April 21, 2020

Science Advisory Board Review: Identifying Research Needs to Address the Environmental and Human Health Impacts of COVID-19

COVID-19 issues are the top priority for the U.S. EPA, and it has been actively engaged and supporting response efforts to the SARS-CoV-2 pandemic. As part of these efforts the Agency has also been considering how current and future EPA research activities might enhance and inform EPA's current and any future responses to SARS-CoV-2 and has developed a compendium summarizing current understanding and capabilities related to SARS-CoV-2. The document identifies short- and long-term research needs that could build on and extend EPA's understanding in different research categories (See Attachment).

At the Administrator's request, the EPA is seeking a rapid review with the Science Advisory Board (SAB) to provide feedback on the identified research needs. SAB comments will inform and help guide the Agency as it enhances its capabilities to address the environmental and human health impacts of SARS-CoV-2.

<u>Background on EPA Science/Research Questions</u>

As the SARS-CoV-2 pandemic unfolds, understanding of the virus and its impacts is evolving. EPA has a role to play to help the Nation respond to disasters and emergencies. Activities span across the Agency, to ensure the protection of human health and the environment and to take the lead on safely and effectively cleaning the environment following an incident. A responsibility of EPA's Office of Research and Development is to ensure its research portfolio advances the capabilities of the Agency, as well as other federal, state, and tribal partners, to address threats to human health and the environment, including from biological origins.

Agency subject matter experts, in the table below, have identified research areas where there are opportunities to refine and improve on the current understanding of SARS-CoV-2. This activity was conducted with a goal of enhancing capabilities, capacity, and expanding the knowledge base to further support decision-making within the Agency and across the Nation. Maintaining a focus on the Agency's mission, the specific research categories identified include:

- Environmental Disinfection
- Environmental Sample Collection Methods
- Environmental Sample Analysis
- Environmental Stability/Persistence on Surfaces
- Environmental Exposure
- Water/Wastewater
- Air
- Environmental Factors affecting transmission and severity of COVID-19
- Human Health Risk Factors affecting transmission and severity of COVID-19

- Personal Protective Equipment (PPE)
- Human Health Risks of Exposure to Disinfectants

In the column titled "Current State of Knowledge and Capabilities," subject matter experts identified key points in our understanding of the SARS-CoV-2 pandemic as it relates to each research category, and what capabilities EPA already has at hand to address current needs. From that foundation, subject matter experts proceeded to identify additional research areas that could benefit EPA (column titled "Research Questions that Can Enhance Knowledge and Capabilities"). In several instances, the Agency has already identified research questions on which to initiate work (see highlighted questions in the Attachment).

Within these research categories, short-term and long-term research needs were broadly identified. "Short-term" activities are those efforts that could be aimed at helping with the current response to the SARS-CoV-2 pandemic, results likely to be available within several weeks or months. "Long-term" research means studies that would take longer to complete, 1-2 years, and may not impact the immediate response to the SARS-CoV-2 pandemic but would add to our long-term understanding. It is also likely that longer term efforts would evolve and adjust based on results from short-term research efforts. No prioritization was developed.

<u>Charge Questions</u>

Referring to the attached table, EPA seeks input from the SAB members in the following general areas:

1. Within each research category, please discuss whether there is sufficient clarity to indicate how addressing a research question might inform Agency activities related to the SARS-CoV-2 pandemic? Specifically,
    a. Which research questions within a category are particularly suited to EPA's mission and will have the most impact on EPA's role in responding to the SARS-CoV-2 pandemic?
    b. Are there research questions that could more effectively be addressed by another Federal partner, the private sector, academia or some combination?
2. Within each research category, please identify if there are other research questions that have not been identified by the Agency, that have the potential to refine or improve our understanding and further support its role with respect to the pandemic.
3. Within a research category, EPA roughly identified what research could be accomplished in the short-term, and what would be longer-term efforts. Within each research category, are there other considerations that might impact prioritization? How might research be prioritized across the landscape of research categories that have been identified?
4. Are there any other important categories of research, focused on the Agency's role in responding to the SARS-CoV-2 pandemic, that are not captured in the existing table? If so, please discuss the current state of knowledge in the research category and identify

what research would be relevant and inform EPA's efforts. Please provide some sense of prioritization and whether the effort is a short-or-long term research effort.

