



**Comments presented at the
AAMI/CN, Small-bore Connectors Committee WebEx meeting
14 March 2016**

A meeting of the AAMI/CN Small-bore connectors committee was held on 2016-03-14 at 10:00 am.

At the time of the meeting, the ISO/FDIS 80369-3 ballot was open. Stakeholders representing different interests were represented at the meeting, and some of them made comments. Those comments, as well as comments from one additional individual which were received after the meeting, are attached.

Any questions should be directed to Colleen Elliott at celliot@aami.org.

COMMENTS FOR AAMI WEBEX PHONE CONFERENCE ON ENFIT, MONDAY, MARCH 15, 2016

10:00 – 11:30; COMMENTARY: 10:15 – 11:15 5 MINUTES/SPEAKER
CALL IN NUMBER 1-650 479-3208
ACCESS CODE 669 371 139
EVENT PASSWORD 80369
VIDEO/COMPUTER INFO
<https://aamievents.webex.com/aamievents/onstage/g.php?MTID=ebdc5b4a0e3ba1ce303e7d6eb4>

Hello. My name is David Gould. I am a retired educator living in Durham, N.C. and have been an enteral feeder for 3 plus years. I was forced into tube feeding because of radiation damage from my treatment for Head and Neck cancer in 2005. That radiation also cost me the use of my left arm and the loss of my voice. Hence, my wife is reading my prepared remarks.

Since I began tube feeding, my current system has worked wonderfully. I have a 20French Mic-Key 'button' tube and use Extension Feeding tubes with a funnel that press connects to my 140 ml. syringe. Thus far, I have had no problems whatsoever using a mix of commercial formula and real food that I blend in my Vitamix. I also put crushed medication through my tube and have never had trouble with clogging. Mostly I gravity feed with ease.

I want to comment on three specific parts of FDIS ISO 80369-3.

The first is on Page 11 Annex B Table B.1 which shows the male connector nominal inner dimension to be 2.9mm.

This dimension is troublesome. My current nutrition consists of a mix of Jevity 1.5 and blenderized food, and my medication consists of using crushed large tablets both morning and evening. Additionally, because of reflux problems associated principally with formula food, I must have 5-6 separate feedings per day.

Watching a YouTube video comparison of ENFit (an 80369-3 compliant product) versus current funnel connectors was eye opening. The flow rate of ENFit was 2-3x slower using commercial formula. Second, when blended food was used, the ENFit connector clogged almost immediately while the feeding tube system I currently use does not clog. My home blended food is thicker than that which clogged ENFit, so it is clear ENFit would force me to abandon nutritious blended food. The small inner bore will also absolutely compromise getting thicker viscosity medications into my body. As well, my 5-6 feedings per day will now take up a huge chunk of time. Compromising a feeding tube that is one's only, let me repeat that, ONLY lifeline, is simply wrong and borders on the immoral. And the ISO committee's decision not to test ENFit for blenderized food borders on the unethical.

One cannot solve this 2.9mm problem by simply increasing the dimension because doing so will correspondingly make the dead-space overdosing issue more problematic. As such it's clear that Table B.1 must be scrapped.

My second comment specifically relates to "Page 26 clause E.5 which states that connectors should be easy to connect, disconnect, and manipulate". The 80369-3 design clearly does not meet the criteria of clause E.5.

I no longer have use of my left arm, so statement E.5 is particularly critical. The current 'press' fit allows me to feed myself independently, a minimum of five times a day. The screw thread design will rob me of that independence. Anyone with dexterity problems will be in the same boat. Why force a medical device on dexterity challenged patients which will instantly make their lives worse? Medical devices are supposed to help, not hinder.

The best solution to the screw thread problem is to simply scrap 80369-3! Please allow those with dexterity problems to maintain their independence, by not adopting this design, thus insuring the continuance of current connectors that have worked problem free for many, many years.

My third comment deals with infection control and relates to "Page 25 clause E5(b) which says that connectors should have surfaces that are easy to keep clean". The 80369-3 design does not meet this criteria because the specifications in Table B.1 necessitate a deep, narrow and difficult to clean moat area.

This is potentially the most deadly problem because the moat area of the male connector will be a breeding ground for bacteria. Because of our condition, most all tube feeders' immune system is compromised, hence we must be far more careful of avoiding infections than others. The crevice specified in 80369-3 will make infections more, rather than less, probable because it will be virtually impossible to keep the moat area clean.

Now, I can easily clean and reuse my funnel extension tube for 2 weeks. However, I would only feel safe using the 80369-3 extension tube with male connector, one time. Like you, I would choose not to eat off a dirty plate.

The solution to this infection control problem? Scrap 80369-3 as it requires this 7mm deep by 1.5mm recessed moat crevice and puts tube users at risk.

Thank you.

From: David/Carolyn [mailto:cdrowland@comporium.net]

Sent: Monday, March 14, 2016 4:18 PM

To: Colleen Elliott

Subject: For the Record !

Dear Colleen,

Please find below the speech I presented at this morning's WebEx. Please include in the record.

Thank you,

David Rowland

AAMI Meeting March 14, 2016

I want to express my thanks to AAMI for convening this WebEx Conference today and also to each of those who are participating ! It is my hope that you will take my comments and concerns very seriously, and move towards taking action to stop ISO 80369-3 from ever being implemented.

My name is David Rowland. Many of you have heard me previously, expressing my concerns relative to issues concerning 80369-3. There are many.

I survived stage 3 squamous cell cancer which was an aggressive cell type. It was on the base of my tongue and metastasized to 3 lymph nodes in my neck. I had a radical neck dissection surgery. That all happened 19 years ago and I am blessed to be here today. Since then I have incurred several side effects from radiation. Thyroid issues, vagas nerve damage, narrowing of my right carotid artery resulting in stent placement, 4 aspiration pneumonias, swallowing problems from the radiation damage resulting in going on a feeding tube 3 ½ years ago. In spite of all I have been through I have remained a very active and very positive person. It's not always easy, but I press on !

