我國因應流感大流行準備
第三期計畫

衛生福利部疾病管制署

2015 年 5 月

2017 年 10 月修訂

我國因應流感大流行準備第三期計畫

目　錄

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壹、計畫緣起

一、依據

(一) 行政院 102 年 4 月 11 日第 3342 次行政院會院長提示（參考附錄 1），新興傳染病仍將不斷出現，在全球化交通便利、疫病無國界的情況下，防疫工作仍然不能掉以輕心，衛生署應持續充實防疫量能，並加強與國際交流合作。

(二) 行政院 103 年 7 月 10 日院臺衛字第 1030037881 號函指示「我國因應流感大流行準備第二期計畫[1]（下稱第二期準備計畫）將於 104 年屆滿，後續請衛生福利部依業務實際執行量能及政府預算編列預為規劃，以持續強化整體防疫效能」（參考附錄 2）。

(三) 前衛生署疾病管制局原推動奉行政院核定之第二期準備計畫，計畫期程將於 104 年 12 月 31 日截止，為延續該計畫未完成之工作，以及配合世界衛生組織（WHO）於 102 年 6 月公布之「流感大流行風險管理過渡指引（Pandemic Influenza Risk Management: WHO Interim Guidance）」[2]（參考附錄 3），納入其各項建議，並考量 102 年中國大陸 H7N9 流感疫情防治之需求，爰依行政院上開函示，研提本中程計畫報院核定。

二、未來環境預測

(一) 流感大流行威脅日益增加

92 年底在越南發現 H5N1 禽流感病毒，並被認為是最可能引發流感大流行之型別，98 年 4 月底在墨西哥爆發 H1N1 新型流感疫情且引發流感大流行，102 年 4 月中國大陸爆發 H7N9 禽流感疫情，我國、香港及馬來西亞陸續出現境外移入個案，之後中國大陸及香港亦陸續發現人類感染 H10N8 及 H9N2 禽流感病毒病例，另國內亦在 102 年 6 月間確

診全球首例 H6N1 禽流感人類感染個案，在在顯示流感大流行的風險持續存在，且已非單純侷限於 H5N1 禽流感等特定病毒型別，下一波流感大流行之病毒及流行病學特徵、傳播模式及疾病嚴重度等防治政策訂定之基礎訊息之預測難度已相對提高，威脅有增無減。

(二) 流感大流行之風險具差異性

從 98 年 H1N1 新型流感大流行及 102 年大陸 H7N9 流感疫情，可以發現不同型別流感病毒引發的疾病嚴重性有差異性，對各國造成威脅之風險亦不同，且大流行之各級別界線已不明顯，另 WHO 對於大流行各級別建議措施，也無法一體適用於全球各國，各國建立自己的風險評估機制，勢將成為未來的潮流與趨勢。

(三) 疫病無國界防治需借重國際合作

92 年嚴重急性呼吸道症候群（SARS）疫情席捲全球，WHO 為確保對全球公共衛生需求做出及時反映，防範國際傳染病，修訂 IHR 2005，要求各國設置「IHR 國家聯繫窗口」，以及需有偵測、評估、通報及報告相關公共衛生緊急事件的能力，並加強全球防疫的合作、加速疫病控制，降低疾病爆發的人命與經濟損失。

(四) 儲備有限防疫資源

流感疫苗、抗病毒藥劑及個人防護裝備等防疫物資，仍是流感大流行最重要的防疫物資，囿於全球產能與大流行發生時短時間需求量大，該等防疫物資取得不易，為因應大流行防疫需求，各國仍需訂定策略儲備定量物資，以因應緊急疫情。

三、問題分析

(一) 運用風險評估採取彈性應變機制

流感病毒的高變異性增加流感大流行之發生風險，此類風險須透過有效的風險管理機制以降低可能的影響；WHO 於 102 年 6 月公布之「流

感大流行風險管理過渡指引」[2]即指出流感大流行準備工作應與國家整體緊急風險管理計畫整合。基於流感大流行風險多元且來源難以預測，加以地球村時代之來臨，增加大流行發生之可能性，故風險評估在後大流行間期（post-pandemic）亦應持續進行，且應更為縝密；另因為各種流感病毒型別引起的大流行特性迥異，如西元 1918 年西班牙大流行與 98 年 H1N1 新型流感大流行，不論是流行規模抑或是死亡人數，均大不同，且 WHO 於前揭指引亦強調各國之防治策略應以反映各國疫情及地方性的特殊需求為主，如 98 年 H1N1 新型流感大流行與 102 年大陸 H7N9 流感疫情對於我國之風險並不相同，過往各國防治作為依循相同疫情等級進行整備與防治之觀念已非主流，各國整備防治勢必須更具彈性，以避免過度僵化之策略影響大流行時之緊急應變及危機處理。

(二) 永續防疫物資儲備策略

疫苗、抗病毒藥劑及個人防護裝備等防疫物資儲備是大流行應變的重要策略，惟該等防疫物資全球產能有限，又政府預算逐年縮編，加以現階段流感大流行發生時間及規模難以預測，因此防疫物資儲備策略之整體效益與逐年緊縮之公務預算間如何取得合宜之動態平衡，以及屆期物資如何合理處置，已成為流感大流行整備工作之新課題。然全球流感病毒之變異並未停歇，各項整備工作無法停滯，因此，如何在撙節預算之原則下，有效進行資源分配，達整備之最大效益，是當前艱難課題。

(三) 病患收治機制與量能維持

當前我國應變醫院之醫事人力不足及財務預算之限制，未能澈底改善老舊設備及病患收治人力問題，影響傳染病病人之收治量能。美國匹茲堡大學醫學衛生安全中心於 101 年 12 月「SARS 十週年之臺灣公共衛生緊急準備計畫評估」（參考附錄 4）即建議我國應規劃於大流行期間收治大量病人之替代方案，並就有限醫療照護資源作階段性調整，

此亦符合 WHO 於 97 年「Addressing ethical issues in pandemic influenza planning」[3] 提出有關醫療照護之倫理概念。因此，在大流行時如何收治暴增之病患，將是防疫醫療體系持續性的考驗。

(四) 國際合作機制建立

全球人口交流日益頻繁，流感大流行病毒的高致死率或高傳染力，使人類健康遭到極大威脅及社會經濟損失。因此要進行新興傳染病防治，就需有快速評估及應變的能力，以將疾病迅速控制及限制其傳播，除了發生地國家的防疫能量須提昇外，建立國際合作機制益顯重要。

四、社會參與及政策溝通情形

(一) 廣納民眾意見：建置 24 小時免付費之 1922 疫情諮詢專線做為民眾反映意見或諮詢的單一窗口，並提供署長信箱平台，提高民眾反映意見的可近性與方便性，並確實處理各項民眾意見。

(二) 善用網際網路等多媒體辦理溝通宣導：建立有流感專屬網頁及部落格適時公布疫情等資訊，並於變時採行召開記者會、徵用媒體等管道，快速進行分眾宣導。

(三) 辦理民意調查：針對流感大流行相關議題進行民意調查，獲知民眾對政策認知、態度和行為，參考修正政策內容。

(四) 聽取專家意見:不定期透過衛生福利部傳染病防治諮詢會-流感防治組，邀集病毒學、臨床醫學、公共衛生、衛生政策、大眾傳播等專家就重要政策進行討論諮詢。

(五) 建立公眾參與監督機制：在網路上主動公開重大計畫資訊，民眾可上網針對計畫執行提供相關建議，提升計畫執行成果符合民眾需求。

貳、計畫目標

一、目標說明

(一) 建立藥劑、疫苗、個人防護裝備等防疫物資永續儲備機制。

(二) 提升傳染病防治醫療網應變醫院收治量能。

(三) 建立依風險評估結果調整應變策略之彈性機制。

(四) 建立緊急疫情啟動快速提升應變量能採購機制。

(五) 建立國際合作、人才訓練管道。

二、達成目標之限制

(一) 流感大流行之發生時間、地點與規模均具有高度不確定性，且因涉及國家安全、衛生、經濟、社會等廣泛層面，倘無整合性應變機制恐難竟全功。

(二) 公務預算逐年縮減，將是限制防疫物資儲備與維持的最大因素。

(三) 各國皆面臨難以藉由風險評估精準設定各項防疫物資儲備量之難題，加以疫苗接種率與藥劑使用率易受民眾意願及社會輿論等因素影響。

(四) 我國國際衛生參與管道雖已較以往寬廣，惟受國際政治環境限制仍多。

三、績效指標、衡量標準及目標值

績效指標	衡量標準	基礎值 (102.12 之狀況)	分年達成目標
流感大流行前疫苗之儲備	依衛生福利部傳染病防治諮詢會建議，適量儲備 WHO 最新公布之流感大流行候選疫苗株之大流行前疫苗或以預購協議建立大流行疫苗儲備模式	依衛生福利部傳染病防治諮詢會建議量儲備大流行前疫苗。	105 年：流感大流行前疫苗儲備量達成率 100% 106-107 年：規劃大流行疫苗儲備之預購協議 108-110 年：以預購協議建立大流行疫苗儲備模式達成率 100%
流感抗病毒藥劑之儲備	依衛生福利部傳染病防治諮詢會建議，維持適當之抗病毒藥劑儲備量	儲備克流感及瑞樂沙等抗病毒劑共約 235-350 萬人份，約可提供 10-15%人口使用。	105-110 年：流感抗病毒藥劑儲備量維持 10-15%人口數

績效指標	衡量標準	基礎值 (102.12 之狀況)	分年達成目標
個人防護裝備之儲備	醫療院所、地方政府及中央政府維持依衛生福利部傳染病防治諮詢會建議之個人防護裝備安全存量進行儲備	落實防疫物資醫療院所、地方政府及中央政府三級庫存[註1]制度，全國三級庫存安全儲備量達成率 100%。	105-110 年：全國三級庫存安全儲備量達成率 100%[註2]
強化醫療網整體應變量能	委託專業機構辦理負壓隔離病房檢測之及格率，以維持隨時啟動收治病患量能	無。委託專業機構辦理負壓隔離病房之檢測自 103 年起辦理。	及格率：檢測及格之負壓隔離病房數/檢測病房數*100%；及格標準為下列 3 項檢測均符合。 (1)換氣次數：8-12 次/小時。 (2)負壓值：病室相對於走廊之負壓至少 8Pa。 (3)發煙測試：護理站流向病房走廊、病房走廊流向獨立前室、前室流向病室。 105 年：達 70% 106 年：達 80% 107 年：達 85% 108 年：達 90% 109 年：達 95% 110 年：維持 95%
	網區指定應變醫院提升應變人員緊急應變能力，以確保大量病患應變量能	網區指定應變醫院每年完成 30 場次分眾教育訓練，及格率達 70%。	及格率需達： 105 年：達 85% 106 年：達 100% 107-110 年：維持 100%
國際合作	薦派專業人員參與流感大流行防治之國際訓練、研習或交流	無。	105-110 年：2 人次/年
	於國際研討會發表論文	無。	105-110 年：每年至少 2 篇

註 1： 防護裝備使用單位分為中央、地方主管機關及醫療(事)機構三級，故參考上開三級使用單位對各品項裝備近年的平時領用情形，訂定三級庫存之安全存量。其中，中央主管機關之庫存係供防疫及緊急統籌調度之用，地方主管機關之庫存供所轄地區公共衛生及區域調度整備，醫療(事)機構則為防疫物資耗用之主體。

註 2： 個人防護裝備(外科等級口罩、N95 等級口罩、全身式防護衣)安全儲備量達成率公式:安全儲備量達成率％＝ (全年每季平均實際儲備量÷法定安全儲備量)×100％，另適時由專家評估檢討全國三級庫存個人防護裝備安全儲備量及汰舊機制。

參、現行相關政策及方案之檢討

一、我國流感大流行準備第二期計畫之檢討

(一) 我國流感大流行準備第二期計畫之執行已使我國大流行因應整備工作大致完備。

(二) 儲備抗病毒藥劑維持 10%以上人口使用之儲備目標，並因應流感疫情之需要擴大公費流感抗病毒藥劑使用對象，且廣為設置公費流感抗病毒藥劑配置點，及時提供民眾用藥需求。

(三) 儲備適量流感大流行前疫苗 A/H5N1，並辦理人用流感 A/H5N1 疫苗自願接種計畫，提供 WHO 建議之高風險族群接種，維護國人健康。

(四) 已依衛生福利部傳染病防治諮詢會專家建議，按大流行流行風險及藥劑效期儲備抗病毒藥劑，並建立防疫物資流通機制，避免物資屆期，並維持安全庫存量。

(五) 檢討調整傳染病防治醫療網應變醫院家數及經費補助方式，現階段各醫療網區指定一家應變醫院，並補助各網區應變醫院及離島縣市應變醫院負壓病房維護費。

(六) 建立隔離醫院分級啟動應變機制，當法定傳染病或新興傳染病流行時，依疾病種類及疫情流行規模之等級啟動。

(七) 已完成社區防疫人力之輔導建置及其品質提升，並將風險溝通及社區防疫概念列為地方衛生機關防疫業務考評指標之一。

(八) 已要求縣市政府每年檢視修訂縣市流感大流行應變計畫，並列入地方衛生機關防疫業務考評指標之一。

(九) 強化人禽介面管理，辦理禽畜相關從業人員健康監測方案，及早發現

可能發生之人禽共通疾病疫情。

(十) 公告實施傳統市場禁止活禽宰殺及販售政策，並配合前開政策訂定查核機制，以有效阻絕人禽共通之流感病毒傳播途徑，降低禽源傳染風險。

(十一)透過國家單一窗口（IHR Focal Point）與國際交換最新流感疫情資訊，以及與英國 HPA/新加坡「預防醫學住院醫師計畫」進行交流及參與各類流感相關國際研討會並發表國內相關研發成果，積極進行國際合作事宜，掌握國際大流行疫情及防治策略。

(十二)美國匹茲堡大學醫學衛生安全中心於 101 年底「SARS 十週年之臺灣公共衛生緊急準備計畫」中評估我國經歷 SARS 大流行之 10 年來，在補強國家公共衛生緊急應變方面有顯著進展，尤其是傳染病早期偵測及防止疫情散播等強化措施，而許多應變措施更可讓其他國家仿效學習（參考附錄 4）。

(十三)導入 ISO 9001 品質政策「重大（含新興）傳染病緊急應變作業程序」之年度複評，提升流感大流行政策品質與防治策略之公信力及確保管考計畫之品質。

二、H7N9 流感疫情因應之檢討

(一) 102 年 3 月底中國大陸出現 H7N9 禽流感人類疫情，即在已建立之基礎下，迅速將「H7N9 流感」公告為第五類法定傳染病，並報經行政院核准成立 H7N9 流感中央流行疫情指揮中心，統籌跨部會資源、設備及人員，以及統一指揮、督導及協調各機關/組織/團體因應。

(二) 啟動全面性監視系統、建立及精進檢驗技術及量能、落實邊境檢疫、傳染病防治醫療網之啟動待命及持續進行風險溝通及輿情處理等事宜，以及透過與中國疾病控制中心建立工作平台及制度化之聯繫管道，積極進行資訊交換、緊急事件通報及處置等事項，及時有效因應疫情。

(三) 依海峽兩岸醫藥衛生合作協議，首次進行生物病原檢體交換，順利取

得中國大陸 H7N9 流感病毒株。

(四) 獲美國疾病預防控制中心（CDC）與日本國家感染症研究所（NIID）同意分讓 H7N9 流感候選疫苗病毒。

三、整體流感大流行防治之檢討

本計畫為我國流感大流行準備之最高位階指導原則，著重於流感大流行應變量能之建置與維持，其他如疫情監視、邊境檢疫及檢驗診斷等部分，將於「因應流感大流行執行策略計畫」中呈現。

肆、策略及方法

一、主要工作項目

(一) 建立彈性之緊急應變機制。

(二) 儲備及管理大流行（前）疫苗。

(三) 儲備及管理流感抗病毒藥劑。

(四) 儲備及管理個人防護裝備。

(五) 維持「傳染病防治醫療網」效能。

(六) 建構多邊合作及國家區域聯防之國際合作機制。

二、分年執行策略

年度	執行策略
105 年	1.適量儲備流感大流行前疫苗或抗原原液或佐劑或以預購協議取得儲備大流行疫苗之優先供應權。 2.辦理季節性流感疫苗接種計畫或大流行前疫苗自願接種計畫，以維持接種作業機制。 3.汰換屆期流感抗病毒藥劑，並維持 10-15%儲備量。 4.辦理流感抗病毒藥劑之物流維運(倉儲管理、配送)，並監測藥劑安定性分析結果。

	5.建立個人防護裝備流通、代庫存機制，並持續維持安全庫存量。 6.辦理個人防護裝備之物資維運(倉儲管理、理貨配送) 及年度防疫物資儲備查核計畫。 7.辦理 105 年度防疫物資－個人防護裝備儲備查核計畫。 8.架構傳染病防治醫療網區域聯防網絡。 9.儲備傳染病防治醫療網區應變量能。 10.培訓傳染病監測/風險評估/檢驗人才。
106 年	1. 適量儲備流感大流行前疫苗或抗原原液或佐劑或以預購協議取得儲備大流行疫苗之優先供應權。 2.辦理季節性流感疫苗接種計畫或大流行前疫苗自願接種計畫，以維持接種作業機制。 3.汰換屆期流感抗病毒藥劑，並維持 10-15%儲備量。 4.辦理流感抗病毒藥劑之物流維運(倉儲管理、配送)。 5.建立個人防護裝備流通、代庫存機制，並持續維持安全庫存量。 6.辦理個人防護裝備之物資維運(倉儲管理、理貨配送) 及年度防疫物資儲備查核計畫。 7.辦理 106 年度防疫物資－個人防護裝備儲備查核計畫。 8.架構傳染病防治醫療網區域聯防網絡。 9.儲備傳染病防治醫療網區應變量能。 10.培訓傳染病監測/風險評估/檢驗人才。
107 年	1.適量儲備流感大流行前疫苗或抗原原液或佐劑或以預購協議取得儲備大流行疫苗之優先供應權。 2.辦理季節性流感疫苗接種計畫或大流行前疫苗自願接種計畫，以維持接種作業機制。 3.汰換屆期流感抗病毒藥劑，並維持 10-15%儲備量。 4.辦理流感抗病毒藥劑之物流維運(倉儲管理、配送)。 5.建立個人防護裝備流通、代庫存機制，並持續維持安全庫存量。 6.辦理個人防護裝備之物資維運(倉儲管理、理貨配送) 及年度防疫物資儲備查核計畫。

	7.辦理 107 年度防疫物資－個人防護裝備儲備查核計畫。 8.架構傳染病防治醫療網區域聯防網絡。 9.儲備傳染病防治醫療網區應變量能。 10.培訓傳染病監測/風險評估/檢驗人才。
108 年	1.適量儲備流感大流行前疫苗或抗原原液或佐劑或以預購協議取得儲備大流行疫苗之優先供應權。 2.辦理季節性流感疫苗接種計畫或大流行前疫苗自願接種計畫，以維持接種作業機制。 3.汰換屆期流感抗病毒藥劑，並維持 10-15%儲備量。 4.辦理流感抗病毒藥劑之物流維運(倉儲管理、配送)。 5.建立個人防護裝備流通、代庫存機制，並持續維持安全庫存量。 6.辦理個人防護裝備之物資維運(倉儲管理、理貨配送) 及年度防疫物資儲備查核計畫。 7.辦理 108 年度防疫物資－個人防護裝備儲備查核計畫。 8.架構傳染病防治醫療網區域聯防網絡。 9.儲備傳染病防治醫療網區應變量能。 10.培訓傳染病監測/風險評估/檢驗人才。
109 年	1.適量儲備流感大流行前疫苗或抗原原液或佐劑或以預購協議取得儲備大流行疫苗之優先供應權。 2.辦理季節性流感疫苗接種計畫或大流行前疫苗自願接種計畫，以維持接種作業機制。 3.汰換屆期流感抗病毒藥劑，並維持 10-15%儲備量。 4.辦理流感抗病毒藥劑之物流維運(倉儲管理、配送)。 5.建立個人防護裝備流通、代庫存機制，並持續維持安全庫存量。 6.辦理個人防護裝備之物資維運(倉儲管理、理貨配送) 及年度防疫物資儲備查核計畫。 7.辦理 109 年度防疫物資－個人防護裝備儲備查核計畫。 8.架構傳染病防治醫療網區域聯防網絡。 9.儲備傳染病防治醫療網區應變量能。

	10.培訓傳染病監測/風險評估/檢驗人才。
110 年	1.適量儲備流感大流行前疫苗或抗原原液或佐劑或以預購協議取得儲備大流行疫苗之優先供應權。 2.辦理季節性流感疫苗接種計畫或大流行前疫苗自願接種計畫,以維持接種作業機制。 3. 汰換屆期流感抗病毒藥劑，並維持 10-15%儲備量。 4.辦理流感抗病毒藥劑之物流維運(倉儲管理、配送)。 5.建立個人防護裝備流通、代庫存機制，並持續維持安全庫存量。 6.辦理個人防護裝備之物資維運(倉儲管理、理貨配送) 及年度防疫物資儲備查核計畫。 7.辦理 110 年度防疫物資－個人防護裝備儲備查核計畫。 8.架構傳染病防治醫療網區域聯防網絡。 9.儲備傳染病防治醫療網區應變量能。 10.培訓傳染病監測/風險評估/檢驗人才。

三、執行方法與分工

(一) 建立彈性之緊急應變機制

1. 建立緊急應變體系及流程，以應無法預期且可能突發之大流行時可即時啟動，並據以運作。(衛生福利部疾病管制署、各直轄市及縣市政府)

2. 建立各項物資調度供應之標準流程，並進行相關演練，以確保疫情發生時防疫物資調度供應無虞。(衛生福利部疾病管制署、各直轄市及縣市政府)

3. 建立緊急採購大流行疫苗之實務流程，以因應突發疫情，採購足以供應達到疫苗接種群體免疫效應所需施打之疫苗數。(衛生福利部疾病管制署)

4. 建立緊急採購流感抗病毒藥物之實務流程，以因應突發疫情，採購藥物

供病例治療、接觸者預防及快速圍堵作業之用。(衛生福利部疾病管制署)

5. 建立緊急採購防護裝備之啟動機制及作業流程，以因應突發疫情之需要，項目包括平面口罩、N95 口罩及防護衣等。(衛生福利部疾病管制署)

6. 為避免辦理緊急採購時程延宕，逐年編列預算時應保留適當之預算科目別。(衛生福利部疾病管制署)

(二)儲備及管理大流行(前)疫苗

1. 依據衛生福利部傳染病防治諮詢會，就疫苗儲備量之使用及屆效情形、自製及外購量能等因素評估後之建議，適時檢討修正儲備量。(衛生福利部疾病管制署)

2. 研議適量儲備 WHO 最新公布之流感大流行候選疫苗株之大流行前疫苗，並視風險程度辦理大流行(前)疫苗接種計畫；或研議及辦理簽訂流感大流行疫苗預購協議(Advanced Purchase Agreement, APA)，取得大流行疫苗之優先供應權；或研議適量儲備可增強疫苗免疫反應之佐劑或大流行候選疫苗株之抗原原液，提升國內製造大流行疫苗之量能；其中 APA 屬取得疫苗優先供應權之「權利金」性質，故如該年度未發生流感大流行，將該權利金轉換為實體疫苗相關產品或原料，如季節性流感疫苗、大流行前疫苗、佐劑或抗原原液等，而轉換之實體產品/原料數量，將併入整體整備/採購需求數量考量。(衛生福利部疾病管制/食品藥物管理署署、行政院公共工程委員會)

3. 透過年度季節性流感疫苗接種計畫，建立並維持中央、地方政府間疫苗使用、分配管理及溝通機制。(衛生福利部疾病管制署、各直轄市及縣市政府)

4. 持續執行因應緊急疫情疫苗之快速進口及審查機制，以保障國內使用具上市許可證之疫苗。(衛生福利部食品藥物管理署)

5. 依倫理原則及風險程度，規劃疫苗之優先使用對象。(衛生福利部疾病

管制署）

(三) 儲備及管理流感抗病毒藥劑

1. 多元儲備抗病毒藥劑

(1) 參考各國儲備量，及依據衛生福利部疾病管制署我國因應流感大流行疫苗及藥物策略規劃專家會議與傳染病防治諮詢會議討論及決議，維持流感抗病毒藥劑儲備量、檢視修訂抗病毒藥劑儲備量之使用及屆效情形，及評估自製及外購量能等策略並將持續定期/不定期檢討修正。（衛生福利部疾病管制署）

(2) 儲備多種流感抗病毒藥劑，以因應臨床適應症以及病毒可能產生抗藥性之情況。（衛生福利部疾病管制署）

(3) 鼓勵私部門視其型態，在現行法規規範下，自行儲備藥物供員工使用，俾利營運持續，降低疫情對社會經濟的影響。（衛生福利部疾病管制署）

2. 規劃屆效藥品之處理：對於已屆原標示效期之藥物則予以銷毀，以確保民眾用藥安全。（衛生福利部疾病管制署、衛生福利部食品藥物管理署）

3. 建立藥物使用機制

(1) 依倫理原則及風險程度，規劃用藥優先順序，並規劃於大流行時透過健保體系及時給藥之機制。原則上，大流行時期，主要以治療性用藥為主，預防性用藥僅用於可能感染之高風險族群。另可能視疫情控制需要使用，以利圍堵策略之執行。（衛生福利部疾病管制署/中央健康保險署）

(2) 地方政府應妥善管理及調度因應所分配藥物，並預先規劃抗病毒藥劑合約醫療機構及藥劑配送流程，適時辦理演習，以提升流感大流行時之分配量能。（各直轄市及縣市政府）

(四) 儲備及管理個人防護裝備

1. 中央政府應儲備符合安全存量之個人防護裝備，並建立防疫物資供應鏈之資訊及物資汰舊換新機制，使儲備之防疫物資保持新品狀態並維持庫存量，以兼顧平時之物資推陳、疫情期間之物資需求，及變時之物資儲備、調度與流通管理。(衛生福利部疾病管制署)

2. 醫療機構須依防疫物資及資源建置實施辦法第 6 條規定，儲存 30 天安全儲備量之個人防護裝備，並隨時評估安全儲備量之適當性；亦須遵照感染控制指引辦理教育訓練。(衛生福利部疾病管制署、各直轄市及縣市政府)

3. 建立及檢討物資調度規範，並辦理演練，俾於疫情期間能即時支援轄區內防疫單位及醫療機構之緊急防疫需求。(各直轄市及縣市政府)

4. 儲備其他防疫物資：其他各項相關防護設施亦應預先準備，如清消車之採購及維護、大量遺體處理及緩和/支持性醫療儀器設備(如呼吸器與葉克膜等)之全國儲備量及緊急取得方式相關資訊掌握及規劃等。(衛生福利部醫事司/疾病管制署、內政部、各直轄市及縣市政府)

(五) 維持「傳染病防治醫療網」效能

1. 架構傳染病防治醫療網區域聯防網絡：將全國區分成 6 個醫療網區，各醫療網區自隔離醫院中擇優指定 1 家應變醫院；且指定轄內 1 家醫學中心做為醫療網區應變醫院之支援合作醫院，平時提供醫療網區應變醫院傳染病專業諮詢，變時依醫療網區指揮官調度提供醫療網區應變醫院專業醫療協助。(衛生福利部疾病管制署)

2. 儲備傳染病防治醫療網區應變量能

(1) 提升應變人員緊急應變能力：網區應變醫院應訂定傳染病緊急應變計畫，辦理教育訓練，並據以施行演習驗證，確保大量病患之緊急應變量能。(衛生福利部疾病管制署、各直轄市及縣市政府)

(2) 強化應變醫院疫情啟動時隔離收治病患量能：基於第一類及第五類傳染病患以收治在應變醫院負壓隔離病房為原則，補助應變醫院病房維護費，以維持負壓隔離病房功能，隨時保持在可啟動狀態。（衛生福利部疾病管制署、各直轄市及縣市政府）

3. 提升醫療支援人力量能及品質

(1) 依支援人力名冊適時徵調：為因應大流行時之病患暴增（surge）超過應變醫院現有照護人力，平時由各醫療網區規劃臨床照護所需支援人力，並由地方政府據以提報/建置名冊，以及建立調度原則，變時由中央流行疫情指揮中心指揮官授權醫療網區指揮官，指揮地方主管機關，依法按調度原則及名冊徵調照護人員，協助傳染病病患照護。（衛生福利部疾病管制署、各直轄市及縣市政府）

(2) 提供教育訓練：基於 WHO 對於流感大流行「倫理」的建議，除了病患應獲得「醫療利益」，醫療照護工作人員的「權責相當」也應被重視，政府及雇主都應確保其接受到適當的教育和訊息；因此網區指定應變醫院之網區支援合作醫院每年皆應辦理相關教育訓練，以確保服務品質，並增加支援人員服務意願與保障該等人員權利。（衛生福利部疾病管制署、各直轄市及縣市政府）

(六) 建構多邊合作及國家區域聯防之國際合作機制

1. 持續透過 IHR focal point 與 WHO 及其他國家單一窗口保持密切聯繫，掌握最新國際疫情。（衛生福利部國際合作組/疾病管制署）

2. 藉由派員參與流感大流行相關國際會議、研習及訓練，加強國際經驗交流及知能提升。（衛生福利部國際合作組/疾病管制署）

3. 與美國 CDC 等機構辦理各項物質交換、資訊提供、經驗分享及訓練交流等事宜,提升流感監測與診斷能力、提供流感疫苗種株製作技術協助，並發展可估算全球每年因季節性流感死亡人數之模式。（衛生福利部疾病管制署）

伍、期程與資源需求

一、計畫期程

105 年 1 月 1 日至 110 年 12 月 31 日，計畫執行期間為流感大流行準備階段，不包含大流行爆發時之應變動員階段。

二、資源需求及說明

(一) 人力資源：各項工作由本署編制內人力統籌辦理，衛生福利部相關單位、中央相關部會及地方政府依本計畫「肆、策略及方法」「三、執行方法與分工」所列各項分工辦理；未來將配合計畫需要，適時進用額外之人力。

(二) 經費資源

1. 平時依中央政府編列預算執行。

2. 流感大流行疫情時，除由各相關單位先行移緩濟急，得視需要提報行政院動支第二預備金因應；另得視縣（市）政府財力級次，依中央對直轄市及縣（市）政府補助辦法規定，以不同補助比率部分補助地方政府辦理相關防治工作經費。

(三) 其他：本計畫相關之採購案，依政府採購法相關程序及規範辦理。

三、經費來源及計算基準

本計畫各項執行計畫將視疫情狀況，逐年循預算之程序辦理，一旦大流行爆發時，則另行編列應變動員所需經費，整體需求擬提報行政院；所需經費參考 98 年 H1N1 流感大流行疫情經驗進行預估，該次為期 1 年餘之溫和大流行總計花費（含本預算、特別預算及動支第二預備金）近 150 億元，爰屆時將以此為譜，編列疫苗、抗病毒藥劑、防護裝備、實驗室檢測、檢疫、指揮中心會務及額外人力需求等相關經費需求。

各項目經費之細項及計算結構如下：

(一) 疫苗之儲備及使用

適量儲備流感大流行前疫苗或抗原原液或佐劑或以預購協議取得儲備大流行疫苗之優先供應權；依據國際間報價，流感大流行前疫苗每劑至少 10 美元（換算為新台幣約 350 元估算），佐劑約 120 元，抗原原液則以實體疫苗價格 6 成估算，每劑約 210 元，至簽訂大流行疫苗預購協議，每年需支付訂金約大流行疫苗價格之 1/10。本項儲備以預購協議儲備大流行疫苗 300 萬劑作為估算基準，總計約需 90,000 千元。各項可行策略之搭配，將視國內外疫苗研發技術/產能及適法性，於保障足量儲備量的前提之下，審慎評估具效益之儲備形式辦理。

(二) 抗病毒藥劑之儲備及管理

1. 為永續流感大流行抗病毒藥劑儲備策略，達成行政院核定儲備量全人口數 10 至 15%之目標，並分散大量藥劑同時屆效之風險，將以分年平均採購方式儲備，依抗病毒藥劑交貨驗收時效期 6.5 年，將全人口數 10%藥劑分 6 年採購，每年平均採購 2%藥劑，並釋出效期最短之 2%藥劑作為季節性流感高峰期防疫之用，自 106 年起每年採購 40 萬人份藥劑，預估採購價格為 700 元/盒，每年所需採購經費約計 280,000 千元。

2. 因應 105 年將面臨大量藥劑屆期，105 年則規劃以分批交貨方式再採購 120 萬盒藥劑，以符合報院核定之最低儲備量及分散大量藥劑屆效風險之原則，預估採購價格為 700 元/盒，所需採購經費約計 840,000 千元。

3. 屆期藥劑銷毀費用依當年度預估屆期藥物數量，以 60 元/每公斤核估費用。

4. 藥物儲備、管理及使用所需相關費用 100 千元/年。

(三) 防疫物資之儲備

為維持安全儲備量，執行防疫物資流通/換貨/代庫存倉儲費用/物流維運費用/裝備維護/耗材/檢驗，以及預留每年 3 至 7%之緩衝量，每年約需 31,800 千元。

(四) 維持傳染病防治醫療網應變量能

為維持醫療網應變醫院隨時啟動收治病患及緊急應變之量能，每年需39,500 千元，其中補助醫療網應變醫院病房維護費約 20,000 千元，補助應變醫院支援合作醫院每年約 6,000 千元，醫療網指揮官工作津貼6,000 千元，以及配合疫情初期緊急應變所需經費約 7,500 千元等。

(五) 國際合作交流

參與流感大流行相關之國際性會議、研習或訓練，或邀請國外專家來台進行流感大流行相關交流，每年約需 2,500 千元。

四、經費需求及與中程歲出概算額度配合情形

本計畫 6 年之總經費為 2,234,475 千元整（均為經常門）；各策略之分年所需經費詳如下表。

(單位：千元)

經費項目		105 年	106 年	107 年	108 年	109 年	110 年	總計
一、疫苗之儲備及使用		**10,350**	**901**	**10,350**	**90,000**	**90,000**	**90,000**	**291,601**
儲備大流行前疫苗/佐劑/抗原原液/簽定大流行疫苗預購協議	經常門	10,350	901	10,350	90,000	90,000	90,000	291,601
二、抗病毒藥劑之儲備及管理		**249,621**	**252,411**	**220,792**	**280,900**	**280,900**	**280,900**	**1,565,524**
1.流感抗病毒藥劑採購	經常門	248,782	251,572	220,759	280,000	280,000	280,000	1,561,113
2.屆期藥劑安定性分析	經常門	806	806	0	0	0	0	1,612
3.屆效藥品銷毀	經常門	0	0	0	800	800	800	2,400
4.藥物儲備、管理及使用	經常門	33	33	33	100	100	100	399
三、防疫物資之儲備		**12,943**	**12,609**	**23,536**	**31,800**	**31,800**	**31,800**	**144,488**

儲備個人防護裝備	經常門	12,943	12,609	23,536	31,800	31,800	31,800	144,488
四、儲備傳染病防治醫療網應變量能		**41,700**	**38,550**	**26,612**	**39,500**	**39,500**	**39,500**	**225,362**
維持隨時啟動收治病患及緊急應變之量能	經常門	41,700	38,550	26,612	39,500	39,500	39,500	225,362
五、國際合作交流		**0**	**0**	**0**	**2,500**	**2,500**	**2,500**	**7,500**
參與國際會議/研習/訓練或邀請國外專家來台	經常門	0	0	0	2,500	2,500	2,500	7,500
總計	資本門	0	0	0	0	0	0	0
	經常門	314,614	304,471	281,290	444,700	444,700	444,700	2,234,775
	加總	**314,614**	**304,471**	**281,290**	**444,700**	**447,700**	**444,700**	**2,234,475**

另本計畫配合中程歲出概算規劃額度控管機制，依行政院核定之年度主管機關「中程歲出概算規劃額度」內據以編列歲出概算，以賡續實施中程計畫預算作業制度。如於年度中有修正「中程歲出概算規劃表」之需求，將調整各項計畫優先順序及經費安排，並敘明修正理由，復報請國家發展委員會備查。

陸、預期效果及影響

一、有效儲備及管理流感大流行相關之各項防疫物資，並建立使用規劃，以達善用防疫資源及流感疫情防治之目的。

二、完善整體傳染病防治醫療體系之人力、物力及設備。

三、藉由國際交流、多邊合作及國家區域聯防機制，提昇我國流感大流行整備之國際化。

四、建立足夠量能及得以即時啟動之防疫及生物病原災害的整備基礎，以應未來疫情/災害發生之因應。

五、最小化新流感病毒所造成之死亡率、經濟損失及社會衝擊。

柒、財務計畫

本計畫為中央主辦計畫，其經費依中央主管相關法令規定，由疾病管制署年度預算支應，並依中央各級機關辦理預算相關辦法，所需經費均於中程歲出概算額度內容納，且經費均依目前可掌握之單價及數量等資訊進行估算，總經費結構均為經常門(詳見本計畫「伍、期程與資源需求」之「四、經費需求及與中程歲出概算額度配合情形」)。另得視情況評估補助地方政府辦理相關防治工作經費。

本計畫非公共建設計畫，亦無民間機構參與，且非屬自償性質；另本計畫為整備性質，故以非財務指標及成果性指標為計畫評估依據，無設定特定之財務指標，將配合政府機關預算執行管考機制進行管考。

捌、附則

一、替選方案之分析及評估

傳染病不若天然災害通常有地理屏障，且因人類及動物頻繁且快速隨著航空或海運而跨越國界遷徙，使疾病流行得於極短時間內蔓延，其屬於「社會災害」的疾病，有可能進一步成為「災難（Disaster）」，造成大規模災害損傷、大量人員死亡及巨額財物損失之風險[4]，例如 92 年的 SARS 及 98 年的 H1N1 流感大流行，因此需要預先作足各項整備工作，以備不時之需；因此本計畫具有不可替代之特性，尚無可替選之方案。

二、風險評估

流感大流行之風險辨識始於 93 年，爰流感大流行之風險種類非屬於新辨識之風險，而屬處理（控制）中之風險，需透過本計畫各項整備策略之實施，將風險往更低度之危險降低。

