Short-term outcomes of a COVID-adapted triage pathway for colorectal cancer detection

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Abstract

Aim: The dramatic curtailment of endoscopy and CT colonography capacity during the coronavirus pandemic has adversely impacted timely diagnosis of colorectal cancer (CRC). We describe a rapidly implemented COVID-adapted diagnostic pathway to mitigate risk and maximize cancer diagnosis in patients referred with symptoms of suspected CRC.

Method: The ‘COVID-adapted pathway’ integrated multiple quantitative faecal immunochemical tests (qFIT) to enrich for significant colorectal disease with judicious use of CT with oral contrast to detect gross pathology. Patients reporting ‘high-risk’ symptoms were triaged to qFIT+CT and the remainder underwent an initial qFIT to inform subsequent investigation. Demographic and clinical data were prospectively collected.

Outcomes comprised cancer detection frequency.

Results: Overall, 422 patients (median age 64 years, 220 women) were triaged using this pathway. Most (84.6%) were referred as ‘urgent suspicious of cancer’. Of the 422 patients, 202 (47.9%) were triaged to CT and qFIT, 211 (50.0%) to qFIT only, eight (1.9%) to outpatient clinic and one to colonoscopy. Fifteen (3.6%) declined investigation and seven (1.7%) were deemed unfit. We detected 13 cancers (3.1%), similar to the mean cancer detection rate from all referrals in 2017–2019 (3.3%). Compared with the period 1 April–31 May in 2017–2019, we observed a 43% reduction in all primary care referrals (1071 referrals expected reducing to 609).

Conclusion: This COVID-adapted pathway mitigated the adverse effects on diagnostic capacity and detected cancer at the expected rate within those referred. However, the overall reduction in the number of referrals was substantial. The described risk-mitigating measures could be a useful adjunct whilst standard diagnostic services remain constrained due to the ongoing pandemic.

KEYWORDS
colorectal cancer, COVID-19, faecal immunochemical tests, qFIT, triage

What does this paper add to the literature?
This COVID-adapted pathway for those presenting with symptoms of colorectal cancer during the pandemic has the ability to mitigate risk and instigate treatment and could be incorporated into...
INTRODUCTION

The collateral damage from the COVID-19 pandemic will have a lasting impact on colorectal cancer (CRC) survival [1,2]. The aerosol-generating potential of endoscopy, coupled with the faecal presence of COVID-19 [3–6], has led to multiple colorectal and gastroenterological societies suggesting immediate cessation of all but emergency colonoscopy [7,8]. This resulted in suspension of the UK National Bowel Screening Programme, which detected 20.3%–20.9% of all CRCs since the start of bowel cancer screening in our unit in 2018. A similar rationale led to a pause in full CT colonography (CTC), suggested by the British Society of Gastrointestinal and Abdominal Radiology [9]. It was clear, through a combination of delayed presentation to primary care, decreased referral rates and lack of diagnostics, that there would be an inevitable delay in CRC diagnosis.

Given the foreseeable fallout from a tertiary unit managing over 500 CRC patients annually, we assembled a team to ensure rationing of available diagnostics which was evidence-based and would further enrich the traditional symptom-based approach [10]. Whilst the sensitivity of unprepared CT scans for CRC compared with CTC is lower (75%–80% vs 95%), guidance advised deferral of luminal investigation in patients with a negative standard CT scan [9,11]. The other tool available for CRC detection is the quantitative faecal immunochromatographic test (qFIT) used for screening and as a triage tool in ‘low-risk’ populations [12,13]. qFIT does enrich for bowel pathology but cannot be used as a ‘rule-out’ for CRC, given the test sensitivity [14].

Hence, we designed and rapidly implemented a pragmatic approach to mitigate risk and maximize cancer diagnosis utilizing plain CT and qFIT [15]. A collaborative approach involved colleagues from biochemistry, radiology, general practice (GP) and gastroenterology. GP referrals of ‘urgent suspicion of cancer’ patients (USOC) were triaged daily by colorectal consultants using age, symptoms (‘high-risk versus low-risk’) and haemoglobin to prioritize those most likely to have CRC [13]. Patients were triaged to the limited diagnostics accounting for the limited availability of both surgical and oncological services, staff and appropriate personal protective equipment (PPE). Here, we present the outcomes of this approach and assess the extent to which our COVID-adapted pathway for USOC patients mitigated the risk of delayed diagnosis due to the pandemic.