So, just when I am happy with the current way I feed and have adjusted to my feeding tube, along comes 80369-3 to create difficulty and stress in my life. For me personally, and for most others, I don't want to take 4 times longer to feed. I don't want to get

infections from bacteria gathering in the moat area. I don't want medications and blenderized food to clog my connector. I don't want to catch my tube on something or fall and my whole tube be ripped from my body because a delivery set is threaded to my tube connector. I don't want to have someone else connect my syringe to my tube because my dexterity issues won't allow me to manipulate the screw threads. Line Zero F, 2.9mm, in Table B.1 is a big problem. The entire Table B.1 should be deleted.

Also, I don't want to see infants having the risk of being overdosed because of an 80369-3 Syringe. I don't want to see someone with a trach tube have formula inadvertently administered into their lungs by an 80369-3 syringe or delivery set. I could have a trach one day. Dimension Zero H in Table B.2 is big problem. The entire Table B.2 should be deleted.

Clause 4.1, Paragraph 3 says that 80369-3 syringes and delivery sets are allowed to fit snugly inside of a trach tube. That's crazy because the standard is supposed to prevent misconnections not create new ones. Current enteral syringes don't fit snugly with trach tubes.

The language in clause 4.1 should say:

Small-bore connectors for use in enteral applications **shall not connect** with the cones and sockets of ISO 5356.

I know that many tube feeders must vent their tube. Some vent simply, by opening up their cap. But others connect their tube to foley bags or to tubing which then connects to a suction pump. However, they can't do that with 80369-3 connectors.

The small 2.9mm inner diameter of the male connector will not allow for venting. History shows that a larger diameter is necessary for passive drainage. Also, the male connector cannot physically connect to a portable suction pump or to hospital wall suction. It will be impossible.

It's interesting that ANNEX E.5 (g) says that one criteria for the connector is that

"The bore size needs to be adequate to allow aspiration of gastric contents and passive drainage."

But clearly this criteria cannot be met because of the very dimension in Table B.1 line Zero F.

Again, the entire Table. B.1 should be deleted.

When you hear all I have just said, can you understand why anyone would push such a piece of junk connector on people with a disability ? There are no advantages to the 80369-3 connector. Only Disadvantages !! This is pushing us back to the stone age of enteral feeding methods.

Sometimes I wonder who is listening as it's difficult to understand why there is a vote going on with ISO 80369-3 when it has not been properly tested and vetted. In reality the vote should never be taking place currently for such a faulty designed medical device. That just doesn't make any sense.

There is more specific language in the ISO 80369-3 final draft that troubles me but time restraints don't allow me to say what needs to be said. That's sad. However, I will submit in writing those additional comments.

Thank you,

David Rowland

Below this line are things that time didn't permit me to talk about !

I. 4.1, Paragraph 3

Because the following connectors are inadequately specified, small-bore connectors for use in enteral applications should not, but may connect with the following:— the cones and sockets of ISO 5356-1:2004, ISO 5356-1:2015, ISO 5356-2:2006 and ISO 5356-2:2012;

Comment:

ISO 80369-3 is supposed to prevent misconnections to other cones and sockets. The female connector will fit snugly into an adult Shiley trach. This is very dangerous and could be fatal as formula could enter a patient's lungs. Therefore, ISO 80369-3 does not prevent misconnections issues.

Proposed Change:

The language should be replaced as follows:

Small-bore connectors for use in enteral applications shall not connect with the following: — the cones and sockets of ISO 5356-1:2004, ISO 5356-1:2015, ISO 5356-2:2006 and ISO 5356-2:2012;

II. ANNEX E, Use environments, E.5 Generic USER needs

a) The amount of rotation required to seal the connector should also be considered, as many elderly caregivers do not have the finger dexterity to manipulate small connectors.

Comment:

There is much involved in being able to put the male/female connector together, especially for those who have limited arm/hand use due to severe arthritis, radiation damage restricting the use of the arm/hand, or any other issues that restrict the use of the arm/hand. Additionally, if the connector is inadvertently tightened too much it will crack.

Proposed Change:

The designed shall be changed to something other than a screw type male/female connector since many users will not be able to work the male/female screw thread type.

III. ANNEX E, Use environments, E.5 Generic USER needs

a) Patient end connections need to be durable, so that a secure fit is maintained over time.

Comment:

The connector is plastic and is weak and brittle as it is poorly designed. In contrast the current g/tube funnel connector is strong and durable. by its very design dimensions is a fragile complex little plastic device.

Proposed Change:

Table B.1 should be deleted in its entirety as the criteria of “durability” cannot be achieved by the very dimensions set forth in Table B.1.

IV. ANNEX E, Use environments, E.5 Generic USER needs

b) Connectors should have surfaces that are easy to keep clean (e.g. avoiding as much as possible areas where residual feed solution could collect bacteria and other contamination could gather).

Comment:

The male connector is not conducive to cleaning since the design creates deep crevices. This will create bacterial growth causing the consumer an infection.

Proposed Change:

Table B.1 should be deleted in its entirety as the criteria of “easy to keep clean” cannot be achieved by the very dimensions set forth in Table B.1.

V. ANNEX E, Use environments, E.5 Generic USER needs

f) The bore size needs to be sufficient to allow adequate nutrition flow and ease of fluid passage. The rate-limiting factors are the inner bore of the tubing and connector and the viscosity of the solutions. Required flow rate is under discussion.

Comment:

The connector bore size is very small at 2.9mm. It's actually smaller than any current connectors that tube feeders are using. The flow will be so reduced that blenderized feeding will be next to impossible and taking medication will be problematic as well. Clogging will be a very serious problem. This have a very negative effect for tube feeders.

Proposed Change:

Table B.1 should be deleted in its entirety as the criteria of "to allow adequate nutrition flow and ease of fluid passage". This flow will not be possible based on the dimensions set forth in Table B.1.

VI. ANNEX E, Use environments, E.5 Generic USER needs

g) The bore size also needs to be adequate to allow aspiration of gastric contents and passive drainage.

