Practice Patterns for N-acetylcysteine Dosing for Acetaminophen Toxicity in the United States

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Abstract
Background: Although the FDA approved acetaminophen toxicity dosing regimen for intravenous n-acetylcysteine (NAC) is a three-bag regimen, alternate regimens have been published which are generally simpler, and decrease errors and adverse effects. It is not clear how pervasive alternative regimens are used in hospitals in the US and reasons for a change from the FDA regimen. *Objective:* Characterize practice patterns for treating acetaminophen toxicity. *Methods:* A pilot-tested, electronic survey containing demographic and practice pattern questions for acetaminophen toxicity management was sent to residency program directors. The survey was open for 4 weeks with several reminder e-mails sent to non-responders. Descriptive statistics were used to summarize the data. *Results:* There were 119 responses (9.2% response rate). Responses were representative of all geographic areas in the US and were most commonly from community hospitals (67.2%) and those with 300 or more beds (72.2%). Nearly two-thirds used the FDA approved NAC regimen, whereas others used an alternate regimen. Reasons for making the change were for simplicity, to decrease errors or adverse events, or based on local poison center recommendations. More than one-third of respondents reported not using a maximum dosing weight. *Conclusions:* N-acetylcysteine is usually administered intravenously using the FDA approved regimen for acetaminophen toxicity. The weight for dosing was commonly capped at 100 kg, but some institutions did not use a maximum. Alternative intravenous regimens have been implemented at some institutions with the impetus for change being safety and simplicity.

Keywords: Acetaminophen, n-acetylcysteine (NAC), toxicity

Introduction

Acetaminophen is a common source of poisoning. In 2022, more than 90,000 cases were logged by US poison centers involving acetaminophen, many requiring treatment with n-acetylcysteine (NAC). Additionally, acetaminophen was one of the most common substances mentioned when a fatality was logged.[1]

The major toxic acetaminophen metabolite, generated primarily through cytochrome P450 2E1, leads to liver injury is N-acetyl-p-benzoquinone imine (NAPQI). With therapeutic doses of acetaminophen, NAPQI is detoxified by glutathione. However, when normal metabolic pathways such as sulfation and glucuronidation become saturated, the amount acetaminophen metabolized through cytochrome P450 2E1 increases which increases NAPQI concentrations and depletes glutathione stores. NAPQI then can act on hepatocytes to cause liver damage.[2] Early work in acetaminophen toxicity demonstrated hepatotoxicity to be associated with higher acetaminophen serum concentrations when they crossed a pre-defined threshold; this became known as the Rumack-Matthew nomogram.[3]

In the 1970's NAC was recognized as an effective antidote in the management of acetaminophen toxicity.[4] Both oral and intravenous NAC regimens have been used since that time.[5]

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However, it was not until 2004 that an FDA approved intravenous product was available with the product labeling recommending a three-bag regimen.[6] Non-allergic anaphylactic reactions and errors with the three bag regimen lead to investigations into simpler regimens.[7] Recently, alternative regimens have been proposed which decrease errors and improve tolerability.[8-15] Wong and Graudins found non-allergic anaphylactic reactions (NAARs) decreased from 40% to 9% when using a two-bag regimen versus the three-bag regimen.[11] Mcnulty and colleagues reported NAARs decreased from 14% to 5% when using the three-bag versus the two-bag regimens, respectively.[14] Error rates of 33% have been reported with the three-bag regimen.[16] Published reports using alternative regimens have been from Australia[11-12,14] or Europe[10,15] and thus it is not clear what practice patterns are occurring within hospitals in the US. Therefore, the purpose of this study was to characterize practice patterns from healthcare institutions in the US.

Methods

An electronic survey instrument was developed by the investigators to capture demographic characteristics, NAC dosing practices, and reasons for the use of alternative dosing regimens when applicable. A question regarding use of fomepizole was added based on practice experiences of the authors and the pilot testers. Survey questions are included in appendix 1. The instrument was built in Qualtrics (Qualtrics, Provo, UT), pre-tested by the authors, then pilot tested with three pharmacists who had extensive clinical experience in hospital settings to ensure clarity, completeness, and functionality. The pilot testers were not involved in the design

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of the study, but provided valuable insights to improve the instrument.

