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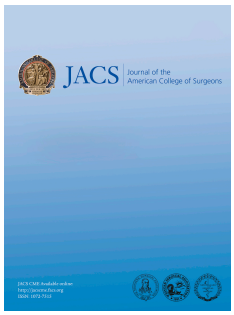

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Medically Necessary, Time-Sensitive Procedures: Scoring System to Ethically and Efficiently Manage Resource Scarcity and Provider Risk During the COVID-19 Pandemic

Vivek N Prachand, MD, FACS[a], Ross Milner, MD, FACS[a], Peter Angelos, MD, FACS[a], Mitchell C Posner, MD, FACS[a], John J Fung, MD, FACS[a], Nishant Agrawal, MD, FACS[a], Valluvan Jeevanandam, MD, FACS[a], Jeffrey B Matthews, MD, FACS[a]

[a]Department of Surgery, University of Chicago Medicine and Biological Sciences, Chicago, Illinois

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Correspondence address:

Vivek N Prachand MD FACS
5841 S. Maryland Ave. MC 5031
Chicago, IL 60637
(773) 702-0190
vprachan@uchicago.edu

Brief Title: Surgical Prioritization during Global Pandemic

Abstract

Hospitals have severely curtailed the performance of non-urgent surgical procedures in anticipation of the need to redeploy healthcare resources to meet the projected massive medical needs of patients with Coronavirus Disease 2019 (COVID-19). Surgical treatment of non-COVID-19 related disease during this period, however, still remains necessary. The decision to proceed with Medically-Necessary, Time-Sensitive (MeNTS) procedures in the setting of the COVID-19 pandemic requires incorporation of factors (resource limitations, COVID-19 transmission risk to providers and patients) heretofore not overtly considered by surgeons in the already complicated processes of clinical judgment and shared decision-making. We describe a scoring system that systematically integrates these factors to facilitate decision-making and triage for MeNTS procedures and appropriately weighs individual patient risks with the ethical necessity of optimizing public health concerns. This approach is applicable across a broad range of hospital settings (academic and community, urban and rural) in the midst of the pandemic and may be able to inform case triage as OR capacity resumes once the acute phase of the pandemic subsides.

Introduction

In anticipation of the projected increase in Coronavirus Disease 2019 (COVID-19) and the massive healthcare resources required to meet the acute medical needs of the population, most hospitals have severely curtailed the performance of non-urgent surgical procedures based on the guidance of hospital epidemiologists, state and local health care departments, and national surgical organizations[1,2]. Curtailing these procedures allows hospitals to offload the inpatient census and divert and redeploy resources either currently or projected to be scarce [personal protection equipment (PPE), COVID-19 testing materials and personnel, ventilators, ICU beds]. This approach further facilitates healthcare workforce protection and preservation given the anticipated surge in the hospitalization requirements for patients with severe COVID-19 infection. As such, surgical practices and departments have had to contact patients to inform them of the need to cancel or postpone previously scheduled procedures that, in the context of a global pandemic, are appropriately categorized as lower in acuity and for which the term "elective" is typically used as descriptive shorthand.

In a crisis setting, however, there is an inevitable tendency to conflate the term "elective" with the word "optional" with regards to surgical procedures. Yet, with perhaps the exception of purely aesthetic procedures, there is always a clinical rationale underpinning the decision made between surgeon and patient to undergo "elective" surgery. These include treatment of malignancies and other potentially life or limb-threatening medical conditions, alleviation of pain, improvement of function and quality of life, and prevention of serious complications or disease progression associated with surgically-treatable conditions. Discussion of the relative effectiveness of non-operative treatment options is an integral part of the collaborative decision-making process between surgeons and patients, and it is in fact exceedingly rare that

patients opt to undergo even “elective” surgery without a sense of feeling that the surgical procedure is, in fact, necessary.

Instead, it is important to recall that “elective” refers to the fact that the acuity of the condition being treated surgically allows for the patient and the surgeon to *elect* the timing and scheduling of surgery without negative impact on the surgical outcome or disease process. As such, it may be more appropriate to describe these operations as Medically-Necessary, Time-Sensitive (MeNTS) procedures.

