CPSA 6(b)(1) Cleared
No Mfrs/PrvtLblrs or Products Identified
Excepted by
Firms Notified,
Comments Processed.

U.S. Consumer Product Safety Commission

LOG OF ~~MEETING~~ Telephone Call

SUBJECT: Baby bathing aids

Telephone Call

DATE OF ~~MEETING~~: January 18, 2001

LOG ENTRY SOURCE: Dennis Wilson, Special Assistant (Legal) to Commissioner Gall

DATE OF LOG ENTRY: March 1, 2001

LOCATION: CPSC Headquarters, Bethesda, MD

CPSC ATTENDEE(S): Dennis Wilson, Pam Weller, Celestine Kiss, Renae Rauchschwalbe

NON-CPSC ATTENDEE(S): Dr. Clay Mann, University of Utah

Telephone call

SUMMARY OF ~~MEETING~~: In a conference telephone call, the participants discussed some statistical and technical aspects of Dr. Mann's study of the use of baby bath seats and their association with infant tub drownings. The conversation is reflected in the attached e-mails sent before and after the telephone conference call.

Wilson, Dennis B.

From: Rauchschwalbe, Renae
Sent: Thursday, January 18, 2001 9:40 AM
To: Wilson, Dennis B.; Weller, Pamela L.; Kiss, Celestine T.; 'Clay.Mann@hsc.Utah.edu'
Subject: Questions to be discussed at 1:30 conference call

For review and to update Celestine Kiss, here are the questions Dennis Wilson asked after Clay Mann's taped presentation of "Infant Seat Bathtub Drowning: Who's to Blame."

1) At some time it sounds as though Dr. Mann dropped the log transformed elapsed time methodology. When and why did he drop it?

2) What would happen to the outcome if you added the cases in which a child was in the tub with the victim?

3) The figure .05 means it is significant, correct? The lower the number, the more significant, right?

4) Isn't this about the smallest sample you can have and still be able to report meaningful statistics? (I said we could pick up another year to increase the sample size.)

5) Is the study going to be published?

I think that's it.

Pamela - Do you mind if we use your conference room again? As you know, the time has been changed to 1:30.

Wilson, Dennis B.

From: Wilson, Dennis B.
Sent: Thursday, January 18, 2001 10:48 AM
To: Rauchschwalbe, Renae; Weller, Pamela L.; Kiss, Celestine T.; 'Clay.Mann@hsc.Utah.edu'
Subject: RE: Questions to be discussed at 1:30 conference call

Ladies and Gentlemen:

Renae's e-mail accurately states most of the questions. I have some clarifications and an additional question.

1. Are the differences between "median elapsed time unattended" either statistically significant or reliable? I don't think that you consider them either significant or reliable, but I'd like confirmation.

2. Are the differences between "median bath water depth" both statistically significant and reliable? I think that you consider them both significant and reliable, but I'd like confirmation?

3. What was the variance in the case of median bath water depth?

4.. What about the materiality of the differences in median bath water depth? In other words, if an infant can drown in 4.5 inches of water, does it matter that a caregiver filled the tub to a level of 7 inches (on average) in the presence of a bath seat?

5. Renae's question number 2 goes to the issue of sensitivity analysis. If you did the same analysis in cases where a sibling was present, do you get results similar to, or dramatically different from, the results that you got in your analysis?

6. Following up on question 5, did you do the analysis and exclude the 5 bath nets and one flotation device that were included in the original study? If so, what were the results?

7. What is the meaning of the "1.13-11.05" under the line of "95% CI" in the reported reason left alone? That seems to be a large spread.

Finally, what is your opinion of the reliability of the reported reason left alone, given that it, like the estimate of time, based on recollection?

I appreciate Dr. Mann's willingness to answer questions and hope that this e-mail helps.

Dennis Wilson

-----Original Message-----
From: Rauchschwalbe, Renae
Sent: Thursday, January 18, 2001 9:40 AM
To: Wilson, Dennis B.; Weller, Pamela L.; Kiss, Celestine T.; 'Clay.Mann@hsc.Utah.edu'
Subject: Questions to be discussed at 1:30 conference call

For review and to update Celestine Kiss, here are the questions Dennis Wilson asked after Clay Mann's taped presentation of "Infant Seat Bathtub Drowning: Who's to Blame."

1) At some time it sounds as though Dr. Mann dropped the log transformed elapsed time methodology. When and why did he drop it?

2) What would happen to the outcome if you added the cases in which a child was in the tub with the victim?

3) The figure .05 means it is significant, correct? The lower the number, the more significant, right?

4) Isn't this about the smallest sample you can have and still be able to report meaningful statistics? (I said we could pick up another year to increase the sample size.)