The final survey was sent by e-mail to 1288 postgraduate year one pharmacy residency program directors in health-systems. This population was targeted as residency program directors tend to be knowledgeable regarding pharmacy activities within their institutions and contact information could be gathered through public websites. The survey was open for four weeks between October 24 and November 22, 2023. Two reminder e-mails were sent to non-responders. One was sent two weeks after the initial e-mail invitation and the final reminder was sent the day the survey was set to close. Results were exported from Qualtrics into SPSS V29 (IBM Corp., Armonk, NY). Descriptive statistics were used to report findings. This project was approved by the Samford University Institutional Review Board.

Results

There were 119 completed responses which represents a 9.2% response rate (Table 1). Respondents were from the Midwest (30.3%), Northeast (14.3%), South (30.3%), and West (25.2%). They were primarily from community hospitals (67.2%) and academic medical centers (28.6%) that were 300 or more beds (72.2%). Few respondents had a medical toxicology service (16.0%) or had pharmacists credentialed as Diplomates of the American Board of Applied Toxicology (DABAT) (11.8%).

Of the 106 respondents who reported having NAC protocols at their institutions, 65 (61.3%) included both oral and intravenous NAC regimens whereas 41 (38.6%) exclusively used intravenous regimens. However, when NAC was used, nearly 85.7% primarily used intravenous regimens. The most common intravenous regimen used was the FDA approved 3 bag regimen, 76 (68.5%) and 35 (31.5) used other regimens. The frequency of use for alternative regimens is listed in Table 2. The reasons cited for changing to a modified regimen were typically multifactorial, leading to 68 responses from 35 respondents (Table 3). Pharmacists (51.1%), hospital committees (22.2%), and local poison control centers (17.7%) were the most common champions for driving this change.

Dosing weight was actual body weight for most institutions (84.9%). Some used a maximum dosing weight of 100 kg (58.1%), whereas others did not use any upper limit for dosing weight (38.2%). Fomepizole was reported as used for acetaminophen toxicity by 28 respondents (23.5%), typically initiated in massive overdose in conjunction with poison control center guidance.

Discussion

This study is the first of its kind and provides significant insights into the current practice trends in the management of acetaminophen toxicity across a variety of healthcare institutions. Despite a response rate of 9.2%, our survey captures a diverse representation of community hospitals and academic medical centers across all major regions in the US.

The FDA-approved three-bag NAC regimen continues to be the standard of care (68.5%). The significant use of alternative regimens (31.5%) indicates a growing inclination towards simplifying treatment protocols to mitigate potential errors and delays associated with the three-bag regimen. Importantly, all regimens delivered at least 300 mg/kg within the first 20-24 hours, which is consistent with the dosing recommendations included in recent guidelines.[17] This trend towards the use of modified regimens is supported by previous studies, which have shown that simplified regimens do not appear to compromise the efficacy of NAC in preventing hepatotoxicity and may reduce the incidence of adverse effects.[10] The results from a randomized controlled trial found rates of alanine aminotransferase increases to be similar with a two-bag regimen versus the standard three-bag regimen (adjusted OR 0.6, 97.5% CI 0.2-1.83).[10]

Pharmacists, hospital committees, and local poison control centers were identified as the primary champions for changing to a modified regimen. The driving factors include the desire for increased safety, streamlined administration, and reduced complexity (e.g., timing considerations and number of bags required).

Our study also sheds light on the dosing weights used for NAC administration. The majority of institutions dose based on actual body weight, with a significant proportion applying a maximum dosing weight of 100 kg, consistent with the FDA approved dosing regimen. Surprisingly, 38.2% of institutions did not incorporate an upper limit to dosing weight in their protocols. This insight provides an opportunity for improvement to prevent excessive NAC dosing in patients over 100 kg which is in alignment with recent guidelines published by four toxicology societies in the US and Canada.[17]

Additionally, the reported use of fomepizole for managing acetaminophen toxicity by 23.5% of respondents reflects an emerging trend, particularly in cases of massive overdose. Fomepizole's role in inhibiting the cytochrome P-450 system and reducing the formation of NAPQI provides a rational adjunctive treatment in high-risk cases.[18]

The study's limitations include the relatively low response rate, which may affect the generalizability of the findings. Although the population the survey was sent to is diverse, it does not represent all hospitals. Additionally, the reliance on self-reported data could introduce bias. Nevertheless, the study offers valuable insights regarding current practices for NAC treatment protocols in the management of acetaminophen toxicity.

