




REVIEW ARTICLE

What gastroenterologists should know about SARS-CoV 2 vaccine: World Endoscopy Organization perspective

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Abstract

Background: The novel Coronavirus (SARS-CoV-2) has caused almost 2 million deaths worldwide. Both Food and Drug Administration and European Medicines Agency have recently approved the first COVID-19 vaccines, and a few more are going to be approved soon.

Methods: Several different approaches have been used to stimulate the immune system in mounting a humoral response. As more traditional approaches are under investigation (inactivated virus vaccines, protein subunit vaccines, recombinant virus

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vaccines), more recent and innovative strategies have been tried (non-replicating viral vector vaccines, RNA based vaccines, DNA based vaccines).

Results: Since vaccinations campaigns started in December 2020 in both the US and Europe, gastroenterologists will be one of the main sources of information regarding SARS-CoV 2 vaccination for patients in their practice, including vulnerable patients such as those with Inflammatory Bowel Disease (IBD), patients with chronic liver disease, and GI cancer patients.

Conclusions: Thus, we must ourselves be well educated and updated in order to provide unambiguous counseling to these categories of vulnerable patients. In this commentary, we aim to provide a comprehensive review of both approved COVID-19 vaccines and the ones still under development, and explore potential risks, benefits and prioritization of vaccination.

KEYWORDS

Coronavirus, endoscopy, prevention, public health, vaccine

INTRODUCTION

Since December 2019, when the World Health Organization (WHO) was informed of the first cases of pneumonia of unknown etiology,¹ the novel Coronavirus (SARS-CoV-2) has caused more than 94,000,000 cases and almost 2 million deaths worldwide, as of 16th January.² The world community has responded to the deadly challenge of Coronavirus-related disease (COVID-19) by relying on several public containment measures in order to slow down the spread of the virus.^{3,4} As of today, no drug has been proved to be a game-changer in the fight against the COVID-19,^{5,6} and our hope for an end to this pandemic led to an unprecedented fast track path for developing a reliable vaccine. (Table 1)

Though primarily considered as a respiratory disease, gastroenterologists had to face the SARS-CoV 2 pandemic in different ways in their everyday practice. First, COVID-19 may affect various systems including the digestive tract, causing gastrointestinal (GI) symptoms such as diarrhea, nausea, and abdominal pain in around 12% of patients.⁷ Furthermore, the risk of exposure of health care workers has been relevant in endoscopy units, considering that COVID-19 is spread via an airborne route. Indeed, endoscopy demands short physical distance from patients to personnel and endoscopists are exposed to various biological material.⁸⁻¹⁰ This risk could be even more relevant considering the detection of SARS-CoV 2 in biopsy specimens and stool, suggesting a possible faecal-oral transmission.⁷ However, adequate use of personal protective equipment and other infection control measures¹¹ seemed to lead to a low risk of COVID-19 transmission in GI endoscopy units.¹²⁻¹⁴

After Food and Drug Administration (FDA) and European Medicines Agency (EMA) approval, vaccinations campaigns started in December 2020 in both the US and Europe. Gastroenterologists will be one of the main sources of information regarding SARS-CoV 2 vaccination for patients in their practice, including vulnerable patients such as those with Inflammatory Bowel Disease (IBD),¹⁵

patients with chronic liver disease, and GI cancer patients.¹⁶ Thus, we must ourselves be well educated and updated in order to provide unambiguous counseling to these categories of vulnerable patients.

In this commentary, we provide a comprehensive review of both approved COVID-19 vaccines and the ones still under development, and explore potential risks, benefits and prioritization of vaccination in order to properly guide patients' awareness and choices.

SARS-CoV 2 VACCINES

Coronaviruses are single-stranded, positive-sense RNA enveloped viruses.^{17,18} Two Alphacoronaviruses (229E and NL63) and two Betacoronaviruses lineage A (OC43 and HKU1) are known to elicit common cold symptoms and are endemic.¹⁹ Severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) are Betacoronaviruses with epidemic spread and may cause lethal infection in humans. SARS-CoV-2 shares 50% genome sequence identity with MERS-CoV and 79% with SARS-CoV.²⁰

The first attempts to develop a vaccine against SARS-CoV began in the early 2000s,^{21,22} but trials were stopped because of the disappearance of the disease. MERS-CoV vaccines are under active development.

