



JOHNS HOPKINS
Office of
Critical Event Preparedness and Response

**Johns Hopkins Institutions H1N1 Vaccination Protocol and Plan
V2.0**

(Oct 1, 2009)



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*Office of
Critical Event Preparedness and Response*

I. Introduction

Novel H1N1 Influenza A continues to be a great concern at all levels in the nation. A major component of the national strategy to mitigate the effects of the expected pandemic is to vaccinate much of the population. The federal government will provide vaccine to the states as it becomes available. In turn, each state will distribute its allotted supply to various health outlets capable of providing access and administering the vaccine. At the time of this writing, the State of Maryland is registering such outlets and will later determine appropriate distribution.

Vaccine production is a national priority. Clinical trials are underway for both adults and children. National, and thus regional, supply of the vaccine is expected to be constrained initially although it is expected that eventually (over several months) sufficient supply to meet the national strategy will be met. Once vaccine becomes available, an incremental allotment based on production will be made available to the states each week.

This document details the approach and, where appropriate, specifics of the H1N1 Vaccination Program applicable to all entities of the Johns Hopkins Institutions (JHI). The document may be revised and updated as appropriate based on new scientific information, institutional experience with H1N1, and vaccine behavior (e.g., effectiveness, safety).

II. Framework for Access and Administration of H1N1 Vaccine to JHI Community

In August, CEPAR issued a draft “Statement on Access to Novel H1N1 Vaccine for JHI Community” (Appendix A).¹ The document was reviewed by subject matter experts (SMEs) and sent to institutional leadership for feedback and comments. The principles outlined in that document were the bases of the program described herein.

Briefly, anticipating an initial scarcity of vaccine, access to H1N1 vaccine for members of the JHI community needs to be prioritized based on publicly defensible reasons and principles that account for JHI’s obligations to health care providers, patients, other employees, students, family members of employees, and society at large. The hierarchy for H1N1 vaccine access and its basis for JHI are found below.

¹ http://www.insidehopkinsmedicine.org/cepar/flu/downloads/CEPAR_Statement_on_Access_to_Novel_H1N1_vaccine_for_JHI.pdf

III. Development of Priorities for Access to H1N1

CEPAR convened a meeting of institutional SMEs on August 18, 2009 (Appendix B), and further vetted the priorities with other experts and stakeholders. The priorities were developed with the following guiding principles and considerations:

- Adherence to the framework referenced above (Appendix A).
- Consensus opinion of JHI SMEs.
- Centers for Disease Control and Prevention (CDC) recommendations for prioritized access to H1N1 vaccine for the U.S. population.
- Best known scientific evidence at this time (Appendix C).
- Ethical principles on access and distribution of scarce resources (Appendix C).
- Biological, epidemiological, but not psychological factors.²
- Exposure risks between patients and providers.
- Application across all of JHI.
- Review of approaches by other similar institutions.

IV. Priority Categories in Consideration of Access to H1N1

The Advisory Committee on Immunization Practices (ACIP) has identified cohorts within the population who should be considered as priority to receive the vaccine (see Appendix A). These cohorts were determined based on those most likely to specifically benefit, or confer societal benefit, from the protection afforded by vaccination; i.e., those with risk of serious complications and death from H1N1 infection, and those who may readily spread the disease among a vulnerable population such as health care providers. The CDC, recognizing that the list was still very broad, issued a more “constrained” list (see Appendix A). Even the CDC constrained list remains a formidable challenge while vaccine supplies remain short.

Order of access to the vaccine in the JHI program will be based on a 3-tier prioritized category; with the top grouping further subdivided into 3 tiers should there be an initial severe scarcity. Access for individuals falling into the third tier implies unfettered availability of vaccine for all JHI entities.

Health Care Providers, patients, other employees and family members are subclassified within these 3 priority tiers based on degree of medical risk to self or others. Priorities are to be applied across the following groups, who are in turn further subclassified within these 4 tiers based on degree of medical risk to self or others. Definitions of these groups are given in the next section.

² Placing psychological factors such as offering vaccine to the family members of, for example, high priority health care providers as incentive or reassurance to come to work is not considered sufficient to over-ride access to vaccine for other individuals to whom JHI has obligations who are at increased personal risk of serious harm from H1N1 infection. This judgment assumes that sufficient numbers of top-tier health care providers who themselves will be vaccinated are willing, ready and able to come to work without this incentive or reassurance, and that they will follow appropriate personal protective practices with respect to their family members.