Comment

The small 2.9mm inner diameter of the male connector is will not allow for venting. History shows that a larger diameter is necessary for passive drainage.

Also, the male connector cannot physically connect to a portable suction or a hospital wall suction. It will be impossible.

Proposed Change:

Table B.1 should be deleted in its entirety as the criteria of "to allow aspiration of gastric contents and passive drainage" cannot be accomplished by the very dimensions set forth in Table B.1.

VII. ANNEX E, Use environments , E.5 Generic USER needs

h) Very small volumes (less than 0,1 ml) are sometimes administered and require precise dosage possibilities.

Proposed Change:

Table B.2 should be omitted as the "precision dosage" cannot be accomplished by the dimensions set forth in Table B.2.

I am Richard Reynolds, a feeding tube user because of cancer treatment.

I am very worried that ENFit would adversely affect my life and the lives of others. ENFit has many disadvantages without a single advantage.

One disadvantage is flow rate. Elementary physics tells us that the small inside diameter specification of 80369-3 can more than double feeding times.

Flow rate should not be degraded. It is both a medical and a quality of life issue.

An additional disadvantage is clogging that puts a halt to feeding, especially of blenderized foods. Consequently, Annex B Table B.1 of 80369-3 should be deleted.

Likewise, clogging is both a medical and a quality of life issue: The depressed or weak can easily forego feeding if feeding is regarded as too laborious, time consuming, or taxing. Feeding hits the core of people's life and well-being. Consequently, Annex B Table B.1 should be deleted.

Blenderized food will clog in 80369-3 connectors. Even pulp orange juice clogs in them.

It is immoral to promote a connector that requires two agile hands. People with only one hand living independently can use the current slip on connector. With 80369-3, they will no longer be able to feed themselves.

Thus forcing them to have a caregiver in their home for every meal and medication or move to a care giving facility. This will cause a dramatic change in their lives because two hands are required instead of one,

Two agile hands should not be a requirement to eat.

It is not a requirement of the current system. It conflicts with the 80369-3 design standard that specifies in clause E.5(a) quote "connectors should be easy to connect, disconnect, and manipulate". End quote. That criterion cannot be met with the proposed small screw thread connector that requires two hands.

More humanely, the clause should read, quote "Connectors should not require rotation to seal the connector." End quote.

The standard creates many disadvantages -- including

- the life threatening misconnection risk to the trachea,
- some rigid IV luer side ports and vascular needle cannulas, and
- the risk of medication over dosing to infants.

Consequently, Annex B, Table B.2 should be deleted.

There is no reason to adopt the system with its known safety hazards when the existing system does not have them.

Making me highly suspicious is the strong drive to adopt 80369-3 in spite of it not having a single advantage. None whatsoever. So, it should not be forced on people.

In a free market, such products do NOT succeed. Unfortunately, this is not a free market.

Ordinarily, medical products launch only after they have extensive confirmed data of safety and efficacy.

ENFit's launch seems driven by the commencement of California law Section 1279.7 (d) of the California Health and Safety Code that states, quote "a health facility...is prohibited from using an enteral feeding connector that would fit into a connector other than the type it was intended for." End quote

Because 80369-3 connectors do mate with connectors to which they should not, they should not be forced on patients. They present dangers we do not have today.

Because 80369-3 does not conform to the California Bill, Annex B, Table B.2 should be deleted.

My comments are a Cautionary Tale to all of you.

I urge the retention of the existing safe one-hand connectors and reject 80369-3. To do otherwise injures the public.

Thank you.

Tabitha Hasin, Ph.D., J.D.

My name is Tabitha May Hasin, and I reside in Newport Beach, CA . Currently, I am a full-time caregiver for my 94-year-old mother. She received a feeding tube after a major stroke in 2013.

80369-3 shows the female E1 design on Annex B, table B.2. These dimensions allow for very dangerous misconnections between the female enteral connector on both the enteral formula delivery set and on the enteral formula syringe and:

1. certain adult tracheostomy tubes,
2. certain intravenous (hereinafter I.V.) ports,
3. certain I.V. needle cannulas.

All of these possible misconnections are a matter of grave concern. For example, many gastrostomy tube patients also have tracheostomy tubes. If enteral formula is administered inadvertently into a tracheostomy tube, it can lead to death. This type of dangerous situation has been noted on the FDA Calendar as an adverse event with “high potential for harm.” As such, the entirety of 80369-3 Annex B, Table B.2 should be deleted.

Moreover, page 3, clause 4.1, third paragraph reads:

*“Because the following connectors are inadequately specified, small-bore connectors for use in enteral applications should not, **but may connect** with the cones and sockets of ISO 5356-1:2004, ISO 5356-1:2015, ISO 5356:2:2006 and ISO 5356-2:2012.*

Please note that the cones and sockets of ISO 5356 referenced in said clause 4.1 include the Shiley 15mm respiratory tracheostomy tube fitting connector. The language “**may connect**” is highly objectionable as it is stark conflict with the stated purpose of 80369-3 as set forth in the INTRODUCTION page vi, first paragraph:

“This part of ISO 80369 was developed because of several incidents, with catastrophic consequences..... from enteral solutions being administered via incorrect routes, including.....into the airway.”

The female E1 connector (feeding delivery set and syringe) can physically form an interlocking wedge fit with the internal flow path of:

- A Shiley 15mm respiratory tracheostomy tube fitting-connector.

Hopefully the intention is not to endorse or push through an unsafe design. Certainly that would be in conflict with the stated goal of 80369-3.

Again, clause 4.1 language “*may connect*” with tracheostomy connectors is highly objectionable. It should be replaced with the following text:

“SMALL-BORE CONNECTORS for use in ENTERAL APPLICATIONS shall not connect with: the cones and sockets of ISO 5356-1:2004, ISO 5356-1:2015, ISO 5356:2:2006 and ISO 5356-2:2012.

If this proposed standard passes with the current Annex B, Table B.2 Female E1, California hospitals will be in the unfortunate position of either using 80369-3 compliant connectors and syringes or attempting to remain compliant with section 1289.7(d) of the California Health and Safety Code which commences July 1, 2016.

