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Karen M. Templeton-Somers
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Food and Drug Administration
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Re: SYRUP OF IPECAC

Dear Ms. Templeton-Somers,

I am writing to provide information regarding the recommendation of the FDA Nonprescription Drug Advisory Committee (NDAC) to discontinue the over-the-counter status of Syrup of Ipecac. This letter will make five points:

- **The presentations made at the NDAC meeting do not adequately reflect the diversity of opinion in the community of clinical toxicologists.**
- **A substantial portion of the Clinical Toxicology and Poison Center communities believe that Syrup of Ipecac is needed for clinical use in the United States.**
- **There are reasonable and medically valid uses of Syrup of Ipecac**
- **A major proposed benefit of this decision, to reduce the abuse of Syrup of Ipecac, is not plausible and has not been evaluated adequately.**
- **The FDA should engage Poison Centers and Clinical Toxicologists, the primary community recommending Syrup of Ipecac, before adopting the position of advocates for its elimination.**

NDAC Presentations
I have reviewed several portions of the transcript of the NDAC meeting and feel that they do not adequately represent the perspective of many practicing medical toxicologists. I was particularly concerned that a list of participants in a consensus guidelines process was shown to the NDAC and that a first draft of the proposed Ipecac guideline was apparently provided to the committee. As one of the panel participants, I presume my name was among those shown to NDAC. It is important for NDAC and FDA to understand that the presentation involved does not reflect my assessment. Indeed, t it appears very likely that the final guideline will specifically state that there are clinical uses for Syrup of Ipecac. I believe the FDA should review the final guideline before making a decision.

Perspective of the Clinical Toxicology and Poison Center Communities
In order to obtain a more representative sample of the toxicology community, I queried a list server maintained by the American College of Medical Toxicology. This list server includes all members of the college as well as large number of other health professionals involved in the care of the poisoned patient. For example, the managing directors and medical directors of poison centers are included on this list.

The results are striking. Appended, please find verbatim copies of the replies. I will only comment in an overview fashion because the replies speak for themselves. Please note that this was not a consensus process. I simply asked what these practitioners thought about the NDAC recommendation and these are all the replies I received. (A few replies were not included because the individual did not reply to my request for permission to distribute their comments.)

There are comments regarding both pro and con aspects of the issue, although the majority support retaining the over-the-counter availability of ipecac. My impression is that many of the replies make the point: "We are the ones that recommend Syrup of Ipecac. Many of us conclude that it is still needed. We do not want to see it removed." You will also read some replies that state "We don't have data that proves an improved outcome". That is a true statement, but I believe there are data that indicate that it is not unreasonable to conclude that Syrup of Ipecac can improve outcome in some cases. As some of the respondents indicate: "Lack of evidence is not evidence of a lack of effect."

Reasonable Uses of Syrup of Ipecac

It is important to realize that there are data supporting the use of Ipecac. Studies have shown in volunteer subjects that Syrup of Ipecac removes drugs and lowers blood concentration of numerous drugs. For example, it has been shown that emesis reduces the blood level of acetaminophen in children who have taken an accidental ingestion of acetaminophen. Emesis occurring up to an hour after ingestions reduced the blood levels in this population (Bond 1993). Since the treatment of acetaminophen (e.g. acetylcysteine) is based on the serum blood level, it is reasonable to conclude that the use of Ipecac in a population of patients with a potentially toxic acetaminophen ingestion would lead to fewer patients being treated with the antidote.

There are many studies that show that ipecac reduces the blood level of various poisons. Since the blood level often correlates with toxicity, it is logical to conclude that there is a beneficial effect from Syrup of Ipecac. Further, when clinical toxicologists were presented with a test case in 1998, 81.7% of them replied that they would have used Syrup of Ipecac (this citation is included in the comments). Some of the replies include additional citations supporting the potential clinical usefulness of Ipecac.

Several of the correspondents provided examples of how they use Syrup of Ipecac. While this list is not complete, it provides useful examples of its applications:

- Iron ingestion
- Households in rural areas
- Potentially toxic plant ingestions
- Acetaminophen
- Suspected large and recent (but still asymptomatic) ingestion of a life threatening agent
- Drug whose formulation is too large to fit through a lavage tube (long acting calcium channel blocker)
- Mushrooms

You can see that these indications potentially affect millions of people. Like a fire extinguisher, few of these people may actually end up using Ipecac; however, it needs to be available to them.