Conclusions

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These data indicate that N-acetylcysteine is usually administered intravenously using the FDA approved regimen for acetaminophen toxicity. The weight for dosing was usually based on actual body weight, but commonly capped at 100 kg. Alternative intravenous regimens have been implemented at some institutions with the impetus for change being safety and simplicity. These data can help institutions compare their current practice to the current landscape for treating acetaminophen toxicity and the reasons why change from the FDA regimen occurs.

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Disclaimer: The statements, opinions, and data contained in all publications are those of the authors.

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Table 1: Demographics of Respondents

Characteristic	Number (%)
Hospital Type (n=119)	
Academic (affiliated with a medical school)	34 (28.6)
Community	80 (67.2)
VA/Government	3 (2.5)
Other	2 (1.7)
Hospital Location (n=119)	
Midwest (IN, IL, MI, OH, WI, IA, KS, MN, MO, NE, ND, SD)	36 (30.3)
Northeast (CT, ME, MA, NH, RI, VT, NJ, NY, PA)	17 (14.3)
South (DE, DC, FL, GA, MD, NC, SC, VA, WV, AL, KY, MS, TN, AK, LA, OK, TX)	36 (30.4)
West (AZ, CO, ID, NM, MT, UT, NV, WY, AK, CA, HI, OR, WA)	30 (25.2)
Licensed Beds (n=119)	
<50	2 (1.7)
50-99	1 (0.8)
100-199	6 (5.0)
200-299	24 (20.2)
300-399	22 (18.5)
400-599	29 (24.4)
600 or more	35 (29.4)
Number of Annual Emergency Department Visits (n=119)	
<20,000	4 (3.4)
20,000-29,999	9 (7.6)
30,000-39,999	10 (8.4)
40,000-49,999	7 (5.9)
50,000-59,999	18 (15.1)
60,000-69,999	11 (9.2)
70,000-79,999	13 (10.9)
80,000-89,999	11 (9.2)
90,000-99,999	10 (8.4)
100,000-124,999	10 (8.4)
125,000-149,999	7 (5.9)
150,000 or more	9 (7.6)
Respondent Primary Area of Practice (n=119)	
Administration/Management	33 (27.7)
Intensive Care Unit	26 (21.8)
General Medical Unit	22 (18.5)
Emergency Department	21 (17.6)
Other Clinical	9 (7.6)
Other (Inpatient, Sterile Compounding)	3 (2.5)
Education	2 (1.7)
Medication Safety Officer	2 (1.7)
General Surgical Unit	1 (0.8)
Toxicology Service (n=119)	
Yes	19 (16.0)
No	100 (84.0)
Diplomate of the American Board of Applied Toxicology Pharmacists (n=119)	
None	105 (88.2)
1	11 (9.2)
2	2 (1.7)
3 or more	1 (0.8)

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Table 2: Frequency of NAC regimens used by respondents

Number of Bags	Dosing Regimen	Frequency (percent)
3	150 mg/kg over 1 hour, then 50mg/kg over 4 hours (12.5 mg/kg/hr), then 100 mg/kg over 16 hours (6.25 mg/kg/hr)	76 (68.5)
2	200 mg/kg over 4 hours (50 mg/kg/hr), then 100 mg/kg over 16 hours (6.25 mg/kg/hr)	14 (12.6)
2	150 mg/kg over 1 hour, then 360 mg/kg over 24 hours (15 mg/kg/hr)	6 (5.4)
2	150 mg/kg over 1 hour, then 250 mg/kg over 20 hours (12.5 mg/kg/hr)	5 (4.5)
1	150 mg/kg over 1 hour, then 12.5 mg/kg/hour	3 (2.7)
2	100 mg/kg over 2 hours (50 mg/kg/hr), then 200 mg/kg over 10 hours (20 mg/kg/hr)	1 (0.9)
2	150 mg/kg over 1 hour, then 280 mg/kg over 20 hours (14 mg/kg/hr)	1 (0.9)
2	150 mg/kg over 1 hour, then 300 mg/kg over 20 hours (15 mg/kg/hr)	1 (0.9)
2	200mg/kg over 4hr, then 200mg/kg over 16 hours	1 (0.9)
1	150 mg/kg over 1 hour, then 50mg/kg over 4 hours (12.5 mg/kg/hr), then 100 mg/kg over 16 hours (6.25 mg/kg/hr)	1 (0.9)
	Unsure	2 (1.8)
	Total	111