Effective management of Operating Room (OR) resources in “normal” circumstances has always required a case prioritization process that integrates medical necessity and time sensitivity for hospitalized, emergency room, and trauma patients requiring urgent surgical care in a way that minimally disrupts previously scheduled cases and effectively matches that need to available OR resources. Both surgeons and OR managers have extensive familiarity with the complexity that such triage entails. The decision to proceed with operative treatment in the setting of the COVID-19 pandemic, however, requires incorporation of factors heretofore not overtly considered by surgeons in the already complicated process of clinical judgment and shared decision-making. In addition to the resource limitations described earlier, other crucial factors requiring careful proactive consideration include risk of COVID-19 infection to the health care team (and their subsequent inability to provide care to patients during their own COVID-19 treatment or quarantine), infection risk to the COVID-19 negative patient who has been physical distancing themselves at home and now must enter an environment where the virus may be present, and COVID-19 specific impact on surgical outcomes including acute postoperative respiratory failure[3,4,5]. Furthermore, these decisions must be made in the absence of widely disseminated prospectively collected COVID-19

patient outcomes data, let alone actual clinical trials, and in a setting in which knowledge of the disease, testing methodologies for detection of COVID-19 infection and its acquired immunity, and treatment technologies (medication, convalescent serum, etc.) is rapidly-evolving. Finally, despite the appropriate attention being dedicated to managing the medical needs of COVID-19 patients and safety of the healthcare workforce, necessary resources must remain available to meet the ongoing non-urgent surgical needs of patients without COVID-19 disease. In an early stage of the current pandemic, we as an institution cancelled all MeNTS procedures beginning March 16, 2020, with the exception of a very limited number of MeNTS cases based on cautious vetting on a case-by-case basis by section and department leadership after priority cancelled cases were flagged by individual surgeons for review. As a point of reference, the American College of Surgeons made the recommendation to cancel all "elective" surgery on March 17, 2020.[6]

Nonetheless, given the lack of sustainability of this approach, it was clear to us that a tool that systematically integrates novel factors such as resource limitations and COVID-19 transmission risk into pre-existing processes was needed in order to facilitate decision-making and triage for Medically-Necessary, Time-Sensitive (MeNTS) procedures during the COVID-19 pandemic. Ideally, any such process must be transparent, afford dynamic flexibility in accordance to rapidly changing resources and conditions, and be applicable both within and across surgical specialties and different practice environments. In doing so, resources can be allocated more safely, efficiently and equitably. Perhaps even more importantly, the emotional and ethical workload that will undoubtedly predispose physicians to burnout and inflict moral injury[7,8,9,10] when making these extraordinarily difficult decisions can be significantly relieved. We herein proposed an approach that we feel is applicable across a broad range of

hospital settings (academic and community, urban and rural) in the midst of the pandemic and to inform case triage as OR capacity resumes once the acute phase of the pandemic subsides.

METHODS

Plausible factors contributing to poorer perioperative outcomes, risk of COVID-19 transmission to healthcare professionals, and increased hospital resource utilization were identified through review of the limited outcomes data currently available regarding medical and perioperative outcomes of COVID-19 patients as well as within the context of COVID-19 planning discussions that took place at the departmental and institutional level. For each of these factors, a five point scale was created with a higher value assigned for poorer perioperative patient outcome, increased risk of COVID-19 transmission to the health care team, and/or increased hospital resource utilization during the pandemic. Value anchors were assigned to the 1-5 scale based on both objective measures as well as perceived clinical probabilities. The summation of the points assigned to these individual factors generates a cumulative MeNTS score. As a retrospective proof of concept assessment, the cumulative MeNTS scores of a sampling of MeNTS procedures performed and deferred from the week of March 20, 2020 to March 26, 2020 were calculated by faculty members of our departmental Quality committee.

RESULTS

Twenty one factors were identified as significant contributors to MeNTS procedure triage and prioritization in the setting of the COVID-19 pandemic. As such, the resulting cumulative MeNTS score range was 21-105 points. These identified factors fell into three general categories: procedure (7), disease (6), and patient (8).

