	Images from other hospitals not ready so patient gets postponed*	.*	1	Retained as logistical issues
19	Clinician who knows the patient is not present*	.*	1	Retained as logistical issues
20	Not all MDT members present	.68	1	Retained as logistical issues
21	Failure of videoconferencing*	.*	1	Retained as logistical issues
22	Higher number of patients on MDT list*	.*	.50	Excluded
23	Increased distance between patient location and treating centre*	.*	0	Excluded
24	Input required from other specialty MDTs	.75	0	Excluded
25	Competing treatment pathways available with equal evidence of benefit	.58	0	Excluded
26	Dilemma of quantity versus quality of life with the proposed treatment	.54	.25	Excluded
27	Lack of engagement in case-discussion	.53	0	Excluded
28	Input required from team members from multiple disciplines within the MDT	.41	0	Excluded
29	Patient has strong views on treatment options	.38	0	Excluded
30	Post RT/Chemo (as adjuvant therapy)	.35	0	Excluded
31	Post RT/Chemo (as primary treatment)	.34	0	Excluded
32	Post RT/Chemo (as neo-adjuvant therapy)	.31	0	Excluded
33	Significant drug history (e.g. anticoagulation)	.31	.75	Excluded

34	Positive family history / Genetic risks	.31	0	Excluded
35	Patient may be eligible for trial	.22	0	Excluded
36	Candidate for hormone therapy	.18	0	Excluded
37	Positive for recognised phenotypes (e.g. ER+, HER2+)	.14	0	Excluded
38	Unexpected treatment failure*	.*	0	Excluded
39	New diagnosis	.12	0	Excluded
40	Post-operative	.12	0	Excluded
41	Highly symptomatic (e.g. excessive pain, hospitalised)	.41	0	Excluded
42	Recurrent cancer	.60	0	Excluded
43	Secondary cancer	.49	0	Excluded
44	CiS (Carcinoma in situ)	.15	0	Excluded
45	Primary cancer	.10	0	Excluded
46	Grade 1	.08	0	Excluded
47	Grade 2	.06	0	Excluded
48	Grade 3	.13	0	Excluded
49	T1	.04	0	Excluded
50	T2	.04	0	Excluded
51	T3	.18	0	Excluded
52	T4	.30	0	Excluded
53	N2	.27	0	Excluded
54	N1	.24	0	Excluded
55	Metastases	.32	0	Excluded
56	0-24 years of age	.51	0	Excluded
57	25-49 years of age	.41	0	Excluded
58	50-74 years of age	.18	0	Excluded
59	75+ years of age	.33	0	Excluded
60	Exposed to environmental risks for cancer	.12	0	Excluded

Note. *Added by the respondents in Phase 2 Survey as part of the free text comments. I-CVI = Content Validity Index. †I-CVI for 5+ expert judges >0 .78 excellent, >0.71 good, >0.67 fair, and <0.67 weak ‡I-CVI for less than 5 expert judges = 1, i.e. all have to agree for item to be retained.

3. Survey Ratings by the Respondents (per Discipline) of the Cancer Research UK led Survey

#	Complexity Item	Mean rating (I-CVI*) per discipline					
		CNS	Oncologists	Pathologists	Physicians	Radiologists	Surgeons
		<i>n</i> = 262	<i>n</i> = 171	<i>n</i> = 79	<i>n</i> = 107	<i>n</i> = 113	<i>n</i> = 241
1	Unusual or rare tumour type	4 (0.75)	4 (0.88)	4 (0.84)	4 (0.76)	4 (0.85)	4 (0.84)
2	Conflict of opinions regarding treatment options	4 (0.75)	4 (0.89)	4 (0.82)	4 (0.86)	5 (0.91)	4 (0.80)
3	Guidelines/ pathway do not account for patients situation	4 (0.63)	4 (0.79)	4 (0.79)	4 (0.72)	4 (0.83)	4 (0.69)
4	Mental health and cognitive comorbidity	4 (0.62)	4 (0.67)	3 (0.35)	4 (0.62)	4 (0.60)	4 (0.63)
5	Treatment toxicity and contraindications	3 (0.45)	3 (0.46)	4 (0.59)	4 (0.60)	3 (0.50)	4 (0.57)
6	Significant physical comorbidity	3 (0.50)	4 (0.55)	4 (0.47)	4 (0.58)	4 (0.56)	3 (0.50)
7	Significant surgical history	3 (0.45)	3 (0.44)	4 (0.54)	4 (0.49)	4 (0.57)	4 (0.55)
8	Poor performance status	3 (0.34)	3 (0.37)	3 (0.22)	3 (0.40)	3 (0.37)	3 (0.47)
9	Socio-economic issues	3 (0.34)	3 (0.36)	3 (0.31)	3 (0.37)	3 (0.32)	3 (0.30)
10	Lifestyle risks	3 (0.29)	3 (0.31)	3 (0.24)	3 (0.36)	3 (0.34)	3 (0.30)
Free text item							
11	Previous history of cancer		✓				✓
12	Recurrence		✓				✓
13	Multiple cancers	✓	✓			✓	✓
14	Diagnostic uncertainty & inconclusiveness		✓	✓	✓		✓
15	Further tests needed due to		✓	✓	✓		✓
16	Further input needed from other specialties	✓				✓	✓
17	Previous oncological treatments	✓	✓	✓			
18	Trial eligibility	✓	✓				
19	Patient choice and family opinion	✓			✓	✓	
20	No one present has seen the patient					✓	