基於 WHO 提醒流感大流行發生之風險持續存在，惟時間及嚴重程度未知，例如，98 年爆發之 H1N1 流感大流行即為輕微（mild）大流行，其殘餘風險圖像可自衝擊程度（風險影響程度）及可能性（風險機率等級）評估如表 8.2.1。其中因流感大流行將導致民眾感染疾病、併發重症，甚至死亡，也將帶來國內甚至國際間新聞媒體報導負面新聞等之影響，故其衝擊程度視其病毒型別、病毒特性及流行病學等，界定於「嚴重」至「非常嚴重」之間。

另疾病管制署自 94 年起即逐年配合行政院各部會風險管理專案進行「流感大流行」之風險管理，完整檢視及考量各項風險之處理對策、應變流程及監控措施，可與本計畫相互對應。

表 8.2.1 流感大流行之風險圖像表

影響（後果）	**風險分布**		
非常嚴重			
嚴重		流感大流行	
輕微			
	幾乎不可能	可能	幾乎確定
	機率		

三、有關機關配合事項

以下相關機關須配合計畫執行，配合事項詳如本計畫「三、執行方法與分工」所列。

(一) 中央相關部會：公共工程委員會、內政部及農委會等；中央流行疫情指揮中心成立時，在整體社會（Whole Society）及防疫一體（One Health）概念下，各相關部會皆應依法定執掌，配合指揮官指示辦理相關事項。

(二) 衛生福利部相關單位：衛生福利部疾病管制署、食品藥物管理署、中央健康保險署、醫事司及國際合作組等。

(三) 各直轄市及縣市政府相關局處。

四、中長程個案計畫自評檢核表及性別影響評估檢視表（如附表）

附表一

中長程個案計畫自評檢核表

檢視項目	內　容　重　點 (內容是否依下列原則撰擬)	主辦機關		主管機關		備註
		是	否	是	否	
1、計畫書格式	(1)計畫內容應包括項目是否均已填列(「行政院所屬各機關中長程個案計畫編審要點」（以下簡稱編審要點）第 5 點、第 12 點)	✓		✓		
	(2)延續性計畫是否辦理前期計畫執行成效評估，並提出總結評估報告(編審要點第 5 點、第 13 點)	✓		✓		
	(3)是否依據「跨域加值公共建設財務規劃方案」之精神提具相關財務策略規劃檢核表？並依據各類審查作業規定提具相關書件		✓		✓	(3)不符合「跨域加值公共建設」。
2、民間參與可行性評估	是否填寫「促參預評估檢核表」評估(依「公共建設促參預評估機制」)		✓		✓	無民間參與。
3、經濟及財務效益評估	(1)是否研提選擇及替代方案之成本效益分析報告(「預算法」第 34 條)	✓		✓		(1)無替選方案。 (2)無設定特定之財務指標。
	(2)是否研提完整財務計畫	✓		✓		
4、財源籌措及資金運用	(1)經費需求合理性(經費估算依據如單價、數量等計算內容)	✓		✓		
	(2)資金籌措：依「跨域加值公共建設財務規劃方案」精神，將影響區域進行整合規劃，並將外部效益內部化		✓		✓	(2)不符合「跨域加值公共建設」。
	(3)經費負擔原則： a.中央主辦計畫：中央主管相關法令規定 b.補助型計畫：中央對直轄市及縣(市)政府補助辦法、依「跨域加值公共建設財務規劃方案」之精神所擬訂各類審查及補助規定	✓		✓		
	(4)年度預算之安排及能量估算：所需經費能否於中程歲出概算額度內容納加以檢討，如無法納編者，應檢討調減一定比率之舊有經費支應；如仍有不敷，須檢附以前年度預算執行、檢討不經濟支出及自行檢討調整結果等經費審查之相關文件	✓		✓		
	(5)經資比 1：2（「政府公共建設計畫先期作業實施要點」第 2 點）		✓		✓	(5)不屬公共建設計畫。
	(6)屬具自償性者，是否透過基金協助資金調度		✓		✓	(6)非屬自償性。
5、人力運用	(1)能否運用現有人力辦理	✓		✓		俟緊急事件或動員階段時，再行評估是否增加臨時人力
	(2)擬請增人力者，是否檢附下列資料： a.現有人力運用情形		✓		✓	

檢視項目	內　容　重　點 (內容是否依下列原則撰擬)	主辦機關		主管機關		備註
		是	否	是	否	
	b.計畫結束後，請增人力之處理原則 c.請增人力之類別及進用方式 d.請增人力之經費來源					
6、營運管理計畫	是否具務實及合理性(或能否落實營運)		✓		✓	不適用
7、土地取得	(1)能否優先使用公有閒置土地房舍		✓		✓	不適用
	(2)屬補助型計畫，補助方式是否符合規定（中央對直轄市及縣(市)政府補助辦法第 10 條）		✓		✓	
	(3)計畫中是否涉及徵收或區段徵收特定農業區之農牧用地		✓		✓	
	(4)是否符合土地徵收條例第 3 條之 1 及土地徵收條例施行細則第 2 條之 1 規定		✓		✓	
	(5)若涉及原住民族保留地開發利用者，是否依原住民族基本法第21條規定辦理		✓		✓	
8、風險評估	是否對計畫內容進行風險評估	✓		✓		
9、環境影響分析(環境政策評估)	是否須辦理環境影響評估		✓		✓	不適用
10、性別影響評估	是否填具性別影響評估檢視表	✓		✓		
11、涉及空間規劃者	是否檢附計畫範圍具座標之向量圖檔		✓		✓	不適用
12、涉及政府辦公廳舍興建購置者	是否納入積極活化閒置資產及引進民間資源共同開發之理念		✓		✓	不適用
13、跨機關協商	(1)涉及跨部會或地方權責及財務分攤，是否進行跨機關協商		✓		✓	不適用
	(2)是否檢附相關協商文書資料		✓		✓	不適用
14、依碳中和概念優先選列節能減碳指標	(1)是否以二氧化碳之減量為節能減碳指標，並設定減量目標		✓		✓	
	(2)是否規劃採用綠建築或其他節能減碳措施		✓		✓	
	(3)是否檢附相關說明文件		✓		✓	
15、資通安全防護規劃	資訊系統是否辦理資通安全防護規劃	✓		✓		

主辦機關核章：承辦人　　單位主管　　首長

主管部會核章：研考主管　　會計主管　　首長

附表二

中長程個案計畫性別影響評估檢視表

【第一部分】：本部分由機關人員填寫

填表日期： **106** 年 **6** 月 **7** 日		
填表人姓名：林美凌	**職稱：**技士	**身份：**■業務單位人員
電話：02-23959825 轉 3678	**e-mail：** wawamei@cdc.gov.tw	□非業務單位人員，（請說明：_____ ）

填 表 說 明

一、行政院所屬各機關之中長程個案計畫除因物價調整而需修正計畫經費，或僅計畫期程變更外，皆應填具本表。

二、「主管機關」欄請填列中央二級主管機關，「主辦機關」欄請填列擬案機關（單位）。

三、建議各單位於計畫研擬初期，即徵詢性別平等專家學者或各部會性別平等專案小組之意見；計畫研擬完成後，應併同本表送請民間性別平等專家學者進行程序參與，參酌其意見修正計畫內容，並填寫「拾、評估結果」後通知程序參與者。

壹、計畫名稱	**我國因應流感大流行準備第三期計畫**		
貳、主管機關	衛生福利部疾病管制署	**主辦機關（單位）**	新興傳染病整備組

參、計畫內容涉及領域：	**勾選（可複選）**
3-1 權力、決策、影響力領域	
3-2 就業、經濟、福利領域	✓
3-3 人口、婚姻、家庭領域	
3-4 教育、文化、媒體領域	
3-5 人身安全、司法領域	
3-6 健康、醫療、照顧領域	✓
3-7 環境、能源、科技領域	
3-8 其他（勾選「其他」欄位者，請簡述計畫涉及領域）	

肆、問題與需求評估

項 目	**說 明**	**備 註**

4-1 計畫之現況問題與需求概述	前衛生署疾病管制局原推動奉行政院核定之第二期準備計畫，計畫期程將於 104 年 12 月 31 日截止，為延續該計畫未完成之工作，並配合世界衛生組織（WHO）於 102 年 6 月公布之「Pandemic Influenza Risk Management: WHO Interim Guidance」，及考量 102 年中國大陸 H7N9 流感疫情防治實務經驗，爰依行政院 103 年 7 月 10 日函示，研提本中程計畫報院核定。 目前我國流感大流行準備所面臨之問題包括： (一)流感大流行威脅日益增加； (二)流感大流行之風險具差異性； (三)疫病無國界防治需藉重國際合作； (四)儲備有限防疫資源。	簡要說明計畫之現況問題與需求。
4-2 和本計畫相關之性別統計與性別分析	1. 本署對於流感防治之監測係多元進行，包括 P&I、病毒、住院及死亡病例等監視，其中包含性別變項。 2. 總計前二個流感流行季（101 年至 102 年及 102 年至 103 年）之流感併發症確定病例，女性及男性分別有 1,241 人及 1,431 人，性別比（女男比）約 0.9:1，未有明顯男女罹病差異。 3. 本署之流感防治對於男性及女性之防治作為無差異。 4. 查 WHO 及美、英、日、中國等國家感染 H1N1 新型流感流行病學資料顯示，感染者人數無顯著性別差異。	1.透過相關資料庫、圖書等各種途徑蒐集既有的性別統計與性別分析。 2.性別統計與性別分析應儘量顧及不同性別、性傾向及性別認同者之年齡、族群、地區等面向。
4-3 建議未來需要強化與本計畫相關的性別統計與性別分析及其方法	無。	說明需要強化的性別統計類別及方法，包括由業務單位釐清性別統計的定義及範圍，向主計單位建議分析項目或編列經費委託調查，並提出確保執行的方法。
伍、計畫目標概述（併同敘明性別目標）	為能積極準備因應多元化之流感大流行，本計畫目標如下： (一)建立藥劑、疫苗、個人防護裝備等防疫物資永續儲備機制。 (二)提升傳染病防治醫療網應變醫院收治量能。 (三)建立依風險評估結果調整應變策略之彈性機制。 (四)建立緊急疫情啟動快速提升應變量能採購機制。 (五)建立國際合作、人才訓練管道。	
陸、性別參與情形或改善方法（計畫於研擬、決策、發展、執行之過	「衛生福利部傳染病防治諮詢會-流感防治組」係我國流感防治政策擬訂及實務執行等之重要專家諮詢機制，其設有召集人 1 人及委員 18 人，其中女性委員 8 人，為總委員數之 42%，超過規定之 1/3。	

程中，不同性別者之參與機制，如計畫相關組織或機制，性別比例是否達 1/3）	

柒、受益對象

1.若 7-1 至 7-3 任一指標評定「是」者，應繼續填列「捌、評估內容」8-1 至 8-9 及「第二部分－程序參與」；如 7-1 至 7-3 皆評定為「否」者，則免填「捌、評估內容」8-1 至 8-9，逕填寫「第二部分－程序參與」，惟若經程序參與後，10-5「計畫與性別關聯之程度」評定為「有關」者，則需修正第一部分「柒、受益對象」7-1 至 7-3，並補填列「捌、評估內容」8-1 至 8-9。

2.本項不論評定結果為「是」或「否」，皆需填寫評定原因，應有量化或質化說明，不得僅列示「無涉性別」、「與性別無關」或「性別一律平等」。

項　目	評定結果 (請勾選) 是	評定結果 (請勾選) 否	評定原因	備　註
7-1 以特定性別、性傾向或性別認同者為受益對象		✓	本計畫未涉及特定性別、性傾向或性別認同者。	如受益對象以男性或女性為主，或以同性戀、異性戀或雙性戀為主，或個人自認屬於男性或女性者，請評定為「是」。
7-2 受益對象無區別，但計畫內容涉及一般社會認知既存的性別偏見，或統計資料顯示性別比例差距過大者		✓	國內外相關統計皆無性別之顯著差異。	如受益對象雖未限於特定性別人口群，但計畫內容涉及性別偏見、性別比例差距或隔離等之可能性者，請評定為「是」。
7-3 公共建設之空間規劃與工程設計涉及對不同性別、性傾向或性別認同者權益相關者		✓	本計畫無公共建設之空間規劃及工程設計。	如公共建設之空間規劃與工程設計涉及不同性別、性傾向或性別認同者使用便利及合理性、區位安全性，或消除空間死角，或考慮特殊使用需求者之可能性者，請評定為「是」。

捌、評估內容

（一）資源與過程

項　目	說　明	備　註
8-1 經費配置：計畫如何編列或調整預算配置，以回應性別需求與達成性別目標		說明該計畫所編列經費如何針對性別差異，回應性別需求。

8-2 執行策略：計畫如何縮小不同性別、性傾向或性別認同者差異之迫切性與需求性		計畫如何設計執行策略，以回應性別需求與達成性別目標。
8-3 宣導傳播：計畫宣導方式如何顧及弱勢性別資訊獲取能力或使用習慣之差異		說明傳佈訊息給目標對象所採用的方式，是否針對不同背景的目標對象採取不同傳播方法的設計。
8-4 性別友善措施：搭配其他對不同性別、性傾向或性別認同者之友善措施或方案		說明計畫之性別友善措施或方案。
（二）效益評估		
項　目	**說　明**	**備　註**
8-5 落實法規政策：計畫符合相關法規政策之情形		說明計畫如何落實憲法、法律、性別平等政策綱領、性別主流化政策及CEDAW之基本精神，可參考行政院性別平等會網站(http://www.gec.ey.gov.tw/)。
8-6 預防或消除性別隔離：計畫如何預防或消除性別隔離		說明計畫如何預防或消除傳統文化對不同性別、性傾向或性別認同者之限制或僵化期待。
8-7 平等取得社會資源：計畫如何提升平等獲取社會資源機會		說明計畫如何提供不同性別、性傾向或性別認同者平等機會獲取社會資源，提升其參與社會及公共事務之機會。
8-8 空間與工程效益：軟硬體的公共空間之空間規劃與工程設計，在空間使用性、安全性、友善性上之具體效益		1.使用性：兼顧不同生理差異所產生的不同需求。 2.安全性：消除空間死角、相關安全設施。 3.友善性：兼顧性別、性傾向或性別認同者之特殊使用需求。
8-9 設立考核指標與機制：計畫如何設立性別敏感指標，並且透過制度化的機制，以便監督計畫的影響程度		1.為衡量性別目標達成情形，計畫如何訂定相關預期績效指標及評估基準（績效指標，後續請依「行政院所屬各機關個案計畫管制評核作業要點」納入年度管制作業計畫評核）。 2.說明性別敏感指標，並考量不同性別、性傾向或性別認同者之年齡、族群、地區等面向。
玖、評估結果：請填表人依據性別平等專家學者意見之檢視意見提出綜合說明，包括對「第二部分、程序參與」主要意見參採情形、採納意見之計畫調整情形、無法採納意見之理由或替代規劃等。		

<table>
<tr><td>9-1 評估結果之綜合說明</td><td colspan="2"></td></tr>
<tr><td rowspan="2">9-2 參採情形</td><td>9-2-1 說明採納意見後之計畫調整</td><td></td></tr>
<tr><td>9-2-2 說明未參採之理由或替代規劃</td><td></td></tr>
<tr><td colspan="3">9-3 通知程序參與之專家學者本計畫的評估結果：
已於　　年　　月　　日將「評估結果」通知程序參與者審閱</td></tr>
</table>

＊ 請機關填表人於填完「第一部分」第壹項至第捌項後，由民間性別平等專家學者進行「第二部分－程序參與」項目，完成「第二部分－程序參與」後，再由機關填表人依據「第二部分－程序參與」之主要意見，續填「第一部分－玖、評估結果」。

＊ 「第二部分－程序參與」之 **10-5**「計畫與性別關聯之程度」經性別平等專家學者評定為「有關」者，請機關填表人依據其檢視意見填列「第一部分－玖、評估結果」**9-1** 至 **9-3**；若經評定為「無關」者，則 **9-1** 至 **9-3** 免填。

＊ 若以上有１項未完成，表示計畫案在研擬時未考量性別，應退回主管（辦）機關重新辦理。

【第二部分－程序參與】：本部分由民間性別平等專家學者填寫

<table>
<tr><td colspan="4">拾、程序參與：若採用書面意見的方式，至少應徵詢 1 位以上民間性別平等專家學者意見；民間專家學者資料可至台灣國家婦女館網站參閱 (http://www.taiwanwomencenter.org.tw/)。</td></tr>
<tr><td colspan="4">（一）基本資料</td></tr>
<tr><td>10-1 程序參與期程或時間</td><td colspan="3">106 年 6 月 22 日至 106 年 6 月 22</td></tr>
<tr><td>10-2 參與者姓名、職稱、服務單位及其專長領域</td><td colspan="3">王秀紅、教授兼院長、高雄醫學大學護理學院
婦女健康、高齡長期照護、性別政策、衛生政策</td></tr>
<tr><td>10-3 參與方式</td><td colspan="3">□計畫研商會議 □性別平等專案小組 ■書面意見</td></tr>
<tr><td rowspan="2">10-4 業務單位所提供之資料</td><td>相關統計資料</td><td>計畫書</td><td>計畫書涵納其他初評結果</td></tr>
<tr><td>☑有 ☑很完整
□可更完整
□現有資料不足須設法補足
□無 □應可設法找尋
□現狀與未來皆有困難</td><td>□有，且具性別目標
☑有，但無性別目標
□無</td><td>☑有，已很完整
□有，但仍有改善空間
□無</td></tr>
<tr><td>10-5 計畫與性別關聯之程度</td><td colspan="3">□有關 ☑無關
（若性別平等專家學者認為第一部分「柒、受益對象」7-1 至 7-3 任一指標應評定為「是」者，則勾選「有關」；若 7-1 至 7-3 均評定「否」者，則勾選「無關」）。</td></tr>
<tr><td colspan="4">（二）主要意見：就前述各項（問題與需求評估、性別目標、參與機制之設計、資源投入及效益評估）說明之合宜性提出檢視意見，並提供綜合意見。</td></tr>
<tr><td>10-6 問題與需求評估說明之合宜性</td><td colspan="3">合宜</td></tr>
<tr><td>10-7 性別目標說明之合宜性</td><td colspan="3">無性別目標</td></tr>
<tr><td>10-8 性別參與情形或改善方法之合宜性</td><td colspan="3">無相關資料</td></tr>
<tr><td>10-9 受益對象之合宜性</td><td colspan="3">合宜</td></tr>
<tr><td>10-10 資源與過程說明之合宜性</td><td colspan="3">合宜</td></tr>
<tr><td>10-11 效益評估說明之合宜性</td><td colspan="3">合宜</td></tr>
<tr><td>10-12 綜合性檢視意見</td><td colspan="3">1. 建議未來可針對不同型別之流感感染情形做性別差異分析。
2. 各項防疫物資，例如疫苗、個人防護設備需足夠提供第一線女性健康照護工作者。
3. 每年安排 2 人之國際合作人才培訓宜考量性別的衡平性。</td></tr>
<tr><td colspan="4">（三）參與時機及方式之合宜性：合宜</td></tr>
<tr><td colspan="4">本人同意恪遵保密義務，未經部會同意不得逕自對外公開所評估之計畫草案。
（簽章，簽名或打字皆可） 王秀紅</td></tr>
</table>

玖、附錄

附錄 1：行政院第 3342 次行政院會院長提示（102 年 4 月 11 日）

附錄 2：行政院對於「第二期準備計畫屆滿後繼續就強化整體防疫效能預為規劃」指示（103 年 7 月 10 日）

附錄 3：WHO: Pandemic Influenza Risk Management: WHO Interim Guidance（102 年 6 月）

附錄 4：美國匹茲堡大學醫學衛生安全中心「SARS 十週年之臺灣公共衛生緊急準備計畫評估」（101 年 12 月）

附錄 5：流感抗病毒藥劑及防疫物資儲備量及儲備比例

拾、參考文獻

1. 衛生署疾病管制局：我國因應流感大流行準備第二期計畫。99 年 5 月。
2. WHO：Pandemic Influenza Risk Management: WHO Interim Guidance. Jun. 2013.
3. WHO：Addressing ethical issues in pandemic influenza planning. 2008.
4. Nigg, J.M. Social science approaches in disaster research: Selected research issues and findings on mitigation natural hazards in the urban environment. In F.Y. Cheng & M.S. Sheu (Eds.), Urban disaster mitigation: The role of engineering and technology (pp. 303-310). New York: Elsevier Science. 1995.

附錄 1：行政院第 3342 次行政院會院長提示（102 年 4 月 11 日）

行政院第 3342 次院會決議

日期：102 年 4 月 11 日

院長提示：略。

報告事項

一、略。

二、本院衛生署陳報「SARS 後十年我國防疫改革及 H7N9 流感疫情因應作為」報告，請鑒核案。

決定：

（一）准予備查。

（二）傳染病疫情對國人健康及國家安全都會造成很大的危害與衝擊，衛生署記取民國 92 年抗 SARS 經驗，全面檢視並建構我國傳染病醫療及防治體系，近十年來已成功渡過 H1N1 新型流感等重大疫情考驗，基本上可看出防疫體系建立與否的差別。但新興傳染病仍將不斷出現，尤其在全球化、交通便利、疫病無國界的情況下，防疫工作的挑戰愈來愈大，衛生署仍然不能掉以輕心，請持續充實防疫量能，並加強與國際交流合作。

（三）目前大陸爆發 H7N9 流感疫情，我們秉持「料敵從寬、禦敵從嚴」的態度謹慎因應，已於 102 年 4 月 3 日迅速成立「H7N9 流感中央流行疫情指揮中心」，統合中央及地方防疫資源，同時公告「H7N9 流感」為法定第五類傳染病，提高國人警覺性。請衛生署、農委會等相關機關及地方政府務必做好各項防疫工作，加強疫情監測及防治作為，落實衛教宣導，並即時有效運用傳播媒體，提供最新、最正確的防疫訊息，讓社會

大眾充分瞭解，避免引發國人不必要的恐慌，同時呼籲境外入境、前往大陸的民眾及臺商，確實做好各項防護措施。

（四）依衛生署報告顯示，近年來愛滋感染者有年輕化趨勢，這是必須嚴肅面對的重要防疫課題，請衛生署會同教育部、法務部及內政部等相關部會積極研商，儘速擬訂妥適有效的防治策略，特別是加強年輕族群防治、非法藥物管理等，透過各部會的通力合作，期能建立迅速有效的控制機制。

（五）面對 H7N9 流感疫情的潛在威脅，如只由衛生署單一部會處理，一定不能充分發揮防疫實效，此正是挑戰政府的統合與協調。從過去經驗得知，國家的重要施政需要跨部會的合作，雖然政府在疫情防治工作上建立了比十年前更好的體系，但仍須透過不斷的檢討及相關部會的加入，強化防疫功能。因此，請衛生署務必利用這次成立「中央流行疫情指揮中心」的機會，將橫向的聯繫、中央與地方的垂直分工做得更好，由疾病管制局將過去沒發現的防疫漏洞補起來，以安然渡過此次疫情考驗，並強化我們的防疫體系。

討論事項：略。

附錄 2：行政院對於「第二期準備計畫屆滿後繼續就強化整體防疫效能預為規劃」指示（103 年 7 月 10 日）

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國家發展委員會　函

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主旨：承囑審議衛生福利部函報修正「我國因應流感大流行準備第二期計畫」一案，經會同有關機關（單位）審議竣事，原則支持，以下相關意見建請該部參照辦理，請　查照。

說明：

一、復　貴秘書長103年4月8日院臺衛字第1030019395號函。

二、本計畫將於104年屆滿，後續請依業務實際執行量能及政府預算編列預為規劃，以持續強化整體防疫效能。

三、有關調整傳染病防治醫療網運作機制，由原25家調整為6個網區各指定1家應變醫院，另由各縣市衛生局自轄區內隔離醫院中選定1家以上為應變醫院部分，請衛生福利部督導網區應變醫院及縣市應變醫院間對新興傳染病疫情之應變量能，包括加強跨縣市轉運送或就地收治病人之作業流程規範及定期演練，以有效因應可能疫情高峰之醫療需求。另各縣市應變醫院負壓隔離病房之負壓值或換氣率，仍請參酌網區應變醫院，另訂定妥適合格率，俾確保因應緊急防疫需求。

四、經費需求表100年至103年度部分，請依實際預算數修正。

五、 建議可依不同對象之性別、年齡、近用管道等差異性規劃不同之溝通內容與宣導途徑。至性別影響評估檢視表4-2流感併發症確定病例性別統計誤植，請修正。

正本：行政院秘書長
副本：

Pandemic Influenza Risk Management

WHO Interim Guidance

WHO/HSE/HEA/HSP/2013.3

Contents

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Abbreviations

CAR	Clinical attack rate
CFR	Case-fatality ratio
ERMH	Emergency Risk Management for Health
GAP	Global Action Plan for Influenza Vaccines
GISRS	Global Influenza Surveillance and Response System
GOARN	Global Outbreak Alert and Response Network
IHR (2005)	International Health Regulations (2005)
PHEIC	Public Health Emergency of International Concern
PIP Framework	Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits
SAGE	Strategic Advisory Group of Experts on Immunization
UN	United Nations

Executive summary

Influenza pandemics are unpredictable but recurring events that can have consequences on human health and economic well-being worldwide. Advance planning and preparedness are critical to help mitigate the impact of a pandemic. This WHO guidance document, *Pandemic Influenza Risk Management*, updates and replaces *Pandemic influenza preparedness and response: a WHO guidance document*, which was published in 2009. This revision of the guidance takes account of lessons learnt from the influenza A(H1N1) 2009 pandemic and of other relevant developments.

The influenza A(H1N1) 2009 pandemic was both the first of the 21st century and the first since WHO had produced pandemic preparedness guidance. The experience of Member States during the pandemic varied, yet several common factors emerged. Member States had prepared for a pandemic of high severity and appeared unable to adapt their national and subnational responses adequately to a more moderate event. Communications were also demonstrated to be of immense importance: the need to provide clear risk assessments to decision-makers placed significant strain on ministries of health; and effective communication with the public was challenging. These, and other areas with improvement potential, were identified by the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009.

The influenza A(H1N1) 2009 pandemic provided a wealth of additional information to the established and growing body of knowledge on influenza viruses at the human–animal ecosystem interface. Other notable developments since the publication of the 2009 guidance include the adoption by the Sixty-fourth World Health Assembly of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. In addition, risk management of acute public health events that have the potential to cross borders and threaten people worldwide continues to improve as a result of the International Health Regulations (2005) and States Parties' obligations on capacity strengthening.

This guidance can be used to inform and harmonize national and international pandemic preparedness and response. Countries should consider reviewing and/or updating national influenza preparedness and response plans to reflect the approach taken in this guidance. The roles and responsibilities of WHO relevant to pandemic preparedness, in terms of global leadership and support to Member States, are also articulated. This document is not intended to replace national plans, which should be developed by each country.

New in the 2013 guidance

Emergency Risk Management for Health

The approach taken in this 2013 guidance applies the principles of all-hazards emergency risk management for health (ERMH) to pandemic influenza risk management. The objectives of emergency risk management for health are to: strengthen capacities to manage the health risks from all hazards; embed comprehensive emergency risk management in the health sector; and enable and promote multisectoral linkage and integration across the whole-of-government and the whole-of-society. This guidance therefore aligns more closely with the disaster risk management structures already in place in many countries and underscores the need for appropriate and timely risk assessment for evidence-based decision-making at national, subnational and local levels.

Risk-based approach

This guidance introduces a risk-based approach to pandemic influenza risk management and encourages Member States to develop flexible plans, based on national risk assessment, taking account of the global risk assessment conducted by WHO. To support implementation, content on the application of assessments of risk and severity have been strengthened.

Approach to global phases and uncoupling global phases from national actions

In response to lessons learnt from the influenza A(H1N1) 2009 pandemic, a revised approach to global phases is introduced in this guidance. The phases, which are based on virological, epidemiological and clinical data, are to be used for describing the spread of a new influenza subtype, taking account of the disease it causes, around the world. The global phases have been clearly uncoupled from risk management decisions and actions at the country level. Thus, Member States are encouraged as far as possible to use national risk assessments to inform management decisions for the benefit of their country's specific situation and needs.

PIP Framework

The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits, commonly known as the PIP Framework, brings together Member States, industry, other stakeholders and WHO to implement a global approach to pandemic influenza preparedness and response. Its key goals include:

- to improve and strengthen the sharing of influenza viruses with human pandemic potential; and
- to achieve, *inter alia*, more predictable, efficient and equitable access for countries in need of life-saving vaccines and medicines during future pandemics.

The Framework was developed by Member States and became effective on 24 May 2011, when it was adopted by the Sixty-fourth World Health Assembly.

1. Introduction

The influenza A(H1N1) 2009 pandemic was the first to occur since WHO had produced preparedness guidance. Guidance had been published in 1999, revised in 2005 and again in 2009 following advances in the development of antivirals and experiences with influenza A(H5N1) infections in poultry and humans. The emergence of the influenza A(H1N1)pdm09 virus provided further understanding of influenza pandemics and requirements for pandemic preparedness and response. The report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009 concluded: "The world is ill-prepared to respond to a severe influenza pandemic or to any similarly global, sustained and threatening public-health emergency" (*1*).

The Review Committee recommended that WHO should revise its pandemic preparedness guidance to support further efforts at the national and subnational level. Revisions recommended included: simplification of the pandemic phases structure; emphasis on a risk-based approach to enable a more flexible response to different scenarios; reliance on multisectoral participation; utilization of lessons learnt at the country, regional and global level; and further guidance on risk assessment. The Review Committee's report reflected the broad experiences of Member States during the influenza A(H1N1) 2009 pandemic – and the key point that previous pandemic planning guidance was overly rigid. Member States had prepared for a pandemic of high severity and appeared unable to adapt their responses adequately to a more moderate event. Communications also proved to be of immense importance during the influenza A(H1N1) 2009 pandemic, within the health and non-health sectors and to the public. Provision of clear risk assessments to decision-makers placed significant strain on ministries of health, and effective communication with the public was challenging.

This 2013 guidance is based on the principles of all-hazards emergency risk management for health (ERMH), thereby aligning pandemic risk management with the strategic approach adopted by WHO, in accordance with World Health Assembly resolution 64.10.[1] Commensurate with this approach, this guidance promotes building on existing capacities – in particular those under the International Health Regulations (2005) (*2*) (IHR [2005]) core capacities, in order to manage risks from pandemic influenza. Certain aspects of implementation of ERMH for national pandemic preparedness may therefore be linked with the core capacity strengthening activities required by the IHR (2005). This guidance can therefore be used as a model to illustrate how the mechanisms required for response to and recovery from pandemic influenza can be applied, as appropriate, to the management of all relevant health emergencies.

A risk-based approach to pandemic influenza management is emphasized and Member States are encouraged to develop flexible plans, based on national risk assessments. This guidance also places pandemic planning in the whole-of-society context. This 2013 revision therefore (1) reflects the approach taken at national level where pandemic influenza planning often rests with national disaster management authorities and (2) introduces or promotes all-hazards ERMH at Ministry of Health level, including mechanisms for wider national engagement.

This guidance also summarizes the roles and responsibilities of WHO relevant to pandemic preparedness, in terms of global leadership and support to Member States.

[1] WHA Resolution 64.10 in 2011, urges Member States to (1) integrate all-hazards health emergency and disaster risk management programmes (including disaster risk reduction) into national or subnational health plans; and (2) institutionalize capacities for coordinated health and multisectoral action to assess risks, proactively reduce risks, and prepare for, respond to, and recover from, emergencies, disasters and other crises.

2. WHO global leadership

WHO is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to Member States and monitoring and assessing health trends. WHO promotes health as a shared responsibility, involving equitable access to essential care and collective defence against transnational threats.

As the directing and coordinating authority for health within the United Nations (UN) system, WHO has a mandate for global pandemic influenza risk management, (*3*, *4*) which is reflected at all levels of the Organization. Key mechanisms by which WHO fulfils this obligation are summarized below.

2.1 Coordination under the International Health Regulations (2005)

The IHR (2005) are binding upon 196 States Parties[2] and provide a global legal framework to prevent, control or respond to public health risks that may spread between countries.

Convening of an Emergency Committee, declaration of a Public Health Emergency of International Concern and issuance of IHR (2005) temporary recommendations

The IHR (2005) provide the regulatory framework for the timely and effective management of international public health risks. In addition, the Regulations provide a basis for collective global action for certain rare events of particular importance. Such serious events that endanger global public health are specified by the Regulations as public health emergencies of international concern. The term Public Health Emergency of International Concern (PHEIC) is defined in the IHR (2005) as "an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response". This definition implies a situation that: is serious, sudden, unusual or unexpected; carries implications for public health beyond the affected State's national border; and may require immediate international action.[3]

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[2] Non-Member States of WHO can notify the Director-General of their acceptance of the IHR (2005) which enters into force for them three months after the said notification. Two non-Member States have made such notifications.

[3] Article 12 Determination of a public health emergency of international concern

1. The Director-General shall determine, on the basis of the information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations.
2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State Party in whose territory the event arises regarding this preliminary determination. If the Director-General and the State Party are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee") on appropriate temporary recommendations.
3. If, following the consultation in paragraph 2 above, the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49.
4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:

The responsibility of determining whether an event is within this category lies with the WHO Director-General and requires the subsequent convening of a committee of health experts – the IHR Emergency Committee. This committee advises the Director General on the recommended measures to be promulgated on an emergency basis, known as temporary recommendations. Temporary recommendations include health measures to be implemented by the State Party experiencing the PHEIC, or by other States Parties, to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.

The Emergency Committee also gives advice on the determination of the event as a PHEIC in circumstances where there is inconsistency in the assessment of the event between the Director-General and the affected country/countries. The Emergency Committee continues to provide advice to the Director-General throughout the duration of the PHEIC, including any necessary changes to the recommended measures for control and on the determination of PHEIC termination. WHO maintains an IHR roster of experts and the members of an IHR Emergency Committee are selected from this roster and/or WHO expert advisory panels and committees. At least one member of the Emergency Committee should be an expert nominated by a State Party within whose territory the event arises, and such States Parties are invited to present their views to the Emergency Committee.

Provision of information and support to affected States Parties

The IHR (2005) also provide a mandate to WHO to perform public health surveillance, risk assessment, support States Parties and coordinate the international response to significant international public health risks. After preliminary assessment, WHO is obliged by the IHR (2005) to obtain verification of event reports from States Parties.[4] If verification is sought, including in the context of potential pandemic influenza, States Parties are required to respond to WHO within a prescribed time period and include available relevant public health information. The regulatory requirement to respond to requests for verification by WHO aims to provide early identification of any public health event that may constitute a PHEIC. WHO

(a) information provided by the State Party;
(b) the decision instrument contained in Annex 2;
(c) the advice of the Emergency Committee;
(d) scientific principles as well as the available scientific evidence and other relevant information; and
(e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.

5. If the Director-General, following consultations with the State Party within whose territory the public health emergency of international concern has occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49.

[4] IHR Article 10 – Verification

1. WHO shall request, in accordance with Article 9, verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify.
2. Pursuant to the foregoing paragraph and to Article 9, each State Party, when requested by WHO, shall verify and provide:
   (a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO;
   (b) within 24 hours, available public health information on the status of events referred to in WHO's request; and
   (c) information to WHO in the context of an assessment under Article 6, including relevant information as described in that Article.
3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.
4. If the State Party does not accept the offer of collaboration, WHO may, when justified by the magnitude of the public health risk, share with other States Parties the information available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned.

is also obligated to provide event information to States Parties regarding public health risks, whenever that information is necessary for them to protect their populations.

When WHO intends to make information available to other States Parties, it has an obligation to consult with the country experiencing the event. WHO may also make information related to an arising influenza pandemic available to the public, if other information about the event is already in the public domain, and if a need exists for public availability of information that is authoritative and independent. Under the IHR (2005), WHO must offer assistance to States Parties in assessing or controlling public health events occurring within their territories. This support can be in the form of technical advice and guidelines, specialized materials, deployment of international teams to affected areas, and coordination of international support from various sources.

Measures adopted by States Parties in relation to travel or trade

The IHR (2005) seek to limit the public health measures taken in response to disease spread to those "that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade". To achieve this objective, WHO regularly issues advice on trade and travel measures related to public health events where such measures are likely or relevant. While the IHR (2005) do not prevent States Parties from implementing specific trade and travel related measures, they do require States Parties to inform WHO of these measures and the justification for their introduction when they will result in significant interference, defined in the IHR (2005) as resulting in delays to movement of international travellers, baggage, cargo, containers, conveyances, goods, and the like, of greater than 24 hours. In addition to providing other States Parties with information on these measures, WHO can request the implementing State Party to reconsider their application.

2.2 Pandemic phases

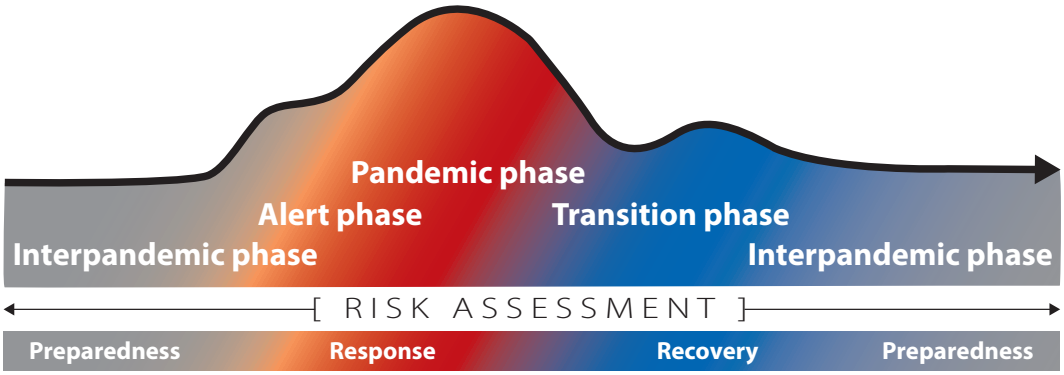
The pandemic influenza phases reflect WHO's risk assessment of the global situation regarding each influenza virus with pandemic potential that is infecting humans. These assessments are made initially when such viruses are identified and are updated based on evolving virological, epidemiological and clinical data. The phases provide a high-level, global view of the evolving picture.

