TKC EXPERT PANEL FOR THE PUBLIC HEALTH ASSESSMENT OF AIR QUALITY IN FEMA TEMPORARY HOUSING

MAY 1-2, 2008

BOULDER, COLORADO

SUMMARY OF PROCEEDINGS (FINAL VERSION)

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BACKGROUND INFORMATION

Approximately 143,600 households lived in temporary housing units (THUs) in Mississippi and Louisiana after Hurricanes Katrina and Rita. At the time of the expert panel, approximately 38,000 families still lived in THUs. Based on concerns about potential respiratory health and dermatological effects associated with living in the trailers, the Federal Emergency Management Association (FEMA) asked the Centers for Disease Control and Prevention (CDC) to assess the health risk to people who lived in the THUs for extended periods. TKC Integration Services (TKCIS) convened a scientific panel of experts to guide CDC in its assessment. This report summarizes the second meeting of this expert panel.

MEETING PURPOSE AND OVERVIEW

This second meeting of the panel was designed to review results from completed and ongoing CDC and FEMA studies and to guide future studies into possible exposures and health impacts from living in the THUs. During the first part of the meeting, CDC presented results from completed studies and designs for future studies. Next, the expert panel convened in a closed-door session without CDC to answer five (5) specific questions that will help guide future CDC and FEMA efforts. Finally, all meeting attendees reconvened to hear and discuss the panel's recommendations.

INTRODUCTION

Dr. Michael McGeehin called the meeting to order at 8:37 am Mountain Time. McGeehin welcomed the panel, thanked them for their efforts up to this point, and provided an overview of the agenda for the meeting. McGeehin mentioned to the panelists that CDC would like the panelists to officially review the final occupied trailer formaldehyde measurement study report (not the interim report provided for this meeting), ideally by June 1. Next, meeting participants introduced themselves and explained their affiliations with this task. After a brief discussion,

CDC reminded participants that this is a TKCIS expert panel, not a CDC panel and that the panel is a closed session. This structure gives the panelist the freedom to speak frankly and provide the best advice to CDC through TKCIS.

OCCUPIED TRAILER ASSESSMENT FINDINGS

Presentation

Drs. Jim Lando and Matthew Murphy presented the findings from the investigation of formaldehyde levels in occupied FEMA-supplied THUs (the occupied trailer study). In October 2005, FEMA distributed THUs, including travel trailers, park models, and mobile homes, to the victims of hurricanes Katrina and Rita in the Gulf Coast region. Travel trailers were by far the most frequently distributed THU. Travel trailers are small (less than 320 square feet), temporary, and regulated by state transportation authorities (not federal housing authorities). The park models are slightly larger (less than 400 square feet) and, although temporary, can be placed on a more permanent site than the trailers. The park models are exempt from U.S. Department of Housing and Urban Development (HUD) regulations regarding formaldehyde and building materials. The mobile homes are larger than the park models and trailers (more than 320 square feet), are more permanent residences, and are regulated by HUD.

This study randomly selected 519 THUs from Louisiana and Mississippi. The sample was broken into 11 strata by unit type (e.g., travel trailer) and brand (e.g., Gulfstream). The Gulfstream was oversampled because it was the most frequently distributed THU. Each stratum was weighted according to the proportion of that type out of all THUs. The study used 40,000 occupied trailers as the sampling frame. Eligibility criteria included that the THU had an adult resident who was at least 18 years of age, that the adult resided in a FEMA-supplied THU in Mississippi or Louisiana at the time of the telephone recruitment, and that the adult respondent spent at least six (6) hours each day in the THU. The study used a two-part consent procedure in which participants provided assent during the scripted recruitment call and written consent at the time of sampling.

Air samples were collected in each THU. The formaldehyde sampling was conducted in a central location of the THU at a height of four feet for one hour using National Institute for Occupational Safety and Health (NIOSH) method 2016 and a flow rate of 500mL/min. Bureau Veritas Laboratory analyzed the samples (through a competitive bid). A questionnaire and walk-thorough survey were also conducted. Then multivariate linear regression models were constructed using SAS version 9.1. Measures of central tendency are expressed as geometric means.

Recruiters attempted to contact 1,499 potential participants. Of those, 1,137 (76%) were able to be contacted. Of those contacted, 717 (63%) were eligible for the study. Of those that were eligible, 616 (86%) agreed to participate over the telephone and 519 (84%) of those agreed to participate at the time of sampling. Thus, the overall response rate for eligible participants was 72% (519 out of 717 eligible).

The major finding was that for all occupied THUs, the geometric mean of the formaldehyde was 77ppb. For travel trailers, the geometric mean was slightly higher than the average for all THUs (approximately 81ppb). Mobile homes were lower than average (approximately 58ppb) and park model homes were even lower than mobile homes (approximately 40ppb). All formaldehyde levels for the three categories were statistically significantly different from each other. The formaldehyde levels were also assessed by brand. Although some brands showed much lower geometric means than others (e.g., the Fleetwoods and Silver Creeks), the ranges for all brands include 100ppb. The percentage of THUs for each brand with formaldehyde levels equal or greater than 100ppb and equal or greater than 300ppb was calculated. The Gulfstream travel trailer had 56% greater than or equal to 100ppb while the Silver Creek park model had only 3%. These data have raised questions about why some models had relatively lower formaldehyde concentrations and others did not. There is public and Congressional concern that the THU contractors lowered manufacturing standards to build the THUs quickly as the need demanded.

Panel participants asked about the age of the THUs at sampling. All the THUs were produced and used at approximately the same time. In addition to the ones that were built specifically for FEMA to provide relief after hurricanes Katrina and Rita (i.e., the snowballs), FEMA also

purchased THUs off retail lots. Those purchased off retail lots tended to be about six (6) months older and usually had more windows.

Formaldehyde levels were plotted against temperature (range: 41 to 91 degrees Fahrenheit) and humidity (range: 23 to 88 percent). The plots indicate that as temperature and humidity rise, so does the formaldehyde level. A multivariate linear regression was performed with the log of formaldehyde levels. The stratum, average temperature, relative humidity, and windows/doors open three hours prior to testing accounted for 31% of the variance in formaldehyde levels. Adding the use of propane was statistically significant, but only increased the R^2 by 1%. The use of glue and paints or furniture finish were also statistically significant, but also only increased the R^2 by 1% each. All these factors accounted for 34% of the variance.

A USPHS officer and FEMA representatives notified participants of the results. A series of community meetings were held in Louisiana and Mississippi to present the results. In addition, CDC met with federal, state, non-profit, and for-profit organizations to discuss the results. The report was also posted on the CDC Web site.

In summary, the geometric mean formaldehyde levels are four (4) to 10 times that of traditional homes and two (2) to five (5) times that of previous mobile home studies. The travel trailers had significantly higher formaldehyde levels than other THU types. There are several limitations to the study. The results likely underestimate the occupants' long-term formaldehyde exposure. The sampling was conducted in cooler winter months, and given the relationship between formaldehyde levels and temperature and humidity, the levels may be higher in the summer. In addition, the THUs that were sampled averaged two (2) years of age and it is likely that levels were higher when the THUs were newer.

From this study, CDC recommended that FEMA relocate travel trailer occupants and prioritize the relocation of vulnerable populations. CDC recommended that FEMA assess the potential for formaldehyde exposure in travel trailers and mobile homes used in other places and contexts. FEMA and CDC will establish a registry of people residing in THUs. Possible points of discussion from this study include that one quarter of the THUs had non-working smoke

detectors, smoking variables were associated with lower formaldehyde levels in the univariate analyses only, and outdoor air samples were not taken concurrently. In addition, CDC asked the panelists if it would be useful to see the distributions of formaldehyde levels by brand or type of THU.

Discussion

FEMA is trying to get people out of the THUs by June 1; however, this seems unlikely. The THU parks have been closed, which is about 3,500 of the 38,000 THUs being used. The trailers often are placed on the lots of the owners' houses that are being rebuilt. The THUs used in the Gulf region will not be reused.