METHOD

To support referrals for USOC patients during the pandemic a process was developed based on local endoscopy and imaging capacity and qFIT testing. This was done to channel the type and timing of investigations, interspersed with safety-netting mechanisms including telephone or outpatient assessment and prioritization to urgent colonoscopy as appropriate. A summary of our COVID-adapted pathway is shown in Figure 1 [15].

Eligibility criteria and index testing

Through direct communication, GPs were advised to continue to refer USOC patients or those with symptoms suggestive of serious lower gastrointestinal (GI) disease. USOC referrals are made in keeping with Scottish referral guidelines based on high-risk features.

All patients referred with USOC (high-risk) symptoms (palpable abdominal mass, persistent change in bowel habit to looser stool not just simple constipation, repeated rectal bleeding without an obvious benign anal cause or blood mixed in with the stool, abdominal pain with weight loss ± iron deficiency anaemia (IDA)) consecutively entered the pathway between 1 April and 31 May 2020. All patient referrals were electronically triaged by colorectal consultants to one of three arms:

1. ‘High-risk’ symptoms ± IDA: in this patient group a qFIT and CT minimal preparation scan were requested at the same time. Scans were reported by consultant radiologists as being ‘grossly normal’, ‘equivocal’ or ‘definite cancer’. All equivocal CT findings were double-reported by a second consultant radiologist. Those with an elevated qFIT but negative CT underwent repeat qFIT testing ± colonoscopy.

2. Palpable rectal mass: these patients were seen in person in the clinic. In the absence of a mass, qFITs were ordered to inform the next investigation.

3. Those with ‘lower risk’ symptoms underwent qFIT testing only initially. Patients were then stratified according to qFIT values to enrich for those most likely to have serious bowel pathology.

It would not have been pragmatic to use 10 μg/g as the threshold for urgent investigation given that data from several health boards suggest the positivity rate is about 23%. The initial threshold for further investigation was therefore based on the Scottish bowel screening guidelines (80 μg/g) [16].

The HM-JACKArc analytical system (Hitachi Chemical Diagnostics Systems, supplied by Alpha Labs) based in Dundee, Scotland was used to analyse all samples. The FIT kit was sent from a single office in secondary care. Patients returned the test kits by post to the biochemistry lab and all samples were processed in the standardized way. FIT platforms have a limit of detection of 10 μg/g and so results under this level are described as ‘negative’.

All patients who returned a test result <80 μg/g underwent repeat testing. Following two qFITs <80 μg/g, and a negative CT for some patients, safety-netting advice was given. For all patients who...
returned tests with results at an intermediate level (80–399 μg/g) a repeat qFIT and CT was ordered, if the first entry investigation was qFIT only. All those with a qFIT >400 μg/g proceeded to CT without a second qFIT result. The type of CT undertaken was CT minimal preparation, which was a plain CT with the patient taking oral contrast at home and without rectal insufflation. If any gross pathology was identified, a CT chest was added at the time as staging to maximize the resource.

Colonoscopy was only performed on those patients with the most urgent need, for example those with a CT result highly suspicious but not diagnostic for cancer that required a biopsy.

Safety-netting and postacute pandemic plans

Safety-netting protocols were enabled to allow for further clinical assessment if symptoms persisted or worsened. Patients in the ‘low-risk’ symptoms arm who had negative qFITs were reassured via letter that their results suggested a low residual risk of cancer but further investigation based on symptoms may be required later. These patients were not discharged from the pathway on the basis of a single qFIT alone and were kept on a waiting list for eventual standard investigation and triaging consultants were asked to make a clinical decision based on symptoms and/or follow-up telephone calls to assess the risks and timing of further investigation. Investigations in vulnerable patients who met the referral criteria but were shielding were deferred based on patient preference after telephone consultation [17]. The pathway was adapted following the return of limited access to CTC and colonoscopy in June 2020. Due to the initial wide variability observed in double-testing, all patients who were already on the pathway and had two negative qFITs were recalled and offered a CT minimal preparation scan. Those with test results 10–399 μg/g underwent CTC and those >400 μg/g were referred for colonoscopy. All patients were therefore ‘safety-netted’.