The global phases – interpandemic, alert, pandemic and transition – describe the spread of the new influenza subtype, taking account of the disease it causes, around the world. As pandemic viruses emerge, countries and regions face different risks at different times. For that reason, countries are strongly advised to develop their own national risk assessments based on local circumstances, taking into consideration the information provided by the global assessments produced by WHO. Risk management decisions by countries are therefore expected to be informed by global risk assessments, but based on local risk assessments.

The risk-based approach to pandemic influenza phases is represented in **Figure 1** as a continuum, which also shows the phases in the context of preparedness, response and recovery, as part of an all-hazards approach to emergency risk management. Both WHO guidance and international standards exist that describe formats and conduct of such risk assessment (see **Section 4.2**). One of the underlying principles of this guidance is to acknowledge that emergency risk management at country level needs to be sufficiently flexible to accommodate different consequences within individual countries, for example, different severities and different numbers of waves of illness.

The global phases will be used by WHO to communicate the global situation. They will be incorporated into IHR (2005) related communications to National IHR Focal Points, in Disease Outbreak News releases and various other public and media interactions, including through social media channels.

Figure 1. The continuum of pandemic phases[a]



[a] This continuum is according to a "global average" of cases, over time, based on continued risk assessment and consistent with the broader emergency risk management continuum.

Interpandemic phase: This is the period between influenza pandemics.

Alert phase: This is the phase when influenza caused by a new subtype has been identified in humans.[5] Increased vigilance and careful risk assessment, at local, national and global levels, are characteristic of this phase. If the risk assessments indicate that the new virus is not developing into a pandemic strain, a de-escalation of activities towards those in the interpandemic phase may occur.

Pandemic phase: This is the period of global spread of human influenza caused by a new subtype. Movement between the interpandemic, alert and pandemic phases may occur quickly or gradually as indicated by the global risk assessment, principally based on virological, epidemiological and clinical data.

Transition phase: As the assessed global risk reduces, de-escalation of global actions may occur, and reduction in response activities or movement towards recovery actions by countries may be appropriate, according to their own risk assessments.

The global phases and their application in risk management are distinct from (1) the determination of a PHEIC under the IHR (2005) and (2) the declaration of a pandemic. These are based upon specific assessments and can be used for communication of the need for collective global action, or by regulatory bodies and/or for legal or contractual agreements, should they be based on a determination of a PHEIC or on a pandemic declaration.

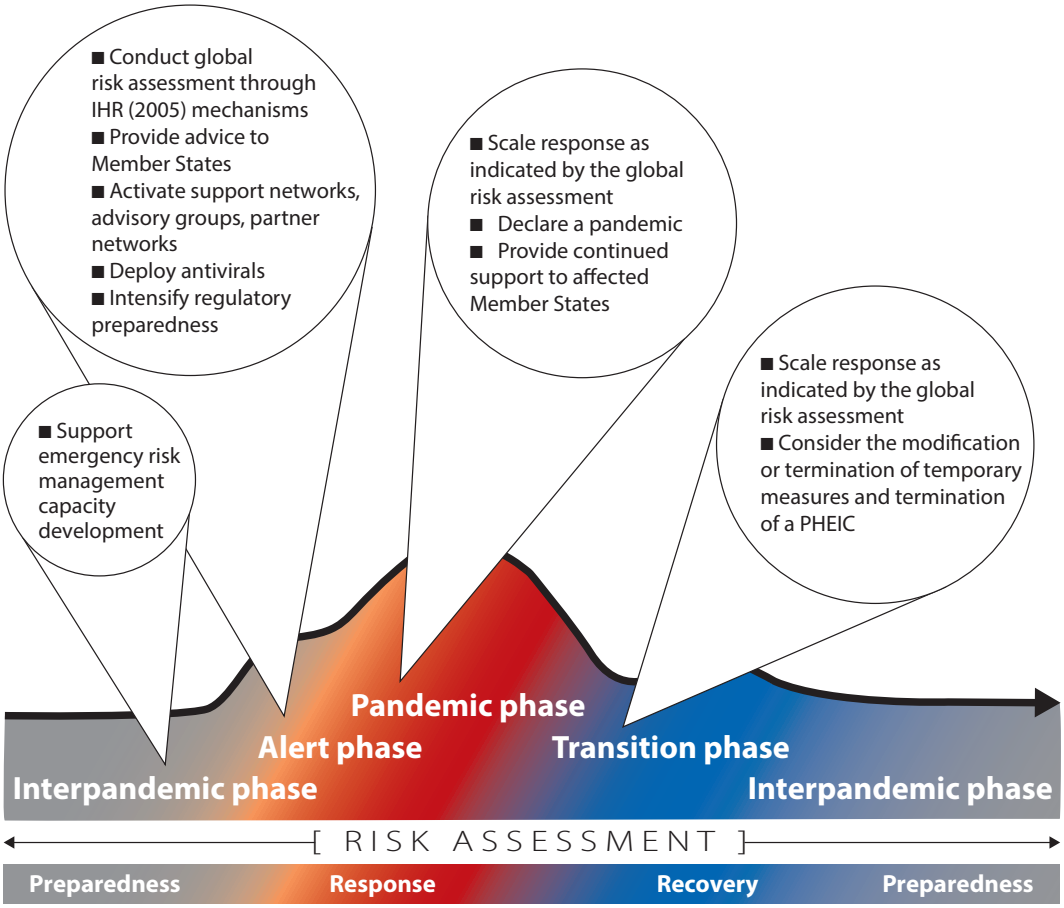
Determination of a PHEIC: The responsibility of determining a PHEIC lies with the WHO Director-General under Article 12 of the IHR (2005). The determination leads to the communication of temporary recommendations, see **Section 2.1**.

Declaration of a pandemic: During the period of spread of human influenza caused by a new subtype, and appropriate to the situation, the WHO Director-General may make a declaration of a pandemic.

While the determination of a PHEIC and/or declaration of a pandemic may trigger certain regulatory actions by WHO and Member States, actions at national level should be based on national/local risk assessments and be commensurate with risk.

[5] The IHR (2005) Annex 2 includes "human influenza caused by a new subtype" among the four specified diseases for which a case is necessarily considered "unusual or unexpected and may have serious public health impact, and thus shall be notified" in all circumstances to WHO.

Figure 2. The continuum of pandemic phases with indicative WHO actions



Actions by WHO occur throughout the phases continuum; their nature and scale at any point in time will be in line with the global risk assessment. Indicative actions by the Organization are illustrated in **Figure 2**. For further examples of WHO actions, see **Section 3.2**.

National actions: The nature and scale of national actions at any point in time will be in line with the current national risk assessments, taking into consideration the global risk assessment. The uncoupling of national actions from global phases is necessary since the global risk assessment, by definition, will not represent the situation in individual Member States. For further information on suggested national actions, see **Section 5**.

2.3 Pandemic Influenza Preparedness Framework

The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits – widely known as the PIP Framework – brings together Member States, industry, other key stakeholders and WHO to implement a global, Member State-developed approach to pandemic influenza preparedness and response (*5*). The Framework aims to improve the sharing of influenza viruses with pandemic potential and to achieve, *inter alia*, more predictable, efficient and equitable access for countries in need of life-saving vaccines and medicines during future pandemics. The PIP Framework became effective on 24 May 2011, when it was adopted by the Sixty-fourth World Health Assembly. The Framework has three core components, described below.

Virus sharing

Member States share PIP biological materials[6] to ensure ongoing global monitoring and risk assessment and the development of safe and effective influenza vaccines. Standard Material Transfer Agreement 1 establishes the rights and obligations of Global Influenza Surveillance and Response System (GISRS)[7] laboratories when transferring PIP biological materials within GISRS and to parties outside GISRS.

Benefit sharing

Member States and WHO aim to ensure that benefits arising from the sharing of PIP biological materials are made more accessible and available to countries based on public health risk and need. Various key points are as follows:

- Standard Material Transfer Agreement 2 are binding contracts between WHO and all recipients of PIP biological materials outside of GISRS, which include: influenza vaccine, diagnostic and pharmaceutical manufacturers; biotechnology firms; and research and academic institutions. Non-GISRS recipients must assess benefits they can commit, or consider committing, to the PIP benefit-sharing system based on their nature and capacity.
- Partnership contribution: An annual contribution to WHO by influenza vaccine, diagnostic and pharmaceutical manufacturers who use WHO GISRS. The Framework specifies that the contribution will be used to improve global pandemic influenza preparedness and response.
- Other benefits: As listed under Section 6 of the PIP Framework, other benefits include laboratory and surveillance capacity building; regulatory capacity building; and the establishment of antiviral and interpandemic vaccine stockpiles.

Governance and review

The Framework puts in place an oversight mechanism with three pillars.

- The World Health Assembly to oversee implementation of the PIP Framework.
- The WHO Director-General to promote implementation.
- The Advisory Group to provide guidance to the Director-General, monitor PIP Framework implementation and report thereon annually to the Director-General.

WHO acts as the secretariat for implementing the PIP Framework and works with private and public partners to facilitate achieving results as efficiently as possible.

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[6] For the purposes of the PIP Framework and its annexed Standard Material Transfer Agreements and terms of reference and the Influenza Virus Tracking Mechanism, "PIP biological materials" include human clinical specimens; virus isolates of wild-type human H5N1 and other influenza viruses with human pandemic potential; and modified viruses prepared from H5N1 and/or other influenza viruses with human pandemic potential developed by WHO GISRS laboratories, these being candidate vaccine viruses generated by reverse genetics and/or high growth reassortment. Also included in "PIP biological materials" are RNA extracted from wild-type H5N1 and other human influenza viruses with human pandemic potential and cDNA that encompass the entire coding region of one or more viral genes.

[7] GISRS monitors which influenza viruses are circulating in humans around the world throughout the year. GISRS comprises WHO Collaborating Centres; National Influenza Centres; H5 Reference Laboratories; and Essential Regulatory Laboratories. The major technical roles of GISRS are to: monitor human influenza disease burden; monitor antigenic drift and other changes (such as antiviral drug resistance) in seasonal influenza viruses; obtain suitable virus isolates for updating of influenza vaccines; and detect and obtain isolates of new influenza viruses infecting humans, especially those with pandemic potential. WHO also develops logistics management capacity to ensure that public health laboratories have access to protocols, tests and diagnostic reagents necessary to identify non-seasonal influenza virus infections. (See http://www.who.int/influenza/gisrs_laboratory/en/index.html, accessed April 2013.)

Member States' responsibilities

Under the Framework, Member States are responsible for (1) ensuring the timely sharing of influenza viruses with human pandemic potential with GISRS; (2) contributing to the pandemic influenza benefit-sharing system, including by working with relevant public and private institutions, organizations and entities so they make appropriate contributions to this system; and (3) continuing the support of GISRS.

2.4 Pandemic vaccine production

WHO issues biannual recommendations on the composition of seasonal influenza vaccines. Since 2004, WHO has also been reviewing vaccine candidate viruses for A(H5N1) and other influenza subtypes with pandemic potential. This process is undertaken in consultation with WHO Collaborating Centres for Influenza, National Influenza Centres, WHO H5 Reference Laboratories and key national regulatory reference laboratories. It is based on surveillance conducted by GISRS. The recommendations and availability of vaccine viruses are announced in a public meeting and simultaneously on the WHO web site (*6*). They are also communicated to influenza vaccine manufacturers via the International Federation of Pharmaceutical Manufacturers and Associations and the Developing Country Vaccine Manufacturers Network.

A critical action of WHO during an emerging pandemic is the selection of the pandemic vaccine strain and determination of when to move from seasonal to pandemic vaccine production. As soon as there is credible evidence to suggest that an influenza virus with pandemic potential has acquired the ability to sustain human-to-human transmission, WHO will expedite the process of review, selection, development and distribution of vaccine viruses for pandemic vaccine production, as well as vaccine potency testing reagents and preparations, involving all stakeholders as necessary. The efficiency of this process depends on the timely sharing of viruses and clinical specimens with WHO via GISRS and the WHO Collaborating Centres for Influenza.

The decision to recommend a move to pandemic vaccine production will be taken in collaboration and consultation with relevant technical advisory bodies including the Strategic Advisory Group of Experts on Immunization (SAGE) and GISRS, with due consideration to applicable requirements under the IHR (2005), including advice from an IHR Emergency Committee, should one be convened. WHO will then announce its recommendations on whether and when to move production to pandemic vaccine and the virus strain that should be used in the pandemic vaccine.

The decision to revert to seasonal vaccine production will be based on the formal recommendation for the composition of influenza vaccines, which is based on the virological and epidemiological information provided by GISRS and on the advice of relevant technical advisory bodies.

3. Emergency risk management for health

3.1 Principles of Emergency Risk Management for Health

Health and the systems that support it are vulnerable to loss and disruption from a variety of acute hazards including: (1) health events, such as pandemic influenza, chemical spills and nuclear contamination; (2) hazards secondary to emergencies and disasters, such as cholera outbreaks following floods; as well as (3) system destabilizers, such as earthquakes or acute energy shortages. Management of the risk associated with such hazards is central to the protection and promotion of public health.

To a varying extent, risk is managed within existing health systems and via programmes focused on specific hazards. However, some functional components of hazard-specific preparedness and response systems are common to all hazards and can therefore be consolidated into a comprehensive system of emergency risk management for health (ERMH). The objectives of ERMH are to:

- strengthen country and community capacities to manage the health risks from all types of hazards (7).
- ensure that the essential components required in a comprehensive emergency risk management programme are in place in the health sector.
- link and integrate these components into (1) health systems, (2) multisectoral disaster management systems, and (3) other mechanisms across the whole of society, including relevant risk management within non-health sectors.
- enable the health sector to advocate for and strengthen the health aspects of national and international policies and frameworks related to emergency and disaster risk management, particularly in the reduction of risk and health impact from all hazards.

The emergency risk management for health continuum describes the range of measures to manage risks through prevention and mitigation, and preparing for, responding to and recovering from emergencies.[8] Risk management measures for any health emergency, including pandemic influenza should be made on the basis of national and local risk assessment, taking account of the global assessment produced by WHO as appropriate.

Emergency risk management for health is based on the principles listed below.

Comprehensive risk management: A focus on assessment and management of risks of emergencies rather than events.

All-hazards approach: Use, development and strengthening of elements and systems that are common to the management of risks of emergencies from all sources.

Multisectoral approach: Recognition that all elements of government, business and civil society have capacities relevant to ERMH.

[8] For the purposes of risk management for pandemic influenza, three main groups of measures are used – preparedness, response and recovery. Prevention and mitigation are important in the context of comprehensive ERMH. They are reflected in both preparedness and response activities to be considered in national Pandemic Influenza Risk Management, Section 5.

Multidisciplinary approach: Recognition of the roles of many disciplines in health required to manage the health risks of emergencies through risk assessment, mitigation, prevention, preparedness, response, recovery and capacity strengthening.

Community resilience: Utilization of capacities at community level for risk assessment, reporting, providing basic services, risk communication for disease prevention and long-term community care and rehabilitation.

Sustainable development: Recognition that development of country and community capacities in health and other sectors requires a long-term approach to protect health and build resilience.

Ethical basis: Consideration of ethical principles throughout health emergency risk management activities.

3.1.1 Ensuring ethical Emergency Risk Management for Health

Management of an influenza pandemic, as with any urgent public health situation, requires certain decisions that balance potentially conflicting individual and community interests. For example, during the influenza A(H1N1) 2009 pandemic, countries experienced pressures on critical services that required prioritization (*8*) and impacted at the individual level. In addition, questions about social distancing measures, forced isolation and quarantine arose, together with debates on mandatory vaccination of health-care workers.

Ethics do not provide a prescribed set of policies; rather, ethical considerations will be shaped by the local context and cultural values. Nevertheless, it is important that any emergency measures that limit individual rights and civil liberties are necessary, reasonable, proportional, equitable, non-discriminatory and in full compliance with national and international laws (**Annex 3**) (*9*).

3.1.2 Emergency Risk Management for Health throughout the whole-of-society

A pandemic will affect the whole of society. No single agency or organization can effectively prepare for a pandemic in isolation, and uncoordinated preparedness of interdependent public and private organizations will reduce the ability of the health sector to respond. A comprehensive, coordinated, whole-of-government, whole-of-society approach to pandemic preparedness is required (**Annex 4**).

In the absence of effective planning, the effects of a pandemic at country level could possibly lead to social and economic disruption, threats to the continuity of essential services, lower productivity, distribution difficulties and shortages of supplies and human resources. It is therefore essential that all organizations – private and public – plan for the potential disruptions that a pandemic may cause. Business continuity planning should be considered for all essential service providers (**Annex 5**).

3.2 Emergency Risk Management for Health: essential components

The six categories of ERMH essential components are: policies and resource management; planning and coordination; information and knowledge management; health infrastructure and logistics; health and related services; and community emergency risk management capacities. A summary of the essential components in each of the categories is provided in **Table 2**.

WHO has been mandated by a series of World Health Assembly resolutions to provide Member States with guidance and technical support regarding pandemic influenza (*3*, *4*). Some of these obligations are specific to pandemic influenza and others overlap with the Organization's responsibilities in all health emergencies. Examples of the various functions, which are fulfilled at all levels of WHO, are provided for each category of essential component.

Table 2. Essential components in each category

Categories	Essential components
Policies and Resource Management	• Policies and legislation
	• Capacity development strategies
	• Monitoring, evaluation and reporting
	• Financing
	• Human resources
Planning and Coordination	• Coordination mechanisms
	• ERMH units in Ministry of Health
	• Prevention and mitigation planning and coordination
	• Preparedness and response planning and coordination
	• Recovery planning and coordination
	• Business continuity management
	• Exercise management
Information and Knowledge Management	• Risk assessments
	• Early warning and surveillance
	• Research for ERMH
	• Knowledge management
	• Information management
	• Public communications
Health infrastructure and logistics	• Logistics and supplies
	• Safer, prepared, and resilient health facilities
Health and related services	• Health-care services
	• Public health measures
	• Specialized services for specific hazards
Community ERMH capacities	• Local health workforce capacities and community-centred planning and action

3.2.1 Policies and resource management

Appropriate policies, plans, strategies and legislation form the basis of effective governance of ERMH. Policies and legislation should use an all-hazards approach, i.e. one that recognizes that risk management measures for hazard-specific emergencies have common elements and should cover the ERMH continuum through prevention and mitigation, preparedness, response and recovery.

Legislation should clearly articulate procedures for declaring and terminating a national public health emergency, based on national risk assessment. It should also define emergency management structures across the government national emergency/disaster management authority and should articulate the precise roles, rights and obligations of different organizations during a health emergency, based on an ethical framework to govern policy development and implementation. National legislation should be consistent with legally binding international agreements and conventions. Policies specific to the health sector should be compatible with legislation and should include defined roles and responsibilities, procedures and standards of implementation of ERMH. Policies and mechanisms to finance all ERMH activities need to be considered.

This category of essential components also includes the management of human and material resources. A human resource plan should be developed and should contain the staffing requirements for the management of health emergencies and define the competencies needed.

These plans should also specify the roles, responsibilities and authorities of the responders with written terms of reference for each specific function.

Capacity development is central to ensure that the health workforce is well equipped to implement ERMH. These efforts should be systematic and start with a thorough capacity assessment and analysis of training available for different target groups. Based on these analyses, training programmes that are appropriate, effective and efficient should be developed and instigated within educational institutions and as continuing professional development for the workforce.

Role of WHO in supporting policies and resource management

- Provide support to assess, strengthen and maintain core capacities in order to meet IHR (2005) obligations (*10*).
- Provide technical support to document the disease burden and economic impact of seasonal influenza and develop a national vaccine policy, if indicated.
- Advise on ethical frameworks to govern policies.
- Provide support and guidance to strengthen workforce capacities, e.g. health-care worker training.
- Strengthen GISRS and other laboratories to increase influenza diagnostic and surveillance capabilities and provide technical support, capacity building and technology transfer for influenza vaccines and diagnostics.
- Promote the increase of global production capacity for pandemic vaccines in developing countries, though the Global Action Plan for Influenza Vaccines (GAP) (*11*).

3.2.2 Planning and coordination

The health sector should be properly represented at all levels of government in any emergency/disaster risk management coordination forum to ensure that health needs are identified and technical advice provided to other sectors. One of the roles of these fora will be to develop and strengthen appropriate command and control systems across the national disaster management authority, within each government ministry and at subnational levels. Another important role of these fora is to ensure that the most current evidence is available to inform policy decisions.

In addition, an operational entity within the Ministry of Health or related institution should be responsible for coordinating and supervising emergency risk management implementation throughout the health sector, with stakeholder involvement. Similar entities should be in place at all subnational and local administrative levels.

Prevention and mitigation actions for any risk should be determined following a detailed risk assessment and be included in ERMH programmes at the national and subnational levels. The implementation of prevention, mitigation and preparedness measures should be coordinated with relevant technical departments inside the Ministry of Health and with the whole of government, business and civil society (**Annex 4**).

Effective coordination should be integral to all aspects of the response, starting with the initial risk assessment and including: the development of short- and long-term action plans; the assignment of resources to priority needs; and the provision of urgent community care and support. Incident management systems may be considered to facilitate the coordination under a common management structure. ERMH processes should be well documented in contingency plans and should include standard operational procedures that are appropriately disseminated, regularly updated and exercised.

Recovery needs to be an integral part of response planning and should be done in parallel with other risk management actions, i.e. well in advance of an emergency. Sufficient attention should be given to recovery planning for the health sector.

Role of WHO in planning and coordination

- Consistent with the whole-of-society, whole-of-government approach required for robust risk management for pandemic influenza, advocate collaboration and coordinate prioritized activities with organizations of the UN system, bilateral development agencies, nongovernmental organizations, the private sector and stakeholders in non-health sectors.
- Establish joint initiatives for closer collaboration with national and international partners in (1) early detection, reporting and investigation of influenza outbreaks of pandemic potential and (2) coordination of research on the human–animal ecosystem interface.
- Collaborate with the animal health sector, e.g. the Food and Agriculture Organization of the United Nations and the World Organisation for Animal Health, on preparedness, prevention, risk assessment and risk reduction mechanisms to decrease exposure of humans to influenza viruses at the human–animal ecosystem interface.
- Promote agreements for international technical assistance, resource mobilization and fair sharing of influenza products such as through the UN prequalification programme, Essential Medicines List and the PIP Framework (*5*, *12*, *13*).
- Provide guidance and/or technical support to Member States in the preparation of pandemic influenza risk management plans and in identifying priority needs and response strategies and assessing preparedness.
- Facilitate regional/cross-border collaborations.

3.2.3 Information and knowledge management

Information and knowledge management encompasses technical guidance for risk management, communications and early warning and surveillance, which are highlighted below, as well as risk assessment, (see **Section 4.1**) research for emergency risk management and information management.

3.2.3.1 Technical guidance

Practitioners should be provided with practical technical guidance on all aspects of ERMH. These guidelines should include clinical and operational aspects of the event. Continuity of health-care provision strategies should be periodically updated, as well, to reflect new research findings and lessons learnt from past health emergency events.

3.2.3.2 Communication

Effective and efficient communication is critical throughout the ERMH continuum and include information dissemination within the health sector, between health and other sectors and, crucially, with the public.

In risk communication, national and local government authorities provide information to the public in an understandable, timely, transparent and coordinated manner before, during and after a health emergency. The objectives are to develop and maintain public trust in local and national health systems and to convey realistic expectations about capacities for health emergency risk management. Risk communication also promotes the effective exchange of information and opinion among science, public health and veterinary experts, which facilitates assessment, implementation and coordination of risk management activities.

A communications strategy involves processes to collect, develop and distribute information in a timely manner and procedures to ensure that formats are appropriate to the target audiences. The strategy should take into account behavioural aspects of how people react to and act on advice and information they receive, not only from authorities but also from sources such as mass and social media. Public understanding of hazards and risks is complex, context-dependent and culturally mediated, thus communications strategy development may benefit from community participation (*14*).

ERMH plans and activities across all hazards should use the principles of risk communication to build the capacity to understand and anticipate public concerns and develop effective and responsive dialogue mechanisms. This can be achieved through an emergency communications committee that has developed and tested standard operating procedures to ensure streamlined, expedited dissemination of information for decision-making and public communication.

3.2.3.3 Early warning and surveillance

Accurate, timely information is one of the most valuable commodities during a health emergency or disaster. This information serves as the evidence base for critical decisions at all levels of administration and defines the messaging for public communication and education. An effective system, with minimal data sets of information required throughout the management of an emergency, should be developed and tested in preparation for a response.

The systems required for early warning and surveillance should be robust and enable the capture of data required for assessment of severity, the implementation of protocols for operational research, including efficacy studies on interventions applied, and assessments of national impact based on criteria such as workplace and school absenteeism, regions affected, groups most affected and essential worker availability.

Role of WHO in information and knowledge management

- Provide guidance and/or technical support to Member States on identifying priority needs and response strategies to inform preparedness planning.
- Facilitate development of national guidelines for relevant activities such as targeted vaccination campaigns, laboratory biosafety and safe specimen handling/shipping.
- Promote public health research priorities relevant to all resource settings for pandemic, non-seasonal and seasonal epidemic influenza over the medium- to long-term period via the WHO Public Health Research Agenda for Influenza.[9]
- Provide support and guidance on capacity building for health systems (*15*), infection prevention and control in health-care settings (*16*), surge capacity and national vaccine deployment (*17*).
- Assess and monitor the type and pathogenicity of circulating influenza viruses through information provided through GISRS.
- Provide technical guidance and advice to support Member States to develop effective and responsive pandemic communications, including risk communication and behavioural interventions messaging (*18*, *19*).
- Provide guidance, technical support and tools for detection, investigation, rapid risk assessment and reporting (*20*).

[9] The WHO Public Health Research Agenda for influenza has five thematic streams: (1) reducing the risk of emergence of pandemic influenza; (2) limiting the spread of pandemic, non-seasonal and seasonal epidemic influenza; (3) minimizing the impact of pandemic, non-seasonal and seasonal epidemic influenza; (4) optimizing the treatment of patients; and (5) promoting the development and application of modern public health tools. The research agenda also aims to facilitate discussion and coordination among researchers, donors and public health experts. See http://www.who.int/influenza/resources/research/about/en/index.html, accessed February 2013.

- Provide technical support and information to national authorities:
  - to enhance surveillance and collection of clinical, virological and epidemiological data to facilitate assessment of the extent of human-to human transmission and the epidemiological situation;
  - on risk assessment of clusters of influenza-like illness; and
  - on interventions to reduce the spread of influenza disease.
- Define standards for initial case investigations and for routine sentinel surveillance.
- Establish and refine global case definitions for reporting by countries of human cases of influenza caused by viruses with pandemic potential.
- Coordinate and disseminate relevant public health messages through channels such as the WHO web site, published materials, press conferences and the media.
- Provide regular and timely feedback on the results of the analysis of data reported by Member States to WHO.
- Periodically reassess and modify recommended interventions in consultation with appropriate partners, including those outside the health-care sector, on the acceptability, effectiveness and feasibility of interventions.
- Provide principles and update guidance for appropriate: infection prevention and control; laboratory biosafety; clinical management in health-care facilities and home-based care; use of antivirals; and use of seasonal and pandemic vaccines.

3.2.4 Logistics and infrastructure

Effective management of health emergencies requires access to and management of adequate infrastructure and logistics, the most important of which involve transportation, telecommunications, stockpiling and distribution of medicines and supplies, and establishment of temporary health facilities. To ensure that logistic support will be available during health emergencies, the Ministry of Health should consider making advance arrangements with government departments responsible for transport, communications, public works and the armed forces together with external agencies, such as nongovernmental organizations, UN agencies and private companies. The type and quantity of supplies and medicines will be determined by the nature of the hazard. The most critical supplies for pandemic influenza are those needed to prevent and treat the disease and its complications while maintaining critical non-influenza health services.

The Ministry of Health or the central coordinating body could also consider identifying, supporting, training and deploying operational and logistics response teams.

Role of WHO in supporting health infrastructure and logistics

- Manage the WHO strategic global stockpile of antivirals and vaccines and develop standard operating procedures to ensure rapid deployment of the WHO global "stockpile" of pandemic vaccines, based on existing pandemic vaccine deployment guidelines.
- Develop logistics management capacity to ensure that public health laboratories have access to protocols, tests and diagnostic reagents to be able to identify non-seasonal influenza virus infections (*21*).

3.2.5 Health and related services

Regardless of the nature of a health emergency challenge faced, health and related services will need to be provided to the affected population to save lives, manage public health, prevent secondary effects and maintain essential non-hazard-related emergency services. While many

of these health services do not differ from services provided in non-emergency situations, their organization and delivery may change significantly during a health emergency. This will require thoughtful planning beforehand. Health services related to triage, emergency care and maintenance of non-influenza acute care are among the many specified services requiring effective planning for implementation during a pandemic. Examples include activating contingency plans for health and laboratory facilities to deal with potential staff shortages, adjust triage systems as required and implementing mortuary management procedures as necessary.

In addition to service provision and public health measures, this essential component also includes identifying priorities and response strategies for public and private health-care systems triage and surge capacity. Surge capacity should be planned in advance for different scenarios with predetermined procedures for mobilizing staff on short notice. Mechanisms for ensuring adequate human resources for long-term events, such as an influenza pandemic should be considered, including planning for staffing of alternative care facilities for cohorting influenza patients, based on national plans. It is also important to consider ensuring that health-care workers have the opportunity for rest and recuperation.

Role of WHO in supporting health and related services

- Provide advice and technical guidance on organization and delivery of health and related services, e.g. laboratory services, blood services, non-pharmaceutical measures and mass casualty management systems.
- Utilize existing clinical networks to review clinical information and effectiveness and safety of clinical interventions.
- Provide advice on measures for controlling international disease spread through temporary recommendations issued under IHR (2005).
- Support health system capacity assessments for emergency risk management (*22*).

3.2.6 Community capacities

Community capacities are a vital component of ERMH. The community-based health workforce is a crucial front line for ERMH activities and has the language and cultural skills to implement effective local ERMH activities, including social mobilization. This workforce may include appropriately trained and accredited community health workers, trained volunteers, community-based organizations that promote health, health education and social mobilization, and those from key sectors (water, sanitation, hygiene, agriculture, food security, shelter and education) that contribute to promoting health. Developing local action plans based on national plans for any hazard is also an important consideration for strengthening community capacities.

Role of WHO in supporting community capacities

- Promote the role played by the community-based health workforce in emergency risk management and advocate for scale-up of this vital resource (*23*).
- Advise on strengthening community-based health workforce programmes, including recruitment, training, supervision, evaluation, deployment and retention (*24*).
- Provide guidance on training community health workers (*25*).
- Provide advice and guidance on community capacity building activities during pandemic influenza (*15*).

4. National pandemic influenza risk assessment

4.1 Influenza viruses and pandemics

Influenza, a viral respiratory disease, can cause high morbidity and mortality in humans and is known to affect some animal species. Clinical disease can range from mild to severe and in some cases result in death. While influenza B remains a human disease, influenza A viruses are found in human, avian and some mammalian species. An influenza pandemic occurs when an influenza A virus to which most humans have little or no existing immunity acquires the ability to cause sustained human-to-human transmission leading to community-wide outbreaks. Such a virus has the potential to spread rapidly worldwide, causing a pandemic.

At the genetic level, pandemic influenza viruses may arise through: (1) genetic reassortment: a process in which genes from animal and human influenza viruses mix together to create a human–animal influenza reassortant virus; (2) genetic mutation: a process in which genes in an animal influenza virus change allowing the virus to infect and transmit easily in humans.

Influenza pandemics are unpredictable but recurring events that can have significant global consequences. Since the 16th century, influenza pandemics have been described at intervals ranging between 10 and 50 years with varying severity and impact. Characteristics of the past four pandemics are summarized in **Table 3**.

Table 3. Characteristics of the past four influenza pandemics (*26*)

Pandemic year of emergence and common name	Area of origin	Influenza A virus sub-type (type of animal genetic introduction/ recombination event)	Estimated reproductive number (*27*, *28*)	Estimated case fatality	Estimated attributable excess mortality worldwide	Age groups most affected (*29*)
1918 "Spanish flu"	Unclear	H1N1 (unknown)	1.2–3.0	2–3% (*30*)	20–50 million	Young adults
1957–1958 "Asian flu"	Southern China	H2N2 (avian)	1.5	<0.2%	1–4 million	All age groups
1968–1969 "Hong Kong flu"	Southern China	H3N2 (avian)	1.3–1.6	<0.2%	1–4 million	All age groups
2009–2010 "influenza A(H1N1) 2009"	North America	H1N1 (swine)	1.1–1.8 (*31*)	0.02% (*32*)	100 000–400 000 (*33*)	Children and young adults

In June 2009, WHO declared the first influenza pandemic of the 21st century after the emergence of the new A(H1N1)pdm09 virus subtype. This virus was first isolated from humans in Mexico and the United States of America in April 2009. Within a few weeks, the virus had spread rapidly, and there was sustained human-to-human transmission worldwide. The triple-reassortant virus contained a unique combination of gene segments from avian, swine and human influenza viruses. Risk factors for severe influenza A(H1N1)pdm09 disease were similar to those for seasonal influenza, e.g. pregnancy and many chronic medical illnesses, although younger age groups were more affected than usual.

Prior to 2009, much of the focus on influenza viruses with pandemic potential was on the avian influenza subtype A(H5N1). A human outbreak of avian influenza A(H5N1) was detected

in 1997 in Hong Kong SAR, China. This was the first recognized instance in which a highly pathogenic avian influenza virus had been transmitted to humans and resulted in serious illness. Since its widespread re-emergence in 2003–2004, this avian virus has resulted in millions of poultry infections and over 600 human cases. On rare occasions, human-to-human transmission of influenza A(H5N1) has occurred – most often to a family or other household member acting as a caregiver. However, none of these events has so far resulted in sustained community-level transmission.

Most animal influenza viruses do not cause disease in humans. However, viruses circulating in animals or derived from viruses circulating in animals have caused infections in humans, including avian and swine viruses and reassortants, notably of the H1, H3, H5, H7 and H9 subtypes. Most of these human infections have been mild and the viruses have not spread further to other people. In contrast, the influenza A(H1N1)pdm09 virus, which is thought to have originated in swine, would be an example of a swine influenza virus that was able to spread easily among people and cause disease.

Humans generally acquire these infections through direct contact or close exposure to infected animals or contaminated environments. Control of influenza among animals is therefore essential both to reduce the risk of human infection and the potential for pandemic strains to evolve and to prevent or reduce the economic consequences. Successfully meeting this challenge requires long-term commitment from countries and strong coordination between animal and human health authorities and practitioners.

Experience with the emergence of such a variety of different influenza strains that transmit from animals to humans illustrates the highly unpredictable nature of influenza viruses such that assumptions about where the next influenza virus with pandemic potential will emerge, or what its characteristics will be, cannot easily be made. This uncertainty underscores that planning should not focus only on avian influenza but should be based on broad and robust surveillance and evidence-based risk assessment.

4.2 National risk assessments

Risk assessment is a sy*stematic process for gathering, assessing and documenting information to assign a level of risk (20*). Risk assessment aims to determine the likelihood and consequences of events that impact public health at global, national, subnational and local levels. It provides the basis for taking action to manage and reduce the negative consequences of risks to public health.

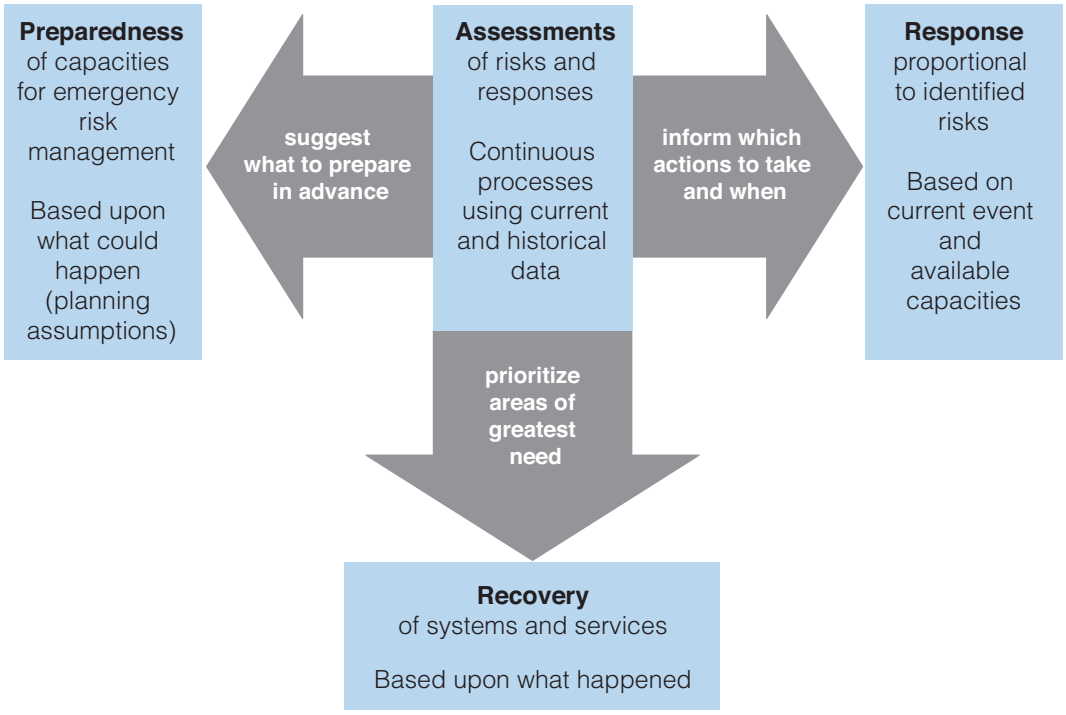
Use of risk assessment (*35*) promotes an understanding of the risks and attendant uncertainties of pandemic influenza and their potential influence on sustained health and other development objectives. It also facilitates the communication of risks and uncertainties. Risk assessment allows the provision of evidence-based information for policy-makers.

In an all-hazards approach, risk assessments can be performed to identify and prioritize preparedness, including mitigation and prevention, activities, response and recovery programmes, as illustrated in **Figure 3**.

For each influenza virus with pandemic potential, WHO will conduct global risk assessments in collaboration with the affected Member State(s), to inform decision-making for risk management (*36*). While WHO will communicate these global assessments and the uncertainties that surrounds them throughout the event, each Member State is strongly advised to assess national risk related to pandemic influenza in the context of their local experience, resources and vulnerabilities. Member States are also encouraged to share their risk assessments through networks or multilateral arrangements and to utilize regional resources for risk assessment.