The current multivariate model does include relatively high temperatures and could be used to project what might happen at higher temperatures and humidity, as will be seen this summer. However, with an R^2 of 34%, there is much that is unknown that would go into the projection. There are additional data that FEMA has collected that could be added to this model. In the summer, people will likely be using air conditioning, but we do not know if this is true and what the effect will be. One degree of temperature increase leads to about a 10ppb increase in formaldehyde. One percent humidity increase leads to a 3ppb increase in formaldehyde. Even though two-thirds of the variability is unaccounted for, for non-experimental data an R^2 of 34% is informative. An updated report with final numbers will be sent to the panelists shortly.

UPDATE ON CURRENT FEMA ACTIVITIES

Presentation

Gary Noonan provided an overview of FEMA activities related to the THUs and formaldehyde. FEMA is testing THUs for the residents who have requested formaldehyde testing. The FEMA methodology is the same as that for the occupied trailer study, but the participants are included on a request basis, which loses the randomness. This data could be combined with the occupied trailer data. Currently, FEMA has collected data from about 911 units, but the statistics that are presented here are from 540 units. The maximum formaldehyde level is 1100ppb. FEMA was

very concerned about the unit that had formaldehyde levels over 1ppm, but they could not see anything different about this unit. They have since resampled this unit, but FEMA has not yet provided these data to CDC. Overall, the highest THU category is a geometric mean of 71ppb for travel trailers and 55ppb for mobile homes. CDC does not know the age of the units that FEMA included in this assessment.

In addition, FEMA is testing THUs before they are deployed. Some states have developed a criteria of 40ppb for which they will accept THUs coming into their states in natural disasters. CDC did not develop this level. From CDC's understanding, approximately 53% of the units tested were below 40ppb.

FEMA has created specifications for park models that are high performance units. They are keeping the medium density fiberboard (MDF) to a minimum and are putting in metal cabinets. The criteria FEMA is using for these units is 16ppb of formaldehyde based on a NIOSH recommendation. These specifications have been met, but they increase the cost of the unit by $1200.

Discussion

FEMA announced that they will no longer use travel trailers in response to disasters and that they will use mobile homes instead. However, mobile homes may be harder to maneuver into the places that have disasters. There is nothing inherently wrong with travel trailers if their emissions can be brought down to the level of the Fleetwoods and if the trailers can provide adequate ventilation. Travel trailers do work and are a good option if they are used properly, but people should not be in them for longer than 6 months because the trailers are not designed for long-term habitation.

Cottages are becoming a popular option to replace the THUs under discussion. CDC has not done any studies with these units. The Sierra Club does have some data on these units that shows high levels of formaldehyde. There are many wood cabinets in these units, which will affect formaldehyde levels. CDC does not have a contract in place to study these units and these units

are under state control. FEMA money went to the states and the states are buying the cottages, so the purchase of cottages is not directly in FEMA's control.

The method FEMA is using for predeployment testing involves air conditioning the unit for three days, then shutting the air off for 24 hours and then sampling the unit. The units in Alabama have a higher non-acceptability rate (i.e., formaldehyde levels greater than 40 ppb) than do those in Arkansas.

HANCOCK STUDY

Presentation

Dr. Paul Garbe presented the findings from the assessment of respiratory illness among children living in FEMA temporary housing for Hancock County, Mississippi from 2005 to 2007 (the Hancock Study). This case series assessment was conducted using a rapid assessment protocol. Last November, two (2) Epidemic Intelligence Service (EIS) officers were sent to Hancock, MS to follow up on requests from physicians who were seeing an increase in respiratory illnesses in children.

Hancock County was an area directly affected by Katrina. It has a relatively closed medical system with most of the children in Hancock under the care of a few physicians. The study mostly focused on respiratory illness; however, because the physicians also said they were seeing an increase in rashes, CDC examined dermatological conditions as well. CDC reviewed the medical records that were available. However, many of the records had been destroyed in the hurricane and subsequent flood. If records did exist, they were often stored haphazardly to promote drying. Medical records were abstracted if the child was age two (2) to 12 years, had one health care visit for illness possibly related to indoor air quality before Hurricane Katrina, and resided in Hancock County. In addition, CDC conducted telephone interviews with parents or guardians.

The total number of health care visits decreased the year after the hurricane (272 visits) but returned to before-hurricane levels (411 visits) by the second year (414 visits). Two-thirds of the 144 children in the final sample lived in or had lived in a THU after Hurricane Katrina. The pattern of visits for upper respiratory and lower respiratory illnesses followed the same pattern among children living in THUs compared with those who had not lived in THUs; specifically, the proportion of visits for upper respiratory symptoms decreased in the second year after the hurricane compared to the previous two years and the proportion of visits for lower respiratory symptoms increased in the second year after the hurricane compared to the previous two years.

There are several limitations to this study. First, the representativeness of the included children as a result of existing medical records is unknown. Second, absence of denominator information on the population at risk coupled with the unknown number of missing records prevented the calculation of population-based rates; therefore, the analysis used the proportion of healthcare visits. Third, unknown factors likely influenced a family's decision to return to Hancock County after Hurricane Katrina, a criterion for eligibility, and could be associated with health outcomes. Fourth, only sick children who visited one of the five health care facilities at least once in the year before Hurricane Katrina were included, potentially biasing comparisons. Finally, children were required to have at least one health care visit potentially related to indoor air quality during the year before Hurricane Katrina.

Discussion

Because the medical facilities in the study might not have been open immediately after the hurricane and people may have gone elsewhere for health care, the first year numbers are highly unreliable and should be discounted.

Panelists asked about the initial 35 cases that led to this study and whether these cases were included. CDC does not have any identifying information on the 35 cases, but the pediatric group to which those cases belonged was included in the study.

Because the study uses proportions, if there is an increase in one type of condition, there must also be a decrease in another type of condition, so the interpretation is challenging. The

conclusion from this study is that there is no difference in respiratory and dermal illnesses for those living in THUs and those not living in THUs. However this was a difficult study with many limitations that the children's health study will hopefully address.

Mold could be a strong confounder in this study. The children who did not live in THUs may have had higher exposure to mold, so although they may have had different risk factors, they may have had similar health problems. The whole area was exposed to some air quality issues. Although the children not living in THUs were not selected to be a control group, the comparison of results by type of residence does make an important point that children living in the THUs were not worse off than those not living in the THUs. Despite the low power and limitations of this study, CDC feels somewhat reassured that there is not a major epidemic of respiratory illnesses in children living in THUs. However, it is possible that children in THUs are not seeking health care as frequently because of their displacement.

UNOCCUPIED TRAILER ASSESSMENT ACTIVITIES

Presentation

Dr. Michael Gressel presented findings from studies in unoccupied trailers. FEMA requested CDC to identify potential solutions to reduce or eliminate formaldehyde concentrations in THUs, including travel trailers. They wanted to characterize the unoccupied trailers to see if there is something about the trailers' characteristics that affects the formaldehyde levels. NIOSH staff were assigned to CDC's National Center for Environmental Health (NCEH) because of their expertise in exposure assessment and engineering controls. The studies had the objectives of developing and evaluating cost-effective solutions to control or eliminate formaldehyde concentrations, identifying THU characteristics that contribute to formaldehyde levels, and evaluating the efficacy of inexpensive direct reading formaldehyde monitors, which are simpler than the NIOSH method. Studies on the concentration of formaldehyde have already been conducted. The group has several sources of information about THU formaldehyde concentrations, including the CDC sampling of occupied THUs, FEMA sampling of occupied THUs, and FEMA pre-deployment sampling of park model and manufactured homes.

Direct Monitoring Study

The reason that CDC is evaluating direct reading instruments for monitoring formaldehyde concentrations is because the current validated analytical methods can be costly, require specialized equipment, and need time-consuming lab analysis. To assess the effectiveness of direct reading monitors, side-by-side samples will be collected using a validated analytical method and direct reading monitors. CDC has not planned on comparing passive dosimeters ("buttons" or "badges") as part of this study. This is a concern because CDC gets information and requests about sampling conducted by other groups and they do not know if this data is comparable to the NIOSH method.