Receptor binding and membrane fusion of the virion are mediated by a single surface protein, the spike protein. SARS-CoV-2 shares more than 90% amino acid identity with SARS-CoV, with the most differences in the spike protein.^{20,23} The receptor-binding domain of the spike protein of SARS-CoV-2 binds to angiotensin-converting enzyme 2 (ACE2)²⁴ receptors in the nasal cavity, the respiratory tract and other ACE2 receptor locations including intestinal enterocytes,²⁵ leading to endocytosis and release of the viral genome after fusion of membranes. As antibodies directed

TABLE 1 Developed and developing COVID-19 vaccines. EUA: emergency use authorization; MHRA: Medicines and Healthcare Products Regulatory Agency; DCGI: Drugs Controller General of India

Category	Name	Developer	Target	Schedule	Phase	Comments
mRNA	BNT162b2	BioNTech–Pfizer	Prefusion stabilized, membrane-anchored, full-length spike protein	Two doses (30 µg; day 0, day 21)	Post-EUA	95% efficacy. Protection against severe disease. No differences in subgroups. Cold chain logistic difficulties.
mRNA	mRNA-1273	Moderna	Prefusion stabilized, full-length spike protein	Two doses (100 µg; day 0, day 28)	Post-EUA	Anaphylaxis incidence: approx. 1 in 100/000. 94% efficacy. Protection against severe disease. No differences in subgroups. Similar excipient composition to BNT162b2
Nonreplicating adenovirus	ChAdOx1 nCoV-19 (AZD1222)	AstraZeneca and University of Oxford	Full length spike protein	Two doses (4 weeks apart)	Phase 3	Nonreplicating simian adenovirus vector ChAdOx1. MHRA and DCGI EUA. No profit.
Nonreplicating adenovirus	Ad26.COVS2S	Janssen	Stabilized prefusion spike protein	Single dose	Phase 3	Nonreplicating adenovirus serotype 26 vector. Phase 3 enrollment completed in Dec 2020. Interim data available by late January.
Protein subunit	NVX-CoV2373	Novavax	Stable prefusion protein antigen of the spike protein	Two doses (day 0, day 21)	Phase 3	Glycoprotein nanoparticle with Matrix M1 adjuvant.

All trials compared the safety and efficacy of the vaccine against normal saline, except for ChAdOx1 nCoV-19 that was compared to Meningococcal group A, C, W, and Y conjugate vaccine or normal saline. All vaccines are administered intramuscularly.