- **Health Care Providers³ (HCPs)** (includes residents, fellows, medical students, and other trainees in clinical settings)⁴
 - High risk setting³
 - Moderate risk setting³
 - Low risk³
 - General risk

- **Patients** (inpatient and outpatients)
 - Major co-morbid conditions⁵
 - Pregnant⁶
 - Other CDC priority conditions on “constrained list”
 - Other ACIP defined priorities
 - Other

- **Non-clinically Involved Employees**
 - Mission critical⁷
 - Major co-morbid conditions⁵
 - Pregnant
 - Mission essential⁷
 - Other CDC priority conditions on “constrained list”
 - Other ACIP defined priorities
 - Other

- **Full-time Students⁷**
 - Similar to employees and patients

- **Family Members** (see page 7 for special comment on family members)

It should be noted that individuals will be assigned the highest tier classification based on their highest priority condition. For example, generally, employees who are not health care providers will fall into a lower tier group. However, an employee with a high risk co-morbid condition who is also a patient at JHI is elevated to the appropriate tier based on the “patient with co-morbid condition” alone.

³ See next section for definitions and detailed classification of High, Moderate, and Low HCP Risk groups.

⁴ Includes those rotating from other institutions. Includes agency and travel nursing staff.

⁵ Co-morbid conditions are defined in the next section. Major conditions are those shown to have particular high rate of death or complications. Pregnancy, not being a morbid condition, is considered separately.

⁶ There is some evidence that H1N1 is a factor only in the third trimester or late second trimester (i.e., second half of pregnancy). However, given that immunity may only be conferred 6-8 weeks after initiation of vaccination, affording priority to first trimester pregnancies appears appropriate. Individuals in late 3rd term pregnancies are also considered a priority, as immediately after delivery, the woman then falls into another high risk category (i.e., caring for children under 6 months in the home).

⁷ See Definitions in Section V.

V. Definitions

Patients: Patients are defined as formally registered within the JHHS system, either as an inpatient or outpatient.

Co-morbid conditions: At the time of this writing, co-morbid conditions particularly influencing the course of H1N1 are:

Major: Reactive Airway Disease (Asthma, COPD), Neurodevelopmental Conditions (Children <5 yrs), Immunosuppression.⁸

Moderate: Diabetes, Chronic Cardiovascular Disease, I Neurologic (neurocognitive, neuromuscular, seizure) disorders.

Low to no specific association: Obesity, smoking, chronic renal disease.

Health Care Provider: HCPs, as defined here, have direct patient care responsibilities, work in close proximity, or handle patient samples. In the hospital setting, these are individuals credentialed to provide direct patient care.

For the purposes of the H1N1 vaccination program, HCPs include: physicians, mid-level providers,⁹ nurses, residents and clinical fellows providing direct patient care, other trainees with potential direct patient contact (medical, nursing, nurse practitioners, and physician assistants, etc.), respiratory, physical and occupational therapists, social workers, laboratory staff, pastoral care givers, radiology and other medical technicians and allied staff. Travel nurses and agency will be included. Full and part-time providers are not distinguished for the purposes of this program.

Part-time faculty and other HCPs who are not employed by a Hopkins' entity who actively avail themselves of their hospital privileges are also covered by this program.¹⁰

High Risk:¹¹ HCPs who work in situations of high likelihood of communicable exposure from patients with H1N1, or risk transmission of undiagnosed H1N1 to high risk patients. Direct raw specimen handling from possible or known H1N1 infected patients fall within this risk group.

⁸ The definition of immunosuppression is left to the discretion of JHHS health entities.

⁹ Nurse practitioners and physician assistants.

¹⁰ Should the program become mandatory, they will have to comply to see patients at any of the hospitals or JHHS sites.

¹¹ The CEPAR Pandemic Influenza Plan and Appendix 11 of the JHH Comprehensive Plan for Epidemic/Pandemic Respiratory Illness Surveillance and Response were used to derive definitions of "High", "Moderate", and "Low" risk HCPs. The CEPAR Pandemic Plan has a 4th category definition related to HCPs, "Very High Risk" in addition to "High Risk". The H1N1 considers both under a single rubric of "High Risk".

Moderate Risk: HCPs who may have contact with patients not in settings defined as high risk (see above) for H1N1 complications, and they themselves would generally not come into frequent close (within 6 feet) or prolonged contact with patients with defined high risk (for H1N1) co-morbid conditions.

Low Risk: HCPs who may come into contact with the general patient population. Some of these patients, of course, may have H1N1 or be at risk of complications from H1N1; however, expected interactions are not much different than in society.

General Risk: The HCP is unlikely to be in contact with patients or patient care areas.

Employers: Any JHHS, JHM or JHU entity. Schools or affiliates in the greater Baltimore Washington area will also be accommodated under this program. This program will not extend to the international theater, except those individuals who may be assigned to a Hopkins' entity in the Baltimore/Washington region.