Mitigation Study

Due to legal restrictions on sampling the previously occupied travel trailers and given that residents may not be transferred out of travel trailers before the summer, the group's priority has shifted to short-term mitigation efforts. CDC is working with the National Aeronautics and Space Administration (NASA) to compare the different engineering controls for short-term mitigation of formaldehyde in travel trailers. The goals of this study are to identify and evaluate solutions for reducing or eliminating formaldehyde concentrations in travel trailers, evaluate potential solutions in a comparison of THUs with and without the modifications, focus on short-term solutions for residents who must remain in travel trailers into the summer, and identify long-term solutions for park model and manufactured homes for future residents, if needed. The study will use approximately 15 trailers and test 12 different technologies in them (one technology per trailer) to see if any of the technologies are effective in reducing formaldehyde levels. CDC currently has an interagency agreement to do this work.

CDC and NASA are looking at several potential mitigation solutions. These include ventilation solutions, such as stand-alone units and replacement air conditioning units. The stand alone unit is the size of a small refrigerator, so it probably will not be a viable solution for the travel trailers. However, CDC wants to see if the technology is sound for reducing formaldehyde levels. All the units currently have 100% recirculation of their air for air conditioning, so there is no fresh air coming in. There is an option of a replacement air conditioning unit that is more

expensive and larger that will bring in outside air. It is a product that is on the books, but it is not in production because there is no demand for it. So the company is going to build or find one so that the technology can be tested.

Room air cleaners, such as photocatalytic oxidation, and sorbents are the focus of much of the study and would provide short-term solutions. It is possible that some of the solutions, like photocatalytic oxidation, could create additional volatile organic compounds (VOCs) including formaldehyde. CDC and NASA will be monitoring this. Other potential solutions include 1) removal of materials, which is a potential solution for future trailers, but is not viable for the existing study; 2) treatments, such as coatings and sealants, which is not viable in already built trailers; 3) temperature and humidity control, which is viable, but likely is not effective enough and is subject to the occupants' comfort; and 4) plants, which have been shown to be effective in the laboratory, but may not be practical in travel trailers because of the space required and the potential for mold and pollen.

The 15 travel trailers are all Gulfstream Cavalier models with similar manufacture dates from the same manufacturing plant with the same building materials. These restrictions attempt to control for the variation in materials often used for the same model units produced by the same plant. Building materials were used based on what was available at the time of manufacturing. Twelve (12) different potential solutions will be placed into the trailers. There is no plan to include ozone air cleaning in the study because of the lack of scientific evidence. The study will run for two months and include samples for formaldehyde and other VOCs. Air samples will be taken from the trailers at regular intervals.

CDC has received several inquiries about plants as a mitigation technology. Dr. B. C. Wolverton developed an eco-planter to help remove formaldehyde. Other than a critique by John Girman, there has not been much work done on the use of plants. Girman did not believe in the technology in 1992 and states that there is nothing he has seen since then that has changed his mind about the technology. The eco-planter works as a result of bacteria at the root-soil interface that remove the formaldehyde. The eco-planter uses a fan to draw air down through the expanded shale or clay and zeolite that serves as the soil. In theory, the bacteria around the roots strip out

the VOCs and convert them to plant food. The planter uses ultraviolet (UV) light to clean outgoing air to address concerns about mold and bacteria. CDC would like to know if this is technology that they should consider as a short-term solution for the FEMA trailers.

Material-Specific Emissions Study

The material-specific emissions study is being completed through an interagency agreement with Lawrence Berkeley National Laboratory. This study involved air sampling in four (4) different brands of travel trailers. Two (2) of the units were from dealer lots and two (2) were spec models. After the air sampling, the trailers had small (6-inch square) pieces of materials removed that were tested in chambers to assess VOCs and aldehydes. Eighty (80) VOCs were identified and 45 of those were quantified. Aldehydes, including formaldehyde, were also sampled. Acetic acid was also sampled, but the tests have not yet been completed.

To assess the formaldehyde equilibrium concentrations, the trailers were closed up with no ventilation running at the time of sampling. A hole was drilled in the door through which the air samples were taken. Therefore, these samples would not represent occupied conditions (e.g., with more ventilation). The range of formaldehyde concentrations in the morning was 310 to 520 ppb with an indoor temperature range of 22 to 25 degrees Celsius. The afternoon concentrations were 350 to 780 ppb with an indoor temperature range of 26 to 30 degrees Celsius. Only two VOCs that were compared to previously published data were found to have higher emissions; TMPD-DIB and Phenol. None of the VOC concentrations other than formaldehyde were considered to be of concern.

Of the 45 different materials tested, all but one sample met the current HUD materials standard (Title 24 Part 3280.406). The materials were all two (2) to two and a half (2.5) years old, so we do not know if the materials met the standard when the trailers were first constructed. Some of the materials could have had formaldehyde built up in the materials due to sorption out of the trailer air, that was released (reemitted) when the materials were tested. The ventilation rate was low in the trailers (0.15 to 0.39 air changes per hour). The combination of low ventilation rate and high formaldehyde loading results in the high concentrations of formaldehyde in the trailers.

The HUD standard for building guidance are concentrations as tested in an ASTM chamber. These are building material standards only, not what we would see in the trailer. For particle board and hardwood plywood, the standards are 0.3 ppm and 0.2 ppm respectively. The industry has recently committed to using materials that meet the new California Air Resources Board (CARB) emissions standards. These standards have an interim value and a final value that the industry will meet. The standards are: hardwood plywood (0.08, 0.05 ppm), particle board (0.18, 0.09 ppm), MDF (0.21, 0.11 ppm), and thin MDF (0.21, 0.13 ppm). By meeting CARB standards, the industry might be able to reduce formaldehyde to a quarter of that which is currently allowed. From this research, NCEH staff will prepare reports for FEMA. These reports will be posted on CDC's Web site and published in peer-reviewed journals.

Future Work

Based upon findings of the research outlined, additional research may be warranted. This might include an assessment of ventilation solutions in park and manufactured homes and additional research with Lawrence Berkeley National Laboratory, such as additional chamber studies and temperature and humidity effects. Park and manufactured homes have more opportunities for mitigation solutions. In addition, CDC would like to do additional tests of the Fleetwood trailer models (which had low emissions) and take a closer look at temperature and humidity effects.

Discussion

The panel asked CDC what kind of interest has been demonstrated in the plant technology (i.e., is it just one person with a financial interest who is pushing the technology). In addition to the interest from Wolverton, the Sierra Club and the distributor with the rights to the product expressed interest in including the technology. If the evidence for the technology is strong, then one of the panelists did not see why it should not be included. However, CDC does have to balance many different inquiries about technologies and decide which ones are most promising.

The main reason for the work with NASA is that FEMA made a commitment to get people out of the THUs by June 1. If FEMA does not meet this deadline, CDC wants to find a mitigation strategy that can be put into existing trailers this summer and into any trailers that FEMA might need to use in the future.

The process used to mitigate formaldehyde (not the eco-planter specifically) is plant-specific. Pollen is not a concern from most household plants because they have large pollen that settles rather than remaining in the air. Unless there are a substantial number of plants, mold is not a concern. However, watering the plants could increase the humidity within the trailer. One criticism of using plants is that many plants are needed to lower formaldehyde levels effectively and the trailers are small. However, Wolverton has increased the effectiveness of the plants by the air flow system. They have been able to increase formaldehyde removal by a couple orders of magnitude using the ventilated planter. One of the panelists had some concerns about the UV light as a cleaner.

The panelists expressed concern about the timeline (i.e., the two-month study period) and the possibility that people will be out of the trailers before the study is completed. CDC plans to have continuous results and analysis. If they obtain promising results, they will immediately make recommendations to FEMA to get the technology to people in the trailers. It may be that one solution or a combination of solutions is most effective. Whatever solution is found, CDC hopes to be able to generalize the results to manufactured homes in mobile home parks.