80369-3 shows the male connector design on Annex B, Table B.1. A major company that assisted in the development of these male design dimensions is also a company that markets and sells commercial formula. For no medically necessary reason, the inner diameter of the 80369-3 male patient side connector is drastically smaller than the inner diameter of existing patient side connectors. The 2.9mm internal diameter means that pretty much only commercial formulas will flow through the male 80369-3 connectors, and these new connectors will lead to a much higher rate of clogging. It will make administering medications much more difficult, and will make the ingestion of blenderized food through a feeding tube next to impossible. As such, the entirety of 80369-3 Annex B, Table B.1 should be deleted.

Given that both Annex B, Table B.1 and Annex B, Table B.2 have greatly objectionable dimensions, I recommend the committee delete both Tables, reconvene and find meaningful solutions to any real problems with current connectors.

Thank you,

Tabitha Hasin, Ph.D., J.D.

Ronald Coppinger
RJCoppinger@hotmail.com

March 14, 2016

I am speaking today because I will not be able to gravity feed or even bolus push syringe feed through the 80369-3 male 2.9mm I.D. constricted connector. It will be impossible. Bottom line – my life will be extremely altered in a huge negative way if this standard is adopted.

I use a 20fr PEG tube with a 3.8mm I.D connector.

Table B.1 establishes a 2.9mm nominal inner diameter of the male patient side connector. This inner diameter reduces the flow rates of nutrition through the tube and even limits nutrition to specific high sugar, chemical manipulated, high priced commercial formulas. The 2.9mm size will always be associated with 80369-3 connectors.

This is not an advancement. Table B.1 should be deleted.

How can any organization, ISO or AAMI, which emphasizes the advancement of medical devices, allow a product to come to fruition that does nothing to advance the ability of tube feeders to live a better, healthier life?

Table B.1 of ISO 80369-3 also establishes a hard to clean narrow moat area in the male connector which places feeding tube individuals at risk, as bacteria and debris will accumulate in the moat causing infection and resulting in further visits to physicians, Emergency Rooms and Hospitals. Table B.1 should be deleted.

Table B.1 and Table B.2 set forth the mating assembly of the male and female connectors of 80369-3. But these new connectors create the added risk of feeding tube pull-out and stoma damage if snagged on anything from wheelchairs, door knobs, IV poles, bed boards, dining chairs to car doors, once again causing visits to the ER for replacements and damage to the existing stoma because the delivery set and tube are twist locked together, and a snag creates a retraction pull force on the tube (rather than simply separating at the tube to funnel juncture). As such, Table B. 1 and Table B.2 should be deleted.

Lastly, the 80369-3 connector does not meet the goal of solving misconnections, which was the only goal of the standard. The female connector (syringes filled with formula and pump delivery sets) fit easily, perfectly, and directly into an adult tracheostomy tube per the dimensions of Table B.2. This creates a deadly misconnection. Table B.2 should be deleted.

It's irresponsible for the committee to now say that such a misconnection is acceptable for 80369-3 products, when in fact the FDA has called out this misconnection as a high risk deadly event. Will the deaths from such misconnections be considered acceptable collateral damage? If nothing else, the product should be labeled with a clear warning that a deadly misconnection is possible. The lives of feeding tube patients are at stake.

There has been a failure to communicate -- from the designers, government agencies, and those in key positions -- who should have been more concerned about patient care. If professional clinical institutional incompetence of those who made misconnections needs to be addressed, then address that issue. Although I have NOT seen any data over the last 5 years of any enteral misconnections in the U.S., if there has been misconnections in the institutional setting, then perhaps better training and supervision of the folks that make small bore connections is in order, rather than upsetting hundreds of thousands of users who are very happy with their current products.

The ISO committee, in concert with GEDSA and the FDA have worked on the 80369-3 standard in an effort to make existing connectors obsolete. Some have even advocated for labeling on existing connectors to say that they are unsafe. Will such labeling be part of any proposed standard?

I'd like an answer to that question after I finish speaking.

The adoption of the standard will, by all measures, put the tried and true products on the road to extinction. The motive of the standard is a forced elimination of the connectors that keep us alive. Individuals associated with the standard have been running around saying that our funnels are unsafe. Really? My connector is unsafe? This is an utter falsehood. There is nothing unsafe about my 4.65mm ID funnel connector. Stop the lies, please.

My connector does not connect to rigid or flexible, male or female IV luer. My connector does not connect to any tracheostomy tubes. It is safer than what you are proposing.

Thank you for your time.

I would now like an answer to my question.

Will a warning label on existing connectors be part of any proposed standard?

BRIAN MCCALL
BrianAtnucciNY@aol.com

March 14, 2016

Thank you to the AAMI organization for this opportunity.

My name is Brian McCall. I am 54 years old. 10 years ago, in the summer of 2005 I had a stroke. The doctor said my brain stem stroke was caused by whiplash from riding on a roller coaster. I wasn't feeling well when I got home, and when I went to take an aspirin, I discovered that I could no longer swallow. The last food that I have ever eaten was some munchkins and a cup of tea on the morning of August 12.

I had a feeding tube installed 3 days after being in hospital.

I did not have a disease, or a gastro intestinal malady. I was not comatose. A feeding tube was thrust upon (into) me very suddenly. And here I am, 10 years later.

Upon discharge from hospital, I followed the same regimen as the nurses had used. I poured my formula through an open syringe. One 8 ounce can of the thick formula would take a bit of time to pour. And since I have some knowledge of liquids, and my doctor told me I should have more water, I began adding water to the formula to thin it out. This resulted in a much quicker pour time.

I then changed tubes to a low profile button style. I immediately noticed a slower pour time, but it still flowed pretty quickly. I can now pour in two 8 ounce cans with about ½ a liter of water each in about 6 minutes. And to this day, I experience some clogging when taking medications. I must make sure the pills are completely crushed to avoid any obstruction. I attribute this to small size of the bolster of the button.