At any point in a pandemic, one or many Member States may be responding to a national-level epidemic, while other Member States may not be affected for some months to come.

Figure 3. Pivotal role of risk assessment in preparedness, response and recovery actions



Consequently, each Member State is encouraged to conduct its own risk assessments, which will determine the timing, scale, emphasis, intensity and urgency of the actions required at their national and local levels. More information on suggested national actions is provided in **Section 5**.

National pandemic influenza risk assessment should involve a multidisciplinary team representative of the whole of government, together with stakeholders, and linked to relevant decision-makers. Since pandemic risk assessment has similar components across the whole of society, it should be conducted collaboratively with stakeholders at national, subnational and local levels.

A risk assessment considers hazard, exposure and context coupled with risk characterization. A hazard assessment relevant to pandemic influenza includes: identifying influenza viruses of concern; reviewing key virological and clinical information about each influenza virus; and ranking them by pandemic potential and possible consequences.

An exposure assessment seeks to define the groups of individuals known to have been, or likely to be, exposed to an influenza virus of concern and to delineate the susceptibility of these groups in terms of immunity and disease severity. This process incorporates epidemiological and susceptibility factors such as travel history, incubation period and estimation of potential for transmission.

These two assessments are then complemented by a context assessment. A context assessment is an evaluation of the environment in which the event takes place. It examines factors that affect risk, including: social; technological and scientific; economic; ethical; and policy and political factors, see **Table 4**.

Table 4. Factors to consider in context assessments

Factor	Examples
Social	• population size and characteristics such as distribution of high-risk groups
	• behaviours
	• impact of seasonal influenza
	• impact on lifestyle, e.g. acceptability and applicability of any social distancing recommendations
Technical and scientific	• ability to implement surveillance and mitigation activities
	• the likelihood that all suspect cases can be identified
	• the availability of mechanisms to reach specific high risk groups
	• the availability and acceptability of effective preventive measures and of treatment or supportive therapies
Economic	• direct and indirect financial costs including:
	• household income
	• hospitalization costs
	• potential impacts on tourism and trade
Ethical	• privacy issues
	• use of unlicensed products
	• transparency
	• unequal risk burden
	• potential requirements for the protection of critical infrastructure
Policy and political	• likely response of key stakeholders and media
	• government capacity to participate in risk management efforts
	• the country's recent experience with influenza
	• past and ongoing emergencies with implications for future hazards, vulnerabilities and capacities.

Once the hazard, exposure and context assessments are conducted, the risk can be characterized. Risk characterization seeks to organize the assessments into a determination of likelihood and impact of each risk. In the context of pandemic influenza, risk characterization employs these assessments to evaluate whether a particular influenza virus has pandemic potential and the degree to which such an event will impact on society, and, consequently, the urgency and scale of risk management actions to be implemented.

Throughout the risk assessment process, the uncertainty for each part of the assessment should be recorded and shared by the evaluating team. This documentation should include an overview of the basis for each assessment to ensure ongoing consistency in risk assessment processes.

Risk assessment is a continuous process throughout the risk management continuum. Member States are encouraged to conduct risk assessments at the national, subnational and local levels, in order to prioritize the development of risk management programmes tailored to the hazards present.

4.3 Assessment of pandemic severity

Gauging the severity of an influenza pandemic – a critical component of overall pandemic risk assessment – is an important consideration for WHO and Member States in planning for and responding to a pandemic. Early information about severity can help support decision-making at global and country levels. As a pandemic spreads from country to country, data derived from existing influenza disease and virological surveillance, coupled with field investigations and other data sources, can be used to adjust global and national responses. Some of these data-collection processes are provided through existing WHO guidance and related resources (*37*).

Early assessments in countries first affected by human infection with a new influenza subtype will inform the global community. However, each country's context and pandemic-influenza-related severity will differ, requiring careful evaluation not only of the data reported but the capacities, demographics and other features of the country in which the observations are made. In addition, continual severity assessments will be necessary over the course of a pandemic since the accuracy and precision of severity-related information will change.

Severity assessments should be conducted at the community, national and global level. Each of these assessments will enable refinement of risk assessments at the other levels. As when conducting other components of risk assessments, a country may measure a severity parameter directly, do so with the assistance of an external partner or rely on applicable information from others. For example, during the influenza A(H1N1) 2009 pandemic, informal networks of experts in epidemiology, clinical medicine, virology and mathematical modelling shared preliminary information with WHO to enable a global assessment of severity.

To be useful, the severity assessments should be done when public health decisions are needed. To that end, a risk assessment, incorporating severity, should provide as much information as possible to answer the following key questions about an emerging pandemic.

- How rapidly are new cases accruing?
- What groups of people (e.g. age groups or groups at risk of severe outcomes) will become severely ill and die?
- What types of illnesses and complications are being seen?
- Is the virus sensitive to antiviral agents?
- How many people will become ill?
- What will be the impact on the health-care sector, including such factors as health-care utilization and impact on the health-care work force?

Operationally, these questions will help guide decisions regarding vaccine production and strategy for usage, antiviral use, mobilization of health-care resources, school closures and other social distancing strategies.

The data that answer each of these key questions will be considered in the context of three indicators. Each of these indicators will contain information derived from a variety of different types of data, including virological, epidemiological, and clinical. The data will be grouped into the following indicators to help make them more accessible and understandable to the public and policy makers.

Transmissibility: Reflects the ease of movement of the virus between individuals, communities, and countries. The factors that will go into describing transmissibility include both virological factors and epidemiological observations. As with all of the indicators, the values of each of the observations or measurements that are used to reflect transmissibility will be interpreted in the context where they are made as they will be influenced by social and climatic factors.

Seriousness of Disease: A pandemic virus that has a high level of clinical severity can result in a disproportionate number of persons with serious or grave illness, some of whom will die in the absence of effective treatment or adequate clinical management. However, the severity or virulence of a virus will also depend on the presence of underlying medical conditions that predispose individuals to severe illness, as well as age. An infection is likely to be much more severe for some segments of a population than others and descriptions of the groups at risk will be part of this indicator.

Impact: If the health-care sector is impacted at a high level it may not be able to accommodate the stress on its resources. The impact on the health sector will also be influenced by public concern and health-care policies put in place in response to the event. As such, assessing

impact will aid in understanding how these issues interact with inherent characteristics of the virus and the way it behaves.

As appropriate, some of these data may also be communicated directly to policy-makers and planners. Examples of representative parameters informing each indicator are provided in **Annex 6**. WHO will communicate with its geographically and technically diverse group of staff, networks and external experts to help interpret the available qualitative and quantitative data. The severity assessments must be flexible in order to accommodate unforeseen characteristics of the pandemic as it evolves (e.g. a new indicator could be included or a known one excluded).

Any severity assessment plan has inherent limitations. Assessments are dependent upon the data available. Data first must be sought, then found, collected, shared, analyzed and communicated. Resource availability and competing interests may impede any of these steps and the ways in which these steps proceed will affect the validity of the data. Even under the best operational circumstances, data must accumulate over time before accuracy can be achieved. Case-fatality ratio, a commonly sought and communicated severity-related parameter, is well reported to have significant variability over the course of a pandemic and is not useful in the very early stages of an event because it is likely to be inaccurate and misleading (*38*, *39*). In these very early stages, the proportion of known cases requiring mechanical ventilation, for example, might be used instead of case-fatality ratio.

Severity varies within a population owing to a variety of risk factors (*40*). Population risk factors in terms of community resilience have not been carefully studied. However, antecedent general health status, availability of resources, including health-care services and medications, and cultural dynamics that affect transmission and care-seeking are likely to be relevant and will complicate comparisons between populations. As such, WHO will attempt to interpret the observations described above in the context in which they are made and project how they might affect subsequently affected Member States whose context is different. To do this, it will be necessary to communicate a wide variety of data to describe the full profile of the event. These considerations further increase the need for severity assessments to occur in the context of robust risk assessments. Further information on the representative parameters for core severity indicators is provided in **Annex 6**.

5. National pandemic influenza risk management

Individual countries may be exposed to the pandemic influenza virus at different times, have different case and case fatality rates, surveillance and response capacities, and vulnerabilities. They may experience different numbers and severities of waves of illness arising from the pandemic virus. Therefore, flexibility must be embedded in planning such that movement between the groups of activities below can be done with agility to reflect the national situation and meet local needs. For example, activities in the recovery period may need to be supplemented, as necessary, by response actions, should there be a subsequent pandemic wave. Mechanisms must be in place to enable this flexibility and for national emergency response procedures to be implemented – as guided by national risk assessment – irrespective of the global phase.

The following national actions are grouped by the six categories of essential components of ERMH (**Table 2**) and are indicative of actions to be considered following risk assessments. The degree of implementation should be commensurate with the degree of risk, national priorities and needs. These suggested national actions are intended to build on the progress made in developing and strengthening existing systems.

5.1 Policy and Resource Management

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Review or develop national pandemic risk management programmes, including preparedness activities and response plans, and establish, as needed, the full legal authority and legislation required to sustain and optimize pandemic preparedness, capacity development and response efforts across all sectors.
- Perform forecasts of the national economic impact of a pandemic and cost-effectiveness of preparedness to advocate for funding and to aid risk management planning.
- Integrate pandemic risk management plans into existing national emergency risk management programmes.
- Establish goals and priorities for the use of pandemic influenza vaccines and antiviral drugs.
- Explore ways to provide drugs and medical care free of charge (or cover by insurance) to encourage prompt reporting and treatment of human cases caused by a non-seasonal influenza virus or virus with pandemic potential.
- Strengthen and maintain capacities to detect, assess, notify and report events, the capacity to respond promptly and effectively and the capacities at designated points of entry relating to the identification and management of pandemic risks in accordance with IHR (2005) Annex 1A and 1B.2.
- Advise subnational and local governments on best practices in pandemic planning and implement a quality control system to regularly monitor and evaluate the operability and quality of local and regional plans.
- Develop procedures for access to and timely allocation of resources for preparedness, capacity development and intervention implementation at national and subnational levels, including activities to be fulfilled by humanitarian, community-based or nongovernmental organizations.

- Create a national roster of experts to provide high-level technical advice in areas such as ethics, risk assessment, infection prevention and control, respiratory diseases and emergency management.
- Assess existing capacities and identify priorities for pandemic risk management at national and subnational levels.
- Develop strategies, plans and training to enable all health-care workers, including community-level workers, to respond during influenza outbreaks and throughout a pandemic (*24*).
- Develop occupational health policies for essential services workers and develop guidance and policies to enable workers to stay home when ill.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Prioritize and guide the allocation and targeting of additional human and material resources to achieve the goals of pandemic risk management plans.
- Assess whether international assistance is required to meet humanitarian needs. Alternatively, consider providing resources and technical assistance to countries experiencing outbreaks of influenza with pandemic potential (*41*).

Recovery activities to be considered

Based on national/local risk assessments, resources and needs:

- Review the lessons learnt about policies and resource management and revise national and subnational pandemic risk management plans; encourage stakeholders across all public and private sectors to do likewise.

5.2 Planning and coordination

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- If not already in place, consider appointing a cross-governmental, multi-agency national pandemic risk management committee. Suggested activities of this committee could include the following:
  - Develop, exercise (*42*) and periodically revise national and subnational pandemic risk management plans in close collaboration with all relevant public and private partners. Review subnational pandemic plans against the national plan and involve subnational and local representatives in testing interoperability.
  - Provide the key assumptions, guidance and relevant information to promote development of pandemic business continuity plans and strategies for public and private sector workplaces (**Annex 5**).
  - Lead and coordinate multisectoral resources to mitigate the societal and economic impact of a pandemic (**Annex 4**).
  - Consider planning for containment measures (**Annex 7**).
- Planning and coordination activities of the Ministry of Health entity responsible for ERMH could include the following activities:
  - Identify, brief regularly and train key personnel to be mobilized as part of a multisectoral expert response team for influenza outbreaks of pandemic potential.

— Encourage collaboration with neighbouring countries on aspects of pandemic preparedness planning that may have regional or cross-border implications through information sharing, participation in regional and international initiatives, exercises and coordination of responses to address trans-border issues including interoperability of plans.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Update leadership and other relevant sectors on global and national pandemic influenza risk assessments.
- Provide the key assumptions, guidance and relevant information to public and private sectors to facilitate implementation of their pandemic business continuity plans.
- Finalize preparations for an imminent pandemic by activating national and subnational command and control systems.
- Activate pandemic contingency planning arrangements for the health sector and all sectors deemed critical for the provision of essential services.
- Switch to pandemic working arrangements.
- Respond, if possible, to requests for international assistance by offering resources and technical assistance to countries with ongoing pandemic activity.
- Collaborate with neighbouring countries on information sharing.
- Provide regular updates on the evolving situation to WHO and other partners to facilitate response coordination.
- Review and, if necessary, revise pandemic risk management plans to manage possible future pandemic wave(s).
- Evaluate the resources and capacities needed to monitor and respond to subsequent waves.

Recovery activities to be considered

Based on national/local risk assessments, resources and needs:

- Review the lessons learnt about planning and coordination across all sectors and share experiences with the international community. Review and, if necessary, revise pandemic risk management plans to manage a possible future pandemic.

5.3 Information and knowledge management

5.3.1 Technical guidance

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Develop and disseminate guidance on all aspects of pandemic response including: clinical management; prevention and control of health-care associated infections; surveillance throughout the pandemic; public health measures; surge capacity; and management of non-influenza acute care patients.
- Anticipate the need for rapid revision and dissemination of guidance, e.g. new laboratory protocols as the diagnostics for the new strain become available.
- Develop and test guideline dissemination mechanisms.
- Develop case-finding, treatment and management protocols/algorithms.

- Provide guidance to health-care workers to test and report cases of suspected pandemic influenza infection in patients with respiratory illness, especially those who have travelled to an affected country/countries or their close contacts.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Update, if necessary, national guidance and recommendations on the use of planned interventions taking into account information from affected countries.
- Update, if necessary, laboratory protocols for virus detection, identification, shipping and sharing with WHO Collaborating Centres for Influenza.
- To the extent possible, use standardized protocols to monitor safety, efficacy and supply of pharmaceutical interventions.
- Revise case definitions and diagnostic and treatment protocols/algorithms, as required.

Recovery activities to be considered

Based on national/local risk assessments, resources and needs:

- Communicate to the public and other stakeholders the lessons learnt about the effectiveness of policy and technical guidance during the pandemic and how the gaps that were discovered will be addressed. Evaluate guidance dissemination mechanisms and work with professional associations towards improvement. In addition, analyse data collected during the event for dissemination and consider revising the national risk assessment algorithms.

5.3.2 Communications

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Develop effective strategies to inform, educate and communicate with individuals and families to improve their ability to take appropriate actions before, during and after a pandemic.
- Identify appropriate spokespeople.
- Identify communications channels and assess their ability to reach all target population groups. Develop protocols and provide training to spokespeople for each communication channel.
- Pre-test messages through each medium, including social media, and test communications procedures through exercises.
- Build effective relations with key journalists and familiarize them with influenza and pandemic related issues.
- Develop communication strategies to support the implementation of non-pharmaceutical interventions including restrictions on mass gatherings and school closures.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Provide regular briefing updates to all spokespeople to ensure that the information conveyed is consistent and up-to-date.
- Conduct frequent and pre-announced public briefings through popular media outlets such as the web, television, social media and radio to counter panic and dispel rumours.

- Activate mechanisms to ensure the widest possible dissemination of information. Topics likely to require regular communication include :
  - What is known and not known about the virus, the state of the outbreak, use and effectiveness of measures and likely next steps.
  - What is known and not known about the pandemic disease, including transmission patterns, clinical severity, treatment and prophylaxis options.
  - The importance of compliance with recommended measures to stop further spread of the disease.
  - Societal concerns, such as the disruption to travel, border closures, school closures and the impact on the economy or society in general.
  - Sources of emergency medical care, resources for dealing with urgent non-pandemic health-care needs, and resources for self-care of medical conditions.
  - Any changes to the status of the pandemic.
  - The ongoing need for vigilance and disease-prevention efforts to prevent any upswing in disease levels.
  - Advice for travellers.
- Ensure effective communication of public health measures to reduce the spread of pandemic influenza, e.g. hand and respiratory hygiene, reduction of unnecessary travel and overcrowding of mass transport systems, self-isolation for sick individuals, except their nominated caregiver, and minimization of contact with others.
- Gather feedback from the general public, vulnerable populations and at-risk groups on attitudes towards the recommended measures and barriers affecting their willingness or ability to comply.
- Update communications strategies as feedback from the general public and stakeholder organizations is collected and analysed.

Recovery activities to be considered

Based on national/local risk assessments, resources and needs:

- Publicly acknowledge the contributions of all communities and sectors to the pandemic effort. Review the lessons learnt about communications and revise in readiness for the next major public health event. Communicate that the event may be over but that a second (or subsequent) wave(s) is/are possible and that the pandemic virus will revert to a seasonal pattern and be present as one of the circulating viruses for some time to come.

5.3.3 Early warning and surveillance

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Ensure that mechanisms are in place for meeting obligations under IHR (2005) to detect, assess, notify and report events. Such mechanisms include the capacities to respond promptly and effectively and requisite capacities at designated points of entry relating to the identification and management of pandemic risks in accordance with IHR (2005) Annex 1A and 1B.2.
- Develop or strengthen national surveillance to collect up-to-date virological, epidemiological and clinical information on trends in human seasonal influenza infections to aid estimates of additional capacities needed to detect increases in pandemic activity.

- Enhance virological and epidemiological surveillance to detect and investigate unusual cases/clusters of influenza-like respiratory illness or deaths associated with non-seasonal influenza viruses, identify potential animal sources of human infection; and assess the risk of human-to-human transmission.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Undertake a comprehensive assessment of the earliest national cases of pandemic influenza.
- Ensure that, as required under the IHR (2005), any notification is followed by ongoing communication to WHO of timely, accurate and sufficiently detailed public health information on the event, including, where possible, case definitions, laboratory results, source and type of risk, number of cases and deaths, conditions affecting the spread of the disease and the public health interventions employed.
- Collect and analyse available data to evaluate the virological, epidemiological and clinical characteristics of the national epidemic.
- Modify national case definitions and update clinical and laboratory algorithms for diagnosis, as necessary.
- Collect specimens for testing and virological characterization using protocols and procedures developed in collaboration with WHO.
- Document the evolving national epidemic including population susceptibility, changes in epidemiological and clinical features, geographical spread, trends and impact.
- Collect more detailed epidemiological and clinical data as time and resources permit.
- Maintain adequate virological surveillance to detect antigenic and genetic changes and changes in antiviral susceptibility and pathogenicity (*43*, *44*).
- Continue to update the health sector and other relevant ministries and decision-makers on new information or other changes that affect disease status, signs and symptoms, case definitions, protocols and algorithms.
- Activate the surveillance activities required to detect subsequent pandemic waves.
- Monitor and assess national impact using criteria such as workplace and school absenteeism, regions affected, groups most affected and essential worker availability.

Recovery activities to be considered

Based on national/local risk assessments, resources and needs:

- Review and revise situation monitoring and assessment tools for subsequent waves of disease, the next pandemic and other public health emergencies. In addition, resume seasonal influenza surveillance programmes incorporating the pandemic virus subtype as part of routine surveillance.

5.4 Health infrastructure and logistics

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Develop pandemic risk management plans throughout the health sector, including for health facilities, laboratories and other allied health services.
- Plan for the increased need for antibiotics, antipyretics, hydration, oxygen and ventilation support within the context of national clinical management strategies.

- Develop mechanisms and procedures to select, procure, stockpile, distribute and deliver antivirals, essential pharmaceuticals, personal protective equipment, diagnostics tests and vaccines, when available and based on national goals and resources. Consider whether these mechanisms are adequate to conduct containment measures (**Annex 7**).
- Develop a deployment plan to deliver pandemic influenza vaccines to national and subnational distribution points within 7 days from when the vaccine is available to the national government and develop a mass vaccination campaign strategy (*17*).

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Implement vaccine procurement plans.
- Implement distribution and deployment plans for antivirals, vaccines and other pharmaceuticals, other medical supplies and personal protective equipment, according to national plans.
- Monitor essential health-related resources such as: medical supplies; antivirals, vaccines and other pharmaceuticals; health-care worker availability; hospital occupancy/availability; use of alternative health facilities; laboratory material stocks; and mortuary capacity.
- Deploy pandemic vaccine when available in accordance with national plans, priorities and vaccine availability.

Recovery activities to be considered

Based on national/local risk assessments, resources and needs:

- Restock medications and supplies and service and renew essential equipment in preparation for possible subsequent waves of pandemic virus-induced disease or other health emergencies. In addition, review the status of, and replenish, national and local stockpiles.

5.5 Health and related services

5.5.1 Health services

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Consider policy and needs of an in-country approach to antivirals and vaccination, including mechanisms for evaluating effectiveness and monitoring for adverse events.
- Estimate and prioritize requirements for antiviral treatment or prophylaxis and vaccination during a pandemic.
- Consider capacity and resources for stockpiling essential medicines and equipment.
- Assess health system capacity to detect and contain outbreaks of pandemic influenza disease in hospital settings (*45*).
- Develop mechanisms to monitor uptake, compliance, safety and effectiveness of mitigation measures and share findings with the international community and WHO.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Implement national plans for antivirals and/or vaccine campaigns according to priority status and availability, in accordance with the evidence or modify/adapt antiviral and vaccine strategies based on monitoring and surveillance information.

- Enhance infection prevention and control practices in health-care and laboratory settings and issue personal protective equipment as needed in accordance with national plans.
- Activate alternative strategies for case isolation and management as needed.
- Address the psychological impacts of the pandemic, especially on the health workforce, and provide social and psychological support for health-care workers, patients and communities.
- Reassess the capacity to implement mitigation measures to reduce the spread of pandemic influenza.
- Consider vaccination of health-care workers, when available and based on national goals and policies.
- Conduct ongoing evaluations of antiviral effectiveness, safety and resistance, and vaccine coverage, effectiveness and safety, throughout their deployment, according to national plans, mechanisms and procedures.

Recovery activities to be considered

Based on national/local risk assessments, resources and needs:

- Conduct a thorough evaluation of all the specific responses and interventions used, including: (1) antiviral effectiveness, safety and resistance; (2) vaccine coverage, effectiveness and safety, and share findings with the international community.
- Begin rebuilding essential services in preparation for subsequent waves of disease and/or other health emergencies.
- Work to increase seasonal influenza vaccine coverage levels of all groups at high risk, in accordance with national policy.

5.5.2 Public health-related measures

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Identify the range of non-pharmaceutical interventions that might be recommended and develop protocols and communications to support their implementation.
- Develop a framework to facilitate decision-making for activation and de-escalation of specific measures, such as school closures or cancellation or restriction of mass gatherings based on appropriate risk assessment criteria.
- Plan for actions relating to temporary recommendations issued under IHR (2005), especially measures to slow the spread of disease.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Assess and determine whether cancellation, restriction or modification of mass gatherings is indicated.
- Implement social distancing measures, as indicated in national plans, such as school closures and other societal-level disease control measures including adjusted working patterns.

Recovery activities to be considered

Based on national/local risk assessments, resources and needs:

- Conduct a thorough evaluation of the effectiveness of the individual, household and societal measures implemented and update guidelines, protocols and algorithms accordingly.

5.6 Community capacities

Preparedness activities to be considered

Based on national/local risk assessments, resources and needs:

- Develop guidance and plans to provide necessary support for prevention, treatment and infection prevention and control for ill persons isolated at home and their household contacts.
- Develop plans and mechanisms to enable increased access to treatment and care for community members.
- Develop public health education campaigns, including creating messages and feedback mechanisms targeted towards hard-to-reach, disadvantaged or minority groups.

Response activities to be considered

Based on national/local risk assessments, resources and needs:

- Initiate public health education campaigns in coordination with other relevant authorities on individual-level infection control measures.
- Implement appropriate individual/household medical and non-medical disease control measures for suspect cases and their contacts in households.
- Advise household contacts to minimize their level of interaction outside the home and to isolate themselves at the first symptoms of influenza.
- Advise individuals to stay home when ill.
- Provide infection control guidance for household caregivers taking into account relevant WHO guidance.

Recovery activities to be considered

Based on national/local risk assessments, resources and needs:

- As needed, provide psychosocial services to facilitate individual and community-level recovery.

References

1. Implementation of the International Health Regulations (2005). Report of the Review Committee on the Functioning of the International Health Regulations (2005) in Relation to Pandemic (H1N1) 2009. Geneva, World Health Organization, 2011. (Available at: http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf, accessed February 2013.)
2. *International Health Regulations* (2005). Geneva, World Health Organization, 2008. (Available at: http://www.who.int/ihr/en/, accessed February 2013.)
3. Resolution WHA56.19. *Prevention and control of influenza pandemics and annual epidemics*. Geneva, World Health Assembly, 2003. (Available at: http://apps.who.int/gb/archive/pdf_files/WHA56/ea56r19.pdf, accessed April 2013.)
4. Resolution WHA58.5. *Strengthening pandemic influenza preparedness and response*. Geneva, World Health Assembly, 2005. (Available at: https://apps.who.int/gb/ebwha/pdf_files/WHA58/WHA58_5-en.pdf, accessed April 2013.)
5. *Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits*. Geneva, World Health Organization, 2011. (Available at: http://www.who.int/entity/influenza/resources/pip_framework/en/index.html, accessed February 2013.)
6. Influenza vaccine viruses and reagents http://www.who.int/influenza/vaccines/virus/en/, accessed May 2013.
7. *Risk reduction and emergency preparedness – WHO six-year strategy for the health sector and community capacity development*. Geneva, World Health Organization, 2007. (Available at: http://www.who.int/entity/hac/techguidance/preparedness/emergency_preparedness_eng.pdf, accessed February 2013.)
8. Hine D. *The 2009 influenza pandemic – an independent review of the UK response to the 2009 influenza pandemic*. London, Cabinet Office, 2010. (Available at: http://www.cabinetoffice.gov.uk/sites/default/files/resources/the2009influenzapandemic-review.pdf, accessed February 2013.)
9. *Ethical considerations in developing a public health response to pandemic influenza*. Geneva, World Health Organization, 2007. (Available at: http://www.who.int/csr/resources/publications/WHO_CDS_EPR_GIP_2007_2c.pdf, accessed February 2013.)
10. *IHR (2005): Introduction to and toolkits for implementation in national legislation*, available at: http://www.who.int/ihr/legal_issues/legislation/en/index.html, accessed February 2013.
11. *Global Action Plan for Influenza Vaccines*, available at: http://www.who.int/influenza_vaccines_plan/en/, accessed February 2013.
12. *Current WHO Model List of Essential Medicines*, available at: http://www.who.int/entity/medicines/publications/essentialmedicines/en/index.html, accessed February 2013.
13. *Prequalification programme – a United Nations Programme managed by WHO*, available at: http://apps.who.int/prequal/default.htm, accessed February 2013.

14. *Communication for behavioural impact (COMBI) – a toolkit for behavioural and social communication in outbreak response*. Geneva, World Health Organization, 2012. (Available at: http://apps.who.int/iris/bitstream/10665/75170/1/WHO_HSE_GCR_2012.13_eng.pdf, accessed February 2013.)

15. *Capacity building activities during pandemic influenza*. Geneva, World Health Organization, 2010. (Available at: http://whqlibdoc.who.int/hq/2010/WHO_HSE_GIP_ITP_2011.1_eng.pdf, accessed April 2013.)

16. *Infection prevention and control during health care for confirmed, probable, or suspected cases of pandemic (H1N1) 2009 virus infection and influenza-like illnesses*. Geneva, World Health Organization, 2009. (Available at: http://www.who.int/csr/resources/publications/cp150_2009_1612_ipc_interim_guidance_h1n1.pdf, accessed February 2013.)

17. *Guidance on Development and Implementation of a National Deployment and Vaccination Plan for Pandemic Influenza Vaccines*. Geneva, World Health Organization, 2012. (Available at: http://apps.who.int/iris/bitstream/10665/75246/1/9789241503990_eng.pdf, accessed April 2013.)

18. *Behavioural interventions for reducing the transmission and impact of influenza A(H1N1) virus: a framework for communication strategies*. Geneva, World Health Organization, 2009. (Available at: http://www.who.int/csr/resources/publications/swineflu/framework_20090626_en.pdf, accessed February 2013.)

19. *Outbreak communication planning guide*. Geneva, World Health Organization, 2008. (Available at: http://www.who.int/ihr/elibrary/WHOOutbreakCommsPlanngGuide.pdf, accessed February 2013.)

20. *Rapid risk assessment of acute public health events*. Geneva, World Health Organization, 2012. (Available at: http://www.who.int/csr/resources/publications/HSE_GAR_ARO_2012_1/en/, accessed February 2013.)

21. *Use of influenza rapid diagnostic tests*. Geneva, World Health Organization, 2009. (Available at: http://whqlibdoc.who.int/publications/2010/9789241599283_eng.pdf, accessed February 2013.)

22. *Toolkit for assessing health-system capacity for crisis management*. Copenhagen, WHO Regional Office for Europe, 2012. (Available at: http://www.euro.who.int/__data/assets/pdf_file/0008/157886/e96187.pdf, accessed February 2013.)

23. *Scaling-up the community-based health workforce for emergencies*. Joint Statement by the Global Health Workforce Alliance, WHO, IFRC, UNICEF, UNHCR, 2011. (Available at: http://www.who.int/workforcealliance/knowledge/resources/chwstatement/en/index.html, accessed February 2013.)

24. *Global Health Workforce Alliance: Community health workers*, available at: http://www.who.int/workforcealliance/knowledge/themes/community/en/index.html, accessed February 2013.

25. *Community case management during an influenza outbreak – a training package for community health workers*. Geneva, World Health Organization, 2011. (Available at: http://www.who.int/influenza/resources/documents/community_case_management_flipbook/en/index.html, accessed February 2013.)

26. *Pandemics of the 20th–21st centuries*. Stockholm, European Centre for Disease Prevention and Control. (Available at: http://ecdc.europa.eu/en/healthtopics/pandemic_preparedness/basic_facts/Pages/historical_pandemics.aspx, accessed April 2013.)

27. Vynnycky E, Trindall A, Mangtani P. Estimates of the reproduction numbers of Spanish influenza using morbidity data. *International Journal of Epidemiology*, 2007, 36(4):881–889.

28. Jackson C, Vynnycky E, Mangtani P. Estimates of the transmissibility of the 1918 (Hong Kong) influenza pandemic: evidence of increased transmissibility between successive waves. *American Journal of Epidemiology*, 2010, 171(4):465–478.

29. Miller MA et al. The signature features of influenza pandemics – implications for policy. *New England Journal of Medicine*, 2009, 360:2595–2598.

30. Taubenberger JK, Morens DM. 1918 influenza: the mother of all pandemics. *Emerging Infectious Diseases*, 2006, 12(1):15–22.

31. Fraser, C et al. Pandemic potential of a strain of Influenza A (H1N1): Early Findings. *Science* 2009, 324(5934):1557-1561

32. Van Kerkhove MD et al. H1N1pdm serology working group. Estimating age specific cumulative incidence for the 2009 influenza pandemic: a meta-analysis of A(H1N1) pdm09 serological studies from 19 countries. *Influenza and Other Respiratory Viruses*, 2013, Jan 21. doi: 10.1111/irv.12074. [Epub ahead of print].

33. Dawood FS et al. Estimated global mortality associated with the first 12 months of 2009 pandemic influenza a H1N1 virus circulation: a modelling study. *Lancet Infectious Diseases*, 2012, 12(9):687–695.

35. *Risk management – risk assessment techniques*. ISO/IEC 31010:2009. Geneva, International Organization for Standardization, 2009.

36. WHO Influenza at the Human-Animal Interface (HAI) at: http://www.who.int/influenza/human_animal_interface/en/, accessed May 2013.

37. WHO Influenza surveillance and monitoring at: http://www.who.int/influenza/surveillance_monitoring/en/, accessed April 2013.

38. Ejima K et al. The time required to estimate the case fatality ratio of influenza using only the tip of an iceberg: joint estimation of the virulence and the transmission potential. *Computational and Mathematical Methods in Medicine*, 2012, 2012:978901.

39. Garske T et al. Assessing the severity of the novel influenza A/H1N1 pandemic. *British Medical Journal*, 2009, 339:b2840.

40. Van Kerkhove MD et al. Risk factors for severe outcomes following 2009 influenza A (H1N1) infection: a global pooled analysis. *PLoS Medicine*, 2011, 8(7):e1001053.

41. *Lessons learned review – Public Health Agency of Canada and Health Canada response to the 2009 H1N1 pandemic*. Ottawa, Public Health Agency of Canada and Health Canada, 2010. (Available at: http://www.phac-aspc.gc.ca/about_apropos/evaluation/reports-rapports/2010-2011/h1n1/pdf/h1n1-eng.pdf, accessed February 2013.)

42. *A guide for conducting table-top exercises for national influenza pandemic preparedness*. New Delhi, World Health Organization Regional Office for South-East Asia, 2006. (Available at: http://www.searo.who.int/entity/emerging_diseases/documents/SEA_CD_156/en/index.html, accessed February 2013.)

43. *Manual for the laboratory diagnosis and virological surveillance of influenza*. Geneva, World Health Organization, 2011. (Available at: http://whqlibdoc.who.int/publications/2011/9789241548090_eng.pdf, accessed February 2013.)

44. *Recommendations and laboratory procedures for detection of avian influenza A(H5N1) virus in specimens from suspected human cases*. Geneva, World Health Organization, 2007. (Available at: http://www.who.int/influenza/resources/documents/h5n1_laboratory_procedures/en/index.html, accessed February 2013.)

45. *Clinical management of adult patients with complications of pandemic influenza A (H1N1) 2009: emergency guidelines for management of patients with severe respiratory distress and shock in district hospitals in limited-resource settings*. Geneva, World Health Organization, 2010. (Available at: http://whqlibdoc.who.int/publications/2010/9789241599610_eng.pdf, accessed February 2013.)

46. *Whole-of-society pandemic readiness – WHO guidelines for pandemic preparedness and response in the non-health sector*. Geneva, World Health Organization, 2009. (Available at: http://www.who.int/entity/influenza/preparedness/pandemic/2009-0808_wos_pandemic_readiness_final.pdf, accessed February 2013.)

47. *Recommendations for good practice in pandemic preparedness – identified through evaluation of the response to pandemic (H1N1) 2009*. Copenhagen, World Health Organization Regional Office for Europe, 2010. (Available at: http://www.euro.who.int/en/what-we-do/health-topics/communicable-diseases/influenza/publications/2010/recommendations-for-good-practice-in-pandemic-preparedness-identified-through-evaluation-of-the-response-to-pandemic-h1n1-2009, accessed February 2013.)

48. *Avian influenza and the pandemic threat, UN response*, available at: http://www.un-influenza.org/content/un-response, accessed February 2013.

49. *UN system and partners consolidated action plan for animal and human influenza, revision July 2011*. (available at: http://un-influenza.org/files/UNCAPAHI-June2011.pdf, accessed February 2013).

50. *United Nations medical directors influenza pandemic guidelines, October 2011*. (available at: http://un-influenza.org/files/RevisedPandemicGuidelines_Oct2011.pdf, accessed February 2013.)

51. WHO Collaborating Centre for Pandemic Influenza and Research, University of Nottingham, Unpublished observations 2013.

52. Longini IM et al. Containing pandemic influenza at the source. *Science*, 2005, 309:1083–1087.

53. Ferguson NM et al. Strategies for mitigating an influenza pandemic. *Nature*, 2006, 442:448–452.

Annexes

Annex 1. Guidance revision process

The content of this WHO guidance document, *Pandemic influenza risk management*, has been largely based on *Pandemic influenza preparedness and response: a WHO guidance document*, which was published in 2009. The draft content was reviewed by a WHO Internal Steering Committee, comprising technical experts in influenza, multisectoral collaboration for influenza, risk management, event management, communications, influenza at the human–animal ecosystem interface, antivirals, vaccine research and emergency risk management for health, and assessed for relevance and continued applicability to the risk management of pandemic influenza.

Throughout the revision process, the Internal Steering Committee met four times, with significant e-mail correspondence between meetings. Members of the Internal Steering Committee were invited to provide inputs and updates to relevant sections of the document, according to their expertise.

During 11–12 April 2013, an external Peer Review Group meeting was convened to: (1) consider the revised guidance in relation to emergency risk management for health as well as recommendations from the report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009; and (2) provide feedback, comment and input on the draft guidance.

The peer reviewers' comments were noted, and taken into account in a revised draft of the document. The revised draft was sent to the peer reviewers for acknowledgement of the changes requested and inclusion of additional comments, then finalized for Member State engagement.

Declaration of interests

All external peer reviewers acknowledged herein completed and submitted a WHO Declaration of Interest for WHO Experts form. These declarations of interest were assessed and presented to the Peer Review Group meeting. The Chair of the Peer Review Group formally declared no interests. Of the 16 other external peer reviewers who participated in the review of this guidance document, three declared interests. The peer reviewers with declared interests are listed below, together with a short description of the interests concerned.

Peer reviewers with declared interests

Dr Nick Phin

At the time of the Peer Review Group meeting, Dr Nick Phin was about to undertake a retrospective review of clinical and safety data on patients given aqueous zanamivir during the influenza A(H1N1) 2009 pandemic and the 2010–2011 influenza season as part of the compassionate use programme. The research is being led by Public Health England with some sponsorship from GlaxoSmithKline. This sponsorship consists of £25 000 for a short-term researcher post and £25 000 to reimburse the resources used by hospitals to identify and provide the data. As the review is retrospective and there is no specific information on the use of medicines included in this project, no conflict of interest was determined.

Professor Lone Simonsen

In 2011, Professor Simonsen provided consulting services in the area of influenza and respiratory syncytial virus disease burden modelling and methodological issues with observational study designs to GlaxoSmithKline and BioCryst for US$ 10 000 and in 2012 received less than US$ 5000 to participate in expert panels for GlaxoSmithKline, Merck, AstraZeneca and Novartis. As no specific information on burden modelling is included in this guidance, no conflict of interest was determined.