U.S. EPA – COVID-19 Science/Research Question List (April 20, 2020)

(Note: Yellow highlighting indicates where research efforts are already initiated within ORD)

Research Category	Current State of Knowledge and Capabilities	Research Questions that Can Enhance Knowledge and Capabilities
Environmental Disinfection	• EPA List N - Disinfectants for Use Against SARS-CoV-2 – lists many disinfectants as effective for use against SARS-CoV-2 on pre-cleaned, hard, non-porous environmental surfaces. ▪ Narrower list of products for porous materials. ▪ Narrower list of products for use as fogs, mists, vapors, or gases for volumetric disinfection. • The stringency of the registration process provides a high degree of confidence in the effectiveness of these products when used according to the product label (https://www.epa.gov/pesticide-registration/efficacy-requirements-antimicrobial-pesticides) • EPA uses standard laboratory methods (e.g., ASTM E1053-20 and ASTM E2197-17) to quantitatively evaluate the performance of disinfectants against viruses, and which are currently considered suitable for evaluating SARS-CoV-2 claims. • Registered disinfectants do not require confirmatory sampling (post-application to ensure disinfection is achieved). (https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf) • Enveloped viruses (such as SARS-CoV-2, the virus that causes COVID-19)) are generally more susceptible to disinfection than non-enveloped viruses, vegetative bacteria, and bacterial spores.[1,2,3] • According to technical support requests that EPA has been involved with, the availability of disinfectants may be limited in supply in some areas. Alternative disinfection methods and products are being sought in these instances.	Short-Term • Can basic cleaning techniques (e.g., using soap/water) alone be effective for surfaces to reduce environmental exposure to SARS-CoV-2? • How effective are devices such as UV, ozone generators or steam devices at reducing or eliminating exposure to SARS-CoV-2 from surfaces or objects? • What available disinfection methods can be effective for complex and difficult to disinfect areas/surfaces (such as porous materials, soft surfaces, and HVACs)? What are alternative disinfection methods, if such methods are not readily available or efficacious for an area? • What are readily available alternative disinfectants (not currently on EPA List N) for large-scale or special situation use and by what methods can these disinfectants be applied effectively? • Do methods of application of List N products via fogging and/or electrostatic spraying provide the necessary contact time on surfaces to be efficacious against SARS-CoV-2? • How effective are products that claim to offer residual/long-term (e.g., hours to months) ability to reduce potential exposure risk to SARS-CoV-2? • What disinfection methods (including using List N products) are suitable for residential and business-owner conducted disinfection? • How susceptible to disinfectants are each of the human coronavirus isolates used for antimicrobial product registration, SARS-CoV and SARS-CoV-2? This comparative research may lead to the use of a safer-to-handle surrogate virus for future regulatory and research purposes, thus facilitating additional product and technology development.

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		Long-Term
		• Are there situations where environmental disinfection of surfaces or objects may not be effective to reduce or eliminate potential exposure to SARS-CoV-2?
		  ○ In situations where the frequency of recontamination is high, how often is disinfection needed to effectively reduce or eliminate potential exposure to SARS-CoV-2?
		  ○ If SARS-CoV-2 is airborne and continues to settle onto surfaces (e.g., after surface disinfection), does disinfection of surfaces alone effectively reduce potential exposure to SARS-CoV-2?
		• How effective are surface coatings impregnated with antimicrobials or other antimicrobial surfaces (e.g. copper) in reducing or eliminating exposure to SARS-CoV-2 and how should disinfectants be used in combination with these treated surfaces?

Environmental Sample Collection Methods	• Studies have reported detection of coronavirus RNA on surfaces by environmental sampling.[4,5,6,7,8,9] • The detection of coronavirus RNA does not equate to an exposure risk. RNA detection does not confirm that infectious virus is present. • Infectious dose combined with exposure is used to estimate public health risk. Environmental sampling may inform potential exposure.[10] • Researchers believe that the infectious dose for SARS-CoV-2 is less than that for SARS (estimated for SARS as an average of 240 viral particles).[11,12] • The efficiency of environmental sampling (e.g., of surfaces) for viruses is typically very low; detection limits are generally higher than infectious dose and thus higher than required to adequately assess potential risk.[13] • Due to the sampling inefficiencies for viruses on environmental surfaces, sampling would not be	Short-Term • Under what situations does environmental contamination need to be assessed? (e.g., when is it useful to enhance or enable decision making.) • What methods (e.g., swabs, wipes, material types) are most appropriate for surface sample collection for SARS-CoV-2? • What are the detection limits and sample collection efficiencies specifically for SARS-CoV-2 for various environmental sample collection methods? • What environmental sampling strategy(ies) (including number of samples, sample locations, frequency of sampling, and timing of sampling) will provide the most effective characterization of the presence/absence of SAR-CoV-2 on both non-porous and porous surfaces?

