

Date: 11/28/12

**Title:** Safe use of iodine-based skin preparation products in the perioperative area among patients with known or stated food allergy to shellfish or fish

**Clinical Question:**

- P (Population) Among patients with a known or stated food allergy to shellfish or fish,  
I (Intervention) does using iodine-based products prior to a surgical procedure  
C (Comparison)  
O (Outcome) increase the risk for experiencing an allergic reaction?

*Definitions for terms marked with \* may be found in the Supporting Information section.*

**Target Population for the Recommendation:**

Patients who require skin preparation prior to a surgical procedure and have a known or stated food allergy to shellfish or fish.

**Recommendation:** (See *Dimensions for Judging the Strength of the Recommendation*)

It is recommended that all patients receive skin preparation products using iodine-based medical products prior to surgical procedures, as appropriate (Schabelman & Witting, 2010 [1b]; Beaty, Lieberman, & Slavin, 2008 [4a]; Coakley & Panicek, 1997 [5a]; Katelarius, 2009[5a]; Lieberman, 2012 [5a]).

**Note:** Patients with known or stated food allergy to shellfish or fish may not have a higher risk of experiencing an allergic reaction to iodine-based products (Schabelman & Witting, 2010 [1b]; Beaty, Lieberman, & Slavin, 2008 [4a]; Huang, 2005 [4a]; Coakley & Panicek, 1997 [5a]; Katelarius, 2009[5a]; Lieberman, 2012 [5a]).

**Discussion/Synthesis of Evidence Related to the Recommendation:**

A total of five articles were found which addressed the clinical question, including one systematic review, two descriptive studies and three expert opinion articles. Evidence supported that patients with a known food allergy to shellfish or fish do not have a higher risk for allergic reaction when exposed to iodine based medical products as compared to patients with no known food allergy to shellfish or fish (Schabelman & Witting, 2010 [1b]; Beaty et al., 2008 [4a]; Huang, 2005 [4a]; Coakley & Panicek, 1997 [5a]; Katelarius, 2009[5a]; Lieberman, 2012 [5a]). Three articles addressed the misconception between shellfish and fish allergy and radiocontrast agents, with the underlying emphasis on iodine misinformation (Schabelman & Witting, 2010 [1b]; Beaty et al., 2008 [4a]; Huang, 2005 [4a]).

The association between iodine and shellfish or fish allergies has not been shown to exist, rather it is a long-held belief that has been perpetuated by some physicians and healthcare providers (Beaty et al., 2008 [4a]). The erroneous belief was based upon the thought that iodine content in fish and shellfish caused allergic reaction (Coakley, Panicek 1997[5a]). This erroneous belief has been documented among patients and families (Huang, S., 2005 [4a]). However, scientific evidence indicates the major allergen in shellfish and fish are the proteins tropomyosin and parvalbumin respectively, rather than the iodine contained in shellfish or fish (Schabelman & Witting, 2010 [1b]; Lieberman [5a]). According to Huang, "the crux of the matter is that we do not educate the public about the amount of iodine that exists in other common foods. Therefore, we can argue that the chance of iodine sensitivity, if it ever occurs, could not only happen often consuming non-seafood items, but may actually happen more frequently" (Huang, 2005 [4a]). Schabelman (2010 [1b]) is more succinct, "Iodine is not and cannot be an allergen. Iodine is found throughout our bodies in thyroid hormones and amino acids....without iodine in the body, a person cannot survive" (Schabelman & Witting, 2010 [1b]).

**Reference List:** (*Evidence Level in [ ]*; See [Table of Evidence Levels](#))

- Beaty, A. D., Lieberman, P. L., & Slavin, R. G. (2008). Seafood allergy and radiocontrast media: Are physicians propagating a fallacy? *The American Journal of Medicine*, 121(2), 158.e1-158.e4. [4a]
- Coakley, F. V., & Panicek, D. M. (1997). Iodine allergy: An oyster without a pearl? *American Journal of Roentgenology*, 169(4), 951-952. [5a]
- Huang, S. (2005). Seafood and iodine: An analysis of a medical myth. *Allergy and Asthma Proceedings: The Official Journal of Regional and State Allergy Societies*, 26(6), 468-469. [4a]
- Katelarius, C.H. (2009). 'Iodine allergy' label is misleading. *Australian Prescriber*, 32(5), 125-128. [5a]
- Lieberman, P. (2012). Retrieved from American Academy of Allergy, Asthma & Immunology <http://www.aaaai.org/ask-the-expert/Shellfish-allergy-and-the-use-of-Betadine.aspx> [5a]
- Schabelman, E., & Witting, M. (2010). The relationship of radiocontrast, iodine, and seafood allergies: A medical myth exposed. *Journal of Emergency Medicine*, 39(5), 701-707. [1b]

## IMPLEMENTATION

**Applicability Issues:**

There are several aspects to be considered prior to implementation of the recommendation.