Table 3: Rationale for Using a Modified Regimen

Rationale	Frequency (%)
Desire to simplify nursing administration	24 (35.3)
Desire to decrease workload from preparation in the pharmacy	15 (22.1)
Dosing errors have occurred with the FDA approved regimen	7 (10.3)
Other: Recommended by poison control center	7 (10.3)
Desire to decrease the rate of adverse effects with the FDA approved regimen	6 (8.8)
Compounding errors have occurred with the FDA approved regimen	3 (4.4)
Other: Health system standardization	2 (2.9)
Other: Dosing and timing optimization	2 (2.9)
Other: not specified	2 (2.9)
Total	68

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Appendix 1. Survey Questions

Please Classify the type of hospital into one of the following categories:

- ☐ Community
- ☐ Academic (affiliated with a medical school)
- ☐ VA/Government
- ☐ Other (please specify):

In which region is your hospital located?

- ☐ West (AZ, CO, ID, NM, MT, UT, NV, WY, AK, CA, HI, OR, WA)
- ☐ Midwest (IN, IL, MI, OH, WI, IA, KS, MN, MO, NE, ND, SD)
- ☐ South (DE, DC, FL, GA, MD, NC, SC, VA, WV, AL, KY, MI, TN, AK, LA, OK, TX)
- ☐ Northeast (CT, ME, MA, NH, RI, VT, NJ, NY, PA)
- ☐ Other (please specify):

Approximately how many licensed beds are in your facility?

- ☐ <50
- ☐ 50-99
- ☐ 100-199
- ☐ 200-299
- ☐ 300-399
- ☐ 400-599
- ☐ 600 or more
- ☐ Not Applicable – Stand Alone ED

What is the approximate number of ED visits per year in your facility?

- ☐ <20,000
- ☐ 20,000 to 29,000
- ☐ 30,000 to 39,000
- ☐ 40,000 to 49,000
- ☐ 50,000 to 59,000
- ☐ 60,000 to 69,000
- ☐ 70,000 to 79,000
- ☐ 80,000 to 89,000
- ☐ 90,000 to 99,000
- ☐ 100,000 to 124,999
- ☐ 125,000 to 149,000
- ☐ 150,000 or more

Is there a toxicology service available (i.e., a medical toxicologist will see patients in the emergency department or hospital)?

- ☐ Yes
- ☐ No

How many pharmacists employed by your institution have the Diplomate of the American Board of Applied Toxicology (DABAT) designation?

- ☐ None
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5 or more

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In which clinical area do you primarily work (20 or more hours per week) in the hospital?

- ☐ Emergency department
- ☐ Intensive care unit
- ☐ General medical unit
- ☐ General surgery unit
- ☐ Other (please specify):

Questions specific to N-acetylcysteine administration

Does your institution have a policy or protocol for N-acetylcysteine administration for acetaminophen toxicity?

- ☐ Yes, includes both oral and intravenous N-acetylcysteine regimens
- ☐ Yes, includes oral N-acetylcysteine only
- ☐ Yes, includes intravenous N-acetylcysteine only
- ☐ No
- ☐ Unsure

Which route of N-acetylcysteine administration is primarily used (at least 80% of the time) at your institution?

- ☐ Oral
- ☐ Intravenous
- ☐ Both routes are used and the decision is based on patient characteristics

When intravenous N-acetylcysteine is used, which regimen is primarily used (at least 80% of the time) at your institution for acetaminophen toxicity?