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	effective at confirming the efficacy of a registered disinfectant or at determining potential exposure risk prior to disinfection. • Negative sampling results cannot be equated with the absence of viable virus.[10] • Registered disinfectants are routinely and appropriately used without confirmatory sampling (post-application to ensure disinfection is achieved) (https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf)	
Environmental Sample Analysis[14]	• Molecular methods (e.g., reverse transcription polymerase chain reaction, RT-PCR) are rapid (less than a day), available and provide specific detection of the virus; however, do not indicate viability or infectivity.[15] • As noted by the National Academies of Sciences, "Studies that rely on PCR to detect the presence of viral RNA may not represent viable virus in sufficient amounts to produce infection."[16] • After disinfection with an EPA List N product per the label's instructions, it is possible that inactive viral remnants will remain on the surface. • Viral remnants detected from environmental sampling via molecular analysis methods do not indicate the presence of infectious virus (i.e., false positives). • The tissue culture-based method provides information on the viability of the virus; however, this method is not specific for SARS-CoV-2. Confirming viability and infectivity requires running a 4-7 day, tissue-based culture method.	<u>Short-Term</u> • What are the SARS-CoV-2 sample analysis objectives (adequate specificity, limits of detection, viability assessment, turnaround time) and which methods are most suitable or can be developed to meet those objectives? • What are the most appropriate sample custody, preservation, transport, and storage conditions to maintain sample viability prior to analysis for SARS-CoV-2? • What is the current laboratory capability and capacity for molecular and viability analysis for SARS-CoV-2 and what method improvements can be made to increase capability/capacity? How does this reflect on the required environmental sample analysis needs?
Environmental Stability/Persistence on Surfaces	• Viable SARS-CoV-2 can persist on plastic and stainless-steel surfaces for up to 3 days (at 21-23°C, 40% RH), with a half-life of 13-16 hours.[17]	<u>Short-Term</u> • How long does SARS-CoV-2 remain active on frequently touched surfaces (e.g., escalator & subway hand holds,

Research Category	Current State of Knowledge and Capabilities	Research Questions that Can Enhance Knowledge and Capabilities
	• Experience with other coronaviruses suggests that viable SARS-CoV-2 may persist on other surfaces up to several days, suggesting surfaces may be potential sources of exposure.[18,19,20] • Lower temperature (4-6 ℃) and moderate humidity (~50% RH) promote longer virus survival on surfaces.[21] • SARS decay rates increase as temperature increases. Low (<30%) and high (>80%) humidity also increase decay rates.[21] • Testing with SARS and other enveloped viruses suggests that heat can accelerate virus decay on surfaces and in liquids.[22] • Presence of viral RNA or viable virus on surfaces does not necessarily imply exposure risk to the individual.[23]	railings, door handles, etc.) as a function of environmental conditions? ○ How does temperature and humidity impact persistence indoors? ○ How long does SARS CoV-2 remain viable on surfaces and ambient air in outdoor conditions such as direct sunlight? ○ How long can SARS-CoV-2 remain viable on fomites (e.g., dust)? ○ How long can SARS-CoV-2 remain viable on mail or clothing, and does it pose a take-home risk? • Can alternate environmental conditions (heat and humidity) be used to effectively reduce or eliminate the presence of SARS-CoV-2 on environmental surfaces?
Environmental Exposure	• Contact transmission and inhalation and/or oral exposure to respiratory droplets produced when an infected person coughs or sneezes are thought to be the primary routes of transmission.[24,25,26] • There is a potential for exposure through touching contaminated surfaces and then touching of the mouth, nose or eyes, however this is not considered a primary route of exposure.[24,25,26] • Surfaces and objects frequently touched by multiple people, including but not limited to doorknobs, handrails, light switches, gas pumps, etc. have a higher potential as a source for surface exposure. Walls, ceilings, mirrors, and floors are considered lower touch (and lower exposure potential) surfaces.[27]	Short-Term • How effective are sampling and analysis methods for assessing potential risk from environmental exposure? What improvements are necessary? • What measures can be used to mitigate environmental exposure to SARS-CoV-2? • Which exposure scenarios pose the highest potential risk for individuals self-isolated at home (e.g., shopping, handling mail, outdoor exercise, etc.)? Long-Term • If SARS-CoV-2 settle on carpets, clothing, or other objects, does it present a hand-to-mouth hazard? • Considering infectious dose and transmissibility, what amount of SARS-CoV-2 on widely prevalent surfaces poses a risk to public health?
Water/ Wastewater	• Based on existing CDC information there is no indication that water or wastewater exposures pose a significant risk to human health.[28]	Short-Term • What uncertainties exist and what refinements are necessary to more accurately quantifying SARS-CoV-2 in the various