## Documentation of Allergies in Medical Record

- Routine verification and documentation of patient allergy information by health care provider
- Documentation of patient allergies in medical record needs to be kept up-to-date and accurate
- Medical records should provide specific allergy information to health care provider

## Resources

- Assess the types of skin preparations currently available for use in the perioperative area
- Assess the cost of purchasing multiple skin preparation to ensure appropriate, safe utilization

## Staff Education

- Assess health care providers' beliefs about association between food allergy of shellfish or fish and iodine
- Assess health care providers' knowledge of skin preparation product's manufacturer recommendations
- Provide education and training to health care providers on proper selection of skin preparation product based on type of surgical procedure and body location

**Relevant CCHMC Tools for Implementation:**

No relevant CCHMC Tools for Implementation were found

**Outcome or Process Measures:**

- Percent of health care providers reporting belief that use of iodine based product is contraindicated with food allergy to shellfish or fish
- Percent of health care providers able to correctly identify appropriate skin preparation product for surgical type and location
- Number of patients with reported shellfish, fish and Betadine allergy requiring skin preparations prior to surgery and receiving correct match of skin preparation product
- Percentage of surgical cases with correct match of skin preparation product and surgical type/location

## SUPPORTING INFORMATION

### Background/Purpose of BEST Development:

There is a widespread belief that allergic reactions to shellfish and/or fish are related to the food's iodine content (Schabelman & Witting, 2010 [1b]). In healthcare settings, this belief has influenced the clinical practice of avoiding iodine-based product usage with patients who have shellfish or fish allergies based on parent report or medical documentation. Alternative surgical skin preparation products (e.g., Phisohex, Chlorohexadine) are contraindicated for use on certain parts of the body. For example, Phisohex is potentially damaging to the cornea, therefore Ophthalmic Betadine is often selected by surgeons as the safest surgical skin preparation for the face. The confusion regarding allergic reactions and the perceived association with iodine-based products among patients with shellfish or fish allergies make this clinical decision more complicated. This issue led to the development of the clinical question: Among patients with a known or stated food allergy to shellfish or fish does using iodine-based prior to a surgical procedure increase the risk for experiencing an allergic reaction?

### Search Strategy:

*Databases:* MEDLINE, CINAHL, Cochrane Database of Systematic Reviews, Google Scholar

*Search Terms:* iodine sensitivity/allergy, seafood sensitivity/allergy, fish sensitivity/allergy, hypersensitivity, providone-iodine, betadine, immunology

*Limits and Filters:* None

*Search Dates:* Default date parameters were used for each database (date parameters not limited).

*Date Last Search Done:* June 25, 2012

### Relevant CCHMC Evidence-Based Documents:

No relevant CCHMC Evidence-Based documents were found.

### Group/Team Members:

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### Conflicts of Interest were declared for each team member:

- No financial conflicts of interest were found.
- No external funding was received for development of this BEST.
- The following financial conflicts of interest were disclosed:

**Note:** Full tables of the [LEGEND evidence evaluation system](#) are available in separate documents:

- [Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality](#) (abbreviated table below)
- [Grading a Body of Evidence to Answer a Clinical Question](#)
- [Judging the Strength of a Recommendation](#) (dimensions table below)

**Table of Evidence Levels** (see note above):

Quality level	Definition
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5a or 5b	General review, expert opinion, case report, consensus report, or guideline
5	Local Consensus

