Wednesday, October 23, 2024

This is a supplement to a complaint filed on Oct. 29, 2023 (the "**Primary Complaint**") with the HHS Inspector General by the WHN about violations of law by employees of HHS regarding the conduct of the Healthcare Infection Control and Prevention Advisory Committee ("**HICPAC**"). An additional complaint was filed on August 15, 2024.

This supplementary complaint is issued based on observations made during HICPAC's Aug. 22, 2024 meeting and in light of the upcoming meeting scheduled for November 14-15, 2024. The accompanying "Supporting Materials," submitted under the Evidence section of the on-line filing form, expands on the points made in this complaint and offers evidence to support them.

HICPAC is still conducting itself in a manner that is grossly negligent for at least the following reasons:

A. HICPAC still fails to be composed of 14 members

The HICPAC Charter requires that the committee be composed of 14 members. This violation of its Charter had already been brought to the attention of the Inspector General in WHN's Primary Complaint. However, on August 22, 2024, HICPAC held a meeting with only 11 members. This action by HICPAC demonstrates that it ignores its own Charter and the authority of the Inspector General to enforce it. From the time of WHN's original Complaint up until the present day, HICPAC has been and remains an illegally constituted committee with no legal validity or enforceability.

B. The current HICPAC members have an active conflict of interest by being asked to decide upon infection prevention in a healthcare setting

The Federal Advisory Committee Act (FACA) does not entirely prohibit conflicts of interest and, in some cases, even encourages them to foster debate. However, when the conflict of interest is widespread across most, if not all, committee members and contradicts the committee's core purpose, it undermines the committee's ability to function and raises questions about its legitimacy. HICPAC's Charter mandates providing guidance on "prevention, and control of healthcare-associated infections" Therefore, committee members that are compensated for encouraging spread of infection (or compensated for being knowingly or willfully ignorant of the science of infection control in a healthcare setting), are in conflict of interest with HICPAC's objective.

More specifically, it is well established that direct payment systems can lead to perverse incentives against the prevention of hospital-acquired infections (HAIs). In fee-for-service payment models, hospitals are reimbursed for services provided, including the treatment of

HAIs. In such a system, hospitals can generate more revenue by providing additional care to treat these infections, rather than by preventing them in the first place.

To address such perverse incentives, the Centers for Medicare & Medicaid Services (CMS) instituted countermeasures. In 2008, CMS implemented a policy that no longer reimburses hospitals for the extra costs associated with certain hospital-acquired conditions, including HAIs like catheter-associated urinary tract infections (CAUTIs) and central line-associated bloodstream infections (CLABSIs). This policy forces hospitals to absorb the additional cost of treating patients with these infections, counteracting the perverse financial incentives of the fee-for-service model.

Despite these efforts, hospital management is still financially incentivized not to prioritize the prevention of airborne HAIs, such as hospital-acquired COVID-19. The financial structure of current payment models specifically undermines efforts to prevent airborne transmission, the primary mechanism for hospital-acquired COVID-19.

Many members of HICPAC are from hospital management, and as such, have direct financial interests that conflict with the prevention of HAIs. This conflict of interest, long recognized in the context of other HAIs, must now also be addressed for COVID-19 and other airborne diseases.

Further, multiple members of HICPAC have other financial incentives that create conflicts of interest. A high proportion of them receive substantial funding from the CDC, specifically from the National Center for Emergent and Zoonotic Infectious Diseases (NCEZID), the CDC center with which HICPAC is associated.

An important principle of FACA is that employees of the agency that is being advised (in this case, the CDC) are not allowed to be members of the committee due to the inherent nature of financial relationships that may preclude independence. While funding is not strictly forbidden, it is apparent that conflict of interest should be avoided.

A financial relationship between the institution and individual members such as that which currently exists between CDC and virtually all of the members of the HICPAC committee seriously risks comprising the independence of their judgment. This is the case not merely because funding links may influence particular decisions, but also because the relationships created by such funding may well incentivize the committee to advance or reject decisions of certain types, such as refusing to recognize the full impact of an airborne pathogen on hospital-based infection and the practical steps that must be taken to address this pathogen.