Note. N=973. CNS = Cancer Nurse Specialist. *I-CVI > 0.78 excellent, > 0.71 good, > 0.67 fair, and < 0.67 weak.

4. Items from Phases 2-5 with Frequency, Discussion Time, Item-Content Validity Indices and Mean Ratings

#	Item	Phase 5 (N=82)				Phase 4		Phase 3	Phase 2
		Item Frequency		Average time per patient‡		N=52		N=4	N=973
		Count	%	With the item	Without the item	I-CVI**	Mean rating††	I-CVI**	I-CVI**
Items with consensus in Phase 3 expert agreement (frequency range 0 to 33.3%)									
1	Unusual or rare tumour type	5†	6.2	04:18‡	02:42	.82	4	1	.82
2	Conflict of opinions regarding treatment options	8†	9.9	05:50*	02:28	.84	4	1	.60
3	Guidelines/ pathway do not account for patient's situation	1†	1.2	05:15	02:46	.74	4	1	.67
4	Mental health and cognitive comorbidity	0†	0	-	02:47	.60	4	1	.75
5	Treatment toxicity and contraindications to standard treatment*	1†	1.2	04:09	02:46	.53	3	1	.59
6	Significant physical comorbidity	24	29.6	03:26*	02:31	.53	3	1	.51
7	Significant surgical history¶	27	33.3	02:19*	03:44	.51	3	1	.56
8	Poor performance status	0†	0	-	02:47	.36	3	1	.46
9	Socio-economic issues	0†	0	-	02:47	.33	3	1	.46
10	Lifestyle risks	1†	1.2	01:03	02:49	.31	3	1	.12
Items added by the respondents in the Phase 4 Survey (frequency range 1.2 to 43.2%)									
11	Previous history of cancer	18	22.2	03:53*	02:29	-	-	-	-
12	Recurrence	3†	3.7	06:11*	02:40	-	-	-	-
13	Multiple cancers (incl. multiple primaries)	14	17.3	03:55*	02:33	-	-	-	-
14	Diagnostic uncertainty & inconclusiveness¶	35	43.2	01:45*	02:25	-	-	-	-
15	Further tests and patient assessment needed	32	39.5	03:54*	02:04	-	-	-	-
16	Further input needed from other specialties	14	17.3	04:58*	02:20	-	-	-	-
17	Previous oncological treatment	12	14.8	04:34*	02:29	-	-	-	-
18	Trial eligibility	1†	1.2	01:03	02:49	-	-	-	-
19	Patient choice and family opinion	2†	2.5	03:28	02:47	-	-	-	-
Items added via the initial feasibility testing in Phase 5 (frequency range 9.9 to 45.7%)									
20	Malignancy	37	45.7	03:42*	02:02	-	-	-	-
21	Invasive component	33	40.7	03:47*	02:06	-	-	-	-
22	Residual tumour left	13	16	04:52*	02:23	-	-	-	-
23	Increased size	12	14.8	02:23	02:40	-	-	-	-
24	Nodal involvement	18	22.2	03:50*	02:29	-	-	-	-
25	Metastases	13	16	04:08*	02:32	-	-	-	-
26	Advanced, progressive, high grade disease	22	27.2	03:54*	02:22	-	-	-	-
27	Unusual anatomy/ distribution of tumour	8†	9.9	06:21*	02:42	-	-	-	-

Note. In Phase 5, N refers to patient-discussions, while in phases 2-4, it refers to health professionals. * $p < .05$, tested using non-parametric Mann-Whitney U test. †Sample size is small. ‡Marginal significance. Items in boldface are related to shorter discussions, however, those marked with ¶ are significantly positively correlated with discussion time, while for lifestyle risks and trial eligibility coefficient is close to 0. †Expressed as minutes and seconds. **I-CVI = Content Validity Index. †I-CVI for 5+ expert judges > 0.78 excellent, > 0.71 good, > 0.67 fair, and < 0.67 weak ‡I-CVI for less than 5 expert judges = 1 i.e. all have to agree for item to be retained. ††Mean rating (scale 1-5) is the weight added to each variable when calculating the overall complexity score.