One panelist recommended including the eco-planter given the political pressure. However, CDC has to weigh the fact that they have 12-13 slots available to test different technologies, so that if the eco-planter is included another technology will not be included. CDC already has two dozen promising solutions. The eco-planter might be effective, but it is a sophisticated solution, takes up some of the limited space, and must be maintained by the residents to be effective. If the plants die then there is no longer formaldehyde mitigation.

Another panelist suggested developing engineering parameters for the amount of space that each solution takes and how much formaldehyde it is expected to remove. If the technology does not have this information, then it should not be included. Then the solutions could be ranked by how much formaldehyde they are supposed to remove for each unit of space that is taken up by the technology. CDC mentioned that they do not have a good peer-reviewed article about the effectiveness of plants. Most of the technologies that are being considered only have evidence

based on case studies, not peer-review journal articles because most of these devices have not been well studied. The panelists suggested that another option is to have a university study the plant technology. CDC mentioned that the University of Syracuse is taking a look at the technology, but that they are hesitant to provide CDC with the data on it because of patent issues.

CHILDREN'S HEALTH STUDY

Presentation and Discussion

Before the presentation of the study began, Dr. McGeehin commented that in all his years of doing epidemiology this is one of the most challenging studies he has seen. There is tremendous public interest is this study. Therefore, CDC is trying to obtain feedback and reviews upfront. Internally, CDC epidemiologists have reviewed the study. In addition, three (3) external reviewers (Gary Adamkiewicz, Helene Margolis, and Mark Mendell) provided comments prior to this meeting, so the expert panel was asked to provide comments on the reviewer comments in addition to their comments on the study proposal.

The panelists also were asked to think about the best way to complete this study. The study is beyond CDC's capabilities unless they have a tremendous increase in staff. There are two options to conduct this long-term cohort study: 1) contract the study out to a large research firm or 2) put out a request for applications for a university to do the research. CDC could also divide up the study into pieces and use both mechanisms. CDC has not yet proposed a budget to FEMA. The only comparable study that has been done is the Hanford thyroid disease study, which was 13 years and cost $25 million just for the data collection. The parallel project to the thyroid disease study that estimated environmental radiation dose also cost $25 million. This was a huge investment, but the study did not give the public the answers they were looking for. This study will likely be about $5 million per year for six years.

Dr. Fuyuen Yip described the proposed investigation of health effects in child residents of storm damaged housing and temporary housing along the U.S. Gulf Coast (children's health study). In addition to the concern about short-term health effects from living in the trailers, there is

continued concern about the long-term health effects to children because they are such a vulnerable population. The purpose of this study is to obtain a more comprehensive assessment. The goals of the study are to determine if an association exists between children's exposure and the occurrence and severity of respiratory and dermal symptoms. Exposure is broken into two categories 1) occupancy in storm damaged housing or in FEMA-issued THUs and 2) ongoing exposures in the home.

The panelists pointed out that the goals need to be changed to include prior as well as ongoing exposure. This change is based on the inclusion criteria—to qualify for the study participants have to have been in the area for a small amount of time. The second goal (ongoing exposure) is not written the same way that the rest of the study is written. Yip mentioned that in the data analysis, CDC suggests examining prior and ongoing exposures.

Another panelist pointed out that there is a problem comparing storm damaged housing and THUs because both groups may be at increased risk of respiratory diseases although the risks stem from different exposures (i.e., to mold or formaldehyde). A third group of participants that are from the area, but are not living in storm damaged housing and have not lived in a THU are needed to serve as a control group. The control group would need to be defined so that they could be systematically recruited.

Dr. Yip explained that the objectives of the study are to 1) describe clinical and demographic characteristics, 2) characterize environmental and behavioral risk factors, and 3) develop recommendations for public health strategies and messages. CDC proposes that the participants be drawn from FEMA's National Emergency Management Information System (NEMIS). This database includes all individuals who requested and/or received aid from FEMA after Hurricanes Katrina and Rita. The database includes incident activities and preliminary damage assessments. The inclusion criteria for participation in the study include that the child is aged 0-12 years, has ever had primary residence in a FEMA-issued THU and/or in storm damaged housing, resides in AL, MS, LA, or TX at time of recruitment, and resides in a household with a parent or guardian who is at least 18 years old. The exclusion criteria include 1) that the household never returned to, or never resided in, a storm damaged house *and* was never issued a FEMA THU, 2) the

parent or guardian refuses to have the child provide blood or urine samples, 3) the child is unable to provide blood or urine, or 4) the household does not have a parent or guardian at least 18 years old.

One panelist mentioned an e-mail he had written explaining his concern that as it is designed this will be a negative study (i.e., there will be no significant results) because both groups have exposure to risk factors (storm damaged housing and the THUs). This panelist suggested that one option is to use mobile homes and park models that have low exposure as the control group. However, the households that were put in mobile homes and park models may be different on some characteristics than those in travel trailers. During the discussion it was clarified that mobile homes and park models are classified as THUs. The panelists agreed that ideally the control group would have low exposure to mold and low exposure to formaldehyde. Another panelist expressed concern that this study and the control group require retrospective reconstruction of exposure which can be challenging. The panelists asked if it possible to find a population that did not file for help with water damage and also did not live in a FEMA THU. This group would have been exposed to the general increase in mold in the area, but would control for the additional exposures that people in storm damaged housing might have faced. This geographic environmental exposure control group is important to being able to answer the questions that CDC and FEMA are asking. There are outlying areas that did not get flooded that might be able to serve as controls. There may also be houses that had some damage, but not flooding. However, it may be hard to find houses in the area that did not have water damage. As it is designed, the study will answer if the people in THUs had greater risk than those in storm-damaged housing, but the storm-damaged housing will not be uniform in their damage and exposure. The FEMA database may allow CDC to stratify houses by the amount of damage sustained.

A few participants in the discussion were concerned that there is potential for selection bias in this control group. There may be a socio-economic component to the houses that were undamaged. These children might have had better access to health care, a better diet, and fewer pre-existing confounders. It might be possible to match the control group with the study groups

based on neighborhood. The people who moved out of the THUs faster were likely those with higher SES. SES will need to be controlled for in this study.

Another concern of the panelists is that there is at least a 25% (and possibly more than 30%) prevalence of smoking in the THU households. The children are going to be under much greater risk for effects of second hand smoke in the smaller THUs than in larger homes. This will be a confounder for the study. Although smoking will be a confounder, smokers will not be excluded from the study.

Continuing her presentation of the study, Dr. Yip explained that participants will be selected through a three-step process. First, CDC will receive a randomized list of all persons in the NEMIS database. Next, the researchers will systematically contact households to identify eligible children using a screening questionnaire. Then the researchers will meet with eligible households to obtain informed consent and assent. The sample size calculation was conducted with the following parameters: 95% confidence interval, 80% power, 30% attrition over the study period, 25% outcome prevalence among the unexposed population (based on asthma prevalence), and the ability to detect a minimum of a 5% increase in the outcome among the exposed population. The total sample size required is 4,200.

The panelists expressed concern about the sample size calculation. A concern of the panelists related to the sample size calculation is that exposure in the storm damaged homes will be constant while exposure in the THUs will be extremely variable due to the variation in time spent in the THU. So a one-to-one set up may not be possible. The panelists also expressed concern that people in the storm-damaged houses may have left the area for a long time. Thus, there may need to be an inclusion criteria for the amount of time spent in the storm-damaged home.

Dr. Yip continued her description of the study protocol explaining that it is a cohort study with 4,200 children. The study is planned to be six years long with an option to continue the study for an additional six years. The health and environmental exposures will be assessed twice annually. The assessments include 1) baseline, health-based, and mental health questionnaires, 2) well-child exams, pulmonary function testing, sampling for biomarker analysis, and annual chart

reviews for a random sample of 25% of participants, and 3) a visual home inspection and air sample collection.

The panelists strongly recommended that the data be analyzed and reported at the end of each year for two primary reasons: 1) to provide timely feedback and intervention as needed to provide adequate health care and information to former THU residents and 2) that sufficient information may be available sooner than the planned six years that allows the study to be terminated.