Employee: All not classified as an HCP, regardless of entity of employment as defined above. Full and part-time employees will be considered equally under this program.¹²

Mission Critical: Each affiliate defines its own Mission Critical staff.¹³ These are individuals involved in critical work, maintenance of critical infrastructure, or safeguarding the institution. The general premise assumes that this designation is restricted to employees without whom a given affiliate cannot function and has no redundancy or few options of replacement, and can only perform duties on site. The designation "Mission Critical" is independent of CDC/ACIP priorities.¹⁴

Mission Critical is not synonymous with Mission Essential.¹⁵ Mission Critical applies to specific individuals, and not those who fall into an "essential" designated position that has redundancy. There should be *very few if any* Mission Critical personnel for most affiliates. Mission Critical individuals are also not synonymous with leadership or seniority, but rather the term implies a critical role without which the institution could not function. Many senior leadership positions have sufficient redundancy, or can effectively lead without direct presence in the institution, precluding the "Mission Critical" designation.

¹² This would include contractors.

¹³ APL definition serves as an example. This definition includes: staff working on government sponsored endeavors in support of government operational activities important to national security, and those providing necessary infrastructure in support of such work or to safeguard the facility.

¹⁴ The CDC/ACIP guidelines address only a broad societal public health benefit perspective. They do not address those not themselves at a health risk, but essential to promoting the public's health or safeguarding the nation's critical infrastructure.

¹⁵ Mission Essential is a term predominantly used in health care settings within JHI. Virtually all HCPs are considered mission essential, and thus that designation is not useful in situations of great scarcity.

Students: All traditional students registered as full time at a JHU school, not involved in health care as defined above,¹⁶ are covered under this program. This includes SAIS and those attending other Washington D.C. affiliates. It does not include: students attending international affiliate sites, part-time students, or full-time students in continuing education, evening, or non-traditional programs.

Family: The definition of “Family” is difficult for the usual societal reasons. Given that family members fall into the last tier of eligibility for vaccine (see Table 1), restricting access based on strict definitions for what constitutes a family member can be disregarded since it can be assumed that vaccine supplies are abundant at the point the program is open to Tier 4 individuals. Pregnant family members and those with co-morbid conditions as outlined above who are patients at a JHHS/JHM facility fall into a higher tier category by virtue of their patient status (see below).

VI. JHI Community Hierarchical Access to H1N1 Vaccine

Table 1 below shows the SMEs’ consensus of hierarchy of access to H1N1 vaccine during times of scarcity. Tier 1 is the highest category (with 3 subsections), and Tier 3 the lowest. Generally speaking, in any given tier HCPs and mission critical employees are given priority, followed by patients, employees and students. Family members, except those qualifying as patients (see below), are the lowest priority. The acute care hospitals in JHHS/JHM have detailed plans based on these parameters.

The priority hierarchy is displayed in two forms. Table 1 is designed to show which groupings belong within a given tier for easy reference, as the vaccination program will be administered one Tier at a time. Table 2 is designed to identify the tier for a given individual with certain characteristics.

¹⁶ Those students involved in direct health care are classified as HCPs.

Table 1. JHI Hierarchy of Access to H1N1 Vaccine

	HCP	Patients	Non HCP Employees	Students	Family Members
Tier 1a	Pregnant 24+ wks	Pregnant 24+ wks	Pregnant 24+ wks	Pregnant 24+ wks	
		5y-18y with major co-morbidities ¹⁷		<=18y with major co-morbidities ¹⁷	
	High Risk Setting	6 mo-4 yrs	Mission Critical		
Tier 1b	Moderate Risk Setting	5y-18y with moderate co-morbidities ¹⁷		<=18y with moderate co-morbidities ¹⁷	
Tier 1c	19y-64y with major or moderate comorbidities ¹⁷	19y-64y with major or moderate co-morbidities ¹⁷	19y-64y with major or moderate co-morbidities ¹⁷	19y-64y with major or moderate co-morbidities ¹⁷	
	Caring for Children < 6 months	Caring for Children < 6 months	Caring for Children < 6 months	Caring for Children < 6 months	
	Low Risk Setting				
Tier 2	Pregnant <24 wks	Pregnant <24 wks	Pregnant <24 wks	Pregnant <24 wks	
	Age <=24y	Age 5y-24y	Age <=24y	Age <=24y	
	General Risk Setting				
Tier 3	All				Available

Comment on Rationale for Tier 1 Prioritization

HCPs in high risk settings, women who are pregnant late mid trimester and beyond, and a small cadre of mission critical employees are placed in the highest tier and will be the first to be offered H1N1 vaccine when it becomes available. These three categorizations are considered ahead of all others for reasons delineated in the following comments:

¹⁷ Co-morbidities are defined in the text.