†a = good quality study; b = lesser quality study

**Table of Language and Definitions for Recommendation Strength** (see note above):

Language for Strength	Definition
It is strongly recommended that... It is strongly recommended that... not...	When the dimensions for judging the strength of the evidence are applied, there is high support that benefits clearly outweigh risks and burdens. (or <i>visa-versa</i> for negative recommendations)
It is recommended that... It is recommended that... not...	When the dimensions for judging the strength of the evidence are applied, there is moderate support that benefits are closely balanced with risks and burdens.
There is insufficient evidence and a lack of consensus to make a recommendation...	
Given the dimensions below and that more answers to the left of the scales indicate support for a stronger recommendation, the recommendation statement above reflects the strength of the recommendation as judged by the development group. (Note that for negative recommendations, the left/right logic may be reversed for one or more dimensions.)	
<b>Rationale for judgment and selection of each dimension:</b>	
<b>1. Grade of the Body of Evidence</b>	<input type="checkbox"/> High <input type="checkbox"/> Moderate <input checked="" type="checkbox"/> Low
<i>Rationale:</i> See evidence synthesis	
<b>2. Safety/Harm</b> (Side Effects and Risks)	<input type="checkbox"/> Minimal <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Serious
<i>Rationale:</i> There is no increased risk of harm when using an iodine-based product among patients with a known or stated food allergy to shellfish or fish.	
<b>3. Health benefit to patient</b>	<input type="checkbox"/> Significant <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Minimal
<i>Rationale:</i>	
<b>4. Burden on staff to adhere to recommendation</b>	<input checked="" type="checkbox"/> Low <input type="checkbox"/> Unable to determine <input type="checkbox"/> High
<i>Rationale:</i> Once staff is educated that there is no evidence supporting a link between shellfish/fish food allergies and the use of iodine-based products, staff should accept and implement the recommendation.	
<b>5. Cost-effectiveness to healthcare system</b>	<input type="checkbox"/> Cost-effective <input checked="" type="checkbox"/> Inconclusive <input type="checkbox"/> Not cost-effective
<i>Rationale:</i> The evidence reviewed did not address any issues related to cost with using iodine-based products vs. non-iodine based products.	
<b>6. Directness of the evidence for this target population</b>	<input type="checkbox"/> Directly relates <input checked="" type="checkbox"/> Some concern of directness <input type="checkbox"/> Indirectly relates
<i>Rationale:</i> Evidence primarily evaluated the use of IVP dye rather than iodine-based surgical skin preparation. However both are iodine-based products and the evidence addressed there was no increased risk for allergic reaction among patients with a known or stated food allergy to shellfish or fish. The crux is the misunderstanding of iodine allergy, not the mode of delivery.	
<b>7. Impact on morbidity/mortality or quality of life</b>	<input type="checkbox"/> High <input checked="" type="checkbox"/> Medium <input type="checkbox"/> Low
<i>Rationale:</i> There is no increased risk for experiencing an allergic reaction when iodine-based products are used. Therefore the impact on morbidity/mortality or quality of life is no different than when using non-iodine based skin preparation products.	

Copies of this Best Evidence Statement (BEST) and related tools (if applicable, e.g., screening tools, algorithms, etc.) are available online and may be distributed by any organization for the global purpose of improving child health outcomes.

Website address: <http://www.cincinnatichildrens.org/service/i/anderson-center/evidence-based-care/bests/>

Examples of approved uses of the BEST include the following:

- Copies may be provided to anyone involved in the organization's process for developing and implementing evidence based care;
- Hyperlinks to the CCHMC website may be placed on the organization's website;
- The BEST may be adopted or adapted for use within the organization, provided that CCHMC receives appropriate attribution on all written or electronic documents; and
- Copies may be provided to patients and the clinicians who manage their care.

Notification of CCHMC at [EBDMinfo@cchmc.org](mailto:EBDMinfo@cchmc.org) for any BEST adopted, adapted, implemented, or hyperlinked by the organization is appreciated.

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This Best Evidence Statement has been reviewed against quality criteria by two independent reviewers from the CCHMC Evidence Collaboration. Conflict of interest declaration forms are filed with the CCHMC EBDM group.

Once the BEST has been in place for five years, the development team reconvenes to explore the continued validity of the guideline. This phase can be initiated at any point that evidence indicates a critical change is needed. CCHMC EBDM staff perform a quarterly search for new evidence in an horizon scanning process. If new evidence arises related to this BEST, authors are contacted to evaluate and revise, if necessary.

*For more information about CCHMC Best Evidence Statements and the development process, contact the Evidence Collaboration at [EBDMinfo@cchmc.org](mailto:EBDMinfo@cchmc.org).*

### **Note**

**This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.**