Statistical analysis

All pathway patients were prospectively entered into a Microsoft Excel spreadsheet. Data were collected on entry route, triage category, demographics, presenting symptoms, blood results and past medical history. Results of all qFITs and colorectal investigations were recorded when complete. Given the limited access to CTC and colonoscopy there was no reference standard. Cancer detection rates during the pandemic were therefore compared with those from previous years when patients had undergone the standard diagnostic pathways. All clinical information was available to those reviewing both qFIT and CT results. All patients (including those who did not have a complete set of tests) were included in the analysis. Statistical analysis was performed using R software version 4.0 (http://www.R-project.org) with appropriate packages. The Shapiro–Wilk method was used to test for normality. Nonparametric data are presented as median and interquartile range (IQR). Variability in two qFITs was measured using Pearson’s correlation coefficient. Ethical
approval to report pathway outcomes was not required given it was part of clinical care.

RESULTS

Patient demographics and initial triage outcomes

The first iteration of the COVID-adapted pathway ran from 1 April to 31 May 2020. There were 422 patients included, median age 64 years (55–74) with 220 being female. Patients were predominantly referred under the USOC category (357), with 48 urgent and 17 routine referrals being upgraded to USOC by the triaging colorectal consultant.

The time to first test was a median of 14 days (IQR 10–18 days) and there was no difference between testing time in CT (median 15 days, IQR 10–24 days) or qFIT (median 13 days, IQR 10–17 days). The median time from referral to qFIT completion was 22 days (IQR 15–37 days).

Of the 422 patients, 202 (47.9%) were triaged to CT and qFIT based on 'high-risk' symptoms, 211 (50.0%) to qFIT only based on 'low-risk' symptoms, eight (1.9%) straight to the outpatient clinic as 'palpable mass PR', and one to colonoscopy and qFIT due to the patient having undergone a recent CT prior to lockdown with a
suspicious finding requiring luminal investigation. Of the patients who entered the pathway 15 (3.6%) declined any investigation and seven (1.7%) were deemed unfit due to shielding, severe cognitive impairment or being admitted to hospital for other reasons at the time of testing. There were 82 (19.4%) patients who had an incomplete set of results; they did not return either qFIT within 6 weeks despite proactive encouragement from nursing teams or declined to attend for CT [17]. Thirty-six of these patients were from the ‘high-risk’ arm. The COVID-adapted pathway detected 13 CRCs (3.1%). This was on a par with our performance of a yearly 3.3% cancer detection rate from all referrals in 2017–2019. The flow of patients leading to cancer diagnosis is shown in Figure 2.

Quantitative FIT results

Of 422 patients, 366 (86.7%) completed at least one qFIT. The majority of patients (266, 72.7%) had a ‘negative’ (<10 µg/g) result, 51 patients (13.9%) had levels between 10 and 79 µg/g, 18 patients (4.9%) had levels between 80 and 399 µg/g and 31 patients (8.5%) had levels ≥400 µg/g. The overall positivity rate was higher (27.3%) than our qFIT levels in symptomatic populations pre-COVID (22% from audit data), suggesting an already enriched population presenting and completing the tests.

Two hundred and sixty three patients (62.3%) completed at least one qFIT and either a CT or colonoscopy as a definitive colorectal investigation on the pathway: 72.0% had a negative qFIT, 12.6% had a result between 10 and 79 µg/g, 6.3% had a result between 80 and 399 µg/g and 9.1% had a qFIT at or over 400 µg/g. Interestingly, we noted differences in the distribution of qFIT values between ‘high-risk’ and ‘low-risk’ groups. Contrary to intuitive assumptions, there were more patients with negative qFITs in the ‘high-risk’ group (78.4%) than the ‘low-risk’ group (68.8%), whilst there were more patients with a qFIT over 400 µg/g in the ‘low-risk’ group (9.5%) than the ‘high-risk’ group (7.0%). However, these differences were not statistically significant (p = 0.19).