Dr Benjamin Cowling

Dr Benjamin Cowling was paid US$ 2000 for consultation work on influenza treatment and prevention strategies for Crucell NV in 2012. He was also the principal investigator and account-holder for an investigator-initiated trial of influenza vaccine supported by significant funding from MedImmune in 2009–2010. This was vaccine-specific research. As there are some references to vaccines and vaccine policy throughout this guidance, it was felt this research could constitute a conflict of interest and therefore Dr Cowling was excluded from discussions on vaccine-related issues.

Annex 2. Planning assumptions

Planning for a future influenza pandemic is challenging in part because important features of the next pandemic are not known. In this situation, assumptions relating to the epidemiology of influenza are needed to make decisions in public health planning, as well as estimating required resources.

This Annex provides some planning assumptions to be considered by national authorities in developing a pandemic influenza risk management strategy. These assumptions are based on information known at the time of publication about seasonal influenza, avian influenza and past influenza pandemics. These data should not be taken as predictive of features of the next pandemic. The characteristics and impacts of past pandemics have varied between and within countries. These differences are most likely attributable to both the characteristics of the pandemic virus and the local ability to respond to the disease.

It is not the intention of this Annex to provide a comprehensive review of the epidemiology of influenza. However, it will be updated as new scientific data become available that significantly change these assumptions. Key references are provided for readers to review the existing literature.

A2.1 Modes of transmission

Assumptions

Modes of virus transmission of pandemic influenza are expected to be similar to those of seasonal influenza: via the large droplet or contact (either direct or indirect) route, with a contribution by particle airborne route, or a combination of both.

The relative contribution and clinical importance of potentially different modes of transmission of influenza are unknown. However, epidemiological patterns suggest that the spread of the virus is mostly through close contact via the droplet or contact route.

Implications

- To decrease viral transmission, good hand hygiene, isolation of ill people and the use of personal protective equipment are important measures when caring for people with influenza.
- An airborne precaution room is not indicated for routine care. However, health-care workers should wear eye protection, a gown, clean non-sterile gloves and particulate respirators during aerosol-generating procedures.

Scientific basis

- Droplet and contact transmission appear to be major routes of transmission for seasonal influenza (Brankston G et al, 2007; Bridges CB et al, 2003).
- However, data are insufficient to determine the relative importance of the different modes of transmission. In addition, there is lack of standardization and consensus about the technical definition (i.e. particle size) of an aerosol versus a droplet (Tellier R, 2006; Lemieux C et al, 2007, Lindsley W, 2012).
- Relative heat and humidity affect the efficiency of transmission of influenza via aerosol. (Hanley BP, 2010). Some have reported the lack of aerosol transmission at 30 °C, while transmission via the contact route was equally efficient at 30 °C and 20 °C. (Lowen AC et al, 2007; Lowen AC et al, 2008).
- Certain procedures performed in health-care settings can create aerosols. Some of these procedures have been associated with a significant increase in the risk of disease transmission and have been termed “aerosol-generating procedures associated with pathogen trans-

mission" (WHO, 2007). These procedures include intubation, cardiopulmonary resuscitation, bronchoscopy, autopsy and surgery where high-speed devices are used (WHO, 2007).

Selected references

Brankston G et al. Transmission of influenza A in human beings. *Lancet Infectious Diseases*, 2007, 7(4):257–265.

Bridges CB, Kuehnert MJ, Hal CB. Transmission of influenza: implications for control in health care settings. *Clinical Infectious Diseases*, 2003, 37:1094–1101.

Hanley BP, Borup, B. Aerosol influenza transmission risk contours: A study of humid tropics versus winter temperate zone. *Virology Journal*, 2010, 7:98.

Lemieux C et al. Questioning aerosol transmission of influenza. *Emerging Infectious Diseases*, 2007, 13(1):173–174.

Lindsley WG et al. Quantity and size distribution of cough-generated aerosol particles produced by influenza patients during and after illness. *Journal of Occupational and Environmental Hygiene*, 2012, 9:443–449.

Lowen AC et al. Influenza virus transmission is dependent on relative humidity and temperature. *PLoS Pathogens*, 2007, 3(10):1470–1476.

Lowen AC et al. High temperature (30 degrees C) blocks aerosol but not contact transmission of influenza virus. *Journal of Virology*, 2008, 82(11):5650–5652.

Tang JW et al. Factors involved in the aerosol transmission of infection and control of ventilation in health-care premises. *Journal of Hospital Infection*, 2006, 64(2):100–114.

Tellier R. Review of aerosol transmission of influenza A virus. *Emerging Infectious Diseases*, 2006, 12(11):1657–1662.

Infection prevention and control of epidemic- and pandemic-prone acute respiratory diseases in health care – WHO interim guidelines. Geneva, World Health Organization, 2007. (Available at: http://www.who.int/csr/resources/publications/WHO_CDS_EPR_2007_6c.pdf, accessed February 2013.)

A2.2 Incubation period and infectivity of pandemic influenza

Assumptions

- Incubation period: 1–3 days.
- Latent period: 0.5–2 days.
- Duration of infectiousness: about 5 days in adults and possibly longer in children.
- Basic reproduction number (R0): 1.1–2.0.

Implications

- The incubation period and the duration of infectiousness are useful for planning purposes with regard to: length of isolation for cases; development of a definition for contacts of cases; and the length of quarantine for contacts.
- A relatively short incubation period would make it difficult to stop the spread of pandemic influenza by contact tracing and quarantine.
- Viral shedding before symptoms develop would make it difficult to stop the spread of pandemic influenza solely by screening and isolating clinically ill persons.

- Once the pandemic begins, it will be important for countries to undertake surveillance and special studies to assess the incubation period and the duration of infectiousness of the pandemic virus.

Scientific basis

- An early study using Australian maritime statistics suggested that the mean incubation period of the 1918 pandemic influenza was 32.71 hours (1.4 days). (McKendrick and Morison as reviewed by Nishiura, 2007).
- A meta-analysis of 56 volunteer studies (Carrat et al, 2008) found that:
  - an increase in the average total symptoms score was noted by day 1 after inoculation, total scores peaked by day 2 and returned to baseline values by day 8;
  - viral shedding increased sharply between 0.5 and 1 day after challenge and consistently peaked on day 2 (mean generation time 2.5 days) and the average duration of viral shedding was 4.8 days;
  - viral shedding curves and total symptom score curves showed similar shapes, although viral shedding preceded illness by 1 day.
- Longer durations of viral shedding are not rare. As reviewed by Carrat et al, in one study subgroup, five participants (20%) shed influenza B virus 8 days after inoculation, while another study also reported 9 days of shedding for influenza A(H3N2).
- Reasonable estimates of the basic reproduction number (R0): for past pandemic viruses as well as seasonal influenza viruses converge between 1.5 and 2.0 (Ferguson NM et al, 2005; Ferguson NM et al, 2006; Colliza V et al, 2007; Vynnycky E et al, 2007) and for A(H1N1)2009 ranged from 1.1-1-8 (Fraser et al, 2009; Lessler et al, 2010; Opatowski, et al 2011).
- The incubation period of influenza A(H5N1) human cases (7 days or fewer; mostly 2–5 days) appears to be longer than that of seasonal influenza. In clusters in which limited human-to-human transmission has probably occurred, the incubation period appears to be approximately 3–5 days, although in one cluster it was estimated to be 8–9 days (WHO writing committee, 2008).
- Patients with influenza A(H5N1) disease may have detectable viral RNA in the respiratory tract for up to three weeks; data, however, are limited. (Reviewed by WHO writing committee, 2008; and Gambotto et al, 2007).

Selected references

- Carrat F et al. Time lines of infection and disease in human influenza: a review of volunteer challenge studies. *American Journal of Epidemiology*, 2008, 167:775–785.
- Colliza V et al. Modelling the worldwide spread of pandemic influenza: baseline case and containment interventions. *PLoS Medicine*, 2007, 4(1):95-110.
- Ferguson NM et al. Strategies for containing an emerging influenza pandemic in Southeast Asia. *Nature*, 2005, 437(8):209–214.
- Ferguson NM et al. Strategies for mitigating an influenza pandemic. *Nature*, 2006, 442:448–452.
- Fraser C et al. Pandemic potential of a strain of influenza A(H1N1): Early findings. *Science* 2009, 324:1557–1561.
- Gambotto A et al. Human infection with highly pathogenic H5N1 influenza virus. *Lancet*, 2007, 371:1464–1475.
- Lessler J et al. H1N1pdm in the Americas. *Epidemics* 2010 2:132–138.

- Nishiura H. Early efforts in modeling the incubation period of infectious diseases with an acute course of illness. *Emerging Themes in Epidemiology*, 2007, 4:2.
- Opatowski L et al. Transmission characteristics of the 2009 H1N1 influenza pandemic: comparison of 8 Southern hemisphere countries. *PloS pathogens* 2011, 7(9):e1002225.
- Vynnycky E, Trindall A, Mangtani P. Estimates of the reproduction numbers of Spanish influenza using morbidity data. *International Journal of Epidemiology*. 2007, 36:881–889.
- Writing committee of the second WHO consultation on clinical aspect of human infection with avian influenza A(H5N1) virus. Update on avian influenza A (H5N1) virus infection in humans. *New England Journal of Medicine*, 2008, 358:261–273.

A2.3 Symptom development and clinical attack rate

Assumptions

- About two-thirds of people with pandemic influenza are expected to develop clinical symptoms.
- Uncomplicated clinical symptoms of pandemic influenza are expected to be similar to those of seasonal influenza: respiratory symptoms; fever and abrupt onset of muscle ache and headache or backache.
- Averaged overall (across all age groups), population clinical attack rates are expected to be 25% to 45%.

Implications

- Existing clinical criteria for influenza-like illness can serve as the basis for pandemic disease surveillance. However, countries are encouraged to monitor closely the evolution of clinical characteristics of pandemic influenza and to facilitate refinement of a clinical case definition.
- Since clinical presentations of influenza are usually nonspecific, pandemic surveillance should be supported by laboratory diagnosis. This step is critical to confirm and describe comprehensively the first cases in each country.
- Because the number of ill persons may overwhelm existing health-care capacities, countries should plan for rapid scale up of health-care capacity and prioritization of limited resources.
- Wide variations in clinical attack rates among different age groups and localities have been observed with previous pandemics. Countries are encouraged to estimate clinical attack rates based on their own data and experiences.

Scientific basis

- A pooled analysis of 522 persons who were voluntarily infected with influenza reported the proportion of symptomatic infection (any symptoms) as 66.9% (95% CI: 58.3, 74.5). No significant differences were noted according to the virus type or the initial infectious dose (Carrat et al, 2008).
- A modelling study using 1957 pandemic data from the United Kingdom estimated that 60–65% of infected individuals experienced clinical symptoms (Vynnycky E et al, 2008).
- An analysis of an influenza outbreak experience in an isolated island, Tristin da Cunha, in 1971 suggested that almost all susceptible persons developed symptomatic illness (Mathews JD et al, 2007).
- During the 1918 pandemic in the United States of America, influenza-like illness rates averaged 28%, with a low of 15% and a high of 50% (Frost WH, 1919). These data were derived from house-to-house surveys.

- In one report, age-specific serological attack rates for the 1957 pandemic averaged 40%, with a low of 5% and a high of 70%. In contrast, a 20% serological attack rate was reported for the 1968 pandemic (Stuart-Harris CH, 1970).
- A retrospective questionnaire survey from one USA city revealed the overall clinical attack rate during the 1968 pandemic was 39%; and it was similar among all age groups (Davis LE et al, 1970). Another serological survey found that about 25% (range of 21% to 27%) of children tested positive for antibodies to the influenza strain that circulated in 1968 (Chin J et al, 1974).
- Clinical attack rates calculated from an estimated basic reproduction number (R0): between 1.5 and 2.0; range from approximately 25% to 45% (Ferguson NM et al, 2005; Ferguson NM et al, 2006; Germann TC et al, 2006; Colliza V et al, 2007; Halloran ME et al, 2008).
- Clinical attack rates from A(H1N1)pdm 2009 were estimated to be 7% to 15% (Fraser C et al, 2009) with a secondary attack rate from 7–13% (Cauchemez S et al, 2009, WHO writing group 2009).
- Gastrointestinal symptoms have been observed among patients with influenza A(H5N1) but have varied by clades (WHO writing committee, 2008).

Selected references

Cauchemez S et al. Household transmission of 2009 Pandemic Influenza A(H1N1) Virus in the United States *New England Journal of Medicine* 2009, 361:2619-2627.

Frost WH. The epidemiology of influenza. Public Health Reports, 1919, 34(33). Republished in *Public Health Reports*, 2006, 121(S1):149–158.

Stuart-Harris CH. Pandemic influenza: an unresolved problem in prevention. *Journal of Infectious Diseases*, 1970, 122:108–115.

Davis LE, Caldwell GG, Lynch RE. Hong Kong influenza: the epidemiologic features of a high school family study analysed and compared with a similar study during the 1957 Asian influenza epidemic. *American Journal of Epidemiology*, 1970, 92:240–247.

Chin J, Magoffin RL, Lennette EH. The epidemiology of influenza in California, 1968–1973. *Western Journal of Medicine*, 1974, 121:94–99.

Germann TC et al. Mitigation strategies for pandemic influenza in the United States. *Proceedings of the National Academy of Sciences of the United States of America*, 2006, 103(15):5935–5940.

Halloran ME et al. Modeling targeted layered containment of an influenza pandemic in the United States. *Proceedings of the National Academy of Sciences of the United States of America,* 2008, 105(12):4639–4644.

Mathews JD et al. A biological model for influenza transmission: pandemic planning implication of asymptomatic infection and immunity. *PLoS ONE*, 2007, 2(11):e1220.

WHO Writing Group. Transmission dynamics and impact of pandemic influenza A(H1N1) 2009 virus. *Weekly Epidemiological Record* 2009, 46:481-484.

Vynnycky E, Edmunds WJ. Analyses of the 1957 (Asian) influenza pandemic in the United Kingdom and the impact of school closures. *Epidemiology and Infection*, 2008, 136(2):166–179.

A2.4 Dynamics and impact of a pandemic

Assumptions

- An influenza pandemic can begin at any time of the year and in any place in the world; it is expected to spread to the rest of the world within several weeks or months.
- The duration of a pandemic wave is expected to be from several weeks to a few months but will likely vary from country to country; within a single country, variations may be seen by community.
- Most communities are expected to experience multiple waves of different magnitudes of a pandemic.
- Increased hospitalizations, excess mortality and secondary complications are expected to vary widely among countries and communities. Vulnerable populations are expected to be affected more severely.
- Workplace absenteeism is expected to be higher than the estimated clinical attack rate.

Implications

- Each county should develop and strengthen its capacity to detect the early emergence of a potential pandemic event and to respond rapidly.
- Countries should guide their local governments and communities to develop their own pandemic influenza risk management plans.
- Actions during the post-peak periods between pandemic waves should be considered in overall pandemic risk management plans.
- Countries are encouraged to further estimate and prepare health-care needs based on their own resources and experiences, with particular concern to vulnerable populations.
- In a series of waves as experienced with 20th century pandemics, an early wave may lead to depletion of stocks of consumables, such as personal protective equipment and pharmaceuticals, before later waves.
- Countries are encouraged to further estimate excess workplace absenteeism during a pandemic based on their own contexts and to guide all sectors to develop business continuity plans for high and possibly fluctuating levels of absenteeism throughout the pandemic.

Scientific basis

- Early reports and later analysis of epidemiological evidence suggest that milder epidemic waves (in Europe in April and May, 1918 and in the USA in the (Northern Hemisphere) Spring of 1918 preceded the most severe pandemic wave in (Northern Hemisphere) Autumn 1918 (Frost WH, 1919; Olson SR et al, 2005).
- A review of data from the North Denmark region indicated three waves with the third in December 2010-January 2011 being the most severe (Orsted et al, 2013)
- An influenza virus A(H1N1) resistant to oseltamivir was first reported from Norway in January 2008 and then spread throughout much of the Northern Hemisphere during the next two months (WHO, 2008). It was subsequently detected in the Southern Hemisphere during the influenza season of 2008.
- Excess mortality data from 1918–1920 show that population mortality varied more than 30-fold across countries (Murray CL et al, 2006).
- Variation among countries ranged from a low of 0.20% (Denmark) to a high of 4.39% (India).

- Variation within countries ranged from 2.12% to 7.82% in India and from 0.25% to 1.00% in the USA.
- During the 1918 pandemic in the United States of America, there were marked and consistent differences in morbidity and mortality among persons of different economic status: the lower the economic level, the higher the attack rate. This relationship persisted even after adjustments were made for factors such as race, sex, age and other conditions (Sydenstricker E, 1931).
- A multinational analysis of the 1968 pandemic showed very different epidemic patterns in the six countries studied (Viboud C et al, 2005).
  - In the USA, a large epidemic was observed in 1968–1969, followed by a milder wave in 1969–1970, late in the winter season.
  - In Canada, the two epidemic patterns were similar in amplitude and timing.
  - In other countries (Australia, France, the United Kingdom and Japan), the first epidemic was mild, followed by a much more intense epidemic in the next season.
- A simulation study in the United Kingdom estimated that, overall, about 16% of the workforce is likely to be absent due to school closures during a pandemic. This estimate rises for sectors with a high proportion of female employees, such as health and social care (Sadique MZ et al, 2008).

Selected references

- Cockburn WC, Delon PJ, Ferreira W. Origin and progress of the 1968–69 Hong Kong influenza epidemic. *Bulletin of the World Health Organization*, 1969, 41:345–348.
- Murray CL et al. Estimation of potential global pandemic influenza mortality on the basis of vital registry data from the 1918–20 pandemic: a quantitative analysis. *Lancet*, 2006, 368:2211–2218.
- Olson DR et al. Epidemiological evidence of an early wave of the 1918 influenza pandemic in New York City. *Proceedings of the National Academy of Sciences of the United States of America*, 2005, 102(31):11059–11063.
- Orsted I et al. The first, second and third wave of pandemic influenza A (H1N1)pdm in North Denmark Region 2009–2011: A population based study of hospitalizations. *Influenza and other Respiratory Viruses*, 2013, Feb 9 2013, DOI: 10.1111/irv.12093.
- Sadique MZ, Adams EJ, Edmunds WJ. Estimating the costs of school closure for mitigating an influenza pandemic. *BioMed Central Public Health*, 2008, 8:135.
- Sydenstricker E. The incidence of influenza among persons of different economic status during the epidemic of 1918. Public Health Reports, 1931, 46(4). Republished in *Public Health Reports*, 2006, 121(S1):191–204.
- Viboud C et al. Multinational impact of the 1968 Hong Kong influenza pandemic: evidence for a smoldering pandemic. *Journal of Infectious Diseases*, 2005, 192:233–248.
- WHO expert committee on respiratory virus diseases. First Report. WHO Technical Report Series No 170. Geneva, World Health Organization, 1959.
- Influenza A (H1N1) virus resistance to oseltamivir: preliminary summary and future plans. Geneva, World Health Organization, 2008. (Available at: http://www.who.int/influenza/patient_care/antivirals/oseltamivir_summary/en/, accessed April 2013.)

Annex 3. Ethical considerations

Preparedness planning for an influenza pandemic involves balancing potentially conflicting individual and community interests (*9*). In emergency situations, the enjoyment of individual human rights and civil liberties may have to be limited in the public interest. However, efforts to protect individual rights should be part of any policy. Measures that limit individual rights and civil liberties must be necessary, reasonable, proportional, equitable, non-discriminatory and in full compliance with national and international laws.

Ethics do not provide a prescribed set of policies; rather, ethical considerations will be shaped by the local context and cultural values. The principles of equity, utility/efficiency, liberty, reciprocity and solidarity are especially helpful in the context of influenza pandemic preparedness planning.

For example, the principle of utility suggests that resources should be used to provide the maximum possible health benefits, often understood as "saving most lives". Utility considerations include the following:

For individual benefit:

- the likelihood that an individual with pandemic influenza disease will experience a medical benefit if provided antiviral or adjuvant treatment;
- the likelihood that an individual at risk of infection will become infected/ill if influenza-specific antiviral prophylaxis is not provided.

For community benefit:

- the likelihood that an infected individual will infect other persons if not given access to antivirals (for treatment or prophylaxis) and infection control measures;
- the overall reduction in disease burden expected to result from the intervention;
- the potential value of giving priority to:
  - essential health-care workers,
  - other workers who provide life-saving services,
  - workers who provide critical services necessary for society to function as normally as possible; such policies should be developed with great care, given the danger that decisions favouring certain categories of workers may be perceived as unfair and undermine public trust.

Another important principle, which may sometimes conflict with utility considerations, is equity. Considerations of equity in use of antivirals may lead to giving priority to:

- the worst-off (in terms of severity of illness);
- vulnerable and disabled populations;
- uninfected persons who are at high risk of developing severe complications and death if they become infected.

Regardless of the criteria selected to govern the allocation of therapeutic and preventive measures, certain basic elements will be important in all plans; for example, those which:

- Facilitate access to the highest level of treatment possible given available resources, with careful attention to the needs of all populations.
- Provide health-care workers with clear and transparent screening and treatment protocols in line with the latest guidance from WHO or relevant national health authorities.

- Incorporate mechanisms that:
  - ensure that the guidelines and protocols are followed;
  - enable health-care workers to inform health authorities when clinical experience suggests the need for revisions of protocols;
  - enable health-care workers to (1) take part in the process of updating guidelines and protocols as the pandemic progresses, and (2) propose prioritization criteria for maintenance of a functioning health-care system in a crisis situation;
  - ensure a fair balance of treatment for pandemic influenza patients and patients with other serious conditions;
  - enable prioritization protocols for non-influenza patients and their access to the general health-care infrastructure;
  - identify the pandemic influenza patients who will receive hospital-based versus home-based care and criteria for early discharge (potentially even if still infectious).

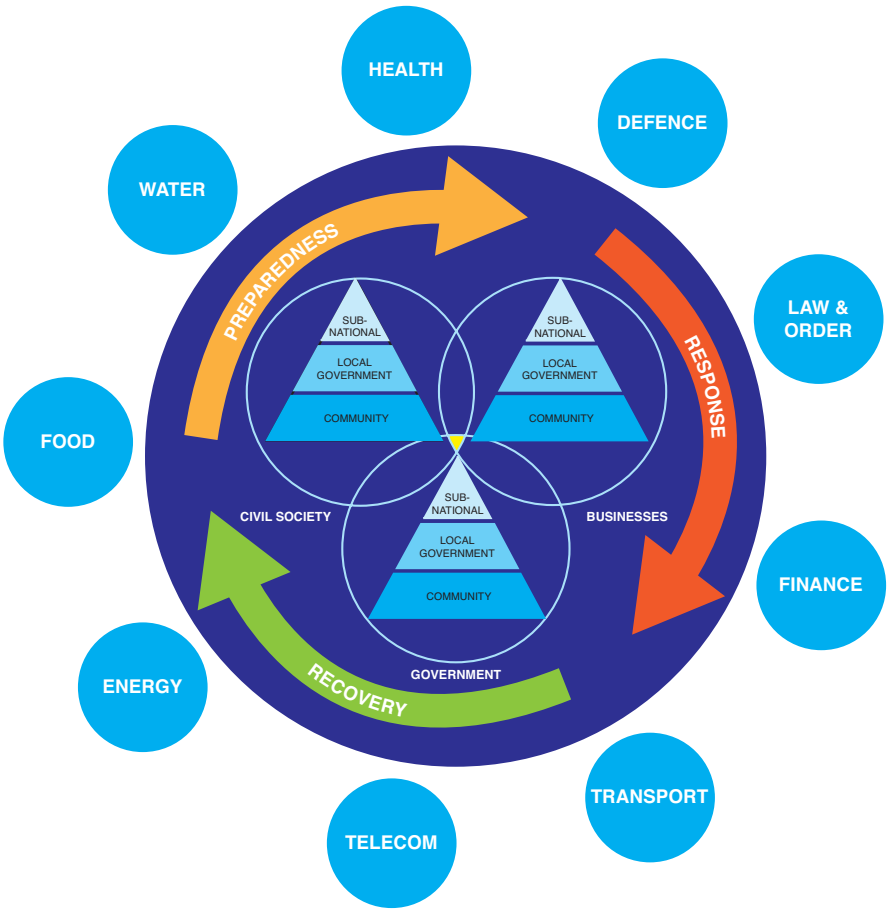
As part of pandemic influenza planning, policy-makers are encouraged to establish a fair process for setting priorities and promoting equitable access to services and supplies that: (1) involves civil society and other major stakeholders in the decision-making process so that decisions about the criteria to be used in allocating scarce resources are made in an open, transparent and inclusive manner and (2) incorporates clear, pre-established mechanisms for revising decisions based on new evidence when appropriate. An open, trusted process will strengthen solidarity and enhance the whole-of-society approach to pandemic risk management.

Annex 4. Whole-of-society approach

An influenza pandemic will test the resilience of nations, businesses, and communities, depending on their capacity to respond. No single agency or organization can prepare for a pandemic on its own. Inadequate or uncoordinated preparedness of interdependent public and private organizations will reduce the ability of the health sector to respond during a pandemic. A comprehensive approach to pandemic risk management is required.

As illustrated in F**igure 4**, the whole-of-society approach encompasses three major groups in society – governments, business and civil society – at the global, national, subnational, local and community levels. The nine circles around the disaster management continuum of mitigation, prevention, preparedness, response, and recovery represent nine key essential areas: health, defence, law and order, finance, transport, telecommunications, energy, food and water.

Figure 4. Whole-of-society approach (*46*)



All sectors of society should be involved in pandemic risk management. A concerted and collaborative effort is required by government ministries, businesses and civil society to sustain essential infrastructure and mitigate impacts of pandemic influenza on health, the economy and the functioning of society.

All levels – global, national, subnational, local and community – should prepare for a pandemic. The global and national levels should provide leadership and strategic planning while the local level should prepare to take specific actions. All organizations should incorporate pandemic preparedness into existing crisis and continuity management systems. As the impact and

duration of pandemic waves are unpredictable, and may continue for multiple seasons, local communities should develop flexible plans to support the full spectrum of their potential needs.

A4.1 Role of government

In national pandemic influenza risk management, the government is the natural leader for overall pandemic coordination and communication efforts. The national government should help other public and private agencies and organizations by providing guidance, planning assumptions and making appropriate modifications to the laws or regulations at all levels and sectors to enable appropriate pandemic response. These efforts are supported by WHO and other United Nations Organizations under the IHR (2005) (10). As part of their capacity building activities under the IHR (2005), governments globally have been assessing and revising their national legislation and regulations to ensure they can fully comply with their obligations. These activities include intersectoral collaboration and ERMH at all governmental levels.

Leadership should be based on strong political will and engagement with all stakeholders and sectors with good coordination and command and control mechanisms between the Ministry of Health, national public health authorities and non-health sectors. Emergency management roles, responsibilities and mechanisms also need to be clarified, communicated and tested, with particular attention to sustainability of response capacity and decision-making roles (*47*).

Pandemic risk management is a whole-of-government responsibility. All ministries should work with the Ministry of Health within the national coordination system to ensure a consistent approach to preparedness and business continuity planning. Plans that encompass a variety of scenarios should be developed from risk-based assumptions generated by the Ministry of Health and should be tested for compatibility. In addition, pandemic risk management processes need to take place at the national, subnational, local and community levels; central government should stipulate which level is responsible for specified activities. The central government should also provide guidance to local authorities on preparedness planning; conduct training to ensure effective dissemination at all levels; and design and implement exercises to test plans and encourage community mobilization. Throughout the whole of government, roles, responsibilities, designated leads and chains of command should be clearly mapped. Standard operating procedures can help generate common understanding and coordinated implementation (*46*).

All ministries are responsible for ensuring their respective sectors are well prepared to respond to and recover from pandemic influenza; examples of ministry-specific activities are provided below.

- **Ministries of Transportation** should plan to minimize infection risks and staff absences in vital transportation, airports and sea ports, and loading and unloading facilities, to enable continued supply of medicines and food. Mechanisms for communication and education of public transport users should be considered well in advance.
- **Ministries of Finance** should plan to maintain essential cash, credit, banking, payment, international funds transfers, salary, pension and regulation services in the face of significant absenteeism; systemic resilience to pandemic risk should be tested. National-level financial planning for pandemic risk management is also a task for the national emergency committee and the Ministry of Finance and the mechanisms to draw down emergency funding for interventions should be tested prior to a pandemic.
- Ministries of Justice should consider how to maintain all essential legal and administrative operations during a pandemic. Measures should also be considered to minimize the spread of infection in prisons and other institutions under their authority. Plans for infection control and risk reduction in facilities should be tested in conjunction with the Ministry of

Health plans to ensure that messaging is consistent and that public health principles are upheld.

- **Ministries of Defence** should consider which military assets could be released and mobilized in the event of a pandemic, based on Ministry of Health planning assumptions and risk assessment.
- **Ministries of Education** should have a key role in the surveillance and reduction of influenza risk to communities. Surveillance of absenteeism in schools can be used as a proxy indicator of community transmission. Linking of school surveillance systems with the Ministry of Health is therefore vital to ensure that school-based interventions, including closures, are guided by public health principles.
- **Ministries of Energy** should ensure that key providers within the energy sector have well-developed and well-exercised preparedness plans. Alternative plans for energy supplies, in case of major disruptions, should be evaluated.
- **Ministries of Communication** should have the responsibility to ensure that communications channels remain open at times of crises. As the formal partner to the Ministry of Health in disseminating information, the Ministry of Communication should be closely involved in the development of a national communications plan across the government.
- **Ministries of Agriculture and Animal Health** should have a key role in the surveillance and monitoring of non-seasonal influenza viruses and on preparedness, prevention, risk assessment and risk reduction mechanisms to decrease exposure of humans to influenza viruses at the human–animal ecosystem interface.
- In addition to leading the health sector response, **Ministries of Health** should provide planning assumptions and technical input for the development of plans by other sectors, provide public education and other communication messages and provide advice on reducing risk of infection in essential workers.

A4.2 Role of business

In many countries, essential services are provided by a mix of public and private providers. It is therefore vital that, along with public agencies, private essential goods and service providers undertake pandemic risk management activities. At a national level, the business sector should be represented in the national planning committee, to ensure a consistent planning approach and establish formal communication channels.

The continuity of activities by businesses involved in medical supplies and services, e.g. manufacturers, distributors and providers, is critical to pandemic risk management. Other business sectors also have important roles. For example, human resource surveillance systems in larger businesses to monitor absenteeism can provide valuable information for national risk assessment and the retail sector can use strategies to reduce population density in shopping areas. Businesses have an obligation to protect their employees during any health emergency; the provision of accurate and timely communication messages developed on the national communication plan, personal protective equipment and training is encouraged.

A4.3 Role of civil society

In many countries, national and international civil society and community-based organizations will have a key role in providing community-based services to meet the needs of vulnerable populations. It is therefore critical that these organizations have planned how to maintain or expand their essential services during a pandemic. In addition, community-based organizations can translate scientific and government messages and recommendations, which otherwise may be met with mistrust or scepticism by parts of society. Community leaders can build public confidence, disseminate information and identify people at risk. Governments should

therefore involve civil society and local communities in developing pandemic risk management plans. Governments should also work with local and international humanitarian agencies and organizations to identify how the basic needs of vulnerable populations will be met in a pandemic. The adoption of this whole-of-society approach will clarify responsibilities, identify gaps and avoid duplication in planning and implementation.

Throughout the UN system, agencies, funds, programmes and partners support pandemic risk management efforts, in particular assisting countries and promoting multisectoral and whole-of-society approaches, facilitating and enhancing regional and global synergies and establishing norms for effective work (48). The overarching objectives through which this work has been pursued are captured in the UN System and Partners Consolidated Action Plan for Animal and Human Influenza, which identifies specific outputs and activities of the UN system and partners under seven strategic objectives, namely: animal health and biosecurity; sustaining livelihoods; human health; coordination of national, regional and international stakeholders; communication: public information and supporting behaviour change; continuity under pandemic conditions; and humanitarian common services support (49). The UN system also works to ensure continuity of its essential operations during pandemics and to maintain staff health and safety to ensure a timely, consistent and coordinated response across the UN system to a possible global threat (*50*).

A4.4 Critical interdependencies among essential services

Although there are variations between countries, key essential services are: health, defence, law and order, finance, transport, telecommunications, energy, food and water (**Figure 4**). Public and private providers of these essential services are interdependent and rely on the goods and services of other sectors in order to sustain their operations. Pandemic plans should take into account potential failures generated by interdependencies. These include failures of individual businesses or small numbers of businesses representing the sole providers of an essential good or service. Interdependencies need to be identified by each individual essential service provider. Issues that need to be clarified in the process of identifying interdependencies include:

- critical goods and services necessary for the organization to provide its essential service/s;
- key interdependencies for each critical good or service;
- the impact of the loss or reduction of any of the critical goods or services to the customers/beneficiaries;
- critical employee groups;
- the impact of the loss or reduced availability of critical employee groups; and
- likely points of failure.

The health-care sector always faces especially severe challenges during a pandemic. Health-care institutions depend on goods and services that are delivered by the following sectors:

- transport for the movement of supplies, personnel and patients;
- telecommunications to support patient care, provide teletriage and maintain business processing;
- energy to power facility, clinical and security systems;
- water for health-care facilities, pharmaceutical operations and sanitation services;
- pharmaceuticals, including consumables, for treatment of patients; and
- finance to ensure the supply chain.

Flexible business continuity plans should be developed for multiple scenarios ranging from some delays/interruptions to significant interruptions to essential services, with corresponding action plans.

Annex 5. Business continuity planning

Business continuity plans, which document business continuity management processes, are at the heart of preparing all levels and groups of society for an emergency; pandemic risk management should be an integral part of any establishment's business continuity management. Business continuity plans should be based on risk assessment of the potential effects of a pandemic on the ability to maintain or expand operations. The risk assessment should include consideration of vital components outside the specific organization, such as the resilience of supply chains for essential goods and services. The plans can be used to manage business interruptions, including significant absences of staff or disruption of supplies.

Business continuity plans should be based on explicit assumptions that characterize the parameters of a pandemic and its potential impacts. Public health authorities should communicate planning assumptions and guidance to other sectors of society.

Regardless of the type of the organization, business continuity plans should include the following actions :

- Identify the critical functions that need to be sustained.
- Identify the personnel, supplies and equipment vital to maintain critical functions.
- Consider how to deal with staff absenteeism to minimize its impact on critical functions.
- Provide clear command structures, delegations of authority and orders of succession.
- Assess the need to stockpile strategic reserves of supplies, material and equipment.
- Identify units, departments or services that could be downsized or closed.
- Assign and train alternative staff for critical posts.
- Establish guidelines for priority of access to essential services.
- Train staff in workplace infection prevention and control and communicate essential safety messages.
- Consider and test ways of reducing social mixing (e.g. telecommuting or working from home and reducing the number of physical meetings and travel).
- Consider the need for family and childcare support for essential workers.
- Consider the need for psychosocial support services to help workers to remain effective.
- Consider and plan for the recovery phase.
-

Annex 6. Representative parameters for core severity indicators

Indicator	Representative parameters
Transmissibility	**From initial investigations** • Number of symptomatic cases of influenza/influenza-like illness per week • Basic reproduction number (R0): the average number of secondary cases generated from one case at the start of the epidemic • Generation time: the mean delay between the time of infection of an index case and the times of infection of secondary cases infected by the index case • Serial interval: the average length of time between symptom onset of individual cases and the persons they infect • Secondary attack rate: the proportion of individuals exposed to a known case who become infected, e.g. in a household where a case is discovered • Clinical attack rate (CAR): the proportion of the population that is symptomatically infected in a given time period. CAR is relatively simple to measure since it does not rely on detection of asymptomatic individuals. CARs can be calculated for different age groups, different settings (e.g. school, workplace) and different risk groups (e.g. pregnant women) • Spatial distribution of cases: mapping of countries/regions in which the virus has been detected in a given time period **From later investigations** • Attack rate: the proportion of the population that become infected in a given time period (e.g. as obtained from population serologic studies) • Incidence proportion: the proportion of people who develop new disease during a specified time period • Prevalence: the proportion of people who have disease at a specific time • Mode of transmission, particularly if new modes or previously uncommon modes of transmission (e.g. faecal–oral) are important
Seriousness of disease	**From initial investigations: molecular** • Sensitivity to available antiviral medicines • Presence of genetic markers that have been associated with increased risk of severe disease • Pre-existing immunity in the population, as measured by the level of cross-reactive antibodies **From initial investigations: clinical** • Case-fatality ratio (CFR): the proportion of symptomatic cases that die. Estimations of CFR are particularly difficult at the early stages of a pandemic. Since reliable case-fatality ratios will only be available in later stages of a pandemic, other parameters that may be of use are: — the proportion of cases of pneumonia that are influenza positive from sentinel surveillance that uses a representative sampling system — the ratio of hospital admissions and deaths attributed to respiratory causes to total admissions at the sentinel site — the proportion of hospital admissions attributed to respiratory causes that require mechanical ventilation or die — the proportion of influenza admissions, intensive-care admissions and deaths with pre-existing medical conditions **From later investigations** • Number of deaths attributed to influenza • Crude disease-associated mortality rate: the number of persons in a given population who die of the illness, expressed in terms of confirmed or suspected cases • The proportional distribution of cases by clinical illness (i.e. the proportions of cases that are asymptomatic/have mild illness/severe illness/die – the “clinical severity pyramid”) • The number of cases of influenza-associated pneumonia and death compared with previous seasons or pandemic events based on comparisons with historical surveillance data

Indicator	Representative parameters
Impact	**From initial investigations** • Daily hospitalization rate: the number of persons in a given population who are hospitalized each day, expressed in terms of confirmed or suspected cases • The proportion of emergency department visits attributed to pandemic influenza • The proportion of emergency department visits that require hospitalization • The proportion of hospitalized cases that require admission to an intensive-care unit or require mechanical ventilation • The proportion of all hospital beds occupied by patients with pandemic influenza • The percentage of overall laboratory capacity directed to influenza testing **Potential societal impact parameters from other sectors** • Interruption of critical infrastructure and services • Work and school absenteeism • State of tourism • Sales of core capital (privately held land, livestock) • Gross Domestic Product • Border, travel and trade actions by countries • Nature of public perception

Annex 7. Containment measures

Before the presence of human infection with a new influenza subtype is identified, the clinical syndrome associated with a new influenza subtype is likely to be similar to that caused by currently circulating seasonal viruses. It will therefore be very difficult to recognize an emerging pandemic sufficiently early to achieve containment at source, given current capacities for detection and intervention (51). Evidence supporting containment at source is extremely limited, with theoretical evidence only. Modelling studies suggest that containment may be possible in certain near-ideal scenarios characterized by low to moderate transmissibility (basic reproduction number, R_0 ≤1.7); very early detection of initial cluster/outbreak (within 15–21 days); a non-urban pandemic epicentre with limited size (*52*), density and mobility; access to well-trained response workers within a highly organized response infrastructure; a short period of communicability and low rate of asymptomatic illness; and antiviral drug susceptibility.