Table 2. JHI Hierarchy of Access to H1N1 Vaccine

Category	Subgroups	Priority Tier
HCP	HCP in Direct Contact with High Risk Patient (Tier 1a, 1b)	1a
	HCP in Direct Contact with Patients at Moderate Risk	1b
	HCP in Direct Contact with General Patients	1c
	HCP with any patient access	2
Age	6 mo-4 yrs (regardless of comorbidities)	1a
	5y-18y with major comorbidities	1a
	5y-18y with moderate comorbidities	1b
	19y-64y with major or moderate comorbidities	1c
	5y-24y all	2
	25y+ All	3
Comorbid Conditions	Age Dependent (see above)	
Mission Critical		1a
Pregnancy	24+ wks	1a
	<24 wks	2
Other	Caring for Children < 6 mo age	1c
Family	All	3

Comment on Rationale of HCPs Prioritization

The twin goals of pandemic response are to minimize the attendant health burdens and to ensure fair distribution of mitigating scarce resources. In accordance with these two principles, there are several compelling reasons for generally assigning HCPs to a higher priority tier than most other categorizations. First influenza is readily transmitted in the hospital setting. There are strong data to indicate that a vaccinated health care provider population has a direct effect in decreasing up to 50% flu related mortality among hospitalized patients.¹⁸ Minimizing H1N1 infection in the JHI healthcare workforce, particularly those working with patients in defined risk groups, underscores the JHI commitment to minimize the burden of disease from H1N1 among the patient population. Second, given that health care is a paramount JHI societal mission, it is essential to protect the very workforce upon which that mission depends. A high rate of HCPs' absenteeism, estimated to reach peak daily levels of close to 20% in unprotected populations,¹⁹ would severely impact the ability to effectively carry out the JHI health care mission when it is most needed, i.e., during a pandemic. Finally, HCPs, unlike any other JHI categorization,

¹⁸ See References (Appendix C).

¹⁹ CEPAR has used the CDC FluWorkLoss (<http://www.cdc.gov/flu/tools/fluworkloss/index.htm>) for estimates.

assume a particularly high degree of risk of acquiring H1N1 by the nature of their work. This risk, to some degree, is further transferred to family and other close contacts.

Comment on H1N1 Vaccination Program for HCPs at High Risk for Complications

The Society for Healthcare Epidemiology of America (SHEA), Association for Professionals in Infection Control and Epidemiology, Inc. (APIC), the Infectious Diseases Society of America (IDSA), and the American College of Occupational and Environmental Medicine (ACOEM) have issued a statement advising against reassignment of HCPs with known risks associated with complications of H1N1 infection, as being inappropriate and unfeasible.²⁰ CEPAR endorses this statement. Thus, reassignment should not be used as a viable strategy to influence priority for vaccination among HCPs themselves at risk for complications of H1N1.

Comment on H1N1 Vaccination Program as Applied to Pregnant Women

Late pregnancy merits consideration as a Tier 1a condition for three reasons. First, current data indicates that pregnancy is equivalent to a major co-morbidity.²¹ Second, there is evidence that mothers immunized by inactive vaccine significantly reduce influenza illness in infants up to six months.²¹ Finally, pregnant women will also shortly fall into another CDC and ACIP risk/priority -- those caring for infants less than 6 months of age. Infants cannot be immunized, but are at risk of complications from H1N1 infection.²²

However, there is considerable evidence that complications related to H1N1 occur in the third trimester of pregnancy. Thus during vaccine scarcity, it is prudent to restrict access to the top tier in this group to late second trimester. In time, vaccine supply will be sufficient for all pregnant patients falling into earlier gestations to be protected by the third trimester.

During times of great scarcity, HCPs who are pregnant in late second trimester and beyond will be given preference for vaccine among all who are similarly pregnant. For family members, pregnancy per se is not a consideration for priority assignment under the JHI program. However, given that virtually all pregnant individuals are, or should be, in prenatal care, if they are registered or become a JHHS patient they are placed in Tier 1a access. Otherwise, they would have to wait until Tier 3 access was declared or seek a higher access from their non-JHHS prenatal care provider.

²⁰ http://www.shea-online.org/Assets/files/policy/FINAL_Joint_SHEA_APIC_IDSA_ACOEM_Position_Statement_High_Risk_HCW.pdf

²¹ See references.

²² Newborns are not appropriate for vaccination.

Comment on H1N1 Vaccination Program as Applied to Individuals with Co-morbidities

Co-morbidities are divided into *Major* and *Moderate*, because the consequences of complications are higher for the conditions that fall into the former category compared to the later. With the potential for great scarcity of vaccine initially, this may prove to be an important distinction.