Elimination of Syrup of Ipecac is unlikely to reduce its abuse
It is particularly striking that the advocates for removal of Ipecac use "lack of proven efficacy" as a primary reason. This statement surely applies to their assertion that removal of Ipecac will somehow improve the condition of patient with anorexia nervosa, bulimia or related conditions. It is likely true that this medication has been abused by these populations. It has never been demonstrated, however, (to my knowledge) that removing Ipecac as a source would improve the outcome of this disease. These patients are highly motivated for psychiatric reasons to either gorge and purge themselves or to deprive themselves of food altogether. I've seen nothing (and I would appreciate receiving this data if it exists) that demonstrates that removing this one method of achieving their aims would prevent them from achieving them through another route. It is extremely unlikely that the overall course of their disease would be substantially altered simply by removing Ipecac.

The FDA should engage the primary community utilizing Syrup of Ipecac before adopting the position of those advocating for its elimination.
I believe this remarkable response to a single email provides ample evidence to the FDA that the NDAC did not have the opportunity to fully consider both sides of the question. There is no doubt that the Poison Center and Toxicology Communities are interested and willing to work with the FDA to further evaluate this issue. Since nearly all use of this drug arises from the recommendations of this group, it would seem reasonable for the FDA to fully understand and evaluate their perspective in this matter. As mentioned earlier, it is likely the final consensus guideline will specifically provide for limited use of syrup of ipecac. I urge the FDA to wait until the final guideline is adopted before making its decision on the fate of syrup of ipecac.

In the end, if the question is whether the risk-benefit ratio for the availability of Ipecac in the United States is favorable. I believe that the truthful answer is that we just don't know. The attached correspondence indicates that Clinical Toxicologists agree with this evaluation. As for any drug, we can identify positive and negative aspects. In the case of Ipecac, there are mostly theoretical and some real advantages to having the drug available. Conversely, we don't know the negative aspect of this drug either. It is poorly described both for acute or chronic use. We simply do not have the means available to perform a meaningful risk-benefit analysis for this type of product.. Since syrup of ipecac is specifically used by a substantial number of health care providers in situations outlined above, it should remain available for consumer use, under the direction of the Poison Control Center or other health care professional.

Sincerely,

Richard C. Dart, MD, PhD
Director, Rocky Mountain Poison and Drug Center
Professor, University of Colorado Health Sciences Center

Conflicts of Interest: None

Bond GR, Requa RK, Krenzelok EP, et al. Influence of time until emesis on the efficacy of decontamination using acetaminophen as a marker in a pediatric population. Ann Emerg Med 1993;22(9):1403-1407.

Responses from ACMT net:

Mary Ann Howland, PharmD *(New York City Poison Center)* [MhowlandNY@aol.com],
Lewis Goldfrank, Robert S Hoffman (Director, NYC Poison Center)
Lewis Nelson, Neal Lewin, Neal Flomenbaum

We feel strongly that there is a continued role for syrup of ipecac, albeit it a small one. Therefore, based on a few reported instances of abuse, we think it would be a mistake to remove syrup of ipecac from OTC status. We have not encountered patients with problems related to syrup of ipecac abuse in our setting in New York City. By analogy, many patients abuse laxatives for the purposes of weight loss. Those patients develop fluid and electrolyte problems, yet no one is suggesting that laxatives be relegated to prescription status.

Volunteer studies demonstrate that if given while drug is still in the stomach, syrup of ipecac decreases the amount of drug absorbed following ingestion.1-6 In comparison to activated charcoal, syrup of ipecac is usually less effective when studied for drugs adsorbed to activated charcoal. However not all drugs are adsorbed to activated charcoal. In addition patient acceptance of activated charcoal makes outpatient administration a challenge.

We acknowledge that syrup of ipecac should not be used routinely in overdose patients. However we do believe that syrup of ipecac remains a beneficial therapeutic modality, especially in patients living in remote areas or who have limited access to health care facilities.