5) Is the study going to be published?

I think that's it.

Pamela - Do you mind if we use your conference room again? As you know, the time has been changed to 1:30.

Wilson, Dennis B.

From: Wilson, Dennis B.
Sent: Monday, January 22, 2001 12:00 PM
To: Kiss, Celestine T.; Rauchschwalbe, Renae; Weller, Pamela L.; 'Clay.Mann@hsc.Utah.edu'
Subject: Follow-Up to January 18, 2001

Ladies and Gentlemen:

I am attaching a document that goes over the conversation that the five of us had last Thursday, January 18. I believe that it summarizes the conversation accurately. I have keyed each numbered topic 1-8 to my e-mail of January 18, except for the last one, which refers to Renae's e-mail question number 1 of the same date.

I am asking Dr. Mann to review this document and to make sure that it is accurate. If it contains errors or something needs to be explained further, please do not hesitate to provide corrections or explanations. I plan to submit the document and the e-mails to the Office of the Secretary of the Commission, so that they will be part of the official record when the Commission votes on whether to grant the petition that it has received which asks the Commission to commence a rulemaking proceeding to ban baby bath seats.

Again, I appreciate Dr. Mann's willingness to answer questions and to follow up with us.

Dennis Wilson

SUMMARY OF CONVERSATION WITH DR. CLAY MANN

January 18, 2001

1. Median Elapsed Time Unattended

The differences between those instances in which a seat was present and those instances in which no seat was present were not statistically significant. As far as reliability is concerned, the wide ranges shown are acceptable as long as they are not demonstrating a bias. The sample for the instances in which no seat was present is not a bell-shaped curve; the instances tend to cluster toward the shorter estimates of time elapsed. (This lack of a bell shaped curve was the reason why the first analysis was done with a log transformed elapsed time.)

There was a great deal of "slop" in the data, in the sense that there were often multiple estimates of how long the child was left unattended in the tub. In order to control for recall bias in the case of elapsed time, the study used the time report that was closes to the incident. Where multiple times were recorded, the study did an analysis using the mean time and all of the times. For the study report, you chose the first time report because it was a standard. You do not recall what effect the different analyses using mean or all of the times had on the differences in median elapsed time unattended when a bath seat was present and when it was not, or of the statistical significance of any such differences.

2. Median Bath Water Depth

The differences between those instances in which a seat was present and those instances in which no seat was present were statistically significant. The intercortal ranges are very wide. There were reliability problems with the estimates of water depths since there were lots of empty tubs by the time anyone got around to reconstructing events, and some reports showed two or more estimates of tub water depth. In order to control for recall bias, a system similar to that used for median elapsed time unattended was used; the first recorded depth of bath water was used.

3. Variance in the Case of Median Bath Water Depth

Since the measure here was median rather than mean, there was no variance. The pertinent measure is the intercortal range. You noted previously that the intercortal range was very wide. You noted further that these measures are very sensitive to sample size.

4. Materiality of Differences in Median Bath Water Depth

Your study did not attempt to assess whether the difference in median bath water depth (7 inches in the cases where a seat was present versus 4.5 inches in the cases where a seat was not present) represented a greater danger to the infant involved. (Drownings occurred in cases of as little as 2.5 inches of water.) You know of no data indicating that a depth of seven inches represents a greater danger to an infant in a tub (with or without a bath seat) than does 4.5 inches of water. Your study assumed that people regarded more bath water as more dangerous and that median bath water depth was, therefore, a measure of risk-taking behavior.

5. Presence of a Sibling

You did not do any sensitivity analysis to see whether cases involving both bath seats and siblings left alone in a tub yielded results similar to, or different from, the results that you found. You emphasized that data involving siblings in tubs is even "dirtier" than data involving infants left alone in tubs because there are more complicating factors.

6. Cases Involving Bath Nets and a Flotation Device

An analysis has been performed of the data excluding the five cases involving bath nets and one case involving a flotation device (which had been lumped with conventional bath seats in the first analysis). The results of that analysis have been provided to Renae Rauchschwalbe, who will pass them along to the Special Assistants.

7. Confidence Interval for Odds Ratio

The 95% confidence interval for the odds ratio means that you have confidence that the actual odds ratio for reported reason left alone lies somewhere between 1.13 and 11.05. A figure of 1 would be essentially meaningless; people would be just as likely to leave a child unattended for a willful reason in a bath seat as they would in the absence of a bath seat. If the figure was 11 it means that people would be eleven times more likely to leave a child unattended for a willful reason in the presence of a bath seat than in the absence of a bath seat. The odds ratio of 3.54 lies somewhere in between.