Double qFIT testing

There are limited published data on the use of double qFIT testing to enrich or safety-net CRC patients. Although multiple tests may enrich a few patients, we found considerable variation in interval double-test qFIT values (two tests at least 2 weeks apart). Two hundred and twenty patients (52.1%) completed two qFITs of whom 184 (83.6%) had both qFIT values under 80 µg/g. Eighteen patients (8.2%) had at least one qFIT >80 µg/g which triggered a CT and a further 18 patients (8.2%) had both qFITs >80 µg/g. There were three cancers amongst those who had two <10 µg/g qFITs. Two patients had both qFITs under 80 µg/g and one patient had both qFITs above 80 µg/g, as shown in Figure 3. Pearson’s correlation coefficient was 0.63, showing moderate test–retest reproducibility, and the proportion of patients who had one qFIT <80 µg/g and another qFIT >80 µg/g was 8% (potential incremental diagnostic yield).

**FIGURE 3** Distribution of double quantitative faecal immunochemical test (qFIT) results. Double qFIT testing showed variability of results. Eighty-four per cent of patients had both results <80 µg/g, 8% had one result <80 µg/g and one >80 µg/g and a further 8% had two results >80 µg/g. There were two cancers diagnosed in those with two qFITs <10 µg/g and one in a patient with two qFITs >400 µg/g (USOC, urgent suspected of cancer)
CT scan results

Of 265 CTs done, 241 were reported as normal, 15 as equivocal and 9 as cancer: one of the 15 equivocal scans was found to be cancer and one of the patients with a scan reporting cancer was subsequently found to have benign disease. The remaining ‘equivocal’ findings were investigated by endoscopy or CTC: five patients had diverticular disease, four patients were found to have polyps, two patients had colitis (ulcerative colitis, collagenous colitis), one was normal, one was presumed to be a normal change due to previous surgery but awaiting MRI for further clarification, and one did not attend the endoscopy appointment.

Cancer diagnosis

Thirteen CRCs were diagnosed overall. The median age at cancer diagnosis was 71 years (range 67–78 years) with six patients being female. The distribution of pathology and initial treatments are shown in Table 1 along with final TNM staging for those patients who have already proceeded to surgery. One patient had metastatic disease in the liver at presentation.

Seven cancers were identified from the CT and qFIT arm (3.5%), two cancers from the qFIT only arm (0.9%) and four cancers from the outpatient clinic arm (50%). These results highlight that our pathway design, based on symptoms, was appropriate given that the greatest number of cancers came from the CT and qFIT arm (54%). Four cancers were diagnosed in the group with a qFIT result >400 µg/g, two with qFIT results of 10–79 µg/g and three patients with a qFIT result <10 µg/g (Figure 4). Of those patients with a qFIT <10 µg/g one patient had frequency and tenesmus, another loose stool, anaemia and weight loss and the third had constipation and rectal bleeding. Given the smaller number of cancers diagnosed in this group there are potentially patients with undiagnosed cancer. Results of this will become apparent over time and once safety-netting investigations are complete. Two hundred and twenty two (52.8%) out of 422 referrals had documentation of digital rectal examination by primary care, of whom 12 stated there was the possibility of a rectal mass. Eight of these patients were fast-tracked to the outpatient clinic. Of the remaining four, two were triaged to CT and qFIT and two to qFIT only. Only one patient with a palpable mass had a qFIT undertaken, with the result being 21 µg/g. Of the cancers that were anorectal a further two would have been diagnosed by rectal examination had it been done. There were a range of other diagnoses in those without the target condition that are summarized in Table 2.

Adverse events from index tests

No adverse events were reported from the qFIT test. There were no perforations in those patients who proceeded to colonoscopy. One patient who was radiologically diagnosed as cancer was found to have complicated diverticular disease at final pathology but was symptomatic enough to require operation. One patient did not undergo CT scan due to an iodine allergy. Two patients died following referral, with neither starting the pathway. One patient had a CT confirmed diagnosis of advanced cirrhosis and died with decompensated liver and cardiac failure 21 days following referral. Another died within 9 days of referral from an unknown cause, they had a history of weight loss and anaemia but declined investigation for this the previous year.