Comment on H1N1 Vaccination Program as Applied to Families

At the time of this writing, management of JHI community family members has not been fully resolved.²³ Family members who do not fall into health-defined risk groups are considered in the lowest tier of access to vaccine. As noted earlier, when fourth tier individuals are eligible for vaccination under the JHI H1N1 vaccination program, by definition there will no longer be a vaccine shortage and thus, all family members as other individuals can access the JHHS to receive vaccine. *No H1N1 family vaccination program will be initiated until all affiliates are satisfied that they have sufficient vaccine to fulfill their obligations to their JHI constituents (e.g., employees).*

Family members who are pregnant or have certain medical co-morbid conditions are essentially patients, and on that basis can avail themselves of a higher tier priority for vaccination. If they are inpatients or already receiving primary health care within JHHS/JHM, they are considered to be in the “Patient” category. Thus, access to vaccine in such a situation would be the same as for any other patient. If they are not already a patient within JHHS/JHM, they can obtain access through normal channels.²⁴ Similarly, pregnant family members by the nature of the pregnancy are considered prenatal patients, either already within the JHHS system, or with the ability to access such care through normal channels.

The potential to vaccinate large numbers of family members when Tier 4 vaccine supply is reached may require significant logistic consideration, which at the time of this writing is being explored.

VII. Acquisition of Vaccine for JHI Entities

For seasonal flu, entities wishing to administer vaccine usually place orders directly with pharmaceutical vendors. Given national strategic importance, the federal government is supplying available H1N1 vaccine and related supplies, without cost to the states. Allotment is population based. Each state distributes their vaccine allotment according to a state derived plan to health outlets that can administer the vaccine to the public and patients. The State of

²³ At this time it is unclear if JHI would have the resources to undertake a major family (essentially population) vaccination program outside of the usual JHHS programs. However, discussions are underway with JHI leadership regarding desirability, infrastructure requirements, methodology, and cost to undertake such an endeavor.

²⁴ For many, this would be Johns Hopkins Community Physicians’ (JHCP) sites, or primary care clinics at Green Spring Station and White Marsh.

Maryland has requested that health entities that wish to distribute and administer vaccine follow a two step plan. First is to register their intent with the State (mid to late August), and subsequently (late August, early September) request a given supply indicating populations for which the supply is intended.

Initial national allotment is expected mid-October. The federal government recently announced that 3.4 million doses will be distributed the first week it is available, about 10% of what was initially announced. Understanding that the distribution to states is population based, Maryland can expect about 60 thousand initial doses. However, there will be supplementation each week. Eventually 10-30 million doses are expected each week, for a total of about 200 million doses.

CEPAR has considered the strategy of requesting one large vaccine supply on behalf of all JHI. Given that the vaccination program described herein is JHI-wide, there would be several advantages to this approach. However, it is judged that registering several JHI (JHHS, JHM, JHU, JHU-APL, and CEPAR) entities would be prudent. JHI would likely realize a larger aggregate supply with several requests than one large one, given that JHI is the only entity undertaking the ambitious institution-wide vaccination program.

CEPAR is overseeing and co-coordinating the ordering process of the various JHI entities, and will track its use and assist in redistribution among entities as appropriate.

VIII. Vaccine Administration

CEPAR has organized a JHI-wide Vaccine Management Committee to oversee this program (see Appendix D).

Estimates of numbers of individuals falling into the various tiers defined here are not readily forthcoming, but CEPAR is working with affiliates for best estimates. ***It is understood that each affiliate will adhere to the standards delineated in this document.*** CEPAR will announce the stage (tier) of the program based on feedback from the affiliates involved in vaccine administration, and aggregate availability of H1N1 vaccine.

As much as possible, JHI health services usually engaged in vaccine administration will be used. For example, Occupational Health has traditionally taken on this role within JHM and Student Health for JHU. This may not suffice for the H1N1 program. For some entities such as Peabody, SAIS and satellites in the Baltimore Washington region, a special venue may need to be created. At the time of this writing, CEPAR is exploring the logistic options for vaccine administration for these types of entities. In addition, CEPAR is exploring logistic options for mass vaccination of JHI community in addition to the usual venues should that become necessary.^{25,26}

²⁵ The State of Maryland has written to Hospital CEOs requesting them to consider vaccinating local populations.

²⁶ At the time of this writing, CEPAR is working with JHHS Community Physicians, and JHHS White Marsh to potentially provide broad wide scale vaccinations. In addition, CEPAR has developed a modular medical “Go Team” that can be stood up, and travel to distant campuses to offer this service.

The U.S. Food and Drug Administration have approved a single dose vaccine for persons age 10 years and older. Children younger than 10 years will require two doses of H1N1 vaccine. Infants less than 6 months of age are too young to receive vaccine. For those requiring two doses, the CDC recommends an optimal interval of 4 weeks, however, a minimum of 21 days is still considered valid. Persons with documented H1N1 may forgo the vaccine unless their illness (regardless of treatment), was fairly recent.

Anticipating incremental supply week-by-week, no vaccine will be held in reserve for anyone in anticipation of the second inoculation requirement. While this entails some risk of inadequate downstream supply, this risk is preferable to initial inoculation of only half the number of individuals possible.