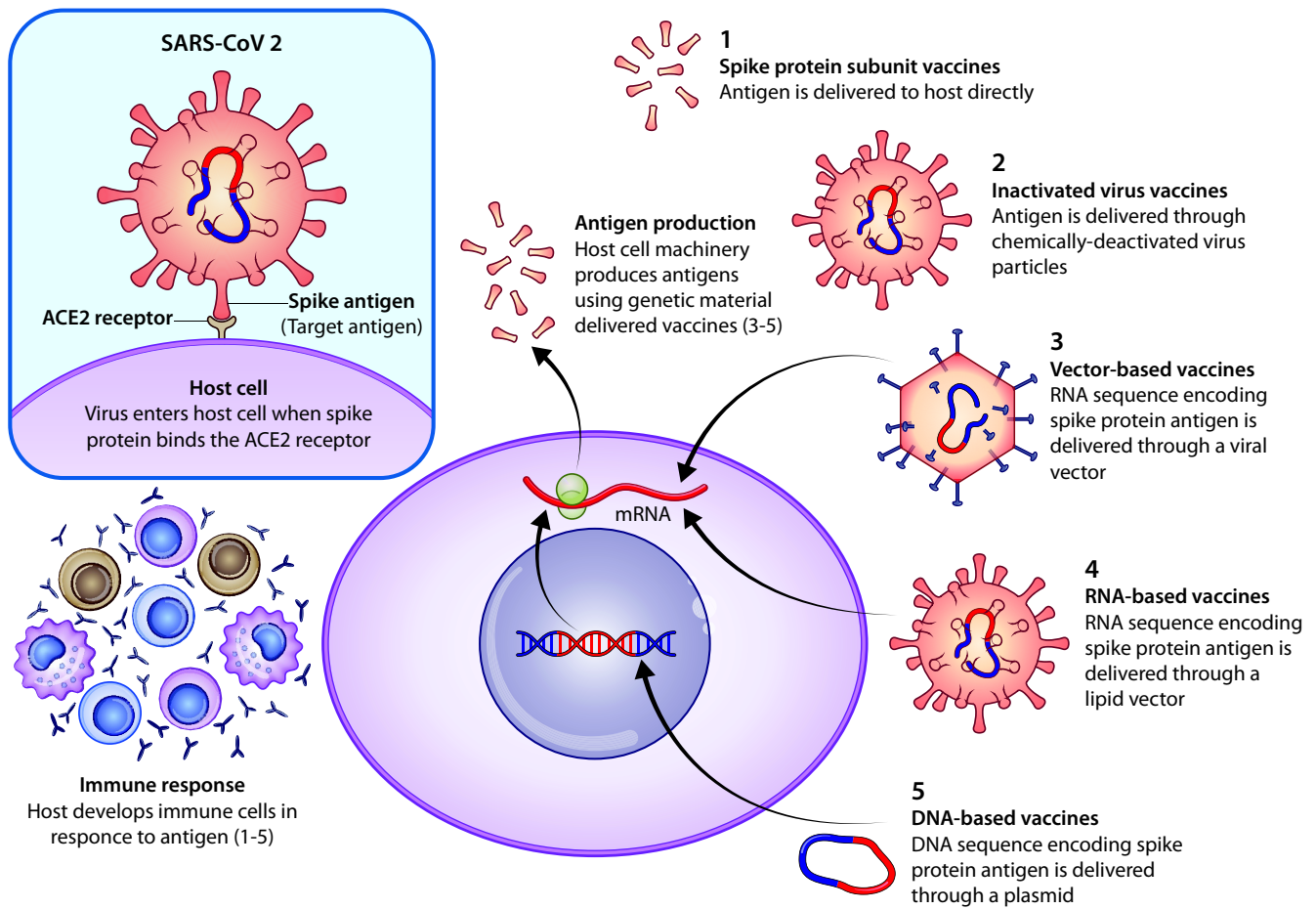


FIGURE 1 COVID-19 vaccines mechanisms

against the spike receptor-binding domain inhibit the entrance of the virion in SARS-CoV and in MERS-CoV, the spike protein was identified as the main target of SARS-CoV-2 vaccines.

A cause of concern is the evidence for some betacoronaviruses of antibody-dependent enhancement (ADE) of the virus.²⁶ Instead of neutralizing the virions, antibodies may promote viral invasion in some types of cell. In particular, SARS-CoV viruses enter macrophages through the antibody Fc portion and skew macrophage function.²⁷ In MERS-CoV, the interaction of a monoclonal antibody induces conformational changes and causes viral entry through the Fc portion.²⁶ This phenomenon is partly dependent on the concentration of the antibody, so a high titer of neutralizing antibodies may prevent ADE of the virus.²⁶ Further, the introduction of an adjuvant may promote Th2-type immunity and reduce the immunopathology.²⁸

There is no clear evidence of ADE of the virus in SARS-CoV-2, but it may explain conflicting results in the use of convalescent plasma.²⁹ Also, it mandates to evaluate candidate vaccines for prevention of either mild or severe COVID-19. To date, no approved vaccine for SARS-CoV-2 demonstrated ADE of the virus.³⁰⁻³²

In phase 1/2 trials, efficacy was measured as immunogenicity^{33,34} defined as antibody titer against the defined antigen. In phase 3 trials, the efficacy was defined as difference in number of symptomatic

infections.^{30,31} Up to date, no test is recommended to assess vaccine efficacy after the scheduled doses; it seems reasonable, though, to measure antibody titer in selected patients.

Also, as no trial published results for asymptomatic carriage, it is not yet known if vaccinated people may still carry and transmit the virus (i.e., “sterilizing immunity”).³⁵ Therefore, prevention strategies should be maintained in the vaccinated population.