8. Reliability of Reported Reason Left Alone

You emphasized that this data was difficult to work with. You had two research assistants read the reports and categorize the reason as either "impulsive" or "willful." The classification was by category and there was no attempt to numerically rank decisions as "more willful" or "more impulsive." The research assistants did not know in which a case a bath seat was involved and in which case a bath seat was not involved, but they did know that: (1) a drowning had occurred; and (2) that something had been "blacked out" in cases involving a bath seat (although they did not know that the "blacked out" portion involved a bath seat).

The research assistants agreed on the categorizations of willful versus impulsive except in the case of burning food, which one researcher characterized as willful because the food had been cooking prior to the start of the bath, and which the other characterized as impulsive because the burning occurred after the bath had started. I don't remember how that difference of opinion was resolved.

There was no attempt to control for recall bias in this case. The reason stated in the report was accepted as the reason why the person involved left the infant unattended.

Renae Rauchschwable's e-mail Question 1: Log Transformed Elapsed Time Methodology

As mentioned earlier the estimates of time that the infant was left unattended tended to cluster on the low end of the scale and did not describe a bell-shaped distribution curve. In order to achieve a bell-shaped distribution, one can log-transform the reports of elapsed time and use a t-test for statistical significance. Readers, however, tend not to understand reports of time when log-transformed, so you used real time reported and used a different test of statistical significance (the name of which I don't remember) that is less "powerful" than a t-test.

Wilson, Dennis B.

From: Rauchschwalbe, Renae
Sent: Tuesday, January 23, 2001 9:40 AM
To: Wilson, Dennis B.
Cc: Kiss, Celestine T.; Weller, Pamela L.; 'Clay.Mann@hsc.Utah.edu'
Subject: Comments on your Follow-up to January 18, 2001 Conference Call

1. Median Elapsed Time Unattended - 2nd paragraph - You state that : "For the study report, [Dr. Mann] chose the first time report because it was a standard." I don't recall, what standard are we talking about?

2. Median Bath Water Depth - last sentence - "... a system similar to that used for median elapsed time unattended was used; the first recorded depth of bath water was used." You may want to add "usually taken by the police or emergency people first on the scene."

3. No comments.

4. Materiality of Differences in Median Bath Water Depth - Last sentence should read: "Your study assumed that people **perceived** more bath water as more dangerous and that median bath water depth was, therefore, a measure of risk-taking behavior." "Perceived" rather than "regarded." Regarding Dr. Mann not knowing of data indicating that **people perceive "...** a depth of seven inches represents a greater danger to an infant in a tub (with or without a bath seat) than does 4.5 inches of water," check out section 2.1 of the Shugoll Focus Panel Study. Under "Examine General Bathing Practice" there is a section that talks about the amount of bath water parents use. Regarding our discussion about risk taking behavior and the assumption that parents perceive more water as higher risk ... there is parent's statement that would indicate this perception. One parent states: "I'm often in the tub with the kids so it's a lot of water. If it's primarily my infant, then it's just four inches and he sits up and I bathe the top of him. If we are talking the baby seat and my other child, 2 1/2 years old, it's higher." It appears he/she perceives that he/she can add more water (and be more risky) if the bath seat and older sib are present. If you need a copy of the study, I can provide one.

5. The last sentence should read: "You emphasized that data involving siblings in tubs is **more complicated** than data involving infants left alone in tubs because there are more **variables.**

6. "Bath Nets" in your title should be "Bathinettes." I believe there are seven bathinette cases and one flotation device. I will provide the revised risk factor analysis on bath seats (only) today.

7. The last sentence of Confidence Interval for Odds Ratio should read: "The odds ratio of 3.54 lies somewhere in between **and means that people are 3.5 times more likely to leave a child unattended for a willful reason in the presence of a bath seat than in the absense of a bath seat.**

8. Reliability of Reported Reason Left Alone - has a typo in the third sentence "The research assistants did not know in which a case a bath seat ...." Take out the "a" before "case." I'm not positive but I think the difference of opinion was not resolved - the research assistants simply disagreed on the categorizations of willful versus impulsive.

No comment on last page.

Wilson, Dennis B.

From: Weller, Pamela L.
Sent: Tuesday, January 23, 2001 12:29 PM
To: Wilson, Dennis B.; Kiss, Celestine T.; Rauchschwalbe, Renae; 'Clay.Mann@hsc.Utah.edu'
Subject: RE: Follow-Up to January 18, 2001

Dennis, just a few comments:

1. Median Elapsed Time Unattended: you don't specifically say it as you do in the next section, but my notes show that Dr. Mann indicated that the differences were not reliable and you may want to make that clearer for the public record;

2. Median Bath Water Depth: I also got the impression there were problems with the water depth because in some instances the water continued to run after the child was removed resulting in a much fuller tub than when the child drowned. I'd be curious to know how often a measurement was made (assuming the water had been turned off before the child drowned) and in how many instances we are dealing with memory recall of water depth.