References:

1. Corby D, Decker W, Moran M, et al: Clinical comparison of pharmacologic emetics in children. Pediatrics 1968;42:361-364.
2. Curtis R, Barone J, Giacona N: Efficacy of ipecac and activated charcoal and cathartic: Prevention of salicylate absorption in a simulated overdose. Arch Intern Med 1984;144:48-52.
3. McNamara R, Aaron C, Gemborys M, Davidheiser S: Efficacy of charcoal versus ipecac in reducing serum acetaminophen in a simulated overdose. Ann Emerg Med 1988;17:243-246.
4. Neuvonen P, Vartiainen M, Tokola O: Comparison of activated charcoal and ipecac syrup in prevention of drug absorption. Eur J Clin Pharmacol 1983;24:557-562.
5. Tenenbein M, Cohen, Sitar D: Efficacy of ipecac-induced emesis, orogastric lavage, and activated charcoal for acute drug overdose. Ann Emerg Med 1987;16:838-841.
6. Young WF, Bruin SMG: Evaluation of gastric emptying using radionucleotides: Gastric lavage versus ipecac-induced emesis. Ann Emerg Med 1993;22:1423-1427.

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Neal E. Flomenbaum, MD, FACP, FACEP
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Consultant, NYCPCC

Shu Shum ***(Medical Director, Texas Panhandle Poison Center)***
Dear Dr. Dart:
Texas Panhandle Poison Center did a survey on the use of ipecac amongst the medical toxicologist, ABATs and CSPIs in 1998. The survey was presented in the 1998 annual meeting, and subsequently published in Vet Human Toxicol Vol.41 (1) 47-48 February 1999. 81.8% of medical toxicologists responded would use syrup of ipecac in a potentially toxic ingestion under the case described.
I agree with Dr. Goldfrank's group's comment that there are some situation that syrup of ipecac would be valuable.
Thank you for all your work.
Shu.

Prashant Joshi, MD (*Medical Director, Western NY Poison Center)*
[KIDSDOC@BUFFALO.EDU]
I do not support a move to prescription status for ipecac. Although I recommend it only very rarely, I still believe there are limited uses for it. I would rather see it relegated to "behind the counter" so it would still be available for legitimate use.

Bill Banner ***(Medical Director Oklahoma Poison Center)*** [WBANNER@AOL.COM]

I too am dinosaur-like in thinking that there are rare but useful times for ipecac. It will be unfortunate to lose this altogether. My feeling is that a lot of pediatricians still recommend it and we will alienate them further with ill-considered action. How we reach these decisions is sometimes mystifying to me.

Martin Caravati ***(Medical Director, Utah Poison Center)***
[MARTIN.CARAVATI@HSC.UTAH.EDU]
At the Utah PCC, we are not convinced that there is absolutely no role for ipecac in clinical toxicology. Like many other therapies in medicine, it has some logical basis for use but the data are not available to show definitive improvement in patient outcomes (is avoiding an ED visit considered a benefit?). If a poison center currently includes the use of ipecac for certain ingestions, will these patients be referred to the ED now or just observed at home without any decon? It will be good medicine for us to review these triage protocols but most of the decisions will not be driven by outcome data. The studies haven't been done. That's why some centers use ipecac to increase the margin of safety where the toxic dose data is poor or absent. Its removal from OTC status will probably result in a small increase in pediatric referrals to hospital EDs for a more costly and equally non-proven therapy: charcoal.

Charles McKay, CT Poison Control Center ***(Associate Medical Director)***
[CMCKAY@HARTHOSP.ORG]
Certainly there are limited situations (from a nationwide perspective) where syrup of ipecac is still recommended by SPIs and medical toxicologists participating in initial poison center triage/recommendations. Of course, its recommendation does not mean that it has been demonstrated in high quality studies to improve outcome. Then again, much of what we do would be eliminated if the same standards were applied. Studies such as the pediatric APAP determinations with and without home use of ipecac can be extrapolated to support its use in situations where other treatment options are delayed or unavailable - I remember the calls I had while in Denver from ranches in Montana or Wyoming where access to "formal" healthcare is in the range of hours, rather than minutes.

So I guess the question is whether there is more harm from its abuse by those with eating disorders and its inappropriate use in poisonings than there is benefit in providing parents in remote locations with something to do that may benefit their child and make us feel better that we are actively managing an ingestion.