Vaccine platforms

Up to January 16, 2021, 237 vaccine candidates for COVID-19 had been reported, and 64 of them were in human clinical trials.³⁶ Three of them have completed phase 3 trials, and reports are published³⁰⁻³²; 19 more vaccines are in phase 3 studies.

Several different approaches have been used to stimulate the immune system in mounting a humoral response.³⁷ As more traditional approaches are under investigation (inactivated virus vaccines, protein subunit vaccines, recombinant virus vaccines), more recent and innovative strategies have been tried (Non-replicating viral vector vaccines, RNA based vaccines, DNA based vaccines; Figure 1). See Appendix for an insight on different vaccine platforms.³⁹⁻⁶¹

SPECIFIC CONSIDERATIONS FOR VULNERABLE PATIENTS WITH DIGESTIVE DISORDERS

Oncological patients

Cancer patients have been shown to be at higher risk of severe COVID-19, with mortality rates ranging from 5% to 61%.^{62,63} Of note, this increased risk appears to be higher for patients with a recent diagnosis of both solid and hematologic tumors.^{64,65} Moreover, substantial increases in the number of avoidable cancer-related morbidity and mortality may be expected as a result of diagnostic delays due to the COVID-19 pandemic.^{66,67}

Studies on immune response to antiviral vaccination in neoplastic patients are scarce, and most of them are related to the influenza vaccination.⁶⁸ Nevertheless, based on the mechanism of action of the vaccines against COVID-19, along with data extrapolation from other vaccines, COVID-19 vaccine may be estimated to have similar efficacy and safety to those patients without cancer. As a matter of fact, patients receiving chemotherapy are expected to show lower rates of seroconversion and seroprotection compared to general population.⁶⁹ However, observational clinical studies investigating the impact of influenza vaccination showed lower infection and mortality rates due to influenza in cancer patients receiving the vaccine,⁷⁰ implying an efficient immune response, which was proved to be higher in patients with solid tumors.⁷¹ According to the recent European Society for Medical Oncology guideline on COVID-19 vaccination and the National Comprehensive Cancer Network,^{62,72} the vaccine should be administered before initiation of chemotherapy whenever possible. On the other hand, in patients who have already initiated systemic therapies, specific timing of administration is not supported by current evidence.^{72,73} In those patients, multiple doses of vaccine might help to reach adequate efficacy.⁷³

In summary, although conclusive data regarding vaccination in patients with cancer are still lacking, there is enough evidence to support the administration of COVID-19 vaccine, even in patients with cancer undergoing immunosuppressive therapy.⁷⁴⁻⁷⁶ Indeed, according to the Advisory Committee on Immunization Practices within the Centers for Disease Control and Prevention and the American Association for Cancer Research COVID-19 and Cancer Task Force, patients with an active cancer should be considered at a higher risk for severe COVID-19, and should be considered for early COVID-19 vaccination.⁷⁷

IBD patients

Unlike cancer patients, there is no evidence suggesting any increased susceptibility to COVID-19 for IBD patients.⁷⁸ Indeed, although the persistent concerns about patients on high and prolonged dose of steroids,^{79,80} the range of immune-active therapies (biologicals, JAK inhibitors or other immunosuppressive agents) used in IBD management, have been proposed to have some beneficial effects considering the theoretical role in preventing the cytokine storm

which is thought to be the main cause of COVID-19-related acute respiratory distress syndrome.⁸¹

After having overcome the fear of being high-risk targets for COVID-19, IBD patients have to face the feeling of being excluded from the common hope brought by the vaccines. From patients' point of view, the main concerns imply vaccine safety, and the risk of triggering disease flares. In this regard, previous experiences coming from influenza, HBV and pneumococcal vaccinations, do not suggest any association between vaccines and IBD exacerbation. Even in IBD patients receiving immunosuppressive therapies, the main concerns are related to the theoretical risk of sub-optimal vaccine responses rather than vaccine side effects. Several studies have evaluated the impact of immunosuppressants on the efficacy of vaccines among patients with IBD,^{82,83} confirming a blunted immune response. Further, rapid decline of protective antibody titers may be expected.^{84,85} However, a lower response does not imply vaccine inefficacy, and COVID-19 vaccine should be strongly suggested even in these patients, whichever approved vaccination is offered to them.^{82,86} In addition, for some infections like hepatitis B, it might be appropriate to assess antibodies titers and consider possible additional booster dosing.⁸⁴