I can't imagine any part of this liquid delivery system being any smaller. Table B.1 line Of, of the standard, says that the nominal dimension of the inner diameter of the connector is 2.9 millimeters. The keyway of my button is 3.1mm. 80369.3 will add another constriction upstream of this keyway on my extension tube. I recommend Table B.1 be deleted.

So, in my opinion, if ISO 80369-3 is being proposed as a safety issue, the solution would be better training of institutional staff that deals with all sorts of tubes every day.

My experience every day is with my tube. I'm glad that have some skills to make things work. I notched syringes so the beaker doesn't miss. I've purchased larger syringes which make for a better target. The catheter tip syringe seems to fit so many applications as it is now, a change, to me, would only complicate things.

I understand most "change is good", but regarding this particular issue, ISO 80369-3 would have negative impact on myself and thousands of others. To quote a line from a movie, "the needs of the many out-weigh the needs of the few". Changing tube colors might be a better alternative to changing connections. Please consider all the voices you hear.

Thank you.

Brian McCall

March 14, 2016

Thank you once again for this opportunity to speak.

My name is Shelley Buma and I am president of GI Design Associates, a medical device design and consulting company.

The push and endorsement of 80369-3 continues from the U.S. and now the vote is in process and just 3 weeks before its conclusion, but we are here today, to say again, what we have said countless times.

3 decades ago, Microvasive was the first company to introduce a PEG tube. It was 14fr with a mating 2.9mm I.D. connector. I was product manager for the company that supplied the 2.9mm I.D. connector. Even then, patients were choosing to blenderize their own food. Complaints about the 2.9mm connector clogging from all market segments soon began. As a result, an 18fr PEG was introduced, but still, complaints of connector clogging were heard. Then a 20fr PEG with a 3.8mm I.D. connector, and finally a 24fr PEG with a large lumen 4.65mm I.D. connector was introduced. These large lumen connectors have been tremendously well received by end users for the last 20 years. That's the story of progress.

80369-3 however, is a reversal of years of user feedback that bigger is better in terms of flow, clogging, and manage-ability. The 2.9mm nominal dimension set forth in Table B.1 line Zero F is much too small for proper flow rates, for blenderized feeding, non-clogging, and for venting.

The FDA has said that it will allow manufacturers to market existing connectors. The publicly unspoken reality, however, is that new PEG kits and new syringes and delivery sets will feature 80369-3 connectors as manufacturers want to highlight their compliance with the standard, and have banned together to launch these products. Consequently, the inferior product will be thrust upon new patients (the unknowing individuals) who will then suffer with a small lumen, large narrow moat, screw thread product and mating syringes and delivery sets which dangerously misconnect to trach tubes. The economics of putting both connectors in the PEG kit doesn't make sense, and the economics of promoting a non-80369-3 compliant product doesn't make sense.

So the market forces will take over. And the individuals who have benefitted from the large lumen, easy to clean, easy to connect products will sadly, eventually die off, leaving a new generation of users worse off than those that came before them. Besides, more clogged connectors, means more connectors sold. Smaller ID connectors means more formula sold. It's a regression, not an advancement in quality of care and it should not be supported.

Current catheter tip syringes do **not** fit snugly inside of an adult tracheostomy tube. But the very dangerous 80369-3 compliant syringe does, allowing for the high risk lethal possibility of formula being administered into a patient's airway. Keep in mind that syringes are used all the time, in fact routinely, with tracheostomy tubes for irrigation prior to suctioning to liquefy secretions. 80369-3 compliant syringes will be manufactured in various volumes, including 5ml, 10ml, and 20 ml, increasing the chance of this deadly event.

The very dimensions of Table B.2 line Zero H is the fixed outside thread dimension of the female connector which fits inside of adult Shiley tracheostomy tubes. Table B.2 should be deleted.

In addition, 80369-3 compliant syringes can result in fluid displacement and a large dead space, which impacts medication delivery in the infant population. You've all heard about that and about the deadly consequences. Table B.2 should be deleted.

Moreover, the decision to **not** engage with users early in the process during the design phase speaks volumes to those who will be stuck with an inferior system. Reasonable people agree that real world, real patient testing, in many locations with the various feeding and medication modalities was prudent, but did not occur.

Multiple requests have been made to the ISO committee and to the FDA for hard data as to any U.S. enteral misconnections since 2011. The committee and the FDA have failed to provide any data. As such, once again I request the data. Products should solve a real problem, not create problems.

Current connectors in commercialization are safer than 80369-3 connectors.

80369-3 does more harm than good. No data of misconnects since 2011, yet the proposed standard immediately creates **the most high risk** misconnection possible.

80369-3 has been more about meeting deadlines than about meeting patient need and patient safety.

Please oppose 80369-3 now.

Thank you for your time.

Shelley J. Buma

Wilson Bacon

March 14, 2016

Thank you.

I am a 61 y/o throat cancer survivor and g-tube user. x 2 and happy to say that I've been cancer free now for about 5 years. That's not to say that I don't still have some problems. After my treatments I was left disabled. I have difficulty talking, swallowing and I now have a feeding tube that I use to get my food into my stomach. I have a 20fr dangling tube with a 3.8mm connector.

I've been using a Moog Infinity Enteralite pump without problems for years until recently when the ENFit connectors were introduced.

Since Moog switched to the ENFit transition piece connector on their pump delivery sets, I have had multiple problems with leaks from cracked ENFit fittings.

I contacted Moog/Nestle several times and asked if they had plans to modify their design but have yet to hear back from them. I am aware that other individuals have notified the FDA of this serious problem, as the leaks cause end users to not receive required nutrition. Please realize that individuals are often pump fed at night while they sleep, so the leak is not recognized until the morning.

I am surprised that the FDA has not required a recall of all Moog/Nestle formula delivery sets with ENFit fittings.

Since I am dependent on my feeding tube and the associated equipment for my survival, I am concerned that the adoption of 80369-3 will continue to make my life more difficult as I believe products that comply with 80369-3 will fail while in use.

At a minimum, my current leaking/cracking ENFit transition set makes a mess. Worst case scenario of this problem is that parts of the connector could crack off and get stuck in my g-tube making it necessary to go to the ER for a replacement.