However, even in these near-ideal situations, it is unlikely that this approach would be feasible given the large amount of resources (antiviral drugs, geographical cordon, health-care personnel) that would need to be mobilized (53). The data from theoretical modelling studies are based on mass use of neuraminidase inhibitors within a defined "containment zone" coupled with movement restrictions (geographical cordon) and targeted at a population of 500 000 people. Moreover, the experience in 2009 was that obtaining initial data on the R0, communicability and rate of asymptomatic illness associated with influenza A(H1N1)pdm09 was challenging, thus data in a future pandemic would be unlikely to be available within the timescale that would make this approach feasible.

Nevertheless, measures that have been associated with containment such as social distancing, hand/respiratory hygiene and judicious use of antiviral drugs may be effective in mitigating the impact of outbreaks of a new influenza subtype in individual countries. These measures are most likely to be successful and are better supported by data demonstrating effectiveness when implemented in specific local (smaller scale) circumstances, e.g. households and closed or semi-closed institutions. Although there is no evidence of any wider population-level containment effect, these measures may reduce the spread and overall impact of the pandemic and could be considered as part of a country's national preparedness plan, depending on available resources.

Taiwan's Public Health Emergency Preparedness Programs 10 Years after SARS

Report Prepared by

Center for Biosecurity of UPMC

for Taiwan Department of Health

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Project for Promoting Health Cooperation in North America

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Executive Yuan, Republic of China (Taiwan)

Report on Taiwan's Public Health Emergency Preparedness Programs 10 Years after SARS

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Executive Summary

The Center for Biosecurity of UPMC is pleased to provide this review of public health preparedness in Taiwan, which was conducted initially at the request of Minister Wen-Ta Chiu, Taiwan Department of Health, when he visited the Center in August 2011 and later under an open-bidding contract. The purpose of this assessment is to document the noteworthy progress that has been made since the SARS outbreak in 2003, identify the strengths of Taiwan's public health preparedness systems, and recommend possible new or complementary approaches to improving preparedness and continuing to strengthen existing systems in advance of a future epidemic.

This assessment was derived from background research on the origins, history, and current structure of Taiwan's public health and healthcare systems conducted by reviewing pertinent literature, government reports, and discussions with Taiwanese colleagues and by a week-long research visit to Taiwan that included extensive bilateral briefings with senior government, public health, and medical officials.

Over the past 15 years, Taiwan has experienced several major outbreaks of infectious diseases, including Enterovirus 71, SARS, and 2009 H1N1 influenza. These 3 outbreaks illustrate the national urgency of and rationale for building strong preparedness systems and plans to control highly contagious disease outbreaks. Each outbreak spurred investments to improve response to epidemics and yielded systems that have proven useful in subsequent outbreaks.

Findings and Recommendations

Taiwan has made many impressive gains in boosting its national preparedness for public health emergencies. Over the past 10 years, the Department of Health (DOH) and the Taiwan Centers for Disease Control (CDC) have built a number of important and robust programs aimed at providing earlier detection and controlling the spread of infectious diseases. Indeed, many aspects of these programs should be emulated by other countries committed to improving public health preparedness.

Comparing Taiwan's current state of readiness with its readiness levels 10 years ago, it is clear that the country has made concerted and focused efforts to advance the health of its citizens and its critical public health preparedness programs. For example, Taiwan has achieved success in:

- improving collection of disease surveillance data;
- running a state-of-the-art Epidemic Intelligence Center that can integrate, analyze, and report on surveillance data from a variety of diverse sources;
- creating a functional network of laboratories that can perform diagnostic tests and rapidly report results;

- establishing a medical network that includes 6 respected Regional Commanders who can provide expert advice and recommendations to DOH and CDC on medical response and disease control issues in the event of an outbreak;

- exercising systems to practice response activities and to regularly test readiness levels;

- raising general awareness of the public and international travelers of the risks of infectious diseases and good practices for controlling transmission; and

- investing in a domestic vaccine manufacturing capability to help ensure that Taiwanese people have access to influenza vaccines, even during times of worldwide surges in demand for vaccine.

In addition to the many essential preparedness programs established over the past 10 years, Taiwan is fortunate to have dedicated leaders and experts in government who are committed to improving national readiness for disease outbreaks. Taiwan's government servants who are responsible for these issues have a strong sense of purpose, and key personnel at all levels recognize that the systems will be challenged by new infectious disease outbreaks in the future.

The World Health Organization (WHO) and infectious disease experts and researchers around the world understand the serious challenge posed by emerging zoonotic infectious diseases, which include both new pathogens and mutated versions of existing pathogens. Therefore, it is critical in Taiwan and elsewhere to give priority to the continuing improvement of existing public health preparedness systems and programs.

This report proposes a range of suggestions for consideration and review by the DOH as it seeks independent views on possible improvements to existing systems. Taking into consideration its own priorities and resources, the DOH may wish to consider the following activities:

- Exploration of the use of benchmarks to measure progress in building national preparedness;

- Maintenance of modern technical capabilities in its surveillance and laboratory diagnostic systems;

- Analyses to assess current personnel levels and future personnel needs;

- Continuing assessment of the contents and adequacy of the national stockpile;

- Review of how the current system of designated isolation hospitals would be tested if challenged by a highly contagious and fast-spreading infectious disease outbreak, and ways of bolstering critical care capabilities for infected patients;

- Continued planning for scarce resource scenarios;

- Consideration of the benefits of the current airport quarantine strategy;

- Preservation of domestic capacity to manufacture vaccines for yearly use as well as in a crisis by further strengthening the current public-private relationship between government and the local vaccine producer;

- Assessment of Taiwan's legal framework for response to communicable disease outbreaks to permit flexible decision making to minimize the spread of disease while effectively caring for infected patients;

- Expansion of tabletop exercises and scenarios to include political leaders so as to increase political support and public awareness of the importance of public health emergency preparedness programs; and

- Further publication of the many successes and lessons learned in Taiwan following the 2003 SARS outbreak so as to engage with the international community on these important topics.

Conclusion

The above suggestions reflect the fact that preparedness for public health emergencies is not an end state, but rather an ongoing commitment to support the people, information systems, technologies, and other assets that contribute to overall public health resilience in the face of infectious disease threats. We encourage Taiwan to maintain the state-of-the-art capabilities that will protect the people of Taiwan from future public health emergencies.

Report on Taiwan's Public Health Emergency Preparedness Programs 10 Years after SARS

The Importance of Assessing Taiwan's Public Health Emergency Preparedness Programs

The SARS epidemic was transformative. It alerted governments to the acute and prolonged health, economic, and social impacts that infectious diseases can have. The global outbreak prompted many governments, including the government of Taiwan, to examine whether they had the plans, policies, resources, and expertise to protect their people in the face of emerging infectious disease threats and to invest in improving these areas. Taiwan, like the rest of the world, was challenged again in 2009 during the H1N1 pandemic. Other infectious disease threats can be expected to emerge and reemerge, but often in unpredictable ways. The purpose of this assessment is to take account of the progress that has been made since the SARS outbreak, to identify the strengths of Taiwan's public health preparedness systems, and to recommend ways to further improve such systems in advance of a future epidemic.

Over the past 15 years, Taiwan has experienced several major outbreaks of infectious disease. In April 1998, an outbreak of hand, foot, and mouth disease, caused by Enterovirus 71, began. The total reported cases reached 129,106, which were estimated to be only 10% of the actual number of cases. By the end of the summer, 78 young children had died as a result of the disease.[1] Patients flooded emergency rooms and outpatient facilities, and many children were admitted for observation. A portion of admitted patients were moved to intensive care units after developing complications including pulmonary hemorrhage and pulmonary edema. The health system was additionally challenged by the lack of any antiviral treatment for Enterovirus 71. The outbreak caused worry and confusion among the population, particularly because some atypical deaths were caused by a disease that had not previously been known to be lethal.[2] Many changes were implemented following the outbreak. The government of Taiwan invested in developing a vaccine and increased laboratory capacity and testing for all enteroviruses.

In 2003, Taiwan experienced the third largest SARS epidemic, after mainland China and Hong Kong, with 346 confirmed cases and 73 deaths.[3] At the epidemic's peak, there were 20 confirmed cases per day, but many more suspected cases were being reported: up to 90 per day. The first case was imported from Guangdong province in late February before the World Health Organization (WHO) issued its first alert. Approximately 2 dozen cases were imported from mainland China and Hong Kong over the course of the epidemic, but the vast majority of cases were attributable to local spread within hospitals in Taiwan. The largest hospital outbreak occurred at Hoping Hospital, where 43 healthcare workers were infected. On ward B8, 15 of 24 staff (62%) became infected. Hoping Hospital was closed to new patients, and hospital personnel were placed on home quarantine. But prior to these measures, the outbreak had spread from Hoping Hospital to several other hospitals. In total, during the epidemic, 131,132 people

(50,319 close contacts and 80,813 travelers from affected areas) were placed in quarantine.[3] The economic loss attributed to SARS in Taiwan was estimated at 0.49% of Taiwan's GDP in 2003, or approximately $1.5 billion.[4]

The SARS epidemic highlighted a number of challenges, especially related to hospital infection control and timely reporting of cases. After 2003, Taiwan invested in many efforts to strengthen their infectious disease response capabilities. These included changes in laboratory biosafety standards and practices,[5] a nationwide emergency department–based syndromic surveillance network,[6] strengthened infection control practices, changed hospital accreditation, and education of the public to change behavior.

At the onset of the 2009 H1N1 pandemic, when WHO raised the influenza pandemic alert to phase 4, the Taiwan CDC convened the Central Epidemic Command Center (CECC), according to its Pandemic Response Plan. The CDC made H1N1 2009 an immediately notifiable disease and directed that all suspect patients should be hospitalized in isolation. Many of the surveillance and alert systems that had been introduced after SARS were applied during the H1N1 pandemic of 2009. On-board quarantine inspections were conducted on direct flights from North America in which passengers were encouraged to report flulike symptoms to quarantine officers. On-board screening was suspended after the first imported case was confirmed. Subsequent contact tracing revealed multiple imported cases from a variety of countries. Six weeks after the first confirmed case, virologic surveillance confirmed community transmission in Taiwan.[7]

Initially, during the spring wave of the 2009 pandemic, schools were closed when a single student case was identified. In the fall, the policy was changed such that only classrooms in which 2 or more students came down with suspected influenza in a 3-day period would have classes suspended for 5 days (the "325" rule).[8] The number of class suspensions peaked in late November, when more than 2,000 classrooms were under suspension. By this time half of the students in elementary or middle school had been vaccinated, and the rule for class suspension shifted from "325" to "814," meaning that if more than 80% of the students in a class had been vaccinated for more than 2 weeks, class suspension was no longer indicated.[9]

The CECC began the process of acquiring H1N1 2009 vaccine at the beginning of June. Eventually, 15 million doses of vaccine, enough for 60% of the population, were purchased from Adimmune and Novartis. A vaccine priority list was developed during the late summer, in advance of a mass vaccination campaign that began in November. Healthcare workers were vaccinated first, followed by certain high-risk groups and school-aged children.[10] On December 12, 2009, vaccination was made available to everyone, and a "National Immunization Day" campaign was conducted. Vaccination stations were set up in hospitals, clinics, department stores, and community centers.[11] Over 2% of the population was vaccinated on that one day. By the end of January, approximately 24% of the total population of Taiwan had been immunized. Special telephone lines were set up by local health departments to enable the

public to make appointments for vaccination. Vaccination stations were set up in airports and rail stations in February to vaccinate travelers during the Chinese New Year travel season.

To communicate with the public, Taiwan CDC provided daily and weekly updates of H1N1 statistics through its website. CDC and other government officials conducted press conferences and issued press releases when there was important news. Celebrities were recruited to make public health videos.[12] The CDC operated a 24/7 hotline for the public that received up to 3,000 calls per week. The CECC used an online publication to disseminate clinical information to healthcare providers.

These 3 outbreaks—Enterovirus 71, SARS, and 2009 H1N1—have spurred investments in improving response to epidemics and yielded systems that have proven useful in subsequent outbreaks. For example, systems built after SARS were employed during the 2009 influenza pandemic to monitor disease in the population.

The government of Taiwan is to be commended on the remarkable improvements that have occurred in its systems, policies, and practices for responding to emerging infectious diseases and public health emergencies. Yet, Taiwan, like all countries, continues to face a difficult task in protecting its population from emerging diseases. This assessment is intended to help identify the many public health preparedness gains that need to be preserved while advising additional ways to improve these systems to prepare for future epidemics.

Center for Biosecurity of UPMC

Over the past decade, the Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC) has undertaken in-depth and independent evaluations of US public health emergency preparedness efforts and programs. As the leading US nongovernmental organization focused on these issues, the Center has insights into the relative merit of various government initiatives aimed at increasing preparedness, response, and community resilience to public health emergencies. The Center offers a unique interdisciplinary approach, providing expert advice in public health, medicine, infectious diseases, law, basic science, drug and vaccine development, and social sciences. Center staff members have extensive experience in government, public health practice, medicine, and other related fields.

The Center was founded by Dr. D. A. Henderson, a world-renowned expert in public health, infectious disease, and global health issues. Dr. Henderson has served as a leader of the WHO smallpox eradication program and subsequently held high academic posts at the University of Pittsburgh and Johns Hopkins University and taken leadership in the federal government on public health issues in the White House and the US Department of Health and Human Services. Dr. Henderson has also previously advised the government of Taiwan on infectious disease preparedness and response, particularly concerning pandemic influenza.

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Methodology

The Center for Biosecurity conducted background research on the origins, history, and current structure of Taiwan's public health and healthcare systems, including how these entities have been governed and funded. This research was conducted by reviewing pertinent literature and government reports and engaging in discussions with Taiwanese colleagues.

A 4-member team (Inglesby, Cicero, Nuzzo, and Adalja) from the Center conducted a week-long research visit to Taiwan. The agenda of this visit included meetings with the Minister of Health, the Deputy Minister of Health, the Director General of Taiwan CDC, former leaders in the Department of Health and the CDC, and many government, public health, and medical officials in meetings arranged by the liaison of the Taiwan DOH. Logistics and coordination were provided by the Taiwan CDC. See Appendix B for the detailed agenda. During the visit the Center research team provided briefings to the Taiwan CDC on:

- US Preparedness Efforts for Public Health Disasters
- US Response to the 2009 H1N1 Influenza Pandemic
- Biosurveillance in the US: Current Approaches and Lessons Learned
- US Approach to Developing and Acquiring Medical Countermeasures for the Civilian Population

In addition, the Center team provided a briefing on Healthcare System Preparedness for Mass Casualty Events at a meeting with the Director General of Taiwan CDC and the 6 Regional Commanders. See Appendix C for the presentations used in these briefings. The Center team received a number of informative briefings throughout the week, including presentations from Taiwan CDC officials on, among other topics, the 2009 H1N1 response in Taiwan, the country's infectious disease surveillance systems and laboratory diagnostic capabilities, and Taiwan's Epidemic Intelligence Center. The report authors also toured the Adimmune facility, a number of hospitals, and the Health Bureau of New Taipei City.

This report and the findings and recommendation herein are derived solely from this background research and these meetings.

Findings and Recommendations

Taiwan has made impressive strides in boosting its national preparedness for public health emergencies. Over the past 10 years, the DOH and CDC have built a number of important and robust programs aimed at providing earlier detection and controlling the spread of infectious disease threats. Indeed, many aspects of these programs should be emulated by other countries committed to improving public health preparedness.

Comparing Taiwan's current state of readiness with its readiness levels 10 years ago, it is clear that the country has made concerted and focused efforts to advance the health of its citizens and its critical public health preparedness programs. For example, Taiwan has achieved success in:

- improving collection of disease surveillance data;
- running a state-of-the-art Epidemic Intelligence Center that can integrate, analyze, and report on surveillance data from a variety of diverse sources;
- creating a functional network of laboratories that can perform diagnostic tests and rapidly report results;
- establishing a medical network that includes 6 respected Regional Commanders who can provide expert advice and recommendations to DOH and CDC on medical response and disease control issues in the event of an outbreak;
- exercising systems to practice response activities and to regularly test readiness levels;
- raising general awareness of the public and international travelers of the risks of infectious diseases and good practices for controlling transmission; and
- investing in a domestic vaccine manufacturing capability to help ensure that Taiwanese people have access to influenza vaccines, even during times of worldwide surges in demand for vaccine.

In addition to the many essential preparedness programs established over the past 10 years, Taiwan is fortunate to have dedicated leaders and experts in government who are committed to improving national readiness for disease outbreaks. As we learned, Taiwan's government servants who are responsible for these issues have a strong sense of purpose, and key personnel at all levels recognize that the systems will be challenged by new infectious disease outbreaks in the future.

WHO and infectious disease experts and researchers around the world understand the serious challenge posed by emerging zoonotic infectious diseases, which include both new pathogens and mutated versions of existing pathogens. Therefore, it is critical in Taiwan and elsewhere to give priority to continuing to improve existing public health preparedness systems and programs.

A range of suggestions are discussed below for consideration and review by the DOH, as it seeks independent views on possible improvements to existing systems. Taking into consideration its own priorities and resources, the DOH may wish to consider the following activities.

- **Further Development of Operational Exercises and Benchmarks to Measure Progress**

Measuring public health preparedness at the national and local level is recognized by many countries as both important and challenging. Taiwan DOH and CDC have a clear interest in further developing their own approaches to measuring public health preparedness. Taiwan is continuing to improve and refine drills and functional exercises. We were encouraged to hear that Taiwan CDC has retained an outside consultant to help it evaluate the exercises being used by the Communicable Disease Management Network. Some countries have developed systems for measuring the quality of an exercise and for measuring improvements in capabilities made over time. For example, the United States has created a national benchmark for assessing performance during exercises. The Homeland Security Exercise and Evaluation Program (HSEEP) provides a methodology and terminology for exercise design, development, conduct, evaluation, and improvement planning.[13] Toolkits like those available on the HSEEP website may be a helpful resource for Taiwan DOH and CDC to consider.

Another important means of gauging progress that Taiwan DOH and CDC might consider would be the establishment of an annual index or report that quantifies various key public health measures. In the United States there are a few notable examples of such efforts that might be worth examining in Taiwan. The Trust for America's Health (TFAH) "Ready or Not?" report,[14] written by a respected public health advocacy organization in the US, gauges 10 categories of preparedness in each of the 50 US states each year. It is a widely cited and influential independent assessment of US state public health preparedness.

Another effort in development in the US now is the National Health Security Preparedness Index, which is being developed by a coalition of federal agencies, state and local health agencies, laboratories, professional associations, and academic organizations. Its purpose is for participants to come to broad

agreement on a series of state metrics that will be measured and benchmarked each year and used to assess progress and inform future investments.

If Taiwan were to undertake such measurements, it could focus on elements of preparedness such as per capita numbers of medical personnel in different areas of the country, numbers of isolation beds and intensive care unit beds, numbers of mechanical ventilators per capita, numbers of epidemiologists in a given region, capacity to do mass distribution of medicine and vaccines, and specific lab capacity measures. These numbers could be examined against available benchmarks from other countries and could help identify potential preparedness disparities between population centers in different geographic locations (eg, New Taipei City vs Taipei) to help shape future areas of investment and work.

- **Maintenance of Technical Capabilities in the Surveillance and Laboratory Diagnostic System**

Ensuring the availability of surveillance information is critical for rapid detection and response to public health infectious disease threats and to keep political leadership informed so that they can advise and reassure their constituents during a crisis. Recent reports have found that having a robust national surveillance capability is an essential component of national and global security from health threats.[15-17] Although there are many important components of an effective national surveillance program, 2 key elements stand out: (1) maintaining a functional network of laboratories that can perform tests and rapidly report results; and (2) maintaining an ability to integrate data from multiple surveillance programs.[18]

Over the past 10 years, Taiwan has developed outstanding surveillance programs, and it should endeavor over the next 10 years to sustain these gains and to keep these systems current with new technologies. The national laboratory network and the Epidemic Intelligence Center are 2 aspects of Taiwan's surveillance system that are highly valued by practitioners involved in Taiwan's preparedness programs. Together, these 2 assets help create a well-rounded, modern capability for conducting surveillance for known priority disease threats, as well as to provide an early indication of newly emerging disease situations.

Taiwan CDC's Epidemic Intelligence Center serves to integrate ongoing traditional, indicator-based, and syndromic surveillance, with information obtained through event-based surveillance. These functions are important components of a modern surveillance program for infectious disease outbreaks and other public health emergencies. WHO has identified event-based surveillance as one of the "essential components of a single national surveillance system" and has recommended that countries develop such systems to complement traditional (indicator-based) public health surveillance approaches.[19]

Taiwan's national laboratory program is also a critical element of its surveillance capabilities. Greatly expanded during the SARS epidemic, Taiwan's national reference laboratories and network of participating clinical laboratories seem well-positioned to diagnose routine public health threats

and, during a crisis, to expand capabilities for conducting surveillance for previously unrecognized pathogens, such as the recent cases of novel coronavirus that were detected among people from the Middle East. Taiwan should continue to support its laboratory capacity and may want to give priority in the future to enhancing existing efforts to improve electronic reporting of laboratory data. Electronic laboratory reporting can provide a standardized and near real-time snapshot of a disease of interest, thus enhancing situational awareness. Although there are ongoing efforts to implement electronic reporting from laboratories, more work is needed to ensure full participation of clinical labs. In addition, work will be needed to ensure that the laboratory reports received from clinical labs can be integrated with existing surveillance systems.

Both Taiwan's laboratory assets and the Epidemic Intelligence Center will require continual upgrades to ensure they stay up to date, relevant, and effective. As technology evolves, both of these assets require investments in hardware (new diagnostic equipment, computers, servers, etc.) and continual training of personnel. Planning for sustained investments in these areas is critical but does not appear to be a part of routine budgetary consideration. It may be wise to set aside reserve funds on an annual or semiannual basis to provide training and hardware improvements to ensure that these surveillance assets can continue to function to effectively track disease and keep leadership informed during crises.

- **Evaluation of the Adequacy of Current and Anticipated Personnel Needs**

The strength of public health preparedness programs is in the caliber of the experts that staff them. The field of public health preparedness is growing more complex, with an ever-increasing need for highly skilled technical personnel. Taiwan DOH and CDC are already considering the adequacy of current staffing levels, and they have concerns regarding their capacity to recruit the highly qualified, expert people who will be needed to run critical programs in the future. Many governments, including that of the US, have had a difficult time recruiting and retaining well-trained personnel, such as epidemiologists, laboratorians, and bioinformaticists, to staff critical preparedness programs. In the United States, traineeship funding and scholarships have been used to support the pipeline of individuals trained and qualified to work in critical fields, including public health.[20] Taiwan might benefit from establishing similar kinds of programs to recruit, train, and retain needed personnel before there are significant gaps in staffing.

- **Assessment of the National Stockpile Contents**

The Taiwan national stockpile is comprised of influenza antivirals, influenza vaccine, and personal protective equipment. Moving forward, Taiwan might consider comparing its stockpile approach with that of other nations, while recognizing that these comparisons would need to be informed and guided by Taiwan's own national risk assessments and epidemic response strategy. The US Strategic National Stockpile (SNS) contains a wide range of items that reflect a threat analysis that includes many hazards, such as bioterrorism, natural disasters, and other mass casualty events in addition to infectious disease

epidemics. The SNS was first established in response to terrorism. It was not until the threat of an influenza pandemic was fully appreciated, coinciding with the reemergence of H5N1, that the stockpile expanded to contain items essential for the response to pandemic influenza. The US response strategy assumes that the full spectrum of care, including critical care services, will be provided to all patients to the degree possible. Accordingly, the US stockpile includes medical countermeasures against all category A bioagent diseases (anthrax, smallpox, plague, tularemia, and botulism), mechanical ventilators, and medical supplies such as thoracostomy tubes as well as personal protective equipment, influenza antivirals, and influenza vaccines.[21,22] Canada and Australia take a similar approach, reflecting an "all-hazards" preparedness strategy.[23,24]

With the information gleaned from cross-national comparisons, Taiwan will be in a position to review its stockpile in the context of its own strategy. Taiwan may choose to continue its current approach, or it may alter or augment the types of materials stored. For example, stockpiling mechanical ventilators might be considered if the overall isolation hospital strategy includes plans to provide critical care on a large scale during an event.

Additionally, a strategic view as to how the stockpile should be managed might best reflect the fact that funding flows differently during a crisis situation than in a prepandemic or preoutbreak period. When public health and political interests are aligned in responding to a present threat, procuring government funds for such purposes may not face much difficulty. However, as time passes after an acute event such as the SARS epidemic, the impetus for sustained investments in preparedness activities wanes, as has occurred in the US. One means to maintain momentum on these issues is to use the numerous smaller-scale infectious disease outbreaks and disasters that occur regularly as reminders to both the public and political leaders of the need for preparedness.

An exploration of the noninfectious public health emergencies for which Taiwan prepares, through the DOH's Bureau of Medical Affairs, may reveal areas of potential integration, synergism, and economies of scale that may defray costs and harness additional expertise. In the US, an "all-hazards" approach to preparedness is embraced in which preparedness for infectious disease emergencies are integrated with preparedness activities for natural disasters, radiological emergencies, and other incidents that have an impact on the health of the nation's residents. Using such an approach minimizes duplicative efforts while fostering expertise in responding to these incidents in a manner that engages multiple facets of the government.

- **Assessment of the Benefits of Alternative Planning Scenarios for Major Outbreaks of Communicable Diseases**

Taiwan's current strategy for the management of a category I or category V communicable disease outbreak within its borders includes the mandatory hospitalization of patients in 22 designated isolation hospitals located throughout the country. Category I diseases include such conditions as smallpox, SARS, H5N1 influenza, and anthrax, while category V diseases refer to novel emerging infectious diseases. These hospitals are described as being medium sized, affiliated with larger hospitals, and fitted with a varying number of low acuity nursing wards that maintain negative pressure isolation standards. These designated contingency hospitals serve the purpose of sequestering potentially infectious patients from the remainder of the population and healthcare system in an attempt to prevent nationwide spread.

This system was created in the aftermath of the SARS pandemic and is the foundation of Taiwan's infectious disease healthcare response. Essential to the operation of this system are the 6 regional medical commanders of the Communicable Disease Network. These commanders, who are all distinguished physicians with extensive expertise, have the responsibility for the critical medical decision making in the 6 regions of Taiwan. Depending on the need, they could provide medical personnel and equipment to assist designated hospitals during a public health emergency. Through the medical commanders' guidance to DOH and CDC, direction of exercises, and coordination of crucial medical assets, Taiwan is poised to respond in a highly coordinated and well-informed fashion to infectious disease emergencies on a nationwide scale—a significant advance from the pre-SARS era.

As DOH continues its ongoing efforts to evaluate, test, and refine national response plans for infectious disease emergencies, it will be useful to consider the medical challenges that a highly contagious SARS-like disease could present to the designated contingency hospitals. While the hospital plan provides great detail and strategy regarding the containment of contagious disease outbreaks, there are 2 particular challenges to the existing plan that are likely to arise in the event of a large infectious disease emergency: the need for mechanical ventilation and the need for surge care.

Most of the contingency hospitals where patients would be isolated and hospitalized in Taiwan in a major infectious disease emergency are not major medical centers. This is by design, to support the goal of preserving the capacity of major medical centers so they can continue to provide health care for the rest of the community without losing overall organizational capacity and being quarantined. This is what occurred at Hoping Hospital in 2003.

The reason that mechanical ventilation and intensive care is likely to be a challenge is that infectious disease emergencies historically often lead to a large number of critically ill patients. During the SARS epidemic, 20% to 38% of patients required ICU admission, and 59% to 100% of those patients required mechanical ventilation.[25,26] Given that infectious disease epidemics of the future (unless they are quite small) will also likely lead to high numbers of patients needing mechanical ventilation, Taiwan DOH and

CDC may want to consider planning that would expand their capacity to provide critical care and mechanical ventilation in such a crisis. Such capacity would depend on the provision of mechanical ventilators in intensive care units along with the necessary trained personnel (eg, critical care physicians, respiratory therapists, critical care nurses). Adding critical care capabilities at the designated isolation hospitals would require additional funding, which may or may not be available. It may be more cost-effective to augment existing infection control measures at the major hospitals where critical care is routine. In considering the attributes and potential challenges of this type of alternative approach, planners could take note of the fact that once careful attention to infection control was implemented during the SARS outbreak, nosocomial spread of the SARS virus ceased.[27] Patients were successfully and safely treated in intensive care units with adequate infection control measures in place.

The other related challenge in future infectious disease epidemics will be the need to effectively respond to a sudden surge in patient load. The designated isolation hospitals are committed to this mission, and they conduct regular training. But despite those efforts, these hospitals could be overwhelmed by a large number of patients during an outbreak. Planning should allow for some scalability and flexibility in responding to events of differing magnitudes. Such "surge" planning could take into account limitations of facility infrastructure in addition to personnel, equipment, and supplies. Facility limitations include the number of potential beds but also include fixed infrastructure, such as the adequacy and reserve capacity of oxygen delivery in hospitals. Unpublished data from the US indicate that some US hospitals may not be able to deliver adequate oxygen flow rates to power large numbers of additional ventilators because of inadequate oxygen piping, and they must reevaluate their oxygen delivery systems.

An approach that Taiwan may wish to evaluate is to match the acuity of the patient with the capabilities of the hospital. For example, during the 2009 H1N1 influenza pandemic, many patients in the US were transferred to large academic medical centers where they could receive "rescue" therapies such as extracorporeal membrane oxygenation.[28] The United States has also followed a similar approach with those infected with the hemorrhagic fever virus, Sin Nombre hantavirus.[29] Canada, a nation that experienced 251 cases of SARS and 43 deaths,[30] also follows an approach that relies on the provision of care for the critically ill and contagious patients at major medical centers.[31] In the UK, a similar approach is followed, in which the ability to "increase capacity of these [critical care] services are an important aspect of planning."[32] This stance on the provision of critical care to patients in the UK is illustrated by the recent ICU admission of a novel coronavirus patient.[33]

To date, there has been relatively little financial support to hospitals for preparedness. An investment in augmenting infection control measures may pay significant dividends for both routine patient care and infectious disease emergencies.

As Taiwan refines components of its epidemic preparedness strategy, the ability to optimally care for the critically ill could be a consideration in selecting the facilities tasked with response. Providing additional flexibility for regional commanders to delineate sites and levels of care during an outbreak could also be considered.

- **Continued Planning for Scarce Resource Scenarios**

In its pandemic influenza plan, Taiwan has appropriately developed a policy of identifying priority groups for potentially scarce resources such as vaccines and antivirals during an event. These priority groups were implemented for mass vaccination of the population during the 2009 H1N1 pandemic. Priority groups may also need to be identified in order to allocate resources other than medical countermeasures. Therefore, extending this approach to encompass a broader "allocation of scarce resources" approach, with continuous dialogue with relevant stakeholders, may further augment preparedness. A plan that also incorporates a method for how ventilators, hospital beds, intensive care unit beds, and other medical procedures can be employed in the most effective manner would complement the work already undertaken with respect to vaccines. Such planning for allocation of scarce resource is one aspect of a broader "crisis standards of care" dialogue that is currently underway in the US. Taiwan may want to review the results of the US Institute of Medicine's (IOM) recent Crisis Standards of Care project.[34]

The IOM approach reflects the fact that, during certain emergencies, "substantial change in the usual health care operations and the level of care it is possible to deliver" will occur and be "justified by specific circumstances and . . . formally declared by a state government in recognition that crisis operations will be in effect for a sustained period."[34] As a disaster unfolds, with the ensuing surge of patients, the standard of patient care will move along a continuum. The IOM refers to normal patient care as conventional care, in which all the hospitals' resources are employed as needed. When the capacity for conventional care is exceeded, "contingency" care occurs, in which a normal standard of care is maintained by modifications such as converting a recovery room to an intensive care unit. Once capability for contingency care is exceeded and there are insufficient resources to care for patients in the usual manner, "crisis" care standards will be used.[35]

The framework of the IOM's work includes a system-wide approach to planning for catastrophic disaster that reflects the need for the entire community of healthcare and other stakeholders (not just hospitals) to plan for such a modification of the standards of care. The IOM calls for such plans to be integrated into existing hospital, hospital coalition, and national disaster plans. By planning for such a drastic change in standards of care, it is believed that overall morbidity and mortality can be minimized. Moreover, by engaging all relevant stakeholders in a preevent discussion of how resource allocation decisions will be undertaken, public and political resistance may be dampened.

- **Evaluation of Airport Quarantine Strategy**

Taiwan uses an airport quarantine strategy to identify febrile travelers. In addition to its screening function, this post-SARS effort, by its mere presence, serves to enhance awareness among travelers of global infectious disease threats. Furthermore, it serves a public education function by dispensing general advice regarding hygiene as well as information on warning symptoms of particular diseases. The system involves thermal scanning coupled with a mandatory evaluation of febrile patients. These patients may be released to home or hospitalized, depending on the situation. Under this system, a number of imported dengue fever cases and other medical cases have been identified.

Some elements of this program differ from the airport quarantine strategies used by other nations such as Canada and the US. The following information about Canada's approach is provided in response to DOH's request for international benchmarking data in this area.

Canada's experience with quarantine measures during the SARS outbreak may be instructive. Canada's border screening for SARS involved 3 components costing Can$7.55 million. The first was an information phase in which health alert notices were distributed to passengers arriving from Southeast Asia that advised them of the signs and symptoms of SARS and advised them to consult a physician if symptoms developed. Similarly, alerts were distributed to departing passengers asking them to *self-defer* travel to avoid the risk of exporting SARS. The second, or screening, phase (prompted by the ongoing spread of SARS) involved the requirement that all passengers respond to a questionnaire regarding potential SARS symptoms and risk factors. If considered at risk for SARS, the passenger was referred to a nurse for more detailed evaluation that would result in referral or release. In conjunction with these measures, a pilot project of thermal scanning was also deployed. The final phase involved special measures such as passenger contact tracing.

The Public Health Agency of Canada, in a review of these measures, deemed them to be of limited benefit for identifying SARS for several reasons, including the nonspecific nature of the screening and the low prevalence of the emerging disease. In fact, of the 5 SARS patients who entered Canada during March through May of 2003, none had symptoms at the airport. These findings prompted Canadian officials to conclude that "the positive predictive value of a positive screening result is essentially zero." Canadian officials also warn of the false sense of reassurance such measures may engender among the populace and political leadership.[30] A similar lack of cost-effectiveness has been identified in the tracing of the spread of measles from an airport[36] and with thermal scanning in Japan.[37] There are, of course, other considerations in addition to cost-effectiveness that Taiwan and other countries take into account when setting their airport quarantine policies.

- **Preservation of Domestic National Capacity to Manufacture Vaccines in a Crisis**

Taiwan deserves praise for becoming the 15th nation to develop the domestic capability to manufacture influenza vaccines. Countries without such capacity are vulnerable to vaccine shortages during pandemics and periods of a surge in worldwide demand. Maintaining a viable domestic manufacturing base therefore helps to ensure that Taiwan can care for its own citizens during a pandemic.

In the future, preserving and adequately supporting this domestic capacity will be an important component of the self-reliance and resilience that characterizes preparedness. Taiwan CDC currently has a public-private partnership with Adimmune, whereby CDC has a modest ownership interest in the company and purchases a certain amount of domestically produced seasonal influenza vaccine yearly. This type of public-private partnership will be crucial, but not necessarily easy, to sustain. A number of market realities make it difficult, if not impossible, for a domestic company such as Adimmune to stand at the ready to fulfill government needs if it lacks other sources of revenue or support during periods of decreased government demand. In the United States, the government and private companies that are engaged in the development of medical countermeasures for bioterror agents also struggle with the dilemma that government funds are limited but companies are unable to sustain development and manufacturing capabilities without significant government support, since there is not a robust commercial market for these countermeasures.

Adimmune appears to be responsibly undertaking a number of strategies to address the reality of the natural fluctuations in government demand. Such strategies include developing novel vaccines for pandemic use, attempting to expand its presence in international markets, offering contract manufacturing services, and providing fill and finishing capabilities for other companies. In addition to these strategies, it would also be worthwhile for DOH to consider the use of advanced purchase agreements with multiyear commitments. These types of arrangements may strengthen the public-private partnership and allow the company to have a more secure and predictable financial footing as it expands operations and pursues innovative vaccine approaches (eg, potentially pursuing cell-based influenza vaccines).

In the United States, seasonal influenza vaccine is primarily a private purchase made by individual healthcare facilities and providers. However, a large proportion of this vaccine is not produced domestically. In light of the threat of avian influenza and the necessity for a large domestic manufacturing base, the US government has in recent years decided to provide funding to bring on line new domestic manufacturing capacity for influenza vaccines. For example, with US government support, Novartis recently opened the first American cell-based influenza manufacturing plant—the culmination of a $1 billion private-public partnership.[38]

- **Integration of Public Concerns with Public Health Law**

In addition to pharmaceutical interventions, nonpharmaceutical interventions, such as isolation of contagious sick people and social distancing, may help to limit the spread of communicable diseases. The effectiveness of quarantine—that is, the preemptive sequestration of individuals who are not yet sick but may have been exposed to a contagious disease—is less clear. Some experts have cautioned that quarantine may have unintended consequences, such as enhanced spread of the disease in the quarantined population, violence among those quarantined, the need to employ force to maintain the quarantine, stigmatization of the affected population, and economic disruption.[39-41]

Nonpharmaceutical measures available to public health authorities vary worldwide, as does the legal authority for public health officials to enforce these measures.[42]In fact, law itself may appropriately be considered a form of nonpharmaceutical intervention, and, thus, legal preparedness is an essential part of public health preparedness.[*]

Quarantine and isolation authority in Taiwan is defined by the Communicable Disease Control Act, which has undergone significant revision since SARS, including as recently as January 2009. The Act requires relatively expansive disease control measures for managing the occurrence, infection, and spread of communicable diseases through isolation and quarantine, as well as penal provisions for not complying with instructions from public health authorities or otherwise interfering with infection control. Indeed, relative to other countries, there is widespread support among the people of Taiwan for aggressively attempting to control infectious disease spread through using expansive compulsory quarantine.[43] Still, citizens of Taiwan have significant worries about their own health and well-being, should they be quarantined.[43] Thus, it is worth considering potential benefits to addressing concerns about social stigma, economic loss, and medical treatment for those who are quarantined.