Kathleen Delaney ***(North Texas Poison Center)***
[KATHLEEN.DELANEY@UTSOUTHWESTERN.EDU]
I believe that there remain some cases where ipecac is still useful. Considered the suspected large and recent (but still asymptomatic) ingestion of a life threatening agent whose formulation is too large to fit through a lavage tube (long acting calcium channel blocker) or large pill not absorbed to charcoal (lithium). These are cases where it remains rational to try and get out as much as possible from both ends. While ipecac may have been significantly overused in the past, it is going to far to say that it never has a role to play in acute decontamination.

Robert Geller ***(Medical Director, Georgia Poison Center)***
[RGELLER@GEORGIAPOISONCENTER.ORG]

It is my opinion that ipecac does have limited but definite uses. We continue to espouse its availability in homes with young children in Georgia, but that it should not be used without contacting the poison center
or their physician prior to its use. Our most common use continues to be ingestion of unknown amounts of potentially toxic mushrooms; the second most common is ingestion of potentially toxic doses of iron.

Wasserman, Gary, DO [gwasserman@cmh.edu]
I sent response to one of our organizations when opinions were asked a couple of months ago. I emphasized that Ipecac has a place in the early prevention of poisoning from iron/multiVits and acetaminophen ingestions. But this is only effective if given within about 10 minutes of ingestion.
Why wait for patient to visit ER and then get level to see if antidote needed if you can prevent absorption and therefore prevent the intoxication in the first place by simply using the time-proven Ipecac? And there is no contraindication to SOI in these ingestions because toxicity is delayed. I'm sure there are a few other similar toxins that fit the profile of iron and APAP, how about poisonous mushrooms (controversial here but reasonable to prevent later intoxication)? Without SOI we will have many more families racing to ERs for simple ingestions that could have been prevented by home treatment. Not to mention the cost of these cases. Anyway this is my 2 cents worth.

Kent Olson ***(Medical Director, San Francisco Poison Division of California Poison Center)***
Rick,
I agree with you. You put it very eloquently, and I'd be happy to sign on.

Steven Marcus ***(Director, New Jersey Poison Center)***[SMARCUS@NJPIES.ORG]
Face the facts, we have no chance to win on this one! I wrote to the American Academy of Pediatrics and was told that I was the only pediatrician in the US who wrote to keep recommending ipecac in the home when the AAP was considering eliminating this recommendation 18 months ago! The fact that
the FDA stated that they want data-driven comments shows the pseudo-scientists are in the driver seat. So much of what we do in medicine can not be proven with data that it is ludicrous to look at this one thing that critically. Everyone should view the testimony delivered at the FDA! It is amazing when some of our brethren can so mock the use of this substance with such abandon.

I would like everyone's opinion on the following cases, perhaps we can use data from consensus to help keep ipecac as OTC. Would you use ipecac in the following cases:

1. a mother called and stated that she just had a fight with her 18 yo daughter who locked herself in the bathroom and took 100 ES Tylenol which had just been purchased. The mother was sure it had to have been consumed because the toilet had not flushed and the bottle was just purchased and wasn't opened. The family lived at least 30 minutes from the nearest hospital.

2. a mother called and stated that her 16 year old took 60 aspirin 325 mg. She was sure of the dose. The family was 20 minutes from the hospital.

3. a mother stated that her 18 month old just ate a small white mushroom (about 1 1/2 to 2 inches in diameter growing in her lawn, she did not know if it was in association with any decaying wood but she could tell that it had gills and greenish-yellow spots on the top.

William Meggs [MEGGSW@MAIL.ECU.EDU]
In reply to Dr. Dart's note on Ipecac, I agree that there are clinical uses for Ipecac. When used early after an ingestion in selected cases, it can prevent toxicity. One case I recall when a tox fellow in New York was a prisoner at Riker's Island who was placed in an examination room with a bottle containing two to three hundred theophylline tablets. When the physician came to examine him, he had consumed the entire bottle. Ipecac was given immediately and EMS called. While being loaded on the stretcher, he
vomited up over 200 pills as counted by the paramedics. No toxicity ever developed from this potentially lethal dose of theophylline.