It's my understanding that the goal of manufacturers is to do away with the transition piece, leaving the pump delivery set with the female screw thread ENFit piece and my feeding tube would feature a male screw thread ENFit Connector. Certainly the cracking and breaking of this female to male interface is a critical problem.

I am very concerned about the deep pocket moat area in the male patient side connector and how it is pretty much impossible to clean. I see this as a hazard since food can get caught in the

pocket and spoil and stomach contents can remain in this area. My immune system is compromised and I worry about bacterial infection from a contaminated ENFit male connector.

It is shocking that the FDA did not require manufacturers to provide evidence supporting the ability to keep the ENFit male deep pocket moat area clean, so as to avoid the potential for patient infection including *C. difficile*, classified by the CDC as an urgent and serious threat. Instead, FDA clearance was granted without this evidence. Clearly the ENFit patient side connector is not substantially equivalent to the existing funnel connector.

Another concern is that the inside diameter of the 80369-3 patient side connector is smaller than the inside diameter of current connectors. It is only 2.9mm in I.D. It will make bolus feeding more difficult when using blenderized foods and commercial real food formulas. I already have connector clogging problems with these types of foods and the 80369-3 male smaller ID will only make it worse. Table B.1 should be deleted.

I am disappointed and upset that the FDA did not require manufacturers to provide evidence supporting the ability of the ENFit male patient side connector to accommodate various modes of feeding including blenderized food and commercial real foods. Instead, FDA clearance was granted without this evidence. Clearly the ENFit male patient side connector is not substantially equivalent to the existing funnel connector.

Thank you.

Regards,
Wilson Bacon

From: Brandis . [mailto:brandisgoodman@gmail.com]
Sent: Monday, March 14, 2016 11:22 AM
To: Colleen Elliott
Subject: Re: AAMI meeting 3/14

To Whom It May Concern:

The Feeding Tube Awareness Foundation serves tens of thousands of parents and caregivers of children who are tube fed. Our facebook page support forum has over 41,000 followers. It is a very active page for questions and information sharing.

A good percentage of our families use a blenderized diet with their children. The children have varied medical conditions. Many use syringe push methods, while others use gravity or feeding pumps to deliver blended feeds. Blended foods cover the full spectrum from commercially available blended foods, baby food blends, home blended foods, blended foods mixed with commercial formulas.

Early on in the ENFit transition, we heard from a number of those who use blenderized diets who had concerns about being able to use a blenderized diet with ENFit. These concerns were shared with GEDSA and resulted in many of the Q&As on the GEDSA website-

<http://stayconnected.org/.../frequently-asked-question-enter.../>

The vast majority of concerns centered on the availability of “O Ring” syringes that are used in syringe push delivery of blended foods. There were limited concerns around the bore size from parents. Once it was communicated that “O Ring” syringes would be available with ENFit from one or more manufacturers, many parents were satisfied. We have not heard from parents with concerns about blended diets and ENFit in months. The Oley Foundation conducted a survey a few months back, which we shared with parents. Comments regarding the survey tended to be about the transition adapters.

We heard many concerns about the transition adapters when they were first released, but as knowledge and experience about how to work with the new adapters has grown, we hear less about those, too. The cracking that many people were experiencing, our staff members included, can be remedied by not overtightening the transition adapters. Tightening slightly prevents them from twisting off but also does not cause cracking.

Overwhelmingly, children use button style G-tubes in smaller French sizes – 12Fr – 16Fr being most common. Among the blenderized diet community – it is usually recommended that a child use at least a 14Fr. It is exceedingly rare for a child to have anything larger than an 18Fr.

It is recommended that parents use a commercial blender – either a Vitamix or Blendtec – so that their blends do not clog. If other blenders are used, blends need to be strained. When we hear from parents needing help with feeding tube clogs, 99.9% of the time, it is a clog due to medication. Parents are successfully feeding blended diets with the smaller French size button style tubes. Among the FTAF staff, several members have used blenderized diets with their children at various times. One staff member has used a Moog Infinity Pump to continuously feed a blenderized diet that is home blended without complications.

Blenderized recipes can be constructed to achieve any density to allow for better flow. In the book Complete Tubefeeding by the late Eric Aadhaar O’ Gorman (and founder of the Blenderized Food for Tubies group on Facebook and www.foodfortubies.org), he shares his experience blending foods for

his own tube feeding diet.

He outlines foods that tend to thin and thicken blends. He lists “watery vegetables (including cucumber, tomatoes, leafy greens), enzyme-containing fruit (including papaya, mango, kiwi, and pineapple), and most oils” as ways to thin blends without adding additional water. He notes that certain foods tend to thicken blends, including avocado, banana, almonds, sesame seeds, blueberries, uncooked grains, pasta, potato, and amaranth flour. (Lists can be found on page 173).

Moreover, broths, milk and milk alternatives, juices, etc. can all be used to thin blends while still maintaining caloric concentration.

Parents are very used to having to make changes in their child’s tube feeding regimen. There is nothing static about tube feeding a child.

- Children’s caloric needs change as they grow and develop
- Schedules change when children go to daycare, preschool, kindergarten, school, and therapy.
- Children have changes in their medical conditions that can require dietary changes
- Changes can occur because there are other children in the household who have their own schedules

It could be that ENFit is just another change for parents that they can and will adapt to. The majority of the parents we hear from understand the need for the change and are ready for the change to be complete. A recent story about a child in Illinois who receives dual therapy at home (TPN and enteral feeding) where a home nurse administered enteral medication into a central line on her first day on the job was widely distributed. Many commented that this would not have occurred if ENFit was already in place. The child survived, but it underscored the need for ENFit within the pediatric community.

We have been seeing more chatter in pediatric tube feeding groups (other than the FTA Facebook page) about just wanting the change to be complete so that we no longer have the adaptors. The change has been so delayed that there is acceptance, and we are ready to move forward.

If you have any further questions, we would be happy to address them.