In summary, we may reassure our patients about the safety and the efficacy of the major candidate vaccine mechanisms. This recommendation is consistent with current knowledge and first statements of national and international societies.^{87,88} However, we should continue to evaluate the SARS-CoV-2 vaccine research and outcomes with a particular focus on immunosuppressed patients.

Liver diseases

Liver diseases of viral etiology are not per se associated with COVID-19 disease severity or outcome and the same holds true for liver transplanted patients⁸⁹⁻⁹²).

Importantly, COVID-19 has been demonstrated to be associated with liver function deterioration and elevated mortality in patients with cirrhosis in studies from Europe and the US.^{93,94} However, the main determinant of mortality in both studies was the Charlson Comorbidity Index score, highlighting that frailty often found in patients with advanced cirrhosis rather than liver disease is the main determinant of mortality. These findings although derived from small studies cohort studies, are consistent and have been replicated also in patients from Asia.

Recent data from the European Reference Network for Rare Liver Diseases show that autoimmune liver diseases are not a specific risk factor for COVID-19, and similar to any other etiologies, the risk is determined by the stage of cirrhosis.

With regards to Covid-19 vaccination, subjects with liver diseases were excluded from most clinical trials evaluating the new COVID-19 vaccines. When included, the criteria used to define liver disease and classify its severity remain unclear.⁹⁵ A detailed understanding of SARS-CoV-2 vaccine safety and the immunological response in patients with liver disease may have to wait for

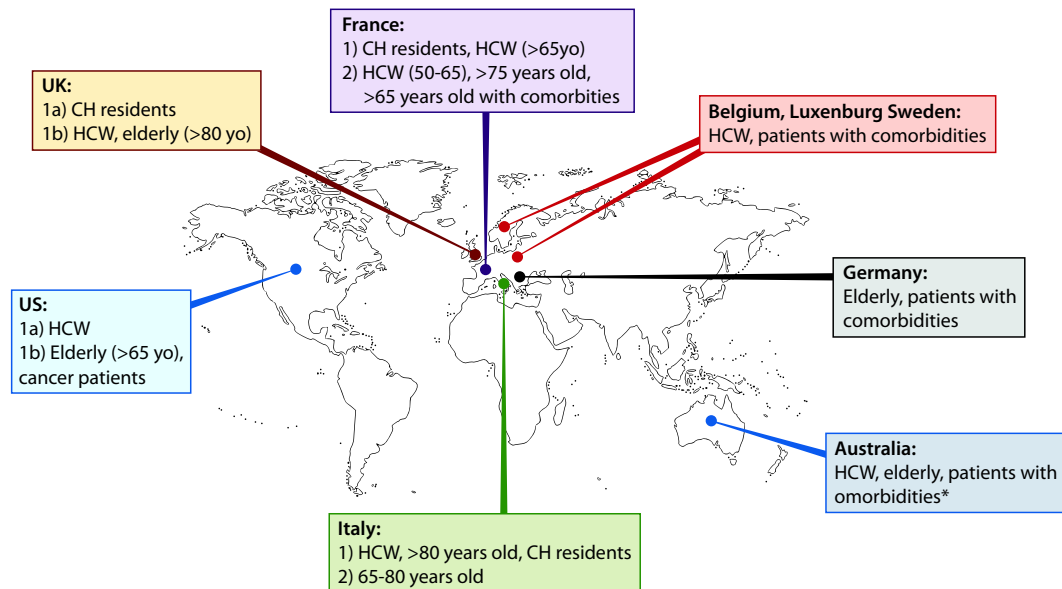


FIGURE 2 High priority patients. CH: care home. HCW: health care workers. *immunocompromised, multiple comorbidities, chronic lung disease, diabetes, cardiovascular disease and severe obesity

post-licensing, real-world investigation. However, considering previous experience with other vaccinations,^{96,97} there are no data suggesting that any of the available and developing COVID-19 vaccines would not be safe and effective in protecting these patients. Thus, these categories, including liver transplant recipients,⁹⁸ should be strongly encouraged to get vaccinated against COVID-19 with any of the approved vaccines when one is offered to them, as recently recommended by national and international societies^{99,100}

Finally, we would like to emphasize that other recommended vaccinations for patients with chronic diseases and/or immunosuppression (i.e., influenza, pneumococcal vaccines) should be administered during this pandemic just as they would have in pre-COVID era.