Studies of experimental ingestions with radio-labeled ingestions found large variability in recovery of tracer in emesis after Ipecac, ranging from 20% to 80% in some subjects. Given its potential for abuse and morbidity and mortality with chronic use, strong arguments can be made to rescind over-the-counter sells. Though indications are limited, to ban the product is unwarranted.

Bateman, Nick [NICK.BATEMAN@LUHT.SCOT.NHS.UK]
>From a European perspective surprised by you attachment to this- haven't
used or recommended for 20 years!!

Richard F. Clark ***(Medical Director, San Diego Division, California Poison System)***
[RFCLARK@UCSD.EDU]
There has been some interesting "opinion" expressed in this discussion of ipecac. I still have trouble locating one controlled animal study, one human case series, even one published anecdotal case report of a situation where ipecac affected the outcome of a case of poisoning or overdose to improve an expected bad outcome. There may be some, but none that are well documented in the literature. Our experience in the past 15 years with a dramatic decrease in the numbers of cases for which our poison center has recommended ipecac has shown no difference in outcome, need for hospitalization, or recommendations for 911 or emergency department referrals. Perhaps this is in part due to a declining number of significant poisonings or safer medications in general but that is not apparent from our data. In this age of "evidence-based" health care, it is time we become a little more scientific in our use of decontamination.

Seger, Donna ***(Medical Director, Central Tennessee Poison Center)***
[donna.seger@Vanderbilt.Edu]
There are many similarities between ipecac and activated charcoal: Neither have been shown to change outcome. the administration of these agents is based on theory, properties of the agent, and "beliefs" not data. Data from volunteers with nontoxic ingestions has been extrapolated to poisoned patients. There is no evidence that this extrapolation is valid. There has not been a careful analysis of benefit:risk of administering either agent. If no benefit has been demonstrated, and there is an increased morbidity or mortality for any patient, the agent may be more harmful than helpful.

Regarding ipecac:
It is difficult for me to accept any arguments about the need for it in any situation.
If the patient has taken a toxic amount of a toxin he will be sent to the hospital whether symptomatic or asymptomatic. poison center data demonstrates that the incidence of administration of ipecac has decreased dramatically in the last 5 years. Morbidity and mortality has not increased. I think all would agree that it is not a good idea to administer this drug to patients who have a potential for a decrease in sensorium, which is a significant number. The outcome for the patients who have ingested agents which do not decrease the sensorium and receive no treatment is very good. If a patient has a nontoxic ingestion and is asymptomatic, the patient will be kept at home. Poison center data demonstrates that these patients do well with no treatment. Administering ipecac would increase their morbidity and mortality. It doesn't make sense to say that ipecac would be useful in certain ingestions if the patient were in a remote areas if we wouldn't administer it in a nonremote area. I think these statements also apply to activated charcoal administration. We have no data that demonstrates a change in outcome with administration of the agent. The study published that advocated home charcoal administered charcoal for mushroom ingestion in over 80% of the cases. IT could be argued that outcome was completely unaffected by charcoal in this situation. There has been discussion that there may be a group of patients in which we could administer home charcoal and keep the patient at home. Are these patients with toxic or nontoxic ingestions? I'm not sure this patient population even exists.

There have been a number of deaths reported following the administration of activated charcoal. The deaths have been a result of aspiration and inability to obtain an airway or aspiration and development of acute lung injury. At least 2 deaths have been reported in toddlers who aspirated charcoal which was administered for what subsequently turned out to be a nontoxic ingestion.

If a treatment can result in death, and the outcome would have been good without the treatment, we need to carefully assess the treatment. The treatment should not be more toxic than the poison.

Woo, Olga [Olga_Woo@firstdatabank.com]

During my tenured years (17) working in a PCC, I was not been a strong advocate for the use of SI.

It had been my bias to avoid recommending SI to induce emesis for an assessed mild or moderate intoxication. However, there have been cases and situations where its use benefited the child and parent when the medication or plant was returned from the stomach. The child experienced no effect and the parent was spared worry and angst, and a potential hospital bill. It is doubtful that any study could be performed to provide the "evidence-based" studies that include objective data as well as subjective (psychological) and economical impact showing efficacy and benefit.