Change in activity during the pandemic

The number of overall referrals and activities were compared with the previous 3 years (2017–2019) during the same period (April and May). There are three categories in our referral systems: USOC, urgent and routine. The total number of combined referrals decreased by 43% from an average of 1071 to 609 during the pandemic, with a 79% reduction in urgent (324 to 69) and a 64% reduction in routine (581 to 211) referrals. However, the number of USOC referrals increased by 40% (235 to 329). The decrease in overall referral numbers highlights that there may be as many as 50% more CRCs in the community that are yet to present or be referred. The average number of monthly cancer diagnosis in our unit was 44 during the last 3 years (2017–2019) whilst the average since February 2020 was 30 per month. A comparison of referral rates from primary care over the 4 years is shown in Figure 5. A further 16 cancers were diagnosed as emergencies during April and May 2020; an increase of 33% on 2019. Following the initial peak of the pandemic, referral numbers for June and July 2020 did not increase (377 and 337, respectively, down from 425 and 500 in 2019).

### Table 1: Pathological diagnoses in cancer patients

| Disease site                  | n  |
|------------------------------|----|
| Anal canal                   | 2  |
| Rectum                       | 5  |
| Rectosigmoid junction        | 1  |
| Sigmoid                      | 5  |
| Caecum                       | 1  |
| Initial treatment            |    |
| Radiotherapy                 | 5  |
| Surgery                      | 4  |
| Chemoradiotherapy            | 1  |
| Polypectomy                  | 1  |
| Palliative stent             | 1  |
| Awaiting decision            | 1  |
| Final pTNM stage             |    |
| T2N0 M0                      | 1  |
| T2N1bM0                      | 1  |
| T3N1aM0                      | 1  |
| T3N0 M0                      | 1  |
| T4aN1 M0                     | 1  |

Note: The majority of patients were diagnosed with cancers of the rectum and sigmoid. Five patients have so far proceeded to definitive surgery.

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![Image](image-url)
Discussion

We describe a novel COVID-adapted triage pathway for CRC detection which has mitigated risks for those referred with USOC symptoms during the pandemic. We have shown that it is possible to implement change rapidly if all stakeholders are committed, and in doing so have highlighted the impact of delayed presentation to primary care on the potential number of missed cancers during this period. We have examined the impact of using qFIT and CT minimal preparation scanning on cancer detection rates and have demonstrated that the use of this novel COVID-adapted pathway has allowed us to match the expected cancer detection rate in those referred. The variability in double qFIT testing further emphasizes the importance of clinical examination and adequate referral information. This pathway has helped to standardize treatment and optimize the balance between delivery of effective cancer care and minimization of risks to patients and staff. We have developed a responsive framework which is ready to be utilized during further COVID-19 peaks.

These data have shown that there was a 43% reduction in referral numbers. This was possibly due to the blanket ‘lockdown’ message by the government and media encouraging people to stay at home, compounded by the cessation of cancer screening services. Patient anxiety about attending hospital also increased in the elderly in particular – a group at high risk from COVID-19 but also most likely to have serious bowel pathology. It was expected that red flag symptoms such as rectal bleeding or a new lump would continue to present; however, there was concern that more vague symptoms including change in bowel habit, symptoms of anaemia or weight loss would be dismissed by patients for fear of wasting doctors’ time with non-COVID-19 problems [18–20].

The decrease in referral numbers was potentially increased by the reduced availability of face-to-face appointments in primary care and the huge shift towards telephone triage. As we have shown, half of those patients referred with a rectal mass had a malignancy, suggesting that many may have missed examination findings due to the increased use of remote consulting. This style of consultation is also less suited to those from lower socioeconomic backgrounds thus potentially increasing inequalities that already exist in cancer care [21].

It is expected that given the drop in referral numbers, there will be a significant number of patients in the community with CRC who are as yet undiagnosed. Large-scale modelling studies have estimated that more than 4700 deaths could be attributed to a 3-month delay to all cancer surgery in England, with further impacts on death and life years lost if diagnostic services are delayed in returning to normal [1,22]. There are likely to be many patients presenting with cancer symptoms or advanced cancer as emergencies in the future. For patients with localized CRC, the risk of delay in presentation is not known; however, it may lead to upstaging of disease, with one study predicting that delays in diagnosis and management may lead to...
to a 17.2% reduction in survival for those with Stage I disease increasing to >29% in those presenting with Stage III disease [2]. Delays in diagnosis not only lead to reduced survival but also potentially more morbid surgery and increased likelihood of neoadjuvant and adjuvant treatments. Patients presenting as emergencies are also more likely to require longer hospital stays and critical care [23].