The panelists expressed that the mental health assessment seems problematic. One panelist explained that determining mental health in a four (4) year old is challenging. The panelists suggested that the mental health component needs to be considered in light of the comments in Dr. Margolis's review. The mental health assessments currently included in the study protocol have not been validated in children or in people who live in difficult circumstances. Overall, the panelist believed that the mental health component is important, but it may be a separate arm of this study. Additionally, they were concerned that the study is not powered well enough for the inclusion of the component nor is the component appropriate as it is currently designed.

The panelists discussed that this study is a prospective study from January 2009, but there is pressure to find out what has happened in the last three (3) years. Once the people move out of THUs (which is expected to happen before the study starts), many of the exposures of concern will not exist anymore – at least for short-term health effects. Therefore, some of the panelists recommended that this study have a larger retrospective component. The retrospective component would have to be based on interviews because medical records are challenging to access because many have been lost in the hurricanes. One panelist expressed concern about the validity of recall beyond six months. Dr. Yip clarified that the current questionnaire asks for a history of what participants can remember since 2005 (when Katrina hit).

The panelists were asked for their opinions about a separate protocol for the mental health component as part of this study. The consensus seemed to be that the mental health component is

important, but needs to be more clearly defined (e.g., what is going to be measured, how, and with whom) before a decision can be made.

In presenting the biomarkers that will be included in the study, Dr. Yip explained that the biomarker for formaldehyde is still being developed, so the researchers will collect the specimens and store them until the test is ready.

Regarding the biomarkers, the panel cautioned that exhaled nitric oxide (eNO) is not a great test and CDC should be aware of the limitations of this test, especially in six year olds. It is important not to see this biomarker as reliable as cotinine. One panelist explained that eNO is a point measure that is affected by whether a person has had a cold, has taken nasal steroids, is on cold medication, etc. Thus, it does not say anything about overall functioning. The panelists commented that biomarkers for flame retardants should be added to this list and also should be added to the exposure studies. Similarly, stress markers such as cortisol could be added as recommended by Dr. Margolis. The participants also suggested that pesticides need to be added to the biomarkers.

Cotinine is a good marker for nicotine exposure and is a useful and important component of the biomonitoring for this study. However, cotinine is a nicotine-based marker that might not reliably reflect second hand smoke exposure and may result in misclassification of children who have been exposed to nicotine, but not to second hand smoke. Parents could be doing a good job of trying to decrease second hand exposure by not smoking when the children are present, but nicotine is adsorbed onto walls and other surfaces. This nicotine offgases over time, so children may be exposed to nicotine (a gas) while their exposure to inflammatory second hand smoke particles will be minimal. There is no biomarker for second hand smoke particles yet, so environmental second hand smoke exposure monitoring is necessary in addition to the blood cotinine measurement. Several studies (Apte et al., 2003; Singer et al., 2002a; Singer et al., 2002b) support the observation that the dynamic behavior of nicotine is vastly different from other second hand smoke-generated constituents.

One limitation to the biomarkers that the panelists commented on is finding a laboratory that is equipped to do these tests. Thus, CDC might have to use multiple laboratories.

One panelist recommended that if the biomarker testing starts at six years old, it may not be worthwhile to include younger children in the biomarker cohort because there will be lost data on these children. The age limit of six for biomarker collection may need to be lowered to age four or five.

Continuing her description of the study protocol, Dr. Yip explained that the environmental exposure assessment will include a home visual inspection survey that will be conducted inside and outside the home to assess household characteristics, lifestyle issues (e.g., smoking), and other potential risk factors (e.g., presence of pests, pets, dampness or mold). The assessment will also include an air sample collection.

The panel suggested that indoor air quality modeling could lead to decent exposure reconstructions. This modeling would be better than just the single point that we have already. The model could include the different types of environments. Another panelist suggested that one criterion for inclusion be that participants are currently living in the units at the start of the study.

The panelists suggested that although the study will not begin until at least January 2009 (due to getting out the request for proposals and going through the Office of Management and Budget [OMB]), it might be possible to obtain some data while people are still in the trailers. This could be a pilot study for the full study. CDC participants commented that although FEMA might be able to provide money for a pilot study, OMB approval takes six to nine months. The only way to be out in the field over the summer is to obtain an emergency OMB or clinical exemption. The panelists strongly urged CDC to try to obtain these exemptions.

The panelists recommended including monitoring just outside the trailers, including climate (temperature and relative humidity) and the air quality parameters measured indoors, especially

formaldehyde and the criteria pollutants. They also stressed the importance of environmental monitoring for smoking.

The panelists agreed that a question that this study should answer is: given the children's historical exposure, what is the time to occurrence of the health outcome and the severity of the health outcome. Each of the potential predictors would be an independent variable that the researchers would control.

The panelists expressed concern about the dermal health outcomes, asking if they are acute or chronic conditions that are being assessed. They commented that assessing rashes will be challenging. The panelists also commented that nosebleeds are being assessed, but people usually do not see a health care provider for a nosebleed. The panel expressed concern that the study is not really assessing severity of disease, but is assessing frequency of disease. These terms should be used carefully and the health outcomes of interest should be better specified.

Continuing her discussion of the protocol, Dr. Yip stated that this study has many limitations. Historical exposures will be difficult to assess. Existing baseline health effects can confound comparison of THU and storm damaged housing residency. Many historical records prior to Hurricane Katrina may not be available. In addition, the study is observational and the assignment of subjects in each group is outside the researchers' control.

Dr. Yip explained that the results of the study will be disseminated in a variety of ways. Medical reports will be mailed annually to participating families with follow-up phone calls. Information will be shared with the participant's primary health care physician, if approved. Air sampling results will be shared annually. Appropriate action steps will be in place to report specific levels and intervals of exposure or biomarker results.

QUESTIONS FOR THE PANEL

1. The occupied trailer study did not collect ambient air samples of formaldehyde at the time of the study because of logistic issues and because ambient air levels had been shown to be low (average 3 ppb). The unoccupied study sampled ambient air at 2 and 3 ppb in two samples. Can the panel comment on the extent to which this omission might affect our conclusions?

2. For the unoccupied trailer studies, are there gaps in the research plan that should be addressed that are not currently being addressed. Conversely, are there aspects of the existing protocol that are not relevant or inappropriate?

3. FEMA has made the decision to no longer use travel trailers in disaster response, based on this should CDC direct all of its unoccupied trailer work on mobile homes and park models? Conversely, should CDC further investigate the differences between the travel trailer levels with high formaldehyde levels verses those with lower levels?

4. Please discuss and comment on the methodology of the children's health study.

5. Please comment on CDC's overall approach to the FEMA Trailer issue and identify any gaps that should be addressed by our research plan.

EXPERT PANEL DISCUSSION AND RECOMMENDATIONS

Question 1. The occupied trailer study did not collect ambient air samples of formaldehyde at the time of the study because of logistic issues and because ambient air levels had been shown to be low (average 3 ppb). The unoccupied study sampled ambient air at 2 and 3 ppb in two samples. Can the panel comment on the extent to which this omission might affect our conclusions?

This omission does not change the conclusions of the study. The lowest measurements from the occupied trailer study are still an order of magnitude higher than that in the ambient air. However, the 2-3 ppb ambient air measurements came from a rural area (Weisel et al., 2005). Automobile emissions increase formaldehyde; thus, ambient formaldehyde may be higher in areas with substantial traffic. During the summer, ambient formaldehyde in high traffic areas might be as high as 20ppb. However, even if the lowest measured levels of formaldehyde from the study were assumed to reflect ambient formaldehyde and were subtracted from all the other formaldehyde levels, levels would still be of concern and the conclusions of the study would not be effected.