Season flu vaccine is currently available, and both H1N1 and seasonal flu vaccine can be administered (different sites) at the same time. ***JHI HCPs, employees and students falling into a top priority group must agree to seasonal flu vaccine in order to receive H1N1 vaccine.***

Comment on use of H1N1 Live Attenuated Influenza Virus (LAIV; “Flumist”) Vaccine

Flumist is likely to be available before the inactivated vaccine. There are certain contraindications to the use of LAIV. However, the priority hierarchy will still be followed, excepting those with contraindications. It is possible that the State will direct the use of limited supplies of flumist. The JHI program will comply with the States directives.

IX. Vaccine Safety

Since the H1N1 vaccine is new, there are concerns regarding safety. The FDA approval process for the H1N1 vaccine is the same as for the seasonal flu vaccine. Manufacturers are using exactly the same design and implementation scheme. This approval process is streamlined (every flu season), and consists of a single, smaller-than-usual hybrid Phase I/II trials. Thus, safety precautions and expected outcome are similar to the seasonal flu vaccine.

H1N1 vaccine for the U.S. population is being produced by five different U.S. licensed manufacturers; four of these are based on inactivated viral particles, and one is an attenuated vaccine.²⁷ It is possibly and even likely that JHI will receive vaccine produced by different manufacturers. Similar types of vaccine by different manufacturers or different lots are likely to be used between first and second inoculations. Inactivated and attenuated vaccine cannot be substituted for each other.

Vaccine safety will be closely monitored by the CDC through weekly reports and population surveys. The Vaccine Adverse Event Reporting System (VAERS), co-sponsored by the CDC and the FDA analyzes reports. Reports can be made by the public, in addition to providers and public health officials.

²⁷ The JHI H1N1 vaccination program does not anticipate routine use of the attenuated vaccine.

Safety parameters of H1N1 will be disclosed to each individual prior to vaccination in the JHI program.

X. Vaccine Effectiveness

Trials in both adults and children are currently underway and will soon provide insight regarding expected effectiveness. The CDC has several monitoring programs to determine effectiveness.

XI. Other Measures

The vaccine is not an outright substitute for standard communicable disease precautions and hygiene. Until vaccine effectiveness has been appropriately assessed and shown to confer immunity in a high proportion of individuals, affiliate pandemic plans related to masking and other mitigating strategies should be strictly adhered.

These mitigating measures should indeed be the primary reliance for what is a widely anticipated early fall resurgence. Given that even limited vaccination cannot start until October, mass vaccination not until several weeks thereafter, 6-8 weeks to confer immunity, and unknown effectiveness, **standard mitigation infection control strategies remain the first line of defense against the spread of H1N1.**

XII. Other Issues

a. Mandatory Vaccination

At the time of this writing, CEPAR has not taken a position on mandatory vaccination. Although there are strong arguments to consider mandatory vaccination at least for some JHI constituents, there is also considerable reason to be very cautious in this regard. CEPAR is studying the issue, and after consultation with SMEs and institutional leaders will issue a statement in the coming weeks.

This is a very difficult and controversial issue, with complex biologic and psychosocial consideration. The issue of mandatory vaccination may be differentially considered by entities within JHI, although like entities should have the same position. For example, each hospital within JHHS should have similar policies. Even within institutions, a mandatory policy can be differentially applied. For example, HCPs working in high risk areas could be required to be vaccinated, similar to taking other precautions, whereas other hospital employees may not be required to hold that standard.

Any position to make vaccination mandatory can expect significant protest from various JHI constituents at this time. Concerns over vaccine safety, real or imagined, will be raised, as will demands of proof of effectiveness. There is concern that minorities historically have

distrusted vaccine programs. Some entities would have to contend with union issues. Finally, the fact of so few deaths worldwide clearly attributed to H1N1 makes invoking a mandatory policy difficult. At the time of this writing the CDC reports 522 deaths and 7,983 hospitalizations. Case fatality is in the range of 0.7% among known cases, and likely significantly less given large numbers of undiagnosed cases not coming to the attention of authorities.

b. Tracking H1N1 Vaccinations and Health Information Systems

The vaccination program requested by JHI leadership is likely the most ambitious by any similar institution in the country. An effective health tracking or information system will need to be developed and integrated should vaccine administration be expanded beyond traditional sites. The CEPAR Vaccine Management Committee will be charged with developing or assuring an appropriate system for tracking vaccinated individuals, adherence to the 3-5 week interval between doses, if applicable, and for reporting of adverse events.

c. Obligations to Local Community

Many members of the East Baltimore Community surrounding JHH are medically disenfranchised and without a regular source of care. It is unclear if JHH should undertake to actively encourage registration in some way within JHI for those with CDC defined co-morbid conditions. There are similar communities within the sphere of JHBMC and many communities served by JHCP.

d. Seasonal Flu Vaccination Program

Seasonal flu vaccine is available now. Some risk groups for seasonal flu overlap H1N1 complication risk, but there are several differences. Care will need to be taken that individuals vaccinated for one or both understand which they received and why. All who receive H1N1 as a priority must agree to receive the seasonal flu vaccine. However, not all eligible to receive seasonal flu vaccine are in a priority cohort for H1N1.