Procedure factors are shown in Table 1. A higher score for each factor is associated with poorer perioperative patient outcome, increased risk of COVID-19 transmission to the health care team, and/or increased hospital resource utilization. OR Time takes into consideration the sequestration of OR resources during the predicted length of the procedure. Anticipated Length of Stay captures the personnel and hospital resources required and reduced inpatient capacity and flexibility associated with increased postoperative hospitalization and intensive care unit resources. Estimated Blood Loss was felt to be important due to shortage of blood availability related to shelter in place requirements that reduce public access to blood donation facilities. Surgical Team Size captures the increased risk of virus transmission from patient to the surgical team as well as between team members given the inability to adhere to physical distancing recommendations intraoperatively. Because endotracheal intubation and extubation have been identified as high risk events for potential virus transmission due to airway secretion aerosolization that persists for several minutes after they take place[11,12], an even modestly increased likelihood requiring intubation substantially increases this factor score. Similarly, a score of 5 is assigned to upper aerodigestive tract and thoracic procedures due to increased aerosolization and transmission risk. The other anchoring values for Surgical Site are based on their known impact on postoperative respiratory function[13,14,15] which has the potential to be impactful in the setting of COVID-19, as patients with oxygen requirements that cannot be met by nasal cannula with a flow of 5 liters/minute[16] generally require intubation. There have been concerns raised regarding potentially increased risk of concentrated aerosolization and rapid dissemination of aerosolized particles containing virus associated with the use of energy devices during laparoscopy, but as of this writing, there has been no strong evidence recommending against the use of laparoscopy by national and

international surgical societies.[17,18] As such, the score assigned to laparoscopy is based on the known impact on post-operative pulmonary function.

A higher score in the Disease factors group (Table 2) is generally indicative of *less* harm to the patient when non-operative treatment of the disease is pursued and/or surgical treatment is delayed. In the setting of the COVID-19 pandemic, we felt that limited resources are better deployed for diseases where non-operative care is significantly less effective or is not an option. For this reason, we include an assessment of "Nonoperative Treatment Option Effectiveness" which highlights not only the availability of non-surgical treatment but its comparative effectiveness to surgery. Furthermore, we also include "Non-Operative Treatment Option Resource/Exposure risk" as a factor to assess the resources and exposure risks associated with non-operative therapy. For example, while radiation and surgery may be equally effective for treatment of prostate cancer, the cumulative risks of viral exposure and overriding "shelter-in-place" directives need for the multiple required visits to a healthcare facility to receive radiotherapy must be weighed against a single overnight hospital stay associated with robotic-assisted prostatectomy. In order to capture the time sensitivity of a procedure, we chose to independently assess the impact of surgical delay on disease outcome and surgical outcome at two different time points (2 weeks, 6 weeks) so as to integrate the natural history of the disease and time-sensitivity of surgical safety and technical feasibility into the prioritization process.

The Patient factors (Table 3) include those that are known to be associated with greater severity of COVID-19 illness (i.e. requiring mechanical ventilation and ICU care) and worse outcomes (including mortality). These include advanced age, preexisting pulmonary disease, cardiovascular disease, diabetes, and immunocompromised state[19, 20, 21]. It also captures

instances where there is greater likelihood that the patient has COVID-19, either asymptomatic or symptomatic, when their infection status is not known. Obstructive sleep apnea (OSA) is included in the group as patients with OSA are at increased risk of postoperative respiratory impairment[22, 23] and the aerosolization risk associated with the use of some positive airway pressure devices.[24]

UTILITY OF THE CUMULATIVE MeNTS SCORE

A higher cumulative MeNTS score, which can range from 21 to 105, is associated with poorer perioperative patient outcome, increased risk of COVID-19 transmission to the health care team, and/or increased hospital resource utilization. Given the need to maintain OR capacity for trauma, emergency, and highly urgent cases, an upper threshold MeNTS score can be designated by surgical and perioperative leadership based on the immediately anticipated conditions and resources at each institution. Performing a MeNTS procedure whose score exceeds this upper threshold at that particular point in time is unlikely to be justifiable given the associated risks, though sound clinical judgement always takes precedent. In a similar but complementary manner, a lower threshold MeNTS score can be assigned, below which it would be reasonable to proceed with MeNTS procedures while preserving OR capacity for trauma, emergency, and highly urgent cases. Once again, both thresholds can be dynamically adjusted so as to respond to the immediate and anticipated availability of resources and local conditions. This general concept is illustrated in Figure 1.