Large-scale quarantine is likely to be most effective when it is willingly participated in, rather than enforced with criminal penalties.[39] Laws aimed at controlling the spread of disease should incentivize compliance and reduce the likelihood that potentially infected individuals make efforts to avoid control measures, such as occurred in China during SARS.[44] Therefore, legal authority for nonpharmaceutical interventions such as quarantine and isolation could address concerns the public may have about being quarantined. This in turn could improve the likelihood of the public's acceptance of and active participation in infection control measures. Toward this end, laws that enable health authorities to flexibly scale implementation of treatment and control measures according to patient needs and population concerns may be more effective than a one-size-fits-all approach.

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[*] Legal preparedness contains at least 4 core elements: laws (statutes, ordinances, regulations, and implementing measures); the competencies of those who make, implement, and interpret the laws; information critical to those multidisciplinary practitioners; and coordination across sectors and jurisdictions.

In the US, most states have wholly or partially adopted the Model State Emergency Health Powers Act (MSEHPA), which aims to ensure effective response while also respecting individual rights.[45,†] MSEHPA contains a comprehensive framework for quarantine and isolation, both with notice and without notice, and defines conditions and principles for the public health authority to adhere to when isolating or quarantining individuals or groups of individuals. The model legislation prescribes that failure to obey rules and orders concerning quarantine and isolation shall constitute a misdemeanor.[‡] Among conditions and principles outlined are requirements that:

- Measures taken are the least restrictive means necessary to prevent the spread of the disease;
- Quarantined or isolated individuals are regularly monitored;
- Needs of people isolated and quarantined shall be addressed in a systematic and competent fashion, including, but not limited to, providing adequate food, clothing, shelter, means of communication with those in isolation or quarantine and outside these settings, medication, and competent medical care;
- Premises used for isolation and quarantine are to be maintained in a safe and hygienic condition and be designed to minimize the likelihood of further transmission of infection or other harms to people isolated and quarantined; and
- Individuals are immediately released when they no longer pose a substantial risk of transmitting the disease to others.

Beyond the scientific, disease-specific analysis required for developing an effective disease containment strategy, public health law plays an important role in limiting the spread of disease. Given support in the population of Taiwan for quarantine and isolation, there is an opportunity to improve compliance by using law to accommodate the concerns of those potentially subject to quarantine.

[†] In the United States, state and local governments have the primary authority to control the spread of dangerous diseases within their jurisdictions and states conduct quarantine and isolation activities in accordance with their particular state laws and policies.

[‡] In the United States, misdemeanors are considered lesser offenses relative to felonies and are generally punishable by monetary fines, probation, community service, and/or short-term jail terms.

- **Consideration of the Strategic Use of Tabletop Exercises and Scenarios**

Taiwan DOH may wish to consider the development of public health preparedness exercises and scenarios aimed at political leadership with the explicit purposes of raising awareness of the national challenges posed by epidemics and providing the rationale for strong public health preparedness programs. After the SARS epidemic, public confidence in the Taiwan government was threatened by dissatisfaction with the government response, highlighting the political importance of these issues. Devising tabletop exercises that emphasize these dimensions of response will allow political leaders to become acutely aware of the vital role infectious disease preparedness plays in national security.

Tabletop exercises are frequently used to inform leaders about the issues raised and decisions that must quickly be made during times of national crises. These types of exercises are as important as operational drills and exercises, but they are designed differently and for a different audience.

Since 2001, there has been an increasing use of exercises for public health emergency scenarios. Two high-profile exercises convened by the Center for Biosecurity of UPMC, Dark Winter (2001)[46] and Atlantic Storm,[47,48] have been instrumental in raising the profile of infectious disease outbreaks among political leaders in the US and Europe. Both of these exercises prompted significant media attention and Congressional testimonies and hearings and ultimately helped leaders reexamine existing policies for responding to infectious disease outbreaks. In 2006, WHO along with participants from several member nations of the Global Health Security Initiative (GHSI), a collaboration among Canada, the US, Mexico, France, Italy, Germany, Japan, the UK, and the European community, participated in the Global Mercury exercise, which highlighted the importance of international collaboration, communication, and resource sharing during a bioterrorism event.[49] Reviewing the lessons and outcomes of exercises like these may be helpful to Taiwan DOH as it considers how to sustain national support for its preparedness initiatives.

- **Consideration of Broader Publication of Lessons Learned**

Compared to many other nations, Taiwan has made great strides in strengthening its preparedness for infectious disease outbreaks. Taiwan DOH and CDC should consider how best to share these accomplishments with the international community.

In many countries, it continues to be a struggle to analyze, document, and incorporate into future plans the lessons learned from exercises and real public health emergencies. The US has made some effort to improve this process by setting up a secure website for practitioners, called Lessons Learned Information Sharing (or LLIS.gov), to post and share lessons with their peers. Although the existence of this website has improved the sharing of lessons in the practitioner community, applying these lessons to existing plans continues to be a challenge for the US preparedness community. Preliminary evaluations of the recent response to Hurricane Sandy, which struck the US east coast in October 2012, suggest the need for better incorporation of lessons learned into plans for handling public health emergencies.[50]

It may be beneficial for the staff of the Taiwan DOH and CDC to document advances made and publish peer-reviewed articles that describe program changes and lessons learned since SARS. Enhanced recognition of Taiwan's preparedness program will help to sustain national commitment to these programs and will facilitate ongoing and additional collaborations with international organizations with an interest in public health preparedness.

Conclusion

The report recommendations reflect the fact that preparedness for public health emergencies is not an end state, but rather an ongoing commitment to support the people, information systems, technologies, and other assets that contribute to overall public health resilience in the face of infectious disease threats. We encourage Taiwan to maintain the state-of-the-art capabilities that will protect the people of Taiwan from future public health emergencies.

References

1. Ho M, Chen ER, Hsu KH, et al. An epidemic of enterovirus 71 infection in Taiwan. Taiwan Enterovirus Epidemic Working Group. *N Engl J Med*. 1999 Sep 23;341(13):929-935.

2. Ho M. *Several Worlds: Reminiscences and Reflections of a Chinese-American Physician.* Singapore: World Scientific Publishing;2005.

3. World Health Organization. Regional Office for the Western Pacific. SARS: How a Global Epidemic Was Stopped. Geneva: WHO Press; 2006.

4. Lee J-W, McKibbin WJ. Estimating the global economic costs of SARS. In: Knobler S, Mahmoud A, Lemon S, Mack A, Sivitz L, Oberholtzer K, eds. *Learning from SARS: Preparing for the Next Disease Outbreak—Workshop Summary*. Washington, DC: National Academies Press; 2004:92-107.

5. Wu H-S, Wu W-C, Kuo H-S. A three-year experience to implement laboratory biosafety regulations in Taiwan. *Appl Biosaf.* 2009;14(1):33-36.

6. Wu TS, Shih FY, Yen MY, et al. Establishing a nationwide emergency department-based syndromic surveillance system for better public health responses in Taiwan. *BMC Public Health*. 2008 Jan 18;8:18.

7. Hsieh MC, Tsou TP, Chen WC, Kuo S. The response to novel influenza A (H1N1) epidemic in Taiwan and analysis of the initial 61 confirmed cases. *Epidemiol Bull (Taipei Taiwan)*. 2009 Aug 25;25(8):556-567. http://web.cdc.gov.tw/public/Attachment/23172_25-8-%E8%8B%B11-556-567.pdf. Accessed December 18, 2012.

8. Lu M, Wang F. New infections include very young and old. *Taipei Times*. September 3, 2009. http://www.taipeitimes.com/News/taiwan/archives/2009/09/03/2003452671/1. Accessed December 18, 2012.

9. Wang HK, Wang F. Taiwan announces new rules to stem H1N1 infections at schools. *GlobalSecurity.org*. December 3, 2009. http://www.globalsecurity.org/security/library/news/2009/12/sec-091203-cna01.htm. Accessed December 18, 2012.

10. Taiwan prepared for H1N1 with domestic vaccine. *Taiwan Insights*. January 15, 2010. http://www.taiwaninsights.com/2010/01/15/taiwan-prepared-for-h1n1-with-domestic-vaccine/. Accessed December 18, 2012.

11. Nationwide H1N1 vaccination campaign on December 12, 2009 proceeds smoothly. Centers for Disease Control, ROC (Taiwan) website. December 16, 2009. http://www.cdc.gov.tw/english/info.aspx?treeid=bc2d4e89b154059b&nowtreeid=EE0A2987CFBA3222&tid=A30C2D06EB4BCDA4. Accessed December 18, 2012.

12. Chien-Ming Wang returns to Taiwan, participates in H1N1 prevention campaign and urges teamwork in the battle against H1N1. Centers for Disease Control, ROC (Taiwan) website. December 22, 2009. http://www.cdc.gov.tw/english/info.aspx?treeid=bc2d4e89b154059b&nowtreeid=EE0A2987CFBA3222&tid=C030B06582014349. Accessed December 18, 2012.

13. Homeland Security Exercise and Evaluation Program (HSEEP). US Department of Homeland Security website. https://hseep.dhs.gov/pages/1001_HSEEP7.aspx. Accessed December 13, 2012.

14. *Ready or Not? Protecting the Public from Diseases, Disasters, and Bioterrorism*. Trust for America's Health website. December 2012. http://healthyamericans.org/report/101/. Accessed December 19, 2012.

15. *National Strategy for Biosurveillance*. White House website. July 2012. http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Biosurveillance_July_2012.pdf. Accessed December 17, 2012.

16. National Security Council. *National Strategy for Countering Biological Threats*. November 2009. http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf. Accessed December 17, 2012.

17. National Biosurveillance Advisory Subcommitee. *Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats: First Report of the National Biosurveillance Advisory Subcommittee*. April 2009. http://www.cdc.gov/osels/pdf/NBAS%20Report%20-%20Oct%202009.pdf. Accessed December 19, 2012.

18. Toner ES, Nuzzo JB, Watson M, et al. Biosurveillance where it happens: state and local capabilities and needs. *Biosecur Bioterror*. 2011 Dec;9(4):321-330.

19. World Health Organization. Western Pacific Region. *A Guide to Establishing Event-based Surveillance*. 2008. http://www.wpro.who.int/emerging_diseases/documents/docs/eventbasedsurv.pdf. Accessed December 17, 2012.

20. Recovery Act funding for health professions: public health traineeships. HHS.gov/Recovery website. http://www.hhs.gov/recovery/programs/hrsa/healthpros.html. Accessed December 18, 2012.

21. Strategic National Stockpile (SNS). Centers for Disease Control and Prevention website. Updated October 15, 2012. http://www.cdc.gov/phpr/stockpile/stockpile.htm. Accessed December 12, 2012.

22. Malatino EM. Strategic national stockpile: overview and ventilator assets. *Respir Care*. 2008 Jan;53(1):91-95.

23. National emergency stockpile system. Public Health Agency of Canada website. Updated March 14, 2012. http://www.phac-aspc.gc.ca/ep-mu/ness-eng.php. Accessed December 12, 2012.

24. Health emergency preparedness and response. National medical stockpile fact sheet. Australian Government Department of Health and Agein website. Updated February 14, 2011. http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-bio-factsht_stckpile.htm. Accessed December 12, 2012

25. Manocha S, Walley KR, Russell JA. Severe acute respiratory distress syndrome (SARS): a critical care perspective. *Crit Care Med* 2003;31(11):2684-2692.

26. Peiris JS, Yuen KY, Osterhaus AD, Stöhr K. The severe acute respiratory syndrome. *N Engl J Med*. 2003 Dec 18;349(25):2431-2441.

27. Public health guidance for community-level preparedness and response to severe acute respiratory syndrome (SARS). Centers for Disease Control and Prevention website. Updated May 3, 2005. http://www.cdc.gov/sars/guidance/I-infection/index.html. Accessed December 18, 2012.

28. Adalja AA, Watson M, Waldhorn RE, Toner ES. A conceptual approach to improving care in pandemics and beyond: severe lung injury centers. *J Crit Care* 2012 Nov 14. http://www.jccjournal.org/article/S0883-9441%2812%2900326-7/abstract. Accessed November 19, 2012.

29. Dietl CA, Wernly JA, Pett SB, et al. Extracorporeal membrane oxygenation support improves survival of patients with severe Hantavirus cardiopulmonary syndrome. *J Thorac Cardiovasc Surg*. 2008 Mar;135(3):579-584.

30. St. John RK, King A, de Jong D, Bodie-Collins M, Squirees SG, Tam TW. Border screening for SARS. *Emerg Infect Dis*. 2005 Jan; 11(1):6-10.

31. Prevention and control of influenza during a pandemic for all healthcare settings. Public Health Agency of Canada website. Updated September 1, 2011. http://www.phac-aspc.gc.ca/cpip-pclcpi/annf/vi2-eng.php#VI-2-2-2. Accessed December 12, 2012.

32. The UK influenza preparedness strategy 2011. Department of Health website. November 10, 2011. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_130903. Accessed December 18, 2012.

33. Acute respiratory illness associated with a new virus identified in the UK. Health Protection Agency website. September 23, 2012. http://www.hpa.org.uk/NewsCentre/NationalPressReleases/2012PressReleases/120923acuterespiratoryillnessidentified/. Accessed December 18, 2012.

34. *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response*. Institute of Medicine website. March 21, 2012. http://www.iom.edu/Reports/2012/Crisis-Standards-of-Care-A-Systems-Framework-for-Catastrophic-Disaster-Response.aspx. Accessed December 12, 2012.

35. Hick JL, Hanfling D, Cantrill SV. Allocating scare resources in disasters: emergency department principles. *Ann Emerg Med*. 2012 Mar;59(3):177-187.

36. Dayan GH, Ortega-Sánchez IR, LeBaron CW, Quinlisk MP; Iowa Measles Response Team. The cost of containing one case of measles: the economic impact on the public health infrastructure—Iowa, 2004. *Pediatrics*. 2005 Jul;116(1):e1-e4.

37. Nishiuria H, Kamiya K. Fever screening during the influenza (H1N1-2009) pandemic at Narita International Airport, Japan. *BMC Infect Dis*. 2011 May 3;11:111.

38. Novartis Holly Springs cell culture influenza vaccine manufacturing facility first to be declared pandemic ready by US government [press release]. Cambridge, MA: Novartis; December 12, 2011. http://www.novartisvaccines.com/newsroom/media-releases/2011/Holly_Springs_HHS_pandemic_ready_US_Template_FINAL.pdf. Accessed December 17, 2012.

39. Barbera J, Macintyre A, Gostin L, et al. Large-scale quarantine following biological terrorism in the United States: scientific examination, logistic and legal limits, and possible consequences. *JAMA* 2001 Dec 5;286(21):2711-2717.

40. Bell DM; World Health Organization Writing Group. Non-pharmaceutical interventions for pandemic influenza, international measures. *Emerg Infect Dis*. 2006 Jan;12(1):81-87.

41. Nuzzo JB, Henderson DA, O'Toole T, Inglesby TV. Comments from the Center for Biosecurity of UPMC on proposed revisions to federal quarantine rules. *Biosecur Bioterror*. 2006;4(2):204-206.

42. *Comparative Analysis of National Pandemic Influenza Preparedness Plans*. Geneva: World Health Organization; January 2011.

43. Blendon RJ, DesRoches CM, Cetron MS, Benson JM, Meinhardt T, Pollard W. Attitudes toward the use of quarantine in a public health emergency in four countries. *Health Aff (Millwood).* 2006 Mar-Apr;25(2):w15-w25.

44. Greenfeld KT. *China Syndrome: The True Story of the 21st Century's First Great Epidemic*. New York: Harper Perennial; 2007.

45. The Model State Emergency Health Powers Act (MSEHPA). Centers for Law & The Public's Health: A Collaborative at Johns Hopkins and Georgetown Universities website. Updated January 27, 2010. http://www.publichealthlaw.net/ModelLaws/MSEHPA.php. Accessed December 17, 2012.

46. O'Toole T, Mair M, Inglesby TV. Shining light on "Dark Winter." *Clin Infect Dis*. 2002 Apr 1;34(7):972-983.

47. Hamilton DS, Smith BT. Atlantic storm. *EMBO Rep*. 2006 Jan;7(1):4-9.

48. Smith BT, Inglesby TV, Brimmer E, et al. Navigating the storm: report and recommendations from the Atlantic Storm exercise. *Biosecur Bioterror*. 2005;3(3):256-267.

49. Global Health Security Initiative. *Exercise Global Mercury: Post Exercise Report*. http://www.ghsi.ca/documents/ExerciseGlobalMercuryreport.pdf. Accessed December 17, 2012.

50. Abramson DM, Redlener I. Hurricane Sandy: lessons learned, again. *Disaster Med Public Health Prep*. 2012 Dec;6(4):328-329.

Appendix A: Research Team Biographical Sketches

Thomas Inglesby, MD

Dr. Inglesby was appointed Chief Executive Officer and Director of the Center for Biosecurity of UPMC in November 2009. He served as Chief Operating Officer and Deputy Director from 2004 to 2009, and was one of the Center's founding members in 1998.

Dr. Inglesby is an internationally recognized biosecurity expert whose work over the past decade has helped shape the development of the field. He played a leading role in all of the Center's high-impact initiatives, including the *Atlantic Storm* and *Dark Winter* exercises and a series of seminal *JAMA* articles on medical and public health response to the most dangerous biological agents. Dr. Inglesby has played a central role in development of the Center's strategic priorities and programs over the years. He has expanded and deepened the Center's expertise in biosecurity while at the same time establishing new initiatives to improve response to emerging infectious diseases and natural disasters and preparedness for nuclear terrorism and radiation disasters.

Dr. Inglesby was recently named Chair of the Board of Scientific Counselors to CDC's Office of Public Health Preparedness and Response. He has been chair or a member of a number of National Academy of Sciences committees, and he has served in an advisory capacity to the Defense Science Board, the US Departments of Health and Human Services and Homeland Security, the National Institutes of Health, and the Office of the Director of National Intelligence. Most recently, in 2009-2011, Dr. Inglesby was a member of the National Academy of Sciences expert committee that reviewed the scientific approaches used during the investigation of the 2001 anthrax letters.

Dr. Inglesby has been invited to brief White House officials from the past 3 presidential administrations on national biosecurity challenges and priorities, and he has delivered Congressional testimony on biological threats and preparedness.

Since 1999, Dr. Inglesby has authored or co-authored more than 75 peer-reviewed articles, reports, and commentaries on a wide range of public health and national security issues. In 2010, he co-authored "Necessary Progress in Biosecurity" with Senator Tom Daschle for the *Harvard Law and Policy Review*. He is Coeditor-in-Chief of the journal *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, which he helped establish in 2003 as the only peer-reviewed journal in the field. In addition, Dr. Inglesby was principal editor of the 2002 *JAMA* book *Bioterrorism: Guidelines for Medical and Public Health Management*. He is regularly consulted by major news outlets for his expertise and insight on issues pertaining to biosecurity, biodefense, and response to public health disasters.

Dr. Inglesby is an Associate Professor of Medicine and Public Health at the University of Pittsburgh Schools of Medicine and Public Health. He completed his internal medicine and infectious diseases

training at Johns Hopkins University School of Medicine, where he also served as Assistant Chief of Service in 1996-97. Dr. Inglesby received his MD from Columbia University College of Physicians and Surgeons and his BA from Georgetown University.

Anita Cicero, JD

Ms. Cicero joined the Center in early 2010 as Chief Operating Officer and Deputy Director. Working with Dr. Inglesby, she directs operations, strategic and budget planning, and program development. Since her arrival at the Center, she has helped to expand its initiatives in the realms of nuclear preparedness and detection and response to international disease epidemics. In collaboration with Nuclear Threat Initiative, she recently provided strategic and governance advice for the creation of CORDS, a new international organization dedicated to improving global infectious disease detection and response through linkage of regional disease surveillance networks.

Ms. Cicero has nearly 2 decades of experience as a practicing attorney in both the US federal government and the private sector. Before joining the Center, Ms. Cicero served as Managing Partner in charge of the Washington, DC, office of Drinker, Biddle & Reath, LLP, where she was responsible for more than 300 lawyers and staff.

At Drinker, Biddle, and Reath, she formed and managed a range of biopharmaceutical consortia focused on scientific, regulatory, and policy issues, through which she acquired considerable skills in structuring consensus approaches to complex regulatory and scientific challenges. Her work in that realm required collaboration with members of the US Congress, the World Health Organization, the European Commission, the US Food and Drug Administration, and the Environmental Protection Agency, as well as the US Departments of State, Defense, and Health and Human Services. On behalf of her clients, Ms. Cicero led a number of major initiatives related to compliance with international environmental treaty mandates, international data protection and security laws, and human subject research protections for clinical trials.

In the realm of biosecurity, Ms. Cicero managed a consortium of companies that focused on advancing public policy to foster research and development of medical countermeasures. Among its accomplishments, the consortium provided invited analysis to the US government on strategy and organizational capacity and developed recommendations for advancing the science of efficacy studies for countermeasures in the absence of human subject data.

Before entering private practice, Ms. Cicero focused on environmental litigation and counseling. As a trial attorney in the Honors Program at the US Department of Justice, Environmental Enforcement Section, Ms. Cicero represented the EPA in civil litigation under the Clean Air Act, the Clean Water Act, and the Comprehensive Environmental Response, Compensation and Liability Act.

Ms. Cicero is a graduate of the Yale Law School and Oberlin College.

Jennifer Nuzzo, SM

Ms. Nuzzo is a Senior Associate at the Center for Biosecurity of UPMC. An epidemiologist by training, her work focuses on international and domestic biosurveillance, situational awareness, and disease mitigation strategies. She also has worked on problems related to water security, public/private partnerships for public health preparedness, mass critical care, and hospital preparedness.

Ms. Nuzzo is an Associate Editor of the peer-reviewed journal *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, and she was Co-managing Editor of the *Biosecurity Briefing*, a weekly internet-based news, science, and policy update. Ms. Nuzzo has published in the scientific literature on waterborne pathogens and has co-authored several manuals on environmental policy and planning.

In addition to her work at the Center for Biosecurity, Ms. Nuzzo has advised national governments and nonprofit organizations. She served as a consultant to the National Biosurveillance Advisory Subcommittee, as a member of the US Environmental Protection Agency's National Drinking Water Advisory Council (NDWAC), and as a member of the NDWAC's Water Security Working Group. She has also served as a project advisor for the American Water Works Association Research Foundation (now called the Water Research Foundation), a primary funding organization for drinking water research in the United States. Ms. Nuzzo has also been consulted on pandemic influenza planning efforts in the Republic of Indonesia.

Ms. Nuzzo joined the Center for Biosecurity at its founding in 2003. Before that, she served as a Research Analyst with the Center for Civilian Biodefense Strategies at the Johns Hopkins Bloomberg School of Public Health.

In 2002 and 2003, Ms. Nuzzo worked as a public health epidemiologist for the City of New York, where she was involved with disease and syndromic surveillance efforts related to the city's Waterborne Disease Risk Assessment Program. Central to her duties in New York was management of the city's drug sale monitoring program for surveillance of diarrheal illness. She also worked on a local climate change initiative for the City of Cambridge, MA.

Amesh Adalja, MD, FACP

Dr. Adalja is a Senior Associate at the Center for Biosecurity, Assistant Clinical Professor in the Department of Critical Care Medicine, Assistant Clinical Professor in the Department of Emergency Medicine, and Adjunct Instructor in the Department of Medicine's Division of Infectious Diseases at the University of Pittsburgh School of Medicine and UPMC. He is board certified in internal medicine, emergency medicine, infectious diseases, and critical care medicine.

Dr. Adalja is a member of the Allegheny County (PA) Metropolitan Medical Response Team, the American College of Emergency Physicians Pennsylvania Chapter's EMS & Terrorism and Disaster

Preparedness Committee, the Allegheny County Medical Reserve Corps, and the US Department of Health and Human Services' National Disaster Medical System Disaster Medical Assistance Team (PA-1), with which he was deployed to Haiti after the earthquake in 2010. He previously was a member of Allegheny County's Metropolitan Medical Response System

Dr. Adalja is an Associate Editor of the quarterly journal *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science.* He is a contributing author for the *Handbook of Bioterrorism and Disaster Medicine*, and he has published in such journals as *Journal of Infectious Diseases* and *Emerging Infectious Diseases*. He also serves as a book reviewer for *JAMA*.

Dr. Adalja is a fellow of the American College of Physicians, and a member of various medical societies, including the American Medical Association, the Infectious Diseases Society of America, the HIV Medical Association, the American College of Emergency Physicians, and the Society of Critical Care Medicine.

Prior to joining the Center, Dr. Adalja completed 2 fellowships at the University of Pittsburgh—one in infectious diseases, for which he served as Chief Fellow, and one in critical care medicine. He completed a combined residency in internal medicine and emergency medicine at Allegheny General Hospital in Pittsburgh, where he served as Chief Resident and as a member of the infection control committee.

He is a graduate of the American University of the Caribbean School of Medicine, and he obtained a Bachelor of Science degree in industrial management from Carnegie Mellon University.

Eric Toner, MD

Dr. Toner, who is an internist and emergency medicine physician, is a Senior Associate with the Center for Biosecurity of UPMC. His primary areas of interest are healthcare preparedness for catastrophic events, pandemic influenza response, and medical response to bioterrorism. He is a Managing Editor of *Clinicians' Biosecurity News*, which provides clinical biosecurity reports to thousands of clinicians across the country and around the world. He is an Associate Editor of the journal *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, the leading peer-reviewed journal in this field.

Dr. Toner has authored numerous scholarly papers, commentaries, and editorials on hospital and pandemic preparedness, and he has organized several meetings of national leaders on the topics of hospital preparedness, pandemic influenza, mass casualty disasters, biosecurity, biosurveillance and nuclear preparedness . He has spoken at many national and international conferences on a range of biosecurity topics and appeared on several high-profile national television and news features on pandemic flu and bioterrorism preparedness. He was the principal investigator of a multi-year project to evaluate the achievements of the HHS Hospital Preparedness Program and to propose a vision and strategy for healthcare preparedness for the future. He also led a project for HHS to improve healthcare

situational awareness. Dr. Toner is a member of the Institute of Medicine's Forum on Medical and Public Health Preparedness for Catastrophic Events.

Dr. Toner has been involved in hospital disaster planning since the mid-1980s. Prior to joining the Center, Dr. Toner was the Medical Director of Disaster Preparedness at St. Joseph Medical Center in Towson, Maryland, where he practiced emergency medicine for 23 years. During this time, he also headed a large emergency medicine group practice, founded and directed one of the first Chest Pain Centers in Maryland, and co-founded and managed a large primary care group practice and an independent urgent care center. In 2003, he spearheaded the creation of a coalition of disaster preparedness personnel from the 5 Baltimore County hospitals, the Health Department, and the Office of Emergency Management.

Dr. Toner received his BA and MD degrees from the University of Virginia. He trained in internal medicine at the Medical College of Virginia.

Kunal Rambhia, MS

Mr. Rambhia is the Managing Senior Analyst at the Center for Biosecurity of UPMC. He conducts research in support of Center programs, with a focus on hospital and healthcare preparedness, pandemic influenza, biotechnology, infectious disease agents, and international biosecurity issues. Mr. Rambhia is Co-managing Editor of *Biosecurity News Today*, a daily biosecurity news update. He also serves as an Associate Editor of the peer-reviewed journal *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science.*

Prior to joining the Center, Mr. Rambhia worked as an intern for 454 Life Sciences, where he was involved in DNA sequencing projects. In 2005 he traveled to Ghana as part of the Unite for Sight program, providing basic eye care, access to surgery, and eye health education in rural areas of the country. He also served as a member of AmeriCorps in 2004.

Mr. Rambhia obtained a Master of Science degree in biotechnology at the Johns Hopkins University Zanvyl Krieger School of Arts and Sciences in 2011. Mr. Rambhia earned a BS degree in molecular, cellular, and developmental biology and a BA in political science from Yale University in 2007. His thesis was a study of light-dependent plant development with a focus on ubiquitin-directed proteolysis in *Arabidopsis thaliana.*

Ryan Morhard, JD

Mr. Morhard is an Associate at the Center for Biosecurity of UPMC whose research focuses on biosecurity and nuclear preparedness policy, and related legal, governmental, legislative, and technical issues and developments.

Mr. Morhard co-authored the *Rad Resilient City Preparedness Checklist* (www.radresilientcity.org) and has briefed the checklist to numerous federal, state, and local officials, as well as to medical, public health, and public safety professionals.

Mr. Morhard is an Associate Editor of *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* and Editor of the journal's *Legal Perspectives* column. Mr. Morhard is also Editor of *Preparedness Pulsepoints*, the Center's weekly update on US government action on readiness and response.

Mr. Morhard graduated in spring 2011 from Washington University in St. Louis School of Law, where his studies focused primarily on legal aspects of national security, international relations, and foreign policy. He received his BS in neuroscience and in the history and philosophy of science from the University of Pittsburgh. As an undergraduate, he researched, published, and presented on methods to improve neurological condition following emergency preservation and resuscitation procedures as well as attention deficits following traumatic brain injury.

Appendix B: Annotated Agenda of UPMC Experts Visit in Taiwan, December 1–7, 2012

December 1:

- Meeting with Professor Chien-Jen Chen, Vice President of Academia Sinica. Discussion topics included the history and organization of the SARS response in Taiwan in 2003, public health programs developed since SARS, and the role of Academia Sinica in supporting the research and development enterprise in Taiwan.

December 3:

- Meeting with Minister of Health, Professor Wen-Ta Chiu. Minister Chiu and Dr. Thomas Inglesby, CEO and Director of the Center for Biosecurity of UPMC, discussed the Minister's commitment to pursue an independent assessment of Taiwan's public health preparedness programs and reviewed the agenda of meetings organized during the week to facilitate the Center for Biosecurity's assessment.

December 4:

- Meeting led by Director-General of Taiwan CDC, Professor Feng-Yee Chang. This meeting included several presentations by CDC officials. Dr. Chin-Hui Yang presented on the 2009 H1N1 response. Dr. Wan-Ting Huang presented on the infectious diseases surveillance system. Dr. Ho-Sheng Wu presented on the laboratory diagnostic capabilities. CDC director Dr. Feng-Yee Chang moderated the session and presented an overview of the CDC. Experts from the Center for Biosecurity also made a series of presentations. Dr. Inglesby presented on US preparedness efforts for public health disasters. Dr. Adalja presented on US response to the 2009 H1N1 influenza pandemic. Ms. Jennifer Nuzzo presented on current approaches to biosurveillance in the US and lessons learned. Deputy Director Anita Cicero presented on the US Approach to developing and acquiring medical countermeasures for the civilian population.

- Center for Biosecurity experts were given a tour of the EIC by Medical Officer, Dr. Yu-Lun Liu.

- Dr. Feng-Yee Chang moderated a meeting of the 4 Center for Biosecurity experts and the 6 Regional Commanders of the Communicable Disease Control Network. Drs. Shan-Chwen Chang, Hsieh-Shong Leu, Jen-Hsien Wang, Yin-Ching Chuang, Yao-Shen Chen, and Jen-Jyh Lee each provided information and observations about their role in the Network. The focus was on understanding the system constructed to respond to infectious disease outbreaks and the role of the commanders in directing regional response. During the meeting, Dr. Amesh Adalja presented on US healthcare system preparedness for mass casualty events.

- The Center for Biosecurity experts were taken on a tour of the National Taiwan University Hospital, guided by Dr. Yi-Chun Lo, Director of FETP. The tour included a focus on both inpatient and outpatient infectious disease care areas.

December 5:

- The Center for Biosecurity experts visited the Taoyuan General Hospital and Hsinwu Hospital. These meetings included discussions with the leaders of each hospital, including Dr. Yuan-Nian Hsu, Superintendent of Taoyuan General Hospital, and Dr. Fan Chiang Yu Lung of Hsinwu Hospital. Participants discussed Hsinwu's role as a designated isolation hospital, preparedness activities that have been undertaken, and challenges.

- Center for Biosecurity experts visited Adimmune Corporation for a meeting and tour. President, Dr. Hung-Cheng Liu, and other senior leadership provided a detailed briefing on the history and current activities of Adimmune. Following a tour of the vaccine facilities led by Jack Hsu, the group reconvened to discuss challenges related to maintaining a national vaccine manufacturing capability and discussed various approaches used in Taiwan and in the United States.

December 6:

- Dr. Ming-liang Lee, Distinguished Investigator, Institute of Population Health Sciences, met with Center for Biosecurity experts to discuss the ways in which Taiwan responded to SARS, the role of the SARS Task Force, relevant history related to development of domestic vaccine manufacturing capability in Taiwan, and ongoing opportunities and challenges.

- Center for Biosecurity experts met with Taiwan CDC leadership, including Dr. Feng-Yee Chang, to provide preliminary observations and findings of the Center's assessment.

- Center for Biosecurity experts met with representatives of the Health Bureau of New Taipei City. Lee Chia-Chi, Chief of the Health Bureau provided an overview of local health department activities, influenza preparedness, and their coordination with the Taiwan CDC.

- A radiological emergency official from the Jin-Shan Branch Hospital gave a presentation that highlighted the hospital's response plans for a nuclear power plant emergency.

- Center for Biosecurity experts were given a tour of Taiwan Power Company nuclear power plant visitor's center, led by Daniel K.M. Juo, Subsection Head, North Visitors Center.

The UPMC team also engaged in substantive conversations during informal meetings with the following people: Deputy Minister of Health Tzou-Yien Lin; Department of Health Director of Medical Informatics Center Min-Huei Hsu; Taipei Medical University Professor Nai-Wen Kuo; YFY Biotech Management Company Chairman and CEO Hong-Jen Chang; Food and Drug Administration Director-General Jaw-Jou Kang; and Taipei City Department of Health Commissioner Chi-Hung Lin.

Appendix C: Presentations by Center for Biosecurity of UPMC to Taiwan CDC

US Preparedness for Public Health Disasters

Tom Inglesby, MD, Chief Executive Officer, Center for Biosecurity of UPMC

US Preparedness for Public Health Disasters

The ongoing efforts at federal, state, and local levels to prepare to protect the health of the public following epidemics, natural disasters, technological accidents, and terrorism

- **Federal roles:** Provide scientific guidance, funding, technical assistance during health emergencies
  - Two major funding streams: CDC for public health agencies; HHS Assistant Secretary for Preparedness and Response (ASPR) for hospitals.
- **State and local roles:** On the ground preparations and response: epidemiology, surveillance, risk assessment, public communication, emergency vaccination programs, hospital care, etc.

How Federal Responsibilities are Divided in Public Health Preparedness

- White House National Security Staff: Policy setting, strategy, coordination.
- HHS—ASPR: Hospital preparedness programs; BARDA (medical countermeasures development); National Disaster Medical System; volunteer registration programs.
- HHS—Public Health Service: Public health professionals on call to respond to crises
- CDC—Office of Public Health Preparedness: Support for state and local public health programs, national pharmaceutical stockpile, select agent program, and emergency operations.
- DHS: Environmental surveillance.
- FDA: Approval of new medicines, vaccines, diagnostics, and devices.
- Department of State: International biosurveillance and capacity building programs.
- Department of Defense: International biosurveillance programs and medical countermeasure development.

Public Health Emergency Preparedness Program (PHEP)

- Run by the CDC; provides funding and technical assistance to 50 states, 4 major cities, and 8 territorial public health departments.
- Established in 2002 after 9/11 and anthrax letter attacks; provides yearly guidance and reporting requirements.
- In 2011, implemented systematic process to define set of public health preparedness capabilities to measure progress.
- Funding:
  - FY 2010 (actual): $761 million
  - FY 2011 (actual): $664 million
  - FY 2012 (estimated): $657 million
  - FY 2013 (budgeted): $642 million

PHEP Program Goal: Building Key Capabilities

Biosurveillance

- Public health laboratory testing
- Public health surveillance and epidemiologic investigation

Community resilience

- Community preparedness
- Community recovery

Countermeasures and mitigation

- Medical countermeasure dispensing
- Medical material management and distribution
- Nonpharmaceutical interventions
- Responder safety and health

Incident management

- Emergency operations coordination

Information management

- Emergency public information and warning
- Information sharing

Surge management

- Mass care
- Medical surge
- Fatality management
- Volunteer management

US National Hospital Preparedness Program

- Run by HHS Assistant Secretary for Preparedness and Response (ASPR).
- Assists states, cities, hospitals, healthcare coalitions to identify gaps in preparedness, determine priorities, develop plans for building healthcare capacity.
- Established in 2002 at same time as PHEP grants, with same 62 grantees.
- Began to align with PHEP grants in 2011 and identified 8 capabilities, in conjunction with 15 PHEP capabilities.

Funding:

- FY 2010 (actual): $417 million
- FY 2011 (actual): $375 million
- FY 2012 (estimated): $375 million
- FY 2013 (budgeted): $255 million

HPP Program Goal: Building Key Capabilities

- Healthcare system preparedness
- Healthcare system recovery
- Emergency operations coordination
- Information sharing
- Medical surge
- Responder safety and health
- Fatality management
- Volunteer management

HPP Performance Measures

- **Healthcare Coalition (HCC):** A collaborative network of healthcare organizations and their respective public and private sector response partners in a region that help coordinate preparedness, response, recovery, and mitigation efforts related to healthcare organization disaster operations.
  - Percentage of HCCs that have demonstrated their ability to function and execute the capabilities for healthcare preparedness, response, and recovery as defined by ASPR.
  - Percentage of HCCs that have developed processes for short-term recovery of healthcare service delivery and continuity of business operations.