In June 2020, following the end of the initial pathway, referral numbers had not returned to the usual expected numbers. There was increased, but considerably constrained, access to endoscopy and CTC. Unless capacity is markedly increased there will continue to be delays to diagnosis and management of these patients which may persist over a long period of time. Our median time to index test was 14 days. Given the existing prolonged waiting lists for endoscopy in many centres, the use of this pathway to triage patients will be required for the foreseeable future. COVID-19 has generated the opportunity to overhaul unwieldy triage systems and implement a streamlined approach to patient assessment [24]. Hence, planning at the outset was undertaken to embed the pathway into routine service so as to reduce the never-ending burden on colonoscopy lists. There remains a residual risk for patients and safety-netting plans have been initiated to offer all patients who return a qFIT <80 µg/g a second qFIT and CT minimal preparation scan. There was considerable variation in initial triage category assigned by individual consultants and this should be standardized following the acute phase. The qFIT is a useful test to prioritize access to endoscopy and CTC, with the caveat that symptomatic patients with a negative test will ultimately require investigation in the long term [25]. Our data, presented here, and prepandemic audit data (unpublished) do not support the use of a single qFIT result as a rule-out test for CRC. However, qFIT is useful to enrich for pathology and in combination with CT is able to safeguard those who do not get prioritized for endoscopy.

Limitations

It was not possible to validate the use of qFIT or CT minimal preparation scan at this time given the inability to compare it with a reference standard. Our approach was based on the ability of the tests to diagnose gross pathology and as such these data will become available over time. We have focused solely on the detection of overt CRC, with the detection rate of advanced polyps currently unknown. The sensitivity of qFIT for advanced adenomas has been shown to be low at 35.7% [26]. The value of qFIT is known to be significantly lower for more proximal adenomas and cancers than those found distally, with double qFIT testing enriching for pathology [26]. Although there were three cancers diagnosed in patients with a negative qFIT only one was a caecal malignancy, the others being sigmoid and anorectal lesions. The number of cancers diagnosed in those with two negative qFITs was too small to comment on whether double-testing enriched for pathology. Throughout the devolved nations different thresholds have been used to determine what constitutes a positive result for screening patients (80 µg/g in Scotland, 120 µg/g in England and 150 µg/g in Wales) [27]. The threshold for determining an abnormal result is lower (10 µg/g) in the symptomatic population [28]. It is used to enrich information and target patients with ‘low risk but not no risk’ symptoms [29]. Therefore, even a negative result may require further investigation in order to manage risk and demand. There are concerns, therefore, that the use of qFIT testing alone could miss cancers in some patients.

A small percentage of USOC referrals, as shown, lead to the eventual diagnosis of other cancers or pathologies. It is not known how a triage system based on qFIT alone would impact these diagnoses. We focused on patients referred with USOC symptoms and did not include those referred via routine referrals or those under long-term polyp or genetic surveillance.

CONCLUSION

The coronavirus pandemic has led to a marked decrease in referrals and cessation of key diagnostic services. Public awareness campaigns should encourage those with ‘high-risk’ symptoms to come forward, stressing the importance of timely cancer diagnosis. Prioritization of symptomatic patients through the use of qFIT and CT minimal preparation scans has been shown to be a rational
approach to mitigate risk and prevent delay to treatment when access to endoscopy is limited. It is likely that the effect of the pandemic on non-COVID patients will outweigh the current effects on health and economy.

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CONFLICT OF INTERESTS
The authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS
JM, FG and YM helped run the pathway. JM, FG and SA collected data. JM, YM, MGD and FVND wrote the manuscript. YM, LP, RP, PM, CN, SG, MGD and FVND designed and set up the pathway. YM analysed data. Data were verified by JM, FVND and MGD. All authors critically appraised and approved the final manuscript.

ETHICS APPROVAL
No ethical approval was required as this work formed part of routine care.

PERMISSION TO REPRODUCE MATERIAL
No material has been reproduced from other sources.

PATIENT CONSENT
Patient consent was not required.

DATA AVAILABILITY STATEMENT
Deidentified data will be available on request from the corresponding author.

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