PROOF OF CONCEPT OF THE MeNTS SCORING PROCESS

In an effort to assess relative concordance of the ad hoc review process of MeNTS cases permitted during the cessation of “elective” surgery to the MeNTS Scoring system, the

cumulative MeNTS scores of a sample of MeNTS procedures performed during the week of March 20, 2020 to March 26, 2020 were calculated by faculty members of our departmental Quality committee. MeNTS scores for a smaller sample of procedures that remained cancelled were also calculated. The cases represent a broad range of surgical specialties including general surgery, surgical oncology, otorhinolaryngology, cardiothoracic surgery, neurosurgery, vascular surgery, urology, and plastic surgery and were performed by Quality committee members representing each of those specialties so as to provide appropriate clinical context. As seen in Figure 2, the MeNTS cases that were performed generally had relatively low MeNTS scores, while the cancelled procedures had somewhat higher scores, suggestive of relative concordance with the ad hoc decisions made prior to the creation of the MeNTS scoring system. Of note, although interobserver reliability of the scoring process was not assessed, the proof of concept scoring that did take place was performed by faculty who did not directly participate in the care of those patients.

DISCUSSION

We have described a scoring system that systematically integrates factors that are novel to the COVID-19 pandemic (resource limitations, COVID-19 transmission risk) to facilitate decision-making and triage for Medically-Necessary, Time-Sensitive (MeNTS) procedures. This scoring system appropriately weighs individual patient risks with the ethical necessity of optimizing public health concerns. The transparency offered by this process to surgeons, perioperative teams, trainees, and even to patients and can inform the complex and difficult discussions involving the decision to proceed or postpone procedures as well as specific COVID-19-related perioperative risks. Assigning values to each factor serves as a “forcing function” that compels the surgeon to contemplate additional factors that have not generally

required consideration in a systematic manner and prevents the omission of their consideration in a manner similar to that in which a properly-conducted perioperative checklist facilitates high reliability care in the OR environment. Using a 5-point scale allows for a reasonable degree of clinical nuance for each factor as compared to binary options. Because much of the scoring is derived by assessment of disease acuity, time sensitivity, and the effectiveness and availability of non-operative therapies (as opposed to prioritizing specific diseases treated by surgery such as cancer, cholelithiasis, or peripheral vascular disease), this system can be applied both within and across surgical specialties. The ability to adjust the upper and lower MeNTS score thresholds based on day-to-day personnel and resource availability and based on the status of COVID-19 in the state, region, and hospital offers dynamic flexibility while simultaneously preserving OR capacity for emergency and urgent cases. Finally, in addition to substantively incorporating the potential for the harm of viral exposure and infection to the healthcare team, the MeNTS scoring and triage process can partially offload the emotional and ethical burden associated with having to make difficult decisions weighing patient needs in the midst of scarcity of resources and the plausible risk of viral transmission to both the surgeon and to other members of the healthcare team. Having the knowledge that these factors were carefully considered in the decision to proceed or defer a MeNTS procedure may mitigate the moral injury associated with a feeling of being less capable of advocating for the care and resources that the healthcare team would normally be able to provide to each individual patient prior to the pandemic.

The MeNTS scoring system has several limitations. In this initial iteration, each of the 21 factors has been given an equal weight in the cumulative MeNTS score. Given the current paucity of COVID-19 perioperative outcomes data, disproportionate weighting of factors is

inevitable. Because there are insufficient data upon which to systematically identify factors, it is likely that important factors have been inadvertently omitted. Additionally, within each individual factor score, the point values assigned to each anchor are not quantitatively proportionate. Furthermore, there can be a false sense of objectivity associated with the generation of a single numerical value given that there is significant subjectivity in assigning values to several of the identified factors. Moreover, our approach does not take into consideration the COVID status of the patient. Instead, we currently consider patients whose COVID infection status is not known as being potentially positive even when asymptomatic in an abundance of caution given preliminary reports of unexpectedly severe pulmonary complications in asymptomatic patients subsequently found to have COVID-19. This cautious approach is reflected in the inclusion of ILI symptoms and known exposure to COVID-19 individuals in the 14 days preceding surgery each as scoring factors. In the future, as pre-operative testing for markers of COVID-19 recovery and immunity (IgG) becomes more widely available, COVID-19 immune patients may require a substantially modified MeNTS scoring process in which many of the factors are no longer applicable with regards to risk of provider or patient infection. Finally, although the dynamic adjustment of MeNTS score thresholds may facilitate day-to-day completion of MeNTS procedures, this process does not anticipate the availability of resources for the management of complications, readmissions, or other deviation from a routine post-operative course.