5. Reliability and Validity Statistics on the Complexity Items tested in the Preliminary Assessments in Phase 5

	#	Item	Item weighing	Assessor Reliability	Item Reliability	Correlation¶				Discussion time	
				Kappa	Cronbach's Alpha if item removed†	Item-Total		Discussion time			
						r (unadjusted)	% variability explained	r (adjusted§)	% variability explained	r	% variability explained
Phase 3 items	1	Unusual or rare tumour type	4	1.000	.767	.28**	8.07	.35**	12.46	.18	3.13
	2	Conflict of opinions about treatment options	4	.934	.767	.30**	9.00	.43**	18.06	.46**	21.16
	3	Mental health and cognitive comorbidity††	4	-	.771	-	-	-	-	-	-
	4	Significant surgical history	3	1.000	.756	.51**	26.52	.66**	42.76	.30**	9.24
	5	Socio-economic issues††	3	-	.771	-	-	-	-	-	-
	6	Significant physical comorbidity (incl. poor PS§§)	3	1.000	.769	.35**	12.46	.47**	22.09	.19	3.57
	7	Guidelines do not account for patients situation*	4	.661	.769	.22	4.62	.26*	6.60	.13	1.59
	8	Treatment toxicity and contraindications	3	1.000	.768	.28*	7.78	.28*	7.67	.07	0.49
	9	Lifestyle risks*	3	1.000	.771	.09	0.72	.05	0.26	-.09	0.79
Phase 4 added items	10	Previous history of cancer	1	1.000	.765	.38**	14.52	.41**	17.06	.27*	7.08
	11	Recurrence	1	1.000	.762	.43**	18.75	.38**	14.29	.30**	9.24
	12	Further tests and patient assessment needed	1	.949	.766	.40**	16.24	.33**	10.63	.41**	16.73
	13	Further input needed from other specialties	1	1.000	.766	.34**	13.11	.34**	11.56	.46**	20.79
	14	Previous oncological treatments	1	1.000	.759	.45**	21.86	.48**	23.43	.34**	11.49
	15	Multiple cancers	1	1.000	.769	.30*	9.06	.26*	6.86	.24*	5.25
	16	Diagnostic uncertainty & inconclusiveness	1	1.000	.777	.28**	7.95	.29**	8.24	.25*	6.10
	17	Trial eligibility*	1	1.000	.771	.09	0.72	.05	0.26	-.09	0.79
	18	Patient choice and family opinion	1	1.000	.773	.03	0.08	.04	0.19	.04	0.12
Phase 5 added items	19	Malignancy	1	1.000	.743	.65**	41.99	.54**	28.73	.38**	14.52
	20	Invasive component	1	1.000	.744	.64**	40.70	.50**	25.20	.38**	14.44
	21	Residual tumour left	1	1.000	.756	.50**	24.80	.43**	18.84	.42**	17.31
	22	Unusual anatomy/ distribution of tumour	1	.934	.760	.43**	18.66	.39**	14.98	.25*	6.05
	23	Nodal involvement	1	1.000	.755	.52**	26.94	.40**	15.68	.26*	6.60
	24	Metastases	1	1.000	.746	.64**	41.47	.54**	29.16	.27*	7.13
	25	Advanced, progressive, high grade disease	1	1.000	.738	.71**	49.84	.57**	32.95	.31**	9.55
	26	Increased size	1	1.000	.765	.35**	12.11	.28*	7.78	.14	2.05
27	Logistical complexity (occurrences per discussion) #	1 (0, 3) ‡‡	1.000‡	-	.09	-	-	-	.13	-	
Total clinical complexity (sum of items 1 to 27)			6.5 (0, 22) ‡‡	0.931‡	-	-	-	-	.66**	-	
Total complexity (sum of clinical and logistic scores)			7.5 (0, 23) ‡‡	0.931‡	-	.98**	-	-	.66**	-	