5. Re Renae's comment, I recall the word "dirty" being used by Dr. Mann, too.

8. I think he ended up using the 2-sample Kolmogorov-Smirnov test.

Wilson, Dennis B.

From: Clay Mann [Clay.Mann@hsc.utah.edu]
ent: Tuesday, January 23, 2001 12:57 PM
o: CKiss@cpsc.gov; DWilson@cpsc.gov; PWeller@cpsc.gov; RRauch@cpsc.gov; Clay.Mann@hsc.Utah.edu
Subject: Re: RE: Follow-Up to January 18, 2001

PLEASE SEE COMMENTS BELOW.

>>> "Weller, Pamela L." <PWeller@cpsc.gov> 01/23 10:28 AM >>>

Dennis, just a few comments:

1. Median Elapsed Time Unattended: you don't specifically say it as you do in the next section, but my notes show that Dr. Mann indicated that the differences were not reliable and you may want to make that clearer for the public record; I WOULD BE CAREFUL USING THE TERM "NOT RELIABLE". PLEASE NOTE THAT THE WORD "RELIABLE" DEALS WITH HOW OFTEN THE SAME RESPONSE IS GIVEN AT DIFFERENT TIMES AFTER THE EVENT. FOR EXAMPLE, A CAR IS RELIABLE IF IT STARTS EVERY TIME YOU TURN THE KEY (PERFORMS THAT SAME EVERY TIME YOU TRY TO START IT). THE DATA WAS NOT RELIABLE...IN THAT DIFFERENT ESTIMATES OF ELAPSED TIME WERE RECORDED IN THE SAME REPORT. BUT BY CHOOSING A STANDARD REPORTING TIME (FIRST ESTIMATE AFTER THE EVENT) AND BY COMPARING MEAN (OR MEDIAN VALUES), YOU REMOVE MOST OF THE RANDOM VARIANCE INCLUDED IN THE REPORTS. UNLESS THERE IS A REASON FOR A "SYSTEMATIC" REPORTING BIAS....THE FINDINGS SHOULD BE THE BEST TEST OF THE SIGNIFICANCE OF THE FINDINGS.

2. Median Bath Water Depth: I also got the impression there were problems with the water depth because in some instances the water continued to run after the child was removed resulting in a much fuller tub than when the child drowned. I'd be curious to know how often a measurement was ade (assuming the water had been turned off before the child drowned) and n how many instances we are dealing with memory recall of water depth. BECAUSE THE DISTANCE BETWEEN THE BOTTOM OF THE TUB AND THE EMERGENCY DRAIN IS FAIRLY STANDARDIZED, WE ESTIMATED THE DEPTH OF WATER FOR REPORTS THAT INDICATED THE TUB WAS "FULL", "HALF-FULL", OR "OVERFLOWING". I CAN PROVIDE INFORMATION REGARDING HOW OFTEN WATER DEPTH WAS ESTIMATED. I DO NOT KNOW OF A WAY TO DETERMINE HOW OFTEN THE DATA WAS AFFECTED BY RECALL BIAS.

5. Re Renae's comment, I recall the word "dirty" being used by Dr. Mann, too. AGAIN, THE WORD "DIRTY" IS NOT VERY DESCRIPTIVE AND MAY MEAN DIFFERENT THINGS TO DIFFERENT PEOPLE. I ADDED A CLARIFICATION OF THIS ITEM IN MY REVISION.

8. I think he ended up using the 2-sample Kolmogorov-Smirnov test.

THANK YOU!

Wilson, Dennis B.

From: Clay Mann [Clay.Mann@hsc.utah.edu]
ent: Tuesday, January 23, 2001 12:41 PM
o: CKiss@cpsc.gov; DWilson@cpsc.gov; PWeller@cpsc.gov; RRauch@cpsc.gov; Clay.Mann@hsc.Utah.edu
Subject: Re: Follow-Up to January 18, 2001

Thank you for the opportunity to speak with you and to respond to your summary of our conversation. I have attached a WORD file that includes my revisions and thoughts. Please let me know if I can help in any other way.

>>> "Wilson, Dennis B." <DWilson@cpsc.gov> 01/22 10:00 AM >>>
Ladies and Gentlemen:

I am attaching a document that goes over the conversation that the five of us had last Thursday, January 18. I believe that it summarizes the conversation accurately. I have keyed each numbered topic 1-8 to my e-mail of January 18, except for the last one, which refers to Renae's e-mail question number 1 of the same date.