Despite these limitations, we feel that the use of the MeNTS surgery scoring system has significant utility as a conceptual framework for triage decisions that must be made in order to continue to provide much-needed treatment for which non-operative options are less effective or not available. This approach also acknowledges those cases where excessive delay of care

can negatively impact the likelihood of successful treatment of the disease or unnecessarily add increased technical and safety risks to the surgical procedure. Furthermore, by routinely "forcing" the surgeon to consider factors that may utilize scarce resources and/or subject their teams to increased risk of viral infection, surgeons must take into account the public health ethics concern of protecting resources. In our institution, we are now asking that surgeons calculate and submit the cumulative MeNTS score as part of their request to schedule MeNTS cases and tracking those scores prospectively. Over time, surgeons will be able to incorporate these concepts into their decision-making in a less proscribed manner. The scoring system can also be used to facilitate organization and prioritization of the large backlog of MeNTS cases that will await completion when the pandemic begins to subside. Though it may seem premature to discuss the post-pandemic future while its peak is projected to be several weeks away at the time of this writing, if nothing else, the COVID-19 pandemic has taught us the importance of planning for future conditions.

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Table 1. Procedure Factors

Variable	**1**	**2**	**3**	**4**	**5**
OR time, min	< 30	30-60	60-120	120-180	≥180
Estimated LOS	Outpatient	<23 hrs	24-48 hrs	≤ 3 d	>4 d
Postop ICU need, %	Very unlikely	<5	5-10	10-25	≥25
Anticipated blood loss, cc	< 100	100-250	250-500	500-750	≥ 750
Surgical team size, n	1	2	3	4	>4
Intubation probability, %	≤ 1	1-5	5-10	10-25	≥25
Surgical site	None of the following	Abdominopelvic MIS Surgery	Abdominopelvic open surgery, infraumbilical	Abdominopelvic open surgery, supraumbilical	OHNS/upper GI/thoracic

GI, gastrointestinal; LOS, length of stay; MIS, minimally invasive surgery; OHNS, otolaryngology, head & neck surgery; OR, operating room

Table 2. Disease Factors

Factor	**1**	**2**	**3**	**4**	**5**
Nonoperative treatment option effectiveness	None available	Available, <40% as effective as surgery	Available, 40% to 60% as effective as surgery	Available, 60% to 95% as effective as surgery	Available, equally effective
Nonoperative treatment option resource/exposure risk	Significantly worse/not applicable	Somewhat worse	Equivalent	Somewhat better	Significantly better
Impact of 2 wk delay in disease outcome	Significantly worse	Worse	Moderately worse	Slightly worse	No worse
Impact of 2 wk delay in surgical difficulty/risk	Significantly worse	Worse	Moderately worse	Slightly worse	No worse
Impact of 6 wk delay in disease outcome	Significantly worse	Worse	Moderately worse	Slightly worse	No worse
Impact of 6 wk delay in surgical difficulty/risk	Significantly worse	Worse	Moderately worse	Slightly worse	No worse

Table 3. Patient Factors

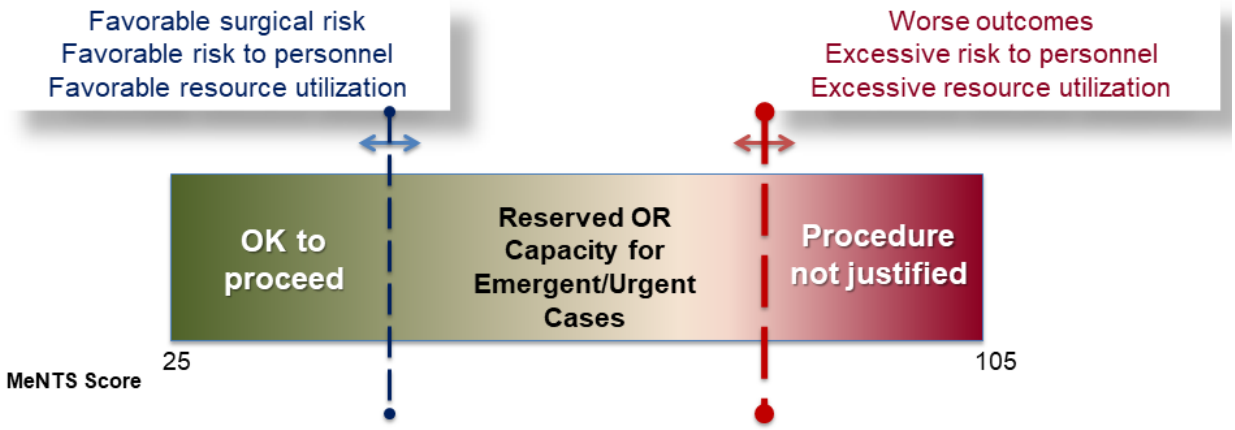
Factor	**1**	**2**	**3**	**4**	**5**
Age, y	<20	20-40	40-50	50-65	>65
Lung disease (asthma, COPD, CF)	None	--	-	Minimal (rare inhaler)	> Minimal
Obstructive sleep apnea	Not present	-	-	Mild/moderate (no CPAP)	On CPAP
CV disease (HTN, CHF, CAD)	None	Minimal (no meds)	Mild (≤ 1 med)	Moderate (2 meds)	Severe (≥ 3 meds)
Diabetes	None	-	Mild (no meds)	Moderate (PO meds only)	> Moderate (insulin)
Immunocompromised	No			Moderate	Severe
ILI symptoms (fever, cough, sore throat, body aches, diarrhea)	None (Asymptomatic)	-	-	-	Yes
Exposure to known COVID-19 positive person in past 14 days	No	Probably not	Possibly	Probably	Yes