Many thanks,
Feeding Tube Awareness Foundation

Mary K. Slachter
520-881-8733
Mslachter@yahoo.com

March 14, 2016

My name is Mary Slachter. I am a 63 year old women with gastroparesis and with a JPEG feeding tube for 3 1/2 years now.

I am a widow, mother of two wonderful boys, and grandmother of 4. I have been a business owner for 40 years now as a certified arborist. I am an active member of my church and my community .

I developed gastroparesis in 2010 and did a low fat, low fiber, high protein diet. It didn't work. A dietitian then put me on an all-liquid diet and it didn't work. My body didn't process my food or medications so it was highly recommended to go on a feeding tube. It was placed in Dec of 2012 and changed out every 3-4 months. Then I went to a nursing home for rehab to get stronger. They ended up ripping my tube out which required emergency surgery to replace. Then they overdosed me badly even with the feeding tube.(10,000 mg of Dilantin). Then I received a new tube but developed a seizure disorder. I went home to my new life. I needed a little adjustment period, but overall I was ok.

In December 2015 I came home from a hospital stay with an ENFit transition connector pump set. I wasn't asked if I wanted a change. It was thrust upon me. It's a Covidien ENFIT delivery set pump product. I was also given new formula - you guessed it - Nestle soy and milk and corn GMOs and preservative. Again I had no choice: "Take it or leave it. This is what you get!" Two more formulas are all just as hard on my stomach. I developed a bacterial infection of staph. They placed a new tube, but it wasn't stationery so a new tube was placed again 1 month later. I developed another new bacterial infection and one more new tube again.

Since December 2015, I have had 3 new tubes, 3 infections, 2 ER visits, 1 hospital stay, 5 doctor visits, and many more days in bed than I would like to count.

I do believe, however, that the very deep and narrow crevice in the male piece connector on my ENFIT is a direct cause of these chronic infections I have been having.

I've been having a very swollen distended abdomen so my tube isn't staying stationery at all now so a ultrasound is planned.

With the ENFIT product, it NOW takes me 22 1/2 hours to feed four cans of formula at 50 mls per hour. It used to only take me 7 1/2 hours at 50mls/hr.

I don't have a choice of food, and I don't have of bags or connectors.

YOU, the governing agencies that are there to protect us the consumers

- 1) never had human trials,
- 2) never gave consumers a choice,
- 3) let large companies that are manufacturing (the bags, formulas, tubes)

propose changes to the industry without giving us the consumer the opportunity for trials, input, or testing first, to see if it was in the best safest interest of the user!

I have friends that have children on tubes that aren't even aware that this product will be forced on them in the very near future.

The women that spoke today from Tube Awareness must have her head in the sand. These new connectors are so very, very wrong and they will put the feeding tube industry back 30 years.

Mothers, wives, husbands, children, cancer survivors, ALS patients, and Gastroperesis patients all deserve their God given right to a healthy diet and a SAFE Bag delivery set to transport the food, as well as a safe tube to prevent damage to the body.

These, as a American citizen of the USA are my rights.

Won't you please take this into consideration, all you governing bodies, as you vote.

Please think, would you want this way of life if this was you? Or would you want to make your own choice based on the safest solution for you?

So I implore you the FDA, GEDSA, AAMI, ISO, and all 39 Nations to vote against the ENFIT 2.9mm ID product (the same inner diameter that consumer didn't want some 20 years ago because of all the problems it had then) to not go back in time.

Let's move forward to the best and safest solution for people like myself today.

I beg you to vote NO on the ENFIT Product.

I thank you ahead of time for your consideration in this matter,

Mary K. Slachter

520-881-8733

Mslachter@yahoo.com

Sanford Flach
Saraland, Alabama

March 14, 2016

Thank for the opportunity to speak out against the horrible design standard ISO 80369-3. I am a 69 year old retired Navy Master Chief who has been 100% dependent on my "LIFELINE" feeding tube for the past 2 1/2 years.

My first question to you is, "How many of you are 100% dependent on the performance of a tiny silicone tube for your total subsistence and your daily survival?"

Next, when the US committee votes, I would like to know how many voted YES and how many voted NO. After all, the committee supposedly will be voting in the BEST INTERESTS of feeding tube users, and NOT the best interests of the purveyors of commercial formula and medical devices.

We feeding tube users fear that due to the political correctness that has engulfed this nation, that the U.S. Committee is still overwhelmingly in favor of passing ISO 80369-3 in spite of the facts that:

- End users do not want products that conform to 80369-3.
- 80369-3 only benefits formula and medical device sellers
- 80369-3 is a solution looking for a problem to solve.
- No end user studies were ever done on devices that conform to 80369-3.
- 510k clearances were wrongly issued by the FDA for ENFit products that are not substantially equivalent to the legacy products.
- The CDC is currently sending out urgent warnings to medical facilities to reduce patient exposure to HAIs (hospital acquired infections), while the FDA is promoting is promoting the forced introduction of ENFit which will increase them tremendously due to the deep moat area on the male connector that cannot be overcome by the required dimensions of FDIS 80369-3.
- The tiny 2.9mm bore of the ENFit connector is entirely too small for gravity feeding by end-users. Table B.1 of the FDIS 80369-3 should be deleted.
- The ENFit syringes are deemed so dangerous to infants that two of the world's largest syringe manufacturers have refused to make and sell them. Table B.2 of the FDIS should be deleted.

I realize that you wanted me to cite the paragraph numbers of items that need to be changed to make ISO 80369-3 acceptable to us end-user, and to put things into a language you could understand. But the REAL TRUTH is that there is absolutely nothing that can be done to make a "silk purse out of this sow's ear" 80369-3 Proposal.

Please vote "NO" on ISO Proposal 80369-3 because of its complete failure.

Once the most recent changes to connectors finally worked their way through the medical care system back in 2011, there have been no more enteral misconnections, yet the industry and you seem to think that since you have already invested so much time and money into developing 80369-3 that you simply have to force it into our lives.