I am asking Dr. Mann to review this document and to make sure that it is accurate. If it contains errors or something needs to be explained further, please do not hesitate to provide corrections or explanations. I plan to submit the document and the e-mails to the Office of the Secretary of the Commission, so that they will be part of the official record when the Commission votes on whether to grant the petition that it has received which asks the Commission to commence a rulemaking proceeding to ban baby bath seats.

Again, I appreciate Dr. Mann's willingness to answer questions and to follow up with us.

Dennis Wilson

<<Dr. Mann Conversation Summary.doc>>

SUMMARY OF CONVERSATION WITH DR. CLAY MANN

January 18, 2001

1. <u>Median Elapsed Time Unattended</u>

The differences between those instances in which a seat was present and those instances in which no seat was present were not statistically significant. As far as reliability is concerned, the wide ranges shown are acceptable as long as they are not demonstrating a bias. The distribution of elapsed times are not normally distributed for either ~~sample for the instances in which no seat was present is not a bell shaped curve~~; the times ~~instances~~ tend to cluster toward the shorter estimates of time elapsed. Thus, median values and interquartile ranges are reported. In addition, the difference in elapsed time between the two samples was tested with a nonparametric test. ~~(This lack of a bell shaped curve was the reason why the first analysis was done with a log transformed [illegible].)~~

There was a great deal of "slop" in the data, in the sense that there were often multiple estimates of how long the child was left unattended in the tub in each incident report. In order to control for recall bias in the case of elapsed time, the study used the time report that was closest to the incident. Where multiple times were recorded, the study did an ancillary analysis using the mean time drawn from ~~and~~ all of the reported times. For the study report, ~~you chose~~ the first time report was used as a ~~because it was a~~ standard. You do not recall what effect the different analyses using mean or all of the times had on the differences in median elapsed time unattended when a bath seat was present and when it was not, or of the statistical significance of any such differences. However, these additional tests can be made available upon request.

2. <u>Median Bath Water Depth</u>

The differences between those instances in which a seat was present and those instances in which no seat was present were statistically significant. The interquartile ~~[illegible]~~ ranges are very wide. There were reliability problems with the estimates of water depths since there were lots of empty tubs by the time anyone got around to reconstructing events, and

some reports showed two or more estimates of tub water depth. In order to control for recall bias, a system similar to that used for median elapsed time unattended was used; the first recorded depth of bath water was used.

3. Variance in the Case of Median Bath Water Depth

Since the measure here was median rather than mean, a formal measure of variance was not required ~~[illegible]~~. The pertinent measure is the interquartile ~~[illegible]~~ range. You noted previously that the intercortal range was very wide. You noted further that these measures are very sensitive to sample size.

4. Materiality of Differences in Median Bath Water Depth

Your study did not attempt to assess whether the difference in median bath water depth (7 inches in the cases where a seat was present versus 4.5 inches in the cases where a seat was not present) represented a greater danger to the infant involved. (Drownings occurred in cases of as little as 2.5 inches of water.) You know of no data indicating that a child is more likely to drown in a depth of seven inches of water compared to ~~represents a greater danger to an infant in a tub (with or without a bath seat) than does~~ 4.5 inches of water. Alternatively, ~~Y~~ your study assumed that people regarded deeper ~~[illegible]~~ bath water as more dangerous and, therefore, ~~that~~ median bath water depth was ~~[illegible]~~ a measure of risk-taking behavior.

5. Presence of a Sibling

You did not do any sensitivity analysis to see whether cases involving both bath seats and siblings left alone in a tub yielded results similar to, or different from, the results that you found. This approach was taken since published work [illegible] presence of a [illegible] in the tub with the victim is an independent risk factor promoting [illegible] in the bathtub. In an effort to isolate the effect of bathing aids in parental risk-taking behavior, cases with a sibling present in the tub at the time of death were removed. You emphasized that data involving siblings in tubs is even "dirtier" than data involving infants left alone in tubs because there are more complicating factors. For example, cases document that siblings may inadvertently be implicated in the death of the child by removing the infant from the bath seat while [illegible].

6. Cases Involving Bath Nets and a Flotation Device

An analysis has been performed of the data excluding the five cases involving bath nets and one case involving a flotation device (which had been lumped with conventional bath seats in the first analysis). The results of that analysis have been provided to Renae Rauchschwalbe, who will pass them along to the Special Assistants.

7. Confidence Interval for Odds Ratio

The 95% confidence interval for the odds ratio means that [illegible] that the actual odds ratio for "reported reason left alone" lies somewhere between 1.13 and 11.05. A [illegible] of 1.0 would mean — essentially [illegible]; people would be just as likely to leave a child unattended for a willful reason in a bath seat as they would in the absence of a bath seat. If the figure was approximately 11, it means that people would be eleven times more likely to leave a child unattended for a willful reason in the presence of a bath seat than in the absence of a bath seat. The "best estimate" odds ratio of 3.54 lies [illegible] between [illegible].