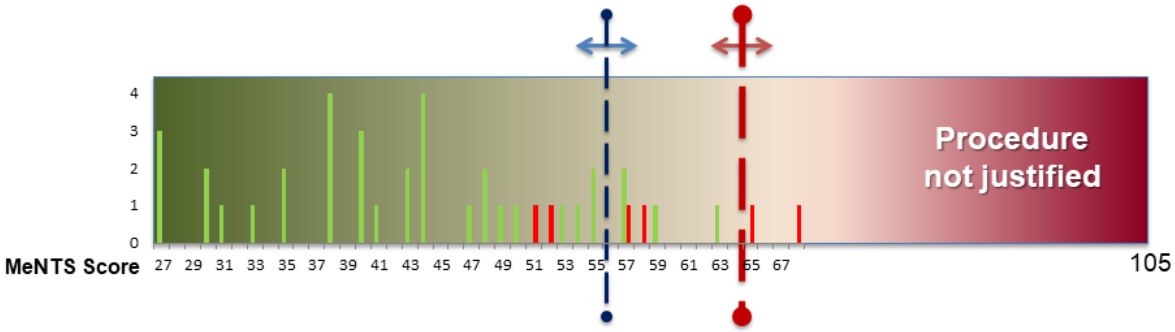
* Hematologic malignancy, stem cell transplant, solid organ transplant, active/recent cytotoxic chemotherapy, anti-TNFα or other immunosuppressants, >20mg prednisone equivalent/day, congenital immunodeficiency, hypogammaglobulinemia on IVIG, HIV, with CD4<200
CAD, coronary artery disease; CF, cystic fibrosis; COVID-19, novel coronavirus; CPAP, continuous positive airway pressure; CV, cardiovascular; CHF, congestive heart failure; HTN, hypertension; ILI, influenza-like illness; med. medication

Figure Legend

Figure 1. Use of the Cumulative Medically Necessary Time-Sensitive (MeNTS) Score. Upper and lower threshold MeNTS scores can be assigned and dynamically adjusted so as to respond to the immediate and anticipated availability of resources and local conditions while preserving operating room capacity for trauma, emergency, and highly urgent cases.

Figure 2. Proof of Concept of the Medically-Necessary Time-Sensitive (MeNTS) scoring system. Cumulative MeNTS scores of a sample of MeNTS procedures performed after ad hoc case review (n=35, green bars) and procedures cancelled (n=6, red bars) between March 20-26, 2020 after initial cessation of all MeNTS procedures on March 16 were calculated. Y-axis represents the number of cases with a specific MeNTS score. MeNTS cases that were performed had generally lower MeNTS scores than those of cancelled procedures, demonstrating concordance with the ad hoc decisions made prior to the creation of the MeNTS scoring system.


Favorable surgical risk
Favorable risk to personnel
Favorable resource utilization
Worse outcomes
Excessive risk to personnel
Excessive resource utilization
OK to proceed
Reserved OR Capacity for Emergent/Urgent Cases
Procedure not justified
MeNTS Score
25
105


4
3
2
1
0
MeNTS Score
27 29 31 33 35 37 39 41 43 45 47 49 51 53 55 57 59 61 63 65 67
105
Procedure not justified