Let's be sure that we are aiming at the right 'tree'. Are we being asked to choose between the innocent pediatric patient and the intentional behavior of an adolescent or adult by switching SI from OTC to Rx?

Is there evidence-base information to indicate that switching SI from OTC to Rx will lessen the abuse potential?

Look at our current state of the war against drug abuse. If there is any evidence, it is clear from the world's eye that restrictive control does not work! From the I Ching: Do not treasure goods that are hard to get, And people will not become thieves.

We do not need more young people going to jail. I have worked in a Jail Health Medical Service environment for 5 years and the phrase: "Where there is a will, there is a way." is overflowing.

Banning and branding syrup of ipecac is not the answer. A partial answer would be to keep it behind the shelf where the pharmacist can intercede in its sale. I hope that we can find the big picture to hang on the wall.

Robert Hoffman (not Bob) [rjhoffman@pol.net]
Good points have been made regarding this ipecac issue, but I think the strongest have to do with evidence. I'm not certain why the FDA preference for data is "pseudo-science". At some point, toxicologists will have to abandon the "because I say so and I'm the expert" approach and base our practices on scrutinizable data. Regarding ipecac, data is scant, and pretty much limited to anecdotes such as that presented by Dr. Meggs (a nice example of the benefits of ipecac in a theo ingestion).

How about the evidence in support of changing the OTC status of ipecac?- ipecac is the preferred emetic agent of bulemics, a preferred agent in cases of munchausen's-by-proxy, and historically has been associated with cardiomyopathy. Available evidence more strongly evidences harm or misuse from ipecac OTC availability than it does improved outcomes from ipecac OTC availability.

If a primary care physician decides to prescribe ipecac for storage in their patients' home for use after ingestions, it appears that this FDA activity will not prevent such.

Cyrus Rangan [CyrusR8248@aol.com]

I would agree strongly with Dr. Clark's analysis. We could probably argue till we're all blue-in-the-face about usage rates and singular contrived scenarios... but it seems to me that the forthcoming FDA actions actually present us with an opportunity, not a controversy: As a pediatrician, I can certainly say that my colleagues will soon be vocal in their demands for an alternative home poisoning remedy. Most toxicologists would agree that, perhaps with the exception of iron, there aren't many COMMON ipecac-treated ingestions that we wouldn't also treat with activated charcoal. Why NOT use this FDA/Ipecac issue as a launching pad to influence pediatricians to get activated charcoal into the home?

Nay-sayers will note the messiness, the unpalatability, "..it's no better than ipecac.." etc... but let's just IMAGINE astonishment of the CSPI, when the mother on the other end of the line says, "I've got this bottle of powdered charcoal, should I give it?" We might make a pharmacokinetic difference in hundreds of stay-home cases AND in send-in cases. What about outcome measures? Who knows... but, we'd all love to give AC in a boat-load more cases than in the miniscule number of instances in which PCC's
currently recommend ipecac. Pretty soon, pediatricians are going to want an answer. Let's take the reins and move our subspecialty into the 21st century.

Hedge, Matthew [MHEDGE@DMC.ORG]

Yes, there are uses but there are also numerous examples for public misuse. A case recently reported to our PCC, 3 yo drank pine-sol and mom administered ipecac. Then mom contacted PCC. Then the child became somnolent and started vomiting. Fortunately he had a good outcome but it provides a clear example of the potential for public misuse of this product.

Prashant Joshi , MD ***(Director, Western NY Poison Center)*** [KIDSDOC@BUFFALO.EDU]

I had already put in my 2 cents, so now I'll go for the whole nickel. I absolutely agree with Steve Marcus. In fact, I just recommended Ipecac for the first time in at least a year for a special case in the same vein as the ones he enumerated.
As for the lack of data showing its efficacy, I can only quote an old mentor
who said "absence of evidence is not evidence of absence."