8. Reliability of Reported Reason Left Alone

You emphasized that this data was difficult to work with. You had two research assistants independently read the reports and categorize the reason as either "impulsive" or "willful." The classification was by category and there was no attempt to numerically rank decisions as "more willful" or "more impulsive." The research assistants did not know in which a case a bath seat was involved and in which case a bath seat was not involved, but they did know that: (1) a drowning had occurred; and (2) that something had been "blacked out" in cases involving a bath seat (although they did not know that the "blacked out" portion involved a bath seat).

The research assistants agreed on most — categorizations of willful versus impulsive except in the case, for example, of burning food, which one researcher characterized as willful because the food had been cooking prior to the start of the bath, and which the other characterized as impulsive because the burning occurred after the bath had started. [illegible]

There was no attempt to control for recall bias in this case. The reason stated in the report was accepted as the reason why the person involved left the infant unattended.

Renae Rauchschwable's e-mail Question 1: Log Transformed Elapsed Time Methodology

As mentioned earlier the estimates of time that the infant was left unattended seemed to cluster on the low end of the scale and did not distribute in a traditional bell-shaped curve. In order to achieve a bell-shaped distribution, one approach would be to log-transform the reports of elapsed time and use a t-test for statistical significance. Readers, however, tend not to understand reports of time when log-transformed, so you used real time reports and submitted the data to a non-parametric test (Kolmogorov-Smirnov test which is not sensitive to deviations from "normality") as a [illegible] test of statistical significance. [illegible] less "powerful" than traditional parametric tests, such as a t-test.

Wilson, Dennis B.

From: Rauchschwalbe, Renae
ent: Wednesday, January 24, 2001 11:01 AM
o: Wilson, Dennis B.; Weller, Pamela L.
Cc: Kiss, Celestine T.; 'Clay.Mann@hsc.Utah.edu'
Subject: Revised Risk Factor Analysis on Bath Seats (only)

Pamela and Dennis - Here is the revised risk factor analysis on bath seats (rather than bath aids).

Reported reason left alone (%)

Variable	Seat		No Seat	Odds Ratio	95%CI
Willful decision	75%	45%	4.56		1.31-15.87
Impulsive decision	25%	54%			

Mean Water Depth:
with seat: 8.2 + - 3.9
ithout seat: 6.4 + - 4.8 (no significant difference)

Wilson, Dennis B.

From: Weller, Pamela L.
Sent: Wednesday, January 24, 2001 11:45 AM
To: Rauchschwalbe, Renae; Wilson, Dennis B.
Cc: Kiss, Celestine T.; 'Clay.Mann@hsc.Utah.edu'
Subject: RE: Revised Risk Factor Analysis on Bath Seats (only)

Renae, now that we are down to only 24 bath seats, is that sample size too small from which to draw valid statistical conclusions? We were right at the bare minimum, I thought with 32.

-----Original Message-----
From: Rauchschwalbe, Renae
Sent: Wednesday, January 24, 2001 11:01 AM
To: Wilson, Dennis B.; Weller, Pamela L.
Cc: Kiss, Celestine T.; 'Clay.Mann@hsc.Utah.edu'
Subject: Revised Risk Factor Analysis on Bath Seats (only)

Pamela and Dennis - Here is the revised risk factor analysis on bath seats (rather than bath aids).

Reported reason left alone (%)

Variable	Seat		No Seat	Odds Ratio	95%CI
Willful decision	75%		45%	4.56	1.31-15.87
Impulsive decision	25%		54%		

Mean Water Depth:
with seat: 8.2 + - 3.9
ithout seat: 6.4 + - 4.8 (no significant difference)

Wilson, Dennis B.

From: Rauchschwalbe, Renae
Sent: Wednesday, January 24, 2001 1:48 PM
To: Wilson, Dennis B.
Subject: FW: RE: Revised Risk Factor Analysis on Bath Seats (only)

Dennis - I think you should see the response to Pamela's question too.

-----Original Message-----
From: Clay Mann [mailto:Clay.Mann@hsc.utah.edu]
Sent: Wednesday, January 24, 2001 1:05 PM
To: PWeller@cpsc.gov
Cc: rrauch@cpsc.gov
Subject: Re: RE: Revised Risk Factor Analysis on Bath Seats (only)

Very good question Pam. The significance of a test is very sensitive to sample size. That is, the smaller the sample size, the bigger the effect must be to find it statistically significant. The fact that the finding for "care giver" activity remains significant (odds ratio 4.56, 95% CI = 1.31 to 15.87) points to the fact that the effect is so large (4.56 times more likely to leave the child alone based on a willful decision when a bath seat is in use compared to when one is not in use) that the finding to remains significant (meaning the findings probably are real and did not happen by chance) even though the sample size has been reduced.