In future studies, CDC (and other agencies) should include ambient air samples (not just limited to formaldehyde) and consider local environmental conditions (e.g., highways). Other ambient air exposures might affect health outcomes of interest and should be measured. To decrease the cost of collecting these samples, the samples might be taken from a randomized subset of the locations. If the locations occur in clusters, then outdoor air samples might be taken for each of the clusters. Future studies should consider local environmental conditions, like highways, and other sources that might affect formaldehyde levels and the health outcomes of interest.

The panel also expressed some concern about the comparison of the occupied trailer data with data from studies by Weisel and by Gordon (on page 26 of the occupied trailer report; the first reference to this data occurs on page 7 in the last sentence of paragraph 2). The Weisel and Gordon data use a 24-hour sample method, which may account for the difference between the occupied trailer data and the Weisel and Gordon data. The 24-hour sample method is the same method as that used for the occupied trailer study, but is of longer duration. However, to the panelists' knowledge, the dinitrophenylhydrazine (DNPH) samplers are not designed for 24-hour measurements and have a limited capacity. If this capacity is expended during the 24-hour sample, the collected derivatized mass from formaldehyde on the DNPH in the sampler could be less than the true mass that was sampled, leading to an underestimate of the formaldehyde concentration. In addition, there may be temporal variation in conditions during the 24-hour test period that may impact air concentrations. The panelists cannot know for certain if the Weisel

and Gordon studies underestimate formaldehyde levels. The panelists do not have a particular recommendation for CDC about these data, but wanted CDC to be aware of the possible distinctions between these data and the data from the occupied trailer study to assist in interpretation.

The more standard size of the housing units in the Weisel and Gordon studies have a much larger volume and a smaller surface to volume ratio (loading ratio) than the THUs. In the THUs which have a high loading ratio, almost the entire indoor surface is covered in wood, thus more formaldehyde is emitted into the homes per volume. The comparison of the occupied trailer data to Weisel's and Gordon's data highlights how design and material use can impact indoor formaldehyde concentrations. Standards for small temporary housing should be developed and codified that not only address the emissions of formaldehyde from materials, but also the surface area of material being applied and the air exchange rate of the structure.

Question 2. For the unoccupied trailer studies, are there gaps in the research plan that should be addressed that are not currently being addressed. Conversely, are there aspects of the existing protocol that are not relevant or inappropriate?

This research is still relevant to the overall project goals and should be conducted.

If possible, CDC should expand the number of trailers in the study to be greater than 15 so that more technologies can be tested. Additional never-occupied trailers could be added so that all promising technologies can be tested.

The panel recommends that CDC test only technologies that have published evidence of their effectiveness. If few technologies have published evidence, then looser criteria of proof of the effectiveness of similar products and technologies might be sufficient. However, the panel does recommend that CDC use effectiveness criteria (however loose or stringent is appropriate) to determine which technologies will be tested.

The two-month test period might not be long enough for some of the technologies that are being tested. The panel is particularly concerned about photocatalytic methods that may begin to fail after three months.

In addition to the technical effectiveness, CDC and FEMA should take practicalities such as availability, feasibility, energy consumption, noise output, comfort, space demands, etc., into consideration when recommending a mitigation technology for deployment in occupied THUs. Many of the technologies that are being tested are likely prototypes, which means that industry would have to gear up to manufacture these products. In addition, the logistics for distributing the products into homes even if the products are ready may be challenging. It will take a long time to schedule and coordinate getting the technologies into people's homes.

Question 3. FEMA has made the decision to no longer use travel trailers in disaster response, based on this should CDC direct all of its unoccupied trailer work on mobile homes and park models? Conversely, should CDC further investigate the differences between the travel trailer levels with high formaldehyde levels verses those with lower levels?

It might be appropriate to validate the FEMA method for predeployment testing (to meet the 40ppb criterion). The testing can likely be improved by using a temperature-humidity-exposure curve to normalize the data. The panel expressed concern about the validity and reliability of the FEMA predeployment measurement given the variation in test results based on geographic location (and the temperature and humidity in those locations). To the panel's knowledge there is not yet a standardized protocol for measurement of formaldehyde levels in trailers.

CDC and/or other agencies still need to focus on trailers to obtain better temperature-humidity-emissions curves and to study mitigation strategies. The levels of formaldehyde in the trailers can be used to predict exposures better. CDC should try to better predict the emissions as a function of temperature and humidity and develop prototypical curves to adjust measured indoor concentrations to a standard temperature and humidity condition. In addition to its utility

for trailer selection, the results of this effort will help estimate regional exposures and worst case scenarios for different areas. The data from the four trailers showed that trailers' emissions in the morning and afternoon are statistically significantly different. This kind of data may allow for more specific estimations of exposure (e.g., school children would not be exposed during schools hours). An engineering approach should be taken to determine the emissions curve for humidity and temperature. In addition, because people are not going to be out of the trailers immediately, the mitigation study in trailers is necessary.

CDC and other agencies might also need to look at the cottages because they are becoming more popular. If the cottages are becoming the solution of choice, CDC and other agencies need to understand the emissions and possible health effects of this housing type.

CDC and/or other agencies need to obtain additional information on exposures and health effects in mobile homes and park models. Although continuing efforts in the trailers are recommended, efforts should not focus exclusively on trailers, but also should include mobile homes and park models particularly in light of future deployments that might use mobile homes and park models.

Other federal agencies or relevant organizations should continue to examine low versus high emissions trailers to see if the trailers can be made to be safe, particularly because the trailers are easier to move into damaged areas. Identification of factors that make a trailer safe can be used for 1) development and dissemination of building standards that are based on science and engineering and 2) minimum requirements for any contractor that is building trailers for FEMA or other agencies. FEMA and other agencies should not abandon travel trailers; the trailers just need to be made to be safe. If in fact trailers can be designed that have acceptable formaldehyde emissions levels (as determined by a group or organization with appropriate expertise), then these trailers would be a viable solution for disasters. Trailers must be examined because they can be deployed into areas that are smaller and can be installed in rougher terrain than can mobile homes and parks. Therefore, it is still worthwhile to examine high versus low emissions trailers. Data from these studies can be used to determine factors that make for low emissions. These factors can then be used as the minimum standard for any contractors that

provide trailers to FEMA and other agencies. In addition, realistic standards that are based on science and engineering should be developed, reviewed, and published so that industry can use these standards in building trailers. These efforts may be beyond the mission of CDC and should be undertaken by other federal agencies and relevant standards bodies (e.g., American Society of Heating, Refrigerating and Air Conditioning Engineers [ASHRAE]) and industry organizations.

Question 4. Please discuss and comment on the methodology of the children's health study.

The study must have a control group that does not have the primary exposures of concern (formaldehyde and water damage), but does have comparable regional exposures. For the study to have validity, it needs a control group. At present this study is designed such that the results are most likely to be negative; the consequences of conducting a study of this type could be devastating in this political environment. The study is biased towards the null (showing no effects) in that it is possible that the people in the trailer will have similar adverse health outcomes as those in the storm damaged housing. CDC may be able to identify a suitable control group from the FEMA NEMIS database by looking at housing units that had minimal (e.g., just wind) damage. It is also possible that access to the appropriate controls will not be identified within the NEMIS database. In that case, CDC will need to identify control homes and use neighborhood matching to control for regional differences in storm effects and SES. It is possible that some group has done a physical analysis that can be put in a GIS map to examine damage and density of mold exposure. Rao et al., (2007) looked at different kinds of molds in the different parishes. These resources could be used to help define areas from which an appropriate matched control group could be selected. It would be simpler if CDC could use the existing NEMIS database, but if not, they need to use existing information about environmental exposures to identify control homes. The statistical power, sample size calculations, and sample selection procedures will also need to be changed to account for the control group.