Health care workers

As the current critical pressures squeeze health-care systems worldwide, frontline health care workers (HCW) have been unanimously considered as a priority in the vaccination strategy¹⁰¹⁻¹¹⁰ (Figure 2). If a significant number of HCWs were unable to work due to COVID exposure of illness, this could be devastating considering the problems health care facilities are already struggling with regarding staff shortages. Furthermore, this would also result in slowing down the proper rollout of the vaccine itself, which needs to be administered by healthcare staff. In the area of gastroenterology and endoscopy, HCWs are considered potentially more exposed and at higher risk of developing COVID infection because of the multiple issues related to aerosol-generating endoscopic procedures as well as potential persistence of viral components in the stool of infected patients with GI symptoms. This is why all HCWs involved in the practice of gastroenterology and endoscopy should be regarded as a priority in the vaccination list of the medical facilities around the world.

Finally, we should consider that HCW attitude and utilization of vaccines is a positive example for others and an accepted factor for reducing patient's hesitation and improving adherence to vaccination schedules.¹¹¹ Thus, HCWs should be informed, prioritized and encouraged to undergo COVID-19 vaccination (see the American Collage of Gastroenterology-ACG-virtual Grand Round at https://urldefense.proofpoint.com/v2/url?u=https-3A_webfiles.gi.org_video_s_media_vgr-5Fcovid.mp4&d=DwMFAg&c=shNJtf5dKgNcPZ6Yh64b-A&r=tiVVdsJMY-BPrudjrMffg9U_QLXXI_XIAwOFM7Y6EYU&m=WpF8q7Q8BISrq33IIUX2ck1L-2bt6uZsl_5Amv04OI&s=62Z6Ch-LY4I7j9oisKNCggyLbIIVGzLcZ8k1CCCh04H8&e=).

CONCLUSIONS

As Gastroenterologists, patients will be looking to us for guidance regarding vaccination, especially those patients who may be more vulnerable to COVID-19 due to their underlying digestive diseases. Thus, we must be ready to advocate for our patients and ourselves regarding SARS-CoV-2 vaccines promoting scientific research and rigor.

Different guidelines for vaccination strategies have been published worldwide in order to prioritize different populations.¹⁰¹⁻¹¹⁰ However, our patients with digestive disorders do not represent a homogeneous population and different recommendations will be applied. Importantly, most of these categories were excluded from clinical trials evaluating SARS-CoV 2 vaccines, and therefore recommendations are not based on evidence form the current RCTs.

To the best of our knowledge, we recommend COVID-19 vaccination for our patients, even for fragile, immunosuppressed patients such as IBD patients, GI cancer patients or patients with chronic liver disease. For these categories, lower rates of complete

immune response are expected, however a partial protection may still have a relevant clinical role. Nevertheless, considering that any vaccine will not be 100% effective in preventing SARS-CoV-2 transmission, we should still highlight the need of maintaining prevention strategies including hygienic practices such as handwashing, face masking and social distancing. Of note, data from clinical trials indicate that COVID-19 vaccines can safely be given to persons with prior SARS-CoV-2 infection.^{30,31} However, since vaccine supply are limited, they may temporarily delay vaccination.

DISCLAIMER

This review is based on the available evidence at the time of its preparation and may not apply in all situations. Recommendations should be interpreted in light of specific clinical situations and resource availability.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

AUTHOR CONTRIBUTION

Marco Spadaccini, Lorenzo Canziani, Alessio Aghemo and Alessandro Repici drafted the manuscript. All the Authors revised and approved the final manuscript.

DATA AVAILABILITY STATEMENT

Data sharing not applicable – no new data generated.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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