>>> "Weller, Pamela L." <PWeller@cpsc.gov> 01/24 9:44 AM >>>
Renae, now that we are down to only 24 bath seats, is that sample size too small from which to draw valid statistical conclusions? We were right at the bare minimum, I thought with 32.

-----Original Message-----
From: Rauchschwalbe, Renae
Sent: Wednesday, January 24, 2001 11:01 AM
To: Wilson, Dennis B.; Weller, Pamela L.
Cc: Kiss, Celestine T.; 'Clay.Mann@hsc.Utah.edu'
Subject: Revised Risk Factor Analysis on Bath Seats (only)

Pamela and Dennis - Here is the revised risk factor analysis on bath seats (rather than bath aids).

Reported reason left alone (%)

Variable	Seat	No Seat	Odds Ratio	95%CI
Willful decision	75%	45%	4.56	1.31-15.87
Impulsive decision	25%	54%		

Mean Water Depth:
with seat: 8.2 + - 3.9
ithout seat: 6.4 + - 4.8 (no significant difference)

Wilson, Dennis B.

From: Weller, Pamela L.
Sent: Friday, January 26, 2001 10:29 AM
To: Wilson, Dennis B.
Subject: FW: RE: RE: Revised Risk Factor Analysis on Bath Seats (only)

FYI, Dennis. I've been having a little back and forth with Clay.

-----Original Message-----
From: Clay Mann [mailto:Clay.Mann@hsc.utah.edu]
Sent: Thursday, January 25, 2001 7:18 PM
To: PWeller@cpsc.gov
Cc: rrauch@cpsc.gov
Subject: Re: RE: RE: Revised Risk Factor Analysis on Bath Seats (only)

No problem.....This is a really a good question and worth describing to ensure that others understand it as well. Also, after reviewing this data, I have found two errors I had made. First, I think when I shipped the revised data to Renae, I neglected to revise the percentages on the table describing the alleged reason for leaving the victim alone. You are right, the "no seat" percentages should not change. Also, my estimation of the revised odds ratio (removing the 7 cases) was slightly off (a very small difference).

The odds ratio increases even though the sample size drops because the percentage of parents leaving bathing victims in a bath seat for a "willful" reason increased compared to the number leaving for an impulsive reason. Here is the data:

Old Data

	Seat	No Seat	OR = 3.54, 95% CI = 1.13 to 11.05
Willful	75%	45%	
Impulsive	25%	55%	

New Data

	Seat	No Seat	OR = 4.49, 95% CI = 1.31 to 15.29
Willful	79%	45%	
Impulsive	21%	55%	

The increased percentage in the overall sample that left the child for a willful decision (once the 7 cases were dropped) increased the odds ratio....but as you can see, increase the width of the confidence interval.....as one might expect as the sample size decreases.

I hope this helps.....I am sorry for not mailing the right percentages the first time.....I cant believe I was so careless! I am sorry.

>>> "Weller, Pamela L." <PWeller@cpsc.gov> 01/24 11:33 AM >>>
I'll show my statistical dumbness here, Clay. Why does the odds ratio increase when the number of cases with bath seats goes down? And why did the percentage deemed making an impulsive decision with no seat change when the seven being excluded should have all been in the "seat" category? I promise not to belabor this!

-----Original Message-----
From: Clay Mann [mailto:Clay.Mann@hsc.utah.edu]
Sent: Wednesday, January 24, 2001 1:05 PM
To: PWeller@cpsc.gov
Cc: rrauch@cpsc.gov
Subject: Re: RE: Revised Risk Factor Analysis on Bath Seats (only)

Very good question Pam. The significance of a test is very sensitive to sample size. That is, the smaller the sample size, the bigger the effect must be to find it statistically significant. The fact that the finding for "care giver" activity remains significant (odds ratio 4.56, 95% CI = 1.31 to 5.87) points to the fact that the effect is so large (4.56 times more likely to leave the child alone based on a willful decision when a bath seat is in use compared to when one is not in use) that the finding to remains significant (meaning the findings probably are real and did not happen by chance) even though the sample size has been reduced.

>>> "Weller, Pamela L." <PWeller@cpsc.gov> 01/24 9:44 AM >>>
Renae, now that we are down to only 24 bath seats, is that sample size too small from which to draw valid statistical conclusions? We were right at the bare minimum, I thought with 32.