Appendix A
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CEPAR Statement on Access to Novel H1N1 Vaccine for JHI Community

(August 18, 2009)

As of this writing, a vaccine against novel H1N1 Influenza A is undergoing clinical safety and efficacy trials in the U.S. The Federal Government has indicated that the vaccine will be free. This is in contradistinction to usual distribution of seasonal flu vaccine,²⁸ in which entities purchase vaccine on the open market. Traditionally, entities such as Johns Hopkins have arranged for, or acquired their own vaccine supplies for patient, student and employee vaccination programs. However, the national plan is to distribute H1N1 vaccine as it becomes available to individual states. The states will then be responsible for distribution to appropriate outlets in their jurisdiction.

At this time, it is anticipated that limited amounts of vaccine may be available by about mid-October. The American Committee on Immunization Practices (ACIP), an advisory committee to the Centers for Disease Control and Prevention (CDC) has identified cohorts of individuals who should be considered as priority to receive the H1N1 vaccine. These include:

Pregnant women,
People who live with or care for children younger than 6 months of age,
Healthcare and emergency services personnel,
All people age 6 months to 24 year, and
People age 25-64 with certain co-morbid conditions.

Given that more than 50% of the U.S. population belongs to one of these risk groups, it is unlikely that initial supplies of vaccine will be available for all belonging to a priority identified group. The CDC has suggested further refinement of the above as follows:²⁹

Pregnant women,
People who live with or care for children younger than 6 months of age,
Healthcare and emergency services personnel **with direct patient contact**,
Children 6 months through 4 years of age, and
Children **5-18 years** of age with chronic medical conditions.

²⁸ During scarcity the Federal Government and individual States may be involved in distribution.

²⁹ www.cdc.gov/media/pressrel/2009/r090729b.htm

However, vaccinating even the restricted CDC priority groupings noted above may prove a challenge to JHI during initial limited availability. Thus, the Johns Hopkins Institutions require further refinement of the CDC priority groupings and a prudent strategy for the distribution of this important countermeasure. Thus, CEPAR is collaborating with JHM and JHU to develop plans for appropriate distribution and access of available H1N1 vaccine across all Johns Hopkins entities.

The JHI H1N1 vaccination program will be based on the following principles:

- When scarce, H1N1 vaccine will be made available based on prioritization.
- Prioritization will be based on the nationally identified risk groups, and the need to maintain essential missions of JHI.
- Prioritized access to limited vaccine supplies will be based on input and consultation from subject matter experts, ethicists, and disaster control.
- Prior to adoption, the plan will be circulated to Hopkins leadership for further comment and input. Adoption will require approval of the institutional leadership. The final plan will be made public on the CEPAR intranet website.
- Obligations under any JHI H1N1 vaccination protocol extend to patients, faculty, staff, as well as full-time students.
- Family members will be accommodated within the priority framework, and via standard health care access.
- CEPAR will work with affiliates to ensure fair equitable distribution and access to the vaccine to those whom an obligation has been extended under this protocol. As adequate supplies of H1N1 vaccine become available, the program will be extended beyond prioritized groups.
- CEPAR will collaborate with affiliates to develop appropriate communications plans regarding the JHI H1N1 vaccine program.
- The H1N1 vaccination program may be modified, as new information becomes available.
- The H1N1 vaccination program does not directly address the seasonal flu vaccination program.³⁰

³⁰ If season flu vaccine is simultaneously available it can be given at the same time.

Appendix B
Subject Matter Experts Meeting
August 18th, 2009

John Bartlett, MD³¹

The Johns Hopkins University
SOM, DOM Infectious Diseases
1830 E. Monument Street, Room 447
Baltimore, MD 21287
410-955-7634 (o)

Christina L. Catlett, MD, FACEP

Associate Director, CEPAR
Assistant Professor, Department of Emergency Medicine
The Johns Hopkins School of Medicine
5801 Smith Avenue
Davis Building, Suite 3220
Baltimore, MD 21209
410-735-6451 (o)
410-948-9858 (cell)

Gai Cole, MBA, MHA

Program Manager, PACER
The Johns Hopkins University
The Department of Emergency Medicine
5801 Smith Avenue
Baltimore, MD 21209
410-410-735-6447 (o)
410-935-0688 (cell)

Elizabeth Lee Daugherty, MD, MPH

Medical Control Chief
Office of Emergency Management
Johns Hopkins Hospital and School of Medicine
Instructor
Division of Pulmonary and Critical Care Medicine
Johns Hopkins School of Medicine
1830 East Monument St., 5th Floor
Baltimore, MD 21205
410-955-3467 (o)

³¹ Did not attend meeting or respond to requests for review of document.