Note. N=81 discussions (all double rated). **Green** = good measure of complexity. **Yellow** = fair. **Red** = weak and could be removed. * $p < .05$ ** $p < .01$. †Cronbach's Alpha is 0.770. ‡Interclass Correlation Coefficient. §Adjusted for item weighing. ¶Total clinical complexity. ¶¶Point-biserial correlation coefficients for items 1-26; Partial correlation controlling for tumour type for discussion time, clinical, logistical and overall complexity. #The most frequent numbers of logistical problems were 1 (53%), 2 (15%), and 3 (5%); 27% of cases had no observed logistical issues. ††Statistics cannot be computed because it is constant.‡‡Mean (Min, Max).§§ Performance status. R between Total and Logistical Complexity is .30*.Data was bootstrapped on 5000 stratified samples with tumour type as a stratification variable. **MeDiC Copyright 2017 © Soukup Sevdalis Green.**

6. Item-total Correlation for Individual Cancer Teams on the Final List of the MeDiC Tool

#	Complexity Items	Breast team (n=241)			Colorectal team (n=185)			Gynaecological team (n=396)		
		%	Time per case <i>r</i>	Total Complexity [†]	%	Time per case <i>r</i>	Total Complexity <i>r</i>	%	Time per case <i>r</i>	Total Complexity <i>r</i>
Pathology										
1	Malignancy	46.9	.53**	.58**	66.5	.28**	.36**	51.3	.16**	.38**
2	Invasive component	33.2	.51**	.52**	43.6	.29**	.40**	23.9	.10	.40**
3	Residual tumour	5.4	.10	.11	4.8	.06	.13	6.6	.23**	.23**
4	Recurrence	2.1	.24**	.26**	5.3	.24**	.30**	6.3	.26**	.26**
5	Multiple cancers (incl. multiple primaries)	8.7	.48**	.41**	10.6	.22**	.20**	7.1	.21**	.35**
6	Increased size (T3, T4)	7.5	.35**	.40**	27.1	.16*	.26**	2.9	.11*	.328**
7	Nodes affected	13.3	.37**	.37**	22.9	.13	.24**	7.4	.35**	.483**
8	Mets (local or distant)	13.3	.37**	.48**	21.3	.37**	.40**	10.3	.28**	.552**
9	Advanced stage, progressive	11.6	.33**	.42**	13.3	.34**	.39**	12.1	.26**	.470**
10	Unusual or rare tumour type	3.7	.19**	.26**	5.9	.60	.37**	3.7	.17**	.429**
Patient factors										
11	Previous history of cancer	8.7	.17*	.29**	16.5	.05	.31**	9.7	.17**	.313**
12	Previous oncological treatments	6.6	.26**	.38**	11.2	.22**	.42**	2.4	.42**	.528**
13	Significant surgical history	8.7	.14*	.28**	18.6	.10	.47**	7.1	.23**	.585**
14	Significant physical comorbidity	8.3	.28**	.41**	22.9	.18*	.50**	13.7	.12*	.502**
15	Mental health and cognitive comorbidity	1.2	.10	.29**	4.3	.08	.29**	0.5	.01	.101*
16	Socio-economic issues	0.8	.06	.19**	0.5	.19**	.21**	-	-	-
17	Lifestyle risks	-	-	-	1.6	-.08	.07	1.1	.00	.079
18	Patient choice and family opinion	7.9	.31**	.35**	8.5	.08	.15*	7.1	.03	.151**
Treatment factors										
19	Diagnostic uncertainty / inconclusiveness	13.7	.36**	.31**	21.3	.26**	.21**	8.4	.30**	.426**
20	Further tests and patient assessment needed	26.1	.36**	.30**	40.4	.26**	.11	24.2	.25**	.297**
21	Further input needed from other specialties	9.1	.22**	.28**	21.3	.12	.17*	14.2	.18**	.276**
22	Unusual anatomy/ distribution of tumour	0.8	.03	.05	12.2	.33**	.30**	3.2	.27	.383**
23	Pathway do not account for patients situation	0.4	.07	.08	-	-	-	-	-	-
24	Conflict of opinions about treatment options	8.7	.40**	.45**	1.6	.16*	.25**	5.8	.30**	.344**
25	Treatment toxicity and contraindications	0.8	.06	.12	0.5	.07	.25**	0.5	.13*	.271**
26	Trial eligibility	0.4	-.01	-.01	0.5	.07	.25**	0.3	.01	.022
27	Logistical complexity (frequency counts)	-	.32**	.36**	-	.19**	.21**	-	.44**	.336**
Total clinical complexity (sum of 1 to 26)		-	.80**	.98**	-	.50**	.98**	-	.50**	.985**
Total complexity (sum of 1 to 27)		-	.82**	-	-	.53**	-	-	.55**	-

Note. % = frequency of item within the dataset. Differences between tumours are coloured green with significances marked in boldface.

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