> -----Original Message-----
> From: Rauchschwalbe, Renae
> Sent: Wednesday, January 24, 2001 11:01 AM
> To: Wilson, Dennis B.; Weller, Pamela L.
> Cc: Kiss, Celestine T.; 'Clay.Mann@hsc.Utah.edu'
> Subject: Revised Risk Factor Analysis on Bath Seats (only)
>
> Pamela and Dennis - Here is the revised risk factor analysis on bath seats
> (rather than bath aids).
>
> Reported reason left alone (%)

Variable	Seat	No Seat	Odds Ratio 95%CI
Willful decision	75%	45%	4.56 1.31-15.87
Impulsive decision	25%	54%	

>
Mean Water Depth:
with seat: 8.2 + - 3.9
> ithout seat: 6.4 + - 4.8 (no significant difference)

Wilson, Dennis B.

From: Wilson, Dennis B.
ent: Wednesday, February 14, 2001 10:56 AM
o: 'Clay.Mann@hsc.Utah.edu'
Cc: Rauchschwalbe, Renae; Kiss, Celestine T.; Weller, Pamela L.
Subject: Baby Bath Seat Study

Dr. Mann:

I have two follow-up questions on the baby bath seat study that was the subject of our earlier telephone conference call and e-mail correspondence.

1. Did you claim that the statistically significant difference in the ages of infant tub drowning victims in the presence of, or without bath seats, is an indication of parents or caregivers increased willingness to engage in risk-taking behavior in the presence of a bath seat? If so, what is the basis for the assertion?

2. What human factors training, education or experience did the research assistants who entered decisions as "willful" or "impulsive" have?

Reply at your convenience. I appreciate your assistance.

Dennis Wilson
Special Assistant (Legal) to Commissioner Gall

Wilson, Dennis B.

From: Clay Mann [Clay.Mann@hsc.utah.edu]
Sent: Wednesday, February 14, 2001 7:22 PM
To: DWilson@cpsc.gov
Cc: rrauch@cpsc.gov
Subject: Re: Baby Bath Seat Study

Mr. Wilson:

Thank you for your continued questions and comments. Hopefully the detail with which you are approaching this topic will educate some folks and strengthen the review process.

With regards to differences in age: our initial presentation to the 2000 National Congress on Childhood Emergencies did indicate that children drowning in the presence of a bathing aid were significantly younger than those drowning without the presence of a bathing aid. This finding was statistically significant. One comment here: please remember that the presentation to the National Congress included incidents that occurred in the presence of other types of bathing aids (not just "bath seats"). To my knowledge, this analysis has not been reproduced using the more "focused" sample that has been developed since this initial presentation.

The a priori hypothesis that generated the age analysis was this: Parents gain more and more confidence that a child can bath alone as the child grows older. That is, I would presume that most 5 year old children bath alone with parents confident that the child has the necessary skills and strength to protect himself (or herself) against drowning. The opposite of this idea formed our working hypothesis. That is, the younger the child is, parents are assumed to consider the child more susceptible to a drowning incident and, therefore, require additional (or more intense) supervision. With this hypothesis in mind, our findings may suggest that parents may feel more comfortable leaving younger children with less than adequate supervision in the presence of a bathing aid. If our results are interpreted in this manner, the findings suggest that the presence of a bathing aid may be instilling a sense of "safety" among parents.....some much so, that "bathing aid drownings" are more prevalent among younger children. If the two samples of children were found to be the same age (or there was no statistical difference in ages) then we would have rejected this idea (or hypothesis).....but this was not what we found.

Your second question: What human factors training did my research assistants have the assigned cases as "willful" or "impulsive" decisions to leave the victim alone in the tub. Interesting question. I am not sure what is meant by "human factors training" or where one would gain such training. I can tell you this, my research assistants were graduate students seeking a Master of Science degree in Public Health with an emphasis on injury control. Course work in this program teaches students to understand the mechanisms of injury and what causal factors (i.e., behavioral, environmental, etc) are associated with an increased risk of injury. I am not sure if this answers your question. However, at the least, you could consider my students informed consumers.

>>> "Wilson, Dennis B." <DWilson@cpsc.gov> 02/14 8:56 AM >>>
Dr. Mann:

I have two follow-up questions on the baby bath seat study that was the subject of our earlier telephone conference call and e-mail correspondence.

1. Did you claim that the statistically significant difference in the ages of infant tub drowning victims in the presence of, or without bath seats, is an indication of parents or caregivers increased willingness to engage in risk-taking behavior in the presence of a bath seat? If so, what is the basis for the assertion?

2. What human factors training, education or experience did the research assistants who entered decisions as "willful" or "impulsive" have?

Reply at your convenience. I appreciate your assistance.

Dennis Wilson

Special Assistant (Legal) to Commissioner Gall