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	• 53% of stool specimens from infected patients test positive for the virus, however, it has not been confirmed to be viable/infectious virus. • There is limited research to suggest that the virus might be transmitted via the fecal-oral route.[29,30] • SARS-CoV-2 can be inactivated using sodium hypochlorite and other disinfectants recommended by EPA.[27]	water types (i.e., drinking water, wastewater, surface water, and groundwater)? Long-Term • What is SARS CoV-2 persistence in untreated water (i.e., sewage or wastewater before final disinfection, surface water, and groundwater)? • Do commonly used POTW biosolids stabilization methods effectively deactivate SARS-CoV-2?
Air	• Respiratory droplets produced when an infected person coughs or sneezes are thought to be a primary route of transmission.[31,32] • Recent reports indicate that SARS-CoV-2 can remain viable in aerosols for up to three hours.[33] • Research indicates that aerosols from a sneeze or cough could take an hour to settle and possibly longer for smaller aerosols.[34]	Short-Term (non-healthcare setting) • How long does the virus remain viable in ambient air (as a function of temperature, humidity, UV, precipitation)? • Can air vented outside from contaminated indoor environments carry significant infectious viral load outdoors, particularly in dense urban environments, or in cases of re-entrainment of exhausted air back indoors? • Are there potential indoor sources that can contaminate areas or lead directly to exposure, through aerosolization? (e.g., drain traps, toilet flushing, vacuuming, dusting, wiping, re-aerosolization from surfaces) • Does SARS-CoV-2 remain viable after traveling through an HVAC system? How does the answer vary for different types of HVAC systems in different types of buildings or indoor environments (hospitals, large commercial buildings, residences, schools, airplanes, trains, buses)? Long-Term (non-healthcare setting) • If aerosol risks are excessive, how can aerosol exposure indoors be reduced? • What precautions, if any, must be taken when cleaning or replacing different types of HVAC or portable air cleaner filters? • Can airborne SARS-CoV-2 deposit in water bodies and lead to exposure via contaminated water? • Does home vacuuming remove SARS-CoV-2 from the surface or cause it to aerosolize?

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Environmental Factors affecting transmission and severity of COVID-19	• We know that certain types and levels of air pollution exposure increase hospital admissions for respiratory infections including influenza.	Long-Term • Can particulate matter in the atmosphere serve as a vehicle for the transmission of SARS-CoV-2? • Does exposure to air pollutants, including wildland fire smoke or other air pollutants (e.g. ozone, particulate matter, diesel exhaust, pollen) increase the susceptibility to respiratory viruses like SARS-CoV-2? Or exacerbate existing COVID-19 infection? • Does ambient or indoor temperature or humidity affect the transmission of SARS-CoV-2 and severity of the COVID-19 illness?
Human Health Risk Factors affecting transmission and severity of COVID-19	The CDC maintains the COVID-19 website to provide the latest information on what is known about the disease, its transmission, impacts, and what individuals can do to protect themselves and to help stop the spread. https://www.cdc.gov/coronavirus/2019-ncov/index.html	Long-Term • Are there particular health risk factors (aside from pre-existing conditions) that make certain individuals or subpopulations more sensitive or vulnerable to COVID-19, e.g. characteristics of the built environment, seasonal allergies, chronic exposure to aerosolized pollutants, demographic conditions, etc.? • Do factors, such as socioeconomic status, gender, race, stress, and characteristics of the built environment affect transmission of SARS-CoV-2 and severity of the COVID-19 illness?
Personal Protective Equipment (PPE)	Appropriate PPE decontamination procedures are necessary. Guidance for PPE can be found on OSHA and CDC websites: https://www.osha.gov/SLTC/covid-19/standards.html https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/businesses-employers.html https://www.cdc.gov/coronavirus/2019-ncov/hcp/healthcare-supply-ppe-index.html https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html	Short-Term • What are recommended procedures for disinfecting PPE for the purposes of reuse? • How many times can it be disinfected before it must be disposed? • Does hand sanitizer work on disposable gloves so they could be reused? This would include suits, N95s, gloves, and booties.

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Human Health Risks of Exposure to Disinfectants	• Exposure to disinfectants can pose risks to children and sensitive subpopulations, including those with respiratory sensitivity. • The CDC has specific guidance for communities, schools, workplaces, and events (https://www.cdc.gov/coronavirus/2019-ncov/community/index.html). For example, information on childcare facilities that remain open during the COVID-19 pandemic is available (https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/guidance-for-childcare.html) • EPA's Office of Pesticide Programs conducts human health risk assessments for disinfectants using well-established, peer reviewed and science-based methodologies (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide). • Disinfectants are currently undergoing registration review, the 15-year review cycle to determine whether they continue to meet the FIFRA standard for registration.	Long-Term • Some additional research would allow for more refined estimates of exposure for post application exposures. For example, measurements on residue transfer for disinfectants applied to toys and floor surfaces, amount of mopping solution used and volatilization of disinfectants into indoor air would provide useful information for assessing the risk of children and other susceptible populations. Is there other exposure information that would be informative? • The EPA has exposure data for trigger pump spray and hand-held spray wants (hand-held mechanical application). Are there any novel SARS-CoV-2 control application techniques (e.g., electrostatic sprayer) that would not be represented by the currently available exposure data? • With regard to assessing risk to people with respiratory sensitivity, are there laboratory animal models or non-animal methods (e.g., *in vitro* or computational approaches) that would be useful?

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