A non-exhaustive list of the funding to members of HICPAC and their institutions is provided in Supporting Materials Appendix **A**.

Furthermore, members of HICPAC, recognized for their expertise in areas such as bloodstream infections, sepsis, sharps injuries, hand hygiene, fomite transmission, sterilization and disinfection, antimicrobial resistance, and Ebola, are funded specifically for their work in these fields and would not be funded for airborne transmission prevention. This creates a potential conflict of interest which may interfere with a decision to shift the focus of infection prevention to airborne diseases, which is required to deal effectively with the hospital-based transmission of COVID-19.

Such a shift could threaten the funding that supports their salaries, research, staff, and programs, as well as their positions of authority in infection prevention and control, and that of their colleagues. This inherent tension is compounded by similar conflicts of interests among CDC officials responsible for nominating HICPAC members and setting the committee's agenda, including the current and former HICPAC Federal Officers and the director of NCEZID.

Additionally, the Secretary of HHS should be informed that COVID-19 infections acquired in healthcare institutions must be classified and treated as healthcare-associated infections (HAIs) within the same programs that have been in place since 2008 to prevent HAIs. These programs address, in part, the conflicts of interest arising from the fee-for-service model.

For context, a recent report from NSW Australia, with a population of 8 million, found that thousands of COVID-19 infections were caused by healthcare-associated transmission in hospitals, leading to hundreds of deaths in the past year [Footnote 1 in Supporting Materials]. This underscores the urgent need for stronger prevention measures and transparent reporting to prevent further avoidable harm.

These conflicts of interest prevent the majority of HICPAC's members from objectively assessing and addressing the committee's stated objective in relation to an airborne pathogen of COVID-19, i.e. controlling and preventing infection in healthcare settings.

C. The unlawful constitution of a HICPAC Workgroup

HICPAC has composed the Isolation Precautions Guideline Workgroup (Workgroup, see Supporting Materials Appendix **B**) to assess the matter of airborne infection transmission in healthcare settings. However, the dealings of this Workgroup are not open to the public contrary to 5 U.S.C. App. § 10(a)(1), where the exceptions to having meetings open to the public under 5 U.S.C. App. § 10(d) do not apply.

The composition of the Workgroup emphasizes that the current HICPAC members do not possess the required expertise to decide upon airborne transmission in healthcare settings. While HICPAC, in direct violation of its Charter, still has three vacancies, and the Workgroup has

qualified airborne transmission experts, rather than bringing the committee into legal compliance, it decided instead to establish a Workgroup with these experts.

We submit that this act of constituting a Workgroup can be construed by the public as a tactic for HICPAC to avoid having delicate and potentially contentious debates exposed to the scrutiny of the public eye. WHN submits that HICPAC should instead concentrate on filling its remaining vacancies with experts versed in airborne transmission.

D. HICPAC still fails to include members with an expertise in airborne transmission

As submitted in the Primary Complaint, the COVID-19 pandemic and the continuous presence of COVID-19 in the United States have increased the urgency of understanding airborne transmission of infection in healthcare settings. In fact, in 2024, the CDC has confirmed the airborne nature of COVID-19 transmission [Footnote 2 in Supporting Materials]. However, despite still having three vacancies, HICPAC continues to fail to include members with an expertise in airborne transmission.

CONCLUSION

The CDC has historically been slow to respond to pathogen-related threats, waiting until the threat became so flagrant that it had little choice but to react. Tens of thousands will continue to die from COVID-19 unless the CDC, and its HICPAC committee, break free from their past pattern and include experts qualified to address the current threat. Here, that threat is COVID-19. We respectfully urge the officials of the OIG not to cast a blind eye on what is literally a life and death situation, perhaps for one of your own dear friends or family members. Please review the present complaint and the activities of HICPAC. Require that HICPAC obey the law and comply with its Charter.

Respectfully yours, WHN