Power calculations for the study need to be redone to account for the control group and to allow for comparisons between different strata within the study (including tobacco use) and

between different lengths of exposure. The 4,200 sample size may need to be re-evaluated in light of these factors. A 30% attrition rate (which may be optimistic) brings the sample to 2,940 and with the large number of factors that are being examined as well as the length of exposure variable, the study may be underpowered at the current numbers. The study will not have a one-to-one ratio (as is currently assumed in the protocol sample size calculations) because of the difference in length of exposure (exposure is constant for people in stormed damaged housing and the controls, but will vary widely for those in THUs). The different strata, the length of exposure, and the control group need to be accounted for in a recalculation of the sample size to make sure that the study has enough power to compare the strata and the different lengths of exposure. For example, if exposure to second hand smoke interacts with formaldehyde exposure, there also need to be enough smokers in the study to determine this effect. Smoking may be the trigger that causes health effects in children whose bronchial pathways have become sensitized as a result of the formaldehyde exposure. At present, the power calculations are simplistic and optimistic. In regression models, the power becomes lower as you control for other variables. A simple two-by-two power calculation overestimates the power and does not account for the decrease in power resulting from controlling covariates (most importantly smoking) and examining different strata.

Because the study objectives have been modified, we recommend that the hypotheses that underlie the power calculation be better clarified to match new specific research questions.

There needs to be a clear definition of the study goals and aims. The health outcomes (e.g., respiratory events vs. infections) that match the goals and aims need to be better defined. This includes clarifying definitions of severity, incidence, and prevalence (which are currently used interchangeably in the protocol). The goals of the study need to be changed to reflect examination of prior and ongoing exposures. In addition, the comparisons necessary to answer study questions need to be reconsidered in light of the control group and need to be clearly defined.

Exposure measures and estimating power using simulation studies. A simulation approach should be considered to conduct sample size predictions and reconstruct exposures. However,

there is a critical gap because of the lack of summer exposure measurements. (This is addressed in Q5.) Summer conditions formaldehyde measurements in the THUs are needed to ensure accurate exposure reconstruction data. When you look at the dose-response data and stratify on the exposure variable, the power will drop off. Using the summer and winter exposure data, we can develop a prediction model of exposure. The best method for developing the predictions is to use a broad set of simulations (simulating conditions and the length of exposure) and to put the exposure into categories such as zero to six months, six months to one year, etc.

Another task that the panel recommended a simulation approach for is sample size estimation. The best way to estimate the needed sample size (power calculation) for the study is to simulate the sample population using a Monte Carlo approach, varying the parameters that are expected to be confounders, using estimated distributions of prevalence of exposure and uncertainties to draw from the population. The simulations and power calculations should contain one stratum representing people who are currently living in THUs. The only way to do this is to collect data from households living in THUs this summer.

If people are still living in THUs when the study begins, the study should include enough people who are still living in the THUs to examine the acute effects of exposure and to compare these people to those who are not living in THUs. This stratum also needs to be included in the power calculation. In examining people still living in THUs, researchers should be aware that there may be a bias in the population that is still living in the THUs (particularly those still in travel trailers). That is, these people may be inherently different than those who are no longer living in THUs.

There is a major opportunity in this study to look at other end points (e.g., mental health or infectious diseases) and other populations (e.g., other household members) and there should be sufficient flexibility in the protocol to allow for adding these components either at the start of the study or as the study progresses. The protocol for the study should be flexible enough that other substudies can be added into it. For example, a substudy might also collect data from all members of the households in which the children live. If researchers are going to these houses anyway, they could at the same time be measuring the other members of the household. The

panelists recognize that the cost of analyzing samples from all household members may be prohibitive, but recommend that samples from all household members be collected even if analysis of these samples may be delayed due to funding concerns. The chart review also creates an additional cost, so CDC might want to consider only reviewing a subset (e.g., 25%) of the charts for household members. A concern with this approach is that adults may be suspicious of what will be done with their blood and urine samples (e.g., testing for substance abuse). CDC should examine the feasibility of including all members of the household in the study.

Elderly, immunocompromised, unemployed, and other vulnerable populations are important populations to examine and this may be the one opportunity to do this type of study with these populations. Some members of these vulnerable groups might be living in the households with children. The desire to obtain additional information about vulnerable and other populations might be a good reason to create a registry of people who lived in THUs. A registry would be able to track the health outcomes of all people who have spent time in these trailers. However, a registry may of limited use if it does not have detailed information on both exposures and health outcomes of the study subjects.

Protocol flexibility should allow for the measurement of other health outcomes. Although the primary intention of this study is to examine the impact of exposure to the indoor environment in THUs on health, respiratory and dermal effects are not the only ones that occur in these populations. For example, other studies (e.g., Usher-Pines et al., in press) have shown that the effects of displacement on the elderly can be severe (including increased fractures). Thus, the study should also be flexible enough to add other health outcomes.

The consent form and other protocols should be designed to accommodate other researchers who have the ability to examine these additional populations and health outcomes. If possible, the study should be designed so that the environmental and other samples would be available for other researchers to analyze or examine the resulting data.

Biological samples and other data should be archived for longer than three years.

This group does not have the expertise to tell CDC whether and how to include the mental health component. The experts recommend that CDC obtains feedback from mental health experts to determine if this study is feasible and important and if so, how it should be done. If the study is conducted, it should be treated as a separate sub-study to the main health study. The health study presents a good opportunity to look at mental health outcomes, but to do it well requires a much more intense study than the one that is currently proposed. The study needs to be more specific about what groups will be measured, the health outcomes that will be measured, the specific questionnaires that have been used, and whether the questionnaires have been validated in the population with which they will be used.

The mental health study is substantially beyond the original purpose for which the expert panel was convened (i.e., formaldehyde emissions and health effects). CDC should verify that this component fits within its current objectives regarding this population and their health and that CDC is the best federal agency to lead this study. FEMA should know how disasters and living in the THUs affect the occupants and should determine if FEMA's intervention in the Gulf region impacted the occupants in a positive or negative way. It is possible that the study will show that people in THUs did better than those in mold-contaminated housing. There may even be psychological damage from living in storm-damaged homes that is greater than living in the THUs.

Mental health effects such as depression affect respiratory disease. The confined space and crowding has broader mental and physical health effects. Emotional factors exacerbate chronic conditions, particularly those related to inflammation. Thus, these are important outcomes to be examining.

Time is of the essence, so as much as possible CDC should push to get an OMB waiver to get the study conducted as quickly as possible. Getting the study into the field as quickly as possible is important because 1) the delay compromises an opportunity to get unique data (i.e., while people are still living in the trailers) and 2) the community and people in the THUs need answers to important questions about their health. The later the study begins, the larger the number of people who will be out of the THUs. As of February 1, 2008 there were 38,297 trailers in AL,

MS, LA, and TX with approximately 114,000 individuals in them. On average FEMA has been moving 810 households out of trailers and mobile homes weekly across the Gulf Coast.

Yearly preliminary analyses should be conducted, disseminated, and (if appropriate) acted upon. As currently written, the study only includes dissemination of findings after six years. This is unacceptable. Yearly analyses are necessary to provide information that can be acted upon to improve health care for this population. Some action would need to be taken after the first year if the study shows that there are detrimental effects. As a result of the yearly analyses, it may be possible to end the study at an early time if sufficient information has been obtained.

The study needs to measure second hand smoke exposure, pesticides, polybrominated diphenyl ethers (PBDEs), perfluorooctanoic acid (PFOA), and all relevant NHANES environmental exposure markers. In particular, the study needs a good measure of second hand smoke. Serum cotinine is an important biomarker for nicotine exposure, but may not be a good biomarker of second hand smoke exposure.

The study should use the latest quantitative technologies for detecting mold (in addition to observations of mold). The best way to predict mold is to do mold observation. However, recent methods like real-time polymerase chain reaction (PCR), including validated panels of molds such as the Environmental Relative Moldiness Index (ERMI; which includes 36 molds) and the American Relative Moldiness Index (ARMI; which includes 13 molds that covers 92% of exposure) are now more reliable. The cost is much less for ARMI than ERMI.

The study should use appropriate medical quality of life questionnaires. Based on the comments by Dr. Margolis, appropriate measures should be used.

To assist in mapping environmental exposures, the study should collect GPS coordinates for the locations of the households that can be included in GIS maps. The panelists recognize that this needs to be done in a manner that preserves participant privacy, while maximizing study understanding of exposures that differ spatially and that are better characterized by geospatial tools. If privacy concerns are raised, the coordinates might not need to be specific to the

household (which is considered identifying information), but to the neighborhood or other region.