Anthony S. Manoguerra [AMANOGUERRA@UCSD.EDU]

If one leaves their subjective feelings aside and closely examines the literature on the subject of ipecac, there is really only one conclusion that can be reached. For the first ten years of my career I was a staunch supporter of ipecac and convinced of its effectiveness. I sat back one day, however, and asked myself exactly what was being gained from the use of this substance for which there is no evidence of effectiveness and which has produced serious, life-threatening, although rare adverse effects. We stopped using ipecac 15 years ago and I cannot recall one patient that I believe has been harmed through that decision. I can also remember the time before then where we made hundreds of children ill from ipecac who would have been just fine without it. I was one of those asked to present to the FDA last month. I gave my personal opinion but the decision of the advisory panel was also based on a review of the literature conducted by the FDA staff that was provided to the panel members prior to the hearing. Most of the panel members came to their own decisions based on their review of the literature as well as the testimony. It was clear from the discussion that if ipecac was being presented to the panel today as a new drug for OTC use, it would not meet the standards for safety and efficacy that currently exist. It is amazing when some of our brethren can so accept the use of this substance with such abandon.

Philip D. Walson, M.D.

We do not need more young people going to jail. I have worked in a Jail Health Medical Service environment for 5 years and the phrase: "Where there is a will, there is a way." is overflowing.

Banning and branding syrup of ipecac is not the answer. A partial answer would be to keep it behind the shelf where the pharmacist can intercede in its sale.

I hope that we can find the big picture to hang on the wall.

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Suzanne White, MD, ***(Children's Hospital of Michigan Regional Poison Center)***
Rick:
I would just like to weigh in here (pardon the pun) that I believe there are still situations where ipecac may be useful. We all have anecdotal, dramatic cases. I also believe that the issue of ipecac abuse by bulimics is being exaggerated. I have not seen any hard data on the extent of this problem. Since those with psychiatric illness and intent to cause self-harm can potentially abuse any over-the-counter substance or other chemical, we cannot fully protect them. And we are losing something from our pediatric treatment armamentarium in an attempt to do so.

(I'm aware that my next series of comments will be obvious to you, but am stating them here in case others have not already done so, for possible use in your letter). There is evidence that ipecac as a safe and efficacious method for emptying the stomach. There is not good evidence that any form of gastric emptying improves patient outcome, except in patients who are obtunded that present within one hour of ingestion. However, we are basing this lack of improved outcome on a very limited data set, in a medical condition associated with a very low mortality, so demonstrating improved outcome is difficult. Each case must be assessed individually for appropriateness of gastric emptying.

Thanks, Suzanne

Robert Geller ***(Medical Director, Georgia Poison Center)***
[RGELLER@georgiapoisoncenter.org]
We at the Georgia Poison Center have found, as presented at a recent meeting, that ipecac continues to be recommended in selected settings by our clinical toxicologists and SPIs. There are, in my opinion, continued indications for ipecac. Some of those include scenarios such as those Steve Marcus is presenting.

The argument that decreasing ipecac use over the past decade or more has not affected outcomes is incomplete, in my opinion, since so much else has also evolved in the same time frame.

We must also acknowledge that much ipecac is mis-used. Whether that makes the benefit-risk ratio in favor of continued ipecac availability is the point of discussion. Personally, I will be disappointed to see ipecac become unavailable, though I feel that it is inevitable at this point.

Steven A. Seifert, MD, FACMT, FACEP *(Medical Director, Nebraska Poison Center)*
Rick,
I don't think I responded to the ACMT net thread at the time. We no longer routinely have ipecac in any of our protocol, but we have some very remote areas in Nebraska and Wyoming where there are long delays to initial medical care. In those instances, I would probably still recommend that it be available, but used only on the advice of the poison center.

Steve
Steven A. Seifert, MD, FACMT, FACEP
Email: sseifert@pol.net

Tom Kurt, MD
Richard,
Sorry about the miscommunication. Keep activated charcoal in our own household
and threw out the syrup of ipecac years ago.
Understand what you're saying about rural areas. Would favor chocolate flavored charcoal being distributed by pediatricians and family practitioners at age two on "wellness" followups. Feel this could be a real marketing thing for some organization who's heads up on this. In over a dozen years of out
poison center supervision I never have favored giving syrup of ipecac to anyone less than two years old unless specifically reviewed circumstances. Know that past advice has cautioned that such should be done with the child over your knees with the face and airway in a downward position to prevent aspiration
when the vomiting occurs.
And, yes, you can refer in my comments without the concurrence.
Charcoal can be just as "fit" for rural situations as ipecac.
Kindest regards, Richard,
Tom