{skip logic to next three questions for any options except FDA dosing}

- ☐ 150 mg/kg over 1 hour, then 50mg/kg over 4 hours (12.5 mg/kg/hr), then 100 mg/kg over 16 hours (6.25 mg/kg/hr) – FDA Approved Dosing
- ☐ 100 mg/kg over 2 hours (50 mg/kg/hr), then 200 mg/kg over 10 hours (20 mg/kg/hr)
- ☐ 200 mg/kg over 4 hours (50 mg/kg/hr), then 100 mg/kg over 16 hours (6.25 mg/kg/hr)
- ☐ 150 mg/kg over 1 hour, then 360 mg/kg over 24 hours (15 mg/kg/hr)
- ☐ 150 mg/kg over 1 hour, then 280 mg/kg over 20 hours (14 mg/kg/hr)
- ☐ 150 mg/kg over 1 hour, then 250 mg/kg over 20 hours (12.5 mg/kg/hr)
- ☐ Other (please specify):

You selected a modified intravenous regimen. What prompted the change at your institution? [SELECT ALL THAT APPLY]

- ☐ Dosing errors have occurred with the FDA approved regimen
- ☐ Compounding errors have occurred with the FDA approved regimen
- ☐ Desire to decrease workload from preparation in the pharmacy
- ☐ Desire to decrease the rate of adverse effects with the FDA approved regimen
- ☐ Desire to simplify nursing administration
- ☐ Desire to decrease time of admixture preparation in the pharmacy
- ☐ Other (please specify):

When did your institution change to a modified protocol?

- ☐ < 1 year ago
- ☐ 1-3 years ago
- ☐ 4-5 years ago
- ☐ Over 5 years ago

Who was the champion to change the protocol at your institution? [SELECT ALL THAT APPLY]

- ☐ Hospital committee (i.e., Medication Safety, Pharmacy and Therapeutics, etc…)
- ☐ Local poison control center
- ☐ Pharmacist
- ☐ Physician or physician group
- ☐ Toxicologist

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- ☐ Unknown
- ☐ Other (please specify):

{This question was visible only if the FDA regimen was selected using skip logic}
You selected that you use the FDA approved regimen for most acetaminophen toxicity. Do you intend to change to a modified protocol? If so, to which of the following protocols?

- ☐ No, there are not any plans to change
- ☐ Yes, 100 mg/kg over 2 hours (50 mg/kg/hr), then 200 mg/kg over 10 hours (20 mg/kg/hr)
- ☐ Yes, 200 mg/kg over 4 hours (50 mg/kg/hr), then 100 mg/kg over 16 hours (6.25 mg/kg/hr)
- ☐ Yes, 150 mg/kg over 1 hour, then 360 mg/kg over 24 hours (15 mg/kg/hr)
- ☐ Yes, 150 mg/kg over 1 hour, then 280 mg/kg over 20 hours (14 mg/kg/hr)
- ☐ Yes, 150 mg/kg over 1 hour, then 250 mg/kg over 20 hours (12.5 mg/kg/hr)
- ☐ Yes, but unsure which protocol will ultimately be adopted
- ☐ Other (please specify):

{All respondents were presented with the remaining questions}
Does your institution use a maximum weight for the dosing of intravenous N-acetylcysteine?

- ☐ No maximum weight
- ☐ Maximum weight of 100 kg
- ☐ Other maximum weight (please specify):

Which weight do you use for dosing NAC in adults?

- ☐ Actual body weight
- ☐ Adjusted body weight
- ☐ Ideal body weight

For acute acetaminophen ingestions, when is the intravenous N-acetylcysteine initiated for most patients?

- ☐ As soon as possible after patient history supports an acetaminophen overdose
- ☐ As soon as possible once AST/ALT elevations are noted
- ☐ As soon as possible after an acetaminophen concentration is above the treatment line on the Rumack-Matthew nomogram (4-24 hours post ingestion)

To your knowledge, has fomepizole been used at your institution specifically for the management of acetaminophen toxicity?

- ☐ Yes
- ☐ No

Please detail anything else you would like the investigators to know.

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