We "Tubies Against ENFit" have now been fighting against these ill-thought-out products for well over a year now, and we are fully prepared to turn our opposition up a notch, by bringing the U.S. Justice Department into the fray, if, by any chance the uncaring individuals on the various similar committees around the world, are also more interested in corporate profits, than in the lives and the quality of lives of feeding tube users.

Thank you for this chance to tell you the things that you obviously do not want to hear, but I personally believe that truth is far more important than being politically correct.

80369-3 and ENFit are un-fit no matter what changes you make to it.

YOU MUST VOTE AGAINST IT!

Thank you,

Sanford Flach

Comments from Lisa Metzger, The Oley Foundation

The Oley Foundation informs and advocates for home parenteral and enteral nutrition consumers. We serve over 15,000 members. The safety and well-being of all nutrition support consumers is in the forefront of all that we do. We are aware of several issues and concerns surrounding ISO 80369-3 and ENFit and remain committed to facilitating an open dialogue between consumers, members of industry, the FDA and the clinical community, and to work towards seeing these issues resolved.

We recognize that this is a process; it includes listening, learning, and responding.

We have heard and understand that there are going to be challenges. We have also learned about misconceptions, as the spotlight has been shown on this issue over the past couple of years. We have polled our community—which consists of home nutrition support consumers and caregivers, and professionals in this and related fields—with a survey and with notices in our newsletter asking for feedback. We have received calls and e-mails and contact through social media.

This feedback has helped define the issues consumers face in the home setting, and how consumers use their feeding tubes in the home. We have also been in contact with clinicians in some of the larger tube feeding programs and with clinicians who work with home care companies. We have brought stakeholders together to learn from one another; these efforts include a summit in December in Atlanta, Georgia (recording of which is available on YouTube) and a meeting that followed in January.

We are encouraging continued dialogue, staying in touch with all stakeholders, and creating printed resources to answer questions for consumers. We applaud AAMI, the FDA, consumers, and other stakeholders for maintaining an open dialogue in an effort to resolve issues and concerns.

Comments from Rory Jaffe, MD, MBA, CHPSO Patient Safety Organization

Dr. Jaffe spoke about the California hospitals' effort on connectors. He stated that misconnections were recognized as a rare but catastrophic event, and asked for legislation to change connectors about eight years ago. They recognized that training was not the solution, because human error is inevitable, so another solution was needed. He stated that has been involved in the AAMI and ISO committees, and they came to realize that preventing all misconnections was impossible due to the vast number of connectors that are available, some of which are unstandardized and/or incompletely dimensioned, for example the inner diameter of endotracheal tubes. Design decisions were based a risk assessment of the potential misconnections.

Dr. Jaffe stated that he recognizes that some patients have specialized needs, and that those individuals should discuss options with their clinicians.

March 18, 2016

Dear Members of the AAMI/CN Small-Bore Connectors Committee:

Thank you for the opportunity to listen in on Monday's committee meeting. I was not invited to join the meeting until a few hours in advance and was unaware of the opportunity for consumers to provide comment. As a result, I am asking that you please let this serve as my comments to the committee.

I am a 41-year-old female who has been enterally fed since December 2010. I currently have an 18 French low-profile transgastric-jejunal feeding tube and require elemental formula (Peptamen 1.5) administered via pump into my j-tube daily as my primary source of nutrition. My diagnosis is post-viral gastroenteropathy causing severe gastroparesis, slow-transit constipation, and esophageal dysmotility.

Thus far, I have tried to stay neutral on the ENFit connector issue. Personally, I haven't had any issues with the ENFit transition sets since I started using them in May 2015, more specifically, I have not had any stoma site infections during this time nor have I had any of the materials crack or leak.

When I first learned of the change, I was actually looking forward to the concept of ENFit and not waking up in a pool of formula and intestinal juices all over my bed due to a disconnection while I slept, which occurred occasionally over the past five years. That said, one concern I have that did not come up on Monday's call is the potential for my tube to be pulled out or dislodged due to the new male-female locking design on the new ENFit connectors. From what I understand, it would actually take a great deal of force to do so, but it is still a concern of mine. Currently, I pin the extension set to my clothing while feeding and also use a grip lock when I'm being more active while feeding. This is an extra safety measure I have used to prevent my tube from being pulled out since long before ENFit was introduced into the picture. I also used to do this with my standard g-j tube, prior to having a low-profile tube. Through the Oley Foundation, I have suggested the introduction of a quick-release disconnect mechanism on the pump set side as it seems like a reasonable solution. I hope to see this suggestion come to fruition.

While I certainly would never want a product that could harm anyone being released, I also recognize the need to prevent tubing misconnections. If there are scientifically-documented safety and access issues, then I absolutely support the manufacturers addressing them before they come to market. Unlike many of the enteral community members you heard from during the call, I believe regulators and manufacturers have the consumer's best interests in mind and I trust that they will resolve any genuine safety and access issues with the new connectors prior to being released to market.

This is a heated issue and I realize some in the enteral tube feeding community feel very passionate about their way of life and independence being threatened by the transition to ENFit connectors. At the same time, building consensus requires mutual respect and I feel like some of the rhetoric that's been used around this issue has not fostered an open

environment for a civil dialogue. For example, the accusations that ENFit is a conspiracy created by industry to force commercial formula on the blenderized diet community is appalling to me. I am disturbed by the continued accusations and threatening tone by some members of the community. I firmly believe the motivation for the ISO standard was based on clinically-documented cases of misconnections and the concern for patient safety by organizations like the Joint Commission and the World Health Organization. This was underscored by California law.

While I have read a lot of posts online from consumers suggesting this is a rare occurrence and only happens in hospital settings, the fact is, tubing misconnections happen in both hospital and home settings. In fact, the most recent incident I heard about was only a few months ago and occurred in a home setting. So when consumers say ENFit has no benefits to our community, I would disagree and I think those who have lost loved ones to tubing misconnections would disagree as well.

I would be happy to talk with anyone on your committee who may have questions about my experiences using the ENFit transition sets or from an enterally-fed consumer in general.

Thank you for your willingness to listen to my perspective.

Sincerely,

Joy McVey Hugick
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