Ruth R. Faden, PhD, MPH

Philip Franklin Wagley Professor of Biomedical Ethics
Director, Johns Hopkins Berman Institute of Bioethics
Johns Hopkins University
624 N. Broadway, Hampton House 352
Baltimore, MD 21205
443-287-0413 (o)
410-614-9567 (f)

Howard S. Gwon, MS

Administrator
Johns Hopkins Hospital
Office of Emergency Management
Billings Administration 325
410-502-6122 (o)
443-713-8163 (cell)

Peggy Hamilton, MSN, RN

Operations Director Capitol Region
Johns Hopkins Community Physicians
Wyman Park Internal Medicine
410-338-3000 (o)

Ruth A. Karron, MD³¹

Professor, The Johns Hopkins University
School of Public Health
Center for Immunization Research Vaccine Scis Cir
Hampton House 125
410-614-0319 (o)

Frederick Levy, MD, JD

Associate Professor
The Johns Hopkins University
The Department of Emergency Medicine
5801 Smith Avenue, Davis Building
Baltimore, Maryland 21209
410-735-6418 (o)
443-414-7230 (cell)

Jonathan M. Links, PhD

Professor, The Johns Hopkins University
CEPAR, Deputy Director
School of Public Health
Division of Toxicological Sciences
Wolfe Street, Building E7531
410-955-9622 (o)
410-292-5251 (cell)

Spyridon Marinopoulos, MD, MBA

The Johns Hopkins University
School of Medicine
SOM DOM General Internal Medicine
Assistant Professor of Medicine
Director, University Health Services
401 N. Caroline Street
Baltimore, MD 21231
410-502-7384 (o)

Paula Moore

Risk Manager, JHCP
The Johns Hopkins Medical Institutions
Wyman Park Administration
410-338-3099 (o)

Ruth Nimmo³²

Assistant Director, Operations
The Johns Hopkins University
Applied Physics Laboratory
11100 Johns Hopkins Road
Laurel, MD 20723
443-778-5974 (o)

³² Was not at SME meeting, but did vet various drafts of the document.

Andrew Pekosz, PhD

Associate Professor
W. Harry Feinstone Department of Molecular
Microbiology and Immunology
Johns Hopkins University
Bloomberg School of Public Health
615 North Wolfe Street, Suite E5132
Baltimore, MD 21205-2103
410-502-9306 (o)
443-287-8750 (lab)
410-955-0105 (f)

Trish M. Perl, MD, MSC

Director, Hospital Epidemiology & Infection Control (HEIC)
The Johns Hopkins Hospital
600 N. Wolfe Street, Osler 425
Baltimore, MD 21286
410-955-8384 (p)
410-615-1331 (cell)

James J. Scheulen, PA

Chief Administrative Officer
The Department of Emergency Medicine
1830 E. Monument Street
Suite 6-100
Baltimore, MD 21286
410-955-5204 (o)
443-604-5618 (cell)

Meridith Thanner, PhD

The Johns Hopkins University
PACER, Project Manager, Education Domain
CEPAR, Research Associate
The Department of Emergency Medicine
5801 Smith Avenue, Suite 3220
Baltimore, MD 21209
410-735-6442 (o)

Dianne Whyne, RN, MS

CEPAR, Director of Operations
The Johns Hopkins University
5801 Smith Avenue, Suite 3220
Baltimore, MD 21209
410-735-6438 (o)

Appendix C

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Appendix D Vaccine Management Group

Steering Committee

Gabe Kelen	CEPAR
Jim Scheulen	CEPAR
Jonathan Links	CEPAR
Christina Catlett	CEPAR
Dianne Whyne	CEPAR

Vaccine Management Group

Ed Bernacki	JHH Occupational Health
Fran Humphries	JHH OH
Shirley Geise	JHH Pharmacy
Nancy Tzeng	BMC Pharmacy
M. Khamesian	HCGH Pharmacy
M. Erchadi	Suburban Pharmacy
Susan Crocetti	Community Physicians
John Schaefer	Community Physicians
Dawn Hohl	Home Care
Amanda Bucci	BMC
Cindy Notobartolo	Suburban Hospital
Mardy Colson	Greenspring/White Marsh
Howie Gwon	JHH/JHM DCA
Howard Garber	JH Health Care
Dan Hendrickson	Kennedy Krieger Institute
Ken Shaw	HCGH
Alain Joffe	JHU Homewood
Spiro Marinopoulos	Caroline St University Health
Mary lasky	JHU-APL
Tim Connolly	JH Security – Broadway Services

Subject Matter Experts

(See Appendix B)