Lessons Learned in Measuring Preparedness

- There needs to be measurement. Program started out without a measurement plan. Major weakness.
- Then there was too much measurement. Public health flooded with reporting requirements. Overwhelming.
- Need to measure the right things. Just because it's measurable does not mean it is meaningful.

- Progression from assets (capacities) to capabilities. Capabilities harder to measure, but more important.
- Fed/state/local collaboration needed to identify performance indicators. Cannot sort these out from national position without local knowledge and input.
- Tension between accountability and continuous quality improvement.
    - Accountability—people afraid to show weaknesses.
    - Quality Improvement—the point is to identify weaknesses.

Outside Scientific Assessments

US Government makes use of outside scientific assessment to get expertise not available in government, to gather independent views, to answer complex questions.

- Scientific advisory boards, eg:
    - Institute of Medicine Preparedness Forum (National Academy of Sciences)
    - ASPR National Biodefense Science Board
    - CDC OPHPR Board of Scientific Counselors
    - CDC National Biosurveillance Advisory Subcommittee

Preparedness and Emergency Response Research Centers (PERRCs)

- Research to evaluate the structure, capabilities, and performance of public health systems for preparedness and emergency response.
- Requirement to help translate the research to public health practice.
- Priorities include: Best approaches to public health training, programs for at-risk populations, legal issues related to preparedness.
- Multi-year funding for 9 universities: Harvard, Pittsburgh, Emory, Johns Hopkins, UC Berkeley, UCLA, University of Minnesota, University of Washington, University of North Carolina.

Congressional Oversight

- Many committees of US Congress (Senate and House of Representatives) oversee these programs.
- Annual budget hearings.
- Oversight hearing driven by external events, audits, interests of Congressional leadership, and need for new legislation.
- Many hearings and Congressional inquiries during H1N1, SARS, H5N1 events.
- Government Accounting Office (GAO) & Congressional Research Service (CRS).

Hospitals Rising to the Challenge: The First Five Years of the US Hospital Preparedness Program and Priorities Going Forward, March 2009

- **Methodology:** >150 hours of interviews and 14 site visits with >120 hospital and PH officials from all states.
- **Findings:** Hospitals are individually better prepared:
    - Emergency Managers designated
    - More realistic planning
    - Improved training, better exercises
    - Upgraded communications
    - Stockpiled supplies and equipment

- **Most importantly:** Coalitions of hospitals, PH agencies and emergency management agencies have been created in every location.
  - Improvement is mostly due to federal government funding and guidance.
  - BUT no hospitals prepared for catastrophic disasters.

Trust for America's Health: *Ready or Not?*

- NGO focused on community health, making disease prevention a national priority.
- Provides independent analysis of public health preparedness.
- Examines series of 10 indicators of preparedness across each state.
- States receive score based on those indicators, one point for achieving an indicator.
- Each state receives overall score from 0-10.

National Health Security Preparedness Index

- **Objectives**
  - Identify current state public health and health system capabilities, assess gaps.
  - Assess investments made to date, inform future funding decisions.
  - Provide consistency in measures over time.
- **Approach**
  - Design index collaboratively–feds, states, professional societies, academics.
  - Gather indicators from each state that reflect the extent to which states have developed major public health and hospital preparedness capabilities.
  - Weigh them appropriately through expert judgment and models.
  - Combine them into index score, measure annually.
- **Timeline**
  - Prototype index to be released in March.

US Experiences that Have Shown the Value of Public Health Preparedness

- Annual report from CDC describing the public health successes of the PHEP program—from responses to disease epidemics, wildfires, floods, tornadoes.
- Hospital evacuations in NY during hurricane—1,000 patients moved from NYU Langone and Bellevue under austere conditions with one immediate untoward effect).

Joplin, Missouri, Tornado: 2011

- EF-5 tornado hit the heart of the city destroying or damaging 8,000 homes, killing 161, and injuring 1,371.
- Made a direct hit on St. John's Hospital, killing 6, injuring hundreds; 183 patients were evacuated in 90 minutes.
- Coalition had planned for evacuation of one hospital to another and had just exercised it.

Public Health Preparedness: Challenges Ahead

- Public health preparedness is a common good.
  - People value it, but it's not always clear how to pay for it.
- Sustaining resources for this work is a challenge.
  - Swings from crisis to crisis.

- Need to tell the story, make the case strongly, persuade national leaders of the benefits and of the consequences of not funding.
- We should learn from each other's mistakes & successes.
  - We all have something to teach, something to learn.
- Epidemics spread; we are all at risk together.
  - We all are safer and better prepared when we work together.

US Response to the 2009 H1N1 Influenza Pandemic

Amesh Adalja, MD, FACP, Senior Associate, Center for Biosecurity of UPMC

Pillars of Preparedness Before 2009

- Several surveillance systems
- 4 antivirals
- Public health and hospital preparedness for bioterrorism and H5N1

CDC Influenza Surveillance Systems

- Multi-component US surveillance system:
- Outpatient illnesses
- Influenza hospitalizations
- Influenza/pneumonia deaths
- Geographic spread of influenza
- Virologic data
- BioSense

System Components

- **Virologic**—National Respiratory and Enteric Virus Surveillance System: 140 labs submit data on number of samples tested and number positive (type, subtype, age of patient).
- **Outpatient**—Influenza-Like Illness Surveillance Network: 3,300 healthcare providers submit number of patients seen and number with influenza-like illness (collaborations with state/local health departments).

System Components

- **Hospitalizations:** Emerging Infections Program
  - Collaboration among CDC, state health departments, and academic centers in 10 states; covers 7% of US population.
- **Deaths:** 122 Cities Mortality Reporting System
  - 122 US-wide cities submit weekly reports on total number of death certificates received and number of certs listing pneumonia or influenza.
  - Influenza-associated Pediatric Mortality Surveillance System—reports of nationally notifiable conditions.
- **Geographic spread:** Reported by state epidemiologists.

BioSense

- CDC program launched in 2003 to establish an integrated national public health surveillance system.
- Syndromic surveillance using chief complaint data from emergency departments in collaboration with state and local health departments.

- Pools information from Department of Veterans Affairs, DoD, and civilian hospitals around US, tracking emergency department visits and hospitalizations.
- Example: During the 2009 H1N1 pandemic, BioSense gathered info from EDs, labs, and pharmacies, and shared data with state/local public health departments and CDC.

Limitations of Flu Surveillance

- Reporting time lag: ~1 week in best scenarios.
- Not a comprehensive nationwide system.
- Severity indicators not robust.
- No risk factor delineation.

Drugs & Diagnostics

- **Drugs:** Amantadine, Rimantidine, Oseltamivir, and Zanamivir.
  - No IV formulations; all are oral + inhaled formulations.
- **Diagnostics:** Chiefly rapid antigen detection tests.
  - Some academic centers had PCR, fluorescent antibody, viral culture.
  - Commercial PCR tests not available.
  - Luminex

H5N1 Preparations Useful for H1N1

- Develop new diagnostic tests and improved diagnostic capabilities
- Improve surge capacity
- Develop policy and regulatory preparedness
- Improve access to viruses and reagents
- Provide guidance for clinicians
- Improve virologic surveillance
- Conduct antiviral resistance testing

US Detection of 2009 H1N1 Virus

- March 2009: 2 cases of febrile respiratory illness in children (un-related, no pig contact); residents of adjacent counties in southern California ill in late March.
- April 15, 2009: CDC began pandemic influenza A (H1N1) virus testing.
- April 22, 2009: CDC activated EOC.
- April 26, 2009: US declares national public health emergency.
- June 11, 2009: WHO declares global pandemic of novel influenza A (H1N1) virus.

Detection of 2009 H1N1 Virus

- **1st Case**—CDC and US Navy program using Meso scale diagnostic device: Untypable → Marshfield Clinic, WI State DOH.
- **2nd Case**—Border Infectious Disease Surveillance Project in collaboration with US Navy: Untypable → CDC

Implications of 2009 H1N1 Detection

- When influenza surveillance is being conducted, untypeable isolates must be followed up—high yield.
- Programs in place to systematically analyze untypeable strains will foster this approach as standard of care.
- Discovery of next pandemic strain may be late due to limitations in diagnostics (rapid antigen testing vs. PCR).

National Public Health Emergency

- HHS Secretary made public health emergency and public readiness and emergency preparedness (PREP) act declarations.
- US president declared national emergency.
- June 2009: $5.8 billion funding.

CDC Response

- **Strategic National Stockpile (SNS):** Began release of 25% of specific supplies.
  - 11 million drug regimens
  - Personal protective equipment (39 million)
  - Purchased more oseltamivir
- **Diagnostic support:** Test kits based on CDC PCR.
  - May 1: shipped to public health labs
- **Heightened surveillance:** New system that addressed problems of other systems:
  - Aggregate Hospitalizations and Deaths Reporting Activity–web-based system used to track state reports of laboratory-confirmed and syndromic flu-related hospitalizations and deaths
  - Clinical guidance; antivirals, infection control, etc.

FDA Response: Emergency Use Authorization (EUA)

- Project Bioshield Act (2004) included EUA.
- Allows distribution of unlicensed products.
- Multiple EUAs issued for respirators, diagnostic tests, and peramivir.

Vaccine Issues

- Pandemic occurred during production of regular trivalent seasonal vaccine.
- CDC created vaccine seed stock in April 2009; distributed to manufacturers.
- Difficulty growing; delays in delivery.
- FDA approval September 15, 2009.
- Priority groups.
- September 30, 2009: States able to place first orders for 2009 H1N1 vaccine.
- First doses administered on October 5, 2009.

Nonpharmaceutical Intervention: School Closings

- Several states closed schools (e.g., NYC).
- Issues arose, i.e., caretakers, congregation outside of school, etc.
- Efficacy in future pandemics questionable.

Hospital Issues

- Use of ECMO at tertiary care centers.

- Heightened use of antivirals emphasized, especially for high-risk groups (pregnant women, obese people).
- Mandatory vaccination for healthcare workers.
- Use of N-95 vs. surgical masks.

N-95 vs. Surgical Masks

- Component of airborne transmission of influenza.
- National Academies of Sciences (IOM) and CDC endorsed N-95 use based on CDC (NIOSH) study.
- American Hospital Association and CDC's Healthcare Infection Control Practices Committee did not concur.
- Economic and supply issues: ~35% of hospitals did not agree that N-95s were readily available in Society for Healthcare Epidemiology study. Another study reported 26% of hospitals ran out of N-95s.
- UPMC and many hospitals used N-95s only for aerosol generating procedures.

Conclusions

- US government pandemic response involved augmenting prior influenza activities and instituting new approaches based on H5N1 preparedness and bioterrorism policy.
- Several hurdles remain:
  - Vaccine technology (adjuvants, cell-based, whole virion)
  - Infection control

Biosurveillance in the US: Current Approaches and Lessons Learned

Jennifer Nuzzo, SM, Senior Associate, Center for Biosecurity of UPMC

Insufficient Information During 2001 Anthrax Attacks

- Insufficient surveillance → difficulties in determining scope of attack.
  - No rapid test to rule in/out anthrax among those at hospitals.
  - Hospital-based surveillance systems were quickly overloaded with reports due to nonspecific nature of anthrax symptoms.
- Not enough information to guide clinical care of anthrax patients.
  - Clinical community largely unfamiliar with anthrax disease.
  - CDC did not publish information aimed at clinicians.
- Leadership did not have enough information to address the public.
- Regarding first anthrax patient, HHS Secretary Thompson said: "We do know that he drank water out of a stream when he was traveling to North Carolina last week."

"Biosurveillance"

- No single definition.
- Many potential sources of information:
  - Traditional public health surveillance systems, data from environmental monitoring systems, school/worker absenteeism reports, purchases of over-the counter medicines/products, hospital admissions and chief complaint data, unstructured open-source information such as social medial, etc.
- Most data come from nonfederal sources.
  - State and local health departments are critical.

Aims of Biosurveillance

Have sufficient information to answer at least the following:

- What is happening now?
  - How many people are already sick?
  - How is the disease spreading?
  - How severe are the cases?
- Who is most at risk?
  - How is this event likely to unfold?
  - How will the epidemic unfold?
  - What interventions are useful?
- Do we have what we need to respond?
  - What treatments are beneficial?
  - What is the supply of countermeasures?
  - What medical resources are available?

Biosurveillance Before 2001

- States/locals had very limited capacity:
  - Fewer than half of state and local public health departments had continuous access to high-speed internet or the ability to send broadcast faxes to alert clinicians about important outbreaks.
  - Few health departments had 24 hour/7 days a week monitoring capabilities.
  - Public health laboratories were not connected and were not equipped to detect many biological agents.
- Few dedicated sources of funding or policies aimed at improving capabilities.

Many Improvements After 2001

- National Center for Emerging Zoonotic and Infectious Diseases, Division of Preparedness and Emerging Infections, Laboratory Response Network Branch.
- Improved Biosurveillance became a goal, eg:
  - The 9/11 Commission Report
  - HHS: National Health Security Strategy
  - NSC: National Strategy for Countering Biological Threats
  - National Strategy for Biosurveillance

Improved Surveillance Now an International Obligation

- **International Health Regulations (2005):** US has legal obligation to improve its capacity to detect and respond to disease outbreaks and to help other countries improve theirs as well.
  - Improving biosurveillance capabilities across the globe now a key program of several US agencies, including Department of Defense.

Current US Approach to Biosurveillance

- States and locals receive federal funding for biosurveillance and other preparedness efforts.
- Many US agencies are involved:
  - Health, Defense, State, Homeland Security, Intelligence Community, Agriculture, Commerce, Transportation, Energy, Environmental Protection, Postal Service, etc.

- Many disparate systems already in place (too numerous to count).
- US spends >$300 M/year on international biosurveillance.

- The Center for Biosecurity and other outside groups have called for a unified biosurveillance strategy and better coordination at federal level.

BioWatch

- Managed by Department of Homeland Security since 2003.
- Deployed in 30 cities (outdoors and indoors).
- Current technology uses filters that collect air samples, filters that must be collected manually and tested at state/local public health laboratories.
  - Results obtained 12-36 hours.
- Program has been highly controversial.
  - Pushback from users.
  - Questions about how to respond following positive results.
  - Efforts to modernize technology experiencing setbacks.

BioSense

- Operated by US CDC since 2003.
- Aggregates syndromic data from states and hospitals.
- Initially launched to be a national early warning system for bioterrorism and other emergencies.
- Concept of operations has changed since inception; redesigned several times.

PulseNet

- Coordinated by the US CDC since 1996.
- Operates in all US states and in many countries.
- National network of public health and food regulatory agency laboratories that perform standardized molecular subtyping of foodborne disease-causing bacteria.
  - Has led to meaningful improvements in food safety by identifying unrecognized pathogens and sources of contamination.
- Frequently cited as most valued national surveillance program due to specificity of information provided.

Lessons Learned So Far: Design of Biosurveillance Must Involve Users

- Users must value data in order to participate support program.
  - Public health agencies still don't trust BioWatch results and won't act on them without conducting separate investigations.
  - Redesign of BioSense started with asking users what they wanted out of program.
- Compulsory reporting may not better than voluntary.
  - Redesigned BioSense leaves data sharing decisions to states.
  - CDC expects they will get greater participation and more complete/timely data than earlier iterations of program.

Lesson: Faster Is Not Always Better

- Initial US approach to biosurveillance sought "more data, faster."
- Resulted in development of systems that overwhelmed users with data and alerts.

- Did not provide actionable information.

Lesson: Biosurveillance Should Support Decision-Making

- US did not give sufficient attention to information needs for responding to event once it is detected.
- During 2009 H1N1 flu pandemic, decision makers could not implement existing pandemic response plan due to lack of adequate information.
- Focus of new US Strategy for Biosurveillance is information to support decision-making.

Lesson: Biosurveillance Must Improve Exchange between Public Health and Health Care

- Improved information flow from the clinical sector is essential for biosurveillance.
  - Problems with compliance and timeliness of disease reports.
  - Few systems capture in-patient data.
  - Need better information about health system demand and available resources.
  - Need faster, more complete information on deaths.
- Electronic health records (EHRs) are seen by many as an important step in improving information exchange between public health and healthcare sector.
  - Current efforts to develop/adopt EHRs doesn't adequately address public health's needs.

Biosurveillance Requires Information from Multiple Sectors

Lesson: Biosurveillance Requires Long-term Investments

- Biosurveillance requires skilled analysts more so than technology.
- Requires sustained funding, rather than onetime purchase.
  - Loss in federal funding, combined with state budget cuts has made it difficult for health departments to maintain newly developed surveillance systems and analytical staff.
  - Local health departments have lost 15% of their workforce since 2008.
  - In US, 40% of public health departments have reduced programs and services, including emergency preparedness efforts.

US Approach to Developing and Acquiring Medical Countermeasures for the Civilian Population

Anita Cicero, JD, Chief Operating Officer, Center for Biosecurity of UPMC

Brief History of US MCM Strategy

- **Prior to 2001**
  - MCM programs for military use
  - No structured MCM program and no market for civilian population
- **After 2001**
  - Congress set up a fund to procure MCMs for civilian use
  - Congress established new authority at HHS to fund and oversee advanced development of MCMs
- **Currently**
  - FDA has new initiative focused on speeding up regulatory process for MCMs

- Ongoing efforts to secure adequate funding and to acquire needed MCMs

Creation of Fund to Purchase MCMs

- **Need for legislation:**
  - Following the 9/11 attacks, the US committed to developing new diagnostic tests, drugs, vaccines, and other treatments to respond to an attack of chemical, biological, radiological, or nuclear (CBRN) agents.
  - The pharma industry was not invested in CBRN MCMs because of lack of a significant commercial market.
- **Purpose of "Project BioShield" Act of 2004**
  - Set up $5.6 billion fund from FY2004-FY2013 for procurement of MCMs for the national stockpile
  - Guaranteed a federal government market for new CBRN medical countermeasures
  - Permitted "emergency use" of medical countermeasures not yet approved by the FDA

"Valley of Death" for MCMs

- NIH funds basic research
- Prior to 2006, no funding for advanced development of MCMs ["Valley of Death"]
- BioShield funds procurement of countermeasures

Funding Advanced Development of MCMs

- In 2006 Congress created the Biomedical Advanced Research and Development Authority ("BARDA") in the Department of Health & Human Services
- Mission is to fund advanced development of MCMs for chemical, biological, radiological, and nuclear incidents; pandemic influenza; and emerging infectious diseases
- BARDA funding bridges the "valley of death" during the late stages of product development

Centers for Innovation in Advanced Development and Manufacturing

Goals:

- Develop public/private partnerships for MCM development and manufacture
- Assist smaller companies that don't have resources or expertise to do advanced development/manufacturing
- Build plants to incorporate flexible manufacturing platforms that can be used to produce more than one product. The facilities will use modern cell- and recombinant-based vaccine technologies that have the potential to produce vaccines for pandemic influenza and other threats.

Agency Responsibilities Related to MCMs

- **NIH/NIAID**
  - The National Institute of Allergy and Infectious Diseases (NIAID) supports the basic research and discovery work needed to develop countermeasures against emerging infectious diseases and agents of bioterrorism.
  - NIAID funds internal and extramural research, with an operating budget in FY2013 of $1.3 billion
- **Department of Homeland Security**
  - DHS assesses the risk for bioterrorism in analyses called "Material Threat Assessments" and "Material Threat Determinations"
  - DHS gathers scientific information, intelligence, and expert/stakeholder input to develop an MTA
  - MTDs are issued following consideration of all threats for which there is an MTA
  - HHS/BARDA is responsible for setting priorities in MCM development based on these MTDs

- **Department of Health and Human Services**
  - The Assistant Secretary for Preparedness & Response in HHS has leadership of medical countermeasure development
  - Within ASPR, BARDA has responsibility for developing and acquiring medical countermeasures
  - BARDA works with DHS to determine priorities, with FDA to address regulatory challenges, and with industry to guide the development of products
- **Food and Drug Administration**
  - The FDA is responsible for approving safe and effective products in two main centers
  - Center for Drug Evaluation and Research
  - Center for Biologics Evaluation and Research
  - Diagnostics are evaluated by the Center for Devices and Radiological Health
  - In addition to its regular role in biopharmaceutical regulation, FDA has dedicated resources to biosecurity
  - Medical Countermeasures Initiative (MCMi) $23.6 million
  - FDA Bioterrorism MCM development $121.3 million
- **Centers for Disease Control and Prevention**
  - CDC manages the Strategic National Stockpile, which maintains stockpiles of MCMs purchased by BARDA
  - $486 million in FY2013
  - CDC is also responsible for coordinating the distribution of MCMs during a public health emergency
  - CDC also advises the USG and the states on how to deploy vaccines, via the Advisory Committee on Immunization Practices
- **Department of Defense**
  - Department of Defense has different needs than civilian biodefense agencies, but often collaborates with HHS, DHS, and FDA to develop MCMs
  - The primary goal for DoD is to develop MCMs to protect US troops and personnel against biological weapons, endemic diseases, and emerging infectious diseases
  - DoD has its own dedicated R&D funding arm and a separate acquisition structure

MCMs Procured under Project BioShield

- HHS has entered into ~9 contracts for development and acquisition of CBRN MCMs valued at over $2 billion and has stockpiled 17 MCMs against CBRN threats
- Examples of MCMs in the stockpile:
  - Monoclonal antibodies to treat anthrax
  - Anthrax immune globulin to treat anthrax
  - Anthrax vaccine
  - Botulinum antitoxin
  - New smallpox vaccine
  - Potassium iodide for pediatric use
  - Treatments for internal radioactive particle contamination
  - 50 million doses of H5N1 vaccine

Influenza Efforts

- US goal is to make vaccine available for all Americans within 6 months of the emergence of a virus with pandemic potential
- The USG provides support for influenza vaccine manufacturing, as part of pandemic preparedness efforts.

- The government has purchased potential pandemic vaccines for stockpiling.
- BARDA has invested approximately $2 billion since 2005 on domestic and international manufacturing capacity using current HA-head, egg-based, or cell-culture–based vaccines.

BARDA Goals for Influenza Vaccine

- Develop more modern platforms for manufacturing influenza vaccines in order to increase flexibility, surge capacity, and reliability of production
  - Develop improved vaccine seed strains, sterility tests, and potency reagents and testing
  - Support development of faster, more scalable next-generation recombinant influenza vaccines
  - Complete development and evaluation of adjuvanted pandemic influenza vaccines
  - Expand number of FDA-licensed influenza vaccines, to include cell-based products

Cell Based Influenza Vaccines

- US investment in cell-based technology
  - Domestic plant opened in December 2011 capable of producing 25% of US vaccine needs
  - Approximately $1B total government investment in facility and vaccine
  - Novartis and US partnered to develop vaccine and facility
- First cell-based vaccine approved by FDA in November 2012
  - Previous experience with cell-based vaccines for polio, rubella, and Hep A
- Advantages:
  - Ability to maintain an adequate supply of readily available, previously tested and characterized cells for use in vaccine production—not reliant on egg supply
  - Increased speed and faster start-up of the vaccine manufacturing process in the event of a pandemic
  - Cell-based technology is more flexible and adaptable for making other vaccines—eg, for an emerging infectious disease

Lessons Learned

- Secure government funding for developing and purchasing MCMs for dangerous pathogens was needed to incentivize industry
- Government should not wait until the end of the process to consider:
  - The concept of use for MCMs
  - A plan and resource allocation for warm base manufacturing
  - Life cycle management issues for MCMs in stockpile
- Lack of government clarity and consistency on specific needs and product requirements discourages biotech companies and venture capitalists from investing in MCMs
- The uncertain regulatory approval process for MCMs is a major barrier to development

Remaining Challenges

- Difficulty of developing broad spectrum countermeasures
- Unclear return on investment for industry
- Challenge of obtaining sufficient and sustained funding for advanced development and procurement of MCMs
  - Over a decade since anthrax attacks, so policymakers not as focused on MCMs for civilian population
  - Hard for Congress to understand high product failure rate in advanced development and to accept inevitability of funding unusable products

- Setting priorities in MCM development during austere funding environments
- Unclear regulatory pathway for MCMs for diseases with no patient population
- Developing plans on how to use MCMs strategically in the event of an epidemic or attack

Healthcare System Preparedness for Mass Casualty Events

Amesh Adalja, MD, FACP, Senior Associate, Center for Biosecurity of UPMC

Definitions

- **Mass casualty event:** Any event, of any type, that requires the coordinated response of at least several hospitals within a community to provide adequate medical care for those affected.
  - Could be as small as a bus accident or as large as a pandemic
- **Catastrophic health event:** Any natural or manmade incident, including terrorism, that results in a number of ill or injured persons sufficient to overwhelm the capabilities of immediate local and regional emergency response and healthcare systems.

Elements of US Hospital Preparedness

- Varies among hospitals; based on size, location, specialty status, etc.
- Major improvements occurred after 9/11 and in response to pandemic concerns
- Several federal efforts to augment preparedness have been implemented (e.g., Hospital Preparedness Program)

Healthcare Preparedness: Significant Events 1989-2007

- 1989: Loma Prieta earthquake
- 1991: Gulf war—discovery of Iraq's biological weapons program
- 1992: Disclosure of Soviet bioweapons program
- 1993: World Trade Center bombing
- 1994: Northridge earthquake
- 1995: Aum Shinrikyo Sarin gas attack (Japan)
- 1995: Oklahoma City bombing
- 1996: MMRS created
- 1997: CDC "Emergency – Ready" public health department funding
- 1999: National pharmaceutical stockpile established
- 2001: 9/11; anthrax letters; JC updates emergency management standards
- 2002: P.L. No. 107-188; CDC PHEP funding established; NBHPP created
- 2003: SARS; NPS became SNS
- 2004: Indian Ocean tsunami; CRI established
- 2005: Hurricane Katrina
- 2006: PAHPA
- 2007: ASPR created; HPP moved to ASPR

Individual Institutions: Important Points

- The appropriate extent of planning and preparedness efforts will vary among healthcare institutions.
  - No one template or set of capabilities will fit all institutions
  - Not all institutions will fulfill the capabilities in the same way
- Healthcare institutions could be overwhelmed and unable to provide patient care in the usual way.
  - Limited resources must be allocated optimally
- Disaster victims will need care, as will the healthcare institution's usual patients and patients who cannot access their normal site of care

Hospitals Rising to the Challenge

- **Purpose:** Assessment of the progress in healthcare preparedness for mass casualty disasters achieved as a result of the first 5 years (2002-2007) of the HPP
- **Methodology:** Comprehensive literature review and extensive interviews
  - 91 interviews with 133 individuals involved in public health and hospital preparedness (in all states and major cities)
- **Findings:**
  - The state of preparedness of individual hospitals improved significantly from 2002-2008
  - Planning for catastrophic health events, including crisis/disaster standards of care, is in its early stages
  - Hospitals are much more prepared than they were in 2001, in large part due to the HPP
  - Grants: Funding for stuff, disaster coordinators, exercises and drills; process stimulated development of a forum for collaborative work on preparedness
  - Healthcare coalitions and partnerships have developed and are the most effective instruments for advancing preparedness and utilizing grant resources effectively
  - Engagement of hospital leadership varies; this is most significant in communities that have faced disasters and threats in the past, i.e., "their local threat"
  - Large hospital systems have internal disaster response plans for hospitals in multiple states or regions
  - Drills, exercises, approach to incident command and NIMS needs to be standardized and reviewed for relevance to healthcare setting
  - Situational awareness and communication: There has been progress in bed tracking; less progress in tracking of personnel, supplies, pharmaceuticals
  - Catastrophic health event emergency planning—considered "too hard, paralyzing" in most cases; most plan are for smaller-scale, more frequent occurring disasters. The most common areas for catastrophic emergency planning are pandemic flu and evacuation
  - Allocation of scarce resources in a disaster: Shift from individual to population based priorities is under discussion
  - Alternative care sites: Planning has started in many states, but no clear definition of scope of care and concept of operations

"Healthcare Coalition"

- Formal collaboration among hospitals that includes public health.
- May include other healthcare entities.
- Close relationship with emergency medical services and emergency management Agency.
- Should have role in both preparedness and response.

Healthcare Coalitions: Important Characteristics

- Include and formally link at least all hospitals, public health and emergency management agencies, and emergency medical services
- Conduct joint threat assessment, planning, purchasing, training, and drills
- Serve as an information clearinghouse with systems for tracking patient load and assets
- Have a formal role in local/state incident command system
- Coordinate volunteers in healthcare settings
- Provide forum for decisions regarding allocation of resources
- Coordinate alternate care facilities

Preliminary Evidence of Coalition Value

Events in which coalitions improved response (examples from HPP interviews and HFPP reviews)

- Virginia Tech shooting (2007): Southwest Virginia Healthcare Coalition
- Minnesota bridge collapse (2007): Regional Hospital Resource Center
- Tulsa tornados & ice storm: Medical Emergency Response Center
- Seattle snow storm (2008): Seattle-King County Healthcare Coalition
- Hurricanes Gustav and Ike (2008): Galveston, Texas
- Alaska RSV outbreak (2008): All Alaska Pediatric Partnership
- Southern California wildfires (2005): Disaster Resource Centers
- Florida hurricanes, wild fires, and race horse poisoning: Palm Beach, FL, Healthcare Emergency Response Coalition

H1N1 (2009)

- Seattle, Northern Virginia, NYC, Los Angeles, and Connecticut activated medical coordination centers
  - Collected healthcare situational awareness data
  - Coordinated plans to distribute/use stockpiled antivirals
  - Translated, coordinated, and distributed clinical guidance
  - Coordinated messages to media
- UC Davis Emergency Care Coalition
  - Initiated rural telemedicine connection to coalition hospitals to support care of critically ill H1N1 patients

The Next Challenge in Healthcare Preparedness: Catastrophic Health Events

Description of capabilities of a prepared healthcare system

- Analysis of current response strategy and structure
- Recommendations to build on current successes and existing structures to make all-hazards healthcare preparedness and response scalable to include catastrophic health events
- Provisional assessment criteria for ongoing assessment of progress toward these national preparedness and response capability goals

A Healthcare System Prepared for Catastrophic Events is Able to…

- Provide care for disaster victims, protect the well, and maintain essential healthcare services for the general population
- Respond quickly and agilely to mass casualty events of all sizes and causes, including those that cross jurisdictional boundaries
- Function under a variety of adverse circumstances:
  - Prolonged surge of patients
  - Patients needing prolonged care
  - Contaminated or contagious environment
  - Loss of infrastructure
  - Imperfect situational awareness and disruption of incident management
- Harness all useful national resources, public and private
- Recover quickly after a disaster, still providing essential healthcare to the population

Problems Derived from CHE Scenarios

- Local hospitals are at risk of becoming dysfunctional quickly and may not be able to care for the sick and injured
- The need for critical care services will far exceed the local and geographically contiguous regional capacity
- Triage/first aid centers will be needed immediately and in large numbers
- Screening will be needed for patients who might have had significant exposures (radiation, combined injury, incubating anthrax), but no rapid diagnostics exist
- Deployable medical resources are too few and too slow
- Local, state and federal governments do not have sufficient situational awareness capabilities or transportation capacity to move patients to where they can get care and track them
    - ~13,000 in both scenarios will need to be moved within 100 miles
    - In the nuclear scenario, an additional 100,000 patients with ARS will need to be transported to hospitals beyond 100 miles before they become critically ill

2009 H1N1 Experience Reveals Vulnerabilities

- Cannot predict where or when next pandemic will arise or how severe it will be
- Challenges in this mild pandemic reveal persistent vulnerability for truly catastrophic health events
    - Time required to produce, deploy novel vaccine or medical countermeasure
    - Screening and situational awareness limited by absence of good rapid diagnostic testing
    - Limitations of disease containment strategies
    - Inadequacy of medical surge capacity

Healthcare Response to CHE: Strategic Challenges and Recommendations

- **Strategic Challenges**
    - No mechanism exists to achieve situational awareness needed to coordinate all public and private healthcare resources and manage and track distribution of patients.
    - Current transport plans and resources are grossly inadequate to move the expected number of patients in time to save lives and maintain essential services.
    - Incident management structures may be inefficient early on in CHE due to inadequate situational awareness, long chains of authority, overwhelmed decision makers, and "analysis paralysis."
    - Large parts of the healthcare sector (e.g., urgent care and surgical centers, long term care facilities) are not well integrated into disaster preparedness systems; they may provide additional surge capacity and maintain essential medical services.
- **Recommendations**
    - Promote fully functional healthcare coalitions in every community.
    - Ensure close operational relationships between neighboring healthcare coalitions (even across state lines) for mutual aid to supplement state and federal incident command systems.
    - Incentivize all healthcare entities to participate in healthcare coalitions for disaster response.
    - Create a patient transportation system that harnesses private sector resources.
    - Create a National (not federal) concept of operations plan for healthcare response to a CHE down to the local level.

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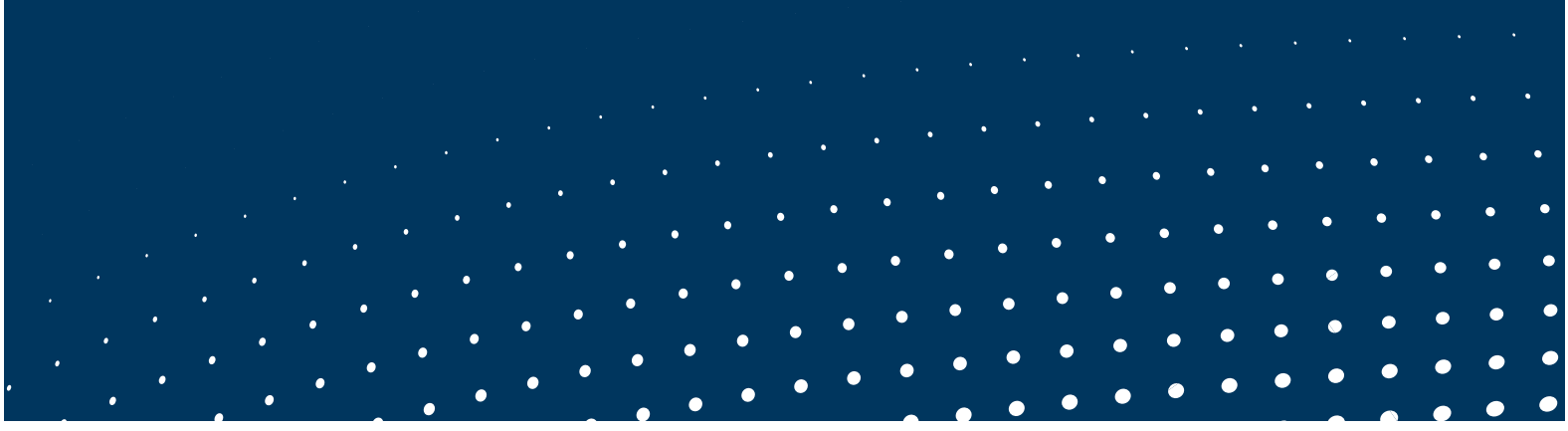

附錄 5：流感抗病毒藥劑及防疫物資儲備量及儲備比例

一、 抗病毒藥劑

考量疫情之不確定性，且抗病毒藥劑產能有限，為避免大流行發生時各國皆搶貨情況，故規劃儲備至少 11%以上，以維持藥劑整體儲備量達全人口 10%以上之目標及因應疫情之防治需求，依我國目前抗病毒藥劑儲備量及儲備比例，估算各年度採購量及經費如下：

104-110 年藥劑使用情形及採購規劃一覽表

(單位：萬盒、萬元；更新日期：104/5/29)

年度		104 年	105 年	106 年	107 年	108 年	109 年	110 年
年初庫存量(A)		276.0	324.6	249.6	249.6	249.6	249.6	249.6
當年屆期量		0	113.9	0	0	8	109	44
預估當年屆期量[1](B)		0	95	0	0	0	0	0
當年預估使用量(C)		15[3]	40	40	40	40	40	40
當年底庫存量(D)	庫存量(=A-B-C)	261.0	189.6	209.6	209.6	209.6	209.6	209.6
	D/2300[2]%	11.3%	8.2%	9.1%	9.1%	9.1%	9.1%	9.1%
經費需求(維持法定最低目標10%以上)	採購量(E)	63.6	60	40	40	40	40	40
	採購經費(E*700)	26,524[4]	42,000	28,000	28,000	28,000	28,000	28,000
	(D+E)/2300[2]%	14.1%	10.9%	10.9%	10.9%	10.9%	10.9%	10.9%
經費需求(維持法定目標 12%以上)	增加採購量(F)	0	60	0	0	0	0	0
	採購經費((E+F)*700)	26,524[4]	84,000	28,000	28,000	28,000	28,000	28,000
	(D+E+F)/2300[2] %	14.1%	13.5%	13.5%	13.5%	13.5%	13.5%	13.5%

備註：

1. 預估當年屆期量：假設當年所使用的皆為將屆期的藥劑，105 年屆期藥劑 113.9 萬盒，扣除可能使用量，估算屆期數量約 95 萬盒。
2. 全國人口數設定為 2300 萬人。
3. 截至 104 年 5 月 29 日已使用 23.8 萬劑，故預估 104 年約再使用 15 萬劑。
4. 104 年採購經費為(API 轉換 44 萬盒*291 元/盒)+(新購 19.6 萬盒*700 元)。

二、 防疫物資

（一）查依據 100 年 1 月 27 日「行政院禽流感防治第 62 次聯繫會議」及 102 年 12 月 27 日衛生福利部傳染病防治諮詢會流感防治組第 29 次會議決議疾病管制署應儲備防護裝備（下稱 PPE）品項及其安全庫存量為：外科等級口罩 2,700 萬片（包括防疫用 300 萬片及代庫存民生口罩 2400 萬片）、N95 等級口罩 90 萬片及防護衣 14 萬件。本案並經提報 103 年 1 月 7 日「H7N9 流感中央流行疫情指揮中心第 20 次會議暨行政院禽流感防治第 95 次聯繫會議」會議確認。

（二）爰疾管署據以儲備上開 PPE，並委託廠商代庫存，惟 PPE 有保存效期須汰舊換新，再加上為因應突發疫情時須依中央流行疫情指揮中心指示調撥 PPE 供相關單位防疫使用之需求，設定 PPE 儲備緩衝量，故疾管署每年除需編列儲備 PPE 倉儲經費外，尚需編列汰舊換新之換貨服務費，以及採購撥用相關單位使用之 PPE 等預算，以確保並維持 PPE 之安全庫存量。