An academic consortium that includes universities from the affected region and has a large contractor to help with sampling may be the best way to conduct this study in a timely and credible manner. An academic consortium likely has the expertise and resources to conduct this study, while CDC does not. The consortium should include some level of university participation from the effected regions as well as researchers from other universities and research institutions with the expertise needed for the study. A large contractor will also be needed to manage sampling and conduct of the study. A consortium of this type would significantly improve the credibility and acceptability of the study because the consortium will be seen as more independent of the government than if the study was conducted solely by a contractor or by CDC. Depending on the mechanism used for to work with the consortium (i.e., Request for Applications, unsolicited proposal, grant, cooperative agreement), the consortium may be able to conduct the study faster than CDC or a contractor.

Question 5. Please comment on CDC's overall approach to the FEMA Trailer issue and identify any gaps that should be addressed by our research plan.

The lack of summer exposure data is a critical gap in the overall study plans.

A study of formaldehyde exposure in THUs and ideally respiratory effects must be collected during this summer. Ideally, it would be good if the health study could be started in the summer, but this is likely unrealistic. However, some form of data collection that is better than the Hancock data should be conducted. To the extent possible, the current political pressure should be used to encourage fast-tracking data collection.

At minimum, the occupied trailer study, or a feasible variation of it, should be replicated. This would allow the summer data to be paired with the winter data that has already been collected. The panelists do recognize that the pairing will not be complete because some winter study

participants will have moved out of their THUs by summer. This information would augment the retrospective exposure reconstruction for the children's health study.

Ideally a control group and the ISSAC questionnaire which assesses respiratory disease in children, and mold assessment would be added to the "summer" occupied trailer study. The ISSAC questionnaire is designed to measure respiratory disease and would give CDC a qualitative measure of disease burden. The ISSAC questionnaire would provide information about the acute respiratory effects of living in the trailers. It would be best to do the study in occupied trailers, storm damaged housing, and non-storm damaged housing in the area and add an assessment of mold. Even without adding the control group, CDC could go to the same 518 trailers and add the mold assessment and the ISSAC questionnaire and this would be an improvement. Without a control group, there is enough variation in the formaldehyde levels to get within group comparisons of low, medium, and high formaldehyde exposures. If, in addition, they went to 264 families in the Hancock control group study that did not have mold, this group could be the control group. By using already identified participants, some recruitment time could be cut.

The study would be imperfect, but would take advantage of a data opportunity that politically and scientifically should not be missed. The study would be imperfect given the time constraints, but it could be designed to maximize the amount of useful data gathered while people are still living in the THUs and can assist in the implementation of the larger health study and provide critical information for historical exposure reconstruction. The work on the study would have to start immediately and run throughout the summer.

DISCUSSION

All participants reconvened to discuss the expert panel recommendations described above. There was no discussion about the recommendations for question 1.

Question 2

There may not be 15 technologies that have some evidence of effectiveness. This is one of the reasons CDC chose to reject ozone as a solution because there is no published evidence of its effectiveness. CDC has been looking at which technologies are being proposed and whether these technologies have published literature to back up their potential effectiveness. They are also looking at how the technologies are packaged to make sure they are suitable to implementation in the trailers (e.g., some technologies are designed for traditional heating/cooling system and this would not be viable in trailers). Those technologies that are inappropriately packaged or have no evidence to support them are rejected.

The two-month testing period was selected to get some of the technologies past the point of failure. Ideally, the study would go for six months to a year, but CDC needs to get information back to FEMA fairly quickly to let them know what technologies might work. If the study was to go on longer, preliminary analyses would be needed to provide effectiveness information to FEMA as quickly as possible.

Question 3

The expert panel feels that there will be situations in the future for which trailers will still be useful and that they are an important option in disaster response. Primary prevention (e.g., standard setting) is still needed, but this may not be CDC's role. However, CDC might serve as an adviser. Standard setting and enforcement agencies should be taking the lead on these issues, particularly over the long-term, as the scope of the work creeps beyond CDC's mission.

Question 4

By designing the study without a control group, CDC could be accused of designing a study to show that there are no effects of formaldehyde. The lack of summer exposure measures affects the science and credibility of this overall study. The panelists recommend developing an exposure model with summer and winter data to reconstruct exposure based on housing type. Using the data from the summer and winter studies, CDC can make year-round formaldehyde estimates based on temperature and humidity variation. Although this exposure model will not be perfect and will not tell us what happened during the first year that people were living in the

trailers and this data is better than no data. It is also likely that back calculations could be conducted to estimate the first years of exposure based on published data of the decay of formaldehyde exposure levels in building materials.

Some participants believed that although the outdoor temperature does fluctuate between winter and summer, the indoor temperature does not so that summer data will not be greatly different than winter data. However, there was some discussion about the effect of external heat and humidity on the temperature gradient across the wall that might (or might not) have a significant impact on formaldehyde emissions. We do not have information about emissions when the trailers were brand new and this may be a bigger concern than the summer versus winter data given how much the trailers have aged and the possibility for re-emission. The panelists pointed out that if CDC is interested in chronic effects, then year one and summer data are essential to assessing exposure. However, if the interest is primarily in acute effects, then only the summer data is needed. For the chronic effect, there will be all the uncertainties that are inherent in retrospective data.

Regarding the recommendation that the sample include enough people living in THUs at the start of the study, all the people living in THUs should be out before the study starts. However, if they are not, the recommendation stands.

Question 5

CDC does not currently have a contract that would enable them to replicate the occupied trailer study. In addition, the questionnaire could not be added without going through OMB clearance, which would minimize any possibility of summer fielding. Further thought needs to go into whether there is any sort of data collection activity that can be completed during the summer. FEMA is currently collecting data and if that data collection goes through July then there will be formaldehyde emissions information, but not health information. Although developing a new study and new health questions is not feasible by summer, the panelists strongly urge CDC and FEMA to consider ways of gathering summer emissions data. Without these data, the opportunity to measure the impact of this exposure will be lost forever.

CONCLUDING STATEMENT

The expert panel recognizes the tremendous complexity of conducting these investigations and commends CDC and the other participating agencies for their extraordinary efforts in rapidly mobilizing the field investigations, initiating exposure research, and designing a comprehensive children's health study.

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MEETING ATTENDEES

Expert Panel

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Leslie Staner, University of Illinois at Chicago

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Meeting Staff

Caroline Bailey, TKCIS, meeting organizer

Amy Chadwick, Penn State University, notetaker

Nadine Riviera, transcriber

AGENDA

Thursday – May 1

8:30 a.m. – 8:50 a.m.	Welcome, Background, and Charge	Michael McGeehin
8:50 a.m. – 9:00 a.m.	Update on Current FEMA Activities	Gary Noonan
9:00 a.m. – 9:20 a.m.	Occupied Trailer Assessment Findings	Jim Lando Matthew Murphy
9:20 a.m. – 9:40 a.m.	Hancock County Case Study Findings	Paul Garbe
9:40 a.m. – 10:00 a.m.	Break	
10:00 a.m. – 10:30 a.m.	Unoccupied Trailer Assessment Activities LBNL – Current Findings and Proposed Follow-Up Activities NASA Study	Chad Dowel Mike Gressel
10:30 a.m. – 10:50 a.m.	Discussion	
10:50 a.m. – 11:30 a.m.	Children's Health Study	Paul Garbe Fuyuen Yip
11:30 a.m. – 12 NOON	Questions and Discussion	
12 NOON – 1:30 p.m.	Lunch	
1:30 p.m. – 4:30 p.m.	Executive Session - Panel Addresses Questions	
4:30 p.m.	Summary	

Friday – May 2

8:30 a.m. – 9:30 a.m.	Executive Session – Panel Addresses Questions
9:30 a.m. – 10:30 a.m.	Debrief and Wrap up
10:30 a.m.	Adjourn